

## The Role of Antibiotic Prophylaxis in Elective Tension Free Mesh Inguinal Hernioplasty Sunil Kumar Maini<sup>1\*</sup>, Neeraj Gupta<sup>1</sup>, Vikas Kumar Malviya<sup>2</sup>, Pradeep Kumar Saxena<sup>1</sup>

<sup>1</sup>Associate Professor, Department of General Surgery, RKDF Medical College and Research Centre, Bhopal, India

<sup>2</sup>Associate Professor, Department of General Surgery, LN Medical College and Research Centre, Bhopal, India

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### Abstract

**Objective:** To determine whether the use of prophylactic antibiotics is effective in the prevention of postoperative wound infection after open tension free repair of inguinal hernia. **Methods:** 150 Patients with a primary inguinal hernia repair were randomized in two groups. One group given a preoperative single dose of 1.5 g intravenous cephalosporin and the other group was given a placebo. Patients with recurrent hernias, immunosuppressive diseases, or allergies for the given antibiotic were excluded. Infection, seroma, wound dehiscence etc was defined and their incidence noted. Follow up of the patients were done at 1 week, 2 week and than 1 month. **Results:** Groups were well matched for all preoperative variables studied, including comorbid conditions. Superficial surgical site infection developed in 2 patients (1.7%) from the antibiotic group and 3 (3.3%) from the placebo group (p = 0.50). One from each group developed deep surgical site infection. Both patients were readmitted and underwent repeated debridement, which eventually resulted in graft loss. **Conclusion:** A low percentage of wound infection after primary open mesh inguinal hernia repair was found, and there was no significant difference between the antibiotic prophylaxis or placebo group. The results show that in primary hernia repair, antibiotic prophylaxis is not indicated in low-risk patients.

**Keywords:** Prophylactic Antibiotics, Postoperative Wound Infection, Tension Free Repair, Inguinal Hernia

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### Introduction

Mesh repair is the most popular technique for repair of inguinal hernia. Of the open mesh repair techniques, a tension-free repair of the weakened inguinal floor using a polypropylene mesh is mostly done nowadays. It is uncertain whether antibiotic prophylaxis is necessary as prevention against postoperative wound infections, which occur in 0% to 9% of inguinal hernia repairs. Few clinical trials have addressed this issue. One trial showed a significant (10-fold) decrease in wound infections with intravenous antibiotic prophylaxis in mesh repair, others did not. A Cochrane meta-analysis in 2003 concluded that "antibiotic prophylaxis for elective inguinal hernia repair cannot be firmly recommended or discarded" and "further studies are needed, particularly on the use of mesh repair." [1-8] More than 1 lakh inguinal hernia repairs are performed annually in India; therefore, any improvement in their treatment could have a large medical and economic impact. Especially a reduction in the number of wound infections would have a great impact. Conversely, discarding 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 and reduced costs. To assess if systemic antibiotic prophylaxis prevents wound infection in open inguinal hernia repair, a single center, double-blind placebo controlled randomized trial was performed in the our college. [3-6]

### Materials and Methods

**Inclusion criteria** Patients with a primary uni- or bilateral inguinal hernia and an indication for open hernia repair were eligible for the

study.

**Exclusion criteria:** Age under 35, the need for antibiotics for a different reason, immunosuppressive disease (diabetes mellitus, malignancy, HIV) or medication (glucocorticoid therapy), allergy to the given antibiotic, recurrent hernia, or the inability to get an informed consent.

**Consent:** Written consent was obtained from the relatives of patients after explaining them the nature and purpose of the study. They were assured that confidentiality would be strictly maintained. The option to withdraw from the study was always open.

### Methodology

The patients were double-blinded randomly assigned to either intravenous placebo or antibiotic prophylaxis. A pharmacist carried out randomization according to a computer-generated list.

### Data Collection and Follow-up

Data collection was standardized and performed by residents & surgeons. The patients were requested to return to the outpatient clinic at 1, 2, and 12 weeks for a standardized history taking and physical examination. In most cases, the surgeon who performed the operation did not perform the follow-up. In case of missing observations, the patients were contacted and a standardized telephone interview was performed.

### Endpoints

The primary endpoint of the study was wound infection. In this definition, superficial infection occurs within 30 days after operation and involves only skin or subcutaneous tissue; deep infection involves fascial and muscle layers. Seroma was defined as a collection of fluid that builds up under the surface of skin. Infections if occurs after one month was not considered to be surgery induced and was not included in study.

