E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.02.523

Research Article

Role of Preoperative Prophylactic Antibiotics in Prevention of Surgical Site Infections in Clean Wounds

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Received: 09.07.26, Revised: 03.08.26, Accepted: 11.08.26

ABSTRACT

Background: The role of routine antibiotic prophylaxis in clean elective surgery remains uncertain. This study evaluated its effectiveness in preventing surgical site infection (SSI).

Methods: This prospective comparative study included 50 patients undergoing clean elective surgery, with 25 patients each in the antibiotic and no-antibiotic groups. Patients were followed for 30 days for SSI and wound-related outcomes.

Results: Baseline characteristics were comparable between the groups. SSI occurred in 3 (12%) patients receiving prophylactic antibiotics and 4 (16%) patients without prophylaxis (p=0.69). Superficial SSI occurred in 8% and 12% of patients, respectively, while deep SSI occurred in 4% of each group. Mean wound-healing duration was 8.4 ± 2.1 versus 9.1 ± 2.5 days (p=0.21). Antibiotic prophylaxis was associated with lower odds of SSI (OR 0.62; 95% CI 0.10–3.93), but the association was not statistically significant (p=0.615).

Conclusion: Preoperative antibiotic prophylaxis did not significantly reduce SSI or improve wound-healing outcomes in clean elective surgery. A selective, risk-based approach to prophylactic antibiotic use may be appropriate.

Keywords: Antibiotic Prophylaxis, Clean Surgery, Surgical Site Infection, Wound Healing, Antimicrobial Stewardship.

INTRODUCTION

Surgical site infections (SSIs) remain among the most common healthcare-associated infections and are an important cause of postoperative morbidity worldwide.[1,2] They contribute to delayed wound healing, prolonged hospitalization, increased readmission and reintervention rates, higher healthcare costs, and, occasionally, mortality.[3] The burden is particularly significant in low- and middle-income countries, where limitations in infection-control infrastructure and variable adherence to preventive measures may increase the risk of SSI.[4]SSIs are classified as superficial incisional, deep incisional, and organ/space infections according to the anatomical structures involved.[2,5] Their development is multifactorial and depends on microbial contamination, host susceptibility, and operative factors. Important patient-related risk factors include advanced age, diabetes mellitus, obesity, malnutrition, smoking, immunosuppression, and malignancy, while procedure-related factors include wound contamination, prolonged operative duration, tissue trauma, emergency surgery, use of drains, and higher American Society of Anesthesiologists (ASA) physical status.[2,6–9]Surgical wounds are categorized as clean, clean-contaminated, contaminated, and dirty/infected based on the degree of microbial contamination.[2,10] Clean wounds are uninfected operative wounds in which no inflammation is encountered, aseptic technique is maintained, and the respiratory, gastrointestinal, genital, or urinary tract is not entered.[2] Consequently, clean surgical procedures have a relatively low baseline risk of SSI, generally reported to be below 2% under optimal surgical conditions.[1]Prevention of SSI involves a multimodal approach including appropriate patient preparation, skin antisepsis, maintenance of aseptic technique, glycaemic control, normothermia, careful tissue handling, and appropriate postoperative wound care.[4,10,11] Preoperative antibiotic prophylaxis is an established preventive measure, particularly for clean-contaminated and contaminated procedures.[9,13] Its objective is to achieve adequate antimicrobial concentrations in serum and tissues at the time of incision and during the period of potential microbial contamination.[9] Appropriate administration before incision has been shown to reduce SSI rates in procedures for which prophylaxis is indicated.[9,14]However, the role of routine antibiotic prophylaxis in clean surgical wounds without prosthetic implantation remains controversial. Because the intrinsic infection risk is low, routine prophylaxis is generally not considered necessary for many clean procedures.[9] Nevertheless, antibiotics are frequently administered in clinical practice even in clean surgeries, resulting in considerable variation in prescribing practices.[15] Unnecessary antimicrobial exposure may contribute to antimicrobial resistance and can increase the risk of adverse drug reactions, *Clostridioides difficile* infection, disruption of normal microbiota, and healthcare costs.[16,17]However, certain patients undergoing clean surgery may have an increased risk of SSI because of diabetes, obesity, immunosuppression, prolonged operative duration, or other clinical factors.[6–8] Differences in institutional infection-control practices may further influence infection rates.[4] Therefore, evidence regarding the actual benefit of prophylaxis in clean wound surgery is important for balancing SSI prevention with rational antibiotic use.The present study was therefore undertaken to evaluate the role of preoperative prophylactic antibiotics in preventing surgical site infections in patients undergoing clean wound surgeries, with the aim of generating evidence to guide appropriate perioperative antibiotic use and antimicrobial stewardship.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of General Surgery, SGT Hospital, Budhera, Gurugram, Haryana, over a period of 18 months. The study was designed to evaluate the role of preoperative prophylactic antibiotics in preventing surgical site infections (SSIs) following clean elective surgical procedures.

