

## Original Research Article

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# Evaluation of administration of prophylactic antibiotics in mesh repair of inguinal hernia

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## ABSTRACT

**Background:** The benefit of use of prophylactic antibiotic in mesh inguinal hernia repair needs evaluation in view of emergence of resistant micro-organisms with indiscriminate use of antibiotics and also to avoid unnecessary expenditure.

**Methods:** 100 patients of primary inguinal hernia, fulfilling inclusion criteria, were recruited in a prospective, randomized, double blind study where single dose of prophylactic antibiotic half hour prior to mesh repair surgery was administered to 50 patients in study group and routine antibiotics to remaining 50 in control group. Follow up was done for any evidence of infection till one month after the surgery.

**Results:** The incidence of infection in both the groups was analyzed. Prophylactic antibiotic group reported to have an infection rate of 12% as compared to 10% in control group. Incidence of infection in both groups was 2% at time of discharge and 0% after one week, at the time of suture removal. Two week after discharge 6% in study and 4% in control groups had infection. After one month of surgery, incidence of infection was 4% in both prophylactic antibiotic group and control group. None of the patients required mesh removal and results was statistically similar in both groups.

**Conclusions:** The use of prophylactic antibiotic in our study was seen to be as effective as routine preoperative and postoperative antibiotics and should be recommended as it reduces the cost burden to the patient significantly and also prevents development of bacterial resistance to drugs.

**Keywords:** Hernia, Inguinal, Mesh, Prophylactic, Antibiotic

## INTRODUCTION

Abdominal wall hernias are common, with a prevalence of 1.7% for all ages and 4% for those aged over 45 years. Inguinal hernias account for 75% of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women.<sup>1</sup> Inguinal hernias present with a lump in the groin that goes away with minimal pressure or when the patient is lying down. Most cause mild to moderate discomfort that increases with activity.<sup>2</sup> Surgery is the treatment of choice varying from a nylon darn, open mesh repair,

should ice layered, Lichtenstein mesh to a laparoscopic repair. Mesh hernioplasty has gained wide spread acceptance due to its superior outcome in terms of reduced recurrence rates which are in the range of 1 to 2%. The Lichtenstein mesh hernioplasty is currently the most popular operative technique for open repair of inguinal hernia.<sup>3</sup>

The objective of groin hernioplasty is to prevent peritoneal protrusion through the myopectineal orifices. Hernias are repaired either anteriorly through groin

incision in which case the structure in and around the inguinal canal must be divided in order to reach the inner most aponeurotic fascial layer, or posteriorly through abdominal incision in which case, the hernial orifices are exposed directly on entry to the preperitoneal space.<sup>4</sup>

Lichtenstein presented his open mesh repair technique for inguinal hernia in 1986. The Lichtenstein technique has since become the most commonly used (with various modifications) on account of its ease of operation and because it provides a tension-free repair with good longterm results. The advantages of this repair were its association with less pain, rapid postoperative recovery, early return to normal activity and very low recurrence rate. Tension-free mesh repair is nevertheless associated with complications such as foreign body reaction, infection, pain (The incidence of chronic groin Pain following this procedure is reported to be as high as 75.5%), fistula formation, migration, shrinkage, and recurrence. Other complications include skin anaesthesia, bruising and haematoma formation, seroma formation, orchitis and testicular atrophy. A large number of materials have been tested but currently three are in common use: Polyester mesh (Dacron, Mersilene), Polypropylene (Marlex, Prolene) and expanded polytetrafluoroethylene (PTFE).<sup>5</sup>

The description of Lichtenstein tension free mesh repair introduced a new era in groin hernia repair.<sup>6</sup> The properties of polypropylene mesh that make it more acceptable than other types of mesh include readily inserted into any size without fragmentation, used in the groin without discomfort by the patient, less affected by infection, having high tensile strength, resistant to most chemicals, softening temperature 260<sup>0</sup> F (127<sup>0</sup> C) and so sterilization by boiling was not a problem.<sup>7</sup>

