CELL PHONES AND PENS-UBIQUITOUS ACCESSORIES OF DOCTORS AND HEALTHCARE WORKERS- ARE THEY A SOURCE OF WORRY IN THE OPERATION THEATRE?

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ABSTRACT

BACKGROUND

Hospital-associated infections are an important cause of patient morbidity and mortality. Cell phones and pens are ubiquitous accessories of doctors and other Healthcare Workers (HCWs) in a hospital as well as outside for various purposes. But, they may serve as reservoirs of infection allowing the transportation of the contaminating bacteria to many different clinical environments.

The aim of the study is to find out the prevalence of various bacteria in mobile phones and pens of doctors and other staff working in operation theatres of Government Medical College, Kottayam, Kerala, for a period of one year.

MATERIALS AND METHODS

400 samples of microbiological swabs were collected from pens and mobile phones of medical personnel working in the operation theatres of Government Medical College, Kottayam, for one year. If growth was present in cultures, identification of organisms and sensitivity to routine antibiotics was checked by disc diffusion method according to the organism isolated.

RESULTS

About 2/3rd of mobile phones and pens carried by healthcare workers inside operation theatres contained bacteria, of which, skin commensals prevailed in number. Presence of faecal microflora and multidrug-resistant bacteria detected in some of the samples are alarming.

CONCLUSION

This study emphasises the need for creating awareness among healthcare workers regarding the role of mobile phones and pens as carriers in transmission of nosocomial infections.

KEYWORDS

Bacteria, Cell Phones, Healthcare Workers, Operation Theatres, Pen.

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BACKGROUND

The term 'environmental monitoring' indicates the microbiological testing of air, water, surfaces and equipments in order to detect changing trends of microbial counts and microflora.[1] Hospital-associated infections are important causes of patient morbidity and mortality. Control of infection and basic sanitation should be at the heart of good hospital management. Emergence of new pathogens and multidrug-resistant bacterial strains compel us to review our current practices and focus on educating the healthcare workers about the importance of basics of hospital hygiene and infection prevention. Cell phones, being inexpensive and conveniently small in size, are used by doctors and other Healthcare Workers (HCWs) in a hospital for immediate communication during emergencies, ward rounds and even in operation theatres and intensive care units.[2,3] Surgical site infection may be caused by a number of organisms including gram-positive, gram-negative or anaerobic organisms.[4,5] Rarely, skin commensals may even cause infection especially in immunocompromised situations.[5] The new trend of using broad-spectrum antibiotics inadvertently caused the rise of a new generation of multidrug-resistant organisms. Staphylococci and Enterococci are notorious in this sense. Mobile phones were found to carry these bacteria because count of these bacteria increases in high temperature and moisture. Our phones are ideal multiplication sites for these microbes as they are kept warm and snug in our pockets and handbags. Also, there are no guidelines for the care, cleaning and restriction of mobile phones in our healthcare

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settings. Not only mobile phones, but pens, white coats, stethoscopes and other personal articles also carry these organisms (60-94%).[6,7,8] Taking all these factors into consideration, we believe that a proper study should be conducted in our institution to know whether our personal articles harvest harmful pathogens in quantities significant enough to cause a threat and we would like to propose strategies to minimise chances of surgical site infection from these personal articles, if these were found to be contaminated.

MATERIALS AND METHODS

Aims and objectives of the study is to find out the prevalence of various bacteria in mobile phones and pens of doctors and other staff working in operation theatres of Government Medical College, Kottayam, for a period of one year from October 2013 and to study the antibiotic sensitivity patterns of bacterial isolates. It also aims to learn the individual prevalence of organisms in different strata of healthcare workers.

Government Medical College, Kottayam, Kerala, is a tertiary care institution in Kerala. A descriptive study was conducted for a period one year starting from October 2013 to find out prevalence of bacteria in personal articles of healthcare workers. 200 samples of microbiological swabs were collected from pens and 200 samples from mobile phones of medical personnel working in the operation theatres of Government Medical College, Kottayam, using sterile saline swabs provided from the Microbiology Department. Samples were collected randomly without prior intimation about the study after taking signature in consent forms to participate in the study. The collected specimens were properly labeled with serial numbers and microbiological request forms filled with corresponding serial number, object details and date of collection. To make sure of the sterility of saline used, one saline-soaked swab was sent as control along with each group of samples collected. Collected microbiological specimens were promptly transferred to Department of Microbiology for immediate processing. Received swabs were immediately dipped in sterile glucose broth (backup broth) and aerobic bacterial cultures (5% sheep blood agar, MacConkey agar, salt agar and glucose broth) and fungal cultures (Sabouraud's Dextrose agar) were done.[9] The plates were incubated at 37°C. Culture plates were examined for growth after 24 hours of incubation. If growth was present in cultures, Gram staining of the organism was done. After Gram staining, gram-positive and gram-negative bacteria were processed accordingly. Identification of organisms were done based on microscopy (Gram staining), cultural characteristics and metabolic characteristics (catalase test, coagulase test, methyl red test, indole production). Sensitivity to routine antibiotics was checked by Kirby-Bauer disc diffusion method, vancomycin agar dilution method and Epsilometer test (E-test).[10] If there was no growth after 24 hours of incubation and glucose broth showed turbidity, subcultures were done from glucose broth. If primary plate culture and glucose broth subculture didn't show any growth, the sample was labeled as sterile.

RESULTS

200 samples were taken from mobile phones and another 200 samples were taken from pens, out of which, 140 (70%) samples of mobile phones and 122 (61%) samples of pens showed growth (Figure 1 and 2). Mobile phones showed a significantly higher number of methicillin-resistant coagulase-negative Staphylococci (22%) compared to pens (17.5%) Klebsiella, Corynebacteria and Fungi were seen only in mobile phones, while Acinetobacter and Citrobacter spp. were seen only in pens (Figure 3 and 4).

Distribution of organism among different professional strata showed 51% of doctor's mobiles carried bacteria while 63% nurses carried bacteria in their mobiles. 68% of medical students carry bacteria in mobile phones (Figure 5 and 6).

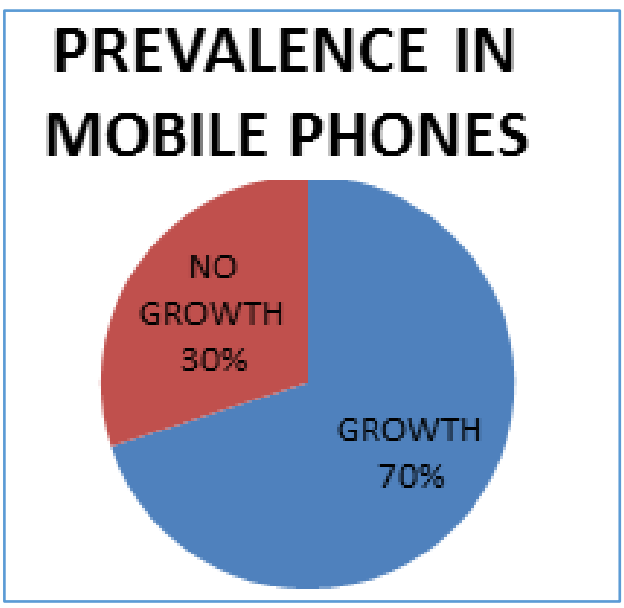

Figure 1. Prevalence of Organisms in Mobile Phones Showed 70% Growth

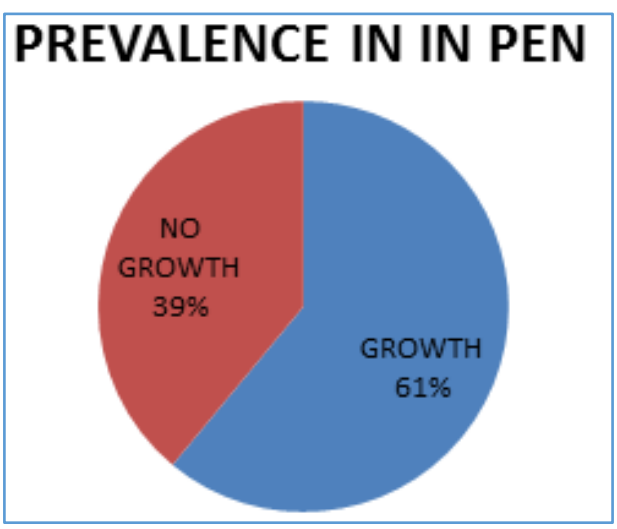

Figure 2. Prevalence of Organisms in Pens Showed 61% Growth

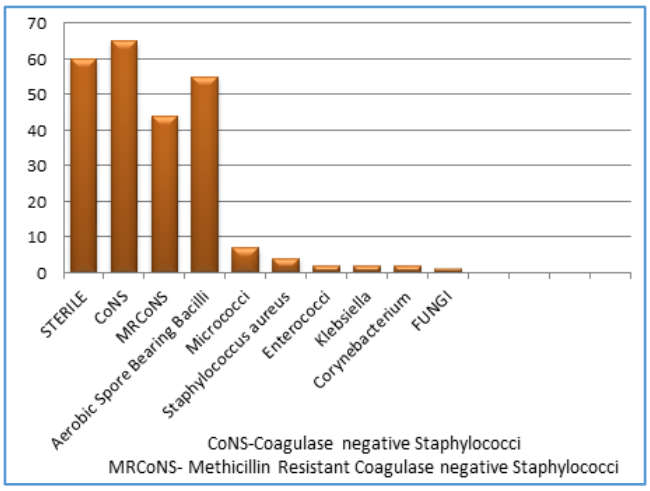

Figure 3. Organisms in Mobile Phones

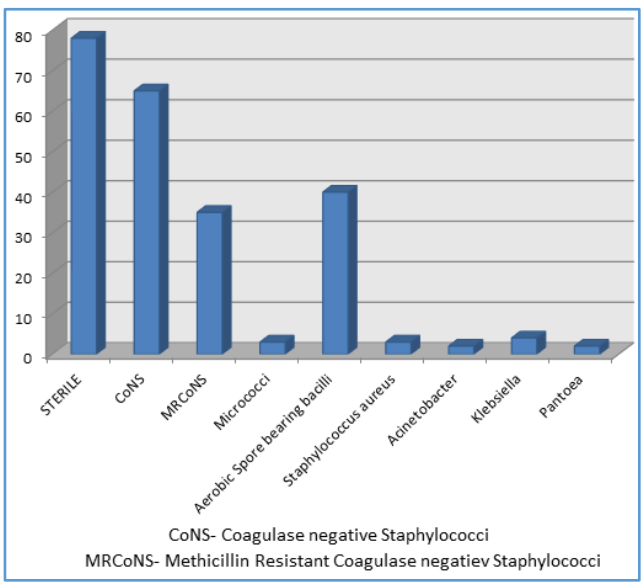

Figure 4. Organisms in Pens

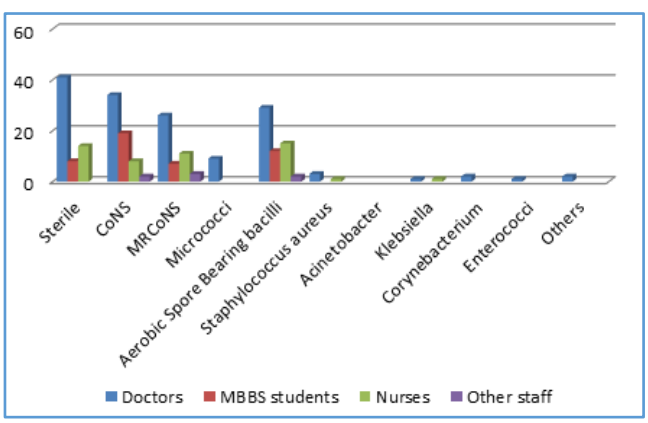

Figure 5. Distribution of Organisms According to Professional Strata in Mobile Phones

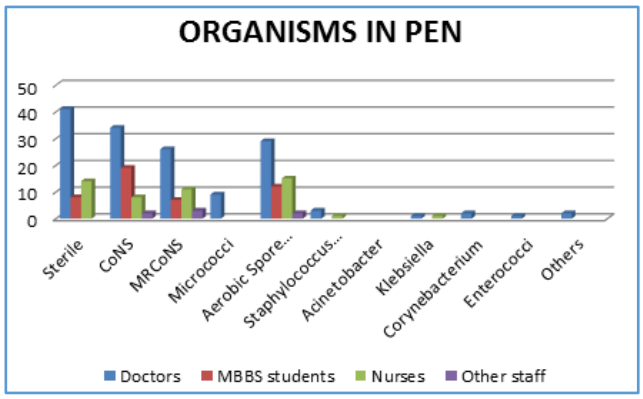

Figure 6. Distribution of Organisms According to Professional Strata in Pens

DISCUSSION

Present study revealed 70% of mobile phones contained some sort of bacteria (Figure 1). A study conducted by Dr. Dutta and Dr. Chander shows a prevalence of 72% bacteria in mobile phones, which is equivalent to present study,[6] while a study by Dr. Pandey et al showed prevalence of 47.6% bacteria in mobile phones.[7] A third study conducted by Pal S et al showed a 94.5% of prevalence.[8] Another study by Boonderowa et al showed 91.67% growth in mobile phones.[9] Ustun C et al also demonstrated 97.8% growth in mobile phones.[11] Another study by Fatma Ulgel et al showed a total growth of 94.5%.[12,13] Prevalence of organisms was found out to be slightly lesser in the present study. On studying the prevalence of individual organisms in mobile phones, commonest isolate were coagulase-negative Staphylococci (31.5%) followed by aerobic spore bearing bacilli (27.5%). Methicillin-resistant Coagulase-negative Staphylococci were present in 22% of samples. Micrococci (4%), Staphylococcus aureus (2%), Enterococci, Corynebacteria and Klebsiella (1% each) were also present (Figure 3). On comparing with other studies, Dutta and Rani Chander study showed presence of aerobic spore bearing Bacilli (47%) followed by methicillin-sensitive Staphylococcus aureus (46%), then methicillin-resistant Staphylococci (MRSA) (26%) and coagulase-negative Staphylococci (19%) as major isolates. Micrococci (2%) and viridans streptococci (1%) were also present.[6] Study of Anitha Pandey et al showed coagulase-negative Staphylococci (20%) as the predominant organism followed by Acinetobacter (14%),[7] Staphylococcus aureus (7.9%), E. coli (4.7%), Pseudomonas (2%) and Klebsiella (2%). A third study conducted by Pal S et al showed Staphylococci as the main pathogen (87%) of which 29% was MRSA. Micrococci (22%), Enterococci and Viridans Streptococci together formed 13%.[8] Another study by Boonderowa et al showed coagulase-negative Staphylococci as predominant isolate (69.3%) like the present study.[9] Micrococci were found in 57.8% samples. Rest of the samples contained Klebsiella (1.5%) and pseudomonas (1%). Unlike other studies E. coli, Pseudomonas and MRSA were not seen in present study samples.

Prevalence of bacteria in pens during the present study is 61% (Figure 2). Anitha Pandey et al showed 66% pens were hosting bacteria. Both results are comparable.[7] Analysis of individual organisms of pens showed coagulase-negative Staphylococcus as predominant organism (31.5%) followed by aerobic spore bearing bacilli (21%). Methicillin-resistant coagulase-negative Staphylococcus (18%) a few numbers of streptococci (2%) and other bacteria were present (Figure 4). Study by Anitha Pandey et al showed coagulase-negative Staphylococci (26%) as predominant isolate just as the present study.[7] Staphylococcus and E. coli were present in (14%) of samples followed by (6%) Pseudomonas, (4%) Klebsiella and (2%) Acinetobacter.

On analysing the sensitivity patterns to routine antibiotics, most of the gram-positive organisms present in day-to-day objects were resistant to conventional penicillin group of antibiotics except for cloxacillin. But, they show good sensitivity to first generation cephalosporins and tetracyclines. None of the isolates from mobile phones and pens were vancomycin resistant. There is not much difference in sensitivity patterns between organisms in mobile phones and in pens.

Distribution of organisms among different professional strata were also analysed (Figure 5 and 6). All of the samples (100%) collected from the cleaning staff contained organisms. 51% of doctors' mobiles carried bacteria, while 63% nurses carried bacteria in their mobiles. 68% of medical students carry bacteria in mobile phones. Only personal articles of doctors and nurses showed growth of faecal flora like Klebsiella and Enterococci. This maybe because doctors and nurses keep more proximity to patients than other study groups.[14] However, the presence of fecal microflora in some of the samples should raise an alarm.[15]

CONCLUSION

This study was initiated with an intention of creating awareness among healthcare workers regarding the role of mobile phones and pen as carriers in transmission of nosocomial infections. This study should remind us of the importance of hand washing once again and the importance of cleaning our personal articles at regular intervals. Also, use of mobile phones in operation theatres should be restricted to emergencies only and use of disposable pens in the theatres should be encouraged.

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EFFECTIVENESS OF PROSTAGLANDIN E1 IN THE PAIN MANAGEMENT OF PATIENTS WITH CRITICAL LIMB ISCHAEMIA- A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

BACKGROUND

Critical Limb Ischaemia (CLI) was defined for the first time in 1982 by P. R. F. Bell as a manifestation of peripheral artery disease, which describes patient with typical chronic ischaemic rest pain or ischaemic skin ulcers or gangrene.[1] This term of CLI should only be used in patients with chronic ischaemic disease defined as presence of recurring rest pain that persists for more than two weeks requiring regular analgesics and with ulceration or gangrene of the foot or toes. These criteria correspond to stage 3 and 4 of Fontaine's classification of POVD. Observational studies have shown that one year after diagnosis of CLI, 25% of patients experience a major amputation, 25% had died and only 50% survived without requiring a major amputation, though some have rest pain, ulcer or gangrene persisting. The primary goals in treating CLI are to relieve claudication pain and rest pain, to heal the ulcer, to prevent amputation of limbs, to improve quality of life and to prolong survival.

The aim of the study is to study the improvement of claudication pain, rest pain and improvement of the level of amputation in patients with diffuse peripheral arterial disease (CLI) after administration of PGE1.

MATERIALS AND METHODS

From June 2013 to November 2014, a total of 45 patients having advanced CLI (Fontaine's grade III and IV) not suitable for angioplasty and stenting or bypass procedures received different courses of PGE1. 20 patients (44.44%) received 6 full courses of PGE1,3 patients (6.66%) received 5 courses, 5 patients (11.11%) received 4 courses, 4 patients (8.8%) received 3 courses, 4 patients (8.8%) received 2 courses and 9 patients (20%) received one course. PGE1 was administered through intravenous infusion (alprostadil 100mcg) over 10 hours a day for 5 days in one month (1course). The reduction in claudication and rest pain, improvement in level of amputation and complications were assessed.

RESULTS

In all cases, there was reduction in pain scale and Fontaine's grade irrespective of the courses of PGE1 taken. 14 patients (31.1%) did not require amputation of limbs/toes, 24 patients (53.3%) have the same amputated status, while 7 patients (15.6%) required higher amputation.

CONCLUSION

PGE1 is an alternative treatment for amputation in patient presenting with advanced CLI and it is effective in reducing the claudication pain, rest pain and improving the level of amputation.

KEYWORDS

Critical Limb Ischaemia, Rest Pain, Prostaglandin E1.

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BACKGROUND

Critical Limb Ischaemia (CLI) was defined for the first time in 1982 by P. R. F. Bell as a manifestation of peripheral artery disease, which describes patient with typical chronic ischaemic rest pain or ischaemic skin ulcers or gangrene.[1] This term of CLI should only be used in patients with chronic ischaemic disease defined as presence of recurring rest pain that persists for more than 2 weeks requiring regular analgesics and with ulceration or gangrene of the foot or toes. These criteria correspond to stage 3 and 4 of Fontaine's classification of POVD. Observational studies have shown that one year after diagnosis of CLI, 25% of patients experience a major amputation, 25% had died and only 50% survived without requiring a major amputation,

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though some have rest pain, ulcer or gangrene persisting. The primary goals in treating CLI are to relieve claudication pain and rest pain, to heal the ulcer, to prevent amputation of limbs, to improve quality of life and to prolong survival.

Aims and Objectives

To study the improvement of claudication pain and rest pain of POVD patients after the administration of prostaglandin E1 (PG E1).