Study Population

A total of 50 patients undergoing clean elective surgical procedures were included. Patients were allocated into two groups of 25 each using the sealed-envelope randomization method. Group A (n=25) received preoperative antibiotic prophylaxis, whereas Group B (n=25) did not receive preoperative prophylactic antibiotics. Patients were recruited consecutively from eligible cases admitted to the Department of General Surgery.

Eligibility Criteria

Patients undergoing clean elective surgical procedures who provided written informed consent were eligible for inclusion. Patients with immunocompromised states, those who did not provide consent, and those undergoing clean-contaminated, contaminated, or dirty/infected surgical procedures were excluded. Patients with active remote infections, including respiratory or urinary tract infections, were treated appropriately and considered for surgery only after resolution of infection and a minimum interval of two weeks.

Study Procedure

After obtaining written informed consent, demographic and clinical information, including age, sex, diagnosis, comorbidities, risk factors for SSI, and relevant preoperative investigations, was recorded using a predesigned proforma. All patients underwent standard preoperative assessment and preparation. Preoperative hospital stay was kept to the minimum possible duration to reduce exposure to hospital-acquired infections.Patients in Group A received a single preoperative dose of ceftriaxone as antimicrobial prophylaxis, while patients in Group B received no prophylactic antibiotic. Standard aseptic precautions, operative preparation, surgical technique, and postoperative wound-care practices were followed in both groups. Efforts were made to maintain comparability between the groups with respect to demographic characteristics, type of surgery, comorbidities, and established risk factors for SSI.

Postoperative Assessment and Follow-up

All patients were followed for 30 days after surgery. Surgical wounds were clinically evaluated on the third postoperative day, at the time of discharge, and on the 30th postoperative day. Wounds were assessed for redness, local warmth, pain or tenderness, swelling, fever, serous discharge, and purulent discharge.

Patients with clinical features suggestive of SSI underwent further evaluation. Wound swabs were obtained, where indicated, and submitted for microbiological culture and antimicrobial susceptibility testing. SSIs were categorized according to the depth and extent of infection as superficial incisional or deep incisional infections. The duration required for complete wound healing was also documented.

Outcome Measures

The primary outcome was the occurrence of SSI within 30 days of surgery and its comparison between the prophylactic-antibiotic and no-antibiotic groups. Secondary outcomes included the clinical characteristics and type of SSI, microbiological profile of infected wounds, and duration of wound healing. The associations of SSI with potential risk factors, including BMI, diabetes mellitus, smoking, duration of surgery, and hospital stay, were also evaluated.

Statistical Analysis

Data were entered and analyzed using IBM SPSS Statistics version 25.0. Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables as frequency and percentage. Continuous variables, including age, BMI, duration of surgery, length of hospital stay, and duration of wound healing, were compared between the two groups using the independent-samples Student's *t*-test. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate.

Multivariable logistic regression analysis was performed to identify independent predictors of SSI, including preoperative antibiotic prophylaxis, BMI, diabetes mellitus, smoking status, duration of surgery, and hospital stay. Results were expressed as adjusted odds ratios (AORs) with 95% confidence intervals (CIs). Receiver operating characteristic (ROC) curve analysis was performed to assess the ability of operative duration to predict SSI, and predictive performance was expressed as the area under the curve (AUC). A two-sided p-value <0.05 was considered statistically significant.

