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SHORT COMMUNICATION

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Case Report

Computed Tomography Findings in a Case of Situs Ambiguous with Polysplenia: A Case Report

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Abstract

Eternity has rightly established the fact that nature hates symmetry and to cite a perfect example of it, we present a rare entity, situs ambiguous before you. Situs ambiguous is a congenital anomaly in which the major visceral organs are distributed abnormally within the chest and abdomen. We report a case of a 44-year-old lady, presented to our casualty department with waxing and waning pain abdomen and vomiting. Patient's contrast-enhanced computed tomography (CECT) was done which had features of left isomerism of heterotaxy syndrome. Our case describes about the findings of situs ambiguous with polysplenia which is a rare entity. Early diagnosis by appropriate imaging modality results in reduction of the fatal consequences.

Key words: Congenital disease, Heterotaxy syndrome, Isomerism, Polysplenia

INTRODUCTION

Heterotaxy in general refers to any defect of the left-right laterality and arrangement of the visceral organs. Additional estimation of incidence and prevalence of isomerism is difficult due to failure to diagnose and underestimation of the disease by clinicians. Classically, there is malposition of the liver, stomach, and spleen and is divided into the right and left isomerism. The right isomerism displays severe cyanotic congenital heart disease, absence of spleen, bilateral eparterial bronchi, bilateral trilobed lungs, bilateral right atrial appendages, midline/transverse liver, and intestinal malrotation. The left isomerism displays multiple splenules without a parent spleen, azygos, or hemiazygos continuation of the inferior vena cava, bilateral hyparterial bronchi, bilateral bilobed lungs, common AV valves and atrium, midline/transverse liver, and intestinal malrotation.

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CASE REPORT

A 44-year-old lady presented to our accident and casualty department with waxing and waning pain abdomen and vomiting for the past 4 years which got aggravated for the past 2 days. General physical examination revealed pallor in bilateral lower palpebral conjunctivae. The history reveals medically managed Type II diabetes mellitus. On abdominal examination, no guarding, rigidity, organomegaly, and deep and superficial tenderness are noted. Substantially, low hemoglobin levels have been energetically corrected with FFP and pRBC transfusions. Dyselectrolytemia and raised plasma glucose levels have also been corrected.

On Imaging

A plain and intravenous contrast-enhanced 128 slice spiral computed tomography (CT) scan of whole abdomen with oral contrast performed at the hospital revealed a midline transverse liver with an enlarged left lobe extending into the left subdiaphragmatic region with no focal parenchymal lesion and a normal gall bladder [Figure 1]. Altered gastric configuration is noted with fundus and body seen in the right subdiaphragmatic region and antropyloric region in midline [Figure 2]. The duodenum was appreciated having a tortuous and serpiginous course secondary to mass effect from the splenules and pancreas and the duodenojejunal junction is displaced left lateral to L2 vertebra [Figure 3].

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The jejunal, ileum loops, and cecum are seen in normal position. Small pancreatic tissue is noted in midline closely abutting the duodenum. The spleen is replaced by multiple small splenules extending to the midline with each splenule supplied by multiple splenic vessels [Figure 4]. The left renal hydronephrosis is seen along with a dilated left ureter. Altered configuration of superior mesentery artery and vein is noted with the vein lying anterior and left lateral to the artery [Figure 2]. The portal vein has altered course posteriorly superior to the duodenum. Retroaortic left renal vein is seen [Figure 5]. The left common iliac vein joins the IVC by a course behind the aorta. Mild free fluid is seen in abdomen.

On correlation with plain computed tomography (CT) of thorax, separate post-hepatic drainage of hepatic vein is seen into the right atrium with the renal segment of IVC draining into the azygos vein, giving it an appearance of double IVC [Figure 6]. Bilateral bilobed lung is seen with mild pleural effusion and cardiomegaly [Figure 7].

Therefore, the imaging findings give an impression of situs ambiguous with the left isomerism.

Figure 1: The axial view of CECT abdomen shows midline transverse liver with enlarged left lobe

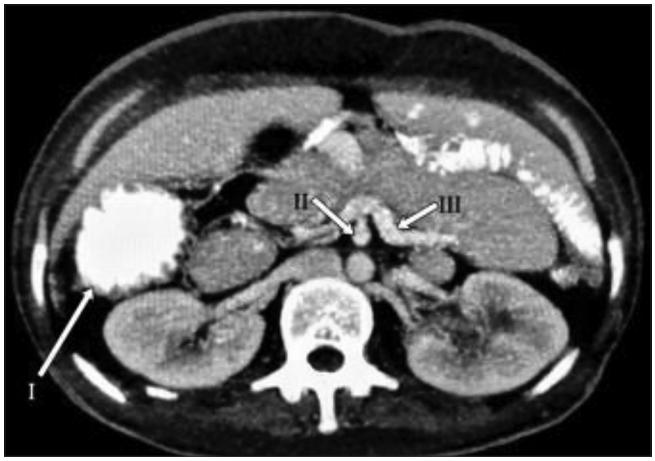

Figure 2: The axial view of CECT abdomen shows (i) gastric funds under right subdiaphragmatic region; (ii and iii) altered positions of superior mesenteric vessels showing SMV lying anterior and left lateral to SMA

DISCUSSION

A rare, genetic, developmental defect during embryogenesis characterized by a partial mirror image transposition

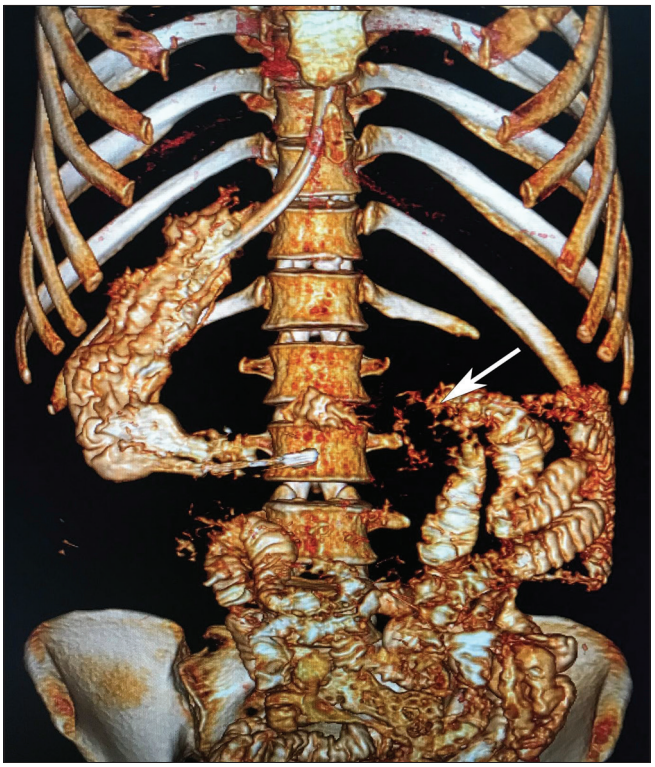

Figure 3: The coronal reconstructed view of CT abdomen shows the duodeno-jejunal junction displayed left lateral to L2 vertebra

Figure 4: The axial view of CECT abdomen shows Polyspenia i.e. presence of multiple splenules instead of a parent spleen

Figure 5: The axial view of CECT abdomen shows (i) Retroaortic left renal vein i.e. left renal vein travels behind the aorta and drains into the dilated azygous vein acting as IVC

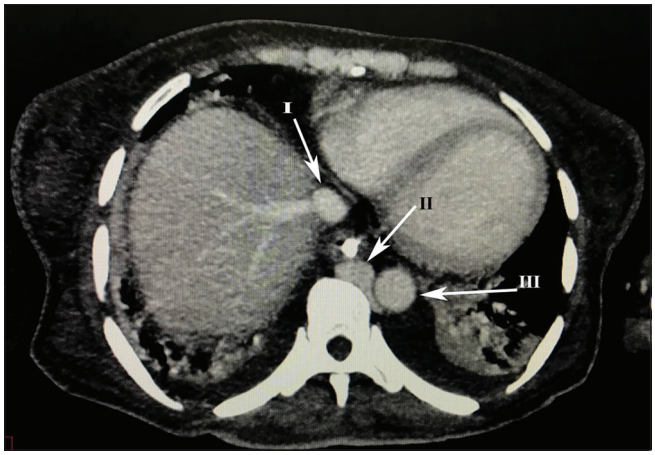

Figure 6: The axial view of CECT Abdomen shows – (i) Short IVC draining the hepatic veins, (ii) Dilated azygous vein – Both together gives a picture of "Double IVC", (iii) Malpositioned aorta i.e. displayed left laterally

of intrathoracic and/or intra-abdominal organs across the left-right axis of the body. It is different from situs inversus which involves all organs. Isomerism refers to the symmetric development of normally asymmetric organs or organ system. These syndromes comprise a combination of cardiac, vascular, and visceral changes.[1]

Although no specific risk factors have been identified, it is thought that the underlying etiology of these abnormalities is a primary defect in lateralization around day 28 of gestation which leads to deviation from normal position of viscera. Mutation in the zinc finger transcription factor (ZIC3) is a cause of X-linked heterotaxy. These arrangements are generally multifactorial in inheritance pattern and the coincidence of aneuploidy or other chromosomal abnormalities is very low.[2]

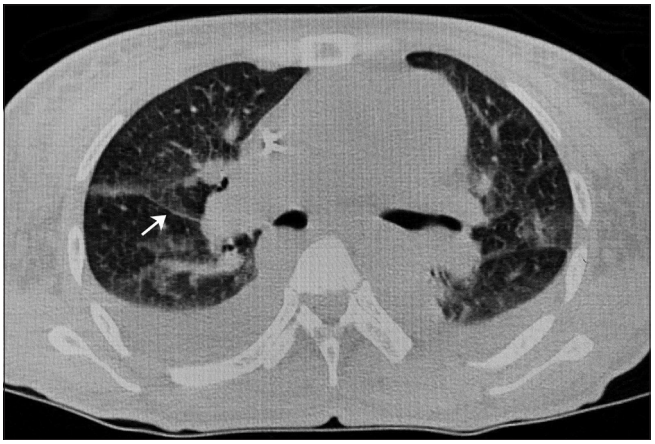

Figure 7: The axial view of plain CT Thorax shows presence of a single fissure in the right lung giving it a picture of bilateral bilobed lung

Situs ambiguous is divided into two general categories – left isomerism (situs ambiguous with polysplenia) and right isomerism (situs ambiguous with asplenia). The left isomerism has an incidence of 1:10,000 new born births and a female predominance. It is usually characterized by abnormal arrangement of solid organs and presence of multiple spleen.[3] However, it should be remembered that this anomaly does not have a fixed set of characteristics that are present in all cases. Some studies report patients with single, lobulated, or even a normal spleen. Liver and gallbladder were generally left sided but may also be transverse or along the midline. Pancreas may be truncated or short and stubby or atrophied. Aorta may be displaced slightly to the left or right side. The arrangement of stomach and C-loop of duodenum was directed to the opposite side with intestinal malrotation a common finding.[4,5]

Assessment of the intrathoracic contents can be made with plain film, echocardiography, CT, and MRI as well as angiography. Below the diaphragm, the abdominal contents can be imaged with ultrasound, GI contrast studies, and MRI. Treatment is completely dependent on the malformation and the impact they have on the daily lifestyle of the patient.[6,7]

REVIEW OF LITERATURE

Situs ambiguous occurs in 1 out of every 10,000 live births.

CONCLUSION

Although the condition is rare, the ability to recognize and diagnose situs ambiguous using radiodiagnostic tools is important for radiologists and clinicians specially due to its potential implications. If the condition goes undiagnosed or

there is delay in diagnosis, situs ambiguous results in unnecessary cardiopulmonary and gastrointestinal complications. Proper diagnosis by appropriate imaging modality prenatally results in reduction of the fatal consequences.

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Case Report

Invasive Paranasal and Pulmonary Aspergillosis in a Post-COVID Patient with Diabetes

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Abstract

COVID-positive patients and those recovering from COVID affliction are more susceptible to fungal infections. It is especially true in patients who are diabetic, on prolonged glucocorticoid medications and transplant patients. In critically ill patients, invasive fungal infections have a bad prognosis resulting in grim figures of morbidity. Glucocorticoid medications may aggravate hyperglycemia in patients with diabetes which present a favorable ground for fungal infections. In this case, we have come across a patient who has a long-standing history of diabetes. She has been suffering from invasive pulmonary aspergillosis while recovering from COVID-19. The diagnosis of invasive aspergillosis is difficult using clinical criteria, thus imaging modalities are the mainstay for diagnosis. Intravenous voriconazole (400 mg BD tapered down to 200 mg) has been used to treat her condition. Patients who are on glucocorticoids, have deteriorating pulmonary functions, and are diabetic have increased risk of developing aspergillosis.

Keywords: COVID-19, Diabetes, Fungal infection, Glucocorticoids, Invasive aspergillosis

INTRODUCTION

COVID-19, caused by betacoronavirus SARS-CoV-2 which originated in Wuhan, China, in 2019, has resulted in a global pandemic and cases have been skyrocketing ever since.[1] India especially has witnessed multiple waves of this deadly virus that has resulted in high mortality and morbidity.[2] Many fungal coinfections may be associated with patients with preexisting comorbidities like diabetes mellitus. Chronic hypertension, cardiac, and lung diseases aggravate the severity of this infection. India is presently the diabetic capital of the world, therefore, being on the precipice for developing complications.[3] Glucocorticoids have contributed to an immunocompromised state of the patients resulting in an increased number of invasive fungal infections. Here, we present a case of a diabetic woman recovering from COVID-19 who has developed invasive pulmonary and paranasal aspergillosis.

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PRESENTATION OF CASE

A 64-year-old COVID-19-positive woman presented to the Emergency Department of IQ City Medical Hospital on May 23, 2021, with the chief complaint of a fall in the bathroom. On examination, she was breathless and had intermittent fever (>38.5°C).

She had a history of insulin-dependent type 2 diabetes mellitus and hypertension. She had tested COVID positive on May 14. She received the following medications antihypertensives, proton-pump inhibitors, antipyretics, antibiotics, antihelminthics, glucocorticoids, zinc and multivitamin supplements, insulin injection, and nonsteroidal anti-inflammatory drugs.

Her partial pressure of O_2 was 96%, respiratory rate 22/min, temperature 98.6°F, arterial blood pressure 140/80 mmHg, pulse rate 70/min, and GCS 15. Hemoglobin was 10.2 g/dl, WBC total count 25.7 × 1000/μL, and C-reactive protein 395 mg/L.

The patient was shifted to the COVID isolation ward. Her CBG* level peaked up to 352 mg/dl

*CBG - Capillary Blood Glucose (Normal Level - Fasting 72–99 mg/dl, Postprandial – Up to 140 mg/dl). She was

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given injection human actrapid through subcutaneous route as a medication.

Chest X-ray PA View

It shows bilateral asymmetric interstitial and septal opacities [Figure 1].

Axial Section of CT Thorax

It revealed patchy areas of ground-glass haziness with vascular thickening noted in bilateral lung field – features are in keeping with atypical interstitial pneumonia – CORADS 5 [Figure 2].

CT scan of paranasal sinus with magnetic resonance imaging orbit screening revealed right-sided acute on chronic pansinusitis with rarefaction of bony walls along with small bony fenestration in the anteroinferior wall of the maxillary sinus with overlying soft-tissue inflammatory changes, air foci in the adjoining hard palate [Figure 3].

Figure 1: Bilateral asymmetric interstitial and septal opacities

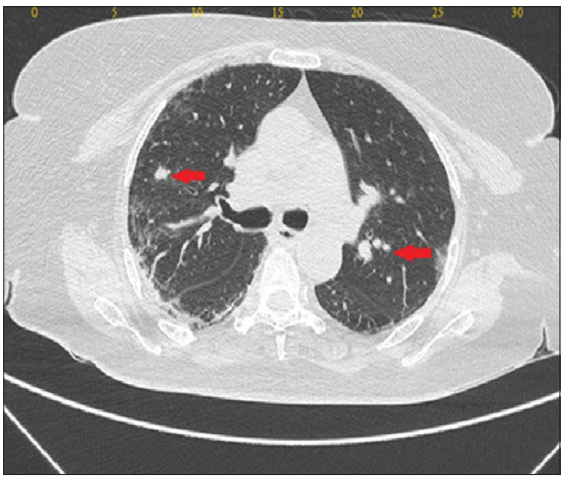

Figure 2: Axial section of CT thorax: Multiple nodular lesions with a ground-glass halo are seen in both lung fields as shown by red arrow

Additional extra paranasal sinus involvement is seen in the right intraorbital and periorbital space with edema and inflammation. There was associated orbital and periorbital cellulitis [Figures 4 and 5].

ECG findings revealed left ventricular hypertrophy with inferior wall ischemia.

She tested negative for COVID-19 on RTPCR on May 25 [Figure 6].

On further examination by an ophthalmologist, it was revealed that she had periorbital edema, orbital cellulitis, ecchymosis, and chemosis in the right eye [Figure 7]. Pupillary reactions were positive. History of dental infection was also elicited. She also had redness of the right cheek.

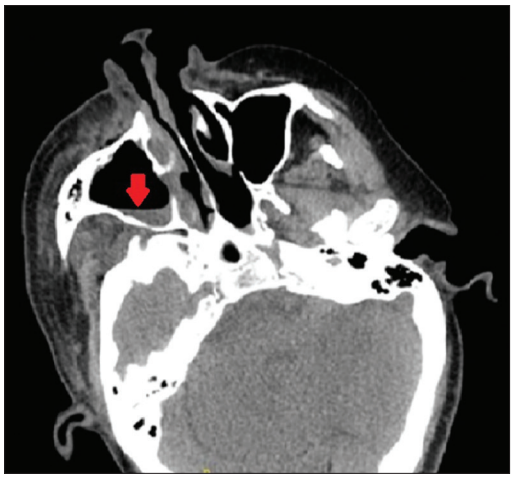

Figure 3: Axial section of CT PNS: Right-sided maxillary sinusitis with rarefaction and thinning of the bony walls (arrow)

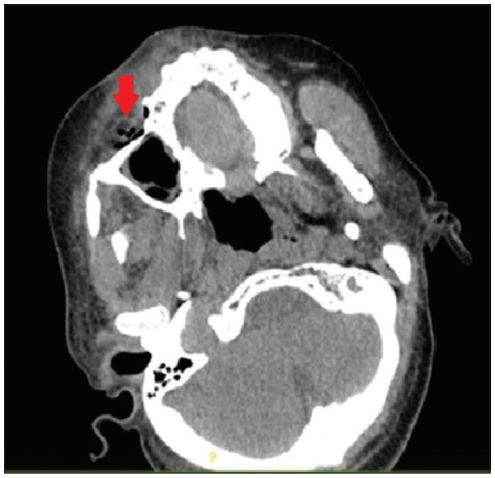

Figure 4: Axial section of CT PNS: Erosion in the anterior-inferior wall of the maxillary sinus was present. There was adjoining soft-tissue inflammatory changes in gingiva with intervening air lucencies (arrow)

On inspection of the oral cavity, there was a presence of blackish discoloration and erosion of the palate [Figure 8]. Scraping was done from all over the margins and center of the discoloration. It was sent for KOH mount and culture. She has suspected to have mucormycosis.

Microbiological Finding

The sample showed numerous thin hyphae with acute-angled branching [Figure 9 black arrow] and frequent septae [Figure 9 white arrow].

In this case, our microbiological finding was typical of the Ascomycetes family.

DISCUSSION

According to recent statistics, 8% of COVID-19 patients have developed fungal or other secondary infections during their hospital stay. There was no underlying evidence of infection, yet 72% of patients had received broad-spectrum antibiotics.[4] In an observational multicentric study conducted by clinicians in Bengaluru, India, it was seen that there is a relationship between SARS-CoV-2, corticosteroid administration, uncontrolled diabetes mellitus, and incidence of aggressive maxillofacial and rhino-cerebro-orbital fungal infections.[5]

The COVID-19 patients who have a cytokine storm develop inflammation in the lungs which may result in acute lung injury and damage to other organs which eventually leads to multiorgan failure. Steroids being one of the best anti-inflammatory drugs, COVID-19 patients are treated with it. Advocacy by NATIONAL CLINICAL MANAGEMENT PROTOCOL COVID-19 states that intravenous methylprednisolone 0.5–1 mg/kg/day should be administered for 3 days in moderate cases and 1–2 mg/kg/day in severe cases.[6] On the other hand, steroids also suppress the body's immune system.[7] Hence, the body becomes more prone to developing a wide range of infections, especially fungal infections. In India, a huge

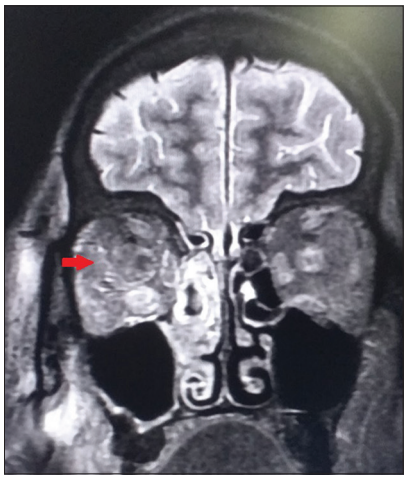

Figure 5: MRI coronal STIR image of the patient shows diffuse intraconal fat stranding, as shown by the red arrow

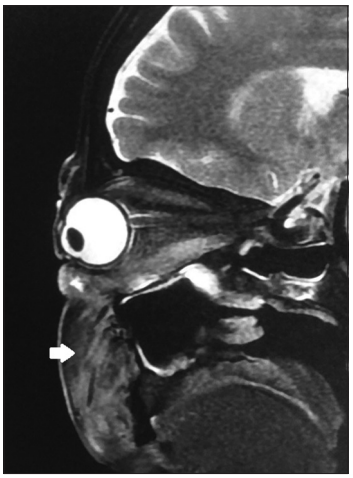

Figure 6: MRI sagittal STIR image of the patient shows pre-maxillary inflammatory focus, as shown by the white arrow

Figure 7: Periorbital oedema, orbital cellulitis, ecchymosis and chemosis in the right eye

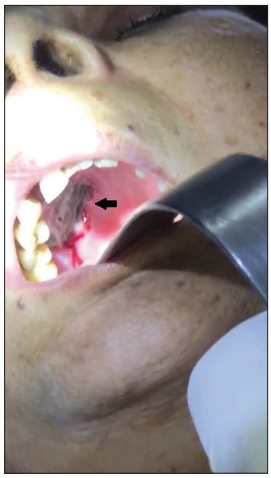

Figure 8: Blackish discoloration and erosion of the palate (Black arrow)

Figure 9: Numerous thin hyphae with acute-angled branching [Figure 9 black arrow] and frequent septae [Figure 9 white arrow].

number of patients suffering or recovering from COVID-19 have been suffering from fungal infections resulting in high mortality and morbidity. While COVID-19- associated mucormycosis is increasingly recognized, invasive pulmonary and paranasal aspergillosis is not common. The global prevalence of aspergillosis was 5.4%.[8]

Here, in IQ City Medical College and Hospital, we have come across a patient who has a long-standing history of diabetes. She has been suffering from invasive pulmonary aspergillosis while recovering from COVID-19. Intravenous voriconazole (400 mg BD tapered down to 200 mg) has been prescribed. The signs of orbital cellulitis were discerned only after 4 days of admission to the hospital. In our case, a previously undiagnosed invasive pulmonary and paranasal aspergillosis infection may have been aggravated or it may have subsequently developed.

CONCLUSION

A significant increase in the incidence of both bacterial and fungal infections in COVID-19 is possibly due to immunosuppression. As the treatment protocol of COVID-19 includes the use of steroids, it has led to the development of opportunistic fungal diseases. Physicians should circumspect the possibility of invasive secondary fungal infections like aspergillosis in patients with COVID-19, especially in patients with preexisting risk factors. This report is a conscious effort to promulgate the significance of early detection and treatment of opportunistic infections. The most calamitous ones are SARS-CoV-2-associated mucormycosis and invasive pulmonary and paranasal aspergillosis. Hence, a due cognizance of this fact with a well thought out approach toward treatment may be able to reduce the morbidity and mortality associated with COVID-19 complications.

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Case Report

Autosomal Dominant Polycystic Kidney Disease: A Risk Factor for Berry Aneurysm

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Abstract

Autosomal dominant polycystic kidney disease is a genetical disorder caused by changes occurred in PKD1 and PKD2 genes and is characterized mainly by the growth of multiple kidney cysts. It is progressive disorder with symptoms of high blood pressure, pain in the back and the sides, and also headache. Patients having ADPKD are having a high risk of formation of intracranial aneurysms. Presenting a case of ADPKD associated with subarachnoid hemorrhage with berry aneurysm and discussed about the diagnostic approach with imaging modalities in this patient and the treatment.

Key words: Autosomal dominant polycystic kidney disease, Aneurysms, Subarachnoid hemorrhage

INTRODUCTION

Autosomal dominant polycystic kidney disease is a disorder with a genetic cause of changes occurred in PKD1 and PKD 2 genes. Age specificity of this disease distribution is between ages of 30 and 40. The most common symptoms of this disease are pain in the back and sides, headaches, urinary tract infection symptoms, high blood pressure, blood in the urine, and fullness of abdomen. The other manifestations are liver and pancreatic cysts, abnormal heart valves, kidney stones, and brain aneurysms. Berry aneurysms are intracranial saccular aneurysms which has a well-known association with ADPKD. CT brain with angiogram being the imaging modality to show the berry aneurysms initially and digital subtraction angiography for the precise diagnosis. Treatment options for berry aneurysms being three: Surgical clipping, endovascular coiling, or conservative management.

CASE REPORT

A 45-year-old male presented to the emergency department with the chief complaints of vomiting, more than 10–15 episodes per day for 2 days, vomiting was not blood stained and not preceded by nausea. Furthermore, he had complaints of back pain and severe headache both in frontal and occipital regions associated with neck pain. The patient does not have a history fever, abdominal pain, loose stools, and blurring of vision. The patient was a known case of systemic hypertension for 5 years and was on regular medication. On examination, the patient was thin built, conscious, oriented to time, place, and person and was afebrile. Systemic examination and cardiovascular system examination-S1, S2 were normal, no murmurs and split. On respiratory system examination, bilateral air entry was equal, no added sounds were heard. Abdomen was soft and non-tender, non-distended. Central nervous system examination revealed no focal neurological deficit. On checking vitals, his blood pressure was 180/110 mmHg, pulse rate was 68 and regular and was maintaining normal oxygen saturation.

Routine blood investigations were done showed normal complete blood count analysis and serum electrolytes. There was mild elevation in values of urea and serum creatinine such as urea – 57 mg/dl and serum creatinine was 1.6 mg/dl, respectively. Nephrologist opinion was obtained in view of elevated renal function parameters and USG abdomen was taken showed multiple cysts of various sizes in both the kidneys indicating adult polycystic kidney disease. In view of persistent severe headache, MRI brain was taken showed features of raised

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intracranial hypertension and subarachnoid hemorrhage in basal cisterns, both the Sylvian fissures, and posterior subarachnoid space over the thoracic region.

USG Abdomen showing multiple cysts in the kidneys [Figure 1].

CT brain angiogram showing subarachnoid hemorrhage, few berry aneurysms in the right MCA, and proximal ACA and also "puff of smoke" like appearance (Moyamoya disease) [Figure 2].

Neurologist opinion was obtained and was treated with steroids such as, antiepileptics to prevent seizures, antihypertensives, calcium channel blockers to prevent vasospasm, and other supportive drugs. Moreover, as per neurologist suggestion, CT brain with angiogram was done and neurosurgeon opinion was obtained. CT brain angiogram showed, few small approximately 5 mm berry aneurysms in the right middle cerebral artery and its branches and proximal anterior cerebral artery and also the appearance of Moyamoya disease. As per neurosurgeon advice, digital subtraction angiography was done and treated surgically with neurosurgical clipping of the aneurysm. Post-surgery patient was under intensive care unit for some period, was shifted to ward once general condition was stable and the patient was discharged after symptomatic improvement.

DISCUSSION

Autosomal dominant polycystic kidney disease (ADPKD) is a genetic disease caused by changes in the genes such as PKD1 and PKD2. Polycystic kidney disease (PKD) is of two variants depending on the inheritance such as autosomal dominant and autosomal recessive. Autosomal dominant variant causes cysts to grow only in the kidneys and it is also called as adult PKD and patients with this variant may not notice any of the symptoms until the age of 30–50. Autosomal recessive variant causes cysts to grow both in kidneys and liver, which is also named as infantile PKD, as the babies may show symptoms during their 1st months of life. ADPKD being the common variant affects 1 in 500–1000 people all over the world. As it causes progressive growth of cysts in kidney, it causes the kidneys to enlarge and damage the kidneys and reduces its function, leading to ESRD in many cases. It is fourth important cause for end-stage renal disease. PKD is mostly always inherited either from one of the parents or both the parents. People affected are of both genders, all age groups, nationalities, and ethnicities equally. It is that if there is family history of ADPKD in a blood relative, its more likely to have ADPKD. However, it can also occur without a family history of ADPKD because of the new genetic change that occurs in the gene that causes ADPKD. Polycystin 1 is responsible to regulate tubular epithelial cell adhesion and for its differentiation and polycystin 2 usually functions as ion channel along with mutations that cause cysts fluid secretion. These protein mutations alter the main function of renal cilia that is to enable the tubular cells for sensing the flow rates. Moreover, this ciliary dysfunctions lead to the cystic transformation. Hemorrhage may also occur in these cysts causing hematuria. During the initial period, patients do not develop any symptoms. The common symptoms being pain in the back, flank pain, and headache and signs such as hematuria, proteinuria, high blood pressure, and polyuria. Other manifestations may be development of liver cysts, pancreatic cysts colonic diverticula, and hernias, can lead to valvular heart disorders most often mitral valve prolapse and also aortic regurgitation, coronary artery aneurysms, and the most serious being the cerebral aneurysms which are about 5% in young adults and to a range of 10% in aged patients.[1]

Diagnosis is suspected in patients with a positive family history, with symptoms or signs. Diagnosis is usually made by USG abdomen imaging which shows extensive cystic changes throughout the kidneys which are usually enlarged. If USG results are not conclusive, then the next step being CT or MRI, whereas these both tests are very sensitive. Other routine tests such as urinalysis, renal function tests, and complete blood count were done. Genetic testing is done for patients who are suspected to have PKD but not with family history, where imaging studies are not definitive and in more young patients.[2,3] Treatment part being strict control of blood pressure with ACE inhibitors or ARBs which reduces the renal scarring and decreases the progression of loss of kidney function. Other drugs such as tolvaptan, a vasopressin receptor 2 antagonist, used to slow the increasing renal volume and declining kidney function but it may cause severe liver failure and is contraindicated in liver disease patients. If symptoms of urinary tract infection persists, then it is to be treated and if severe symptoms occur due to massively enlarged kidneys then nephrectomy option is being choosed. Hemodialysis, peritoneal dialysis, or transplantation of kidney are done for patients who develop chronic kidney disease.[2]

Most serious complication being cerebral aneurysms and is noted in 9–12% of ADPKD patients. Aneurysmal walls are mainly featured by the elastic tissue disruption and the vascular smooth muscle cells loss. Thus, the decreased level of polycystin in the vascular smooth muscle which is caused by the mutations in polycystic kidney disease facilitates the development of aneurysms. Berry aneurysms also named as saccular aneurysms represent more than 90% of the cerebral aneurysms. There is a ballooning that happens from the weak area in the wall of the concerned blood vessel of brain. Symptoms range from no symptoms to intracranial hemorrhage may be subarachnoid in some

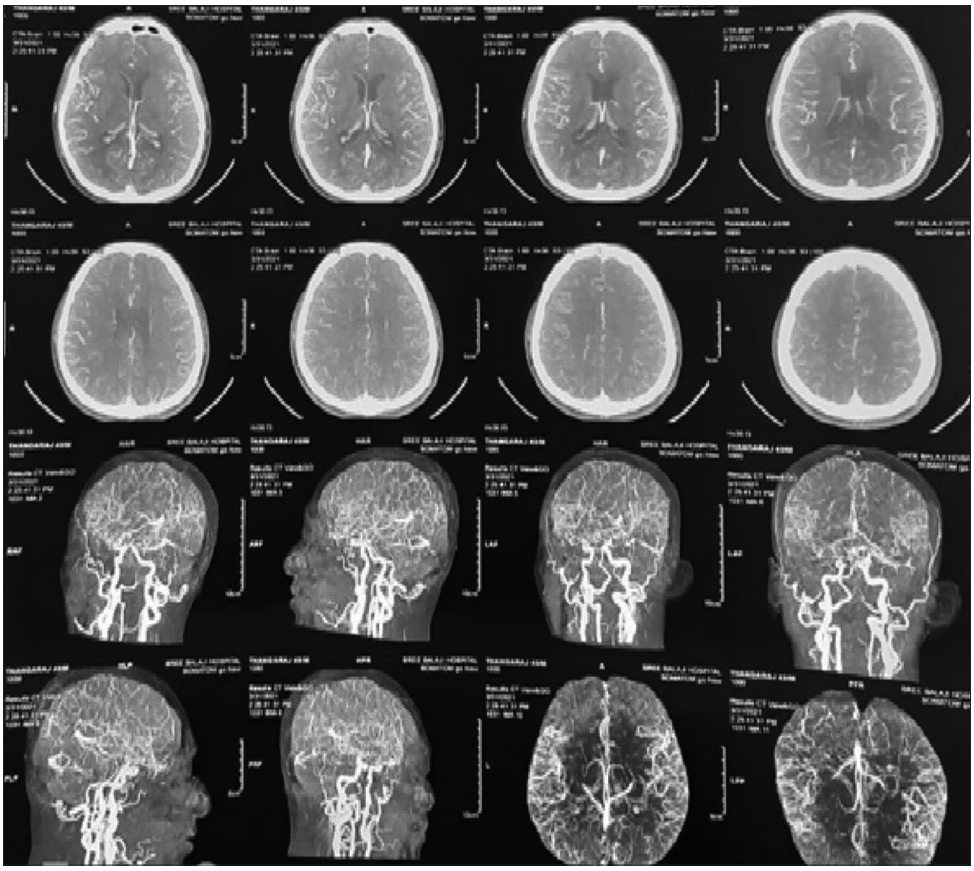

Figure 1: CT brain angiogram showing subarachnoid haemorrhage, few berry aneurysms in right MCA and proximal ACA and also "puff of smoke" like appearance (MoyaMoya disease)

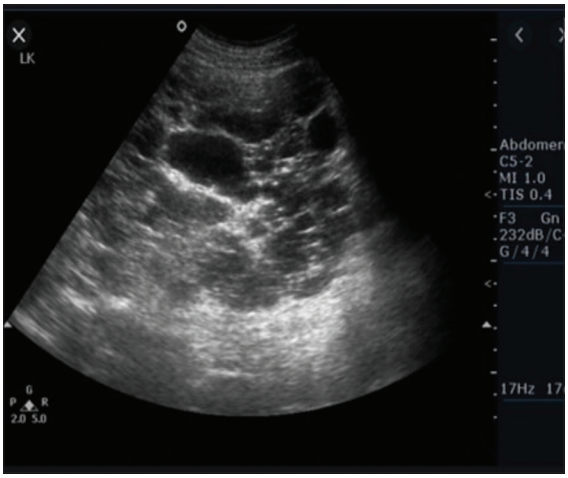

Figure 2: USG abdomen showing multiple cysts in the kidneys

cases. The causes of berry aneurysms commonly are connective tissue disorders, polycystic kidney disease and arteriovenous malformations, and less commonly cigarette smoking, drugs abuse, alcoholism, and trauma.[3] In that, aneurysmal rupture is the most fearing consequence and its about 0.7% rupture rate annually. Aneurysmal subarachnoid hemorrhage happens at the rate of 6–16 persons per 100,000 population. Moreover, this rupture of aneurysms accounts for about 0.5% of all deaths. Around 20–30% of patients with aneurysms will have more than 1 aneurysm.

More than 85% of aneurysms are in anterior circulation. Usually these aneurysms are located in the anterior circulation on the Circle of Willis that is in the junction of anterior communicating artery with anterior cerebral artery, and in the junction of posterior communicating artery with the internal carotid artery and also in the division of middle cerebral artery. In posterior circulation, basilar apex is the most common area to be involved. Important symptoms being headache, change in consciousness level, seizure episodes, neck pain and stiffness, speech disturbances, and visual disturbances also.[4] Physical examination should include cranial nerve testing, limb sensations, and power and signs for meningismus, Kernig's and Brudzinski's.

Diagnosis is made by CSF analysis to rule out other differential diagnosis, imaging techniques such as NCCT of brain, MRI brain CT angiogram of brain, and digital subtraction angiography. Medical management includes control of high blood pressure to reduce the risk of rebleeding, with nicardipine and labetalol, adequate pain control, nimodipine the drug to be given in the first 96 h mainly to help decrease the vasospasm along

with anti-seizure medications given.[5] Surgical options are chosen in patients who had rupture of aneurysm or who are at risk for rupture. Three methods are being used such as neurosurgical clipping of the aneurysmal artery, endovascular coiling of the aneurysm and the newer option being flow diverters, and tubular stent-like implants to divert blood flow away from aneurysm. Prognosis depends on age factor, comorbidities, previous neurological conditions, location site of aneurysm, and bleeding extent in aneurysmal rupture patients. Near about 25% with ruptured aneurysms may not survive the 1st day of diagnosis and some patients around 25% may die in the next 6 months of diagnosis due to complications.

CONCLUSION

The prevalence rate of intracranial aneurysms in patients with ADPKD is 9–12%. In many cases, patients with ADPKD may develop intracranial aneurysms and diagnosis of intracranial aneurysms is made only after the symptoms become worse and severe. As the diagnosis gets delayed, in some cases, aneurysms are diagnosed after rupture which is a more serious condition and the cause for death in many patients. As ADPKD being the identifiable risk factor for intracranial aneurysms, the brain imaging screening is recommended in all the cases of ADPKD for early diagnosis and to prevent further complications and mortality.

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Case Report

Acute Pancreatitis as a Manifestation of Primary Hyperparathyroidism: An Uncommon Association

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Abstract

The manifestation of primary hyperparathyroidism (PHPT) as acute pancreatitis (AP) is a rare entity. We report a case of a 55-year-old female, admitted to the intensive care unit of the general surgery department presenting with features of acute abdomen with a clinical and radiological diagnosis of AP. Further evaluation revealed hypercalcemia and PHPT due to parathyroid adenoma. Hypercalcemia due to PHPT plays a vital role in the pathogenesis of pancreatitis. The patient underwent parathyroidectomy and pathological examination of the parathyroid gland confirmed a parathyroid adenoma. After aggressive medical management of AP and hypercalcemia, parathyroidectomy has been shown to improve clinical outcomes and prevent further recurrences of pancreatitis.

Key words: Acute or chronic pancreatitis, Hypercalcemia, Parathyroid adenoma, Primary hyperparathyroidism

INTRODUCTION

Acute pancreatitis (AP) induced by hypercalcemia due to primary hyperparathyroidism (PHPT) is a rare event and the reported incidence range from 0.23% to 6.8%.[1] The causes of pancreatitis are largely dominated by gallstones and alcohol. PHPT is also considered a metabolic cause of acute or chronic pancreatitis (CP). Hypercalcemia secondary to the secretion of parathyroid hormone (PTH), is postulated to induce pancreatic injury through the activation of trypsinogen to trypsin and intraductal precipitation of calcium, leading to ductal obstruction and subsequent attacks of pancreatitis. Furthermore, genetic defects in (serine protease inhibitor Kazal Type 1 (SPINK 1) and cystic fibrosis transmembrane conductance regulator genes have been suggested as possible mechanisms of AP in the setting of hypercalcemia.[2] Approximately 1.5–13% of patients with PHPT develop AP. Normal or elevated calcium levels during acute or CP should always get attention.

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CASE REPORT

A 55-year-old hypertensive woman, presented to the casualty with complaints of upper abdominal pain, radiating to the back, for the past 2 days. She did not report any recent medication use or alcohol intake. On physical examination, she was hemodynamically stable and per abdominal palpation revealed severe epigastric tenderness with guarding. Initial laboratory studies revealed leukocytosis of 12 thousand/μL, hemoglobin 10.6 g/dL, creatinine 1.05 mg/dL, amylase, and lipase were elevated at 220 IU/L and 542 IU/L, respectively. Serum calcium level was found to be 15.5 mg/dL. Her alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and total bilirubin were normal. Contrast-Enhanced computed tomography of the abdomen and pelvis [Figure 1] showed features suggestive of AP with mildly enlarged pancreas with peripancreatic inflammation and no evidence of cholelithiasis or common bile duct dilatation. Soft tissue density nodules in the momentum, transverse mesocolon,

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and hepatorenal recess suggestive of fat necrosis and degenerative changes and end-plate sclerosis noted in the spine and bilateral sacroiliac joints with lysis of pars interarticularis of L4 and L5 vertebrae. Patient was initially managed conservatively with aggressive fluid therapy, I.V. Antibiotics, pain management, and three doses of Injection. zoledronic acid. After adequate resuscitation and stabilization of the patient, patient was discharged and readmitted 3 weeks later for further evaluation. On examination of the neck [Figure 2], she was found to have a swelling in the anterior aspect on the left side of size 3 cm × 3 cm, which moved with deglutition. Ultrasonography of the neck [Figure 3] showed complex mixed cystic solid lesion of size 5.1 cm × 3.2 cm × 3.4 cm (Volume 30 cc) arising from the inferior pole of the left lobe of the thyroid: TIRADS IV (moderately suspicious). About 5 ml of colloid-like fluid was aspirated and FNAC results showed the possibility of cystic colloid goiter in view of abundant colloid and occasional thyroid follicular cells. Given the absence of biliary, alcohol-induced, or medication-associated pancreatitis, hypercalcemia was considered to be the probable cause. Serum intact PTH level was found to be significantly elevated at 1002.8 pg/mL (12–88 pg/mL). 99mTc - Sestamibi parathyroid single-photon emission computerized tomography-computed tomography scan [Figure 4a and b] showed features suggestive of left inferior parathyroid adenoma. It also revealed altered trabeculae and lytic areas showing lace-like pattern and mildly increased 99mTc - Sestamibi uptake in the skull, bilateral scapulae, bilateral few ribs, multiple visualized cervical, and dorsal vertebrae likely Brown's tumor. Hence, proceeded with left parathyroidectomy with left thyroid lobectomy under general anesthesia. Procedure started with a transverse collar incision in the neck, followed by raising of superior and inferior flaps. Deep fascia and strap muscles were opened and retracted. Cystic mass [Figure 5a] of size 4 cm × 3 cm × 3 cm involving the left lower pole of thyroid extending from tracheoesophageal groove upto the suprasternal notch. The interior part of the cystic lesion had solid components of size 2 cm × 2 cm. The left lobe of the thyroid was mobilized medially and cystic mass was completely excised [Figure 5b] after delineating from the recurrent laryngeal nerve and inferior pole of the thyroid. The left superior parathyroid gland was identified and excised along with the left lobe of the thyroid. Hemostasis secured. Wound closed in layers. Postoperatively, serial monitoring of serum calcium levels and PTH assays were done. Serum intact PTH level was found to be 0.02 pg/mL (12–88 pg/mL), on postoperative day 1. Patient showed a gradual drop in the serum calcium levels from postoperative day 1 (8.8 mg/dL) and was managed with intravenous calcium accordingly. Serum calcium levels were found to be within normal limits and were managed

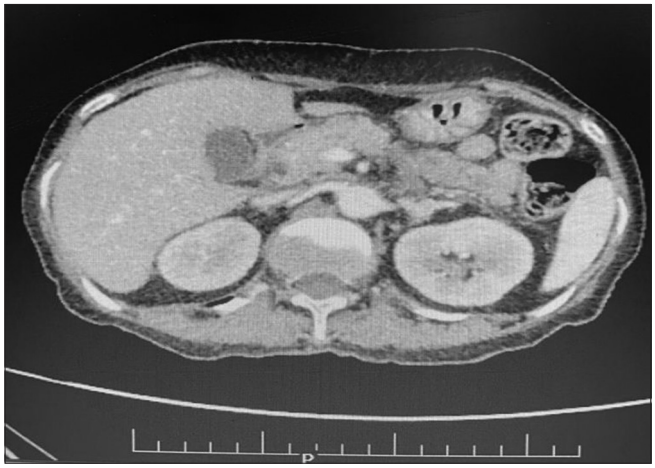

Figure 1: Contrast-Enhanced computed tomography of the abdomen showing features sug-gestive of acute pancreatitis with mildly enlarged pancreas with peri-pancreatic inflammation

Figure 2: Clinical image of swelling over the left lower anterior aspect of the neck

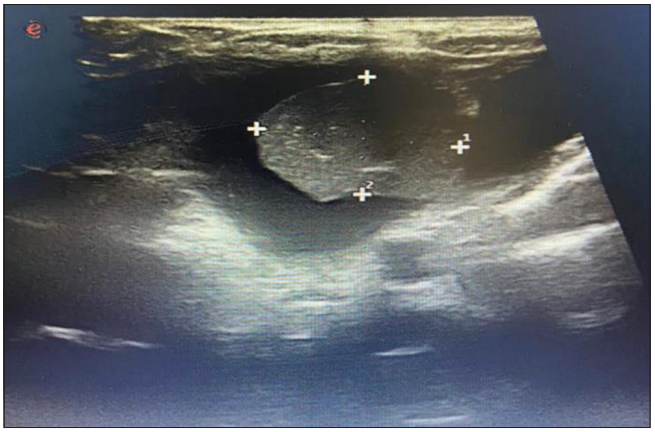

Figure 3: Ultrasonography of the neck showing Complex mixed cystic solid lesion arising from the inferior pole of the left lobe of the thyroid

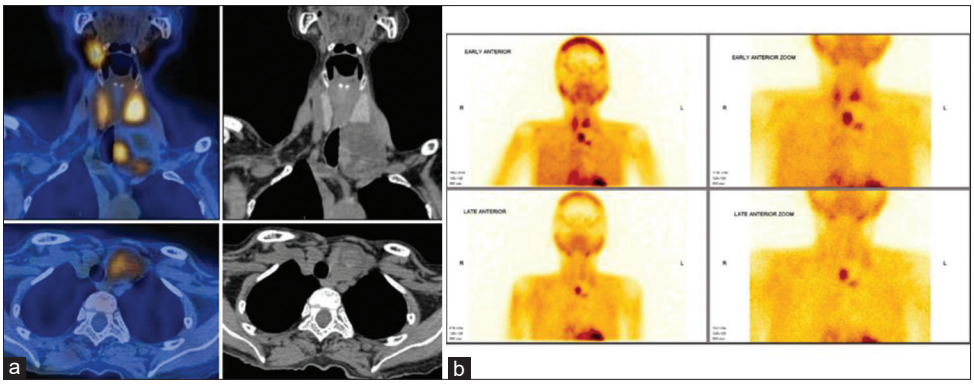

Figure 4: (a and b) 99mTc - Sestamibi parathyroid single-photon emission computerized to-mography-computed tomography scan showing features suggestive of left inferior parathy-roid adenoma

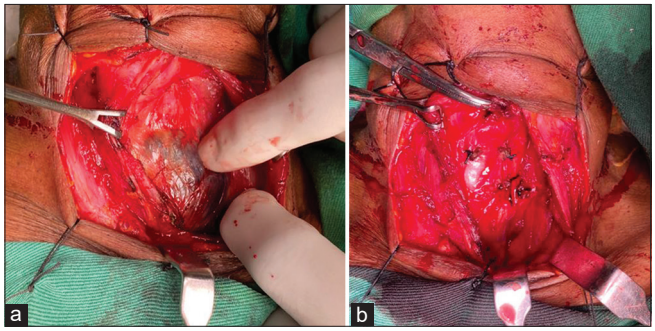

Figure 5: Intra-operative images of (a) Left parathyroid adenoma and (b) Post excision of the adenoma

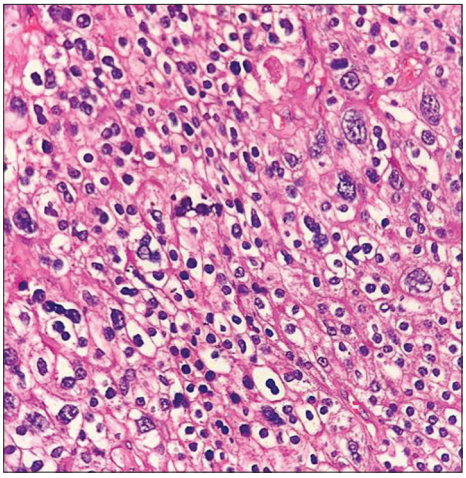

Figure 6: Microscopic image shows chief cells arranged in sheets with a foci showing tumor cells exhibiting nuclear atypia with bizarre nuclei, prominent nucleoli, and some spindle cells interspersed in fibro collagenous tissue

with oral calcium supplementation upon discharge. Histopathological reports were consistent with features of atypical parathyroid adenoma [Figure 6]. Thus, patient had a favorable outcome and did not develop any further attacks of pancreatitis or other complications of the procedure, on any of the follow-up visits.

DISCUSSION

The incidence of AP in PHPT was found to be no different than in the general population in recent studies, although the pancreatitis risk is known to be 10 fold elevated in PHPT. Biliary stones and alcohol are responsible for 80% of AP cases whereas the remaining 20% can be related to various etiologies such as infection, ductal obstruction, hypercalcemia of any cause, hyperlipidemia, impaired pancreatic perfusion, or idiopathic. Patients with PHPT have shown to have an increased incidence of pancreatitis, peptic ulcer disease, cholelithiasis, probably due to an increase in biliary calcium, which leads to the formation of calcium bilirubinate stones. Hypocalcemia is a poor prognostic factor in AP.[3] However, when hypercalcemia is detected in AP it should compel clinicians to search for alternative explanations such as malignancy or hyperparathyroidism. In this case, the presence of hypercalcemia in AP guided us to detect undiagnosed PHPT and a parathyroid adenoma. The absence of any other explanation for AP and clinical improvement after parathyroidectomy supports a likely relationship between PHPT and AP in this case.

CONCLUSION

The occurrence of acute or CP is rarely associated with PHPT. The pointer to find the parathyroid adenoma was the hypercalcaemia. This case report highlights the importance of fully investigating for PHPT in a pancreatitis patient with high normal or raised serum calcium level, especially in the absence of other common causes of pancreatitis. The return of serum calcium levels to normal values and remission of AP episodes after surgical intervention, thus suggests a positive cause and effect relationship between hyperparathyroidism and AP.

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Original Article

Randomized Controlled Trial of Comparison of Absorbable Extra Long-Term (Poly Hydroxy Butyrate) Suture Versus Non-Absorbable (Polypropylene) Suture for Abdominal Wall Closure

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Abstract

Introduction: In patients undergoing midline incisions, rectus sheath can be closed with continuous or interrupted suture using absorbable or non-absorbable materials. Despite major improvements in antibiotics, better anesthesia, superior instruments, earlier diagnosis of surgical problems, and improved techniques for post-operative vigilance, post-operative complications such as incisional hernias, burst abdomen, and wound infections continue to occur, which causes significant surgical health-care problem.

Aims and Objectives: The objectives of the study were to continuous technique with non-absorbable sutures (polypropylene) – Group I and to interrupt technique with non-absorbable suture (polypropylene) – Group II.

Materials and Methods: Randomized controlled, prospective study on 271 patients with primary elective midline laparotomy in Mahatma Gandhi Memorial Hospital. Patients operated from January 2018 to June 2019 are included in this study and are followed up for a minimum period of 1 year.

Observation and Results: Group I includes 102 patients with continuous technique using non-absorbable polypropylene, Group II includes 91 patients with interrupted technique using non-absorbable polypropylene, and Group III includes 78 patients with continuous slowly absorbable polyhydroxybutyrate.

Key words: Absorbable polyhydroxybutyrate, Laparotomy, Non-absorbable polypropylene

INTRODUCTION

In patients undergoing midline incisions, rectus sheath can be closed with continuous or interrupted suture using absorbable or non-absorbable materials. Despite major improvements in antibiotics, better anesthesia, superior instruments, earlier diagnosis of surgical problems, and improved techniques for post-operative vigilance, post-operative complications such as incisional hernias, burst abdomen, and wound infections continue to occur, which causes significant surgical health-care problem.

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Decrease of the post-operative surgical complications can reduce the length of hospital stay, significant morbidity, and even mortality and financial burden to the health-care system.

In our hospital, routinely non-absorbable polypropylene is used for the closure of rectus sheath in midline laparotomy, which remains as a foreign material throughout the life after wound gains tensile strength. Several studied were conducted previously using absorbable materials for the rectus closure, with negative results. However, recently, studies in other countries showed that slowly absorbable suture materials can reduce the challenges of abdominal wall closure, which was least explored in our country.

Having good infrastructure and surgical faculty, with an enormous patient inflow, recently FDA approved slowly absorbable suture material (2010), i.e., polyhydroxybutyrate was analyzed in our hospital with all the ethical and medical factors taken into consideration.

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Aims and Objectives

The aim of study is to compare,

- Continuous technique with non-absorbable sutures (polypropylene) – Group I
- Interrupted technique with non-absorbable suture (polypropylene) – Group II
- Continuous technique with slowly absorbable sutures (polyhydroxybutyrate) – Group III, of rectus sheath closure.

Focusing mainly on incidence of incisional hernias, burst abdomen, wound infections, chronic wound pain, suture sinus, stitch granuloma, and time for rectus closure.

PATIENTS AND METHODS

Design

This was a randomized controlled, prospective study on 271 patients with primary elective midline laparotomy in our hospital.

Duration

Patients operated from January 2018 to June 2019 are included in this study and are followed up for a minimum period of 1 year.

Inclusion Criteria

The following criteria were included in the study:

1. Patients undergoing elective primary midline laparotomy,
2. Expected length of incision of at least 10 cm,
3. Informed consent about the study,
4. Age in between 18 and 70 years.
5. Life expectancy more than 1½ year.

Exclusion Criteria

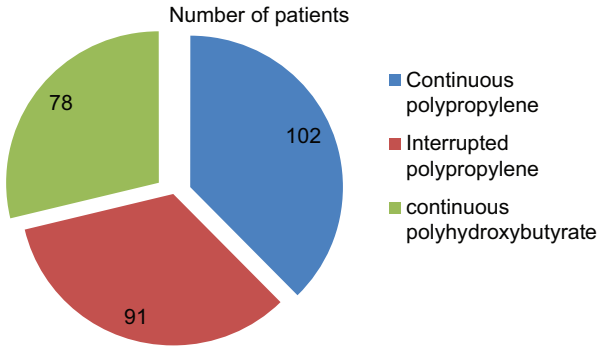
The following criteria were excluded from the study:

1. Patients requiring emergency surgery,
2. Patients undergoing immunosuppressive therapy,
3. Patients undergoing chemotherapy within 2 weeks before surgery
4. Patients undergoing radiotherapy longer than 8 weeks before surgery,
5. Patients with coagulopathy,
6. Patients with disorders that preclude study participation (dementia, and language problems).

OBSERVATION AND RESULTS

This trial was conducted on 271 randomized patients in our hospital.

1) Group I includes 102 patients with continuous technique using non-absorbable polypropylene,
2) Group II includes 91 patients with interrupted technique using non-absorbable polypropylene,
3) Group III includes 78 patients with continuous slowly absorbable polyhydroxybutyrate



Incidence of Wound Infection

In continuous non-absorbable polypropylene (Group I) – 15 patients out of 102 patients developed surgical site infection.

i.e., 15/102 × 100 = 14.70%

In interrupted non-absorbable polypropylene (Group II) – 14 patients out of 91 patients developed surgical site infection.

i.e., 14/91 × 100 = 15.38%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – 12 patients out of 78 patients developed surgical site infection.

i.e., 13/78 × 100 = 16.66%

Incidence of Incisional Hernia

In continuous non-absorbable polypropylene (Group I) – 13 patients out of 102 patients developed incisional hernia.

i.e., 13/102 × 100 =12.74%

In interrupted non-absorbable polypropylene (Group II) – 12 patients out of 91 patients developed incisional hernia.

i.e., 12/91 × 100 = 13.18%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – five patients out of 78 patients developed incisional hernia.

i.e., 05/78 × 100 =06.41%

Incidence of Burst Abdomen

In continuous non-absorbable polypropylene (Group I) – four patients out of 102 patients developed burst abdomen.

i.e., 4/102 × 100 = 3.92%

In interrupted non-absorbable polypropylene (Group II) – three patients out of 91 patients developed burst abdomen.

i.e., 03/91 × 100 = 3.29%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – three patients out of 78 patients developed burst abdomen.

i.e., 03/78 × 100 = 3.84%

Incidence of Stitch Granuloma

In continuous non-absorbable polypropylene (Group I) – five patients out of 102 patients developed stitch granuloma.

i.e., 5/102 × 100 = 4.90%

In interrupted non-absorbable polypropylene (Group II) – eight patients out of 91 patients developed stitch granuloma.

i.e., 08/91 × 100 = 8.79%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – two patients out of 78 patients developed stitch granuloma.

i.e., 02/78 × 100 = 2.56%

Incidence of Suture Sinus

In continuous non-absorbable polypropylene (Group I) – two patients out of 102 patients developed suture sinus.

i.e., 2/102 × 100 = 1.96%

In interrupted non-absorbable polypropylene (Group II) – five patients out of 91 patients developed suture sinus.

i.e., 5 / 91 × 100 = 5.49 %

In continuous slowly absorbable polyhydroxybutyrate (Group III) – one patients out of 78 patients developed suture sinus.

i.e., 1 / 78 × 100 = 1.28%

Incidence of Chronic Wound Pain

In continuous non-absorbable polypropylene (Group I) – five patients out of 102 patients developed chronic wound pain.

i.e., 5/102 × 100 = 4.90%

In interrupted non-absorbable polypropylene (Group II) – ten patients out of 91 patients developed chronic wound pain.

i.e., 10/91 × 100 = 10.9%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – two patients out of 78 patients developed chronic wound pain.

i.e., 2/78 × 100 = 2.56%

Average Time for Rectus Closure

In continuous non-absorbable polypropylene (Group I), avg. time for rectus closure for 10 cm mid line incision – 9.20 min.

In interrupted non-absorbable polypropylene (Group II), avg. time for rectus closure for 10 cm mid line incision – 16.50 min.

In continuous slowly absorbable polyhydroxybutyrate (Group III), avg. time for rectus closure for 10 cm mid line incision – 9.40 min.

DISCUSSION

Wound Infection

Wound infection defined as redness, edema, culture positive secretion, or culture negative with antibiotic treatment more than 6 days (within 30 days of surgery). Incidence of surgical site infection in Group I, Group II, and Group III in this study is 14.70%, 15.38%, and 16.66%, respectively.

