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Case Report

Anemia the Culprit of Oral Ulcers: A Case Report Unveiling the Gravity of Comprehensive History Taking and Clinical Evaluation

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Abstract

Recurrent aphthous stomatitis (RAS) is an ulcerative disease of the oral cavity and can occur in isolation or as a manifestation of many systemic diseases. In this case report, the patient came with the complaint of multiple recurring ulcers. Comprehensive history and clinical evaluation helped us to diagnose the condition as RAS associated with anemia and constipation. The patient was treated topical and systemic steroids therapy along with multivitamins consisting of vitamin b12 and folic acid. RAS should not be overlooked as a single entity, always try to look for the etiology behind the condition and this requires the detailed knowledge, history taking, and clinical evaluation by the oral physician.

Key words: Recurrent apthous stomatitis, Anemia, Oral ulcers, RAS

INTRODUCTION

Recurrent aphthous stomatitis (RAS) is a common condition characterized by recurring ulcers confined to oral mucosa in patients with no other signs of disease. Its clinical features include multiple round or ovoid ulcers generally with well-defined borders and erythematous halo surrounding the periphery of the ulcer. Although the etiology of RAS is non-specific, numerous etiological factors have been suggested such as hereditary, trauma, deficiency states, psychological factors, endocrine disorders, allergic conditions, infections, blood dyscrasias, drugs, GI diseases, urological disorders, dermatological, and immunological disorders. The literature review reveals that approximately 25% of the population is affected with RAS and rate of reoccurrence is approximately 3 months.[1]

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There are three forms of RAS which has been recognized clinically as following:

a. Minor aphthous ulcer (Mikulicz ulcer)
b. Major aphthous ulcer (Sutton's ulcers; periadenitis mucosa necrotica recurrents)
c. Herpetiform ulcers.

Enlisting the following systemic diseases, in which we can find the similar-appearing lesions:[2]

- Behcet's disease
- Sweet's syndrome
- Cyclic neutropenia
- Benign familial neutropenia
- MAGIC syndrome
- A periodic syndrome with fever and pharyngitis
- Various nutritional deficiencies with or without underlying gastrointestinal disorders.

Hematinic deficiency (iron, folic acid, or vitamin B12) is twice as common in RAS patients as demonstrated by various studies from the UK, United States, and Spain.[2]

Broides *et al.*[3] outlined that patients with Imerslun Grabeck syndrome had a vitamin B12 deficiency related with a neutrophil chemotactic defect that may become an etiological factor of RAS. Inflammation of the lining of the stomach is a condition known as chronic gastritis which

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develops gradually and can be more difficult to get rid of and may become an etiological factor of RAS.[4] Vitamin B12 malabsorption is induced by chronic gastritis which results in developing the pernicious anemia. The association of deficiency of vitamin B12 and RAS has been infrequently delineated in the literature.[5] Deficiency of vitamin b12 can be a causative factor of RAS as demonstrated by Wray *et al.*[6] Piskin *et al.*[7] observed 35 patients with RAS and concluded that serum vitamin B12 levels were low in eight patients (22.8%). Koybasi *et al.*[8] and Burgan *et al.*[9] conducted various studies and observed that 35.2% of the patients had RAS and 26.6% of the patients had vitamin B12 deficiency. In this case report, the clinical features and management of RAS related to anemia and vitamin B12 deficiency have been described.

CASE REPORT

A 19-year-old male patient came to our department with complaints of painful ulcers in the lower lip, upper lip, and tongue areas for 4 days. The patient gave history of recurrent ulcers in mouth at an interval of 10–15 days for 1 year and heals itself. The patient gave medical history of occasional constipation and is not taking any medications for this. On examination, small whitish colored ulcer of approximately 1 mm* 1 mm with erythematous boundary present on right side of lower labial mucosa opposite to 42, as shown in Figure 1. There are two ulcers of approximately 3 mm* 3 mm in size covered with whitish necrotic material and erythematous boundary present on left side of commissure area, as shown in Figure 2. There are three tiny ulcers covered with whitish necrotic material and erythematous boundary on the tip of the tongue, as shown in Figure 3. There are five ulcers of approximately 2 mm* 2 mm in size covered with whitish necrotic material and erythematous boundary present on the right side of maxillary labial mucosa opposite to 11, 12, 13, 14, and 15, as shown in Figure 4. Other findings include generalized mild supragingival calculus present and generalized mild extrinsic stains present. A provisional diagnosis of recurrent aphthous ulcer was made. The patient was prescribed medications which include topical application of triamcinolone acetonide 0.1% (kennacort) 4–5 times daily on the affected area for 4 days and then tapered to 3 times a day for next 3 days and 2 times a day for next 2 days and once a day for next 1 day. Tablet Prednisolone 5 mg (Omnacortil) twice a day for 4 days and then tapered to once a day for next 3 days. Along with topical patient was prescribed vitcofol 10 ml intramuscular injection alternately for 10 days. The patient was prescribed multivitamins once a day for next 30 days. The patient was also advised to maintain meticulous oral hygiene. The patient was advised diagnostic tests which include complete blood count (CBC) and vitamin b12. The patient was recalled to the department with reports.

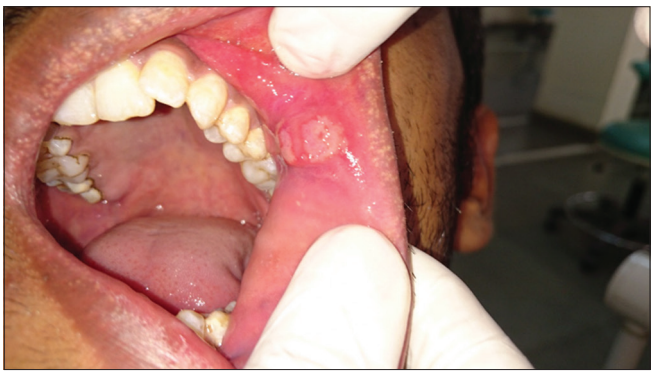

Figure 2: Ulcers on the left side of commissure area

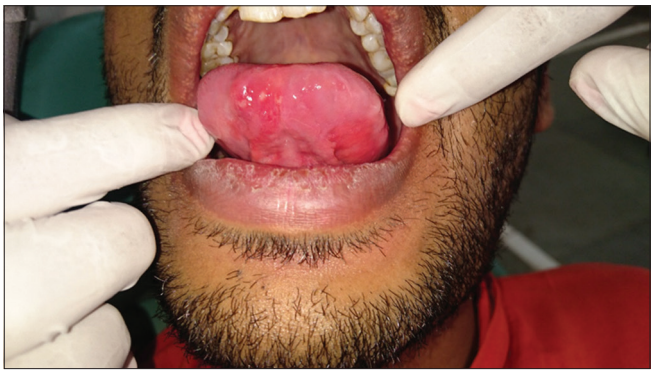

Figure 3: Multiple ulcers on the tip of the tongue

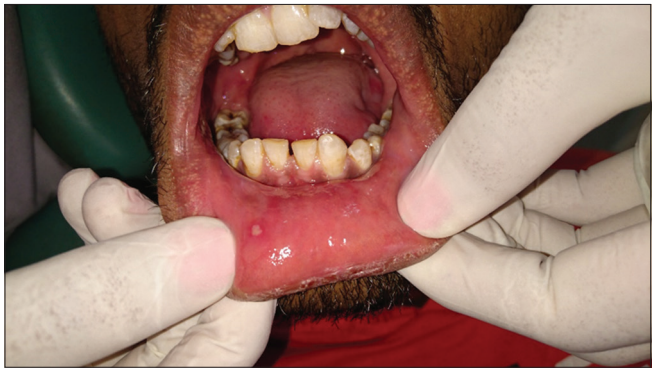

Figure 1: Small ulcer on the right side of lower labial mucosa

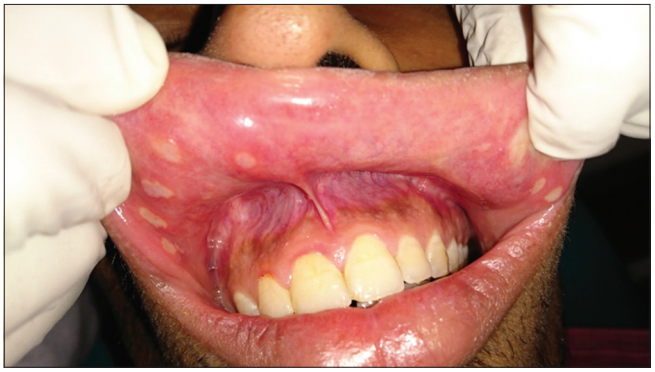

Figure 4: Multiple ulcers right side of upper labial mucosa

The patient came to the department with reports after 10 days. On examination, after 10 days, ulcers were healed completely without scarring. The patient brought his diagnostic test reports which include CBC which shows Hb 13.2 g/dl, decreased RBC value 3.88 10^6/mm^3, increased MCH value 34.0 pg, and decreased vitamin b12. The patient was referred to the physician and gastroenterologist along with prescription. The patient was advised laxatives for the treatment of constipation and tablet ferrous ascorbate 100 mg and b9/folic acid 1.5 mg (brand name "fericip xt") with tablet vitamin c (brand name "limcee") 500 mg once a day for 1 month and tablet vitamin b12 1500 Mcg (brand name "nurokind od) and recalled him after 1 month.

DISCUSSION

RAS remains a challenge for oral physicians due to its non-specific etiology and disparate clinical presentations. Most patients with RAU need no treatment because of the mild nature of the disease. Few patients are treated with perpetuation of meticulous good oral hygiene, toothpaste without irritating sodium lauryl sulfate, for example, Biotene and palliative therapy for pain management. Mouth rinses include chlorhexidine gluconate, benzydamine, and betadine mouth washes. The following is the topical steroid agents: Hydrocortisone hemisuccinate, triamcinolone acetonide, flucinonide, betamethasone valerate, betamethasone-17- benzoate, flumethasone pivolate, and beclomethasone dipropionate in tapering doses. Systemic steroids include prednisolone in tapering doses. Antibiotics like tetracyclines for topical application and immunomodulators like levamisole, colchicine, gammaglobulins, azathioprine, dapsone, thalidomide, pentoxifylline, prednisolone, azelastine, cyclosporine, and amlexonox can be prescribed topically as well as systemically depending on the severity of the disease.[2]

A huge stride has been made concerning the epidemiology, description, etiology, and treatment of RAS during the past 3 decades. The case reported here supports a diagnosis of RAS due to anemia and vitamin B12 deficiency along with the elucidation of its clinical features and patient response to the management.[1]

Diagnostic tests to check the hematologic status of patients should be done which include CBC, serum ferritin, folate, and B-vitamin levels. These tests should be advised and monitored in suspected cases. If the hematologic work up reveals deficiencies, then either make a congruous referral to the physician or start with replacement therapies. The foremost option for the treatment of RAS is the topical agents which include steroids, antibiotics, and immunomodulators depending on the severity of the lesion. They are inexpensive, effectual, and secure. The use of anti-microbial mouthwash in RAS is contemplated to manage microbial contamination and secondary infection. An antibiotic mouthwash (for example, tetracycline) shows marked reduction in ulcer size, duration, and pain due to its ability to inhibit collagenase activity. The obstacle of the application of topical medications is the washing away from the target area easily with oral fluids. To resolve, this obstacle disparate adhesive vehicle in amalgamation with the drug can be used. For example, strong topical corticosteroids when amalgamated with mucosal adherents are efficacious even with slight contact time. Fluocinonide, triamcinolone, and clobetasol are the topical glucocorticoids which have been efficacious for RAS.[2]

In this case, also patient was having decreased values of vitamin b12, decreased Hb along with gastric problem (constipation). Sir William Osler stated " the oral cavity a mirror of the rest of the body." This patient was reported with the complaints of the recurrent oral ulcers, with the help of knowledge, comprehensive history and clinical evaluation patient was diagnosed with RAS associated with anemia and B12 deficiency. Hence, the patient was advised diagnostic tests which include CBC and vitamin b12, and then, referral to the physician and gastroenterologist for the treatment of anemia and constipation was made.

RAS is diagnosed on the basis of comprehensive history and clinical presentation, but histopathology may be advised to exclude any other chronic ulcerative pathology. The appearance of systemic disease is established based on the discoveries allied to that pathology.[10]

CONCLUSION

RAS is a familiar oral mucosal disease in the world. Appropriate clinical evaluation and detailed history taking to rule out any systemic disease are crucial before prescribing the medication. Besides with conventional RAS management, iron, folic acid, vitamin B deficiencies, and nutritional deficiencies must be scrutinized. Replacement therapy should be based on the levels of vitamin B12 and other hematologic deficits. These therapies can be assumed of great benefit in RAS patients due to its uncertain etiology. RAS could be a possible signal to systemic illness, so it should never be overlooked as an isolated disease, always try to find out the etiology and manage appropriately.

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Case Report

Appendicitis as a Presentation of COVID-19: An Autobiographical Case Report

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Abstract

Coronavirus disease 19 (COVID-19) is an infectious respiratory disease presenting with respiratory symptoms and flu-like presentation. However, gastrointestinal symptoms have been reported in a small portion of the population, rarely resembling the acute appendicitis. The simultaneous presence of the acute appendicitis and COVID-19 is being reported, the temporal association between appendicitis and COVID-19 is difficult to establish. The authors and coauthors, hereby, are reporting my own case. I am a 33-year-old male. I had periumbilical abdominal pain for 2–3 days which later localized to the right iliac fossa. Abdominal ultrasound was advised which revealed acute appendicitis. On the same day of ultrasound, I started to have sore throat and malaise, for which i got a RT-PCR done which was found to be positive for COVID-19. I was managed conservatively initially with interval appendicectomy after 4 weeks. SARS-CoV-19 is a generalized inflammatory condition and the temporal association of appendicitis and COVID-19 has been ascertained. However, to prove, the exact cause and effect relationship further studied with larger sample size are required.

Key words: Appendicitis, Appendicectomy, Coronavirus disease 19, Gastrointestinal symptoms

INTRODUCTION

The gastrointestinal symptoms are one of the most common ignored presentations of coronavirus disease 19 (COVID-19) and the prevalence has reached as high as 92% in children in some reports.[1] Gastrointestinal manifestation of COVID-19 may mimic and/or cause acute abdominal findings including appendicitis, intussusception, gastrointestinal bleeding, and pneumatosis intestinalis.[2-5] Primary symptoms such as fever and abdominal pain in patients with COVID-19 can be confused with appendicitis or, conversely, a true appendicitis may go unnoticed due to these symptoms.

The previous studies suggest a relationship between upper respiratory viral diseases and appendicitis.[6] A recent case report describes patients presenting with appendicitis-like symptoms, but ultimately was discovered to be SARS-CoV-2 positive with COVID-19 and not have appendicitis.[7] SARS-Cov-2 pandemic has been reported to impact management of acute appendicitis with possibly fewer cases presenting to the hospital,[8] a delay the time of diagnosis, increased frequently peritonitis,[9] and more severe septic abdominal diseases.[10] These previous reports suggest a potentially harmful impact of SARS-CoV-2 pandemic on access to emergency surgery services.

Abdominal pain and pathological features resulting in abdominal discomfort in adult COVID-19 infections are reported to be in the region of 2.2–5.8% in cohort studies. Few cases of COVID-19 presenting with acute abdomen with features of pancreatitis and appendicitis have also been reported. Many studies revealed that fewer or the same number of patients presented with acute appendicitis to the emergency room during the COVID-19 pandemic compared to the non-pandemic period, and those who did, presented with complications.[11]

However, to the best of our knowledge, an association between testing positive for SARS-CoV-2 and presentation

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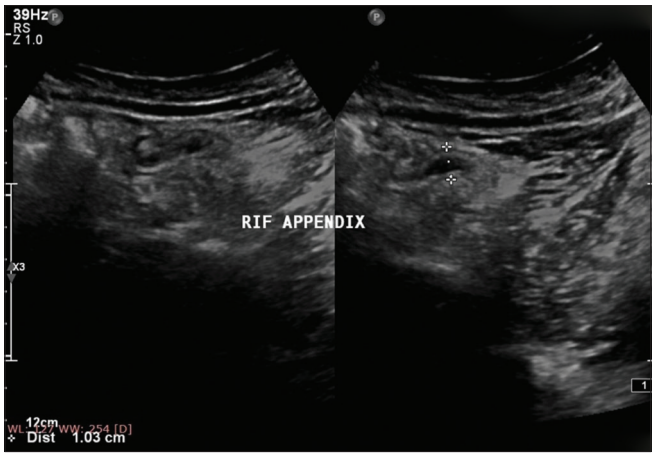

Figure 1: Ultrasound images show a dilated, aperistaltic tubular structure in the right iliac fossa measuring ~ 1 cm with surrounding inflammatory changes

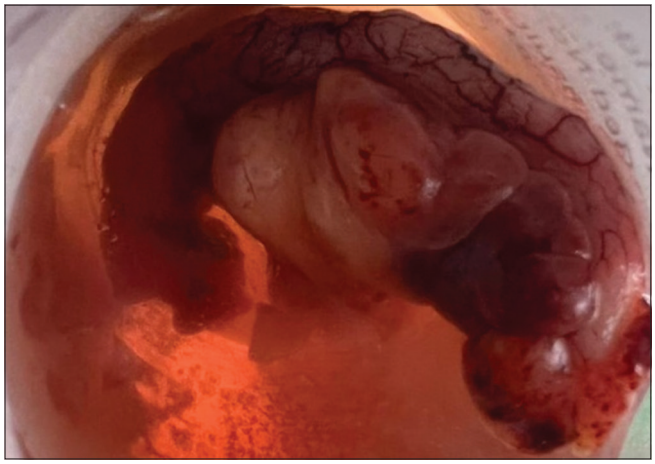

Figure 2: Post-operative specimen shows inflamed, dilated, and thick-walled appendix

to the hospital with acute appendicitis has rarely been reported. We are hereby reporting my own case with both acute appendicitis and positive for SARS-CoV-2 simultaneously.

CASE REPORT

I am a 33-year-old male patient. I had periumbilical abdominal pain for 2–3 days which later localized to the right iliac fossa. All other vitals were normal. On clinical examination, abdomen was soft and tenderness was present in the right iliac fossa. No palpable lump was noted. Abdominal ultrasound was advised which revealed an aperistaltic tubular structure in the right iliac fossa [Figure 1]. It measured ~ 1 cm in axial dimension and showed surrounding fat stranding. Rest of the abdominal structures were normal. Complete blood picture was found to be normal. C-reactive protein was found to be slightly raised.

On the same day, I started to have sore throat and malaise, for which i was advised RT-PCR which was found to be positive for COVID-19. My past medical, surgical, drug, and allergic history is insignificant with no history of similar episodes among family members I was managed conservatively initially with antibiotics. Interval appendicectomy was done after 4 weeks. Intraoperative findings revealed inflamed, dilated, and thick-walled appendix [Figure 2]. Histopathological examination of the post-operative specimen revealed. Transmural infiltration with polymorphs and lymphomononuclear cells was noted. The Serosa showed vascular congestion and inflammatory infiltrates.

DISCUSSION

COVID-19 is gastrointestinal symptoms are not uncommon. Anorexia, diarrhea, vomiting, and abdominal pain are the most common reported symptoms.[12-14] Moreover, these symptoms might appear before the respiratory symptoms.[15] Gastrointestinal symptoms such as nausea, vomiting, abdominal discomfort, and diarrhea have been reported in some patients with SARS-COV-2. These GI symptoms varied significantly among different study populations with the early- or mid-onset along with usual respiratory symptoms.[11] Some studies claim appendicitis to be a presenting symptom apart from the common respiratory symptoms.[7,16]

Multiple case reports had also shown that COVID-19 could present as acute abdominal pain sometimes even mimicking as acute appendicitis with anorexia, nausea, and vomiting.[7,17-19] According to Saeed's study, nine out of 76 patients with acute abdominal pain tested positive for COVID-19.[18] Likewise, two other case reports suggest a probable association between COVID-19 and appendicitis.[7,20] Therefore, this demands a greater vigilance for rapid diagnosis and intervention in individuals with GI symptoms and concomitant SARS-CoV-2 infection.

In my case, the patient was diagnosed with COVID-19 before the surgery for appendicitis. An RTPCR for COVID-19 was sent following the suspicion of COVID-19 for sore throat, which came out to be positive. Ahmed *et al.*[7] found that COVID-19 is extremely unlikely to present clinically appendicitis like symptoms (Right lower iliac fossa pain, anorexia, nausea, and vomiting), in laboratory and imaging findings, there were leukopenia, lymphopenia, and ground glass appearance. These findings raised the suspicion of COVID-19 especially the radiological findings (bilateral lung basal consolidations and ground-glass attenuations) that were typical for COVID-19.

Our case study shows the limited effectiveness of clinical diagnosis for the surgical abdomen in COVID-19 patients as these two conditions share symptoms such as fever, anorexia, nausea, vomiting, and even acute abdominal pain. It also reflects that SARS-COV-2 could be one of the possible causes of acute abdominal cases such as acute appendicitis.

Avoidance of surgery in these patients is important because it reduces the risk of exposing the operating room staff, particularly in case of inadvertent release of pneumoperitoneum during laparoscopy, or direct exposure of COVID positive peritoneal fluid. Moreover, post-operative mortality in COVID-19 positive patients seems to be higher than expected, even for elective surgery where morbidity is usually low. This is another reason why a non-surgical alternative is so important in patients with confirmed or suspected COVID-19 infection.[21]

CONCLUSION

COVID-19 is an inflammatory condition that can involve multiple systems. During the current SARS-CoV-2 pandemic, clinicians must have a high level of suspicion regarding the possibility of COVID-19 on various clinical manifestations including gastrointestinal symptoms. Although the temporal association of acute appendicitis with COVID-19 has been seen in my case, a timely imaging of abdomen has a critical role in the diagnosis of AA and further studies are required for direct association of both which can prove to be vital during pandemics. Temporal association has been proved; however, definite relationship needs to be proven. This may require studies with large sample size to prove the cause and effect relationship.

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Original Article

Clinical Profile and Surgical Outcomes of Snodgrass Urethroplasty in Distal Hypospadias

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Abstract

Background: Hypospadias is complex disorder affected by both genes and the environment. Chordee and penile torsion is frequent, particularly in more advanced forms of hypospadias. Several classification systems have been suggested for hypospadias. Many methods for the surgical repair of hypospadias have been described throughout history. To minimize the risk of fistula formation a fascial layer (Buck's or Darto's) can be interposed between the suture lines.

Objectives: The objectives of the study were to assess the clinical profile in children with Distal Hypospadias and surgical outcomes after Snodgrass Urethroplasty.

Methods: It was a prospective observational study on patients of distal Hypospadias admitted in Department of Surgery presented with abnormal meatus location, glans configuration, skin coverage, and mild degree of chordee <30°. A detailed local examination was done in every patient. In addition to type of hypospadias each patient was looked for meatus stenosis and chordee, shape of glans, and size of penis. Special attention was given to prepuce whether intact, circumcised or utilized in the previous operation. Surgical procedure done was Snodgrass Urethroplasty; patients were followed up to 2 years.

Results: Patients were distributed as per type of hypospadias and it was observed that subcoronal hypospadias, distal penile, and coronal hypospadias were found in 25 (50%), 17 (34%) and 8 (16%) patients, respectively. Shape of meatus was slit shaped in 24 (48%) patients, stenotic in 21 (42%) patients and circular in 5 (10%) patients in our study. Out of 50 patients studied, midline raphe was found in 32 (64%) patients while as deviated from midline raphe was seen in 18 (36%). Only 10 (20%) patients had associated chordee in our study. After 24 months of follow-up, acceptable cosmetic results were observed in 47 (94%) patients. Small meatus was seen in 2 (4%) patients while as bulky tissue was present in 1 (2%) patient.

Conclusion: The conclusion of our study was that most of the patients in our study presented late because of unawareness among people about the disease. The surgical procedure done was Snodgrass Urethroplasty for distal hypospadias and was associated with good surgical outcomes and fewer complications.

Key words: Hypospadias, Chordee, Snodgrass urethroplasty, Prepuce, Midline skin raphe

INTRODUCTION

Hypospadias is a common congenital malformation in boys. Hypospadias is complex disorder affected by both genes and the environment. It is an isolated malformation in the majority of cases, although it can also occur in association with other abnormalities, most frequently undescended testes or micropenis.[1] During a time window in gestational weeks 8 and 9, the Müllerian ducts regress in a cranio-caudal direction under the influence of AMH.[2] By week 10, the Müllerian ducts become insensitive to AMH.[2] The continued differentiation of the Wolffian ducts into the epididymis, vas deferens, and seminal vesicles requires such high testosterone concentrations that it can only occur in the immediate vicinity of the Leydig cells of the testes. During this time, the labioscrotal swellings develop as additional swellings lateral to the urethral folds.[3]

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At nine weeks, virilization of the external genitalia by DHT and testosterone begins with the lengthening of the anogenital distance.[2] The walls of the cloacal membrane in the genital tubercle then come together in a distal-to-proximal direction, resulting in the formation of a solid plate of endodermal epithelium, the urethral plate.[4] This replaces the urogenital membrane and extends to the tip of the phallus.[5]

Elucidation of the development process for the normal male genitalia and urethra has indicated that hypospadias results from a disruption of the normal closure of the edges of the urethral groove that inhibits formation of the urethral tube.[6,7] Chordee and penile torsion is frequent, particularly in more advanced forms of hypospadias.[8,9] Congenital ventral curvature can also occur in association with a normal urethral meatus, which is commonly called chordee without hypospadias or crypto-hypospadias. In these cases, the glanular urethra is often normal while the spongio-penile urethra is deficient.[10] Rarely, the curvature can exist in association with a completely normal urethra.[11] The cause of ventral curvature is debated,[10] as is the use of the term chordee to describe the ventral curvature.[12] Ventral curvature can occasionally be surgically released after degloving of the penile skin, although this is not the case for most patients,[13] who will require a orthoplasty with excision of chordee tissues. Penile torsion usually presents with the penile shaft rotated to the left and the raphe deviating to the right.[9] Torsion can occur in the absence of hypospadias or chordee, but it is most commonly found in association with these anomalies.[14] The cause of the torsion is unknown,[15] though an association with asymmetric ventral tissues is reported.[16,17]

Several classification systems have been suggested for hypospadias,[18] mainly based up on the position of the meatus.[19] However, a comprehensive classification of the phenotype must also account for the position of the meatus after correction of the ventral curvature (excision of the chordee).[18]

Many methods for the surgical repair of hypospadias have been described throughout history.[8] Improvements in equipment and materials, such as magnification glasses and sutures, as well as refinements to surgical technique, have made it possible for many patients to have defects repaired in one session, minimizing complications, rather than in two sessions followed by possible secondary repairs due to complications. Ultimately, the phenotype or the degree of the malformation will determine the choice of surgical technique and the risk for complications.[8,20] Local tissues in the immediate vicinity of the urethral plate can be used for construction of the neo-urethra in some cases, but preputial flaps or transplants are often required to allow for adequate length of the neo-urethra in more advanced cases.[8,21] In patients with ventral curvature, the repair must begin with excision of the chordee.[8] The most frequently used local flap is from the prepuce. Use of scrotal flaps has also been described.[21] However, when skin from the proximal penile shaft or the scrotum is used, the surgeon must account for the (future) presence of hair, as a neo-urethra with internal hairs can cause both cosmetic and obstructive problems.[22] When local tissues are absent or inadequate, grafts, most frequently oral mucosa, must be used.[21,23] In general, the more advanced reconstructions are performed in two steps. The first for excision of the chordee with repair of the ventral defect with a flap or graft which leaves a surplus of tissue on the ventral side that is used in the second session for the urethral repair.[23] The two sessions should be separated in time to allow for adequate tissue healing and neovascularization.[24] The challenges of constructing a long neo-urethra in patients with proximal hypospadias are considerably greater than in the more distal cases. The neo-urethra also lacks the native propulsive qualities of the native, spongiosum-covered urethra, and the longer the reconstruction, the greater the risk of abnormal micturition and ejaculation. Furthermore, the risk of vascular scarcity in long reconstructions is always greater as the base of the flap has to be thinned in order to reach the required distance.[15,25] But, as there is, yet, no reconstructed urethra that possesses the same biological and urodynamic properties as the native urethra, functional outcomes can be affected even in uncomplicated cases.[26] To minimize the risk of fistula formation a fascial layer (Buck's or Darto's) can be interposed between the suture lines.[27]

Ventral curvature with chordee is common in hypospadias, although the true nature of the chordee, in terms of its role in the pathology of the ventral curvature and the importance of its excision, remain unclear[12,28-30] Recent literature has recommended three ways to manage chordee with respect to the urethral plate: (1) Division and excision of the urethral plate followed by extensive ventral dissection along the corporal bodies; (2) extensive mobilization, without division, of the urethral plate, followed by further dissection at the ventral corporal bodies; and (3) preservation of the urethral plate as a template for an onlay island flap combined with dorsal plication for residual penile curvature.[28]

Hypospadias surgery is beset with difficulty and complications. The most common complications include recurrent curvature, preputial dehiscence, glans dehiscence, urethral fistula, meatus or urethral stenosis, urethral stricture, urethral diverticulum, hairy urethra, penile skin deficiency, and abnormal penile skin configuration.[20] Although complications can be isolated, they are often

clustered.[31,32] The term hypospadias cripple describes those patients who are affected by the greatest incidence of multiple complications and failed repairs, in whom the penis may be scarred, hypovascular, and shortened.[20]

Aims and Objectives

The objectives are as follows:

- To assess the clinical profile in children with distal hypospadias
- To assess the surgical outcome in children with distal hypospadias after Snodgrass Urethroplasty.

MATERIALS AND METHODS

The study was conducted in the Postgraduate Department of General Surgery at Government Medical College Srinagar from November 2018 to November 2020. It was a prospective observational study on patients of hypospadias admitted in department of surgery over a period of 24 months and was conducted after taking consent from parents of patients and getting clearance from intuitional ethical committee. A detailed history and examination of patients was recorded.

Inclusion Criteria

All cases of distal hypospadias presenting with abnormal meatus location, glans configuration, skin coverage, and mild degree of chordee <30° were included in the study.

Exclusion Criteria

- All patients with proximal hypospadias (proximal penile, penoscrotal, and perineal)
- Patients having severe degree of chordee more than 30°
- Patients having congenital ventral curvature with normal meatus
- All patients having contraindications to general anesthesia.

In addition to general physical and systemic examination, a detailed local examination was done in every patient. In addition to type of hypospadias each patient was looked for meatus stenosis and chordee, shape of glans and size of penis. Special attention was given to prepuce whether intact, circumcised or utilized in previous operation. Local examination also included shape of scrotum, midline raphe, nature of urinary stream, any cryptorchidism, or ambiguous genitilia. Patients operated previously will be examined for any scarring, fistula, and stricture. Pre-operative antibiotic prophylaxis was given one hour before intubation. Meticulous part preparation was done with 10% Povidone-Iodine. All the procedures will be done as elective surgeries under general anesthesia. To obtain a bloodless field, a tourniquet (released every 30–45 min) used. Hemostasis is ensured using bipolar diathermy. Urethroplasty was performed around a 7/8 feeding tube catheter to avoid subsequent stenosis. A compressing dressing was applied post-operatively for 48 h for hemostasis, and feeding tubes removed on 10th post-operative day.

All patients had mild degree of Chordee <30°. Surgical procedure done for Distal Hypospadias was Snodgrass Urethroplasty for Glanular, Coronal, Subcoronal and Distal Penile Hypospadias. The tubularized incised plate urethroplasty combines modifications of techniques of urethral plate incision and tubularization. The concept of a urethral plate "relaxing incision" as an adjunct to hypospadias repair is to allow tension-free neourethral tubularization. Urethral calibration was routinely done intraoperatively with a urethral sound to exclude any distal stenosis, thereafter presence, location, number of fistulas was assessed, probing every pit in the skin with the probe to avoid missing smaller fistulae under loupe magnification. In doubtful cases methylene blue was injected under pressure from the terminal portion of neourethra while a tourniquet was applied at the base of the penis to occlude the proximal urethra. Patients were regularly followed up for 2 years for outcome and complication of hypospadias. The follow up was done on outpatient department (OPD) basis at an interval of 2 weeks for 1 month then 6 monthly for 2 years.

Statistical Method

The recorded data were compiled and entered in spreadsheet (Microsoft Excel) and the exported to data editor of SPSS version 20.0(SPSS Inc., Chicago, Illinios, USA). Continuous variables were expressed as mean SD and categorical values were summarized as frequencies and percentages. Graphically, the data were presented by bar and pie diagrams.

RESULTS

Our study patients age ranged between 5 months and 12 years with maximum patients, that is, 19 (38%) falling in their 6th decade of life followed by 12 (24%) patients aged between 5 and 6 years with a mean age of 5.4 ± 1.89 years. Majority of patients i.e. 35 (70%) came with abnormal urinary stream followed by cosmetic deformity of penis in 15 (30%) patients. 38 (76%) were diagnosed at birth while as 12 (24%) patients were diagnosed at circumcision. No family history of hypospadias was seen in all the 50 patients. 46 of the 50 patients (92%) had no associated congenital abnormalities. Only 4 patients were found to have associated congenital abnormality including 2 (4%) patients with undescended testes and 2 (4%) patients with inguinal hernia. Only 8 (16%) of the 50 patients were circumcised. Patients were distributed as per type of hypospadias and

it was observed that subcoronal hypospadias, distal penile and coronal hypospadias were found in 25 (50%), 17 (34%), and 8 (16%) patients, respectively. Shape of meatus was slit shaped in 24 (48%) patients, stenotic in 21 (42%) patients, and circular in 5 (10%) patients in our study.

Out of 50 patients studied, midline raphe was found in 32 (64%) patients while as deviated from midline raphe was seen in 18 (36%). Only 10 (20%) patients had associated chordee in our study. Catheter was removed on 10th post-operative day in 45 (90%) patients, catheter was removed on 11th POD and >13th POD in 2 (4%) patients while as catheter was removed on 12th POD in 1 (2%) patient. 12 (24%) patients had postoperative complications comprising of urethrocutaneous fistula in 8 (16%) patients, meatus stenosis in 3 (6%) patients and 1 (2%) infection. At 24 months acceptable cosmetic results were observed in 47 (94%) patients. Small meatus was seen in 2 (4%) patients while as bulky tissue was present in 1 (2%) patient [Tables 1 and 2].

DISCUSSION

In our study, we had total number of 50 patients. Mean age of presentation is 50 months minimum age is 5 months and maximum age is 12 years. Age of presentation is early as compared to study of clinical profile of hypospadias in Medical College South Gujarat[33] where mean age of presentation was 7.5 years. In our study age of presentation is still late, that is, 15 months, ideally patient should be operated between 6 and 18 months of age.[34] Parents of the patients are still unaware about the disease and present late. 35 cases that are 70% presented abnormal urinary stream while 30% presented with cosmetic deformity of penis.

In our study, 38 (76%) were diagnosed at birth and 12 (24%) were diagnosed at the time of circumcision. In our study, no patients had associated family history of hypospadias. In our study, 11 cases that are 22% had already circumcised penis while 39 cases that is 78% had uncircumcised penis. Still there needs a lot of awareness in our society about delaying of circumcision in hypospadias as lot of patients about 22% are already circumcised, but in our patients most of the circumcised patients have distal hypospadias and it did not overall affected the surgical outcome but circumcision should be avoided in hypospadias encountered especially in proximal hypospadias where prepuce may be needed for surgical reconstruction. In our study, associated external genital anomalies were undescended testes and inguinal hernia. 2 (4%) patients had associated undescended testes and 2 (4%) had inguinal hernia. There were no other anomalies associated. During antenatal period 1 case that is 2% cases had history small for gestational age. Type of hypospadias was assessed on clinical examination. 25 cases that is 50% had subcoronal type of hypospadias, 8 cases that is 16% had coronal and 17 cases that is 34% had distal penile. Shape of meatus was also assessed on clinical examination 24 cases that are 48% had slit shaped meatus 21 cases that is 42% had stenotic and 5 that is 10% cases had circular type of meatus. In our study, skin raphe was midline in 32 cases that is 64% while 18 that is 36% patients had deviated raphe. 10 (20%) patients of cases had associated mild degree of meaning chordee <30°. Mean age at the time of surgery was 50 months that is 4.166 years.

We operated patients immediately after diagnosing them on OPD basis. Catheter was removed on post-op 10th day in 90% of cases while 10% cases needed catheterization for more than 10 days because they failed to pass urine after giving trial and developed retention and were catheterized again. Surgical procedure done was Snodgrass urethroplasty. This procedure was associated with good surgical outcomes and less complication and was procedure of choice in distal hypospadias our study was consistent with the Hamid *et al.*[34] comparative study of Mathieu and Snodgrass Repair of hypospadias which favored Snodgrass repair as procedure of choice in distal hypospadias with good surgical outcomes and fewer complications. Our study results are consistent with the current study done at Alribat University Hospital, Department of Paediatric Surgery by Yassir *et al.*,[35] for patients who underwent distal hypospadias repair in the period August 2012–September using patient's record. 31 children (aged between 2 years and 13 years) with distal hypospadias have been treated from August 2012 to September 2013. The average age at operation was 5.8 years. They underwent primary repair using different type of operations, and they had no history of previous hypospadias repair. The pre-operative meatus sites were glanular in seven patients, coronal in eight patients, and sub coronal in 16 patients. Data collected using predesigned questionnaire including information such as age, family history, type of hypospadias, type of surgery, and complications. Results were that all Patients enrolled in this study have no family history of hypospadias most of the patients were diagnosed at birth (87.1%), and only 12, 9% diagnosed at circumcision. The most common presentation of patients is abnormal shape of penis and abnormal stream of urine (71% and 25.8%, respectively). According to the site of meatus sub coronal hypospadias is the commonest 51.6% of patient. Associated chordee is present in 19.4% of patients (6 patients). Associated external genitalia anomalies are inguinal hernia and undescended and they are equals 3.2% for each. Only one patient had been circumcised before surgery representing about 3.2%. Mean age at time of surgery was 5.8 and 74.2% of patients underwent surgery after 3 year of age postoperatively 35% of our patients had been catheterized

Table 1: Age, symptoms at presentation, associated congenital abnormality, history of circumcision, type of hypospadias

Patient characteristics	Number of patients (%)
Age (years)	
<3	7 (14)
3–4	4 (8)
4–5	8 (16)
5–6	12 (24)
≥6	19 (38)
Total	50 (100)
Mean±SD (range)	5.4±1.89 (5 months–12 years)
Symptoms	
Abnormal urinary stream	35 (70)
Cosmetic deformity of penis	15 (30)
Associated congenital abnormality	
Undescended testes	2 (4)
Inguinal hernia	2 (4)
No congenital abnormality	46 (92)
History of circumcision	
Yes	8 (16)
No	42 (84)
Type of hypospadias	
Subcoronal	25 (50)
Coronal	8 (16)
Distal penile	17 (34)

SD: Standard deviation

Table 2: Distribution of study patients as per shape of meatus, midline skin raphe, associated chordee, post-operative complications, and cosmetic results

Patient characteristics	Number of patients (%)
Shape of meatus	
Slit shaped	24 (48)
Stenotic	21 (42)
Circular	5 (10)
Midline skin raphe	
Midline	32 (64)
Deviated from midline	18 (36)
Associated chordee	
Yes	10 (20)
No	40 (80)
Postoperative complications	
Urethrocutaneous fistula	8 (16)
Meatal stenosis	3 (6)
Infection	1 (2)
Cosmetic results	
Small meatus	2 (4)
Bulky tissue	1 (2)
Acceptable cosmetic results	47 (94)

more than 7 days. All these results of study are almost matching to our study. Chordee associated in our patients was also supported by another study by Gohil *et al.*[32] which found association of chordee in 19% of patients. Assessment of surgical outcome in hypospadias was done by assessing complications Cosmetic appearance of penis. In our study, most common complication during follow-up was urethrocutaneous fistula in about 16% of patients followed by meatus stenosis in about 3% of patients and 2% developed post-operative infection as our study is consistent with study of Appeadu-Mensah *et al.*[36] on Complications of hypospadias surgery: Experience in a tertiary hospital of a developing country in which 18% patients developed urethrocutaneous fistula and 3% developed meatus stenosis during follow-up period. Cosmetic results were assessed during follow-up of 24 months 2 cases that is 4% of patients had small meatus, 1 case that is 2% had bulky tissue. Rest cases had acceptable cosmetic results. Complications and cosmetic outcome during follow-up in our study was consistent with study done by Aslam *et al.*[37] a retrospective case note review was undertaken of all patients undergoing a primary, single stage, tabularized, incised plate (TIP) hypospadias repair between April 2000 and January 2003, mean age of 3.5 years with a mean follow-up of 56 months. Data were recorded regarding complications such as re-operation, fistula, meatus stenosis, and urethral stricture. Indications of cosmesis and long-term function were also recorded. The complication rates for the two groups and the overall complication rate were assessed. This study had similar complications and cosmetic outcome to our study.

CONCLUSION

The conclusion of our study was that most of the patients in our study presented late because of unawareness among people about the disease. Good amount of patients had already circumcised penis. Patients usually presented with abnormal urinary stream more than concerning about cosmetic deformity. The surgical procedure done was Snodgrass Urethroplasty for distal hypospadias and was associated with good surgical outcomes and fewer complications.

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Original Article

Morphometric Analysis of Mental Foramen by Cone-Beam Computed Tomography

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Abstract

Introduction: Due to the increase in surgical procedures and increased risk of mental nerve damage, cone-beam computed tomography (CBCT) plays an important role to detect and evaluate the anatomical variations. Therefore, the goal of this research is the Morphometric Analysis of the Mental Foramen using the CBCT.

Materials and Methods: The CBCT images of 108 patients were collected from a CBCT center. Data were analyzed using descriptive statistics: mean, standard deviation, and range. Student's independent t-test was used to compare various parameters between the right and left mandibles.

Results: Out of 108 patients, 56 had a mental foramen of round shape. The most frequent position of the mental foramen was position IV-50% (In line with 2nd premolar).

Conclusion: Determining the shape, size, and location of the MF is important because many dental procedures are performed on the jaw. Therefore, further studies are recommended to analyze invariant landmarks such as inferior border of mandible to locate mental foramen.

