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Effectiveness of prophylactic single-dose IV antibiotic versus postoperative multi-dose oral antibiotic regimen for preventing surgical site infections: A prospective comparative study

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ABSTRACT

Objective: Surgical site infections (SSIs) are among the most common postoperative complications, contributing to morbidity, prolonged hospital stays, and healthcare costs. Prophylactic antibiotics are widely used, but the optimal regimen for clean elective surgeries remains debated.

Material and Methods: A hospital-based analytical cross-sectional study was conducted over a six-month period (March-August 2025) in the department of general surgery of a tertiary-care teaching hospital. Ninety-four consecutive patients undergoing clean elective surgeries were enrolled and allocated to two groups: Group A (n=52) received a single intravenous (IV) dose of cefotaxime 30 minutes prior to incision, and Group B (n=42) received postoperative multidose oral antibiotics according to institutional protocol. Baseline demographic and clinical data were recorded, and patients were monitored for signs of SSI, including fever, tachycardia, redness, and wound discharge.

Results: The mean age of Group A participants was 28.3±5.9 years compared to 36.4±7.3 years in Group B (p=0.042), though other socio-demographic variables were comparable. The overall incidence of SSI signs was low in both groups. Fever occurred in 13.4% of Group A and 14.2% of Group B; tachycardia occurred in 9.6% and 7.1%; redness in 1.9% and 7.1%; and wound discharge in 3.8% and 2.3% in Groups A and B, respectively; none of these differences were statistically significant (p>0.05 for all).

Conclusion: Single-dose IV prophylaxis was as effective as postoperative multi-dose oral antibiotics in preventing SSIs in clean elective surgeries. Short-course prophylaxis is sufficient in this setting and supports rational antibiotic stewardship.

Keywords: Surgical site infection, prophylaxis, intravenous antibiotics, oral antibiotics, elective surgery, antimicrobial stewardship

INTRODUCTION

Surgical site infections (SSIs) represent the third most frequently reported hospital-acquired infection and considerably affect patient outcomes by causing complications that hinder recovery and diminish quality of life. They also impose a substantial clinical and financial strain on healthcare systems (1,2). SSIs are described as infections involving the surgical wound or deeper tissues occurring within 30 days of the procedure, or up to one year if an implant is used (3). According to the World Health Organization, they are characterized by purulent discharge, local cellulitis, or infection at a drain insertion site (4). Globally, around 160,000-300,000 SSIs are documented annually, many of which require re-operations, prolong hospital stay, delay wound healing, and negatively influence cosmetic outcomes (5-7).

While most SSIs remain limited to superficial tissues, some can progress to severe necrotizing infections. Common clinical features include pain, redness, swelling, local warmth, and discharge of pus (8). These infections substantially increase healthcare costs and length of hospitalization (9-11). Patients who develop SSIs have over a 60% higher likelihood of requiring intensive care unit admission, are 15 times more likely to be readmitted within 30 days, and typically have an additional hospital stay of 6.5 days, with an average direct cost of about $3000 per episode (12). Methicillin-resistant *Staphylococcus aureus*-related SSIs are associated with higher morbidity and mortality compared to methicillin-sensitive strains (13).

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The use of prophylactic antibiotics has significantly reduced SSI rates in the last two decades. Ensuring adequate drug concentrations in tissues above the minimum inhibitory level during surgery is crucial to reinforce host defences (12,13). Consequently, perioperative prophylaxis, in conjunction with strict aseptic measures, has become a standard preventive practice in major surgeries (13).

The effectiveness of antibiotic prophylaxis largely depends on its timing. Classen et al. reported that infection risk was minimal when prophylaxis was administered within two hours before incision, whereas the TRAPE trial suggested the most effective window was within 30 minutes for cephalosporins and one hour for vancomycin or fluoroquinolones (14,15). Administration after incision is linked to a significantly higher risk of infection. Given that perioperative prophylaxis accounts for a substantial proportion of hospital antibiotic usage (16), this study focuses on evaluating the effectiveness of single-dose antibiotic prophylaxis in elective surgeries, specifically when administered 30 minutes before incision, in clean and clean-contaminated cases.

