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Original Article

Comparative Study of Effectiveness of Short Course versus Long Course Antimicrobial Prophylaxis after Clean Orthopedic Surgery - A Prospective Study of 200 Patients

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Abstract

Introduction: Surgical site infection (SSI) is one of the most devastating complications associated with any surgical procedure. It is associated with prolonged morbidity, disability, and increased mortality. We assess the effectiveness of short-term (<48 h) versus long-term (14 days) antimicrobial prophylaxis therapy in preventing SSI after clean orthopedic surgeries.

Materials and Methods: A random sample of 200 patients admitted for elective orthopedic surgeries performed under all aseptic precautions was divided into two equal groups with Group I given short-term (<48 h) and Group II given long-term (14 days) prophylaxis of the same antibiotic protocol. Both the groups underwent the predetermined protocol of investigations (complete blood count, erythrocyte sedimentation rate, C-reactive protein, BT/computed tomography, liver function tests, renal function test, urine routine, radiographs, and viral markers). They were evaluated on the basis of wound condition as per predetermined criteria on 2nd, 5th, 14th, and 28th days' post-operative procedure.

Results: The mean age of the patients in Groups I and II was 41.68 ± 16.95 years and 40.71 ± 17.22 years, respectively, and the female-to-male ratio in both the groups showed no significant statistical difference ($P > 0.05$). Mean duration of surgery in both the groups showed no significant difference. Two patients (2%) in Group I and three patients (3%) in Group II developed SSI which on statistical comparison showed no significant difference ($P > 0.05$).

Conclusions: There is no benefit of prophylactic antibiotic after 48 h in clean elective orthopedic surgeries with short course antimicrobial prophylaxis being as effective as long course antimicrobial prophylaxis in developing country after clean elective orthopedic surgery.

Key words: Short term, Long term, Antimicrobial, Prophylaxis, SSI, Infection

INTRODUCTION

Infection is one of the most devastating complications associated with any surgical procedure. It is associated with prolonged morbidity, disability, and increased mortality. Of nearly 30 million operations in the United States each year, more than 2% are complicated by surgical site infection (SSI). Mortality rates are 2–3 times higher in patients in whom SSI develops compared with uninfected patients.[1] The Centers for Disease Control and Prevention (CDC) considers SSI to include both incisional SSI and organ space SSI. SSI was defined according to the CDC and Prevention.[2,3,4]

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Superficial incisional SSIs must meet the following criteria:

- Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision and
- Patient has at least one of the following criteria:
  a. Purulent drainage from the superficial incision
  b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

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c. At least one of the following signs or symptoms of infection.

Pain or tenderness, localized swelling, redness or heat, and superficial incision are deliberately opened by surgeon and are culture-positive or are not cultured (a culture-negative finding does not meet this criterion)

d. Diagnosis of superficial incisional surgical by the surgeon or attending physician.

Deep incisional SSIs must meet the following criteria:

- Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and
- The infection appears to be related to the operative procedure and involves deep soft tissues (e.g., fascial and muscle layers of the incision) and
- Patient has at least one of the following criteria:

a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least one of the following signs or symptoms: Fever (>38°C) or localized pain or tenderness (a culture-negative finding does not meet this criterion).

c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

d. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Surgical wounds are stratified into four classes:

- Class I (clean) - An uninfected operative wound in which no inflammation is encountered, and the respiratory, alimentary, genital and urinary tracts are not entered as part of the surgical procedure such as neurological procedure, eye surgery, orthopedic surgery (all closed fracture, arthroplasty, amputation, and removing of old implant), and vascular surgery.
- Class II (clean-contaminated) - Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled, uncomplicated conditions such as any wound open for drainage and reoperation at the same site.
- Class III (contaminated) - Wounds are open, fresh accidental wounds, or incisions made as part of operation, during which major breaks in sterile technique or gross spillage of gastrointestinal contents have occurred such as foreign body in a wound, open fracture, old burns, and open traumatic wounds.
- Class IV (dirty-infected) - Wounds are old traumatic wounds from dirty source or those that involve existing clinical infection or perforated viscera.

