

# CLINICAL PROFILE AND ANTIMICROBIAL PRESCRIPTION PATTERN IN PATIENTS UNDERGOING CHOLECYSTECTOMY AT A TERTIARY CARE HOSPITAL

Shailendra Yadav,<sup>1</sup> Gajendra Prasad Rauniar,<sup>2</sup> Deependra Prasad Sarraf,<sup>2</sup> Dipesh Raj Panday,<sup>2</sup> Vijay Shrestha,<sup>3</sup>

<sup>1</sup>Department of Pharmacology, Madhesh Institute of Health Sciences, Janakpurdham, <sup>2</sup>Department of Clinical Pharmacology & Therapeutics, <sup>3</sup>Department of Surgery, B.P Koirala Institute of Health Sciences, Dharan, Nepal

## ABSTRACT

Although guidelines advise against routine antibiotic prophylaxis in low-risk elective laparoscopic cholecystectomy, overprescribing remains common. Evidence on patient profiles and antibiotic use in Eastern Nepal is limited. This study aimed to determine the clinical profile and antibiotics prescription pattern in patients undergoing cholecystectomy. A descriptive cross-sectional study was conducted among 254 patients undergoing cholecystectomy at B.P. Koirala Institute of Health Sciences between September 2023 and June 2024. Demographic, clinical, and prescribing data were extracted from patient files and prescription cardex. Antibiotics utilization pattern was evaluated using WHO core drug use indicators. Data were analyzed using SPSS-20. Out of 254 patients, most patients were female (78.35%), with a mean age of 46.21±14.46 years. Symptomatic gallstone disease was the main indication (92.52%). A total of 748 antibiotics were prescribed, averaging 2.94±0.46 per patient. Penicillin-β-lactamase inhibitor combinations predominated (49.19%), with ampicillin/sulbactam accounting for 48.79% of all prescriptions. Only 0.67% of antibiotics were prescribed by generic name, 11.09% were from the National List of Essential Medicines, and 78.20% were fixed-dose combinations. Injectable antibiotics accounted for 69.12% of prescriptions. The mean duration of therapy was 8.18±3.15 days. Culture testing was performed in only 0.40% of cases. Antibiotic use in cholecystectomy showed excessive use of broad-spectrum fixed-dose combinations, prolonged therapy, and poor adherence to essential medicine and generic prescribing principles. Strengthening antimicrobial stewardship and implementing procedure-specific guidelines are urgently needed.

## KEYWORDS

Antimicrobial prescription pattern, gallstone, cholecystectomy

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## CORRESPONDING AUTHOR

Dr. Shailendra Yadav,  
Lecturer,  
Department of Pharmacology,  
Madhesh Institute of Health Sciences,  
Janakpurdham, Nepal  
Email: shailendrayadav4417@gmail.com  
Orcid No: <https://orcid.org/0009-0003-4557-1931>  
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## INTRODUCTION

Gallstone disease (cholelithiasis) is characterized by the formation of calculi within the biliary tract and is the underlying cause of more than 98.0% of gallbladder and biliary disorders and primarily involves an imbalance in biliary cholesterol or bilirubin.<sup>1</sup> The reported global prevalence varies, ranging from 10.0-15.0% in developed nations. In South Asia, prevalence estimates are approximately 10.0-20.0% in India and 2.44-6.45% in Nepal.<sup>2</sup>

Cholecystectomy, the surgical removal of the gallbladder, is the standard curative intervention for symptomatic gallstone disease and can be performed via either an open or a laparoscopic approach. At present, laparoscopic cholecystectomy (LC) is widely regarded as the gold standard for this procedure due to its advantages of shorter operative time, reduced hospital stay, and lower overall treatment costs.<sup>3</sup> Despite these established benefits, the routine use of prophylactic antibiotics in conjunction with LC remains a common practice among surgeons, primarily intended to mitigate postoperative complications such as surgical site infections.<sup>4</sup> This practice persists despite evidence-based guidelines—including those from the Scottish Intercollegiate Guidelines Network (SIGN) and the American Society of Health-System Pharmacists (ASHP)—which do not recommend antibiotic prophylaxis for low-risk patients undergoing elective laparoscopic cholecystectomy.<sup>5</sup> The continued overuse of antibiotics in this setting is concerning, as it contributes directly to increased adverse drug events, promotes antimicrobial resistance, and imposes an unnecessary economic burden on the healthcare system.<sup>6</sup>

