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Original Article

Adherence to National Antibiotic Guidelines for Surgical Prophylaxis in A Tertiary Care Centre in Central Travancore, Kerala: A Prospective Observational Study

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ABSTRACT

Introduction: Surgical antimicrobial prophylaxis (SAP) is essential for preventing surgical site infections (SSIs), yet inappropriate use of broad-spectrum antibiotics contributes to antimicrobial resistance (AMR), increased healthcare costs, and adverse patient outcomes. This study aimed to evaluate adherence to the National Antibiotic Guidelines 2019 (ICMR) for surgical prophylaxis at a tertiary care centre in Central Travancore, Kerala, and to assess the incidence of SSIs.
Methodology: A three-month prospective observational study was conducted in the general surgical wards from January to March 2025. Adult patients undergoing elective clean or clean-contaminated surgeries were included using universal sampling. Data on antibiotic choice, timing, dosing, duration, and SSI occurrence (30-day follow-up) were collected using a standardized surveillance form. Adherence was assessed against ICMR guidelines (2019).
Results: Among 92 patients, the majority were clean-contaminated wounds (62.0%). Hepatobiliary (34.8%) and colorectal (20.7%) procedures were most common. Cefoperazone (58.7%) was the most prescribed antibiotic, followed by metronidazole (35.9%). Overall guideline adherence for antibiotic choice was 76.1%. Prophylaxis was administered within one hour pre-incision in 82.6% of cases. Intraoperative re-dosing was omitted in 34.6% of prolonged surgeries (>4 hours). Prophylaxis was discontinued within 24 hours postoperatively in 73.9% of cases. SSI occurred in 14.1% of patients. No significant association was found between guideline adherence and SSI ($p = 0.312$).
Conclusion: While overall adherence exceeded 70%, gaps remain in antibiotic selection, intraoperative re-dosing, and postoperative duration. Targeted antimicrobial stewardship programs are needed to optimize SAP practices in this setting.

Keywords*: antibiotic prophylaxis; surgical site infection; guideline adherence; antimicrobial stewardship.*

INTRODUCTION

Surgical site infections (SSIs) remain a significant cause of postoperative morbidity, prolonged hospitalization, and increased healthcare costs worldwide [1]. Surgical antimicrobial prophylaxis (SAP) the brief administration of antibiotics before surgical incision has proven effective in reducing SSI rates in clean and clean-contaminated procedures [2,3]. However, the effectiveness of SAP depends critically on appropriate antibiotic selection, correct timing, proper dosing, and limited duration [4].

The widespread and inappropriate use of broad-spectrum antibiotics for surgical prophylaxis has emerged as a major public health concern globally [5]. In India, the problem is particularly acute, with studies reporting irrational antimicrobial use

in over 50% of surgical inpatients [6]. The overuse of third-generation cephalosporins has been linked to the emergence of extended-spectrum beta-lactamase (ESBL)-producing organisms, methicillin-resistant *Staphylococcus aureus* (MRSA), and *Clostridium difficile* infections [7].

In response to the growing threat of antimicrobial resistance (AMR), the Indian Council of Medical Research (ICMR) published the "Treatment Guidelines for Antimicrobial Use in Common Syndromes" in 2019, which includes specific recommendations for surgical prophylaxis [8]. Kerala, recognized as a leader in AMR containment in India, has launched the "Antibiotic Smart Hospital Initiative" (ASHI) as part of the Kerala Antimicrobial Resistance Strategic Action Plan (KARSAP) [9]. Despite these efforts, data on guideline adherence for surgical prophylaxis in Kerala's tertiary care centres remain limited.

A tertiary medical college, located in the Central Travancore region of Kerala, serves as a major referral centre for a predominantly rural population. To date, no systematic evaluation of SAP practices has been conducted at this institution. This study aimed to assess adherence to national antibiotic guidelines for surgical prophylaxis and to determine the incidence of SSIs, thereby identifying areas for quality improvement in antimicrobial stewardship.

METHODOLOGY

Study Design and Setting

This prospective observational study was conducted in the Department of General Surgery at Pushpagiri Medical College Hospital, a tertiary care teaching hospital in Thiruvalla, Central Travancore, Kerala, India. The study was carried out over a three-month period from 1 January 2025 to 31 March 2025.

Ethical Considerations

Approval was obtained from the Institutional Ethics Committee of Pushpagiri Medical College (PIMSRC/E1/456A/894/2024). Informed written consent was obtained from all participants prior to inclusion. Confidentiality of patient data was maintained throughout the study.

