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Original Research Article

SINGLE-DOSE VERSUS MULTIDOSE CEFTRIAXONE PROPHYLAXIS FOR PREVENTION OF SURGICAL-SITE INFECTION IN ELECTIVE CLEAN AND CLEAN-CONTAMINATED GENERAL SURGERY: A HOSPITAL-BASED COMPARATIVE STUDY

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ABSTRACT

Background: Surgical antibiotic prophylaxis reduces the risk of surgical-site infection, but prolonged postoperative administration may increase cost, adverse effects and antimicrobial selection pressure without providing additional benefit. This study compared the frequency of surgical-site infection following single-dose and multidose ceftriaxone prophylaxis in patients undergoing elective clean or clean-contaminated general surgical procedures.

Materials and Methods: This hospital-based comparative experimental study was conducted in the Department of General Surgery, Hind Institute of Medical Sciences, Barabanki, from July 2020 to June 2021. One hundred patients undergoing elective clean or clean-contaminated surgery were randomly allocated in equal numbers to two groups. Group I received a single preoperative dose of ceftriaxone 30–60 minutes before incision, whereas Group II received the preoperative dose followed by postoperative ceftriaxone. Patients were monitored for surgical-site infection, and wound discharge was subjected to culture and antimicrobial-susceptibility testing. Categorical and continuous variables were analysed using the chi-square test and unpaired t-test, respectively, and relative risk with a 95% confidence interval was reported for surgical-site infection.

Results: The mean age was 43.54 ± 17.54 years in Group I and 38.88 ± 19.23 years in Group II. Males constituted 64.0% and 66.0% of the respective groups. Laparoscopic cholecystectomy was the most frequent procedure and was performed in 29 (58.0%) patients in Group I and 18 (36.0%) in Group II. Surgical-site infection occurred in 1/50 (2.0%) patients receiving single-dose prophylaxis and 2/50 (4.0%) receiving multidose prophylaxis. The relative risk for Group I compared with Group II was 0.50 (95% confidence interval: 0.05–5.4). All three infections were superficial. Staphylococcus aureus was isolated in two cases and Klebsiella pneumoniae in one.

Conclusion: The observed frequency of surgical-site infection did not differ significantly between the single-dose and multidose groups. The small number of infection events and wide confidence interval prevent a conclusion of equivalence, but the findings did not demonstrate an advantage of continued postoperative prophylaxis.

Keywords: Antibiotic prophylaxis; Ceftriaxone; Clean-contaminated surgery; Elective surgery; Surgical-site infection.

INTRODUCTION

Surgical-site infection (SSI) remains an important postoperative complication and contributes to prolonged hospitalisation, additional treatment, readmission and increased healthcare expenditure. Patients undergoing surgery in low- and middle-income settings may experience a greater burden of healthcare-associated infection than those treated in higher-income settings.[1] SSI may involve the skin and subcutaneous tissue, deeper fascial and muscular layers or an organ or space related to the operation.[2]

Appropriate surgical antibiotic prophylaxis is one component of a broader SSI-prevention strategy. Effective prophylaxis requires selection of an antimicrobial agent active against the organisms most likely to contaminate the operative field and administration at a time that provides adequate tissue concentrations during surgery.[2,3] The optimal timing for most intravenously administered prophylactic antibiotics is within 30–60 minutes before incision.[4]

Prolonged postoperative antibiotic administration may increase treatment costs, drug-related adverse events and selection pressure for antimicrobial resistance without necessarily improving SSI prevention. Antimicrobial-stewardship principles therefore emphasise appropriate indication, selection, timing, redosing and duration of surgical prophylaxis.[3,5] However, variation in perioperative prescribing remains common, and extended antibiotic courses continue to be used after clean and clean-contaminated operations.[6,7].

This study aimed to compare the frequency of SSI following single-dose and multidose ceftriaxone prophylaxis among patients undergoing elective clean or clean-contaminated general surgical procedures. The secondary objectives were to describe the clinical characteristics, causative microorganisms and antimicrobial-susceptibility patterns of the infections identified.

