ISSN: 2394-0026 (P)
ISSN: 2394-0034 (O)

Original Research Article

Role of antibiotic prophylaxis in open inguinal hernioplasty – A prospective randomized clinical trial

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How to cite this article: N Vinoth, CRM Karthikeyan, Hiren Parmar. Role of antibiotic prophylaxis in open inguinal hernioplasty – A prospective randomized clinical trial. IAIM, 2015; 2(3): 57-67.

Available online at www.iaimjournal.com

Received on: 09-02-2015 **Accepted on:** 19-02-2015

Abstract

Background: Inguinal hernia surgery is the most commonly performed surgery worldwide. Lichtenstein tension free repair using polypropylene mesh is the gold standard procedure for inguinal hernioplasty. Wound infection is the most common complication encountered in any surgical procedure. Antibiotic prophylaxis for open inguinal hernioplasty in minimizing wound infection has been a subject of debate since the beginning of mesh repair. We have conducted a randomized clinical trial in our hospital to analyze the usefulness of antibiotics in open inguinal hernioplasty.

Material and methods: 60 patients were included in this prospective randomized control trial. 30 of them received 1 g of Injection Cefataxim half an hour before surgery and remaining 30 received injection Multivitamin infusion. Lichtenstein tension free hernia repair using polypropylene mesh was done. Superficial SSI was diagnosed according to CDC criteria.

Results: Totally 5 patients developed SSI (8.33%). Out of the five, 2 (6.67%) were in antibiotic group and remaining 3 (10%) were in placebo group (p = 0.64). Odd's ratio was 0.6429 (CI=0.0995 to 4.1531). All 5 had only superficial SSI; there was no deep surgical site infection (SSI). 2 patients were managed with dressing alone and remaining 3 with antibiotics. After 2 weeks, 2 had wound gapping and at four weeks wound was normal in all patients. 2 out of 5 were above 60 years of age and no SSI occurred >30 years of age (p value = 0.59).

Conclusion: Routine use of antibiotics is not necessary in all open inguinal hernioplasty. Antibiotics can be reserved only for patients who are in high risk of SSI. Regularizing the use of antibiotics will have a good cost benefit and decrease the emergence of drug resistant organisms.

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Key words

Open inguinal hernioplasty, Antibiotic prophylaxis, Surgical site infection.

Introduction

Hernia is a protrusion of a viscus through an abnormal opening in the walls of its containing cavity [1]. 75% of all hernia occurs in groin and inguinal hernia is the most common form of all [2]. Inguinal hernias can be either congenital or acquired. Congenital hernias usually occur when there is impedance in normal developmental process rather than an acquired weakness [2]. This is because of patent processus vaginalis (PPV) and this explains the higher incidence of congenital hernias in preterm babies. Acquired hernia can be direct, indirect or combination of both. In adult males 65% of inguinal hernias are indirect and 55% of them are right sided [2]. Cause of the hernia is multi-factorial. Increased intra abdominal pressure and weak abdominal wall are the basis of hernia formation. Inguinal hernia surgery is the most commonly performed surgery worldwide [3]. About one third of the surgical interventions made by general surgeons are inguinal hernia repair [4]. Mesh repair has become the most popular technique in the West for inguinal hernia since 1975 [5, 6, 7, 8, 9]. In the United States and Europe more than ten lakhs hernia surgeries are performed annually and the figure is nearly equal in India [3, 10]. First mesh repair was used for recurrent hernia and then for all others [11]. Among the open mesh repair procedures Lichtenstein technique is the most frequently performed technique [12]. Lichtenstein repair for inguinal hernia is a tension free strengthening of posterior inguinal floor using polypropylene mesh [13, 14]. It is also proven that recurrence of hernia is very low with mesh repair [9]. As of now, numerous clinical trials and meta-analysis have concluded that mesh repair is the "gold standard" in inguinal hernia repair [10, 15, 16]. Wound infection is the most common complication encountered in any surgical procedure. In case of open inguinal hernioplasty the incidence of infection is reported to be very low, 0.4 – 2% [17, 18, 19]. Incision site infection has found to be the frequent problem faced in mesh repair [20, 21]. Most worrisome problem is mesh rejection, occurring following deep surgical site infection. Moreover infection following hernia repair causes fourfold increased chance of hernia recurrence, but this is in particular with herniorraphies [22, 23]. 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 [24]. The antibiotic prophylaxis is also indicated in 'clean' surgeries' such as Hip or knee arthroplasties, cardiac or vascular graft where foreign material is used. It is uncertain 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 [12, 25]. Therefore, antibiotic prophylaxis for open inguinal hernioplasty in minimizing wound infection has been a subject of debate since the beginning of mesh repair in 1975 [11]. One trial has reported a 10 fold decrease in SSI with antibiotic prophylaxis [26] while two other studies did not [27, 28]. One study have has concluded that antibiotic prophylaxis cannot be recommended firmly or discarded blindly [29]. Unnecessary use of antibiotics is discouraged for its inherent complication. Routine use of antibiotic prophylaxis in mesh repair of inguinal hernia can lead to bacterial resistance and increase in hospital costs [30, 31, 32, 33]. Being a commonly performed procedure worldwide, limiting the indiscriminate use of antibiotic will have greater influence in cost benefits, emergence of drug resistant bacteria and also a possibility in reducing toxic or allergic effects of