Key words: Anatomy, Cone-beam computed tomography, Foramen, Mandible, Mental nerve

INTRODUCTION

The inferior alveolar nerve branches into the mental nerve and the incisive nerve in the mental foramen, which is located on the lateral section of the mandible.[1] The location of mental foramen varies in different age groups. In children before the eruption of teeth, it is located closer to the alveolar crest whereas in adults it is located midway between the alveolar crest and lower border of mandible. As the bone resorbs, it gets closer to the alveolar crest or even can be found over it.[2] Therefore for any surgical procedure like implant surgery, knowledge of the accurate mental foramen position is of utmost importance for any in the region of mental foramen.[3] Damage to the neurovascular bundles may cause serious complications such as paresthesia by any invasive procedure performed in this region. With different methods such as macroscopic investigations on dry skulls, plane radiographs, and computed tomography images.[4] The location and number of MF can be evaluated.[5]

An image that is three-dimensional in nature and has a very high spatial resolution at low exposures would be the ideal image for the planning of surgeries in the area of the mental foramen. These attributes can be achieved with cone beam computed tomography (CBCT), which not only make it an ideal form of imaging, but also allow for a precise understanding of the relationship between structures in ananatomically complex area.[6]

CBCT has proven to have an error of <0.6% when measuring mandibular anatomy.[7] It also has proven to be accurate when measuring simulated bone defects in acrylic blocks with a mean width accuracy of −0.01 mm and mean height difference of −0.03 mm.[8]

Hence, CBCT plays an important role to detect and evaluate the anatomical variations. Therefore the aim of this study is the Morphometric Analysis of the Mental Foramen using CBCT.

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MATERIALS AND METHODS

This study has been reviewed and approved by the Ethical Committee of Vyas Dental College Jodhpur. Permission was obtained from the respective CBCT center authority. It was a Retrospective type of Study which was conducted in the Department of Oral Medicine and Radiology, Vyas Dental College Jodhpur. This study was conducted in the age group of 15 years and above with a sample size of 108. Patients with impacted teeth, radiolucent or radiopaque bony lesions, any surgical procedure or graft placed in the mandible, related syndromes or orthodontic treatments. From the list of CBCT centers, two CBCT centers were randomly selected by simple random sampling. Of the collected CBCT's who met the inclusion and exclusion criteria, 108 were selected. Daily three CBCT's were evaluated in the department of Oral Medicine and Radiology. This way it took 36 working days to evaluate 108 CBCT's. 108 patients' CBCT pictures were obtained from a CBCT center. CBCT images were taken using a New Tom VGi scanner (QR srl; Verona, Italy) in standard resolution mode [palatal plane parallel to the horizontal plane, allowing axial cuts parallel to the palatal plane with voxel size of 0.3 mm] with exposure parameters of kVp=110, 3.6 s, and FOV 808 cm, or 812 cm. Axial, Coronal, and Sagittal cross sections of 1mm thickness were produced at 0.5 mm intervals [Figures 1-3]. According to Tebo and Telford, the position of the mental foramen in reference to the lower teeth is represented as[45] [Figure 4]:

I. Mesial to the first premolar
II. Beneath the first premolar
III. Between the premolars
IV. Beneath the second premolar
V. Between the second premolar and first molar
VI. Beneath the mesial root of the first molar
VII. Edentulous, hence unable to determine the position.

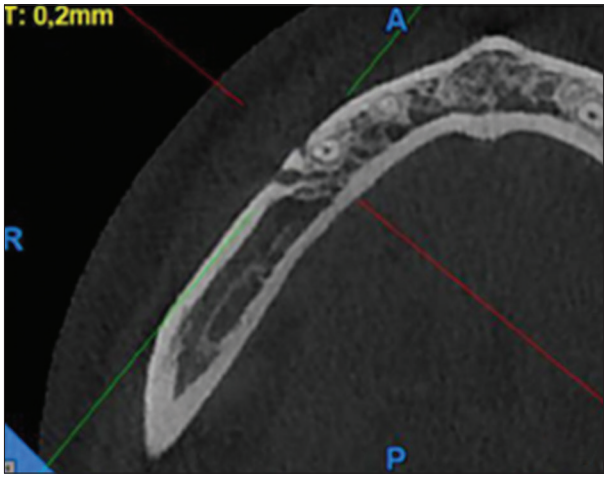


Figure 1: Cone-beam computed tomography image of axial section of MF

The shape of the mental foramen, whether oval or round, the number of mental foramina, the position of the mental foramen in relation to the roots of mandibular teeth, and the distance between the upper and lower cortical areas of the mental foramen to the alveolar crest and the inferior border of the mandible, respectively, were all recorded [Figures 5-8].

Statistical software SPSS (version 22.0) and Microsoft Excel (version 5.00) were used to carry out the statistical analysis of data. Descriptive statistics, such as means, standard deviations, and ranges, were used to analyze the data. For comparison of various parameters between right and left mandible, Student's independent *t*-test was employed.

RESULTS

Table 1 and Graph 1 show that the mean age of patients with right mandibular measurements was 34.07 years (SD = 12.31), whereas the mean age of patients with left

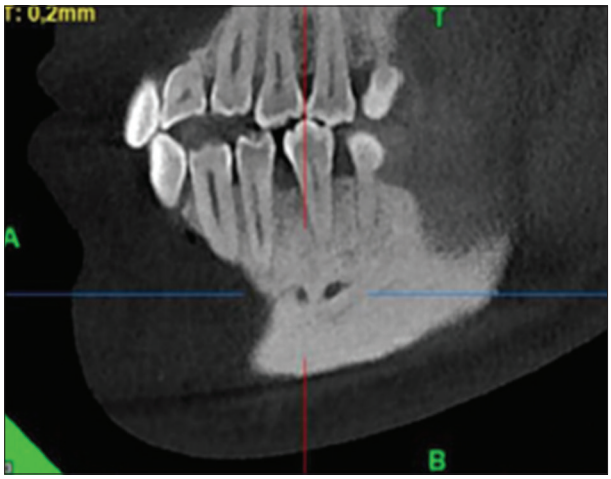


Figure 2: Cone-beam computed tomography image of sagittal section of MF

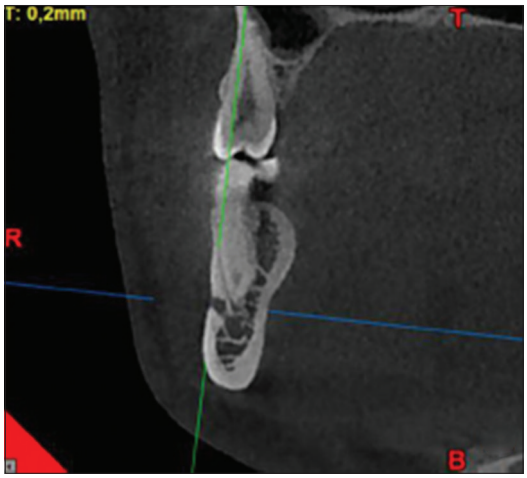


Figure 3: CBCT image of Coronal section of MF

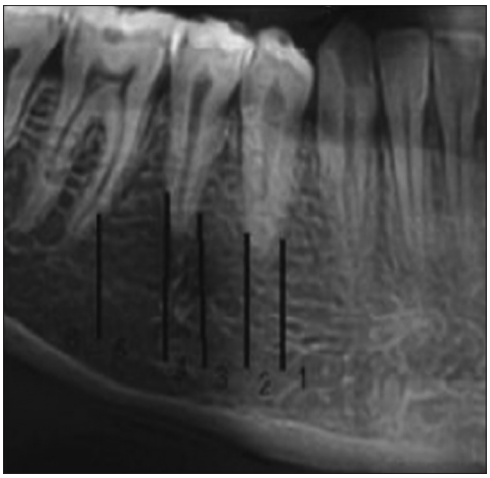


Figure 4: Position of MF

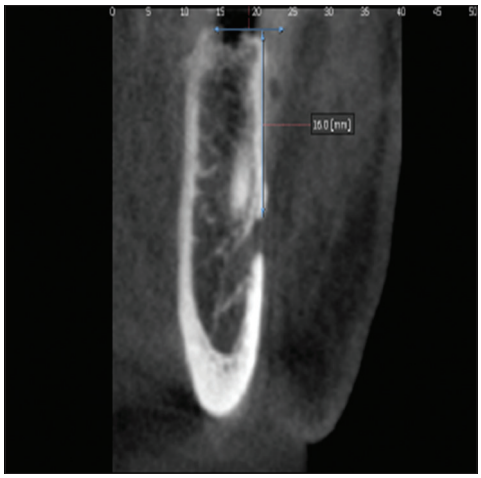


Figure 7: Measurement from the upper cortical area of foramen to alveolar crest

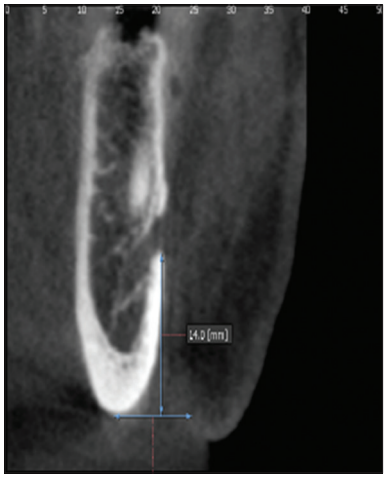


Figure 5: Measurement from base of foramen to inferior border of mandible

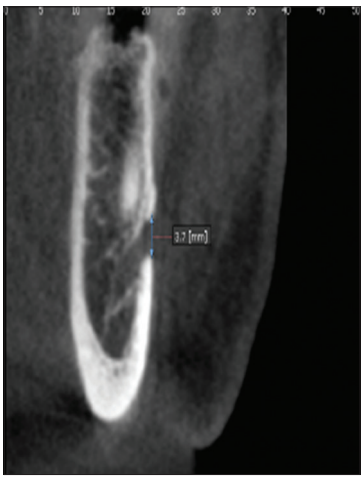


Figure 8: Size of mental foramen

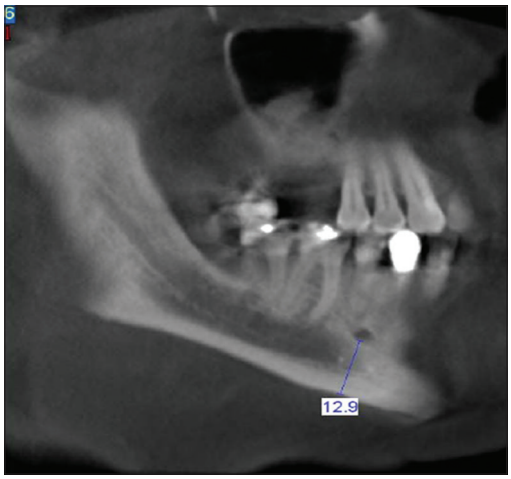
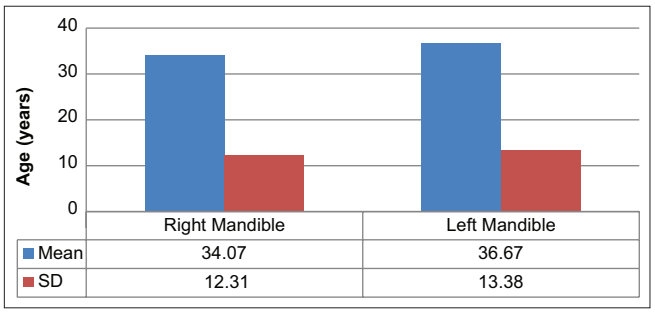


Figure 6: Measurement from base of foramen to inferior border of mandible



Graph 1: Mean age of patients with right mandibular measurements

mandibular measurements was 36.67 years (SD= 13.38), with no statistically significant difference ($P > 0.05$) between the right and left mandibles.

Table 2 and Graph 2 demonstrate that the most common shape in this sample was round, with no significant difference between right and left. Out of 108 patients, 56 had a mental foramen of round shape and 52 patients were found with a mental foramen of oval shape.

Table 3 and Graph 3 show that the most frequent position of the mental foramen was position IV-50% (In line with 2nd premolar) followed by positions III-39%

(Between 1st and 2nd premolars), Position V-8% (Between 2nd premolar and 1st molar) and position VI- 3% (In line with mesial root of 1st molar). No mental foramen was found in position I (Mesial to 1st premolar) and position II (In line with 1st premolar).

Table 4 and Graph 4 show that the distance from the upper cortical area of the mental foramen to the alveolar crest was measured. Mean distance from the upper cortical area to alveolar crest (mm) on the right side of mandible was found to be 12.91 (SD 1.92). Mean distance from the upper cortical area to alveolar crest (mm) on the left side of mandible was found to be 13.03 (SD 2.01). There was no statistically significant differences found between the right and left sides ($P = 0.081$).

Table 5 and Graph 5 show the distance from the lower cortical area of the mental foramen to the mandibular base. Mean distance the lower cortical area of the mental foramen to the mandibular base (mm) on the right side of mandible was found to be 12.20 (SD 1.61). Mean distance the lower cortical area of the mental foramen to the mandibular base (mm) on the left side of mandible was found to be 13.40 (SD 1.95). There was no statistically significant differences found between the right and left sides ($P = 0.983$).

Table 6 and Graph 6 show that the size of the mental foramen was measured on both the right and left sides of the mandible, with a range of 0.8 mm to 6.0 mm. The mean size of mental foramen on the right side of mandible was found to be 3.17 mm (SD 1.41); however, on the left side of mandible the mean size was found to be 2.96 mm (SD 1.13). There was no significant difference observed between the two sides ($P = 0.413$).

Table 1: Mean age of patients

Age (years)	*n*	Mean	SD	Range	*P*
Right mandible	54	34.07	12.31	17–62	0.613
Left mandible	54	36.67	13.38	16–62	

SD: Standard deviation

Table 2: Shape of mental foramen

Shape	*n* (%)
Round	56 (52)
Oval	52 (48)
Total	108 (100)

Table 3: Location of mental foramen

Location	*n* (%)
Mesial to first premolar (position-1)	0
In line with first premolar (position-II)	0
Between first and second premolars (position-III)	42 (39)
In line with second premolar (position-IV)	54 (50)
Between second premolar and first molar (position-V)	9 (8)
In line with mesial root of 1stmolar (position-VI)	3 (3)
Total	108 (100)

Table 4: Distance from the upper cortical area to alveolar crest (mm) as per the right and left mandible

Parameter	Right mandible		Left mandible		*P*
	Mean	SD	Mean	SD	
Distance from upper cortical area to alveolar crest (mm)	12.91	1.92	13.03	2.01	0.081

SD: Standard deviation

DISCUSSION

For any surgical operation involving implant surgery in the mental foramen region, knowing the exact position of the mental foramen is essential. The position, shape, and size of the mental foramen, as well as the presence of accessory canals, can all be precisely determined by CBCT.[9]

When considering the mental incisive anesthetic block and surgery in the outer premolar mandibular region, the position of the MF is crucial.[10] However, there are significant differences reported among different ethnic groups in the location of MF.[11]

Shape

There are several studies reported whose results do not agree on the classification of shapes of mental foramen itself.[12] Round was the most frequent shape found in our

Table 5: Distance from lower cortical area to mandibular basal bone (mm) as per right and left mandible

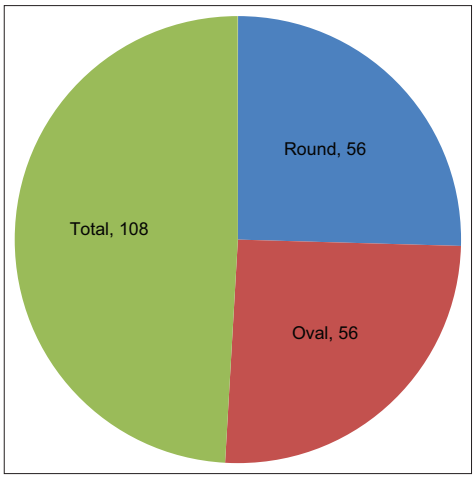
Parameter	Right mandible		Left mandible		*P*
	Mean	SD	Mean	SD	
Distance from lower cortical area to mandibular basal bone (mm)	12.20	1.61	13.40	1.95	0.983

SD: Standard deviation

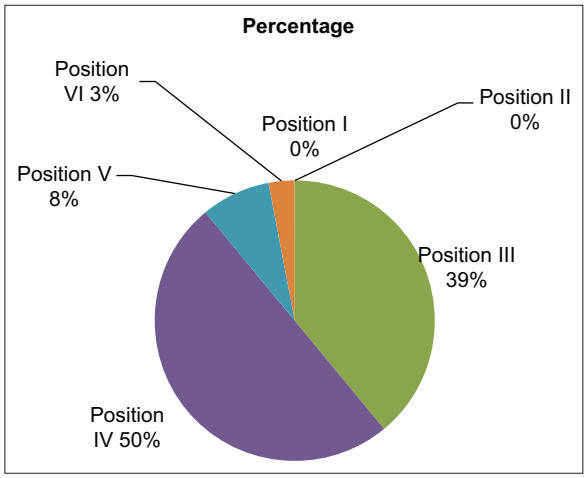
Table 6: Size of foramen

Size of foramen (mm)	*n*	Mean	SD	*P*
Right mandible	54	3.17	1.41	0.413
Left mandible	54	2.96	1.13	

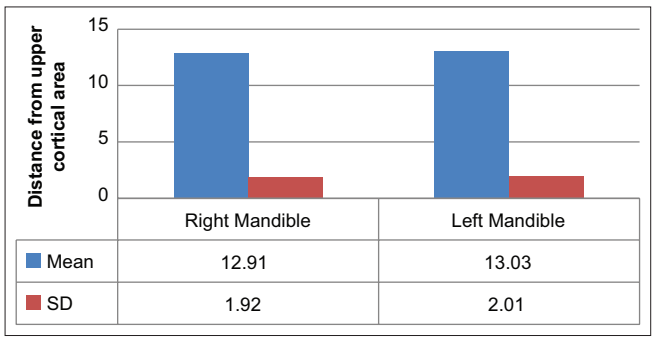
SD: Standard deviation



Graph 2: Most common shape

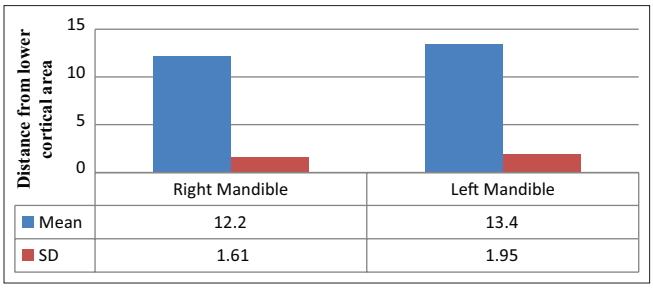


Graph 3: Most frequent position of the mental foramen

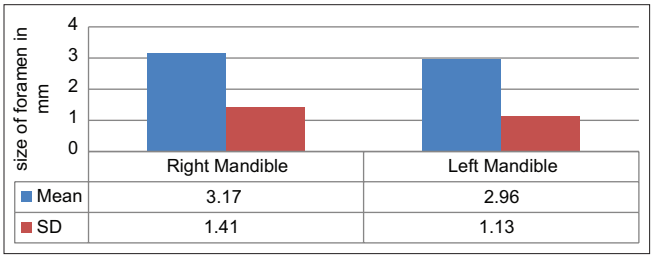


Graph 4: Distance from the upper cortical area of the mental foramen to the alveolar crest

study with no significant difference observed between right and left. This was in consistent with the studies conducted by Gupta and Soni[13] and Córdova,[14] Singh and Srivastav[15] and Sekerci.[16] However, the studies by Chalkoo *et al.*,[17] Padilla *et al.*,[18] Igbigbi and Lesbona[1] Budhiraja *et al.*,[19] Agarwal and Gupta[12] Oliveira *et al.*,[20] Ilayperuma *et al.*,[21] and Hasan.[22] have reported the oval shape as the most frequent one. These results were not in accordance with the present study. This variation may be because of the fact



Graph 5: Distance from the lower cortical area of the mental foramen to the mandibular base



Graph 6: Size of the mental foramen

that these studies were conducted on dry skulls or because of the different races and ethnic groups selected.

Frequent Position of the Mental Foramen

In the literature, there is a lot of disagreement over where the mental foramen is located in different ethnic groups. Position IV (In line with 2nd premolar) was the most frequent position of the mental foramen in our study (that was 50%). In position I (Mesial to 1st premolar) and position II (In line with 1st premolar) no mental foramen was found. Similar results were observed by Igbigbi and Lesbona,[1] Amorin *et al.*,[23] and Chalkoo *et al.*[17] where as Haghanifar and Rokouei[24] Oliveira *et al.*,[20] Rupesh *et al.*,[25] and Gungor *et al.*[26] showed that the most frequent locate on of the mental foramen was position III. The different feeding habits subsequently affecting the mandible development may be the reason related to the variability in the position of mental foramen.

Distance of Mental Foramen from Upper Cortical Plate and the lower Cortical area to the Mandibular Basal Bone

The findings of our study were in accordance with the studies conducted by Igbigbi and Lesbona and Agarwal and Gupta[1] Oliveira *et al.*[20] and Budhiraja *et al.*[19] They observed measurements on dry mandibles and reported shorter distances as compared to this study.

SUMMARY AND CONCLUSION

Following conclusions can me made:

i. Round was the most frequent shape found in this study with no significant difference observed between right and left

ii. The most frequent position of the mental foramen was position IV-50% (In line with 2nd premolar).

Thus, further studies are recommended to analyze the invariable landmarks like the inferior border of mandible to locate mental foramen. However, variations do exist in the position, shape and size of mental foramen in different population groups. It is essential to be aware of the possibility of these anatomical variations while planning surgery in that region to avoid nerve damage and also to enable effective mental nerve block anesthesia.

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Original Article

Correlation of Serum Calcium, Phosphorous, Parathyroid Hormone, and Calcium × Phosphorous Product in CKD Patients on Hemodialysis

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Abstract

Introduction: Chronic kidney disease (CKD) is characterized by progressive decline in glomerular filtration rate with prevalence about 17% in India. Hyperphosphatemia induces hypocalcemia leading to hyperparathyroidism with incidence of about 50% in CKD patients on hemodialysis. The derangements in Sr. calcium and phosphorous levels and raised Calcium × Phosphorous (Ca × P) product accelerate vascular calcification and increase stiffness of pulmonary vasculature that increases cardiovascular events and mortality in CKD patients on hemodialysis. In this context, we aimed to evaluate the correlation between serum parathyroid hormone (PTH) and Ca × P product in CKD patients on hemodialysis.

Objectives: The aim of the study was to estimate Sr. PTH, calcium, and phosphorous levels in CKD patients on hemodialysis and calculate Sr. Ca × P product and to compare these parameters with apparently healthy controls.

Materials and Methods: This study was done at Gandhi Hospital, Secunderabad, Telangana, from August 2019 to January 2020, which included 50 CKD patients on hemodialysis aged between 35 and 70 years and 50 age and sex matched apparently healthy controls. Data were collected from clinical biochemistry laboratory.

Results: Sr. PTH (268.80 ± 68.30 pg/ml), sr. phosphorous (7.41 ± 0.77 mg/dl), and Ca × P product (53.84 ± 9.49 mg^2/dl^2) were significantly increased ($P < 0.001$) and sr. calcium (7.27 ± 0.99 mg/dl) was significantly decreased ($P < 0.001$) in cases compared to controls (27.7 ± 9.57 pg/ml, 3.2 ± 0.49 mg/dl, 32.5 ± 5.29 mg^2/dl^2,10.1 ± 0.59 mg/dl respectively). Sr. PTH shown negative correlation with Sr. calcium, positive correlation with Sr. phosphorous, and Ca × P product levels.

Conclusion: Increased serum PTH and calcium × phosphorous product levels in CKD patients on hemodialysis, put them into risk of developing vascular calcification and pulmonary hypertension leading to increase cardiovascular morbidity. Therefore, all CKD patients on hemodialysis need to be screened regularly for Sr. PTH and Ca × P product that helps to decrease the cardiovascular events and mortality in these patients.

Key words: Chronic kidney disease, Parathyroid hormone, Ca × P product, Vascular Calcification

INTRODUCTION

Chronic kidney disease (CKD) is associated with an irreversible damage in kidney functioning and progressive decline in glomerular filtration rate (GFR) and CKD is defined when GFR <60 ml/min/1.73 m^2 for 3 months and CKD prevalence in India is up to 17%.[1-3] Serum parathyroid hormone (PTH) levels starts increasing typically when the GFR drops to <60 ml/min/1.73 m^2. Serum PTH levels in the initial stages increase renal phosphorus excretion but further decline in GFR leads to hyperphosphatemia and induce hypocalcemia by binding bioavailable calcium as calcium phosphate. This indirectly leads to a further rise in PTH production to maintain calcium and phosphorous homeostasis, resulting in hyperparathyroidism and the prevalence of hyperparathyroidism is about 50% in CKD patients on hemodialysis.[4,5]

The derangements in serum calcium and phosphorous levels and raised Calcium × Phosphorous (Ca × P) product

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accelerate vascular calcification of coronary artery and cardiovascular tissue and increase stiffness of pulmonary vasculature that leads to development of pulmonary hypertension and all these increase cardiovascular events and mortality in CKD patients on hemodialysis.[4,6,7] In this context, we have undertaken this study to evaluate the correlation between Serum PTH and Ca × P product levels in CKD patients on hemodialysis.

Aim

- The aim of the study was to study the correlation of serum parathyroid hormone, calcium, phosphorous, and Ca × P product in CKD patients on hemodialysis.

Objectives

The objectives of the study are as follows:

1. To estimate Serum PTH, Calcium and Phosphorous levels in CKD patients on hemodialysis
2. To calculate serum calcium × phosphorous product
3. To compare these parameters with apparently healthy controls to assess the correlation of these parameters in CKD patients on hemodialysis.

MATERIALS AND METHODS

This was a retrospective case–control study done from August 2019 to January 2020 in Biochemistry department, Gandhi Hospital, Secunderabad, Telangana, India. The sample size was 100 that included 50 CKD patients on hemodialysis aged between 35 and 70 years as cases and 50 age and sex matched apparently healthy individuals as controls. Data collected from test results available in the Clinical Biochemistry laboratory based on inclusion and exclusion criteria. Serum PTH was estimated by chemiluminiscence method in Siemens advita centaur XP machine, serum calcium and phosphorous were estimated by spectrophotometric method in Beckman coulter 5800 machine.

Inclusion Criteria

- Fifty clinically diagnosed CKD patients on hemodialysis aged between 35 and 70 years were included in the study.

Exclusion Criteria

- Patients with parathyroidectomy, thyroidectomy, and low serum albumin were excluded from the study.

Statistical Analysis

All continuous variables were presented in Mean ± SD. Student's t-test and Pearson correlation were applied and P value < 0.05 was considered statistically significant

RESULTS

The mean age of CKD cases was 47.22 ± 9.62 years and of controls was 46.02 ± 10.37 years with no significant difference among them. There were 45 males and 55 females included in this study. The Mean ± values of biochemical parameters are given in Table 1.

Serum PTH ($P < 0.0001$), serum phosphorous ($P < 0.001$), and serum calcium × phosphorous product ($P < 0.0001$) levels were significantly increased in CKD cases compared to healthy controls. Serum calcium levels were significantly decreased ($P < 0.001$) in cases compared to controls.

As shown in the Chart 1, Sr. PTH levels were significantly increased in cases as compared to controls.

As shown in the Chart 2, sr. calcium levels were significantly decreased in cases as compared to controls.

As shown in the Chart 3, Sr. phosphorous levels were significantly increased in cases as compared to controls.

Ca × P product levels were significantly increased in cases as compared to controls as shown in Chart 4.

There was negative correlation of Sr. PTH with Sr. calcium as shown in Chart 5.

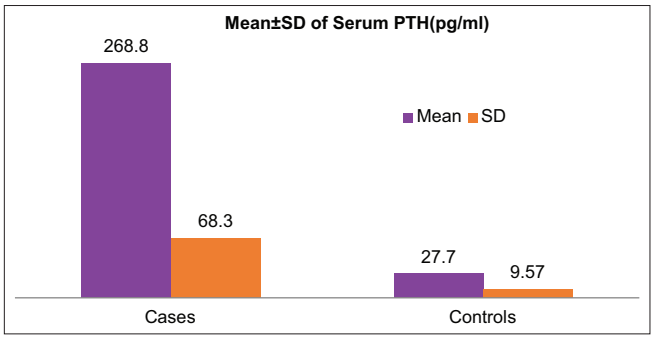

Chart 1: Comparison of serum PTH levels between CKD cases and controls

Table 1: Mean±standard deviation values of biochemical parameters in chronic kidney disease cases and controls

Mean±SD	Cases	Controls	*P*
Blood urea (mg/dl)	175.82±26.08	18.32±5.85	<0.0001
Serum creatinine (mg/dl)	7.88±0.96	0.94±0.18	<0.0001
Serum PTH (pg/ml)	268.80±68.30	27.7±9.57	<0.0001
Serum calcium (mg/dl)	7.27±0.99	10.1±0.59	<0.001
Serum phosphorous (mg/dl)	7.41±0.77	3.2±0.49	<0.001
Ca×P product (mg^2/dl^2)	53.84±9.49	32.5±5.29	<0.0001

SD: Standard deviation, PTH: Parathyroid hormone, Ca × P product: Calcium × phosphorous product

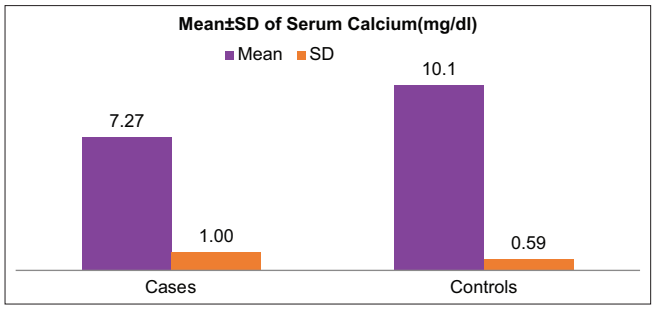

Chart 2: Comparison of serum calcium levels between CKD cases and controls

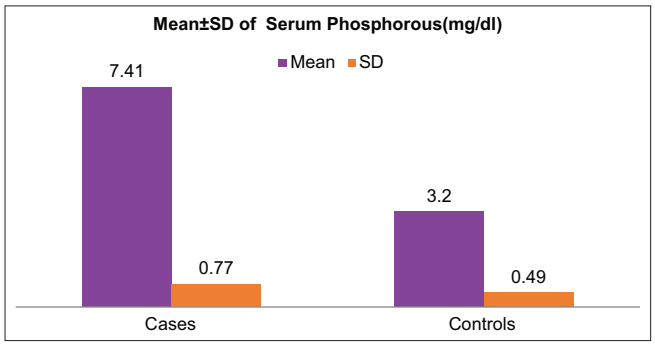

Chart 3: Comparison of serum phosphorous levels between CKD cases and controls

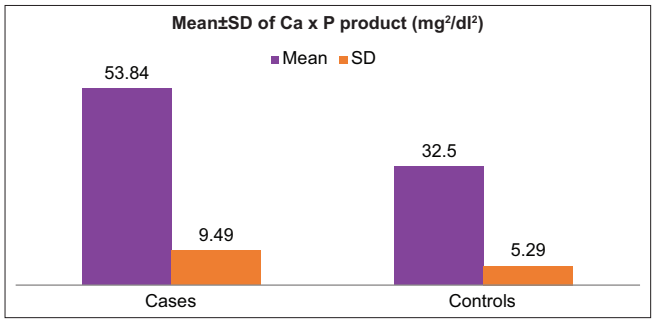

Chart 4: Comparison of calcium × phosphorous product levels between CKD cases and controls

There was positive correlation of Sr. PTH with Sr. calcium as shown in Chart 6.

There was positive correlation of Sr. PTH with Ca x P product as shown in Chart 7.

DISCUSSION

CKD is mostly associated with alterations in calcium and phosphates homeostasis resulting in increased serum PTH levels leading to hyperparathyroidism. The increased PTH levels with the progression of renal failure are a compensatory mechanism necessary to maintain the homeostasis of calcium and phosphorus metabolism and also causes myocardial calcium deposition, valvular calcification, and vascular stiffness and calcification which leads to increased cardiovascular complications.[8]

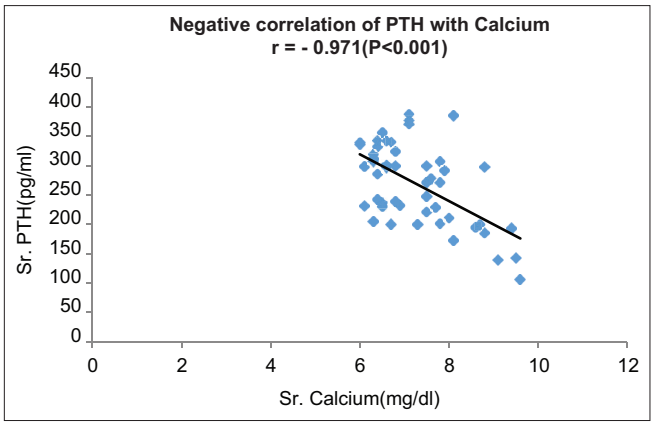

Chart 5: Correlation of Sr.PTH with Sr. calcium

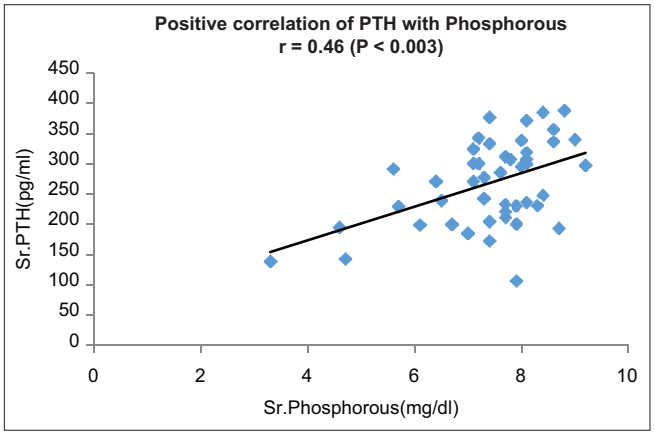

Chart 6: Correlation of Sr. PTH with Sr. phosphorous

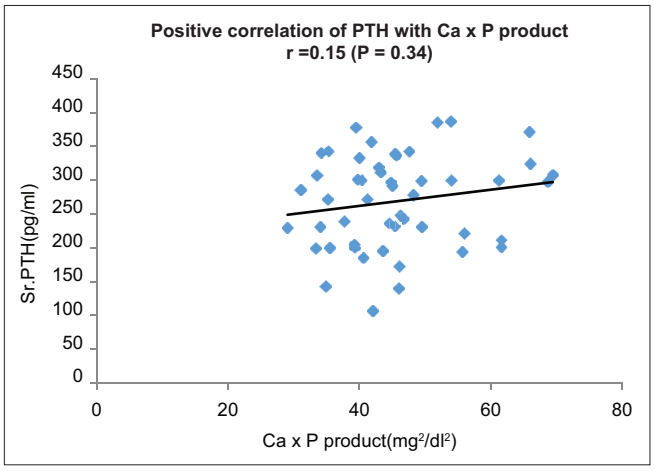

Chart 7: Correlation of Sr.PTH with Ca × P product

The serum PTH [Chart 1], serum phosphorous [Chart 3], and serum calcium × phosphorous product levels [Chart 4] levels were significantly increased ($P < 0.001$) and serum calcium [Chart 2] levels were significantly decreased ($P < 0.001$) in cases as compared to controls. Moreover,

our results were in consistent with similar studies done by Natikar *et al*.[1] with 50 CKD cases in 2022 and by Arora *et al*.[9] in 2018.

We observed that, among 50 CKD cases, 10% cases had Ca × P product levels more than 70 mg^2/dl^2. The Ca × P product levels more than 70 mg^2/dl^2 are considered as an important factor in ectopic calcification and calcific uremic arteriolopathy in CKD patients.[10] and a study done by Mario Cozzolino *et al*.[11] reported that increased Ca × P product levels increases cardiovascular mortality in CKD patients with hyperparathyroidism.

We found a linear negative correlation of Sr.PTH with Sr. calcium with r value −0.971 [Chart 5] with significant $P < 0.001$ and a linear positive correlation of Sr. PTH with Sr. Phosphorous with $r = 0.46$ [Chart 6]) with significant $P < 0.003$ and Similar results were observed by Arora *et al*.[9]

In our study, we observed a positive linear correlation between Sr.PTH and Ca × P product levels [Chart 7] with $r = 0.15$ but it was not significant as *P*-value was above 0.05 and similar observation was found by Kumar *et al*.[2]

CONCLUSION

Increased serum PTH and calcium × phosphorous product levels in CKD patients on hemodialysis put them into risk of developing vascular calcification and pulmonary hypertension leading to increase cardiovascular morbidity and mortality. Therefore, all CKD patients on hemodialysis need to be screened regularly for serum PTH and calcium × phosphorous product that helps to decrease the cardiovascular events and mortality in these patients.

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Original Article

Clinicopathological and Laboratory Findings in the Cases of MIS-C in a Tertiary Care Hospital

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Abstract

Introduction: The coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respirator syndrome coronavirus 2 (SARS-CoV-2) has affected almost all the countries, overwhelming the health-care system, causing significant mortality. Multi-system inflammatory syndrome in children (MIS-C) is a rare complication that appears to be linked to COVID-19 and develops as a result of an, as yet, unspecified immune dysregulation with an excessive inflammatory response.

Aims: The aim of the study was to assess and evaluate clinical, pathological, and laboratory findings and treatment outcomes among 15 MIS-C patients using electronic medical records.

Result: The 15 children ranged in age from 4 to 17 (median age 8.8), 12/15 were boys and all them came from different parts of the state. The most commonly involved organ systems were the gastrointestinal (15/15), hematologic (14/15), cardiovascular (15/15), skin and mucosa (15/15), and respiratory (12/15) ones. The estimated median duration of fever was 7 (IQR 5.75–7.25) days. All patients exhibited skin and mucocutaneous lesions. Maculopapular rash (11/15), cracking and hyperemia of lips (12/15), conjunctival injection (10/15), swelling and hyperemia of hands and feet (5/15), oral mucosal changes (11/15), and periorbital edema (11/15) were among the most common findings In addition. All 13 patients had acute gastrointestinal symptoms on admission, including abdominal pain (11/15), vomiting (10/15), and diarrhea (7/15).

Conclusion: During the current pandemic, every child with a fever should have a clearly defined epidemiological history of COVID-19, a careful clinical assessment of possible multiple organ-system involvement, with a special focus on children with severe abdominal pain and/or skin and mucocutaneous lesions.

Key words: Coronavirus disease 2019, Multi-system inflammatory syndrome in children, Severe acute respirator syndrome coronavirus 2

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has affected almost all the countries, overwhelming the health-care system, causing significant mortality. Initial reports worldwide showed that most children are asymptotic or have mild-to-moderate disease.

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We, in our institute Burdwan Medical College and Hospital, have conducted a study on the patients of multi-system inflammatory syndrome in children (MIS-C) admitted our institute over a period of 8 weeks (May 2022–July 2022) and have described their clinical features, laboratory parameters, treatment modalities, and outcome in the following study.

Criteria of MIS-C

The centers for disease control and prevention have declared MIS-C to be a reportable illness as of May 14, 2020. The Health and Family Welfare Department, Government of West Bengal has recently provided a diagnostic criterion of MIS-C which includes patients with age between 0 and 19 years, fever for more than equal to 3 days, clinical signs of multi-system involvement (at least 2 of the following – mucocutaneous, cardiac, hypotension, shock,

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coagulopathy, acute gastrointestinal symptoms), elevated markers of inflammation (e.g. ESR, CRP, Pro-calcitonin), no other obvious microbial cause of inflammation, and evidence of SARS-COV-2 infection (Any one of the following – Positive SARS-CoV-2 RT- PCR, Positive serology, Positive Rapid Antigen Test, and Contact with an individual with COVID-19). All six criteria must be met to fulfill the case definition of MIS-C. Based on the initial signs, symptoms and laboratory parameters, MIS-C has been grouped into three types: (1) MIS-C with febrile inflammatory state; (2) MIS-C with predominant Kawasaki like features; and (3) Severe MIS-C/MIS-C with shock.

Pathogenesis

The possible pathogenesis suggested for the development of MIS-C is immune mediated injury resulting in a hyperinflammatory state and inflammatory vasculopathy. Thus, clinical features delineated from studying several cases worldwide show overlapping features with Kawasaki Disease (KD), Toxic Shock Syndrome, KD Shock Syndrome, and Macrophage Activation Syndrome. Multiple reports of pediatric inflammatory multi-system syndrome temporally associated with SARS-CoV-2 (PIMS-S), MIS-C, KD, and Kawasaki-like syndrome were published from the countries with high case load of COVID-19 like the UK, France, Italy, and the United States of America describing the demographic details, clinical features, investigations, treatment details, and outcome.

Following the World Health Organization's announcement on March 11, 2020, that the spread of the novel coronavirus (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had reached the scale of a global pandemic, the Latvian government announced a national state of emergency on March 12 to slow the spread of the disease in the country. In 2020, Latvia had a total population of 1.908 million and by March 2021 SARS-CoV-2 infection had been confirmed in 4.8% of the total population (90,997 individuals), of whom only 8.7% (7883) were children under 19 years of age.[1] Most of the children had a mild or moderate course of the disease and were treated at home, but 83 patients had more severe manifestations, necessitating hospitalization at Riga Children's Clinical University Hospital.