Aim & Objectives

Aim: The study aims to evaluate the role of prophylactic antibiotics to prevent SSIs in clean and elective surgeries

Objectives: 1. To study the effectiveness of intravenous (IV) single dose pre-operative prophylactic antibiotic vs. multiple postoperative oral doses of antibiotics in preventing SSI. 2. To compare the SSIs in both groups of patients.

MATERIAL and METHODS

Study Design

This investigation was a hospital-based prospective comparative study.

Study Population

The participants comprised patients admitted through the outpatient and inpatient departments and scheduled for minor surgical procedures. The study population included all individuals undergoing elective clean and clean-contaminated surgeries in the department of general surgery during the specified period.

Study setting: The research was conducted in the department of surgery of a tertiary care teaching hospital.

Study period: The study was conducted from March 2025 to August 2025 (six months).

Inclusion Criteria

i) Patients undergoing clean or clean-contaminated surgeries at the study site during the study period.
ii) Patients who provided written informed consent for participation.

Exclusion Criteria

i) Patients unwilling or unable to provide informed consent.
ii) Patients undergoing contaminated procedures where wound exposure to blood, body fluids, or bowel contents occurred.
iii) Patients with comorbidities that could independently influence SSI occurrence, such as uncontrolled diabetes, malnutrition, or anemia.
iv) Patients undergoing emergency surgical interventions.

Sample Size

The sample size was estimated using OpenEpi software (version 3). A prior study by Srivastav et al. (17) reported a 5.2% SSI rate. With approximately 1000 surgeries performed annually at the study hospital and considering an absolute precision of 5%, the required sample size was calculated to be 76. However, during the six-month study period, 94 eligible cases were available and included (17).

Ethical

Approval for the study was obtained from the Institutional Ethics Committee of NKP Salve Institute of Medical Sciences & Research Center, and Lata Mangeshkar Hospital (date: 27.03.2025, registration number: ECR/88/Inst/MH/2013/RR-24). Written informed consent was obtained from all participants.

Data

Collection: Eligible patients undergoing clean and clean-contaminated surgeries were enrolled. Socio-demographic variables such as age, sex, place of residence, educational level, and socio-economic background were collected using a pretested questionnaire. Patients were allocated into two groups:

- **Group A** (study group) received 1 g IV cefotaxime 30 minutes prior to skin incision.
- **Group B** (control group) did not receive prophylactic preoperative antibiotics but received postoperative antibiotics according to institutional guidelines. They were given oral cefixime 200 mg BD for five days.

All surgical procedures were performed under uniform aseptic precautions to reduce bias. Cases from both groups were followed up in the outpatient department after 30 days; those who did not attend (6 cases from group A and 2 cases from group B) were contacted by telephone to inquire about any signs or symptoms of SSI.

Clinical

Assessment: Data regarding type and duration of surgery, wound classification, presence of drains, comorbidities, and duration of hospital stay were recorded. Patients were monitored for manifestations of postoperative SSI, including fever, erythema, induration, stitch abscess, wound discharge, granuloma, and

wound dehiscence. In suspected cases, complete blood counts and pus cultures with antimicrobial sensitivity testing were performed. Wound swabs from infected cases were processed using standard microbiological techniques, as per institutional protocols, for both study groups (18).

The SSIs were defined in accordance with the CDC criteria for superficial SSIs, that included infection occurring within 30 days after the operation involving only skin or subcutaneous tissue of the incision and at least one of the following: i) purulent drainage, with or without laboratory confirmation, from the superficial incision ii) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision. iii) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative and iv) diagnosis of superficial incisional SSI by the surgeon (19).

