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Case Report

Mid-ventricular Obstruction in Hypertrophic Cardiomyopathy: A Case Report

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Abstract

Mid-ventricular hypertrophic obstructive cardiomyopathy (HOCM) is an uncommon type of hypertrophic cardiomyopathy (HCH). In this case study, we reported the case of a 48-year-male patient with HCH, he was admitted because of severe rheumatic MS in pulmonary edema. After initial treatment, decision was made to put the patients on a peripheral VA extracorporeal membrane oxygenation (ECMO). He recovered well by minimal invasive therapy under the support of ECMO. Thereafter, he was shifted from intensive care unit with a decreasing creatinine values, good urine output, and good left ventricular and right ventricular functions and released from hospital without any further complications.

Key words: Mid Ventricular Obstruction, Hypertrophic Cardiomyopathy, Systolic Anterior Motion Of Anterior Mitral Leaflet

INTRODUCTION

Hypertrophic cardiomyopathy (HCM) is characterized by the occurrence of abnormal left ventricular (LV) wall thickening that is typically asymmetrical and not exclusively explained by conditions such as hypertension, aortic valvular stenosis, or valvulopathies.[1,2] It is also linked with myocardial fiber disarray.[3,4] The LV hypertrophy is mainly affecting the interventricular septum. In adults, majority of HCM is caused by mutations of the cardiac sarcomere genes. It is inherited by autosomal dominant trait.[5] Genetic variation in at least eleven genes and mutations involving myosin heavy chain (MYH7) and myosin-binding protein C3 (MYBPC3) are most common in HCM.[6]

In majority of HCM patients, dynamic LV outflow tract (LVOT) obstruction occurs which is a classic pathophysiological characteristic of the disease.[7] Outflow obstruction is usually produced by mitral valve systolic anterior motion (SAM) and septal contact due to flow drag, also resulting in mitral regurgitation. Under resting conditions or during exercise (physiological provocation), the LV outflow obstruction (gradients ≥30–50 mmHg) is found in approximately 70% of HCM patients.[8] LVOT obstruction occurs mainly at the subaortic level, mostly due to SAM of the mitral valve.[1,2] SAM is formed by a pull effect in the occurrence of high-velocity LV ejection, and it is mainly accountable for concomitant mitral regurgitation due to partial leaflet apposition.[6,7] Moreover, in variant HCM cases, the obstruction to flow arises at the mid-ventricular level, unlike to SAM. Mid-ventricular is mainly caused by contact of septal hypertrophy with a hypercontractile anterolateral LV wall (interposition of anterolateral papillary muscle and hypertrophic longitudinal muscle bands on the posterolateral wall of the LV).

Mid-ventricular hypertrophic obstructive cardiomyopathy (HOCM) is a rare variety of HCM, mostly overlooked. HOCM is characterized by asymmetric LV hypertrophy and by a pressure gradient between basal and apical sites in the left ventricle. Mid-ventricular HOCM in association with an apical aneurysm has rarely been reported. This can remain occult and manifest only when a trigger worsens it. HOCM is a big challenge for clinician, once it is linked with severe symptoms and unstandardized management and treatments. This case study is an attempt to address this matter; therefore, we conducted a case report of mid-ventricular obstruction in HCM patients. Our case conference describes such an example where occult HOCM became evident with high

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gradients in the post-operative period triggered by worsening of the right ventricular (RV) dysfunction.

CASE DESCRIPTION

A middle-aged person of 48 years old, known case of rheumatic heart disease (RHD), had undergone AVR in 1998 for severe AS and AR. Nine years down the line, he had stuck aortic valve prosthesis, got lysed successfully. Now, he complained of mild dyspnea and frequent palpitations. He presented with severe rheumatic MS, in pulmonary edema. Transthoracic echocardiogram (TTE) showed severe MS, dilated LA, good LV function, no PAH, RV basal TDI 6.8, and mild TR. He was taken up for MVR. Induction with etomidate, fentanyl, and vecuronium was uneventful. Re-do sternotomy was uneventful. The echocardiogram (ECG) showed asymmetric hypertrophy of the LV, MVR with a 23 mm OnX valve, clamp time 90 min, and pump time 120 min. He had one e/o VT during rewarming, was defibrillated with 50 J came off CPB on dobutamine 5 mcg/kg/min. Furthermore, TEE post-CPB showed good LV systolic function, dysfunctional RV with TAPSE 15, FAC was 18%, trivial TR, prosthetic mitral valve functioning well, mean gradient 3, DVI 1.1, and aortic valve prosthesis functioning well.

Moreover, the patient was wheeled into ICU with a cardiac index of >2, lactates of 5, and P/F ratio 400, on mechanical ventilation sedated. After 24 h, the patient experienced rapid breathing (tachypnea) with rise in airway pressures, also fall in urine output and rise in potassium levels. However, the cardiac index (CI) was found to be relatively stable around 1.8–2.00, the sudden increase in CVP from 7 to 23, with mild PAH. About 22% of MVO_2 was observed at this time. Furthermore, the systemic pressures dropped, along with fall in SVR. Transthoracic echocardiogram (TTE) further showed good LV function but dysfunctional RV and an LV mid-ventricular gradient of 120 mmHg (Figure 1) and dysfunctional Right ventricle (Figure 1). At that moment, to maintain systemic pressures, noradrenaline and vasopressin infusions were administered. In view of the MVO, dobutamine was discontinued for its inotropic action that would worsen the obstruction. Then, iNO was initiated to recover and improve RV forward output. With iNO, the airway pressures stabilized and CVP came down to ~10–11. Thereafter, the patient was carefully filled using crystalloid solutions. MVO_2 saturation improved further to 40%. Then, inhaled nitric oxide (iNO) was weaned due to rise in metHb and was bridged with Sildenafil (tab). Following day, the patient went into oliguria, and RV dysfunction further worsened dramatically, with a fall in P/F ratios up to <100. Although small dose of adrenalin was initiated for the RV inotropy, there was not much positive response

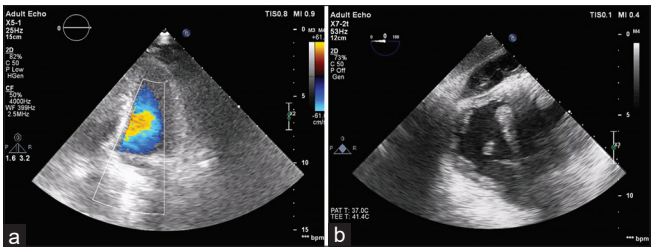

Figure 1: (a) Mid-ventricular turbulence. (b) Empty left ventricular with dysfunctional right ventricular

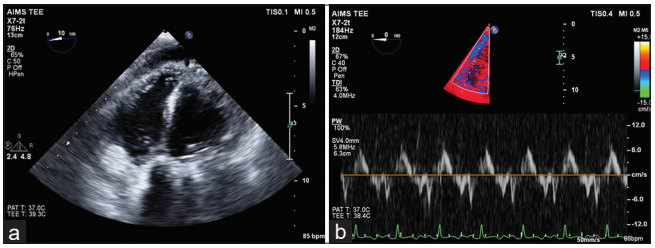

Figure 2: After 4 days of extracorporeal membrane oxygenation (ECMO) support. (a) Post-ECMO weaning, (b) post-ECMO right ventricular (RV) function better: Peak velocity TDI- RV lateral wall ≈8

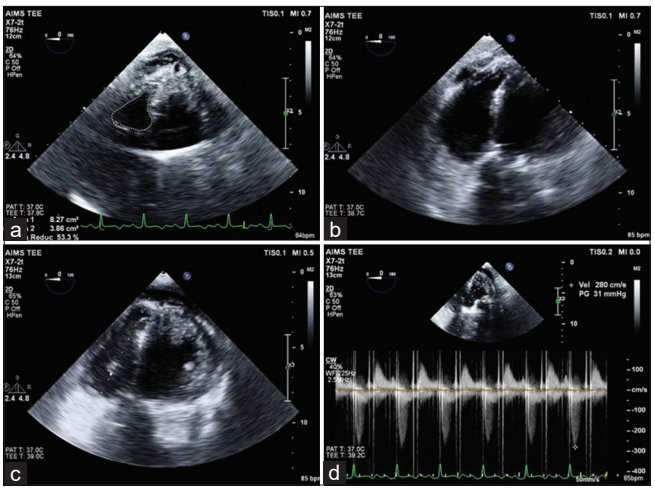

Figure 3: (a) FAC improved, (b) right ventricular (RV) contractility longitudinal excursion, (c) RV contraction short axis, and (d) RV function better, mid left ventricular gradient disappeared

and in that circumstances, decision was made to put the patients on a peripheral VA extracorporeal membrane oxygenation (ECMO). Moreover, femoral vein and artery were cannulated under TEE guidance with a limb perfusion cannula and ECMO was initiated. Perfusion pressures were maintained at `60 mean, and vasopressin was tapered off. Furthermore, UF was done using the ECMO circuit. ECMO was discontinued on the 4th day. During weaning off ECMO, a minimal dose of adrenalin and noradrenalin was maintained. TEE revealed fairly good RV function and LV function, with minimal turbulence but no mid ventricular gradient (Figures 2 and 3).

There was a transient rise in CVP after ECMO decannulation but it settled with a hike up of adrenalin dose and fluid removal with CRRT. Patient was tracheostomized and subsequently over the 2 days was weaned off inotropes and mechanical ventilation. By 2 weeks, parent renal parameters started improving and HD could be made less frequent. He had grown *Klebsiella* and *Enterococcus* from blood, was treated with sensitive antibiotics. The patient was then shifted to the ward on POD 25 with a decreasing creatinine values, good urine output, and good LV and RV functions.

DISCUSSION

Mid-ventricular HOCM is an uncommon type of HCH that is frequently accompany by the apical aneurysm.[9] Prior study suggested that patients with a history of HCM and mid-ventricular obstruction, had great chance of sudden death.[10] The exact pathogenesis of HOCM remains unclear, however, it had been demonstrated that apical aneurysm might be resulting to the enlargement after increase of apical pressure from the mid-ventricular obstruction seen in the degenerative process of hypertrophic HCH.[11] Other causes of apical aneurysm development are small-vessel disease with reduced coronary flow reserve, strained of coronary artery because of the increased wall pressure in the hypertrophic myocardial part, reduced coronary perfusion pressure due to mid-ventricular obstruction, and decreased capillary myocardial fiber ratio and coronary artery spasm.[11,12] Since the patient exhibited dysfunctional RV in the severe stage of his illness, we assume that the apical aneurysm has its beginning in a severe coronary artery episode, for instance, coronary artery compression or coronary microcirculation due to elevated pressure overload and systolic myocardial wall pressure linked with an intensely occurred mid-ventricular obstruction.

Appropriate management and treatment of HOCM is ambiguous, however, failure to intrude may result in lethal ventricular arrhythmias and death. In HOCM condition, β-blockers are the initial choice of treatment,[13] however, the management for mid-ventricular HOCM has still unknown. The presented case was considered as drug-resistant mid-ventricular HOCM since even after initiation of two medicines, the LVOT pressure gradient was found abnormal, and thereafter, ECMO support was administered. Thus, the patient was suitable candidate for minimal invasive therapy, in view of his age and responses.

CONCLUSION

Mid ventricular obstruction is a rare variant Hypertrophic cardiomyopathy and awareness of this mid ventricular obstruction and management can avoid catastrophe.

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Case Series

Clinical Presentations of Soft-Tissue Sarcoma – A Case Series

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Abstract

This article will be dealing about multiple clinical presentations of various musculoskeletal tumors. They are a rare and heterogeneous group of malignancies, which are best managed by multidisciplinary teams in specialist sarcoma referral centers. Historically, the standard for local control of these tumors has always been amputation. Evolution in multimodality treatment has seen a shift toward preservation of the limb. Advances in limb sparing surgery have seen the quality of life in sarcoma patients to improve drastically; however, unplanned surgical excision of sarcomas remains a major treatment dilemma in the control of local disease. A 30-year-old female presented with swelling over lower back and on investigations revealed to have a large fibromyxoid sarcoma. Neoadjuvant was not indicated and the patient was planned for surgical excision first. A 30-year-old male presented with swelling over nape of neck associated with weakness in the right upper limb and on investigation was found to have neurofibroma. The patient underwent surgical excision first and then sent for radiotherapy. A 62-year-old male presented with the complaint of swelling over the left side neck and upper chest wall, and on investigations, the diagnosis was under dilemma between lymphangiosarcoma and liposarcoma. The patient was planned for excision. A 35-year-old male presented with swelling over the left upper limb. On investigation, malignant fibrous histiocytoma was noted and the patient was planned for excision. Although sarcomas are diverse in nature, the treatment approach is same. It is a multidisciplinary approach with the surgical excision being the mainstay of treatment in non-metastatic sarcoma and chemotherapy in metastatic carcinoma. Limb salvation is always tried. Advances in radiotherapy have helped decrease local adverse effects and sustain good local control of the disease. Hence, the importance of team management cannot be overlooked and if possible, all three modalities can be tried for better prognosis of the patient.

Key words: Sarcoma, Soft Tissue, Tumours

INTRODUCTION

Sarcomas make up <1% of all cancers. Sarcomas occur in 2–4 people/100,000 population and its >60 subtypes are divided into two broad categories: STS and bone sarcomas.[1]

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Rhabdomyosarcoma is the most common STS (soft-tissue sarcoma) in children, whereas undifferentiated pleomorphic sarcoma is the most common in adults.[2]

The analysis of large SEER database shows that the age-adjusted incidence of sarcomas arising in soft tissue is 3.1/100,000 irrespective of gender. These rates are little higher in men (3.8/100,000) than woman (2.6/100,000).[3]

Soft-tissue sarcoma (STS) is a diverse group of more than 60 neoplasms that can arise from virtually any anatomic site and can affect the very young as well as the elderly. Sarcomas are of mesenchymal origin. The tissue types of

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STS origin include skeletal muscle, adipose cells, blood and lymphatic vessels, and connective tissue or those cells with a common mesoderm origin. Taxonomy of soft-tissue sarcoma mentioned in Table 1.

Large published series demonstrate that extremity and trunk STS is more common than intraperitoneal and retroperitoneal STS.[5]

The adverse prognostic factors for soft-tissue sarcomas' are: Size, increasing age, high grade, metastasis at diagnosis, local recurrence at diagnosis (following unplanned excision), positive surgical margin, deep to muscular fascia, and high levels of tumor necrosis.[6-8]

MATERIALS AND METHODS

- Place: Department of General Surgery, M. Y. Hospital, Indore
- Duration: July 2021–July 2022
- We identified four patients (three men and one woman, mean age at presentation 41 years, range 15–79 years).

Patients were eligible for inclusion if they had histologically confirmed soft-tissue sarcoma that came in MYH Hospital, Indore, in General Surgery Department. We extracted the following information from each patient's medical record: Age at presentation, sex, disease status at presentation (primary, locally recurrent, or metastatic), prior treatment, medical history, histological diagnosis, lesion characteristics (tumor size, location, depth, grade, and involvement of neurovascular and vital structures), details of treatment (pre- or post-operative chemotherapy or radiation therapy, resected structures, surgical margins, reconstructive technique, and complications), and condition at follow-up. Staging was performed using the system proposed by the American Joint Committee on Cancer (AJCC).

Study Protocol

- After proper consent from the patient, complete history taking was done.
- Complete joint and limb examination was done with orthopedic and cancer opinion.
- All blood investigations were sent along with chest X-ray, respective limb X-rays, and complete cardiac workup of the patient.
- High-end radiological investigation was done to rule out any metastasis and to evaluate the locoregional spread and margins of the tumor for proper planning of the treatment plan.
- Biopsy of the tumor and histopathology report taken into consideration.
- Treatment plan formulated in multidisciplinary fashion.

CASE SERIES

Case Report 1

A 30-year-old female presented with swelling over lower back, apparently noticed 2 years back. The patient also had intermittent episodes of back ache. The patient underwent local excision of the mass which reoccurred and came to MYH Hospital for definitive treatment.

On examination, no lower limb sensory-motor neuropathy noticed. Size of mass was ~25 × 20 cm over lower back which was soft and cystic in consistency and not fixed to the underlying structures [Figures 1 and 2].

Figure 1: Lateral View of mass

Figure 2: Posterior Aspect

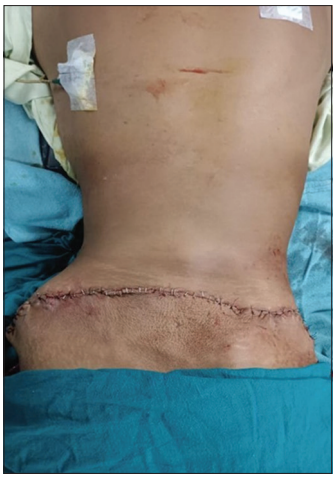

Figure 3: Post-operative image

MRI LS spine was suggestive of neurofibroma. The patient underwent excision of mass and intraoperatively "GOOEY" like content ~2 L aspirated from the mass and sent for histopathology, which was suggestive of fibromyxoid sarcoma [Figure 3].

The patient was later referred for radiotherapy.

Case Report 2

A 30-year-old male belonged low socioeconomic status and presented with the complains of swelling over nape of the neck which he apparently noticed 2 years back which gradually increased in size. The patient came to the surgery department when he developed pain in the back of neck and upper back which radiates to right upper limb with slight weakness.

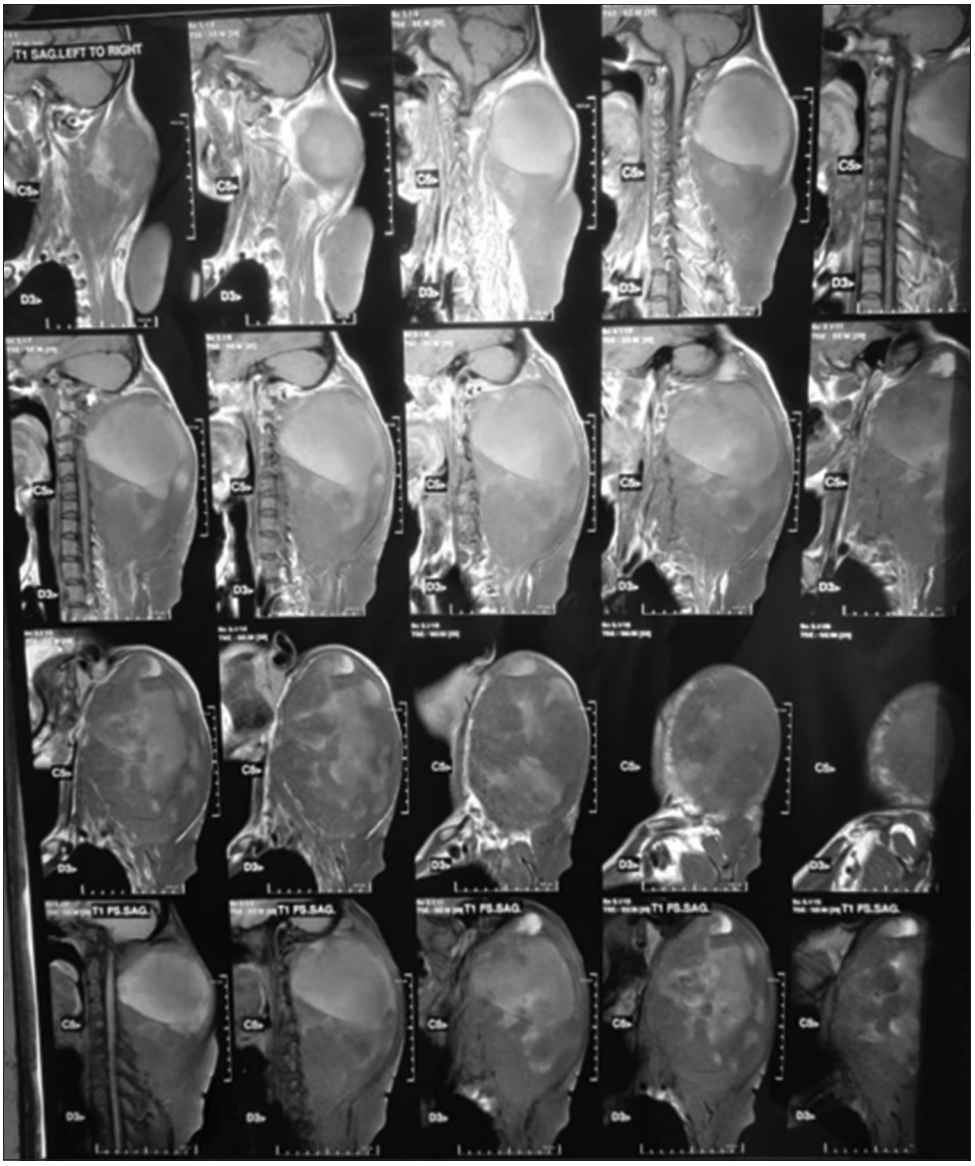

Figure 4: MRI- Showing extent of tumor

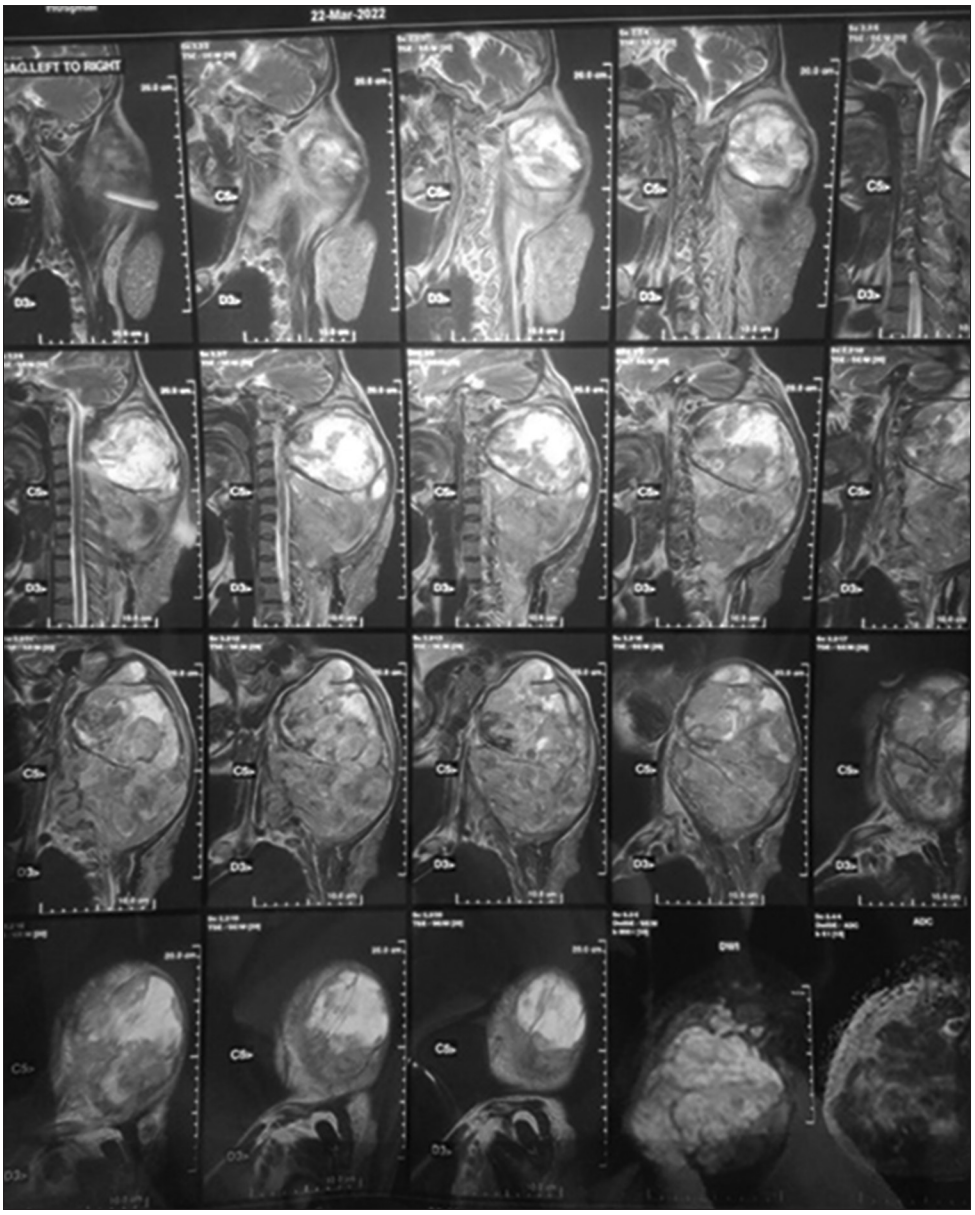

Figure 5: MRI- Showing extent of tumor

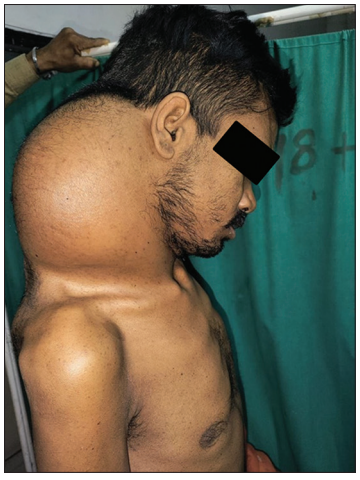

Figure 6: Lateral view

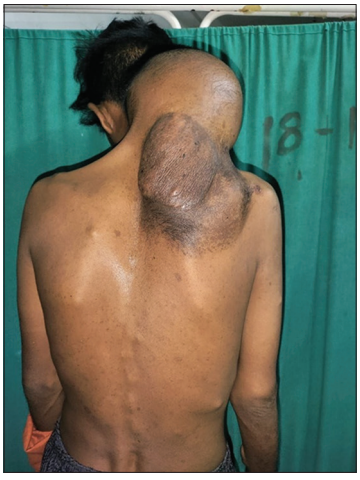

Figure 7: Posterior View

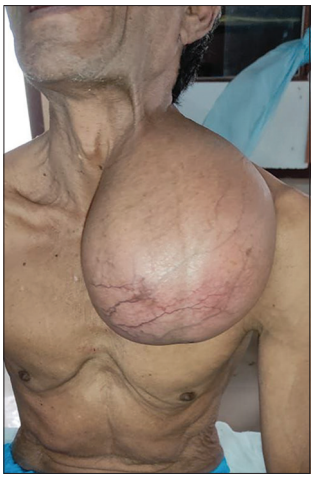

Figure 8: Pre-operative image

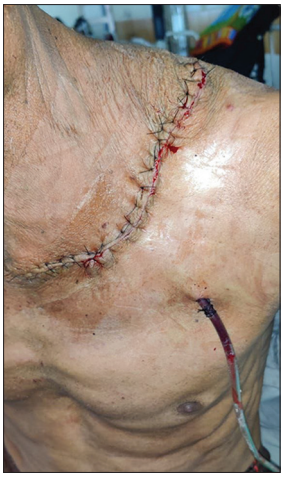

Figure 9: Post-operative image

On examination, a large ~20 × 20 cm soft to firm in consistency solid mass located at right side nape of neck, which was fixed to the underlying structures associated with restriction of neck movements. Similar small hard nodular multiple lesions were present over torso.