RESULTS

A total of 50 patients undergoing clean elective surgical procedures were included in the study, with 25 patients allocated to the antibiotic prophylaxis group and 25 to the no-antibiotic group.The baseline demographic and clinical characteristics were comparable between the two study groups (Table 1). The mean age was 40.04 ± 11.49 years in the antibiotic group and 40.26 ± 12.04 years in the no-antibiotic group, with no statistically significant difference (p=0.949). Males constituted 52.0% (13/25) and 56.0% (14/25) of the antibiotic and no-antibiotic groups, respectively (p=0.91).The mean BMI was 24.8 ± 3.4 kg/m² in the antibiotic group and 25.4 ± 3.7 kg/m² in the no-antibiotic group (p=0.66). Diabetes mellitus was present in 6 (24.0%) patients in the antibiotic group and 7 (28.0%) in the no-antibiotic group (p=0.74), while smoking was reported by 8 (32.0%) and 9 (36.0%) patients, respectively (p=0.76). Thus, no statistically significant differences were observed in the baseline demographic or major clinical risk factors between the groups (Table 1).

The mean duration of surgery was 85 ± 20 minutes in the antibiotic group compared with 89 ± 21 minutes in the no-antibiotic group, with no statistically significant difference (p=0.47). The corresponding median (IQR) durations were 83 (70–100) minutes and 87 (72–104) minutes, respectively (Table 2).

The mean duration of hospital stay was 4.2 ± 1.1 days in the antibiotic group and 4.6 ± 1.3 days in the no-antibiotic group (p=0.28). Similarly, the mean wound-healing duration was 8.4 ± 2.1 days and 9.1 ± 2.5 days, respectively (p=0.21). The median wound-healing duration was 8 (7–10) days in the antibiotic group and 9 (7–11) days in the no-antibiotic group. None of the operative or postoperative parameters differed significantly between the groups (Table 2).

Surgical site infection (SSI) occurred in 3 (12.0%) patients receiving antibiotic prophylaxis compared with 4 (16.0%) patients in the no-antibiotic group. Although the incidence was numerically lower in the antibiotic group, the difference was not statistically significant (p=0.69) (Table 3).

Superficial SSI occurred in 2 (8.0%) patients in the antibiotic group and 3 (12.0%) in the no-antibiotic group (p=0.64). Deep SSI was observed in 1 (4.0%) patient in each group (p=1.00), while no organ/space SSI was observed in either group. Overall, the distribution of SSI according to type was comparable between the two groups (Table 3).

Postoperative wound findings showed a progressive reduction in both groups during follow-up (Table 4, Figure 1). On postoperative day 3, redness was observed in 2 (8.0%) patients in the antibiotic group and 3 (12.0%) in the no-antibiotic group (p=0.64). Tenderness or pain was present in 3 (12.0%) versus 4 (16.0%) patients (p=0.69), fever or local warmth in 1 (4.0%) versus 2 (8.0%) (p=0.55), swelling in 2 (8.0%) versus 3 (12.0%) (p=0.64), and serous or purulent discharge in 2 (8.0%) versus 3 (12.0%) patients (p=0.64), respectively.

At discharge, redness was present in 1 (4.0%) patient in the antibiotic group compared with 2 (8.0%) in the no-antibiotic group (p=0.55), while tenderness or pain was observed in 2 (8.0%) and 3 (12.0%) patients, respectively (p=0.64). Swelling and serous/purulent discharge were each observed in 1 (4.0%) patient in the antibiotic group and 2 (8.0%) patients in the no-antibiotic group (both p=0.55). Fever or local warmth was absent in the antibiotic group and occurred in 1 (4.0%) patient in the no-antibiotic group (p=0.31) (Table 4, Figure 1).

