

Prospective, Longitudinal Study Comparative Assessment of the Impact of Single Dose versus Multidose Prophylactic Antibiotics in Elective Hernia Repair

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Abstract

Aim: To assess the impact of single and multiple-dose antibiotics in clean and clean contaminated elective hernia surgeries concerning surgical site infection and associated complications.

Methodology: This prospective, longitudinal study was conducted for 1 year at Jagannath Gupta institute of medical sciences and Hospital, Budge Budge, Kolkata, West Bengal, India in the general surgery department. 120 suitable patients were included in this study. All the patients were randomly assigned two groups (n=60) single-dose pre-operative (SD) group and multiple-dose (MD) in each group. Master chart for Protocol of the procedure was designed along with Performa, patient identification details, and informed written consent form for all study. Both groups were homogenized in terms of age, type of hernia, and clinical findings. SD group was given amoxicillin-clavulanic acid (2 gm) intravenously at the time of induction of anesthesia. MD group was given amoxicillin-clavulanic acid (2 gm) parentally at the time of induction of anesthesia and following it up with the same antibiotic (1 gm) intravenously twice a day for two days post-operatively.

Results: Data collected from both single antibiotic group I (n=60) and group II multi-dose group (n=60) who underwent elective hernia surgery. Out of 60 patients of group SD, only 8.3% of patients developed surgical site infection compared to none in group MD. Statistically, there was no appreciable difference in the incidence of SSI in both SD and MD groups with a p value of 0.273. Seroma was found in the 3rd postoperative day in 3 patients in group I, fluid aspirated, and culture turned out to be negative. Five of the SD group developed an infection, which subsided with the continuation of antibiotics. Expenditure incurred by the patient only for antibiotic analyzed of antibiotic (amoxicillin and clavulanic acid) and found the average cost of antibiotic per patient in SD group was Rs. 150 while the cost of antibiotic per patient in group II was Rs. 1200. P value is < 0.05, found to be significant.

Conclusion: From this study, we can conclude that single-dose antibiotic prophylaxis is economical in uncomplicated elective surgery. A multidisciplinary and multifaceted approach to surgical site infections is absolutely necessary to continue to improve these critical outcomes of surgery.

Keywords: Antibiotics, hernia, infection

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Introduction

Abdominal hernia repair is one of the most common operations performed worldwide, with estimates of around 770,000 inguinal hernia repairs and 350,000 ventral hernia repairs performed annually in the US [1, 2]. Abdominal wall hernias occur due to weakness in any portion of the abdominal wall and also include umbilical, epigastric, and Spigelian hernias [3]. The lifetime risk for inguinal hernia operation is 27% in men and 3% in women, and incisional hernias occur in up to 11% of patients after laparotomy [4, 5].

Surgical Site Infection (SSI) is a major post-operative complication associated with any surgery which will lead to increased hospital stay, loss of productive hours, hospital cost and patient morbidity and mortality [6]. Although antimicrobial prophylaxis plays an important role in reducing the rate of SSIs, other factors such as attention to basic infection-control strategies, the surgeon's experience and technique, the duration of the procedure, hospital and operating-room environments, instrument sterilization issues, preoperative preparation (e.g., surgical scrub, skin antisepsis, appropriate hair removal), perioperative management (temperature and glycemic control), and the underlying medical condition of the patient may have a strong impact on SSI rates.

Amoxicillin-clavulanic acid is considered a relatively safe antibiotic and used worldwide as prophylactic antibiotics as prophylactic anti biotic. Amoxicillin-clavulanic acid is considered relatively efficient, safe, and less toxic with appreciable antimicrobial activity and target tissue concentration. In this paper, our study is aimed to compare the effect of single-dose antibiotic versus multiple

doses of antibiotics in uncomplicated herniorrhaphy in terms of post-operative surgical site infection and related complications. The rational and effective use of prophylactic antibiotics for the prevention of expected surgical site infection guidelines are well documented in the American society of health-system pharmacists (ASHP) based on prevailing clinical audits and issues. ASHP guidelines are very useful for the clinicians to the effective and ration uses of antibiotics in the prevention of surgical site infections in uncomplicated elective surgery like hernia repair [7].