Comparison between Group III and Group I (Null Hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of surgical site infection is 16.66%.

In continuous non-absorbable polypropylene (Group I), incidence of surgical site infection is 14.70%.

P value between Group III and Group I is 0.75 (>0.05), i.e., null hypothesis I is accepted and the study shows that there is no significant difference in incidence of surgical site infection with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null Hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of surgical site infection is 16.66%.

In interrupted non-absorbable polypropylene (Group II), incidence of surgical site infection is 15.38%.

P value between Group III and Group II is 0.50 (>0.05), i.e., null hypothesis II is accepted and the study shows that there is no significant difference in incidence of surgical site infection with polyhydroxybutyrate when compared with interrupted polypropylene also.

Various previous studies from Table 1 show that the incidence of wound infections does not vary with the suture material used for fascial closure.

Wide range of variation of wound infection rates in various centers shows that incidence of wound infections is center dependent.

Most of the surgeries included in this study are clean and clean contaminated wounds, expected incidence of wound infection is <10% (clean – 1–3%, and clean contaminated 5–8%). Reaching 17%, the rate of wound infection in our hospital was much higher the antibiotic prophylaxis in today's surgical practice would lead to expect. Indeed, almost all patients received antibiotic prophylaxis and most of them suffered an opening of gastrointestinal tract during the operation.

A possible explanation for the high incidence may be due to poor hygienic condition of the patient and surroundings in our government hospital.

Limitations of the Study

Wound infections in relation to specific surgery were not analyzed in this study.

The study published in J. Am. Coll. Surg. - Aug 2011; 213(2); 236-44 – Surgical site infection and analytic morphometric assessment of body composition in patients undergoing midline laparotomy – showed that body mass index plays a role in the study, which was not taken into consideration in this study. Other important factors of wound infection such as obesity, subcutaneous fat, and collagen disorders also not analyzed in this study.

Higher incidence of wound infections in our hospital can be prevented by: (1) Careful handling of tissues, (2) meticulous dissection, hemostasis, an débridement of devitalized tissue, (3) compulsive control of all intraluminal contents, (4) preservation of blood supply of the operated organs, (5) elimination of any foreign body from the wound, (6) maintenance of strict asepsis by the operating team (e.g., no holes in gloves, avoidance of the use of contaminated instruments, and avoidance of environmental contamination, such as debris falling from overhead), (7) thorough drainage and irrigation of any pockets of purulence in the wound with warm saline, and (8) ensuring that the patient is kept in a euthermic state, well monitored, and fluid resuscitated.[1]

Incisional Hernia

Incisional hernia was defined as a fascial dehiscence after completed wound healing with or without the prolapse of abdominal organs, confirmed by abdominal ultrasound.

The incidence of incisional hernia in Group I, Group II, and Group III in this study is 12.74%, 13.18%, and 6.41%, respectively[2].

Comparison between Group III and Group I (Null hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of incisional hernia is 6.41%.

In continuous non-absorbable polypropylene (Group I), incidence of incisional hernia is 12.74%.

P value between Group III and Group I is 0.05, i.e., null hypothesis I is rejected and the study shows that there is significant difference in incidence of incisional hernia with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of incisional hernia is 6.41%.

In interrupted non-absorbable polypropylene (Group II), incidence of incisional hernia is 13.18%.

P value between Group III and Group II is 0.05, i.e., null hypothesis II is rejected and the study shows that there is significant difference in incidence of incisional hernia with polyhydroxybutyrate when compared with interrupted polypropylene also[3,4].

In Table 2, the INLINE meta-analysis study clearly showed the decrease in incidence of incisional hernias with continuous slowly absorbable sutures, where PDS (Polydioxanone) suture was used. Having longer 50% tensile strength maintenance period of 90 days (whereas, PDS has 50% tensile strength maintenance period for 4 weeks) polyhydroxybutyrate is a positive alternative for the rectus closure.

Most important etiological factor for incisional hernia is wound infections. As there is no significant difference

Table 1: Significance of *P* value in wound infections

Comparison	*P* value	Significance
Group III and Group I	0.75	Not significant
Group III and Group II	0.50	Not significant

Table 2: Significance of *P* value in incisional hernia

Comparison	*P* value	Significance
Group III and Group I	0.05	Significant
Group III and Group II	0.05	significant

in wound infection rate and surgical technique is also randomized in this study, decrease in incidence of hernias signifies the importance of suture material. Possible explanation for the decrease in incidence of incisional hernias with polyhydroxybutyrate may be the elasticity property of material which does not interfere with respiratory abdominal movements postoperatively.

Limitations of the Study

Major limitation of this study is follow-up period of only 1 year. The study conducted by The Study Centre of the German Surgical Society – Incisional hernia rate 3 years after midline laparotomy (C. Fink, P. Baumann, M. N. Wente , P. Knebel, T. Bruckner, A. Ulrich, J. Werner, M. W. B¨uchler and M. K. Diener) signified that significant increase in incidence of hernias from 1 to 3 year follow-up period. Thus, 3 years follow-up period may be needed for further reference.

Besides surgical technique and suture material, numerous additional factors are believed to play a role in hernia formation including obesity, diabetes, and malignancy. These factors were not analyzed. Hernias in relation to specific surgery were also not analyzed in this study.

Moreover, the pathophysiology of wound healing has to be considered as a major unknown variable of hernia formation. Collagen malformation in particular was linked to hernia formation in both clinical and biochemical studies. Within this context matrix metalloproteinases, which regulate the components of the extracellular matrix, play an important role in scarring process. Likewise, Klinge *et al*. found reduced matrix metalloproteinases expression patterns in patients with incisional hernias. Moreover, smoking was related to increased collagenolysis and inappropriate repair. Genetic influences and the corresponding molecular mechanisms have to be explored in the future since various connective tissue disorders are known to be heritable or caused by genetic mutation (e.g., Homocystinuria, Marfan's, and Ehlers – Danlos syndrome).

Thus, multimodal concept of optimizing the surgical technique, the suture material, and wound healing are believed capable of reducing incisional hernia sufficiently.

Burst Abdomen

Burst abdomen defined as post-operative separation of the abdominal musculoApo neurotic layers or disruption of laparotomy wound which requires relapse operation. Incidence of burst abdomen in Group I, Group II, and Group III in this study is 3.92%, 3.29%, and 3.84%, respectively.

Comparison between Group III and Group I (Null hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of burst abdomen is 3.84 %.

In continuous non-absorbable polypropylene (Group I), incidence of burst abdomen is 3.92%.

P value between Group III and Group I is −0.90 (>0.05), i.e., null hypothesis I is accepted and the study shows that there is no significant difference in incidence of burst abdomen with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of burst abdomen is 3.84 %.

In interrupted non-absorbable polypropylene (Group II), incidence of burst abdomen is 3.29%.

P value between Group III and Group II is –0.95 (>0.05), i.e., null hypothesis II is accepted and the study shows that there is no significant difference in incidence of burst abdomen with polyhydroxybutyrate when compared with interrupted polypropylene also.

The results from the previous studies from Table 3 and this study show that the incidence of burst abdomen mostly not related with suture material used.

Most important etiological factor for burst abdomen is wound infections most importantly deep space infections. Although type of suture material does not influence wound dehiscence, technical errors in fascial closure may be responsible.

Good pre-operative general condition of the patient, adequate fascial closure without tension and good post-operative care are the three main strategies which will prevent the acute wound failure. Limitation of this study is factors such as obesity, diabetes are not analyzed in this study.

Stitch Granuloma

A stitch granuloma is a small mass of clustered immune cells that may develop around the site of a surgical procedure. Suture granuloma originates when the area around a surgical incision becomes irritated or the

Table 3: Significance of *P* value in incisional burst abdomen

Comparison	*P* value	Significance
Group III and Group I	0.90	Not significant
Group III and Group II	0.95	Not significant

body's immune defenses identify medical sutures as a foreign body needing elimination. Immune cells rush to the site of the surgery and attach themselves to the medical sutures or staples. Since it is not possible to break sutures down the way an invading virus or bacteria breaks down, the body continues to send immune cells to the area where they create a large inflexible mass. The incidence of stitch granuloma in Group I, Group II, and Group III in this study is 4.9%, 8.79%, and 2.56%, respectively.

Suture Sinus

Sinus is a blind ending tract, usually lined with granulation tissue that leads from an epithelial surface into the surrounding tissue, often into an abscess cavity. The incidence of suture sinus in Group I, Group II, and Group III in this study is 1.96%, 5.49%, and 1.28%, respectively.

Chronic Wound Pain

Chronic wound pain is a condition described as unremitting, disabling, and recalcitrant pain experienced by individuals. Chronic wound pain is present for 6 months or more and occurs without any manipulation of the wound. Chronic wound pain is persistent and exists at rest. The incidence of suture sinus in Group I, Group II, and Group III in this study is 4.9%, 10.98%, and 2.56%, respectively.

Average Time for Rectus Closure

Average time for rectus closure for 10 cm mid line incision in Group I, Group II, and Group III is 9.20 min, 16.50 min, and 9.40 min, respectively.

CONCLUSIONS AND SUMMARY

No significant difference observed in incidence of wound infections in all the three groups. However, relatively higher incidence of wound infections in noted our hospital. Further studies needed to decrease the incidence of infections in our hospital.

No significant difference was observed between the three groups with regard to burst abdomen, i.e., acute wound failure mostly depends on adequate surgical closure and post-operative care rather than suture material used.[5]

The incidence of stich granuloma is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of suture sinus is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of chronic wound pain is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of incisional hernias, suture complications such as suture sinus, stitch granuloma can be more effectively reduced with slowly absorbable continuous sutures.

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Original Article

Outcome in Moderate and Severe Traumatic Brain Injury among Elderly Individuals Analytical Study in Government Rajaji Hospital Madurai

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Abstract

Background: Head injuries are among the most common types of trauma encountered in emergency department. Many patients with severe brain injuries die before reaching a hospital; in fact, nearly 90% of pre hospital trauma related deaths involve brain injury.

Objectives: Aim of the study was to study the age as an important prognostic factor in the prediction of outcome in Head Injury patients, to find out the incidence and type of traumatic intracranial lesions in the elderly, to study and analyze the cause of head injury among elderly patients, and to compare conservative, medical, emergency surgical treatment, and outcome.

Results: The poor outcome at all levels in the elderly patients, even with good Glasgow coma scale (GCS) on admission. Although they have lower impact injuries and multiple injuries, their computed tomography scan show more number of intracranial mass lesions, sub arachnoid hemorrhage, and midline shift. Age has been cited as a significant risk factor for the poor outcome in this study.

Conclusion: The mortality rate increases with age mainly from the medical complications to prolonged coma. GCS is a good reliable predictor of prognosis even in the 1st day after admission. If the doctors are persuaded to elicit and record them carefully, predictions can be made reasonably accurate at the bed side.

Key words: Diffuse axonal injury, Extradural hemorrhage, Glasgow coma scale, Intracerebral hemorrhage, Intracranial pressure, Sub arachnoid hemorrhage, Sub dural hemorrhage, Traumatic brain injury

INTRODUCTION

Head injury with brain injury another wise is called traumatic brain injury (TBI). Head injuries are among the most common types of trauma encountered in emergency department (ED). Many patients with severe brain injuries die before reaching a hospital; in fact, nearly 90% of pre hospital trauma related deaths involve brain injury. Approximately 75% of patients with brain injuries who receive medical attention can be categorized as having mild injuries, 15% as moderate, and 10% as severe.

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TBI survivors and often left with neuropsychological impairments that result in disabilities affecting work and social activity. Every year, an estimated 80,000–90,000 people in the India experience long-term disability from brain injury.

Given these statistics, it is clear that even a small reduction in the mortality and morbidity resulting from brain injury can have a major impact on public health.

The primary goal of treatment of patients with suspected TBI is to prevent secondary brain injury. The most important ways to limit secondary brain damage and hereby improve a patient's outcome are to ensure adequate oxygenation

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and maintain blood pressure as a level that is sufficient to perfuse the brain. After managing the ABCDEs, patients who are determined by clinical examination to have head trauma and require care at a trauma center should be transferred without delay. If neurosurgical capabilities exist, it is critical to identify any mass lesson that requires surgical evacuation, and this objective is best achieved by rapidly obtaining a computed tomography (CT) scan of the head. CT scanning should not delay patient transfer to a trauma center that is capable of immediate and definitive neurosurgical intervention.

The management of severe and moderate TBI in critical care unit is well advanced and expensive nowadays. Those who survive have protracted hospital stay requiring multi-disciplinary rehabilitative and supportive care, thus resulting in heavy financial and emotional burden to the families. This is especially true for the elderly with TBI.

Many studies have revealed the poor outcome at all levels in the elderly patients, even with good glasgow coma scale (GCS) on admission. Although they have lower impact injuries and multiple injuries, their C.T scan show more number of intracranial mass lesions, sub arachnoid hemorrhage, and midline shift. Age has been cited as a significant risk factor for the poor outcome in several studies.

Aim of the Study

The aim is as follows:

1. To study age as an important prognostic factor in the prediction of outcome in Head Injury patients.
2. To find out the incidence and type of traumatic intracranial lesions in the elderly.
3. To study and analyze the cause of head injury among elderly patients.
4. To compare conservative, medical, emergency surgical treatment, and outcome.
5. Associate with comorbid condition and other injuries.[1-59]

MATERIALS AND METHODS

Elderly patients with their comorbidities and increasing physical frailties are at significant risk from TBI. Aiming at maintaining adequate cerebral perfusion pressure comparable to existing guidelines for the management in moderate and severe TBI a standardized protocol is followed in our neurosurgical intensive care unit.

To evaluate this protocol, we decided to review elderly patients (Group A) with moderate and severe TBI and their outcomes as compared to younger (Group B) patients managed on a standardized protocol.

According to the various standard neurosurgical text books, the severity of head injury is divided, based on GCS at the time of admission of head injury patients.

Head injury severity scale

Severity grade	GCS
Minimal	15 (LOC or amnesia)
Mild	14 (Amnesia/LOC/impaired alertness)
Moderate	9–13 (LOC for 5 min or FND)
Severe	5–8
Critical	3–4

In this study, the moderate and severe grade patients were taken into study based on the above said severity scale. We reviewed the patients with moderate and severe TBI retrospectively over the period of January 2019 to December 2019 admitted in head injury ward, Government Rajaji Hospital (GRH), Madurai Medical College, Madurai, Tamil Nadu. Some of the patients required intubations and artificial ventilation or close neurological monitoring. They were managed in the Neurosurgical Intensive care unit.

In this study, elderly patients are named as Group A and other control group is named as Group B. Of the 250 patients selected based on above mention criteria, 101 (40%) were aged >60 years and 149 (60%) were aged between 20 and 40 years old. They were admitted to Neurosurgical Intensive care unit according to established criteria for moderate and severe head injury and were managed on a standardized protocol with the available facilities in our hospital. Early detection and treatment of secondary insults include hypotension, hypoxia, hyperpyrexia, and hypoglycemia.

For the selection of patients; in this study, a uniform criteria were followed the minimum criteria for that one followed by Becker *et al.*[5]

1. The patients failed to obey commands, failed to speak and have no verbal response to painful stimuli.
2. The motor response ranged from failure to obey commands to no motor response at all.

Data collected, included patients demographics, clinical findings on admission (including admission and post-resuscitative GCS, Pupillary signs, presence of poly trauma and spine injuries, ingestion of alcohol, and mechanism of injury) and C.T scan findings graded using the classification suggested by Marshall *et al.*[42]

A six-category scheme to classify head injury based on Initial CT Scan brain,classified into six categories. Lawrence Marshall and colleagues published it in the Journal of Neurosurgery. It was based on their experience in the pilot phase of the Traumatic Coma Data Bank (TCDB).

An increase in mortality was noted with increasing grade of diffuse injury.

Categories

- Diffuse Injury Type I
  No CT visible intracranial pathology,
- Diffuse Injury Type II
  Cisterns present with middle shift 0–5 mm
  No high – or mixed-density lesion >25 cc.
- Diffuse Injury Type III
  Cisterns compressed or absent with middle shift 0–5 mm
  No high-or mixed-density lesion >25 cc
- Diffuse Injury Type IV
  Midline shift >5 mm
  No high- or mixed-density lesion >25 cc.
- Evacuated Mass Lesion
  Any lesion surgically evacuated.
- Non-Evacuated Mass Lesion
  High- or mixed-density lesion >25 cc.

CT-scans are helpful in assessing the degree of intracranial injury, in predicting outcome, and, if finding is normal, in avoiding unnecessary hospitalization.[43,44]

CT scans are very sensitive to acute hemorrhage or skull fractures. CT scans aid in evaluating.[1] intracranial hemorrhage,[2] skull fractures,[3] mass effect and midline shift,[4] obliteration of the basal cisterns, and[5] evidence of herniation (subfalcine, tonsillar, or uncal) CT scan cannot diagnose a concussion (which is a clinical diagnosis) and is poor for diagnosing diffuse axonal injury (DAI). If DAI has occurred, CT scans may show small hemorrhages in the corpus callosum and cerebral peduncles. In this case, on magnetic resonance imaging (MRI) of the brain should be obtained on an elective basis when the patient is clinically stable because no effective treatment of DAI is currently available. MRI is more sensitive for detecting brainstem injuries, posterior fossa lesions, and brain edema.

As a general rule, a repeat head CT scan is recommended within 4–8 h of the initial scan in patients with intracranial hemorrhages and/or coagulopathies.[33] A repeat brain CT scan is recommended sooner in patients who are deteriorating neurologically or lowering GCS

Treatment Protocol

Few specific treatment options for intracranial hypertension have been subjected to randomized trials, however, and most management recommendations are based on clinical experience.[11,27,32]

In the average adult, the skull encloses a total volume of 1450 Ml: 1300 mL of brain, 65 mL of cerebrospinal fluid (CSF), and 110 mL of blood. The Monroe-Kellie hypothesis states that the sum of the intracranial volumes of blood, brain, CSF, and other components is constant and that an increase in any one of these must be offset by an equal decrease in another.

Medical Management

Hyperventilation became a popular means of reducing intracranial pressure (ICP) in the past. However, recent studies raise concern that aggressive hyperventilation exacerbates cerebral ischemia.[11,27] At present, hyperventilation (PCO_2 of 30–35 mmHg) is recommended to reduce ICP for only a short period, as a temporary measure while other methods of ICP control are initiated. Hyperventilation reduces ICP only temporarily, progressively losing effectiveness after 16 h of continuous use.

Mannitol probably has several mechanisms of action. One obvious mechanism is through osmotic diuresis through drawing edema fluid from the cerebral parenchyma. This usually takes 15–30 min, and the effect usually lasts 1.5–6 h. Serial serum osmolarity levels must be checked to maintain an osmolarity of no >315–320 mOsm/kg H_2O to avoid acute renal failure. For this reason, patients treated with Mannitol must be kept euvolemic with isotonic fluid resuscitation as required.

A barbiturate-induced coma with EEG burst suppression is often a "last ditch effort" to reduce the ICP and should be reserved only for patients with refractory ICP who are unresponsive to other measures. One may even consider decompressive craniotomy before the use of barbiturates.

One must give special attention to preventing hypotension.[30] Data from the TCDB reveal that hypotension in patients with severe TBI increases the mortality rate from 27% to 50%. Traditional management has included fluid restriction to minimize cerebral edema, but this practice may be dangerous in patients who already have intravascular volume depletion. Cerebral edema may occur regardless of the amount of intravenous fluid administered.

The ultimate goal of the management of patients with closed head injuries is to maintain a state of euvolemia. In a euvolemic patient who is hemodynamically stable, two-thirds maintenance of isotonic solution is recommended. Avoid hypotonic fluids because they may decrease serum osmolarity and increase brain swelling. Hypertonic saline may use with caution.

In addition patients with closed head injuries are more prone to acute coagulopathies.[33,40] In patients with acute intracranial hemorrhages, these coagulopathies must be addressed and corrected promptly.

Fresh frozen plasma transfusions until the coagulopathy is corrected are the preferred method. This is especially true for individuals who are taking anticoagulants (e.g., Warfarin) and who are at high risk of continued bleeding.[65]

Pyrexia commonly occurs in patients with head injuries, possibly because of post-traumatic inflammation, direct damage to the hypothalamus, or secondary infection. The most common cause is fever secondary to an underlying infection. Less common is an unexplained fever or "neurogenic" fever estimated to occur to approximately 8% of patients who have head injuries with pyrexia. The source of the fever must be identified and corrected.

Hyperglycemia has also been shown to have a determined effect on induced brain ischemia. Clinical trials support the correlation between hyperglycemia and poor overall outcome in patients with head injuries and recommended that euglycemia be maintained at all times.

Some patients with severe head injuries may develop hypertension, either from an exacerbation of a chronic process or as a result of the head injury. We have to keep systolic blood pressure <180 mm Hg, particularly in patients who have an intracranial hemorrhage if possible, avoid nitroprusside

Because it is a cerebral vasodilator and my actually increase ICP. A Labetolol drip is preferred in patients who blood pressure is difficult to control. Corticosteroids have no proven benefit for patients with severe head injuries.[10,11]

Effective treatment of intracranial hypertension involves the meticulous avoidance of factors that precipitate or aggravate increased ICP. When ICP becomes elevate, ruling out new mass lesions that should be surgically evacuated is important.[15] Medical management of increased ICP should include sedation and paralysis, drainage of CSF, and osmotherapy with either Mannitol or hypertonic saline.[32] For intracranial hypertension refractory to initial medical management, barbiturate coma, hypothermia, or decompressive craniotomy should be considered.

Surgical Management

As a general rule, indications for surgery include any intracranial mass lesion (Extradural hemorrhage [EDH], sub dural hemorrhage [SDH], and intracerebral hemorrhage [ICH]) that causes significant or progressive neurological compromise, particularly a decreased level of consciousness.[41] and death. The overall outcome of individuals with an intracranial lesion that causes significant mass effect is improved with rapid decompression; therefore, operating on these patients as soon as possible is advisable.[63,64]

Before operating, one must always consider the patient's condition and refrain from relying solely on radiographic evidence. For example, elderly patients with severe cerebral atrophy may accommodate a large intracranial hemorrhage,[48] whereas most young individuals may experience neurological deficits with relatively smaller intracranial hemorrhages.

Note that some intracranial hemorrhages may be actively bleeding during the initial head CT scan; what may appear as relatively small on the initial scan may actually become quite significant in a short period of time. In this case, the patient's physical examination finding is more valuable in evaluating his or her intracranial status than the initial head CT scan findings.

Surgical interventions including craniotomy, simple decompression, and evacuation of clot for mass lesions performed according to the existing criteria, were also collected.[57,60] The multi-modality monitoring of physiological monitoring in these patients includes continuous electrocardiogram pulse oximetry, Hourly Urine output, and core temperature. Specific treatment targets for conventional intensive care unit management regarding nutrition, infection surveillance. Deep vein thrombosis- Prophylaxis and ventilator protocols were followed.

The outcome was assessed at post injury using the Glasgow outcome scale (GOS). For early analysis, se divided outcomes into three categories –

1. Death (GOS-1)
2. Unfavorable (GOS 2 and 3)
3. Favorable (GOS 4 and 5).

Clinical findings as well as C.T scans and radiological findings and surgical intervention were correlated to outcome in both age groups. Since the initial seriousness of the injury may be due to other extracranial complications all those patients selected in this study must be in this state for at least 6 h after the injury as recommended by Jennet *et al.*[28] Patients who had spoken after injury before development of coma that issued for 6 h or more are also included.

Exclusion Criteria

Patients in whom the depressed level of consciousness was due to alcohol, drug over dosage and metabolic coma were excluded from this study. Furthermore, all the patients who were apnoeic with dilated and fixed pupils all the time of admission were excluded from this study.

The information collected regarding all the selected cases were recorded in a Master Chart and data analysis was done.

Clinical Assessment

After ABCDE resuscitation, clinical examination and neurological examination were carried out. Of equal importance in the initial examination of patients with impaired consciousness is the vital signs, pupils, eye movements, GCS, and autonomic abnormalities. Of these pulse, respiratory rate, blood pressure, and ICP are monitored at regular interval for the general condition assessment, whereas GCS, oculocephalic response, oculo vestibular response (OVR), etc., are recorded for the prognostic point of view. These are the most powerful predictors of outcome. Apart from GCS, sex and age were taken into account for the analysis. In this study, more emphasis is given for the clinical factors in predicting the prognosis, since they are the factors, which can be assessed easily in any center irrespective of the availability of sophisticated diagnostic, and treatment facilities.

The following factors are assessed

1. Parameter of unconsciousness as in Glasgow Coma Scale. As soon as, the patient was admitted in the ER, patient was examined, and the neurological status was assessed. The eye opening response and verbal response are assessed and entered in the case sheet. It was reassessed every 4 h regularly, When the eyes were closed by edema, the eye opening response was marked as "C," if tracheostomy was done the verbal response was marked as "T."
2. Age and sex
3. Pupillary Reaction: It was tested with a good pinpoint torch light. It was recorded whether the reaction was present or absent. The category that is sluggishly reacting pupils to light was avoided because there might be variability between the observers. Care was taken to avoid errors namely temporary unreacting pupils after epileptic fit or non-reacting dilated pupils due to bilateral local damage to peripheral structures or due to instillation of local eye drops or after an episode of anoxia.

Oculocephalic Response (OCR)

a. OCR is tested by moving the patient's head on either side and observing the ocular mobility. Before eliciting this, cervical spine fractures should be ruled out. It consists of four defined levels.
b. Suppression of eye movements – Normal response in conscious patients.
c. Intact response: Bilateral conjugate righting movements.
d. Impaired response: Dysconjugate movements of the eyes.
e. Absent response.

In this study, the OCR or the doll's eye movement was recorded whether present or absent. Impaired response was taken as brain stem function.

OVR

For eliciting this response, the head should be rotated to 30° to one side and flexed about 30°. The drum must be intact and is not obscured by cerumen. Ice-cold water introduced in 20 ml amounts with the help of syringe.

For declaring this response as "Absent" at least 100 cc should have been used. All those patients with obvious bleeding through the ears were omitted.

The response has four defined levels.

a. Nystagmus to the same side in the normal conscious patients and in lethargic subjects.
b. Tonic conjugate deviation to the irrigated side.
c. Dysconjugate response
d. No response.

OVR is recorded as "Present" or "Absent". Among the oculocephalic and OVR, OVR is more reliable because of its more powerful stimuli. Hence, the eye movement reflexes cannot be declared as absent unless the ocular vestibular response is done.

Management

The protocol used was uniform in all cases. It consisted of preliminary assessment of cases, endotracheal tube intubation whenever necessary, pulse, oxygen monitoring, early diagnosis, and treatment of intracranial complications, routine respiratory and urinary bladder care, and the effective treatment of other associated injuries: Antibiotics and anti-epileptics were given almost to all the patients and Mannitol was used to reduce intracranial tension.

Assessment of Outcome

The physical and mental disabilities combine to produce a social and overall outcome. However, after analysis many of the problems associated with it, Jennett and Bond[26] proposed Glasgow outcome scale. Glasgow outcome scale consists of five categories:

- Gr 1 Death
- Gr 2 Vegetative state
- Gr 3 Severely Disabled (conscious but dependent)
- Gr 4 Moderately Disabled (Independent but disable)
- Gr 5 Good recovery (Minor sequelae).

Within the category death, every effort should be made to distinguish death due to primary (or) secondary brain damage and death due to other systemic complications such as pneumonia, fat embolism, and renal failure. The term persistent vegetative state was coined by Jennett and Plum.[25] This term describes the survivor of acute brain damage who is breathing spontaneously but who remain

unresponsive and speechless with no psychologically meaningful response but the cerebral cortex is functionally inactive.

The moderately disabled patients can be described as independent but disabled. They are able to travel by public transport and can undertake work of a sheltered or reduced kind. However, they are unable to return to their former occupational level. Those who have had good recovery have been able to return to their former occupational level through not necessarily to their former occupation. They may have mild neurological (or) mental deficit.

RESULTS

In Group A, mean age was 67.3 years and standard deviation as 6.7 years. In Group B, Mean age was 29.3 years and SD was 6.7 years ($P = 0.0001$).

The ratio of male and female was 4: 1. Of the 101 patients aged above 60 years old, 73 were male and 28 were female (Age range 60–86 years). In Group A, there were 72.3 male and 27.7% female and in Group B they were 91.9% and 8.1%, respectively ($P = 0.0001$). In the younger cohort, aged 20–49 years, 137 were males and 12 were females.

In Group A, GCS of 5–8 were 74.3% and GCS of 9–13 were 25.7% and in Group A it was 58.4% and 41.6%, respectively ($P = 0.0148$).

In Glasgow outcome scale among Group A patients deaths were 25.7%, poor outcomes in 11.9% and good outcome was 62.4%. In Group B, GOS showed deaths in 58.4% and poor outcome in 10.1% and good outcome in 31.5% ($P = 0.0001$).

Analyzing the mechanisms of injury, in Group a road traffic accident (RTA) cases were 63.4%, followed by 26.7 accidental fall and 9.9% assault cases. In Group B RTA, Fall, and Assault were 77.2%, 17.4%, and 5.4%, respectively.

On observation of eyes in Group A, pupils were normal in 40.6% cases and they were abnormal in 59.4% cases. In Group B, it was normal in 68.5% and abnormal in 31.5% cases ($P = 0.0001$)

In CT findings, Group A showed EDH – 23.8%, SDH – 13.9%, ICH- 11.9%, subarachnoid hemorrhage (SAH) – 24.8%, and DAI – 42.6%. In Group B, CT showed EDH – 31.5%, SDH – 10.1%, ICH – 10.7%, SAH – 3.4%, and DAI-41.6%.

In Group A, OCR was present in 44.6% and absent in 55.4% cases. In Group B, optical character recognition was present in 64.4% and absent in 35.6% cases ($P = 0.0029$).

Regarding OVR in Group A, it was present in 51.5% and absent in 48.9% cases. In Group B, OVR was present 69.8% and absent in 30.2% cases ($P = 0.0051$).

With intracranial traumatic mass lesion 33.3% cases in Group A and 66.7% cases in Group B operated with in 24 h. In Group A and Group B patients, 50% each were operated after 24 h.

Relationship between Outcome and Various Parameters [Tables 2-10].

DISCUSSION

The mechanism of injury between two groups was very different, which was also seen in many studies. The elderly group patients had lower impact injuries. In our study, mainly falls accounted for up to 27% of injuries, and 63 patients involved in RTA injuries, which is contrast to other studies. In RTA majority of injuries were drivers or motorcyclists and others were due to fall from heights and a significant number from Assault (10%).

Multiple injuries were more in younger age group (34%), compared to the elderly where it was only 14%. Co-existing cervical spine injury was also more in younger ones (9%) compared to the older ones where it was only 1% C.T. Scan findings, based on the classification system of Marshall *et al.*, were more severe in the elderly group, with 76.4% exhibiting mass lesion compared to 55.6% in the young cohort. The elderly had a 29% incidence of SAH on C.T. Scan, which was comparable to the young, who had 30.2%. The mean GCS on admission in the elderly was (8.3) and it was (8.59) in the young. A GCS of <8 on admission was statistically significant in the elderly group as well as in young age group in predicting outcome and mortality. The distribution of patients, when grouped under GCS 5–8, and GCS 9–12 were also quite comparable in both the groups.

The mortality rate for the Group A was 62.3% compared to 32.2% in the younger age cohort. The outcome rate of the elderly was good about half that of the young (i.e.) 26% compared to 52.5% (Mean 66.8 in Group A and mean 33.2 Group B) [Table 11].

When the GCS on admission was taken into account, there was a trend of poor outcome at all levels in elderly patients compared to the young. The poor outcome was 23.4% in the elderly group compared to the younger age group of 13.5%. The poor outcome rate in those admitted with GCS <8 in the elderly group was lower than the younger group, because most of elderly patients had died due to co morbid conditions and its complications.

Table 1: Age

Age in years	Group A (Study cases)	Group B (Control cases)	Total
Range	60–86 years	20–59 years	20–86 years
Mean	67.3 years	29.3 years	44.3 years
S.D.	6.7 years	6.7 years	19.8 years
"*P*"		0.0001 Significant	

Table 2: Sex

Sex	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Male	73	72.3	137	91.9	21	084
Female	28	27.7	12	8.1	40	16
"*P*"			0.0001 significant			

Table 3: Glasgow coma scale

Glasgow coma scale	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
5–8	75	74.3	87	58.4	162	64.8
9–13	26	25.7	62	41.6	88	35.2
"*P*"			0.0148 Significant			

Table 4: Glasgow outcome scale

Glasgow Outcome Scale	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Death	26	25.7	87	58.4	113	45.2
Vegetative and S.D.	12	11.9	15	10.1	27	10.8
M.D. and Good	63	62.4	47	31.5	110	44
"*P*"			0.0001 Significant			

Table 5: Mechanism of injury

Mechanism of injury	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
RTA	64	63.4	115	77.2	179	71.6
Accidental fall	27	26.7	26	17.4	53	21.2
Assault	9	9.9	8	5.4	18	7.2
Total	101	100	149	100	110	44

RTA: Road traffic accident

Table 6: Pupils

Pupils	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Normal	41	40.6	102	68.5	143	57.2
Abnormal	60	59.4	47	31.5	107	42.8
"*P*"			0.0001 Significant			

Table 7: C.T. Findings

C.T. findings	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Epidural hematoma	24	23.8	47	31.5	71	28.4
Subdural hematoma	14	13.9	15	10.1	29	11.6
Intracerebral hematoma	12	11.9	16	10.7	28	11.2
Sub arachnoid hemorrhage	25	24.8	5	3.4	30	12
Diffuse axonal injury	43	42.6	62	41.6	105	42
Total	100	100	149	100	250	100

CT: Computed tomography

Table 8: OCR

OCR	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Present	45	44.6	96	64.4	141	56.4
Absent	56	55.4	53	35.6	109	43.6
"*P*"			0.0029 Significant			

OCR: Oculocephalic response

Table 9: OVR

OVR	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Yes	52	51.5	104	69.8	156	62.4
No	49	48.9	45	30.2	94	37.6
"*P*"			0.0051 Significant			

OVR: Oculovestibular response

Table 10: Treatment

Treatment	Group A (Study cases)		Group B (Control cases)		Total	
	No.	%	No.	%	No.	%
Within 24 h	24	33.3	48	66.7	72	100
Surgery (72)	47	39.8	71	60.2	118	100
Conservative (118)	71	37.4	119	62.6	190	100
After 24 h Surgery (60)	30	50	30	50	60	100
Total	101	40.4	149	100	250	100

Table 11: Age and outcome

Outcome	Group A (Study cases)		Group B (Control cases)		Total	
	Mean	S.D.	Mean	S.D.	Mean	S.D.
Good	66.8	7.1	33.2	4.8	52.4	17.8
Bad (Poor and Death)	68.1	6.1	27.5	6.7	38.5	19.2
"*P*"	0.185 Not significant		0.0001 Significant		0.0001 Significant	

In this study, among Group B, about 78 cases were operated for intracranial mass lesions with a mortality of 25 cases.

At the same time, in the elderly Group A, 54 cases were operated with a mortality of 26 cases. In the younger group, 48 cases were operated <24 h of admission whereas 30 cases were operated after 24 h of admission, with the mortality of 72% and 56%, respectively. In elderly group, 24 cases were operated in 24 h and 30 cases were operated after 24 h with the mortality of 50% and 20%, respectively. The outcomes as well as mortality following surgery for the traumatic intracranial mass lesions are showed in Table 19, in which 65% in the younger age group and 39% in the elderly group show good outcome.

More than 50% patients in the elderly group were not suitable for any neurosurgical intervention after re-assessment by the duty neurosurgeon; moreover, their families did not give consent for the proposed surgery. Nevertheless, they were given supportive treatment under the protocol aimed at minimizing secondary insults (such as preventing hypotension, hypoxia, hyperglycemia, and hyperpyrexia). The majority of 78% cases had a GCS of 5–7 on admission, with CT scan findings of skull fractures, Sub Dural Hematoma, Epidural Hematoma, intracerebral hematoma, and Sub Arachnoid Hemorrhage.

About 40% patients were aged >70 years old and 27.7% were females. Of the 101 patients in the elderly 62.3% died and 11.8% survived in a vegetative state. When these vegetative patients were excluded, the "true" mortality rate in the elderly group was still substantial at 70%, which was still nearly twice that of the younger group. The female mortality in the elderly age group was 42.8% compared to the male mortality rate of 69.8%. This gender difference was not seen in the young age group. Other factors including papillary signs incidence of hypoxia and hypotension did not reveal any significant difference between both age groups, which could account for the difference in outcome in the two age groups.

Injury and Outcome [Table 14]

In Group A following RTA 32.8%, after fall 51.9% and after assault 30% cases were in the poor outcome and deaths. In Group B, the poor outcome and deaths were altogether 67.8% in RTA, 80.8% in accidental fall, and 37.5% in assault cases.

Despite aggressive treatment out of 250 patients, only 38 survived among elderly giving a mortality of 62.3% and only 101 survived in younger cohort group giving mortality of 32.2%. They were called for neurological and functional examination periodically.

Factors Influencing the Outcome

Age and outcome [Table 11]

Most of the studies confirm that the age is the most important significant factor in deciding the outcome from severe head injury.[48] Mortality is very high in the elderly age group in many series.[17,29] In the age group of Group B mortality is low. In general patients of Group B age groups make a relatively better recovery after severe head injury. In this study, Group A shown mean value 68.1 (mean) in bad outcome with SD of 7.1 and 6.1, respectively, so *"P"* value was 0.185 that was not significant. However, in Group B, it was significant and his associates.[12] However, in older age group, the mortality is not directly due to head injury but mainly due to systemic complications such as chest infection, and other co-morbid conditions. About 45% of patients above the age of 60 had high blood urea level at the time of death and 22% had Florid Lung infection at the time of death. The same picture is reflected in the works of Caresson *et al.* and Becker *et al.*[12]

Sex and outcome [Table 12]

In Group A, among male 69.9% good and 30.1% poor and death outcome were seen in this study with significant *"P"* value (0.0227). In Group B in male, 32.1% were good outcome and 67.9% were poor and deaths. In female, 25% were good outcome and 75% were poor outcome with "*P*" value 0.4406 which was not significant.

Outcome related to GCS [Table 13]

Although G.C.S. is not intended to use as a prognostic indicator, the depth and duration coma is related to the outcome. In general, there was a strong correlation between decreasing G.C.S. and increasing mortality, whether the observation was made in the emergency room after resuscitation or after 24 h from the time of admission.

Table 12: Sex and outcome

Sex	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Male	51	69.9	22	30.1	44	32.1	93	67.9	95	45.2	115	54.8
Female	12	42.9	16	57.1	3	25	9	75	15	37.5	25	62.5
"P"	0.0227 Significant				0.4406 Not Significant				0.4655 Not Significant			

Table 13: GCS and outcome

GCS	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
5-8	51	69.9	22	30.1	44	32.1	93	67.9	95	45.2	115	54.8
9-13	12	42.9	16	57.1	3	25	9	75	15	37.5	25	62.5
"P"	0.0016 Significant				0.0705 Significant				0.0001 Not Significant			

Table 14: Injury and outcome

Injury	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
RTA	43	67.2	21	32.8	37	32.1	78	67.8	80	44.7	99	55.3
Accidental Fall	13	48.1	14	51.9	5	19.2	21	80.8	18	34	35	66
Assault	7	70	3	30	5	62.5	3	37.5	12	12	6	33.2

Group-A Patients showed good out come more than 50%. Group-B Patients showed poor of deaths more than 65%

Table 15: Pupillary reaction and outcome

Pupillary Reaction	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Normal	19	46.3	22	53.7	20	19.6	82	80.4	39	27.3	104	72.7
Abnormal	44	73.3	16	26.7	27	57.4	20	42.6	71	66.4	36	33.6
"P"	0.0111 Significant				0.0001 Significant				0.0001 Significant			

GCS if < 8 is associated with mortality of 28% in elderly (Group A) and 62.1% in younger age group (Group B): Likewise it was 65.4% when GCS is >8 in elderly (Group A). ("*P*" = 0.0016 – significant). In the Miller *et al.*[6] series, the mortality increases as GCS decrease.

Outcome and pupillary reaction [Table 15]

There was a strong correlation between bilateral absence of papillary light response and poor outcome following severe TBI. In Group a cases abnormal papillary reaction in 26.7% cases showed poor outcome. ("*P*" = 0.0111-significant). In Group B, 42.6% cases of abnormal papillary reaction showed poor outcome ("*P*" = 0.0001-significant).

Outcome and oculocephalic, oculovestibular response [Tables 16 and 17]

Both oculocephalic and oculovestibular response were found to be powerful predictors of outcome. In the elderly, Group A 73.3% patients with absent oculocephalic response were either dead or survived with severe disability and 26.7% had good recovery. However, in Group B, 94.8% patients with impair oculocephalic response were either dead or left with severe disabilities, but only 5.2% had good recovery; ("*P*" = 0.0001 – significant).

Likewise, 89.6% patients with impaired OVR had poor prognosis[30] when compared to 11% of patients who had good recovery in the elderly Group A, the outcome was same as in young Group B.

Outcome and mass lesion [Table 18]

Table 18 shows the outcome based on CT findings.

It has been found that intracranial mass lesion has an important significance to outcome. Miller *et al.*[6] had shown that mass lesion intracranial region had a worst outcome.

Table 16: OCR and outcome

OCR	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Yes	12	26.7	35	73.3	5	5.2	91	94.8	17	12.1	124	87.9
No	51	91.1	5	8.9	42	79.2	11	20.8	93	85.3	16	14.7
"P"	0.0001 Significant				0.0001 Significant				0.0001 Significant			

OCR: Oculocephalic response

Table 17: OVR and Outcome

OVR	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and Death		Good		Poor and Death		Good		Poor and Death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Yes	21	40.4	31	89.6	17	16.3	87	83.7	38	24.4	118	75.6
No	42	85.7	7	14.3	30	66.7	15	33.3	72	76.6	22	23.4
"P"	0.0001 Significant				0.0001 Significant				0.0001 Significant			

OVR: Oculo vestibular response

In this series among elderly age, Group A 56.5% mortality among operated cases whereas among younger cohort only 31.6% mortality among operated cases irrespective of time of operation. The mortality rate in the elderly those who were operated within 24 h was 39.2% and after 24 h it was 83.3%. In the younger Group B, the mortality of operated cases (<24 h of admission) was 22.7% and after 24 h operated cases the morality was 42.8%.

Outcome and epidural hematoma [Table 18]

Epidural hematoma results from tearing of dural or skull vessels caused by fracture in most of the cases. Epidural hematomas can occur at all ages but are seen primarily

Table 18: CT findings and outcome

CT findings	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and Death		Good		Poor and Death		Good		Poor and Death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Epidural Hematoma	17	70.8	7	29.2	12	25.5	35	74.5	29	40.8	42	59.2
Subdural Hematoma	10	71.4	4	28.6	7	46.7	8	55.3	17	58.6	12	41.4
Intracerebral Hematoma	7	58.3	5	41.7	7	43.8	9	56.2	14	50	14	50
Sub Arachnoid Hemorrhage	18	72	7	28	2	40	3	60	20	66.7	10	33.3
Diffuse axonal injury	25	58.1	18	41.9	22	35.5	40	64.5	47	44.8	58	55.2

CT: Computed tomography

Table 19: Treatment and outcome

Treatment	Group A (Study cases)				Group B (Control cases)				Total			
	Good		Poor and death		Good		Poor and death		Good		Poor and death	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
1. Within 24 h Surgery (72)	12	50	12	50	13	27.1	35	72.9	25	34.7	47	65.3
Conservative (118)	27	57.4	20	42.6	21	29.6	50	70.4	48	40.7	70	59.3
"P"	0.7505 Not significant				0.9294 Not significant				0.506 Not significant			
2. After 24 h Surgery (60)	24	80	6	20	13	43.3	17	56.7	37	61.7	23	38.3

in young patients (below 40 years).[35,37] Acute epidural hematoma with significant mass effect is not a common complication of head injury, and its incidence is about 2% of patients.

In adults, the incidence of epidural hematoma is lower than that of subdural and intracerebral hematoma. Most epidural hematoma occurs over the convexity of the cerebral hemisphere in the territory of middle meningeal artery. Separation of dura and bone is thought to occur at the time of injury, with subsequent bleeding in the preformed epidural space, rather than stripping of the dura of the inner table of the skull with progressive enlargement of the clot.

In epidural hematoma, there is an initial loss of consciousness after trauma followed by recovery (lucid interval), and then (as the blood clot enlarges) a rapid progression of neurological symptoms, obtundation, contralateral hemi paresis, ipsilateral oculomotor nerve paralysis, decerebrate rigidity, arterial hypertension cardiac arrhythmias, respiratory disturbances, and finally apnea and death. EDH any occur in bilateral location, coup, and contra coup or at vertex.[2,13,56]

Epidural hematoma is associated with a good recovery (70.8%) in the elderly Group A and 22.5% in younger age Group B. Death in this category is the result of other factors such as brain parenchymal damage and prolonged duration of coma. If the patients with extradural hematoma had bilateral dilated unresponsive pupils and decerebrate spasm, the prognosis was very poor.[21] In the elderly Group A with EDH, the mortality rate was 29.2% when compared to 75% among younger age group.

Sub dural hematoma and outcome [Table 18]

Sub dural hematomas may be venous or arterial origin. Most frequently, these hematomas result from the tearing of bridging veins between the cerebral cortex and draining venous sinus. About 50%–60% of acute post-traumatic hematomas are sub dural hematomas. Acute sub dural hematomas are twice as common after injuries that involve a sudden movement of the head, such as fall or assault, than injuries caused by RTA.[16]

Most acute sub dural hematomas result from venous vascular injury that is produced by strain forces at the brain surface. Cerebral ischemia is an important component of brain injury caused by sub dural hematoma. Brain compression by the hematoma, resulting in impairment of the microcirculation, may be an important component.

A hemorrhagic mass should be considered as an intra-cerebral hematoma, when there is a homogenous collection of blood with relatively well-defined margins.[39] Multiple intra-cerebral hematomas are found in approximately 20% cases. Intra-cerebral hematomas are caused primarily by direct rupture of intrinsic cerebral vessels. The hematomas tend to form in the inferior frontal and temporal lobes. Intracerebral hematomas are commonly seen in head injuries in which force is applied to the head over a small area such as missile injuries, perforating wounds, and depressed fractures.[4,5]

Acute sub dural hematoma and intracerebral hematoma had been said to be associated with a very high mortality.[50] Various authors report the mortality ranges from 45% to 90%. In our series, among elderly age Group A, the

mortality for acute sub dural hematoma is 28.6% and with intracerebral hematoma, it is 41.7%: where as in Group B the mortality for acute SDH is 55.3% and with ICH it is 56.2%.

In general, patients with epidural hematoma fare better than patients with acute SDH and ICH. In this study, a slight change with good outcome in SDH and ICH but poor outcome in EDH cases.

Diffuse brain injury

Diffusion brain injury may be concussion or DAI. DAI results from more severe angular or rotational acceleration shear and tensile forces acting on the axons during acceleration and deceleration are thought to cause DAI. DAI is believed to be responsible for the severely impaired neurological function in patients without gross parenchymal contusions, lacerations, or hematomas.

DAI is most often associated with coronal or lateral acceleration injury, which produces the most severe DAI. Histological findings consist of axonal swelling, disruption of the axons, and "retraction balls" (swollen proximal ends of the severed axons). In this study, among elderly Group A the diffuse brain injury showed 41.9% mortality whereas it was 64.5% in the younger group.

Sub arachnoid hemorrhage

Sub arachnoid hemorrhage is common after severe head injury. The centri petal theory of Ommaya and Gennarelli holds that lesion depth is dependent on the force of injury.[45] Traumatic sub arachnoid hemorrhage results from relatively severe injury to the brain.[53] High angular acceleration of long duration is necessary to produce a strain that causes rupture of the superficial vessels in the sub arachnoid space, especially at the base of the skull. In this study, the incidence of the SAH with poor outcome and death was 28% in the elderly Group A and it was 60% in the young cohort (Group B) irrespective of either intracranial hematoma or diffuse brain injury.

Head injury is having significance proportion of neurosurgical condition afflicting the elderly.[4] The complications of a head injury are disproportionately more severe in the elderly. Due to the severity of head injury, patients who are elderly need admissions, prolonged neurosurgical intensive care and longer hospital stay. The epidemiological profile appears to be similar to those in the west.

Men appear to be more commonly affected, especially among younger patients when compared to the elderly individuals [Table 1]. The elderly group usually tends to have injuries of a lower impact, such as those sustained in falls. It may be due to frailties associated with advancing age, poor eyesight, impaired balance, postural hypotension, and cerebrovascular accidents. Volmer *et al.* concluded that multiple injuries do not seem to be a major determinant of death in head injury patients in any age group from the TCDB Study.[40,62]

As such, these elderly patients seem to have less associated multiple injuries or accompanying cervical injuries. This was echoed by Baltar *et al.*[4,6]

At the same time, elderly patients with moderate and severe head injury tend to have a higher incidence of traumatic ICH. In this study, if the patient presented with coma CGS <8 only 22.3% had a favorable outcome compared to 46.5% who had good outcome if the presenting CGS >8.

An increasing incidence of intracerebral hematoma with advancing age is associated with decreasing chances of survival[55] and it has been noted in other studies.[5,52] The clinical course of a patient with an epidural hematoma was first described by Jacobson in 1884.[58] Haselberger *et al.* demonstrated that patients with a pure epidural hematoma in whom the outcome fared significantly better than those with associated intradural lesions. (70% and 40%, respectively). The classic contralateral hemi paresis results from direct pressure on the underlying motor cortex and is seen only with epidural hematomas occurring in the frontotemporal region (70%–80 cases).[39,47]

Hemiparesis, however, may also be ipsilateral and occurs when the opposite cerebral peduncle is pressed against the tentorial edge, classically called Kernohan's notch. Epidural hematomas in the posterior fossa are rare finding. Of all post-traumatic intracranial mass lesions, only 5% are found in the posterior fossa.[21,66,69] Of these, epidural hematomas are most prevalent.[57] Pickard *et al.* showed that the surgical management of the post-traumatic epidural hematoma is one of the most cost effective of all surgical procedures in terms of quality of life and years preserved.[49]

In our study, among the intracranial lesions, epidural hematoma cases (47 cases) are more common in younger group with 74.5% mortality rate. However, in the elderly group, there is slight increase in epidural hematoma (24 cases) when compare to sub dural hematoma (14 cases) with mortality (29.2% and 28.6%, respectively). In a study of pure acute sub dural hematomas, it was found that in 72% of patients, head injury was produced by a fall or assault, in only 24% was the cause a motor vehicle collision.[58] Acute sub dural hematomas may also occur (after trivial Injury) in patients given anti-coagulants and in those with coagulopathies.

Even after operative decompression, the prognosis of subdural hematoma is still poor in many cases. It is though that the co-existing brain damage (DAI) is mainly responsible for the poor outcome. However, compression of the microcirculation and resulting low cerebral blood flow may explain the poor clinical condition and patients who develop acute sub dural hematoma have a worse prognosis than other head injury types with mortality between 50% and 60% in various series.[37]

Intracerebral hematoma account for approximately 20% of all hematomas.[41] Patients on long term anti-coagulant therapy are at increased risk of developing intracerebral hematoma, even after mild head injury.[33] Intracerebral hematoma generally does not require surgical intervention unless there is significant mass effect or increase in intracranial pressure. In this study, both young and elderly group show high mortality in the ICH (intracerebral hematoma) with 40% and 62%, respectively, which was reflected in other series also. In the sub dural hematoma cases, the mortality rate of elderly group after surgery doubles when compare to younger age group (86% and 39%, respectively).

Some studies showed that the presence of traumatic SAH on initial C.T. Scan is also an adverse prognostic factor. It was postulated that the presence of subarachnoid bleed appeared to predict an abnormal ICP. A two-fold increase in mortality was noted in the age group with subarachnoid bleed in the United State trauma Coma Bank Study. In a study from the National institute of health TCDB, sub arachnoid hemorrhage was identified in 39% cases with severe head injury. The presence of subarachnoid bleed may represent major vessel injury with its attendant problems of vasospasm and tissue ischemia. This adverse prognostic effect was also noted in patients with acute subdural hematoma.

Some studies have even suggested that age can be considered an adverse risk factor in head injury. The poor outcome rates quoted in other studies on closed head injury in the elderly ranged from 46% to 98% and age has been identified as a strong prognostic indicator. The threshold has been suggested to be between 55 and 60 years of age. In this review, the poor outcome in the elderly with closed head injury is in line with that found in other studies. Although elderly patients have a much higher incidence of pre-existing systematic disease, age has been discounted as predictor of poor outcome in other studies.

In this study, nearly half of the patients showed diffuse brain injury with or without mass lesion, and therefore they were not subjected to any neurosurgical intervention, but were still managed as per the protocol. The factors which persuaded with not to perform invasive cranial procedures include poor anesthetic risk, from pre-existing co-morbid disease states, coagulopathy, or a very poor neurological condition at presentation (CGS – 3). While it may be argued that this group of patients may theoretically confound out results, we think that it would be highly unlikely as they represent patients with a very poor risk to benefit ratio for surgical intervention and or survival.

Nevertheless, even when this group of patients was disregarded, the mortality rate was still 56.5%; this is twice that of the younger group (31.6%). Overall, despite recent advances in the management of moderate and severe TBI, the mortality rate of the elderly remain high.[55] It still unclear that why the elderly have a greater propensity to develop a hematoma after an apparently trivial injury. Certainly, cerebral atrophy with a change in the visco elastic properties of the brain, alterations in the mechanical properties of the bridging veins and stress placed on the venous structures secondary to cerebral atrophy may all contribute.

The other systemic factors, including higher mean blood pressure, increased vascular rigidity and alterations in hemostatic mechanisms may result in the development of larger hematomas, mechanisms may result in the development of larger hematomas, as would the greater potential volume of the sub dural space following brain atrophy.[62] While current results compare favorably with the previous reports, the fact remains that only one in five is expected to have a favorable outcome, with most have a GCS more than 8 on admission. The poor prognosis for elderly patients with severe TBI (GCS <8) with traumatic intracranial hemorrhage on CT scan has important ethical consequences. How far should we pursue intensive and surgical management in this group? Perhaps an individualized approach may be more appropriate.

Obviously, patients who have a poor pre morbid condition, poor GCS, and massive traumatic intracranial hemorrhage may lead the surgeon towards a more conservative approach, while patients who have a good pre morbid state and GCS more than 8 may require a more aggressive approach. Several studies of severely head injured patients have confirmed the influence of clinical factor such as age and intracranial mass lesion, on the final outcome.[41] In our series a study of 160 severely head injured patients have confirmed the influence of age, intracranial mass lesion, papillary reaction, impaired eye movements, and motor response on the final outcome.

Our study shows that Glasgow Coma Scale is of value not only as a methods of quantifying the degree of neurological impairment but also a basis for making early, accurate

predictions of the likely outcome of head injured patients. Initial GCS score alone is enough to make reliable outcome prediction. The other factors such as papillary reaction, brain stem function vital signs, and age can also be used as a basis to predict outcome. Our study suggests that although individually these factors are song predictors of outcome, combination of these factors increased the accuracy.

The predictive power of these simple clinical parameters is undesirable and the amount of data required to make a prediction has to be quite small. Although various advanced investigations (MRI, SSEP, and Bio chemical values) help in prediction of outcome, they are not as useful as clinical parameters. Another aspect of these advanced and sophisticated laboratory data is the cost of their acquisition and their non-availability in the many different kinds of hospitals to which head injured patients are admitted.[60-67]

CONCLUSION

The elderly with head injury needs to be reassessed by neuro surgeons after initial resuscitation. In cases when the presenting GCS is poor and the patient has significant co-morbidities, counseling and discussions of the potential out comes with their families should be done before further therapies are instituted. This will help in the judicious use of limited resources available, as well as to reduce the conditions and financial burdens to the families concerned. The mortality rate increases with age mainly from the medical complications to prolonged coma. GCS is a good reliable predictor of prognosis even in the 1st day after admission. If the doctors are persuaded to elicit and record them carefully, predictions can be made reasonably accurate at the bed side.

Bilateral absence of papillary light reflex and impaired or absent OCR predicted a poor outcome. Abnormal or absent motor responses were also significantly correlated with poor outcome.

Age is probably the most significant factor in the prediction of outcome. If GCS, ocular vestibular response, Glasgow outcome score is included in the study.

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PROFORMA

NAME : I.P. No.:

AGE : D.O.A.:

SEX : D.O.O:

ADDRESS :

GCS ON ADMISSION :

AFTER 24 HOURS :

OCULOCEPHALIC RESPONSE :

OCULO VESTIBULAR RESPONSE :

MECHANISM OF INJURY : RTA/ASSULT/ACCIDENTAL FALL/ OTHERS

PUPILLARY ABNORMALITY :

PUPIL REACTION TO LIGHT:

ADMISSION PULSE :

ADMISSION BP :

RESPIRATORY RATE :

TEMPERATURE :

ANY SYSTEMATIC DISEASE : HYPERTENSION/DIABETES/CAD

BLOOD UREA:

(Serum Creatine and Electolotes)

BLOOD SUGAR :

BLOOD GROUPING :

BLEEDING TIME :

CLOTTING TIME :

CT SCAN FINDINGS :

VENTILATORY CARE:

TYPE OF SURGERY :

DURATION BETWEEN ADMISSION

AND SURGERY :

POST OP COMPLICATION :

GOS : GOOD/POOR/DEATH

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Original Article

A Comparative Study of Cartridge-based Nucleic Acid Amplification Test, Histopathological Examination, and Culture and Sensitivity in Suspicious Cases of Tubercular Lymphadenopathy

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Abstract

Introduction: Tuberculosis (TB) is one of the most important diseases in the history of mankind and remains as an extraordinary burden to humanity even today. Tuberculous lymphadenitis (TBLN) is the most common extrapulmonary TB which accounts for 25–30% of TB cases. Lymph node (LN) TB is frequent among HIV infected patients. TBLN, abdominal, or cervical is caused largely due to *Mycobacterium tuberculosis* which was once caused by *Mycobacterium bovis*. In this study, we evaluated the performance of cartridge-based Nucleic Acid Amplification Test (CB-NAAT) for the diagnosis of TBLN on histopathological examination (HPE) of excisional LN biopsy and culture and sensitivity.

Aims and Objective: (1) The objective of the study was to evaluate and compare three modalities, that is, CBNAAT, HPE and Culture and Sensitivity for diagnosis of TB in cases of lymphadenopathy, (2) sensitivity and specificity of each modality, (3) to assess efficacy of CBNAAT over other modality, and (4) to identify Rifampicin-resistant cases.