MIS-C is a rare complication that appears to be linked to COVID-19 and develops as a result of an, as yet, unspecified immune dysregulation with an excessive inflammatory response.[2] Several reports have suggested that children could still develop MIS-C despite an asymptomatic and mild course of SARS-CoV-2.[3,4] The definition of MIS-C is based on the following principal elements: Age, presence of fever, increased levels of

Table 1: Demographic and clinical characteristics of all 13 patients with multi-system inflammatory syndrome in children

Characteristic	Total
Sex, *n*	
Female	3/15
Male	12/15
Age in years, range, median	4–17, 8.8
Comorbidities, *n*	5/15
Days in hospital, median (IQR)	12 (11–18)
Outcome	Recovery
PICU admission, *n*	7/15
Days in PICU, median (IQR)	2 (1.25–2.75)
Clinical characteristic	
Duration of symptoms at admission, median days (IQR)	5 (4–6)
Days with fever, median (IQR)	7 (5.75–7.25)
Number of organ systems involved, *n*	
2–3	0/15
4–5	15/15
≥6	0/15
Clinical manifestations, *n*	
Fever	15/15
Rash	
Maculopapular	11/15
Petechiae	4/15
Mucocutaneous lesions	
Cracking/hyperemia of lips	12/15
Strawberry tongue	4/15
Oropharyngeal erythema	8/15
Conjunctival injection	10/15
Extremity changes	
Swelling/hyperemia of hands and feet	5/15
Cervical lymphadenopathy >1.5 cm D	8/15
Gastrointestinal	
Abdominal pain	11/15
Ileus	5/15
Vomiting	10/15
Diarrhea	7/15
Cardiovascular	
Hypotension	5/15
Tachycardia	15/15
Myocarditis	2/15
Congestive heart failure	3/15
Cardiac dysfunction	10/15
Respiratory	
Cough	12/15
Shortness of breath, tachypnea	3/15
Desaturation	6/15
Chest pain	2/15
Pneumonia	7/15
Pleural effusion	9/15
Neurologic	
Headache	6/15
Dizziness	3/15
Meningism/photophobia	5/15
Hyperesthesia	2/15
Emotional lability	4/15
Unsteady gait	2/15
Other	
Periorbital edema	11/15
Skin peeling of hands and feet	2/15
Hepatomegaly	6/15
Splenomegaly	4/15

IQR: Interquartile range, PICU: Pediatric intensive care unit

Table 2: Laboratory values and radiographic findings in the patients with multi-system inflammatory syndrome in children

Characteristic	Results The median of peak values (IQR)
Initial laboratory criteria, (reference ranges)	
CRP (0–5) mg/L	183.04 (135.65–241.09)
ESR (0–15) mm/h	45 (40.7–65.3)
Lymphopenia (0.97–4.28) (10^3 μL)	0.55 (0.44–0.65)
Thrombocytopenia (175–369) (10^3 μL)	112 (94–131.20)
Hyponatremia (132–145) mmol/L	125.60 (125.9–130.29)
Hypoalbuminemia, (38–54) g/L	24.19 (24.1–30.14)
Additional inflammatory markers	
IL-6 (0–2) pg/mL	190 (149–330)
Ferritin (20–200) ng/mL	580.5 (511.5–860.1)
LDH (120–300) U/L	330 (325.79–342.27)
Cardiac biomarkers	
NT-Pro BNP (0–125) pg/mL	7219 (2432–17130)
Troponin (0–19) ng/mL	93.5 (46.5–131.3)
Coagulation parameters	
D-dimer (0–0.55) (mg/mL)	5.95 (3.30–10.50)
Fibrinogen (1.7–4.2) (mg/dL)	5.69 (4.80–7.04)
Chest X-ray	
Interstitial edema/thickening	6/15
Pleural effusion	2/15
Inflammation	4/15
Bronchial obstruction, drainage disorder	5/15
Enlarged heart	2/15
Electrocardiography	
Various changes of ST-segment or T-wave	13/15
Bradyarrhythmias	8/15
Tachyarrhythmias	8/15
Intraventricular conduction defects	12/15
AV dissociation	1/15
Echocardiography	
Valvular insufficiency	
Mitral	9/15
Tricuspidal	8/15
Aortal	5/15
Pulmonal	1/15
Pericardial effusion	4/15
Decreased LV ejection fraction	6/15
RV, RA dilatation	1/15
Abdominal ultrasonography	
Ascites	2/15
Hepato- and/or splenomegal	4/15
Mesadenitis	3/15
Renal parenchymal changes, cystitis	5/15
Pericholecystitis	1/15
Effusion in the abdominal cavity/pelvis	3/15
Pleural ultrasonography-effusion	9/15
Computed tomography of the lungs	
Bilateral polysegmental pneumonia	2/15
Fibrotic changes	2/15
Cardiac magnetic resonance-myocarditis	1/15
SARS-CoV-2 test results at the admission	
Positive nasopharyngeal RT-PCR	0–15
Positive serology	15–15
History of COVID-19 (+) contact	15–15

IQR: Interquartile range, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, IL-6: Interleukin 6, LDH: Lactate dehydrogenase, SARS-CoV-2: Severe acute respirator syndrome coronavirus 2

inflammatory markers, the involvement of more than two organ systems, temporal relation to COVID-19 infection or exposure, and exclusion of other diagnoses.[5] All 13 had documented fever >38.0°C for ≥24 h at the time of presentation, severe illness involving more than two organ systems, and laboratory evidence of inflammation; equally, they all were linked to SARS-CoV-2 infection.

Aims and Objective

The aim of the study was to assess and evaluate clinical, pathological, and laboratory findings and treatment outcomes among 15 MIS-C patients using electronic medical records.

RESULTS

Clinical and pathological findings in MIS-C patients [Table 1] developed 2–6 weeks after acute illness or contact with a COVID-19 positive person in all 15 patients, and they were hospitalized on the 3rd–7th day of illness (median five, interquartile range [IQR] 4–6 days). Only five patients out of the 15 were symptomatic during the acute COVID-19 phase; four had mild symptoms (subfebrility, cough, anosmia, and loss of taste), while one had a severe course of the disease and was admitted to hospital before the onset of MIS-C. The 15 children ranged in age from 4 to 17 (median age 8.8), 12/15 were boys and all them came from different parts of the state. Overall, 11/15 patients had no reported underlying medical conditions; one had bronchial asthma, another had autism spectrum disorder (ASD), while another had gallstone disease. The patient with ASD is the one who had a severe course of acute COVID-19.

Initial signs and symptoms of all study patients had a documented fever >38.0°C for ≥24 h at the time of presentation and severe illness involving at least four organ systems. The most commonly involved organ systems were the gastrointestinal (15/15), hematologic (14/15), cardiovascular (15/15), skin and mucosa (15/15), and respiratory (12/15) ones.

The estimated median duration of fever was 7 (IQR 5.75–7.25) days. All patients exhibited skin and mucocutaneous lesions. Maculopapular rash (11/15), cracking and hyperemia of lips (12/15), conjunctival injection (10/15), swelling and hyperemia of hands and feet (5/15), oral mucosal changes (11/15), and periorbital edema (11/15) were among the most common findings. In addition. All 13 patients had acute gastrointestinal symptoms on admission, including abdominal pain (11/15), vomiting (10/15), and diarrhea (7/15). Two patients underwent diagnostic laparoscopy –

one with an acute ileus and another with suspected acute appendicitis. Respiratory symptoms occurred in 12 patients overall, including a cough (12/15), acute respiratory distress with shortness of breath and tachypnea (9/15), desaturation episodes (6/15), and chest pain (2/15). Neurologic symptoms were present in (12/15) and acute cardiovascular manifestations in all 15 study patients. Five patients were hypotensive at the time of admission.

Laboratory markers and additional diagnostics initial laboratory criteria for strongly suspected MIS-C (9) as elevated C-reactive protein (CRP) ≥30 mg/L and/or erythrocyte sedimentation rate (ESR) >40 mm/h plus lymphopenia <1000 or thrombocytopenia <150 × 10^3 or hyponatremia <135 mmol/L were met in all 15 MIS-C patients. CRP was elevated in all 15 cases, median 183.04 (IQR 135.65–241.09) mg/L, elevated ESR in 12/15 patients, median 45 (IQR 40.7–65.3) mm/h, lymphopenia in 13/15 cases, median 555 (IQR 440–650) μL, thrombocytopenia in 12/15 cases, median 112 (IQR 94–131.20) μL, and hyponatremia in 9/15, median 125.60 (IQR 125.9–130.29) mmol/L.

Additional laboratory evidence of inflammation included increased serum ferritin with median 580.5 (IQR 511.5–860.1) ng/mL and serum cytokine interleukin 6 (IL-6) 190 (IQR 149–330) mg/L in all 15 cases. Lactate dehydrogenase was elevated in 9/15 patients with a median 330 (IQR 325.79–342.27) μ/L. Hypoalbuminemia was observed in 15/15 cases, median value 24.19 (IQR 24.1–30.14) g/L. All 15 patients had increased coagulation marker D-dimer, median 5.95 (IQR 3.30–10.50) mg/L, and fibrinogen in 8/15, median 5.69 (IQR 4.80–7.04) g/L. Blood tests also revealed elevated levels of cardiac troponin I in 9/15 patients with a median of 93.5 (IQR 46.5–131.3) ng/mL and N-terminal pro B-type natriuretic peptide in all 15 cases with a median 7219 (IQR 2432–17130) pg/mL.

Pathological changes in echocardiography were observed in 13/15 patients; the most common findings included valvular insufficiency: Mitral (9/15) and tricuspidal (8/15) and decreased left ventricular ejection fraction (6/15). In electrocardiography (ECG), various changes of ST-segment or T-wave (13/15), bradyarrhythmias (8/15), tachyarrhythmias (8/15), intraventricular conduction defects (12/15) were observed. Three patients out of all 15 had signs of myocarditis by elevated cardiac biomarkers in conjunction with clinical signs and ECG and echocardiographic findings, and one of them was diagnosed with myocarditis by cardiac MRI. Altered chest radiographs were found in 12/15 patients. Pleural effusion was found in nine patients by ultrasonography.

Link to SARS-CoV-2, all study patients were linked to SARS-CoV-2 by having been in contact with COVID-19-positive people 2–6 weeks before MIS-C symptoms developed. Only five patients out of the 15 were symptomatic during the acute COVID-19 phase, and three of them were tested for SARS-CoV-2 by PCR at that time – two were found to be positive. For the other 12 patients, SARS-CoV-2 RNA testing was completed at the time of MIS-C admission, and of this one patient had positive SARS-CoV-2 RNA by rapid molecular testing, but was negative by PCR. All 15 patients had a positive serology for SARS-CoV-2 [Table 2].

Treatment and clinical course seven patients of all 15 required admission to the pediatric intensive care unit (PICU) for a median two (IQR 1.27–2.73) days' stay because of hemodynamic instability, of whom five patients required inotropic support with epinephrine or norepinephrine. Oxygen support was required in six patients due to respiratory distress or desaturation, but mechanical ventilation was not needed.

Antimicrobials were prescribed for all the patients treated in the hospital. All received intravenous immunoglobulins (IVIG), glucocorticosteroids, and acetylsalicylic acid (AAS) according to the indications. Two children received methylprednisolone pulse therapy.

The median length of hospitalization was 15 (IQR 13–16.1) days for PICU patients and 19 (IQR 11.27–19.3) days for children treated on the hospital ward. There were no deaths among this group of patients.

DISCUSSION

This report describes our first clinical experience of Latvian patients with MIS-C. In our study, MIS-C cases occurred 2–6 weeks after acute illness or contact with a COVID-19-positive person after the COVID-19 infection peaked in Latvia. This was similar to the previous studies reported in Europe.[6] We observed a tendency for children to be hospitalized at a relatively late stage in their illness, as observed in Santiago. Moreover, in the case studies presented here, the children were most frequently treated in an outpatient setting with antibiotics used to treat other suspected diseases, including scarlet fever, gastrointestinal infections, or acute appendicitis. Neither the children's parents nor the outpatient doctors associated these conditions as a sequelae after the COVID-19, perhaps, due to the mild or even asymptomatic course of the disease in children. This is also the reason why diagnostic tests were performed less frequently following exposure to COVID-19, although symptoms were displayed after that. Since PCR and anti-SARS-CoV-2 antibodies can often

be negative, the careful acquisition of an epidemiological history is essential. To date, studies have indicated that males may be overrepresented.[7] In our study, 12/15 were boys and, overall, the majority of patients were previously healthy.

In our series, the median age was 8.8 years. Rafferty *et al.*, based on the available studies, reported that the median age of children who developed MIS-C varied from 7 to 10 years.[2] The most common clinical presentation was persistent fever along with dermatological, mucocutaneous and gastrointestinal features, similar to other reports.[8] Given that 100% of our study patients had acute gastrointestinal symptoms and all of them had multi-organ involvement, it has become essential to assess further the involvement of other organ systems in all children with a fever, and especially those with severe abdominal pain. For example, Belhadjer *et al.* reported gastrointestinal involvement in more than 80% of patients.[9] Gastrointestinal manifestations in MIS-C can present in a similar way to many other infectious diseases in children. In our study, abdominal pain was the most common gastrointestinal symptom. Two patients needed surgery because of this initial suspicion of acute abdominal symptoms. In the Jackson report, which described one clinical case, abdominal pain also mimicked acute appendicitis. In fact, all our patients had skin and mucocutaneous involvement. Dermatological manifestations are the top clinical manifestations in children with MIS-C, as mentioned in other studies.[10]

In the present study, we report that 100% of patients had cardiac involvement. The systematic review by Abrams *et al.* noted that 71% of MIS-C cases had cardiovascular symptoms.[11] These findings suggest that patients with MIS-C should always be closely monitored for cardiovascular function, since the majority of them have severe manifestations including shock, hypotension, arrhythmias, and myocarditis. Nevertheless, it is also important to monitor arterial blood pressure and other possible signs of shock requiring immediate treatment. Patients with multi-organ system involvement require medical care in a tertiary-level hospital from a multidisciplinary team.

Laboratory evidence of systemic inflammation, myocardial dysfunction, and coagulation activation has been consistently documented in the previous reports.[10] All children in the present study had positive initial laboratory criteria for strongly suspected MIS-C, such as elevated CRP and/or ESR plus lymphopenia or thrombocytopenia or hyponatremia. Given that they are easy to perform, these analyses are recommended as additional screening tools that can be used in an outpatient setting or a regional hospital.

There are known few clinical practice recommendations regarding treatment for MIS-C by several organizations.[5] Ramcharan *et al.* reported favorable outcomes in treatment plans with IVIG and corticosteroids.[10] Similarly, our experience showed good outcomes from using IVIG, corticosteroids, AAS, and anticoagulants.

Hospitalization was longer due to the general condition of the children. Seven patients of all 15 required admission to the PICU. Similar to our study, Tolunay *et al.* also reported median duration of hospitalization 12,5 days in an article "Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with COVID-19: A case series experience in a Tertiary Care Hospital of Southern Turkey."[12]

Finally, this study has the limitation of representing a small case group. Only 15 children were enrolled. Collaboration is needed at national and international levels. Thus, a larger sample study should be used to confirm these results.

CONCLUSIONS

In the present pandemic, where the incidence of COVD-19 has peaked, every child with a fever should have a well-defined epidemiological history, and a careful clinical assessment of possible multiple organ-system involvement, with a special focus on those with severe abdominal pain and/or skin or mucocutaneous lesions. Before hospitalization or transfer to a university hospital, vital signs should be carefully monitored, intravenous rehydration and antibacterial therapy should be provided, and initial laboratory tests should be performed. Any signs of shock should be assessed and treated immediately. Both members of the public and medical staff need to be further educated about the possible late manifestations of COVID-19.

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Original Article

Comparison of Extraction Socket Healing in Non-diabetic and Diabetic Patients: A Prospective Study

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Abstract

Aims and Objectives: The purpose of this study is to evaluate the effect of diabetes on healing of extraction socket.

Patients and Methods: Total of 100 patients were included in the study who required tooth extraction. Study participants were divided into two groups Diabetic and non-diabetic, 50 participants in each group. Parameters such as extraction socket size, post-operative pain, post-operative swelling, infection, and dry socket were assessed.

Results: Statistical difference was noted between the two groups in terms of post-operative swelling, size of extraction socket which was more in diabetic group than non-diabetic group. Pain score was also more in diabetic group than non-diabetic group. Infection of extraction socket was noted in diabetic group in nine cases whereas no infection was noted in non-diabetic group. Dry socket was absent in both groups.

Conclusion: The study concluded that the socket dimension, pain, infection, and post-operative facial swelling were more on post-operative day 7 in patients with diabetes when compared to non-diabetic patients which suggest delayed healing.

Key words: Diabetes, Extraction, Delayed healing

INTRODUCTION

Diabetes mellitus is a metabolic disorder having multiple etiology which is characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action, or both. Diabetes mellitus is rapidly spreading as epidemic in India with more than 62 million people affected. By 2030, it would rise to 79.4 million.[1] The disease is classified as Type 1 (also referred to as insulin- dependent diabetes) or Type 2 (also referred to as non-insulin dependent diabetes).

Type 1 diabetes is characterized by deficiency of insulin production or defective production of insulin within the pancreas. Type 2 diabetes is characterized by both insulin deficiency and tissue resistance to insulin. Both Type 1 and Type 2 diabetes leads to long-term complications, which is divided into macrovascular, microvascular, and neuropathic complications.[2] Macrovascular complications include diabetic patients to suffer atherosclerosis, peripheral vascular disease, and myocardial infarction. Microvascular complications are associated with a thickening of the basement membrane that leads to reduced capillary permeability. Overall the microvascular circulation is disturbed that leads to reduce inflammatory response. As a result of which, there is decrease leukocyte migration, tissue perfusion, and impaired hyperemia. Delivery of nutrients and removal of metabolic by products are affected, due to which diabetic patients are at increased risk of post-operative infection and delayed wound healing. Perioperative and post-operative hyperglycemia is associated with higher infection rate in general surgery patients.[3] *In vitro* studies have shown that high glucose concentration leads to reduce collagen fibril formation and, therefore, less cross-

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linking of collagen fibers.[4] Less amount of cross linking makes the collagen susceptible to digestion by collagenase. Therefore, high glucose concentration leads to delayed wound healing.

Aims and Objectives

The purpose of the study was to evaluate the effect of diabetes on healing of extraction socket. Various parameters such as extraction socket size, post-operative pain, swelling, infection, and dry socket were assessed.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Oral and Maxillofacial Surgery, Indira Gandhi Government Dental College, Jammu. A sample size of 100 patients was taken in the study.

Patients were divided into two groups (Group A and Group B). Glycated hemoglobin (HbA1c) and random blood glucose were recorded for all the participants before the procedure in patients suffering from diabetes mellitus. Based on the HbA1c values, participants were categorized into two groups as non-diabetic and diabetic. Patients were recalled on post-operative day 7. Sutures were not placed to approximate the mucoperiosteal flaps. Informed consent was obtained from all the patients.

Inclusion Criteria

Patients who are 18 years and above and those who required tooth extraction were included in the study.

Exclusion Criteria

1. Patients who required a transalveolar tooth extraction were exluded from the study
2. Conditions that may impair wound healing (HIV/AIDS), chemotherapy, systemic steroids, radiotherapy, bisphosphonates, benign, or malignant pathology within jaws were excluded from the study
3. Smokers and alcoholics were also excluded from the study.

Parameters

1. Measurement of extraction socket was done using periodontal probe from buccal to lingual gingival margin
2. Pain was measured using visual analog scale (VAS) (Score-0–10) [Figure 1]
3. The facial swelling was recorded by a thread, which was transferred to a standardized scale. The horizontal facial measurement was taken as distance from the corner of the mouth to the tragus of the ear. The vertical measurement was taken as the distance from the outer canthus of the eye to the angle of the mandible by palpating the inferior border.[5]

$$\text{Facial measurement} = \frac{\text{Horizontal measurement} + \text{Vertical measurement}}{2}$$

4. For infection, there were three criteria out of which two must be met.[6]
   - An obvious area of palpable fluctuance adjacent to an extraction socket
   - Serosanguineous or purulent drainage from or around the extraction site
   - Worsening induration, tenderness, erythema, and swelling around the extraction site.

5. For Dry socket, there were three criteria out of which two must be met[6]
   - Increase throbbing pain that was not relieved by analgesics
   - Dark fragments from a resorbed blood clot on irrigation of painful extraction socket
   - Substantial relief of pain with reduction on the VAS of greater than 4 points within 10 min of dry socket dressing application.

Radiographic bone imaging using conventional plain dental or panorex radiographs requires at least 30–50% loss of bone mineral density before disease detection, therefore, may appear normal for up to 3 weeks after onset of symptoms. Then, radiographic finding shows bony destruction and increased radiolucency with a moth eaten appearance.

Statistical Analysis

Statistical analysis was performed using Software Package of Statistical Analysis (SPSS for Windows, version 20, Armonk, NY: IBM Corp). Socket dimensions were compared using the "t" test. Categorical variables were compared using the Chi-square test. The level of significance for the present study was set at $P < 0.05$.

RESULTS

A significant decrease in the mean socket size was observed after day 7 among non-diabetic and diabetic groups when compared to the socket size on day 0 [Table 1]. On day 0, no significant difference in the mean socket size was seen among the two study groups ($P = 0.121$). However, a significant difference was seen in the mean socket size on day 7 among the non-diabetic and diabetic group ($P = 0.00001$).

The pain score among the study subjects was measured on the basis of VAS (visual analogue score) scale. It was observed that in the non-diabetic group, only 1 (2%) patient has reported no pain, 48 (96%) patients reported mild pain and only 1 (2%) patient reported moderate pain. Whereas, in the diabetic group 6 (12%), patients reported mild pain, 43 (86%) patients reported moderate pain, and only 1 (2%) reported severe pain [Table 2 and Figure 2].

No significant difference was seen in the pre-operative face swelling among the study groups ($P = 0.135$) whereas significant difference was seen in the post-operative face swelling on day 7 ($P = 0.005$) [Table 3].

In the non-diabetic group, the infection was not present in any of the study subject whereas in case of diabetic group, there was infection in nine study subjects and no infection was reported among 41 study subjects. Further, dry socket was absent in both the groups among all the study subjects [Table 4 and Figure 3].

DISCUSSION

A total of 100 participants were included in this study. Out of 100 study subjects, there were 61 males and 39 females. The mean age of the total participants was 45.6 ± 15.32 years. The total study participants were divided into two groups, that is, diabetic and non-diabetic, there were 50 study participants in each group. In the non-diabetic group, there were 25 males and 25 females and the mean age among this group was 35.56 ± 13.84. Whereas, in the diabetic group, there were 36 males and 14 females, the mean age among the diabetic group was 55.64 ± 8.79. A significant difference was seen with respect to age among the two groups ($P = 0.024$) [Table 5]. Males were significantly more (72%) in the diabetic group than the females (28%) whereas in non-diabetic group, male: female ratio was equivalent [Figure 4].

In the present study, no significant difference was seen in mean socket size among the diabetic and non-diabetic study groups on day 0. However, a significant difference was seen in the mean socket size on day 7 among diabetic and non-diabetic study group ($P = 0.00001$).

Finding of the study supported the fact that higher the glycemic level could delay the healing.[2]

However, some studies suggest that patients with diabetes or glycemic control are not a risk factor for experiencing post-operative complications in people undergoing dental extractions.[7]

Similarly in the non-diabetic group, 96% patients reported mild pain whereas in diabetic group 86% patients reported moderate pain.

Table 1: Comparisons of extraction socket size on post-operative day 0 and 7

Group	Mean±SD	
	Day 0	Day 7
Non-diabetic (52)	7.97±1.499	2.8±0.808
Diabetic (34)	7.52±1.865	5.3±1.644
P	0.121	0.00001

SD: Standard deviation

Table 2: Distribution of post-operative pain scores among the two study groups

Group	No pain, *n* (%)	Mild, *n* (%)	Moderate, *n* (%)	Severe, *n* (%)
Non-diabetic	1 (2)	48 (96)	1 (2)	0
Diabetic	0	6 (12)	43 (86)	1 (2)

Table 3: Comparisons of facial swelling pre- and post-operative (day 7)

Group	Mean±SD	
	Pre-operative	Post-operative (day 7)
Non-diabetic (50)	10.548±1.731	11.088±1.751
Diabetic (50)	10.118±1.040	11.894±0.983
P	0.135	0.005

SD: Standard deviation

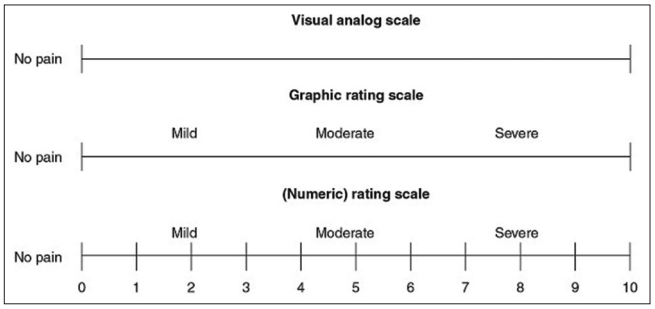

Figure 1: Visual analog scale

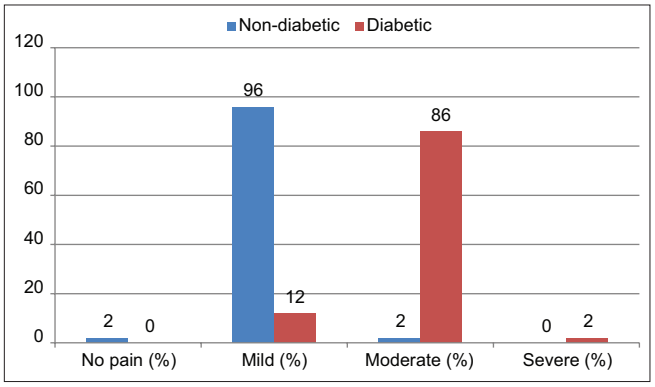

Figure 2: Post operative pain score

The introduction of NSAIDS has significantly reduce the intensity or severity of pain.[8] Difficulty and duration of the operation increased the intensity of pain.

Table 4: Status of infection (present/absent) among the study groups

Group	Infection present, *n* (%)	Infection absent, *n* (%)
Non-diabetic	0	50 (100)
Diabetic	9 (18)	41 (82)
Total	41	60

Table 5: Distribution of age and gender among the study groups

Group	Age, mean±SD	Male, *n* (%)	Female, *n* (%)
Non-diabetic	35.56±13.84	25 (50)	25 (50)
Diabetic	55.64±8.79	36 (72)	14 (28)
Total	45.6±15.32	61 (61)	39 (39)

SD: Standard deviation

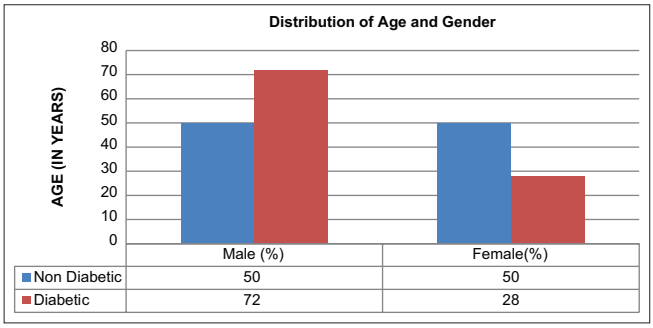

Figure 4: Distribution of age and gender

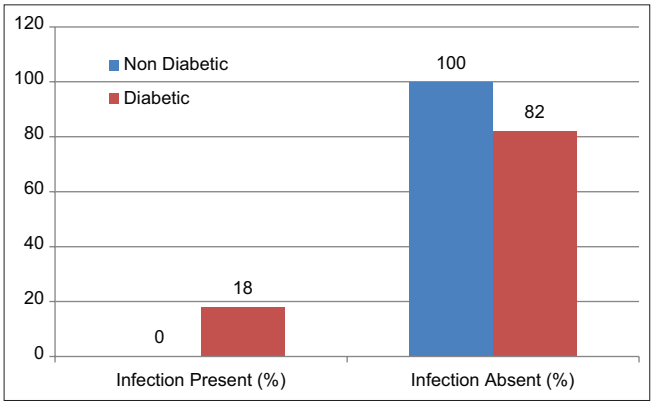

Figure 3: Status of infection

In our study, a significant difference was seen in the post-operative facial swelling between the two study groups on day 7 ($P = 0.005$).

In the non-diabetic group, the post-operative infection was not present in any study subject whereas in case of diabetic group, there was post-operative infection in nine study subjects.

Further, dry socket was absent in both the study subjects.

The present study assessed that factors such as swelling, infection, and pain were more likely to be seen in people with diabetes than non-diabetes.

CONCLUSION

The study concluded that the socket dimension, pain, infection, and swelling were more on post-operative day 7 in people with diabetes when compared to non-diabetics which suggest delayed healing.

Statement of Ethics

This research complies with the guidelines for human studies and was conducted after clearance from Ethical Committee of the Institution.

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Original Article

Clinicoradiological Predictive Factors for Difficult Cholecystectomy

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Abstract

Laparoscopic cholecystectomy is benchmark for all laparoscopic surgery in terms of efficacy,safety, patient acceptance, and market penetration. Like any surgery, cholecystectomy can be difficult to perform in the diseased state, due to anatomical abnormalities or due to patient or surgeon factors. These factors can make laparoscopic surgery difficult and increase the chances of complications. Higher conversions and iatrogenic injuries are associated with difficult gallbladder operations. Conversion rates ranging from under 5% to 30% have been reported.

Key words: Cholecystectomy, Laparoscopy, Surgery

INTRODUCTION

Laparoscopic cholecystectomy is the flagship of laparoscopic surgery and the benchmark for all laparoscopic surgery in terms of efficacy, safety, patient acceptance, and market penetration. It is the foundation of laparoscopic surgery. Like any surgery, cholecystectomy can be difficult to perform in the diseased state, due to anatomical abnormalities or due to patient or surgeon factors. These factors can make laparoscopic surgery difficult and increase the chances of complications.[1-3]

Higher conversions and iatrogenic injuries are associated with difficult gallbladder operations. Conversion rates ranging from under 5% to 30% have been reported. Commonly encountered difficulties are peri-GB adhesions and mass formation, difficult entry and access to peritoneal cavity, distended and friable gall bladder with difficulty in holding, and adhesions around calot's triangle, during Gall bladder dissection from Liver bed, while extracting the Gall bladder.[4-6]

Aims and Objectives

The objectives of the study are as follows:

- To determine the clinicoradiological predictive factors for difficult laparoscopic cholecystectomy
- To study the clinical presentation of cholelithiasis.

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MATERIALS AND METHODS

This study was conducted in the Department of General Surgery, Civil hospital, Ahmedabad, 100 cases of elective cholecystectomies done from May 2019 to August 2021, that fell in inclusive criteria. Patients were followed from the time of admission, perioperative period, till the time of discharge, with pre-operative routine blood investigations and imaging (USG and CECT when required).

Study Period

The study period was from May 2019 to August 2021.

Study Type

This was a prospective study.

Study Design

The patients were initially evaluated and routine worked up in the outpatient department including ultrasound abdomen and then admitted for surgery.

Cases Were Selected on the Basis of Following Criteria Inclusion criteria

The following criteria were included in the study:

1. Patients undergoing laparoscopic cholecystectomy for gall stone disease
2. Age >18 years
3. Patient giving consent and willing to participate in the study.

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Exclusion criteria

The following criteria were excluded from the study:

1. Age <18 years
2. Patients who are unfit for general anesthesia ASA Grade 4 or more
3. Patients not willing to participate in the study.

OBSERVATIONS AND RESULTS

A prospective study was carried out from May 2019 to August 2021 in the Department of general surgery in 100 patients undergoing laparoscopic cholecystectomy. Complete observation and analysis of all the parameters of the study are as follow.

Age Incidence

The mean age in this study was 44.7 years. The age group of the patients in this study ranged from 17 years to 81 years. The highest incidence is seen in the age group of 31–45 years.

Sex Distribution

In 100 cases, 23 were males and 77 were females the ratio of male to female 1:3. The data given below show that gall stone diseases have higher incidence in females than male.

Among male patients difficulties were found in 52.17% of patients and among female patients difficulties were found in 49.35% of patients.

Among total of 23 male patients, two were converted (16.67%) whereas among 77 female patients, three were converted (7.89%).

DISCUSSION

- Age is a risk factor for difficult surgery. In the present series, the age was equally distributed with 56% patients who were below 45 years of age and 44% patients were above 45 years of age. In the present study, we found no correlation between age and difficult surgery
- Male sex has been described to be associated with difficult LC. In the present surgery, out of 23 males, 12 patients had difficult surgery and out of 77 female 38 had difficult surgery; thus sex had no correlation with difficult surgery in our study
- However, conversion to open surgery rate is higher in male patients in our study (16.67% for males compared to 7.89% in females)

  Obesity poses a great challenge to safe and timely completion of the procedure due to various factors in the form of abdominal access and dissection of fatty calot. In the present study, 4 patients (4%) were obese with BMI >27 and we found difficulty in port entry in all four patients.
- About 8% of patients in the present study had history of hospitalization due to episodes of acute cholecystitis. In all these (100%) patients, intraoperatively, some difficulty was encountered. This factor was the most significant predictor of difficult laparoscopic cholecystectomy. Acute cholecystitis

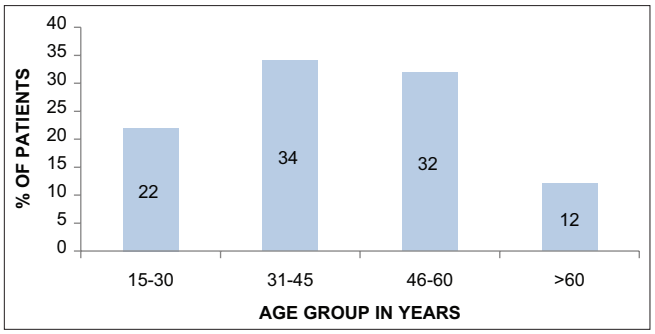

Figure 1: Age distribution of patients according to age-group in years

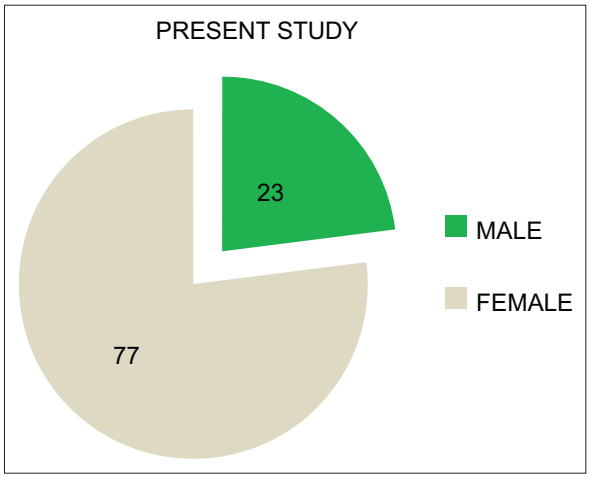

Figure 2: Sex distribution in different studies

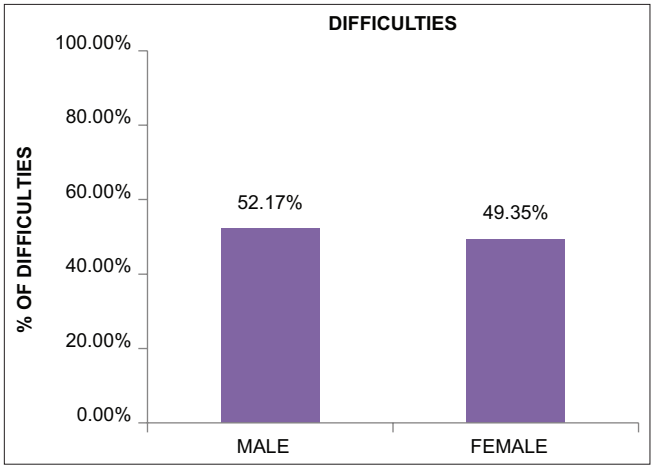

Figure 3: % of difficulties in males and females

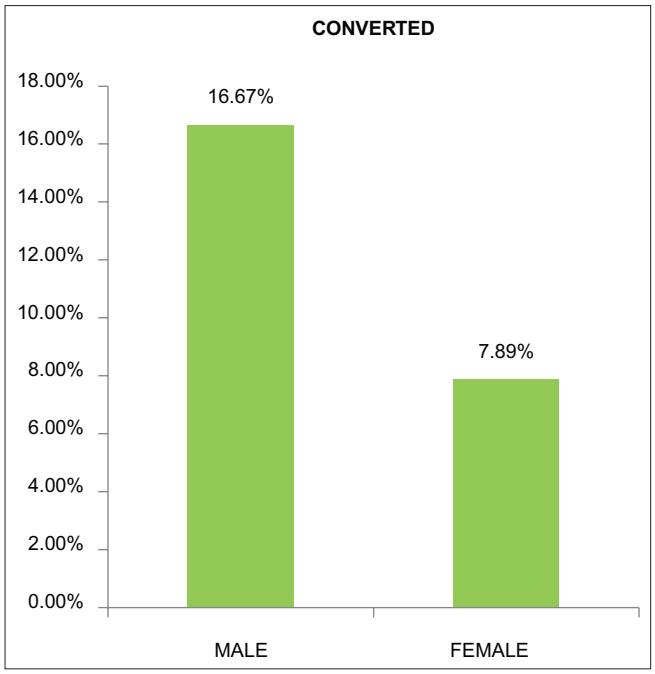

Figure 4: % of male and female patients converted to open surgery

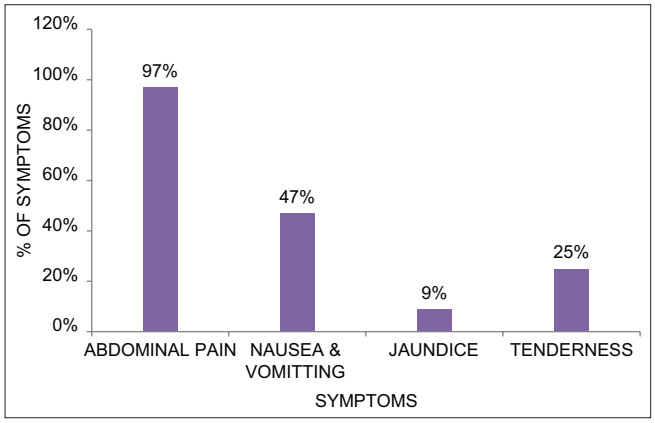

Figure 5: % of symptoms in patients of gall stone disease

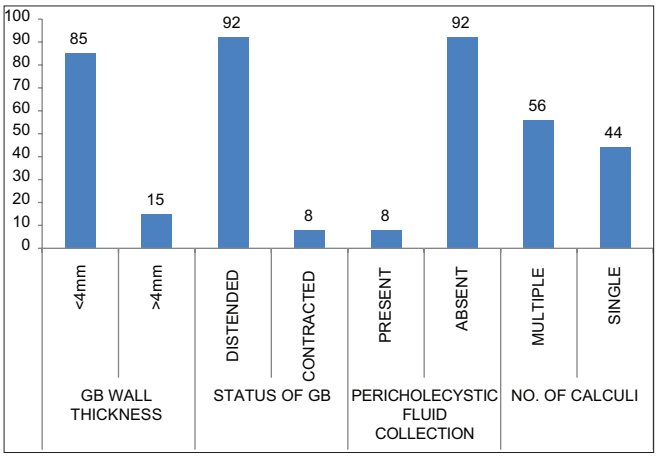

Figure 6: Radiological factor prevalence

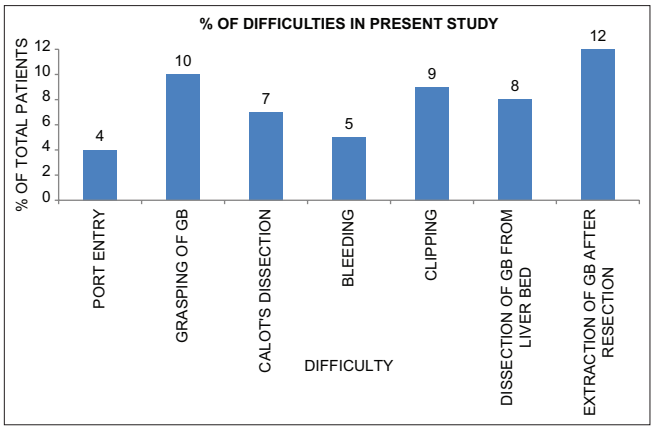

Figure 7: % of various difficulties encountered in the present study

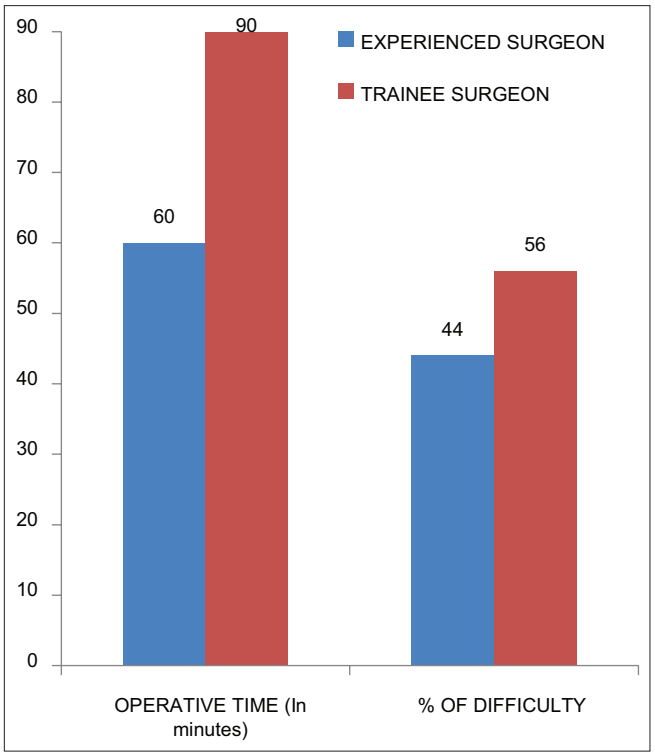

Figure 8: % of difficulty and operative time according to surgeon's experience

may lead to increased gall bladder wall thickness and cause scarring and fibrosis in and around gall bladder, making subsequent surgery difficult. This assumption is supported by the findings. In the present study, we tried to correlate predictive factor with type of intraoperative difficulty. The previous history of acute cholecystitis caused significant difficulty in calot's dissection and difficulty in dissection of gall bladder from liver bed.