According to the guidelines, any antibiotic considered to be active against the contaminating pathogens in most of the cases likely to infect the surgical site, given in the right dose and route of administration that ensures required serum and tissue concentrations. Prophylactic antibiotics are effective during the time of potential contamination, safe and administered for the shortest effective period to minimize adverse drug effects, the development of a resistant organism, and considered cost-effective [8]. This study aims to assess the impact of single and multiple-dose antibiotics in clean and clean contaminated elective hernia surgeries concerning surgical site infection and associated complications.

Materials and Methods:

This prospective, longitudinal study was conducted for 1 year at Jagannath Gupta institute of medical sciences and Hospital, Budge Budge, Kolkata, West Bengal, India in the general surgery department. 120 suitable patients were included in this study.

Inclusion criteria:

Includes patient with elective open hernioplasty, age group of 18-60 years of both sexes

Exclusion criteria:

Pediatric patients, hernia with complications, recurrent hernias, and patients with comorbid excluded from our study

Methodology

All the patients were randomly assigned two groups (n=60) single-dose pre-operative (SD) group and multiple-dose (MD) in each group. Master chart for Protocol of the procedure was designed along with Performa, patient identification details, and informed written consent form for all study. Both groups were homogenized in terms of age, type of hernia, and clinical findings. SD group was given amoxicillin-clavulanic acid (2 gm) intravenously at the time of induction of anesthesia. MD group was given amoxicillin-clavulanic acid (2 gm) parentally at the time of induction of anesthesia and following it up with the same antibiotic (1 gm) intravenously twice a day for two days post-operatively.

Patients with uncomplicated inguinal hernia and operated as elective cases only included. All data related to wound site infection, number of days in the hospital,

expenditure all collected tabled and analyzed. Both groups met all inclusion criteria and homogenized in all the aspects are only included in the study.

Procedure: Group I (SD) received single-dose pre-operative prophylaxis of injection amoxicillin and clavulanic acid 2 gm I/V half an hour before the scheduled procedure. Group II (MD) cases were given single-dose preoperative antibiotic prophylaxis followed by multiple doses of the same antibiotic (injection I/V amoxicillin and clavulanic acid 1.2 gm) BD for 3 days post-procedure followed by tablet amoxicillin and clavulanic acid 1.2 mg TDS for the next 2 days in addition to all the patients were operated on under regional anesthesia by consultant surgeons as per World Health Organization (WHO) safety guideless and standard aseptic precautions. Monofilament polypropylene mesh was used for hernioplasty. Postoperative findings including wound site infections like seroma and wound infection documented serially till 12 post-operative day (POD) when patients got discharged and followed up in surgery outpatient department (OPD) after two weeks. Stitch removal was done on the 8th postoperative day.

Results:

Table 1: Incidence of surgery related infections in both groups

Study group	Group 1 (single dose)		Group II (multiple dose)		P value
	(n=60)	%	(n=60)	%	
Surgery related infections	5	8.3	0	0	0.273

Data collected from both single antibiotic group I (n=60) and group II multidose group (n=60) who underwent elective hernia surgery. Out of 60 patients of group

SD, only 8.3% of patients developed surgical site infection compared to none in group MD.

Table 2: SSI incidence of in relation to various observations days in SD versus MD groups

Groups	Surgery related infections			
	Day 2	Day 4	Day 8	Day 12

Single dose (group I)	0	4	1	0
Multidose (group II)	0	0	0	0

Statistically, there was no appreciable difference in the incidence of SSI in both SD and MD groups with a p value of 0.273, which is in agreement with earlier studies. Main complaints by many patients in the post-operative period were pain and headache managed well with intravenous

fluids for spinal headache and analgesics. Seroma was found in the 3rd postoperative day in 3 patients in group I, fluid aspirated, and culture turned out to be negative. Five of the SD group developed an infection, which subsided with the continuation of antibiotics.

