

Original Article

The Role of Antibiotic Prophylaxis in Lichtenstein Repair of Primary Inguinal Hernia: A Prospective Double-Blind Randomized Placebo-Controlled Trial

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ABSTRACT

Objective: The objective is to study the role of antibiotic prophylaxis, if any, in the prevention of wound infection after open mesh repair of primary inguinal hernias. **Materials and Methods:** Patients coming to outpatient department for open mesh repair of inguinal hernia were randomized into the placebo group and antibiotic group, a total of 150 patients were enrolled in the study. Follow-up was done up to 1 month to look for any evidence of surgical site infection using the criteria of Centers for Disease Control on wound infection. **Results:** Twelve patients in the antibiotic group and nine patients in the placebo group were found to have evidence of surgical site infection. This difference was found to be insignificant with $P = 0.14$. Three patients in the placebo group developed deep surgical site infection but on analysis, this difference was also found to be insignificant with $P = 0.122$. None of these patients required mesh removal. **Conclusion:** The result of the present study suggests that the use of prophylactic antibiotics during mesh repair of primary inguinal hernias does not give any extra protection from infections. Multicenter meta-analysis is required to give definite guidelines regarding the use of prophylactic antibiotics.

KEYWORDS: Antibiotic, mesh inguinal hernia repair, prophylaxis

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INTRODUCTION

Inguinal hernia repair is among the most common surgeries performed by general surgeons.^[1] Tension-free mesh repair has emerged as one of the most popular techniques.^[2] The use of antibiotic prophylaxis to avoid surgical infections in mesh repair of groin hernia is routine in centers with high rates of infection and for patients with advanced age, recurrent hernia, use of steroids/drains, or emergency repair.^[3] Withholding the use of antibiotic prophylaxis in inguinal hernia repair could reduce the risks of toxic and allergic side effects, the possible development of bacterial resistance, or superinfections, reduced costs, and reduced hospital stay. Currently, the use of antibiotic prophylaxis for elective open mesh inguinal hernia repair is not universally accepted.^[4] Contradictory results from various reported clinical trials investigating the effectiveness of antibiotic prophylaxis have complicated this situation. Therefore, we decided to perform a randomized prospective

double-blind controlled trial to evaluate the effectiveness of antibiotics in mesh hernia repair.

MATERIALS AND METHODS

This study was conducted in the Department of Surgery, Maulana Azad Medical College, and Lok Nayak Hospital, New Delhi, from September 2011 to April 2013. The study population consisted of cases of inguinal hernias presenting to outpatient department of general surgery, Lok Nayak Hospital, New Delhi. In this period, 150 patients with primary unilateral inguinal hernia were included in the study provided they fulfilled the inclusion criteria. The patients were randomized into two groups, i.e., the antibiotic group

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receiving a single dose of antibiotic at the time of incision and control group which received a similar amount of placebo (normal saline) at the time of giving incision. The approval was obtained from the research and ethical committee of the institution before starting the study.

Exclusion criteria were

1. Patients with recurrent, irreducible, strangulated, bilateral, or femoral hernias
2. Patients with systemic disease (e.g., diabetes, liver, or renal impairment)
3. Patients receiving steroids for any reason
4. Patients younger than 18 years
5. Patients allergic to antibiotics
6. Patients who were using or had used antibiotics < a week before surgery
7. Immune-compromised patients
8. Patients with local skin infections or disease at the site of incision

Randomization was done using sealed envelopes containing random numbers generated by a computer. The envelopes were picked by a surgeon in the operation theatre who was not a part of the operating team. The patient and the operating surgeon were blinded toward the result of randomization.

The antibiotic used was 1.2 g of amoxicillin and clavulanic acid which is a broad-spectrum antibiotic. It was prepared in 20 ml of normal saline. Similar amount of placebo in the form of normal saline was used for the control group. The antibiotic and placebo were administered intravenously by the anesthetist at the time of incision. The anesthetist was also blinded.

Surgical procedure

Lichtenstein mesh repair was done by the same team on every patient.

Follow-up

All wounds were inspected before discharge and re-examined at the time of suture removal (7 days after the operation) and 4 weeks after discharge. The examination was done by a surgeon who was not a part of the surgical team and did not know whether the patient belonged to the control or antibiotic group. Patients were educated to report to the surgical outpatient clinic in case of any wound discharge, pain, or redness of wound up to 3 months.

Wound infections were categorized as superficial surgical site infection and deep surgical site infection (DSSI), according to the definitions of the Centers for Disease Control (CDC).^[5]

Statistical analysis

All data were analyzed using SPSS software (IBM, Chicago, US). A Chi-square test was used for nonparametric data. Fisher exact test and Student *t*-test were used for parametric data.

RESULTS

Of 150 patients, 75 were in the antibiotic group and 75 were in the placebo group. Both the groups were well matched for age, type of hernia, and side of hernia [Tables 1 and 2]. The mean age in the antibiotic group was 37.36 years, the youngest being 18 years and the oldest 75 years. The mean age in the placebo group was 40.12 years, with an age range from the lowest 20 years to a maximum of 72 years.

