

Original Research Article

The efficacy of antibiotic prophylaxis in preventing SSI (surgical site infection) in patients undergoing Lichenstein's hernioplasty at our tertiary care centre

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ABSTRACT

Background: Inguinal hernia surgery is the commonest surgery performed 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 inguinal hernia surgery. Antibiotic prophylaxis for open inguinal hernioplasty in minimizing wound infection has been a subject of debate since the beginning of mesh repair.

Methods: This study is a randomized control trial (double blind study) designed to study the efficacy of antibiotic prophylaxis in preventing SSI (surgical site infection) in patients undergoing Lichtenstein's hernioplasty at our tertiary care centre.

Results: The overall SSI incidence was found to be 12% in the study population. Among the placebo group, SSI was observed in 7 patients (14%). In the patients in whom antibiotic prophylaxis was administered, SSI was observed in 5 patients (10%).

Conclusions: Antibiotic prophylaxis was associated with decreased incidence of wound infection when compared to control group, but the difference was not statistically significant. This study only gives a baseline data about the status of SSI associated with hernia repair in our tertiary care centre highlighting the need for further research in this field.

Keywords: Antibiotic prophylaxis, Lichtenstein's hernioplasty, SSI

INTRODUCTION

Inguinal Hernia repair is the most common surgery performed worldwide.¹ As of now, numerous clinical trials and meta-analysis have concluded that Lichtenstein's hernioplasty is the "gold standard" in inguinal hernia repair.²⁻⁴

Inguinal hernia repair is classified under clean surgery, where prophylactic antibiotic is not indicated. As surgical site infection is the most common complication of hernia surgery and use of foreign body (mesh in hernia repair) necessitates administration of prophylactic antibiotic in hernia mesh repair.⁵ But the role of prophylactic antibiotic in Lichtenstein's mesh repair is still

controversial. A Cochrane meta-analysis on the topic conducted in 2004 concluded that the antibiotic prophylaxis in mesh repair is neither recommended nor discarded.

In developing country like ours where Government institution have limited funds and patients are treated free of cost, irrational use of antibiotics in a common procedure like hernia mesh repair will have greater influence on cost effectiveness. Unwarranted administration of antibiotics may cause an alarming emergence of drug resistance. Since review of literature had conflicting results, it was decided to conduct a RCT at our tertiary care centre to define the role of prophylactic antibiotic in open inguinal hernioplasty.

METHODS

After obtaining the Institutional Ethical Committee's approval, and informed consent from patients enrolled in the study population, this randomized control trial (double blind study) was conducted over a period of six months from October 2016 to March 2017 at Government Vellore medical college hospital, a tertiary care centre in Vellore, Tamil Nadu, India.

The Department of General Surgery of our tertiary care hospital which caters to four neighbouring districts of Northern Tamilnadu including Vellore, Tiruvannamalai, Kanchipuram and Thirupattur.

All the adults who presented at our tertiary care centre, with unilateral Inguinal hernia requiring Lichenstein's hernioplasty were included in our study.

100 patients (50 placebo group and 50 antibiotic prophylaxis administered group).

Inclusion criteria

All the Patients older than 15 years admitted with unilateral inguinal hernia planned for Lichenstein's hernioplasty were included in our study.

Exclusion criteria

- Patients with recurrent inguinal hernia
- Patients who are immunocompromised
- Patients with bilateral inguinal hernia
- Patients with history of antibiotic intake within last 5 days before operation
- Existing indication for antibiotic prophylaxis (valvular heart disease and post splenectomy patients).

In this prospective randomized controlled trial, placebo group and prophylactic antibiotic administered group were chosen by double blinding. The patients in the prophylactic antibiotic group were given a single dose of Inj. Cefatoxime 1g at the time of induction and the cases were given placebo (Inj. saline). Post operatively the surgical site was inspected from 2nd day till discharge and after 10th day, 20th day and 30th day. If any Surgical Site Infection was found it was graded using Southampton scoring system as described by Bailey.⁶

The results were tabulated and analysed statistically. Statistical analysis was performed using 'R' statistical software.

RESULTS

This study was conducted in 100 patients who underwent Lichtenstein's hernia repair. Main objective of our study was to analyze the usefulness and necessity of prophylactic antibiotics in inguinal hernioplasty.

All patients were randomized into two groups, antibiotic group and placebo group. 50 patients were included in each group. Both males and females were included in both groups.

All patients were distributed among different age groups from 15 to 80 years of age.

Table 1: Age wise distribution of placebo and antibiotic group: n=100 (50 placebo group + 50 antibiotic group).

Age group in years	Placebo group	Antibiotic group
15-30	6 (12%)	5 (10%)
31-40	15 (30%)	18 (36%)
41-50	14 (28%)	12 (24%)
51-60	12 (24%)	10 (20%)
>60 years	3 (6%)	5 (10%)
Total	50	50

Table 1 shows the age-wise distribution of the study population. In both the groups, the maximum number of patients with inguinal hernia were in the 31 - 40 years age group (33%), followed by the 41-50 years age group (26%). The minimum number of patients in the placebo group were in the elderly age group of more than 60 years (8%).

Table 2: Side distribution of inguinal hernia in the study population.

Side of hernia	Placebo group	Antibiotic group
Right	29 (58%)	34 (68%)
Left	21 (42%)	16 (32%)
Total	50	50

Table 2 shows the side distribution of inguinal hernia in our study. The inguinal hernia distribution was more on the right side, among both the groups in the present study.

