

Prospective Comparative Study to Assess the Impact of Single Dose Versus Multidose Prophylactic Antibiotics in Elective Hernia Repair

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Abstract

Aim: Impact of single dose versus multidose prophylactic antibiotics in elective hernia repair

Methods: This prospective, comparative study was done the Department of General Surgery, Patna Medical College & Hospital, Patna, India, for 12 months. 120 suitable patients who were admitted for elective groin surgery were included in this study were randomly assigned two groups (n=60) single-dose pre-operative (SD) group and multiple- dose (MD) in each group. 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: Out of 60 patients of group SD, only 8.33% 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 0.31. 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. 5 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. 1500. P value is 0.0001 (p value <0.05) found to be significant.

Conclusion: We concluded 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.

Keywords: Single Dose, Multidose, Prophylactic Antibiotics, Hernia.

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Introduction

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 [1]. 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. But frequently, antibiotics are used irrationally for unduly long period in an attempt to reduce the SSI, which will increase the financial burden to the hospital and probable emergence of drug resistance and drug related adverse effects. So, a systematic predefined approach is to be followed to prevent it. Herniorrhaphy is a clean and less invasive surgery. So, there is no consensus on usage of prophylactic antibiotic in Herniorrhaphy [2,6]. Do not recommend the use of prophylactic antibiotics in Herniorrhaphy because they will not decrease the already low rate of postoperative infectious complications. Many other authors have also drawn the same conclusion. Worldwide, Amoxicillin-Clavulanic acid is being used frequently as prophylactic antibiotics. The reason being, they are safe, effective, nontoxic, having excellent antimicrobial activity and good tissue penetration. Our study is aimed to compare the impact of single vs. multiple doses of antibiotic in herniorrhaphy in terms of post-operative infection related complications [7,8].

American Society of Health-System Pharmacists (ASHP) has published therapeutic guidelines on antimicrobial prophylaxis in surgery [9]. The guidelines

are intended to provide practitioners with a standardized approach to the rational, safe and effective use of antimicrobial agents for the prevention of surgical-site infections (SSIs) based on currently available clinical evidence and emerging issues. According to the guidelines, an antimicrobial agent should be active against the pathogens most likely to contaminate the surgical site, given in an appropriate dosage and at a time that ensures adequate serum and tissue concentrations during the period of potential contamination, safe and administered for the shortest effective period to minimize adverse effects, the development of resistance and costs [10].

Material and methods

This prospective, longitudinal study was done the Department of general surgery, Patna medical college & hospital, Patna for 12 months, after taking the approval of the protocol review committee and institutional ethics committee.

Grouping

120 suitable patients who were admitted for elective groin surgery were included in this study 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. 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 18-58 years of both sexes. Pediatric patients, hernia with complications, recurrent hernias, and patients with comorbid excluded from our study.

Methodology

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=60) and group II multidose group (n=60) who underwent elective hernia surgery. Out of 60 patients of group SD, only 8.33% 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 0.31, 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 3 patients in group I, fluid aspirated, and culture turned out to be negative (Table 2). 5 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. 1500. P value is 0.0001 (p value <0.05) found to be significant.

Table 1: Incidence of surgery related infections in both groups

| Study group | Group 1 (single dose) (n=60) | Percentage | Group II (multiple dose) (n=60) | Percentage | P value |
|----------------------------|------------------------------|------------|---------------------------------|------------|---------|
| No. of patients (N) | 60 | | 60 | | |
| Surgery related infections | 5 | 8.33 | 0 | 0 | 0.31 |

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) | 60 | 0 | 5* | 0 | 0 |
| Multidose (group II) | 60 | 0 | 0 | 0 | 0 |

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 [10]. 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 [1]. 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 [2]. 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 [11]. 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 [12]. 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 [13]. In our

study the percentage of infection in only 8.33% 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].

120 patients who met inclusion criteria were operated as elective open inguinal hernia repair and randomly divided into two equal groups of groups 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 (8.33%) whereas in the group II it was nil (0%), 5 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=0.31).

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 were 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 [15]. 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 [16].

Conclusion

We concluded 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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