MATERIALS AND METHODS

Study design and setting: This was a hospital-based comparative experimental study conducted in the Department of General Surgery, Hind Institute of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh, India.

Study period: The study was conducted from July 2020 to June 2021.

Participants: One hundred patients undergoing elective surgery in the Department of General Surgery were included. Patients were randomly divided into two groups of 50 each.

Sample size: A total of 100 eligible patients were included, with 50 participants in each study group.

Inclusion criteria

- Undergoing elective surgery;
- Clean, class I, or clean-contaminated, class II, operative wound;
- Surgery performed in the Department of General Surgery;
- Either sex;
- Any age group.

Exclusion criteria

- Contaminated, class III, or dirty/infected, class IV, operative wounds;
- A pre-existing infection;
- Hypertension, diabetes mellitus, chronic obstructive pulmonary disease, neurological disease or other specified major comorbidity;
- Current corticosteroid use;
- Recent surgery;
- Massive transfusion;
- Three or more preoperative medical diagnoses;
- Severe malnutrition;
- Severe anaemia;
- An immunocompromised state.

Antibiotic-prophylaxis groups: All participants received ceftriaxone, a third-generation cephalosporin, 30–60 minutes before the surgical incision.

Group I received only the single preoperative dose and did not receive postoperative prophylactic antibiotics.

Group II received the preoperative dose followed by continued postoperative antibiotic doses.

Clinical assessment and follow-up: A clinical history was obtained and physical examination was performed. When a patient could not provide an adequate history, information was obtained from an attendant or relative. Data were entered in a predesigned, pretested, semi-structured questionnaire.

Patients were assessed postoperatively for erythema, wound discharge, seroma, wound fluctuation, constitutional symptoms, wound dehiscence and other evidence of SSI. In patients developing wound discharge, a specimen was sent for culture and antimicrobial-susceptibility testing. Infected wounds were dressed using aseptic precautions, and antimicrobial treatment was modified according to the culture and sensitivity report. Patients with SSI were followed until the infection subsided and the surgical wound healed.

Outcome measures: The principal outcome was the occurrence of SSI in each prophylaxis group. Additional outcomes included: Type of SSI; Clinical characteristics of infected wounds; Organisms isolated from wound discharge; Antimicrobial-susceptibility pattern and Wound condition during follow-up.

Statistical analysis: Categorical variables were presented as frequencies and percentages, while continuous variables were presented as mean ± standard deviation. Categorical comparisons were performed using the chi-square test. Mean haemoglobin and total leucocyte count values were compared using the unpaired t-test. Relative risk and

95% confidence interval were reported for SSI. Logistic regression was performed to assess the relationship of prophylaxis group, age, sex and duration of surgery with SSI.

Ethical considerations: Approval was obtained from the institutional ethics and scientific committee before commencement of the study. Written informed consent was obtained from each patient or from the attendant in the case of a minor. Confidentiality of the collected information was maintained.

RESULTS

Participant characteristics: All 100 included patients were analysed, with 50 patients in each prophylaxis group. The overall mean age was 41.21 ± 18.46 years. The mean age was 43.54 ± 17.54 years in the single-dose group and 38.88 ± 19.23 years in the multidose group. The age distribution did not differ significantly between groups (p=0.173).

Sixty-five patients were male and 35 were female. Males constituted 32/50 (64.0%) patients in Group I and 33/50 (66.0%) in Group II, with no statistically significant difference in sex distribution (p=0.834). Baseline haemoglobin and total leucocyte count values were also not significantly different between groups.

Clinical diagnoses and operative procedures: Gallstone disease was the most frequent diagnosis and was present in 47 (47.0%) patients. Indirect inguinal hernia was the next most frequent diagnosis, occurring in 22 (22.0%) patients. The diagnostic distribution did not differ significantly between groups (p=0.415).