MATERIALS AND METHODS

This study was conducted after receiving approval from Institutional Research Committee and Institutional Ethical Committee. A written informed consent was obtained from all the subjects before their enrolment in the research study. This prospective study was conducted at Government Medical College, Kottayam, over a period of 15 months, between June 2013 and November 2014 with 45 CLI patients. Diagnosis of disease was made on the basis of clinical examination and Doppler study. Fontaine's grading system was used to grade the symptoms of patient. Parameter taken into account was pain (6 grades).

Inclusion Criteria

All cases of peripheral occlusive vascular disease with diffuse atherosclerotic changes not suitable for angioplasty and stenting or bypass procedures who present during the study period and who have not received PG E1 treatment.

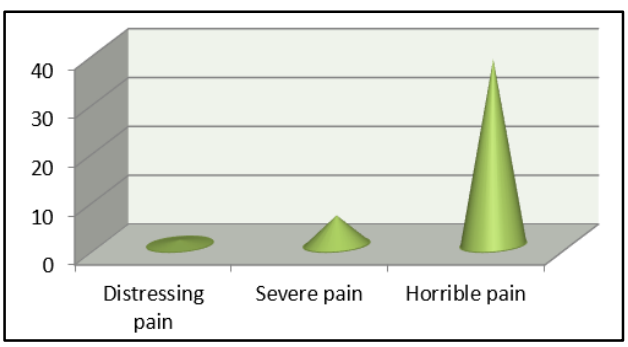
Exclusion Criteria

Patient not willing to undergo treatment with PG E1 and those not willing to give consent.

PG E1 was administered as continuous slow intravenous infusion once a day for 5 days in a month (1 course) up to 6 months for those with end-stage POVD where no alternative treatment available. One ampoule contains 500 micrograms of PG E1. It is diluted with 9 mL of normal saline in a 10 mL syringe. 2 mL (equivalent to 100 micrograms) is put in 500 mL of normal saline and given as continuous intravenous infusion with microdrip set at 50 microdrops/minute to be completed in 10 hours. If given rapidly, it can induce myocardial ischaemia due to coronary steal effect produced by peripheral vasodilatation. The results were analysed using Microsoft Excel, Chi-square test and T-test.

Data Analysis

The research work was done on 45 patients, 30 (66.7%) males and 15 (33.3%) females. The most common age group affected is 60-70 years. Patients usually present to outpatient department with complaints of recurring rest pain that persists for more than 2 weeks requiring regular analgesics. Visual analogue pain scale was used to assess the pain scale of the patient when they were admitted to the hospital (Table 1). The same pain scale was used to compare the reduction in the pain scale after PG E1 administration.[2] Majority of the patients describe the pain as a horrible pain, which wakes them from sleep and typically is relieved on hanging the leg by the side of the bed.



Graph 1

*Majority of the patients describe the pain as a horrible pain.

Of the 45 patients, 20 (44.4%) completed 6 full courses, 3 patients completed 5 courses (6.7%), 5 patients (11.1%) completed 4 courses, 4 patients (8.9%) completed 3 courses, 4 patients (8.9%) completed 2 courses and 9 patients took only one course. Three patients dropped out of this study after taking the first course. The main reason given by the patients for non-completion of the course is due to absent pain (relief of pain) and wound healing.

The sum of the total course of PGE1 taken by the patients (6 courses + 5 courses + 4 courses + 3 courses + 2 courses + 1 course) is 172. The sum of the reduction in pain scale for the patients irrespective of the course completed was 156 and reduction in Fontaine's grade was 110. The overall reduction in pain scale was 3.46 and that of Fontaine's grade was 2.44(Table 2).P-value is significant in all the comparisons (Table3), i.e. pain scale before and after PGE1 administration and Fontaine's grade before and after PGE1 administration.

Descriptive Statistics						
	N	**Minimum**	**Maximum**	**Sum**	**Mean**	**Std. Deviation**
Reduction in pain scale	45	0.00	4.00	156.00	3.4667	0.86865
Reduction in Fontaine's grade	45	0.00	3.00	110.00	2.4444	0.86748
Valid N (list wise)	45					

Table 1. Overall Reduction in Pain Scale and Fontaine's Grade

** Overall reduction in pain scale and Fontaine's grade.

		t	**df**	**Sig. (p-value)**
Pair 1	Visual analogue pain scale - Pain scale after prostaglandin E1 administration	26.772	44	0.000
Pair 2	Fontaine's grading-Before- Fontaine's grading-After	37.195	44	0.000

Table 2. Significant Table (p-value)

***Significant table (p-value).

In the follow up period, 1 death each were registered in the patient group receiving 6 full courses and in patient group receiving 5 courses. Two patients died after receiving 2 courses and 3 deaths were registered in patients receiving only one course of PGE1. All these deaths were registered after the end of PGE1 treatment and none were related to the administration of PGE1.

So, this research study and analysis justify the role and use of PGE1 in the treatment of advanced cases of critical limb ischaemia for reduction of pain as an alternative treatment option for those in whom angioplasty, stenting and bypass procedures are not possible.[3,4,5]

DISCUSSION

Diffuse Peripheral Vascular Disease (POVD) involving the lower limb is a debilitating illness with high incidence of morbidity and mortality. The highest incidence of critical limb ischaemia was seen in the 60-70 age groups with a mean age incidence of 65.23 years.[6] The incidence of CLI is more common in males. Hypertension in association with diabetes was the most common comorbid condition for CLI. Early diagnosis and intervention is the key to successful outcome.

Clinical examination with Doppler study was done to diagnose a patient with CLI.[3] 22 patients (48.88%) presented with claudication pain, rest pain and gangrene of toes while 14 patients (31.11%) had non-healing ulcer in addition to the pain and gangrene of toes (Fontaine's grade IV). 9 patients (20%) had claudication pain and rest pain only putting them in Fontaine's grade III[2,7] which was used to assess the pain status at the time of admission as well as after the administration of PGE1.

Increase of blood flow in the ischaemic leg is believed to represent the main action of PGE1 in the therapy of POVD. PGE1, known pharmaceutically as alprostadil increases the blood flow by peripheral vasodilatation and induces angiogenesis and also improves the endothelial function.[8] The anti-ischaemic effect mechanisms of PGE1 in POVD patients are probably complex and clearly not limited to a direct vasodilator action alone.[8] In addition to the known effects of PGE1 on blood flow, platelet aggregation, fibrinolysis and viscosity, it also inhibits monocytes and neutrophil function suggesting that PGE1 has anti-inflammatory effects. Prostaglandin E1 improves the endothelial function in patients with CLI. Several randomised trials have now been completed and combined in meta-analysis with proven improved outcomes after PGE1 in CLI. The transient side effects of PG E1 therapy, which never led to interruption of therapy include headache (4%), erythema and pain of injected vein (8%).[9]In a nutshell, intravenous PGE_1infusion is effective and safe in the treatment of outpatients with intermittent claudication.[9]

A more recent meta-analysis of the administration of PGE1 for patients with POVD stage III or IV not eligible for arterial reconstruction shows that it not only has significant beneficial effects over placebo on ulcer healing and pain relief, but also increases the rate of patients surviving with both legs after 6-months follow up.[5,10] After treatment with PGE1, some studies noted a significant reduction in analgesic use and in pain score.[5]

Though PGE1 is used for treatment of advanced CLI by Indian doctors, studies have so far not been published about the effects of PGE1 on the reduction of pain after administration amongst Indian population. Among our 45 patients, 20 patients (44.4%) completed 6 full courses, 3 patients completed 5 courses (6.7%), 5 patients (11.1%) completed 4 courses, 4 patients (8.9%) completed 3 courses, 4 patients (8.9%) completed 2 courses and 9 patients took only 1 course. Three patients dropped out of this study after taking the first course. The main reasons given by the patients for non-completion of the course are relief of pain and wound healing.

The overall reduction in pain scale is 3.46 and that of Fontaine's grade is 2.44.P-value is significant in all the comparisons (Table3), i.e. pain scale before and after PGE1 administration and Fontaine's grade before and after PGE1 administration. In the follow up periods, 7 deaths were observed. All deaths were registered after the end of PGE1 therapy, but never related to the therapy.

So, our study justifies the role and use of PGE1 treatment in advanced cases of critical limb ischaemia for reduction of pain as an alternative treatment option.[6,7,11] The cost analysis and the quality of life evaluation done by some studies indicated a benefit of preserving limbs.[12,13] Limb salvage will continue to be the primary goal for most patients undergoing vascular therapy.[14,15]

CONCLUSION

This study proves the beneficial effects of PGE1 in reducing the pain as well as Fontaine's grade in patients with CLI. Short duration of the study, limited number of surgical units practicing the use of PGE1 for advanced CLI cases and defaulters are the limitations of this study.

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Case Series

Surgery Section

Rare Hernias Presenting as Acute Abdomen- A Case Series

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ABSTRACT

Hernia is an abnormal protrusion of an organ or tissue through a defect in its surrounding walls. It can be divided into internal, external and diaphragmatic hernias. Most of them can be asymptomatic. If they become symptomatic they can present with features of intestinal obstruction, incarceration or strangulation. In this case series we compare the incidence of these rare presentations of hernias with world literature and to warn surgeons not to cut the obstructing band in cases of internal hernias. In this case series, we review the clinical details of 7 rare presentations of hernia, who presented with various types of hernias to a tertiary care centre in Kerala over a period of one year. Of these 7 cases 6 cases were internal hernias (3 left paraduodenal hernias, 2 transmesentric hernias, and 1 pericaecal hernia) and a case of spigelian hernia above the level of umbilicus. All of them presented as acute abdomen in the emergency department. Among these 7 cases, only one case was diagnosed preoperatively. Three patients had bowel gangrene and had to undergo resection-anastomosis of the bowel. The survival rate among these cases was 100% as compared to 50% in the world literature if they had been left untreated. Even though internal hernias are a rare entity, we need to have it as a differential diagnosis in case of intestinal obstruction, in a previously non-operated abdomen.

Keywords: Abdominal wall abscess, Internal hernia, Intestinal obstruction, Spigelian hernia

CASE SERIES

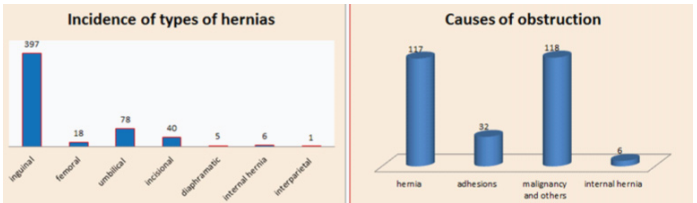
Over a period of one year from March 2014 to March 2015, a total of 695 patients with hernia and intestinal obstruction were considered retrospectively. Of these, 545 patients were hernia cases (both elective and emergency), and the rest were intestinal obstruction cases, from other causes. Among the hernias most were inguinal hernias (397 patients) and internal hernias were constituted by 6 cases. All of them presented as acute intestinal obstruction, constituting 1.8% of acute intestinal obstruction cases [Table/Fig-1].

CASE 1: Patient presented to our emergency department with features of intestinal obstruction. History of similar complaints were present previously which had subsided on its own. He was dehydrated and tachycardia was present. Abdomen was distended with diffuse tenderness and guarding. X ray abdomen showed multiple air fluid levels and dilated bowel loops. He was posted for emergency exploratory laparotomy. Intraoperatively ileum was found herniating through the left paraduodenal fossa with constricting band formed by inferior mesenteric vein and the proximal small bowel was found dilated [Table/Fig-2]. The contents of the hernia were reduced and the inferior mesentric vein was preserved. Defect was closed with the free peritoneum to the lateral border of duodeno-jejunal flexure, retroperitonialising the inferior mesenteric vein. Postoperative period was uneventful and he was discharged on day 7.

CASE 2: Patient presented to our casualty with features of intestinal obstruction. He was febrile and dehydrated, tachycardia was present. Abdomen was distended, with diffuse tenderness, guarding and rebound tenderness. X ray abdomen showed multiple air fluid levels and dilated small bowel loops. He was posted for emergency exploratory laparotomy. During laparotomy ileum was found herniated in the left paraduodenal fossa with 50 cm of ileum found gangrenous within it and proximal segment dilated [Table/Fig-3,4]. The constriction band was formed by inferior mesenteric vein. The contents were reduced, gangrenous bowel was resected and an end to end ileo-ileal anastomosis was done in two layers. The defect was closed with peritoneum to the DJ flexure after preserving the inferior mesenteric vein. Postoperative period was uneventful and he was discharged on postoperative day 9.

CASE 3: A chronic liver disease patient admitted in medicine ward presented to emergency department with features of intestinal obstruction. X ray abdomen showed multiple air fluid levels and Contrast Enhanced Computerized Tomography (CECT) abdomen showed encapsulation of distended bowel loops in an abnormal location in the left hypochondrium, with hepatomegaly and ascites [Table/Fig-5]. She was transferred to the surgery department for emergency exploratory laparotomy. Intraoperatively ascites was present. Liver was massively enlarged and ileum was found herniating through the left paraduodenal fossa and covered by peritoneal sac and the constricting band was formed by the inferior mesenteric vein causing obstruction [Table/Fig-6]. Sac was opened, contents were reduced and the defect was closed with the peritoneum to the lateral aspect of duodeno-jejunal flexure after preserving the inferior mesenteric vein. Postoperatively she was transferred to surgery ICU because of hypotension. She could not be revived and expired on postoperative day 3 due to cardiac cause.

CASE 4: Patient presented to our casualty with features of intestinal obstruction. He was febrile, dehydrated and tachycardia was present. Abdomen was distended with rebound tenderness. Total leukocyte count was 27,000\mm^3. X ray abdomen showed multiple air fluid levels and dilated small bowel loops. He was posted for emergency exploratory laparotomy. Intraoperatively



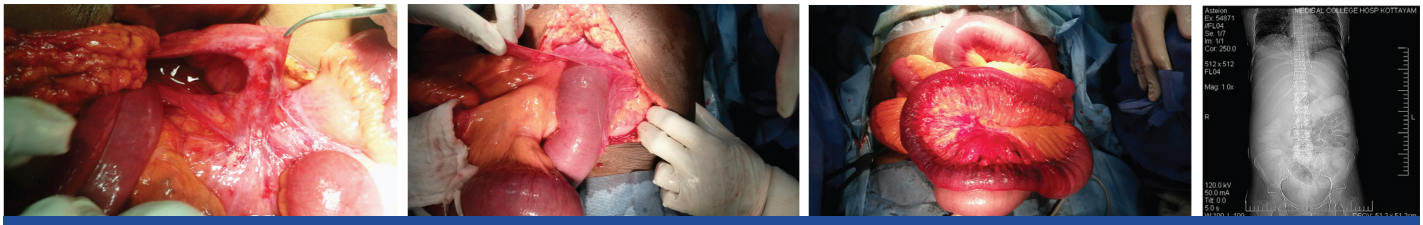
[Table/Fig-1a]: Total incidence of various types of hernias in our tertiary care centre over a period of one year. Internal hernias forms 1.1% of all types of these hernias. **[Table/Fig-1b]:** Shows the total intestinal obstruction cases over a period of one year. 1.8% of these obstruction cases were constituted by obstruction due to internal hernias.

small bowel was found herniated in the pericaecal region, between peritoneal bands, with 75 cm of ileum gangrenous and proximal small bowel found dilated [Table/Fig-7]. The contents were reduced. Gangrenous segment was resected and an end to end ileo-ileal anastomosis was done in two layers. The hernial defect was closed by approximating the peritoneal bands. He was discharged on postoperative day 10.

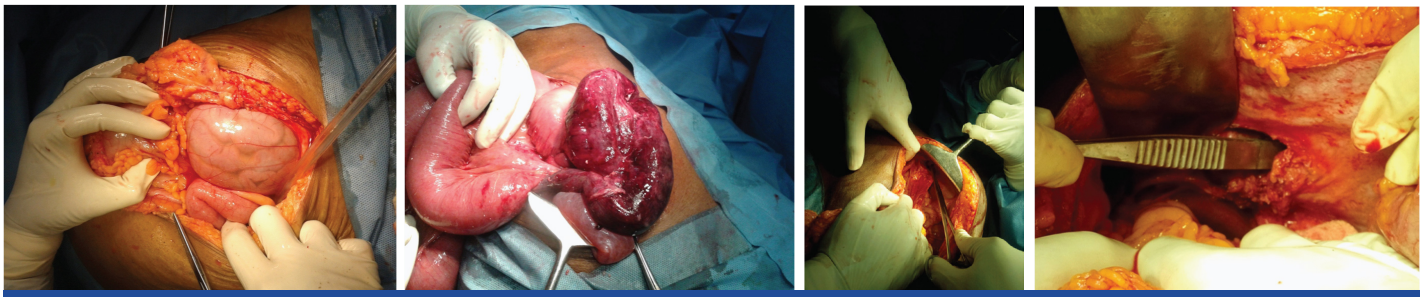
CASE 5: A chronic calcific pancreatitis patient who had undergone Frey's procedure from a hospital in Tamil Nadu 2 years back, now presented with complaints of intestinal obstruction. CECT abdomen showed features of mechanical obstruction of bowel. He was posted for emergency exploratory laparotomy. During laparotomy the small bowel was found herniating through a defect in the transverse mesocolon near the previous anastomotic site with 50 cm of ileum found gangrenous within. Contents were reduced, the gangrenous segment was resected, and an end to end ileo-ileal anastomosis was done in two layers. The defect in the transverse mesocolon was closed. He was discharged on postoperative day 9.

CASE 6: A 57-year-old female who had undergone subtotal gastrectomy with a Roux- en- Y reconstruction for a stomach GIST 2 years back. Now she presented to our casualty with complaints of intestinal obstruction. She was dehydrated, tachycardia was present. Abdomen was distended with diffuse tenderness. X ray abdomen showed dilated small bowel loops with multiple air fluid levels. Initially she was managed conservatively by nasogastric aspiration and IV fluids. But symptoms were persisting and hence she was posted for exploratory laparotomy. Intraoperatively ileum was found herniating though a rent in the Roux loop of jejunum causing obstruction. The ileum was reduced. The defect was closed by approximating mesocolon to the roux loop. She was discharged on postoperative day 7.

CASE 7: A-45 year-old female came to emergency department with complaints of a swelling over left side of the abdomen, associated with fever and pain. No history of any trauma, or any similar illness in the past. She was febrile with a 10 x 8 cm tender parietal swelling in the left lumbar region extending to the left hypochondrium, the rest of the abdomen was normal. Ultrasound scan of the abdomen was suggestive of an abdominal wall abscess and it was drained with a catheter under ultrasound guidance. Despite this, after 4 days the swelling was persisting. Repeat ultrasound was taken, which showed persistence of pus in the region with some intra-abdominal structure communicating with the abscess cavity. She was posted for exploratory laparotomy. Intraopetratively the abscess cavity was laid open, and proceeded with laparotomy. It was found that the cavity was tracking to the left hypochondrium with a defect in the abdominal wall through which omentum was herniating which got strangulated [Table/Fig-8,9]. The contents were reduced. Strangulated omentum was resected, defect in the abdominal wall closed in layers with polypropylene. Postoperative



[Table/Fig-2]: Shows the left paraduodenal fossa (Landzert's fossa) with the inferior mesenteric vein forming the free edge of the defect through which the bowel was found herniating. **[Table/Fig-3]:** Shows the dilated small bowel in the left paraduodenal fossa. **[Table/Fig-4]:** Shows the segment of the small bowel which was found gangrenous in the left paraduodenal hernia sac, which was later resected and an end to end ileo-ileal anastomosis was done. **[Table/Fig-5]:** CECT abdomen of the patient showing encapsulated small bowel in an abnormal location in the left side of the abdomen.



[Table/Fig-6]: Showing the small bowel within the sac in the landzert's fossa. **[Table/Fig-7]:** Showing a segment of small bowel, seen gangrenous in the pericaecal hernia, which was later resected and an end to end ileo- ileal anastomosis was done. **[Table/Fig-8]:** Shows the omentum herniating through the defect in the left hypochondrium, which was strangulated in the interparietal region presenting as an abscess. **[Table/Fig-9]:** Shows the defect in the left hypochondrium.