By the 30-day follow-up, wound-related complications were infrequent. Tenderness or pain was present in 1 (4.0%) patient in each group (p=1.00). Redness and swelling were absent in the antibiotic group but were each observed in 1 (4.0%) patient in the no-antibiotic group (both p=0.31). Serous or purulent discharge was present in 1 (4.0%) patient in the antibiotic group and 2 (8.0%) patients in the no-antibiotic group (p=0.55). No patient in either group had fever or local warmth at 30 days. None of the wound findings differed significantly between the two groups at any follow-up time point (Table 4, Figure 1).

The distribution of organisms isolated from wound cultures is presented in Table 5 and Figure 2. *Staphylococcus aureus* was isolated in 1 (4.0%) patient in the antibiotic group and 2 (8.0%) patients in the no-antibiotic group (p=0.55). *Escherichia coli* and *Klebsiella* species were each isolated in 1 (4.0%) patient in both groups (both p=1.00). No growth was reported in 22 (88.0%) patients in the antibiotic group and 21 (84.0%) patients in the no-antibiotic group (p=0.69). There was no statistically significant difference in microbiological culture findings between the groups (Table 5, Figure 2).

On multivariable logistic regression analysis, preoperative antibiotic prophylaxis was associated with lower odds of developing SSI (adjusted OR 0.62; 95% CI 0.10–3.93); however, this association was not statistically significant (p=0.615) (Table 6, Figure 3).

BMI was not associated with SSI (adjusted OR 1.00; 95% CI 0.76–1.32; p=0.994). Similarly, diabetes mellitus (adjusted OR 1.52; 95% CI 0.19–12.07; p=0.693), duration of surgery (adjusted OR 1.05; 95% CI 0.99–1.11; p=0.107), and hospital stay (adjusted OR 0.94; 95% CI 0.48–1.83; p=0.845) were not significant independent predictors of SSI. Smoking showed an adjusted OR of 0.13 (95% CI 0.01–1.41; p=0.093), but this association also did not reach statistical significance. Thus, none of the variables included in the multivariable model were independently associated with SSI (Table 6, Figure 3)

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants

Variable	Antibiotic group (n=25)	No antibiotic group (n=25)	p-value	Statistical test
Age (years), mean ± SD	40.04 ± 11.49	40.26 ± 12.04	0.949	Independent-samples t-test
Male, n (%)	13 (52.0)	14 (56.0)	0.91	Chi-square test
Female, n (%)	12 (48.0)	11 (44.0)		
BMI (kg/m²), mean ± SD	24.8 ± 3.4	25.4 ± 3.7	0.66	Independent-samples t-test
Diabetes mellitus, n (%)	6 (24.0)	7 (28.0)	0.74	Chi-square test
Smoking, n (%)	8 (32.0)	9 (36.0)	0.76	Chi-square test

Table 2. Operative and Postoperative Characteristics of the Study Participants

Variable	Antibiotic group (n=25)	No antibiotic group (n=25)	p-value	Statistical test

Duration of surgery (min), mean ± SD	85 ± 20	89 ± 21	0.47	Independent-samples t-test
Duration of surgery, median (IQR)	83 (70–100)	87 (72–104)	—	—
Hospital stay (days), mean ± SD	4.2 ± 1.1	4.6 ± 1.3	0.28	Independent-samples t-test
Hospital stay, median (IQR)	4 (3–5)	4 (3–6)	—	—
Wound healing duration (days), mean ± SD	8.4 ± 2.1	9.1 ± 2.5	0.21	Independent-samples t-test
Wound healing duration, median (IQR)	8 (7–10)	9 (7–11)	—	—

Table 3. Incidence and Type of Surgical Site Infection According to Study Group

SSI outcome	**Antibiotic group (n=25)**	**No antibiotic group (n=25)**	**p-value**	**Statistical test**
Any SSI	3 (12.0)	4 (16.0)	0.69	Fisher's exact test
No SSI	22 (88.0)	21 (84.0)	—	—
Superficial SSI	2 (8.0)	3 (12.0)	0.64	Fisher's exact test
Deep SSI	1 (4.0)	1 (4.0)	1.00	Fisher's exact test
Organ/space SSI	0 (0.0)	0 (0.0)	—	—