Materials and Methods: Enlarged LN is biopsied. One part of this material was put in a sterile container and sent for CB-NAAT and the other part was smeared on 2–3 slides and send for Lowenstein Jensen culture. Third part of the biopsy sample taken in sterile container with 10% formalin sent for HPE.

Result: CBNAAT is the most sensitive technique. As the rate of drug resistant TB is in increasing trend, it is essential to use a rapid method which detects *M. tuberculosis* and rifampicin resistance simultaneously. Thus, CBNAAT is the best method in the diagnosis of TB. Earlier detection can reduce the death rate and prevent the spread of TB in the community.

Key words: Tuberculosis, Cartridge-based nucleic acid amplification test, Histopathology, Rifampicin, Lowenstein Jensen culture

INTRODUCTION

Tuberculosis (TB) has co-existed with humanity even before recorded history and has been found in the skeletal remains of mummies. Hippocrates described the disease and named it "phthisis" which means to mart or waste away. TB is one of the most important diseases in the history of mankind and remains as an extraordinary burden to humanity even today.

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TB remains a major threat to global health, with estimated 10 million people fell ill with TB worldwide. 5.7 million men, 3.2 million women, and 1.1 million children. Cases being recorded in all countries and all age groups, but TB is curable and preventable.

In 2018, 87% of new cases were diagnosed in the 30 highly TB burdened countries. Of which two-third of the total

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from eight countries, with India leading the count, followed by China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh, and South Africa.

Extrapulmonary TB is a condition where TB affects any organ other than the lungs. Tuberculous lymphadenitis (TBLN) is the most common extrapulmonary TB which accounts for 25–30% of TB cases. Lymph node (LN) TB is frequent among HIV infected patients. TBLN, abdominal or cervical is caused largely due to mycobacterium TB which was once caused by *Mycobacterium bovis*.

Extrapulmonary TB is generally difficult to diagnose and diagnosis is based mostly on clinical signs and symptoms, radiograph, tuberculin test, and history of contact with known cases of TB. Most often clinical features are non-specific and do not give conclusive evidence for the disease. Demonstration of tubercle bacilli in the tissues and nodes remain the gold standard, but it is not often possible due to paucibacillary nature of the illness. The histopathological examination (HPE) of LN biopsy for macroscopic caseation, typical tuberculous granulation, examination of direct smear from the cut surface for acid fast bacilli (AFB), and culture specimen can make the diagnosis.

Diagnosis of extrapulmonary TB is often made on HPE. HPE diagnosis is made when there is caseous necrosis in a granulomatous lymphadenitis. When compared, excisional biopsy has the highest sensitivity. To obtain faster results, nucleic acid amplification test (NAAT) is being increasingly used worldwide for the rapid diagnosis of TB.

Cartridge Based NAAT (CB-NAAT) is an automated DNA test that detects *Mycobacterium tuberculosis* and rifampicin resistance (an indicator of multidrug-resistant TB [MDR-TB]) within 2 h for the investigation of patients who might have TB.

However, due to paucity of data, more studies are needed to recommend CB-NAAT testing as the initial test in suspected TB lymphadenopathy. In this study, we evaluated the performance of CB-NAAT for the diagnosis of TBLN on HPE of excisional LN biopsy and culture and sensitivity.

This study aimed to assess the applicability of CB-NAAT in early diagnosis of tubercular peripheral lymphadenopathy and early identification of MDR-TB (rifampicin resistance) in LN TB.

MATERIALS AND METHODS

Place of Study

This study was conducted at the Department of Surgery, M.G.M Medical College and M.Y Hospital, Indore.

Source of Data

All suspicious cases of tubercular lymphadenopathy operated in Dept. of Surgery, M.G.M Medical College and M.Y Hospital, Indore.

Study Period

12 months.

Study Design

The study design was prospective and comparative study.

Inclusion Criteria

The following criteria were included in the study:

1. All patients with lymphadenopathy including male and female, of ages 5–70 years
2. Patients who give written informed consent, in pediatric cases consent will be given by parents.

Exclusion Criteria

Patients and parents not willing to give written consent were excluded from the study.

Sample Size

The minimum sample size was 50 cases.

Methodology

A total of 50 patients were taken for this study. Data for the study were collected using convenient sampling techniques after obtaining written consent. The data were collected with face to face interview of the patients, using a pre-designed questionnaire, which included patient's identification data and socioeconomic status (SES).

Patient will be anesthetised locally or systemically accordingly.

The skin of the patient, over the suspected LN/nodes to be excised is marked and cleaned (painting and draping done). An incision is made through the skin and blunt dissection done to identify the enlarged LN/nodes. Part or all of the enlarged LNs are excised out. Wound is closed in layers after achieving hemostasis.

One part of this material was put in a sterile container and sent for CB-NAAT and the other part was smeared on 2–3 slides and send for Lowenstein Jensen culture. One smear slide was heat fixed and stained with carbol fuchsin stain and heated to enable the dye to penetrate the waxy mycobacterial cell wall. After staining, an acid decolorizing solution is applied. This removes the red dye from background cells and any organism in the smear except mycobacteria which retain the dye and are therefore referred to as AFB. The slides were examined under the microscope for visualization of AFB.

Third part of the biopsy sample taken in sterile container with 10% formalin sent for HPE.

Thus, the reports of CBNAAT, bacteriological investigations, and HPE will be compared among themselves and diagnosis will be made.

RESULTS

Table 1 depicts that out of total 50 subjects studied in our study, 62% were males and 38% are females [Figure 1].

Table 2 shows that out of total patients under observation 16% belongs to middle SES and 84% belongs to low SES [Figure 2].

The above graph and table show that 88% of lymphadenopathy on the basis HPE report is tubercular lymphadenitis, 4% of the total cases were neoplastic and 8% shows chronic granulomatous changes (non-tuberculous) [Figure 3 and Table 3].

Above table and graph show more common frequency, that is, 96% of total patients included for excision biopsy for cervical LN. Each 2% frequency is for right inguinal region and diagnostic laparoscopy with mesenteric LN [Figures 4,5 and Tables 4,5].

The above graph helps us to conclude that percentage of lymphadenopathies that resolved after medication is about 94% and 2% in abdominal lymphadenopathies. Percentage of lymphadenopathies that did not resolved after medication is only 2% and also neoplastic cervical lymphadenopathies that were another 2% [Figure 6 and Table 6].

The graph shows that no complication, that is, local wound infection was noticed in 88% of the patients. Local wound infection was present in 12% of the study group [Figure 7 and Table 7].

Table 1: Distribution of study subjects on the basis of gender and age

Gender	Frequency	Percentage
Male	31	62
Female	19	38
Total	50	100
Variable	Mean±SD	Min–Max
Age	31.52±16.20184	6–62

Table 2: Distribution of study groups on the basis of socioeconomic status

Socioeconomic status	Frequency	Percentage
Low	42	84.0
Middle	8	16.0
Total	50	100.0

As per Figure 8 and Table 8, distribution of 50 study subjects according to follow up was done in which 46% patients completed ATT, 44% patients were on ATT, 4% patients completed their course of antibiotics, 4% were started on chemotherapy and in remaining 2% there was no recurrence of lymphadenopathy [Figure 8, Table 8].

- Sensitivity = 31/(31+13) = 70.45%
- Specificity = 5/(5+1) = 83.33%
- Positive predictive value (PPV) = 31/(1+31) = 96.88%
- Negative predictive value (NPV) = 5/(13+5) = 27.78% [Figure 9 and Table 9].

On comparing the sensitivity and specificity of CBNAAT and HPE, $P < 0.05$ is significant. This concludes that CBNAAT is better than HPE.

- Specificity = 6/(6+0) = 100%
- Sensitivity= 17/(17+27) = 38.6%
- PPV = 17/(17+0) = 100%
- NPV = 6/(27+6) = 18.2% [Figure 10 and Table10]

On comparing, the sensitivity and specificity of smear AFB and HPE, $P > 0.06$ is insignificant [Figure 10 and Table 10]. This concludes that HPE is better than smear AFB.

- Specificity = 6/(6+0) = 100%
- Sensitivity = 15/(15+29) = 34.09%
- PPV = 15/(15+0) = 100%
- NPV = 6/(29+6) = 17.14% [Figure 11 and Table 11].

On comparing, the sensitivity and specificity of LJ culture and HPE, $P > 0.05$ is insignificant. This concludes that HPE is better than LJ culture.

On comparing sensitivity, specificity, PPV, NPV, and accuracy, we hereby conclude that CBNAAT is a better test that can be used for screening of lymphadenopathy [Figure 12 and Table 12].

DISCUSSION

Despite the discovery of the tubercle bacillus more than a 100 years ago and all the advances in our knowledge of the disease made then, TB still remains one of the major health problems facing mankind particularly in developing countries. Early diagnosis of TB and initiation of optimal treatment would not only enable a cure of an individual patient but will also curb the transmission of infection and disease to others in the community.[1]

Tuberculous lymphadenitis being the most common extrapulmonary tuberculous infection is often diagnosed

on clinical evidence only. TBLN often presents a diagnostic challenge especially when clinical presentation is suggestive but bacteriological proof is lacking.

The culture isolation of tubercle bacilli from LN biopsy specimen remains the gold standard confirmatory test for the diagnosis of the disease.

However, here in the present study, which is being conducted in a tertiary care hospital, various diagnostic techniques, including CBNAAT, were done from excisional LN biopsy to confirm the diagnosis of TBLN and the results are compared, to find out which of the techniques are more sensitive and specific and gives earlier results.

The sex distribution in this study showed that among the clinically suspected TBLN cases, there was a slight male preponderance. The percentage of male patient being 62 and female. However, no causing factor has been identified for which there can be any striking discrepancy in the sex distribution of TB. A similar Madurai Study conducted by TB Research Centre (TRC) where there were equal number of male and female.[2] Globally, the prevalence of infection with *M. tuberculosis* is similar in males and females until adolescence, after which it is higher in males. However, there is possibility that cases of TB among women are under-reported in developing countries. This is supported by the results of a study comparing active and passive case finding in which women with TB were under-notified to public health authorities when relying on passive case-finding.[3]

This study showed that TBLN is most frequently found in the age group between 15 and 40 years, 54%, which consists of the productive age group. In the recent past, numerous studies have shown a peak age range of 20–40 years. This shift in age probably reflects the falling incidence of childhood TB in the developed countries. In India, the disease is still common in children and young adults.[4,5] In a large clinical trial on LN TB conducted by TRC in Madurai, 35% of patients were aged 12 years or less and 87% were aged 30 years or below. More than 50% of patients were still in the age group of 13–30 years in a similar study in Chennai.[6] Overall, the age distribution of TB diagnosed incident cases shows a predominance in the adolescent and young adult age groups between 15 and 30, indicating ongoing disease transmission.[7]

In our study, out of 50 patients, 42, that is, 84% belonged to low socio-economic status and eight patients that is 16% belonged to middle socio-economic status. The association between poverty and health is well documented.[8] Exactly how poverty may lead to TB remains unclear. Poor SES with its attendant poor education is associated with poor knowledge of TB, risks of infection and dissemination, and with inadequate and/or delayed availability of health care. Poverty also results in poor nutrition and low body weight, which are likely to render the immune system more vulnerable to the invading organisms.[9] There is a significant SES-health gradient in TB prevalence; TB risk increases with lowering of socio-economic status.[10]

Table 3: Percentage of various possible diagnosis of lymphadenopathy on the basis of histopathology report

HPE	Frequency	Percentage
Chronic granulomatous change present	4	8.0
Neoplastic Change	2	4.0
Tubercular lymphadenitis	44	88.0
Total	50	100.0

HPE: Histopathological examination

Table 4: Distribution of study subject according to type of surgery

Type of surgery	Suspected Tubercular lymphadenitis	Percentage
Diagnostic laparoscopy with excision of mesenteric LN	1	2.0
Excision biopsy of cervical lymph node	48	96.0
Excision biopsy of Rt inguinal lymph node	1	2.0
Total	50	100.0

Table 5: Distribution of study subject according to diagnosis

Diagnosis	Frequency	Percentage
Neoplastic Lymphadenopathy	1	2.0
Non tuberculous lymphadenopathy	4	8.0
Tubercular lymphadenitis	45	90.0
Total	50	100.0

Table 6: Percentage of lymphadenopathies that resolved after treatment

Outcome	Frequency	Percentage
Abdominal lymphadenopathy resolved	1	2.0
Lymphadenopathy not resolved	1	2.0
Lymphadenopathy Resolved	47	94.0
Neoplastic cervical ln	1	2.0
Total	50	100.0

Table 7: Table depicting percentage of complications after excision biopsy and treatment

Complication	Frequency	Percentage
Local wound infection	6	12.0
Nil	44	88.0
Total	50	100.0

Table 8: Distribution of study subject according to follow-up

Follow-up	Frequency	Percentage
Completed antibiotics	2	4.0
completed ATT	23	46.0
no recurrence of lymphadenopathy	1	2.0
patient on ATT	22	44.0
Started chemotherapy	2	4.0
Total	50	100.0

Table 9: Comparison between sensitivity and specificity of CBNAAT and HPE

CBNAAT	HPE		Total	*P*-value
	Positive	Negative		
Positive	31	1	32 (64%)	0.01
Negative	13	5	18 (36.0%)	
Total	44	6	50 (100%)	

CB-NAAT: Cartridge-based nucleic acid amplification test, HPE: Histopathological examination

Table 10: Comparison between sensitivity and specificity of smear AFB and HPE

Smear AFB	HPE		Total	*P*-value
	Positive	Negative		
Positive	17	0	17 (34%)	0.06
Negative	27	6	33 (66%)	
Total	44 (88%)	6 (12%)	50 (100%)	

HPE: Histopathological examination, AFB: Acid fast bacilli

Table 11: Comparison between sensitivity and specificity of LJ culture and HPE

LJ culture	HPE gold		Total	*P*-value
	Positive	Negative		
Positive	15	0	15 (30%)	0.08
Negative	29	6	35 (70%)	
Total	44	6	50 (100%)	

HPE: Histopathological examination

Table 12: Comparing sensitivity, specificity, PPV, NPV and accuracy of CBNAAT, Smear AFB and LJ Culture

Diagnostic parameters	CBNAAT	Smear AFB	LJ Culture
Sensitivity	70.45%	38.64%	34.09%
Specificity	83.33%	100%	100%
PPV	96.88%	100%	100%
NPV	27.78%	18.18%	17.14%
Accuracy	72.00%	46.00%	42.00%

In the present study, excision biopsy has been taken from suspected cases of tubercular lymphadenopathy for confirming the diagnosis. Of these 50 cases, excision biopsies were taken mostly from cervical nodes, 46 cases accounting for 96% of cases, 2% from inguinal LN, and 2% from mesenteric LN by diagnostic laparoscopy and excision of mesenteric LN [Figure 5 and Table 5].

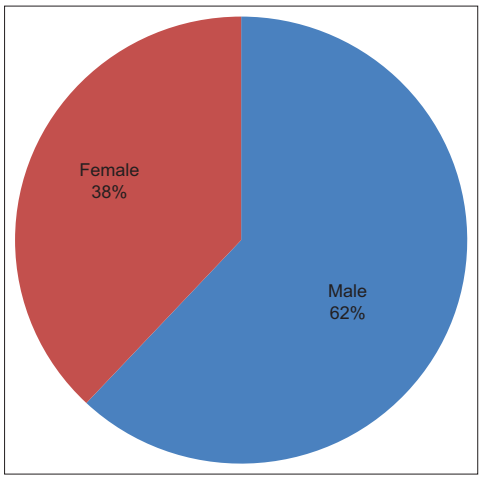

Figure 1: Distribution of study subject according to the gender

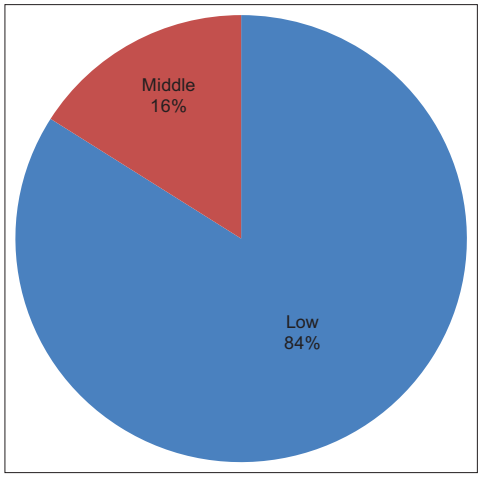

Figure 2: Distribution of study subject according to the socio-economic status

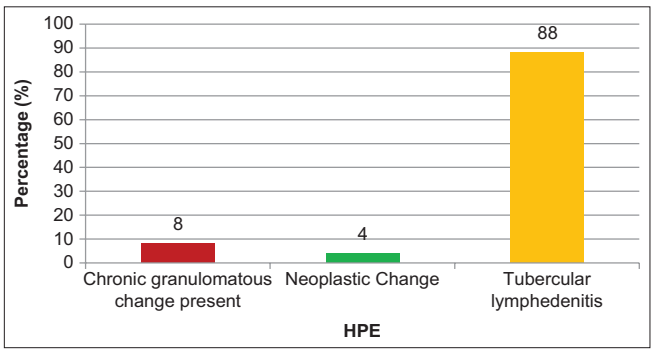

Figure 3: Distribution of study subject according to the histopathological examination

Histopathological diagnosis of TB depends on demonstration of epithelioid cells and Langerhans's giant cells in smears. However, epithelioid granulomas can be seen in non-tuberculous lesions such as Sarcoidosis,

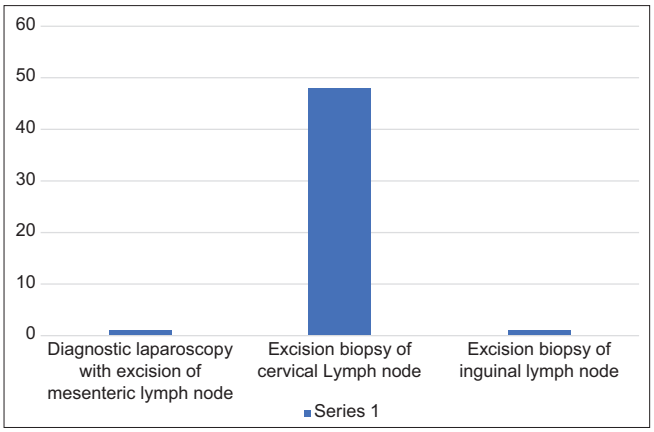

Figure 4: Distribution of study subject according to the type of surgery

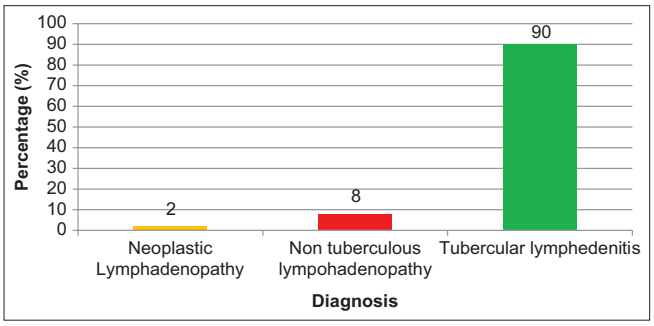

Figure 5: Distribution of study subject according to the diagnosis

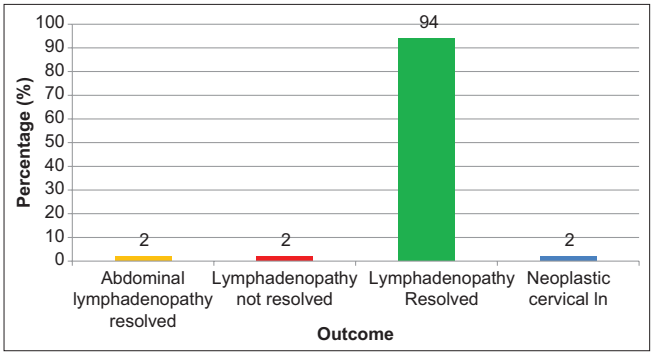

Figure 6: Distribution of study subject according to the outcome

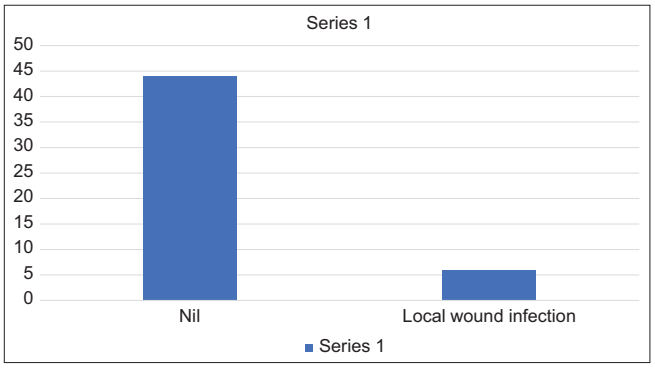

Figure 7: Distribution of study subject according to the complication

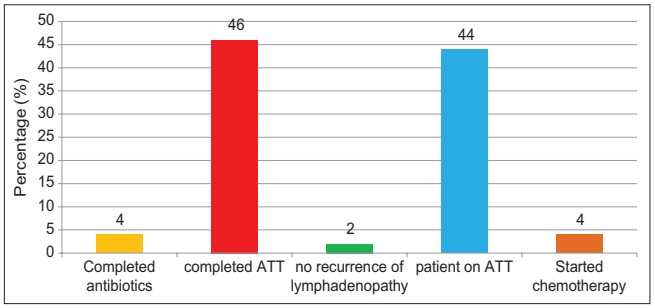

Figure 8: Distribution of study subject according to follow-up

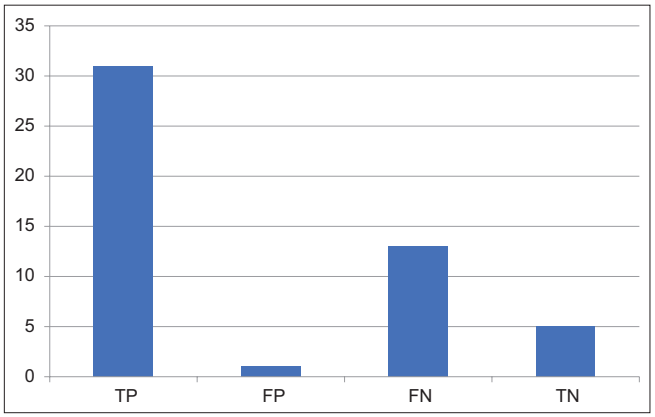

Figure 9: Comparison between sensitivity and specificity of cartridge-based nucleic acid amplification test and histopathological examination

Brucellosis, Cat Scratch disease, Leprosy, and occasionally malignancies such as Hodgkin's disease and metastatic lesions also. The presence of epithelioid cells is the first feature suggestive of diagnosis of TBLN while further data on morphological, microbiological and clinical features can be of additional help.

In the present study, out of 50 excisional biopsies, histopathological diagnosis of TBLN was made on 45 samples (90%), non-tuberculous lymphadenopathy in 8% cases and neoplastic lymphadenopathy in 2% cases. In a study conducted by Arora and Arora *et al.*, at the Department of Pathology and Microbiology, Medical College, Rohtak, out of 200 clinically suspected TBLN cases, HPE showed positivity of 62% for tubercular lymphadenitis.[11] Similar results were obtained by Nataraj *et al.*, at Mumbai.[12]

In the present study in 50 samples, the direct smears by Neelsen method were positive in 15 cases. On comparing with HPE as gold standard, its sensitivity was 38.6% and specificity was 100%. The detection rate of AFB from biopsy materials in extrapulmonary TB is usually low because of the paucibacillary nature of the disease and direct smear could be positive only if the number of AFB

is more than 10^4/ml in the specimen.[13] Positive predictive value being 100% and negative predictive value 18.2% in case of direct smear test by Ziehl Neelson method for diagnosing TB. On comparing sensitivity and specificity of smear AFB and HPE, $P = 0.06$ which is >0.05 are insignificant. This concludes that HPE is better than smear for AFB (ZN staining).

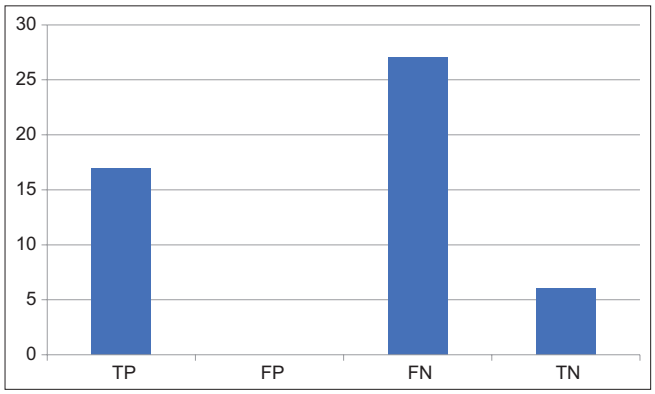

Figure 10: Comparison between sensitivity and specificity of smear acid fast bacilli and histopathological examination

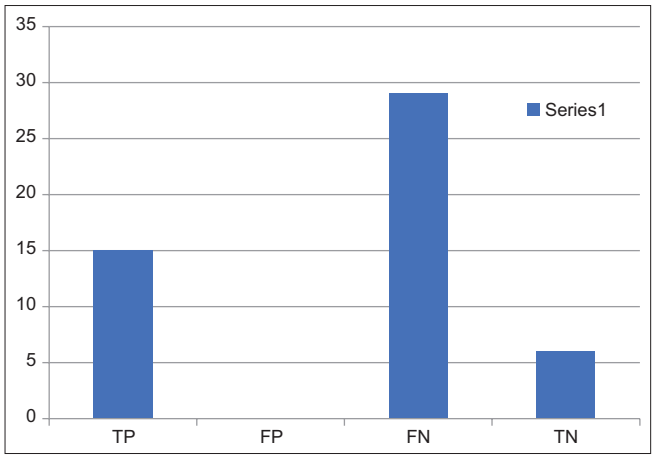

Figure 11: Comparison between sensitivity and specificity of LJ culture and histopathological examination

In the present study, culture isolation of *M. tuberculosis* and the HPE reports is compared. 15 samples out of 44 with tuberculous cytomorphology grew *M. tuberculosis*. Failure to obtain growth of tubercle bacilli is certainly not a conclusive evidence of their absence in the lesions (Middle Brook 1965). The natural healing process, previous antituberculosis treatment and unrepresentative specimens of LNs used for culture can all account for negative cultures (Braunstien and Adriaro: 1961, Kubica and Diji: 1967). Otherwise, the culture negative cytology positive samples may be due to smears, which are richly cellular with occasional clusters of epithelioid cells but no necrosis. In such cases, other granulomatous conditions have to be taken into consideration.[14] Thus, in the present study, sensitivity and specificity were 34.09% and 100%, respectively, when HPE report kept as gold standard here. On comparing, the sensitivity and specificity of LJ culture and HPE, $P = 0.08$, that is, >0.05 is insignificant [Tables 11, 12 and Figure 12].

As a part of analysis in this study, CBNAAT results were compared with the results of any other conventional method such as HPE, Direct Smear or Culture and it was observed that, out of 44 samples positive by any method, CBNAAT was positive in 31 samples. The sensitivity of CBNAAT against any other method was 70.45% and specificity was 83.33%. This finding suggests that CBNAAT can be used as an effective screening and confirmative test in the diagnosis of tuberculous lymphadenopathy from the excisional biopsy samples, which can be obtained with ease from the clinically suspected patients of tubercular lymphadenitis.

This shows that CBNAAT is the most sensitive single technique available to date for the demonstration of

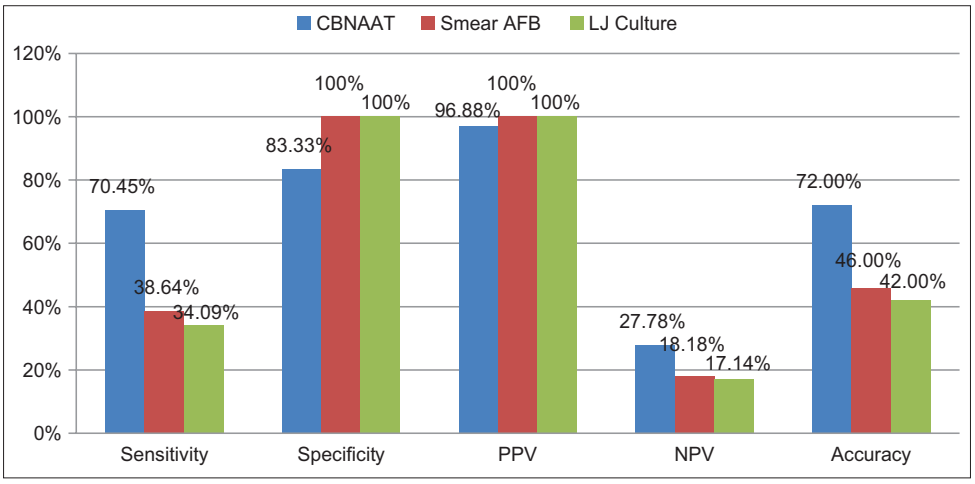

Figure 12: Comparing sensitivity, specificity, positive predictive values, negative predictive values, and accuracy of cartridge-based nucleic acid amplification test, smear acid fast bacilli, and LJ culture

M. tuberculosis in specimen derived from patients with a clinical suspicion of TBLN. Furthermore, the value of CBNAAT lies in its use as a supplementary test in the diagnosis of TBLN, particularly in those patients where conventional methods fail.

CBNAAT has more significant statistical association with HPE ($P = 0.01$ which is <0.05), in comparison with other conventional test such as culture and direct smear and also it is found that CBNAAT is a highly sensitive tool. For the above reasons, CBNAAT has to be considered as an ideal test alone or along with other conventional techniques.

In the present study, it is also seen that no local wound infection was noticed in 88% of the patients and local wound infection was present in 12% of patients which were subsequently treated with antibiotics.

In the present study, after diagnosis being made as tubercular lymphadenopathy, non-tubercular lymphadenopathy, and neoplastic lymphadenopathy, treatment was started accordingly and 4% cases were found where lymphadenopathy did not resolve; whereas in 96% cases of lymphadenopathy got resolved.

In the present study, when CBNAAT, smear AFB, and LJ culture are compared with their sensitivity, specificity, PPV, NPV, and accuracy, CBNAAT found to have the best sensitivity 70.45%, best NPV 27.78%, and best accuracy 70%. Thus, CBNAAT can be used as a single best modality to detect TB cases and can also detect rifampicin resistance. CBNAAT detected *M. tuberculosis* in 1 day rather 2 h compared to an average of 24 days required to detect by culture. This is supported by earlier studies by Pahwa *et al*.[14]

CONCLUSION

Diagnosis of TBLN based on clinical finding alone gives false positive results.

Single diagnostic parameter alone is not sufficient for correct diagnosis.

Among Direct smear (AFB stain), Lowenstein Jensen culture and CBNAAT, CBNAAT ($P < 0.05$, i.e. $P = 0.01$) is most significantly associated with HPE.

CBNAAT is the most sensitive technique. As the rate of drug resistant TB is in increasing trend, it is essential to use a rapid method which detects *M. tuberculosis* and rifampicin resistance simultaneously. Thus, CBNAAT is the best method in the diagnosis of TB. Earlier detection can reduce the death rate and prevent the spread of TB in the community.

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Original Article

Role of Otoacoustic Emission Test in Active Rheumatoid Arthritis Patients

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Abstract

Introduction: Rheumatoid arthritis (RA) is an autoimmune, chronic systemic inflammatory disease affecting the small joints and also has extra-articular manifestations. The early active stage of RA shows increased titer of anticyclic citrullinated protein antibodies in serum. Cochlear involvement resulting in Sensorineural hearing loss is one of the extra-articular manifestations in its active stage which can be identified at its subclinical level by screening with otoacoustic emission (OAE) test. OAE are sounds produced by healthy hair cells of the cochlea which shows a decrease or disappearance in active RA.

Materials and Methods: Thirty RA patients in active stage satisfying 2010 American College of Rheumatism/European League Against Rheumatism and Disease Activity Score IV criteria with normal hearing ability between 25 and 45 years of age and 30 age- and sex-matched controls were subjected to OAE test. Both males and females were included in the study.

Results: Statistical analysis was done using software SPSS version 21. All controls PASSed the test indicating normal hair cell function in both ears (60 ears). Thirty active stage patients were tested for both ears (60 ears). Out of 60, 19 PASSed the test and 41 showed REFER indicating subclinical hair cell dysfunction.

Conclusion: Study revealed subclinical hair cell dysfunction in 2/3rd of cases. Thus, OAE has a key role in screening, diagnosing and in preventing hearing disability in RA patients.

Key words: Anticyclic citrullinated protein antibodies, Otoacoustic emissions, PASS, REFER, Rheumatoid arthritis

INTRODUCTION

Rheumatoid arthritis (RA) is a multifactorial, chronic systemic inflammatory disease affecting the small joints of the body in a symmetrical manner and also affects the other systems of the body in 15–25% of individuals[1] resulting in extra-articular manifestations. The auditory system can be affected in active stage of the disease. The active disease is defined according to Disease Activity Score of 28 joints (DAS 28 score) >5.1, increased titer of Anticyclic Citrullinated Protein Antibodies (ACPA). ACPA's in the serum are the powerful biomarker in the diagnosis of RA at an early active stage.[2]

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The healthy cochlear hair cells are damaged by the expression of antigens such as 58Kda protein and 68 Kda protein immune complex deposition[3] and by pro-inflammatory cytokines such as interleukin-6 (IL-6) resulting in sensorineural hearing loss (SNHL) ranging from undetectable degree of disability to profound loss of hearing ability. The early subclinical involvement of hair cells can be identified by screening with otoacoustic emissions (OAE) test. Early assault to the hair cells are identified by screening for OAE.[4]

OAE are sounds produced by healthy hair cells of the cochlea which shows a decrease or disappearance in hearing dysfunction. OAE is a biomarker of cochlear hearing impairment at an early stage.[5] Those with abnormal OAE may be subjected to diagnostic OAE

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and the severity of hearing deficit is determined and intervened early.

Aim and Objectives

The aim of the study is to evaluate the role of OAE in active RA patients in comparison with age- and sex-matched controls. The objective of the study is to identify the subclinical hair cell damage and measures instituted early aiming at preserving the functional integrity of hair cells thus preventing the hearing impairment and improving the quality of life in these patients.

MATERIALS AND METHODS

The study was conducted at the Institute of Physiology and Experimental Medicine, Madras Medical College, Chennai-3, after ethical approval from the Institutional Ethics Committee, Madras Medical College, Chennai.

Inclusion Criteria

Thirty active RA patients 25–45 years of age with duration of illness <1 year diagnosed according to 2010 American College of Rheumatism/European League Against Rheumatism criteria with normal hearing ability confirmed by Pure Tone Audiometry participated in my study. The active disease is confirmed by increased titer of ACPA's by ELISA method and with DAS 28 score >5.1.

Thirty age- and sex-matched controls were included in the study.

Exclusion Criteria

Children, pregnant women, subjects with diabetes, hypertension, tumors, and hearing abnormalities including presbyacusis were excluded from the study.

After obtaining informed and written consent, they were subjected to OAE test at the Institute of Audiology, Rajiv Gandhi Government General Hospital, Chennai-3.

Principle

OAE screening is a sensitive and specific tool in the evaluation of subclinical hair cell damage in early active RA. It was first reported by Kemp in 1978. When the inner ear is stimulated by the sounds, the hair cells vibrate and produce an inaudible sound, echoed to the middle ear and measured by the probe placed in the external auditory canal. OAE are not generated with a hearing loss of 25–30 decibels. PASS indicates normal hair cell function and REFER abnormal hair cell function with increased risk of hearing impairment in future that recommends early diagnostic OAE.[6]

Procedure

After a preliminary general and ENT examination, the microphone of the device is inserted into the external auditory meatus of the subject and click stimulus given with PORTABLE LABAT machine and screened for Transient Evoked OAE. The results are displayed as PASS or REFER.

RESULTS

Statistical analysis was done using the software SPSS version 21. The mean age in the study group is 38.47 ± 5.06 in cases and 38.30 ± 4.41.

Study showed highly significant titer of ACPA in active RA patients when compared to controls, $P < 0.0001$ [Table 1 and Graph 1] with student *t*-test confirming active disease. Both the ears of controls and cases were subjected to OAE screening test. Control ears PASSed the test indicating normal hair cell function. Out of 60 ears of cases, ten right ears and nine left ears PASSed the test and 41 ears showed REFER [Graphs 2 and 3].

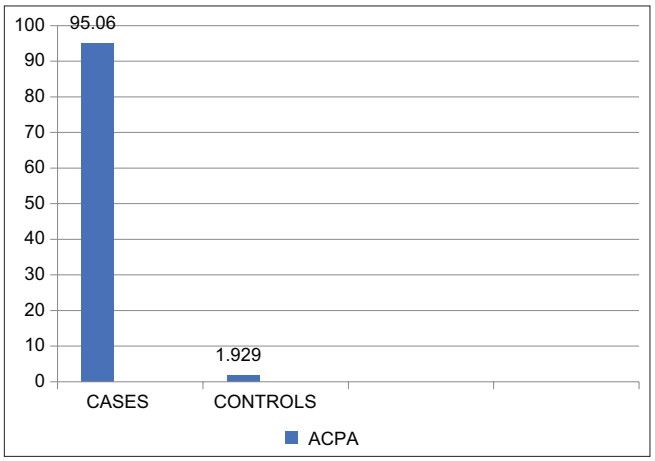
DISCUSSION

Study shows significant reduction in OAE in 41 ears out of 60 ears of active RA patients who had normal hearing

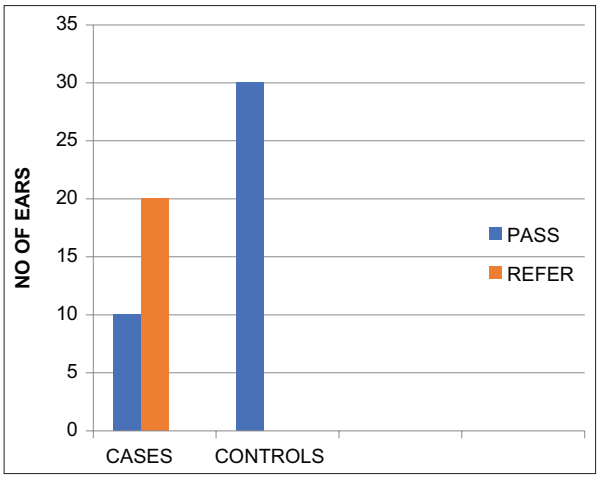
Table 1: Comparison of mean values of ACPA (RU/ml) between active RA patients and controls

ACPA	MEAN	SD	*P*-value
Cases	95.060	50.3	0.0001***
Controls	1.929	0.76	

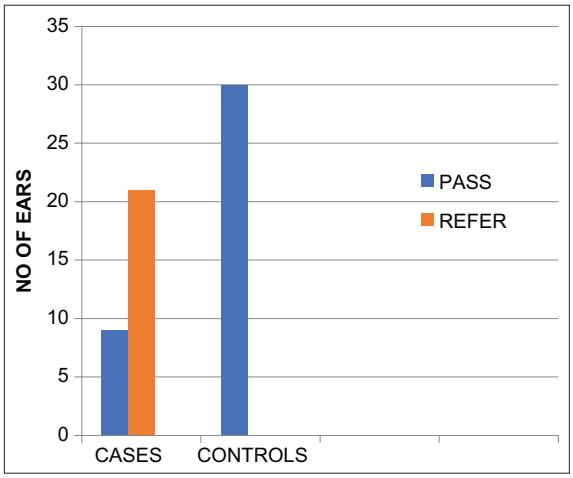
ACPA: Anticyclic citrullinated protein antibodies, RA: Rheumatoid arthritis. Table shows highly significant titer of ACPA in active RA patients when compared to controls ($P < 0.0001$)



GRAPH 1: Comparison of mean values of ACPA between active RA patients and controls



GRAPH 2: Comparison of PASS & REFER in right ears of active RA patients between cases and controls. Graph indicates that ten right ears and all controlsPASSed the OAE indicating normal hair cell function. 20 right ears had REFER indicating subclinical hair cell dysfunction



GRAPH 3: Comparison of PASS & REFER in left ears of active RA patients between cases and controls. Graph indicates that nine left ears and all controls PASSed the otoacoustic emissions indicating normal hair cell function. Twenty-one left ears had REFER indicating subclinical hair cell dysfunction

in Pure Tone Audiometry. This goes in line with studies by Emamifar *et a1*.,[7] Murdin *et al*.,[8] Bayazit *et al*.,[9] Dikici *et al*.,[10] Baradaranfar and Doosti[11] who reported the decrease in OAE's are seen in patients with normal hearing status in active RA indicating an early stage of hearing impairment.

The present study showed a significant increase in the titer of ACPA's confirming the active stage of the disease which coincides with the work done by Aggarwal *et al*., 2009,[12] where he pointed out that ACPA remains the specific and sensitive biomarker of the active stage of the disease. Aletaha *et al*.,[13] Virginia *et al*.,[14] Shyam *et al*.,[15] and Yunye *et al*.[16] recruited patients with active disease of <1 year duration with DAS 28 >5.1 and explained that SNHL with cochlear involvement is very common.[13] This study is similar to our study which included active disease of <1 year. Emamifar *et al*.[7] have explained that patients with active RA are more prone to develop SNHL and also revealed that the hair cells are affected sub clinically in active disease with the risk of hearing impairment in future. Similar trend was observed in our study proved by OAE test. Takatsu *et al*. and [3] Kumar *et al*.[17] have described that the hair cells are damaged by the oxidative process in RA by the deposition of immune complexes and inflammatory cytokines like IL-6 which are released during active disease and results in SNHL. Immune-mediated SNHL occurs in 25.2–60% as defined by Magaro *et al*.[18]

OAE is an important test for the evaluation of cochlear function.[19] Kemp has explained that OAE's play an important role in screening and diagnosis of hearing loss due to hair cell dysfunction at an earlier stage to prevent functional disability.

CONCLUSION

The study shows that cochlear hair cells are affected in the active stage of RA, which is confirmed by ACPA titer. Screening with OAE test can identify subclinical hearing defects. Early diagnosis and intervention with antioxidants, intratympanic steroids, vasodilators, etc., may preserve the hair cells thus preventing hearing disability promising a better quality of life in the society for these patients.

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Original Article

Prevalence of Neck and Back Musculoskeletal Disorders among Dentists in Punjab: A Questionnaire Study

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Abstract

Background: The prevalence of musculoskeletal disorders (MSDs) in neck and back was investigated, along with the risk factors in association with MSDs were evaluated among dentists in Punjab.

Methods: This cross-sectional study was carried out among dentists using self-administered, Nordic musculoskeletal questionnaire. Descriptive statistics and Chi-square test were used for the data analysis. Statistical analysis were done using SPSS version 20.

Results: A total of 160 dentists were included in the study. More than half of the respondents had experienced symptoms in the neck (67.5%), upper back (56.25%), and lower back (63.75%). The prevalence of trouble in the neck increased when the number of days worked per week increased. Risk factors ($P < 0.05$) included being >40 years of age, body mass index <18.5 as well as more than 24, no physical activity, increasing years of practice, and working with no more than one dental assistant.

Conclusion: There is a dire need to address and to change the way dentistry is practiced to the lower the risks to dental practitioners. Dental professionals should be cautious and well trained to stop certain behaviors that can put their health at risk as well as posture issues and ergonomics be inculcated in the educational system of dentistry.

Key words: Dentist, Dentistry, Ergonomics, Musculoskeletal disorder, Nordic questionnaire, Pain

INTRODUCTION

The Center for Disease Control and Prevention in the USA defines musculoskeletal disorders (MSDs) as "injuries or disorders of the muscles, nerves, tendons, joints, cartilage, and spinal discs".[1] They may be caused by an interplay of specific risk factors acting during work related activities, such as repetitive motions, obstinate or static positions, forceful movements, exposure to vibration (Raynaud's disease), and mechanical stress. When these factors exist simultaneously, the risk of developing MSDs increases significantly.[2]

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The prevalence of MSDs among dental-care teams ranges from 64% to 93% around the world.[3] The results of these studies also showed a high prevalence of back pain, followed by neck pain as compared to the other anatomical region (shoulders, hand, and wrists and lower extremities). The prevalence of back pain among dentist in Australia (54%), Brazil (58%), Denmark (59%), Taiwan (66%), Saudi Arabia (79%), and neck pain in Saudi Arabia (64%), Denmark (65%), and Taiwan (72%).[4] MSDs account for the most common reason (29.3%) for early retirement age in dentists worldwide.[5]

Despite the evidence of MSDs in dentistry, research conducted among the dentists in Punjab region specifically aimed at neck and back is very scanty. Hence, the present study is aimed to describe the prevalence of Neck and Back MSDs experienced by dentists during their clinical work in Punjab. The study also aimed to find the association between MSDs and selected socio-demographic, professional, and working characteristics variables.

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METHODS

In this cross-sectional study, participants included a convenience sample of 160 dentist of Punjab Region. Written informed consent was obtained from all participants before the start of the study.

A self-administered standardized Nordic musculoskeletal questionnaire[6] was conducted on dentists in state of Punjab, over a period of 2 months. Before the study, a pilot study was undertaken to test the questionnaire for comprehensibility and relevance among ten dentists. The purpose of the questionnaire and how they should be answered was explained, and whenever necessary further information was provided. They were not included in the study.

A 1-year recall of MSDs was used in this study, as this was shown to be an appropriate time scale in Taiwan,[7] Japan,[8] Korea,[9] Saudi Arabia,[10] Australia,[11] and Denmark.[12] In addition, the questionnaire contained general items such as gender, age, body mass index (BMI), education level, seniority, and working conditions, including the work place, frequencies, and duration of work tasks, number of dental assistants, and durations of being in a bent position and using hand pieces.

The collected data were thoroughly screened and entered into MS-Excel spread sheets and analysis was carried out using Statistical Package for the Social Sciences version 20. Descriptive statistics and Chi-square test was used to assess statistical significance of differences observed. $P \leq 0.05$ was considered statistically significant.

RESULTS

During the survey, effective responses from 160 dentists were received, among them, 104 (65%) were female [Figure 1]. Nearly half of the dentists (45%) were 161–170 cm tall [Figure 2]. Values of the BMI of nearly half of the respondents (43.125%) were in over weight range (43.125%), about one-third (29.375%) were within normal range, and 19.375% were obese.

Among the study sample about three-fourths (74.375%) had completed graduation in the year 2011–2020 [Figure 2]. Among the 160 dentists, 54 (33.75%) had a master's degree and the remaining 106 (66.25%) were graduates. About one-half (56.875%) worked with no dental assistant, and also nearly another one-half (41.875%) had 1 to 6 dental assistants.

Majority of them (85.625%) worked 6 days in a week. Nineteen dentists (11.875%) worked seven days per week.

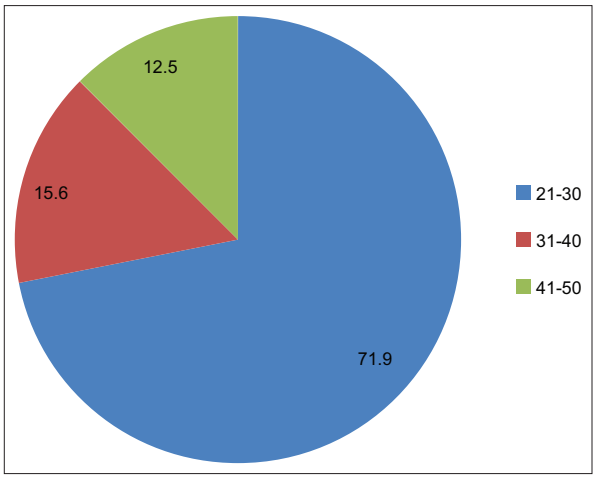

Figure 1: Distribution of study subjects according to the age groups

Majority of dentists (85%) treated no more than 10 patients per day while about one-tenth (11.875%) treated about 11–30 patients per day. About half of dentists (53.125%) spent around half an hour per patient daily while around one-fourth (26.875%) spent more than 50 min per patient daily. During treatment, around 60% (60.625%) of dentists bent their back forward for an average time of 1–10 min/patient.

Amongst the sample, 84.375% (135 dentists) reported pain in one of the regions and 37.5% (60 dentists) had pain in all the three regions whereas 15.625% (25 dentists) reported no pain in these three regions.

Out of 160 dentists, 115 belonged to 21–30 years of age, and among them 79 dentist had trouble with neck, which was statistically insignificant. About 136 dentists said that they had 1–10 years of practice, among them 88 (55%) dentist had trouble with neck, which was statistically significant. 137 dentists worked 6 days a week and amongst them 98 had pain in neck, which was statistically significant [Table 1].

Amongst the 160 respondents, 115 dentists belonged to the age group of 21–30, among them 70 had pain in upper back, which was statistically significant. 69 dentists had BMI ranging between 24.1 and 27, among these 39 had pain in upper back, which was statistically significant. 105 had education level as BDS, amongst them 65 had pain in upper back which was statistically significant. 91 Dentists had no Dental Assistant as a result 60 had pain in upper back which was statistically significant [Table 2].

Among the 160 dentists, 115 belonged to the age group of 21–30, among them 78 had pain in lower back which was statistically significant. 69 dentists had BMI ranging between 24.1 and 27, among these 45 had pain in lower

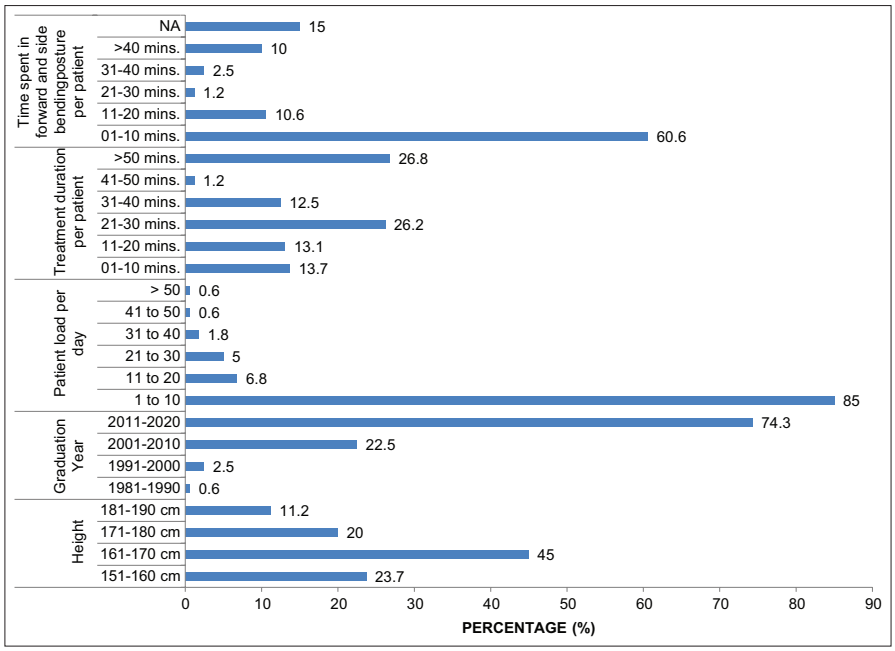

Figure 2: Distribution of study subjects according to the different variables

Table 1: Distribution and association of independent variables with neck

Factors	Trouble with locomotive organs (Neck)		Significance (*P*-value)
	No	Yes	
Age(years)			0.120
21–30	36	79	
31–40	12	13	
41–50	4	16	
Gender			
Male	20	36	0.524
Female	32	72	
BMI			
<18.5	2	11	0.080
18.5–24	18	29	
24.1–27	17	52	
27.1–35	12	14	
>35	3	2	
Physical activity			
Yes	36	75	0.978
No	16	33	
Years of Practice			
1–10	48	88	0.006*
11–20	2	20	
21–30	2	2	
Education level			
BDS	36	70	0.580
MDS	16	38	
Number of Dental Assistants			
1	16	19	0.063
2–6	7	25	
6–10	0	1	
>10	1	0	
NA	27	64	
Work days in a week			0.030
≤4	1	1	
5	2	0	
6	39	98	
7	10	9	

*$P<0.05$ - statistically significant, BMI: Body mass index

Table 2: Distribution and association of independent variables with the upper back

Factors	Trouble with locomotive organs (Upper Back)		Significance (*P*-value)
	No	Yes	
Age(years)			
21–30	45	70	0.000
31–40	20	5	
41–50	5	15	
Gender			
Male	26	30	0.616
Female	44	60	
BMI			
<18.5	2	11	0.007
18.5–24	25	22	
24.1–27	30	39	
27.1–35	8	18	
>35	5	0	
Physical activity			
Yes	53	58	0.125
No	17	32	
Years of Practice			
1–10	62	74	0.474
11–20	7	15	
21–30	1	1	
Education level			
BDS	40	65	0.032
MDS	30	29	
Number of Dental Assistants			
1	22	13	0.024
2–6	16	16	
6–10	0	1	
>10	1	0	
NA	31	60	
Work days in a week			
≤4	2	0	0.139
5	2	0	
6	57	80	
7	9	10	

*$P<0.05$ - statistically significant, BMI: Body mass index

back, which was statistically significant. 49 dentists had no physical activity and among them, 37 had had pain in lower back, which was statistically significant [Table 3].

Amongst the total respondents, 67.5% (108 Dentists) presented with trouble in NECK; 56.25% (90 Dentists) presented with trouble in upper back while 63.75% (102 Dentists) presented with pain in lower back.

DISCUSSION

The Nordic standardized questionnaire has been used for analyzing musculoskeletal symptoms since 1987[5] and is an internationally respected instrument for evaluating musculoskeletal complaints.[13] It is a self-reported survey method, and disorders include aches, pains, and discomfort in the musculoskeletal system,[11] which might not be diagnosed as a disease by physicians.

Table 3: Distribution and association of independent variables with the lower back

Factors	Trouble with locomotive organs (Lower Back)		Significance (*P*-value)
	No	Yes	
Age (years)			
21–30	37	78	0.006
31–40	16	9	
41–50	5	15	
Gender			
Male	23	33	0.352
Female	35	69	
BMI			
<18.5	2	11	0.005
18.5–24	26	21	
24.1–27	24	45	
27.1–35	4	22	
>35	2	3	
Physical activity			
Yes	46	65	0.040
No	12	37	
Years of Practice			
1–10	50	86	0.833
11–20	7	15	
21–30	1	1	
Education level			
BDS	35	71	0.234
MDS	23	31	
Number of Dental Assistants			
1	15	20	0.229
2–6	13	19	
6–10	1	0	
>10	1	0	
NA	28	63	
Work days in a week			
≤4	1	1	0.874
5	1	1	
6	48	89	
7	8	11	

*$P<0.05$ - statistically significant, BMI: Body mass index

This study examined the prevalence and distribution of self-reported musculoskeletal complaints in neck, upper back, and lower back among across section of Punjab dentists' population.

Age was seen as important contributory factor toward MSDs with 75% of respondents in the age group of 41–50 suffered from discomfort and pain in body. Gender difference was not of much significance with respect to problem in neck, upper back, and lower back wherein about similar prominences were discovered. Hence, it is critical for the dentists heading toward elder age to monitor their body for pain and visit physiotherapists to get relief and advise to alter the working atmosphere as well as lifestyle.

This study revealed that BMI is an important contributor towards MSDs whereby higher numbers (80) were noticed in dentists in the underweight (<18.5), overweight (24.1–27.0) and obese (>27.0) dentists. Fewer numbers in normal category suggests that maintaining ideal BMI goes a long way in keeping MSDs at bay.

Physical Activity is peculiarly helpful in combating back troubles as lesser number of dentists showed the presence of MSDs who were indulging in some kind of physical exercise; whereas not much difference was noticed with respect to neck pain as similar numbers were noticed across the group.

Higher Proportion of graduate dentists complained of MSDs as compared to post graduate dentists which explains that with age and experience, dentists are able to tackle the problem of MSDs with appropriate changes in lifestyle and ergonomics.

Additional help is always of great use in a dental setup as dentists working without any dental assistants showed far higher numbers (around 70%) as the added tasks of dental assistant makes the dentist more prone to MSDs. Having a dental assistant reduces added physical stress of certain activities such as mixing of dental materials which in turn decreases the to and fro motion of limbs and joints.

Less intermittent breaks in between patients and more number of working days has a strong correlation with early retirement among the dentists as around 100 dentists showed the presence of MSDs working for 6–7 days a week. It is highly recommended that sufficient breaks be taken in between patients by the operator so that the strained body parts attains ample rest. Similarly dental chair time per patient as well as total working hours and days be adjusted keeping in mind the status of the body.

A strong co-relation was noticed between neck and posture as dentists working in awkward postures with side bending

and forward bending for longer durations tend to observe MSDs in their Neck. It is crucial that fundamentals of ergonomics should be a vital part of dental curriculum as well as during Dental Conferences and workshops.

Similarly a strong co-relation was observed between Back and Physical Activity of the Dentists. Dentists who were physically active in some kind of exercises tend to observe MSDs in their backs in fewer numbers. Moreover, being physically indulged in exercises, sports and hobbies is helpful in keeping the BMI in check, which as discussed about earlier is an important contributor to MSDs.

Recommendations

1. Some kind of physical activity should be a part of daily routine so that the BMI is maintained in normal range.
2. Appropriate number of dental assistants should be employed according to the number of patients
3. Keeping work days in a week no more than 5 and keeping appropriate chair time with intermittent breaks is crucial
4. Working in bent postures should be avoided as well as suitable measures such as dental loupes and dental stools with arm rest be strongly recommended so that the dentist can work without strain and sprain.
5. There is a need for revisiting the dental curricula for undergraduates with respect to ergonomics and more collaboration through dental institutions, workshops and conferences is needed.

CONCLUSION

Dental studies and dental work often involve time spent in static, uncomfortable positions, which can lead to musculoskeletal symptom seen over the relatively short clinical training period. Dental professionals should be vigilant and try to stop certain behaviors that can put their health at risk. Continued education and tools such as magnification loupes and coaxial illumination can dramatically help improve their ergonomic posture, reduce the number of routine movements, and make it easier for them to be more efficient when they perform their job. There is a critical need to address ergonomic issues in the educational system and to change the way dentistry is practiced to lower the risks of MSDs in dental practitioners.

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Original Article

Outcome of Augmented Versus Anastomotic Urethroplasty Comparison in Bulbar Stricture Urethra of 2–3 cm Length

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Abstract

Introduction: Stricture urethra, that is, fibrous narrowing of urethra is one of the challenging urethral conditions which occur due to inflammation of urethra, trauma to urethra, or due to idiopathic cause. There are various methods of the treatment of stricture urethra which depends on length, location, depth, and density. Because the bulbar urethra is relatively mobile, removal of the narrowing of lesser size and re-join the ends over a catheter is called anastomotic urethroplasty. Longer, recurrent, or complicated strictures need to be widened by cutting into the narrowed area and inserting a graft material is known as augmentation urethroplasty.

