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Magnetic Resonance Imaging Evaluation of Supratentorial Tumors: A Hospital Based Descriptive Study

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Abstract

Background: Brain tumors can be classified by location into supratentorial, infratentorial, and midline tumors. Magnetic resonance imaging (MRI) has earned recognition as the optimal screening technique for the detection of most intracranial tumors. MRI using spin echo, gradient echo, and combination of spin echo and gradient echo pulse sequences before and after intravenous administration of paramagnetic contrast agents provides inherently greater contrast resolution between structural abnormalities and adjacent brain parenchyma and has proved to be more sensitive in the detection of focal lesions of the brain.

Methods: A total of 40 patients with symptoms of intracranial pathology were subjected to MRI and those cases found to have supratentorial tumors and proven by histopathology were studied during the period from December 2012 to September 2014.

Results: The MRI features of 40 supratentorial tumors were reviewed, out of which 63% were found to be extra-axial tumors and 37% intra-axial tumors. About 27% were found to be glial tumors and 73% were found to be non-glial tumors. Astrocytomas and meningiomas formed majority of the glial and non-glial tumors, respectively. Astrocytomas were predominantly located in the frontoparietal and frontal lobes, whereas majority of meningiomas were located in bilateral cerebral convexities and parafalcine regions.

Conclusion: MRI proves to be a valuable modality of imaging in evaluating the characteristics, distribution, localizing, and assessing of the extent of various intra- and extra-axial tumors in the supratentorial region.

Key words: Brain tumors, Gliomas, Magnetic resonance imaging, Meningioma, Supratentorial tumors

INTRODUCTION

The designation “brain tumors” is commonly applied to a wide variety of intracranial mass lesions that are distinct in their location, biology, treatment, and prognosis. Since many of these lesions do not arise from brain parenchyma, the more appropriate term would be “intracranial tumors.” Majority of these tumors present with nonspecific complaints such as headache, stroke, like syndromes, or seizures. Often diagnosis is made or suggested initially by

the findings on imaging studies. However, prognosis of these patients has improved considerably due to recent advances in diagnostic techniques, microsurgery and radiotherapy. Clinical evaluation, radiology and pathology play big roles in deciding the long-term prognosis.¹

Recent advances in imaging techniques have exploded into the horizon of using many different modalities such as magnetic resonance imaging (MRI), and computed tomography (CT) perfusion, positron emission tomography, and single photon emission CT. These imaging modalities have revolutionized the diagnosis and management of brain tumors.²

MRI has earned recognition as the optimal screening technique for the detection of the most intracranial neoplasms. MRI using spin echo, gradient echo, and combination spin echo and gradient echo pulsing

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sequences before and after intravenous administration of paramagnetic contrast agents provides inherently greater contrast resolution between structural abnormalities and adjacent brain parenchyma and has proved to be more sensitive in the detection of focal lesions of the brain. Moreover, the multiplanar capability of MR is very helpful to determine the anatomic site of origin of lesions and to demarcate extension into adjacent compartments and brain structures.³

The aim of the study is to evaluate the characteristics, distribution, localizing, and assessing the extent of various intra- and extra-axial tumors in the supratentorial region by MRI. This study will enable to develop an imaging method for evaluation of supratentorial tumors and also help in prognosis and treatment.

MATERIALS AND METHODS

A hospital based descriptive study was conducted on 40 patients with histologically proven cases. This study was done in Department of Radio-diagnosis and Imaging of Vydehi Institute of Medical Sciences and Research Centre in a period of 2-year from December 2012 to September 2014. Patients with tumors other than supratentorium, patients with claustrophobia, cardiac pacemakers, and cochlear implants were excluded from the study.

MRI scan was performed on 1.5 Tesla Philips Achieva. Conventional Spin Echo sequences like axial T1, T2 and fluid-attenuated inversion recovery (FLAIR), coronal T2, sagittal T1, postcontrast SE T1 axial, sagittal and coronal: Diffusion-weighted imaging (DWI), multivoxel PRESS spectroscopy MRI images were evaluated for location, consistency, hemorrhage, necrosis, margins, edema, contrast enhancement, and any additional features of the tumors. Pre-operative diagnosis was compared with post-operative pathological diagnosis.

Topographically, tumors were divided into supratentorial and infratentorial and classified into intra- and extra-axial. Radiological diagnosis was based on topography of the lesion, characterization into intra versus extra parenchymal location; morphological analysis for the presence of secondary changes adjacent to the lesion was sought. The WHO classification based on histopathology was done.

OBSERVATION AND RESULTS

In our study of 40 cases, we had 11 (27%) glial tumors (low grade glioma, high grade glioma, astrocytoma, and glioblastoma multiforme [GBM]) and 29 (73%) non-glial tumors (meningioma, pituitary macroadenoma,

and craniopharyngioma, metastasis, pineocytoma, and dysembryoblastic neuroepithelial tumor respectively. Among the glial tumors, astrocytomas were the most common glial tumors (5 of 11 cases) and meningiomas were the most common non-glial tumors (14 of 29 cases) (Figures 1 and 2).

Astrocytoma

We observed that 8/40 (20%) the cases had astrocytomas with mean age of 31.6 ± 4.7 years and male:female ratio of 5:3. Most of the cases presented with convulsions 5/8 followed by headache and ataxia 4/8 and had the initial clinical diagnosis of intra cranial space occupying lesions (ICSOL) in 4/8 patients and epilepsy in 2/8 patients (Table 1). Most of the patients on MRI were isointense to hypointense on T1-weighted images (T1WI) and were

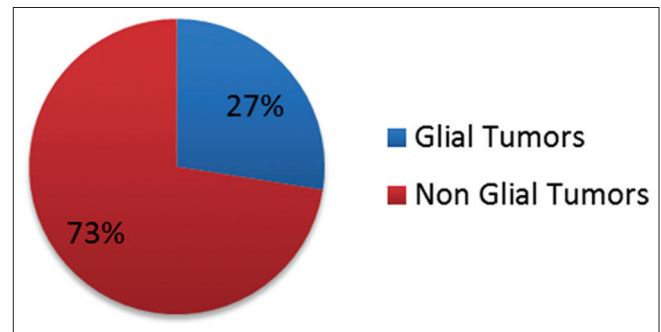


Figure 1: Classification of the tumors based on cell of origin

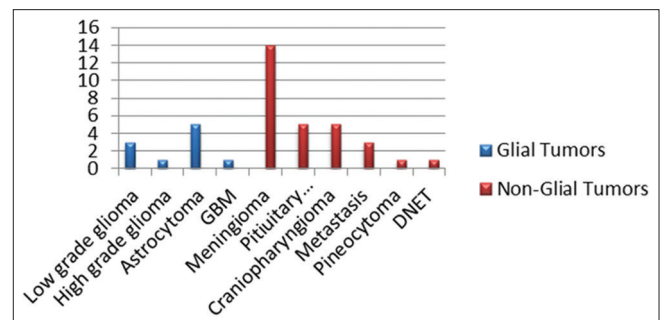


Figure 2: Distribution of glial and non-glial tumors (n=40)

Table 1: Clinical parameters of astrocytoma tumors

Clinical findings	n=8
Age (years)*	31.7±4.7
Gender (male:female)	5:3
Vomiting	3 (37.5%)
Headache	5 (62.5%)
Convulsions	7 (87.5%)
Hemiplegia/paresis	0 (0%)
Ataxia	4 (50%)
Blurring of vision	0 (0%)
ICSOL	4 (50%)
Epilepsy	2 (25%)

*Value express as mean±SD, SD: Standard deviation, ICSOL: Intra cranial space occupying lesions

homogenously hyperintense on T2-weighted images (T2WI). On FLAIR 6 of 8 cases were hyperintense and the remaining were hypointense. Perilesional edema was evident in most of the cases but there was no contrast enhancement or calcification. DWI showed no restriction. On MR spectroscopy (MRS), there was elevated choline with reversal of choline creatine ratios (7/8) and low N-acetyl aspartate (NAA) peak (Table 2 and Figure 3).

Meningioma

We observed that 14/40 (35%) the cases had meningioma with mean age of 50.07 ± 3.7 years and male:female ratio of 6:8. Most of the cases presented with a headache 9/14 and convulsions 6/14 followed by hemiplegia 4/14 and ataxia 3/14 and had the initial clinical diagnosis of ICSOL in 7/14 patients (Table 3). Most of the patients on MRI were isointense to hypointense on T1WI and isointense to hyperintense T2WI; mostly variable signal intensities were noted. On FLAIR the lesions were hyperintense and all the cases showed contrast enhancement. Perilesional edema and contrast enhancement was evident in all the cases. On DWI, restriction was observed in all the cases. On MRS, there was an elevated NAA, CHO, glutamate, and CR peak with no lactate peak observed. All the observed tumors were benign meningiomas and hence most of the tumors on MRS NAA and creatine peaks were observed. Two of the fourteen cases showed lipid peak, which was suggestive of necrosis (Table 4 and Figure 4).

Table 2: MRI characteristics of astrocytoma tumors

Sequences	n=8
T1W	Hypointense 8 (100%)
T2W	Hyperintense 8 (100%)
FLAIR	Hyperintense 6 (75%)
	Hypointense 2 (25%)
DWI	No restriction 8 (100%)

MRI: Magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, FLAIR: Fluid-attenuated inversion recovery, DWI: Diffusion-weighted imaging

Additional findings

Peri-lesional edema	5 (75%)
Necrosis	0 (0%)
Bone erosion	3 (37.5%)
Hydrocephalus	0 (0%)
Contrast enhancement	0 (0%)

Craniopharyngioma

We observed that 4/40 (10%) the cases had craniopharyngioma with mean age of 30.0 ± 7.1 years and male:female ratio of 3:1. Most of the cases presented with headache 3/4 and ataxia 3/4 and had the initial clinical diagnosis of ICSOL in 4/4 patients (Table 5).

Most of the patients on MRI were isointense on T1W sequences and hypointense on T2W sequences. On FLAIR, the lesions were hyperintense. Significant heterogeneous contrast enhancement was evident in one case and cystic degeneration was evident on all the cases. DWI showed restriction in all the cases (Table 6).

Table 3: Clinical parameters of meningioma tumors

Clinical findings	n=14
Age (years)*	50.07±3.7
Gender (male:female)	6:8
Vomiting	3 (21.4%)
Headache	9 (64.3%)
Convulsions	6 (42.9%)
Hemiplegia/paresis	4 (28.6%)
Ataxia	3 (21.4%)
Blurring of vision	0 (0%)
ICSOL	7 (50%)
Epilepsy	0 (0%)

*Value express as mean±SD, SD: Standard deviation, ICSOL: Intra cranial space occupying lesions

Table 4: MRI characteristics of meningioma tumors

Sequences	n=14
T1W	Hypointense 5 (35.7%)
	Isointense 9 (64.3%)
T2W	Hyperintense 6 (42.9%)
	Isointense 8 (57.1%)
FLAIR	Hyperintense 14 (100%)
DWI	Restriction 14 (100%)

MRI: Magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, FLAIR: Fluid-attenuated inversion recovery, DWI: Diffusion-weighted imaging

Additional findings

Peri-lesional edema	14 (100%)
calcifications	5 (35.7%)
necrosis	2 (14.3%)
Bone erosion	7 (50%)
Hydrocephalus (compressive)	4 (28.6%)
Contrast enhancement	14 (100%)

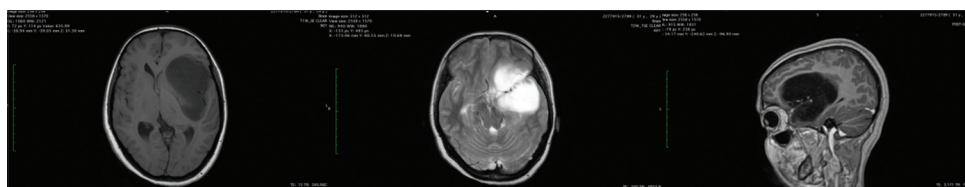


Figure 3: Axial T1-weighted (T1W), T2-weighted (T2W) and sagittal T1W postcontrast low grade glioma. A well-defined left frontotemporal homogeneously enhancing T1W and T2W cystic lesion with no enhancement on T1W sagittal section

Pituitary Macroadenoma

We observed that 4/40 (10%) the females cases had pituitary macroadenoma with mean age of 27.3 ± 5.7 years. Most of the cases presented with headache 4/4 and vomiting, ataxia 3/4 and had the initial clinical diagnosis of ICSOL in 4/4 patients (Table 7 and Figure 5).

Most of the patients on MRI were isointense on T1W sequences and isointense on T2W sequences. On FLAIR, the lesions were isointense. Calcifications, necrosis and

bone erosion was evident in all the cases (3 of 4 cases) and all the cases showed heterogeneous intense contrast enhancement (Table 8 and Figure 5).

Metastasis

We observed that 3/40 (7.5%) the male cases had metastasis with mean age of 49.8 years. Most of the cases presented with headache, vomiting, and ataxia. We had 3 cases on cerebral metastases, which were seen in all male patients and seen in the age group of 40-55 years. Patients presented with symptoms of headache, paresis, and vomiting (Table 9).

Most of the patients on MRI were isointense to hypointense on T1W sequence and hyperintense on T2W sequence. On

Table 5: Clinical parameters of craniopharyngioma tumors

Clinical findings	n=4
Age (years)*	30.0±7.1
Gender (male:female)	3:1
Vomiting	2 (50%)
Headache	3 (75%)
Convulsions	0 (0%)
Hemiplegia/paresis	1 (25%)
Ataxia	2 (50%)
Blurring of vision	3 (75%)
ICSOL	4 (100%)
Epilepsy	0 (0%)

*Value express as mean±SD, SD: Standard deviation, ICSOL: Intra cranial space occupying lesions

Table 6: MRI characteristics of craniopharyngioma tumors

MRI sequences	n=4
T1W	Isointense 4 (100%)
T2W	Hypointense 4 (100%)
FLAIR	Hyperintense 4 (100%)
DWI	restriction 4 (100%)

MRI: Magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, FLAIR: Fluid-attenuated inversion recovery, DWI: Diffusion-weighted imaging

Additional findings

Cystic areas	4 (100%)
Bone erosion (sella)	4 (100%)
Hydrocephalus	0 (0%)
Contrast enhancement	1 (25%)

Table 7: Clinical parameters of pituitary macroadenoma tumors

Clinical findings	n=4
Age (years)*	27.3±5.7
Gender (male:female)	0:4
Vomiting	2 (50%)
Headache	4 (100%)
Convulsions	1 (25%)
Hemiplegia/paresis	0 (0%)
Ataxia	0 (0%)
Blurring of vision	3 (75%)
ICSOL	4 (100%)
Epilepsy	0 (0%)

*Value express as mean±SD, SD: ICSOL: Intra cranial space occupying lesions

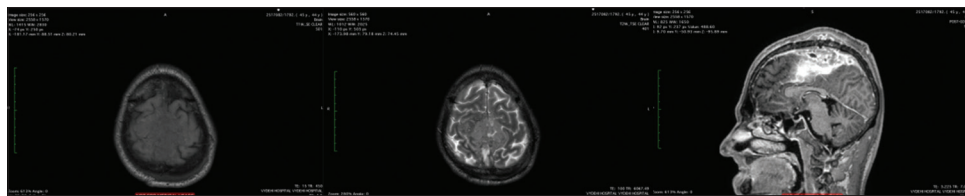


Figure 4: Axial T1-weighted images (T1WI), T2-weighted images and sagittal postcontrast T1WI. Meningioma. An extra-axial midline heterogeneous lesion with post contrast enhancement, the lesion is isointense on T2 and T1W sequences with cystic areas within s/o necrosis noted in the high parietal region with perilesional edema predominantly in the left cerebral hemisphere



Figure 5: Axial T2-weighted, coronal T1-weighted (T1W) and postcontrast T1WI images of pituitary macroadenoma. Large well defined intensely and homogenously enhancing sellar- suprasellar mass lesion compressing third ventricle with obstructive hydrocephalus, compressing and elevating optic chiasm, invading left cavernous sinus with encasement of left internal carotid artery and invasion of skull base on left side as described above, s/o pituitary macroadenoma

FLAIR, the lesions were hyperintense. There was intense enhancement following contrast administration. Pattern of Contrast enhancement observed was uniform and ring enhancing. On MRS, the lesion showed elevated choline, lactate and lipid peaks. As a result of hypercellular tumoral activity, choline peak was observed in all the 3 cases. Lipid peak was observed in 1 case with necrosis. DWI showed no restriction (Table 10 and Figure 6).

DISCUSSION

Astrocytoma

Astrocytomas are a heterogeneous group of tumors that arise from the glia. We observe that 8/40 (20%) cases had astrocytomas with mean age of 31.6 ± 4.7 years and male:female ratio of 5:3. They are reported to be most

Table 8: MRI characteristics of pituitary macroadenoma

MRI sequences		n=4
T1W	Isointense	4 (100%)
T2W	Hyperintense	4 (100%)
FLAIR	Isointense	4 (100%)
DWI	Restriction	4 (100%)

MRI: Magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, FLAIR: Fluid-attenuated inversion recovery, DWI: Diffusion-weighted imaging

Additional findings

Calcifications	3 (75%)
necrosis	2 (50%)
Bone erosion (sella)	3 (75%)
Hydrocephalus	1 (25%)
Contrast enhancement	4 (100%)

Table 9: Clinical parameters of metastatic tumors

Clinical findings		n=3
Age (years)		49.3±5.3
Gender (male:female)		3:0
Vomiting		2 (66.7%)
Headache		3 (100%)
Convulsions		0 (0%)
Hemiplegia/paresis		3 (100%)
Ataxia		0 (0%)
Blurring of vision		3 (100%)

common type of intra-axial supratentorial brain tumors and account for 60% of all intracranial neoplasms in the pediatric population as reported by Poussaint.⁴

The clinical presentation of patients with an astrocytoma varies on the basis of the location and aggressiveness of the tumor. In the present study, most of the cases presented with convulsions (5/7) followed by headache and ataxia (4/7) and had the initial clinical diagnosis of ICSOL in (4/7) patients and epilepsy in (2/7) patients. Gupta, reported that signs and symptoms may be nonspecific such as headache, nausea, and seizures. Low-grade tumors typically cause minimal neurologic deficits because of the lack of tissue destruction, and patients can present with generalized seizures. Patients with more aggressive tumors may present with complex partial seizures and neurologic deficit.⁵ All the studied cases were fibrillary astrocytoma Grade II in the present study. Lesions were seen either in frontal 3/7 or frontoparietal lobes 4/7. Histologically, they are reported by Louis *et al.*,⁶ to vary from low- to high-grade and are classified according to their histopathology pattern, biologic behavior, and genetic characterization. They also reported that this group of tumors includes diffuse astrocytoma, pleomorphic xanthoastrocytomas (PXA), subependymal giant-cell astrocytoma (SEGA), anaplastic astrocytoma, GBM, and pilocytic astrocytoma. They also reported that low-grade astrocytoma (WHO Grades I and II) were more common than high-grade astrocytomas and include pilocytic astrocytoma, SEGA, PXA, and diffuse astrocytoma. Anaplastic astrocytomas

Table 10: MRI characteristics of metastatic tumors

Sequences		n=3
T1W	Isointense	2 (66.7)
	Hypointense	1 (33.3)
T2W	Hyperintense	3 (100)
FLAIR	Hyperintense	3 (100)
DWI	No restriction	3 (100)

MRI: Magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, FLAIR: Fluid-attenuated inversion recovery, DWI: Diffusion-weighted imaging

Additional findings

Perilesional edema	3 (100%)
Hydrocephalus	1 (33.3%)
Contrast enhancement	3 (100%)

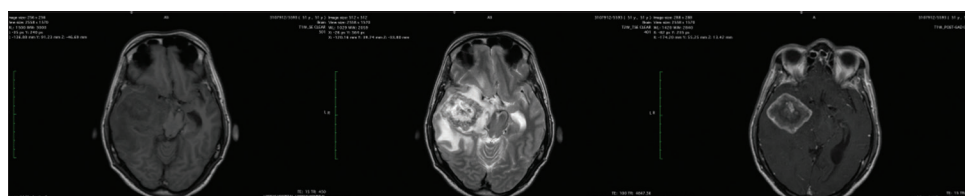


Figure 6: Axial T1-weighted (T1W), T2-weighted (T2W) and postcontrast T1W images of cerebral metastases. Well-defined T1W hypointense, T2W hyperintense lesion in the right temporal region with significant perilesional edema and intense ring enhancement of the lesion on T1W postcontrast

are considered Grade III because of histologic evidence of malignancy, and GBMs are classified as Grade IV because of their aggressive behavior and fatal outcome.⁷

Most of the patients in the present study were hypointense on T1W and hyperintense on T2W. Poussaint reported that the imaging characteristics of astrocytomas also vary depending on the grade of malignancy.⁴ Gupta, reported that they can be solid and cystic and have calcification in up to 20% of cases,⁵ but this was not observed in present study which may be because of small sample size.

On imaging, Smirniotopolous *et al.* reported that diffuse astrocytomas are most often characterized by a homogeneous infiltrating, ill-defined white matter mass that is relatively hypointense to gray matter on T1WI, appears hyperintense on T2WI, and shows no enhancement.⁸ This observation is in conformity with the observations in the present study. In the present study, tumors are homogeneously hyperintense on FLAIR imaging in 6 out of 8 patients. Salzman *et al.*, reported that these tumors are homogeneously hyperintense on FLAIR imaging and usually do not restrict on DWI. Peritumoral edema and hemorrhage are rare and higher-grade lesions should be suspected if enhancement is noted.⁹ On MRS, there was elevated choline, low NAA peak and elevated CHO: CR ratios (7/8). MRS findings are nonspecific, showing elevated choline and low NAA levels similar to findings in many other tumors.

Meningioma

Verheggen and Mahmood *et al.*,^{10,11} reported that meningiomas constitute approximately 20% of all intracranial tumors and are easily diagnosed using routine MR imaging. In the present study, we observed that that 14/40 (35%) the cases had meningioma with mean age of 50.07 ± 3.7 years and male:female ratio of 6:8. Furthermore Mahmood *et al.*,¹¹ reported that malignant and atypical meningiomas, although relatively uncommon and accounting for approximately 7.2% and 2.4% of all meningiomas, respectively,^{10,11} were associated with less favorable clinical outcomes because they are more prone to recurrence and aggressive growth.¹²

In the present study, we did not observe any malignant meningioma among the studied patients. According to the WHO classification of meningiomas, those meningiomas with low-risk of recurrence and aggressive growth are classified as WHO Grade I.¹² The Grade I classification includes the most common types of meningioma (fibrous or fibroblastic, transitional or mixed, and meningothelial) and the following benign subtypes: Psammomatous, angiomatous, microcystic, secretory, lymphoplasmacyte-rich, and metaplastic.¹²

Most of the patients on MRI were isointense on T1W, T2WI and hyperintense on FLAIR. On MRS, there was elevated CHO (10/14), glutamate (10/14) and creatinine (7/14) peaks. Perilesional edema and contrast enhancement was evident in all the cases. MRS does not play a significant role in diagnosis but can help distinguish meningiomas from mimics. DWI showed restriction.¹²

In the present study, calcification was noted in 5/14 patients. Louis *et al.*,⁶ reported that these meningiomas with abundant psammoma bodies form irregular calcified and occasionally ossified masses. The decreased diffusion constant may relate to the paramagnetic properties of calcium. It is reasonable to postulate that a densely calcified mass would create a cellular environment in which the presence of this mineral would change the normal translational movement of water molecules across membranes.

Craniopharyngioma

In the present study, we observe that 4/40 (10%) the cases had craniopharyngioma with mean age of 30.0 ± 7.1 years and male:female ratio of 3:1. Bunin *et al.*, and Haupt *et al.* reported that distribution by age is bimodal with the peak incidence in children at 5-14 years and in adults at young to middle age group.^{13,14}

In the present study, most of the cases presented with headache (3 of 4 cases) and ataxia (3 of 4 cases) and had the initial clinical diagnosis of ICSOL in 4/4 patients.

Jagannathan and Karavitaki^{15,16} reported that symptoms develop insidiously and there is often a delay of 1-2 years between symptom onset and diagnosis. They also reported that usual symptoms on presentation as headaches, nausea, and vomiting either from mass effect from the tumor itself or from secondary hydrocephalus caused by obstruction of the Foramen of Monro, the third ventricle or the aqueduct of sylvius. Classically, a bitemporal hemianopia from inferior chiasmatic compression but alternatively patients may have a homonymous hemianopia, optic atrophy with papilledema.

The classical appearance of a craniopharyngioma is of a sellar/suprasellar mass partly solid, partly cystic calcified mass lesion. In the present study, we observed all the cases in sellar or suprasellar region. Rossi *et al.*,¹⁷ reported that these tumors occur in the suprasellar (75%), supra and infrasellar (20%) and infrasellar (5) regions. The suprasellar tumors may be subdivided into further groups depending on their relationship to the third ventricle and the optic chiasm.¹⁸

MRI with and without contrast will, accurately delineate the extent of the tumor and, in particular, its involvement

with the hypothalamus. Rossi *et al.*, reported that magnetic resonance angiography is useful in not only delineating the course of the vessels, which can be through the tumor, but also to help differentiate a tumor from a possible vascular malformation.¹⁷ It is the investigation of choice to plan the surgical approach. In the present study, most of the patients on MRI were isointense on T1W, hypointense on T2W and hyperintense on FLAIR. Calcification and necrosis was evident in all the cases.

Pituitary Macroadenoma

In the present study, we observe that 4/40 (10%) the females cases had Pituitary adenoma with mean age of 27.3 ± 5.7 years. Most of the cases presented with headache 4/4 and vomiting ataxia 3/4 and had the initial clinical diagnosis of ICSOL in 4/4 patients. Wolffenbittel *et al.*¹⁷ reported that the clinical features of pituitary adenoma vary depending on the location and size of the tumor and its secretory capability. Pituitary adenomas typically appear during early adulthood, and no sex predilection is known. The symptoms of functioning tumors are related to the specific hormone the tumor produces.^{19,20}

Currently, MRI is the examination of choice for sellar and parasellar pathologies due to its superior soft tissue contrast, multiplanar capability, and lack of ionizing radiation. In the present study, most of the patients on MRI were isointense on T1W and T2W. Calcification and necrosis and bone erosion was evident in all the cases (3 of 4 cases) and all the cases showed contrast enhancement.

On MRI, Suzuki *et al.*²¹ reported that pituitary macroadenoma on T1W MRIs are typically isointense to grey matter and larger lesions are often heterogeneous and vary in signal intensity due to areas of cystic changes/necrosis/hemorrhage. On contrast enhancement the lesion demonstrates moderate to bright enhancement. On T2W MRIs the lesions demonstrate isointense signals to grey matter. On FLAIR, the lesions were hyperintense. These observations are similar to present study.

Metastasis

Brain metastases occur in 15-40% of patients with cancer,^{22,23} Many of whom are asymptomatic. Certain malignancies are often associated with brain metastases, including cancers of the lung, breast, skin, colon, pancreas, testes, ovary, cervix, renal cell carcinoma, and melanoma.^{22,23} Although many case reports of intracranial metastatic disease from various other cancers exist. In the present study, we observed that 3/40 (7.5%) the females cases had metastasis with mean age of 49.8 years.

The detection of brain metastases is important for initial staging of patients with systemic malignancy. In the

present study, Most of the cases presented with headache and vomiting ataxia (3 of 3 cases) and had the initial clinical diagnosis of ICSOL in 3 out of 3 patients. In some cases, Silvestri *et al.*, reported that the presence of brain metastases comes to clinical attention through new neurological signs and symptoms, and imaging is therefore indicated in such patients.²⁴ Soffietti *et al.*, reported that symptoms may include headache, seizure, syncope, focal neurological deficit, or papilledema.^{22,23} Metastatic disease can involve different compartments of the central nervous system. The most common, metastatic disease affects the skull and/or brain parenchyma. Metastases can also involve the leptomeninges and pachymeninges.²⁵ In the present study, the tumors were seen in temporal or parietal lobes.

MRI is a sensitive screening test for brain metastasis. It is also useful to further evaluate mass lesions found on NECT to refine the differential diagnosis. In the present study, most of the patients on MRI were isointense on T1W and hyperintense on T2W.

On MRI, Chen *et al.*, reported that metastases are usually isointense or hypointense on T1, hyperintense on T2, and exhibit avid enhancement.²⁶ Some metastases, such as melanoma, are T1 hyperintense due to the paramagnetic effects of melanin. Hemorrhagic metastases may also demonstrate T1 signal hyperintensity, depending on the age of hemorrhage. DWI usually demonstrates facilitated diffusion (i.e., bright on apparent diffusion coefficient map), rather than diffusion restriction. This is comparable to the present study. Vasogenic edema can be substantial, and is unrelated to lesion size. Hakyemez *et al.*,²⁵ found a significantly increased ratio of vasogenic edema to contrast enhancing lesion size in metastases compared with high grade primary brain tumors, although metastases may display little or no vasogenic edema. Small cortically based metastases may not demonstrate any visible edema, and must therefore be looked for carefully.²⁷

Gadolinium contrast enhancement is vital to detect small metastases. Balériaux and Healy *et al.*, have documented the utility of contrast in the detection of additional lesions compared with noncontrast studies.²⁸⁻³⁰ In these studies, contrast administration improved diagnostic confidence. Contrast administration is also important to distinguish non-neoplastic white matter disease from metastases.

CONCLUSION

Proton MRS is a useful tool to distinguish whether a brain mass is neoplastic or non-neoplastic, but has not been shown to reliably distinguish metastasis from high-grade primary glial neoplasm such as glioblastoma.³¹ in the

present study, on MRS, most of the cases showed elevated choline peak. Necrosis and contrast enhancement was evident in all the cases.

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Evaluation of Post Dural Puncture Headache Using Various Sizes of Spinal Needles

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Abstract

Introduction: Post-dural puncture headache (PDPH) is one of the most common complications encountered by physicians following spinal anesthesia or lumbar puncture.

Aims and Objectives: This study was done for evaluating the incidence of PDPH following spinal anesthesia in the south Indian population using various gauges of Quinckes spinal needle.

Materials and Methods: A total of 75 American Society of Anesthesiologists I-II patients undergoing lower limb or lower abdomen surgery under spinal anesthesia were randomized into three groups each consisting of 25 patients. Patients belonging to Group I, Group II, and Group III received spinal anesthesia using 23 gauge, 25 gauge, and 26 gauge Quinckes spinal needle, respectively. Moreover, all the patients were followed up post-operatively for 5 days and evaluated for PDPH.

Results: The incidence of PDPH in the present study was 20% in Group I, 12.5% in Group II, and 4.5% in Group III, which was statistically insignificant.

Conclusion: In the present study for PDPH using three different gauge Quincke spinal needles, the incidence was found to be minimum with 26 G Quincke needle.

Key words: Post-dural puncture headache, Quincke needle, Spinal anesthesia

INTRODUCTION

Post-dural puncture headache (PDPH) is one of the most common complications encountered by physicians following spinal anesthesia or lumbar puncture. The first recorded incidence of PDPH was by Augustus Bier on his first ever demonstration of spinal anesthesia using cocaine.^{1,2} Even after a century of practicing spinal anesthesia there has been a less advance in methods for completely preventing the occurrence of PDPH.

There are multiple factors that may lead to a headache following spinal anesthesia, hence before diagnosing PDPH

it is mandatory to rule out other causes of the headache.^{3,4} This study was done for evaluating the incidence of PDPH following spinal anesthesia in the south Indian population using various gauges of Quinckes spinal needle.

MATERIALS AND METHODS

After getting approval from Institutional Ethics Committee, the study was conducted in Department of Anesthesiology, Rajah Muthiah Medical College and Hospital, Chidambaram, Tamil Nadu, India from a period of August 2006 to December 2008.

A total of 75 patients who were planned to undergo lower limb or lower abdomen surgery under spinal anesthesia, and satisfying the inclusion criteria were enrolled into the study. A written informed consent was taken from all the patients. The inclusion criteria was defined as American Society of Anesthesiologists Physical Status I and II, age between 25 and 75 years

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who are planned to undergo below umbilical surgeries under spinal anesthesia. Patients with previous history of PDPH, migraine, history of a chronic headache, with contraindications for spinal anesthesia, multiple punctures for spinal anesthesia, failed spinal anesthesia, poor follow-up, and patient refusal to give consent were excluded from the study.

The study subjects were randomly divided into three groups, Group I, II, and III each consisting 25 patients. All patients were uniformly preloaded with intravenous ringer lactate 10 ml/kg and positioned in sitting position for lumbar puncture. Under all aseptic precautions, a lumbar puncture was made in the L3-L4 interspace using Quinckes spinal needle of size 23 gauge, 25 gauge, and 26 gauge, respectively, in patients belonging to Group I, Group II, and Group III. In all the study, subjects uniformly 0.5 ml of cerebrospinal fluid (CSF) was allowed to spill out before injecting the local anesthetic.

The intraoperative period was managed as per protocols used for managing routine spinal anesthesia. Moreover, the patients were shifted to the post-operative wards after completion of surgery and were followed up daily for the next 1 week to evaluate the incidence of PDPH. Patients complaining of the headache and satisfying the criteria for PDPH as laid out by International Society of Headache (Table 1) were diagnosed to have PDPH and treated accordingly. Moreover, the severity of headache was assessed using Cocker's scale (Table 2).

Once the patients were diagnosed with PDPH, the severity of the headache was assessed using Cocker's scale.

RESULTS

The data were analyzed using Statistical Package for Social Sciences 12 software and Chi-square and paired *t*-test were

used to compare the incidence and validity of the study. The results are summarized in the form of Tables 1-9 and Graphs 1-5.

Table 2: Severity of headache by Cockers (1976)

Mild headache which permitted long periods of sitting/erect position and no other symptoms
Moderate headache, which made it difficult for the patient to stay upright for more than ½ h, occasionally accompanied by nausea, vomiting, auditory and ocular symptoms
Intense headache immediately upon getting up from bed, alleviated while lying horizontal in bed, often accompanied by nausea, vomiting, ocular and auditory symptoms
Headache that occurred even while lying horizontal in bed and greatly aggravated immediately upon standing up, eating is impossible because of nausea and vomiting

Table 3: Demographic distribution

Characteristics	Mean (SD)		
	Group I	Group II	Group III
Age (years)	23.6 (2.9)	23.1 (2.7)	23.7 (2.1)
Weight (kg)	56.8 (8.9)	56.9 (8.9)	52.6 (6.1)

SD: Standard deviation

Table 4: Incidence of PDPH

Groups	Number of cases (%)	P value	Significance
Group I	5 (20)	0.5041	NS
Group II	3 (12.5)	0.914	NS
Group III	1 (4.5)	2.509	NS

PDPH: Post-dural puncture headache, NS: Not significant

Table 5: Onset of PDPH

Post-Operative Day	Group I (%)	Group II (%)	Group III (%)
1 st day	0	0	0
2 nd day	3 (33.33)	1 (11.11)	1 (11.11)
3 rd day	1 (11.11)	2 (22.22)	0
4 th day	1 (11.11)	0	0

PDPH: Post-dural puncture headache

Table 1: Diagnostic criteria for defining PDPH defined by International society of headache

A. Headache that worsens within 15 min after sitting or standing, and improves within 15 minutes after lying, with at least one of the following (1 to 5) and fulfilling criteria C and D

1. Neck stiffness
2. Tinnitus
3. Hypoacusia
4. Photophobia
5. Nausea

B. Dural puncture has been performed

C. Headache develops within 5 days after dural puncture

D. Headache resolves either

1. Spontaneously within 1 week
2. Within 48 h after effective treatment of the spinal fluid leak (usually by epidural blood patch)

PDPH: Post-dural puncture headache

Table 6: Location of PDPH

Site/ Localization of Headache	Group I (%)	Group II (%)	Group III (%)
Frontal	4 (44.44)	2 (22.22)	1 (11.11)
Generalized	1 (11.11)	1 (11.11)	0
Occipital	0	0	0

PDPH: Post-dural puncture headache

Table 7: Severity of PDPH

Severity of PdpH	Group I	Group II	Group III
Mild	5	3	1
Moderate	0	0	0
Severe	0	0	0

PDPH: Post-dural puncture headache

Table 8: Duration of PDPH

	Group I	Group II	Group III
<24 h	4	3	1
24-48 h	1	0	0
>48 h	0	0	0

PDPH: Post-dural puncture headache

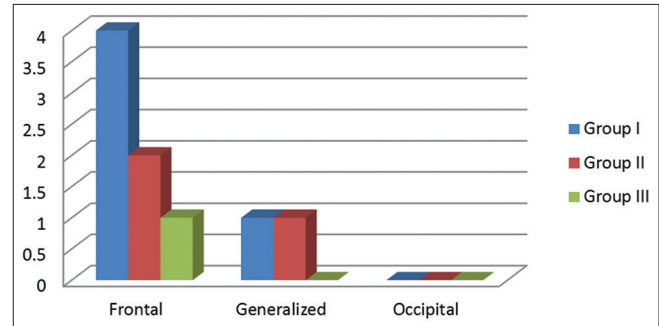
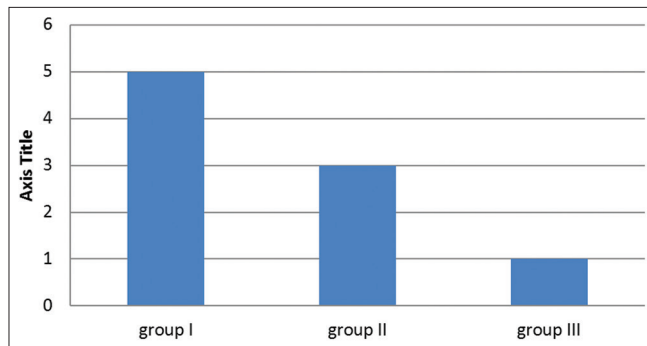
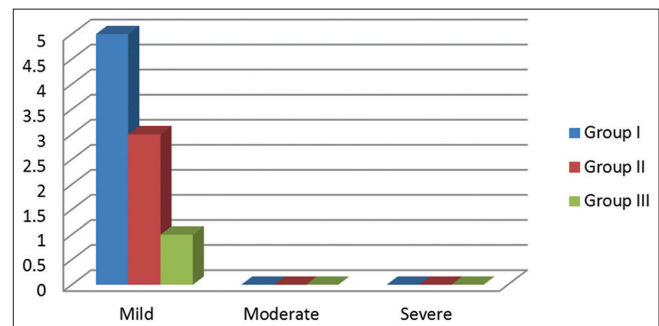
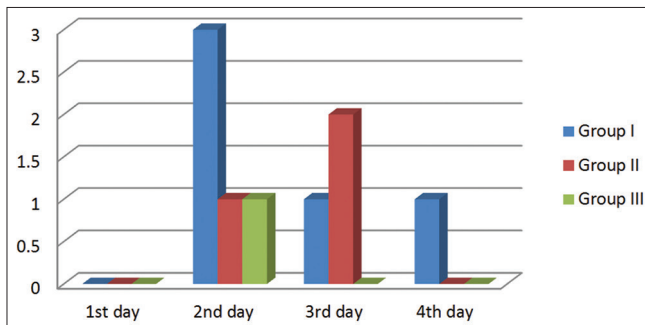
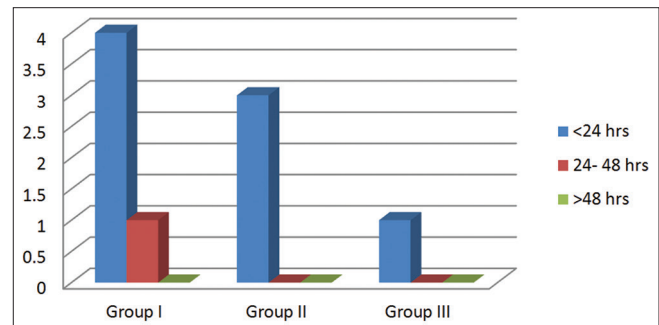
Table 9: Post spinal headache

	N (%)		
	Group I	Group II	Group III
Incidence	5 (20)	3 (12.5)	1 (4.5)
Chi-square significance	Group I versus II 0.5041 NS	Group II versus III 0.9147 NS	Group III versus I 2.509 NS
Onset			
1 st day	-	-	-
2 nd day	3 (33.33)	1 (11.11)	1 (11.11)
3 rd day	1 (11.11)	2 (22.22)	-
4 th day	1 (11.11)	-	-
Location			
Frontal	4 (44.44)	2 (22.22)	1 (11.11)
Generalized	1 (11.11)	1 (11.11)	-
Occipital	-	-	-
Severity			
Mild	05	03	01
Moderate	-	-	-
Severe	-	-	-
Duration			
<24 h	04	03	01
24-48 h	01	-	-
>48 h	-	-	-

DISCUSSION

PDPH is due to a low CSF pressure consequent upon seepage of CSF through the dural puncture hole and choroid plexus is unable to secrete sufficient fluid to maintain the CSF pressure. CSF leakage from the dural hole produces CSF hypotension, which in turn leads to intracranial venous dilation resulting in an increase in the brain volume in the upright position. Venous dilation and a compensatory increase in brain volume will result in brain sag and stimulate pain sensitive anchoring structures such as dural vessels, basal dura, and tentorium cerebelli causing a post-spinal headache. Larger the hole in the dura mater more will be the leakage of CSF and longer will be the time required for repair. It takes about 2 weeks or more for the holes to seal.³⁻⁵

The overall incidence of distressing post-spinal headache has varied from 0% to 37.2% as reported by Flaatten and

**Graph 3: Location of post-dural puncture headache****Graph 1: Incidence of post-dural puncture headache****Graph 4: Severity of post-dural puncture headache****Graph 2: Onset post-dural puncture headache****Graph 5: Duration of post-dural puncture headache**

Raeder.⁶ The most important factor contributing to the higher incidence of PDPH was the gauge and type of needles used. Use of wide bore and cutting type of needles led to more incidence of post-spinal headache.^{7,8}

The incidence of PDPH in our study was 20% in Group I, 12.5% in Group II, and 4.5% in Group III. This difference is statistically insignificant. In the study by Shah, the incidence of the headache was 20%, 12.5%, and 4.5% with 25 G Quincke, 27 Quincke, and 27 G Whitacre needle, respectively.

Duration of the headache was found to be 27.77 h (range 24-48 h). In 8 out of 9 patients, headache lasted <24 h. In one patient, headache was lasted up to 48 h. In the study by Lynch⁹ (1991), duration of headache was 48 h and 57.5 h in the 25 and 22 G groups, respectively. In the 7 out of 9 patients who had PDPH, the location of the headache was frontal region. Only one patient had generalized headache.

All patients who developed PDPH had the mild headache; none of the patients developed a severe headache or neurological sequelae because of the use of fine gauge needle, proper hydration, bed rest, and analgesics. In a study of Flaatten *et al.*,¹⁰ a much decreased severity of the headache was observed in the 29 G Quincke needle and the moderate headache was observed in 26 G needle. Onset of headache was from 2nd to 3rd day, respectively. 3 out of 5 patients (75%) had headache on the 2nd day in Group I and 1 patients (25%) had headache on the 3rd day, whereas in Group II 1 had headache on the 3rd day and 1 had headache on the 2nd day, in Group III in our study.

Once the patient had the headache, the patient was instructed to take complete bed rest, good hydration therapy with 5% 500 ml of dextrose transfused as an additional fluid and injection diclofenac sodium 75 mg intramuscularly was given. All patients responded to this treatment and none required epidural blood patch.

There is a universal consensus about the fact that the thicker the lumbar puncture needle, the higher could be the incidence of PDPH. A cutting type of needle inserted through the dural wall tears off a number of fibers in the wall and a permanent opening in it is ensured. The puncture site has typical crescent like appearance produced by cutting type of needle. The anatomical feature of dura is such that longitudinal dispersion of its fiber plus a copious interspersed of elastic fibers keeps the hole open once the dural fibers are cut. Cappe¹¹ suggested the use of a pencil point needle separates the longitudinal dural fibers without producing the serious injury. When the needle is withdrawn the fibers return to a state of close approximation.

In the present study, the bevel of the needle was inserted parallel to the longitudinal dural fibers, so that these fibers are separated and are not damaged and a narrow slit-like opening is obtained, with a greater tendency to contraction and a plugging of the hole, decreasing the leakage of CSF. In a study by Lybecker *et al.*,¹² the incidence of PDPH among patients in whom the bevel was inserted parallel to the longitudinal dural fibers was 0.56 times the incidence among patients in whom the bevel was inserted perpendicular to the longitudinal dural fibers.

PDPH is due to loss of CSF through the dural hole. Increase in blood volume by means of hydration facilitates choroid plexus to produce more CSF. Therefore, increasing the production of CSF will neutralize the loss due to leakage and when the balance is maintained, there should be no post-spinal headache. All the patients were hydrated in a similar manner.

Almost all the recent studies have expressed the opinion that early ambulation does not enhance the incidence of PDPH nor does it increase the severity of the syndrome. However, in the present study, all the patients were instructed to remain in supine position for 24 h in the post-operative period.

Age of the patient did not play any significant role in our study. All the patients in varying groups were of the similar age groups. However, the incidence is found to be lower in older patients. In an older patient, an altered pain sensitivity of vascular pain receptors and narrowed route of escape of CSF from epidural space are assumed to be the explanation for lower incidence. In a study by Rasmussen *et al.*,¹³ the incidence of PDPH in the young patient was 27.6% (with 20G) and 12.6% (with 25G). In the elderly patients, incidence of the headache with 20 and 25 G needles was 10.8% and 7.8%, respectively. The incidence PDPH is more common among women than men; particularly prone are the parturients because of the reduction of both the intra-abdominal and epidural pressure after delivery, thereby promoting extra leakage of CSF than usual. Sex bound difference is caused by emotional and hormonal factors. Spielman mentioned the factors responsible for an increase incidence of PDPH in obstetric patients as stress of labor, changing hormonal level, and dehydration.

CONCLUSION

In the present study for PDPH using three different gauge Quincke spinal needles, the incidence was found to be minimum with 26 G Quincke needle (although statistically insignificant).

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Role of Functional Endoscopic Sinus Surgery in Sinonasal Diseases: A Case Study and Review of Literature

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Abstract

Background: Functional endoscopic sinus surgery (FESS) has revolutionized surgical care, opening new horizons in the management of chronic rhinosinusitis and other paranasal sinus disorders. Messerklinger established and reiterated the importance of the sinus ventilation and pattern of mucociliary clearance. FESS was first described independently by both Messerklinger in German literature and Wigand.

Aim: To assess the efficacy, safety, and benefits of FESS in cases of chronic recurrent rhinosinusitis with or without nasal polyposis in terms of morbidity, mortality, and recurrent of disease.

Materials and Methods: This study was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh from August 2012 to August 2015. A total of 80 patients with clinical evidence of sinonasal diseases were evaluated with nasal endoscopy and computed tomographic (CT) evaluation prior to FESS.

Results: Out of 80 patients; 45 were male and 35 were female in the present study. Male:Female ratio = 1.28:1. On CT-scanning, the sinonasal pattern was seen in 36 patients (45%) followed by ostiomeatal unit in 24 patients (30%). Infundibular pattern and unclassified/sporadic pattern was seen in 9 patients (11.25%) and 8 patients (10%), respectively. Septoplasty was done in association with FESS to get wide access for a nasal endoscope. Polypectomy were done in 37 (46.25%) out of which 19 (23.75) patients underwent bilateral polypectomy. Anterior ethmoidectomy were performed in 48 (60%) patients, of which 6 patients (7.5%) underwent unilateral and 19 patients (23.75%) underwent bilateral ethmoidectomy.

Conclusion: FESS provides an excellent and safe method for treating sinonasal disease. The success rates are encouraging but because of the nature and chronicity of the disease, longer follow-up may be necessary to truly assess the surgical effectiveness of the procedure.

Key words: Surgery, Sinonasal diseases, Uncinectomy

INTRODUCTION

Functional endoscopic sinus surgery (FESS) has revolutionized surgical care, opening new horizons in

the management of chronic rhinosinusitis (CRS), and other paranasal sinus disorders.¹ Hirshman² was called the father of nasal endoscopy, who used only 4 mm diameter endoscope to examine the middle meatus and study the sinus ostia and also examined maxillary antrum via molar tooth socket, for diagnostic purpose in 1903, also by Maltz³ in 1925. During 1950 Hopkins² working, to developed solid rod lens system and proximal "cold light" source allowing better optical view and the introduction of the nasal endoscopes of various viewing angles have revolutionized the way nasal and sinus diseases are approached and treated.²

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FESS technique was not brought into common use until the work of Messerklinger in 1978.⁴ Messerklinger established and reiterated the importance of the sinus ventilation and pattern of mucociliary clearance. FESS was first described independently by both Messerklinger^{5,6} in German literature and Wigand,⁷ Steiner, and by Jaumann in the English literature in 1978. Moreover, it was introduced in the United States in 1984 by Kennedy *et al.*

The principle of the technique is limited resection of localized inflammatory disease or obstructive anatomical defect thus, restoring normal physiology by re-establishing normal mucociliary drainage and ventilation of sinuses.¹ It is the result of the acceptance of the pioneering work of Messerklinger⁸ and Wigand *et al.*⁹ on the importance of establishing drainage and preserving mucosa, as well as the development of special instruments, particularly compact, multi-angled endoscopes, which allow the precise, safe accomplishment of this goal. The term FESS was coined by Kennedy.¹⁰

The development of FESS makes it possible to diagnose more accurately and treat these inflammatory and infective conditions of the nose and paranasal sinuses refractory to non-invasive therapy.¹¹ The present study focuses on the assessment of the efficacy, safety, and benefits of FESS in cases of chronic recurrent rhinosinusitis, allergic, and non-allergic nasal polyposis in terms of morbidity, mortality, and recurrence of disease.

Aims and Objectives

To assess the efficacy, safety, and benefits of FESS in cases of chronic recurrent rhinosinusitis with or without nasal polyposis in terms of morbidity, mortality, and recurrent of disease.

MATERIALS AND METHODS

This study was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh from August 2012 to August 2015. A total of 80 patients with clinical evidence of sinonasal diseases were evaluated with nasal endoscopy and computed tomographic evaluation prior to FESS. The cases for the study were selected from the patients attending the ear nose and throat (ENT) outpatient department (OPD) with clinical evidence of chronic or recurring acute rhinosinusitis for more than 3 months non-responsive to appropriate medical therapy. All the patients in the study group were subjected to a detailed history of a wide spectrum of presenting symptoms *viz.* facial pain, headache, nasal discharge (whether it is watery, mucoid,

purulent or blood mixed), nasal obstruction (its duration, whether it is continuous or intermittent and whether it is associated with any external nasal deformity). The presence of other symptoms, such as postnasal discharge, sneezing, acute/chronic/serous otitis media, was also noted in full details. The complete personal, past, and family history were also elicited in addition with past medical/surgical history to know about any chronic use of antihistaminic, steroid sprays, and other medications in the past.

All patients were subjected to thorough ENT examination with special emphasis on anterior and posterior rhinoscopy. Nasal Endoscopy was done using Hopkins rod endoscopes (0°, 30°, 45°, 70°, and 90°) computed tomography (CT) of paranasal sinuses was done in all the patients. After a detailed nasal endoscopy and CT-scan study, patients underwent surgery-FESS. The patients included in the present study were explained in details about alternative modes of treatment, nature of the surgery, outcomes of surgery including benefits as well as possible complications of surgery. They were also detailed with the need for regular post-operative follow-up to monitor healing and avoid post-operative complications.

The operative technique used was planned in accordance to the need of the individual case. Surgical endoscopic management of concha bullosa and surgery of deviated nasal septum (DNS) was always planned in concert with the treatment of inflammatory disease in adjacent osteomeatal complex, ethmoid, and maxillary sinus. In the case of presence of extensive inflammatory disease in ethmoids and maxillary sinus, coherent FESS was done after endoscopic excision of concha bullosa was carried out. In all the patient's concepts of the "Messerklinger technique" of FESS were followed. Post-operative medication included an oral course of broad spectrum antibiotic, analgesics, and antihistaminic. Depending on the intraoperative bleeding the pack was removed 24-48 h after surgery. Following which suction cleaning done to remove blood and fibrin clots from the operated cavity without creating new trauma to the mucosa. Antibiotic steroid ointment applied over raw areas. Patients were instructed to avoid nose blowing so as to avoid subcutaneous emphysema.

All patients were seen on a weekly basis in OPD until the turbinate and cavity healed completely. At each visit, local care consisted of suction of surgical cavities to remove discharge, clots, crusts to prevent synechiae formation between the middle turbinate and lateral nasal wall. If any adhesions were formed, they were released.

Statistical Analysis

The data from data collection forms were tabulated in a Microsoft Excel[®] spreadsheet. Data were then exported to SPSS, version 20.0 for statistical analysis. The level

of agreement between CT and endoscopy findings was determined by calculating kappa statistics; considering kappa coefficient: ≤ 0 poor, 0.01-0.20 slight, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1 almost perfect. Chi-square and Student's *t*-tests were used for statistical analyzes. $P < 0.05$ was considered statistically significant.

OBSERVATION AND RESULTS

In our present study, 7.5% of the cases belonged to 0-10 years age group, 27.5% were in age group 11-20; 32.5% cases in the age group 21-30; and 18.75% cases in group 31-40 years age. 7.5% were seen in the age group 41-50 years, 5.0% were seen in 51-60 years age group, and 1.25% were above 60 years of age. Out of 80 patients; 45 were male and 35 were female in the present study. Male: Female ratio = 1.28:1 (Graph 1).

In the present study, the chief presenting symptoms were nasal discharge in 96.25% cases and next were nasal obstruction in 88.75%, post nasal discharge in 52.50%, followed by sneezing in 50%, nasal mass (polyposis) in 46.25%, headache in 45%, ear problem (discharge/heaviness) in 16.25%, and epistaxis present in 8.75%, cases (Graph 2).

On anterior rhinoscopic, the most obvious abnormality

found was DNS, which was seen in 56 cases, i.e. 62.50%. Inferior turbinate hypertrophy was seen in 44 (55%) while middle turbinate hypertrophy was present in 03 (03.75%) cases. Nasal discharge present in of the patients 77 (96.25%), in which most of discharge was mucopurulent. unilateral discharge in 41 (51.25%) and 36 (45%) was bilateral. 37 (46.25%) patients had clinical evidence of polyps in the nasal cavity. Unilateral polyp were found 13 (16.25%) and bilateral in 24 (30%) cases (Table 1).

X-rays Paranasal Sinuses (PNS) (Water View) Findings

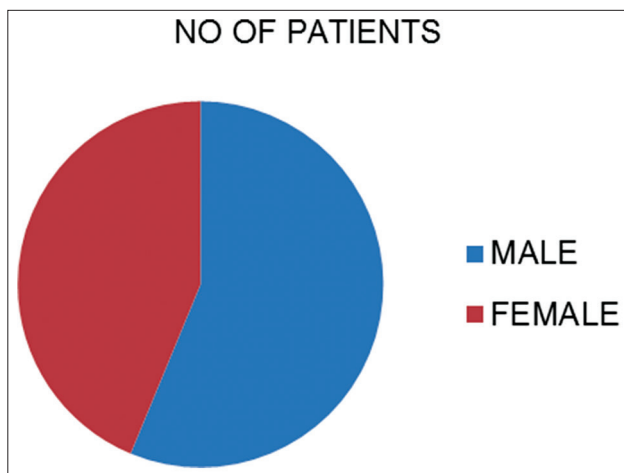
In the present study, out of total 80 cases, 76% patients show haziness of maxillary sinus on X-ray PNS with 50% unilateral and 50% bilateral. While 18% involvement of frontal sinus in which 44.44% were unilateral and 55.56% bilateral (Table 2).

CT-scan Evaluation: Anatomic Variations

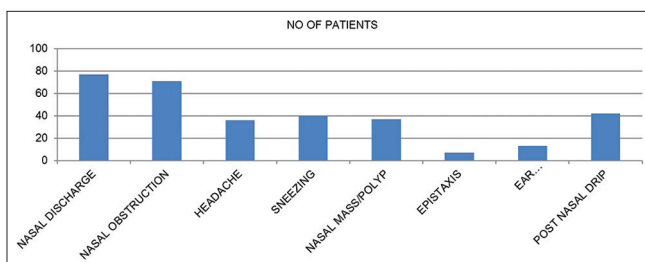
More than 50% of the patients showed soft tissue hypertrophy in either one or in both of the inferior turbinates. DNS was found in 51 (63.75%) cases. The nasal septum was predominantly found to be deviated on the left side. Paradoxical middle turbinate was seen in 23 (28.75%) out of 80 patients, 17 (21.25%) patients had agger nasi cells while Haller's cell was found in 11 (13.75%) cases and over pneumatized ethmoidal bulla was seen in 16 cases (20%).

In the present study, we observed the various type of mucosal pattern on the pre-operative screening of paranasal sinuses coronal CT revealed SNP pattern in 36 patients (45%) followed by an ostiomeatal unit (OMU) in 24 patients (30%). Infundibular pattern and unclassified/sporadic pattern were found in 9 patients (11.25%) and 8 patients (10%), respectively. with the least found pattern being the sphenoethmoidal recess pattern in 3 patients (3.75%) (Table 3).

Mucosal abnormality detected on CT-scan coronal view ranged from minimal mucosal thickening to total sinus opacification. As shown in Table 4, the most frequently involved sinus area was the maxillary sinus 76.25%, in which 55.73% were bilateral, and 44.46% were unilateral. Followed by anterior ethmoid involvement 53.75%, in which 48.83% were bilateral, and 51.16% were unilateral sphenoid sinus was the least commonly involved 15%. The most frequent anatomical variation seen on nasal endoscopy was DNS in 51 patients (62.50%) in which 76.75% were in the left side deviation while in right side 23.52%. Paradoxical middle turbinate was found in 8 patients (10%). The most common pathological abnormality detected by nasal endoscopy was inferior turbinate hypertrophy seen in 55% cases with 65.9% unilateral and 34.1% bilateral. Polyp in middle meatus and at anterior ethmoid region (i.e., osteomeatal complex area) was seen in 46.25% cases with 35.13%



Graph 1: Male:female ratio



Graph 2: Symptoms of the patients

unilateral and 64.8% bilateral. Ethmoidal polyp was 67.56% out of total cases of polyposis in which 24% were unilateral and 76% bilateral, antrochoanal polyp were 32.43% out of total cases of polyposis in which 100% were unilateral. The next most frequent finding which was seen during nasal endoscopy was mucopurulent discharge in nose/middle meatus were 41.25%, of which 63.63% had unilateral, and 36.36% had bilateral.

After complete pre-operative evaluation, FESS was performed. Septoplasty was also done in association with fess to get wide access for a nasal endoscope. Polypectomy were done in 37 (46.25%) out of which 19 (23.75) patients underwent bilateral polypectomy. Anterior ethmoidectomy were performed in 48 (60%) patients, of which 6 patients (7.5%) underwent unilateral and 19 patients (23.75%) underwent bilateral ethmoidectomy. Posterior ethmoidectomy was carried out in 2 patients (2.5%). Uncinectomy done almost all patients (Table 5).

No major per-operative complication occurred in this; however, 2.5% (2 patients) presented post-operative synchia formation, 2.5% echymosis, one patient presented diplopia and blurring in vision, 1 patient presented with the headache, one with orbital subacute emphysema, 3 patients with the headache.

DISCUSSION

The concept of FESS is the removal of tissue obstructing the osteo metal complex (OMC) and the facilitation of drainage and ventilation while conserving the normal non-obstructing anatomy and mucous membrane, which is essential for mucosal regeneration. The rigid fiberoptic nasal telescope provides superb intraoperative visualization of the OMC, allowing the surgery to be focused precisely on the key areas to achieve the main goal: Adequate and permanent post-operative patency of ethmoid sinus.¹²

Use of microdebridors further improved to remove the pathologic tissue while preserving normal mucosa. Moreover, with the combination of suction with powered dissection has revolutionized endoscopic sinus surgery. FESS, like all minimally invasive surgery, is designed to combine an excellent outcome with minimal patient discomfort.¹³ As mentioned, the main advantage of FESS compared with traditional techniques is that it is less invasive, resulting in minimal post-operative discomfort. Scars and damage to the nerve supply of the teeth are also avoided. The use of the endoscope permits a better view of the surgical field, and this is probably responsible for the lower rate of complications. The long-term success rate of FESS for symptomatic improvement in patients

with CRS is approximately 90%. With the advent of more sophisticated endoscopic surgical experience and instrumentation.^{14,15}

The study group consisted of 80 patients with chronic sinonasal diseases and nasal polyposis, in which conservative management had failed. They underwent complete clinical evaluation and routine screening by pre-operative nasal endoscopy, X-rays (water's view), CT-scan coronal section (Axial and sagittal when required). All patients included in the present study were having symptoms for more than a month duration, and all were treated medically first. The patients who were symptomatic even after medical treatment were operated on by FESS approach. Moreover, Messerklinger technique was used in all the surgery.

In this study, we found ranged from 7 to 65 years. The majority of patients 10-40 years were affected which constitute a total of (62 patients) 77.5% and overall Male: Female ratio was 1.28:1. Mustafa Golam *et al.*, (2011)³ in his study, total 60 cases in which maximum (44 cases) 73.33% of patients were in age group of 20-40 years, the male patients were (42 cases) 70% and female patients were (18 cases) 30%. The Male:Female ratio was 2.3:1. They also found that nasal discharge 50%, nasal obstruction 70%, headache/ facial pain 65%, post nasal drip 33%, sneezing 25%, and the chief complaint, in his study, was nasal obstruction followed by the headache while in our study the chief complaint is nasal discharge followed by nasal obstruction. we also in our study found that the most common symptoms were nasal discharge 96.25% and next were nasal obstructions 88.75%, post nasal discharge 52.50%, followed by sneezing 50%, nasal mass 46.25%, headache 45%, ear problem 16.25%, and epistaxis 8.75%. Kennedy *et al.*¹⁵ also show the similar finding in his study, nasal discharge, headache and nasal obstruction or congestion as the most frequent symptoms in patients with CRS.

Kamel¹⁶ noted in his study of 50 cases of the nasal polyp; nasal endoscopy finding were most of the patients 76% had an ethmoid polyp. 8% were suspected to have an antrochoanal polyp and 14% presented with a non-specific polypoidal nasal mass. In our study, total (37 cases) 46.25% cases were seen with nasal polyps out of which 67.56% ethmoidal polyps, and antrochoanal polyp cases 32.43%, of all cases of nasal polypi. For FESS CT-scan evaluation of the patients who have to undergoing FESS is essential. Most of the anatomical abnormalities can be studied on by CT-scan, but however, endoscopy also gives other valuable information Sheetal *et al.*¹⁷ High-resolution CT evaluates the extent of the inflammatory disease and assesses important anatomical landmarks and their variations. These variations include nasal septal deviation, septal spur, paradoxical middle turbinate, concha bullosa, haller cells, and abnormal

deviation of the uncinate process. These variations can result in narrowing of the infundibulum or the maxillary ostium Gupta *et al.*¹⁸

Comparison with other study

Anatomical variant	Our study (%)	Naimi 2006 (%)	Dua 2005 (%)	Maru <i>et al.</i> , 2001 (%)	Zinreich 1993 (%)	Bolger 1991 (%)
Agger nasi cells	21.25	8	50	88.5	Nearly all	98.5
Concha bullosa	47.50	24	15	42.6	33	53
Haller cells	13.75	12	17.5	36.1	10	45.1
Septal deviation	62.5	40	65	55.7	28	18.8
Paradoxical MT	28.75	4	-	11.5	-	27

Five basic radiological patterns of sinonasal inflammatory disease were identified among 80 patients. These were (I) OMU 30% (II) infundibular 11.25% (III) sinonasal polyposis 45% (IV) sphenoethmoidal 3.75% (V) unclassified 10%.

After the complete pre-operative evaluation and confirmation by nasal endoscopy and CT-scan paranasal sinuses, FESS was performed using Messerklinger technique, according to need and minimal surgery was done to preserve the normal physiology and anatomy of sinus as much as possible. Septoplasty was done in (23 cases) 28.7%, and polypectomy was done in (37 cases) 46.25%, of which (19 patients) 51.35% underwent bilateral polypectomy and the remaining (18 patients) 48.64% patients underwent unilateral polypectomy.

The anterior ethmoid region is known for being the main source of infection and reinfection of maxillary and frontal sinuses. Anterior ethmoidectomy was performed in (43 cases) 53.7%, of which (21 patients) 48.83% underwent unilateral and (22 patients) 51.16% underwent bilateral ethmoidectomy. Posterior ethmoidectomy was carried out in (6 patients) 7.5%. Uncinectomy was done in almost all patients. Uncinectomy also known as infundibulotomy alone can clear the disease from the maxillary and frontal sinuses as the uncinate process makes the medial wall of ethmoid infundibulum which is most important transition space. Uncinectomy serves the purpose of opening of infundibulum for normal drainage and ventilation of sinuses. Uncinectomy was done in total (78 cases) 97.5% in which (38 cases) 48.7%, were bilateral and (40 cases) 51.28% were unilateral. Concha bullosa was exteriorized in 5% cases. Frontal recess clearance was done in total 5% patients.¹⁹

In the hands of the experienced clinician, reported complications are surprisingly few and similar to those reported by other approaches. In a series of over 4000 cases reported only two cases of CSF rhinorrhea, no intracranial complications and no ophthalmic problems.²⁰ Stankiewicz²¹

suggested that the complication rate decreases with increasing experience, reporting a rate of 29% in the first 90 cases which he performed compared with only 2.2% in the subsequent 90. Most of the cases were minor, such as adhesions, but there were two cases of CSF rhinorrhea and one case of temporary blindness.

Patients were completely satisfied with the result (CS) of surgery in 48.51% cases. Out of 80 patients under

Table 1: Clinical findings on anterior rhinoscopy

Findings	Total cases n (%)
Inferior turbinate hypertrophy	44 (55)
Middle turbinate hypertrophy	03 (03.75)
Polyp or mass in nasal cavity	37 (46.25)
Discharge in nasal cavity	42 (52.5)
Sinus tenderness	15 (18.15)
DNS	51 (63.75)

DNS: Deviated nasal septum

Table 2: X-ray PNS waters view findings

Sinus Involved	Number of cases	Percentage
Maxillary sinus haziness	72	90
Frontal sinus haziness	22	27.5

PNS: Paranasal sinuses

Table 3: Pattern of sinonasal inflammatory diseases

Mucosal pattern	Number of cases	Percentage
Infundibular pattern	9	11.25
OMU pattern	24	30
Sphenoethmoidal recess pattern	3	03.75
Sinonasal polyposis	36	45
Unclassified/sporadic	8	10

OMU: Ostiomeatal unit

Table 4: CT-scan detection of sinus involvement (mucosal changes)

Site of involvement	Number of patients	Percentage
Frontal	21	26.25
Anterior ethmoid	43	53.75
Posterior ethmoid	23	28.75
Maxillary	61	76.25
Sphenoid	12	15

CT: Computed tomography

Table 5: Surgical procedure used in present study

Surgery	Number of cases	Percentage
Polypectomy	37	46.25
Uncinectomy	78	97.5
Anterior ethmoidectomy	43	60
Middle meatus antrostomy	78	97.5
Posterior ethmoidectomy	6	7.5
Partial middle turbinectomy	8	10
Septoplasty	23	28.7

study, 41.67% patients were generally satisfied with their result (GS) after surgery 9.95% patients did not have improvement after surgery (NI). The overall satisfactory rate can be calculated just by adding the 1st and 2nd points mentioned above which comes as 85.49%.

CONCLUSION

CRS usually affects mostly the people of age group ranging from 20 to 40 years with the common mode of presentation being nasal obstruction, nasal discharge, headache, and post nasal drip. Endoscopically allow an exceptionally clear and well-illuminated field with the added advantage of the ability to inspect the recess with angled distal lenses. It helps in diagnosis of sinonasal pathology by revealing structural details and anatomical variation in the nasal cavity to a greater extent. It allows accurate definition of the extent of the lesion and early diagnosis of recurrence is also possible. It can also serve as an excellent teaching tool and source of photo documentation.

Coronal CT-scan accurately defines micro anatomical locales in and around the OMU and also identifies dangerous anatomical variants such as dehiscent optic nerve canal and carotid artery canal. Thus, it seems to be a variable guide to the surgeon in the planning of the operative procedure, avoiding intraoperative complications and assessing programs, and the success thereof. FESS provides an excellent and safe method for treating sinonasal disease. The success rates are encouraging but because of the nature and chronicity of the disease, longer follow-up may be necessary to truly assess the surgical effectiveness of the procedure. FESS has proven to be a better surgical, and therapeutic technique means over the conventional methods and has opened a new horizon for possibilities of positive results in further studies and more complicated cases work to be performed in the hands of further inquisitive workers.

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Effectiveness of Computed Tomography-Guided Percutaneous Chemical Lumbar Sympathectomy in Peripheral Arterial Vascular Disease

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Abstract

Introduction: Lumbar sympathectomy was first developed in 1924 by Hunter and Royle. Lumbar sympathectomy has been performed without image guidance by anesthetists and surgeons in earlier days. Now, it is performed under image guidance as it is effective and safe procedure for the relief of pain produced by severe peripheral arterial vascular disease.