MRI was suggestive of soft-tissue sarcoma which was extended from occipital region to D3 with cord abutment at C5-6 level. True-cut biopsy suggestive of neurofibroma [Figures 4 and 5].

Excision was planned and specimen sent for histopathology. Histopathology suggestive of spindle cell tumor with neural differentiation (malignant peripheral nerve sheath tumor) [Figures 6 and 7].

The patient was sent for radiotherapy.

Case Report 3

A 62-year-old male presented with the complaint of swelling over the left side neck and upper chest wall, apparently noticed 1.5 years back which gradually increased in size with no complaint of pain, respiratory distress, facial swelling, and any neurological deficit.

On examination, large ~20 × 20 cm soft, solid mass was present over the left side of neck, non-tender, and mobile. Investigations were not clearly depictive of histological type [Figures 8 and 9].

USG suggestive of lymphatic malformation whereas CECT neck was suggestive of liposarcoma which was extending in lateral aspect of left thorax as well with no pleural extension.

Table 1: Taxonomy of soft-tissue sarcoma[4]

Tissue of origin (histogenesis)	Type of sarcoma
Adipocytic	Myxoid/round cell liposarcoma
	Pleomorphic liposarcoma
	De-differentiated liposarcoma
	Well-differentiated liposarcoma
Chondro-osseous	Mesenchymal chondrosarcoma
	Extraskeletal osteosarcoma
Fibro-/myofibroblastic	Desmoid-type fibromatosis
	Superficial fibromatosis
	Myxoinflammatory fibroblastic sarcoma
	Solitary fibrous tumor
	Dermatofibrosarcoma Protuberans
	Adult fibrosarcoma
	Low-grade fibromyxoid sarcoma
	Myxofibrosarcoma
	Sclerosing epithelioid fibrosarcoma
	Congenital fibrosarcoma
	Myofibroblastic sarcoma
Fibrohistiocytic	Giant cell tumor of soft tissue
	Plexiform fibrohistiocytic tumor
	MFH
Uncertain differentiation	Mixed tumor/myoepithelioma
	Chordoma
	Ossifying fibromyxoid tumor
	Epithelioid sarcoma
	Malignant mesenchymoma
	Alveolar soft part sarcoma
	Clear cell sarcoma
Nerve sheath	Malignant nerve sheath tumor
Pericystic	Malignant myopericytoma
	Malignant glomus tumor (and variants)
Skeletal muscle	Pleomorphic rhabdomyosarcoma
	Sclerosing rhabdomyosarcoma
	Spindle cell rhabdomyosarcoma
	Embryonal rhabdomyosarcoma
	Alveolar rhabdomyosarcoma
Smooth muscle	GIST
	Deep-seated/visceral leiomyosarcoma
	Cutaneous leiomyosarcoma
Vascular	Epithelioid hemangioendothelioma
	Angiosarcoma
	Kaposi's sarcoma
	Retiform hemangioendothelioma
	Composite hemangioendothelioma
	Kaposiform hemangioendothelioma

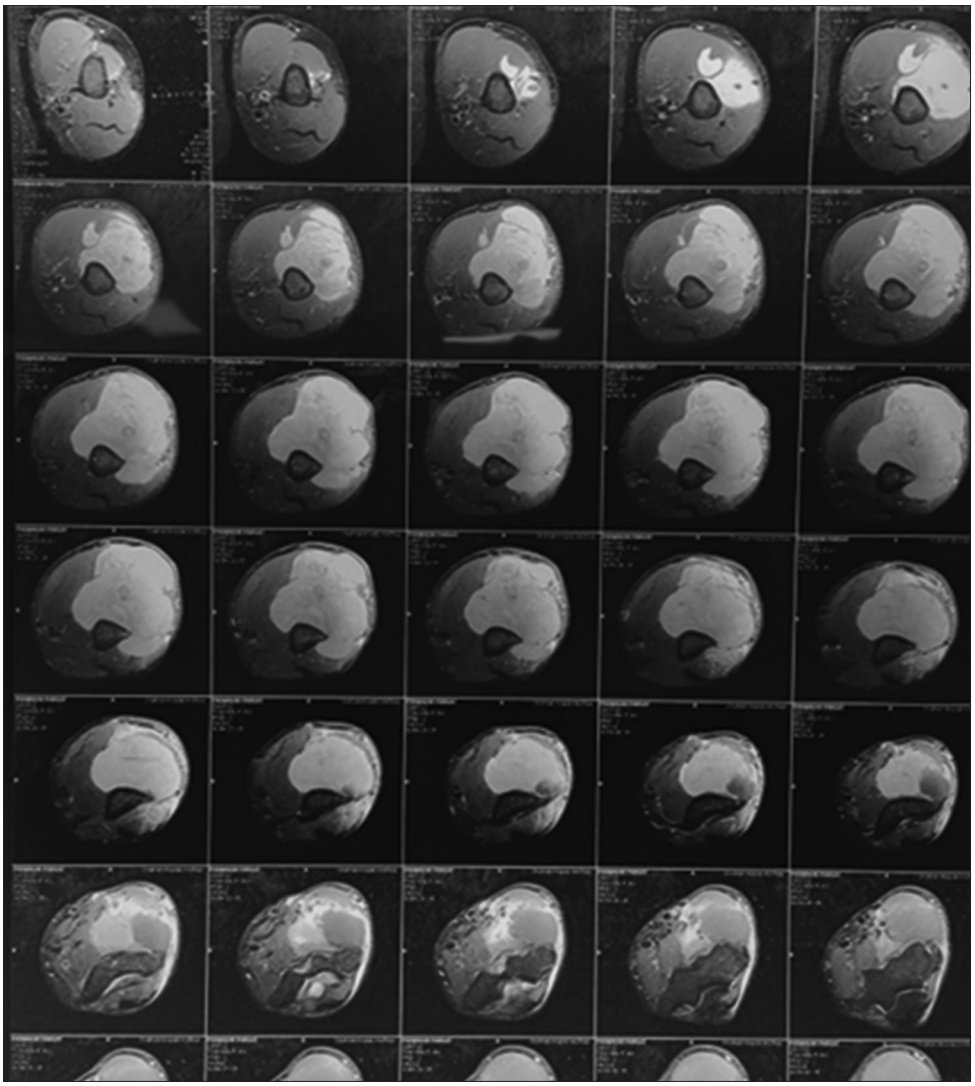

Figure 10: MRI- Showing extent of tumor

Surgical excision was planned. Intraoperatively, mass was found extending into the thorax through infraclavicular route [Figure 9]. Due to lack in proper planning, wide local excision of mass was done and specimen sent for histopathology. The patient has been asked to follow up with report to plan for thoracotomy and excision of the residual mass.

Case Report 4

A 35-year-old male presented with swelling over the left upper limb (forearm) for 4 years which gradually increased in size over the time, leading to difficulty in weight lifting and physical day-to-day activity. The patient had no complaints of sensory loss.

On examination, 10*10 cm large mass presents over lateral aspect of forearm just below cubital fossa [Figures 10 to 14.

The patient on MRI did not show any bony invasion and mass had a clear delineation from the underlying bone. Histopathology was suggestive of malignant fibrous histiocytoma.

Excision of mass was done and no functional disability in hand functioning was noted in the post-operative period.

DISCUSSION

As STS constitutes a heterogeneous group of rare tumors, management by experienced multidisciplinary team of specialists should be the standard of care from the time of diagnosis. Recent studies found that patients with STS who underwent treatment with multidisciplinary approach at high-volume hospitals had far better survival rates than those at low-volume setups without specialist care[9] and even when managed adequately have a 5-year survival rate of 62–84%.[10] For successful treatment of STS, early diagnosis is the key.

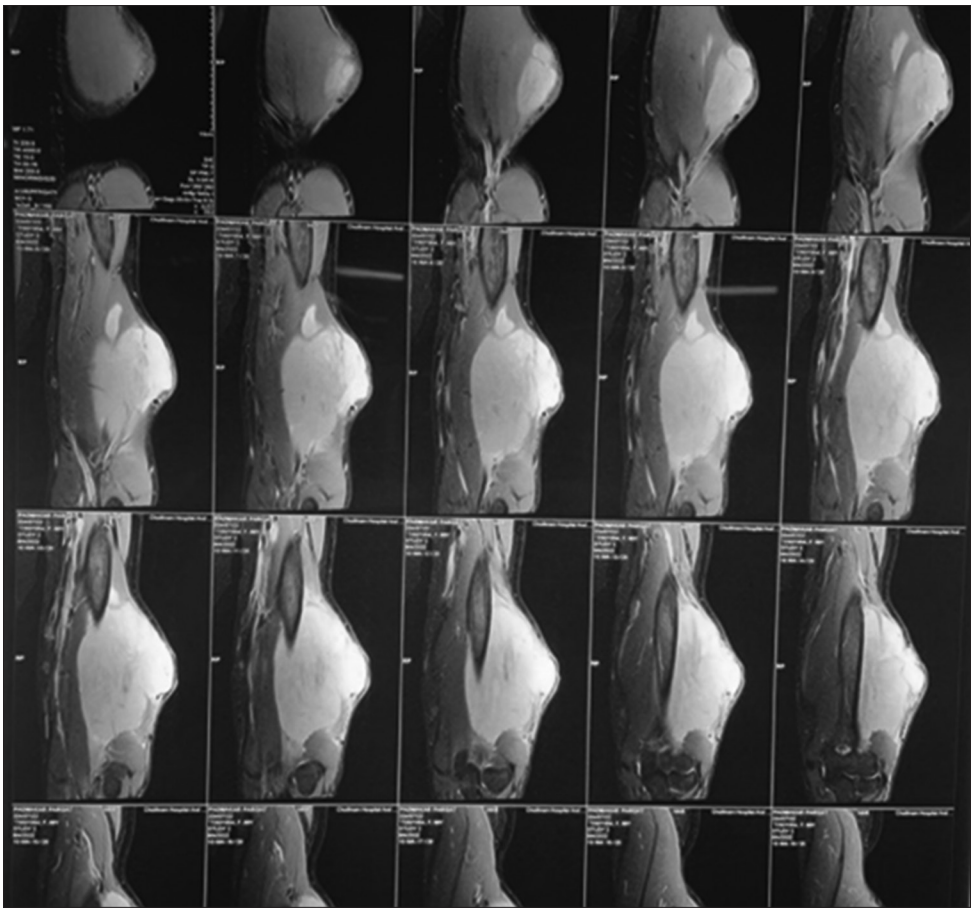

Figure 11: MRI- Showing extent oftumor

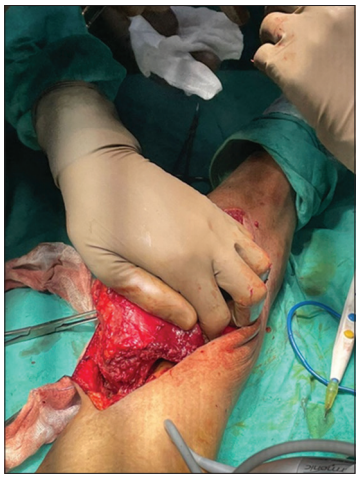

Figure 12: Intra-operative image

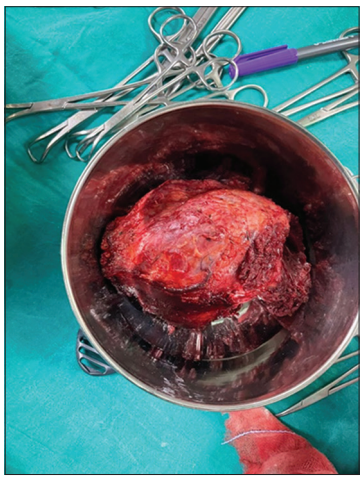

Figure 13: Excised tumor

A study by Blay *et al.* suggested lower extremity to be the most common site for sarcomas whereas, leiomyosarcoma and undifferentiated pleomorphic sarcoma as the common histologic types in adults.[11] According to the eighth edition of the *AJCC Cancer staging Manual*, site-specific staging system of STS has been developed which has used sarcoma stage, tumor size, lymph node involvement, metastasis, and histologic grade as prognostic factors suggesting the major drawback of not using histological types into consideration.[12]

Ramu *et al.* study suggests that soft-tissue sarcoma is best managed by surgical resection with or without radiotherapy. Chemotherapy is mainly reserved for the patients who present with metastasis with or without deep tissue invasion.[13]

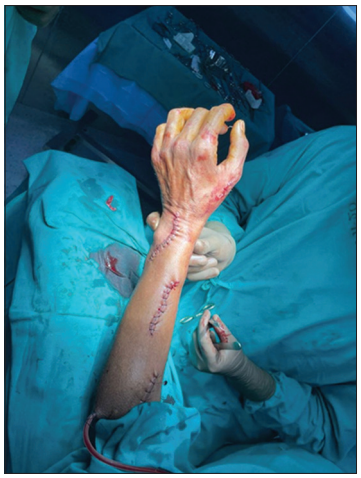

Figure 14: Post-operative image

In this series, three of the patients were treated surgically and sent for further radiotherapy and one is waiting for further surgery in view of residual disease. Smith *et al.* have suggested in their study that limb salvage has been applied for major soft-tissue sarcomas of lower extremities and amputations have been as low as 4.1%.[14]

CONCLUSION

Clinical presentation of soft-tissue sarcoma is variable and anatomic site varies as well with commonly arising from the extremities. It presents aggressively and usually leads to functional impairment of the involved region of the patient. These sarcomas need proper clinical assessment, complete metastatic workup with reconstructive surgical plan (if the defect is large) followed by further treatment in oncology and physiotherapy department. Surgery is the main stay of treatment. Early diagnosis improves the prognosis of the patient and chances of limb salvage rate.

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Original Article

A Randomized Control Study of Comparison of Ondansetron and Combination of Ondansetron and Dexamethasone as a Prophylaxis for Post-operative Nausea and Vomiting in Adults Undergoing Elective Laparoscopic Surgery

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Abstract

Aim: The aim of study is to compare Ondansetron's effectiveness in preventing post-operative nausea and vomiting in laparoscopic procedures under general anesthesia with combination of Ondansetron and dexamethasone

Materials and Methods: In this randomized, double-blind clinical study, we looked at 86 ASA Grades I and II patients between the ages of 18 and 60 who were having an elective laparoscopic cholecystectomy under general anesthesia. They were divided into two groups of 43 people each at random, for example, Groups O and OD are two different groups. Ondansetron 4 mg intravenous (IV) was given to group O, and both 4 mg ondansetron and were given to group OD. IV Ondansetron and 4 mg dexamethasone as a preventive antiemetic, 05 min before induction. All post-operative cases were monitored for post-operative nausea and vomiting from 0 to 6 h, 6 to 12 h, and 12 to 24 h. The number of emesis and nausea episodes was counted.

Results: When the nausea and vomiting in the ondansetron and ondansetron + dexamethasone groups was compared it was discovered that the nausea and vomiting in the ondansetron + dexamethasone group were significantly less than the nausea and vomiting in ondansetron group alone which is statistically significant.

Conclusion: We conclude that an IV combination of ondansetron and dexamethasone given before induction is safer and more effective than IV ondansetron or IV dexamethasone given alone in preventing early nausea and delayed vomiting.

Key words: Ondansetron, Dexamethasone, PONV

INTRODUCTION

Anesthesia and surgery are known to cause pain, nausea, and vomiting. The foremost thing is the unpleasant sensation of pain. Nausea and vomiting might cause delay in hospital release.

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In the last few decades, pain treatment has gotten a lot more attention than post-operative nausea and vomiting (PONV). Despite the availability of newer medications, the prevalence of PONV remains high. It's somewhere between 15% and 30%. The combination of medicines produces better antiemetic effects. There are at least 3 forms of vomiting, 1st of which is caused by anesthetic medications, the 2nd by reflex responses, and the third by narcotics like opioids. There has been a general trend towards decrease in the incidence and severity of the problem due to a shift in anesthesia practice to non-opioid or supplemented opioids, use of less emetic anesthetic agents, improved pre- and post-operative medication,

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refinement of operative techniques, and identification of patient predictive factors.

Despite these developments, the prevalence of PONV associated with surgery and anesthetic remains unacceptable. The patient's nausea and vomiting might have serious medical consequences, as well as financial consequences of postponed hospital discharge.

PONV has been linked to a variety of problems, including incision site pain, hematoma formation, wound dehiscence, pneumothorax, and aspiration pneumonitis.

Intractable nausea is uncomfortable, possibly dehydrating, and difficult to manage at home; nonetheless, the cost of a hospital stay for most healthy outpatients is disproportionate to the real morbidity of nausea.

Dexamethasone has been shown to be an effective antiemetic in cancer patients undergoing chemotherapy. The hunt for a newer and better antiemetic agent was prompted by the negative effects of traditional using drugs.

Ondansetron, a selective 5 HT3 receptor antagonist with no effects on other receptors, was a prospective new entrance into the antiemetics market. Ondansetron is structurally similar to serotonin. Ondansetron's antiemetic effect can be mediated peripherally, centrally, or both. It has been seen as an exceptionally effective antiemetic with no major side effects in patients taking cytotoxic chemotherapy. Ondansetron is being used for PONV on a regular basis. Several studies have validated the efficacy of ondansetron, which has a lower side effect profile. Ondansetron has now become the gold standard against which other antiemetic drugs are measured. Due to the multifactorial nature of emesis, antiemetic benefits are best achieved when a 5HT3 antagonist is used in conjunction with steroids.

PONV has been observed to be reduced when dexamethasone and ondansetron are used together. Because the causes of PONV are diverse, antiemetics can work in concert. From nausea to severe vomiting, PONV has a wide range of effects.

Aim of the Study

The aim of study is to compare ondansetron's effectiveness in preventing PONV in laparoscopic procedures under general anesthesia with combination of ondansetron and dexamethasone has been shown to be effective with respect to:

1. Vomiting
2. Nausea
3. The use of a rescue antiemetic if required
4. Side effects.

To start vomiting, the emetic center delivers motor output from the dorsal nucleus of the 10th cranial nerve and the nucleus ambiguous. Despite the fact that there no alternate pathway for emetic response, no drug has been discovered that can inhibit it and hence work as an antiemetic.

Different types of receptors send diverse signals to the vomiting center. Emesis caused by the stimulation of a receptor may be alleviated by signal antagonists. However, no medicine currently on the market can block all of the mechanisms involved in the emetic reaction.

Dopaminergic, histaminic (H1), cholinergic, muscarinic, and 5HT 3 neurotransmitter systems appear to play essential role in modulating emetic response. Because there are four different types of receptors, medicines have at least four separate receptor site of action. Antiemetic medicines may operate on multiple receptors, but they usually focus on one or two of them.

As a result, a combination of medications will almost certainly have a stronger antiemetic effect than a single agent. Sedation itself may help in the prevention of vomiting.

MATERIALS AND METHODS

Source of Data

1. This study was done at Siddhartha Medical College, Government general hospital, Vijayawada, from December 2019 to June 2021
2. The trial included 86 individuals who were scheduled for laparoscopic cholecystectomy
3. In this randomized, double-blind clinical study, we looked at 86 ASA grade I and II patients between the ages of 18 and 60 who were having an elective laparoscopic cholecystectomy under general anesthesia.

The ethical committee gave their approval, and all patients signed written informed permission. They were divided into two groups of 43 people each at random, for example, Groups O and OD are two different groups. Ondansetron 4 mg intravenous (IV) was given to Group O, and both 4 mg were given to group OD. IV Ondansetron and 4 mg dexamethasone as a preventive antiemetic, 05 min before induction.

Patients are Chosen at Random

Inclusion criteria

The following criteria were included in the study:

1. Patients aged 18–60 years old
2. ASA I and II physical status
3. Cholecystectomy (laparoscopic) is scheduled as an elective procedure.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with ASA III and IV physical status
2. Patients who received opioids, nonsteroidal anti-inflammatory drugs, or antiemetic drugs 48 h before surgery
3. Patients on ASA I and II having a history of (a) an allergic reaction to any drug or food (b) body mass index of more than 25 kg/m^2 (c) motion sickness or migraine (d) alcohol, drug addiction, or smoking
4. The patient's cholecystectomy was modified to an open procedure.

Methods

Pre-operative assessment

1. One day previous to surgery, the patient was assessed and given typical institutional pre-operative instructions
2. All patients had basic investigations such as hemoglobin, total leukocyte count, differential leukocyte count, urinalysis, and liver function tests, and further investigations such as electrocardiogram (ECG), fasting and postprandial blood sugars were done preoperatively based on the patient's ASA status, age, and clinical profile
3. The anaesthesiologist performing all laparoscopic operations was ignorant of the preventive therapy administered. All patients were given 0.5 mg Alprazolam tablets and kept NPO for 8 h before to surgery.
4. Using a computer-generated random number table, patients were randomly assigned to one of two groups (n = 43 each)
5. Study medicine was produced by a non-study PG trainee in two identical syringes labelled A and B, containing Ondansetron 4 mg and Ondansetron 4 mg + Dexamethasone 4 mg, respectively, given 5 min before anesthesia induction. The guide had the master list of cases.

Monitoring Before Surgery

1. NIBP
2. 3 lead ECG
3. Oxygen saturation with pulse oximeter
4. Heart rate (HR).

Laparoscopic Surgery Anesthesia Technique

1. Premedication: Inj Fentanyl 2 g/kg and Inj Glycopyrrolate 5 mcg/kg, both of which were induced by Propofol at a dose of 2–2.5 mg per kg body weight
2. Vecuronium 0.1 mg per kg body weight was used to help with tracheal intubation. The gastric contents were emptied using a nasogastric tube
3. N_2O + O_2 + Isoflurane were used to maintain anesthesia (0.6–0.8%). During anesthesia, 1/5th of loading dose of vecuronium is administered to ensure appropriate muscular relaxation throughout the surgery
4. During the procedure, the patient's HR, blood pressure, oxygen saturation, ECG, and urine output were all monitored
5. The abdomen was insufflated with CO_2 at a pressure of 8–12 mm Hg during laparoscopic surgery
6. The surgeon deflated the abdomen when the operation was completed
7. The patient was extubated at the end of operation by reversing the patient with neostigmine and glycopyrrolate (dose according to body weight). Patients' vitals were checked in the post-operative period
8. All post-operative cases were monitored for post-operative nausea and vomiting from 0 to 6 h, 6 to 12 h, and 12 to 24 h. Metoclopramide was utilized as a rescue antiemetic in patients who complained of vomiting.

Assessment

The number of emesis and nausea episodes was counted. Single emesis was defined as repeated vomiting in a period of 1–2 min. The intensity of each case of nausea, vomiting, and pain was also measured using the VAS system.

a. Nausea was assessed using an 11-point visual number scale, with 0 indicating no nausea and 11 indicating severe nausea
   - 10 = The worst nausea you've ever had.
   - A score of more than five indicates that the problem is severe. 5 is a moderate score.
   - 5 is the bare minimum.
   - Major nausea was defined as a score of severe or moderate.

b. Vomiting was classified as severe if it was more than 2 times the normal amount <2 is Mild
   - 2 = Moderate.
   - Even for a single bout of vomiting, a rescue antiemetic of 0.15 mg/kg metoclopramide IV was given.