Aim: This study aims to know outcome of augmented and anastomotic urethroplasty in strictures of 2–3 cm by retrospective analysis.

Materials and Methods: This was a retrospective study performed in 64 patients of bulbar urethral strictures equal or <3 cm admitted to the department of urology. It is compare of success rate, complications, and patient satisfaction in two types of urethroplasties augmented versus anastomotic. Patient's basic demographic parameters, diagnostic investigations for the urethral strictures, pre-operative uroflowmetry, surgical procedures, post-operative complications, and follow-up uroflowmetry and cystoscopy findings were analyzed and compared.

Results: Most of the patients in the age groups of 31–40 and trauma is the leading cause of stricture. Anastomotic group patients stayed more in the hospital. Augmented urethroplasty had very superior success rates (100%) than to the anastomotic urethroplasty (84.6%). Complications were also more in anastomotic urethroplasty.

Conclusion: In this study augmented, urethroplasty is superior to anastomotic urethroplasty with fewer post-operative complications.

Key words: Complication, Fibrotic narrowing, Mucosal graft, Spongiogibrosis, Trauma, Urethrography

INTRODUCTION

Urethral stricture is the fibrotic narrowing of the urethra.[1] Spongiofibrosis due to fibrosis of periurethral corpus spongiosum causing the loss of distensibility of the urethra. It is caused by inflammation, trauma, and idiopathic. Trauma is usually iatrogenic mainly due to per urethral instrumentation. Straddle injuries and pelvic fractures are other contributory traumatic etiology. Idiopathic urethral strictures are believed to part of congenital anomaly. Pathology of urethral stricture disease is less understood but structural and functional change of the urethral epithelium and sub-epithelial spongy tissue caused by any its etiological factors are supposed to result of narrowing of the urethra. Prolong urethral obstruction may cause secondary complications in the rest of the urinary tract.[2] Its treatment is very challenging due to high failure rates and multiple post-operative complications. Maisonneuve (1854) and Otis (1872) developed the urethrotome to cut the structured part of

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the urethra.[3] Sachse (1974) revolutionized the treatment by optical urethrotomy.[4] Excision of the stricture and primary end-to-end anastomosis is preferred for short segment strictures. For long segment, strictures augmented graft urethroplasty is preferred. Humby was the first who describe about use of buccal mucosal graft for urethral reconstruction.[5] Due to high failure rate treating surgeon surgeons should concentrate on the correct indications and surgical techniques based on advantages and disadvantages of the different types of urethroplasties. In this study, success rate, complications, and patient satisfaction assessed after two type's urethroplasties augmented versus anastomotic.

MATERIALS AND METHODS

This retrospective observational study was carried out on 64 stricture urethra patients admitted to the department of urology September 2016 to March 2019. Informed consent was taken from all patients. Patient's basic demographic parameters, diagnostic investigations for the urethral strictures, pre-operative uroflowmetry, surgical procedures, post-operative complications, and follow-up uroflowmetry and cystoscopy findings were analyzed and compared. Bulbar urethral strictures ≤3 cm are included in the study. All female patients with urethral stenosis, urethral stricture developed after partial or total amputation of penis, staged urethroplasy, pelvic floor urethral distraction defect, and stricture after hypospadias or epispadias repair were excluded from the study. The exact length of the stricture and its site was diagnosed with the help of combined retrograde urethrography (RGU) and micturating cysto-urethrography (MCU) [Figure 1]. The infant feeding tube was used to assess the distal end of the stricture from the external urethral meatus. Patients were divided into two groups: Group-1 who underwent augmented urethroplasty and Group-2 of anastomotic urethroplasty. Twelve patients had undergone augmented urethroplasty. This technique of urethroplasty was decided on basis of urethral stricture calibration which was equal or more than 8 French and healthy oral mucosa. Buccal mucosa or lingual mucosa was taken for augmentation from the mucosal surface of the cheek or lateral tongue, respectively [Figure 2]. The length of graft was dependent on the length of stricture. In all these patients, dorsal onlay technique was used. After defating graft was quilted over the dorsal aspect of urethral bed [Figure 3]. Margins of the longitudinally incised strictured segment were stitched with that of the margins of quilted graft over a silicone Foley catheter size 14Fr. Group-2 patients which include 52 urethral stricture patients underwent anastomotic urethroplasty [Figure 4]. All these patient had either urethral stricture calibration less than 8 French or unhealthy oral mucosa. Both the groups after complete patient workup were planned for surgery under spinal anesthesia. Patients

Figure 1: Retrograde urethrography+ micturating cysto urethrography combined study

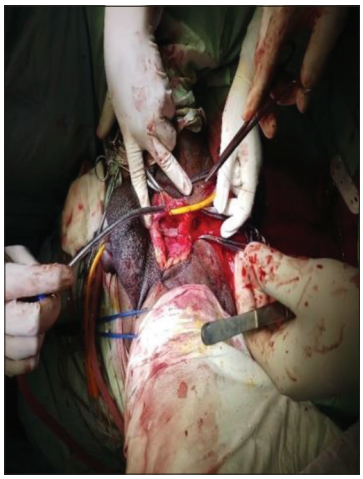

Figure 2: Intraop Dorsal onlay buccal mucosa graft urethroplasty

Figure 3: Oral mucosal graft

were placed in the lithotomy position. A midline or lambda perineal incision was made. Subcutaneous tissue incised to expose the bulbospongiosus muscle. The bulbospongiosus muscle divided in the midline to expose the underlying urethra. Circumferential mobilization of urethra was done. In Group 2, patients strictured segment was excised with 5 mm of normal urethral tissue on either side of the stricture segment with both ends spatulation and then anastomosis on urethral catheter number-14, by interrupted PDS 3-0 sutures [Figure 4]. The mobilized urethra was then hitched to the urethral bed. Wound was closed in layers with corrugated drain. Compression dressing applied. In both the groups', suprapubic catheter was maintained. Drain was removed on post-operative day 2. The silicone catheter was removed on post-operative day 21, and then micturating cystourethrogram was done and if no contrast extravasation seen and 16Fr perurethral catheter were placed and simultaneously suprapubic catheter was removed, after 1 week, perurethral catheter was removed. Follow-up uroflowmetry, cystoscopy, and International index of erectile function (IIEF-15) scoring were done at 6 and 12. All complications were recorded. Success rate and post-operative complications of these two types of urethroplasty were compared and analyzed.

RESULTS

A total of 64 patients analyzed retrospectically during the study period in which 12 underwent augmented urethroplasty where as in 52 patients anastomotic urethroplasty was done. All the post-operative events in these patients during follow-up period of 15 months recorded and evaluated. Mean age in Group 1 is 33.3 years where as in Group 2 it is 40.2 years [Table 1].

Most patient's develop urethral stricture due to trauma and mostly occurred at bulbar part of urethra [Table 1]. Stricture length which was measured by RGU and patient having stricture length 2–3 cm who was operated by any of the two procedures analyzed. Average length in Group 1 patients was 2.9 cm where as in Group 2 it was 2.1 cm. Traumatic stricture was develop mostly by straddle injury. Complications which include both intra-operative and post-operative were noted and analyzed. Post-operative complications such as fever, wound discharge, and urinary tract infections were analyzed according to Clavien-Dindo grading system. Most of the patients in both the groups having Clavien 1 and 2 grade classification which subsided by observation and conservative management. Mean duration of surgery in Group 1 is 152 min whereas 130 min in Group 2 [Table 2]. Hospital stay was more in Group 2 and major complications in post-operative period occurs in Group 2. Wound infections occurs 33.3% in Group 1 and 69.2% in Group 2. Wound gap [Figure 5], recurrent stricture urethra, urethra-cutaneous fistula, and erectile

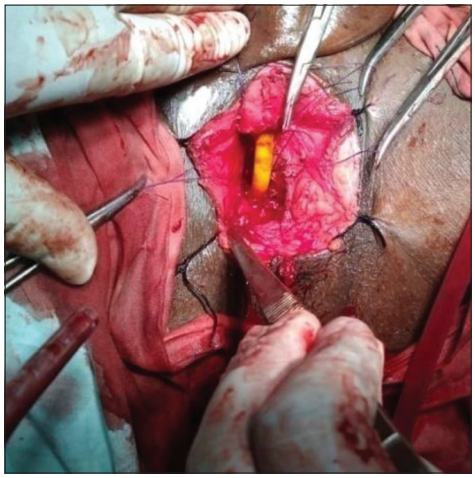

Figure 4: Intraoperative PEEAU

Figure 5: Post-operative wound gap

Table 1: Age distribution, etiology, and location of stricture in the study

Age (years)	Group 1 (*n*=12)	Group 2 (*n*=52)	Etiology	Number *n*=64	Location of stricture	Number *n*=64
21–30	4	7	Idiopathic	9	Bulbar	39
31–40	6	22	Trauma	38	Penobulbar	14
41–50	2	15	Post-infective	12	Panurethral	7
51–60	0	5	Post-catheterization Or instrumentation	5	Penile	4
61–70	0	3				

Table 2: Post-operative complications and success rate

Clavien-dindo grade	Group 1 (*n*=12)	Group 2 (*n*=52)
1 and 2	8 (66.7%)	36 (69.2%)
3	1 (8.3%)	8 (15.3%)
4	0	8 (15.3%)
Mean duration of surgery (minute)	152	130
Major complications		
Average hemoglobin drop (gm)	2	1.8
Hospital stay day (mean)	5	6.2
Wound gap	0	4 (7.6%)
Wound infections	4 (33.3%)	36 (69.2%)
Urethrocutaneous fistula	0	6 (11.5%)
Recurrent stricture	0	8 (15.3%)
Erectile dysfunction	0	2 (3.8%)
Success rate	100%	84.6%

dysfunction occurs in Group 2 in 7.6%, 15.3%, 11.5%, and 3.8%, respectively, where as these complications were not recorded in Group 1 patients up to the follow-up period. Hence, the result of augmented urethroplasty (Group 1) had very superior success rates (100%) than to the anastomotic urethroplasty (84.6%) [Table 2]. Minor infections were treated by antibiotics and wound gaps were managed by regular dressing. Only four patients were transfused blood in post-operative period. Urethrocutaneous fistula was repaired surgically by different method of fistula repaired.

Recurrent urethral stricture requires second operation which occurred in Group 2 patients and re perineal end to end urethroplasty was done. Although, minor complications common in both the groups but most of the morbid complications associated in Group 2 only. All the reoperations are done in Group 2 patients. Erectile dysfunction was also occurred in anastomotic group patients [Table 2].

DISCUSSION

For clinical purpose, male urethra divided into anterior and posterior urethra. Anterior urethra includes penile and bulbar urethra whereas posterior urethra contains membranous and prostatic urethra.[6] The term urethral stricture refers to anterior urethral disease, or a scarring process involving the urethral epithelium or spongy erectile tissue of the corpus spongiosum (spongiofibrosis). In contrast, posterior urethral "strictures" are not included in the common definition of urethral stricture. Posterior urethral stricture is an obliterative process in the posterior urethra that has resulted in fibrosis and is generally the effect of distraction in that area caused by either trauma or radical prostatectomy.[7] Consequences of the obstruction of any part of urethra can impair patient's quality of life by causing micturition disturbances also damage the entire urinary tract. It can affect any age groups but in our study, most of the patients in the age group between 30 and 40 years. Oguike *et al.* in his publication showed that 61.9% patients were aged between 21 and 50 years, and 55.9% of the strictures were traumatic in origin.[8] Beard and Goodyear found an incidence of 56.4% in middle age in a series of 211 patients between the ages of 30 and 50.[9] According to the publication by Shadab *et al.*, maximum 24% of the cases were in the age group of 31–40 years followed by age group 41–50 years (20%).[10] In a series of 100 cases, Webster *et al.* found a mean patient age of 47.[11] Tritschler *et al.* published that 45% of urethral strictures are iatrogenic, 30% idiopathic, and 20% due to bacterial urethritis. Iatrogenic causes result from urethral manipulations during traumatic indwelling catheter, transurethral interventions, correction of hypospadias, prostatectomy, and brachytherapy.[12] Pelvic trauma during road and traffic accident also one of the important cause of urethral stricture. The development of broad spectrum antibiotics has reduced the incidence of urinary tract infections, infective urethritis and its sequel of stricture formation also have significant portion of etiology contribution. The main symptoms of urethral stricture are increased urination time, feeling of incomplete bladder emptying, increased micturition frequency, and urgency. Although the diagnosis of urethral stricture is based on RGU and MCU, urethral calibration with Infant feeding tube helps significantly to locate the distal end of the stricture. Stricture urethra can be managed by different modalities of treatments. Urethral dilatation was the first method for relieving partial stricture. Urethrotomy good suited for single, short, and primary stricture. The overall recurrence rate recorded by Pansadoro and Emiliozzi after the first attempt urethrotomy is 68% and repeated urethrotomies do not improve the success rate.[13] Good results can be achieved by urethrotomy if the stricture is single or primary, shorter than 10 mm and if the caliber is wider than 15F.[13] Results of Mohanty *et al.* study revealed that 35% had recurrence who underwent repeated urethrotomies under local anesthesia.[14] Optical internal urethrotomy with steroids decreases recurrence rate of stricture urethra.[15] Importantly long stricture can be treated by augmented urethroplasty. Augmentation during urethroplasty repair can be done with different body tissues, such as prepuce, skin from the pinna, oral (buccal/lingual) mucosa, and even urinary bladder mucosa. Among these, buccal mucosal graft has become an ideal urethral substitute because it can be easily harvested under local anesthesia; it is hairless, compatible in a wet environment and is early taken up by the urethral bed.[16,17] All these unique characteristics

make buccal mucosa an integral part of reconstructive urology. End-to-end anastomotic urethroplasty is also one of the treatment modality for stricture urethra and Micheli *et al.* in his publication concludes it is as the treatment of choice for short bulbous urethral strictures, giving cure rates close to 100%.[18] In this study, the two best techniques (end-to-endanastomosis and augmented urethroplasty) were considered. The success rate of augmented urethroplasty is 100% and stricture excision and end-to-end anastomosis of the urethra is 84.6%. Published literatures on performed resection and end-to-end anastomotic urethroplasty recorded a good result.[19,20] These proposed that tension free anastomosis could be achieved by excision of the stricture of shorter length with adequate mobilization of urethra although penile chordee may be concerning. This chordee problem is not noticed with augmented urethroplasty. In augmented urethroplasty augmented tissue can be placed dorsally or ventrally. In the penile urethra, most surgeons would place it dorsally where as in bulbar urethra, ventrally, or combined ventral, dorsal, and even laterally. Both dorsal and ventral tissue placement provides good blood supply and mechanical support. Standard bulbar urethroplasties using buccal grafts should have a lifetime success rate approaching 92%.[21] Barbagli *et al.* showed that success rates are equal between dorsal and ventral buccal mucosal graft urethroplasty.[22] Dubey *et al.* retrospectively compare the outcome of various techniques of substitution urethroplasty and concludes that dorsal free graft/flap onlay urethroplasty gives better results than ventrally placed free grafts/flaps. Dorsal onlay buccal mucosal urethroplasty is a versatile procedure and associated with fewer complications than other substitution methods.[23] Ventral-onlay buccal mucosal graft placement has comparable success rates (84–100%).[24-27] Kulkarni *et al.* described a full length pan urethral repair using buccal mucosal graft with a success rate of 91–100% and concluded it better than staged repair.[28] Sawant *et al.* retrospectively review records of patients who underwent urethroplasty for anterior urethral strictures and found that success rate for anastomotic urethroplasty was 87%; 85% for staged urethroplasty and 57% for augmented urethroplasty.[29] Secondary success rate for augmented urethroplasty after single Visual Internal Urethrotomy was 86%.[25] In our study, success rate for augmented urethroplasty is more mostly due to lesser number of patients in that groups in comparison to other because patent urethral lumen required for augmentation. However, it is retrospective study so more experimental studies are required with more patients with longer follow-up period. Selection and randomization of patients into groups should free of biases with proper matched base line characteristics.

CONCLUSION

In this study, the success rate of augmented urethroplasty is superior to anastomotic urethroplasty with fewer post-operative complications. Result of this study is comparable to other published literature. Although success rate depends on many factors, augmented urethroplasty can be done in proper selected patients.

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Original Article

Introduction to Early Clinical Exposure as a Learning Tool in the 1st Year Medical Students

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Abstract

Objective: As medical education moves to new curricular models, including competency based education with defined objectives, benchmarks and outcomes and more standardized approaches, it is important to understand and set objectives for early clinical exposure.

Method: The study was conducted in MGM Medical College, Jamshedpur in October, 2019. 50 students participated with their consent. The department faculty was sensitized to ECE, and the feedback questionnaire was approved by them.

Result: ECE is associated with better co-relation clinically (52%), building concept (26%), making subject interesting(48%), retention (26%) and interactive (26%).

Conclusion: It can be summarized that teaching physiology in clinical context is the need of the hour.

Key words: Chronic kidney disease, Early clinical exposure, Medical Council of India

INTRODUCTION

The Medical Council of India's (MCIs) Vision-2015 document envisages coordinated interdepartmental efforts to provide early clinical exposure (ECE) and to develop communication skills among students during the 1st year of Bachelor of Medicine, Bachelor of Surgery Course.[1]

ECE helps students to better their understanding of a particular topic, makes teaching more relevant improve their retention power, and helps them to relate clinical conditions to basic sciences.[2]

It is also seen that the students find ECE valuable it helps them remember the subjects better and helps them integrate their knowledge.[3]

It can be summarized that teaching physiology in clinical context is the need of the hour.

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ECE can be done by any one of the following methods:
1. Taking the students to hospital or to a live patient
2. By discussing case histories, laboratory reports, photographs, X-rays, or any other clinical material
3. Taking the students to community visits.[4]

Objectives

The objectives of the study were as follows:
1. To integrate knowledge of physiology with patient care system.
2. To study the knowledge difference after ECE
3. To study the perception and attitude of students regarding ECE.

MATERIALS AND METHODS

The 1st year MBBS students were sensitized to ECE by taking a lecture. The meaning of ECE, the purpose, and the methods of conducting ECE were explained to the students.

A didactic lecture on renal system was scheduled. At the end of lectures, second session of ECE (2 h duration) was conducted as follows:

- A case of chronic kidney disease (CKD) (Stage V) with fluid overload and anemia was selected. After

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consulting the clinicians in medicine department, case history, finding, and investigation reports of the patients were collected. (Pt. identity not revealed). Videos from YouTube were downloaded
- Video from YouTube was shown which contained patient's story
- The case history and findings of the patient collected from medicine department was presented to the students. Case history, including chief complaints, H/o present and past illness, and personal history was discussed
- New terms such as hematuria and pyuria were explained
- Findings from general examination and systematic examination were discussed
- Renal function test was discussed. Abnormal values with normal values were compared. Ultrasound diagnosis of CKD was conveyed
- Video showing pathophysiology of kidney disease was shown
- Video on stages of kidney disease was also shown
- Management involving lifestyle modification, dietary changes, drugs, and renal replacement therapy was explained.

After the session, students feedback was taken by a questionnaire. The questionnaire consisted of students perception and feedback on ECE sessions.

Statistical Analysis

Student's perception of ECE was recorded by taking feedback on 10 closed-ended items on Likert scale and two open-ended questions. Closed-ended questions were analyzed by the options chosen and with percentages, whereas open-ended questions were analyzed by screwing and extracting themes.

OBSERVATION AND RESULTS

The feedback of participating students was taken by a questionnaire on 10 items on 5-point Likert scale after the ECE session. These 5 points were:
1. Strongly disagree
2. Disagree
3. Neither agree or disagree
4. Agree
5. Strongly agree.

The questionnaire consisted of 10 closed-ended questions and two open-ended questions.

DISCUSSION

Analysis of the open feedback [Table 1] showed that the program had significant impact on the building concept (26%), retention of topic (36%), interactive (26%), and correlating physiology to clinical (52%).[5]

Table 1: Students feedback (on 5-Point Likert scale serial number 10) with statistical analysis

Items	Strongly disagree	Disagree, *n* (%)	Neither agree not disagree, *n* (%)	Agree, *n* (%)	Strongly agree, *n* (%)
ECE is more interesting method of teaching-learning compared to traditional lecture	0	0	5 (10)	28 (56)	17 (34)
ECE has increased my attention in class	0	2 (4)	8 (16)	26 (52)	14(28)
ECE motivated me to read more about the topic	0	1 (2)	12 (24)	28(56)	9 (18)
ECE helped me to understand the topic better	0	0	10 (20)	29 (58)	11 (22)
ECE has helped me in better retention of the topic	0	0	7 (14)	28 (56)	15 (30)
ECE helped me in correlating physiology with clinical case	0	0	5 (10)	28 (56)	17 (34)
ECE made me understand the importance of learning physiology	0	0	4(8)	24(48)	22 (44)
ECE should be incorporated as a teaching-learning method along with regular lectures for other topics in physiology for undergraduates	0	0	3 (6)	26 (52)	21 (42)
ECE should be incorporated as a teaching-learning method along with regular lectures in other basic science subjects for undergraduates	0	0	6 (12)	24 (48)	20 (40)
ECE should be made a part of curriculum in basic sciences for future batches of MBBS students.	0	0	6(12)	18 (36)	26(52)
Top points/suggestions					
Enlist three good points about ECE as method of teaching-learning					
Helps to correlate physiology to clinical				26 (52%)	
Interesting				24 (48%)	
Retention				18 (36%)	
Build concept				13 (26%)	
Interactive				13 (26%)	
Please give three suggestions for improving ECE					
Hospital visits				25 (50%)	
More sessions				16 (32%)	
More videos				6 (12%)	

Data shown as number of students (percentage). ECE: Early clinical exposure

In an Indian setting, as ours patients are not a limiting factor for learning. For skill learning which is an integral part of clinical teaching-learning in medical education, we had an encouraging experience. The perception gathered from students reinforced the affirmative nature of ECE, which provide holistic learning to them.[6]

As suggested by students, ECE should be made part of other systems. Because of logistic difficulty, there was no actual patient contact. About 50% of students were in favor of actual patient contact. These could be considered as limitations of the study. The questionnaire was not pre-validated – another limitation of the study.

CONCLUSION

ECE sessions were introduced to the 1st year MBBS student. Medical students received it positively. ECE is an effective method to supplement the traditional teaching. MCI has introduced ECE in the new curriculum of admission batch 2019. ECE will help bridge the gap between preclinical and clinical subjects and making learning more interesting. Early clinical experience may be associated with better academic performance,[7] career interest in relevant specialties,[8] improvement in the "shock of practice" as students transition into clinical setting[9] and greater comfort entering clerkships.[10]

Value of ECE can be explained in one line by Benjamin Franklin's words of wisdom: "Tell me and I forget, teach me and I may remember, involve me and I learn."[11]

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Original Article

Empathy and its Correlates among Undergraduate Medical Students at a Medical College in India

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Abstract

Introduction: Empathy is a highly desirable professional trait, since empathic communication skills promote patient satisfaction, establish trust, reduce anxiety, increase adherence to treatment regimens, improve health outcomes, as well as decreasing the likelihood of malpractice suits. It is beneficial to the physician as well, cognitively defined empathy can lead to personal growth, career satisfaction resulting from the optimal clinical outcomes.

Purpose: The purpose of the study was to assess empathy level of medical students and its correlates.

Methodology: A cross-sectional observational study was conducted among undergraduate medical students of Veer Chandra Singh Garhwali Government Institute of Medical Science and Research, Srinagar, Uttarakhand, with a survey tool employing Jefferson Scale of Physician Empathy (JSE-S). JSE-S comprising certain details such as age, gender, year of medical school, specialty of choice, and an inventory of 20 questions half of which are negatively phrased. The students recorded their response on a scale of 1 of the 7, provided on a Likert scale in response to each item (1 = strongly disagree and 7 = strongly agree). Scale is reversed (that is, 1 = strongly agree and 7 = strongly disagree) for the negatively phrased items.

Results: The mean empathy score among males was 103.4 (standard deviation [SD] – 17.33), and among females, it was 109.4 (SD – 15.37). In our study, this difference was found to statistically significant. A majority of students reported having made the decision to enter the medical profession on their own accord, *n* = 355 (68.5%). For the rest, it was either their family member's decision or a combined decision, *n* = 66, 12.7% and *n* = 97, 18.7%, respectively. A majority of students, *n* = 360, 69.5%, preferred to join a medical specialty involving direct patient contact.

Conclusion: The empathy score varied with gender, with a higher mean score for females. It was also more for those satisfied with their career choice compared to those who were unsatisfied. Semester wise, there was no increasing or decreasing pattern of scores and was found to be variable. An impetus for empathy was provided with the introduction of foundation course for medical students where life skills education is being imparted.

Key words: Empathy, Medical students, Choice of specialty

INTRODUCTION

Empathy is a highly desirable professional trait, since empathic communication skills promote patient satisfaction, establish trust, reduce anxiety, increase adherence to treatment regimens, improve health outcomes, as well as decreasing the likelihood of malpractice suits.[1-6] It is beneficial to the physician as well, cognitively defined empathy can lead to personal growth, career satisfaction resulting from the optimal clinical outcomes.[7-9]

There is a conceptual ambiguity in terms of whether empathy is a cognitive (predominantly involves understanding another person's concerns) or an affective attribute (primarily involves feeling another person's pain and suffering)[10-13] which is made clear in its definition "a predominantly cognitive (rather than an affective or emotional) attribute that involves understanding (rather

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than feeling) of the patient's experiences, concerns, and perspectives, combined with a capacity to communicate this understanding, and an intention to help."[7,8,14] An alternate definition is "the ability to understand the patient's situation, perspective, and feelings (and attached meanings), communicate that understanding and check its accuracy, and act on that understanding with the patient in a helpful (therapeutic) way."

Empathy in medical students depends on many factors, that is, age, gender, year/semester of medical education, satisfaction with the decision of a medical career, specialty choice, quality of life, personality trait, and mental health.[15-21] Many studies have reported that empathy scores of medical students have decreased with progression of medical training.[21-25] Some proposed reasons for the decline in empathy over the years of medical education are less interaction with patients, lack of role models, and academic stress.[26-29]

Empathy is a major component of an optimal doctor-patient relationship. Hence, the cultivation of empathy is one of the learning objectives proposed by the Medical Council of India for medical students which say that an understanding of empathy for the medical students will help keep the patient perspective in mind during their learning.[30]

Some of the specific competencies that are advocated in the curriculum for medical graduates in India are – "Demonstrate empathy in patient encounters;" "Establish rapport and empathy with patients;" and "Display empathy in the care of patients with cancer."[31]

Similar recommendations are laid out by the Association of American Medical Colleges (AAMC, 2004) for medical schools.[32] In addition, the American Board of Internal Medicine (1983) recommended that humanistic attitudes, including empathy, should be instilled and assessed among residents as an essential part of their postgraduate medical education.[32]

These recommendations by professional organizations indicate that it is important to study issues related to the assessment and factors affecting empathy of in-training and in-practice health professionals. Since, empathy is a cognitive element, it can be taught and measured. It should be integrated and regularly assessed in various stages of medical education as per recommendations of AAMC.[33,34] The student version of the Jefferson Scale of Physician Empathy (JSE-S) was developed by the researchers associated with Jefferson Medical College in the United States to explicitly assess empathy in medical students. The JSE-S has high internal consistency, with a Cronbach's alpha value of 0.80, and has been used before amongst medical students across the world, thereby generating comparable results from different cultural contexts.[35]

There have been only a few published studies related to empathy and its correlates of medical and dental students of India.[21,24,36-38] It is important to find empathy level of doctors and its correlates right from the beginning of their medical education to understand the reasons of the decline in the empathy level over the years of medical education, this information can help to foster an enabling environment to inculcate empathy as a cognitive ability in the medical curriculum. With this background, the current study was designed to assess empathy level of medical students and its correlates.

METHODOLOGY

Study Design

A cross-sectional observational study was conducted among undergraduate medical students of Veer Chandra Singh Garhwali Government Institute of Medical Science and Research (VCSGGIMSR), Srinagar, Uttarakhand, with a survey tool employing JSE-S.

MATERIALS AND METHODS

JSE-S comprising certain details such as age, gender, year of medical school, specialty of choice, and an inventory of 20 questions half of which are negatively phrased. The students recorded their response on a scale of 1 of the 7, provided on a Likert scale in response to each item (1 = strongly disagree and 7 = strongly agree). This scale is reversed (that is, 1 = strongly agree and 7 = strongly disagree) for the negatively phrased items. It was administered by sharing a link for the Google Forms containing the full questionnaire as is, along with two extra questions regarding whose choice was it to pursue a medical career and current place of residence were also asked as possible. Prior permission to use the questionnaire was obtained from the owner of the scale.[39]

It is a 3-factor latent variable scale, with the three factors being "perspective taking," "compassionate care," and "standing in the patient's shoes" that have been validated.[19,20,40,41]

All medical undergraduate students of VCSGGIMSR in 2020 were invited to participate in the study. A total of 518 students consented to participate and data were collected over a period of 3 months (August–October 2020). The students were sent the unique link of the Google Forms containing the full questionnaire including a declaration

of anonymity of data, explanation of the purpose of the study, and the voluntary nature of the participation. They indicated their consent by responding "yes" or "no" to the question – Do you wish to voluntarily participate in the above study? The submission link was kept active for the entire 3 months and the students were contacted twice through e-mail, urging them to participate.

Statistical Analysis

An Excel sheet was generated for the collected data which were handled using MS Excel software (Microsoft 365 version, Microsoft Corp., Redmond, Washington, USA) after verifying the integrity of the data and ruling out any missing data, it was then imported on to Statistical Package for the Social Sciences (IBM SPSS Statistics for Mac, version 21.0, Armonk, NY: IBM Corp.).

Since the scoring algorithm only allows for a maximum of four blank items (out of the 20 item JSE-S inventory), in which case, the missing values were replaced by the mean score of the rest of the items that the participant did respond to. However, if more than 4 items were missing, the form was deemed incomplete and removed from the analysis. Reverse-scored items were scored accordingly.

Descriptive analysis – mean empathy scores were calculated and tabulated for males and females, semester wise (first to ninth), the decision to become a doctor/join medical school was your own? (Yes, No, and Maybe), specialty of choice (people oriented, technology oriented, or others), career satisfaction (on a scale of 1 to five), and current place of residence (home, hostel, or other). Student's *t*-test and analysis of variance were used to compare these means where appropriate with Bonferroni *post hoc* test. *P*-value 0.3 of <0.05 was considered to indicate statistical significance.

Ethical Approval

Prior ethical clearance was obtained from the Institutional Ethics Committee of VCSGGIMSR (vide ref no. MC/IEC/2020/134 dated 10/06/2020).

RESULTS

The mean age of the participants was 21.4 years (standard deviation [SD] 2.43), range 17–28 years. The JSE-S consists of 20 questions scored on a 7-point scale, hence, the empathy score ranged from 20 to 140. In our study sample, the mean empathy score was found to be 106.6 (SD 16.58), range 47–140.

Out of 518 participants, 244 were male (47.1%) and the rest were female (52.9%). Most of the students were in the 1st, 4th, or 6th semester (n = 106, 20.5%; n = 122, 23.6%; and n = 113, 21.8%, respectively). A majority of students reported having made the decision to enter the medical profession on their own accord, n = 355 (68.5%). For the rest, it was either their family member's decision or a combined decision, n = 66, 12.7% and n = 97, 18.7%, respectively.

A majority of students, n = 360, 69.5%, preferred to join a medical specialty involving direct patient contact such as medicine, surgery, dermatology, or emergency medicine. Eighty out of the 518 (15.4%) students have not decided which specialty they will join. Fewer number of students decided to join specialties involving indirect patient contact like pathology, n = 46, 8.9% [Table 1].

Many students were fully satisfied with their career choice, n = 190 (36.7%). The mean empathy score among males and females was 103.4 (SD 17.33) and 109.4 (SD 15.37), respectively. This difference was found to be statistically significant ($P < 0.05$). There was no trend whether upward or downward in the mean empathy scores across the semesters, but it differed with statistical significance among the various semesters ($P < 0.05$) [Figure 1 and Table 2]. Mean empathy score was much higher in students who chose to become a doctor on their own (109.3) as compared to those who became doctors for their family members' decision (97.4). This difference was found to be statistically significant ($P < 0.05$).

There was no statistically significant difference in the mean empathy score of students based on their choice of

Table 1: Distribution of the participants as per the sex, semester, decision to become a doctor, and the choice of specialty

Variable	Attribute	Number	Percentage
Sex	Male	244	47.1
	Female	274	52.9
Semester	1	106	20.5
	2	55	10.6
	3	27	5.2
	4	122	23.6
	5	32	6.2
	6	113	21.8
	7	32	6.2
	8	31	6.0
Decision	Yes	355	68.5
	No	66	12.7
	Maybe	97	18.7
Choice of the type of specialty	No direct contact	32	6.2
	Indirect contact	46	8.9
	Direct contact	360	69.5
	Undecided	80	15.4
Satisfaction with the career choice	1	44	8.5
	2	44	8.5
	3	103	19.9
	4	137	26.4
	5	190	36.7
Total		518	100

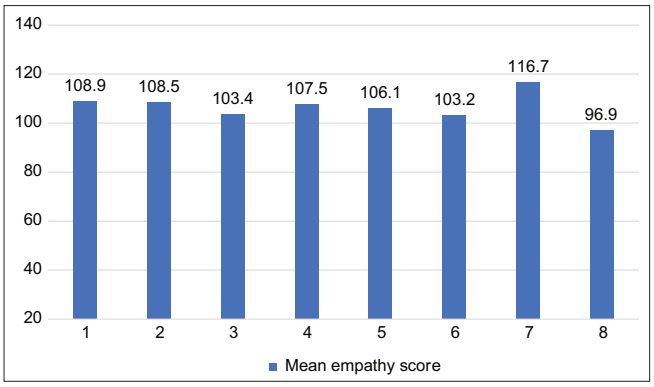

Figure 1: Mean empathy score among students in different semester of study

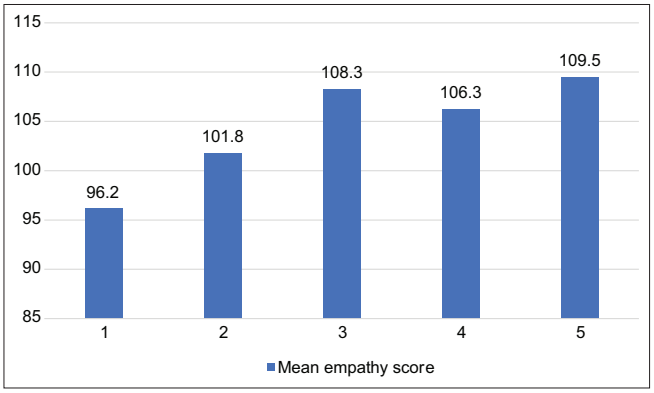

Figure 2: Mean empathy score among students as per their satisfaction with their career choice

Table 2: Comparison of mean empathy score among the participants

Variable	Attribute	Mean empathy score	SD	*P*-value
Sex	Male	103.4	17.33	0.000*
	Female	109.4	15.37	
Semester	1	108.9	13.64	0.000**
	2	108.5	19.86	
	3	103.4	20.65	
	4	107.5	12.36	
	5	106.1	23.94	
	6	103.2	15.82	
	7	116.7	14.60	
	8	96.9	18.90	
Decision to be a doctor	Yes	109.3	13.42	0.000**
	No	97.4	20.33	
	Maybe	103.0	20.92	
Choice of the type of specialty	No direct contact	104.1	24.02	0.166
	Indirect contact	102.1	19.52	
	Direct contact	107.0	15.90	
	Undecided	108.3	13.76	
Satisfaction with the career choice	1	96.2	25.03	0.000**
	2	101.8	20.44	
	3	108.3	14.29	
	4	106.3	15.16	
	5	109.5	14.09	
Total		518	100	

(*): Statistical significance/*t*-test, (**): Statistical significance/ANOVA test

specialty whether it involved direct, indirect, or no patient contact, it was 107, 102.1, and 104.1, respectively, with $P > 0.05$.

As the satisfaction of career choice increased, so did the mean empathy score of the students and this difference was highly statistically significant (<0.05) [Figure 2 and Table 2].

DISCUSSION

A total of 518 medical students participated in the study to assess the empathy level and its determinants. The mean empathy score among males was 103.4 (SD – 17.33), and among females, it was 109.4 (SD – 15.37). In our study, this difference was found to statistically significant. Similar results have been reported by many other studies done in India, Bangladesh, and the USA.[19,21,28] There could be many reasons for this difference but the most prominent one as suggested by some studies could be the traditional gender roles.[42] However, there are some studies which refute this notion that empathy among medical students varies by sex.[20] Therefore, further studies with higher sample size need to be conducted to better understand this relationship.

Satisfaction with career choice had a significant impact on the empathy scores in this study which was coherent with the findings of another study by Biswas *et al*.[36] The study by Biswas *et al*.[36] finds constant decreasing empathy scores with each higher semester. Semester wise, the empathy scores in our study were variable.

In this study, there was no statistically significant difference in the mean empathy score of students based on their choice of specialty, however, some other studies[36,43] show significant difference between the choice of people-oriented versus technology-oriented medical disciplines as a future career.

CONCLUSION

The empathy score varied with gender, with a higher mean score for females. It was also more for those satisfied with their career choice compared to those who were unsatisfied. Semester wise, there was no increasing or decreasing pattern of scores and was found to be variable. An impetus for empathy was provided with the introduction of foundation course for medical students where life skills education is being imparted. This will go a long way in laying the foundations of empathetic care to patients and their families by health-care professionals in future.

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Original Article

Comparative Evaluation of Flexural Strength, Color Stability, Surface Roughness and Weight Change of Various Commercially Available Flexible Denture Base Materials at Various Time Intervals – An *In Vitro* Study

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Abstract

Introduction: Removable partials dentures are the standard treatment modality for edentulous patients. Conventional poly(methyl methacrylate) is still being used for the fabrication of dentures. Flexible denture base materials are the best alternative to conventionally used denture base resins, which provide excellent aesthetics, comfort, and flexibility.

Aim: The aim of this study is to evaluate and compare flexural strength, color stability, surface roughness, and weight change of four commercially available flexible denture base materials immersed in artificial saliva for various time intervals.

Materials and Methods: Stainless steel die prepared with the dimension 40 mm × 10 mm × 3 mm. One hundred and twenty samples were prepared and divided into four groups based on the materials. Materials used are Valplast, Breflex, TCS unbreakable, and Iflex. Initial measurements were recorded for color stability, surface roughness, and water sorption. For flexural strength, the initial measurements were taken as control. Samples were stored in artificial saliva for 1 month and 3 months, respectively, and final measurements were noted. Three-point bend test was done in universal testing machine for flexural strength; color stability with Vita easy shade spectrophotometer. Surface roughness with profilometer and the weight change was evaluated using an analytical balance.

Results: A statistically significant difference was seen ($P < 0.01$) between Valplast, Breflex, TCS, and Iflex for flexural strength, color stability, surface roughness, and weight change with significant difference between time intervals. An increase in surface roughness and weight with increased immersion from 1 month to 3 months was observed whereas flexural strength and color stability decreased from 1 month and 3 months.

Conclusion: Increase in immersion time increases the surface roughness, weight and decreases the color stability and flexural strength of Valplast, Breflex, TCS, and Iflex. Better properties were exhibited by Breflex after 1 month and 3 months of immersion in artificial saliva than Valpalst, TCS, and Iflex.

Key words: Artificial saliva, Breflex, Color stability, Flexible denture base materials, Flexural strength, Iflex, Surface roughness, TCS, Valplast, Weight change

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INTRODUCTION

A removable partial denture has become the most common mode of treating edentulousness as many of the patients choose them because of the cost and physiology.[1] They are fabricated with metal alloys, acrylic resins, and thermoplastic resin. Dr. Walter Wright and the Vernon

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brothers in the year 1937 introduced Acrylic resins which are mostly used material because of its processing technique, easily repairable, excellent aesthetics and also economical. Disadvantages with these prostheses are insertion in undercut areas, fracture of denture due to its brittleness, and the presence of monomer causes allergy.[2]

Various experiments were done by Arpad and Tibor Nagy to resolve the problems encountered with the usage of conventional denture bases and attain the elemental needs of retention, support, and stability and it provides beautiful aesthetics.[3] Thermoplastic resins are using in dentistry for very long period. These resins are softened by heating and hardened by cooling without any chemical change. They are broadly classified as thermoplastic acetal, thermoplastic polycarbonates, thermoplastic acrylic, thermoplastic nylon, and polyolefins.

Acetal resins can resist occlusal wear and maintain vertical dimension during provisional restorations. However, strong acetal does not have the natural translucency and vitality as thermoplastic acrylic and polycarbonate. Polycarbonates are ideally used for provisional restorations. They are not suitable for partial denture frameworks. poly(methyl methacrylate) (PMMA) polymerized thermally demonstrates high porosity, water absorption, volumetric changes, and residual monomer content.

Nylon polyamides were first introduced for the construction of denture bases in the 1950s.[4] The generic name for thermoplastic polymers is Nylon belonging to the class known as polyamides. Polyamides are formed by the condensation reaction between a diamine and a dibasic acid. In certain conditions, where the undercut present on the buccal aspect of the maxillary tuberosity region, the flexibility of nylon is advantageous for easy insertion. The composition of molding powder, the temperature, and pressure used to inject the material determines the flexibility of nylon.[5]

Thermoplastic resins are polyamides, polyolefins, polyesters, and acrylics. Polyolefins are polypropylene or polyethylene, is used in recent years to fabricate for flexible partial dentures. These are light in weight and translucent materials have good chemical and fatigue resistance, coupled to high flexural strength.[6]

MATERIALS AND METHODS

The study consists of 120 samples, divided into thirty samples for each group for the type of material used. The thirty samples were subdivided into ten samples each based on the materials for 3 intervals, i.e. 1 day, 1 month, and 3 months. A stainless steel die prepared with a dimension of 40 mm × 2 mm × 10 mm. Four flexible denture base materials used in this study are VALPLAST, BREFLEX, TCS unbreakable, and IFLEX manufactured by different companies.

Preparation of Samples

Putty impressions were made for the die, and melted wax was poured into the putty impression. The softened modeling wax was allowed to become rigid. The prepared wax samples were flasked in die stone and allowed to sit for 45 min. Injection molding system was used to fabricate the flexible denture materials in specially designed flasks [Figure 1].

The injection molding procedure was done similarly for all the flexible denture base materials following the manufactures instructions of respective materials. After processing all the samples were trimmed using stone burs and rubber wheels in a unidirectional manner for about 10–12 times and polishing was done using pumice with rag wheel. Samples were checked for any porosities and irregularities under light. If any defect was detected, that the samples were discarded. After completing finishing and polishing, the samples were marked from 1 to 10 according to their respective groups so that it makes easier to test the sample for initial and final values after completing the immersion period.

Samples were placed in artificial saliva for 16 hours a day, simulating the time during which the patient uses the denture and the rest 8 hours a day time during which the patient removes the denture to sleep.[7] 1 month and 3 months samples were immersed in artificial saliva and make sure that all the samples were completely dipped [Figure 2]. All the samples except the samples that are to be tested immediately after one day of fabrication, remaining were placed in artificial saliva to simulate the oral environment.

Figure 1: Specially designed flasks and injection moulding system

Figure 2: samples stored in artificial saliva for 1 month and 3 months

Ten samples from each group were tested immediately for flexural strength after 1 day without immersion in artificial saliva. For surface roughness, color stability, and weight change, the initial values were taken for each sample before immersion in artificial saliva. After completion of the immersion period, the samples were washed thoroughly under tap water and wiped with tissue paper and tested for color stability, surface roughness, and weight change after 1 month and 3 months in artificial saliva, respectively. The same samples were tested for flexural strength, and the obtained values were tabulated.

Testing Procedures

Flexural strength

All the samples were subjected to a three-point bending test to evaluate the flexural strength. It was done using universal testing machine (UTM)- Dak system Inc Series 7200 [Figure 3]. Distance between the two supporting wedges is 30mm and the cross-head speed was set at 5mm per min. Force is applied perpendicular to the center of the specimen and the samples were gradually loaded using a UTM. Load and the deflections of each sample were noted. The flexural strength of each specimen was determined by applying increasing load until a permanent deformation occurs. The flexural strength of the samples was calculated as follows:

$$S = 3PL/2BD^2$$

where,
S - flexural strength in MPa
F - fracture load in Newton
L - span length in mm
B - specimen width in mm
D - specimen thickness in mm

Color stability

Color stability measurements were recorded before immersion and after completing the immersion period. The samples were thoroughly rinsed under tap water after immersion and make sure that they are completely dry. Color stability of the sample was evaluated with Spectrophotometer VITA easy shade [Figure 4]. The measuring tip should rest properly on the calibration block and is not lifted up before the signal tone that indicates it is the end of the white balance. Place the measuring tip again as requested. A minimum of three readings was taken for each sample. The mean was calculated and recorded with the CIE Lab system (Commission Internationale de L Eclarirage). In the CIE Lab system, L* represents light-dark shade (value), a* is green-red, and b* is yellow-blue (hue and chroma).

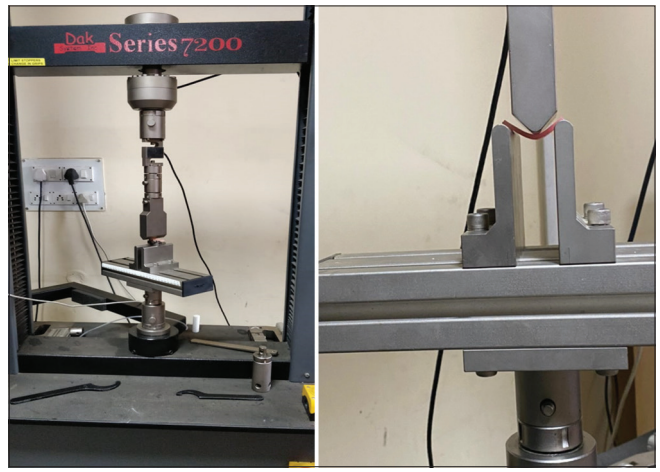


Figure 3: Flexural strength testing and deflection of samples under load

The magnitude of the two samples color difference was represented by a single number in the CIE Laboratory system using a formula $\Delta E = (\Delta L^2 + \Delta a^2 + \Delta b^2)^{1/2}$. To relate the color differences to the clinical environment the color data were quantified by National Bureau of Standards (NBS) units using the formulae NBS units $= \Delta E^* 0.92$.

Surface roughness

Surface roughness measurements were recorded just before and after the immersion. The samples were thoroughly rinsed under tap water after immersion and make sure that they are completely dry. Make sure that the testing surface

of the sample is marked on one side for initial roughness testing so that the same surface of the sample can be tested for final roughness. The samples are placed under Profilometer [Figure 5] for testing the surface roughness. Profilometer consists of a diamond stylus that moves to and fro up to a distance of 3 mm, and R_a values were noted for all samples.

Water sorption

Water sorption leads to weight gain and it was measured using analytical balance [Figure 6] for the control group without immersion in artificial saliva. Samples to be stored are weighed before and after immersion for 1 month and 3 months in artificial saliva. Water sorption is calculated with the formula:

$$\text{Water sorption} = 100\ (W_n - W_0)/W_0$$

W_n is the weight of the sample after immersion in gms and W_0 is the weight of the sample before immersion.

Figure 4: VITA easy shade to test color stability

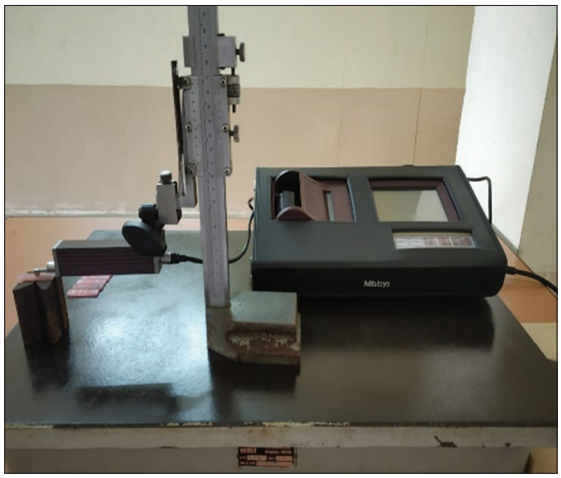


Figure 5: Profilometer for surface roughness

RESULTS

All the results were subjected to statistical analysis. One-way ANOVA test paired *t*-test was performed to measure the significance of the different materials used in the study.

The mean flexural strength of Valplast in control, 1 month and 3 months is 20.56, 18.67, and 16.84. The mean flexural strength of Breflex in control, 1 month and 3 months is 27.57, 26.87, and 25.07. The mean flexural strength of TCS Unbreakable in control, 1 month and 3 months is 26.92, 25.61, and 22.24. The mean flexural strength of Iflex in control, 1 month and 3 months is 24.92, 22.15, and 18.48, respectively [Table 1]. Highest difference in flexural strength is seen from control to 1 month and 3 months in Iflex compared to Valpalst, breflex, and TCS [Graph 1].

Color stability of all the materials the mean difference of Valplast, Breflex, TCS Unbreakable, and Iflex is 0.838, 0.606, 0.900, and 0.943, respectively, at 1 month and 1.071, 0.753, 1.161, and 1.296 at 3 months intervals. There is a slight color change in samples immersed in artificial saliva for Three months than the samples immersed for a period of 1 month and the color change is statistically significant in all the materials $P < 0.001$ [Table 2]. Highest difference in color is seen from control to 1 month and 3 months in Iflex compared to Valpalst, breflex, and TCS [Graph 2].

The mean difference of surface roughness in Valplast, Breflex, TCS Unbreakable, and Iflex is 0.630, 0.540, 0.870, and 0.830 at 1 month and 1.680, 1.530, 1.890, and 1.740 at 3 months intervals respectively. Surface roughness difference between 1 month and 3 months is statistically significant $P < 0.001$ [Table 3]. Highest difference in surface roughness is seen in Iflex compared to Valpalst, Breflex, and TCS from 1 month to 3 months [Graph 3].

Weight change in all the four materials after 1 month of immersion in artificial saliva is –0.080 for Valplast, –0.045

Figure 6: Analytical balance to measure weight change

for Breflex, and -0.077 for TCS unbreakable and Iflex. It shows that there is a statistically significant change in weight in all the materials before and after immersion [Table 4]. Moreover, among all the materials highest weight change is seen in Valplast and least in Breflex [Graph 4]. Weight change in all the four materials after 3 months of immersion in artificial saliva, the mean difference was –0.079 for Valplast, –0.060 for Breflex, –0.091 for TCS unbreakable, and –0.1010 for Iflex. It shows that there is a statistically significant change in weight in all the materials before and after immersion [Table 4]. Moreover, among all the materials highest weight change, is seen in Iflex and least in Breflex [Graph 5].

Table 1: Comparison of Flexural strength of all the materials at various time intervals i.e, control, 1 month, and 3 months after immersion in artificial saliva using RM ANOVA

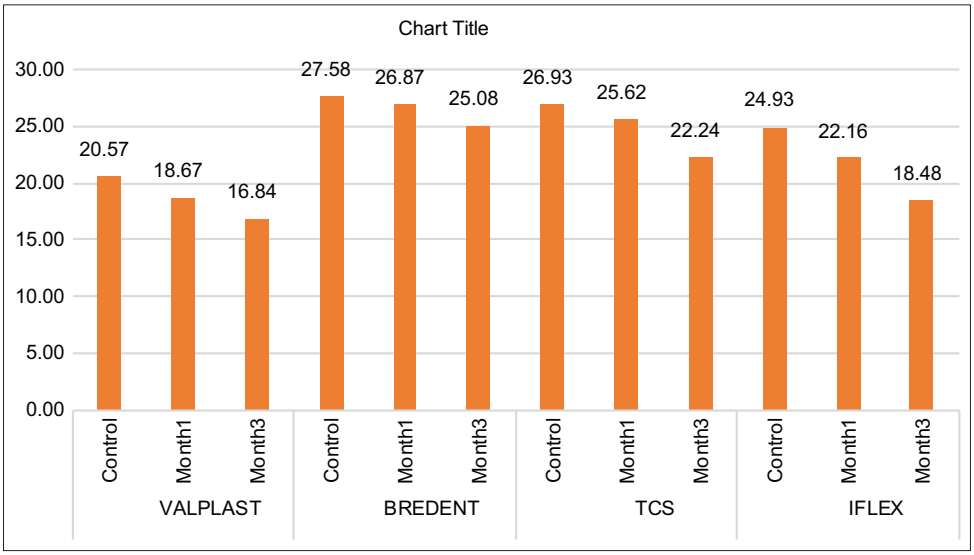
Flexural Strength	Mean	Std. Deviation	RM ANOVA F-value	*P*-value
Valplast				
Control	20.5682	0.88076	122.182	0.001*
1 Month	18.6700	0.58531		
3 Months	16.8435	0.49812		
Breflex				
Control	27.5759	1.23557	25.175	0.001*
1 Month	26.8735	0.72221		
3 Months	25.0769	0.72250		
TCS unbreakable				
Control	26.9298	1.42497	341.312	0.001*
1 Month	25.6192	1.29492		
3 Months	22.2449	1.28639		
Iflex				
Control	24.9287	0.71354	109.959	0.001*
1 Month	22.1589	0.46614		
3 Months	18.4824	0.61409		

ANOVA: Analysis of variance

DISCUSSION

In dentistry, the loss of tooth is the important problem that should be controlled, otherwise treated successfully for healthy living of the patients. Removable partial denture, fixed partial denture and dental implants are many treatment options that are available currently for replacing missing teeth; Every possible treatment option has its own advantages and disadvantages. With the introduction of acrylic polymers and chrome cobalt alloys, removable partial dentures became popular in dentistry many decades ago. Many patients choose removable partial dentures as they are low cost when compared to the other options available.[3]

Therapeutic usage of thermoplastic materials has been increasing recently in this decade. The recent new materials are used to manufacture prosthetic appliances by injecting them after they are softened with heat, without monomer. These Nylon materials have opened new horizons in the fabrication of removable partial dentures.[8] Flexible partial dentures are indicated in ridges where bilateral undercuts as they utilize the undercuts in the ridge for retention. They are also indicated in patients allergic to acrylic monomers. Clasps in esthetic zone like on maxillary canine, Patients whose economical conditions limit the use of implant and patient who does not want fixed prostheses. In patients who have nickel allergy and where large bony exostoses cannot be removed, flexible partial dentures show good retention without the removal.[3]



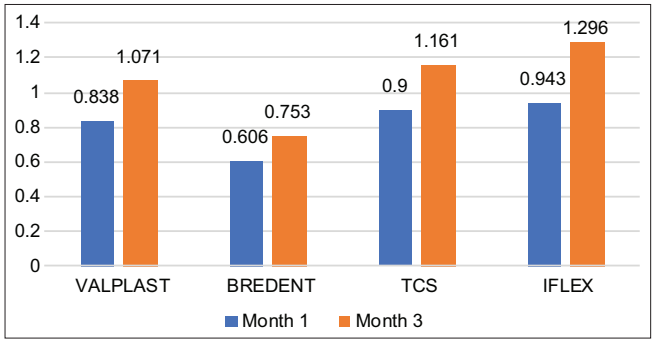
Graph 1: Schematic representation of comparison of Flexural strength of all samples at different time intervals (control, 1 month and 3 month) by using analysis of variance test

Polyamides are promoted as a denture base material on the basis of its good flexural strength, which allows it for engaging certain degree of undercuts for the purpose of retention. They are mainly indicated in conditions such as tori, tuberosities, protuberances, and extremely bulging alveolar processes, especially in the maxillary anterior region posing problems of esthetics along with retention and as an alternative to patients who are allergic to monomer.[9]

Table 2: Comparison of color stability at 1 and 3 months of time interval in all the four materials using One-way ANOVA

Color stability	Mean	SD	ANOVA F-value	*P*-value
1 Month				
Valplast	0.838	0.071	72.170	0.001*
Breflex	0.606	0.062		
TCS Unbreakable	0.900	0.037		
Iflex	0.943	0.047		
3 Months				
Valplast	1.071	0.046	117.224	0.001*
Breflex	0.753	0.063		
TCS Unbreakable	1.161	0.092		
Iflex	1.296	0.061		

ANOVA: Analysis of variance

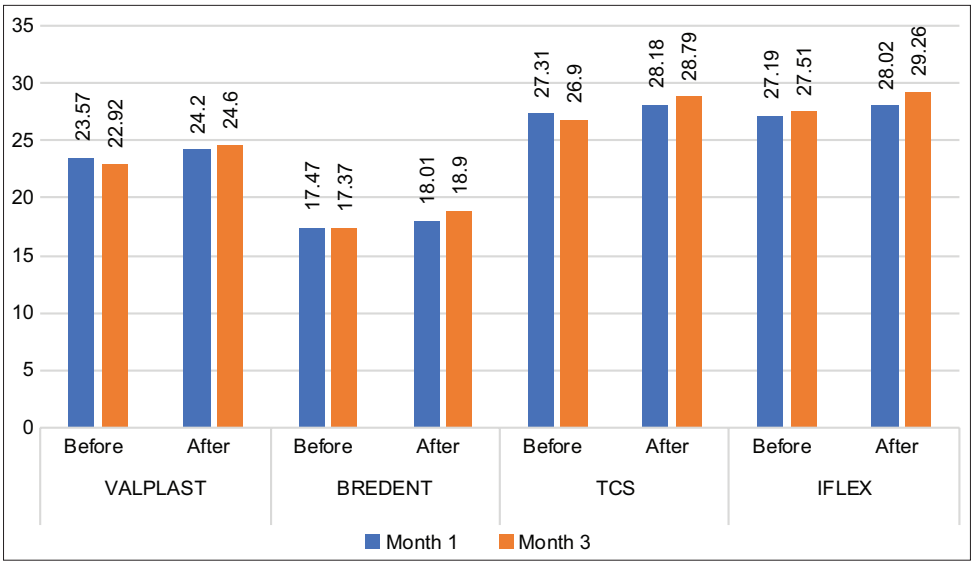


Graph 2: Schematic representation of comparison of Color stability at various times intervals (1 month and 3 month) by using analysis of variance test

As the time increased, there is a decrease in flexural strength which was correlated with the research studies of Yunus *et al.* who showed that water or humid environment has a statistically significant effect on the polymers which decreases the physical properties. Water molecules act as a plasticizer in polymer structure when immersed in water. The absorbed water molecules can interfere with the polymer chains entanglement that results in the plasticization of polymer.[10-12]

Discoloration of denture base resins might be due to various factors. The degree of conversion and residual monomer content, porosity caused by overheating or pressure during processing are intrinsic factors that can influence the color stability. Eating habits and certain external factors such as cleaning solutions, tobacco, composition of saliva, and denture hygiene habits have the effect on color stability of the denture.[13]

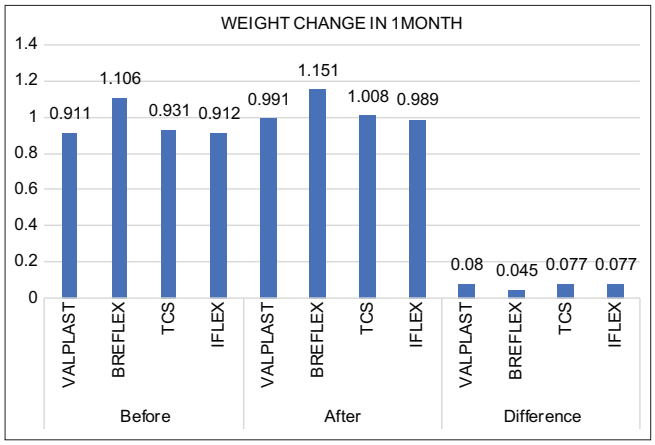
It was observed that at 1 month of immersion in artificial saliva there is not much difference between each material except Breflex which shows statistically significant difference when compared with the other three materials. At 3 months of immersion, there is a statistically significant difference between all the materials including Breflex, but this difference is not clinically acceptable according to the NBS. Increase in color change in Flexible materials with time was correlated with the studies conducted by Song *et al.* similar to the present study.[14-16] Oxidation of tertiary



Graph 3: Schematic representation of Surface roughness of all the samples immersed in artificial saliva at various time intervals (1 month and 3 months) using one way analysis of variance

Table 3: Comparison of Surface roughness difference (before and after immersion) at 1 month and 3 month interval of all the four materials using paired t-test

Surface Roughness	Mean	SD	Mean Difference	Paired *t*-test *t*-value	*P*-value
Valplast					
1 Month	0.630	0.106	–1.050	–19.649	0.001*
3 Month	1.680	0.132			
Breflex					
1 Month	0.540	0.070	–0.9900	–17.593	0.001*
3 Month	1.530	0.164			
TCS unbreakable					
1 Month	0.870	0.106	–1.0200	–18.623	0.001*
3 Month	1.890	0.137			
IFLEX					
1 Month	0.830	0.067	–0.9100	–18.200	0.001*
3 Month	1.740	0.143			



Graph 4: Schematic representation of weight change of all the samples immersed in artificial saliva for 1 month

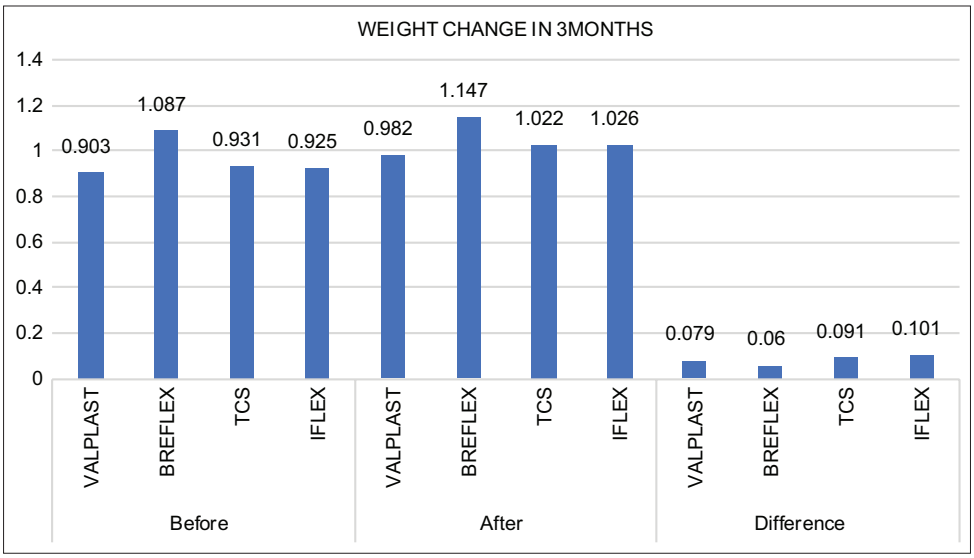
amines present in the denture base resins is one of the reasons for color change.

