

Role of Antibiotic Prophylaxis in Open Inguinal Hernioplasty (Lichtenstein Hernia Repair): A Prospective Randomized Controlled Study

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Abstract

Background: Of all abdominal hernia, inguinal hernia is the most common hernia presenting in groin part of abdomen and open inguinal hernioplasty (Lichtenstein hernia repair) is one of the most commonly performed general surgery. Surgical site infections (SSIs) are the most common complications secondary to hernia repairs. Use of antibiotic prophylaxis in open inguinal hernioplasty (Lichtenstein hernia repair) is a conflicting issue for prevention of SSI. In the present study we compared the rate of postoperative wound infections in patients of antibiotic prophylaxis group and placebo group so that unnecessary use of antibiotics could be avoided.

Method: The present study was a prospective randomized controlled study of 100 cases of open inguinal hernioplasty (Lichtenstein hernia repair) which was done over a period of 15 months from April 2017 to June 2018. 50 patients in antibiotic group received antibiotic ceftriaxon 1 gm and another 50 patient in placebo group received no antibiotic.

Results: Mean age of patients was 45.86±15.49 years in antibiotic group and 43.14 ± 15.44 years in placebo group with range of 18-70 years. All the patients were males and most of the patients were from rural area (78%). Totally 3 patients developed surgical site

infection (3%). In antibiotic group, one patient with superficial SSI and in placebo group, two patients, one with superficial SSI and another with deep SSI were noted (p value =0.557).

Conclusion: There was no clear benefit of administering prophylactic systemic antibiotics for open inguinal hernioplasty (Lichtenstein hernia repair) as use of prophylactic antibiotics did not significantly reduced the incidence of wound infections.

Keywords: Antibiotic Prophylaxis; Inguinal Hernioplasty; Surgical site infections (SSIs).

Introduction

Hernia is a protrusion of a viscus or part of viscus through a normal or abnormal opening in the walls of its containing cavity.¹ Inguinal hernia surgery is one of the most commonly performed general surgery.² Open inguinal hernioplasty (Lichtenstein hernia repair) is traditionally considered as one of the so-called clean operative procedure but some surgeons still use prophylactic antibiotics as use of antibiotics is considered one of the ways of prevention of postoperative wound infections.

Surgical site infections (SSIs) are the most common complications secondary to hernia repairs.^{3,4} Infections following hernia repair result fourfold increased chance of hernia recurrence particularly in herniorrhaphies.^{5,6} SSIs are also the most common nosocomial infections and constitute 38% of all infections in surgical patients. By definition they can occur anytime from 0 to

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30 days after the operation or up to 1 year after a procedure that has involved the implantation of a foreign material (mesh, vascular graft, prosthetic joint and so on). Incisional infections are the most common; they account for 60% to 80% of all SSIs and have a better prognosis than organ/space related SSIs do, with the later accounting for 93% of SSI related mortalities.

Antibiotics prophylaxis has been suggested the most effective way to prevent SSIs. Some studies have identified risk factors for SSIs such as sex (more in women), age (greater in older), comorbidity, operative time, prosthesis, use of drainage and hypoalbuminemia.⁷ SSI is related with an increase in length of stay and costs and a decrease in quality of life.^{8,9} With ongoing use of antibiotics although mortality is decreasing but morbidity is increasing owing emergence of antibiotics resistant bacteria. Antibiotic prophylaxis in inguinal hernia surgery is controversial, especially after the increasing use of mesh implant.²

Most of the randomized studies and their meta-analysis showed no significant difference in the occurrences of postoperative infectious complications between the prophylactic antibiotic group and no prophylactic group. Thus, they all concluded that prophylactic antibiotics were not needed or warranted for low risk open inguinal hernioplasty. Indeed, several trials included in this meta-analysis also pointed out that a larger sample size would be necessary to detect significant difference because of the rarity of complications.

Routine use of antibiotic prophylaxis in mesh repair of inguinal hernia can lead to bacterial resistance and increase in hospital costs.¹⁰⁻¹³ As it is a commonly performed clean surgical procedure and indiscriminate use of antibiotic will have influence in cost benefits, bacterial resistant emergence and also possibility of reducing allergic effects and toxicity of antibiotics. We therefore conducted a prospective randomized controlled study in our hospital to evaluate the role of antibiotic prophylaxis in open inguinal hernioplasty (Lichtenstein hernia repair).