Groin hernia repair is traditionally considered a clean wound operation for which antibiotic prophylaxis is not indicated, since the estimated risk of surgical site infection (SSI) is very low (<1%).<sup>8</sup> It is currently considered as the preferred method for the plastic reconstruction of inguinal region. Inguinal hernia repair is one of the most common procedures performed by general surgeons. Even though hernia is classified as a clean surgery, the reported incidence of wound infection varies from 0% to 9%.<sup>9</sup> It whether antibiotic prophylaxis is necessary in all hernia surgeries as the infection rate is very low, even when a foreign body like mesh is used.<sup>10</sup> The majority of the randomized controlled trials (RCT) published on this topic have failed to prove any benefit from the use of antibiotic prophylaxis, although most of them were limited by having small cohorts.<sup>11</sup> A number of studies have reported a decrease in the incidence of SSIs when surveillance programs have been implemented that included the feedback of postoperative wound infection rates to practicing surgeons.<sup>12</sup>

The purpose of our study was to investigated the extent to which several moderators, such as patient characteristics,

surgical skill, duration of surgery, use of drainage and rate of SSI in patients not receiving antibiotics, could influence the correlation, if any, between antibiotic prophylaxis and SSI incidence..

## METHODS

The present study was conducted over a period of two years from September 2016 to October 2018 in Department of Surgery, Subharti Medical College after obtaining due ethical clearance. Consecutive patients attending surgical OPD with primary unilateral or bilateral inguinal hernia were included in the study provided they fulfilled the inclusion criteria. Surgical intervention with inguinal hernia mesh repair was performed in both groups. The study group was given Injection Cefaperazone (1 gm) as antibiotic prophylaxis half an hour prior to surgery with no further post-operative antibiotics whereas the control group was prescribed routine preoperative and postoperative IV antibiotics.

Exclusion criteria were patients with recurrent, irreducible, strangulated, bilateral, or femoral hernias; patients with systemic disease (e.g., diabetes, liver or renal impairment); patients receiving steroids for any reason; patients younger than 18 years; patients allergic to antibiotics; patients who were using or had used antibiotics less than a week before surgery; immune-compromised patients; patients with local skin infections or disease at site of incision; pregnancy or lactating patients

Patient proforma included demographic data and all other parameters including type of anesthesia and surgery, duration of surgery, antiseptic used for skin preparation, grade of surgeon, incidence of surgical site infection, all infectious complications and microorganism cultured/ isolated from patients with wound infections.

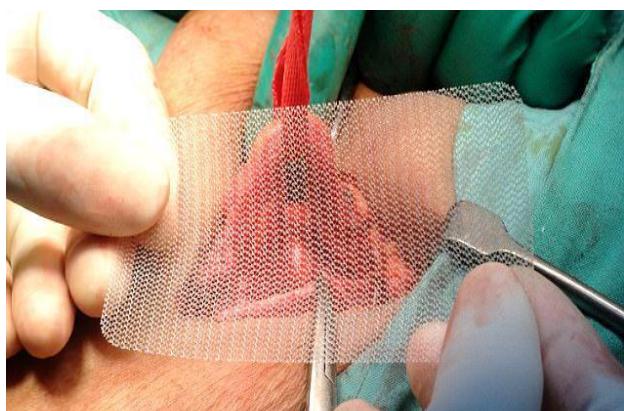
Patients were admitted a day before surgery when preoperative work-up was done. Informed consent was taken from all patients for participation in the study. Patients had option to leave study at any point of time without compromising their right to treatment. Proper informed consent was obtained from all the patients entering into the study and their anonymity was maintained. The study was performed after the approval from hospital ethical committee. 50 patients were randomized into antibiotic group and control group by sealed envelope method on the day before the surgery.

A standard Lichtenstein hernia repair was performed in all the cases. Monofilament polypropylene mesh (VYPROTM Prolene Ethicon) was used as prosthesis (Figures 1 and 2). Povidone iodine was the antiseptic used for skin preparation in all patients. Groin shaving was done the day before surgery. A standard sterile dressing was applied post operatively. No post-operative antibiotics were used. Dressings were removed at 48 h

after surgery, when the first wound inspection was done. No further dressings were applied. The patients were discharged next day with the advice of analgesics only.