- It is presumed that the previous abdominal surgery, especially upper abdominal surgery, may cause

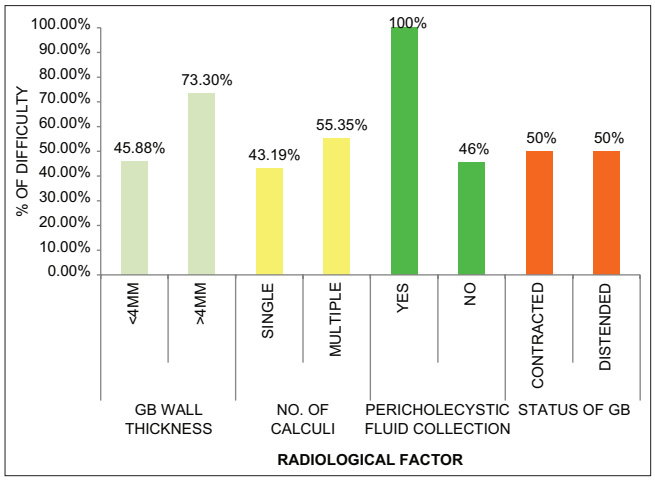

Figure 9: Radiological factors and its association with difficulties in % in the present study

difficulty due to periumbilical and perigall bladder adhesions. In the present study, also no statistically significant correlation between the previous history of abdominal surgery and intraoperative difficulty was found. In the present study, nine patients had history of abdominal surgery and difficulty was found in three out of nine patients, but it was attributed to other factors that were associated

- In the present study, 15% patients had thickened gall bladder wall (>4mm) on pre-operative USG. We encountered difficulty in 73.3% of patients with wall thickness >4 mm, while in 26.7% patients with wall thickness >4mm laparoscopic cholecystectomy was easy. In most of these patients, we encountered difficulty in grasping of gall bladder. We did not find any significant correlation between small/contracted gall bladder or distended gall bladder on pre-operative ultrasonography and difficult surgery. In 96 patients, distended gall bladder was present and in four patients, contracted gall bladder was present. We found no correlation between contracted or distended gall bladder and difficult surgery
- Large calculus at neck region is associated with distension of gall bladder and multiple stones are associated with difficulty in gall bladder extraction through small incision of LC and hence may lead to perforation of gall bladder with spillage of stones and bile. We encountered difficult delivery of gall bladder after resection in 12 out of 100 patients and out of those 12 patients in 11 patients, we found multiple calculi and distended gall bladder. We found significant association between pericholecystic fluid collection and difficult LC. In our study, eight out of 100 patients had pericholecystic fluid collection and in 100% patients, we encountered difficulty in the form of difficult dissection of gall bladder from liver bed and calot's triangle dissection and bleeding [Figures 1-9].[7-10]

CONCLUSION AND RECOMMENDATION

- In the present study of 100 patients has shown that gall stone diseases were more common in females than to males with ratio of 1:3 (23% were male and 77% were females)
- The most common age of presentation of gall stone diseases is 31–45 years
- Most of the patients (97%) presented with pain abdomen as the chief complaint
- Ultrasonography is the most economical, simplest, easiest, and an initial tool for the evaluation of gallstone diseases
- Thickened gall bladder (wall thickness >4mm) and pericholecystic fluid collection are significant predictors of difficult laparoscopic cholecystectomy
- History of acute cholecystitis and BMI of >27 were also significant predictors of difficult laparoscopic cholecystectomy
- About 5% of patients were converted to open surgery and main reason being bleeding and difficult calot's dissection
- Laparoscopic cholecysyectomy is a safe and reliable surgery. With growing experience by the surgeons in laparoscopic technique, complication and conversion rate can be brought down to a minimum
- However, if the factors that are mentioned above such as past history of cholecystitis, BMI of >27, USG finding of thickened gall bladder wall and pericholecystic fluid collection are if present; senior experienced surgeon should remain present during surgery and patient should also be explained about the risks and consent for open cholecystectomy should be taken beforehand.

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Original Article

Anatomical Study of the Ulnar Nerve Variations at High Humeral Level and their Possible Clinical and Diagnostic Implications

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Abstract

Background: Descriptive consideration and evaluation of nerve variations have a key role in the clinical and surgical practice. The anatomical variation of a nerve sets a risk of nerve palsy syndrome. Ulnar nerve (UN) arises from the medial cord of brachial plexus and is one of the common nerves to be involved in neuropathy. In the current anatomical study, the different variations in the UN have been spotted and identified along its potential surgical and clinical implications have been reviewed.

Materials and Methods: Thirty upper limb dissected specimens were examined for possible UN variations. Any communication or any aberrant formation in relation to UN was carefully examined.

Results: Out of the 30 upper limbs specimens, UN in two specimens (4%) showed the abnormal formation and communication with the neighboring nerves of the brachial plexus.

Conclusion: In understanding the severity of the UN neuropathy and its related complications, clinicians such as anesthesiologists, neurologists, radiologists, anatomist, orthopedic, and neurosurgeons should keep these variations that should be taken into consideration. The aim of the study is to layout further additional information about abnormal brachial plexus and there clinical insinuation.

Key words: Cadaver, Dissection, Neuropathy, Ulnar nerve, Upper limb, Variations

INTRODUCTION

Brachial plexus is been formed by the ventral primary rami of spinal nerves from C5 to T1. However, it may receive fibers those originate from ventral rami of C4/T2 called prefixed or post-fixed, respectively.[1]

Ulnar nerve (UN) takes its origin from the medial cord of brachial plexus, present in the axilla. It is made up of fibers of ventral rami of C8 and T1 spinal nerves. It is seen that the nerve occasionally receives additional contributions of C7 fibers from lateral root of median nerve. UN runs medial to axillary artery in the axilla and at the higher humeral level; it runs medially, close to the brachial artery. In the arm, the only important branches are a few fibers to blood vessels.[2]

Unusual communications and emergence of UN in axilla prove to be of great importance. Because, it sometimes adds complications during surgeries.[3] Division of trunks and formation of cords of the brachial plexus showed notable anomalies. Although, arrangement of terminal branches showed no such anomalies.[4] This study's objective is to identify anomalies related to UN. Potential clinical importance is also to be discussed.

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MATERIALS AND METHODS

The present study has been carried out in the Anatomy Department, AIIMS Rishikesh, India. Thirty embalmed

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human cadavers of both sexes from North Indian population were included in the study. Standard landmarks and skin incisions were carried out according to the Cunningham practical manual and the axillary region and arm of cadavers were dissected and exposed. Aberrant formations and communications of UN, with neighboring peripheral nerves were perceived at the higher humeral level.

RESULTS

Out of 30 upper limbs, only two UN variations were observed which made up 4% of incidence cases. Both the variations were noted in the upper limb of the right side. In all 30 upper limb specimens, UN was present. In two limbs, aberrant formation was seen unilaterally with lateral cord of brachial plexus contributing significantly to the UN formation [Figure 1]. The UN received contributions from the lateral cord on its lateral aspect. The contributing branch passed from the lateral to medial side, deep to the median nerve formation. UN had similar emergence as that of median nerve. However, in the arm, the nerve followed a normal course after its aberrant formation. There was no abnormal communication of UN with the neighboring nerves observed, except, in one case, where it was seen that the UN originated from the lateral cord of the brachial plexus and a communication was found between the median nerve and musculocutaneous nerve in the upper arm [Figure 2].

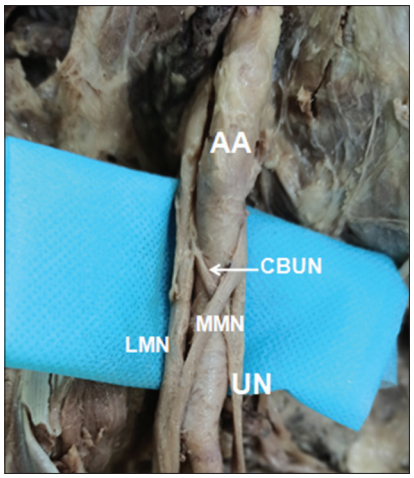

Figure 1: Atypical origin of ulnar nerve with adding contribution from both lateral & medial cords of brachial plexus

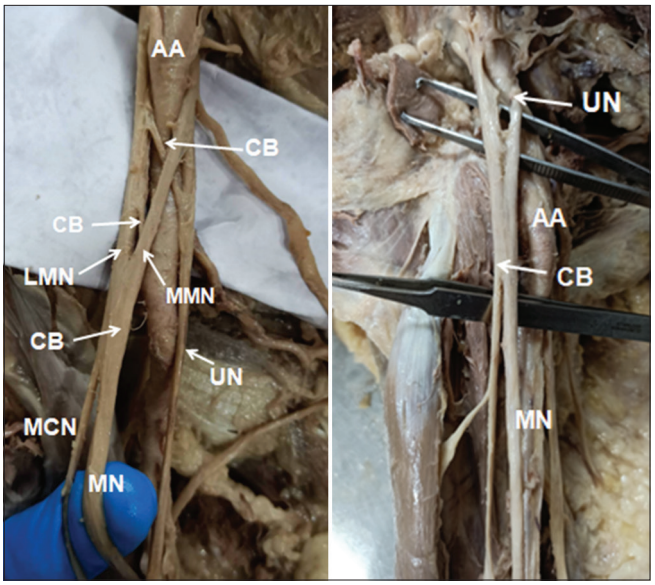

Figure 2: Atypical or unusual formation of the ulnar nerve from lateral cord & medial cord of brachial plexus & showing communication between median and musculocutaneous nerve in the upper arm

DISCUSSION

Adequate awareness of all potential anatomical variations allows for an effective brachial plexus blockade. These include atypical origin or variant communication between its branches. Variation in UN formation is uncommon. There are only a few reported cases. Sachdeva and Singla reported a rare case of origin of UN from the median nerve.[5] In their study, median nerve bifurcated into median nerve proper and UN. Another similar kind of variation was noted by Gupta *et al.* in the formation of the UN. Nevertheless, in this case, only a root from median nerve contributed.[6]

Ramachandran *et al.* observed the lateral root of median nerve giving contribution to the UN.[7]

In this study, significant contributions from lateral cord of the brachial plexus in two of the 30 upper limbs were noted. Variations in their origin, course, dispensation, and distribution makes them prone to entrapment neuropathies.[8] Therefore, aberrant formation of UN must be ruled out before a diagnostic approach.

Anomalous communications are often observed between the various branches of the brachial plexus in medial and lateral cords.[9] Hence, it is the case between radial and UN over dorsal surface of the hand, at the high humeral level, it is a rare finding.[10,11]

In a study conducted by Fazan *et al.* demonstrated a 30% pervasiveness of cases wherein the UN received a communicating branch from musculocutaneous nerve.[12] The incidence of the MCN-MN communication has been bought up reported in diverse and manifold population groups with a wide variability between 2.1% and 63.5%.[13,14] However, in the present study, we found zero communication between the UN

and its nearby peripheral nerves, but in one case of our study, we figured that the UN took its origin from lateral cord of brachial plexus along with median nerve and the musculocutaneous nerve communicating with each other in the arm.

There are limited reports of this variation.[6,15,16]

In this study, there was no communication observed between ulnar and radial nerves. The UN rarely communicates with the medial cutaneous nerve of forearm. Few studies found the MCN of forearm to communicate with the MCN of arm and radial nerve.[6,17] Clinically, this knowledge is beneficial in nerve graftings.

Kroll *et al.* study showed that neuropathies related to UN are the most common nerve injuries, which accounts for a majority with the prevalence of 33%, followed by 23% of incidence cases by brachial plexus injuries.[18]

Knowledge of the variations among the pattern of peripheral nerves is of great use for the radiologists and anesthetists while performing the diagnostic interpretations such as computed tomography scan and magnetic resonance imaging or administrating anesthetic drugs.[19]

CONCLUSION

Huge number of surgeries performed in the high humeral regions for various reasons. This requires awareness of the abnormal communications of UN. It is also useful in diagnostic approaches and management of ulnar neuropathy. It also helps clinicians in finding out the severity. Knowing these variations would be immensely helpful in preventing otherwise avoidable iatrogenic injury to the UN by interventional radiologists, orthopedicians and neurologists during radiological procedures or operations on fractured patients.

CONFLICTS OF INTERESTS

There are no conflicts of interests concerning the publication of this paper.

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Original Article

External Fixator along with Multiple K Wires for Proximal Humerus Fractures

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Abstract

Introduction: Proximal humerus fracture is mostly treated by plating which has many disadvantages. In the literature, it is described that external fixation with K wires has many advantages over other techniques of fixation. Hence, we did this study to see the outcome of this technique.

Materials and Methods: A prospective and cohort study was carried out at MIMER Medical College, Talegaon (D) on 20 patients to see outcomes of external fixation along with multiple k wires for proximal humerus fractures. Postoperatively, X-rays and constant score was assessed at 3, 6, and 9 months.

Results: There were 12 males and eight females with mean age of 52 years. Average duration of surgery was 32 min with fluoroscopy time of 13.5. Constant score was 73.5 at 9 months. Mean fracture union time was 13.2 ± 3.1 weeks. Pin tract infection occurred in four patients.

Conclusion: This technique gives good anatomical reduction with minimal soft-tissue injury and good stability with minimal complication.

Key words: External fixator, Humerus, K wires, Fractures, Complications

INTRODUCTION

Fractures of the proximal humerus occur commonly due to fall on outstretched hand, fall at home in elderly osteoporotic patients or road traffic accidents in the young patients.[1] It the generally agreed on that this fracture if displaced requires operative management. This fracture has an incidence of 4–5% of all.[1] This fracture is mostly treated by internal fixation by plating. There are many disadvantages of open reduction and internal fixation (ORIF) with plating such as more operative time and blood loss, soft-tissue stripping during surgery leading to post-operative stiffness, chance of avascular necrosis of head of humerus, need for second surgery for implant removal, and post-operative infection in few patients.[2] Furthermore, scar of surgery is large after ORIF. However, plating allows immediate post-operative early range of motion if construct is stable and chances of malunion are less if good reduction is obtained intraoperatively, particularly in young patients.[2] Nailing for proximal humerus fracture is not good alternative due to technical issues and poor results.[2] Hence, the only other operative treatment is external fixation with or without K wire but it is not so popular yet. In the literature, it is described that external fixation with K wires has many advantages such as low morbidity stable enough for early range of motion, less operative time, less blood loss, and easy implant removal in office.[3,4] However, some studies have noticed that there is risk of delayed union, non-union, or malunion in few cases as stability provided may not be enough in multi-fragmentary fractures.[3,4] There are not enough studies in the literature which support external fixation with k wires for proximal humerus fracture in non-osteoporotic patients, though it is an accepted modality of treatment for older patient with osteoporosis who are at higher risk for prolonged general anesthesia.[3,4] Hence, we decided to carry out a study to see outcomes of external fixation along with multiple k wires for proximal humerus fractures.

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MATERIALS AND METHODS

A prospective, follow-up, and cohort study was carried out at MIMER Medical College, Talegaon (D) from March 2019 to February 2020. Twenty patients who presented to casualty or orthopedic OPD and who were aged 18 years to 65 years were included in study. Consent for participation in study was taken from patients and institutional ethics committee approval was taken. Patients who had associated other fractures, pathological fractures, compound fractures, Neer's 4 part fractures (where arthroplasty preferred), and osteoporotic fractures on X-ray were excluded from study. Preoperatively, all patients underwent X-ray screening of the affected shoulder in anteroposterior and axillary view for classification of fractures according to Neer's classification.[5]

Operative Technique Followed

Patients were positioned supine on a regular OT table with affected arm left free off the drapes. Image intensifier was placed toward patients head end. Patient was given short general anesthesia usually with ketamine or propofol. A supraclavicular block was given with bupivacaine and lignocaine as per choice of anesthetist. Usually, closed reduction was achieved under C-arm guidance and 3–4 k wires (2–2.5 mm) were placed to secure fixation of fracture. 3 mm Schanz screw was placed through greater tuberosity and advanced into humeral head. Additional 2 schanz screws were placed at some distance from the first pin proximal and distal to it to secure good fixation in humeral head and neck. At least 2–4 mm schanz screws were passed into humerus shaft. External fixator was completed with connecting rod and clamps to give adequate stability to fixation. In those patients in whom closed reduction could not be obtained, open reduction was done through mini incision over fracture site following deltopectoral approach if necessary.

Patients were given I.V antibotics for 48 h and oral antibiotics on discharge. After 2–3 days, patients were allowed to do shoulder pendulum exercises (Codman's), shoulder forward flexion upto 90°, external rotation up to 40°, and internal rotation up to tolerance for initial few weeks.

Patients were called for follow-up at 6 weeks, 3 months, 6 months, and 9 months. Depending on the union further physiotherapy was given at each stage to regain good range of motion at shoulder joint. Postoperatively, X-rays and constant score was assessed at 3 months, 6 months, and 9 months. Constant score was assessed based on pain, activities of daily living, range of movement, and power.[6]

Data were entered into Microsoft Excel (windows 10) and then analysis was done using the Statistical Package for the Social Sciences.

RESULTS

There were 12 males and eight females. Mean age of patients was 52 years.

Duration of surgery was 32 min.

Average fluoroscopy time was 13.5 min.

Average Constant score was 73.5 at 9 months.

Mean fracture union time was 13.2 ± 3.1 weeks.

Pin tract infection was noted in four patients (easily managed with oral antibiotics and pin removal)

One patient developed non-union of fracture.

Closed reduction was achieved in 14 patients but six patients required mini-open surgery for fracture reduction.

There was no mortality.

There were three patients with Neer's Type 1, eight patients of Neer's Type 2, and nine were of Neer's Type 3 of classification.

DISCUSSION

Proximal humerus fractures are commonly encountered in adults and are commonly treated by operative procedure if displaced. There are various operative procedures for its treatment including plating, external fixation, percutaneous pinning, nailing, etc.[7] However, plating has many advantages such as better biomechanical stability and early mobilization but requires extensive surgical dissection with possible damage to the soft tissues, aseptic necrosis of humeral head, blood loss, infection, and hardware failure in few patients.[7] In a study by Gracitelli *et al*. which compared results of locking intramedullary nails with locking plates in proximal humerus fractures, complication rates were significant in nailing groups.[8]

Percutaneous pinning with multiple k wires in different planes can provide fracture reduction in many patients but without good biomechanical stability with loss of reduction or malunion or non-union quite often.[9] External fixation preserves fracture hematoma, avoids soft-tissue stripping, and may allow early mobilization in few patients but loss of reduction, malunion, and non-union chances is significantly high because of excessive rigidity or instability.[10] Hence, we did study by combining both methods of fixation and k wires. We believe that it may prevent complications associated with plating but allow early mobilization to

prevent stiffness. Indication for treatment with external fixator does not lie only in exposed fracture as there may be significant soft-tissue damage even in closed fracture.[10]

In our study, duration of surgery was 32 min which was comparable to other studies by Zhang *et al*. in when duration of study was 29 ± 12 min.[11] Average fluoroscopy time was 13.5 min in our study which was comparable to study by Zhang *et al*. in which it was 12 ± 3.5 min.[11]

In our study, union time was 13.2 ± 3.1 weeks which was comparable to studies in which external fixator was used by Benetos *et al*. (11 weeks), Ghosh *et al*. (10 weeks), and Zhang *et al*. (13 ± 3.6 weeks).[11-13]

In our study, we got average constant score of 73.5 at 9 months which means our results were in good category overall. This was comparable to studies by Zhang *et al*. (excellent to good results in 81% patients), Benetos *et al*. (excellent constant score), Ghosh *et al*.(excellent to satisfactory results in 72.7% patients), Bloona *et al*. (average constant score of 72.5), etc.[11-14]

In our study, average complication rate was 25% which was comparable to other studies by Bloona *et al*. (27%), Ghosh *et al*. (45%), etc. but as noted by them most of the complications were due to pin tract infection or loosening which could be easily managed with oral antibiotics and pin removal, etc.[13,14]

In our study, only one patient developed non-union and required ORIF and plating.

Our results were comparable to study by Patil *et al*. in which fixation of proximal humerus fracture was done with Philos plate in whom constant score was between 70 and 80.[15]

Hence, we got comparable results to other techniques and studies without major complications using external fixator and k wires for proximal humerus fractures.

CONCLUSION

External fixation with multiple k wires gives good anatomical reduction with minimal soft-tissue injury and good stability with minimal serious complication. Overall functional outcome of technique of fixation of proximal humerus fracture with external fixator and k wires is good.

Limitation of Study

Our sample size was small and our study had no control group and hence further randomized and controlled trial for comparison is necessary.

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Original Article

A Retrospective Study of Mucormycosis, Aspergillosis, and Candidiasis Coinfection with COVID-19 Positive Patients in Tertiary care Hospital

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Abstract

Introduction: Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), been sweeping across the globe. In the era of COVID-19 pandemic, the ever-increasing use of immunosuppressive drugs has dramatically increased the incidence of deep mycoses and substantially broadened the range of fungi causing potentially lethal disease.

Purpose: This study aimed to determine the patient demographics and risk factors, which include comorbidities, etiological agents, medications used to treat COVID-19, and the management outcome of COVID-19-associated invasive fungal infection.

Materials and Methods: The study was carried out over a period of 5 months from March 2021 to August 2021. We included 65 swab and tissue samples were collected from ENT department to microbiology laboratory of tertiary care hospital, Ahmedabad, Gujarat. Mucormycosis, *Aspergillus*, and *Candida* infections in COVID-19 patients will require early detection by a comprehensive diagnostic intervention (direct microscopic examination, culture, and histopathology) to ensure effective treatments.

Results: In our study, the most predominant isolate obtained from samples was *Aspergillus* (47.6%), followed by zygomycetes (42.8%) and *Candida* (9.5%). The predominant fungal organism identified from zygomycetes spp. was *Rhizopus*. Patients with elevated levels free iron (not bound to transferrin) are uniquely susceptible to infection in all of our zygomycetes cases, but not to other pathogenic fungi, such as *Candida* or aspergillosis.

Conclusion: Mucormycosis can occur among COVID-19 patients, especially with poor glycemic control, widespread and injudicious use of corticosteroids and broad-spectrum antibiotics, and invasive ventilation. Due to the high mortality, high index of suspicion is required to ensure timely diagnosis and appropriate treatment in high-risk populations.

Key words: SARS-CoV-2, Invasive fungus, Aspergillosis, Mucormycosis, Candidiasis

INTRODUCTION

As the human-to-human transmitted disease, coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has been an emergency global public health events.[1] For the severe COVID-19 patients who have more opportunities to be treat with broad-spectrum antibacterial drugs, parenteral nutrition and invasive examinations, or the patients accompanied with prolonged neutropenia and other immune impairment factors, the risk of infection with Mucormycosis, *Candida* species, and *Aspergillus* species may significantly increase.[1] Critically ill patients, especially the patients who were admitted to the intensive care unit and required mechanical ventilation, or had a longer duration of hospital stays, were more likely to develop fungal coinfections.[1]

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Mucormycosis, a group of filamentous fungi in the subphylum Mucoromycotina that belongs to the order Mucorales can cause life-threatening infections in humans, especially in immunocompromised hosts. The first documented report of human mucormycosis is credited

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to Paltauf, who, in 1885, reported a disseminated infection in a patient with rhinocerebral involvement caused by angioinvasive, ribbon-like hyphae that he termed Mycosis Mucorina. Subsequent descriptions of the infection in the following decades relied on tissue morphology and, as often is the case today, were infrequently confirmed by culture. Hence, the findings of coenocytic (aseptate or pauciseptate) fungal hyphae in tissue invading blood vessels were assumed to be due to *Mucor* spp. and have become synonymous with the clinical term mucormycosis or, simply, *Mucor* infection.[2] Now, increasing incidence of Mucormycosis in COVID19 cases has become a matter of concern globally.[3] Around 11,000 cases of Mucormycosis have been reported all over India. The government of India declared it a notifiable disease on May 20, 2021.[3] Mucormycosis is an acute oppotunistic infection caused by several fungi belonging to phylum Glomeromycota[4] It is a potentially lethal, angioinvasive fungal infection in COVID-19 patients with diabetes mellitus, immunosuppressive drugs therapy, corticosteroids, and primary and secondary immunodeficiency disorder.[3] Amphotericin B lipid complex, liposomal Amphotericin B, and posaconazole oral suspension are treated as the first-line antifungal monotherapy.[1]

Candidiasis, the most interesting period in the history of *Candida* infections, began in the 1940s, when the widespread use of antibiotics was introduced. Since then, the incidence of practically all forms of *Candida* infections has risen abruptly. *Candida* spp. has been the fourth most common organisms recovered from blood of hospitalized patients in the United States during recent decades.[2] In general, patients who are suspected or confirmed with invasive candidiasis should be treated with azoles (fluconazole, voriconazole, and itraconazole), and Amphotericin B and its liposomes.[1]

Aspergillosis is systemic fungal infection found among immunocompromised as well as immunocompetent individuals. This is primarily pulmonary infection with involvement of other body sites such as paranasal sinuses and tissues.[4] In most serious type of infections, invasion of infections, invasion of lung tissue, and dissemination to vital body organs may take place leading to fatal consequences among the immunocompromised patients. It is the most common opportunistic fungal disease after candidiasis.[4] In general, drugs recommended for the treatment and prophylaxis of IA include triazoles (itraconazole, voriconazole, posaconazole, and esaconazole), Amphotericin B and its liposomes and echinococcins (micafungin or carpofenjing). Most patients can choose triazole drugs to treat invasive aspergillosis.[1]

Role of Iron Uptake in Mucormycosis Pathogenesis

Fungi can acquire iron from the host using low-molecular-weight iron chelators (siderophores) or high-affinity iron permeases, such as Ferrirhizoferrin. Of the two mechanisms, it is believed that high-affinity iron permeases play the more critical role for adaptive survival of the fungus in the human host.[2] Of interest, uptake of radiolabeled iron in the presence of deferoxamine is 8- to 40-fold lower in *Candida* and *Aspergillus* compared with R. arrhizus, suggesting this mechanism is a relatively unique pathogenic trait of this fungus. This observation has been confirmed in animal models, where administration of deferoxamine worsens survival of guinea pigs infected with R. arrhizus but not *Candida*.[2] Albicans and [Table 1 and Figure 1] Pathogenesis of invasive mucormycosis.

MATERIALS AND METHODS

We included that 65 samples collected from ENT department from 18 March, 2020, to 19 August, 2021, were six swab and 59 tissue samples.

Eligibility criteria were set as follows:

1. Patients must have had a proven diagnosis of COVID-19 either before or at the time of development of mucormycosis
2. Case with a diagnosis of mucormycosis was included
3. Patients having co-infections of candidiasis and aspergillosis were also included the methods used to confirm the infection are direct microscopy (KOH and Gram stain), culture, and serology. Samples for culture should be placed on Sabouraud dextrose agar in aerobic conditions and observed daily.

Invasive Mucormycosis

1. The microscopic examination of nasal discharge or biopsy material requires a microbiologic and/or histopathologic evidence Direct examination: (a) direct microscopic examination of clinical specimens with 10% KOH shows characteristic broad, non-septate, and ribbon like hyphae with wide angle or right-angle branching at irregular intervals[4]
2. Culture: The mucormycetes can be easily grown on

Table 1: The analyzed data have been summarized

Total	65 (%)
Male	48 (73.8)
Female	17 (26.15)
diabetes mellitus	44 (67.6)
Hypertensive	21 (32.3)
Diabetes mellitus and hypertensive	15 (23)
Angioinvasion	16 (24.6)
Tissue	52 (80)
Tissue, bone invasion with angioinvasion	11 (16.9)
Use of steroids	47 (72.3)
broad-spectrum antibiotics	49 (75.3)
Use of oxygen therapy	27 (41.5)

conventional media like SDA with antibiotics at both temperatures 25 and 37. The Mucorales grow on standard fungal culture media without cycloheximide.[4] [Table 2 and Figure 2] (a) *Rhizopus*, (b) *Mucor*, and (c) *Absidia*.

Invasive Aspergillosis

The diagnosis of invasive aspergillosis requires a microbiologic and/or histopathologic evidence.

(1) Direct examination: (a) Direct microscopic examination of clinical specimens with 10% KOH for demonstration of hyaline septate hyphae of *Aspergillus* species. The septate hyphae are 3–6 μm in diameter with dichotomous branching.[4] (b) Histopathological examination of biopsy material stained with hematoxylin and eosin and periodic acid-schiff stain show acute-angled (45°) branching and hyaline septate hyphae with neutrophilic to granulomatous response. The optical brightener methods, Calcofluor or Blankophor, which may increase the sensitivity and specificity for detecting *Aspergillus*-like features;[1] (2) Culture: The material is inoculated on Sabouraud dextrose agar with antibiotics and without cycloheximide at 25°C and 37°C, respectively. The cultures should be examined daily

Table 2: Age wise distribution

Age duration	Total cases (%)
21–30	2 (3.07)
31–40	11 (16.9)
41–50	15 (23.07)
51–60	18 (27.6)
61–70	11 (16.9)
71–80	8 (12.3)

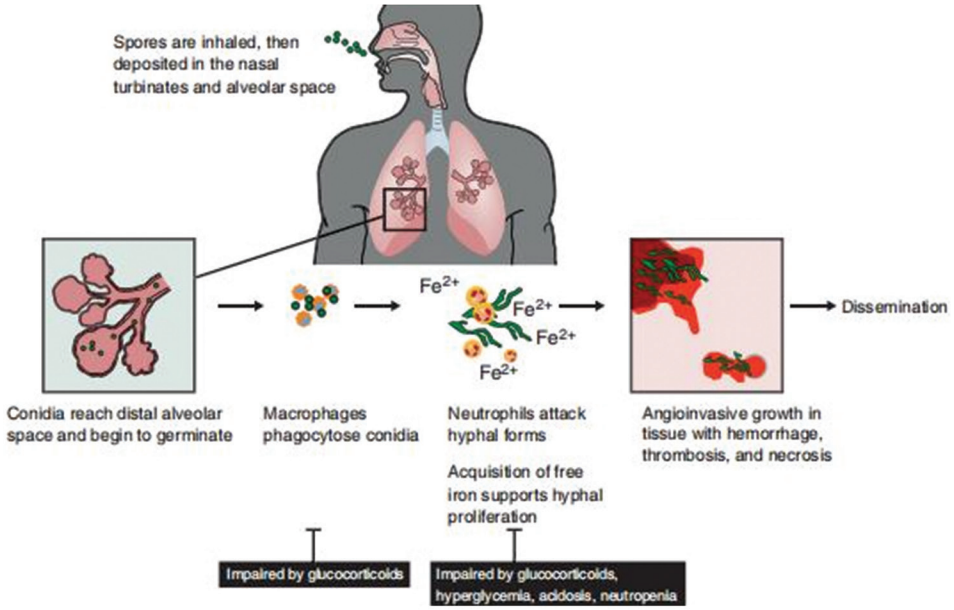

Figure 1: Pathogenesis of invasive mucormycosis[1]

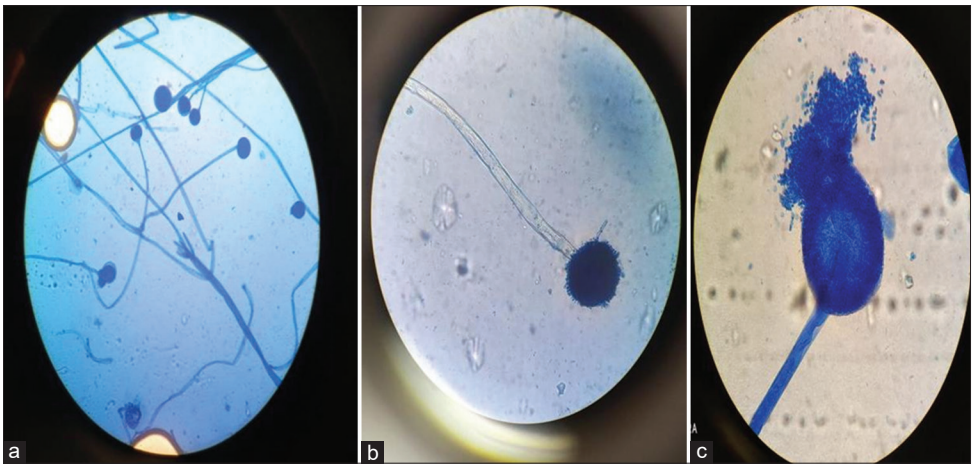

Figure 2: (a) *Rhizopus*, (b) *Mucor*, and (c) *Absidia* (Microbiology department of GMERS Medical college and hospital SOLA, Ahmedabad, Gujarat)

during 1st week and twice a week for further 4 weeks before being considered the plate/tube as sterile.[4] If positive, morphological features of *Aspergillus* can be identified under the microscope or the DNA sequencing may be used in reference laboratories to identify the species accurately, but usually culture yield is low and a negative result does not exclude the diagnosis of invasive aspergillosis.[1]

Table 3: Microbiological profile

Total	65 (%)
KOH positive	40 (61.5)
Culture positive	25 (38)

Table 4: Mixed fungal infection

Rhizopus and *Aspergillus niger*	3
Mucor and *Aspergillus niger*	1
Mucor, *Aspergillus*, *Syncephalastrum*, and *Candida*	1

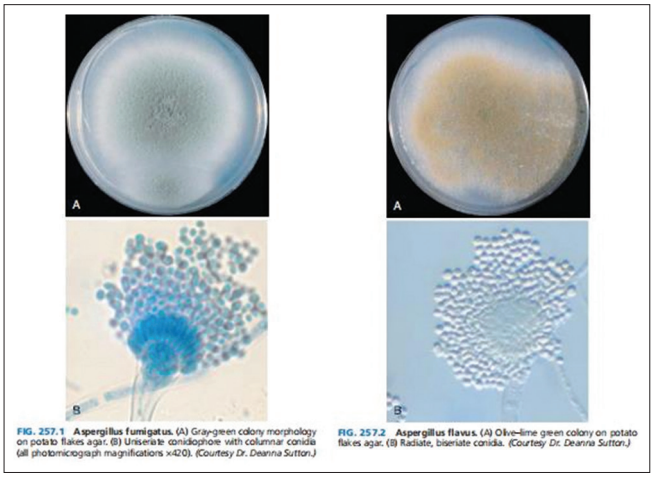

Figure 3: *Aspergillus fumigotus* and *Aspergillus flavus* (Courtesy Dr. Deanna Sutton.)

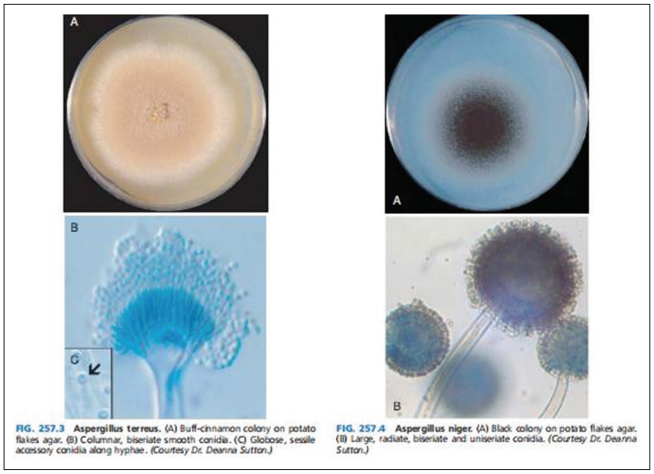

Figure 4: *Aspergillus terreus* and *Aspergillus niger* (Courtesy Dr. Deanna Sutton.)

[Table 3 and Figure 3] *Aspergillus fumigotus* and *Aspergillus flavus* (Courtesy Dr. Deanna Sutton.) [Table 4 and Figure 4] *Aspergillus terreus* and *Aspergillus niger* (Courtesy Dr. Deanna Sutton).

Invasive Candidiasis

The clinical specimens are collected depending on the site of involvement and examined in KOH wet mount or normal saline preparation.

(1) direct microscopic examination (a) Gram stain and KOH: Gram's staining is performed to see presence of yeast and pseudohyphae of *Candida* species. The yeast cells are approximately 4–8 μm with budding and pseudohyphae. The biopsy specimens are kept in tube containing KOH for an overnight period at 37°C and after mincing these are examined under the microscope for yeast cells and pseudohyphae.[4] (2) Culture: The clinical specimens can be cultured on SDA agar with antibacterial antibiotics and incubated at 25°C and 37°C. The colonized appear in

Table 5: Species wise distribution of fungus

Fungal	Total
Zygomycetes spp.(42.8%)	
Rhizopus	4
Mucor	3
Syncephalastrum	2
Aspergillus spp.(47.6%)	
Aspergillus flavus	4
Aspergillus fumigatus	4
Aspergillus terreus	1
Aspergillus niger	1
Candida spp. (9.5%)	
Non-albicans	1
Albicans	1

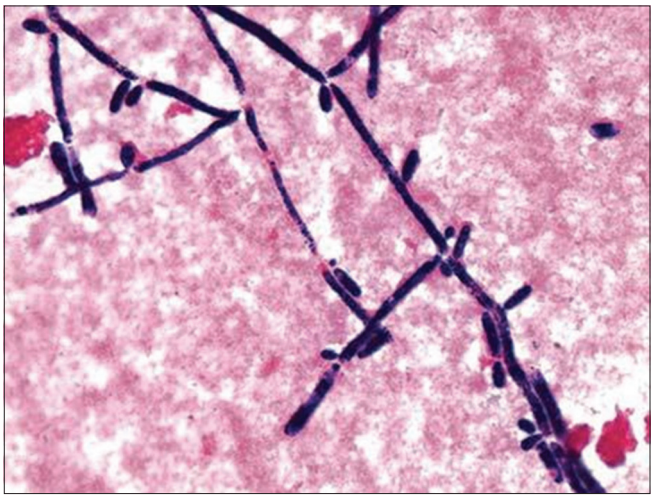

Figure 5: Morphology of *Candida* seen on Gram stain. (From Anaissie EJ, McGinnis MR, Pfaller MA. The laboratory and clinical mycology. In: Anaissie EJ, McGinnis MR, Pfaller MA, eds. Clinical Mycology. 2nd ed. New York: Churchill Livingstone; 2009:55–77.)

2–3 days as cream colored, smooth, and pasty.[4] [Table 5 and Figure 5] Morphology of *Candida* seen on Gram stain. (From Anaissie EJ, McGinnis MR, Pfaller MA. The laboratory and clinical mycology. In: Anaissie EJ, McGinnis MR, Pfaller MA, eds. Clinical Mycology. 2nd ed. New York: Churchill Livingstone; 2009:55–77).

Statistical Data Analysis

EXCEL sheet data analysis.

RESULTS

We included 65 samples collected from ENT department from March 18, 2020, to August 19, 2021, were six swab and 59 tissue samples. All of the patients had a previous history of COVID-19. The median time interval between COVID-19 diagnosis and the first evidence of mucormycosis infection diagnosis was 15 days; however, mucormycosis developed even as late as 42 days and 90 days following COVID-19 diagnosis.[5] In our study, there was a noticeable gender bias, with 73.8% of the cases being male. Mucormycosis is most commonly affects immunocompromised hosts, but are rarely reported in immunocompetent. In total, 65 patients with 44 (67.6%) were diagnosed with diabetes and 21 (32.3%) were diagnosed with hypertension. Although COVID-19 was severe/critical in most patients, mucormycosis developed even in 20% patients without any comorbidity. During management of COVID-19, 72.3% patients received corticosteroids. Imaging revealed tissue invasion 80% [Table 1]. Majority of the isolates were obtained from patients in the age group of 51–60 year [Table 2]. KOH positivity was seen in 61.5% of patients. Among the fungal culture was isolated in 38% of patients [Table 3]. In our study, 20% of patients had more than one invasive fungal involvement. Invasive fungal co-infection also seen in our study which is summerized in Table 4. The most predominant isolate obtained from samples was *Aspergillus* (47.6%) followed by zygomycetes (42.8%) and *Candida* (9.5%). The predominant fungal organism identified from zygomycetes spp. was *Rhizopus* [Table 5]. In our study, serum ferritin elevated in 69.2% of patients, CRP elevated in 78% of patients, and D-dimer elevated 58.4% of patients [Table 6].

Table 6: Inflammatory markers

Serum ferritin	45 (69.2%)
CRP	51 (78.4%)
D-Dimer	38 (58.4%)

Table 7: Comparison between two study

Supportive treatment during COVID-19	Other study Baghel *et al.* (%)	Present study (%)
Steroids	72.6	72.3
Antibiotics	73.4	75.3
Oxygen	55.6	41.5
Mortality rates	33.3	4.5

DISCUSSION

We report the clinical, microbiological, and radiological investigation of invasive fungal infections in a series of COVID-19 patients. Mucormycosis is a potentially fatal infection which arises from the invasion of blood vessels by fungal elements leading to thrombosis, ischemic infarction, and cause necrosis of affective host tissues and bone. Globally, the incidence of mucormycosis has been described to range from 0.005 to 1.7 per million population, where as in India, the reported prevalence was 0.14/1000, approximately 80 times higher than that in developed countries, making it the country with the highest burden of mucormycosis.[6] In one study, conducted by Baghel *et al.*, a rate of steroids received 72.6% of patients, while 73.4% received antibiotics, and 55.6% received oxygen during COVID-19 management, which concords with our present study with 72.3%, 75.3%, and 41.5%, respectively.[7] In the similar study of Baghel *et al.*, the prognosis of invasive fungal infection is poor, with reported mortality rates ranging from 33.3% to close to 100% in disseminated infections even if aggressive debridement and intravenous antifungal agents are utilized. However, in our study, only 4.5% mortality rates seen due to our early laboratory. Early diagnosis and early appropriate treatment is helpful for this deadly disease. Appropriate treatment with precautions and care to effectively manage infected patients which reflect with good prognosis [Table 7]. Over-the-counter sale of these antibiotics and steroids drugs should be prohibited.

CONCLUSION

Invasive fungal infections are most commonly affects the immunocompromised patients. Patients with elevated levels free iron (not bound to transferrin) are uniquely susceptible to infection by *Rhizopus* and other Zygomycetes, but not to other pathogenic fungi, such as *Candida* or aspergillosis. Therefore, fungal iron acquisition is a promising therapeutic strategy to impact clinical outcomes for this deadly and sever disease. Applicable treatment for management of Mucormycosis includes surgical debridement of infected tissue followed by first-line treatment with high-dose liposomal Amphotericin B; in addition, Voriconazole and posaconazol are also prescribed. Fungal infection can be prevented in healthy individuals by good hygiene and nutrition and can be treated with proper and timely

diagnosis. To prevent such a dangerous and costly disease, stricter policies and guidelines have to be implemented and followed to prevent injudicious antibiotic and steroid use. Over-the-counter sale of steroids drugs should be prohibited.

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Original Article

A Retrospective Study of Prevalence and Antibiotic Susceptibility of Methicillin-Resistant Staphylococcus in a Tertiary Care Hospital

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Abstract

Introduction: Nosocomial infection is a major problem globally. Methicillin-resistant Staphylococcus remains one of the most important causes of nosocomial infections worldwide. *Staphylococcus aureus* produces a wide range of infections from soft skin infections to fatal septicemia. Methicillin-resistant Staphylococcus strains or multidrug-resistant *S. aureus* emerged in the past decade as a cause of nosocomial infections responsible for rapidly progressive, fatal diseases including pneumonia, necrotizing fasciitis, endocarditis, osteomyelitis, severe sepsis, and toxinoses such as toxic shock syndrome. The prevalence of Methicillin-resistant Staphylococcus (MRS) has increased in India, of many which are resistant to antibiotic treatment.

Purpose: The purpose of this study was to know the prevalence of MRS in swab samples.

Material and Methods: This was a retrospective study conducted from January 2021 to December 2021 in a tertiary care hospital. All isolates were identified in patients and data provided by the Clinical and Laboratory Standards Institute guidelines and antibiotic susceptibility pattern considered by Kirby–Bauer disk diffusion method. Culture testing was done that AST was done by Kirby–Bauer disk diffusion method as per CLSI.

