



Appropriateness of Surgical Antimicrobial Prophylaxis in a tertiary care hospital: A prospective observational study

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Abstract

Surgical site infections (SSIs) are a significant concern in global healthcare, particularly in middle and low-income countries, leading to increased hospitalizations, morbidity, mortality, and financial strain. Ranked third in the CDC's National Nosocomial Infections Surveillance System, SSIs have prompted a focus on preventive measures, notably surgical antimicrobial prophylaxis (SAP). However, SAP is often used inappropriately, contributing to the rise of Antimicrobial Resistance (AMR). Addressing this, a six-month prospective observational study was conducted in a tertiary care hospital to assess the adherence to SAP guidelines among 386 patients undergoing surgeries in various specialties. The study aimed to evaluate the appropriateness of SAP practices and identify factors leading to non-compliance. Results showed that only 58.3% of patients fully adhered to the guidelines. While 100% compliance was observed in SAP indication, lower adherence was noted in the timing of administration (97.7%), choice of SAP (85%), and duration of prophylaxis (70.2%). These findings underscore a significant gap between recommended SAP practices and actual implementation. This gap highlights the need for stronger Institutional Antimicrobial Stewardship (AMS) programs and the critical role of clinical pharmacists in regularly evaluating SAP and prescribing practices. To combat the rise of antibiotic resistance while ensuring patient safety, enhancing SAP practices in line with national and international recommendations is essential. The study advocates for more active interventions at the time of order to optimize antibiotic use, thereby addressing the challenge of compliance in SAP guidelines.



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INTRODUCTION

Among healthcare-associated infections, surgical site infections (SSIs) are among the most commonly identified. These infections can lead to prolonged hospital stays, readmissions, higher rates of death and morbidity, and significantly add to the cost burden [1][2]. SSI typically develops at or near the surgical incision within 30 days of the operative procedure, or within 90 days if prosthetic material is implanted [3]. SSIs can range from superficial infections involving the

skin to more serious ones affecting tissues beneath the skin, organs, or implanted material [4].

A systematic review and meta-analysis revealed a 2.5% global incidence of SSI [5]. The latest investigation by the World Health Organisation indicates that SSIs are more common in low- and middle-income countries than in wealthy countries and are the second most prevalent type of healthcare-associated infection in both the United States and Europe [6].

Although several therapies have been effective in decreasing SSIs, surgical antimicrobial prophylaxis (SAP) has been shown to be the most effective in preventing initial infections at surgical sites [7][8]. However, SAP is often used excessively and inappropriately, particularly regarding timing and duration, which reduces the effectiveness of prophylactic antibiotics and contributes to the emergence of antimicrobial resistance (AMR) [2][9]. A 2014 international survey by the World Health Organisation found that 43.5% of procedures used prophylactic antibiotics for longer than recommended, with SAP administration prolonged more frequently by more than 60% in countries in the Eastern Mediterranean, Western Pacific, and Africa [10].

AMR is one of the top ten global public health threats facing humanity [11]. According to a 2019 UN Ad hoc Interagency Coordinating Group report, drug-resistant diseases cause at least 700,000 deaths annually. AMR has the potential to push up to 24 million people into extreme poverty by 2030, cause up to 10 million deaths annually by 2050, and inflict economic damage comparable to the global financial crisis of 2008-2009 [12]. The increasing prevalence of AMR raises the likelihood that SSIs may become complicated by resistant bacteria, leading to worse surgical outcomes, including longer hospital stays, more frequent surgical revisions, and higher mortality rates [13]. Antibiotic stewardship (AMS), or better antibiotic usage, is a key approach needed to prevent the development and spread of AMR and to optimize SAP use. The WHO Expert Committee on Selection and Use of Essential Medicines created AWaRe, or Access, Watch, and Reserve, to support AMS in its efforts to curb the spread of antibiotic-related effects resulting from improper usage [14][15][16].

This study was conducted to identify gaps in the use of surgical antimicrobial prophylaxis and to suggest relevant strategies to overcome these discrepancies.

Methodology

Our study aimed to evaluate antimicrobial use in surgical prophylaxis at a tertiary care hospital. The primary objective was to assess compliance with indications, selection, timing, and duration of administration of prophylactic antibiotics among surgical patients, following standard hospital SAP guidelines (based on international guidelines - SIGN, NHS, ASHP). The secondary objective was to identify key factors associated with SAP compliance.