Purpose: Purpose of the percutaneous lumbar chemical sympathectomy under computed tomography (CT)-guidance were to achieve the exact location of needle placement and deposition of neurolytic agent 10% phenol in glycerine to relieve pain in severe peripheral arterial vascular disease. It is cost effective and widely available treatment option which takes less time to staying in hospital as it is out patients procedure.

Materials and Methods: Institutional approval and informed consent from patients were obtained. The study was conducted from March 2004 to July 2015 on 46 patients of either sex (45 male and 1 female), aged between 30 and 78 years, referred to Department of Radio-diagnosis and Department of Anesthesia and Pain Management, Pt. J. N. M. Medical College, Dr. B. R. A. M. Hospital, Raipur, India. Assessment of pain was done by visual analog scale (VAS). Full aseptic precautions were taken during the procedure. Under the guidance of CT scanner (Siemens, Germany) 20 G, 15 cm long graduated sympathectomy needle was inserted, and needle tip was positioned anterolateral to the L3 vertebral body. 10 ml phenol (10%) mixed with 0.5 ml contrast media was injected after negative aspiration.

Result: Mean baseline value of pain intensity by VAS was 6.22, after 72 h and 1 month it was 2.65 and 1.80, respectively, which were statistically significant. None of the patients had a complication.

Conclusion: CT-guided percutaneous chemical lumbar sympathectomy appears to be safe, effective, and less costly palliative procedure for controlling lower limb pain.

Key words: Chemical sympathectomy, Multidetector computed tomography, Phenol, Percutaneous, Peripheral vascular disease

INTRODUCTION

Periarterial sympathectomy on femoral artery done by Jabouly in 1889 and Lericle in 1921 got disappointing result due to reinnervation and vasospasm within weeks

of operation. Lumbar sympathectomy was first developed in 1924 by Hunter and Royle.¹

Chemical lumbar sympathectomy is accepted, and effective therapeutic option in patients of peripheral arterial vascular diseases in outpatients department basis who are not eligible for surgical intervention and are not suitable candidate for reconstructive surgery because there vascular status not permit for it, and have reduced response of oral medication or uncontrolled pain.²

Several imaging modalities have been used for needle guidance such as fluoroscopy, sonography, and magnetic

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resonance (MR) imaging. These methods are less preferred because inconsistent results. MR imaging is incompatible with needle.³⁻⁵ Hence, we preferred computed tomography (CT)-guided imaging for needle placement were needle tip position precisely at the sympathetic trunk and avoided risk of puncturing the surrounding structure and vessels.

Anatomy

The lumbar sympathetic plexus is contiguous with the thoracic sympathetic chain above and the pelvic chain below. It runs along the medial border of the psoas muscle, entering the abdomen from behind the medial arcuate ligament. The right sympathetic trunk lies behind the lateral border of the inferior vena cava (IVC) and the left sympathetic trunk lies close to the lateral border of the aorta. The trunk includes four segmentally arranged ganglia most often present opposite the mid body of L3 and its upper and lower disk spaces. Branches from the lumbosacral sympathetic trunk included (a) postganglionic fibers that are distributed through branches of the spinal nerves to the blood vessels, sweat gland, and erector pill muscles, (b) branches to the sympathetic plexus of the aorta and its branches, and (c) branches to the inferior continuation of the sympathetic plexus including the superior hypogastric plexus. The sympathetic neural fibers have been implicated in the maintenance of chronic pain in certain neuropathic condition.^{6,7}

MATERIALS AND METHODS

Institutional approval and informed consent from patients were obtained. In our study, we included all the patients with the peripheral arterial vascular disease who were not required surgery or who were in Stage II Intermittent claudication. Stage IIa: Intermittent claudication after more than 200 m of pain free walking, Stage IIb: Intermittent claudication after <200 m of walking, Stage III: Rest pain, and Stage IV: Ischemic ulcers or gangrene according to Fontaine classification and those who were post amputated but having pain. The diagnosis was confirmed clinically, laboratory, as well as radiologically. The study was conducted between March 2004 and July 2015 on 46 patients. Out of these 45 were male and 1 was female. Patients were between 30 and 78 years of aged. Visual analog scale (VAS) was used to access the pain before the procedure and consider as a baseline value. The VAS consist of 10 cm line marked at one end with term “no pain” at one end and at the other end the “worst possible pain.” Patients made a cross on the line at the point that best approximates to their pain intensity as explain during patient evaluation on his own language. It was graded as

0-10 (0 = No pain, 10 = Worst pain, Mild = 1-3, Moderate = 4-6, Severe = 7-10).

Patients were kept nil orally 6 h for solid, semisolid, and milk prior to the procedure. 100-200 ml clear fluid allowed 3 h prior to the procedure. Patients may continue to take their existing medications including analgesics. Multipara monitor was attached, and pulse, NIBP, SPO₂, electrocardiogram were monitored. Intravenous access was done and DNS 100 ml/h started.

The patients were placed on the table in prone position. Premonitored the location of needle placement, depth, and direction identified by CT imaging to avoid the puncture of major vascular and visceral structures. (Figure 1). After full aseptic precautions, needle insertion site was infiltrated with 2% lignocaine with adrenaline. A 20 G, 15.0 cm long, graduated sympathectomy needle was inserted gently through the skin tangent to the right lateral or left lateral depending on the side of pain, at the distance approximately 7-9 cm from the midline under CT-guidance at the level of L3 vertebrae. The needle was directed tangentially to the superior articular process. Placement of the needle anterior to the psoas muscle and posterolateral to the IVC or aorta (Figure 2) and confirm the needle tip position under the guidance of CT scan (we also confirmed by loss of resistant (LOR) technique using LOR syringe while the needle was inserted). In this study, the procedure was done on the right side in 32 patients and left side in 14 patients. Prior to injecting phenol negative aspiration was done to check for blood and cerebrospinal fluid. 0.25 ml of contrast media added in bupivacaine 10 ml (0.25%) and 5 ml injected to see the spread of solution, venodilatation, and for effective pain relief.

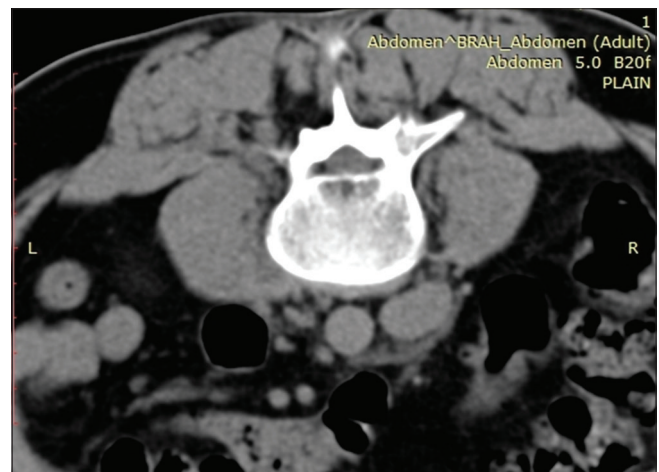


Figure 1: Axial multidetector computed tomography image at L3 vertebral body level shows the sympathetic chain as small dot in fatty triangle between the spine, psoas muscle, and aorta on the left side, and between the spine, psoas muscle, and inferior vena cava on the right side

There after 10 ml 10% phenol mixed with 0.50 ml contrast media in glycerine was injected after negative aspiration and confirmed by CT scan (Figure 3). Finally, small volume of normal saline injected before the needle was withdrawn to minimize the spread of phenol.

RESULT

By the Graphpad's analysis software mean baseline value of pain intensity by VAS was 6.22, after 72 h and 1 month of procedure the mean baseline value of pain intensity reduced to 2.65 and 1.80, respectively (Tables 1 and 2). Statistically significant decrease in pain intensity observed from baseline value. None of the patients had aortic, inferior vena cava puncture, pneumothorax, renal puncture, dural puncture, and nerve damage (Table 3).

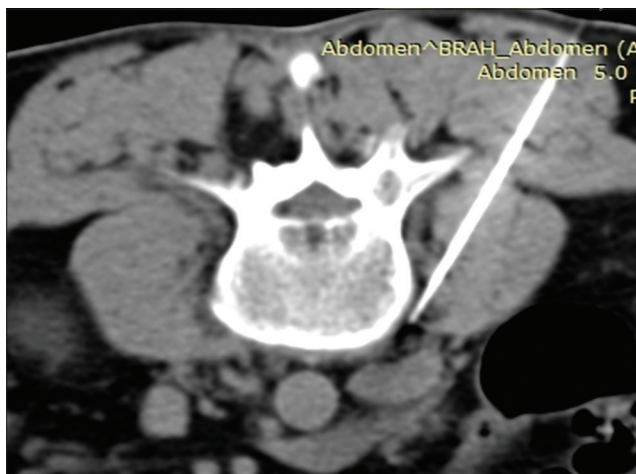


Figure 2: Axial multidetector computed tomography images shows tip of 20 G needle between the spine, psoas muscle, and inferior vena cava on the right side

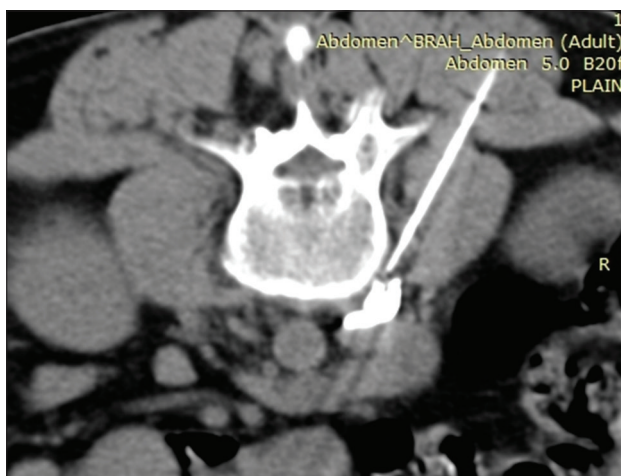


Figure 3: Axial multidetector computed tomography images show spread of phenol mixed contrast material posterolateral to inferior vena cava at the tip of needle on the right side

DISCUSSION

The indication for percutaneous chemical lumbar sympathectomy is pain from lower limb ischemic disease including Raynaud's disease, sympathetic dystrophy, pelvic and perineal pain of malignant or nonmalignant origin. In our study, we included peripheral arterial disease (PAD) of the lower limb and one female patient of Raynaud's disease. The single needle was used at the level of L3 vertebrae. 10% phenol in glycerine was chosen as an agent for therapeutic chemical sympathectomy and 10 ml volume mixed with 0.25 ml of contrast was administered. Viscous nature of glycerine limits the spread. Before injecting, we warm the agent.

According to International Association for Study of Pain define as "an unpleasant sensory and emotional experience associated with actual and potential tissue damage, or described in terms of such damage." "Pain is always subjective."⁸

It is of either acute or chronic in type. PAD pain is chronic in type. It is most commonly occur in low socioeconomic status people, and the most common risk factor is bidhi or cigarette smoking. Other risk factors include diabetes, high blood pressure, and high blood cholesterol. In PAD, there is fatty deposition in the arteries which causes restricted blood supply to the leg muscles. Many patients are asymptomatic, but some feel painful aching in there leg muscles that are aggravated by physical activity like walking or climbing stairs. This type of pain known as intermittent claudication. The pain can range from mild to severe. Pain also occurs at resting condition. Some relief of symptoms is possible with exercise, pharmacotherapy, and cessation of smoking. Primarily it treated by managing lipids, blood sugar, and blood pressure. If the treatment is not effective and the symptoms of PAD often develop slowly over time but if symptoms get suddenly worse it could be a serious problem and requiring immediate treatment. Revascularization is required to restore the flow of blood. These types of patients are considered for surgery,

Table 1: Patients characteristic profile and outcome

Number of case	Indication	Pain duration prior to procedure (months)	Effective pain relief after 72 h	Effective pain relief after 1 month
2	PAVD	8	Improved	Improved
7	PAVD	10	Improved	Improved
15	PAVD	12	Improved	Improved
10	PAVD	18	Improved	Improved
7	PAVD	24	Improved	Improved
4	PAVD	30	Improved	Improved
1	Raynaud's disease	32	Improved	Improved

PAVD: Peripheral arterial vascular disease

Table 2: VAS score

VAS score	Baseline VAS score		After 72 h			After 1 month		
	Number of patients	Mean \pm SD	Number of patients	Mean \pm SD	P value	Number of patients	Mean \pm SD	P value
1-3	0		34			41		
4-6	34	6.2 \pm 1.69	12	2.65 \pm 1.70	<0.0001	5	1.8 \pm 1.17	<0.0001
7-10	12		0			0		

VAS: Visual analog scale, SD: Standard deviation

Table 3: Complication

IVC/aortic puncture	Nil
Visceral structure (kidney/lungs) injury	Nil
Nerve injury	Nil
Dural puncture/CSF aspiration	Nil

IVC: Inferior vena cava, CSF: Cerebrospinal fluid

and we excluded them from our study. We included the patients according to fontaine classification⁹ Stages II-IV and previously amputated patients having pain. The pain was graded by VAS.

Lumbar sympathectomy indicated for peripheral arterial vascular disease; It can be used as temporarily or irreversibly block. It can be performed by open surgery. It can be performed as a blind procedure. Other imaging modalities are fluoroscopically¹⁰ and sonographically⁴ guided lumbar sympathetic blocks have been performed with varying success rate. These methods are less likely than CT-guided lumbar sympathetic block to result in the needle tip being positioned precisely at the sympathetic trunk.

In our study, the procedure was more beneficial for pre-gangrenous patients Stages II-III and the patients who were even unable to sleep. The patients who were already developed gangrene or Stage IV had less beneficial effect although they were also improved, but all the patients had not developed any complication during or after the procedure. On follow-up after 1 month, they were feel comfortable during walking, and even they increases there walking distance from previous, had no rest pain and improved lifestyle.

Lumbar sympathectomy causes increased distal perfusion by elimination the vasoconstriction caused by sympathetic nerve and reduces the sympathetic pain.

Before CT-guidance, pain management physicians used either an unguided method or fluoroscopic guidance to provide general localization of the needle. In the blind procedure of lumbar sympathectomy, there is a risk to puncture of major vascular structures such as the aorta, IVC, and injury to nerve.

At our institution, CT-guidance is preferred for needle insertion. It is more precise because needle tip is targeted at the expected location of sympathetic trunk which is located within fat tissue between the lumbar spine, psoas muscle¹¹ and aorta or IVC.¹² The advantage of CT over blind procedure or other imaging modality like fluoroscopic techniques is that to exact position of needle, distribution of anesthetic medicine or solution, and major vascular structures such as aorta, IVC, surrounding visceral structures such as kidney, lungs can be avoided from puncture. The level of insertion was L3 decreases the risk of pneumothorax; there is a risk of puncture to the renal pelvis, epidural injection, disk perforation, L1 nerve damage and lymphocele formation. So that without any risk patients get relieved from their pain.

According to the literature, Pieri *et al.*,¹³ done percutaneous sympathectomy under CT-guidance by using phenol at the level of L2 and L4 by using two 22 G needles (15 cm long) in 19 patients who had severe vascular disease of the lower extremities with rest pain and gangrene and they were not eligible for surgical revascularization. They found out of the 19 patients, 9 (47.3%) showed clinical improvement, whereas 5 experienced a worsening of ischemia in the months immediately following the procedure.

Schmid *et al.*,¹⁴ evaluate the accuracy of sympathetic skin response (SSR) for monitoring CT-guided lumbar sympathetic blocks, 70 individual lumbar sympathetic blocks were performed in 13 patients with reflex sympathetic dystrophy of the foot. They use a 22 G needle at midlumbar level advanced to sympathetic trunk with CT fluoroscopic guidance; they use 1 ml of iopamidol (200 mg of iodine per ml) and 5 ml of 0.5% bupivacaine. SSR ratio (SSR in the injected foot versus SSR in the contralateral foot) was calculated before injection and repeatedly at 1 min intervals thereafter. They found 30 min after injection, 83% of procedures were considered clinically successful. Sensitivity, specificity, and accuracy of SSR for prediction of clinical success were 84%, 92%, and 86%, respectively, 4 min after injection and 95%, 92%, and 94%, respectively, 7 min after injection.

Tay *et al.*,¹⁵ done chemical lumbar sympathectomy under the guidance of CT-fluoroscopy inoperable peripheral vascular

disease they found improvement in 30.3% cases, 45.4% cases had no change and 24.3% cases get deteriorated. Within 3 months, complication rate was <1% and efficacy were of 30%.

Koizuka *et al.*,¹⁶ done fluoroscopic CT-guided percutaneous lumbar sympathectomy for a safest route for needle insertion in 25 patients. They found the distance from the midline (spinous process) to the entry point and the depth to the target site correlated with body size and the maximal distance from midline to the insertion point in the range of safe needle insertion at L2 was <7 cm in approximately 20% patients.

CONCLUSION

CT-guided percutaneous chemical lumbar sympathectomy appears to be safe, effective, and less costly palliative procedure for controlling lower limb pain in inoperable peripheral arterial vascular diseases.

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Intravitreal Triamcinolone Acetonide in Macular Edema due to Retinal Vein Occlusions: A Comparative Study of 1 mg and 4 mg Doses

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Abstract

Introduction: Macular edema (ME) occurs in a wide variety of ocular situations like uveitis, trauma, vascular retinopathies, hereditary dystrophies, and intraocular surgery. It is one of the most important causes of visual disturbance in patients with retinal vein occlusions.

Materials and Methods: A total of 43 eyes of 43 patients with ME due to retinal vein occlusion were randomized to receive either 1 mg or 4 mg dose of intravitreal injection of triamcinolone acetonide. Each patient had a complete comprehensive ophthalmic examination at baseline and at each subsequent visit. Fundus fluorescein angiography and optical coherence tomography were done at baseline and at 1, 3, and 6 months. Best-corrected visual acuity (BCVA), the status of the lens and intraocular pressure (IOP) were recorded at each follow-up visit. BCVA was measured in Snellen's lines and converted into logarithm of minimum angle of resolution scale for statistical analysis. The data were statistically evaluated using the Wilcoxon signed rank test, Mann-Whitney test, and *t*-tests wherever applicable. A $P < 0.05$ was considered significant.

Results: There was no statistically significant difference in the mean foveal thickness measurement at baseline ($P = 0.159$) or at the 3rd month ($P = 0.605$) between both the groups. There was no statistically significant difference observed in mean BCVA between the two groups at 1 day, 1 month, 3 months, and 6 months. There was no statistically significant difference observed in IOP between the two groups at any follow-up visit.

Conclusions: The results of our study suggest that 1 mg dose of IVTA is as effective as 4 mg dose of IVTA in improving the functional and anatomical outcome in ME associated with retinal vein occlusions.

Key words: Retinal vein occlusion, Macular edema, Triamcinolone Acetonide

INTRODUCTION

Macular edema (ME) is the result of an accumulation of fluid in the retinal layers around the fovea. It contributes to vision loss by altering the functional cell relationship in the retina and promoting an inflammatory reparative response. ME is a nonspecific sign of ocular disease and not a specific entity. It should be considered as a

special and clinically relevant type of macular response to an altered retinal environment. In most cases, it is associated with an alteration of the blood-retinal barrier.

ME may occur in a wide variety of ocular situations including uveitis, trauma, intraocular surgery, vascular retinopathies, vitreoretinal adhesions, hereditary dystrophies, and age-related macular degeneration.¹ It is the most commonly seen following venous occlusive disease, diabetic retinopathy, and posterior segment inflammatory disease.²

The histopathological picture of this condition is an accumulation of fluid in the outer plexiform (Henle's) and inner nuclear and plexiform layers of the retina. The

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increase in water content of the retinal tissue characterizing ME may be intracellular or extracellular.¹

There are various modalities for treating the ME.² Intravitreal triamcinolone acetonide (IVTA) is one of the treatment modalities.² However, IVTA is associated with significant complications like cataract progression and rise in intraocular pressure (IOP).³ Decreasing the dose of IVTA may reduce the complications.

ME treatment varies, depending on the underlying etiology causing the edema.⁴ Traditionally, the main treatment options have included topical and systemic steroids, topical and systemic non-steroidal anti-inflammatory agents, oral carbonic anhydrase inhibitors, and laser photocoagulation therapy. Despite these treatment modalities, patients often have persistent macular edema.⁴

Vascular endothelial growth factors (VEGF) have been implicated in many different mechanisms, which lead to ME. Anti-VEGF agents act by blocking the action of VEGF. Various Anti-VEGF agents considered for the treatment of ME include bevacizumab, ranibizumab, and pegaptanib. Various other drugs such as steroid-sparing immunosuppressive drugs, interferon $\alpha 2$, cyclosporine A, anti-tumor necrosis factor therapy, protein kinase inhibitors, and somatostatin analogs such as octreotide have been used in ME due to various causes.⁵

Intravitreal corticosteroid injections have been used at an increased rate for treating ME. Corticosteroids have likely been successful in the treatment of various forms of ME, due to its known anti-angiogenic, anti-edematous,⁶ anti-inflammatory,⁷ and anti-proliferative effects.⁸

Furthermore, it has also been demonstrated that activation of the glucocorticoid receptor is protective to the retinal photoreceptors due to its anti-apoptotic effect.⁹

The commonly used intravitreal steroid is triamcinolone acetonide. In various case reports and series, IVTA has been shown to be safe and effective when used for the treatment of ME caused by retinal vein occlusion.¹⁰ While studies have been done using varying dosages of 1-20 mg,¹¹ the commonly used dosage is 4 mg. The efficacy, duration of action and risk of side effects could be expected to increase with higher doses of IVTA.¹² The two most common side effects of IVTA are the elevation of IOP and cataract formation. Decreasing the dose of IVTA may reduce complications. Pharmacokinetics of triamcinolone acetonide after a 4 mg intravitreal injection for ME in non-vitreotomized eyes showed that the mean elimination half-life was 18.6 days, suggesting that triamcinolone acetonide would be present in measurable concentrations for 3 months.¹³

Aim

To compare the efficacy and safety of 1 mg and 4 mg doses of IVTA injection in the treatment of ME due to retinal vein occlusion.

Objectives of the Study

Primary objectives

To compare the best corrected visual acuity (BCVA) and foveal thickness on optical coherence tomography (OCT) between 1 mg and 4 mg doses of IVTA injections.

Secondary objectives

To compare the steroid related complications as seen by IOP measurements and cataract progression.

This was a prospective randomized comparative interventional study done on patients who attended the Vitreo-Retina Department of Sarojini Devi Eye Hospital, Hyderabad from December 2010 to May 2012. The study included 43 eyes of 43 patients with retinal vein occlusion associated with ME, randomly assigned to receive either 1 mg or 4 mg dose of IVTA. The patients were explained about the diagnosis, prognosis, different treatment options and the likely complications. An informed consent was taken before enrolment.

MATERIALS AND METHODS

Inclusion Criteria

- ME due to retinal vein occlusion
- BCVA <6/12
- ME seen on slit lamp bio microscopy
- Fundus fluorescein angiography showing leakage at macula
- OCT showing foveal thickness of >200 μ

Exclusion Criteria

- Reduced visual acuity due to significant cataract
- Posterior capsular opacification in pseudophakic eyes
- Intravitreal or peribulbar steroids or any macular photocoagulation 4 months prior to injection
- Prior pars plana vitrectomy
- Cataract surgery or yttrium aluminum garnet capsulotomy 4 months prior to injections
- Any epiretinal membrane or vitreomacular traction on OCT
- Eyes with thin sclera
- Any glaucoma or pseudoexfoliation.

A complete comprehensive ocular examination was done in all patients, including BCVA; slit lamp examination of anterior segment and posterior segment (using 90 D lens), indirect ophthalmoscopy, gonioscopy, applanation tonometry at baseline and at each subsequent visit. FFA

and OCT were done at baseline, 1 month, 3 months, and at 6 months follow-up. BCVA was recorded in Snellen's lines and converted to logarithm of minimum angle of resolution (log MAR) scale for analysis.

All the patients were evaluated for systemic risk factors for retinal vein occlusion including diabetes, hypertension, and coronary artery disease and were investigated for blood and urine sugars, glycated hemoglobin (Hb), Hb%, Serum lipids, anemia, and serum homocysteine. A cardiovascular evaluation was done by a physician/cardiologist including a 2 D echo and Doppler examination. Any abnormal parameters found on systemic evaluation were treated by physician.

Gatifloxacin eye drops 3 times a day were given 1 day before and on the day of injections. The intravitreal injections were given in the operation theater using topical anesthesia (proparacaine hydrochloride 0.5%). Asepsis was achieved by surface preparation of eye including the lashes using 2-3 drops of 5% povidineiodine. 0.1 ml (either 1 mg or 4 mg) of triamcinolone acetonide was injected, using 1 ml syringe with 30 G needle, at pars plana in the inferotemporal quadrant 3.5 mm posterior to limbus in pseudophakic eyes and 4 mm posterior to limbus in phakic eyes. The patients were reviewed the next day and proper placement of the drug confirmed. Topical gatiflox eye drops were used 4 times a day for 1 week after the injection.

Patients were re-examined at 1 day, 1 week, 1 month, 3 months, and 6 months after the injection. The minimum period of follow-up was 6-month.

The data, thus, collected was subjected to statistical analysis. Snellen's VA was converted to the log MAR and averaged for the purpose of statistical analysis. Statistical analysis was performed using commercial statistical software (IBM SPSS for Windows, Version 20). The data were statistically evaluated using the Wilcoxon signed rank test, Mann-Whitney test, and *t*-tests wherever applicable. A $P < 0.05$ was considered significant.

RESULTS AND OBSERVATIONS

Out of the total 43 patients, two patients receiving 1 mg of IVTA and one patient receiving 4 mg of IVTA were lost to follow-up. 40 patients completed 6 months follow-up. Therefore, 40 eyes of 40 patients with a minimum follow-up period of 6-month were included for analysis.

Demographic Profile

Gender distribution

Our study comprised predominantly of males; a total 40 patients of which 26 patients were male and 14 patients were female (Table 1 and Figures 1 and 2).

Age distribution

The mean age was 50.25 ± 14.37 in 1 mg group and 48.5 ± 13.59 in 4 mg group (Figure 3).

Type of retinal vein occlusion

Out of 20 eyes in each group 7 eyes (35%) were diagnosed as central retinal vein occlusion (CRVO), 2 (10%) with hemi-retinal vein occlusion, 11 (55%) with branch retinal vein occlusion (BRVO) (Figures 4 and 5).

Duration of symptoms

The mean (\pm standard deviation [SD]) duration of symptoms was 55.3 ± 23.06 (range 20-90) days in 1 mg

Table 1: Gender distribution

Gender	n=20	
	1 mg	4 mg
Males	12	14
Females	8	6

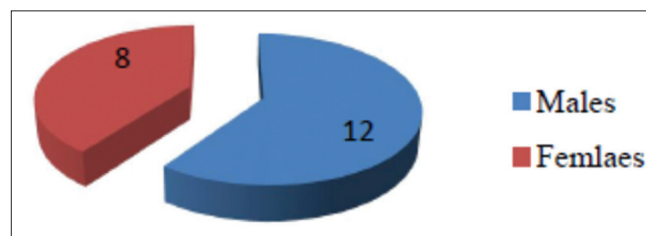


Figure 1: 1 mg group

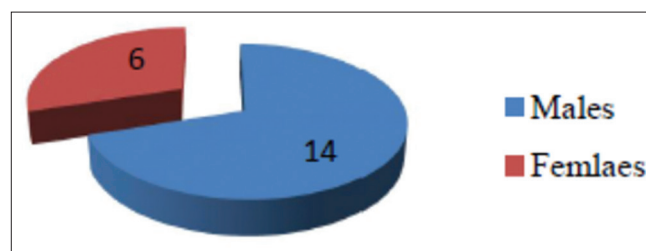


Figure 2: 4 mg group

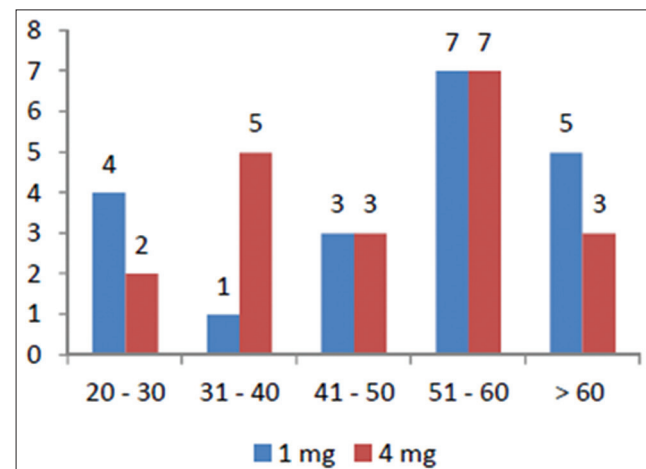


Figure 3: Age distribution

group and 51.25 ± 30.55 (range 15-120) days in 4 mg group.

Foveal thickness

The mean (\pm SD) foveal thickness was 423.77 ± 105.45 ($n = 13$) in 1 mg group and 502 ± 169.75 ($n = 16$) in 4 mg group.

Mean change in foveal thickness (Table 2 and Figure 6)

The mean foveal thickness significantly improved from baseline in both the groups. There was no statistically significant difference in the mean foveal thickness measurement at baseline ($P = 0.159$) or at 3rd month ($P = 0.605$) between both the groups.

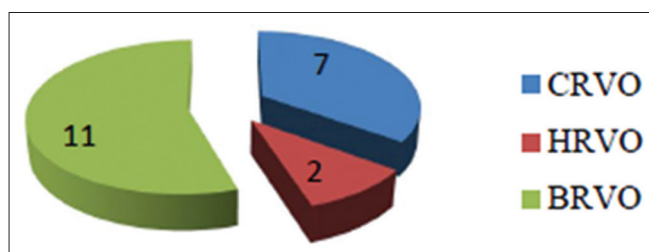


Figure 4: Types of retinal occlusion (1 mg)

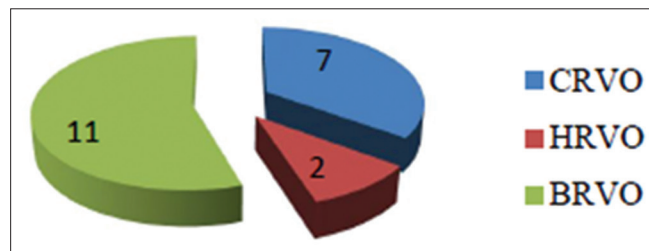


Figure 5: Types of retinal occlusion (4 mg)

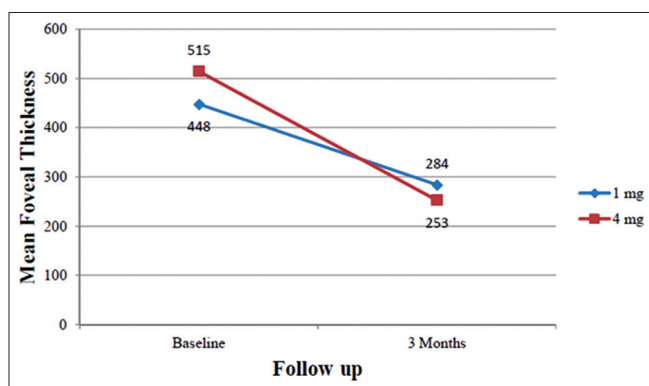


Figure 6: Mean change in foveal thickness

Visual acuity

Mean change in BCVA (Table 3 and Figure 7)

The mean (\pm SD) baseline BCVA was 1.30 ± 0.33 in 1 mg group and 1.13 ± 0.44 in 4 mg group. In 1 mg group, the mean BCVA was significantly improved from baseline to 1.19 ± 0.26 ($P = 0.010$), 0.95 ± 0.33 ($P < 0.0001$), 0.71 ± 0.48 ($P < 0.0001$), 0.62 ± 0.56 ($P = 0.001$), 0.75 ± 0.56 ($P = 0.002$) at 1 day, 1 week, 1 month, 3 months, and 6 months, respectively.

In 4 mg group, the mean BCVA was significantly improved from baseline to 0.99 ± 0.46 ($P = 0.002$), 0.65 ± 0.37 ($P < 0.0001$), 0.51 ± 0.38 ($P < 0.0001$), 0.50 ± 0.47 ($P = 0.001$), 0.48 ± 0.45 ($P = 0.003$) at 1 day, 1 week, 1 month, 3 months, 6 months, respectively. There was no statistically significant difference observed in the mean baseline BCVA between the two groups ($P = 0.166$). The mean BCVA was better in 4 mg group at 1 week ($P = 0.026$). There was no statistically significant difference observed in mean BCVA between the two groups at 1 day, 1 month, 3 months, and 6 months.

Visual Acuity Change in Snellen's Lines (Table 4 and Figure 8)

Complications

Increase in intraocular pressure (Table 5 and Figure 9)

Mean change in IOP during follow-up period: The mean (\pm SD) baseline IOP was 14.9 ± 2.29 in 1 mg group and

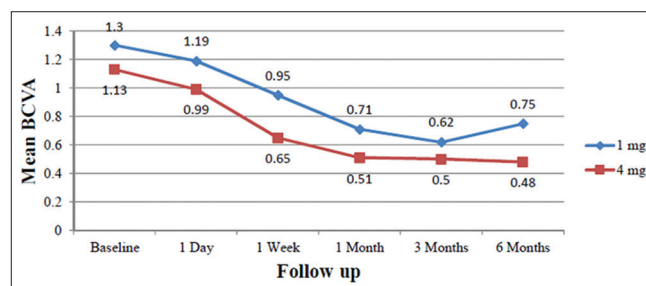


Figure 7: Mean change in best corrected visual acuity

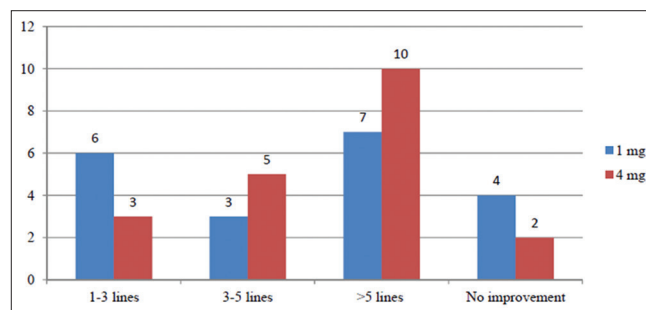


Figure 8: Visual acuity change in Snellen's lines

Table 2: Mean change in foveal thickness

Visit	1 mg (n=10)	P value	4 mg (n=15)	P value	P between sub-groups
Baseline	448.80 \pm 94.50		515.67 \pm 166.35		0.159
3 months	284.00 \pm 160.41	0.037	253.93 \pm 169.37	0.001	0.605

14.8 ± 2.46 in 4 mg group. In 1 mg group, the mean IOP was significantly increased from baseline to 17.7 ± 3.90 ($P = 0.007$), 18.1 ± 4.17 ($P = 0.001$), 17.6 ± 4.03 ($P = 0.006$),

Table 3: Mean change in BCVA

Visit	1 mg (n=20)	P value	4 mg (n=20)	P value	P between sub-groups
Baseline	1.30±0.33		1.13±0.44		0.166
1 st day	1.19±0.26	0.010	0.99±0.46	0.002	0.107
1 week	0.95±0.33	<0.0001	0.65±0.37	<0.0001	0.026
1 month	0.71±0.48	<0.0001	0.51±0.38	<0.0001	0.192
3 months	0.62±0.56	0.001	0.50±0.47	0.001	0.512
6 months	0.75±0.56	0.002	0.48±0.45	0.003	0.114

BCVA: Best corrected visual acuity

Table 4: Visual acuity change in Snellen's lines

Change in Snellen's lines	1 mg	4 mg
1-3 lines	6 (3.0%)	3 (15%)
4-5 lines	3 (15%)	5 (25%)
>5 lines	7 (35%)	10 (50%)
Not responded	4 (20%)	2 (10%)
Worsening after initial improvement	3	3

Table 5: Mean change in IOP during follow-up period

Visit	1 mg (n=20)	P value	4 mg (n=20)	P value	P between sub-groups
Baseline	14.9±2.29		14.8±2.46		0.895
1 st day	14.5±2.41	0.330	15.0±2.63	0.716	0.536
1 week	17.7±3.90	0.007	17.4±3.50	0.012	0.800
1 month	18.1±4.17	0.001	18.2±6.67	0.029	0.955
3 months	17.6±4.03	0.006	17.6±4.92	0.020	1.00
6 months	16.3±2.36	0.023	17.5±4.34	0.005	0.285

IOP: Intraocular pressure

Table 6: Incidence of elevated IOP/glaucoma

Within and including 6 months	n (%) (n=20)	
	1 mg	4 mg
Increase ≥5 mmHg from baseline	6 (30)	9 (45)
Increase ≥10 mmHg from baseline	3 (15)	4 (20)
30% increase from baseline	7 (35)	9 (45)
IOP-lowering medication	5 (25)	5 (25)
Glaucoma surgery (trabeculectomy)	0	1 (5)

IOP: Intraocular pressure

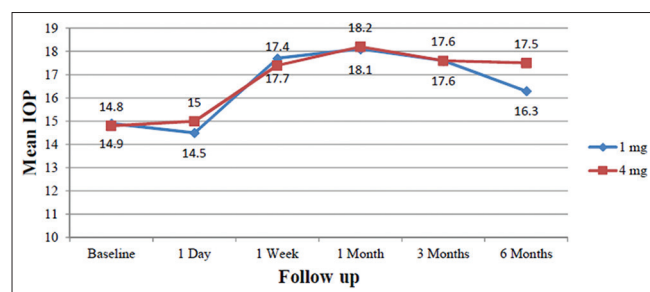


Figure 9: Mean change in intraocular pressure during follow-up period

16.3 ± 2.36 ($P = 0.023$) at 1 week, 1 month, 3 months, and 6 months, respectively. In 4 mg group, the mean IOP was significantly increased from baseline to 17.4 ± 3.50 ($P = 0.012$), 18.2 ± 6.67 ($P = 0.029$), 17.6 ± 4.92 ($P = 0.020$), 17.5 ± 4.34 ($P = 0.005$) at 1 week, 1 month, 3 months, and 6 months, respectively. There was no statistically significant difference observed in the mean baseline IOP between the two groups ($P = 0.895$). There was no statistically significant difference observed in IOP between the two groups at any follow-up visit.

Incidence of elevated IOP/glaucoma (Table 6)

6 eyes (in 1 mg group) and 9 eyes (in 4 mg group) had an elevation of ≥5 mmHg of IOP from baseline. Three eyes (in 1 mg group) and 4 eyes (in 4 mg group) had an elevation of ≥10 mmHg of IOP from baseline. Seven eyes (in 1 mg group) and 9 eyes (in 4 mg group) had ≥30% elevation from baseline. IOP-lowering medication required in 5 eyes in each group. One eye underwent trabeculectomy in 4 mg group for refractory elevation of IOP.

Cataract

About 18 eyes were phakic and 2 eyes were pseudophakic at presentation in 1 mg group. In 4 mg group, 19 eyes were phakic, and 1 eye was pseudophakic at presentation. Out of 18 eyes, 1 patient showed increase in nuclear sclerosis in 1 mg group. Out of 19 eyes, 3 patients showed increase in nuclear sclerosis and 2 patients developed posterior subcapsular cataract in 4 mg group. In 4 mg group, 2 patients underwent cataract surgery 6 months post-injection.

Figure 10a shows right eye superotemporal BRVO, and Figure 10b shows the OCT of the same eye with increased foveal thickness and multiple cystic spaces. Figure 11a and b shows the same eye 3 months post IVTA with decreased ME and normal foveal contour on OCT.

Figure 12a shows the fundus picture of a case of CRVO with Figure 13a showing cystoid ME on OCT of the same case. Figures 12b and 13b show the fundus and OCT 3 months post IVTA with resolved ME.

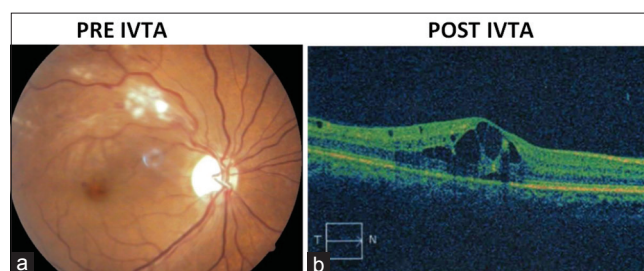


Figure 10: (a) ST branch retinal vein occlusion pre-intravitreal triamcinolone acetonide (IVTA), (b) optical coherence tomography pre IVTA, cystic spaces and increased foveal thickness

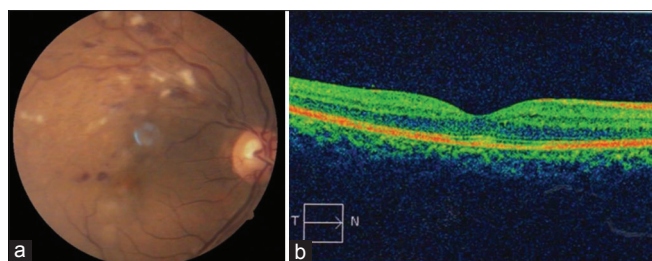


Figure 11: (a) 3 months post-intravitreal triamcinolone acetonide (IVTA), (b) optical coherence tomography shows normal foveal contour with normal thickness, 3 months post IVTA

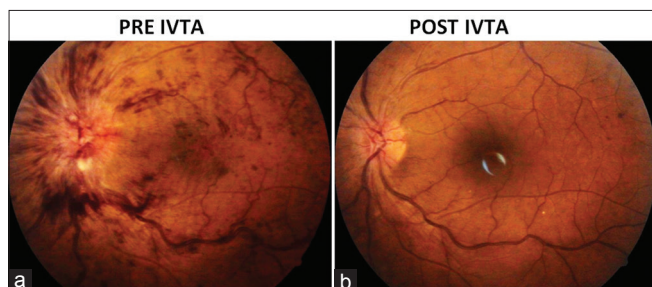


Figure 12: (a) Central retinal vein occlusion, (b) 3 months post-intravitreal triamcinolone acetonide

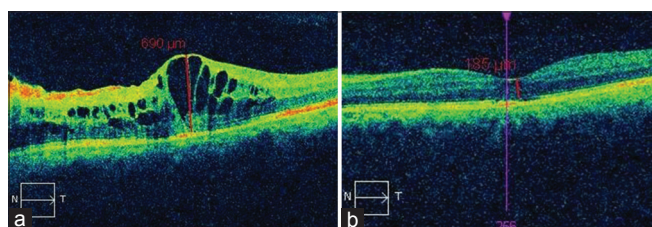


Figure 13: (a) Cystoid macular edema on optical coherence tomography, (b) resolved edema post-intravitreal triamcinolone acetonide

DISCUSSION

In our study, the mean duration between symptoms and treatment was 55.3 days in 1 mg group and 51.25 days in 4 mg group.

We observed that (Table 4) in 1 mg group, 15 eyes (75%) showed at least 1 line improvement in visual acuity, 10 (50%) eyes showed more than 3 lines improvement and 6 (30%) eyes showed more than 5 lines of improvement at the end of 6 months follow-up. In 4 mg group, 16 eyes (80%) showed at least 1 line improvement, 12 (60%) eyes showed more than 3 lines improvement and 9 (45%) eyes showed more than 5 lines of improvement at the end of 6 months follow-up. Three eyes in each group showed worsening of visual acuity after initial improvement. In SCORE-BRVO trial,¹⁴ 25.6%, and 27.2% participants showed a gain in visual acuity letter score of 15 or more from baseline in 1 mg and 4 mg triamcinolone groups, respectively.

The results of the SCORE-BRVO trial demonstrate no significant differences among the 2 treatment groups for gain in visual acuity letter score of 15 or more at 12 months, though an early positive treatment response of a gain in visual acuity letter score of 15 or more was observed at month 4 in the 4 mg triamcinolone group compared with the 1 mg triamcinolone. In SCORE-CRVO trial,¹⁵ 26.5%, and 25.6% participants showed gain in visual acuity letter score of 15 or more from baseline in 1 mg and 4 mg triamcinolone groups, respectively. The results of the SCORE-CRVO trial¹⁵ demonstrate no significant differences among the 2 treatment groups for a gain in visual acuity letter score of 15 or more at 12 months.

In our study, both the groups showed decrease in foveal thickness from baseline. At 3 months the decrease in foveal thickness was similar in both the groups. In SCORE-CRVO Trial,¹⁵ there was no difference between groups in retinal thickness at 12 months. At month 4, there was a greater reduction in OCT-measured center point thickness in the 4 mg IVTA group than in the 1 mg group ($P < 0.001$). SCORE-BRVO trial¹⁴ also concluded that at month 4, there was a greater reduction in OCT-measured center point thickness in the 4 mg IVTA group than the 1 mg group. In a similar study done in diabetic ME comparing 1 mg IVTA and 4 mg IVTA,¹⁶ we observed that in 1 mg group, 80% showed at least 1 line improvement, 40% eyes showed more than 3 lines improvement and 10% eyes showed more than 5 lines of improvement at the end of 6 months follow-up. In 4 mg group, 85% showed at least 1 line improvement, 40% eyes showed more than 3 lines improvement and 10% eyes showed more than 5 lines of improvement at the end of 6 months follow-up.

In the present study, the incidence of adverse events were higher in the 4 mg IVTA group compared with the 1 mg group. Six (30%) eyes and 9 (45%) eyes showed ≥ 5 mmHg elevation of IOP from baseline in 1 mg and 4 mg groups, respectively. Five (25%) eyes in each group required IOP-lowering medication. One eye in 4 mg group underwent trabeculectomy for refractory elevation of IOP. In SCORE-BRVO trial¹⁴ IOP-lowering, medication was initiated in more eyes through 12 months in the 4 mg IVTA group (41%) compared with the 1 mg IVTA group (7%). In the 4 mg group, one participating underwent trabeculectomy and another received a tube shunt to control IOP. In SCORE-CRVO trial,¹⁵ more eyes in the 4 mg IVTA group (35%) initiated IOP-lowering medication through 12 months compared with the 1 mg IVTA (20%) group.

In our study, the incidence of lenticular changes was more in 4 mg group than 1 mg group. One (out of 18) eye and 5 (out of 19) eyes developed lenticular changes in

1 mg and 4 mg groups respectively. Two eyes underwent cataract surgery in 4 mg group. In SCORE-BRVO trial,¹⁴ the estimate of new-onset lens opacity or progression of an existing opacity based on clinical assessment through month 12 was 25% and 35% in the 1 mg and 4 mg IVTA groups, respectively. More cataract surgeries were performed in the 4 mg group.

CONCLUSION

The results of our study suggest that the functional and anatomical outcome in the management of ME due to retinal vein occlusions is as effective with 1 mg IVTA as with 4 mg IVTA with fewer complications like secondary glaucoma and cataract.

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Clinico-Epidemiological Study of Dengue in a Tertiary Care Hospital in Jaipur, Rajasthan

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Abstract

Introduction: Dengue fever (DF) is a common mosquito borne disease caused by dengue virus and is transmitted by Aedes mosquito. It is one of the major public health problems in India which affects all levels of society but the burden of disease is a higher in poor people who live together in communities.

Aim and objectives: The present study is aimed to assess the incidence, signs, symptoms, and epidemiological characteristics of cases of DF in a Tertiary Care Hospital in Jaipur, Rajasthan.

Materials and Methods: A cross-sectional study was conducted in all diagnosed cases of DF admitted at Mahatma Gandhi Hospital, Jaipur from 1st September to 31st October, 2015. Rapid immunochromatographic card test was used to detect dengue nonstructural protein 1 (NS1) antigen and dengue immunoglobulin M/immunoglobulin G (IgM/IgG) antibodies in the microbiology laboratory of the hospital to confirm the diagnosis. A predesigned and pretested questionnaire was used to collect socio-demographic profile, signs and symptoms of serologically diagnosed cases.

Results: Out of 1226 patients, 545 patients were tested serologically positive for DF (NS1, IgM and IgG). The highest number of cases (110 cases) was reported in the 3rd week of September. Maximum number of dengue cases reported were males belonging to 31-40 years age group from urban area. Fever was the main complaint in all the cases followed by vomiting, headache, and abdominal pain.

Conclusion: Dengue is one of the major public health problems in India. A large number of cases are reported in the monsoon and post-monsoon period in the month of September and October. Measures can be taken both at personal and government level to reduce morbidity and mortality from dengue.

Key words: Dengue, Epidemiology, Fever, Signs, Symptoms

INTRODUCTION

Dengue fever (DF) is a common mosquito borne disease caused by dengue virus (DENV) which belongs to family Flaviviridae and is transmitted by Aedes mosquito. There are four serotypes of virus namely DENV-1, DENV-2, DENV-3, and DENV-4.¹ All four serotypes can cause the

full spectrum of disease from a subclinical infection to a mild self-limiting disease, the DF, a severe disease that may be fatal, and the dengue hemorrhagic fever (DHF)/dengue shock syndrome. Each DENV is an encapsulated RNA virus which has seven structural proteins (nonstructural protein 1 [NS1], NS2a, NS2b, NS3, NS4, NS4b, and NS5) and three structural protein genes which encode the nucleocapsid or core (C) protein, a membrane-associated (M) protein, and an enveloped (E) glycoprotein. There is no cross protective immunity but lifelong immunity develops with infection of one type of DENV. More severe signs and symptoms develop in patients infected with DEN-2 as compared to DEN-1, DEN-3 and DEN-4. DEN-2 and DEN-3 have been mostly linked with dengue hemorrhagic fever.

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The most important and suitable arthropod vector for DENV is *Aedes aegypti* due to its social behavior and frequent biting habit before breeding. Urbanization of *A. aegypti* mosquito has occurred due to biodiversity, increase in population, global warming, and climate change.

Dengue is one of the major public health problems in India. However, during the last decade more frequent and severe epidemics of dengue have been reported in several Indian cities. DF affects all levels of society but the burden of disease is higher in poor people who live together in communities.² The World Health Organization estimates that 50-100 million infections occur every year, including 500,000 DHF cases and 22,000 deaths mostly affecting children.

A study on dengue outbreak in Kolkata in 2012 revealed that maximum number of cases of DF occurs during the month of August-November indicating increased vector transmission in the monsoon and post-monsoon periods. Maximum number of cases were from 11 to 30 years age group with male preponderance.³ Another study in Faisalabad, Pakistan showed that there are various other factors also found to be associated with DF like excessive travelling, travelling during epidemic, presence of disease in the family or neighboring houses, people living near watery areas, immunocompromised persons and low level of awareness.⁴

A study done in KEM hospital, Mumbai showed that there is an association between platelet counts and treatment outcome. Severity in signs and symptoms lead to complication and death in dengue cases.⁵ A study done in North Karnataka showed that dengue should be suspected in all cases presenting with symptoms such as fever, vomiting, and headache. Rapid immunochromatographic card test (RICT) is used to detect serologically positive cases by detecting NS1, immunoglobulin M (IgM), or immunoglobulin G (IgG) antibodies. The use of dengue RICT helps in the prompt and early diagnosis and management of the case and prevents complications of dengue.⁶ There is no specific treatment for dengue other than symptomatic and supportive measures with judicious fluid therapy.

Despite large number of cases being reported every year in Jaipur, not much of literature is available on clinico-epidemiological profile of cases of DF. The present study is aimed to assess the incidence, signs, symptoms and epidemiological characteristics of cases of DF in a tertiary care hospital in Jaipur, Rajasthan.

MATERIALS AND METHODS

It was a cross-sectional study done at Mahatma Gandhi Hospital, Sitapura, Jaipur. Due approval was taken from

the Institutional Ethical Committee of Mahatma Gandhi Medical College before conducting the present study.

All the patients admitted from September 1st, 2015 to October 31st, 2015 with fever or dengue like symptoms were serologically tested for DF. The serological test was done using RICT to detect dengue NS1 antigen and dengue IgM/IgG antibodies in the microbiology laboratory of the hospital. Detection of at least one component (NS1, IgM, or IgG) was considered to be positive for serodiagnosis. Informed consent was taken from the patient in the local language prior to the interview. A predesigned and pretested questionnaire was used to collect the following socio-demographic and clinical manifestation of serologically diagnosed cases:

- Age
- Sex
- Area of residence (rural/urban)
- Clinical manifestations:
 - Fever
 - Vomiting
 - Headache
 - Abdominal pain
 - Hepatomegaly
 - Myalgia
 - Bleeding manifestations
 - Generalized weakness
 - Cough
 - Splenomegaly
 - Rashes
 - Diarrhea etc.

RESULTS

A total of 1226 patients visited in Mahatma Gandhi Hospital, Jaipur with the complaint of fever and other dengue like symptoms. Out of these patients, 545 patients were tested serologically positive for DF. Figure 1 shows the week wise distribution of dengue cases in the month of September and October 2015. The highest number of cases (110 cases) was reported in the 3rd week of September from September 15, 2015 to September 21, 2015.

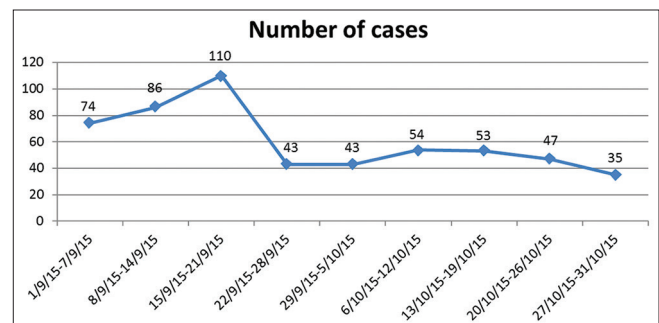


Figure 1: Week wise distribution of dengue cases

Highest number of dengue cases was reported in 31-40 years age group (37.24%). Dengue cases in age group 10-20 years and 21-30 years were 26.05% and 25.32%, respectively. However, dengue cases in <10 years, 41-60 and >60 years age group were reported to be 2.01%, 6.05% and 3.30%, respectively (Table 1).

Tables 2 and 3 showed sex wise and area wise distribution of dengue cases. Out of all reported cases, 70.09% cases were males and only 29.90% cases were females. 61.83% cases belonged to urban area while 38.16% belonged to rural area.

Fever was the main complaint in all the cases of dengue reported in the hospital. Vomiting, headache and abdominal pain was reported in 43.48%, 40.55%, and 30.82% of cases, respectively. Hepatomegaly, myalgia, bleeding manifestations was reported in 27.70%, 27.33% and 20.55% cases, respectively. Generalized weakness, cough, and splenomegaly were reported in 17.79%, 16.88%, and 10.45% cases, respectively. Rashes and diarrhea were the least common complaint reported in 5.32% and 2.01% cases, respectively (Table 4).

DISCUSSION

A total of 1226 patients visited in Mahatma Gandhi Hospital, Jaipur with the complaint of fever and other dengue like symptoms. Out of these patients, 545 patients were tested serologically positive for DF. On studying the week wise distribution of these cases, highest number of cases (110 cases) was reported in 3rd week of September from September 15, 2015 to September 21, 2015. A similar study conducted by Bandyopadhyay *et al.*, in Kolkata, India (2012) also showed that a maximum number of cases are reported from 1st week of September to almost mid-October.³ This is due to increased vector transmission in the monsoon and post-monsoon periods. A study conducted on epidemiology of DF in district Faisalabad, Pakistan by Nasreen *et al.*, stated that relative incidence was the highest (43%) in the month of October.⁴

Highest number of dengue cases was reported in 31-40 years age group (37.24%). Dengue cases in age group 10-20 years and 21-30 years were 26.05% and 25.32%, respectively. However, dengue cases in <10 years, 41-60 and >60 years age group were reported to be 2.01%, 6.05% and 3.30%, respectively. A similar study by Pardeshi *et al.*, in KEM hospital, Mumbai revealed that maximum number of dengue cases were in the age group of 21-30 years.⁵ Nasreen *et al.*, also reported maximum cases in 21-30 years group in Faisalabad, Pakistan.⁴ Bandyopadhyay *et al.*, reported maximum cases in age group 11-30 years.³ Kumar *et al.*, in their study in North Karnataka reported a higher number of cases of DF in 14-30 years age group.⁶

Table 1: Age wise distribution of Dengue cases

Age (in years)	n (%)
<10	11 (2.01)
10-20	142 (26.05)
21-30	138 (25.32)
31-40	203 (37.24)
41-50	33 (6.05)
51-60	18 (3.30)

Table 2: Sex wise distribution of dengue cases

Gender	Number of cases	Percentage
Male	382	70.09
Female	163	29.90

Table 3: Area wise distribution of dengue cases

Area	Number of cases	Percentage
Urban	337	61.83
Rural	208	38.16

Table 4: Distribution of dengue cases according to clinical manifestations

Clinical manifestations	n (%)
Fever	545 (100)
Vomiting	237 (43.48)
Headache	221 (40.55)
Abdominal pain	168 (30.82)
Hepatomegaly	151 (27.70)
Myalgia	149 (27.33)
Bleeding manifestations	112 (20.55)
Generalized weakness	97 (17.79)
Cough	92 (16.88)
Splenomegaly	57 (10.45)
Rashes	29 (5.32)
Diarrhea	11 (2.01)

*Multiple response

In the present study, out of all reported cases of DF, 70.09% cases were males while only 29.90% cases were females. Nasreen *et al.*, in her study in Faisalabad, Pakistan also reported similar finding. Relative incidence of DF was significantly higher in males (71%) than in females (29%).⁴ Male preponderance of dengue cases was also reported in studies by Kumar *et al.*, in North Karnataka⁶ and Bandyopadhyay *et al.*, in Kolkata, India.³

In the present study 61.83% of dengue cases belonged to urban area while 38.16% belonged to rural area. Similar findings were reported by study conducted by Nasreen *et al.*, in Faisalabad, Pakistan. In her study, relative incidence of DF was 62% in urban area and 38% in rural area.⁴

In the present study, fever was the main complaint in all the cases of dengue reported in the hospital. Vomiting, headache and abdominal pain was reported in 43.48%,

40.55% and 30.82% of cases, respectively. Hepatomegaly, myalgia, bleeding manifestations was reported in 27.70%, 27.33% and 20.55% cases, respectively. Generalized weakness, cough, and splenomegaly were reported in 17.79%, 16.88%, and 10.45% cases, respectively. Rashes and diarrhea were the least common complaint reported in 5.32% and 2.01% cases, respectively. Similar findings were reported in study conducted by Kumar *et al.*, in North Karnataka. Fever was the presenting symptom in all the cases followed by vomiting and headache.⁶

Similar study conducted by Kashinkunti *et al.*,⁷ Kumar *et al.*, in Udupi, Karnataka⁸ and Khan *et al.*, in Karachi, Pakistan⁹ also showed that fever, vomiting and abdominal pain are the most common symptoms in patients with DF.

In the present study petechiae, gum bleeding and other bleeding manifestations were reported in 20.55% dengue cases. Kashinkunti *et al.*,⁷ Kumar *et al.*,⁶ also reported 21% and 19.5% bleeding manifestation, respectively, in their study.

CONCLUSION

Dengue is one of the major public health problems in India. A large number of cases are reported in the monsoon and post-monsoon period in the month of September and October owing to increased vector transmission. Young males belonging to 21-40 years of age are more susceptible to infection due to more outdoor activity. Fever, vomiting, headache, and abdominal pain are the most common clinical manifestation of DF.

Recommendations

Following measures can be taken both at personal and government's level to reduce morbidity and mortality from DF:

- Source reduction: Avoid collection of water
- Spraying of insecticide and larvicide: Both regular and focal spraying can be done depending on the incidence of disease
- Personal protection: Wearing full clothes, use of mosquito repellants, use of bed nets, screening of building, etc.
- Health education: Any person with fever, vomiting, headache and abdominal pain should immediately report to the hospital and should be investigated for DF.

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Psychiatric Morbidities in Postpartum Period in Primiparous Women Attending Tertiary Care Center

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Abstract

Introduction: Postpartum period refers to period of 6-week after delivery. During pregnancy, there are progressive anatomical and physiological changes not only confined to genital organs, but also to all systems of the body. The postpartum period represents one of the most important life stages in which the accurate detection and treatment of psychological distress are required. We have done this study to find out the prevalence of mental illness in primipara patients in the postpartum period. Furthermore, we studied its correlation with other significant obstetric profile.

Materials and Methods: The study conducted on 96 patients above 18 years age, who delivered (including all modes of delivery) recently within 7 days and who were primipara, i.e., delivered the first baby. Participants were recruited from Department of Obstetrics and Gynecology, were assessed for psychiatric morbidity by applying dukes general health questionnaire and Diagnostic and Statistical Manual-5th Edition self-rated level 1 cross-cutting symptom measure - adult.

Results: We found the prevalence of psychiatric morbidity in postpartum primipara to be 27.08%. Among these, depression (11.45%), anxiety (9.37%), and psychosis (4.16%) were more prevalent. Young mothers and working mothers had a heightened risk of developing psychiatric morbidity following delivery. Unplanned pregnancy, female gender of the baby, and forceps delivery were significant obstetric profiles in relation to psychiatric illness in the postpartum period.

Conclusion: Psychiatric morbidities in the postpartum period in primiparous patients attending tertiary care center have high prevalence mainly of depressive and anxiety disorders. Furthermore, the majority were under diagnosed and not assessed for psychiatric evaluation, thus remained untreated.

Key words: Mental disorders, Morbidity, Postpartum period, Prevalence, Psychiatry

INTRODUCTION

Puerperium has been defined as the time period extending from the delivery of the placenta to the following 6 weeks. Usually, during this period, the majority of the changes that have taken place during pregnancy, labor, and delivery resolve, reverting the body back to the non-pregnant

state. During pregnancy, there are progressive anatomical and physiological changes not only confined to genital organs, but also to all systems of the body. Therefore, the postpartum period has been recognized as an important stage of life during which the accurate detection and treatment of psychological distress, if any, becomes necessary.

Postpartum psychological health is more critical, especially in primiparous women. Primipara has been defined as a woman who had been pregnant with a fetus that attained a weight of 500 g or a gestational age of 20 weeks, irrespective of whether the infant was born alive or stillborn and whether it was a single or multiple births.

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The transition to new motherhood has been found to be associated with emotional distress in up to 30% of women. It involves changes in the nature of relationships between couples as well as within families, thereby causing additional financial burden, even among households of high socio-economic status. Over the years, several studies have identified the resultant impact of stressful life events and social health issues on maternal psychological morbidity.^{1,2}

Postpartum psychiatric disorders may include transient depressive symptoms (i.e., the “postpartum blues”), postpartum depression, postpartum psychosis, and postpartum anxiety (including new onset or exacerbation of obsessive-compulsive disorders).³

Postpartum blues are the most commonly observed puerperal mood disturbance. Its symptoms arise within a few days of delivery, most probably on the 3rd or 4th day and persist from few hours to over several days. The symptoms include irritability, tearfulness, mood lability, generalized anxiety, sleep, and appetite disturbance. Postpartum blues are by definition time limited, mild, do not require treatment other than reassurance, and remit within days.^{4,5} Non-psychotic postpartum depression is the most common complication of childbearing, occurring in 10-15% of women after delivery.⁶ The onset is usually within the first 6 weeks postpartum with the clinical features same as those associated with a major depression episode occurring at other times. Suicidal ideation has also been found to be reported.

Puerperal or postpartum psychosis is the most severe and uncommon form of postnatal illness with rates of one to two episodes per 1000 deliveries.⁷ Clinical onset is rapid with symptoms presenting as early as the first 48-72 h postpartum, a majority of episodes developing within the first 2 weeks of delivery. Manic episodes are less frequent, accounting for 15% of psychotic reaction,⁸ whereas schizophrenic disorder comprises about 30% of postpartum psychosis.⁹

Postpartum anxiety disorder as such is common but present predominantly as a symptom of other postpartum psychiatric disorders. Miller *et al.*,¹⁰ were able to show in a recent study employing a self-report measure that 10% of women suffered symptoms of anxiety and stress 6 weeks to 6 months postpartum.

A study by Glasheen *et al.*,¹¹ of maternal postnatal psychological distress suggests that exposure is related to adverse psychological problems in children. Solitary living, smoking, multiparity, low socio-economic status, and a body mass index of 30 or more were found to have a significant association with a psychiatric diagnosis

in the postpartum period. Since there is no formal screening mechanism for postpartum psychiatric disorders, recognition falls to obstetricians, who may only see the patient once at the 6 weeks postpartum check-up, or to pediatricians. For these and other reasons, detection of postpartum psychiatric disorders remains a major problem. Optimally, the obstetrician should have an established screening and referral process for new mothers to enhance the detection and treatment of postpartum psychiatric disorders. Pediatricians may be in a better position to follow the mother for mood and anxiety symptoms during well-baby visits.³

According to Diagnostic and Statistical Manual-5th Edition (DSM-5), psychiatric diagnoses in postpartum period include brief psychotic disorder postpartum onset, bipolar mood disorder with peripartum onset and major depressive disorder with peripartum onset.¹²

The aim of this study was to determine the prevalence of psychiatric morbidity in postpartum women, who are primipara and to examine the associated factors of these disorders.

MATERIALS AND METHODS

This prospective observational study was conducted on 96 patients from outpatient and inpatient Department of Obstetrics and Gynecology Dr. PDMMC Hospital and Research Centre Amravati, Maharashtra. Patients included in the study were those who fulfilled the inclusion criteria. All the cases were informed about the nature of the study beforehand, and a written informed consent was obtained from each of them for the same. The Ethical Committee of the Institute approved the study.

Inclusion Criteria

1. Women who delivered including all modes of delivery within 7 days
2. Women who were primipara, i.e., who delivered their first baby.

Exclusion Criteria

1. Multiparous women
2. Women with a history of psychiatric illness
3. Women having associated medical illness.

All study subjects were evaluated postpartum on 7th, 15th, 30th, and 45th day of delivery postpartum in four sittings. A psychiatric evaluation was carried out on the basis of a structured proforma which contained the socio-demographic details and information regarding the physical and mental status examination of the subjects. All subjects were assessed for psychiatric comorbidity by applying

Dukes general health questionnaire.¹³ and DSM-5 self-rated level 1 cross-cutting symptom measure - adult.¹⁴

Statistical Analysis

A descriptive analysis was done. Data analysis were performed using the open Epi Version 3, with significance levels set at $P < 0.05$. Statistical methods include Chi-square test, t -test, P -value for significance, and correlation coefficient for correlation between different variables.

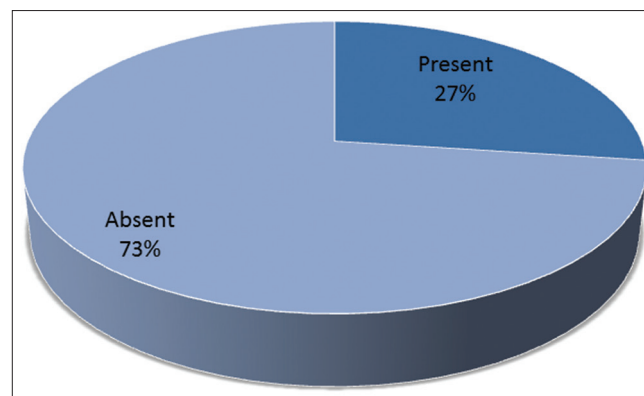
RESULTS

This study was conducted on 96 primipara subjects who were in postpartum period. Most of them were Hindu (83.33%); 47.91% subjects belonged to rural and 41.66% to an urban background. About 74 subjects were literate and 22 illiterate. Among them, the majority were housewives 68 (70.83%) and others 28 (29.16%) were working.

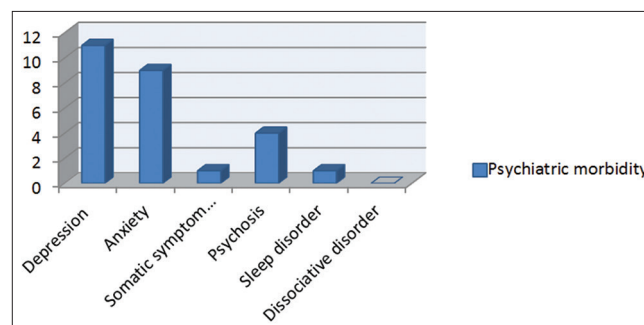
We correlated demographic profile with psychiatric morbidity. As shown in Table 1, early age of the pregnancy (18-25 years) and working women were having significantly higher prevalence of psychiatric morbidity and other demographic factors were not significantly related. Our study revealed as in Table 2 and Graph 1 that out of the 96 subjects, 26 (27.08%) had developed psychiatric morbidity and in 70 (72.91%) cases, the postpartum period was uneventful and no psychiatric disturbance was reported.

All the 96 subjects selected were primipara in postpartum period; of these 46 (47.91%) had delivered male and 49 (51.04%) had female baby. Mode of delivery was normal vaginal delivery in 60 (62.5%) subjects, whereas cesarean section was performed in 26 (27.08 %) and 10 (10.41%) had a forceps delivery. 64 (64.58 %) subjects reported their pregnancy was planned, and 34 (35.41%) said that pregnancy was unexpected and unplanned.

The correlation between obstetric profiles shown in Tables 3-5 suggested that prevalence of psychiatric morbidity was high when the gender of a baby born was female (30.61%) and when pregnancy was unplanned (47.05%). After further analysis (Table 6 and Graph 2), we found that among all subjects, there was a higher prevalence of depression (11.45%) in primiparous women during their postpartum period compared to the prevalence of anxiety (9.37%) and postpartum psychosis (4.16%).



