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Original Article

Comparison of Steroid Injection and Platelet-rich Plasma Injection in the Treatment of Chronic Plantar Fasciitis

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Abstract

Objective: The aim of this study was to evaluate the therapeutic effect of corticosteroid injections and platelet-rich plasma (PRP) injections in the treatment of chronic plantar fasciitis. **Materials and Methods:** The study group comprised 50 patients divided into two equal groups. In the corticosteroid group (Group A; *n* = 25), 2 ml of methylprednisolone (40 mg/ml) was injected along with 1 ml of 0.5% bupivacaine. In the PRP group (Group B; *n* = 25), PRP was obtained from the patients' blood and injected in a single dose. Peppering technique was used for injecting the doses in both the groups. Results were calculated using pre-injection and post-injection visual analog scale (VAS), America orthopedic foot and ankle society (AOFAS), and foot and ankle disability index (FADI). **Results:** All patients enrolled in the study completed a 3 months follow-up. There were no complaints of any side effects to the administered corticosteroid or PRP. No infection or any other complications were reported at the end of 3 months. The outcome between the 2 groups was comparable in terms of VAS, AOFAS, and FADI scores. **Conclusion:** PRP therapy proves to be more effective in relieving pain than corticosteroid injections in the treatment of plantar fasciitis.

Key words: Corticosteroid, Growth factor, Heel pain, Plantar fasciitis, Platelet-rich plasma

INTRODUCTION

Plantar fasciitis is the most common cause of heel pain in orthopedic practice. A typical patient complains of sharp pain along the heel that is maximum on taking the first step in the morning and also after periods of rest.[1] It is most commonly seen in the age group of 40–60 years with equal sex preponderance.[2] The underlying pathological process that leads to plantar fasciitis is essentially a degenerative condition with myxoid degeneration, collagen necrosis, and angiofibroblastic hyperplasia.[3-5]

A large number of treatment options have been considered in treating plantar fasciitis including nonsteroidal anti-inflammatory drugs (NSAIDs), physiotherapy, ultrasonic therapy, plantar fascia stretching exercises, modified footwear, customized insoles, and also extracorporeal shock-wave therapy. Corticosteroid injections locally have also been used over the past. Recently, platelet-rich plasma (PRP) injections have also been used with promising results.[6-8]

The purpose of this study was to evaluate the therapeutic effect of corticosteroid injections and PRP injections in the treatment of chronic plantar fasciitis.

MATERIALS AND METHODS

The present retrospective study includes 50 consecutive patients diagnosed with chronic plantar fasciitis between December 2016 and September 2017. The diagnosis was done clinically by the same orthopedic team as characteristic heel pain lasting for more than a period of 6 months, localized along the medial aspect of the heel. All the patients had symptoms non-responsive or recurrence of symptoms following conservative and physical therapy. Patients with previous history of fracture or surgery on the affected heel,

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those with previous history of steroid injections, infections or systemic diseases, arthritis, radiculopathy, and patients on anti-platelet medication and oral steroids were excluded from the study. All patients were instructed to stop taking NSAIDs 3 weeks before the procedure.

Patients were randomly divided into two groups. The study was explained to every patient, and informed consent was obtained from them before the procedure. Patients in Group A were administered steroids whereas in Group B were subjected to PRP therapy. The procedure was performed in the operative room under all sterile aseptic precautions. The patient was made to lie prone with the heel hanging from the ankle on the inferior end of the table. The injection area was cleaned with Povidone-iodine and normal saline.

In Group A, a 22-gauge needle connected to a 5 cc syringe containing 2 ml of methylprednisolone (40 mg/ml) with 1 ml of 0.5% bupivacaine was prepared. The maximally tender spot on the medial heel was identified by palpation. The injection was done using the peppering technique, where multiple punctures were done on the plantar fascia.

In Group B, 30 ml of patients' blood was withdrawn and inserted into pre-packed PRP kits (Tricell) along with 5 ml of anticoagulant 10% sodium citrate. The PRP sample was prepared by a double centrifugation process. The first centrifuge was done at 3200 rpm for 4 min. The cellular component was separated from the fluid component and a second centrifuge was them performed at 3300 rpm for 3 min. Following this, approximately 3–4 ml was obtained. The injection was done with the same peppering technique.

After the procedure, all patients were advised non-weight bearing for the first 48 h and gradual return to activities after 1 week of the procedure. Ice fomentation on the injection site was encouraged, and patients were advised to wear comfortable footwear.

Pre-procedure and on final follow-up, patients were assessed for their symptoms using visual analog scale (VAS), America Orthopedic Foot and Ankle Society (AOFAS), and foot and ankle disability index (FADI).

RESULTS

The present study included 50 patients equally divided into two groups. The mean age of patients in Group A was 43.16 years and in Group B was 44.44 years. Group A had 9 males and 16 females, whereas Group B comprised 11 males and 14 females, comprising a total of 20 males (40%) and 30 females (60%). In Group A, the right heel was affected in 11 patients whereas the left heel was affected in 14 patients, whereas in Group B, the right heel was involved in 13 patients and the left heel was involved in 12 patients, comprising a total right heel involvement in 23 patients (46%) and left heel involvement in 27 patients (54%). Table 1 illustrates the demographic distribution of the patients in this study.

At the end of 3 months follow-up, 3 patients from Group A and 2 patients from Group B were lost to follow-up. There were no complaints of any side effects to the administered corticosteroid or PRP. No infection or any other complications were reported at the end of 3 months. An important fact to note that while all patients in Group B showed a steady decline in symptoms, 3 patients from Group A showed initial improvement in the first 4 weeks, and then later on the symptoms showed recurrence, however, not as debilitating as in pre-procedure records.

Figures 1-3 compare the pre-procedure and post-procedure records of VAS, AOFAS, and FADI scores.

DISCUSSION

The present study aimed to compare the efficacy of corticosteroid versus PRP in the treatment of chronic plantar fasciitis. In our study, we found significant differences between both groups relative to VAS, AOFAS, and FADI scores before and 3 months after treatment.

Table 1: Demographic distribution of patients

Group A (Corticosteroid)			Group B (PRP)		
Age (years)	Sex	Side affected	Age (years)	Sex	Side affected
35	F	Left	42	F	Right
41	F	Left	44	M	Left
45	M	Right	47	F	Right
46	F	Left	40	M	Left
39	M	Right	48	F	Right
52	F	Left	38	M	Left
39	M	Right	40	F	Right
44	M	Left	44	M	Right
49	F	Left	48	F	Right
42	F	Right	46	M	Left
43	F	Left	42	F	Left
40	M	Right	46	M	Right
50	F	Left	45	M	Right
42	F	Right	45	F	Left
48	M	Right	45	F	Right
42	F	Left	48	F	Left
39	F	Left	42	M	Right
44	M	Right	40	F	Left
46	M	Left	39	F	Right
32	F	Right	51	M	Left
45	F	Left	45	M	Right
48	M	Right	50	F	Right
47	F	Left	45	F	Left
41	F	Left	49	F	Left
40	F	Right	42	M	Left

PRP: Platelet-rich plasma

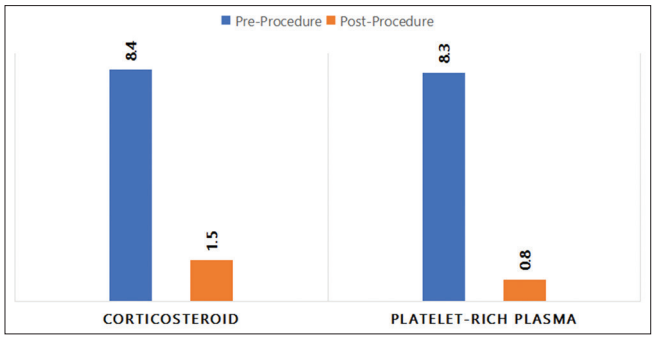

Figure 1: Comparison of pre-procedure and post-procedure visual analog scale scores

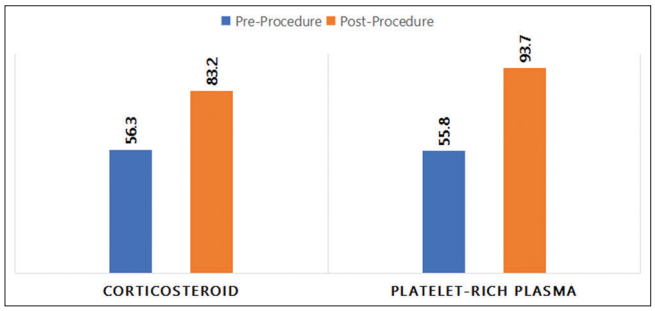

Figure 2: Comparison of pre-procedure and post-procedure America Orthopedic Foot and Ankle Society scores

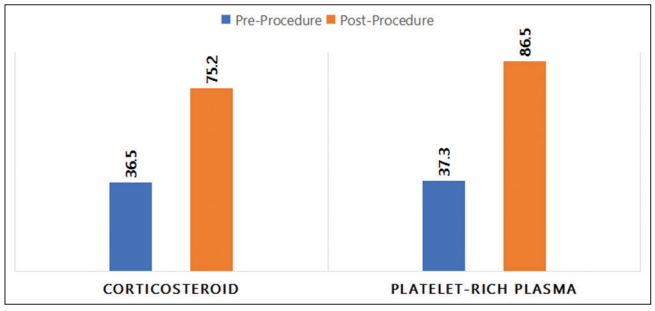

Figure 3: Comparison of pre-procedure and post-procedure foot and ankle disability index scores

The etiopathology of plantar fasciitis is debatable; histologic findings have suggested an etiology of degenerative changes, subsequent to repetitive microtrauma due to overuse injuries causing subsequent micro-tears and degeneration.[9-11] In a study performed by Lemont *et al.*, the authors termed this condition as plantar fasciosis, suggesting it to be a degenerative process rather than an inflammatory one with micro-tears and necrosis of the plantar fascia.[12] Snider *et al.* performed histological examinations of specimens obtained from the affected plantar tissue, wherein no inflammatory markers were found, rather it was significant for degenerative changes in terms of necrosis, metaplastic changes, and dystrophic calcification.[13]

Corticosteroid injections have been in use for a long time in treating plantar fasciitis. In a study performed by Saba and El-Sherif they found corticosteroid injections to be an effective method for treating plantar fasciitis with significant symptomatic relief at 4 weeks follow-up.[14] Similar results were seen in a study performed by McMillan *et al.*, where dexamethasone was shown to have good treatment response when compared to the placebo group at 4 weeks follow-up. However, at 12 weeks follow-up, to significant difference was seen in both corticosteroid and control groups.[15] This is consistent with the study performed by Tatli and Kapasi, where corticosteroid was found to have a high frequency of recurrence and relapse.[16] A more serious complication associated with the use of corticosteroids is that steroids may predispose the tissue to fragility and subsequent rupture. In a study performed by Acevedo and Beskin, they studied a total of 765 patients with plantar fasciitis. From these, 51 patients suffered a rupture of the plantar fascia and 44 of these were directly attributed to corticosteroid injection.[17]

PRP has been used to treat plantar fasciitis over the past decade. PRP, being rich in growth factors and platelets, has been hypothesized to help in the healing of the plantar tissue.[18-21] Martinelli *et al.* performed a study on 14 patients diagnosed with chronic plantar fasciitis treated with ultrasound-guided PRP having significant improvement in their symptoms.[22] A similar study was performed by Ragab and Othman, where ultrasound-guided PRP was found to be effective in treating plantar fasciitis.[23] Many have argued the use of ultrasound guidance for delivering PRP to the target tissue in plantar fasciitis. However, in a study performed by Kane *et al.*, no significant difference was seen in the results of ultrasound-guided versus palpation method for treatment of plantar fasciitis with PRP.[24]

Muto *et al.* performed a study on the effect of PRP and corticosteroids on human rotator-cuff derived cells. In their study, they showed that while PRP and corticosteroids both show a progressive decrease in inflammatory markers on the target tissue, corticosteroids have shown to have an increase in degenerative markers in contrast to PRP which shows a decrease in the degenerative markers on the target tissue.[25] This may explain the predisposition of corticosteroids to rupture of the plantar fascia and also to recurrence of symptoms. Treatment with PRP has not known to have any significant long-term complications nor incidences of relapse or recurrences.

In our study, 3 patients from the corticosteroid group had given a history of recurrence of symptoms 4 weeks after the procedure. This could be consistent with the findings of Muto *et al.*, with a subsequent increase in the degenerative markers and decrease in overall therapeutic effect.

Our study had a few limitations. First, we did not have a control group. Peppering technique was used to administer

corticosteroids as well as PRP to the target tissue; hence, the response obtained could be attributed to the technique itself. We did not use ultrasound guidance to administer the injections; hence, we were not aware of the pre-procedure thickness of the plantar fascia. Hence, there were no definite guidelines to the dose of the steroid to be administered. With the use or PFP, we did not measure the pre-centrifuge and post-centrifuge platelet concentration in any of the samples; hence, no standard dose of administration could be quantified. Furthermore, our study had a short follow-up period of 3 months. Hence, the long-term effects therapeutic effect, as well as the drawbacks of the therapy, could not be studied. Another notifiable drawback of our study was the exclusion of patients previously treated with corticosteroids. It has been long argued whether patients refractory to corticosteroids can be treated with PRP injections, but such patients were excluded from our study.

CONCLUSION

Although limited by many factors, our study showed that corticosteroid and PRP both have a significant therapeutic effect in treating plantar fasciitis; however, PRP has been proven to be superior to corticosteroid. Our study design could be useful in larger clinical trials to determine the long-term potency and comparison among the two treatment modalities.

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Original Article

Comparison of the Efficacy of Topical Natamycin 5% and Fluconazole 0.3% Eye Drop Therapy versus Topical Natamycin 5% Alone in Deep Fungal Keratitis in Garhwal Region of Uttarakhand, India

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Abstract

Aims: The study aims to compare the efficacy of topical natamycin 5% and fluconazole 0.3% eye drop therapy versus topical natamycin 5% alone in deep fungal keratitis.

Study Design: A prospective, randomized, clinical study was conducted on patients.

Place and Duration of Study: This study was conducted at the Department of Ophthalmology, VCGS Government Medical College, Srinagar, Uttarakhand, between October 2017 and September 2018.

Materials and Methods: This study included two groups of 50 patients each. 50 patients in Group 1 were randomly started on combined therapy of natamycin 5% and fluconazole 0.3% and another 50 patients in Group 2 were randomly started on just natamycin 5% drops. Response to the therapy was recorded after a minimum of 10–14 days on the parameters of healing, efficacious, or inefficacious, and the results were compared.

Results: In the group receiving combined therapy of natamycin 5% and fluconazole 0.3%, that is, Group 1: 21 of 50 patients were healed (42%), 20 of 50 patients showed treatment efficacy (40%), and 9 of 50 patients showed inefficacious results to the therapy (18%), whereas in the group receiving monotherapy with natamycin 5% alone, that is, Group 2: Three patients of 50 were healed (6%), 14 of 50 patients showed treatment efficacy (28%), and 33 of 50 patients had inefficacious results (66%). Overall, efficacy rate when compared of both the groups had $P < 0.0001$, indicating significant results of Group 1, that is, patients receiving combined therapy.

Conclusion: After the comparison of the data in both the groups, the patients started on combined therapy of topical natamycin 5% and fluconazole 0.3% showed better response to therapy ($P < 0.0001$) as compared to the patients started on natamycin 5% alone therapy, indicating that combined therapy is better as compared to monotherapy with just natamycin 5% drops.

Key words: Fluconazole, Fungal keratitis, Healing ulcer, Natamycin

INTRODUCTION

The first case of fungal corneal ulcer was reported by Leber, in 1879. This keratomycosis was caused by *Aspergillus glaucus*.[1] Since then, the ophthalmologists and microbiologists have realized the importance of fungal infections in relation to cornea. In fact, keratomycosis constitutes up to one-third to half of the suppurative keratitis in tropical parts of the world.[2] In spite of increasing awareness and recognition during the past 20 years, keratomycosis still remains a diagnostic and therapeutic challenge to the ophthalmologists.

It is due to awareness, better recognition, and improved laboratory diagnostic technique, the correct diagnosis of keratomycosis has increased. Srinivasan *et al*.[3] reported the

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highest incidence (up to 51.9%) fungal infections among all culture-positive corneal ulcer patients. This high prevalence of keratomycosis in South India is significantly higher than found in similar studies in Nepal (17%), Bangladesh (36%), and South Florida (35%).[2,3]

The epidemiological pattern of keratomycosis varies significantly from country to country, and even from region to region within the same country. It is also climate specific. At least 70 different types of fungi have been identified as causative agent of keratomycosis.[4]

In tropical and subtropical countries, filamentary fungi predominate. *Candida* species, however, is a part of indigenous human flora and is present worldwide. Its relative frequency as a cause of keratomycosis is increasing in the temperate zone.[5]

During the past 15 years, there has been a major change in the outlook for fungal infections of the cornea. In any suppurative keratitis, corneal scraping followed by simple potassium hydroxide (KOH) mount preparation is a simple way to diagnose keratomycosis early. Newer antifungal agents with relatively low toxicity are now available to treat keratomycosis more effectively. Emphasis should be given on preventive aspect and early diagnosis. Better understanding of pathogenic mechanisms in corneal inflammation will help further advancement in treating these difficult cases in future.

In recent decade, the incidence of fungal keratitis in Uttarakhand has shown an increase with *Fusarium* sp. and *Aspergillus* sp. as major pathogens.[6] This is probably a result of the hilly terrain and vegetation of this area, leading to high rate of vegetative trauma. Medicine administration seldom yields to a desirable efficacy against fungal keratitis. Moreover, delayed diagnosis and treatment worsens the severity of this disease and increase difficulty of treatment, leading to a poor efficacy, a high rate of blindness, and even loss of eyeball.

Combined use of medicines has been frequently adopted to elevate their antifungal activity.

Hence, the present study compares the efficacy of the combined therapy of natamycin and fluconazole eye drops versus natamycin alone in the treatment of deep fungal keratitis.

MATERIALS AND METHODS

This prospective, randomized, and clinical study was conducted on patients attending the eye OPD of VCSG Government Medical College, Srinagar, Uttarakhand, India, during October 2017–September 2018.

A total of 100 patients with severe form of deep fungal keratitis were studied and patients were divided into two groups.

- Group-1: Comprised 50 patients receiving combined therapy of natamycin 5% and fluconazole 0.3% eye drops 1 hourly 12 times a day for 10–14 days.
- Group-2: Comprised 50 patients receiving monotherapy of natamycin 5% eye drops 1 hourly 12 times a day for 10–14 days.

Informed consent was obtained from all participants. Sampling was performed at the ulcer base, observed with a microscope (KOH examination), and samples were subjected to fungal culture.

Grading of Keratitis

Based on the depth of corneal inflammation infiltration, size of the ulcer, and hypopyon, the keratitis was graded into severe and non-severe types.

In non-severe type, the ulcer inflammation infiltrated into shallow and medium layers, <2/3 of stroma thickness, and ulcer diameter <6 mm.

In severe type, corneal ulcer inflammation infiltrated into deep layer, >2/3 of corneal thickness or full-thickness cornea, ulcer diameter >6 mm, and complicated hypopyon.

Treatment Method

All patients in Group 1 received combined use of 5% natamycin and 0.3% fluconazole eye drops, once per hour, and patients in Group 2 received 5% natamycin also once per hour. During the first administration, fluconazole was initially given and 15 min later, natamycin was delivered, allowing for sufficient time for the natamycin to adhere to the ulcer surface. The drops were administered once an hour, 12–13 times daily. Atropine was also given for mydriasis as necessary in both the groups. The patients also took oral itraconazole 100 mg twice a day. All the patients followed a treatment course for 10–14 days and surgical methods if necessary were considered and timely performed.

Efficacy Evaluation

Healing

Corneal ulcer was healed, negative for fluorescein dye, stromal inflammation infiltration was basically recovered, scar formation was evident, and hypopyon was absorbed.

Efficacious

Corneal ulcer or inflammation was alleviated and hypopyon was decreased or completely absorbed.

Inefficacious

Corneal inflammation remained the same or was aggravated, no changes in hypopyon, deteriorated corneal

ulcer, and corneal perforation were evident.

RESULTS

Laboratory Examination

Direct smears were obtained from all 100 patients in the study and were observed under microscope (KOH examination). Of these, 90 cases were positive for fungal hyphae (positive rate 90%) and 10 were negative. However, these 10 cases were positive for fungal culture and fungal growth was noted. The fungal species identified were as follows: 56 cases of *Aspergillus* spp. (56 %), 24 cases were of *Fusarium* spp. (24%), 10 cases were of *Curvularia* spp. (10%), 5 cases were of *Helminthosporium gramineum* (5%), 3 cases were of *Penicillium* (3%), and rest were not identified.

Treatment Results

The treatment results are demonstrated by the given self-explanatory tables and graphs. $P < 0.05$ was considered statistically significant.

Age

As shown in the Table 1 – The mean age of patients put on combined therapy(Group 1) was 57.87+_14.84 and mean age of patients receiving monotherapy was 53.28+_14.19 (p=0.121)

Sex

Regarding laterality of gender as in Table 2. Group 1 had 34 male and 16 female patients whereas group 2 had 32 males and 18 female patients.

Healing

As shown in Table 3 -21 patients in group 1 were healed whereas only 3 patients in group 2 were actually healed (p<0.0001)

Efficacy

Regarding Efficacy 20 patients in group 1 showed signs of treatment efficacy according to Table 4 whereas 14 patients in group 2 showed signs of efficacy.(p=0.071)

Inefficacy

Regarding Inefficacy only 9 patients in group 1 showed inefficacious results (Table 5) whereas its number was 33 in the group 2 showing significant results.(p<0.0001)

Overall Efficacy

Overall per cent efficacy was way better in group 1 (82%) as compared to group 2 (17%) as shown in Table 6.(p<0.0001)

DISCUSSION

Recent studies conducted in Uttarakhand region of India indicated that the incidence of fungal keratitis by *Aspergillus* spp. and *Fusarium* spp. has constantly increased in the past decade.[6] The hilly mountain terrain of this region and occupation of local people are a chief factor contributing to this high incidence in this region. The incidence of fungal infection will be significantly higher compared to other regions if scanty attention was paid to public and individual

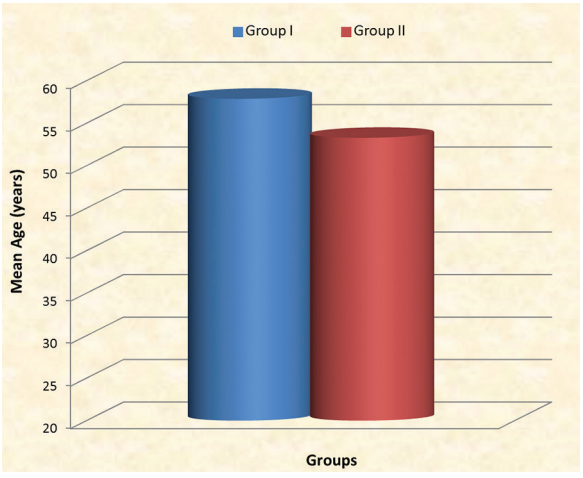
Table 1: Group comparison for the age of patients

Groups	Age of patients (mean±SD)
Group 1	57.87±14.84
Group 2	53.28±14.19
P	0.121

Group 1: Patients receiving combined therapy of 5% natamycin and 0.3% fluconazole eye drops. Group 2: Patients receiving 5% natamycin alone.
SD: Standard deviation

Table 2: Group comparison of patients according to sex

Sex distribution	Number of patients (%)	
	Group 1	Group 2
Male	34 (68.0)	32 (64.0)
Female	16 (32.0)	18 (36.0)
P	0.554	



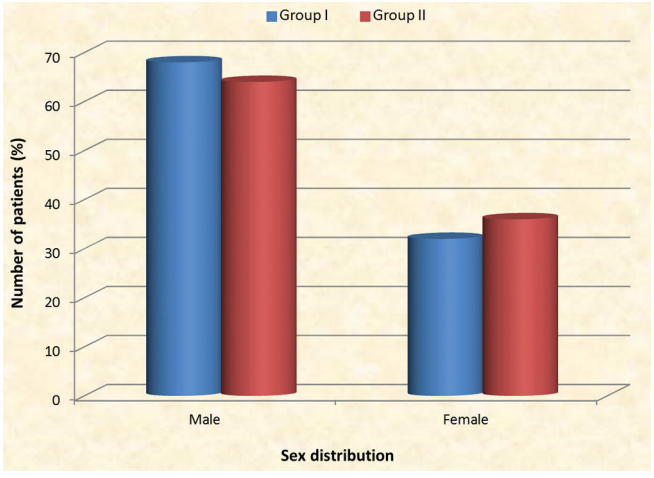


Table 3: Group comparison of patients according to healing

Healing	Number of patients (%)	
	Group 1	Group 2
Yes	21 (42.0)	3 (6.0)
No	29 (58.0)	47 (94.0)
P	<0.0001	

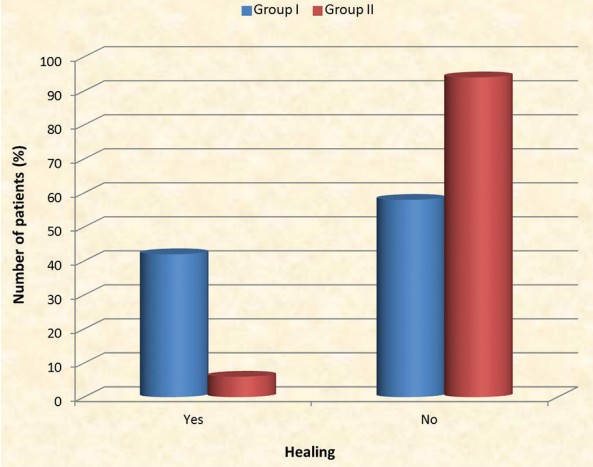


Table 4: Group comparison of patients according to efficacious

Efficacious	Number of patients (%)	
	Group 1	Group 2
Yes	20 (40.0)	14 (28.0)
No	30 (60.0)	36 (72.0)
P	0.071	

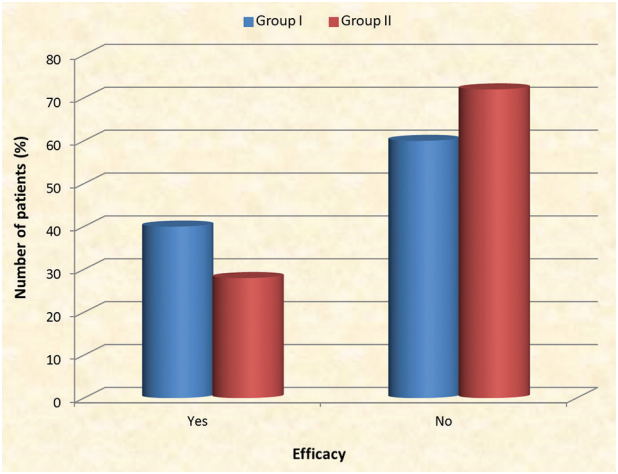


Table 5: Group comparison of patients according to inefficacious

Inefficacious	Number of patients (%)	
	Group 1	Group 2
Yes	9 (18.0)	33 (66.0)
No	41 (82.0)	17 (34.0)
P	<0.0001	

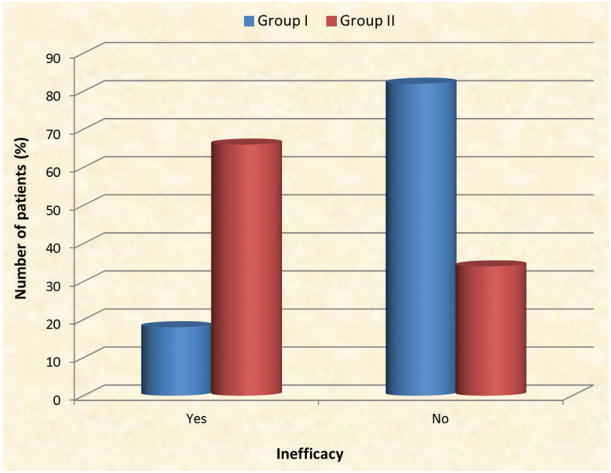
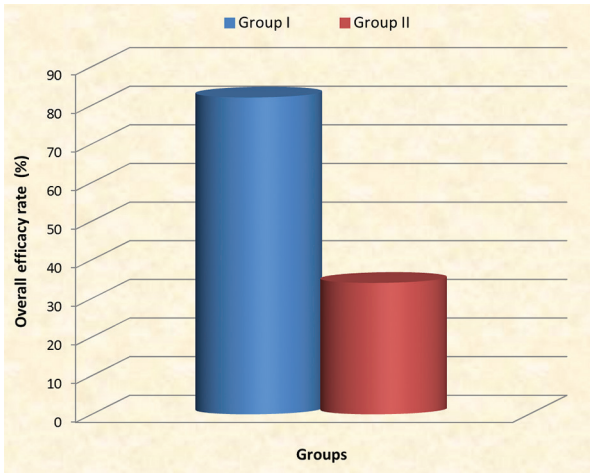


Table 6: Group comparison of patients according to overall efficacy

Overall efficacy	Number of patients (%)	
	Group 1	Group 2
Healing	21 (42.0)	3 (6.0)
Efficacious	20 (40.0)	14 (28.0)
Overall	41 (82.0)	17 (34.0)
P	<0.0001	



hygiene. The number of cases in this study was 56 of 100 of *Aspergillus* spp. and 24 cases of 100 of *Fusarium* spp. Rest were of *Curvularia*, *Penicillium,* and *Helminthosporium* spp. However, the ranking of alternative pathogenic fungi changes and species of infectious fungi become intricate.

At present, administration of topical ocular drops serves as the primary treatment for fungal keratitis and the medicine used must be highly efficacious and yield low toxicity. Previously, amphotericin B was frequently applied for the treatment of fungal keratitis, but it is gradually substituted

by natamycin due to high toxicity and other limiting factors.[7] Natamycin acts as a broad-spectrum antifungal agent against *Candida*, *Fusarium*, *Curvularia, Penicillium,* etc.

The sensitivity of *Fusarium* toward natamycin was as high as 93.4%.[8] Natamycin eye drops are stable and cause no irritation or toxicity. Similar to amphotericin B, natamycin has poor penetration into corneal epithelia. However, the injured epithelial layer in patients with fungal keratitis provides access to the medicine molecular penetration. In addition, the binding between natamycin and corneal tissues prolongs the contact time, reduces the dilution effect of conjunctival sac tears,[7] and increases the antifungal concentration of natamycin within the cornea. Since the majority of cases have severe fungal keratitis, the use of 5% natamycin and 0.3% fluconazole is combined with the aim of improving antifungal efficacy and minimizing the incidence of drug resistance.

Komdima *et al*. reported that the application of natamycin in combination with ketoconazole is efficacious for Aspergillus keratitis in an animal experiment. It has been suggested that the combined use of natamycin and econazole eye drops yields neither additive nor toxic effects.[9] The cure rate of amphotericin B combined with fluconazole is reported to range from 81% to 88.9%.[10]

In the present study, natamycin and fluconazole eye drops were selected due to lower toxicity compared with amphotericin B. In addition, natamycin is highly sensitive toward mycelia fungi, especially *Fusarium* and *Aspergillus*.[11] Furthermore, fluconazole is effective against a variety of *Candida* and infiltrates into the deep corneal layer and anterior chamber. These advantages collectively enhance the treatment efficacy of deep fungal keratitis. Clinical observation in this study revealed efficacy rate of 82% for combined therapy and no toxic responses were noted. Sun *et al.* utilized 5% natamycin eye drops alone to treat deep keratitis after debridement. The achieved cure rates were 71% and 43%,[12] smaller than achieved in previous studies. The combined use of two medicines is likely to have additive effect rather than antagonistic effects. In addition, the combined therapy of natamycin and fluconazole is an efficacious treatment against *Fusarium*, *Aspergillus,* and *Penicillium*-induced keratitis.

In Uttarakhand, the incidence of fungal keratitis is constantly increasing, mainly attacking peasants. Most cases are correlated with ocular trauma of various degrees. In the study, most of the cases of deep keratitis were associated with delayed treatment. The combined therapy of 5% natamycin and 0.3% fluconazole was significantly efficacious for the patients of deep keratitis, and this therapy is highly recommended for rapid control of corneal fungal infections (including filamentous fungi and yeast-like fungi) and increasing cure rate of fungal keratitis.

CONCLUSION

The present study concludes that the treatment efficacy of the combined therapy of natamycin 5% eye drops and fluconazole 0.3% (overall efficacy rate of 82%) and ($P < 0.0001$) is better than the monotherapy with natamycin 5% alone (overall efficacy rate of 33%). This is due to the ability of fluconazole to penetrate into the deeper corneal layers as compared to natamycin which acts at a more superficial layer of cornea. Combined therapy, hence, provides an additive effect or rather a synergistic effect rather than a monotherapy with natamycin alone.

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Original Article

Study on Role of Imaging Modalities in the Diagnosis of Abdominal Tuberculosis in a Tertiary Care Hospital of Bihar

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Abstract

Objective: The objective of this study was as follows: (1) To find the role of various investigation modalities in diagnosing abdominal tuberculosis and (2) to compare ultrasonography and computed tomography (CT) scan findings in abdominal tuberculosis.

Materials and Methods: This study was a prospective descriptive study and has been done in 1 year during October 2006–September 2007 in the Department of Radio Diagnosis, Indira Gandhi Institute of Medical Sciences, Patna. 55 adult patients of clinically suspected abdominal tuberculosis were included in this study. After consent detailed history and physical examination, routine investigation was done. Followed by X-ray abdomen, ultrasonography (USG) and CT scan abdomen, ascitic fluid examination, and fine-needle aspiration cytology from abdominal lymph node were done. Sometimes, endoscopy was done to rule out other disease conditions.

Results: Of all 55 patients, 42 were diagnosed as abdominal tuberculosis by combining several investigation modalities. USG and CT abdomen were more sensitive modalities in detecting abdominal lymphadenopathy and ascites. CT was equally or more accurate than USG in identifying abnormalities of abdominal tuberculosis except bowel dilatation.

Key words: Abdominal lymphadenopathy, Abdominal tuberculosis, Ascites, Computed tomography scan, Ultrasonography

INTRODUCTION

Tuberculosis is one of the most common and prevalent diseases in our country. According to annual report TB India 2017, India accounts for one-fourth of the global TB burden.[1] Resurgence of the disease has been found since the HIV epidemic and rise in immunocompromised host. The pattern of tuberculosis has been changed in the recent years. According to Mukewar *et al*., the abdominal TB not so common as pulmonary TB, and it can be a source of significant morbidity and mortality and is usually diagnosed late due to its non-specific clinical presentation.[2] It can mimic most gastrointestinal disease including inflammatory bowel disease, malabsorption syndrome, and colonic cancer.

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Radiological investigations are the mainstay in the diagnosis of abdominal tuberculosis. Conventional X-ray imaging including barium study plays a very limited role, especially if bowel itself is involved. Ultrasonography (USG) and computed tomography (CT) scanning are very useful investigating tool these days. The present study was carried out to assess the value of imaging, especially USG and CT scan of abdomen in the diagnosis of the abdominal tuberculosis.

MATERIALS AND METHODS

This study was a prospective descriptive study and has been done in 1 year during October 2006–September 2007 in the Department of Radio Diagnosis, Indira Gandhi Institute of Medical Sciences, Patna, referred patients from Gastroenterology and General Medicine. This study was done as part of DNB thesis. 55 adult patients of clinically suspected

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Table 1: Demographic profile of the patients of abdominal tuberculosis

Age group in years	Males	Females	Total (% of cases)
	Number (% of cases)	Number (% of cases)	
≤19	03 (7.1)	07 (16.7)	10 (23.8)
20–29	09 (21.4)	06 (14.3)	15 (35.7)
30–39	02 (4.8)	03 (7.1)	05 (11.9)
40–49	07 (16.7)	03 (7.1)	10 (23.8)
>50	01 (2.4)	01 (2.4)	02 (4.8)
Total	22 (52.4)	20 (47.6)	42

Age and sex distribution of the patients

Table 2: Distribution of the patients of abdominal tuberculosis according to symptoms

Symptoms	Number of patients (%) (*n*=42)
Anorexia and weight loss	31 (73.8)
Fever	21 (66.7)
Abdominal pain	24 (57.1)
Abdominal distension	22 (52.4)
Malaise and lethargy	20 (47.6)
Diarrhea	11 (26.2)
Diarrhea alt. constipation	04 (9.5)
Subacute intestinal obstruction	02 (4.76)
Occasional bleeding with stool	02 (4.76)

*Multiple symptoms were present in most of the patients

Table 3: Findings of chest radiographs of the patients of abdominal tuberculosis

CXR findings	Number of patients (%) (*n*=42)
Normal	30 (71.4)
Abnormal	12 (28.6)
Consolidation	07 (16.7)
Pleural effusion	05 (11.9)
Unilateral hilar lymph nodes	03 (7.1)
Pleural thickening	02 (4.7)
Fibrocavitary lesion	02 (4.7)
Calcified nodule	01 (2.4)
Fibrosis	01 (2.4)

*Multiple abnormalities were present in most of the patients. All the patients in the study underwent X-ray chest examination. 12 (28.6%) patients among the abdominal tuberculosis patient showed chest X-ray features suggestive of active or healed pulmonary tuberculosis

abdominal tuberculosis were included in this study. After consent detailed history and physical examination, routine investigation was done. These patients were then investigated in systematic stepwise manner. Moreover, accordingly, patients were subjected for X-ray abdomen, USG and CT scan abdomen, ascitic fluid examination, and fine-needle aspiration cytology from abdominal lymph node. Sometimes, endoscopy was done to rule out other disease conditions.

Inclusion Criteria

The following cases were included in the study:

1. Clinically suspected cases of abdominal tuberculosis presenting with varying combination of clinical features.
2. Both male and female.

Table 4: Findings of barium contrast studies of the patients of abdominal tuberculosis

Barium contrast study findings	Number of patients (*n*=23)
Barium meal follow through	(*n*=20)
Normal	04
Abnormal	16
Dilated small bowel loops	12
Narrowing of terminal ileum	08
Stricture of ascending colon	07
Contracted pulled up cecum	05
Distended cecum	03
Deformed ileocecal angle	03
Mucosal irregularity	02
Barium enema	(*n*=02)
Normal	02
Barium swallow	(*n*=01)
Normal	01

*Multiple abnormalities were present in most of the patients. Barium contrast studies were performed in 26 patients suspected to have intestinal tuberculosis. The result of 23 patients among the patients of finally diagnosed abdominal tuberculosis shows abnormal barium meal follow through in 16 patients and normal in four patients who underwent this examination. Barium enema was normal in both patients who underwent this. Barium swallow was done in one patient for dysphagia and was found to be normal

Table 5: Findings of ultrasonography of the patients of abdominal tuberculosis

USG findings	Number of patients (%) (*n*=42)
Normal	06 (14.3)
Abnormal	36 (85.7)
Abdominal lymphadenopathy	26 (61.9)
Ascites; free/loculated	20; 19/01 (47.6)
Bowel dilatation	15 (35.7)
Bowel wall thickening	12 (28.6)
Mesenteric thickening (>15 mm)	03 (7.1)
Omental thickening	02 (4.8)
Hepatomegaly	04 (9.5)
Splenomegaly	01 (2.4)
Hepatosplenomegaly	02 (4.8)
Hepatic/splenic tiny hypoechoic foci	02 (4.8)

USG: Ultrasonography *Multiple ultrasonographic features were present in most of the patients. All the patients in the study underwent ultrasonographic evaluation of abdomen. 36 (85.7%) patients reveal abnormal findings. Abdominal lymphadenopathy, ascites, bowel dilatation, and bowel wall thickening comprise 61.9%, 47.6%, 35.7%, and 28.6% of cases. Rest of the findings include mesenteric and omental thickening, hepatomegaly, splenomegaly, or both

Table 6: USG features of ascites in the patients of abdominal tuberculosis

USG features of ascites	Number of patients (%) (*n*=20)
With debris/septae	18 (90)
Without debris/septae	02 (10)

USG: Ultrasonography Distribution of ascites according to the presence or absence of debris/septae in the patients of abdominal tuberculosis is 90% and 10%, respectively

Exclusion Criteria

The following criteria were excluded from the study:

1. Confirmed cases of abdominal tuberculosis coming to this hospital.
2. Not willing to participate in the study.

Table 7: USG features of abd. lymph nodes in the patients of abdominal tuberculosis

USG features of abdominal lymphadenopathy	Number of patients (%) (*n*=26)
Anatomic location	
Mesenteric	22 (84.6)
Periportal/peripancreatic	07 (26.9)
Pericaval/para-aortic	08 (30.8)
Pattern	
Conglomerated	14 (53.8)
Discrete	12 (46.2)
Echogenicity	
Mixed heterogeneous	26 (100)
Homogeneous	00 (0)
Central hypoechogenicity	
Present	08 (30.8)
Absent	18 (69.2)
Calcification	
Present	01 (3.8)
Absent	25 (96.2)

USG: Ultrasonography *Multiple groups of lymph nodes were involved in many patients. Distribution of abdominal lymphadenopathy according to their anatomic location and characterization was conglomerate, mixed heterogeneous echotexture type without central hypoechoic area, or without calcifications in the mesenteric group

Table 8: Findings of CT scan in patients of abdominal tuberculosis

CT scan features	Abdominal tuberculosis (%) (*n*=14)
Abdominal lymphadenopathy	08 (57.1)
Ascites	06 (42.8)
Bowel wall thickening	05 (35.7)
Bowel dilatation	04 (28.6)
Omental thickening	03 (21.4)
Mesenteric thickening	02 (14.3)
Hepatomegaly	03 (21.4)
Splenomegaly	01 (7.1)
Hepatosplenomegaly	01 (7.1)
Hepatic/splenic tiny hypoattenuating foci with minimal peripheral enhancement	02 (14.3)

CT: Computed tomography *Multiple CT scan features were present in most of the patients. Contrast-enhanced CT of abdomen was performed in 17 patients enrolled in the study. The CT scan findings of finally diagnosed 14 patients of abdominal tuberculosis out of 17 who underwent this examination showed 57.1% of patients with lymphadenopathy followed by ascites (42.8%), bowel wall thickening (35.7%), bowel distention (28.6%), and omental thickening (21.4%), respectively. Ascites was loculated in one patient and free in other five

Table 9: CT scan features of abd. lymph nodes in the patients of abd. tuberculosis

CT scan features of abdominal lymphadenopathy	Number of patients (%) (*n*=8)
Anatomic distribution	
Mesenteric	07 (87.5)
Periportal/peripancreatic	05 (62.5)
Pericaval/para-aortic	03 (37.5)
Hypodense center	05 (62.5)
Enhancement pattern	
No definite enhancement	02 (25)
Peripheral rim enhancement	04 (50)
Homogeneous enhancement	01 (12.5)
Heterogeneous enhancement	01 (12.5)

CT: Computed tomography *Multiple groups of lymph nodes were involved in most of the patients. Abdominal lymphadenopathy was present in eight of 14 patients of abdominal tuberculosis who underwent CT scan examination showed involvement of the mesenteric group of lymph nodes with hypodense center and peripheral rim enhancement was the most common pattern

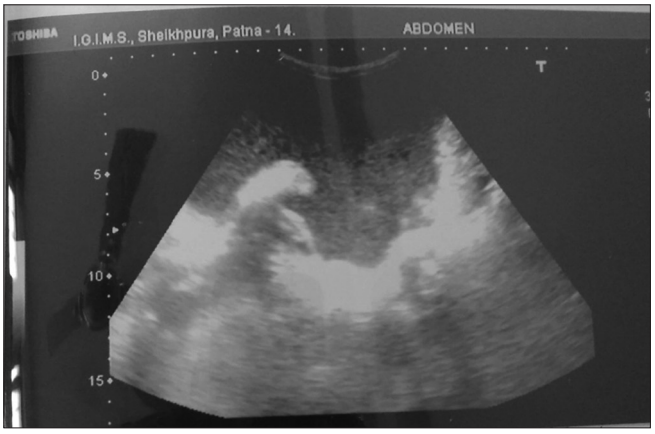

Figure 1: Ultrasonography showing free fluid in peritoneum

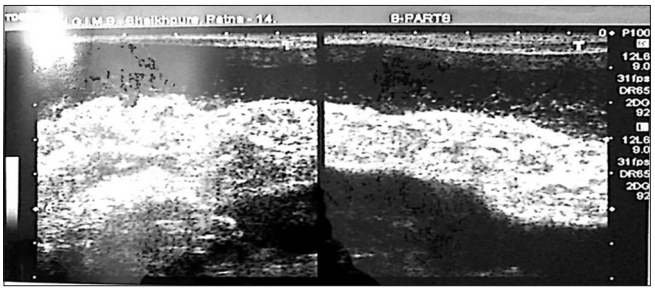

Figure 2: Marked thickening of omentum and ascites

RESULTS

There were 55 subjects enrolled on the basis of inclusion criteria for the study. Three of the subjects lost during study, while the diagnosis remained inconclusive in two subjects. Of 55, 42 patients were diagnosed abdominal tuberculosis.