Within the context of Nepal, and specifically the Eastern Region, there is no published data on the clinical profile of patients undergoing cholecystectomy and the associated antibiotic prescribing patterns. To address this evidence gap, the present study aimed to investigate the demographic and clinical profiles of these patients, analyze the prevailing antimicrobial prescription patterns, and assess the associated direct medication costs.

## MATERIALS AND METHODS

A descriptive cross-sectional study was conducted among patients undergoing cholecystectomy in surgery department at B.P. Koirala Institute of Health Sciences (BPKIHS),

Dharan from September 2023 to June 2024. Patients with age 18 years or more undergoing laparoscopic or open cholecystectomy in the department of general surgery were enrolled in the study. Patients having associated medical co-morbidities like diabetes mellitus, renal failure, chronic liver disease, immune compromised patients and those not giving consent were excluded. Convenience sampling technique was used to enroll the patients.

*Sample size estimation:* In a study by Khan et al,<sup>7</sup> the proportion of Cefuroxime prescription was 8.68%. Therefore, estimated population proportion with antimicrobial prescription ( $p$ ) = 0.08 at 95% confidence interval (CI) and 80% power.

Compliment of  $p$  ( $q$ ) =  $1 - p = 0.92$

Margin of error ( $d$ ) = 5% = 0.05

Reliability coefficient ( $Z$ ) = 1.96 for 95% CI

Using formula,

$$\begin{aligned} \text{Sample size } (n) &= Z^2pq/d^2 \\ &= (1.96)^2 * 0.08 * 0.92 / (0.05)^2 \\ &= 113.09 \text{ i.e., approximately } 113 \end{aligned}$$

Taking 10.0% as non-responders, the final sample size = 124. All eligible patients presenting during the study period were included, resulting in a total sample of 254. A larger sample was included to enhance representativeness and reduce sampling bias.

Verbal informed consent was obtained from all participants after explaining the purpose of the study. A self-designed proforma was used to collect the data. The proforma underwent content validation through expert review and minor revisions were made accordingly. Basic socio-demographic data along with a short history were taken from the patient about the onset, clinical symptoms and signs and progression of the disease. The patient files and prescription cardex were reviewed to collect the relevant data regarding prescribed antibiotics with their dose, frequency, duration and route of administration during their stay in hospital on daily basis. The patients were followed up till discharge for any addition of drugs. The study was approved by Institutional Review Committee of BPKIHS (Ref.: 2629/023).

Data were entered in Microsoft Excel 2010. Descriptive statistics like mean, standard deviation, frequency and percentage were calculated. The WHO core drug use indicators like average number of antibiotics per patient,

percentage of antibiotics prescribed by generic name, percentage of antibiotics prescribed in injection form and percentage of antibiotics prescribed from National List of Essential Medicine (NLEM) were calculated.<sup>8</sup> The data were analyzed using SPSS-20.

## RESULTS

**Sociodemographic and clinical profile:** A total of 254 patients undergoing cholecystectomy were included in the study. The majority were female (78.35%), resulting in a female-to-male ratio of 3.6:1. Most patients were married (94.88%) and housewives (71.65%) (Table 1). The mean ( $\pm$ SD) age of patients was  $46.21 \pm 14.46$  years, with the highest proportion of patients belonging to the 31–40 years and 41–50 years age groups (22.83% each) (Fig. 1). Nearly half of the patients (47.24%) were residents of Sunsari district (Fig. 2).