Table 3: Distribution of types of hernia in the study population.

Types of hernia	Placebo group	Antibiotic group
Indirect	24 (48%)	22 (44%)
Direct	26 (52%)	28 (56%)
Total	50	50

Table 4: Distribution of surgical site infections observed among the placebo group and antibiotic group in the present study.

	Placebo group	Antibiotic group
SSI observed	7 (14%)	5 (10%)
No SSI observed	43	45
Total	50	50

Table 3 shows the distribution of types of inguinal hernia in the study population. Among 100 subjects, who underwent Lichtenstein's hernioplasty 54% of them had direct type of hernia and 46% had of them had indirect type.

Table 4 shows the incidence of SSI in the study population. The overall SSI incidence was found to be 12% in the study population.

Table 5: Southampton wound grading of SSI in the study population.

Southampton wound grading	Antibiotic group	Placebo group
II ^a	2	2
II ^c	2	2
III ^b	1	1
IV ^a	0	2

Among the 50 patients who underwent Lichtenstein's hernioplasty without antibiotic prophylaxis (placebo group), SSI was observed in 7 patients (14%). In the patients in whom antibiotic prophylaxis was administered, SSI was observed in 5 patients (10%). Though the number of infected patients was less in the antibiotic group (p-value = 0.538253). There was no statistically significant difference in the incidence of wound infection between the two groups operated with and without antibiotic prophylaxis.

DISCUSSION

The overall SSI incidence was found to be 12% in the study population. This incidence is slightly higher than the other studies. But a few other studies from South India show an incidence of 8.33% and 8.7% respectively.^{7,8} There is no reliable data regarding the wound infection rates in the hospitals in the developing world. The present study may play a role in enlightening us the reality about SSI in developing countries. The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.⁹ Such a wide range on SSI rates is due to the fact that studies differed in various aspects like difference in study design (retrospective, non-randomized versus prospective, randomized), surveillance methods (surgical team versus independent observer), definition of wound infection (no definition versus CDC definitions), duration of follow-up, type of operation (mesh repair versus non-mesh repair).¹⁰ The association of incidence of SSI with other risk factors like age, duration of surgery, person performing surgery could not be observed in our study. Out of 12 patients with SSI, 8 (4 in each group) were managed by wound dressing with or without removing a suture. Remaining 2 patients (1 in antibiotic group and 1 in placebo group) were managed with antibiotics and daily dressing. Among the 12 patients who developed SSI, 2 patients had wound gaping after two weeks. Both of them were in placebo group.

Table 6: Randomized control trials.

First author	Country	Control group	Sample size	Infections		Antibiotic prophylaxis	Sample size	Infections	
				n	%			n	%
Morales	Spain	Placebo	287	6	2.09	Cefazolin 2 g. i.v.	237	4	1.7
Yerdel	Turkey	Placebo	133	12	9.0	Ampicillin + sulbactam 1.5 g. i.v.	136	1	0.7
Aufenacker	Netherlands	Placebo	505	9	1.8	Cefazolin 1 g. i.v.	503	8	1.6
Celdran	Spain	Placebo	49	4	8	Cefazolin 1 g. i.v.	50	0	0
Oteiza	Spain	No treatment	123	0	0	Amoxicillin + clavulanic acid 2 g i.v.	124	1	
Perez	Philippines	Placebo	180	7	3.9	Cefazolin 1 g. i.v.	180	4	2.2
Tzoravas	Greece	Placebo	193	9	4.6	Amoxicillin + clavulanic acid 1.2 g. i.v.	193	5	2.6
Jain	India	Placebo	60	1	1.7	Amoxicillin + clavulanic acid 1.2 g. i.v.	60	1	1.7
Shankar	India	Placebo	162	17	10.5	Cefazolin 1 g. i.v.	172	12	7
Ergul	Turkey	Placebo	100	7	7	Cefazolin 1 g. i.v.	100	5	5
Othman	Egypt	Placebo	48	6	2.88	Amoxicillin + clavulanic acid 1.2 g. i.v.	50	4	2
Mazaki	Japan	Placebo	100	13	13	Cefazolin 1 g. i.v.	100	2	2
			1940	91	4.7		1905	47	2.5

In the present study, incidence of SSI in open inguinal hernioplasty was 12% (12 out of 100).

The incidence of SSI in the present study was slightly higher than the study done by Yerdel MA et al and Aufenacker TJ et al.^{11,12} 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 et al showed that the incidence of SSI was 1.8% in the control group and 1.6% in the antibiotic group.¹² 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.¹³ A similar conclusion was drawn by Tzovaras et al, where the incidence of SSI in control and antibiotic groups were 4.7% and 2.6% respectively.¹⁴

Table 6 shows prospective randomised trials, 12 trials out of which 3 demonstrated the efficacy of antibiotic prophylaxis in the prevention of SSI and 9 trials recommended against its routine use.

CONCLUSION

In the present study, surgical site infection rates were high both in the antibiotic (10%) and the Placebo group (14%), compared to the incidence of SSI in hernia mesh repair, reported worldwide. In our study, even though the rates of SSI were high in both the antibiotic and control groups, the difference was not statistically significant. Based on our results we conclude that routine use of prophylactic antibiotic does not decrease the incidence of SSI in mesh hernia repair. The present study highlights the need for further research with larger study group and the correlation of associated risk factors with SSI. This will be of great benefit to check unwarranted administration of antibiotics, which may further lead to drug resistance and at the same time will increase the cost of treatment per patient in a developing country like India with limited resources.

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