Patient	Age	Sex	Presenting complaints	Past history/ co-morbidities	Type of hernia	Procedure done
Case 1	35	M	Abdominal pain, vomiting, constipation	History of similar complaint present.	Left paraduodenal hernia	Reduction of hernia, closure of defect.
Case 2	58	M	Bloody loose stools, vomiting, pain	Nil	Left paraduodenal hernia	Reduction of hernia, resection and anastomosis, closure of defect.
Case 3	48	F	Abdominal distension, pain	Chronic liver disease	Left paraduodenal hernia	Reduction of hernia, closure of defect.
Case 4	73	M	Abdominal pain, vomiting, constipation	Nil	Pericaecal hernia	Reduction of hernia, resection and anastomosis, closure of defect.
Case 5	30	M	Abdominal pain, vomiting, constipation	Post frey's procedure	Trans-mesenteric hernia	Reduction of hernia, resection and anastomosis, closure of defect.
Case 6	57	F	Abdomen pain, vomiting, abdomen distension, constipation.	Post subtotal gastrectomy for stomach gist.	Trans-mesenteric hernia	Reduction of hernia, closure of defect.
Case 7	45	F	Swelling left lumbar region, abdomen wall abscess	Nil	Spigelian hernia	Abscess drainage, laparotomy and closure of defect

[Table/Fig-10]: Summary of the case series

period was uneventful and she was discharged 2 weeks after admission.

In this case series, we had 7 rare cases of hernias, of which, one was a spigelian hernia occurring above the level of umbilicus. Other 6 cases were internal herniation (3 left paraduodenal hernias, 2 transmesentric hernias and 1 pericaecal hernia) presenting with features of intestinal obstruction [Table/Fig-10]. Among them, only one had preoperative diagnosis of internal hernia. Considering the statistics of the incidence of various types of hernias in our institution over a period of one year, they correspond with that of world literature. The statistics are same for incidence of intestinal obstruction due to these types of hernias. Among these 7 cases 4 patients had strangulation of the contents. The survival in these cases was 100%. The statistics of these rare presentations of hernia are similar to those in the world. All the patients presented with acute abdomen, one had previous history of similar symptoms which subsided on its own.

DISCUSSION

A hernia is a bulging of part of the contents of the abdominal cavity through a weakness in the abdominal wall [1]. Hernia can occur in all areas, when there is congenital or acquired defects in the walls of body cavities in a case of external hernia or inside the abdominal cavity in a case of internal hernia through which the bowel prolapses [2]. Hernias are common diseases of the abdomen with a global incidence of approximately 4%- 5% [3] and are the most common reason for surgery in patients more than 50 years of age [4]. Of these, inguinal hernias are the most common with prevalence of 75%, followed by femoral (15%), and umbilical (8%) [3]. The male:female ratio is as high as 8:1. In the case of femoral hernia; females are the more commonly affected [4]. Hernias have a wide range of presentation. Mostly they are asymptomatic or may present with non-specific symptoms. But in some cases, the patients can have pain or nausea and, in some cases they can develop acute complications (incarceration, obstruction, volvulus & strangulation) that need prompt diagnosis and treatment [4]. Diagnosis is almost always clinical, but can be difficult in patients with obesity, pain or in rare presentations of hernias; where preoperative imaging may help in the diagnosis. Sometimes it can be an accidental finding intra operatively.

In 1857, Treitz defined an internal hernia as a retroperitoneal protrusion of an abdominal organ through a peritoneal fold [5]. Internal hernia is a rare type of hernia in which the abdominal content herniates through the defect in the peritoneal cavity, which is found either congenitally or is acquired. Congenitally they may be pre-existing anatomical structures like recesses, foramina, or fossa [2]. Internal hernias account for < 1% of all abdominal hernias worldwide. Most of these patients may have nonspecific symptoms, until they present to the casualty with features of intestinal obstruction, abdominal pain, or distension. They mostly present with features of intestinal obstruction, which account for 5.8% of all small bowel obstruction cases [2]. It is classified by Ghahremaani into 6 groups [6]. They are: 1) Paraduodenal hernias (50-55%); 2) Hernias through foramen of Winslow (6-10%); 3) Transmesentric hernias (8-10%); 4) Pericaecal hernias (10-15%); 5) Intersigmoid hernias (4-8%); 6) Paravesical hernias (<4%). Paraduodenal hernias are mainly congenital, due to malrotation of the small bowel and entrapment of the small intestine beneath the mesocolon [7-9]. Two types are seen, left and right. Of these, left paraduodenal hernia is more common. This occurs through the Landzerts fossa [2,9]. Preoperative diagnosis by radiography, oral contrast study or CECT abdomen shows encapsulated bowel loops, at the duodeno-jejunal junction between the stomach and pancreas to the left of the ligament of Treitz in a case of left paraduodenal hernia with or without features of obstruction. The free edge of the defect in the right and left paraduodenal fossa are formed by colonic vessels and usually these structures form the obstructing band. So in these cases we need to be cautious in cutting the obstructing band. Internal herniation through the foramen of Winslow accounts for 6-10% of the internal hernias. The predisposing factors are larger than a normal opening at the foramen of Winslow and, also redundant small bowel with large mesentry [10]. Transmesentric variety of internal hernia accounts for 8-10%, and its incidence is seen to be increasing. It is mainly acquired, occurring due to herniation of bowel loops through defects in the mesentry, following previous surgeries. Other rare varieties are pericaecal, intersigmoid, and paravesical hernias [2]. Even though the treatment for obstructed hernia is release of the obstructing band and reducing the contents, it is not normally done in case of internal hernias as the obstructing band could be major vessels. Here the dilated loops are decompressed and reduced, and the defect is closed either by retroperitonealising the fossa or by approximating the peritoneal bands [10-12].

Spigelian hernia in itself is very rare and is difficult to diagnose clinically. It has been estimated that it constitutes 0.12% of abdominal wall hernias [13]. It was named after Adriaen Van den Spigehel, an anatomist from Belgium who described the fascial defects associated with this rare hernia [14]. It usually occurs along the semilunar line. This defect creates the plane for inter parietal hernias, between the rectus and the oblique muscles. Spigelian hernias usually occur below the level of the umbilicus [1]. Until now, only 3 other reported cases, were seen above the level of umbilicus [15] and one case reported to present like abdominal wall abscess, but below the level of umbilicus [16]. Our patient presented with a Spigelian hernia seen above the level of umbilicus presenting as an abdominal wall abscess. The treatment for spigelian hernias is surgery as there is more chance for strangulation due to narrow fibrous neck. It can be done by mesh repair either by open or laparoscopic technique.

CONCLUSION

Though internal hernias are rare, in a previously non operated abdomen presenting as intestinal obstruction, especially when there is a history of similar episode subsiding by itself, we should have a differential diagnosis of internal hernia and we should always be cautious of cutting the obstructing band in internal hernias as it may hamper important vascular supplies. In a case of internal hernia; early intervention prevails better survival.

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Carcinosarcoma of the pancreas: A case report with emphasis on histopathology and review of the literature

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Case report

Carcinosarcoma of the pancreas: A case report with emphasis on histopathology and review of the literature

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Abstract

Introduction: Carcinosarcomas are rare tumours, usually seen in the uterus. They are histologically characterized by a carcinomatous and sarcomatous component. We report this case because of its rarity.

Case report: Our patient was a 50 year old male who presented with signs and symptoms of obstructive jaundice. Examination revealed a palpable liver and distended gallbladder. Laboratory investigations showed deranged liver function tests. Radiology work up showed an irregular growth involving the periampullary region. Whipple procedure was done. Grossly an ill defined infiltrating growth was seen involving the periampullary region and extending into the pancreas. Histology showed malignant epithelial and stromal components. Immmunohistochemical studies revealed positive cytokeratin expression by the epithelial component and vimentin expression by the sarcomatous component; hence a diagnosis of carcinosarcoma pancreas was made.

Conclusion: Though carcinosarcomas are rare in pancreas, presence of atypical spindly cells and immunohistochemical studies help in diagnosing such rare neoplasms.

Key words : Carcinosarcoma, Histology, Pancreas

Introduction

Carcinosarcomas are biphasic neoplasms with malignant epithelial and stromal elements. Though commonly encountered in the uterus, lungs, breast and GIT are other sites[1,2,3]. Occurrence in the pancreas is rare and till date only 18 cases have been reported[1,3] .Carcinosarcomas constitute a very small subset of primary pancreatic malignancies and are grouped along with sarcomatoid carcinoma and anaplastic carcinoma under undifferentiated carcinomas of pancreas [4].Since reported cases are less, an assessment of age and gender predilection for pancreatic carcinosarcomas may not be very accurate. Immunohistochemistry is very pertinent in the diagnosis of carcinosarcomas especially when it occurs in rare locations. Regarding the histogenesis of such tumors there are 4 main explanations; the collision, combination, conversion and composition tumor theories[1,2,5]. However the molecular workup done in certain cases favours a monoclonal origin[6].

Case report

A 50 year old moderately built and nourished male presented to our surgery department for evaluation of jaundice. He gave a history of intermittent episodes

of abdominal pain for the past 1yr; itching and yellowish discolouration of urine since 3months.He was an alcoholic and a smoker; stopped 3yrs back. On examination the patient had jaundice and clubbing of fingers and toes. Abdomen was soft with a palpable liver and gall bladder. Laboratory investigations showed serum bilirubin of 9.5mg/dl, serum alkaline phosphatase 582 IU/L and SGOT/SGPT -98/110 IU/L. The clinical differentials considered were carcinoma head of pancreas and cholangiocarcinoma.

Ultrasonography revealed dilatation of intrahepatic biliary radicles, distended gall bladder, dilated CBD (20mm) with a mass lesion in the head of pancreas measuring 1.6 x1.4cm. CECT confirmed these findings, and there was no evidence of metastasis to liver, peritoneum or lymph nodes. Whipple pancreaticoduodenectomy was done and intra operatively a growth was found in the periampullary region measuring 3x 2.5cms. Patient required re-exploration on 4th postoperative day for evacuation of supracolic haematoma. After that the patient had an uneventful recovery and was discharged after 47days.

Histopathology

The gross examination revealed an ill defined infiltrating growth in the periampullary region, measuring 6 X 3.5 x2cms which was involving most of the pancreatic tissue [Figure 1a].The rest of duodenum, jejunum and stomach were unremarkable. Gall bladder was enlarged. The microscopic examination revealed both carcinomatous and sarcomatous components [Figure 1b]. The carcinomatous component was an adenocarcinoma, composed of cells arranged in glandular pattern and in cords [Figure 1c]. Focal squamoid areas were present [Figure1d].The sarcomatous component was seen as spindly cells with pleomorphic nuclei, surrounding and intermixed with the adenocarcinomatous elements. Occasional bizarre cells were also present. Perineural invasion was shown by the adenocarcinomatous component. The neoplasm was infiltrating the distal part of common bile duct in the ampullary region. The adjacent pancreas showed areas of fibrosis and acinar atrophy. Resected ends of stomach, jejunum, cut end of CBD and all resected margins of pancreas, except the lateral margin were free of neoplasm. 9/9 lymph nodes showed reactive change only. Gall bladder showed evidence of chronic cholecystitis. A pTNM stage of pT3N0M0 was assigned. Immunohistochemical studies confirmed the diagnosis of carcinosarcoma. The epithelial component was positive for cytokeratin (CK) and epithelial membrane antigen (EMA) [Fig 2a &d].Mesenchymal component showed positive cytoplasmic staining for vimentin and smooth muscle actin (SMA) [Fig 2b&c]. However it was negative for desmin, S 100, CD34 and CD 117. Ki67 proliferation index was low.

Figure 1a.gross appearance of carcinosarcoma pancreas, an ill-defined growth involving most of the pancreas;1b.(H&E x 200) showing malignant epithelial and mesenchymal elements; 1c.(H&E x 40) showing adenocarcinomatous component 1d.(H&E x 100) shows focal squamoid areas-Inset shows bizarre stromal cells(H&E x 400)

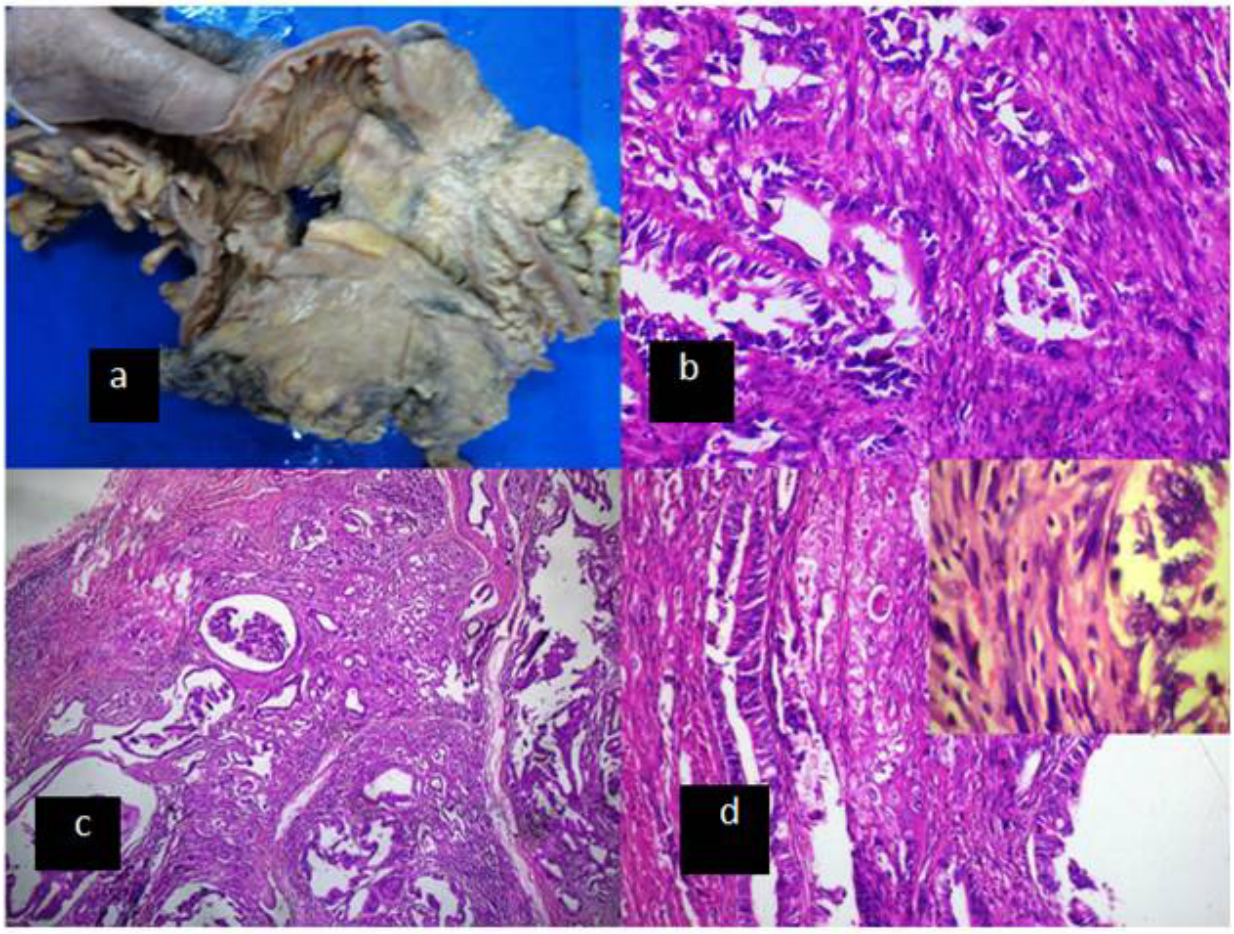

Figure 1a.gross appearance of carcinosarcoma pancreas, an ill-defined growth involving most of the pancreas;1b.(H&E x 200) showing malignant epithelial and mesenchymal elements; 1c.(H&E x 40) showing adenocarcinomatous component 1d.(H&E x 100) shows focal squamoid areas-Inset shows bizarre stromal cells(H&E x 400)

Figure2a&d.Glandular elements showing immunopositivity for CK (a. x 400) and EMA (d. x 200);

2b&c.Mesenchymal elements showing immunopositivity for vimentin (b. x 400) and SMA (c. x 200)

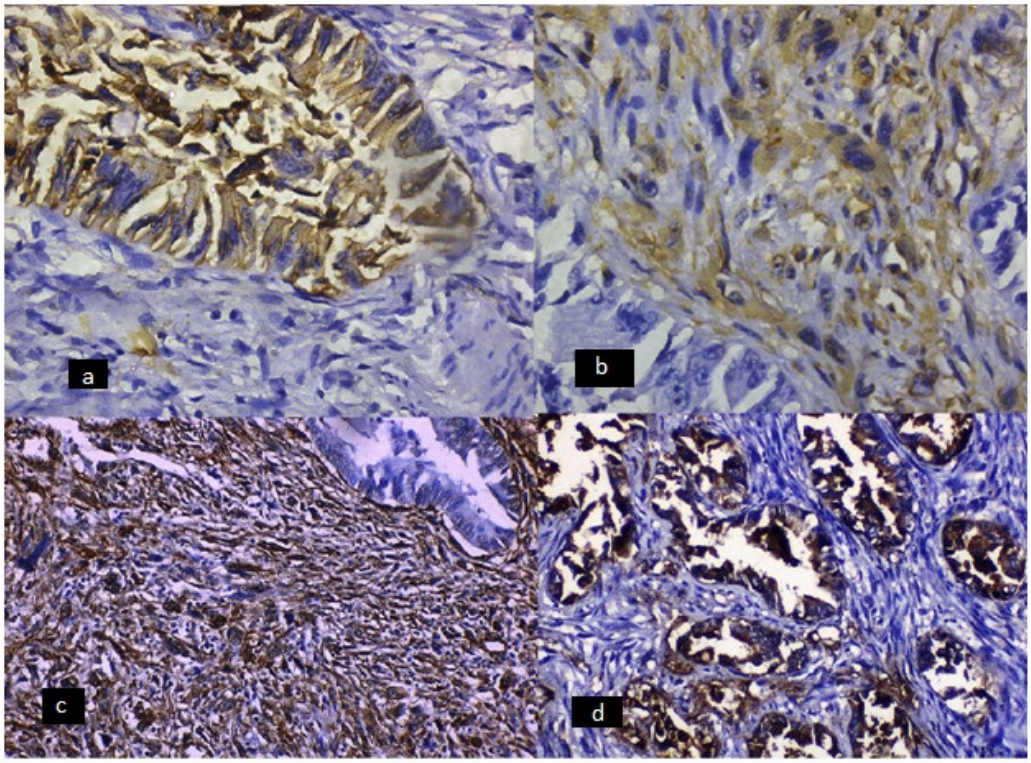

Figure2a&d.Glandular elements showing immunopositivity for CK (a. x 400) and EMA (d. x 200); 2b&c.Mesenchymal elements showing immunopositivity for vimentin (b. x 400) and SMA (c. x 200)

Discussion

Carcinosarcomas are biphasic tumors with both malignant epithelial and mesenchymal elements without areas of transition between them. They have distinct immunohistochemical and ultrastructural features[3,7,8] .Uterus is the common location, where they are also called malignant mixed mullerian tumors. Pancreas is an unusual site for carcinosarcoma. Since first reported by Millis *et al* in 1994, review of literature yielded only a handful of cases[9]. Most malignant tumors of pancreas are adenocarcinomas (85%) and show a male predilection. However carcinosarcomas showed a greater incidence in females (10:9) (Table1).They are usually seen in elderly patients with mean age of 65yrs (46 to 90). The usual presenting symptoms were upper abdominal pain and jaundice [3].Carcinosarcomas are different from sarcomatoid carcinomas which are true carcinomas as shown by positivity for CK but have spindle cell morphology. On the other hand in carcinosarcomas, the carcinomatous component shows positivity for epithelial markers (CK and EMA), while the sarcomatous component shows positivity for mesenchymal markers (vimentin). Certain cases showed positivity for SMA, Muscle specific actin, S100, CD10 and p53 by stromal component [10, 11].In our case the carcinomatous component was positive for CK and EMA, while the sarcomatous component was positive for vimentin and SMA (diffuse cytoplasmic staining).However S100, desmin, CD 34, and CD117 were negative.

Table1: Epithelial and mesenchymal components detected in reported cases of Carcinosarcoma Pancreas

[*]NIA – No information available. [**] HOP – Head of Pancreas. [†]IDPM – Intraductal papillary mucinous.