Comorbid conditions were present in 69 patients (27.17%). Among these, hypertension was the most frequent comorbidity, observed

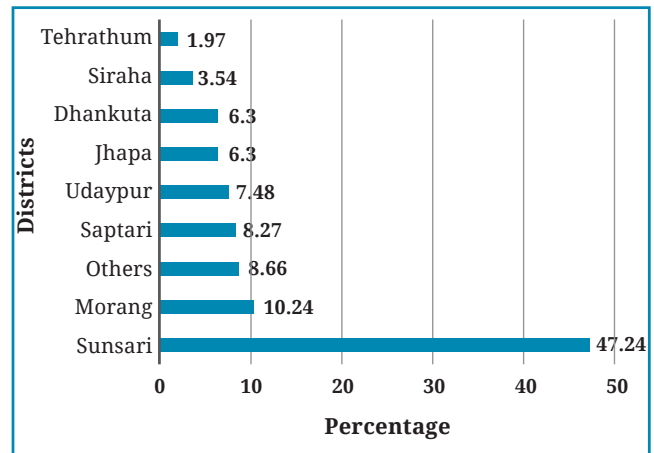


Fig. 2: Residence of the patients (n=254)

in 60 patients (77.92%) (Fig. 3). Right upper quadrant abdominal pain was the most common presenting symptom, reported by 222 patients (47.74%) (Fig. 4). The predominant indication for surgery was symptomatic gallstone disease (92.52%). Laparoscopic cholecystectomy was performed in 253 patients (99.61%), with only one case (0.39%) requiring conversion to open surgery (Table 2).

**Antimicrobial prescription patterns:** A total of 748 antibiotics were prescribed to 254 patients, with a mean ( $\pm$ SD) of  $2.94 \pm 0.46$  antibiotics per patient. Penicillin- $\beta$ -lactamase inhibitor combinations accounted for the highest proportion of prescriptions (49.19%).

Table 1: Sociodemographic data of the patients (n=254)

Variables	n	%	
Gender	Female	199	78.35
	Male	55	21.65
Marital status	Married	241	94.88
	Unmarried	13	5.12
Occupation	Housewife	182	71.65
	Farmer	40	15.75
	others	17	6.69
	Service	8	3.15
	Unemployed	5	1.97
	Retired	2	0.79

Table 2: Final diagnosis in the patients (n=254)

Final diagnosis	n	%
Symptomatic gallstone disease	235	92.52
Gallbladder polyp	13	5.12
Symptomatic gallstone disease with gallbladder polyp	2	0.79
Acute cholecystitis	2	0.79
Acute biliary pancreatitis	1	0.39
Chronic cholecystitis	1	0.39

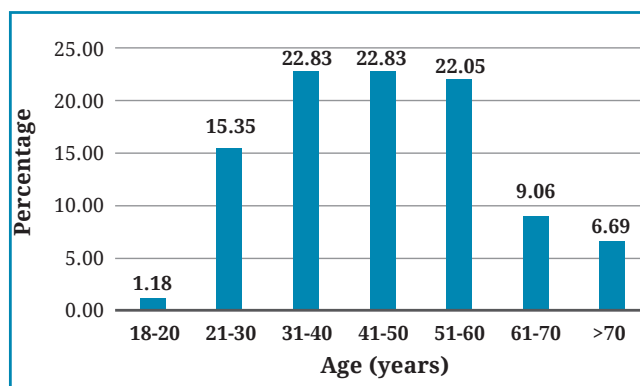


Fig. 1: Age category of the patients (n=254)

Table 3: WHO core drug use indicators

Prescribing indicators	Data
Average number of antibiotics prescribed per patient	2.94
Antibiotics prescribed by generic name	0.67%
Antibiotics prescribed from NLEM	11.09%
Antibiotics prescribed in injection form	69.12%