ISSN: 2394-0026 (P)
ISSN: 2394-0034 (O)

the antibiotics. Since the review of world literature does not show any clear advantage in using antibiotics in hernia surgery, we have conducted a randomized clinical trial in our hospital to analyze the usefulness of antibiotics in open inguinal hernioplasty.

Aim and objectives

- To assess the role of antibiotic prophylaxis in open inguinal hernioplasty.

Material and methods

This study was performed after getting approval from the human ethical committee and the post graduate coordinating committee of Mahatma Gandhi Medical College and Research institute. This study was conducted in Mahatma Gandhi Medical College and Research Institute. Faculty and residents in department of general surgery performed the surgeries. All the patients participated in the study were informed about the merits and demerits of the study and informed written consent was obtained.

Characteristics of the study

- **Participants:** 60 patients who underwent inguinal hernia mesh repair.
- **Group:** Two groups (30 in each).
- **Type of study:** Randomized control clinical trial.
- **Randomization:** Simple randomization.
- **Statistical analysis:** Chi Square test.
- **Intervention:** Surgery – Hernioplasty; Medication - Injection Cefotaxime 1 g in antibiotic group and injection multivitamin infusion in placebo group.
- **Outcome analyzed:** Superficial Surgical Site Infection (SSI).

Characteristics of the patients

Inclusion criteria: Patients with primary or recurrent, unilateral or bilateral inguinal hernia between 14-80 years of age and who underwent Lichtenstein hernia repair from September 2011 to June 2013 were included in the study. Sixty patients were included in the study.

Exclusion criteria: Patients with diabetes mellitus, on steroid therapy, immunocompromised status like HIV, malignancy, local sepsis in incision site like Tinea cruris, complicated hernia (obstructed and strangulated hernia).

Randomization of treatment groups

All the patients were double blinded randomly into one of the two groups – antibiotic or placebo group. Randomization was done using simple randomization technique. Randomization chart was made before starting the study, and patients were allotted to either of the group based on their serial number in the randomization chart.

Surgical technique and antibiotic prophylaxis

Trial medication consisted of either 50 ml of dextrose saline with multivitamin infusion or 50 ml of dextrose saline with 1 g of Cefotaxime (third generation cephalosporin). Multivitamin infusion was chosen as placebo to match the color of cefotaxime, so that the optical difference was excluded and the patient or the operating surgeon was not aware of the group to which the patient was belonging to. In short, the groin of the patient was prepared by trimming or clipping of the groin hair in the previous night. Then the surgical site was cleaned with betadine scrub for 3 - 5 minutes before the surgery. After anesthetizing the patient, the trial medication was given. Then the incision site was painted at least four times with 5% betadine solution for 3 - 5 minutes. The operation was performed by faculty or by resident assisted by a senior surgeon. A standard open Lichtenstein hernia repair was performed as described by Lichtenstein Hernia Institute [14]. A monofilament polypropylene

ISSN: 2394-0026 (P)
ISSN: 2394-0034 (O)

flat mesh was sutured in place using monofilament polypropylene (prolene). Types of anesthesia and skin closure were not standardized. If the procedure exceeded two hours of time then the patients were excluded from the study.