Table 3: Expenditure incurred by the patient

Study group	Group 1 (single dose)	Group II (multiple dose)	P value
Mean cost (in rupees)	150	1200	<0.005

Expenditure incurred by the patient only for antibiotic analyzed of antibiotic (amoxicillin and clavulanic acid) and found the average cost of antibiotic per patient in SD group was Rs. 150 while the cost of antibiotic per patient in group II was Rs. 1200. P value is < 0.05, found to be significant.

Discussion:

The benefit of antibiotic prophylaxis in elective surgical procedures, such as inguinal hernia surgery repair, the prophylactic antibiotic is considered debatable [9]. The negligible rate of wound infections and the technically sound surgical management are all considered as factors against routine use of antibiotic prophylaxis in inguinal hernia repair [10]. Surgical site infection following hernia repair is associated with a high rate of recurrence in hernia repair subsequently leading to recurrence. The benefit of antimicrobial prophylaxis was reported as far back as the 1960s from randomized trials, and this practice has had a marked impact on surgical practice. General guidelines with respect to prophylaxis advocate the necessity for high tissue concentrations of antibiotics at the time when bacterial contamination is most likely to occur, i.e., from the first incision. Typically, prophylactic antibiotics are administered intravenously

at induction of anesthesia. A seminal study of 7000 patients confirmed there is variation in clinical practice with regards to the timing of prophylaxis. Administration of prophylactic antibiotics two hours prior to surgery is effective in reducing SSI. The administration of a first dose earlier than this prior to surgery or post-operatively is ineffective as a prophylactic measure [11-13].

In our study the percentage of infection in only 8% compared to the multi-dose antibiotics group and comparable with several studies have been compared to the multi-dose antibiotics group and comparable with several studies have been conducted on the choice of antibiotic and timing of use of antibiotics. Most of the studies have recommended the first dose to be given 30-60 minutes preoperatively, and long-acting antibiotics must be selected [14]. Borade S et al. reported 3% of superficial surgical site infection in his study [15]. Jogdand S et al, studied 183 clean surgical procedure with single dose antibiotics and found that multiple-dose antibiotics requirement after surgery was reduced [16]. Shah YD et al, compared single dose antibiotics prior to surgery with multiple dose antibiotics treatment, and reported 11% of SSI in single dose regimen and multiple dose antibiotic regimen in patients undergoing laparoscopic surgery and reported that a

single dose of antibiotics are more patient compliant, cost-effective, less adverse effects and prevents the emergence of antibiotic resistance [17].

Most studies have reported an incidence of wound infection of 2.7-11.3% in patients who underwent open colectomy compared with 5.7-26% in laparoscopic colectomy [18-20]. A meta-analysis of post-operative wound infection [17] reported a significantly lower incidence of SSI after laparoscopic colectomy (3.9%, 21/537) than after open colectomy (8.3%, 43/518; $P = 0.005$). In the present study, the rates of SSI in open and laparoscopic surgery were 16.6% (4/24) and 8.7% (6/69), respectively ($P = 0.278$). It seems to show that skillful surgical technique is more important than wound length for preventing wound contamination [21]. Platt et al randomized double-blind study which was aimed to throw light into this use of antibiotics in elective surgery. They had concluded, surgery-related infections and complications dropped from 4.2% to 2.3% when prophylactic intravenous antibiotic prophylaxis. Our study which was done to compare the effectiveness of a single multidose antibiotics [22].

In our study, the results of the average cost of antibiotics in the single-dose group are significantly less than the average cost of antibiotics in the multi-dose group. Difference in cost of antibiotics in both group I and group II was found statistically significant (p value < 0.005). These results were similar to the study conducted by Pavan et al in which the average cost of antibiotic for each patient in group I was Rs. 35 while that in the group II was in the range of 145-340 without SSI to a maximum of Rs. 340 with SSI. The difference in cost of antibiotics in both groups was statistically significant as also seen in the present study [23, 24].

Conclusion:

From this study, we can conclude that single-dose antibiotic prophylaxis is economical in uncomplicated elective

surgery. A multidisciplinary and multifaceted approach to surgical site infections is absolutely necessary to continue to improve these critical outcomes of surgery.

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