[#]OTGC – Osteoclastic tumor giant cell. [Y]SMA- Smooth muscle actin

Cases	Age& sex	SITE	GROSS	HISTOLOGY	
				Epithelial component	Mesenchymal component
1.Millis *et al* 1994	50/F	HOP[**]	NIA[*]	Adenocarcinoma	Leiomyosarcoma focal chondroid differentiation
2.Weing *et al* 1997	48/F	Tail	Multicystic	Mucinouscystadenocarcinoma	Undifferentiated Spindle cell sarcoma
3.Weing *et al* 1997	66/F	Tail	Multicystic	Mucinouscystadenocarcinoma	Undifferentiated Spindle cell sarcoma
4.Weing *et al* 1997	67/M	Tail	Multicystic	Mucinouscystadenocarcinoma	Undifferentiated Spindle cell sarcoma
5.Yoshiharu *et al* 1997[12]	75/M	HOP[**]	Solid & cystic	Anaplastic carcinoma	Sarcoma
6.Darvishan *et al* 2002	74/M	HOP[**]	Solid,yellowish white,firm	Adenocarcinma	Malignant fibrous histiocytoma
7.Yamazaki *et al*2003[13]	90/M	NIA[*]	Solid	Adenocarcinoma	Undifferentiated spindle cell sarcoma
8.Bharathulla *et al* 2005[14]	67/F	NIA[*]	NIA[*]	Adenocarcinoma	Spindle cell sarcoma. (triphasic,OTGC[#])
9.Bloomston *et al* 2006	67/F	HOP[**]	Solid and cystic	Mucinous cystadenoma	spindle cell sarcoma
10.Gelos *et al* 2008	61/F	HOP[**]	Solid exophytic localized to duodenum	MD Adenocarcinoma	Poorly differentiated sarcoma
11.Nakano *et al* 2008	82/f	HOP[**]	NIA[*]	Adenocarcinoma	Spindle cell sarcoma
12.Okamura *et al* 2010[15]	64/F	Tail	Solid polypoidal	Adenocarcinoma(IDPM[†])	Osteosarcoma
13.Shen *et al* 2010[16]	72/f	HOP[**]	Solid,yellow white	Adenocarcinoma	Pleomorphic spindle cell sarcoma

14.Kim et al 2011	48/M	Tail	Solid &Cystic with mural nodule	Mucinous adenocarcinoma&anaplastic carcinoma	Pleomorphic spindle cell sarcoma
15.Palani *et al* 2011	46/M	HOP**	Solid with mucoid areas	Adenosquamous carcinoma	Leiomyosarcoma
16.Wen Yang *et al* 2012	53/F	HOP**	Solid yellowish white	Adenocarcinoma	Pleomorphic spindle cell sarcoma (SMA$^{\Upsilon}$+ve)
17.Wayne *et al* 2013	46/m	Neck, body &tail	Multiple cysts	Mucinous cystic neoplasm	Sarcomatous stroma
18.E.Oymaci *et al* 2013	66/m	HOP**	Cyst with mural nodule	Adenocarcinoma	Malignant fibrous histiocytoma (focal SMA$^{\Upsilon}$ +ve)
19.Ours 2012	50/M	HOP**	Solid yellowish white	Adencarcinoma with focal squamous areas	Pleomorphic spindle cell sarcoma(SMA$^{\Upsilon}$+ve)

Table1: Epithelial and mesenchymal components detected in reported cases of Carcinosarcoma Pancreas

*NIA – No information available. ** HOP – Head of Pancreas. ŧIDPM – Intraductal papillary mucinous. #OTGC – Osteoclastic tumor giant cell. ΥSMA-Smooth muscle actin

Of the total 19 cases compiled, the epithelial component in 11 were adenocarcinoma, 1 adenosqamous, 4 mucinous cystadenocarcioma, 2 mucinous cystadenoma ,1 showed 2 epithelial components(anaplastic carcinoma and mucinous cystadenocarcioma),and 1case showed anaplastic carcinoma. The sarcomatous components in descending order were pleomorphic spindle cell sarcoma (9), undifferentiated spindle cell sarcoma (5), leiomyosarcoma (2), malignant fibrous histiocytoma (2) and osteosarcoma (1).

There are different theories and controversies regarding the origin of carcinosarcomas, but molecular studies favour a monoclonal origin[1,6] .Some have proposed an initial carcinomatous origin with acquisition of subsequent genetic alterations causing sarcomatous differentiation[3,6].Even in tumors with benign epithelial elements presence of sarcomatous foci confers an aggressive nature [17].Molecular workup was not done in our case. Prognosis is dismal and the overall survival is 6 months [1,7,8] .Treatment options are surgical excision and chemoradiation .The longest reported survival was 28 months with combined surgery and chemotherapy[3].Some authors have suggested chemotherapy with Gemcitabine and surgery in similar cases[1,18,19].

Conclusion

In a rapidly growing pancreatic tumor, with the gross specimen showing solid, firm areas the possibility of

a sarcomatous component should be kept in mind. Adequate sampling and detailed immunohistochemical studies are necessary to exclude different sarcomatous elements in suspicious cases, since desmoplastic stroma is seen in pancreatic carcinomas. This becomes important as it influences the behavior and hence the prognosis of the neoplasm. Inspite of its rarity, recognition of carcinosarcomas are important for planning further management.

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Research Paper Medical Science

Giant Pseudo Cyst of Adrenal Gland – An Unusual Presentation

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ABSTRACT

Giant adrenal pseudo cysts are very uncommon lesions which often produce much diagnostic and treatment dilemmas. An adrenal pseudocyst is a fibrous-surrounded cyst within the adrenal gland devoid of a recognizable layer of lining cells. The three most prominent clinical features are: a dull pain in the adrenal area; gastrointestinal symptoms; and a palpable mass. We are presenting a case which preoperatively diagnosed as renal malignancy and per operatively turned out to be a giant pseudo cyst of adrenal gland. Removal of the lesion with partial nephrectomy done and HPR was Giant pseudocyst of adrenal gland. An adrenal pseudocyst is an uncommon clinical finding and is even rarer when it is giant-sized. Surgery is required for symptomatic cases in order to relieve the symptoms and in cases of uncertain diagnosis. Radiological and clinical features of the tumor are nonspecific, thus, histopathological examination is essential in order to establish a definitive diagnosis.

KEYWORDS : Adrenal pseudo cyst, Renal cell carcinoma, Cystectomy with partial nephrectomy.

INTRODUCTION:

Cystic lesions of the adrenal gland are uncommon and demonstrate a spectrum of histological changes and may vary from pseudocysts to malignant cystic neoplasms. An adrenal pseudocyst is a fibrous-surrounded cyst within the adrenal gland devoid of a recognizable layer of lining cells. The incidences of Giant pseudocysts of adrenal glands are extremely rare.

CASE PRESENTATION:

A 53 year old female, Mrs. X, a moderately nourished lady presented with a mild generalized left sided abdominal pain and abdominal distension of six months duration.

Examination findings: Abdomen was soft and moderately distended, Bowel Sounds +, Minimal tenderness+ on , left upper abdomen. Mass felt in left hypochondrium extending to lumbar, umbilical and epigastric region. BRE & URE – WNL, LFT, RFT, Electrolytes – Normal. Plane X ray Abdomen – 4 fluid levels present USS Abdomen – Complex cystic lesion ? arising from left adrenal/pancreas/ renal CT Abdomen (Fig. 1) – 12X11X12 cm retroperitoneal mass from level of celiac axis to aortic bifurcation in left side, cystic predominantly with high density non-enhancing areas and few irregular enhancing solid areas with possible hemorrhage within.

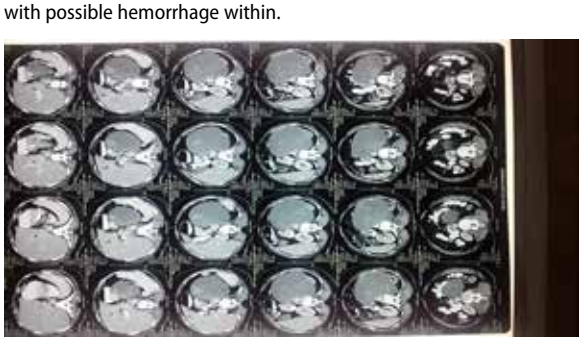


Figure: 1 CT scan picture suggestive of kidney tumor (Renal Cell Carcinoma)

Displacement/infiltration of adjacent structures, body and tail of pancreas and splenic vessels anterosuperiorly. Mass encasing SMA, left RA, left and anterior Wall of aorta. IVC anteriorly displaced and stretched. Left ureter not visualized. Left renal parenchyma was compressed and displaced inferolaterally. Infiltration of left diaphragmatic crura and left lateral abdominal wall.

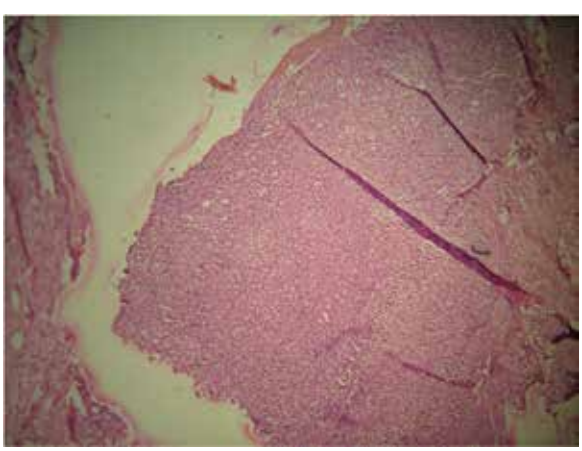
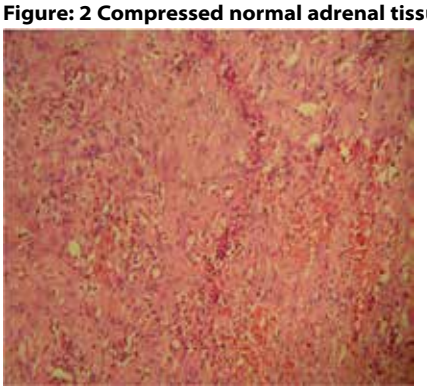


Figure: 2 Compressed normal adrenal tissue



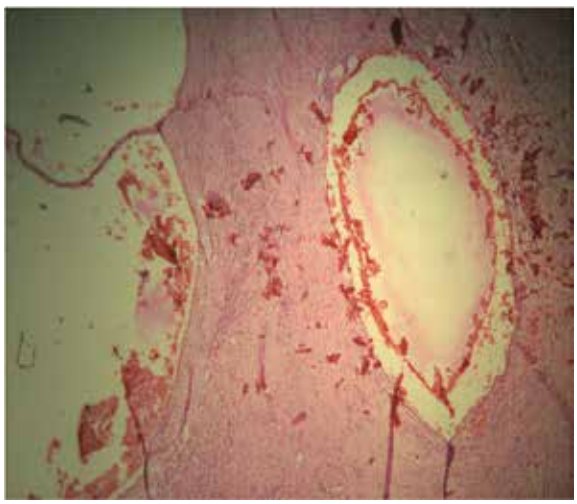


Figure 3 and 4: The cystic wall consisted of dense fibrous tissue without an epithelial lining. A rim of normal adrenal tissue was found compressed within the cystic capsule. (Haematoxylin and eosin stain, Scale bar = 1 mm).

With a provisional diagnosis of adrenal malignant tumor/ RCC we went with laparotomy. Per operatively large complex retroperitoneal tumor arising from left adrenal gland was found (Figure. 5).

Figure 5: Large complex retroperitoneal tumor arising from left adrenal gland

Removal of the lesion with partial nephrectomy done and HPR was Giant pseudocyst of adrenal gland

DISCUSSION: Adrenal cysts are rare and the documented incidence varies between 0.064% and 0.18% in autopsy series. However, the rate of detection of adrenal cysts has risen dramatically due to the more frequent use of CT and MRI imaging studies in recent years, which account for approximately 5% of incidentally discovered adrenal lesions. Adrenal pseudocysts are rare cystic masses that arise from the adrenal gland and which are usually non-functional and asymptomatic. Adrenal pseudocysts consist of a fibrous wall without an epithelial or endothelial lining.

In 1903, Doran attributed the first case of adrenal cyst to Greiselius , In 1670, he described a 45-year-old man whose death resulted from a rupture of the cyst. There were only seven cases of adrenal cyst reported by 1906. Wahl questioned the rarity of adrenal cysts in 1951 and found an autopsy incidence of 1 in 1555. The paucity of reports in the literature was a manifestation of clinical silence rather than true rarity. In 1966, Foster described 220 cases of adrenal cyst in the world's literature. In 1979 Incze *et al*. reported 250 cases. Adrenal cysts are rare and the documented incidence varies between 0.064% and 0.18% in autopsy series. However, the rate of detection of adrenal cysts has risen dramatically due to the more frequent use of CT and MRI imaging studies in recent years, which account for approximately 5% of incidentally discovered adrenal lesions. Adrenal cysts may occur at any age but most are found in the 3rd to 5th decades. In some series, a female preponderance of about 3:1 has been noted for unknown reasons.

Classification

- Four types;
- Parasitic
- Epithelial (true cysts)
- Endothelial (vascular cysts with an endothelial lining)
- Pseudo cysts

More infrequent subtypes such as lymphangiomas, mesothelial cysts, dermoid cysts or cystic adrenal carcinomas

Adrenal pseudocysts represent approximately 80% of cystic adrenal masses. Adrenal pseudocysts are devoid of an epithelial or endothelial lining, arise within the adrenal gland and are surrounded by a fibrous tissue wall. The true origin of adrenal pseudocyst remains a mystery. One theory suggests that these lesions result from an intra-adrenal hemorrhage caused by trauma, a sepsis event or some other form of shock . The initial injury leads to the development of a cavity with a scarred, fibrous lining that slowly enlarges over time. Another theory suggests that these lesions are true cysts that have lost their cellular lining because of the inflammation and bleeding within the cyst.

The three most prominent clinical features are: a dull pain in the adrenal area; gastrointestinal symptoms; and a palpable mass. They seldom cause adrenal hypofunction, Cushing's syndrome or pheochromocytoma. Acute abdomen or a tender mass may occasionally be found, when intracystic hemorrhage, rupture or infection occurs a preoperative confirmatory diagnosis of a large adrenal cyst can be very difficult because of the indistinct boundary with surrounding organs and adhesion to neighboring organs. Furthermore, even with integrated PET, adrenal lesions may be identified as false-positive at PET, including adrenal adenomas, adrenal endothelial cysts and inflammatory and infectious lesions. The differential diagnosis of adrenal pseudocysts includes splenic, hepatic and renal cysts, as well as mesenteric or retroperitoneal cysts, urachal cysts and solid adrenal tumors. An exact diagnosis is clinically important in large lesion because adrenal incidentalomas larger than 5 cm carry an increased risk of adrenal malignancy.

The reported incidence of malignancy in adrenal cystic lesions is approximately 7% . CT features of pseudocysts are more complicated than simple cysts due to the complicated components such as septa, blood and soft-tissue components. The cysts wall shows occasional calcification. MRI is the best modality for visualizing the complicated intracystic components. Moreover, MRI is particularly sensitive for detecting intracystic hemorrhage, which shows hyperintense on both T1- and T2-weighted images.

Treatment:

Treatment of adrenal cysts is determined by size and the symptoms related to the mass. Surgical excision is indicated by the presence of symptoms, a suspicion of malignancy and an increase in size, or the detection of, a functioning adrenal cyst. Surgical treatment may not be necessary for small asymptomatic lesions as most cysts are benign. If the adrenal lesion is diagnosed as a simple nonfunctioning cyst, the patient may be treated conservatively with aspiration alone.

CONCLUSION:

An adrenal pseudocyst is an uncommon clinical finding and is even rarer when it is giant-sized. Surgery is required for symptomatic cases in order to relieve the symptoms and in cases of uncertain diagnosis. Radiological and clinical features of the tumor are nonspecific, thus, histopathological examination is essential in order to establish a definitive diagnosis

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Original Research Article

Skin stapler versus sutures in abdominal wound closure

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ABSTRACT

Background: Wound closure is as important as any other action performed by the surgeon. Apart from the need for producing a healthy and strong scar, it is the surgeon's responsibility to ensure its aesthetically pleasing physical appearance. Skin staples are an alternative to regular sutures in offering this advantage. The present study has helped to highlight the benefits of skin stapler.
Methods: Out of the 120 participants, 60 underwent skin closure with Stainless steel skin staples and the remaining 60 with non-absorbable Polyamide mattress sutures randomly. They all received one mandatory dose of pre-operative parenteral antibiotic 1 hour prior to the incision. On the 3rd postoperative day, the wound was evaluated for inflammation, infection and wound gape. Participants were re-evaluated for infection/gape/inflammation during follow-up on 7th day. The wounds were evaluated at 1 months follow up which were rated for cosmesis by Visual Analogue Score. The data was coded and entered in Microsoft excel and then analysed using statistical software SSPS.
Results: Study population consisted of 79 males (65.8%) and 41 females (34.2%). Mean age of the study population was 49.35 with an SD 16.739. Wound infection was found to be higher in stapler group (30%) when compared to conventional suture group (11.7%)which was found to be statistically significant with chi-square value 6.114 and p value 0.013. Mean time for closure was significantly shorter in stapler group 4.55 minutes, when compared to suture group (11.22 minutes). Better cosmetic outcome was observed in conventional suture group.
Conclusions: Preventing wound infection, especially in abdominal wounds, is of importance as it may lead to wound gaping. Incidence of post-operative wound infection was more with skin staples. Cosmesis is essential and important aspect in this day and age. A cosmetic scar not only gives satisfaction to the patient but also mental ease to the surgeon. Conventional sutures provided better cosmetic result when compared with skin staplers.

Keywords: Stainless steel staples, Skin staples, Wound healing, Wound infection

INTRODUCTION

The suturing of any incision or wound needs to take into consideration the site and tissues involved and the technique for closure should be chosen accordingly. Therefore, the correct choice of suture technique and suture material is vital, but will never compensate for inadequate operative technique, and for any wound to heal well, there must be a good blood supply and no tension on the closure.[1] The selection of the proper incision, suture material, and closure technique is very important to assist the patient's own repair mechanism and restore normal anatomic relationships after surgery. Attention to these details also prevents such complications as dehiscence and infection, assuring a good cosmetic result.[2]

Surgical site infections (SSIs) are infections of the tissues, organs, or spaces exposed by surgeons during performance of an invasive procedure. SSIs are classified into incisional and organ/space infections, and the former are further sub-classified into superficial (limited to skin and subcutaneous tissue) and deep incisional

categories.[3,4] Surgical site infections (SSIs) are serious operative complications that occur in approximately 2% of surgical procedures and account for some 20% of health care-associated infections.[5]

The type of suture material for skin closure is also reported to influence postoperative wound complications. However, other studies have failed to demonstrate significant differences between different types of suture material. The surgical scar remains the only visible evidence of the surgeon's skill and not infrequently, all of his efforts are judged on its final appearance. The aim of the study was to compare the incidence of post-operative wound infection between skin staples and conventional sutures in abdominal skin closures and to compare the cosmetic outcome of stapled closure with conventional sutures.

METHODS

Present study was prospective observational study, carried out in the Department of General Surgery, Medical College Hospital, Kottayam. Duration of the study 6 months

Sample Size: In a study conducted by Chandrashekar N et al, comparing skin sutures and skin staples in abdominal surgical wound closure, proportion of wound infection among staple group was found to be 38.09% and among suture group was 16%.[6]

Using this data, minimum sample size required for the study is calculated using the formula

$n = (Z\alpha+Z\beta)^2\{P1(1-P1) + P2(1-P2)\}/(P1-P2)^2$

where,
$Z\alpha$ = Z value of α error at 5% = 1.96
$Z\beta$ = Z value of β error with 80% power = 0.84
P1 = Proportion of infection among staple group = 38.09%
P2 = Proportion of infection among suture group= 16%

$n = (1.96+0.84)^2\{0.3809(1-0.3809) + 0.16(1-0.16)\}/(03809-016)^2$

= 59.48
= 60

Minimum sample size for this study is 60 subjects in each group. A total of 120 patients.

Inclusion criteria

All patients undergoing abdominal surgeries.

Exclusion criteria

Patients having skin loss.