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 25. Descriptive statistics such as mean, standard deviation, frequencies, and percentages were calculated for baseline variables. The incidence of SSI in the two groups was compared using the chi-square test or Fisher's exact test, as appropriate. Continuous variables were analyzed using Student's t-test or Mann-Whitney U test, depending on the data distribution. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 94 consecutive patients undergoing clean elective surgeries were included in the study. Of these patients, two groups were formed based on the antibiotic regimen received: One received a single prophylactic IV dose preoperatively, while the other received multiple postoperative oral doses. The baseline demographic and clinical characteristics, such as age, sex, and type of surgery, were comparable between the two groups, ensuring homogeneity for analysis.

The incidence of SSIs was systematically recorded and compared between the two groups. The outcomes were evaluated in terms of the proportion of patients who developed SSI, the time to onset of infection, and the severity of infection, if any.

A total of 94 patients undergoing clean-contaminated elective surgeries were included in the study: 52 in Group A (single-dose IV antibiotic) and 42 in Group B (postoperative multi-dose oral antibiotic). The baseline characteristics of the participants are summarized in Table 1.

The mean age of participants in Group A was 28.3±5.9 years, while in Group B it was 36.4±7.3 years, and this difference was statistically significant (p=0.042). However, when participants were stratified into age groups, no significant difference was observed between the two age groups (p=0.9297). The gender distribution was comparable, with males constituting 57.6% in Group A and 52.0% in Group B (p=0.5154). Similarly, residence (urban vs. rural) and socio-economic status, assessed using the Modified B.G. Prasad scale, did not differ significantly between groups ($p>0.05$). These findings indicate that the groups were generally comparable at baseline, except that Group B had a marginally higher mean age.

The clinical diagnoses of participants are shown in Figure 1. In group A, breast lump accounted for 40.0% of cases, whereas in group B, lipoma predominated, accounting for 36.2% of cases. Both groups were comparable in terms of surgical indications and operative procedures, thereby minimizing the likelihood of confounding due to the type of surgery performed. The occurrence of SSI signs in both groups is presented in Table 2. Fever was observed in 13.4% of patients in Group A and 14.2% in Group B (p=0.908). Tachycardia was present in 9.6% of participants in Group A and in 7.1% of participants in Group B (p=0.669). Redness at the suture line was noted in 1.9% of Group A patients and 7.1% of Group B patients, though this difference was not statistically significant (p=0.213). Wound discharge was observed in 3.8% of Group A, compared with 2.3% of Group B (p=0.687).

Overall, no statistically significant difference was found in the incidence of SSI-related signs between the single-dose IV antibiotic group and the multi-dose oral antibiotic group. The rates of fever, tachycardia, wound discharge, and local redness were low and comparable in both groups, suggesting that prophylactic single-dose IV antibiotics were as effective as postoperative multi-dose oral regimens in preventing SSIs.

The findings of this study indicate that both regimens—single-dose IV prophylaxis and postoperative oral multi-dose antibiotics—were effective in preventing SSIs in clean, elective surgeries, with no significant difference in infection-related outcomes between the two groups. Importantly, the low overall incidence of SSI highlights the adequacy of short-course prophylaxis, supporting antibiotic stewardship by reducing unnecessary exposure to prolonged postoperative antibiotics.

DISCUSSION

In this prospective comparative study of 94 patients undergoing clean elective operations, we found no statistically significant difference in SSI indicators between patients who received a single prophylactic IV antibiotic dose and those who received a postoperative multi-dose oral antibiotic course. Comparable frequencies of fever, tachycardia, erythema, and wound discharge in both groups suggest no statistically significant difference between single-dose prophylaxis and multi-dose regimens for clean surgical procedures.