Inclusion and Exclusion Criteria

Patients aged 18 years or older undergoing elective surgical procedures with wound classification as clean or clean-contaminated (according to CDC criteria) were eligible for inclusion [10]. Patients with documented preoperative infection, those receiving therapeutic antibiotics prior to surgery, immunocompromised patients, and those with known antibiotic allergy contraindicating guideline-recommended agents were excluded.

Sample Size and Sampling

Using universal sampling, all eligible patients undergoing elective surgery in the general surgical wards during the study period were enrolled. A total of 92 patients met the inclusion criteria.

Data Collection

A standardized case record form was developed based on the WHO Surgical Surveillance form and adapted to local requirements [11]. Data were retrieved from patient medical records, medication charts, anaesthesia records, and nursing notes. Information collected included:

Demographic data (age, gender, comorbidities)

- Surgical details (type of procedure, wound class, duration of surgery)
- Antibiotic prophylaxis parameters (agent, dose, route, timing of first dose, intraoperative re-dosing, duration of postoperative administration)
- Reasons for prolonged prophylaxis (>24 hours)
- Occurrence of SSI within 30 days postoperatively
- Patients were followed up until discharge and subsequently at outpatient clinics at postoperative days 7, 14, and 30. For patients who missed follow-up, telephone interviews were conducted. Wound assessment was performed by attending surgeons, and SSI was defined according to CDC criteria [10].

Guideline Recommendations

Adherence was assessed against the ICMR "Treatment Guidelines for Antimicrobial Use in Common Syndromes" (2019) [8].

- The following parameters were evaluated:
- Choice of antibiotic: Consistency with guideline recommendations for each surgical category (Table 1)
- Timing of prophylaxis: Administration within 60 minutes preceding surgical incision
- Intraoperative re-dosing: Administration of a repeat dose when surgery duration exceeded two half-lives of the antibiotic (or >4 hours for most agents)
- Duration of prophylaxis: Discontinuation within 24 hours postoperatively

When multiple antibiotics were prescribed for a single procedure, all parameters were evaluated for each agent. Deviation in any parameter resulted in classification as non-adherent for that parameter.

Outcome Measures

- Primary outcomes:
- Proportion of patients receiving guideline-concordant antibiotic choice
- Proportion receiving prophylaxis within recommended timing
- Proportion with appropriate intraoperative re-dosing
- Proportion with duration ≤24 hours

Secondary outcome:
Incidence of SSI within 30 days postoperatively

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics (frequencies, percentages, mean, standard deviation) were used to summarize demographic and clinical characteristics. Associations between guideline adherence parameters and SSI occurrence were analyzed using Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS
Patient and Surgical Characteristics
A total of 92 patients met the inclusion criteria during the study period. The mean age was 52.8 years (SD ±15.2), with males comprising 56.5% (n=52). The majority of patients (65.2%) had at least one comorbidity, with diabetes mellitus (32.6%) and hypertension (29.3%) being most common.

Clean-contaminated wounds accounted for 62.0% (n=57) of procedures, while clean wounds constituted 38.0% (n=35). Hepatobiliary surgery (cholecystectomy) was the most common procedure (34.8%), followed by colorectal surgery (20.7%), hernia repair with mesh (13.0%), breast surgery (9.8%), upper gastrointestinal surgery (8.7%), and vascular surgery (7.6%) (Table 2).

The mean duration of surgery was 2.8 hours (range: 0.75–6.5 hours). Procedures lasting more than 4 hours constituted 27.2% (n=25) of the cohort.

Antibiotic Utilization Patterns
Four main classes of antibiotics were used for surgical prophylaxis. Cefoperazone was the most frequently prescribed agent (58.7%), followed by metronidazole (35.9%), amoxicillin-clavulanate (29.3%), and cefuroxime (7.6%). The combination of cefoperazone plus metronidazole was observed in 32.6% (n=30) of cases (Table 3).

Table 4 presents the distribution of antibiotic choices according to surgical type. In hepatobiliary surgery, cefoperazone alone was used in 56.3% and cefoperazone plus metronidazole in 31.3%. Notably, the addition of metronidazole in hepatobiliary procedures (not recommended by the guideline) accounted for 68.4% of all discordant antibiotic selections. Similarly, in upper gastrointestinal surgery, 62.5% of patients received cefoperazone plus metronidazole, representing deviation from the guideline.

All antibiotics were administered intravenously, and doses were consistent with guideline recommendations in all cases.