All the collected data were recruited using a predesigned proforma. Data was entered in the Microsoft excel sheet. Statistical analysis was done using chi-square test. Patients were first examined on second post operative day for SSI. Then patients were reviewed after two weeks and four weeks. Thorough clinical examination was done to rule out surgical site infection. Wound infection was defined by the Centers for Disease Control and prevention Criteria [30]. If the patient had developed SSI, he 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 was progressing, antibiotics were started.

Results

This study was conducted in 60 patients who underwent Lichtenstein Hernia repair. All patients were randomized into two groups – Antibiotic group and Placebo group. 30 patients were included in each group. All the patients were male in both the groups.

All patients were evenly distributed among different age groups from 19 years to 80 years of age. The mean age in the antibiotic group was 44.33 with standard deviation of 17.235 and that in placebo group was 45.77 with SD of 12.20. Maximum patients were in 19 - 30 years. Minimum patients were in 41 - 50 years. The age wise distribution of patients in both the groups was statistically insignificant (p value = 0.711). Age wise distribution of two groups was as per **Table – 1**.

In the total study subjects, 28 (46.7%) had hernia on right side. Among the 28 right sided inguinal hernias, 11 were in antibiotic group and 17 were in placebo group. Twenty two (36.7%) patients had left sided inguinal hernia, 13 in antibiotic group and 9 in placebo group. Among 60 patients 10 (16.7%) patients had bilateral hernia. Among them 6 were in antibiotic group and 4 in placebo group as per **Table - 2**.

Among the 10 patients who had bilateral hernia, only 6 patients underwent bilateral hernia repair. Remaining 4 underwent hernia repair on one side (three in left side and one in right side). So in 60 subjects, 66 hernia surgeries were performed. Out of the 66 surgeries, 37 (56.06%) of them were indirect type, 24 (36.36%) of them were direct type and 5 (7.58%) of them were pantaloon type as per **Table - 3**.

SSI incidence in the study population was 8.33% (5 out of 60). Out of the five, 2 (6.67%) were in antibiotic group and remaining 3 (10%) were in placebo group. That is 60% of SSI occurred in placebo group and 40% in antibiotic group. The incidence of SSI in the two groups was statistically insignificant. p value was 0.6400 and Chi-Square value was 0.2180. Odd's ratio was 0.6429 with 95% CI of 0.0995 to 4.1531.

Out of sixty patients, five of them developed SSI. Among the five patients who developed SSI two were above the age of 60 years. No patients were less than 30 years of age. The correlation between age and development of SSI was not statistically significant. P value was 0.59 and chi-Square value was 2.812 as per **Table - 4**.

In the five patients who developed SSI, SSI occurred in 4^{th} post operative day in 2 patients and on 5^{th} post operative day in remaining 3. In the antibiotic group SSI occurred on 5^{th} post operative day in both the patients. In the placebo group two patients developed SSI on 4^{th}

ISSN: 2394-0026 (P)
ISSN: 2394-0034 (O)

post operative day and one developed on 5th post operative day.

Out of five SSI, 2 (one in each group) were managed by wound dressing with or without removing a suture. Remaining three (1 in antibiotic group and 2 in placebo group) were managed with antibiotics and daily dressing. Among the five patients who developed SSI, 2 patients had wound gapping after two weeks. Both of them were in placebo group. There was no wound gapping in patients who did not develop SSI. After four weeks surgical site in all the patients were healthy.

Discussion

This study was conducted in Mahatma Gandhi Medical College and Research Institute, Puducherry for a period of one and half years, from September 2011 to June 2013. 60 patients who underwent inguinal hernioplasty were included in the study. Main objective was to analyze the usefulness and necessity of prophylactic antibiotics in inguinal hernioplasty. In the present study, incidence of SSI in open inguinal hernioplasty was 8.33% (5 out of 60). The incidence of SSI in the present study was slightly higher than the study done by Yerdel MA, et al. [26] in 280 patients. Aufenacker TJ, et al. [12] did a study in 1040 patients and reported SSI incidence as 1.7%. Both the studies showed lower incidence of SSI than the present study, which could be attributed due to smaller study population.

