Section: General Surgery

Original Research Article

ANTIBIOTIC PROPHYLAXIS AND IT'S ROLE IN ELECTIVE OPEN MESH HERNIA REPAIR OF INGUINAL HERNIA. A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: One of the so-called clean operations is hernia repair. However, despite a lack of solid data to support this practice, many surgeons utilize antibiotics, particularly in the mesh repair era. **Materials and Methods:** It was a prospective double- blind randomized controlled study conducted in the department of general surgery. All consecutive patients with primary unilateral or bilateral uncomplicated inguinal hernia who underwent mesh repair during a period of 1year in the department of general surgery in our institute were included in our study. Out of 421 patients in the study around 221 were excluded due to recurrent hernia or Immunosuppressive medications or HIV. So the total sample size of the study was 200. **Result:** The mean age of patient group was 58.9 years while for control group was 59.65. Control group was the placebo group while patient group was treated with Ceftriaxone. Both groups has direct hernia as most common which was not significant. Among the side involved right side involvement was most common in both groups (79% in patient group and 81% in control group) but it was not significant (p>0.05). Surgical site infection in patients treated with ceftriaxone was 7% and in placebo group was 11% which suggest the effect of prophylactic antibiotic was helpful but it was not significant (p>0.05). **Conclusion:** In comparison to the control group, antibiotic prophylaxis was linked to a lower incidence of wound infection; however, this difference was not statistically significant. Our findings lead us to conclude that routine use of antibiotic prophylaxis during elective mesh surgery for inguinal hernias is not advised.

INTRODUCTION

One of the so-called "clean" surgeries that might not require antibiotic coverage is hernia repair. Nonetheless, a lot of surgeons still administer antibiotics as a preventative measure. Because of the concern over the foreign body being infected, this procedure became more popular when the tension-free mesh repair technique was established as the preferred way for hernia repair. Even before mesh repair techniques were introduced, a number of controlled randomised trials were published on this subject, yielding inconsistent outcomes.[1,2]

One of the most frequent procedures that general surgeons do is the correction of inguinal hernias. In the US, Europe, and Asia, an estimated 3,000,000 inguinal herniorrhaphes are performed annually. When it comes to non-mesh repairs, inguinal hernia repairs are thought of as clean surgeries in which prophylactic antibiotics play no part. Despite being categorized as a clean procedure, hernias have a 0% to 9% documented wound infection rate.[3,4] Since more and more surgeries are being performed as day care procedures, many of these infections are frequently identified in the outpatient setting following hospital discharge.[5]

It is unknown how prophylactic antibiotics may affect inguinal hernia mesh repair. Antibiotic prophylaxis in mesh repair for inguinal hernias was the subject of the first randomized control trial, conducted which recommended prophylactic antibiotic usage.[6] Subsequent experiments, however, have yielded inconsistent outcomes. Because of this, we created this study to examine the function that prophylactic antibiotics use Ceftriaxone play in preventing wound infection after mesh inguinal hernia surgery as well as to identify and evaluate the risk variables associated with such an infection.

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MATERIALS AND METHODS

It was a prospective double- blind randomized controlled study conducted in the department of general surgery. All consecutive patients with primary unilateral or bilateral uncomplicated inguinal hernia who underwent mesh repair during a period of 1year in the department of general surgery in our institute were included in our study. Out of 421 patients in the study around 221 were excluded due to recurrent hernia or Immunosuppressive medications or HIV. So the total sample size of the study was 200.

After informed consent, 100 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 Ceftriaxone 1 g intravenously at the time of induction of anesthesia. Normal saline was used as the placebo in the control group.

All patients' skin was prepped using OT- prep, an antiseptic and groin was shaved before the procedure. Every patient had a polypropylene mesh repair utilizing a typical tension-free mesh procedure. Following surgery, a standard sterile dressing was placed. Antibiotics were not administered after surgery. When the first wound examination was performed 48 hours following surgery, the dressings were taken off. There were no more dressings used. The decision to discharge a patient rested with the operating surgeon.

During the patient's hospital stay, wounds were examined every day, and a follow-up visit was planned for seven to ten days later, when the patients were scheduled for suture removal. Every patient received education regarding the warning signs and symptoms of SSI, as well as instructions to notify us should they manifest any of these symptoms? On the 30th post-operative day, the following wound examination was planned. Residents who were blind to the medicine used conducted follow-up. The Centers for Disease Control's (CDC) standards were followed in defining SSI. The parameters which were studied are patient related factors like demographic data, type of hernia and co morbid illnesses if any.

Statistical Analysis: The statistical analysis was performed using SPSS for Windows version 22.0 software. The findings were present in numbers and percentages analyzed by frequency, and percent. The chi-square test was used to find the association among variables. The critical value of P indicating the probability of significant difference was taken as <0.05 for comparison.

RESULTS

As per [Table 1] the mean age of patient group was 58.9 years while for control group was 59.65. Control group was the placebo group while patient group was treated with Ceftriaxone. Both groups has direct hernia as most common which was not significant. Among the side involved right side involvement was most common in both groups (79% in patient group and 81% in control group) but it was not significant (p>0.05). Hypertension was the most common co-morbidity in placebo group (23%) while patient group has 13% hypertensive and 16% diabetic.

As per [Table 2] surgical site infection in patients treated with ceftriaxone was 7% and in placebo group was 11% which suggest the effect of prophylactic antibiotic was helpful but it was not significant (p>0.05). Among the SSI, cellulitis was the most common infection in both groups but not significant.

As per [Table 3] association of demographic variables with SSI shows no significant association with any parameters.