Statistics Analysis

Statistical Package for the Social Sciences was used to conduct statistical analysis. The qualitative factors were expressed as percentages, whereas the quantitative data were expressed as Mean ± SD (standard deviation). The student t-test was used to examine age, weight, operation duration, and anesthetic duration, whereas the Chi-square test was used to examine gender, ASA physical status, nausea and vomiting frequency, and usage of rescue antiemetic. Student's t-test for unequal variances was used to examine the potency of ondansetron, dexamethasone individually or in combination among groups.

P = 0.05 was deemed insignificant.

RESULTS AND OBSERVATIONS

Demographic Information

a. A total of 86 patients were randomized into two groups O and OD, each with 43 patients, and received PONV prophylaxis either IV ondansetron or a combination of ondansetron and dexamethasone
b. Sex distribution — The baseline characteristics of all the groups were similar, with Group O having 20 males and 23 females and Group OD having 21 males and 22 females.

Distribution of Age in the Study Population in Both the Groups

Mean age of the study population identified as 33.77 ± 7.52 and 34.47 ± 6.09 in ondansetron group and Ondansetron + Dexamethasone group, respectively, and the difference is not statistically significant [Table 1].

The percentage of males and females was identified to be 23.2 and 26.7 in the 'O' group followed by 25.5 and 24.6 females and males, respectively, in 'OD' group [Table 2].

The study population's mean operation duration was 35.30 + 5.44 in ondansetron group and 36.63 + 5.74 in the Ondansetron + Dexamethasone group, respectively, and the difference was not statistically significant [Table 3].

The above table shows the mean values of systolic blood pressure, diastolic blood pressure, and HR, and the difference between those clinical measures was not significant statistically [Table 4].

AHA I accounted for 46.5% of the study population in both groups, while AHA II accounted for 3.5% in both [Table 5].

When the nausea in the ondansetron and ondansetron + dexamethasone groups was compared at 0–6 h, it was discovered that the nausea in the ondansetron + dexamethasone group was significantly less than the nausea in ondansetron group alone [Table 6].

On comparing the nausea at 6–12 h in ondansetron and ondansetron + dexamethasone groups, it is observed that there is no difference in occurrence of nausea and it is not statistically significant [Table 7].

On comparing the nausea at 12–24 h in ondansetron and ondansetron + dexamethasone groups, there is no difference in occurrence of nausea and it is not statistically significant [Table 8].

When comparing vomiting at 0–6 h in ondansetron and ondansetron + dexamethasone groups, it is shown that vomiting is reduced in the ondansetron + dexamethasone group, which is statistically significant [Table 9].

When the vomiting in the ondansetron and ondansetron + dexamethasone groups was compared at 6–12 h, it was discovered that there was no difference in the frequency of vomiting and that it was not statistically significant. At 12–24 h, no patient in either group reported vomiting [Table 10].

About 2.17% of patients in the Ondansetron + Dexamethasone group required a rescue antiemetic, whereas 37% of patients in ondansetron group did, and this difference is statistically significant [Table 11].

There is no difference in occurrence of side effects in both groups [Table 12].

DISCUSSION

For a patient undergoing anesthesia and surgery, PONV is the most uncomfortable experience. It is a common side effect of general anesthesia and an unexpected hospital admission following a day care procedure. The cause of nausea and vomiting following laparoscopic surgery is unknown.

Multimodal Analgesia is a type of systemic analgesia. Only if given before the onset of pain, prophylactic IV acetaminophen as part of a multimodal analgesic regimen lowers nausea.

Following a gastrectomy, IV acetaminophen, along with continuous epidural analgesia, resulted in the lower opioid use

Table 1: Age distribution

Age in years	Ondansetron (Mean+SD)	Ondansetron + Dexamethasone (Mean±SD)	*P*-value
Mean±SD	33.77±7.52	34.47±6.09	0.63

Table 2: Gender distribution of study population in both the groups

Gender	Frequency (n)	Percentage
Ondansetron group		
Females	23	26.7
Males	20	23.2
Ondansetron+Dexamethasone		
Females	22	25.5
Males	21	24.6
Total	86	100

Table 3: Ondansetron and ondansetron+ dexamethasone groups duration of surgery comparison

Duration of surgery	Ondansetron (Mean±SD)	Ondansetron + Dexamethasone (Mean±SD)	*P*-value
Mean±SD	35.30±5.44	36.63±5.74	0.27

Table 4: Comparison of mean SBP a DBP among Ondansetron and Ondansetron+Dexamethasone groups

Clinical parameters	Ondansetron (Mean±SD)	Ondansetron+Dexamethasone (Mean±SD)	*P*-value
Mean systolic BP	126.28±4.82	125.00±5.72	0.22
Mean diastolic BP	79.77±3.52	78.60±3.19	0.11
HR	72.98±5.68	72.14±4.94	0.46

BP: Blood pressure, HR: Heart rate, SBP: systolic blood pressure, DBP: Diastolic blood pressure

Table 5: Comparison of ASA grades

AHA grading	Ondansetron %	Ondansetron+Dexamethasone
I	46.5	46.5
II	3.5	3.5
Total	50	50

Table 6: Comparison of nausea using vas scale scoring in both the groups (At 0–6 h)

Score	Ondansetron	Ondansetron + Dexamethasone	Total	*P*-value
0	19	38	57	*P*=0.000*
2	3	0	3	
3	4	2	6	
4	14	3	17	
5	3	0	3	
Total	43	43	86	

Table 7: Comparison of nausea using vas scale scoring in both the groups (At 6–12 h)

Score	Ondansetron	Ondansetron+Dexamethasone	Total	*P*-value
0	37	40	77	*P*=0.21
2	3	3	6	
4	3	0	3	
Total	43	43	86	

Table 8: Comparison of nausea using vas scale scoring in both the groups (At 12–24 h)

Score	Ondansetron	Ondansetron+Dexamethasone	Total	*P*-value
0	42	43	85	*P*=0.31
5	1	0	1	
Total	43	43	86	

Table 9: Comparison of vomiting using vas scale scoring in both the groups (At 0–6 h)

Score	Ondansetron	Ondansetron+Dexamethasone	Total	*P*-value
0	39	43	82	*P*=0.04
4	4	0	4	
Total	43	43	86	

Table 10: Vomiting comparison in both groups using vas scale scoring (at 6–12 h)

Score	Ondansetron	Ondansetron+Dexamethasone	Total	*P*-value
0	42	43	85	*P*=0.31
5	1	0	1	
Total	43	43	86	

and a lower incidence of PONV. While oral acetaminophen has been found to minimize opiate need and is significantly less expensive, its impact on PONV has not been well investigated. The reported incidence of PONV during the ether era was high (70–85%). It was then proposed that the PONV could be caused by something other than anesthesia. At least 3- types of vomiting have been identified, 1st of which is related to anesthesia drugs 2nd to reflex responses and 3rd to narcotics. In most cases, using regional anesthesia to totally avoid general anesthesia in children is impractical. It could, however, be considered in older children undergoing minor procedures, with the goal of reducing N_2O, volatile agents, and narcotic exposure. Long-term fasting should be avoided, and good hydration should be encouraged to reduce PONV. With the shift from opioid-based anesthesia to non-opioid or supplemented low-dose opioids and non-ether anesthesia, the use of less emetic anesthetic agents, improved pre- and post-operative medication, refinement of operative techniques, and identification of patient predictive factors, the incidence and severity of the problem has decreased. Despite these advances, nausea and vomiting continue to be an unacceptably common side effect of surgery and anesthesia.

Long periods of CO_2 insufflation, intraoperative use of isoflurane, fentanyl, and glycopyrrolate, female sex, and post-operative opioid use may all play a role in these events. Other factors include intraoperative hypotension and abdominal viscera manipulation.[1,2]

According to Apfel *et al.*[3] one of the known risk factors for PONV is female sex. PONV is also increased by laparoscopic surgeries such as ovum retrieval and other gynecological procedures.

Female patients getting operated for total abdominal hysterectomy with or without oopherectomy have been identified as a high-risk group for PONV, and Watcha and White[4] have investigated the incidence of PONV in this group. The efficacy of any mono or combination antiemetic medicine is better studied in such patients who are at risk.

Neurokinin-1 receptor antagonists are a promising new family of antiemetics that were developed and approved to treat emesis caused by chemotherapy. When given orally before surgery, aprepitant has a similar antiemetic effect

Table 11: Comparison of anti-emetic rescue in both groups

Requirement of rescue antiemetic	Ondansetron (n)	Ondansetron+Dexamethasone (n)	Total	*P*-value
No	26	41	67	*P*=0.000*
Yes	17	2	19	
Total	43	43	86	

*Highly significant

Table 12: Comparison of side effects in both the groups

Side effects	Ondansetron (n)	Ondansetron+Dexamethasone (n)	Total	*P*-value
No	42	42	84	*P*=1.0
Yes	1	1	2	
Total	43	43	86	

on nausea and a stronger effect on vomiting than other regularly used antiemetics.

In fact, aprepitant reduced the incidence of vomiting by 70–80% in two randomized controlled trials. Aprepitant is not linked to QTc prolongation or sedative effects, but its expensive price makes it only suitable for high-risk individuals.

Antiemetic medications such ondansetron, dexamethasone, and droperidol, as previously mentioned, are similarly effective, each lowering the patient's risk by 28%. Their actions are cumulative because they work on distinct receptor classes. Patients with a low-to-moderate risk can receive one or two interventions (e.g., TIVA and antiemetic medications), while those with increased risk factors can receive three or four. Expert guidelines propose using the patient's risk to personalize antiemetic prophylaxis is beneficial. It is critical to think about the patient's risk as well as the safety and relative efficacy of the various therapies. But putting in place an institutional protocol to prevent and treat PONV is much more crucial.

Ondansetron is a serotonin type-3 receptor antagonist that is selective. The STN and chemoreceptor trigger zone have the highest concentration of 5HT3 receptors in the central nervous system (CNS), and 5HT3 antagonists decrease nauseating sensation and emetic episodes by acting at these regions. They do not have the sedative and dysphoric side effects of Droperidol, as well as the extrapyramidal adverse effects of Metoclopramide at large doses. In the laparoscopic cholecystectomy,[5] It has been shown to be useful in both treating and preventing PONV.

Ondansetron is more effective than dexmedetomidine and metoclopramide 10 mg. Because no single antiemetic, including ondansetron, is completely successful in all patients, the notion of combination therapy was developed.[6,7]

A quantitative systemic review found that combination of dexamethasone with a serotonin type-3 receptor antagonist provides the best prophylactic for PONV currently available. PONV has been controlled in numerous studies using various combinations of therapy.[8,9] In all of these investigations, the incidence of nausea was quite variable, most likely due to the different types and lengths of operation.

A 5-HT3 receptor antagonist with either Droperidol or with steroids has been the most widely researched combination. The efficacy of both combination regimens appears to be equal. The absolute risk of PONV was lowered to zero when dexamethasone was taken in conjunction with a 5HT3 receptor antagonist. This combination also has few side effects, the majority of which are caused by the 5 HT3 receptor antagonists. As a result, dexamethasone with a 5HT3 receptor antagonist appears to be a sensible choice for PONV treatment.

Our findings suggest that when Dexamethasone 4 mg and ondansetron 4 mg iv are given together to patients undergoing laparoscopic surgery, the incidence of PONV is much lower than when they are given separately. In comparison to the ondansetron 4 mg group, the combination group with Dexamethasone 4 mg + ondansetron 4 mg had a lower overall (0–24 h) rate of failure of PONV prophylaxis.

In a study of male surgical outpatients, Kovac *et al.* assessed the preventive role of ondansetron and found that 4 mg doses were more efficient than placebo in preventing PONV.

We chose the lowest effective dose of ondansetron, 4 mg IV, because we were studying the efficacy of antiemetic combinations. Khalil *et al.*[10] and Kovac *et al.* [11] employed a low dosage drug in their study, which we have taken as reference. Because it is the usual antiemetic at our institution, we chose 4 mg of ondansetron as

monotherapy. After a cesarean delivery, laparoscopic surgery, or day case surgery, this dose avoids PONV. In the adult population, dexamethasone 8 mg given alone has been useful to prevent PONV after general surgery and chemotherapy.

Because either 4 or 8 mg doses of ondansetron is equally effective in the prophylaxis of PONV and both doses are reported to be equally safe after rapid iv administration in terms of cardiovascular adverse effects, the incorporation of 4 mg ondansetron combination may offer a more cost-effective option, a smaller dose of 4 mg Ondansetron was chosen in this study both alone and in combination with dexamethasone 4 mg was chosen in this study both alone and in combination dexamethasone 8 mg IV significantly reduced the incidence of PONV in a study with 120 parturient who received epidural morphine 3 mg compared to placebo (18% and 51%, respectively).

Dexamethasone, alone or in combination with ondansetron, may have antiemetic effects throughout the postoperative phase, according to data. It's worth noting that the combination of dexamethasone 4 mg and ondansetron 4 mg antiemetic costs <8 mg ondansetron alone.

Dexamethasone has an extra benefit over 5-HT3 receptor antagonists in that it reduces the need for analgesics in many studies.

It is fair to consider cost effectiveness if patients are not at danger of drug interactions due to polypharmacy. Ondansetron, a specific 5-hydroxytryptamine-3 antagonist, has been shown to reduce the incidence of PONV associated with elective cesarean delivery. Dexamethasone has a long biological half-life of 36–72 h and is suggested to provide better control of delayed PONV (i.e., after 24 h) after chemotherapy.

We hypothesized that the combination of dexamethasone 4 mg plus 4 mg ondansetron would reduce the incidence of PONV when compared to dexamethasone 8 mg alone or ondansetron 4 mg alone, based on the positive effects of the medications and prior research. In our study, 58% of patients in Group O experienced early nausea, while only 16 percent experienced delayed nausea.

Only 12% of patients in the combination group had delayed nausea, compared to 38% in the control group, according to Lopez *et al.*[8]

.In our study, 17 patients (56%) in Group O experienced mild nausea, 02 patients (16%) had moderate nausea, and 01 patients (8%) in Group OD had moderate nausea after receiving both antiemetic medicines. 10% of the participants experienced minor nausea. None of the participants in either group suffered significant nausea.

Vomiting is shown to be significantly lower in the mixture compared to the solo antiemetic prophylaxis group in our investigation.

Similarly, Rajeeva *et al.*[9] discovered that a combination of Dexamethasone and ondansetron is more successful as a PONV prophylaxis, they claimed that PONV that was delayed (2–24 h) was better controlled. Dexamethasone in combination with being more effective in PONV prophylaxis adds to earlier research.

Compared to other regimens of placebo, ondansetron, or Dexamethasone alone, López-Olaondo *et al.*[8] concluded that prophylactic administration of a combination of Dexamethasone and is effective in preventing PONV in patients undergoing gynecological surgery with fewer patients requiring rescue anti-emetics.

In addition, Biswas *et al.*[12] discovered that a combination of dexamethasone and ondansetron offered acceptable control of PONV in patients having laparoscopic tubal Ligation, in 78% of patients. However, due to restricted staff resources, the total frequency of PONV was determined in hours rather than at distinct intervals in this investigation.

In their meta-analysis, Henzi *et al.*[13] found that the best available prophylactic for PONV is a combination of dexamethasone and the 5-HT3 receptor antagonist ondansetron. There is remarkable reduction in PONV when ondansetron alone was used instead of dexamethasone alone, which is consistent with earlier research. Females had a higher rate of PONV than males, which is consistent with previous research. Patients in our study only had minor side effects that did not necessitate any active intervention.

In women undergoing major gynecological surgery, McKeniez *et al*. tested Ondansetron 4 mg and ondansetron 4 mg with dexamethasone 4 mg and found that the combination was more effective than ondansetron alone.

As a result, we used a combination of antiemetic medications in our study: Dexamethasone and ondansetron.

Patients receiving dexamethasone plus ondansetron required less analgesia than those receiving monotherapy, according to our findings. The afferent nerve fibers that mediate pain, which are a subset of polymodal

C-nociceptors, may play a role, with prostaglandins enhancing their transmission to the CNS.

PGE2 production is inhibited by dexamethasone, which may give analgesia. Ondansetron is also linked to pain processing in the brain. The analgesic characteristics of both drugs may have contributed to the lower analgesic use in the dexamethasone plus ondansetron group in our study.

In conclusion, IV dexamethasone + ondansetron was more successful than standard antiemetic medication, ondansetron or dexamethasone alone, in the prevention of PONV in patients undergoing laparoscopic cholecystectomy, which was linked with a high failure rate of PONV prophylaxis.

CONCLUSION

We conclude that an IV combination of ondansetron and dexamethasone given before induction is safer and more effective than IV ondansetron or IV dexamethasone given alone in preventing early nausea and delayed vomiting, as well as long-term prevention and PONV in patients posted for elective laparoscopic cholecystectomy under general anesthesia.

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Original Article

Clinical Efficacy between a Probiotic and 0.2% Chlorhexidine Mouth Rinse on Oral Health: A Randomized and Controlled Trial

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Abstract

Introduction: Chlorhexidine digluconate, a broad-spectrum antibacterial agent, is considered the gold standard in the dental field but its side effects limit its long-term use and acceptance as a mouthwash. Probiotics have an amazing potential for not only preventing the attack of oral pathogens and the ability to treat various oral diseases. The advantages of using probiotic strains are that the bacterial strains present in them are not harmful to the oral cavity and there is no occurrence of antibiotic resistance and no proven toxicities.

Aims and Objectives: The aim of the study was to clinically compare the efficacy of a Probiotic mouth rinse to chlorhexidine mouth rinse on the level of plaque accumulation and gingival inflammation.

Materials and Methods: The study was conducted among patients and their attendants visiting the Department of Public Health Dentistry at the Institute of Dental Sciences, Bareilly. Informed consent from each study participant was obtained. Ninety participants were randomly allocated into two groups – Group 1 – Chlorhexidine (0.2%) and Group 2 – Probiotic mouth rinse. Both the groups were instructed to rinse their mouth with 10 ml of their respective mouthrinse, for 1 min twice daily for 14 days. Clinical parameters such as plaque index, gingival index, and oral hygiene index (OHI)-simplified for each group were assessed at the baseline, 7th day, 14th day and 28th day, respectively. Intragroup and then intergroup comparison was done between both the groups.

Results: There was a decrease in mean scores of plaque index, gingival Index, and OHI. There was a significant improvement in all the scores from baseline to the 28th day within the groups but when intergroup comparisons were made there was no statistically significant difference.

Conclusion: In our study, there was an improvement in the oral hygiene status of both groups but the mean difference in the CHX group was more as compared to the probiotic over 28 days.

Key words: Chlorhexidine, Probiotic mouthwash, Plaque, Gingivitis, Oral hygiene

INTRODUCTION

Biofilms are increasingly being referred to as the cause of human infections and diseases. Plaque, respiratory infections, gastric ulcers, atherosclerosis, kidney stones, ear infections, prostatitis, and many other microbial-induced diseases are associated with biofilms.[1]

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These biofilms can be removed through proper oral hygiene maintenance and this includes measures to control plaque deposits. Plaque control can be achieved through chemical agents also, of which chlorhexidine digluconate is the most widely and effectively used anti-plaque and anti-gingivitis agent.[2]

Chlorhexidine gluconate is a cationic bisbiguanide with low toxicity and broad antimicrobial activity. When used as a mouthwash, it causes flushing, bacterial membrane destruction, concentration-dependent growth inhibition, and cell death and secondary interactions occur by inhibiting photolytic and glycoside enzymes. Chlorhexidine has increased substantivity in the oral cavity. However, some people experience bitter taste, light brown spots

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on the teeth, and loss of taste. These side effects limit its long-term use as a mouthwash.[2] Therefore, search for new rinse continues and the scientific focus has shifted toward biogenic agents.[3]

In addition to increasing bacterial resistance to antibiotics, reducing oral pathogens at this age requires new approaches such as complete bacterial replacement therapy.[4]

Probiotic therapy is a natural and alternative method that has been used to combat infectious disease by displacing pathogenic microorganisms with non-pathogenic endogenous or commensal bacteria.[5] According to the World Health Organization, probiotics are live microorganisms that when administered in sufficient amount to produce a health benefit for the host with minimal risk of side effects.[6] Consumption of foods that contain a live bacterial component such as milk, yogurt, and cheese has been advocated for centuries for their benefit on gastrointestinal health.[5]

Several studies have been conducted in the past one decade regarding the usefulness of various mouth rinses such as chlorhexidine, listerine, and fluoride, but only a few studies have been done on probiotic mouth rinse. There has been considerable clinical interest in the use of probiotic on day to day life because of developing antimicrobial drug resistance. Due to ill effects of staining teeth by chlorhexidine, additives of alcohol in listerine and fluoride toxicity and ingestion by children have led probiotic mouth rinse a clinical interest in dentistry. They recommended that probiotic mouthwash should be considered one of the effective oral hygiene regimens.[7] Thus, probiotic can also be used as a mouth rinse, due to its beneficial effect.

Very few studies have investigated the use of probiotic mouthwashes in India to reduce the clinical parameters of plaque, gingivitis, and oral hygiene so this study was undertaken to clinically compare the efficacy of a probiotic mouth rinse to a chlorhexidine mouth rinse (0.2%) on the level of plaque accumulation, gingival inflammation, and oral hygiene status.

MATERIALS AND METHODS

The present study was randomized and controlled trial with two parallel groups. The study was conducted in the Department of Public Health Dentistry, Institute of Dental Sciences Bareilly, Uttar Pradesh, India.

Ethical clearance was obtained from the Institutional Review Board (IRB) of the Institute of Dental Sciences, Bareilly, India. Informed consent, both written and verbal, was obtained from each study participant after explaining the nature of the study.

Sample Size

It was determined that 90 participants would be necessary to provide 80% power with an α of 0.05 using G Power Software.

Inclusion Criteria

The following criteria were included in the study:

1. Subjects in the age range of 20–30 years
2. Subjects having a dentition with ≥20 evaluable teeth (minimum of five teeth per quadrant)
3. Patients willing to give informed voluntary written consent.

Exclusion Criteria

The following criteria were excluded from the study:

1. Subjects with any systemic diseases
2. Subjects on any other oral hygiene regimen other than routine tooth brushing
3. Subjects undergoing any specialized dental treatment, for example, orthodontic and prosthodontic treatment
4. History of oral prophylaxis within 6 months previous to the study
5. Tobacco consumers and smokers.
6. Subjects undergoing antibiotic therapy.

The kappa coefficient value for intraexaminer reliability for recording the plaque index, gingival index, and oral hygiene index (OHI) was found to be 0.84, 0.86, and 0.89, respectively. These values reflected high degree of conformity in observation.

Group Allocation

A complete clinical oral assessment of all participants was carried out based on inclusion and exclusion criteria from the outpatient Section Department of Public Health Dentistry, Institute of Dental Sciences, Bareilly, India.

Ninety study participants of age group between 20 and 30 years were selected based on inclusion and exclusion criteria.

In this randomized, controlled, and clinical trial, participants were enrolled and assigned to a computer generated table to assign the respective mouth rinse.

Study participants were randomly allocated into two groups with 45 participants in each group:

- Group 1 – Chlorhexidine mouth wash. (0.2% Chlorhexidine gluconate, Nitofresh, INTRA LIFE, Bangalore, India)
- Group 2 – Probiotic mouth rinse [Probilife-P (INTRA LIFE, Bangalore, India) + distilled water]

The participants in Group 2 were given Probilife-P Sachets (containing 1.25 billion freeze-dried bacterial cells of *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium longum*, and *Saccharomyces boulardii*) and 10 ml ampules of distilled water commercially available at the chemist.

The patients were demonstrated the preparation of the probiotic mouthwash by mixing the sachet contents with 10 mL of distilled water. Particular attention was paid to explain to the patient that the solution must be thoroughly mixed until all contents are completely dissolved in the water. The prepared mouth rinse cannot be stored, so it must be prepared and rinsed immediately.

Both the groups were instructed to rinse their mouth with 10 ml of their respective mouthrinse, undiluted for 1 min twice daily, 30 min after brushing for 14 days.

Clinical Examination

The clinical parameters were recorded in a case history proforma.

The following indices were recorded in the study participants:

1. Turesky-Gilmore-Glickman Modification of the Quigley-Hein Plaque Index (1970)
2. Loe H. and Silness J. Gingival Index (1963)
3. Greene J.C. and Vermillion J.R. OHI-Simplified (OHI-S) (1964).

The data obtained from each group were assessed individually at baseline, 7th day, 14th day, and 28th day, respectively, intragroup and then intergroup comparison was done between both the groups.

All of the examinations were conducted by one trained and calibrated examiner. The evaluation was carried out at baseline, 7th day, 14th day, and 28th day in the department.

Statistical Analysis

The statistical analysis was done using (Statistical Package for the Social Sciences) Version 22.0 statistical analysis software. Results were expressed as the mean and standard deviation. Repeated measures ANOVA was employed within the two groups and ANOVA was employed between the two groups.

RESULTS

The present study was conducted among 90 study participants with 45 participants in each group.

Table 1 shows the gender-wise distribution of the study participants in two groups. Out of 90 study participants, 41 were males and 49 were females. Twenty-two males and 23 females participated in the chlorhexidine group, 19 males and 26 females participated in the probiotic group.