The purpose of study was to look for infectious complications after elective open inguinal hernioplasty (Lichtenstein hernia repair) in two groups and whether antibiotic prophylaxis was useful or not in preventive these complications. The cases selected were without other comorbid status such as patients with immuno-suppression, patients having diabetes mellitus or patients on regular corticosteroids and so on. The data collected from study was analyzed and discussed in light of available literatures.

Materials and Methods

This was a hospital based study, conducted in department of General Surgery, S. P. Medical College & A. G. of PBM Hospitals, Bikaner, Rajasthan. This was a prospective randomized controlled study comparing the prophylactic use of antibiotic ceftriaxone (Group A) versus placebo (Group B) in open inguinal hernioplasty (Lichtenstein hernia repair).

Study place – Department of General Surgery, S. P. Medical College & A. G. of PBM Hospitals, Bikaner, Rajasthan.

Study design – Hospital based prospective randomized controlled study.

Study population – All the patients between 18 and 70 years of age requiring open inguinal hernioplasty (Lichtenstein hernia repair).

Sampling technique – Simple random sampling (Lottery method).

Sample size – 50 cases in each of the both groups; group A (antibiotic) and group B (non-antibiotic).

Duration of study – From 01/04/2017 to 30/06/2018.

Inclusion criteria

- Patients requiring open inguinal hernioplasty (Lichtenstein hernia repair) for inguinal hernia.

Exclusion criteria

- Patients with unwillingness to join study.
- Patients who were pregnant.
- Patients with Age <18 or >70 years.
- Patients with incision site infections like tinea cruris, complicated hernia (obstructed and strangulated).
- Patients with immunocompromised status like with steroid medication, malignancy, diabetes mellitus, cirrhosis, HIV, etc.
- Patients with antibiotic intake owing other reasons.

Procedure of Data Collection

After admission, informed written consent was obtained from patients fulfilling the inclusion criteria. The findings of history, clinical examination, and demographic characteristics were noted for each patient. All patients were evaluated

by thorough clinical examination, followed by routine investigations including hemogram, renal function tests, liver function tests, chest X-ray, thyroid function tests, and FNAC.

Open inguinal hernioplasty (Lichtenstein hernia repair) was done after overnight fasting. The groin of the patient was prepared by trimming or clipping of the groin hair in previous night. The surgical site was prepared by painting povi-done iodine solution (10%) for 3–5 minutes before surgery. The operation was performed by faculty or by resident assisted by a senior surgeon in supine position of the patient. A standard open Lichtenstein hernia repair was performed as described by Lichtenstein Hernia Institute.¹⁴ A monofilament polypropylene flat mesh was sutured in place using monofilament polypropylene (prolene). Types of skin closure and anesthesia were not standardized.

The patients were to be randomized in two groups of equal size with simple randomization technique (Lottery method). Patients in the Antibiotics prophylaxis group (Group A) were given a total of three 1 gm doses of intravenous ceftriaxone; the first, just before skin incision, and the second and the third at 12h and 24h respectively, after the operation. Patients in the no antibiotics prophylaxis group (Group B) were received no antibiotics.

Data Analysis

To collect required information from eligible patients a pre-structured pre-tested pro forma was used. For data analysis Microsoft excel and statistical software SPSS was used and data was analyzed with the help of frequencies, figures, proportions, measures of central tendency, appropriate statistical test.

Results

This was a hospital based study, conducted in department of General Surgery, S. P. Medical College & A. G. of PBM Hospitals, Bikaner, Rajasthan. This was a prospective randomized controlled study comparing the prophylactic use of antibiotic ceftriaxon (Group A) versus placebo (Group B) in open inguinal hernioplasty (Lichtenstein hernia repair).

Hundred patients who met inclusion criteria were selected for the study after obtaining written consent. Patients were divided into two groups, 50 patients in case group received antibiotic ceftriaxone (Group A), 50 patients in control group (Group B) received no antibiotics. The patients were

followed-up for 4 weeks duration after surgery.

In our study in the both groups the majority of numbers of patients were between the 18 and 40 years of age. Mean age in group A was 45.86 ± 15.49 years and in B Group was 43.14 ± 15.44 years (Table 1).

