ROLE OF ANTIBIOTIC PROPHYLAXIS IN ELECTIVE MESH INGUINAL HERNIOPLASTY

B. Santhi[1], Kenny Robert[2], Sudhagar Rengasamy[3]

[1]Associate Professor, Department of General Surgery, Villupuram Medical College and Hospital, Tamil Nadu.
[2]Assistant Professor, Department of General Surgery, Villupuram Medical College and Hospital, Tamil Nadu.
[3]Assistant Professor, Department of General Surgery, Villupuram Medical College and Hospital, Tamil Nadu.

ABSTRACT

BACKGROUND

Antibiotic prophylaxis use in mesh inguinal hernioplasty is controversial. A recent Cochrane review based on 17 randomised trials did not reach a conclusion on this important topic. Hence this study is designed to define the role of prophylactic antibiotics in mesh repair of inguinal hernia.

MATERIALS AND METHODS

We conducted a prospective, randomized control trial comparing wound infection rates in 60 patients (30 of them received intravenous Cefotaxime 1g stat and remaining 30 received a placebo) undergoing primary inguinal hernia repair electively using polypropylene mesh. All the 60 patients who completed a follow up period of one month were analysed. Age, co-morbidities, type of hernia, type of anaesthesia, pre and postoperative hospital stay and duration of surgery were recorded. CDC criteria was used to define wound infection.

RESULTS

Of the total 60 patients analysed, the overall infection rate was 1.7% (1 out of 60). Only one patient from control group developed a superficial SSI between 7th and 10th post-operative day (3.3%-1 out of 30). The incidence of wound infection in antibiotic group was none.

CONCLUSION

Antibiotic prophylaxis was associated with decrease in the incidence of SSI when compared to control group, but the difference was not statistically significant. Based on our study results we do not recommend the routine use of antibiotic prophylaxis in elective mesh repair of inguinal hernias.

KEYWORDS

Inguinal Hernia, Mesh Repair, Antibiotic Prophylaxis, SSI.

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BACKGROUND

Hernia repair is one of the most commonly performed general surgical procedures worldwide with an estimated 20 million operations performed annually. It is estimated that about 3,000,000 inguinal herniorrhaphies are performed per year in the United States, Europe and Asia.[1] Inguinal hernia repair is considered as a clean surgery, where prophylactic antibiotics do not have any role, at least in non-mesh repairs. Even though hernia is classified as a clean surgery, the reported incidence of wound infection varies from 0% to 9%.[2] As more and more surgeries are done as day care procedures, many of these infections are often recognized first in the outpatient setup, after discharge from the hospital.[3]

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Corresponding Author:
Dr. B. Santhi,
Flat no. 2B, Daawing G. T. Housing,
Koyambedu, Near Rail Nagar,
Chennai – 600107.
E-mail: drb.shanthi@gmail.com
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The role of prophylactic antibiotics in mesh repair of inguinal hernia is unclear. 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.[4] However, subsequent trials have produced varied results. 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.[5] Hence, we designed this study to define the role of prophylactic antibiotics in prevention of wound infection in mesh inguinal hernia repair and to analyse the risk factors for wound infection in mesh inguinal hernia repair.

MATERIALS AND METHODS

The study was conducted in the department of general surgery, Villupuram Medical College Hospital. It was a prospective randomized controlled study.

Inclusion Criteria

All consecutive patients with primary unilateral or bilateral uncomplicated inguinal hernia who underwent mesh repair during a period of six months from January 2016 to June 2016 in the department of general surgery in our hospital

were included in our study. Out of the 62 patients who underwent meshplasty during the study period, 2 patients were excluded as per the exclusion criteria.

Exclusion Criteria

The patients with recurrent hernia, and Immunosuppressive disease (HIV, Malignancy) or medication were excluded from the study.

Surgery and Postoperative Management

After informed consent, all patients were randomized into antibiotic group and control group by sealed envelope method on the day before the surgery. Patients in the antibiotic group received injection Cefuroxime 1 g intravenously at the time of induction of anaesthesia. Normal saline was used as the placebo in the control group.

Povidone iodine was the antiseptic used for skin preparation in all patients. Groin shaving was done the day before surgery. All patients underwent a standard tension free mesh repair using a polypropylene mesh. A standard sterile dressing was applied post operatively. No postoperative antibiotics were used. Dressings were removed at 48 h after surgery, when the first wound inspection was done. No further dressings were applied. Patients were discharged at the discretion of the operating surgeon.