Study setting and design

This prospective observational clinical study of patients undergoing surgery was conducted in the orthopaedics, gastroenterology, neurology, nephrology, and obstetrics and gynaecology wards over a 6-month period in a tertiary care hospital. The study focused on examining the utilization pattern of prophylactic antimicrobials in surgical patients with clean, clean-contaminated, and contaminated wounds.

Participant selection

All patients over 18 years of age with clean, clean-contaminated, or contaminated wounds who underwent elective or emergency surgeries in the departments of orthopaedics, gastroenterology, neurology, nephrology, and obstetrics and gynaecology were included in the study. Excluded were patients under 18 years of age, those undergoing surgery for dirty wounds (as these wounds are already infected and require specific treatment prior to surgery rather than prophylactic measures for the prevention of surgical site infections [SSIs]), critically ill patients requiring admission to the Intensive Care Unit (ICU), and those admitted to other wards in the hospital.

Data Collection Process

Data were collected from 386 patients who underwent surgery over a 6-month period. We recorded only the prophylactic antimicrobials used during their hospital stay. Our data collection form, which was based on prior publications, was divided into four key sections:

- Patient Demographic and Medical Data:** This included age, gender, co-morbidities, chief complaint, diagnosis, length of hospital stay, duration of antibiotic prescription, and post-operative hospitalization duration.
- Preoperative Factors:** Such as the ASA score and surgical wound classification (clean, clean/contaminated, or contaminated).
- Surgical Data:** Covering the type of surgery, surgical specialty, incision time, closure time, time of prophylactic antibiotic administration, and the duration of the surgery.
- Antimicrobial Utilization Data:** Including the generic name, strength of the antibiotic, antimicrobial class (ATC code), AWaRe classification, as well as the frequency and duration of administration.

Result

In this observational study, we assessed the appropriateness of surgical antimicrobial prophylaxis (SAP) in 386 patients scheduled for surgery across various specialties including orthopaedics, gastroenterology, neurology,

Statistical Analysis

Table 1: Sociodemographic and clinical characteristics of study participants

| Variable | Categories | Frequency | Percentage |
|---|--------------------|-----------|------------|
| Gender | Male | 142 | 36.8 |
| | Female | 244 | 63.2 |
| Age range (Years) | 20 and below | 19 | 4.9 |
| | 21-40 | 156 | 40.4 |
| | 41-60 | 90 | 23.3 |
| | 61 and above | 121 | 31.3 |
| | | | |
| Type of Surgery | Emergency | 63 | 16.3 |
| | Elective | 323 | 83.7 |
| Surgical Speciality | Obstetrics | 79 | 20.5 |
| | Gynaecology | 66 | 17.1 |
| | Gastroenterology | 60 | 15.5 |
| | Orthopedics | 108 | 28.0 |
| | Neurology | 18 | 4.7 |
| | Urology | 55 | 14.2 |
| Type of Wound | Clean | 124 | 32.1 |
| | Clean Contaminated | 256 | 66.3 |
| | Contaminated | 6 | 1.6 |
| Presence of Co-morbid Condition | Yes | 182 | 47.2 |
| | No | 204 | 52.8 |
| Duration of Surgery | less than 1 hour | 166 | 43.0 |
| | 1-2 hours | 157 | 40.7 |
| | 2-3 hours | 39 | 10.1 |
| | 3-4 hours | 17 | 4.4 |
| | more than 4 hours | 7 | 1.8 |
| Post-operative hospitalization duration | 1 day and below | 89 | 23.1 |
| | 2-5 days | 292 | 75.6 |
| | 6-9 days | 5 | 1.3 |

nephrology, obstetrics, and gynaecology. **Table 1** provides a summary of the sociodemographic and clinical characteristics of all study participants. The average age of the participants was 47.5 ± 19.3 years, with a distribution of 63.2% (n = 244) female and 36.8% (n = 142) male. A majority of the surgeries, 83.7% (n = 323), were elective, while 16.3% (n = 63) were emergency procedures. Obstetric and gynaecological procedures were the most frequent, accounting for 37.6% (n = 145) of surgeries, with caesarean sections comprising 19% (n = 73) of these. Orthopaedic surgeries followed, making up 28% (n = 108) of the cases, with ORIF (Open Reduction and Internal Fixation) procedures being particularly common at 16.3% (n = 63). The study found that 66.3% (n = 256) of the surgical wounds were clean-contaminated, while 32.1% (n = 124) were clean. Regarding the duration of surgeries, approximately 43.0% lasted less than one hour, and 40.7% lasted between one and two hours. About 14.5% of the surgeries took between two and four hours, and 1.8% exceeded

