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Original Article

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

Debasis Ray[1], Abhishek Bhaumik[2], Sudeb Saha[3]

[1]Associate Professor, Department of Surgery, Nil Ratan Sirkar Medical College, Kolkata, West Bengal, India, [2]Post Graduate Student, Department of Surgery, Nil Ratan Sirkar Medical College, Kolkata, West Bengal, India, [3]Professor, Department of Surgery, Nil Ratan Sirkar Medical College, Kolkata, West Bengal, India

Abstract

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

Corresponding Author: Dr. Debasis Ray, Department of Surgery, Nil Ratan Sirkar Medical College, Kolkata – 700 014, West Bengal, India. Phone: +91-9433126240. E-mail: dr_debaray@rediffmail.com

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

Aims and Objectives

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

Null hypothesis

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

Alternate hypothesis

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

MATERIALS AND METHODS

Study Design

This was a randomized controlled trial.

Study Period

This study was from January 2016 to June 2017.

Study Population

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

Type of Intervention

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

Sample Size

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

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

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

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

Sampling Technique

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

Inclusion Criteria

The following criteria were included in this study:

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

Exclusion Criteria

The following criteria were excluded from the study:

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

Data Collection Tool

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

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

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

Data Collection Procedure

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

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

These include:

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

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

Operative Technique

A standard operative technique was followed

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

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

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

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

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

Post-operative

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

Follow-up

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

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

Ethical considerations

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

Plan of statistical analysis

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

RESULTS

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

Baseline Characteristics

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

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

Duration of Surgery

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

Post-operative Findings

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

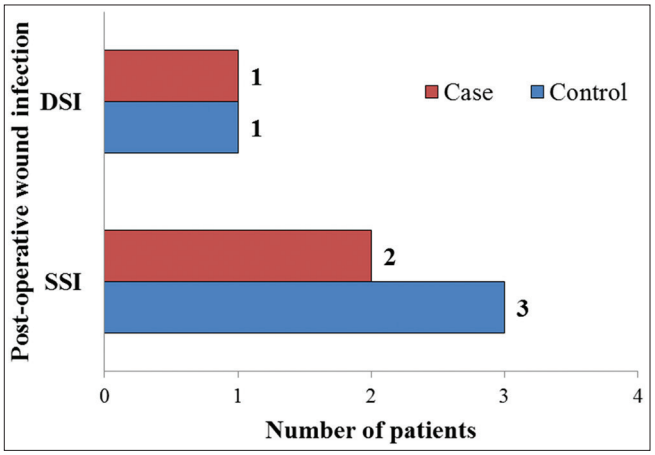

Figure 1: Post-operative wound infection among cases and controls

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

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

Table 2: Details of the patients with wound infection

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

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

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

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

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

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

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

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

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

DISCUSSION

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

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

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

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

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

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

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

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

CONCLUSION

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

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

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