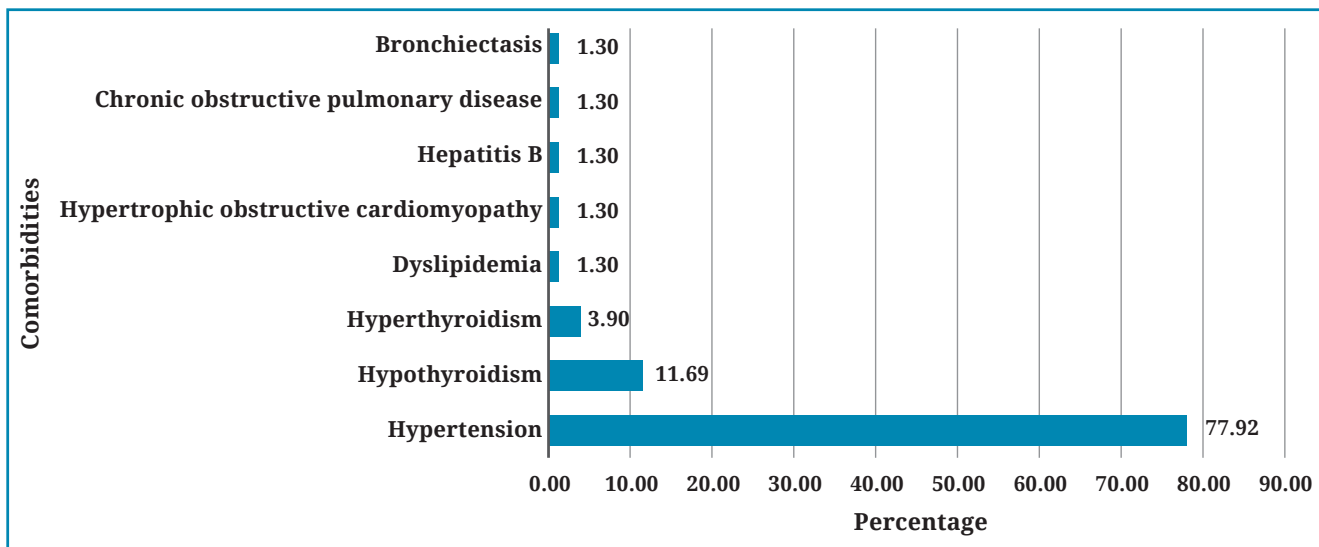


Fig. 3: Comorbidities in the patients (n=77)

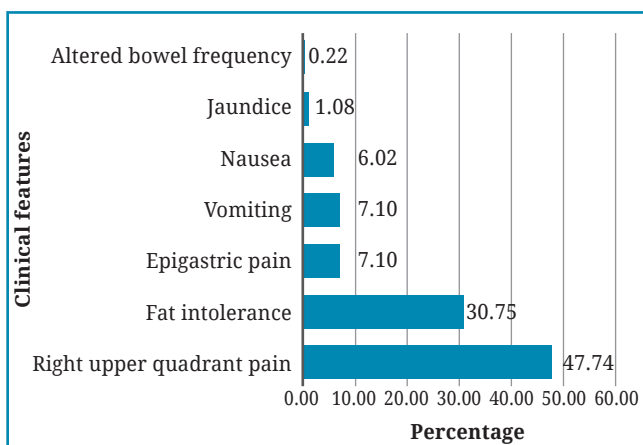


Fig. 4: Clinical features observed in the patients (n=465)

Ampicillin–sulbactam alone constituted 48.79% of all antibiotics prescribed, followed by Ceftriaxone–tazobactam (27.9%). Together, these two fixed-dose combinations (FDCs) represented 76.7% of all antibiotic prescriptions in this surgical cohort (Fig. 5 and 6). The mean ( $\pm$ SD) number of antibiotics prescribed during

the preoperative, postoperative, and discharge phases was  $1.00\pm 0.06$ ,  $1.03\pm 0.23$  and  $0.90\pm 0.34$ , respectively. The mean ( $\pm$ SD) duration of antibiotic therapy was  $8.18 \pm 3.15$  days, with more than half of the patients (55.90%) receiving antibiotics for 6–10 days (Fig. 7). Culture and sensitivity testing was performed in only one patient (0.40%), and antibiotic therapy was adjusted accordingly in that case.

**WHO core prescribing indicators:** Adherence to WHO core prescribing indicators was notably low. Antibiotics were prescribed predominantly by brand name (99.33%), with only 0.67% prescribed generically. Injectable formulations accounted for 69.12% of prescriptions. Only 11.09% of antibiotics were prescribed from the National List of Essential Medicines (Table 3). Fixed-dose combinations constituted 78.20% of all antibiotic prescriptions.