Guideline Adherence
Choice of antibiotics: Overall adherence for antibiotic selection was 76.1% (n=70). Discordance was identified in 23.9% (n=22) of cases, primarily due to the addition of metronidazole to cefoperazone in hepatobiliary (n=10) and upper gastrointestinal (n=5) procedures. Other deviations included the use of cefoperazone alone in colorectal surgery without metronidazole (n=4) and the use of amoxicillin-clavulanate in breast surgery where cloxacillin was recommended (n=3).

Timing of prophylaxis: The majority of patients (82.6%) received the first dose within one hour preceding surgical incision. Within this group, 71.7% received the dose between 30 and 60 minutes pre-incision, while 10.9% received it within 30 minutes of incision. Prophylaxis was administered at the time of incision in 10.9% and postoperatively in 6.5% of cases (Figure 1). The rate of appropriate timing (≤60 minutes pre-incision) was comparable to studies from other Indian tertiary care centres [12].

Intraoperative re-dosing: Among the 25 patients (27.2%) with surgery duration exceeding four hours, intraoperative re-dosing was administered in only 40.0% (n=10). The remaining 60.0% (n=15) did not receive a repeat dose despite prolonged procedure duration, representing a significant gap in adherence.

Duration of prophylaxis: Prophylactic antibiotics were discontinued within 24 hours postoperatively in 73.9% (n=68) of patients. Among the 26.1% (n=24) who received antibiotics for >24 hours, the reasons documented were: unknown or not specified (54.2%, n=13), suspected infection without confirmed SSI (29.2%, n=7), and presence of surgical drains (16.7%, n=4). None of the latter cases had documented indications for continued prophylaxis according to guidelines.

Surgical Site Infections

SSI occurred in 13 patients (14.1%) within 30 days postoperatively. Of these, superficial incisional SSI accounted for 69.2% (n=9), deep incisional SSI for 23.1% (n=3), and organ/space SSI for 7.7% (n=1). The most common clinical presentations were erythema (84.6%), purulent discharge (69.2%), and localized tenderness (61.5%). Fever (>38°C) was documented in 30.8% (n=4) of SSI cases. Wound cultures were obtained in 10 patients (76.9%), with *Escherichia coli* (n=5), *Klebsiella pneumoniae* (n=3), and *Staphylococcus aureus* (n=2) being the predominant isolates. Among the *E. coli* isolates, two were ESBL-producers.

The highest SSI rates were observed in colorectal surgery (26.3%), followed by upper GI surgery (25.0%) and hepatobiliary surgery (18.8%) (Table 5). No significant association was found between adherence to antibiotic choice and SSI occurrence ($p = 0.312$). Similarly, timing of prophylaxis (≤1 hour vs. >1 hour pre-incision) did not demonstrate a statistically significant association with SSI ($p = 0.408$), consistent with findings from the Malaysian study that served as a model for this investigation [13].

Table 1. Recommended antibiotics for surgical prophylaxis (adapted from ICMR Guidelines 2019) [8]

Type of Surgery	Recommended Agents	Alternative Agents
Hepatobiliary	Cefuroxime 1.5g IV	Amoxicillin-Clavulanate 1.2g IV; Cefoperazone 1g IV
Colorectal	Cefuroxime + Metronidazole IV	Cefoperazone + Metronidazole; Amoxicillin-clavulanate
Upper GI	Cefuroxime IV	Cefoperazone; Amoxicillin-Clavulanate
Hernia (mesh)	Cefazolin 1g IV / Cloxacillin 1g IV	Amoxicillin-Clavulanate
Breast	Cefazolin 1g IV / Cloxacillin 1g IV	Amoxicillin-Clavulanate
Vascular	Cefazolin 1g IV / Cefuroxime 1.5g IV	Amoxicillin-Clavulanate

Table 2. Demographic and surgical characteristics of patients (N=92)

Characteristic	Number (N=92)	Percentage (%)
Age (years) Mean ± SD = 52.8 ± 15.2		
Gender		
Male	52	56.5
Female	40	43.5
Comorbidities		
Diabetes mellitus	30	32.6
Hypertension	27	29.3
None	32	34.8
Wound classification		
Clean	35	38
Clean-contaminated	57	62
Type of surgery		
Hepatobiliary	32	34.8
Colorectal	19	20.7
Hernia (with mesh)	12	13
Breast	9	9.8
Upper GI	8	8.7
Vascular	7	7.6
Other	5	5.4
Duration of surgery (hours)		
< 2	25	27.2
2 to 4	42	45.7
> 4 to 6	18	19.6
> 6	7	7.6