Study procedure

After getting institutional review board clearance, a hospital based observational study was conducted in patients undergoing abdominal surgeries in Department of General Surgery, Government Medical College, Kottayam. Informed consent was obtained from the patients willing to participate in the study. A detailed history of each patient was obtained starting with history of presenting symptoms and any co-existing, co-morbid conditions like, DM, HTN were ruled out. A thorough general physical examination was done. Preoperatively all patients underwent following investigations: complete blood count, urine examination, blood sugar, blood urea. serum creatinine, liver function test, chest x-ray, electrocardiogram. Shaving of the abdomen was done prior to Surgery. Patients were grouped into two categories- suture and staplers group based on the technique of wound closure. Age group matching of the cases was done in both categories of closure technique. On the 3rd and 7th postoperative day, the wound was evaluated using Southampton wound grading system. The wounds were evaluated at 1 month follow up and rated for cosmesis on Visual Analogue Score by a senior surgeon. Data thus collected was coded and entered in Microsoft excel and analyzed using statistical software SPSS.

RESULTS

Age

Mean age of the study population was 49.35 with a standard deviation of 16.739. Minimum age: 18 years; maximum age: 80 years, range: 62. Mean age among suture group was 48.05 and that of stapler group was 50.65. This difference was found to be not statistically significant at P value= 0. 397. Hence, the study group was comparable in terms of age.

Gender

79 patients were male, 41 patients were female.Majority of the study population were males (65.8%). Two study groups were comparable in terms of gender distribution. (P value= 0.083)

Closure technique

60 patients underwent suturing for wound closure whereas 60 patients underwent stapler closure

Type of wound closure and outcome

Among the Suture group, 7 out of the 60 had wound infection whereas in stapler group 18 out of the 60 had wound infection. 11.7% among conventional suture group developed wound infection where as 30% among stapler group developed infection and this difference

wasfound to be statistically significant with a chi square value of 6.114 and p value 0.013.

Table 1: Distribution of study population based on type of incision and type of wound closure.

Closure technique					Total
			Suture	Stapler	
Type of incision	Midline laparotomy incision	Count	54	60	114
		% within SUR	47.4%	52.6%	100.0%
		% within CLOSRE	90.0%	100.0%	95.0%
	Subcostal incision	Count	6	0	6
		% within SUR	100.0%	0%	100.0%
		% within CLOSRE	10.0%	0%	5.0%
Total		Count	60	60	120
		% within SUR	50.0%	50.0%	100.0%
		% within CLOSRE	100.0%	100.0%	100.0%

Table 2: Study population based on type of wound closure and outcome.

Outcome					Total
			Normal healing	Wound infection	
Closure	Suture	Count	53	7	60
		% within CLOSRE	88.3%	11.7%	100.0%
		% within outcome	55.8%	28.0%	50.0%
	Stapler	Count	42	18	60
		% within CLOSRE	70.0%	30.0%	100.0%
		% within outcome	44.2%	72.0%	50.0%
Total		Count	95	25	120
		% within CLOSRE	79.2%	20.8%	100.0%
		% within outcome	100.0%	100.0%	100.0%

Table 3: Distribution of study population based on type of wound closure and wound infection grade.

Southampton grading							Total
			Normal healing	Normal healing with mild bruising/erythema	Erythema+other signs inflamation	Pus	
Closure type	Suture	Count	53	2	1	4	60
		% within CLOSRE	88.3%	3.3%	1.7%	6.7%	100.0%
		% within INSPD3	55.8%	28.6%	25.0%	28.6%	50.0%
	Stapler	Count	42	5	3	10	60
		% within CLOSRE	70.0%	8.3%	5.0%	16.7%	100.0%
		% within INSPD3	44.2%	71.4%	75.0%	71.4%	50.0%
Total		Count	95	7	4	14	120
		% within CLOSRE	79.2%	5.8%	3.3%	11.7%	100.0%
		% within INSPD3	100.0%	100.0%	100.0%	100.0%	100.0%

Type of wound closure and wound infection

Among the suture group 88.3% showed normal healing, 3.3% showed normal healing with mild bruising/erythema, 1.7% showed Erythema+other signs of inflammation and 6.7 % developed pus at the site where as among the stapler group 70% showed normal healing, 8.3% showed normal healing with mild

bruising/erythema, 5 % showed Erythema+other signs of inflammation and 16.7 % developed pus at the site.

Diabetic status and wound infection

Out of the 120 patients, 90 had no diabetes mellitus and in them 16 patients had wound infection. 30 patients had diabetes and were on treatment. Out of the 30, 9 patients had post-operative wound infection.

Hypertension and wound infection

Out of the 120 patients, 94 had no hypertension and in them 21 patients had wound infection. 26 patients had diabetes and were on treatment. Out of the 26, 4 patients had post-operative wound infection.

Technique of closure and mean time of closure

Mean time for suture closure was 11.22 minutes with an SD of 2.108 and for stapler closure was 4.55 minutes with an SD of 1.016. This difference was found to be statistically significant with a t value of 22.069 and a P value of <0.001

Type of closure technique and Visual Analogue Score

Mean visual analogue score among suture closure wound was 74.97 with an SD of 4.555 and among stapler closure wound was 38.34 with an SD of 16. 057.This difference was found to be statistically significant on applying Mann- Whitney U test, with P value of <0.001.

Table 4: Distribution of study population based on type of closure technique and mean time for closure.

	CLOSRE	N	Mean time (minutes)	Standard deviation	T	P value
Time	Suture	60	11.22	2.108	22.069	<0.001
	Stapler	60	4.55	1.016		

Table 5: Table showing distribution of study population based on Visual analogue score and type of wound closure.

	CLOSRE	N	Mean score	Standard deviation	Mean rank	Mann-Whitney U	P value
Type of closure	Suture	60	74.97	4.555	82.66	470.500	<0.001
	Stapler	60	65.15	16.057	38.34		
	Total	120					

DISCUSSION

Type of closure technique and incidence of wound infection

The present study shows a statistically significant higher incidence of wound infection among stapler group as compared to conventional sutures (30% and 11.7% respectively).

A study conducted by Tuuli MG et al, showed that Staple closure was associated with a twofold higher risk of wound infection or separation compared with subcuticular suture closure.[7] A multicentric study among 1080 patients conducted by Tsujinaka T et al, showed no significant difference in wound infection between the two groups.[8]

Type of closure technique: Mean time for closure and cosmetic appearance

Present study showed a significantly shorter time for stapler closure and a better cosmetic appearance for conventional suture closure. Kanagaye JT et al, at the Children's hospital, Los Angles, USA, following a study, revealed that staple closure was safe, rapid and cost effective. Staples were six times faster than the standard sutures with no observed complication rate. Removal was less painful and the scar was cosmetically acceptable.[9]

Eldrup et al, analysed 137 patients undergoing abdominal or thoracic surgery, and concluded that the main advantage of using staples was the time saved, as closure with mechanical sutures took one third of the time required for the conventional method. On the other hand, closure with staples resulted in the major disadvantages of additional expense, as the cost was forty-seven times higher than that of the suture with Dermalon.[10]

Meiring et al, reported slightly better cosmetic results in a group of 40 patients undergoing laparotomy with an 80% in time saving. They also concluded that the final cost of the stapler was crucial for selecting the method.[11]

Harvey and Logan studied a group of 20 patients undergoing surgery for varicose veins in both lower limbs, using a different method of skin closure in each leg. They reported a saving of 66.6% in closure time and a similar cosmetic result. They considered the use of staples a valid method for selecting patients with a large number of wounds; however, the additional cost would not be justified for small sutures.[12]

Ranabaldo and Rowe-Jones compared sutures with staples and subcuticular suture in 48 patients undergoing laparotomy and concluded that the difference in time was significant. Nevertheless, the cost was five times greater with staples; hence, the use of subcuticular sutures was preferred.[13]

Medina dos Santos LR et al, in their study of 20 consecutive patients concluded that the use of skin staplers speeds up closure by 80%, with a better cosmetic result, and does not increase the incidence of complications, although the slightly higher cost was involved.[14]

Basha et al, determined that staples were associated with increased risk of wound infection. Wound complications led to a decrease in patient satisfaction, however it was not statistically significant to associate staples with decreased satisfaction.[15] Cromi et al, found there were equivalent cosmetic outcome amongst closure methods.[16]

CONCLUSION

Several methods of skin closure are available to close the skin incisions in place of sutures like staples, clips, steristrips and glue adhesives. Wound infection is a great hazard in abdominal skin closure as it can lead to disastrous complications. Cosmesis is essential and important aspect in this day of modern surgical practice. A cosmetic scar gives satisfaction to the patient and also to the surgeon. Preventing wound infection is necessary as it may lead not only to an ugly scar but also occurrence and recurrence of hernia.

In the present study, skin staplers versus sutures in abdominal wound closure, we found that incidence of post-operative wound infection was more with skin staples, sutures provided better cosmesis than skin staples and skin staplers saves operative time as compared to sutures. Hence, we conclude that Sutures are associated with low incidence of wound complications, provides good cosmetic outcome but takes considerably more time for skin closure.

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Original Research Article

A study on prostaglandin E1 therapy in critical limb ischaemia patients to evaluate the improvement in vascularity

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ABSTRACT

Background: Diffuse peripheral arterial disease or peripheral occlusive vascular disease (POVD) involving the lower limb is a debilitating illness with high incidence of morbidity and mortality. The objective of this study was to assess the improvement of ulcer healing and improvement of the level of amputation in patients with diffuse peripheral arterial disease after administration of prostaglandin E1.
Methods: From June 2013 to November 2014, a total of 45 patients having critical limb ischaemia (Fontaine's grade III and IV) not suitable for angioplasty and stenting or bypass procedures received different courses of Prostaglandin E1 (PGE1). 20 patients (44.44%) received 6 full courses of PGE1, 3 patients (6.66%) received 5 courses, 5 patients (11.11%) received 4 courses, 4 patients (8.8%) received 3 courses, 4 patients (8.8%) received 2 courses and 9 patients (20%) received one course. PGE1 was administered through intravenous infusion (Alprastodil 100mcg) over 10 hours a day for 5 days in one month (1course). They were followed up for 3 years till June 2017.The improvement in level of amputation, ulcer healing and complications were assessed.
Results: 14 patients (31.1%) did not require amputation of limbs/ toes, 24 patients (53.3%) have the same amputated status while 7 patients (15.6%) required higher amputation. This study justifies the role of PGE1 therapy in improving the peripheral arterial pulsations and thereby augmenting ulcer healing and improving the level of amputation.
Conclusions: After diagnosing a patient with advanced CLI where angioplasty and stenting or bypass procedures are not possible, aggressive treatment for the non-healing ulcer, amputation of gangrenous limbs or toes and starting the PGE1 therapy early not only arrest the progression of POVD but even reverses it to some extent.

Keywords: Critical limb ischemia, Level of amputation, Prostaglandin E1, Ulcer healing

INTRODUCTION

Diffuse peripheral arterial disease or peripheral occlusive vascular disease (POVD) involving the lower limb is a debilitating illness with high incidence of morbidity and mortality. Early diagnosis and starting of intervention early is a key to successful outcome.[1,2]

The goals in treating CLI are to relieve claudication pain and rest pain, to heal ulcer, to prevent amputation of limbs, to improve quality of life and to prolong survival.[1,2]

Increase of blood flow in the ischemic leg is believed to represent the main action of PGE1 in the therapy of POVD. Though PGE1 is used for treatment of advanced Critical Limb ischaemia (CLI) by Indian doctors, studies have so far not been published about the effects of PGE1 on the improvements in peripheral pulsations, ulcer healing, or amputation levels after administration of PGE1 amongst Indian population. This research is done

to study the effects of PGE1 in Indian patients with diffuse peripheral arterial disease.

The objective of this study was to study the improvement of ulcer healing and improvement of the level of amputation, if necessary, in patients with peripheral occlusive vascular disease after administration of prostaglandin E1.

METHODS

The research was conducted after receiving approval from Institutional Research Committee and Institutional Ethical Committee. A written informed consent was obtained from all the subjects before their enrolment in the research study. This prospective study was conducted in the Department of General Surgery Government Medical College Kottayam over a period of 4years, between June 2013 and June 2017 with 45 CLI patients. Diagnosis of disease was made on the basis of clinical examination and Doppler study. Parameters taken into account were ulcer (infected or debrided), amputated status and peripheral pulsations of the extremities. Fontaine's grading system was used to grade the symptoms of patient. After the PGE1 therapy the patients were followed up for 3years till June 2017 for assessing long term benefits in improving ulcer healing, improvement in peripheral pulsations and level of amputation. The improvement in peripheral pulsations was assessed by clinical examination and Doppler study.

Inclusion criteria

All cases of POVD not suitable for angioplasty and stenting or by-pass procedures who presented during the study period and who have not received prostaglandin E1 treatment.

Exclusion criteria

Patient not willing to undergo treatment with prostaglandin E1 and those not willing to give consent.

Injection prostaglandin E1 was administered as continuous slow intravenous infusion once a day for 5 days in a month (1 course) up to 6 months, for those with end stage POVD where no alternative medical management was available. 1 ampoule contains 500 micrograms of PGE1. It was diluted with 9 ml of normal saline in a 10-ml syringe. 2 ml (equivalent to 100 micrograms) was put in 500 ml of normal saline and was given as continuous intravenous infusion with micro drip set at 50 micro drops/ minute to be completed in 10 hours because rapid infusion can induce myocardial ischaemia due to coronary steal effect produced by peripheral vasodilatation. The result was analyzed using Microsoft excel, Chi square test and T-test.

RESULTS

The research work which was done on 45 patients included 30 (66.7%) males and 15 (33.3%) females. The most common age group affected was 60-70 years and majority of patients have no peripheral pulsations on admission. 14 patients (31.1%) in this study presented with non-healing ulcers which required a thorough debridement before administration of PGE1.

Of the 45 patients, twenty patients (44.4%) completed 6 full courses, three patients completed 5 courses (6.7%), 5 patients (11.1%) completed 4 courses, four patients (8.9%) completed 3 courses, four patients (8.9%) completed 2 courses and nine patients took only one course. 3 patients dropped out of this study after taking the first course. The main reason given by the patients for non-completion of the course was due to relief of pain or wound healing.

The sum of the total course of PGE1 taken by the patients (6 courses + 5 courses + 4 courses + 3 courses + 2 courses + 1 course) is 172. The sum of the reduction in Fontaine's grade for the patients irrespective of the course completed was 110. The overall reduction in Fontaine's grade was 2.44.

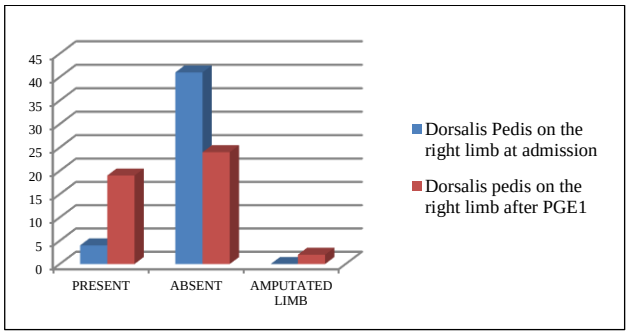

Figure 1: Improvement in pulsation of right Dorsalis pedis artery after PGE1 administration. The third row represents patient who had undergone a higher amputation because of which the pulsation could not be assessed.

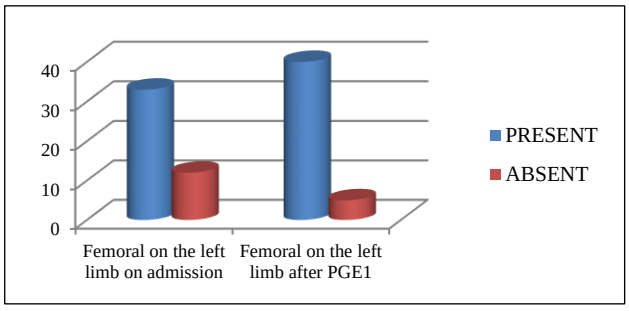

Figure 2: Improvement in pulsation of left femoral artery after PGE1 administration.

PGE1 therapy also improved the pulsations at all the levels. Improvement in peripheral pulsations were

assessed separately for dorsalis pedis, popliteal, and femoral arteries on either side. Representative charts of right Dorsalis pedis and left femoral arteries are given in Figure 1 and 2. After PGE1 administration, only 7 patients (15.5%) needed higher amputation as the wound was infected, not getting better with debridement or ascending gangrene.

Table 1: Paired samples correlations.

		N	Correlation	Sig. (p-value)
Pair 1	Dorsalis pedis on the right limb at admission and Dorsalis pedis on the right limb after PGE1	45	0.341	0.022
Pair 2	Dorsalis pedis on the left limb on admission and Dorsalis pedis on left limb after PGE1	45	0.564	0.000
Pair 3	Popliteal on the right limb at admission and Popliteal on the right limb after PGE1 administration	45	0.547	0.000
Pair 4	Popliteal on the left limb at admission and Popliteal on the left limb after PGE1	45	0.623	0.000
Pair 5	Femoral on the right limb on admission and Femoral on the right limb after PGE1	45	0.584	0.000
Pair 6	Femoral on the left limb at admission and Femoral on the left limb after PGE1	45	0.586	0.000

Table 2: Significant table (p-value).

		t	df	Sig. (p-value)
Pair1	Amputated status-before - Amputation status after prostaglandin E1 administration	4.509	44	0.000
Pair 2	Fontaine's grading-BEFORE - Fontaine's grading-6	37.195	44	0.000

P-value is significant in all the comparisons, vise, Fontaine's grade before and after PGE1 administration, amputated status before and after PGE1 administration and pulsation levels before and after PGE1 administration (Tables 1 and 2).

In the follow up period, 1 death was registered in the patient group receiving 6 full courses. Patient died due to cerebrovascular accident. Death happened 6 months after receiving the full course. 1 death also was registered in patient group receiving 5 courses. Patient died, 3 months after receiving 5 courses, of cerebrovascular accident and 2 patients died after receiving 2 courses. Both were known cases of coronary artery disease. One died 2 weeks after PGE1 administration while the other died one month after PGE1 administration. Both died of myocardial infarction. 3 deaths were registered in patients receiving only one course of PGE1. One patient was a known case of coronary artery disease died after 1 week after discharge, second patient was a known case of pulmonary tuberculosis with COPD died 6 months after PGE1 therapy due to pulmonary tuberculosis and the third patient underwent left AK amputation, had POVD on the right lower limb and the patient expired one month later. All these deaths were registered after the end of PGE1 treatment and none were related to the administration of PGE1.

Thus, this research study and analysis justify the role and use of PGE1 treatment in advanced critical limb ischemia patients for reduction of Fontaine's grade and improvement of ulcer healing and amputated status.

DISCUSSION

Critical Limb Ischemia (CLI) was defined for the first time in 1982 by P. R. F. Bell as a manifestation of peripheral artery disease which describes patient with typical chronic ischemic rest pain or ischemic skin ulcers or gangrene.[3] This term of CLI should only be used in patients with chronic ischemic disease, defined as presence of recurring rest pain that persists for more than two weeks, requiring regular analgesics and with ulceration or gangrene of the foot or toes. These criteria correspond to stage 3 and 4 of Fontaine's classification of POVD.[4]

Observational studies have shown that one year after diagnosis of CLI, 25% of patient experiences a major amputation, 25% had died and only 50% survived without requiring a major amputation though some have rest pain, ulcer or gangrene persisting and it is also associated with excessively high risk for cardiovascular events including myocardial infarction and death.[2,5]

PGE1, known pharmaceutically as Alprastodil. Although widely used, the exact mechanism of the known beneficial effects is not completely understood.[6] PGE1 therapy increases the blood flow by peripheral vasodilatation and by inducing angiogenesis. The anti-ischemic effect mechanisms of PGE1 in POVD patients are complex and clearly not limited to a direct vasodilator action alone. Effects of PGE1 therapy has been described on cellular factors in the blood, haemostasis and fibrinolysis and endothelium. PGE1 improves the endothelial function in patients with CLI and also inhibits monocytes and neutrophil function suggesting that PGE1 has anti-inflammatory effects.[7] A more recent meta-analysis of the administration of PGE1 for patients with POVD stage III or IV not eligible for arterial reconstruction shows that it not only has significant beneficial effects over placebo on ulcer healing and pain relief, but also increases the rate of patients surviving with both legs after 6 months follow up.[8,9] The quality of life evaluation and the cost analysis indicated a benefit of preserving limbs in some studies.[10,11] The side-effects of therapy include headache (4%), erythema and pain of injected vein (8%). All these transient side effects never led to the interruption of therapy.[12]

The total number of cases involved in the research study was 45. The most common age group affected is the 60-70 years group. Males are more commonly affected. Hypertension in association with diabetes was the most common co-morbid condition for CLI.