**Cost of the antibiotic therapy:** The mean direct antibiotic cost per patient was NRs.  $1643.06\pm$ SD (range: NRs. 1501–2000).

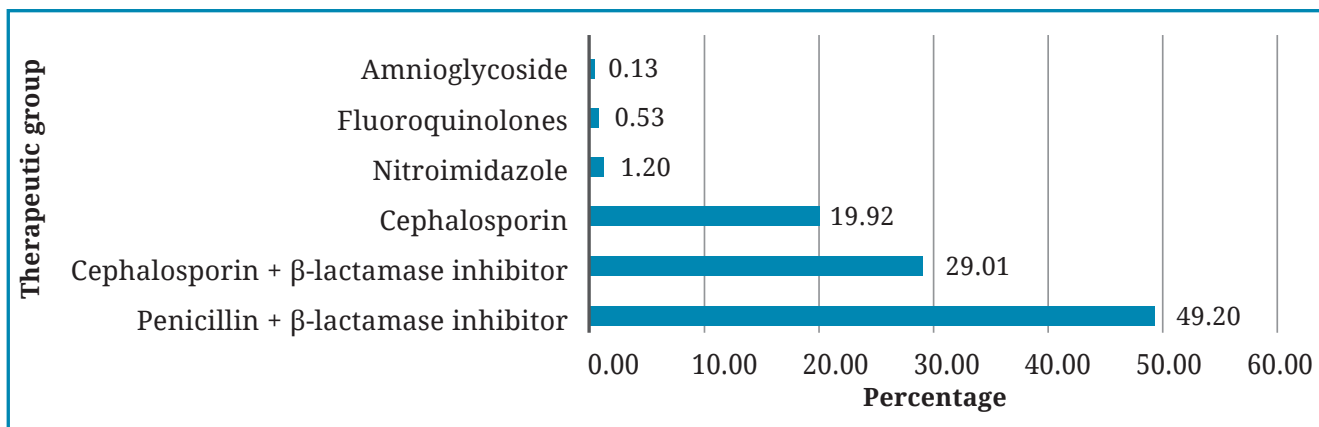


Fig. 5: Prescription of AMAs based on therapeutic group (n=748)