Table 3. Parameters of antibiotic usage (N=92)

Parameter	Number (N=92)	Percentage (%)
Choice of antibiotics		
Cefoperazone 1g IV	24	26.1
Cefoperazone + Metronidazole 500mg IV	30	32.6
Amoxicillin-clavulanate 1.2g IV	27	29.3
Cefuroxime 1.5g IV	5	5.4
Cefuroxime + Metronidazole	4	4.3
Other	2	2.2
Timing of first dose		
≤60 min pre-incision	76	82.6
>60 min pre-incision	0	0
At incision	10	10.9
Postoperative	6	6.5
Intraoperative re-dosing (n=25 surgeries >4h)		
Given as recommended	10	40
Omitted	15	60
Duration of prophylaxis		
≤24 hours	68	73.9
>24 hours	24	26.1

Table 4. Choice of antibiotics according to type of surgery (N=92)

Surgery Type	Cefoperazone	Cefoperazone + Metro	Amox-clav	Cefuroxime	Cefuroxime + Metro
Hepatobiliary (n=32)	18 (56.3%)	10* (31.3%)	4 (12.5%)	0	0
Colorectal (n=19)	3* (15.8%)	12 (63.2%)	2 (10.5%)	1 (5.3%)	1 (5.3%)
Upper GI (n=8)	2 (25.0%)	5* (62.5%)	1 (12.5%)	0	0
Hernia (n=12)	1 (8.3%)	0	8 (66.7%)	2 (16.7%)	1 (8.3%)
Breast (n=9)	0	0	7* (77.8%)	1 (11.1%)	1 (11.1%)
Vascular (n=7)	0	0	5 (71.4%)	1 (14.3%)	1 (14.3%)
Other (n=5)	0	3 (60.0%)	0	0	0

*Discordant with ICMR guidelines 2019

Table 5. SSI incidence according to antibiotic choice and type of surgery

Surgery Type	Antibiotic Regimen	SSI Cases / Total	SSI Rate (%)
Hepatobiliary	Cefoperazone alone	3 / 18	16.7
Hepatobiliary	Cefoperazone + Metro*	3 / 10	30
Colorectal	Cefoperazone + Metro	3 / 12	25
Colorectal	Cefuroxime + Metro	1 / 1	100
Colorectal	Other	1 / 6	16.7
Upper GI	Cefoperazone + Metro*	1 / 5	20
Hernia	Amoxicillin-clavulanate	1 / 8	12.5
Vascular	Amoxicillin-clavulanate	0/5	0

