

IMPACT OF USING PROPHYLACTIC ANTIBIOTIC ON PREVENTION OF WOUND INFECTION IN INGUINAL HERNIORRHAPHY

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ABSTRACT

Objective: To compare the effect of antibiotic prophylaxis with placebo in prevention of wound infection amongst patients undergoing clean open inguinal herniorrhaphy (without mesh).

Study Design: Randomized Controlled Trial.

Place and Duration of Study: Pakistan Air Force Hospital, Faisal Base Karachi from October 2009 to November 2011.

Material and Methods: One hundred and fifty patients undergoing inguinal herniorrhaphy were included and randomly assigned to one of the two groups using random numbers table. Group A patients were given intravenous antibiotic while those in Group B were given equal volume of normal saline just before the induction of anaesthesia. Patients from both groups were observed for the presence of wound infection.

Results: Total seven cases (4.7%) of surgical site infection were detected; two cases (2.7%) occurred in group A whereas five cases (6.7%) occurred in group B. The low frequency of post-operative wound infection was seen in group A as compared to group B but the difference was statistically insignificant.

Conclusion: Antibiotic prophylaxis has no significant effect on prevention of wound infection in inguinal herniorrhaphy.

Keywords: Antibiotic prophylaxis, Herniorrhaphy, Inguinal hernia, Surgical site infection.

INTRODUCTION

In the first couple of decades of antibiotic discovery, the mortality from infection dropped dramatically, although the morbidity increased with emergence of antibiotic resistant bacteria. It was then recognized that high concentration of appropriate antibiotics in tissues at the time of wound incision was the most effective way of prevention of infection¹ and this type of antibiotic use is termed as prophylaxis.

Inguinal hernia is one of the most common general surgical entities in adults. Although many patients are asymptomatic, yet the hernia itself has potential feared complications such as incarceration or strangulation. To avoid such feared complications, surgical repair at an appropriate time is needed². Of the available treatment, minimal invasive hernia repair is the gold standard because of its low morbidity and high rate of success but owing to paucity of such facilities in peripheral hospitals, conventional open herniorrhaphy with or

without prosthetic materials is recommended³⁻⁴.

Surgical site infections(SSI) are the most common complication secondary to hernia repairs, and antibiotic prophylaxis has been suggested as the most effective way to prevent it⁵. Some studies have identified risk factors for SSI such as sex (greater in women), age (older than 70 years), comorbidity, operative time, hypo- albuminemia and routine use of drainage and prostheses⁶. SSI is related with an increase in length of stay and costs and a decrease in quality of life⁷⁻⁸. In an attempt to reduce indiscriminate use of antibiotics in clean and contaminated surgeries, various aspects have been studied but all with conflicting results. The risk of SSI in inguinal hernia repair usually arises from contaminants of the operation theater environment, the surgical staff or most commonly skin flora and *Staphylococcus aureus*⁹ being the commonest micro-organism. For some authors, hernia and breast surgery are clearly considered examples of the benefits of antibiotic prophylaxis in clean surgery while others argue that low frequency of SSI in hernia surgery does not justify prophylaxis¹⁰. Main objective of antibiotic prophylaxis is to reach high serum levels of antibiotic at surgical site to avoid colonization by skin micro-organisms

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Received: 10 Dec 2012; revised received 17 Aug 2013; accepted 02 Jan 2014

and secondary infection. Foregoing in view, antibiotic prophylaxis in inguinal hernia surgery is controversial, especially after the increasing use of mesh implants¹¹. However, in order to settle this debate, larger sample sizes would be needed to have significant results and validation of any such study¹². Obviously, to carry out such an ideal study is difficult, amidst the financial constraints and paucity of available resources, especially in developing countries like Pakistan. It has been observed that many surgeons in our country use broad spectrum antibiotics indiscriminately in clean surgery cases for fear of wound infection. This practice not only causes theoretical risk of emergence of resistant bacteria but also puts financial burden over our economy. Therefore the idea in this study has been generated to evaluate the role of antibiotic prophylaxis for prevention of wound infection in non-implant inguinal hernia repairs.

