ISSN: 2515-8260 Volume 08, Issue 04, 2021

THE ROLE OF SINGLE DOSE ANTIBIOTIC PROPHYLAXIS DURING HERNIA SURGERY: A RANDOMIZED CONTROL TRIAL

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Abstract

Background: This prospective, randomised control experiment was conducted to determine the role of single-dose antibiotic prophylaxis after hernia surgery. This research also provides evidence for determining whether stringent aseptic precautions can reduce antibiotic use.

Materials and Methods: This study included 60 patients with inguinal hernias (direct or indirect) who were admitted to the surgical ward at the Pt. B.D. Sharma Post Graduate Institute of Medical Sciences in Rohtak. Prior to admission, each patient was given a thorough screening as well as a rigorous clinical evaluation that included Haemoglobin, Bleeding time, Clotting time, Urine complete examination, Blood urea, Blood sugar, Serum electrolytes, Chest X-ray and ECG.

Results: The average age of the presenters was 45.88 years old. The majority of the patients, sixteen (26.66 percent), were between the ages of 41 and 50. The youngest patient was an 18-year-old man, while the oldest was an 80-year-old man. Males made up 98.33% (n=59) of the cases, while females made up 1.66 percent (n=1). Lichtenstein's repair was performed in forty patients (66.66%) for indirect inguinal hernias, and Lichtenstein's repair was combined with posterior wall plication in eighteen patients (30%) for direct inguinal and Pantaloons' type hernias. Indirect inguinal hernias accounted for the most occurrences (40), with two having a sliding component.

Conclusion: There is substantial evidence in the international literature to support the claim that prophylactic antibiotic treatment does not reduce the incidence of wound infection. Given the findings of this study, it is possible to conclude that the variations in infection rates are not substantial, and that prophylactic antibiotics do not reduce the rate of SSI in mesh repair of inguinal hernias, and that routine use of prophylactic antibiotics is not indicated.

Keywords: Antibiotics,inguinal hernia, SSI

Introduction

The word hernia is derived from the Greek word hernios, meaning "a bud". It refers to a protrusion of an organ through its integument[1].An inguinal hernia is an out-pouching of peritoneum, with or without its contents, that arises at the level of the inguinal canal in the groynethrough the muscles of the anterior abdominal wall. Because of the intrinsic weakness of the abdomen wall where the spermatic cord goes through the inguinal canal, it is more common in men. A lump in the groyne might result from a segment of bowel becoming lodged in the peritoneal pouch. The hernia might expand into the scrotum, causing pain or discomfort.

Inguinal hernias are not inherently harmful in and of themselves, but they can lead to life-threatening consequences. As a result, surgical treatment of a hernia that is painful or growing larger is likely to be recommended. Inguinal hernia surgery, also known as herniorrhaphy or hernioplasty, is now frequently performed as an ambulatory, or "day surgery" technique. Tension-free mesh repair is the gold standard procedure for hernia repair[2].

It is estimated that 3,000,000 inguinal herniorrhaphies are performed per year in the United States, Europe and Asia[3].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%[4].Many of these infections are commonly detected initially in the outpatient setting, after departure from the hospital, as more and more surgeries are performed as day care procedures[5].

The most common consequence of inguinal herniorrhaphy is surgical site infection (SSI)[6].Female sex, age greater than 70 years, comorbidities, operation time, and routine use of drainage and prosthesis have all been found as risk factors for SSI in several studies[7-10].SSI is linked to a longer length of stay, higher expenses, and a lower quality of life[11, 12].

Antibiotic prophylaxis is recognised to minimise the risk of postoperative wound infection in most types of surgery. Across many different types of surgery, ranging from clean to extremely contaminated procedures, the relative risk decrease appears to be around 60%[13].In order to achieve optimal serum medication levels, prophylactic antibiotics should be administered 30-60 minutes before to surgical incision[14]and post-operative antibiotic therapy is now largely considered to be of minimal benefit in ordinary practise[15].

Whether or not antibiotic prophylaxis is helpful in elective inguinal hernia repair is, however, a point of contention.

In 2012, reviewers from the Cochrane Collaboration determined that evidence from 17 randomised controlled trials (RCT) on the use of antibiotic prophylaxis in inguinal hernia repair with and without mesh was equivocal, thus they couldn't recommend or discourage it[16].
In an effort to clarify the role of single dose antibiotic prophylaxis during hernia surgery, this prospective, randomized control trial was conducted. This study also gives us evidence to analyse whether strict aseptic measures can reduce use of antibiotics.