Rougher surface can cause discoloration and can be a source for the accumulation of biofilm causing discomfort to the patient.[17] All the materials showed an increase in surface roughness in all the materials which was in accordance with the study conducted by Ayaz *et al.*, and Mohsin *et al.* showed that there in increase in surface roughness of polyamide samples when compared with PMMA samples after thermocycling. This might be due to physical properties of the materials and the presence of amide groups on the main chain and provide the hydrophilic nature to the material. Immersion in water and immersion in artificial saliva may cause swelling of the samples and deposition of salts in artificial saliva which increases its R_a (mean surface roughness). As the size of the crystal inflexible material is large which makes it difficult to polish.[11,18]

There is change in weight among all the materials and absorption of water molecules has impact on other properties. This was correlated with the research study conducted by Hamanaka *et al.* and Lai *et al.* who showed that flexible materials are hydrophilic in nature when immersed in water absorbs water and these water molecules interfere with the polymer structure that results in water absorption. This water sorption had a statistically significant effect on flexural strength and elastic modulus.[13,19]

Limitations of the Study

1. As this is an in-vitro study, the samples tested were not able to simulate the oral environment as it might slightly alter the results



Graph 5: Schematic representation of weight change of all the samples immersed in artificial saliva for 3 months

Table 4: Comparison of weight change in all the four materials after 1 month and 3 months of immersion in artificial saliva using paired *t*-test

Weight Change	Time	Mean	SD	Mean difference	Paired *t*-test *t*-value	P-value
1 month						
Valplast	Before	0.911	0.032	–0.0800	–5.316	0.001*
	After	0.991	0.035			
Breflex	Before	1.106	0.026	–0.04500	–4.011	0.001*
	After	1.151	0.024			
TCS Unbreakable	Before	0.931	0.017	–0.077	–7.765	0.001*
	After	1.008	0.027			
Iflex	Before	0.912	0.045	–0.077	–3.795	0.001*
	After	0.989	0.046			
3 months						
Valplast	Before	0.903	0.038	–0.0790	–5.103	0.001*
	After	0.982	0.031			
Breflex	Before	1.087	0.045	–0.0600	–3.152	0.001*
	After	1.147	0.040			
TCS Unbreakable	Before	0.931	0.024	–0.0910	–7.676	0.001*
	After	1.022	0.029			
Iflex	Before	0.925	0.034	–0.1010	–6.279	0.001*
	After	1.026	0.037			

2. Operator variables might alter for surface roughness, as mechanical operator method of polishing would be consistent without any human error
3. Injection temperature and pressure of the material may vary with the manufacturers might alter the properties of the materials
4. Samples were not subjected to thermocycling to simulate the oral environment.

CONCLUSION

Within the limitations of the above-conducted study, the following findings were drawn:

1. Samples immersed in saliva for 3 months show increase in flexural strength when compared to control and 1 month. The highest flexural strength was seen in Breflex, followed by TCS unbreakable, Iflex, and Valplast, and the difference was statistically significant
2. Samples immersed in saliva for 3 months show the highest difference in Color stability than 1-month samples. The highest color stability is seen in Breflex, followed by Valplast, TCS Unbreakable, and Iflex the difference was statistically significant
3. 3 months of immersion shows the highest difference in surface roughness compared to 1 month of immersion. The highest surface roughness is seen in TCS Unbreakable, followed by Iflex, Valpalst, and Breflex the difference was statistically significant
4. 3 months of immersion showed the highest difference in weight change compared to 1 month of immersion. All the materials showed a statistically significant difference for 1 month and 3 months before and after immersion
5. Among time intervals, there is an increase in surface roughness and water sorption and a decrease in color stability and flexural strength as the time of immersion increases. The samples immersed for 3 months have shown statistically significant differences in all the properties compared to 1 month of immersion and control samples
6. Among all the materials Breflex showed superior properties when compared to Valplast, TCS Unbreakable, and Iflex.

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Original Article

Knowledge, Attitude, and Practice Regarding Biomedical Waste Management among Dentists

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Abstract

Background: With increase in number of dental clinics every year, biomedical waste (BMW) production increases accordingly. Management of these wastes is a major part of clinical practice.

Aim and Objective: The objective of this study is to assess knowledge, attitude, and practice of BMW management among dental students and practitioners.

Materials and Methods: This study involved 105 participants from undergraduates to private practitioners. The self-structured questionnaire survey comprised 30 questions and it was conducted online. The data collected were transferred to version 20 SPSS software for statistical analysis.

Results: This study shows that about 60–80% of participants were aware of different categories of waste segregation, steps in waste disposal and they also practice it. Around 70% of them practice the correct method for mercury disposal and 84% in disposal of sharp needles. The major concern is about radiological waste disposal. Only 34% knew about desilvering of fixer solution and 24% about recycling lead. More than 80% of the participants propose for proper training of the staffs handling BMWs.

Conclusion: In this study, the postgraduates and interns had more awareness compared to the undergraduate students. There is a lot of inadequacy in knowledge and practice which can be rectified from proper education and training at their early days of clinical practice.

Key words: Biomedical waste, Lead, Scrap amalgam, Waste disposal

INTRODUCTION

Biomedical wastes (BMWs) are any form of wastes (solid, liquid, and fluid) produced from a health-care setup. Dental practitioners contribute to a large amount of BMWs, though comparatively less than the medical wastes, it can be equally hazardous. According to the BMW management rules, 2016 BMW is defined as any waste produced during examination, management, or immunization of humans/animals or research activities associated or in the laboratories or health camps.[1] BMW management rules provide guidelines and protocol to be followed at every steps of waste management which includes waste survey, waste segregation followed by color coding, waste accumulation, waste storage, waste transportation, waste treatment, and waste disposal.[2,3] It is necessary for every health-care professional to be aware of the guidelines of BMW management and to follow them appropriately.

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BMWs from dental health care include both hazardous and non-hazardous wastes. The hazardous wastes are infectious, pathological, pharmaceutical, sharps, and chemical and radiological wastes. These hazardous wastes are produced in lesser amount but improper handling can contaminate non-hazardous wastes and pose a greater risk to both human health and environment. Improper management of BMWs can lead to various health hazards such as HIV

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and hepatitis B and C infections.[2] Hazards that are resulted from BMWs are environmental burden.[4]

Dentists are at higher risk of infection due to direct or indirect exposure to human blood and saliva. The infection can be transmitted by contaminated dental materials and equipment, aerosols, and droplets.[5] Improper disposal of mercury and X-ray processing solutions can be more dangerous to the environment and the dentists. Health care workers who are exposed to and handling BMWs are more prone to health hazards. Hence, it is necessary for them to be trained and to follow all the guidelines to ensure proper management of BMWs.[5,6]

Objective

With increase in number of dental clinics every year, production of BMWs also increases which demands appropriate way of managing the wastes.[2,5,7] It is essential for every health-care provider to be aware of management protocols. Hence, the purpose of this study is to assess the knowledge, attitude, and practice (KAP) among dentists in BMW management.

MATERIALS AND METHODS

A questionnaire-based survey was conducted on KAP of BMW management among dentists. There were totally 105 participants in this study which included all undergraduates, interns, postgraduates, and private practitioners.

The survey consisted of self-structured questions regarding KAP of BMW management. Initial part of the questionnaire contained demographic details of the participants such as age, gender, and educational qualification followed by 30 questions. The questionnaire survey was conducted online and the data were collected in Google Forms. Thereupon, the collected data were tabulated in Microsoft Excel sheet and transferred to version 20 SPSS software for statistical analysis.

RESULTS

The study involved about 105 participants in total, among them 33 were male and 72 were female [Figure 1] with minimum age of 17 years to maximum age of 39 years. The educational qualification of the participants was distributed as 23.8% of the 1st year, 1% of the 2nd year, 3.8% of the 3rd year, 15.2% of the 4th year, 13.3% of house surgeons, 19% of postgraduates, and 23.8% of private practitioners [Figure 2]. The participants had 30 questions to answer based on their knowledge, awareness/attitude, and practice of BMW management.

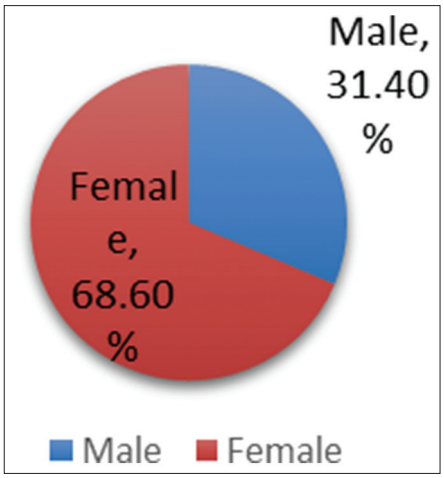

Figure 1: Distribution of gender among the participants

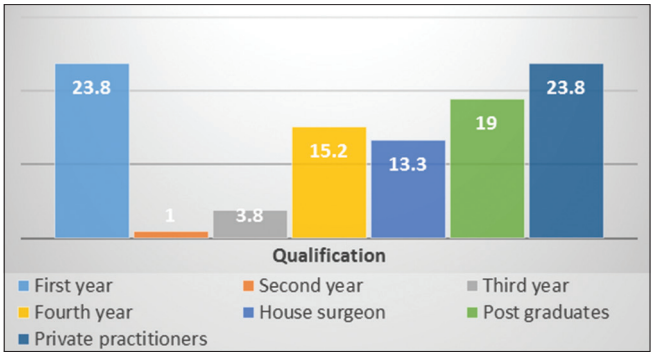

Figure 2: Distribution of educational qualification

Based on the knowledge about the government guidelines on BMW management, majority of the participants were well known that the guidelines are applicable to the dentists as they produce considerable amount of BMWs. However, they were not fully aware of the maximum storage time for untreated wastes, which is not more than 24 h. On awareness about the disposal of BMW, about 60–80% had awareness about the different categories of waste segregation, steps involved in management, and color coding of BMWs and they also practice it. About 67.6% were able to differentiate hazardous dental wastes from the given options. About 55.2% chose the right color codes used for waste disposal.

Disposal of mercury is the major part of the BMW management in dental practice. Mercury obtained in scrap amalgam form or elemental form should be properly stored in a sealed airtight container. More than 70% of the participants seem to be well aware of it. About 84% of them discard sharp needles by breaking it before disposing.

Radiological waste disposal is also a major concern in the management of BMW. Only 34% knew about desilvering fixer solution, the rest were oblivious of it. Lead toxicity

can be prevented by collecting and recycling it without having to lead into a sewer. In this study, only 24% have the similar opinion while 25% were clueless and the rest proposes to store the lead separately. About 64% of the participants believe that the use of digital X-rays might help in minimizing radiological wastes.

Almost 80% of them anticipate the use of personal protective equipment (PPE) and proper training for those who handle BMWs.

DISCUSSION

The KAP study was conducted among 105 participants which included practicing dentists, dental interns, and dental students. The student category comprised both UG and PG, starting from the 1st to final year. With fast-growing dental clinics in the community, questions comprising basic knowledge of BMWs, awareness of managing BMW, and practical steps taken in workplaces were put in the questionnaire and answers were collected. Around 92% of the participants in this study were aware of BMW management guidelines that are applicable to dental professionals. This is similar to the study done by Khubchandani *et al.*[2] and slightly differs with that of Mazhar *et al.*[1] which had only 63% of the participants being aware of the guidelines. About 96% of the participants think that improper way of BMW disposal can lead to environmental hazards which is similar to the study of Chopra *et al.*[8] According to WHO, there are about eight categories of BMWs and according to Central Pollution Control Board, there are about 10 categories of BMWs.[6,9] In our study, about 60–70% were aware of the different categories of BMW segregation and also claim to have been following it in their workplace. This observation was poor compared to the study of Pawar and Patil and Naidu *et al.*, but a slightly better than the study of Sudeep *et al.*[5,10,11] As the steps involved in BMW management are mentioned above,[1] awareness of those steps among the participants in our study constitutes to 76.2%. Awareness about color coding of BMW is 80% in our study which is close to the studies of Pawar and Patil[10] and Naidu *et al.*,[5] but very high compared to other studies.[1,11] The BMWs can be separated as hazardous and non-hazardous wastes.[6] About 81% of this study participants were able to differentiate BMWs which is in contrast to other study done by Mehta *et al.*[12] Among the most hazardous type of wastes produced by dentists, the mercury is of great consequence. The scrap mercury that is obtained from the remains of amalgam fillings has to be stored in an airtight container and disposed, the sharp needles from syringes have to be broken before disposal and have to be discarded strictly in white color bags. Around 70% of the participants in this study were well aware of mercury waste disposal while only 42% and 41.7% of them disposed correctly according to the study done by Naidu *et al.*[5] and Pawar and Patil,[10] respectively. Around 84% in our study were aware of the proper disposal of needles which was way more when compared to the study conducted by Pawar and Patil[10] that is only 31.2%. Another major contribution to the BMWs from dentists is radiological wastes. With the fact that fixer solution has to be desilvered before disposing, only 34% of them were right and this is better considering the study of Naidu *et al.*,[5] in which 17.6% chose to dilute and led into sewer. Lead toxicity can lead to several health and environmental hazards.[9] This can be prevented when this is collected and recycled in the right way.[6] In this study, about 25% of them were clueless about it and 24% of them claimed to have known about it and practicing it, while in the study conducted by Naidu *et al.*,[5] majority of them do not use X-ray films and about 20% suggests to store separately which is in similar to our study. Avoiding conventional X-ray films lead us to the use of digital X-rays.[3,13] About 64% of the participants believe that with increased usage of digital X-rays, a huge percentage of radiological wastes can be reduced. Incineration is the better option for BMW destruction.[3,6,14] It has the advantage of reducing the wastes by 50–400 times[15] but it cannot be used for every category of BMW which is accepted by 58% of the participants. However, incineration releases dioxins which seem to be harmful for the environment.[15] In our study, only 23% of them feel that incineration is harmful. Furthermore, half of the participants think that infectious wastes need to be sterilized or disinfected before shredding/disposal which is in contrast to the study of Khubchandani *et al.*[2] About 80% of the participants think that it is necessary to properly label the disposing bags and containers which is closely related to the study by Khubchandani *et al.* and Mehta *et al.*[2,12] and also they were very clear about reaching out to certified BMW carriers once the color coded bags are full but still 11% of them were not fully aware about BMW carriers and claimed to have been dumping the BMWs in municipal bins. This correlated to the study of Kumar and Padmaja.[4,16] The percentage of answers was equally distributed among 24 and 48 h when it comes to the maximum storage timing of untreated BMWs as 29–48%, respectively. This was approximately close to other studies. [1,2,8,11,12] This is due to the lack of knowledge about the guidelines that are released by the government. It must be made sure that everyone to be properly educated in storing and disposing the wastes in right manner and time period.

When it comes to the knowledge of whether the staffs handling BMWs should be trained, 81% of the participants gave a positive answer. The usage of PPE for the personnel handling BMW had a wavering percentage between 50% and 41% answering YES and MAY BE which is similar

to the study of Mazhar *et al.*[1] With PPE, a lot of health hazards can be reduced and radiological harms can be kept at bay. This includes acquiring infections such as HIV and hepatitis. A little infected needle prick might go a long way for the handlers if not disposed in a prick proof bag. About 45% of the participants do not seem to think that BMW management is expensive and time consuming while the remaining feels contrast to this. This study proved that not all practitioners are familiar with certified BMW carriers and methods. This is mainly because around 42.9% of the participants have not registered under an authorized government organization for BMW disposal where only 39% of them have proper registration for BMW disposal.

In entirety, most of the participants are aware but still need a review of all the steps, methods, and procedures followed in BMW disposal. In this study, the postgraduates and interns had more awareness compared to the dental undergraduate students. There are a lot of inadequacy in knowledge and the practices that are followed. This can be rectified by taking students to the actual area for field visits where wastes are disposed and processed so they gain better idea of the actual procedures and tend to start practicing in their early days of clinical practice. The practitioners should also be up to date in all the rules and regulations that are issued by the government.

CONCLUSION

It is the sole responsibility of every health-care professional to ensure safe environment to the public. Lack of concern and motivation among the dentists on BMW management should be corrected. Minimization of BMWs should be practiced by every individual. It is important for every dental student and practitioner to follow proper guidelines for the management of BMWs. Any lack of knowledge or proper training over waste disposal shall be improved. BMW management has to be part of the dental curriculum to ensure proper knowledge and practice among dental students.

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Original Article

Stress-related Orofacial Diseases in Information Technology Professionals

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Abstract

Introduction: Stress is believed to have major impact on the physical well-being of the individual and it does not spare the oral cavity as well. These stress-induced orofacial disorders have various manifestations and are more prevalent in professionals working in information technology (IT) field due to prolonged working hours and unreasonable deadlines.

Aim: This study aims to determine the prevalence of stress and stress-related orofacial diseases among the IT professionals.

Materials and Methods: A cross-sectional study was carried among 109 IT professionals working in a private firm after obtaining clearance from the Institutional Ethical Committee and concerned authorities. It is performed by history taking using a questionnaire based on perceived stress scale that had 14 questions and clinical examination. The data collected were statistically evaluated.

Results: Among the 109 participants, 88 were male and 21 were female. This study revealed that they were stressed due to the job and that xerostomia and aphthous ulcer were more prevalent (22.9%) in IT professionals followed by bruxism, burning mouth syndrome, and temporomandibular joint disorders.

Key words: Aphthous ulcer, Bruxism, Burning mouth syndrome, Stress, Temporomandibular joint disorder, Xerostomia

INTRODUCTION

Stress is defined as a physical or psychological response to events that lead to somatic or emotional tension.[1] Psychological stress has long been proved to have adverse reactions on physical and mental conditions of the body, due to which a group of oral manifestations is exhibited.[2] The people working in information technology (IT) sector are more susceptible to stress due to their unreasonable deadlines, unfavorable working hours, negative work life balance, prolonged period of sedentary activity, and job-related insecurities. Stress or emotional factors lead to the onset and development of various diseases of the oral cavity.[3,4] The various oral manifestations exhibited due to stress are myofascial pain dysfunction syndrome (MPDS), temporomandibular joint disorders (TMDs), dryness of mouth, bruxism, aphthous ulcer, and burning mouth syndrome (BMS).[5,6] These stress-induced oral health disorders largely affect the quality and quantity of the life lead by these professionals and hence this study was conducted to study the prevalence of stress-induced orofacial diseases in IT individuals.

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Aim

The aim of the present study was to determine the prevalence of stress in people working in IT sector and to evaluate the correlation between stress and various orofacial conditions such as MPDS, TMDs, dryness of mouth, bruxism, aphthous ulcer, and BMS.

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MATERIALS AND METHODS

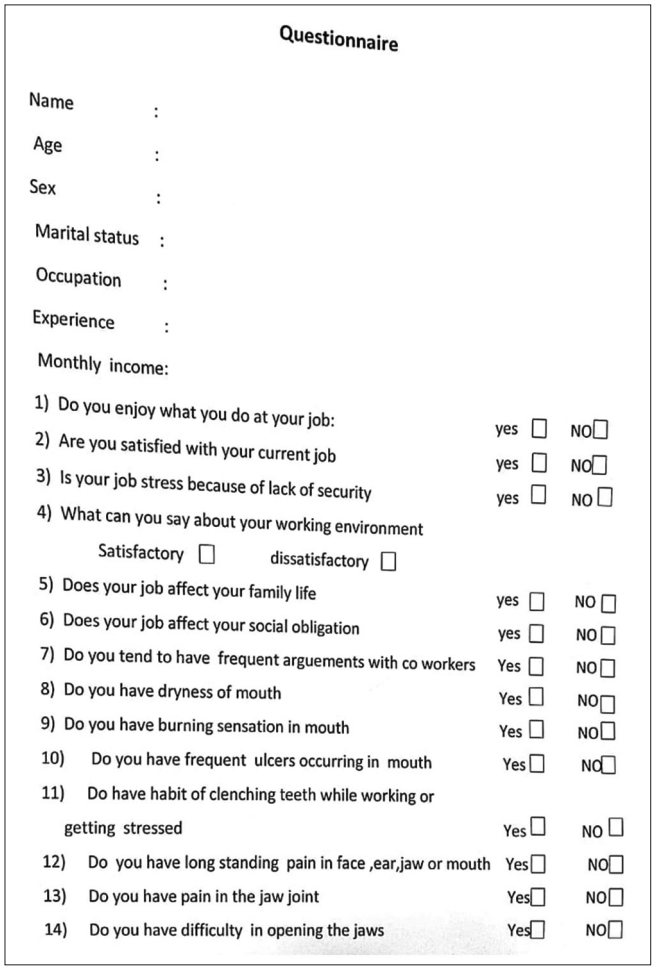
A cross-sectional study was carried out among 109 IT professionals working in a private firm. Clearance was obtained from the Institutional Ethical Committee and concerned authorities. A questionnaire was prepared based on perceived stress scale[7] to assess the prevalence of stress. The questionnaire totally had 14 questions [Figure 1] apart from demographic data, the first seven questions assessed stress and remaining seven assessed the prevalence of symptoms of various orofacial disorders. The study was performed by history taking and clinical examination, informed consent was taken. The data collected were statistically evaluated to determine the prevalence of stress-related orofacial diseases in IT professionals.

Inclusion Criteria

- Individuals of age 20 years–40 years were included in this study.

Exclusion Criteria

- People with systemic illness are excluded from this study
- Persons working in IT company but who are not IT personals such as stenographers, security guards, and housekeeping staffs were not included in this study.



Questionnaire

Name :

Age :

Sex :

Marital status :

Occupation :

Experience :

Monthly income:

1) Do you enjoy what you do at your job: yes ☐ NO☐
2) Are you satisfied with your current job yes ☐ NO☐
3) Is your job stress because of lack of security yes ☐ NO ☐
4) What can you say about your working environment
Satisfactory ☐ dissatisfactory ☐
5) Does your job affect your family life yes ☐ NO ☐
6) Does your job affect your social obligation yes ☐ NO☐
7) Do you tend to have frequent arguements with co workers Yes ☐ NO☐
8) Do you have dryness of mouth Yes ☐ NO☐
9) Do you have burning sensation in mouth Yes ☐ NO☐
10) Do you have frequent ulcers occurring in mouth Yes☐ NO☐
11) Do have habit of clenching teeth while working or getting stressed Yes☐ NO ☐
12) Do you have long standing pain in face ,ear,jaw or mouth Yes☐ NO☐
13) Do you have pain in the jaw joint Yes☐ NO☐
14) Do you have difficulty in opening the jaws Yes☐ NO☐

Figure 1: Questionnaire

RESULTS

The study population comprised 109 IT professionals, among which 88 (81%) were male and 21 (19%) were female. The marital status was 43 (39.5%) were married and 66 (60.5%) were single. The participants had a wide array of work experience, with 28 (26%) having less than a year, 38 (35%) <5 years, and 43 (39%) having more than 5 years [Figure 2].

The first four questions in the questionnaire were directly related to job and job environment, out of which 96% of participants gave positive response to three questions relating to satisfaction and working environment and only 4% gave negative responses. However, to the third question pertaining to job stress due to lack of job security, 94.5% gave negative responses and only 5.5% gave positive responses [Table 1].

Table 1: Responses got from Questionnaire

Questions	Positive response to questions (%)	Negative response to questions (%)
Do you enjoy what you do in your job?	97.2	2.8
Are you satisfied with your current job?	95.4	4.6
Is your job stress due to lack of security?	5.5	94.5
What can you say about your working environment?	95.4	4.6
Do your job affect your family?	13.8	86.2
Does your job affect your social obligation?	17.4	82.6
Do you tend to have frequent arguments with co-workers?	17.4	82.6
Do you have dryness of mouth?	22.9	77.1
Do you have burning sensation in mouth?	9.2	90.8
Do you have frequent ulcers occurring in mouth?	22.9	77.1
Do you have habit of clenching teeth while working or getting stressed?	11	89
Do you have long standing pain in face, ear, jaw or mouth?	5.5	94.5
Do you have pain in jaw joint?	8.3	91.7
Do you have difficulty in opening the jaws?	3.7	96.3

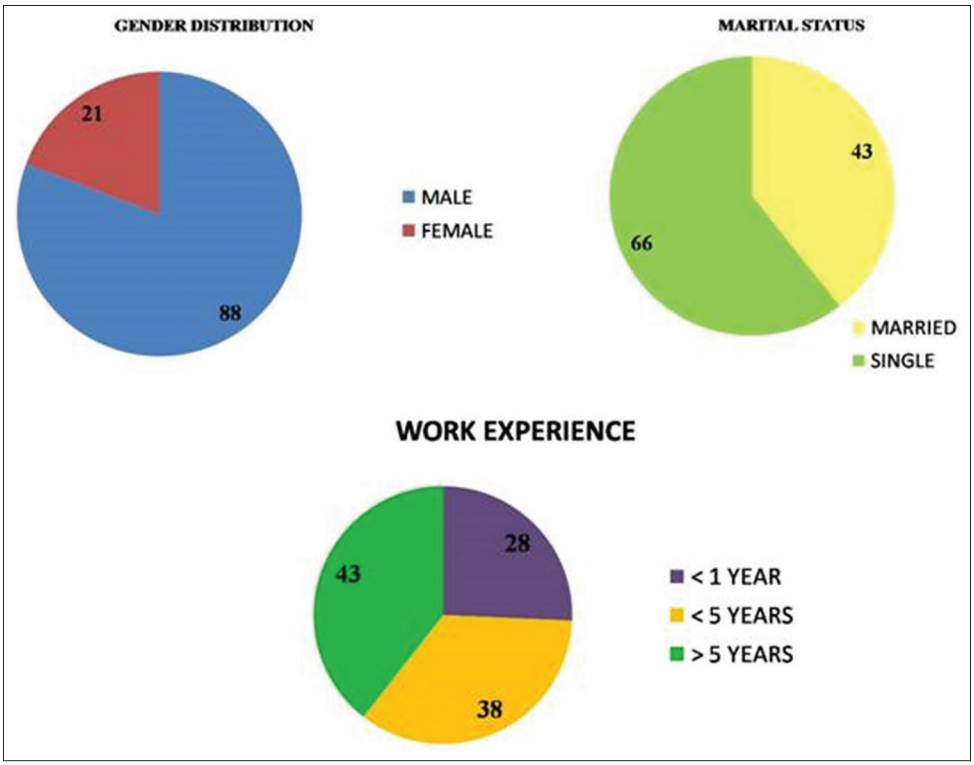


Figure 2: Distribution of gender, marital status and work experience of IT professionals screened in this study

The following next three questions were directed to evaluate the effect of the job on their personal life and positive responses were given by around 16.2% of the participants and 83.8% of participants gave negative responses [Table 1].

The final seven questions in the questionnaire focused on the presence of various symptoms of stress-induced orofacial disorders. Only 22.9% of the participants had mouth dryness, whereas 9.2% had burning sensation in their oral cavity, 22.9% reported frequent occurrence of ulcers in their mouth, 11% had the teeth clenching habit while working or stressed, 5.5% had chronic pain in the orofacial region, 8.3% had pain in their jaw joints, and 3.7% had difficulty in mouth opening [Table 1].

There was no statistically significant difference in the prevalence of oral manifestation based on gender or marital status but there was a statistically significant difference between married and unmarried persons in the response offered to questions concerning to job security and social obligations.

DISCUSSION [TABLE 2]

Xerostomia

It is the abnormal reduction of salivary flow, causing dryness of mouth and affecting the quality of life.[8] In young adults, it is usually associated with stress, anxiety, depression, alcohol abuse, use of illicit drugs, and nutritional deficiencies.[9] The prevalence of xerostomia was found to be only 3% in normal population[9] whereas it was found to be increased (22.9%) in our study which can be contributed to stress.

Table 2: Stress related oral manifestations found in IT professionals

Oral manifestations	IT professionals (%)	Common population (%)
Xerostomia	22.9	3
Aphthous ulcer	22.9	20
Bruxism	11	8
BMS	9.2	4
TMJ disorder	8.3	10-15
MPDS	5.5	0.8

BMS: Burning mouth syndrome, MPDS: Myofascial pain dysfunction syndrome, TMJ: Temporomandibular joint, IT: Information technology

Recurrent Aphthous Stomatitis (RAS)

RAS is characterized by occurrence of recurring ulcers in oral mucosa in apparently normal individuals and is classified as minor, major, and herpetiform based on appearance. The various predisposing factors are positive family history, nutritional, hematological, immunological abnormalities, local trauma, smoking, and local immune dysfunction.[10] In case of aphthous ulcers, acute stressful conditions had proved to aggravate the incidence of the disease. Stress triggers release of cascade of pro-inflammatory cytokines directed against oral mucosa.[11] RAS is present

approximately in 20% of the general population,[12] whereas in our study, it is found to affect 22.9% of IT professionals suggesting the role of stress in these individuals.

Bruxism

Bruxism is excessive grinding of the teeth that usually occur during sleep causing mild-to-severe attrition of occlusal surfaces. Sleep disturbances and behavioral/psychiatric disorders and distress are common etiological factors for bruxism.[9] This habit is seen only in 8% of the normal population,[9] whereas 11% of IT professionals in our study had the habit of bruxism due to work pressure.

BMS

BMS is burning sensation of apparently healthy oral cavity. The most important etiology of BMS is psychological cause such as depression, anxiety, obsessive compulsive disorder, somatoform disorder, and psychosocial stressor. In a classification proposed by Lamey and Lewis, 55% of BMS is caused due to psychological disorder.[13] Only 4% of the general population had BMS compared to 9.2% in our study population.

MPDS

Laskin psychophysiological theory states that MPDS is primarily a result of emotional rather than occlusal and mechanical factors. This theory states that stress can cause clenching and grinding, which, in turn, can lead to muscle fatigue and finally spasm.[14] Patients with MPDS report psychological symptoms such as frustration, anxiety, depression, and maladaptive behavior such as pain, poor sleep, dietary habits, and clenching. Bruxism is seen when the problem becomes prolonged.[15] The prevalence of MPDS in general population is found to be 0.8%, whereas in our study population, it was 5.5% due to stress and teeth clenching habits.

CONCLUSION

This study evaluated the manifestations of various stress-induced orofacial disorders in IT professionals. A significant percentage of the study population felt that the job affected their personal life although they gave positive feedback for direct questions on job. Xerostomia and RAS were the most common stress-induced oral disorders followed by bruxism, BMS, and TMDs, respectively. These stress-induced oral manifestations were more prevalent in IT professionals than the normal population due to their work nature. Their dental health-care needs may be different from that of others, but a holistic approach must be adopted in delivering dental treatment to address their somatic and psychological problems which may not be apparent on routine examinations.

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Original Article

Comparative Study to Find Out the Role of Nutritional Factors in Hair Growth between Tribal and Semi-Urban Population

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Abstract

Introduction: Hair is an important appendageal structure in the skin and hair growth is influenced by various factors like nutritional, hormonal, psychosocial and genetic factors. All these factors affect hair growth by altering the microenvironment of hair follicle which inturn results in changes in the hair cycle.

Materials and Methods: Our study was aimed to determine the role of nutritional factors such as Zinc, Iron, Calcium and Protein in promoting hair growth and decreasing chronic hair loss in tribal and semiurban population. A set of questionnaire were used to analyse the role of life style, nature of work and stress factors in influencing hair fall. The serum values of zinc, iron, calcium and protein were measured for each individual in both tribal and semiurban population and the mean value of all the four nutritional parameters were calculated separately and the results were analysed.

Results: The mean serum values of zinc, calcium and protein were almost similar in both tribal and urban people except serum ferritin value which was more in tribal people. We compared the role of stress influencing hair cycle in semiurban and tribal groups by analyzing the questionnaire.

Conclusion: The lifestyle without stress, good iron reserve with high ferritin level, usage of natural hair care products and genetic factors could be the reason for healthy hair growth in tribal population. Reduction of stress factors in daily life, adequate sleep and improving nutritional status may help to reduce hair fall in semiurban and urban population.

Key words: Alopecia, Hair cycle, Nutritional factors, Stress

INTRODUCTION

Alopecia is a common problem encountered by many people and diffuse thinning of scalp hair is associated with loss of confidence in some individuals. Although hair is one of the appendages of the skin, it plays a major role in the external appearance of an individual. The factors essential for the normal hair growth are iron, zinc, calcium, niacin, folic acid, biotin, selenium, and many other micronutrients.

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Psychological and physical stress may also lead on to diffuse hair loss in this modern machinery of life. By estimating the levels of certain biochemical analytes and also comparing the lifestyle of tribal and semi-urban people, we could able to find out the cause for hair loss in the study groups and the solution for promoting hair growth in people with hair loss.

Aim

This study aims to determine the role of nutritional factors such as zinc, iron, calcium, and protein in promoting hair growth and decreasing chronic hair loss in tribal and semi-urban population.

Objectives

The objectives of the study were as follows:

1. To estimate the serum levels of zinc, ferritin, calcium, and protein and compare the values in tribal and semi-urban population.

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2. To determine the influence of socioeconomic factors in nutritional status and hair growth cycle in the study population.

MATERIALS AND METHODS

This study was conducted in semi-urban population of a northern district of Tamil Nadu and in the tribal population of a hilly area in Nilgiris of Tamil Nadu state, India.

About 30 tribal people and 30 semi-urban people were taken randomly for this study. The study population were divided into four groups based on their age, namely, 21–25 years (Group A), 26–30 years (Group B), 31–35 years (Group C), and 36–40 years (Group D). People with thyroid disorders, diabetes, anemia, androgenic alopecia, females with polycystic ovarian disease, and people on medication for certain chronic illnesses were excluded from this study.

A standard questionnaire was used to obtain relevant information about the history of hair fall, its severity and duration, usage of hair care products, food habits, nature of work, lifestyle habits such as inadequate sleep, changes in the sleeping pattern, any other chronic disease, and the history of any major illness in the recent past. The results of the questionnaire were analyzed. The serum values of zinc, iron, calcium, and protein were measured for each individual in both tribal and semi-urban population after obtaining written and informed consent from them. The mean value of all the four nutritional parameters was calculated separately in the four groups and the results were analyzed. This study was approved by our Institutional Ethical Committee.

Statistical Analysis

Statistical analysis was done using Stata. Independent sample *t*-test was used to compare the mean value between two groups. $P < 0.05$ was taken as statistically significant.

RESULTS

Among the study population, Group A (21–25 years) comprised 24 individuals belonging to semi-urban (12 individuals) and tribal population (12 individuals), Group B (26–30 years) comprised 16 individuals with eight people from tribal and eight people from semi-urban population, Group C (31–35 years) had 16 individuals in total with eight people from each population. and Group D (36–40 years) had four individuals in total with two people from each population. The answers of the questionnaire obtained from both tribal and semi-urban population were analyzed.

The history of hair fall, its severity, and duration were more in semi-urban people 73% (22 individuals) when compared to tribal population 6.6% (three individuals). The usage of chemical-based hair care products in the form of shampoos, hair oil, and hair serum was more in semi-urban people 83% (25 individuals). The tribal population were mainly using certain seeds and plant products for hair washing and buffalo milk butter for regular application over the scalp hair. The volume of hair is more in tribal population and the hair is also shiny and thick when compared to semi-urban people. The tribal population in our study were vegetarians. Rice, buffalo milk, milk products, roots, and green leafy vegetables were the main food items in their daily life. The quantity of intake of milk, roots, and green leafy vegetables was less in semi-urban population and their staple diet is rice. The main occupation was cattle herding in tribes whereas the semi-urban people were working as daily wages in farms, factories, and small industries. The stress in the working environment was more in semi-urban groups. Some of the people in semi-urban group were doing their work at night (eight individuals). There were no significant illnesses during the study period or in the past in the study groups.

On analyzing the values of micronutrients in Group A [Table 1], Group B [Table 2], and Group C [Table 3], the mean serum values of zinc, calcium, and protein were almost similar in both tribal and urban people except serum ferritin value which was more in tribal people in all three groups. Statistical analysis was not done in Group D because of the small sample size. Even though, there was not much difference in the mean serum values of calcium between the tribal and semi-urban population in Group B, *P* value was statistically significant ($P < 0.02$) for serum calcium estimation.

DISCUSSION

Hair growth in human being is controlled by both intrinsic and extrinsic factors. The stem cells in outer root sheath of hair follicles and the mesenchymal cells in dermal papilla play a major role in the intrinsic control of hair growth cycle. Hormonal factors and micronutrients are the important extrinsic factors responsible for normal hair follicle cycling.

Chronic telogen effluvium is defined as telogen hair shedding lasting for more than 6 months. Chronic telogen effluvium and androgenic alopecia are the common causes of diffuse non-scarring alopecia. Zinc deficiency, iron deficiency anemia, malnutrition, and thyroid disorders are the common accepted causes of chronic hair loss. The exact mechanism by which zinc and iron deficiency inducing hair loss is not known. Some researchers have demonstrated that ferritin is important for the dividing cells in the hair matrix. Hard and Kantor *et al.* suggested the role of iron in diffuse hair loss.[1,2]

Table 1: Group A (21–25 years)

Variables		Mean	Mean difference	t-Statistics	Degrees of freedom	*P* value
Semiurban	Zinc	158.33 µg/dL	4.5	0.44	22	0.6
Tribal	Zinc	153.83 µg/dL				
Semiurban	Ferritin	78.78 ng/ml	−25.75	-0.68	22	0.5
Tribal	Ferritin	104.54 ng/ml				
Semiurban	Calcium	10.14 mg/dL	0.25	1.60	22	0.1
Tribal	Calcium	9.88 mg/dL				
Semiurban	Protein	8.81 g/dL	0.04	0.21	22	0.8
Tribal	Protein	8.77 g/dL				

Table 2: Group B (26–30 years)

Variables		Mean	Mean difference	t-Statistic	Degrees of freedom	*P* value
Semiurban	Zinc	145.75 µg/dL	−3.5	−0.8	14	0.4
Tribal	Zinc	149.25 µg/dL				
Semiurban	Ferritin	68.27 ng/ml	−17.78	−0.31	14	0.7
Tribal	Ferritin	86.06 ng/ml				
Semiurban	Calcium	10.05 mg/dL	0.43	2.44	14	0.02
Tribal	Calcium	9.61 mg/dL				
Semiurban	Protein	8.38 g/dL	−0.07	−0.34	14	0.7
Tribal	Protein	8.46 g/dL				

Table 3: Group C (31–35 Years)

Variables		Mean	Mean difference	t-Statistic	Degrees of freedom	*P* value
Semiurban	Zinc	150 µg/dL	−6.62	−0.88	14	0.3
Tribal	Zinc	156.62 µg/dL				
Semiurban	Ferritin	46.7 ng/ml	−77.93	−1.76	14	0.09
Tribal	Ferritin	124.63 ng/ml				
Semiurban	Calcium	9.75 mg/dL	0.06	0.66	14	0.5
Tribal	Calcium	9.68 mg/dL				
Semiurban	Protein	8.38 g/dL	0.1	0.42	14	0.6
Tribal	Protein	8.28 g/dL				

Zinc is important for immune function, cell division, and barrier function in the skin. Cellular enzyme DNA polymerase is a zinc-dependent enzyme. Zinc deficiency is proved to be associated with alopecia areata and telogen effluvium.[3,4]

The role of protein and amino acids in hair growth is shown in many studies.[5] Amino acids such as L-lysine are important for iron uptake and are also present in the inner hair root and L-cysteine is a major component in hair keratin.[6] Protein malnutrition associated with hair loss and changes in hair texture have clearly been demonstrated in marasmus and kwashiorkor. Calcium concentration in hair is more than the concentration in the serum. Calcium deficiency in postmenopausal period may be one of the reasons for hair loss in menopausal age group females.[7] Supplementing diet with protein, vitamins, and minerals improves hair growth in patients with deficiency of the above-mentioned factors.

Even though stresses of everyday life are attributed to telogen effluvium, evidence for this factor influencing hair loss is less. Stress-induced local and systemic mediators such as catecholamines, prolactin, substance P, corticotrophin-releasing hormone, central hypothalamic stress hormone, and stress associated nerve growth factor may be responsible for hair loss by altering hair cycle.[8,9] In our study, we compared the role of stress influencing hair cycle in semi-urban and tribal groups by analyzing the questionnaire. The time bound work pattern, working at night, and physical and psychological stress associated with various occupation had a role in hair loss in semi-urban population. The traditional hair care methods influenced the hair cycle in tribal groups by lessening the damage to the hair and scalp and lessening the hair loss.

Ferritin plays an important role in hair growth by inducing proliferation of hair matrix cells during anagen stage of hair cycle. Non-vegetarian foods are good sources of iron when compared with vegetarian foods. Moderate iron deficiency has been reported with vegetarian food items. Serum ferritin level indicates the iron reserve and intracellular iron level. Some studies suggested the role of iron in maintaining hair growth while others did not show

any such association.[10,11] In our study, we could able to find out high serum ferritin level in tribal population in all three groups in spite of their vegetarian dietary habits. The values of other dietary factors such as zinc, protein, and calcium did not show much difference between the two comparison groups.

Limitations

The study was done on small population sample size. To generalize the results, it has to be conducted on more number of samples from the research population.

CONCLUSION

The lifestyle without stress, good iron reserve with high ferritin level, usage of natural hair care products, and genetic factors could be the reason for healthy hair growth in tribal population. Reduction of stress factors in life, adequate sleep, and improving nutritional status may help to reduce hair fall in patients and detailed analysis of underlying factors causing hair fall is important for proper counseling and treatment.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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Original Article

Impact of Different Endodontic Sealers on Retentive Strength of Fiber Posts – An *In Vitro* Study

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Abstract

Aim: The aim of the study was to evaluate the effect of two different root canal sealers in relation to the retention of the prefabricated fiber posts.

Materials and Methods: Twenty extracted single-rooted mandibular premolar teeth were prepared and randomly divided into two groups. In Group 1, eugenol-based sealer was used while in Group 2, a resin-based root canal sealer was used. Prefabricated fiber posts were luted into the prepared post-spaces with the same composite resin cement in both the groups. After calculating the pullout forces required for dislodgment of posts post-spaces, the data were recorded and statistically analyzed.

Results: The resin-based root canal sealer group had significantly greater retentive strengths for the posts as compared to eugenol-based sealers group ($P > 0.0001$).

Conclusion: The retentive strength for prefabricated fiber posts luted with resin cement was much more than those luted with eugenol-based sealers. This was attributed to the different chemical composition of the two dealers.

Key words: Endodontic sealer, Prefabricated Fiber Post, Retentive strength

INTRODUCTION

The retentive capacity of the post used for retention of core is critical for the long-term survival of the final restoration.[1] Various factors such as shape, design, length, diameter, type of luting agent used to cement it, the coronal tooth preparation after cementation, and the endodontic obturation sealer have a bearing on the retention of the post.[2-5] In recent times, fiber-reinforced endodontic posts have become more popular as they have better biocompatibility and physical properties.[6] The role of dental cements on post-retention has already been established.[7,8] Endodontic sealers are play an important role in the retention of the post.[9] Sealers based on epoxy resin have good physical properties and adequate biological performance.[9,10] Still, eugenol-based sealers remain the most commonly used root canal sealer.[11] However, eugenol is thought to inhibit composite resin polymerization because of its radical scavenging properties.[12-20] There is little agreement between studies on whether this interaction is clinically relevant.[12,13,14] There is limited information in the literature about the effect of the various types of sealers the bond strength of endodontic posts luted with core build up materials. This *in vitro* study was undertaken to evaluate the influence of two chemically different sealers on the retention of the prefabricated fiber posts.

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MATERIALS AND METHODS

Twenty extracted single-rooted, human permanent mandibular first premolars of approximately the same size having a straight single canal with closed apex radiographically were selected for this study. Teeth were sectioned 1 mm coronal to the midfacial cementoenamel junction using a low-speed diamond saw under copious water

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coolant. After removing the pulpal tissue, working length at 1 mm from the root apex was established. The canals were prepared, cleaned, and shaped with a rotary system according to the manufacturer's instructions following the crown-down technique. One milliliter of sodium hypochlorite (NaOCl; 5.25%) was reintroduced into each root canal after every instrument. Each tooth was irrigated with 2 ml of distilled water after preparation and the teeth were divided into two groups (n = 10). Obturation was done with laterally condensed gutta-percha with either a eugenol-based sealer or a resin-based sealer. After storing the obturated teeth in 100% relative humidity at 37°C for 10 days, gutta-percha was removed and post-spaces were prepared using a no. 5 Peeso Reamer at low speed to a depth of 9 mm such that 5 mm of the gutta-percha always remained in each tooth radiographically. Standardized post-spaces (1.5 mm diameter and 9 mm long) were prepared using a no. 6 ParaPost Drill at low speed and each post-space was irrigated with 2 ml of distilled water. Parallel sided, size 6 prefabricated fiber posts were checked for a passive fit in their respective canals before luting. Carbide burs were used to notch the roots. After canal irrigation with 5.25% NaOCl and then distilled water, the canals were dried with absorbent paper points. The posts were then luted with the selected composite resin cement. After acid etching of the root canal walls 37% phosphoric acid for 15 s, followed by thorough water rinsing and removal of excess surface moisture with paper points, corresponding bonding material was applied to the canal using a microbrush for 10 s, and excess adhesive was removed using paper points. The luting cement material was applied into the prepared post-space in the root canal and on each fiber post. Then, the fiber post was inserted into the canal using slight pressure. Excess cement was removed and then light polymerized for 40 s was carried out.

The specimens were stored in 100% relative humidity at 37°C for 24 h before testing. After securing each tooth in the universal testing machine, pneumatic grips that grasped the post head at its long axis were used to determine the force required to dislodge the post. A constant loading rate of 0.5 mm/min was applied until cement failure was achieved the point of bond failure was recorded in Newtons when the post - segment extruded from the specimen. The data were statistically analyzed using statistic package – SPSS version 23.

RESULTS

The means and standard deviations (SD) of the results are summarized in Table 1. The posts obturated with gutta-percha and resin bonder sealer (240.8 N) required higher force to dislodge the post than the group of eugenol-based sealer (94.2 N).

DISCUSSION

Better retention, less microleakage, and a higher resistance to tooth fracture can be achieved the cementation of fiber posts with an adhesive resin cement.[14,20] The present study assessed the influence of eugenol- and resin-based root canal sealers on the retention of fiber posts composite resin designed for core buildup restorations of teeth and luting of fiber posts. Teeth with relatively equal dimensions and canal configuration were prepared for standardized post-space using a large ParaPost Drill (1.5 mm in diameter) and same size posts were inserted. Retention of cemented fiber posts into prepared root canals relies on the interface resistance.[7,8] As per studies, resin-based root canal sealers are more effective in sealing root canals than the zinc oxide-eugenol-based sealers as they do not shrink during setting and adhere to dentin, ensuring a permanent seal.[9] However, eugenol-based sealer used for obturation cause a significant reduction in the adhesive effectiveness or modify the polymerized resin's surface,[16] resulting in decreased bond strength of the resin cement. Some studies demonstrated that eugenol could inhibit the polymerization process.[5,16,17] Our study showed that higher mean bond strength values were needed for vertical dislodgment of the fiber posts luted after the resin sealer had previously been used as part of the root canal obturation compared with those canals eugenol-based sealers had previously been used as part of the root canal obturation. Carvalho *et al.*[18] observed that a temporary sealing cement containing eugenol reduced the bond strength of adhesive systems. However, Hagge *et al.*[14] concluded that the retention of posts cemented with resin cements was not significantly affected by the chemical formulation of endodontic sealers. Schwartz *et al.*[4] reported no changes in the bond strength of posts luted with Panavia cement in canals filled with eugenol and previously treated with acid while Hagge *et al.*[5] reported significant differences in groups treated with eugenol. The use of 37% phosphoric acid as the etching reportedly eliminates the contaminated smear layer and results in demineralization of dentin. Studies have demonstrated that etch-and-rinse systems allow more effective bonding to the eugenol contaminated dentin surfaces, compared to the self-etch approach, due to the non-removal of the sealer's debris entrapped within the smear layer. In our study, no special canal treatment was performed before post-cementation which might be the cause of reduced bond strength for the eugenol group. Tjan and Nemetz[3] found that the presence of eugenol within the root canal resulted in significant loss of retention and that residual eugenol in the root canal could be removed without any effect on retention of the post by irrigating the canal with ethyl alcohol (ethanol) or etching with 37% phosphoric acid. Push-out tests lead to a shear stress, which is comparable to the stress under clinical conditions at the interface between dentin and luting cement, as well as between the post and luting cement.[21]

Table 1: Mean and SD in forces applied

Group	*n*	1	2	3	4	5	6	7	8	9	10	Mean±SD
Group 1	Push-out force *(n)*	67.1	59.7	110.6	122.7	130.6	86.4	87.6	94.8	99.5	83.4	94.2±36.4
Group 2	Push-out force *(n)*	165.4	246.3	325.4	253.4	190.6	186.7	204.8	212.9	310.8	301.4	240.8±84.6

SD: Standard deviation

Goracci *et al.*[22] noticed that the push-out test was a more reliable technique in the determination of bond strengths between fiber posts and post-space dentin due to the high number of premature failures occurring during specimen preparation. Non-uniform stress distribution is a disadvantage of the push-out test when it is performed on thick root sections.[23] Therefore, this testing model was preferred for the present study. The pullout test has been used by several studies to determine the values required to remove the post from the root canal.[3,23] In the current study, although teeth were selected with similar size and canal shapes and received standardized post preparations, a wide range of strengths and relatively large SD was obtained. However, comparison of the values reported in some earlier studies dealing with the retention of root canal posts that used extracted human teeth also revealed wide ranges in their measurements.[2,23] One possible explanation is that the size and shape of the root canals differ and/or the texture and properties of the inner surfaces of the root canals differ among the teeth used. In addition, the diameter of the individual root canal preparation could affect how much of the canal was still covered with some eugenol-containing sealer. Our study indicates that type of root canal sealer affected the retention of a fiber post-cemented with resin cement. However, controlled prospective long-term clinical trials with a larger sample and *in vivo* studies are required to definitely comment on the results.

CONCLUSION

Within the limitations of this study, it was concluded that pre-fabricated fiber posts luted with composite resin in canals previously obturated with gutta-percha and eugenol based had significantly reduced bond strength compared to fiber posts luted with the resin-based sealers cement.

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Original Article

Ultrasound-Guided Percutaneous Transhepatic Biliary Drainage Outcome at Tertiary Care Centre of North India

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Abstract

Aims: The aim of this study is to know the feasibility and outcome of ultrasound-guided percutaneous transhepatic biliary drainage (PTBD) at tertiary care center of North India.

Materials and Methods: This is a prospective observational study conducted on patients affected by biliary tree obstruction with jaundice referred to department of radiodiagnosis for management of obstructive jaundice. Procedure (PTBD) has been performed by single step puncturing the biliary system under ultrasound guidance.

Results: 110 patients affected by biliary tree obstruction were included in this study. The biliary obstruction was malignant in 102 and benign in eight cases. Technical success considered as positioning of a drainage tube into the biliary tree by only ultrasound guidance and single step puncture was 100%.

Conclusions: Only ultrasound guidance to access the biliary tree and single step puncture of bile duct for PTBD was a safe, low cost, and effective technique for the management of obstructive biliary pathology.

Key words: Percutaneous transhepatic biliary drainage, Obstructive biliary pathology, Ultrasound, Jaundice, Complications

INTRODUCTION

Obstructive jaundice can be of benign and malignant etiologies. Of the malignant cause's carcinoma gall bladder, cholangiocarcinoma, pancreatic adenocarcinoma, metastasis, and lymph nodal compression of common bile duct (CBD) constitute the majority of cases. Most of the cases of malignant obstructive jaundice are already advanced and unresectable by the time they are diagnosed, hence carry dismal prognosis with palliation being the only option left. Obstruction needs to be drained even in such cases for alleviation of pain, cholangitis, and pruritus or in certain cases to initiate chemo or intrabiliary brachytherapy. Over the years, palliative care has evolved with the introduction of newer methods and improvisation of existing techniques. Recent palliative measures not only prolong longevity but also improve the quality of life, hence increasing the acceptance to such procedures.

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Methods of Biliary Drainage Include

a. Surgical bypass
b. Minimally invasive procedures
   I. Endoscopic retrograde cholangiopancreatography (ERCP)
   II. Percutaneous transhepatic biliary drainage (PTBD).

Both ERCP and PTBD are well-established and effective means of biliary drainage for palliation in unresectable cases. With increased technical success rate and expertise in these

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minimally invasive procedure, recent time has witnessed an exemplary surge in the demand for such procedure over surgical bypass. Selecting an option over other, however, is a multidisciplinary opinion, which not only involves expertise of operator and the site of obstruction but also takes into consideration other factors such as expected survival and the level of post-procedural care provided to the patients. ERCP is usually performed in cases of distal CBD block (beyond hilum), where primary and secondary confluence are patent and only one stent is required, which proximal end is placed in common hepatic duct or intrahepatic bile duct and distal end in the duodenum or beyond the stricture. ERCP is not preferred in patients with loss of primary or secondary hepatic confluences due to need of multiple stent and technical difficulty. PTBD is preferred in proximal biliary obstruction with loss of primary or secondary hepatic confluence because multiple segments can be drained with multiple external/internal bile drainage catheter. PTBD is also indicated in post roux-y anastomosis patients with biliary obstruction because endoscopic procedure is technically not feasible. In patients with severe cholangitis and other comorbidities where patient is not fit for pre procedure anesthesia PTBD can be done which may be lifesaving procedure. Only ultrasound-guided PTBD can be done at low infrastructure center where fluoroscopy X-ray machine is not available or endoscopic biliary stenting facility not available or failed endoscopic biliary stenting.

MATERIALS AND METHODS

The prospective study was conducted on 110 patients from October 2020 to April 2021 with obstructive jaundice and referred from department of Radiation Oncology, Medical Oncology, Gastro-medicine, Gastro-surgery, General Medicine, and General surgery for PTBD and palliative relief of jaundice.

The computed tomography (CT) and/or magnetic resonance (MR) examinations in details, evaluation of stenosis/occlusion level and interposing anatomical limiting factors (bowels and ascites) were evaluated for the best access to biliary system in terms of lesions and anatomy. Patients consuming clopidogrel and aspirin were strictly recommended to withhold for 5 days before procedure. Wide-spectrum antibiotics were administered prophylactically in accordance with specific-site protocols.

Inclusion Criteria

All patients of obstructive jaundice referred for biliary drainage.

(Patients of obstructive jaundice in which either endoscopic biliary drainage procedure is failed or not done due to time constrain, cost constrain or any other hindrance which precludes endoscopic drainage and patients were not fit for surgical drainage procedures).

Exclusion Criteria

Un-correctable bleeding diathesis, INR >1.5, Thrombocytes count <50,000 were excluded from the study.

Equipments

Samsung HD 60 color Doppler machine was used as USG guidance for biliary duct puncture and liver tissue visualization. Vygone/Chiba 18 gauze puncture needle, Ultra stiff guidewire (0–035" × 80/145 cm,), 10 f fascial dilator and malecot drainage catheter along with connector, urine bag, and suture material.