The age group for the study was 20–30 years; however, the mean age was 25 years.

Tables 2 and 3 show a comparison of mean values of variables at baseline, 7th day, 14th day, and 28th day for chlorhexidine and probiotic mouth rinses.

OHI-S

For chlorhexidine group, the mean OHI-S score was 1.33 ± 0.21 at the baseline, which reduced to 0.83 ± 0.27 at 7th day, 0.33 ± 0.21 at 14th day, and 0.19 ± 0.09 at the 28th day.

Similarly, for the probiotic group, the mean OHI-S score at the baseline was 1.21 ± 0.21 which reduced to 0.80 ± 0.16 at 7th day, 0.30 ± 0.13 at 14th day, and 0.20 ± 0.12 at 28th day.

The difference in the mean values of OHI-S between baseline, 7th day, 14th, and 28th day in both groups was found to be statistically significant ($P < 0.001$).

Mean Plaque Score

For chlorhexidine group, the mean plaque score at the baseline was 0.30 ± 0.07 which reduced to 0.11 ± 0.05

Table 1: Gender wise distribution of study participants

Groups	Male	Female	Total
CHX	22	23	45
Probiotic	19	26	45

Table 2: Intragroup comparison of mean values of variables at baseline, day 7, day 14, and day 28 for Chlorhexidine

Variable		Mean value			p value
CHX	Day 0	Day 7	Day 14	Day 28	
OHI-S	1.33±0.21	0.83±0.27	0.33±0.21	0.19±0.09	0.001*
PI	0.30±0.07	0.11±0.05	0.06±0.03	0.04±0.02	0.001*
GI	0.78±0.08	0.19±0.06	0.06±0.03	0.04±0.02	0.001*

Repeated measure ANOVA; * Significance at p<0.05

Table 3: Intragroup comparison of mean values of variables at baseline, day 7, day 14, and day 28 for Probiotic

Variable		Mean value			p value
Probiotic	Day 0	Day 7	Day 14	Day 28	
OHI-S	1.21±0.21	0.80±0.16	0.30±0.13	0.20±0.12	0.001*
PI	0.30±0.06	0.12±0.05	0.07±0.02	0.04±0.02	0.001*
GI	0.77±0.12	0.18±0.11	0.07±0.02	0.04±0.01	0.001*

Repeated measure ANOVA; * Significance at p<0.05

Table 4: Intergroup comparison of mean values of variables between two groups.

Variable	Interval	Mean score		p value
		CHX	Probiotic	
OHI-S	Baseline	1.33±0.21	1.21±0.21	0.896 (NS)
	7th day	0.83±0.27	0.80±0.16	0.795 (NS)
	14th day	0.33±0.21	0.30±0.13	0.694 (NS)
	28th day	0.19±0.09	0.20±0.12	0.863 (NS)
PI	Baseline	0.30±0.07	0.30±0.06	1.286 (NS)
	7th day	0.11±0.05	0.12±0.05	1.277 (NS)
	14th day	0.06±0.03	0.07±0.02	0.177 (NS)
	28th day	0.04±0.02	0.04±0.02	0.156 (NS)
GI	Baseline	0.78±0.08	0.77±0.12	0.404 (NS)
	7th day	0.19±0.06	0.18±0.11	0.270 (NS)
	14th day	0.06±0.03	0.07±0.02	0.092 (NS)
	28th day	0.04±0.02	0.04±0.01	0.081 (NS)

ANOVA test; NS – Not significant; * significance at $P<0.05$

at day 7, 0.06 ± 0.03 at day 14, and 0.04 ± 0.02 at day 28.

Similarly, for the probiotic group, the mean plaque score at the baseline was 0.30 ± 0.06 which reduced to 0.12 ± 0.05 at 7th day, 0.07 ± 0.02 at 14th day, and 0.04 ± 0.02 at 28th day.

The difference in the mean values of Plaque Index between day 0, day 7, day 14, and day 28 in both groups was found to be statistically significant ($P < 0.001$).

Mean Gingival Score

For chlorhexidine group, the mean gingival score at the baseline was 0.78 ± 0.08 which reduced to 0.19 ± 0.06 at day 7, 0.06 ± 0.03 at day 14, and 0.04 ± 0.02 at day 28.

Similarly, for the probiotic group, the mean gingival score at baseline was 0.77 ± 0.12 which reduced to 0.18 ± 0.11 at 7th day, 0.07 ± 0.02 at 14th day, and 0.04 ± 0.01 at 28th day.

The difference in the mean values of the Gingival Index between day 0, day 7, day 14, and day 28 in both groups was found to be statistically significant ($P < 0.001$). On the 28th day, plaque scores, gingival scores, and OHI-S scores were significantly lower for both the chlorhexidine and probiotic groups; however, the reduction in all the mean scores was found to be greater for chlorhexidine group than the probiotic group.

Intergroup comparison in all time periods between the two groups was not found to be statistically significant [Table 4].

When an intergroup comparison was done between the probiotic and chlorhexidine mouth rinse with respect to the oral hygiene status, there was a reduction in mean score; however, it was not found to be statistically significant.

When probiotic and chlorhexidine mouth rinse were compared regarding the plaque index scores, the reduction was seen in both the groups but it was not found to be statistically significant and when the two mouth rinses were compared regarding the gingival index, reduction in the gingival scores was observed; however, it was also not found to be statistically significant.

DISCUSSION

Chlorhexidine has been regarded as the "gold" standard anti-plaque and anti-gingivitis agent in dentistry. Antibacterial mouth rinses work by reducing the levels of both healthy and harmful oral bacteria non-specifically.

Probiotic technology represents an innovative approach to maintain oral health by utilizing healthy oral microflora to provide a natural defense against harmful bacteria. *Lactobacillus and Bifidobacterium* genera constitute the most probiotic species.[8]

The first probiotic species included in the study are *L. acidophilus* and *Bifidobacterium bifidum*. In dentistry, the previous studies of *Lactobacillus* strains such as *L. rhamnosus*, *Lactobacillus casei*, *Lactobacillus reuteri*, or *Lactobacillus* mixtures have shown mixed results for oral microflora.[9]

Several experimental studies are investigating the use of probiotics in periodontal disease. Krasse *et al.* conducted a study in patients with moderate-to-severe gingivitis who received either $2 \times 10^{[8]}$ CFU/day or an appropriate placebo of either type of *L. reuteri* (LR-1 or LR-2). *L. reuteri* effectively reduced gingivitis and plaque formation in patients with moderate-to-severe gingivitis.[10]

Harini and Anegundi evaluated the clinical efficacy of a probiotic and chlorhexidine mouth rinses in children on plaque accumulation and gingival inflammation for 14 days and concluded that the probiotic mouthwash effectively reduced the plaque accumulation and gingival inflammation.[11]

The present study was designed to evaluate and compare the efficacy of probiotic and chlorhexidine mouthwashes on plaque accumulation and gingival inflammation.

The indices used were Plaque Index (Turesky-Gilmore-Glickman Modification of The Quigley-Hein Plaque Index), Gingival Index (Loe H and Silness J), and OHI-S at baseline, 7th day, 14th day, and 28th day. The age group selected to carry out this study was 20–30 years.

The results obtained showed that there was a reduction in the plaque accumulation, gingival bleeding, and improvement in oral hygiene status after 28 days in both groups. These results add to the body of data supporting

the efficacy of these two products for anti-plaque and anti-gingivitis.

The advantage of using a probiotic mouthwash is that it contains friendly commensals, there are no concerns about antibiotic resistance, and there are no known toxic effects associated with the use.[12]

In the present study, probiotics (Probilife-P) contained 1.25 billion freeze-dried bacterial cells from *L. acidophilus*, *L. rhamnosus*, *B. longum*, and *S. boulardii*.

Lactobacilli produces a low molecular weight bacteriocin that has an inhibitory effect against a wide range of bacterial species associated with oral diseases.[13]

L. rhamnosus shows high antimicrobial activity and high resistance to environmental stress.[14]

Bifidobacterium species metabolize lactose and generates lactic ions from lactic acid and also produces beneficial short-chain fatty acids with vitamin synthesis.[15] *S. boulardii* has antibacterial properties.[16] Since the synthesis of compounds such as bacteriocin or biosurfactant, inhibition of cell association, colonization, and invasion of pathogenic bacteria may explain the anti-plaque effect of probiotics. Hence, in the present study, probiotics improved gingival health due to the above-mentioned facts.[17]

The results of our study showed a significant reduction in plaque levels and gingival inflammation at the end of 28th day in chlorhexidine group which was in accordance with studies done by Singh *et al*., where chlorhexidine showed a statistically significant difference in the plaque levels when compared with HiOra Regular Mouthwash[17] and Biswas *et al*., who found that CHX was better in improving plaque and gingival index scores than the herbal mouth rinse.[18] and Mishra *et al*., where chlorhexidine showed maximum reduction in Plaque Index, followed by herbal and probiotic mouthwash at the end of 1 week.[19] This was in contrast with the study conducted by Purunaik *et al*., where probiotic mouth rinse was significantly more effective in the reduction of plaque level and gingivitis than chlorhexidine at 14th day,[20] and Parwani *et al*., where both chlorhexidine and herbal mouthwash showed no significant difference in the plaque scores.[21]

In our study, there was an improvement in the oral hygiene status of both groups but the mean difference in the CHX group was more as compared to the probiotic over 28 days, this was found to be in contrast with the study conducted by Nadkerny *et al*., who showed equal efficacy of probiotic and chlorhexidine mouthwashes in the reduction of OHI-S, PI, and GI at the end of 28th day[22] and Shetty *et al*., where there were no statistically significant differences between CHX and HiOra groups with regards to OHI, PI, and GI.[23]

However, we would like to point out that the most important limitation of probiotic preparations is that they must be used immediately after preparation and cannot be stored. Therefore, we recommend an appropriate probiotic dispensing agent to help improve patient compliance.[24]

No adverse effects on the oral mucosa such as ulcerations were noted with probiotic mouth rinse. Likewise, it would be interesting to evaluate the additional gastrointestinal effects of probiotics in studies instructing patients to swish and swallow probiotic mouthwash rather than expectorate.

CONCLUSION

Probiotics are a newer approach to the maintenance of human health and also implied on the maintenance of oral health. Probiotics used to treat oral diseases can reduce the cost of traditional treatment and prevention programs. The idea of replacing harmful microbes with innocent, inactive, or genetically modified bacteria is fascinating.

Most of the studies conducted with probiotic strains originally suggest for gut health. The interest in oral probiotics has been growing since the last few decades.

The literature shows that the improvement in oral health is mainly due to reduction in caries causative microorganisms. With an increasing global problem of antibiotic resistance and ill effects of certain mouthwash, probiotics contribute to the effective treatment of microbial diseases.

The possibilities of using probiotics with a focus on disease prevention and optimal health for people of all ages are enormous. Efforts should be made to raise awareness of general dentists about these aspects of oral healthcare.

The presence of probiotics in the local microbiota of the human oral cavity should be investigated, as these bacteria have the advantage of being ideally adaptable to the oral ecosystem and much more scientific research is needed to better understand these tiny creatures and expand their applications.

Hence, our study concludes that:

1. Probiotic mouth rinse was found to be a potent plaque inhibitor
2. Probiotic mouth rinses can be used as an adjunct in maintaining oral health and preventing healthy oral status as they are safe with no side effects having good anti-plaque and anti-gingivitis action.

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Original Article

Usefulness of Tranexamic Acid in Reducing Blood Loss in Obstetrics and Gynecology: A Prospective Observational Study

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Abstract

Introduction: Uterine bleeding in reproductive age is due to hormonal causes in 14% of women as a whole which is medically treatable. Hemorrhage is a major killer in obstetrics. Uterine bleeding is a main cause of modifying health related quality of life in child bearing age group. To avoid major surgical intervention, there is a need for a medical modality which will act quickly and effectively. Here, we address outcomes of use of tranexamic acid (TXA) in mild postpartum hemorrhage (PPH), abnormal uterine bleeding (AUB), and threatened abortion.

Purpose: In this study, we intended to find effect of various doses and routes of drug in improving blood loss, hemoglobin, and hematocrit increase.

Methods: 145 gynecology and 40 obstetric patients were recruited in C.R. Gardi Hospital, Ujjain over 20 months in 2017–2020 having various types of bleeding pathology. In gynecology pictorial blood loss assessment chart (PBAC) was used to assess blood loss improvement and visual blood loss assessment was used in Obstetrics. Assessing blood loss, hemoglobin and hematocrit; before and after treatment was observed. Doses of 1.5–10 g/day of TXA were used. In PPH 1–5 g was used.

Results: About 65% and 35% women with ≤120 and ≥120, respectively, showed improvement in PBAC. Increase in hemoglobin, hematocrit, and reduction in PBAC score (P = 0.00) are major findings. No significant difference was found in improvement of hemoglobin in mildly and severely bleeding patients. Average gain in hemoglobin was 0.5 g% and hematocrit of 7.4 in 1 week. In 33% of PPH, patient's major surgery could be postponed.

Conclusion: Improvement in pictorial PBAC score in AUB patients, hemoglobin, and hematocrit with avoidance of major surgical treatment in mild PPH are major findings of this study.

Key words: Tranexamic acid, Capillary bleeding in obstetrics and gynecology, Abnormal uterine bleeding, PBAC score

INTRODUCTION

In this observational study, we have evaluated the usefulness of tranexamic acid (TXA) in reducing blood loss in various obstetric conditions, such as threatened abortion and minor post-partum hemorrhage (PPH), as well as its usefulness in abnormal uterine bleeding (AUB). Hemorrhage as a whole, both in obstetrics and gynecology, in addition to mortality risks, causes trauma to woman's mental and physical health. It is a major contributor of maternal mortality.[1] Nearly all (99%) of these deaths are in low- and middle-income countries.[2] Estimated prevalence of PPH varies widely, from 3% to 15% of deliveries globally.[3-6] In India, PPH is a major cause of maternal mortality and is responsible for 30% of all maternal deaths.

TXA is a lysine analog that binds to lysine receptors on plasminogen and plasmin, thereby inhibiting plasmin-mediated fibrin degradation and hence prevents fibrinolysis. None of the previous trials reported any significant increase in adverse events related to the use of TXA, including thromboembolic events. Thus, it appears that TXA is a safe and effective agent for the prevention and treatment of hemorrhage. The WOMAN trial conducted from 2009 to

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2017 strongly recommends early use of this drug to control PPH. In India, there is no fixed guideline for use of TXA. In this study, we intended to observe the efficacy of its use in the treatment of PPH. Besides PPH, early pregnancy bleeding has negative impact on the growing fetus, as well as on maternal health. Approximately 25% of pregnant women experience bleeding before 12 weeks of gestation, that is, in early pregnancy.[7] TXA was used in these women as a first line therapy in addition to progestogens.

Addressing AUB, 14% of women in reproductive age suffer from AUB. It impairs quality of life by creating significant physical, social, emotional, and sexual life disturbances and is a major material and financial burden.[8-10] Women with AUB make up 32.7% of clinical visits in gynecological outpatients.[11] About 30% of women overall consult a physician for heavy menstrual bleeding (HMB). HMB creates a clinically significant burden for affected women by interfering with daily activities and negatively impacting health-related quality of life (HRQL). The impact of HMB on HRQL derives from both the mechanics of managing bleeding and the consequences of excessive blood loss, such as fatigue and iron deficiency anemia.[12] Women with HMB appear to have higher number of endometrial plasminogen activators and more local fibrinolytic activity than women with normal menses. In the treatment of HMB, TXA has proven to be superior to placebo, mefenamic acid, and luteal-phase progestins.

We aim to study AUB patients with milder symptoms, without structural and pathological abnormalities; mostly having idiopathic etiology, who do not require immediate surgical intervention and will not progress to severe one. Around 35% of women with HMB will undergo a hysterectomy, which is a definitive cure for menorrhagia. Many guidelines of different nations consider medical alternatives as a first-line treatment, especially for idiopathic HMB. Women who are of younger age, who want to preserve their fertility, and who are nearing menopause are candidates for conservative treatment. There is no single line drug available to use as a short-term therapy in management of menorrhagia, to conserve the fertility of women, to arrest bleeding and to avoid surgical intervention. The purpose of this study is to assess the effectiveness of TXA in less severe obstetric and gynecological hemorrhage in patients in rural India.

MATERIALS AND METHODS

This was a prospective cross-sectional study conducted on 185 women at the Department of Obstetrics and Gynaecology, R.D. Gardi Medical College Ujjain between 2017 and 2019. The study began after researchers obtained ethical approval from the Institutional Ethics Committee at R.D Gardi Medical College, Ujjain, M.P. The aims of the study and procedure were clearly explained to all participants and confidentiality was assured.

Study subjects were women from both obstetrics and gynecology.

Recruitment of Gynecology Patients

One hundred and forty-five women attending C.R. Gardi Hospital, Obstetrics and Gynecology outpatient department with complaints of menorrhagia, menometrorrhagia and metrorrhagia were recruited. All women underwent estimation of complete blood count and ultrasonography evaluation. Physical examination was done to rule out any organic and endometrial pathology; and women with fibroids <2 cm in size were included in the study. Women with fibroids of more than 2 centimeter in size, polyps, adenomyosis, and endometrial or cervical carcinoma were excluded from the study. Women with coagulopathy, ovulatory dysfunction and iatrogenic causes were also excluded from the study. Menstrual blood loss was graded by self-assessment of the amount of blood loss using a pictorial blood loss assessment chart (PBAC).[13] A score was completed by multiplying the number of lightly, moderately, and heavily soiled pads. The score also has different points for different sizes of blood stains. A PBAC score of more than 100 refers to a blood loss of more than 80 ml and is considered heavy bleeding. Premenopausal women (18–45 years) with complaints of heavy period, or irregular and heavy period and reporting PBAC score of more than 100 for two consecutive cycles were included in the study. In our study, TXA was used as an adjunctive treatment, along with conventional treatment. PBAC score was noted in all participants before starting TXA. Patients included in the study were given 500 mg of TXA orally, three to four 3 times a day/4 times a day (TDS/QID) times daily according to the estimated bleeding at the time of examination. Total doses of 1.5–2.0 g/day for the first 5 days (i.e., total of 7.5–10 g) were given. Patients were asked about improvement in the condition by history and were examined 7 days and 1 month following the treatment. PBAC scoring was done at the time of follow-up visit. Women with the previous PBAC scores between 100 and 120 were classified as bleeding less heavily, and those with scores >120 were classified as bleeding heavily. A PBAC score below 100 signifies a reduction in menstrual blood loss of <80 ml. Patient satisfaction was assessed by asking the patient to indicate (yes or no) whether they were satisfied with the treatment. We categorized the patients in different subgroups of anemia based on hemoglobin levels at the time of first visit: Mild anemia hemoglobin 10–11.9 g/dl, moderate anemia 7.0–9.9 g/dl, and severe anemia <7 g/dl. Hemoglobin and hematocrit levels were

measured after 1 month of treatment, and thereafter again if patients followed up with some complaint. We noted the changes in hemoglobin levels according to category, after treatment with TXA. Total doses of TXA given were noted in the outcome.

Recruitment of Obstetric Patients

In obstetrics, 16 women attending C.R. Gardi Hospital, Obstetrics, and Gynecology OPD with complaints of minor ailment such as threatened abortion, and post medical abortion bleeding were recruited and given TXA (500 mg TDS) orally for 4–5 days, depending on the clinical blood loss at the time of examination. In admitted patients, 24 women of PPH having more than average blood loss by our clinical judgment (average blood loss in vaginal delivery is 500 ml and in cesarean section 1000 ml) were recruited. In both the conditions, conventional treatment with TXA was given. For PPH, patients were given 1 g of TXA by IV injection over a period of 20 min. A second dose of 1 g of TXA was given if bleeding continued after 30 min following the first dose, or if bleeding stopped and restarted within 24 h of the first dose. A third dose was given to women who continued to bleed more than average after the second dose or if bleeding stopped and restarted within 24 h after the second dose. The patients with less bleeding received TXA (500 mg TDS) orally for 4 days. All patients received TXA as an adjuvant therapy. The primary therapy for each obstetric patient was noted in the outcome. The time of stoppage of bleeding was noted in all patients receiving TXA as an adjuvant therapy. The outcome variable is the number of obstetric cases of bleeding in which bleeding stopped after the first dose, second dose, and third dose of intravenous TXA. Another secondary outcome is the number of patients requiring other adjuvant therapy and the number of patients requiring operative intervention after the third dose of TXA.

Analysis of patients with respect to the above parameters was done for each group of patients separately. Data were analyzed using the student t-test, student paired t-test, and one-way ANOVA test and Shewhart control chart for mean. Data were represented by suitable diagrams and graphs and significance was defined as $P < 0.05$, to assess the efficacy of drug.

The study proposal was approved by Institutional Ethics Committee at R D Gardi Medical College, Ujjain (34/2019).

RESULTS

A total of 185 patients were recruited in the study, out of which 145 were gynecology patients and 40 were obstetrics patients.

Gynecology Results

Out of 145 cases of gynecology, patients with menstrual blood loss of more than 80 ml (i.e., PBAC score >100) were included in the study after excluding those having exclusion criteria. Of 145 cases, three women did not follow-up and one underwent a hysterectomy (opted for surgical treatment in the middle of the study), and were excluded from the analysis. Thus, there were 141 patients in gynecology group.

Response in Terms of PBAC Score after Treatment

Out of a total of 141 patients, 92 had PBAC scores of <120 before treatment with TXA. In this category, the score reduced to <100 in 78 patients, and to >100 in 14 patients after treatment. Before treatment, 49 patients had scores ≥120, of which 41 patients had reduction of scores to <100 and 8 patients had reduction of scores to >100, that is, between 100 and 120.

This table signifies that improvements in PBAC scores, and hemoglobin and hematocrit levels are all statistically significant ($P = 0.0$ in all parameters).

Obstetrics Results

C. A total of 40 patients were recruited in obstetrics, out of which 24 are PPH cases and 16 are abortion cases, in which we have given TXA at different doses according to the clinical condition and severity of bleeding**.** We will observe the results of the characteristics of study subjects in obstetrics and then we will observe the results in PPH patients, followed by the results in threatened abortion and post medical abortion cases separately.

Out of 24 patients, 14 (58%) were given 1 g of TXA and bleeding stopped within 1 h of treatment, 7 (29%) were given 2 g of TXA and bleeding stopped within 2 h of treatment and 3 (12.5%) were given 3 g of TXA and bleeding stopped within 3 h of treatment. The changes were all significant, with $P =$ of 0.000.

Women Requiring Operative Interventions

Out of 24 women, eight cases (33.33%) required operative intervention and 16 cases (66.66%) recovered without surgery – in the latter group, bleeding stopped after TXA was given.

Out of 16 women, bleeding stopped 1 day after giving 3 g or less of TXA in three women, bleeding stopped 2 days after giving 3 g or less of TXA in six women, bleeding stopped 3 days after giving more than 3 g of TXA in three women, and 4 days after giving more than 3 g of TXA in four patients. The patients whose bleeding stopped early required three grams or less of TXA relative to those whose bleeding stopped after 2 days, who required more than 3 g

of TXA. After applying Chi-square test, the p value of the change is significant ($P = 0.001$) for all groups.

DISCUSSION

Serum concentration of tissue plasminogen activator doubles, possibly because of tissue damage during childbirth within 1 h of giving birth. Thereafter, the concentration of plasminogen activator falls. Increased fibrinolytic activity has been described in obstetric hemorrhage secondary to uterine atony, placental abruption, and placenta accrete.[14] This concept provides the basis for a plausible role of antifibrinolytic agents (i.e., TXA) for the prevention, treatment, or both of PPH. In this study, we have given oral and injectable TXA in different doses, from 1 g to 10 g, over periods of 1 h–5 days in obstetrical and gynecological patients. Study subjects belong to various strata of society, representing diversity in economical and literacy backgrounds. For women who are ambulatory, it is difficult to assess improvement in blood loss. PBAC is a pictorial PBAC that is simple, yet more accurate method for the assessment of menstrual blood loss. Fraser *et al.* in 1984 devised PBAC, in addition to recording the number of towels and tampons used, and considered the degree to which individual items were soiled with blood. PBAC is not as accurate as objective methods like the standard hematin method. It provides simple and useful adjuvant therapy to enable clinician to identify women who require treatment and those who should be counseled. It also avoids unnecessary drug therapy, hospital stay, and surgical interventions in quite a significant number of women.

We found PBAC score to be a good criterion for assessing blood loss. The final charting of PBAC score was carried out after extensive questioning of women to assess blood loss and counseling was done in a contusive atmosphere. We feel a woman always tells her own story when she is allowed to talk to the gynecologist for some length of time. As such, for measuring improvement in blood loss, the subjective criteria of PBAC were used. Two objective criteria: Improvement in hemoglobin and hematocrit levels after 1 month was used. These two are definite and standard criteria to assess improvements in status of patients following treatment. In acute PPH, visual assessment by an obstetrician of time required to stop bleeding was used.

