E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.01.241

Original Research Article

A Comparative Study of No Antibiotic versus Single Dose Prophylactic Antibiotics in Clean and Clean Contaminated Surgical Cases

Dr. Mythreye Sm. R.[1], Dr. Pushpa Satish Kumar[2*], Dr. Nithya T.[3], Dr. Ananda B.B[4]
[1]Senior Registrar, Manipal Hospital, Sarjapura Road, Bengaluru, Karnataka, India.
[2*]Associate Professor, Department of General Surgery, Dr. B. R. Ambedkar Medical College & Hospital, Bengaluru, Karnataka, India.
[3]Senior Resident, Department of General Surgery, Dr. B. R. Ambedkar Medical College & Hospital, Bengaluru, Karnataka, India.
[4]Ex - Professor, department of General Surgery, Dr. B.R. Ambedkar Medical College and Hospital, Bengaluru, Karnataka, India.
Corresponding Author: Dr. Pushpa Satish Kumar
Associate Professor, Department of General Surgery, Dr. B. R. Ambedkar Medical College & Hospital, Bengaluru, Karnataka, India.

Received: 20.02.26, Revised: 23.04.26, Accepted: 29.04.26

ABSTRACT

Background: Surgical site infections remain a significant cause of postoperative morbidity, increasing hospital stay and healthcare costs. Although antibiotic prophylaxis has improved surgical outcomes, its overuse contributes to antimicrobial resistance and adverse effects. The necessity of prophylactic antibiotics in clean and clean-contaminated surgeries remains controversial. This study evaluates the role of single-dose prophylactic antibiotics compared to no antibiotic use in preventing SSI (Surgical Site Infections).

Methods: This randomized prospective study was conducted on 100 patients undergoing clean and clean-contaminated surgeries between December 2017 and April 2019. Patients were divided into two groups: Group A (n=50) received a single preoperative dose of third-generation cephalosporin, and Group B (n=50) received no antibiotics. Wounds were assessed for SSI on postoperative days 2, 5, and 7 using Southampton scoring. Statistical analysis was performed using chi-square and t-tests with significance set at $p<0.05$.

Results: Out of 100 patients, 17% developed SSI. In Group A, 18% (9 patients) developed SSI, while in Group B, 16% (8 patients) developed SSI. No statistically significant association was found between antibiotic use and SSI occurrence ($p=0.590$). SSI rates were 14% in clean cases and 20% in clean-contaminated cases. Risk factors such as prolonged preoperative hospital stay, advanced age, smoking, diabetes, and drain placement contributed to higher SSI incidence. No significant association was observed with sex, BMI, or smoking individually. Conversion from no-antibiotic to full antibiotic therapy occurred in 6% of cases.

Conclusion: Single-dose prophylactic antibiotics did not significantly reduce SSI compared to no antibiotic use in clean and clean-contaminated surgeries. SSI occurrence is more strongly associated with patient-related and procedural risk factors rather than antibiotic prophylaxis alone. Rational antibiotic use, improved surgical techniques, and risk factor management are essential to minimize SSI and prevent antibiotic resistance.

Keywords: Surgical Site Infection (SSI), Prophylactic Antibiotics, Clean Surgery, Clean-Contaminated Surgery, Antibiotic Resistance.

INTRODUCTION

Surgical site infections are among the most common postoperative complications and contribute significantly to patient morbidity, prolonged hospital stay, and increased healthcare costs.[1] SSI accounts for approximately 20% of all healthcare-associated infections worldwide, making it a major concern in surgical practice.[2] Despite advances in aseptic techniques, sterilization, and perioperative care, SSI continues to remain a persistent problem, particularly in developing countries.[3]

The introduction of antibiotics in the 20th century revolutionized surgical outcomes by significantly reducing infection-related mortality.[4] Prophylactic antibiotic administration, especially in contaminated and clean-contaminated surgeries, has been shown to reduce the incidence of SSI.[5] However, the routine use of antibiotics in clean surgical procedures remains controversial, as these procedures inherently carry a low risk of infection (1–5%).[6]

In recent decades, there has been a growing concern regarding the irrational and prolonged use of antibiotics in surgical practice. Studies have shown that extended antibiotic use does not provide additional benefit in preventing SSI but instead contributes to antimicrobial resistance, increased cost, and drug-related adverse effects.[7,8] The emergence of resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) has further emphasized the need for judicious antibiotic use.[9]

Current guidelines, including those from the World Health Organization (WHO), recommend a single preoperative dose of prophylactic antibiotics, administered within 120 minutes before incision, and advise against prolonged postoperative antibiotic use.[10] Several studies have demonstrated that a single-dose regimen is as effective as multiple-dose regimens in preventing SSI in many surgical settings.[11,12] Furthermore, some studies suggest that in selected clean and clean-contaminated cases, omission of antibiotics may not significantly increase the risk of infection.[13]

However, clinical practices vary widely, particularly in resource-limited settings, where prolonged antibiotic use is still common due to fear of infection and lack of standardized protocols.[14] There remains a need for well-designed comparative studies to evaluate whether antibiotic prophylaxis is truly necessary in all clean and clean-contaminated surgeries.