Pre-procedural patient's Preparation

1. Adequate antibiotic coverage (preferably intravenous) was instituted before and after the procedure, as manipulations in obstructed system carry the risk of cholangitis and sepsis.
2. Patient was preferably fasting or on clear liquid diets for at least 4 h before the procedure.
3. Written informed consent was obtained from all patients before the procedure.

Technique

Routinely PTBD procedure is performed under ultrasound and fluoroscopic combined method but in our study, it was done by only ultrasound guidance. Before the initiation of procedure, three-dimensional cross-sectional imaging, that is, CT or MR imaging of the patient needs to be reviewed to determine the following:

Site of obstruction

High or low: In proximal obstruction, primary biliary confluence may be blocked with variable involvement of secondary confluence. Low obstruction occurs beyond the level of primary biliary confluence (i.e., distal to cystic duct insertion). PTBD and ERCP are the preferred drainage procedures in high and low biliary obstructions, respectively.

Selection of appropriate target duct in PTBD

Right versus left PTBD: In case of involvement of biliary confluence, selected duct should drain at least one-sixth of the liver parenchyma. However, in distal obstruction, since primary biliary confluence is patent, a single puncture with placement of single drainage catheter usually suffices. There should be no atrophy or portal vein involvement of the targeted lobe, as even after biliary drainage liver function would not improve due to the lack of functioning hepatic parenchyma. The procedure can be performed either through right

(subcostal or intercostal) or left ductal (subxiphoid) approach. Selection of appropriate side duct (right or left) is a personal preference, although there are certain advantages and disadvantages of both. Reviewing ultrasound before biliary puncture is invaluable for assessing the suitability of puncture as well as any contraindication to the procedure. In case of suitably dilated biliary radicle dilatation, with an 18G puncture needle, under ultrasound guidance, appropriate segmental duct is punctured. In portal triad, biliary radicle is flanked by the branch of hepatic artery and portal vein, caliber of which increases toward the hepatic hilum. Due to this, site of puncture should be as peripheral as possible as more central puncture incurs more risk of major vascular injury. When the outflow of bile starts, a 0.035-inchultra-stiff guide wire is passed through the puncture needle, punctured needle is withdrawn over the guidewire, tract is dilated under the vision of ultrasound to avoid vascular injury and hepatic parenchymal injury, position of dilater is assessed by ultrasound, after adequate dilation 10f malecot was placed over the stiff guidewire. Position of malecot catheter is again assessed by ultrasound. If catheter tip was suitable in position and adequate drainage of bile noted, after confirmation of satisfactory position of catheter tip the catheter is fixed with suture. In our study, terumo guide wire was not used because it is not visible under ultrasound. Sometime free flow of bile not seen through puncturing needle although needle tip is inside the biliary system due to thick pus content in the biliary system, in that cases pus is aspirated with help of 20 ml syringe. More flexible or PTFE guidewire were used in some cases but more incidence of wire displacement during dilatation or catheter displacement over the guidewire noted with more softer the guidewire. Merits of left-sided PTBD are relatively easy to perform, better patient's compliance with less catheter pulled out rate, preferred in ascites due to less peri catheter leakage of ascitic fluid. Merits of right sided PTBD-more segment of liver cover. Right lobe catheter placement is more difficult than left lobe and in right lobe segment vii and viii are more difficult than segment v and vi. Right lobe difficulty is due to intercostal approach, angulated tract of biliary access, pleural and lung base interference in complete visualization of needle tract and dilatation of diaphragm in the tract. Segment iii puncture is straight and more superficial access of biliary system, subcostal location and easier tract dilatation make it relatively easier as compared with other segments or right lobe.

Complications of PTBD

With increased expertise and better instrumentation, observed technical success rate of PTBD is approx. 95–100% with fewer complications observed nowadays. These complications can be further reduced by keeping the biliary manipulation to minimum and good antibiotic coverage.

Minor complications - pain, peri catheter leak, catheter dislodgment, or blockage.

Major complications - Cholangitis, sepsis, Biliary peritonitis, Hemorrhage, Pancreatitis, Pleural effusion, and pneumothorax (inadvertent pleural puncture).

Catheter dislodgement is more common in external than internal drainage catheters due to better anchorage in the latter. It can be managed by repositioning or probing by a guide wire through previous catheter's tract or fresh tract. Peri catheter leak (bile leak along catheter) is a frequently observed complication. It can be due to side holes catheter lying outside the biliary system, catheter kink/block, or ascites. Management in such cases consists of repositioning or upgradation depending on the findings of check cholangiogram or by percutaneous peritoneal drain catheter placement. Catheter blockage is either due to kinking of tip/shaft of catheter or due to luminal narrowing with debris/biliary sludge. Cholangitis and biliary sepsis are inevitable complications which can occur despite adequate antibiotic coverage. Risk of cholangitis is very less as compared with fluoroscopy-guided PTBD in which if positive contrast media is injected into biliary system and drainage of bile is not adequate or incomplete drainage, in that condition severe cholangitis may develop which may be fatal. Although exact etiology is unknown, it can occur due to multitude of factors such as retrograde reflux of intestinal flora during the procedure, *ex vitro* infection tracking along the drainage catheter, or may be of hematogenous origin. Prophylactically, broad spectrum intravenous antibiotics covering Gram-negative bacteria were given to prevent any risk of cholangitis. In addition, during the procedure, manipulations should be kept to minimum coupled with no use of iodinated contrast during ultrasound-guided PTBD procedures. No any case of hemorrhage or pancreatitis developed in our study.

PTBD performed from October 2020 to April 2021 have been included in this analysis. Data have been collected prospectively in Microsoft excel data sheet. Data analysis is done with Microsoft excel software. Collected demographic data included: Age, gender, bilirubin value, dilation of the biliary tree, anatomical level of the biliary stenosis/occlusion, and etiology of the lesions. Procedural evaluated factors were as follows: Technical and clinical successes, right-/left-sided access, and number of liver punctures (intended as passage of the needle through the hepatic capsule) to gain the biliary tree and complication rates.

OBSERVATION AND DISCUSSION

A total of 110 cases of PTBD were done between October 2020 and March 2021. All patients were drained with external biliary drainage with 10 f malecot catheter and catheter is sutured with mersilk 1-0 or 2-0 suture. No fluoroscopy or iodine contrast media is used in all the procedures. No any pancreatitis, hemorrhage or procedure related mortality noted during procedure or after post-procedure follow-up. Etiology of obstructive biliary pathology in our study was carcinoma gall bladder in 90 cases, seven cases of cholangiocarcinoma, nine cases periampullary carcinoma and two cases of benign biliary stricture (post cholecystectomy), and two cases of CBD calculus with cholangitis and septicemia. Gall bladder carcinoma cases were mostly in the fourth and fifth decades but case as young as 20-year-old male and as older as 78 years female were also noted. Cholangiocarcinoma cases show age incidence in 4 and 5 decades. Periampullary carcinomas age incidence is in 5 and 6 decades. Majority of gall bladder carcinoma show hilar infiltration with lack of formation of primary confluence and endoscopic drainage procedure was failed, out of 90 gall bladder carcinoma 18 have patent primary confluence, 60 have lost primary confluence, and 22 have lost primary as well as secondary confluence. Out of total 110 cases 104 cases are approached through left lobe (segment iii) and 60 cases by both left and right lobe and 6 cases are through only right lobe. In right lobe segment v approach is more common. Left lobe approach is easier approach because subcostal location, shorter distance of puncturing segment iii ducts, no intervening pleura for obscuration of segment iii duct visualization and easier tract dilatation. In 22 of the cases show loss of primary as well as secondary confluence, in these cases 2 or 3 ductal system with good liver volume were drained because draining all obstructed segments (4–8 no.) is cumbersome and increased morbidity. Most of the periampullary carcinoma cases are drained by single left lobar drainage. Four cases of periampullary carcinoma with mild dilated biliary system were drained by transhepatic cholecystostomy when patients were irritable and incomparable. Transhepatic cholecystostomy was an alternative and rapid procedure to drain the obstructed biliary system with patent common hepatic duct and primary hepatic confluence. Cholecystostomy may be also done in distal CBD stricture or mass in morbid and irritable patients. Cholecystostomy in empyema gall bladder decrease morbidity associated with primary cholecystectomy. In our study, most of the cases show moderate or grossly dilated biliary system. Biliary duct punctured with 18 gauze vygon needle is not too difficult. Introduction of guidewire in the biliary duct punctured needle were also not difficult but guidewire advancement in the ductal system up to obstruction site is difficult in ten cases due to tortuous course of ducts. Tract dilatation were easy with ultra-stiff guide wire with little chances of guidewires displacement; however, it was more difficult with flexible or PTFE guidewire with more incidence of guidewire dislocation especially in stiff liver. In two cases, there was puncture of left hepatic artery branch however bleeding is stopped within few minutes and no e/o pseudoaneurysm or fistula formation. Six cases show puncture of portal vein branches but no e/o excessive blood loss or persistent hemobilia. None of the cases show procedure induced septicemia. Peri catheter leak or bilioma formation noted in eight cases and mostly due to partial pulled out of catheter, these cases were managed with reinsertion of PTBD catheter along with drainage of peritoneal collection with 12 f pigtail catheter drainage.

From the first description of fluoro-guided PTBD in 1962,[1] several techniques have been proposed without clear standardization. According to the literature data, procedural related complications rates are substantial even if heterogeneous.[2] Especially for biliary ducts puncture, multiple fluoroscopic and US-guided approaches have been reported. Even if US-guided PTBD has been described as an effective and safe method since time,[3] only limited data are available in literature.[2,4-7] Actually, both fluoro-guided and US-guided techniques are adopted in the clinical practice and the choice depends mainly on operator preference; some interventionalists prefer US guidance only for technically challenging cases and left-sided puncture, to avoid gastrointestinal structures.[8,9] In moderate to grossly dilated IHBR USG guided biliary puncture and canulation are not difficult [Figure 1], and after catheterization position of catheter can be demonstrable in USG as parallel echogenic lines [Figure 2]. Moreover, US guidance may allow to avoid the accidental puncture of liver lesions in case of bilobar intrahepatic metastatic disease. The SIR guidelines for PTBD recommended a procedural threshold for major complications of 10% and a biliary tree cannulation success rates of 95% and 70% in case of dilated and non-dilated ducts, respectively.[10] In this series, the complication rate was 5% with low grades (all between Grade I and Grade III of CIRSE classification complications system), while the cannulation of the biliary tree was feasible in 100%; these data, compared to literature-reported outcomes of fluoro-guided PTBD,[1,5,8,10-14,25] seems to encourage US guidance. This is in accordance with two previous published studies in 1995[6] and 2004[15] and a recent study of 2017[14] which described an advantageous overall interventional complications rate for US-guided PTBD over fluoro-guidance.

Portal branches run ventrally to the biliary tree and may be intercepted along the PTBD track. Compared to literature

data,[16] the low rate of cholangitis-related fever may be due to the high percentage of internal drainage positioned. An alternative to PTBD may be endoscopic ultrasound-guided biliary drainage: This novel procedure involves accessing the biliary tree from within the lumen of the gastrointestinal system using echo endoscopy and fluoroscopy, creating a fistulous tract and deploying a stent in a single-step procedure, obviating the need for external drain.[17] Compared to PTBD, main advantages of this procedure are a better nutrition absorption avoiding electrolyte loss and preventing the stress of external drain;[18] however, the procedure is technically complex requiring specialized training and a steep learning curve to avoid complications.

A meta-analysis study in 2017 show that PTBD has a lower rate of complications than EBD as the initial procedure to perform preoperative biliary drainage in resectable pancreatic head carcinoma and it is associated with less conversion and lower rates of pancreatitis and cholangitis.[19]

Gupta study in 2020 show that PTBD can be effectively and safely performed even in situations deemed to predispose patients to increased risk for adverse events.[20]

A systematic review and network meta-analysis in 2018 show that no pre-operative biliary drainage may be the best management of pre-operative jaundice in patients with resectable pancreatic head carcinoma before pancreaticoduodenectomy.[21]

PTBD was associated with similar overall complication rates in patients with dilated versus non-dilated bile ducts in a study in 2021.[22]

Major drawback of external PTBD catheter drainage is accidental/inadvertently pull out of the catheter which time duration is extends from 1 days to 90 days with mean duration is of 34 days. However, the advantage of external biliary drainage is replacement of external drainage catheter with minimal effort and very much cost effective Few of the failed endoscopic drainage cases show concurrent and large cholangiolar abscesses in which concurrent percutaneous drain was placed. Two cases of endoscopically placed metallic stent with non-decreasing trend of serum bilirubin were also placed external ptbd catheter after which downtrends of serum bilirubin noted. Four cases of gall bladder mass where retrospective stenting not possible by endoscopically were antegrade metallic stenting done after external biliary drainage. Accidental/inadvertently catheter pulled out was common with prolonged percutaneous biliary drainage, though it was observed that when catheter pulled out occur after 2 weeks of its placement then repeat introduction of the catheter over the guidewire through the previous tract is more feasible. Another advantage of percutaneous drainage is that whenever catheter get blocked it is much easier to flush the catheter or exchange the catheter over the guidewire as contrast with endoscopic catheter exchange which is more costly, require anesthesia and time taking. Cost effectiveness is another advantage of PTBD and external drainage, consumables cost is hardly 60 dollars. Further cost cutting were done by using the guidewire and dilater sterilized by glutaraldehyde (cidex) solution. Almost all cases with obstructive jaundice subsided completely or decreased markedly with PTBD procedures. In cases with blockage of primary as well as secondary hepatic duct confluence reduction in serum bilirubin was gradual or even complete reduction was not possible. All the septicemia cases with all segmental drainage recovered with PTBD procedures. All patients with intact primary confluence relief from obstructive jaundice and patient with intact secondary confluence get definite improvement in their bilirubin level by doing bilobar PTBD. Patients with lost primary as well as secondary confluence have poor reduction in bilirubin level even after bilobar PTBD. Five cases undergo for antegrade metallic stenting after PTBD procedure. ERCP with placement of plastic stent (polyethylene endoprosthesis) is another effective method of biliary drainage. It is the preferred procedure in cases of obstruction beyond the level of hilum, that is, if the primary biliary confluence is patent as adequate biliary drainage can be accomplished by the placement of single stent. Furthermore, in such cases of low biliary obstruction, ERCP is preferred, as it is a safer procedure in comparison to PTBD.

Endoscopic (ERCP) Versus Percutaneous Drainage (PTBD) - In inoperable malignancies causing biliary obstruction, ERCP with placement of plastic endoprosthesis or PTBD with metallic stenting remains the minimally invasive options. However, choosing a procedure over other depends on the level of obstruction, operator's expertise, and the level of post-procedural care provided to the patient.

Distal biliary obstruction ERCP is unambiguously the preferred procedure worldwide as it is a comparably safer procedure with relatively fewer contraindications. Unlike PTBD, burden of percutaneous drainage catheter and bag is obviated which further compounds the psychological burden of terminally ill patients. In the current scenario, in cases of distal CBD obstruction, ERCP is the preferred technique unless contraindicated, for which PTBD is done. Proximal biliary obstruction opinion is divided regarding the choice of technique with nearly comparable results regarding overall patient's survival and procedure related complication. However, at many institutions, PTBD is preferred in hilar isolation as ultrasound-guided puncture of appropriate segmental biliary radicle can be done, thus maximizing the drainage of functioning liver parenchyma. Further, malignant

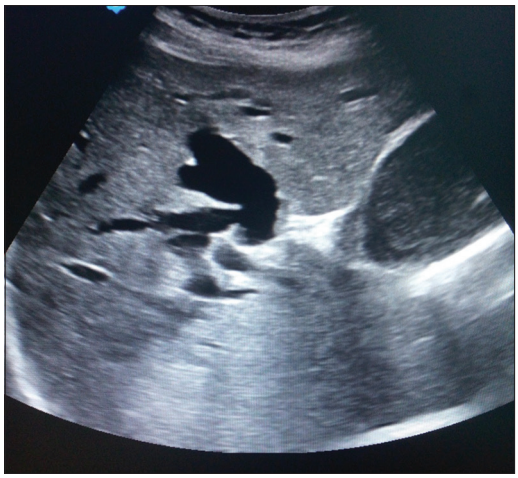

Figure 1: Grossly dilated biliary system made biliary puncture not difficult

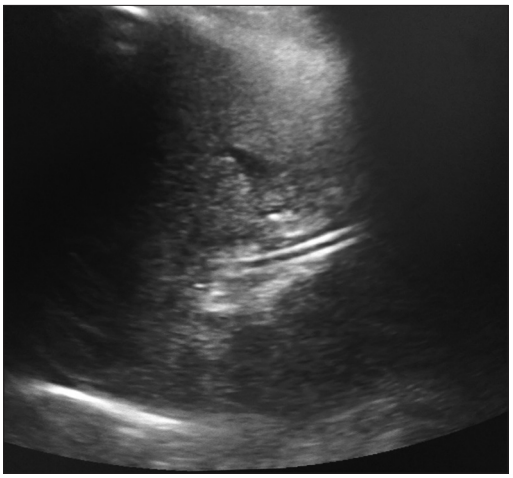

Figure 2: External biliary catheter visualization by ultrasound as parallel echogenic line

stricture is better negotiated in PTBD and the risk of inadvertent contrast instillation into isolated biliary segment is lesser as compared to ERCP. Various studies comparing PTBD and ERCP in distal CBD block have reported that both these procedures have nearly equivalent technical success rate with comparable incidences of procedure-related complications and mortality. The American College of Radiology (ACR) has recently proposed an evidence-based algorithmic approach for radiological management of malignant biliary obstruction. In the proposed criteria, various management options are rated based on their appropriateness for particular site of obstruction.

In general, as per the ACR recommendations of the various management options, PTBD is preferred for hilar block whereas ERCP with stenting in distal block. Endoscopic verses percutaneous biliary drainage.

- Proximal biliary obstruction (hilar involvement) - PTBD or ERCP.
- Distal (beyond hilum) obstruction: ERCP preferred.
- Inoperable cases with short life expectancy (6–12 months) - Metallic biliary stenting.

CONCLUSION

Single step and ultrasound-guided percutaneous biliary drainage (PTBD) is feasible, rapid, and effective method for relief of obstructive jaundice as well as associated septicemia. Fluoroscopy machine as well as contrast is not required for this procedure so it is cost effective and feasible at low infrastructure set up where ultrasound machine and trained radiologist are available. PTBD is very effective in decreasing the morbidity and mortality of not only neoplastic lesion but also benign lesions such as benign biliary stricture, choledocholithiasis with septicemia, and cholangitis due to other benign lesions.

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Original Article

Perspective Study of Elevated First Trimester C-reactive Protein as Predictor of Gestational Diabetes in South Karnataka Population: A Retrospective Study

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Abstract

Background: The C-reactive protein (CRP) derived from the liver is sensitive and systemic biomarker of inflammation and has been associated with increased risk of developing diabetes mellitus in pregnancy.

Materials and Methods: Ninety-two pregnant women having gestational diabetes of the first trimester and same number of normal pregnant women of controlled group were studied. Blood sugar (fasting and postprandial) and CRP, body mass index (BMI), age, and period of gestation/weeks of gestation were compared in both groups.

Results: The BMI of gestational diabetes group was 26.05 (SD ± 3.40) and 22.80 (SD ± 2.14), *t*-test was 7.75, and *P*-value was highly significant. Laboratory findings, blood glucose (fasting and post-meal), and CRP (mg/l) were higher in gestation diabetes and *P*-values were highly significant ($P < 0.00$). CRP values were more or less constant in blood glucose (fasting and post-meal) hence *P*-value was insignificant ($P > 0.98$).

Conclusion: CRP values were higher in gestational diabetes due to inflammation and oxidative stress. These finding are important for obstetrics and gynecologist to treat such patient efficiently to prevent morbidity and mortality of fetus and mother too.

Key words: Andhra Pradesh, Blood glucose, C-reactive protein gestational, Type-II diabetes mellitus

INTRODUCTION

C-reactive protein (CRP) is synthesized by the liver and has been shown to be a sensitive and systemic biomarker of inflammation.[1] It is reported that a number of case–control studies have reported that CRP is associated with increased risk of developing type-II diabetes mellitus (type-II DM).[2] The positive relation in cross-sectional studies or case–control studies could be due to CRP being a consequence of hyperglycemia. Therefore, a prospective study is carried out to ascertain the elevation of to ascertain onset of hyperglycemia in the development of type-2 DM.[3] Hence, attempt is made to study in the first trimester pregnant women; the level of CRP and blood glucose levels is correlated and same parameters are also compared normal (controlled) group. CRP is also synthesized in the adipose tissue and may be present in excessive quantities in patients with abdominal obesity, eventually resulting in insulin resistance and diabetes.[4]

The role of CRP in predicting diabetes in pregnancy is ruled out because, during pregnancy, all endocrine glands are more active than normal life period in females.

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MATERIALS AND METHODS

Ninety-two patients regularly visiting Obstetrics and Gynaecology Department of Basaveshwara Medical College, Chitradurga-577502, Karnataka, were studied.

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Inclusion Criteria

Pregnant patients having of gestation and diabetic with above 20 weeks of gestation, multipara were selected. Normal pregnant women above 20 weeks of gestation were studied as control groups.

Exclusion Criteria

Known diabetics, having history of gestational diabetes mellitus (GDM) in the past pregnancy patients associated with endocrine disease such as thyroid, adrenal, or immune compromised diseases.

Method

Ninety-two pregnant women having gestational diabetes and same number of normal pregnant women selected as control group. Diagnosis of GDM based on 4th International workshop conference on gestational diabetes which adapts the Carpenter-Coustan criteria.[5] About 8 ml of blood from each patient was collected after an overnight fast (after 12 h) by venipuncture 4 ml is collected in clean plain bulb and remaining in the EDTA and fluoride bulb. Blood was allowed to clot serum which was then separated by centrifugation. Blood sugar was studied by glucose oxidize and peroxidase and point (enzymatic method), and CRP by immune turbidimetric method. The duration of study was October 2018–April 2020.

Statistical Analysis

The studied parameters in gestational diabetic women and controlled group were compared by *t*-test. The statistical analysis was carried out in SPSS software.

OBSERVATION AND RESULTS

In Table 1, comparison clinical manifestation (baseline) in GDM patients and controlled group:

1. The age (year) 23.60 (SD ± 2.55) in control group *t*-test was 0.82 and *P*-value was insignificant ($P > 0.07$)
2. Gestation age (weeks) 31.86 (SD ± 2.85) in GDM patients, 31.82 (SD ± 2.82) in controlled group *t*-test was 0.096 and *P*-value was insignificant 0.92
3. Body mass index (BMI) in GDM was 26.05 (SD ± 3.40), 22.80 (SD ± 2.14) in controlled group *t*-test was 14.1 and *P*-value was highly significant ($P < 0.000$).

In Table 2, comparison of laboratory findings:

1. Blood glucose (fasting) 123.25 (SD ± 18.42), 83.60 (SD ± 4.90) in controlled group *t*-test was 19.9 and *P*-value was highly significant ($P < 0.000$)
2. Blood glucose (post meal) 228.46 (SD ± 12), 110.69 (SD ± 6.68) in controlled group *t*-test was 82.2 and *P*-value was highly significant ($P < 0.00$)

Table 1: Comparison of clinical manifestation (baseline) in both groups

Parameter	Gestation DM 92	Control group 92	*t*-test	*P*-value
Age (year)	23.60 (SD±2.55)	23.29 (SD±2.55)	0.82	*P*>0.07
Gestational age (weeks)	31.86 (SD±2.85)	31.82 (SD±2.62)	0.096	*P*>0.92
BMI	26.05 (SD±3.40)	22.80 (SD±2.14)	7.75	*P*<0.000

P<0.000 = Highly significant, DM: Diabetes mellitus, BMI: Body mass index

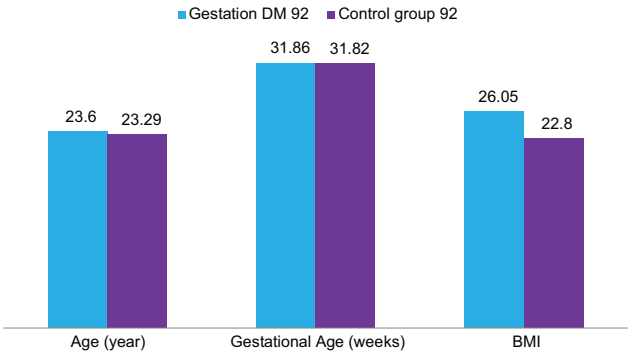
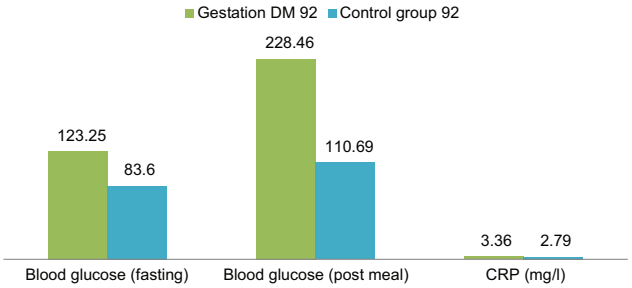


Table 2: Comparison study of laboratory findings in both groups

Parameter	Gestation DM 92	Control group 92	*t*-test	*P*-value
Blood glucose (fasting)	123.25 (SD±18.42)	83.60 (SD±4.90)	19.9	*P*<0.000
Blood glucose (post meal)	228.46 (SD±12)	110.69 (SD±6.68)	82.2	*P*<0.000
CRP (mg/l)	3.36 (SD±0.37)	2.79 (SD±0.11)	14.1	*P*<0.001

P<0.001 = Highly significant, DM: Diabetes mellitus, CRP: C-reactive protein



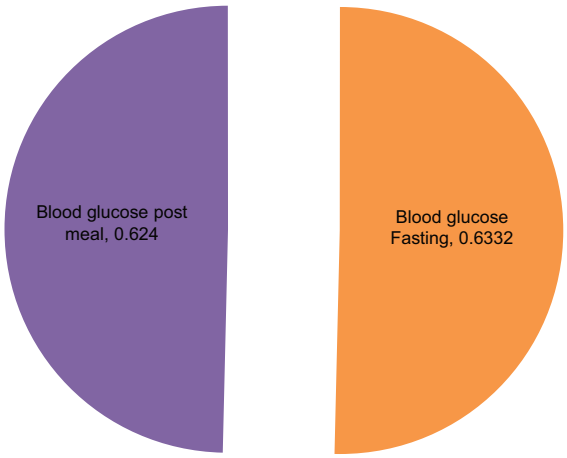
3. CRP (mg/l) 3.36 (0.37) in GDM and 2.79 (SD ± 0.11) in controlled group *t*-test was 14.1 and *P*-value was highly significant ($P < 0.001$).

In Table 3, CRP parameter in blood glucose fasting and blood glucose post-meal 0.032 (SD ± 0.2) in blood glucose

Table 3: CRP parameter in fasting and post-meal blood glucose

CRP	Blood glucose fasting	Blood glucose post-meal	*t*-test	*P*-value
Parameter	0.6332	0.6240	0.017	*P*>0.98

CRP: C-reactive protein



is 0.6240 (SD ± 0.4) blood glucose post meal, *t*-test 0.017, $P > 0.98$, *P*-value insignificant.

DISCUSSION

The present study of elevated C-reactive Protein in first trimester as a predictor of GDM in the Karnataka population. The BMI in GDM group was 26.05 (SD ± 3.40) and 22.80 (SD ± 2.14) in controlled group, *t*-test was 7.75, and *P*-value was highly significant ($P < 0.000$) [Table 1]. The comparative study of laboratory findings – Blood glucose level (fasting) 123.2 (SD ± 18.42) in gestation DM group and 86.60 (SD ± 4.90) in controlled group The t-test was 19.9 and *P*-value was highly significant ($P < 0.00$). In Blood glucose (post meal) study 228.4 (SD ± 12) in gestation DM group and 110.69 (SD ± 6.68) in controlled group. The t-test was 82.2 and ($P < 0.00$) *P*-value was highly significant. CRP value in was 3.36 (SD ± 0.37) in gestation DM group and 27.9 (SD ± 0.11) in controlled group. The t-test was 14.11 and *P*-value was highly significant ($P < 0.00$) [Table 2]. The CRP value was insignificant or more or less same 0.6232 (SD ± 0.2)/0.6240 (SD ± 0.4) in both fasting and post-meal blood glucose studies [Table 3]. These findings are more or less in agreement with the previous studies.[6-8]

GDM is the most common medical complication during pregnancy prevalence of such cases varies between 12% and 18% globally.[9] The increase in BMI seems to play a role in significant increase of CRP serum level. The gain during pregnancy and nutrition factors such as intake of saturated fatty acids is among other risk factors associated with FGDM.[10] The cornerstone of management is glycemic control and poor control during pregnancy has been associated with miscarriage, preterm birth, stillbirth, macrosomia, urinary tract infection, polyhydramnios shoulder dystocia, operative delivery neonatal hyperbilirubinemia, and hypocalcemia.[11] In normal pregnancy, there is an increase of lipid peroxidation products in serum with advancing gestation, which is balanced by an adequate antioxidative response. In GDM, increased blood glucose levels cause auto-oxidation of unsaturated lipids in plasma and membrane proteins which is responsible for generation of free radicals. Hence, this cycle of tissue damage and cell death, leading to increased free radical production and compromised free radical scavenger, exaggerates the oxidative stress.

The first trimester markers may help to predict this complication and improve the management of such cases. Hence, the first trimester of pregnancy is known as insulin sensitive period. Insulin resistance increases during the second trimester of pregnancy.[12] In the management GDM, treatment modalities aimed to improve insulin sensitivity may be useful. It is hypothesized that high sensitivity CRP may cause insulin resistance by increasing insulin receptor substrate-1 (IRS-1) phosphorylation at ser307 and ser612 through Jun N-terminal kinesis and extracellular signal regulated kinases I and II, respectively, leading to impaired insulin, stimulated glucose transporter translocation, and glycogen synthesis.[13] Controlling weight gain during pregnancy reduces the incidence of GDM.

SUMMARY AND CONCLUSION

The present study of elevated first trimester CRP as a predictor of gestational diabetes will be helpful for obstetrician and gynecologist, radiologist, neonatal physician to predict complications to fetus, and mother as well. This study demands further hormonal, pathophysiological, genetic, and nutritional studies because exact pathogenesis of gestational diabetic is still unclear.

This research paper is approved by Ethical Committee Basaveshwara Medical College, Chitradurga-577502, Karnataka.

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Original Article

Demographic and Clinical Profile of Celiac Disease in Kashmiri Children: An Observational Study

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Abstract

Introduction: Celiac disease is a common disorder in North India. No study is available regarding its clinicopathological profile in Kashmiri children. Kashmir valley is abode to three different ethnicities principally constituted by Kashmiris and small population of Pahari and Gujjar.

Aims and Objective: This study aims to study demographic and clinical profile of celiac disease in Kashmiri children.

Materials and Methods: The current study is hospital-based descriptive observational study conducted over $1_{1/2\ year}$. All patients in the age group of 6 months–12 years presenting with chronic diarrhea and unexplained failure to thrive were evaluated for celiac disease. A total of 62 patients were evaluated during the study period and 12 came positive for celiac disease (19%).

Results: Mean age of presentation is 6 years. Regarding principal modes of presentation, chronic diarrhea is observed in 10 (83%), unexplained failure to thrive 2 (16%), short stature 4 (33%), 7 out of 12 with wasting (58%), anemia 6 (50%), electrolyte disturbance like hypokalemia in 7 (58%), with severe hypokalemia (k+<2) in three patients, and isolated hypertransaminasemia in 4 (33%). Majority of the patients are Pahari/Gujjar (66%) despite constituting very little of whole population. This means that a case of chronic diarrhea and unexplained failure to thrive is more likely to be celiac if belonging to this section of society.

Conclusion: Celiac disease is well present in Kashmiri children with case positivity rate among chronic diarrhea and unexplained failure to thrive comparable to rest of North India and clinical spectrum shows malnutrition, anemia, and dyselectrolytemia in majority of patients. Its prevalence varies between different ethnic groups being more in Pahari and Gujjar children as compared to ethnic Kashmiri population.

Key words: Anemia, Chronic diarrhea, Failure to thrive, Malabsorption

INTRODUCTION

Celiac disease is a chronic systemic autoimmune disorder triggered by ingestion of dietary gluten and is characterized by small intestinal inflammation and villous atrophy.[1] It was not until the middle of the 20th century that a link between certain cereals and celiac disease was made by William Karel Dickle, a Dutch pediatrician. He became convinced that the consumption of bread and wheat floor was directly responsible for deterioration in patients suffering from this condition.[2] Subsequent work by Van de Kamer showed that it was the water insoluble portion or gluten moiety of wheat that produced intestinal injury in patients with celiac disease.[2] Since the 1980s, we have seen substantial advances in our understanding of genetic, immune, and molecular mechanisms fundamental to pathogenesis of celiac disease. In 1986, Howell *et al.* observed that celiac disease was associated with human leukocyte antigen (HLA)-DQ2 haplotypes. In 1993, Lundin *et al.* demonstrated that DQ2 gene products preferentially present gluten-derived gliadin peptides to intestinal mucosal T-cell in celiac disease. Subsequently, the enzyme Ttg type 2 was identified as a celiac autoantigen, leading to more accurate serological diagnostic tests. Celiac disease exhibits a spectrum of clinical presentation. Atypical celiac is fully expressed gluten sensitive enteropathy manifest only by extraintestinal symptoms and signs including short stature, anemia, osteoporosis, and infertility. Silent celiac

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is fully expressed gluten-sensitive enteropathy usually found after serological testing in asymptomatic patients. The atypical and silent variants are more common than classical or typical celiac which is fully expressed gluten-sensitive enteropathy found in association with classic gastrointestinal (GI) symptoms of malabsorption. This combination of serologic, genetic, and histologic data also led to the identification of two other types of celiac disease. Patients with latent celiac disease have normal villous architecture on a gluten containing diet but at another time have had or will have gluten-sensitive villous atrophy. Patients with potential celiac disease have never had a biopsy consistent with celiac disease but show immunological abnormality consistent with disease like positive immunoglobulin (Ig)A Ttg2.

Clinical features of celiac disease vary considerably. Intestinal symptoms are common in children whose disease is diagnosed within the first 2 years of life, failure to thrive, chronic diarrhea, vomiting, abdominal distention, muscle wasting, anorexia, and irritability which are present in most cases. Occasionally, there is constipation rectal prolapsed or intussusception.[1]

The most common extraintestinal manifestation of celiac disease is iron deficiency anemia,[1] unresponsive to iron therapy. Osteoporosis may be present. There may be short stature, arthritis, arthralgias, endocrinopathies, epilepsies with bilateral occipital calcification peripheral neuropathies, cardiomyopathies, chronic lung disease, aphthous stomatitis, alopecia, and isolated hypertransaminasemia. Some diseases with an autoimmune pathogenesis are found in higher than normal incidence in celiac patients. Among these are type 1 diabetes, autoimmune thyroid disease, Addison disease, Sjogren's disease, autoimmune cholangitis, autoimmune hepatitis, primary biliary cirrhosis, IgA nephropathy, and dilated cardiomyopathy.[1] The mean age of onset of symptoms in Indian children is 2.4 years and mean age of diagnosis is 8.3 years.[3] There is considerable variation in clinical profile of celiac disease in India and west, whereas studies in India show higher prevalence of diarrhea (88%) and failure to thrive (90%),[3] studies in west have shown a low percentage of celiac disease patients suffering from diarrhea.[4-6] Again studies have challenged the symptoms and associated conditions as a tool for case finding and screening.[4-6] Celiac disease is a common disorder with about 1% prevalence of biopsy proven cases in Western countries.[1] The term celiac iceberg was coined to describe the wide variation in nature and intensity of clinical presentation of which overt celiac is only the emerging peak. The discovery of large immersed part of celiac iceberg has transformed the status of celiac disease, long considered a rare disease to that of a common health problem.

The availability of new, simple, very sensitive, and specific serological tests has shown that celiac disease is not only common in Europe but also in developing countries. The prevalence of celiac disease in India is not well documented. Most of the studies in the past two decades in India have focused on classical celiac disease in which chronic diarrhea is a predominant feature. With advent of simple and accurate serological markers, population screening has shown higher prevalence of 1 in 70 to 1 in 250 in North India with diagnosed to undiagnosed ratio of 1:75.

There are limited data on prevalence of celiac disease in India. The majority data are from North India. There are regional variations in prevalence of celiac disease in India due to genetic and dietary factors that are wheat rice shift as we go from north to south in India.[10] It is most common cause of chronic diarrhea in children over 2 years of age in North India.[7] Among adults, it accounts for 26% of chronic diarrhea.[8]

Our study shows demographic and clinical profile of celiac disease in children with:

- Chronic diarrhea and malabsorption
- Unexplained failure to thrive.

MATERIALS AND METHODS

The study was conducted at GB Pant Hospital, Srinagar, an associated hospital of GMC, Srinagar. The study was a hospital-based observational study of admitted patients/children conducted from April 1, 2014, to October 1, 2015.

Inclusion Criteria

Children between 6 months and 12 years both males and females presenting with chronic diarrhea and/or failure to thrive were included in the study. Children were labeled as having chronic diarrhea if they had diarrheal episodes lasting for 14 days or more. Children were labeled as having fat malabsorption if there was a clinical evidence of fat-soluble vitamin deficiency or documented weight loss or wasting or presence of fat globules on stool microscopy. Children with stool positive for reducing substances and PH <5.5 were considered to have carbohydrate malabsorption. Children hospitalized for unexplained failure to thrive formed the second group of patients to be screened for celiac disease.

Children were excluded in which failure to thrive was secondary to chronic systemic disease, chronic infections, child abuse and neglect, children with chronic diarrhea secondary to giardiasis, clinical or laboratory evidence of cholestasis liver disease, cystic fibrosis, abetalipoproteinemia, and patients who have undergone gut resection. Children

fulfilling the inclusion criteria of the study underwent detailed relevant history and clinical examination recorded in a preset pro forma. Anthropometric assessment was done. Dietary evaluation including feeding history, age at introduction of gluten containing diet was done. Other tests such as hemogram, blood chemistry, coagulation profile, stool microscopy, stool for fat, and X-ray wrist were done. Serological testing with IgA TTG was also done. Serology was supplemented with serum IgA levels. If it came positive, children were subjected to small intestinal biopsy. Histopathological examination of biopsy specimen was done and reporting was done according to MARSH grading. Positive cases were followed up after introduction of gluten-free diet.

RESULTS

A total of 62 patients in the age group of 6 months–12 years presenting with either chronic diarrhea or unexplained failure to thrive/gain weight were evaluated for celiac disease in time span of $1_{1/2\ \text{year}}$s. Twelve out of 62 study patients came positive for celiac disease with a case positivity rate of 19%. Mean age at presentation was 6 years. Earliest presentation was in one infant presenting at 11 months with chronic diarrhea and failure to thrive, positive for celiac disease both on serology and biopsy. Under nutrition was present in 7 out of 12 (58%). Four patients (33%) were with short stature, anemia was present in 6 patients (50%), and electrolyte abnormalities, especially hypokalemia, were present in 7 patients (58%). The most common presentation seen was chronic diarrhea present in 83% of patients.[10] Unexplained failure to thrive/gain weight without diarrheal disease was present in 2 patients (16%). Upper GI endoscopy was grossly normal in 75% of cases. Only 3 patients (25 %) showed gross changes on upper GI endoscopy. Out of total 62 patients that were evaluated, 27 (43%) were from Pahari/Gujjar population (non-ethnic group) whereas 35 patients (56%) were from ethnic population. Case positivity rate seen was 29% (8 out of 27 study subjects) in Pahari/Gujjar population and 11.4% (4 out of 35 study subjects) in ethnic population.

DISCUSSION

The current study is well-documented account of celiac disease its clinical and demographic profile in Kashmiri children. No study was available regarding celiac disease in Kashmiri children. Public health importance of celiac disease is still underestimated among primary child physicians. The prevalence of celiac disease in Indian children is not well documented. It has been seen that celiac disease is the most common cause of chronic diarrhea in children above 2 years in North India.[7] Among adults, it accounts for 26% of chronic diarrheas.[8] Celiac disease is submerged in an ocean of malnutrition. The limited data on CD in India can be attributed to several factors like common belief like:

1. Celiac disease is uncommon in India
2. Recognition of tropical sprue and GI TB as major causes of chronic diarrhea and malabsorption
3. Non-realization that partial villous atrophy may be a feature of CD
4. More pressing problem of malnutrition and lack of awareness regarding non-diarrheal manifestation of CD.[9-12]

Regarding age of presentation, this varies from late infancy to adolescence in our study, with one infant presenting at 11 months of age, positive for celiac disease on serology and histology. Mean age at presentation is 6 years. This depends on prolonged breastfeeding and other feeding practices and time of gluten supplementation. Delayed onset of disease in other developing countries with similar feeding practices may be due to prolonged breastfeeding and delayed gluten introduction. In our study, principle mode of presentation is chronic diarrhea and failure to thrive. Chronic diarrhea is present in 83% of patients. Two patients presented with failure to thrive without any diarrheal illness. Increased awareness about this disease is thus required for its early diagnosis, particularly in children presenting without diarrheal illness. In Western studies, proportion of patients without diarrhea is up to 20–40%.[13,14] Among the various clinical and biochemical features, anemia, undernutrition, and short stature are very common. Undernutrition in 58%, anemia in 50%, and short stature in 33%. Iron deficiency anemia is the most common extraintestinal manifestation of celiac disease. Dyselectrolytemia, especially hypokalemia, is very common among celiac patients (58%). Most of our celiac patients had abnormalities of fat malabsorption, anemia, short stature, and dyselectrolytemia. The frequency of common features such as chronic diarrhea, failure to thrive, anemia, and fat malabsorption was similar to those reported earlier from both developing and developed countries.[15,16] No gross difference was found in clinical and laboratory features of celiac disease in Kashmiri children and elsewhere. On endoscopy, gross pathological changes are found in some patients of celiac disease. In our study, only three out of 12 showed gross finding on endoscopy, that is, scalloping. In other words, 75% of patients will not have any grossly identifiable finding on endoscopy. The duodenum may be normal or may show findings like scalloped duodenal folds but these findings are not specific for CD17. All patients in our study were biopsy confirmed with different subclasses of Marsh Grade 3, which is consistent with celiac disease.

With the upcoming of new ESPGHAN18 guidelines, biopsy and histopathology are no more required to confirm the celiac disease, provided the serology comes strongly positive that is more than 10 times the upper limit of normal. It is worthwhile to mention that in our study, all of the patients with positive serology had serum antibody levels <10 times of normal value.

In our country, serology and biopsy are simpler, cheaper, widely available, and more reliable method of diagnosing CD as the restricted availability, reliability of reporting, and high cost of HLA and EMA testing limits its universal use. The prevalence of celiac disease may vary among different communities in one particular geographic region depending on difference in genetic makeup and dietary practices.[17-20]

In our study, case positivity rate among Gujjar and Pahari children is much more (3 times) as compared to ethnic Kashmiri children with chronic diarrhea and failure to thrive. This means that a case of chronic diarrhea or failure to thrive is much more likely to be celiac if belonging to this section of society as compared to majority community.

This difference may be attributed to genetic makeup and dietary difference in two groups. Rice is the major staple diet of ethnic Kashmiris followed by wheat. In Gujjar and Pahari, principal staple diet is wheat and maize followed by rice. Principal trigger wheat is consumed by both of the communities. This difference may be more due to difference in genetic makeup. The main genetic factors are HLA-DQ genes that are the genes encoding DQ2 and DQ8 in HLA complex. Adequate data about DQ2 and DQ8 distribution in India are lacking.

CONCLUSION

Celiac disease is well present in Kashmiri children with case positivity rate among chronic diarrhea and unexplained failure to thrive comparable to rest of North India and clinical spectrum shows malnutrition, anemia, and dyselectrolytemia in majority of patients. Its prevalence varies between different ethnic groups being more in Pahari and Gujjar children as compared to ethnic Kashmiri population.

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Original Article

Development and Evaluation of Gastroretentive Floating Matrix Tablets of Quetiapine Fumarate

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Abstract

Introduction: The present study was carried out to evaluate gastroretentive floating matrix tablets of Quetiapine Fumarate (QFR) to reduce the dose frequency and higher bioavailability.

Materials and Methods: Floating matrix tablets of QFR were prepared by employing gel-forming polymers such as hydroxypropyl methylcellulose (HPMC) (K100M, K15M), methyl cellulose (MC), and xanthan gum (XG). The formulations were evaluated for various physicochemical characteristics (weight, thickness, hardness, and diameter), drug and polymers compatibility, *in vitro* buoyancy, swelling index (SI), *in vitro* drug release characterization, and *in vivo* X-ray studies.

Results: The differential scanning calorimetry studies revealed no interaction between the drug and polymers. All the physicochemical properties of the developed formulations were found within the specified limits. Formulation containing HPMC K100M and a higher concentration of MC floated immediately, followed by formulations with HPMC K15M. The SI was directly associated with polymers concentrations (HPMC K100M, HPMC K15M and XG). The *in vitro* release studies showed that the formulation F1 (HPMC K100M 80%) sustained the drug release (101.01%) for about 12 h. All the formulations followed zero-order kinetics and non-Fickian diffusion mechanism. *In vivo* X-ray studies of the selected formulation F1 (HPMC K100M 80%) showed gastric retention time of about 12 h.

Conclusion: The present study results indicated a successful approach to achieve controlled release of QFR in the stomach for 12 h. Further studies can be pursued to confirm improve the bioavailability of the QFR from the present formulation.

Key words: Buoyancy, Gastroretentive floating matrix tablets, *In vitro* release, *In vivo* study, Quetiapine fumarate, Swelling

INTRODUCTION

Oral drug administration is the most convenient and preferred means of any drug delivery to the systemic circulation. Some drugs have ideal characteristics for good absorption throughout the gastrointestinal tract (GIT), while the others present difficulties due to narrow absorption window in the stomach and proximal intestine, stability problems in intestinal fluids, poor solubility in intestine (or) requirement of local action in the stomach. Rapid and unpredictable gastrointestinal transit could result in incomplete drug absorption from the tablet leading to diminished efficacy of the administered dose.[1] Quetiapine Fumarate (QFR) is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives and is indicated for the treatment of schizophrenia as well as for the treatment of acute manic episodes associated with bipolar I disorder. Since the drug is preferentially absorbed in the proximal small intestine (narrow absorption window), the drug displays oral bioavailability problems in conventional dosage forms.[2] As conventional dosage forms can only partly satisfy therapeutic and biopharmaceutical needs, they do not take into account the site-specific absorption rates within the GIT. Therefore, there is a need for developing a delivery system that releases the drug at the right time, at the specific site, and at the desired rate.

To overcome these problems, different approaches have been proposed to retain dosage form in the stomach. One

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of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GIT is to control the gastric retention time (GRT).[3] This dosage form can be retained in the stomach and assist in improving the sustained oral delivery of drugs that have an absorption window in a particular region of the GIT, thus ensuring optimal bioavailability. Gastroretention can be achieved via intragastric floating drug delivery system, high-density system, swelling (or) expandable system, and super-porous hydrogels.[4] The principle of floating drug delivery system is exploited using gel-forming polymers such as semi-synthetic derivatives of cellulose and polysaccharides, which swell in gastric fluids with a bulk density of <1.[5] As a result, it remains buoyant and floats on gastrointestinal fluids and thus prolonging GRT.

The present study aims to develop gastro retentive floating matrix dosage forms of QFR are prepared by a non-effervescent technique using different concentrations of hydrophilic swellable gel-forming polymers. Further, the formulations are evaluated for the effect of hydrophilic polymer on i*n vitro* drug release, floating behavior, and i*n vivo* X ray studies.

MATERIALS AND METHODS

Materials

QFF, hydroxypropyl methylcellulose (HPMC) K15M, and HPMC K100M were obtained as a gift sample from Shasun Pharmaceuticals, Pondicherry, Stedmann Pharmaceuticals, Chennai, and Pharmafabricon, Madurai, Tamil Nadu, India, respectively. In addition, lactose, talc, xanthan gum (XG), and magnesium stearate (Central Drug House, New Delhi) were purchased locally. All other solvents and reagents used were of analytical grade.

Methods

Drug-polymer compatibility study

Differential scanning calorimetry (DSC) studies of pure drug alone and mixed with different polymers were (DSC Q 200 Thermal Analyzer) to establish the compatibility of the drug with polymers.[6,7]

Preparation of floating matrix tablets

Non-effervescent Floating matrix tablets containing QFR were prepared by wet Granulation technique using variable concentrations of HPMC K100M, HPMC K15M, methyl cellulose (MC), and XG Table 1. All the ingredients as per formula were weighed and mixed except magnesium stearate and talc. The mixed powder was granulated with isopropyl alcohol and dried at 50°C for 2 h. Dried granules were mixed with talc and magnesium stearate after passing through the #12 sieve and finally compressed with a 10 mm flat-faced punch on the compression machine (Cadmach Machinery Co. Pvt., Ahmadabad).[1,8]

Evaluation of Floating Matrix Tablets

Physical properties

The powder blends and developed tablets were evaluated for various physical parameters, that is, bulk density (BD), tapped density (TD), compressibility index (CI), Hausner's ratio (HR), angle of Repose parameters for powder blend and thickness, diameter, hardness, friability, weight variation, and drug content parameters for tablets.[9,10]

In vitro buoyancy

The floating behavior of tablets was measured in a beaker containing 250 ml of 0.1N Hydrochloric acid (HCL) as dissolution medium and the temperature was maintained at 37°C ± 1°C. The time required for the tablet to rise to the surface was determined as floating lag time and the period up to which the tablet remained floating was determined as total floating time.[1]

Swelling index (SI) studies

The swelling behavior of tablets was measured in a beaker containing 200 ml of 0.lN HCL as dissolution medium and the temperature was maintained at 37 ± 0.5°C. After 12 h, the tablets were removed from the beaker and the percentage of swelling was calculated using the following equation.[1]

$$\% \text{ Swelling } = \frac{\text{Final weight } - \text{ Initial weight}}{\text{Initial Weight}} \times 100$$

In vitro release studies

In vitro release studies were performed in a USP type II paddle apparatus containing 900 ml of 0.1N HCL as dissolution medium at 50 rpm at 37° ± 1°C temperature for 12 h. In addition, 5 ml samples were withdrawn every 15 min for the 1st h and every 30 min up to 12 h and analyzed spectrophotometrically[1] at 209 nm.

In vivo X-ray studies

The animal (rabbit) weighing 2–3 kg was fasted overnight but allowed to take water *ad libitum*. Then, 30 ml of 5% dextrose solution was given before administering the tablets using a stomach tube (No. 12 French catheters) and 20 ml syringes. The tablets were made opaque by incorporating Barium sulfate (BaSO4) 50 mg instead of drug. The rabbit was exposed to X-ray imaging in the abdominal region, and photographs were taken at 0, 2, 4, 8, 10, and 12 h after administration of tablet. At hourly intervals, 30 ml of 5% dextrose solution was given to maintain optimum fluid level in the stomach.[8]

Stability studies

The best formulation was kept in a stability chamber maintained at 40°C ± 5% and relative humidity (RH) 75 ± 5% for 3 months. Samples were analyzed for the drug content, floating behavior and other physiochemical parameters periodically.[11,12]

Table 1: Formulation of non-effervescent floating matrix tablets

Ingredients	Quantity (mg) for 1 tablets (Total weight 300 mg)																			
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16	F17	F18	F19	F20
QFR	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
HPMC K100M	240	225	210	195	180	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
HPMC K15M	–	–	–	–	–	240	225	210	195	180	225	210	195	180	165	–	–	–	–	–
MC	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	240	225	210	195	180
XG	–	–	–	–	–	–	–	–	–	–	15	30	45	60	75	–	–	–	–	–
Lactose	4	19	34	49	64	4	19	34	49	64	4	19	34	49	64	4	19	34	49	64
Talc	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Magnesium Stearate	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Iso Propyl Alcohol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

HPMC: Hydroxypropyl methylcellulose, QFR: Quetiapine Fumarate, XG: Xanthan gum, MC: Methyl cellulose

RESULTS AND DISCUSSION

Infrared (IR) and DSC studies

In the DSC graph, QFR exhibits a sharp endothermic peak at 175.51°C. In addition, an endothermic peak of QFR was prominent in all the drug-polymer mixtures [Figure 1].

Physical properties

The physical properties of the powder blend of all formulations (F1-F20) were found within the specified limits [Table 2]. The powder blend of all formulations exhibited good flow properties. The tablets were biconvex round-shaped and white in color. The various physical properties of tablets were within the specified limits of pharmacopeia [Table 3].

In Vitro Buoyancy Studies

The formulations containing HPMC K100M (F1-F5) and a formulation containing a higher concentration of MC (F16-F17) were floated immediately, followed by formulations containing HPMC K15M alone (F6-F10) had a lag time of 15–25 s. Whereas F11-F15 containing a combination of HPMC K15M and XG had 40–50 s and formulations with a lower concentration of MC F18-F20 showed a lag time between 10 and 30 s [Table 1].

Formulations containing HPMC K100M (F1-F5) and MC (F16-F20) floated more than 12 h, but in the case of formulations containing HPMC K15M alone (F6-F10) or along with XG containing formulations (F11-F15) floated for 7.30–9 h followed by erosion [Table 1 and Figure 2].

SI Studies

In formulations containing HPMC K100M (F1-F5), F5 showed the maximum SI 433.53% followed by F4 406.43% and least showed by F1 342.06% [Figure 3]. Among five formulations with HPMC K15M (F6-F10), F10 showed a maximum SI of 91.47%, followed by F9 83.51% and least observed by F6 70.93% [Table 1 and Figure 3].

The formulations containing HPMC K15M and XG combination (F11-F15), F15 exhibited the highest SI of 159.10%, followed by F14 with SI 144.51% and minimum observed by F11 with SI 128.24% [Table 1 and Figure 3].

Table 2: Precompression evaluation of powder blend

Formulation Code	BD g/cc*	TD g/cc*	CI (%)	The angle of repose (θ)*	HR	% Drug Content±S.D*
F1	0.42	0.54	22.22	$26^0.21^1$	1.285	98.48±1.03
F2	0.41	0.55	25.45	$26^0.91^1$	1.325	98.45±0.82
F3	0.43	0.53	18.87	$26^0.56^1$	1.233	97.96±1.15
F4	0.42	0.52	19.23	$27^0.14^1$	1.238	97.15±0.31
F5	0.40	0.51	21.57	$25^0.23^1$	1.275	98.26±0.58
F6	0.41	0.51	19.61	$27^0.74^1$	1.244	97.19±1.54
F7	0.39	0.51	23.53	$27^0.20^1$	1.307	98.52±0.72
F8	0.38	0.50	24	$25^0.23^1$	1.316	98.16±0.51
F9	0.41	0.52	21.15	$26^0.77^1$	1.268	98.90±0.62
F10	0.41	0.52	21.15	$28^0.69^1$	1.268	98.22±0.86
F11	0.43	0.53	18.87	$24^0.07^1$	1.233	97.93±0.98
F12	0.40	0.50	20.00	$24^0.60^1$	1.215	98.65±0.72
F13	0.40	0.53	24.53	$29^0.20^1$	1.325	98.47±0.76
F14	0.40	0.52	23.08	$28^0.19^1$	1.300	99.33±0.38
F15	0.43	0.53	18.87	$26^0.90^1$	1.233	98.83±0.67
F16	0.42	0.54	22.22	$26^0.42^1$	1.286	97.97±0.99
F17	0.39	0.50	22.00	$24^0.17^1$	1.282	98.50±0.10
F18	0.40	0.52	23.08	$25^0.25^1$	1.300	97.67±1.66
F19	0.41	0.53	22.64	$25^0.38^1$	1.293	97.50±1.65
F20	0.41	0.54	24.07	$26^0.32^1$	1.317	99.20±0.53

n=3*, BD: Bulk density, TD: Tapped density, CI: Compressibility index, HR: Hausner's ratio

Finally, in formulation developed with MC, the maximum SI was observed in F 20 285.58% than by F19 276.78% and minimum by F16 with SI value of 243.81% [Table 1 and Figure 3].