Prophylactic antibiotics have been described as antibiotics given for the purpose of preventing infection when infection is not present, but the risk of post-operative infection is present.[5] The use of prophylactic antibiotic therapy before the induction of anesthesia and continuing it after surgery is an accepted method of avoiding post-operative infection.[6,7] Essentially, prophylaxis augments the host's natural immune defense mechanism by increasing the amount of bacterial contamination needed to cause an infection.[8]

While the benefits of preventing surgical infections are apparent, one must also keep in mind the disadvantages of excess antimicrobial use. All infections cannot be prevented by the use of prophylactic antibiotics. Each patient has a unique set of immune defense against the risk of infection. The use of broad-spectrum antibiotics contributes to the development of multidrug-resistant organisms.[8] Infections due to resistant organisms are associated with a worse clinical outcome for each individual patient. There must be a delicate balance between the use of antimicrobial agents to prevent infection and the overuse of antimicrobial agents, which are associated with the development of multidrug-resistant organisms.[8] Cephalosporins and other antibiotics are used widely for prophylaxis in India and several reports have compared other antibiotics with cephalosporins.[7,12]

Patient risk factors thought to increase the chance of SSI include advanced age, poor nutritional status, obesity, smoking, diabetes, altered immune response, length of pre-operative stay, colonization with microorganisms, coexisting infections remote from operative site, setting of the procedure (elective or emergent, clean or contaminated, and others), and other risk factor such as duration of surgery, drain, and blood loss.[9-11]

The goal of antimicrobial prophylaxis is to achieve serum and tissue drug levels that exceed the minimum inhibitory concentration for the organisms likely to be encountered during the operation.[6] The idea is not to sterilize tissues but to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses.

There is no consensus with regard to the optimal duration of prophylaxis. The standard practice is to administer prophylactic intravenous (i.v.) antibiotics only on the day of surgery in Western countries.[13-15] However, in Japan, prophylactic i.v. antibiotics are administered for several days postoperatively, and 1 day antibiotic infusion is rare.

A questionnaire survey of Japanese orthopedic surgeons showed that 86% of surgeons administered i.v. antibiotics for 7 days or longer after prosthetic surgery.[15] Benefits of perioperative antimicrobial prophylaxis need to be balanced against risks. Before the understanding of surgical asepsis and the study and acceptance of the principles of antibiotic prophylaxis, postoperative infections were nearly universal. The benefits of decreased infection rate, length of hospital stay, mortality, and costs have been shown in various populations.[17]

MATERIALS AND METHODS

A prospective, randomized, comparative study was conducted in 200 patients who were admitted in orthopedic ward of K. J. Somaiya Medical College and Research Centre, Mumbai, for surgery for a period of 1 year.

Participants were randomly allocated to two groups by block randomization method. In each group, equal number of patients, i.e., 100 was included. The patients in Group I were given second-generation cephalosporin (cefuroxime 1.5 g) for 30 min prior to the induction of anesthesia which was continued till 48 h after surgery 12 h apart, then it was discontinued.

The patients in Group II were given perioperative long-term prophylactic i.v. antibiotic second-generation cephalosporins (cefuroxime 1.5 g) 30 min before the induction of anesthesia which was continued for 5 days of the post-operative period 12 h apart then they were further given an oral antimicrobial agent (tab cefuroxime 500 mg) 12 h apart until 14 days.

Patients were admitted a day before surgery. The operative area was cleaned of hairs night before surgery (use of razors over operative area avoided).[23] The patient took a bath with an antiseptic agent at least once on the night before the operation.[24]

Routine blood investigations such as complete hemogram, bleeding time, clotting time, erythrocyte sedimentation rate, C-reactive protein, renal function test, and liver function test were done.

Other investigations include:

- Radiographs including chest X-rays.
- Viral markers such as HIV, hemoglobin (Hb) Ag, and HCV.
- Urine routine and microbiology examination.

Aseptic Precautions in Operation Theater

All necessary precautions were followed such as using autoclaved gloves, sterile instruments and drapes, standard surgical scrub for 5 min before operation, cleaning of operative area with povidone-iodine and spirit,[25-29] minimal tissue handling, maintaining of adequate hemostasis, and minimal use of cautery, using drains wherever necessary.

Criteria to assess Infection

Our criteria for judging whether or not a wound infection occurred were as follows which has been modified from that of Pavel *et al*.[37]

1. If a wound drained purulent material irrespective of whether an organism was cultured or not, it was considered infected.
2. When a wound has become red, painful or tender, swollen, and hot for >48 h, the wound was considered infected.
3. When the patient had fever for >48 h and no other cause could be traced, the wound was considered infected.
4. If the patient had a stitch abscess with a small amount of purulence directly around a suture, but without any signs of inflammation or fever, the wound was not be considered infected.

Post-operative Care

All participants were treated by the standard surgical techniques. They were evaluated for the development of wound infections daily until the time of discharge. The wound was clinically observed on 2nd and 5th days after surgery when the dressings were done.

Drain was removed on 2nd post-operative day dressing. Apart from this, the patients were evaluated daily for any signs of wound infection such as local erythema, induration, local rise of temperature, and any discharge, and daily temperature charting was done. The ptient was discharged on 5th day after surgery. A clinical follow-up was done on 14th day when the patient's sutures were removed. Surgical site assessment was done for patients who came after suture removal for routine follow-up in OPD on the 28th day.