Results: In our study, we have 115 (13.12%) Staphylococcus strains isolated from 833 swab samples, Out of 115 *S. aureus* isolates, 83 (72.17%) were methicillin-resistant *S. aureus* in our labs. Although, the majority of the MRSA isolates were resulted in gynecology ward swab samples. However, in antibiotic susceptibility pattern in our study, it was found that highest resistant to ciprofloxacin, moderate level resistant to cotrimoxazole, tetracycline, erythromycin, and clindamycin and least resistant to vancomycin and linezolid.

Conclusion: High rate of MRS isolation is a threat, and so, the importance of Isolation of MRSA patients and carriers in the hospitals, regular surveillance of hospital associated infections including monitoring antibiotic sensitivity pattern and strict drug policy for antibiotics, may be helpful for reducing the incidence of these infections.

Key words: Methicillin-resistant Staphylococcus, Nosocomial infection, Pneumonia, Toxic shock syndrome, Aspartate aminotransferase

INTRODUCTION

Staphylococcus aureus is considered to be one of the most clinically important staphylococcal pathogens are affecting humans, have acquired resistance to different types of antibiotics, and are a leading cause of hospital and community acquired infections, manifesting from minor skin diseases to life-threatening infections.[1] Methicillin-resistant *S. aureus* (MRSA) was first time described in 1961, reported after 1 year of introduction of methicillin and has now emerged as one of the most important nosocomial pathogens, especially in the past two decades.[2,3] The percentage of hospitals isolating MRSA in the developed countries has increased from 2% to 30%.[4] Moreover, half of *S. aureus* in different states of India are methicillin-resistant (multidrug resistant), which are the

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major therapeutic challenge.[5] MRSA is highly prevalent in hospitals worldwide in which high rates (>50%) were reported in Asia, Malta, North and South America country. The incidence of MRSA varies according to the different region, 25–50%. MRSA is now one of serious concern for current therapeutic options for MRSA which is few expensive, limited drugs now available such as vancomycin, linezolid, teicoplanin, daptomycin, and streptogramin.[6,7] Another recently alarming sign has been that emergence of resistance to Vancomycin, although at a low level has been reported. Glycopeptides and linezolid continue to remain the mainstay of treatment for MRSA.[8] Both endemic and epidemic MRSA in infections happen globally as infected and colonized patients in hospitals mediate the dissemination of these isolates and hospital staffs assist further transmission.[9] Although many studies have been done in different regions on the prevalence and antibiogram of Staphylococcus, many of these studies have concentrated only on MRS. Our study has been carried to conduct to determine the prevalence of MRSA and antibiotic susceptibility pattern of *S. aureus*.

MATERIALS AND METHODS

This study was done in January 2021–December 2021 and based on retrospective data of swab sample sent from different wards and OPDs of hospital to microbiology laboratory. *S. aureus* were characterized by their morphology on Gram staining, growth characteristics, and coagulase production.[10]

Screening for MRSA

Methicillin resistance was isolates by disk diffusion method using 30 μg cefoxitin disk. The diameter of the zone was, according to Clinical and Laboratory Standards Institute (CLSI) guidelines. Our isolate was considered to be an MRSA strain if cefoxitin inhibition zone diameter was <22 mm. Since *S. aureus* can be a colonizer, special emphasis on the clinical significance of all the isolates. This was done by correlating with a Gram stained smear examination with the clinical history.[11]

Statistical Analysis

Tables 1 and 2 & Figures 1-6 are prepared from Excel data sheet.

RESULTS

In our study we have 115 (13.12%) Staphylococcus strains isolated from 833 swab samples, Out of 115 *S. aureus* isolates, 83 (72.17%) were methicillin resistant *S. aureus*.

In our study, the majority of the MRSA isolates were resulted in gynecology ward swab samples.

Table 1: Frequency of methicillin-resistant *Staphylococcus aureus* cases from swab sample received from different department and wards

Total swab sample	Total *Staphylococcus aureus*	Total MRSA
833	115 (13.81)	83 (72.17)

MRSA: Methicillin-resistant *Staphylococcus aureus*

Table 2: Comparative study

Prevalence and antimicrobial susceptibility of methicillin-resistant *Staphylococcus* in present study (%)	Prevalence and antimicrobial susceptibility of methicillin-resistant *Staphylococcus* in other study (%)	Publication
83 (72.17)	69 (29.1)	Pai *et al.*[12]
83 (72.17)	58 (32.22)	Bilal Ahmad and Srikanth[9]
83 (72.17)	112 (69.1)	Tiwari *et al.*[13]
83 (72.17)	196 (26.14)	Kumari *et al.*[14]

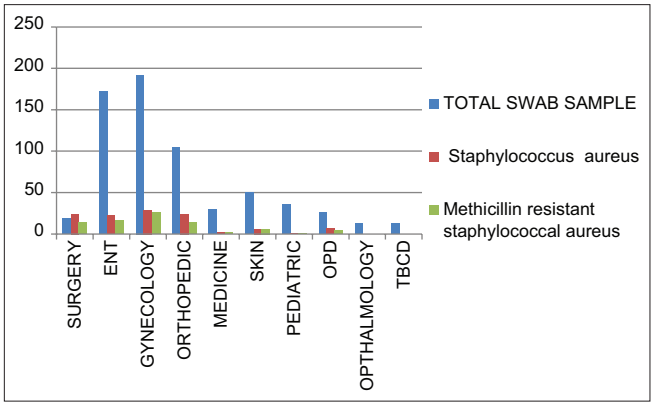

Figure 1: Frequency of methicillin-resistant *Staphylococcus aureus* cases from different department and wards of the hospital

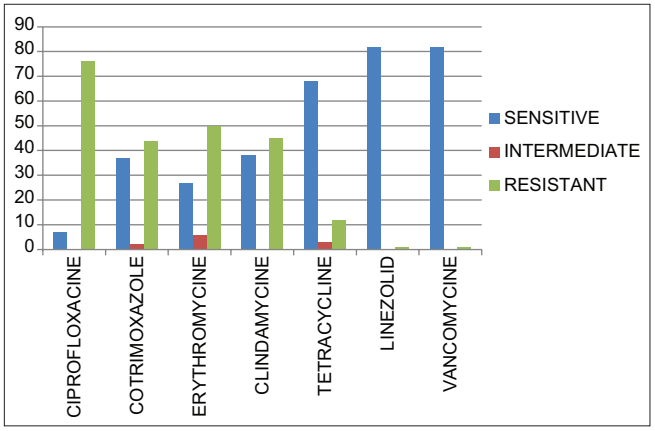

Figure 2: Sensitivity pattern of antibiotics other than beta lactum in methicillin-resistant *Staphylococcus aureus* in swab sample

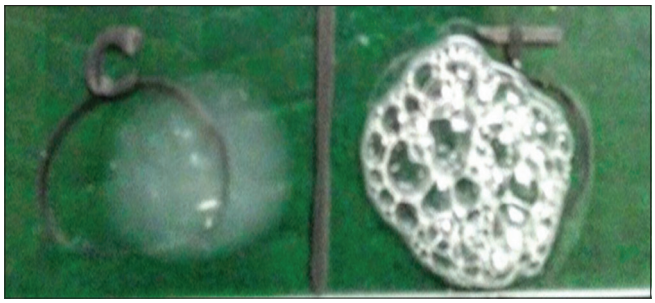

Figure 3: Catalase test

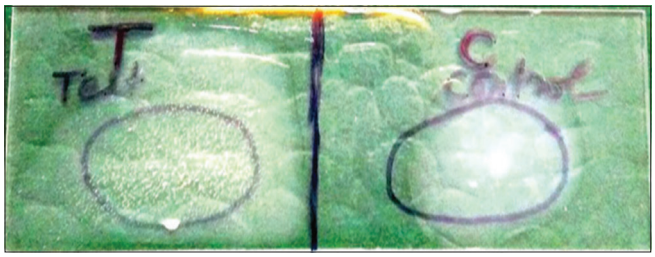

Figure 4: Slide coagulase test

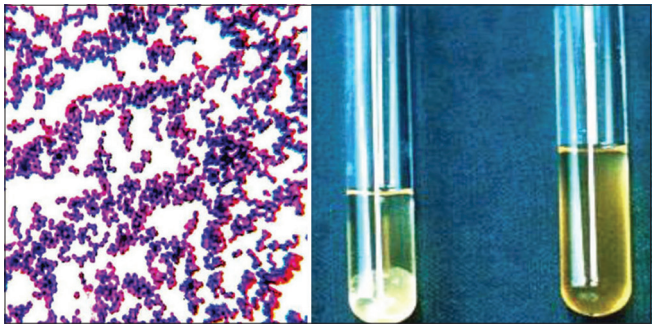

Figure 5: *Staphylococcus aurous* gram staining and tube coagulase test

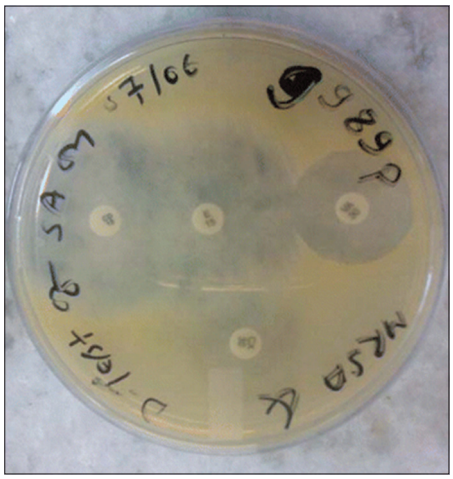

Figure 6: Antimicrobial susceptibility testing

In antibiotic susceptibility pattern in our study it was found that highest resistant to ciprofloxacine , moderate level resistant to cotrimoxazole,tetracycline,erythromycin and clindamycine and least resistant to vancomycine and linezolid.

DISCUSSION

Methicillin resistance in *S. aureus* is a major problem in hospitals worldwide and is increasingly recovered from community. There is a growing concern about MRSA with reduced susceptibility to vancomycin, which is currently the most extensively used antibiotic for its treatment; in our study, we have 115 (13.12%) Staphylococcus strains isolated from 833 swab samples. Out of 115 *S. aureus* isolates, 83 (72.17%) were MRSA in our laboratories. Although, the majority of the MRSA isolates were resulted in gynecology ward swab samples. However, in antibiotic susceptibility pattern in our study of methicillin resistant *Staphylococcus aureus*, it was found that higher level resistant to ciprofloxacine, moderate level resistant to cotrimoxazole, tetracycline, erythromycin, and clindamycine and least resistant to vancomycine and linezolid.

CONCLUSION

As per our study, >50% *S. aureus* isolates where MRSA which is a major concern the strict of isolation of MRSA patients and carriers in the hospitals, regular surveillance of hospital associated infections, including monitoring antibiotic sensitivity pattern and strict drug policy for antibiotics may be helpful for reducing the incidence of these infections. In our study, vancomycin was the only antibiotic found to give uniform sensitivity (100%). When antimicrobials including, vancomycin is considered for treatment, this inevitably requires the need for *in vitro* susceptibility testing of every isolate of MRSA in the clinical laboratories.

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Original Article

A Retrospective Study on Isolation and Identification of Various Species of Dermatophytes in Samples Received at Department of Microbiology at a Tertiary Care Hospital

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Abstract

Introduction: Dermatophytes is the most common superficial mycoses affecting skin, hair, and nail; group of fungi that are capable of infecting keratinized tissues. Over the past decades, the prevalence of these infections has been rising. These infections are more common in the tropical countries due to humidity, sweating, and elevated temperature.

Purpose: The purpose of the study was to know the prevalence of dermatophytosis in different samples like skin, hair, and nail and to identify species of dermatophytes.

Materials and Methods: In this study, total 414 skin scrapings, nail clippings, and hair root samples by plucking were collected and processed by direct microscopy in potassium hydroxide and cultured on sabouraud dextrose agar (SDA) with antibiotics and cycloheximide. Identification of the species was done by colony morphology, lactophenol cotton blue mount, hair perforation test, and urease test.

Results: Out of 414 sample collection, 95 were either positive in direct microscopy or show growth in culture or both. Out of 95 samples, 45 were dermatophytes. Among this 55.6% of affected population were male and 44.4% were females. Out of 45 dermatophytes, 29 were positive in both direct microscopy and culture and 16 were only culture positive. Most common isolated dermatophytes is *Trichophyton* (89.5%) followed by microsporum (7.9%) and *Epidermophyton* (2.6%). Out of *Trichophyton* species, most common isolated species are *Trichophyton rubrum* (43.9%) followed by *T. mentagrophyte* (39.0%) and *T. violeceum* (12.2%).

Conclusion: *T. rubrum* is the commonly isolated dermatophytes in this area. Male has higher prevalence rate than females with 1.3:1 ratio. Tinea corporis is the most common type of infection. Identification of causative dermatophyte species would help with treatment approach and for the implementation of control measures.

Key words: Dermatophytes, Superficial mycoses, Tinea corporis, *Trichophyton rubrum*, *Trichophyton* species

INTRODUCTION

Dermatophytosis is the most common type of superficial cutaneous fungal infection seen in men and animals.[1] Over the past decades, the prevalence of these infections has been raised, accordingly, they have affected 20–25% of the world's population.[2] Dermatophytes have been recorded all over the world with variation in distribution, incidence, epidemiology, and target hosts from one location to another.[3] Geographic location, climate (temperature, humidity, wind, etc.), overcrowding, healthcare, immigration, environmental hygiene, culture, and socioeconomic condition have been incriminated as major factors for these variations.[3] The prevalence of the fungal infection of the skin is on a growing trend in

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India due to its climate conditions, such as its temperature and humidity setting the ground for the spread of this infection.[2]

Dermatophytes are aerobic fungi that produce proteases that digest keratin and allow colonization, invasion, and infection of the stratum corneum of the skin, hair shaft, and nail.[4] Infection is generally cutaneous and restricted to the nonliving cornified layers because fungi are not able to penetrate the deeper tissue or organ of a healthy immunocompetent host.[5] Dermatophytes are hyaline and septate molds with more than a hundred species. There are divided into three main anamorphic genera depending on their morphological characteristics, (1) *Trichophyton*-infect skin, hair, and nail, (2) Microsporum-infect skin and hair, and (3) *Epidermophyton*-infect skin and nail.[1,6]

The dermatophytes are referred to as zoophilic, anthropophilic, or geophilic depending on whether their primary source is an animal, human, or soil, respectively.[7] Of all the zoophilic dermatophytes, *Microsporum canis* is the most prevalent throughout the world, in both temperate regions and some tropical regions.[1] The distinction between geophilic and zoophilic species may not always be obvious and even may be controversial at times.[1] The infections caused by anthropophilic species tend to be chronic and inflammation is minimal. The infections caused by anthropophilic species tend to be chronic and inflammation is minimal and infections caused by geophilic and zoophilic species tend to be self-healing and resultant inflammation is more severe.[1] Dermatophytes grow in a centrifugal pattern in the stratum corneum, leading to the formation of well-demarcated annular-shaped pruritic scaly skin lesions with central clearing and raised edges.[8] Depending on the site of involvement, various clinical types of dermatophytes or tinea infections are produced.[1] (1) Tinea capitis – infection of the scalp, (2) Tinea corporis – infection of non-hairy skin of the body (trunk and limbs), (3) Tinea pedis – infection of web space between the toes, (4) Tinea cruris – infection of the groin area, (5) Tinea barbae – infection of the beard and mustache area, (6) Tinea faciei – infection of the non-bearded area of the face, (7) Tinea unguium – nail plate infection, and (8) Tinea Mannum – infection of the palmar aspect of hands.

Objectives

The objetives of the study are as follows:

1. To determine the prevalence of dermatophytosis in different samples like skin, hair, and nail
2. To identify the species of dermatophytes isolated in culture.

MATERIALS AND METHODS

This study was conducted in the department of microbiology at the tertiary care center. In this study, a total of 414 samples (Skin scraping, nail, and hair root samples) were collected from patients attending various outpatient department with the suspicion of fungal infection.

Direct Microscopic Examination (Potassium Hydroxide [KOH] Mount)

Scraping

In all cases, cleaning the local site with 70% alcohol, which is allowed to evaporate before taking the specimen, may be helpful and should always be done if greasy ointments or powders have already been applied as medication.[1] The material should be collected by scraping outward from the edges of active lesions with a scalpel blade held at an angle of 90% of the skin surface.[1] The specimens from the scalp are obtained by scraping with a blunt scalpel so that they include hair stubs, contents of plugged follicles, and scales.[1] In the case of onychomycosis, after disinfecting with 70% alcohol, the nail is clipped from the free edge, taken as far back as possible, and should include its full thickness.[1]

KOH Mount

The samples were subjected to direct microscopic examination for the presence of fungal elements using KOH (10% for skin scrapings or hair and 20–40% for nail clippings[1]). These specimens were mounted under cover slip in KOH on slide.[1] This clears material within 5–20 min, depending on its thickness.[1]

Culture

All specimens were cultured irrespective of positive or negative direct microscopic examination SDA containing chloramphenicol with cycloheximide to prevent bacterial contamination then inoculated plates were incubated for 10 days to 3 weeks at 25°C and 37°C. Culture plates were examined on an alternate day for any fungal growth. Cultures of dermatophytes were identified on the basis of colony characteristics and pigmentation.[1]

Lactophenol cotton blue (LCB) Stain

Take a transparent tape and touch its sticky surface to the fungal colony grown in the culture plate and place it on the slide where a drop of LCB is already added and examine it under a microscope.[1]

Urease Test

Christensen's urea agar was used for the differentiation of *Trichophyton mentagrophytes* and *Trichophyton rubrum*.[1] The identification of dermatophytes was accomplished using fungal morphology, hyphal organization (septate/aseptate),

and the presence and arrangement of microconidia and macroconidia.

RESULTS

Out of 95 samples, 45 were dermatophytes. Among this 55.6% of affected population were male and 44.4% were females. Male to female ratio was 1.3:1. The most common age group affected with dermatophytosis was 21–30 years with 11 cases [Tables 1 and 2].

Out of 95 sample collected, 73 were skin scraping, 13 were nail scraping and clippings, and nine were hair stubs [Table 3].

Out of 45 dermatophytes, 29 were positive in both direct microscopy and culture and 16 were only culture positive [Table 4].

Most common isolated dermatophytes is *Trichophyton* (89.5%) followed by microsporum (7.9%) and *Epidermophyton* (2.6%). Out of *Trichophyton* species, the most common isolated species are *T. rubrum* (43.9%) followed by *T. mentagrophytes* (39.0%), *T. violeceum* (12.2%) [Table 5].

Most common infection was tinea corporis 37.8% followed by tinea cruris 24.5% [Table 6].

Table 1: Frequency of dermatophytes in relation to sex

Sex	Total	Dermatophytes (%)
Male	55	25 (55.6)
Female	40	20 (44.4)
Total	95	45 (47.4)

Table 2: Age-wise distribution of clinically diagnosed dermatophytosis

Age (years)	Number of cases
<10	6
11–20	6
21–30	11
31–40	6
41–-50	7
>50	9
Total	45

Table 3: Distribution of clinical samples and results of microbiological investigation

Sample	Total number	Dermatophytes (%)
Skin scraping	73	38 (84.4)
Nail	13	2 (4.5)
Hair follicle	9	5 (11.1)
Total	95	45 (47.4)

DISCUSSION

In the present study of 45 cases of dermatophytic infections, the following clinical forms were observed: Tinea corporis, tinea cruris, tinea pedis, tinea mannum, tinea unguium, tinea barbae, and tinea faciei.

In this study, dermatophytosis is more commonly seen with age group of 21–30 years which is same as other studies done by Doddamani *et al.* While in other study by Bindu and Pavithran, the most common age group was 11–20 years.[9] The highest incidence in age group of 21–30 years may be due to increased physical activity and increased degree of exposure to infection.

In the present study, males were commonly affected than females. Male to female ratio was 1.3:1, which is compatible with other studies done by Singh *et al.*, Bindu and Pavithran, and Doddamani *et al.* The higher incidence in males could be due to greater physical activity and increased sweating.[5]

Table 4: Potassium hydroxide and culture analysis of clinical specimen of dermatophytes

Samples	Number of culture positive cases	Number of cases positive by KOH	Number of cases negative by KOH
Skin	73	25	48
Nail	13	1	12
Hair	9	3	6
Total (%)	45	29 (64.44)	16 (35.55)

KOH: Potassium hydroxide

Table 5: Prevalence pattern of dermatophytes

Species	Positive (%)
Trichophyton	41 (89.5)
T. rubrum	18 (43.9)
T. mentagrophytes	16 (39.0)
T. violaceum	5 (12.2)
T. scholenii	2 (4.9)
Microsporum	3 (7.9)
Epidermophyton	1 (2.6)
Total	45

T. rubrum: Trichophyton rubrum, T. mentagrophytes: Trichophyton mentagrophytes, T. violaceum: Trichophyton violaceum, T. scholenii: Trichophyton scholenii

Table 6: Clinical types of dermatophytosis

Clinical types	Number of cases (*n*=45), *n* (%)
Tinea corporis	17 (37.8)
Tinea cruris	11 (24.5)
Tinea capitis	5 (11.0)
Tinea facei	4 (8.9)
Tinea barbae	1 (2.2)
Tinea mannum	3 (6.7)
Tinea pedis	2 (4.5)
Tinea unguium	2 (4.5)

Table 7: Dermatophytes isolated in various studies

Studies	*T. rubrum* (%)	*T. mentagrophytes* (%)	*Microsporum* (%)	*Epidermophyton* (%)
Upadhyay *et al*.[2]	73.27	17.24	0	7.75
Surendran *et al*.[5]	67.5	20	5	5
Doddamani *et al*.[10]	46.87	36.46	6.24	8.33
Singh and Beena[11]	73.27	17.24	0	7.75
Patel *et al*.[12]	60.71	23.80	1.19	1.19
Hanumanthappa *et al*.[13]	58.9	24.6	8.2	0.7
Kalyanappa and Surekha[14]	52.38	33.33	4.76	0
Belurkar *et al*.[15]	53.52	0	8.92	0
Present study	43.9	39	7.9	2.6

T. rubrum: Trichophyton rubrum, T. mentagrophytes: Trichophyton mentagrophytes

Among clinical types, tinea corporis was highest (17 cases) followed by 11 cases of tinea cruris. This is in accordance with the Bindu and Pavithran.

In the present study, it was possible to demonstrate fungi on direct microscopy with KOH in 29 cases but overall positivity by culture was 45 which is same as other studies done by Belurkar *et al.* and Huda *et al*.[16]

Species identification findings of the present study are compared with other studies as shown in [Table 7].

CONCLUSION

The prevalence of dermatophytes infections depends on environmental factors, personal hygiene, and individual susceptibility. In this study, dermatophytes had an isolation rate of 10.9%, which is quite lower than the rates reported in other studies. This can be due to the fact that the majority of the investigated patients who were from urban regions and hygienic condition predispose the inhabitants to low risk of cutaneous fungal infections.

Among all cases, Tinea corporis was the predominent type of dermatophytosis with 37.8% followed by tinea cruris. KOH mount were positive in 64.4% of cases and all cases were culture positive. In 35.6% of KOH negative cases culture were positive. Hence, it is advisable always go for fungal culture irrespective of KOH results. *T. rubrum* is the commonly isolated dermatophytes in this area. Male have higher prevalence rate than females with 1.3:1 ratio.

Identification of causative dermatophytes species would help with treatment approach and for implementation of control measures.

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Original Article

Comparative Study between Buprenorphine and Butorphanol when Administered Epidurally in Abdominal and Lower Limb Surgeries

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Abstract

Introduction: It was a randomized controlled study to compare the effects of Buprenorphine and Butorphanol in the lower limb surgeries when administered epidural route in terms of analgesia and side effects.

Materials and Methods: The study was conducted on 60 randomly selected patients based on inclusion and exclusion criteria in AC Subba Reddy Govt Medical College, Nellore during the period of 1 year, that is, June 2021 to June 2022.

Results: In our study, we compared Buprenorphine and Butorphanol's safety and efficacy when given epidurally for postoperative pain relief on 60 patients undergoing elective lower limb and abdominal surgeries. We found that both drugs as safe and effective postoperative analgesics. There is no significant difference between the drugs with respect to the onset of analgesia. Epidural buprenorphine significantly reduced pain with a longer duration of action and was a better alternative to butorphanol for post-operative pain relief. It was found to be safe due to less incidence of side effects like sedation and vomiting compared to butorphanol. We did not find any case of hypotension or respiratory depression in both groups. No other complications were seen.

Conclusion: We conclude that epidural buprenorphine was a better alternative to epidural butorphanol for providing post-operative pain relief.

Key words: Buprenorphine, Butorphanol, Epidural

INTRODUCTION

Pain is always a subjective, personal, and unpleasant experience. Pain is the predominant complaint of most individuals following surgical intervention. Patients are often unable to breath adequately and cough effectively due to pain. They may not able to mobilize enough to do their daily activities. Due to this, they may experience feelings of helplessness, fear, anxiety, and depression. Effective pain relief is necessary for early mobilization and postoperative discharge. Being anesthesiologist, we should have a concern to help patients to relieve their pain adequately, which can lead to better outcomes for both the patient and the health care system.

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Various techniques have been developed to relieve the post-operative pain. Epidural opioids were used in large number of studies for the relief of post-operative pain. They provide better analgesia for early mobilization which reduces the risk of thromboembolic events and respiratory complications.

Aims and Objectives

The objecyives are as follows:

1. To compare the efficacy of epidurally administered Buprenoirphine and Butorphanol tartrate in providing post-operative pain relief in abdominal and lower limb surgeries.
2. To compare the duration, quality of analgesia, cardiorespiratory effects, and side effects between Buprenorphine and Butorphanol tartrate.

Inclusion Criteria

The following criteria were included in the study:

- Patients of either sex
- Age between 18 and 65 years
- Patients with ASA Grades 1 and 2

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- Patients undergoing elective surgeries of abdomen and lower limb.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients who did not provide consent
- Patients with ASA Grades 3 and 4
- Patients with clotting disorders
- Patients with known allergies to opioids
- Patients with sepsis - local and systemic
- Patients with spinal deformities like kyphoscoliosis
- Patients who underwent previous spinal surgeries or injuries in lumbar region
- Patients who were physically and psychologically dependent on opioids.

MATERIALS AND METHODS

The current study was conducted at Siddhartha Medical College on 60 patients undergoing lower limb and abdominal surgeries after getting permission from the institutional ethics committee.

Sample Size, Study Type, Duration

The study was conducted on 60 randomly selected patients based on inclusion and exclusion criteria.

Sample size: Approximately 12% of patients underwent undergo lower limb or lower abdominal surgeries who received buprenorphine or butorphanol at our institution for post-operative analgesia, epidurally. Hence, the prevalence as estimated by us is 10% Around 500 lower limb or lower abdominal surgeries happened under at SMC during the study duration.

$$N = z^2pq/e^2$$

N - Population size
Z - confidence level of 95%-standard value of 1.96
p - Expected prevalence or proportion: p=0.1 (since prevalence is 10%)
e - Allowable error-7%
Basing on this formula, the sample size came as 62.

Two patients did not provide consent to participate in this study, so we included 60 patients in the current study. The current study is a prospective, randomized, double blinded, comparative study, and conducted for 18 months from December 2019 to June 2021.

Methodology

Preoperative preparation

The patient's age, body weight, and ASA grades were recorded. Informed consent was taken from all the participants. ECG, pulse oximetry, and blood pressure (BP) monitoring were done continuously. All the patients were divided in to two groups: Group BT, those who received Butorphanol 1 ml in 1 mg, and Group BP, those who received Buprenorphine 1 ml in 0.3 mg. These injections were given over 10–15 s. Drugs were diluted to 10 ml with NS and injected through an epidural catheter. Patients are observed in the recovery room. Observations are recorded by the investigator visual analog pain scales that are assessed every hour till the 6th h, then the 2nd h till the 12th h subsequently every 6th h till 48 h after surgery.

Preoperative investigations

- Hb%
- Blood grouping and typing
- Bleeding time, clotting time
- RBS, S. Creatinine
- 12 lead ECG and CXR PA view

Procedure

An intravenous line was established using an a18 G IV cannula and preloading with 500ml of Ringer's Lactate solution was done with the patient in the left lateral decubitus position. Under aseptic precaution, L3-L4 intervertebral space was identified with the highest point of the iliac crest as the anatomical landmark. After local infiltration, an epidural puncture was made by the loss of resistance technique to air at L3/L4 space with a Tuohy needle. An epidural catheter passed through the needle. Needle removed and catheter secured 3cc. of 2% xylocaine with adrenaline given as test dose.

Statistical analysis

Categorical values were given percentages. Differences between buprenorphine's duration and butorphanol's duration, onset, and effects on BP, respiratory rate (RR), and pulse rate (PR), visual analog score (VAS) were compared with the student's unpaired T-test. $P < 0.05$ was considered statistically significant.

Ethical considerations

The permission from the institutional ethical committee attached to Siddhartha Medical College was taken before conducting the study. Every patient explained the whole process and advantages of the study. After he/she accepts, an informed consent form is given in the local language or patient understandable language, and the person was asked to sign it or put a thumb impression. The procedure for assessing study parameters has minimal interference. The patients were told that their information is kept confidential. Patients were informed that their participation is purely voluntary.

RESULTS

Statistical analysis was done using statistical software named Statistical Package for the Social Sciences version 21.0.0

(SPSS Inc., Chicago, Illinois, USA). All categorical variables (qualitative data) are expressed in percentages. 60 patients were evaluated in this study. They belonged to two groups. 30 members belonged to Buprenorphine group and 30 patients belonged to Butorphanol group.

Demographic Variables

Age of patients

The age of patients involved in this study ranged from 30 to 60 years. Most common age of patients found to be 30–40 years. The average age of all patients was 39.63 years [Table 1].

Gender

More patients are females in this study.

Onset of analgesia

There is no significant difference in the onset of analgesia produced by Buprenorphine or Butorphanol. Student *t*-test was applied to compare between these two groups $P < 0.05$ so there is significant difference [Table 3].

Duration of analgesia

The mean duration of analgesia for all 60 patients was 7.61 h. The mean duration in BT group was 6.03 ± 0.99 h or around 360 min. In BP group was 9.2 ± 0.76 h or around 560 min.

Rescue drug

It was given for 12 patients. It was not required for 48 patients.

About 33% patients required rescue drug in BT group indicating that butorphanol may be less efficacious compared to buprenorphine, as only 10% required rescue drug in buprenorphine group. The rescue drug used in the current study was IV Diclofenac.

Side effects

61.6% patients had no side effects. Sedation and vomiting were seen in remaining patients [Table 5].

More patients suffered from sedation in BT group and there is significant difference with respect to sedation between both groups, as evident from the *P* value. More patients suffered from vomiting's in BP group and there is significant difference with respect to vomiting between both groups, as evident from the *P* value [Table 7].

PR

PR was monitored at various intervals. It ranged from 70 to 90 bpm for most of the patients. No patient had extreme changes in PR.

There is no significant difference between both groups with respect to PR at various intervals between both groups [Table 8].

Table 1: Age of patients

Age	Number of patients (%)
30–40	41 (68.335)
41–50	14 (23.3)
51–60	5 (8.3)

Table 2: Gender of patients

Gender	Number of patients (%)
Male	12 (20)
Female	48 (80)

Table 3: Onset of analgesia in both groups

Onset of analgesia in minutes	Mean and SD	P value
BT group	11.63±1.72	0.36
BP group	12.06±1.94	

Difference	0.430
Standard error	0.473
95% CI	-0.5175 to 1.3775
t-statistic	0.908
DF	58
Significance level	P = 0.3674

SD: Standard deviation, CI: Confidence interval

Table 4: Duration of analgesia in both groups

Duration of analgesia in hours	Mean and SD	P value
BT group	6.03±0.99	< 0.0001
BP group	9.2±0.76	

ifference	3.170
Standard error	0.228
95% CI	2.7139 to 3.6261
t-statistic	13.912
DF	58
Significance level	P < 0.0001

SD: Standard deviation, CI: Confidence interval

Table 5: Rescue drug in both groups

Rescue drug	BT group	BP group
Given	9	3
Not given	21	27
Total *n*=60		

Table 6: Side effects among patients

Side effects	Number of patients (%)
Nil	46 (76.6)
Sedation	8 (13.3)
Vomiting	6 (10)

Table 7: Side effects in both groups-comparison

Side effects	BT Group	BP Group	*P*
Nil	22	24	
Sedation	7	1	0.028
Vomiting	1	5	0.017

Table 8: Pulse rate in both groups

Pulse rate	Mean±SD		*P*
	BT group	BP group	
Baseline	79.80± 6.88	79.5±6.75	0.89
30 min	78.37± 6.9	78.13±6.7	0.9
1 h	77.23± 5.87	76.13±6.55	0.81
2 h	78.4± 7.1	76.13±7.2	0.64
6 h	76.5± 6.23	77.12±6.8	0.21
12 h	77.1± 6.12	77.2±6.42	0.28

SD: Standard deviation

RR

RR was monitored at various intervals. It ranged from 11 to 18/min in most of the patients. No patient had extreme changes in RR in this study.

There is no significant difference between both groups with respect to RR at various intervals between both groups [Table 9].

VAS

It was monitored at various intervals. It ranged from 0 to 4 in most of the patients. No patient had extreme pain in this study. There is no significant difference in VAS score at 6 and 12 h between both groups. It was more in BT group less in BP group [Table 10].

Systolic blood pressure (SBP)

SBP was monitored at various intervals throughout the study. SBP ranged from 110 to 140 mm of hg for most of the patients.

There is no significant difference between both groups with respect to SBP at various intervals between both groups [Table 11].

Diastolic blood pressure (DBP)

DBP was monitored at various intervals throughout the study. DBP ranged from 70 to 90 mm of hg for most of the patients.

Table 9: RR in both groups

RR	Mean±SD		*P*
	Mean and SD in BT group	Mean and SD in BP group	
Baseline	14.2±4.1	14.93±2.96	0.67
30 min	15.8±3.54	15.43±3.29	0.222
1 h	15.57±4.39	16.07±5.19	0.189
2 h	16.03±2.65	16.33±2.23	0.23
6 h	14.5±3.2	15.1±3.92	0.12
12 h	15.1±4.0	15.1±2.9	0.98

RR: Respiratory rate, SD: Standard deviation

Table 10: VAS

VAS	Mean±SD		*P*
	BT group	BP group	
Baseline	4.27±0.96	4.23±1	0.82
6 h	2.9±0.9	1.8±0.57	0.056
12 h	1.3±2.0	1.1±0.53	0.08

VAS: Visual analogue score, SD: Standard deviation

Table 11: SBP

SBP	Mean±SD		*P*
	BT group	BP group	
Baseline	131.100±5.7974	128.500±4.1084	0.129
30 min	122.000±4.3072	120.367±4.5900	0.025
1 h	119.033±9.2680	118.200±12.7723	0.052
2 h	105.433±9.5545	108.400±8.2821	0.391
6 h	98.900±11.5739	98.333±10.3934	0.609
12 h	102.633±8.8454	99.200±11.0933	0.343

SBP: Systolic blood pressure, SD: Standard deviation

There is no significant difference between both groups with respect to DBP at various intervals between both groups [Tables 2, 4, 6 and 12].

DISCUSSION

In the present study, 60 patients undergoing lower limb and abdominal surgeries were evaluated. 30 members belonged to Buprenorphine group and 30 patients belonged to Butorphanol group. The most common age of patients found to be 30–40 years. The average age of all patients was 39.63 years. About 80% are females in the current study. There is no significant difference in the onset of analgesia produced by Buprenorphine or Butorphanol.

The mean duration of analgesia for all 60 patients was 7.61 h. The mean duration of analgesia was more in Buprenorphine group, indicating that Buprenorphine acts for long duration compared to Butorphanol. Rescue medication was given for 12 patients. It was not required for 48 patients. More patients in Butorphanol group required

Table 12: DBP in both groups

DBP	Mean±SD		*P*
	BT group	BP group	
Baseline	84.633±4.4989	84.822±3.7700	0.653
30 min	75.769±5.9055	74.800±7.2369	0.833
1 h	73.333±4.4515	70.967±9.4010	0.246
2 h	75.267±5.0986	72.733±7.5060	0.301
6 h	74.667±5.1013	75.267±5.0986	0.859
12 h	76.333±4.7874	76.000±7.7992	0.762

DBP: Diastolic blood pressure, SD: Standard deviation

rescue medication, indicating that Buprenorphine's efficacy is more than Butorphanol.

More patients suffered from sedation in BT group and there is significant difference with respect to sedation and vomiting between both groups. This indicates that Buprenorphine is safe compared to butorphanol. PR ranged from 70 to 90 bpm for most of the patients. No patient had extreme changes in PR. There is no significant difference between both groups with respect to PR at various intervals between both groups. RR ranged from 11 to 18/min in most of the patients. No patient had extreme changes in RR in this study. There is no significant difference between both groups with respect to RR at various intervals between both groups. VAS ranged from 0 to 4 in most of the patients. No patient had extreme pain in this study. There is significant difference in VAS score at 6 and 12 h between both groups. It was more in BT group. This indicates that pain relief can be best achieved by Buprenorphine compared to Butorphanol. SBP ranged from 110 to 140 mm of hg for most of the patients. There is no significant difference between both groups with respect to SBP at various intervals between both groups.

DBP ranged from 70 to 90 mm of hg for most of the patients. There is no significant difference between both groups with respect to DBP at various intervals between both groups. This indicates that hemodynamic stability can be maintained by both the drugs used in this study.

Comparison with Dona's Study[1]

Dona's study was done in 2016 to compare the safety and efficacy of epidural buprenorphine and butorphanol for PO analgesia. It concluded that epidural buprenorphine significantly reduced pain and increased the quality of analgesia with a longer duration of action and was a better alternative to butorphanol for postoperative pain relief. We are of same opinion, and we conclude the same.

Comparison with Gayatri's Study[2]

Gayatri's study was done during 2020 to compare the safety and efficacy of postoperative analgesia with epidural Buprenorphine with Butorphanol. 60 patients who belonged to the ASA physical status class I and II, aged between 30 and 50 years, scheduled for elective laparoscopic surgeries were included, similar to our study. Patients were randomized into 2 groups giving Buprenorphine diluted to 10 ml with NS and Butorphanol Tartrate diluted to 10 ml with NS through the epidural catheter, similar to our study.

Results were recorded by a blind observer anesthesiologist. To evaluate sedation, the Ramsay sedation score was used. In our study, sedation incidence was only 13% cases and we didn't assess RSS. Student's *t*-test and Mann–Whitney's tests were used for analysis. In our study, percentages and student's *t*-test were used. Results showed that there was significant difference in the duration of analgesia between the two groups. It was more in buprenorphine group, similar to our study. In Gayatri's study, respiratory depression was not seen in both the study groups, similar to our study.

Nausea, vomiting, and headache were more in the Buprenorphine group in Gayatri's study, in contrast in our study vomiting was more common in Buprenorphine group. Pruritus was found to be more with Butorphanol, but in our study, pruritus was not seen.

Comparison with Bhoopal Naik's Study[3]

This study was done in 2018 to compare PO analgesics-buprenorphine and butorphanol in combination with bupivacaine Duration of analgesia was more in buprenorphine group in both the studies.

Comparison with Neerja Bharti, Pramila Chari's Study[4]

This study was done to assess the effectiveness of epidural butorphanol with and without bupivacaine for PO analgesic effect after abdominal hysterectomy. Neerja's study[1] concluded that the addition of 2 mg of Butorphanol to 0.125% of epidural bupivacaine produced quick onset and longer duration of analgesia compared to butorphanol alone.

Comparison with Endoh, Matsuda study[5]

Endoh's study[5] compared the efficacy of epidurally given 0.2 mg of Buprenorphine after CSE and general with epidural anesthesia. In our study, comparison was done between epidural buprenorphine and butorphanol. Endoh's study found that the duration of pain relief with epidural buprenorphine was almost alike in both groups. It is about 11 h duration. In our study, Buprenorphine provided analgesia for around 9 h duration. The time period until postoperative first walk and the number of pain relief medication were also similar in both groups. In our study, rescue medication was used more for butorphanol

group compared to Buprenorphine group. Endoh's study concluded that the onset of pain relief was quicker in CSE group, due to flux of buprenorphine through a dural hole after epidural administration. In our study, we did not compare drugs; effect through various modes of anesthesia administration. We assessed only epidurally given medications.

Comparison with Chada Poorvi's Study[6]

This study was done on 60 patients undergoing abdominal surgery under GA. Patients were divided into two groups, 30 each. Our study analyzed 60 patients undergoing both lower limb and abdominal surgeries and they were also divided to two groups and given Buprenorphine and Butorphanol.

In Chada's study,[6] one group received fentanyl and another group received Buprenorphine as transdermal patch 12 h before the surgery. VAS score was lower in fentanyl group compared to Buprenorphine group at various intervals but there is no significant difference. In our study, VAS scores are less for Buprenorphine group compared to butorphanol group and there are significant statistical differences. Rescue analgesia was required for 16.7% in Buprenorphine group and 10% in fentanyl group. In our study, rescue analgesia was needed for 3% patients in Buprenorphine group. In chada' study, 1 patient had intractable nausea and vomiting with Buprenorphine patch. In our study, vomiting's were seen in 5 patients in Buprenorphine group.

Benefits and Strengths of the Present Study

- Knowing better post-operative analgesia agent helps improve patient care, satisfaction, and outcomes
- Studies with fewer subjects (60) like the present study were quick to conduct – a short duration of time is needed
- Easy to review patients' case record forms at any time
- Research question was addressed in a relatively short span of time
- Perfect vigilance of all parameters was done using the multiparameter
- Monitor on all 60 patients for 2 years of study duration, which helped avoid patient discomfort with no intervention.

The Economic Benefit to the Participants

- Physical examination, systemic examination, vitals were analyzed free of cost for all the subjects involved in the study
- A part of travel expenses for patients has been reimbursed
- All investigations were done to 60 patients free of cost
- Lower limb and abdominal surgeries were done free of cost
- Medications such as buprenorphine and butorphanol were provided freely to all study participants.

Recommendations for Future Studies

1. Data on patients below 20 years and above 60 years of age is required.
2. Multi-canter studies including various tertiary care hospitals and certain specialized clinics could be done as more patient populations from different backgrounds could be involved.
3. Research on other drugs like fentanyl could be done.
4. Meta-analysis of existing research could be done.
5. Studies could be done comparing epidurally given drugs with CSE, and general anesthesia.
6. Studies comparing different doses of buprenorphine and butorphanol could be done.
7. Studies can be done on pregnant women undergoing caesarean section.
8. Systematic reviews can be done on post-operative analgesics which carry more scientific validity than original research articles.
9. Pharmaco-economic studies comparing various drugs can be done.