Gynecology Patients

Improvement in PBAC Score

For comparison, we divided patients into two groups: Those having PBAC scores before treatment of more than 120, and those with PBAC scores between 100 and 120. In gynecology patients, the overall improvement in PBAC score was 116 ± 8.32–95.90 ± 5.44 ($P < 0.00$) [Table 1]. This significant improvement was present in 84% of women having PBAC scores of more than 120 before study [Table 2]. Out of this, 65% of women were having heavy bleeding (PBAC scores of more than 120). Another 35% of patients who had moderate menorrhagia (PBAC scores between 100 and 120) showed an improvement following treatment by TXA. Other studies documented improvements of 38% and 60%, respectively, in heavily and moderately bleeding women. Figure 1 shows that changes

Table 1: "t-test" Comparison of Means of hemoglobin level, PBAC score, and hematocrit level before and after treatment with TXA

Variable		Mean	(*n*)	*P* value
1	Hb before	9.55±0.45	141	0.000
	Hb after	10.06±0.39	141	
2	PBAC before	116.63±8.32	141	0.000
	PBAC after	95.90±5.44	141	
3	Hematocrit before	24.73±4.18	141	0.000
	Hematocrit after	32.149±4.82	141	

Table 2: Improvement in PBAC score in gynae patients

PBAC score before treatment	PBAC score after treatment (*n*)		Percentage
	<100	>100	
<120	78	14	65
≥120	41	8	35
Total	84%	16%	100

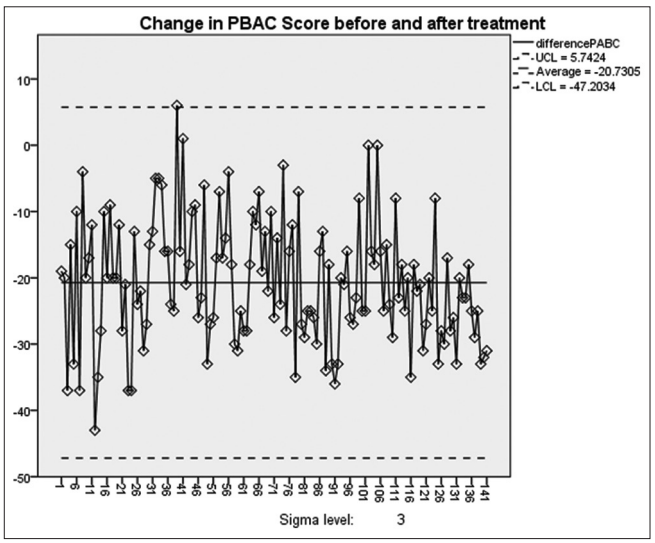

Figure 1: Statistical quality control list for change in pictorial blood loss assessment chart (PBAC) score before and after treatment. The average change in PBAC score is 20. After plotting all the patients on a control chart, the maximum patients experienced a change in PBAC score that was close to the average. PBAC scores decreased in almost all patients; in only four patients, PBAC scores were not reduced; signifies that tranexamic acid appears to stop the bleeding effectively

in PBAC scores occurred in all but four patients. The previous studies, dating back to 1995–1996, documented a reduction in menstrual blood loss of <80 ml/cycle in 56–100% patients following treatment with TXA.[15]

Improvement in hemoglobin level

In 85% of women having PBAC scores of 120 or more, there was a significant improvement in hemoglobin levels 1 month following treatment of 1-week duration. Improvement in hemoglobin levels was seen in each different category of patients (mild, moderate, and severe anemia) following treatment with TXA. Most women who were in the moderate anemia category before treatment shifted to the mild anemia category and women in the mild anemia category shifted to normal hemoglobin levels [Tables 1 and 3]. Average improvement in hemoglobin was 0.5 g % [Figure 2]. A previous study found a reduction in menstrual blood loss of 47% and a rise in hemoglobin level in none.[16] Another study found a reduction in PBAC scores of 60% ($P < 0.005$) and a rise in hemoglobin level ($P < 0.003$).[17]

An Indian study comparing TXA and ethamsylate use in dysfunctional uterine bleeding demonstrates the superiority of TXA in terms of effectiveness, reduction in blood loss and improvement in quality of life.[17] The geographical setting of this study is the same as ours (i.e., India).

Obstetric Patients

Improvement in PPH patients

In our study, bleeding stopped in 58% of patients within 1 h of receiving one gram of TXA, while bleeding stopped after 2 h in 29% of patients after a dosage of 2 g, and in 12.5% of patients, bleeding stopped after 3 h after a dosage of 3 g [Table 4]. Other researchers have given TXA as a preventive measure for PPH, and found that the treatment significantly reduced bleeding.[18] Some studies report infusion of more than 800 ml of TXA in women with PPH.[19] Other reports measuring blood loss between enrollment and 6 h after TXA found that TXA significantly reduced bleeding ($P = 0.041$).[20] These findings are comparable to those of our study. A big trial on 20060 patients with a diagnosis of PPH and being given TXA or placebo demonstrated a reduction in deaths due to bleeding by one third with use of TXA. This multicentric WOMAN trial was carried out over 6 years and analyzed on narrative data reporting deaths due to PPH. Collaborators of the same trial measuring outcome measures of mortality, hysterectomy, and other morbidities in women with clinical PPH and use of TXA in a placebo-controlled trial report significant difference between TXA and placebo groups ($P = 0.045$).[21-23] In our study, 66% of patients did not need any operative intervention and 33% patients needed operative intervention after treatment with

Table 3: Improvement in hemoglobin levels under various anemia categories before and after treatment with TXA

Anemia status	Treatment with TXA	
	Before	After
Normal	1	2
Mild anemia	24	81
Moderate anemia	116	58

Table 4: Correlation of TXA dose and time of stoppage of bleeding in PPH patients

Time of stoppage of bleeding		Dose of tranexamic acid			*P*-value
		1 g	2 g	3 g	
1 h	(n)	14	0	0	0.000
	% within time of stoppage of bleeding	100.00%	0.00%	0.00%	
2 h	(n)	0	7	0	
	% within time of stoppage of bleeding	0.00%	100.00%	0.00%	
3 h	(n)	0	0	3	
	% within time of stoppage of bleeding	0.00%	0.00%	100.00%	

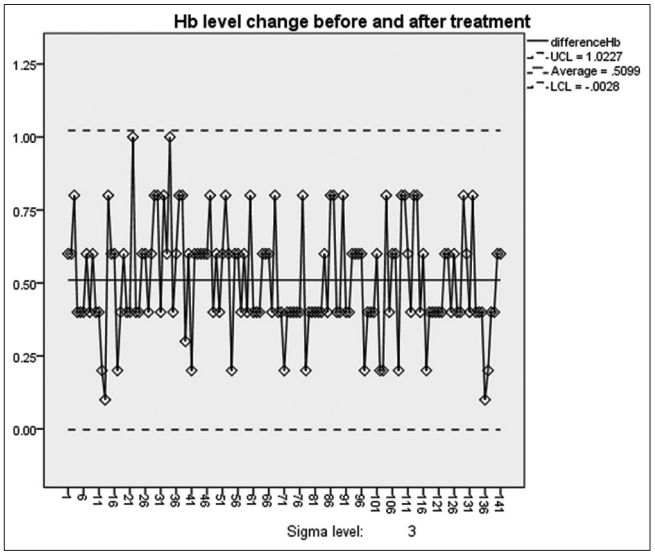

Figure 2: Statistical quality control list for changes in hemoglobin levels before and after treatment. The average change in hemoglobin level is 0.5 g%. After plotting all the patients on a control chart, all the patients experienced close to an average change in hemoglobin level, and experienced positive changes in hemoglobin levels. A reduction in hemoglobin was not seen in any patient, signifying that tranexamic acid improves hemoglobin status

TXA. Use of TXA within the first 3 h of birth in women with PPH is recommended by the International Federation of Obstetrics and Gynecology and the International Confederation of Midwives.[24] A very recent report has also mentioned a very positive outcome of the early use of TXA in PPH. In this study, administration of TXA was

the dominant strategy at all probability of maternal deaths due to hemorrhage >0.00002.[25]

Hemoglobin levels may not increase with TXA, but TXA will definitely prevent a decrease in hemoglobin, and provide early control of bleeding, hence stabilizing hemoglobin and prevent the development of anemia. In our study, the peripartum reduction in hemoglobin was −0.171 ± 0.33, with a $P = 0.02$, which is comparable to some researchers who in 2018 found reductions in mean hemoglobin levels of −0.77 ± 1.23, with $P = 0.64$.[16]

TXA also reduced the surgical treatment rate [Figure 3]. About 66.6% of patients did not require surgical treatment, while 33.3% did require a hysterectomy following treatment.

Improvement in abortion patients

No previous studies have been reported on the use of TXA in abortion. There were five women having threatened abortion, out of which two cases (40%) needed 3 g or less of TXA, while three women (60%) required more than 3 g of TXA [Table 5]. 11 women were suffering from medical abortion, out of whom seven women needed 3 g or less, while four women needed 3 g or more. Threatened abortion patients needed higher doses of TXA relative to those with post abortal bleeding. $P = 0.377$ is not significant while comparing doses for threatened abortions and post medical abortion. In 18.7% of patients, bleeding stopped after 1 day of treatment, in 38% after 2 days of treatment, in 18.7% after 3 days of treatment and in 25% after 4 days of treatment with TXA. Mean hemoglobin levels prior to TXA treatment was 9.56 ± 0.51, and following TXA treatment for various days to stop the bleeding was 10.13 ± 0.34. There is a rise in hemoglobin of 0.57, which is significant ($P = 0.001$). Out of all the abortion patients, only 6% had undergone evacuation and in the remaining 94% of patients, treatment with TXA stopped the bleeding in medical abortion patients, and helped continue the pregnancy in other patients.

Table 5: Correlation of dose of tranexamic acid with no. of days of stoppage of bleeding in threatened abortion

Days of stoppage of bleeding	Dose of TXA given		*P* value
	≤3 g	>3 g	
One	*n*=3	*n*=0	0.001
% Days of stoppage of bleeding	100.00%	0.00%	
Two	*n*=6	*n*=0	
% Days of stoppage of bleeding	100.00%	0.00%	
Three	*n*=0	*n*=3	
% Days of stoppage of bleeding	0.00%	100.00%	
Four	*n*=0	*n*=4	
% Days of stoppage of bleeding	0.00%	100.00%	

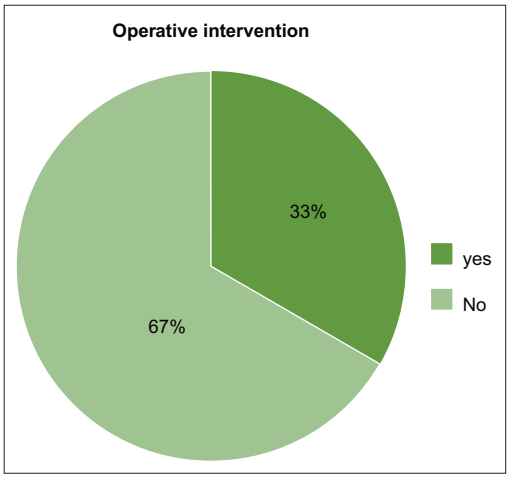

Figure 3: Obstetric patients requiring surgical Treatment

Recently, a recommendation has been made for all perinatal nurses to administer TXA as early as possible following a slightest prediction of PPH. Identifying the nurse's role in the management of PPH and its implementation is a best practice for treatment of PPH.[26,27]

CONCLUSION

Improvement in PBAC score in AUB patients, improvement in hemoglobin and hematocrit levels; and avoidance of major surgical treatments in AUB and mild PPH are major findings of this study. We conclude that TXA is a very good adjuvant tool for milder forms of bleeding in obstetrics and gynecology. Improvement of 0.5 g% hemoglobin in 1 week in gynecology patients and significant improvement in reducing menstrual blood loss in AUB patients are major findings of this study. Its role in optimizing management of PPH at the stage of uncertainty is appreciable.

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Institutional Committee Approval

This study was approved by Institutional Ethics Committee at R D Gardi Medical College, Ujjain, India (Approval no.-34/2019). We all authors confirm that informed written consent was obtained from all participants to carry out this work.

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Original Article

Clinical Profile of Ocular Trauma in Tertiary Hospital of Central India

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Abstract

Introduction: Ocular trauma is the significant public health problem in developing countries like India. It constitutes 7% of all bodily injuries and 10–15% of all eye diseases. WHO estimated the global annual incidence of ocular trauma of around 55 million per annum. It remains an important cause of monocular visual impairment and blindness. Health education and safety strategies should be addressed for the prevention of the serious ocular trauma, thus, we aim to highlight the clinical profile, risk factors and prevalence of ocular trauma in patients attending outdoor clinic at a tertiary care hospital of central India. **Material and Methods:** A prospective observational hospital based study of the patients with primary diagnosis of ocular trauma attending outdoor clinic of Ujjain charitable trust, Ujjain was conducted for a period of year. A cohort of 156 patients was finally included in the study during the study period. A detailed history of trauma and ophthalmology examination of patient was carried out as needed and the data was analyzed using SPSS software. **Results:** In our study, the prevalence rate is 5.8%. The most common age group is between 16-45 years with male predominance. The most common mode of ocular injury was agriculture followed by industrial and RTA. Corneal aberration, foreign body over cornea, corneal/corneo-scleral tear, iris prolapse were the most common findings. **Conclusion:** The incidence and prevalence of ocular trauma was more in rural population with male predominance. Most common modes of ocular injuries are agricultural followed by industrial.After lid lacerations and conjuctival hemorrhage, cornea was the most commonly affected ocular structure. Emphasis on public awareness and education about the use personal protective measures like goggles during work to reduce the occurrence of ocular trauma must be given.

Key words: Agriculture, Male predominance, Ocular trauma, Prospective observational study, Road traffic accidents

INTRODUCTION

Ocular trauma is among the significant public health problem particularly in developing countries like India. It constitutes 7% of all bodily injuries and 10–15% of all eye diseases.[1] Ocular trauma is a serious public health problem having high socioeconomic burden that affects a person's quality of life and has psychological impacts on patients.[2] The World Health Organization (WHO) estimated the global annual incidence of ocular trauma of around 55 million per annum.[2-5] Worldwide the annual incidence rate of hospitalization for ocular trauma per lakh population per year is 5–16%, while the blindness due to the same is estimated around 1.6 million people per year.[5-8] It remains an important cause of monocular visual impairment and blindness. It is a preventable cause of visual morbidity, if treated timely. It may occur at any age and in either gender, with males preponderance.[4,5,9-13] Late presentation of patient to eye health facilities after 24 h from time of trauma adds on to increase morbidity and complication rates.[2,3,9,10,14]

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The epidemiology of ocular injury is influenced by life style, socioeconomic status, traffic state, and sport and out-doors activities and can be by assault, workplace trauma, road traffic accidents (RTA), self-fall, thermal burns, and non-accidental injuries. These injuries are more common in adults. The most common pediatric eye injuries are sports-related, wooden stick, and thermal burns due to firecrackers. The most common ocular morbidities seen in ocular trauma are corneal tear, sclera tear, and lens damage.[9,10,14,15]

The occupational injuries can be due to high-risk occupations such as the manufacturing industry, plumbing, mining, and agriculture. Non-occupational can be sports

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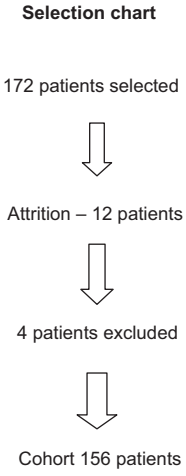
and domestic violence.[16] The commonly noted ocular traumas are corneal tear, sclera tear, and lens damage[9,10,14,15] along with associated facial or multiple injuries.

Health education and safety strategies should be addressed for the prevention of the serious ocular trauma; thus, we aim to highlight the clinical profile, risk factors, and prevalence of ocular trauma in patients attending outdoor clinic of Ujjain Charitable Trust Hospital, a tertiary care hospital of central India.

MATERIALS AND METHODS

A prospective observational hospital-based study of the patients with primary diagnosis of ocular trauma attending outdoor clinic of Ujjain charitable trust, Ujjain was conducted for a period of year. Out of total 172 patients were enrolled, following attrition of 12 patients and exclusion of six patients due to severe comorbid conditions, a cohort of 156 patients was finally included in the study during the study period. The ethics permission was granted by the Institutional Ethics Committee. A written informed consent was obtained from the study participants. The data were anatomized and confidentiality was maintained. The demographic data of the patient as age, gender, religion, caste, residential area, marital status, occupation, per capita family income, and educational status were recorded in a predesigned form.

Selection Chart



A detailed history of trauma including time, place, nature of injury whether mechanical or non-mechanical, circumstances of injury either occupational or non-occupational, and type of trauma whether blunt or sharp was recorded. Ophthalmology examination of patient was carried out as needed including visual acuity (Snellen's chart) check, slit lamp examination; indirect ophthalmoscopy with 90D and 20D; and measurement of intraocular pressure by Goldman applanation tonometer. B-scan was done for posterior segment. Radiological investigations such as skiagram orbit, computed tomography scan, and magnetic resonance imaging were done as indicated. Past history of any treatment taken for the same problem was also recorded. Terminologies were used based on Birmingham Eye Trauma Technology. All cases that had injury to the eyeball, optic nerve, orbit, upper and lower lids, eyebrows, and the lacrimal system were included in the study. The data were entered in Excel files and analyzed using the version 23 of the Statistical Package of the Social Science (SPSS) software.

RESULTS

Out of the total number of patients, that is, 2653 presenting to ocular outpatient department or casualty with ocular symptoms, a cohort of 156 patients was obtained. This results in prevalence rate of 5.8% in our study.

Sociodemographic Characteristics

In our study, out of 156 patients, 132 (84.61%) were male and 24 (15.38%) were female. Most of the patients were from rural area, that is, 93 out of 156 (Tables 1 and 2).

Age Pattern

The most common age group vulnerable to trauma is between 16 and 45 years (Table 3).

Common Cause of Ocular Injuries

The most common mode of ocular injury was agriculture followed by industrial and RTA (Table 4).

Clinical Findings

Lid lacerations/trauma and subconjunctival hemorrhage were seen in almost all case of ocular trauma, while corneal aberration, FB over cornea, corneal/corneoscleral tear, hyphema, and iris prolapse were also commonly seen (Table 5).

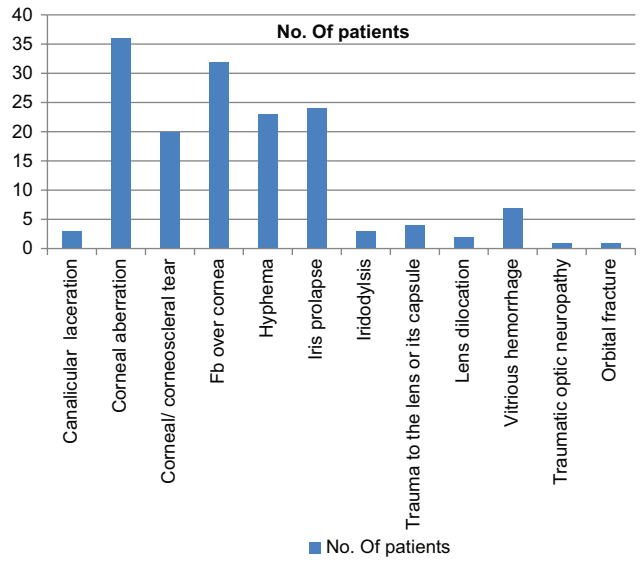


Table 1: Gender distribution

Gender	Total number of patients (*n*=156)
Male	132
Female	24

Table 2: Demographic distribution

Demographic distribution	Total number of patients (*n*=156)
Urban	63
Rural	93

Table 3: Age pattern

Age	Number of patients (*n*=156)
0–15 years	12
16–30 years	46
31–45 years	78
46–60 years	16
61–75 years	4

Table 4: Common cause of ocular injury

Causes	Number of patients
RTA	27
Toys/writing material	4
Firecraker	6
Sports	15
Abuse/assault	7
Chemical burns	13
Agriculture	43
Occupational/industrial	29
Fall	12

Table 5: Clinical findings

Clinical findings	Number of patients
Canalicular laceration	3
Corneal aberration	36
Corneal/corneoscleral tear	20
Fb over cornea	32
Hyphema	23
Iris prolapse	24
Iridodylsis	3
Trauma to the lens or its capsule	4
Lens dislocation	2
Vitrious hemorrhage	7
Traumatic optic neuropathy	1
Orbital fracture	1

Out of 156 patients, 126 patients required minor or major surgical interventions, while remaining patients were treated medically.

DISCUSSION

Ocular trauma is the major cause of preventable blindness and visual impairment, worldwide. In our study, the prevalence rate of ocular trauma was 5.8% which is in accordance with the Aravind Comprehensive Eye Study[17] who had prevalence rate of 4.5%. On the other hand, the Andhra Pradesh Eye Disease Study[18] had higher prevalence rate of 10.6%, while the lower prevalence of ocular trauma was observed in Maurya *et al.*[19] study (2.4%).

It is established fact that males have more incidence of ocular trauma and our study corroborates the same.[4,5,9,10,12,13] In our study, out of 156 patients, 132 (84.61%) were male.

The most common age groups observed in our study, who are more prone for ocular trauma, were between 16 and 45 years [124 out of 156 patients], that is, the young active working age group who drives the economy of the society. This is consistent with the study done by Charles *et al.*, where they recorded higher frequency of ocular injuries between 11 and 49 years (85.6%).[9] Our findings were similar to Dhasmana *et al.* who observed that the predominant age group of patients who are prone to ocular trauma was 21–40 years consisting of 55.29%.[3] On the contrary, Hawassa university study observed more of pediatric prevalence (62.87%).[20]

According to our study, the most common cause observed was agricultural [43 cases], followed by occupational and followed by RTA. This pattern may be due to more rural based population presenting at our hospital. While in study done by Guly *et al.*,[21] RTA was the most common cause [57.3%] of ocular injuries. In a study done by Maurya *et al.*,[19] the majority of ocular injuries were occurred at work and home.

In our study, Lid lacerations and subconjunctival hemorrhage were seen in almost all case of ocular trauma, while corneal aberrations [36 cases], followed by F.B. over cornea [32 cases], followed by iris prolapse [24 cases] and hyphema [23 cases] were the most common ocular findings. Corneal or corneoscleral tear were seen in 20 cases. The most common ocular morbidities seen in most of the studies in ocular trauma are corneal tear, sclera tear, and lens damage.[9,14,15] In study done by Guly *et al.*,[21] they observed 31% of cases having corneal involvement and 12.9% of cases with conjuctival involvement. In a study undertaken at Hawassa University, corneal tear was the most frequently observed case (39.33%),[20] while, a study done in western India, it was 15.2%.[10] Alem *et al.*[20] observed eyelid damage in 12.55%, whereas Tejas *et al.* observed it in 15.66% and Tehmina *et al.* IN 64%.[5,10] AC abnormality was in 18.37% of cases in Hawassa University study and it was seen in >50% cases in study done at Peshawar.[14] In contrast, the findings were lower in Nigeria (5.9%) and western India (8.29%).[9,10] Uveal prolapse was observed in 20.70% cases and about 24% lens damage was observed in study done by Alem *et al.*[20]

Figure 1: (a) Pre-operative lid laseration, post-operative – after 1 month, (b) before and after lid repair, and (c) open globe injury

Out of 156 patients, 126 patients required surgical interventions, (Figure 1) while remaining patients were treated medically. Our study is in accordance with Hawassa University study who too reported 53.17% of all cases undergoing ocular surgery secondary to ocular trauma.[20] While in study of,[19] 64.5% of patients receive medical treatment primarily.

CONCLUSION

The incidence and prevalence of ocular trauma were seen more common in males as compared to female. The prevalence of trauma was observed more in rural population. Most ocular injuries in this rural population occurred at the workplace, that is, on agricultural fields, which, in turn, signify most common cause of ocular trauma being agricultural in our study followed by industrial. After lid lacerations and conjunctival hemorrhage, cornea was the most commonly affected ocular structure. Emphasis must be given on public awareness and strict legislation to use personal protective measures like goggles during work to reduce the occurrence of ocular trauma.

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Original Article

Clinical Study of Intravenous Clonidine as a Hypotensive Agent in Functional Endoscopic Sinus Surgery: A Prospective Randomized Clinical Trial

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Abstract

Background: Functional endoscopic sinus surgery requires blood less field, controlled hypotension, good analgesia to prevent complications during the procedure. Clonidine promises such conditions as per various studies.

Aim: The aim of the study was to evaluation of hypotensive effect of clonidine in functional endoscopic sinus surgery (FESS).

Objective: The objective of the study was to (1) assess hypotension, systolic blood pressure, and diastolic blood pressure, mean arterial pressure, (2) Assess requirement of additional dose of fentanyl, metoprolol, and propofol during procedure. (3) Assess complications during surgery.

Materials and Methods: Study was carried out in SVRRGG hospital, Tirupati. Patients were included into study after informed written consent from the patients. Patients were randomly allocated into two groups, Group A clonidine) and Group B (non-clonidine). Each group has 30 patients. Demographic data such as age, sex, and weight of patients were collected. Other parameters such as systolic and diastolic blood pressure, mean arterial blood pressure, blood loss, requirement of additional drugs, and complications were analyzed.