*Discordant with guideline recommendations

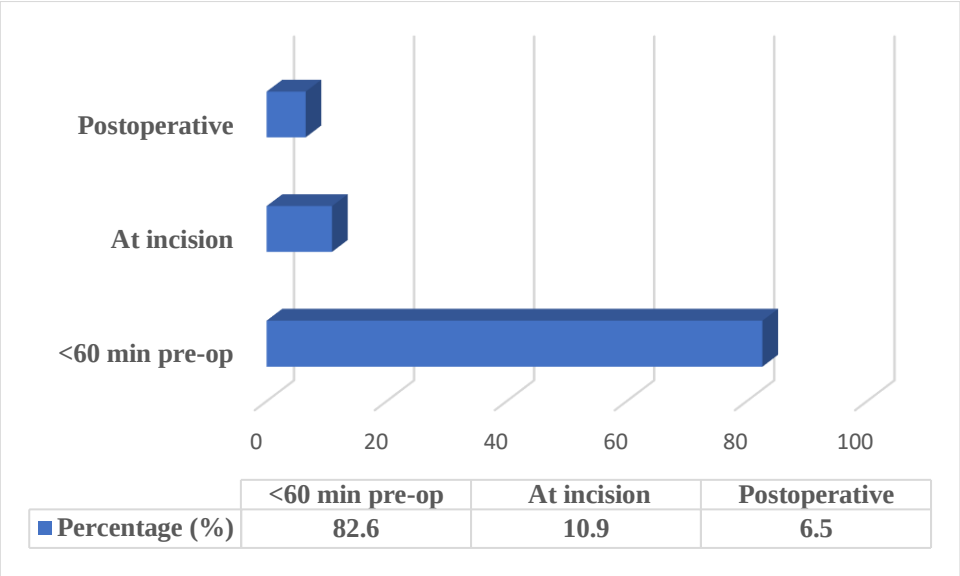

Figure 1. Timing of surgical antimicrobial prophylaxis administration

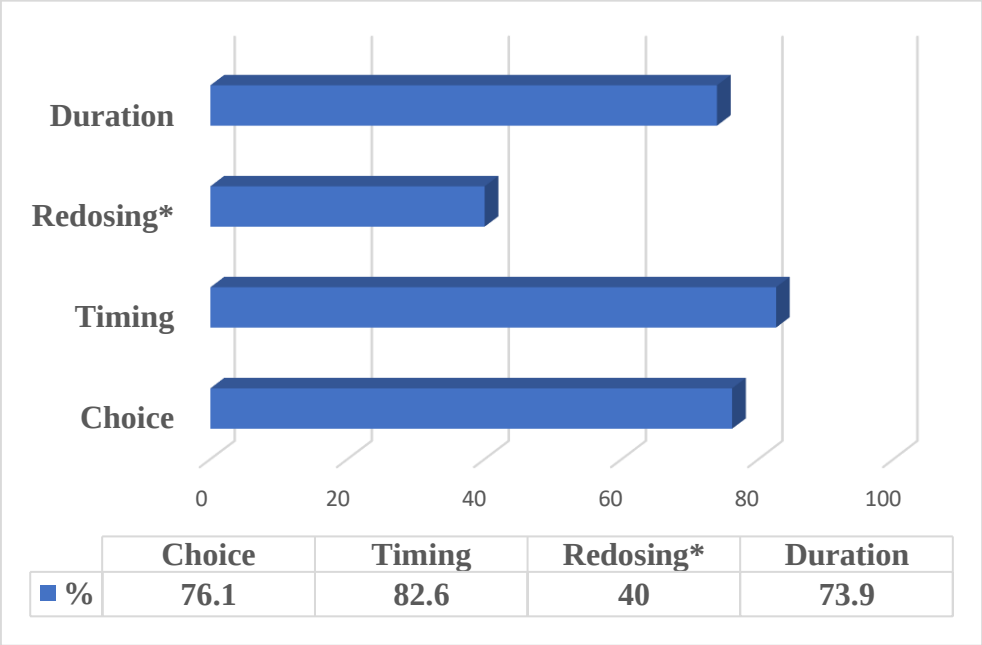

Figure 2. Adherence to key surgical prophylaxis parameters
Adherence rate (%)

***Among procedures >4 hours duration**

DISCUSSION

This prospective study evaluated adherence to national antibiotic guidelines for surgical prophylaxis at a tertiary care centre in Central Travancore, Kerala, and assessed the associated SSI rates. The overall adherence rate of 76.1% for antibiotic choice compares favourably with the Malaysian study (78.2%) that served as a model for this investigation [13]. However, notable gaps were identified in intraoperative re-dosing (40.0% adherence) and postoperative duration (73.9% adherence), highlighting areas requiring targeted antimicrobial stewardship interventions.

Antibiotic Selection Practices

The preference for third-generation cephalosporins (cefoperazone) as the first-line prophylactic agent in hepatobiliary, colorectal, and upper gastrointestinal surgery is concerning. While cefoperazone is an acceptable alternative in the ICMR guidelines, second-generation cephalosporins (cefuroxime) are recommended as preferred agents due to their narrower spectrum and lower risk of selecting for resistant organisms [8]. This pattern mirrors findings from other Indian institutions, where third-generation cephalosporins dominate surgical prophylaxis prescribing [6,14]. A ten-year trend study from Central India similarly reported that third-generation cephalosporins (41%) were the most prescribed prophylactic agents [15].

The frequent addition of metronidazole to cefoperazone in hepatobiliary and upper GI procedures accounting for 68.4% of all discordant selections suggests a perceived need for enhanced anaerobic coverage not supported by current evidence. However, our data showed higher SSI rates with the combination regimen in hepatobiliary surgery (30.0% vs. 16.7% with cefoperazone alone), consistent with the Malaysian study's observation that metronidazole addition may not confer benefit in this setting [13]. This finding warrants further investigation through larger comparative studies.

Timing of Prophylaxis

The 82.6% adherence rate for preoperative timing (within 60 minutes of incision) is comparable to the Malaysian study (80%) and exceeds rates reported from Dutch (50%) and US hospitals (55.7%) [13,16,17]. This relatively good performance may reflect increased awareness of the importance of timing following the implementation of surgical safety checklists in Indian hospitals. Nevertheless, the 17.4% of patients receiving prophylaxis at incision or postoperatively represent missed opportunities for SSI prevention, as delayed administration has been associated with significantly higher infection rates [18].