Graph 1: Psychiatric morbidity in primiparous postpartum subjects



Graph 2: Types of psychiatric morbidity in postpartum primiparous subjects

Table 1: Correlation of psychiatric morbidity and demographic factors

Factor	Subdivision	Number of patients <i>n</i>	Number of patients with psychiatric morbidity	Percentage of morbidity	<i>P</i> value
Age in years	18-25	44	18	32.65	0.013
	26-30	30	6	25.92	
	31 or more	22	2	15.0	
Religion	Hindu	80	20	25.0	0.162
	Muslim	16	6	37.5	
Occupation	Housewife	68	14	30.88	0.016
	Working	28	12	17.85	
Domicile	Urban	40	9	22.5	0.077
	Rural	46	17	36.95	
Literacy	Literate	74	21	28.37	0.312
	Illiterate	22	5	22.72	

Table 2: Psychiatric morbidity in primiparous postpartum subjects

Psychiatric morbidity	n (%)
Present	26 (27.08)
Absent	70 (72.91)
Total	96 (100)

Table 3: Correlation between gender of baby and psychiatric morbidity

Gender of baby born	Number of patients n (%)	Psychiatric morbidity present	Percentage of morbidity	P value
Male	46 (47.91)	11	23.91	0.25
Female	50 (51.04)	15	30.00	

Table 4: Correlation between mode of delivery and psychiatric morbidity

Mode of delivery	Number of patients n (%)	Psychiatric morbidity present	Percentage of morbidity	P value
Still birth	1 (1.04)	0	0	0.90
Vaginal	60 (62.50)	16	26.66	
Forceps	10 (10.41)	3	30	
Cesarean	26 (27.08)	8	30.76	

Table 5: Correlation between mode of pregnancy and psychiatric morbidity

Mode of pregnancy	Number of patients n (%)	Psychiatric morbidity present	Percentage of morbidity	P value
Planned	62 (64.58)	10	16.12	0.0008
Unplanned	34 (35.41)	16	47.05	

Table 6: Types of psychiatric morbidity in postpartum primiparous subjects

Psychiatric morbidity	n (%)
Depression	11 (11.45)
Anxiety	9 (9.37)
Somatic symptom disorder	1 (1.04)
Psychosis	4 (4.16)
Sleep disorder	1 (1.04)
Dissociative disorder	0

DISCUSSION

Although there are many studies about postpartum psychiatric morbidity, this is a first of its kind in which we carried out a study in especially primipara subjects. Postpartum mental disorder is a spectrum of illnesses ranging from the very mild postpartum blues, through postpartum depression that is of moderate severity to the very severe puerperal psychosis.^{15,16} In our study, we found

that the prevalence of psychiatric morbidity in postpartum primipara subjects was found to be 27.08%, which was also correlated with other studies done before. Our results showed the higher prevalence with young 18-25 years maternal age (32.65%) and with working women (30.88%).

One previous study concluded that the incidence of postpartum mental illness in our practice was 2.9 per 1000 births along with a preponderance of primiparity and young maternal age in the study group.¹⁷

Bener *et al.*, study¹⁸ showed that working women were more likely to suffer from anxiety (51.8%) and stress (60.7%) disorders in their postpartum period. The major factors associated with depression include an unplanned pregnancy, lack of support from the family, and mothers living as housewives. On the other hand, lack of family support and dissatisfaction in married life were the major correlates for anxiety disorders.

Our study suggested that prevalence of psychiatric morbidity was high when the gender of a baby born was female (30%), and when delivery carried out by forceps delivery 70% but it was statistically not significant. The high prevalence (47.05%) was observed with an unplanned pregnancy, and it was statistically significant ($P = 0.008$), which may be because of a lot of stress suffered during unplanned pregnancy. Bener *et al.*, study¹⁸ stated the most common life events that affected women during their postpartum period were unplanned pregnancy and poor relationships with their mothers-in-law.

This study identified a higher prevalence of depression (11.45%) in primiparous women during their postpartum period compared to the prevalence of anxiety (9.37%) and postpartum psychosis (4.16%). A study by Matthey *et al.*,¹⁹ showed a similar psychological morbidity, with 17% experiencing depression and 13% experiencing anxiety.

Postpartum depression is a public health problem that has several adverse effects on the mother, the infant, and the whole family. Affonso *et al.*,²⁰ found that the European and Australian women were least affected by the postpartum depressive symptoms, whereas mothers from the non-western countries such as Taiwan and India suffered the most. Nearly half of the depressed mothers reported experiencing more than one stressful life event in their postpartum period such as low income or unplanned pregnancy.

CONCLUSION

The results of this study imply that adequate postpartum care is essential in the diagnosis of psychological distress.

Therefore, it is imperative to sensitize the health care personnel to a range of social health issues that are observed during the postpartum period. The health care personnel, on their part, also need to be alert considering the high prevalence of psychological morbidity among the women during this period. The need of the hour is to develop several preventive strategies that will either reduce or eliminate the causative and associated factors thereby improving and enhancing the emotional well-being of women during the postpartum period.

Limitations of the Study

The limitations of our study were small sample size. The bigger sample size is required to prove or disprove the conclusion. The study did not assess the prevalence of stress, anxiety, and depression in the studied women during their antenatal period. According to WHO definition, postpartum period lasts for up to 6-month and hence patients should be followed up from antenatal period up to 6-month of postpartum.

Future Directions

The evidence from this paper and many papers done before it has established that postpartum period is a risk factor for depression. Regularizing antenatal checkups and screening for psychiatric disorders during antenatal and postnatal checkups will further aid in the early detection of antepartum and postpartum psychological disorders. Training the obstetrician will help in better and early identification of psychological disorders. Screening during the antenatal and postnatal visit and increase, in general, awareness among the health workers, mother, and her family members about the commonness of psychiatric disorders in postpartum period will help them to seek medical care rather than quick care.

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Prevalence and Genotype Distribution of *Rotaviruses* in Children Hospitalized with Acute Gastroenteritis

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Abstract

Introduction: *Rotavirus* is the leading cause of severe diarrhea in infants and young children. *Rotavirus* immunization has been effective in developed countries, where the genotype G1P[8] is the predominant *Rotavirus* strain.

Objective: The present study was therefore undertaken to assess the *Rotavirus* prevalence, genotypes and to know the circulating strains in a population.

Materials and Methods: This study was conducted in MOSC Medical College, Kolenchery from February 2009 to January 2011. *Rotavirus* was identified by enzyme-linked immunosorbent assay (ELISA) test on stool specimens of hospitalized children <5 years of age. *Rotavirus* positive specimens were genotyped by reverse transcriptase polymerase chain reaction (RT-PCR) at Christian Medical College, Vellore.

Result: Of the 1807 stool specimens, a total of 648 (35.9%) were positive for *Rotavirus* by the rotaclone ELISA test. Of the 648 positive cases, G1P[8] (49.7%) was the most common strain identified by RT-PCR followed by G9P[8] (26.4%), G2P[4] (5.5%), G9P[4] (2.6%), and G12P[6] (1.3%).

Conclusion: Our study provides important information on the *Rotavirus* genotypes prevalent in our area and also imparts light on the fact that *Rotavirus* accounts for a large population of diarrheal disease in hospitalized children <5 years of age.

Key words: Children, Diarrhea, Enzyme-linked immunosorbent assay, Genotype, *Rotavirus*

INTRODUCTION

Diarrheal diseases continue to be a marked and significant cause of morbidity in infants and young children in developed countries. *Rotavirus* causes severe diarrhea in infants and young children worldwide. It significantly contributes to childhood morbidities and mortalities in developing countries.^{1,2} This virus accounts for approximately 20-30% of all hospitalized diarrhea cases in India.³ Improvements in hygiene and sanitation in

developed countries do not appear to have reduced or prevented the prevalence or spread of *Rotavirus* infection.⁴

Rotavirus, which constitutes a genus within the *Reoviridae* family, is a medium sized (70 nm) non-enveloped RNA virus. The name *Rotavirus* comes from the characteristic wheel-like appearance of the virus when viewed by electron microscopy (the name *Rotavirus* is derived from the Latin *Rota*, meaning “wheel”). There are eight species of *Rotavirus*, referred to as A, B, C, D, E, F, G, and H. Humans are primarily infected by species A, B, and C, most commonly by species A.⁵ Within *Rotavirus* A there are different strains, called serotypes.⁶ The RNA genome is located inside a triple layered structure containing a core, an inner capsid and an outer capsid.⁷ The outer capsid is composed of 2 proteins, VP7 (G-genotype) and VP4 (P-genotype), both of which elicit neutralizing antibody responses. As with influenza virus, a dual

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classification system is used based on these two proteins on the surface of the virus. Because the two genes that determine G-types and P-types can be passed on separately to progeny viruses, different combinations are found.⁸ So far, there are 23 G-genotypes and 32 P-genotypes identified.⁹

Until the mid 1990s, the most common human *Rotavirus* genotypes were G1P[8], G2P[4], G3P[8], and G4P[8]. Two additional types G9 and G12 associated with P[8] or P[6] have emerged since 1995 and 2001, respectively, and have been associated with diarrhea in humans.^{10,11}

The World Health Organization recommends surveillance for the burden of *Rotavirus* diarrheal disease and circulating Rota virus strains, before and after inclusion of *Rotavirus* vaccination in national expanded programs on immunization.¹²

This study estimates the prevalence of *Rotavirus* diarrheas and also presents the *Rotavirus* genotypes identified in hospitalized children <5 years of age.

MATERIALS AND METHODS

This was a prospective study conducted with 8 hospitals in total in the Kunnathunad Taluk, Ernakulam district, Kerala. The Kunnathunad Taluk comprised 23 villages. The study was conducted at MOSC Medical College, a tertiary care referral hospital, which was considered as the base hospital, over a period of 24-month between February 1, 2009 and January 31, 2011. All children aged <5 years hospitalized with acute watery diarrhea were enrolled after informed consent was obtained from the parent or guardian.

The stool specimens were collected from the hospitalized patients, stored temporarily in the refrigerator at 4°C prior to transport to the microbiology laboratory. These specimens were then stored in the laboratory at -20°C. *Rotavirus* antigen (Group A *Rotavirus* - specific VP6 protein) was detected in the stool specimens using enzyme-linked immunosorbent assay (ELISA) testing (Rotaclone, Meridian diagnostics, Cincinnati, OH), which was carried out twice weekly. In this test, monoclonal antibodies against the product of the sixth viral gene (VP6) were used in a sandwich type method. The assay was conducted according to the manufacturer's instructions. The ELISA was highly sensitive (100%) and specific (97%) for *Rotavirus* antigen. ELISA *Rotavirus* positive samples were analyzed by reverse transcriptase polymerase chain reaction for G and P typing at Christian Medical College, Vellore, by previously reported methods.¹³

RESULT

During the period February 2009-January 2011, 1807 stool specimens were tested by ELISA of which 648 (35.8%) were positive for *Rotavirus* by the Rotaclone ELISA test. Within the ELISA-positive specimens, the prevalence of *Rotavirus* diarrhea in infants <6 months of age was 24.7%, 6-11 months 31.9%, 12-23 months 41.9%, 24-35 months 46.9%, and 33.3% in 36-59 months (Table 1).

Of the 648 ELISA-positive specimens, genotyping was done for 450 (81.6%) randomly selected samples. All the 450 specimens were assigned both G and P-genotype. The majority (49.7%) of the *Rotavirus* strains typed were G1P[8] strains followed by G9P[8] (26.4%), G2P[4] (5.5%), G9P[4] (2.6%), and G12P[6] (1.3%). Non-typable *Rotavirus* comprised 12 (2.6%) (Table 2).

DISCUSSION

In this study, *Rotavirus* was detected in 35.9% of diarrhea related hospitalized children <5 years of age. The prevalence of *Rotavirus* diarrhea in infants aged <6 months was 24.7% with high prevalence in children aged 6-11 months and 12-23 months (31.9% and 41.9%, respectively). In the study by Linhares *et al.*, children until the age of 6 months

Table 1: Age wise prevalence of *Spubwjsvt* in children

Age group (months)	n (%)		
	RV positive (n=648)	RV negative (n=1159)	Total (n=1807)
<6	58 (24.7)	177 (75.3)	235 (100)
6-11	181 (31.9)	387 (68.1)	568 (100)
12-23	233 (41.9)	322 (58)	555 (100)
24-35	91 (46.9)	103 (53.1)	194 (100)
36-59	85 (33.3)	170 (66.7)	255 (100)

RV: *Rotavirus*

Table 2: Distribution of G and P genotypes

Genotype	n (%), (n=450)
G1P[8]	229 (49.7)
G9P[8]	119 (26.4)
G2P[4]	25 (5.5)
G9P[4]	12 (2.6)
G12P[6]	6 (1.3)
G1P[6]	4 (0.8)
G12P[8]	4 (0.8)
G1P[4]	1 (0.2)
G1P[untypable]	2 (0.4)
G9P[untypable]	11 (2.4)
Partially typed	6 (1.3)
Mixed infections	24 (5.3)
Both G and P untypable	12 (2.6)

did not develop *Rota* viral infection, implying that maternal antibodies do play an important role in protection from the disease.¹⁴ The effect of maternal protection can be expected to wane at 6 months of age or with cessation of breast feeding, as most *Rota* viral disease was seen in children in the 6-24 months age group.¹⁵ This data is also important because they demonstrate that the vast majority of cases could be immunized by an effective *Rotavirus* vaccine along with their routine primary immunization series.

Our study also documents the genetic characterization of Group A *Rotavirus*-associated with acute diarrhea in children <5 years of age. G1P[8] and G9P[8] were the most prevalent strains isolated. The G1-genotype was the most common cause of acute *Rotavirus* diarrhea in this study as in other populations.^{16,17} G1P[8] caused 49.7% of the infections contributing to half the number of cases.

This is the first of its kind study done in Kerala to provide information on both *Rotavirus* G and P-genotype. This finding is also consistent with the results from the National *Rotavirus* surveillance in India showing that the G1P[8] strain was one among the two most common strains from December 2005 to November 2007. However, in our study, G9P[8] strains was the second most common strain followed by G2P[4] (26.4% and 5.5%, respectively). This was in contrast to the National Indian Surveillance Network where 25.7% and 8.5% accounted for G2P[4] and G9P[8] strains.¹⁸ The proportion of untypable strains may suggest the potential for emergence of new *Rotavirus* strains in Kerala. The data presented here helps us to understand the basis of severity of *Rota* viral disease in a community. It also emphasizes the need for continued and intensive surveillance for *Rota* viral disease in countries considering the introduction of a *Rota* viral vaccine.

CONCLUSION

Our study provides important information on the *Rotavirus* genotypes that should be considered for the selection of vaccine strains and the introduction of a *Rotavirus* vaccine in the National Immunization Programs. Continuation of

strain surveillance after the introduction of vaccination is recommended for evaluating the impact of vaccination and assessing the effectiveness of the *Rotavirus* vaccine.

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Psychosocial Problems among Students of Central University of Karnataka: A Comparative Study

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Abstract

Background: Psychosocial problems have been identified as the vital among university students at particular times when they enter the university, examination stress, personal and family life events. Psychosocial problems occur in a wide variety of settings they often negatively impact on students' mental health. There were very few studies have been conducted on psychosocial problems among university students. The aim of the study is to find out the psychosocial problems of university boys and girls students.

Methods: The study is a cross-sectional study with a between group research design. The sample consists of 25 boys and 25 girls. The convenient sampling method is used to select the participants. Moreover, the tool used is general health questionnaire.

Results: Results of the study indicated that there were no significant difference in the psychosomatic, anxiety/insomnia, and social dysfunction domains. But, in the dimension of Depression University boys found to have more depression than university girls.

Conclusion: From the results, it was found university boys and girls significantly differed in the dimension of depression. It is very important to emphasize on the contributing factors of these problem to formulate the intervention strategies.

Key words: Anxiety, Depression, Insomnia, Psychosocial problems, Social dysfunction

INTRODUCTION

For students, the transition from secondary schools to higher education centers is a life challenge. It offers new opportunities for their psychosocial development,¹ even though entering into a new space may be a source of strain and acute stress.¹ College is a new space and time period for the students-most of them in their late adolescent age, physically getting mature, and psychologically unstable. During this period, students are undergoing confusion and ambivalence.² There will be a lot of opportunities and challenges available in the colleges. This may lead to some competitions or conflict among the students and within the student. The unhealthy levels of stresses

can have the capacity to hinder the students' abilities to socialize and achieve their academic goals. Finding out such stresses and its sources to prevent it to become a threat to the students is very important.³ Most of the University students are facing academic stress to study, to complete their assignments, to participate in various programs in the college, and the stress is because of the imbalance between environment and demand.⁴ According to Porter,⁵ most of university students did not finish their course and left the university especially within first 2 years because of their inability to cope up with the situation. Steinberg and Darling⁶ mentioned that most of university students who visited for the mental health service reported the problems of anxiety, depression, problems related to the academics. A study conducted by Anson *et al.*,⁷ found that anxiety was inversely related with grades obtained by the students.

Academic demands as well as family and work commitments, create tension and anxiety, and it may lead to mental health problems.⁸ when people experience stress, it affects their physical and psychological health. Studies reported that

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stress affects the psychological and physical health of students.⁹ Anxiety, depression, and anxiousness to perform better are correlated to the academic performance.¹⁰ It is also found that students who are from poor socio-economic backgrounds will have financial problems which lead to depression, anxiety, and stress.¹¹ It is also reported that students, who are from rural areas, are more prone experience stress, depression, and anxiety as compared to the students from urban areas.¹² University students who are doing jobs due to financial problems are more prone to experience of mental health problems.¹³

The term psychosocial problems described as the maladaptive, unhealthy, intrapersonal, emotional and behavioral states. If people experience psychosocial problems, it may lead to maladaptive, unhealthy interpersonal networks, human relationships, social connections, and social malfunctioning.¹⁴ If social support is not available for this issue, it negatively hampers the mental health.¹⁵ Study conducted on psychosocial problems of adolescence were found to be associated with development of mental health disorders especially depression, anxiety, substance abuse, and psychosis also.¹⁶

In this study, the researchers intended to find out the psychosocial problems among college students. Pathak *et al.*,¹⁷ reported that when comparing with boys, girls are facing more psychosocial problems. Hence, here, the researcher tries to study is there any differences between girls and boys regarding the psychosocial problems.

Rationale of the Study

College life is the most enjoyable time as well as time for psychosocial development in every person. Because of tight schedules, the new atmosphere in colleges, exams, inter personal relation with teachers and fellow students and late adolescent age most of the students are facing some psychosocial problems such as anxiety, depression, and lack interest in studies. So, it is very important to assess and analyze to what extent these psychosocial problems are affecting the students and how they are varying by their gender differences. Hence, in this study, the researchers are attempting to trace out these informations.

METHODS

The study is a cross-sectional study with between group research design. The sample consists of 50 under-graduate and post-graduate students (25 girls and 25 boys) from Central University of Karnataka. The convenient sampling method is used for selecting the participants. Moreover, the tool used for data collection was general health questionnaire (GHQ). The self-administered questionnaire

is an ideal screening device for identifying non-psychotic and minor psychiatric disorders to help inform further intervention.

GHQ is a 28 item scaled questionnaire developed by Goldberg in 1978.¹⁸ GHQ-28 has been divided into four subscales. These are somatic symptoms (items 1-7), anxiety/insomnia (items 8-14), social dysfunction (items 15-21), and severe depression (items 22-28).

Reliability and validity: Various studies have investigated reliability and validity of the GHQ-28 in various clinical populations. Test-retest reliability of the tool is (0.78-0.09)¹⁹ and inter-rater and inter-rater reliability have both been shown to be excellent (Cronbach's α 0.9-0.95).²⁰ High internal consistency has also been reported.²⁰

Before proceeding to the data collection, the consent of subjects was taken, the rapport was established to make them comfortable. The researcher introduced himself and explained the purpose of his research to students. Then researcher circulated the copies of questionnaires to students. Subjects were instructed to go through the instructions written in the questionnaires before answering the questions. After data collection, scoring of the responses was done according to the scoring procedure given for each scale.

Statistical Analysis

Statistical Package for Social Sciences for Windows version 20.0 will be used for analyzing the data. Descriptive statistics and independent sample *t*-test were used for analyzing the data.

RESULTS

Table 1 shows demographic details of the students, from the table we can see that students between the age group of 20 and 30 are 98%, and more students are from under-graduate 64%, and most of the students are from the rural background 54%.

Table 2 shows the psychosocial problems of university students. Results of the study indicated that there were no significant difference in the psychosomatic, anxiety/insomnia, and social dysfunction domains. Moreover, it was found university boys and girls significantly differed in the dimension of depression. Boys are more depressed (boys, mean = 1.80, standard deviation (SD) = 1.52; girls, mean = 0.91, SD = 1.01). The domains psychosomatic (boys, mean = 1.84, SD = 1.68; girls, mean = 1.29, SD = 1.30), social dysfunction (boys, mean = 1.34, SD = 1.26; girls, mean = 1.21, SD = 1.31), and anxiety/

insomnia (boys, mean = 1.46, SD = 1.36; girls, mean = 1.08, SD = 1.21) domains are not showing much difference.

Graph 1 shows mean scores of boys and girls on Y-axis and psychosocial dimensions (psychosomatic, depression, social dysfunction, anxiety/insomnia) on X-axis.

DISCUSSION

Results of the study indicated that there were no significant difference in the psychosomatic, anxiety/insomnia, and social dysfunction domains. Moreover, in the dimension of depression, boys are more depressed. The present study result contradicts the study of Pathak *et al.*,¹⁷ They reported that when comparing with boys, girls are facing

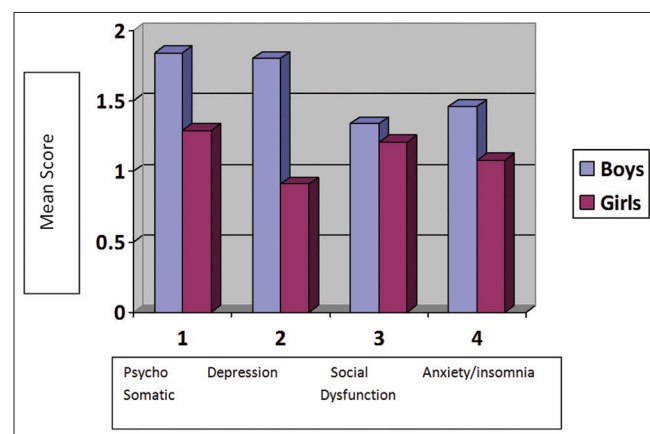
Table 1: Demographic details

Characters	Frequency	Percentage
Age		
20-30	49	98
30-40	1	2
Educational qualification		
Under-graduate	32	64
Post-graduate	18	36
Residence		
Rural	27	54
Urban	23	46

Table 2: Psychosocial problems among university students

Dimension	Gender				t-test
	Boys		Girls		
	Mean	SD	Mean	SD	
Psychosomatic	1.84	1.68	1.29	1.30	0.20
Depression	1.80	1.52	0.91	1.01	0.02
Social dysfunction	1.34	1.26	1.21	1.31	0.71
Anxiety/insomnia	1.46	1.36	1.08	1.21	0.31

SD: Standard deviation



Graph 1: Difference in psychosocial domains among boys and girls

more psychosocial problems. Studies conducted on nursing students revealed that most of them were facing psychosomatic issues¹² and which substantiates the dimension of psychosomatic problems in the present study. Numerous studies (1, 2, 16, 21) have been shown the results that students are facing psychosocial problems from educational institutions. The present study also supports those studies. The studies in the field of educational sector regarding the psychosocial problems of students, most of them are focusing there is a great need to emphasize on the issues.

CONCLUSION

Student life especially college life is a very important time period for the students- most of them in their late adolescent age, physically getting mature, and psychologically unstable. They are undergoing different kinds of stress to study, to complete their assignments, to participate in various programs in the college, and the stress is because of the imbalance between environment and demand. From the result of this study, it was found that the students are undergoing psychosocial problems such as depression. In this regard, there have not any significant difference between boys and girls, even though the problem is still there. So, it is very important to address these issues. The future research should focus on interventions that help to overcoming these problems.

Limitations of Study

The present study consists 50 sample size which is small sample size for generalizing the results. So, future research could be on a larger sample. In the present study, we used convenient sampling method which will limit the generalization.

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Clinical Profile of Patients of Uveitis with Optical Coherence Tomography Diagnosed Macular Edema

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Abstract

Background: Uveitis is a complex intraocular inflammatory process involving uveal and retinal tissues and is one of the leading blinding disorders in India. Macular edema and its sequelae are among the most important causes of decreased vision in patients with uveitis. Optical coherence tomography (OCT) is a safe and non-invasive diagnostic modality for investigation of macular diseases by allowing morphological assessment by producing two-dimensional images of the retina. We have described the clinical profile of uveitis patients having OCT detected macular edema.

Aim: Evaluation of clinical profile of patients of uveitis with OCT diagnosed macular edema.

Materials and Methods: This is a hospital-based, cross-sectional, descriptive study. Uveitis patients presenting to a tertiary care center between November 2010 and July 2012 underwent systemic and complete ophthalmic examination including OCT. All patients with OCT diagnosed macular edema were included in the study. Clinical profile of these patients was described.

RESULTS: 66 patients of uveitis had macular edema on OCT (87 eyes). 3 patterns were found on OCT evaluation, namely diffuse macular edema (DME), cystoid macular edema, and serous retinal detachment, of which 64 eyes had DME. A significant percentage of the cases we studied (32.2%) had anterior uveitis as their anatomic diagnosis. 68% of cases were unilateral. Mean age of patients was 43.5 years. 30 out of 87 eyes had posterior uveitis as an anatomic diagnosis. The etiological diagnosis could be established in 10 patients.

Conclusion: Most of our cases were idiopathic in etiology. DME may go undetected unless OCT is performed. Macular edema may cause visual morbidity even in anterior uveitis cases. Studies with larger sample sizes are required to assess if macular edema is really a cause of visual morbidity in anterior uveitis cases.

Key words: Anterior uveitis, Macular edema, Optical coherence tomography, Uveitis, Visual acuity

INTRODUCTION

Uveitis is an intraocular inflammatory process involving uveal and retinal tissues. With a prevalence of 310/100,000, uveitis is one of the leading blinding disorders in India.^{1,2}

Macular edema and its sequelae are among the most important causes of decreased vision in patients with uveitis. Studies have shown three different types of macular edema-cystoid macular edema (CME), diffuse macular

edema (DME), and serous retinal detachment (SRD) demonstrable on optical coherence tomography (OCT) associated with uveitis.^{3,4} CME is commonly associated with visual loss in uveitis patients.⁵

Fluorescein angiography, which was used to detect and confirm macular edema, is an invasive technique and may even cause anaphylaxis.^{3,6} OCT is safer and a non-invasive diagnostic modality for investigation of macular diseases, allowing morphological assessment by producing two-dimensional (2D) images of the retina. It allows quantification of macular edema objectively and allows for serial follow-up of cases.³

Studies of uveitic macular edema have shown significant correlations between macular thickness measured by OCT and visual acuity.^{3,4,7}

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In this study, we describe the clinical profile of such uveitic macular edema patients. Furthermore, macular edema is usually seen in cases of intermediate and posterior uveitis.³ We looked for subclinical macular edema in anterior uveitis cases as well.

Aims

Evaluation of clinical profile of patients of uveitis, with OCT, diagnosed macular edema.

MATERIALS AND METHODS

This is a hospital-based, cross-sectional, descriptive study. The study was approved by our local ethics committee, and consent was obtained from each patient.

Uveitis patients presenting to a tertiary care center between November 2010 and July 2012 underwent complete ophthalmic and systemic examination. The ophthalmic examination included best-corrected Snellen visual acuity, slit-lamp examination, fundus bio microscopy, indirect ophthalmoscopy, and OCT. We used a STRATUS OCT machine.

The OCT scans were performed through a dilated pupil. The macula was scanned first with fast macular thickness scan protocol and then line scan protocol in horizontal and vertical meridians as appropriate. For each eye, the pattern of macular edema was noted along with the central retinal thickness on STRATUS OCT. All patients with OCT diagnosed macular edema were included in the study; excluding patients with other causes of macular edema such as diabetic or hypertensive retinopathy. 66 patients (87 eyes) qualified for our study.

Uveitis was classified based on International Uveitis Study Group classification system.¹ Other significant findings observed during evaluation were noted and described.

Laboratory investigations including complete blood count with differential leukocyte count, fluorescent treponemal antibody absorption test, angiotensin-converting enzyme, antinuclear antibodies, and Toxoplasma antibody titers were performed when indicated.

Radiologic investigations, such as chest X-ray and imaging of sacroiliac joints, were done as and when the relevant diagnosis was suspected.

Clinical profile of these patients was described.

RESULTS

Three patterns of uveitic macular edema were recorded on OCT imaging.

1. DME (Figure 1)
2. CME (Figure 2)
3. SRD (Figure 3).

Some patients also had an epiretinal membrane (Figure 4).

In our study, 66 patients of uveitis had macular edema on OCT (87 eyes), of which the laterality and gender distribution were as shown in Graphs 1 and 2.

21 of our cases had bilateral, and 45 cases had unilateral uveitis.

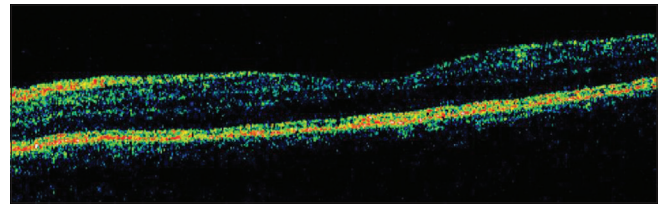


Figure 1: Diffuse macular edema as seen on optical coherence tomography

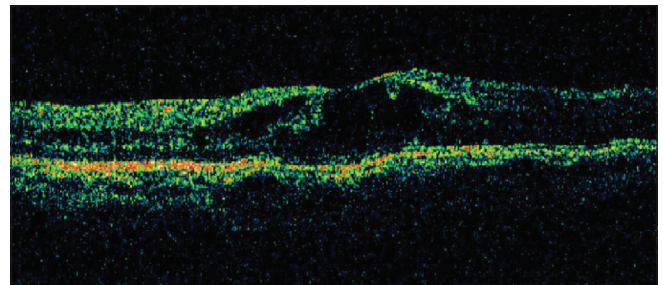


Figure 2: Cystoid macular edema

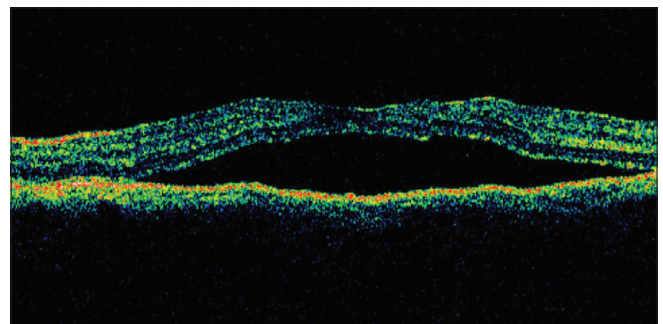


Figure 3: Serous retinal detachment

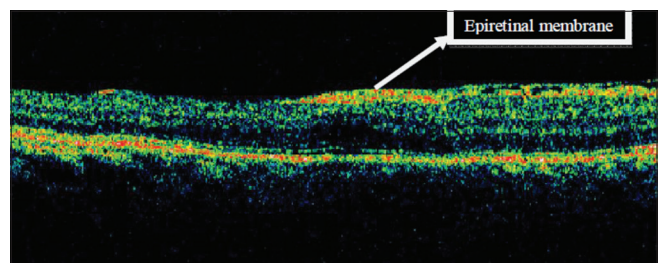


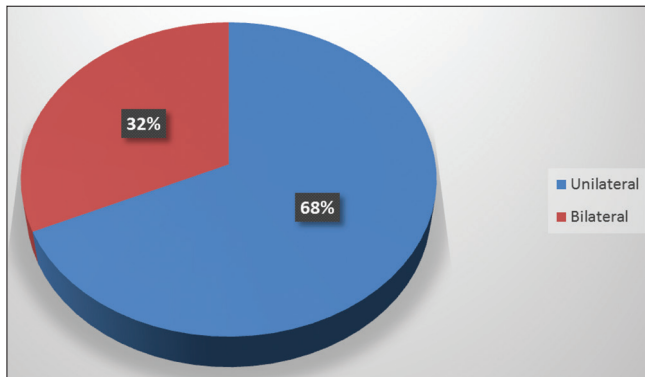
Figure 4: Epiretinal membrane with diffuse macular edema

47 were males, and 19 patients were females.

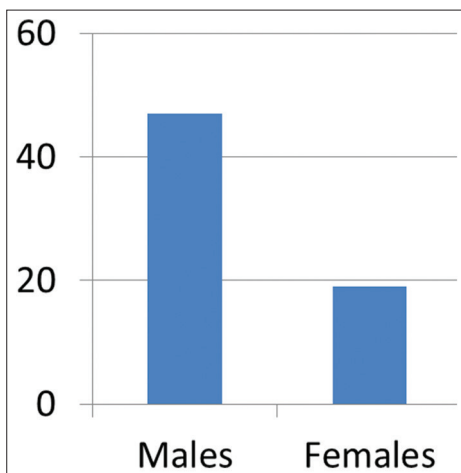
Age distribution varied from 12 to 75 years (mean 43.5 years).

Posterior uveitis was the most common type of anatomic type of uveitis in our study, followed by anterior uveitis (Graph 3).

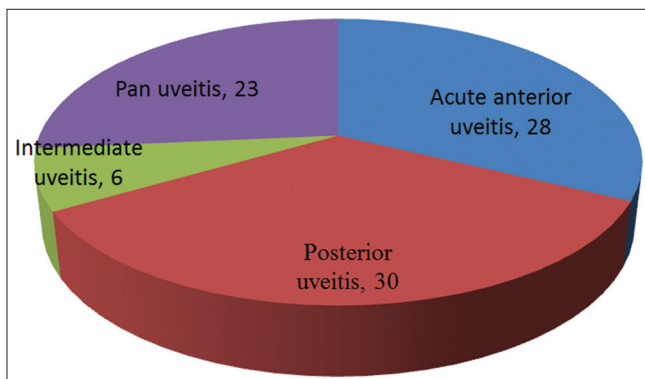
We saw 30 eyes having posterior uveitis, 28 anterior, 23 pan uveitis, and 6 intermediate uveitis cases.



Graph 1: Laterality



Graph 2: Gender distribution



Graph 3: Anatomic types of uveitis

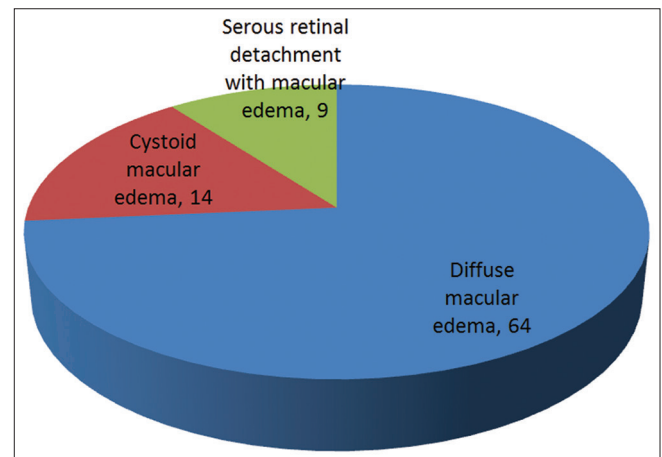
DME was the most common type of macular edema that we saw on OCT (72%), followed by CME and SRD (Graph 4).

64 eyes had DME, 14 eyes CME, and 9 eyes had SRD.

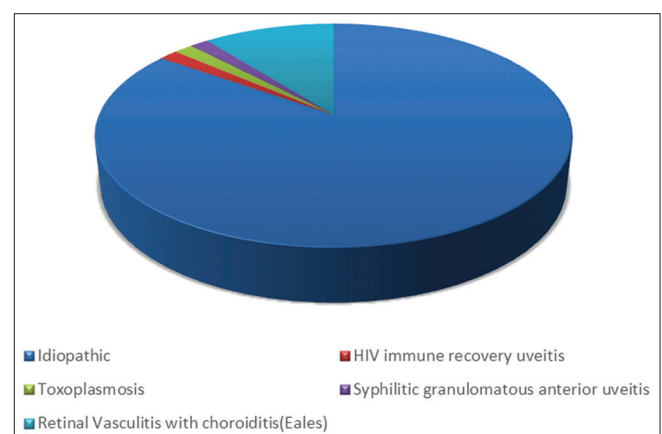
The etiological diagnosis could be established in 10 patients only. All others were deemed idiopathic. One patient each had HIV immune recovery uveitis, toxoplasmosis, and syphilitic granulomatous anterior uveitis. Seven patients had retinal vasculitis with choroiditis, possibly Eales disease (Graph 5).

DISCUSSION

OCT is a safe and noninvasive diagnostic modality for investigation of macular diseases, allowing morphological assessment by producing 2D images of the retina. It allows quantification of macular edema objectively.³ It is not compromised by a low or medium degree of optical haze.⁸ OCT is more sensitive than slit-lamp biomicroscopy to changes in retinal thickness and helps in objectively



Graph 4: Morphologic types of macular edema on optical coherence tomography



Graph 5: Etiology

monitoring patients with macular edema.⁹ Detailed interpretation of OCT images can replace fluorescein angiography for evaluation of macular edema, especially in uveitis cases.¹⁰

Markomichelakis *et al.* found in their study that DME was the most common type of uveitic macular edema (54.8%). 42 of 60 patients (70%), they studied had intermediate uveitis as their anatomic diagnosis and three patients had anterior uveitis.³ DME was the most common (73.5%) type of macular edema that we found in the 87 eyes in our study, and 30 of 87 eyes (34.5%) with uveitic macular edema had posterior uveitis.

In our study, of the 87 eyes of uveitic macular edema, 28 eyes had acute anterior uveitis (32.2%), with 25 eyes having the first episode of anterior uveitis. There have not been many reports of the occurrence of macular edema in cases of anterior uveitis. In one study conducted in Pakistan, CME was seen in 8 of 46 eyes of anterior uveitis evaluated (17%).¹¹

We were able to establish a diagnosis in 10 of our 66 patients (13 eyes). One patient each had HIV immune recovery uveitis, toxoplasmosis, and syphilitic granulomatous anterior uveitis. Seven patients had retinal vasculitis with choroiditis, possibly Eales disease. In the other studies that we reviewed, syphilis was not a cause in any of them.^{3,12} Even in our study, only one patient had syphilis with granulomatous anterior uveitis of both eyes, and with only one eye having OCT detected macular edema. It appears to be a very rare cause. In the other 56 patients, in our study, we could not arrive at a specific diagnosis.

CONCLUSION

We found three patterns of uveitic macular edema on STRATUS OCT evaluation, namely DME, CME, and SRD. DME was the most common type.

A significant percentage of the cases we studied (32.2%) had anterior uveitis as their anatomic diagnosis; with most

of these patients having DME. This suggests that macular edema may cause visual morbidity even in anterior uveitis cases. It is important to note, however that we picked up macular edema in most anterior uveitis cases only on OCT evaluation. This may mean that cases of anterior uveitis having subclinical edema go undetected unless subjected to OCT. Studies with larger sample sizes are required to assess if macular edema is really a cause of visual morbidity in anterior uveitis cases.

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Primary Intramedullary Nailing in Open (Grade-I and Grade-II) Tibial Fractures: A Functional Outcome

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Abstract

Background: Tibia shaft fractures have always been a challenge to the orthopedic fraternity; particularly if it is associated with soft tissue trauma, being prone to various complications such as infection, delayed union, malunion, and non-union. There are differences of opinion regarding the use of intramedullary implants in open fractures of tibia shaft.

Aims of Study: To evaluate the overall functional outcome in the management of open (Gustilo–Anderson-Type I and II) fractures of tibia shaft when treated by intramedullary interlock nailing.

Materials and Methods: A prospective study was done on 34 patients, who attended emergency at Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, a tertiary care hospital. All patients were managed by thorough debridement and intramedullary interlock nailing (Gustilo–Anderson Type I and Type II). Wounds were loosely stitched or left open for secondary closure. In some cases, lateral skin release or split thickness skin grafting was required.

Results: Average union time in our series was 16.4 weeks. Out of total 34 patients of open tibia shaft fractures (Gustilo–Anderson Type I and II) treated by primary interlock nailing, 26 patients (76.5%) showed union by the end of 14 weeks. Infection occurred in 3 patients (8.8%). 6 patients (17.6%) required skin grafting. 3 patients (8.8%) had delayed union and 5 patients (14.7%) required bone grafting because of non-union, which took approximately 32-weeks period in the union after nailing. According to Karlström and Olerud scoring, functional outcome was excellent in 21 patients (61.7%), good in 8 patients (23.5%) patients, and satisfactory in 5 patients (14.7%).

Conclusion: We can conclude that primary intramedullary interlock nailing is a good option for open (Gustilo–Anderson Type I and Type II) fractures, meticulous debridement, early soft tissue coverage, and stable fixation is conducive to faster healing of fracture and good rehabilitation and early return to normal routine work.

Key words: Open fractures, Intramedullary interlock nailing, Tibia, Gustilo–Anderson

INTRODUCTION

With the increasing number of motor vehicular accidents on the roads, tibial fractures are very common, particularly with two wheeler (motor bike) accidents. The tibial shaft is one of the most common sites of open fractures. Approximately 63% open fractures are involving tibia.¹ Many problems arise when tibial

fractures are associated with soft tissue trauma. Soft tissue trauma is directly proportional to the energy dissipated in the collision. Associated soft tissue trauma invites many complications such as nonunion, delayed union and infection etc.

Management of open fractures, particularly in the tibia, has always been a challenge to the orthopedic fraternity. Surgeons were very much reluctant to use intramedullary implants in open fractures of the tibia for a long but with the advent of high-class antibiotics and meticulous debridement technique, stabilization of fractures, and soft tissue cover^{2,3} many orthopedic surgeons are now using intramedullary interlock nailing as a primary method of fixation in open fractures of tibia-Grade-I and II (Gustilo–Anderson classification). Ultimate functional

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outcome depends on timely union and joint movements preservation.

Aims of Study

The aim of our study was to analyze the functional outcome and incidence of complications such as non-union, delayed union infections (superficial/deep) and compartment syndrome in our series of 34 patients of tibia fracture (open Grade I and II) treated by Interlock nailing of tibia.

MATERIALS AND METHODS

This study is based on patients who attended the emergency at SRMS Institute of Medical Sciences, Bareilly, Uttar Pradesh, India, between May 2012 to December 2014. All fresh cases of Open tibia fractures - Grade I and II, treated in the Department of Orthopedics at SRMIMS by intramedullary-interlocking nail, were taken up for study. Simple fractures and Grade-III open fractures were not included in the study.

- Patients were taken to O.T. at earliest possible. All fractures were fixed by intramedullary interlock tibial nailing. There were 12 Type I and 22 patients of Type II as per Gustilo–Anderson classification. Associated injuries were treated as per standard methods
- We used a medial incision approximately 1.0 cm medial to tibial tuberosity and 1.0-1.5 cm distal to joint line for the insertion of the interlocking nail. The nail was statically locked by two proximal and two distal bolts. The wound was stitched loosely after making margins fresh to facilitate the drainage, if at all.

In the patients of delayed wound healing, skin grafting was performed. Later range of motion (ROM) exercises for knee and ankle were started on the 3-4th post-operative day. Walking with crutches or walker started after a week or 10 days with partial weight bearing. Patients were followed up every 4 weeks. The assessment was done as regards the union, delayed union, non-union, infection-superficial/deep, and stiffness at ankle and knee. Full weight bearing was started as soon as minimal callus formation was visible on X-ray. Functional outcome was evaluated using criteria suggested by Karlström and Olerud.⁴

RESULTS

The majority of patients were in the younger age group 20-40 years. Mainly males were the victims of roadside accidents. Less common were domestic injuries due to fall. Right side tibia was more commonly fractured. Out of 34 cases, 12 were Type I and 22 were Type II (Gustilo–Anderson classification).⁵ 26 patients (76.5%) had a union at the fracture site by the end of the 14-weeks period after nailing [Figure 1]. 3 patients (8.8%) patients developed a

deep infection, 5 patients (14.5%) landed into non-union [Figure 2]. Bone grafting was required in all cases of non-union, which ultimately showed union by the end of 32 weeks time. 2 patients had a superficial infection which was managed conservatively by dressing and antibiotics. 3 patients (8.8%) showed the signs of delayed union which took 24-26 weeks time in union [Figure 3]. 5 patients required skin grafting to cover the wound after granulation. There was no mortality as such. No case of limb length discrepancy. Wounds of injury healed within 2-3 weeks period. In 8 patients, dynamization was done at 6 weeks by the proximal screw [Figures 1-3].

DISCUSSION

For a long time use of implants nail or plate in open fractures of tibia, has been a matter of controversy because of very high rate of infection, nonunion, and delayed union. Tibia being a subcutaneous bone, is always prone to damage or loss of skin cover. The outcome is variable depending on the degree of soft tissue trauma, contamination, fracture geometry, and the comminution. On the surface, use of plates and screws further devitalizes the soft tissue and has been found to be associated with high vulnerability for infection.⁶ Use of POP cast is again associated with higher chances of delayed union and malunion. External fixators have been used extensively for the management of open fractures of the tibia, to facilitate the wound care. Though, it has been associated with pin track infection, deep infection, delayed healing of fracture and is very cumbersome to the patient to wear. Sometimes replacing the external fixator with Nail or plate, after healing of the wound, still remains a potential danger for deep infection, in spite of adequate antibiotic coverage, due to pintract infection. The majority of cases were young adults in the third and fourth decade of life, comparable to other study series – Keating,⁷ Freedman and Johnson,⁸ and Whitelaw *et al.*⁹ This is because of their outdoor activities and exposure to roadside traffic. The majority of fractures were due to roadside accidents, resulting from poor road conditions and lack of awareness regarding traffic rules and regulations among the general population.

But, with the current trend of intramedullary nailing in open Grade I and Grade II fractures (Gustilo–Anderson classification) patient can be made ambulatory soon after 3-5 days, post-operatively. Our main aim of this study was to evaluate the functional outcome and various complications in treating the open fractures of tibia (Grade I and Grade II) with intramedullary interlock nailing. The overall incidence of infection was (8.8%). All these were Grade II fractures.

Kessler *et al.*¹⁰ advocated against reamed nailing in open



Figure 1: (a) Injury wound healed in 3 weeks time, (b) post-operative 8 weeks, (c) post-operative at 14 weeks, (d) nail removed after 2 years



Figure 2: Post-operative at 24 weeks (non-union)



Figure 3: Open fracture tibia-united after 24 weeks (delayed union)

fractures of tibia shaft because there is minimal soft tissue coverage surrounding tibia, particularly in lower 1/3. This soft tissue envelope is disturbed with open injury and further reaming the medullary cavity can jeopardize the endosteal vascularity. Delayed primary closure was done in 11 cases and split thickness skin graft was done in 5 cases to cover the wound after granulation. Walking with walking frame usually started within 3-5 days. ROM exercises at ankle/knee were begun on the 2-3rd day of nailing. The average time for the union was 14.8 weeks. Edge and Denham¹¹ reported average union time 26 weeks in open fractures, treated conservatively by plaster application. Clifford *et al.*¹² reported an average time of union 24 weeks in patients of open fracture of tibia treated by plating. Keating reported an average union time 24 weeks with intramedullary nailing in open fractures of tibia. In our series, functional outcome was excellent in 61.7% cases good in 23.5% and satisfactory in 14.7% of the patients treated by intramedullary interlock nailing.

Sargeant *et al.*¹³ suggested that cortical necrosis is less likely with a loosely fitted nail, rather than a snugly fitted reamed, thicker nail. Reaming is supposed to spread the contamination to inside the medullary cavity. In 80% of our cases, we have used 8 mm diameter nail without reaming. Minimal endosteal contact of unreamed nails may concentrate the stresses at the screw hole junction which could be responsible for screw breakage or nail failure. Hahn *et al.*¹⁴ suggested that all screw holes should be filled up with bolts to avoid the concentration of stresses at screw hole junctions. In our study, we have used two proximal and two distal screws to lock. There was no case of screw breakage/nail breakage in our series. Blick *et al.*¹⁵ reported 9.1% incidence of compartment syndrome in open fractures because trauma to musculature may elevate the compartment pressure. In our study, there was no case of compartment syndrome. We did not require fasciotomy in any case. Court-Brown *et al.*¹⁶ reported 36% incidence of anterior Knee pain. In our series, only 20.3% patients complained of mild anterior knee pain, particularly in whom the proximal end of the nail was prominent and palpable.

Joshi *et al.*¹⁷ reported 14.3% incidence of Knee stiffness, in a similar study. In our series, we recorded restriction of knee and ankle movements in 5 cases (6.8%). We started knee and ankle exercise on the 2nd/3rd post-operative day. So, very less number of patients reported knee and ankle stiffness. Use of external fixator has been emphasized very much in the past for initial management of open fractures, but it was found with a high rate of pin tract infection (16%) and moreover, it required a second surgery for definitive fixation. So, it is not advisable now Maurer *et al.*¹⁸

CONCLUSION

After analysis of results of intramedullary interlock nailing in the study group, we concluded that it is an effective and safe method for treating open fractures (Gustilo–Anderson Grade I and II). Maximum number of patients treated by intramedullary, interlocking nail of tibia had excellent functional outcome and very fewer complications, Average time of union was lower in the study, as compared to conservative management and patients treated by plating but one should always keep in mind the grade of injury, soft tissue coverage, and contamination of the wound, while opting for intramedullary nailing in open fractures of tibia.

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Management of Congenital Talipes Equinovarus by Joshi's External Stabilizing System

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Abstract

Introduction: Joshi's external stabilizing system (JESS) is a useful option to correct the deformities in patients who present to the orthopedic department with neglected congenital talipes equinovarus, Plaster of Paris (POP) drop out cases, or failed surgical procedures.

Purpose: We aimed to analyze a short term follow-up study of 16 patients with 4 bilateral cases treated with JESS at the Department of Orthopedics, JJM Medical College, Davangere, in terms of cosmetic, functional, and anatomical outcome.

Methods: A total of 16 children underwent 20 JESS procedures at the Department of Orthopaedics, JJM Medical College, affiliated to Chigateri Government Hospital, Davangere and Bapuji Hospital, Davangere, during the period from September 2008 to September 2010. Patients were followed up regularly. Three-dimensional corrections were achieved by the use of the distractor device.

Results: Excellent results were obtained in 15 feet, good results in two feet, fair in one foot, and poor in one foot. The most common complication we encountered was pin tract infection which eventually healed on an outpatient basis without any residual sequelae.

Conclusion: The Joshi's external stabilization system frame is ideally suited for children in whom clubfoot deformities remain uncorrected by POP cast manipulations as well as recurrent/relapsed clubfoot. The procedure is minimally invasive, and the results are good irrespective of the severity of the deformity.

Key words: Clubfoot, Congenital foot deformity, Congenital talipes equinovarus, Distraction histogenesis, External fixator, Joshi's external stabilizing system, Pediatric orthopedics

INTRODUCTION

Clubfoot is one of the most common congenital orthopedics that still challenge the skills of the pediatric orthopedic surgeons today. This may be due to the fact that it has a notorious tendency to relapse, irrespective of whether the foot is treated by conservative or operative means. In idiopathic congenital clubfoot, the ankle is in equinus, the heel in varus, and the forefoot adducted. Other morphological features include tibial torsion, lateral rotation of the talus within the ankle mortise, medial

angulation of the neck of the talus, subluxation of the talonavicular joint, shortening of the deltoid ligament, and abnormal tendon insertions.

The goal of treatment is to reduce or eliminate all the components of congenital clubfoot deformity so that the patient has a pliable, plantigrade, and cosmetically acceptable foot without calluses, and requiring no modified shoes. The best method of achieving this result with least risk to the patient is debated among pediatric orthopedic surgeons.¹ Over the years, many different forms of treatment ranging from gentle manipulation and strapping, serial plaster corrections, and forcible manipulations including the use of mechanical devices for surgical correction have been tried.

Most surgeons favor early manipulative treatment followed by an early surgical correction in cases of rigid clubfoot which do not respond to treatment by manipulation alone.

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There has been much debate in the past as to whether a conservative or operative treatment was more effective in the treatment of clubfoot. Those feet which have had numerous manipulations and operations are stiff, deformed, and rigid due to scar tissue formation; thus, many patients are not suitable candidates for management by soft tissue release procedures.

Joshi *et al.* devised a simple controlled differential distraction system and stabilization in 1988. Joshi's external stabilizing system (JESS) is a simple, versatile, and light fixator system with tremendous potential.² It includes a bloodless, semi-invasive procedure that avoids fibrous tissue formation, further shortening (unlike bony procedures), post-operative complications, and scarring. JESS ensures proper control of all the components of correction by causing actual physiological lengthening and histogenesis of soft tissues thereby reducing the pressure on the growing epiphysis. However, meticulous post-correction care is crucial for success.

We aimed to assess the efficacy of controlled differential distraction as a method of treatment in idiopathic clubfoot (neglected, recurrent, and relapsed cases) and critically assess the results based on the clinical and radiological findings. Furthermore, we hoped to evaluate the various technical problems and complications of the JESS technique and suggest ways to overcome them.

MATERIALS AND METHODS

This study includes 20 congenital talipes equinovarus (CTEV) feet in 16 patients from the Department of Orthopedics, Bapuji Hospital and Chigateri Government General Hospital affiliated to JJM Medical College, Davangere, comprising 8 patients from each hospital. The study was conducted between September 2008 and September 2010. Out of the 16 patients, 7 patients were neglected cases, 3 patients were recurrent or relapsed cases, and 6 patients were plaster of Paris (POP) dropout cases of idiopathic clubfoot and were surgically treated by JESS fixator. The patients were between 1 and 3 years old, and those who were medically unfit for surgery were excluded from the study.

On admission of the patient, a thorough history was elicited from the parents/attendants to reveal the duration and previous treatment of the deformed foot. A careful marital history was elicited where four patients' parents were found to have a history of second degree consanguinity. No other associated congenital abnormalities were detected.

Feet receiving a score of ≤ 7 by clinical examination by Carroll's assessment were included in the study. The feet were radiologically evaluated, and the following values were calculated: Talo - calcaneal angle (in anteroposterior

[AP] and stress dorsiflexion views), talo - first metatarsal angle (in AP view), tibio - calcaneal angle (in lateral view), and talo - calcaneal index. Routine blood and urine investigations were performed regularly. Following approval of fitness for surgery, the patients in this study were operated under general anesthesia with the patient in supine position. No tourniquet was used in this procedure.

Insertion of K-Wires

- **Tibial:** Two parallel transfixing wires were passed in the tibia about 2.5 cm below and lateral to the tibial tuberosity, perpendicular to the longitudinal axis. The length of the middle segment of the 'Z' bar was marked below the first wire. The second wire was passed parallel to the first wire at this level
- **Metatarsal:** One transfixing wire was passed from the fifth to first metatarsal at the level of the neck. 2 separate wires, one from the medial and the other from the lateral aspects were inserted parallel to the first wire. It was made sure that all the metatarsals had been impaled by at least one of the wires
- **Calcaneal:** Two transfixing parallel wires were passed into the tuber of the calcaneum from the medial side. The axial calcaneal wire was passed posterior to anterior just distal to the insertion of the Achilles tendon in the longitudinal axis of the calcaneum.

Attachment of "Z" and "L" Rods

- **Tibial attachment:** The tibial wires were attached to the middle segment of the "Z" rods by link joints on the medial and lateral aspects. One connecting rod was used to span the anterior limbs of "Z" rod and another to span the posterior limbs
- **Metatarsal attachment:** Two small "L" rods were attached to the metatarsal wires on the medial and lateral aspect of the foot
- **Calcaneal attachment:** Two large "L" rods were attached to the transfixing calcaneal wires on either side of the heel. Behind the foot, these rods were connected to each other by a connecting rod to which the axial calcaneal wire was clamped.

Connecting the Segmental Hold

- **Calcaneo-metatarsal connection:** A pair of appropriately sized distractors was attached to the calcaneal and metatarsal wires on either side of the foot
- **Tibio-calcaneal connection:** Posterior limbs of the "Z" rods were attached to "L" rods of the calcaneal hold by a distraction on either side. Distractors were attached near the transfixing pins
- **Tibio-metatarsal connection:** The anterior limbs of the "Z" rods were connected by a pair of rods to the small "L" rods anterior to the attachment of the metatarsal wires.

Connection of Anterior Stabilizing Rods

Two anterior connecting rods were connected on the medial and lateral aspects of the assembly from the transverse connecting rod of the superior limbs of the Z rods (proximally) to the metatarsal wires/inferior limbs of the metatarsal L rods (distally).

Sterile dressing was applied to the pin tract sites, and a foot plate was applied to prevent clawing of the toes. Distal pulsations (dorsalis pedis and posterior tibial arteries) were checked manually using a pulse oximeter. Capillary filling time was noted. The patient was shifted to the post-operative ward, monitored for a day, and then shifted to the wards. The dressings were changed on alternate days during the hospital stay for a week with spirit and betadine lotion. Pin sites were covered with dry gauze, and the patients were advised to report immediately if there was any discharge from the pin tracts.

On the 3rd post-operative day, differential fractional calcaneo-metatarsal distraction on the medial side was started at twice the rate than that on the lateral side (medial - 0.25 mm every 6 h; lateral - 0.25 mm every 12 h). The tibio-calcaneal distraction was carried out in two positions: (1) The distractors mounted between the inferior limbs of the “Z” rods and posterior limbs of the calcaneal “L” rods lying parallel to the leg and just posterior to the transfixing calcaneal wires (medial - 0.25 mm every 6 h; lateral - 0.25 mm every 12 h) and (2) the distractors shifted posteriorly and connected above to the transverse bar connecting the posterior limbs of “Z” rods and below to the posterior calcaneal bars connecting the posterior limbs of “L” rods and axial calcaneal pin (both - 0.25 mm every 6 h). The end point for distraction was assessed clinically and radiologically. The above explained distraction was very clearly demonstrated to the patient’s attender and supervised for 2 days. 7 days following the surgery, the patient was fit enough to be discharged and was advised for a regular follow-up at weekly intervals for 6 weeks to look for a progressive correction of the deformity, persistent edema, rule out pin tract infections, and tighten the loosened link joints.

Following the correction, the assembly was held in static position for a further 3-6 weeks to allow soft tissue maturation in the elongation position. Single stage removal of the whole assembly was done under general anesthesia and a well molded above-knee plaster cast was applied in maximum correction for 2 weeks. Once the pin tracts healed completely, a below knee cast was applied, and the patient was asked to ambulate with full weight bearing in the plaster. It was removed after 4 weeks.

Full correction of forefoot adduction, varus, and equinus was achieved, usually at the end of 6 weeks. X-ray of the

operated foot with ankle AP and stress dorsiflexion views were taken finally after the removal of the below knee plaster and talocalcaneal index calculated ($>40^\circ$). For all patients, CTEV corrective shoes were advised for 5 years to maintain the correction and prevent recurrence. Using the Hospital for Joint Diseases Orthopedic Institute Functional Rating System for clubfoot (Lehman; Atar *et al.*) and Carroll’s assessment, the results were classified as excellent 85-100, good 70-84, fair 60-69, and poor <60 (out of a total score of 100) at follow-up intervals of 3, 6, and 9 months. The parents care and compliance played an important role in the success of this procedure.

The parents care and compliance played an important role in the success of this procedure. (Figures 1-8)

RESULTS

The age of these patients ranged from 1 to 3 years with an average of 1.9 years. Out of 20 feet, 14 feet (70%) were male and 6 feet (30%) were female patients. There were 12 feet (60%) unilateral and 8 feet (40%) bilateral cases. There were 8 feet (40%) belonging to neglected cases, 8 feet (40%) to POP dropout cases, and 4 feet (20%) to relapsed/recurrent cases (Table 1). Out of 20 feet, 12 feet (60%) underwent the previous procedure in the form of manipulation and serial casting and for the remaining 8 feet (40%), no treatment was given. In this study of 20 feet treated by JESS, there were 4 feet (20%) pin tract infections, 1 foot (5%) skin necrosis, 1 foot (5%) persistent edema, 1 foot (5%) flexion contractures of toes, and 1 foot (5%) loosening of the pin (Graph 1). 15 feet (75%) were excellent, 2 feet (10%) were good, 2 feet (10%) were fair, and 1 foot (5%) was poor as graded by the Hospital for Joint Diseases Orthopedic Institute Functional Rating System for clubfoot (Graph 2). Radiological assessment was done using talocalcaneal index and it was compared with other case series showing good radiological correction (Table 2).

DISCUSSION

External fixators are a versatile method of correcting complex three-dimensional deformities of the foot such as clubfoot. The basic principle of external fixation (JESS) in this study was the same as advocated by

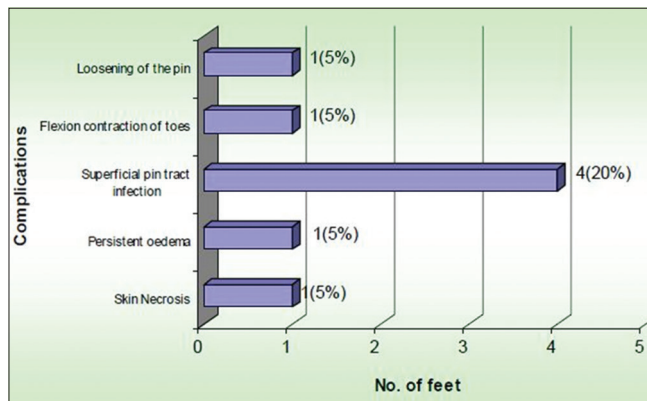
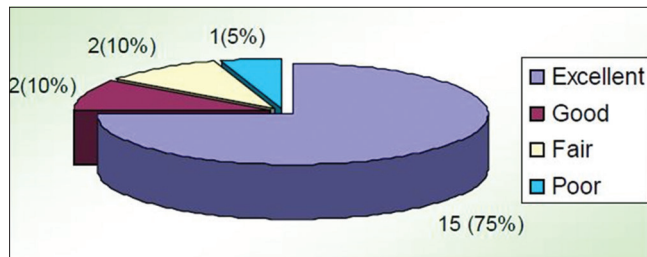
Table 1: Distribution of cases

Type of clubfoot	Number of cases	Number of feet	%
Neglected	7	8	40
POP drop out	6	8	40
Recurrent/relapsed	3	4	20
Total	16	20	100

POP: Plaster of paris

Table 2: Average calculated pre-operative and post-operative talocalcaneal parameters

Pre-operative		Post-operative	
Talocalcaneal angle	Talocalcaneal index	Talocalcaneal angle	Talocalcaneal index
AP view	Lateral view	AP view	Lateral view
13°	18°	23°	30°
Pre-operative TC index <40°, Post-operative TC index >40°		53°	

**Graph 1: Postoperative complications****Graph 2: Clinical results**

Ilizarov. Physiological tension and stress applied to the tissue stimulates histogenesis of tissues, while controlled differential distraction gradually corrects the deformities and realigns the bones. The major difference between the fixators that was used in this study (JESS) and circular fixators described by Ilizarov was that the wires in this study were not tensioned but only prestressed to prevent them from cutting through the soft bones. JESS fixators are also lighter in weight, shorter, cheaper, and have an easier application than Ilizarov's fixators. Furthermore, this device is an unconstrained device, using soft tissue as a hinge and hence, this feature has the disadvantage of developing pin tract infections. The absence of hinges also fails to correct rotational deformities.² The results of our study employing JESS proved to be better than the outcome of the study of Ilizarov's fixator conducted by Fernando where only 58.3% of cases showed excellent results³ and the study conducted by Bradish and Noor where only 47% of cases were successful.⁴

**Figure 1: Unilateral neglected pre-operated foot (Case 1)****Figure 2: Post-operative foot after Joshi's external stabilizing system removal (Case 1)**

In this study, excellent results were obtained due to the fact that except for a few cases which had superficial pin tract infection, no other complications occurred. Of the two cases with scores between 84 and 70, flexion contracture of toes was noted in one case, and forefoot adduction persisted due to the decrease in the rate of metatarso-calcaneal distraction. However, it was treated with physiotherapy and corrective shoes. By 6 months, the flexion contracture was corrected and pain free. Fair results were because of skin necrosis in one foot and persistent edema in another, which lead to temporary cessation of correction for a week with gradual and supervised distraction. In one foot, the results were poor due to the loosening of the axial calcaneal pin due to improper hold in the calcaneum. Hence, the pin was removed, and the scoring was <60 due to persistent equinus and varus deformities at the end of correction phase.

Post-operative assessment yielded results that were comparable to those of other external fixator systems of

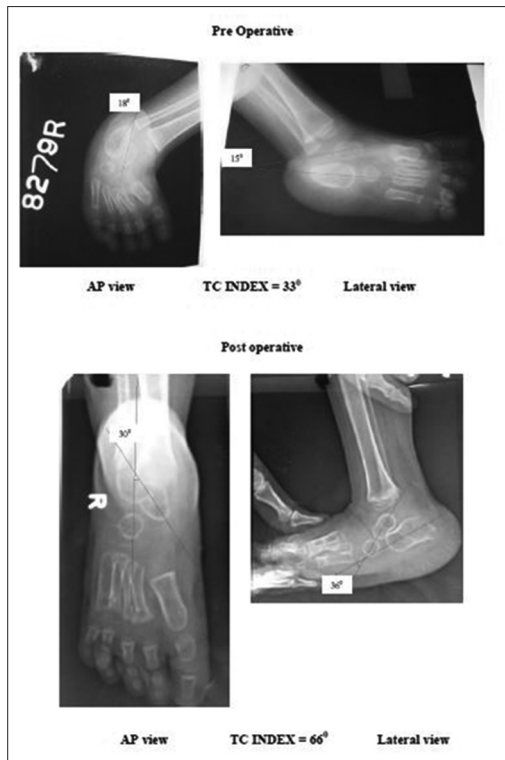


Figure 3: Pre-operative and post-operative radiographs (Case 1)



Figure 4: Bilateral plaster of Paris drop out pre-operative foot (Case 2)

Oganesian and Istomina (75.7% good results).⁵ Our study seemed to show better results than that of Anwar and Arun (59.7% excellent and good results)⁶ and Shrivastava *et al.* (40% excellent results).⁷ In the study by Suresh *et al.* of 44 feet treated by JESS, there were 77% excellent, 13% good, 0% fair, and 9% poor results.⁸ Their results may have been better because of the younger study population. A recent study by Manjappa shows 14 satisfactory corrected feet out of 15 CTEV cases operated by JESS as per Simon's Criteria.⁹

Eight cases were presented with complications in this study. Out of 20 feet, four feet with superficial pin tract



Figure 5: Foot with Joshi's external stabilizing system fixator (Case 2)



Figure 6: Bilateral post-operative feet (Case 2)

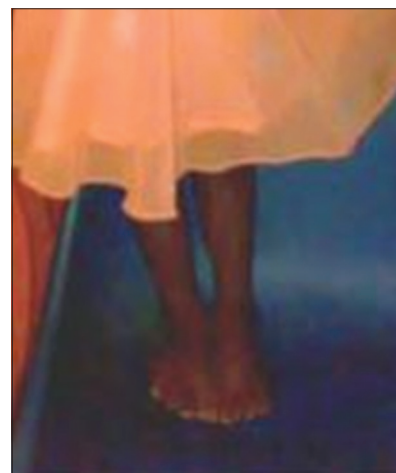


Figure 7: Follow up after 18 months (Case 2)

infections were treated with regular sterile dry dressings and oral antibiotics for a week which eventually subsided. Loosening of the axial calcaneal pin secondary to pin tract infection required premature removal of the fixator in one



Figure 8: Congenital talipes equinovarus shoes

foot which lead to poor results. One foot with flexion contracture of toes may have occurred due to relative inelasticity of the flexor tendons. Skin necrosis in one foot was attributed to the rapid rate of correction of deformities. In this case, the distraction was stopped and reversed until tension relieved. The distraction was continued after a few days under supervision. In one foot, persistent edema was observed due to the same cause mentioned above and was treated similarly with an elevation of the limb and anti-edema measures. Similarly, in the studies by Suresh *et al.* and Anwar and Arun, the predominant complication was pin tract infections.^{6,8} Manjappa, however, reported significant edema as the leading complication and only one case of pin-tract infection.⁹

CONCLUSION

The goal of any clubfoot surgery is to obtain a cosmetically acceptable, pliable, functional, painless, and plantigrade foot, and to spare the parent and the child from the ordeal of frequent hospitalization and years of treatment with casts and braces. The best treatment for clubfoot that does not respond to conventional treatment remains controversial. The procedure used in the current study holds promise for fulfilling the above-mentioned goals. This procedure is ideally suited for children in whom the clubfoot deformities remain uncorrected by POP casts and manipulation, as well as for recurrent clubfoot. If performed at round 9 months of age, the procedure enables the child to walk with a plantigrade foot by the time he or she reaches the walking age group.¹⁰

Functional distraction using JESS apparatus is an easy method, which does not require any sophisticated instrumentation and minimal image intensifier. Parents learn the distraction technique easily and comply with the procedure. Pin tracks should be cared meticulously. An adequate period of static phase is necessary before removal of the apparatus. Strict postoperative management and follow-up are mandatory.