CONCLUSION

We found that both drugs as safe and effective post-operative analgesics.

There is no significant difference between both the drugs with respect to the onset of analgesia. Epidural buprenorphine significantly reduced pain with a longer duration of action and was a better alternative to butorphanol for post-operative pain relief. It was found to be safe due to less incidence of side effects such as sedation and vomiting compared to butorphanol.

We did not find any case of hypotension or respiratory depression in both the groups. No other complications were seen. We conclude that epidural buprenorphine was a better alternative to epidural butorphanol for providing post-operative pain relief. The study is self-sponsored.

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Original Article

Clinical Study of Cystic Duct Remnant Stone Disease and Its Management Options in a Tertiary Care Hospital

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Abstract

Background: Post-cholecystectomy syndrome (PCS), the term coined by Womack and Crider in 1947, is defined as the recurrence of symptoms similar to those experienced before the cholecystectomy. The incidence of which varies largely in different studies, ranging from 10% to 30% of the patients, and its onset may range from a few days to 20 years after surgery. The cystic duct remnant calculus is one of the causes of PCS.

Objectives: The objectives of the study were to assess the incidence cystic duct remnant stone in follow-up cases of cholecystectomy and its management options.

Materials and Methods: Patients presenting to surgical OPD or emergency in SMHS hospital with symptoms of pain right hypochondrium, recurrent biliary colics, epigastric pain, nausea, yellow discoloration of eyes, and with prior history of cholecystectomy (open/laparoscopic) were evaluated for cystic duct remnant calculi in following order. Patient having persistence of symptoms after cholecystectomy was subjected to ultrasonography (USG) abdomen pelvis with focus on hepatobiliary system using curvilinear prove of 3–5 MHz frequency after proper bowel preparation. Magnetic Resonance Cholangio Pancreaticography (MRCP): Being a non-invasive procedure, not requiring sedation or radiation exposure and being equally sensitive (96%) and specific (88%) as EUS, it becomes the investigation of choice. All patients were subjected to MRCP.

Results: Out of 1872 patients who presented as a follow-up case of cholecystectomy with symptoms of pain right upper abdomen, 39 patients were found to have cystic duct remnant stone. The mean age of the patients in our study was 42.9 ± 9.98 years with youngest patient being 17 years and 58 as the oldest one. Females outnumbered males. Mean duration of past surgery was 4.1 ± 2.21 years. Liver function test was done in all patients. Mean bilirubin was 1.82 ± 2.59, mean ALP was 132.1 ± 51.07, mean AST was 48.02 ± 15.05, and mean ALT 46.36 ± 17.47. On USG 82.1% patients were found to have stump calculus, 7.7% patients had stump calculus and calculus in common bile duct (CBD), and 10.3% had no stump calculus. On MRCP findings were suggestive of stump calculus in 87.17% patients and only 12.83% patients were found to have stump calculus and calculus in CBD. Therapeutic procedures including laparoscopic completion cholecystectomy were performed in 74.34% patients, open completion cholecystectomy was performed in 12.82% patients, and open completion cholecystectomy with choledocotomy was performed in 7.70% patients while as Endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic completion cholecystectomy was performed in 5.14% patients. Out of five patients whom ERCP was used for stone clearance, in 3 (60%) patients ERCP failed while stone was successfully cleared by ERCP in 2 (40%) attempts.

Conclusion: Laparoscopic re-intervention performed for cystic duct remnant calculi is safe, feasible and may be offered as the treatment of choice in centers performing advanced laparoscopic procedures.

Key words: Post-cholecystectomy syndrome, cystic duct remnant calculus, right hypochondrium, Magnetic Resonance Cholangio Pancreaticography

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INTRODUCTION

Post-cholecystectomy syndrome (PCS), the term coined by Womack and Crider in 1947,[1] is defined as the recurrence of symptoms similar to those experienced before the cholecystectomy. This usually takes the form of upper abdominal pain (mainly right upper quadrant)

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and dyspepsia, pancreatitis with or without jaundice. The incidence of which varies largely in different studies, ranging from 10% to 30% of the patients, and its onset may range from a few days to 20 years after surgery.[2-4]

Table 1: Incidence of cystic duct remnant stone in study population

Total number of follow-up patients of cholecystectomy=1872
Number of patients with cystic duct remnant calculi stone=39
Incidence of cystic duct remnant stone=39/1872=2.1%

Table 2: Age, gender, chief complaints, history of previous surgery, and duration of past surgery

Patient characteristics	Number of patients (%)
Age (years)	
<30	4 (10.3)
30–39	10 (25.6)
40–49	11 (28.2)
50–59	14 (35.9)
Mean±SD (range)	42.9±9.98 (17–58)
Gender	
Male	11 (28.2)
Female	28 (71.8)
Chief complaints	
Pain right upper abdomen	22 (56.4)
Pain epigastrium with nausea	9 (23.1)
Yellow discolouration of eyes	5 (12.8)
Pain epigastrium with fever	3 (7.7)
History of previous surgery	
Laparoscopic cholecystectomy	32 (82.1)
Open cholecystectomy	7 (17.9)
Duration of past surgery (years)	
1–3	13 (33.3)
3–6	18 (46.2)
6–9	5 (12.8)
≥9	3 (7.7)

SD: Standard deviation

Table 3: Ultrasonography, magnetic resonance cholangio pancreaticography findings, therapeutic and outcome of endoscopic procedure

Patient characteristics	Number of patients (%)
USG findings	
Cystic duct remnant calculus	30 (76.92)
Cystic duct remnant calculi and calculus in	5 (12.82)
Unremarkable	4 (10.26)
MRCP findings	
Cystic duct remnant calculi	34 (87.17)
Cystic duct remnant calculi and calculus in CBD	5 (12.83)
Therapeutic procedure	
Laparoscopic completion cholecystectomy	29 (74.34)
Open completion cholecystectomy	5 (12.82)
Open completion cholecystectomy with choledocotomy	3 (7.70)
ERCP followed by laparoscopic completion cholecystectomy	2 (5.14)
Outcome of endoscopic procedure	
Successful ERCP	2 (40)
Failed ERCP	3 (60)

USG: Ultrasonography, MRCP: Magnetic resonance cholangio pancreaticography, CBD: Common bile duct, ERCP: Endoscopic retrograde cholangiopancreatography

The cystic duct remnant calculus is one of the causes of PCS. Florcken first reported the concept of "cystic duct remnant" in 1912; since then, many researchers have studied this ambiguous entity with varying theories.[5]

The incidence of cystic duct remnant stone after cholecystectomy is <2.5%.[6] There may also be gender-specific risk factors for developing symptoms after cholecystectomy. In one study, the incidence of recurrent symptoms among female patients was 43%, compared to 28% among male patients.[7] This problem may arise as a result of improper dissection of Calot's triangle especially at the hand of inexperienced surgeons, leaving too long a cystic duct to avoid injury to common bile duct (CBD) or a partial cholecystectomy in a patient with unclear anatomy, Mirizzi syndrome, inflammation at Calot's triangle, low insertion of cystic duct, parallel cystic duct, tissue friability, cirrhotic liver, and junior/inexperienced surgeons carrying out the surgery.[8-11]

Palanivelu *et al*.[12] reported that the incidence of cystic duct stump stone in cases who underwent laparoscopic subtotal cholecystectomy was 4.19% and 0.02% in patients who underwent conventional cholecystectomy. Rozsos *et al*.[13] found that the cause of PCS was cystic duct stump stone in 16% of the patients. In the era of laparoscopy, long cystic duct stump is increased, especially by inexperienced surgeons fearing BDI.[9-11,14,15]

Conventionally, gallbladder or cystic duct remnant stone has been managed with open completion cholecystectomy. In view of the effects of the previous operation which results in considerable adhesions, performance of such procedures with laparoscopic approach was discouraged.[13] Now, there are increasing reports in the treatment of this problem with laparoscopic approach.[5,9,10,16,17] Since most of the patients could be treated laparoscopically but dissection in most situations is difficult, so safety-first strategy should hold the key and conversion to open should not be considered a failure.

Aims and Objectives

The main aims and objectives of this study are:

1. To assess the incidence of remnant cystic duct stone following cholecystectomy.
2. Various management options for cystic duct remnant stone.

MATERIALS AND METHODS

After obtaining the ethical clearance from the Institutional Ethical Committee, the present observational study was

conducted in the Postgraduate Department of Surgery, Government Medical College, Srinagar.

Inclusion Criteria

The following criteria included in the study:

- Sex – Both male and female
- Ultrasonography (USG)/Magnetic Resonance Cholangio Pancreaticography (MRCP) documented cystic duct remnant stone in cystic duct or GB remnant.

Patients presenting to surgical OPD or emergency in SMHS hospital with symptoms of pain right hypochondrium, recurrent biliary colics, epigastric pain, nausea, yellow discoloration of eyes, and with prior history of cholecystectomy (open/laparoscopic) were evaluated for cystic duct remnant stone with baseline investigations, USG, and MRCP.

Patients were subjected to completion laparoscopic cholecystectomy though some of them were amenable to open/CBD exploration.

RESULTS

In our study, out of 1872 patients who presented to as follow-up cases of cholecystectomy, 39 were found to have cystic duct remnant stone making it 2.1% incidence of cystic duct remnant in our study. The mean age of the patients in our study was 42.9 ± 9.98 years with youngest patient being 17 years and 58 as the oldest one. Females outnumbered males in our study with 71.8% females versus 28.2% males. Pain right upper abdomen was the most common presenting complaint in 56.4% followed by pain epigastrium with nausea in 23.1% patients. About 82.1% patients had undergone laparoscopic cholecystectomy while as 17.9% underwent open cholecystectomy. Mean duration of past surgery was 4.1 ± 2.21 years. Liver function test was done in all patients. Mean bilirubin was 1.82 ± 2.59, mean ALP was 132.1 ± 51.07, mean AST was 48.02 ± 15.05, and mean ALT 46.36 ± 17.47.

On USG, 76.92% patients were found to have cystic duct remnant calculi, 12.82% patients had cystic duct remnant calculi, and calculus in CBD and 10.26% unremarkable study. On MRCP findings were suggestive of cystic duct remnant calculi in 87.17% patients and only 12.83% patients were found to have cystic duct remnant calculi and calculus in CBD. Therapeutic procedures including laparoscopic completion cholecystectomy were performed in 74.34% patients, open completion cholecystectomy was performed in 12.82% patients, and open completion cholecystectomy with choledocotomy was performed in 7.70% patients while as endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic completion cholecystectomy was performed in 5.14% patients. Out of five patients whom ERCP was used for stone clearance, in 3 (60%) patients ERCP failed while stone was successfully cleared by ERCP in 2 (40%) attempts.

In the present study, we did not encounter any complications which are common with the procedure like bile duct injury, bowel injury and wound infection. In laparoscopic group, the post-operative hospital stay was maximum of 1–2 day in comparison with the open group who stayed in hospital for maximum of 5 days. None of the patients in our study came with any post-operative complaints such as pain epigastrium, dyspepsia, and fever. Patients were followed up for maximum 1½ year duration [Tables 1-3].

DISCUSSION

A total of 1872 follow-up cases of cholecystectomy in which 39 were found to have cystic duct remnant calculi making it 2.1% incidence of cystic duct remnant calculi in our study. Demetriades *et al.*[10] and El-Nakeeb *et al.*[6] reported <2.5% incidence of cystic duct remnant calculi following cholecystectomy. Majority, that is, 14 (35.9%) of patients belonged to the age group of 50–59 years followed by 11 (28.2%) patients who belonged 40–49 years, 10 (25.6%) patients were aged 30–39 years while as only 4 (10.3%) patients were aged <30 years. The mean age of the patients in our study was 42.9 ± 9.98 years with youngest patient being 17 years and 58 as the oldest one. Females outnumbered males in our study with 28 (71.8%) females in comparison with 11 (28.2%) males. El-Nakeeb *et al.*[6] conducted a study in which mean age of the patients was 50 ± 15.43 years (26–78 years) with 16 women and 5 men. Seven patients (5 women and 2 men) were seen with an average age of 43.4 years (age range 29–70 years) by Jayant and Kaushik.[18] Chowbey *et al.*[9] reviewed laparoscopic re-intervention for cystic duct remnant calculi over a period of 10 years. Mean age of the patients was 51 years (range 32–67 years). There were 10 males and 16 females. Pain right upper abdomen was the presenting complaint in 22 (56.4%), pain epigastrium with nausea in 9 (23.1%) patients, yellow discoloration of eyes was seen in 5 (12.8%) patients while as pain epigastrium with fever with the presenting complaint in 3 (7.7%) patients. Chowbey *et al.*[9] reviewed laparoscopic re-intervention for cystic duct remnant calculi over a period of 10 years. The presenting complaints including recurrent biliary colic followed by jaundice. Similar findings were observed by El-Nakeeb *et al.*[6] wherein recurrent biliary colic was the most common presenting complaints in 95.2% followed by

jaundice in 42.9% and fever in 23.9% patients. 32 (82.1%) patients underwent laparoscopic cholecystectomy while as open cholecystectomy was done in 7 (17.9%) patients in our study. El-Nakeeb *et al*.[6] conducted a study in which majority of patients under laparoscopic cholecystectomy in comparison with open cholecystectomy (66.7% versus 33.3%). Chowbey *et al*.[9] reviewed laparoscopic re-intervention for cystic duct remnant calculi over a period of 10 years.

Duration from past surgery was 3–6 years in majority of patients, that is, 18 (46.2%) followed 1–3 years in 13 (33.3%) patients, and 6–9 years in 5 (12.8%) patients while as the duration since last surgery was ≥9 years in 3 (7.7%) patients with a mean duration from past surgery was 4.1 ± 2.21 years. Gupta *et al*.[19] reported the recurrence of symptoms after index operation after 3 years with most of the studies reported a median time interval in many years after the index operation.[11,13,17,19-22] Liver function test was done in all patients. Mean bilirubin was 1.01 ± 0.78, mean ALP was 121.5 ± 40.27, mean AST was 46.3 ± 12.28, and mean ALT 46.9 ± 14.45. El-Nakeeb *et al*.[6] conducted a study in which mean serum bilirubin (mg%) 1.7 ± 1.9 (0.4–7.9) and mean serum SGPT (IU) 84.23 ± 116.1 (20–470). Compared with cases with no GD, the GD group was characterized by a significantly higher AST/ALT ratio and lower ALT (mean ALT 51 ± 28 and AST/ALT 0.84 ± 0.4 in GD vs. 65 ± 40 and 0.71 ± 0.31 non GD) (Fracanzani *et al*., 2012).[20] All the 39 patients underwent USG in which 30 (76.91%) were found to have cystic duct remnant calculi, 5 (12.83%) patients had cystic duct remnant calculi and calculus in CBD and 4 (10.3%) had unremarkable study. All the 39 patients enrolled in this study underwent MRCP and findings were suggestive of cystic duct remnant calculi in 34 (87.17%) patients and only 5 (12.83%) patients were found to have stump calculus and calculus in CBD. The primary diagnosis in a study done by Mageed *et al*.[21] was established by expert abdominal USG detection in 74.1%, or ERCP modality in 48.1%, but the gold standard of diagnosis was MRCP that was done nearly in all cases. Diagnosis was established by abdominal US or MRCP in the study of Parmar *et al*.,[11] while Chowbey *et al*.[22] reported that the primary diagnosis was established by abdominal US, MRCP, ERCP, and EUS, while Palanivelu *et al*.[12] reported that abdominal US identified cystic duct remnant in nine patients, and MRCP identified calculus in all patients. The diagnoses of all case with cystic duct stump stone were carried out by using abdominal US and MRCP. MRCP was accurate in detecting cystic duct stump stone in all cases and US was accurate in 15 cases (71.4%). ERCP and papillotomy were carried out before completion of cholecystectomy in nine cases (42.9%) and CBD was cleared in all cases (El-Nakeeb *et al*., 2016).[6]

Laparoscopic cholecystectomy was done in majority of patients, that is, 29 (74.34%) because it is safe, feasible with small incision, less post-operative pain, better cosmesis, shorter hospital stay, and early resumption to daily routine work. Eight elderly patients who were not fit for laparoscopic procedure were operated by open method including open completion cholecystectomy in 5 (12.82%) patients and open completion cholecystectomy with choledocotomy in 3 (7.70%) patients. ERCP followed by laparoscopic completion cholecystectomy was performed in 2 (5.14%) patients. El-Nakeeb *et al*.[6] conducted a study in which open completion cholecystectomy was performed in nine cases (42.9%) and laparoscopic completion cholecystectomy was completed successfully in 11 cases (52.4%). Tantia *et al*.[17] performed laparoscopic completion cholecystectomy for seven cases. Chowbey *et al*.[9] studied 26 cases with remnant GB stone/cystic duct stump stone. Laparoscopic completion cholecystectomy was successful in all cases.

Out of five patients whom ERCP was used for stone clearance, in 3 (60%) patients ERCP failed while stone was successfully cleared by ERCP in 2 (40%) attempts. In a study done by El-Nakeeb *et al*.[6] 9 cases (42.9%) were subjected to a preoperative ERCP, and CBD was cleared in all cases. ERCP is a valuable tool in the hands of surgeons for preoperative, intraoperative, and postoperative management of biliary obstruction. Open completion cholecystectomy was performed in nine cases (42.9%) and laparoscopic completion cholecystectomy was completed successfully in 11 cases (52.4%), and conversion was needed in one case due to marked adhesion and distorted anatomy (El-Nakeeb *et al*., 2016).[6] There Palanivelu *et al*.[12] reported that the incidence of cystic duct stump stone in cases who underwent laparoscopic subtotal cholecystectomy was 4.19%, and 0.02% in patients who underwent conventional cholecystectomy. Rozsos *et al*.[13] found that the cause of PCS was cystic duct stump stone in 16% of the patients. In the era of laparoscopy, long cystic duct stump is increased, especially by inexperienced surgeons fearing BDI.[6-10] Partial cholecystectomy has received some criticism because of the risk for residual GB stone but the data on incidence of this complication are still unknown. In a study by Chowbey *et al*.,[22] 59 patients who underwent partial cholecystectomy were reported to have developed recurrent or residual stones. Beldi and Glättli[24] reported residual GB stones in six out of 46 patients who underwent partial cholecystectomy. In era of laparoscopy, laparoscopic partial cholecystectomy to mange difficult GB (acute cholecystitis, Mirazzi GB, cirrhotics) to reduce the incidence of conversion rate to open surgery will increase the number of cases of residual stones in GB remnant. The time interval between partial excision of GB and development of PCS symptoms varies largely from a few days to years.[5,14,15,17,25]

CONCLUSION

Cystic duct remnant stone form a small percentage of treatable causes of PCS. A high index of suspicion should be maintained in patients with persistent biliary symptoms. Some of the patients may be amenable to open/CBD exploration but laparoscopic re-intervention performed for cystic duct remnant stone is safe, feasible and may be offered as the treatment of choice in centers performing advanced laparoscopic procedures.

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Original Article

Point of Care Ultrasound Echocardiography in COVID Patients – A Single-Center Study

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Abstract

Introduction: POCUS increasingly used for efficient detection of cardiorespiratory complications of COVID-19 Cardiac POCUS may have similar benefits to transthoracic echocardiography while decreasing staff exposure to patients with COVID-19. Cardiac POCUS has utility, with up to 50% of patients with COVID-19 having cardiac abnormalities on echocardiography, leading to management changes in nearly one-third.

Purpose: This study aimed to define abnormalities and TTE analysis in acute COVID-19 infections and to determine their implications in management and prognosis.

Methods: Sick patients in COVID wards of Government Rajaji Hospital, Madurai were subjected to POCUS echocardiography with 2D portable Echo machine with adult transducer 3–5 MHz using 2D, M mode, PW, CW, and CFM with the help of trained cardiac sonology technicians with PPE. The images were supervised by cardiologist by video calls. Study period is from April 2021 to March 2022 during second wave of COVID-19 pandemic.

Results: Out of 17,562 patients of COVID-19, 1552 patients were subjected to POCUS Echocardiography Examination. Out of those, 55.54% were male and 44.46% were female. Five hundred and ninety-six patients were above 60 years. From the 1552 patients, 26.6% showed structurally normal heart. Abnormal findings were classified follows CAD – 15.34%, cardiomyopathy – 5.41%, calcific AS – 2.2%, in acute coronary syndrome – STEMI – 2.4%, RHD – 1.42%, pleural effusion – 0.97%, PAH in 5.54%, and pericardial effusion – 3.87%. According to symptoms, 42.33% had pneumonia, 34.6% – diabetic, 31.19% – hypertensive, and 4.51% had CKD. Possible myocarditis is in 0.13% and pulmonary embolism in 0.13%.

Conclusion: In the pandemic situation, cardiologist can use telemedicine as a tool to diagnose abnormal cardiac conditions making use of portable echo machines with the help of cardiac sonology technicians.

Key words: Cardiac POCUS, COVID-19, Telemedicine, Cardio Sonology Technician, Screening

INTRODUCTION

Point of care ultrasound echocardiography (POCUS) is an aid to help the medical world to diagnose cardiac abnormalities quickly. Good training and dedication are needed for any medical doctor (non-sonologist) to do fast screening in the bed side.[1] Especially in the COVID pandemic situation, all medical doctors are diverted to look after COVID patients and there is shortage of qualified sonologist and cardiologist.[2] Good portable echocardiography enabled ultrasound machine and well-trained cardiac sonology technician is enough to do the screening echocardiography to COVID patients in COVID isolation wards. POCUS Echo is used in ED, Triage, ICU, IMCU, and IRCU. It is a game changer in the management of seriously ill patients. Knowing cardiac status by POCUS Echo is a boon for emergency management.

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Table 1: The total number patients admitted in Madurai Government Rajaji Hospital during the COVID-19 pandemic

	Total in patients	
Sex	**Number of patients**	**Percentage (for 17,562 patients)**
Male	10,339	58.88
Female	6937	39.5
Children	286	1.63
Total	17,562	

Table 2: The month-wise total number of patients who have undergone point of care ultrasound echocardiography

	Number of patients who underwent POCUS echo	
Month	**Number of patients**	**Percentage (for 1552 patients)**
July-21	217	13.99
August-21	219	14.11
September-21	203	13.08
October-21	230	14.82
November-21	143	9.21
December-21	89	5.73
January-22	317	20.43
February-22	134	8.63
Total	1552	

POCUS: Point of care ultrasound echocardiography

Table 3: The gender-wise total number of patients who have undergone point of care ultrasound echocardiography

	Sex	
Sex	**Number of patients**	**Percentage (for 1552 patients)**
Female	690	44.46
Male	862	55.54
Total	1552	

Table 4: The age-wise total number of patients who have undergone point of care ultrasound echocardiography

	Age – group	
Age	**Number of patients**	**In percentage (for 1552 patients)**
<10	12	0.77
11–20	49	3.16
21–30	135	8.7
31–40	174	11.21
41–50	243	15.66
51–60	343	22.10
>60	596	38.40
Total	1552	

Bed side echocardiography screening can be done by them and if in doubt they can contact qualified echo cardiographer/cardiologist using video calling showing the images and videos acquired for sick patients using standard views. Review examination can be ordered if the views are not clear enough to give impression.[3]

Improved portability of the ultrasound machine has enabled cardiac ultrasound imaging to be performed at the bed side offering cardiac status to their clinical scenario. Artificial intelligence (AI) is utilized by many handheld echocardiographic machines. Miniaturized technology is used in such hand held portable cardiac ultrasound system. During COVID-19 pandemic, this POCUS method posed logistical challenges in holistic care of patients, highlighting the need for accurate easily disinfected equipment that could be used at the patient's bed side. Basic software implemented to enhance 2D/M mode/CPM, PW, and CW facilities. AI-based automated LVEF is possible to reduce the time of examination.[4]

In COVID patients, time taken for POCUS examination is 5–10 min[5] and the contact time for entire examination is <20 min. Life-threatening condition such as mechanical complication (ventricular septal rupture, free wall rupture, and papillary muscle rupture) following acute coronary syndrome (ACS), massive pericardial effusion (PE), acute pulmonary embolism, aortic dissection, and myocarditis can be picked up in the bedside and enable them to manage appropriately in the right time. The reliability is good, because the POCUS examinations done by technicians are supervised over telemedicine (video calls) [Figure 1] using Android type of phones at both ends.

By this method, shortage of qualified cardiologist is managed by trained cardio sonology technicians who are mostly younger than 40 years. Further, doctors more than 50 years with comorbidities when compared to young technicians are having more risk to get infected.[6] Advantage is the reproducibility as many times if the patient is hemodynamically stable. We can do review POCUS examination if needed. Detailed echocardiography can be done if the patient's infectivity period is over. Some may need Balloon Valvotomy, Surgical Management or Percutaneous Device Closure. The chance of getting infection is very low, due to reduced time of contact, good immunity system of young technicians, and use of PPE.

MATERIALS AND METHODS

Study Population

The study comprises patients admitted at COVID wards, Government Rajaji Hospital and Madurai Medical College, Madurai with cardiac symptoms such as fever, easy fatigue, chest discomfort, palpitation, and shortness of breath.

Study Period

The study was April 2021–March 2022.

Selected Patients for the Study

Sick patients in ED, critical care unit and SARI wards, those with undue tachycardia and other ECG abnormalities ordered by physician in charge of the wards.

Machine Used for the Study

Mindray – M6 Ultrasound and 2D Echo Machine Portable over cart wheel using adult Echo transducer 3–5 MHz facilitating the following methods: Basic software implemented to enhance 2D/M mode, CPM, CFM, PW, CW, and POCUS echocardiography using standard views.

The cardio sonology technician did POCUS (PLAX, LAX, SAX, A4C, A5C, and sub-coastal views) echocardiography examination. They performed in standard views. Those images and videos were recorded and shown by telemedicine (video calling) to cardiologist [Figure 2]. If any doubt, Echo was repeated or sent to cardiology OP. Reports given in standard format meant for POCUS echocardiogram.

Statistical analyses of the data are conducted using the software IBM SPSS 20.0 version. Statistical inference was derived using Chi-square test.

The cardio sonology technician who did POCUS echocardiography examination takes necessary precautions as follows:

1. PPE level II–III.
2. Social distancing of 1–2 feet.
3. Doffing and donning.
4. Cleaning with spirit after every examination.
5. 7 days of work for 6 h followed by 7 days of quarantine (two technicians alternately can work).
6. Subjecting themselves for RTPCR test after 5 days of work.
7. Sterilization of the utensils and fomites
8. Keep them isolated during duty period and 5 days after duty period until their nasopharyngeal RTPCR swab

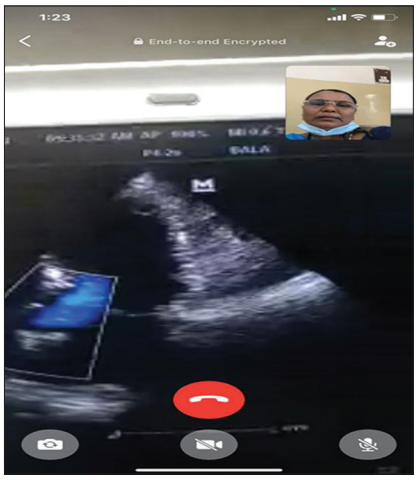

Figure 1: The cardiologist supervising the POCUS examinations over telemedicine (video calls)

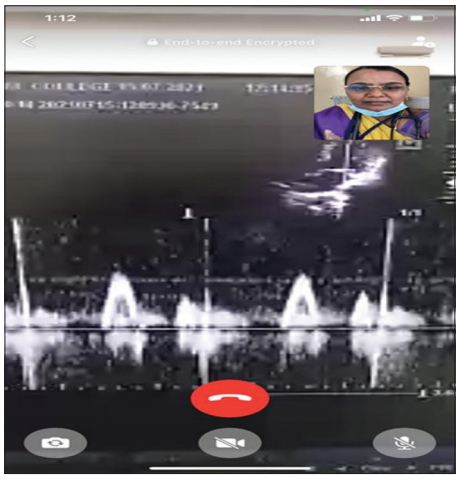

Figure 2: The taken POCUS echocardiography examination has been showed and examined by the cardiologist

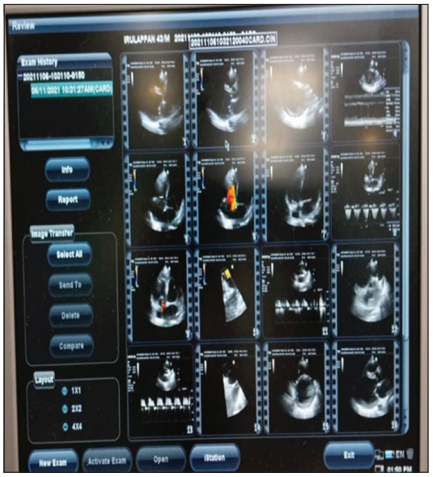

Figure 3: The image of dilated cardiomyopathy view in POCUS echocardiography.

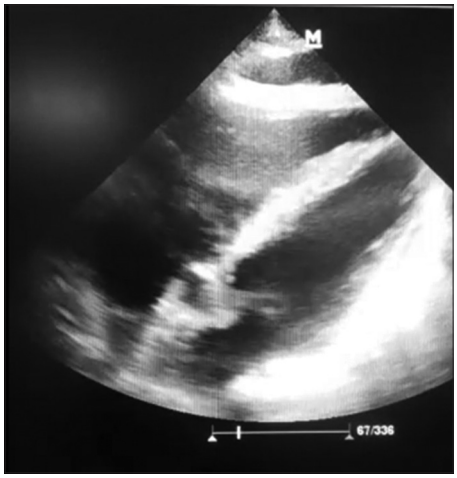

Figure 4: The image of dilation of RA and RV

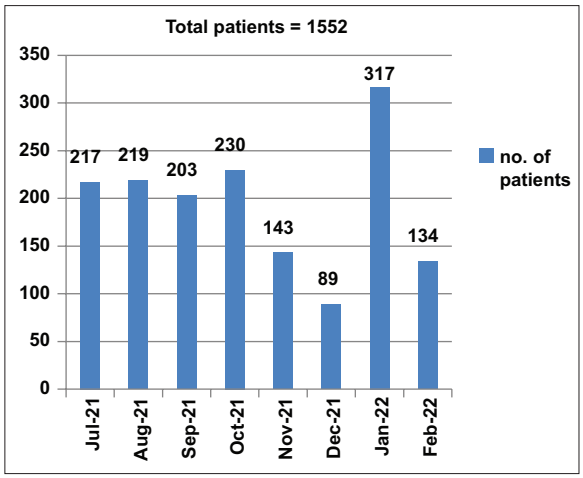

Chart 1: Represents the month-wise total number of patients who have undergone POCUS echo

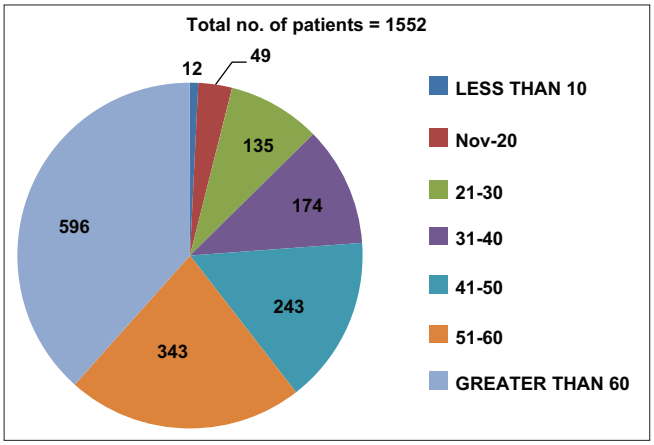

Chart 2: Represents the age-wise total number of patients who have undergone POCUS echo

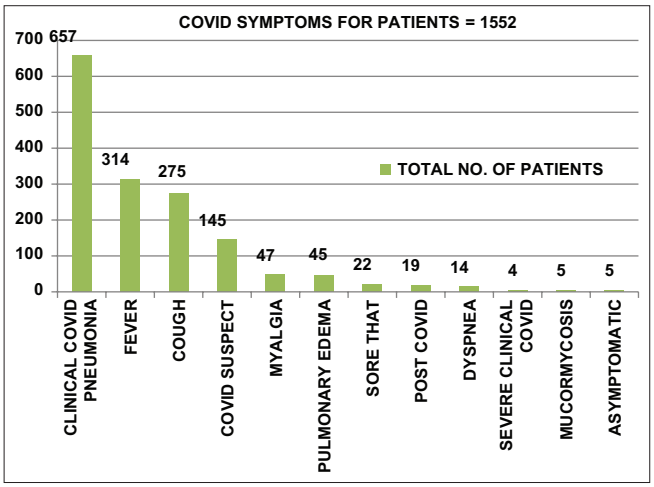

Chart 3: Represents the COVID symptoms for the patients undergone POCUS echo

test results are published.

9. Prophylactic measures such as vaccination and soap bathing.
10. Nutritious food, etc.

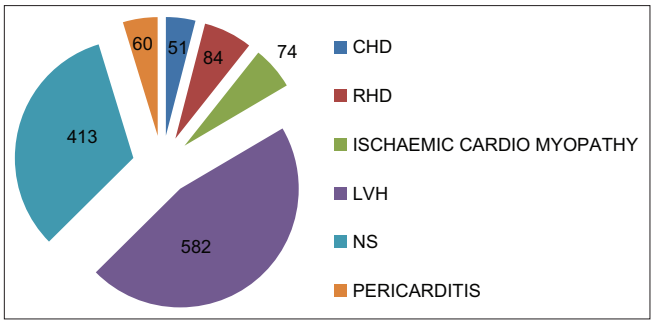

Chart 4: Represents the cardiac conditions of patients who have undergone POCUS echo

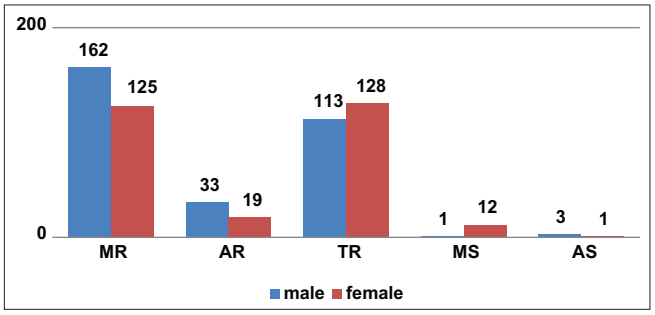

Chart 5: Represents the number of patients with both rheumatic and non-rhematic valvular heart diseases who have undergone POCUS echo

Inclusion Criteria

Patients admitted in COVID wards who were symptomatic and referred cases from ED, ICU, patients with cardiac murmurs, and ECG abnormalities for cardiac evaluation were included in the study.

Exclusion Criteria

Those patients who are not willing to undergo Echo Cardiogram were excluded from the study.

RESULTS AND ANALYSIS

Totally 1552 COVID-19 patients were subjected to POCUS echocardiography evaluation [Tables 1 and 2] and [Chart 1].

Sex and Age Criteria

Eight hundred and fifty-two were male, 674 were female, and 15 were children. Male↔Female ratio is 1.25:1. The highest age group is more than 60 years (596 out of 1552 patients) [Chart 2].

Normal Heart

Four hundred and thirteen (26.65%) – (M-211; F-202) were diagnosed to have structurally normal heart [Tables 3 and 4] and [Chart 4 and Video 1].

Concentric Left Ventricular Hypertrophy (LVH)

Concentric LVH was present in 582 (M-330; F-252) patients (37.5%) among total cases. It constitutes 51.09% among

Table 5: The COVID symptoms for the patients undergone point of care ultrasound echocardiography

	COVID symptoms			
Covid	**Male**	**Female**	**Grand total**	**Percentage (for 1552 patients)**
Clinical COVID pneumonia	359	298	657	42.33
Fever	157	157	314	20.23
Cough	131	144	275	17.72
COVID suspect	82	63	145	9.34
Myalgia	21	26	47	3.03
Pulmonary edema	20	25	45	2.9
Sore throat	11	11	22	1.42
Post covid	10	9	19	1.22
Dyspnea	6	8	14	0.90
Severe clinical covid	1	3	4	0.3
Mucormycosis	2	3	5	0.32
Asymptomatic	3	2	5	0.32
Total	803	749	1552	

those with abnormal Echocardiography. LVH diagnosed using IVS/PW thickness and LV mass [Tables 7 and 8].

Diastolic Dysfunction

Two hundred and seventy-seven patients (17.85%) – (M-171; F-106) had diastolic dysfunction out of 1552 patients. Among them, 266 patients (17.13%) had Grade I, six patients had Grade II, five patients had Grade III, and none had Grade IV diastolic dysfunction.

CAD and ACS

Among abnormal echocardiographic findings, CAD tops the list with 238 (15.34%) – (M-155; F-83) followed by Cardiomyopathy (Ischemic, DCM [Figure 3], HCM and PPCM). ACS accounts to 62 cases (4%) which include STEMI, NSTEMI and Unstable Angina. Stress Cardiomyopathy in one patient (F-1) [Tables 9 and 10] and [Video 2].

Rheumatic and Non-Rheumatic Valvular Heart Diseases: 597 (38.46%) – (M-312; F-285)

Patients had valvular diseases out of 1552 patients. Among them, 287 patients (3.86%) – (M-125; F-162) had Mitral Regurgitation (MR), RHD could be diagnosed in 22 cases (1.41%) – (M-8; F-14), 13 patients (M-1; F-12); had mitral stenosis (MS), five patients (M-0; F-5) had severe MS. (MVOA < 1 m^2), four patients (M-3; F-1) had aortic stenosis (AS), no patients had severe AS, 52 patients (M-33; F-19) had aortic regurgitation (AR), and tricuspid regurgitation (TR) found in 241 patients (M-113; F-128) (all are functional TR) [Table 11 and Chart 5].

Severe Pulmonary Arterial Hypertension

Present in five patients (M-2; F-3). Among them, D-shaped LV due to severe pulmonary arterial hypertension was present in two cases (M-1; F-1). Escalation of oxygen therapy was recommended for those who had moderate-to-severe pulmonary arterial hypertension without pre-existing heart disease. Serial examinations have done

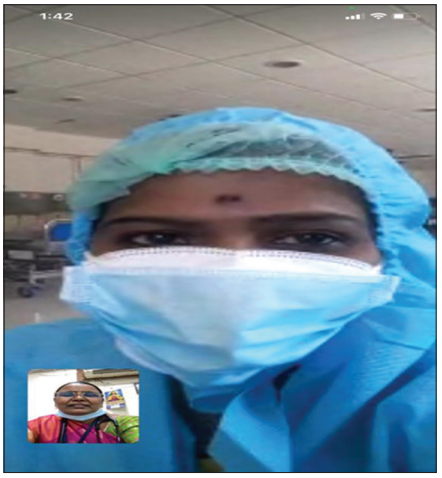

Figure 5: The technically qualified and trained cardiac sonologist in telemedicine under supervision of the cardiologist.

which showed reduction in TRPG. Severe hypoxia patients on ventilator had significant TR. Such patients were kept as high-risk group and intense monitoring recommended [Table 12].[7]

LV Systolic Dysfunction

LVSD was present in 238 patients (15.33%) – (M-155; F-83). Ninety-three patients (6.37%) had ejection fraction of <50% by teicholtz method.[8]

PE: 60 patients (3.86%) – (M-32; F-28) had PE. Among them, two patients had massive PE [Video 3]. One had tamponade and she underwent emergency pericardial tapping under Echo guidance [Figure 6].

Cardiologist did it with full COVID precautions in the IMCU ward under careful monitoring. Thin sheet of PE was seen in 22 cases. Mild PE in 18 cases. [Table 13] Moderate PE was in eight cases. Known hypothyroid cases had PE predominantly.[9]

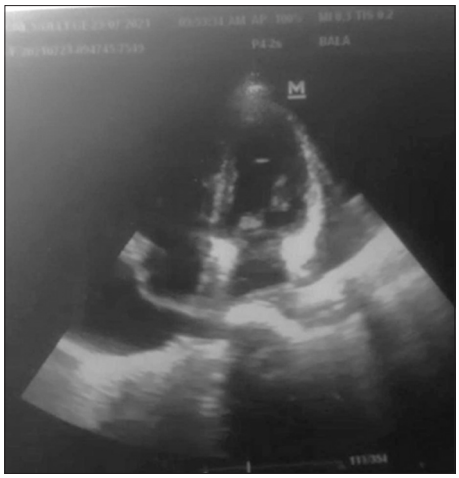

Figure 6: The image of massive pericardial effusion with cardiac tamponade

Pleural Effusion

Echo free space behind descending thoracic aorta in 15 patients (0.97%) – (M-9; F-6). They had left-sided mild effusion.[10]

Pulmonary Embolism

Since COVID predispose patients to pulmonary embolism due to dehydration and cytokine release mediated endothelial damage and possible abnormal coagulation profile.[11] Unprovoked acute pulmonary embolism could be identified by Echo Cardiograph criteria such as dilated right atrium (RA) and right ventricle (RV) with moderate TR [Figure 4]. Echo Cardiograph (ECG) was abnormal for that case showing $S_1Q_3T_3$ pattern. He was lysed with alteplase. However, the patient succumbed to death due to massive PE and hypoxia due to severe lung involvement. He was a 34-year-old male with WELL's score of 2. He was not on any drugs and there were no comorbid illness. Another patient with sub-massive PE was treated with Heparin Infusion followed by oral anticoagulant. In our center, rivaroxaban was advised 15 mg twice a day for 3 months.

Myocarditis

All breathless patients with tachycardia and heart rate >120 were screened for possible myocarditis.[12] Clinical, ECG, and Echo showing LV systolic dysfunction with dilatation of LV cavity.

Eleven patients had possible Myocarditis. Among them, two had severe LVSD. Both died in COVID wards. They were around 40 years and the lung involvement was around 40% [Table 5]. Hence, we were about to name them as "40–40 COVID syndrome." All were started on Inj.methyl prednisolone – 1 mg body weight twice a day dosage for 3–7 days depending on the response. Cardioprotective drugs were given. Anti-failure drugs were given. Digoxin and beta-blockers were judiciously used. Ivabradine used to control sinus tachycardia. Oxygen therapy escalated to keep SpO_2 > 92%. Endomyocardial biopsy and cardiac MRI could not be done since patients were too sick.

Congenital Heart Diseases (CHD)

Totally, 51 patients had **CHD**s. Among those, mitral valve prolapse (MVP) tops the list followed by atrial septal defect (ASD), patent foramen ovale (PFO), ebstein anomaly, and dextrocardia.