Followup

Wounds were inspected daily during the hospital stay and the next followup visit was scheduled 7–10 days later when the patients came for suture removal.

All patients were educated about the symptoms and signs of SSI and were instructed to report to us in case they developed any such symptoms and signs. The next wound inspection was scheduled on the 30th post-operative day. Followup was done by residents who were blinded to the drug used. SSI was defined as per the CDC (Center for Disease Control) criteria.

Parameters Studied

The parameters studied included the following-

[1] Patient related factors like demographic data, ASA score (determined by anaesthesiologists preoperatively), preoperative hospital stay, type of hernia and co morbid illnesses if any.
[2] Surgery related factors like type of anaesthesia, antiseptic used for skin preparation, grade of surgeon, duration of surgery.
[3] Incidence of surgical site infection

The study was concluded in June 2016, by then, out of 60 patients who had entered the study, all 60 patients had completed one-month followup.

RESULTS

Statistical Analysis

Among the 60 patients with one-month followup, 30 were in the antibiotic group and 30 were in the control group. Demographic data were comparable between the two groups. Mean age of the patients was 49, with range from 15 to 74 years. Majority of the patients had unilateral hernia, while there were bilateral hernias including both the groups. Most of the patients did not have any associated co morbid illness (Table 1).

Surgery related factors like type of anaesthesia, grade of surgeon and duration of surgery were analysed and were comparable in the two groups. The mean duration of surgery was 59 minutes and was comparable in the study groups. The mean pre-operative hospital stay, mean postoperative stay as well as the total hospital stay was comparable in both the groups.

Infection	Antibiotic Group	Control Group	Total
	No. (%)	No. (%)	No. (%)
Present	0 (0%)	1 (3.33%)	1 (1.66%)
Absent	30 (100%)	29 (96.66%)	59 (98.33%)

Table 1. Surgical Site Infection

- SSI was grouped as follows (using CDC criteria):
- Superficial SSI- Wound cellulitis/erythema/purulent discharge from the wound
- Deep SSI- Mesh infection.

No significant difference was found between the study groups on analysing the sub types of infection. Age, gender, ASA grade, co morbid illness, uni/bilateral hernia did not have any significant correlation with SSI rates. The grade of the surgeon did not have any statistically significant bearing on the incidence of SSI ($p = 0.669$). The mean duration of surgery was 68 minutes in the group of infected patients when compared to 58 minutes in patients without infection, which was of borderline statistical significance ($p = 0.05$) (Table 5). Patients with wound infection had a significantly longer preoperative hospital stay ($p = 0.035$). The postoperative stay was similar in both groups. However, the total hospital stay was significantly longer in patients with wound infection ($p = 0.001$) (Table 6).

	Infected Group	Uninfected Group
Age[a]	51	49
Sex[b]		
Male	1	54
Female	0	5
ASA Grade[b]		
ASA I	1(100%)	56(94.9%)
ASA II	0(0%)	3 (5.01%)
Co Morbidity[b]		
Present	0 (0%)	7 (11.8%)
Absent	1 (100%)	52 (88.1%)
Type of Hernia[b]		
Unilateral	1 (100%)	55(93.22%)
Bilateral	0 (0%)	4 (6.77%)

Table 4. Correlation between Patient Parameters and Surgical Site Infection

	Infected Group	Uninfected Group
Preoperative stay (in days)[a]	1 (100%)	57 (96.61%)
Anaesthesia[b]	0	2 (3.38%)
Duration of surgery (in minutes)	68	58

Table 5. Correlation between Operative Variables and Surgical Site Infection

A. Values expressed in mean ± standard deviation.
B. Values expressed in numbers and percentage.

	Infected group	Uninfected group	p Value
Postoperative Stay[a]	3.38 ± 3.86	2.5 ± 1.3	0.070
Total hospital Stay[a]	9.69 ± 4.37	7.53 ± 3.10	0.001

Table 6. Correlation between Hospital Stay and Surgical Site Infection

A. Values expressed in mean ± standard deviation (in days).

DISCUSSION

The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.[3] 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 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).[6] In our study, the overall infection rate was 1.66%, in patients undergoing elective mesh repair of primary inguinal hernias. The incidence of wound infection was 3.33% in the control group and 0% in the antibiotic group. Even though the incidence of wound infection was higher in the control group, it was not statistically significant (p = 0.344).