The mean age of patients was 28.9 years, there were 22 males and 20 females Table 1. Male-to-female ratio was 1.1:1. Anorexia and weight loss, pain abdomen, and fever were common symptoms and were present in 31, 24, and 21 of 42 patients, respectively Table 2. X-ray chest was abnormal in 12 of 42 patients (28.6%) Table 3.

Barium contrast study was performed in of 26 patients Table 4. Among these, 23 of 26 patients diagnosed as abdominal tuberculosis. Barium follow-through studies were abnormal in 16 of 20 patients. Dilated small bowel loops and narrowing of terminal ileum were common findings.

Ultrasound was done in all 42 confirmed cases and 36 of them had abnormalities. Abdominal lymphadenopathy

Table 10: USG and CT scan comparison in 14 patients of abd. tuberculosis

Findings	Detected on ultrasound number of patients (*n*=14)	Detected on CT scan number of patients (*n*=14)
Abdominal lymphadenopathy	08	08
Mesenteric	07	07
Periportal/peripancreatic	02	05
Pericaval/para-aortic	01	03
Ascites	06	06
Bowel wall thickening	04	05
Bowel dilatation	05	04
Omental thickening	01	03
Mesenteric thickening	02	02
Hepatic/splenic lesion	02	02

CT: Computed tomography, USG: Ultrasonography Findings detected on both ultrasound and CT scan of abdomen in the patients with abdominal tuberculosis were compared and it shows that detection of the lymph nodes, omental thickening, and bowel wall thickening was better detected in CT scan. Equal sensitivity for ascites, hepatic/splenic lesion, and mesenteric thickening

and ascites were common observation, 61.9% and 47.6%, respectively Table 5-7 and Figure 1,2.

CT abdomen was done in 17 cases. Of all 14 confirmed cases, lymphadenopathy and ascites were present in 8 and 6 of 14 patients, respectively Table 8,9.

Findings detected on both ultrasound and CT scan of abdomen in the patients with abdominal tuberculosis were compared and it showed that detection of the lymph nodes, omental thickening, and bowel wall thickening was better in CT scan studies Table 10.

Ascitic fluid aspiration was done in 19 of 20 patients having free abdominal fluid. Of all 19 patients had fluid total cell count >1000/ml with lymphocytic predominance. Protein was raised >3 g in 18 of 19 patients.

DISCUSSION

In our study, 55 clinically suspected patients of abdominal tuberculosis were enrolled. A total of 42 of 55 patients were labeled diagnosis of abdominal tuberculosis.

The diagnosis remained inconclusive in two patients while three patients were lost during the study.

The age range of the patients of abdominal tuberculosis in our study was 13–55 years and the mean age was 28.9 years. There were 22 males and 20 females with male-to-female ratio of 1.1:1. Although many studies suggested abdominal tuberculosis to be predominantly a disease of young adults with equal sex predilection, Kapoor[3] has suggested a slight female predilection. We have found slight male predilection with nearly half (47.6%) of the patients in 20–39 years age group.

Chest X-ray features suggestive of active or healed pulmonary tuberculosis were present in 12/42 patients of abdominal tuberculosis in our study group; 10 (23.8 %) of them had features suggestive of active disease. Recent studies reported the evidence on chest X-ray, suggesting active pulmonary tuberculosis in as low as 4.8% of the patients in Khan *et al.*[4] series to approximately in one-third, that is, 35.2% of patients in Uygur-Bayramicli *et al.*[5] series.

The most common finding on barium meal follow-through examination was dilated small bowel loops being present in 12/16 positive studies. It is, however, largely non-specific finding unless present with distal stricture or narrowing.[6] Strictures of ascending colon were present in 7/16 and contracted pulled up cecum was present in only 5/16 positive studies. These findings are suggestive of intestinal tuberculosis when present as isolated findings and highly suggestive of abdominal tuberculosis when present along with shortening/involvement of ileocecal region and abnormal ileocecal angle/terminal ileum, respectively.[6] Thus, barium contrast studies seem to have good diagnostic yield when performed in patients with suspected intestinal tuberculosis.

Abdominal lymphadenopathy was most common USG finding present in 61.9% followed by ascites in 47.6% patients. Ascites, however, was reported as the most common USG finding in many studies, being present in 48.4–53.2% of the patients of abdominal tuberculosis.[5,7] Abdominal lymphadenopathy was reported to be present in 12.9–56% of the patients of abdominal tuberculosis in various studies.[7]

USG identified mesenteric thickening of >15 mm in 7.1% and omental thickening in 4.8% of the patients of abdominal tuberculosis in our study group. A thickening of the small bowel mesentery of 15 mm or more and an increase in mesenteric echogenicity combined with mesenteric lymphadenopathy has been reported as the

characteristic sonographic feature of early abdominal tuberculosis.[8]

Contrast-enhanced CT of abdomen was performed in 17 patients enrolled in the study. 14 of them were finally diagnosed abdominal tuberculosis. The most common CT scan finding was abdominal lymphadenopathy in 57.1% followed by ascites in 42.8% of patients, respectively, in our study group. Leder and Low[9] also reported abdominal lymphadenopathy as the most common finding of abdominal tuberculosis on CT scan as in many other studies. Ascites on CT scan was present in 6/14 (42.8%) patients of abdominal tuberculosis in our study and all of them were high-density ascites; however, many recent studies also reported ascites to be most common CT scan manifestation in these cases.[5,7]

In our study, CT was equally or more accurate than USG in identifying abnormalities of abdominal tuberculosis except bowel dilatation. Although overall detection of the number of patients with abdominal lymphadenopathy was similar with both modalities, CT scan more commonly detected periportal, peripancreatic, pericaval, and para-aortic lymph nodes was more common. This may be explained by the fact that CT scan is not affected by retroperitoneal bowel gas. CT scan was found to be equally good as USG for detecting ascites. However, unlike ultrasonography, the complex nature of the ascites is difficult to demonstrate by CT scan. Bowel wall thickening in patients of abdominal tuberculosis was more commonly detected on CT scan than USG, being picked up in 5/14 by CT scan and in 4/14 by USG. This may be due to the occasional obscuration of USG window by bowel gas. Bowel dilatation, however, was more commonly detected on USG than CT scan, being picked up in 5/14 by USG and in 4/14 by CT scan. CT scan more commonly identifies omental thickening than USG. Mesenteric thickening and hepatic or splenic lesions were, however, picked up equally with both modalities.

SUMMARY AND CONCLUSION

A total of 42 cases of the abdominal tuberculosis were diagnosed of 55 cases enrolled in the study. The role of imaging with special reference to USG and CT scan was assessed in diagnosis of abdominal tuberculosis.

The salient features are as follows:

- The age range of the patients of abdominal tuberculosis was 13–55 years and the mean age was 28.9 years. Overall, slight male predilection was observed with male-to-female ratio of 1.1:1. Symptoms and signs were non-specific. Constitutional symptoms were seen in large number of cases. A high index of suspicion needed for early diagnosis. Hematological and biochemical investigations were non-specific and were of little help.
- Ascitic fluid analysis may be suggestive/diagnostic of peritoneal tuberculosis.
- USG is a useful diagnostic tool in the patients of abdominal tuberculosis.
- In patients with high index of suspicion, the presence of the USG findings of conglomerated mesenteric lymph nodes of heterogeneous attenuation with central hypoechogenicity or calcification, ascites with internal echoes/septae, mesenteric thickening ≥15 mm, or omental thickening is suggestive of tubercular etiology.
- CT scan was equally or more accurate than USG in identifying abnormalities of abdominal tuberculosis except bowel dilatation. CT scan has advantage of not being affected by bowel gas; therefore, it more commonly identified periportal, peripancreatic, pericaval and para-aortic lymph nodes, and bowel wall thickening.
- It also more commonly identified omental thickening. USG, however, more commonly identified bowel dilatation and has edge over CT scan in defining complex nature of ascites.
- The two undiagnosed patients despite fully covered protocols were the limitation of our study.

RECOMMENDATION

Clinical suspicion is a key to the early diagnosis of abdominal tuberculosis. In all suspected cases, ultrasonography should be used as early investigation modalities.

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Original Article

Prophylactic Amnioinfusion during Labor Complicated by Moderate to Thick Meconium - A Prospective Randomized Study

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Abstract

Introduction: Transcervical amnioinfusion is a simple, easy, and efficacious method by which normal saline is infused into the amniotic cavity following spontaneous or induced rupture of membranes in laboring patients with moderate to thick meconium. Saline thus infused dilutes the amniotic fluid which, in turn, becomes amenable to oropharyngeal suctioning and reduces the incidence of meconium aspiration and neonatal respiratory distress syndrome, thereby improving the neonatal outcome.

Materials and Methods: This prospective randomized controlled study was performed on 40 patients admitted to the labor room in District Hospital, Doda, from October 2016 to December 2017. The patients included women in the first stage of labor who were found to have thick meconium on spontaneous or artificial rupture of membranes and a regular FHR.

Results: Maximum number of patients were in 37–40 weeks group. In Group-I, 65% of the patients had normal delivery as compared to 40% in the control group. This difference was statistically significant. The percentage of cases delivered by lower (uterine) segment cesarean section (LSCS) was also higher (50%) in Group-II as against Group-I (25%) which was again statistically significant.

Conclusion: The results of the study suggest that transcervical amnioinfusion should be considered in patients with moderate to thick meconium during labor as it improves the maternal and neonatal outcome in a setup with limited intrapartum surveillance facilities.

Key words: Amnioinfusion, Amniotic fluid, Aspiration, Meconium, Syndrome

INTRODUCTION

Meconium, a viscous dark green substance, is the first intestinal discharge in a fetus or neonate and is composed of intestinal epithelial cells, mucus, bile, vernix, lanugo hair, and glycerophosphates secreted from lungs, as its solid content amounting to about 5–15% and water as its major constituent (85–95%). The presence of meconium in amniotic fluid can be detected in 8–20% of all births after 34 weeks of gestation, 1–9% of these may develop meconium aspiration (Clark and Clark, 2002).

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The amount of meconium in the fetal intestine is small during the first two trimesters but increases during the third, probably reflecting the physiological maturation of fetal gut (Matthews and Warshaw, 1979). As the internal and external anal sphincters are closed during fetal life, the amniotic fluid usually remains clear; however, various stimuli are known to cause relaxation of sphincter tone and passage of meconium into the amniotic fluid. Fetal hypoxia is one of the most important factors that induce hyperperistalsis, contraction of the smooth muscles of colon, and relaxation of fetal anal sphincters resulting in intra-amniotic defecation (Rosenfeld and Porter 1985). However, parasympathetic stimulation resulting from cord compression may also cause meconium passage without concomitant hypoxia (Eriksen, 1994).

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Aspiration of meconium-stained amniotic fluid is one of the important causes of neonatal respiratory distress syndrome. Carson *et al.* (1976) reported that meconium aspiration syndrome could be prevented by oropharyngeal suctioning of neonate following delivery of head followed by laryngoscopic visualization of vocal cords with additional suctioning of trachea when meconium was visualized. In this study, meconium aspiration syndrome was reduced but not eliminated, this suggested that only delivery factors were not solely responsible. Since then, obstetric-pediatric delivery protocol became common. Other techniques such as squeezing the chest of baby and inserting finger into the mouth of baby have been proved to be harmful.

It was found that intrauterine aspiration of meconium is more common than aspiration during the course of labor. Any episode of intrauterine fetal gasping such as physiological breathing, umbilical cord occlusion, or chronic placental insufficiency can result in aspiration of meconium into fetal trachea and lungs (Brown and Gleicher, 1981).

Dooley *et al.* (1985) reported that liberal cesarean delivery (60%) for meconium did not alter the frequency of meconium found below vocal cords.

When a patient is discovered to be in labor with thick meconium without any evidence of fetal distress or hypoxia, whether some intervention during labor to prevent the ill effects of meconium would be ideal in such patients who would otherwise be good cases for vaginal delivery. Amnioinfusion is a new technique with important implications for such cases. It involves infusion of a sterile physiological solution into the amniotic cavity abdominally or transcervically. Transcervical amnioinfusion is a relatively simple method of increasing the amniotic fluid volume following rupture of membranes.

Miyazaki and Nevarez (1985) noted that amnioinfusion dilutes the amniotic fluid and suggested the possibility of meconium-exchange amnioinfusion in patients with moderate to thick meconium with otherwise signs of a healthy fetus.

The present study has been done to evaluate the role of amnioinfusion in patients with moderate to thick meconium under conditions of limited intrapartum surveillance at a District Hospital level.

REVIEW OF LITERATURE

The incidence of meconium-stained amniotic fluid and its *in utero* aspiration varies in different studies. Gregory *et al.* (1974) found an 8.8% incidence of meconium-stained amniotic fluid, meconium was present in the trachea of 50% of such neonates, but only 20% developed meconium aspiration syndrome. Routine endotracheal intubation and suctioning was recommended in these neonates to prevent the aspiration syndrome.

Carson *et al.* (1976) observed a marked reduction in the frequency of meconium aspiration syndrome with their combined obstetric-pediatric method. As soon as the head was delivered, but before the delivery of shoulders, oropharyngeal and nasopharyngeal suction was done. After completion of delivery, trachea was intubated under direct vision. Endotracheal suction was done only if meconium was present on the vocal cords, this reduced the incidence of meconium aspiration syndrome from 1.9% to 0.4%.

It was in 1976 that Gabbe *et al.* gave the concept of amnioinfusion. They postulated that infusion of normal saline into amniotic fluid increased its volume and served as cushion that prevented umbilical cord compression.

In 1983, Miyazaki and Taylor also observed that transcervical amnioinfusion was a safe and effective treatment for fetal heart rate (FHR) variable decelerations.

Wenstrom and Parson (1989) concluded that amnioinfusion was a simple and safe technique that reduced the incidence of meconium below the vocal cords and improved the obstetric outcome in patients laboring with thick meconium.

Macri *et al.* (1991) demonstrated that amnioinfusion was an effective technique for improving the perinatal outcome of pregnancies with thick meconium and oligohydramnios.

Macri *et al*. (1992) studied amnioinfusion and oligohydramnios and found that rates of fetal distress, cesarean section for fetal distress, and meconium aspiration were significantly reduced by amnioinfusion.

Glantz and Latteney (1996) found that the use of amnioinfusion was associated with a decreased risk of fetal distress, meconium below the cords, and cesarean delivery.

Rathore *et al.* (2002) in a prospective randomized controlled study used intermittent auscultation of fetal heart during labor and found that in an under-resourced labor ward, amnioinfusion decreases cesarean section rate and fetal morbidity.

Sahu and Induvadani (2003) have reported that transcervical intrapartum amnioinfusion for meconium-stained amniotic fluid using normal saline and nasogastric tube

was technically feasible, safe, and effective in developing country situation with limited intrapartum facilities.

Aims and Objectives

This study aims to study the maternal and neonatal outcome of transcervical amnioinfusion in labor complicated by thick meconium in terms of:

- Mode of delivery.
- Maternal complications.
- Neonatal Apgar score.
- Admission in neonatal intensive care unit (NICU).
- Meconium below vocal cords.
- Meconium aspiration syndrome.
- Mortality.

MATERIALS AND METHODS

This prospective randomized controlled study was performed on 40 patients admitted to the labor room in District Hospital, Doda, from October 2016 to December 2017. The patients included women in the first stage of labor who were found to have thick meconium on spontaneous or artificial rupture of membranes and a regular FHR. No patient with maternal comorbidity as hypertension, diabetes, heart disease, polyhydramnios, cord prolapse, fetal malformation, fetal malpresentation, or fetal distress was included in the study.

Material Used

- Foleys catheter No. 14.
- Normal saline.
- Drip set.
- Artery forceps.
- Sims vaginal speculum.
- Anterior vaginal wall retractor.
- Sterile swabs, drapes, gloves, and betadine lotion.

Methods

Patient was prepared and draped in dorsal position; vaginal examination performed to confirm cervical dilatation and fetal presentation. A Foleys catheter no. 14 was inserted through cervix into the uterine cavity between fetal head and amniotic sac under direct vision using a Sims vaginal speculum. The other end of the catheter was connected to a bottle of normal saline at room temperature. Initially, 500 ml normal saline was infused over a period of 1 h. FHR was noted every half hourly by auscultation. Uterine tone and frequency of contractions were assessed every 30 min. Cervical dilatation was noted before and after the bolus infusion. In patients where the decision was taken to continue with monitoring of labor, infusion was continued at the rate of 5 ml/min. Cesarean sections were performed for fetal indication or for failure in the progress of normal labor. After delivery, all patients received prophylactic antibiotics. A pediatrician was present at all the deliveries. Infants underwent oropharyngeal and nasopharyngeal suctioning on delivery of head. After delivery, they were intubated by the pediatrician for the presence of meconium below vocal cords and accordingly tracheal intubation and suctioning done. Neonatal outcome was assessed by the pediatrician. Mothers and babies were followed for 1 week postpartum and data on neonatal outcome were obtained from record in the neonatal ward (sick newborn care unit).

Observations

This randomized controlled study was conducted on 40 women in labor with thick meconium and a normal FHR. Of 40 patients, 20 were randomized as a study group (Group-I) and 20 patients as a control group (Group-II). Group-II patients received the usual treatment, whereas Group-I cases received amnioinfusion in addition to the usual management for meconium.

In both the groups, most of the patients were in the age group of 20–24 years.

Most of the patients were primigravida.

Maximum number of patients were in 37–40 weeks group.

In Group-I, 65% of the patients had normal delivery as compared to 40% in the control group. This difference was statistically significant. The percentage of cases delivered by lower (uterine) segment cesarean section (LSCS) was also higher (50%) in Group-II as against Group-I (25%) which was again statistically significant.

1 min Apgar score <7 was found in 30% of neonates in Group-I as against 50% in Group-II; similarly, 5 min Apgar score <7 was observed only in 5% of cases in Group-I as compared to 10% in Group-II. 15% of neonates in Group-I had need for positive predictive value (PPV) as against 25% in Group-II. Only 5% of babies had meconium below vocal cords in the amnioinfusion group versus 15% in the control group. In Group-I, only 10% of neonates were admitted to NICU as compared to 30% in Group-II. No neonate in the study group developed meconium aspiration syndrome, whereas in the control group, 15% of babies suffered from it. There was only one perinatal death that too in the control group [Tables 1-5].

DISCUSSION

Passage of meconium *in utero* has been noted in 7–22% of live births (Katz and Bowes, 1992). Meconium aspiration syndrome has been reported in 6.6–30% of cases of meconium-stained amniotic fluid (Brown and Glicher

Table 1: Age distribution of patients

Age group (years)	Group-I	Group-II
	n (%)	*n* (%)
<20	1 (5)	0 (0)
20–24	9 (45)	10 (50)
25–29	8 (40)	9 (45)
>29	2 (10)	1 (5)

Table 2: Distribution of patients according to parity

Parity	Group-I	Group-II
	n (%)	*n* (%)
P0	10 (50)	9 (45)
P1	6 (30)	7 (35)
P2	3 (15)	3 (15)
P3 and >	1 (5)	1 (5)

Table 3: Distribution of patients according to gestational age

Gestational age (weeks)	Group-I	Group-II
	n (%)	*n* (%)
34–37	1 (5)	1 (5)
37–40	14 (70)	13 (65)
>40	5 (25)	6 (30)

Table 4: Mode of delivery

Mode of delivery	Group-I	Group-II
	n (%)	*n* (%)
Normal	13 (65)	8 (40)
Forceps	1 (5)	1 (5)
Ventouse	1 (5)	1 (5)
LSCS	5 (25)	10 (50)

LSCS: Lower (uterine) segment cesarean section

Table 5: Comparison of neonatal outcome

Characteristics	Group-I	Group-II
	n (%)	*n* (%)
1 min A/S<7	6 (30)	10 (50)
5 min A/S<7	1 (5)	2 (10)
Need for PPV	3 (15)	5 (25)
Meconium below vocal cords	1 (5)	3 (15)
NICU admission	2 (10)	6 (30)
Meconium aspiration syndrome	0 (0)	3 (15)
Perinatal death	0 (0)	1 (5)

PPV: Positive predictive value, NICU: Neonatal intensive care unit

1981). It has been noted that intrapartum dilution of meconium by transcervical amnioinfusion reduces the rate of meconium aspiration syndrome. The purpose of this study was to evaluate the safety and efficacy of transcervical amnioinfusion during labor complicated by thick meconium in a setting with limited intrapartum surveillance and to evaluate clinically perinatal and maternal outcomes.

In this study, a total of 40 women in labor with moderate to thick meconium were included, of these 20 were given transcervical amnioinfusion besides the usual management for meconium and 20 patients were taken as control in whom only usual management was done. Both the study and control groups were found to be almost similar in terms of age, parity, and gestational age. No patient with comorbidity as hypertension, diabetes, and heart disease was included in the study.

Average volume of normal saline needed for amnioinfusion was 800 ml and 90% of the patients required maintenance after bolus infusion. Operative delivery was noted in 35% of the patients in Group-I and 60% of cases in Group-II. The incidence of 1 min Apgar score <7 was 30% in the study group as against 50% in the control group, whereas 5 min Apgar score <7 was noted to be 5% in Group-I and 10% in Group-II. Meconium below vocal cords was observed in 5% of cases as compared to 15% in the control group. The number of neonates admitted to NICU was also higher (30%) in the control group as against 10% in the study group. Meconium aspiration syndrome occurred in 15% of neonates in the control group with one perinatal death (5%); however, no neonate developed meconium aspiration syndrome in the study group. No maternal complication was noted related to amnioinfusion.

CONCLUSION

- Transcervical amnioinfusion during labor complicated by moderate to thick meconium is a simple, safe, and effective procedure.
- It improves the maternal morbidity by reducing the rate of LSCS and instrumental deliveries.
- It improves neonatal outcome by improvement in Apgar score, reduction in meconium below vocal cords, and decreasing the need for PPV and admission to NICU.
- It also decreases the incidence of meconium aspiration syndrome and neonatal mortality.

The results of the study suggest that transcervical amnioinfusion should be considered in patients with moderate to thick meconium during labor as it improves the maternal and neonatal outcome in a setup with limited intrapartum surveillance facilities.

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Original Article

Histopathological Study of Neoplastic and Non-neoplastic Lesions of the Ovary in Sanjay Gandhi Memorial Hospital/Gandhi Memorial Hospital, Rewa, Madhya Pradesh, India

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Abstract

Introduction: Tumors of the ovary are common forms of neoplasms in women. In the developed world, ovarian carcinoma is the fourth or fifth most common cause of death from all cancers in women, and 7% of patients with these tumors present with advanced stage disease. Ovarian cancers account for 6% of all cancers in females. 80% are benign and these occur mostly in young women between the ages of 20 and 45 years. Malignant tumors are common in older women between the ages of 40 and 65 years.

Aims: This study aims to the incidence of different histological types of ovarian lesions, histomorphological features, categorize ovarian lesions into neoplastic and non-neoplastic group, and correlate incidence of neoplastic and non-neoplastic lesion with particular age group and parity.

Materials and Methods: The study was conducted on approximate 50 patients of ovaries received these include surgically resected ovaries, either as part of total abdominal hysterectomy with bilateral salpingo-oophorectomy or as a clinically diagnosed ovarian lesions from Shyam Shah Medical College and Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh, from the duration of April 2017 to march 2018.

Results: The total number of ovarian lesions studied during the study period was 50 cases, among them, 15 (30%) cases were non-neoplastic and remaining 35 (70%) cases were neoplastic. The most common non-neoplastic lesion seen was follicular cyst 6 (40%) cases followed by corpus luteal cyst 4 (26.66%) cases. Among the 35 neoplastic ovarian lesions, 26 (74.28%) cases were benign, 1 (2.85%) case was at borderline, and 8 (22.85%) cases were malignant. In benign ovarian neoplasm, most commonly lesion were serous cystadenoma 17 (48.57%) cases followed by benign cystic teratoma 4 (11.42%) cases. In malignant cases, the most common lesion were serous cystadenocarcinoma 3 (8.57%) cases followed by mucinous cystadenocarcinoma 2 (5.71%) cases. Overall, ovarian lesions were more common in age group of 20–39 years followed by 40–59 years. The youngest patient was 9 years old and the oldest patient was 69 years old. The malignant tumors were more common in nulliparous women (33.33%) than benign neoplasm (15.38%). Of total 35 neoplastic ovarian lesions, 32 (91.42%) cases were unilateral and 3 (8.57%) cases were bilateral.

Conclusion: The histological type of ovarian tumor correlates with the prognosis of the tumor. Serum CA-125 screening along with annual pelvic examination after 35 years of age in women along with transvaginal ultrasonography can be used as regular screening methods to evaluate early detection of ovarian cancer. An accurate histopathological diagnosis combines with clinical staging will help in rendering prompt and appropriate treatment to the patients.

Key word: Histopathology, Incidence, Neoplastic ovarian lesions, Non-neoplastic lesions, Ovarian tumor

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INTRODUCTION

Tumors of the ovary are common forms of neoplasms in women.[1] In the developed world, ovarian carcinoma is the fourth or fifth most common cause of death from all cancers in women, and the primary cause of death from gynecological malignancies; 7% of patients with these

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tumors present with advanced stage disease.[2] Ovarian tumor and non-neoplastic lesions present a great challenge to gynecological oncologist. Certain non-neoplastic lesions of the ovary frequently form a pelvic mass and potentially mimic an ovarian neoplasm.

The most important clinical feature in ovarian tumor is the age of the patient. One of the eight ovarian tumors in patients <45 years of age is malignant; by contrast, in older women, the proportion is one to three. The single most common ovarian tumor, the mature cystic teratoma (dermoid cyst) is encountered at all ages, like most tumors in the sex cord-stromal category.[3] Ovarian cancers account for 6% of all cancers in females. 80% are benign and these occur mostly in young women between the ages of 20 and 45 years. Malignant tumors are common in older women between the ages of 40–65 years.[4] Classification of ovarian tumors is primarily morphological. It is based on that the ovary containing four major types of tissue: [4] Surface, coelomic or germinal epithelium, germ cells, sex cord and ovarian stroma, specialized, and non-specific.

The treatment for ovarian neoplasms depends on the grade and stage of the tumor at presentation. Treatment modalities include cystectomy or oophorectomy, salpingo-oophorectomy, hysterectomy, chemotherapy, and/or radiotherapy.[5] This study shows the patterns of ovarian lesions with regard to age, parity, origin, risk factors, clinical presentation, and histopathological classification.

Aims and Objectives

This study aims to the incidence of different histological types of ovarian lesions, histomorphological features, categorize ovarian lesions into neoplastic and non-neoplastic group, and correlate incidence of neoplastic and non-neoplastic lesion with particular age group and parity.

MATERIALS AND METHODS

The study was conducted on approximate 50 patients of ovaries received these include surgically resected ovaries, either as part of total abdominal hysterectomy with bilateral salpingo-oophorectomy or as a clinically diagnosed ovarian lesions from Shyam Shah Medical College and Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh, from the duration of April 2017 to march 2018. All sections were routinely processed under standardized conditions for paraffin embedding and then cut into 5 μ or thinner as needed and stained with hematoxylin and eosin (H and E) stain using standard procedure. For classification of ovarian lesion, the World Health Organization (WHO) was being used. Statistical tools, incidence, and percentage were calculated.

Inclusion Criteria

All the specimens of ovarian lesion (neoplastic and non-neoplastic) sent to the Department of Pathology, shyam shah medical college, rewa, were included in the study. Hysterectomy specimen with ovarian lesion was also be included in the study.

Exclusion Criteria

Decomposed and poorly and improperly fixed specimens.

All the specimens received at the Department of Pathology, Shyam Shah Medical College, Rewa, were procedure fixation → grossing → dehydration → wax impregnation → blocking section cutting and followed by H and E section.

Data collection of the histopathological slides of patients included in the study was retrieved and reviewed by me and experienced histopathologist to confirm ovarian neoplasm diagnosis, determine the histopathological type of the tumor, and classify the ON using the WHO classification. Data analysis for quantitative data mean, standard deviation, etc., was obtained and for qualitative data, proportion will be obtained and analyzed using statistical software or MS Excel.

RESULTS

The present study of 50 cases of the ovarian lesions, 35 cases were neoplastic. The neoplastic lesion comprised 26/35 (74.28%) benign, 1/35 (2.85%) borderline, and 8/35 (22.85%) malignant tumors (Table 1).

Table 2 shows that in non-neoplastic lesions, follicular cyst was the most common lesion 6/15 (40%), followed by corpus luteal cyst 4/15 (26.66%), hemorrhagic cyst (20%), endometriosis (6.66%), and inclusion cyst (6.66%) (Table 2).

Table 1: Distribution of benign, borderline, and malignant neoplasm

Ovarian neoplasm	Number of cases (%)
Benign	26 (74.28)
Borderline	01 (2.85)
Malignant	08 (22.85)
Total	35 (100)

Table 2: Distribution of various types of the non-neoplastic ovarian lesions

Non-neoplastic ovarian lesion	Number of cases (%)
Follicular cyst	6 (40.0)
Corpus luteal cyst	4 (26.66)
Hemorrhagic cyst	3 (20.00)
Inclusion cyst	1 (6.66)
Endometriosis	1 (6.66)
Total	15 (100.0)

Table 3 shows that neoplastic tumors were divided into four groups, namely, surface epithelial tumors, germ cell tumors, sex cord-stromal tumors, and metastatic tumor. Surface epithelial tumors were maximum in number 26/35 (74.28%), followed by germ cell tumors 5/35 (14.28), sex cord-stromal tumors 3/35 (8.57%), and metastatic tumor 1/35 (2.85%).

Table 4 shows that in non-neoplastic lesions, the most common histopathological pattern was follicular cyst 6/15 (40%), followed by corpus luteal cyst 4/15 (26.66%), hemorrhagic cyst 3/15 (20%), inclusion cyst 1/15 (6.6%), and endometriosis 1/15 (6.6%).

Tables 5 and 6 show that in neoplastic lesion, the most common histological class is surface epithelial tumors 26/35 (74.28%) followed by germ cell tumors 5/35 (14.28%). Among all the benign lesions (n = 26), serous cystadenoma is the most common 17/26 (65.38%) while the benign cystic teratoma (dermoid cyst) is the second most common 4/26 (15.38%). On the other hand, among all the malignant lesions (n = 8), serous cystadenocarcinoma is the most common 3/8 (37.50%) followed by mucinous cystadenocarcinoma 2/8 (25.00%).

In germ cell tumor, the most common benign tumor was dermoid cyst and most common malignant tumor was dysgerminoma. In sex cord-stromal, the most common benign tumor was fibroma and most common malignant tumor was granulosa cell tumor. Under metastatic group, one case of Krukenberg tumor comprising 2.85% of all ovarian tumor was reported.

Table 7 shows that non-neoplastic lesions were common in parity 2 and parity 4 patients.

Table 3: Distribution of various types of the neoplastic ovarian lesions

Classes of ovarian tumor	Number of cases (%)
Surface epithelial-stromal tumor	26 (74.28)
Germ cell tumor	05 (14.28)
Sex cord-stromal tumor	03 (8.57)
Metastatic tumor	01 (2.85)
Total	35 (100.0)

Table 4: Histopathological patterns of the non-neoplastic lesions of ovary

Histopathological patterns	Number of cases (%)
Follicular cyst	6 (40.0)
Corpus luteal cyst	4 (26.66)
Hemorrhagic cyst	3 (20.0)
Inclusion cyst	1 (6.6)
Endometriosis	1 (6.6)
Total	15 (100.0)

In neoplastic lesions, benign lesions were common in parity 2 and parity 3 followed by nulliparous patients.

Borderline neoplasm was common in nulliparous patient.

Malignant neoplasm was most common in nulliparous patients followed by parity 2 patients.

In the present study, it was observed that malignant tumors were more common in nulliparous women (33.33%) than benign neoplasm (15.38%). Figure-3 in neoplastic lesions of ovary most common clinical presentation was lump in abdomen 19/35 (54.28%) followed by pain in abdomen 12/35 (34.28%), GIT complaints 2/35 (5.71%), loss of weight/appetite 1/35 (2.85) and ascites 1/35 (2.85%).

Non-neoplastic Lesions of Ovary

- Follicular cyst - six cases of follicular cyst were studied. Microscopically, the cyst wall of all cases was lined by outer layer of thick theca interna cells. A single inner layer of granulosa cells were resting on a thick theca layer.
- Corpus luteal cyst - four cases of luteal cyst were studied. Microscopically, the cyst wall is composed of an inner connective tissue layer, a middle layer of large luteinized granulosa cells, and an outer layer of small luteinized theca interna cells.
- Hemorrhagic cyst - three cases of hemorrhagic cysts were studied. Cyst filled with hemorrhagic material and lined by single layer of cells.
- Inclusion cyst - one case of inclusion cyst was studied. Cyst being formed through invagination of the surface epithelium. Microscopically, they were lined by columnar cells.
- Endometriosis - one case of endometriosis was studied. Microscopically, they were composed of endometrial

Table 5: Histopathological patterns of the neoplastic lesions of ovary

Histopathological patterns	Number of cases (%)
Surface epithelial-stromal tumor	26 (74.28)
A Serous tumor	
Serous cystadenoma	17 (48.57)
Borderline serous cystadenoma	1 (2.85)
Serous cystadenocarcinoma	3 (8.57)
B Mucinous tumor	
Mucinous cystadenoma	3 (8.57)
Mucinous cystadenocarcinoma	2 (5.71)
Germ cell tumor	5 (14.28)
Benign cystic teratoma	4 (11.42)
Dysgerminoma	1 (2.85)
Sex cord-stromal tumor	3 (8.57)
Granulosa cell tumor	1 (2.85)
Fibroma	2 (5.71
Other	1 (2.85)
Metastatic tumor	1 (2.85)

Table 6: Frequency of different classes of the neoplastic ovarian tumor (*n*=35)

Histological classes of ovarian tumors	Benign tumors (*n*=26)	Borderline tumors (*n*=1)	Malignant tumors (*n*=8)	Total (%)
Surface epithelial tumor	Serous cystadenoma (17) mucinous cystadenoma (03)	Borderline serous cystadenoma (01)	Serous cystadenocarcinoma (03) mucinous cyst adenocarcinoma (02)	26 (74.28)
Germ cell tumor	Benign cystic teratoma (04)	-	Dysgerminoma (01)	05 (14.28)
Sex cord-stromal tumor	Fibroma (02)	-	Granulosa cell tumor (01)	03 (8.57)
Metastatic tumor	-	-	Krukenberg tumor (01)	01 (2.85)
Total	26	01	08	35 (100)

Table 7: Distribution of ovarian masses in marital status and parity of patients with both non-neoplastic and neoplastic ovarian masses

Marital status and parity	Non-neoplastic	Benign neoplasm	Borderline neoplasm	Malignant neoplasm	Total
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Unmarried	1 (6.66)	1 (3.84)	-	-	2 (4.0)
Nulliparous	-	4 (15.38)	1 (100.0)	3 (37.50)	8 (16.0)
Parity 1	3 (20.1)	1 (3.84)	-	1 (12.50)	5 (10.0)
Parity 2	4 (26.66)	9 (34.61)	-	2 (25.00)	15 (30.0)
Parity 3	3 (20.0)	5 (19.23)	-	1 (12.50)	9 (18.0)
Parity 4	4 (26.66)	3 (11.53)	-	1 (12.50)	8 (16.0)
Parity 5 and above	-	3 (11.53)	-	-	3 (6.0)
Total	15 (100.0)	26 (100.0)	1 (100.0)	8 (100.0)	50 (100.0)

glands, endometrial stroma, and accumulation of hemosiderin-laden macrophages and hemorrhagic foci also seen.

Neoplastic lesions of Ovary

- Serous cystadenoma - 17 cases of serous cystadenoma were studied. Gross findings - outer surface of all the cases was showing dilated veins. On cut, they were filled with serous fluid. Wall was variably thickened of all cases.
- Microscopically, the cyst was lined by single layer of columnar epithelium. In some cases, cyst was lined by single layer of flattened/cuboidal epithelium.
- Serous papillary cystadenoma - one case also reveals stromal papillae with single layer of columnar epithelium.
- Borderline serous cystadenoma - one case was studied. Microscopically, they were showing cyst wall lined by columnar epithelium. Epithelium was showing stratification (4–5 layers) and mild nuclear atypia and minimum mitotic activity. No stromal invasion was seen.
- Serous cystadenocarcinoma - three cases were studied. Microscopically, they were showing marked nuclear atypia, including pleomorphism, atypical mitotic figures, and multinucleation. They were also showing epithelial stratification, complex papillary architecture, branching papillary fronds, and destructive stromal invasion.
- Mucinous cystadenoma - three cases were studied. Microscopically, the cyst was lined by single layer of mucin filled columnar epithelial cells with basally located nuclei. Stromal element minimal between cyst wall.

Mucinous cystadenocarcinoma - two cases were studied.

- Microscopically, they were showing sheets, papillae, and trabeculae of tumors cells having round to oval pleomorphic nuclei, vesicular chromatin, and scanty amount of eosinophilic cytoplasm. Tumor cells embedded in mucinous background. In between tumor cells, there are bands of fibrocollagenous tissue separated by tumor cells in lobules.

Benign cystic teratoma - four cases were studied.

- Microscopically, they were showing areas of hemorrhage along with islands of sebaceous glands, shafts of hair follicles, and areas of chondroid differentiation.
- One case was showing sheets and nests of endoderm, mesoderm, and ectoderm mainly composed of thyroid follicles, respiratory epithelium, cartilage, neuroepithelium, shafts of hair follicles, and sebaceous glands with focal areas of squamous differentiation and keratin pearl formation.

Dysgerminoma - one case was studied.