Calcific Aortic Stenosis

Thirty-four patients had calcified aortic stenosis of mild-to-moderate severity. They were advised to have followed up.

Arrhythmias

Nineteen patients (1.2%) – (M-15; F-4) had tachy arrhythmia and atrial fibrillation (AF)[13,14] was the most common tachy arrhythmia. Ventricular tachycardia (VT) was present in one patient (55/F) with DM and HT. She survived. Sinus tachycardia during study was found in 64 cases (4.12%) – (M-37; F-27). Sinus bradycardia was found in nine cases (0.58%) – (M-6; F-3). There were 2 cases of Complete Heart Block (0.1%) [M-2; F-0]. All tachy arrhythmia reverted either by DC cardio version or chemical cardio version, followed up for tachy cardiomyopathy, features of myocarditis.

Invasive Fungal Sinusitis/Mucormycosis

Totally, six cases were diagnosed to have mucormycosis among those 1552 patients who underwent POCUS echocardiography. Many cases were suspected to have fungal sinusitis around 100 cases. There was one case of isolation, one case had pulmonary mucormycosis, and one had orbital mucormycosis. Overall prognosis was bad in those with COVID pneumonia with mucormycosis infection. Diabetic patients were more prone to have mucormycosis infection.[15]

DISCUSSIONS

Symptoms Analysis

Among 1552 cases, who underwent POCUS echocardiography, five cases were asymptomatic. Others were symptomatic.

Fever was the predominant symptom in 314 cases (20.23%), followed by cough – 275 cases (17.72%), suspected COVID – 145 cases (9.02%), myalgia – 47 cases (3.03%), and acute pulmonary edema, which was given the diagnosis in 45 cases (2.9%).[16,17]

Twenty-two cases (1.42%) had sore throat; post-COVID patients were admitted due to persistent dyspnea – 14 cases (1.22%). All the 14 patients were having severe breathlessness during POCUS echo study and most of

Table 6: The co-morbid conditions for the patients who have undergone point of care ultrasound echocardiography

Co-morbid conditions						
Serial number	**Co-morbid conditions**	**Male**	**Female**	**Total**	**In percentage (for 1552 patients)**	***P***
1	DM	309	228	537	34.60	0.484
2	HTN	279	205	484	31.19	0.160
3	CKD	52	18	70	4.51	0.031
4	Anaemia	7	13	20	1.29	0.005
5	Thyroid	1	19	20	1.29	0.472
6	PTB – active	16	3	19	1.22	0.433
7	DKA	3	2	5	0.32	0.922
8	AKI	2	3	5	0.32	0.970
9	Portal HTN/DCLD	5	0	5	0.32	0.007
10	CKD on HD	3	0	3	0.2	0.782
11	Connective tissue disorders (CHD)					
	SLE	0	1	1	0.06	0.495
	RA	0	3	3	0.2	0.470
12	PAOD	1	0	1	0.06	0.742
13	DVT	3	1	4	0.26	0.828
14	PLHA	3	1	4	0.26	0.084
15	RTA	4	0	4	0.26	0.001
16	s/p renal transplant	2	1	3	0.2	0.668
17	Cancer					
	AML	1	1	2	0.19	0.437
	CML	2	0	2	0.19	0.858
	Breast	0	1	1	0.06	0.952
18	Omicron	1	0	1	0.06	0.105
19	Dengue	2	1	3	0.2	0.000
20	Typhoid	1	0	1	0.06	0.952
21	Invasive fungal sinusitis	0	1	1	0.06	0.742
22	Lung diseases					
	COPD	14	14	28	1.8	0.583
	Asthma	15	8	23	1.5	0.305
	TB	6	2	8	0.52	0.914
	ARDS	4	2	6	0.4	0.388
	ILD	1	2	3	0.2	0.737
	Cavitation in mediastinum	1	0	1	0.06	0.952
23	Thrombocytopenia	2	1	3	0.2	0.052
24	DUB	1	0	1	0.06	0.742
25	CNS					
	CVA	20	7	27	1.74	0.518
	Suspected covid altered sensorium for evaluation	1	0	1	0.06	0.742
	CIDP	2	0	2	0.19	0.869
	Systemic sclerosis	0	1	1	0.06	0.742
	Hyponatremia	1	0	1	0.06	0.952
	Metabolic encephalopathy	3	0	3	0.2	0.567
26	ICH on mechanical ventilation	1	0	1	0.06	0.952
27	Psychiatric illness	0	1	1	0.06	0.952
	Grand total	769	540	1309	84.34	

P>0.05 not reject (accept) the null hypothesis and *P*<0.05 reject the alternative hypothesis. DM: Diabetes mellitus, HTN: Hypertension, CKD: Chronic kidney disease, DKA: Diabetic ketoacidosis, AKI: Acute kidney Injury, HD: Haemodialysis, CHD: Congenital heart disease, RA: Right atrium, PAOD: Peripheral arterial occlusive disease, DVT: Deep vein thrombosis, PLHA: People Living With HIV/AIDS, RTA: Road traffic accident, AML: Acute Myeloid Leukaemia, CML: Chronic myelogenous leukaemia, COPD: Chronic obstructive pulmonary disease, TB: Tuberculosis, ARDS: Acute respiratory distress syndrome, CVA: Cerebral vascular accident, SLE: Systemic lupus erythematosus, CIDP: Chronic inflammatory demyelinating polyneuropathy, DCLD: Decompensated chronic liver disease, PTB: Pulmonary tuberculosis, ILD: Interstitial lung disease, DUB: Dysfunctional Uterine Bleeding, CNS: Central Nervous System, ICH: Intracerebral Brain Hemorrhage

them were on ventilator therapy (0.9%), severe COVID infection with poor prognostic markers were there in four cases (0.32%).

Comorbid Conditions

Among 1552 patients who underwent POCUS echocardiography, 537 patients were diabetic irrespective of type of diabetes (34.6%), 484 patients were hypertensive (31.18%), 70 patients has chronic kidney disease (CKD) – (4.5%), three cases were getting regular hemodialysis (HD), 20 patients (1.29%) had severe anemia (Hemoglobin [HB] <8 g/dL), 20 patients had hypothyroidism (1.29%), consistent finding was mild PE in them, and 19 patients (1.22%) had active pulmonary tuberculosis (TB), for them ATT started with the help of thoracic physician [Table 6 and Chart 3].[18,19]

Five patients had diabetic ketoacidosis (DKA) as a complication due to poor control of diabetes mellitus (DM) and use of steroids, one patient (male) had peripheral arterial occlusive disease (PAOD), four patients had deep vein thrombosis (DVT) – (M-3; F-1), 4 patients had people living with HIV/AIDS (PLHA) – (M-3; F-1), status post renal transplant were of 3 patients – (M-2; F-1), acute myeloid leukemia (AML) cases were 2 in number, chronic myelogenous leukemia (CML) cases were 2 in number, CA breast was in 1 case, 27 cases (1.74%) with acute cerebral vascular accident (CVA) were examined, road traffic accident (RTA) – four cases underwent echo, few were taken for emergency surgery, acute kidney injury (AKI) cases were 5 who underwent POCUS echo, 51 cases (3.29%) of chronic obstructive pulmonary disease (COPD) and asthma, and six cases of acute respiratory distress syndrome (ARDS).

Table 7: The number normal and abnormal study of cardiac patients who have undergone point of care ultrasound echocardiography

	Normal			
Cardiac status (Normal / Abnormal)	**Male**	**Female**	**Total**	**Percentage (for 1552 patients)**
Normal study	211	202	413	26.6
Abnormal study	651	488	1139	73.39

Around five cases underwent emergency amputations due to acute limb ischemic gangrene.

COVID Plus Syndromes

Three patients – (M-2; F-1) had dengue, one patient (male) had typhoid,[20,21] and one patient had leptospirosis.

Common echo finding was significant tricuspid regurgitation (TR). The subcostal views were taken in patients who were connected to HFNO, NRM mask, and ventilators.

Temporary Pace Makers *In Situ*

Three cases underwent echo who had lead in RV apex. Subcostal views showed it better. Femoral vein route were used for all the three cases. Among them, one later underwent permanent pacemaker implantation (PPI), other recovered to have around 40 per minute discharged against medical advice (AMA) with oral orciprenaline 10 mg twice a day dosage. We lost follow up of that patient. All the three patients were male.

Pregnancy and COVID Cases

Among 48 women with pregnancy[22] with RTPCR positive (38 cases) and rest with Clinical COVID who underwent POCUS echo had fever as predominant symptom followed by cough and pneumonia. Lung involvement was not more

Table 8: The abnormal cardiac conditions of patients who have undergone point of care ultrasound echocardiography

	Abnormal cardiac conditions by echo				
Serial number	**Abnormal cardiac status by echo**	**Male**	**Female**	**Total**	**Percentage (for 1552 patients)**
1	CAD	155	83	238	15.34
2	Cardio myopathy	58	26	84	5.41
3	Calcified aortic stenosis	14	20	34	2.20
4	ACS				
	STEMI	28	9	37	2.4
	Unstable angina	14	6	20	1.3
	N-STEMI	3	2	5	0.32
5	VHD (organic+functional)	312	285	597	38.47
6	RHD	8	14	22	1.42
7	Pleural effusion	9	6	15	0.97
8	CAD (known case)	6	5	11	0.71
9	Para doxical septal motion	1	1	2	0.13
10	Pulmonary embolism	2	0	2	0.13
11	Corpulmonale	0	1	1	0.06
12	Myocarditis	1	1	2	0.13
13	Pericardial effusion	32	28	60	3.87
14	Possible myocarditis	0	2	2	0.13
15	CHD				
	MVP-AML	14	22	36	2.32
	ASD	2	7	9	0.58
	PFO	2	2	4	0.26
	Ebstein anomaly	1	0	1	0.06
	Dextro cardia	1	0	1	0.06
16	Impending cardiac tamponade	0	1	1	0.06
17	Pulmonary hypertension	45	41	86	5.54
18	Concentric LVH	330	252	582	37.5

CAD: Coronary artery disease, ACS: Acute coronary syndrome, ST-Elevation Myocardial Infarction, NSTEMI: Non-STEMI, CAD: Coronary artery disease, CHD: Coronary heart disease, MVP: Mitral valve prolapse, AML: Acute myeloid Leukaemia, ASD: Atrial septal defect, PFO: Patent foramen ovale, VHD: Valvular heart disease, RHD: Rheumatic heart disease, LVF: Left Ventricular Hypertrophy

than 40%. Three cases only underwent CT chest with precautions preferably in 2nd and 3rd trimester.

Thirty-eight mothers had mild-to-moderate hypoxia, two were diabetic, and two were hypertensive, 28 mothers had normal study, mild global hypokinesia was there in one case, left ventricular systolic dysfunction (LVSD) moderate was there in one case, four mothers had trivial mitral regurgitation (MR), three mothers had mild mitral regurgitation (MR), and one mother had moderate mitral regurgitation (MR)

Table 9: The number of patients with coronary artery disease who have undergone point of care ultrasound echocardiography

CAD				
Coronary artery territory	Male	Female	Total	Percentage (for 1552 patients)
Global/mild global	102	62	164	10.57
LAD territory (AWMI)	28	16	44	2.84
RCA/LCX territory (IWMI)	25	5	30	1.93
Total	155	83	238	15.34

CAD: Coronary artery disease, AWMI: Anterior wall myocardial infarction, LAD: Left Anterior Descending Artery, RCA: Right coronary artery, LCX: Left Circumflex, IWMI: Inferior wall myocardial infarction

Table 10: The number of patients with cardio myopathy who have undergone point of care ultrasound echocardiography

Cardio myopathy				
Type of cardio myopathy	Male	Female	Total	Percentage (for 1552 patients)
Ischaemic cardio myopathy	52	22	74	4.77
DCM	5	3	8	0.52
HCM	1	-	1	0.06
PPCM	-	-	-	-
Takotsubo cardiomyopathy/apical blooning syndrome	-	1	1	0.06
Total	58	26	84	5.41

DCM: Dilated cardiomyopathy, HCM: Hypertrophic cardiomyopathy, PPCM: Peripartum cardiomyopathy

Table 11: The number of patients with both rheumatic and non rhematic valvular heart diseases who have undergone point of care ultrasound echocardiography

ECHO – VHD															
Severity	Male					Female					Total				
	MR	AR	TR	MS	AS	MR	AR	TR	MS	AS	MR	AR	TR	MS	AS
Trival	51	13	14	0	0	36	5	16	0	0	87	18	30	0	0
Mild	81	19	81	1	2	59	13	89	4	1	140	32	170	5	3
Moderate	30	1	15	0	1	29	1	17	3	0	59	2	32	3	1
Severe	0	0	3	0	0	1	0	6	5	0	1	0	9	5	0
Total	162	33	113	1	3	125	19	128	12	1	287	52	241	13	4

MR: Mitral regurgitation, MS: Mitral stenosis, AR: Aortic regurgitation, AS: Aortic stenosis, TR: Tricuspid regurgitation, VHD: Valvular heart disease

Global hypokinesia may be due to hypoxia sequelae or peripartum cardiomyopathy. She is under follow-up. Since her left ventricular ejection fraction (LVEF) was 55%, she was advised to undergo elective lower segment caesarean section (LSCS) at the time of delivery. Team approach was followed.

There was difficulty in getting views by standard parasternal long axis (PLAX), short axis (SAX), Apical 4 Chamber (A4C), and apical 5 chamber (A5C) in critically ill cases and those on ventilators. Modified views were used to demonstrate interested structures (Subxiphoid views).

All screening echo examination gave details about situs, chambers, valves, and left ventricular (LV) function. Tricuspid annular plane systolic excursion (TAPSE) could be seen in A4C view when asked for it. Other modalities such as tissue doppler imaging and contrast imaging were not used for want of technical expertise. Difficult to examination cases were reviewed next day with available views. Detailed echo examinations were asked for in five

Table 12: The number of patients with pulmonary hypertension who have undergone point of care ultrasound echocardiography

Pulmonary hypertension				
Severity	Male	Female	Total	Percentage (for 1552 patients)
Mild	31	35	66	4.25
Moderate	6	5	11	0.71
Severe	2	3	5	0.32
No	2	2	4	0.26
Total	41	45	86	5.54

Table 13: The normal and abnormal functions of the left atrium and left ventricle for patients who have undergone point of care ultrasound echocardiography

LA and LV				
Chamber, Size, Shape and Function	Male	Female	Total	Percentage (for 1552 patients)
LA				
Shape				
Dilated	35	29	64	4.12
LV				
Shape				
"D"-shaped	1	1	2	0.13
Dilated	35	27	62	3.9
Normal	1	0	1	0.06
Function				
Adequate	7	3	10	0.64
Mild	36	23	59	3.8
Moderate	8	5	13	0.84
Severe	4	6	10	3.8
Total	125	94	219	14.11

LV: Left ventricle, LA: Left atrium

patients – (0.32%). They were to attend regular cardiology OP if they need further evaluation.[23] PTCA elsewhere done for 1 ACS[24] case that had anterior wall myocardial infarction (AWMI) lysed at COVID ICU and discharged at request. He was a teacher by occupation holding private insurance coverage. We collected information over phone. Echo showed stunning with EF 47%.

From April 2021 to March 2022, total in patients were in COVID wards 17,562. Among them, 1552 patients (8.84%) only underwent this POCUS echo, mostly on the day of admission in SARI ward and ICU itself. Among 286 Children,[25] only 15 children were screened and all were normal. Four hundred and twenty-six patients succumbed to death during that period out of 17,562 patients (2.43%). Overall mortality rate for male is 1.49% (N-263) and female is 0.93% (N-163). No children died during this period. There was a mean time to scan of 2 days from ICU admission. This information collected from database in COVID control room with the permission of Nodal Officer.

Comparison

Echocardiographic studies were recorded for 1552 patients.[26] RA and RV dysfunction [Figure 4] was identified in 77 patients (4.96%) – (M-37; F-40) [Video 4].

LV dysfunction was identified in 92 patients (5.93%) – (M-55; F-37). These results compared with Parulekar *et al.* data. Eighty-three out of 241 cases (37.7%) had RA and RV dilatation. In that study, LVSD was there in 23 cases out of 241 cases (9.5%). Our patients had lower incidence in RA, RV dilation, and LV dysfunction.

Outcome

Outcome for normal hearts was good. Hospital Stay, in Hospital Mortality and Morbidity were increased among abnormal cardiac status when comparing to normal cardiac status. We could use POCUS echo examination as a tool to quickly take a decision for treating patients. One patient with massive PE could be saved by echo diagnosis and echo-guided aspirations.

Treating physicians are comfortable when they are provided with necessary investigations. Hence, it is mandatory to do quick screening of heart by POCUS echo especially when the patient is critically ill and hemodynamically unstable.

Limitations of Study

Cardio sonology – echo technician worked only for 6 h in the morning shift. They could not examine case out of their hours. Health-care provider ward and mild COVID cases were not offered this POCUS echo facility. Duplications could not be avoided in few cases (for example, LVH can be due to aortic stenosis or hypertension). We have not studied the in hospital mortality in correlation with abnormal cardiac conditions.

CONCLUSION

A systematically applied POCUS protocol in COVID patients by a dedicated Cardiac Sonologist assisted by telemedicine [Figure 5] is the best non-invasive bed side diagnostic tool in reducing the mortality thus improving the survival in high risk COVID patients.

In both cardiac patients with COVID and COVID patients diagnosed with cardiac ailments, POCUS has made an impact in the outcome both in the mortality and morbidity. Cardiac POCUS examination by cardiac Sonology Technician supervised by a cardiologist helps the COVID-19 patients in arriving at quick diagnosis of certain cardiac conditions. It is also useful to rule out certain cardiac conditions. Any sick COVID-19 case presents with dyspnea that may not be due to lung involvement alone. Among extra pulmonary involvement, cardiac involvement of COVID in heart may be diagnosed by cardiac POCUS examination. Case management will change if life-threatening situation like cardiac tamponade is diagnosed by cardiac POCUS examination.

It will definitely have good impact on the outcome. In the pandemic situation, cardiologist can use telemedicine as a tool to diagnose abnormal cardiac conditions making use of portable echo machines with the help of cardiac sonology technicians. Further, comparative studies will show survival benefit. Being harmless, non-invasive, and reproducible procedure, cardiac POCUS can be advised as a screening tool in emergencies by a technically qualified and trained cardiac sonologist in telemedicine under supervision of cardiologist.

POCUS usefulness as an adjunctive tool in the management of COVID-19 is indispensable. The portability, availability, and the real-time nature of ultrasound provides physicians with a safe imaging modality for pulmonary, cardiac, and vascular COVID-19 manifestations. With no risk of radiation exposure, ultrasonography is beneficial when used to assess lung involvement in pregnant women. In addition, ultrasound is practical and effective for use in pregnant and pediatric COVID-19 patients.

ETHICAL APPROVAL

This study was approved by the Institutional Ethics Committee of Madurai Medical College and Government Rajaji Hospital.

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Original Article

Assessment of QTc Interval in Type 2 Diabetic Patients Asymptomatic for Cardiovascular Disease: A Cross-sectional Study in a Tertiary Care Hospital in North East India

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Abstract

Background: Diabetes mellitus is a disease of inadequate control of blood levels of glucose resulting in a group of metabolic disorders due to defects in insulin secretion, insulin action, or both. One of the common long-term complications of type 2 diabetes mellitus (T2DM) is cardiovascular disease in the form of coronary artery disease (CAD) and cardiac autonomic neuropathy (CAN). The QTc interval reflects the duration of the ventricular myocardial depolarization and repolarization and is a good indicator of cardiovascular status of the individual.

Aims and Objectives: The study aims to observe the QTc interval in patients with T2DM for early detection of cardiovascular changes, asymptomatic for cardiovascular diseases and to observe the effect of duration of disease, and glycemic control on QTc interval.

Materials and Methods: A cross-sectional study was carried out in a tertiary care hospital affiliated to a medical college situated in the North-East India among 100 T2DM patients. Detail history was taken as per the case study format. Blood samples were analyzed for glucose (fasting and postprandial) and HbA1C. Resting 12 leads that ECG was recorded and QTc interval was calculated.

Results: Statistical analysis was carried out using SPSS software 15.0 and results were statistically analyzed and correlated. $P < 0.05$ was considered significant. Mean QTc interval in T2DM patients was 495.58 ± 68.9 ms. There was a significant positive correlation between the duration of disease and QTc interval ($P = 0.032$).

Conclusion: Resting QTc abnormalities in patients with T2DM indicate the onset of cardiovascular changes which deteriorate as the disease duration increases. Regular monitoring of T2DM patients with ECG can help in the early detection of cardiovascular disease.

Key words: Cardiovascular complications, Diabetes mellitus, QTc interval

INTRODUCTION

Diabetes mellitus is a disease of inadequate control of blood levels of glucose due to insulin deficiency or resistance to insulin action or both. Type 2 diabetes mellitus (T2DM) is the most common type of diabetes affecting the metabolic pathways and consequently causes end-organ damage in multiple organ-systems of the human body.[1] Long-term complications of diabetes mellitus includes both macrovascular and microvascular complications. One of the most common complications of T2DM is cardiovascular disease.[2] Cardiovascular complications can be in the form of coronary artery disease (CAD) or cardiac autonomic neuropathy (CAN) even arrhythmias. Silent ischemia of myocardial tissue where ischemic pain is blunted is one of the major causes of mortality due to

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cardiovascular complications of type 2 diabetes.[3] CAN is associated with several variety of outcomes resulting in cardiovascular deaths[4] and is often overlooked by the physicians due to its insidious onset and not routinely being tested in diabetic clinics. Several non-invasive tests are available like cardiac autonomic reflex tests, 24 h heart rate variability, spontaneous baroreflex sensitivity, and cardiac radionucleotide imaging, but these are costly as well as time consuming.[5] The QT interval in ECG reflects the duration of the ventricular myocardial depolarization and repolarization and is a good indicator of cardiovascular status of the individual. Various studies have shown the ECG abnormalities such as prolonged corrected QT interval (QTc) in patients with T2DM. Prolongation of QTc interval has been demonstrated to be a specific indicator of CAN. Although ECG abnormalities are found in diabetic patients in different studies, very few studies are done to assess the QTc interval in type 2 diabetics in Northeastern part of India. The aim of our study is to assess the corrected QT (QTc) interval in T2DM patients who are symptomatic for cardiac disease and to find out the correlation between ECG changes and duration of disease and HbA1C level.

Objectives

The objectives of this study were as follows:

1. To study the QTc interval in patients with T2DM for the early detection of cardiovascular changes, asymptomatic for cardiovascular diseases.
2. To study the effect of duration of disease and glycemic control on QTc interval.

MATERIALS AND METHODS

A hospital-based cross-sectional study was done in adults with T2DM attending diabetes and nutritional clinic OPD of AGMC and GBP Hospital, Agartala who had no complaints of cardiovascular diseases. Ethical clearance was obtained from the Ethical Committee of AGMC and GBPH. The study subjects were evaluated by general history, clinical examination, and blood HBA1c level. Study was conducted between the periods from May 2021 to April 2022.

Total sample size – 100.

Inclusion Criteria for the Cases

The following criteria were included in the study:

1. Patients aged between 30 and 60 years.
2. Diagnosed cases of T2DM as given by the American Diabetes Association (ADA)

Patients who fulfill the following criteria for the diagnosis of diabetes mellitus:

   a. Symptoms of diabetes plus random blood glucose (RBS) concentration ≥ 11.1 mmol/l (200 mg/dL) or
   b. FBS ≥7.0 mmol/L (126 mg/dL) or
   c. HbA1c ≥6.5% or
   d. PPBS ≥ 11.1 mmol/L (200 mg/dL) during an OGTT.
3. Patients having no cardiovascular complaints.
4. Co-operative and willing to participate in the study.

Exclusion Criteria for the Cases

The following criteria were excluded from the study:

1. Already existing microvascular complications of diabetes such as retinopathy, neuropathy, and nephropathy.
2. Known cases of cardiovascular disorders such as hypertension, coronary artery disease, and congestive cardiac failure.
3. Presence of any other concomitant diseases disrupting cardiovascular homeostasis like thyroid disorders, pheochromocytoma, chronic renal failure due to any cause, respiratory disorders, and dyselectrolytemia.
4. History of smoking, alcoholism or intake of any drugs such as vasodilators, diuretics, anti-arrhythmic, beta-blockers, alpha-agonist, or alpha-blockers.
5. Those who are not willing to participate in the study.

Study Tools

- Electrocardiograph:- Model No. CARDIART 6108T
- Sphygmomanometer
- Stethoscope
- HbA1C kit
- Case study format.

Recording of ECG

Patients were made to relax comfortably in the ECG recording room. Resting ECG parameters of the patients were recorded (selected as elaborated in the sub-heading sampling procedure) only after obtaining their informed consent as per the inclusion criteria. All the variables such as name, age, and sex were noted as per the case study format. The following ECG parameter was assessed using Standardization (Calibration): 10 mm = 1 mV

QT interval – 0.39 ± 0.04 s/390 ± 40 ms
RR interval – 60-100/min
QTc interval was calculated using the formula

$$\text{QTc interval} = \frac{QT\ interval}{\sqrt{RR\ interval}}$$

Data Analysis

Data were analyzed using SPSS 15.0. *P* value was calculated to assess the significance of difference of ECG parameters. $P < 0.05$ was considered significant. Correlation between

QTc interval and HBA1c level and duration of disease had been analyzed.

RESULTS

A total of 100 T2DM patients had participated in this study. Mean HbA1C level was 9.51±2.65%. Mean QTc interval in T2DM patients was 495.58 ± 68.9 ms as mentioned in Table. 1. Correlation between HBA1c level and QTc interval was not statistically significant as shown in Figure 1. There was a significant positive correlation between the duration of disease and QTc interval ($P = 0.032$), as shown in Figure 2. Percentage of Prolong QTc interval in T2DM Patients is shown in Figure 3.

DISCUSSION

The present study included 100 known diabetic subjects who are asymptomatic for cardiovascular disease. Their blood glucose parameters were estimated and resting ECG was recorded and QTc interval was calculated in these patients to observe whether any changes were present. QTc interval was prolonged in type 2 diabetic patients. There was a positive correlation between the HbA1C level and QTc interval, but the correlation was not statistically significant. Disease duration had significant positive correlation with QTc interval ($P = 0.032$). The presence of prolonged QTc indicated onset of cardiovascular complications which deteriorated with increasing HbA1C as well as with duration of disease. Prolonged QTc interval increases the risk of ventricular arrhythmias and ventricular fibrillations.

Table 1: Electrocardiograph parameters in type 2 diabetes mellitus patients

Sample size (*n*=100)	
ECG parameter	**QTc interval (ms)**
Values	495.58±68.9

ECG: Electrocardiograph

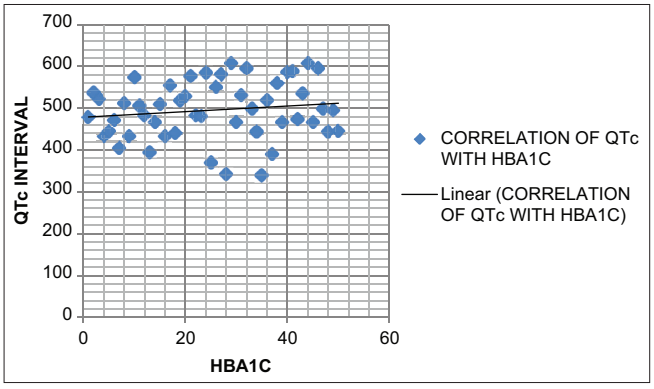

Figure 1: Correlation Graph of HbA1C with QTc interval

In a study comprising 200 patients in two referral centers in Nigeria, prolonged QTc interval was found in 25.5% cases of diabetes mellitus. The mean duration of disease in this study was 20 years.[6] Ewing *et al., in* 1991, showed in their studies that typical impairment of ECG parameters in diabetic people was in QT region of the ECG.[7] Rossing *et al.* observed in their study that QTc interval was significantly prolonged in cases of diabetes.[8] Maser *et al.* also concluded in their study that diabetic people were at increased risk of ventricular arrhythmias as indicated by prolonged QTc interval.[9] Khoharo and Halepoto, in their study, concluded that in patients with diabetes mellitus, QT_C prolongation and autonomic dysfunction are closely correlated, and QT_C prolongation is considered to be a specific sign of autonomic cardiac dysfunction and high mortality risk.[10] Prolongation of QT_C was studied by Chugh *et al.*, Nelson *et al.* individually concluded that prolonged QT_C is indeed a sign of CAN and a predictor of cardiovascular mortality in type 2 diabetes.[11,12]

Finding of all these studies supports the finding of our study. Increased blood glucose level in diabetics leads to the activation of protein kinase C, which can cause atherosclerotic changes in the blood vessels, retarding the blood flow to the myocardium. Altered blood flow can lead to ischemic damage to the myocardial cells.

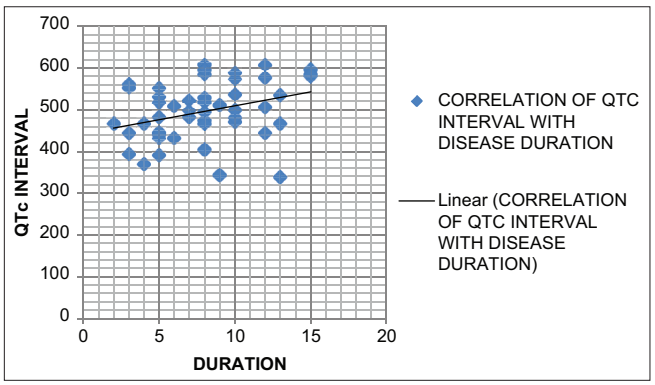

Figure 2: Correlation graph of duration of disease with QTc interval ($P = 0.03$)

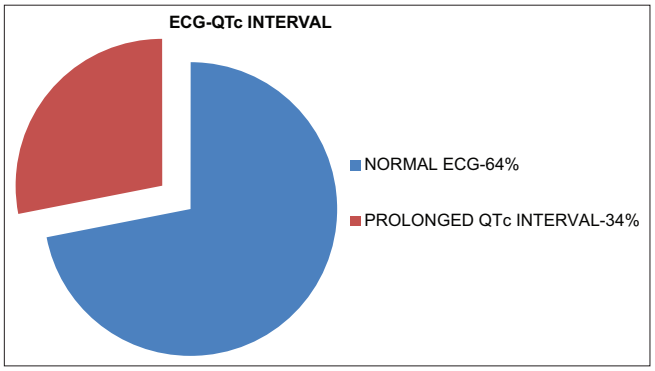

Figure 3: Pie chart representation of percentage of prolong QTc interval in type 2 diabetes mellitus patients

Microvascular and macrovascular complications are well known in diabetes mellitus. Hyperglycemia is proposed to cause end-organ damage and damage to the nerve fibers by increasing the generation of reactive oxygen species. In T2DM, hyperglycemia also leads to the formation of the advanced glycation end product (AGEs), which can cause degeneration of autonomic neurons leading to CAN. The combined effect of all these factors can lead to increased risk of cardiovascular morbidity and mortality.

The findings of our study, that is, the presence prolonged QTc interval even when the patients are asymptomatic for cardiovascular disease, emphasize on regular ECG monitoring of diabetic patients. Prompt management of diabetes and controlling HbA1c level can prevent further cardiac complications. All type 2 diabetic patients should be screened for cardiovascular changes at the time of diagnosis and regularly there after using simple 12 lead ECG recording to reduce the burden of cardiovascular morbidity and mortality.

CONCLUSION

Prolonged QTc interval in T2DM patients even in absence of any symptoms indicates development of cardiovascular disease and increased risk for cardiac arrhythmias. Regular ECG monitoring can help in screening for cardiovascular complications among those T2DM patients who are asymptomatic for cardiovascular diseases. Regular assessment of ECG parameters and maintaining strict glycemic control can delay the cardiovascular complications in asymptomatic diabetic patients.

Limitations of the Present Study

The sample size in the present study is relatively small. Furthermore, unknown and subclinical complications, which are unaccounted for, may contribute to ECG changes.

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Original Article

Complications and Outcomes of Oral Mucosa Graft Urethroplasty for Anterior Urethral Strictures

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Abstract

Objective: We present our short term experience with oral mucosa grafts, placed either dorsally or ventrally with their early and late complications.

Material and Methods: We treated 50 patients of anterior urethral stricture with buccal mucosa graft urethroplasty placed either dorsally or ventrally from May 2017 to May 2019. The graft was harvested from the cheek with patient under general anesthesia. Failure was defined postoperatively if the patient had an abnormal Micturating Cystourethrogram (MCU), need for any intervention and poor flow rate (q_{max} <15 mL/s). All the patients were followed up at 1, 3, 6, and 12 months postoperatively.

Results: Most common location of stricture observed intraoperatively was bulbar urethra (36%), followed by peno-bulbar (24%), pan-urethral (18%), penile in (14%), and penile with fossa navicularis (8%). The most common etiology of stricture urethra was iatrogenic (44%), followed by infective (24%), lichen sclerosis (22%), and idiopathic (05%). Four patients developed re-stricture out of which two had good flow after single attempt of direct visual internal urethrotomy and other two required re-surgery. Two patients had developed small urethra-cutaneous fistula which was managed conservatively. Graft donor site complication includes postoperative pain which was seen in most patients till 2nd post-operative day and was managed by good analgesia. Facial swelling was seen in 5 patients which resolved in a week and 2 patient reported restriction in mouth opening. The overall success rate of oral mucosa urethroplasty was 92%.

Conclusion: Oral mucosa graft urethroplasty has emerged as a most versatile surgical option which can treat urethral strictures of almost all etiologies and length but is associated with fewer short and long term complications. Furthermore, the site and etiology of the stricture did not have impact with the outcome of oral mucosa graft urethroplasty.

Key words: Urethral stricture, Oral mucosa graft urethroplasty, Complications

INTRODUCTION

The urethral stricture is a narrowing of the anterior urethra caused by scarring of the urethral epithelium and the spongy erectile tissue of corpus spongiosum. The main causes of urethral stricture in India are trauma, iatrogenic, inflammation, and lichen sclerosis. Buccal mucosa graft (BMG) has emerged as a reliable urethral substitute with long-term results comparable or superior to penile flaps. Although many attribute British surgeon Graham Humby.[1,2] as the first to successfully use buccal mucosa for urethral reconstruction, it was initially described by Russian urologist kirill sapezhko in 1894. The technique did not get wide acceptance until 1990s. It has become an ideal urethral substitute because of ease of harvest,[3] surgical handling characteristics, hairlessness,[4] more resistant to infection than skin, and flexible and has thin lamina propria, excellent microcirculature favorable for graft imbibition and inosculation, compatibility in a wet environment, and its early ingrowth and graft survival. Because of these unique characteristics, buccal mucosa has endeared itself to the realm of reconstructive urology. Standard urethroplasties using oral mucosa grafts have a lifetime success rate of 88–97%[5-7] as per different studies.

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Objectives

The objectvies of the study were to study the efficacy, complications and long-term outcomes of oral mucosa

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graft urethroplasty in patients suffering from anterior urethral stricture.

MATERIALS AND METHODS

After approval from the ethical committee, a prospective cohort study of 50 patients was done from May 2017 to 2019, who were diagnosed to have anterior urethral strictures that were of non- traumatic origin and required oral mucosa graft urethroplasty.

The patients with inflammatory/infective stricture of any origin, stricture more than 1 cm in length, Pan urethral stricture, patients with H/O internal urethrotomy or dilatations, lichen sclerosis were only included in the study. In all the patients, the protocol of documentation was followed and a detail history, physical examination, ultrasound, uroflowmetry, and radiological investigation such as retrograde urethrogram (RGU) and micturating cystourethrogram (MCU) [Figure 1] was done to evaluate the patient. All the patients underwent either dorsal or ventral onlay buccal mucosa graft urethroplasty (Dr. Kulkarni's technique) [Figure 2] under general anesthesia with nasal intubation. We have used the Clavien Dindo system (CDS) to grade the complications of the surgery.

Patients were followed up in terms of history, physical examination, MCU at 4 weeks in post-operative period [Figure 3], uroflowmetry at 1, 3, 6, and 12 months. Failure was defined postoperatively if anyone of the following was seen:

1. Poor flow rate (Q_{max} < 15 mL/s)
2. Abnormal MCU
3. Need for any intervention postoperatively.

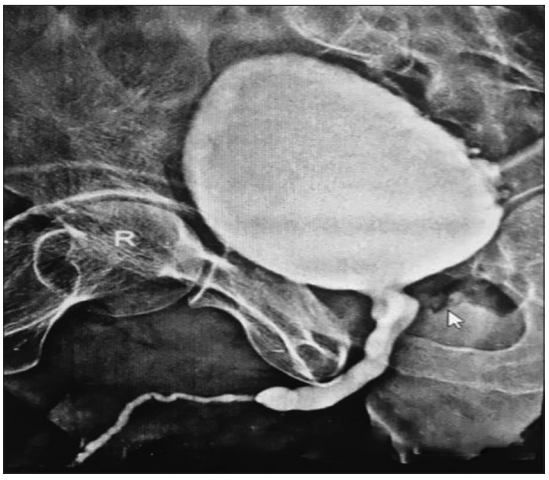

Figure 1: Micturating Cystourethrogram showing long length penile urethral stricture

RESULTS

A total of 50 patients with mean age of 36.3 years (range 23–64 years) underwent BMG urethroplasty by dorsal or ventral graft. 45 patients underwent dorsal BMG urethroplasty and 5 patients required ventral BMG urethroplasty. All the patients were followed up for a period of 1 year.

Most common location of stricture observed intraoperatively was bulbar urethra in 18 cases (36%). The most common etiology of stricture urethra [Table 1] was iatrogenic (44%), that is, either catheterization or post-transurethral resection of prostate (TURP) or instrumentation. In the case of panurethral stricture lichen sclerosis was the most common etiology.

Four patients (08%) developed re-stricture [Table 2] out of which two had good flow after single attempt of direct visual internal urethrotomy (DVIU) (CDS Grade-3b) and other two required re-surgery (CDS Grade 3b). Two patients had developed small urethra-cutaneous fistula which were managed conservatively (CDS Grade 1). Erectile dysfunction (transient) was seen in seven patients (14%), five of which responded to PDE5 inhibitors (CDS

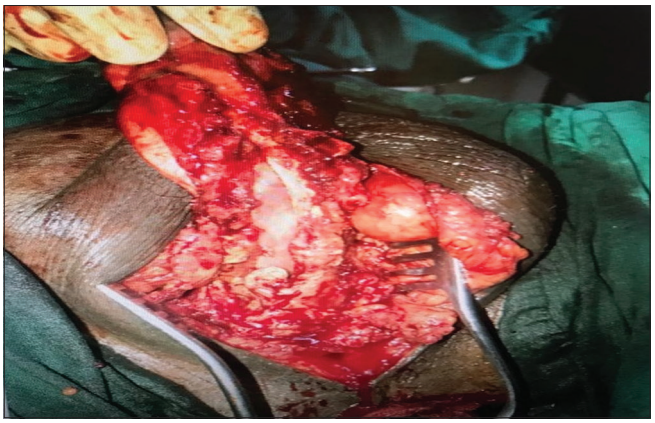

Figure 2: Buccal mucosa graft placed and urethroplasty were done

Figure 3: Post-operative retrograde urethrogram showing extravasation of contrast

Grade 1), and two had lost follow-up. Four patients (08%) developed febrile UTI which treated with culture specific antibiotics (CDS Grade 1). Wound infection (CDS Grade 1) was seen in 06 patients (12%) and was treated by giving pus culture specific antibiotics.

Graft donor site complication [Table 3] includes post-operative pain which was seen in most patients till 2nd post-operative day and was managed by good analgesia. Pain resolved in all patients within 2 weeks of surgery. Facial swelling was seen in 5 patients (10%) which resolved in a week and 2 patient (04%) reported restriction in mouth opening (CDS Grade 1). All complains were resolved in the first month of surgery. Peak urinary flow rates improved from a mean of 4.2 mL/s (range 2.1–9.7 mL/s) preoperatively to 20.2 mL/s (range 18.3–28.1 mL/s) after 1 year.

Table 1: Etiology of stricture

Serial number	Cause of stricture	Number of patients (%)
1	Iatrogenic	22 (44)
2	Infective	12 (24)
3	Idiopathic	5 (10)
4	Lichen sclerosis	11 (22)
	Total	50 (100)

Table 2: Complications of oral mucosa graft urethroplasty

Serial number	Complications Early (<4 weeks)	Number of patients (%)
1	Bleeding	0
2	Wound infection	6 (12)
3	Peri-urethral pus discharge	2 (4)
4	Urosepsis	0
5	Penile oedema	5 (10)
6	Scrotal edema	4 (8)
7	Contrast extravasation during MCU	2 (4)
8	Failure to void	0
Serial number	**Complications Late (>4 weeks)**	**Number of patients (%)**
1	UTI	4 (8)
2	Post void leak	1 (2)
3	Wound discomfort	5 (10)
4	Irritative LUTS	2 (4)
5	Stream splaying	0
6	Ejaculatory dysfunction	1 (2)
7	Erectile dysfunction	7 (14)
8	Urethro-cutaneous fistula	2 (4)
9	Recurrence	4 (8)

MCU: Micturating cystourethrogram, UTI: Urinary tract Infection, LUTS: Lower urinary tract symptoms

Table 3: Oral graft site complications

Serial number	Complication	Number of patients (%)
1	Haemorrhage	0
2	Pain	3 (6)
3	Facial swelling	5 (10)
4	Damage to stensen's duct	0
5	Paraesthesia	0
6	Restriction of mouth opening	2 (4)

DISCUSSION

There have been a myriad of different types of tissue used for the purpose of graft tissue transfer in urethral reconstructive surgery; some have been more successful than others. Oral mucosa possesses many of the ideal graft characteristics for urethral reconstruction. From a technical standpoint, it is easily harvested with minimal morbidity. In addition, its native environment is wet, similar to urethra. Buccal mucosa has endeared itself to the realm of reconstructive urology. Oral mucosa also offer an inherent resistance to lichen sclerosis.[8,9]

In the present series, buccal mucosa graft has a success rate of 92% at a follow-up of 1 year. Elliot *et al.*[9] in the year 2003 on 60 patients with a mean follow-up of 47 months reported 97% success rate after one attempt of DVIU. Kane *et al.*[6] reported a success rate of 94.3% after a mean follow-up of 25 months. Iselin and Webster in their series of 29 men reported a high early success rate of 97% after a median follow-up of 19 months.