Laparoscopic cholecystectomy was the most frequent operation, performed in 47 (47.0%) patients. Mesh hernioplasty was performed in 26 (26.0%), mesh hernioplasty with anatomical repair in 5 (5.0%), eversion of sac in 6 (6.0%), excision of lipoma in 8 (8.0%), wide local excision in 5 (5.0%) and enucleation in 3 (3.0%) patients. The distribution of procedures was not significantly different between groups (p=0.340).

Table 1: Demographic and baseline characteristics of the study groups

Characteristic	Group I: single dose (n=50)	Group II: multidose (n=50)	Total (N=100)	p-value
Age group, n (%)				0.173
<20 years	2 (4.0)	8 (16.0)	10 (10.0)	
20–39 years	21 (42.0)	21 (42.0)	42 (42.0)	
40–59 years	16 (32.0)	10 (20.0)	26 (26.0)	
≥60 years	11 (22.0)	11 (22.0)	22 (22.0)	
Age, mean ± SD, years	43.54 ± 17.54	38.88 ± 19.23	41.21 ± 18.46	
Sex, n (%)				0.834
Male	32 (64.0)	33 (66.0)	65 (65.0)	
Female	18 (36.0)	17 (34.0)	35 (35.0)	
Haemoglobin, mean ± SD	13.47 ± 1.60	12.99 ± 1.79	—	0.164
Total leucocyte count, mean ± SD	8518.00 ± 1494.44	8122.00 ± 1705.73	—	0.220

SD, standard deviation. Age and sex distributions were compared using the chi-square test. Haemoglobin and total leucocyte count were compared using the unpaired t-test.

Table 2: Diagnoses and surgical procedures in the study groups

Variable	Group I: single dose (n=50)	Group II: multidose (n=50)	Total (N=100)
Diagnosis, n (%)			
Gallstone disease	29 (58.0)	18 (36.0)	47 (47.0)
Indirect inguinal hernia	9 (18.0)	13 (26.0)	22 (22.0)
Direct inguinal hernia	1 (2.0)	3 (6.0)	4 (4.0)
Hydrocele	3 (6.0)	3 (6.0)	6 (6.0)
Inguinal and umbilical hernia	1 (2.0)	4 (8.0)	5 (5.0)
Vascular malformation	2 (4.0)	3 (6.0)	5 (5.0)
Fibroadenoma	2 (4.0)	1 (2.0)	3 (3.0)
Lipoma	3 (6.0)	5 (10.0)	8 (8.0)
Surgical procedure, n (%)			
Laparoscopic cholecystectomy	29 (58.0)	18 (36.0)	47 (47.0)
Mesh hernioplasty	10 (20.0)	16 (32.0)	26 (26.0)
Mesh hernioplasty with anatomical repair	1 (2.0)	4 (8.0)	5 (5.0)
Eversion of sac	3 (6.0)	3 (6.0)	6 (6.0)
Excision of lipoma	3 (6.0)	5 (10.0)	8 (8.0)
Wide local excision	2 (4.0)	3 (6.0)	5 (5.0)
Enucleation	2 (4.0)	1 (2.0)	3 (3.0)

The p-values for intergroup comparison were 0.415 for diagnosis and 0.340 for surgical procedure.

Operative characteristics: A standard four-port laparoscopic incision was used in 47 (47.0%) patients, an inguinal incision in 26 (26.0%), a vertical incision in 17 (17.0%), an elliptical incision in 5 (5.0%) and combined inguinal and upper-midline incisions in 5 (5.0%). Incision type did not differ significantly between groups (p=0.198).

Most operations lasted 60–120 minutes. The mean duration was 74.60 ± 33.03 minutes in Group I and 67.90 ± 28.39 minutes in Group II. The duration-

category distribution was not significantly different between groups (p=0.861).

