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Original Research Article

Impact of single dose versus multidose prophylactic antibiotics in elective hernia repair: an institutional study

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ABSTRACT

Background: Antibiotics used prophylactically in anticipation of surgery-related infection are not indicated for elective surgical procedures where the chance of infection is very low and the expected benefit of antimicrobial treatment is not well documented. Routine prophylactic use of antibiotics in clean cases and the difficulty in balancing the benefits of the intervention with the potential adverse drug reaction is debatable. There are not much randomized, controlled trials or patient-specific information to assess his balance precisely, but only general guidelines for the clinician to decide for his patients. This study was conducted in our Institute to inquire the basis that prevention of surgery related infection in elective groin hernia repairs equally effective when patients were given either preoperative single-dose or multi-dose antibiotics postoperatively**.**
Methods: This prospective, longitudinal study, 100 eligible patients who were admitted for elective hernioplasty, were randomly assigned in two equal groups with 50 each. Single dose (SD) group was given a single antibiotic of 2 gm parental amoxycillin-clavulanic acid at the time of induction of anesthesia. The multidose group was given through intravenous route same antibiotic (2 gm) preoperatively followed by amoxycillin-clavulanic acid (1 gm) twice a day for two days in their post-operative period also and their effect compared**.**
Results: In the single-dose prophylactic antibiotic group (group I) the surgery related infection rate was only 8%, compared to those who received postoperative multiple-dose groups (group II)**.**
Conclusions: The postoperative wound-related infection rate after a single dose antibiotic parenterally at the induction of anesthesia is favorably compared with that of multiple-dose antibiotics**.**

Keywords: Single dose, Multiple dose, Antibiotic prophylaxis, Wound-related infections, Herniorrhaphy

INTRODUCTION

Post-operative surgical wound site-related infection (SSI) is an anticipated major complication associated with any surgery that may lead to a prolonged hospital stay, loss of work, and medicine expenditure especially among the rural population in addition to increased morbidity and mortality.[1] Antimicrobial prophylaxis plays an important role in reducing the rate of postoperative SSIs, in addition to operation theatre (OT) sterilization, autoclaving of instruments and linen, technical expertise of the operating surgeon, the duration of the procedure, hospital and operating-room environments, instrument sterilization issues, preoperative preparation of the patient and co morbid conditions all have a major role.[2] Indiscriminate use of antibiotics for an unreasonably prolonged period in anticipation to reduce the SSI, not only will increase the financial burden to the patient, hospital and lead to the emergence of drug resistance organism and drug-related adverse effects. Studies have shown that there is unanimity on the usage of prophylactic antibiotics in uncomplicated elective herniorrhaphy and use of prophylactic antibiotics

in elective herniorrhaphy is not recommended because they are no evidence that will decrease the already negligible rate of postoperative infectious complications.[3] Amoxycillin-clavulanic acid is considered a relatively safe antibiotic and used worldwide as prophylactic antibiotics as prophylactic anti biotic. Amoxycillin-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.[4] 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.[5] This longitudinal study was done to assess the single-dose prophylactic antibiotic against multiple doses of antibiotic prophylaxis in the postoperative period in clean and clean-and clean-contaminated herniorrhaphy and to analyze the efficacy and cost-effectiveness of both the variants can be evaluated. Our 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.

METHODS

This prospective, longitudinal study was conducted for a period of 18 months from March 2018 to August 2019 at Karpaga Vinayaga Institute of Medical Sciences and Research in the general surgery department. 100 suitable patients who were admitted for elective groin surgery were included in this study were randomly assigned two groups (n=50) 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 amoxycillin-clavulanic acid (2 gm) intravenously at the time of induction of anesthesia. MD group was given amoxycillin-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. The Chi-square test was used to analyze the data and the difference in the rate of wound-related infection in both the groups was found to be statistically insignificant inclusion criteria includes elective open hernioplasty, age group of 18-60 years of both sexes. Pediatric patients, hernia with complications, recurrent hernias, and patients with comorbid excluded from our study.

Collection of data

Institutional ethical committee approval obtained for this study and written well-informed consent obtained from enrolled patients. The study population (n=100) randomly divided into two groups of groups: group I (n-50) SD and group II (n=50) MD groups using computer-generated numbers.

Group I SD received single-dose preoperative prophylaxis of injection amoxicillin and clavulanic acid 2 gm I/V half an hour before the scheduled procedure. Group II MD (n=50) 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.

Statistical analysis

Data collected from both groups from the point preoperative single-dose antibiotic number of patients got wound site infections, dose, and frequency of antibiotic given and all these data were quantitatively analyzed for mean and standard deviation. To determine any significant association between the two study groups was analyzed applying the Chi-square test and ‘p’ value less than 0.05 is taken as statistically significant.