In general, the complications are less after BMG urethroplasty in experienced hands. Post-operative complications can occur in two areas, the site of harvest and the site of urethral stricture repair. In our study, the most common complication from oral graft site was facial swelling seen in 5 patients (10%) followed by pain (6%) and restriction in mouth opening (4%). However, all these symptoms resolved within 1 month of the surgery. Facial swelling was seen in patients in whom the length of the graft required was longer. In one study by Venn and Mundy,[10] 57% of the patient had developed oral numbness after surgery, in that, in 16% the complaints tend to persist for a year. Wood *et al.*[11] reported that closure of the harvest site was associated with more pain and suggested that this may be improved by not closing when the length of the graft required is long. Although Dublin *et al.*[8,12] reported that patients did well with closure of the donor site, but 16% and 32% had long term complaints of numbness and mouth tightness, respectively. In a study by Barbagli *et al.*[13] in 2010 a prospective study of 350 patients showed that, the majority of patients (85.2%) showed no pain (49.2%) or slight pain (36%) in the immediate post-operative course, and only 3.7% of patients required use of anti-inflammatory drugs for oral pain. The majority of patients (65.8%) showed slight (41.2%) or moderate (24.6%) swelling in the immediate postoperative course, but 58.6% were able to resume a normal diet 3 days after surgery. In our study, we had left the graft site open. Overall the inner cheek harvest site for BMG regardless of the management appears to heal without complications as reported in our study.

Perineal complications are also less. In our study, six patients (12%) had wound infection which was managed by change of culture specific antibiotics. Erectile dysfunction was reported by 7 patients (14%) out of which 4 patients had some amount of erection but it was less than what they use to have earlier. It was seen in patients who had a long length of stricture and the mean age was more than 45 years. Six patients responded well to PDE5 inhibitors. Out of 7 patients 5 patient were eventually weaned off the drug by 6-9 months of surgery. One patient had lost the follow-up. Similarly Erickson and colleagues showed that patient greater than 50 years old had a higher decline in erectile function after urethroplasty. Sexual function in immediate post-operative period is poor and as the healing occurs, it tends to improve. Dogra and colleagues, in their study showed that erectile function is worst at 3 months after surgery and then recovers at pre-operative level in most patients at 6 months and then remains stable. Penile edema was seen in 5 patients (10%) and scrotal edema was seen in 4 patients (08%) and both were resolved within 10 days of surgery. Two patients had developed tiny urethro-cutaneous fistula which was managed conservatively and it was resolved by keeping suprapubic catheter for a longer time. In a study by Fichtner *et al.*[5] they reported overall complication rate of 25% (8 of 32). In a study by hosam s. al-qudah in 2005 reported complications (3% early and 18% late) after urethroplasty. While all the early complications were resolved and most (97%) were minor, less than half of the late complications were resolved, although most (82%) were minor.

CONCLUSION

Reconstruction of urethra continues to be challenging for reconstructive surgeon; oral mucosa has proved to be useful alternative to skin but it is not without minimal morbidity and complications. In experienced hands, the success of oral mucosal graft for urethroplasty is similar regardless of location of stricture. BMG has been used successfully for treating all types of strictures in anterior urethra with less donor site morbidity and fewer complications. Because of its inherent advantages oral mucosa graft has become the recommended source for tissue substitution during urethral reconstruction.

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Original Article

Implications of Neoadjuvant Chemoradiotherapy on Surgical Management of Locally Advanced Rectal Cancers

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Abstract

Background: Rectal cancer it accounts for over a third of mortality and morbidity worldwide in cancer cases. The lack of a peritoneal covering for the most part of the rectum is a major reason for the higher risk for local recurrence after primary surgical management. Pre-operative chemo radiotherapy has better remission rates compared to stand-alone surgery. With the advantage of better local control, low toxicity rates and reducing local recurrence. The study was undertaken to evaluate the implications of neoadjuvant chemoradiotherapy (NACRT) on surgical management of locally advanced rectal cancers.

Methods: This was an observational, longitudinal study in Kashmir valley over period of 28 months where patients with locally advanced rectal cancers (stage 2 [cT3-4N0M0] and stage 3 [cT1-4N1-2M0]) were subjected to NACRT for over a period of 6–8 weeks and restaging was done in all patients after a gap of 6 weeks and all patients were assessed for radiological response and a down staging of tumor was assessed before surgery. After the surgical intervention, surgical specimen was sent for histopathological response of tumor.

Results: Total number of patients in a study was 34, the maximum patients between of age 51–60 year (38.2%) females outnumbered males. We analyzed the patients for pre NACRT staging and observed that almost (44.1%) were in T3N2M0 stage followed by (35.3%) in T4N2M0 staging and (20.6%) in T3N0M0 stage. After receiving NACRT it was observed that most of the patients constituting (50%) were in T3N0M0 stage followed by (26.5%) in T2N0M0 stage, (14.7%) were in T0N0M0 stage post therapy and only (8.8%) of patients remained unchanged. We noticed (79.4%) patients were in N2 and (20.6%) patients were in N0 in pre NACRT staging. After neo adjuvant (91.2%) were in N0 stage and only (8.8%) were in N2 which means almost (71%) down-staging in N2. We observed that no patient were in T0 and T2 staging and (64.7%) and (35.3%) were, respectively, in T3 and T4 staging before NACRT. We observed that most common procedure was LAR constituting about (38.2%) followed by ultra LAR and APR equally constituting (26.5%), the rarest procedure was inter sphintric constituting about (8.8%) of cases. We observed that (14.7%) patients showed complete response while as (76.5%) showed partial pathological response and (8.8%) patients did not respond to the treatment.

Conclusion: We observed a significant down-staging of TNM classification of patients who received NACRT. There was no progression of disease during the study period and the total down-staging in T was 61.8%, in N it was 88.9%.

Key words: Neoadjuvant chemoradiotherapy staging, Neoadjuvant chemotherapy, Rectal cancer, Chemoradiotherapy

INTRODUCTION

Rectal cancer is being increasingly observed in Indian population with increase in change in diet and lifestyle habits.[1] It accounts for over a third of mortality and morbidity worldwide in cancer cases.[2] Recent studies have shown that preoperative chemoradiotherapy has better remission rates compared to stand-alone surgery. It especially has increased benefit and has become the standard of treatment for locally advanced cases of carcinoma rectum, namely, (stage 2 [cT3-4N0M0] and stage 3 [cT1-4N1-2M0]) with the advantage of better local control, low toxicity rates, and reducing local recurrence.[3]

Total mesorectal excision coupled with neoadjuvant chemo-radiotherapy is currently considered the standard treatment

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for patients with locally advanced rectal cancers (LARC). This multimodality treatment has resulted in improved local control rates, although showing no long-term survival benefits.[4-9] Various studies across literature have reported pathological downstaging and a complete pathological response rate (ypCR) of 15–27% following neoadjuvant chemoradiotherapy (NACTRT) before radical surgery.[10] This has translated into not only a superior and improved survival but also decreased locoregional and systemic recurrence. Rectal cancer accounts for 30% of all colorectal carcinoma. The use of preoperative radio chemo therapy has been used in treatment of rectal cancers for two decades and its use gradually increased especially in T3–T4 or N1-N2.[11,12] The strategy of performing preoperative instead of post-operative treatment has proven advantages of the lower acute toxicity,[13] lower total dose of radiation needed,[14] and eventually tumor regression and down staging to enable curative resection and even sphincter preservation.[15-18]

nCRT not only minimizes tumor size but goes along with the increasing tumor resection rate with a very minor side effect. nCRT is more effective than adjuvant therapy, it is associated with tumor down-staging and high rate of pathological complete response, down-staging pT and pN stage and fewer cases of venous, perineural, or lymphatic invasion, increased tumor resectability, reduction in local recurrence and decreasing toxicity.[5,19] Statistical multivariate analyses have confirmed that the response to nCRT was predictive of improved OS among the patients with locally advanced rectal cancer.[20,21]

Contrast-enhanced computed tomography abdominal pelvis and MRI pelvis was used for staging in pre and post neoadjuvant settings with MR used for loco-regional staging and the following TNM staging was used as follows.

Aims and Objectives

To evaluate the implications of NACRT on surgical management of locally advanced rectal cancers with respect to:

1. Down staging of tumor (primary and nodal)
2. Histopathological responses
3. Sphincter preservation

MATERIALS AND METHODS

This study was conducted in Postgraduate Department of General Surgery, Government Medical College Srinagar over a period of 29 months after obtaining ethical clearance from Institutional Ethical Committee.

Inclusion Criteria

The following criteria were included in the study:

- All histologically documented cases of rectal adenocarcinoma
- Locally advanced rectal cancers, that is, stage II (c T3-T4 N0 M0) and stage III (cT1 – T4 N1 – N2 M0)
- Any age group

Exclusion Criteria

The following criteria were excluded from the study:

- Stage-I rectal carcinoma
- Pregnancy
- Patients with distant metastasis
- Recurrent rectal carcinoma

Methodology

This was an observational, longitudinal study where patients with locally advanced rectal cancers were subjected to neo-adjuvant chemoradiotherapy for 25–28 cycles over a period of 6–8 weeks and restaging was done in all patients after a gap of 6 weeks and all patients were assessed for radiological, local response and a down staging of tumor was assessed before surgery. After the surgical intervention, surgical specimen was sent for histopathological response of tumor.

RESULTS

The maximum patients were between of age 51 and 60 years (38.2%) and the least number of patients belonged to < 30 years (11.8%). Females outnumbered males with 19 (55.9%) females against 15 patients (44.1%) males.

MRI down staging was taken as a standard to get the radiological response and we observed that (64.7%) and (35.3%) were in T3 and T4 staging before nCRT. However, post nCRT, we observed (50%) patients were in T3, (26.5%) in T1T2, (14.7%) T0 and (8.8%) T4 and eventually reduction of T grading was calculated. Total 22 patients were in T3 in Pre nCRT downgraded to T1T2 (7) patients and T0 (5) patients. Total 12 patients were in T4 in Pre nCRT downgraded to T3 (7) patients, T1T2 (2) patients, and 3 patients remained in T4. Hence, 61.8% downgrading was seen in T stage, clearly there was no progression of tumor staging in patients statistically significant. We noticed (79.4%) patients were in N2 and (20.6%) patients were in N0 in pre nCRT staging. After nCRT (91.2%) were in N0 stage and only (8.8%) were in N2, which means 24 out of 27 who were in N2 stage downgraded into N0 and which means almost (88.9%) downgrading in nodal staging. There was no progression of nodal staging with significant statistical difference.

Mesorectal fascia (MRF) involvement on MRI was taken one of the radiological modality to assess the response of nCRT. Out of 34 patients 16 patients had involvement of MRF (47.1%), rest of the patients were not involving the MRF. After receiving the neoadjuvant MRF involvement

was reassessed and following results were shown. Out of 16 patients, 12 patients had shown response which is nearly (75%) down staging, only four patients who did not show any down grading there was no progression of disease during the study period. We analyzed pre nCRT and post nCRT MRF involvement in association with histopathological MRF and observed that there is a significant difference between pre nCRT MRF and histopathological MRF involvement because out of 16 Pre nCRT MRF cases no one had histopathological MRF involvement. 16 patients were recorded with anal verge distance <4 cm and 18 patients were observed with anal verge distance >4 cm. There were 16 patients who fall in low rectal tumors distance from anal verge was <4 cm.

After receiving the nCRT tumor response for low rectal tumors was assessed on DRE and following findings were taken. There were three patients (18.8%) who had no palpable mass on DRE, 9 patients had tethered growth (56.3%) and 4 patients showed no response had fixed growth. Among 8 patients who had fixed growth, 4 changed into tethered growth, 4 remained unchanged. Among 8 patients who had tethered growth 3 patients showed complete response 5 remained unchanged. Total downstaging was 43.8%, there was no progression of disease during the study period. Pathological response of concurrent nCRT was taken from histopathological report of surgical specimen of a patient. Mandrad grading was used for pathological response, we observed that (14.7%) patients showed TRG1 (complete response), (76.5%) showed TRG2, TRG3, and TRG4 partial response, respectively. Only three patients out of 34 showed (TRG5) no response 8.8%.

Patients who have undergone APR have external sphincter involvement and intersphincteric space involvement (pre-nCRT). Out of 9 patients who underwent APR, in pre-nCRT 5 patients have T3N2M0, 3 patient have T4N2M0, and 1 patient had T3N0M0. Other factors were taken into consideration such as age, anal tone, surgeons choice, and patients consent. Three patients underwent intersphincteric resections, in pre-nCRT 1 patient was T3N0M0, 1 patient T4N2M0, and 1 patient T3N2M0. After nCRT 1 T3N0M0, another patient T1/T2 N0M0, 1 patient showed complete response T0N0M0 [Tables 1-4].

DISCUSSION

In this present study on implications of neo-adjuvant chemoradiotherapy on locally advanced rectal cancers, we observed that mean age of patients who qualified the inclusion criteria of the study was (47.8 ± 14.51) years. The maximum number of patients belonged to the age interval of (51–60) years. In the same kind of study, Laishram *et al.*[22] reported the maximum number of patients was in the age interval of (60–69) years and Ibrahim *et al.*[23] observed that maximum number of patients were below 40 years of age. However, Vinay and Vybhav[24] reported that most of the patients were in between (30 and 60) years of age. Out of the total of 34 patients included in the study we observe that almost (56%) were females and rest were males, similar kind of gender distribution was reported by Vinay and Vybhav[24] but contrary to this Laishram *et al.*[22] and Ibrahim *et al.*[23] reported that maximum number of cases were males. We analyzed the patients for pre nCRT staging and observed that almost (44.1%) were in T3N2M0 stage followed by (35.3%) in T4N2M0 staging and (20.6%) in T3N0M0 stage. All the patients who received the nCRT, clinical staging was done by local examination, colonoscopy/sigmoidoscopy and MRI pelvis was done. All the patients who have even complete response on imaging principally on MRI were operated. Surgery was done according to the local regional response, but final response of tumor was taken from histopathological specimen using TNM staging. After receiving nCRT it was observed that most of the patients constituting (50%) were in T3N0M0 stage followed by (26.5%) in T2N0M0 stage, (14.7%) were in T0N0M0 stage post therapy and only 3 patients remained unchanged constituting (8.8%) which was pre nCRT, clearly there was a down-staging in each stage post nCRT. In our study, we observed reduction in both T and N staging after nCRT, we noticed (79.4%) patients were in N2 and (20.6%) patients were in N0 in pre nCRT staging. After neoadjuvant (91.2%) was in N0 stage and only (8.8%) was in N2 which means almost (71%) down-staging in N2. There was no progression of nodal staging in any patient with a significant nodal response ($P < 0.001$). We also analyzed in our study that in pre nCRT there was no patient with T0 and T2 staging and (64.7%) and (35.3%) were, respectively, in T3 and T4 staging. However, post nCRT, we observed (14.7%) in T0, (26.5%) in T2, (50%) in T3, and (8.8%) were in T4 staging. Evidently, a reduction of (14.7%) in T3 stage and (18.2%) reduction in T4 stage after nCRT. Wen *et al.*[25] reported in their study that after nCRT, T stage decreased in almost (73%) of cases, increased in (2.4%) and remained unchanged in (24.8%); they also noticed that N stage also decreased in (55%), increased in (6.2%) cases and remained unchanged in 20 patients. In the same way, Vinay and Vybhav[24] observed a significant decrement in T and N staging after nCRT. Abdalla *et al.*[26] reported overall down-staging in (86.11%) in their study, similarly Rashid *et al.*[27] reported down staging in (56.7%) of cases while as a study from Duke's university revealed a down-staging in (82%) of cases almost compatible with our findings. We analyzed the distribution type of surgeries performed according to the local regional tumor status and distance of tumor from anal verge; we observed that most common

procedure was LAR constituting about (38.2%) followed by ultra LAR and APR equally constituting (26.5%), the rarest procedure was inter sphintric constituting about (8.8%) of cases. Gerard *et al.*[28] conducted a study on improved sphincter preservation in low rectal cancer with high dose of pre-operative radiotherapy and observed that most of the patients who underwent sphincter-preserving surgery for low rectal cancer have good post-operative sphincter function but almost (20%) will be more or less incontinent not only for flatus and loose stool but also for solid stool In a study conducted by Mark *et al.*,[29] observed that out of 140 patients who underwent for nCRT, 46 cases underwent sphincter-preserving surgery LAR. In a study conducted by Vinay and Vybhav,[24] it was observed that 19 out of 33 underwent sphincter preserving LAR procedure and 8 cases were reportedly performed by AR, 3 patients underwent APR. In our study, we analyzed the patients with respect to pathological response and observed that (14.7%) showed complete response while as (76.5%) showed partial pathological response, and (8.8%) patients did not respond to the treatment. In a study conducted by Yu *et al.*,[30] it was observed that out of 105 patients 13 (12.38%) almost similar to our observation. Dunst *et al.*[31] reported the (7%) complete response rate post neoadjuvant therapy while as in a similar kind of study by Rashid *et al.*[27] (3.3%) complete response rate was observed. However, in another likewise study by Sinukumar *et al.*[32] (61%) complete pathological response was observed. Some studies have reported an improved in survival rate[22,33,34] in patients with pathological down staging and post-operative chemotherapy while others are of the opinion that adjuvant chemotherapy be administered only in residual nodal disease patients.[35]

The present study investigated the effect of nCRT in terms of MRF involvement using magnetic resonance induction (MRI). Even though MRI is known to be highly accurate in predicting the involvement of the MRF at primary staging[36,37] but the assessment on post nCRT is more difficult because of the presence of fibrosis. We observed that 16 patients constituting (47.1%) had MRF involvement before nCRT. However, post nCRT it reduced to about (75%), that is, 11 out of 16 showed no MRF involvement and interestingly there was a strong statistical significant difference between pre nCRT MRF involvement and histopathological MRF involvement because out of 16 Pre nCRT MRF cases no one had histopathological MRF involvement. Only around (11.8%) did not show down grading. In a study conducted by Syed Nadeem *et al.*,[38] it was observed on initial staging MRI examination that eight out of 64 patients had advanced T3 tumors with a tumor close to the MRF, 31 had T3 tumors with MRF invasion, and 25 patients had T4 tumors (organ invasion). We compared pre nCRT involvement with histopathological MRF involvement and observed that there is a strong

Table 1 : Patient characteristics

Patient characteristics	Number of patients (%)
Age (years)	
≤30	4 (11.8)
31–40	7 (20.6)
41–50	5 (14.7)
51–60	13 (38.2)
>60	5 (14.7)
Mean±SD (range)	47.8±14.51 (24–80)
Gender	
Male	15 (44.1)
Female	19 (55.9)
Pre-nCRT staging	
T3N0M0	7 (20.6)
T3N2M0	15 (44.1)
T4N2M0	12 (35.3)
Post-nCRT staging	
T0N0M0	5 (14.7)
T1/T2N0M0	9 (26.5)
T3N0M0	17 (50.0)
T4N2M0	3 (8.8)

SD: Standard deviation, nCRT: Neoadjuvant chemoradiotherapy

Table 2: Comparison based on T-staging and nodal staging before and after nCRT

Patient characteristics	Pre nCRT, *n* (%)	Post nCRT, *n* (%)	*P*
T-staging			
T0	0	5 (14.7)	0.002*
T1/T2	0	9 (26.5)	
T3	22 (64.7)	17 (50.0)	
T4	12 (35.3)	3 (8.8)	
Nodal staging			
N0	7 (20.6)	31 (91.2)	<0.001*
N2	27 (79.4)	3 (8.8)	

nCRT: Neoadjuvant chemoradiotherapy

Table 3: Mesorectal fascia involvement; pre-nCRT, post-nCRT, and histopathology

MRF involvement	Pre-nCRT, *n* (%)	Post-nCRT, *n* (%)	Histopathological MRF involvement, *n* (%)
Yes	16 (47.1)	4 (11.8)	0
No	18 (52.9)	30 (88.2)	34 (100)
Total	34 (100)	34 (100)	34 (100)
P	Pre-nCRT MRF involvement versus histopathological MRF involvement <0.001 (statistically significant)		

MRF: Mesorectal fascia, nCRT: Neoadjuvant chemoradiotherapy

Table 4: Pathological response and type of surgery

Patient characteristics	Number of patients (%)
Pathological response	
Complete response	5 (14.7)
Partial response	26 (76.5)
No response	3 (8.8)
Type of surgery	
Ultra LAR	9 (26.5)
LAR	13 (38.2)
APR	9 (26.5)
Inter sphinteric	3 (8.8)

LAR: Low anterior resection, APR: Abdomino-perineal resection

statistical significant difference between pre nCRT MRF and histopathological MRF involvement because out of 16 Pre nCRT MRF cases no one had histopathological MRF involvement.

In the current study, we observed that around (47.10%) had low rectal tumor distance (<4 cm) from anal verge and rest had >4 cm. Before subjecting patients for neoadjuvant, we performed DRE in all patients and it was observed that (50%) of patients had fixed growth while as (50%) had tethered growth. On post nCRT, tumor response for low rectal tumors was assessed on DRE whereby we observed that (18.8%) had no palpable mass, (56.3%) had tethered growth, and rest (25%) had fixed growth. Overall, there was (43.8%) down staging and no progression of disease was observed during the study period. In a similar kind of study due to Vinay and Vybhav,[24] patients were evaluated with respect to any novel growth on DRE, it was observed that around (87%) patients did not had any growth and (6%) of patients including two (02) patients died during the 3 months follow-up period. They reported that in one patient, there was no change in the preoperative period and mass was felt per rectum on examination.

CONCLUSION

In the present study, we observed a significant down-staging of TNM classification of patients who received nCRT. Due to this significant response we performed various types of surgeries and then evaluated the pathological responses. The most common pathological response was partial response constituting 77% followed by 15% with complete response. There was no progression of disease during the study period and the total down-staging in T was 61.8%, in N it was 88.9% (radiological response on MRI).

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Original Article

Comparing the Effects of Dexmedetomidine and Clonidine as Adjuvants to Ropivacaine Delivered Epidurally on Analgesic and Sedative Effects and To See If Dexmedetomidine and Clonidine Have Any Side Effects When Given Epidurally

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Abstract

Background: The effects of dexmedetomidine and clonidine as adjuvants to ropivacaine delivered epidurally on analgesic and sedative effects and any side effects when given epidurally.

Aim: A comparative study to compare the effects of dexmedetomidine and clonidine as adjuvants to ropivacaine delivered epidurally on analgesic and sedative effects. To see if dexmedetomidine and clonidine have any side effects when given epidurally.

Methods: After obtaining institutional ethical committee approval and informed consent, a total number of 100 patients were planned for the lower abdominal and lower limb surgeries. All 100 patients were randomly divided into two groups: Group RD and Group RC. Group RD (n = 50): Will receive epidural study solution of 17 mL of 0.75% ropivacaine + 1.5 μg/kg dexmedetomidine. Group RC (n = 50): Will receive epidural study solution of 17 mL of 0.75% ropivacaine + 2 μg/kg clonidine.

Results: In our study, we compare: 1. Onset of sensory block, 2. maximum level of sensory blockade, 3. time to attain maximum sensory level, 4. time to complete motor blockade, 5. time for two-segment regression, 6. duration of analgesia, 7. duration of motor block, 8. post-operative pain, and 9. grading of sedation. There was statistically significant quick onset of sensory block in patients of Group RD when compared with patients of Group RC (P < 0.0001). There statistically significant increase duration of analgesia in patients of Group RD when compared with patients of Group RC (P < 0.0001). This study indicating that the RD group receiving Ropivacaine with Dexmedetomidine has an early onset of analgesia and post-operative block prolonged significantly compared to RC group receiving ropivacaine with clonidine.

Conclusion: Our study demonstrated that 0.75% of ropivacaine with dexmedetomidine (1.5 mcg/kg body weight) is better adjuvant when administered epidurally compared to Clonidine (2 mcg/kg body weight), showing significantly longer duration of sensory and motor block with better intraoperative sedation and prolonged post-operative analgesia.

Key words: Ropivacaine, Dexmedetomidine, Clonidine, Duration of sensory and motor block, Sedation and analgesia

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INTRODUCTION

Regional anesthesia is the safest and most cost-effective option and is the technique of choice for post-operative analgesia. Epidural anesthesia offers several advantages, including the ability to provide anesthesia for lengthy periods of time with many top-ups, as well

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as being the favored approach for giving great post-operative analgesia. inj. Morphine, inj. Fentanyl, inj. Ketamine and α-2 agonists such as inj. Clonidine and inj. Dexmedetomidine, all of these drugs provide the patients with long lasting anaesthesia and analgesia, as well as great sedation, forgetfulness and anxiety relief while maintaining adequate hemodynamic stability. Dexmedetomidine is a highly selective agonist for the α-2 adrenergic receptor, with an affinity 8 times that of clonidine. When taken in the epidural route, the dose of clonidine is 1.5–2 times larger than dexmedetomidine. A prospective and clinical study was planned at our institution with the goal of comparing the efficacy and clinical profile of two alpha-2 adrenergic agonists, clonidine, and dexmedetomidine when used as adjuvants in epidural anesthesia in patients undergoing lower abdominal and lower limb surgeries, with a focus on their sedative effects and their ability to provide smooth intraoperative and post-operative analgesia.

Aims and Objectives of Study

The objectives of the study are as follows: To compare the effects of dexmedetomidine and clonidine as adjuvants to ropivacaine delivered epidurally on analgesic and sedative effects. To see if dexmedetomidine and clonidine have any side effects when given epidurally.

MATERIALS AND METHODS

Source of Data

This study was conducted in the Department of Anesthesia, Guntur Medical College, from January 2020 to December 2021 in Government General Hospital, Guntur. This study was approved by the Local Ethical Committee. The protocol of the study was reviewed and approved by Dr. NTR University of Health Sciences.

Methods of Collection Data

After obtaining institutional ethical committee approval and informed consent, a total number of 100 patients were planned for the lower abdominal and lower limb surgeries. All 100 patients were randomly divided into two groups: Group RD and Group RC.

- Group RD (n = 50): Will receive epidural study solution of 17 mL of 0.75% ropivacaine + 1.5 μg/kg dexmedetomidine.
- Group RC (n = 50): Will receive epidural study solution of 17 mL of 0.75% ropivacaine + 2 μg/kg clonidine.

The following block characteristics has to be observed and recorded:

1. Onset of sensory block
2. Maximum level of sensory blockade
3. Time to attain maximum sensory level
4. Time to complete motor blockade:
5. Time for two-segment regression
6. Duration of analgesia
7. Duration of motor block
8. Post-operative pain
9. Grading of sedation.

Inclusion Criteria

The following criteria were included in the study:

1. Age group - 18–60 years both male and female
2. Weight 30-80 kgs
3. ASA Grade 1 and 2
4. Patients who give informed valid consent
5. Patients who are Scheduled to undergo various lower abdominal and lower limb surgical procedures under epidural anesthesia.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients not willing to be a part of the study
- Patients having local skin infection along lumbar spine, spinal deformity, chronic backache, headache, drug addiction, neurological deficit, bleeding/clotting disorder, cardiovascular disease, and systemic metabolic disorders such as severe hepatic or renal disease were excluded from the study
- Cesarean sections.

Methodology

- One hundred ASA-I and II patients undergoing lower abdominal and lower limb surgeries under epidural anesthesia were selected.
- A day before the procedure, a pre-anesthetic examination was performed.
- Patients were checked for systemic illnesses and laboratory tests were taken.
- Patients were informed about the epidural anesthetic procedure and taken informed and signed consent.
- Overnight fasting was part of the patients' preparation.
- Tab.Rantac 150 mg and Tab.Anxit 0.5 mg H.S. were given to the patients as a premedication.

Procedure

With an 18G Tuohy needle, a test dosage of 3 mL of 2% of lignocaine hydrochloride solution containing adrenaline 1:2,00,000 was injected into the epidural space after placing the catheter 3–4 cm into the epidural space.

- Group RC receives 17 mL of 0.75% of ropivacaine with 2 mcg clonidine/kg
- Group RD: Receives 17 mL of 0.75% of ropivacaine with 1.5 mcg dexmedetomidine/kg body weight.

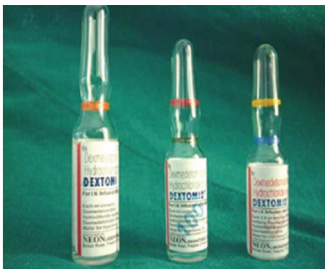
Modified Bromage Scale and Ramsay Sedation Scale for Sedation Score Was Used

Time of onset of sensory block level at T10, peak sensory block level, motor block level, intensity of motor block, and duration of analgesia was recorded.

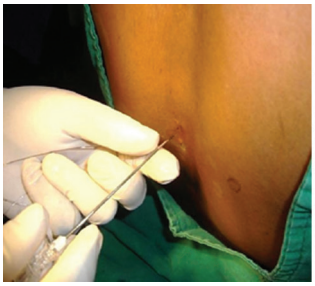
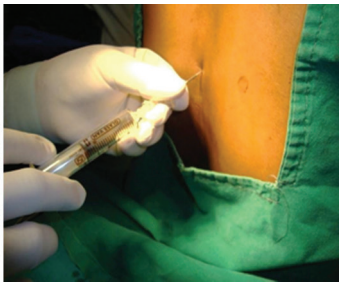
- Heart rate (HR), blood pressure (BP), and oxygen saturation (SPO2) were continually monitored, with recordings made every 5 min for 10 min, then every 10 min for 30 min, then every 15 min for 60 min, and lastly every 20 min for 120 min.
- Comparison of post-operative block characteristics
  1) Mean time to 2 segment regression
  2) Duration of motor block
  3) Mean time sensory regression to L2
  4) Complete motor recovery.

Any adverse effects, such as hypotension (defined as a drop in systolic arterial pressure of more than 20% mmHg), were observed and treated with inj. Ephedrine 6 mg in bolus doses caused bradycardia (heart rate <50 bpm), was treated with 0.6 mg inj. Atropine.

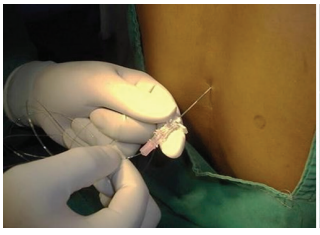
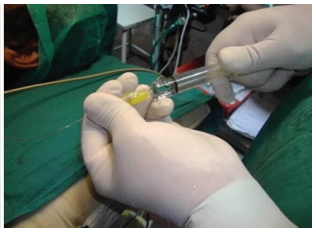
Drugs



Epidural Needle Insertion and Loss of Resistance Method

Epidural Catheter Insertion and Drugs Injection

RESULTS

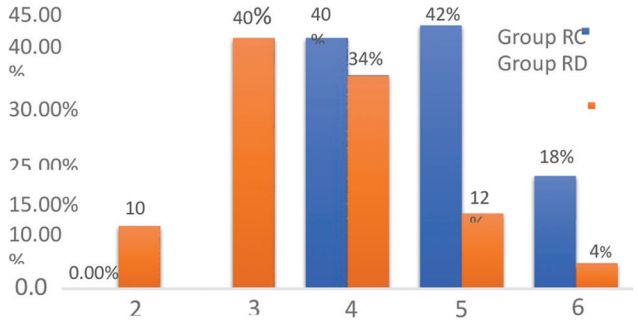
Age Distribution

Age group – 18–60 years both males and females.

ASA Status

ASA Grades I and II patients were selected.

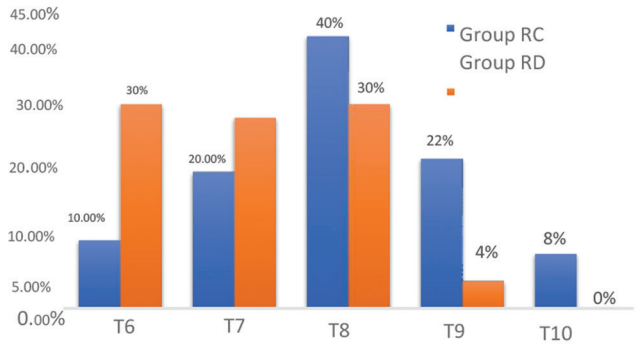
Onset of Sensory Block in min



S. No.	Group RC		Group RD		Total	
	N	%	N	%	N	%
1	0	0.0	5	10	5	5
2	0	0.0	20	40	20	20
3	20	40	17	34	37	37
4	21	42	6	12	27	27
5	9	18	2	4	11	11
Total	50	100.0	50	100.0	100	100

Chi square test = 38.03, $P \leq 0.0001$*, statistically significant

Maximum Level of Sensory Blockade



	Group RC		Group RD		Total	
	N	%	N	%	N	%
T6	5	10	15	30	20	20
T7	10	20	18	28	28	28
T8	20	40	15	30	35	35
T9	11	22	2	4	13	13
T10	4	8	0	0.0	4	4
Total	50	100	50	100	100	100

Chi-square test = 18.23, $P \leq 0.0001$*, statistically significant

Time to Maximum Sensory Block in min

	Group RC	Group RD	*T* value	*P* value
Time to maximum sensory block	14.80±1.73	10.86±1.24	13.08	<0.0001*

Onset of Motor Blockade

	Group RC		Group RD		Total	
	N	%	N	%	N	%
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	1	2	1	1
5	0	0	16	32	16	16
6	21	42	20	40	41	41
8	29	58	10	20	39	39
10	0	0	2	4	2	2
12	0	0	1	2	1	1
Total	50	100	50	100	100	100

Chi-square test = 29.28, *P* = 0.0001*, statistically significant

Time to Complete Motor Block in min

	Group RC	Group RD	*T* value	*P* value
Time to Complete motor block	19.78±3.62	15.34±4.15	5.70	<0.0001*

Duration of Motor Block in min

	Group RC	Group RD	*T* value	*P* value
Duration of motor block	300.60±8.42	389.80±8.68	52.15	<0.0001*

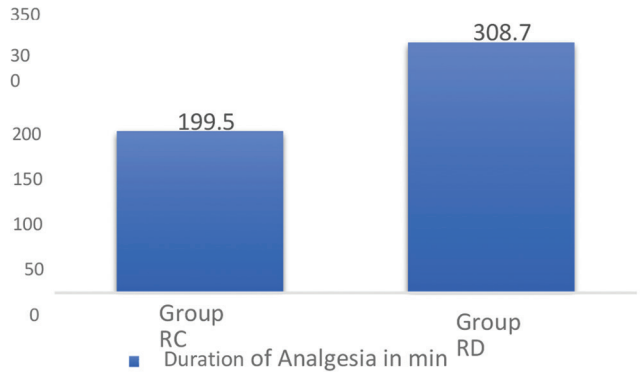
Quality of Motor Blockade

	Group RC		Group RD		Total	
	N	%	N	%	N	%
	50	100	50	100	100	100
Total	50	100	50	100	100	100

Complete Motor Recovery

	Group RC	Group RD	*T* value	*P* value
Complete motor recovery	164.35±13.32	168.82±12.10	1.57	0.12

Duration of Analgesia



	Group RC	Group RD	*T* value	*P* value
Duration of Analgesia in min	199.5±8.15	308.7±10.74	51.22	<0.0001*

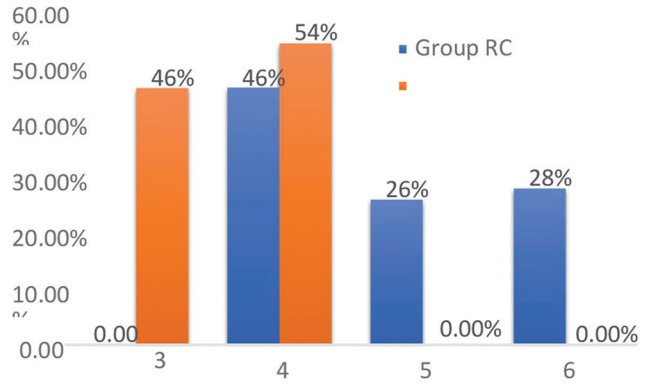
Two Segment Regression

	Group RC	Group RD	*T* value	*P* value
Two segment regression	69.25±7.30	96.75±10.71	13.41	<0.0001*

Sensory Regression to L2 Level

	Group RC	Group RD	*T* value	*P* value
Sensory regression to L2	127.55±1.60	149.87±3.19	39.55	<0.0001*

VAS



	Group RC		Group RD		Total	
	N	%	N	%	N	%
3	0	0.0	23	46	23	23
4	23	46	27	54	50	50
5	13	26	0	0.0	13	13
6	14	28	0	0.0	14	14
Total	50	100.0	50	100.0	80	100
Mean±SD	5.03±0.83		3.68±0.47			

Chi-square test = 50.32, *P* ≤ 0.0001*, statistically significant

Complications

	Group RC		Group RD		Total	
	N	%	N	%	N	%
Bradycardia	2	4%	1	2%	3	3%
Hypotension	2	4%	3	6%	5	5%
Nausea, Vomiting	2	4%	3	6%	5	5%

Chi-square test = 0.66, *P* = 0.71, Not statistically significant

DISCUSSION

Epidural anesthesia is one of the most useful and versatile procedure in modern anesthesiology. It is better than spinal anesthesia, giving the opportunity to provide analgesia and anesthesia. It can be used to supplement general anesthesia, to maintain hemodynamic stability and reduces the drugs needed in general anesthesia.

It may be combined with regional anesthesia or other forms of general anesthesia. It can provide intraoperative hemodynamic stability and has been proven to reduce perioperative stress response thus causing a decrease in the complications and help in improving patient outcome. It also helps in early mobilization of the patient by providing relief to post-operative pain and decreases the incidence of thromboembolic events.

Epidural anesthesia is widely regarded as a boon for patients as it provides pain relief for prolonged duration with top-ups and continuous infusion through epidural catheter thus providing an uneventful and smooth recovery.

Ropivacaine has increasingly replaced Bupivacaine because of its similar analgesic properties, lesser motor blockade, and decreased propensity of cardio toxicity. An adjuvant added to ropivacaine help in reduction of the local anesthetic dose and also enhance the effectiveness of local anesthetics by intensifying and prolonging the blockade. The overall response to α-2 agonists is related to the stimulation of α-2 receptors located in brain and spinal cord causing sedation, sympatholytic, and anti-nociception.

Clonidine is an α-2 adrenergic agonist. Clonidine has antihypertensive action and the ability to augment the effects of local anesthetics. Dexmedetomidine is an alpha-2 adrenergic agonist related pharmacologically to clonidine, approved by FDA in 1999. Initially it is used for analgesia and sedation in ICU. IV Dexmedetomidine is used to attenuate hemodynamic response to laryngoscopy. It is selective alpha-2 agonist and has 8 times more affinity than clonidine. The receptor binding selectivity of dexmedetomidine and clonidine is 1:1620 and 1:220, respectively. A prospective study was done among 100 patients underwent lower abdominal and lower limb surgeries.

All the 100 patients were randomly categorized into two study groups:

- Group RD: 50 patients received epidural study solution of 17 mL of 0.75% Ropivacaine + 1.5 μg/kg dexmedetomidine
- Group RC: 50 patients received epidural study solution of 17 mL of 0.75% Ropivacaine + 2 μg/kg clonidine

In the present study, majority of patients (28%) belong to age group of 51–60 years followed by 26% of patients belong to age group of 31–40 years, 24% of patients belong to age group of 41–50 years, and 22% of patients belong to age group of 18–30 years in group RC with mean age of 40.25 ± 11.48 years. Majority of patients (30%) belong to age group of 41–50 years followed by 26% of patients each belong to age group of 18–30 years and 31–40 years and 18% of patients belong to age group of 51–60 years in group RD with mean age of 36.55 ± 10.60 years. There was no statistically significant ($P = 0.66$).

In the present study, majority of patients (42%) had onset of sensory block in 5 min followed by 40% of patients had onset of sensory block in 4 min and 18% of patients had onset of sensory block in 6 min in Group RC. Majority of patients (40%) had onset of sensory block in 3 min followed by 34% of patients had onset of sensory block in 4 min, 12% of patients had onset of sensory block in 5 min, 10% of patients had onset of sensory block in 2 min, and 4% of patients had onset of sensory block in 6 min. There was statistically significant quick onset of sensory block in patients of Group RD when compared with patients of Group RC ($P < 0.0001$).

In the present study, majority of patients (40%) achieved maximum level of T8 block followed by 22% of patients had T9, 20% of patients had T7, 10% of patients had T6 and 8% of patients had T10 block maximum in Group RC. Majority of patients (30%) achieved maximum level of T6 and T8 block each, 28% of patients achieved maximum level of T7 block and 4% of patients had maximum of T9 block. There was statistically significant ($P < 0.0001$).

In the present study, the mean duration of analgesia in patients of Group RC was 199.5 ± 8.15 min whereas the mean duration of analgesia in patients of Group RD was 308.7 ± 10.74 min. There statistically significant increase duration of analgesia in patients of Group RD when compared with patients of Group RC ($P < 0.0001$).

Duration of analgesia compared with the previous studies

S. No.	Study	Group RC	Group RD
1	Present study	199.5±8.15 min	308.7±10.74 min
2	Bajwa *et al*.[1]	310.76±23.76 min	342.88±29.16 min
3	Rastogi *et al*.[2]	216.58±25.56 min	429.25±90.44 min
4	Krishnappa *et al*.[3]	269.20±51.61 min	303.20±48.65 min
5	Varsha *et al*.[4]	365.68±12.72 min	434.70±24.51 min
6	Shah *et al*.[5]	283.5±5.58 min	374.30±6.79 min

CONCLUSION

The aim of our study is to compare the effects of dexmedetomidine and clonidine as adjuvants to ropivacaine delivered epidurally on analgesic and sedative effects and to see if dexmedetomidine and clonidine have any side effects when given epidurally.

One hundred patients underwent lower abdominal and lower limb surgeries satisfying inclusion and exclusion criteria. All the 100 patients were randomly categorized into two study groups of 50 each. Group RD having 50 patients

received epidural study solution of 17 mL of 0.75% ropivacaine + 1.5 μg/kg dexmedetomidine. Group RC having 50 patients received epidural study solution of 17 mL of 0.75% ropivacaine + 2 μg/kg clonidine.

Our study concluded that the RD group receiving ropivacaine with dexmedetomidine has an early onset of analgesia and post-operative block prolonged significantly compared to RC group receiving ropivacaine with clonidine.

Our study showed that there was statistically significant higher sedation in Group RD when compared with RC between 30 min and 90 min. This study concluded that intraoperative hemodynamics showed no much difference in both groups.

In conclusion, 0.75% of ropivacaine with dexmedetomidine (1.5 mcg/kg body weight) is a better adjuvant when administered epidurally compared to clonidine (2 mcg/kg body weight), showing significantly longer duration of sensory and motor block, with better intraoperative sedation and prolonged post-operative analgesia.

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