Regarding the usage of prophylactic antibiotics in open inguinal hernioplasty, there is still considerable debate. Aufenacker TJ, et al. [12] in 2003 conducted a multicenter double blinded randomized control trial in 1040 patients with a primary inguinal hernia scheduled for Lichtenstein repair. They were randomized to an either preoperative single dose of 1.5 g intravenous cephalosporin or a placebo. There were 8 infections (1.6%) in the antibiotic prophylaxis group and 9 (1.8%) in the placebo group (P 0.82). There was 1 deep infection in the antibiotic prophylaxis group and 2 in the placebo group (P 0.57).

Perez AR, et al. [34] also concluded similar results like Aufenacker TJ, et al. study. Whereas Perez AR, et al. conducted a prospective, randomized, double-blind, placebo-controlled trial comparing wound infection rates in 360 patients (lesser than Aufenacker TJ, et al.) who underwent primary inguinal hernia repair electively using polypropylene mesh. One hundred and eighty patients received prophylactic antibiotics and 180 received a placebo. Superficial SSI developed in 3 patients (1.7%) from the antibiotic group and 6 (3.3%) from the placebo group (p = 0.50). One from each group developed deep SSI.

Both the above mentioned studies showed no significant difference in incidence of SSI between the antibiotic group and the placebo group. This is very much comparable to the present study where the incidence of SSI in antibiotic group (6.67%) and that in placebo group (10%) was statistically insignificant (p value = 0.64).

Present study was also comparable to other studies mentioned as per **Table - 5**. Odd's ratio was less than one in all the studies. All these trials did not recommend routine use of antibiotics in open inguinal hernioplasty.

Certain studies showed results which are not comparable to the present study. Yerdel MA, et al. [26] performed a double-blinded prospective, randomized trial in 1998 in 280 patients underwent mesh inguinal hernia repair. 140 of them received prophylactic 1.5 g intravenous ampicillin-sulbactum and remaining 140

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received placebo. SSI occurred at a rate of 0.7% in the antibiotic group and 9% in the placebo group (p = 0.00153). Out of twelve in placebo group, three patients suffered deep infections. This study documented a significant (10-fold) decrease in overall wound infections when single-dose intravenous antibiotic was used during Lichtenstein hernia repair. Difference of SSI between the two groups was significant, which is contradictory to the present study.

In 2007, Sanabria A, et al. [21] conducted a meta-analysis by compiling the databases of Cochrane Hernia Trialists Collaboration, Cochrane Collaboration, MEDLINE, EMBASE and LILACS. Study included six randomized controlled trials that evaluated mesh inguinal hernia. A total of 2507 patients were analyzed. The SSI frequency was 1.3% in the antibiotic group and 2.89% in the control group (odds ratio 0.48, 95% confidence interval (CI) 0.27–0.85). From this study it was reported that antibiotic use in patients with mesh inguinal hernioplasty decreased the rate of SSI by almost 50%. Both the studies (Yerdel MA, et al. and Sanabria A, et al.) are contradictory to the present study, where there was no significant difference between antibiotic and placebo group.

Age is an important risk factor in the development of any surgical site infection [36, 38, 39]. But in the present study age was not associated to the development of SSI. P value was 0.59 which is not significant. This is against another study conducted by Taylor EW, et al. [40], which showed that age more than 70 years is a risk factor for SSI. This could be due to lesser elder study population (11 out 60 were > 60years of age) in the present study.

All five SSI occurred were only superficial, no deep surgical site infection was encountered in the present study. But there were 3 out of 1040 deep SSI in study conducted by Aufenacker TJ, et al. and 2 out of 360 deep SSI in study conducted by Perez AR, et al. All Superficial SSI were managed by either antibiotics or wound dressing. No mesh rejection or mesh infection was encountered in the present study.