- Microscopically, section was showing large areas of hemorrhage with distortion of architecture. However,

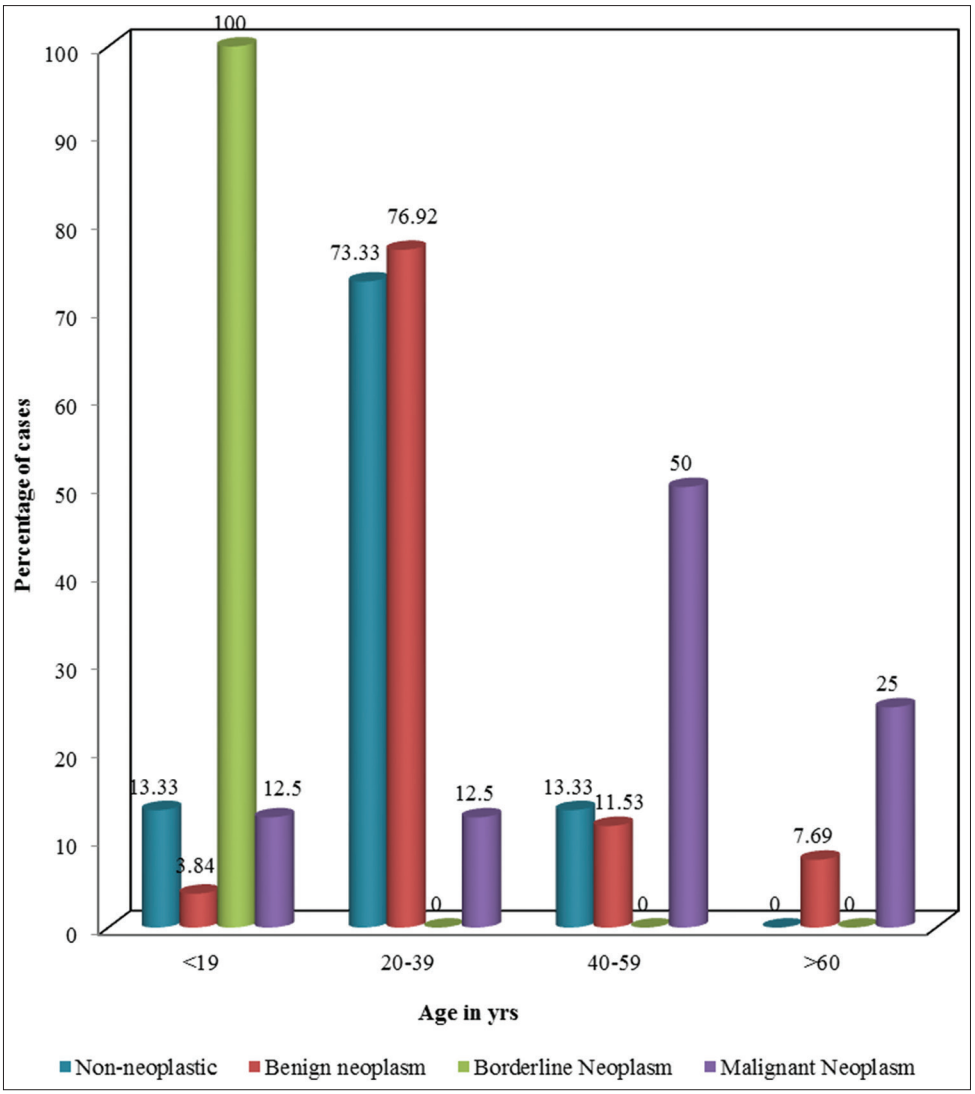

Figure 1: Ovarian masses in various age groups of patients with both non-neoplastic and neoplastic ovarian masses

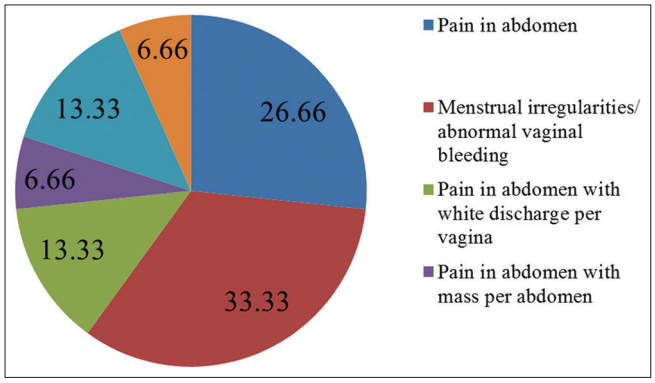

Figure 2: Clinical presentation of non-neoplastic cases

areas reveal few round cells having clear to eosinophilic cytoplasm with round or flattened nuclei. Occasional syncytiotrophoblastic cells are also seen.

Fibroma - two cases were studied.

- Microscopically, they were composed of spindle-shaped cells with uniform, bland nuclei, and scanty cytoplasm. The cells were arranged in fascicles or a storiform pattern.

Granulosa cell tumor - one case was studied.

- Microscopically, section was showing solid sheets of tumor cell having polygonal enlarged pleomorphic, hyperchromatic nuclei with scanty cytoplasm, and Call-Exner bodies. At few places, mitotic figures were also evident. Section was also showing areas of necrotic material and hemorrhage.

Metastatic tumor (Krukenberg tumor) - one case was studied

- Microscopically, section was showing highly fibrous stroma diffusely infiltrated signet ring cells containing abundant mucin.

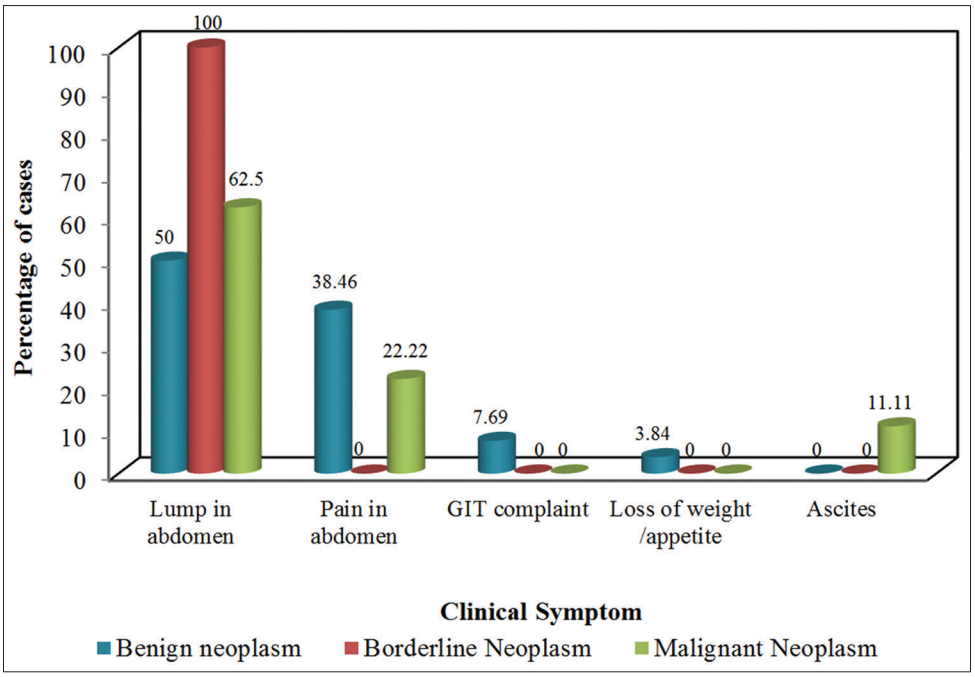

Figure 3: Clinical presentation in neoplastic ovarian masses

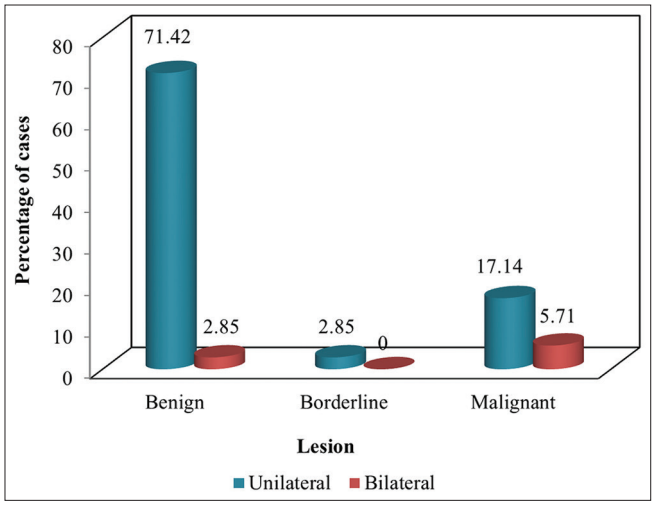

Figure 4: Laterality of ovarian neoplastic lesions

DISCUSSION

Ovarian cancer is the second leading cause of mortality among all gynecological cancers.[6] Due to similar clinical presentations, there is confusion in the diagnosis of non-neoplastic and neoplastic lesions of ovary although it is diagnosed as a mass or cystic lesion on ultrasonography (USG) and, hence, removed prophylactically in routine oophorectomies and hysterectomies.[7] In the current study, 50 ovarian lesions of non-neoplastic and neoplastic origins were evaluated to find out incidence, age, parity, marital status, clinical, and histopathological features. Kreuzer *et al.*[8] reported 82 (40.39%) non-neoplastic lesions of 203 ovarian lesions and Martínez-Onsurbe *et al.*[9] reported 55 (41.67%) non-neoplastic lesions of 132 ovarian lesions. Incidence reported in our study regarding non-neoplastic lesions was lower and concurring with the above studies. The non-neoplastic lesions such as follicular or corpus luteum cysts are the commonly encountered conditions.[10] Figure -1 In neoplastic lesions benign tumours were more common in age group of 20-39 year, borderline tumours was more common in age group of <19 year while malignant tumours were more common in age group of 40-59 years. In the current study, 14 cystic lesions were reported of which follicular 6 (42.85%), corpus luteum 4 (28.57%), three hemorrhagic cyst, and one inclusion cyst. Incidence of these cysts was accordance with to Kreuzer *et al.*[8] (55% follicular cyst and 45% corpus luteal cyst) and Martínez-Onsurbe *et al.*[9] (55% follicular cyst and 45% corpus luteal cyst). Gupta *et al.*[11] reported follicular and corpus luteal cyst (80.2%). In the present study, the incidence was 93.32%, which was higher than this study. Endometriosis is common condition found in women of reproductive age. The most common location of endometriosis is the ovary and posterior cul-de-sac.[12] In our study, one case (6.66%) was reported. This finding was higher than to Gupta *et al.*[11] (2.9%), Carey and Kirk,[13] and Clement *et al.*[14] Al-Fozan and Tulandi[12] in a study conducted for 6 years reported 340 lesions, of which 155 (45.59%) were ovarian endometriosis. In clinically suspected ovarian pathology cases, the most common clinical symptoms were menstrual irregularities/abnormal vaginal bleeding in 5 cases (33.33%), pain in abdomen in 4 cases (26.66%), pain in abdomen with white discharge per vagina in 2 cases (13.33%), and mass per abdomen only

in 2 cases Figure - 2 (13.33%). These findings were similar to van Winter *et al*.[15] study.

- In the present study, 35 neoplastic lesions were diagnosed. The most common were benign tumors 26 cases (74.28%) followed by malignant tumor 8 cases (22.85%) and borderline malignancy 1 case (2.85%) (Table 1).
- In the present study, maximum numbers of cases were in the 3rd–4th decade of life. The present study is in concordance with Pilli *et al*.[16] and Ramachandra *et al*.[17] where the incidence of ovarian neoplastic lesions was more common in 20–39 years of age group. Tushar *et al*.[18] reported high incidence of ovarian tumors in 40–59 years age group.
- There is inverse relationship between ovarian cancer risk and parity. Parous women are at significantly lower risk than nulliparous women. In our study, the incidence of nulliparity (16%) is comparable with Misra *et al*. (16.00%) and Madan *et al*. (14.54%).[19-21]
- Based on histomorphological features, the incidence of surface epithelial tumors was most common (74.28%), followed by germ cell tumors (14.28%), sex cord-stromal tumors (8.57%), and metastatic (2.85%). Similar observations were seen in other studies (Table 3).
- In benign and malignant ovarian neoplasm, lump in abdomen was the most common complaint, followed pain in abdomen, gastrointestinal disturbances with loss of weigh/appetite, and ascites. These findings were in accordance with other studies.
- The present study is concordant with studies by Gupta *et al*.[22] and Misra *et al*.[23] and with Nucci *et al*.[5] which showed high incidence of malignant tumor having more number of tumors with solid and mixed consistency. Majority of the benign lesions (68.57%) in the present study were cystic in consistency. Moreover, majority of malignant lesions (14.28%) were having mixed consistency. This result is concordant with studies by Gupta *et al*.[21] and Misra *et al*.[23]
- In the present study, of total 35 neoplastic ovarian lesions, 32 cases were unilateral and three cases were bilateral. The present study is concordant with studies by Goldzieher *et al*. [24] Mushtaq *et al*.[25] and Couto *et al*.[26] Tushar *et al*.[18] reported more number of bilateral tumors compared to the present study. Most of the benign tumors (71.42%) were unilateral and most of malignant tumors (17.14%) were also unilateral tumors. This result is concordant with studies by Misra *et al*.[23] and Prabhakar *et al*.[27]
- Ovarian cancers are called as "silent killer" as in most of the primary ovarian tumor, they remain asymptomatic until the advanced stage Figure 4[28]. Out of total 35 neoplatic ovarian lesions, 32 cases were unilateral and 3 cases were bilateral.

CONCLUSION

Effective therapeutic management of ovarian malignant tumors continues to be a challenge to the oncologist. An accurate histopathological diagnosis combines with clinical staging will help in rendering prompt and appropriate treatment to the patients.

The histological type of ovarian tumor correlates with the prognosis of the tumor. Serum CA-125 screening along with annual pelvic examination after 35 years of age in women along with transvaginal USG can be used as regular screening methods to evaluate early detection of ovarian cancer.

RECOMMENDATIONS

- Further, in-depth studies are highly recommended to be carried out for more evaluation of risk factors and to find out the causes for the high rate of the disease in this country. For unnecessary removal of the ovary, frozen section is recommended.
- Screening policy for ovarian cancer should be established for early detections.
- Improvement of the cancer reporting and registration. Detailed histopathological reporting, grading and staging.

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Original Article

Public Health Effect of Financial Crisis and Governance: Evidence from Asian Countries

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ABSTRACT

Background : Over the past three decades, international financial turmoil led to severe losses. The backlash of this financial instability has affected developed and developing countries around the world. Increased unemployment, loss of income and increased vulnerability have been among the dominant social impacts of the crisis. This paper aims to investigate the effects of financial crisis and governance on health care using a panel data of 35 Asian countries over the period 1996–2016.

Method: The empirical analysis is carried out using the generalized method of moments estimator to deal with potential endogeneity of the explanatory variables.

Results: Findings show that there is a strongly negative relationship between financial crisis and health on the one hand, and a positive relationship between governance indicators and health on the other hand. Moreover, the direct and negative effects of financial shocks on health may be reduced by the indirect and positive effects through good governance and institutions.

Conclusions: This indicates that the financial crisis impacts health and the magnitude of the effects could be reduced through the presence of good governance and institutional interventions. These empirical insights are of particular interest to policymakers as they help identify causes of financial crises and to develop a sound financial system able to resist to external chocks. Policymakers should also regulate and enhance the role and efficiency of domestic institutions.

Key words: Financial Crisis, Governance, Health, Asian Countries

INTRODUCTION

The financial crisis has spurred tremendous interest in their economic and social consequences. Recent studies show that financial crisis is commonplace throughout history and across developed and developing countries and that their consequences can be huge (Claessens *et al*., 2009; Reinhart and Rogoff, 2009; Luc and Valencia, 2010; Laeven and Valencia, 2012). Economic literature provides a great number of theoretical and empirical studies that link financial crisis to macroeconomic variables. Among these researches, a large body of these studies examine the effects of financial instability on economic growth, inequality, poverty, and education... and although there is much work that has studied the social impacts of the financial crisis, there is not enough empirical work in literature that links financial crisis to health-care services.

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Given the rapid evolution of the crisis and the uncertainty surrounding its impact in different countries, monitoring its effects on the health sector is a priority. The main purpose of the present study is so to fill this research gap by examining the relationship between the financial crisis and health-care quality for the case of 35 Asian countries during the period 1996–2016 using the dynamic of generalized method of moments (GMM) estimator. It can be expected that if the crisis, with its attendant consequences for unemployment, low incomes and poverty, is prolonged to the households health. Worsening nutrition, homelessness and stress due to job loss, the fear of it and the experience of more straitened economic circumstances will all eventually have negative effects on healthcare quality.

Experiences showed that the financial crisis has a very severe social impact especially for developing countries

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like Asia because it increased inflation which leads to depreciation of domestic currency savings and lowers income in households. The unemployment rates have increased and destroying household income and wealth depreciation. Furthermore, the risk of psychiatric disorders and suicides tend to increase (due to loss of jobs), and public expenditure for health and welfare services are diminished to allocate investments to other areas. Those cuts may lead to a restructure of the roles and functions of the health-care personnel, resulting in a deterioration of the quality of services provided (Notara *et al*., 2010; Kentikelenis *et al*., 2011; Zavras *et al*., 2012; Stuckler and McKee, 2012; Ruckert and Labonté, 2014). In fact, the population's access to healthcare has been negotiated during a recession through mechanisms of demand and/or supply for healthcare. Countries that have suffered financial crisis face problem that when social security programs are cut, government tax revenues shrink and, health-care access, especially for low-income families, and health service delivery become problematic.

From an empirical overview, Van Dijk (2013), using data on 187 banking crisis in 126 countries over the period 1970–2009, they found that exposes broad-ranging implications for society. For example, in the 6 years following a crisis, average life expectancy declines by 9 months. Karanikolos *et al*. (2016) performed also a systematic narrative review of the health effects of the latest economic crisis based on studies of high-income countries. Papers published between January 2009 and July 2015 were selected. Ultimately, 122 studies were selected. The review finds that the 2008 financial crisis had negative effects on mental health, including suicide, and to a varying extent on some non-communicable and communicable diseases and access to care.

For example, Greece is one of the countries most severely hit by the financial shocks, and the studies that have examined the impact of the crisis on health-care provided evidences reductions in public health spending and changes in health-care quality and the pharmaceutical market, with an increasing number of admissions in the public health-care sector (Vandoros and Stargardt, 2013; Ifanti *et al*., 2013; Simou and Koutsogeorgou, 2014). It was also reported that in the wake of the recent global crisis, in Greece, suicides went up by 45% and HIV infections by 60 % and the rate of stillbirths increased from 3.31/1000 live births in 2008 to 4.36 in 2010. De Belvis *et al*., 2012, showed also that Italy after the latest subprime crisis faced the risk of investment reductions for preventive medicine, evidence-based medicine infrastructure, and health information systems extra. Rucket and Labonté (2014) examined the channels through which financial crisis affected health equities in Canada. They found that government austerity budgets weakened social programs that address the social redistribution of social and economic determinants of health outcomes. For the case of Indonesian crisis of 1997, basic health care becomes unaffordable for the majority of poor people, particularly women. Primary health-care clinics are shutting down due to lack of supplies and the nonpayment of health workers. In the main vein of studies, Hopkins (2006) showed a significant drop in health expenditure in Indonesia, Thailand, and Malaysia during the East Asian financial crisis 1998. Baldacci *et al*. (2002) showed also that during the Mexican crisis, average monthly household income fell 31% between 1994 and 1996 and health expenditure dropped by about 25%.

It is showed that from this existing works presented above that people's health status is definitely affected by the financial crisis and consequently the health-care sector will be charged to meet efficiently the increasing needs. For that reason, improving health around the world is an important social objective, which provides direct payoffs in terms of longer and better lives. We believe that one way to reduce the scale of the financial crisis is to ameliorate governance and institutions because a new global governance architecture in both financial and health sectors may be a solution for stability and sustainability. Institutions and governance have emerged as the backbone of development and are increasingly being shown as critical to income levels (Rigobon and Rodrik, 2004; Rodrik *et al*., 2004; Kaufmann and Kraay, 2002), fostering thus overall households health. Indeed, institutional quality and the legal framework are likely to affect financial development through the ability of the financial sector to channel resources to finance health sector (Grigorian and Martinez, 2001; Law and Azman-Saini, 2008). Good governance complements financial supervision and is an integral factor to implementing effective risk-based financial oversight. In theory, governance plays an important role in the prudent operation of financial institutions and the stability of the financial sector. Principles of good governance have been a major component of international financial standards, and many regulators view effective governance as the first line of defense.

This paper contributes to the existing literature in the following two ways: First, our study gains interest by what it covers the countries of Asia; the economic literature of recent decades has shown that many countries in this region have been hardly affected by financial crisis including the crisis of 1997 and 2009. Second, although there exists seldom empirical works covering financial crisis and health nexuse; to the best of our knowledge, there is no study that seeks to take in to account the role of governance in mediating the financial crisis-health relationship.

The portions of the study are as follows. The second section covers the model description, empirical methodology, and data sources. Regression results and findings are shown in section three; and finally, section four suggests some conclusions and policy implications.

Empirical Methodologies

The present study aims to examine the impact of the financial crisis on health status with especial emphasis on the role played by governance in the health sector. To do this, the study is based on a panel data of 35 Asian countries for which data are available from 1996 to 2016. The analysis is subdivided into two steps. We examine first, the direct impact of financial crisis and governance indicators on health status. Then, we assess the indirect effect of the financial crisis on health through governance channels. Based on some existing empirical works (Kentikelenis *et al.*, 2011; Fountoulakis *et al.*, 2012; Vandoros and Stargardt, 2013; Ifanti *et al.*, 2013; Dhrifi, 2018 a,b), the following model is specified:

$$H_{it} = \delta_i + \lambda' X_{it} + \varepsilon_{it} \quad (1)$$

Where δ_i is the country-specific effect which is also distributed independently and constant over the countries, i denotes the country i =1, 2,…, 35) and □ denotes time period (t = 1996,…, 2016); ε_{it} is the error-term assumed to be distributed independently in all time periods of the country i. H_{it} is health indicator and X_{it} is a vector of some determinant variables which are hypothesized to affect health status.

The GMM for panel data analyses proposed by Arellano and Bond (1991) and then further developed by Blundell and Bond (1998), is employed here to control for endogeneity in our estimations. The dynamic analysis of the GMM approach includes lagged health as an explanatory variable. This method meets the need of the panel data study by providing solutions to common problems in this area: The heterogeneity of behavior of individuals in the sample, the endogenous (presence of endogenous lagged variables among the regressors model), and simultaneity (bidirectional causality problem between variables). We will estimate a dynamic model (where the endogenous variables are included as explanatory variables with one or more lags). Certainly, we will face these problems that skew estimators. Therefore, the dynamic version of Equation (1) is expressed in the following form:

$$(H_{i,t} - H_{i,t-1}) = \delta_i + \lambda_0 H_{i,t-1} + \lambda'_i X_{it} + \xi_{it} \quad (2)$$

The use of lagged variables in levels as instruments in the estimation of the equation in first difference is proposed by Arellano and Bond (1991):

$$(H_{i,t} - H_{i,t-1}) - (H_{i,t-1} - H_{i,t-2}) = \lambda_0 (H_{i,t-1} - H_{i,t-2}) + \lambda'_i (X_{it} - X_{it-1}) + (\xi_{it} - \xi_{it-1}) \quad (3)$$

Then, based on Arellano and Bond (1991), moment conditions are applied in determining the difference estimator as follows:

$$\left.\begin{aligned} E\left[H_{i,t-s}(\xi_{i,t} - \xi_{i,t-1})\right] = 0 \quad \text{For} \quad s > 2 \quad t = 3,.....T \\ E\left[X_{i,t-s}(\xi_{i,t} - \xi_{i,t-1})\right] = 0 \quad \text{For} \quad s > 2 \quad t = 3,.....T \end{aligned}\right\} \quad (4)$$

This step is required in the estimation since lagged differences of the explanatory variables are used as instruments in levels equation with the presence of two important assumptions, namely the error term is not correlated and correlation does not exist between difference in the explanatory variables and the error term despite association between the levels of the explanatory variables and the country-specific error term may occur.

As a result, the following stationarity properties are obtained:

$$E\left[H_{i,t+p}\eta_i\right] = E\left[H_{i,t+q}\eta_i\right] \text{ and}$$

$$E\left[X_{i,t+p}\eta_i\right] = E\left[X_{i,t+q}\eta_i\right] \quad (5)$$

For all p and q

Arellano and Bover (1995), the additional moment conditions for the regression in levels are as follows:

$$\left.\begin{aligned} E\left[(H_{i,t-s} - H_{i,t-s-1})(\eta_{i,t} + \xi_{i,t-1})\right] = 0 \quad \text{For s = 1} \\ E\left[(X_{i,t-s} - X_{i,t-s-1})(\eta_{i,t} + \xi_{i,t-1})\right] = 0 \quad \text{For s = 1} \end{aligned}\right\} \quad (6)$$

By utilizing the moment conditions in Equations (4, 5, and 6), the GMM system estimator is derived. The validity of the instruments determines how consistent the GMM estimator would be. The Sargan test of over-identifying restrictions is used to examine the validity of the instruments. Finally, to assess the financial crisis and effects on health status, we specify the basic empirical model as follows:

$$H_{it} = \delta_i + \delta_1 H_{it-1} + \delta_2 FC_{i,t} + \lambda' X_{it} + \xi_{it} \quad (7)$$

Where H_{it} denotes the dependent variable which is infant mortality rate per 1000 live births, FC_{it} is the financial crisis variable, X_{it} is a vector of explanatory variables generally used in this type of model, this is GDP growth, financial development, trade openness, inflation, urbanization, density of physicians, environmental degradation and health-care expenditure, λ refers to a vector of parameters to be estimated and ε_{it} is the error term.

Then, for the purpose of testing how much does the impact of financial crisis on health is influenced by governance, the interaction term between governance indicators and financial crisis needs to be included into Equation (7) as follows:

$$H_{it} = \delta_i+\delta_1 H_{it-1}+\delta_2 FC_{i,t}+\lambda' X_{it}+\gamma' (FC_{it}*GOV_{it})+\xi_{it} \quad (8)$$

Where X_{it} are control variables as already defined to include λ_1 $GDPG_{it}$; λ_2 FD_{it} and λ_3 $OPEN_{it}$; λ_4 URB_{it}; λ_5 $DENS_{it}$, λ_6 ENV_{it}, and λ_7 $HEXP_{it}$; λ_8 INF; $FC_{it}*GOV_{it}$ is the interaction term between financial crisis and governance, γ' captures the role of governance in mediating the impact of financial crisis on health system. As mention above, a good governance is deemed to be more able to reduce the negative effect of financial chocs, thus contributing on ameliorating health status. If the estimated γ is positive and significant, it would indicate that a complementarity exists and governance is important in mediating the financial crisis impact on health care services. We are particularly interested in the effect of the interaction term because we expect that the magnitude of financial shocks may be absorbed by other conditions including better governance.

GOV is a matrix of contributing governance indicators to include voice and accountability (VA), government effectiveness (GE), political stability and absence of violence (POL), regulatory quality (RQ), rule of law (RL), and control of corruption (CC). These measures are used individually to compare the importance of each variable in influencing health status. This is basically due to the high correlation that might exist among these indicators and which is suspected, might create serious issues in the analysis due to problems of multicollinearity. We will also use the principal component factor method (PCF) to construct another indicator of institutional and legal development (*GOV*). This indicator is constructed from the six governance indicators cited above. The choice of this governance variable was made so that it should look synthetic because it contains simultaneously much informations on economic risk, political risk, and social risk. The interest of the decomposition of this variable comes from the fact that it takes into account all the institutions in explaining the links between financial crisis and health-care services. Another reason for the choice of this synthetic variable is the importance of its role as an indicator of good governance. Theorists attribute to it the benefit of having allowed to guarantee an appropriate mode of governance including all the dimensions of the regulations.

Table 1: Descriptive statistics

Variables	Obs	Mean	SD	Min	Max
IMR	735	39.25	5.645	2.31	163
LO	735	−0.193	0.432	−1.146	0.572
VA	735	−0.884	0.409	−1.765	−0.221
GE	735	−0.225	0.483	−1.198	0.638
CCOR	735	−0.149	0.651	−1.093	1.354
RQ	735	−0.272	0.553	−2.023	0.836
PS	735	−0.604	0.663	−2.037	0.395
GDPG	735	4.068	3.685	−4.678	10.691
FD	735	75.354	3.568	49.343	93.848
TRADE	735	0.763	1.863	0.637	0.838
URB	735	3.364	1.235	1.180	7.382
INF	735	4.935	2.673	2.836	11.506
ENV	735	12.617	6.823	2.193	27.394
HEXP	735	13.954	4.382	2.392	36.685
PHYS	735	9.364	7.394	2.046	138.923

Source: Statistics provided by the authors

Data Sources

To achieve the research objectives for this paper, the study is based on a panel data of 35 Asian countries for which data are available from 1995 to 2016. The selection of countries and time period is strictly based on the availability of the data. Thus, as a result, 35 Asian countries[1] were chosen to achieve the objectives of the study. Some missing data are dealt with by averaging the available data since it is found that country values do not change significantly over time. Selected indicators are more relevant and commonly used in explaining health status. All variables are taken from World Development Indicators and International Country Risk Guide (ICRG); health indicator is measured by infant mortality per 100 live births, environmental degradation indicator is measured by per capita CO_2 emission, TRADE is defined as the sum of exports and imports as a share of GDP, financial development is proxied by domestic credit to private sector (% GDP), and urbanization is measured by the urban population as a share of the total population. Density of physicians measured as the number of doctors per 1000 population and health expenditure represented by total per capita expenditure on health, including government and private spending. For governance indicators, the dataset obtained from the ICRG includes six variables, namely VA, political stability and absence of violence, GE, RQ, RL, and CC**.** The descriptive statistics of all these variables are listed in Table 1.

RESULTS

The main purpose of the paper is to test the extent of the effects of financial crisis on household health with

1 The list of the sample countries is presented in Table A.1 in appendix.

special emphasis on the role played by governance in such relationship for a panel of 35 Asian countries using GMM technique over the period 1996–2016. The dynamic GMM is used because it may eliminate any country-specific effect or any time-invariant variable by differencing the model. Further, it can also help to get rid of endogeneity problem caused by the correlation between the country-specific effects and the right-hand side variables (Baltagi *et al*., 2009). This technique is also used due to the fact that it is a useful technique to estimate the effects of financial crisis on households' health in the sense that it helps to solve the problem of endogeneity involving these variables, Blundell and Bond (1998). The problem can be dealt with by taking the lagged values of the explanatory variables as instruments. Next, Sargan test is applied to examine whether the validity of instruments used. It is with the purpose of examining the null hypothesis that there is no correlation between the instruments used and the residuals. In all the equations, the Sargan test statistic shows that the null hypothesis, Ho: Over-identifying restrictions are valid, cannot be rejected.

To take into account the interrelationships between our interest variables, and to assess the impact of the financial crisis which may affect health through governance indicators, we start by discussing the results from the estimation of the direct impact of financial crisis and governance on health care. Then, we carry out the results of the indirect effects of the financial crisis through its interaction with different indicators of governance.

Table 2 presented below reported the results obtained from the estimation of our model. The dependent variable is health measured by infant mortality rate per 1000 live births, and our variables of interest are a financial crisis and governance indicators. The coefficients of these variables of interest have the correct signs and are statistically significant. Indeed, from model 1 to 7 all the coefficients of financial crisis indicator have positive coefficients and ranges from 0.08 to 0.69. A one standard deviation increase financial crisis leads to 0.08–0.69 increase in infant mortality rate. This confirms the hypothesis that financial shocks have a negative and statistically significant effect on health which can be viewed as an obstacle for households health (Stuckler *et al*., 2008; Stuckler *et al*., 2009a; Stuckler *et al*., 2009b; Kentikelenis *et al*., 2011; Bonovas and Nikolopoulos, 2012; Fountoulakis *et al*., 2012; Vandoros and Stargardt, 2013; Ifanti *et al*., 2013). This implies that the health status of a population of a country depends on its financial sector which suggests that a developed and sound financial sector stimulates economic growth, increases the budget allocated by governments to the health sector which may by consequences ameliorate health-care services (Mladovsky, 2012).

Table 2 indicates also the estimation results using governance indicators. These indices reflect VA, GE, political stability and absence of violence (POL), RQ, RL, and CC, all these indicators are statistically significant, and they have the expected signs. The column 1 to column 7 present, respectively, the change in health status due to one

Table 2: The direct effects of financial crisis and governance on health

Variables	Dependent variable: Health (IMR's/1000 live births)						
	1	2	3	4	5	6	7
Hit-1	2.354*** (0.000)	2.671*** (0.000)	1.983*** (0.003)	2.625*** (0.002)	2.064*** (0.000)	1.375*** (0.000)	2.364*** (0.000)
FC	−0.361** (0.000)	−0.471*** (0.000)	−0.533*** (0.001)	−0.265*** (0.002)	−0.636*** (0.000)	−0.695*** (0.000)	−0.086*** (0.000)
LO	−3.812** (0.032)	-	-	-	-	-	-
VA	-	−3.77* (0.051)	-	-	-	-	-
GE	-	-	−3.748** (0.066)	-	-	-	-
PS	-	-	-	−3.523** (0.037)	-	-	-
RQ	-	-	-	-	−3.292** (0.025)	-	-
COR	-	-	-	-	-	3.475** (0.049)	-
GOV (PCF)	-	-	-	-	-	-	−4.023*** (0.009)
GDPG	−0.954*** (0.000)	−1.139*** (0.000)	−0.894*** (0.000)	−1.092 (0.002)	−0.731** (0.000)	−1.014*** (0.000)	−1.174*** (0.000)
FD	−2.076** (0.03)	−2.348*** (0.000)	−2.456*** (0.000)	−2.051** (0.025)	−2.065*** (0.000)	−2.096*** (0.000)	−2.117*** (0.000)
TRADE	−2.845** (0.058)	−1.984** (0.045)	−1.562** (0.024)	−2.141** (0.033)	−1.635 (0.135)	−1.547* (0.06)	−3.367** (0.012)
URB	−0.155*** (0.010)	−0.185** (0.032)	−0.173*** (0.000)	−0.161*** (0.000)	−0.169*** (0.000)	−0.185*** (0.000)	−0.191*** (0.000)
INF	0.15*** (0.000)	0.067* (0.097)	0.391** (0.056)	0.079** (0.032)	0.232 (0.112)	0.491*** (0.000)	0.035*** (0.000)
ENV	0.039** (0.148)	0.0287* (0.095)	0.055 (0.235)	0.011 (0.165)	0.0255 (0.285)	0.0667*** (0.000)	0.129* (0.070)
HEXP	−0.761*** (0.000)	−0.871*** (0.000)	−0.432*** (0.002)	−0.854*** (0.000)	−0.765*** (0.000)	0.593* (0.082)	0.961*** (0.000)
PHYS	−3.761*** (0.000)	−3.571*** (0.000)	−2.122*** (0.000)	−4.965*** (0.000)	−3.705*** (0.000)	−2.668*** (0.000)	−4.807*** (0.000)
CST	4.48** (0.000)	5.767*** (0.000)	7.943*** (0.000)	2.687*** (0.000)	6.245*** (0.001)	3.257*** (0.000)	4.387** (0.000)
Diagnostic checkinig							
Sargan Test	0.536	0.687	0.465	0.604	0.557	0.484	0.679
Obs	735	735	735	735	735	735	735

P values are in parentheses. ***, **, and* indicate statistical significance at the 1, 5 and 10% levels, respectively, units and measurements of variables are presented in Table A.2 in appendix

standard deviation increase of governance. Findings show that the effect ranges from 3.4% to 4.02% points. For the political stability indicator, results show that it appears to be significantly negative at 5% level with a coefficient of 3.52 which confirm the hypothesis that countries with more political stability achieve relatively low-level infant mortality. For law and order, the coefficient is found to be negative 3.81 and shown by column (1) indicating that better law and order contribute to good health. Similarly, the coefficient on the VA is reported as negative 3.77 and significant at 5% significance level. As regard the coefficient of GE, appears significantly negative at 5% level reflecting that good perceptions of the quality of public services, good quality of the civil service lead to a better health status. However, CC is discovered to have a negative relationship with the infant mortality rate, as the coefficient is positive (3.47) and significant at 1% level. The result suggests that high scores of CC are associated with lower level of mortality. As regard the synthetic variable of governance conducted by the PCF method and that contain simultaneously much information on the economic risk, political risk, and social risk, it appears statistically positive at 5% level. Results show that infant mortality per 1000 live births declines by 4.02% for every 1% increase of governance.

Overall, the estimated coefficient of governance shows that there is a clear negative relationship between institutions and infant mortality suggesting that institutions quality may be the main factor of health status. Good governance is important in ensuring effective health-care delivery, and that returns to investments in health are low where governance issues are not addressed. This incites countries to develop regulatory structures that encourage internal incentive structures within financial institutions that promote financial stability across the financial system, to avoid incentive structures that encourage short-term returns or excessive risk-taking. It is because good institutions may provide a favorable environment for cooperative solutions that bring about better economic performance (Dhrifi, 2018a).

As for all other relevant variables of control, they present expected signs and are statistically significant. For the GDP growth, results demonstrate that per capita income growth has a positive and significant effect on infant mortality where a 1% increase in per capita incomes infant deaths by 0.73–1.17 point. Findings indicate also that trade has a positive effect on health status. Indeed, exposure to larger markets increases domestic sectors competitiveness and as a result improves market efficiency leading to economic growth which may by consequence affect positively household health. That means that an increase in the volume of trade leads to a decrease in the infant mortality rate. For the estimated coefficient on health spending, it appears to be positively related to health variable. The coefficients which range from 0.43 to 0.96 indicating that a standard deviation increase in health expenditure would result in a 0.43–0.96 unit decrease in infant mortality rate. This confirms the hypothesis that health expenditure has a positive and statistically significant impact on infant mortality rate which can be viewed as a determinant factor of household's health. It means also that infant health depends on the level of spending on health. This suggests that an increase in health expenditure implies broader access to health care and services which help decrease mortality rates. This result coincides with those found by Berger and Messer, 2015; Dhrifi, 2018b.

Results show also that the coefficients of inflation appear to be significantly negative showing that a 1% change in the inflation index increases infant deaths by about 0.03–0.49 point. For the coefficients of financial development, it appears to be significantly negative showing advanced efficiency of financial intermediates leads to GDP per capita growth which may by consequence contribute positively at financing the health sector. This result illustrates that better financial development is an important factor in relationships between the financial system and health sector. Regarding the coefficient of the physicians' density variable, it appears to be statistically significant at the 1% level suggesting that a higher density of physicians indicates more easily accessible health care, and should, therefore, correlate with good health. For the estimated coefficient on urbanization, results show that increasing urban population by 1% will decrease infant death's rate by about 0.17% point. As regard the environmental quality variable, the estimated coefficient of CO_2 emission appears to be statistically non significative which contradicts results found by Dhrifi, 2018b.

Finally, results presented above regarding the effects of the financial crisis on the health sector, do not reflect comprehensively the relationship between financial instability and health because they reflect only the direct impacts. While financial shocks may also affect health system indirectly through governance and institutions, which constitutes the object of the following section.

The Indirect Impact of Financial Crisis on Health through Governance Indicators

Bearing in mind that the financial crisis may influence health through the quality of institutions, we use, therefore, different measures of governance to test the empirical relationship between these institutional indicators, environmental degradation, and health. Models (1) to (7) include the interaction terms, constructed as a product of governance indicators and financial crisis.

Table 3: The indirect effect of financial crisis on health through governance

Variables	Dependent variable: Health (IMR's/1000 live births)						
	1	2	3	4	5	6	7
Hit-1	1.654** (0.036)	1.591** (0.027)	2.027** (0.033)	0.972* (0.074)	1.376** (0.021)	2.792* (0.085)	2.102*** (0.004)
FC	−0.069** (0.000)	−0.397*** (0.000)	−0.294*** (0.001)	−0.265*** (0.002)	−0.376*** (0.000)	−0.425*** (0.000)	−0.573*** (0.000)
LO*FC	−1.379** (0.007)	-	-	-	-	-	-
VA*FC	-	−1.198*** (0.001)	-	-	-	-	-
GE*FC	-	-	−2.346** (0.066)	-	-	-	-
PS*FC	-	-	-	−1.674*** (0.008)	-	-	-
RQ*FC	-	-	-	-	−2.672*** (0.006)	-	-
COR*FC	-	-	-	-	-	1.354** (0.127)	-
GOV*FC	-	-	-	-	-	-	−2.827*** (0.000)
GDPG	−2.604*** (0.000)	−1.932*** (0.000)	−2.795*** (0.000)	−1.792*** (0.000)	−2.306** (0.000)	−1.413*** (0.004)	−0.937*** (0.000)
FD	−4.267** (0.032)	−4.935*** (0.000)	−3.391*** (0.000)	−2.929** (0.007)	−3.795*** (0.000)	−4.926*** (0.000)	−2.782** (0.021)
TRADE	−0.928*** (0.008)	−1.066** (0.045)	−0.791*0* (0.001)	−1.173*** (0.000)	−0.668** (0.043)	−1.053*** (0.009)	−0.748** (0.012)
URB	−2.356** (0.039)	−1.528** (0.053)	−0.868*** (0.000)	−1.368*** (0.000)	−1.096** (0.080)	−2.455*** (0.002)	−1.836*** (0.000)
INF	0.426*** (0.000)	0.637** (0.027)	0.671*** (0.006)	0.499** (0.032)	0.536*** (0.003)	0.491*** (0.000)	0.560*** (0.000)
ENV	0.165* (0.108)	0.084* (0.095)	0.096 (0.132)	1.326 (0.110)	1.391 (0.125)	1.958 (0.215)	0.792 (0.176)
HEXP	−1.385** (0.025)	−1.094*** (0.000)	−0.892*** (0.002)	−1.159*** (0.000)	−1.222*** (0.000)	−0.993*** (0.002)	−1.358*** (0.000)
PHYS	−2.365*** (0.000)	−1.783** (0.031)	−3.641*** (0.000)	−2.682*** (0.005)	−3.387*** (0.000)	−1.628*** (0.000)	2.673*** (0.000)
CST	7.365** (0.001)	4.681*** (0.000)	6.969*** (0.009)	5.964*** (0.000)	4.972*** (0.002)	7.928*** (0.006)	6.492** (0.000)
Diagnostic checking							
Sargan Test	0.497	0.591	0.516	0.643	0.597	0.694	0.572
Obs	735	735	735	735	735	735	735

P values are in parentheses. ***, **, and* indicate statistical significance at the 1, 5, and 10% levels, respectively

Table 3 presented above summarize the results regarding the impact if financial crisis on health taking into account governance indicators variables; the estimated coefficients for the financial crisis are still negative and statistically significant and ranges from 0.06 to 0.57. This may be explained by the poor regulatory systems or excessive financial liberalization (Arcand *et al*., 2012). However, the interaction terms between governance indicators and the financial crisis appear to be positively significant expected of the interaction term between the financial crisis and CC. Institutional quality and the legal framework are likely to affect financial development through the ability of the financial sector to channel resources to finance health sector. This indicates that a better quality of institutions may absorb the magnitude of financial shocks (La Porta *et al*., 1997). This finding confirms the hypothesis that proper improving governance may reduce the magnitude of financial crisis which helps to decrease infant mortality rate. Moreover, good institutions might, therefore, reduce the health effect of financial instability through their general impact on universal health policy issues, such as universal access to high-quality services and universal health insurance and accessible programs. Good institutions may, in addition, provide information and advice about hygiene, good health practice, and other knowledge useful for the population. These arguments predict the stability of financial system channeled by institutional quality. More precisely, a high level of institutional quality decreases the marginal effect of the financial crisis and therefore reduces the negative effect of financial shocks which implies that the crisis, through their global range, may revealed the weakness of global governance and brought new long time risks with it. This confirms the hypothesis that good institutions can significantly affect health by improving health care services. Overall, a good governance is deemed to be more able to reduce the negative effect of financial instability, thus contributing on ameliorating health status.