The results showed that overall SI among all polymers are observed in the following order, HPMC K100M > MC > HPMC K15M and XG > HPMC K15M

In Vitro Dissolution Studies

The *in vitro* release studies of formulations containing HPMC K100M (F1-F5), HPMC K15M (F6-F10), MC (F16-F20), and HPMC K15M with XG (F11-F15) show in Figure 4a-d, respectively. The controlled release profiles were observed in the following order of 80% > 75% >

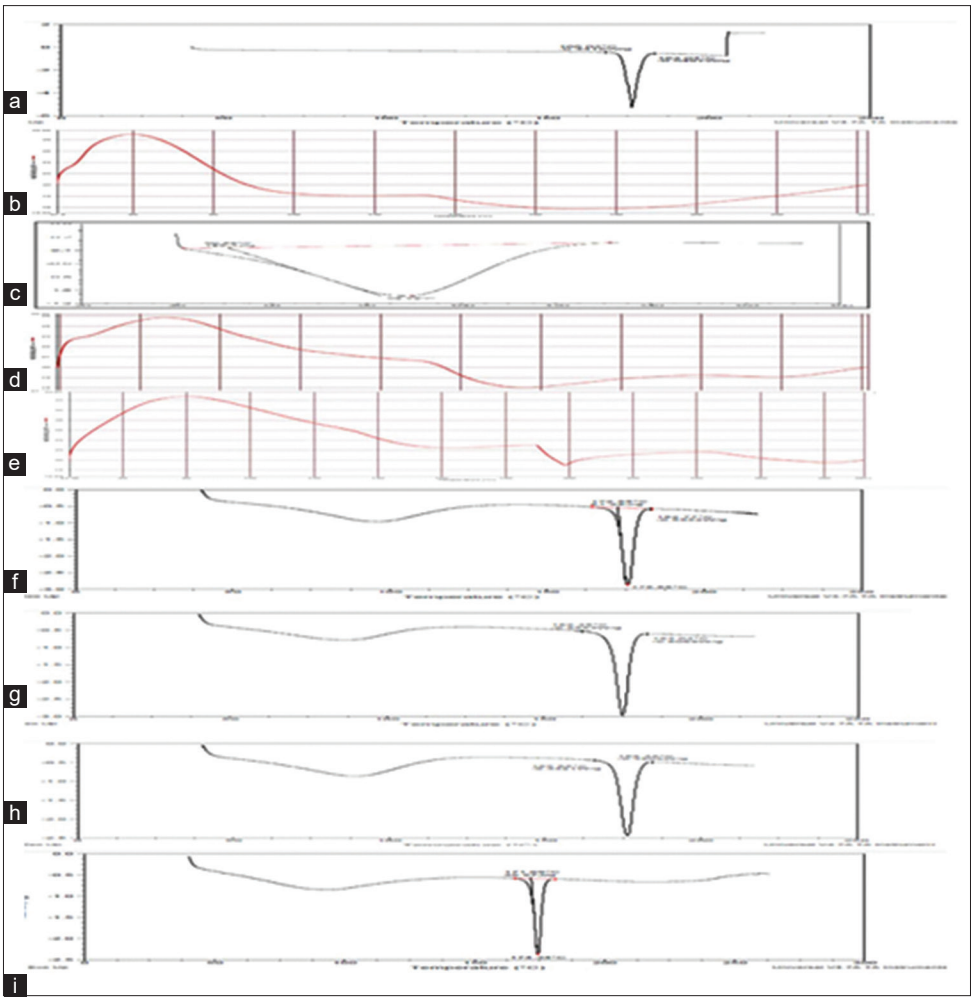

Figure 1: Differential scanning calorimetry Thermogram of (a) Quetiapine fumarate, (b) Hydroxypropyl methylcellulose (HPMC) K100M, (c) HPMC K15M, (d) Methyl cellulose, (e) Xanthan gum, (f) Drug+HPMC K100M, (g) Drug+HPMC K15M, (h) Drug+MC, (i) Drug+HPMC K15M+XG

Table 3: Post-compressional evaluation of floating matrix tablet

Formulation Code	Hardness (kg/cm^3)	Thickness (mm)	Diameter (mm)	Friability (%)	Average Weight (mg±5%)*	Drug Content (%)±S.D*
F1	3–4	3.9	10	0.61	298.32	100.1±0.29
F2	3–4	4.0	10	0.54	298.81	98.47±0.49
F3	3–4	4.0	10	0.69	298.96	99.33±0.64
F4	3–4	4.1	10	0.49	299.28	99.20±0.44
F5	3–4	3.9	10	0.43	298.18	99.90±0.50
F6	3–4	4.0	10	0.57	299.40	99.50±0.75
F7	3–4	4.0	10	0.67	298.82	99.70±0.20
F8	3–4	3.9	10	0.64	297.75	100.2±1.64
F9	3–4	4.1	10	0.22	298.67	99.50±0.56
F10	3–4	4.0	10	0.46	297.20	99.00±0.96
F11	3–4	4.1	10	0.30	301.42	99.43±0.21
F12	3–4	4.0	10	0.35	296.08	99.87±1.85
F13	3–4	3.9	10	0.58	299.48	98.83±0.40
F14	3–4	4.1	10	0.44	296.35	97.80±0.36
F15	3–4	4.0	10	0.69	297.46	99.69±0.10
F16	3–4	3.9	10	0.64	297.55	98.70±1.06
F17	3–4	4.0	10	0.86	298.63	98.50±0.10
F18	3–4	3.9	10	0.37	295.29	99.83±0.06
F19	3–4	4.0	10	0.86	299.52	99.70±0.46
F20	3–4	4.1	10	0.41	296.29	100.2±0.42

n=3*

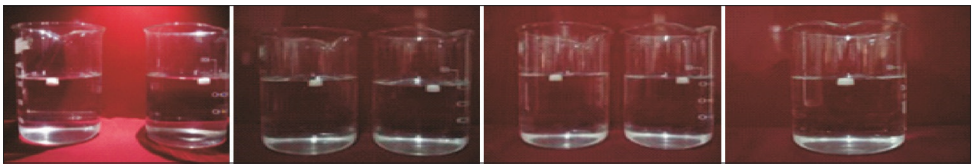

Figure 2: *In vitro* Floating Behavior of Formulations (F1, F5 and F16, F17), (a) Hydroxypropyl methylcellulose (HPMC) K100M 80%, 75% (b) HPMC K100M 70%, 65% (c) HPMC K100M 60%, Methyl cellulose (MC) 80% (d) MC 75%

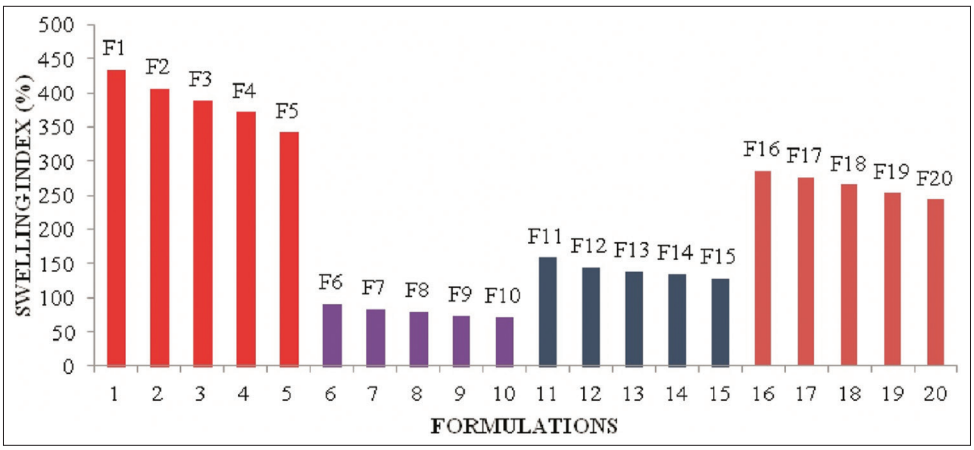

Figure 3: Swelling Index of All formulations

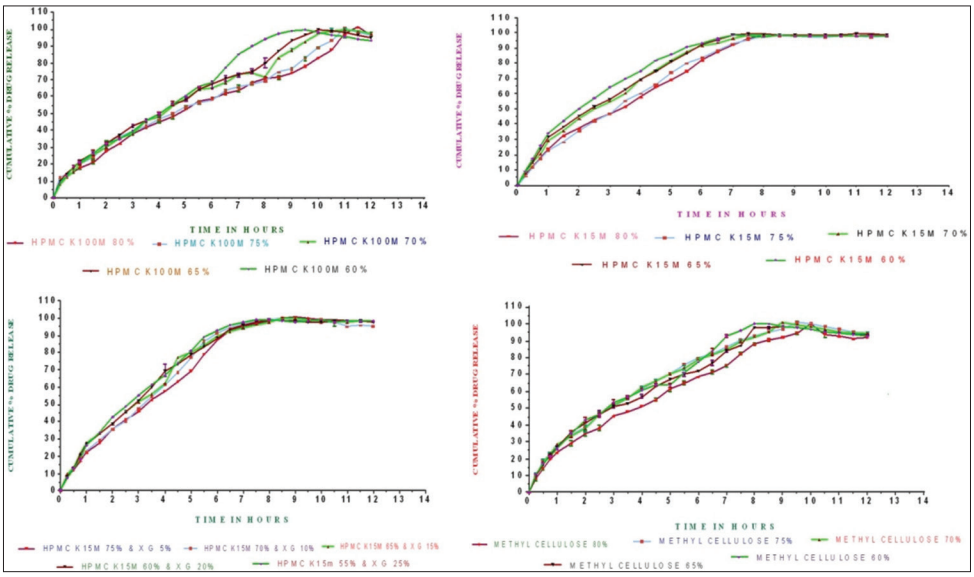

Figure 4: *In vitro* release profile of Quetiapine fumarate with (a) Hydroxypropyl methylcellulose (HPMC) K100M, (b) HPMC K15M, (c) HPMC K15M, and Xanthan gum (d) Methyl cellulose at different concentrations

70% > 65% > 60% concentrations irrespective of the type of polymer.

The *in vitro* release of formulations containing only HPMC K15M (F6-F10) released their whole drug content in 8–7 h, but along with XG (F11-F15), was able to control the release up to 9 h. Formulation with MC (F16-F20) showed controlled release up to 10 h, while HPMC K100M (F1-F5) containing formulations showed controlled release (101.01%) in 11.5 h.

In Vivo X-ray Studies

The results obtained from floating behavior, SI, *in vitro* release studies, and kinetic analysis formulation F1 were selected as optimized formulation. The only F1 formulation was subjected to *in vivo* X-ray and stability studies. The *in vivo* floating behavior of formulation F1 was carried out in rabbits by X-ray image techniques. The results showed that the tablet was retained in the GIT for up to 12 h confirmed its *in vivo* floating behavior [Figure 5].

Stability Studies

Optimized formulation F1 was subjected to stability studies at 40°C ± 5% and RH 75% ± 5%. The results showed no significant change in the physical appearance, drug content, hardness, friability, floating lag time, and total floating time during storage [Table 4].

DISCUSSION

DSC study showed a sharp endothermic peak at 175.51°C, corresponding to the melting point of pure drug. Moreover, this peak was prominently observed in all drug-polymer mixtures, suggesting that there was no interaction between the drug and the polymers.[7,12]

The powder blend of all formulations showed a BD of 0.38–0.43 gm/cc, TD of 0.50–0.55 gm/cc, angle of repose between $24^0.60^1$–$28^0.69^1$, HR of 1.233–1.325, and CI of 18–25%. The angle of repose below 30^0 and CI below 25% indicate good flow property during tableting.[9] Other physical properties of tablets such as thickness, hardness, friability, diameter, weight variation, and drug content were within the specified limits of pharmacopeia, which is required for ideal formulations.

The formulations containing HPMC K100M (F1-F5) floated immediately, followed by formulations containing HPMC K15M alone (F6-F10), which showed a lag time of 15–25 s. This might be due to the more hydrophilic nature of the HPMC K100M polymer. Whereas F11-F15 containing a combination of HPMC K15M with XG exhibited 40–50 s lag time.[6] This might be due to the denser matrix formed by incorporating XG. Thus, XG had a negative effect on floating properties. In addition, formulations containing a higher concentration of MC (F16-F17) floated immediately, while formulations containing a lower concentration of MC (F18-F20) showed a lag time between 10 and 30 s. This finding is in accordance with earlier reported studies.[5,6]

Formulations containing HPMC K100M (F1-F5) and MC (F16-F20) floated more than 12 h, but in the case of formulations containing HPMC K15M alone (F6-F10) or along with XG containing formulations (F11-F15) floated for 7.30–9 h. An increase in the floating time of the formulations is attributed to the increased concentration of polymers in the formulation. In addition, the floating lag time decreased with an increase in the hydrophilic nature of the polymer, which

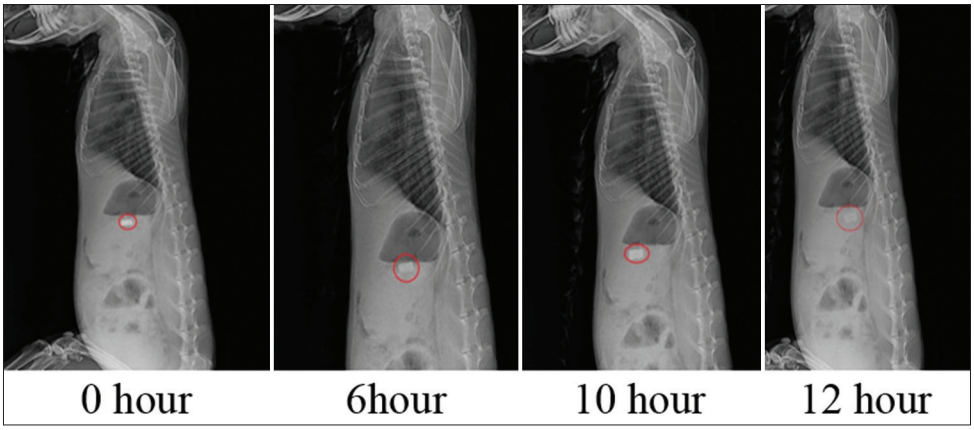

Figure 5: *In vivo* X-ray studies of floating of optimized formulation F1

Table 4: Stability study of optimized formulation (F 1)

Parameters	Intervals of Testing			
	At 0 day	At 15 days	At 30 days	At 60 days
Physical appearance	White color, biconvex	White color, biconvex	White color, biconvex	White color, biconvex
Hardness (Kg/cm^2)	3.5	3.5	3.5	3.5
Diameter (mm)	10	10	10	10
Thickness (mm)	3.9	3.9	3.9	3.9
Friability (%)	0.61	0.60	0.59	0.57
Weight Variation	298.32	298.05	297.92	297.4
Drug Content (%)	99.09	98.8	98.3	97.8
Floating Lag Time	Floats immediately	Floats immediately	Floats immediately	Floats immediately
Total Floating Time	>24 h	>24 h	>24 h	>24 h

allowed penetration of liquid through pores formed on the surface of the tablet.[6]

Our study observed that formulation developed with HPMC K100M showed maximum SI followed by formulations with MC and HPMC K15M combination with XG and least by formulations with HPMC K15M. The SI was found to be increased with an increase in the concentration of the polymer irrespective of the type of the polymer present.[13,14] This might be due to higher viscosity of HPMC K100M (75,000 to 140,000 cps) than K15M (13,500 to 25,200 cps). Paudel *et al.*[15] also report this finding in their earlier study where HPMC K100M exhibited significantly higher SI than HPMC K15M.

The *in vitro* release profile of all the developed formulations showed that maximum prolongation of drug release of 11.5 h was observed with HPMC K100M formulation followed by MC 10 h and HPMC K15M of only 8 h. This might be due to the higher molecular weight of HPMC K100M, which on imbibition with water resulting in a higher number of chain elongation, thereby significantly prolonging the drug release.[1,16] Whereas in formulations of HPMC K15M with XG release extended to 9 h. This might be due to the XG ability of gel formation when is exposed to water hence further prolonging the drug release. The earlier studies have also reported the same findings.[17]

The *in vivo* behavior of optimized F 1 formulation showed a 12-h stay in the stomach there, confirming its gastroretentive property.[8] The stability study results of formulation F1 also showed that environmental factors such as temperature and humidity would not affect the quality of the formulation.[12]

CONCLUSION

The studies concluded that gastroretentive floating matrix tablets of QFR were successfully formulated by a non-effervescent technique using gel-forming hydrophilic polymers. Among all the formulations, F1 (HPMC K100M 80%) exhibited the best results based on all evaluation parameters and stability studies. Hence, the present study showed a feasible approach to achieve controlled release of QFR in the stomach for a period of 12 h with good stability.

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Original Article

Evaluation of Various Prognostic Factors in Diabetic Foot: A Clinical Study

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Abstract

Introduction: Diabetic foot complications remain major medical, social, economic problems that are seen in all types if diabetes in every country; however, the reported frequencies of amputation and ulceration vary considerably as a consequence of different diagnostic criteria used.

Aim: The aim of the study was to study the etiology, presentation, and the management of diabetic foot ulcers to study the prognostic factors of diabetic foot in relation to plan of treatment and to increase the meager awareness of diabetic foot problems.

Materials and Methods: In this case study, 50 patients were studied. This study was conducted from September 2017 to November 2019.The protocol for the study was approved both by the Department of General Surgery, Mahatma Gandhi Memorial hospital, Kakatiya Medical College, Warangal.

Results: Findings were tabulated according to age and other clinical aspects.

Conclusion: Age, gender, duration of diabetes, mode of treatment of diabetes, and tobacco smoking did influence whether or not a diabetic with a foot lesion will have major amputation, an unsatisfactory outcome of primary treatment, prolonged hospital stay or will die Furthermore, the presence of foot infections alone, microangiopathy (nephropathy, retinopathy), foot ischemia alone or neuropathy alone had no relationship to poor prognostic indices.

Key words: Amputation, Diabetes, Foot, Infection, Ulcer

INTRODUCTION

Diabetic foot complications remain major medical, social, and economic problems that are seen in all types if diabetes in every country however, the reported frequencies of amputation and ulceration vary considerably as a consequence of different diagnostic criteria used. Among the many chronic complications of diabetes, diabetic foot has remained the most feared complication, with both patients and treating health care professionals sharing the dread in equal measure. Major challenges remain in getting across important messages relating to the diabetic foot:

a. Foot ulceration is common, affecting up to 25% of patients with diabetes during their lifetime
b. Over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains the most common cause of non-traumatic amputation
c. Prevention is the first step towards solving diabetic foot problems. It is estimated that a leg is lost to diabetes somewhere in the world every 30 s; a more important fact is that up to 85% of all amputations in diabetes should be preventable
d. Reduction in amputations will only be achieved if healthcare.

Professionals from all specialties realize that, as Brand once stated, "pain is God's greatest gift to mankind:" It is the loss of pain that permits patients with neuropathy to develop ulcers and continue walking on them despite the presence of often over-whelming infection.

Strategies aimed at preventing foot ulcers are cost-effective and can even be cost saving if increased education and effort are focused on those patients with recognized risk factors for the development of foot problems.

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Diabetes is now the most common cause of Charcot neuroarthropathy another condition that should be preventable.

Aim and Objectives

The objectives are as follows:

1. To study the etiology, presentation, and the management of diabetic foot ulcers
2. To study the prognostic factors of diabetic foot in relation to plan of treatment
3. To increase the meager awareness of diabetic foot problems
4. To understand the role of various factors involved in the complications arising out of diabetic foot and ascertain their role in the prognosis in relation to the plan of treatment
5. To reduce the risk of lower limb complications in people with diabetes
6. To empower diabetics in better foot care, early problem detection, and in seeking timely help.

MATERIALS AND METHODS

Source of Data

Source of data of minimum 50 patients with diabetes mellitus admitted at MGM Hospital surgical ward who have foot manifestations during the period of September 2017 to November 2019.

Method of Collection of Data

All the patients with diabetes mellitus having foot infections and ulcerations admitted in the surgical ward and also referred from the other specialty departments. The data regarding patient particulars, detailed clinical history, clinical examination, diagnosis, investigations, and surgical procedures are collected in a specially designed case recording format.

Sample Size

Calculated sample was 50 patients.

Statistical Methods

My study is a type of prospective study and results are expressed in, Diagrammatic presentation Mean ± SD Tests of significance such as "Z", "T", test were applied.

Inclusion Criteria

All the patients with diabetes mellitus presenting with foot ulcers, infection of foot, and gangrene of foot.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with foot infections without diabetes
2. Patients with ulcer and Gangrene of foot other than diabetic etiology.

RESULTS

An analysis of 50 cases of diabetic foot ulcer was done. These cases were admitted and treated in Department of General Surgery MGM Hospital, Warangal, during the period of September 2017 to December 2019.

Age

Age of the 50 patients were studied and ranged from 30 years to 86 years average being 61 years.

Sex

In the present study, out of 50 cases 34 were males and 16 were females.

Sex	No. of cases	Percentage
Males	34	68
Females	16	32
Total	50	100

Mode of Clinical Presentation

During our study, out of 50 cases 23 presented with cellulitis, 16 cases with ulcer, four cases with gangrene, and seven cases with abscess.

Mode of presentation	No. of cases	Percentage
Cellulitis	23	46
Ulcer	16	32
Abscess	07	14
Gangrene	04	08
Total	50	100

Site of Lesion

The most common site of lesion in diabetic foot was sole of the foot which accounted for 40% of all cases.

Site	No. of cases	Percentage
Dorsum	16	32
Toes	14	28
Sole	20	40
Total	50	100

Duration of Diabetes Mellitus

In our study, 11 cases were freshly detected at the time of admission and 39 patients were known diabetics. In 20 patients, 40% duration was between 1 and 5 years.

Among the 39 known diabetic patients, 16 patients were on regular treatment, 23 patients on irregular treatment, and remaining 11 patients were diagnosed on admission.

Incidence of Bone Infection

Out of 50 patients, nine patients showed osteomyelitis in X-ray.

So the incidence of osteomyelitis in present study was 18%.

Treatment

Treatment	No. of cases	Percentage
I and D, Fasciotomy	8	16
Slough excision, regular dressing and SSG	28	56
Tarsal tunnel release	10	20
Disarticulation	2	4
Transmetatarsal amputation	1	2
Below knee amputation	1	2
Total	50	100

Shows treatment received by the patients in my study. Most patients underwent thorough debridement then split skin grafting once the wound becomes healthy.

Hospital Stay

In my study, average duration of hospital stay was about 31.94 days with minimum being 3 days with maximum being 110 days. The maximum number of patients was in 21–40 days group.

Hospital stay (days)	No. of. cases	Percentage
0–20	16	32
21–40	22	44
41–60	06	12
61–80	05	10
81–100	00	00
101–120	01	02
Total	50	100

Table shows the most patients stayed between 21 and 40 days [Tables 1-3].

DISCUSSION

Foot infections are frequent and serious complication of diabetes mellitus which is a syndrome of metabolic, vascular and neuropathic components which are interrelated. The prevalence of foot infections among diabetics is 12%. About 15% of all diabetics develop foot ulcer in their life time and 50% of non-traumatic amputations are due to diabetes mellitus. About 50% of amputations can be reduced in diabetics by educating about DO'S and DON'TS in diabetics as mentioned before. In my study, total 50 patients studied in the period of September 2017 to November 2019 and discussion of this is as follows.

Age

Most common age group who presented with diabetic foot in my study was between 51 and 60 years with an average of 60.8 years. In JOS university study,[1] it is 63.2 years and in Seattle series it is 64.7 years. Thus, in my study presentation is most common in 5th to 6th decades. This early presentation may be due to poor glycemic control and good health awareness.

Sex

In my study, 68% were males and 32% were females. In seattle study its 67% and in JOS university study its 65%. Male preponderance in my study is may be due to males are more exposed to injuries during their occupational and recreational activities. This is comparable to Diabetic Research Center (2005) Chennai Study At 2005.[2]

Mode of Clinical Presentation

In my study, majority of patients presented with cellulitis (46%), 32% with ulcer, 14% with abscess, and 8% with gangrene. And this is comparable to JOS University[1] study in which cellulitis was 50% ulcer 28% abscess 12% and gangrene 10%.

History of Trauma

In the present study, 76% of patients were presented with history of trauma and it was absent in 24% of remaining patients. This was comparable to Ge *et al.* series in which 77% of patients had history of trauma. Because of sensory neuropathy diabetics will be having insensate foot so they are predisposed to repetitive unrecognized minor trauma and abnormal distribution of pressure on the feet hence emerge as a principle factor in causing foot ulcers.

Site of Lesion

Out of 50 patients studied, most common site of lesion is was sole of foot (40%).

Site of lesion	Present study %	Apelquist study %[3]	Ge *et al.* series %[4]
Sole	40	28	37
Dorsum	32	14	11
Toes	28	51	52

This is comparable only in the sole lesions with the other studies. It is also observed in our study that 60% of diabetic foot occurred among those who walked bare foot and 35% in those wearing only slippers or chappals while only 5% prevalence was observed in those wearing shoes.

Duration of Diabetes Mellitus

Most of the patients presented between 1 and 5 years and mean age is 3.12 years. It is 14.8 and 11.6 in Manchester, Seattle series and 8.2 in John Hopkins[5] study, respectively. This shows that foot complications accrued early in our study most probably due to lack of strict glycemic control.

Incidence of peripheral vascular disease (PVD) and Neuropathy

Incidence of PVD and neuropathy in the present study was 12% and 20% and both in 36% of patients. When only neuropathy is taken in to consideration, 56% of patient in present series had neuropathy. The incidence of neuropathy

in other series are 39.4% and in Kerala -53.8%. When only PVD is taken in to consideration 48% of patients in the present study had PVD in Manchester series -39% and Walter -24.2%.

The most common lesion is atherosclerosis of tibial arteries leads to decreased blood flow resulting in decreased delivery of oxygen, nutrients and antibiotics to foot hampering the chance of healing. The increased incidence of these complications in our study is probably due to lac of strict glycemic control.

Osteomyelitis

In the present study, 18% of the patients had osteomyelitis in the X-ray. Demineralization, periosteal reaction, and bony destruction are classic radiographic triad of osteomyelitis appear only after 30–50% of bone destruction. It is the nidus for infection unless it is controlled wound never going to heal. It is comparable to JOS University study[1] (14%) and Manchester series (20%).

Causative Organism

In the present study, most common organism isolated was *Staphylococcus aureus* (64%), next is *Pseudomonas* (10%), and Str. Pyogenic (10%). These results are comparable with JOS university study.[1]

Table 1: % of patients in different age groups

Age	No. of cases	Percentage
30–40	03	6
41–50	09	18
51–60	14	28
61–70	11	22
71–80	07	14
81–90	06	12
Total	50	100

Table 2: Duration of diabetes

Duration of diabetes in years	No. of cases	Percentage
Newly detected	11	22
<1	04	08
1–5	20	40
6–10	05	10
11–15	07	14
16–20	01	02
>21	02	04
Total	50	100

Table 3: Incidence of osteomyelitis

Osteomyelitis	09	18
Normal	41	82
Total	50	100

Infection is the 3rd most common factor responsible in the pathogenesis of diabetic foot lesion. When associated with ischemia frequently leads to amputation.this is comparable to JOS University study[1] and Seattle study in which *S. aureus* was the most common organism.

Necessity of Strict Glycemic Control

In the present study, all 50 patients treated with insulin. Insulin requirement was more initially and as the infection is under control the requirement became less and less. Among 50 patients only 12% had hemoglobin A1c (HbA1c) level <7 mg% and they have shorter hospital stay indicating that strict glycemic control is necessary for faster healing of wounds and decrease the incidence of amputation. Compared to Manchester University study, foot complications such as neuropathy and vasculopathy, appeared early in the course of diabetes mellitus in our study. This is mainly due to lack of strict glycemic control in our patients and tells us the necessity of strict glycemic control to reduce the foot complications.

Hospital Stay

Hospital stay was related to type, extent, severity of disease, and effective short- and long-term glycemic control. In the present study, average duration of hospital stay was 34.64 days. Stay for non-healing wounds are 28.4 days and for neuropathy it was 16 days. Causes for long hospital stay were uncontrolled diabetes, life-threatening infections, malnutrition, and multiple medical comorbidities.

Foot Care

Patient education in foot care, prophylactic skin and nail care, and footwear reduces the risk for foot ulcers and lower extremity amputation by 25% in those patients with no specific risk factor.

Prescription footwear accommodating deformity and decreasing pressure and shear forces applied to skin overlying bone prominence, keep individuals ambulatory, and protect them from ulcer formation.[6] In the present study, all patients educated regarding DOS AND DONTS. All are advised to wear MCR slippers selected patients referred to foot clinic Manager Jain hospital Bangalore, as this facility is not available in our hospital.

CONCLUSION

This study comprised 50 cases of diabetic foot patients with emphasis on surgical management and its complications over a period of 1 year. After analysis of the data the following are the conclusions.

The highest number of patients was seen in the age group of 51–60 years (28%). Youngest patient was 30 years old

and the oldest 88 years. Males are more vulnerable to trauma and almost 3 times more affected than females because of their occupation and recreational activities. History of trivial trauma of some kind was the most common initiating factor in nearly half of the cases.

The most common presenting lesion was Cellulitis 46%, ulcer 32%, abscess 14%, and Gangrene 8%. Duration of diabetes varied from 1 year to 25 years and few patients were diagnosed post admission. Only 12% had HbA1c level <7 mg% and they have shorter hospital stay indicating that strict glycemic control is necessary for faster healing of wounds and decrease the incidence of amputation.

HbA1c level <7 mg% in only 12% of patient indicates poor compliance of patient regarding long term glycemic control. Commonest microorganism isolated in our hospital was *S. aureus*. Conservative treatment consisting of control of diabetes with Plain/Lente insulin along with appropriate oral/IV antibiotics was effective in some cases. Wound debridement, slough excision followed by dressing with Povidone/magnesium sulfate/plermin/saline resulted in healing in some cases.

Tarsal tunnel release in selected neuropathic patients resulted in improved neuropathic symptoms. Split skin grafts, disarticulation, transmetatarsal amputation, and below knee were the other modes treatment.

SUMMARY

Foot ulceration in diabetic patients is a resource consuming, disabling morbidity that often is the first step towards lower extremity amputation. Prevention is the best treatment. The hallmark of diabetic foot problem in our populations is gross infection, and major contributing factors for late presentation include bare foot gait, attempts at home surgery, trust in faith healers and undetected diabetes.[7] Diabetic patients have always suffered from complications affecting the lower limbs. Foot infection and the subsequent amputation of a lower extremity are the most common cause of hospitalization among diabetic patients.[8] It is more common in male agriculturists. Most common in middle aged males. Most commonly presents as cellulitis are non-healing ulcer over plantar aspect of foot common precipitating factor is trivial trauma. Neuropathy, ischemia and infections are the most common cause of foot lesions. *S. aureus* is the most common organism isolated from foot lesions.

Early thorough surgical debridement is helpful. Saline with Oxum gave good results. Tarsal tunnel release gave good results with symptoms of neuropathy and ulcer recurrence and patients were followed up for 6 months. Later they lossed follow-up. Education regarding foot care plays a key role in the prevention of recurrence.

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Original Article

Comparison of Efficacy of Labetalol versus Alpha-methyldopa in the Management of Preeclampsia

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Abstract

Introduction: Hypertension is a common medical problem encountered during pregnancy and is associated with an increased risk of adverse outcomes. Preeclampsia is a multi-system disorder of unknown etiology, unique to pregnancy characterized by the occurrence of gestational hypertension along with proteinuria after the 20th week of pregnancy in a previously normotensive and non-proteinuric patient.

Aim: The aim of the study was to study the efficacy of oral labetalol versus oral Alpha-methyldopa in the management of preeclampsia.

Methods: Hundred patients included in this study were assigned to two groups randomly of 50 patients in each group. Group 1: Tablet Alpha-methyldopa (Aldomet) 250 mg was given thrice daily, and Group 2: Tablet Labetalol 100 mg was given twice daily. Blood pressure (BP) and proteinuria were recorded every 12th h.

Results: Significant fall in the diastolic BP after 48 h occurred only in the labetalol group ($P = 0.007$). In the Alpha-methyldopa group, there was a significant need to increase the drug dose after 48 h ($P = 0.043$). There appears to be no significant difference in induction rate between the two groups ($P = 0.585$). The mean birth weight was significantly higher ($P = 0.00$) in the labetalol group (3.11 kg) compared to the alpha methyldopa group (2.67 kg). There was no significant difference in the Appearance, Pulse, Grimace, Activity, and Respiration scores ($P = 0.090$) and rate of neonatal admissions ($P = 0.240$) in both groups.

Conclusion: Labetalol controls systolic and diastolic BP more rapidly and effectively than methyldopa. The safety profile and adverse effects of Labetalol and Methyldopa are similar to each other.

Key words: Labetalol, Methyldopa, Pregnancy-induced hypertension

INTRODUCTION

Preeclampsia is a multi-system disorder of unknown etiology, unique to pregnancy characterized by the occurrence of gestational hypertension along with proteinuria after the 20th week of pregnancy in a previously normotensive and non-proteinuric patient.[1] Gestational hypertension is defined as systolic blood pressure (BP) of 140 mm of Hg or more and Diastolic BP of 90 mm of Hg or more on two occasions, measured at least 6 h apart but within 7 days.[2] Proteinuria is defined as excretion of 0.3 g or more of protein in a 24-h urine sample or >1+ on the dipstick in a random sample after excluding urinary tract infection.[3]

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Preeclampsia complicates 2–8% of pregnancies.[4] Preeclampsia can affect virtually every organ system in the body and is a major cause of maternal and perinatal mortality and morbidity. Pre-eclampsia, when not controlled or left untreated, can lead to catastrophes like Eclampsia, Abruptio placenta, HELLP syndrome, fetal growth restriction, and intrauterine fetal death.[5] Although the definitive treatment of preeclampsia is the termination of pregnancy, aggressive treatment is necessary to ameliorate the disease progression to carry on the pregnancy till adequate fetal maturity is obtained. Therefore, oral antihypertensive drugs have a major role in the management of pre-eclampsia.[6] A comparison is

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made here between labetalol and the commonly used drug Alpha-methyldopa in the management of pre-eclampsia.

Aim

The aim of the study was to study the efficacy of oral labetalol versus oral Alpha-methyldopa in the management of preeclampsia.

MATERIALS AND METHODS

This randomized prospective comparative study was conducted at the Institute of Social Obstetrics and Government Kasturba Gandhi Hospital for Women and Children, Triplicane, Chennai, on 100 patients diagnosed with preeclampsia and admitted in the Eclampsia ward from September 2010 to August 2011.

The patients included in this study were assigned to two groups randomly of 50 patients in each group. Group 1: Tablet Alpha-methyldopa (Aldomet) 250 mg was given thrice daily and Group 2: Tablet Labetalol 100 mg was given twice daily.

Inclusion Criteria

All patients with gestational hypertension (more than 20 weeks of gestation till term), systolic BP of 140 mm of Hg or more, diastolic BP of 90 mm of Hg or more, and proteinuria (0.3 g in 24 h or more/1+dipstick or more) were included in the study.

Exclusion Criteria

Chronic hypertension, renal disease, liver disease, bronchial asthma, GDM, cardiac disease, and eclampsia were excluded from the study. Informed consent was obtained from these patients before administration of the drugs. BP was recorded every 12th h. The treatment was continued till delivery if the BP is controlled. If the BP was not controlled within 48 h, the dose of drugs was doubled. BP was measured by a mercury sphygmomanometer over the right arm in the sitting position after a period of rest for 15 min. Korotkoff phase 5 was used to define diastolic BP. Proteinuria was detected using the sulfosalicylic acid test. The period of study was 1 year. The change in BP after 48 h need for induction, and mode of termination of pregnancy, birth weight, Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score, and neonatal admissions was recorded. The results were subjected to statistical analysis using the *t*-test and Chi-square test.

RESULTS

These 100 patients were assigned to two groups at random of 50 patients in each group. Group 1 was started on tablet Alpha-methyldopa 250 mg thrice daily, and Group 2 was started on tablet Labetalol 100 mg twice daily. Most of the patients in both groups were in the age group of 21–25 years. 42% of cases in Group 1 and 38% of cases in Group 2 were in the age group of 21–25 years. About 60% of women in Group 1 and 40% of women in Group 2 were primigravidae. About 40% of women in Group 1 and 58% of women in Group 2 were multigravidae [Table 1]. The difference between the mean gestational ages between the two groups is not statistically significant, in Group 1 37.90 ± 1.93 weeks and Group 2 37.90 ± 1.59 weeks ($P = 0.910$). The difference between the mean BMI between the two groups is not significant, in Group 1 27 ± 3.28 and Group 2 27.30 ± 3.76 ($P = 0.671$).

Before drug administration, there is no statistical difference in systolic BP and diastolic BP. However, after drug administration, a significant fall in the diastolic BP after 48 h occurred only in the labetalol group ($P = 0.007$). During the time of delivery, there is no statistical difference in systolic BP and diastolic BP [Table 2].

About 36% of the cases in Group 1 needed an increase in the dose when compared to 18% in Group 2. There is a statistically significant need to increase the dose after 48 h in Group 1 compared to Group 2 ($P = 0.043$) [Table 3].

The need for induction in both Groups, 14% in Group 1 and 18% in Group 2 were induced with PGE2 gel [Table 4].

The mode of delivery in both the groups 44% of cases in Group 1 and 40% of cases in Group 2 underwent Emergency LSCS. About 36% of cases in Group 1 and 34% of cases in Group 2 were delivered by labor natural [Table 5].

The difference between the mean birth weights between the two groups is 442 g, which is statistically significant. The difference between the mean APGAR score between the two groups is 0.4, which is not statistically significant ($P = 0.090$). The need for NICU admission in both groups 10% of babies delivered in Group 1 and 4% of babies delivered in Group 2 needed NICU admission [Table 6].

DISCUSSION

Preeclampsia is an important cause of maternal mortality and perinatal mortality and morbidity. Oral antihypertensive drugs have played a major role in controlling the disease progression, preventing eclampsia and other dreaded complications, prolonging pregnancy, and reducing fetal prematurity. Although methyldopa has been used routinely

because of its safety profile, several controlled trials have suggested labetalol to be a better drug in controlling hypertension with the least side effects. A prospective study was carried out at City Hospital, Nottingham, the UK, in 1979. Nineteen patients with pregnancy induced hypertension (PIH) whose Mean arterial pressure was >103.3 mm of Hg were selected. They were randomly allocated to two groups. They were given either Labetalol 400 mg or Alpha methyldopa 750 mg daily. This dose was doubled 3 days later if satisfactory BP control had not occurred. Significant falls in BP only occurred in the group treated with labetalol, and daily BP control was better in this group. There was a higher incidence of spontaneous labor in the labetalol group and a significant difference in the Bishop score of the cervix between the two groups. There were no apparent detrimental effects on the fetus antenatally, during labor, or postpartum.[7]

In our study, the initial daily dose of labetalol was 200 mg, and the initial daily dose of alpha methyldopa was 750 mg. The dose was increased after 48 h if satisfactory BP control had not occurred. Statistically, significant falls occurred only in the diastolic BP in the labetalol group after 48 h ($P = 0.007$). There was no statistically significant difference between the need for PGE2 induction between alpha methyldopa and labetalol groups. About 86% of cases in the alpha methyldopa group and 82% of cases in the labetalol group went in for spontaneous labor. Only 5% of babies born in the alpha methyldopa group and 2% of babies born in the labetalol group required NICU admission. This difference was also not statistically significant ($P = 0.240$). A prospective study (2005) was carried out at Al-Jahra Hospital, Jahra, Kuwait, to assess the efficacy and safety of labetalol compared with methyldopa in the management of mild and moderate cases of PIH. One hundred four primigravidae with PIH were randomly allocated to receive either labetalol (Group A) or methyldopa (Group B).

The dose of the drugs was doubled every 48 h to maintain a mean arterial BP ≤103.6 mmHg. Ten patients in Group B (18.5%) developed significant proteinuria, whereas none developed proteinuria in Group A. Labetalol was quicker and more efficient at controlling BP, having a beneficial effect on renal functions and causing fewer side effects compared with methyldopa. The rate of labor induction and the cesarean section for uncontrolled PIH was less in Group A (48% and 1%, respectively) than Group B (63.0% and 5.6%, respectively). Moreover, a higher Bishop score at induction of labor was noticed in Group A. Labetalol is better tolerated than methyldopa, gives more efficient control of BP, and may have a ripening effect on the uterine cervix.[8] In our study, 44% of cases were in the alpha methyldopa group and 40% of cases in the labetalol group

Table 1: Comparison of patient characteristics

Variables	Group 1	Group 2	Total
Age group			
<20	6	6	12
21–25	21	19	40
26–30	17	20	37
>30	6	5	11
Parity			
Primi	30	21	51
Multi	20	29	49

Table 2: Comparison of BP

BP	Group 1	Group 2	*P*-value
Before drug administration			
SBP	150.6±8.6	150.2±8.2	0.813
DBP	103.40±4.78	102.40±4.78	0.275
48 h			
SBP	146.20±8.3	144.60±8.62	0.347
DBP	95±7.35	91.20±6.27	0.007
Time of delivery			
SBP	143±9.53	139.40±9.98	0.068
DBP	91.60±7.91	89.40±6.19	0.125

BP: Blood pressure, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 3: Comparison of dosage

Need to increase the dose	Group 1	Group 2	Total	*P*-value
No	32	41	73	0.043
Yes	18	9	27	

Table 4: Comparison of induction

Induction	Group 1	Group 2	Total	*P*-value
Nil	43	41	84	0.585
Pge2 Gel	7	9	16	

Table 5: Comparison of mode of delivery

Mode of delivery	Group 1	Group 2	Total	*P*-value
Elective LSCS	2	2	4	0.75
Elective RPT LSCS	1	4	5	
Emergency LSCS	22	20	42	
Emergency RPT LSCS	7	7	14	
Labor Natural	18	17	35	
Total	50	50	100	

LSCS: Lower segment Cesarean section

Table 6: Comparison of neonatal characteristics

Variables	6.092 mm	Group 2	*P*-value
Birth weight	2.68±0.60	3.12±0.61	<0.0001
APGAR	8.24±1.31	8.64±1.06	0.09
NICU admission	5	2	0.24

APGAR: Appearance, Pulse, Grimace, Activity, and Respiration, NICU: Newborn intensive care unit

delivered by Emergency LSCS; 36% of cases in the alpha methyldopa group and 34% of cases in the labetalol group delivered by Labor Natural. In a Randomized controlled trial (1988), labetalol was compared with methyldopa in a randomized controlled trial involving 176 pregnant women with mild to moderate hypertension. Diastolic BP below 86 mmHg was obtained in a similar proportion of women given labetalol or methyldopa. Intrauterine death occurred in four women treated with methyldopa, and the one neonatal death on day 1 occurred in the labetalol group. The average birth weight and the proportion of preterm or small-for-gestational-age babies were similar in both groups. Heart rate, BP, blood glucose, respiratory rate, and Silverman score of the babies did not differ between the two treatment groups, whether the comparison was made for all the infants or only for preterm or small-for-gestational-age. These data indicate that maternal beta-blockade with labetalol is as safe as methyldopa for the fetus and the newborn.[9] In our study, there were no reports of intrauterine deaths. There was a statistically significant increase in the mean birth weight in the labetalol group when compared to the alpha-methyldopa group (3.11 kg and 2.67 kg, respectively, $P = 0.001$).

CONCLUSION

Pregnancy-related hypertension is a leading cause of morbidity and mortality around the world. Therefore, antihypertensive drugs are crucial in the management of maternal BP. Labetalol reduces systolic and diastolic BP more quickly and effectively than methyldopa, according to our study. In addition, labetalol has a ripening effect on the cervix, increasing the likelihood of spontaneous labor and normal vaginal delivery.

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Original Article

Clinical Study of Chronic Lower Limb Ischemia and Correlation with Color Doppler Scan

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Abstract

Introduction: Chronic lower limb ischemia of the lower limb is a widely spread disease at the present time. It is a progressive disease and mainly comprises of atherosclerosis and Buerger's disease. Chronic critical limb ischemia is defined not only by the clinical presentation but also by an objective measurement of impaired blood flow using radiological investigations like color Doppler.

Aim: The aim of the study was to clinically evaluate patients of chronic lower limb ischemia and correlate the clinical findings with color Doppler study.

Materials and Methods: This study includes 50 patients admitted at Index Medical College, Indore with symptoms of chronic lower limb ischemia. Data were collected on basis of detailed history, clinical examination and color Doppler ultrasound findings.

Results: Out of the 50 patients observed the clinical diagnosis showed 24 patients as atherosclerosis and 26 patients as Buerger's disease. While color Doppler diagnosis revealed 26 patients as atherosclerosis and 24 patients to be Buerger's disease.

Conclusion: Current study establishes a strong correlation between diagnosis made on clinical basis and color Doppler findings.

Key words: Ischemia, Limb, Scan

INTRODUCTION

Chronic lower limb ischemia is a very common clinical occurrence in day to day out patients as well as admissions. This is a progressive disease broadly encompasses Atherosclerosis and Buerger's disease or Thromboangiitis Obliterans.[1-3]

Depending on its severity, lower extremity arterial disease can present in different ways, including (1) asymptomatic arterial insufficiency, (2) symptomatic disease presenting as intermittent claudication with positive noninvasive tests, and (3) critical leg ischemia, which defines the subgroup of patients with symptomatic lower extremity arterial disease in which the ischemic process endangers part or all of the lower extremity.

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Doppler US is a good method for screening and follow-up, as well as for the definitive diagnosis of peripheral arterial disease,[4-6] It does not require contrast enhancement, preparation of the patient before the study, or radiation exposure.[7,8]

Chronic lower limb ischemia limits the patients' lifestyle and causes significant morbidity in those suffering from it caused due to significant reduction in blood flow to the extremity manifesting in rest pain, intermittent claudication, rapidly progressing ulcers, gangrene, and even loss of limb.[9] Hence, early identification of symptoms and clinical features and their correlation of their severity with radiological studies like color Doppler ultrasound are of utmost important in their management.

MATERIALS AND METHODS

This study includes 50 patients admitted at Index Medical College, Indore with symptoms of chronic lower limb ischemia. Data were collected on basis of detailed history, clinical examination, and color Doppler ultrasound findings.

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Exclusion Criteria

Patients with acute lower limb ischemia, with traumatic, neurological, or infective etiology with no evidence of the lower limb vascular occlusion on Doppler were excluded from the study.

RESULTS

Out of the 50 patients observed the clinical diagnosis showed 24 patients as atherosclerosis and 26 patients as Buerger's disease. While color Doppler diagnosis revealed 26 patients as atherosclerosis and 24 patients to be Buergr's disease [Table 1].

The presence of intermittent claudication was found to be highly associated with the chronic lower limb ischemia. About 91.67% of atherosclerotics presented with claudication and 96.15% of Buerger's disease patients presented with claudication while on color Doppler 92.31% patients with atherosclerosis had intermittent claudication and 95.83% patients with Buerger's disease had intermittent claudication [Table 2].

Out of the total 24 patients with atherosclerosis diagnosed clinically 6 (25%) showed well palpable pulse (Grade 3), 16 (66.67%) showed diminished pulsations (Grade 2), and 2 (8.33%) showed absent femoral pulse. In 26 patients diagnosed clinically as Buerger's, 11 (42.31%) showed well palpable pulse (Grade 3) 15 (57.69%) showed diminished pulse (Grade 2) and none of the patients showed absent pulsation (Grade 1). Affection of femoral pulses was found to be greater in patients with atherosclerosis. Doppler findings were also consistent with clinical findings, that is, among the patients of atherosclerosis, 8 (30.77%) showed well palpable pulse, 16 (61.54%) showed diminished pulse, and 2 (7.69%) showed absent femoral pulse. In Buerger's disease patients, 9 (37.5%) showed well palpable pulse, 15 (62.5%) showed diminished pulse, and none showed absent pulsations. Similar higher affection of femoral pulse was found with atherosclerosis [Table 3].

Clinically diagnosed atherosclerosis patients showed 1 (4.17%) as well palpable, 17 (70.83%) as diminished and 6 (25%) as absent popliteal pulse while clinically diagnosed Buerger's patients showed 4 (15.38%) as well palpable, 12 (46.15%) as diminished, and 10 (38.46%) as absent popliteal pulse. Higher affection was found in popliteal pulse with Buerger's disease.

In color Doppler diagnosis of atherosclerosis, two patients (7.69%) showed well palpable pulse, 17 (65.38%) showed diminished pulse, and 7 (37.5%) showed absent pulsation. in Buerger's disease patients, three showed well palpable pulse (12.5%), 12 (50%) showed diminished pulse, and 9 (37.5%) showed absent popliteal pulse. Again a higher affliction was noted with Buerger's disease in popliteal pulse study [Table 4].

Anterior Tibial Pulse

Atherosclerosis patients diagnosed clinically showed 1 (4.17%) as well palpable, 12 (50%) as diminished pulse, and 11 (45.83%) as absent anterior tibial pulse. In clinically diagnosed Buerger's disease patients, none were well palpable for anterior tibial pulse, 6 (23.08%) showed diminished pulse, and 20 (76.92%) showed absent pulses. Higher affiliation was found in Buerger's disease with anterior tibial pulse.

Only 1 patient with atherosclerosis showed well papableata pulse with color Doppler diagnosis, 13 (50%) showed diminished and 12 (46.15%) showed absent pulse. On the other hand, none of the patients with Buerger's disease showed well palpable at a pulse, 5 (20.83%) showed

Table 1: diagnosed cases on the basis of color Doppler

Clinical	Color Doppler		Total
	Atherosclerosis	Buerger's Disease	
Atherosclerosis	21	3	24
	80.77	12.5	48
Buerger's Disease	5	21	26
	19.23	87.5	52
Total	26	24	50
	100	100	100

Table 2: Intermittent Claudication

	Clinical (%)		Color Doppler (%)	
	Present	Absent	Present	Absent
Atherosclerosis	22 (91.67)	2 (8.33)	24 (92.31)	2 (7.69)
Buergers' Disease	25 (96.15)	1 (3.85)	23 (95.83)	1 (4.17)

Table 3: Femoral Pulse

Femoral Pulse	Clinical Diagnosis (%)		Color Doppler (%)	
	Atherosclerosis	Buerger's	Atherosclerosis	Buerger's
1	2 (8.33)	0 (38.46)	2 (7.69)	0
2	16 (66.67)	15 (57.69)	16 (61.54)	15 (62.5)
3	6 (25)	11 (42.31)	8 (30.77)	9 (37.5)

Table 4: Popliteal Pulse

Popliteal Pulse	Clinical Diagnosis (%)		Color Doppler (%)	
	Atherosclerosis	Buerger's	Atherosclerosis	Buerger's
1	6 (25)	10 (38.46)	7 (26.92)	9 (37.5)
2	17 (70.83)	12 (46.15)	17 (65.38)	12 (50)
3	1 (4.17)	4 (15.38)	2 (7.69)	3 (12.5)

Table 5: Dorsalis Pedis Pulse

Dorsalis Pedis	Clinical Diagnosis (%)		Color Doppler (%)	
	Atherosclerosis	Buerger's	Atherosclerosis	Buerger's
1	12 (50)	20 (76.92)	13 (50)	21 (79.17)
2	12 (50)	6 (23.08)	13 (50)	5 (20.83)

Table 6: Ankle Brachial Index

Abi	Clinical Diagnosis (%)			Color Doppler (%)		
	Atherosclerosis	Buerger's	Total	Atherosclerosis	Buerger's	Total
a	1 (4.17)	0	1	1 (3.85)	0	1
b	9 (37.5)	4 (15.38)	13	10 (38.46)	3 (12.5)	13
c	3 (12.5)	2 (7.69)	5	3 (11.54)	2 (8.33)	5
d	11 (45.83)	20 (76.92)	31	12 (46.15)	19 (79.17)	31

diminished, and 19 (79.17%) showed absent pulsation. Higher involvement was seen in Buerger's disease in color Doppler study as well.

Posterior Tibial Pulse

None of the patients showed well palpable pta pulse overTotal in the study. in atherosclerosis 11 (45.83%) patients showed absent pulses while 13 (54.17%) patients showed diminished pulses while 20 (76.92%) patients showed absent pulsation and 6 (23.08%) showed diminished pta pulses in Buerger's disease patients. *P*-value of 0.0404367 showed the association to be significant. 12 (46.15%) patients with atherosclerosis showed absent pta pulses with color Doppler study as compared to 14 (53.85%) showing diminition of pulse. 19 (79.17%) patients with Buerger's disease showed absent pta pulse and only 5 (20.83%) showed diminition of the pta pulse. *P*-value of 0.015 showed the association to be significant.

12 (50%) patients with atherosclerosis showed absent and 12 (50%) showed diminished dorsalispedis pulse. While 20 (76.92%) showed absent dp pulse and 6 (23.08%) showed diminished dp in Buerger's disease patients clinically. *P*-value of 0.0765287 showed no significant association of impaired dp pulse among the two.

Again 50% patients showed absent and 50% patients showed diminished dp in patients with atherosclerosis, while 19 (79.17%) showed absent and only 5 (20.83%) showed diminished dp pulse in patients with Buerger's disease. *P*-value of 0.0420436 depicted this association between color Doppler diagnosis of Buerger's disease and affliction of dppulstion to be significant, that is, more commnltdp was involved in buergers disease. Gangrene was more extensively found in patients of Buerger's disease than atherosclerosis on clinical study.

Atherosclerosis patients diagnosed clinically showed 1 patient with abi >0.9 (4.17%) of the total atherosclerosis patients, 9 with Grade b (37.5%), 3 with Grade c (12.5%), and 11 with Grade d (45.83%). Buerger's disease patients showed none with abi as Grade a, 4 as Grade b (15.38%), 2 as Grade c (7.69%), and 20 as Grade d (76.92%).

Total 1 (2%) patient was found to have Grade a abi, 13 (26%) with Grade b abi, 5 (10%) patients with Grade c abi, and 31 (62%) patients with Grade dabi [Tables 5 and 6].

DISCUSSION

Strong correlation was found between the clinical diagnosis and color Doppler diagnosis among these patients presenting with features of chronic lower limb ischemia. Similar studies were conducted by Gray in 2011[10] and Hartimath and Sangma. in 2017[11] and strong correlation was found between clinical and color Doppler diagnosis in both the studies.

47 patients presented with intermittent claudication and only three patients did not have intermittent claudication as their presenting complaint. With both clinical and color Doppler study, intermittent claudication was found to be almost equally associated with both atherosclerosis and Buerger's disease. Suresh Clement *et al.* found a similar association of intermittent claudication as presenting complaint in their study in 2017.[12]

Reduced temperature in the affected limb was found in 39 patients with significantly higher number of such patients subsequently diagnosed as Buerger's disease both clinically as well as through color Doppler very similar to the study of Hartimath and Sangma.,[12]

33 patients presented with the complaint of rest pain with varying intensities. The association of rest pain was found to be similarly present in patients with both atherosclerosis and Buerger's disease in both clinical and color Doppler investigations contrary to the results comprehended in the study of Hartimath and Sangma. in 2017. While rest pain itself associated strongly with advanced lower limb ischemia as a whole. The same study also took into account the presence of swelling in the patients with PAD although only in a few cases with more commonly present in atherosclerosis patients as observed similarly in the current study.[12]

Palpation of lower limb arterial pulses was performed on femoral, popliteal, anterior tibial, posterior tibial and dorsalis pedis arterial pulses and grading was done as 3- palpable pulse, 2- diminished pulsation, 1- absent or

impalpable pulse. The involvement of femoral pulse was more commonly seen in patients with atherosclerosis than with Buerger's disease both clinically as well as with color Doppler with well palpable pulse more commonly encountered in Buerger's disease and diminished or absent pulsation more commonly encountered in atherosclerosis patients.

Palpation of popliteal pulses revealed absent or diminished pulsations more so in patients with Buerger's disease than atherosclerosis patients. Anterior tibial arterial pulsations were markedly affected in Buerger's disease patients than in atherosclerosis patients with more number of Buerger's disease patients showing absent pulsation. This observation was almost equally encountered with both clinical assessment and color Doppler scan.

Absent pulsation in posterior tibial arteries was much more frequently encountered in Buerger's disease with none of the patients having well palpable arteries. Diminished pulsation was seen more in atherosclerosis patients' limbs. Both the clinical study and color Doppler scan were concordant with the observation.

Similarly dorsalis pedis artery pulsation was absent more frequently in Burger's disease patients than atherosclerosis patients on clinical as well as color Doppler assessment.

This study on arterial pulsations was consistent with the study of Clement *et al.* in 2017, 39 Jandaghi *et al.* in 2013[13] and Larch *et al.* in 1997.[14]

Ankle brachial pressure index was also studied in all the patients and grading was done according to the severity of stenosis, that is, Grade a ≥ 0.9 (normal), Grade b = 0.8–0.89 (mild ischemia), Grade c = 0.5–0.79 (moderate ischemia), and Grade d ≤ 0.5 (severe ischemia). More predilection of the latter two was seen in advanced disease with Buerger's disease showing more inclination towards lower abpi. Similar results were observed in the study by Aboyans in December 2012.[15]

Therefore, chronic lower limb ischemia almost always presents with intermittent claudication which being present with about same frequency in both atherosclerosis as well as TAO.

CONCLUSION

The current study encompassed various clinical features commonly presented associated with chronic lower limb ischemia and compared them with the diagnoses obtained through both clinical as well as color Doppler diagnosis. The various aspects of the clinical study well conformed to the diagnosis made by color Doppler analysis and strong correlation was observed among the two.

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Original Article

Comparative Study of Intrathecal 0.5% Hyperbaric Bupivacaine with Dexmedetomidine and Fentanyl for Lower Abdominal Surgeries: A Randomized Double-blind Clinical Trial

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Abstract

Background: In this modern year, the intrathecal adjuvants use has gained good acceptance in the field of anesthesiology. The spinal anesthesia quality is very much improved with addition of opioids and other drugs and as we know, no drug is without side effects. Spinal block has rapid onset, lower risk of infection rate and is very cost effective. However, post-operative pain is a very significant problem as the drugs used have limited duration of action. Hence, the administration of analgesics plays a key role postoperatively. To increase the duration and to reduce side effects, various local anesthetics and analgesics are used in combination. Some of the drugs have been used as adjuvants in spinal anesthesia to prolong intra- and post-operative analgesia which includes opioids, $\alpha 2$ agonists, vasoconstrictors, and other drugs.

Aim of the Study: The aim of the current study is to compare the efficacy of dexmedetomidine and fentanyl added to intrathecal bupivacaine to evaluate the onset and duration of sensory and motor block, post-operative analgesia, hemodynamic effects, and adverse effects of either drug in lower abdominal surgeries.

Materials and Methods: Sixty patients with the American Society of Anesthesiologists Grade I and II posted for lower abdominal surgeries were allocated to two groups randomly (30 patients each): Group D received 2.5 ml 0.5% hyperbaric bupivacaine and 5 μg of dexmedetomidine intrathecally and Group F received 2.5 ml 0.5% hyperbaric bupivacaine and 25 μg of fentanyl intrathecally.

Results: Patients in Group F had faster onset of sensory block and motor block than Group D ($P = 0.000$). Patients in Group D had significantly longer duration of motor and sensory blockade as compared to those in Group F ($P = 0.000$). Post-operative analgesia was significantly longer in Group D than Group F ($P = 0.000$). Incidence of side effects among the two groups was not statistically significant.

Conclusions: Fentanyl has its own benefits like faster onset compared with dexmedetomidine, but prolonged duration of motor and sensory blockade with post-operative analgesia was seen with dexmedetomidine without significant side effects.

Key words: Dexmedetomidine, Fentanyl, Intrathecal, Pain management, Post-operative analgesia, Spinal anesthesia, Spinal block

INTRODUCTION

Lower abdominal surgeries can be performed under local, general, and neuroaxial anesthesia, wherein, neuroaxial block is the most preferred method. Spinal block has rapid onset, lower risk of infection rate and is very cost effective. However, post-operative pain is a very significant problem as the drugs used have limited duration of action. Hence, the administration of analgesics plays a key role postoperatively.[1,2] To increase the duration and to reduce side effects, various local anesthetics and analgesics are used in a combination.[3] Some of the drugs have been used as adjuvants in spinal anesthesia to prolong intra- and post-operative analgesia,[1,2] which includes opioids, $\alpha 2$ agonists, vasoconstrictors, and other drugs.

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Dexmedetomidine and clonidine are two α2 agonists affecting through pre- and post-synaptic α2 receptors.[4] Dexmedetomidine has been used widely for anesthesia and analgesic purposes. Dexmedetomidine has sedative, analgesic, anti-anxiety, neuroprotective, and additional anesthetic effects.[5] To increase the duration of analgesia, dexmedetomidine along with other drugs has been used in caudal, subarachnoid, and epidural blocks.[6,7]

Fentanyl is the most common short-acting opioid which is used intrathecally along with local anesthetics and also has synergistic effects with local anesthetics where it improves the outcome and post-operative analgesia.[8] It also has been reported that intrathecal administration of fentanyl at the dose of 10–25 mg can prolong the duration of post-operative analgesia for approximately 180–240 min.[5] However, intrathecal opioids can cause some side effects such as itching, vomiting, urinary retention, nausea, and also respiratory depression.[6,7] Intrathecally, fentanyl has rapid onset of action being lipophilic opioid. It does not tend to migrate to the fourth ventricle in sufficient concentration to cause delayed respiratory depression. It provides better intraoperative analgesia and a safer alternative than morphine for the management of early post-operative pain.[9-11]

MATERIALS AND METHODS

The study entitled – A comparative study of intrathecal 0.5% hyperbaric bupivacaine with dexmedetomidine and fentanyl for lower abdominal surgeries is a prospective, randomized, double-blind clinical trial was conducted after approval by the Ethics Committee of Viswabharathi Medical College and Hospital, Kurnool, from April 2018 to March 2019. The research plan is carried out safely and methodologically and probable side effects of the drugs used were explained to the patients in their native language and were included in the study after obtaining written informed consent from all patients.