All patients had claudication pain or rest pain. Majority of patients (36 patients -80%) had associated gangrene of limbs/ toes of which 14 patients (31.11%) had non-healing ulcers as well.

Clinical examination with Doppler study was done to diagnose a patient with CLI.[12,13] 22 patients (48.88%) presented with claudication pain, rest pain and gangrene of toes while 14 patients (31.11%) had non-healing ulcer in addition to the pain and gangrene of toes (Fontaine's grade IV). 9 patients (20%) had claudication pain and rest pain only, putting them in Fontaine's grade III.[4] Patients who had gangrene of limbs/ toes underwent amputation (Ray amputation/ Above Knee/ Below Knee amputation)

PGE1 therapy showed improvement in pulsations in the lower limb and the level of amputation also improved with PGE1 therapy (Figure 3). Only 7 patients (15.6%) needed higher amputation but ultimately had a healthy amputated stump. In the follow up periods, 7 deaths were observed but never related to the therapy.

This research proves the beneficial effects of PGE1 in reducing the pain as well as in Fontaine's grade in 45 patients with CLI. 7 patients (15.6%) required higher amputation due to ascending gangrene and deterioration of wound while 24 patients (53.3%) after having undergone an amputation did not have progression of the disease after starting PGE1 therapy. The side effects of the therapy (2.2%) were insignificant. It became clear that PGE1 is a real alternative in preventing progression to higher disability where no other alternative medical management is available.[13-15]

Figure 3: Clockwise from above left; (A) 72-year-old male patient was admitted with gangrene of the left big toe and the second toe. He underwent ray amputation of the left big toe and the second toe. After first course of PGE1, gangrene of the wound was found ascending and hence mid-tarsal amputation done. On the third course, the wound is showing healing red granulating wound; (B) Wound was completely healed at the end of 6th course; (C) a female patient who took 5 courses, after 3year follow up; (D) healthy BK stump after 2years follow up.

After diagnosing a patient with advanced CLI where angioplasty and stenting or bypass procedures are not possible, aggressive treatment for the non-healing ulcer, amputation of gangrenous limbs or toes and starting the PGE1 therapy early not only arrest the progression of POVD but even reverses it to some extent. Limitations of study include only a few surgical units practicing the use of PGE1 for advanced CLI cases and ignorance of patients for follow up.

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Ethical approval: The study was approved by the institutional ethics committee

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Topical timolol promotes healing of chronic leg ulcer

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ABSTRACT

Background: Chronic ulcers are a common problem, with chronic diabetic and venous ulcers forming a large proportion. This is the first case-control study to assess the effect of topical timolol on healing of chronic venous and chronic diabetic ulcers.

Methods: The study included 60 patients with chronic leg ulcers. The ulcers in the study group (n = 30) were treated with topical 0.5% timolol maleate solution along with antibiotics and dressings; those in the control group (n = 30) received only antibiotics and dressings. The ulcers in both groups were evaluated at 4, 8, and 12 weeks, and ulcer area was calculated. Healing rate was assessed by calculating the percentage change in ulcer area.

Results: The mean percentage change in area at 4, 8, and 12 weeks was 25.29, 43.77, and 61.79 in the study group and 11.92, 22.40, and 29.62 in the control group. Analysis showed that there were significant differences in percentage change in ulcer of the study and control groups at all three time points and also within the groups. The type of ulcer, history of alcohol consumption, and smoking did not affect the healing rates in the study group.

Conclusions: Topical β-blockade using timolol improves the healing of chronic leg ulcers. (J Vasc Surg: Venous and Lym Dis 2017;5:844-50.)

A chronic ulcer is a break in the continuity of an epithelial surface of the skin or mucosa that shows no tendency to heal after 6 weeks of appropriate treatment. Ulcer healing follows overlapping phases of inflammation, proliferation, and maturation and remodeling, each with distinct cellular and biochemical activities. Chronic skin ulcers somehow fail to progress through this orderly process of healing. Venous stasis and resultant hydrostatic backpressure produce chronic venous ulcers. The leakage of macromolecules, like fibrinogen and α_2-macroglobulin, and the perivascular fibrin cuffs trap growth factors and impair the healing of wounds.[1] Ten percent to 25% of diabetic patients run the risk for development of ulcers. Diabetic ulcers develop in limbs with features of ischemia and neuropathy. β_2-Adrenergic receptor antagonists have been reported to promote wound healing by several mechanisms, the most important by improved keratinocyte migration.[2] Timolol is a propanolamine derivative and acts as a nonselective β-adrenergic blocker. Timolol maleate is the maleate salt of timolol. Timolol has been shown to promote wound re-epithelialization by blocking the autocrine β_2-adrenergic receptor network within the epidermis in in vitro studies and case reports. Here we studied the effect of topical timolol on chronic venous ulcer and chronic diabetic ulcer healing.

METHODS

This prospective observational study included 60 patients admitted to general surgery wards or treated as outpatients with ulcers of the lower extremity due to diabetes or venous insufficiency of >6 weeks in duration, from February 2015 to August 2015. In the study group, 30 patients with chronic leg ulcer underwent treatment with topical application of 0.5% timolol maleate apart from conventional therapy; in the control group, 30 patients with chronic leg ulcer underwent treatment with conventional therapy alone. Both groups had 15 patients each with chronic venous leg ulcer and chronic diabetic leg ulcer who consecutively underwent the respective treatment modalities. The modality of treatment received was decided by the primary treating physicians, and the investigators had only an observational role. Topical timolol is being used at the institute for treatment of chronic leg ulcers by choice of the patient and treating physician. This observational study included only the consecutive patients who underwent treatment with timolol during the study period. Informed written consent was obtained for sequential examinations and data to be taken for research study. For the purpose of this study, chronic venous leg ulcer was defined as an ulcer that typically occurs in the gaiter area and is shallow, with irregular margins, sloping edges, and pigmented surrounding skin, in individuals with clinical or ultrasound evidence of venous insufficiency, with no evidence of peripheral arterial disease (ankle-brachial index >0.9) or diabetes mellitus, and >6 weeks in duration. Chronic diabetic leg ulcer was defined as a

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below-knee ulcer >6 weeks in duration in a known diabetic in the setting of neuropathy or peripheral arterial disease without any clinical or ultrasound (venous Doppler) evidence of venous insufficiency. Patients with bronchial asthma, chronic obstructive pulmonary disease, sinus bradycardia, second- or third-degree atrioventricular block, cardiac failure, ischemic heart disease, or venous obstruction were excluded from the study.

The study group received topical application of 0.5% timolol maleate, one drop for every 2 cm of wound perimeter daily, apart from conventional therapy (including antibiotics per culture reports, glycemic control, absorbent dressing every 2 days unless excessively soaked, and débridement of devitalized tissue when required; no other topical applications were used). Timolol solution was allowed to dry before placement of the absorbent dressing. The control group received conventional therapy alone. Ulcer area was measured by plotting ulcer perimeter on graph paper at 0, 4, 8, and 12 weeks, and the area was calculated manually. Healing rate was assessed by calculating the percentage change in ulcer area at 4, 8, and 12 weeks. The effect of topical application of timolol was studied by comparing the healing rates between different groups. The healing rates at 4, 8, and 12 weeks were compared using repeated-measures analysis of variance, and P value $<$ .05 was considered significant. The research was conducted after approval was received from the Institutional Review Board and ethical committee.

RESULTS

Among the 60 patients included in the study, there were 17 women and 43 men. Patients were divided into a study group of 30 and a control of 30, each having 15 patients with chronic diabetic ulcer and chronic venous leg ulcer. There was no statistical difference in the ulcer area at 0 weeks or in duration of ulcer of the study and control groups. The details of the study population are given in Table I. Glycemic control was maintained in all patients during the period of study. The ulcer areas at all time points are given in Table II.

Analysis of healing between the study group and the control group showed the mean percentage of change in area at 4, 8, and 12 weeks to be 12.98, 14.58, and 16.52 in the control group and 24.04, 27.39, and 40.76 in the test group. Statistical analysis using analysis of variance found this difference to be significant with P value $<$ .05 for all the three means, indicating a better healing rate of the case group that is treated with topical timolol.

The percentage change in ulcer area at 4, 8, and 12 weeks of follow-up was 25.29, 43.77, and 61.79 for the study group and 11.92, 22.40, and 29.62 for the control group (Fig 1; Table III). Analysis using repeated-measures mixed analysis of variance showed that there was a significant difference across the three time points, $F(1.25,72.56) = 94.49$ ($P < .001$), and significant differences between study and control groups, $F(1,58) = 14.41$ ($P < .001$), in percentage change in ulcer area. It was seen that there were significant differences in percentage change in ulcer of the study and control groups at all three time points and also within the groups. Thus, there was a difference in healing over time (repeated measures), there was a significant interaction of treatment with time, and at each of the three time points, there was a significant difference in the treatments. There were no significant differences in the healing rates between chronic diabetic ulcer patients and chronic venous ulcer patients in the study and control groups (Fig 2). Four patients of the study group (one venous, three diabetic) had completely healed ulcers at 12 weeks, whereas none from the control group had complete healing. Ulcer recurrences were not seen during the study period.

The study did not reveal any significant difference in healing rates between smokers and nonsmokers among the cases or in consumers of alcohol. There also was no difference in healing of timolol-treated cases by sex.

There were no major adverse effects due to timolol application. Three patients reported occasional itching around the ulcers.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective nonrandomized single-center study
- **Take Home Message:** Venous and diabetic leg ulcer healing rates were significantly better at 4, 8, and 12 weeks in the 30 patients who received topical timolol in addition to conventional management than in the 30 patients who received conventional treatment alone.
- **Recommendation:** The authors suggest adding topical timolol to local antibiotics and dressings to accelerate healing of chronic venous and diabetic leg ulcers.

DISCUSSION

Healing of a cutaneous ulcer is a complex process. Migration of fibroblasts, keratinocytes, and other cell types to the site of ulcer and their proliferation under stimulation by cytokines and growth factors occur during this process. The synthesis of components of extracellular matrix and re-epithelialization are brought about by this complex interplay.[1,3] Normal ulcer healing follows a predictable pattern of inflammation, proliferation, and maturation and remodeling. Chronic skin ulcers fail to progress through this orderly process of healing. Ulcers that fail to heal after 6 weeks are considered to be chronic.

Venous stasis and the hydrostatic backpressure thus produced cause leakage of macromolecules like

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Table I. Details of the study population

Group	Type of ulcer		Range	Mean	SD	*P* value
Control (n = 30)	Total (N = 30) 11 women 19 men 7 S, 8 A	Age, years	32-81	56.10	11.415	>.05
		Duration, weeks	7-16	10.9	2.77	
		Initial ulcer area, mm^2	308-4849	1517.63	1072.05	
	Diabetic (n = 15) 7 women 8 men 3 S, 4 A	Age, years	37-75	57.07	11.701	
		Duration, weeks	7-16	11.2000	3.00476	
		Initial ulcer area, mm^2	563-4849	1752.40	1245.021	
	Venous (n = 15) 4 women 11 men 4 S, 4 A	Age, years	32-81	55.13	11.445	
		Duration, weeks	7-15	10.6000	2.52982	
		Initial ulcer area, mm^2	308-3548	1282.87	844.100	
Study (n = 30)	Total (N = 30) 6 women 24 men 15 S, 9 A	Age, years	36-87	60.8	13.403	
		Duration, weeks	7-15	10.7	2.208	
		Initial ulcer area, mm^2	121-8457	2136.1	2334.79	
	Diabetic (n = 15) 3 women 12 men 8 S, 4 A	Age, years	50-87	67.20	9.915	
		Duration, weeks	7-15	10.4667	2.41622	
		Initial ulcer area, mm^2	121-8457	2136.33	2412.557	
	Venous (n = 15) 3 women 12 men 7 S, 5 A	Age, years	36-80	54.53	13.705	
		Duration, weeks	8-15	10.9333	1.98086	
		Initial ulcer area, mm^2	141-7942	2135.87	2339.125	

A, Alcohol consumers; *S*, smokers; *SD*, standard deviation.
The age, duration of ulcer, and initial ulcer area of the study and control groups were not statistically different ($P > .05$).

fibrinogen and α_2-macroglobulin. These molecules as well as the perivascular fibrin cuff (fibrin cuff hypothesis) trap growth factors and impair wound healing, resulting in chronic venous ulcers.[1] Another proposed mechanism is the clogging of capillaries by neutrophils, which diminishes dermal blood flow The treatment of venous ulcers has long been compression therapy and wound care. Modern approaches also include the use of sprayed allogenic keratinocytes and fibroblasts and the use of skin substitutes.[4]

Chronic diabetic ulcers develop in 10% to 25% of diabetic patients. Neuropathy, foot deformity, and ischemia contribute to the formation of diabetic ulcers. The poor sensory function allows unrecognized injury to occur. This may be from minor trauma, foreign bodies, or ill-fitted footwear. Once ulceration occurs, most diabetic ulcers become infected, and the chances of healing are poor. Treatment involves achievement of blood glucose control and eradication of the infection, wide débridement of all necrotic and infected tissue, and off-loading of the ulcerated area. Topical application of platelet-derived growth factor and granulocyte-macrophage colony-stimulating factor has met with some success in achieving closure.[5] Significant success has been obtained with the application of engineered skin allograft substitutes, which remain expensive.[4]

The normal regulatory signals and biologic changes that accompany healing in a wound are found to be defective in chronic ulcers. These include failure of normal growth factor synthesis,[1] raised proteolytic activity resulting in increased breakdown of growth factors, and failure of normal antiprotease inhibitor

Table II. Ulcer area of study and control groups at 0, 4, 8, and 12 weeks

Group	Ulcer area, mm²			
	0 weeks	4 weeks	8 weeks	12 weeks
Control				
Total (N = 30)	1517.63 ± 1070.05 (1117.32-1917.94)	1363.67 ± 1054.81 (969.79-1757.54)	1194.83 ± 929.80 (847.64-1542.03)	1086.00 ± 890.41 (753.52-1418.48)
Venous (n = 15)	1282.87 ± 844.10 (815.42-1750.31)	1138.80 ± 726.07 (736.71-1540.89)	1028.60 ± 668.84 (658.21-1398.99)	899.67 ± 617.86 (557.50-1241.83)
Diabetic (n = 15)	1752.40 ± 1245.02 (1062.93-2441.87)	1588.53 ± 1291.96 (873.06-2304.00)	1361.07 ± 1133.25 (733.49-1988.64)	1272.33 ± 1089.09 (669.21-1875.45)
Study				
Total (N = 30)	2136.10 ± 2334.79 (1264.27-3007.93)	1552.10 ± 1590.92 (958.04-2146.16)	1137.87 ± 1164.90 (702.88-1572.85)	735.23 ± 990.026 (365.55-1104.92)
Venous (n = 15)	2135.87 ± 2339.12 (840.50-3431.23)	1562.73 ± 1605.77 (673.48-2451.98)	1088.20 ± 031.55 (516.94-1659.46)	652.13 ± 692.81 (268.46-1035.80)
Diabetic (n = 15)	2136.33 ± 2412.55 (800.30-2472.36)	1541.47 ± 1632.21 (637.58-2445.36)	1187.53 ± 1319.67 (456.72-1918.34)	818.33 ± 1239.16 (132.11-1504.56)

Values are reported as mean ± standard deviation (95% confidence interval).

mechanisms.[6] Fibroblasts from chronic wounds also were found to have decreased proliferative potential and decreased expression of growth factor receptors.[7]

Even though β-adrenergic receptors have been identified in human skin for a long time, their function has only recently been explained.[8] The β_2-adrenergic subtype is the only subtype expressed on the cell membranes of cutaneous cell types like fibroblasts, keratinocytes, and melanocytes. Catecholamine ligands are also synthesized by skin keratinocytes, thus forming a hormonal network that is self-sustained.[9-13]

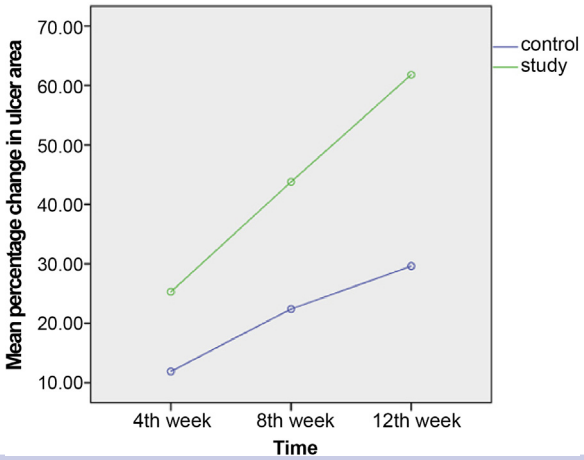

Fig 1. Percentage change in ulcer area of study (timolol; n = 30) and control (n = 30) groups at 4, 8, and 12 weeks of follow-up. Analysis using repeated-measures mixed analysis of variance showed that there was a significant difference across the three time points, F(1.25,72.56) = 94.49 ($P < .001$), and significant differences between study and control groups, F(1,58) = 14.41 ($P < .001$), in percentage change in ulcer area. There was also significant interaction between groups and time, F(1.25,72.56) = 11.42 ($P = .001$). Following up this interaction, it was seen that there were significant differences in percentage change in ulcer of the study and control groups at all three time points and also within the groups.

The influence of catecholamines in wound healing was studied first in 1984 by Donaldson and Mahan. They studied wound closure in adult newts and observed the effects of catecholamines on migration of epidermal cells.[14] They found that the catecholamines isoproterenol, epinephrine, and norepinephrine inhibited migration of epithelial cells. They noted that a β-antagonist like propranolol could block the effects of isoproterenol, whereas α-blockade using phentolamine was less efficient. These results concluded that the catecholamines exerted their influence on migration of epidermal cells through β_2-adrenergic receptors.

In 2002, Turchi et al used cultures of human epidermal keratinocytes to show that mechanical injury immediately stimulates the tyrosine phosphorylation of many cellular proteins.[15]

In 2003, a series of extensive in vitro studies on human epidermal keratinocyte cultures were conducted by Pullar et al.[16] They discovered a novel regulatory mechanism of keratinocyte migration. Re-epithelialization of the wound surface occurs in a coordinated manner. The keratinocytes in the epidermis migrate from the edges of the wound to facilitate re-epithelialization. Epidermal growth factor receptor is an important mediator of this process.[17,18] Binding of epidermal growth factor to its receptor results in the activation of mitogen-activated protein kinases, extracellular signal-related kinases 1 and 2 (ERK1 and ERK2), by phosphorylation by tyrosine phosphatase. They are inactivated by dephosphorylation by serine/threonine phosphatases.[19] Thus, the action of epidermal growth factor is tightly controlled.

In 2006, Pullar et al studied the effects of β-adrenergic receptor agonists on human skin cells.[20] They found that β-adrenergic receptor agonists reduced ERK

Table III. Percentage change in ulcer area of study and control groups at 4, 8, and 12 weeks of follow-up

Group	Percentage change in ulcer area			*P* value
	4 weeks	8 weeks	12 weeks	
Control				
Total (N = 30)	11.92 ± 12.98 (7.07-16.77)	22.40 ± 18.93 (15.33-29.47)	29.62 ± 24.22 (20.58-38.67)	<.001
Venous (n = 15)	10.25 ± 7.53 (6.08-14.42)	18.70 ± 11.26 (12.46-24.94)	28.05 ± 21.87 (15.94-40.16)	
Diabetic (n = 15)	13.58 ± 16.93 (4.20-22.96)	26.10 ± 24.21 (12.69-39.51)	31.19 ± 27.05 (16.21-46.18)	
Study				
Total (N = 30)	25.29 ± 17.98 (18.58-32.01)	43.77 ± 28.23 (33.22-54.31)	61.79 ± 36.59 (48.12-75.45)	
Venous (n = 15)	24.42 ± 17.67 (14.63-34.20)	43.74 ± 30.28 (26.97-60.51)	61.99 ± 36.64 (41.70-82.29)	
Diabetic (n = 15)	26.17 ± 18.86 (15.73-36.62)	43.80 ± 27.09 (28.79-58.80)	61.58 ± 37.82 (40.63-82.53)	

Values are reported as mean ± standard deviation (95% confidence interval).

phosphorylation by a cyclic adenosine monophosphate-independent and a protein phosphatase 2A-dependent process. This resulted in decreased keratinocyte migration. Their results concluded that β-adrenergic signaling affects ERK phosphorylation and thereby keratinocyte migration and wound healing.