Observations

Majority of patients were male, i.e., 63% and 68% in Groups I and II. We also found equal number of female cases, i.e., 37% in Group I and 32% in Group II. Statistical comparison of both the groups showed no significant difference ($P > 0.05$). Mean age 41.68 ± 16.95 in Group I and 40.71 ± 17.22 in Group II showed no statistical significant difference ($P > 0.05$). Thus, we can say that both the groups were found to be comparable with each other. Mean body mass index (BMI) of all the cases was 23.21 ± 1.9 in Group I and 23.04 ± 3.0 in Group II.

We noted that laboratory investigations of both the groups are compared with each other, thus showing no statistical

difference among them ($P > 0.05$). Mean duration of the operation in the present study of all the cases was 65.27 ± 29.21 in Group I and 66.50 ± 25.11 in Group II. Statistical comparison of the duration of surgery of both the groups was found to be statistically non-significant ($P > 0.05$). A maximum number of patients were non-smoker, i.e., 76% in Group I and 73% in Group II. Only 24% and 27% of cases were found to be with smoking habits in Groups I and II, respectively. Statistical comparison of smoking habits of both the groups showed no significant difference ($P > 0.05$). Two patients (2%) developed SSI infection in Group I and three patients (3%) developed in Group II. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$). We did not find any case of deep SSI in any of the groups in our study. Two cases in Groups I and two cases in Group II in the age group of >60 years having superficial SSI. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$). Equal number of male, i.e. two cases each was found in both the groups and no female in Group I and 1 female in Group II suffered with infection. On statistical comparison, we found no significant difference between the two groups ($p>0.05$). One case in Group I and one case in Group II infected with SSI with BMI range from 18.5 to 24.9, and one case in Group I and two cases infected with SSI with BMI range from 25 to 29.9. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$).

DISCUSSION

Post-operative wound infections have been shown to significantly increase morbidity, extend patients hospital stay, drastically increase the cost of medical system, and cause severe physical limitations that diminish the quality of life. Decreasing the incidence of SSI is a matter of utmost interest to both patient and surgeon.

The use of prophylactic antibiotics is one of the most important factors in decreasing infection, and there is wide variability in the duration of their use.[18,22]Available literature recommends the use of prophylactic antibiotics for 24 h only.[39,44] Administration of prophylactic antibiotics for longer than 24 h has not been demonstrated to be effective and may actually lead to superinfection with drug-resistant organisms.[31,33]

The present study was conducted in K. J. Somaiya Medical College and Research Centre, Mumbai, with an aim to find optimal duration of prophylactic antibiotics in elective orthopedic surgeries.

A total of 200 patients who were undergoing clean elective orthopedic procedures were selected. These were divided into two groups of 100 patients each by block randomization method. he patients in the first Group received same i.v. antibiotic protocol as in the Group II for 48 h, then it was discontinued. The patients in Group II received perioperative long-term prophylactic i.v. antibiotic second-generation cephalosporins (cefuroxime 1.5 g) 30 min before the induction of anesthesia, which continued for 5 days of the post-operative period 12 h apart then they were further given an oral antimicrobial agent (tab cefuroxime 500 mg) 12 h apart till 14 days.

Cephalosporins and other antibiotics are used widely for prophylaxis in India and several reports have compared other antibiotics with cephalosporins.[7,12] The trend in Western literature is to use second-generation cephalosporins (cefuroxime) prophylactic antibiotics 30 min to 1 h before skin incision and preferable for 24 h to 3 days in i.v. infusion postoperatively.[21] Cefuroxime has high bioavailability in tissue and serum after a single dose and is efficacious for preventing perioperative infection.[34,36] Yeap *et al*[16] studied antibiotic prophylaxis in state-level hospitals and found out that 1st generation antibiotics as advised were not practiced in any of patients. Second-generation followed by third-generation cephalosporins were most popular antibiotics, with trend using third-generation antibiotics in arthroplasty patients. Cephalosporins are by far the most popular choice of antibiotics for prophylaxis.

In our study, of 200 patients, 131 (65.5%) were males and 69 (34.5%) were females. 4 (3.05%) of 131 males developed SSI compared to 1 (1.58%) of 63 females developed SSI. Shrestha *et al*.[19] found that infection rate among males was nearly twice that of females.