Cephalosporins were the most commonly administered class of antibiotics. Notably, cefuroxime was extensively used in patients with clean-contaminated wounds (53.4%) and clean wounds (30.6%). Cefoperazone plus sulbactam, another cephalosporin, was significantly administered in patients with clean-contaminated wounds (11.1%). The majority of prescribed antibiotics fell into the 'Watch' category.

Assessment of SAP parameters with recommended guidelines

In 225 of the 386 procedures (58.3%), there was complete adherence to recommended guidelines for all parameters. Noncompliance with one or more of the five parameters of antibiotic administration for prophylaxis occurred in 41.7% (161 of 386 patients). Parameters were also evaluated individually to ensure that missing data for one did not preclude assessment of the others.

According to standard guidelines, SAP was

Table 2: Utilization pattern of Prophylactic Antibiotics among surgical patients

| Antibiotics Prescribed | WHO AwaRe Classification | Wound Types | | | Total n (%) |
|------------------------------------|--------------------------|-------------|--------------------|--------------|-------------|
| | | Clean | Clean-Contaminated | Contaminated | |
| Cephalosporins | | | | | |
| Cefuroxime (J01DC02) | Watch | 118 | 206 | 4 | 328 (85.0) |
| Ceftriaxone (J01DD04) | Watch | 1 | 2 | - | 3 (0.8) |
| Cefoperazone + Sulbactam (J01DD62) | Watch | 5 | 43 | 2 | 50 (13.0) |
| Penicillins | | | | | |
| Amoxicillin clavulanate (J01CR02) | Access | - | 1 | - | 1 (0.3) |
| Piperacillin Tazobactam (J01CR05) | Watch | - | 3 | - | 3 (0.8) |
| Others | | | | | |
| Meropenem (J01DH02) | Watch | - | 1 | - | 1 (0.3) |

four hours.

Antimicrobial Utilization Patterns for Surgical Prophylaxis

Table 2 displays the total antibiotic usage across all five departments. The various antimicrobial classes prescribed for surgical prophylaxis, depending on wound surgery type, included penicillins (combined with beta-lactamase inhibitors), cephalosporins (both as monotherapy and in combination with beta-lactamase inhibitors), and carbapenems.

indicated for all 386 procedures, achieving 100% compliance for this parameter. Compliance with the appropriate choice of antimicrobials was 85% (n=328), where the remaining 15% of non-compliance was due to the administration of penicillins (in combination with beta-lactamase inhibitors), third-generation cephalosporins (both as monotherapy and in combination with beta-lactamase inhibitors), and carbapenems, which are not recommended for surgical prophylaxis according to the guidelines. **Figure 1** illustrates non-compliance in each surgical specialty.

In 271 of 386 procedures (70.2%), the duration of SAP was concordant with the hospital guideline, while in 115 procedures (29.8%), the duration was longer than recommended. **Figure 2** depicts the non-compliance with the duration of SAP across specialties.