Table 1: Distribution of patients according to their age

Sr. No.	Age Distribution (in years)	Group A	Group B
1	18–30	12(24%)	12(24%)
2	31–40	10(20%)	11(22%)
3	41–50	7(14%)	13(26%)
4	51–60	13(26%)	5(10%)
5	60–70	8(16%)	9(18%)
	Total	50(100%)	50(100%)

In our study maximum patients were from rural area (78% out of the total 100 patients). Distribution of rural patients in group A was 76% and in group B was 80%. Distribution of urban patients in group A was 24% and in group B was 20% (Table 2).

Table 2: Distribution of patients according to their place of residence

Area	Group A	Group B
Rural	38(76%)	40(80%)
Urban	12(24%)	10(20%)
Total	50(100%)	50(100%)

Postoperative wound infection developed in one patient (2%) in the case group A and two patients (4%) in the control group B. The difference in both groups was statistically insignificant with p-value 0.557 (Table 3).

Table 3: Postoperative wound infection rate in both groups

Postoperative wound infection	Group A (n=50)	Group B (n=50)
Wound infection	1(2%)	2(4%)
No infection	49(98%)	48(96%)
Total	50(100%)	50(100%)
p-value	0.557	

In the group A, one patient with superficial surgical site infection (SSSI) and in group B, two patients, one with superficial surgical site infection (SSSI) and another with deep surgical site infection (DSSI) were noted. The patients with superficial surgical site infection 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.

The patient with DSSI in group B developed purulent pus discharge from the wound on 10th postoperative day (POD) and immediate drainage of the wound was done and pus sent of culture sensitivity. Patient was initially started on Cephalosporins and later on broad spectrum antibiotics were added based on culture sensitivity. Discharge gradually reduced over time and the wound healed over the 3 months period. There was no need of mesh removal.

Discussion

In this study, open inguinal hernioplasty (Lichtenstein hernia repair), which is a very common surgical procedure in general surgical units, was taken for study to compare the rate of postoperative wound infections in patients of group A and group B that is antibiotic prophylaxis and no antibiotic group, respectively. In this study, 50 cases in each group were randomly taken for the study.

In this study of 100 patients operated for open inguinal hernioplasty (Lichtenstein hernia repair), one patient developed superficial surgical site infection (SSSI) in each group and one patient developed deep surgical site infection (DSSI) in group B after the patients were discharged. All postoperative wound infections were reported beyond 4th day after surgery.

In group A of prophylactic antibiotic (Ceftriaxone 1 gm), one patient who developed wound infection had signs and symptoms of SSSI without systemic signs. So the rate of wound infection was found 2% in prophylactic antibiotic group A. In group B of no antibiotic, two patients who developed wound infection had signs and symptoms of SSSI in one patient and DSSI in another patient without systemic signs. So the rate of wound infection was found 4% in no antibiotic group. The difference in both groups was statistically insignificant with p -value 0.557.

In 2004, Aufenacker *et al.*¹⁵ did a study to determine whether the use of prophylactic antibiotics is effective in the prevention of postoperative wound infections after Lichtenstein open mesh inguinal hernia repair. There were 8 wound infections (1.60%) in the antibiotics prophylaxis group and 9 wound infections (1.80%) in the placebo group ($p = 0.82$). There was 1 deep wound infection in the antibiotic prophylaxis group and 2 deep wound infection in the placebo group ($p = 0.57$).

In 2005, Perez *et al.*¹⁶ also concluded similar results like Aufenacker *et al.*¹⁵ study. Superficial SSI

developed in 3 patients (1.70%) from the antibiotic group and 6(3.30%) from the placebo group ($p=0.50$). One from each group developed deep SSI.

In 2007, Tzovaras *et al.*¹⁷ described that hernia repair was one the so-called clean operations. Many surgeons, however, were using antibiotics, especially in the mesh hernia repair era, without strong evidence to support the policy. The two groups were comparable regarding demographic data. Of total, 19(5%) cases with infectious complications were detected. 14 cases of these had wound infections (3.70%). There were 5 cases of wound infections in group A and 9 cases of wound infections in group B ($p=0.4$, Fisher's exact test).

In 2010, Thakur *et al.*¹⁸ described that there was ambiguity about the use of antibiotic prophylaxis in inguinal mesh hernioplasty. They tried to assess the efficacy of antibiotic prophylaxis in this procedure. The groups were well matched for all variable studies excluding wound infections, which occurred at rate of 10.34% ($n=3$) in antibiotic group and 15.38% ($n=4$) in placebo group ($p \geq 0.01$).