CONCLUSION

While financial liberalization was touted as the surest route to the prosperity of developing countries, it provoked acute financial crises. This has resulted in economic and social crises leading to increased unemployment rates, lower household income, wealth depreciation, leading to health, and social welfare disaster in many countries. The objective of this paper is to investigate the role of financial crisis and governance on healthcare services. More specifically, this work stains to investigate how governance could be considered as an additional channel through which financial instability affects health-care quality. To do so, we use a sample of 35 Asian countries for the period 1996–2016. In terms of methodology, we estimate the health model using the dynamic GMM estimator to deal with potential endogeneity of the explanatory variables. Our empirical results suggest that Asian regions exhibit a monotonically decreasing relationship between financial shocks and health-care quality on the one hand, and a positive relationship between governance indicators and health on the other hand. Moreover, the direct and negative effects of

financial shocks on health may be decreased by indirect and positive effects through better governance. This indicates that the financial crisis impacts health and the magnitude of the effects could be reduced through the presence of good governance and institutional interventions. This implies that good institutions affect directly and indirectly not only financial stability but also health care quality in the Asian countries through the strengthening of the financial system and the efficiency of health public expenditure. It has an important role to play in overcoming the financial crisis and restoring confidence for the secure future.

As a policy implication, certain measures must be taken to reduce the magnitude of financial crisis and to ameliorate health care services: Since governance has an important role to play in overcoming the financial crisis, governments must restore confidence in the future and preventing regulatory overkill that would damage the entrepreneurialism needed to secure future economic growth. Global authorities should continue to work with market participants to develop enhanced governance practices that will underpin other regulatory actions being taken to address health problems. In the event of a financial crisis and when the financial system is unable to finance the health sector, global health funds and programs may become increasingly important as sources of aid. Should this be the case, it will be important, particularly for the Global Fund, to look at country grants in the light of the need to ensure adequate delivery systems ones that benefit the health sector as a whole.

Finally, if the present paper presents a detailed analysis of the direct and the indirect impact of financial crises on health, it does not dissociate (due to the lack of data on the different type of crises) between banking crises, currency crises, and twin-crises.

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APPENDIX

Table A1: List of the sample countries

Afghanistan, Bahrain, Bangladesh, Brunei, China, India, Indonesia, Israel, Iran, Iraq, Japan, Jordan, Kuwait, Lebanon, Malaysia, Mongolia, Myanmar, Nepal, North Korea, Oman, Pakistan, Philippines, Qatar, Saudi Arabia, Singapore, South Korea, Sri Lanka, Syria, Taiwan, Thailand, Turkmenistan, United Arab Emirates (UAE), Uzbekistan, Vietnam, Yemen

Table A2: Units and measurements of variables

Units	Measurements
LO	Low and order
VA	Voice and accountability
GE	Government effectiveness
COR	Control of corruption
RQ	Regulatory quality
PS	political stability and absence of violence
GDPG	Gross domestic product growth
FD	Financial development measured by domestic credit to private sector (% GDP)
TRADE	Sum of exports and imports to GDP
URB	urbanization is measured by the urban population/the total population
INF	Inflation measured by the consumer price index
ENV	Environment al quality measured by CO_2 emissions in metric tons per capita
HEXP	Health public expenditure
PHYS	Number of doctors per 1000 population
FC	Financial crisis (Binary variable)
H	Health indicator measured by infant mortality rate's per 1000 live births

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Original Article

A Cross Sectional Study of Knowledge, Attitude and Practices about Menstruation and Menstrual Hygiene among Medical Students in Ranchi, Jharkhand

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Abstract

Introduction: Menstruation and menstrual practices are associated with taboos and sociocultural restrictions. Misconception and unhygienic practices associated with menstruation may cause adverse health outcomes. Undergraduate medical students are the future main health-care providers, and thus, their knowledge helps in transforming the community practices.

Aims and Objectives: This study aims to assess the knowledge, attitude, and practices of menstrual hygiene of undergraduate medical students of Ranchi, Jharkhand.

Materials and Methods: A cross-sectional study was conducted on 110 girls of the 1st and 2nd year MBBS students of Rajendra Institute of Medical Sciences, Ranchi.

Results: Out of 120 girl students of first and second year MBBS 110 students were participated in the study. Most girls 60% (*n* - 66) were in the age group of 17–20 years. Surprisingly, 36% of girls were ignorant about menstruation before menarche. We also found that 60.9% (*n* - 67) of students menstrual habits was inculcated by their mother. Almost all girls experienced premenstrual symptoms. 81.18% (*n* - 90) of girl students were forced to practice restrictions during menses.

Key words: Menstrual hygiene, Menstruation, Premenstrual symptoms

INTRODUCTION

The reproductive system of women shows regular cyclic changes that teleologically may be regarded as periodic preparations for fertilization and pregnancy. In human and other primates, the cycle is a menstrual cycle and its most conspicuous features are the periodic vaginal bleeding that occurs with the shading of the uterine mucosa (mensuration).[1]

Mensuration has been surrounded by taboos and myths that prohibit woman from many aspects of sociocultural life. Many cultures hold on different belief and myths that restrict women from daily activities and hygienic health practices, which lead to adverse outcomes such infections.[2,3]

Studies reported that many girls had lots of misconceptions about the physiological changes during menstrual period. Most of these information acquired from their mothers, television, friends, and teachers.[4] Such taboos affect girl's and women's emotional states, mentality, lifestyle, and most importantly health.

In India, even mere mention of topics was a taboo in the past and even this state the cultural and social influences appear to be a hurdle for advancement of the knowledge of subject. Many girls and women are subject to restriction in their daily lives simply because they are menstruating. Not entering the puja room is the major restriction among the urban girls, whereas not entering the kitchen is the main restriction among the rural girls during mensuration. Menstruating girls and women are also restricted from offering prayers and touching holy books.[5,6] The underline

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basis of this myth is also the cultural beliefs of impurity associated with menstruation. It is further believed that menstruating women are unhygienic and unclean, and hence, the food they prepare or handle can get contaminated. According to the study by Kumar and Srivastava, in 2011,[7] participating women also reported that during mensuration the body emits some specific smell or rays, which turns preserve food bad. Moreover, therefore, they are not allowed to touch sour foods like pickles. However, as long as general hygiene measures are taken in account, no scientific test has shown mensuration as the reason for spoilage of any food making.

Menstrual disturbances are the most common presenting complaint in adolescent group and unhygienic practices during mensuration can lead to untoward consequences such as pelvic inflammatory disease and even infertility.[8] Special health-care needs and requirement of women during monthly cycle of mensuration are collectively given the term "menstrual hygiene."[9]

Medical students are the future main health-care providers; hence, their knowledges help in transforming the community practices. This is the reason for taking the medical students in this study.

Aims and Objectives

The objectives of this study were as follows:

1. To assess the knowledge, attitude, and practices of menstrual hygiene of medical students.
2. To find out the beliefs, perceptions, and sources of information regarding menstruation among the medical students.

MATERIALS AND METHODS

Study Design

The study was a cross-sectional questionnaire-based study. A self-developed, prevalidated questionnaire was used. Data are expressed as count and percentage.

Study Area

This study was conducted in Rajendra Institute of Medical Sciences, Ranchi, in the Department of Physiology, from August 2018 to December 2018.

Study Population

First and second year MBBS girl students of RIMS Ranchi.

Inclusion Criteria

Those girl students who shown willingness to participate in the study. Informed consent was taken from each and every student. A preform pre-tested questionnaire was used. Some question had multiple options to choose from; therefore, the sum total of percentages is not always hundred percent.

Exclusion Criteria

Incompletely filled questionnaire was excluded from the study.

Statistical Analysis

Data were analyzed statistically by simple percentage.

RESULT

A total of 120 girl students of the 1st and 2nd years MBBS took part in questionnaire, but only 110 responses were obtained. Incompletely filled questionnaire was excluded from the study. Most girls 60% (*n* - 66) were in the age group of 17–20 years followed by 40% (*n* - 44) of girls in the age group of 21–24 years.

In spite of the fact that most girls having well-educated family background, only 66.73% (*n* - 74) of girls have knowledge of menstruation before menarche, while 32.73% (*n* - 36) of girls were ignorant about it. We found that the mean age of menarche was 12.5 years ranged from 10 to 15 which is shown in Table1 and Figure 1.

In our study, we found that 60.90% (*n* - 67) of girl students have taken information for menstrual habits from their mother while friends are the main source of information in 13.63% (*n* - 15) as shown in Table 2 and Figure 2.

Table 1: Age of the attainment of menarche

Age (years) of attainment of menarche (years)	Number of girls (%)
10	10 (9.09)
11	28 (25.45)
12	28 (25.45)
13	27 (24.55)
14	14 (12.73)
15	3 (2.73)

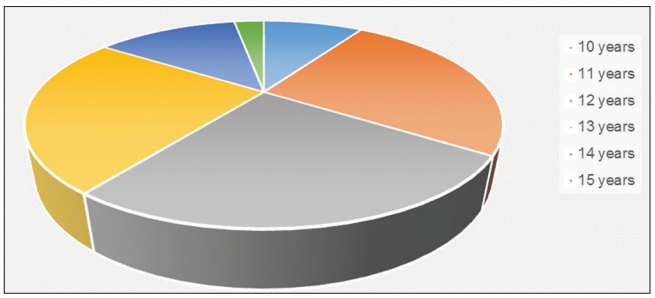

Figure 1: Age of the attainment of menarche

Almost all girls used sanitary napkin as absorbent material during their menstrual cycle. 100% of girls were reported to have the habit of washing hands after changing the pad, but only 48% (*n* - 53) were doing vaginal wash daily.

Our result shows that most of the girls have moderate menstrual flow 88.18% (*n* - 97) followed by mild menstrual flow 9.09% (*n* - 10), then heavy flow 1.8% (*n* - 2) and spotting only in 0.9% (*n* - 10) as shown in Table 3.

About 14.54% (*n* - 16) of girls used to change their pads 4 hourly during first 2 days of their menstrual cycles followed by 6 hourly 50% (*n* - 55), then 8 hourly and least was once a day 1.8% (*n* - 5).

All girls reported that they experienced premenstrual symptom with a variation in the symptom such as headache, backache, lower abdominal pain, fatigue, weakness, and mood swings. We also found that 34.5% have menses that disturb their daily routine while 76.2% have no disturbances at all.

About 81.18% (*n* - 90) of female were forced to practice restriction during menses and 18.18% (*n* - 20) were not forced to practice restriction as shown in Table 4 and Figure 3.

Table 2: First informer about menstrual habits

1st informer	*n* (%)
Mother	67 (60.90)
Friend	15 (13.64)
Teacher	10 (9.09)
Magazine	8 (7.27)
Newspaper	2 (1.82)
Television	3 (2.73)
Internet	5 (4.55)

Table 3: Categorization of the menstrual flow

Categorization of menstrual flow	*n* (%)
Mild	10 (9.09)
Moderate	97 (88.18)
Heavy	02 (1.82)
Only spotting	01 (0.91)

Table 4: Restriction followed by medical student in study

Type of restriction	*n* (%)
Cannot go to religious place	69 (62.73)
Cannot enter into puja room	02 (1.82)
Cannot touch pickle	12 (10.90)
Cannot consume sour food	07 (6.36)
Not any restriction	20 (18.18)

DISCUSSION

This study shows that the age of menarche ranged from 10 to 15 years with maximum number of girls falling between 11 and 12 years of age, almost similar study was conducted by Deo *et al.*[10]

In our study, 67.2% of students had previous knowledge of menstrual practices attending the menarche and this result is more than other studies done on medical students by Sharma *et al.*[11] Mother was main source of information, but only 9.09% obtained information from possible authentic sources like teachers. Mother was also the main source of information in Nigerian study.[12] However, in a study done by Juyal *et al.*, in Uttrakhand, friends were the first source of information in 31.8% of girls.[12]

In our study, we found, almost all medical students were using sanitary napkin as absorbent material during their menstrual cycle, which is in accordance with Pokle *et al.* study.[13] However, in a study done by Sharma *et al.*,[11] only 86.36% of medical students were using sanitary napkin as absorbent material.

In the present study, 21.81% (*n* - 24) of students reported irregular menstrual cycle. This finding is more if it is compared with Pokle *et al.*[13]

We found that 80% of girls were forced to practice restriction during menses like they cannot go to religious places, not allowed to attend the religious ceremony, cannot touch pickle, and cannot consume sour food. Similar types

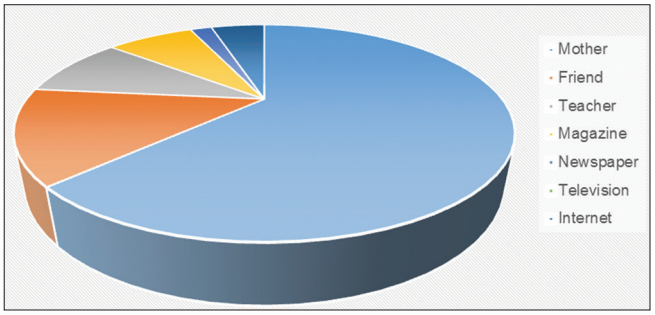

Figure 2: First informer

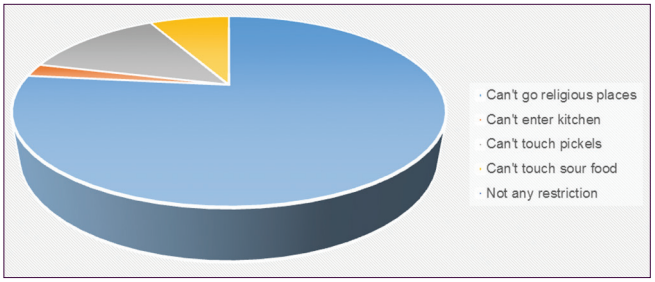

Figure 3: Restriction followed by medical student

of restrictions were reported by other studies also.[11]

CONCLUSION

Despite being medical students, many respondents did not change their absorbent pad more frequently during menses and lack proper knowledge of information relevant to menstruation. This included the importance of increasing awareness and giving accurate information using scientific sources such as school, colleges, or health team members. It is recommended that the menstruation be discussed in courses such as science to increase the level of knowledge of female students and consequently to improve their attitude toward this physiological process.

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Original Article

Bacteriological Study and Antimicrobial Sensitivity Pattern of Dacryocystitis

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Abstract

Introduction: Dacryocystitis is an infection and inflammation of lacrimal sac and duct secondary to obstruction of nasolacrimal duct. It is a most common ailment encountered in ophthalmology practice and we had tried to find mean and measures to combat this malady with the best possible measures.

Aims: The aim of this study was to identify the pathogenic organisms and also to determine the antimicrobial sensitivity pattern against those organisms.

Materials and Methods: This prospective study was conducted with 166 cases of patient having dacryocystitis over a period of 2.5 years. The organisms were identified from the samples collecting from lacrimal sac and conjunctiva, by conventional methods, and antimicrobial sensitivity pattern was established.

Analysis: The results were analyzed using mean, median, and the Chi-square (χ^2) test.

Results: Women were more affected than men. Chronic dacryocystitis (102) was the most common type of dacryocystitis as compared to acute (40) and congenital dacryocystitis (18). *Staphylococcus aureus* (52), *Streptococcus pneumoniae* (44), and *Pseudomonas aeruginosa* (28) were the most common organisms which were found. The Gram-positive organisms were most sensitive to vancomycin 100%. The Gram-negative organisms were most sensitive to tobramycin and gentamicin (100%).

Conclusion: Chronic dacryocystitis was most dacryocystitis than acute dacryocystitis. Gram-positive organisms were most commonly isolated than Gram-negative organisms. Women were affected more than men.

Key words: Antimicrobial sensitivity, Dacryocystitis, Epiphora

INTRODUCTION

Lacrimal apparatus is one of the important structures of ocular appendage. Its malfunction poses numerous unavoidable difficulties in proper functioning of ocular tissues. Dacryocystitis is the obstruction of nasolacrimal duct or nasolacrimal sac, leading to inflammation. It may be congenital or acquired. Acquired dacryocystitis has two forms: (a) Acute and (b) chronic. The bacteriological study would contribute to the choice of effective antibacterial agents which would also help in reducing the unnecessary load of antimicrobial agents.[1] Hence, this study was done.

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MATERIALS AND METHODS

A total of 172 patients were selected, who attended the ophthalmology outpatient department at tertiary hospital in Kolkata (West Bengal) and were studied over a period of 2.5 years.

Inclusion Criteria

All the patients coming with the symptoms and signs of dacryocystitis were included in the study.

Exclusion Criteria

Patients on systemic or topical antibiotics as well as patients with secondary dacryocystitis were excluded from the study.

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Specimen Collection

Specimen for microbiological analysis was obtained after aseptically cleaning the surrounding area of lacrimal sac. The samples were collected in two sterile cotton swabs from the lacrimal sac either by applying pressure over the lacrimal sac and allowing purulent material to reflux through the lacrimal puncta or by lacrimal syringing. The samples from the refluxing material were collected by ensuring that the lid margins or the conjunctiva was not touched. One swab was inoculated immediately on plates of MacConkey's agar, chocolate agar, and 5% sheep blood agar, and another swab was used for Gram staining. These were examined daily and discarded after 48 h if growth was not seen.

Microbial culture was considered significant if growth of the same organism was demonstrated on more than one solid-phase medium, and/or if it was confluent growth at the site of inoculation on one solid medium and/or if growth of one medium was consistent with direct microscopy finding (i.e., appropriate staining and morphology with Gram stain) and/or if the organism was grown from more than one specimen. The antimicrobial susceptibility testing was done by Kirby-Bauer disc diffusion method on Muller-Hinton agar according to Clinical and Laboratory Standards Institute, 2003.

Statistical Analysis

Statistical analysis was done by Chi-square test. P (predictive) value <0.05 was considered as a statistically significant association both the variables which were tested.

RESULTS

Out of 172 samples clinically diagnosed dacryocystitis over a period of 2 years, 160 were culture positive and 12 were culture negative. 160 samples were culture positive and 12 were culture negative. Bilateral cases were 16 (10%), only the right eye involved 64 (40%) and the left eye involved 80 (50%) cases as shown in Table 1.

In our study, males 48 (30%) were affected less than females 112 (70%). Hence, male: female ratio is 1:2.3. Both in acquired dacryocystitis (62.5%) and congenital dacryocystitis (7.5%), females were affected more than males.

In this study, 80 (50%) cases showed only epiphora and 64 cases (40%) showed epiphora and discharge (mucous/mucopurulent/purulent) as their major symptom. 16 cases (10%) presented with swelling and redness.

Chronic dacryocystitis was the most common type of dacryocystitis as compared to acute dacryocystitis 40 cases (25%) and congenital dacryocystitis 18 (11%) as shown in Table 2. 122 (65%) isolates were Gram-positive and 66 (35%) isolates were Gram-negative.

Of 160 samples, 66 samples (82.5%) showed a single organism and 28 samples (17.5%) showed mixed organisms (Tables 3 and 4).

Table 1: Distribution of eye affected versus sex determination

Eye affected	Number of cases		
	Female (%)	Male (%)	Total (%)
Right	40 (25)	24 (15)	64 (40)
Left	60 (37.5)	20 (12.5)	80 (50)
Bilateral	12 (7.5)	4 (2.5)	16 (10)
Total	112 (70)	48 (30)	160 (100)

Table 2: Types of dacryocystitis versus sex distribution

Clinical type of Dacryocystitis	Number of cases		
Clinical type	Female number (%)	Male number (%)	Total (%)
Acute	30 (18.75)	10 (6.25)	40 (25)
Chronic	70 (43.75)	32 (20)	102 (63.75)
Congenital	12 (7.5)	6 (3.75)	18 (11.25)
Total	112 (70)	48 (30)	160 (100)

Table 3: Distribution of dacryocystitis cases according to the spectrum of Gram-positive organism

Gram positive organisms	Number of cases		
Organism	Congenital (20)	Acquired (168)	Total 188 (%)
Staphylococcus aureus	2	50	52 (27.65)
Streptococcus pneumoniae	10	34	44 (23.40)
Staphylococcus epidermidis	2	14	16 (8.5)
Diphtheroids	0	6	6 (3.2)
β-hemolytic streptococcus	0	2	2 (1.05)
Streptococcus viridans	0	2	2 (1.05)
Total	14	108	122 (64.9)

Table 4: Distribution of dacryocystitis cases according to the spectrum of Gram-negative organism

Gram Negative Organisms	Number of cases		
Organism	Congenital (20)	Acquired (168)	Total 188 (%)
Pseudomonas aeruginosa	4	24	28 (14.9)
Klebsiella pneumoniae	0	14	14 (7.45)
Non-fermenting Gram-negative bacilli	0	10	10 (5.35)
Haemophilus influenzae	0	6	6 (3.2)
E. coli	0	6	6 (3.2)
Citrobacter freundii	2	0	2 (1.05)
Total	6	60	66.35

The most common Gram-positive organism was *Staphylococcus aureus* 52 (27.5%) and the most common negative organism was *Pseudomonas aeruginosa* 28 (14.9%). *S. aureus* was the predominant Gram-positive organism in chronic dacryocystitis. *Streptococcus pneumoniae* was the predominant Gram-positive organism in acute and congenital dacryocystitis. *P. aeruginosa* was the most common Gram-negative organism in both congenital and acquired dacryocystitis. The antibiotic sensitivity was done for all organisms. The sensitivity pattern is shown in Tables 5 and 6.

DISCUSSION

The lacrimal excretory system is prove to infection and inflammation for various reasons as mucous membrane-lined tract is contiguous with two surfaces (conjunctival and nasal mucosa) that are usually colonized with bacteria.[2] Dacryocystitis can become life-threatening infection with the potential to progress to orbital cellulitis, orbital abscess, meningitis, and cavernous sinus thrombosis.[3] It requires special attention with respect to the initiation of appropriate treatment at the earliest. In our study women were found to be more affected than men with the findings of Badhu *et al*.;[4] Rizvi *et al*.[5]

Reasons for female affected more because bony nasolacrimal canal is narrower and fatter against the nasal floor in female than in male patients.[5] Most of the female came from middle and lower socioeconomic class who used cow dung and wood for cooking which gave a lot of smoking particle which could have settled down in the conjunctival sac, entered nasolacrimal duct through tears, and blocked the nasolacrimal duct. Artificially prepared kajal may have been contaminated with organisms when applied to lower eyelid margin may have infected the lacrimal sac. The stagnation of tears due to obstruction and resultant accumulation of the debris in the lacrimal sac together acts as a potential nidus for the organism causing hyperemia, edema, inflammation, and hypertrophy of mucosal epithelium. Accumulation of mucoid and mucopurulent exudates causes the sac to dilate, ultimately leading to pyocele.

Table 5: Antibiotic sensitivity pattern of Gram-positive isolates

Penicillin	-	76%
Erythromycin	-	82%
Clindamycin	-	90%
Linezolid	-	99%
Cotrimoxazole	-	72%
Vancomycin	-	100%
Chloramphenicol	-	94%
Ciprofloxacin	-	78%
Tetracycline	-	90%
Gentamycin	-	90%
Tobramycin	-	99%
Cefotaxime	-	99%
Bacitracin	-	99%

Table 6: Distribution of growth according to discharge

Epiphora	-	50%
Epiphora with discharge	-	40%
Swelling and redness	-	10%

In our study, chronic dacryocystitis is the most common clinical type 102 cases (63.75%) followed by acute dacryocystitis 40 cases (25%) and congenital dacryocystitis 18 cases (11.25%). This was probably because acute dacryocystitis invariably led to chronic dacryocystitis.[6]

In this study, the disease was mainly unilateral (90%) either right or left. However, there were also few bilateral cases (10%). This was correlated with the finding of Ghose *et al*.[7] It was found that high incidence of the disease on the left side (40%) as compared to the right side (32%) which was also correlated with the findings of Brook and Frazier.[3] This was probably due to the narrow bony canal in females.[8] The nasolacrimal duct and nasolacrimal fossa formed a greater angle on the right side than on the left side.

In our study, single organism was isolated in 132 (82.5%) cases and multiple organisms were isolated in 28 (17.5%) cases which were correlated with the findings of Sainju *et al*.[9] and Kundu *et al*.[10] The mixed growth might be due to the stagnation of the tear for a longer time which provided a better environment for the pathogenic organisms to grow by suppressing normal flora.

The bacterial organisms have been changing from time to time and also from place to place. In our study, 122 (64.89°o) were Gram-positive organisms and 66 (35.11%) were Gram-negative organism. In congenital dacryocystitis, the most common Gram-positive organism was identified *Streptococcus pneumoniae* 10 (50%) cases and the most common Gram-negative organism was *P. aeruginosa* 4 (20%) cases which correlated with the findings of Bareja and Ghore.[11,12] In acquired dacryocystitis, the most common Gram-positive organism was *S. aureus* (29.76%) and the most common Gram-negative organism was *P. aeruginosa* (14.28%) which correlated with the finding of Briscoe *et al*.[13] McCulloch[14] studied the origin of *Pseudomonas* in the conjunctiva in general and found that this organism may be present in the eye as a result of

a) Being a part of normal conjunctival flora.
b) Contaminated solution which was used as drops.

c) Being associated with *Pseudomonas* infections elsewhere in the body (nose, mouth, palate, otitis media, etc.)

The antimicrobial sensitivity pattern varies from region to region. This is due to the emergence of resistant strains as a result of the indiscriminate uses of antibiotics. The Gram-positive organisms were most sensitive to vancomycin (100%) followed by tobramycin (99%). The least sensitive antibiotic against Gram-positive organism was penicillin.

The Gram-negative organisms were most sensitive to tobramycin (100%) and gentamicin followed by chloramphenicol (98%). The least sensitive antibiotic against the Gram-negative organism was ciprofloxacin (60%). In this study, the limitation was time and number of patients. For better outcomes, a larger study population should be taken for a longer duration to know the bacteriology and to select the effective drugs for dacryocystitis.

CONCLUSION

Chronic dacryocystitis was the most common type of dacryocystitis than acute dacryocystitis. Serous discharge was the most common clinical presentation. The females had higher predilection for the disease than males. The left eye was involved more than the right eye. Gram-positive cases were most commonly identified which highlighted the significance of this clinical condition for the ophthalmologists to specifically investigate for the presence of the symptoms of nasolacrimal obstruction before planning of any intraocular surgeries or procedures.

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Original Article

Clinical Analysis of Emergence Delirium and Post-operative Pain after ENT Surgeries under General Anesthesia in Children in a Tertiary Teaching Hospital

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Abstract

Background: Post-operative restlessness in children undergoing ENT surgeries under general anesthesia is very common. The post-operative negative behavior in children may be due to emergence delirium (ED) or due to pain and is difficult to differentiate. The management of both these conditions also differs.

Aim of the Study: The aim of the study was to identify clinical variables of ED and pain behavior due to post-operative pain in children undergoing ENT surgeries under general anesthesia.

Materials and Methods: A total of 150 consecutive children undergoing ENT surgeries under general anesthesia were included in the present study. The American Society of Anesthesiology (ASA) I and II grade children were included in the study. Induction was done with sevoflurane (2–5%); propofol (2–7 mg kg^{-1}) and fentanyl (1.5–2 mcg kg^{-1}) administered before tracheal intubation. Anesthesia was maintained using sevoflurane (2–3%), fentanyl was used as required, and paracetamol (15 mg kg^{-1} intravenous [I.V.]) was given intraoperatively. Two anesthetists, who were trained, observed and determined simultaneously and independently each single item of faces, legs, activity, cry, and consolability (FLACC) and pediatric anesthesia ED (PAED) scales every 5 min during the first 20 min after awakening in the operation theater to observation in the post-operative recovery room. Awakening was defined as "spontaneous eyes opening." FLACC scales are routinely used clinically in the hospital's participants.

Observations and Results: A total of 150 children following ENT surgeries under general anesthesia with the ASA status I and II were observed for ED and post-operative pain. 97 children (64.66%, −95% confidential interval [CI] 61–77) showed ED and/or during the 20 min post-awakening period in the recovery room. There were 95/150 (63.33%) male children and 55/150 (36.66%) female children. The mean age was 8.16 ± 2.55 years. 111/150 (74%) children displayed early post-operative negative behavior (e-PONB) with minimum one episode of ED and/or pain during the first 20 min following awakening. Children were more than twice likely demonstrated e-PONB with sevoflurane than with propofol. ED at awakening was seen in 51/111 at the time of awakening (45.94%, 95% CI 41–49); 42/111 (37.83%, 95% CI - 32–39) after 15 min; and 18/111 (16.21%, 95% CI - 14–18) after 20 min. The prevalence of ED seems to decrease with the passage of time during post-operative recovery of children.

Conclusions: The clinical scales PAED and FLACC allowed clear distinction between ED and pain in the early awakening phases after general anesthesia. Children with ED demonstrated "no eye contact" and "no awareness of surroundings." The association of these two characteristics had a high sensitivity to identify ED during the first 20 min after awakening. The combination of "abnormal facial expression," "crying," and "inconsolability" has a high sensitivity and specificity to detect pain in the early post-operative period.

Key words: Awakening, Emergence delirium, ENT diseases, General anesthesia, Pain, Sedation

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INTRODUCTION

The common problem in children undergoing ENT surgeries under general anesthesia is their negative behavior also called as early post-operative negative behavior (e-PONB).[1] Identifying the e-PONB and its management in post-operative recovery room is a challenge to the

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anesthetist despite the availability of multiple assessment tools and treatment options.[2-4] As this condition leads to self-injury of the child or accidental pulling of intravenous (I.V.) catheters, drainages, or dressing by the child which requires extra nursing care, stay of extra time in recovery room. The child also requires supplemental sedatives or analgesic drugs.[5,6] e-PONB dissatisfies the parents/caregivers or onlookers as the child is restless.[7,8] In terms of short- or long-term psychological implications of e-PONB in children are not clear. Children with e-PONB may have a higher risk of developing separation anxiety, apathy, and sleep and eating disorders up to 30 days after surgery.[9-11] Emergence delirium (ED) and post-operative pain are two indistinct clinical terms of e-PONB and present in the early post-operative period following general anesthesia.[12] The children may also have both the clinical conditions of ED and post-operative pain simultaneously.[2,3,13] This leads to unnecessary pharmacological treatment of ED or under or delayed treatment of post-operative pain. There are different tools for the assessment of e-PONB available in the literature; the pediatric anesthesia ED (PAED) scale is the only validated scale to quantify ED, the most commonly used behavioral pain scales during the post-operative period, generate composite scores to characterize ED and pain.[14] It shares some descriptors with the faces, legs, activity, cry, and consolability (FLACC) scale,[15] children's and infants' post-operative pain scale; or children's hospital of eastern Ontario pain scale.[16-18] The clinical need of a simple scale allowing reliable identification of the two major components of e-PONB (ED and pain) during the early post-anesthesia period is the need of the time. In the present context, the study was conducted with an aim to identify clinical variables of ED and behavior due to post-operative pain in children undergoing ENT surgeries under general anesthesia.

Type of Study

This is a prospective cross-sectional analytical study.

Institute of Study

This study was conducted in Viswabharathi Medical College Hospital, RT Nagar, Penchikalapadu, Kurnool, Andhra Pradesh.

Period of Study

The study duration was from December 2014 to November 2016 (2 years).

MATERIALS AND METHODS

A total of 150 consecutive children undergoing ENT surgeries under general anesthesia were included in the present study. An ethical committee clearance from the institution was obtained. An ethical committee cleared consent form was used for the study.

Inclusion Criteria

(1) Children aged between 6 and 12 years were included. (2) Children undergoing elective ENT surgeries were included. (3) Children undergoing surgeries under general anesthesia were included. (4) Children who were not given preanesthetic medication were included. (5) Children of both genders were included. (6) Children with the American Society of Anesthesiology (ASA) Grades I and II only were included in the study.

Exclusion Criteria

(1) Children aged <6 and above 12 years were excluded. (2) Children with intra-operative or post-operative complications were excluded. (3) Children who were given preanesthetic medication were excluded. (4) Children on psychiatric treatment were excluded. (5) Children with nutritional deficiencies were excluded. (6) Children with the ASA grading >III grade were excluded from the study. All the children were assessed preoperatively using the ASA anesthetic grading. Children were induced with sevoflurane (2–5%); propofol (2–7 mg kg^{-1}) and fentanyl (1.5–2 mcg kg^{-1}) administered before tracheal intubation. Anesthesia was maintained using sevoflurane (2–3%), fentanyl was used as required, and paracetamol (15 mg kg^{-1} I.V.) was given intraoperatively. Two anesthetists, who were trained, observed and determined simultaneously and independently each single item of FLACC and PAED scales every 5 min during the first 45 min after awakening in the operation theater to observation in the post-operative recovery room. Awakening was defined as "spontaneous eyes opening." FLACC scales are routinely used clinically in the hospital's participants. No medication (sedatives or analgesics) was given for 20 min after they were shifted to the recovery room. Patients were defined as having ED (if PAED score ≥10), pain (if FLACC score ≥4), both ED and pain (if PAED score ≥10 and FLACC score ≥4), or normal behavior (if PAED score <10 and FLACC score <4). The onset of ED, defined as the first evaluation for each patient with PAED score ≥10, and the onset of pain, defined as the first evaluation with a FLACC score ≥4 were analyzed during the course of observation time. The categories "no eye contact" and "no awareness of surroundings" are included in the PAED scale and are considered as the most important items for ED identification. Each evaluation was analyzed as a single event to characterize ED and pain. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

A total of 150 consecutive children undergoing ENT surgeries under general anesthesia with the ASA status

I and II were observed for ED and post-operative pain. 97 children (64.66%, - 95% confidential interval [CI] 61–77) showed ED and/or during the 20 min post-awakening period in the recovery room. There were 95/150 (63.33%) male children and 55/150 (36.66%) female children with a male to female ratio of 1:1.72. The youngest child was aged 6 years, and the eldest one was 12 years with a mean age of 8.16 ± 2.55 years. Adenotonsillectomy was undertaken in 38/150 (25.33%) children, mastoidectomy with tympanoplasty was done in 25/150 (16.66%) children, adenoidectomy was undertaken in 24/150 (16%) children, adenoidectomy with grommet insertion was done in 20/150 (13.33%) children, functional endoscopic sinus surgery was done in 19/150 (12.66%) children, adenoidectomy with antral lavage was done in 13/150 (08.66%) children, and tongue tie release in 11/150 (07.33%) children and (Table 1). Sevoflurane was used as general anesthesia maintenance in 92/150 (61.33%) and propofol in 68/150 (45.33%) children.

A total of 150 children with the ASA status I and II undergoing ENT surgeries under general anesthesia were observed, and 450 individual evaluations were made in this study (Table 1). 111 children of 150 (74%) with CI 95% and CI 66–79, displayed e-PONB with minimum one episode of ED and/or pain during the first 20 min following awakening. The children who received sevoflurane were 76/111 (68.46%), and 35/111 children (31.53%) received propofol. Children were more than twice likely to have e-PONB with sevoflurane than with propofol. The number of children observed with ED at awakening was 51/111 at the time of awakening (45.94%, 95%, and CI, 41–49); 42/111 (37.83%, 95% CI - 32–39) after 15 min; and 18/111 (16.21%, 95% CI - 14–18) after 20 min. The prevalence of ED seems to decrease with the passage of time during post-operative recovery of children in this study (Table 2). 10/111 (9.0%, 95% CI - 4–10) children were evaluated to have pain at the time of awakening. 21/111 (18.91, 95% CI - 11–18) children had pain at 15 min after awakening, and 39/111 (35.14%, 95% CI - 32–36) children were observed as having pain after 20 min. The number of children with the combination of both ED and pain was observed in 12/111 (10.81%, 95% CI - 8–13) at awakening, 09/111 (8.10%, 95% CI - 17–11) at 15 min, and 6/111 (05.40%, 95% CI - 15–21) at 20 min (Table 2).

Table 1: The demographic data and types of ENT surgeries (*n*=150)

Observation	*n* (%)	*P* value
Male	95 (63.33)	NS
Female	55 (36.66)	NS
Adenotonsillectomy	38 (25.33)	NS
Mastoidectomy and tympanoplasty	25 (16.66)	NS
Adenoidectomy	24 (16)	NS
Adenoidectomy with grommet insertion	20 (13.33)	NS
Adenoidectomy with antral lavage	19 (12.66)	NS
Functional endoscopic sinus surgery	13 (8.66)	NS
Tongue tie release	11 (7.33)	NS

DISCUSSION

The present study was analyzed and found that the behavior scales used were useful in the quantitative description of e-PONB children undergoing general anesthesia during elective ENT procedures. "No eye contact" and "no awareness of surroundings" were distinctive clinical features of ED and help in identifying positively ED episodes in the early post-operative period. Whereas the characteristics of pain behaviors in the study group was found to be more complicated. However, the observation of "abnormal facial expression," "crying," and "inconsolability" demonstrated high sensitivity and specificity to detect pain in young children during the first 15 min after awakening. Review of literature showed the variability in clinical presentations of e-PONB which makes the identification and the management of ED or pain in young children difficult.[2,4] ED is described in the literature as an early self-limiting behavior.[12,18,19] In the present study, ED began almost always at the awakening, resolved within 15 min, and did not recur even without pharmacological treatment. The children complaining of pain as the first behavioral upset after awakening developed ED later. In the present study, 10/111 (9.0%, 95% CI - 4–10) children were evaluated to have pain at the time of awakening. 21/111 (18.91, 95% CI - 11–18) children had pain at 15 min after awakening, and 39/111 (35.14%, 95% CI - 32–36) children were observed as having pain after 20 min. Nearly 45% of children with ED also presented with pain behavior during the early awakening period. Similar studies showed and postulated a cause-effect association between pain and emergence agitation during the early phases of the post-operative

Table 2: The e-PONB scores in the study group children (*n*=150)

Observations	Awakening (%)	15 min (%)	20 min (%)
ED onset PAED score≥10	51 (45.94) 41–49	42 (37.83) 32–39	18 (16.21) 14–18
Pain onset FLACC score≥4	10 (9) 4–10	21 (18.9) 11–19	39 (35.13) 32–36
Combination of ED and pain	12 (10.81) 8–13	9 (8.10) 7–11	6 (5.40) 5–8

e-PONB: Early-post-operative negative behavior

period.[20,21] The present study showed and proved that ED and pain were independent of each other and had a different trend over time. In this study, the children who received sevoflurane were 76/111 (68.46%), and 35/111 children (31.53%) received propofol. Children were more than twice likely to have e-PONB with sevoflurane than with propofol. This finding was consistent with similar studies which concluded that propofol anesthesia was associated with a reduced incidence of ED.[22] The observational scales used in assessing ED and pain in this study are critical in identifying the major components of e-PONB due to the following main reasons: (1) There are no behavioral indices clearly specific to pain or distress or agitation or ED. (2) The same observational variables are used to assess different behaviors. (3) These scales are open to subjectivity in scoring with suboptimal interobserver reliability.[23,24] Our results suggested that ED and pain could be assessed independently using five simple, observational, and dichotomous (true/false) criteria in children after receiving general anesthesia. The observations such as abnormal facial expression and crying are part of most of the observational scales that assess pain. The results of this study confirm the relationship with pain, during the early post-operative period. A similar study also confirms that crying is a nonspecific symptom of ED and could occur equally in other situations of distress, such as pain, hunger, or parental separation.[25] In this study, inconsolability was the most important indicator of pain behavior in children. In this study, the combination of abnormal facial expression, crying, and inconsolability demonstrated high sensitivity and specificity to detect pain behavior but not ED. Only >20% of children with ED also demonstrated these three characteristics. This study applies 2 scales namely PAED and FLACC at a single time point, and hence does not allow the discrimination between ED and pain in approximately 11% of children. This could be explained probably due to a real overlap of the two behaviors ED and pain. The association of no eye contact and no awareness of surroundings in children presenting both pain and ED decreased significantly every 5 min. The number of children with the combination of both ED and pain was observed in 12/111 (10.81%, 95% CI - 8–13) at awakening, 9/111 (08.10%, 95% CI - 17–11) at 15 min, and 6/111 (05.40%, 95% CI - 15–21) at 20 min (Table 2). This suggests that if a child presents an unclear etiology of e-PONB, clinicians should observe the child for a period of 5–15 min. Further study may be required to find whether it is possible that decision time may be reduced further. If e-PONB persists, clinicians should consider pain treatment as the primary option. The limitation of the present study is that it is a small sample and observation duration was only 20 min.

CONCLUSIONS

The two different scales PAED and FLACC scales used for observation of post-operative behavior of children undergoing ENT surgeries under general anesthesia allowed clear distinction between ED and pain in the early awakening phases after general anesthesia. All the children with ED demonstrated "no eye contact" and "no awareness of surroundings." The association of these two characteristics had a high sensitivity to identify ED during the first 20 min after awakening. The combination of "abnormal facial expression," "crying," and "inconsolability" has a high sensitivity and specificity to detect pain in the early post-operative period. In case of an unclear etiology for e-PONB, an observation period of 5 min may be useful to distinguish between ED and pain, potentially allowing the identification of children requiring treatment.

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Original Article

Role of Prophylactic Antibiotics in Open Mesh Inguinal Hernioplasty: A Prospective Study

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Abstract

Background: Surgical site infection is the most frequent complication in inguinal hernioplasty. Although there is no controversy in the use of prophylactic antibiotics in clean-contaminated, contaminated and dirty wounds in other type of surgeries, there is controversy surrounding the use of prophylactic antibiotics in clean wounds like Lichtenstein mesh hernioplasty.

Aims and Objectives: The aim of the study was to determine the effectiveness of prophylactic antibiotics on the prevention of post-operative wound infection in open mesh inguinal hernioplasty.

Materials and Methods: This single-blinded randomized controlled trial was conducted at the Department of General Surgery in Nil Ratan Sirkar Medical College and Hospital, Kolkata among patients requiring mesh inguinal hernioplasty. Among the case group, there were 50 patients who were administered antibiotic prophylactically, and among 50 controls, placebo was given before the surgery. Patient record sheet was used to enter the details of each patient.