As per [Table 4] the post-operative stay and total hospital stay was less in placebo group but they were significant (p<0.05).

Table 1: Demographic and Morbidity Profile of study groups (N=200)

Variables	Patient group (100)	Control group (100)	p-value
Mean age (years)	58.9±6.4	59.65±4.2	0.19
Type of hernia			
Indirect	15	14	0.11
Direct	85	86	
Side involved			
Right	79	81	0.10
Left	18	16	
Bilateral	3	3	
Comorbidity			
Diabetes	13	14	0.21
Hypertension	16	23	
Both	02	05	

Table 2: Comparison of Surgical site infection in both groups

Variables	Patient group (100)	Control group (100)	p-value
SSI			
Present	7 (7%)	11 (11%)	0.21
Absent	93 (93%)	79 (79%)	
Cellulitis	4 (4%)	5 (5%)	0.29
Mesh infection	2 (2%)	5 (5%)	
Pus discharge	1 (1%)	1 (1%)	

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Table 3: Association between Demographic variable and SSI groups

Variables	SSI present (18)	SSI absent (182)	p-value
Mean age (years)	57.9±6.4	58.65±4.2	0.19
Type of hernia			
Indirect	4	12	0.34
Direct	14	172	
Side involved			
Right	9	166	0.23
Left	7	10	
Bilateral	2	6	
Comorbidity			
Present	6	3	0.11
Absent	12	-	

Table 4: Association of Hospital stay and SSI

Variables	SSI present (18)	SSI absent (182)	p-value
Post-operative stay	3.12±1.45	2.75±1.3	0.07
Total hospital stay	10.39±4.35	8.54±3.32	0.04*

DISCUSSION

Along with thyroid and breast surgery, hernia repair has always been regarded as one of the "clean" operations. But according to data from recent prospective studies, the prevalence of wound infection following elective hernia repair is likely underestimated and can even reach 10% when patients are properly followed up.[7,8] This number is unquestionably unacceptable for a clean operation, and some writers have proposed that hernia repairs should really be reclassified as clean-contaminated procedures.

However, during the past ten years, tension-free mesh repair techniques have gained popularity all over the world and are now recognized as the preferred approach for elective inguinal hernia repair. Antibiotic prophylaxis may play a protective effect in preventing infections from foreign bodies like non-absorbable mesh, as demonstrated by other clean procedures such vascular graft implants and arthoplasties. This concern was brought up in light of these findings.[9,10] Given the aforementioned information, many surgeons do elective mesh hernia repairs using antibiotics; nonetheless, this is an empirical rather than an evidence-based procedure.

Throughout the past ten years, a number of prospective trials have investigated the question of the role of antibiotic prophylaxis in elective hernia repair, with inconsistent findings. This is mostly because the experiments' different designs and methodologies.

As far as we are aware, the role of intravenous antibiotic prophylaxis in a homogeneous population has only been studied in two prospective randomised trials that were organized in a comparable manner.[7,9] Both were substantially ahead of our trial and had contradicting outcomes when they were published. Staphylococcus aureus, a common bacteria found in the natural skin flora, was the most often isolated organism. Numerous investigations have shown that staphylococcus is the most prevalent isolate in surgical site infections that occur after hernia repairs.

After an inguinal hernia is repaired using mesh, the rate of surgical site infection has been reported to range from 0% to 9%.[10] The reason for the wide variation in SSI rates is that different studies used different study designs (retrospective, non-randomized vs. prospective, randomized), different surveillance techniques (surgical team vs. independent observer), different definitions of wound infection (none vs. CDC definitions), different follow-up durations, and different types of operations (mesh repair vs. non-mesh repair).[11] The total infection rate among patients receiving elective mesh surgery for primary inguinal hernias was 8.7% in our study. In the antibiotic group, the incidence of wound infection was 7.0%, compared to 10.5% in the control group.

Theoretically, because to the potentially dangerous effects of an infection that penetrates the mesh, antibiotic prophylaxis in prosthetic hernia repair may be more crucial than in non-implant surgery. Regardless of the use of biomaterials or antibiotics, the rate of infection was roughly 1% in a retrospective multicentric analysis conducted by few studies.[12,13] The use of a foreign body during hernia repair does not seem to affect the incidence of superficial wound infection, and late-onset deep graft infection has not been observed frequently, according to a recent review.[14]

The antibiotic utilized in our investigation was ceftriaxone. It was selected due to its demonstrated effectiveness against common species including Staphylococcus aureus, extended duration of action and affordable price. Since Staph. aureus accounted for the majority of SSI in our analysis, the possibility that ineffective antibiotics caused prophylaxis to fail is eliminated. According to our research, the emergence of post-operative SSI is not significantly associated with the length of the pre-operative hospital stay but number of days of hospital stay was less in placebo group. Patients with SSI had a mean pre-operative hospital stay of 3.12 days, while patients without SSI had a mean pre-operative hospital stay of 2.75± 3.03 days. There was statistically significant difference. It is commonly recognized that a longer hospital stay prior to surgery

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was associated with a higher chance of colonization by resistant germs. The increased preoperative hospital stay in our study can be attributed to the fact that we do not have a day care center and that all of our patients were treated as inpatients. We think that most developing-world institutes will operate in this manner.

CONCLUSION

In conclusion, we were unable to show any appreciable benefit from the addition of antibiotic prophylaxis in patients who were not at high risk of experiencing septic complications during elective inguinal hernia tension-free repair with a polypropylene mesh. In our study even though the rates of SSI were high in both the antibiotic, and control groups, the difference was not statistically significant except hospital stay which was significant in those who were not having SSI. 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 more studies with larger sample size are recommended.

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