In 2012, Sanchez-Manuel *et al.*¹⁹ (Cochrane meta-analysis) concluded that "administration of antibiotics prophylaxis for elective inguinal hernia repair cannot be universally recommended". They also stated that "antibiotic prophylaxis cannot either be recommended against when high rates of wound infection are observed". Overall infection rates were 3.10% and 4.50% in prophylaxis and control group, respectively (OR 0.64, 95% CI 0.50–0.82). The subgroups of patients with hernioplasty had infection rates of 2.40% and 4.20% in prophylaxis and control groups, respectively (OR 0.56, 95% CI 0.38–0.81).

In 2013, Wang *et al.*²⁰ described that wound infection was one of possible complications after prosthetic material hernia repair surgery. Antibiotic prophylaxis was being routinely applied in China; but its effects were controversial. Their study aimed to offer direct clinical evidence on prevention of wound infections after tension-free inguinal hernia repair. Surgical site infections including wound infections, cellulitis or mesh-related infections were found in 20 cases (5.10%) of the control group, 15 cases (3.92%) of Cefozolin group and 17 cases (4.42%) of Levofloxacin group, and difference among the three groups was not statistically significant ($p = 0.803$).

On the other hand, Yerdel *et al.*²¹ reported that a decrease of 9% infection rate was found by the use of prophylactic antibiotics. A meta-analysis by Gravante *et al.*²² stated that infection rate of 1.70% in the antibiotics group and 3.70% in the placebo

group were found in patients using mesh. Some studies included only assessed low-risk patients, so conclusion could be applied solely to these kind of patients.⁴

Our study was also comparable to other mentioned studies and similar to our study, most of the studies concluded that antibiotic prophylaxis did not seem to affect the incidence of SSIs and was not necessary for elective open inguinal hernioplasty (Lichtenstein hernia repair). The potential drawback of this study was a smaller study population. Depending on the sample size formula and base rate of SSI, to perform a randomized controlled trial with enough power to detect a 50% decrease in SSI rates, it is necessary to include 1600 to 3000 patients. So, larger study population is needed to detect even smaller percentage decrease in SSI. Another drawback was that we followed-up the patients only up to four weeks duration postoperatively but according to CDC criteria, if implant is used, then any infection occurring up to 1 year will be considered as SSI. But development of SSI after one month of hernia surgery is rare.

It should be noted that studies in which the rates of SSI were higher had reported that prophylactic antibiotics were beneficial, whereas similar conclusion could not be derived in the studies with low rates of SSI. Therefore, surgeons and hospitals must assess their own SSI rates to define if prophylactic antibiotics are being widely used in all patients.¹⁷ It is concluded that the decision to use prophylactic antibiotic, therefore, must be based on balancing possible benefits against adverse effects.²³

It is already mentioned that clean operation is a procedure with no mistakes in sterilization, and with no leaks in the digestive, respiratory and urinary tracts. The four sources of infections are the medical staff, sterilization techniques, environment, and patient risk factors. A surgeon should be able to minimize such factors. Antibiotics should not be used to replace proper aseptic and antiseptic methods; along with good surgical techniques and proper tissue handling, infections can be prevented.²⁴

Conclusion

Our study showed that there was no clear benefit in administering prophylactic systemic antibiotics for open inguinal hernioplasty (Lichtenstein hernia repair). Thus, it can be concluded from our study that regular use of antibiotic prophylaxis is not necessary in low- risk patients undergoing open inguinal hernioplasty (Lichtenstein hernia repair).