Results: It was found that the adjusted odds ratio came out to be 0.65 with a confidence interval of 0.565–0.95. This means that the odds of having wound infection postoperatively were 0.65 times lower among cases as compared to controls. Statistically, the difference was found to be significant with $P < 0.05$.

Conclusion: Antibiotic coverage before open mesh hernioplasty incurs protective effect against post-surgical wound infection.

Key words: Antibiotic prophylaxis, India, Lichenstein hernioplasty, Randomized controlled trial

INTRODUCTION

Hernia repair is one of the most commonly performed general surgical procedures worldwide.[1] Mesh repair is, in many countries, rapidly becoming the most popular technique for repair of an inguinal hernia.[2,3] Of the mesh repair techniques, the Lichtenstein tension-free hernia repair is most frequently used. The Lichtenstein technique is a tension-free repair of the weakened inguinal floor using a polypropylene mesh.[4] Since many randomized trials and meta-analysis have shown that mesh repair reduces the risk of hernia recurrence, the prosthetic repair is worldwide accepted as the standard in inguinal hernia repair.[5]

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Surgical site infection and Superficial surgical infection (SSTI and SSI) is the most frequent complication in inguinal hernioplasty.[6] Although there is no controversy in the use of prophylactic antibiotics in clean-contaminated, contaminated and dirty wounds in other type of surgeries, there is still some controversy surrounding the use of prophylactic antibiotics in clean wounds like Lichtenstein mesh hernioplasty.

The incidence of infection after inguinal hernia repair has been reported to vary from 0% to 9%.[7] When a foreign body like polypropylene mesh is used, a deep infection should be prevented. On the contrary inadvertent use of antibiotics in these cases leads to an unnecessary increase in cost to the patient as well as the development of antibiotic resistance, as the development of resistance to antibiotics by microorganisms have become a growing concern.

Hence, we conducted a case–control study at Nil Ratan Sirkar Medical College and Hospital, Kolkata from

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January 2016 to July 2017 to assess if systemic antibiotic prophylaxis prevents wound infection in Lichtenstein inguinal hernioplasty.

Aims and Objectives

The aim of the study was to determine the effectiveness of prophylactic antibiotics on the prevention of post-operative wound infection in open mesh inguinal hernioplasty.

Null hypothesis

There is no difference in the incidence of wound infection among cases who are administered prophylactic antibiotics before open mesh inguinal hernioplasty as compared to controls who are administered placebo before the surgery.

Alternate hypothesis

There is the difference in the incidence of wound infection among cases who are administered prophylactic antibiotics before open mesh inguinal hernioplasty as compared to controls who are administered placebo before the surgery.

MATERIALS AND METHODS

Study Design

This was a randomized controlled trial.

Study Period

This study was from January 2016 to June 2017.

Study Population

All patients of an inguinal hernia presenting to the Department of General Surgery of Nil Ratan Sirkar Medical College and Hospital, Kolkata, requiring mesh inguinal hernioplasty were selected.

Type of Intervention

The design was conducted using a classical randomized controlled trial design. The case group arm received antibiotic (inj. ceftriaxone 1 g) prophylactically at the time of induction. The antibiotic was chosen after considering the most common pathogen and its antimicrobial resistance from surgical site infections at the hospital. The control group received normal saline placebo. No prophylactic antibiotic was administered to control group.

Sample Size

Considering the efficacy of prophylactic antibiotics in the prevention of post-operative wound infection to be around 80% with a precision of 10% at 95% confidence interval and 80% power of the study. The estimated sample size, according to following formula at 10% precision came to be 64.

$$n = 4\frac{pq}{d^2} \text{ where } p = 80, q = (100 - 80 = 20 \text{ and } d = 10)$$

$n = 4*80*20/10 = 64$

Considering the limited time available for data collection and number of patients appearing in the outpatient department within the given time frame of data collection, 50 patients were enrolled in both the case and control groups.

Sampling Technique

Convenient sampling was used which means that all the patients who required mesh inguinal hernioplasty were enrolled for the study after applying inclusion and exclusion criteria. We screened 260 patients, and out of them, 100 were found to be eligible for this study. Rest of the patients were rejected following the inclusion and exclusion criteria of the study. Single blinding was done that is the surgeon knew whom to administer the antibiotic and whom to give placebo. Double blinding could not be achieved due to lack of resources.

Inclusion Criteria

The following criteria were included in this study:

- Inguinal hernia requiring hernioplasty.
- Age group 18–70 years.
- Males.

Exclusion Criteria

The following criteria were excluded from the study:

- Complicated inguinal hernias.
- When antibiotics are indicated for a different reason (urinary tract infection, respiratory infection, and benign prostatic hyperplasia (BPH).
- Immunosuppressive disease (diabetes mellitus, malignancy, and HIV).
- Immunosuppressive medication (glucocorticoid therapy).

Data Collection Tool

A case record form was developed to be filled for each patient. The first section captured the personal information such as name, age, place of residence, date of admission, and IPD number [Annexure 1]. The second section dealt with the chief complaints or the presenting symptoms of present illness. The third section explored the medical history so as to address the exclusion criteria. Details of general physical and systemic examinations were recorded in the subsequent sections along with the information on vitals. The pre-operative investigations of blood and urine were carried out to assess the overall fitness of the patient before surgery.

Post-operative information regarding procedure and duration of surgery was recorded. Three follow-ups were done on day 2, day 5, and day 8 and information regarding the status of the wound was filled in for each patient. In case, there was pus in the wound; it was sent for pus culture to identify the organism and its susceptibility to antibiotics.

Pre-testing of the study tool was done on five patients who were operated in the department of general surgery to assess if it was capturing all the required information.

Data Collection Procedure

Patients who presented with pain and/or swelling in the groin of varying duration along with the diagnosis of direct or indirect uncomplicated inguinal hernia were screened for eligibility criteria of the study. A detailed relevant clinical history was taken, and physical examination including general, systemic, and local examination was done as the approved case record form.

Investigations were carried out to assess the fitness of patients for surgery and anesthesia.

These include:

- Blood: Hemoglobin percentage/total and differential white cell count/fasting blood sugar/serum urea and creatinine.
- Urine: Albumin/sugar/microscopy.
- Electrocardiogram.
- X-ray of the chest was done to rule out any lung pathology.
- Ultrasound of the groin and scrotum.
- Ultrasound of the abdomen and pelvis was done when indicated.
- Cardiac evaluation such as two dimensions ECHO, pulmonary function test evaluation of BPH in patients with associated comorbidities.

Once the patients were deemed fit and met the inclusion criteria, patients were divided into two groups of 50 each randomly as described in the sampling technique. The surgical procedure was explained and informed consent was taken. The first group of patients received antibiotic (inj. ceftriaxone 1 g) at the time of induction, the antibiotic was chosen after considering the most common pathogen and its antimicrobial resistance from surgical site infections at Nil Ratan Sirkar Medical College and Hospital. Normal saline was administered as placebo in the second group which received no antibiotic. Parts preparation was done on the day of surgery using the electronic trimmer. Patients were advised scrub bath on the morning of surgery using soap. All surgeries were posted as the first case of the day. Patients skin was prepared with 10%. Povidone-iodine solution extending well beyond the margins of the surgical site and waited for the solution to dry before incision. Draping was done using sterilized standard double thickness linen cloth. Spinal anesthesia was preferred in all cases.

Operative Technique

A standard operative technique was followed

A classical incision was used for hernia repair - above and parallel to the medial 3/5th of the inguinal ligament, and then the fascia of the external oblique muscle was split along the fibers to expose the inguinal canal. Using blunt dissection, superior and inferior flaps of the external oblique aponeurosis were elevated. The cord was mobilized.

For indirect hernia repair, a high dissection of the neck of the hernial sac was performed.

For direct hernia repair, the floor of the inguinal canal was imbricated with stitches, if needed.

A 15 cm × 15 cm polypropylene mesh was tailored to fit the patient's inguinal floor. The first stitch was taken over the connective tissue at pubic tubercle with polypropylene 2–0; the mesh was fixed with polypropylene 2–0 suture material, and inferior to the inguinal ligament by intermittent stitches up to deep ring laterally. A slit was made at the lateral end of the mesh, after positioning the cord between the two tails of the mesh. The upper edge of the mesh was sutured to the internal oblique aponeurosis or muscle using few interrupted sutures. The lower edges of the two tails were fixed to the inguinal ligament in the end.

After achieving hemostasis, 14 Fr drain was placed in selected patients who had an extensive dissection, and where excessive oozing was noted. The external oblique aponeurosis was closed with continuous interlocking stitches using polyglactin 2–0. Sub cutaneous tissue was approximated using polyglactin 3–0 in obese patients. The skin was approximated using polyamide 3–0.

Post-operative

All patients were managed in the post-operative ward. The drain was removed at the earliest after assessing drain output.

Follow-up

Patients' wound was inspected for infections in terms of increasing pain at operated site, erythema, tenderness, edema, abscess, pus on post-operative day 2, before discharge, at first follow-up and 1 month after surgery. Wounds that showed signs of infection were given a trial of broad-spectrum antibiotics, surgical drainage of the wound was done at the earliest indication, and specific antibiotics were started based on culture sensitivity report. The

patients who had uneventful recovery were followed up at regular intervals to look for any signs of complications arising later.

Ethical considerations

The permission for this study was granted by the Institute's Ethical Committee. Further, after explaining the purpose of the study and its benefit, informed consent was taken from the patient. The patient was allowed to withdraw from the study at any stage without having any implications of his further treatment.

Plan of statistical analysis

Descriptive and comparative analysis was done using the Statistical Package for the Social Sciences 15 software. During the planning stage, age and sex were considered as potential confounding variables. However, as the study was limited to only males; hence, sex as the confounder variable was taken care of at the outset of study. Age and any other confounding variable were controlled at the time of analysis by stratification method of Mantel-Haenszel's for computing adjusted odds ratio in case age was the only confounding variable. In case, if along with age any other variable was identified as confounder at the analysis stage, it was decided to use logistic regression.

RESULTS

A randomized controlled trial study design was done to conduct the present study to explore the role of prophylactic antibiotics in controlling wound infection among patients operated for hernia through mesh inguinal hernioplasty. For this, the case group was administered antibiotic prophylactically whereas the patients in control arm were given placebo injection of normal saline.

Baseline Characteristics

Table 1 represents the age and inguinal hernia characteristics of case and control group.

It was found that among control group 42 individuals were in the age group of 18–50 and rest were above the age of 50 years whereas among case group, 32 individuals were in the age group of 18–50 years, and 18 patients were above the age of 50 years. There was a statistically significant difference among the distribution of patients as per age among the two groups as indicated by the Chi-square and *P* value in Table 1. For rest of the two parameters, that is, type of hernia and location of hernia, the characteristics are similar among the case and control group. Hence, among the baseline characteristics, there was one known potential confounder, i.e., age which needs to be adjusted in further analysis.

Duration of Surgery

The duration of surgery was statistically similar in both the groups as per *z*-test ($P > 0.05$). It was reported that the duration of surgery among cases was 59.3 min and that among control group was 59.1 min. This showed that duration of surgery was not the potential confounder in the study.

Post-operative Findings

Postoperatively, it was found that among cases, there were two cases of superficial site infection (SSI) and only case of deep site infection (DSI). In the control group, there were three cases of SSI and one case of DSI as depicted in

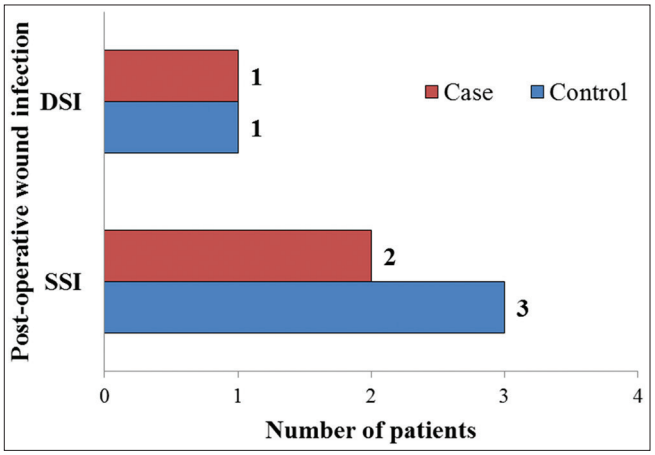

Figure 1: Post-operative wound infection among cases and controls

Table 1: Baseline characteristics of cases and controls (*n*=50 in each group)

Baseline characteristics	Case *n*=50	Control *n*=50	Total=100	Chi-square (*P* value)
Age (in years)				
18–50	32	42	74	5.2 (0.022)*
51 and above	18	8	26	
Type of hernia				
Direct	21	20	41	0.01 (0.92)
Indirect	29	29	58	
Combined	0	1	1	
Laterality of hernia				
Right	30	29	59	0.01 (0.83)
Left	20	21	41	

Table 2: Details of the patients with wound infection

Group	Time of diagnosis	Type of infection	Culture sensitivity	Treatment	Outcome
Case	POD 3	SSI	E. Coli	Antibiotics	No recurrence
Case	POD 14	DSI	*S. aureus*	Antibiotics, drainage, and later mesh removal at 8 weeks	Wound kept open after mesh removal. later secondary suturing was done when wound swab cultures showed no growth.
Case	POD 6	SSI	No growth	Antibiotics	No recurrence
Control	POD 5	SSI	*Acinetobacter sp*	Antibiotics	No recurrence
Control	POD 2	SSI	*S. aureus*	Antibiotics	No recurrence
Control	POD 4	SSI	No growth	Antibiotics	No recurrence

POD: Post-operative day, *E. coli: Escherichia coli, S. aureus: Staphylococcus aureus*, DSI: Deep site infection

Figure 1. The odds ratio came out to be 0.73 which implies that the odds of having wound infection among cases was 0.73 times less as compared to controls or we can imply that the risk of having wound infection among control group was 27% more as compared to cases. The confidence interval for this odds ratio was 0.12–4.18 which indicates that the difference is not significant. Statistically also, there was no difference in the number of patients having wound infection among cases and controls ($P = 0.35$).

This finding could be a result of the difference in age distribution of patients between two groups. Among all the exposure variables, namely age, type of hernia, laterality of hernia and mean duration of surgery, only age was found to be significantly associated that is, the distribution of patients as per age was different among two groups. Hence, to see the real association whether the administration of prophylactic antibiotic played any role in controlling post-operative wound infection among cases, adjusted odds ratio was calculated using stratification of infected patients among cases and controls as per age by Mantel-Haenszel's method.

It was found that the adjusted odds ratio came out to be 0.65 with confidence interval of 0.565–0.95. This means that the odds of having wound infection postoperatively were 0.65 times lower among cases as compared to controls. Statistically, the difference was found to be significant also with $P < 0.05$. The possible explanation for this important finding could be that during the recruitment process, there were 18 patients aged 50 and more among cases whereas there were only 8 such patients among controls in the same age group. After administering prophylactic antibiotic among cases, the chances of contracting wound infection among these patients aged 50 and above lowered significantly. Hence, it can be concluded that the odds of wound infection among controls were 35% higher as compared to cases.

It was observed that all the infected cases had indirect sac and the mean duration of surgery was 80 min among the infected cases in comparison with 58.25 min among the non-infected cases. There was statistically significant difference between the mean duration of surgery among infected and non-infected cases as tested by unpaired *t*-test ($P < 0.05$) which implies that longer duration surgeries may prone the patient to wound infection postoperatively.

The wound infected patients in both the groups were treated as per standard treatment protocol as mentioned in Table 2.

The patients with SSI showed sufficient improvement with antibiotics alone; there was no need for incision and drainage. On follow–up, there was no recurrence or extension of the infection to deep space. Patients with DSI developed purulent pus discharge from the wound on post-operative day 14 and 20, immediate drainage of the wound was done and pus sent of culture sensitivity.

Patient 1 was initially started on ceftriaxone and later linezolid was added based on culture report. Discharge gradually reduced over time and the wound healed over the period. There was no need for mesh removal. Patient 2 was also started on ceftriaxone initially. Later amoxicillin-clavulanic acid and netilmicin was added according to culture report. Discharge initially reduced but later persisted with radiological (ultrasound) confirmation of extension to deep space which needed removal of mesh under coverage of inj. piperacillin tazobactam. After removal, the wound was left open for healing by secondary intention. Later secondary suturing of the wound was done when wound swab cultures were negative for any growth.

DISCUSSION

Inguinal hernia is the most common surgical abdominal entity in adults.[8] Lichtenstein repair has become the gold standard for treatment of inguinal hernias because its recurrence rate is very low.[9] Among the several complications like inguinodynia, haematoma, seroma, ischemic orchitis, testicular atrophy etc. associated with the surgery, wound infection is the most common of them.[10]

Incidence of wound infection post hernioplasty varies from 1% to 14%. For surgeries requiring prosthesis like joint arthroplasty, cataract surgery, cardiac or vascular implant the use of antibiotic prophylaxis has been well established. However in hernioplasty, low rates of infection and straight forward treatment in cases of infection may preclude need for prophylaxis. At the same time, it has been reported that wound infection in hernioplasty is associated with fourfold increase in the recurrence rate and therefore may cause serious sequelae.[11-14]

Several risk factors for surgical site infection have been identified which includes both intrinsic factors like diabetes, obesity, chronic smoking, steroid use and extrinsic factors like scrubbing technique, pre op skin preparation, ventilation of the OT room, duration of surgery and use of mesh.[15,16] Since the intrinsic factors cannot be modified, the incidence of surgical site infection can be reduced by influencing the extrinsic factors. With mesh repair, wound infection rate is higher with absorbable mesh (10%) than the permanent mesh. Thus, it is clear that antibiotic prophylaxis is necessary for most clean contaminated surgical procedures to prevent infectious complications.[17-20] But there is dearth of evidence in the literature regarding the use of prophylactic antibiotics during hernioplasty by Lichenstein method. Hence, we carried out this Randomized Controlled Trial at Department of General Surgery in N.R.S. Medical College and Hospital, Kolkata among patients requiring mesh inguinal hernioplasty.

The overall incidence of surgical site infection in our study was found to be 7% ($n = 7$) with 6% n1= 3) incidence in case group and 8% (n2=4) incidence in control group in comparison to other studies. Yerdel *et al.*. noted an overall incidence of 4.64% with 0.7% incidence in antibiotic group and 8.6% incidence in placebo group.[21] Amit *et al.* noted an overall incidence of 2% with 1% incidence in antibiotic group and 3% incidence in placebo group.[22] Lovellen *et al.* noted an overall incidence of 12.72% with 10.34% in the antibiotic group and 15.38% in the placebo arm.[23] Raja Najam-ul-Haq *et al.* noted an incidence of 3% in his study which included only cases where no antibiotic was given.[24] Hence, the risk of wound infection among cases varied from 0.7% to 10.34% in various studies.[21-24]

The results in our study show that the odds of having wound infection post-operatively were 0.65 times or 65% lower among cases as compared to controls. Statistically, the difference was found to be significant also with $P < 0.05$ after controlling for confounding for age. We recognized age as a potential confounder during the analysis stage when it was noticed that the age distribution among cases and controls varied significantly. Older people were more in the case group as compared to control group. Owing to advanced age, the risk of any wound infection increases. Hence, the administration of antibiotic prophylactically in the case group definitely provided protection cover against wound infection. The incidence of wound infection is not much different among control group (8%) as compared to case group (6%) as in the control group, people belonging to younger age group were more, owing to better immunity. However, controlling for confounding at analysis stage, helped to compute adjusted odds ratio and hence, better association measure between administration of prophylactic antibiotic and wound infection.

Yerdel *et al.* also concluded that there was a significant (10-fold) decrease in overall wound infections when single-dose, intravenous antibiotic was used during Lichtenstein hernia repair. Deep infections and wound infection-related readmissions were also reduced by the use of antibiotics.[21] Similarly Jian-Fang Li conducted a meta-analysis and proposed that antibiotic prophylaxis use in patients undergoing tension-free hernioplasty decreases the rate of incision infection by 55%.[25] Celdran *et al.* suspended for ethical reasons when differences reached values close to statistical significance and concluded antibiotics reduce incidence of wound infection following hernioplasty.[26] Hence, our study results are in sync with these studies.

There are studies conducted by Amit *et al.*, Lovellen *et al.*, and Raja Najam-ul-Haq *et al.* who concluded that there was no evidence of increased infection risk with mesh implant, and there is no need to use prophylactic antibiotics in these cases.[22-24] The drawback with these randomized trials has been their small sample size. Aufenacker *et al.* with adequate sample size of more than 500 cases in both case and control group found no difference between the antibiotic prophylaxis or placebo group, and concluded antibiotic prophylaxis is not indicated in low-risk patients.[27] But as the study by Aufenacker *et al.* was done among low- risk patients and the results were not controlled for confounding, their study and analysis were different in all aspects from the current study.

Hence, to conclude, that in a hospital setting like us, the administration of prophylactic antibiotic to patients undergoing herniplasty by Lichenstein method, reduces the risk of wound infection with the odds of 65%.

CONCLUSION

The results of this study illustrate that there is difference in the incidence of wound infection among cases who are administered prophylactic antibiotics before open mesh inguinal hernioplasty as compared to controls who are administered placebo before the surgery. Thus means

antibiotic coverage before open mesh hernioplasty provides protective coverage against post surgical wound infection.

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Original Article

Pancreatic Trauma - A Management Conundrum, whether to Operate or Not to Operate and Management of Complications: A Study from a Tertiary Care Hospital in South India

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Abstract

Introduction: Abdominal trauma has become one of the leading causes of mortality and morbidity around the world. There is much confusion about the management of pancreatic trauma. We present our data on the management of pancreatic trauma.

Materials and Methods: A retrospective analysis of trauma patients between October 2002 and October 2018 was carried with analysis of demographics, mode of trauma, grade of pancreatic trauma, and treatment and management of complications.

Results: A total of 506 patients with abdominal trauma were admitted with abdominal trauma, 32 patients with pancreatic injuries. 28 patients suffered blunt trauma and 4 patients had penetrating trauma. All patients with penetrating injuries underwent emergency laparotomy. Nine patients suffered Grade I injury, seven Grade II injury, eight with Grade III, and four each with Grade IV and Grade V injuries. All patients with Grade V injuries were operated with one mortality due to laceration of retrohepatic trauma. All patients with Grade I and II injuries with blunt injury were managed non-operative management (NOM). Four patients with Grade III injuries were operated initially due to sepsis. Four patients with Grade III injuries were managed initially with NOM with three operated later failure of NOM due to complications.

Conclusion: Pancreatic injuries should be managed non-operatively initially except for Grade V injuries and complications arising out of NOM could be managed later with lower morbidity and mortality.

Key words: Complications, Management, Non-operative management, Pancreatic trauma

INTRODUCTION

Trauma has become quite an important cause of morbidity and mortality around the world. Around 1.35 million people die in road traffic accidents every year and have become one of the leading causes of death among young people.[1] Abdominal trauma forms an important cause of these mortalities. Injury to the pancreas is a rare occurrence, as the pancreas is a well-protected retroperitoneal organ. Pancreatic injuries take a heavy toll as it is associated with high morbidity and mortality. We present our data and analysis on pancreatic injuries in a tertiary care hospital in South India.

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MATERIALS AND METHODS

The case records of abdominal trauma patients admitted in a single unit in our hospital between October 2002 and October 2018 were retrieved. The demographic profiles of these patients were recorded and out of these those patients who had suffered pancreatic injuries were segregated. Apart from the demographic details, we investigated the mode of injury, grade of pancreatic injury, and modality of treatment and management of complications. The American Association for the Surgery

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of Trauma (AAST) classification was used to grade all pancreatic injuries.

RESULTS

A total of 506 patients with abdominal trauma were admitted between October 2002 and October 2018. 354 of these were male and 152 were female. The median age was 28 years. Of these patients, there were 32 patients with pancreatic injuries. 20 were male and 12 were female patients [Figure 1]. The median age was 26 years. There were nine patients with Grade I injuries, seven with Grade II, eight with Grade III, four with Grade IV, and four patients with Grade V injuries [Figure 2]. 24 patients had suffered blunt trauma, four had fallen from height while four patients had suffered penetrating injuries [Figure 3]. All Grade V injuries were associated with disruption of the second part of duodenum. Other associated injuries were liver injuries in 18 patients, splenic injuries in 14 patients, rib fractures in 20 patients, fracture of lumbar vertebrae in 20 patients, and pelvic fractures in 6 patients [Figure 4]. Four patients, who had penetrating injuries, underwent emergency laparotomy. There was extensive small and large bowel injury in one patient, gastric perforation in one patient, and other two had mesenteric injuries of small bowel. Of these four patients, two patients had pancreatic contusions to the left of superior mesenteric vein amounting to Grade I injury and one patient had laceration of the pancreas to the left of the superior mesenteric vein without ductal injury accounting for Grade II injury. One patient had laceration of retrohepatic vena cave. The rest of the three patients were not bleeding intraoperatively and no further intervention was carried out. We could not clearly ascertain bowel contusions or mesenteric tears among blunt injury patients as most of the patients were managed non-operatively. Among the Grade V injuries, three injuries were due to blunt trauma and one was due to penetrating trauma. The incidents of injury of all these patients had taken place within a radius of 4 kms around our hospital and all these patients were operated with an hour of reaching the hospital. Emergency Whipple's pancreaticoduodenectomy was carried out in three of these patients. For the remnant pancreatic stump, the anastomosis carried out was pancreaticogastrostomy in two and pancreaticojejunostomy in one patient. One patient had an associated laceration of retrohepatic vena cave and had unfortunately died intraoperatively due to hypovolemic shock. All Grade IV patients except one were managed conservatively. One patient with Grade IV injury had complete avulsion of common bile duct and underwent hepaticojejunostomy with pancreatic duct stenting. Patients with Grade I and Grade II injuries due to blunt trauma with no ductal disruption were managed conservatively without

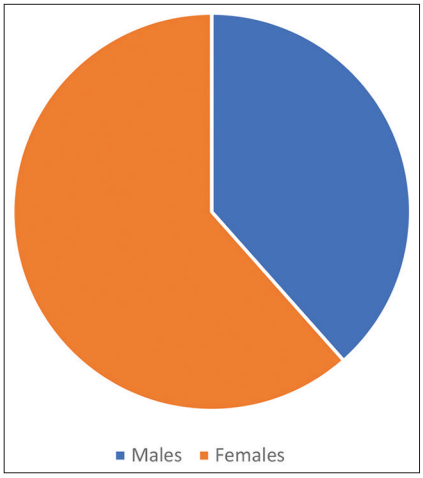

Figure 1: Gender distribution of pancreatic trauma

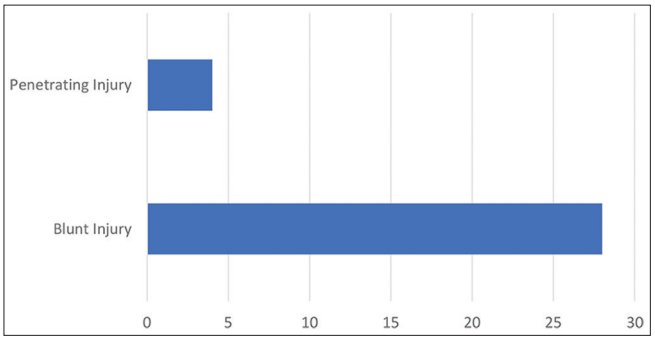

Figure 3: Modes of injury

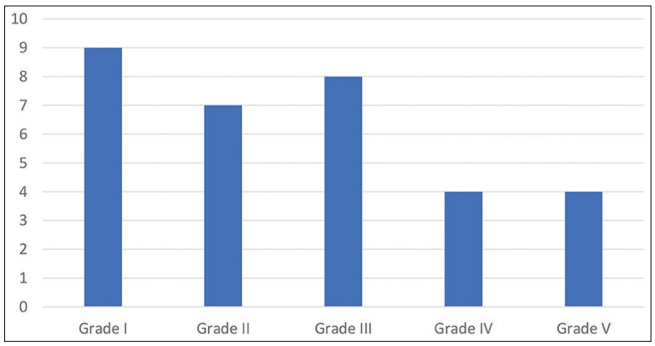

Figure 2: Grades of pancreatic injuries

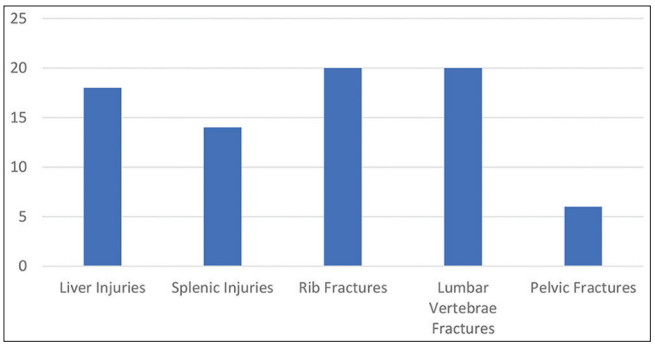

Figure 4: Associated injuries of other organs

developing any complications. Among the eight patients with Grade III injuries with pancreatic duct disruption, four patients presented to us late beyond 1 week of injury after they were managed initially in another hospital and referred to us for the associated complications such as fever, pancreatic ascites, necrosis, and localized collections. Of the eight patients with Grade III injuries, four patients developed high-grade fever due to necrosis and collection; they underwent necrosectomy and drainage. One of these four patients required further two laparotomies and drainage of collections. Of the remaining four patients, two were pigtailed for peripancreatic collection and underwent subsequent laparotomy and debridement of walled of the necrosis later. One patient developed pancreaticopleural fistula and was treated with intercostal drainage and pigtail drainage of peripancreatic collection. One patient developed pancreatic ascites due to complete disruption of main pancreatic duct to the left of superior mesenteric vein. A pigtail drainage of the peripancreatic collection was carried out followed by necrosectomy later.

DISCUSSION

The study is a retrospective study on pancreatic injuries in a tertiary care hospital in South India. We have used the AAST classification[2] for assessing the pancreatic injuries. In our series, pancreatic injuries form about 6.3% of abdominal trauma. Grade I injuries form the most common presentation making up to 28.12% of injuries, closely followed by Grade III injuries with 25%. There was equal number of Grade IV and Grade V injuries each with 12.5% share. In a large series by Siboni *et al*.,[3] pancreatic injuries formed 3.1% of abdominal injuries with Grade II injuries forming the bulk of the injuries at 82.7% followed by Grade II with 7.9% injuries with Grade IV and V making 5.5% each. In a series by Gupta *et al*.[4] from India, looking into 4 years data with 53 pancreatic injuries, blunt trauma was the most common cause of pancreatic injuries as in our series. The study reveals Grade III injuries as the most common presentation of pancreatic injuries. This is comparable to data from our series. Both our series and the data from Gupta *et al*. are from referral institutes in India where more complex injuries tend to present, whereas the series from Siboni *et al*., sf from a National Trauma data bank that is representative of the whole population from a western.

Solid organ injuries of the abdomen due to blunt trauma are increasingly being managed by non- operative management (NOM).[5] There has been a significant shift in the management of blunt injuries of the pancreas from operative management to NOM. In a national trend reported by Ragulin-Coyne *et al*.[6] in 27, 216 patients with pancreaticoduodenal trauma, patients, the percentage of patients managed by operative management showed a significant decline from 21.7% to 19.8% overtime, whereas non-operatively managed patients showed a significant increase from 56.7% to 59.1%. There was a significant decline in mortality among the non-operatively managed patients. The study reported the presence of combined pancreatic and duodenal injury, penetrating trauma, and age >50 years as independent predictors of mortality.

All our Grade I and Grade II injuries were managed non-operatively and they did not show any further complications. There is not much controversy regarding management of Grade I and II injuries as there is no duct disruption and could be managed non-operatively. It is with Grade III injuries upward that there has been a change from operative to NOM.[7] The options of NOM would be observation (NO-endoscopic management [EM]), EM, and pigtailing. In a study on 132 patients,[8] Kong *et al*. showed the proportion of the failure of NOM (FNOM) to be 20%, with 30% in NO-EM group and 9% in EM group. Addition of EM significantly reduced the FNOM rates in Grade III patients. The success rate of NOM is higher among Grade I and II patients compared to Grade III, IV, and V patients. NOM management carries the risk of pseudocyst formation which can, however, be managed conservatively later on.[9] The presence of necrosis and necrosis and associated other organ injuries seem to predict the failure of NOM of pancreatic trauma.[10] In our series, we had eight patients with Grade III injuries. Four of these had developed sepsis and had to undergo necrosectomies. The remaining four were managed non-operatively, with pigtailing initially. Two patients underwent necrosectomies late as their sepsis had not controlled with NOM. One patient with pancreatic fistula[11] was treated with intercoastal drainage, whereas one patient who had developed pancreatic ascites, had pig tailing initially, and underwent necrosectomy due to the failure of NOM. Thus, we had FNOM in seven of eight patients in Grade III injuries. Distal pancreatectomy has been described for Grade III injuries with significant ductal disruption.[12] However, distal pancreatectomy has shown higher morbidity and mortality than by treating the patient with initial NOM and later deal with pseudocyst or walled of necrosis.[13]

We had three patients with Grade V injuries. All these patients had suffered their injuries within a radius of 4 km from the hospital. All these patients had undergone emergency laparotomy. However, unfortunately, one patient had died on the operating table due to exsanguination from an injury to major vessel. We had one mortality that was due to injury to retrohepatic vena cava. Mortality in pancreatic trauma in the earlier stages is due to bleeding and in later stages due to infection and sepsis.[12]

CONCLUSION

Pancreatic injuries are rarer injuries in abdominal trauma. The injuries should be managed non-operatively initially except for Grade V injuries, and complications arising out of NOM could be managed later with lower morbidity and mortality.

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Original Article

Role of Magnetic Resonance Diffusion Imaging and Apparent Diffusion Coefficient Values in the Evaluation of Extradural Spinal Pathologies

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Abstract

Background: In this study, besides, routine imaging additional diffusion-weighted imaging (DWI) and apparent diffusion coefficient (ADC) sequences were applied to extradural pathologies of the spine to increase the diagnostic confidence in differentiating malignant and benign pathologies.

Aims: The aims are as follows: (a) To differentiate malignancy from infection qualitatively on the basis of DWI sequence and quantitatively on the basis of ADC values. (b) To assign ADC values for infectious/inflammatory pathologies of the spine.

Materials and Methods: This is a prospective study of 53 patients who presented to the department of radiodiagnosis for magnetic resonance imaging spine with extradural spinal pathology. Patients were assessed on 3 Tesla MR SIEMENS LTD.

Results: Mean ADC value in abnormal soft tissue was found to be significantly lower in malignant lesion compared to benign ($P < 0.0001$). Mean ADC value in the affected vertebral body (bone) was found to be significantly lower in malignant lesion compared to benign ($P < 0.0001$). Diagnostic significance of mean ADC value in the affected vertebral body (bone) was assessed using receiver operating characteristic curve. The area under the curve was found to be 95%, and the diagnostic cutoff for the malignant condition was found to be 1.065 (<1.065 malignant) with sensitivity 100% and specificity 83.3%. Diagnostic significance of mean ADC value in abnormal soft tissue showed the area under the curve was found to be 97.4%, and the diagnostic cutoff for the malignant condition was found to be 1.28 (<1.28 malignant) with sensitivity 100% and specificity 93.3%.

Conclusion: In the present study, vertebral bone-marrow pathologies were differentiated as benign or malignant with high sensitivity and specificity with the aid of ADC values calculated from maps obtained by DWI. We conclude that the evaluation of pre/paravertebral soft tissue component should be done to increase the sensitivity and specificity for lesion characterization.

Key words: Apparent diffusion coefficient, Diffusion-weighted magnetic resonance imaging, Vertebral lesions

INTRODUCTION

Diffusion-weighted imaging (DWI) and apparent diffusion coefficient (ADC) have recently appeared as a new method of screening in characterizing lesions without necessitating contrast material and in evaluating the vertebrae quantitatively.[1-3]

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ADC is a quantitative parameter calculated from DWI that combines the effects of capillary perfusion and water diffusion.[4] Previous studies have been able to differentiate acute benign compression fractures from malignant compression fractures according to ADC values.[5-10] In a comparatively small number of surveys, ADC values have been studied in discriminating the infectious lesions from the malignant lesions.[6,11,12]

Hence, the present study was done at our hospital to assess the utility of ADC obtained in DW magnetic resonance imaging (MRI) for the differentiation between benign and malignant vertebral lesions, and to determine the sensitivity and the specificity of these vertebral body lesions according to the optimal ADC value cutoff.

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MATERIALS AND METHODS

This study was done in the Department of Radiodiagnosis, Pt. J.N.M Medical College and Dr. B.R.A.M. Hospital, Raipur (C.G), between February 2016 and September 2017 on 53 patients who presented to the Department of Radiodiagnosis. Patients were assessed on 3 Tesla MR SIEMENS LTD.

Prior Institutional Ethical Committee clearance and approval were obtained for the study.

Patients with various extradural spinal pathologies were included in the study, while the patients with spine involvement due to trauma were excluded from the study. All these patients were followed up for confirmation of diagnosis either by bone or soft tissue biopsy/fluid aspirate culture. Informed consent was obtained from the subjects for the inclusion of their images in the study.

Details of clinical history, other related investigations, family history of tuberculosis, anti-tubercular treatment, etc., were taken from all patients before MRI examination. All patients underwent a routine plain MRI of the spine. DW-MRI was also performed in the same sitting in axial images, and at least six ADC values were taken from affected vertebrae and associated soft tissue component.

RESULTS

A hospital study was conducted with 53 patients to assess the role of magnetic resonance diffusion imaging and ADC values in the evaluation of osseous spinal pathologies. The following observations were noted:

- Majority of the patients (41.5%) were in the age group of ≤30 years followed by 51–60 years (20.8%), 31–40 years (18.9%), 41–50 years (15.1%), and >60 years (3.8%).
- There was an almost equal distribution of male (50.9%) and female patients (49.1%) in our study.
- The most common site of involvement was thoracic (56.6%), followed by lumbar (35.8%), sacral (5.7%), and cervical (1.9%).

The radiological findings in our study are summarized in Table 1.

DISCUSSION

DWI is a powerful adjunct to the routine imaging regimen used to detect and characterize extradural lesions. Studies have shown that diffusion is impaired within neoplastic tissue and that a decrease in diffusion coefficient may indicate disease progression.[13]

DWI adds sensitivity to the presence of osseous lesions of the spine. Added to the routine sequences employed for the assessment of suspected metastatic disease and myeloma, DWI improves the detectability and conspicuity of many lesions.[14] In recently presented trials,[15,16] approximately 50% of lesions, identified as part of a neoplastic MRI spine survey, were most conspicuous on trace weighted DWI compared to a combination of routine sequences including sequences and short tau inversion recovery (STIR) and T1 pre- and post-contrast techniques. While approximately 20% of lesions were better seen on routine sequences, up to 10% of lesions were seen only on DWI or were solely evident in retrospect with routine scanning techniques. However, in our study, all the cases were consistent on both routine imaging and DWI.

In the present study, the majority of the patients (41.5%) were in the age group of ≤30 years, followed by 51–60 years (20.8%), 31–40 years (18.9%), 41–50 years (15.1%), and >60 years (3.8%). There was an almost equal distribution of male (50.9%) and female patients (49.1%) in our study.

According to Wahab-Abo-Dewana *et al.* study assessing the utility of ADC obtained in DW-MRI for the differentiation between benign and malignant vertebral lesions found 50 patients 31 males and 19 females, with mean age of 58.45 years and the age ranged from 22 to 87 years presenting with vertebral collapse in one or more vertebral body on conventional MR sequences.[17]

The most common site of involvement in this study was thoracic (56.6%), followed by lumbar (35.8%), sacral (5.7%), and cervical (1.9%).

It was observed in the present study that in 19 (35.8%) cases 2 vertebral bodies were involved while in 11 (20.8%) cases 3 vertebral bodies were involved. 1 and 4 vertebral bodies each were involved for 9 (17%) patients while in 4 (7.5%) and 1 (1.9%) cases 5 and 6 vertebral bodies, respectively, were involved. Benign lesions usually had contiguous vertebral body involvement while the malignant lesions were observed to have non-contiguous involvement.