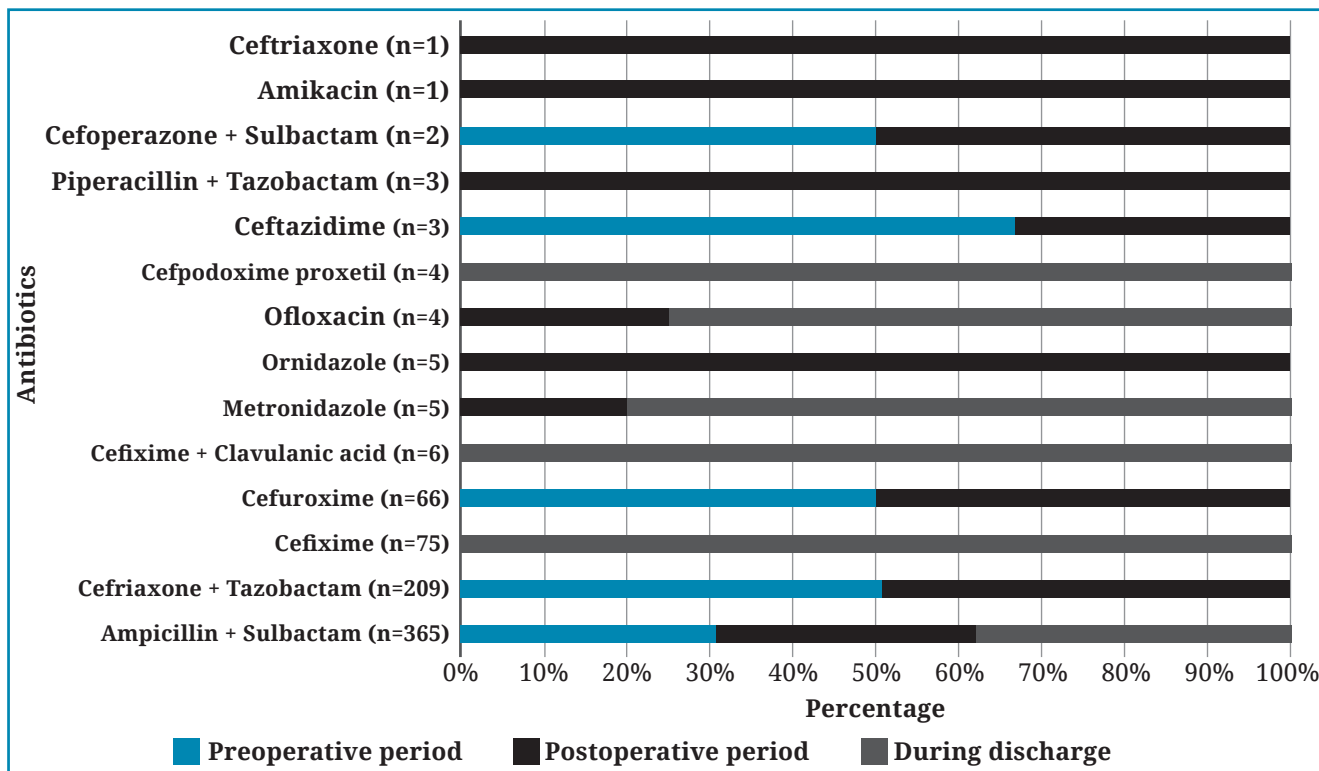


Fig. 6: Distribution of antibiotic prescriptions across the perioperative period (n=748)

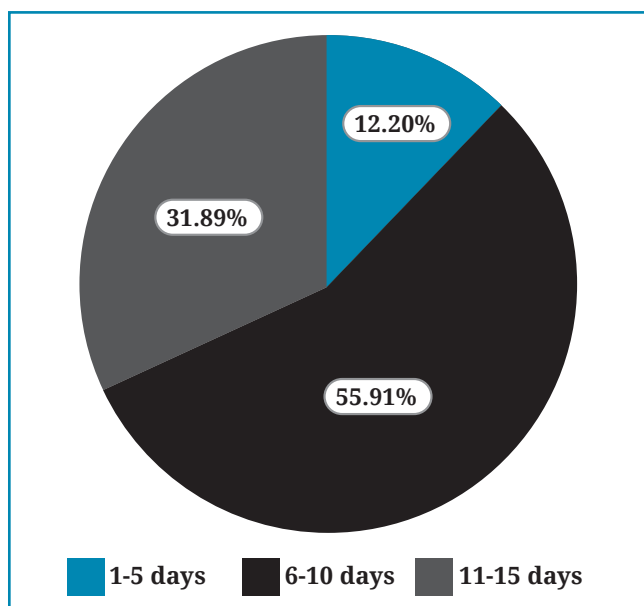


Fig. 7: Duration of antibiotic prescription (n=254)

## DISCUSSION

The present study evaluated the clinical profile and antimicrobial prescribing patterns among patients undergoing cholecystectomy at a tertiary care hospital in Eastern Nepal. Our findings revealed several critical deviations from established guidelines and antimicrobial stewardship principles. The predominance of female patients and the mean age observed in this study are consistent with previously

reported epidemiological patterns of gallstone disease in other studies.<sup>9,10</sup> Hormonal factors, reproductive history, and lifestyle-related risk factors may partly explain the higher prevalence of gallstone disease among females.<sup>11</sup> A mean age in the fifth decade was consistent with other studies.<sup>12,13</sup> In contrast, the mean age of patient was 38.46 years in study by Shrestha *et al.*<sup>14</sup> The change in age group might be due to variation in age related adoption of diet and life style which promote the formation of gallstone.<sup>12</sup> The high prevalence among housewives may reflect sedentary lifestyles and dietary patterns that predispose to gallstone formation.<sup>15</sup>

Almost half of the patients (47.74%) presented with complains of right upper quadrant pain. This was in consistent with other reports.<sup>9,11</sup> In most of the patients (92.52%), indication for cholecystectomy was symptomatic gallstone disease. Similar results were also reported by Kurmi *et al.*<sup>12</sup> Most patients (99.61%) underwent laparoscopic cholecystectomy, reflecting the widespread adoption of minimally invasive techniques as the standard surgical approach. The extremely low conversion rate to open surgery further suggests favorable surgical outcomes and case selection.