Table 3: Operative characteristics of the study groups

Characteristic	Group I: single dose (n=50)	Group II: multidose (n=50)	Total (N=100)	p-value
Type of incision, n (%)				0.198
Inguinal	10 (20.0)	16 (32.0)	26 (26.0)	
Elliptical	2 (4.0)	3 (6.0)	5 (5.0)	
Vertical	8 (16.0)	9 (18.0)	17 (17.0)	
Inguinal and upper midline	1 (2.0)	4 (8.0)	5 (5.0)	
Standard four-port	29 (58.0)	18 (36.0)	47 (47.0)	
Duration of surgery, n (%)				0.861
<60 minutes	7 (14.0)	9 (18.0)	16 (16.0)	
60–120 minutes	41 (82.0)	39 (78.0)	80 (80.0)	
>120 minutes	2 (4.0)	2 (4.0)	4 (4.0)	
Duration, mean ± SD, minutes	74.60 ± 33.03	67.90 ± 28.39	71.25 ± 30.83	
SD, standard deviation.				

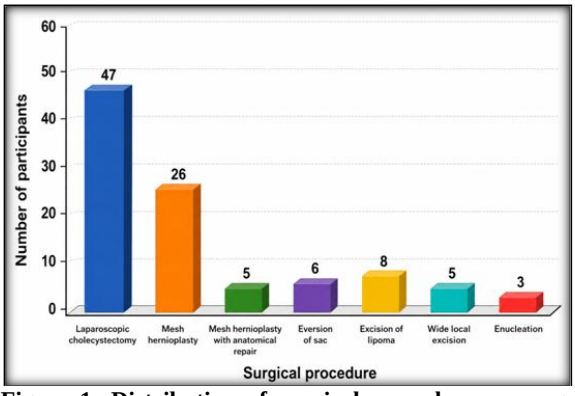

Figure 1: Distribution of surgical procedures among the study participants (N=100).

Vicryl 2-0 round-body suture was the most frequently used Vicryl material and was used in 52 (52.0%) patients. Nylon 2-0 cutting-body suture was used in 85 (85.0%) patients. Suture-material distributions did not differ significantly between groups for Vicryl (p=0.850) or nylon (p=0.736).

Surgical-site infection: SSI occurred in 3/100 (3.0%) patients. One infection occurred in Group I and two in Group II. The relative risk of SSI in Group I compared with Group II was 0.50 (95% confidence interval: 0.05–5.4).

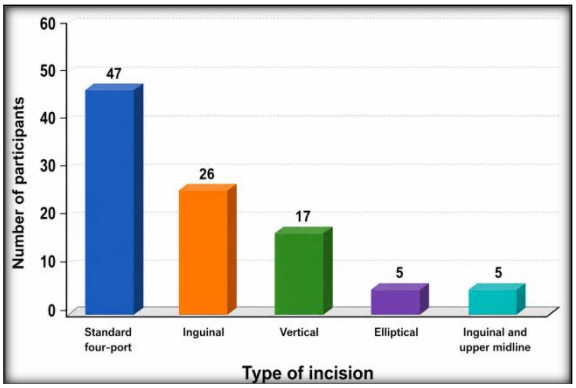

Figure 2: Distribution of incision types among the study participants (N=100).

Table 4: Surgical-site infection according to prophylactic-antibiotic regimen

Outcome	Group I: single dose (n=50)	Group II: multidose (n=50)	p-value
No SSI, n (%)	49 (98.0)	48 (96.0)	
SSI, n (%)	1 (2.0)	2 (4.0)	0.558
Relative risk	0.50	2.00*	
95% CI for relative risk	0.05–5.4	0.19–21.4*	
95% CI for group-specific SSI proportion	0.0–5.9%	0.0–9.4%	
The reciprocal relative risk is shown for Group II compared with Group I. CI, confidence interval; SSI, surgical-site infection.			