Table 4. Postoperative Wound Findings during Follow-Up

Wound finding	**Time point**	**Antibiotic group n (%)**	**No antibiotic group n (%)**	**p-value**	**Statistical test**
Redness	Day 3	2 (8.0)	3 (12.0)	0.64	Fisher's exact test
	Discharge	1 (4.0)	2 (8.0)	0.55	
	Day 30	0 (0.0)	1 (4.0)	0.31	
Tenderness/pain	Day 3	3 (12.0)	4 (16.0)	0.69	
	Discharge	2 (8.0)	3 (12.0)	0.64	
	Day 30	1 (4.0)	1 (4.0)	1.00	
Fever/warmth	Day 3	1 (4.0)	2 (8.0)	0.55	
	Discharge	0 (0.0)	1 (4.0)	0.31	
	Day 30	0 (0.0)	0 (0.0)	—	—
Swelling	Day 3	2 (8.0)	3 (12.0)	0.64	Fisher's exact test
	Discharge	1 (4.0)	2 (8.0)	0.55	
	Day 30	0 (0.0)	1 (4.0)	0.31	
Serous/purulent discharge	Day 3	2 (8.0)	3 (12.0)	0.64	
	Discharge	1 (4.0)	2 (8.0)	0.55	
	Day 30	1 (4.0)	2 (8.0)	0.55	