**Figure 1: The separated hernial sac.**



**Figure 2: The mesh being placed in situ.**

Surgeon who was not involved in surgery followed the case after 1 week and 4 weeks postoperatively and wound inspected for any wound discharge, pain or redness in which case follow up was continued up to 1 month. Wound infections were categorized as superficial surgical site infection and deep surgical site infection, according to the definitions of centers for disease control. The primary end point of the study was wound infection, defined by ASEPSIS criteria and CDC criteria:

Superficial SSI was diagnosed using the following criterion: Infection occurs within 30 days after operative procedure and involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

- Purulent drainage from the superficial incision.
- Organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision.
- Superficial incision that is deliberately opened by a surgeon and is culture-positive or not cultured and

patient has at least one of the following signs or symptoms of infection: pain or tenderness; localized swelling; redness; or heat.

- Diagnosis of superficial SSI by the surgeon or attending physician.

Deep SSI was diagnosed using the following criterion: Infection occurs within 30 or 90 days after the operative procedure and involves deep soft tissues of the incision (e.g. facial and muscle layers) and patient has at least one of the following:

- Purulent drainage from the deep incision.
- A deep incision that spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and patient has at least one of the following signs or symptoms: fever ( $>38^{\circ}\text{C}$ ); localized pain or tenderness.
- An abscess or other evidence of infection involving the deep incision found on direct examination, during invasive procedure, or histopathology examination or imaging test.
- Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Thorough clinical examination was done to rule out surgical site infection. Wound infection was initially managed with dressing alone. If required even a suture was removed to let out the discharge. If there was no response or infection progressing, antibiotics were started. The outcome was analyzed with respect to superficial and deep surgical site infection (SSI).

#### **Statistical analysis**

All data was analyzed using SPSS software. Chi-square test was used for non-parametric data. Fisher exact test and Student test were used for parametric data.

#### **RESULTS**

Antibiotic and control group consisted of 50 patients each. The two groups were matched demographically with respect to age, sex, side and type of hernia. Mean age in the prophylactic group was 37.36 years and 39.13 years in control group, with the youngest patient of 18 years and the oldest patient of 75 years.

Out of the total 50 patients in the prophylactic group 30 (60%) patient had right sided hernia while 20 (40%) had left sided hernia. In the control group, 26 (52%) patients had right sided hernia while 24 (48%) had left sided in a total of 50 patients. When analyzed with respect to the type of hernia, the prophylactic group had 40 (80%) patients with an indirect hernia and 10 (20%) patients with direct hernia. The control group had 32 (74%) patients with an indirect hernia and 18 (36%) patients with a direct hernia. Overall 72 (72%) patients had an indirect hernia and 28 (28%) had a direct hernia (Table 1).

**Table 1: Demographic profile of patient.**

		Study group (n=50)	Control group (n=50)	Total
<b>Age (years)</b>	Mean value	37.36 years	39.13 years	Range 18-75 yrs
<b>Site of hernia N (%)</b>	Right	30 (60)	26 (52)	56 (56)
	Left	20 (40)	24 (48)	44 (44)
<b>Type of hernia hernia N (%)</b>	Direct	40 (80)	32 (64)	72 (72)
	Indirect	10 (20)	18 (36)	28 (56)

**Table 2: Wound infection in patients on follow up at discharge and after discharge.**

	Prophylactic group (n=50)		Control group (n=50)		(n=100)
<b>Time after surgery</b>	Infection present N (%)	Infection absent N (%)	Infection present N (%)	Infection absent N (%)	Total infected N (%)
<b>At discharge</b>	1 (2)	49 (98)	1 (2)	49 (98)	2 (2)
<b>At suture removal- one week after discharge</b>	0 (0)	50 (100)	0 (0)	50 (100)	0 (0)
<b>Two weeks after discharge</b>	3 (6)	47 (94)	2 (4)	48 (96)	5 (5)
<b>One month after discharge</b>	2 (4)	48 (96)	2 (4)	48 (96)	4 (4)