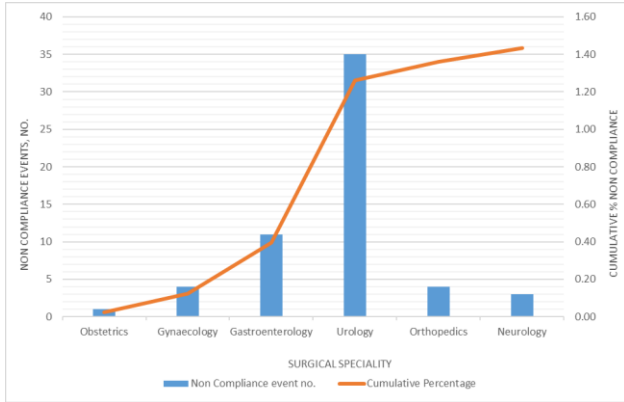


Figure 1: Antibiotic selection noncompliance: Pareto chart

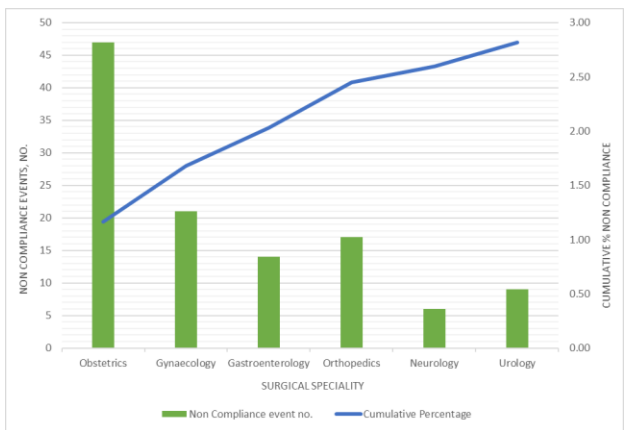


Figure 2: Duration of prophylactic antibiotic non-compliance: Pareto chart

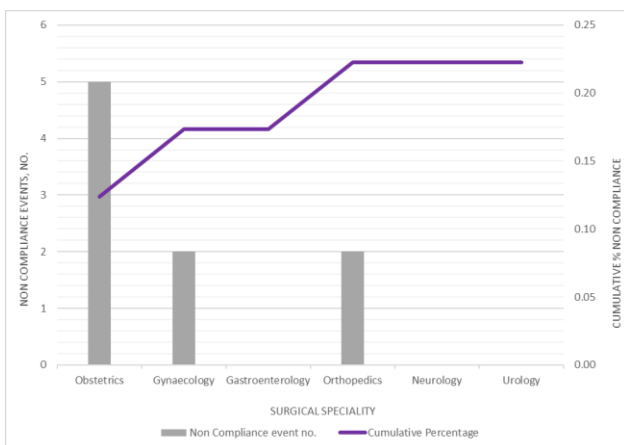


Figure 3: Non-compliance in the timing of SAP administration prior to surgical incision: Pareto chart

Regarding the timing of antibiotic administration, in 377 of the 386 procedures (97.7%), timing was in line with the recommended guidelines. Timing was earlier than recommended in 4 (1.0%) procedures and later in 5 (1.3%). **Figure 3** displays the non-compliance with the timing of SAP. Among the cephalosporins used in the study, there were no cases of timing noncompliance for Cefoperazone plus Sulbactam and ceftriaxone, and 2.3% noncompliance for cefuroxime. For other classes of antibiotics used, there were no instances of noncompliance with timing for penicillins (combined with beta-lactamase inhibitors) and meropenem.

Bivariate Analysis of the Association Between SAP Compliance and Clinical Characteristics

The bivariate analysis, as shown in **Table 3** indicated that the appropriateness of SAP administration was significantly associated with the presence of co-morbid diseases ($\chi^2 = 274.2$; 1 df; $p < 0.001$), ASA score ($\chi^2 = 97.8$; 1 df; $p < 0.001$), surgical wound class ($\chi^2 = 26.5$; $p < 0.001$), type of surgical procedure ($\chi^2 = 50.3$; 5 df; $p < 0.001$), SAP duration appropriateness ($\chi^2 = 228.9$; 1 df; $p < 0.001$), SAP timing appropriateness ($p < 0.001$), SAP choice appropriateness ($\chi^2 = 95.38$; 1 df; $p < 0.001$), and postoperative hospitalization duration ($\chi^2 = 17.7$; $p < 0.001$).

Discussion

In our study, we used hospital guidelines based on international standards (SIGN, NHS, ASHP) to assess the appropriateness of surgical antimicrobial prophylaxis (SAP) use across various specialties. According to the reference guidelines, SAP is generally not indicated in clean surgeries, except for those involving prostheses. It is recommended for clean-contaminated and contaminated procedures, while standard antimicrobial therapy plus surgical antibiotic prophylaxis is indicated for dirty wounds. The guidelines also specify that SAP is not indicated for low-risk laparoscopy but is recommended for high-risk laparoscopic procedures. In our study, all 386 procedures indicated SAP, showing 100% compliance with the guidelines. In a similar study by Gurunthalingam MP *et al.* [17], compliance with SAP indication guidelines was 88.83%, with non-compliance stemming from administering SAP even in clean surgeries due to concerns about potential breaches of asepsis in the operative area

and post-operative wards. This may be attributed to insufficient awareness of recent guideline updates.