Results: Average age of patients was 37 years. There was significant reduction in blood loss during surgery. There was controlled hypotension achieved in clonidine group. There was no requirement of additional dose of fentanyl and metoprolol for control of blood pressure and decreased use of propofol for maintenance of anesthesia. Clonidine administration preoperatively resulted in decreased blood loss. Complications of hypotension, bradycardia, nausea, and vomiting were less in clonidine group. Good sedation was also possible with clonidine.

Conclusion: Clonidine is good in controlling blood pressure, cheap and provides blood less field in FESS surgeries.

Key words: FESS, Clonidine, Mean arterial pressure, Blood pressure

INTRODUCTION

Functional endoscopic sinus surgery carried out in nasal polyps and other chronic sinusitis requires blood less field during the procedure. This is because of good vascularity in these areas and any surgery here results in good per operative bleeding. This could result in decreased visibility and difficulty in carrying out surgery.[1,2] Further there are other complications which could occur such as anosmia, nasal synechiae, cerebrospinal fluid leaking meningitis, nasolacrimal duct damage, optic nerve damage, and ocular muscle damage which can be the result from decreased field visibility during functional endoscopic sinus surgery (FESS).[3] The synthesis of clonidine was done by Stahle and Associates.[4,5] Derivative of imidazoline that exists as a mesomeric compound is a centrally acting alpha agonist agent. The effective dose of clonidine was found to be 4 microgram/Kg bodyweight. Moreover, this dose has no adverse effects.[6] It was found that clonidine performed well in controlling systolic and diastolic blood pressure, mean arterial pressure (MAP) on comparison with placebo.[7] Clonidine also controlled post-operative

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Table 1: Various observations in study Groups A and B

Module	Group A	Group B	Test used	P-value	Significant
Age	37.13±13.253 years	37.73±12.244 years	Chi-square test	*P*=0.932 *P*=0.05	Nil significant
Male/female	13/17	11/19	Chi-square test	*P*=0.598 *P*>0.05	Nil significant
Weight	60.1±11.9 Kgs	60.77±12.38	*t*-test	t-value–0.212 (Significance–0.832)	Nil significant
Diagnosis (Nasal polyps/ Chronic sinusitis)	22/8	19/11	Fischer test	*P*=0.405 *P*>0.005	Nil significant
Achievement of controlled hypotension (Y/N)	18/12	19/11	Chi-square test	Chi-square value-10 *P*=0.001 *P*<0.05	Significant
Additional dose of fentanyl requirement (Y/N)	12/18	24/6	Chi-square test	Chi-square value-10 *P*=0.001 *P*<0.05	Significant
Additional dose of metoprolol requirement (Y/N)	4/26	21/9	Chi-square test	Chi-square value-19.81 *P*=0.00001 *P*<0.05	Significant
Additional requirement of propofol (Y/N)	2/28	4/26	Chi-square test	Chi-square test-0.77 *P*=0.4 *P*<0.05	Not significant

shivering. It was found clonidine decreased bleeding during surgery, decrease in dose of analgesia, and use of additive drugs during FESS.[8] It was also found that clonidine reduced the dose of propofol and provided good control over hypotension during procedure.[9,10]

Some studies showed that dexmedetomidine better than clonidine during the FESS.[10,11]

In the presence of these studies, we planned for a study to study the effect of clonidine alone in comparison with normal anesthesia drugs during the FESS.

MATERIALS AND METHODS

The study was conducted in Department of Anaesthesiology, S.V.R.R.G.G. Hospital, Tirupati. Patients with 60–100 ASA Grades I and II posted for FESS were included into study after fulfilling inclusion and exclusion criteria as follows. A sealed envelope method was used for randomization for allotment of groups. Group A received clonidine, Group B control group. Study population was proposed 30 patients in each group for better comparison.

Inclusion Criteria

The following criteria were included in the study:

1. Patient in the age range of 20–60 years
2. ASA category I, II
3. No known history of allergy or other forms of sensitivity reactions to anesthetic drugs
4. Patient and relatives are willing to sign informed consent.

Exclusion Criteria

The following criteria were excluded from the study:

1. Hypertension on treatment other than clonidine
2. Diabetes with autonomic dysfunction
3. Patients on a beta-blocker or with contraindication for beta-blockers
4. Heart block of any degree/bradyarrhythmia
5. Ischemic heart disease
6. Patients on pacemakers
7. Patients taking clonidine/allergic to clonidine
8. Pregnant mothers.

A day before the surgery in the evening, pre anesthesia evaluation of patient was carried out. Patient was kept nil per orally 6 h before surgery. Well informed and written consent were taken from the patient before including into the study. Demographic date age, sex, and mean body weight were recorded.

Before the procedure in operation theaterrr, intravenous line with lignocaine infiltration secured and basal vital signs recorded. These included non-invasive blood pressure for every 5 min, electrocardiogram, pulse oximeter, and consciousness level monitored continuously.

The patients randomized into two groups using block randomization. Patients assigned to the intervention (Clonidine, Group A) group or control (Group B) group. Based on randomization, the patients received 3 micrograms/kg of the drug (Group A) intravenously 30 min before induction of anesthesia. The vital signs, as mentioned previously, are monitored for the next 30 min. General anesthesia induced with intravenous thiopentone

(5 mg/kg) after fentanyl (1.5 mcg/kg). After ensuring the ability to ventilate with oxygen, endotracheal intubation facilitated with succinylcholine (2 mg/kg). Anesthesia maintained with oxygen and sevoflurane. If necessary, further doses of clonidine administered for MAP of 55–65 mmHg, while Group B is control group without clonidine administration. Vital parameters continuously monitored as described till the end of the surgery. Despite the above measures, alternative methods are used for deliberate hypotension if the target MAP not achieved.

If the heart rate is <50/min, atropine (0.02 mg/kg) is given to treat bradycardia. If the MAP <55 mmHg, mephentermine 6 mg in incremental dosage administered to treat hypotension.

After completing the surgery, throat pack removed, and residual paralysis reversed with neostigmine (0.05 mg/kg) and glycopyrrolate (0.02 mg/kg). The patients are extubated when awake and monitored in the recovery room.

Blood loss estimated by measuring the number of gauge pieces soaked in blood during the procedure. Sedation assessed using Brussel's sedation score in the immediate post-operative period. Heart rate, systolic and diastolic blood pressure, and MAP, in both the groups, were recorded at various intervals such as pre and post induction, post intubation, and post extubation. Average heart rate, systolic and diastolic blood pressure, and MAP were calculated during the procedure. No of patient with achieved controlled hypotension in both groups was calculated. Other parameters such as blood less field of surgery and intraoperative blood loss in ml were calculated. Patients were monitored for complications such as hypotension, bradycardia, nausea, sedation, and vomiting.

Statistical Analysis

Various tests such as Chi-square, Fischer, and student t test are used for analysis of observations.

OBSERVATIONS AND RESULTS

We included in 30 patients in each group. They were randomly allocated into two groups. Each patient included in the study had equal possibility of getting into clonidine and non-clonidine groups. Average age of patient in the study was 37.43 ± 12. 654 years. Average weight of patient is 60.77 ± 12.384 kgs Table 1.

In our study, we found that controlled hypotension in Group A (clonidine) on comparison with Group B which was significant. We found 60% (18 patients) in clonidine group had good controlled hypotension when compared to 20% (6 patients) in non-clonidine group. Patient in Group B required additional dose of fentanyl for blood pressure control. Non-clonidine group required additional dose of metoprolol and propofol during general anesthesia for FESS.

Mean blood loss was found to be 90 ml in clonidine group than 200 ml in non-clonidine group, which was significant. Moreover, VAS score was much less in clonidine group.

DISCUSSION

FESS has been advised for patients with acute and chronic Sino nasal disease, not responding to conventional treatment. FESS has been advised for patients with sinusitis and nasal polyps. These tiny nasal structures have good vasculature, and surgeons do require good visibility during the procedure. Any surgery involving nasal mucosa results in severe sympathetic response resulting in tachycardia and hypertension. This can result in severe bleeding during surgery. Even a small amount of bleeding of the area results decreased visibility resulting complications.[12,13] Controlled hypotension is required to perform the procedure which not only decreases blood pressure and bleeding in surgical field area.[12,13]

Clonidine, an alpha two agonist used for premedication in adult and pediatric patients. This stimulates pre and post alpha two agonists in central nervous system resulting in analgesia, sedation, and sympathetic tone reduction.[10] A single pre-operative dose of clonidine can help in reducing the blood loss, in turn, reducing the surgical time and prevents surgical complications.[14]

Majority of patients in our study were having bilateral Sino-nasal polyp followed by chronic sinusitis. A similar observation was observed in Jiwanmall *et al.* study.[8]

We had lower MAP in clonidine group when compared Group B (non-clonidine). This has resulted in blood less field. There was significant lower MAP in clonidine group on comparison with placebo group as observations by Rajkumar *et al.* They also had significantly lower heart rate and MAP during and after recovery postoperatively in clonidine group.[15]

We had to use additional dose of fentanyl to decrease or to attain target blood pressure during surgery in non-clonidine group. Clonidine effectively helped in reaching target blood pressure during surgery. Clonidine was good in reduction of dose of fentanyl, isoflurane, and beta-blockers during anesthesia in the Hackmann *et al.* study.[3]

Table 2: Various complications observed during study in various groups

Complications	Group A	Group B
Hypotension	8	11
Bradycardia	2	0
Sedation	4	2
Nausea	2	7
Vomiting	1	4

Administration of metoprolol was required in non-clonidine group on comparison with clonidine group in various studies such as Jiwanmall *et al.* and Lee *et al.*[8,16] We also had similar findings. In our study, we had add metoprolol in four patients (clonidine group) when compared to 24 patients (non-clonidine group). This was statistically significant.

Addition of propofol during procedure was required in two and four patients in Groups A and B, respectively. This addition was required to control blood pressure, which was not controlled by fentanyl and metoprolol. There was no statistical significance between both groups. In Jiwanmall *et al.* study, they gave additional propofol in majority of non-clonidine group, where fentanyl and metoprolol failed to control blood pressure.[8]

There was 47% of reduction of blood loss during procedure in Rajkumar *et al.* study.[15] Jiwanmall *et al.* reported 33% reduction in blood loss.[8] we had 90 ml of blood loss in Group A when compared with 200 ml in Group B.

Pain score was very much reduced postoperatively in clonidine group in our study. Per- and post-operative analgesic effect was good in clonidine group in other studies.[2]

We had few complications reported such as hypotension, bradycardia, nausea, and vomiting as presented in [Table 2]. Jiwanmall *et al.* and Rajkumar *et al.*[14] also had complications of hypotension and bradycardia in their studies.[2,8]

CONCLUSION

Clonidine effectively achieves controlled hypotension as a single bolus dose when used with balanced anesthesia in FESS and reduces the intraoperative requirement of additional fentanyl and metoprolol. It effectively reduces intraoperative blood loss and provides a dry operating field. Clonidine also provides adequate analgesia without any significant side effects such as sedation, hypotension, and bradycardia. Use of clonidine for controlled hypotension is simple, safe, and cheap, making economic sense for developing and developed countries.

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Original Article

Clinical Audit of Pediatric Urolithiasis: A Cross-sectional Study

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Abstract

Background: Urolithiasis is a common cause of hospitals visits in emergency department. The epidemiology of the disease has been dramatically increased. In India, the lifetime prevalence of urolithiasis was 7.9% (5.7–10.8%). Around 7% of all stones occur in children younger than 16 years. Developing countries are endemic for bladder calculi and contribute a majority of stones from 10% in Nepal, and 21% in Tunisia, to 18% in Pakistan and 70% in Cameroon. In contrast to this bladder stones are rarely reported from the developed countries. Urolithiasis is associated to an increased risk of chronic nephropathy, so early detection is very important for these patients.

Materials and Methods: A total of 70 patients, suffering from urinary tract stones, were enrolled in the study over a period of 2 years. A detailed history relating to the disease process and about socioeconomic, cultural, and economic backgrounds of the patient is taken.

Results: In our study, we observed that 75.7% patients were males with majority of them belonging to 6–12 year age group (48.6%). Majority of the patient belonging to the lower socioeconomic status (68.6%) and consuming mixed diet (72.9%) and hard water (71.4%). Majority of the patients had single stone (75.7%) and were composed of calcium (58.6%). Most commonly located in bladder (52%). Most common symptom was pain (97.1%).

Conclusions: Gender of the patient, socio economic status of the family, their dietary habits, and source of drinking water have a direct relation with the presence of stones. Majority of the patients had single stone and most commonly it was found in urinary bladder followed by renal stones. Majority of the stones were symptomatic, with pain being the most common symptom which was present in almost all the patients.

Key words: Urolithiasis, Calcium stones, Bladder calculi

INTRODUCTION

Urolithiasis is a common cause of hospitals visits in emergency department. The epidemiology of the disease has been dramatically increased. In India, the lifetime prevalence of urolithiasis was 7.9% (5.7–10.8%).[1] The incidence of stone disease peaks around fourth to sixth decade and is more common in men than in women. While considered to be relatively rare in the pediatric patient, a growing body of evidence suggests that urolithiasis is becoming more common in children.[2] Around 7% of all stones occur in children younger than 16 years.[3] Developing countries are endemic for bladder calculi and contribute a majority of stones from 10% in Nepal, and 21% in Tunisia, to 18% in Pakistan and 70% in Cameroon. In contrast to this bladder stones are rarely reported from the developed countries.[4] In comparison with adult stone diseases, children are more likely to have etiological factors such as UTI, anatomic abnormalities, and surgical alterations. At present, the incidence of upper tract calculi

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Table 1: Age distribution

Age groups	Frequency	Percent
<3 years	3	4.3
3–6 years	18	25.7
6–12 years	34	48.6
12–18 years	15	21.4
Total	70	100.0

Table 2: Sex distribution

Sex	Frequency	Percent
Female	17	24.3
Male	53	75.7
Total	70	100.0

Table 3: Distribution based on socio-economic status

Socio-economic status	Frequency	Percent
Lower	48	68.6
Middle	22	31.4
Upper	0	0.0
Total	70	100.0

Table 4: Distribution based on dietary habits

Dietary habits	Frequency	Percent
Mix	51	72.9
Vegetarian	19	27.1
Total	70	100.0

Table 5: Distribution based on water source

Water source	Frequency	Percent
Hard Water	50	71.4
Normal	20	28.6
Total	70	100.0

in children is increasing worldwide. The reason for such an increase is not clear, but is associated to climactic (global warming seems to predispose to urolithiasis, thanks to the reduced urine output and to insufficient water intake), and diet changes (foods rich in sodium, animal protein and carbohydrates, typical from industrialized countries, and would favor the formation of calculi), genetic inheritance and, possibly, other environmental factors. Natural passing or surgical removal of the stone does not eliminate the cause, and many such patients suffer recurrences.

Urolithiasis is associated to an increased risk of chronic nephropathy, so early detection is very important for these patients. However, with such light cast upon this issue, it is critical for urosurgeon to strive for a stronger understanding of pediatric urolithiasis. During this review, we hope to spot the factors potentially contributing to rise in the childhood prevalence of urolithiasis.

Table 6: Distribution based on type of stone

Type of stone	Frequency	Percent
Calcium	41	58.6
Mixed+Not Diagnosed	29	41.4
Total	70	100.0

Table 7: Distribution based on number of stones

Number of stones	Frequency	Percent
1	53	75.7
2	4	5.7
Multiple	13	18.6
Total	70	100.0

Table 8: Association between number of stones and different locations

Location	Number of Stones			Total
	1 (*n*=53)	2 (*n*=4)	Multiple (*n*=13)	
Bladder				
Count	46	1	5	52
%	86.8	25.0	38.5	74.3
Renal				
Count	4	3	13	20
%	7.5	75.0	100.0	28.6
Urethral				
Count	2	0	0	2
%	3.8	0.0	0.0	2.9
Ureteric				
Count	1	2	1	4
%	1.9	50.0	7.7	5.7

MATERIALS AND METHODS

This was a cross-sectional study conducted at M.Y. Hospital and M.G.M Medical College, Indore, Madhya Pradesh, during 2020–2021. A total of 70 patients of 1 month–18 year age group from various socioeconomic, cultural, and economic backgrounds were included in this study who were suffering from various kind of urinary stones. Patients with congenital abnormalities, metabolic/intestinal disorders, endocrinal diseases, and renal or hepatic insults were excluded from the study. Informed consent (Assent) was taken from all patients or parents of the patient included in the study.

Patients were categorized into four groups on the basis of age-

1. Group 1: 1 months–3 years.
2. Group 2: 3–6 years.
3. Group 3: 6–12 years.
4. Group 4: 12–18 years.

All patients in study underwent a detailed history taking along with general examination and investigations. Their personal history, medical history, family history, dietary history, socio economic history, clinical history pertaining to pain hematuria, and fever were recorded and documented. Various blood investigations (CBC, RFT, SE, URINE R/M, URINE C/S, and Sr. Calcium); radiological investigations (X-ray KUB, USG KUB, IVP, DMSA, and CT Urogram); and stone analysis were done. All the data were processed to establish the relationship between the above mentioned factors and pattern of urinary stone diseases in pediatric population.

RESULTS

This was a cross-sectional study consisting of 70 cases suffering from different kinds of urolithiasis [Tables 1-8].

DISCUSSION

Age Distribution

In our study, it was observed that maximum number of patients were in 6–12 year age group (48.6%). In this age group, children are more communicative about their symptoms, therefore higher chances of them showing up in the hospitals. Furthermore, all the dietary and demographic factors have a cumulative effect with advancing age, leading to formation of stones. Similar results were found in the other study such as Barata and Valete,[5] Rizvi *et al.*,[6] and Qaader *et al.*[7]

Sex Distribution

In our study, we found that majority of the patients were male (75.7%) compared to females (24.3%). Males have high resistance pathway in urinary system which causes stasis of urine for longer duration and that could cause increased incidence of the development of stones. Similar results were also seen in Barata and Valete,[5] Rizvi *et al.*,[6] Qaader *et al.*,[7] Wathigo *et al.*,[8] and Faridi and Singh[1] study.

Distribution Based on Socio-economic Status

In our study, we observed that majority of the patients belonged to the lower income society with 68.6% belongs to the lower class and 31.4% belonging to the middle class according to modified Kuppuswamy scale[9] It is significantly related to the presence of stone. Lower socioeconomic status is associated with poor nutrition, heavy water with high mineral content, and higher incidence of UTI due to inadequate hygiene. Furthermore, the study was conducted in the public hospital, patients belonging to the upper class are unlikely, and hence a significant relationship could not be established.

Distribution Based on Dietary Habits

In our study, we observed that 72% of the patients consume mixed diet and rest 27.1% was consuming vegetarian diet. Mixed diet is high in protein and mineral content which leads to increased acidity of urine and increased urinary excretion of mineral which when added together can lead to stone formation.

Distribution Based on Water Source

In our study, we observed significant relation on the type of water consumption with that of the presence of stones, hard water was consumed by 71.4% of patients under study. Hard water is high in mineral content, which could be causative of stones.

Distribution Based on Type of Stone

In our study, we observed that the most common stone that was seen in the studied patients was found to be calcium oxalate stones 58.6%. Most of the dietary and environmental factors have role in development of calcium stones. High mineral and protein diet, hard water, dehydration due to climatic factors, and poor nutrition all are causative for stone formation. The results seen in the following studies, that is, Barata and Valete,[5] Rizvi *et al.*,[6] Qaader *et al.*,[7] and Wathigo *et al.*[8] showed calcium as a major constituents of urinary stone.

Distribution Based on Number of Stones

In our study, it was observed that the 75.7% of the stones were single. Similar results were observed in Faridi and Singh[1] study.

Distribution Based on Location of Stones

In our study, it was observed that most common location of the stone was bladder which was 74.3%. According to the literature, developing nations are endemic for bladder stones. Furthermore, urinary bladder is the dilated part of the urinary system and distally sphincters are present, therefore stasis of urine occurs for longer duration which can cause crystallization of stones. This is in contrast to other study like Rizvi *et al.*[6] where renal stones were found to be predominant. Wathigo *et al.*[8] observed in their study that the most common were ureteric stones 47%. In Qaader *et al.*[7] study, upper urinary tract stone was common in both children (84.6%) and in adults (80.7%). Studies that were conducted in developed countries were found to have upper urinary tract stones.

CONCLUSION

From our study, we can conclude that urolithiasis have a relation with multiple factors.

1. Gender of the patient, socio economic status of the family, their dietary habits, and source of drinking water have a direct relation with the presence of stones.

2. In our study, majority of the patients under study belonged to the lower socioeconomic status, which could be due to the poor nutrition availability or the water supply which makes them more prone for the development of the stones. Furthermore, the study was conducted in a government hospital set up which has more number of patients from the lower socioeconomic status due to economic reasons.
3. Dietary habits are very much influenced by the culture and economic status of the family of the patients. In our study, we found that those following vegetarian diet have fewer incidences of urinary stones.
4. Our study concluded that the males have higher predilection for the development of stones.
5. In our study, we found that the patients with stone majorly consumed hard water, which is significantly related with the type of stone. Hard water consists of added mineral which leads to higher incidence of stone formation.
6. From our study, we can conclude that majority of the stones are calcium oxalate stones.
7. Majority of the patients had single stone and most commonly it was found in urinary bladder followed by renal stones. According to the literature, developed countries has change in incidence from the lower to upper urinary tract stones, but developing countries have lower urinary system, stones are more common than the other.
8. Our study included a total of 70 patients, which has showed the result as described. We need to do a study with large sample size to establish any significant relations with the factors.

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Original Article

Effect of Duration of Infertility on IUI Outcome in Unexplained Infertility: A Prospective Study

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Abstract

Background: The purpose of this study was to study the effect of duration of infertility on IUI outcome in unexplained infertility.

Methods: This study was done in 40 couples with unexplained infertility. Mean age of female partner was 30 ± 5 years (25–30) years. In 6 (15%) couples, duration was <2 years; in 22 (55%) duration was between 2 and 5 years and in 12 (30%) duration was greater 5 years or more. A maximum of two cycles of IUI were done in two consecutive cycles after ovarian stimulation with clomiphene citrate 50 mg using double density gradient method of semen preparation.

Results: Two pregnancies (33.3%) were achieved in six couples with duration of infertility <2 years; 4 (18.2%) pregnancies were achieved in 22 couples with duration of infertility between 2 and 5 years and no (0%) pregnancy was achieved in couples with duration of infertility 5 years or more.

Conclusion: The success rate of IUI decreases with increase in duration of infertility.

Key words: IUI, HCG, Pregnancy rate, Unexplained infertility

INTRODUCTION

Unexplained infertility is best characterized as Subfertility.[1] It affects 10–30% of couples seeking treatment for infertility.[2,3] For unexplained infertility, both IUI alone and IUI with controlled ovarian stimulation appears to be more effective than expectant management.[4]

Overall success rate of ovarian stimulation with IUI varies between 8% and 22%.

Factors that influence IUI outcome include age of the female, duration of infertility, use of ovulation induction drugs, semen analysis, semen preparation techniques, timing, and number of inseminations.

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Aims and Objectives

The aim of the study was to study the effect of duration of infertility on IUI outcome.

MATERIALS AND METHODS

This study was done in Lal Ded Hospital Srinagar from January 2019 to September 2020 in 40 couples with unexplained infertility. Couples enrolled strictly followed the definition of unexplained infertility and an informed consent was taken from them. The mean age of female partner was 30 ± 5 years (25–30 years). The mean duration of infertility was 3.4 ± 2.28 years (1.12–5.68 years) [Table 1].

Ovulation induction with clomiphene citrate 50 mg was given from Day 2 of cycle for 5 days. Transvaginal ultrasonography to monitor follicular growth was done from day 9 till dominant follicle was 18–20 mm. HCG 5000 IU injection was given intramuscularly. IUI was planned 36–48 h after HCG trigger. Semen preparation was done using double density gradient centrifugation technique. Intercourse was advised for 3 days after IUI.

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Table 1: Distribution of couples based on duration of infertility

Duration (years)	No. of couples	Percentage
<2 years	6	15
2–5 years	22	55
≥5 years	12	30
Total	40	100

Mean±SD (Range)=3.4±2.28 (1.12–5.68)

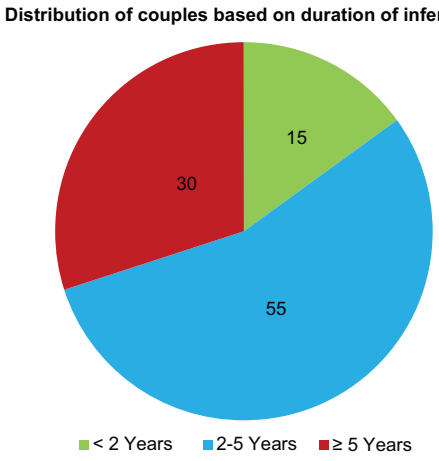
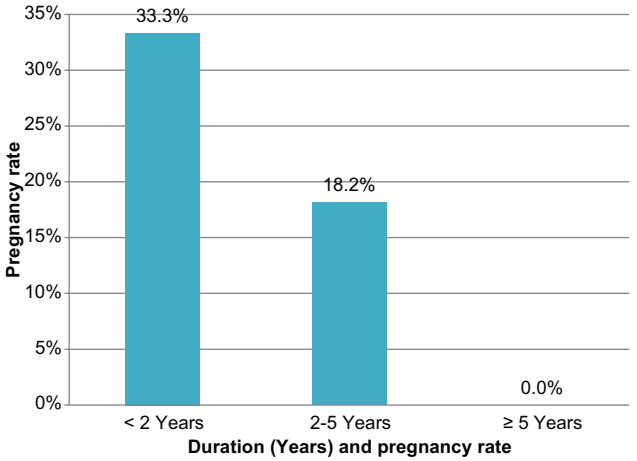


Table 2: Duration of infertility and pregnancy rate (PR)

Duration of infertility	No. of couples	No. of pregnancies	PR (%)	*P*-value
<2 years	6	2	33.3	<0.001*
2–5 years	22	4	18.2	
≥5 years	12	0	0.0	
Total	40	6	15.0	

*statistically significant (P<0.05)



Micronized progesterone 200 mg was given twice a day for 14 days. A Gravindex test was performed after 14 days.