Differential distraction technique gives good result in children, but results are excellent in younger children and those who have not undergone any previous operative procedure. All cases of CTEV are not amenable to this technique; only those cases which are neglected, recurrent, and POP drop out cases should be operated. In relatively mild and moderate varieties of clubfoot, probably traditional soft tissue surgery still holds good. Motivated and compliant parents were a pivotal factor on which the success of the study depended. Although the technique has many advantages, one should not forget that injudicious and unsupervised distraction may lead to catastrophic results in the small developing foot. Long-term studies (10 years) are required to accurately assess the functional outcome of treatment of clubfoot by JESS.

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Management of Rhinosporidiosis: Our Experience

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Abstract

Background: Rhinosporidiosis is a chronic granulomatous disease caused by aquatic parasite *Rhinosporidium seeberi* belonging to novel group of fish parasite *Mesomyxozoa*. It commonly affects nose and nasopharynx. This disease is endemic in India and Sri Lanka.

Materials and Methods: This is a prospective study of distribution pattern and management of 54 cases of rhinosporidiosis in around Srikakulam district, Andhra Pradesh and also to study the pattern of involvement according to age, sex, site, laterality, and their management. It emphasizes the importance of excision under local anesthesia once the stalk of the lesion is identified.

Results: Our study of 54 patients was shown slightly farmer male preponderance around the age of 11-20 years, with a clear cut history of having a bath in contaminated pools and rivers in and around Srikakulam. Nasal obstruction was the predominant symptom than epistaxis as everybody would think of its vascularity. The majority of cases had been excised endoscopically under local anesthesia with less bleeding and minimal recurrence rate. It also reveals the importance of general anesthesia when the lesions involving posterior aspect of nasal cavity and in the nasopharynx to prevent spillage of blood into the laryngeal inlet and also for better accessibility.

Conclusion: Endoscopic identification of stalk is mandatory before excising the lesion under local anesthesia. The bleeding is less when excision done under local anesthesia.

Key words: Endoscopic excision, Granulomatous, Management, *Rhinosporidium seeberi*, Recurrence

INTRODUCTION

Rhinosporidiosis is a chronic granulomatous disease caused by an aquatic parasite. *Rhinosporidium seeberi* belonging to a novel group of fish parasite *Mesomyxozoa*.¹

It commonly affects nose and nasopharynx. Occasionally, conjunctiva, lacrimal sac, maxillary antrum, larynx, trachea, bronchi, urethra, and skin are affected. Disseminated type affects deep viscera and is known as malignant rhinosporidiosis.² This disease is endemic in India and Srilanka³ and few parts of Africa, South America, etc. In India, large numbers of cases are from southern states of Tamil Nadu, Kerala, and Andhra Pradesh. It presents with

soft highly vascular sessile or pedunculated polyps. Most successful treatment is endoscopic excision with cauterization of base.⁴ Incomplete excision leads to recurrences.

MATERIALS AND METHODS

The current study was conducted in Department of Otorhinolaryngology, RIMS, Srikakulam between 2010 and 2015 after taking proper approval by our local ethics committee. Each and every patient has also given consent for this study. This is a prospective study of a total of 54 cases who presented to our outpatient department. Patients presented with history of nasal obstruction, epistaxis, and nasal mass, etc. All patients have undergone complete ear, nose, throat (ENT), and head and neck examination including pre-operative diagnostic nasal endoscopy to assess the site and extension and number of lesions. All patients underwent complete hemogram and blood grouping and typing before being taken up for surgery. Computed tomography scan of nose and paranasal sinuses was undertaken to know the extent and site

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of origin of disease. All the patients underwent endoscopic excision with cauterization of the base. The diagnosis is confirmed with histopathological examination.

RESULTS AND OBSERVATIONS

This was a prospective study conducted in Department of ENT, RIMS Srikakulam.

Total numbers of patients are 54. Duration of symptoms like nasal obstruction, nasal bleeding, and nasal discharge varied from 2 to 6 months.



Figure 1: Rhinosporidiosis lesion in left nasal cavity after tip elevation



Figure 2: Polypoidal rhinosporidiosis lesion in right nasal cavity



Figure 3: Diagnostic nasal endoscopy reveals strawberry like rhinosporidiosis lesion

DISCUSSION

Rhinosporidiosis is thought to be caused by parasite *R. seeberi* belonging to class of *Mesomycetozoa*. All our cases came from rural areas surrounding Srikakulam district. All cases had history of taking bath in ponds and swimming in contaminated ponds and rivers in their respective villages may indicate the most common mode of transmission.⁵ Mostly involves lateral wall followed by septum, floor, and nasopharynx. Predominant symptoms were a nasal obstruction and nasal bleeding. They presents clinically as papillomatous and polypoid lesions. The lesions are soft, highly vascular, sessile or pedunculated and grayish



Figure 4: Diagnostic nasal endoscopy reveals rhinosporidiosis lesion in left nasal cavity



Figure 5: Rhinosporidiosis lesion in left nasal cavity



Figure 6: Extension of rhinosporidiosis lesion in to the oropharynx

Table 1: Sex distribution

Sex	n (%)
Male	38 (70.37)
Female	16 (29.63)

Table 2: Age distribution

Age in years	n (%)
0-10	8 (14.81)
11-20	24 (44.44)
21-30	14 (25.92)
31-40	6 (11.11)
41-50	1 (1.85)
51-60	1 (1.85)

Table 3: Presenting features

Presenting features	n (%)
Nasal obstruction	48 (88.88)
epistaxis	44 (81.48)
Nasal discharge	26 (48.14)
Mass in the nose	43 (79.62)
Change of voice	18 (33.33)
Headache	12 (22.22)

Table 4: Occupation

Occupation	n (%)
Agricultural laborer	28 (51.85)
Students	18 (33.33)
House wife	8 (14.81)

undersurface resembling strawberry studded with white dots representing sporangia.

Differential Diagnosis

Nasal polyp, hemangioma, malignancy, coccidioides immitis, etc. The organism stains with periodic acid Schiff agent⁶ at all stages. Possible causes for recurrences include incomplete removal in inaccessible areas or continued exposure to the infective environment.

It has been observed in our study that the rhinosporidiosis the most common seen in males⁷ and commonly observed in the age group of 11-20 years. Predominant symptoms were nasal obstruction and nasal bleeding. It is mostly unilateral seen on left side. Most common site is lateral wall of nose. It is mostly seen in agricultural laborers. It is mostly solitary in nature. Few recurrences were seen. We have done majority of cases (38/54) done under local anesthesia without much difficulty. We have preferred general anesthesia to perform on patients who have multiple, bilateral, and lesions arising from the posterior aspect of nasal cavity and nasopharynx. Only one patient who underwent endoscopic excision under general anesthesia required post-nasal packing

Table 5: Laterality

Laterality	n (%)
Right	23 (42.59)
Left	28 (51.85)
Bilateral	3 (5.55)

Table 6: Site distribution

Site distribution	n (%)
Lateral wall	33 (61.11)
Nasal septum	6 (11.11)
Nasopharynx	5 (9.25)
Floor	2 (3.70)
Multiple sites	8 (14.81)

Table 7: Number of lesions

Number of lesions	n (%)
Solitary	46 (85.18)
Multiple	8 (14.81)

Table 8: Mode of anesthesia

Mode of anesthesia	n (%)
LA	38 (70.37)
GA	16 (29.63)

LA: Local anesthesia, GA: General anesthesia

Table 9: Type of stalk

Type of stalk	n (%)
Pedunculated	41 (75.92)
Sessile	13 (24.08)

with Foleys catheter and compatible blood transfusion in the post-operative period. Total number of cases with recurrences after 1 year follow-up is 6. The recurrences were due to excision done in inaccessible areas like inferior meati and incomplete excision for which repeat surgery was done. Treatment with dapsone after surgical treatment may minimize the recurrences.⁸ Treatment with dapsone after surgical treatment may minimize the recurrences. (Table 1-9), (Figures 1-6).

Advantage of Endoscope

It reduces the risk of recurrence. Removal of entire mass can be done with endoscope which cannot be seen on routine anterior rhinoscopy. It gives better illumination for removing the entire pathology precisely with minimal manipulation and least resection of surrounding normal mucosa. Post-operative complications like hemorrhage and synechiae are less. For lesions located posterior aspect of nasal cavity and nasopharynx, endoscopic visualization is must and en bloc removal can be done only after

endoscopic guided cauterization of the base. Bleeding is minimal provided the Stalk of the lesion is identified endoscopically.

Recent Advance

Recently, KTP-532 laser was used for larger granulomas which pose difficulties of bleeding and impair vision during surgery.

CONCLUSION

Rhinosporidiosis is a chronic granulomatous disease of the nose and nasopharynx.⁹ It is commonly seen in certain areas of Srikakulam district such as Pathapatnam and Kothur Mandals and Parlakhimudi of Odhissa. Taking bath in contaminated ponds and in Vamshadhara river is the main mode of transmission. Surgical excision with cautery of the base is the treatment of choice. Endoscopic identification of stalk is mandatory before excising the lesion under local anesthesia. The bleeding is less in excision under local anesthesia. The patients who have multiple, bilateral and lesions arising from posterior aspect of nasal cavity and

nasopharynx have to be undergoing endoscopic excision under general anesthesia.

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Histopathological Review of Dermatological Disorders with a Keynote to Granulomatous Lesions: A Retrospective Study

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Abstract

Background: The spectrum of dermatologic disorders varies greatly according to geographical distribution, gender, age, and co-existing disorders. The objective of this study was to determine the histopathological profile of dermatological lesions, to study morphology and attempt to identify the etiology of granulomatous lesions on skin biopsies in a rural population of our set-up.

Materials and Methods: This is a retrospective study over a period of 2-year in the Department of Pathology at our rural area based tertiary care institute. The data of 180 skin biopsies received for histopathological examination were reviewed. Slides stained with routine stain and special stains like Ziehl-Neelsen stain, periodic acid-Schiff, Alcian blue, and Fite-Faraco were reviewed.

Results: Out of 180 cases, 40 (22.22%) cases of non-specific dermatitis, 35 cases (19.44%) of granulomatous lesions, followed by 21 (11.67%) cases of psoriasiform dermatitis, 7 cases of vesiculobullous and vesiculopustular diseases, and 4 (2.22%) cases were reported as connective tissue disorders. Pigmentary disorders of the skin were reported in 6 (3.33%), 23 (12.78%) cases of tumors and cysts of the epidermis and a miscellaneous category, 3 (1.67%) cases. Leprosy accounted for 23 cases of granulomatous lesions followed by 6 cases of lupus vulgaris. Positivity for acid fast bacilli was recorded in 11 cases of these cases.

Conclusion: The incidence of skin lesions was observed to occur more frequently in males and in the age group of 20-30 years. Granulomatous dermatitis is still rampant with infections predominantly leprosy and tuberculosis as the leading causes.

Key words: Bullous lesions, Granulomatous, Histopathology, Papulosquamous diseases, Vesicles

INTRODUCTION

The pattern of skin diseases varies from country to country and various regions within the same country.¹ Occasionally, skin diseases may be alone manifestation of systemic diseases.² Skin diseases are also influenced by various factors such as environment, economy, literacy, racial, and social customs.² It is more so in our country with a tropical climate, with a wide difference in socio-economic

status, diverse religions, and customs in different parts of the country.³

Our study aimed at describing the histopathological profile of non-neoplastic dermatological disorders in a rural based Tertiary Care Institute of Northern India. Granulomatous dermatitis frequently poses a diagnostic challenge to dermatopathologists, as has been discussed in few studies,^{4,6} since an identical histological picture is produced by several causes and conversely, a single cause may produce varied histological patterns.

MATERIALS AND METHODS

This retrospective study was carried out in the Department of Pathology, BPS Government Medical College for Women located in a rural area of Khanpur Kalan, Sonapat, Haryana.

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All the skin biopsies received from 2012 to August 2015 were reviewed. Clinical history and relevant data were recorded from request forms of biopsies received. Slides stained with routine hemotoxin and eosin stain and special stains such as Ziehl-Neelsen (ZN) stain, periodic acid-Schiff, Alcian blue, Fite-Faraco, and Congo red for amyloid were reviewed. From the histopathology section reporting point of view, the skin is divided into four anatomical compartments or units:

1. The first compartment/unit includes the epidermis, papillary dermis, and superficial vascular plexus
2. The second compartment/unit consists of the reticular dermis and the deep vascular plexus
3. The third compartment/unit consists of the pilosebaceous units, the eccrine glands, and in certain anatomical locations, the apocrine glands
4. The fourth compartment/unit is the subcutaneous tissue (panniculum).

Ideally the skin biopsy should consist of all four compartments along with hair follicles. A 4 mm punch biopsy is preferred, and usually adequate for the histological evaluation of most inflammatory dermatoses. A superficial or shave biopsy should be avoided, because it might be misleading, producing an erroneous pattern and diagnosis.

RESULTS

A total of 180 cases were studied during the study period and classified into different age groups. The age distribution pattern revealed that the maximum biopsies received were in the age range of 21-30 years, and the least number were in the age range of 0-10 years (Table 1).

Out of these patients, 102 cases (56.67%) males and 78 cases (43.33%) females. A classification of categories of all histological diagnoses is presented in Table 2. The frequencies and percentages were “non-specific dermatitis” $n = 40$ (22.22%), followed by granulomatous lesions $n = 35$ (19.44%). 14 cases of vacuolar interface dermatitis were observed (erythema multiforme-2, phototoxic dermatitis-1, lichen sclerosus et atrophicus-1, xanthema-1, lupus erthematosus-3, and pigmented purpuric dermatitis-1). A total of 15 cases of lichenoid eruptions were seen which included 8 cases of lichen planus, 2 each of pityriasis lichenoid chronica and post-inflammatory hyperpigmentation and 1 case each of porokeratosis, ashly dermatosis, and lichen nitidus. A total of 35 (19.44%) cases with granulomas were observed (Table 3).

12 cases of malignant tumors were observed comprising of basal cell carcinoma (7 cases), squamous cell carcinoma (4 cases), and basosquamous carcinoma (1 case). Benign tumors and cyst comprise of 11 cases. These include tumors with any epithelioma component (e.g., with seborrheic

Table 1: Distribution of dermatologic lesions according to age groups

Age group	Number of patients	Males	Females
0-10	13	5	8
11-20	34	23	11
21-30	38	23	15
31-40	25	14	11
41-50	27	13	14
51-60	17	11	6
>60	26	13	13
Total	180	102	78

Table 2: Detailed distribution of skin lesions on the basis of histological diagnosis

Skin lesions	n (%)
Non-specific dermatitis	40 (22.22)
Psoriasiform dermatitis	21 (11.67)
Interface dermatitis with lichenoid eruptions	15 (8.33)
Interface dermatitis with vacuolar interface lesions	14 (7.78)
Spongiotic dermatitis	4 (2.22)
Granulomatous lesions	35 (19.44)
Vesiculobullous lesions	7 (3.89)
Calcinosis cutis	6 (3.33)
Pigmentary disorders	6 (3.33)
Benign tumors	11 (6.11)
Malignant tumors	12 (6.67)
Disorders of connective tissue	4 (2.22)
Vasculitis	2 (1.11)
Miscellaneous lesions	3 (1.67)
Total	180 (100)

Table 3: Distribution of granulomatous skin lesions according to classification and gender

Type of lesion	Number of cases	Percentage	Males	Females
Lupus vulgaris	6	17.14	4	2
Tuberculosis	5	14.28	3	2
Verrucous type TB	1	2.85	1	-
TT leprosy	7	20	5	2
BT leprosy	4	11.42	3	1
BL leprosy	2	5.72	-	2
LL leprosy	6	17.14	4	2
Histoid leprosy	2	5.72	1	1
Indeterminate type	2	5.72	1	1
Total	35	100	22	13

TB: Tuberculosis, TT: Tuberculoid leprosy, BT: Borderline tuberculoid leprosy, BL: Borderline lepromatous leprosy, LL: Lepromatous leprosy

keratosis $n = 5$), papilloma $n = 1$, pilomatrixoma $n = 3$, apocrine adenoma $n = 1$, and condyloma accuminata $n = 1$.

A total of 35 (19.44%) cases with granulomas were observed. The most common etiology recorded was leprosy accounting for 23 cases followed by 6 cases of lupus vulgaris. Leprosy cases were further classified into sub-groups according to Ridley and Jopling. The majority of the cases were tuberculoid leprosy (TT) followed by lepromatous leprosy. Special stain for acid-fast bacilli (AFB) was positive in 11 cases of granulomatous etiology.

DISCUSSION

This study has documented the histopathological profile of skin lesions at our tertiary care center with a fairly high presence of non-specific dermatoses (22.22%) and granulomatous lesions (19.44%). The sex distribution pattern revealed that most of the patients were males (56.67%). The age distribution pattern revealed that the maximum biopsies received were in the age range of 21-30 years (Table 1) with most of the patients falling below the age of 40 years. The youngest patient was 5 years old, and oldest was 74 years old.

An analysis of the broad categories revealed that the most frequently encountered lesions were non-specific dermatoses (22.22%) and granulomatous lesions (19.44%) (Table 2). Inflammatory lesions are grouped initially into general categories and then specific features are sought to narrow the diagnoses. Combining the available information on the gross appearance and the clinical differential diagnosis with the histological diagnosis is the vitally important prior to rendering a final diagnosis.⁷ Dermatitis reactions may have acute, subacute, and chronic inflammatory phases with fairly specific histological correlates, incited by external or internal antigens. Since the pathogenesis of most inflammatory dermatitis is unknown, they are best classified using morphologic criteria.⁸

Psoriasiform dermatitis, observed in 21 (11.67%) cases, revealed a characteristic pattern of epidermal hyperplasia typified by elongation of the epidermal rete ridges. Interface dermatitis with lichenoid eruption was observed in 15 (8.33%) cases in our study. It refers to a morphologic alteration at the junction of epidermis and dermis with vacuolization within basilar keratinocytes or basement membrane.⁹ These cases had an inflammatory cell-rich dense band-like infiltrate filling the papillary dermis. Interface dermatitis with vacuolar interface lesions had a poor density or patchy presence of inflammatory cell infiltrate in the papillary dermis and was observed in 14 (7.78% cases). Spongiotic dermatitis, also referred to as eczematous dermatitis, was observed in 4 cases (2.22%) in our study. It refers to the presence of spongiosis or intercellular edema that stretches apart keratinocytes along with the occasional formation of intra epidermal vesicles.^{6,8} Spongiosis was variable, multifocal, and accompanied by intracellular edema and exocytosis of inflammatory cells.

Infectious granulomatous lesions were observed in 19.44% cases in the present study which in accordance with the study done by Mohan *et al.*⁶ The most common etiology of granuloma in our study was leprosy, accounting for 23 cases (12.77% of total). Leprosy presents clinically as macular, infiltrative nodular and diffuse type, affecting both the skin and peripheral nerves.¹⁰ Histologically, it exhibited

an extensive cellular infiltrate separated from the flattened epidermis by a narrow Grenz zone of normal collagen. In most of the cases, this infiltrate caused the destruction of the cutaneous appendages extending into the subcutaneous fat.¹¹ The Fite-Faraco stain showed globi of lepra bacilli within the foamy macrophages (Figure 1).

Erythema nodosum leprosum, a Type-2 lepra reaction, is an acute inflammatory reaction seen in a patient with borderline TT and occasionally in lepromatous subtypes.¹⁰ Here, the foci of acute inflammation superimposed on chronic leprosy were observed (Figure 2).

TT was the most common lesion encountered. In our study, most of the patients with granulomatous lesions were in the 21-40 years age group. The underlying dermis showed epithelioid cell granulomas in the underlying dermis (Figure 3). Neural invasion is also frequently observed in stained sections.

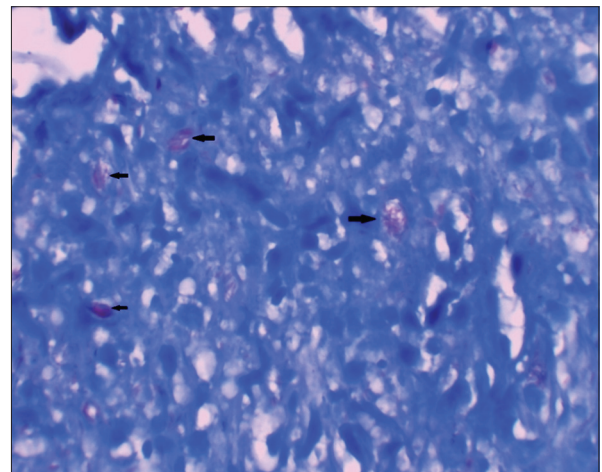


Figure 1: Fite-Faraco staining with globi of lepra bacilli within the foamy macrophages (arrows), (x100)

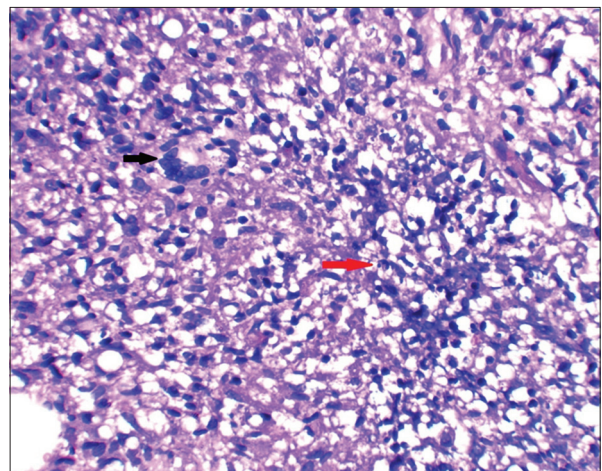


Figure 2: Giant cells (black arrow) along with abundant polymorphonuclear cells (red arrow), (x20)

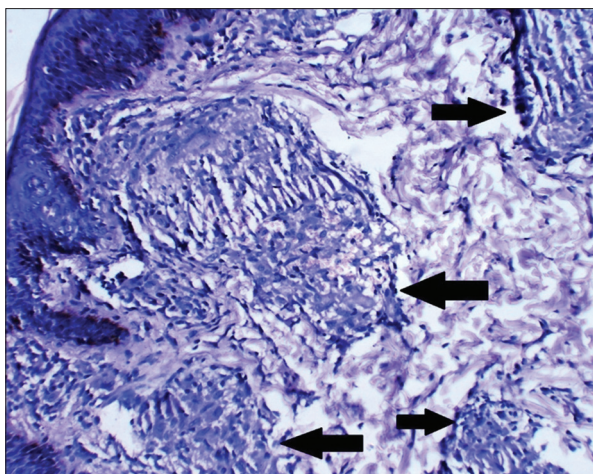


Figure 3: H and E stain (x20): Section showing numerous granulomas in the dermis (arrows)

Studies done in Pakistan⁵ reveal out of a total of 97 cases of tuberculosis (TB) 17 (17.5%) were children (age <16 years) while Kumar and Muralidhar¹² observed 75 children (18.7%) out of 402 cases of cutaneous TB. Cutaneous TB is a relatively rare clinical entity in western countries but is still prevalent in the developing world as in far East, where it accounts for 0.4% of patients with skin disease.¹³ In developing countries like India, the incidence has fallen from 2% to 0.15%. In our study, 6 out of 12 cases of TB were typified which included lupus vulgaris and TB cutis (5 cases). Cutaneous TB is an infection of the skin, and subcutis caused by *Mycobacterium* TB occurs by three routes, i.e., direct inoculation, hematogenous spread, and direct extension from underlying tuberculous lymph node (causing scrofuloderma). Scrofuloderma is the most common form of cutaneous TB in children. It results as a direct extension from an underlying TB focus, such as a regional lymph node or infected bone or joint, to the overlying skin.^{12,14,15} Here, tissue sections revealed tuberculoid granuloma surrounding areas of necrosis.

In a study done by Uz Zafar *et al.*,⁵ out of 47 typified cases of cutaneous TB, lupus vulgaris was the most common form, seen in 18 (38.29%) of these patients, followed by other types. Similar results were also seen by Singh¹⁰ and Kumar *et al.*¹⁵ who found lupus vulgaris the most common form in 44% and 48%, respectively. On the contrary, we observed an incidence of lupus vulgaris in 6 cases (17.1% among granulomatous lesions). In the present study, special stain for AFB was positive in 11.5% of all cases. According

to Veena *et al.*,¹¹ AFB were found in 2 (6.45%) out of 31 skin biopsies in leprosy patients.

CONCLUSION

Our study showed that the incidence of skin lesions was more frequent in males and in the age group of 20-30 years. Moreover, cases where skin biopsy delivered a non-specific diagnosis, it aided in ruling out infective or malignant etiology. Granulomatous dermatitis is still rampant with infections predominantly leprosy and TB as the leading causes. Demonstration of AFB by ZN stain is specific; however, they are not detected with ease, thereby further emphasizing the significance of adequate clinical data and work up which helps in the elucidation of specific etiology.

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Oculocardiac Reflex during Strabismus Surgery in Pediatric Patients: A Randomized Case-Control Study

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Abstract

Introduction: Maintaining the adequate depth of anesthesia and use of anti-cholinergics is the mainstay to reduce or eliminate the risk of oculocardiac reflex (OCR). If stimulus for OCR is reduced or completely stopped OCR can be reduced or eliminated.

Aims and Objective: (1) To evaluate the overall incidence the of OCR, (2) to evaluate the incidence of OCR in patients under general anesthesia with peribulbar block, (3) to evaluate the effect of peribulbar block with general anesthesia on post-operative nausea and vomiting (PONV).

Materials and Methods: It is a prospective, randomized, case-control study. Total 32 cases are evaluated. Group GA: Total 15 cases received general anesthesia only, i.e. without peribulbar block. Group GB: Total 17 cases received general anesthesia with peribulbar block using injection lignocaine 2% in the dose of 3 mg/kg body weight.

Observations: Among the 15 patients from Group GA, two had ventricular ectopic beats and one patient had bradycardia during the handling of rectus muscles. After surgical stimulus is withdrawn cardiac activity is regained. Total 20% of Group GA cases had OCR. However, PONV was observed in four patients in this group. None of 17 patients from Group GB suffered from OCR, and three patients had PONV.

Conclusion: Use of peribulbar block with injection lignocaine along with general anesthesia can reduces or eliminates the incidence of OCR. Moreover, use of injection ketamine may be an additional factor for not to have OCR. There is no effect of peribulbar block on the incidence of PONV.

Key words: Anesthesia general, Arrhythmia, Local anesthesia, Pediatric, Reflex oculocardiac, Strabismus

INTRODUCTION

Strabismus is one of the common health problems among the children.¹ It is being taken care of by the health workers under the school health program. The cases are identified and further followed up to ensure the proper surgical treatment. For these surgeries, anesthesia services are rendered by the anesthesia department. The cases, in this

study, are done at Civil Hospital, Nandurbar and at Shree Bhausaheb Hire Govt. Medical College.

Patients of strabismus surgery are high risk for the oculocardiac reflex (OCR). Exaggerated OCR may be life threatening. Maintenance of the adequate depth of anesthesia and use of anti-cholinergics is the mainstay to reduce this risk. The routine prophylaxis could not eliminate the risk of OCR.²

The incidence of the OCR during strabismus varies with the premedication and use of an anesthetic agent. There are studies which conclude that general anesthesia is with a higher incidence of OCR as compared with regional anesthesia.³ Strabismus surgery in pediatric patient calls for the general anesthesia and consequently aggravates the

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risk of OCR. There are various prophylactic measures to minimize the OCR. As no one measure is reliable, there is continues effort to search for the better option to decrease this risk.

In a recent study by Karaman *et al.*, it is again confirmed that depth of anesthesia reduces the incidence of OCR. But, even with the advance mode of monitoring like bispectral index (BIS) strabismus surgery is not free of OCR.⁴ The reflex arc is trigeminovagal. The afferents are from the eyeball and the extra ocular tissue including the periosteum. If the surgical stimulus is reduced or completely stopped, OCR can be reduced significantly or eliminated. The surgical stimulus can be minimized or stopped with the help of peribulbar block. With this background, the peribulbar block was used to evaluate its effect on OCR.

It is also correlated that manipulation of extraocular muscles may aggravate post-operative nausea and vomiting (PONV).^{5,6} Along with OCR this finding is also evaluated.

Aims and Objective

1. To evaluate the overall incidence the of OCR
2. To evaluate the incidence of OCR in patients under general anesthesia with peribulbar block
3. To evaluate the effect of peribulbar block with general anesthesia on PONV.

MATERIALS AND METHODS

This is the randomized case-control study. The cases were divided into two groups.

Group GA: Total 15 cases who received general anesthesia only, i.e., without peribulbar block.

Group GB: Total 17 cases who received general anesthesia with peribulbar block using injection lignocaine 2% in the dose of 3 mg/kg body weight.

All cases had a routine pre-operative check-up, starved for 6 h and hydration was maintained with the intravenous (IV) fluid ringer lactate. Written informed consent taken. All cases premedicated using is injection glycopyrrolate 0.01 mg/kg of body weight IV, injection ondansetron 0.1 mg/kg IV, injection midazolam 0.05 mg/kg IV, and injection pentazocine 0.3 mg/kg IV.

After adequate pre-oxygenation, induction accomplished with injection propofol 2 mg/kg IV and injection ketamine 0.5 mg/kg IV. Endotracheal intubation was facilitated by injection succinylcholine 1.5 mg/kg IV. General anesthesia was maintained with a combination of oxygen, nitrous oxide, and 0.7-1.0% of halothane.

Muscle relaxation is achieved with non-depolarizing muscle relaxant injection vecuronium 0.08 mg/kg IV. It was reversed with injection glycopyrrolate 0.01 mg/kg body weight and injection neostigmine 0.05 mg/kg body weight IV.

In Group GB - After induction of anesthesia peribulbar block was given with injection lignocaine 2%, 3 mg/kg body weight.

Intra operative continuous monitoring with electrocardiography monitor and pulse oximeter was done, and adequate hydration was taken care with IV fluid ringer lactate until the oral intake was allowed.

In both the group adequate depth of anesthesia was maintained. The stable vital parameters, i.e., no tachycardia or rise in blood pressure and clear surgical field without excessive oozing or bleeding was considered as the adequate depth of anesthesia.

All the patients were observed for PONV. Oral intake is allowed after 3-4 h.

OBSERVATIONS

Demographic comparison is shown in (Table 1). Among 15 patients from Group GA, two had ventricular ectopic beats and one patient had bradycardia during the handling of rectus muscles. In all the three cases, the surgical stimulus was stopped and observed for any further cardiac irregularity. After surgical stimulus is withdrawn cardiac activity is regained to a normal pattern. Rest of the intra operative period was uneventful for these patients and no other patients in this group had shown any cardiac irregularity. Total 20% of Group GA cases had OCR (Table 2).

However, PONV was observed in four patients in Group GA (Table 3). These patients responded to the adequate analgesia with paracetamol suppository 25 mg/kg of bodyweight and injection ondansetron 0.1 mg/kg.

None of 17 patients from Group GB suffered with OCR. Three patients had PONV. These patients also responded to the adequate analgesia with paracetamol suppository and injection ondansetron.

PONV was present among 23.5% of participants of Group A as compared to 17.6% among the Group B participants. The association between type of anesthesia and PONV is considered to be not statistically significant (Fisher's exact test: The two-tailed $P = 0.6783$).

Table 1: Age group sex and weight wise distribution of the study participants

Group	Age group Mean±SD	Sex (%)		Weight Mean±SD
		Male	Female	
Group GA (general anesthesia only)	10.46±2.89 years (range 7-15 years)	11 (63.6)	04 (36.4)	25.3±9.8 kg (14-45 kg)
Group GA (general anesthesia with peribulbar block)	9.8±2.76 years (range 7-15 years)	09 (53)	08 (47)	22.4±9.4 kg (11-45 kg)

SD: Standard deviation

Table 2: Comparison of the presence of OCR among the study groups

Group	OCR (%)		Total
	Present	Absent	
Group GA (general anesthesia only)	03 (20.0)	12 (80.0)	15
Group GA (general anesthesia with peribulbar block)	00 (0.0)	17 (100.0)	17
Total	03 (9.4)	25 (90.6)	32

OCR: Oculocardiac reflex

Table 3: Comparison of the PONV among the study groups

Group	PONV (%)		Total
	Present	Absent	
Group GA (general anesthesia only)	04 (23.5)	11 (76.5)	15
Group GA (general anesthesia with peribulbar block)	03 (17.6)	14 (82.4)	17
Total	07 (21.9)	25 (78.1)	32

P>0.05 not significant. PONV: Post-operative nausea vomiting

DISCUSSION

The OCR was first described by Aschner and Dagnini in 1908. Traction on the extraocular muscles or pressure on the globe causes bradycardia, atrioventricular block, ventricular ectopy, or asystole. In particular, it is seen with traction on the medial rectus muscle, but it can occur with stimulation of any of the orbital content including the periosteum.⁷

The reflex arc is trigeminovagal. The afferent limb is from orbital contents to ciliary ganglion to ophthalmic division of the trigeminal nerve which relays to the sensory nucleus of the trigeminal nerve near the fourth ventricle. The efferent limb is via the vagus nerve to the heart.⁸

Definition

The OCR is defined as a 20% decrease in heart rate (HR) from baseline, dysrhythmias, or sinoatrial arrest associated with ocular muscle traction or pressure on the globe.

Many studies have defined this reflex to include a 10-30% decrease in HR from baseline.⁹

OCR is of high concern to the anesthesiologist during the management of squint surgery. Various anesthesia regimes and BIS monitors are used to minimize or prevent the OCR. However, no single regime is surely effective.¹⁰ Use of anti-cholinergics is not adequate to prevent the OCR.^{11,12} There are chances of ventricular arrhythmia.⁹

It remains controversial whether the anesthetic depth, as assessed by BIS monitoring influences the OCR during squint surgery. BIS value of 40-60 is of adequate depth of anesthesia to minimize the incidence of OCR. But, monitoring with BIS does not ensure the prevention of OCR.¹³

Use of injection ketamine reduces the incidence of OCR.^{3,14,15} However, it does not eliminate it. Sevoflurane is the agent of choice among the inhalational agents for maintenance of anesthesia. The BIS monitoring and use of sevoflurane decreased the incidence of OCR but does not assure the prevention of OCR.^{16,17} To assess the depth of anesthesia BIS monitoring is desirable. Yet, its availability in every set up of developing country like India is not possible. Grover *et al.* claimed its reduced incidence is because of peribulbar block as against of conventional general anesthesia. The ocular cardiac reflex is observed because of stimulus in the afferent limb of which the origin is in the eyeball and peribulbar tissue. If we prevent this stimulus with adequate use of local anesthetic like injection lignocaine along with the adequate depth of anesthesia significant reduction or elimination of OCR is possible. This will ensure the high safety level for OCR.¹⁸

Gupta *et al.* also found that the incidence and severity of OCR intra operatively was significantly reduced in children who received a peribulbar block. The incidence of PONV was significantly reduced in patients receiving either peribulbar block or topical local anesthesia combined with general anesthesia, compared to general anesthesia alone.¹⁹ However, our study revealed no significant difference in both groups.

Adequate blocked of stimulus in an afferent limb by local anesthetics along with anti-cholinergics will help in preventing OCR.

In Group GA, out of 15 patients, 3 had OCR which amounts to 20% and other Group GB is not with any case of OCR. In this group, in addition to peribulbar block injection ketamine is also used at the time of induction of general anesthesia. To evaluate the significance of PONV, the data were analyzed by unpaired *t*-test. It is not found statistically significant. It is said that patients with OCR do show more incidence of PONV, but we do not find such association.

CONCLUSION

Use of peribulbar block with injection lignocaine along with general anesthesia can reduce or eliminate the incidence of OCR. Moreover, use of injection ketamine may be an additional factor for not to have OCR. There is no effect of peribulbar block on the incidence of PONV.

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Prevalence of Dental Erosion in School going Children of South Bangalore: A Cross-Sectional Study

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Abstract

Introduction: Dental erosion is recognized as a major problem in both children and adults. There is a progressive, irreversible loss of dental hard tissues by a chemical process without the bacterial involvement and causes tooth structure loss which results in tooth sensitivity, poor esthetics, and in severe cases may cause pulp exposure and abscess. There is a limited literature with regard to the prevalence of dental erosion in school going children. Hence, this study was undertaken to assess the prevalence and severity of dental erosion in school going children of South Bengaluru.

Materials and Methods: The present study was done among randomly selected 500 school children of South Bengaluru aged between 4 and 15 years. Each child's teeth were examined using mouth mirror and probe. A single investigator did all the examination. The examination was done in a systematic approach, and the degree of tooth wear and scoring were recorded according to modified Smith and Knight Index.

Results: Of 500 children examined, dental erosion was seen in 73 (25.17%) boys and 55 (24.09%) girls. 5-year-old children showed 42.10% of dental erosion. 23.93% of primary teeth and 8.55% of permanent teeth had dental erosion. Of the surfaces examined the labial surface of deciduous maxillary central and lateral incisor (32.81% and 28.39%, respectively) and the occlusal surface of mandibular first deciduous molar (26.92%) were affected predominantly. 82 children (64.06%) had low dental erosion, 26 children (20.31%) had moderate erosion, and 20 children (15.62%) showed severe erosion.

Conclusion: The findings of the present study give an inference that there is a need for enhancing awareness about dental erosion among the school children, their parents and should be recognized and treated early.

Key words: Children, Dental erosion, Primary teeth

INTRODUCTION

Tooth wear has recognized a major problem in both children and adults for many years, which includes the triad of erosion, attrition, and abrasion, but the contribution of erosion to tooth wear is increasing. Dental erosion is defined as the progressive, irreversible loss of dental hard tissues by a chemical process without bacterial involvement and not directly associated with mechanical or traumatic factors, or with dental caries.¹

Dental erosion is increasingly recognized as a cause of tooth structure loss, not only in adults, but also in children and adolescents which results in tooth sensitivity, eating difficulties, poor esthetics, altered occlusion and in severe cases may cause pulp exposure and abscesses.² It has a multifactorial etiology which may be intrinsic or extrinsic acid sources. Intrinsic is when gastric acid enters the mouth secondary to gastro-esophageal reflux, eating disorders, chronic vomiting, persistent regurgitation, or rumination. Extrinsic acid sources include acidic beverages and foods, medications, battery and fertilizer factory workers, professional wine tasters, laboratory technicians, environmental acids, and in competitive swimmers. In addition, many modifying factors affecting the host and parafunctional habits significantly increases tooth susceptibility to dental erosion.³ Clinical features of erosion include shallow, broad, smooth, glazed wedge-shaped depression within the enamel surface adjacent to cemento

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enamel junction, cupping of cusp tips and grooving of incisal edges, wear on non-occlusal surface, non-tarnished and raised amalgam surface.¹ Symmetrical erosive dentine exposures on the cuspal inclines of the molar teeth are described as a cup or bowl-shaped lesions. The erosive potential of acid may be decreased by educating the child and parent, appropriate oral hygiene practices, dietary alterations, fluoride supplementation, restorative care.²

There is a limited literature with regard to the prevalence of dental erosion in school going children. Hence, this study was undertaken to assess the prevalence and severity of erosive tooth wear in school going children of South Bengaluru.

MATERIALS AND METHODS

The present study was done among randomly selected 500 school children of south Bangalore with 280 boys and 220 girls aged between 4 and 15 years. Institutional ethical clearance was obtained before conducting the study. Prior informed consent was taken from the parents and the school authorities for participation in the study. Each child's teeth were dried thoroughly, and examination was performed in their respective classrooms under natural daylight using mouth mirror and probe. The single investigator did all the examination.

The examination was done in a systematic approach starting from upper first quadrant followed by second, third, and fourth quadrant. Examination of the surface of teeth was proceeded in an orderly manner starting from occlusal/incisal, buccal, palatal/lingual surfaces. The degree of tooth wear and scoring were recorded according to modified Smith and Knight Index.¹

Modified Smith and Knight index (2003)

Code	Tooth structure involved
0	Normal
1	Enamel only
2	Enamel and dentine
3	Enamel, dentine, and pulp
9	Assessment cannot be made

Code	Criteria
0-1	Low erosion
2	Moderate erosion
3-9	Severe erosion

RESULTS

A total of 500 children were examined with 280 boys and 220 girls. The highest number of participants was among

6-year-old children with 37 boys and 35 girls (Table 1 and Figure 1). Dental erosion was seen in 73 (25.17%) boys and 55 (24.09%) girls (Table 2 and Figure 2). 5-year-old children showed dental erosion with 42.10% (Table 3 and Figure 3). Among 128 children, 23.93% of primary teeth and 8.55% of permanent teeth had dental erosion (Table 4 and Figure 4). Of the surfaces examined the distribution of dental erosion was more predominant on the labial surface of deciduous maxillary central and lateral incisor with 32.81% and 28.39%, respectively (Table 5 and Figure 5), and on the occlusal surface of a mandibular first deciduous molar with 26.92% (Table 6 and Figure 6). Among 128 children, it was observed that 82 children (64.06%) had low dental erosion, 26 children (20.31%) had moderate erosion, and 20 children (15.62%) showed severe erosion (Table 7 and Figure 7).

Table 1: Age and sex distribution of children

Age in years	Males	Females	Total number of children examined
4	30	21	51
5	25	13	38
6	37	35	72
7	36	25	61
8	37	19	56
9	30	17	47
10	15	16	31
11	17	21	38
12	10	13	23
13	15	9	24
14	14	19	33
15	14	12	26

Table 2: Sex distribution of children with dental erosion

Sex	Number of the children examined	Children with dental erosion	% affected
Male	280	73	25.17
Female	220	55	24.09
Total	500	128	

Table 3: Prevalence of dental erosion (both sexes)

Age in years	Number of children examined	Number of children with dental erosion	Percentage of children with dental erosion
4	51	8	15.68
5	38	16	42.10
6	72	26	36.11
7	61	13	21.31
8	56	12	21.42
9	47	13	27.65
10	31	13	41.93
11	38	10	26.31
12	23	5	21.73
13	24	4	16.66
14	33	3	9.09
15	26	5	19.23

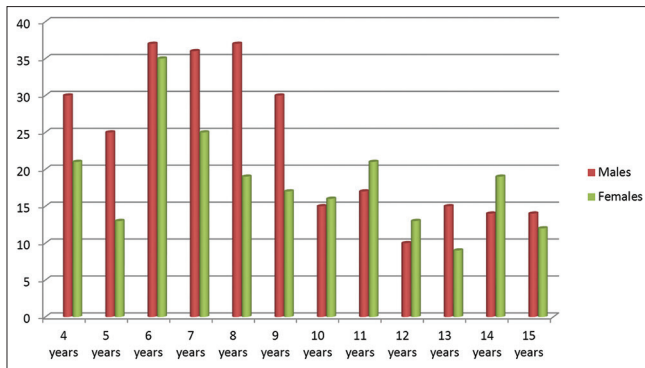


Figure 1: Age and sex distribution of children

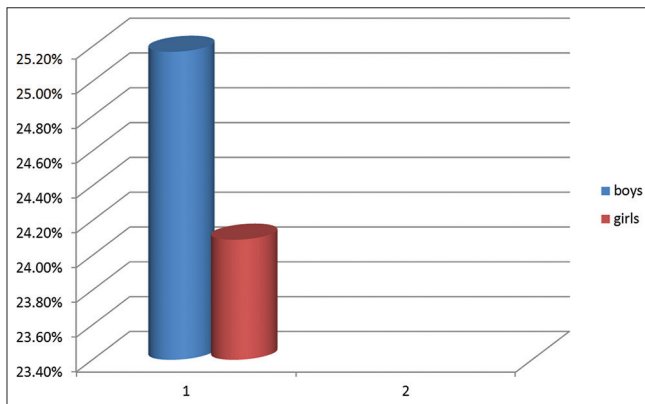


Figure 2: Sex distribution of children with dental erosion

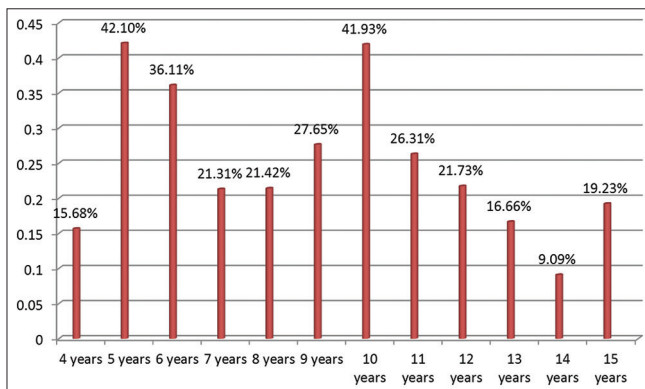


Figure 3: Prevalence of dental erosion (both sexes)

Table 4: Teeth with dental erosion

Dentition	Total number of teeth examined	Teeth with dental erosion	% affected
Primary teeth	940	255	23.93
Permanent teeth	1180	101	8.55

DISCUSSION

The present cross-sectional study was done among 500 school going children of South Bengaluru, between the age group of 4 and 15 years.

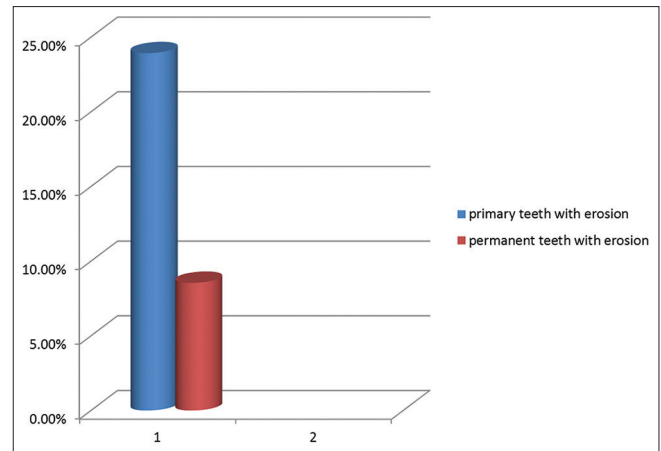


Figure 4: Teeth with dental erosion

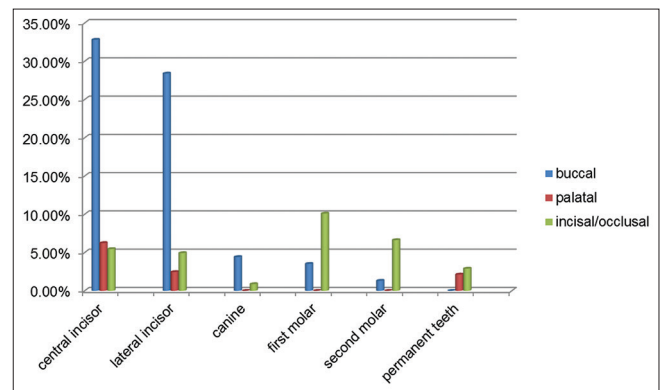


Figure 5: Number of surfaces of maxillary teeth involved with dental erosion

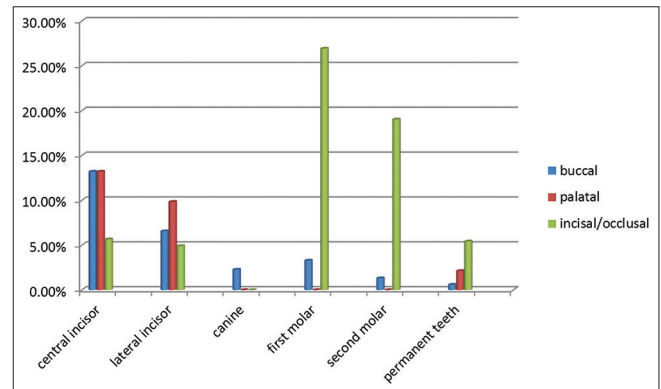


Figure 6: Number of surfaces of mandibular teeth involved with dental erosion

Table 5: Number of surfaces of maxillary teeth involved with dental erosion

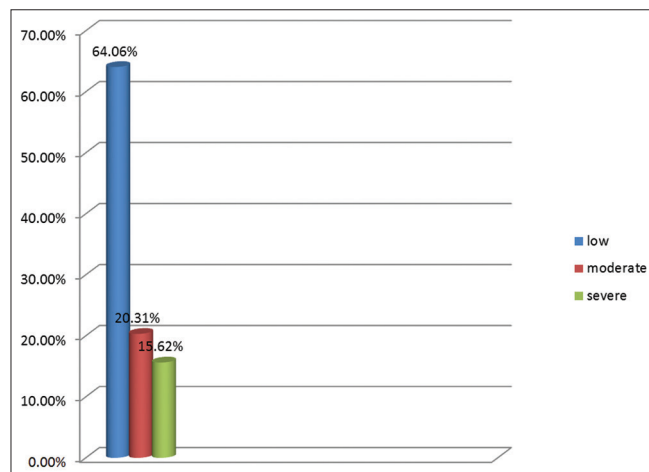
Maxillary	Buccal (%)	Palatal (%)	Incisal/occlusal (%)
Central incisor	42 (32.81)	8 (6.25)	7 (5.46)
Lateral incisor	46 (28.39)	4 (2.46)	8 (4.93)
Canine	10 (4.42)	0	2 (0.88)
First molar	7 (3.53)	0	20 (10.10)
Second molar	3 (1.32)	0	15 (6.63)
Permanent teeth	0	11 (2.13)	15 (2.90)

Table 6: Number of surfaces of mandibular teeth involved with dental erosion

Mandibular	Buccal (%)	Lingual (%)	Incisal/occlusal (%)
Central incisor	14 (13.20)	14 (13.20)	6 (5.66)
Lateral incisor	8 (6.55)	12 (9.83)	6 (4.91)
Canine	4 (2.27)	0	0
First molar	6 (3.29)	0	49 (26.92)
Second molar	3 (1.32)	0	43 (19.02)
Permanent teeth	4 (0.60)	11 (2.13)	36 (5.42)

Table 7: Severity of dental erosion

Severity	Number of children with dental erosion	% affected
Low	82	64.06
Moderate	26	20.31
Severe	20	15.62

**Figure 7: Severity of dental erosion**

In the last 20 years, studies have been published showing that prevalence of erosive tooth wear was increasing especially in the children and adolescence. This is due to change in their dietary habits and lifestyle. There is a limited literature with regard to the prevalence of dental erosion in school going children. Hence, this study was undertaken to assess the prevalence and severity of erosive tooth wear in school going children of South Bengaluru.

The prevalence of dental erosion in the present study was found to be 25.6%. Similarly Wiegand *et al.* showed a prevalence of 32% in 2-7 years old children.⁴ However, in contrast to this, Ayers *et al.* reported 82% prevalence in 5-8 years old children.⁵ There were wide ranges in results due to differences in the populations studied, age, sample size, length of time the teeth were exposed to acid. Furthermore, there was a difficulty in comparing prevalence studies due to differences in diagnostic criteria, indices, different teeth assessed, socioeconomic conditions, and cultural factors.

Dental erosion in boys was found to be 25.17% which was more than in girls with 24.09%. This was in accordance with the studies conducted by Dugmore and Rock, Milosevic *et al.*, and Al-Dlaigan *et al.* who reported more erosion in boys than in girls.⁶⁻⁸ This might be due to consumption of soft drinks was more among boys than in girls.

The percentage of dental erosion among 5-year-old children was 42.10%. Millward *et al.* reported 38% at 4-5 years age.⁹ Similarly, Al-Majed *et al.* showed 82% in 5-6 years old children.¹⁰ Harding *et al.* reported 47% in 5-year-old.¹¹ Furthermore, Luo *et al.* showed a prevalence of 57% in 3-5 years.¹² This might be due to the exposure of carbonated drinks, medications more at a younger age. However, in contrast to this study, increased percentage of erosion at 6 years age group with 30.70% and at 5 years of age with 28.57% was reported by Deshpande and Hugar.¹

Among 128 children with dental erosion, the primary teeth were affected more commonly with 23.93%, while the permanent teeth showed 8.55%. Similarly, Ganss *et al.* reported increased the percentage of dental erosion in primary teeth with 70.6% than in permanent teeth with 11.6%.¹³ Kazoullis *et al.* also showed the percentage of dental erosion in primary teeth with 78% and in permanent teeth with 25%.¹⁴ This is due to the thinner enamel layer and morphological differences in the primary teeth. Johansson *et al.* reported microhardness of enamel in primary teeth was less compared to permanent teeth.¹⁵ Furthermore, primary enamel contains more water and has increased permeability compared to permanent enamel.

When the teeth with erosion were considered, the primary maxillary central incisors (32.81%) and primary mandibular first molar (26.92%) were affected predominantly. Similarly, Wiegand *et al.* reported that the most affected teeth were primary maxillary incisors (15.5-25%) and primary mandibular first molar (3.5-5%).⁴ The upper incisors are located in the front of the oral cavity which are exposed more to extrinsic acids, such as acidic beverages predisposing to the dental erosion. The lower first molars present in the oral cavity for a longer period and are exposed to erosive challenges for a longer period of time.

Among the surfaces examined, distribution of erosion was seen more predominantly on the labial surface of deciduous maxillary central and lateral incisor with 32.81% and 28.39%. Deshpande and Hugar reported that the buccal and palatal surfaces of central incisor showed maximum erosion with 35% and 21.6%, respectively.¹ This is due to the labial surface of upper incisors are in direct contact with dietary intake of acidic beverages, foods, and medication. Furthermore, tooth brushing performed after consumption of acidic drinks or an erosive episode such as vomiting.

The study showed a predominant distribution of erosion on the occlusal surface of a mandibular first deciduous molar with 26.92%. Similarly Deshpande and Hugar showed maximum erosion of 13.3% on occlusal surface of first deciduous molar in the mandibular arch.¹ Furthermore, Wiegand *et al.* reported erosions were mostly seen on the occlusal surfaces of the primary first and second molars (75.9%).⁴ Chewable Vitamin C preparation or acidic foods left in direct contact with tooth, increases risk for dental erosion on the occlusal surface.

According to the severity of dental erosion, 82 children (64.06%) had low dental erosion, 26 children (20.31%) had moderate erosion, and 20 children (15.62%) showed severe erosion. This was comparable with the study by Deshpande and Hugar, who reported 20 cases (66.6%) had low severity and 9 cases (30%) had moderate severity.¹ Furthermore, Al-Dlaigan *et al.* reported 48% mild erosion, 51% moderate erosion, and 1% severe erosion.⁸ Similarly, Ganss *et al.* also reported 70.6% had low erosion and 26.4% had moderate erosion.⁹ The severity of dental erosion is increasing in children, and may cause severe loss of dental hard tissues that adversely affects esthetics and function of the mouth, hence should be recognized and treated early.¹⁶

Further survey to be carried with a detailed questionnaire proforma and dietary chart which shall investigate the intrinsic and extrinsic causes of dental erosion in children.

CONCLUSION

- Dental erosion showed a high prevalence in 5-year-old children. Erosion was seen more in boys than girls and primary teeth affected more commonly
- Distribution of erosion was seen more predominantly on labial surface of deciduous maxillary central and lateral incisor and on the occlusal surface of mandibular first deciduous molar

- The findings of the present study give an inference that there is a need for enhancing awareness about dental erosion among the school children, their parents and should be recognized and treated early.

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Use of Intramedullary Nail in Distal Metaphyseal Fractures of Tibia

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Abstract

Background: The ideal treatment of distal metaphyseal tibia fractures is still controversial. With the development of extremely distal locking multidirectional holes, the application of intramedullary nailing has extended to the treatment of distal metaphyseal tibial fractures. The aim of the study was to evaluate the results of interlocking intramedullary nailing in extra-articular distal metaphyseal fractures of tibia.

Patients and Methods: The study had been done in Mahatma Gandhi Medical College and Research Institute, Department of Orthopaedics. It included 15 patients with age ranging from 25 to 50 (mean 38), who were treated with interlocking intramedullary nailing for distal metaphyseal tibia fractures. About 13 cases were closed and two cases were compound. According to AO classification 12 cases were A1, two cases were A2 and one case was A3. All are due to road traffic accident. 12 patients had concomitant fibula fractures. In all cases, tibial nail with multiple multidirectional distal holes was used. 12 cases were locked dynamically and three cases (AO A2 and A3) were locked statically. Patients were followed up clinically and radiologically with mean follow-up of 16 months (12-20 months).

Results: Union was achieved in all patients within a mean of 5 months (4-8 months). No serious complication was noticed. One patient (6.67%) had knee pain which was due to a protrusion of nail that subsided after nail removal. Two patients (13.33%) had the limitation of ankle range of motion in magnitude of 5-10°. One patient (6.67%) had valgus malalignment of 5°. No rotational malalignment was found in any patients. Shortening of 1.5 cm was found in single patient (6.67%).

Conclusion: Intramedullary interlocking nailing is a reliable method of treatment for distal metaphyseal tibial fractures with a high union rate and low complication rate.

Key words: Distal tibia, Intramedullary nailing, Metaphyseal fracture

INTRODUCTION

Distal tibial fractures are caused by road traffic accident, fall from height, and sports injury. The prevalence of these fractures has increased in parallel with increase in motor vehicle accidents and sports activity. AO classification is most accepted classification. Type A: Extra-articular fractures, Type B: Partial intra-articular fractures, and Type C: Intra-articular fractures. Type A is divided into three subtypes: Simple fractures (A1), fractures with partial comminution (A2), and fractures with large comminution

(A3). These fractures are due to high-energy trauma by torsional or compression forces. Clinical examination usually shows pain, swelling, and deformity of the distal tibia. Passive and active ankle movements are painful and restricted. The neurovascular examination is a must. Anteroposterior and lateral radiographs of the distal third of the tibia are of great importance for the diagnosis. The management of these fractures is usually operative. Plate fixation for distal tibia fracture is associated with non-union, delayed union, sloughing of overlying skin, and infection. Interlocking intramedullary nailing is now more preferred technique for these fractures. To achieve good functional result proper alignment must be obtained so that nail will be central in both proximal and distal fragment. Factors leading to non-union are a disturbance of local blood flow by high energy trauma, damage to soft tissue, comminution of fractures, and open reduction method along with other independent additive factors such as

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smoking, alcohol, metabolic abnormalities, and diabetes. Instability due to osteoporosis of the area or improper alignment during reduction leads to breakage of nail or screws, malalignment, delayed union, non-union, and pseudarthrosis.

The aim of our study was to evaluate the results of interlocking intramedullary nailing in distal metaphyseal tibia fractures.

PATIENTS AND METHODS

The study has been done in Mahatma Gandhi Medical College and Research Institute, Department of Orthopaedics. A total of 15 patients, 13 male and 2 female, with mean age of 38 (range 25-50) were treated with interlocking intramedullary nail for distal metaphyseal tibia fracture. The right side was involved in 10 patients and left in 5 patients. About 13 were closed fracture and two were compound. According to AO classification Type A1 were 12, A2 were two and Type A3 was one. About 12 patients had concomitant fibula fracture as well. Closed reduction was done in 14 cases and open reduction in one. Tibial interlocking nail with multiple multidirectional distal holes was used. Average nail diameter was 10 mm (range 9-11 mm). 12 fractures were dynamically locked (all AO Type A1) and rest were statically locked. At least two distal screws were put, if possible three. To prevent varus, valgus or anteroposterior malalignment a ball tip guide wire was inserted and checked radiographically for central placement of tip. Eight out of 12 fibula fractures fixed with 1/3 tubular plate. In our study, we fixed fibula first, so that it helped in aligning the fractured tibia. All compound fractures were debrided in one sitting and nailed after 72 h of antibiotic coverage. There was no intraoperative complication in any patient. All patients were discharged on 10th post-operative day after stitch removal with advice of partial weight bearing. Full weight bearing was allowed after 6-8 weeks depending on union status radiologically. The patient was accessed clinically and radiologically first on the 6th week and then at 4 weekly interval until bony union.

Radiographic evaluation includes progression of union, axial angulation on sagittal and frontal plane, shortening and torsion. Clinical examination included range of motion of knee and ankle and existence of pain in adjacent joints and at fracture site. Mean follow-up was up to 16 months (range 12-20 months).

RESULTS

All fractures united within a mean of 5 months (ranges from 4 to 8 months). Dynamization was not needed in any patient. The mean time to union in dynamic locking group was 4.8 months and statistically locked group was 5.2 months. No intraoperative complication occurred in any cases. No skin necrosis and no superficial or deep infection occurred. Shortening of 1.5 cm was observed in a single patient with AO Type A3 fracture pattern. Knee pain was complained by single patient which was due to protrusion of nail that subsided on nail removal after fracture healing. Nail or screw breakage did not occur. Two patients had limitation in range of motion of ankle within a magnitude of 5-10°. None had experienced limitation of knee motion (Figures 1-4).

DISCUSSION

Extra-articular fractures of the distal tibia account for 14.5% of all fractures of distal tibia.¹ The prognosis of these fractures depends on several factors including the presence of comminution, soft tissue damage, osteoporosis, surgical technique, post-operative care and whether the fracture is open or closed. Some authors advocate the use of a locking plate with minimally invasive plate osteosynthesis technique.²⁻⁴ Closed reduction can be achieved with the use of temporary external fixation.⁵ Other authors use external fixation with or without minimal internal fixation (screws and K-wires).^{6,7} Another alternative is the use of interlocking intramedullary nailing. The technique is demanding in that the guide should be placed approximately 1 cm close to the joint of the ankle without causing damage to the articular surface.⁸ Two



Figure 1: Case 1: (a) Pre-operative, (b) immediate post-operative, (c) follow-up at 4 months, (d) follow-up at 6 months

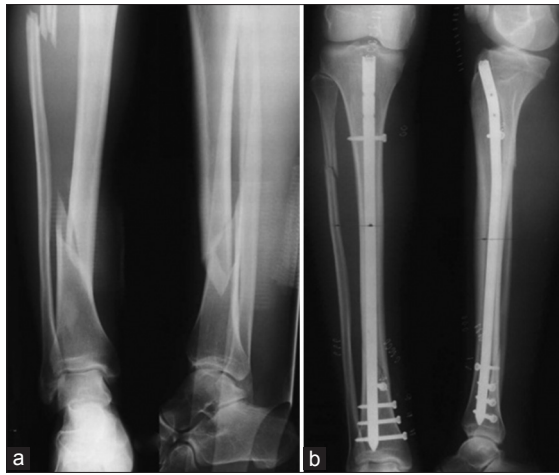


Figure 2: Case 2: (a) Pre-operative, (b) immediate follow-up



Figure 3: Case 3: (a and b) Pre-operative anteroposterior (AP) and lateral view, (c and d) follow-up at 5 months AP and lateral view



Figure 4: (a-c) Case 3: Post-operative clinical photographs at 6 months

screws should be placed to achieve fracture stability.⁹ This technique may require the use of an tibial interlocking nail

with multiple multidirectional holes near the distal tip of the nail.^{10,11} Fibular fixation with plates is necessary because it increases rotational stability, allows early weight bearing, restores ankle mortise, and prevents the development of post-traumatic arthritis.¹²⁻¹⁴ Fibular fixation can be performed before or after tibial fixation. In our study, we first fixed the fibula and then the tibial fracture, which facilitated alignment of the tibial fracture and nail insertion. A comparative study evaluating plate and nail fixation by Egol *et al.* (2006) showed similar results. Tylianikis *et al.* (2000) and Yang *et al.* (2005) state that plate achieves better anatomical reduction whereas nailing has a shorter operation time, better functional results (ankle motion), and lower rates of skin necrosis. There is no method without disadvantages. Plating is associated with relatively higher rates of skin necrosis, infection, and pseudarthrosis, while external fixation with or without minimal internal fixation (screws or K-wires) may result in pin tract infections, malunion, and non-union. The use of nailing decreases these problems, but it is a demanding technique. This method cannot be used in intra-articular fractures (pilon) because open reduction with restoration of the articular surface is required. Our findings are in accordance with the results reported in the aforesaid literatures.

CONCLUSION

The results of our study, which are comparable to the results published in other series, reinforce our opinion that interlocking intramedullary nailing is an efficacious method of treatment for distal tibial fractures provided that there is no intra-articular fracture and incongruity. Good surgical technique, close insertion of the nail, proper alignment, use of two distal screws, and early weight bearing are mandatory to achieve axial restoration, satisfactory functional outcome, high rate of union, and low incidence of complications.

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Adherence of Primary Health Care Physicians to Hypertension Management Guidelines in Aljouf Region of Saudi Arabia

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Abstract

Introduction: Hypertension affects more than one-third of the world population and is a common public health problem. Primary health care physician's (PHCP's) adherence to the hypertension management guidelines constitutes an essential step for controlling hypertension.

Purpose: The present study examines the adherence practices of PHCPs to hypertension management guidelines using Joint National Committee's Seventh Report (JNC-7) on hypertension guidelines in Aljouf region of Kingdom of Saudi Arabia.

Methods: This cross-sectional descriptive survey covered physicians in PHC setting in Aljouf region of Saudi Arabia. Each physician received a survey package containing a letter of introduction, consent form, and questionnaire. The questionnaire comprised three parts; Part-1 related to demographic data, Part-2 included physician's knowledge and practice regarding hypertension management guidelines, and Part-3 assessed the physicians' choice of anti-hypertensive drug class in co-morbid conditions. Data analysis was carried out using Statistical Package for Social Sciences Version 17 software.

Results: The use of variable sized cuff was practiced by 93% of PHCPs and 80% correctly recorded the blood pressure. The majority of the physicians (80%) followed JNC-7 guidelines for managing patients with hypertension. Nearly all (98%) physicians were interested to involve the family in management of hypertensive patients and 92% encouraged screening programs for hypertension. The mean percentage of correct answers regarding the drug to use and the drug to avoid in selected co-morbid conditions was 55.3%.

Conclusion: Contrary to the earlier literature on non-adherence of PHCPs to hypertension management guidelines, our study observed that the majority of them adhere the JNC-7 guidelines for hypertension in Aljouf region of Saudi Arabia. The study showed a lack of knowledge among PHCPs in managing hypertension in patients with the co-morbid condition.

Key words: Blood pressure, Guidelines, Hypertension, Knowledge, Primary health care physicians

INTRODUCTION

Hypertension is considered one of the common public health problems worldwide and it is a major risk factor for

stroke, myocardial infarction (MI), vascular disease, and chronic kidney disease.¹⁻³ Hypertension affects more than one-third of the world population.^{4,5} Hypertension affects approximately 21% of all Saudis aged between 18 and 64 years.⁶ By the year 2025, it is expected that hypertension will increase by 80% in developing countries and 24% in developed countries.⁵

Appropriate control and early diagnosis of hypertension are the key to prevent and lower the risk of associated complications such as renal disease, stroke, and heart disease.⁷⁻¹⁰ Hypertension is one of the major modifiable

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risk factors for cardiovascular disease (CVD) and a leading cause of premature deaths and disability-adjusted life years.^{11,12} CVD risk can be reduced ultimately by strategies designed to lower blood pressure (BP).^{13,14}

Different guidelines have been proposed from time to time to increase the number of patients with controlled BP. These recommendations have proved their cost-effectiveness in several worldwide studies.¹⁵ It is a well-established fact that poor disease control is largely related to the poor patient compliance to medical advice and medications.^{16,17} However, the other important aspect of the same problem is the physician's adherence to evidence-based management of hypertension, but, unfortunately, this has not been studied adequately.¹⁸

Two National Multistage Surveys reviewed 10,735/4758 Saudis showed that 15.2-25.5% and 40.6% of Saudis were hypertensive or borderline hypertensive, respectively. 44.7-57.8% of them were undiagnosed. Although 71.8-78.9% of hypertensive patients were reported taking medication, 37-45% of them had their BP controlled.^{19,20}

Although there are no well-established methodologies to assess physician's adherence to guidelines for management of hypertension, a substantial number of studies that have been done have found that physicians do not adhere to the recommended guidelines - as reflected on the poor control of hypertension.¹⁹⁻²² Many studies have shown the lack of detailed knowledge of hypertension guidelines by the physicians and prescription of more expensive drugs without evidence of efficacy.²³⁻²⁵ Therefore, health care providers must focus on evidence-based, cost-effective treatment and follow recommended guidelines while prescribing anti-hypertensive treatment.²³

Although Ministry of Health (MOH) of Kingdom of Saudi Arabia (KSA) with Saudi Hypertension Management Society had published guidelines for the management of arterial hypertension in the year 2011, we chose to study adherence to the earlier Joint National Committee's Seventh Report (JNC-7) guideline. This is because in a pilot study awareness with the 2011 guidelines was minimal, possibly because of inadequate training and dissemination in a narrow time frame.²⁶ The importance to access the adherence to hypertensive guidelines becomes even more important viewing the large number of health center visits by the patients reaching 1,268,432 patients in the year 2011 according to Saudi MOH website, where 95% of them are Saudi Nationals. Our cross-sectional descriptive survey was directed to investigate adherence practices of primary health care physicians (PHCPs) to the use of clinical practice guidelines in Aljouf region of KSA.

METHODS

Design, Study Population, and Setting

Aljouf region of Saudi Arabia is divided into three sub-regions as Sakaka, Domat Al-jindal, and Taberjal. Primary Health Care (PHC) is provided through a network of 33 primary health centers distributed in these sub-regions proportionate to their population. This cross-sectional descriptive survey was conducted between May 2012 and April 2013 covering all physicians in PHC setting of Aljouf region. The Ethical Committee College of Medicine; Aljouf University approved the study protocol.