Selecting the right antibiotic is crucial for surgical prophylaxis. Guidelines suggest that antibiotics chosen for SAP should be effective against potential microorganisms likely to contaminate the surgery site without adverse effects [18].

According to hospital guidelines, the antibiotic choices were either first-generation (cefazolin) or second-generation (cefuroxime) cephalosporins, as they are more effective and have a narrower spectrum for infection-causing bacteria in these procedures. In our study, SAP choice was inappropriate in 15%, with non-compliance due to administering penicillins (combined with beta-

Table 3: Bivariate analysis of the association between compliance of SAP with standard treatment guidelines and socio-demographic and clinical characteristics of patients

| Variable | Categories | Compliance with Standard Treatment Guidelines | | P Value | | Phi Value |
|--|--------------------|---|------------|----------------|------------|-----------------------|
| | | Yes, n (%) | No, n (%) | Fisher's Exact | Chi-Square | Relationship strength |
| Age range (Years) ^a | 20 and below | 13 (68.4) | 6 (31.6) | -- | 0.789 | 0.052 |
| | 21-40 | 88 (56.4) | 68 (43.6) | | | |
| | 41-60 | 53 (58.9) | 37 (41.1) | | | |
| | 61 and above | 71 (58.7) | 50 (41.3) | | | |
| Gender ^a | Male | 75 (52.8) | 67 (47.2) | -- | 0.096 | -0.085 |
| | Female | 150 (61.5) | 94 (38.5) | | | |
| Presence of Co-morbid Condition ^a | Yes | 26 (14.3) | 156 (85.7) | -- | <0.001 | -0.843 |
| | No | 199 (97.5) | 5 (2.5) | | | |
| ASA Score ^b | ASA II | 161 (83.0) | 33 (17.0) | -- | <0.001 | -0.504 |
| | ASA III | 64 (33.3) | 128 (66.7) | | | |
| Surgical wound class ^b | Clean | 94 (75.8) | 30 (24.2) | <0.001 | -- | 0.256 |
| | Clean-contaminated | 128 (50.0) | 128 (50.0) | | | |
| | Contaminated | 3 (50.0) | 3 (50.0) | | | |
| | Obstetrics | 30 (38.0) | 49 (62.0) | | | |
| Type of Surgical Procedure ^c | Gynaecology | 42 (63.6) | 24 (36.4) | -- | <0.001 | 0.361 |
| | Gastroenterology | 40 (66.7) | 20 (33.3) | | | |
| | Orthopaedics | 86 (79.6) | 22 (20.4) | | | |
| | Neurology | 8 (44.4) | 10 (55.6) | | | |
| | Urology | 19 (34.5) | 36 (65.5) | | | |
| | less than 1 hour | 99 (59.6) | 67 (40.4) | | | |
| Duration of Surgery ^c | 1-2 hours | 92 (58.6) | 65 (41.4) | 0.454 | -- | 0.098 |
| | 2-3 hours | 24 (61.5) | 15 (38.5) | | | |
| | 3-4 hours | 8 (47.1) | 9 (52.9) | | | |
| | More than 4 hours | 2 (28.6) | 5 (71.4) | | | |
| SAP Duration Appropriateness ^c | Yes | 225 (83.0) | 46 (17.0) | -- | <0.001 | 0.77 |
| | No | 0 (0.0) | 115 (100) | | | |
| SAP Timing Appropriateness ^c | Yes | 225 (59.7) | 152 (40.3) | <0.001 | -- | 0.183 |
| | No | 0 (0.0) | 9 (100) | | | |
| SAP Choice Appropriateness ^c | Yes | 225 (68.6) | 103 (31.4) | -- | <0.001 | 0.497 |
| | No | 0 (0.0) | 58 (100) | | | |
| Post-operative hospitalization duration ^d | 1 day and below | 39 (43.8) | 50 (56.2) | <0.001 | -- | 0.217 |
| | 2-5 days | 186 (63.7) | 106 (36.3) | | | |
| | 6-9 days | 0 (0.0) | 5 (100) | | | |

a Patient-related Factors; b Preoperative Factors; c Intraoperative Factors; d Postoperative Factors

lactamase inhibitors), third-generation cephalosporins (as monotherapy and in combination with beta-lactamase inhibitors), and carbapenems – not recommended for surgical prophylaxis per guidelines. Despite an 85% compliance rate observed with SAP choice in our study setting, non-compliance is associated with prescribers' choices and knowledge.