According to Wahab-Abo-Dewana *et al.* study, L1 was the most commonly fractured vertebra (23 fractures, 23.96%) followed by T12 (20 fractures, 18.4%).[17]

Turna *et al.* in a study on the evaluation of vertebral bone marrow with diffusion-weighted MRI and ADC measurements observed similar findings in their study.[18]

It was observed in the present study that the mean ADC value in the unaffected vertebral body was 0.28 ± 0.01 while

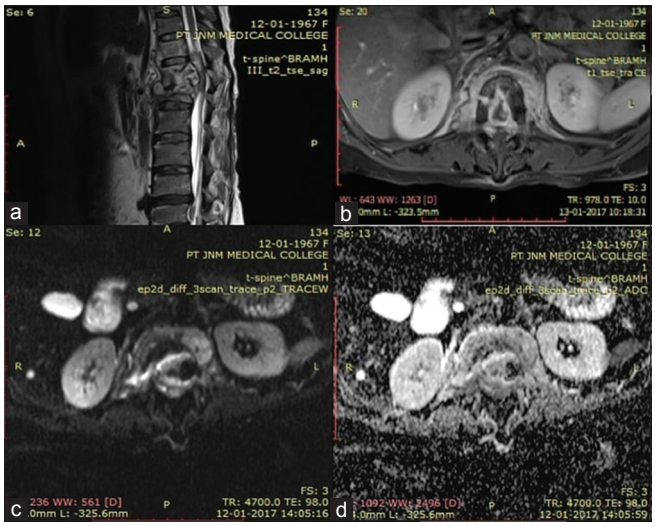


Figure 1: A 50-year-old female presented with bilateral paraplegia (a) sagittal T2-weighted imaging shows heterogeneous hyperintensity with collapse and associated paravertebral and epidural soft tissue component at T12 and L1 vertebrae. (b) Axial T1-weighted post contrast at the level of T12 and L1 vertebrae shows heterogeneous and peripheral enhancement. (c) Axial diffusion-weighted image at same level shows diffusion restriction in the vertebral body and soft tissue. (d) Corresponding axial apparent diffusion coefficient (ADC) map (b = 0 and 1000 s/mm^2 shows decreased signal intensity with an ADC value of 1.26 in bone and 1.55 in soft tissue component). [*On culture, Mycobacterium tuberculosis was grown*]

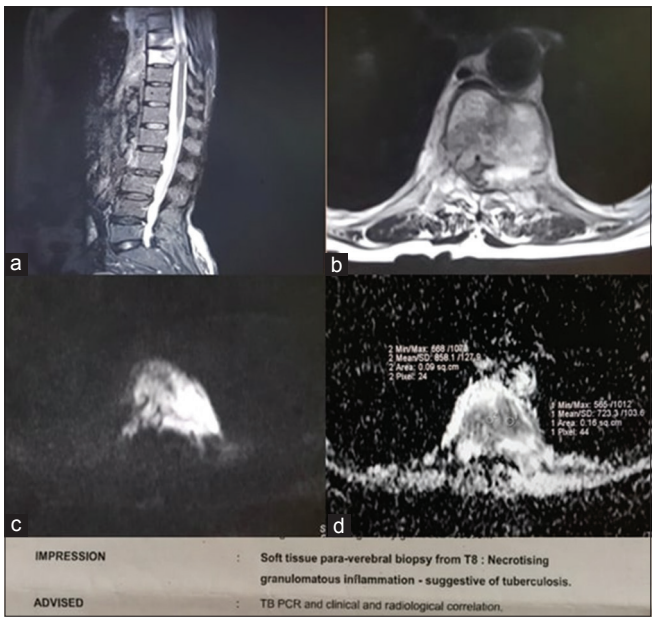


Figure 2: A 61-year-old female presented with bilateral paraplegia. (a) Sagittal T2-weighted imaging (WI) shows heterogenous hyperintensity in T8/9 vertebrae. (b) Axial T2 WI at the level of T9 vertebrae shows expansion with increased signal intensity with the involvement of posterior elements and cord compression. (c) Axial diffusion-weighted image at same level shows diffusion restriction. (d) Corresponding axial apparent diffusion coefficient (ADC) map (b = 0 and 1000 s/mm^2 shows decreased signal intensity with an ADC value of 0.0.79 in bone and 0.94 in soft tissue component). [*Biopsy revealed granulomatous inflammation suggestive of tuberculosis*]

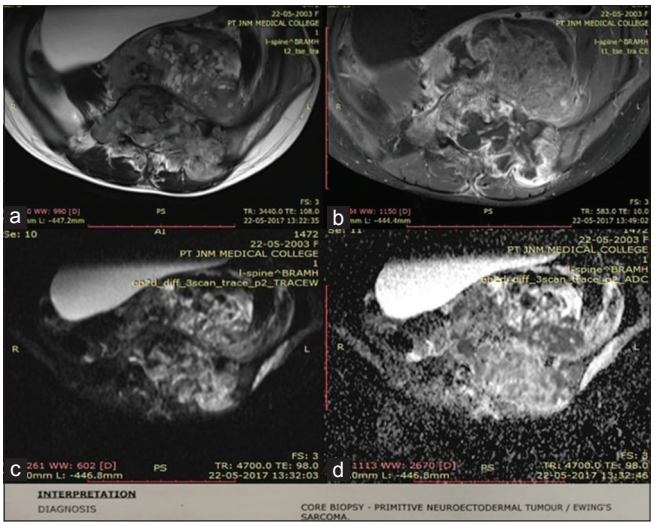


Figure 3: A 14-year-female presented with a large soft tissue mass over the lower back. (a) Axial T2-weighted imaging (WI) shows heterogeneously hyperintensity of L5 vertebrae with associated large soft tissue component. (b) Axial T1-weighted post-contrast image at the level of L5 vertebrae shows heterogeneously enhancement with the involvement of posterior elements and a large paravertebral soft tissue component. (c) Axial diffusion WI at same level shows diffusion restriction in vertebrae and surrounding soft tissue. (d) Corresponding axial apparent diffusion coefficient (ADC) map (b = 0 and 1000 s/mm^2 shows decreased signal intensity with an ADC value of 0.65 in bone and 0.67 in soft tissue component).[Biopsy revealed PNET/Ewing's sarcoma]

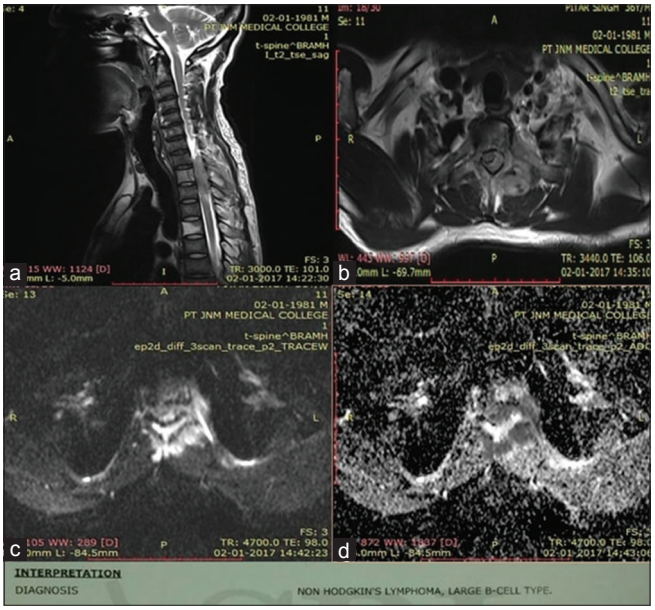


Figure 4: A 36-year-old man presented with quadriparesis. (a) Sagittal T2-weighted imaging (WI) shows heterogeneous hyperintensity of T2 vertebrae. (b) Axial T2 WI at the level of T2 vertebrae shows heterogeneous hyperintensity with the involvement of posterior elements and cord compression. (c) Axial diffusion WI at same level shows diffusion restriction. (d) Corresponding axial apparent diffusion coefficient (ADC) map (b = 0 and 1000 s/mm^2 shows decreased signal intensity with an ADC value of 0.75 in bone and 0.62 in soft tissue component). [*Biopsy revealed large B-cell type Non-Hodgkin lymphoma*]

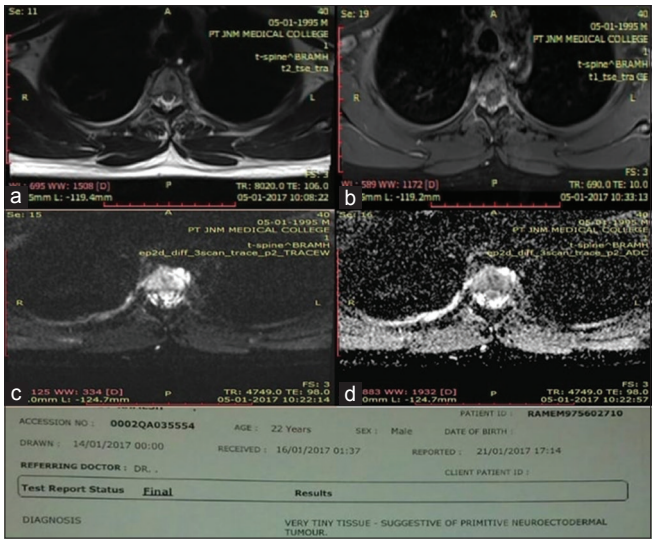


Figure 5: A 22-year-old man presented with bilateral paraplegia. (a) Axial T2-weighted imaging (WI) shows heterogeneous hyperintensity of T5 vertebrae. (b) Axial T1-weighted post-contrast at the level of T5 vertebrae shows heterogeneously enhancement with the involvement of posterior elements and cord compression. (c) Axial diffusion WI at same level shows diffusion restriction. (d) Corresponding axial apparent diffusion coefficient (ADC) map (b = 0 and 1000 s/mm^2 shows decreased signal intensity with an ADC value of 1.05 in bone). [*Biopsy revealed PNET*]

the mean ADC value in the affected vertebral body (bone) was 1.09 ± 0.30. The mean ADC value of abnormal soft tissue component was 1.36 ± 0.54. The most common tissue analyzed in our study subjects was fluid aspirate (49.1%), followed by bone (35.8%) and soft tissue (7.6%).

The histopathology/culture findings in our study showed tuberculous etiology in 49.1% cases while neoplastic etiology in 37.7% cases, respectively. 13.2% of cases showed granulomatous inflammation. The final diagnosis showed 33 (62.3%) cases was benign while 20 (37.7%) cases were malignant.

Diagnostic significance of mean ADC value in the affected vertebral body (bone) was assessed using receiver operating characteristic (ROC) curve in our study. The area under the curve was found to be 95%, and the diagnostic cutoff for the malignant condition was found to be 1.065 (<1.065 malignant) with sensitivity 100% and specificity 83.3% (Table 4).

Wahab-Abo-Dewana *et al.* study reported that mean ADC value of fractured vertebrae was 1.65 ± 0.59 ×10^{-3} mm^2/s. Statistically, significant difference was found between the mean ADC value of normal and fractured vertebrae (P = 0.0001 and P < 0.05).[17]

Diagnostic significance of mean ADC value in abnormal soft tissue was assessed using ROC curve in our study. The area under the curve was found to be 97.4%, and the diagnostic cutoff for the malignant condition was found to be 1.28 (<1.28 malignant) with sensitivity 100% and specificity 93.3%. Diagnostic significance of mean ADC value in the unaffected vertebral body was assessed using ROC curve. The area under the curve was found to be 61.4%, and the diagnostic cutoff for the malignant condition was found to be 0.285 (>0.285 malignant) with sensitivity 57.9% and specificity 69.8% (Grph 2 and Table 4).

Comparison of mean ADC value in unaffected vertebral body between benign and malignant lesions was found to be higher in malignant tissue, but the difference failed to reach statistical significance (P = 0.443). Mean ADC value in the affected vertebral body (bone) was found to be significantly lower in malignant lesion compared to benign (P < 0.0001). Mean ADC value in abnormal soft tissue was found to be significantly lower in malignant lesion compared to benign (P < 0.0001) (Table 3).

Wahab-Abo-Dewana *et al.* study reported that the mean ADC value of the 33 acute benign compression fractures was 1.98 ± 0.44 × 10^{-3} mm^2/s. The mean ADC value of the 22 spondylodiscitis lesions was 1.52 ± 0.14 × 10^{-3} mm^2/s. The mean ADC value of the 31 metastatic lesions was 0.71 ± 0.21 × 10^{-3} mm^2/s. The mean ADC value of the 10 malignant compression fractures was 0.82 ± 0.31 × 10^{-3} mm^2/s. The mean ADC values of the acute benign compression fractures and pyogenic spondylodiscitis were significantly higher than that of the malignant compression fractures (P = 0.0001, 0.007; respectively). The mean ADC value of tuberculous spondylodiscitis was 0.91 ± 0.38 × 10^{-3} mm^2/s, with an overlap with the mean ADC value of malignant CFs (0.75 ± 0.23 × 10^{-3} mm^2/s), and there was a statistically non-significant difference (P = 0.143, P > 0.05) (Figures 1-5 and Table 2). There was a statistically significant difference between all benign CFs and malignant ones (P = 0.002, P < 0.05) (Graph 1).

Balliu *et al.*[6] study on the diagnostic value of ADC to differentiate benign from malignant vertebral bone marrow lesions reported that acute malignant fractures were hyperintense compared to normal vertebral bodies on the DW sequence, except in one patient with sclerotic metastases. Mean ADC value from benign edema (1.9 ± 0.39 × 10^{-3} mm^2/s) was significantly (P < 0.0001) higher than untreated metastatic lesions (0.9 ± 1.3 × 10^{-3} mm^2/s). Mean bone ADC value of infectious spondylitis (0.96 ± 0.49 × 10^{-3} mm^2/s) was not statistically (P > 0.05) different from untreated metastatic lesions. ADC value was low (0.75 × 10^{-3} mm^2/s) in one case of subacute benign fracture.

Biffar *et al.* study on combined DW and dynamic

Table 1: Radiological findings in study subjects

Characteristics	Frequency (%)
MRI T1W sequence	
Hypointense	53 (100)
MRI T2W sequence	
Hyperintense	53 (100)
MRI stir sequence	
Hyperintense	53 (100)
Soft tissue	
Absent	7 (13.2)
Present	46 (86.8)
Enhancement pattern of vertebrae	
Diffuse	21 (39.6)
Heterogeneous	32 (60.4)
Enhancement pattern of soft tissue	
Diffuse	18 (39.1)
Peripheral	28 (60.9)
Cord edema	
Absent	4 (7.5)
Present	49 (92.5)
Intervertebral disc involvement	
Absent	19 (35.8)
Present	34 (64.2)
Posterior element	
Absent	24 (45.3)
Present	29 (54.7)
DWI	
Hyperintense	53 (100)
ADC	
Hypointense	53 (100)

MRI: Magnetic resonance imaging, DWI: Diffusion-weighted imaging, ADC: Apparent diffusion coefficient

contrast-enhanced imaging of patients with acute osteoporotic vertebral fractures reported that mean perfusion parameters and ADCs were significantly ($P < 0.001$) different in the fractures compared to adjacent normal appearing vertebrae (Ktrans: 7.81 mL/100 mL/min vs. 14.61 mL/100 mL/min, extracellular volume [ECV]: 52.84mL/100mLvs.4.61mL/100mL,ADC:1.71×10^{-3}mm^2/s vs. 0.57 × 10^{-3} mm^2/s). ADCs showed a significant correlation with the ECV.[1]

In this study, diagnostic significance of mean ADC value in the affected vertebral body (bone) was assessed using ROC curve. The area under the curve was found to be 95%, and the diagnostic cutoff for the malignant condition was found to be 1.065 (<1.065 malignant) with sensitivity 100% and specificity 83.3%. Diagnostic significance of mean ADC value in abnormal soft tissue was assessed using ROC curve. The area under the curve was found to be 97.4%, and the diagnostic cutoff for the malignant condition was found to be 1.28 (<1.28 malignant) with sensitivity 100% and specificity 93.3%.

Wahab-Abo-Dewana *et al.* found threshold value for the mean ADC value was 1.21 × 10^{-3} mm^2/s. Sensitivity, specificity, positive, and negative predictive values were calculated from this threshold value. When

Table 2: Radiological characteristics

Characteristics	N	Mean	SD	SEM	Minimum	Maximum
Mean ADC value in unaffected vertebral body	52	0.28	0.08	0.01	0.12	0.51
Mean ADC value in affected vertebral body (bone)	53	1.09	0.30	0.04	0.61	1.96
Mean ADC value in abnormal soft tissue	46	1.36	0.54	0.08	0.48	2.28

ADC: Apparent diffusion coefficient, the mean ADC value in unaffected vertebral body was 0.28±0.01 while the mean ADC value in affected vertebral body (bone) was 1.09±0.30. The mean ADC value in abnormal soft tissue was 1.36±0.54

Table 3: Comparison of mean ADC value in abnormal soft tissue and in the affected vertebral body (bony) between benign and malignant lesions

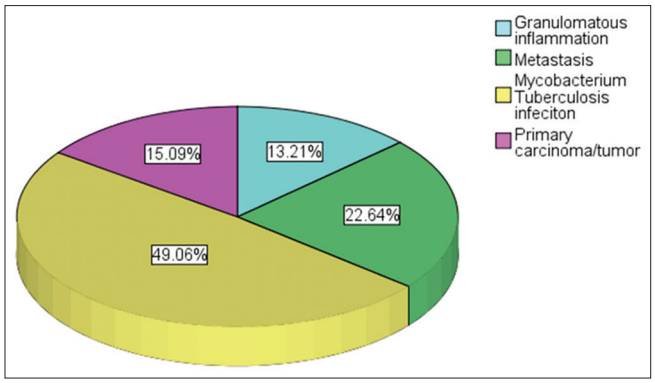
Radiological characteristics	Diagnosis	N	Mean	SD	SE	T	*P* value
Mean ADC value in unaffected vertebral body	Benign	33	0.27	0.09	0.02	−0.77	0.443
	Malignant	19	0.29	0.06	0.01		
Mean ADC value in affected vertebral body (bone)	Benign	33	1.26	0.23	0.04	8.85	<0.0001
	Malignant	20	0.80	0.15	0.03		
Mean ADC value in abnormal soft tissue	Benign	30	1.67	0.35	0.06	9.25	<0.0001
	Malignant	16	0.76	0.23	0.06		

ADC: Apparent diffusion coefficient, Mean ADC value in abnormal soft tissue was found to be significantly lower in malignant lesion compared to benign (*P*<0.0001). Mean ADC value in affected vertebral body (bone) was found to be significantly lower in malignant lesion compared to benign (*P*<0.0001)

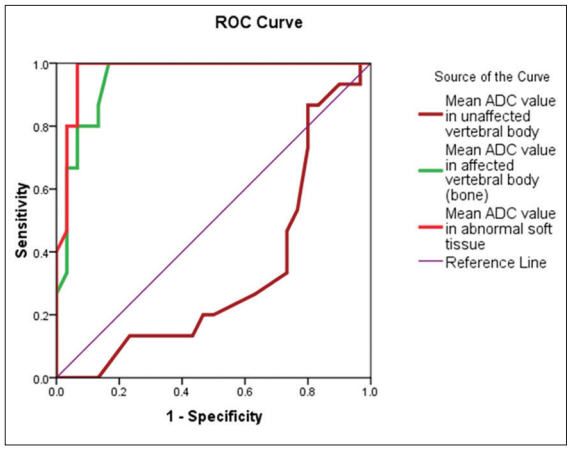
Table 4: Diagnostic significance of various radiological findings

Test result variable (s)	Area under curve	SE	*P* value	Asymptotic 95% CI		Cutoff	Sensitivity (%)	Specificity (%)
				Lower bound	Upper bound			
Mean ADC value in unaffected vertebral body	0.329	0.084	0.064	0.164	0.493	0.335	86.7	20
Mean ADC value in affected vertebral body (bone)	0.950	0.030	<0.0001	0.891	1.009	1.065	100	83.3
Mean ADC value in abnormal soft tissue	0.974	0.021	<0.0001	0.933	1.016	1.28	100	93.3

ADC: Apparent diffusion coefficient



Graph 1: Histopathology/culture findings



Graph 2: Diagonal segments are produced by ties

1.21×10^{-3} mm^2/s was used as the threshold value, the mean ADC values of 4 of the 55 benign lesions were below it, and 2 of the 41 malignant lesions were above it. According to the optimal threshold value of 1.21×10^{-3} mm^2/s set to differentiate vertebral bone marrow lesions as benign or malignant, sensitivity was found to be 95.12%, specificity 92.73%, positive predictive value 90.70%, and negative predictive value 96.23%.[17]

Taskin *et al.*[19] study on value of ADC measurements in the differential diagnosis of vertebral bone marrow lesions stated that according to the optimal cutoff value of 1.32×10^{-3} mm^2/s, determined for the differentiation of benign and malignant vertebral bone-marrow lesions, sensitivity was 96.5%, specificity 95.2%, positive predictive value 96.5%, and negative predictive value 95.2%.

Palle *et al.*[20] study on role of magnetic resonance diffusion imaging and ADC values in the evaluation of spinal tuberculosis found the mean ADC values of 128 vertebral tuberculosis lesions in 56 patients to be 1.4103 mm^2/s and when they took this value as a cutoff in the discrimination of malignant lesions, they found 64.8% sensitivity, 75% specificity, and 74.5% positive predictive values. However, due to the fact that this ADC value displays values overlapping with the ADC values of metastatic vertebral lesions, they emphasized that the ADC values should be evaluated with the clinical history and routine MR findings.

The Limitations of Our Study

The limitations of our study are as follows:

- The imbalance in the age group and sex between the benign and the malignant lesions may have influenced the difference in ADC values.
- Comparisons between low and high field strength machines and their pulse sequences were not taken into consideration while evaluation which may reveal different cutoff values for benign and malignant lesions. Hence, these values cannot be generalized for different scanners from different manufacturers.
- Long-term follow-up of most of the patients who had undergone imaging as a part of our study is not available.

Therefore, we suggest that an understanding of MRI pulse sequences and the normal and age-related appearances of bone marrow is important for the practicing radiologist.

CONCLUSION

In the present study, vertebral bone-marrow pathologies were differentiated as benign or malignant with high sensitivity and specificity with the aid of ADC values calculated from maps obtained by DWI.

ADC values are a useful complementary tool to characterize bone marrow lesions, to distinguish benign infections from malignant bone lesions, particularly for lesions who did not have the classical appearance of either infection or malignancy.

However, there exists a zone of overlap of ADC values in metastatic and infective lesions, which can lead to false negative results. In our study, we suggest use of ADC of paravertebral collection/soft tissue in these cases.

Our study is superior to the previously conducted studies as pre/paravertebral soft tissue component was not evaluated in the previous studies which we strongly recommend to increase the sensitivity and specificity for lesion characterization.

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Original Article

Color Doppler Evaluation of Portal Venous System in Liver Diseases

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Abstract

Introduction: Color Doppler sonography is an important non-invasive procedure for detecting abnormalities in hepatic vasculature in various liver diseases. Not only portal hypertension (HTN) but also various other liver diseases are associated with abnormalities noted in hepatic vasculature. An abnormal liver texture and ascites are also commonly seen and are usually related to accompanying cirrhosis. Helical flow may be seen in the portal vein and is more common in patients with severe liver disease. Color Doppler is a key tool, since the hepatic veins may be difficult to visualize with B-mode imaging alone when the liver is enlarged or cirrhotic. The right, left, and middle hepatic veins are imperceptible wall and show a triphasic pattern similar to inferior vena cava, and flow pattern is phasic in response to both cardiac and respiratory cycles. The hepatic veins have two periods of forward flow during the cardiac cycle, corresponding to the two phases of right atrial filling.

Aims and Objectives: The aims and objectives of this study were to evaluate the abnormalities of portal vein in various liver diseases and the role of color Doppler in portal veins in various liver diseases with histopathological correlation.

Materials and Methods: This is a prospective study and is conducted in the Department of Radiodiagnosis, Netaji Subhash Chandra Bose, Medical College, Jabalpur, Madhya Pradesh, over a period of 1 year (2011–2012). On color Doppler assessment, flow pattern, velocity, and direction, along with its diameter, were studied. A study of collaterals if present was also done (portal venous system detail examination was done only if portal vein diameter >15 mm at hilum), and a statistical analysis was performed according to data collection.

Results: In the present study, of 45 cases, on ultrasonography, 15 (33.33%) cases were detected as having liver metastasis, 15 (33.33) had cirrhosis with portal HTN, 5 (11.1%) patient had hepatocellular carcinoma, 3 (6.6) patients had liver hydatid cyst, and 3 (6.6%) other had abscess, while 1 (2.2%) had liver hemangioma and 1 (2.2%) had fatty infiltration in liver. Final diagnosis was confirmed by histopathology in all these patients.

Conclusion: Color Doppler study in liver hemangioma has not any added advantages over two-dimensional sonography. Color Doppler study in intrahepatic liver cyst has not yield any extra information, and vascular changes were seen in large size liver cyst due to compression of adjacent vessels.

Key words: Color Doppler, Liver hemangioma, Sonography

INTRODUCTION

Color Doppler sonography is an important non-invasive procedure for detecting abnormalities in hepatic vasculature in various liver diseases. Ultrasound findings associated with portal hypertension (HTN) include enlarged diameter of the portal vein, lack of respiratory variation in the portal vein or its tributaries, hepatofugal portal flow direction, decreased portal velocity or volume, and the presence of collaterals or varices,[1,2] Not only portal HTN but also various other liver diseases are associated with abnormalities noted in hepatic vasculature. An abnormal liver texture and ascites are also commonly seen and are usually related to accompanying cirrhosis.[3] Helical flow may be seen in the portal vein and is more common in patients with severe liver disease.[4]

In normal individual, gray scale and Doppler characteristic of various vessels are as follows: Portal vein is seen in

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about 97% of normal patients; failure to visualize it can suggest the presence of pathology, such as thrombosis.[5] On Doppler assessment, it shows low-velocity signal with respiratory variation and smooth color fill in vessel. A sudden onset of ascites should prompt careful examination of the portal vein for thrombosis.[6] With deep inspiration, the normal diameter may increase to about 16 mm, resulting in an overestimation of portal vein diameter.[2] As pressure increases, portal blood flow may become pulsatile.[7] Color Doppler sonography is superior to gray scale and spectral Doppler imaging in diagnosing partially occluded vessels. Clot detection by gray scale imaging is difficult when the thrombus is hypoechoic.[8]

Color Doppler is a key tool, since the hepatic veins may be difficult to visualize with B-mode imaging alone when the liver is enlarged or cirrhotic.[9] Theright, left, and middle hepatic veins are veins with imperceptible wall and show triphasic pattern similar to inferior vena cava (IVC) and flow pattern is phasic in response to both cardiac and respiratory cycles. The hepatic veins have two periods of forward flow during the cardiac cycle, corresponding to the two phases of the right atrial filling.[10]

Aims and Objectives

The aims and objectives of this study were to evaluate the abnormalities of portal vein in various liver diseases and to evaluate the role of color Doppler in portal vein in various liver diseases with histopathological correlation.

MATERIALS AND METHODS

This is a prospective study and is conducted in the Department of Radiodiagnosis, Netaji Subhash Chandra Bose (N.S.C.B.) Medical College, Jabalpur, Madhya Pradesh, over a period of 1 year (2011–2012). All patients (male/female of all age groups) having liver diseases (medical or surgical) as diagnosed on various investigations are included in the study. Sonography and color Doppler study were conducted in the Department of Radiodiagnosis using curvilinear and linear probe of machine Wipro GE (Logic 3 Expert - Ay 15 CUK) and Siemens (Sonoline G-50). First, two-dimensional (2D) sonography was conducted, and then, color Doppler assessment of portal vein was done. On color Doppler assessment, flow pattern, velocity, direction, RI, and its diameter were studied. A study of collaterals if present was also done (portal venous system detail examination was done only if portal vein diameter >15 mm at hilum), and a statistical analysis was performed according to data collection.

RESULTS

Table 1 shows that maximum number of patients with liver disease were in the age group of 51–60 years and it was 26%. The second largest group was in the age group of 41–50 years and it was 24.4%. Liver disease was found more in male gender as compared to female and male gender involvement was 57.7%. In addiction it was observed that the number of cases involved in addiction 24.4%.

Table 2 shows distribution of cases according to presenting complaint, and in the present study, most common presenting complaint was abdominal pain (75.6%). Table 3 shows distribution of studied cases according to diseases of liver., It was observed that the most frequent liver disease was liver mets (33.3%) and cirrhosis with portal HTN (33%), while 11.1% of cases of primary liver tumor hepatocellular carcinoma (HCC), 6.6% cases of liver abscess, 6.6% cases of liver cyst, 2.2% cases of hemangioma of liver, and fatty infiltration of liver constituted rest of the disease.

The distribution of studied cases according to portal vein diameter in liver pathologyis shown in Table 4. It

Table 1: Distribution of cases according to age (*n*=45)

Age group (years)	Number of patients	% age
0–10	3	6.6
11–20	6	13.3
21–30	4	8.8
31–40	6	13.3
41–50	11	24.4
51–60	12	26.6
>61	3	6.6
Gender		
Male	26	57.7
Female	19	42.2
Locality		
Rural	29	64.4
Urban	16	35.6
Addiction		
Present	11	24.4
Absent	34	75.5

Table 2: Distribution of cases according to presenting complaint

Presenting complaint	Frequency	% age
Abdominal pain	34	75.6
Breast lump	1	2.2
Vomiting mixed with blood	2	4.4
Abdominal distension	3	6.7
Swelling	2	4.4
Fever	1	2.2
Bleeding PR	1	2.2
Total	45	100.0

was observed that we found 13.3% of cases of increased diameter of portal vein in liver metastasis, 33.3 of cases of abnormal flow pattern, 33.3% of cases of abnormal flow velocity, and 33.3% of cases of abnormal direction in liver wets. In cirrhosis with portal HTN, we found 66.6% of cases of increased diameter and abnormal flow pattern, abnormal flow velocity, and abnormal direction of flow in portal vein. In primary liver tumor (HCC), we found that there was no change in portal vein diameter, but in 40% of cases, we found abnormal flow pattern, flow velocity, and direction of flow in portal vein.

The distribution of studied cases according to IVC diameter in liver pathology is presented; it was observed that there were no change in diameter in above-mentioned liver diseases. We found only in IVC flow pattern changes. In 13.3% cases abnormal flow pattern in liver metastasis, in 26.6% cases abnormal flow pattern in cirrhosis with portal HTN, in 20% cases abnormal flow pattern in primary liver tumor (HCC) and rest of liver abscess, liver cyst, haemangioma, fatty infiltration there were no change seen in IVC.

DISCUSSION

The present study was conducted in 45 cases, of which majority of cases were in decade age group. In this study, 26 (57.7%) cases were male and rest of 19 (42.2%) cases was female. Of these 45 cases, 29 (64.4%) cases were from rural area and rest of 16 (35.5%) cases belonged to urban area. In our study, 11 (24.4%) cases had a positive history of various types of addiction. Most commonly presenting complaint was abdominal pain which is found in 35 (76%) cases.

In the present study, of 45 cases, on ultrasonography (USG), 15 (33.33%) cases were detected as having liver mets, 15 (33.33) had cirrhosis with portal HTN, 5 (11.1%) patients had HCC, 3 (6.6) patients had liver hydatid cyst, and 3 (6.6%) other had abscess, while 1 (2.2%) had liver hemangioma and 1 (2.2%) had fatty infiltration in the liver. Final diagnosis was confirmed by histopathology in all these patients.

Hepatic Vein Changes in Liver Pathology

In 15 cases of cirrhosis with portal HTN, in 10 (66.6%) cases, we found decreased diameter and loss of respirophasic pattern in the hepatic vein. While rest of our cases showed Colli *et al.* and Bolondi *et al.* found that Liver parenchymal disease impairs the compliance of a hepatic decreasing and flattening phasic oscillations. Flattening of phasic oscillations within the hepatic venous system is seen in 50–75% of patients with cirrhosis.[11,12]

Kane and Eustace found that color Doppler is key tool, since the hepatic veins may be difficult to visualize with Bmode imaging alone when the liver is enlarged or cirrhotic.[9]

Of 5 cases of HCC, in 3 (60%) cases, we found loss of respirophasic pattern in hepatic vein, and in 1 (20%) case, we found decreased (compressed) diameter of the hepatic vein.

Becker and Cooperberg described that hepatic vein obstruction[13] is the presence of echogenic intraluminal material (thrombus or tumor) accompanied by the absence of hepatic vein flow.

If the hepatic vein is narrowed but not completely blocked, focal elevated velocity and post stenotic turbulence may be seen.[13]

Table 3: Distribution of cases according to diseases of the liver

Liver pathology	Number of patients	% age
Mets	15	33.33
Cirrhosis with portal HTN	15	33.33
Primary liver tumor (HCC)	5	11.11
Liver abscess	3	6.6
Liver cyst	3	6.6
Hemangioma of the liver	1	2.2
Fatty infiltration of the liver	1	2.2

HTN: Hypertension, HCC: Hepatocellular carcinoma

Table 4: Distribution of cases according to portal vein parameter in liver pathology

Diagnosis	Portal vein parameter							
	Increased diameter	% age	Abnormal flow pattern	% age	Abnormal flow velocity	% age	Abnormal direction of flow	% age
Mets	2	13.3	5	33.3	5	33.3	5	33.3
Cirrhosis with portal HTN	10	66.6	10	66.6	10	66.6	10	66.6
Primary liver tumor (HCC)	0	0	2	40	2	40	2	40
Liver abscess	0	0	0	0	0	0	0	0
Liver cyst	0	0	0	0	0	0	0	0
Hemangioma of the liver	0	0	0	0	0	0	0	0
Fatty infiltration of the liver	0	0	0	0	0	0	0	0

HTN: Hypertension, HCC: Hepatocellular carcinoma

We found no change in the hepatic vein in case of hemangioma of the liver and fatty infiltration of the liver.

Colli *et al.* demonstrated that hepatic vein changes in the form of dampening of spectral waveform seen in chronic liver disease.[11]

Oguzkurt *et al.* observed that dampening of hepatic vein waveform was associated with fatty infiltration, cirrhosis, metastatic liver disease, and veno-occlusive disease.[14]

IVC Changes in Liver Pathology

Of 15 cases of liver mets, in 2 (13.3%) cases, we found a loss of variation in diameter on inspiration in IVC.

Of 15 cases of cirrhosis with portal HTN, in 4 (26.6%) cases, we found a loss of variation in diameter on inspiration in IVC.

Kitamura *et al.* found that, in the normal liver group, the maximal diameter of the vena cava was 2.35 ± 0.34 cm (mean ± standard deviation), and this was reduced by 1.30 ± 0.67 cm (range, 0.4–2.85 cm) during deep inspiration. In the cirrhotic patient group, the maximal diameter was 1.74 ± 0.35 cm, and this was reduced by 0.03 ± 0.09 cm (range, 0.0–0.4 cm) ($P < 0.0001$) (60) in 5 cases of HCC, and in 1 (20%) case, we found a loss of variation in diameter on inspiration in IVC.

In 3 cases of liver abscesses, hemangioma, liver cyst, and fatty infiltration, we found no change in IVC.

Rajagopal and Bishwas found and published a case of 15 cm × 14 cm cystic mass involving the medial segment of the left hepatic lobe and the anterior segment of the right hepatic lobe and was compressing IVC.[15]

SUMMARY

The present study was carried out in the Department of Radiodiagnosis, N.S.C.B. Medical College and Hospital, Jabalpur, Madhya Pradesh, to evaluate the color Doppler of hepatic vessels and portal venous system in liver disease with pathological correlation.

A total of 45 cases of various liver pathology attending the various surgical, medicine, and pediatric outpatient departments were referred to us with a brief history, physical examination, and a provisional clinical diagnosis.

Liver pathology was evaluated by 5–10 MHz electronically focused curvilinear and linear transducer with a patient in supine position with direct contact method.

In our study group, age ranges from 8 to 73 years. Most common age group affected was between 50 and 60 years.

In this study, 26 (57.7%) cases were male and rest of 19 (42.2%) cases were female. Of these 45 cases, 29 (64.4%) cases were from the rural area and rest of 16 (35.5%) cases belonged to the urban area. In our study, 11 (24.4%) cases had a positive history of various types of addiction. Most common presenting complaint was abdominal pain which is found in 35 (76%) cases.

In the present study, of 45 cases, on USG, 15 (33.33%) cases were detected as having liver mets, 15 (33.33) had cirrhosis with portal HTN, 5 (11.1%) patient had HCC, 3 (6.6) patients had liver hydatid cyst, and 3 (6.6%) other had abscess, while 1 (2.2%) had liver hemangioma and 1 (2.2%) had fatty infiltration in liver. Final diagnosis was confirmed by histopathology in all these patients. In liver abscess, liver fatty infiltration, and hemangioma cases, no changes were detected in any of the vessels.

In portal HTN, portal vein changes seen in maximum patients.

CONCLUSION

Color Doppler study in liver hemangioma has not any added advantages over 2D sonography. Color Doppler study in intrahepatic liver cyst has not yield any extra information and vascular changes were seen in large size liver cyst due to compression of adjacent vessels.

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Original Article

Kinematic Characteristics of Jump Gait in Children with Spastic Diplegia

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Abstract

Introduction and Purpose: One of the few described patterns of gait in children with spastic cerebral palsy is Jump gait. Sagittal motion kinematics of gait in spastic children have been studied by various authors. They have described that in jump gait, rapid knee extension and plantar flexion occur during initial contact, however, as the child gains weight and matures the pattern slows and changes. Instrumented gait analysis enhances the understanding of gait abnormality by providing real-time objective data that cannot be appreciated visually. Very few data describing the jump gait in children with spastic diplegia belonging to the Indian population exists. The aim of this study is to describe the kinematic characteristics of jump gait in children with spastic cerebral palsy.

Methodology: Clinical and physical evaluation, kinematic and spatiotemporal data from three-dimensional gait analysis of 14 children from India with spastic cerebral palsy walking with jump gait diagnosed clinically were compiled and entered into a pro forma after informed consent. Children were grouped according to age, sex, and gross motor functional classification system (GMFCS). The aspects studied were ankle-foot rockers, initial contact during stance phase, knee flexion, hip flexion and hip adduction in relation to incidence, cadence, and mean velocity.

Results: A total of 14 children with spastic jump gait were studied. The mean age was 8.4 years; there were 9 boys and 5 girls. 6 children belonged to GMFCS I and 8 belonged to GMFCS II. 2 children had hip flexion deformity and 6 had knee flexion deformity. The majority of the initial contact during stance phase was on the midfoot (53.6%). Although toe rockers were good in all age groups, children >12 years had deterioration of the other rockers. The rockers were best in the 7–12 age group. Children with hip flexion had decreased cadence and mean velocity so too did the children with knee flexion deformity. Those children who had stiffer gastrocnemius muscle, i.e., static equinus had better cadence than those children who had dynamic equinus. However, most analyses had no significant *P* values. Except for the analysis of knee flexion contracture to cadence (*P* = 0.05).

Conclusion: Children with jump gait mostly landed on their midfoot during initial contact. The ankle rockers were best in the 7–12 age group and knee flexion deformity played a significant role in making the gait slower. Stiffer equinus helped the children to have faster cadence.

Key words: Adductor tightness, Ankle-foot rocker, Cerebral palsy, Equinus, Jump gait, Kinematics, Knee contracture, Spastic diplegia, Three-dimensional gait analysis

INTRODUCTION AND RATIONALE

Jump gait is one of the common gait patterns in spastic cerebral palsy. In a study by de Morais Filho *et al.* of about 1803 children 9.3% were walking with jump gait and 48.6% were having asymmetrical gait.[1] Sutherland and Davids described four pathological gait patterns in spastic diplegia based on knee motion in the sagittal plane (Jump, crouch, equinus, and stiff-knee gait).[2] Rodda *et al.* classified the gait patterns in diplegia into five groups based on the kinematic analysis in the sagittal plane motions of the pelvis hip, knee, and ankle.[3]

Cerebral palsy is a group of disorder of development of movement and posture causing activity limitation that is attributed to non-progressive disturbance that occurs in the developing fetus or the infant brain.[4] Perry has classified

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gait cycle into stance and swing periods, periods into different tasks and tasks into different phases.[5,6] Hence, analyzing the different patterns of disturbance in the various phases gives a better understanding of the various abnormalities of gait in children.

Palisano *et al.* described a simple classification to measure gross motor function, the gross motor functional classification system (GMFCS). This was stratified into five levels:[7]

Level I - Walks without restriction, limitations in high-level skills; Level II - Walks without devices, limitation in walking outdoor; Level III - Walks with devices, limitation in walking outdoors; Level IV - Limited mobility indoors, powered mobility outdoors; and Level V - Very limited self mobility, even with assistive technology.

GMFCS was also described for the age groups up to 2 years, 2–4 years, and 4–6 years, between 6 and 12 years and later revised by adding 12–18 years in 2007.

Kinematics is the term used to describe movement without considering the internal or external forces that cause movement. The measures include velocities, trajectories, joint angles of the hip, knee, and ankle. Common points observed in sagittal motion kinematics are hip flexion-extension, knee flexion/extension, ankle movement, and rockers of the foot and initial contact.

Jump gait is characterized by increased hip flexion and knee flexion with slight dorsiflexion at initial contact followed by rapid knee extension and ankle plantar flexion during loading response.[8] Sutherland and David described the knee as being stiff due to overactivity of the rectus femoris muscle with the ankle in plantar flexion whereas Miller[9] described the ankle as being neutral, the rapid knee extension and hip extension were noted in younger age group as reported by Rodda and Graham.[10] Jump knee gait is seen in patients with diplegia, hemiplegia, and quadriplegia and is most commonly seen in younger patients learning to ambulate, however, as the child gains weight and matures it slowly decreases and changes the pattern.[4]

Instrumented gait analysis enhances the understanding of gait abnormality by providing real-time objective data that cannot be appreciated visually or measured on a static physical examination.[8] It provides information that is critical for describing the gait pattern. IGA is performed using a motion analysis system.

Since the few studies in literature describe the gait patterns of jump gait in children with diplegia in the Western population, the authors decided to study the same in the Indian population. The aim of this study is to describe the kinematic characteristics of jump gait in children from Indian population with spastic cerebral palsy with special reference to rockers of the foot-ankle complex.

Study Design

This was a descriptive and retrospective study.

Duration of the Study

The duration of the study was 3 and ½ years. Data were collected from January 2013 to June 2016

Study Setting

Gait Analysis Laboratory and Cerebral Palsy Clinic of the Department of Physical Medicine and Rehabilitation, Government Medical College, Thiruvananthapuram.

Study Population

Clinically diagnosed children with spastic diplegia walking with jump gait, who underwent three-dimensional (3D) gait analysis at the Department of Physical Medicine and Rehabilitation, Government Medical College, Thiruvananthapuram, Kerala, India, during the above period were selected.

Inclusion Criteria

The following criteria were included in this study:

- Children with cerebral palsy having spastic diplegia and walking with jump gait pattern walking with hip flexed, knee flexed, and ankle in equinus).
- Children belonging to GMFCS Level I and Level II.
- Having independent ambulation for >5 m.

Exclusion Criteria

The following criteria were excluded from the study:

- Children with spastic diplegia walking with gait pattern other than jump gait assessed clinically.
- Children with cognitive deficits unable to follow simple instructions.
- Children who were medically unstable or having ongoing seizures.
- Children with spastic diplegia belonging to GMFCS Level III, Level IV, and Level V.

Sample Size

Consecutive sampling was used.

A total of 14 children with spastic diplegia walking with jump gait who satisfied the above criteria and who underwent 3D gait analysis during the above period were included in the study.

METHODOLOGY

Children with spastic cerebral palsy having jump gait as assessed clinically who underwent 3D gait analysis at the study setting were included in the study.

Details of clinical evaluation and report of 3D gait analysis done on children with spastic diplegia walking with jump gait were collected and compiled and entered in a pro forma after informed consent.

All the children continued their standard treatment and rehabilitation such as antispastic and other medications, serial casting, rehab exercises, occupational therapy, and physiotherapy.

Assessment of power, tone, and range of motion of the joints of the lower extremity were given emphasis in the clinical evaluation along with general evaluation.