Data Collection

Questionnaire used in the present study was adopted from another published study by Ernst in Pretoria in South Africa (2005).²² Faculty of Community Medicine revised the questionnaire. The questionnaire was pretested on a group of physicians, and necessary modifications were made, and this group of physicians was excluded in the final analysis.

Inclusion and Exclusion Criteria

All the PHCPs working in the region at the time of the study were included; physicians who were on leave or on night shifts were excluded.

Each physician received a survey package containing a letter of introduction regarding the importance of this survey and a consent form for his willingness to participate in this study with an approval letter of General Directorate of Health Affairs. Consent form included the purpose of the study, confidentiality, voluntary involvement, and contact information in case of queries. The questionnaire was in English and comprised three parts. Part-1 was related to demographic data of the physician (age, gender, nationality, qualification, and years in practice in health system of KSA), Part-2 included physician's knowledge and practice regarding hypertension management guidelines using JNC-7, and Part-3 assessed the physicians' choice of anti-hypertensive drug class in specific short clinical scenarios of common health conditions. In each of the questions relating to selected scenarios (Part-3 of questionnaire), the participant was asked to name his/her most prescribed drug of choice and the drug to be avoided in these situations.

Third-year medical students of Aljouf University collected the data. To ensure uniformity in data collection, proper training was imparted to the students. When the questionnaire was distributed to the physicians, the student sat with the physician in the same room to prevent any effort to get information from any source. Physicians were also assured verbally that the information will be anonymous and kept confidential.

Data Analysis

Data analysis was carried out using Statistical Package for Social Sciences Version 17 software. Data are shown as numbers, percentages, mean, range, and standard deviation.

RESULTS

Table 1 presents demographic characteristics of the study population. A total of 59 physicians voluntarily participated in the study that included 42 males and 13 females; gender was missing in four responses. Response rate was cent percent. The mean age was 38 ± 7 years (range 23-56 years). About half (49%) of the physicians were Egyptians and the other nationalities included; Sudanese 20%, Indian 14%, Syrian 5%, Pakistani 5%, and Nigerian 2%. Two-third (66%) of participants have only MBCH qualification, higher qualification included diploma (15%), master degree (9%), board (5%), and doctorate (3%). 44% of participants were practicing medicine in KSA for 6-10 years.

Table 2 presents physician's opinion regarding various aspects of hypertension. All the PHCPs were aware that

Table 1: Demographic characteristic of PHCPs in Aljouf province participated in the study (n=59 physicians working in 33 PHCs)

Characteristics	n (%)
Gender	
Male	42 (71)
Female	13 (22)
Missing	4 (7)
Age (in years)	
Mean	38 ± 7
Range	23-56
Nationality	
Egyptians	29 (49)
Sudanese	12 (20)
Indians	8 (14)
Syrians	3 (5)
Pakistani	3 (5)
Nigerians	1 (2)
Missing	3 (5)
Qualification	
MBCH	39 (66)
Diploma	9 (15)
Masters	5 (9)
Board	3 (5)
Doctorate	2 (3)
Missing	1 (2)
Years of practice	
<5	10 (17)
6-10	26 (44)
11-15	16 (27)
16-20	6 (10)
>20	1 (2)

Percentages have been rounded up to the nearest digit. PHCPs: Primary health care physicians

hypertension is a common health problem in Saudi Arabia and that there should be more attention paid to hypertensive patients. Similarly, 98% of participants were interested to involve the family in management of hypertensive patients and agreed that advices on lifestyle modification must be provided to hypertensive patients during counseling. 85% of physicians in PHC centers agree that PHCs play a major role in managing hypertension, while 15% did not.

Eighty one (81%) expressed their comfort in dealing with hypertensive patients compared to 19% who were not comfortable. Of all, 92% encourage screening program for hypertension, and 80% reported that they were trained adequately to manage hypertensive patients, whereas 20% reported that they were not well trained. 83% reported that hypertension leads to patient's excessive anxiety and concern.

Table 3 presents the knowledge and practice of JNC 7 guidelines by PHCP. The majority of the physicians 88% followed JNC-7 guidelines for the measurement of hypertension with respect to position. The use of variable sized cuff was practiced by 93% of physicians. 81% of physicians correctly recorded the systolic BP among non-diabetic patients. Correct recording of diastolic BP was practiced by 80% of physicians among diabetic and non-diabetic patients. 60% of physicians take three readings before labeling the patient as a case of hypertension. The overall (mean of correct answers) adherence of PHCPs to JNC-7 guidelines was found to be 80%.

Regular health education was imparted by 80% of physicians. 27% of physicians were prescribing two or more drugs to a new case of hypertension.

Four to five cases of hypertension were referred to specialist care during the last year. 48% of patients were referred because of their co-morbid health condition, 24% believed that a specialist should treat hypertension; 22% were referred because of patient's request and patient's financial reason account for 4% of the referrals.

Anti-hypertensive Treatment in Co-morbid Conditions

Table 4 present's physician's choice of anti-hypertensive drugs in selected clinical scenarios. For the given scenarios, the physicians had to write the drug of choice and the drug to be avoided for each scenario.

Scenario-1: Hypertension of pregnancy

71% of the respondents correctly chose a central acting alpha-2 agonist as the drug to use and the same percentage of physicians chose a correct drug to be avoided.

Table 2: Opinion of participated PHC physicians regarding hypertension as a health problem in Aljofr province

Variable	Yes n (%)	No n (%)
Hypertension is a common health problem in the province	59 (100)	Nil
Are you interested to involve the family in the management of a patient with hypertension?	58 (98)	1 (2)
More attention should be paid to hypertensive patients	58 (98)	1 (2)
During counseling of patients with hypertension, do you think lifestyle modification should be offered to all patients?	58 (98)	1 (2)
Physicians in primary health care centers are capable of playing a major role in management of hypertension	50 (85)	9 (15)
Are you comfortable in dealing with hypertensive patients?	48 (81)	11 (19)
Screening programs for hypertension are favorable to improve early care of hypertensive patients	54 (92)	5 (8)
Are you trained adequately to manage patients with hypertension?	47 (80)	11 (20)
Hypertension causes patients excessive anxiety and concern	49 (83)	10 (17)

Percentages have been rounded up to the nearest digit. PHC: Primary health care

Table 3: BP measurement and management of a new case of hypertension

Variable	N (%)
Patient's position during measurement	
Sitting position only ¹	7 (12)
Sitting and sometimes other positions ²	52 (88)
Cuff size of sphygmomanometer	
One size for all patients ¹	4 (7)
Variable sizes for different patients ²	55 (93)
Diastolic blood pressure is recorded at	
Korotkoff sound phase 4 ¹	12 (20)
Korotkoff sound phase 5 ²	47 (80)
Diagnosis of hypertension among non-diabetics	
≥140 mmHg ²	48 (81)
≥90 mmHg ²	46 (80)
Diagnosis of hypertension among diabetics	
≥130 mmHg ²	41 (69)
≥80 mmHg ²	47 (80)
Number of repeated measurement of BP for definitive diagnosis	
1 time	1 (2)
2 times	3 (6)
3 times ²	40 (60)
4 times	15 (25)
Giving health education to the patients about hypertension	
Always	48 (80)
Often	7 (12)
Sometimes	4 (8)
Types of hypertensive drugs prescribed to new hypertensive patients	
One	42 (71)
Two	14 (24)
>Two	2 (3)

¹Not consistent with JNC7, ²Consistent with JNC7, Note: Percentages have been rounded up to the nearest digit, BP: Blood pressure

Scenario-2: Hypertension in bronchial asthma

Potassium-sparing drugs or thiazide was correctly selected as the drug of choice by 44% of the respondents in treating a patient with severe persistent bronchial asthma and 74% correctly chose the drug to be avoided.

Scenario-3: Hypertension in bronchial renal artery stenosis

Most respondents 68% chose the correct drug to use and 44% correctly chose the drug to be avoided among patients with bilateral renal artery stenosis.

Scenario-4: Hypertension in diabetes

Most respondents 80% correctly chose angiotensin converting enzyme (ACE) inhibitors as the drug of choice in patient with diabetic nephropathy and 29% correctly chose the drug to be avoided.

Scenario-5: Hypertension with old MI

In treating a patient with old MI 75% of the respondents correctly chose the drug to use and 22% correctly avoided the contraindicated drug.

Scenario-6: Hypertension with sexual dysfunction

An ACE inhibitor was correctly selected by 59% of the respondents as the treatment choice in a 45-year-old patient with sexual dysfunction while 56% correctly avoided the contraindicated drug.

Scenario-7: Hypertension with peripheral artery disease

For a patient with peripheral vascular disease, 46% chose dihydropyridine calcium channel blockers as drug to use and 51% chose β -blockers as drug to avoid.

Scenario-8: Hypertension with gout

77% of respondents correctly prescribed drug to use and 59% of them chose thiazide, furosemide as drug to avoid correctly in treating patient with gout.

The mean percentage of correct answers regarding both (drug to use and drug to avoid) among selected case scenarios was 55.3%.

DISCUSSION

Hypertension is considered one of the common public health problems worldwide, and it is a major risk factor for stroke, MI, vascular disease, and chronic kidney disease. Different guidelines have been proposed from time to time to increase the number of patients with controlled BP. These recommendations have proved their cost-effectiveness in several worldwide studies.¹⁵ Our cross-sectional descriptive survey was directed to investigate

Table 4: Prescribed initial oral anti-hypertensive drug in each proposed clinical scenarios

S. No	Scenario	Correctly prescribed the drug of choice	N (%)	Correctly avoided the drug	N (%)
1	A 24-week pregnant woman with pre-existing chronic hypertension	Methyldopa	42 (71.2)	ACE inhibitors, ARB, thiazide	42 (71.2)
2	A 45-year-old patient with severe persistent bronchial asthma	Potassium-sparing diuretics, thiazide	26 (44)	βBs	44 (74.6)
3	A 65-year-old patient with bilateral renal artery stenosis	Not specific	40 (67.8)	ACE inhibitors, ARB	26 (44)
4	A 50-year-old patient with diabetic nephropathy	ACE inhibitors, ARB	47 (79.7)	Thiazide, βBs	17 (28.8)
5	A 55-year-old patient with old myocardial infarction	ACE inhibitors, ARB, βBs, long-acting DHP (CCB)	44 (74.6)	Short-acting DHP (CCB)	13 (22)
6	A 45-year-old patient with sexual dysfunction	ACE inhibitors, ARB	35 (59)	Thiazide, βBs, alpha-agonist	33 (55.9)
7	A 45-year-old patient with peripheral vascular disease	DHP (CCB)	27 (45.8)	βBs	30 (50.8)
8	A 56-year-old male patient with gout	No specific drug recommended	45 (76)	Thiazide, furosemide	35 (59)
Mean % correct			62.7		47.8

ACE: Angiotensin converting enzyme, ARB: Angiotensin receptor blocker, βBs: Beta-blockers, DHP: Dihydropyridine, CCB: Calcium channel blockers

adherence practices of PHCPs to the use of clinical practice guidelines in Aljouf region of KSA.

A total of 59 physicians voluntarily participated in the study with a mean age was 38 ± 7 years (range 23-56 years). 95% of surveyed physicians were non-Saudis, almost half (49%) of the physicians were Egyptians, and 66% of participants have only MBBS qualification (Table 1). Al-Gelban *et al.*, in their study in Aseer region of Saudi Arabia, found that most of the physicians were non-Saudi (98.1%), males (80.7%), aged 31-50 years (78.3%), and their the highest qualification was MBBS (89.4%).²⁷

Hypertension Awareness among PHCPs

All the participated physicians were aware that hypertension is a common health problem in Saudi Arabia and 85% of physicians in PHC centers were capable of managing hypertension, and most of them thought that they were trained adequately to manage patients with hypertension. 83% reported that hypertension leads to patient's excessive anxiety and concern (Table 2).

98% of PHC physicians had the interest to involve the family in management of patient with hypertension particularly for lifestyle modification (Table 2). Al-Gelban *et al.* also found that the great majority of PHC physicians advice regarding lifestyle modification, including weight reduction (98.8%), sodium restriction (97.5%), physical exercise (96.3%), and behavioral improvement (87.6%).²⁷ Adedeji *et al.*, in their study, found that the adherence to lifestyle modification/non-drug treatment recommendations was low for physical activity (31.2%), dietary modification (46.5%), and advice on stopping/reduction of alcohol intake (34.5%) and stopping smoking (47.2%).²⁸

We found that 92% of physicians suggested screening programs for hypertension were favorable to improve

early care of hypertensive patients (Table 2). Adedeji *et al.*, in their study, found adherence to screening for major cardiovascular risk factors was high for diabetes mellitus (99.2%), moderate for smoking (53.5%), low for obesity (6.1%), dyslipidemias (36.9%), and abdominal obesity (6.2%).²⁸ Al-Gelban *et al.* also found that the great majority of PHC physicians inquired about cardiovascular risk factors.²⁷

Physician's Adherence to Hypertension Management Guidelines using JNC-7

In our study, the overall (mean of correct answers) adherence of PHCPs to JNC-7 guidelines was found to be 80%. In contrast, a study done by Ernst showed that general practitioners in private practice and primary health care physicians in the three academic hospitals in Pretoria did not adhere to the hypertension guidelines suggested by the JNC-6 report.²² Adedeji *et al.* in their study also found overall adherence of doctors to treatment guidelines for hypertension to be low (51.9%) while applying South African Hypertension Guidelines 2006.²⁸ Al-Gelban *et al.*, in their study, found that the PHC physicians did not fully adhere to all JNC-7 hypertension guidelines.²⁷ The reason for high adherence in our study could be due to availability of better facilities at primary health centers *vis-a-vis.* to infrastructure and other logistics needed to manage hypertension. In our study, 32% physicians were having a higher qualification that might have increased the knowledge and affected the attitude of other doctors during their monthly meetings. Furthermore, almost all PHCPs are expatriates working in the KSA hence need to adhere the guidelines for continuity of service.

In our study, the use of variable sized cuff was practiced by 93% of physicians and 80% correctly recorded the BP. 60% of physicians took three readings before labeling the patient as a case of hypertension. Correct recording of

diastolic BP was practiced by 80% of physicians among diabetic and non-diabetic patients (Table 3). Similar results were obtained by Adedeji *et al.*, in their study, where they found adherence to measurement aspects of the guidelines of hypertension was high (99.8%).²⁸ Al-Gelban *et al.*, in their study, found variable cuff sizes for different patients were used by 56.5% of the participants, while 74.8% correctly recorded the diastolic BP at Korotkoff sound, Phase-5. They found that diastolic hypertension was correctly reported by 81.4% among non-diabetics and only by 17.1% among diabetics.²⁷

In our study, regular health education was imparted by 80% of physicians. 27% of physicians were prescribing two or more drugs to a new case of hypertension (Table 3).

Four to five of hypertension cases were referred to specialist care monthly during the last year. 48% of patients were referred because of their health condition, 24% believed that a specialist should treat hypertension, 22% were referred because of patient's request and patient's financial reason account for 4% of the referrals. Adedeji *et al.* found adherence to the ongoing care aspect was high for referral (78.6%), but adherence to discussion of review date was low (5.3%).²⁸

Selected Common Clinical Case Scenarios

The choice of anti-hypertensive treatment by the physicians in different scenarios, such as pregnancy, bronchial asthma, bilateral renal artery stenosis, diabetic nephropathy, old MI, sexual dysfunction, peripheral vascular disease, and gout, was evaluated in our study. The mean percentage of correct answers regarding both (drug to use and drug to avoid) was 55.3%. Similar results were found by Adedeji *et al.* in their study, which showed average adherence to drug/treatment review/adjustment to be 52.2%²⁸ and also by Ardery *et al.* who found 55.9% adherence.¹⁸

Most respondents 79.7% correctly chose ACE inhibitors as the drug of choice in patients with diabetic nephropathy and 28.8% correctly identified the drug to be avoided. Ernst, in his study, found that more than 80% of the participants prescribe ACE inhibitors to patients with diabetic nephropathy.²²

In our study, while treating a patient with old MI, 74.6% of the respondents correctly chose the drug to use and 22% identified the drug to be avoided. Ernst, in his study, found that only 62.5% of all respondents chose beta-blockers as the drug of choice.²²

The overall mean percentage, for selected clinical scenarios, of correctly prescribing a drug was 63% and drugs to be avoided was 47%.

CONCLUSION

Contrary to the earlier literature on non-adherence of PHCPs to disease management guidelines including hypertension management guidelines, our study observed that the majority of PHCPs adhere the JNC-7 guidelines for hypertension in Aljouf region of Saudi Arabia. The only concern being a lack of knowledge regarding integrated management of hypertension in patients with the co-morbid condition. The survey suggested that overall adherence of PHCPs to JNC-7 guidelines was fairly good (80%); future training of PHCPs should focus on integrated management of hypertensive patients with the co-morbid condition.

LIMITATIONS

The study focuses only on adherence of PHCPs to hypertension management guidelines; however, the aspect of patient's compliance evidenced by the proportion of hypertensive cases with adequate control remains to be seen.

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Epidemiological Study of Head Injuries in Andhra Medical College, King George Hospital, Visakhapatnam

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Abstract

Background: Traumatic brain injuries has become a silent epidemic with the rapid economic, demographic, and social transformation in India in recent decades. So, a study was performed in Department of Neurosurgery, King George Hospital (KGH)/Andhra Medical College, Visakhapatnam, a city which is well-developed port city with major public and private sector heavy industries and a rapidly developing IT hub in divided Andhra Pradesh.

Materials and Methods: Study included all patients with head injury attending KGH casualty and admitted to the Neurosurgery Department with a history of trauma for the duration of 1-year from January to December 2014. Data were collected from the medical records of the study included patients in terms of the clinical history and examination, demographic variables of the patients, time of injury, type of trauma, cause and mode, associated injuries, etc., are evaluated.

Results: 753 eligible patients were included in the study and their medical records are analyzed. Road traffic accident was the most common cause of injury (72.77%). The mean age of the study population was 39.81 years (with range <1-85 years). Most of the patients affected were of the age group 21-40 years age group (39.57%), with a male predominance of 614 (81.56%) patients and more than half of the bulk were rural population (56.7%). The most common victims of trauma were skilled and unskilled labourers (34.13%). Two wheeler was the most common vehicle involved (33.53%), in road traffic injury cases. The majority of injuries occurred between 6 in the evening and 12 in midnight (39.17%).

Conclusion: The burden of traumatic brain injury in developing countries like India is increasing, and this study will help in understanding the etiology and patterns of injuries.

Key words: Head injury, Road traffic accidents, Traumatic brain injury, Trauma registry

INTRODUCTION

Trauma remains one of the leading causes of death and disability in both developed and developing countries and is the third most common cause of mortality in India.¹ Traumatic injury is evolving as a major epidemic, one among the triple epidemic namely communicable, non-

communicable diseases and injuries, is now regarded as an important public health problem in India.² Traumatic brain injury (TBI) constitutes to the high morbidity and mortality among the traumatic injuries.³ In the natural history of trauma, the interaction of the agent, the host, and the environment results in an injury or damage. Injuries caused 10% of the total deaths worldwide and 13-18% in India.² Among the total disability-adjusted life-years, 15% were due to injuries.² Road traffic injuries are the leading cause of death worldwide in people aged <30 years.¹ The mortality and financial burden caused by the disability resulting from this spectrum of injuries are largely preventable. However, the development of effective injury prevention efforts depends on reliable and detailed information on the incidence and pattern of injury. Such information is

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under reported and incomplete in developing countries like India, whereas a national wide computerized vital statistics registers and health care records are available in developed countries. This study was conducted to understand the demographic and epidemiological pattern of injuries. Data from this study, along with other similar studies, helps in making policy and planning of trauma program.

MATERIALS AND METHODS

The present study was conducted in Department of Neurosurgery, King George Hospital, Visakhapatnam during the period of January-December 2014. The study group consisted of a total of 753 head injury patients presenting to the casualty department and admitted in neurosurgery ward. The data were analyzed retrospectively from the medical records. Unknown patients were excluded from the study. Basic demographic characteristics: Age, sex, place of injury, time and date, mode of injury, the first aid providers, mode of transport to the hospital, alcoholic intoxication, Glasgow coma scale (GCS) score, severity of head injury (defined as mild [GCS - 13-15], moderate [GCS - 9-12] and severe [GCS - 3-8]), associated injuries, computed tomography results, type of management, surgical intervention or intensive care units care or conservative and Glasgow outcome scale score were recorded. In the case of road traffic injuries, type of vehicle involved and execution of safety measures at the time of the incident were recorded. The collected data are analyzed using Microsoft excel.

RESULTS

Out of the 44,732 total King George Hospital admissions, admissions due to TBI were 753 in the year of 2014. It accounts for 1.68% of the admissions, the annual incidence of TBI. The mean age of the study population was 39.81 years (with range <1-85 years). Most of the patients affected were of the age group 21-40 years age group (39.57%) (Figure 1), with male predominance of 614 (81.56%) patients with male to female ratio of 4.4:1. The highest incidence of cases were noted in the month of January to be 90 cases (11.95%) (Figure 2). The majority of the cases are from rural areas 421 cases (56.7%) followed by urban 258 cases (34.2%) and border districts of neighbour states like Odisha and Chattisgard, 74 (0.095%) who have to travel a long way through difficult transport all the way to Visakhapatnam. Illiterates constitute the major bulk 473 cases (62.86%). The most common victims of trauma were skilled and unskilled labourers (34.13%) followed by unemployed (23.5%) and business men (14.4%) (Figure 3). Married people were 74.7% among the head injury patients followed by unmarried 19.3% and widow 0.02%.

The incidence of injury with respect to the time of occurrence in a day has shown a maximum number of incidents occur between 6.00 pm and 12.00 midnight of 295 (39.17%), followed by 12 noon to 6 pm having 213 cases (28.28%) (Table 1). The incidence of trauma with respect to the place suggests most injuries occur on roads about 448 cases (59.4%) followed by injuries at home

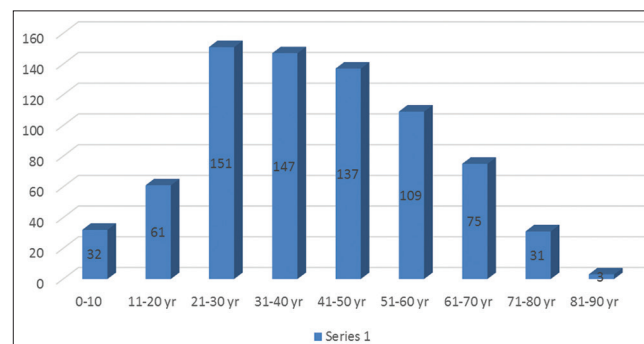


Figure 1: Age distribution

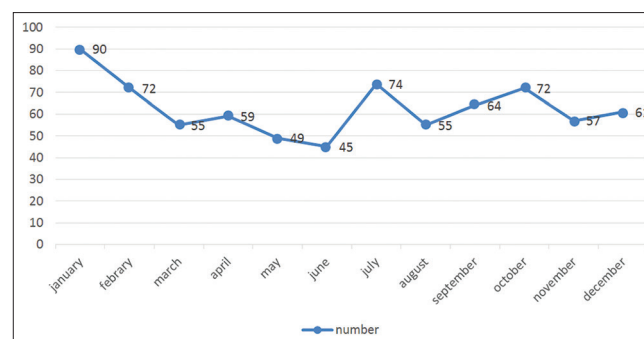


Figure 2: Distribution along month wise

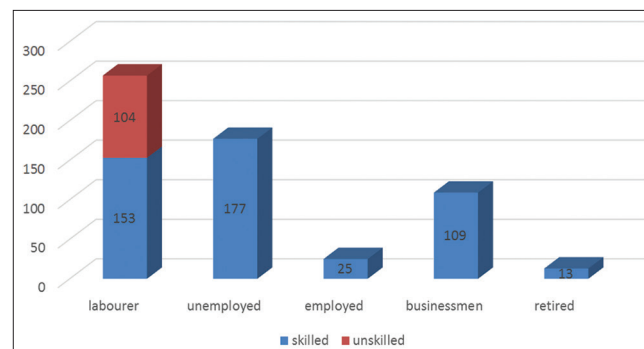


Figure 3: Profession of the patients

Table 1: Incidence of trauma with respect to time of the day

Time	Number	Percentage
06:00-12:00	118	15.67
12:00-18:00	213	28.28
18:00-00:00	295	39.14
00:00-06:00	137	18.19
Total	753	100

231 cases (30.6%), and then workplace showing 52 cases (6.9%) (Figure 4).

The most common mechanism of head injury was road traffic accidents (RTA) 548 cases (72.77%) followed by falls 73 cases (22.9%) (Figure 5). Accidents occurred under the alcoholic influence constitute to 126 cases (16.69%).

Out of 548 cases of RTA, two wheeler is the most common vehicle involved 396 cases (52.58%) followed by pedestrians (hit and run) cases 58 (7.7%), 4 wheeler 55 cases (7.3%), and 3 wheeler auto rikshaw 39 cases (5.1%) (Figure 6).

Almost none of the patients in our study were using any safety precaution like wearing a helmet or fastening seat belts while driving. Amongst the 396 cases of two wheeler injuries, only one was wearing a helmet at the time of accident. Similarly, none (55 cases of four wheeler accident victims) were on seatbelts at the time of accident. helmet, none was on seatbelts. From the site of injury, only 131 cases (17.3%) had transported by 108 ambulance service, rest were by private vehicle or ambulances.

The severity of the head injury of the patients at the time of arrival to the casualty was mild in majority 424 cases (56.3%) 13-15 GCS, followed by moderate (9-12 GCS) severity in 152 cases (20.18%), and severe in 177 cases (23.41%). Three cases were brought dead. Out of 753 case, 177 cases (23.77%) underwent emergency surgery while rest we managed conservatively (Table 2). 32 (4.2%) out of 753 cases had associated other organ injury. 156 cases (18.1%) needed ventilator support. The mortality rate was 21.1% (159 cases), most of them had a severe head injury. 69.7% (525) has a good outcome at the time of discharge (Table 3).

DISCUSSION

Changing and evolving trend of socio-economic factors especially in developing countries like India has made the injuries no more a hidden epidemic, but a major epidemic

Table 2: Diagnosis and mode of management

Diagnosis	Number	Operated	Conservative
Extra dural hemorrhage	98	43	55
Sub dural hemorrhage	118	59	59
Subarachnoid hemorrhage	69		69
Cerebral contusion/oedema	148	46	102
Depressed or compound skull fractures	27	27	
Non-depressed skull fractures	249		249
Intraventricular hemorrhage	2	2	
Diffuse axonal injury	42		42
Total	753	177 (23.5%)	576 (76.4%)

in par with other communicable and non-communicable disease epidemics. The need to implementation of safety protocols and the future progression of the injury burden was emphasized by WHO way back in 1990's, stating trauma will ascend the top 10 causes of disease burden from the ninth position to third by 2020 globally.⁴ With the implementation of the trauma protocols and safety measures lawfully, the epidemic wave has slowed in western developed countries, but the wave is exponentially growing

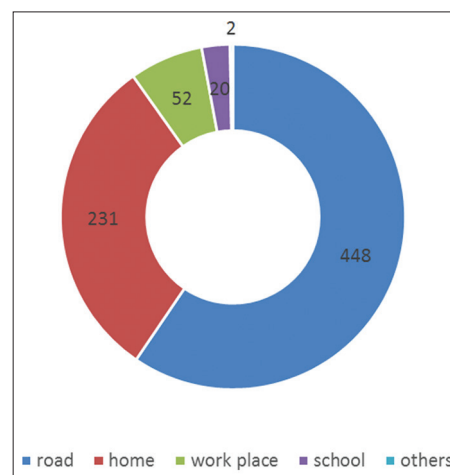


Figure 4: Incidence of trauma with respect to place of accident

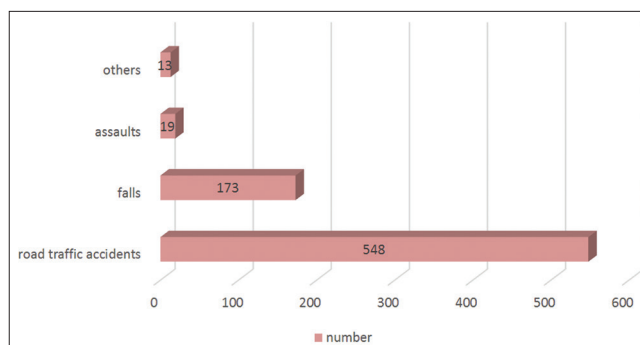


Figure 5: Incidence of trauma with respect to mode of injury

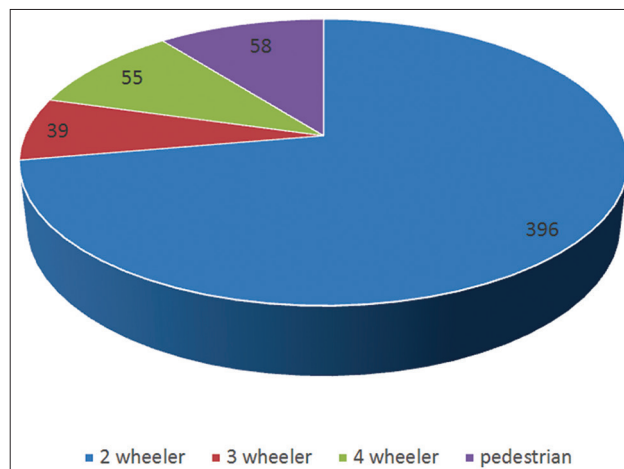


Figure 6: Type of vehicle in road traffic accidents

Table 3: Severity of injury and outcome scores

GCS	Total	Percentage	GCS				
			1	2	3	4	5
			Death	Persistent vegetative state	Severe disability	Moderate disability	Good recovery
Mild (13-15)	424	56.3	20	0	0	0	404
Moderate (9-12)	152	20.18	42	0	3	20	87
Severe (3-8)	177	23.41	97	11	13	22	34
Total	753		159	11	16	42	525
%			21.03	1.4	2.1	5.5	69.72

GCS: Glasgow outcome score

in developing countries. Implementation of protocols in India, which were proven worth full in developed countries are necessary for decreasing the burden of injuries, is the main challenge for public health to execute. The WHO has taken initiative formulated - The Global Plan for the Decade of Action for Road Safety 2011-2020, for this decade (http://www.who.int/roadsafety/decade_of_action/plan/en/).

In our study, 21-50 years age group (57.7%) are the major suffers which are similar to other studies.⁵⁻¹⁰ This is also the same age group who are breadwinning and bread earning members of the family, mortality, and morbidity of the same drives the family deeper into financial crisis and psychological stress especially in families belonging to the lower middle class and below the poverty line. It also leads to economic loss to the country indirectly. Most of the people are married 71% hence any disability or death consequent to trauma leaves an enormous emotional impact on the partner and family. 4.4 times male preponderance is observed as in many other studies.^{5,7} Men for the livelihood are away from homes in comparison to women who are usually housewives. The majority of the drivers or mechanics in the vehicles or machinery as a profession are men who increase the risk of accidents more in men.¹¹⁻¹³ The seasonal variation has shown higher incidence in winter season (January 11.95%), whereas bimodal or summer peaks are seen in other studies.¹⁴ This variation could probably due to the mist and fog commonly associated with these hilly areas which can precipitate injuries due to poor vision.¹⁵

Rural population are having a higher incidence of injuries as compared to urban. This could be due to poor safety precautions of road safety such as poor quality roads, improper sign boards, poor street lights, highways going through the residential rural villages, inadequate knowledge of safety precautions due to illiteracy, and even lack of health facility nearby makes them to travel a long way which delays treatment and can increase the severity of traumatic injury in the transit.^{5,10} Labourers are by far the people commonly encountered with trauma, 34% skilled

as well as unskilled. The peak incidence of occurrence of injuries with reference to diurnal variation has shown to occur between 6.00 pm and midnight. Many studies are correlating with this time.^{6,10} The reasons could be the dim twilight condition with a day-long work stress, tiredness and fatigue and subsequent decreased alertness and caution may lead to increased chance of injuries.^{16,17}

Maximum incidence of injuries in relation to place occurred on the road (59.4%) followed by at home (30.6%), and then 6% at workplace.^{18,19} The most common cause is correlating with the other studies, but second place was injuries at home. Lacunae in the safety protocols and precautions on roads more so outside the perimeter of city limits and highways. Compromise on road dimensions, quality and associated lack of footpaths all along the way, zebra crossings, speed breakers and widespread disregard of traffic rules results in high incidence of roads, and the innocent pedestrians are also paying for it. The most common mechanism of the mode of injury showed RTA as the most common cause of injury (46.85%) followed by fall and assault injuries; these are in concordance with several other studies.^{2,7,9,19,20} National wide statistics in 2014 projected 51 cases of road accidents occur in a span of an hour.²¹ With economic reforms and transformation from agro farming to industrialisation phase in India, increasing population growth, decreasing farming due to various causes, population migration to cities, rapid urbanisation, increased purchasing power of common man, poor public transport system, and rapid motorisation with poor road safety measures has resulted in increasing incidence of RTA.⁵ Fall injuries are the next most common mode attributing to fall from a tree or electrical poll or a terrace or from heights. People due to their profession like toddy collectors or electrical linemen or for collecting wood for cooking causes for fall from tress or polls. People flying kites on the terrace and sleeping on walls of the terrace at night are also causes.²² Two wheeler accidents are the most common type of vehicle involved in accident which reflects the main modality of transport in their respective province.^{5,17,23}

Accidents occurred under the alcoholic influence constitute to 126 cases (16.69%). Both in developed and developing countries, injuries and accidents occurring due to alcohol intoxication is known major factor and is preventable.² The alcoholic breath at the time on first assessment at emergency department delays the diagnosis and in further treatment like alcoholic withdrawal symptoms.²⁴ Only 1 out of 396 cases wore the helmet, none was on seatbelts. This pathetic situation is a reflection of the failure of the authorities in the strict implementation of the road safety measures though mandated by law and lack of public inquisitiveness and responsibility for their own safety, execution of which can dramatically reduce the incidence of TBI. Only in metropolitan cities of India, helmet and seat belt usage is being implemented and being governed by traffic police, rest of the places is of the concern.

The prehospital transport of the patients to the hospital is done by 108 ambulance services in only 17.3% of cases, rest were being done by private ambulances and vehicle. The services by 108 should be extended to most of the traumatic patients with the concept of "Trauma Care for ALL." 117 cases (23.5%) needed emergency craniotomy of burr hole evacuation rest were treated conservatively 32 (4.2%) out of 753 cases had associated other organ injury. 156 cases (18.1%) needed ventilator support the most common surgery was for cerebral contusions. The mortality rate is 21.17%; the bulk of the cases had severe head injuries with GCS <9 at the time of admission.¹⁹ The incidence death rate and morbidity of the injuries is to be reduced by a better-organized systems which include prevention, pre-hospital care, in hospital care, and rehabilitation. To achieve this goal holistic efforts are necessary from resource creation in terms of staff, equipment and funds for establishment and maintenance, awareness building up and education of the public right from the schooling level, legislation, planned and pre-programmed system for first aid provision at the scene of incident, and prehospital and hospital based care and up gradation of the existing centers at various zones within the reach of the people. The trauma care center like JPN Trauma Apex Center in AIIMS, New Delhi need not be established at all centers in India instead a cost effective and economical care centers without compromising the quality of services should be established. For doing so, adopting WHO Essential Trauma Care guidelines for trauma care, with necessary modulations in the Indian context, should be made operational. Compared to various other fields, progress in trauma care is still in a formative stage.^{25,26}

CONCLUSION

The lack of awareness among the pedestrians and disregard for traffic rules by the motorists were important reasons

for most of the accidents. Almost no use of helmets, though mandated by law, use of seat belts sparingly by the vehicle occupants, poor condition of roads, and increased social violence are recognised factors to which attention should be paid. All these aspects are preventable and need to be addressed. With the economic development, trauma care is reforming in India in the recent decade, with rapid industrialisation and motorization, the trauma care should also advance at a much faster rate to achieve the GOAL "Trauma Care for All". The present study is first of its kind to depict the epidemiology of head injuries in and around North Andhra, though a hospital based, multi centric population-based studies are needed for complete epidemiological data. Such similar studies from various regions helps in planning and formulating public health intervention policies and development of a trauma system national wide which is cost effective, at the same time providing universal emergency care which is accessible to all as a basic right.

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Scaler Tip Design and Root Surface Roughness: An *In Vitro* Study

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Abstract

Background: The most unfavorable alterations observed after instrumentation with ultrasonic scaler is root surface roughness. This study evaluates the influence of differently designed tips of ultrasonic scaler on root surfaces.

Materials and Methods: Both maxillary and mandibular premolars ($n = 20$), extracted for orthodontic purposes were used. Root surfaces were rinsed with water and stored in glutaraldehyde. Root planning was performed on the proximal root surfaces at the middle third. Three different tip designs (N1, N2, and N10X) were used. It was carried out on each sample in apicocoronal direction using 10 strokes at 0° angulation and with constant lateral pressure. After instrumentation, roughness was evaluated using 3D Optical Profilometer.

Results: The roughness produced after instrumentation was found to be consistent. The roughness produced with N10X was found to be highly significant in comparison to control, N1 and N2 ($P < 0.01$), while no difference was observed with N1 and N2 in comparison to the controls and in between them.

Conclusion: Roughness produced on the root surface after instrumentation is related to the surface area of ultrasonic tips and is inversely proportional.

Key words: 3D Optical profilometer, Glutaraldehyde, Mroot surface roughness, Root planning, Universal scaler tip

INTRODUCTION

The essential component of conventional periodontal therapy is the effective removal of plaque from the root surface, along with the calculus deposits, to create a biologically compatible root surface.¹ Mechanical debridement, i.e., scaling and root planning (SRP) is a fundamental part in periodontal treatment, and various instruments have been designed to achieve this goal.² Ultrasonic and sonic scalers and hand instruments are used for surgical and non-surgical periodontal therapy.

The use of ultrasonic and sonic scalers in periodontal therapy has been studied since the 1950s. These instruments have shown many advantages such as reduced instrumentation time spent per tooth and better accessibility in furcation defects.^{3,4} However, complete removal of subgingival calculus with hand or machine instruments is difficult to achieve, even when a surgical approach is used.⁵ To deal with this, recently, many tip designs for ultrasonic and sonic scalers have been modified to provide better access and instrumentation.^{6,7}

The ideal goal of periodontal instrumentation is to effectively remove plaque and calculus without causing root surface damage. Studies evaluating differences in root surface alterations due to hand, sonic, and ultrasonic instruments are inconclusive.^{8,9} Tooth substance removal by different ultrasonic devices has shown that magnetostriuctive unit is more aggressive than the piezoelectric device.¹⁰ Different surface alterations could be expected from different working tip designs since the tip geometry may significantly influence the displacement amplitude.¹¹

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Aims and Objectives

To evaluate the effects of different ultrasonic tip designs (N1, N2, and N10X) on root surface roughness post scaling.

MATERIALS AND METHODS

The present study was having two parts:

- Collection and preparation to the sample and,
- Visualization under profilometer.

The first part of the study was conducted in the Regional Dental College and Hospital, Guwahati and the second part in the Indian Institute of Technology, Guwahati.

Collection of Experimental Sample

20 mandibular and maxillary premolars extracted for orthodontic reasons were selected for this study. All teeth selected for the study were rinsed with running tap water for approximately 20 s to remove the surface debris or blood immediately after extraction. The teeth were then stored in 2% glutaraldehyde solution until use.

Tips used in this Study

Three different Piezo Electric Ultrasonic Scaler tips N1, N2, and N10X were used.

Selection Criteria

All teeth had to meet the following criteria:

Inclusion criteria

- Teeth extracted for orthodontic purpose
- Intact root surface
- Absence of caries
- No history of periodontal involvement
- Absence of gross hard and soft tissue debris
- Relatively flat surface.

Exclusion criteria

- Teeth with root concavities or convexities which impeded proper planning of root surfaces were excluded,
- Teeth extracted due to any other reasons other than orthodontic purpose.

Root planning was performed on the proximal root surfaces at the middle third. Three different tip designs (N1, N2, and N10X) were used. It was carried out on each sample in apicocoronal direction using 10 strokes at 0° angulation and with constant lateral pressure. After instrumentation, roughness was evaluated using 3D Optical Profilometer.

Mounting Procedure

After removal from the glutaraldehyde solution, the teeth were thoroughly washed with distilled water. Each tooth

was then mounted in a plastic tube filled with acrylic resin, which is of 2 cm in height keeping either of the two proximal surfaces exposed without any visible surface irregularities (Figure 1). An area approximately of 5 mm which is 2 mm apical to the cemento-enamel junction (CEJ) was selected for instrumentation. The samples were numbered from 1 to 20 and randomly divided into four groups as mentioned below:

- Group 1: Performed no instrumentation, regarded as control
- Group 2: Performed SRP using ultrasonic scaler tip N1
- Group 3: Performed SRP using ultrasonic scaler tip N2
- Group 4: Performed SRP using ultrasonic scaler tip N10X.

Root Scaling

Scaling was done by using piezoelectric ultrasonic scaler tips, i.e., N1, N2, and NX10 on the root surface of Groups 2, 3, and 4, respectively. 8-10 strokes in an apicocoronal direction with zero degree inclination between scaler tip and root surface of teeth was carried out by the same operator to avoid errors. Medium speed was used with water cooling according to the manufacturer's instructions (Figure 2).

Post Instrumentation Roughness Reading

The surface roughness after instrumentation was measured using non-contact based 3D Optical Profilometer (Talysurf 3D CCI Lite from Taylor Hobson, UK). 10 readings were made for each sample, from which mean was calculated. The surface roughness parameters used in this study are Ra and Rz. Ra is defined as the arithmetic mean of the absolute values of vertical deviation from the mean line through the profile. The mean line is the line such that the area between the profile and the mean line above the line is equal to that below the mean line. The Ra was calculated over the entire measured array and Rz is defined as ten points, i.e., the average absolute value of the five highest peak and the five lowest valleys over the evaluation length.

Statistical Analyses

The data collected were analyzed statistically. The following statistical methods were applied:

- Standard deviation
- Analysis of variance
- Duncan multiple range test.

RESULTS

The observation was carried out in 05 numbers of specimens in each category. The root surface roughness produced after instrumentation with tips N1, N2, and N10X was found to be consistent. The roughness

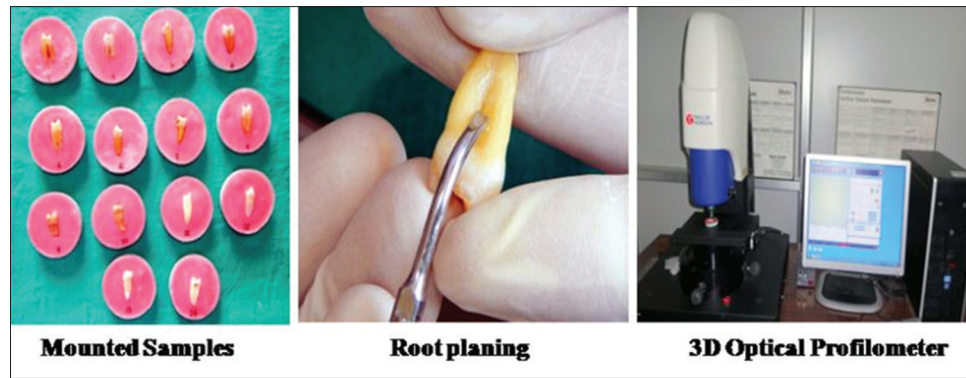


Figure 1: Mounted samples in a tube filled with acrylic resin, samples undergoing SRP and 3D Optical Profilometer used in the study

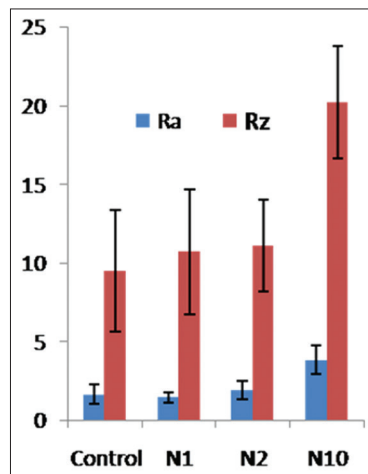


Figure 2: Mean roughness and extreme roughness values in different groups after instrumentation

produced with N10X was found to be highly significant in comparison to control, N1 and N2 ($P < 0.01$), while no difference was observed with N1 and N2 in comparison to the controls and in between them. Roughness values are measured as Ra and Rz; Ra is average of mean roughness and Rz is an average of extreme roughness values.

As shown in Table 1, the mean roughness value (R_a) was found to be the highest in Group 4 where SRP was performed using ultrasonic scaler tip N10X. The value was $3.82 \pm 0.90 \mu\text{m}$, which was followed by Groups 3 (SRP performed using ultrasonic scaler tip N2), Group 2 (SRP performed with ultrasonic scaler tip N1), and control (where no SRP was performed), the values being 1.91 ± 0.59 , 1.63 ± 0.64 , and $1.43 \pm 0.33 \mu\text{m}$, respectively. The lowest surface roughness was seen on the samples where SRP was not performed. These findings are graphically represented in Figure 2.

The mean roughness (R_a) observed in the various experimental groups were compared with the control group using parametric test (analysis of variance). While comparing with the control (Group 1), the roughness on

Table 1: Mean values of roughness and extreme roughness values with standard deviation in various groups

Group	R_a			R_z		
	Mean	SD	P value	Mean	SD	P value
Control	1.43	0.33		9.50	3.85	
N1	1.63	0.64	0.550	10.69	3.97	0.640
N2	1.91	0.59	0.480	11.10	2.93	0.470
N10X	3.82	0.90	0.002	20.20	3.54	0.001

SD: Standard deviation

the root surface in Group 4 was found to be statistically significant ($P < 0.05$).

Similar to the R_a mean of the extreme roughness values, referred to as R_z , was found to be the highest in Group 4, where SRP was performed using ultrasonic scaler tip N10X. It was $20.20 \pm 3.54 \mu\text{m}$. As shown in Table 1, R_z in Groups 1, 2, and 3 was 9.50 ± 3.85 , 10.69 ± 3.97 , and $11.10 \pm 2.93 \mu\text{m}$, respectively.

These findings are graphically represented in Figure 1. The lowest R_z was observed in group 1, where SRP was not performed. Though the differences in R_z are observed among the Groups 2, 3, and 4, Group 4 was significant statistically ($P > 0.05$) (Table 1).

When the root surface roughness in terms of R_a and R_z was compared and assessed, it is observed that a similar trend of roughness was followed, i.e., the control group was found to be the smoothest with least roughness values, which was followed by Groups 2, 3, and 4 (Table 1 and Figure 3).

From the above results, it appears that maximum root surface roughness is produced in the specimens where SRP was performed with ultrasonic scaler tip N10X (Group 4), whereas the smoothest surface was observed in the specimens where no SRP was done (Group 1). Thus, the present study suggests that roughness produced on the root surface after instrumentation with differently designed

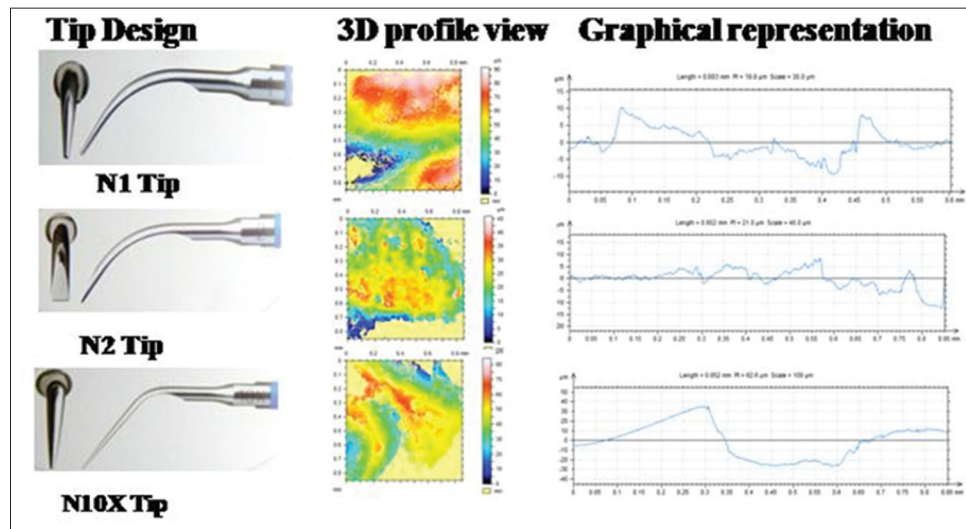


Figure 3: Tip design, with 3D profile view from Optical profilometer and graphical representation

ultrasonic tips is related to its surface area and is found to be inversely proportional.

Then, the surface appearance of one sample from each group was qualitatively assessed under 3D Optical Profilometer. The surface topography of the root surfaces was evaluated in the photographs obtained.

After instrumentation, difference in the surface topography was observed in each of the treated groups when compared to the control, untreated root surfaces. The instrumented surfaces showed surface gouges of varying depth and width along with cracks running in different directions.

Surfaces treated with the ultrasonic device varied greatly in appearance. As shown in Figure 2, the root surfaces after SRP conducted with different ultrasonic scaler tips showed multiple cracks running in various directions along with smooth surfaces in between. The smooth surface may indicate the loss of tooth substances. The variation on the root surfaces varied from relatively smooth to more irregular areas with gouges, fissures, and cracks of varying depths running in various directions over the area of instrumentation.

DISCUSSION

Ultrasonic scalers are becoming increasingly popular for subgingival debridement due to less strain for the operator and more comfort for the patients than hand instruments. It is easy to insert in narrow pockets than curettes.¹² In the present study, N1, N2, and N10X ultrasonic scaler tips were used for instrumentation. In the present study, we used 3D Optical Profilometer to find out the root surface changes after scaling. This instrument is the most sensitive device

to analyze changes in the surface roughness. Ra is the most universally used roughness parameter for general quality control; this is easy to define, easy to measure, and gives a good general description of height variations. Rz is more sensitive to occasional high peaks or deep valleys than Ra.¹³ According to the present study, the roughness reading showed that all treated groups presented a significant increase in roughness compared with the control group and demonstrated that the N10X ultrasonic tip caused increased roughness when compared to controls. Results were statistically significant with respect to Ra and Rz ($P < 0.05$) compared to the control group in Group 4 which was treated with an N10X type of tip.

Most of the studies have evaluated differences regarding the roughness produced by sonic, ultrasonic and hand instruments.¹⁴ However, the angulations and design of instrument tip, sharpness of the working edge, the length of time the instrument is in contact with the root, and the cumulative numbers of strokes have an impact on the degree of root damage. Teeth extracted for the orthodontic purpose were selected for this study because premolars are most commonly extracted for while this treatment and cementum are healthy. In the case of diseased teeth, the cementum will be softened, and tips may remove the cementum more aggressively and it may give false results.¹⁵

Furthermore, the Roughness Loss of Tooth Substance Index has been used by some studies, but the loss of tooth substance of a specific instrument cannot be directly correlated with its produced roughness, and a separate evaluation of tooth substance loss and surface roughness produced is necessary.^{7,14,16-18} Therefore, considering all these variables in previous studies, it is difficult to come to a conclusion regarding the method of instrumentation that causes the least amount of root surface alterations.

Numerous studies have demonstrated that the most important prerequisite for healing after periodontal treatment is a root surface free of plaque and calculus. Quirynen and Bollen (1995) have clarified that supragingival rough surfaces subsequent to professional instrumentation can promote plaque formation and contribute to bacterial adhesion.¹⁹ Supragingival surface roughness and surface irregularities increase the surface area, promoting bacterial colonization, plaque formation and thereby compromising daily plaque removal.^{20,21}

Leknes *et al.*, (1996) demonstrated that roughness resulting from subgingival instrumentation significantly influenced the subgingival microbial colonization.²² Then, a smooth root surface may be advantageous near the gingival margin since a smooth surface is less likely to accumulate plaque than a rough surface.

Japsen *et al.*, (2004) did a similar study by using magnetostriptive and piezoelectric ultrasonic tips on the root surface, and concluded that significant increase in the aggressiveness to root dentin was seen for wide scaler tips as compared to narrow scaler tips. In contrast to that study, this study found root surface roughness is more aggressive by thinner scaler tip design than broader tip design.

Therefore, for clinical application, it can be assumed that a meticulous SRP procedure during initial cause-related therapy should be performed, and the long-term success of this treatment is dependent on the quality of the maintenance therapy.^{18,23} It is important that caution should be taken while utilizing these instruments and that a higher standard of supragingival oral hygiene may be required for such patients. More studies are needed to clarify the influence of different ultrasonic tip design on the root surface roughness.

In the present study, differences in surface roughness have been found among different types of ultrasonic scaler tips, although it remains to be determined whether these differences are of clinical significance. To understand the issue of roughness created after debridement and the success of periodontal treatment, different aspects have to be distinguished: Supragingival or subgingival roughness and supragingival plaque control during healing.

Concerning subgingival roughness, some studies demonstrated that changes over subgingival root topography did not interfere with the response to periodontal treatment.²⁴ Rosenberg and Ash (1974) did not find that the different instruments had a significant effect on histologically assessed healing.⁹ Khatiblou and Ghodossi (1983) have reported that periodontal healing following flap surgery occurs regardless of whether the

subgingival root surface is rough or smooth.²⁵ These results were confirmed by Oberholzer and Rateitschak (1996), who have found no difference in pocket reduction and clinical attachment gain after creating rough or smooth surfaces during a flap operation.²⁶ This indicates that subgingival roughness does not interfere with healing if there is a good supragingival plaque control. In an animal experiment, subgingival roughness following surgery, without supragingival plaque control during healing, favored plaque retention and colonization.²⁷ Leknes *et al.* (1996) demonstrated that roughness resulting from subgingival instrumentation significantly influenced the subgingival microbial colonization.²² Then, a smooth root surface may be advantageous near the gingival margin since a smooth surface is less likely to accumulate plaque than a rough surface.

CONCLUSION

In this study, root surface roughness was measured after scaling with N1, N2, and N10X scaler tips using a 3D Optical Profilometer. Within the limits of the present study, it can be concluded that large surface universal ultrasonic tips produce a more rough surface on the root surface than a thin probe type of tip. It means roughness on the root surface is inversely proportional to the surface area of the scaler tips.

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Bony Healing Following Filling of Post Cystectomy Jaw Bone Defects with Hydroxyapatite and Beta-Tricalcium Phosphate and its Comparison with Non-Filling Case: A Clinical Study

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Abstract

Introduction: Jaw cysts are common findings in day-to-day maxillofacial practice. Enucleation has been traditionally the gold standard of treatment of cysts in maxillofacial region. Recently, several bone substitutes have been used to fill post cystectomy defects with varying degrees of success.

Aims and Objective: This study was undertaken to assess bone healing in post cystectomy defects with or without a bone substitute (hydroxyapatite (HA) or β tricalcium phosphates [TCP]).

Materials and Methods: The study was undertaken on patients with cystic lesions (<5 cm) of maxillofacial regions. The following enucleation, the patients were randomly divided into three groups. In Group 1 ($n = 10$) and Group 2 ($n = 10$), the post cystectomy defect was filled with β -TCP and HA, respectively. Group 3 ($n = 10$) patients underwent primary closure without any bone graft. Patient's pre-operative and post-operative clinical and radiological findings were recorded and subjected to statistical analysis.

Results: The cysts were a more common in the 3rd and 4th decade of life. Males were more common involved than females. The maxilla was the most common site involved. Radicular cysts were present in the majority of patients. There was no statistical difference in healing between the three groups compared.

Conclusion: The present study revealed that spontaneous regeneration of bone occurs in post cystectomy defects with or without the use of filling material.

Key words: Cystectomy, Hydroxyapatite, Jaw cysts, Tricalcium phosphate

INTRODUCTION

Odontogenic cysts are the most common osseous lesions encountered in routine oral and maxillofacial surgical practice. Treatment of mandibular cysts depends on site, size, number, etiology, pathology, soft tissue involvement,

and history of previous treatment.¹ The ideal treatment of these lesions consists of enucleation of the cysts followed by primary closure, which has been described by Partsch as "Cystectomy" (Parts II) in 1910.² The following cystectomy in small cysts spontaneous regeneration of bone occurs in the majority of cases and results in filling of the residual cavity.³ However, some controversy still exists regarding the treatment of large cysts (>4 cm) with cystectomy alone. One-stage cystectomy of large cysts with primary closure of the resultant bone defect predisposes to complications like infection and pathological fracture. To overcome these potential complications and to accelerate the bony healing, numerous bony graft have been used with varying rate of success.⁴⁻⁶

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Autogenous bone has osteoconductive and osteoinductive properties and contains a source of osteoprogenitor cells. Therefore, its transplantation is still the gold standard. However, autogenous bone grafting is often related to disadvantages like limited availability and donor site morbidity, a possible hospitalization, and the need for general anesthesia.^{7,8}

To overcome these problems, large no. of synthetic grafting materials are currently being tried for defect filling after cystectomy. Available synthetic materials include bioactive glasses, glass ionomers, aluminum oxide, calcium sulfate, calcium phosphates, α and β -tricalcium phosphate (TCP), and synthetic hydroxyapatite (HA).⁹ The idea of using these osteoconductive materials is to stabilize the blood clot in the defect avoiding infections and to advance bone regeneration by enhancing the migration of osteoprogenitor cells.¹⁰

Since the 1980s, calcium phosphate ceramics has been used as bone substitute materials because of their non-antigenicity and biocompatibility.^{7,11} TCPs are bone substitute materials that are marked out by their high biocompatibility, favorable resorption properties and osteoconductivity.^{12,13}

HA is known as a slowly biodegradable material with high osteocompatibility and bone binding capability, and its resorption rate is relatively slow compared with the rate of new bone formation.^{11,14} Both these materials have been extensively studied and encouraging results obtained for filling of osseous defects. The main disadvantages of these materials in clinical settings may be low or unpredictable resorption and occasional inflammatory foreign body reactions.^{15,16}

The purpose of this study was to investigate the bony healing following filling of post cystectomy defect with HA (Figure 1) and β -TCP (Figure 1) and to compare the results with non-filling cases.

MATERIALS AND METHODS

This study was conducted on 30 patients ($n = 30$) in the Department of Oral and Maxillofacial Surgery, Buddha Institute of Dental Sciences and Hospital, Patna between 2012 and 2014. Patients with cystic lesions confined within the cortical margins of maxilla and mandible and <5 cm in diameter were included in the study. Lesions involving vital structures like floor of the nasal cavity, maxillary sinus, or inferior alveolar nerve were excluded from the study. Large bony lesions (>5 cm) or lesions eroding the cortical plate with periosteum and spreading to adjacent soft tissues were also excluded from the study.



Figure 1: β -tricalcium phosphates used in study



Figure 2: Hydroxyapatite used in the study

Surgical Technique

The patients were treated with standardized technique under local anesthesia. After elevation of a mucoperiosteal flap, decortication was done to expose the cystic lining. The cystic lining was then enucleated. Care was taken to protect adjacent vital structures. The following enucleation, the patients were randomly divided into three groups:

Group 1 ($n = 10$): The post cystectomy defect was filled with β -TCP

Group 2 ($n = 10$): The post cystectomy defect was filled with HA

Group 3 ($n = 10$): The post cystectomy was primarily closed. No bone graft/substitute was used.

Patient's clinical and radiological findings were recorded preoperatively, immediate post-operative period and 6-month postoperatively in a proforma which was then statistically analyzed.

RESULTS

Table 1 and Figure 3 show the age group and gender distribution of patients in our study. Majority of the patients were middle-aged group (30-45 years). The male:female ratio was 3:2.

Table 2 shows the pre-operative clinical findings. The main complaint was swelling (66.66%) followed by pain (60%).

Figure 4 shows distribution of cyst by anatomic site involved.

Table 3 shows the radiological findings on orthopantomogram and intraoral periapical X-ray. Bone loss was seen in all cases followed by bony expansion.

Tables 4-6 show the comparison between size of cystic cavity preoperatively and postoperatively in Group 1, Group 2 and Group 3, respectively. In all the three groups

the cystic cavity showed statistically significant decrease in size in the 6-month post-operative period.

Figure 5 shows the histopathological findings of the enucleated cyst. Majority of the cysts were radicular cysts (73%).

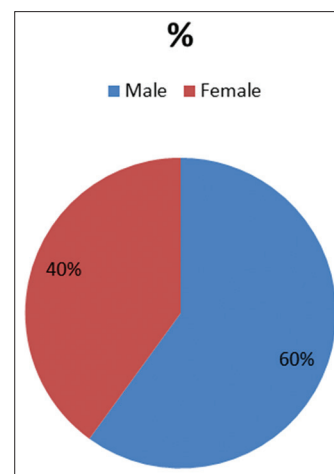


Figure 3: Gender distribution

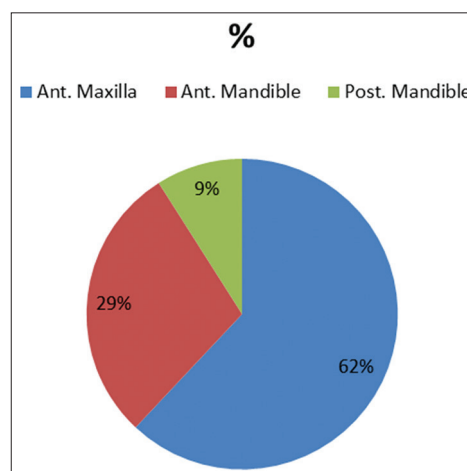


Figure 4: Anatomic site involved

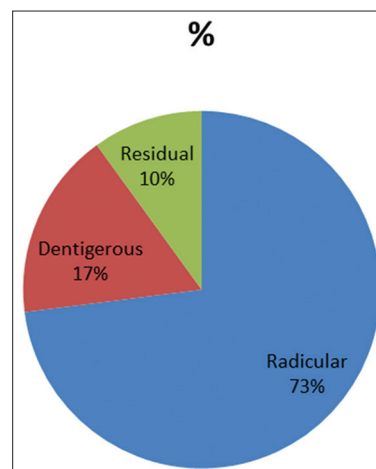


Figure 5: Histopathological findings

Table 1: Age wise sample distribution

Age (years)	n (%)
0-15	4 (13.33)
15-30	10 (33.33)
30-45	13 (43.33)
>45	3 (10)

Table 2: Pre-operative clinical examination

Pre-operative clinical examination (n=30)	n (%)
Pain	
Present	18 (60)
Absent	12 (40)
Swelling	
Present	20 (66.66)
Absent	10 (33.37)
Pus discharge	
Present	15 (50)
Absent	15 (50)
Bony expansion	
Present	11 (36.66)
Absent	19 (63.37)
Mobility of tooth	
Present	6 (25)
Absent	24 (75)
Displacement of tooth	
Present	2 (6.66)
Absent	28 (93.33)

Table 3: Radiological findings

Pre-operative radiological examination (n=30)	n (%)
Bone loss	30 (100)
Bony expansion	11 (36.66)
Root resorption	08 (26.67)
Displacement of the root	05 (16.67)
Impacted wisdom tooth	03 (10)

Table 4: Comparison of cyst size between pre-operative and post-operative follow up at 1st month, 2nd month and 6th month of Group I

Pre-operative	Mean±SD	Post-operative follow up	Mean±SD	P value
1 st day	2.720±3.639	1 st month	1.316±2.093	NS
		2 nd month	1.316±2.093	NS
		6 th month	0.3200±0.593	P<0.01
P value		P<0.01		

SD: Standard deviation, NS: Nonsignificant

Table 5: Comparison of cyst size between pre-operative and post-operative follow-up at 1st month, 2nd month and 6th month of Group II

Pre-operative	Mean±SD	Post-operative follow-up	Mean±SD	P value
1 st day	3.600±0.894	1 st month	1.20±0.737	NS
		2 nd month	1.20±0.737	NS
		6 th month	0.100±0.137	P<0.01
P value		P<0.01		

SD: Standard deviation, NS: Nonsignificant

Table 6: Comparison of cyst size between pre-operative and post-operative follow-up at 1st month, 2nd month and 6th month of Group III

Pre-operative	Mean±SD	Post-operative follow-up	Mean±SD	P value
1 st day	4.150±2.001	1 st month	2.080±1.524	NS
		2 nd month	2.080±1.524	NS
		6 th month	1.020±1.126	P<0.01
P value		P<0.01		

SD: Standard deviation, NS: Nonsignificant

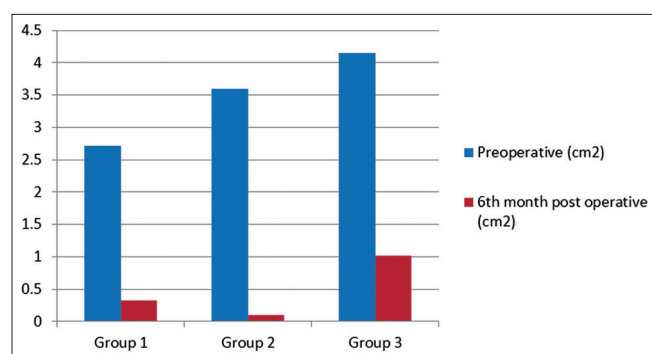
**Figure 6: Comparison of cyst size between Group I, Group II and Group III pre-operative and post-operative follow-up the 6th month**

Figure 6 shows the comparison between the three groups with respect to decrease in cystic size 6 months postoperatively. The results were not significant.

DISCUSSION

Odontogenic cysts account for 7-13% of the lesions diagnosed in the oral cavity.^{17,18} In our study, males were a

more common involved than female and the most common involved age group was middle-aged group (30-450). The radicular cyst was the most common cystic lesion followed by dentigerous cyst. These results are similar to those reported in literature.¹⁸⁻²⁰ The maxilla was the most common involved site (62%) in our study.

Up to date, several studies have reported safe and regular bone healing after enucleation and simple closure of jaw cysts without using bone grafts even in cases of large defects. The complication rate for cyst enucleation, primary closure and peri-operative antibiotic treatment seems to be <5%, even in defects measuring far more than 3 cm.²¹

Chiapasco *et al.* evaluated the spontaneous bone healing after enucleation of a large mandibular (>40 mm) cysts subjectively and with a computer analysis of post-operative panoramic radiographs. They concluded that spontaneous bone regeneration can occur in large mandibular cysts without the aid of any filling materials. Besides, simple cystectomy simplifies the surgical procedure, decreases the economic and biologic costs, and reduces the risk of postoperative complications.²² There are numerous other studies that support the above findings.^{23,24}

The role of HA specially nanoparticulate HA, Ostim has been extensively studied. Bezrukov *et al.* reported the use of lincomycin with ultra-highly dispersed HA (33% OSTIM-100 paste), for filling the bone cavity formed after cystectomy in 49 patients and compared with non-filling cases. They reported that the above preparations decreased the incidence of post-operative complications and created the optimal conditions for bone repair at the site of defects of different size. They concluded that ultra-highly dispersed HA, a biochemically active form of HA, stimulates the repair osteogenesis at the early stages.²⁵ Similar encouraging results with HA have been reported in other studies also.^{26,27}

TCPs are bone substitute materials that are marked out by their high biocompatibility, favorable resorption properties, and osteoconductivity.¹² Horch *et al.* studied the long-term effect of the ceramic β -TCP at different sites of alveolar reconstruction and to evaluate its properties. They found that because of its versatility, low complication rate, and good long-term results, synthetic, pure-phase β -TCP was a suitable material for the filling of bone defects in the alveolar region.²⁸

Palm *et al.* assessed the capacity of β -TCP to stimulate the reossification of 64 defects that resulted from cystectomy in 63 patients. They reported satisfactory healing even in larger defects <2.5 cm.²⁹ Other studies have also reported good success rate with β -TCP.^{30,31}

In our study, post cystectomy defect healing was good in all the three groups, and the results were statistically significant. In comparison of groups with respect to decrease in cyst size, the results were statistically not significant.

Ettl *et al.* reviewed various studies using autogenous, allogenic, xenogenic, and alloplastic bone grafts and compared the results with conservative cyst enucleation without using any filling materials. They concluded that enucleation of jaw cysts the so-called “cystectomy” and primary closure without the use of additional bone grafts represents the “state of the art,” even in large defects of 3 cm and more in diameter.²¹

CONCLUSION

The present study revealed that spontaneous regeneration of bone occurs in post cystectomy defects with or without the use of filling material. We did note any addition advantage with the use of bone substitute. However, our study was limited by small sample size. In future, similar studies with large sample size should be undertaken to arrive at a more definitive conclusion.

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Giant Cell Tumor of Tendon Sheath: Clinicopathological Correlation

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Abstract

Background: Giant cell tumor, excluding its prototype in bone, is usually a benign but local aggressive neoplasm originating from tendon sheath or soft tissue. Malignant behavior is uncommon. Giant cell tumor of tendon sheath (GCTTS) usually originates from the membrane of tendon sheath, bursa, and joints.

Materials and Methods: All the cases of GCTTS received in Pathology Department within the duration of 5-year are reviewed for a macroscopic and microscopic picture in detail. The clinical finding regarding age, gender, tumor location, presentation and size, clinical features, and treatment modality were collected from the medical record.