Potential drawback of this study is a smaller study population. Depending on the sample size formula and base rate of SSI, to perform a RCT with enough power to detect a 50% decrease SSI rates, it will be necessary to include 1600 to 3000 patients. If we want to detect even smaller percentage decrease in SSI larger study population is needed. Another drawback is we followed up the patients only for four weeks 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. Another demerit of the study is culture & sensitivity of the discharge from SSI site was not done, but it is beyond the scope of the study.

Regularizing the use of antibiotics will have a good cost benefit effect on larger scale. It is estimated that around 10 million Euros are spent annually for giving antibiotic prophylaxis in low risk patients in US and Europe [41, 42]. More over emergence of drug resistant microbes because of unwarranted antibiotic use can be grossly minimized. There is an unknown impact on bacterial resistance because of routine use of antibiotics in primary inguinal repair [43]. Also patients can be free of the toxic or allergic effects of the drugs.

Even after considering and analyzing all these data and trials, the argument about antibiotic prophylaxis is still open. There must be a detailed and clear analysis regarding the choice of patients for antibiotic prophylaxis. It is unnecessary to give antibiotics as a routine for all hernia repairs. Patients at high risk like old age, co-morbid factors, and immune

ISSN: 2394-0026 (P)
ISSN: 2394-0034 (O)

compromised status require antibiotic prophylaxis. But still large trials are required to define high risk patients. Large randomized clinical trials involving both high risk and low risk groups are required to analyze the true necessity of antibiotics.

Present study though conducted in smaller population did not show any difference in SSI between the two groups. So we do not recommend the use of antibiotics in inguinal hernioplasty. Surgeons and hospitals should analyse their own SSI rate in their hospital to assess the need of antibiotic prophylaxis.

Conclusion

The overall incidence of SSI in open inguinal hernioplasty is 8.3% (5 out of 60). Incidence of SSI in antibiotic group is 6.8% (2 out 30) and that in placebo group is 10% (3 out of 30). Development of SSI between the antibiotic and placebo groups is statistically insignificant. Age is not a significant risk factor for development of SSI (p value = 0.59). Routine use of antibiotics is not necessary in all open inguinal hernioplasty. Antibiotics can be reserved only for patients who are in high risk of SSI.

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Source of support: Nil **Conflict of interest:** None declared.

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Table – 1: Age wise distribution of two groups.

Sr. No.	Age distribution (in years)	Antibiotic group	%	Placebo group	%
1	19 - 30	11	36.67	4	13.33
2	31 - 40	3	10	8	26.67
3	41 - 50	2	6.67	8	26.67
4	51 - 60	7	23.33	6	20
5	> 60	7	23.33	4	13.33
6	Total	30	100	30	100
Mean age in A group = 44.33 ± 17.235 and in P group = 45.77 ± 12.2; p value = 0.711					

Table – 2: Distribution of side of inguinal hernia.

Side of hernia	In antibiotic group	%	In placebo group	%
Right	11	36.67	17	56.67
Left	13	43.33	9	30
Bilateral	6	20	4	13.33
Total	30	100	30	100

Table – 3: Types of inguinal hernia.

Type of hernia	In antibiotic group	%	In placebo group	%
Indirect	22	62.86	15	48.39
Direct	11	31.43	13	41.93
Pantaloon	2	5.71	3	9.68
Total	35	100	31	100

Table – 4: Age wise distribution of SSI.

Sr. No.	Age group (in years)	SSI distribution among age groups		Total
		Yes	No	
1	< 30	0	15	15
2	31 - 40	1	10	11
3	41 - 50	1	9	10
4	51 - 60	1	12	13
5	> 60	2	9	11
6	Total	5	55	60
p value = 0.59		Chi-Square value = 2.812		

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Table – 5: Comparison of present study with other clinical trials.

Study	Antibiotic group	SSI in Antibiotic group	Placebo group	SSI in Placebo group	p value
Thakur L, et al. [37]	29	3	26	4	> 0.01
Othman I, et al. [33]	50	4	48	6	0.47
Tzovaras, et al. [35]	193	5	193	9	0.4
Jain, et al. [3]	60	1	60	1	> 0.01
Present study	60	2	60	3	0.64