In this study, of 200 patients, 55 (27.5%) patients were more than 50 years of age group and 145 (72.5%) were below 50 years. Of 55 patients above 50 years, 5 patients (9.09%) developed infection. Chhabra *et al*.[39] found that patients aged more than 50 years most commonly developed SSI. Increasing age was found to be a significant influence on the rate of infection in this study; this is keeping with other studies.[32] Increased infection rates among the elderly may be attributed to low healing rates, malabsorption, and low immunity.[37]

In this study, smoking was associated with higher incidence of SSI. 51 patients (25.5%) were smokers and 149 (74.5%) were non-smokers. Of 51 patients who were smokers, 4 (7.84%) developed SSI and 1 (0.67%) of 149 non-smokers developed SSI. Masood *et al*.[38] showed 25% infection rates among smokers in their study. Smoking has detrimental effect on tissue oxygenation, impairing reparative process of wound healing, and neutrophil defense against surgical pathogens.[30]

In our study, average BMI in long duration group was 23.21 ± 1.9 kg/m^2 and short duration group was 23.04 ± 3.0 kg/m^2. Of 200, 31 (15.5%) patients had BMI >25 and 169 (84.5%) had BMI <25. Three patients (9.6%) of 31 patients with BMI >25 developed SSI compared to two patients (1.18%) of 169 with BMI <25. Masood *et al*.,[38] in their study, found out BMI >40 kg/m^2 to be associated with higher rate of SSI.

In our study, we found that mean Hb in long duration group was 11.128 ± 1.79, whereas mean Hb in short duration group was 11.069 ± 1.69. About 67 (33.5%) patients had Hb <10 g/dl, of which 5 (7.46%) developed SSI, whereas 143 (71.5%) patients with Hb >10 g%, of which no patient had developed SSI which was comparable to study done earlier. Masood *et al*.[38] found that higher incidence of SSI was noted in low pre-operative Hb (<10 g%) group. It may be due to poor oxygen and nutritional delivery to tissues.

In this study, of total 200 patients, 30 (15%) had TLC more than reference range, i.e. 11,000/mm^3. Four (13.33%) of these 30 developed SSI. Of 170 (85%) patients with TLC <11,000, one (0.59%) developed SSI. Guohua *et al*.[36] found that pre-procedural white blood cell count >10 × 10^9/L was identifiable risk factor for SSI.

Average duration of surgery in long-term antibiotics group was 65.27 ± 29.21 min and that of short-term antibiotics was 66.50 ± 25.11 min. 13 surgeries lasted more than 2 h, of which 1 (7.6%) developed SSI, whereas of 187 surgeries lasting <2 h, 4 (2.1%) developed SSI. Samuel *et al*.[40] found increased rates of infection in surgeries lasting longer than 2 h. Masood *et al*.[38] found that the rate of SSI was increased in surgeries lasting longer than 150 min.

We observed that the average cost of short course treatment amounted to Rs.800 per patient as compared to Rs. 2900 per patient for prolonged combinational regimens. Mathur *et al*.[20] found that shorter courses of perioperative antimicrobials reduce cost, toxicity, and development of drug resistance. Prolonged courses of prophylactic antimicrobials have tremendous economic consequences for health-care facilities. In developing nations, such resource saving can be utilized for purchase of other life-saving drugs/devices. Since perioperative prophylaxis contributes a significant proportion of in-hospital antimicrobial use, its judicious use will also curtail the cost of hospital treatment.[38-41]

In our study, SSI among long-term group was 2% and short-term group was 3% which was statistically insignificant. Similar results have been quoted by Mathur *et al*.[20] who found out that there is no significant difference between short course of injectable antibiotic cefuroxime 12 hourly for 48 h and long course of same injectable antibiotic for 5 days and then oral antibiotic cefuroxime 12 hourly until suture removal. He also found that the incidence of SSI was comparable in both the groups, i.e., 2% (2 of 100 patients) in short duration group and 2.06% (2 of 97 patients) in long duration group. Williams and Gustilo[41] retrospectively compared outcomes for 1341 joint arthroplasties who had received prophylaxis for 3 days with 450 patients undergone similar procedure and received antibiotics prophylaxis for 1 day. Infection developed in 8 (0.6%) of 1341 patients in Group I compared with 3 (0.67%) of 450 patients in Group II.

CONCLUSIONS

In our study, there was no statistical difference between the rate of infection among those who received 48 h i.v. antibiotics and those who received antibiotics for 14 days. It was concluded that there is no benefit of prophylactic antibiotic after 48 h in clean elective orthopedic surgeries. Short course antimicrobial prophylaxis is as effective as long course antimicrobial prophylaxis in developing country after clean elective orthopedic surgery. There are many risk factors associated with SSI such as age >50 years, male sex, Hb <10 g%, pre-operative TLC >11,000, BMI >25 kg/m^2, smoking, and duration of surgery >2 h.

Prophylactic administration of antibiotics for short term can decrease post-operative morbidity, shorten hospitalization, reduce the overall cost attributable to infection, prevent unnecessary use of antibiotics for longer periods, and reduce the risk of resistance of antibiotic in clean orthopedic surgery. However, since the sample size was less, larger and multicentric studies covering different regions of the country are required to substantiate the role of short-course prophylaxis in our country.

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