Intraoperative Re-dosing

The most striking gap in adherence was observed in intraoperative re-dosing, where 60% of patients undergoing prolonged surgery (>4 hours) did not receive a repeat antibiotic dose. This finding is particularly concerning given that tissue antibiotic concentrations fall below therapeutic levels during extended procedures, increasing SSI risk [19]. The Malaysian study reported a lower omission rate (27.6%) [13], suggesting that awareness of re-dosing recommendations may be particularly limited in our setting. Educational interventions targeting anaesthesia and surgical teams regarding half-life-based re-dosing schedules are urgently needed.

Duration of Prophylaxis

Prolonged prophylaxis beyond 24 hours occurred in 26.1% of patients, with over half of these cases (54.2%) having no documented indication. This rate is higher than the Malaysian study (23%) and Dutch hospitals (18%), though lower than reported in US hospitals (59.3%) [13,16,17]. Importantly, continuing prophylaxis until drain removal—a practice observed in 16.7% of prolonged cases—is explicitly discouraged by both ICMR and international guidelines [8,20]. The lack of clear documentation for continued prophylaxis suggests that protocol-driven discontinuation orders and antibiotic time-outs could substantially reduce unnecessary antibiotic exposure.

Surgical Site Infections

The overall SSI rate of 14.1% is comparable to the Malaysian study (13.8%) but higher than rates reported from high-income countries (2-5%) [21]. The predominance of *E. coli* and *K. pneumoniae* as causative organisms, including ESBL-producers, reflects the high burden of antimicrobial resistance in Indian healthcare settings. Notably, the lack of significant association between guideline adherence and SSI ($p=0.312$) parallels the Malaysian findings [13] and may reflect the multifactorial nature of SSI pathogenesis, where patient factors (diabetes, nutritional status) and surgical technique play substantial roles.

Implications for Antimicrobial Stewardship

Kerala has emerged as a pioneer in AMR containment in India through the Kerala Antimicrobial Resistance Strategic Action Plan (KARSAP) and the Antibiotic Smart Hospital Initiative (ASHI) [9]. These programs mandate prescription audits, antibiotic utilization metrics, and AWaRe classification compliance. Our findings suggest that despite these initiatives, significant gaps persist in surgical prophylaxis practices at the institutional level.

The following stewardship interventions are recommended for a tertiary care Hospital:

- Development of a hospital-specific antibiotic prophylaxis guideline adapted from ICMR recommendations, with input from local surgeons, anaesthesiologists, and clinical pharmacists.
- Implementation of a preoperative antibiotic checklist integrated into the surgical safety timeout, verifying appropriate selection, timing, and planned duration
- Electronic medical record alerts for intraoperative re-dosing when surgery duration exceeds four hours
- Automatic stop-orders for prophylactic antibiotics at 24 hours postoperatively unless therapeutic indication is documented
- Regular audit and feedback to surgical teams regarding individual and departmental adherence rates

Study Limitations

Several limitations should be acknowledged. The sample size (n=92) and single-centre design limit generalizability to other settings in Kerala and India. The three-month study period may not capture seasonal variations in SSI rates or prescribing practices. Data retrieval from medical records may have been affected by documentation quality, particularly regarding reasons for prolonged prophylaxis. The lack of risk-adjusted SSI rates limits comparison with other institutions. Finally, the observational design precludes causal inference regarding the relationship between adherence and SSI.

CONCLUSION

This study demonstrates that while overall adherence to national antibiotic guidelines for surgical prophylaxis at a tertiary care centre in Central Travancore exceeds 70%, significant gaps remain in antibiotic selection (overuse of third-generation cephalosporins and unnecessary metronidazole), intraoperative re-dosing (60% omission rate), and postoperative duration (26.1% prolonged prophylaxis). The SSI rate of 14.1% highlights the ongoing burden of postoperative infections in this setting.

These findings underscore the need for enhanced antimicrobial stewardship interventions tailored to the local context. The Kerala government's Antibiotic Smart Hospital Initiative provides a framework for strengthening surgical prophylaxis practices through prescription audits, adherence monitoring, and healthcare worker education. Implementation of hospital-specific guidelines, electronic decision support, and regular feedback to surgical teams can bridge the identified gaps and improve patient outcomes while preserving the efficacy of available antibiotics for future generations.\

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