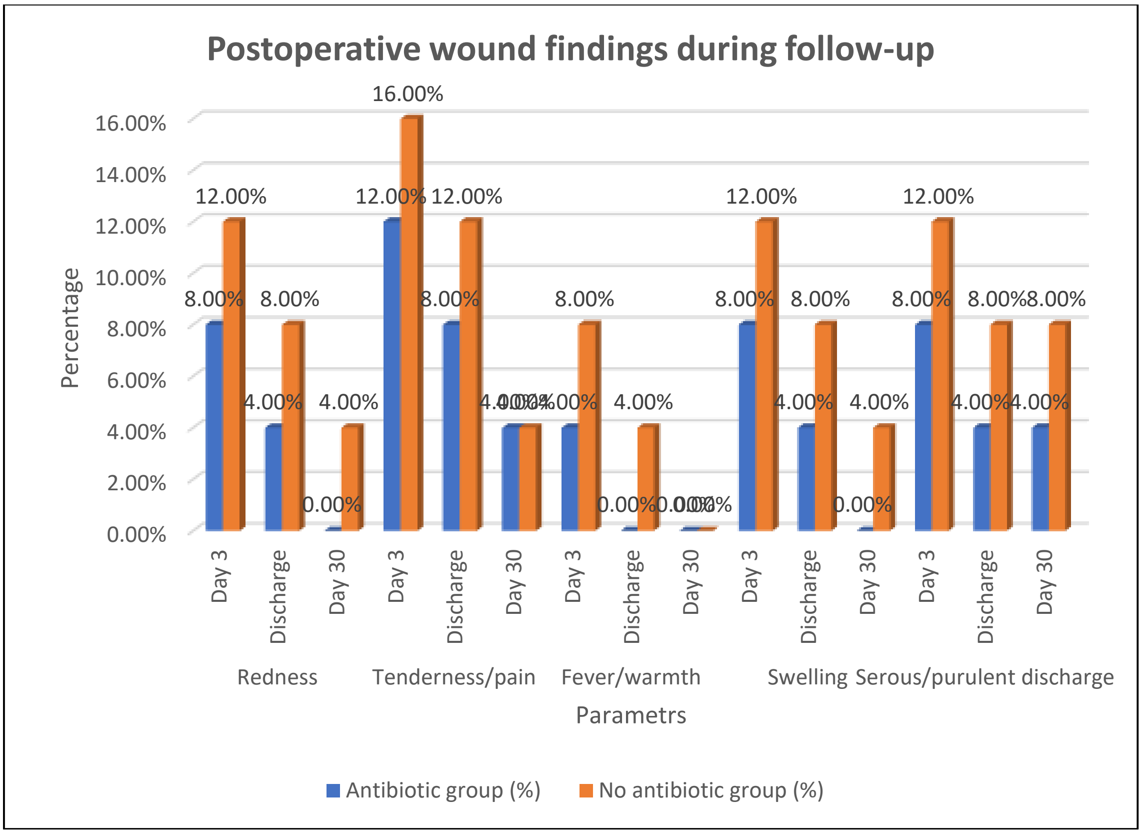

Figure 1. Postoperative Wound Findings during Follow-Up

Table 5. Microbiological Culture Findings

Organism isolated	Antibiotic group n (%)	No antibiotic group n (%)	p-value	Statistical test
Staphylococcus aureus	1 (4.0)	2 (8.0)	0.55	Fisher's exact test
Escherichia coli	1 (4.0)	1 (4.0)	1.00	
Klebsiella species	1 (4.0)	1 (4.0)	1.00	
No growth	22 (88.0)	21 (84.0)	0.69	

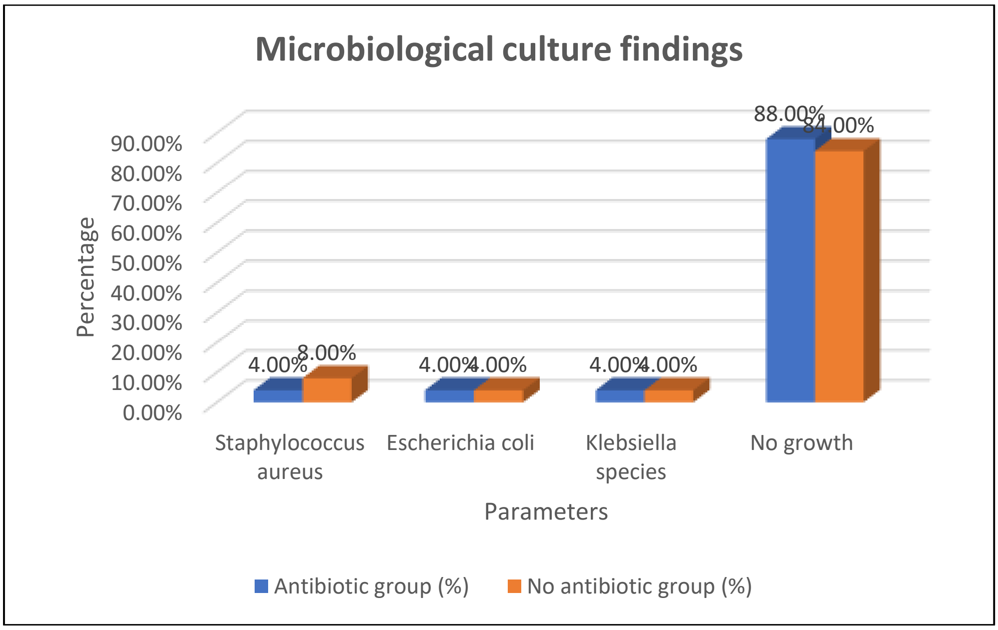

Figure 2. Microbiological Culture Findings

Table 6. Multivariable Logistic Regression Analysis of Factors Associated with Surgical Site Infection

Variable	Adjusted OR	95% CI	p-value	Statistical test
Preoperative antibiotic prophylaxis	0.62	0.10–3.93	0.615	Multivariable logistic regression
BMI	1.00	0.76–1.32	0.994	
Diabetes mellitus	1.52	0.19–12.07	0.693	
Smoking	0.13	0.01–1.41	0.093	
Duration of surgery	1.05	0.99–1.11	0.107	
Hospital stay	0.94	0.48–1.83	0.845	