Goniometer was used for measuring joint angles, medical research council grading for power, and Ashworth grading for spasticity. Further, the 3D gait analysis data acquired and processed on BTS smart DX 600 motion analysis system, at the gait analysis lab of the study setting mentioned, were also compiled. The system consisted of four infrared cameras mounted on the wall, two video cameras, two force platforms embedded into the 5 m walkway.

The process of gait acquisition included recording of anthropometric measurements according to the simple Helen Hayes protocol. Standard weighing scale, measuring tape, and beam calipers were used to capture the measurements. Measurements included calf circumference, leg and thigh lengths, ankle diameter, knee diameter, pelvic depth, anterior superior iliac spine (ASIS) width, weight, and height. After anthropometric measurements were entered into the computer,15 reflective markers were placed on the lower limbs on both right and left sides at the second metatarsal head, lateral malleolus, heel, calf, lateral femoral condyle, middle thigh, and ASIS and one on the sacrum.

The child was made to stand on the force platform for a standing session acquisition followed by a few walking sessions. The best walking sessions were selected, and the data further tracked, elaborated, processed, and report generated. The temporal, distance and clinical data were entered into a pro forma and analyzed. The kinematic data observed were the initial contact of the foot on the floor during initial stance phase, the adequacy of the rockers, (heel, ankle, and toe), knee flexion and extension during swing and stance, hip flexion, and adduction components of the lower extremity.

Analysis

SPSS version 16.0 was used for the statistical analysis which included, mean, standard deviation, *P* value and independent *t*-test was used for determination of differences in the gait parameters against age sex, GMFCS, deformities, and rockers.

On measurement with goniometer, if the child had hip flexion deformity ≥10°, the child was considered to have hip flexion contracture for statistical purposes. So too if the knee flexion contracture was ≥25°, then the child was considered to have knee flexion deformity. Moreover, if the total adductor angle is <80°, then the child was considered to have scissoring or adduction deformity. The child was considered to have equinus if the R1 (first resistance on stretching the gastrocnemius muscle with the knee in extension) was >5° and if the R1 R2 difference was <5°, then the child was considered to have a stiff equinus (static equinus). If the R1 R2 difference was >5°, the child was considered to have dynamic equinus. R1 is the first resistance felt when the ankle was passively stretched to dorsiflexion to assess the gastrocnemius tightness, and R2 is the final tightness after forceful stretching when the knee is extended.

RESULTS AND OBSERVATION

Clinical evaluation and gait analysis report of 14 Indian children with jump gait having spastic diplegia were analyzed. The mean age of the study population was 8.43 ± 4.5 years there were 5 girls and 9 boys. The mean height was 117.8 cm and mean weight was 27.1 kg there were 6 children in the GMFCS I group and 8 children in the GMFCS II group. 2 children had hip deformity >10° and 6 children had knee flexion deformity >25°. 2 had static equinus and 12 had dynamic equinus on the right side and one with static equinus and 13 with dynamic equinus on the left. 2 children had adductor/scissoring deformity at the hip [Tables 1-3 and Figures 1-3].

Table 1: Age distribution in the study group

Age in years	Number of children (%)
<4	2 (14)
5–6	5 (36)
7–12	3 (21)
13–18	4 (29)
Total	14 (100)

Table 2: Sex distribution in the study group

Sex	Number of children (%)
Male	9 (64)
Female	5 (36)
Total	14 (100)

Table 3: GMFCS distribution in the study group

GMFCS	Number of children (%)
I	6 (43)
II	8 (57)
Total	14 (100)

GMFCS: Gross motor functional classification system

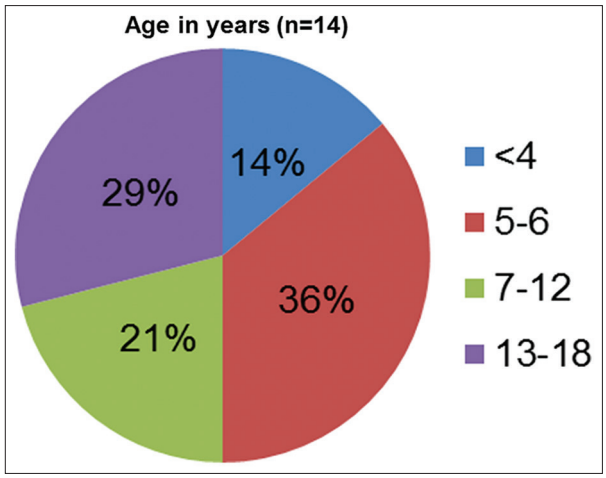

Figure 1: Age distribution in the study group

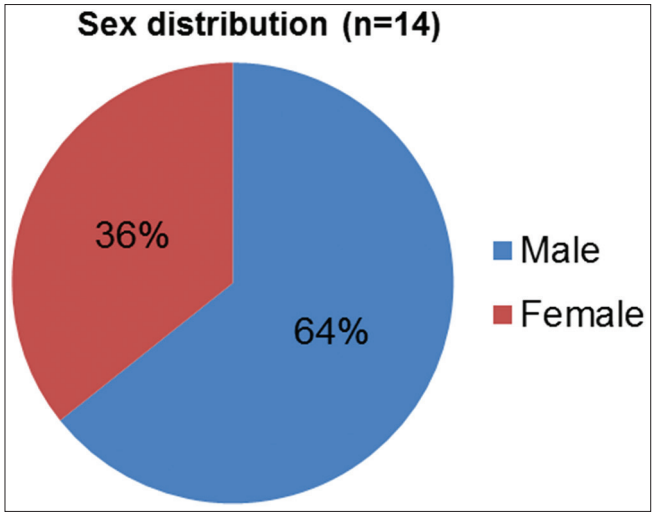

Figure 2: Sex distribution in the study group

The mean cadence was 129.77 ± 40 steps per min and the mean velocity was 66.92 ± 23.7 cm per s. The mean stride length was 79.57 cm on the right and 79.92 on the left. The mean step width was 17.3 cm. The step lengths were 36.5 ± 8 cm and 35.21 ± 8 cm on the right and left, respectively.

When the kinematic parameters were separately observed on the right and left lower limbs, there were 28 samples in a total of the 14 children with spastic jump gait included in the study [Figure 4 and 5].

Initial Contact of the Foot during Stance Phase

Fifteen out of 28 legs (53.6%) had the initial contact during stance phase on the midfoot, 5 out of 28 legs (17.9%) had the initial contact on the forefoot, and 8 of the 28 legs (29.5%) had the initial contact on the heel [Tables 4 and 5].

A 7–12 age group had the best heel-toe pattern (37.5% on the heel), and this pattern deteriorated as age advanced.

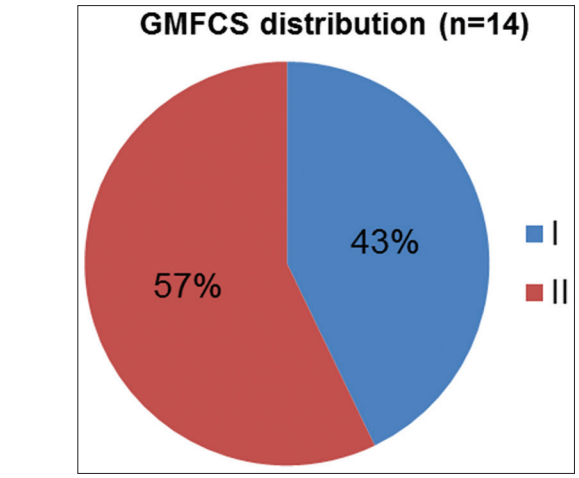

Figure 3: Gross motor functional classification system distribution in the study group

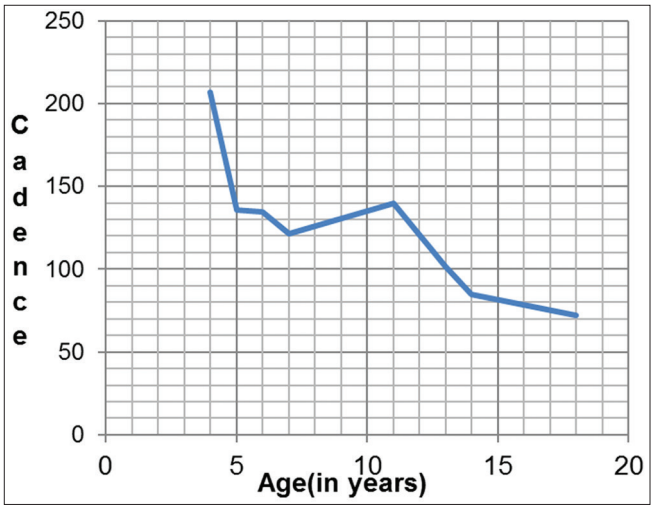

Figure 4: Line diagram showing a variation of cadence with age

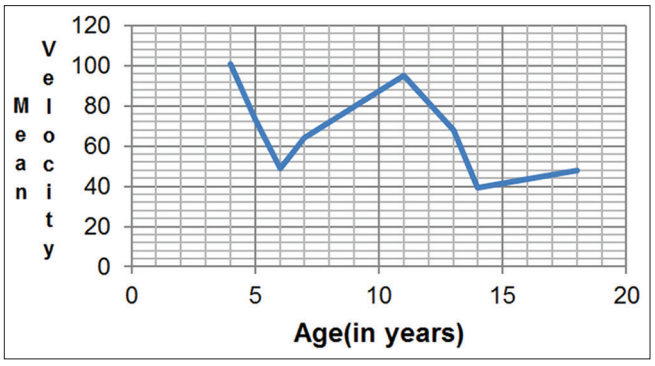

Figure 5: Line diagram showing a variation of mean velocity with age

The very young children with jump gait also walked more on their midfoot (75%) and forefoot (25%).

Rockers of the Foot and Ankle

In stance phase heel rockers were absent, and ankle rockers were good in the age group 5–6 and 7–12, thereafter ankle

rockers reduced considerably as age advanced. The toe rockers were reasonably good in the 5–6 and 7–12 age group indicating a better gait pattern in this particular age group [Table 6].

Knee Flexion Deformity and Spatiotemporal Characteristics

Independent *t*-test conducted on the spatiotemporal parameters in children with knee deformity (Popliteal angle ≥25°) and those without knee deformity in children with jump gait. It was found that those children with knee deformity had decrease in cadence and mean velocity and an increase in stance and swing time than those without. *P* value of cadence (0.054), mean velocity (0.004), and stance time (0.014) on the left was statistically significant [Tables 7 and 8].

Hip Adduction and Spatiotemporal Characteristics

Hip adduction component was present minimally in 4 out of the 14 children [Table 9].

Table 4: Distribution of initial contacts in the study group

Initial contact	Number of initial contacts (%)
Heel	8 (28)
Mid foot	16 (58)
Fore foot	4 (14)
Total	28 (100)

Table 5: Age wise distribution of initial contacts

Age in years (Legs)	Heel (%)	Mid foot (%)	Fore foot (%)
2–4 *n*=2 (4)		3 (75)	1 (25)
5–6 *n*=5 (10)	1 (10)	9 (90)	
7–12 *n*=3 (6)	4 (66.7)	2 (33.3)	
13–18 *n*=4 (8)	3 (37.5)	2 (25)	3 (37.5)
Total *N*=28	8 (28.57)	16 (57.14)	4 (14.28)

n: Number of children, N: Number of samples

Table 6: Age wise distribution of rockers

Age 2–4 category			
***N*=4**	**Absent (%)**	**Poor**	**Good**
Heel rocker	4 (100)	-	-
Ankle rocker	-	4 (100)	-
Toe rocker	-	-	4 (100)
Age 5–6 category			
***N*=10**	**Absent**	**Poor**	**Good**
Heel rocker	7 (70)	2 (20)	1 (10)
Ankle rocker	-	3 (30)	7 (70)
Toe rocker	1 (10)	2 (20)	7 (70)
Age 7–12 category			
***N*=6**	**Absent**	**Poor**	**Good**
Heel rocker	2 (33.33)	1 (16.67)	3 (50)
Ankle rocker	-	2 (33.33)	4 (66.67)
Toe rocker	-	-	6 (100)
Age 13–18 years category			
***N*=8**	**Absent**	**Poor**	**Good**
Heel rocker	5 (62.5)	1 (12.5)	2 (25)
Ankle rocker	-	8 (100)	-
Toe rocker	2 (25)	2 (25)	4 (50)

Table 7: Knee flexion deformity right side and spatiotemporal characteristics

Parameters	POP <25 R *n*=10	POP ≥25 R *n*=4	*P* value
Cadence (steps/min)	138.760±42.04	107.325±29.58	0.20
Velocity (cm/s)	71.00±26.39	56.75±12.42	0.32
Stance time (s) R	0.5490±0.21	0.7125±0.26	0.25
Stance time (s) L	0.5240±0.18	0.7000±0.23	0.16
Swing time (s) R	0.4040±0.09	0.4900±0.09	0.13
Swing time (s) L	0.4580±0.15	0.4925±0.11	0.69
Stride time (s) R	0.9550±0.30	1.2000±0.35	0.21
Stride time (s) L	0.9360±0.29	1.1900±0.34	0.19
Step length (m) R	0.3610±0.09	0.3700±0.04	0.86
Step length (m) L	0.3560±0.08	0.3425±0.08	0.79
Stride length (m) R	0.8100±0.16	0.7600±0.08	0.58
Stride length (m) L	0.8150±0.15	0.7600±0.09	0.53
Step width (m)	0.1640±0.04	0.1975±0.05	0.22

Table 8: Knee flexion deformity left and spatiotemporal characteristics

Parameters	POP <25 L *n*=10	POP ≥25 L *n*=4	*P* value
Cadence (steps/min)	145.056±37.73	102.28±31.94	0.054
Velocity (cm/s)	79.11±19.52	45.00±11.4	0.004
Stance time (s) R	0.4967±0.14	0.774±0.27	0.028
Stance time (s) L	0.4789±0.11	0.74±0.23	0.014
Swing time (s) R	0.3867±0.07	0.50±0.08	0.022
Swing time (s) L	0.4367±0.15	0.52±0.116	0.289
Stride time (s) R	0.8833±0.20	0.88±0.20	0.22
Stride time (s) L	0.8700±0.19	0.87±0.19	0.22
Step length (m) R	0.3433±0.09	0.34±0.09	0.232
Step length (m) L	0.3589±0.08	0.35±0.08	0.692
Stride length (m) R	0.8044±0.16	0.80±0.16	0.779
Stride length (m) L	0.8022±0.15	0.80±0.15	0.922
Step width (m)	0.1611±0.03	0.19±0.06	0.175

Table 9: Hip adduction deformity and spatiotemporal parameters

Parameters	ADD angle >80° *n*=10	ADD angle ≤80° *n*=4	*P* value
Cadence (steps/min)	141.740±47.70	123.133±37.31	0.43
Velocity (cm/s)	72.80±37.81	63.67±12.86	0.51
Stance time (s) R	0.5400±0.29	0.6267±0.20	0.53
Stance time (s) L	0.5260±0.25	0.6011±0.19	0.54
Swing time (s) R	0.4140±0.08	0.4367±0.10	0.69
Swing time (s) L	0.4260±0.12	0.4911±0.15	0.43
Stride time (s) R	0.9560±0.39	1.06±0.3	0.57
Stride time (s) L	0.9420±0.38	1.04±0.29	0.58
Step length (m) R	0.4200±0.09	0.33±0.06	0.052
Step length (m) L	0.3520±0.07	0.35±0.08	0.99
Stride length (m) R	0.8780±0.17	0.75±0.11	0.12
Stride length (m) L	0.8740±0.16	0.75±0.11	0.14
Step width (m)	0.1720±0.04	0.17±0.04	0.92

Comparison of spatiotemporal parameters in children with hip adduction deformity (<80°) and those without adduction contracture showed that those with decreased hip adduction angle tending to scissoring had decreased cadence, mean velocity, and step length. The swing time and stance time correspondingly increased in children with tighter adductor muscles (*P* values were not significant).

Equinus Deformity and Spatiotemporal Characteristics

Two of the 14 legs on the right side had stiffer equinus as evidenced by gastrosoleus stretch <5° (R1 to R2 <5°), whereas the equinus on the left side was stiffer only on one leg in the 14 examined.

On comparing the spatiotemporal parameters in children with static equinus (R1-R2 <5°) and dynamic equinus (R1-R2 >5°), it was found that those with static equinus had better cadence, mean velocity and step width, correspondingly swing and stance time decreased, so did the step length (*P* values were not statistically significant) [Tables 10 and 11].

Table 10: Gastrosoleus tightness on right side and spatiotemporal parameters

Parameters	Ankle R2–R1 >5 right *n*=12	R2-R1 ≤5 right *n*=2	*P* value
Cadence (steps/min)	122.808±37.04	171.600±46.66	0.11
Velocity (cm/s)	65.08±25.24	78.00±4.24	0.49
Stance time (s) R	0.6275±0.23	0.4050±0.09	0.23
Stance time (s) L	0.6008±0.21	0.4150±0.09	0.26
Swing time (s) R	0.4458±0.08	0.3250±0.10	0.10
Swing time (s) L	0.4925±0.13	0.3200±0.09	0.11
Stride time (s) R	1.0742±0.32	0.7300±0.19	0.17
Stride time (s) L	1.0558±0.31	0.7250±0.20	0.18
Step length (m) R	0.3692±0.08	0.3300±0.05	0.55
Step length (m) L	0.3525±0.08	0.3500±0.014	0.97
Stride length (m) R	0.7992±0.15	0.7750±0.04	0.84
Stride length (m) L	0.8067±0.15	0.7550±0.06	0.65
Step width (m)	0.1717±0.04	0.1850±0.007	0.71

Table 11: Gastrosoleus tightness on left side and spatiotemporal parameters

Parameters	Ankle R1–R2 >5° left *n*=13	R1–R2 ≤5° left *n*=1	*P* value
Cadence (steps/min)	124.023±35.74	204	0.05
Velocity (cm/s)	65.85±24.32	81	0.55
Stance time (s) R	0.6154±0.23	0.34	0.27
Stance time (s) L	0.5915±0.26	0.35	0.28
Swing time (s) R	0.4423±0.08	0.25	0.05
Swing time (s) L	0.4846±0.13	0.25	0.11
Stride time (s) R	1.0585±0.31	0.59	0.17
Stride time (s) L	1.0415±0.30	0.58	0.17
Step length (m) R	0.3692±0.08	0.29	0.37
Step length (m) L	0.3531±0.08	0.34	0.88
Stride length (m) R	0.8000±0.15	0.74	0.71
Stride length (m) L	0.8062±0.14	0.71	0.53
Step width (m)	0.1723±0.04	0.19	0.72

DISCUSSION

This study attempted to describe the kinematic characteristics of jump gait in Indian children with spastic cerebral palsy, belonging to the GMFCS I and GMFCS II category. The main parameters studied were initial contact of the foot during early stance, the heel, ankle, and toe rockers which help move the tibia over the ankle-foot complex during stance, the adductor overactivity, knee deformity and to what extent static or dynamic equinus was present in jump gait and how it affected cadence. In general, cadence and mean velocity decreased with age as it advanced especially after 12 years. The step length and step width also decreased as the child grew older.

It was found that majority of the children in the study group had initial contact on the midfoot (53.6%). Toe rockers were good in all the age group studied for jump gait, however, the rockers deteriorated after 12 years of age. The ankle rockers were also poor in the 13–18 age group. The 7–12 age group had the best rockers.

The hip adduction component was present only in three children probably because the GMFCS III and IV category were not included and of the GMFCS I and II category with jump gait, only two children had classical knee flexion deformity, i.e., >25° during mid-stance phase. Moreover, these children had a slower mean velocity.

The rockers of the foot-ankle complex were assessed as absent, poor, and good on an observational basis in the younger age group of 2–4 years heel rockers were absent, and ankle rockers were poor. However, they all moved on the toe rockers with increasing cadence.

Domagalska *et al.* studied the relationship between clinical, measurement, and gait analysis data in children with cerebral palsy.[11] He described that gait pathology in children does not depend on the static and dynamic contractures of hip and knee flexors and that clinical evaluation and gait pattern need to be treated as independent factors that provide information about the functional problems with gait.

This study revealed that children with hip flexion deformity had decreased cadence, mean velocity, and stride length and increased swing and stride time (*P* value was not significant).

Those children with a popliteal angle >25° also showed decreased cadence, mean velocity. The stance time and swing time of the opposite side increased ($P = 0.05$).

Those with stiffer gastrocnemius muscle apparently had increased cadence when compared with those children

with dynamic equinus. (Hence an ankle-foot orthosis could make walking faster for children with a stretchable gastrocnemius).

In this study of the 7–12 age group, the majority had good ankle and toe rockers and half of them also had heel rockers. In the 15–18 age group, heel rockers were absent in majority (62.5%), ankle rocker was poor in all and toe rockers were good in only half the children with jump gait who were older. According to Rab, the most common change with age is from a pattern of toe walking to a pattern with increasing knee and hip flexion and eventually crouch gait.[12]

Studies by Sutherland and Davids describes jump gait as the ankle in equinus, knee, and hip in flexion with anterior pelvic tilt and lordosis, though Miller describes it as ankle being neutral.

Limitations of the Study

Small sample size, only GMFCS I and II were taken. For adductor and knee flexion deformities, the sample size was too small. Further studies need to be done to confirm the findings observed.

CONCLUSION

- Majority of the children with jump gait landed on their midfoot during initial contact.
- The heel-toe pattern or rocker function of the ankle-foot complex was best between the ages 7 and 12 years of age.
- As age advanced to adolescence the rockers deteriorated considerably and so did the step length.
- Knee flexion deformity and equinus deformity slowed the children with jump gait. (However, *P* value was not significant).
- Children with a stiffer gastrocnemius had better cadence than those with dynamic or stretchable equinus.

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Original Article

Comparative Study of the Outcomes of Tympanoplasty by the Conventional Microscopic and Endoscopic Techniques

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Abstract

Introduction: Chronic otitis media, a highly prevalent middle ear disease, poses problems of recurrent ear discharge and hearing impairment. Tympanoplasty is the surgical remedy, and its outcome varies with the surgical technique used. The introduction of the operating microscope improved the accuracy of the technique; however, difficulty in visualization of certain areas of the middle ear including the anterior and posterior epitympanic spaces and sinus tympani made it necessary for frequent adjustments in either the microscope or the patient's head. This made endoscopic tympanoplasty a more favorable technique for better visualization of hidden areas in the middle ear cavity with effective removal of disease.

Purpose: This study, therefore, aimed to correlate the outcome of tympanoplasty by microscopic and endoscopic methods comparing the advantages and disadvantages of both.

Methods: This is a prospective cohort study done on patients undergoing tympanoplasty type I at the Department of ENT, Government Medical College, Kozhikode, from January 2016 to January 2017. They were divided into two groups: Group A tympanoplasty type I by conventional microscopic techniqueand Group B by endoscopic technique respectively. Intraoperatively, the duration of surgery and postoperatively, the graft uptake and hearing improvement were assessed.

Results: In our study with 40 patients, 20 each undergoing tympanoplasty by microscopic and endoscopic techniques, it was found that the graft uptake was 95% in both the groups. There was a significant difference between the two groups in duration of surgery, with a shorter duration in the endoscopic group. There were two cases of wound infection in Group A which was not statistically significant. There was significant improvement in hearing in both groups, but the difference was not statistically significant.

Conclusion: The endoscopic technique is an effective alternative to the conventional microscopic method but requires more training. The advantages with endoscope include that it is less invasive, less morbid, provides better visualization and better cosmetic results with the definite advantage of shorter duration of surgery in well trained hands. The disadvantages include the learning curve, loss of one hand in holding the endoscope and difficulty in cases of bleeding.

Key words: Conventional microscopic technique, Endoscopic technique, Type I tympanoplasty

INTRODUCTION

Chronic otitis media (COM) is a chronic inflammatory disease of the middle ear and mastoid that often results in partial or total loss of the tympanic membrane (TM) and ossicles, leading to conductive hearing loss that can range in severity up to 60 dB. It is an important public health problem with substantial economic and societal costs. Tympanoplasty, the commonly performed surgery, involves eradication of disease in the middle ear, repair of perforated TM, and restoration of the hearing mechanism. The outcome of tympanoplasty varies with surgical technique used such as overlay versus underlay graft placement, type of canal incisions for tympanomeatal flap, placement of vascular strip incision, and no canal incision technique.[1-3] Meticulous use of technique rather than the type of technique determines the outcome.[4]

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The introduction of the operating microscope resulted in drastic improvement in the results of tympanoplasty due to improvement in the accuracy of the technique.[5] Transcanal tympanoplasty can be performed with both microscope and endoscope. However the binocular nature of vision and availability of both hands for surgery makes the microscopic technique, even today the widely preferred one for tympanoplasty. However, as the microscope gives a magnified image in a straight line, visualization and removal of middle ear pathology, especially that of retrotympanum, attic, and hypotympanum, require frequent adjustments of microscope or patient's head and may also necessitate curettage of posterior canal wall, scutum, and canaloplasty.

The transcanal endoscopic tympanoplasty gained popularity in recent years being less invasive with a wider field of vision and short operating time. Endoscopically, the typical transcanal approach is possible by elevating a tympanomeatal flap, thus avoiding unnecessary incisions and soft tissue dissections. The endoscopes also provide better visualization of hidden areas in the middle ear cavity including the anterior and posterior epitympanic spaces, sinus tympani, facial recess, and hypotympanum. Only one-hand surgery is feasible with the endoscopic technique which mandates training for acquiring skill. Even a small amount of blood can totally obscure the view of operating field by soiling the scope. In addition, endoscopes could make direct injury and thermal damage by the light source.[6]

There is a need of reliable data to correlate the outcome of tympanoplasty by microscopic and endoscopic methods and also compare the advantages and disadvantages of these methods; hence, this study helps to compare the two different techniques in performing tympanoplasty.

Aims and Objectives

The aim of this study is to compare the outcome of type I tympanoplasty by microscopic and endoscopic methods and to study the advantages and disadvantages of each method.

The objectives of the study are as follows:

- To compare the percentage of graft uptake in both the groups.
- To compare the improvement in hearing in both the groups.
- To evaluate the advantages and disadvantages of each technique.

METHODOLOGY

Type of the Study

This was a prospective cohort study.

Study Setting

Patients undergoing type 1 tympanoplasty at the Department of ENT, Government Medical College, Kozhikode, from January 2016 to January 2018 were assessed for the inclusion and exclusion criteria and included in the study after getting informed written consent.

Inclusion Criteria

The following criteria were included in the study:

- Patients with unilateral COM mucosal inactive disease.
- Patients with small-to-moderate central perforation.
- Patients with demonstrable conductive hearing loss (air bone gap [ABG] >15 dB).
- Patients with age group of between 15 and 45 years.

Exclusion Criteria

The following patients were excluded from the study:

- Patients with bilateral disease and/or COM mucosal active disease
- Patients with subtotal or total perforation.
- Patients with conductive hearing loss >40 dB.
- Patients with mixed hearing loss or sensorineural hearing loss.
- Patients with comorbidities likely to impede outcome of surgery such as diabetes.
- All revision cases.

The study was conducted on 40 patients undergoing tympanoplasty type I after getting approval from the Institutional Research Committee and Institutional Ethics Committee.

The study population constituted patients with unilateral COM mucosal disease, above 15 years of age who presented to the ENT outpatient department in the specified period with complaints of ear discharge, hearing loss or both. All patients included in the study had a benign central perforation in the pars tensa of the tympanic membrane and were treated sufficiently to ensure a dry ear at least 6 weeks prior to the surgery. They underwent complete evaluation including otoscopic examination, tuning fork tests and pure tone audiometry. The patients were all counselled and those willing for surgery; tympanoplasty type I were then considered for the study

After getting written informed consent, patients satisfying the inclusion criteria were divided into two groups: Group A undergoing tympanoplasty type I by conventional microscopic technique and Group B by endoscopic technique respectively.

After pre-operative evaluation including detailed ENT examination, tuning fork tests, pure tone audiometry, and routine blood investigations, all patients underwent surgery

under local anesthesia. Injection Glycopyrrolate 0.2 mg, injection Promethazine 12.5 mg, and injection Pentazocine 30 mg intravenously were used for premedication. In Group A, postauricular approach and, in Group B, transcanal approach were used. Temporalis fascia was used as graft material in all patients which was harvested intraoperatively. In Group B, a 3-cm incision was made above the temporal line for harvesting the graft and incision was closed after getting the graft. In all patients, graft was kept as underlay after elevating the tympanomeatal flap.

Intraoperatively, the duration of surgery and, postoperatively, the occurrence of any complication were noted in each case. All the patients were followed up for 6 months, and the graft uptake and hearing improvement were assessed. Pure tone audiometry was performed at 3 and 6 months, and the hearing improvement was noted.

A statistical analysis of the data was done using Statistical Package for the Social Sciences software version 18. Qualitative data were compared using Chi-square test. Quantitative data were compared using independent *t*-test. $P < 0.05$ was considered as statistically significant.

RESULTS

A total of 40 patients were included in the study with 20 subjects in each Group A (C: conventional microscopic) and Group B (E: endoscopic). Of the 40 subjects, 23 (57.5%) were females and 17 (42.5%) were males. There were 12 (60%) females in Group A and 11 (55%) females in Group B. There was no difference between the two groups with respect to sex as $P = 0.749$ [Figure 1].

Mean age of the subjects in Groups A and B was 26.6 ± 7.92 and 28.2 ± 8.2 years, respectively. There was no difference between the two groups with respect to age as $P = 0.534$ [Figure 2].

Mean pre-operative pure tone average (PTA) in Groups A and B was 31.15 ± 4.9 dB and 30.89 ± 5.03 dB, respectively. Mean pre-operative ABG in Groups A and B was 18.14 ± 4.77 dB and 19.81 ± 4.23 dB, respectively. There was no difference between the two groups with respect to pre-operative PTA and ABG with $P = 0.869$ and 0.249, respectively [Table 1].

Mean duration of surgery in Groups A and B was 48 ± 6.05 min and 32.3 ± 5.18 min, respectively. This difference in duration of surgery was statistically significant with $P = 0.00$ [Figure 3].

Mean post-operative PTA at 3 months in Groups A and B was 17.14 ± 5.34 dB and 16.47 ± 4.49 dB, respectively, and at 6 months was 16.72±5.11 dB and 16.05 ± 4.37 dB, respectively. Mean post-operative ABG at 3 months in

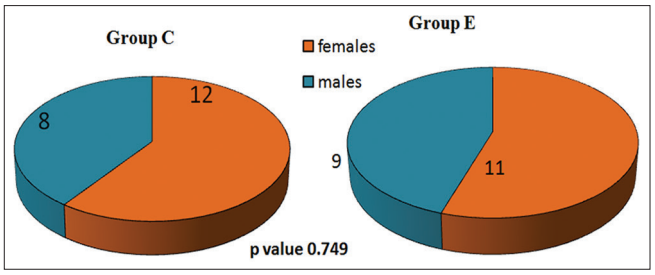

Figure1: Comparison of sex distribution

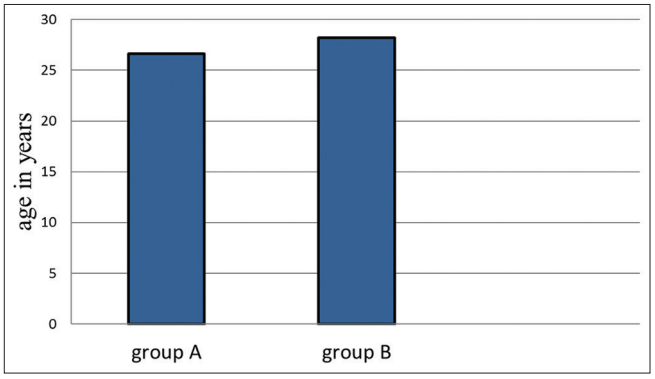

Figure 2: Comparison of mean age

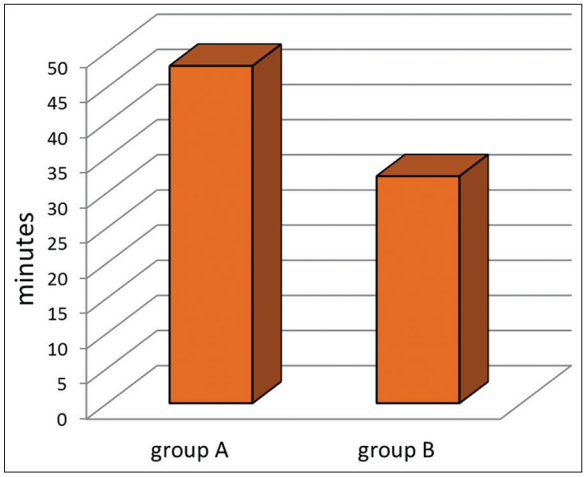

Figure 3: Comparison of the duration of surgery

Table 1: Comparison of pre-operative PTA and ABG

Group	Mean	Standard deviation	Standard error mean	*P* value
Pre-PTA				
A	31.145	4.870	1.089	0.869
B	30.885	5.027	1.124	
Pre-ABG				
A	18.135	4.767	1.066	0.249
B	19.805	4.231	0.946	

PTA: Pure tone average, ABG: Air bone gap

Table 2: Comparison of post-operative PTA and ABG

Group	Mean	Standard deviation	Standard error mean	*P* value
PTA-3				
A	17.140	5.335	1.193	0.670
B	16.470	4.494	1.005	
PTA-6				
A	16.72 0	5.112	1.143	0.658
B	16.050	4.366	0.976	
ABG-3				
A	8.470	5.042	1.128	0.896
B	8.650	3.422	0.765	
ABG-6				
A	8.550	4.777	1.068	0.867
B	8.330	3.533	0.750	

Groups A and B was 8.47 ±5.04 dB and 8.65 ±3.42 dB, respectively, and at 6 months was 8.55 ± 4.78 dB and 8.33 ± 3.53 dB, respectively. There was no difference between the two groups with respect to post-operative PTA and ABG at 3 and 6 months (Table 2).

Graft uptake was 95% in both the groups. There were two cases of wound infection in Group A which was not statistically significant ($P = 0.147$).

DISCUSSION

COM is a highly prevalent disease of the middle ear, especially in the developing countries. COM mucosal disease is characterized by permanent perforation of TM with or without inflammation of the middle ear and variable degree of ossicular destruction, which affects the normal physiology of hearing. A chronically draining ear and impaired hearing affect the quality of life. Since the introduction of tympanoplasty, a variety of graft materials and surgical techniques have been developed to close the perforation in the TM. The introduction of operating microscope has significantly improved the accuracy of the technique and, hence, the outcome. However, it has many limitations. Minimally invasive otologic surgery has recently been developed with the use of endoscope.

Microscope provides magnification in a straight line. Variations of the external auditory canal such as tortuosity, stenosis, and bony overhangs hamper the view of the TM when visualized through the microscope. Therefore, a need to manipulate the patient's head or the microscope repeatedly to visualize all the parts of the TM[7] or sometimes canaloplasty has to be done. The wide angle of the zero degree scope visualizes the entire TM in a single frame.[8] With the angled endoscope, the areas which are difficult to visualize such as hypotympanum, anterior tympanic perforation, sinus tympani, and facial recess can be easily visualized. A high-resolution and relatively clear images can be obtained through the endoscope. The use of endoscope allows transcanal approach, thus avoids postaural or endaural incision and soft tissue dissection, and hence, reduces intraoperative bleeding, operating time, post-operative pain, infection, and visible scar. For harvesting temporalis fascia graft, only 3-cm incision above the hairline is required. The monitor used during endoscopic surgery provides visual content of the procedure for training purposes.[9] Unlike the microscope, the endoscope is easily transportable and, hence, is ideal for use in ear surgery camps in remote places. Endoscope is cost effective compared to microscope. There are still many advantages of microscopic ear surgery. It provides binocular vision along with an excellent magnified surgical view. Using a microscope, two-hand surgery is possible, which is extremely useful to remove blood from the operation field.

The endoscope holds the greatest promise in tympanoplasty and cholesteatoma surgery.[10] It has some disadvantages also. It is a one-handed surgical technique. This becomes, especially, cumbersome when there is excessive bleeding. The learning curve is difficult and needs training. Even a small amount of blood can obscure the view of operating field by soiling the scope, so good hemostasis is mandatory. There are two major safety concerns with the use of endoscope. One is excessive heat production from the light source which can cause damage to surrounding structures, but this can be avoided with lower settings on the regular light source. Furthermore, the tip of the endoscope requires continuous cleaning with anti-fog solution, which probably helps in cooling the endoscope. Accidental patient movement with secondary direct trauma by the tip of the endoscope is also a matter of concern. However, most of the disadvantages of microscope can be overcome using endoscope. Thus, in this study, comparison of the outcome of type 1 tympanoplasty by microscopic and endoscopic method was done.

In our study, of the 40 patients, 20 underwent microscope-assisted type 1 tympanoplasty (Group A) and 20 underwent endoscope-assisted type 1 tympanoplasty (Group B). The groups were comparable with respect to age and sex. The percentages of graft uptake were equal in both the groups (95%). It is consistent with previous studies. In the study conducted by Huang *et al.*[11] on 100 cases (50 endoscopic and 50 microscopic), the graft uptake was 98% in both the groups. In a similar study by Harugop *et al.*[12] the graft uptake in the endoscopic group was 82% and 86% in the microscopic group. Raj and Meher[13] conducted a study to evaluate the role of rigid endoscope in the management of dry central perforation of TM and to

compare the results of endoscopic myringoplasty with that of microscopic myringoplasty using tragal perichondrium as graft material. 40 patients were divided into two equal groups. In the endoscopic group, there was 90% uptake of graft, and in the microscope group, it was 85%. Yadav *et al*.[14] studied endoscopic-assisted myringoplasty carried out in 50 patients aged 18–45 years. 40 (80%) patients had a successful closure of the TM perforation. Even though there are variations in graft uptake rate in both methods, various studies show that it is not statistically significant.

In our study, there was a significant difference between the two groups in duration of surgery with a shorter duration in the endoscopic group. The mean operating time in Groups A and B was 48 ± 6.05 min and 32.3 ± 5.18 min, respectively. This difference may be due to avoiding the postauricular incision, soft tissue dissection, and wound closure. This result is consistent with previous studies. Huang *et al*.[11] reported that the mean operation times were 75.5 min and 50.4 min in patients undergoing microscopic and endoscopic tympanoplasty, respectively. Choi *et al*.[15] found that mean operation time of the microscopic group (88.9 ± 28.5 min) was significantly longer than the endoscopic group (68.2 ± 22.1 min). There are studies reporting that the endoscopic method is more time-consuming. In the study of Harugop *et al*.[12] mean time of endoscopic and microscopic tympanoplasty operations was found to be 128 min and 106 min, respectively.

Hearing improvement in our study was comparable with other studies. There was a significant improvement in hearing in both groups, but the difference was not statistically significant. In the study by Huang *et al*.,[11] theaverage improvement in ABG in microscopic and endoscopic group was 8.3 dB and 8.9 dB, whereas in our study, it was 9.67 and 11.16 dB, respectively, at 3 months and 10.08 and 11.57 dB, respectively, at 6 months. Raj and Meher[13] reported that the mean ABG gain in patients who had undergone endoscopic myringoplasty was 8.0 dB, while in microscopic group, it was 7.5 dB. Sinha *et al*.[16] conducted a prospective study in 44 patients who underwent type 1 tympanoplasty either using microscope (n = 22) or endoscope (n = 22). Here, the pre-operative PTAs in microscopic and endoscopic groups were 46.3 and 39.7 dB, respectively, whereas in our study, 31.15 and 30.89 dB, respectively. The average improvements in ABG postoperatively were 23.68 and 16.13, respectively, which is more than that of our study. Yadav *et al*.[14] studied endoscopic-assisted myringoplasty carried out in 50 patients aged 18–45 years. The maximum number of patients (30) had an improvement of the magnitude of ABG ranging from 11 dB to 20 dB, similar to our study.

Yadav *et al*.[14] from their study of endoscope-assisted myringoplasty in 50 patients concluded that endoscopic myringoplasty is equally effective, less morbid, and cost-effective in small central perforation, whereas in our study, both methods are equally effective in small as well as in moderate central perforation. In a retrospective study by Choi *et al*.,[15] post-operative pain was also assessed and compared between microscopic and endoscopic groups in which we were not included in our study. Immediate post-operative pain was similar in both the groups; however, pain of 1 day after surgery was significantly less in endoscopic group. In the study by Harugop *et al*.[12] a statistically significant difference in favor of endoscope was found in terms of post-operative return of activity of patients and cosmetic results.

There are limitations for our study; the relatively small sample size and limited study period pose a problem in the generalization of findings. The type of surgery was decided by surgeon's preference. Assessment of post-operative pain and patient satisfaction related to cosmetic result could be included in the study.

CONCLUSION

Tympanoplasty, type I can be performed using either the conventional microscope or the endoscope. The advantages using the endoscope include that it takes shorter duration of time for the surgery, provides better visualization and better cosmetic results. The disadvantages of using the endoscope include learning curve with the technique itself, loss of one hand in holding the endoscope, and difficulty in cases of bleeding. However, endoscopic type 1 tympanoplasty is an effective alternative to conventional microscopic method requiring training and more takers to performing the same.

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Original Article

Clinicoepidemiological Study of Parthenium Dermatitis in Relation to Patch Testing

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Abstract

Introduction: Parthenium dermatitis is an immunoinflammatory disease caused by *Parthenium hysterophorus* and is the most common cause of plant dermatitis in India. It is caused by airborne dry and friable plant particles including trichomes, and the most important allergens responsible for allergic contact dermatitis (ACD) are sesquiterpene lactones.

Aim: This study aims to study to the clinicoepidemiological pattern of parthenium dermatitis and do patch testing to determine the causative agent.

Materials and Methods: A total of 100 patients clinically diagnosed as ACD to parthenium were included in the study. Patch test was performed for all 100 patients who were included in the study. For patients with acute eczema, patch test was done after 2 weeks when the lesions got cleared.

Results: Of 100 patients studied, males (75%) were more affected. Age group of 31–40 years was more affected. ACD pattern was dominant 36% followed by CAD pattern. 92% of them were patch test positive.

Conclusion: Parthenium dermatitis still poses a significant problem in India. Different presentations of the disease vary with age, sex, and geography. One should be aware of it and use patch testing for aid in diagnosis.