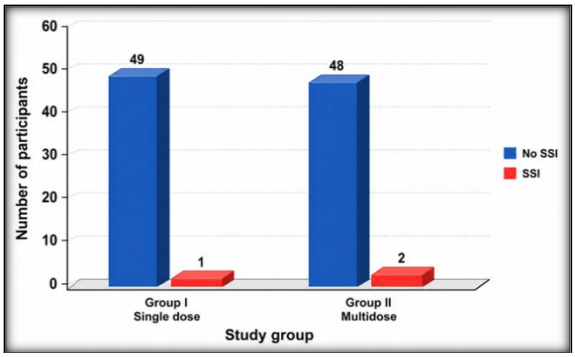

Figure 3: Comparison of surgical-site infection outcomes between the single-dose and multidose prophylaxis groups.

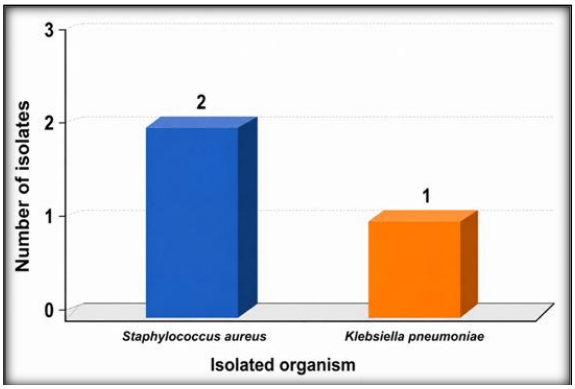

Figure 4: Microorganisms isolated from surgical-site infections (n=3 isolates).

Clinical and microbiological characteristics of SSI: All three infections were superficial. Erythema and wound discharge were present in all affected patients. Two patients had seroma and one had serous discharge. Surrounding erythema was recorded in all three patients, wound fluctuation in one, malaise in one and fever in one.

Staphylococcus aureus was isolated in two cases and Klebsiella pneumoniae in one. Both S. aureus isolates were susceptible to linezolid, vancomycin, gentamicin, amikacin and teicoplanin, while both were resistant to penicillin G. One of the two isolates was susceptible to ceftriaxone, cefixime, erythromycin, clindamycin, levofloxacin, cefoperazone-sulbactam, ciprofloxacin and tetracycline.

The K. pneumoniae isolate was susceptible to tigecycline, colistin and polymyxin B. It was resistant to ceftriaxone, ceftazidime, piperacillin-tazobactam, amoxicillin-clavulanate, gentamicin, ampicillin and cefepime.

Table 5: Clinical and microbiological profile of the three surgical-site infections

Characteristic	Group I: single dose (n=1 SSI)	Group II: multidose (n=2 SSI)	Total (n=3 SSI)
Erythema	1 (100.0)	2 (100.0)	3 (100.0)
Superficial SSI	1 (100.0)	2 (100.0)	3 (100.0)
Seroma	0	2 (100.0)	2 (66.7)
Serous discharge	1 (100.0)	0	1 (33.3)
Culture performed	1 (100.0)	2 (100.0)	3 (100.0)
Staphylococcus aureus	1 (100.0)	1 (50.0)	2 (66.7)
Klebsiella pneumoniae	0	1 (50.0)	1 (33.3)
Positive Gram stain	1 (100.0)	1 (50.0)	2 (66.7)
Wound fluctuation	0	1 (50.0)	1 (33.3)
Malaise	0	1 (50.0)	1 (33.3)
Fever	0	1 (50.0)	1 (33.3)
Data are presented as n (%). Percentages use the number of SSI cases in the corresponding group as the denominator.			

Among the three patients with SSI, one had no wound dehiscence, one had no wound dehiscence or seroma from postoperative day 3 onwards, and one developed slight wound dehiscence.

DISCUSSION

This study compared single-dose and multidose ceftriaxone prophylaxis in 100 patients undergoing elective clean or clean-contaminated general surgical procedures. SSI occurred in 2.0% of patients receiving a single preoperative dose and 4.0% receiving continued postoperative doses. The difference was not statistically significant, and the confidence interval around the relative risk was wide. The study therefore did not demonstrate a reduction in SSI with continued postoperative prophylaxis.