Materials and Methods

This study included 60 patients with inguinal hernias (direct or indirect) who were admitted to the surgical ward at the Pt. B.D. Sharma Post Graduate Institute of Medical Sciences in Rohtak. All patients were fully informed about the procedure and its risks and their participation in the trial was contingent on their written agreement. The patient's written express consent was obtained in his or her own language.
Prior to admission, each patient was given a thorough screening as well as a rigorous clinical evaluation that included Haemoglobin, Bleeding time, Clotting time, Urine complete examination, Blood urea, Blood sugar, Serum electrolytes, Chest X-ray and ECG.
Patients with the following criteria were excluded from the study: 14 years of age, obstructed inguinal hernia, strangulated inguinal hernia, recurrent inguinal, hernia cases admitted through emergency department, patients with systemic or advanced disease (e.g., diabetes mellitus, liver or renal impairment, coagulation abnormalities) or a history of receiving steroids for any reason, patients who were using or had used antibiotics less than a week before.
The preferred form of anaesthetic was spinal anaesthesia. The same surgeon conducted all of the repairs, which were done with the traditional open tension-free mesh approach describe by Lichtenstein *et al*.[17]Mesh repair was done by using the polypropylene mesh in both the groups.
The patients were randomised by using droplets method. The surgeon and the patient were blinded to the group allocated.

Group I (Study group): This group included 30 patients in whom a single dose of prophylactic injection Cefazolin 1g was given preoperatively at the time of induction of anaesthesia.

Group II (Control group): This group included 30 patients in whom no antibiotic was given preoperatively.

Pre-operative phase

Skin was prepped at the operative site with a 10% povidone iodine solution right before the incision. Four layers of coating were applied, then the patients were draped in sterile surgical sheets and washed with spirit. The patients had the usual meshplasty treatment, which is described below. Skin staplers were used to seal the skin on all of the patients. At the conclusion of the procedure, the surgical incision was covered with a sterile surgical dressing.

Postoperative phase

All patients were given an open dressing 24 hours following surgery. Antibiotics were not utilised after the surgery. On the third, seventh, and thirty-first postoperative days, patients were discharged, and wound inspections were planned on the third, seventh, and thirty-first days. On the seventh postoperative day, the sutures were removed. All patients were taught about the symptoms and indicators of SSI and were told to contact us if they developed any of these signs or symptoms.

Technique of the operation

A 5-6 cm skin incision was performed, beginning at the pubic tubercle and extending laterally inside the Langer line, allowing for excellent exposure to the pubic tubercle and internal ring. The external oblique aponeurosis was opened and its lower leaf was liberated from the spermatic cord after a skin incision. The upper leaf of the external oblique was then separated from the underlying internal oblique muscle, revealing the internal oblique aponeurosis and the iliohypogastric nerve.
For a distance of about 2 cm beyond the pubic tubercle, the cord with its cremaster covering was detached from the floor of the inguinal canal and the pubic bone. Cord retaining forceps were used to pull the cord off the inguinal floor. The chord was cut to a point beyond the sac's neck, the sac was opened, and the contents were reduced before being fixated with silk 2-0 suture on a round body needle and inverted into the preperitoneal area.
A 3 inch x 6 inch monofilament polypropylene mesh was employed. With the cord retracted upward, the lower sharper corner was sutured to the insertion of the rectus sheath to the pubic bone with a non-absorbable monofilament suture material (polypropylene 2-0 on round body needle) overhanging the bone by 2 cm. The medial lower edge of the mesh was stitched to the reflected part of the inguinal ligament with two interrupted stitches.
The margins of each of the two tails were repaired with a single non-absorbable monofilament suture, taking a bite

through the internal oblique aponeurosis. This resulted in the formation of a new internal mesh ring. On the lateral side, the surplus patch was clipped to leave at least 5cm of mesh beyond the internal ring. This was tucked beneath the external oblique aponeurosis, which was closed over the cord with non-absorbable polypropylene 2-0 suture material on a round body needle, followed by skin stapler closure.

Statistical analysis

At the end of the study, the data was tabulated and statistically analysed by usingchi-squaremethod for comparison. P-value less than 0.05 was considered as significant.

Results

The mean age of presentation was 45.88 years. Maximum number of patients i.e. sixteen (26.66%) were in 41-50 years of age group. Youngest patient was of 18 years old male and oldest was 80 years of male. Males constituted the majority of 98.33% (n=59) cases, females were 1.66% (n=1).