Result: Of the soft tissue lesion, GCTTS were seen in 15 cases and reviewed in detail. The most common age for GCTTS was ranged from 20 to 40 years. The index finger was the most common site for giant cell tumors. On macroscopy, most of the tumors were mainly well-circumscribed, encapsulated. Microscopy shows mononuclear infiltration, macrophages, and osteoclasts such as giant cells and collagen strands. Recurrence was seen in two cases only.

Conclusion: Giant cell tumors are whether non-neoplastic or neoplastic are still controversial and need further study. A definite pre-operative diagnosis by fine-needle aspiration cytology in collaboration with radiological findings will help in proper treatment planning. All the histopathological slides must carefully look for satellite nodule, cell types, and mitotic activity to avoid recurrence.

Key words: Giant cell, multinucleated cell, thumb

INTRODUCTION

Giant cell tumor of soft tissue is very rare. Giant cell tumor of the tendon sheath (GCTTS) also called by the name of fibrous histiocytoma of synovium, pigmented nodular synovitis, tenosynovial giant cell tumor, localized nodular synovitis, benign synovioma, and fibrous xanthoma of synovium. Each of which exhibits a particular pathological feature.¹

GCTTS is a gradually developing painless soft tissue tumor is the second most common tumors of the hand, with simple ganglion cysts being the most common.^{2,3}

It can also occur in the other part of the body such as spine, ankle and knee, and feet.⁴ According to World Health Organization, 10 synovial or synovial giant cell tumors are of two types localized and diffuse form.⁵ The common localized type (giant cell tumor of synovium) is encapsulated, extra-articular, and commonly found in the tendon sheath of the fingers, whereas the rare diffuse type is non-encapsulated, intra-articular, and commonly found in the joint, considered as the soft tissue counterpart of diffuse pigmented villonodular synovitis. Pathological nature of this disease is still controversial as neoplastic or non-neoplastic.⁶ This because of the fact that recurrence rate in GCTS is reported in 45% cases.⁷ Trauma, inflammation, metabolic disease, and neoplastic etiology are considered etiological factor. Reactive and regenerative hyperplasia in GCTS is associated with an inflammatory process.⁸ The tumor is composed of oval, plump histiocytes, hemosiderin laden macrophage, multinucleated giant cell and collagen strands, and synovial hyperplasia.⁹ Histochemical evidence shows that the mononuclear cells and giant cells present

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in these lesions resemble osteoclast.¹⁰ Polymerase chain reaction assays have shown that GCTTS are polyclonal proliferations suggests that these masses are non-neoplastic proliferation. The common age for the tumor is between 30 and 50 years and is found more in women than in the men.¹¹ It is uncommonly occur in children. GCTTS are associated with the degenerative joint disease. The present study is comprised of clinicopathological features of GCTTS received in the Pathology Department.

MATERIALS AND METHODS

A retrospective study was conducted in the Department of Pathology, and all data were collected from medical records including the age, gender, tumor location, presentation and size, clinical features, and treatment modality.

All the specimen was received in 10% formalin. Routine tissue processing was performed on the tissue to prepare paraffin block. The histopathological slide was prepared and stained with hematoxylin and eosin stain. Sections were further examined under the microscope.

RESULTS

Of all the non-neoplastic lesions ($n = 116$) of soft tissue received in the department, the GCTTS were present in 15 cases (12.93%).

Of the 15 GCTTS, 10 (66.67%) were female and 5 (33.33%) were male. Female to male ratio is 2:1. The age ranges from 12 to 60 years. The most common location is index finger six cases (40%), in thumb four cases (26.67%), ring finger two (13.33%), metacarpal, wrist, knee one case (6.67%) each. Most of swelling was painless, and two patients presented with painful swelling. Duration ranges from 1 to 10 years. Radiographs were abnormal in two patients (Table 1).

Macroscopic

The average mean size of tumors was 3.5 cm. All the lesions were described as a well-circumscribed, capsulated, lobulated or multinodular mass, soft to firm in consistency.

Table 1: Anatomic distribution of GCTTS ($n=15$)

Location	n (%)
Index finger	6 (40.00)
Thumb	4 (26.67)
Ring finger	2 (13.33)
Metacarpal	1 (6.67)
Wrist	1 (6.67)
Knee	1 (6.67)

GCTTS: Giant cell tumor of tendon sheath

External surface was smooth (Figure 1). On a cutting cut, the surface was homogenous in 13 cases. Two cases show hemorrhage and necrosis (Figure 2).

Microscopic

Microscopy examination was characterized by the accumulation of histiocytes and presence of a multinucleated giant cell, fibrohistiocytic proliferation, hemosiderin laden macrophages, and collagen strands. Synovial cell hyperplasia seen in two cases only. No mitotic activity was reported. In follow-up, recurrence was seen in two cases only (Figures 3 and 4).

DISCUSSION

Histologically GCTTS is composed of multinucleated giant cells, polyhedral histiocytes, fibrous material, and hemosiderin deposits.^{12,13} Cellularity and mitosis does not seem to affect the prognosis of cancer.¹⁴ The neoplastic cells are accounting for 2-16% of the cell with the tumor.



Figure 1: Circumscribed, multinodular, smooth external surface of giant cell tumor of tendon sheath on gross



Figure 2: Multiple hemorrhagic areas on cut surface of giant cell tumor of tendon sheath on gross

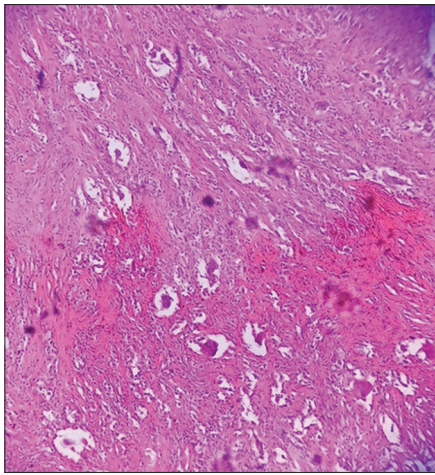


Figure 3: Giant cell tumor of tendon sheath showing multinucleated giant cell, hemosiderin macrophages, collagen strands (H and E, $\times 10$)

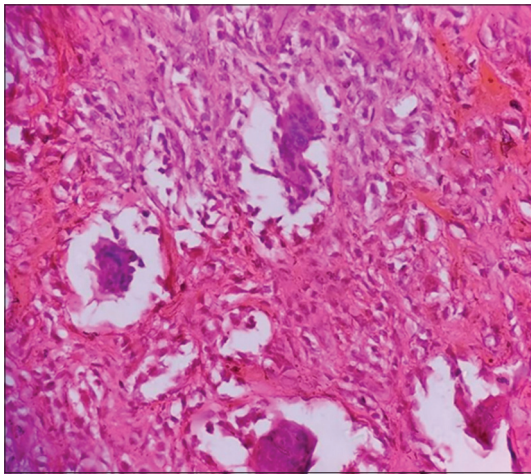


Figure 4: Giant cell tumor of tendon sheath showing mononuclear inflammation, fibrohistiocytic proliferation, and multinucleated giant cell (H and E, $\times 40$)

Jaffe *et al.*, in their study, describe GCTTS as tenosynovitis, a non-neoplastic reaction. Cytokines/hematopoietic growth factor as macrophages colony-stimulating factor (CSF1) plays an important role in the proliferation, differentiation and survival of monocytes, macrophages, and related cells. It is localized to the 1p13 breakpoint and appears to have a major oncogenic role in GCTT.¹⁵ Most of the cells are non-neoplastic, inflammatory cells recruited and activated by CSF1 produced by neoplastic cells, called as landscaping. CSF1 is a Group II receptor tyrosine kinase that shows structural homology with KIT.¹⁶

We found that age, gender, size and presenting symptoms their duration were similar with other studies. Fotiadis *et al.*, in their study, describe that GCTTS are affected more often women, with male to female ratio 1:147 and the mean age ranged from 30 to 50 years.³ In our study, the male to female ratio was 2:1. The findings of our study concurred with

the previous study except in two cases. In our study, two cases presented with 10 and 15 years. Siribumrungwong *et al.* presented a GCTTS in a 7-year-old girl in a facet joint of the thoracic spine.^{17,18} GCTTS are usually painless but when GCTTS affects other sites, it is painful.² Painless swelling of tendon sheath are reported in 84.3%, and sensory disturbances of the digits are recorded in 4.57%.¹⁹ In our case, the pain was present in two, which affect the wrist and knee, respectively.

Di Grazia *et al.*, in their study, observed the most frequent location of the tumor in the long finger (23.5%), followed by the thumb in (20.3%), index finger (20.3%), ring finger in 7.8%, and little finger 7.8%.²⁰ Fotiadis *et al.* and Briët *et al.*, in their study, found the most common location of the tumor is in index finger (29.7%) and 30%, respectively.^{3,21} The findings of our study concurred with the previous study. Radiograph plays an important role in establishing the treatment approach to the tumor. A radiograph was normal in all except two of all GCTTS. Ultrasound can be used as the first method to diagnose GCTTS and to obtain the information regarding tumor vascularity, tumor size and its relationship with the surrounding tissue.²² Fine-needle aspiration is helpful to make the tissue diagnosis pre-operatively.²³

Subcutaneous location of GCTTS from the tendon sheath and its deeper extension to neurovascular bundle makes difficulty in proper excision of the lesions. So that it could be the reason for a high recurrence rate of GCTTS.²⁴ In our study, the recurrence was seen in only two cases (13.33%). The high recurrence rate can depend on proximity to arthritic joint, proximity to distal interphalangeal joint of thumb, and radiological osseous erosion, to types of cells, to mitotic activity, capsular invasion, and incomplete excision.^{25,26}

Research is going on to find out the nature of GCTTS that whether the GCTTS is neoplastic²⁷ or non-neoplastic,⁸ its morphological and ultrastructure features,²⁸ its relation with pigmented villonodular synovitis, fibroma, and giant cell lesion of the bone.^{29,30} Many immunohistochemistry studies have been carried out to through light in the nature of the lesion.^{10,31} Fine-needle aspiration cytology (FNAC) is very useful in pre-operative diagnosis and help in pre-operative planning to prevent recurrence.³²

CONCLUSION

Giant cell tumor is whether non-neoplastic or neoplastic are still controversial and need further study. A definite pre-operative diagnosis by FNAC in collaboration with radiological findings will help in proper treatment planning.

All the histopathological slides must carefully look for satellite nodule, cell types, and mitotic activity to avoid the recurrence.

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Fine-Needle Aspiration Cytology of the Palpable Breast Lump of 106 Cases and Correlation with Histologic Diagnosis: A Prospective Analysis

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Abstract

Aim: Benign as well as breast lesions are quite common in the Indian population. It is the second most common cancer after cancer cervix. Fine-needle aspiration (FNA) provides rapid, accurate diagnosis, serve a cost-effective triage role in the treatment of breast masses and provide psychologic relief of anxiety for a patient with benign breast lesion. To study the frequency of various breast lesions on FNA in a tertiary care center and its histopathological correlation.

Materials and Methods: This was 1-year prospective study carried out from August 2014 to July 2015. Physical examination of breast masses by palpation was done. Smears were stained with hematoxylin and eosin stain.

Results: Of the 106 cases, 54 were in the benign category and 52 were in the malignant category. On the histological correlation of 54 cytological benign cases, 52 were confirmed as benign breast lesion while 2 turned out to be malignant. Similarly, 52 cytological malignant cases, 50 were confirmed as malignant but 2 turned out to be benign. FNA was 96.15% sensitive, 96.29% specific in diagnosing malignant lesions.

Conclusion: The diagnostic accuracy of cytology and mammography is consistently correlated with the histopathology and clinical outcome by the ongoing medical audit. The clinical breast examination and mammography screening in female should be encouraged in developing countries from the third decade onward for early detection of breast carcinoma.

Key words: Benign lesion, Fine-needle aspiration cytology, Histopathology, Malignant lesion

INTRODUCTION

Breast cancer is the most common malignant tumor in women globally. In the USA, approximately 232,670 new cases were diagnosed and 40,000 deaths recorded in 2014, contributing to a significant proportion of health care spending.¹ It is the second most common cancer after cancer cervix in Indian females. Currently, 75,000 new cases of breast cancer are detected in India yearly.² The Nottingham Grading System is derived by scoring tubule formation, nuclear pleomorphism, and mitotic frequency.³ Of all epithelial malignancies

of the breast, upto 80% breast carcinoma fall into infiltrating ductal carcinoma (IDC) of no special type category.⁴ Invasive lobular carcinoma is the second most common histological type of breast cancer, accounting for about 5-15% of cases.⁵ The percentage of errors in the cytological diagnosis of lobular carcinoma ranges from 4% to 60% in different series.⁶ In combination with mammography/ultrasonography and clinical examination, fine-needle aspiration (FNA) forms a diagnostic triad, which has approximately 100% accuracy.⁷ FNA has become widely accepted as a reliable diagnostic tool with high sensitivity and specificity with a minimal rate of complications.⁸ FNA cytology is highly sensitive (65-99%) and specific (96-100%).⁹ A breast mass is generally palpable when it exceeds 2 cm in size. The likelihood of a palpable mass being malignant increases with age. Only 10% of breast masses under the age of 40 are malignant compared to 60% of masses over the age of 50 years.¹⁰

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Aim and Objective

To assess the cytological findings from FNA of breast lesions with conventional smear and its histopathological correlation.

MATERIALS AND METHODS

This 1 year prospective study was conducted on 280 cases attending surgical out patient, department of surgery, during the period from August 2014 to July 2015. The histopathology follow-up of 106 cases was available as only these patients underwent surgery. Appropriate approval of the Institution Ethical Committee was obtained for the same. Informed written consent from each patient was also obtained. The subjects concerned included all the patients who were referred to the Department of Pathology for FNA of a breast mass. The physical examination of the breast mass by palpation was done.

The aspirations of the breast masses were performed with 22- or 25-gauge needles attached to a 5 ml or 10 ml syringe in which non-guided FNA was in 105 cases and guided FNA was in 1 case. One or two passes were taken to obtained adequate material, and 5-7 slides were prepared. The materials collected were smeared directly onto slides, fixed with alcohol, and stained by hematoxylin and eosin (H and E) stain. Tumor typing and grading were done according to the Robinson's cytological grading.

Histopathological Examination

Trucut biopsy (9%), biopsy (10.86%) lumpectomy specimen (47.16%), and radical mastectomy (33%) well-preserved formalin fixed specimens received from the Department of Surgery. The paraffin embedded and formalin-fixed sections were stained by routine H and E staining. The sections were studied for the tumor type and grading using the Nottingham modification of Bloom-Richardson system of grading. The smears and the histopathology tissue sections were evaluated separately. Cytological and histopathological correlation were made.

Inclusion Criteria

Age of patients of 15-75 years with palpable lump irrespective with sex.

Exclusion Criteria

Age of patient of below 15 and above 75 years diagnosed cases of breast lesion, recurrence of malignancy, pregnant patients.

The statistical analyzes were done to find the ability of FNA to detect the presence of malignancy in the breast in comparison to histopathology. For this sensitivity, specificity, positive and negative predictive value, and accuracy/efficiency were calculated.

RESULTS

During the study period, out of 280 cases, 106 (37.5%) cases were correlated with histopathological findings. Age of patients ranged from 15 to 75 years. 99.05% were female, and 0.95% were male. 52% right breast, 46% left breast, and 2% bilateral breast lumps with the majority were over upper outer quadrant. The 46.22% had benign lumps, and 38.67% had malignant lumps were concordance to histology diagnosis.

The cytological spectrum of various palpable breast lesions in the present study shows that out of the total 106 cases, 54 were in the benign category, 4 were in the atypical category, 3 were in the suspicious category, and 43 belonged to the malignant category while the cytology study of 2 cases was unsatisfactory (Table 1).

The cytological spectrum of various benign breast lesions encountered in the present study shows that out of the total 54 cases that could be satisfactorily labeled as benign in the present study, fibroadenoma accounted for 44 (41.5%) cases, fibrocystic disease, and proliferative breast disease with atypia 4 (3.77%) each, fibroadenosis and benign proliferative disease 3 (2.83%) each.

On the other hand, the cytological spectrum of various malignant breast lesions encountered in the present study shows that out of the total 43 cases that could be satisfactorily labeled as malignant, IDC accounted for 41 (38.67%), suspicious accounted for 3 (2.83%) cases, lobular carcinoma, and malignant phyllodes 1 (0.94%) case each. Cancers of the male breast, on the other hand, is quite rare and comprises male to female ratio 1:51 of malignant tumor in the present study. Benign lesions were seen in the age-group of 15-60 years; whereas suspicious and malignant cases are seen in the age-group of 29-75 years.

Total number of 106 cases of FNA cytological study of breast lesions were histological correlated. Out of 54 cytological benign cases, 52 were confirmed as benign on histology, but 2 turned out to be malignant. All 4 cytological atypical cases and 3 suspicious cases were confirmed as malignant. Out of 43 cytological malignant cases, 41 cases were confirmed as malignant, but 2 turned out as benign while in all 2 cytological unsatisfactory cases were malignant histology (Table 2).

The histological correlation with benign lesions on cytology as seen in the present study indicated that out of the total 44 (41.5%) cases of fibroadenoma that had a histological correlation, 43 (40.56%) were confirmed as fibroadenoma and 1 (0.94%) was found to be IDC. Of the 4 (3.77%) cases of fibrocystic disease that had a histological correlation were confirmed as fibrocystic

Table 1: Cytological spectrum of various palpable breast lesions

Year	Benign	Atypical	Suspicious	Malignant	Unsatisfactory	Total
11-20	19					19
21-30	25	1		3		29
31-40	4	2		14		20
41-50	5			13	1	19
51-60	1		3	9	1	14
61-70		1		3		4
>70				1		1
Total	54	4	3	43	2	106

Table 2: Comparative analysis of FNA and histological diagnosis of breast lesions

Cytological diagnosis	Number of cases	Histological diagnosis	
		Concordance	Discordance
Fibroadenosis	3	1	2 Fibroadenoma
Fibrocystic disease	4	3	1 IDC
Benign proliferative disease	3	2	1 benign phyllodes
Proliferative disease with atypia/indeterminate	4	0	3 IDC
Fibroadenoma	44	43	1 lobular carcinoma
IDC	41	37	1 IDC
			1 fibroadenoma
			1 benign proliferative disease
			2 lobular carcinoma
Lobular carcinoma	1	0	1 IDC
Malignant phyllodes	1	1	0
Suspicious/probably malignant	3	3 IDC	0
Unsatisfactory	2	0	2 IDC
Total	106	92	14

IDC: Infiltrating ductal carcinoma, FNA: Fine-needle aspiration

disease in 3 (2.83%) cases, while 1 (0.94%) turned out as IDC. Of the 3 (2.83%) cases of benign proliferative disease that had a histological correlation, 2 (1.88%) were confirmed as a benign proliferative disease, while 1 (0.94%) was labeled as benign phyllodes. Out of 3 (2.83%) cases of fibroadenosis that had histological correlation, 1 (0.94%) were confirmed as fibroadenosis, while 2 (1.88%) turned out as fibroadenoma. FNA smears in these cases had low cellular yield and showed few small cohesive sheets of ductal epithelial cells with occasional myoepithelial cell in clusters and few small bare nuclei.

The histological correlation with malignant lesions on cytology as seen in present study indicated that out of the total 41 (38.67%) cases of IDC that had a histological correlation, 37 (34.9%) were confirmed as IDC and 2 (1.88%) were labeled as lobular carcinoma, one each (0.94%) was found to be due to benign proliferative disease and fibroadenoma, respectively. The single case of lobular carcinoma turned out to be IDC. Lobular carcinoma was often under diagnosed on FNA. The solitary case of malignant phyllodes (100%) on cytology was confirmed to be true on histology, with presence of metastasis on gluteal region. Due to the malignant and metastatic behavior of malignant phyllodes was made ease to diagnosed on

cytology while benign phyllodes were overlap with other benign disease of breast.

On the other hand, the cytological spectrum of unsatisfactory smear in 2 (1.88%) cases was diagnosed as IDC on histology.

In 15.09% of FNA smears were discordance to histological diagnosis. Triple test definitely reduces the rate of inadequate aspiration.

Statistical Analysis of FNA as a Diagnostic Test

FNAC was 96.15% sensitive, 96.29% specific, 96% positive predictive value, 96.29% negative predictive value, 3.48% percentage of false positive, 3.7% percentage of false negative value, and 96.22% efficiency of the study. The *P* value is significant at $P < 0.01$ (SOCSCI statistic software used for calculation).

DISCUSSION

In the present study, age of the patients ranged from 15 to 75 years similar age-group 17-72 years was observed by Chandawale *et al.*¹¹ in 2014, age-group 10->50 years by

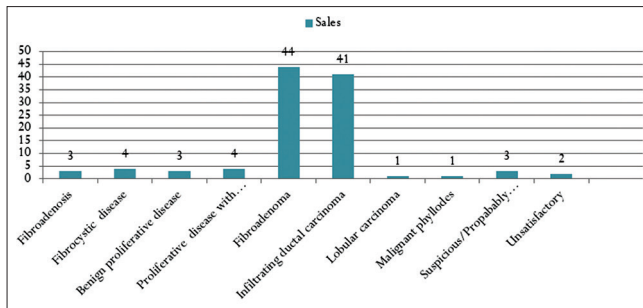


Figure 1: Maximum number of fibroadenoma for 44 (41.5%) cases in benign lesions and infiltrating ductal carcinoma for 41 (38.67%) in malignant lesions in cytological cases

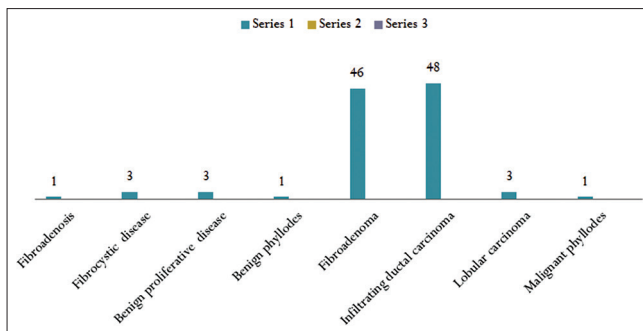


Figure 2: Maximum number of fibroadenoma for 46 (43.39%) cases in benign lesions and infiltrating ductal carcinoma for 48 (45.28%) in malignant lesions in histological cases

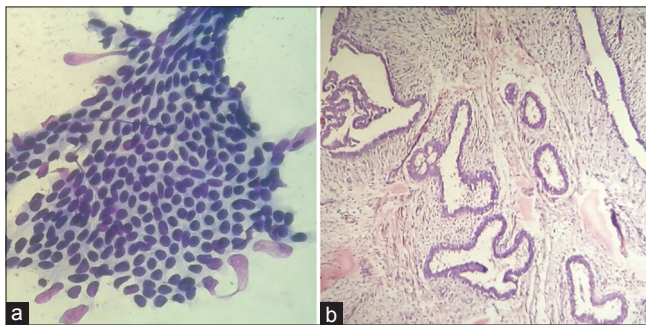


Figure 3: (a and b) Cytological smear of fibroadenoma shows the typical appearance of cohesive benign epithelial cells with admixed myoepithelial cells (H and E, x40) and fibroadenoma of histology (H and E, x40)

Likhar *et al.*¹² in 2013, age-group 22-75 years by Eleuterio *et al.*¹³ 2015.

In present study, out of benign breast lesions, fibroadenoma 46 (43.39%) was most frequently diagnosed lesions similarly 45.91% reported by Likhar *et al.*¹² in 2013, 46.56% by Sankaye *et al.*¹⁴ in 2014, 46.27% by Chandawale *et al.*¹¹

In the present study, fibroadenoma was 1 (0.94%) by Likhar *et al.*¹² in 2013, reported 20%.

In the present study, fibrocystic disease were 3 (2.83%) by Likhar *et al.*¹² in 2013, reported 12.73%, by Sankaye *et al.*¹⁴ in 2014, was 24.43%.

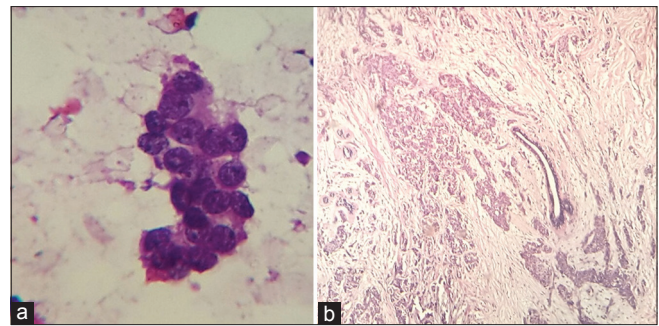


Figure 4: (a and b) Cytological smear of classical infiltrating ductal carcinoma (IDC) shows discohesion and moderate nuclear pleomorphism, prominent nucleoli (H and E stain, x40) and IDC of histology (H and E stain, x10)

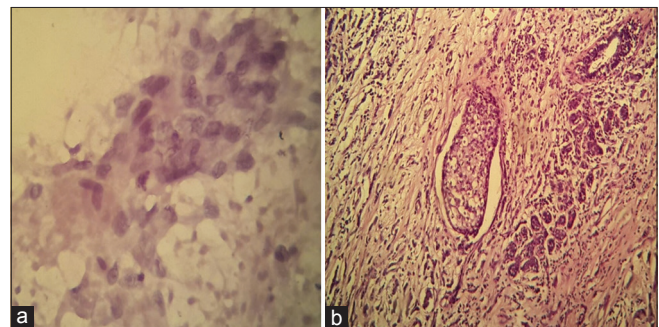


Figure 5: (a and b) Cytological smear of lobular carcinoma shows minimal atypia of the cells and sparse cellularity (H and E stain, x40) and lobular carcinoma of histology (H and E, x10)

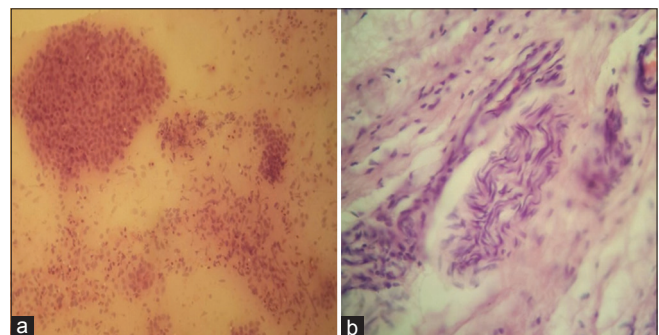


Figure 6: (a and b) Cytological smear of malignant phyllodes shows hypercellular atypical stromal cells and nearby cluster of benign ductal cells (H and E stain, x10) and malignant phyllodes of histology (H and E stain, x10)

In the present study, observed benign phyllodes and malignant phyllodes 1 (0.94%) case each, respectively. By Likhar *et al.*¹² in 2013, phyllodes were reported 1.36%.

In the present study, out of 52 malignant lesions, IDC 50 (47.16%) were a most common diagnosis, fibrocystic disease may mask an adjacent carcinoma, or this may be due to FNA done from the non-representative area. Similarly, 88.60% reported by Sankaye *et al.*¹⁴ in 2014, 78.57% reported by Likhar *et al.*¹² in 2013.

In the present study, lobular carcinoma were often under diagnosed on cytology, but lobular carcinoma 3 (2.83%) was diagnosed on histology. By Sankaye *et al.*,¹⁴ in 2014, reported 1.53% case and by Likhari *et al.*,¹² in 2013, reported 4.76% cases of lobular carcinoma. Crasta *et al.*,⁷ in 2005, reported that 27% were reported as lobular carcinoma 27% were IDC, and 46% were diagnosed as a fibrocystic disease on histology, but all were diagnosed as lobular carcinoma on cytology. Mucha Dulwith *et al.*,¹⁵ 2015 reported cytological diagnosis, 5.1% were benign 30.5% were indeterminate/atypical, 1.7% suspicious all were diagnosed as lobular carcinoma on cytology.

Correlation of cyto-histological findings was 84.90% in the present study. Handa *et al.*,¹⁶ in 2015, cyto-histo correlation reported 78%.

In the present study, FNA was 96.15% sensitive and 96.29% specific, similarly Sankaye *et al.*¹⁴ in 2014 quoted 88.37% sensitive and 96.42% specific in diagnosing malignant lesions. Furthermore, in the present study, FNA had positive predictive value of 96%, negative predictive value 96.29%, and efficiency of the study 96.22%, while Sankaye *et al.*¹⁴ in 2014 reported the positive predictive value of 97.43%, negative predictive value of 84.37% and efficiency of the study of 91.54%. (Figures 1-6)

CONCLUSION

FNA is a valuable diagnostic tool in conjunction with radiological and clinical data of palpable breast lesions. FNA is useful in diagnosis and further planning of treatment without the need for biopsy. Breast cancer is the most common cancer in women after cancer cervix. So that, in developing countries like India, there is a great need for the mass screening program. We recommend multiple clinical set ups with these facilities to be available to all and Government should be providing funds.

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Fasting Lipid Profile in Pre- and Post-Menopausal Women: A Prospective Study

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Abstract

Introduction and Aim: Menopause is a phase of woman's natural aging process and is marked by the cessation of ovarian function. The increased incidence of cardiovascular risk in the post-menopausal women may partly be due to hormonal changes leading to derangement of lipid metabolism. The present study is aimed at determining the degree of dyslipidemia in pre- and post-menopausal women.

Materials and Methods: This prospective study comprised 124 women, 47 pre-menopausal aged between 25 and 45 years and 77 post-menopausal aged between 55 and 70 years. Serum total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C) direct, low-density lipoprotein cholesterol (LDL-C), and very LDL-C (VLDL-C) were evaluated in both the groups and data were statistically analyzed using SPSS software version 16.

Results: In our study, we found significantly high levels of serum TC, serum TGs, serum LDL, and serum VLDL (234.77 ± 58.13 mg/dl, 156.86 ± 70.56 mg/dl, 146.49 ± 52.70 mg/dl, and 31.92 ± 13.76 mg/dl) in post-menopausal subjects when compared with pre-menopausal subjects (201.60 ± 48.50 mg/dl, 125.81 ± 69.96 mg/dl, 124.09 ± 42.71 mg/dl, and 25.28 ± 13.98 mg/dl). However, there was no statistically significant difference in the HDL-C fraction levels between the two groups.

Conclusion: Post-menopausal women are at increased risk of developing cardiovascular disease due to change in the lipid pattern and loss of cardioprotective effect of estrogen. Predicting the factors affecting the lipid profile in post-menopausal women, adopting strategies to control these mechanisms by modifying the relative risk factors during menopausal transition may improve the cardiovascular risk profile in these women.

Key words: Cholesterol, Lipid profile, Menopause

INTRODUCTION

Coronary artery disease (CAD) is the leading cause of death among the post-menopausal women. Post-menopausal women are 4-8 times more likely to die of CAD than of any other disease.¹ Data from the Framingham study suggest that female CAD morbidity rates accelerate more quickly than do those of males after the age of 45 years.² Multiple risk factors have been identified as contributory to the development of CAD.

Menopause is the permanent amenorrhea, which lasts at least for a period of 1-year due to the cessation of ovarian function.³ This results in changes in metabolism of glucose and insulin, body fat distribution, coagulation, fibrinolysis, and vascular endothelial dysfunction.⁴ It has been proposed that estrogen exerts cardioprotective action among pre-menopausal women by maintaining high level of high-density lipoprotein cholesterol (HDL-C) and lowering the low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG).⁵⁻⁸ Lack of estrogen is an essential contributory factor in the derangement of lipid metabolism in post-menopausal women which is associated with increased cardiovascular risk.⁹ Currently, post-menopausal women account for more than 30% of the female population at risk for CAD in India.¹⁰

The present study is aimed at determining the degree of dyslipidemia in pre- and post-menopausal women.

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Modification of specific factors that increase the risk of the disease appears to be the most effective means to decrease the impact of CAD on women's health.¹¹

MATERIALS AND METHODS

This is a prospective study conducted on a group of 124 women, 47 pre-menopausal women aged between 25 and 45 years and 77 post-menopausal women aged between 55 and 70 years at a tertiary referral hospital. Subjects with cardiovascular disease, diabetes mellitus, hypertension, obesity, pregnancy, familial hypertriglyceridemia, history of hysterectomy, oophorectomy, those on exogenous hormone or hormone replacement therapy, heavy exercise, intake of lipid-lowering drugs, or any surgery were excluded from the study. After an overnight fasting of 12-14 h, about 5 ml of venous blood was drawn under aseptic precaution in a sterile plain vacutainer from selected subjects. Serum was allowed to clot, and then separated by centrifugation and used for biochemical analysis.

Total cholesterol (TC) was measured using established enzymatic methods of Allain *et al.*¹² TG was isolated enzymatically by glycerol-3-phosphate oxidase - phenol + aminophenazone method as described by Schettler *et al.*¹³ HDL-C direct was isolated by enzyme selective protection method of Williams *et al.*¹⁴ LDL was calculated using the Friedewald formula:

$$\text{LDL-C} = \text{TC} - (\text{HDL-C} + \text{TG}/5)$$

Very LDL-C (VLDL) was calculated using the formula:

$$\text{VLDL-C} = \text{TG}/5^{15}$$

All the analytes were measured using Agappe Diagnostics kit on Biolis 24i autoanalyzer. The quality check was done by running two levels of quality control material.

Ethics

Study subjects were randomly selected after an informed consent and ethical clearance from the ethical committee were obtained and were in accordance with the Helsinki Declaration of 1975 that were revised in 2000.

Statistics

The results obtained were statistically analyzed and compared between different groups of the study. Baseline characteristics of the study participants are expressed in mean \pm standard deviation. Comparison of mean was done by independent samples *t*-test. The statistical analysis was performed using SPSS 16.0 version computer software for windows. Statistical significance was considered at $P < 0.05$ and highly significance at $P < 0.001$.

RESULTS

The mean age for pre-menopausal women was 34.9 ± 6.71 years and that for post-menopausal women was 59.2 ± 10.2 years.

Serum TC, TGs, LDL-C, and VLDL-C fractions were compared between the two study groups. Serum TC levels were found to be increased in post-menopausal subjects when compared with pre-menopausal subjects which was statistically significant. TG levels were found to be increased in post-menopausal subjects when compared with pre-menopausal subjects which was statistically significant. LDL-C levels were found to be increased in post-menopausal subjects when compared with pre-menopausal subjects which was statistically significant. VLDL-C levels were found to be increased in post-menopausal subjects when compared with pre-menopausal subjects which was statistically significant. However, we observed that there was no statistically significant difference in the HDL-C fraction levels between the two groups (Table 1).

Table 2 shows the HDL/LDL ratio between the two groups. HDL/LDL ratio was seen to be higher in post-menopausal women when compared to pre-menopausal women.

DISCUSSION

The present study was undertaken to evaluate the levels of serum cholesterol and its subfractions in pre- and post-menopausal women.

The incidence of cardiovascular disease after menopause may be partly caused by changes in the plasma lipid levels that

Table 1: Comparison of serum cholesterol and its subfractions between the study groups

Biochemical parameters	Premenopausal women (n=47)	Postmenopausal women (n=77)	P values	Significance
TC	201.60 \pm 48.50	234.77 \pm 58.13	0.001	$P < 0.05^*$
TG	125.81 \pm 69.96	156.86 \pm 70.56	0.019	$P < 0.05^*$
HDL-C	52.15 \pm 14.98	55.84 \pm 22.11	0.314	$P > 0.05$
LDL-C	124.09 \pm 42.71	146.49 \pm 52.70	0.015	$P < 0.05^*$
VLDL-C	25.28 \pm 13.98	31.92 \pm 13.76	0.011	$P < 0.05^*$

*Significant $P < 0.05$, non significant $P > 0.05$, TG: Triglycerides, TC: Total cholesterol, HDL-C: High-density lipoprotein cholesterol, LDL-C: Low-density lipoprotein cholesterol, VLDL-C: Very low-density lipoprotein cholesterol

Table 2: HDL/LDL ratio in pre- and post-menopausal women

Study subjects	HDL	LDL	HDL/LDL
Premenopausal women	52.15	124.09	1:2
Postmenopausal women	55.84	146.49	1:3

HDL: High-density lipoprotein, LDL: Low-density lipoprotein

occur following the menopausal transition.¹⁶⁻¹⁸ Deposition of fatty plaques on arterial walls (arteriosclerosis) is a predisposing factor for coronary heart disease.¹⁹ The increased risk of CAD following menopause is mainly related to the endocrine influences on lipid profile especially when other risk factors such as blood pressure, blood sugar, and body weight are normal. Estrogens have a major beneficial effect on cholesterol metabolism and appear substantially to reduce the risk of atherosclerosis and cardiovascular disease in post-menopausal women.²⁰

The mean age in the post-menopausal women is 59.2 ± 10.2 years and in the pre-menopausal women is 34.9 ± 6.71 years. The mean age in post-menopausal women is greater than that of pre-menopausal women. There is difference in age between both groups of women because it is difficult to design studies that can separate the effects of the normal aging process from natural menopause which occurs between 45 and 50 years.⁹

The findings in our study are in accordance with other studies done by Kalavathi *et al.*, Muzzio *et al.*, and Matthews *et al.*, where the TC is seen to increase in post-menopausal women due to estrogen deficiency when compared to pre-menopausal women and is statistically significant ($P < 0.05$).^{9,16,21}

In our study, when compared to pre-menopausal women, post-menopausal women were having high TG and were statistically significant ($P < 0.05$). These findings are in accordance with other studies done by Welty and Hallberg and Svanborg.^{1,22} In the post-menopausal women, there is increased fat accumulation and increased release of free fatty acids into the circulation, and excessive free fatty acids provide substrate for hepatic TG synthesis.²³

It was observed in our study that the menopausal status is unlikely to alter HDL-C level since no significant differences were found regarding its levels between the pre- and post-menopausal women. This finding was in accordance with certain previous studies done.²⁴⁻²⁷

In our study, post-menopausal women had high levels of LDL when compared to pre-menopausal women and was statistically significant ($P < 0.05$). These findings are in accordance with other studies.^{9,28,29} Lipoprotein lipase (LPL) is regulated by circulating estrogen. LPL catalyzes

the hydrolysis of VLDL to form intermediate-density lipoprotein and later LDL. Estrogen deficiency after menopause increases the plasma LPL and hepatic TG lipase activity causing plasma LDL to accumulate and also leads to down-regulation of LDL receptors.^{21,28,30}

In our study, the VLDL was increased in post-menopausal women when compared to pre-menopausal women and was statistically significant ($P < 0.05$), and these findings are in accordance with studies done by Swapnali *et al.*,²⁸ Welty¹ and Matthews *et al.*¹⁶ Estrogen deficiency in post-menopausal women causes relative enrichment of small VLDL particles with cholesteryl esters (CE) either due to the increased catabolism of VLDL with resulting increased number of VLDL remnant particles or increased activity of cholesterol ester transfer protein or both.¹¹ These small VLDL particles are highly atherogenic as they contain more CE molecules per particle.³¹ The VLDL remnants have a high capacity for interacting with arterial smooth muscle cells.³²

In our study, the HDL/LDL ratio was increased in the post-menopausal group, and it has been shown that HDL/LDL ratio is a significant predictor for development of atherosclerosis.³³

CONCLUSION

Menopause leads to changes in lipid profile by elevating TC, TGs, LDL-C, and VLDL-C, thus increasing the risk for cardiovascular disease. Due to the change in the lipid pattern and loss of cardioprotective effect of estrogen, post-menopausal women are at increased risk of developing cardiovascular disease. There are many studies showing the beneficial effects of hormone replacement therapy on the lipid profile in post-menopausal women.^{34,35} Furthermore, there are several studies which disagree on the beneficial effects of hormone replacement therapy in patients with cardiovascular disease.³⁶ Predicting the factors affecting the lipid profile in post-menopausal women, adopting strategies to control these mechanisms by modifying the relative risk factors during menopausal transition may improve the cardiovascular risk profile in these women.

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Comparison of Butorphanol Tartrate and Tramadol Hydrochloride for Post-Operative Pain Relief Following Abdominal Surgery: A Prospective, Randomized, Double-Blind Study

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Abstract

Background: Butorphanol tartrate is a mixed synthetic agonist-antagonist opioids analgesic used for the management of post-operative pain in minor and major surgical procedures. Tramadol hydrochloride is a centrally acting μ receptor agonist, frequently used as an analgesic.

Aim: The purpose of this study was to compare the analgesic efficacy and side effects of equipotent moderate doses of butorphanol and tramadol.

Materials and Methods: In the present randomized, prospective, double-blind study, 60 patients of either sex, aged between 18 and 60 years, American Society of Anesthesiologists physical status Grade I and II undergoing elective abdominal surgeries under general anesthesia were enrolled in the study. Patients were randomly assigned to two groups (30 patients each); Group B received injection butorphanol 2 mg and Group T received injection tramadol 100 mg, 10 min prior to extubation. Patient's visual analog scale (VAS), duration of analgesia, the number of doses required in 24 h, and side effects were noted.

Results: In the present study, the mean duration of analgesia after the first dose was 3.42 h in Group B and 6.46 h in Group T. The mean number of doses required in 24 h was 4.3 in Group B and 2.4 in Group T. At 0-1/4 h, mean reduction in VAS was 3.0 in Group B and 1.57 in Group T. Mean reduction at 0-4 h was 0.33 in Group B and 4.56 in Group T. Thus, evident that analgesic effect of butorphanol wears off after 4 h while tramadol has peak effect at 3-4 h. Side effects such as vomiting were present in 30% patients in Group B as compared to 60% patients in Group T.

Conclusion: Butorphanol was found to be an effective analgesic than tramadol and has minimal side effects.

Key words: Agonist-antagonist, Analgesic, Butorphanol tartrate, Post-operative pain, Tramadol hydrochloride

INTRODUCTION

Opioids are powerful centrally acting analgesic agents, used to provide the specific anti-nociceptive component of a balanced anesthesia technique.¹⁻³ Post-operative pain relief can be achieved by several methods, including the use of

systemic opioids and regional anesthesia with intrathecal or epidural opioids or local anesthesia. On demand analgesia using a patient-controlled analgesia (PCA) system is regarded as the ideal option for systemic opioids analgesia. While PCA devices are not yet commonly used in all recovery units, the use of repetitive boluses on demand is still the most frequent form of administration in post-operative pain therapy. Butorphanol is mixed agonist-antagonist opioid.⁴ Capable of relieving intense pain. Tramadol is an agonist at μ opioid receptors.⁵ Butorphanol has been used widely in the management of post-operative pain.⁶ Receptor specificity of butorphanol has been used to limit respiratory depression, gastrointestinal side effects, and reduced risk of dependency. Theoretically, it offers

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an advantage over traditional opiates such as morphine and pethidine in the treatment of moderate pain. The analgesic activity of butorphanol is dose related.⁷ Since butorphanol is not a controlled substance, its use can reduce administrative liability for abuse and lower the number of distribution records associated with Schedule II narcotics. Butorphanol injection was approved in 1978;⁸ the nasal spray was approved in 1991.⁹ Butorphanol is an agonist at kappa opioid receptors. The stimulation of kappa receptors seems a likely alternative action for anti-shivering action.^{10,11} The purpose of present study was to compare the analgesic efficacy of intravenous (IV) butorphanol tartrate with IV tramadol hydrochloride for post-operative pain relief following abdominal surgery. Extensive Medline search revealed very limited literature regarding the IV use of butorphanol, and thus the aim of our study was to compare the analgesic efficacy of butorphanol with tramadol, their duration of analgesia and their side effects.

MATERIALS AND METHODS

After approval from the Institutional Ethical Committee and written informed consent, 60 patients of either sex, aged between 18 and 60 years, American Society of Anesthesiologists physical status Grade I and II, were included in a prospective, randomized, double-blinded study to be performed in the Department of Anesthesiology, Teerthanker Mahaveer Medical College and Hospital, Moradabad from January 2014 to December 2014. Patients undergoing elective abdominal surgeries (*viz.* urological and general surgical procedures) under general anesthesia were enrolled in the study. Patients with a history of drug abuse, not given consent, history of drug allergy, pregnant patients, and patients with coagulation disorders were excluded from the study.

A sample size calculation was done using the standard deviation of time to the first request for analgesics. To find a 30 min difference in the mean duration of a request for analgesic (two sided-alpha of 5% and beta of 10%), 22 subjects were enrolled per group. We decided to include 30 patients per group to allow for possible dropouts.

Patients were randomly assigned to two groups (30 patients each) by computer-generated randomization. In Group B, injection butorphanol tartrate (2 mg) was given IV slowly 10 min prior to extubation. In Group T, injection tramadol hydrochloride (100 mg) was given IV 10 min prior to extubation. Drugs were prepared by a blinded anesthesia technician not involved in the study in identical 2 ml syringes and were administered according to the randomization list.

A consultant anesthesiologist assessed all patients during pre-anesthetic evaluation and alprazolam (0.5 mg) was prescribed in all patients on the night before surgery and advised nil per orally from midnight. In the operation theater, monitoring devices for electrocardiogram, heart rate, oxygen saturation (SPO₂), and end-tidal carbon-dioxide (EtCO₂) were attached. All patients were premedicated with injection glycopyrolate (0.2 mg) and injection midazolam (0.03 mg/kg). All patients were subjected to general anesthesia using a standard technique which consisted injection propofol 2 mg/kg. Intubation was facilitated by using injection vecuronium 0.1 mg/kg (IV). Anesthesia was maintained with nitrous oxide (66%) and isoflurane (1-2%) in oxygen. Intra-operative muscle relaxation was maintained with intermittent doses of injection vecuronium. Reversal of neuromuscular blockade was performed with injection neostigmine 0.05 mg/kg (IV) and injection glycopyrrolate 0.1 mg/kg (IV). The first dose of either of the study drug was given 10 min prior to extubation by a blindfolded person. Immediately after extubation patients were monitored (zero order reading) and other vital parameters, such as pulse rate, non-invasive blood pressure, respiratory rates (RR), were recorded.

Systolic blood pressure, diastolic blood pressure, heart rate, SPO₂, and EtCO₂ were monitored intra operatively. The intensity of pain was assessed by visual analog scale (VAS).¹² The score was noted at 0 h, ¼ h, ½ h, 1 h, 2 h, 4 h, 8 h, 12 h, 16 h, and 24 h. Repeated doses were given when patients complained of pain (VAS >4). The side effects were recorded and vomiting score and sedation score were noted.

If satisfactory analgesia was not achieved within 30 min of administration of drug, second dose of the same drug was suggested and if even after second dose pain was not relieved, the patient was excluded from trial study and rescue analgesic (injection diclofenac 75 mg) was given. Antiemetic injection ondansetron 4 mg was given if the patient had one episode of vomiting. Respiratory depression was taken as RR <10 breaths/min. Excessive sedation with respiratory depression, hypotension, and bradycardia were taken as evidence of central nervous system depression.

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS), version 19 (SPSS Inc., USA). Unpaired Student's *t*-test was used to analyze parametric data while Fisher/Chi-square test was applied for non-parametric data. A *P* < 0.05 was considered as statistically significant.

RESULTS

All patients were successfully enrolled and underwent abdominal surgeries in our study without any dropouts. The butorphanol tartrate group and the tramadol group were comparable with respect to patient's demographic data, duration of surgery (Table 1). The duration of analgesia after the first dose was 3.42 h in Group B as compared to 6.46 h in Group T (Table 2). In Group B, the analgesia lasted for 0-2 h in 13.3%. No patient in Group T had duration of analgesia of <2 h. 16.7% patients in Group B and 76.7% patients in Group T had duration of analgesia that lasted for 4-8 h. The mean number of doses required in 24 h was 4.3 ± 1.05 in Group B as compared to 2.4 ± 0.86 in Group T (Table 3). The t score = 7.6619, $P = 0.000$, was highly significant. The mean differences in VAS at 0-1/4 h in Group B was 3.0 (standard deviation [SD] ± 1.72), whereas in Group T mean VAS was 1.57 (SD ± 0.93) ($P < 0.001$), very highly significant. Mean reduction in VAS was 0.33 (SD ± 1.92) in Group B at 0-4 h while mean reduction in VAS was 4.56 (SD ± 1.15) in Group T, $P < 0.000$, very highly significant. Thus, evident that the analgesic effect of butorphanol wears off after 4 h while tramadol has peak effect at 3-4 h (Table 4).

Table 1: Demographic profile

Characteristics	Group B	Group T	P value
Age (years)	40.63 \pm 12.08	40.60 \pm 10.65	0.50
Sex (male:female)	17:13	16:14	
Height (cm)	152.53 \pm 4.42	153.18 \pm 3.76	0.30
Weight (kg)	54.56 \pm 5.36	53.52 \pm 4.32	0.35
Duration of surgery (min)	120.17 \pm 26.44	121.00 \pm 24.21	0.49

Table 2: Duration of analgesia after the first dose

Time (h)	Group B n=30 (%)	Mean duration	Group T n=30 (%)	Mean duration
0-2	4 (13.3)	3.42 \pm 1.37	0 (0)	6.46 \pm 1.35
2-4	21 (70)		3 (10)	
4-8	5 (16.7)		23 (76.6)	
>8	-		4 (13.3)	
Total	30		30	

Unpaired t -test=8.6433, $P < 0.00$ (VHS). VHS: Very highly significant

Table 3: Number of doses required in 24 h

Doses	Group B	Group T
1	0	4
2	2	13
3	3	10
4	13	3
5	8	-
6	4	-
Total	30	30
Mean \pm SD	4.3 \pm 1.05	2.4 \pm 0.86

Unpaired t value=7.6619, $P = 0.000$ (HS). HS: Highly significant, SD: Standard deviation

In Group B, 70% of patients had no side effects, 9 (30%) had nausea compared to 12 (40%) patients in Group T. No patient had vomiting in Group B while 6 (20%) patient in Group T had vomiting (Table 5). In Group B, 43.3% patients were drowsy while 36.7% patients were drowsy in Group T. 7 and 3 patients in Group B and Group T were drowsy and not arousable by verbal commands. 13.4% patients in Group B were arousable by deep pain. No patients in both the groups were unarousable (Table 6).

DISCUSSION

The main aim of post-operative pain relief is to provide subjective comfort, in addition to inhibiting nociceptive impulse caused by trauma and to blunt autonomic as well as somatic reflexes to pain. Subsequently, this might enhance restoration of function by allowing the patient to breathe, cough and to be easily ambulant. Butorphanol is used to treat moderate to severe pain. It is an agonist at kappa-receptor, but it is a weak antagonist at the μ receptor. Several clinical studies with the injectable form of butorphanol have shown effectiveness in relieving moderate-to-severe post-operative pain.¹³ Tramadol, a weak opioid which acts on μ receptor has been most commonly used for management of post-operative pain.¹⁴ Tramadol has been chosen as a reference substance, as its effects are well-documented. Since the study used identical protocols, the results obtained were comparable, combine analysis of trial was valid.

The aim of this study was to know the efficacy of butorphanol in comparison with tramadol with regard to post-operative pain. The patient's age, gender, weight, and duration of surgery were statistically not significant in two groups. Therefore, the effect of age, gender, weight, duration of surgery would be minimized. The concept of using analgesia post-operatively before the onset of significant pain (preventive analgesia) has been used. Each of these modalities has led to decreased total pain after surgery and decreased pain intensity at fixed post-operative time intervals when measured by VAS. Sung *et al.*¹⁵ conducted a retrospective study to compare butorphanol with morphine for use in a balanced anesthesia technique with nitrous oxide, oxygen, and neuromuscular relaxants. Neru *et al.*¹¹ have compared butorphanol and tramadol for analgesic efficacy and safety. The onset of analgesia is rapid as studied by Andrews¹⁶ The mean duration of analgesia after the first dose was 3.42 h in Group B and 6.46 h in Group T. Padmasuta⁵ observed 6.6 h mean duration of intramuscular (IM) tramadol. The mean duration of analgesia with Tramadol was comparable with the study of Padmasuta⁵ where tramadol was used IM. Stehling and Zauder¹⁷ observed 4-5 h mean duration of analgesia of IM butorphanol. Gilbert *et al.* found 4-5 h duration of

Table 4: Mean differences in VAS

Time (h)	0-¼	0-½	0-1	0-2	0-4	0-8	0-12	0-16	0-24
Group B	3.0±1.72	4.3±2.05	4.73±1.92	4.43±1.94	1.60±1.92	1.07±1.74	1.5±2.14	0.53±1.89	0.83±1.93
Group T	1.57±0.93	2.90±2.02	3.10±1.86	4.33±1.15	4.00±0.97	0.33±1.18	3.70±1.15	2.13±2.50	3.07±1.48
P value	0.0002	0.0001	0.0015	0.8093	0.0000	0.0614	0.0000	0.0070	0.0000

VAS: Visual analog scale

Table 5: Incidence of side effects

Side effects	Group B (%)	Group T (%)	P value
Vomiting			
Present	9 (30)	18 (60)	P<0.020
Absent	21 (70)	12 (40)	
Sedation			
Present	24 (80)	14 (46.3)	P<0.007
Absent	6 (20)	16 (53.4)	
Total	30	30	

Table 6: Sedation score

Score	0 (%)	1 (%)	2 (%)	3 (%)	4	Total
Group B	6 (20)	13 (43.3)	7 (23.3)	4 (13.4)	-	30
Group T	16 (53.4)	11 (36.7)	3 (10)	-	-	30

P=0.016, Pearson Chi-square test (1) χ^2 : 10.3121, 0: Alert, 1: Drowsy but arousable by verbal command, 2: Drowsy but not arousable by verbal command, 3: Arousable by deep pain, 4: Unarousable

analgesia with 1-2 mg IM butorphanol. In our study, the average number of doses required in Group B were 4.3 where as in Group T were 2.4 over a period of 24 h. Carter *et al.* reported mean number of doses 3.8 in 24 h which was comparable to our study. Padmasutta⁵ observed the mean dose of 2.5 per 24 h after IM tramadol. The observations of our study are comparable with the study of Padmasutta.⁵ The only variation was the route of administration. In our study, comparing the mean differences in VAS scores in two groups, it was clear that there was a greater reduction in VAS score of butorphanol group compared to tramadol group. The results of Galloway *et al.*¹⁸ and Del Pizzo⁶ were comparable with our results. In Group B, sedation score was 0 in 20% patients compared to Group T, it was 53.4%.

In our study, Group B 70% of patients had no side effects, 30% had nausea while in Group T, 40% had no side effects, 40% patients had nausea, and 20% had nausea and vomiting. Butorphanol does not increase the incidence of post-operative nausea and vomiting as observed by Onake and Yamamoto¹⁹ Nausea and vomiting were more frequent with tramadol 28% and 18% versus 81% and 51% than with pethidine. Ofoegbu²⁰ found that with IM tramadol the incidence of nausea and vomiting was 19%. None of the patients showed post-operative shivering. This can be due to the anti-shivering action of tramadol as has been described by Chen *et al.*²¹ The stimulation of kappa receptors seems likely alternative for the anti-shivering

action of butorphanol. Moreover, being a non-narcotic butorphanol has a low propensity for addiction. This was observed by study conducted by Charlton.²²

As mentioned in previous studies, care is to be taken during the administration of injection butorphanol because of the risk of respiratory depression. However, we did not experience any episode of respiratory difficulty in any of our study group.

CONCLUSION

In this randomized, parallel group study, the following conclusions were drawn; that butorphanol has the short onset of action, better analgesic efficacy, with minimal side effects in comparison tramadol has a longer duration of analgesia with few side effects. Butorphanol appears to be a promising drug in near future, but an extensive study with more patient population would be more conclusive.

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Product of Symphysio-Fundal Height and Abdominal Circumference: A Predictor of Estimated Fetal Weight at Birth

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Abstract

Introduction: Accurate estimation of fetal weight is vital in the management of labor and delivery. Developing countries like India, where sonography to estimate fetal weight is mostly unavailable and clinical techniques based on fundal height can lead to timely referrals from the periphery. We conducted a prospective longitudinal study to assess fetal birth weight by measuring symphysio-fundal height (SFH) and abdominal circumference (AC).

Materials and Methods: Product of SFH and AC was calculated on 303 antenatal women to get estimated fetal weight in grams at birth; then, this weight was compared with actual weight at birth.

Results: Mean fetal birth weight as measured by SFH × AC (in latent stage) was 2712 ± 436.99 g, and actual mean fetal birth weight was 2621 ± 411.09 g, which is statistically not significant.

Conclusion: SFH × AC is a useful alternative to ultrasonography and is a great promise for use in developing countries. To accept this as a screening method for fetal weight estimation in the antenatal period, large sample sized studies are required. However, it can be used by midwives or peripheral health workers as a predictor of birth weight.

Key words: Abdominal circumference, Fetal weight, Symphysio-fundal height

INTRODUCTION

Accurate estimation of fetal weight is vital in the management of labor and delivery. The knowledge of fetal weight in utero helps in the management of diabetic pregnancy, vaginal birth after a previous cesarean section and intrapartum management of fetuses presenting with the breech.^{1,2} Furthermore, when dealing with anticipated preterm delivery salvageability of the baby, the intervention undertaken to postpone preterm delivery, optimal mode of delivery or level of a hospital where delivery should occur is based partly on the estimation of expected birth weight.

Categorization of fetus into small or large for gestational age can lead to timed obstetric intervention.²⁻⁴ This is especially true for developing countries like India, where sonography to estimate fetal weight is mostly unavailable and clinical techniques based on fundal height can lead to timely referrals from the periphery.

With this background, we conducted a simple method to predict estimated fetal weight by multiplying symphysio-fundal height (SFH) and abdominal girth in centimeters and evaluated the efficacy of this method by the actual birth weight of the baby.

MATERIALS AND METHODS

A comparative prospective longitudinal study was conducted on 303 antenatal women, who gave consent to participate in the study until the completion. Prior ethical clearance was obtained from the Institutional Ethical

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Committee. Women were of any parity and age with a period of gestation >28 weeks in any stage of labor admitted in labor ward of our hospital.

Women having obesity, multiple gestations, polyhydramnios or oligohydramnios, malpresentation, and intrauterine device were excluded from the study. In utero, fetal weight and birth weight at delivery was calculated by the same flexible tape calibrated in centimeters and by the same observer. The SFH was taken from mid-point of the upper border of pubic symphysis to the highest point on uterine fundus after correcting the dextrorotation. Abdominal circumference (AC) was measured at the level of the umbilicus. Fetal weight in grams was determined by formula:

$$\text{SFH} \times \text{AC}$$

After delivery, weighing scale was used to weigh the baby within an hour of birth. The results were tabulated and analyzed.

RESULTS

A total of 303 antenatal women were recruited for the study. 38% were primigravida, and 62% were multigravida. The majority (48.8%) of the patients were between 23 and 27 years of age (Table 1). 72.6% women were beyond 38-week period of gestation (Table 2) 91.5% women had normal vaginal delivery, and 9.5% had a cesarean section.

Figure 1 shows the comparison of predicted fetal weight (determined by $\text{SFH} \times \text{AC}$) and actual fetal weight. The intraclass correlation was 0.75 with 95% confidence interval of 0.683-0.802 which was statistically significant.

The mean fetal birth weight as measured by $\text{SFH} \times \text{AC}$ (in latent stage) was 2712 ± 436.99 g, and actual mean fetal birth weight was 2621 ± 411.09 g. The mean birth weight as measured in latent stage of labor (<4 cm dilatation of cervix with the head not engaged) was 2712 g and that measured in an active stage of labor (>4 cm dilatation of cervix with head engaged) was 2780.2 g which was not statistically significant.

DISCUSSION

The prediction of fetal assists in the identification of pregnancy at risk of intranatal complications during normal delivery. Equipped with information about the weight of the fetus, the obstetrician is able to make sound decisions thereby decreasing perinatal morbidity and mortality.⁵ The present study was conducted in a tertiary care center equipped with all facilities of emergency obstetric care.

Table 1: Age distribution

Age of patient (years)	Percentage of patients
18-22	36.20
23-27	48.60
>28	15.10

Table 2: Gestational age distribution

Gestational age (weeks)	Percentage of patients
28-33	0.10
33-38	23
>38	72.30

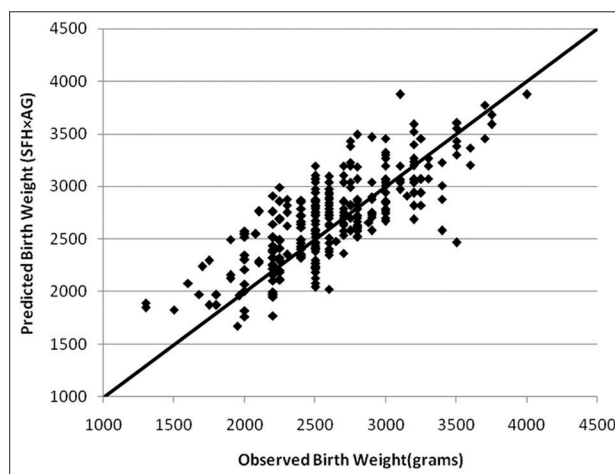


Figure 1: Comparison of predicted fetal weight (determined by symphysio-fundal height \times abdominal circumference) and actual fetal weight

Our study found no correlation of age and parity of mother with fetal weight. While Dare *et al.*⁶ found estimated fetal weights were higher than actual weight in para 0 and para 5 and also reverse to be true in para 6 and 7.

Like our study, Raghuvanshi *et al.*⁷ found Insler and Bernstein formula ($\text{SFH} \times \text{AC}$) and Hadlock's formula to be closer to actual birth weight. Dare *et al.*⁶ also found the product of $\text{SFH} \times \text{AC}$ to correlate with the actual birth weight of the fetus. Amritha *et al.*⁵ found an average error in fetal weight estimation was least with $\text{SFH} \times \text{AC}$ method as comforted with Dawn's formula, Johnson's formula and Hadlock's formula using ultrasound. The standard deviation of prediction error was least with Hadlock's ultrasound method closely followed by $\text{SFH} \times \text{AC}$ method. In the present study, the mean of estimated fetal weight was almost close to mean of actual birth weight.

Similarly, Kathiriya *et al.*⁸ found Insler and Bernstein formula, to be as accurate as ultrasound estimates for predicting actual fetal weight. Lebdev⁹ using similar techniques with correlation factors for maternal weight and duration of gestation achieved similar results. Ojwang and Ouko¹⁰ reported similar

results while applying this formula without correlation factor. They used abdominal girth as the longest circumference of the abdomen while in our study we used circumference along umbilicus as AC making it simpler and more reproducible.

Sowmya *et al.*¹¹ found error in fetal weight except in >3501 g group were least with SFH \times AC method followed by Hadlock's ultrasound method. Johnson's formula showed the least error in group >3501 g. They also found fetal weight was underestimated by SFH \times AC method and Dawn's formula, whereas Johnson's and Hadlock's formula overestimated fetal weight. Willocks *et al.*¹² commented that clinical estimation of fetal weight is little more than guess work because the factors such as abdominal wall thickness, uterine tone, amount of liquor, and uterine position in utero alters the calculation. Shittu *et al.*¹³ found the accuracy of clinical method deteriorates markedly below 2500 g. similarly, Titapant *et al.*¹⁴ observed that ultrasound was more accurate when there is low birth weight. In our study, even low birth weight (<2500 g) babies and good size babies (>3.5 kg) were found to have correlation with SFH \times AC formula.

CONCLUSION

All currently available techniques of *in-utero* estimation of fetal weight have a significant degree of inaccuracy. Clinical estimation, especially by SFH \times AC method, is an accurate method for estimation of fetal weight. This formula is of great value for developing countries where ultrasound is not always available at many health centers especially rural areas. The need is to practically apply this method in obstetrics and guide the management decisions.

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Child and Adolescent Clinic: Recent Trends in Goa

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Abstract

Introduction: Mental health in child and adolescent (C/A) is an integral component of overall health, and its importance is highly recognized. Goa is a State in India which has a total population of 11 lakhs out of which 40% are in age group of 0-18 years. There is only one tertiary psychiatric unit which runs a C/A clinic for the past 20 years. It was found that the number of outpatient department attendance at the clinic had significantly increased in the recent years. A need was felt to try and evaluate the reasons for this growth. In view of these findings, this study was initiated with the aim of exploring and comparing the various socio-demographic variables and the clinical profile of patients attending the clinic.

Materials and Methods: A prospective study was conducted in the C/A clinic at the Institute of Psychiatry and Human Behavior, Bambolim, Goa. Cases attending the clinic for the first time from January 2004 to December 2005 (i.e. 2-year period and meeting the International Classification of Diseases-10 [ICD-10] criteria WHO, 1992) formed the study sample. The data were collected on a structured proforma designed for the study. A comparison was done with a retrospective case notes survey, (January 1994-December 1995), to confirm the same. Data from case note survey were collected on the above-mentioned structured proforma, and the diagnoses were based on ICD-10.

Result: It shows there is a trend for an increase in a number of patients with various psychiatric disorders attending C/A clinic in recent years (January 2004-December 2005) as compared to an earlier period (January 1994-December 1995).

Conclusion: There is a significant rise in the number of C/As attending the clinic. Mental retardation is the most frequent diagnosis in our setting. The majority of the subjects were in school going age group. This study highlighted an urgent need for screening of primary and secondary schools in Goa to detect various C/A psychopathology.

Key Words: Child and adolescent clinic, Child psychiatric disorders, Mental retardation, Socio-demographic co-relates

INTRODUCTION

Mental health is an important component of overall health. The due importance is given to the physical health of children and adolescent (C/A); however, developmental, behavioral, and emotional aspect is not getting enough attention. This could be due to the various reasons such as lack of knowledge of child developmental psychology and various psychopathologies, limited number of professional, poor financial assistance, stigma, and cultural traditions.

The importance of mental health in C/A currently is being recognized globally. India is a country of C/A and young adults. C/A constitute nearly 60% of the population. Though psychiatric morbidity accounts for 5-10 leading causes of disability for those aged 5 years and above, yet there are not enough psychiatric services for them in developing countries.^{1,2} Overall development of any country depends on the positive mental development of its children. Various factors, such as changing family structure, modernization, and industrializations, have negatively influenced child mental health. There is enormous influence of environment on child mental health process. The immediate environment includes parents, teacher, siblings, and companions. Many behavior problems in children are due to the direct effect of the environment. The conflict which a child experiences during his development to maturity is due to the environment in which he grows. Of all the environment, family is the most important. The faulty development

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of the personality is responsible for various behavior problems. Family dynamics plays a vital role in mental health and illness. Children from broken homes presents with various psychopathologies. Child rearing practices can retard or accelerate development of child health. The offspring's of the maladjusted parents are likely to become problem children. Lack of adequate supervision and control on the part of parents also leads to behavior problems of the children. Hence, simple environmental manipulation can cure a problem. A child guidance clinic (CGC) is one of the medico-social amenities and may be best defined as a center for the organized and scientific study and treatment of maladjustment in children. The treatment of the child is carried out not by one person but by a team of workers. The team of staff members is constituted of a psychiatrist, a pediatrician, special educator and language pathologist, a psychiatric health nurse, and educational psychiatric social worker, and playroom workers. The child is treated as a whole, and the personality has many aspects, viz., physical, intellectual, educational, emotional, social, and economic, etc., each of these aspects is studied by the respective staff member who has specialized in that particular field. Whenever a child is referred to the clinic, he usually always comes with other associated problems also.

School mental health has been a major mental health movement which covers up the large population of C/A but has been effectively implemented only in metros and not in smaller towns and urban areas in the last four decades. Earlier research shows mental retardation formed bulk of population attending CGC during that period. While emotional and behavioral disturbances were less identified and referred. The trend has changed. All spectrums of diagnostic categories are now referred and treated at various teaching hospitals, psychiatry departments, pediatric departments, various colleges of social work, and large number run by non-governmental organizations (NGOs).³

Goa is a westernized state with 82% literacy rate and a population of about 14 lakhs of which about 40% is between 0 and 18 years.⁴ The Institute of Psychiatry and Human Behavior (IPHB) is a tertiary care psychiatry hospital at Bambolim in Goa and has a C/A clinic since the past 20 years. Earlier data show that few people were availing the services offered by this clinic. In recent years, the C/A population visiting this clinic has increased substantially. WHO reported 20% of C/As suffer from different types of mental illness worldwide.⁵ The US Department of Health and Human Services have also reported 20% of C/As to have some mental problem during this phase of life, and at least 10% have a serious psychological disturbance at some point in their life.⁶

Studies⁷⁻¹⁰ show that risk factors for mental illness in children are divided into two types:

1. Child characteristics such as age, sex, cultural background, physical health, antenatal, and peri-natal factors, external agents such as food, infections, toxins, and stress
2. Parent/family characteristics: These would be parent's age, education, and socio-economic status, physical and psychological ailments.

Hence, this study was conducted to explore and compare the various socio-demographic characteristics and clinical profile of patients attending the C/A clinic.

MATERIALS AND METHODS

Study Design

A prospective study was conducted in the C/A clinic at the IPHB, Goa. Cases attending the clinic for the first time from January 2004 to December 2005 (i.e. 2-year period) and meeting the International Classification of Diseases-10 (ICD-10) criteria (WHO, 1992) formed the study sample. The data were collected on a structured performa designed for the study.

Study Setting

IPHB, Bambolim, is a tertiary care teaching hospital with inpatient and outpatient facilities, in North District of State of Goa. The C/A guidance clinic is conducted once a week and children up to 18 years of age are evaluated. Information for the clinical history is collected from parents, teachers, patients and NGO's, and other referral sources.