AIM AND OBJECTIVES

The present study aims to compare the outcomes of single-dose antibiotic prophylaxis versus no prophylactic antibiotic use in patients undergoing clean and clean-contaminated surgical procedures, with particular emphasis on understanding the impact of antibiotic use and misuse in preventing surgical site infections. The objectives of the study are to evaluate the incidence of postoperative wound infections in both groups, to assess the effectiveness of prophylactic antibiotics compared to no antibiotic administration in reducing SSI rates, and to determine the proportion of patients in the no-antibiotic group who subsequently require conversion to full-dose antibiotic therapy due to the development of infection or related complications.

MATERIALS AND METHODS

Study Design

This randomized prospective comparative study was conducted over a period of 17 months, from December 2017 to April 2019, at Dr. B. R. Ambedkar Medical College and Hospital, Bangalore. It involves patients undergoing clean and clean-contaminated surgical procedures, who were randomly allocated into two groups: one group receiving a single dose of prophylactic antibiotics and the other group receiving no antibiotics. Data were systematically collected and analyzed to compare outcomes between the two groups with respect to the incidence of surgical site infections.

Inclusion and Exclusion Criteria

The study included patients of all age groups and both sexes with ASA grade I who were posted for clean and clean-contaminated surgical procedures, including open or laparoscopic surgeries with or without prosthesis, performed under general, regional, or local anaesthesia. Patients were excluded if they had a history of hypersensitivity to any group of drugs, were on long-term psychiatric medications, had significant comorbid conditions such as renal, cardiac, or hepatic disease, refused to provide consent, or were morbidly obese with a BMI (Body Mass Index) greater than 35.

Sample Size Calculation

Formula: $N=Z1\text{-}X/2^{2*}p*(1\text{-}P)$ divided by $d^{2\cdot}$ P = Prevalence of population – 12.6% 1-X = confidence level - 0.95.

D =Absolute precision = 0.09

N=minimum sample size = 99

The prospective type of study and the prevalence of SSI in recent studies showed 12.6% with above mentioned confidence interval. So with the help of the formula used above, the minimum sample size is 99. The sample size used in the present study is 100, which is divided into two groups, group A and group B. Each group contains 50 patients in a randomized study.

Data Collection Procedure

After explaining the study protocol and obtaining informed consent, a total of 100 patients were enrolled and randomly allocated into two equal groups of 50 each. Group A received a single preoperative dose of third-generation cephalosporin (inj. cefotaxime 1 g IV or inj. ceftriaxone 1 g IV) administered 30 minutes prior to surgery, while Group B did not receive any antibiotic prophylaxis. Postoperatively, all patients were monitored, and surgical wounds were systematically inspected on postoperative days (POD) 2, 5, and 7 for signs of surgical site infection, including inflammation or discharge. Any suspicious wound discharge was collected and sent for microbiological culture and sensitivity testing, and findings were recorded for analysis.

Statistical Analysis

Descriptive and inferential statistical analyses were performed using SPSS version 20.0, with Microsoft Word and Excel used for generating tables and graphs. Continuous variables were expressed as mean ± standard deviation (SD) with range, while categorical variables were presented as frequencies and percentages. Statistical significance was assessed at a 5% level ($p<0.05$). Chi-square test was used to evaluate associations between categorical variables, and an independent t-test was applied to compare means between two groups. Regression analysis was also performed where appropriate. P-values were interpreted as suggestive ($0.05<p<0.10$), moderately significant ($0.01\leq p\leq 0.05$), and strongly significant ($p\leq 0.01$).

RESULTS

Sex	Frequency	Percentage (%)
Male	46	46%
Female	54	54%
Total	**100**	**100%**

Table 1: Distribution of Study Population by Sex

Table 1 illustrates the gender distribution of the study population, showing a slightly higher proportion of females (54%) compared to males (46%), indicating a fairly balanced sample.

Group	Male	Female	Total
A (Antibiotic)	19	28	47
B (No Antibiotic)	27	26	53
Total	**46**	**54**	**100**

Table 2: Distribution of Antibiotic Groups by Sex

Table 2 shows the distribution of patients across antibiotic groups by sex, demonstrating no significant association between gender and antibiotic allocation ($p=0.292$).

SES Category	Frequency	Percentage (%)
BPL	79	79%
APL	21	21%
Total	**100**	**100%**

Table 3: Socioeconomic Status (SES) Distribution

Table 3 illustrates that the majority of patients (79%) belonged to the BPL (Below Poverty Line) category, suggesting a predominance of lower socioeconomic status in the study population.