A maximum of two cycles of IUI were given.

RESULTS

Among couples who were infertile for <2 years, 2 (33.3%) pregnancies were achieved; 4 (18.2%) in couples infertile for 2–5 years and no (0)% pregnancy was achieved in couples infertile for 5 years or more. The difference was found to be statistically significant with $P = 0.001$ [Table 2].

DISCUSSION

The duration of infertility is an important prognostic factor in success of IUI. In our study, the trend of IUI success declined with increase in infertility duration. The pregnancy rate was 33.3%, 18.2%, and 0% in duration of infertility <2 years, 2–4 years, and 5 or more years, respectively. This was found to be statistically significant ($P = 0.001$). Iberico *et al.*[5] have in their studies mentioned a lower pregnancy rate where duration of infertility was more than 3 years ($P = 0.073$). Delgadillo *et al.*[6] also found that greatest success of IUI was achieved when duration of infertility was 4 years or less ($P < 0.05$) ($P < 0.05$).

CONCLUSION

IUI is an effective treatment to start with in couples with unexplained infertility. The success rate of IUI and duration of infertility vary inversely.

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Original Article

Prevalence of Acute Renal Failure in Dengue at a Tertiary Care Hospital in J and K

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Abstract

Background: Dengue has emerged globally as the most frequent and medically relevant viral infection transmitted by a mosquito bite. Acute kidney injury is a known complication of dengue. Patients who suffer from dengue have various patterns of clinical presentation with unpredictable clinical course, ranging from clinically in apparent forms to severe bleeding and shock, eventually resulting in death that occurs in dengue shock syndrome or dengue hemorrhagic fever.

Aim: The aim of the study was to study the prevalence of acute renal failure in dengue disease at a tertiary hospital.

Materials and Methods: This study was a prospective observational and one point analysis. The study group comprised dengue patients admitted in GMC Kathua, J and K.

Results: A total of 60 patients were taken in which 45 (75%) were males and 15 (25%) were females. Mean creatinine on day 1 was 0.86 ± 0.26 in the patients without renal failure as compared to 1.62 ± 0.31 in the patients with renal failure. Mean creatinine at day 14 was 44.56 ± 7.2 compared to 47.64 ± 6.4 in the patients without and with renal failure, respectively.

Key words: Acute renal failure, Dengue, Creatinine

INTRODUCTION

Dengue disease has emerged globally as the most frequent and medically relevant viral infection transmitted by a mosquito bite. Acute kidney injury (AKI) is a serious complication of dengue.[1] The clinical spectrum of dengue ranges from selflimiting illness to lifethreatening dengue hemorrhagic fever (DHF) or dengue shock syndrome (DSS)[2,3] Acute renal failure is a rare but well recognized complication of dengue infection.[4]

This disease is caused by four closely related serotypes (DENV-1, DENV-2, DENV-3, DENV-4) of dengue virus, an arbovirus belonging to "*Flaviviridiae*" family. This virus is transmitted among humans by the bite of infective female mosquitos.[5] The vector mosquito first appeared in Africa, then disseminated together with the slave trade from the fifteenth to nineteenth centuries. The disease is transmitted through mosquito bites from female *Aedes Aegypti* infected with the virus, which require blood meals to obtain the protein needed for oviposition. This mosquito is a domestic vector with diurnal anthropophilic and zoophilic habits. The virus multiplies inside the mosquito's digestive system then spreads to different tissues. After an extrinsic incubation period of 7–11 days, on average, the virus reaches the mosquito's salivary glands; the period of virus transmission then begins and lasts throughout its lifetime.[6]

Patients who suffer from dengue have various patterns of clinical presentation with unpredictable clinical progression and outcomes, ranging from clinically in apparent forms to severe bleeding and shock, eventually resulting in death that occurs in DSS/DHF.[1] Incidence of DHF/DSS varies from 0.3% to 3.3% in different populations. Reinfection with a different serotype of dengue virus is associated with severe clinical manifestations, likely due to cross-reactive antibodies.[7] The first manifestation of classic dengue is sudden onset of fever, accompanied by headache, prostration, myalgia, arthralgia, retro-orbital pain, and non-maculopapular but itchy exanthema. In

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Table 1 : Clinical presentation

Clinical parameters	Dengue fever (*n*=42)	DSS/DHF (*n*=18)	Total (*n*=60)	*P*-value
Renal Failure	1	9	10	*P*<0.007
Hematuria	1	3	4	*P*<0.004
Proteinuria	2	4	6	*P*<0.003

Table 2: Clinical & Lab parameters

Variables	Renal Failure	
	Absent (*n*=50)	Present (*n*=10)
Urea	28.41±8.4	56.74±8.40
Creatinine (Day 1)	0.86±0.26	1.62±0.31
Creatinine (Day 14)	0.67±0.12	0.90±0.14
Hematocrit (%)	44.56±7.2	47.64±6.4
Platelet (cells/CMM)	81306±64322.24	30946.71±24686.15
Bilirubin (mg/dl)	1.12±1.02	1.89±2.61
Sodium (mmol/l)	134.80±14.30	130.31±6.76
Systolic blood pressure (mm hg)	112.84±12.84	90.81±8.71
Diastolic blood pressure (mm hg)	73.044±7.32	64.32±9.60

addition, anorexia, nausea, vomiting and diarrhea might be present in some of the patients. The initial symptoms in DHS/DSS are similar to those of the classic dengue fever that is followed by bleeding and/or cavity effusion, hemodynamic instability, and/or shock. The hemorrhagic manifestations are associated with decrease in platelet levels.

Various patterns of renal involvement have been observed in patients with dengue that include increase in serum creatinine level, AKI, acute tubular necrosis, hemolytic uremic syndrome, proteinuria, glomerulopathy, and nephrotic syndrome.[8,9] AKI is a significant, poorly studied, and complication that occurs due to dengue. The data available are heterogeneous and mostly originate from retrospective case series and case reports.

Viral infection-induced renal injury are due to various mechanisms like an immune-mediated mechanism triggered by viral antigens that are bound to glomerular structures, direct cytopathic effect of the viral protein on the glomerulus and tubules, tissue injury caused by immune complexes composed of viral antigens and antiviral antibodies and damage caused by inflammatory mediators released in response to the glomerular or tubular cytopathic effects of the viral antigens.[10]

Rhabdomyolysis is considered a rare complication of dengue. Histological abnormalities in kidney biopsy samples, muscle weakness, myalgia, and elevated serum creatine-kinase levels have been obtained in different populations of dengue patients.[11] The pathogenesis of dengue-associated rhabdomyolysis has not been well studied.

The aim of this study was to study about different clinical presentations, frequency, and severity of acute renal failure in dengue.

MATERIALS AND METHODS

This study was performed from August 2020 to January 2022 at Govt. Medical College Kathua, J and K. A total of 70 patients were enrolled for this study after qualifying inclusion/exclusion criteria. The diagnostic criteria of dengue illness were febrile illness associated with one of the following laboratory confirmation tests: (1) Detection of dengue specific IGM antibody or (2) Detection of NS1 Antigen. Exclusion criteria were patients having IgG antibody positive against the dengue virus and patients of chronic kidney disease.

DHF/DSS was labeled in the patients who were having dengue fever and hemorrhagic manifestation, low platelet count, elevation in hematocrit, pleural effusion or ascitis or shock. Patients were diagnosed as having acute renal failure if serum creatinine was more than 1.2 mg/dl.

Study Design

It is an observational prospective study of demographic data of age, gender with severity of dengue infection of each patient recorded. All baseline blood investigations were done at first hospital visit. Proteinuria was defined as *Urinary Protein* more than **1+** by Dipstick Test and more than 5 RBC/HPF was defined as *Microscopic hematuria*.

RESULTS

A total of 60 patients were taken in which 45 (75%) were males and 15 (25%) were females. Among the total of 60 patients, 42 (70%) had dengue fever and 18 (30%) had DHF/DSS. The patients with DHF/DSS were more susceptible to develop renal failure as compared to dengue fever group. Mean urea level was 28.41 ± 8.4 in the patients without renal failure as compared to 56.74 ± 8.40 in the patients with renal failure ($P < 0.001$). Mean creatinine on day 1 was 0.86 ± 0.26 in the patients without renal failure as compared to 1.62 ± 0.31 in the patients with renal failure ($P < 0.001$).

Mean creatinine at day 14 was 44.56 ± 7.2 versus 47.64 ± 6.4 in the patients without/with renal failure, respectively.

In our study, patients with renal failure had higher values of serum bilrubin, lower platelet levels, and higher hemoconcentration. There were no mortality and none of the patient underwent dialysis during hospitalization.

DISCUSSION

Dengue fever along with other tropical infections such as *malaria* and *leptospirosis* has been reported to cause AKI. Classic Dengue fever often presents as self-limiting illness whereas DHF/DSS have been associated with high mortality and morbidity. Renal failure in dengue illness is due to various proposed mechanisms. Dengue causes leakage from capillaries and loss of fluid leading to third space loss which leads to decreased blood flow to kidney and acute tubular necrosis. It also causes rhabdomyolysis, hemolysis and severe DIC which leads to ischemia and multi organ dysfunction. Although rhabdomyolysis is a rare complication of dengue, histological abnormalities in kidney biopsy, myalgia, and muscle weakness have been described in dengue patients. The muscle damage might be cause by direct viral invasion or cytokines. Analysis of renal biopsy samples from patients with severe dengue have shown IgG, IgM, and C3 deposit in Glomeruli, basement membrane thickening and deposition of immune complexes.

In our study, there were statistically significant frequencies of renal failure in DHF/DSS group than dengue fever group. Our findings were consistent with Kuo *et al*.[12] who have showed that patients with DHF/DSS in AKI group had higher mortality and morbidity than those without AKI.

Proteinuria has been associated with the severity of disease and is alleviated in severe dengue. Proteinuria was seen in 10% of patients in our study. Out study was consistent with the study by Eswarappa *et al*.[13] in which proteinuria was seen in 9% patients. There is a wide variability in overall incidence of proteinuria as it was seen as high as 74% in study by Horvath *et al*.[9] meanwhile Garcia *et al*.[14] retrospectively studied 74 patients with dengue fever or DHF who had a platelet count of <125,000/mm^3; the prevalence of proteinuria in this cohort was 30% Meanwhile, hematuria was seen in 6.6% patients.

Limitations

1. Study was a single centered study.
2. Histopathological reports of patients with dialysis were not available.
3. Limited case numbers.
4. There was a lack of long-term follow-up.

CONCLUSION

DHF remains to be viewed as a global issue. Understanding the pathogenesis and validating efficient prevention and control strategy are warranted against dengue invasions to humans. Prediction of the DHF development in the DF patient needs to be closely observed and more clinical manifestations and clinical laboratory tests be considered.

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Original Article

Gender Differences in Relation to Antimicrobial Resistance in *Escherichia coli* among Urinary Tract Infections in Patients from Kerala

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Abstract

Introduction: Urinary tract infections (UTIs) are one of the most common infections requiring medical care. Due to anatomical and physiological variations, the incidence of UTI is more common in females. Among the UTI samples, *Escherichia coli* is the most commonly isolated organism. Antibiotics are prescribed and the dose and duration of antibiotic usage depend on several factors. An estimation of the effectiveness of antibiotics among the male and female patients in the general population can help in prescribing the right antibiotic for the patient.

Aim: The aim of this study was to assess the usefulness of antibiotics against *E. coli* based on CLSI guidelines using Kirby–Bauer method and to estimate the prevalence of extended-spectrum beta-lactamase producing *E. coli*.

Materials and Methods: A total of 1349 Clean Catch Midstream Urine Samples (CCMSUs) were selected during the study period. After exclusions, totally 445 samples of monobacterial growth of more than 10^5 cfu/mL were considered for the study. Among these 179 isolates were *E. coli* and these isolates were considered for the present study. One hundred and twenty-one isolates were from female patients, whereas 78 isolates were from male patients. All samples were cultured on culture enriched and selective media by semi-quantitative method. Antibiotic susceptibility testing of all isolates was performed by Kirby–Bauer's disk diffusion method and interpretation of the results was done based on CLSI 2021. Bacterial suspension was made and compared to 0.5 McFarland turbidity standards in peptone water. Antibiotic disks (HiMedia Laboratories Pvt. Ltd. Mumbai) used were ampicillin (10 μg), gentamicin (10 μg), ciprofloxacin (5 μg), levofloxacin (5 μg), cotrimonazole (25/1.25 μg), amoxicillin–clavulanic acid (20/10 μg), piperacillin/tazobactam (100/10 μg), norfloxacin (10 μg), amikacin (30 μg), ceftazidime (30 μg), ceftazidime + clavulanic acid (20/10 μg), cefuroxime (30 μg), cefotaxime (30 μg), imipenem (10 μg), aztreonam (30 μg), tetracycline (30 μg), nitrofurantoin (300 μg), tobramycin (10 μg), colistin (10 μg), etrapenem (10 μg), doripenem (10 μg), and meropenem (10 μg). Extended-spectrum β-lactamase (ESBL) producing *E. coli* were was confirmed phenotypically using combined disk diffusion method.

Results: The *E. coli* isolates from male patients were more resistant to antibiotics ciprofloxacin, gentamicin, nitrofurantoin tobramycin, and piperacillin-tazobactum. Ciprofloxacin was resistant in 66.7% of isolates from males and 50.4% in females with a statistically significant $P = 0.046$. Gentamicin resistance was at 38.5% of males and 21.5% in isolates from female patients with $P = 0.015$. Nitrofurantoin showed a resistance of 15.4% in males compared to 5.8% in females with $P = 0.045$. Tobramycin was resistant in 38.5% of male isolates compared to 10.7% from female patients with a highly significant $P < 0.001$. Piperacillin-Tazobactam showed a resistance percentage of 16.7% in males compared to 6.6% in *E. coli* isolates from female patients with $P = 0.033$. Ninety-five isolates (53.07%) of isolates of *E. coli* were ESBL producers.

Conclusions: Every health-care institutions must develop its own antimicrobial policy and this policy need to be reassessed at least once in 6 months to know the pattern of emerging resistance as well as to decide about the use of antibiotic recycling for the better usage of available antibiotics for treatment of UTI.

Key words: Adherence, Antibiotics, Enterobacteriaceae, *Escherichia coli*, Extended-spectrum β-lactamase, Pili, Uncomplicated Urinary Tract Infection, Uropathogenic *E. coli*, Uropathogens

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INTRODUCTION

One of the most important events in history of mankind is the discovery of antibiotics. Countless number of lives has been saved over the decades. Antibiotics are being used in treatment of variety of infections. This ranges from prophylactic antibiotics before elective or

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emergency surgeries to life-threatening infections. Over a period of time, the pathogenic bacteria have an ability to exhibit resistance to the antimicrobials and are termed as antimicrobial resistance (AMR). Due to the AMR, the effective usage of antibiotics is coming down leading to increase in economic burden to the patient as well as limiting the therapeutic options available to the treating physician.

Although the exposure of humans to antibiotic resistant strains is uniform, there are definite anatomical, socioeconomic, biological, and cultural differences among the members of different gender. For example, urinary tract infections (UTIs) are more common in women and if left untreated can result in serious health complications. From the literature, it is learnt that about 15% of all prescription antibiotics are used to treat UTI.[1,2] The most important element in decision making is the choice of antibiotic that is effective as well as cost efficient. Wide-spectrum antibiotics are commonly employed to treat UTIs when, instead, a narrow-spectrum antibiotic could have been sufficient for an effective treatment.[3] The effect of blanket use and misuse of antibiotics has led to emergence of resistance.[4-6] Apart from the above-mentioned factors, patient compliance to the prescription and over the counter pharmacy plays a major role in increasing the resistance to commonly used oral antimicrobial agents.

Gender-Wise Differences in Pathogenesis

Due to age and gender, UTIs tend to exhibit different epidemiological and etiological properties.[7] Isolates obtained from males and females might have different resistance profiles. Anatomical factors and alterations play an important role in the pathogenesis of UTI in women. The shortness of the urethra and its close relationship to the anus allows the bacteria to ascend easily into the urinary tract in females. The fecal-perineal-urethral contamination is the most probable explanation for infections caused by enteric bacteria, as demonstrated by experiments evaluating the genotype of *Escherichia coli* strains causing UTI in women.[8,9] Lactobacilli are the dominant bacteria in the vaginal biota and are responsible for maintaining the acidic pH by producing hydrogen peroxide.[10] Incomplete treatment and recurrent infections may shift the local predominance of flora from lactobacilli to coliform Uropathogens or a mix of both leading to loss of protective effects conferred by lactobacillus.[11] An alteration in vaginal flora is also observed during the postmenopausal period as the estrogen stimulating the proliferation of lactobacilli is lacking. Studies suggest that a family history of UTI in a first-degree relative increase the risk of recurrent UTI and pyelonephritis in women.[12] In premenopausal women, 90% of the vaginal flora is *Lactobacilli*, which protect the system against colonization with uropathogens such as *E. coli*. After menopause, the decrease in estrogen levels leads to thinning of vaginal epithelium and decrease amount of glycogen. The end result is a hostile environment to growth of Lactobacilli and reduced ability of the epithelium to resist bacterial colonization.[13]

There are evidences to suggest that human P and ABO blood group antigens play a role in susceptibility to UTI. Individuals with the P1 antigen are more predisposed to invasion by P fimbriated microorganisms.[14] Apart from the above-mentioned factors, the pregnancy and sexual intercourse have been documented as risk factors for women developing UTIs.

As far as the males are concerned, the common risk factors for development of UTI are Diabetes, Urolithiasis, Benign hypertrophy of Prostrate (BPH), an abnormal narrowing of the urethra, incontinence of urine, use of immunosuppressive agents, or history of instrumentation of the urinary tract. Men's risk for UTI increases with age, men are more likely more susceptible to UTIs after 50 years of age, when they are more likely to develop prostate problems. Enlarged prostate gland in BPH impedes and slows the flow of urine, thus raising the risk of infection. It has been observed that men who are not circumcised tend be more prone to developing UTIs, because these bacterial build up much more easily in the folds of the extra skin on the penis, thereby making them more susceptible to developing UTIs.[15]

Antibiotic Microbial Resistance Profile in Indian Scenario

The recent literature on urinary tract infections in India highlight the fact that the 60–80% of infections are seen in the female population. Among the female gender, the most common organism causing UTI is *E. coli* that the antibiotic sensitivity pattern in the recent years shows that the antibiotic resistance of *E. coli* to cephalosporins and fluroquinolones is a Pan-India phenomenon. The fluroquinolones, namely, ciprofloxacin, ofloxacin, and levofloxacin are not effective in 50–70% of the Indian isolates. In the same way, the antibiotics belonging to the cephalosporins are ineffective in 60–70% of *E. coli* isolates.[16-21] The sensitivity to antibiotics varies considerably depending on the local prescribing pattern. In a study done by the author in 2018, the antibiotic sensitivity pattern of *E. coli* showed marked difference between the extended-spectrum β-lactamase (ESBL) and non-ESBL isolates.[18] The ESBL isolates exhibited a remarkable lowering of sensitivity to cephalosporins, fluroquinolones, aminoglycosides, and tetracycline. The National Center for Disease Control under the Ministry of Health and Family Welfare, Government of India has published an important document named National Treatment Guidelines for Antimicrobial Use in Infectious Diseases in the year 2016.

In this guideline, the empiric therapy is with nitrofurantoin or cotrimoxazole or ciprofloxacin along with a comment to modify antibiotics based on culture and sensitivity report.

The guidelines issued by Indian Council of Medical Research (ICMR) in the year 2019 for treatment "Guidelines for antimicrobial use in common syndromes" emphasises *E. coli* as the predominant cause of Urinary Tract Infections and has suggested nitrofurantoin as a drug of choice in empirical therapy and fosfomycin as a go to drug in gram negative multidrug resistant organisms.

MATERIALS AND METHODS

The study was conducted at Azeezia institute of Medical Sciences and Research, Kollam district of Kerala State during the period of January 2021 to January 2022 to assess the antibiotic sensitivity pattern of uropathogenic *E. coli* among the isolates from urinary samples of males and female patients collected in patients reporting to the hospital with complaints suggestive of urinary tract infections.

All non-repetitive midstream urine samples obtained during the study period were included in the study. A total of 1349 Clean Catch Midstream Urine Samples (CCMSUs) were received in the microbiology laboratory during the study period. These samples were subjected to wet mount examination and were inoculated to 5% sheep blood agar and MacConkey agar plates. The plates were kept for incubation at 37°C for 18–24 h. After 24 h of incubation at 37°C 322 samples did not show any evidence of bacterial growth and were reported as no growth. One hundred and six samples showed presence of more than three types of bacterial growth which also corroborated with the wet mount findings and were not processed further. Three hundred and fifty-four samples showed $<10^4$ cfu/mL and in the absence of clinical history of catheterization or antibiotic intake which were reported as insignificant growths. One hundred and twenty-two samples grew Gram-positive yeast such as organisms (candida sp) or Gram-positive spore bearing bacilli and were excluded from the study. After exclusions, totally 445 samples of monobacterial growth of more than 10^5 cfu/mL were considered for the study. Eighty-nine samples grew Gram-positive organisms such as *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus* sp., *and Enterococcus* sp. Three hundred and fifty-six isolates were Gram-negative bacilli out of which 177 isolates were *Klebsiella pneumoniae*, *Citrobacter* sp., *Enterobacter, Proteus vulgaris, Proteus mirabilis, Pseudomonas aeruginosa,* and *Acinetobacter* sp. One hundred and seventy-nine isolates were *E. coli* and these isolates were considered for the present study. Among these 179 isolates of Uropathogenic *E. coli,* 121 isolates were from female patients, whereas 78 isolates were from male patients.

Processing of Samples

All samples were cultured on culture enriched and selective media by semi-quantitative method. Samples were inoculated on 5% Sheep Blood Agar plate and MacConkey agar plate by streaking using sterile calibrated wire loop and incubated aerobically for 18–24 h at 37°C. Samples which showed monobacterial significant grown ($>10^5$ CFU/mL) were included in this study. Isolation and identification of isolates were based on their morphology in Gram staining, cultural characteristics, and biochemical reactions.[22] Antibiotic susceptibility testing of all isolates was performed by Kirby–Bauer's disk diffusion method and interpretation of the results was done based on CLSI 2021. Bacterial suspension was made and compared to 0.5 McFarland turbidity standards in peptone water. Antibiotic disks (HiMedia Laboratories Pvt. Ltd. Mumbai) used were ampicillin (10 μg), gentamicin (10 μg), ciprofloxacin (5 μg), levofloxacin (5 μg), cotrimoxazole (25/1.25 μg), amoxicillin–clavulanic acid (20/10 μg), piperacillin/tazobactum (100/10 μg), norfloxacin (10 μg), amikacin (30 μg), ceftazidime (30 μg), ceftazidime + clavulanic acid (20/10 μg), cefuroxime (30 μg), cefotaxime (30 μg), imipenem (10 μg), aztreonam (30 μg), tetracycline (30 μg), nitrofurantoin (300 μg), tobramycin (10 μg), colistin (10 μg), etrapenem (10 μg), doripenem (10 μg), and meropenem (10 μg).

Procedure

Antibiotic sensitivity testing was done using Kirby–Bauer method. Disks were applied aseptically. Gap of 24 mm center-center was ensured as per CLSI guidelines. Plates were incubated at 35 ± 2°C and examined after a minimum of 16–18 h.