The central finding of this study was the widespread and irrational use of multiple antibiotics in elective laparoscopic cholecystectomy. The average of nearly three antibiotics per patient far exceeds the

recommended prophylaxis of a single pre-operative dose or a short 24-hour course for low-risk procedures. This over-prescription was further compounded by the dominance of broad-spectrum, fixed-dose combinations, particularly Ampicillin/Sulbactam and Ceftriaxone/Tazobactam, which together accounted for over three-quarters of all prescriptions. Similar prescribing trends have been reported in other studies.<sup>3,16-18</sup> This pattern suggests a preference for broad-spectrum empirical therapy, potentially driven by concerns regarding postoperative infections rather than evidence-based prophylactic recommendations. Current international guidelines do not recommend routine antibiotic prophylaxis for elective laparoscopic cholecystectomy in low-risk patients, and certainly do not endorse prolonged, multi-drug, broad-spectrum regimens.<sup>19</sup>

The duration of antibiotic therapy was notably prolonged, with a mean duration exceeding eight days. More than half of the patients received antibiotics for 6–10 days, despite laparoscopic cholecystectomy being classified as a clean-contaminated procedure for which short-course prophylaxis or even no antibiotics is recommended in low-risk cases. These findings were not in line with other studies.<sup>3,20</sup> Prolonged antibiotic use in such settings does not confer additional protective benefits but may increase the risk of adverse drug reactions, antimicrobial resistance, and unnecessary healthcare expenditure.<sup>21</sup>

The near-absence of microbiological culture testing (0.40%) reflects a lack of diagnostic stewardship and perpetuates empirical, often unnecessarily broad-spectrum antibiotic use. This practice not only undermines efforts to combat antimicrobial resistance but also fails to align with the fundamental principle of targeted therapy.

Our data also highlight a significant gap between national drug policy and clinical practice and it further revealed suboptimal adherence to principles of rational drug use. The near-exclusive use of brand-name antibiotics (99.33%) and minimal adherence to the National List of Essential Medicines (11.09%) suggest a systemic failure to promote rational, cost-effective prescribing. These findings were not in line with Demoz *et al.*<sup>22</sup> This is particularly concerning in a resource-limited setting like Nepal, where unnecessary expenditure on expensive FDCs and non-essential antibiotics diverts resources from other critical healthcare needs.

Fixed-dose combinations constituted a substantial proportion of prescriptions (78.20%). Although fixed-dose combinations may offer convenience, their widespread use raises concerns regarding cost, appropriateness, and rationality of therapy, particularly when single-agent alternatives are available.<sup>23</sup> It points toward a gap between national prescribing policies and bedside clinical practice. Overall, the findings of this study suggest a significant gap between current prescribing practices and recommended antimicrobial stewardship principles in the perioperative management of cholecystectomy.

This study has few limitations. As a single-center study, its generalizability to other settings in Nepal may be limited. Additionally, the exclusion of high-risk patients (e.g. those with immunosuppression or acute cholecystitis) means our findings primarily reflect prescribing in low-to-moderate-risk elective surgery, making the observed overuse even more striking.

In conclusion, this study demonstrates a high level of antibiotic utilization among patients undergoing cholecystectomy, characterized by frequent use of broad-spectrum fixed-dose combinations, prolonged duration of therapy, low rates of generic prescribing, and limited adherence to the National List of Essential Medicines. The minimal use of culture-guided therapy further underscores the reliance on empirical prescribing. These findings indicate substantial deviation from evidence-based guidelines for surgical antibiotic prophylaxis and highlight important gaps in antimicrobial stewardship practices. The development and implementation of standardized, procedure-specific antibiotic guidelines, along with regular prescription audits and clinician education, are urgently needed to promote rational antibiotic use, reduce unnecessary healthcare costs, and mitigate the growing threat of antimicrobial resistance in resource-limited settings such as Nepal.

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