In vitro studies using timolol, a nonselective, β-adrenergic receptor antagonist, showed that it promoted wound re-epithelialization by blocking the autocrine β_2-adrenergic receptor network within the epidermis, which slows migration and delays wound healing.[2] β-Adrenergic receptor antagonists enhance the ability of keratinocytes to migrate by increasing ERK phosphorylation and ultimately accelerate wound re-epithelialization. A study conducted in genetically modified mice in 2008 by Ghoghawala et al demonstrated that β_2-adrenergic receptor signaling mediated corneal epithelial wound repair.[21]

These findings led to clinical trials using beta blockers to improve healing of wounds. Mohammadi et al carried out a randomized double-blind trial in burn patients.[22] They included 79 burn patients, 37 in the study group and 42 in the control group. The participants in the study group received oral propranolol at a dose adjusted to decrease the resting heart rate by 20% from baseline; the control group received placebo. Flame was the most common cause of burn in both groups, followed by flash. The patients who received oral propranolol had better wound healing. The burn wound that finally required grafting was smaller in the study group. Similar results were noted for duration of hospital stay.

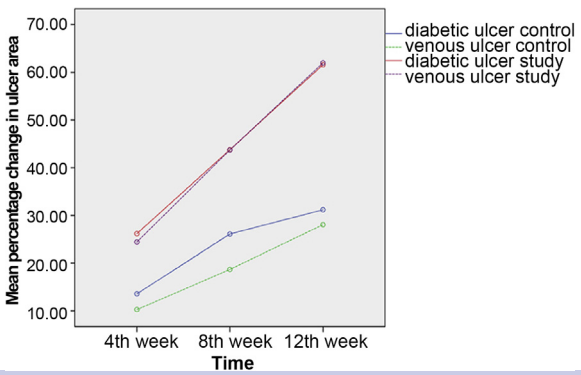

Fig 2. The percentage change in ulcer area of chronic venous ulcer and chronic diabetic ulcer patients does not show significant difference in the study group or in the control group.

Topical timolol application produced complete wound healing in a refractory wound in a 42-year-old woman with a 26 cm^2 ulcer over her back in 2011.[23] Braun et al, in 2013, used topical timolol in five patients with recalcitrant wounds[24]; 0.5% topical timolol was instilled in different chronic, recalcitrant wounds of these five patients, and improvement was noted in all five, including three patients who had complete healing. The mean reduction of wound size after 7 weeks of treatment was 78.2%. In 2012, a cohort study conducted by Chakkittakandiyil et al demonstrated not only the efficacy of timolol maleate 0.5% solution in treating infantile hemangiomas but also the tolerability and safety of topical timolol maleate.[25] Further promise of timolol as a safe and inexpensive drug to treat chronic ulcers came in October 2012, when Manahan et al successfully treated a 92-year-old woman with multiple comorbidities with topical timolol.[26] Topical timolol was successfully used to treat chronic venous leg ulcer by Lev-Tov et al in 2013 and a recalcitrant irradiated scalp wound.[27,28]

Our study showed that the patients treated with topical timolol had a significantly higher ulcer healing rate compared with the control group, 61.79% and 29.62%, respectively. There were no significant differences in the healing rates of chronic venous ulcer patients and chronic diabetic ulcer patients. History of alcohol intake or smoking did not affect the healing rates in our study population. It was seen that both the mode of treatment and the duration of treatment affected the healing rates in our study. Thus, treatment using topical application of timolol as 0.5% results in faster healing rates compared with conventional treatment.

A phase 2 trial looking at the use of topical timolol in ulcers was halted because of lack of funding.[29] It is not clear whether systemic absorption of timolol occurs

when it is used topically for wounds, as most of the data on systemic absorption are based on its ophthalmic use.[30] With the ever-increasing incidence of diabetes and obesity, there is a rising burden on health care costs.[31] Chronic ulcers are a common vexing problem all over the world, and many patients are unable to afford expensive drugs or treatment. Topical timolol is cheap and is easily available as a 0.5% solution and is therefore an attractive treatment option in chronic ulcers. This is the first case-control study to assess the effect of timolol on healing rates of chronic ulcers. Wound healing is a complex process, and an attempt to study any specific factor is extremely difficult. Our study attempts to study the effect of topical β-blockade using timolol on healing of chronic leg ulcer. The stratification used in the study protocol, although rigid, was aimed at incorporating both diabetic and venous causes. The authors do accept that the study is limited by lack of a formal power assessment and lack of randomization. Further randomized clinical trials are required before recommendations on the use of topical β-blockade can be made in regard to chronic leg ulcers.

CONCLUSIONS

Chronic ulcers are a vexing problem and show derangement in the normal pattern of ulcer healing. Topical application of timolol maleate is an effective therapeutic option for the treatment of chronic diabetic ulcer and chronic venous ulcer patients to improve ulcer healing by promoting keratinocyte migration. This is the first case-control study to show that β-blockade accelerates wound healing in chronic ulcer irrespective of gender, smoking, and alcohol habits of the patient. This drug is relatively inexpensive and had few adverse effects. Further studies are required to establish the full usefulness of β-blockade in ulcer healing.

AUTHOR CONTRIBUTIONS

Conception and design: BT, JK, TJ, SU, SV
Analysis and interpretation: BT, TJ, SU, SV
Data collection: BT, JK, TJ, SU, SV
Writing the article: BT, JK, TJ, SU, SV
Critical revision of the article: BT, JK, TJ, SU, SV
Final approval of the article: BT, JK, TJ, SU, SV
Statistical analysis: BT, JK, TJ, SU, SV
Obtained funding: BT, JK, TJ, SU, SV
Overall responsibility: JK

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PRE-OPERATIVE HAIR REMOVAL WITH TRIMMERS AND RAZORS AND ITS IMPACT ON SURGICAL SITE INFECTIONS IN ELECTIVE INGUINAL HERNIA REPAIR

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ABSTRACT

BACKGROUND

Despite major advances in infection control interventions, health care-associated infections (HAI) remain a major public health problem and patient safety threat worldwide. The global data suggests that the SSI incidence rate varies from 0.5 to 20% depending upon the type of operation and underlying patient status. Several factors preoperative, intraoperative & postoperative, determine the occurrence of surgical site infections, Preoperative hair removal is considered as a risk for the development of surgical site infections. The objective of the study is to find out the difference in the incidence of surgical site infections in patients undergoing pre-operative hair removal by shaving with Razor blades and hair trimmers prior to elective inguinal hernia surgery.

MATERIALS AND METHODS

Written informed consent from 160 patients with no significant comorbidities planning to undergo elective inguinal hernia surgery at the general surgery wards in Government Medical College Kottayam and who were willing to participate in the study were to be obtained. 80 of them to undergo pre-operative hair removal with hair trimmers and 80 to undergo preoperative hair removal by shaving with razor blades on the day prior to the surgery randomised into two groups. During their stay in the post-operative ward the surgical wounds of the patients were examined daily for the development of erythema, pain, discharge, induration and gaping of the wound. The daily findings were noted down till the patient was discharged from the ward. The patients were again reassessed 2 weeks later, when they came for review in the Surgery OPD after their discharge from the ward; finally the patients were examined on the 30th day post-surgery to look for the clinical features of surgical site infections.

RESULTS

Out of the total 160 patients who were studied, 29 (18.1%) of them had post-operative infection within 30 days, in the form of erythema, induration, discharge and gaping. Most of the symptoms of surgical site infections were during the initial 3 days (69%), with the most common symptom being erythema (18.1%) followed by induration (12.5%). Gaping (0.6%) and discharge from wound (3%) were very minimal. Those individuals who had undergone preoperative hair removal with trimmers (11.2%) had a lower incidence of surgical site infection when compared to those with razors (20%). The difference was statistically significant, with a p value of 0.024 by Chi-Square tests. The difference in erythema (p- 0.024) and induration (p-0.017) between the two groups was also found to be statistically significant. Other factors, namely type of surgery, age of the individual and sex did not have a statistically significant difference.

CONCLUSION

In this study there is evidence of definite reduction in surgical site infection rates when trimmers were used for pre-operative hair removal than razors in elective inguinal hernia surgery. The difference is statistically significant (p Value – 0.024).

KEYWORDS

Preoperative Hair Removal; Razors; Surgical Site Infection; Trimmers.

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BACKGROUND

Despite major advances in infection control interventions, health care-associated infections (HAI) remain a major public health problem and patient safety threat worldwide. The global data suggests the Surgical Site Infections (SSI) incidence rate varies from 0.5 to 20% depending upon the type of operation and underlying patient status.[1] Surgical site infections are the 3rd most common cause of hospital acquired infections in India, amounting to increased duration of hospital stay, morbidity and increased health care

expenses.[2] In India, the incidence of SSI has previously been reported to vary between 3.03% to 22.41% in studies from different geographic areas.[3]

SSI rates have been reported to range from 2.5% to 41.9% with significantly higher rates in developing countries. Besides, the surgical mortality in developing nations is 10 times higher than developed countries and deaths attributed to anaesthesia are 1000-fold higher. In a recent meta-analysis report of 220 international studies investigating SSI rates in developing countries, the cumulative incidence ranged from 0.4 to 30.9 per 100 patients and from 1.2 to 23.6 per 100 surgical procedures, while the pooled cumulative incidence was 11.8 per 100 patients.[4]

The incidence of SSI also varies more widely between surgical procedures suggesting the type of surgery to be an important determinant. The INICC comparison revealed that the SSI rates amongst hospitals in limited-resource countries including India were significantly higher after abdominal surgeries, cardiothoracic surgeries, and ventricular shunt when compared to those in the US hospitals.[5]

Several factors preoperative, intraoperative and postoperative, determine the occurrence of surgical site infections (e.g.; smoking, diabetes, other comorbidities, duration of surgery, preoperative skin preparation.[6] most of the factors has been extensively studied and researched upon. For a Surgical Site Infection, microbial contamination of the surgical site is a prerequisite.

One of the pre-operative risk factors that has not been extensively studied is pre-operative hair removal and its impact on surgical site infections. Hence the following study is being undertaken to assess the impact of preoperative hair removal on Surgical Site Infections. Latest Indian study on this topic showed a definite decrease in the incidence of Surgical Site infection with the use of trimmers for hair removal.

Aims and Objectives

This study aims to find out the difference in the incidence of surgical site infections in patients undergoing pre-operative hair removal by shaving with Razor blades and hair trimmers prior to elective inguinal hernia repair.

MATERIALS AND METHODS

This prospective study was carried out in the Department of General Surgery of Government Medical College, Kottayam from March 2016 to March 2017 after getting ethical committee clearance. 160 patients aged 20 – 60 yrs. with no significant co morbidities who underwent elective hernia repair surgery at the general surgery wards in our institution and who gave informed written consent were included in the study. 80 of them underwent pre-operative hair removal with hair trimmers and 80 underwent preoperative hair removal by shaving with razor blades on the day prior to the surgery randomly. All the patients underwent elective inguinal hernia surgery and during their stay in the post-operative ward the surgical wounds of the patients were examined daily for the development of erythema, pain, discharge, indurations, gaping of the wound. The daily findings were noted down till the patient was discharged from the ward.

The patients were again assessed 2 weeks later, when they were reviewed in the Surgery OPD after their discharge from the ward; finally, the patients were examined on the 30th day post-surgery to look for the clinical features of surgical site infections.

During every phase of the study the personal details of the patients participating in the study was kept confidential.

Inclusion Criteria

Patients who underwent elective inguinal hernia repair in the department of General Surgery in Kottayam Medical College without any significant comorbidities.

Exclusion Criteria

Patients with deep or organ space infection, immunocompromised patients, diabetics, and patient who underwent emergency hernia repair were excluded from the study.

Data entry was done using Excel and analysis was carried out using SPSS.

DATA ANALYSIS AND RESULTS

The study included 158 male patients and 2 female patients. Majority of the individuals in the study belonged to age more than 50 years. Most common inguinal hernia surgery being done at our institution is Lichtenstein's tension free mesh repair which accounted for almost 70% of the total cases in the study, Followed by Rives preperitoneal mesh repair, which accounted for 28%. Equal number of individuals underwent preoperative hair removal with razors and trimmers (80/80).

The Surgical Site infection rate following elective inguinal hernia repair at out institution is 18.1%, which is in accordance with the national incidence rates (12%-23%)(Figure 1). In the entire study population, erythema of the wound was noted in 29 out of 160 patients (18.1%). Induration was noted in 20 patients (12.5%). Significant discharge was seen in 5 patients (3.1%) and gaping was noted in 1 patient. Commonest symptom (erythema) was detected during the postoperative day 1-3. (Table 1)

Our study shows a statistically significant association between mode of pre-operative hair removal and postoperative Surgical Site Infection. (Table 2) Association between preparation and erythema (Figure 2), preparation and induration (Figure 3) preparation and discharge and, preparation and gaping were separately analysed. There were statistically significant difference favouring the hair removal using trimmers in case of erythema (Table 3) and induration (Table 4). Association between preparation and discharge or gaping did not show any statistically significant difference. Association between type of surgery and postoperative infection also showed no statistically significant difference.

Erythema was seen in 20 patients who underwent hair removal with razors as compared to 9 patients who

underwent hair removal with trimmers (p=0.024) (Table 3). Induration was seen in 15 patients who underwent hair removal with razors as compared to 5 patients who underwent hair removal with trimmers (p= 0.017) (Table 4).

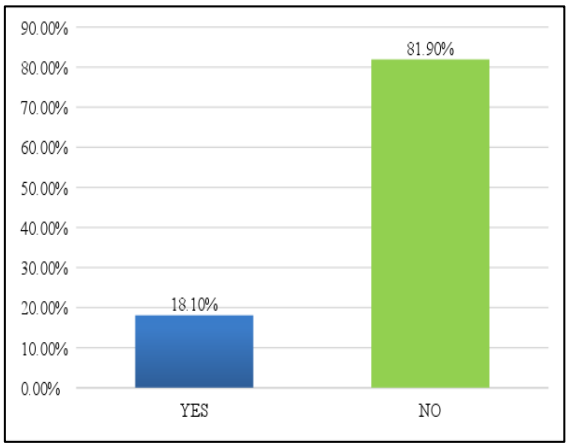

Figure 1. Distribution of Study Subjects Based on Postoperative Infection

Surgical Site infection rate following elective hernia repair surgery at our institution (18.1%).

Day of Findings	Number of Subjects*	%
< 3 Days	20	69.0
3 - 14 Days	8	27.6
> 14 Days	1	3.4
Total	**29***	**100.0**

Table 1. Distribution of Study Subjects Based on day of Findings

Table shows the post-operative day during which the symptoms of surgical site infection were noticed & diagnosed, commonest symptoms were detected during the postoperative day 1-3.*number of subjects having SSI.

Preparation	Postoperative Infection		Total	Chi-Square Value
	Yes	No		
Trimmers	9	71	80	5.096 P=0.024 Significant
	11.2%	88.8%	100.0%	
Shaving	20	60	80	
	25.0%	75.0%	100.0%	
Total	**29**	**131**	**160**	
	18.1%	**81.9%**	**100.0%**	

Table 2. Association between Mode of Preparation and Postoperative Infection

This Table shows a significant association between mode of pre-operative hair removal & Post Op SSI.

Preparation	Erythema		Total	Chi-square value
	Yes	No		
Trimmers	9	71	80	5.096 P=0.024 Significant
	11.2%	88.8%	100.0%	
Shaving	20	60	80	
	25.0%	75.0%	100.0%	
Total	**29**	**131**	**160**	
	18.1%	**81.9%**	**100.0%**	

Table 3. Association between Mode of Preparation and Erythema

Erythema was seen in 20 patients who underwent hair removal with razors as compared to 9 patients who underwent hair removal with trimmers.

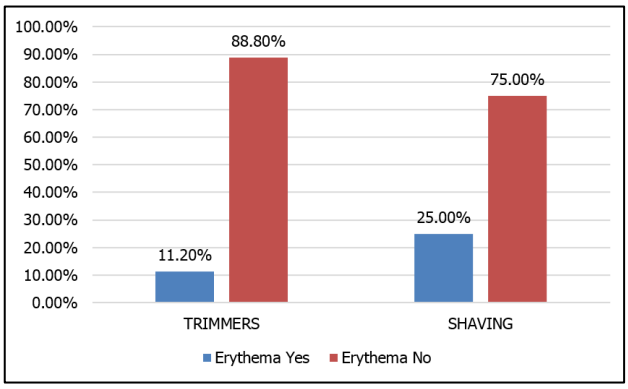

Figure 2. Association between Mode of Preparation and Erythema

Development of erythema was 11.2% when trimmers were used where as it was 25% when razors were used.

Preparation	Induration		Total	Chi-square value
	Yes	No		
Trimmers	5	75	80	5.714 P=0.017 Significant
	6.2%	93.8%	100.0%	
Shaving	15	65	80	
	18.8%	81.2%	100.0%	
Total	**20**	**140**	**160**	
	12.5%	**87.5%**	**100.0%**	

Table 4. Association between Mode of Preparation and Induration

Induration was seen in 15 patients who underwent hair removal with razors as compared to 5 patients who underwent hair removal with trimmers. The Difference is statistically significant.

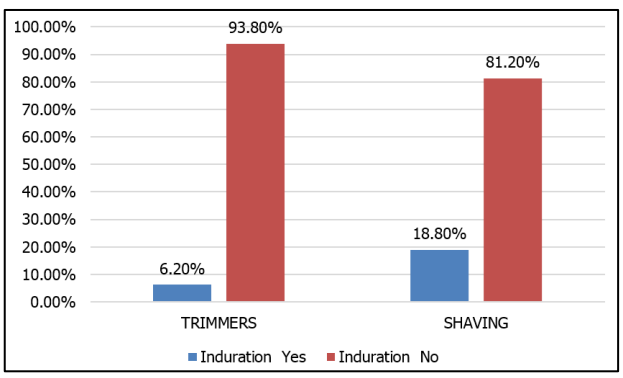

Figure 3. Association between Preparation and Induration

Induration was only 6.2% when trimmers were used in contrast to razors where it was 18.8%.

DISCUSSION

The risk of Surgical Site Infection is markedly increased when a surgical site is contaminated with 10^5 organisms per gram. The endogenous flora of the patient's skin, mucous

membranes, or hollow viscera is the source of pathogens for most Surgical Site infections. When mucous membrane or skin is incised, the exposed tissues are at risk for contamination with endogenous flora. The abrasions produced over the skin, during pre-operative hair removal with razor blades predispose to superficial surgical site infection.

This Study was done to identify the incidence of surgical site infection following elective hernia repair, and the difference in rate of surgical site infection, when the preoperative hair removal was done with razors and trimmers. Out of the total 160 patients who were studied, 29 (18.1%) of them had post-operative infection within 30 days, in the form of erythema, induration, discharge and gaping. Most of the symptoms of surgical site infections were during the initial 3 days (69%), with the commonest symptom being erythema (18.1%) and induration (12.5%). Gaping (0.6%) and discharge from wound (3%) were very minimal. Those individuals who had undergone preoperative hair removal by trimming (11.2%) had a lower incidence of surgical site infection when compared to those with razors (20%) with a significant p value of 0.024 by Chi-Square tests, Erythema in 9 (11.2%) patients who underwent hair removal by trimming and 20 (25%) patients who underwent hair removal by razors. This was statistically significant, with a p Value of 0.024. Induration was present in 5 (6.2%) patients who underwent hair removal by trimming and 15 (18.8%) patients who underwent hair removal by razors, which was statistically significant, with a p Value of 0.017. Incidence of discharge and gaping did not have statistically significant difference in the both sets of patients and symptoms of deep or organ space surgical site infection, did not have association with the preoperative preparation. Also, others factors, namely type of surgery, age of the individual and sex did not yield a statistically significant p Value.

Infection at or near surgical incisions within 30 days of an operative procedure, is called surgical site infection, which contributes substantially to surgical morbidity and mortality each year. Surgical site infection (SSI) accounts for 15% of all nosocomial infections and, among surgical patients, represents the most common nosocomial infection.[7]

The cornerstone is the lack of adherence to recommended infection control guidelines and suboptimal practices in many countries.[8]

Removal of hair from the intended site of surgical incision has traditionally been part of the routine preoperative preparation of patients undergoing surgery. Hair removal may be necessary to facilitate adequate exposure to the site and preoperative skin marking. Furthermore, suturing and the application of wound dressings can be complicated by the presence of hair. Apart from these practical issues, hair has been associated with a lack of cleanliness and the potential to cause surgical site infection (SSI) However, there is also the belief that hair removal inversely increases the risk of SSI by causing microscopic trauma of the skin.[9]

Three methods of hair removal are currently used; shaving, trimming and chemical depilation. Shaving is the commonest and cheapest method of hair removal. This method uses a sharp blade, held within the head of a razor, which is drawn over the patient's skin to cut hair close to the surface of the skin.