The incidence of infection at time of discharge was analyzed in both the groups. 1 (2%) patient in antibiotic group and 1 (2%) patient in control group had infection at the time of discharge. This difference is also statistically insignificant ( $p>0.05$ ). Patients were reassessed at time of suture removal, none of the patients had infection but on examination at 2 weeks after discharge, 3 (6%) patients in the prophylactic group had infection while 2 (4%) had infection in the control group. The incidence of infection at time of suture removal and two weeks after discharge is not significant between the two groups ( $p>0.05$ ). Patients were followed after one month of discharge and incidence of infection was seen. Two (4%) patients in antibiotic group had infection one month after discharge while 2 (4%) patient in control group had evidence of infection.

When analyzed using appropriate test this difference in infection rate between the two groups was found to be insignificant ( $p>0.05$ ). The incidence of deep SSI was 0% in our study. None patient had mesh removal due to SSI in our study (Table 2).

In our study, the overall infection rate is 11%, in patients undergoing elective mesh repair of primary inguinal hernias. The incidence of wound infection is 10% in the control group and 12% in the antibiotic group. Even though the incidence of wound infection is higher in the prophylactic group, it is not statistically significant ( $p>0.05$ ).

Swab for culture was taken from wound site in all wound infected patients. Out of the total of 11 patients having

wound infection maximum were culture positive for *Staphylococcus* and one was positive for *Klebsiella*. The 4 cases positive for streptococcus were all those who came for follow up one month after discharge and appear to be a secondary infection (Table 3).

**Table 3: Microorganisms isolated on culture in infected patients.**

Microorganisms	Total
<i>Staphylococcus</i>	6 (54.5%)
<i>Streptococcus</i>	4 (36%)
<i>Klebsiella</i>	1 (9%)

**Table 4: Number of other complications in both groups.**

Complication	Prophylactic group (n=50)	Control group (n=50)
	N (%)	N (%)
<b>Urinary retention</b>	1 (2)	2 (4)
<b>Hydrocele</b>	0 (0)	1 (2)
<b>Seroma formation</b>	2 (4)	2 (4)
<b>Orchitis</b>	0 (0)	0 (0)

Both the study groups were also assessed with respect to any other complication which occurred post operatively. Two patients in control group developed urinary retention post operatively. Both patients had to be catheterized and were discharged on catheter. Both these patients were

given de-catheterization trial at time of suture removal, which was successful.

One patient in antibiotic group developed retention of urine. This patient also had to be catheterized, which was removed at time of suture removal. One patient in antibiotic group also developed hydrocele which was detected at the time of suture removal. The patient was managed conservatively till one month after surgery.

When the patient was assessed one month after discharge, he was advised to follow up after six months for hydrocele surgery, but the patient was lost of follow up. The complications rate between the groups when analyzed was found to be statistically insignificant ( $p>0.05$ ) (Table 4).

## DISCUSSION

More than one million inguinal hernias repairs are being performed per year in the USA and Europe, and the figure is likely to be same for India. In earlier studies, the first randomized control trial on the role of antibiotic prophylaxis in mesh repair of inguinal hernia was done in 2001 by Yerdel et al, who advocated the use of prophylactic antibiotics.<sup>12</sup>

A cochrane meta-analysis on this topic in 2004 concluded that antibiotic prophylaxis in mesh repair of inguinal hernias can neither be recommended nor discarded. Since groin hernia repair is one of the most common surgical procedures worldwide both the inappropriate use of antibiotics and an excessively high rate of SSI are liable to have a major negative impact on health and social costs. Therefore, acquiring stronger evidence on this topic is even more essential.<sup>13,14</sup> Given the proximity of the groin region to the genitals and perineum, this finding raises the question of whether it would be better to consider this operation as a clean-contaminated procedure, for which antibiotic prophylaxis is mandatory.