Table 1. Baseline characteristics of the study participants (n=94)				
Socio-demographic variables	**Group A (n=52) n (%)**	**Group B (n=42) n (%)**	**Statistic**	**p-value**
Age (in years)				
Mean age ± SD	28.3±5.9	36.4±7.3	t=-2.492	0.042
Range	21-56	24-73		
Age groups				
≤30	7 (13.6)	5 (12.0)	Fischer's Exact test	0.9297
31-40	16 (30.8)	11 (26.1)		
41-50	20 (38.5)	16 (38.0)		
51-60	3 (5.7)	5 (12.0)		
61-70	4 (7.6)	3 (7.1)		
>70	2 (3.8)	2 (4.8)		
Gender				
Male	30 (57.6)	27 (52.0)	Chi-square =0.432	0.5154
Female	22 (42.4)	15 (48.0)		
Place of residence				
Urban	39 (75.0)	33 (78.5)	Chi-square =0.165	0.6843
Rural	13 (25.0)	9 (21.5)		
Socio-economic status*				
Class I (upper)	3 (5.7)	1 (2.4)	Chi-square =5.415	0.2473
Class II (upper-middle)	7 (13.5)	12 (28.6)		
Class III (middle)	15 (28.8)	9 (21.5)		
Class IV (lower-middle)	17 (32.7)	16 (38.0)		
Class V (lower)	10 (19.3)	4 (9.5)		
*: Modified B.G. Prasad scale was used to assess the socio-economic status, SD: Standard deviation.				

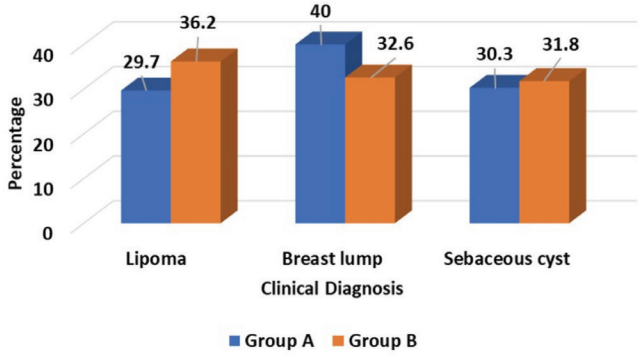

Figure 1. Distribution of the cases according to clinical diagnosis (n=94).

Table 2. Signs of SSI in both groups (n=94)			
Signs of SSI	**Group A**	**Group B**	**p-value**
Fever - Yes	7 (13.4)	6 (14.2)	0.908
Fever - No	45 (86.6)	36 (85.8)	
Tachycardia - Yes	5 (9.6)	3 (7.1)	0.669
Tachycardia - No	47 (90.4)	39 (92.9)	
Redness on the suture line - Yes	1 (1.9)	3 (7.1)	0.213
Redness on the suture line - No	51 (98.1)	39 (92.9)	
Wound discharge - Yes	2 (3.8)	1 (2.3)	0.687
Wound discharge - No	50 (96.2)	41 (97.7)	
SSI: Surgical site infection.			

The mean age difference between the two groups was statistically significant (p=0.042). Group A had a lower mean age (28.3±5.9 years) compared to Group B (36.4±7.3 years). Although the categorical distribution of age groups did not show a significant difference (p=0.9297), the difference in mean age could still be clinically relevant, as age is a potential confounding factor influencing wound healing and susceptibility to infection. Older patients generally have slower tissue repair and may be at higher risk of SSIs due to comorbidities or a reduced immune response. The age disparity between groups should be considered when interpreting the results; statistical adjustments or stratified analyses may be necessary to isolate the true effect of the antibiotic regimen on SSI rates.