Trimmers use fine teeth to cut hair close to the patient's skin, leaving a short stubble that is usually around one millimetre in length. The heads of trimmers can be disposed of between patients to minimise the risks of cross infection.

Depilatory creams are chemicals which dissolve the hair itself. This is a slower process than either shaving or trimming, as the cream has to remain in contact with the hair for between five and 20 minutes. In addition, there is a risk of irritant or allergic reactions to the cream, so patch tests should be carried out 24 hours before the cream is applied for the first time.[10]

During the process of shaving, the skin may experience microscopic cuts and abrasions. It is believed that micro-organisms are able to enter and colonise these cuts, thus contaminating the surgical incision site and causing SSIs.

In addition, abrasions may exude tissue fluid, which provides a culture medium for micro-organisms. Since trimmers do not come into contact with the patient's skin, they are thought to reduce the risk of cuts and abrasions.

Studies have been conducted comparing the efficacy of hair trimmers to that shaving with razor blades, first documented study in 1982 by Eugene R Balthazar MD, James D Colt MD, & Ronald Lee Nichols MD, Department of Surgery, Tulane University school of Medicine showed that there was no significant increase in the incidence rates of surgical site infections with the use of Hair trimmers.[11]

In a prospective study that compared infection rates among 1,980 surgical patients whose hair was either shaved or trimmed pre-operatively, patients who were trimmed had a statistically significantly lower infection rate than patients who were shaved. These results support an earlier study of the effects of shaving versus trimming on infection rates among 1,013 patients undergoing elective surgery. Trimming decreased infection rates both at discharge and at 30-day follow-up. Cost savings of $270,000 per 1,000 patients were estimated (in 1983 dollars) if trimming replaced shaving.[12]

A study comparing the clinical and cost outcomes of shaving and trimming found a moderate initial increase in hospital cost when converting from razors to trimmers, but concluded that substantial long-term cost savings could be expected due to the decreased incidence of postoperative wound infections. This study further recommended discontinuation of razor shaving because of its associated risk of infection.[13]

Study comparing the incidence of surgical site infections and pre-operative hair removal with surgical trimmers and shaving with razors has been conducted in VMMC & SJH (Vardhman Mahavir Medical College & Safdarjang Hospital), New Delhi in 2012. The results obtained after the study showed a definite decrease in the incidence of surgical site infections with the use of surgical trimmers when compared

to shaving with razors. Total of 200 individuals underwent the study, Group I= 100 & Group II= 100, Group I underwent preoperative hair removal by razor blades and Group II underwent hair removal by trimmers, The incidence of Surgical Site Infection is Group I was 7% (7 in 100), The Incidence of Surgical Site Infection in Group II was 1% (1 in 100), with a significant p value of <.05.[14]

The study also calls upon for similar study from different hospitals in the country so that a comparative analysis shall be helpful in the understanding of the area of study.

CONCLUSION

In this study there is evidence of definite reduction in surgical site infection rates when trimmers are used for pre-operative hair removal than razors in elective hernia surgery. Preoperative hair removal with trimmers had a statistically significant lower incidence of erythema and induration at the wound site when compared to use of razors. Other factors namely type of surgery, age of the patient and sex of the patient were not statistically significant. Therefore, preoperative hair removal with the help of trimmers should be recommended since this method significantly reduce the number of surgical site infections.

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RIVES AND LICHTENSTEIN REPAIR IN INGUINAL HERNIA- A COMPARISON OF POSTOPERATIVE COMPLICATIONS TO KNOW WHETHER RIVES REPAIR IS AS SAFE AS THE GOLD STANDARD LICHTENSTEIN REPAIR

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ABSTRACT

BACKGROUND

Hernia repair surgeries underwent a lot of modifications over time. These modifications were an attempt to reduce the recurrence rate and post-operative complications. Current techniques for Inguinal hernia show similar recurrence rate. Therefore, recurrence is no longer the main issue discussed when considering improving the current standards for groin hernia repair. Post-surgical chronic pain presents a major, largely unrecognized clinical problem. Consequently, there is a need to not only decrease an extensive dissection in the inguinal canal but also to minimize the interaction between the mesh and major surrounding structures. As a result, placing a mesh in the preperitoneal space is a viable option. Likewise, studies have shown that return to normal activity and return to work is comparatively quicker in Rives. In this study I am comparing the post op period complications in Rives and Lichtenstein hernia surgeries to know whether Rives is superior to Lichtenstein's repair.

MATERIALS AND METHODS

After obtaining approval for the study from Institutional Review Board, written informed consent from 100 male patients planning to undergo elective hernia repair surgery at the General Surgery wards in Government Medical College, Kottayam & who were willing to participate in the study were obtained and randomly allocated into two groups, 50 undergoing Rives hernia repair & 50 Lichtenstein hernia repair. The patients were evaluated and followed up according to the protocol. In early postop period, patients were assessed for pain using a numeric rating scale. Complications like haematoma, seroma, wound infection and early recurrence were compared. Chronic inguinal pain/Inguinodynia is a significant, though under reported problem. Moderate to severe pain persisting more than 3 months should be considered pathological. Inguinodynia, if present was assessed using a numerical scale. Another parameter that was assessed was testicular atrophy. For this preoperative and postoperative testicular volumes were measured using an orchidometer and compared. All the patients were followed up for a period of 3 months postoperatively to assess recurrence, testicular atrophy and Inguinodynia.

RESULTS

Out of the total 100 patients included in the study, 50 patients were in Rives series and 50 in Lichtenstein series. All the patients were males. Average age of the patients was 53.56 in Rives and 55.08 in Lichtenstein series. There were 49 unilateral hernias and 1 bilateral hernia in Rives series and 48 unilateral hernias and 2 bilateral hernias in Lichtenstein group. Among these, 27 were direct and 23 indirect hernias in Rives series, and 18 direct 31 indirect and 1 pantaloon hernia in Lichtenstein series. The mean immediate post-operative pain score was 3.54 in Rives group and 4.26 in Lichtenstein group. The immediate post-operative pain was significantly low in Rives group with a p value of <.001. There were 2 haematoma cases (4%) in Rives group and 6 in Lichtenstein group (12%). All the cases were managed conservatively. Haematoma cases were more in Lichtenstein group which may be due to increased dissection and mesh fixing sutures in the more vascular subaponeurotic plane compared to relatively avascular preperitoneal space. The difference however is not statistically significant (p=0.307). In Lichtenstein cases there were 6 surgical site infections accounting to 12% which required just letting open the skin clips, irrigation and antibiotics. In Rives group, there were 2 surgical site infection cases accounting to 4%. In our study, there is no significant difference in the incidence of surgical site infection (p=0.14). There were no recurrences in both Rives and Lichtenstein repairs during the study period.

CONCLUSION

Immediate post-operative pain was significantly less in Rives compared to Lichtenstein. There was no significant difference in other post-operative complications like seroma, haematoma, recurrence, surgical site infection or testicular atrophy. Both Rives and Lichtenstein procedures yield excellent results with almost no recurrence, low post-operative complication rates and good long term outcomes.

KEYWORDS

Complications, Hernia, Lichtenstein, Mesh, Rives.

HOW TO CITE THIS ARTICLE: Kurien JS, Varghese SA, Das A, et al. Rives and Lichtenstein repair in inguinal hernia-a comparison of postoperative complications to know whether rives repair is as safe as the gold standard Lichtenstein repair. J. Evid. Based Med. Healthc. 2018; 5(8), 682-686. DOI: 10.18410/jebmh/2018/138

BACKGROUND

Inguinal hernia is one of the most common surgical problems that present to a surgeon in his outpatient department, making hernia repair one of the most common operations performed by general surgeons. In Hernia repair, Mesh repair of inguinal hernia is the most common operation performed. Approximately 20 million groin hernioplasties are performed each year worldwide, over 17,000 operations in Sweden, over 12,000 in Finland, over 80,000 in England and over 800,000 in the USA.[1-3] The inguinal Hernia repair is one the cornerstones of general surgery practice. The word 'Hernia' is derived from a Latin term meaning "a rupture". A hernia is defined as a protrusion of a viscus or a part of viscus through an abnormal opening in the walls of its containing cavity.[4] The concept of avoiding tension by onlay mesh repair was championed by Lichtenstein. Lichtenstein theorized that by using mesh prosthesis to bridge the hernia defect rather than closing it with sutures, tension is avoided, ostensibly resulting in a less painful operation.[5] Now Lichtenstein tension free mesh repair is considered as the gold standard of hernia surgery.[6] The preperitoneal space is used by the Rives repair for repair of an inguinal hernia because of the mechanical advantage gained from prosthesis placement behind the abdominal wall. Rives preperitoneal repair makes use of the abdominal pressure to help fix the prosthetic material against the abdominal wall, adding strength to the repair.[7] The idea of this study is to compare the usefulness of Rives preperitoneal mesh repair with the now gold standard Lichtenstein tension free mesh repair and to assess whether there is any added advantage to this repair over the Lichtenstein tension free mesh repair.

MATERIALS AND METHODS

This prospective study was carried out in the Department of General Surgery, Government Medical College, Kottayam, Kerala after obtaining ethical committee clearance. 100 male patients undergoing elective hernia repair surgery and giving informed consent were included in the study. The study period was from June 2016 to May 2017 for one year. They were allocated into two groups; 50 undergoing Rives hernia repair & 50 Lichtenstein hernia repair. The patients were evaluated and followed up according to the protocol. In early post op period, patients were assessed for pain using a numeric rating scale. Complications like recurrence, hematoma, seroma and wound infection were compared. Chronic inguinal pain/Inguinodynia is a significant, though under reported problem. Moderate to severe pain persisting more than 3 months should be considered pathological. Inguinodynia, if present was assessed using a Numerical scale. Another parameter that was assessed was testicular atrophy. For this preoperative and postoperative testicular volumes were measured using an orchidometer and compared. All the patients were followed up for a period of 3 months postoperatively to assess recurrence, testicular atrophy and Inguinodynia.

RESULTS

Total subjects studied were 100. The mean age among study subjects were 54.32 years with standard deviation of 9.047 years. Minimum and maximum age were 36 years and 73 years respectively.

Side	Surgery				Chi-Square value
	Rives		Lichtenstein		
	No.	%	No.	%	
Right	41	82.0%	41	82.0%	0.4
Left	8	16.0%	7	14.0%	P=0.819
Bilateral	1	2.0%	2	4.0%	Not
Total	50	100.0%	50	100.0%	significant

Table 1. Association between Side and Surgery Type

Graph 1. Association between Side and Surgery Type

Hematoma or Seroma	Surgery				Chi-Square Value
	Rives		Lichtenstein		
	No.	%	No.	%	
Present	1	2.0%	3	6.0%	1.042
Absent	49	98.0%	47	94.0%	P=0.307
Total	**50**	**100.0%**	**50**	**100.0%**	Not significant

Table 2. Association between Hematoma /seroma and Surgery Type

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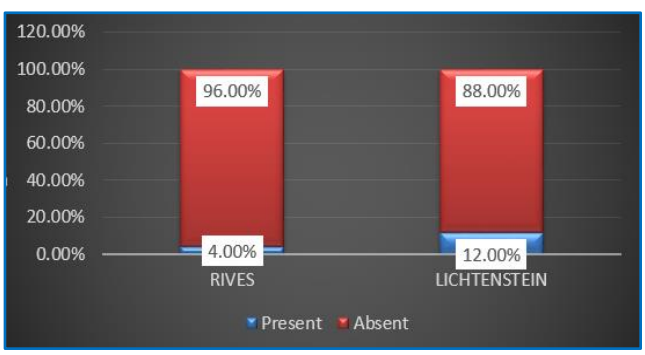
Graph 2. Association between Hematoma/ Seroma and Surgery Type

Surgical Site Infection	Surgery				Chi-Square Value
	Rives		Lichtenstein		
	No.	%	No.	%	
Present	2	4.0%	6	12.0%	2.174 P=0.14 Not significant
Absent	48	96.0%	44	88.0%	
Total	**50**	**100.0%**	**50**	**100.0%**	

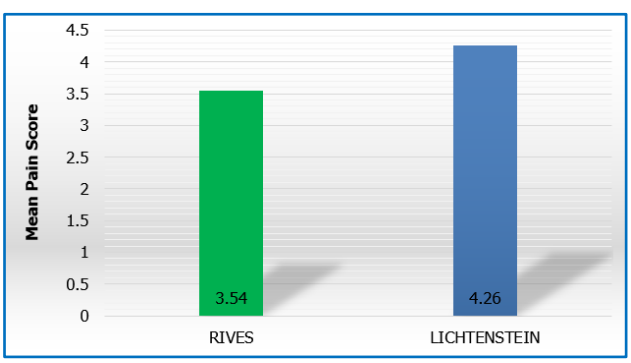
Table 3. Association between Surgical Site Infection and Surgery Type



Graph 3. Association between Surgical Site Infection and Surgery Type

Variable	Surgery	N	Mean	Std. Deviation	T value
Post-Operative Pain	Rives Lichtenstein	50 50	3.54 4.26	.678	-4.385 P<0.001 Significant

Table 4. Association between Type of Surgery and Pain Score



Graph 4. Association between Type of Surgery and Pain Score

Scoring of Post Operative Pain

Numerical scale

0 - No pain

10 - Maximum possible pain.

Severe pain was defined as a score more than 5.

DISCUSSION

Lichtenstein vs anterior preperitoneal prosthetic mesh placement in open inguinal hernia repair: by R.L Muldoon, K.M Marchant, a prospective randomized trial done in Department of Surgery, Central Arkansas Veterans health care system and University of Arkansas for Medical Sciences, 4301 West Markham, USA showed that both anterior repairs are associated with low post-operative morbidity and recurrence rates, the Lichtenstein repair is technically easier and less time consuming.[8] There is no statistical significant difference in the recurrence rates between the two methods.

As per Simons MP et al, the preperitoneal space is the most suitable site for the insertion of a mesh.[9] because the hydrostatic pressure of the abdominal cavity itself will fix the mesh against the abdominal wall, provided there is sufficient mesh extension (4 cm) around the hernial ring. There is less intra-abdominal pressure on the mesh if it is located in the preperitoneal space due to the smaller radius (Laplace's law). The present study was designed primarily to provide an answer to the question of whether preperitoneal prosthetic placement is better tolerated in primary inguinal herniation than onlay positioning. Secondary end points were other early and late complications. There was no statistical difference between the two study groups in terms of demographics or the type of hernia. Out of the total 100 patients included in the study, 50 patients were in Rives series and 50 in Lichtenstein series. All the patients were males. Average age of the patients was 53.56 in Rives and 55.08 in Lichtenstein series. In the R, L Muldoon study average age of the patients were 60.7 in Read Rives series and 63.3 in Lichtenstein series. There were 49 unilateral hernias and 1 bilateral hernia in Rives series and 48 unilateral hernias and 2 bilateral hernias in Lichtenstein group. Among these 27 were direct and 23 indirect hernias in Rives series and 18 direct 31 indirect and 1 pantaloon hernia in Lichtenstein series.

Enrique J. Grau-Talens et al carried out a prospective study on Rives technique performed on 943 patients (1000 repairs). The mean operative time was 31.8 min. Pain assessment after 24 h gave two patients with intense pain and four patients who thought their state was bad. Surgical wound complications were below 1%, and urinary retention was 1.2% mostly associated with spinal anaesthesia and, in one case, bladder perforation. There was spermatic cord and testicular oedema with some degree of orchitis in 17 patients. The clinical follow-up of 849 repairs (86.4%), mean (range) 30.0 (12–192) months, gave five recurrences (0.6%), three cases (0.4%) of testicular atrophy, and 37 (4.3%) of post-operative chronic pain.[10]

The mean immediate post-operative pain score in our study was 3.54 in Read Rives group and 4.26 in Lichtenstein group. The immediate post-operative pain was significantly lower in Rives group with a p value of <.001. The increased post-operative pain in Lichtenstein group can be attributed to the more dissection and sutures in the subaponeurotic neurovascular plane. These results were comparable to a study conducted in Iran, at Baquiyatallah University in 2010 by Jamal Akhavan Moghaddam et al.[11] who arrived at the

result that post-operative pain was significantly lower in Rives group. In this prospective randomized control trial 126 patients with inguinal hernia were studied with 62 each in Rives and Lichtenstein group.

In our study, there were 2 haematoma cases (4%) in Read Rives group and 6 in Lichtenstein group (12%). All the cases were managed conservatively. Haematoma cases were more in Lichtenstein group which may be due to increased dissection and mesh fixing sutures in the more vascular onlay plane compared to relatively avascular preperitoneal space. The difference however is not statistically significant (p=0.307). In the R.L Muldoon study and Jamal Akhavan Moghaddam study there was no significant difference in the incidence of haematoma in the two methods. No cases of chronic groin pain were reported in either study groups. In the R.L Muldoon study and another study published in May 2012 by Wouter Willaert et al.[12] of Department of public health, Ghent university, Belgium, showed less acute and chronic pain in preperitoneal group compared to Lichtenstein group. The increased incidence of chronic pain in Lichtenstein group may be due to increased dissection in onlay neurovascular plane and also due to the constant contact and impingement of the nerves with the foreign body (polypropylene mesh). Erhan et al noted similar incidence of chronic pain in preperitoneal repair and Lichtenstein repair. The incidence rates of chronic pain after Lichtenstein and preperitoneal repair were 6% and 4%, respectively.[13] Sajid et al carried out a meta-analysis of twelve randomized trials evaluating 1437 patients. There were 714 patients in the transinguinal preperitoneal repair group and 723 patients in the Lichtenstein group. Preperitoneal repair was associated with a reduced risk of developing chronic groin pain (P<0.02). Incidence of hernia recurrence, postoperative complications and moderate-to-severe postoperative pain was similar in both groups.[14]

Another interesting finding in our study was a comparison of surgical site infection between the two procedures. In Lichtenstein cases, there were 6 surgical site infections accounting to 12%, which required just letting open the skin clips irrigation and antibiotics. In Rives group there were 2 surgical site infection cases accounting to 4%. However, there was no significant difference in the incidence of surgical site infection (p=0.14), which may warrant further studies in future.

Koning et al carried out a study comparing preperitoneal mesh repair and Lichtenstein repair. The complications in preperitoneal repair were recurrence (n = 1), bleeding (and re-operation) (n= 4); 10 patients (4.4%) experienced chronic pain. Persisting sensation loss occurred in 0.9%. Lichtenstein group had recurrence (n = 3), bleeding (and re-operation) (n=3); 11 Lichtenstein patients (4.1%) experienced chronic pain. Persisting sensation loss occurred in 2.2%. Both groups were comparable with regard to outcomes.[15] There were no recurrences in either Lichtenstein or Rives repair in our study, atleast no early recurrences. A long term followup study may be required to know the incidence of recurrence in either of the two groups.

Reid I et al published a series of ten cases of testicular atrophy occurring after hernia repair in nine patients. Identifiable risk factors were found in eight patients.[16] Previous groin or scrotal surgery are a risk factor for testicular atrophy and when indicated, warn the patient before surgery of the increased risk of testicular atrophy. Overzealous dissection of a distal hernia sac, dislocation of the testis from the scrotum into the wound and concomitant scrotal surgery should all be avoided as these are found to be contributing to testicular atrophy and not the type of hernia repair. There is no statistically significant difference in previous studies between Rives and Lichtenstein methods in causing testicular atrophy. There were no cases of testicular atrophy reported in either of my study groups.

CONCLUSION

Immediate post-operative pain was significantly less in Rives compared to Lichtenstein. There did not appear any significant difference in other post-operative complications like seroma, hematoma, surgical site infection or testicular atrophy. Both Rives and Lichtenstein procedure yield excellent results with no recurrence, low post-operative complication rates and good long term outcomes. Thus, Rives repair for inguinal hernia can be considered as safe as Lichtenstein repair and even superior to it in certain aspects such as postoperative pain.

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