In a similar study by Sefah IA *et al.* [19] in Ghana, Thabit AK *et al.* [20], and Piri A *et al.* [21] in Western Iran, reasonable compliance (67.0%, 71.4%, 92.1%) with the choice of SAP to standard treatment guidelines was observed. In contrast to our study, a higher rate of inappropriateness in the selection of antibiotics for prophylaxis was observed in a study conducted in Islamabad, Pakistan by Khan Z *et al.* [22], where compliance was only 4.2%. These variations in the inappropriateness of SAP selection could be related to differences in practice settings, antimicrobial susceptibility patterns, and the prescriber's knowledge.

For SAP to be effective and appropriate, the CDC recommends administration before incision to achieve adequate serum and tissue antibiotic concentrations exceeding the minimum inhibitory concentration (MIC) for probable organisms at the surgical site, both at incision and throughout the procedure. Low tissue antibiotic concentrations may increase the risk of surgical site infections (SSIs) [23]. Studies recommend administering SAP within 60 minutes before incision and, in emergency surgery, as soon as possible after incision [24]. International evidence-based guidelines highlight timely perioperative antibiotic administration as crucial for reducing SSIs [25][26].

In our study, the timing of SAP was appropriate in 97.7% of cases, similar to the observation made by Segala, F.V *et al.* [27] in Rome, Italy, where appropriateness with SAP timing was 97.6%. In contrast, a lower rate of appropriateness (44.9%) with timing was observed in a similar study conducted in Australia by Ierano C *et al.* [28]. This could be due to a lack of communication between prescribing physicians and nursing staff or unawareness of when SAP should be administered.

As per our reference guidelines, the optimal duration of SAP is 24 - 48 hours, and coverage must be provided from incision to closure.

Extended prophylactic antimicrobial use is linked with antimicrobial resistance (AMR), superinfection risk, and drug toxicity [29]. Prolonging surgical prophylaxis is not recommended based on catheters or surgical drains. This practice lacks support in current studies and could increase antibiotic-associated adverse events [30].

In our study, 70.2% compliance was observed with the duration of SAP, and in 29.8%, the duration exceeded recommendations. In contrast, Gurunthalingam MP *et al.* [17] in India and Sefah IA *et al.* [19] in Ghana observed a lower rate of compliance with the duration of SAP. Non-compliance with SAP duration is associated with unawareness of recommended duration, fear of postoperative infections, and treating physicians assuming SAP within 24 - 48 hours leads to inadequate infection control, with a longer duration reducing SSIs risk – a perspective possibly influenced by factors prevalent in low and middle-income countries, such as suboptimal health status, lack of hygiene, nutritional deficiencies, limited resources, inadequate knowledge, or insecurity over legal pursuits in case of issues due to shorter SAP duration.

Our study highlights a clear discrepancy between SAP practice and recommendations. To prevent antibiotic resistance without compromising patient safety, enhancing SAP practices in line with established national and international recommendations is crucial.

We acknowledge limitations in our study, including the brief clinical audit period limiting our study to SAP use over the whole year. The mono-center design restricts generalizing study results to different contexts; hence, a multicentre study is required for future reference. Some baseline characteristics, such as body mass index, medication use (immunosuppressants, steroids), nutritional status, smoking, and alcohol intake, could not be considered due to inconsistent information. These factors may affect antibiotic prophylaxis decision-making, and future studies should consider them.

Despite these limitations, our findings provide useful information, particularly regarding optimal SAP use and factors associated with SAP compliance.

Conclusion

Compliance with recommended guidelines remains a challenge, as observed globally and in our study. Our study demonstrates inadequate adherence to antibiotic prophylactic guidelines, particularly in choice and duration. This emphasizes the need for institutional reinforcement of antimicrobial stewardship programs and the importance of clinical pharmacists periodically evaluating surgical antimicrobial prophylaxis and daily prescribing practices. These interventions can actively optimize antibiotic use and prevent antimicrobial resistance emergence. Further studies should examine the efficacy of such interventions and the impact of noncompliance on SSIs development.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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