All the children registered with the hospital C/A clinic are initially interviewed by a Junior Resident (post-graduate trainee doctor) who records basic demographic data such as patient's age, gender, education, and place of stay (rural-urban); the head of the family's age, occupation, income, religion and relationship with the patient; and the source of referral. Detailed psychiatric and medical history, mental state examination, etc., are recorded on a case file. The child is then assessed by a qualified general psychiatrist (Senior Resident), who discusses the case with a consultant psychiatrist with special interest in child psychiatry. Child is then referred to a clinical psychologist for assessment of intelligence, learning disabilities, etc. All psychiatric diagnoses are based on ICD-10 descriptions. The management is carried out under the supervision of the consultant, with inputs from psychologists, and other team members as required.

The case file is reviewed at a follow-up by the consultant after 2-4 weeks of the initial detailed assessment, and a

final diagnosis is ascribed to the case based on follow-up information, investigation reports, and treatment response.

Ethical Approval

The protocol was approved by the Local Ethics Committee. Consent was taken from the parents and assent from the children before entering the study.

Data thus generated was presented as a mean standard deviation. The differences in the various co-related variables were analyzed using the Chi-square test. A $P < 0.05$ was considered to be statistically significant.

RESULTS

The socio-demographic characteristics of the study sample and the case note survey are summarized in Table 1. Some of the interesting trends that were observed are:

The number of cases registered at the C/A clinic was 4-5 times increased in the study sample ($n = 768$) as

Table 1: Comparison of socio-demographic characteristics between study sample (January 2004-December 2005) and case note survey (January 1994-December 95)

Patient variables	Sample study $n1=768$ (%)	Case note survey $n2=162$ (%)	Significance χ^2
Age group (years)			
0-3	23 (3.0)	4 (2.5)	114.2
4-7	185 (24.0)	58 (35.8)	df=3
8-11	300 (39.1)	62 (38.3)	$P<0.001$
12-18	260 (33.9)	38 (23.4)	
Sex			
Males	503 (65.5)	99 (61.1)	6.3
Female	265 (34.5)	63 (38.9)	df=1
			$P=0.02$
Birth order			
Only child	161 (21.0)	26 (15.8)	81.05
Eldest	288 (37.5)	35 (21.9)	df=3
Middle	52 (6.8)	29 (17.9)	$P<0.01$
Youngest	267 (34.7)	72 (44.4)	
Literacy in parents			
Illiterates	94 (12.2)	76 (46.9)	372.7
Literates	674 (87.8)	86 (53.1)	df=1
			$P<0.001$
Religion			
Hindu	488 (63.5)	62 (38.3)	216.7
Christian	218 (28.4)	86 (53.1)	df=2
Muslim	62 (8.1)	14 (8.6)	$P<0.001$
Residence			
Urban	488 (63.5)	72 (44.4)	68.2
Rural	527 (68.6)	90 (55.6)	df=1
			$P<0.001$
Socio-economic status			
Low	443 (57.6)	57 (35.2)	191.7
Middle	301 (39.2)	54 (51.9)	df=2
High	24 (3.2)	21 (12.9)	$P<0.001$

Chi-square test, significant value of Pearsons $P<0.05$, $P<0.001$

compared to the case note survey ($n = 162$). The majority of the subjects, i.e. 39.1% ($n = 300$) in the study sample and 38.3% ($n = 62$) in the case note survey belonged to the 8-11 years age group. The mean age was 8.6 years with a standard deviation of 7.7 years. Birth order revealed that the eldest and the youngest siblings in both the study sample, i.e. 37.5% ($n = 288$) and 39.7% ($n = 267$) and case note survey, i.e. 21.9% ($n = 35$) and 44.4% ($n = 72$), respectively, formed the majority. It was seen that there was a preponderance of males in all the age groups in both the study sample and the case note survey. The male:female ratio being approximately 2:1 in the study sample and 1.6:1 in case note survey. Educational status showed that the majority of the parents in both the study sample, i.e. 87.8% ($n = 674$) and case note survey 53.1% ($n = 86$) were literate. About 68.6% ($n = 527$) subjects from study sample and 55.6% ($n = 90$) from case note survey, hailed from rural areas and the rest from urban areas. Most of the patients from the sample study belonged to the low and middle socio-economic status group.

Table 2 shows the comparison of the psychiatric diagnostic breakup between the study sample and the case survey. The most common major diagnoses group was mental retardation in both the study sample and the case note survey. It comprised the greater bulk of the total psychiatric disorders forming 59% ($n = 453$) and 46.4% ($n = 75$) of the study sample and the case note survey, respectively. The other major groups were the specific developmental disorders 12.1% ($n = 93$), hyperkinetic disorders 7.8% ($n = 60$), epilepsy 6.1% ($n = 47$), and conduct disorder 4.2% ($n = 32$) in the study sample, while in the case note survey epilepsy 17.3% ($n = 28$), hyperkinetic disorder 8.4% ($n = 14$), and transient dissociative disorder 6.2% ($n = 10$) formed the other major group.

There was a significant increase in the specific developmental disorder group in the study sample 12.1% ($n = 93$) as compared to case note survey 1.9% ($n = 3$). Furthermore, it was observed that the patients with epilepsy and transient dissociative disorder were few, i.e. 6.1% ($n = 47$) and 1.6% ($n = 12$) in the sample study.

DISCUSSION

The socio-demographic characteristics of the study sample and the case note survey are summarized in Table 1. Some of the interesting trends that were observed are:

In this study, the increase in the attendance of C/A clinic in the study sample can be explained on the basis of probable increase in the public awareness following the training imparted to the Anganwadi workers who had conducted a survey of mentally retarded in 1995, the regular school

Table 2: Comparison of psychiatric diagnostic breakup between study sample (January 2004-December 2005) and case note survey (January 1994-December 1995)

Diagnoses	Study sample n=768 (%)	Case note survey n=162 (%)	Comparison for significance χ^2
Mental retardation	453 (59)	75 (46.4)	26.4, df=1, $P<0.01$
Epilepsy	47 (6.1)	28 (17.3)	55.6, df=1, $P<0.001$
Hyperkinetic disorder	60 (7.8)	14 (8.4)	0.4, df=1, $P=0.50$
Conduct disorder	32 (4.2)	6 (3.7)	0.5, df=1, $P=0.50$
Specific developmental disorder	93 (12.1)	3 (1.9)	405.6, df=1, $P<0.001$
Pervasive developmental disorder	26 (3.4)	6 (3.7)	0.1, df=1, $P=0.7$
Other behavioral/emotional disorder	20 (2.6)	8 (4.9)	8.5, df=1, $P=0.001$
Oppositional defiant disorder	15 (2.0)	7 (4.3)	9.8, df=1, $P=0.001$
Transient dissociative disorder	12 (1.6)	10 (6.2)	27.0, df=1, $P<0.001$
Miscellaneous	10 (1.2)	5 (3.2)	9.0, df=1, $P=0.001$

mental health programs conducted by the IPHB and the workshops held by the NGO's for the teachers and the public.

Various Social Welfare Schemes have been introduced by the Government of Goa since 2003 under the Dayanand Niradhar Yojana. Furthermore, there has been a steady increase in the number of schools in this state. This could have led to the sensitization of the parents of mentally challenged children, thus increasing their attendance at the C/A clinic.

The majority of the subjects were in the 8-11 years age group seen in the study sample as well as in the case note survey. This is in keeping with the study of Malhotra *et al.*¹¹ which says that most common psychiatric disorders in children are diagnosed in the school going age group.

It was seen that there was a preponderance of males in all the age groups in both the study sample and the case note survey. The male:female ratio being approximately 2:1 in the study sample and 1.6:1 in case note survey. Chakrabarti and Arya, 2003¹² have found that 70% patient with mental retardation are first born. D'Souza and D'Souza, 1987, Belmont *et al.*^{13,14} have explained similar finding in their studies by referring to the youngest child as being the favored one in the family.

Educational status showed that the majority of the parents in both the study sample, i.e. 674 (87.8%) and case note survey 86 (53.1%) were literate. These figures can be explained by the simple fact that Goa has a high literacy rate, i.e. 82% as per the statistical handbook of Goa 2001.⁴

Socio-economic status revealed that maximum number of subjects in the study sample belonged to middle and lower income families, whereas in the case note survey they were from middle-class families. This is in keeping with the study by Srinath *et al.*¹⁵

Table 2 shows the comparison of the diagnostic breakup between the study sample and the case survey. The most common major diagnoses group was mental retardation in both the study sample and the case note survey. It comprised the greater bulk of the total psychiatric disorders forming 453 (59%) and 75 (46.4%) of the study sample and the case note survey, respectively. A study by Sidana *et al.*,¹⁶ Chadda and Saurabh (1994),¹⁷ and Hagberg *et al.*,¹⁸ also show that the most common major diagnoses group was mental retardation as seen in both the study sample and the case note survey. The other major groups were the specific developmental disorders, 93 (12.1%); hyperkinetic disorders, 60 (7.8%); epilepsy, 47 (6.1%); and conduct disorder, 32 (4.2%) in the study sample, while in the case note survey epilepsy, 28 (17.3%); hyperkinetic disorder, 14 (8.4%); and transient dissociative disorder, 10 (6.2%) formed the other major group. These figures were much higher than those reported by Sidana *et al.*¹⁶

There was a significant increase in the specific developmental disorder group in the study sample, 93 (12.1%) as compared to case note survey, 3 (1.9%). The reasons could be greater sensitivity and specificity in the diagnosis of developmental disorders in recent years. Furthermore, it could have been prompted by the various scholastic benefits offered by this state for such children.

Furthermore, it was observed that the patients with epilepsy and transient dissociative disorder were few, i.e. 47 (6.1%) in sample survey and 12 (1.6%) in case note survey. Number of subjects reporting with epilepsy and transient dissociative disorder showed a decline in the study sample. This could be because these subjects are availing the services of the neurologists appointed at the general tertiary care Government Hospital.

Limitations

The findings of our study cannot be generalized to the community as it was hospital-based study and the sample

was purposive in nature. Further community-based studies are needed to substantiate the findings of this study.

CONCLUSION

This study highlighted an urgent need for screening of primary and secondary schools in Goa to detect the various C/A psychopathologies, especially learning disability, specific developmental disorders as well as behavioral and emotional disorders.

A need was felt to upgrade the services offered presently by the C/A clinics at IPHB by having a separate play therapy unit, specific counseling services, behavior treatment units, speech therapy units, and support groups for parents of affected children.

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Evaluation of Efficacy of Nucleated Red Blood Cell Count as a Predictor of Perinatal Asphyxia in Karnataka, South India

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Abstract

Background: Early diagnosis of perinatal asphyxia is very essential since it is a major cause of neurologic morbidity and mortality. The present study was undertaken to investigate the association between nucleated red blood cells count (RBCs) per 100 white blood cells (WBCs) and perinatal asphyxia with respect to its severity and prognosis.

Materials and Methods: A prospective case-control study was conducted on asphyxiated and non-asphyxiated term neonates from the neonatal intensive care unit and post-natal wards of the Adichunchanagiri Institute of Medical Sciences, B G Nagara, Karnataka. Cord blood samples from 50 asphyxiated neonates comprising the cases and 50 healthy neonates comprising the controls constituted the material for the study. Levels of nucleated RBCs per 100 WBCs were determined from both the groups and compared.

Results: No significant difference was observed between the control and the study group with respect to birth weight. The mode of delivery (normal/instrumental/cesarean) was statistically significant with a $P = 0.05$. The mean Apgar scores between the study group and the control group showed a $P = 0.001$ which was statistically significant. Nucleated RBCs (NRBCs) on 100 WBCs showed a mean value of 15.74 and standard deviation (SD) of 7.89 in the study group. The control group showed a mean value of 1.55 and SD of 0.78. The $P = 0.001$ was statistically significant and, therefore, a good predictor for birth asphyxia.

Conclusion: Early NRBC count in cord blood is an effective, simple, cost effective baseline diagnostic tool for detecting neonatal asphyxia.

Key words: Early diagnosis, Nucleated red blood cell count, Perinatal asphyxia

INTRODUCTION

Birth asphyxia-hypoxic ischemic insult has been incriminated as one of the most important causes of perinatal mortality. National neonatal - perinatal database suggests that perinatal asphyxia contributes to 20% neonatal deaths in India. Perinatal asphyxia of moderate grade is defined as slow, gasping breathing or the Apgar score of 4-6 and

severe asphyxia as no breathing or the Apgar score of 0-3 at 1 min of life.¹

The World Health Organization defines birth asphyxia as “failure to initiate and sustain breathing at birth” with the Apgar score of <7 at 1 min of life.²

In developing countries, intrapartum hypoxic-ischemic injuries appear to be more common, resulting in a huge burden of disabilities.³⁻⁵

Approximately 8% of the total global pediatric mortalities (age <5 years) are due to birth asphyxia making it a serious problem in developing countries where the conditions are bad in terms of awareness as well as infrastructure.⁶

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Globally, hypoxia of the newborn (birth asphyxia) or the fetus ("fresh stillbirth") is estimated to account for 23% of the 4 million neonatal deaths and 26% of the 3.2 million stillbirths each year.⁶ Majority of asphyxial insults occur in the antepartum or intrapartum periods as a result of placental insufficiency.⁷ Detection of nucleated red blood cells (NRBCs) in cord blood allows early prediction of development and severity of birth asphyxia-hypoxic ischemic insult as this parameter is related to neurodevelopment.⁸

NRBCs are primarily produced in the fetal bone marrow in response to erythropoietin and are stored in the marrow as reticulocytes and mature erythrocytes. They are normally seen in the blood of neonates.⁹ The levels of NRBCs per 100 white blood cells (WBCs) correlates with acute as well antepartum asphyxia and can be used as a reliable index of birth asphyxia and early neonatal outcome.¹⁰

Count of NRBCs per 100 WBCs is a simple marker for presence and assessment of severity of asphyxia as it is an early outcome and has a direct correlation with increased stress and infection.¹¹

NRBC count is also a useful tool for prediction of brain damage and the expected course in hypoxic induced encephalopathy patients.

MATERIALS AND METHODS

A prospective case-control study was conducted on asphyxiated and non-asphyxiated term neonates from the neonatal intensive care unit and post-natal wards of Adichunchanagiri Institute of Medical Sciences, B.G Nagara, Karnataka.

Cases and controls included asphyxiated and non-asphyxiated neonates. Cord blood samples from 50 asphyxiated neonates comprising the cases and 50 healthy neonates comprising the controls constituted the material for the study.

Informed parental consent was obtained in all cases. Inclusion criteria for the study group included gestational age ≥ 37 weeks, the presence of intrapartum signs of fetal distress (on fetal monitoring and thick meconium staining of the amniotic fluid), Apgar score of <7 at 1 min of life. Inclusion criteria for the control group included the gestational age of >37 weeks, birth weight >2500 g, Apgar score >7 at 1 and 5 min, normal intrapartum fetal heart rate pattern, and clear amniotic fluid.

RESULTS

Mean birth weight in the study group was 2.87 kg with standard deviation (SD) of 0.44, whereas mean birth weight in the control group was 2.91 kg with the SD of 0.38. There was no significant difference between the control and the study group with respect to birth weight (Tables 1 and 2).

The statistical value for mode of delivery (normal/instrumental/cesarean) was significant with a $P = 0.05$ (Table 3).

All the neonates in the study group had the Apgar score of <7 at 1 min and had a $P < 0.001$.

The mean Apgar scores between the study group and the control group showed a $P = 0.001$ which was statistically significant (Table 4).

NRBCs on 100 WBCs showed a mean value of 15.74 and SD of 7.89 in the study group. The control group showed a mean value of 1.55 and SD of 0.78. The $P = 0.001$ was statistically significant and, therefore, a good predictor for birth asphyxia (Table 5).

Table 1: Birth weight distribution pattern of neonates

Birth weight (kg)	n (%) (n=50)	
	Cases	Control
2-2.5	8 (16)	3 (6)
2.5-3	27 (54)	29 (58)
3-3.5	11 (22)	16 (32)
>3.5	4 (8)	2 (4)
Total	50 (100)	50 (100)
Mean \pm SD	2.87 \pm 0.44	2.91 \pm 0.38

SD: Standard deviation

Table 2: Comparative mean birth weight pattern of cases versus controls

Cases (n=50)		Control (n=50)		P value
Mean	SD	Mean	SD	
2.87	0.44	2.91	0.38	0.591

Table 3: Mode of delivery in cases versus controls

Mode of delivery	n (%) (n=50)	
	Cases	Controls
Normal	24 (48)	34 (68)
Forceps	2 (4)	-
Vacuum	8 (16)	-
LSCS	16 (32)	16 (32)
Total	50 (100)	50 (100)

LSCS: Lower segment cesarean section

NRBCs (>6 per 100 WBCs) showed a sensitivity of 93.48%, specificity of 98.15%, positive predictive values of 97.7, and negative predictive values of 94.64 (Table 6).

The incidence of meconium-stained amniotic fluid was significantly more in the study group as compared with controls with a $P = 0.001$.

DISCUSSION

In the present study, NRBC count on 100 leucocytes and absolute NRBC in neonates with asphyxia and healthy controls was determined. They were significantly higher in neonates with birth asphyxia. Other contributory causes of increased NRBC count include prematurity, maternal diabetes, congenital infections, cyanotic heart diseases, and pre-eclampsia. The neonates with these conditions were excluded from this study. Several studies have been conducted to evaluate markers that help to diagnose and grade perinatal asphyxia. The present study focused on

the efficacy of a simple and cost effective baseline investigation like estimation of NRBCs to diagnose perinatal asphyxia in a rural hospital where facilities for advanced diagnostic techniques to predict perinatal asphyxia are not available or affordable.

The relation between Apgar score of 1 and 5 in the cases and controls is highly statistically significant. Lower Apgar scores were seen in the study group as observed by Boskabadi *et al.*¹¹

Birth asphyxia showed a statistically significant association with meconium-stained amniotic fluid which is one the signs of fetal distress *in utero* due to asphyxia.

The relation between asphyxia and NRBCs has been studied by many study groups. In the present study, significant statistical difference was noted between the cases and controls in the terms of NRBCs in the cord blood with a $P = 0.001$.¹¹ These results were comparable to the study by Boskabadi *et al.*¹¹

CONCLUSION

Birth asphyxia can be predicted based on NRBCs, and accordingly interventions can be started. Early NRBC count in cord blood is an effective, simple, cost effective baseline diagnostic tool for detecting neonatal asphyxia. It is a special boon in a rural care center, where advanced diagnostic modalities are unaffordable or inaccessible.

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Table 4: Distribution pattern of Apgar score in cases versus controls

Apgar score	n (%) (n=50)	
	Cases	Control
Apgar score at 1 min		
0-3	7 (14)	
4-6	43 (86)	
≥7	-	50 (100)
Apgar score at 5 min		
0-3	-	
4-6	14 (28)	
≥7	36 (72)	50 (100)

Table 5: Mean NRBCs in cases and controls

Statistical indices	NRBC'S/100 WBCs (n=50)	
	Cases	Control
Mean	15.74	1.55
SD	7.89	0.78

NRBC: Nucleated red blood cells, WBC: White blood cells

Table 6: Statistical values of NRBCs for predicting HIE

NRBCs (>6/100 WBCs)				
Sensitivity	Specificity	PPV	NPV	AUROC
93.48%	98.15%	97.7	94.64	0.989

NRBC: Nucleated red blood cells, WBC: White blood cells, PPV: Positive predictive value, NPV: Negative predictive value, HIE: Hypoxic induced encephalopathy

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Clinico-Pathological Study of 170 Cases of Oral Sub-Mucous Fibrosis

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Abstract

Introduction: Oral sub-mucous fibrosis (OSMF) is a chronic, irreversible, disease of the oral cavity characterized primarily by burning sensation in the mouth particularly while eating spicy food and progressive development of the inability to open mouth (trismus). Very few clinico-pathological study of OSMF has been published from India and the Indian subcontinent.

Materials and Methods: We carried out a retrospective hospital-based clinico-pathological study of 170 patients diagnosed with OSMF attending the outpatient department of Oral and Maxillofacial Surgical Hospital, Rajkot, India and compared our findings with those findings published in earlier studies.

Results: In our study of 170 patients with OSMF, male:female ratio was 23.28:1. The highest incidence of OSMF was in the age group 21-30 years (mean 22.70 years), the youngest patient being 8 years old and the oldest 60 years. Inter-incisal distance (IID) varied between 00.00 CM (complete trismus) and 3.70 CMS, average IID being 2.70 CMS. The burning sensation in the mouth was the most common complaint (94.11% patients) followed by vesiculations and ulcerations (83.52% patients). Duration of disease was 2-5 years Buccal mucosa was involved bilaterally in 98.82% patients and palatal mucosa in 92.94% patients. No correlation was found between histopathological and clinical findings.

Conclusions: Incidence of OSMF is rising with the younger population getting involved into pathological oral habits such as tobacco and supari (Areca nut) chewing. This article gives an insight into OSMF and adds to its clinico-pathological profile.

Key words: Mouth diseases, Mouth neoplasms, Oral pathology, Oral sub-mucous fibrosis, Retrospective study

INTRODUCTION

Oral sub-mucous fibrosis (OSMF) is a chronic, progressive, irreversible, scarring disease, which predominantly affects the people of South-East Asian origin. This condition was described first by Schwartz¹ while examining five Indian women from Kenya, to which he ascribed the descriptive term “atrophia idiopathica (tropica) mucosae oris.” Later in 1953, Joshi² from Bombay (Mumbai) redesignated the condition as OSMF, implying predominantly its histological nature.

Described for the first time in detail in the year 1966 by Pindborg and Sirsat,³ OSMF is now definitely being

recognized as a disease of the Indian subcontinent occurring more commonly in countries such as India, Pakistan, Sri Lanka, Nepal, China, and few countries where Indians have migrated like Europe and North America. Very few publications and possibly none clinico-pathological study, on OSMF, has emanated from Western Countries because of the paucity of cases. Until 2008, only 39 cases have been reported from Europe and Canada, including 3 cases reported by Auluk *et al.*⁴

Recent epidemiological data indicates that the number of cases of OSMF has raised rapidly in India from an estimated 250,000 cases in 1980 to 2 million cases in 1993. That figure has crossed 10 million in the year 2013.⁵ In future, this figure is likely to increase many folds.

The number of gutkha consumers in India is, also, rising alarmingly. Prior to 2000, the incidence of OSMF in patients visiting dental surgeons was 0.2-1%, mostly in the age group of 45-54 and sex ratio of 1:3 (male-female).

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After 2000, there has been a 2-5% jump in the incidence of OSMF, mostly in the age group of 15-35 years.

Patients present themselves to the clinician treating OSMF with two major complaints: Burning sensation in the mouth, particularly while eating spicy food and progressive inability to open mouth fully (Trismus).

Epidemiological data and intervention studies suggest that areca nut (Supari) is the main etiological factor for OSMF.⁶⁻¹⁶ Areca nut is believed to be the fourth most addictive substance in the world¹⁷ and is also associated with dependency syndrome.¹⁸ Other etiological factors suggested are chillies, lime, tobacco, nutritional deficiencies such as iron, zinc, and copper, immunological disorders, collagen disorders, and genetic predisposition.

MATERIALS AND METHODS

In this retrospective hospital-based study, patients attending the outpatient Department of Oral and Maxillofacial Surgery Hospital, Rajkot, Gujarat State, India were screened for the presence of OSMF based on pre-determined clinical criteria mainly, burning sensation in the mouth particularly while eating spicy hot food and progressively increasing inability to open mouth (Trismus). Complete records were maintained detailing, apart from routine information such as name, age, and sex, areca nut and tobacco chewing or any other tobacco habit, duration of habit, how long areca nut and tobacco was kept in the mouth, other oral hygiene conditions, the amount of consumption of tobacco and areca nut per day, age since habit was initiated. Inter-incisal distance (IID) (mouth opening) was measured with calipers. All cases of OSF were classified into four stages based on IID.

Very early stage (Stage 1): IID = >3.50 CMS

Early stage (Stage 2) IID = 2.5-3.5 CMS

Moderately advanced stage (Stage 3) IID = 1.5-2.5 CMS

Advanced stage (Stage 4) IID = <1.5 CMS

Radiological examinations were carried out whenever found necessary. Blood and urine examination were carried out for all patients with particular attention to anemia, iron and B-complex deficiency, and protein deficiency.

Inclusion Criteria

1. Patient with chief complaint of burning sensation in the mouth while eating spicy foods and progressive inability to open mouth fully
2. Positive history of consumption or chewing of tobacco or related products
3. Clinical examination shows ulcerations and vesiculations

of the oral mucosa and / or fibrous bands running across buccal mucosa in the vertical direction or horizontal direction in the palate

4. Confirmation of OSMF by biopsy.

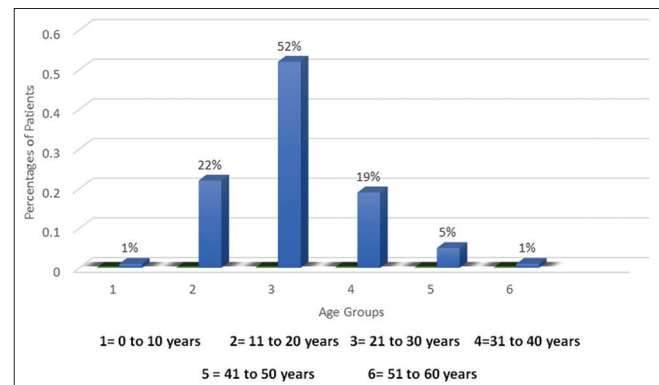
Exclusion Criteria

1. Presence of frank oral squamous cell carcinoma (OSCC)
2. The presence of severe systemic disease.

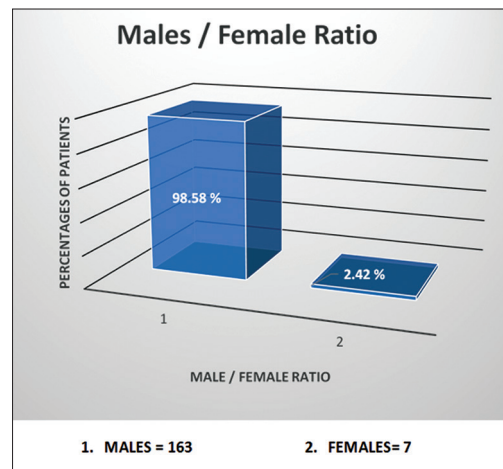
RESULTS

Age and Sex (Graphs 1 and 2)

Totally 170 patients were included in this study, out of which 163 patients were found to be males while only 7 patients were found to be females. Out of 170 patients, the youngest patient was 8 years old while the oldest patient was 60 years old, the average age of the patient being 22.70 years. Percentage wise patients between 0 and 10 years was 1%, 11 and 20 years old patients were 22%, 21 to 30 years patients were 52%, 31 to 40 years old patients were 19%, 41 to 50 years old patients were 5% while 51 to 60 years patients were 2%.



Graph 1: Percentages of patients in each age group



Graph 2: Male to female ratio

Sites of Involvement (Graph 3)

In 170 patients examined, 168 patients showed the bilateral involvement of buccal mucosa, lip mucosa was involved in 108 patients while palatal mucosa was involved in 158 patients. The floor of the mouth was seen to be involved in 109 patients while tongue was involved in 98 patients. The most patients showed multiple sites of involvement in the disease process.

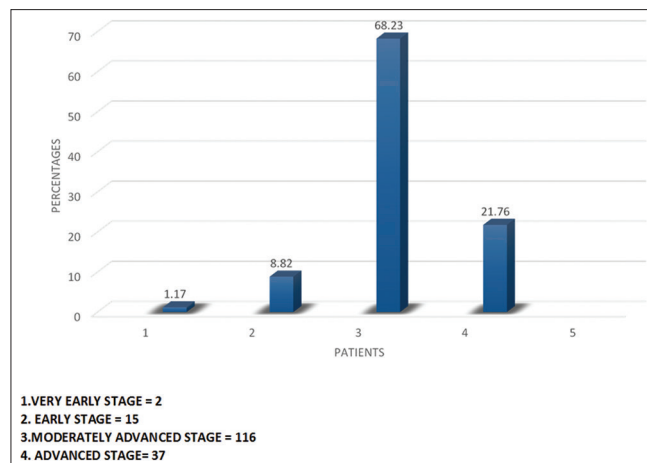
IID

When clinically examined, IID, maximum mouth opening was 3.70 CMS while minimal IID was found to be 0.00 CMS (total trismus). The average mouth opening was 1.79 CMS.

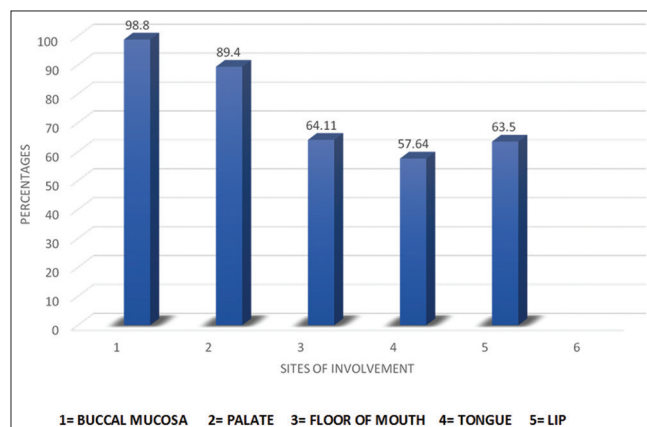
Clinical Presentations (Graph 4)

Two patients were seen to be in very early stage, early stage of disease was seen in 15 patients. OSMF was seen moderately advanced stage in 116 patients while advanced stage of disease was noticed in 37 patients.

Duration of disease refers the time lapse that occurs between patient noticing the first symptoms of OSF



Graph 3: Percentages of patients in each clinical grading



Graph 4: Sites of involvement

and subsequent consultation with the treating clinician. Duration of disease among 170 patients was found to be between 2 and 5 years with average being 3.5 years.

Presenting Symptoms (Graph 5)

Out of 170 patients, 160 patients had a chief complaint of burning sensation in the mouth and inability to open mouth fully. Vesications and ulcerations were found in 142 patients while dryness of mouth was the chief complaint in 102 patients. Surprisingly stiffness of the cheek was chief complaint only in 11 patients. Most patients had multiple complaints.

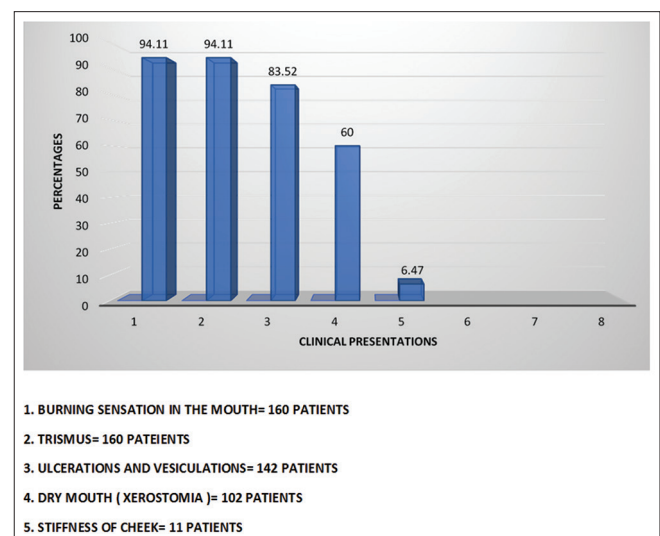
Histopathology (HP) (Graph 6)

On HP examination, all 170 patients ($n = 100\%$) showed various degrees of fibrosis. 36 patients showed no inflammatory changes in the sub-mucosa while 82 patients had mild inflammatory changes in sub-mucosa, moderate inflammation was present in 32 patients, and severe inflammation was present in 20 patients.

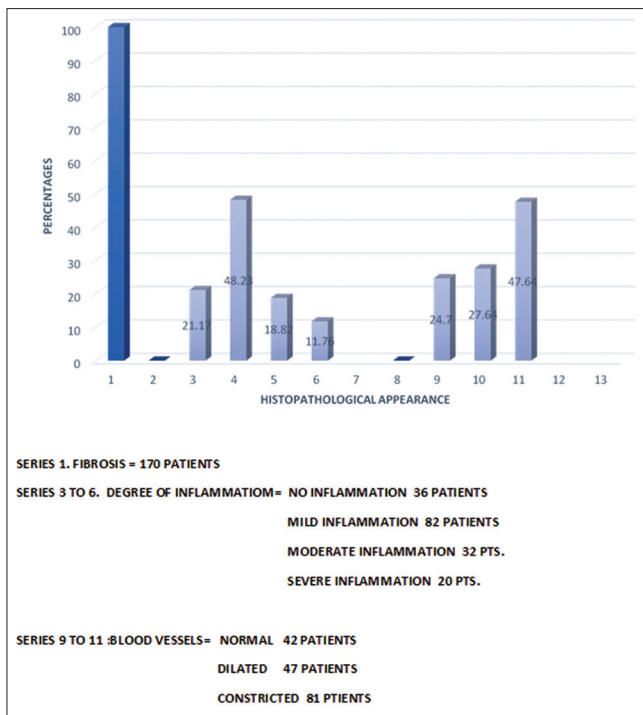
42 patients showed the normal size of the blood vessel while 47 patients had dilated blood vessels. 81 patients showed constricted blood vessels.

Almost all patients belonged to low socio-economic strata and had very low or no education to understand consequences of areca nut or tobacco chewing.

165 patients had habit of chewing mixture of areca nut, tobacco, and lime (known as gutkha or Mava). One patient, the youngest 8 years old had habit of chewing areca nut only while remaining 4 had habit of taking areca nut, tobacco, and lime in green leaf known as paan.



Graph 5: Percentages of patients with various clinical presentations



Graph 6: Percentages of patients showing various histopathological findings

Laboratory tests were carried out in all patients to rule of iron and b-complex deficiency. Since the most patients belonged to low socio-economic strata, the results showed one or more of the following findings:

- Decreased hemoglobin levels
- Decreased iron levels
- Decreased protein levels
- Increased erythrocyte sedimentation rate
- Decreased Vitamin B complex levels.

DISCUSSION

OSMF has also been called as “diffuse OSMF,” “idiopathic scleroderma of mouth,” “idiopathic palatal fibrosis,” “sclerosing stomatitis” and “juxta-epithelial fibrosis.” Pindborg and Sirsat³ gave definition for OSMF as “As an insidious chronic disease affecting any part of the oral cavity and sometimes pharynx, although occasionally preceded by and/or associated with juxta-epithelial inflammatory reaction followed by fibroelastic changes of lamina propria with epithelial atrophy leading to stiffness of oral mucosa and causing trismus and inability to eat”. The WHO definition for an oral precancerous condition is a generalized pathological state of oral mucosa associated with a significantly increased risk of cancer accords well with characteristics of OSMF.¹⁹

It is now unequivocally established fact that OSMF is a disease of India and Indian subcontinent where chewing of areca nut and tobacco is almost endemic, and it is pre-

malignant condition leading to OSCC if the habit is not discontinued. In spite of very high prevalence of OSMF in India and Indian subcontinent very few clinico-pathological studies are available in the literature.^{10,20-30}

The discussion on OSMF will be done under following headings:

1. Age
2. Male-female ratio
3. Sites of involvement
4. Presenting clinical symptoms
5. HP.

Age

Study of age is an important prognostic parameter in the clinical study of OSMF because it gives three important informations:

1. Age at which patient was initiated into pathological oral habits such as beetle-nut or gutkha chewing
2. Age at which the patient developed first signs of OSMF and reported for treatment
3. Age at which patient is likely to develop OSCC and accordingly follow-up plan can be charted out.

There is a wide variation in the range of ages as reported by various authors; however, if one studies these reports in details a definite pattern in the incidence of OSMF emerges. Some of the earlier workers have reported the incidence of OSMF within the age group of 30-40 years. As a matter of fact, Pindborg *et al.*³¹ reported average age range as 53.6 years for males and 37.7 years for females. Recent authors, however, report incidence of OSMF mostly in the younger population age ranging from 20 to 30 years.^{2,15,20,22,23,28,32}

In India, OSMF has already been reported in children. In a study reported by Babu *et al.*²⁹ and Trivedy *et al.*³³ on OSMF, 23% of patients were of ages between 14 and 19 years. In separate studies children as young as 4 years³⁴ and 5 years³² old have been diagnosed with OSMF.

In the study reported by us of 170 patients with OSMF, the youngest patient was only 8 years old while the oldest patient was 60 years old, with mean age as 22.70 years (Figures 1 and 2).

Male-Female Ratio

Though earlier studies on OSMF reported female preponderance,^{2,8,9,36-41} more recent publications show male preponderance.^{7,12,20,24,25,27,28,30,40,42-46}

In the present study carried out in Rajkot, Saurashtra region, Gujarat state, there was male preponderance with 163 males and only 7 female patients. The M:F ratio was 23.28:1.



Figure 1: 8-year-old child with oral sub-mucous fibrosis white blanching of oral mucosa of lower lip is visible



Figure 2: 8-year-old child with oral sub-mucous fibrosis. Notice difficulty in opening mouth

Our study corroborates with the findings of Sinor *et al.*⁷ who reported male to female ratio as 29:1 from the city of Bhavnagar, Saurashtra region, Gujarat State. There seems to be a definite preponderance for male patients from Saurashtra region of Gujarat State, where gutkha chewing is almost endemic, and incidence of oral cancer is the highest in India and therefore in the world.

Male predisposition in recent studies could be due to easy accessibility of gutkha and other products to males than females in the Indian Society and probably females feel uncomfortable in purchasing gutkha products. Furthermore, the financial administration is not in the hands of most females limiting their access to such gutkha products, and most females shy away from medical treatment due to various reasons including financial crunch and societal and cultural traditions. One reason for occurrence of OSMF in female patients could be explained on the grounds that most females in the Indian sub-continent suffer from deficiency of iron and B-complex.⁴⁷ However, it needs to be confirmed whether iron and B-complex deficiency is the cause of OSMF in

female patients or it is effect of OSMF as eating ability reduces considerably in OSMF.

Sites of Involvement

It seems the various sites of the oral cavity involved in OSMF depends on many factors such as the type of material chewed, duration of habit, the way material is chewed and finally on the age of initiation of habit. Involvement of the whole of the oral cavity (pan or total involvement) is common in the advanced cases of OSMF.

Most of the clinicians have reported maximum involvement of buccal mucosa followed by palatal mucosa in OSMF.^{28,38,43,48-50} Occasionally floor of the mouth and tongue may get involved in the disease process as in our study in which 64.11% of the patients showed the involvement of floor of the mouth while 57.64% showed the involvement of tongue.

The involvement of buccal mucosa is the most common observation in most studies, including ours, because most of the patients are habituated to keep beetle-quid or gutkha in the buccal vestibule. In such patients next two commonly involved sites are soft palate and uvula. On the other hand, it was observed that those patients who chewed gutkha and other products for longer time and spat it out; fibrosis mostly got developed in the whole of buccal mucosa, parts of labial mucosa, and also the floor of the mouth. Most of the clinicians including Canniff³⁵ have reported OSMF in which fibrosis was in both sides of buccal mucosa or it was extended into soft palate, uvula, pharynx and root of the tongue. But no one has reported fibrosis on very localized on one side of buccal mucosa and other side completely normal.

Presenting Symptoms

The most common complaints which bring patients to clinicians for treatment are two:

1. Burning sensation in the mouth particularly while eating spicy hot food
2. Progressive inability to open mouth fully (trismus).

Most of the patients are not aware of the presence of the disease until they are told about OSMF and its consequences. Patients become aware of the trismus once they fail to put large size food bolus into their mouth. With advancing trismus, patient shift to a liquid diet or tend to push food into their mouth in small amounts by forcefully pushing it between teeth with their fingers. Such patients are known to develop indentations of teeth on their fingers, particularly thumbs.

According to Sabharwal *et al.*,⁵¹ specific presentations by patients with OSMF include the following:

1. Reduction of the mouth opening (trismus)
2. Stiff and small tongue

3. Blanched and leathery floor of the mouth
4. Fibrotic and depigmented gingiva
5. Rubbery soft palate with decreased mobility
6. Blanched and atrophic tonsils
7. Shrunken budlike uvula
8. Sinking of the cheeks, not commensurate with age or nutritional status.

Most investigators reported trismus as the main clinical presentation by the patients.^{3,38,43,52,53} Sitheeque *et al.*⁵⁴ have suggested depigmentation of oral mucosa as an earliest feature to develop in the natural history of OSMF in their study of Sri Lankan preschool children aged 2-3 years.

According to Hayes,³⁴ the most characteristic feature of OSMF is the marked vertical fibrous ridge formation within the cheeks, and board like stiffness of the buccal mucosa³⁴ leading to trismus and difficulty in blowing cheeks. The fibrosis in the soft tissue leads to trismus, difficulty in eating, and even dysphagia as reported by Pundir *et al.* in the year 2010.⁵⁵

Fibrous bands run vertically in the buccal mucosa while they run across the palate horizontally. Fibrous bands, in advanced stages, are visible to naked eyes and palpable under fingers.

Reduced mouth opening, altered salivation, and altered taste sensation were found to be significantly more prevalent in women when compared with men as reported by Hazarey *et al.* in the year 2007.²⁴

Goel *et al.*³⁰ also found that the patients who used pan masala with a greater frequency per day developed OSMF earlier. In other words, daily consumption (frequency) was more significant than the total duration of the habit.

According to Rajendran,⁴⁷ the exact site and extent of the fibrosis and its role in the causation of trismus are determined by several factors. For example, the anatomical and physiological integrity of the underlying musculature is vital for the degree of mouth opening. Based on electron microscopic observations el-Labban and Canniff⁵⁶ reported muscle degeneration in OSMF, the extent of which may significantly affect the already existing trismus in these patients. Equally important is the involvement of the pterygomandibular raphe, a site commonly reported to accentuate the extent of trismus. Another factor is the duration of the disease in the affected individuals, which depends on the subjective evaluation of signs and symptoms. Current views of a protracted and insidious onset of OSMF and its very slow progression make any sort of objective diagnostic criterion difficult, at least in the earlier stages.⁴⁷

HP of OSMF

HP study does not seem to play a much significant role in the diagnosis of OSMF as most clinicians diagnose OSMF based on clinical findings, and it is likely that facilities to carry out HP diagnosis may not be possible under certain adverse circumstances and in under-resourced countries. However, this does not undermine in any way importance of HP studies. Though most clinico-pathological studies did not find any correlation between HP findings and clinical grading, HP studies of OSMF patients is an important diagnostic and prognostic parameter so far as malignant transformation of OSMF is concerned as high percentages of OSMF patient land into frank OSCC, the incidence of OSMF being degraded to OSCC being reported as high as 7-13%.

According to Mukherjee *et al.*,⁵⁷ currently one of the greatest challenges to oral oncobiologists is to determine and identify the degree of tissue damage or stages of various precancerous states of oral tissue and to detect the exact transition of normal tissue to precancerous state. In this current scenario in which clinicians depend more on clinical findings rather than on HP studies, improved immunohistochemical techniques and morphometric analysis of HP images may go help to provide a better diagnosis and early detection of oral cancer.

In our study, we studied three parameters during the HP study of 170 patients.

1. Inflammation
2. Condition of blood vessels
3. Fibrosis.

Mild to moderate inflammation was present in 114 patients while constricted blood vessels were more common, present in 81 patients. All the patients showed an advanced degree of fibrosis. There was no correlation found between HP grading and clinical grading in our study as well.

Since HP of OSMF is non-specific and no correlation has been found between HP grading and clinical grading, possibly ultrasonographic studies may prove to be more reliable diagnostic tool than biopsy in the future.^{58,59}

CONCLUSIONS

In conclusion:

1. OSMF is mainly disease of the Indian sub-continent where chewing areca nut is rampant; however, it is likely to spread in Western countries like the USA and Europe because of migration of areca nut and tobacco chewing people from the Indian sub-continent to these countries

2. There is an urgent need to initiate public health education measures to educate people about these debilitating oral pre-malignant condition before it is too late, particularly in western countries
3. OSMF is definitely established as a pre-malignant oral condition, the range of OSMF degenerating into OSCC is 7-13%
4. OSMF has male pre-ponderance
5. Most patients of OSMF are within age group between 20 and 30 years, but even children as young as 4-5 years are not immune to OSMF
6. There is no correlationship between clinical findings and HP gradings
7. Burning sensation in the mouth while eating spicy hot food and progressively developing inability to open mouth are hallmark of clinical pictures of OSMF
8. Areca nut and its constituents are chief etiological factors in development of OSMF, while other etiological agents such as lime, tobacco, chillies, genetic predisposition act as co-factors
9. Oral Screening for oral pre-cancer and oral cancer should be part of periodic oral examinations.

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Comparison of 0.25% Bupivacaine Plus 2 µg/kg Dexmedetomidine with 0.25% Ropivacaine Plus 2 µg/kg Dexmedetomidine for Caudal Block in Pediatric Lower Abdominal Surgeries: A Randomized, Double-Blinded Study

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Abstract

Introduction: Caudal dexmedetomidine has been used over last few years as an adjuvant with a local anesthetic to prolong the duration of post-operative analgesia in pediatric lower abdominal surgeries. The aim of this study was to compare the duration of post-operative analgesia and sedation with 0.25% bupivacaine plus 2 µg/kg dexmedetomidine versus 0.25% ropivacaine plus 2 µg/kg dexmedetomidine for caudal block in pediatric lower abdominal surgeries.

Materials and Methods: 60 patients of the American Society of Anesthesiologists physical Status I and II, aged 1-6 years undergoing lower abdominal surgeries, were enrolled for the study and divided into two groups as per lottery. In group ropivacaine plus dexmedetomidine (RD) ($n = 30$), 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml normal saline (NS) and in group in bupivacaine plus dexmedetomidine (BD) ($n = 30$), 0.25% bupivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS, were administered caudally following endotracheal intubation. Following completion of surgery and extubation, all patients were monitored in post-anesthesia care units and duration of post-operative analgesia and sedation was assessed by face, legs, activity, cry, pull score, and Ramsay sedation scale, respectively.

Result and Observation: The duration of caudal analgesia recorded was 16.633 (15.881-17.385) h BD group and 14.7 (14.06-15.43) h in RD group, and the difference is a statistically highly significant ($P < 0.001$). The mean duration of sedation in BD group was 270 (240-300) min and in RD group was 266 (236.27-295.73) min, but the difference is statistically insignificant ($P > 0.05$). We did not evaluate the emergence time and emergence behavior score, time to first micturition in the post-operative period.

Conclusion: 1 ml/kg of 0.25% BD 2 µg/kg in 1 ml NS provide longer duration of post-operative analgesia (but similar duration of sedation) than 1 ml/kg of 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS for caudal block for lower abdominal surgeries in pediatric-aged 1-6 years.

Key words: Bupivacaine, Caudal analgesia, Caudal dexmedetomidine, Pediatric lower abdominal surgery, Post-operative period, Ropivacaine

INTRODUCTION

Historically, children have been under treated for pain because of the wrong notion that they neither suffer nor

feel pain or respond to or remember the painful experiences to the same degree as adults do.¹ It is now established that newborn infants, even pre-term, can appreciate the pain and react to it with tachycardia, hypertension, and neuroendocrine response.² As pain is very difficult to assess in the pediatric population, post-operative pain is often undertreated in this age group.³ Regional anesthetic techniques reduce the overall intraoperative requirement of both inhaled and intravenous (IV) anesthetic agents for general anesthesia and allow more rapid return of consciousness while providing effective post-operative pain relief with minimal sedation.⁴

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The caudal epidural block is a commonly used regional anesthetic technique for intraoperative as well as post-operative analgesia for infra-umbilical surgeries in pediatric age group. It is one of the oldest and the most popular regional block performed in pediatric anesthesia.⁵ It is preferred due to its safety and ease of administration and reliable post-operative analgesia for abdominal surgeries.⁶ The main disadvantage of caudal analgesia is the short duration of action after a single injection.⁷ Caudal catheters for continuous infusion or repeated doses are not preferred in children due to the increased risk of infection.⁸

Both bupivacaine and ropivacaine are long-acting, amide local anesthetic with almost similar pK_a (8.1). Ropivacaine, in comparison to bupivacaine blocks pain transmitting A-delta and C fibers to a greater degree than A-beta fibers controlling motor function.^{9,10} It has a wider margin of safety, is less cardiotoxic and neurotoxic and similar duration of analgesia.^{11,12} As compared with bupivacaine, ropivacaine undergoes lower systemic absorption from the caudal epidural space in children, so persists for longer duration.¹³

The use of various adjuvants, such as epinephrine, opioid, clonidine, dexamethasone, ketamine, and α_2 agonists, has been done in prolonging the duration of single shot caudal analgesia in children.¹⁴ In recent years, studies are being conducted to evaluate the use of dexmedetomidine as adjuvant in regional anesthesia to improve the quality and duration of analgesia. Dexmedetomidine is a novel and highly selective α_2 agonist. It has an eight-fold greater affinity for α_2 adrenergic receptors than clonidine and much less α_1 effects. It has sympatholytic, analgesic, and sedative effects and is remarkably free from side effects except for manageable hypotension and bradycardia.^{15,16} Dexmedetomidine acts on the spinal cord, by activating of α_{2A} and α_{2C} adrenoceptors, situated in superficial dorsal horn neurons, directly reducing pain transmission by reducing the release of pronociceptive transmitter, substance P, and glutamate from primary afferent terminals and by hyperpolarizing spinal interneurons via G-protein-mediated activation of potassium channels.¹⁵ Prolongation of sensory blockade in caudal anesthesia by dexmedetomidine can also be attributed to its vasoconstrictor effect on blood vessels which in turn prevents its systemic uptake.

Very few studies have been done to evaluate the effect of dexmedetomidine as adjuvant to bupivacaine or ropivacaine in caudal analgesia in children. So, in this study, we have compared 1 ml/kg of 0.25% bupivacaine plus 2 µg/kg dexmedetomidine with 1 ml/kg of 0.25% ropivacaine plus 2 µg/kg dexmedetomidine for caudal analgesia in children undergoing lower abdominal surgeries.

Aims and Objective

1. To compare duration of post-operative analgesia of dexmedetomidine (2 µg/kg) plus 0.25% bupivacaine (1 ml/kg) with dexmedetomidine (2 µg/kg) plus 0.25% ropivacaine (1 ml/kg) for pediatric caudal block
2. To compare duration of sedation of dexmedetomidine (2 µg/kg) plus 0.25% bupivacaine (1 ml/kg) with dexmedetomidine (2 µg/kg) plus 0.25% ropivacaine (1 ml/kg) for pediatric caudal block
3. To evaluate any other relevant observations, if they arise.

MATERIALS AND METHODS

This prospective, randomized, parallel, double-blinded study, after obtaining institutional ethical clearance and informed parental consent, included 60 patients of American Society of Anesthesiologists (ASA) physical Status I and II, aged 1-6 years undergoing lower abdominal surgeries. In our study, we included children between 1 and 6 years of age as there is difficulty in identifying caudal epidural space in children >7 years due to the fusion of sacral vertebrae and reduction in the size of sacral hiatus.¹⁷ Study exclusion criteria included ASA physical Status III and IV, a history of developmental delay or mental retardation, which could make observational pain intensity assessment difficult, a known or suspected coagulopathy, a known allergy to any of the study drugs and any signs of infection at the site of proposed caudal block. The children were randomly allocated into two groups as per lottery. In Group RD ($n = 30$), 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml normal saline (NS) and in Group BD ($n = 30$), 0.25% bupivacaine 1 ml/kg with dexmedetomidine 2 µg/kg in 1 ml NS, were administered caudally. We have used 1 ml/kg of 0.25% ropivacaine or 0.25% bupivacaine as the local anesthetic drugs in our study which has been supported by evidence from further studies.¹⁷⁻²¹ The selected caudal dose of dexmedetomidine (2 µg/kg) was based on previous study reports in pediatric patients.^{19,20} Sample size calculation was done based on data obtained from two previous pilot studies^{19,20} taking into account the duration of analgesia from these two studies and using the online calculator available at <http://www.stat.ubc.ca/~rollin/stats/ssize/n2.html>. It was calculated that a sample size of 28 people per group would permit a Type 1 error of $\alpha = 0.05$ with power of 0.8 (statistical difference was defined as $P < 0.05$). So, we took a sample size of 30 patients per group. All health-care personnel providing direct patient care, the subjects, and their parents or guardians were blinded to the caudal medications administered. The anesthesiologist who administered the caudal drugs were blinded to the study groups as well as the drugs used. Sterile syringes containing study drugs

were prepared by another anesthesiologist not concerned or participating in the study. The intraoperative and post-operative monitoring was done by the same anesthesiologist who administered the caudal drugs but was unaware of the content of the syringes.

Patients were given intranasal midazolam (0.3 mg/kg) spray as premedication approximately 5 min prior to anesthetic induction. All the baseline parameters, such as the pulse rate (PR), mean arterial pressure (MAP), peripheral oxygen saturation (SpO₂), were observed and recorded. All patients underwent a standard inhalation induction with sevoflurane in oxygen followed by insertion of an IV cannula and administration of a neuromuscular blocking agent to facilitate endotracheal intubation. After endotracheal intubation, patients were placed in the lateral decubitus position, and a single-dose caudal block was performed according to the Group BD or RD under sterile conditions using a 23 G needle and standard loss of resistance technique. Skin incision was allowed 15 min after caudal block were performed. Maintenance of anesthesia was done with sevoflurane-oxygen-N₂O and patients were mechanically ventilated. Heart rate and blood pressure were recorded before the operation and every 5 min interval after the start of procedure until 30 min. An increase in PR or MAP within the 10-15 min of the start of surgical procedure were deemed as a failure of caudal anesthesia, and rescue analgesia in the form of injection fentanyl was administered (2 µg/kg) IV. Failed caudal blocks were excluded from the study. IV fluids in the form of Isolyte-P® solution were administered according to body weight and the fasting status. The total duration of surgery for each case and intraoperative complications were noted. At the end of the surgical procedure, all the anesthetic gasses were turned off, and the patients were extubated after reversal of neuromuscular blockade with injection neostigmine (50 µg/kg) and injection glycopyrrolate (10 µg/kg). All the patients were observed for 24 h in post-anesthesia care units.

MAP, PR, and SpO₂ were recorded at a 15 min, 30 min, and 60 min after extubation and thereafter hourly up to the maximum duration of analgesia.

Using face, legs, activity, cry, consolability (FLACC) score,¹⁹ pain intensity was assessed at 15 min after extubation and thereafter hourly until FLACC score were ≥4 for all patients. If the FLACC pain scale score was noted to be 4 or more, injection paracetamol (15 mg/kg) slow IV was administered as rescue analgesic. The duration of adequate post-operative analgesia was deemed from the time of extubation to the time when the FLACC pain scale score was noted to be 4 or more.

Duration of sedation was assessed by Ramsay sedation scale²² at 15 min, 30 min, and 60 min after extubation and thereafter hourly until the Ramsay sedation score became 1 in all patients. Duration of post-operative sedation was deemed from the time of extubation until Ramsay sedation score was 2 or less.

The occurrence of post-operative complications, such as post-operative nausea vomiting, respiratory depression, hypotension, and bradycardia, were also noted.

Statistical Analysis

Statistical analyzes were carried out using the statistical software “Graph Pad InStat version 3.0.” Data are presented as a mean and standard deviation for the demographic parameter, duration of post-operative analgesia, and duration of sedation. To estimate differences in normally distributed continuous outcome variables, the “unpaired Student’s *t*-test” for independent samples was used. A *P* < 0.05 was considered statistically significant.

RESULTS AND OBSERVATION

Demographic Parameters

In this randomized, prospective, double-blinded study, no difference could be detected between two groups from the data of 60 children regarding the patient profile. Demographic data of patients are given in Table 1. There was no significant difference in the groups in terms of age, body weight, gender distribution, and duration of surgery.

Intraoperative Hemodynamic Variation

Heart rate

As shown in Figure 1, changes in mean heart rate in both the groups are comparable and statistically insignificant (*P* > 0.05). Both the groups showed gradual decreasing trends in mean heart rate from the pre-operative baseline

Table 1: Comparison of demographic parameters

Demographic parameters	Group BD	Group RD	<i>P</i> value
Age (months)	36±6.3	34±6.9	0.2458
Weight (kg)	16±2.3	15.3±3	0.3147
Sex (M:F)	20:10	23:07	
ASA physical status I/II (<i>n</i>)	25:5	24:6	
Duration of surgery (min)	45.5±15.3	44±16.1	0.7128
Surgical procedures			
Colonic pull-through	7	5	
Undescended testicle	3	3	
Lord’s plication	5	6	
Inguinal hernia repair	8	10	
Umbilical hernia repair	2	1	
Colostomy	2	1	
Hypospadias repair	3	4	

BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine, ASA: American Society of Anesthesiologists

value up to 30 min intraoperatively, which may be attributable to caudal dexmedetomidine.

Blood pressure

As shown in Figure 2, changes in MAP in both the groups are comparable and statistically insignificant ($P > 0.05$). Both the groups showed gradual decreasing trends in MAP from the pre-operative baseline value up to 30 min intraoperatively, which may be attributable to caudal dexmedetomidine.

Post-operative Hemodynamic Variation

Heart rate

As shown in Figure 3, changes in post-operative mean heart rate in Group BD and Group RD are comparable from 15 min until the 13th h and are statistically insignificant ($P > 0.05$). The mean heart rate at the 5th h was slightly higher than the mean heart rate at the 4th h in both the groups, which was probably due to the patients becoming awake in both the groups (the mean duration of sedation in Groups BD was 270 ± 30 min and in

Group RD was 266 ± 29.73 min). There was statistically significant ($P > 0.05$) difference in mean heart rate between the two groups at the 14th, 15th, and 16th h. This rise in heart rate in Group RD at the 14th, 15th, and 16th h was probably due to pain (the duration of analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h).

Blood Pressure

As shown in Figure 4, changes in post-operative MAP in Group BD and Group RD are comparable from 15 min until the 16th h and are statistically insignificant ($P > 0.05$). The MAP at the 5th h was slightly higher than the MAP at the 4th h in both the groups, which was probably due to the patients becoming awake in both the groups (the mean duration of sedation in Groups BD was 270 ± 30 min and in Group RD was 266 ± 29.73 min). There was a slight increase in MAP at the 16th h in the Group RD and 18th h in Group BD, which may be attributable to pain (the duration of analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h).

Duration of Post-operative Analgesia

As shown in Table 2 and Figure 5, the duration of post-operative analgesia in Group BD was 16.633 ± 0.752 h and in RD Group was 14.7 ± 0.64 h, and the difference is statistically significant ($P < 0.0001$).

FLACC score (Figures 6 and 7)

As shown in Figure 6, most patients in Group BD had FLACC score of 4 at 17th and 18th hr. But as shown in

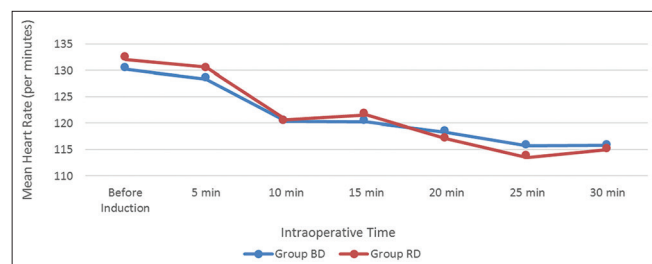


Figure 1: Comparison of intraoperative heart rate

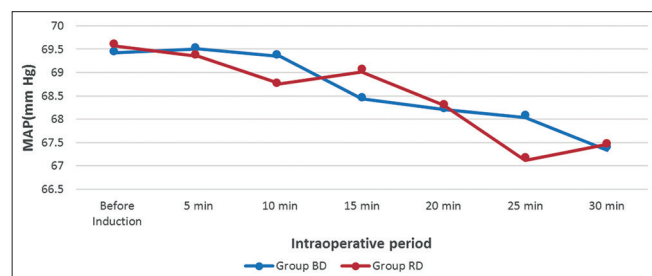


Figure 2: Comparison of intraoperative blood pressure

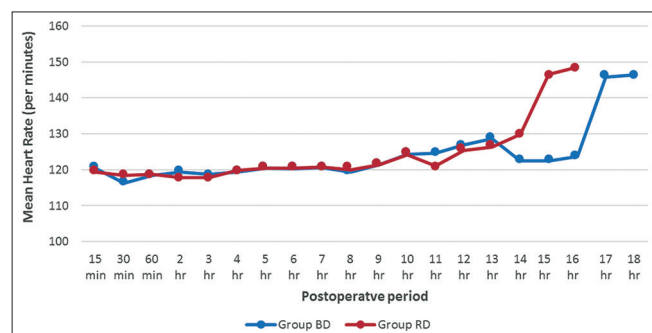


Figure 3: Comparison of post-operative heart rate

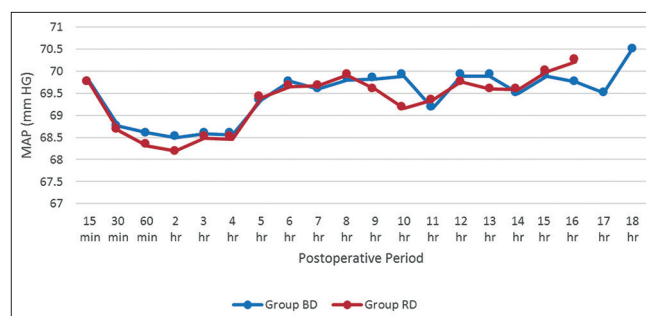


Figure 4: Comparison of post-operative blood pressure

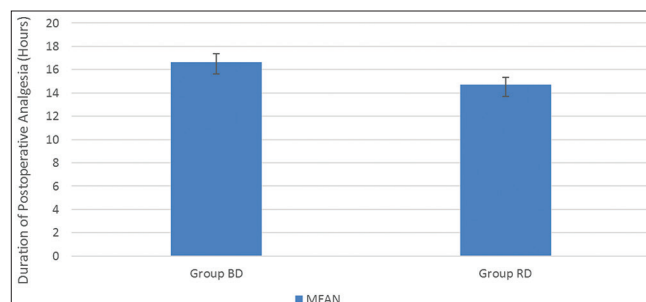


Figure 5: Comparison of duration of post-operative analgesia

Figure 7, most patients in Group RD had FLACC score of 4 at the 15th and 16th hr.

Duration of Sedation

Table 3 and Figure 8 show a comparison of the mean duration of sedation in the Groups BD and Group RD. The mean duration of sedation was greater in Group BD than Group RD, but the difference is statistically insignificant (>0.05).

Ramsay sedation score

As shown in Figures 9 and 10, most of the patients in both Group BD and RD remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min.

DISCUSSION

In caudal block, the duration of analgesia depends on concentration and volume local anesthetics as well as the concentration of the adjuvant used. The volume of local anesthetic required in caudal block is directly proportional to the weight; larger volume of the drug increases the cephalad spread leading to higher levels of block.²³

In a study on caudal analgesia using 0.25% bupivacaine, there was significant prolongation in the duration of caudal analgesia following the addition of dexmedetomidine to 0.25% bupivacaine.²⁰ In another similar study using 0.25% ropivacaine, there was a significant prolongation of the duration of analgesia following the addition of dexmedetomidine to 0.25% ropivacaine for caudal blocks.²⁴ El-Feky and El Abd²⁵ used dexmedetomidine (1 µg/kg) or fentanyl (1 µg/kg), and Bhaskar *et al.*²¹ used dexmedetomidine (2 µg/kg) and fentanyl (2 µg/kg) as caudal adjuvant; in

Table 2: Comparison of duration of post-operative analgesia

Duration of analgesia (h)				P value
Group BD		Group RD		
Mean	SD	Mean	SD	
16.633	0.752	14.7	0.64	0.0001

SD: Standard deviation, BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine

Table 3: Comparison of mean duration of sedation

Duration of sedation (min)				P value
Group BD		Group RD		
Mean	SD	Mean	SD	
270	30	266	29.73	0.6059

SD: Standard deviation, BD: Bupivacaine plus dexmedetomidine, RD: Ropivacaine plus dexmedetomidine

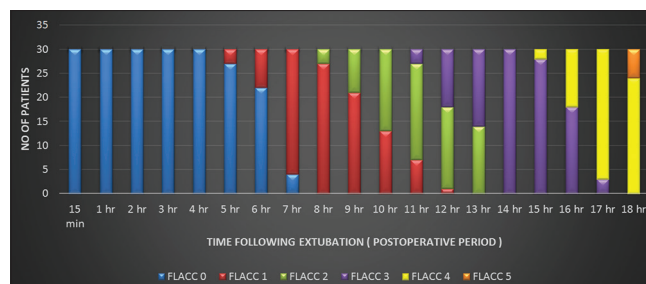


Figure 6: Face, legs, activity, cry, consolability (FLACC) pain score of patients in group bupivacaine plus dexmedetomidine in the post-operative period. Most patients had FLACC score of 4 at 17th and 18th h

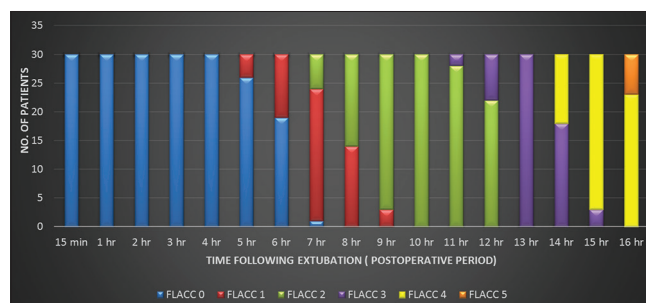


Figure 7: Face, legs, activity, cry, consolability (FLACC) pain score of patients in group ropivacaine plus dexmedetomidine in the post-operative period. Most patients had FLACC score of 4 at the 15th and 16th h

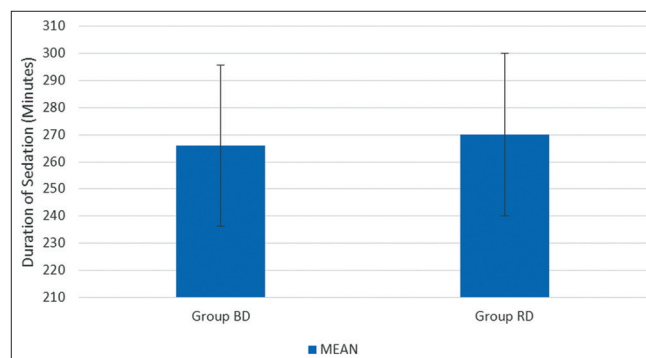


Figure 8: Comparison of duration of sedation (MEAN ± SD)

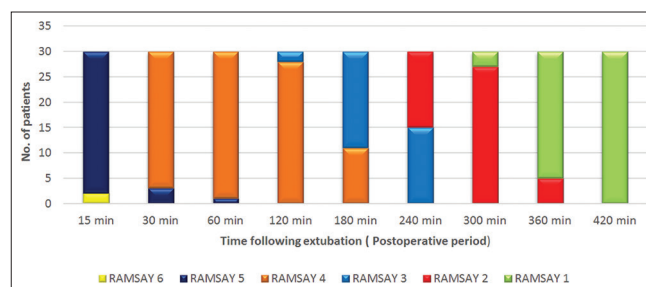


Figure 9: Ramsay sedation score of patients in group bupivacaine plus dexmedetomidine in the post-operative period. Most of the patients remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min

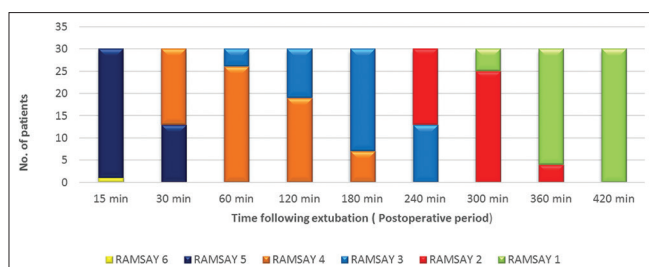


Figure 10: Ramsay sedation score of patients in group ropivacaine plus dexmedetomidine in the post-operative period. Most of the patients remained co-operative, oriented, and calm at 300 min, whereas most of the patients became anxious and agitated or restless, or both at 420 min

both the studies, the duration of caudal analgesia was significantly prolonged with dexmedetomidine as compared to fentanyl, with comparable and stable hemodynamic, lower consumption of post-operative analgesics, and similar levels of sedation. Dexmedetomidine has been used in the range of 1.5-2 µg/kg without any incidence of neurological deficits and without any significant side effect.^{19,22,26}

In our study, we compared the effect 2 µg/kg of dexmedetomidine when added to 1 ml/kg of 0.25% ropivacaine and 1 ml/kg of 0.25% bupivacaine for caudal block in pediatric patients undergoing lower abdominal surgeries and found out that the duration of caudal analgesia recorded was 16.633 (15.881-17.385) h in bupivacaine plus dexmedetomidine (BD) group and 14.7 (14.06-15.43) h in RD group with a highly significant $P < 0.001$.

El-Hennawy *et al.*¹⁹ used dexmedetomidine 2 µg/kg and 0.25% bupivacaine caudally and found the duration of caudal analgesia to be 16 (14-18) h; similarly, Anand *et al.*²⁴ used dexmedetomidine 2 µg/kg with 0.25% ropivacaine and found that the duration of caudal analgesia was 14.5(13.90-15.09) h, in both the studies the duration of analgesia obtained, was similar to our study result.