The power of the trial (α – 0.05, β – 80%,) was based on the assumption that antibiotic prophylaxis will reduce the wound infection rate from 8% (SSI Rates in our institute)[7] to 1.7%(the SSI rate in the largest RCT in this subject).[8] The sample size calculated was 60 patients.

The organism isolated was Staphylococcus aureus which forms a part of normal skin flora. Staphylococcus is the most common isolate in surgical site infection following hernia repair in various studies.[4,7,9,10,11] Staph. Aureus was the organism isolated in 1 patient with culture positive infection.

A few studies have shown that grade of the surgeon may be a significant risk factor for SSI.[12] Majority of the procedures were performed by residents in our study (n = 46), as ours is a teaching institute. The grade of the surgeon was not a statistically significant risk factor for SSI in our study. Taylor et al.[13] in their study concluded that the grade of the surgeon does not influence the rate of SSI in groin hernia repair. Aufenacker et al.[5] also reported similar results from their study.

In our study, there is a positive correlation between the duration of pre-operative hospital stay and the development of postoperative SSI. The pre-operative hospital stay was 11 days in the patient with SSI in comparison to 4 days in patients without SSI. The difference was statistically significant (p = 0.035). It is a well-known fact that increased preoperative hospital stay increased the risk of colonization with resistant bacteria. Since we do not have day care facility; all our patients were operated as in patients, which is the reason for increased preoperative hospital stay in our study. We believe that this will be the case in majority of institutes in the developing world.

In the study done by Perez et al.[10] on the role of antibiotic prophylaxis in mesh repair, all the infections were diagnosed after hospital discharge. This again emphasizes the need for followup to establish the true incidence of SSI.

Vast majority of SSI occurring after hernia repair are superficial surgical site infection and are treated by simple drainage with or without antibiotics.[6] 100% of the SSI in our study was superficial SSI. All the SSIs reported in the studies done by Celdran et al.[8] and Tzovaras et al.[9] were superficial SSI. The incidence of mesh infection reported in literature varies from 0.35% to 1%.[4,5] The incidence of deep SSI was 0.0% in our study. Aufenacker et al.[5] reported an incidence of 0.3% for deep SSI in their study within a followup period of 3 months.

Cefotaxime was the antibiotic used in our study. It was chosen because of its proven efficacy against the common organisms like Staphylococcus aureus, longer duration of action and low cost. Since SSI in our study were due to Staph. aureus, the question of failure of prophylaxis due to inefficient antibiotic is ruled out. Cefazolin was the antibiotic used in studies done by Celdran et al and Perez et al.[8,10] One gram of Cefotaxime was given intravenously at the time of induction of anaesthesia. This is consistent with the studies done by other authors.

The economic impact of SSI was not assessed in our study. However, since 100% of infections were Superficial SSIs, we believe the cost effectiveness of antibiotic prophylaxis in the absence of conclusive benefit is questionable.

The incidence of wound infection was 9% in the control group and 1% in the antibiotic group in the study done by Yerdel et al.[2] The authors showed a significant difference in wound infection between the antibiotic and control groups. Celdran et al.[8] reported SSI rates of 8% and 0% in the control and antibiotic group respectively and had similar conclusions.

Aufenacker et al.[5] showed that the incidence of SSI was 1.8% in the control group and 1.6% in the antibiotic group. 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.[10] were 3.3% and 1.7% in the control and antibiotic group respectively and the author did not find any benefit with prophylactic antibiotics. A similar conclusion was drawn by Tzovaras et al.,[9] where the

incidence of SSI in control and antibiotic groups were 4.7% and 2.6% respectively. It should be noted that studies in which the rates of SSI are higher have reported that prophylactic antibiotics are beneficial, whereas similar conclusion could not be derived in the studies with low rates of SSI.

CONCLUSION

To conclude, in our study, even though the rates of SSI were high in the control group, the difference was not statistically significant. Based on our results we conclude that prophylactic antibiotics do not decrease the rate of SSI in mesh repair of inguinal hernias and hence routine use of prophylactic antibiotics cannot be recommended for the same.

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