Screening for ESBL Isolates

Screening of ESBL producing *E. coli,* according to CLSI guidelines, strains showing zone of inhibition of ≤22 mm for ceftazidime, and/or ≤17 mm for cefpodoxime and/or ≤ 27 mm for cefotaxime were considered for confirmation test for ESBL. ESBL producing *E. coli* isolates were the sub-cultured into sterile Nutrient Agar plates and incubated for 24–48 h. The isolated single colonies were used for further comparative studies. ESBL production among potential ESBL producing isolates was confirmed phenotypically using combined disk diffusion method. Comparison of the zone of inhibition was made for the ceftazidime (30 μg) versus that of the ceftazidime disk in combination with clavulanic acid (30/10 μg), placed 25 mm apart (center to center). A difference in the inhibition zone diameter of ≥5 mm for a combination disk versus ceftazidime disk alone confirmed ESBL production (phenotypic confirmatory disk diffusion test).[18]

RESULTS

The antibiotic sensitivity pattern of *E. coli* showed a marked difference in resistance percentage between the isolates from males and females. The *E. coli* isolates from male patients were more resistant to antibiotics such as ciprofloxacin, gentamicin, nitrofurantoin tobramycin, and piperacillin tazobactum. Ciprofloxacin was resistant in 66.7% of isolates from males and 50.4% in females with a statistically significant $P = 0.046$. Gentamicin resistance was at 38.5% of males and 21.5% in isolates from female patients with $P = 0.015$. Nitrofurantoin showed a resistance of 15.4% in males compared to 5.8% in females with $P = 0.045$. In the same manner, tobramycin showed a resistance percentage of 38.5% in males compared to 10.7% in *E. coli* isolates from female patients with a highly significant $P < 0.001$. Piperacillin-Tazobactam showed a resistance percentage of 16.7% in males compared to 6.6% in *E. coli* isolates from female patients with $P = 0.033$. The resistance percentage of antibiotics such as amoxicillin-clavulanic acid, amikacin, ampicillin, ceftazidime, cefotaxime, imipenem, and cotrimoxazole was similar in males and females. In our study, 95 isolates (53.07%) of isolates of *E. coli* were ESBL producers.

DISCUSSION

Urinary tract infections are one of the most common infections in clinical practice. In our study, total of 1349 samples were collected, out of which 106 samples were identified to have more than three bacterial species. This may be due to errors of sample collection or improper instructions being given to patients during sample collection. Although the percentage of such samples when you look at the total number may be less there is a chance of missing out true cystitis and the probability of patient coming back with a repeat sample is comparatively less in a community set up. Three hundred and fifty-four samples showed no evidence of UTI as per the current diagnostic guidelines. Three hundred and twenty-two samples showed no bacterial growth despite the clinical suspicion of UTI. Both these categories account for nearly 50% of samples. This may be due to the fact that some of the organisms were not cultivable by culture or the more practical explanation that would be the delay in transport of samples to the laboratory leading to reduction in bacterial numbers due to acidity of urine. Although the above said factors are speculative and questionable, the mere numbers highlight the importance of training and repetitive emphasis to the clinicians, nurses, laboratory technicians, and other ancillary staff regarding importance of proper instructions being given to the patient regarding sample collection, specimen handling, transport, and early processing of samples to achieve a microbiological report which coincides with the clinical judgment and the one which will be finally be useful for treatment of UTI.

As it has been noted in various other studies, the most common single bacteria causing UTI in our study were *E. coli*. About 80% of UTI were due to Gram-negative bacteria, out of which 50.28% was due to *E. coli*. Adult women had a higher prevalence of UTI than men may be due to anatomical and physiological factors. *E. coli* belonging to the Enterobacteriaceae family is known to colonize the uroepithelium with adhesion, pili, fimbriae, and P1 blood group phenotype receptor.[23] In our study, 53.07% of *E. coli* isolates were ESBL producers. This higher percentage reflects on the emergence of resistance in the geographical area and local antibiotic usage patterns. It is to be emphasized that the ESBL producing bacteria may not be detectable by routine disk diffusion antibiotic susceptibility testing. This may lead to emergence of resistance as well as treatment failures in the community. The net effect of these factors would be the resultant increase in cost of treatment to the patient.

The National Treatment Guidelines for antimicrobial use in infectious diseases was developed by the National Center for Disease Control under the aegis of Ministry of Health and Family Welfare Government of India. This guideline dictates the use of Nitrofurantoin 100mg BD for 7 days or cotrimoxazole 960 mg BD for 3–5 days or ciprofloxacin 500 mg BD for 3–5 days as presumptive treatment of Urinary Tract Infections. Alternatively, the guidelines also suggest Cefuroxime 250 mg BD for 3–5 days. The empiric therapy prescribed correlates with our findings, where 5.8% of isolates from female patients show resistance to nitrofurantoin, and in case of male patients, 15.4% exhibit antimicrobial resistance (AMR) to nitrofurantoin. As far as cotrimoxazole is concerned, 48.8% isolates from female patients and 51.3% of male patients exhibit resistance. Ciprofloxacin shows resistance of 50.4% in females compared to 66.7% in males. These levels of antibiotic resistance dictate the use of nitrofurantoin as a first-line treatment of UTI. Nitrofurantoin also known as urinary antiseptic has no role in treatment of other infections. Its efficiency in achieving a higher concentration in urine and the ease of administration being an oral antibiotic makes it an ideal choice as a drug for first-line treatment for UTI. However, in India, it would be ideal to rely on culture and sensitivity reports in view of higher antimicrobial resistance pattern, the gradually increasing ESBL produced among Enterobacteriaceae, the reduced compliance of patients to follow-up for treatment, and the socioeconomic factors dictating a fewer number of female patients approaching medical care.

In our study, the higher number of UTI were seen among the female patients which are attributable to the anatomical structure of urinary tract in relation to the gastro intestinal system, the knowledge, attitude, and practice of genital hygiene among Indian women and the natural ability of the Enterobacteriaceae family to adhere to uroepithelium. The antimicrobial resistance of the commonly used antibiotics such as ciprofloxacin, cotrimoxazole, and nitrofurantoin is comparatively less among *E. coli* isolates when compared to males. This may be due to the fact that majority of samples collected were of acute uncomplicated cystitis among female patients, where, as in males, the infections also included the ones accompanied by Benign prostatic hypertrophy, renal stones, and neurogenic bladder. It is worthwhile to be noted that every health-care institution must develop its own antimicrobial treatment policy based on the culture and sensitivity report prevailing in the past 6 months and these policies need to be reassessed at least once in 6 months to know the pattern of emerging resistance as well as to decide about the use of antibiotic recycling for the better usage of available antibiotics for treatment of UTI.

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Original Article

Comparison of the Post-operative Analgesic Efficacy of Ultrasound-Guided Transversus Abdominis Plane Block versus Ilioinguinal and Iliohypogastric Nerve Block in Adult Patients Following Hernia Surgery

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Abstract

Background: Ultrasound (USG)-guided transversus abdominis plane (TAP) block and combined ilioinguinal iliohypogastric (IIN/IHN) nerve blocks are routinely used for post-operative pain relief in patients undergoing inguinal hernia surgery. This study compares post-operative analgesic efficacy of USG-guided TAP versus IIN/IHN block in adults undergoing inguinal hernia surgery.

Materials and Methods: Sixty adult patients between the ages of 20 and 60 with an American Society of Anesthesiologists grade I and II were included in the study. Patients in Group I received USG-guided unilateral TAP block with 0.5% ropivacaine (total volume of 20 mL) after general anesthesia, while those in Group II received IIN/IHN block with 0.5% ropivacaine(total volume of 20 mL). Tramadol (intravenous) IV was used as post-operative rescue analgesia for the first 4 h, followed by oral diclefenac 75 mg. Mean time to the first analgesic request (minutes) was the primary goal, but intraoperative hemodynamics, post-operative pain scores, total analgesia consumption, and patient satisfaction scores were also assessed.

Results: The IINB group had lower VAS scores (1.58 ± 0.69 vs. 2.10 ± 0.53 *P* = 0.001) than the TAP block group indicating that the difference in pain scores was statistically significant. Furthermore, mean time to first request of rescue analgesia (min) in the IINB group 413.10 ± 118.40 and 168.50 ± 32 in the TAP block group (*P* = 0.005). The patients satisfaction score did not differ between the two groups.

Conclusion: Ultrasound-guided IIN/IHN block was effective in producing post-operative analgesia with delayed need for rescue analgesia and reduced analgesic consumption compared to TAP block after open inguinal hernia repair under general anesthesia.

Key words: Iliohypogastric nerve block, Ilioinguinal nerve block, Inguinal hernia, Transversus abdominis plane block, Ultrasound guided

INTRODUCTION

Inguinal hernia repair is one of the most common surgical procedures,[1] and post-operative pain management is difficult in cases of abdominal surgery. Despite effective pain management techniques, 30–75% of people experience moderate or severe pain.[2] The main goal of post-operative pain management is to reduce the analgesic requirement to minimize adverse effects while still providing adequate analgesia. Various pharmacological methods, topical analgesics, epidural analgesia, and non-pharmacological approaches are available to control pain after hernia surgery; however, optimal evidence-based pain therapy remains unknown.[3] Post-operative pain management employs a variety of methods and medications. Peripheral

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nerve blocks with local anesthetics are a technique that may be used in inguinal hernia surgeries for both surgery and pain management.[4] Regional nerve block techniques provide excellent post-operative pain relief, allowing for the early ambulation and discharge. Inguinal hernia repair under general or regional anesthesia is a common surgical procedure.[5] Even in experienced hands, the failure rate with the blind approach is 20–30%. In addition, the blind approach may result in problems. Ultrasound technology has the potential to minimize the incidence of these complications.[6] The ilioinguinal and iliohypogastric (IIN/IHN) nerve blocks are among the most commonly used regional blocks for analgesia after inguinal surgery and have been shown to significantly reduce pain associated with herniorrhaphy.[7,8] The transversus abdominis plane (TAP) block is an advanced, rapidly developing regional anesthetic technique that gives analgesia to the parietal peritoneum as well as the skin and muscles of the anterior abdominal wall after abdominal surgery. Due to its relative simplicity and effectiveness, it has grown in popularity across the globe. The use of ultrasonography enhances the success rate and precision of nerve blocks while also preventing possible complications.[9,10] Several publications have previously compared the effectiveness of TAP and IIN/IHN blocks for post-operative pain after inguinal hernia operations, but the findings are inconsistent.[11] Because there have been no clear studies supporting either of the two aforementioned approaches, the current research compared compares post-operative analgesic efficacy of USG-guided TAP versus IIN/IHN block in adults undergoing inguinal hernia surgery.

MATERIALS AND METHODS

Design and Sampling

Design

The study design was a prospective, randomized, and double-blind comparative study.

Study Period

The research period lasted 7 months (between January 2022 and September 2022).

Study Population

Sixty adult male patients between the ages of 20 and 60 who were scheduled for open inguinal hernia repair surgeries at the Department of Surgery, Government General and Teaching Hospital, Vijayawada, were chosen for the study.

Procedure for Sampling

Patients chosen for open inguinal hernia repair surgeries were admitted in the surgery ward, and the diagnosis and patient data were obtained from the patient's case record.

Justification of Sample Size

The mean time to the first analgesic request was the primary outcome of this study. The sample size was estimated based on the primary outcome of the pilot study, wherein ten patients per group were included and the mean time to first analgesic request in Group I was 229 ± 59.47 min and the Group II was 428 ± 116.4 min representing a >20% variation between the groups. Using $\alpha = 0.05$, $\beta = 0.20$, and the power of the study being 80%, the sample size was calculated to be 30 per group (using power analysis and sample size software, power and sample size software.com). Hence, 30 patients were recruited per group. The subjects in the pilot study were not included in the original study.

Ethical Issues

The hospital ethics committee approval was sought. All patients were informed about the anesthetic technique, including its benefits and drawbacks, and written informed consent was obtained.

Inclusion Criteria

Sixty patients between were included in the study:

1. The age group of 20–60 years
2. ASA status Class 1 and Class II.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patient refusal
2. BMI of >35 kg/m^2,
3. Skin infection at the puncture site,
4. A contraindication to anesthetic drugs,
5. Established chronic hepatic failure,
6. Chronic kidney disease Stages IV and V
7. Pre-operative opioid or non-steroidal anti-inflammatory drug use.
8. Pregnancy
9. alcohol or drug abuse

Group-I (n = 30) patients were given ultrasound-guided TAP block with 0.5% ropivacaine (total volume of 20 mL).

Group-II (n = 30) patients were given ultrasound guided ilioinguinal/iliohypogastric nerve blocks with 0.5% ropivacaine (total volume of 20 mL).

During the pre-anesthetic visit in the evening prior to surgery, patients were taught how to use a visual analog scale[12] (VAS) (0–10 cm) for pain assessment, where no pain was scored as 0 and worst pain was scored as 10. They were given alprazolam 0.25 mg and ranitidine 150 mg tablets at bedtime and at 2 h before surgery.

Intravenous access was established in the operating room, and standard monitors such as an electrocardiogram (ECG),

non-invasive blood pressure (NIBP), and pulse oximeter SpO_2 were installed. An established anesthetic protocol was followed. The patients were given glycopyrrolate 0.2 mg IV and fentanyl 2 $\mu g/kg^{-1}$ IV before preoxygenation. Propofol 2 mg/kg IV was used to induce anesthesia, and atracurium 0.5 mg/kg IV was used to achieve neuromuscular blockade. After 3 min of isoflurane in oxygen ventilation, an appropriate-sized supraglottic device was used to secure the airway. Anesthesia was maintained with isoflurane 1 minimum alveolar concentration and a 67% nitrous oxide in oxygen mixture. On the side of surgery, the patients received TAP or IIN/IHN block, depending on the group to which the patient was assigned using a computer-generated sequence of random numbers.

Anesthetic Techniques and Nerve Block

All patients were educated about anesthesia and post-operative pain management options before surgery. Based on the randomly assigned grouping, IINB or TAP block was performed under US guidance by an experienced anesthesiologist who was not aware of the study protocol, and the intraoperative and post-operative monitoring and recording of the outcome parameters was done by an observer anesthesiologist to ensure double-blinding.

Patients in Group I (n = 30) received TAP block with 0.5% ropivacaine (total volume of 20 mL), while patients in Group II (n = 30) received IIN/IHN block with (total volume of maximum 20 mL) 0.5% ropivacaine. The Sono Site M Turbo ultrasound machine was used, with a high frequency 38 × 13-6 MHz 40 mm broadband linear array probe. The ultrasound probe was placed on the lateral abdominal wall, cephalad to the iliac crest, and caudal to the costal margin at the level of the umbilicus, for TAP block. The probe was tilted in either a cephalad or caudal direction as needed to obtain a clear optimized image of the three lateral abdominal muscles and TAP. The drug was then administered after the needle tip was targeted in the TAP plane between the internal oblique and transversus abdominis muscles using an in-plane technique. For IIN/IHN block, the probe was placed obliquely on a line connecting the anterior superior iliac spine and the umbilicus immediately superior to the anterior superior iliac spine. Following the identification of the plane between the internal oblique and transversus abdominis muscles, the needle tip was placed in the plane and the drug was administered. After the block was administered, the surgery began. At the end of surgery, residual neuromuscular blockade was reversed with appropriate doses of IV neostigmine and glycopyrrolate. When the patient was fully awake and breathing normally, the supraglottic airway device was removed.

Demographic data such as age, weight, and height were collected. Non-invasive blood pressure and heart rate were monitored and recorded before induction, before administering the block, before the incision, and after the incision. They were recorded intraoperatively every 10 min for the first 30 min, and every 15 min after that. In addition to the duration of the surgery, any complications such as vessel puncture, bowel perforation, and femoral anesthesia were recorded.

The VAS score was assessed in the immediate post-operative period, then every 30 min until 2 h, every 2 h until 12 h, and every 6 h thereafter until 24 h postoperatively.

During the first 24 h after surgery, a standard post-operative analgesia regimen was used. If the patients' VAS was ≥4 in the first 4 h after surgery, they were given tramadol 2 mg/kg IV. Patients were given oral tablet diclofenac 75 mg after 4 h if their VAS was ≥4. For post-operative nausea and vomiting, an IV ondansetron (4 mg) injection was administered. The primary goal of the study was to determine the mean time to the first analgesic request in the 24 h post-operative period.

After inquiring about the patient's willingness to have the same analgesia if ever operated on again, the patient satisfaction was measured using a two-point scale.

1. Acceptable: "If I ever need surgery again, I want the same analgesia."
2. Un acceptable: "If I need surgery again, I want a different analgesia."

Statistical Analysis

All the data collected were entered into Microsoft Excel and statistical analysis was performed using GraphPad.com. Data were expressed as mean, standard deviation, and/or ratio or absolute numbers (%) and compared using the Student's *t*-test, Fisher's exact test, and Chi-square test, as appropriate. $P < 0.05$ was deemed statistically significant and $P < 0.001$ is considered to be highly significant.

RESULTS

The study included 60 adult male patients who were randomly assigned to one of the two study arms. TAP blocks and ilioinguinal and iliohypogastric IIN/IHN nerve blocks were all successful in all the patients. The mean age, height, weight, and duration of surgery were comparable in both groups. Statistically, there were no significant differences between the groups [Table 1].

The mean heart rate was comparable between the groups perioperatively with no statistically significant difference [Figure 1].

There was no significant difference in MAP between the groups throughout the perioperative period [Figure 2].

The mean duration of first request of rescue analgesia (min) was 316.20 ± 112.8 min in Group I and in Group II was 413.10 ± 118.4 (min) which was greater compared to Group I with a statistically significant difference of $P = 0.001$ [Table 2 and Figure 3].

The average dose of diclofenac tablet consumption was significantly lesser in Group II 168.50 ± 32.86 compared to Group I 194.04 ± 34.98 ($P = 0.005$) [Table 2].

In the immediate post-operative period and up to 2 h, there is no significant difference in VAS score between Group I and Group II. However, from 2 h to 8 h post-operative period, a statistically significant difference was found between the groups with higher VAS scores in Group I compared to Group II. After 8–24 h post-operative, VAS scores in both the groups were similar [Table 3].

Patient satisfaction scores were comparable with 22 patients in Group II and 18 individuals in Group I satisfied with the block without any statistically significant difference between the groups ($P = 0.411$) [Table 4 and Figure 3].

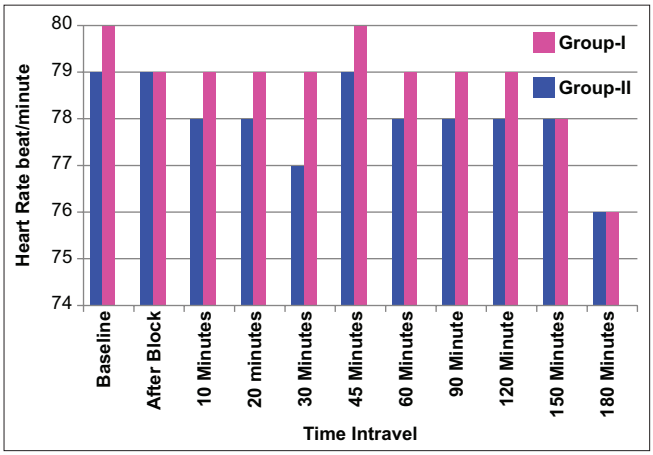

Figure 1: Comparison of heart rates (HR)

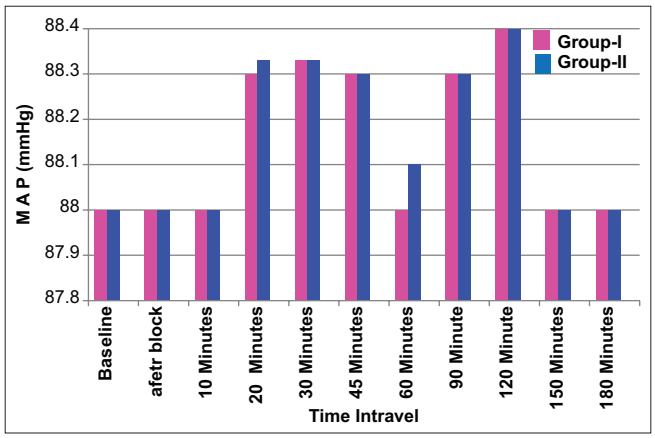

Figure 2: Comparison of mean artterial pressure (mmHg)

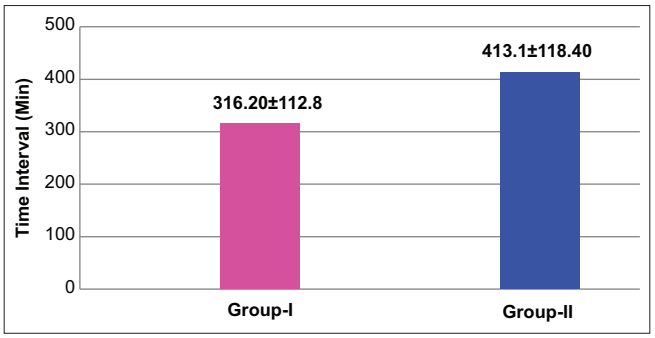

Figure 3: Time of first request of analgesic (min)

Table 1: Demographic data of the patients

Parameters	Mean±standard deviation (*n*=30)		*P*-value
	Group I	Group II	
Age in years	38.81±10.16	40.02±9.92	0.591
Weight in kgs	55.43±5.8	56.20±5.49	0.539
Height in cms	159.65±6.92	159.83±6.70	0.906
ASA I/II	20/10	12/8	0.789*
Duration of surgery (min)	106.35±25.01	104.72±26.21	0.776

Data expressed as mean (SD) or ratio or absolute numbers, Student*t*-test, *Chi-square test/Fisher exact test

Table 2: Comparison of outcome parameters

Parameters	Mean±standard deviation (*n*=30)		*P*-value
	Group I	Group II	
Mean duration of rescue analgesic requirement (min)	316.20±112.80	413.10±118.40	0.001*
Mean dose of tablet diclofenac required per patient (mg)	194.04±34.98	168.50±32.86	0.005*

Data expressed as mean (SD) or ratio or absolute numbers, Student*t*test, **P*<0.05 Statistically significant

Table 3: Variation of visual analogue scale

Time interval	Group I Mean±standard deviation *n*=30	Group II Mean±standard deviation *n*=30	*P*-value
0 min (baseline)	0.63±0.42	0.48±0.38	0.152
30 min	0.65±0.50	0.62±0.42	0.802
1 h	0.80±0.54	0.73±0.47	0.594
2 h	1.09±0.59	0.78±0.53	0.036*
4 h	1.54±0.63	1.02±0.58	0.001*
6 h	2.10±0.53	1.58±0.69	0.001*
8 h	3.08±0.58	2.51±0.76	0.001*
10 h	3.48±0.68	3.10±0.89	0.062
12 h	3.56±0.78	3.20±0.96	0.292
18 h	3.79±0.82	3.54±0.98	0.288
24 h	3.86±0.86	3.62±0.99	0.320

Data expressed as mean (SD) or ratio or absolute numbers, Student*t*test, **P*<0.05 Statistically significant

Table 4: Patients satisfaction score (two points score)

Parameters	Absolute numbers (*n*=30)				*P*-value
	Group I		Group II		
	Acceptable	Un acceptable	Acceptable	Un acceptable	
Patients satisfaction score	18	12	22	08	0.411*

Data expressed ratio or absolute numbers, *Chi-square test/Fisher exact test, *P*<0.05 Statistically not significant

In Group I, a single individual developed hematoma (3.3%). No patients in either group experienced any further complications.

DISCUSSION

The purpose of this study was to compare the post-operative analgesic efficacy of TAP block versus IIN/IHN block in patients undergoing unilateral inguinal hernia repair surgery under general anesthesia.

The literature identifies anatomical landmark and ultrasound guided techniques for IH/II nerve block. Traditional anatomical landmark techniques are rarely used due to the high volumes of local anesthetics used and the high failure rates.[13,14] The application of ultrasound guidance for ilioinguinal or iliohypogastric nerve blocks was found to be more effective and to cause fewer complications.[8,9]

O' Dwyer *et al.*[15] conducted a randomized trial with 276 patients undergoing open hernia repair under local versus general anesthesia. They proposed that the decision between local and general anesthesia should be made jointly by the surgeon and the patient; accordingly, we selected patients undergoing surgery under general anesthesia as per the surgeon's choice in current study.

Pain management is critical for improving patient care quality. Regional nerve block techniques provide excellent post-operative pain relief, allowing for early ambulation and discharge. Ultrasound can improve success rates by allowing for more precise placement of smaller volumes of local anesthetic agents closer to the targeted nerves.[16,17]

Kamal *et al.*[18] conducted a study on 60 patients who had undergone inguinal hernia repair, comparing US TAP block versus IIN/IHN block, and observed no clinically or statistically significant difference between the two groups in terms of heart rate and respiratory rate. In our study, also we observed no clinically or statistically significant difference between the two groups in terms of heart rate and the respiratory rate which is in agreement with his study.

Kamal *et al.,* in their study, used 0.75% ropivacaine for US guided TAP block and IIN/IHN block, whereas we used 0.5% ropivacaine in our study. They found that the mean duration of rescue analgesic requirement was prolonged and the average dose of diclofenac tablet consumption was reduced in IIN/IHN block compared to TAP block in their study. Our findings correlate with their study.

Regarding the VAS scores from 2 h to 8 h post-operative period, a statistically significant difference was found between the groups with higher VAS scores in Group I compared to group II. The results of present study are in contrast to the study of Aveline *et al.*, where they compared ultrasound-guided TAP block to blind IIN/IHN block for analgesia after open inguinal hernia repair and concluded that post-operative VAS scores were lower in the TAP group compared to the IIN/IHN block group. The reduced efficacy of the IIN/IHN block may be due to the blind technique followed. In our study, patient satisfaction scores were similar in both groups.

CONCLUSIONS

Ultrasound-guided IIN/IHN block was effective in producing post-operative analgesia with delayed need for rescue analgesia and reduced analgesic consumption compared to TAP block after open inguinal hernia repair under general anesthesia.

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