Our results are consistent with several recent investigations and systematic reviews that have reported no added benefit of prolonged antibiotic courses over a single perioperative dose in lowering SSI risk (20). A comparative study in general and clean-contaminated surgeries also observed no significant advantage of multi-dose therapy, emphasizing that optimal aseptic techniques may suffice without extended dosing (21). Similarly, a randomized trial in implant-based breast reconstruction found that additional doses did not reduce infection rates but increased adverse reactions, underscoring an unfavorable risk-benefit profile (22). Reviews of gastrointestinal surgery outcomes likewise concluded that single-dose prophylaxis is as effective as longer regimens, discouraging routine extended use (23). These findings collectively indicate that with robust asepsis and perioperative practices, extended prophylaxis offers minimal additional value (23). The findings of this study align with the WHO (2018) and CDC (2017) Surgical Site Infection Prevention Guidelines, both of which emphasize that prophylactic antibiotics should be administered as a single pre-operative dose and not continued postoperatively in clean surgeries. Prolonged or unnecessary antibiotic use offers no additional protection against SSIs and instead contributes to antimicrobial resistance, adverse drug effects, and increased healthcare costs. Therefore, minimizing the duration of antibiotic prophylaxis, as demonstrated in this study, supports key antimicrobial stewardship principles aimed at optimizing patient outcomes while reducing the emergence of resistant organisms (19,24).

Nevertheless, evidence from certain surgical subspecialties cautions against universal application of single-dose protocols. Tamayo et al. (25). reported higher SSI rates with a single cefazolin dose compared to a 24-hour regimen in cardiac surgery. However, the infection risk in cardiac operations—owing to cardiopulmonary bypass, prosthetic grafts, and longer wound exposure—is not directly comparable to clean soft-tissue surgeries. In orthopedic trauma, Slobogean et al. (26) noted SSI rates of 2.5% with single-dose prophylaxis versus 2.0% with multiple doses, a non-significant difference, further supporting shorter regimens in that context. Thus, the antibiotic strategy should remain tailored to the procedure type and the associated risk conditions.

A notable strength of this study is the relatively uniform patient cohort, limited to clean elective surgeries, minimizing confounding factors such as emergency settings or risk of contamination. Baseline demographics, including sex, residence, and socio-economic status, were evenly distributed, and despite minor differences in mean age, stratified analysis confirmed no significant imbalance. Moreover, focusing on direct SSI-related signs (fever, tachycardia, redness, discharge) ensured clinically meaningful outcomes instead of relying on surrogate measures.

From practical and stewardship perspectives, our findings support the use of single-dose IV prophylaxis for clean elective surgeries performed under optimal sterile conditions. This approach reduces unnecessary antibiotic exposure adverse drug effects antimicrobial resistance pressure, and treatment costs. Nonetheless, clinical decisions should incorporate procedure complexity, comorbidity profiles (such as diabetes or immunosuppression), and institutional SSI trends.

Study Limitations

The study is limited by the absence of microbiological data, heterogeneity of surgical procedures that could influence SSI rates, and a small, non-randomized sample size, which may affect the generalizability and validity of the findings.

CONCLUSION

The present study adds to the growing body of evidence that single-dose antibiotic prophylaxis is both safe and effective in clean elective surgical procedures. Larger multicenter randomized trials with microbiological confirmation and longer follow-up are needed to identify situations where extended prophylaxis might still be warranted.

Ethics

Ethics Committee Approval: Approval for the study was obtained from the Institutional Ethics Committee of NKP Salve Institute of Medical Sciences & Research Center, and Lata Mangeshkar Hospital (date: 27.03.2025, registration number: ECR/88/Inst/MH/2013/RR-24).

Informed Consent: Written informed consent was obtained from all participants.

Footnotes

Author Contributions

Surgical and Medical Practices - V.P.P.; Concept - V.P.P.; Design - V.P.P., G.D.; Data Collection or Processing - V.P.P., G.D., P.B., A.H., V.Y., N.V.; Analysis or Interpretation - V.P.P., G.D., P.B., A.H., V.Y.; Literature Search - V.P.P., G.D., P.B., A.H., V.Y., N.V.; Writing - V.P.P., G.D., P.B., A.H., V.Y., N.V.

Conflict of Interest: No conflict of interest was declared by the authors.

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