Table I: Depicts age distribution of cases

e groups (years)	quency (n)	rcentage
20		3%
30		00%
40		00%
50		66%
60		66%
70		33%
80		0%
al		%

Table II: Depicts the sex distribution

	quency(n)	rcentage
les		33%
nales		6%
al		%

According to the protocol all 60 patients were operated by same surgeon. In forty patients (66.66%) Lichtenstein's repair was done for indirect inguinal hernias, eighteen patients (30%) underwent Lichtenstein's repair along with plication of posterior wall for direct inguinal as well as Pantaloons' type of hernia. One patient required orchidopexy for testes as a content of indirect inguinal hernia sac. Lytle's repair was done for a widened deep inguinal ring in one patient.

Table III: Shows distribution of type of surgery performed

pe of surgery done	quency(n)	rcentage
htenstein's Repair		66%
htenstein's Repair & Plication Of Posterior Wall		00%
htenstein's Repair & Plication & Lytle's Repair		6%
htenstein's Repair & Plication & Orchidopexy		6%
al		%

Types of hernia

The following table shows various types of hernia found in the 60 patients operated during the study. Maximum number of cases were of indirect inguinal hernia (40), two had sliding component.

Table IV: Shows various types of hernias

pe of hernia	quency	rcentage
irect inguinal hernia		66%
ect inguinal hernia		66%
taloons hernia (both direct & indirect)		3%
irect inguinal hernia with Sliding component		3%
al		%

Prophylactic preoperative antibiotic

The patients were allotted into two groups. Group I (Study group) included 30 patients in whom single dose of prophylactic injection Cefazolin 1g was given preoperatively at the time of induction of anaesthesia and Group II (Control group) included 30 patients in whom no antibiotic was given preoperatively.

Table V: Prophylactic preoperative antibiotic

phylactic antibiotic	**equency**	**rcentage**
ven (Group I-Study)		%
given (Group II-Control)		%
al		0%

Comparison of antibiotic versus no antibiotic group

In the present study 1 out of 30 patients in the prophylactic antibiotic group developed sign & symptoms of surgical site infection (3.33%). One out of 30 patients who were not given prophylactic antibiotic developed features of surgical site infection (3.33%).

Table VI: Showing comparison between antibiotic and no antibiotic

phylactic antibiotic		**SSI**	**tal**	**rcentage**
ven				3%
given				3%

Discussion

The current study included 60 patients with inguinal hernia who were separated into two groups of 30 patients each. At the time of induction of anaesthesia, one group received a single dose of prophylactic cefazolin 1 g, while the other received no antibiotic. The effects of various factors on the rate of SSI are addressed.

The patients ranged in age from 18 to 80 years old. The average age was 48. The male to female ratio was 59:1, with 59 males and 1 female. The majority of the people were of male sex. This study's findings are consistent with those of Morales *et al*.[18](2000) and Aufenacker*et al*.[19] (2004).

NNT is a method of determining the antibiotic's impact by calculating the number of patients who must be treated in order for one person to be affected. Because the incidence of infection in the antibiotic and control groups is similar, we were unable to calculate NNT in our study. However, theoretically, because the difference between the two groups is close to zero, we can conclude that the NNT is very high, which is consistent with other studies such as Morales *et al*.[18](2000) Aufenacker*et al*.[19] (2004).

Patients were randomly assigned to get prophylactic antibiotics or not. Thirty patients (50%) received prophylactic antibiotics, while the other half (50%) did not. At the time of induction of anaesthesia, we provided injectable cefazolin sodium 1gm (after sensitivity testing) to patients assigned to the antibiotic group. The antibiotic employed in our research was cefazolin. It was chosen due to its proven efficacy against common bacteria such as

Staphylococcus aureus, as well as its longer duration of action and low cost. Goyal*et al*.[19](2008) and Shankar *et al*.[20](2010) had used the same antibiotics in their studies which are comparable.

Polypropylene mesh was employed in all 60 cases and mesh fixation was done with polypropylene suture material in all of them. This was consistent with the mesh type employed in all of the other randomised control studies.

Conclusion

The findings of this study show that good preoperative care, such as bathing the patient before surgery, shaving right before surgery, standard cleaning of the parts with 10% povidone iodine solution, draping, meticulous surgical technique, ensuring haemostasis, closing the wound in layers, and early discharge of the patient the next day, can help prevent surgical site infection. There is substantial evidence in the international literature to support the claim that prophylactic antibiotic treatment does not reduce the incidence of wound infection. Given the findings of this study, it is possible to conclude that the variations in infection rates are not substantial, and that prophylactic antibiotics do not reduce the rate of SSI in mesh repair of inguinal hernias, and that routine use of prophylactic antibiotics is not indicated.

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