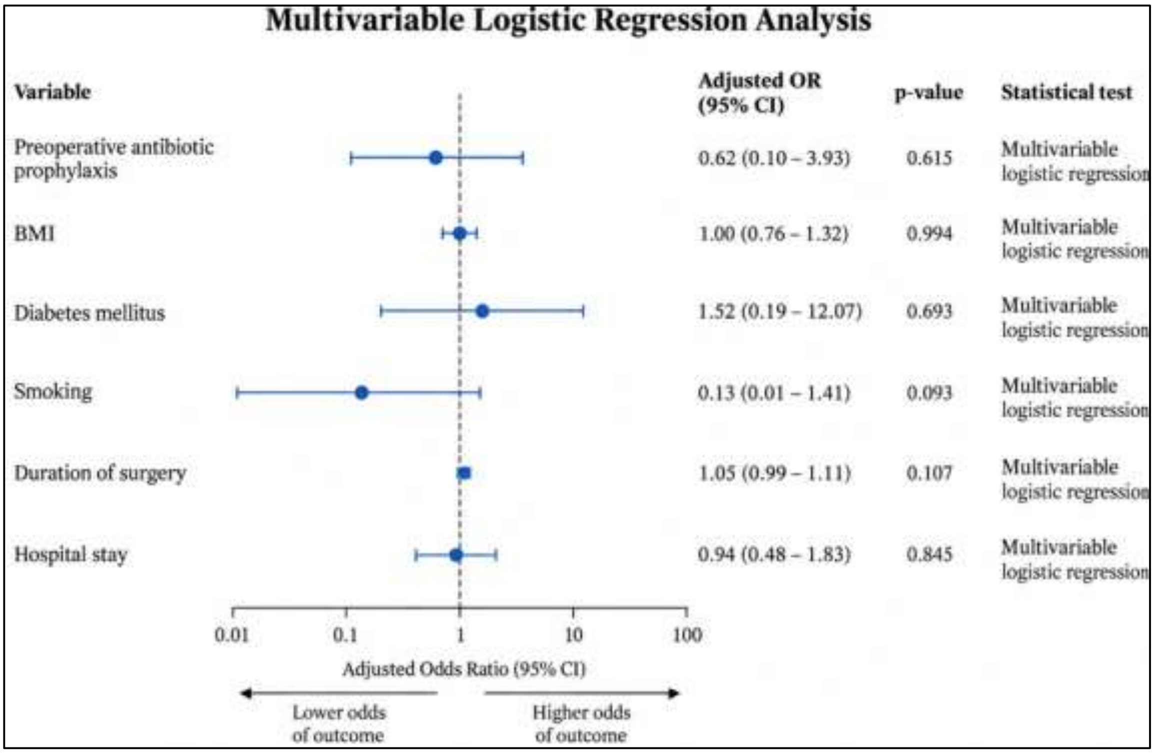

Figure 3. Multivariable Logistic Regression Analysis of Factors Associated with Surgical Site Infection