The demographic, diagnostic and operative profiles of the two groups were broadly similar according to the reported statistical comparisons. Laparoscopic cholecystectomy and mesh hernioplasty constituted most procedures, and 80.0% of operations lasted between 60 and 120 minutes. Differences in incision type, duration of surgery, haemoglobin, total leucocyte count and suture material were not statistically significant.

The principal finding is consistent with the report by Kanayama et al., in which the SSI rate after lumbar-spine surgery was 0.4% with single-dose and 0.8% with multidose prophylaxis, without a statistically significant difference.[8].

Naser et al. similarly compared single-dose and multidose prophylactic antibiotics for elective laparoscopic cholecystectomy, while Chauhan et al. evaluated omission of postoperative prophylaxis after elective laparoscopic cholecystectomy.[9,10].

These studies support the possibility that postoperative extension of prophylaxis may not provide additional benefit in appropriately selected elective procedures.

A meta-analysis by Meijer et al. of antimicrobial prophylaxis in biliary surgery did not establish a consistent advantage of multiple antibiotic doses over shorter prophylactic regimens.[11]. Nevertheless, the absence of statistical significance in the current study must not be interpreted as proof of equivalence. Only three SSI events were observed, producing imprecise effect estimates and a confidence interval compatible with both benefit and harm.

The overall SSI proportion of 3.0% was lower than the 7.57% reported by Mehta in a broader surgical population.[7] Differences in wound class, procedure type, patient risk profile, perioperative practice and duration of surveillance may account for variations between studies. The current study excluded contaminated and dirty procedures and several clinically important comorbidities, thereby selecting a population with a comparatively lower baseline risk of infection.

All infections in the study were superficial. S. aureus was the predominant isolate, followed by K. pneumoniae. This pattern is broadly consistent with the findings of Mundhada and Tenpe, who identified S. aureus among the common organisms isolated from SSI while also reporting gram-negative pathogens, including Klebsiella species.[1].

Both S. aureus isolates remained susceptible to linezolid, vancomycin, gentamicin, amikacin and teicoplanin, while both were resistant to penicillin

G. The K. pneumoniae isolate showed resistance to several beta-lactam and beta-lactam–beta-lactamase-inhibitor agents, including ceftriaxone. These findings illustrate the clinical importance of obtaining cultures from infected wounds and selecting treatment according to susceptibility results rather than extending empirical prophylaxis.

From an antimicrobial-stewardship perspective, unnecessary postoperative antibiotics increase antimicrobial exposure without demonstrated benefit. Stewardship programmes emphasise limiting prophylaxis to the appropriate indication and duration while maintaining correct timing and surgical asepsis.[3,5]. The current findings support further evaluation of restricted prophylactic regimens in adequately powered, procedure-specific trials.

Strengths and limitations: The study directly compared two commonly used prophylactic-antibiotic approaches and included microbiological assessment of all patients who developed wound discharge. The study also recorded demographic, operative and laboratory variables and reported both unadjusted and regression analyses.

Several limitations require consideration. This was a single-centre study with 100 participants and only three SSI events. The study was not designed as a formal non-inferiority or equivalence trial and lacked adequate precision to exclude an important difference between regimens.

The postoperative ceftriaxone dose, frequency and duration in the multidose group were not fully specified. The included operations were heterogeneous, and procedure-specific differences could not be evaluated reliably. Patients with contaminated or dirty wounds, severe anaemia, malnutrition, immunocompromised states and several common comorbidities were excluded, limiting generalisability to higher-risk surgical populations.

CONCLUSION

Among patients undergoing elective clean or clean-contaminated general surgical procedures, SSI occurred in 2.0% of those receiving single-dose ceftriaxone prophylaxis and 4.0% of those receiving multidose prophylaxis, without a statistically significant difference. All infections were superficial, and Staphylococcus aureus was the most frequently isolated organism. The findings do not demonstrate an advantage of continuing postoperative prophylactic ceftriaxone; however, the low event count and wide confidence interval prevent a conclusion of equivalence. Larger, procedure-specific studies with clearly defined antibiotic regimens and adequate post-discharge surveillance are required.

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