Duration (Days)	Frequency	Percentage (%)
0 days	17	17%
1 day	51	51%
2 days	23	23%
3 days	7	7%
4–5 days	2	2%
Total	**100**	**100%**

Table 4: Preoperative Hospital Stay Distribution

Table 4 shows that most patients (51%) had a preoperative hospital stay of one day, and longer preoperative stays were associated with increased incidence of wound infection.

Type of Case	Frequency	Percentage (%)
Clean	61	61%
Clean Contaminated	39	39%
Total	**100**	**100%**

Table 5: Type of Surgical Cases

Table 5 demonstrates that clean cases constituted the majority (61%) of surgeries, while clean-contaminated cases accounted for 39% of the study population.

Smoking Status	Frequency	Percentage (%)
Non-smoker	89	89%
Smoker	11	11%
Total	**100**	**100%**

Table 6: Smoking Status Distribution

Table 6 shows that the majority of patients (89%) were non-smokers, and no significant association was found between smoking status and antibiotic group (p=0.913).

Group	No Infection	Infection	Total
A (Antibiotic)	38	9	47
B (No Antibiotic)	45	8	53
Total	**83**	**17**	**100**

Table 7: Antibiotic Use vs. Wound Infection

Table 7 illustrates the comparison between antibiotic use and wound infection, showing similar infection rates in both groups (18% in Group A vs 16% in Group B), with no statistically significant association (p=0.590).

DISCUSSION

The present study showed an overall surgical site infection (SSI) rate of 17%, with 18% in the antibiotic group and 16% in the no-antibiotic group, demonstrating no statistically significant association between antibiotic prophylaxis and SSI. This finding aligns with existing literature that questions the routine use of antibiotics in clean and clean-contaminated surgeries. The overall SSI incidence in our study is slightly higher than the 12.6% prevalence reported in tertiary care centres,[3] which may be attributed to institutional factors, patient characteristics, and perioperative practices.

The role of antibiotic prophylaxis in preventing SSI has been widely debated. In the present study, single-dose prophylactic antibiotics did not significantly reduce SSI rates, which is consistent with the findings of Knight et al., who reported that prophylactic antibiotics are not indicated in clean general surgical cases.[13] Similarly, Woods and Dellinger emphasized that appropriate selection and timing of antibiotics are more important than prolonged administration.[8] However, studies such as Carlson et al. demonstrated a significantly lower infection rate with prophylactic antibiotic use.[15] and Dhanke et al. reported minimal infection rates in patients receiving prophylaxis.[16] These variations may be due to differences in study design, surgical environment, and adherence to aseptic techniques.

With respect to wound classification, our study observed an SSI incidence of 14% in clean cases and 20% in clean-contaminated cases. These findings are comparable to those reported by Lilani et al., who observed infection rates of 3.68% in clean and 22.4% in clean-contaminated cases.[17] Similarly, Karlatti et al. reported infection rates of 1.95% in clean and 21.05% in clean-contaminated cases.[18] While the infection rate in clean-contaminated cases is comparable, the higher rate in clean cases in our study may reflect local factors such as surgical technique, sterilization practices, and patient-related risk factors.

Age was identified as an important risk factor in our study, with a higher incidence of SSI among patients above 50 years. This observation is supported by Garibaldi et al., who highlighted age as a significant risk factor due to reduced immunity and delayed wound healing.[19] Additionally, the presence of multiple risk factors such as diabetes, smoking, and prolonged operative duration was associated with increased SSI incidence in our study. This finding is consistent with Karlatti et al., who emphasized that the presence of multiple risk factors significantly increases the likelihood of SSI.[18]

Preoperative hospital stay was found to have a strong association with SSI in our study, with increased infection rates observed in patients with longer hospital stays. This is supported by Cheadle, who identified prolonged hospitalization as a key risk factor for surgical site infections.[20] Increased hospital stay exposes patients to nosocomial pathogens, thereby increasing infection risk.

Drain placement was also associated with SSI in our study, with a considerable proportion of infected cases having drains in situ. This observation is consistent with findings from infection control guidelines, which state that drains may act as a conduit for bacterial entry if not managed properly.[1] However, according to WHO guidelines, prolonged antibiotic prophylaxis is not recommended solely due to the presence of drains,[10] which is in agreement with our study findings.

In contrast, factors such as smoking, BMI, and sex did not show a statistically significant association with SSI in our study. While smoking is known to impair wound healing, the lack of association in our study may be due to the smaller number of smokers in the study population. Similarly, BMI did not influence SSI rates significantly, possibly due to the exclusion of morbidly obese patients.