MATERIAL AND METHODS

These randomized controlled trials were conducted at the Department of Surgery Pakistan Air Force Hospital, Faisal Base Karachi from October 2009 to November 2011 after approval from the Hospital Ethics committee. Adult male patients between 18-50 years of age with inguinal hernia were included after written informed consent and subjected to non-implant inguinal hernia repair (herniorrhaphy) through non-probability convenience sampling. Total 150 patients were included in the study fulfilling the inclusion criteria and randomly divided into two groups of 75 each using random numbers table. Group A received prophylactic antibiotic, 1-gram intravenous cloxacillin, while group B received equal volume of normal saline as placebo. Patients with Diabetes, Tuberculosis, Anaemia, Jaundice, Immunodeficiency and other co-morbid conditions were excluded from the trial. Those who had taken antibiotic therapy within 72 hour before operation or found allergic to Cloxacillin were also excluded from the study. All patients below the age of 40 were investigated for Complete Blood Count, Urinalysis and Screening for Hepatitis B and C for anaesthesia fitness. Additional

investigations for those above the age of 40 included Electrocardiography and Chest x-rays according to hospital guidelines. On operation day, Intravenous cannula was secured after arrival of patient in operation theatre. Test dose of Cloxacillin was given subcutaneously before intravenous administration in group A patients while those in group B were administered equal volume of normal saline just before the induction of anaesthesia. The skin was shaved immediately before surgery and was prepared by using povidone iodine and spirit. Darning procedure was performed for inguinal hernia repair with prolene 1 suture. After securing hemostasis, wound was washed with normal saline before layered closure and skin was closed with prolene suture. Sterilized dressing was applied. All surgeries were performed by one of the two senior surgeons. Wound was assessed by the same operating surgeon on 3rd, 7th, and 30th post-operative day to see the signs of infection and findings were entered on pre-formed 'Data Collection Form' along with the demographic data of the patient. The wound infection was to be labeled as superficial Surgical Site Infection (SSSI) if involving only skin and subcutaneous tissue whereas in case of involvement below musculo-fascial plane it was to be considered as Deep Surgical Site Infection (DSSI). The signs of wound infection which were looked for included- spreading cellulitis with erythema, raised local temperature and tenderness around the wound, purulent discharge, wound dehiscence, fever and organisms isolated from wound swab on culture. Postoperative manual and computer record was maintained for these outcome measures. All the collected data had been analyzed using Statistical Package for Social Sciences (SPSS version 17). Descriptive statistics were used to describe results. Chi-square test was applied for the comparison of qualitative variables. Independent samples t-test was applied for the comparison of age. A p -value < 0.05 was considered significant.

RESULTS

A total of 150 cases, 75 in each group were included in the study. Group A on antibiotics (Cloxacillin) and group B, Placebo. Both the

groups were comparable regarding age. The mean age in groups A and B was 35.86 ± 10.14 and 38.62 ± 09.74 respectively ($p=0.589$). Surgical site infection occurred in five cases

last few decades and tension-free repair has become the most popular technique¹⁵ but old conventional tissue repairs are still in use in developing countries due to financial

Table-1: Showing comparison of wound infection on 3rd, 7th post-operative day.

Wound infection	Group A (n=75)	Group B (n=75)	p-value
3 rd day			0.560
• present	01(1.33%)	02(02.66%)	
• absent	74(98.66%)	73(97.33%)	
7 th day			0.311
• present	01(1.33%)	03(04.00%)	
• absent	74(98.66%)	72(96.00%)	

Table-2: Showing post-operative variables group wise.

Variables	Group A	Group B	p-value
Purulent discharge	1(1.3%)	0(0%)	0.316
Culture sensitivity (+)	2(2.7%)	4(5.3%)	0.405
Local tenderness	0(0%)	5(6.7%)	0.023
Local temperature, Redness	2(2.7%)	0(0%)	0.154
Fever	0(0%)	1(1.3%)	0.316

(6.7%) in-group B, while in two cases (2.7%) in group A ($p=0.246$). In all the 7 cases (100%) wound infection was superficial surgical site infection. None developed deep surgical site infection. Post operative day wise wound infection is described in table-1. No case of infection was found on 30th day of operation. Table-2 shows post-operative variables.