RESULTS

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. Data collected from both single antibiotic group I (n=50) and group II multidose group (n=50) who underwent elective hernia surgery. Out of 50 patients of group SD, only 8% 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 0.291, which is in agreement with earlier studies (Table 1). 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 2 patients in group I, fluid aspirated, and culture turned out to be negative (Table 2). 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. 145 while the cost of antibiotic per patient in group II was Rs. 1400. P value is 0.0001 (p value <0.05) found to be significant (Figure 1).

Table 1: Incidence of surgery related infections in both groups.

Study group	Group 1 (single dose) (n=50)	Percentage	Group II (multiple dose) (n=50)	Percentage	P value
No. of patients (N)	50		50		
Surgery related infections	4	8	0	0	0.291

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

Groups	Study population	Surgery related infections			
		Day 2	Day 4	Day 8	Day 12
Single dose (group I)	50	0	5*	0	0
Multidose (group II)	50	0	0	0	0

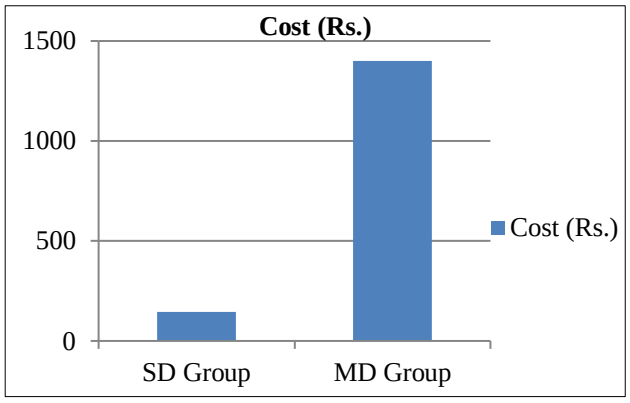

Figure 1: Expenditure SD versus MD.

DISCUSSION

Antibiotic prophylaxis is still indicated in elective surgical procedures where the prosthesis is implanted, anticipating chances of infection can be at times fatal. On the other hand, the benefit of antibiotic prophylaxis in elective surgical procedures, such as inguinal hernia surgery repair, the prophylactic antibiotic is considered debatable.[6] 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.[7] Surgical site infection following hernia repair is associated with a high rate of recurrence in hernia repair subsequently leading to recurrence. 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 dose of prophylactic antibiotic versus multiple doses of antibiotics has shown no significant difference in the surgical wound infection rate in both the studied groups. However, there is an average cost wise there was a significant increase in the expenditure and adverse drug reactions like gastritis, nausea, and diarrhea in group II. 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.[8] SSI following hernia repair is associated with a high rate of recurrence in hernia repair subsequently leading to recurrence. The use of prophylactic antibiotics came into practice ever since it was postulated by Bernard and Cole.[9] Studies conducted in a different setting in many parts of the world also have concurred with the effectiveness of pre-operative single-dose antibiotic over multidose antibiotics.[10] With the advantage of state of the art sterilization, aseptic precaution, technical advancement the need for multidose antibiotics has come down for clean and clean-contaminated surgical cases. In 2001, Naz et al in a comparative study between single-dose prophylactic antibiotics versus conventional dose of antibiotics in major gynecological procedures have documented that prophylactic antibiotic use is sufficient provided standard principles of operative surgery have adhered.[11] 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.[12]

100 patients who met inclusion criteria were operated as elective open inguinal hernia repair and randomly divided

into two equal groups of group I (who received single-dose antibiotic prophylaxis) and group II (who received multiple-dose antibiotics). The rate of wound related infection in the group I recorded as (8%) where as in the group II it was nil (0%), 4 patients developed SSI in the SD group while none of the patients in the group II (MD) developed SSI. No significant difference noted in SSI between group I and group II (p value=0.294).

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 (Figure 1.). Difference in cost of antibiotics in both group I and group II was found statistically significant (p value=0.0001). These results were similar to the study conducted by Pavan et al in which the average cost of antibiotic for each patient in group 1 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.[13] Arjona et al had conducted a study to find out the economic advantages following the use of prophylactic antibiotic rather than traditional 7 days antibiotics, using 5260 patients in a medical centre in Southern Taiwan and stated that use of prophylactic antibiotic alone for the surgical patients had resulted in the gain of 1.5 million dollars for the public.[14]

Limitations

Single institutional study of 100 patients with only one drug (amoxicillin and clavulanic acid). Different antibiotics with more number of patients will be needed to substantiate the results.

CONCLUSION

Prophylactic use of antibiotics in clean elective cases is still a subject of many controversies. Our study on antibiotic prophylaxis for hernia repair consisted of two groups with one group received a single-dose antibiotic and the other group a multi-dose antibiotic and the outcome on surgery related infections and cost compared. We found that the rate of infections is quite similar in SD and MD antibiotics thereby making single-dose antibiotics prophylaxis as effective as multiple doses of antibiotics prophylaxis. We also conclude that single-dose antibiotic prophylaxis is economical in uncomplicated elective surgery.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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