It is well documented that antibiotic prophylaxis is recommended in 'clean-contaminated' procedures like colorectal resection as they can significantly decrease infectious complications such as incision infection. The antibiotic prophylaxis is also indicated in 'clean' surgeries' such as hip or knee arthroplasties, cardiac or vascular graft where foreign material is used.<sup>15</sup>

The main arguments against routine use of antibiotics prophylaxis in Lichtenstein hernia repair are that even infection occurs in the presence of antibiotics, overuse of antibiotics causes development of resistance, since large no of patients undergoes mesh repair so it has a huge cost on health budget, there are unknown chances of allergic reactions which may be fatal sometimes and if infection develops at all it can easily be treated.

Conversely if infection occurs after mesh repair then it has four-fold increase in recurrence rate and may need drainage and even mesh removal. So one can say that the presence of mesh does not increase the chances of infection but when infected then the consequences are severe.<sup>16</sup>

Tzovaras et al designed their study to determine whether antibiotic prophylaxis in elective open inguinal hernia repair with a prosthetic mesh is of any value.<sup>17</sup> Hernia repair is considered as one of the so-called 'clean' operations but this practice has become widely used following tension-free mesh repair technique for fear of infection of the introduced foreign body. However results of their study it did not suggest that antibiotic prophylaxis offers any benefits in the elective mesh inguinal hernia repair. Al-Fatah et al also concluded in the single-centre prospective randomized trial that antibiotic prophylaxis did not seem to offer any benefits in the elective mesh inguinal hernia repair.<sup>18</sup> Conversely Ullah et al, studied the efficacy of antibiotic versus placebo in 166 cases and found antibiotic prophylaxis to be a preferred option for mesh plasty.<sup>19</sup>

**Table 5: Incidence of total infection, superficial infection, deep infection and mesh removal.**

Author	Total infection	Superficial surgical site infection	Deep surgical site infection	Number of patient requiring mesh removal
	N (%)	N (%)	N (%)	
<b>Our study</b>	11 (11)	11 (11)	0 (0)	0
<b>Aufenacker et al<sup>7</sup></b>	17 (1.8)	14 (1.4)	3 (0.3)	0
<b>Celdran et al<sup>23</sup></b>	4 (4)	4 (4)	0 (0)	0
<b>Perez et al<sup>21</sup></b>	9 (2.4)	7 (1.9)	2 (0.5)	0
<b>Tzovaras et al<sup>17</sup></b>	14 (3.6)	14 (3.6)	0 (0)	0
<b>Yerdel et al<sup>12</sup></b>	13 (3.4)	9 (3)	4 (1.4)	3
<b>Jain et al<sup>26</sup></b>	2 (3.4)	2 (3.4)	0 (0)	0
<b>Shankar et al<sup>24</sup></b>	29 (6.4)	27 (6)	2 (0.4)	1
<b>Othman et al<sup>25</sup></b>	10 (10)	8 (8)	2 (2)	1
<b>Ergul et al<sup>22</sup></b>	12 (6)	12 (6)	0 (0)	0

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 like difference in study design (retrospective, non-randomized vs. prospective, randomized), surveillance methods (surgical team vs. independent observer), definition of wound infection (no definition vs. CDC definitions), duration of follow up, type of operation (mesh repair vs. non-mesh repair) (Table 5).

The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.<sup>2</sup> In our study, the overall infection rate is 11%, in patients undergoing elective mesh repair of primary inguinal hernias.

The incidence of wound infection is 10% in the control group and 12% in the antibiotic group. Even though the incidence of wound infection is higher in the prophylactic group, it is not statistically significant ( $p>0.05$ ). In our study the overall incidence of wound infection was slightly higher than reported in literature, but this can be due to small sample size and type I error.