### Observation Chart

\*Correspondence

Dr. Neeraj Gupta

Associate Professor, Department of General Surgery, RKDF Medical College and ReserchCenter, Bhopal, India

E-mail: [neeraj5378@gmail.com](mailto:neeraj5378@gmail.com)

**Table 1: Baseline and Operative Characteristics of Patients**

S. No.	Characteristic	Antibiotic Prophylaxis [n=75]	Placebo [n=75]
1	Age in years	58.28+ 12.9	58.22+ 13.2
2	Sex		
	Male	72 [96%]	73 [97.33%]
	female	03[4%]	02[3.66%]
3	Characteristic of hernia		
a	Direct	32 [42.67%]	34 [45.33%]
b	Indirect	40 [53.33%]	39 [52%]
c	combined	3 [4%]	2 [2.67%]
4	Disinfection by iodine/Betadine	75 [100%]	75 [100%]
5	Duration of Surgery in min.	35 min.	35 min.
6	Mean Incision length in cms.	8	7.5

The variables studied were randomized and the two groups were almost statistically similar .The mean age in years was between 58 - 60 years. Both groups had male predominance as evident from the table. Both groups had almost equal no. of direct and indirect

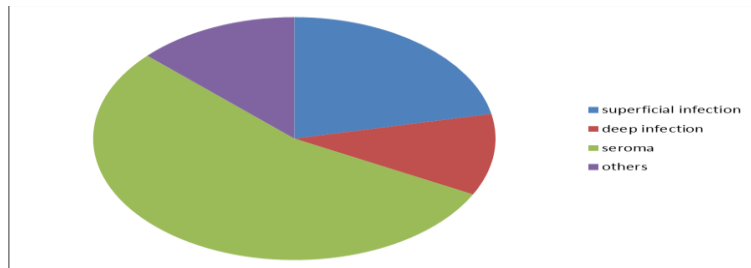
inguinal hernias which were completed in 35 min of mean surgery time [p<.05%] and the mean incision length was 8cm. [p<.05%] In both groups ,the surgical site was adequately scrubbed with betadine scrub and than painted with 10% iodine solution .

**Table 2: Postoperative Complications**

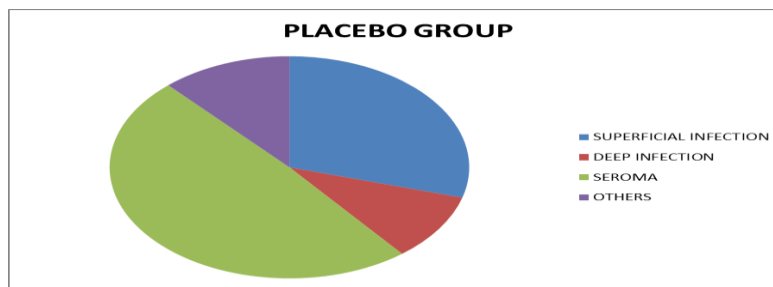
S. No	Variable	Antibiotic Prophylaxis N=75	Placebo N=75
1	Wound infection	3 [4%]	4[5.33%]
	Deep	1[1.33%]	1[1.33%]
	Superficial	2[2.67%]	3[4%]
2	Seroma	5[6.67%]	5[6.67%]
3	Wound dehiscence	0	0
4	Removal of infected mesh	1[1.33%]	1[1.33%]
5	Urinary tract /other infections	2[2.67%]	3[4%]

Table 2 shows postoperative complication in both groups . Superficial infection occurs within 30 days after operation and involves only skin or subcutaneous tissue .The antibiotic group had 2 and placebo had 3 superficial infection patients [p<.05%]; deep infection involves fascial and muscle layers and we saw one patient

in each group [p<.05%]. Both patients were readmitted and underwent repeated debridement, which eventually resulted in graft loss. Seroma was defined as a collection of fluid that builds up under the surface of skin.