DISCUSSION

The present study evaluated the role of preoperative prophylactic antibiotics in preventing surgical site infections (SSIs) in clean elective surgical procedures. The two groups were comparable with respect to age, sex, BMI, diabetes mellitus, smoking status, duration of surgery, and hospital stay, thereby minimizing the influence of baseline differences on SSI outcomes. The mean age was 40.04 ± 11.49 years in the antibiotic group and 40.26 ± 12.04 years in the no-antibiotic group. Similar baseline comparability was reported by Iqbal et al. [18] and Ullah et al. [19]The principal finding was that SSI occurred in 3 patients (12%) receiving prophylactic antibiotics compared with 4 patients (16%) without prophylaxis; however, the difference was not statistically significant (p=0.69). Charernsuk et al. [20] similarly reported SSI rates of 1.3% with and 2.2% without prophylaxis (p=0.427), while Negri et al. [21] found no significant reduction in SSI in clean soft-tissue surgery (RR 1.13; 95% CI 0.91–1.40). Ullah et al. [19] also reported comparable SSI rates of 3.98% and 4.9% with and without prophylaxis, respectively.In contrast, Tang et al.[22], in a meta-analysis of 48 randomized trials involving 16,189 participants, demonstrated an overall reduction in SSI with antibiotic prophylaxis (OR 0.60; 95% CI 0.53–0.68), although the magnitude of benefit varied according to the surgical procedure. Borade et al.[23] also reported a low SSI rate of 3% following a single preoperative dose of cefuroxime in elective clean and clean-contaminated surgeries. Garnier et al.[24] emphasized that the effectiveness of prophylaxis may be influenced by patient-specific and procedure-related risk factors.In the present study, BMI, diabetes mellitus, and smoking were comparable between groups and were not independently associated with SSI. Iqbal et al. [18], however, identified diabetes, obesity, and smoking as important SSI risk factors, while Garnier et al.[24] also emphasized the contribution of these patient-related characteristics to postoperative infection. The lack of significant associations in our study may partly reflect the small number of SSI events.The mean duration of surgery was 85 ± 20 minutes in the antibiotic group and 89 ± 21 minutes in the no-antibiotic group (p=0.47). Charernsuk et al. [20] reported an increased SSI risk with longer procedures, while Basak et al.[25] identified prolonged operative duration as a contributing factor to SSI. However, the relatively shorter operative duration in our patients may explain the absence of a significant association.Hospital stay was also comparable between groups (4.2 ± 1.1 vs 4.6 ± 1.3 days; p=0.28). Tang et al.[22] reported a modest reduction in hospital stay with prophylaxis, whereas Iqbal et al. [18] observed greater benefit among higher-risk patients, with comparatively little difference in low-risk procedures.Superficial SSI was more frequent than deep SSI in the present study, occurring in 8% versus 12% of patients in the antibiotic and no-antibiotic groups, respectively. Deep SSI occurred in 4% of each group, and no organ/space SSI was observed.

Mean wound-healing duration was 8.4 ± 2.1 days with antibiotic prophylaxis and 9.1 ± 2.5 days without prophylaxis (p=0.21). Misganaw et al.[26] and Basak et al.[25] similarly found no significant difference in wound healing attributable to prophylactic antibiotics.*Staphylococcus aureus* was the most frequently isolated organism, followed by *Escherichia coli* and *Klebsiella* species. Iqbal et al. [18] also reported *S. aureus* as an important pathogen in SSI, while Garnier et al.[24] described *E. coli* and *Klebsiella* among organisms associated with postoperative infections.Postoperative redness, tenderness, swelling, warmth, and wound discharge were slightly more frequent in the no-antibiotic group on day 3 and at discharge, but none of these differences was significant. By 30 days, wound complications were minimal in both groups. Similar observations were reported by Iqbal et al. [18], Garnier et al.[24], Tang et al.[22], Basak et al.[25], and Ullah et al. [19], indicating that prophylaxis may have limited influence on minor postoperative wound manifestations in otherwise clean procedures.On multivariable analysis, antibiotic prophylaxis was associated with lower odds of SSI (OR 0.62; 95% CI 0.10–3.93; p=0.615), but this was not statistically significant. BMI, diabetes, smoking, operative duration, and hospital stay were also not significant predictors. Charernsuk et al. [20] similarly found no significant benefit after propensity-score adjustment. ROC analysis showed poor discriminatory ability of operative duration for SSI (AUC 0.623; 95% CI 0.42–0.82), consistent with observations by Tang et al.[22] and Basak et al.[25] that operative duration alone may not reliably determine SSI risk in clean surgery.

CONCLUSION

Preoperative prophylactic antibiotics resulted in a numerically lower incidence of surgical site infection in clean elective surgeries (12% vs 16%); however, the difference was not statistically significant. Antibiotic prophylaxis also did not significantly influence wound healing, hospital stay, or postoperative wound complications. These findings suggest that routine prophylactic antibiotics may not be necessary in all clean elective surgeries, and their use should be individualized according to patient- and procedure-related risk factors.

Limitations

The major limitations of the study were the relatively small sample size and the small number of SSI events, which limited the statistical power and reliability of multivariable analysis. Being a single-centre study with a relatively short follow-up period also limits the generalizability of the findings.

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