Manohar and Yachendra²⁷ used 1 µg/kg dexmedetomidine with 0.25% bupivacaine and 0.25% ropivacaine caudally and found the duration of analgesia to be 532.67 (493.66-571.68) min in BD group and 497 (473.79-520.21) min in RD group. The lower duration of analgesia noted in this study was probably due to the use of lower dose 1 µg/kg of dexmedetomidine.

Saadawy *et al.*,²⁰ in a similar study, on caudal analgesia using 0.25% bupivacaine and 1 µg/kg dexmedetomidine showed a longer duration of caudal analgesia of 18.5 (15.7-21.3) h than our study which was probably because of the wider intervals at which pain score was assessed (6, 8, 10, 12,

16, 20, and 24 h post-operatively) and due to this long interval between subsequent determination of pain score, the estimation of analgesic duration may have been faulty.

Bhaskar *et al.*²¹ used ropivacaine 0.2% with 1 µg/kg dexmedetomidine caudally and found the duration of post-operative caudal analgesia to be 714 (565-863) min which is lower than our study analgesia duration, this may be due to the higher age group and body weight of patients in whom pain threshold may be lower than those included for this study compared to the current study or it may be due to the use of 0.2% ropivacaine for the study as compared to 0.25% ropivacaine used in our study.

In our study, the mean duration of sedation in BD group was 270 (240-300) min and in RD group was 266 (236.27-295.73) min. The mean duration of sedation was greater in Group BD than Group RD, but the difference was statistically insignificant.

In a similar study using 1 µg/kg dexmedetomidine with 0.25% bupivacaine and 0.25% ropivacaine, the duration of post-operative sedation obtained was 139.12 (124.9-153.34) min in BD group and 138.66 (125.45-151.87) min in RD group;²⁷ in another study using 1 µg/kg dexmedetomidine with 0.25% bupivacaine a sedation duration of 210 (138-282) min was observed,²⁰ the use of lower dose (1 µg/kg) dexmedetomidine may be accounted for the decreased duration of sedation in both the studies. In our study, the Ramsay sedation score of 2 was attained by most of the patients in both the groups at 300 min and a sedation score of 1 at 420 min post-extubation.

No episodes of clinically significant post-operative complications, such as respiratory depression, hypotension, and bradycardia, were observed in any of the groups except 1 episode of desaturation in 1 baby in Group RD 2 h post-extubation which was managed by oxygen supplementation.

The major limitation of our study apart from being a single center study was that its sample size was small ($n = 30$). Future study on the larger number of patients may strongly prove the hypothesis. Different local anesthetics and adjuvants with different concentrations and volumes used for the caudal block, drugs used for premedication, and rescue analgesia, various methods to assess pain and statistical analysis may all account for the variability in the duration of analgesia. We did not evaluate the emergence time and emergence behavior score, time to first micturition in the post-operative period.

CONCLUSION

There was no significant difference in the vital parameters and duration of sedation between the two Group BD and Group RD. With the doses and concentrations of the drugs we used, no complication was observed except desaturation in 1 baby in Group RD 1 h post-extubation which was managed by oxygen supplementation. 1 ml/kg of 0.25% BD 2 µg/kg in 1 ml NS produced longer duration of post-operative analgesia and similar duration of sedation as compared to 1 ml/kg of 0.25% RD 2 µg/kg in 1 ml NS in caudal block for lower abdominal surgeries in pediatric age group of 1-6 years.

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Head to Head Comparison of Safety and Effectiveness of Laminectomy and Laminotomy in Lumbar Disc Herniation

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Abstract

Introduction: We compared the clinical effectiveness such as pain relief, duration of hospitalization, time to return to office work, and cost of treatment of micro discectomy and macro discectomy (laminectomy and laminotomy) in patients with lumbar disc herniation performed by a single surgeon.

Methods: 30 patients underwent micro discectomy, 30 underwent laminectomy and remaining 15 laminotomy single-level "virgin" lumbar disc herniation at L4-5 or L5-S1 with unilateral radicular symptoms. Data on demographic, clinical, radiological, complications, time to event data, and cost of treatment (tangible plus intangible) were tabulated.

Results: There was a significant reduction in back pain, leg pain, and numbness before and after surgery in each group. However, no significant differences were observed between the three surgical procedures. Statistically significant differences were observed in the duration of hospitalization and cost of treatment but the differences were not significant in the frequency of use of an analgesic agent after surgery.

Conclusion: For herniotomy for lumbar disc herniation, both macro discectomy and micro discectomy procedures have comparable results in terms of pain reduction at short-term follow-up. However, duration of hospitalization, time to return to office work were less in micro discectomy than other two procedures though the cost of treatment is more.

Key words: Cost effectiveness, Lumbar disc herniation, Macro discectomy, Micro discectomy

INTRODUCTION

Surgical decompression is the conventional surgical treatment modality in patients with lumbar disc herniation and lumbar spinal stenosis.^{1,2} Discectomy and laminectomy are the procedures done to relieve pain associated with trapped spinal nerves, but a discectomy is an operation on the spinal discs, and a laminectomy is an operation on the arched portion of the vertebrae of the spine. As, this later procedure is involved removal of a large amount of normal bone, muscle tissue and sometimes

facet joints which resulted in iatrogenic instabilities to the spine and failed back syndromes.³⁻⁹ However, these conventional techniques were largely replaced by bone-sparing techniques. This study was conducted in an attempt to compare the clinical effectiveness such as pain relief, duration of hospitalization, time to return to office work, and cost of treatment of micro discectomy and macro discectomy (laminectomy and laminotomy) in patients with lumbar disc herniation performed by a single surgeon.

METHODS

A total of 75 patient's data were evaluated retrospectively from the hospital records during the period March 2015 to October 2015. These patients were in the age group of 20-50 years, having lower back and/or leg pain with magnetic resonance radiology notes either bulging,

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Table 1: Comparison of three different techniques for lumbar disc herniation

Clinical parameters	Laminectomy discectomy (n=30)	Laminotomy discectomy (n=15)	Micro discectomy (n=30)	P value
Age (year)	32±6	36±8	38±7	P>0.05
Male/female	20/10	12/3	12/18	P>0.05
Location				
L4-L5	20	5	14	P>0.05
L5-S1	10	10	16	
MRI				
Bulging	22	11	18	P>0.05
Protrusion	5	2	6	
Extrusion	3	2	4	
Sequestration	0	0	2	
At admission				
Pre-operative back pain (cm)	7.4±1.2	8.1±1.6	7.8±1.1	P>0.05
Pre-operative leg pain (cm)	6.4±2.1	7.6±1.6	8.6±1.4	P>0.05
Pre-operative numbness	30	30	30	P>0.05
At discharge				
Post-operative back pain (cm)	2.4±1.4	2.1±1.2	1.2±1.2	P<0.05
Post-operative leg pain (cm)	1.4±0.8	1.6±1.2	1.1±1.4	P<0.05
Post-operative numbness	4	2	2	P>0.05
Median duration of hospital stay (days)	10	5	3	P<0.05
Cost of treatment (USD)	1000±110	1500±200	2000±340	P<0.05
Median time to normal work (weeks)	8	6	4	P<0.05
Complications				
CSF leak	1	0	0	P>0.05
Infection	1	0	0	P>0.05
Failed back	0	0	0	P>0.05
Motor deficit	0	0	0	P>0.05

CSF: Cerebrospinal fluid

protrusion, extrusion, or sequestration. Patients who had suffered trauma or having systemic inflammatory diseases such as tuberculosis, systemic lupus erythematosus, ankylosing spondylitis, osteoporosis, degenerative disk disease, multiple level disk involvement, and malignancy were excluded. 30 patients underwent micro discectomy, 30 underwent laminectomy, and remaining 15 laminotomy single-level “virgin” lumbar disc herniation at L4-5 or L5-S1 with unilateral radicular symptoms. All surgeries were performed by a single surgeon. Each patient was asked to rate his pain and numbness on a scale from 1 to 10 cm (1 = no pain or deficit and 10 = the most severe pain or deficit) pre-operatively and at discharge from the hospital. Additional findings such as demographic, clinical, radiological, complications, time to event data, and cost of treatment (tangible plus intangible) were also tabulated.¹⁰

Statistical Analysis

Data from case record forms were transferred to Microsoft excel spreadsheet 2007. Data were then cleaned and mined for tabulation. Tables were created using pivotal tables. Continuous data were described as mean ± standard deviation and categorical as numbers and percentages. ANOVA and Chi-square test were used as tests for inferring data between groups. A two-tailed $P < 0.05$ was considered statistically significant.

RESULTS

Demographic and clinical presentations were similar across these three groups (Table 1). There was a significant reduction in back pain, leg pain, and numbness before and after surgery in each group. However, no significant differences were observed between the three surgical procedures. Statistically significant differences were observed in the duration of hospitalization and cost of treatment.^{11,12}

DISCUSSION

Herron and Pheasant,¹³ Lee *et al.*,¹⁴ and Weiner *et al.*¹⁵ have projected a number of persevering surgical techniques (endoscopic or open) to decompress the neural elements while preserving the integrity of important posterior elements. Delank *et al.*¹⁶ in his prospective study clinical and radiologic results of laminectomy were compared with laminotomy found parallel results. Omidi-Kashani *et al.*¹⁷ study also provided sufficient evidence to prefer and recommend laminectomy versus laminotomy over other available surgical decompression methods due to its more simplicity and less operative time. Our study results were similar to Rahman *et al.*¹⁸ report and the results of minimally invasive versus the classic open approach for decompressive lumbar laminectomy in 126 patients with lumbar spinal stenosis.

CONCLUSION

For herniotomy for lumbar disc herniation, both macro discectomy, and micro discectomy procedures have comparable results in terms of pain reduction at short-term follow-up. However, duration of hospitalization, time to return to office work were less in micro discectomy than other two procedures though the cost of treatment is more.

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Lignocaine and Dexmedetomidine in Attenuation of Pressor Response to Laryngoscopy and Intubation: A Prospective Study

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Abstract

Background: Dexmedetomidine is a α_2 agonist with sedative, sympatholytic, and analgesic properties and hence, it can be a very useful adjuvant in anesthesia as stress response buster, sedative, and analgesic. We aimed primarily to evaluate the effects of dexmedetomidine on hemodynamic response to critical incidences such as laryngoscopy and endotracheal intubation.

Materials and Methods: In this randomized, comparative, prospective study total 60 patients of either sex, of American Society of Anesthesiologists (ASA) Grades I or Grade II, aged between 20 and 60 years undergoing elective surgical procedures with written and informed consent were selected for the study. 60 patients randomly assigned to one of the two groups of 30 each. Group L received intravenous lignocaine while Group D received intravenous dexmedetomidine. 60 patients of ASA physical Grades I and II undergoing laryngoscopy and endotracheal intubation were randomly allocated into two groups of 30 patients each. Group D patients received intravenous dexmedetomidine (1 mcg/kg) before laryngoscopy and intubation (infusion over 10 min with 50 ml syringe and infusion pump diluted in normal saline), and Group L received intravenous lignocaine (1.5 mg/kg) 3 min before laryngoscopy and intubation. Parameters noted were heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP). Statistical Package for Social Sciences 19.0 version software was used for statistical analysis.

Results: In Group L, significant hemodynamic stress response was seen following laryngoscopy and tracheal intubation. In dexmedetomidine group, the hemodynamic response was significantly attenuated. The results, however, were statistically better after 5 min of laryngoscopy and tracheal intubation than at 1 min. No significant side effects were noted other than bradycardia in a single patient of Group D.

Conclusion: Efficacy of dexmedetomidine (1 mcg/kg) in attenuation of the pressor response to laryngoscopy and intubation compared to lignocaine (1.5 mg/kg) is significantly higher in ASA-I and II patients with respect to HR, SBP, DBP, and MAP.

Key words: Dexmedetomidine, Endotracheal intubation, Hemodynamic stress response, Laryngoscopy

INTRODUCTION

Laryngoscopy and endotracheal intubation are part of the induction of general anesthesia. The occurrence of hemodynamic responses during laryngoscopy and endotracheal intubation is a well-known hazard.¹

Laryngoscopy results in stimulation of larynx, pharynx, epipharynx, and trachea, which are extensively innervated by the autonomic nervous system, activation of which leading to various cardiovascular changes such as increase heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), dysrhythmias, cardiac asystole, and even sudden death.²⁻⁶ These changes may prove to be detrimental especially in patients with ischemic heart disease, cerebrovascular disease, hypertension, old age, and diabetes mellitus. Several techniques have been studied to attenuate this stress response, but none of them are completely satisfactory. Hence, there is a constant search to attenuate the hemodynamic response to laryngoscopy and

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endotracheal intubation. Modern anesthesia practices, therefore, plan to prevent sympathetic discharge and provide hemodynamic stability perioperatively. Various agents in the form of opioid analgesics, benzodiazepines, beta blockers, calcium channel blockers, and vasodilators have been used to achieve this objective with variable success. In last few years, a great enthusiasm has been shown toward the use of α_2 agonists in anesthesia practice because of their anxiolytic, sedative, sympatholytic, and analgesic-sparing properties.⁷

Dexmedetomidine, introduced in 1999 for human use, is a selective α_2 agonist with 8 times more affinity for α_2 adrenergic receptors compared to clonidine and possesses all the properties of α_2 agonist without respiratory depression.^{8,9} Intravenous use of dexmedetomidine in the perioperative period had been found to decrease serum catecholamine levels by 90%,¹⁰ to blunt the hemodynamic response to laryngoscopy, tracheal intubation, pneumoperitoneum, and extubation,¹¹ to provide sedation without respiratory depression and to decrease post-operative analgesic requirements.¹²

The primary aim of this study was, therefore, to evaluate the effects of dexmedetomidine on hemodynamic response to critical incidences such as laryngoscopy, endotracheal intubation, and compare with lignocaine.

MATERIALS AND METHODS

The present study was carried out from June 2010 to June 2011, after taking the permission and approval from the Departmental Ethical Committee and the written informed consent from the patients. It was a prospective, randomized, comparative, clinical study. 60 American Society of Anesthesiologists (ASA) physical status Grades I and II patients between 20 and 60 years, of either sex and posted for surgeries under general anesthesia with laryngoscopy and intubation, were included in the study. Patients with decreased autonomic control such as the elderly, diabetic patients, patients with chronic hypertension, or severe cardiac disease; patients on drugs such as β blockers or calcium channel blockers, pregnant, or lactating women; patients with a history of allergy to egg proteins and drugs particularly α_2 agonists were not considered for the study. The patients were randomly allocated by envelope method into two groups of 30 patients each, Group D received intravenous dexmedetomidine (1mcg/kg) before laryngoscopy and intubation (infusion over 10 min with 50 ml syringe and infusion pump diluted in normal saline) and Group L received intravenous lignocaine (1.5 mg/kg) 3 min before laryngoscopy and intubation for attenuation of stress response. Infusion was prepared according to the Group D on the basis of the weight of the patient; the

pump was set so as to deliver the targeted infusion rate. After taking the patient on the operation table, a multipara monitor was attached, and the baseline HR, SBP, DBP, and MAP were noted down. A wide bore intravenous cannula was inserted for giving the intravenous fluids, and another line was taken up for the infusion pump. Premedication was administered to all with 2 mcg/kg fentanyl, 0.03 mg/kg midazolam, and 5 mcg/kg glycopyrrolate 15 min before induction of general anesthesia by an intravenous route. At the time of induction, all the patients received injection ranitidine 50 mg and injection ondansetron 4 mg by the intravenous route. All patient were received either intravenous lignocaine (1.5 mg/kg) 3 min before laryngoscopy and intubation and Group D were received intravenous dexmedetomidine (1 mcg/kg) before laryngoscopy and intubation (infusion over 10 min with 50 ml syringe and infusion pump diluted in normal saline). Patients were pre-oxygenated with 100% oxygen for 3 min. Anesthesia was induced with 6 mg/kg thiopentone sodium and 0.1 mg/kg vecuronium. Laryngoscopy using Macintosh blade size 3 and intubation using the intratracheal tube (size 7.5-8 mm/cuffed) were carried out by a senior anesthesiologist or by a 2-year trained resident in anesthesiology. HR, SBP, DBP, and MAP were recorded before injection of study drug (baseline), after induction of anesthesia (before laryngoscopy) and 1, 3, and 5 min after intubation. Anesthesia maintained with O₂:N₂O (40:60), isoflurane mixture, and vecuronium. Manipulations, such as painting and draping the area, were not allowed till 5 min after intubation. At the end of the surgery, reversal was done with neostigmine 0.05 mg/kg and glycopyrrolate 10 mcg/kg. Extubation was done after adequate reversal of the non-depolarizing muscle relaxant. An observation made related to adverse effects of drugs and anesthesia-related problems and attended appropriately. Findings noted as per tables for further statistical analysis. The data obtained from the study were organized and analyzed by applying appropriate statistical tests. To test the statistical significance of the difference of categorical variables across two study groups (Group D vs. Group L), we used Statistical Package for Social Sciences 19.0. The statistically significant difference of average clinical parameters (such as HR, SBP, DBP, and MAP) between two study groups has been tested using independent sample *t*-test after confirming the underlying normality and equal variance assumptions. The *P* < 0.05 was considered statistically significant. All the hypotheses were formulated using two-tailed alternatives against each null hypothesis.

RESULTS

Both the groups under study were comparable to each other with respect to gender, ASA grading, age, weight, height, duration of surgery, and anesthesia (Tables 1-5).

Table 1: Gender wise distribution of patients in Group D and Group L

Gender	Group		P value
	Group D	Group L	
Male	18	18	0.99
Female	12	12	
Total	30	30	

Table 2: Distribution of patients with respect to ASA grade in Group D and Group L

ASA grade	Group		P value
	Group D	Group L	
I	22	22	0.99
II	8	8	
Total	30	30	

ASA: American Society of Anesthesiologists

Table 3: Comparison of age (years) in Group D and Group L

Group	Number of patients	Age (years) (mean±SD)	P value
Group D	30	39.50±11.56	0.857
Group L	30	40.03±11.22	

SD: Standard deviation

Table 4: Comparison of weight (kg) in Group D and Group L

Group	Number of patients	Weight (mean±SD)	P value
Group D	30	61.33±12.25	0.687
Group L	30	60.03±16.64	

SD: Standard deviation

Table 5: Comparison of height (cm) in Group D and Group L

Group	Number of patients	Height (mean±SD)	P value
Group D	30	159.67±12.32	0.198
Group L	30	155.07±14.91	

SD: Standard deviation

Comparison between Group L and Group D

Group L (lignocaine group)

In Group L after thiopentone sodium induction, there was increase in HR by 3.63%, fall in SBP by 1.2% and increase in MAP by 0.67% of baseline value (Table 6). 1 min after laryngoscopy and intubation, the HR was further increased by 9.36% of baseline value. At the end of 3 min, the HR remained 11.23% above baseline. At the end of 5 min, HR was 5.93% which was still higher than baseline value (Table 7). 1 min after laryngoscopy and intubation the SBP was increased by 5% of baseline value. At the end of 3 min, the SBP was 4.56% above baseline. At the end of 5 min, SBP was 0.3% which was comparable to the baseline value (Table

Table 6: Comparison of distribution of hemodynamic changes in terms of relative percentages in clinical parameters studied between Group L and Group D

% Change	B	BL	1 min	3 min	5 min
HR (%)					
Group L	0.0	3.63	9.36	11.23	5.93
Group D	0.0	-9.46	-8.13	-6.6	-11.46
SBP (%)					
Group L	0.0	-1.2	5	4.56	0.3
Group D	0.0	-21.28	-12.8	-18.47	-25.17
DBP (%)					
Group L	0.0	1.6	7.06	6.76	0.5
Group D	0.0	-10.5	-9.73	-11.5	-20.73
Mean BP (%)					
Group L	0.0	0.67	6.4	6.1	0.47
Group D	0.0	-13.4	-10.5	-13.53	-22.2

Values are Mean (SD). % Change is calculated with respect to baseline values.

DBP: Diastolic blood pressure, BP: Blood pressure, SBP: Systolic blood pressure, HR: Heart rate

8). 1 min after laryngoscopy and intubation the MAP was increased by 6.4% of baseline value. At the end of 3 min, the MAP was 6.1% above baseline. At the end of 5 min, MAP was 0.47% which was comparable to the baseline value (Table 9).

Group D (dexmedetomidine group)

In Group D after thiopentone sodium induction, there was decrease in HR by 9.46% (compared to increase by 3.63% in Group L), fall in SBP by 21.28% (compared to decrease by 1.14% in Group L), and decrease in MAP by 13.4% of baseline value (compared to increase by 0.67% in Group L) ($P < 0.001$) (Table 6). 1 min after laryngoscopy and intubation the HR was lower than baseline by 8.13% (compared to increase by 9.86% in Group L). At the end of 3 min, the HR remained lower by 6.6% over baseline value (compared to increase by 11.23% in Group L). At the end of 5 min, HR was still on lower side by 11.46% (compared to increase by 5.93% in Group L) of baseline value ($P < 0.001$) (Table 6). 1 min after laryngoscopy and intubation, the SBP was lower by 12.8% of baseline value (compared to increase by 5.93% in Group L). At the end of 3 min, the SBP remained low by 18.8% of baseline (compared to increase by 4.56% in Group L). At the end of 5 min, SBP was still lower by 25.47% of baseline value (compared to increase by 0.3% in Group L) ($P < 0.001$) (Table 6). 1 min after laryngoscopy and intubation, the MAP was lower 10.5% of baseline value (compared to increase by 6.4% in Group L). At the end of 3 min, the MAP remained low by 13.53% of baseline (compared to increase by 6.1% in Group L). At the end of 5 min, MAP was 22.2% of baseline value (compared to increase by 0.47% in Group L) ($P < 0.001$) (Table 6).

Using two independent sample proportion test $P > 0.05$, therefore, there is no significant difference between the proportion of gender in Group D and Group L (Table 1).

Table 7: Comparison of pulse rate at baseline, before laryngoscopy, 1st min after laryngoscopy, 3rd min after laryngoscopy, and 5th min after laryngoscopy in Group D and Group L

Pulse rate	Number of patients	Group		P value
		Group D	Group L	
Baseline	30	78.13±13.73	76.97±10.89	0.717
Before laryngoscopy	30	68.67±11.70	80.60±6.58	<0.001
1 st min after laryngoscopy	30	70.00±11.77	86.83±6.13	<0.001
3 rd min after laryngoscopy	30	71.53±11.22	88.20±4.51	<0.001
5 th min after laryngoscopy	30	66.67±8.54	82.90±4.64	<0.001

Table 8: Comparison of SBP at baseline, before laryngoscopy, 1st min after laryngoscopy, 3rd min after laryngoscopy, and 5th min after laryngoscopy in Group D and Group L

SBP	Number of patients	Group		P value
		Group D	Group L	
Baseline	30	121.80±10.55	122.47±8.01	0.784
Before laryngoscopy	30	100.52±7.94	121.27±7.73	<0.001
1 st min after laryngoscopy	30	109.00±8.98	127.47±8.69	<0.001
3 rd min after laryngoscopy	30	103.33±8.21	127.03±7.30	<0.001
5 th min after laryngoscopy	30	96.63±8.84	122.77±6.13	<0.001

SBP: Systolic blood pressure

Table 9: Comparison of MAP at baseline, before laryngoscopy, 1st min after laryngoscopy, 3rd min after laryngoscopy, and 5th min after laryngoscopy in Group D and Group L

MBP	Number of patients	Group		P value
		Group D	Group L	
Baseline	30	91.00±7.80	90.23±6.44	0.680
Before laryngoscopy	30	77.60±6.87	90.90±5.73	<0.001
1 st min after laryngoscopy	30	80.50±7.09	96.63±6.66	<0.001
3 rd min after laryngoscopy	30	77.47±7.49	96.33±6.89	<0.001
5 th min after laryngoscopy	30	68.80±8.19	90.70±5.33	<0.001

MAP: Mean arterial pressure, BP: Blood pressure

Using independent sample proportion test $P > 0.05$, therefore, there is no significant difference between proportions of ASA grade in Group D and Group L (Table 2).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean age (years) Group D and Group L (Table 3).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean weights (kg) Group D and Group L (Table 4).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean heights (kg) Group D and Group L (Table 5).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean pulse rates at baseline. $P < 0.05$, therefore, there is a significant difference between mean pulse rates at before laryngoscopy,

1st, 3rd, and 5th min after laryngoscopy in Group D and Group L (Table 7).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean SBP at baseline. $P < 0.05$, therefore, there is a significant difference between mean SBP at before laryngoscopy, 1st, 3rd, and 5th min after laryngoscopy in Group D and Group L (Table 8).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean DBP at baseline. $P < 0.05$, therefore, there is a significant difference between mean DBP at before laryngoscopy, 1st, 3rd, and 5th min after laryngoscopy in Group D and Group L (Table 10).

Using two independent sample t -test $P > 0.05$, therefore, there is no significant difference between mean MAP at baseline. $P < 0.05$, therefore, there is a significant difference between mean MAP at before laryngoscopy, 1st, 3rd, and 5th min after laryngoscopy in Group D and Group L (Table 9).

Table 10: Comparison of DBP at baseline, before laryngoscopy, 1st min after laryngoscopy, 3rd min after laryngoscopy, and 5th min after laryngoscopy in Group D and Group L

DBP	Number of patients	Group		P value
		Group D	Group-L	
Baseline	30	76.20±7.13	74.67±6.42	0.385
Before laryngoscopy	30	65.70±6.68	76.27±5.25	<0.001
1 st min after laryngoscopy	30	66.47±6.80	81.73±6.20	<0.001
3 rd min after laryngoscopy	30	64.70±7.36	81.43±6.65	<0.001
5 th min after laryngoscopy	30	55.47±8.88	75.17±5.36	<0.001

DBP: Diastolic blood pressure

DISCUSSION

Dexmedetomidine is a highly selective α_2 adrenergic agonist. It acts through three types of α_2 receptors- α_2 A, α_2 B, and α_2 C situated in the brain and spinal cord. The resultant action is sedation, anxiolysis, analgesia, and sympatholysis, the latter leading to hypotension and bradycardia. Activation of α_2 A receptors in the brain stem vasomotor center results in suppression of norepinephrine release, hypotension, and bradycardia.

Stimulation of α_2 A and α_2 C in locus ceruleus causes sedation. In the spinal cord, activation of both α_2 A and α_2 C receptors directly reduce pain transmission by reducing the release of substance P. Looking at these pharmacological properties, it has been evaluated in the past to assess its effect on hemodynamic responses in patients undergoing laparoscopic surgeries. The molecule has been used in infusion form with or without bolus dose. Infusion rates varying from 0.1 to 10 mcg/kg/h¹³⁻¹⁵ have been studied. However, with higher dose infusion of dexmedetomidine, high incidence of adverse cardiac effects have been observed.¹⁵ A biphasic response to blood pressure occurs with a bolus dose.¹⁰ Initially, there occurs hypertension followed by fall in blood pressure. This response is seen often more in young and healthy patients.¹⁶ Stimulation of α_2 B receptors in vascular smooth muscles is said to be responsible for this. Low-dose infusion of 0.25-0.5 mcg/kg/h results in an amonophasic response of 10-15% fall in mean arterial blood pressure and pulse rate.¹⁰ Furthermore, in low dose, dexmedetomidine exhibits linear kinetics, meaning that a constant amount of drug is eliminated per hour rather than a constant fraction of the drug. Our study confirms the fact that critical incidences such as laryngoscopy and intubation do significantly increase the HR, SBP, DBP, and MAP in patients and dexmedetomidine attenuates this sympathoadrenal response and provides hemodynamic stability.^{17,18} The effective attenuation dose with minimum side effects noted in our study was 1 mcg/kg infusion over 10 min. Apart from providing stress response attenuation, the added effects of dexmedetomidine are sedation and

analgesia. Sedation produced by α_2 agonists is unique in the sense that the patients can be easily aroused to co-operate during procedures and also respond to the verbal commands and then can return to sleep like state when not stimulated.¹⁶ Keniya *et al.*,¹⁸ who also shown that 1 mcg/kg dexmedetomidine effectively attenuated pressor response to laryngoscopy and subsequent intubation, where dexmedetomidine group was compared to the control group. After tracheal intubation, the maximal average increase was 8% in SBP and 11% DBP in dexmedetomidine group as compared to 40% and 25%, respectively, in the control group. Similarly, the average increase in HR was 7% and 21% in the dexmedetomidine and control groups, respectively. In our study, 1 min after laryngoscopy and subsequent intubation SBP and DBP was 12.8% and 9.7% below baseline values. Similarly, HR remained 8.13% below baseline in dexmedetomidine group ($P < 0.001$). So, in our study, attenuation of the pressor response is better than reference study may be due to a higher dose of intravenous fentanyl 2 mcg/kg versus 1 mcg/kg used in induction. Similarly, we used intravenous midazolam 0.03 mg/kg versus fixed dose of 1 mg in reference study for induction of anesthesia.

CONCLUSION

Dexmedetomidine (1 mcg/kg) serves as a very useful anesthesia adjuvant to control hemodynamic stress response to laryngoscopy and intubation, without any significant adverse effects. Efficacy of dexmedetomidine in attenuation of the pressor response compared to intravenous lignocaine (1.5 mg/kg) is significantly higher in ASA-I and II patients with respect to HR, SBP, DBP, and MAP.

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Attenuation of Post-operative Nausea and Vomiting with Granisetron and Ramosetron after General Anesthesia

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Abstract

Background: Nausea and vomiting are one of the most common complications after general anesthesia.

Objective: The aim of present study was to prevent nausea and vomiting after general anesthesia with granisetron and ramosetron.

Materials and Methods: Total 90 patients undergoing general anesthesia were randomly divided into three groups of 30 patients like Group 1 - Granisetron 10 mcg/kg intravenous (IV), Group 2 - Ramosetron 0.3 mg/kg IV and Group 3 - Normal saline 2 ml IV.

Results: In our study, out of both the 5HT₃ receptor antagonist, granisetron was found to be more effective in controlling nausea and vomiting after general anesthesia.

Conclusion: Both the drugs prevent nausea and vomiting after general anesthesia, but granisetron is more effective.

Key words: Granisetron, nausea, ramosetron and vomiting

INTRODUCTION

There are various complications of general anesthesia like hypoxia, post-operative nausea and vomiting (PONV), hypoventilation, hypotension, hypertension, Out of these, PONV is one of the most distressing and frequent adverse effect occurring after general anaesthesia.¹

The present study was undertaken to compare the antiemetic effects of granisetron and ramosetron in preventing PONV after general anesthesia.

Course of PONV

The mechanisms of PONV are multifactorial and include:²

Pre-operative factors

- Food
- Anxiety and stress
- Premedication.

Intraoperative factors

- Anesthetics
- Surgery.

Post-operative factors

- Residual effects of drugs
- Pain.

Mechanism of Action of Antiemetic Agents

Four neurotransmitter systems play important roles in mediating the emetic response:³

- Dopaminergic (D₂)
- Histaminergic (H₁)

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3. Cholinergic muscarinic
4. Serotonin (5HT3).

Pharmacology

Granisetron

Granisetron is a potent and highly selective 5-HT₃ receptor antagonist.⁴ It is rapidly and completely absorbed the following oral administration; although oral bioavailability is reduced to about 60% as a result of first-pass metabolism that ranges from 34% to 59%. Granisetron metabolism involves N-demethylation and aromatic ring oxidation followed by conjugation.⁵

Doses:⁶

1. Oral: 20-40 µg/kg
2. Intramuscular: 10-20 µg/kg
3. Intravenous (IV): 15-25 µg/kg

Ramosetron

Ramosetron is a selective 5-HT₃ receptor antagonist.⁷ After oral administration of ramosetron hydrochloride, the plasma concentration of the unchanged drug exhibits its C_{max} at approximately 2 h after administration, and the half-life is about 5 h.⁸ The effective bioavailability for oral dose is 50% or a higher based on the plasma concentration. About 13% of the drug is excreted unchanged in the urine.⁹

Doses:⁹

1. Oral: 1-2 µg/kg
2. IV: 0.2-0.3 µg/kg

MATERIALS AND METHODS

The study was approved by Institutional Ethical Committee and written informed consent was obtained from each patient. A total of 90 patients, belonging to ASA Grade I and II, 20-60 years age group undergoing surgical procedures under general anesthesia, were enrolled.

Group 1 (*n* = 30): Received injection granisetron 10 mcg/kg IV.

Group 2 (*n* = 30): Received injection ramosetron 0.3 mg IV.

Group 3 (*n* = 30): Received injection normal saline (0.9%) 2 ml IV.

Anesthetic Procedure

Patients were pre-oxygenated with 100% O₂ for 3 min. Then patients were pre-medicated with injection glycopyrrolate 0.005 mg/kg, injection midazolam 0.02 mg/kg and injection fentanyl 2 mcg/kg. Injection granisetron, injection ramosetron or injection normal saline was administered IV 3 min before induction according to the respective study group. Then, the patient was induced with injection thiopentone sodium 3-5 mg/kg body weight and endotracheal intubation was facilitated with injection succinylcholine 1.5 mg/kg.

Maintenance of anesthesia was done with nitrous oxide (60%) and oxygen (40%) and isoflurane and injection vecuronium.

The patient was monitored during anesthesia using continuous electrocardiogram, heart rate, blood pressure and pulse oximetry. On completion of surgery, the neuromuscular block was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.008 mg/kg. Injection diclofenac 1 mg/kg i.m. was given for post-operative analgesia.

Score Table (Wadaskar *et al.*, 2009)

- “0”: No nausea
- “1”: Mild nausea
- “2”: Severe nausea
- “3”: Mild vomiting
- “4”: Severe vomiting

RESULTS

Table 1 represents the mean and standard deviation of age and duration of anesthesia in all the three groups and the comparison of *P* values among all the three groups. No significant difference in the three groups with respect to age and duration of anesthesia was found (*P* > 0.05).

Table 2 represents number and percentage of patients with mild nausea not requiring rescue antiemetic in 24 h. The least incidence of nausea not requiring rescue antiemetic was found in Group 1 (*P* < 0.035).

Table 3 represents number and percentage of patients with severe nausea or vomiting requiring rescue antiemetic in 24 h. The incidence of severe nausea or vomiting requiring rescue antiemetic was least in Group 1 followed by Group 2, and then Group 3.

Table 4 represents number and percentage of patients with no nausea or vomiting for 24 h postoperatively. The incidence of no nausea or vomiting for 24 h postoperatively was maximum in Group 1 followed by Group 2, and then Group 3.

Table 5 represents the mean and standard deviation of all types of PONV scores in all three groups. It is clear that PONV score for all types was least in Group 1 followed by Group 2 and Group 3, respectively.

DISCUSSION

Base Line Comparison of Groups

Age

The study included the patients of age group between 20 and 60 years of age. In present study the age (mean ± standard

Table 1: Comparison of age and duration of anesthesia

Variables	Group 1	Group 2	Group 3	P value (independent t-test)		
				1 versus 2	1 versus 3	2 versus 3
Age (years)	35.36±8.37	35.53±7.32	34.5±6.41	0.9349	0.6670	0.5761
Duration of anesthesia (min)	111.00±26.30	112.00±28.33	109.00±29.98	0.8878	0.7846	0.6919

Table 2: Number (percentage) of patients with mild nausea (PONV 1) not requiring rescue anti-emetic (in 24 h)

Percentage of Patients	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P value (ANOVA)
Number of patients	2	6	5	0.035
Percentage of patients	6.6	20	16.6	

PONV: Post-operative nausea and vomiting

Table 3: Number and percentage of patients with severe nausea or vomiting (PONV 2, 3 and 4) requiring rescue anti-emetic (in 24 h)

Percentage of Patients	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P value (ANOVA)
Number of patients	5	8	19	0.028
Percentage of patients	16.6	26.6	63.3	

PONV: Post-operative nausea and vomiting

Table 4: Number and percentage of patients with no nausea or vomiting (PONV 0) for 24 h

Percentage of Patients	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P value (ANOVA)
Number of patients	23	16	6	0.018
Percentage of patients	76.6	53.3	20	

PONV: Post-operative nausea and vomiting

Table 5: Comparison of mean PONV score in the three groups

Percentage of Patients	Group 1	Group 2	Group 3	P value (ANOVA)		
				1 versus 2	1 versus 3	2 versus 3
PONV (mean±SD)	0.15±0.5747	0.325±0.6412	0.6917±1.0516	0.0341	0.0000	0.0000

PONV: Post-operative nausea and vomiting, SD: Standard deviation

deviation [SD]) in Group 1 was 35.36 ± 8.37 , in Group 2 was 35.53 ± 7.32 and in Group 3 was 34.5 ± 6.41 . The age is comparable in all the three groups. This is shown in Table 1.

Duration of anesthesia

In our study, the duration of anesthesia in minutes (mean \pm SD) in Group 1 was 111.00 ± 26.30 , in Group 2 was 112.00 ± 28.33 and in Group 3 was 109.00 ± 29.98 . The duration of anesthesia in minutes (mean \pm SD) in patients of all the three groups was comparable. This is shown in Table 1.

Comparison of PONV Score among All Groups in 24 h

PONV 1 (mild nausea not requiring rescue antiemetic)

In our study, the number (percentage) of patients with mild nausea (PONV 1) not requiring rescue anti-emetic in Group 1 was 2 (6.6%), Group 2 was 6 (20%), and

Group 3 was 5 (16.6%) (Table 2). Thus, the incidence of mild nausea not requiring rescue anti-emetic was least in granisetron group.

PONV 2, 3 and 4 (severe nausea or vomiting requiring rescue antiemetic)

In our study, the number (percentage) of patients with severe nausea or vomiting (PONV 2, 3, 4) requiring rescue anti-emetic in Group 1 was 5 (16.6%), Group 2 was 8 (26.6%), and Group 3 was 19 (63.3%) (Table 3). Thus, the incidence of severe nausea or vomiting requiring rescue anti-emetic was least in granisetron group.

PONV 0 (No nausea or vomiting)

In our study, the number (percentage) of patients with no nausea or vomiting (PONV 0) in Group 1 was 23 (76.6%), Group 2 was 16 (53.3%), and Group 3 was 6

(20%) (Table 4). Thus, the number (percentage) of nausea and vomiting free patients was least in granisetron group.

CONCLUSION

Hence, it can be concluded that granisetron is a more effective drug than ramosetron for controlling PONV with less incidence of side effects. We observed minimal emetic and nausea episodes in the post-operative period in patients who had received IV granisetron in comparison to IV ramosetron.

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Role of Low Dose Inhaled Corticosteroid in the Management of Bronchiectasis

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Abstract

Introduction: Bronchiectasis is a chronic inflammatory disease of the lungs with pulmonary function abnormality.

Materials and Methods: 23 non-smoker male bronchiectatic subjects were randomized into two arms. The study group consisting of 11 subjects was administered budesonide 400 mcg through spacer while the control group of 12 received placebo for a period of 3-week. The physician and the subjects were blinded. Spirometric indices of forced expiratory volume 1 (FEV1), forced vital capacity (FVC), FEV1/FVC, peak expiratory flow, and reversibility of FEV1 to salbutamol 400 mcg administered through spacer were the outcome measures at 0, 7, 14, and 21 days. The data were analyzed by Student's *t*-test using SPSS 10.

Results: None of the indices showed significant differences between the two groups at different time points. The reversibility of FEV by 15% to salbutamol inhalation suggested a trend of improvement in the study group.

Conclusion: Low dose inhaled corticosteroid ICS does not improve spirometric indices in stable bronchiectatic subjects in the 3-week period. Reversibility of FEV shows a trend of improvement in the subjects. Long-term studies of combination inhalers of low dose ICS and long acting beta 2 agonists in bronchiectatic patients are required to assess the benefit.

Key words: Bronchiectasis, corticosteroid, spirometric indices

INTRODUCTION

Bronchiectasis is a chronic suppurative lung disease still widely prevalent in developing countries such as India. The condition is associated with permanent damage to airways and parenchyma due to inflammation.

A common cause for bronchiectasis is recurrent infection due to the colonization by bacteria. Tuberculosis, the common respiratory infection also results in widespread destruction, fibrosis, cavitation, and atelectasis.

The lung efficiency suffers due to the parenchymal and airway structural disorganization and functional

impairment. Many studies documented a compromise in quality of life and pulmonary function parameters such as spirometry and diffusing capacity of the lung. Observations varied between restrictive, obstructive and mixed spirometric defects possibly due to factors such as the extent of the disease, type of bronchiectasis-cystic or tubular, and frequency and chronicity of infection. Airflow limitation reversible or irreversible and bronchial hyperreactivity are documented in bronchiectasis. In a series of cases, which underwent resectional surgery, prognosis, and recovery were better in patients without prior bronchial hyperreactivity.¹ Recently, the recognition of the overlap syndromes of chronic obstructive pulmonary disease (COPD), asthma, and bronchiectasis resulted in renewed interest in the disease phenotype of bronchiectasis and its response to various medications-bronchodilators, airway anti-inflammatory drugs, and antibiotics whether oral, injectable, or inhaled forms.²

Significant bronchodilator response in bronchiectatic subjects was well-documented by Murphy *et al.* in 1984.³

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The practice of long-term bronchodilator usage in bronchiectasis is common among family physicians and internists in India. Oral theophyllines and short acting beta 2 agonists are also widely prescribed. The benefit of inhaled corticosteroids in bronchiectasis has been justified by a few studies.

Recently, a randomized, double-blind, parallel group study in 40 bronchiectatic patients with formoterol-budesonide (18/640 mcg) combined inhaled therapy observed significant improvement in the quality of life and symptoms. The study, however, failed to show significant changes in spirometric parameters.⁴

Bronchial inflammation and symptoms improved in bronchiectatic patients treated with 1000 mcg of fluticasone dipropionate. The high dose was associated with side effects namely dysphonia, dry mouth, and local irritation.^{5,6}

Low dose inhaled corticosteroids may have a role in the prognosis, frequency of exacerbations, long-term lung function of bronchiectatic patients. The present study was an attempt to examine the effect of low dose budesonide 400 mcg therapy in stable bronchiectatic patients on spirometric indices particularly bronchodilator reversibility which is an important indicator of the likely benefit of long-term treatment with inhaled steroids.

The role of inhaled steroids in bronchiectasis is controversial. None of the previous studies examined the effect of inhaled corticosteroids on post-bronchodilator reversibility in bronchiectatic patients. Effect of inhaled budesonide 400 mcg/day on ventilatory functions of 23 consecutive bronchiectatic patients was studied.

MATERIALS AND METHODS

The Institutional Ethical Committee permission was obtained, and the patient gave well-informed consent for the study after a careful explanation that the medicines were well-established and were in wide use for airway obstructive disease.

Bronchiectasis was diagnosed by clinical and imaging criteria. They were manually randomized into two groups. A total number of 31 subjects were eligible to be included in the study. Eight people did not consent to participate in view of the calendar time required for follow-up. The patients did not show any active bacterial or tuberculous infection at the time of inception into the study. Some of the patients gave a history of pneumonias or tuberculosis in the remote past. None of the patients was a smoker. Spirometry was

performed using MicroLab 3300 (Mfd. MicroLab, Kent, UK). The instrument was auto calibrated. All the subjects underwent high-resolution computed tomography scan of the chest to confirm the diagnosis. Basic laboratory investigations to rule out diabetes, active infection, or immunocompromised state were performed. No attempt was made to diagnose cystic fibrosis since it is rare and not clinically suspected. Study group ($n = 12$) received inhaled budesonide 400 mcg/day through spacer while controls ($n = 11$) received placebo inhaler. Both groups received amoxicillin for a week before the study commenced and regular physiotherapy. Spirometry was performed at 7-day intervals at the same hour of the day. Forced expiratory volume 1 (FEV1), forced vital capacity (FVC), peak expiratory flow rate (PEFR), forced expiratory flow (FEF) 25-75, and "salbutamol reversibility" were tested as per the American Thoracic Society guidelines. Percent change in FEV1, FVC, PEFR, FEF 25-75%, and FEV1 reversibility at 0, 7, 14, and 21 days were analyzed by Student's *t*-test (SPSS 10).

RESULTS

All the subjects hailed from lower socioeconomic status from urban or semi urban areas in and around Hyderabad city. The city is located in semi-arid south central India with uniformly warm weather for the most part of the year with a short spell of monsoon and winter.

Only male subjects were taken into the study for convenience and feasibility of repeat visits or stay in the hospital for assessment.

Demographic characteristics

The study group consisted of 11 subjects with a mean age of 34.81 ± 11.65 years while the control group of 12 subjects had a mean age of 32.83 ± 14.91 . None was a current smoker (Table 1).

No statistically significant change between study and control groups was observed. The study group revealed a higher mean of reversibility in FEV1 to 400 mcg of salbutamol by inhaler with a spacer on day 7 and 14 compared with the control group suggesting a trend of likely benefit from low dose budesonide inhalation on a regular basis (Table 2).

Table 1: Study group

Time	FEV1	FVC	FEV1 reversibility (%)
Day 0	1.58±0.67	1.94±0.97	8.18±7.3
Day 7	1.59±0.74	1.94±0.80	11.27±11.63
Day 14	1.61±0.8	2.07±0.93	11.79±15.48
Day 21	1.66±0.76	2.12±0.87	6.44±4.95

FEV1: Forced expiratory volume 1, FVC: Forced vital capacity

Table 2: Control group

Time	FEV1	FVC	FEV1 reversibility (%)
Day 0	1.28±0.48	1.45±0.65	5.92±8.93
Day 7	1.35±0.45	1.63±0.65	4.75±3.79
Day 14	1.38±0.5	1.72±0.72	4.82±5.90
Day 21	1.48±0.46	1.79±0.78	3.33±5.46

FEV1: Forced expiratory volume 1, FVC: Forced vital capacity

DISCUSSION

The present small study, though the results are not statistically significant, shows a trend of improved “reversibility” of FEV1 in the budesonide-treated bronchiectatic subjects. Spirometric indices, namely FEV1, FVC, FEF 25-75, FEV/FVC, did not show a significant difference at the weekly time-points between the control and study groups. The present study suffers from the limitation of not providing a study arm of combination inhaler of low dose corticosteroid- long-acting beta-agonists (LABA).

Margi Garcia *et al.* documented improvement in symptom score and quality of life on long-term administration of formoterol-budesonide inhaled therapy but failed to show improvement in lung function.⁷ High dose fluticasone of 1000 mcg alone did not confer any benefit in spirometric indices though it had improved symptomatically in an earlier study. Long-term studies with low or medium dose corticosteroids and long acting beta agonists in bronchiectatic subjects are lacking. The above-mentioned studies predominantly included smokers. Inhaled fluticasone dipropionate 500 mcg daily was not found to be effective in improving the symptoms or pulmonary functions in another study.⁸

The common observation and practice of the Indian physicians to administer regular oral bronchodilator, theophylline lacks the support of pharmaco-dynamic data which are scanty in this area. Theophylline does not command merit in the global guidelines of asthma or COPD as an important primary drug for airway obstruction though it is accepted as an add-on drug for the suboptimal responders to steroid and LABA.⁹ Its major advantage is the low price per dose. The combination inhalers of LABA and medium dose corticosteroids have become affordable, cheap, and widely available in India in the recent years. Many governmental and non-governmental health providers reimburse or dispense combination inhalers. Recently, a prescription audit study revealed that 78% of asthmatic patients used a combination of LABA and steroids as well as symptom relievers more than the controllers. Essential drug list of government hospitals did not include inhaled beta 2 agonists and corticosteroids. 60% of drugs were

given by inhaled route.¹⁰ The caveat, however, is the danger of irrational prescription without spirometric diagnosis and monitoring, and over the counter purchase by patients of these combination inhalers with a misconception that all “short-breath and wheezy syndromes” are similar.

Further well-designed studies of long-term corticosteroid inhalers and LABA and/or theophyllines in stable bronchiectatic patients will resolve the dilemma of choice of long-term therapy for bronchiectasis in the Indian context.

CONCLUSION

Our study concludes that the objective spirometric indices do not show significant improvement at weekly intervals in the low dose budesonide 400 mcg inhaler therapy group versus the control group of bronchiectatic subjects.

Reversibility of FEV to 400 mcg of salbutamol as an outcome measure shows a trend of likely benefit in the study group of bronchiectasis. The wider availability and reduced price of combination inhalers of LABA plus inhaled corticosteroid (ICS) have brought them to greater prescription by the family physicians on symptom-based assessment without spirometric evaluation of all the wheezy and short-breath patients. In addition, “over the counter” sales on self-prescription lead to the undesirable practice of over-use of these inhalers. Further studies with comparator arms of ICS plus LABA and ICS-theophylline are required to resolve the issue of appropriate treatment for stable bronchiectasis in India.

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Overview and recent advances in composite resin: A review

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Abstract

Composite dental restorations represent a unique class of biomaterials with severe restrictions on biocompatibility, curing behavior, esthetics, and ultimate material properties. These materials are presently limited by shrinkage and polymerization induced shrinkage stress, limited toughness, the presence of unreacted monomer that remains following the polymerization, and several other factors. Fortunately, these materials have been the focus of a great deal of research in recent years with the goal of improving restoration performance by changing the initiation system, monomers, and fillers and their coupling agents, and by developing novel polymerization strategies. This article discusses the advances in resin restorative materials.

Key words: Antimicrobial, Condensable, Indirect composite, Nano-composite, Self-healing

INTRODUCTION

Composite resins have been introduced into the field of conservative dentistry to minimize the drawbacks of the acrylic resins that replaced silicate cement in the 1940s. In 1962, Bowen developed the bisphenol A glycidyl methacrylate (BISGMA) monomer in an attempt to improve the physical properties of acrylic resins, as their monomers were only allowed linear chain polymers to be formed. Although Bowen's formulation has been available for more than 30 years, the chemistry has remained relatively unchanged. As a result, the mechanical properties also have not improved substantially. The purpose of this article is to discuss new resin systems exhibiting substantial improvements in wear resistance and clinical performance.¹

Direct Composite Resin

Condensable/packable or polymeric rigid inorganic matrix material

This new concept was developed by Dr. Lars Ehrnford of Sweden in 1995. This system is composed of a resin matrix and an inorganic ceramic component. Rather than incorporating the filler particles into the composite resin matrix, devised a unique system by which the resin is incorporated into the fibrous ceramic filler network. This mainly consists of aluminum oxide and silicon dioxide glass particles or barium aluminum silicate or strontium glasses. The glass particles are liquefied to form a molten glass which is forced through a die to form thin strands of glass fibers.

The diameter of these fibers was approximately 2-3 μm . These glass fibers were crushed into small fragments and then reheated to a sufficient temperature to cause superficial fusion of glass fibers at selected sites (silanization), this forms the continuous network of small chambers or cavities (dimensional interfacial chambers = 2 μm). The manufacturers then infiltrate these spaces within the fibrous network with an optimized resin depending on the final application use of the restorative material (BISGMA/urethane dimethacrylate resin). This concept provides a basis for fabricating packable or condensable

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posterior composite resin. Traditional light-cured hybrid resin composites cannot be bulk placed because of excessive polymerization shrinkage and the inability to adequately light-polymerize the resin beyond a 2 mm depth. Manufacturers prescribe bulk placement of packable composites was claiming decreased polymerization shrinkage due to increased filler loading and a reported depth of cure reaching 5 mm. However, certain packable resin composites demonstrated polymerization contraction similar to or higher than conventional hybrid composites. The completeness of polymerization of some packable resin composites was significantly less with bulk cure in comparison to standard incremental polymerization.¹

Packable resin composites were developed to restore surfaces that previous resin composites could not. However, certain principles still hold true. The faciolingual width of the cavity preparation should be no larger than one-third the intercuspal distance and replacement of cusps with packable resin composite are contraindicated. A Class II restoration should ideally end on sound enamel. If this is not present at the cervical margin other procedures such as an “open sandwich technique” should be used. In this glass ionomer is placed as the initial increment filling the first couple of millimeters of the box. Glass ionomers predictable bond to dentin reduces microleakage compared to a resin-dentin margin. Centric stops should be on tooth structure. Clinical signs of excessive wear of bruxing and grinding should be absent. One of the most critical factors for long-term success is the ability to isolate with a rubber dam. Avoiding saliva and blood contamination of the prepared enamel and dentin surfaces is vital to achieve a proper bond. Packable resin composite should not be viewed as a time saver as bulk placement of packable resin composite is not recommended and may compromise the long-term success of the restoration.²

Flowable Composite

A newer type of composite was released in 1996 that has been termed a “flowable composite” because of its low viscosity and ability to be syringed into a cavity preparation with a needle tip. While the heavy-bodied consistency of traditional packable composites is very desirable in gaining the control to shape aesthetic and functional restorations, clinicians have found that a material that can flow into cavity preparations has an important role, especially where the deposition of material into a tight space is required.

Most of the flowable composites presently available are not filled, generally containing from 56% to 70% filler by weight. Accordingly, they have reduced mechanical properties such as a higher susceptibility to wear, a higher polymerization shrinkage, and lower flexural strength. Flowable composite resin materials can be useful not only

as a liner but to build up cavity preps, to block out small undercuts and to use as an indirect or direct pulp cap.³ Low-modulus flowable resin composites have been described as potentially radiopaque “filled adhesives” with implications for improved clinical dentin bonding. In contrast, restorative composites have a relatively high modulus of elasticity, and it has been suggested that this high stiffness contributes to their inability to compensate for contraction stress during polymerization. This can lead to either bond failure or fracture of the tooth structure, resulting in microleakage and post-operative sensitivity. Employing an intermediate layer of low-modulus composites can relieve some of the contraction stress during polymerization. Application of increased thickness of low stiffness adhesive has a similar effect. Use of flowable composites in conjunction with the very high viscosity, high-modulus packable composites is a common clinical technique. However, the effects of the higher-than expected polymerization shrinkage of the flowable material (because of lower filler loading) and the effects of possible flexure of the restoration when it is supported by the lower modulus flowable “liner” are unknown.⁴

Indirect Composite Resin

Because of the major clinical problems clinicians have experienced with direct posterior composite resins, the indirect inlay or onlay systems were introduced. Since the restoration is made on a die rather than directly on the tooth, the restoration has superior adaptation, contour and proximal contact. On the whole, there is a dramatic improvement in the general clinical performance. A number of highly improved indirect resin restorative systems have been introduced with unusually good properties like wear resistance, esthetics, marginal adaptation, control over polymerization shrinkage.

Touati and Mörmann introduced the first generation of indirect resin composites (IRCs) for posterior inlays and onlays in the 1980s. Direct resin composites were composed mostly of the organic resin matrix, inorganic filler, and a coupling agent. The first generation IRCs had a composition identical to that of the direct resin composite marketed by the same manufacturer and the materials also bore names similar to that of the direct materials. For inlay composites, an additional or secondary cure is given extraoral, which improves the degree of conversion and also reduces the side effects of polymerization shrinkage. The only shrinkage that is unavoidable is that of the luting cement. It was observed that the first generation IRCs showed improved properties only in lab studies but had failures in clinical studies. The clinical failures endured with the first generation composites and the limitations faced with ceramic restorations led to the development of improved second generation composites.

The second generation composites have a “microhybrid” filler with a diameter of 0.04-1 μ , which is in contrast to that of the first generation composites that were microfilled. The filler content was also twice that of the organic matrix in the latter composites. By increasing the filler load, the mechanical properties and wear resistance is improved, and by reducing the organic resin matrix, the polymerization shrinkage is reduced. The new composite resins like Artglass and belle Glass HP contain high amounts of filler content, which make them adequate for restoring posterior teeth.⁵

Nanocomposites

Nanotechnology may provide composite resins with a dramatically smaller filler particle size that can be dissolved in higher concentrations and polymerized into the resin system. The molecules in these materials can be designed to be compatible when coupled with a polymer and provide unique characteristics (i.e., physical, mechanical, optical). Currently, the particle sizes of conventional composites are so different from the structural sizes of hydroxyapatite crystals, dental tubules, and enamel rods, compromises in adhesion between the macroscopic (40-0.7 nm) restorative material and the nanoscopic (1-10 nm in size) tooth structure are potential. Nanotechnology can, however, improve this continuity between the tooth structure and the nanosized filler particle and provide a more stable and natural interface between the mineralized hard tissues of the tooth and these advanced restorative biomaterials.⁶ Studies have shown that nanocomposites show greater fracture toughness and adhesion to tooth structure.⁷

Antimicrobial Composite

Antimicrobial properties of composites may be accomplished by introducing agents such as silver or one or more antibiotics into the material. Microbes are subsequently killed on contact with the materials or through leaching of the antimicrobial agents into the body environment.²

Silver and titanium particles were introduced into dental composites, respectively, to introduce antimicrobial properties and enhance the biocompatibility of the composites.¹ Several reports have described the incorporation of a methacryloyloxydodecyl pyridinium bromide monomer in composite resins that showed no release of the incorporated monomer but still exhibited antibacterial properties.⁸ Alkylated ammonium chloride derivatives and chlorhexidine diacetate have also been introduced as an antimicrobial agent into dental composites.

Stimuli Responsive Composite

Stimuli-responsive materials possess properties that may be considerably changed in a controlled fashion by external

stimuli. Such stimuli may be for example changes of temperature, mechanical stress, pH, moisture, or electric or magnetic fields. Stimuli-responsive dental composites may be quite useful for example for “release-on-command” of antimicrobial compounds or fluoride to fight microbes or secondary caries, respectively.⁸

Fiber Reinforced Composite

Fiber-reinforced composites have numerous industrial and aerospace applications because they are light, strong and non-flammable. However, with respect to clinical dentistry, they are relative newcomers into the spectrum of prosthodontic treatment options.⁹ Over the years, these materials have evolved to the extent that they can be used for both direct and indirect restorations.¹⁰

Self-healing Composite

Materials usually have a limited lifetime and degrade due to different physical, chemical, and biological stimuli. These may include external static (creep) or dynamic (fatigue) forces, internal stress states, corrosion, dissolution, erosion, or biodegradation. This gradually leads to a deterioration of the material structure and finally failure of the material.

One of the first self-repairing or self-healing synthetic materials reported interestingly shows some similarities to resin-based dental materials, since it is resin-based. This was an epoxy system which contained resin filled microcapsules. If a crack occurs in the epoxy composite material, that microcapsules are destroyed near the crack and release the resin. The resin subsequently fills the crack and reacts with a Grubbs catalyst dispersed in the epoxy composite, resulting in a polymerization of the resin and a repair of the crack. Similar systems were demonstrated to have a significantly longer duty cycle under mechanical stress *in situ* compared to similar systems with the self-repair.¹¹

CONCLUSION

There is much room for the improvement and further development of resin-based dental materials, such as composites. A new quality of dental composites may, however, be created if nanotechnology is used and other new developments in material science and biomaterials are considered in composites in the future.

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Meckel's Diverticulum and its Presentations: A Case Series

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Abstract

Meckel's diverticulum is a common congenital abnormality of gastrointestinal tract, resulting from an incomplete obliteration of the vitelline duct during the 5th week of the gestation. It may generally remain silent and asymptomatic but life threatening complications like perforation and intestinal obstruction can occur sometimes, making it important to know its detailed anatomy and pathophysiology. The most common complications of Meckel's diverticulum are perforation, intestinal obstruction, hemorrhage, acute diverticulitis, etc. We are presenting six cases of Meckel's diverticulum with varied presentations during a span of 1 year in our institution. One case presented as intestinal obstruction, two with perforation, one case of incidental Meckel's diverticulum, one case of diverticulitis and one double Meckel's diverticulum.

Key words: Capsule endoscopy, Diverticulitis, Intestinal obstruction, Volvulus

INTRODUCTION

Meckel's diverticulum was described by Fabricius Hildanus in 1598.¹ It represent the patent intestinal end of the vitello intestinal duct. It possesses all three coats of intestine. In 20% of the cases the mucosa contains heterotopic gastric, colonic, or pancreatic tissue. The various anomalies includes, a fibrous band from distal ileum to the anterior abdominal wall, an umbilical-intestinal fistula, a mucosa lined cyst, or sometimes an umbilical sinus of these the commonest anomaly is Meckel Diverticulum. It presents in 2% of the population at a ratio of three male to one female. Its usual location is 30-60 cm from ileocaecal valve. The presence of this heterotopic tissue may lead to other complications like hemorrhage, chronic peptic ulceration, and perforation. It generally remains silent but it may present with life threatening complications like intestinal obstruction, perforation, hemorrhage,² etc. These complications present with nonspecific symptoms

which mimic common gastrointestinal disorders³ like appendicitis, making diagnostic difficulty. Most of the cases are diagnosed intraoperatively. Meckel's diverticulum is a true diverticulum containing all layers; it is usually situated on antimesenteric border, approximately seen in 2% of population.⁴ Meckel's diverticulum is usually lined by intestinal mucosa, sometimes it may be lined by heterotopic gastric or pancreatic tissue and less commonly colonic or endometrial or hepatobiliary tissue.⁴ Meckel's diverticulum is a remnant of vitello intestinal duct. Normally vitelline duct regresses by the 5th-7th week of gestation; if it fails to regress it may result in Meckel's diverticulum or a fibrous band attaching the distal ileum to abdominal wall or a fistula or umbilical sinus.⁴ Most patients are asymptomatic and the life time risk of the developing complications is 4-6%.⁵ Hemorrhage is the most common complication in adults and the second most in children;⁶ it is due to presence of heterotopic gastric or pancreatic mucosa causing ulceration of adjacent ileal mucosa. Obstruction due to Meckel's diverticulum is the most common complication in children and second most common complication in adults.⁶ Obstruction is due to volvulus or intussusception or Littre's hernia or adhesion and kinking or due to stricture secondary to chronic diverticulitis.^{4,7} Complications of Meckel's diverticulum include hemorrhage, obstruction, diverticulitis and perforation and technetium 99 m pertechnetate scan

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is used for diagnosis which is highly sensitive and specific in both pediatric and adult population.^{7,8} Other diagnostic modalities include capsule endoscopy and angiography. If conservative methods fail to control hemorrhage diverticulectomy or ileal segment resection with end to end anastomosis are done perforation is due to diverticulitis or ulceration due to heterotopic mucosa or rarely due to foreign body (like fish bone, chicken bone, etc.). Treatment of perforation is segmental resection with end to end anastomosis. Pathophysiology of diverticulitis is similar to that of acute appendicitis, with inflammation secondary to stasis (due to fecolith or parasites or foreign body) and bacterial infection.^{8,9} It may also result from heterotopic mucosa. Usually, treatment is diverticulectomy.

We are herewith reporting six cases of Meckel's diverticulum with varied presentations in 1 year. During our emergency surgeries one case presented as intestinal obstruction because of fibrous band from Meckel's diverticulum to base of appendix. The second case presented with picture of peritonitis which showed a perforated Meckel's diverticulum. Third case presented with intestinal obstruction with a recto sigmoid tumor where a double Meckel's diverticulum was found. Fourth case an incidental Meckel's diverticulum seen during an emergency laparoscopic appendectomy procedure. Another case was presented as acute appendicitis where Meckel's diverticulum was found. One more case presented as peritonitis with hypotension in which an ileal perforation and also a perforated Meckel's diverticulum was found.

CASE REPORT

Case 1

A 26-year-old male patient presented to emergency with complaints of abdominal pain, distension of abdomen of 3 days duration and bilious vomiting for 1 day. On examination vitals were stable, abdominal distension present with increased bowel sounds. A clinical diagnosis of intestinal obstruction was made, confirmed by plain X-ray and ultrasound abdomen. Diagnosis of small bowel obstruction was made, on laparotomy distended ileal loops with volvulus of ileal loop over a fibrous band extending from tip of Meckel's diverticulum to base of umbilicus (Figure 1). Volvulus was undone and fibrous band excised. Meckel's diverticulum was left unresected as it was having wide base. Post-operative period was uneventful.

Case 2

A 40-year-old female presented to emergency with history of pain abdomen for 1 day, distension of abdomen

for 1 day. On examination, patient had hypotension. Per abdomen diffuse tenderness present with guarding and rigidity. Clinical diagnosis of peritonitis secondary to perforation of a hollow viscus was made. After resuscitation X-ray erect abdomen and ultrasound was done which confirmed clinical diagnosis. Patient was posted for laparotomy there was a perforated Meckel's diverticulum. Resection of segment of ileum including diverticulum with end to end anastomosis was done. Post-operative period was uneventful.

Case 3

A 50-year-old male presented to emergency with distension of abdomen for 2 days, not passing stools for 2 days, vomiting for 1 day. On examination, vitals were stable. Per abdomen distension of abdomen present with no palpable masses with increased bowel sounds, on digital rectal examination - rectum was empty with no fecal staining and palpable masses. Clinical diagnosis of obstruction was made, confirmed by X-ray erect



Figure 1: Meckels Diverticulum with Fibrous Band



Figure 2: Double Meckels Diverticulum

abdomen and ultrasound abdomen. Patient was posted for laparotomy, intra-operatively there was a growth at recto sigmoid junction for which resection and end colostomy was done. Incidentally during exploration we noticed double Meckel's diverticulum (Figure 2) with wide mouth, which were left unresected.

Case 4

A 15-year-old male presented to emergency with complaints of pain abdomen for 1 day. On examination vitals were within normal limits per abdomen there was tenderness at McBurney's point with rebound tenderness. Diagnosis of acute appendicitis was made patient was posted for laparoscopic appendectomy; along with inflamed appendix incidentally we noticed Meckel's diverticulum with wide mouth. Appendectomy was done and Meckel's diverticulum left unresected.

Case 5

An 18-year-old female presented to emergency with complaints of pain abdomen for 1 day, vomiting for 1 day. On examination there was tenderness noted in McBurney's point with rebound tenderness. Diagnosis of acute appendicitis was made, planned for open appendectomy. Appendix was normal and on exploration of ileum we noticed Meckel's diverticulum with inflamed tip (Figure 3). Diverticulectomy was done. Post-operative period was uneventful.

Case 6

A 45-year-old female presented to emergency with complaints of pain abdomen and distension of abdomen for 2 days, distension of abdomen for 1 day, anuria for 12 h. Patient had history of fever 15 days prior to pain abdomen which subsided with medication. On examination patient had hypotension, there was distension of abdomen with guarding and rigidity with diffuse tenderness with absent bowel sounds. Clinical

diagnosis of hollow viscus perforation was made, diagnosis was confirmed by X-ray erect abdomen and ultrasound abdomen. After initial resuscitation, Patient was posted for laparotomy and intra-operatively we noticed perforated Meckel's diverticulum and also an ileal perforation 5 cm distal to diverticulum (Figure 4). Resection and anastomosis of ileum (including the diverticulum) was done. Post-operative period was uneventful. Histopathology of resected specimen did not show any evidence suggestive of tuberculosis or typhoid.

DISCUSSION

Pre-operative diagnosis is rare in uncomplicated cases, and the diverticulum is usually observed incidentally, during other procedures for various reasons.¹⁰ "Rule of two" is characteristic for Meckel's diverticulum, which includes the prevalence in 2% of the population; it is usually diagnosed under the age of two; it is in two-inches size and 2 cm diameter, two feet proximal to the ileocaecal valve, twice frequent in men, and symptomatic in 2% of the patients.^{10,11}

Double Meckel's diverticulum is a rare condition, and the first study was reported by Emre *et al.* Although pre-operative diagnosis may be compelling, and the most frequent used modalities are a computerized tomography, technetium-99 m pertechnetate. Scintigraphy, and double-balloon enteroscopy, which is superior to the others,¹² scintigraphy has the capability of observing ectopic gastric mucosa but may have false positive and negative results at high rates.¹⁰

The management of symptomatic Meckel's diverticulum comprises surgical resection. A wedge resection of the Meckel's diverticulum is generally carried out, and occasionally some ileum is resected by end-to-end anastomosis diverticulectomy for Meckel's diverticulum found incidentally has been criticized. The results of surgical excision are generally excellent. Among the patients operated on for complications of Meckel's diverticulum, the cumulative incidence of early post-operative complications was 12%, including mainly wound infection (3%), prolonged ileus (3%), and anastomotic



Figure 3: Meckels Diverticulitis



Figure 4: Ileal Perforation & Meckels perforation

leak (2%). The mortality rate was 1.5%. The cumulative incidence of late post-operative complications during a 20 years follow-up was 7%. Incidental diverticulectomies are safer, with an overall rate of morbidity of 2% and a mortality of 1%.¹³ Due to the difficulty of diagnosing a pathologic Meckel's diverticulum pre-operatively, many surgeons recommend prophylactic diverticulectomy in those found incidentally[14]. This recommendation is based on lower morbidity rates when compared to the resection of pathologic diverticula.¹⁴

CONCLUSION

The present study of six cases of Meckel's diverticulum with varied presentations highlights its importance in many aspects. It is difficult to make a pre-operative clinical diagnosis and most of the times it is an intra-operative diagnosis. In suspected appendicitis during surgery, exploration of small bowel should be done to rule out Meckel's diverticulum, especially when the appendix appears normal. One case revealed ileal and also Meckel's diverticulum perforation which is very uncommon to come across such a presentation.

The optimum management of an asymptomatic Meckel's diverticulum discovered at laparotomy for a separate indication remains unclear. A recent review shows the risk of post-operative complications are higher the following resection than leaving the diverticulum *in situ*.¹⁵

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