DISCUSSION

The use of antibiotic prophylaxis for hernia repair is currently a debatable issue given the disparity among study results in this area. Large studies have compared wound infection rates with and without prophylactic antibiotics, with no apparent difference identified¹³. Last updated Cochrane meta-analysis concluded that "administration of antibiotic prophylaxis for elective inguinal hernia repair cannot be universally recommended". They also stated that "antibiotic prophylaxis cannot either be recommended against when high rates of wound infection are observed"¹⁴. A European Hernia Society guideline also states that 'in clinical settings with low rates <5% of wound infection, there is no indication for the routine use of antibiotic prophylaxis in elective open groin hernia repair in low-risk patients'². Although the use of prosthetic material in inguinal hernia repair has increased over the

constraints. Recurrence rates overall are high except for those surgeons whose darns are so dense that they resemble a mesh¹⁶. Dissimilar to the locally prevailing belief of using antibiotic prophylaxis for prevention of SSI, our study revealed an overall SSI rate of 4.6% which is quite comparable to the results shown by other studies in this domain. The statistical data analysis also revealed that use of antibiotic prophylaxis had no impact on prevention of wound infection in our study. Jain SK et al. carried out a prospective randomized double blind control trial on 120 patients who had undergone hernioplasty with polypropylene mesh in which they also did not find any benefit of the routine use of antibiotic prophylaxis in terms of wound infection rate¹¹. In another prospective randomized double blind study conducted on 98 patients by Othman I, it was also shown that prophylactic antibiotic usage in patients undergoing tension free inguinal hernioplasty (mesh repair) did not show any statistically significant beneficial effects in reduction of surgical site infection¹⁷. Similar results were shown in another randomized study by Goyal A et al in 200 patients undergone open inguinal hernia repair and they also concluded that prophylactic antibiotics in elective open inguinal hernia repair had no significant benefit over placebo¹⁰.

Ahmad M et al in a comparative study of 248 cases of clean surgery. Mostly hernia repairs also revealed that the use of prophylactic antibiotic in clean, non-implant and elective cases is unnecessary¹⁸. In a meta-analysis by Sanabria A et al however, it was revealed that antibiotic prophylaxis use in patients submitted to mesh inguinal hernioplasty did reduce the rate of surgical site infection by almost 50%⁵. Shankar VJ et al in a randomized controlled trial also stated that high incidence of SSI after inguinal hernioplasties was not infrequent¹⁹. In the studies of Yerdel et al and Celdran et al the incidence of infection after antibiotic prophylaxis was around zero i.e. 0.7% and 0% but that after placebo was high i.e. 9.0% and 8.2% respectively. Owing to the high incidence of infection in their control groups, they concluded their studies early for ethical reasons and recommended antibiotic prophylaxis^{20,21}. Although, a single dose of broad spectrum antibiotic prophylaxis is recommended whenever a mesh is implanted¹⁶ but controversy still exists as shown in results of above mentioned studies. However, it is possible to clarify this issue by performing further randomized controlled trials rigorously and recruiting significantly larger numbers of patients as also stated by Biswas S in a review²².

The most common pathogen of SSI is *Staphylococcus aureus*⁹ and this was also the case in our study where most commonly isolated organism was *S aureus*. We selected antibiotic Cloxacillin for prophylaxis because it is cheap, easily available and specific to *S aureus*. We admit that our follow-up was too short for assessment of DSSI which required at least a year.

Encouraging features of our study were the absence of DSSI and that all SSSI responded well to proper antibiotics with or without drainage. The limitations of our study were the lack of data about the nutritional status, obesity, smoking status of patients and exclusion of female gender all of which were patient-related factors that could effect the risk of development of wound infection. As a matter of fact, the incidence of infection in specific hernia centers where only elective hernia repairs are

conducted is not higher than 1%²³ but our results were worse than those of specific centers. This can probably be explained by the fact that in specific centers only hernia surgery is performed but in our setting, inguinal hernia repairs are performed in between major abdominal surgery or contaminated cases. But even then we were not able to demonstrate any significant benefit of antibiotic prophylaxis in our study. We therefore believe that most effective way to further reduce our incidence of wound infection in inguinal hernia repairs would be to improve infection-control procedures rather than emphasizing on administration of broad spectrum antibiotics.

Conflict of interest: None of the authors declare conflict of interest.

CONCLUSION

We did not find any benefit of the routine use of antibiotic prophylaxis for prevention of surgical site infection in elective inguinal hernia repair using non-implant technique. Therefore, antibiotic prophylaxis is un-necessary in clean surgery cases and it does not seem to be a substitute for proper observance of aseptic and antiseptic technique, good clinical judgment and surgical skills.

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