Key words: Allergic Contact Dermatitis to Parthenium, Parthenium Dermatitis, *Parthenium hysterophorus*, Patch Test

INTRODUCTION

Allergic contact dermatitis (ACD) is an inflammatory disorder which is T-cell mediated that occurs at the challenged site with a specific substance of low molecular weight in an already sensitized individual.[1] Contact dermatitis is one of the most common skin disorders all over the world which accounts for 4–7% of all dermatological consultations.[2] Haptens are capable of triggering the Type IV hypersensitivity reaction after single or multiple exposures. ACD occurs due to the breakdown of cutaneous immune tolerance to haptens. The common allergens vary from place to place and from time to time. Parthenium dermatitis is common in India. The gold standard method for identifying the causative allergen of ACD is the patch testing.[3-5]

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Through prospective study was focusing on determining the incidence of ACD to parthenium and the causative allergen of ACD by patch testing and analyzing the morphological patterns of presentation. We did an analysis of clinicoetiologic correlation of ACD with patch testing, and the implications are herewith discussed. The main aim of the study was to study the various morphological patterns of ACD with parthenium allergens, to determine the proportion of positive patch tests in adults with ACD, and to assess the clinical severity of disease in correlation with patch tests grading.

Aim

This study aims to study the clinicoepidemiological pattern of parthenium dermatitis and do patch testing to determine the causative agent.

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MATERIALS AND METHODS

This is an observational, prospective, single group, open-labeled clinical study. A total of 100 patients clinically diagnosed as ACD to parthenium who attended the Department of Dermatology, Thoothukudi Medical College Hospital, from June 2018 to August 2018 were included in the study. Patients in the age group of 18–70 years both males and females were included in the study. A total of 100 patients clinically diagnosed as ACD were recruited in the study. Both informed and written consent were obtained from patients to include them in the study, to do patch tests, and to take clinical photographs. A thorough clinical history, the nature, and duration of symptoms contact with any specific allergen with respect to their occupation and present clinical scenario. Furthermore, history about associated medical illness, personal, and family history of atopy were obtained. A detailed dermatological examination was carried out. The morphological pattern, the extent of skin lesions, and the presence of oozing, crusting, and lichenification were noted down. Skin lesions other than ACD were also recorded. Patients were subjected to routine blood investigations including complete hemogram, LFT, RFT, and blood sugar. Patch test was performed for all 100 patients who were included in the study. For patients with acute eczema, patch test was done after 2 weeks when the lesions got cleared.

We did a patch test using INDIAN STANDARD SERIES BATTERY, which was commercially available at Systopic Laboratories, New Delhi. These allergens were applied on Finn chambers and strapped on the back of the patients with hypoallergenic tapes. The patches were kept undisturbed for 48 h. Patients were advised to avoid strenuous hard work, showering, and sunlight exposure. After 48 h, the Finn chambers were removed, and the squares representing each chamber was marked using a marker pen. Reading was taken after half an hour. A second reading was taken after 72 h to confirm the presence of allergic reaction. Patch test results were interpreted according to the International Contact Dermatitis Research Group criteria. Clinical photographs were taken at the time of the clinical diagnosis of ACD, during patch tests procedure and at the time of reading patch tests.

The patients were treated with topical emollients, immune modulators, and topical and systemic steroids. Patients were followed up periodically, and they were advised to avoid exposure to the particular allergen(s) and the importance of changing their occupation if needed.

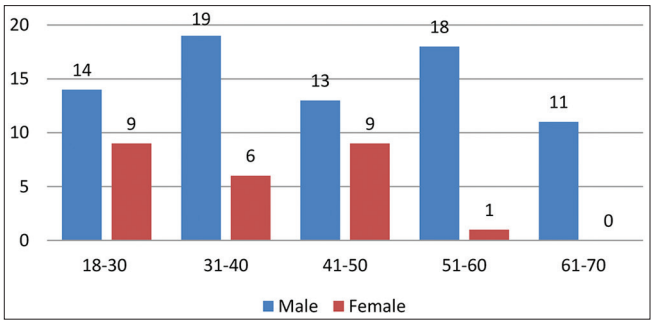

Figure 1: The age- and sex-wise distribution of patients

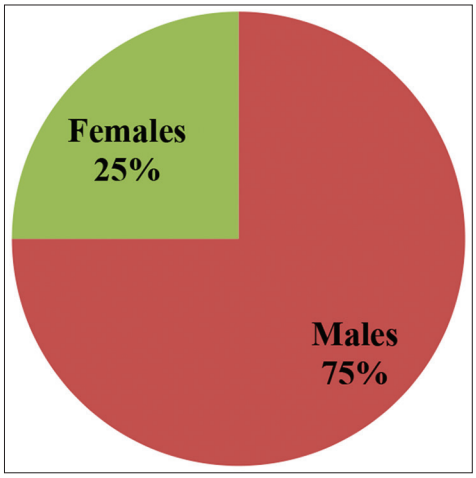

Figure 2: Sex distribution of patients

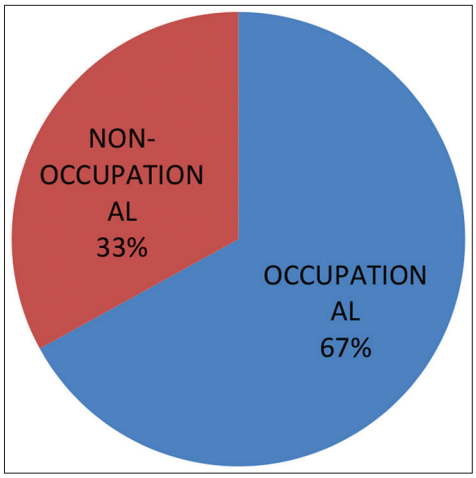

Figure 3: Occupational versus non-occupational causes

RESULTS

In our study, the incidence of ACD to parthenium was found out to be 4.94% (100 of 2024 patients).

In our study, of 100 patients, the male-to-female ratio was 3:1 Figure 2.

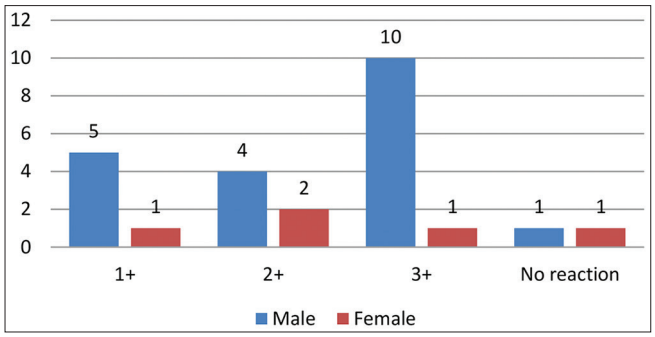

Figure 4: Distribution of patch test grading

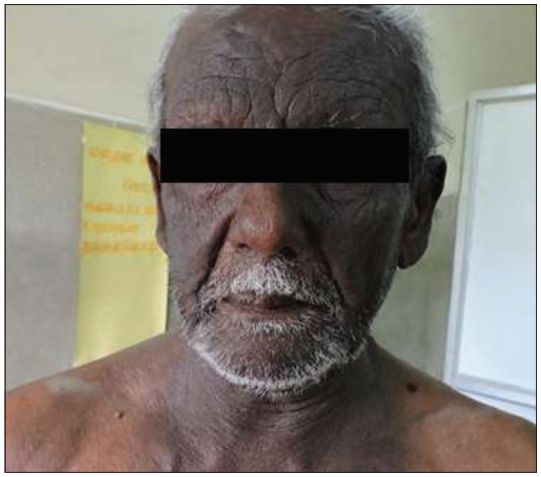

Figure 5: Airborne contact dermatitis pattern

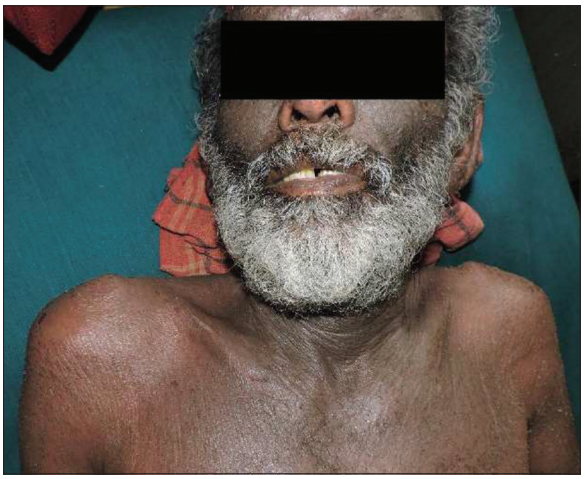

Figure 6: Exfoliative dermatitis due to parthenium

ACD was found to be highest in the age group of 31–40 years followed by <30 years age group Figure 1. The youngest patient in the study was 18 years, and the oldest was 70 years. The mean age observed in the study was 42.56 years with standard deviation of 13.94 years. ACD was found to be common in the fourth decade among males.

Parthenium hysterophorus containing sesquiterpene lactones were implicated. All the patients were related to agricultural occupation Figure3.

ABCD Figure 5 was the most common pattern (36%) of parthenium dermatitis observed in our study similar to the observation made by Sharma and Verma (81%). Even though ABCD was the most common pattern found in both studies, the difference in percentage may be due to the population group selected for the study.

Morphological Patterns of ACD with Parthenium

- Chronic actinic dermatitis pattern 25%.
- Mixed pattern (CAD and ABCD) 14%.
- Erythrodermic type 3% Figure 6.
- Hand and foot type 10%.
- Atopic dermatitis, prurigo nodularis 7%.
- Photosensitive lichenoid type 5%.

In our study, two-third of cases were of occupational (67%) in origin, and the remaining 33% were non-occupationally related. The majority were in agricultural occupation.

Seasonal variation was present in 22% of cases. Among the 22 cases, 15 cases were ACD to parthenium group which had summer/spring exacerbation. The reason for the seasonal variation and dermatitis increased during summer or autumn is, the pollens are destroyed in the months of winter, and the fauna grows well during the period of summer and spring and the dispersion of the pollen grains into the atmosphere.

In our study, 92% of patients showed one or more positive reactions in patch testing.

In our study, 24% had 1+ reading, 24% had 2+ reading, 44 % had 3+ reading, and no reaction was observed in 8%. The patch tests readings were taken on day 2 and 4, and the results were same on both days Figure 4.

DISCUSSION

Incidence of ACD to parthenium was similar to the study by Sudashree *et al.* which showed incidence around 4–7%.[6] In a study done by Narendra and Srinivas, where men outnumbered women.[7] In another study by Priya *et al.*, the male-to-female ratio was 1.27:1.[8] Moreover, the reason for this may be men is employed in preference to women. The age group observed was similar to the study done by Singhal and Singha which showed the most common age group affected as 20–39 years.[9] Our result was in contrast with the observation made by Sudhashree *et al.*, where their mean age was 34.3 years, with a standard deviation of 11.8 years (range, 9–67 years). Males outnumbered

females (2.6:1) in our study population similar to the study done by Singh and Singh (5.5:1).[11] The most common age group involved was middle-aged or elderly males similar to the observation made by Sharma and Verma.[12] These patients were involved in open-air events like farming work, and they were lightly clothed. The mean duration noted in our study was 2.65 years, but in the study done by Sharma and Verma, the mean duration observed was 7.7 years. ABCD pattern was the most common pattern observed in the study. The hands and feet were the most common sites involved in the study done by Sharma *et al*. Even though the percentage varies in both studies, the most common pattern observed was similar in both groups. A study done by Brutti *et al*., where 29% were occupational in origin and 71% were non-occupational in origin.[12] The reason for the difference noted is, in our study group, the population were laborers doing masonry and agricultural work. Another clinical diagnosis of ACD cases showed 100% positivity rate, with respect to specific allergens such as footwear, plaster, oils and greases, and paints and as such the number of patients was less in the study group. Our tropical climate may be partly responsible for this phenomenon.

CONCLUSION

Parthenium dermatitis has a great socioeconomic impact on the patients. Patch testing is a very useful scientific diagnostic tool that unravels the causative allergen and thus by avoiding the allergen, decrease the management cost, and better quality of life. Although parthenium is causing many allergic problems, the weed has not been managed below the threshold level and still creating nuisance in India, and more needs to be done by scientists, agriculturists, and government to work jointly for managing this troublesome weed. Control of parthenium has been tried by various methods, but no single management option would be adequate to manage parthenium, and there is a need to integrate various management options. Successful management of this weed can only be achieved by an integrated approach with biological control as the key element.

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Original Article

Moisturizing Kinetics of Maxrich, a Novel Moisturizing Formula Comprising of Xylitol and Xylitol-based Sugars such as Xylityglucoside and Anhydroxylitol

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Abstract

Introduction: Polyols such as glycerol and xylitol are commonly implicated as moisturizers of the skin and other epithelial tissues. Xylitol was found to augment collagen formation, markedly suppress sodium lauryl sulfate-induced transepidermal water loss (TEWL), exert anti-irritant actions, and increase filaggrin expression and skin hydration.

Materials and Methods: This was open-label, comparative, single-arm, pilot study involving 15 healthy volunteers who were prone to develop dry skin. Two test preparations were used in this study, one preparation was with ordinary cream base (control), while the other preparation was novel moisturizing formulation (MaxRich®) containing a complex of xylitol, xylitylglucoside, and anhydroxylitol. Primary objective of the study was to evaluate the hydration of skin, after application, of Maxrich® versus control over the duration of 24 h, while the secondary objective was to evaluate TEWL over the duration of 24 hours. MoistureMeter-SC (MMSC) and VapoMeter were used to measure skin hydration and TEWL, respectively.

Results: MaxRich® was associated with a significant increase in skin hydration from baseline after 4 hours as shown by increase in mean MMSC reading (22.86 vs. 9.36; $P < 0.05$). The skin hydration was maintained above baseline throughout 24 hours which was statistically significant ($P < 0.05$) as shown by higher mean MMSC reading at 8, 12, and 24 h. Compared to control, MaxRich® was associated with a significant increase in skin hydration (10.12 vs. 22.86, $P < 0.05$). Similarly, MaxRich® was associated with a significant decrease in transepidermal water loss compared to baseline after 4 h as shown by decrease in mean VapoMeter readings (9.22 vs. 5.99, $P < 0.05$). TEWL was maintained below baseline value as shown by lower mean VapoMeter readings at 8, 12, and 24 h. Compared to control, MaxRich® was associated with a significant decrease in TEWL (6.93 vs. 5.99, $P < 0.05$).

Conclusion: Results of our study indicate that MaxRich®, a novel moisturizer containing xylitol, xylitylglucoside, and anhydroxylitol, is associated with intense, fast, and long-lasting moisturizing effect.

Key words: MaxRich, Skin hydration, Transepidermal water loss, Xylitol

INTRODUCTION

It is well known that water content of the stratum corneum is very important factor in the appearance and function of the skin.[1] Natural moisturizing factor (NMF) along with intercellular lipids is responsible for the water holding capacity and barrier function, respectively, thus is fundamental element in maintaining skin hydration.[1,2] Impairment in epidermal barrier, decrease in synthesis of intercellular lipids, and NMF with resultant increase in transepidermal water loss lead to decrease in water content of stratum corneum, leading to dry skin.[1-4]

Dry skin or xeroderma is a very frequent condition which occurs at any age. The incidence of dryness related dermatoses is on the rise due to urbanization, adulteration,

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pollution, increased life span, and abandonment of traditional oil massages and baths.[5]

Moisturizing products constitute one of the largest and most important skin care product categories.[5] The function of moisturizers is to maintain the stratum corneum hydrated. There is plethora of moisturizers available in the market with different constituents and different claims. Despite their widespread use and applications, the scientific literature on moisturizers lacks strong evidence.[5-7] Early studies conducted on individuals with both healthy and diseased skin showed that some moisturizers tend to weaken the skin barrier function, whereas others may strengthen it, and these discrepant results were assumed to be caused by the varied compositions of moisturizers.[8]

Polyols such as glycerol and xylitol are commonly implicated as moisturizers of the skin and other epithelial tissues.[9] While the moisturizing effects of glycerol are very well documented, very limited data are available on the cutaneous effects of a closely related polyol, namely xylitol and xylitol-based sugars.[9] Despite their similar chemical structures, these polyols induce different gene expression changes in the keratinocytes.[10] In few *in vitro* and *in vivo* studies, xylitol was found to augment collagen formation, markedly suppress sodium lauryl sulfate-induced transepidermal water loss (TEWL), exert anti-irritant actions, and increase filaggrin expression and skin hydration.[9-14]

We conducted this pilot study with the purpose to evaluate *in vivo* the stratum corneum hydration and TEWL by the electrical measurements of skin, after treatment with novel moisturizing formula, MaxRich® comprising xylitol and xylitol-based sugars such as xylitylglucoside and anhydroxylitol.

MATERIALS AND METHODS

Primary objective of the study was to evaluate the hydration of skin, after application, of Maxrich® versus control over the duration of 24 h, while the secondary objective was to evaluate TEWL over the duration of 24 h. MoistureMeter-SC (MMSC) and VapoMeter were used to measure skin hydration and TEWL, respectively.

Two test preparations were used in this study, one preparation was with ordinary cream base (control), while the other preparation was novel moisturizing formulation (MaxRich®) containing a complex of xylitol, xylitylglucoside, and anhydroxylitol. The study was conducted according to the ICH-GCP guidelines.

This study involved 15 healthy human volunteers who were prone to dry skin: Seven women and eight men aged 20–30 years. Inclusion criteria were low hydration values (≤10) on the volar forearms, measured with MoistureMeter-SC. Exclusion criteria were - major skin diseases, pregnancy or breastfeeding, systemic corticosteroid or cytostatic therapy within 30 days, any use of local drugs within 30 days that might influence the skin texture, and any skin condition on that could interfere with a clear-cut assessment of the skin. The volunteers were tested for any allergy to tested products, and 3 days before the study, they were advised not to use any moisturizer.

The volar forearms were selected as the test site for conducting this study. Forearms of each volunteer were cleaned, and the volunteers were acclimatized under controlled conditions for the duration of 1 h at the beginning of the study. The humidity was maintained between 40% and 60% and temperature at 20–22°C for the entire study duration. Two 3 cm^2 × 3 cm^2 areas were marked on volar forearm of each participant. Area 1 received control product while Maxrich® was applied on area 2. Approximately 30 mg of study product was applied on the test sites by massaging for 30 s using a fingerstall. Two treatments were applied on test sites for 4 times over the total duration of 24 h at 4, 8, 12, and 24 h.

The MoistureMeter SC measures the hydration of stratum corneum indirectly by measuring the electrical capacitance. The skin is electrically a layered structure. The electrical properties of these layers are related to their water content. The probe, the skin surface, and the deeper skin layers form a structure, similar to an electrical capacitor. The measured capacitance is proportional to the water content of the surface layer of the skin. The higher the reading, the higher the moisture content.

VapoMeter measures the transepidermal water loss indirectly by measuring the relative humidity (RH) and temperature. The VapoMeter is equipped with a closed cylindrical chamber that contains sensors for RH and temperature. There is a linear increase of RH% in the chamber shortly after placing the device in contact with the skin. The TEWL is calculated from the increase in RH%. Values of ambient RH (%) and temperature (°C) are recorded before skin contact. The chamber is passively ventilated between measurements. Reduction in the VapoMeter readings indicates improvement in the skin barrier properties.

Skin hydration and TEWL measurements were carried at baseline and were repeated at 4 h, 8 h, 12 h, and 24 h after product application. Short-term testing, in which the effects are usually determined within a few hours after the initial

application of a defined dose of Maxrich® is extremely useful for the evaluation of the efficacy of product. The interpretation of the results was done by unpaired *t*-test using Microsoft Excel version 2016. $P < 0.05$ was considered as significant statistically difference.

RESULTS

Skin Hydration Measurements Using MoistureMeter SC

The mean MoistureMeter-SC readings are shown in Table 1. At baseline, there was no statistical difference between MMSC readings for MaxRich® and control product.

After application of MaxRich®, there was significant increase in skin hydration from baseline after 4 h as shown by increase in mean MMSC reading (22.86 vs. 9.36; $P < 0.05$). The skin hydration was maintained above baseline throughout 24 h which was statistically significant ($P < 0.05$) as shown by higher mean MMSC reading at 8, 12, and 24 h. When compared to control product, there was statistically significant increase in skin hydration with MaxRich® at 4 h as shown by significantly higher mean MMSC readings (10.12 vs. 22.86, $P < 0.05$). Similar trend was seen at 8 h, 12 h, and 24 h [Figure 1].

TEWL Measurements Using VapoMeter

The mean VapoMeter readings are shown in Table 2. At baseline, there was no statistical difference between VapoMeter for MaxRich® and control product.

Similar to skin hydration, there was a significant decrease in TEWL compared to baseline seen 4 hours after application of MaxRich® as shown by decrease in mean VapoMeter readings (9.22 vs. 5.99, $P < 0.05$). TEWL was maintained below baseline value as shown by lower mean VapoMeter readings at 8, 12, and 24 h. When compared to control product, MaxRich® was associated with statistically significant decrease in transepidermal water loss after 4 h as shown by lower mean VapoMeter readings (6.93 vs. 5.99, $P < 0.05$). Similar trend of lower mean VapoMeter readings was seen with MaxRich® compared to control at 8, 12, and 24 h; however, the difference was not statistically significant [Figure 2].

Table 1: Mean of MMSC readings at different time points

	0 h	4 h	8 h	12 h	24 h
Control	8.96	10.12	10.37	9.83	9.17
Maxrich®	9.36	22.86	20.15	18.96	12.13

MMSC: MoistureMeter-SC

Table 2: Mean of VapoMeter readings at different time points

	0 h	4 h	8 h	12 h	24 h
Control	9.75	7.43	7.21	6.94	7.11
Maxrich®	9.22	5.99	6.44	6.32	7.47

DISCUSSION

Moisturizing products constitute one of the largest and most important skin care product categories.[5] The function of moisturizers is to maintain the stratum corneum hydrated. Despite their widespread use and applications, the scientific literature on moisturizers lacks strong evidence.[5-7] Various studies with moisturizers showed that not every moisturizer is beneficial to skin and some moisturizers may weaken the skin barrier function which is assumed to be caused by varied composition of moisturizers.[15-18]

Polyols like glycerol are most commonly used ingredient in moisturizing products. A structurally similar polyol, xylitol, is also used as humectant and moisturizer. In few *in vitro* and *in vivo* studies, xylitol was found to augment collagen formation, markedly suppress sodium lauryl sulfate-induced TEWL, exert anti-irritant actions, and increase filaggrin expression and skin hydration.[9-14]

Szél *et al.* in their experiment have shown the skin hydrating and anti-irritant effects of xylitol in murine model of

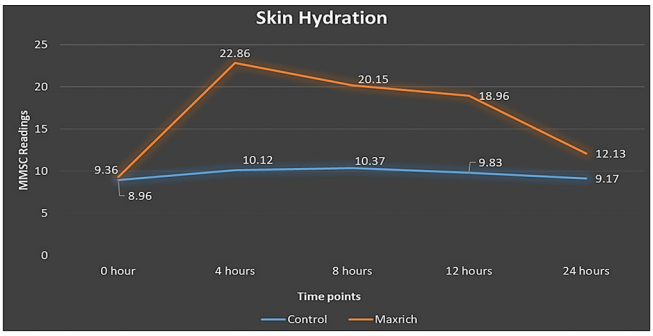

Figure 1: Mean of MoistureMeter-SC readings at different time points

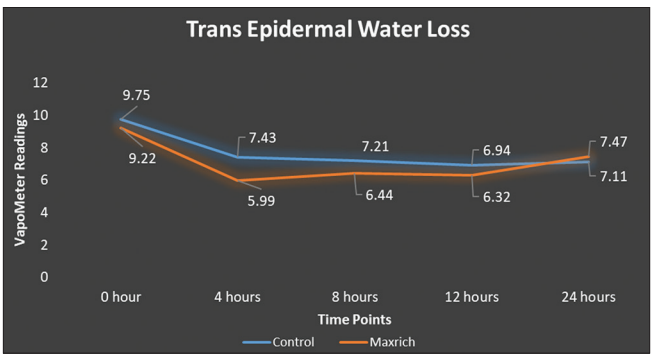

Figure 2: Mean of VapoMeter readings at different time points

irritant contact dermatitis.[19] Katsuyama *et al.* in their study showed the beneficial effect of xylitol-containing cream on atopic dry skin.[20] Erős *et al.*, their study revealed that the combined application of glycerol and xylitol significantly elevated the hydration of the SC in healthy probands within 2 h.[21] Leite e Silva *et al.* in their clinical trial concluded that moisturizer containing xylitol, xylitylglucoside, and anhydroxylitol produced most intense hydration level of the skin surface compared with the gel containing herbal extract and gel containing NMF components.[1] Results of these studies clearly demonstrate the skin hydrating benefits of xylitol.

One of the possible explanations of this skin hydrating effect of xylitol is water-binding capacity originating in their chemical structure. However, this is not the only possible explanation as xylitol and xylitol-based sugars reported to exert profound effects on the expression of certain genes and signaling pathways in keratinocytes. Páyer *et al.* in their experiment reported that both glycerol and xylitol upregulated the expression of proteins associated with barrier repair and skin hydration such as filaggrin, loricrin, involucrin, and occludin, but xylitol exerted somewhat more profound effects.[9] Authors concluded that the cutaneous barrier-repairing, differentiation-promoting, and anti-inflammatory effects of xylitol might be superior to those of glycerol.[9]

Szabó-Papp *et al.* in their study reported that xylitol was associated with a marked upregulation of filaggrin, a key molecule of epithelial regeneration and barrier repair.[10] Authors concluded that "since filaggrin levels were shown to be suppressed in dry skin, our intriguing data suggest that xylitol treatment may induce accelerated regeneration and premature differentiation of the keratinocytes resulting in a faster barrier recovery."[10]

Zappelli *et al.* in their review article commented that xylitylglucoside, a sugar derivative of two plant sugars, xylitol and glucose, stimulated the synthesis of proteins, enzymes (different types of keratin, loricrin, and transglutaminase), and ceramides essential to the function of the skin barrier. Authors also commented that these xylitylglucosides are associated with the increased synthesis of dermal macromolecules such as hyaluronic acid and chondroitin sulfate in fibroblast culture.[22] Korponyai *et al.* also reported similar results in their long-term clinical trial with xylitol, authors reported that xylitol leads to an elevated protein expression of filaggrin, a source of NMF.[14]

The results of the above studies clearly demonstrate that besides skin hydration xylitol effectively improves the barrier function of the skin.

In the present study, there was a significant increase in skin hydration compared to baseline as well as control within 4 h after application of MaxRich®, a novel moisturizing formula containing xylitol-based sugars. This is in accordance with previously discussed studies. Similarly, there was a significant decrease in transepidermal water loss associated with MaxRich® compared to both baseline and control product 4 h after application. Decrease in transepidermal water loss demonstrates that MaxRich® is associated with epidermal barrier repair. These results highlight the intense and fast acting moisturizing effect of MaxRich®.

Another important finding seen in this study is that the skin hydration was maintained above baseline value while transepidermal water loss was maintained below baseline throughout 24-h period after single application of with MaxRich®. This point toward the long-lasting effect of MaxRich®.

This being a pilot study, small sample size, and very short evaluation period are the main limitations of the study. However, these limitations do not undermine the results of the study. Long-term clinical trial with larger sample size is warranted in future.

CONCLUSION

Results of our study indicate that MaxRich®, a novel moisturizer containing xylitol, xylitylglucoside, and anhydroxylitol, is associated with intense, fast, and long-lasting moisturizing effect.

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Review Article

Bacterial Serine/Threonine/Tyrosine Phosphoproteomics: A Current Status and Their Role in Diverse Biological Processes

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Abstract

Protein phosphorylation is the most common post-translational modification in proteins. The majority of amino acids modified in a protein are serine, threonine, and tyrosine. It is estimated that 30–60% of proteins in eukaryotes is phosphorylated and the role of these modifications is well studied. The protein phosphorylation is much less abundant in prokaryotes. The role of protein phosphorylation in prokaryotes is recently being realized. Identification of all the phosphoproteins present in a bacterial cell by high-resolution mass spectrometry and using gel-free protein digestion approaches has revolutionized the field. This review is mainly focused on the role of bacterial phosphoproteome and pathogenicity. A number of biochemical pathways such as glycolysis, translation, response to stress, sugar transport, and most importantly virulence are also regulated by protein phosphorylation.

Key words: Bacterial phosphoproteomics, Mass spectrometry, Serine, Threonine, Tyrosine phosphorylation

INTRODUCTION

Serine, threonine, and tyrosine (Ser/Thr/Tyr) residues are the most common amino acids in a protein that is subjected to phosphorylation. In eukaryotes, this most common protein post-translational modification plays a significant role in a large number of biochemical pathways including signal transduction, regulation of protein function, glycolysis, and protein-protein interaction. Until recently, the protein phosphorylation was thought to be limited to eukaryotes. The importance of protein phosphorylation in bacteria is being realized now. Phosphorylated proteins play an important role in the regulation of almost all physiological processes in prokaryotes. These processes include several key steps in the host infection such as adhesion to the host, triggering and regulation of pathogenic functions, as well as biochemical warfare.

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In prokaryotes, it is believed that about 1–5% proteins are phosphorylated as compared to the eukaryotes which have about 30–60% phosphorylated proteins. Hence, to identify the phosphoproteins in a bacterium, the phosphopeptides must be enriched from non-phosphopeptides. Several methods for phosphopeptide enrichment have been developed, including immobilized metal affinity chromatography, strong cation exchange chromatography, and enrichment by antibodies specific to phosphorylated peptides. The recent developments in the high-resolution mass spectrometry and methods to enrich the phosphopeptides led to the discovery of phosphoproteome in a number of prokaryotes.

In one of the earlier studies, Macek *et al.* identified the Ser/Thr/Tyr phosphoproteome of model bacterium *Escherichia coli*.[1] It was the first prokaryote where the large-scale phosphoproteome was identified using phosphopeptides enrichment and high-resolution mass spectrometry. This publication resulted in a significant interest in bacterial phosphoproteomics and soon a number of other studies were published. Soufi *et al.* identified the phosphoproteome of *Lactococcus lactis* and Misra *et al.* identified the phosphoproteome of *Listeria monocytogenes* by phosphopeptide enrichment and "gel-free"

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high-resolution mass spectrometry.[2,3] Most recently, the tyrosine phosphoproteome of Gram-negative *Shigella flexneri* was determined by Standish *et al*. These studies clearly established that Ser/Thr/Tyr phosphorylation plays a very important role in different aspects of bacterial life including virulence. The list containing some of the bacterial species where the phosphoproteome has been identified by phosphopeptide enrichment and high-resolution mass spectrometry is presented in Table 1.

PHOSPHORYLATED PROTEINS IN VIRULENCE

The most important role played by phosphoproteins is in the pathogenesis of the bacterium. A number of proteins already known to play an important role in host infection and bacterial survival have been reported to be phosphorylated. Examples include superoxide dismutase, catalase, PrfA, and WcaJ proteins.[4-7] Arguably, the tyrosine phosphorylation plays a more important role in virulence than serine/threonine phosphorylation in pathogenic bacteria. Understanding the full role of the phosphoproteins in bacterial pathogenesis is important in discovering novel ways to block the infection by pathogenic bacteria and treat the infection after symptoms develop. The discovery of phosphoproteome of many pathogenic bacteria has opened new ways to achieve this goal.[8-11]

PHOSPHORYLATED PROTEINS IN PEP:SUGAR TRANSFERASE SYSTEM

Bacteria use PEP:sugar transport system also known as PTS system to transport sugars and sugar derivatives. In addition to this, they are involved in a large number of cellular processes. A central protein of this system, Hpr is reported to be phosphorylated on five different sites in *L. monocytogenes*. In *L. lactis*, the fructose-specific EIIABC is phosphorylated on two different serine residues. Mannose-specific EIIAB is serine phosphorylated in *E. coli* and threonine phosphorylated in *S. pneumoniae*. Several other components of PTS system are reported to be phosphorylated on serine or threonine including EIIA, EIIB, and EIIBCA.

Table 1: Ser/Thr/Tyr phosphoproteome of bacteria

Bacterium name	Number of phosphosites	Number of phosphoproteins	Year
Escherichia coli	81	79	2008
Bacillus subtilis	78	78	2007
Lactococcus lactis	73	63	2008
Streptococcus pneumoniae	163	84	2010
Listeria monocytogenes	143	112	2011
Helicobacter pylori	126	67	2011
Mycobacterium tuberculosis	500	301	2010
Klebsiella pneumoniae	93	81	2009
Acinetobacter baumannii	91	77	2014
Clostridium acetobutylicum	52	44	2012

PHOSPHORYLATED PROTEINS OF SUGAR METABOLISM

A large number of proteins of sugar metabolism, like glycolysis, have been identified to be phosphorylated.[12,13] In *L. monocytogenes*, the majority of glycolytic including fructose-1, 6-bisphosphate aldolase, glyceraldehyde 3-phosphate, pyruvate kinase, and enolase are phosphorylated on either serine or threonine amino acids. The site of phosphorylation on these enzymes appears to be conserved. For example, in *L. monocytogenes*, the S211 is phosphorylated, and in *L. lactis*, serine 216 is phosphorylated. Both of these sites are conserved as seen by aligning the protein sequences of these two enzymes. Likewise, glyceraldehyde-3-phosphate dehydrogenase is phosphorylated on threonine 211 in *L. monocytogenes* and threonine 212 in *L. lactis*. Phosphorylation on some of the glycolytic proteins seems to be limited in some bacterial species only. For example, triosephosphate isomerase is phosphorylated only in *Bacillus subtilis*.[14] The widespread conservation of phosphorylated sites on the enzymes of sugar metabolism suggests an important role of phosphorylation in the activity of these enzymes.

PHOSPHORYLATED PROTEINS IN RESPONSE TO STRESS

Bacteria live in an environment where they are subjected to continuous exposure to chemicals and conditions that are stressful. They need a mechanism to survive adverse conditions.[15,16] A large number of proteins have been identified in bacteria that help bacteria in overcoming challenges faced by bacteria. Phosphoproteomics studies identified a number of these proteins to be phosphorylated. DPS family proteins demonstrate potential to bind iron and have been implicated in protecting DNA in bacterial stress conditions. It has been reported to be phosphorylated and phosphorylation might play an important role in its function. Heat shock protein DnaK protects the bacterial DNA in thermal stress. It has been reported to be phosphorylated in *E. coli*, *L. monocytogenes*, and *Streptococcus pneumoniae*.

CONCLUSION

Improvements in phosphopeptide enrichment and mass spectrometry methods for phosphopeptide identification methods allowed the identification of phosphoproteome

of a number of bacterial species including pathogenic bacteria. Phosphoproteins representing almost all the bacterial processes have been identified. The sites of phosphorylation are also mostly conserved. This indicates that phosphorylated proteins play an important role in bacteria including virulence.[17,18]

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Case Report

Squamous Cell Carcinoma of Pelvicalyceal System Completely Replacing Renal Parenchyma - An Incidental Finding: A Case Report

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Abstract

Staghorn calculi are seen in entire or part of the renal pelvicalyceal system. If untreated or inadequately treated, they may lead to complications like the deterioration of renal function. They also cause chronic irritation, inflammation, and infection leading to squamous metaplasia of the renal pelvis epithelium, which may progress to squamous cell carcinoma. Squamous cell carcinoma in renal pelvis is an uncommon and constitutes <1% of all urinary tract neoplasms. We are presenting a Case report of 45-year-old male came with complaints of flank pain and burning micturition, off and on for 5 months with no other significant medical or family history. The general and physical examination was within normal limits with derarranged kidney function tests. Ultrasonography of kidney ureter, and bladder showed left-sided Grade IV hydronephrosis due to obstructing staghorn calculus. Complete loss of corticomedullary architecture with large staghorn calculi. Renal parenchyma completely replaced by squamous cell carcinoma. Our case highlights the importance of keeping this diagnosis in the back of the mind in patients with chronic renal calculi with the non-functioning hydronephrotic kidney.

Key words: Squamous cell carcinoma, Pelvi-caleceal system, Stag horn calculus

INTRODUCTION

Staghorn calculi are seen in entire or part of the renal pelvicalyceal system. If untreated or inadequately treated, they may lead to complications like the deterioration of renal function.[1] They also cause chronic irritation, inflammation, and infection leading to squamous metaplasia of the renal pelvis epithelium, which may progress to squamous cell carcinoma.[2] Squamous cell carcinoma in renal pelvis is an uncommon clinical entity. It constitutes <1% of all urinary tract neoplasms.[3] Squamous cell carcinomas are more common in male urethra and urinary bladder than renal pelvis. This entity is usually clinically unsuspected as it is rare, with ambiguous clinical and radiological features. Hence, patients usually present at advanced stages resulting in poor prognosis. This case highlights the importance of early treatment of renal calculi to prevent the development of squamous cell carcinoma and screening of patients with long-standing staghorn calculi.

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CASE REPORT

A 45-year-old male came with complaints of flank pain and burning micturition, off and on for 5 months. There was no other significant medical or family history. The general and physical examination was within normal limits. His blood urea and serum creatinine levels were 22.3 mg/dl and 1.14 mg/dl, respectively. Urine examination showed the presence of pus cells and red blood cells. Ultrasonography of kidney ureter, and bladder showed left-sided Grade IV hydronephrosis due to obstructing staghorn calculus.

The patient was planned for exploration with the flank incision. Intraoperative findings showed left-sided kidney grossly enlarged in size, containing large staghorn calculus. Cortex was thinned out with the dilated pelvis. Adhesions were present between kidney capsule and surrounding tissues. He underwent left-sided nephrectomy and

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Figure 1: Gross picture showing cut section of kidney showing tumour with dialated pelvi-caleceal system and staghorn calculi

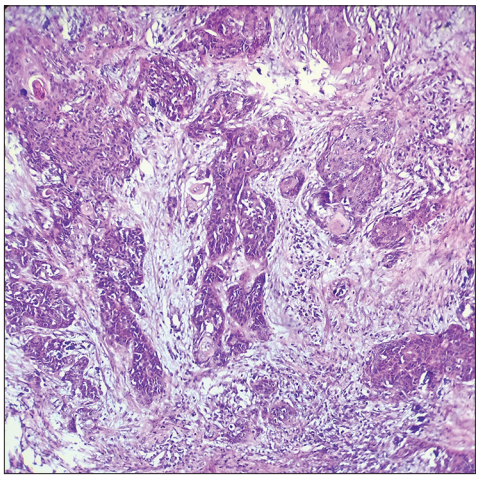

Figure 2: Microscopic picture of tumor on Low power field (H&E stain)

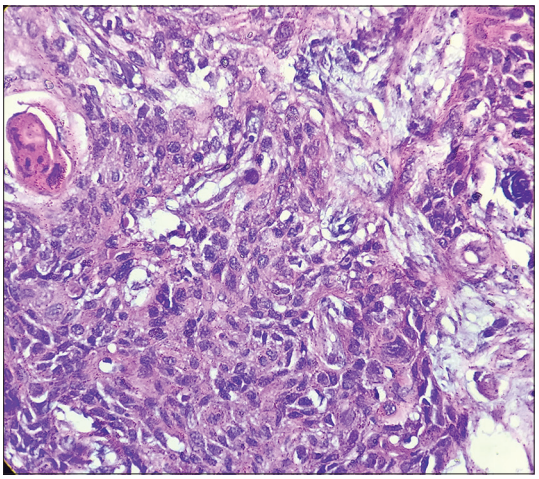

Figure 3: Microscopic picture of tumor on High power field (H&E stain)

specimen was sent for histopathological examination. Gross examination of the left nephrectomy specimen showed grossly enlarged kidney with a lobulated surface measuring 16 cm × 8 cm × 8 cm. The cut surface showed a cystically dilated pelvicalyceal system with presence of grayish white firm mass in the region of renal pelvis measuring 7 cm × 4 cm × 4 cm (Figure 1). Large staghorn calculus of size 8 cm × 6cm × 4 cm identified. Histopathological examination revealed well to moderately differentiated squamous cell carcinoma (Figures 2 and 3) involving the resection margins focally. No lymph nodes were identified in perinephric fat. Thus, the stage was - pT3NxMx. The patient had an uneventful post-operative course.

DISCUSSION

Squamous cell carcinoma of the urinary tract is more common in urinary bladder and male urethra. This entity is rarely encountered in the renal pelvis.[4,5] The etiological factors associated with this rare entity include phenacetin consumption, chronic renal calculi, pyelonephritis, and squamous metaplasia.[5] A population-based study conducted by Chung *et al.* showed the association between urinary calculi and renal pelvis cancers.[6] The suggested mechanism is due to chronic irritation by calculus and infection at the damage site, a plentiful of cytokines and chemokines get secreted by the lymphocytes, which promote the growth of tumor cells and contribute to the onset and progression of cancer.[7]

Various studies show that the mean age of presentation is 56 years, with equal incidence in males and females. The right and left side involvement is equally observed. Presenting symptoms include loin pain, hematuria, and abdominal lump.[8,9] Or patient is 45-year-old male with flank pain and burning micturition. Renal squamous cell carcinoma is difficult to diagnose as they have non-specific clinical features with radiology showing mainly presence of calculi and hydronephrosis.[4,5] These cases are, therefore, diagnosed mainly on the basis of histopathology.

At present, the primary treatment of renal squamous cell carcinoma is nephrectomy or nephroureterectomy.[4,5] Cisplatin-based adjuvant chemotherapy and radiotherapy are usually given in metastatic disease but has shown little benefit. This highlights the importance for early diagnosis. [2,8-10] Our patient underwent left radical nephrectomy with uneventful post-operative period. However, the further course of the disease could not be assessed as the patient was lost to follow-up.

CONCLUSION

Squamous cell carcinomas of renal pelvis are rare tumors, which are difficult to diagnose clinically and even on radiology. They are detected incidentally on histopathological examination of nephrectomy specimen.

As these tumors are associated with renal calculi, the patients with long-standing non-functioning calculous kidney should be carefully assessed with newer imaging modalities for early detection of the tumor, and prompt treatment with surgery and adjuvant chemotherapy for better results. This case highlights the importance of keeping this diagnosis in the back of the mind in patients with chronic renal calculi with the non-functioning hydronephrotic kidney.

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