References

1. Andrew N, Kingsworth, Giorgi G, David HB. Chapter 57: Hernia, Umbilicus and Abdominal Wall. Bailey & Love's Short Practice of Surgery, 25th edition.
2. Jain SK, Jayant M, Norbu C. The role of antibiotic prophylaxis in mesh repair of primary inguinal hernias using prolene hernia system; A randomized prospective double-blind control trial. Trop Doct 2008;38:80-2.
3. Bendavid R. Complications of groin hernia surgery. Surg Clin North Am 1998;78:1089-103.
4. Sanabria A, Dominguez LC, Valdivieso E. Prophylactic antibiotics for mesh inguinal hernioplasty - A meta-analysis. Ann Surg. 2007; 245:392-6.
5. Glassow F. Is postoperative wound infection following simple inguinal herniorrhaphy a predisposing cause for recurrent hernia? Can J Surg 1964;91:870-71.
6. Meyers RN, Shearburn EW. The problem of recurrent inguinal hernia. Surg Clin North Am 1973;53:555-58.
7. Hennessey DB, Burke JP, Ni-Dhonocho T, Shields C, Winter D Mealy K. Preoperative Hypoalbuminemia is an Independent risk factor for the Development of Surgical Site Infection Following Gastrointestinal Surgery: A Multiinstitutional Study. Ann Surg. 2010; 252:325-9.
8. Yasunaga H, Ide H, Imamura T, Ohe K. Accuracy of economic studies on surgical site infection. J Hosp Infect 2007; 65: 102-7.
9. Obaidullah, Sabir S. Clinical audit of antibiotics use and infection rate in plastic surgery unit. J Coll Physician Surg Pak. 2001;11:103-5.
10. Mangram AJ, Horan TC, Pearson ML. Guideline for prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol. 1999;20:247-80.
11. Das S. A Manual on Clinical Surgery. Chapter 38: Examination of a case of hernia, pp- 436-48.
12. Platt R, Zaleznik DF, Hopkins CC, Dellinger EP, Karchmer AW, Bryan CS. Peri-operative antibiotic prophylaxis for herniorrhaphy and breast surgery. N Engl J Med. 1990;322:153-60.
13. Othman I. Prospective randomized evaluation of prophylactic antibiotics usage in patients undergoing tension free inguinal hernioplasty. Hernia 2011;15:309-13.
14. Lichtenstein IL, Shulman AG, Amid PK. The tension free hernioplasty. Am J Surg. 1989;157:188-93.
15. Aufenacker TJ, van Geldere D, van Mesdag T. The Role of Antibiotic Prophylaxis in Prevention of Wound infection after Lichtenstein Open Mesh Repair of Primary Inguinal Hernia- A Multicenter

- Double-Blind Randomized Controlled Trial. *Ann Surg.* 2004;240:955-61.
16. Perez AR, Roxas MF, Hilvano SS. A randomized, double-blind, placebo controlled trial to determine effectiveness of antibiotic prophylaxis for tension-free mesh herniorrhaphy. *J Am Coll Surg.* 2005;200:393-7.
 17. Tzovaras G, Delikoukos S, Christodoulides G, Spyridakis M, Mantzos F *et al.* The role of antibiotic prophylaxis in elective tension-free mesh inguinal hernia repair: result of a single centre prospective randomized trial. *Int J Clin Pract.* 2007;61(2):236-9.
 18. Thakur L, Upadhyay S, Peters NJ, Saini N, Deodher M. Prophylactic antibiotic usage in patients undergoing inguinal mesh hernioplasty – A clinical study. *Indian J Surg.* 2010;8(6):444-7.
 19. Sanchez-Manuel FJ, Lozano-Garcia J, Seco-Gil JL. Antibiotics prophylaxis for hernia repair. *Cochrane Database Syst Rev.* 2012;(2):CD003769.
 20. Wang J, Ji G, Yang Z, Xi M, Wu Y *et al.* Prospective randomized, double placebo controlled trial to evaluate infection prevention in adult patients after tension-free inguinal hernia repair *Int J Clin Pharmacol Ther.* 2013;51(12):924-31.
 21. Yerdel MA, Akin EB, Dolalan S. Effect of single-dose prophylactic ampicillin and sulbactam on wound infection after tension-free inguinal hernia repair with polypropylene mesh. *Ann Surg.* 2001;233:26-33.
 22. Gravante G, Venditti D, and Vincenzino F. The role of single shot antibiotic prophylaxis in inguinal hernia repair. *Annals of Surgery* 2008; 248: 496-97.
 23. Ansari A. S., Saddique M., and Azim W. Antibiotic Prophylaxis in Clean Surgery. *Biomedica.* 2005;21: 121-24.
 24. Rose PA, and Matti A. Prescribing Practices of Surgeons and Factors that Limit Adherence to the Philippines College of Surgeons Clinical Practice Guidelines on Antimicrobial Prophylaxis for Elective Surgical Procedures at the UP-PGH Surgical Wards. *Phil J Microbiol Infect Dis.* 2002;31: 107-124.