All of our patients were male.

Both groups were also well matched in the rate of postoperative complications other than SSI [Table 3].

Postoperative infection rate was also similar in the two groups. Twelve patients developed an infection in the antibiotic group and nine patients developed an infection in the placebo group. Three patients developed a deep infection in the placebo group while none patient developed a deep infection in the antibiotic group. No patient required mesh removal in our study. Patients were discharged on the 3rd postoperative day.

DISCUSSION

In the USA and Europe, around one million inguinal hernia repairs are being performed every year and India is likely to have the same figure.^[6] It is well documented that antibiotic use in “contaminated and dirty” surgical procedures (e.g., colorectal resection) can significantly prevent infectious complications, including wound infection, thereby reducing the overall mortality and morbidity. However, the benefit of antibiotic prophylaxis in “clean” surgical procedures, such as inguinal hernia surgery, is questionable. The low rate of wound infections and the straightforward simple treatment if they occur at all are the main arguments against routine antibiotic coverage during inguinal hernia surgery.

The issue of the role of antibiotic prophylaxis in elective hernia repair has been examined in several prospective trials during the past decade and the results are conflicting. This is because these studies differed in various aspects such as the difference in study design (retrospective, nonrandomized vs. prospective, randomized), surveillance methods (surgical team vs. independent observer), the definition of wound infection (no definition vs. CDC definitions), duration of follow-up, type of operation (mesh repair vs. nonmesh repair).

Table 1: Side of hernia and type of hernia in both groups

Hernia classification	Antibiotic group	Placebo group	P
Right/left	48/27	42/33	0.08
Direct/indirect	30/45	25/50	0.09

Table 2: Age distribution in both the groups

Age distribution (years)	Antibiotic group	Placebo group	P
18-20	7	6	0.21
20-30	15	14	0.16
30-40	14	18	0.11
40-50	15	12	0.13
50-60	9	10	0.18
60-70	9	12	0.14
>70	6	3	0.12

Table 3: Number of postoperative complications in both the groups

Complication	Antibiotic group	Placebo group	P
Urinary retention	3	6	0.16
Scrotal edema	3	0	0.12
Seroma formation	0	0	1
Nerve entrapment	0	0	1
Ischemic orchitis	0	0	1
Infection at discharge	2	3	0.3
Infection at suture removal	6	6	0.23
Infection after one month	4	0	0.59
Total infection	12	9	0.14
SSSI	12	6	0.06
DSSI	0	3	0.12
Mesh removal	0	0	1

SSSI: Superficial surgical site infection, DSSI: Deep surgical site infection

The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.^[7] In our study, the overall infection rate is 14%, in patients undergoing elective mesh repair of primary inguinal hernias. In our study, the overall incidence of wound infection was higher than reported in the literature, but this can be due to a small sample size and type I error. Most of the SSI was discovered during follow-up in the out-patient clinic and superficial in tandem with previous studies.^[6,8-12]

The incidence of mesh infection reported in the literature varies from 0.35% to 1%.^[8] The incidences of deep SSI was 2% in our study. None patient had mesh removal due to SSI in our study. In a study on chronic mesh infection following mesh hernioplasty, all 15 patients required mesh removal, time from hernia repair to mesh removal was between 4 and 204 months.^[13] Johonet *et al.* studied

45 cases of mesh infection in 38 patients, 33 patients recovered after mesh removal was done.^[14] Filippou D reported a case of mesh infection in an inguinal hernia, 12 years after surgery.^[15] Initially, conservative management with excision of sinus tract was done but sinus recurred and mesh had to be removed.^[15]

In cases of SSI and especially DSSI, the risk of recurrence should also be evaluated. However, the results of the Celdran^[9] using prosthesis suggested that the occurrence of infections does not increase the rate of recurrence. Even when the removal of the mesh has been necessary to resolve the infection, the fibrotic reaction around the posterior wall of the inguinal canal may prevent the recurrence. No recurrence was noted in our study in infected patients. However, the follow-up time of our patients is less.

Thus after inguinal hernia repair incidence of infection is low. Moreover, the infections which occur are mostly superficial and do not involve the mesh. These facts necessitate the need to reevaluate the need for antibiotic prophylaxis in open mesh repair of inguinal hernias. One study suggested the use of preoperative antibiotics in inguinal hernia patients with urinary tract infection to have better postoperative outcomes and to reduce the recurrence rate.^[16]

CONCLUSION

The results of the study suggest that antibiotic prophylaxis as such does not prevent wound infection in patients undergoing elective repair of primary inguinal hernias. The rate of infection in both antibiotic and placebo group were almost similar. However, studies involving a larger number of patients are required to resolve the issue. Further investigations are required to identify risk factors for the development of infection, so that subset of patients, who may benefit from the use of antibiotics, may be identified.

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Conflicts of interest

There are no conflicts of interest.

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