Microbiological analysis in our study revealed Escherichia coli and Staphylococcus aureus as the most common organisms isolated. This is consistent with standard microbiological patterns of SSI described in surgical literature, where endogenous flora are the primary source of infection.[21]

The findings of this study suggest that single-dose antibiotic prophylaxis does not significantly reduce SSI rates in clean and clean-contaminated surgeries. Instead, factors such as aseptic surgical technique, control of comorbid conditions, minimizing hospital stay, and proper perioperative care play a more critical role in preventing SSI. These findings support current recommendations that advocate for judicious use of antibiotics to prevent antimicrobial resistance while maintaining effective infection control practices.[10]

CONCLUSION

This randomized prospective study involving 100 patients compared single-dose prophylactic antibiotics with no antibiotic use in clean and clean-contaminated surgeries and found no significant association between antibiotic prophylaxis and the incidence of surgical site infections**.** The study also demonstrated that factors such as drain placement, smoking, sex, and BMI were not significantly associated with SSI**,** whereas preoperative hospital stay and poor nutritional status showed a higher association with infection rates**.** The conversion rate from no-antibiotic group to full-dose antibiotic therapy was 6%, indicating that most patients did not require postoperative antibiotics. These findings suggest that routine use of prophylactic antibiotics may not be necessary**,** and emphasis should instead be placed on aseptic surgical techniques, minimizing hospital stay, and optimizing patient-related risk factors. Additionally, whenever SSI occurs, appropriate culture and sensitivity testing should guide antibiotic therapy, helping to reduce unnecessary antibiotic use and combat the growing issue of antimicrobial resistance.

REFERENCES

1. Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Infection Control & Hospital Epidemiology 1999;20(4):247-80.
2. Allegranzi B, Nejad SB, Combescure C, et al. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. The Lancet 2011;377(9761):228-41.
3. Kumar A, Rai A. Prevalence of surgical site infection in general surgery in a tertiary care centre in India. Int Surg J 2017;4(9):3101.
4. Fleming A. Discovery of penicillin. Br J Exp Pathol 1929.
5. Prophylaxis DO. Antimicrobial Prophylaxis for Surgical Wounds. Arch Surg 1993;128:79-88.
6. Cruse PJ, Foord R. A five-year prospective study of 23,649 surgical

wounds. Archives of Surgery (Chicago, Ill.: 1960) 1973;107(2):206-10.

7. Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. American Journal of Health-System Pharmacy 2013;70(3):195-283.
8. Woods RK, Dellinger EP. Current guidelines for antibiotic prophylaxis of surgical wounds. American Family Physician 1998;57(11):2731-40.
9. Chambers HF. The changing epidemiology of Staphylococcus aureus? Emerging Infectious Diseases 2001;7(2):178-82.
10. World Health Organization. Global guidelines for the prevention of surgical site infection. World Health Organization 2016.
11. Esposito S. Is single-dose antibiotic prophylaxis sufficient for any surgical procedure? Journal of Chemotherapy 1999;11(6):556-64.
12. Ranjan A, Singh R, Naik P. A comparative study of single-dose preoperative antibiotic prophylaxis versus routine long-term postoperative prophylaxis in elective general surgical cases. International Journal of Medical Science and Public Health 2016;5(6):1083.
13. Knight R, Charbonneau P, Ratzer E, et al. Prophylactic antibiotics are not indicated in clean general surgery cases. The American Journal of Surgery 2001;182(6):682-6.
14. Pittet D, Allegranzi B, Storr J, et al. Infection control as a major World Health Organization priority for developing countries. Journal of Hospital Infection 2008;68(4):285-92.
15. Carlson GE, Gonnlanakis C, Tsatsakis A. Pre-incisional single dose ceftriaxone for prophylaxis of surgical wound. American Journal of Surgery 1995;170(4):353-5.
16. Dhanke P, Gurav P, Ugane S. A comparative study for the role of preoperative antibiotic prophylaxis in prevention of surgical site infections. IOSR Journal of Dental and Medical Sciences 2014;13:27-31.
17. Lilani SP, Jangale N, Chowdhary A, et al. Surgical site infection in clean and clean-contaminated cases. Indian Journal of Medical Microbiology 2005;23(4):249.
18. Karlatti S, Havannavar IB. A comparative prospective study of preoperative antibiotic prophylaxis in the prevention of surgical site infections. International Surgery Journal 2016;3(1):141-5.
19. Garibaldi RA, Cushing D, Lerer T. Risk factors for postoperative infection. The American Journal of Medicine 1991;91(3):S158-63.
20. Cheadle WG. Risk factors for surgical site infection. Surgical infections 2006;7(S1):s7-11.
21. Allen SD, Koneman EW, Janda WM, et al. Introduction to microbiology- part 2: wound infections. Konemans color atlas and textbook of diagnostic microbiology. 6th edn. Philadelphia: Lippincott Williams and Wilkins 2006: 95-6.