**Fig 1:Antibiotic Prophylaxis Group**



**Fig 2:Placebo Group**

**Results**

Groups were well matched for all preoperative variables studied, including comorbid conditions. The variables studied were randomized and the two groups were almost statistically similar .The mean age in years was between 58 -60 years. Both groups had male

predominance as evident from the table. Both groups had almost equal no. of direct and indirect inguinal hernias which were completed in 35 min of mean surgery time [p<.05%] and the mean incision length was 8cm. [p<.05%] In both groups ,the surgical site was adequately scrubbed with betadine scrub and than painted with

10% iodine solution .Superficial surgical site infection developed in 2 patients (1.7%) from the antibiotic group and 3 (3.3%) from the placebo group ( $p = 0.50$ ). One from each group developed deep surgical site infection. Both patients were readmitted and underwent repeated debridement, which eventually resulted in graft loss.Seroma was formed in 5 patients of each group.Nointervention ,apart from tight dressing was required .It slowly absorbed in a months time.

#### Statistical Analysis

The power of the trial ( $\alpha = 0.05$ ,  $\beta = 80\%$ , 2-sided) was based on the assumption that antibiotic prophylaxis reduces the wound infection rate from 4% (average in literature) to 1%. Continuous normally distributed data are expressed as median with 25% to 75% quartiles.  $\chi^2$  or Fisher exact test tests were used to compare proportions. Multivariate analysis of various risk factors (when  $P < 0.10$  in univariate analysis) for infection was performed with binary logistic regression analysis. For all analyses, the SPSS package was used. All analyses were made under the guidance of an epidemiologist.

#### Discussion

Antibiotic prophylaxis is being commonly used in mesh repair of inguinal hernia but its role has been questioned in a recent Cochrane analysis performed in 2003. Routine use of antibiotic prophylaxis in mesh repair of inguinal hernia can lead to bacterial resistance and increase in cost. Since there is no benefit in the use of antibiotic prophylaxis for inguinal hernia repair in low-risk patients, its use is not cost-effective. Because of an unknown impact on bacterial resistance the use of routine antibiotic prophylaxis in primary inguinal hernia repair should be discouraged. The cost benefit for patients is relatively limited . However, because of the large number of inguinal hernia repairs performed in low-risk patients (estimated 70% of all hernias), discarding the use of antibiotic prophylaxis will save a huge amount of money.Yerdel MA et al saw the effect of single-dose prophylactic ampicillin and sulbactam on wound infection after tension-free inguinal hernia repair with polypropylene mesh in a randomized, double-blind, prospective trial. Patients were evaluated 1 week, 1 month, 6 months, and 1 year after surgery by an independent surgeon. All complications were recorded. Results were assessed using chi-square, Fisher's exact, and Student t tests as appropriate.This study documented a significant (10-fold) decrease in overall wound infections when single-dose, intravenous AS was used during Lichtenstein hernia repair. Deep infections and wound infection-related readmissions were also reduced by the use of AS. Proponents of mesh repairs may therefore be advised to use prophylactic single-dose intravenous antibiotic coverage in the light of the results of this trial. AS proved to be an effective antimicrobial agent.[1] Zhuo Y et al saw the effectiveness of iv cefuroxime prophylaxis of surgical site infection after elective inguinal hernia repair with mesh in a retrospective observational study. The purpose of this study was to determine the effectiveness of prophylactic antibiotics for prevention of SSI after elective inguinal hernia repair with mesh and the risk factors for SSI.The variables which could influence the rate of SSI were analyzed by multivariate analysis to determine the independent risk factors for SSI.All infections were superficial. Factors independently associated with SSI were advanced age, smoking and preoperative stay.The incidence of SSI among low-risk patients who did and did not receive preoperative antibiotic prophylaxis after elective inguinal hernia repair with mesh differed significantly, particularly among patients of advanced age, smokers and patients with a prolonged preoperative stay in the hospital.[2]

In another study ,Terzi C et al compared single-dose oral ciprofloxacin compared with single-dose intravenous cefazolin for prophylaxis in inguinal hernia repair.The primary outcome was to determine the wound infection rate within one year. There was no statistically significant difference between groups ( $P=0.59$ ). All the infections were superficial incisional surgical site infections, and none progressed to a deep infection. Oral ciprofloxacin prophylaxis was found to be an attractive option with its wide antibacterial

spectrum, low cost and ease of administration in patients undergoing tension-free inguinal hernia repair with polypropylene mesh.[3]