The incidence of wound infection was 9% in the control group and 0.7% in the antibiotic group in the study done by Yerdel et al.<sup>12</sup> The authors showed a significant difference in wound infection between the antibiotic and control groups. Celdran et al reported SSI rates of 8% and 0% in the control and antibiotic group respectively and had similar conclusions.<sup>20</sup> Usang et al in his study on children also reported the same result as infection rate in placebo group (4.8%) was significantly more than in antibiotic group (0%).<sup>21</sup>

Aufenacker et al showed that the incidence of SSI was 1.8% in the control group and 1.6% in the antibiotic group.<sup>7</sup> The author concluded that prophylactic antibiotics did not prevent SSI in open mesh repair of inguinal hernias. The SSI rates reported by Perez et al were 3.3% and 1.7% in the control and antibiotic group respectively and the author did not find any benefit with prophylactic antibiotics.<sup>22</sup> A similar conclusion was drawn by Tzovaras et al who found the incidence of SSI in control and antibiotic groups as 4.6% and 2.5% respectively.<sup>17</sup>

Only 1 out of 7 patients in our study developed wound infection before discharge, whereas the rest of the wound infections were diagnosed during follow-up, most often during their first scheduled visit after suture removal, in the 2nd post-operative week. in the study done by Celdran et al, Usang et al, Perez et al.<sup>20,21,22</sup> all the infections were diagnosed after hospital discharge. So on study is in concurrence with literature Yerdel et al found 5 of 13 infections in his study during hospital stay within hospital diagnosis rate of 30.7%.<sup>12</sup> However the infection rate is very high in this study. Vast majority of SSI

occurring after hernia repair are superficial surgical site infection. 85% of the SSI of our study is superficial SSI. All the SSIs reported in the studies done by Tzovaras et al, Celdran et al, Ergul et al, Jain et al, and all were superficial SSI.<sup>17,20,23,26</sup>

The incidence of mesh infection reported in literature varies from 0.35% to 1%. The incidence of deep SSI was 0% in our study. None patient had mesh removal due to SSI in our study. Aufenacker et al reported an incidence of 0.3% for deep SSI in their study within a follow-up period of 3 months.<sup>7</sup> No patient in their study required mesh removal similar to our study. Perez et al reported a deep infection rate of 0.6% in both the groups.<sup>22</sup> They detected one patient in both groups to have deep infection and subsequent mesh removal was required in both of them.

Yerdel et al reported one patient (7%) with DISSI in antibiotic group and 3 (2.2%) patient in placebo group.<sup>12</sup> This difference was statistically insignificant with a p value of 0.367. Three patients of all patients in placebo group with DISSI required removal of mesh. However, recurrence rate at one year follow up was 0%.

The incidence of DISSI in study by Shankar was 6% with one patient in each group having deep infection.<sup>24</sup> One patient required mesh removal in their study. Othman also noticed one patient in each group with deep infection giving deep infection rate of 2%.<sup>25</sup> No patient required mesh removal.

In cases of SSI and, especially, DSSI, the risk of recurrence should also be evaluated. However, the results of the Celdran using prosthesis suggested that the occurrence of infections does not increase the rate of recurrence.<sup>20</sup> Even when the removal of the mesh has been necessary to resolve 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, follow up time of our patients is very small.

In order to detect a 50% difference between both groups (reduction of the actual rate from 4% to an appropriate rate of 2% in clean surgical procedures) and to have sufficient statistical power, a prospective, randomized blinded study should include at least 800 patients" in each treatment arm. This involves performing multicenter studies or studies with longer recruitment periods. This is the major limitation most studies face. Power of our study is small as we have enrolled very small number of patients and this is the major lacunae of our study.

## CONCLUSION

The result of our randomized, prospective, double blind study suggests that use of prophylactic antibiotic during mesh repair of primary inguinal hernias do prevent wound infection, if it has to happen, as efficiently as

patients receiving preoperative and postoperative IV antibiotics and lead to a considerable reduction in the cost of treatment for the patient. However, studies involving larger number of patients are still required to resolve the issue. Further investigations are required to identify risk factors for development of infection, so that subset of patients, who may benefit from use of antibiotic, may be identified. Even though more than 100 studies have been done on the subject, the topic is still open for debate.

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**Ethical approval:** The study was approved by the Institutional Ethics Committee

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