The participants included 60 patients of both sexes that were scheduled for elective lower abdominal surgeries under spinal anesthesia in the age group of 18–55 years and belonging to American Society of Anesthesiologists (ASA) I and II were enrolled for the study.

The patients with emergency conditions, contraindication to spinal anesthesia, history of valvular heart disease, history of allergy or sensitivity to applied drugs, as well as failed blockade or need for induction of general anesthesia were excluded from the study. The enrolled patients were randomized to one of two groups of equal sized prospective comparative study group using a computer-based program.

Group F (n = 50) received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 25 ug fentanyl intrathecally and Group D (n = 50) received 2.5 mL volume of 0.5% hyperbaric bupivacaine with 5 ug dexmedetomidine intrathecally.

After detail history, complete physical examination and laboratory investigations were carried out. Standard monitors with non-invasive arterial blood pressure, electrocardiogram, and oxygen saturation were applied. All patients were preloaded with intravenous (IV) lactated Ringer's solution 10 ml/kg. Under aseptic precautions, spinal anesthesia was induced in the sitting position at the L3–L4 interspace using a 23 G or 25 G Quincke's spinal needle. To implement and conduct the double-blind clinical trial, our study drugs were prepared by experienced anesthesiologist who was not involved in on coming observations of the patients.

Procedures and Intervention

Study design

This was a prospective, randomized, double-blind study.

Group D

Inj. dexmedetomidine 5 μg plus Inj. bupivacaine 0.5% (H) 2.5 cc (12.5 mg).

Group F

Inj. fentanyl 25 μg and Inj. bupivacaine 0.5% (H) 2.5 cc (12.5 mg).

The above injection was given over 10–15 s and patients were made to lie supine immediately. All patients were given 3 l/min supplemental oxygen with face mask. Blood pressure and pulse rate (PR) were monitored instantly after injection and then every 2 min till 10 min and every 5 min for 30 min and thereafter every 15 min till the end of surgery and recovery period from block. The same was monitored every 2 h till 24 h. Decreased blood pressure <30% of baseline recording (hypotension) was treated with IV fluids and IV 3 mg mephentermine. Decreased heart rate (HR) less than or equal to (bradycardia) 50 beats/min treated with IV 0.6 mg of atropine. The occurrence of adverse effects such as bradycardia, nausea, shivering, vomiting, pruritus, hypotension, and respiratory depression was recorded simultaneously.

Sensory, Motor, and Post-operative Assessments

The sensory block was checked by the pinprick test, and motor block was assessed using the Bromage scale.[12] When the adequate level of sensory block (T4–T6) was reached and confirmed, the surgery was allowed to begin. The onset of sensory block (time to reach T4–T6) was assessed with a pinprick test (using a blunt 25-gauge

needle along the mid-clavicular line bilaterally) every 2 min and modified Bromage scale (0 = no motor block, 1 = inability to flex the hip, 2 = inability to flex the knee, and 3 = complete motor block of limb) was used to evaluate motor block.

Patient's pain score was assessed using visual analog scale (VAS) score, scored from 0 to 10 (where 0 = no pain and 10 = the worst pain imaginable) during the recovery room 0 h (T0) and at 1, 3, and 6 h (T1, T3, and T6) in the post-operative period. If the VAS score was more than 3, a rescue dose of tramadol (50 mg) was administered intravenously after a prophylactic dose of antiemetic.

Duration of analgesia was defined and noted as the time interval between block onset and the first analgesic request. The duration of surgery was recorded. The respiratory depression (respiratory rate <10/min) and the incidence of nausea, vomiting, and shivering were assessed and recorded during 6 h after the surgery.

Analysis of Data

Quantitative data are presented with the aid of mean and standard deviation. Comparison among study groups was done with the help of unpaired *t*-test or Mann–Whitney U-test as per results of normality test. Qualitative data are presented with frequency and percentage tables. Association among study parameters is assessed with the help of Chi-square test (Fisher's exact test for 2 × 2 tables). $P < 0.05$ is taken as statistically significant.

RESULTS

In our study, patients were distributed according to age, gender, height, and weight which was compared and were statistically insignificant ($P > 0.05$) [Tables 1 and 2]. Onset of sensory block was significantly longer ($P < 0.001$) in Group D (461 ± 62.33 s) as compared to Group F (370.30 ± 40.30 s) [Table 3].

The mean time to achieve maximal sensory block in Group D is 10.64 ± 1.72 min and in Group F is 7.93 ± 0.63 min [Table 3]. Similar maximal sensory dermatomal level was achieved by dexmedetomidine and fentanyl in equal potent doses.

The mean time to achieve onset of motor block in Group D (541 ± 65.85 s) was remarkably higher ($P = 0.000$) than Group F (471 ± 50.15 s) [Table 3].

The reason for the observed differences between the results and that seen in the other studies can be attributed to the methodological differences like difference in the drug dosage and baricity or total volume of drug used. Mean time required for two segment regression was significantly higher ($P = –0.000$) in Group d (137.83 ± 12.5 min) than Group F (115.4 ± 9.93 min) [Table 3].

Table 1: Comparison of demographic characteristics including age, height, and weight

Study parameter	Group D	Group F	*P*-value
Age (years)	32.6±10.74	31.6±9.02	0.436 (NS)
Weight (kg)	65.4±5.25	63.76±6.57	0.617 (NS)
Height (cm)	161.5±5.42	159.72±6.35	0.288 (NS)

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Table 2: Comparison of demographic characteristics including gender

Sex	Group D	Group F	*P*-value
Male	21	24	0.371
Female	9	6	0.371
Total	30	30	0.371

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Table 3: Comparison of study group parameters

Study parameter	Group D	Group F	*P*-value
Onset of sensory block	461±62.33	370.30±40.30	0 (significant)
Time to cephalic spread	10.64±1.72	7.93±0.63	0 (significant)
Two segment regressions	137.83±12.5	115.4±9.93	0 (significant)
Onset of motor block	541±65.85	471±50.15	0 (significant)
Duration of motor block	301.67±19.45	268.50±8.2	0 (significant)
Post-operative analgesia	344.67±25.43	241.83±23	0.387 (Not significant)
Duration of surgery	101.17±11.72	97.33±14.41	0 (significant)

(*t*-test applied, *P*-value is significant if <0.05) Values are represented as mean±SD

Mean duration of motor block was significantly higher in Group D (301.67 ± 19.45 min) as compared to Group F (268.50 ± 8.2 min) [Table 3]. Duration of post-operative analgesia was significantly longer in Group D (344.67 ± 25.43 min) as compared with Group F (241.83 ± 23 min) [Table 3].

Thus, dexmedetomidine prolongs the duration of sensory block and also prolongs the duration of the motor block. Dexmedetomidine acts on 2 adrenoreceptors in substantia gelatinosa of spinal cord and blocks C and A delta fibers and increases the potassium conductance intensive the conduction block of local anesthetics.[13] Further, it may have an additive or synergistic effect with local anesthetic in increasing the time of two segment regressions and total duration of complete analgesia. The potentiation of motor block by dexmedetomidine may be an additive or synergistic effect to the local anesthetics or related to the interference with neuromuscular activity or binding of α2-agonists to motor neurons in the dorsal horn.[14] In this study, the mean sedation scores were found to

be comparable and statistically insignificant ($P > 0.05$) preoperatively and intraoperatively among the two groups. Preoperatively and intraoperatively, the difference between mean PR, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), RR, and SpO2 was insignificant ($P > 0.005$).

Intrathecal narcotics enhance the sensory blockade and prolong post-operative analgesia. They are associated with increased risk of nausea, vomiting, itching, and respiratory depression. Opioids are known to depress all phases of respiration by their action on the opioid receptors in the ventral medulla, irrespective of administration route. Fentanyl is a μ receptor agonist which can be administered safely intrathecally. It is highly lipophilic which prevents its rostral spread. However, systemic absorption of the drug could attribute to the lower respiratory rates by direct depressant action on μ receptors in brainstem [Table 4].

DISCUSSION

In the present study, administration of dexmedetomidine and fentanyl intrathecally combined with bupivacaine is compared in patients undergoing lower abdominal surgeries. The results revealed that adding 5 μg of dexmedetomidine to bupivacaine has a better effect on post-operative pain management compared to 25 μg fentanyl.

Today, intrathecal administration of dexmedetomidine has drawn considerable attention during spinal anesthesia with the aim of increasing the duration of analgesia and decreasing post-operative pain. It appears to be that dexmedetomidine induces the activation of α2-agonist receptors in the spinal cord, which leads to a decrease in the transmission of nociceptive signals like substance P and it has also been revealed that its analgesic effects after the surgery are due to the inhibition of the intracellular potassium transport activities.[15,16] As dexmedetomidine binds to α2 receptors in the locus coeruleus, it reduces norepinephrine release, and inhibits sympathetic activity and can cause hypotension and bradycardia. For this reason, evaluation of hemodynamic changes in patients was of great importance in this study.[17] There was no significant difference between the D and F groups in terms of SBP, DBP, HR, MAP, and SpO2 at most of the studied times, which is in accordance with the results of the previous studies.[3,14,18,19] Number of studies have addressed the administration of different doses of intrathecal dexmedetomidine (3 μg, 5 μg, 10 μg, and 15 μg) as an adjuvant to local anesthetics.[14,18,20,21]

Table 4: Comparison of overall incidence of side effects and complications

Complication	Group D (%)	Group F (%)	Total (%)
Hypotension	3 (10)	2 (6.7)	5 (8.3)
Bradycardia	4 (13.3)	1 (3.3)	5 (8.3)
Nausea and vomiting	1 (3.3)	2 (6.7)	3 (5)
Shivering	0 (0.0)	2 (6.7)	2 (3.3)
Pruritus	0 (0.0)	2 (6.7)	2 (3.3)
No complication	22 (73.3)	21 (70)	43 (71.7)
Total	30 (100)	30 (100)	60 (100)

(χ^2=6.357, d(f)=5, *P*-value-0.273 (not significant), (Chi-square test is applied. *P*-value is significant if <0.005)

In addition, the findings of this study have shown that the usage of mephentermine and atropine had no significant difference between the D and F groups, which were similar to the other studies.[3,22,23] However, Contractor *et al.* showed that the possibility of MAP and HR decrease was higher in the dexmedetomidine group compared to the fentanyl group.[8] The results of this study strongly suggest that the onset of block in Group D was faster than in Group F. There was no significant difference between the two groups in sensory block level, which was steady with the findings of other studies.[2,23]

Taking into consideration, the pain intensity based on VAS score, the results revealed that pain intensity was less in Group D during recovery room period (T0). However, at T1, T3, and T6 in the post-operative period, no significant difference was seen between the groups. The observation mentioned may be due to the effects of dexmedetomidine on the inhibition of pain receptors at the spinal cord that decreased c-fiber translocation and hyperpolarization of dorsal horn neurons.[22] This finding was in accordance with opinion with the results of studies conducted by Gupta *et al.* and Mahendru *et al.*[15,23] and was consistent with the study by Sun *et al.*, in the 1st h while at 2 and 4 h after the surgery, patients in the fentanyl group experienced less pain.[22]

Moreover, compared with Group F, the duration of analgesia in Group D was significantly longer. The mentioned findings were entirely consistent with the results of studies by Jain *et al.* and Gupta *et al.*[8,15]

In another observational study, Shukla *et al.* compared the effect of adding dexmedetomidine and MgSO4 to intrathecal bupivacaine and found that the onset of block was faster in the dexmedetomidine group and analgesia duration was also significantly longer in dexmedetomidine group.[18]

The results of this study indicated that the duration of motor block and the length of surgery were almost identical between the two groups. The study findings were in line and in contrast with the findings of Sun *et al.* study in terms of the length of surgery and the motor block duration,

respectively,[22] which dexmedetomidine group in the mentioned study had a longer duration of block that may be due to the higher dose of dexmedetomidine (10 μg) in the mentioned study, whereas the present study used 5 μg dexmedetomidine.

In regard to other complications such as shivering, nausea and vomiting, and respiratory depression, there were no major differences between these two groups in the present study, which was in accordance with the results of other studies.[13] However, Sun *et al.* indicated that shivering, nausea, and vomiting were most commonly observed in the fentanyl group.[2]

CONCLUSIONS

Based on this study result, it can be stated that intrathecal administration of dexmedetomidine is superior to intrathecal fentanyl in lower abdominal surgeries. This study also shown that dexmedetomidine also caused faster block but also led to more extended post-operative analgesia and minimal pain. Moreover, dexmedetomidine provided more stable hemodynamic conditions. Therefore, addition of 5 μg of dexmedetomidine to bupivacaine can be considered as an adjunct to local anesthetic during lower abdominal surgeries under spinal anesthesia.

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AUTHORS' CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. All authors played an important role and contributed equally in designing and concepting of this article and also participated in data acquisition, analysis, and data interpretation.

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Original Article

Efficacy of Superoxide Solution (Oxum) as Compared to Povidone-iodine in Healing of Chronic Ulcers

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Abstract

Background: Wound healing is a dynamic and complex process. The main purpose of wound dressings is to provide the suitable environment for healing. Various treatment modalities have been discovered over the years in the form of different types of wound dressings. As wounds are great burdens on the health-care system contributing to substantial mortality, morbidity and costs hence the need for study.

Materials and Methods: The present study is a single-center, prospective, clinical trial comparing oxum (superoxidized water) and betadine as a topical treatment of chronic wounds conducted in 100 Indian patients, with 50 patients in each group. All patients underwent daily dressing, debridement when needed and appropriate antibiotics. Clinical findings were recorded on day 1, 5, 7, 12, and 21 and compared.

Results: Reduction in wound size in oxum group was more as compared to betadine, however, it was not significant on day 5, 7, and 12 but results were significant for day 21. Rate of secondary infection for Group A was 22.22% and Group B was 38.44%. Appearance of granulation tissue and epithelization was earlier in Group A as compared to Group B. At day 12 in Group A, 96% of patients developed granulation, and in Group B, 56% of patients had granulation. At day 12 in Group A, 68% of patients had epithelization, and in Group B, 36% of patients had epithelization. Average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129. No adverse reaction was seen in either group.

Conclusion: In the management of lower limb ulcer, a superoxide solution (SOS) debrides necrotic tissue, reduces microbial load, promotes granulation, and decreases the healing time, without damaging the normal tissue or complications. Those patients, who have small superficial ulcers or not fit for definite surgery, can be managed conservatively with SOS only. Hence, SOS is safe, more effective, and efficacious as compared to povidone-iodine for ulcer management.

Key words: Chronic, Healing, Ulcers

INTRODUCTION

The management of wounds is fundamental in the practice of surgery. There has always been a search for an ideal antiseptic that is rapidly lethal to all forms of bacteria and their spores, capable of bactericidal property for a prolonged period with no ill effect on host tissues. Superoxidized solution (SOS) is an electrochemically processed aqueous solutions manufactured from pure water and sodium chloride. Oxum is a solution with neutral pH, longer half-life (>12 months), non-toxic, non-irrigating, no rinse dermal wound irrigant used in humans for wound care treatment including post-operative (post-surgical) wound care.[1] It is FDA approved. SOS is bactericidal, fungicidal, virucidal, and sporicidal. Ions and free radicals of Oxum rapidly react and denature proteins of bacterial cell wall, have anti-inflammatory effect, and produce an environment with an unbalanced osmolarity that damages single-cell organism. Multicellular organisms are not prone to such osmolarity changes, therefore, host tissues are

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spared. As wounds are a great burden on the health-care system, keeping in mind, these factors an attempt have been made to study the effect of SOS dressings as compared to povidone-iodine on lower limb ulcers patients who received treatment in IMCHRC, Indore.

Aim

This study aims to study the role of SOS in wound healing and compare the efficacy and outcomes of SOS dressings and those with povidone-iodine solution in various aspects of wound healing.

MATERIALS AND METHODS

The study was conducted at IMCH and RC, Indore, from August 2014 to March 2017. A total of 100 patients with lower limb ulcers were studied. The patients underwent dressings after obtaining informed consent. The patients were randomized to be divided into two different groups. Group A patients were offered SOS dressing while in Group B patients, 5% povidone dressing was done.

Antibiotics were given as per culture and sensitivity reports. Treatment continued until the wound size reduced to <10 cm^2 to reduce the duration of hospital stay and further follow-up was done on outpatient basis. SSG was performed for ulcers whose size was more than 30 cm^2 and bed was ready for skin grafting full of granulation tissue without evidence of residual infection after the initial 21 days of treatment.

Preventive protocols such as minimizing immobility, ensuring adequate nutrition, and hydration were used for both groups. Assessments were done on day 1, 5, 9, 12, and 21 and efficacy was compared in basis decrease in wound size, appearance of granulation tissue, epithelialization, control of infection, and duration of hospital stay.

RESULTS

In Group A, mean wound size at the time of presentation was 47.80 ± 27.81. In Group B, mean wound size at the time of presentation was 49.96 ± 26.82.

At day 5, in Group A, mean wound size was 42.08 ± 25.04, and in Group B, it was 47.84 ± 26.19. Both the results were compared and no significant difference was found between the two ($P > 0.05$). At day 9, in Group A, mean wound size was 37.48 ± 23.44 and in Group B was 42.28 ± 24.174. At day 21, mean wound size for Group A was 12.74 ± 10.81 and for Group B was 21.20 ± 13.84 with $P < 0.05$ which is statistically significant.

Granulation Tissue

In Group A, granulation was initially present in 3 (6%) chronic ulcers which increased to 19 (38%), 31 (62%), 48 (96%), and 50 (100%) on day 5, 9, 12, and 21, respectively.

In Group B, granulation was present initially in 5 (10%) ulcers which increased to 13 (26%), 21 (42%), 28 (56%), and 47 (94%) on day 5, 9, 12, and 21, respectively.

Epithelization

In Group A, epithelization on day 9 was seen in 11 (22%) patients, on day 12 was seen in 34 (68%) patients, and on day 21 was seen in 50 (100%) patients. In Group B, epithelization was noted in 6 (12%), 18 (36%), and 38 (76%) patients on 9, 12, and 21 days, respectively.

Incidence of Infection

Cultures were performed on ulcers on day of presentation, that is, day 1, day 9, and day 21 and following results were found.

In Group A, cultures from 9 out of 50 patients of Group A were found to be negative (primary sterile), out of which two became positive on next culture on day 9 with secondary infection rate of 22.22%.

In remaining 41 (52.56%) primarily infected cases from Group A, cultures of 30 patients were found to be negative on the 9th day culture with infection rate of 38.46%. On culture of the 21st day, number of positive cases reduced to 15 with an infection rate of 19.23%.

In Group B, cultures from 13 out of 50 patients of Group A were found to be negative (primary sterile), out of which five became positive on next culture on day 9 with secondary infection rate of 38.46%. In remaining 37 (47.44%) primarily infected cases from Group B, cultures of 32 patients were found to be negative on the 9th day with infection rate of 41.02%. On culture of the 21st day, number of positive cases reduced to 25 with an infection rate of 32.05%. Most common bacteria isolated from initial culture was *Staphylococcus aureus* in 35 cultures (44.87%).

Outcome

In Group A, SSG was performed in 8 (16%) cases and remaining 42 (84%) patients healed by their own. In Group B, 13 (26%) patients undergone SSG while 37 (74%) patients did not undergo any surgical procedure.

Duration of Hospital Stay

In the current study, average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129 [Tables 1-4].

DISCUSSION

The main purpose of wound dressings is to provide the ideal environment for healing. Although the ideal dressing is still not a clinical reality, novel advances are on their way for the achievement of the same.[1-3] The principle of "Wound Dressing with Superoxide Solution" was officially started in the year 2003 when it achieved a status of "Disinfectant and Antiseptic" in its homeland Mexico.[4]

Healing rates have been reported to be significantly shorter in cases dressed with SOS. Furthermore, duration for cultures to become negative and of antibiotic therapy was also reported to be shorter. SOS has been found to be safe and effective in the management of wide post-surgical lesions in the infected diabetic foot.[5] Hadi *et al.*[6] in Islamabad in 2006 on treating infected diabetic wounds with superoxidized water as antiseptic agent. A preliminary experience revealed that although the initial results of employing superoxidized water for the management of infected diabetic wounds are encouraging, further multicenter clinical trials are warranted before this antiseptic is recommended for general use. In the present study, a total of 100 patients were studied. Patients with lower limb ulcers were selected and randomly divided into two groups. Neither age, sex, nor underlying disease were considered in selection process.

In Group A, mean wound size was 42.08 ± 25.04 cm and for Group B 47.84 ± 26.19 cm. After 21 days of dressing with oxum, wound size reduces to 12.74 ± 10.81 cm while wound size in povidone-iodine group was found to be 21.20 ± 17.84 cm ($P < 0.05$). Dressing with SOS is found to be better in relation to decrease in wound surface area in comparison to povidone-iodine.

In a study conducted by Prabhakar *et al.*, SOS was found to be better with 58.90% ± 5.21% reduction in surface area as compared to 40.90% ± 8.76% in povidone-iodine group.[7]

In a study conducted by Kapur and Marwaha, after the mean follow-up of 21 days, average reduction in wound size in oxum group was 70% as compared to 50% in betadine group.[8]

Healing in Terms of Granulation Tissue, Epithelization

Initially, none of the ulcer had granulation tissue. On day 5, 38% of the cases show early granulation tissue in Group A as compared to 26% of patients in Group B. On day 9, 62% of patients from Group A had granulation tissue while in 42% of patients shown healthy granulation tissue. About 96% wounds from Group A had healthy granulation tissue as compared to 56% in Group B at day 12. At 21 days, 100% of patients of Group A and 94% of patients had healthy granulation tissue in Group B.

Epithelization was noticed earlier in Group A as compared to Group B. At day 12, 68% of patients started epithelization in Group A while it was present in 36% of cases of Group B. At day 21, maximum patients showed epithelization while in Group A, while in Group B, 86% of patients had epithelization. In the study conducted by Kapur and Marwaha, diabetic foot ulcer and chronic leg ulcers patients treated with oxum show early granulation and rapid epithelization when compared to betadine group.[8]

Incidence of Infection

Out of 100 patients, 22 cultures were found negative on day 1, that is, at the time of presentation. Out of which nine patients were from Group A while cultures from 13 patients of Group B were negative.

Out of nine primary sterile cultures from Group A, two cultures became positive with secondary infection rate of 22.22%. While secondary infection rate in Group B was found to be 38.46% in Group B which is higher as compared to SOS group.

Out of 41 positive cultures in Group A, incidence of infection was found to be 38.46% and 19.23% on cultures of the 9th and 21st day, respectively. In Group B, incidence of infection was found to be 41.02% and 32.04% for day 9 and day 21. These data are suggestive of SOS being more efficient in reduction of infection as compared to povidone-iodine. Most common organism isolated on culture was found to be *S. aureus*.

In a study conducted by Pandey *et al.*, rate of secondary infection was found to be 15% and 16%, respectively, and most common organism isolated was coagulase positive *S. aureus*.

Duration of Hospital Stay

In the current study, average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129. On the basis of these data, this can be concluded that rate of wound healing for SOS is better than povidone-iodine and hence duration of hospital stay is less for SOS.

In a study conducted by Paola on 218 patients suffering from chronic diabetic foot ulcers, 110 patients were treated with SOS (oxum) and 108 patients with povidone-iodine. The mean healing time was lower in the oxum group (45 ± 14) days versus (58 ± 20) days in betadine group.[9]

In a study conducted by Satish Kumar *et al.*, average duration of hospital stay was found to be 16.4 days and it was less than that of povidone-iodine.[10]

Table 1: Wound size (in cm²) after day 1, 5, 9, 12, and 21 of dressing

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A	47.80	27.81	42.08	25.04	37.48	23.44	31.94	21.08	12.74	10.81
B	49.96	26.82	47.84	26.196	42.28	24.174	38.02	22.63	21.20	13.84

Table 2: Appearance of granulation tissue

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	No	%	No	%	No	%	No	%	No	%
A	3	6	19	38	31	62	48	96	50	100
B	5	10	13	26	21	42	28	56	47	94

Table 3: Appearance of epithelization

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	No.	%	No.	%	No.	%	No.	%	No.	%
A	0	0	0	0	11	22	34	68	50	100
B	0	0	0	0	6	12	18	36	38	76

Table 4: Incidence of infection

Group	Day 1		Day 9		Day 21	
	No	%	No	%	No	%
A	41	52.56	30	38.46	15	19.23
B	37	47.44	32	41.02	25	32.05

CONCLUSION

The main purpose of wound dressings is to provide the ideal environment for healing. Although the ideal dressing is still not a clinical reality, novel advances are on their way for the achievement of the same. In the management of lower limb ulcer, a SOS debrides necrotic tissue, reduces microbial load, promotes granulation, and decreases the healing time, without damaging the normal tissue or complications. Those patients, who have small superficial ulcers or not fit for definite surgery, can be managed conservatively with SOS only. The results of our study favor the effective role of SOS in wound healing, and we found it to give better efficacy as compared to conventional topical agent (povidone-iodine). It promotes rapid healing without damaging the normal tissue.

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Original Article

Correlation of Bone Marrow Aspiration, Trephine Biopsy, and Imprint Cytology in Pancytopenia/ Bicytopenia Cases in Resource-Limited Area

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Abstract

Context: Bone marrow aspiration is a simple method to study hematopoietic disorders whereas trephine biopsy is of greater value in assessing large piece of marrow. At the same time, imprint is helpful in getting morphological details of individual cell.
Aims: The aim of the present study was to correlate the findings of bone marrow aspirate, bone marrow biopsy (BMB), and touch imprints in the diagnosis of pancytopenia/bicytopenia.

Settings and Design: This was a cross-sectional study.

Subjects and Methods: This 2-year cross-sectional study of 50 cases from year 2017 to 2019 is conducted in the Department of Pathology in GMC, Haldwani. The clinical features of pancytopenia/bicytopenia were noted. Bone marrow aspiration (BMA) along with bone marrow imprint (BMI) was evaluated and BMB was performed in all cases. BMA and imprint smears were stained with Leishman stain and biopsy section was stained with H.E., PAS, and reticulin stain. Findings were studied and analyzed.

Statistical Analysis Used: All the data were compiled and entered into MS Excel. Statistical analysis was performed using software SPSS-20.

Results: In all 50 cases, definite diagnosis was made on BMB and strong positive correlation was seen between BMA, BMI, and BMB ($P < 0.00001$). Furthermore, 100% correlation was seen in combined nutritional anemia, immune thrombocytopenic purpura, and metastasis; whereas 82.6% correlation was seen in megaloblastic anemia, 55.6% in reactive marrow, and 50% in acute leukemia.

Conclusions: The present study concludes that BMA and BMI give good cytomorphological details and take lesser time in reporting as compared to BMB. BMB whereas is useful for assessment of cellularity, topography, and fibrosis. BMA alone is usually sufficient to diagnose nutritional anemia, metastasis, and immune thrombocytopenia whereas trephine biopsy is the sole diagnostic tool in myelofibrosis, granulomatous disease, and aplastic anemia.

Key words: Bone marrow aspiration, Bone marrow biopsy, Bone marrow imprint, Combined nutritional deficiency anemia

INTRODUCTION

Cytopenia is a disorder in which production of one or more blood cell types stops or is greatly reduced. Cytopenia is of two types: Pancytopenia and bicytopenia.[1]

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Etiology of pancytopenia varies according to the geographical distribution and genetic mutations. In developed countries, the most common cause of pancytopenia is aplastic anemia followed by infections. Whereas in developing countries, the most common cause is nutritional deficiency.

Bone marrow aspiration (BMA) is a simple method to study hematopoietic disorders whereas trephine biopsy is of greater value in assessing large piece of marrow. At the same time, imprint is helpful in getting morphological details of individual cell.

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The aim of the present study was to correlate the findings of BMA, bone marrow biopsy, and touch imprints in the diagnosis of pancytopenia/bicytopenia.

SUBJECTS AND METHODS

This 2-year cross-sectional study of 50 cases from year 2017 to 2019 was conducted in the Department of Pathology in GMC, Haldwani. The clinical features of pancytopenia/bicytopenia were noted. Peripheral blood smear and aspirate smears were stained by Leishman's stain and imprint smears were stained with May-Grunwald stain. BMA was performed with Salah's needle whereas bone marrow biopsies (BMBs) were performed with the Jamshidi needle from the posterior iliac crest. Biopsies were then fixed using 10% neutral buffered formalin. Decalcification was carried out by 10% formic acid solution for 24 h. About 4–6 μm thick sections were cut and stained with H and E, PAS, and reticulin.

Criteria for pancytopenia include:
1. Hemoglobin <10 g/dL
2. Platelet count $<100 \times 10^9$/L
3. Absolute neutrophil count $<1.8 \times 10^9$/L.

Inclusion Criteria

All the cases of pancytopenia/bicytopenia in which bone marrow examination was done using all three modalities that are BMA, bone marrow imprint (BMI), and trephine biopsy (BMB) are taken for this study.

Exclusion Criteria

1. Patients with a history of recent blood transfusion
2. Bleeding and coagulation disorders will be excluded
3. Patients with severe thrombocytopenia with platelet count <20,000/mm^3 or platelet functional defect
4. Prolonged prothrombin time, increased international normalized ratio, and prolonged activated partial thromboplastin time
5. Inadequate biopsy specimen
6. Debilitated patients
7. Aspiration or biopsy will not be performed from infected site.

Table 1: Cellularity on BMA, BMI, and BMB

Cellularity	No. of cases (50) BMA	No. of cases (50) BMI	No. of cases (50) BMB
Normocellular	23 (46%)	23 (46%)	23(46%)
Hypocellular	7 (14%)	7 (14%)	22(44%)
Hypercellular	5 (10%)	5 (10%)	5(10%)
Hemodiluted	15 (30%)	15 (30%)	-

BMA: Bone marrow aspiration, BMB: Bone marrow biopsy, BMI: Bone marrow imprint

RESULTS

In this 2-year study, a total of 50 cases of pancytopenia/bicytopenia were analyzed. The age of patient in this study ranges from 21 to 90 years with maximum number of cases in the age group of 11–20 years. Out of 50 cases, 26 cases were of bicytopenia and 24 cases were of pancytopenia. Females were affected more than males.

BMA and imprint were normocellular in 23 cases (46%), hypocellular in 7 cases (14%), and hypercellular in 5 cases (10%); whereas BMB is normocellular in 23 cases (46%), hypocellular in 22 cases (44%), and hypercellular in 5 cases (10%) [Table 1] [Figures 1 and 2].

Among 50 cases of BMB, 24 cases were of pancytopenia. Cellularity of these cases was compared with BMA; in which 12 cases were cellular on BMA as well as on BMB. Three cases which were hypocellular in BMA and nine cases which were hemodiluted turn out to be hypocellular on BMB [Figure 3] [Table 2].

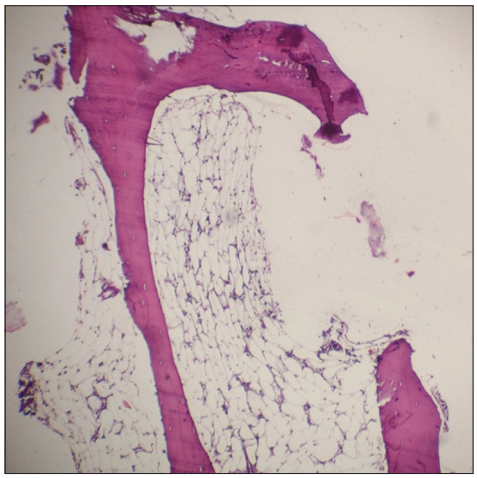

Figure 1: Bone marrow biopsy shows hypocellular marrow (H&E stain, ×100)

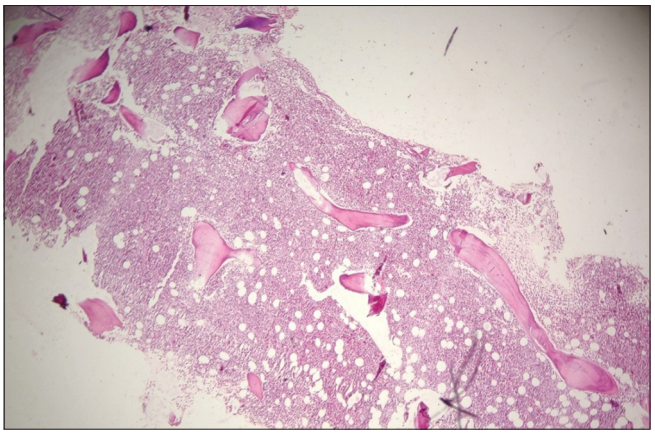

Figure 2: Bone marrow biopsy shows hypercellular marrow (H&E stain, ×100)

Out of 50 cases of BMB, 26 cases were of bicytopenia. Cellularity of these cases is compared with BMA, in which 18 hypocellular and two hemodiluted cases on BMA turned out to be 20 hypocellular on BMB. Two cellular and four hemodiluted cases on BMA turn out to be cellular on BMB [Table 3].

Megaloblastic anemia is the most common finding on BMA, BMB, and BMI and least common cause is metastasis, hairy cell leukemia, and chronic inflammatory disease with gelatinous transformation [Table 4].

About 100% correlation were seen in combined nutritional deficiency, immune thrombocytopenic purpura, metastasis, and hairy cell leukemia followed by 82.06% correlation in megaloblastic anemia, 55.56% correlation in reactive marrow with erythroid hyperplasia, and 50% correlation in acute leukemia [Figure 4] [Table 4].

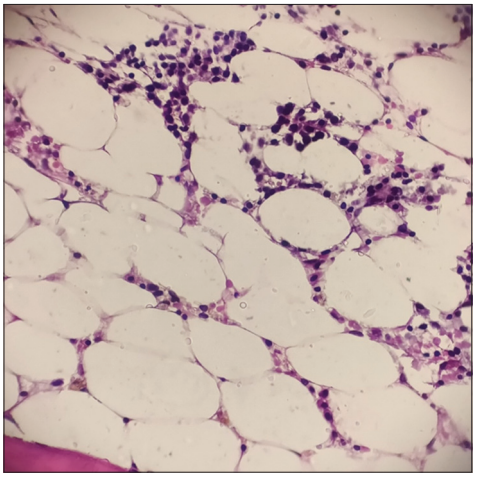

Figure 3: Bone marrow biopsy shows replacement of marrow with fat spaces along with islands of lymphocytes (H&E stain, ×400)

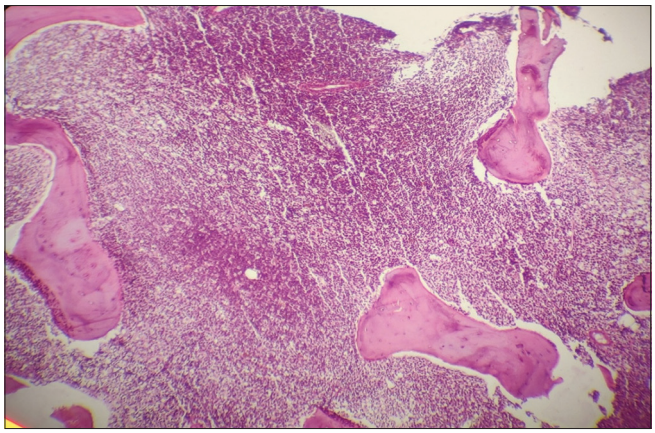

Figure 4: Hypercellular marrow showing diffuse infiltration of marrow with lymphoid cells (BMB; H&E stain, ×100)

In relation to BMB, 100% sensitivity was seen in combined nutritional deficiency, immune thrombocytopenic purpura, metastasis [Figure 5], and hairy cell leukemia.

DISCUSSION

Bone marrow examination is an essential pre-requisite for making diagnosis and the advantage of each procedure differs. These procedures are complimentary to each other and should be performed simultaneously. On all the three modalities, cellularity was assessed and compared according to age. Normocellular and hypercellular marrow was considered as cellular for comparison. Out of 24 pancytopenia cases, BMA and imprint were cellular in 12 cases, hypocellular in three cases, and hemodiluted in nine cases. Whereas in BMB, cellular cases were 12 and hypocellular cases were 12. These findings were in contrast to a study done by Metikurke[2] in which he found 100% correlation between cellularity except in two cases in which they found inadequate BMB.

Table 2: Correlation of cellularity of pancytopenia cases on bone marrow aspirate and biopsy

Cellularity	BMA (*n*=24)	BMB (*n*=24)
Cellular	12	12
Hypocellular	3	12
Hemodiluted	9	-

BMA: Bone marrow aspiration, BMB: Bone marrow biopsy

Table 3: Correlation of cellularity of bicytopenia cases on bone marrow aspirate and biopsy

Cellularity	BMA (*n*=26)	BMB (*n*=26)
Cellular	2	6
Hypocellular	18	20
Hemodiluted	6	-

BMA: Bone marrow aspiration, BMB: Bone marrow biopsy

Table 4: Positive correlation between BMB, BMI, and BMA for various hematological disorders

Diagnosis	BMA	BMI	BMB	Positive correlation (%)
Reactive marrow	5	5	9	55.56
Megaloblastic anemia	19	19	20	82.06
Combined nutritional anemia	3	3	3	100
Acute leukemia	3	3	6	50
Myelofibrosis	0	0	3	0
Immune thrombocytopenic purpura	3	3	3	100
Aplastic anemia	0	0	3	0
Metastasis	1	1	1	100
Hairy cell leukemia	1	1	1	100
Chronic inflammatory disease	0	0	1	0

BMA: Bone marrow aspiration, BMI: Bone marrow imprint, BMB: Bone marrow biopsy

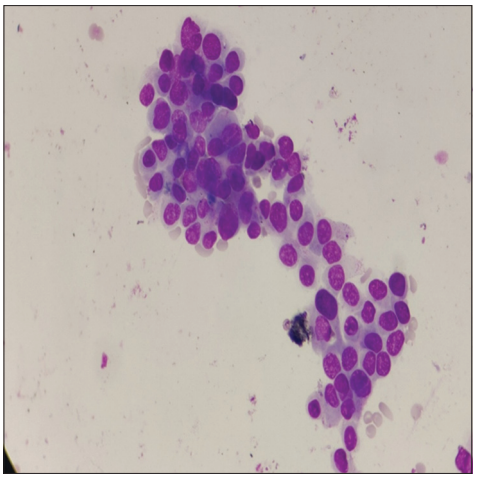

Figure 5: Bone marrow imprint shows sheets of malignant cells (H&E stain, ×400)

Out of 26 bicytopenia cases, BMAs were cellular in two cases, hypocellular in 18 cases, and hemodiluted in six cases. BMB was cellular in six cases and hypocellular in 20 cases. Two cases, which were found hypocellular in BMA, were found to be hypercellular in BMB. Similar finding was made by study done by Gruppo *et al.*[3] in which greatest variance was seen in the hypercellular or normocellular marrows as estimated by biopsy in which 44 of 113 (39%) were interpreted as moderately or severely hypocellular by aspirate.

Out of 24 pancytopenic cases, nine cases were hemodiluted on BMA which turned out to be hypocellular on BMB. Out of six bicytopenia hemodiluted cases on BMA, four cases turned out to be cellular on BMB and two cases were reported as hypocellular. This could be due to faulty BMA technique as our institute being a teaching institute and BMA is mostly performed by postgraduate students. Thus, our study supports that for the assessment of bone marrow cellularity, BMB is the better diagnostic modality.

In all 50 cases, definite diagnosis was made on BMB and strong positive correlation was seen between BMA, BMI, and BMB ($P < 0.00001$).

In our study, combined nutritional deficiency shows 100% correlation which is in contrast to study done Metikurke.[2] Immune thrombocytopenic purpura shows 100% correlation which is similar to study done by Toi *et al.*, Patro *et al.*, and in contrast to a study done by Gilotra *et al.*[4-6]

One case of metastasis diagnosed on BMA/BMI shows acinar arrangement as well as sheets of malignant cells. Furthermore, BMB displayed acinar arrangement and intracellular mucin giving 100% correlation in our study which is in contrast to study done by Toi *et al.*, Tripathy and Dudani, Ghodasara and Gonsai, and Patro *et al.*[5-8]

In the present study, megaloblastic anemia shows 82.6% correlation which is in contrast to a study done by Patro *et al.*, Gilotra *et al.*, and Toi *et al.*[4-6]

Reactive marrow with erythroid hyperplasia shows 55.56% correlation which is in contrast to a study done by Toi *et al.*, Tripathy and Dudani, Ghodasara and Gonsai, and Gilotra *et al.*[4,6-8]

Acute leukemia shows 50% correlation which is in contrast to a study done by Ghodasara and Gonsai, Gilotra *et al.*, and Patro *et al.*[4,5,8]

Our study shows that BMB is the sole diagnostic tool in myelofibrosis (three cases) where BMA yielded diluted marrow or dry tap and BMB demonstrated Grade 3 fibrosis on reticulin stain.

BMB was more helpful in diagnosing aplastic anemia, hairy cell leukemia, and granulomatous lesion. In hairy cell leukemia, BMB demonstrated characteristic spacing of the cells along with Grade 1 fibrosis on reticulin stain. One case of granulomatous lesion, on BMB, demonstrated granuloma with gelatinous transformation which is common finding in chronic inflammatory disease.[9]

CONCLUSIONS

The present study concludes that BMA and BMI give good cytomorphological details and take lesser time in reporting as compared to BMB. BMB whereas is useful for the assessment of cellularity, topography, and fibrosis. BMA alone is usually sufficient to diagnose nutritional anemia, metastasis, and immune thrombocytopenia, whereas trephine biopsy is the sole diagnostic tool in myelofibrosis, granulomatous disease, and aplastic anemia.

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Short Communication

The Interruption of Administering Routine Measles Vaccine in Nepal: A Point of Contention During and Post the Coronavirus Disease 2019 Pandemic?

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Abstract

The interruption of administering routine measles vaccinations has put a significant strain on Nepal's already overburdened health system. Over five significant measles outbreaks have occurred in Nepal since the country's nationwide lockdown began, including in Kathmandu, the Capital. The interruption of immunization programs, as well as a drop in the number of confirmed cases, may have a devastating effect in the coming days, placing the target of eliminating measles by 2023 in jeopardy. In this review, we weigh the long-term impact on public health and consequences of disrupting the national immunization program against staying at home to flatten the coronavirus disease 2019 (COVID-19) surge curve. We speculate that during and post the COVID-19 pandemic; the measles endemic is imminent, particularly due to socioeconomic gaps and unhygienic measures.

Key words: Coronavirus disease 2019, Infectious disease, Measles, Nepal, Southeast Asia region, Vaccine, World Health Organization

INTRODUCTION

A nationwide complete lockdown in Nepal was implemented on March 24, 2020, after the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19) as a Public Health Emergency of International Concern on January 30, 2020.[1,2] The application of the National Immunization Programme (NIP) in the country was widely impacted due to the pandemic-induced lockdowns. NIP is one of the main components of sustainable development goals (SDGs), which has enabled Nepal to complete several milestones of the Millennium Development Goals such as a reduction in under-5 mortality.[3] As a component of SDGs, it is essential to ensure maximal vaccine administration to the pediatric population in Nepal. The immunization and maintenance of vaccine-preventable diseases (VPDs) is pivotal in controlling and eliminating measles, which was endemic in Nepal from 1994 to 2004 and had an annual incidence of 90,000 cases annually. After launching a routine measles vaccination program in the country in the late 1980s, Nepal achieved a 90% reduction in mortality due to measles from 38 in 2003 by more than 90%.[4]

The Government of Nepal collaborated with member countries of the WHO South-East Asian Region (SEARO) to eliminate measles and rubella until 2023, by adopting the "Strategic Plan for Measles and Rubella Elimination 2020–2024." These actions set the groundwork to eliminate both diseases and focus on viable plans to achieve the elimination targets by 2023.[5] However, due to the disruption of immunization by the ongoing COVID-19 pandemic, Nepal faced a major outbreak of measles, especially in five different districts, namely, Jhapa, Sarlahi, Dhading Lalitpur, and Kathmandu.[6] It is pertinent to note that eliminating measles by 2023 is a substantial challenge for the country.

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Given the pandemic-induced setbacks, the following review presents a public health view and perspective of the past, present, and future measles vaccinations.

THE TRENDS AND FEARS OF ACQUIRING ROUTINE VACCINES DURING THE PANDEMIC IN NEPAL

The risk of contracting COVID-19 was perceived to be 49% among respondents in a household survey conducted by UNICEF Nepal between August and October 2020.[7,8] Of 650,000 children who required the measles-rubella vaccines every year, 120,000 (about 20%) missed their scheduled dose in 2020.[9] The coverage of the measles-rubella vaccine is already low in Nepal and the self-perceived risks of contracting COVID-19 by the population have negatively compounded the ongoing efforts to contain the contagious disease. The Government of Nepal completed a nationwide two-phased measles-rubella campaign in 2020 to immunize over 3 million children aged 9 months-5 years. The first phase started in February 1, 2, and 5 and the second phase was planned for March 2020 in provinces Bagmati, Gandaki, Lumbini, and Sudurpaschim, which were significantly affected by the COVID-19 pandemic. The temporary suspension of the second phase of the campaign and routine immunization program is expected to have long-term impacts on eradicating measles by 2023. Although vaccination efforts were resumed amidst the ongoing pandemic, many children were left unvaccinated due to the fear of contracting COVID-19 either through health care workers or visiting health-care centers. The coverage was documented to be 74% in Bagmati Province, the most severely affected province in terms of a measles outbreak and COVID-19 infection. The fear of being exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as well as public movement restriction has led to the low coverage in the province.[10]

MEASLES CASES REPORTED TO THE WHO DURING 2018–2020: TRENDS IN NEPAL

Figure 1 represents the annual incidence of measles cases reported to the WHO through the national disease surveillance system.[11] The plot shows the number of cases reported every month, from 2018 to 2020. A total number of 260 positive cases were reported in 2018 followed by 431 and 401 in 2019 and 2020, respectively. The steep rise in measles cases from February to April 2020 amidst COVID-19 lockdown is a cause of contention for public health strategists in the nation. However, the decline in measles cases from April through December 2020 warrants concern as the lack of strong surveillance systems in Nepal may have led to diminished numbers during the lockdown.

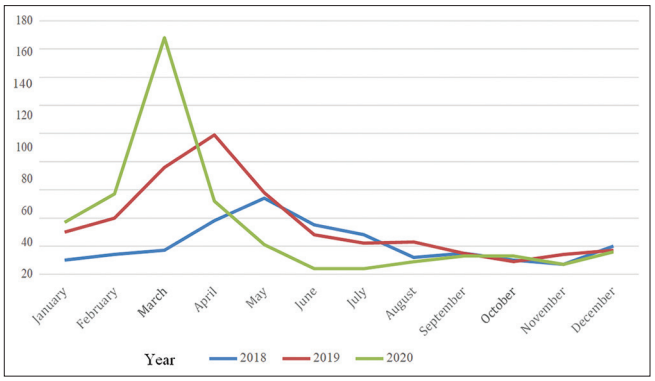

Figure 1: Measles cases were reported to WHO by Nepal for the years 2018, 2019, and 2020 (11)

While the transmission of measles and rubella seems to have been suppressed during the COVID-19 pandemic, it must be acknowledged that vulnerable populations are at direct risk of acquiring measles infections during and post the pandemic. At this juncture, ensuring the access to vaccination of all the susceptible populations is a cause of public health concern in Nepal. While it is currently unclear whether the long-lasting effects of the COVID-19 pandemic will undermine routine immunization efforts, a population-based study analyzing the pediatric population's vulnerability and outcomes are warranted. Robust surveillance of measles-like diseases and identification of high-risk areas with community transmission of measles for immediate action are the key to eliminate measles by 2023.

A BRIEF OVERVIEW OF VACCINATION TRENDS ACROSS THE GLOBE

Progress on immunization coverage is lacking, even before the COVID-19 pandemic struck the globe, at 85% for Diphtheria-Pertussis-Tetanus (DTP3) and measles vaccines. Despite the dearth of data, around 14 million children did not receive life-saving vaccines such as measles and DTP3 in 2019. A majority of these children were African residents and present similar health-care barriers as do Nepalese residents. Two-thirds of these 14 million children are concentrated in 10 low- and middle-income countries (LMICs): Angola, Brazil, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Mexico, Nigeria, Pakistan, and the Philippines.[9] The progress and global success in achieving vaccination milestones is setback due to COVID-19-related barriers to health-care access. Many LMICs with documented epidemiological improvements are at risk of backsliding if immunization services are not restored.[9] Visits of the pediatric patient population to any health facility have decreased drastically all over the world, possibly due to the halt in service provision at the majority of the vaccination centers across the

globe.[9] Moreover, high-income countries have faced a similar decline.[12] The immunization rates in the United States (US) dropped to as much as 73%, translating to the statistic, that three in four children have not received their vaccine dose.[9] The United Kingdom (UK) also faced a fall in emergency department visits by over 90% during April 2020. Legal guardians and parents expressed concerns about overburdening the national health-care system and fears of being exposed to COVID-19 on routine vaccination visits.[13] In parts of Africa like DR Congo, thorough care is recorded for COVID-19 and Ebola virus disease; moreover, there have been 369,520 measles cases with 6779 deaths in the past year suggesting a potential threat of a resurgence of another vaccine-preventable infectious disease.[14]

AN EPIDEMIOLOGICAL OVERVIEW OF MEASLES IN THE SEARO REGION

An epidemiological qualitative overview of measles in the SEARO region is presented, with the following countries: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, and Timor-Leste. As illustrated in Figure 2, the total number of confirmed measles cases has been the highest in India (5598), followed by Bangladesh (2410), Thailand (789), Indonesia (393), and Nepal (388). Nepal is ranked fifth, with the highest number of confirmed cases in 2021. As compared to larger populations like India, the relative incidence in Nepal has peaked through May 2021.

A comparison of the number of measles cases reported by confirmation methods until May 2021 in the SEARO region is illustrated in Figure 3. On noting the methods and the total number of reported cases in the region, India faced the highest burden of disease, with the highest number of lab-confirmed measles cases. An EPI link was also found to be the highest in India followed by Nepal as the second highest country to have lab-confirmed measles cases [Figure 3]. As of May 2021, the population of Nepal is 29,602,256, while India's population is 1,392,086,685. On analyzing these trends qualitatively, it is of note to public health authorities that the individual number of cases in Nepal is comparable to those reported in India, necessitating active surveillance in Nepal.

On noting the incidence rate per 1,000,000 total population as of May 2021, Maldives presented with the highest incidence at 40% [Figure 4]. While surveillance systems have possibly weakened due to lack of accessibility during the pandemic, the trends are significant. Nepal had the second highest incidence with a documented rate of 17% followed by Thailand (15%) and Myanmar (15%). India, which reported the maximum number of cases as of May 2021, had a documented incidence of 5%, which leads to concerns about the rapid uprise in both Nepal and the Maldives [Figure 4].

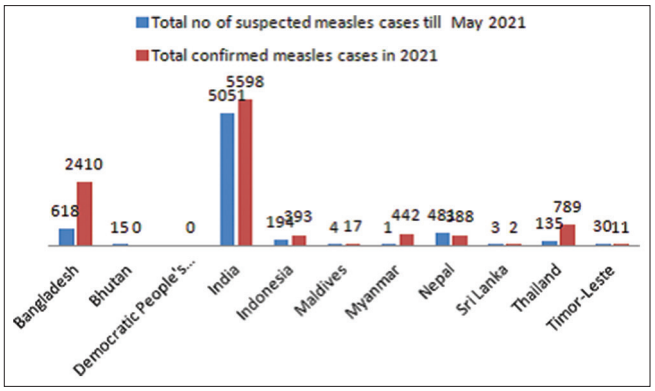

Figure 2: A comparative bar diagram to assess the number of measles cases reported in the SEARO region

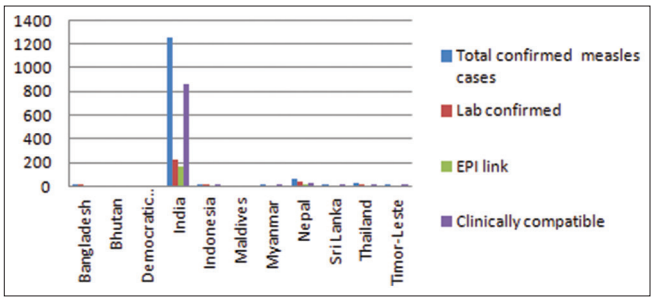

Figure 3: The number of measles cases reported in the SEARO region by confirmation methodsas of May 2021

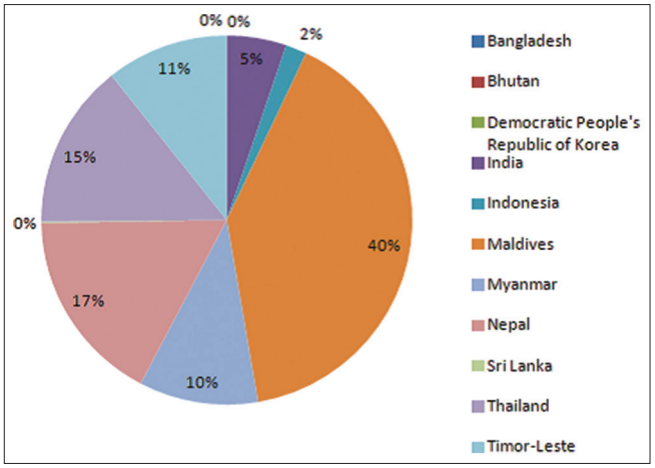

Figure 4: The rate of measles incidence per 1,000,000 total populations as of May 2021

NOTABLE DISCREPANCIES IN OUTCOMES OF SUSPENDED VACCINATION SCHEDULES

As global health authorities have spent their time, finances, and health care workers planning on the impact

of the coronavirus pandemic, measles outbreaks have gained recurrence in the South-East Asian region. A disproportionate proportion of populations, especially those of the socioeconomically stratified group, is impacted indefinitely. According to a Nepalese study, national immunization programs ought to increase immunization coverage in the country at large, with a specific focus on mothers with disadvantaged backgrounds and the economically stratified.[15] Consequently, in the least developed countries such as DRC or Nepal, the logistic and infrastructural limitations within the health-care delivery system contributed to inadequate vaccination coverage. Clinics have been understaffed, lacked vaccine supplies on a rolling basis, and lacked the necessary equipment, power, or generators to ensure cold chain running. In addition, an inefficient cold chain, in combination with a Supplemental Immunization Activity and a 5-day time limit, presents an obstacle, as these limitations prohibit these campaigns from reaching children in rural areas.[16] Dropout rates are also a major challenge, wherein public health authorities have been unable to reach the remotest corners of members in the SEARO, and children have missed their vaccinations because of migration.[7] Many developing countries such as Maldives and Nepal, in Southeast Asia, reported a high incidence of measles per 1,000,000 populations, confirming the discrepancies in vaccination efforts. Measles is a causative factor for mortality in more than 95% of populations with low per capita incomes compounded by inadequate health care surveillance systems. Measles outbreaks can be particularly deadly in countries like Nepal and others in the SEARO that are either actively fighting or recovering from public health burden due to COVID-19. Overcrowding in residential camps significantly raises the risk of infection, and damage to health facilities and services interrupts regular immunization in Nepal.[17]

STEPS FORWARD AND GLOBAL INVOLVEMENT TO PROMOTE MEASLES VACCINATION EFFORTS

As recommended by Acharya *et al.*, direct intervention for the most disadvantaged people is a critical strategy to reach universal immunization coverage and to reach vaccination targets by 2023. Southeast Asian policy-makers must be strategic in tackling social and economic disparities in immunization by placing disadvantaged families at the forefront of health intervention designs, which could minimize the frequency of VPD mortality and morbidity in the pediatric population.[15] The underreporting of measles and rubella infections, as well as collective awareness of the significance of attaining and sustaining high population immunity to eliminate and prevent measles and rubella transmission, is a key to avoiding disease transmission when the vaccine is due but cannot be administered during pandemics.[18] For specific VPDs, WHO-coordinated surveillance networks have been developed to assist Ministries of Health and surveillance sites.[19] The WHO Immunization Preventable Diseases collect data on a weekly, nil, and monthly basis for diseases such as acute flaccid paralysis, measles-like infections, maternal and neonatal tetanus, and acute encephalitis syndrome. Timely surveillance is critical for monitoring and eradicating measles and rubella. Early detection of outbreaks, the study of ongoing transmission, and estimation of true occurrence based on patterns in recorded data are all possible with surveillance. The WHO Member States report measles and rubella cases identified through national disease surveillance systems monthly. However, since both suspected and confirmed cases are underreported, the true number of cases that occur in the population remains uncertain.

The unspecified suspension of routine immunization is an indefinite solution to the COVID-19 pandemic, however, the possible risks of restoring immunization are far lower than contracting measles. To ensure that the pandemic-induced impact is reduced in the upcoming years, regional and international intervention is vital through means of updated yearly goals and provision of more vaccines in Nepal. WHO has planned to safely reinstate the vaccination program by maintaining social distancing; in addition, the joint brief intends to conduct immunization services, screen children for the detection of "fever and dry cough" before vaccination, manage personal protection for the safety of health care workers, provide immunization to all targeted (15 months and below) children, and last inform and coordinate immunization services to the local administration in Nepal.[13] Moving forward, these efforts are likely to contain the resurgence of measles in Nepal and neighboring Southeast Asian countries.

CONCLUSIONS

Outbreaks of VPD cases such as measles, which are otherwise considered low priority for public health contingency plans, have been on the rise since the onset of the COVID-19 pandemic. The fears and stigmas associated with contracting SARS-CoV-2 may be causative in reduced measles vaccination in Nepal and across Southeast Asia, which have contributed to an increased incidence during February and March 2020. The unvaccinated pediatric population is more vulnerable to diseases like measles, as compared to the pre-pandemic vaccinated group, once social distancing and lockdowns are lifted in Nepal. We speculate that during and post the COVID-19 pandemic; the measles endemic is imminent, particularly due to socioeconomic

gaps and unhygienic measures. By maintaining social distancing and hygiene practices in Nepal, in accordance with COVID-19 safety guidelines, and using mitigating factors, a priority set immunization may be the public health response in the prevention of future measles outbreaks.

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