A randomized double blind placebo controlled clinical study was done by Thakur L et al on prophylactic antibiotic usage in patients undergoing inguinal mesh hernioplasty.Study included 55 patients who underwent an inguinal mesh hernioplasty over a 2 year period. The patients were evaluated for the status of the suture line as well as the presence of wound infection.It did not document any statistically significant difference observed between those who received antibiotics and those receiving placebo in terms of any of the prognostic end points evaluated for Lichtenstein mesh hernioplasty.[4]Tzovaras G et al in a single-centre prospective randomised trial elaborated the role of antibiotic prophylaxis in elective tension-free mesh inguinal hernia repair.They divided patients in two groups .The two groups were comparable regarding demographic data. In total, 19 (5%) cases with infectious complications were detected. Fourteen of these were wound infections (3.7%). There were five cases of wound infection in group A and nine in group B ( $p=0.4$ , Fisher's exact test). All wound infections were treated with antibiotics. The wound was opened in some cases. Mesh removal was not required in any of the cases. From the results of this study it does not appear that antibiotic prophylaxis offers any benefits in the elective mesh inguinal hernia repair.[5]Similar study was done by Perez AR et al .They conducted a prospective, randomized, double-blind, placebo-controlled trial comparing wound infection rates in 360 patients (180 received prophylactic antibiotics, 180 received a placebo) undergoing primary inguinal hernia repair electively using polypropylene mesh. Age, gender, American Society of Anesthesiologists class, type of hernia, type of anesthesia, and duration of operation were recorded. Infections were evaluated after operation by an independent surgeon. All complications were recorded. It was concluded that preoperative administration of single-dose antibiotic for tension-free inguinal mesh herniorrhaphy did not markedly decrease risk of wound infection in this patient population. Therefore their results do not support use of antibiotic prophylaxis for tension-free mesh herniorrhaphy.[6]Jain SK et al did a randomized prospective double-blind control trial. They studied the role of antibiotic prophylaxis in mesh repair of primary inguinal hernias using prolene . They did not find any benefit of the routine use of antibiotic prophylaxis in terms of wound infection rate. Aufenacker TJ et al in a multicenter double-blind randomized controlled trial studied the role of antibiotic prophylaxis in prevention of wound infection after Lichtenstein open mesh repair .They included 1040 patients in the study .It was concluded that a low percentage (1.7%) of wound infection after Lichtenstein open mesh inguinal (primary) hernia repair was found, and there was no difference between the antibiotic prophylaxis or placebo group. The results show that, in Lichtenstein inguinal primary hernia repair, antibiotic prophylaxis is not indicated in low-risk patients.[7,8]Celdrán A et al in a similar prospective, randomized, double-blinded trial , initiated to assess the efficacy of antibiotic prophylaxis in the prevention of wound infection during open mesh inguinal hernia repair under local anesthesia on an ambulatory basis. Ninety-nine consecutive hernia repairs were randomized to receive 1 g of parenteral Cefazolin preoperatively or a placebo. No wound infections existed in the therapeutic group (0/50). Four infections appeared in the control group (4/49), and the study was suspended for ethical reasons when differences reached values close to statistical significance ( $P=0.059$ ). So it was concluded that a single dose of intravenous antibiotic decreased the risk of wound infection during open mesh inguinal hernia repair under local anesthesia.[9]

Alexander JW et al proposed recommendations for control of surgical site infections. The objective of this study is to provide updated guidelines for the prevention of surgical wound infections based upon review and interpretation of the current and past literature.The Centers for Disease Control (CDC) provided extensive

recommendations for the control of surgical infections in 1999. Review of the current literature with interpretation of the findings has been done to update the recommendations. This review suggests that uniform adherence to the proposed guidelines for the prevention of surgical infections could reduce wound infections significantly; namely to a target of less than 0.5% in clean wounds, less than 1% in clean contaminated wounds and less than 2% in highly contaminated wounds and decrease related costs to less than one-half of the current amount.[10]

#### Conclusion

A low percentage of wound infection after primary open mesh inguinal hernia repair was found, and there was no difference between the antibiotic prophylaxis or placebo group. The results show that, in primary hernia repair, antibiotic prophylaxis is not indicated in low-risk patients.

#### What This Study Add to Existing Knowledge

Any improvement in the treatment of inguinal hernia could have a large medical and economic impact. Especially a reduction in the number of wound infections would have a great impact. Conversely, discarding 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 and reduced costs.

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