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**CORRESPONDING AUTHOR:**

**Bhupendra Charan Shrestha**
Lecturer,
Department of General Surgery
Birat Medical College Teaching Hospital, Nepal
Email: bcshrestha2023@gmail.com
ORCID: 0000-0002-0400-0636

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# Comparative study of preoperative prophylactic antibiotic versus no antibiotic in patients undergoing elective laparoscopic cholecystectomy

***Bhupendra Charan Shrestha[1], Milan Adhikari[2], Aliza Timsina[2]***

[1] Lecturer, Department of General Surgery, Birat Medical College Teaching Hospital, Morang, Nepal
[2] Medical Officer, Department of Anesthesia and Critical Care, Birat Medical College Teaching Hospital

## ABSTRACT

**Introduction:** Laparoscopic cholecystectomy stands as one of the most commonly performed surgical procedures worldwide, primarily indicated for symptomatic cholelithiasis and associated gallbladder diseases. Despite its minimally invasive nature, concerns persist regarding the risk of postoperative infections, which can significantly impact patient outcomes and healthcare costs. Antibiotic prophylaxis has long been considered a standard practice to mitigate this risk, yet the optimal approach remains a subject of debate.

**Objective:** This research was aimed to elucidate the comparative effectiveness of preoperative prophylactic antibiotic versus no antibiotics in patients undergoing elective laparoscopic cholecystectomy.

**Methodology:** We conducted a prospective comparative study at Birat Medical College Teaching Hospital from 27 November 2023 to 27 February 2024. A total of 200 patients undergoing elective laparoscopic cholecystectomy were enrolled consecutively and assigned to the no antibiotic prophylaxis group and single dose preoperative antibiotic prophylaxis group (SD) on a roll basis. The SD group received a preoperative injection of ceftriaxone (third generation of cephalosporin) (1gm) 30 minutes before the surgical procedure. Data were collected and analyzed using SPSS version 23.

**Results:** The overall rate of SSI was 4% in our study. Five out of 100 patients who received prophylactic and 3 out of 100 patients who did not receive antibiotics developed surgical site infection(SSI). However, the difference was not statistically significant.

**Conclusion:** Our study comparing preoperative prophylactic antibiotics versus no antibiotics in elective laparoscopic cholecystectomy patients reveals no significant association between antibiotic use and outcomes such as surgical site infections and fever.

## INTRODUCTION

Laparoscopic cholecystectomy is a widely performed surgical procedure for managing symptomatic cholelithiasis and gallbladder diseases.[1] Despite its minimally invasive nature, concerns persist regarding the risk of postoperative infections, necessitating the consideration of antibiotic prophylaxis. However, studies also debate the fact that there are no differences in use of antibiotic prophylaxis for prevention of postoperative complications.[2,3] This study aimed to address this gap by comparing two

strategies: administering preoperative prophylactic antibiotics versus omitting antibiotic use entirely in patients undergoing elective laparoscopic cholecystectomy. This investigation sought to provide valuable insights into the efficacy and safety of each approach, aiding clinicians in making informed decisions regarding antibiotic prophylaxis. The rationale for this study lies in the potential drawbacks associated with antibiotic administration, such as the emergence of antimicrobial resistance, adverse drug reactions, and increased healthcare costs.[4,5] Conversely, concerns persist regarding the risk of surgical site infections (SSIs) and other postoperative complications in patients not receiving prophylactic antibiotics. Therefore, a comprehensive evaluation of both strategies is essential to strike a balance between infection prevention and antibiotic stewardship. We intended to compare the incidence of SSIs, overall postoperative complications, length of hospital stay, and healthcare resource utilization between the two study groups.

## METHODOLOGY

This was a hospital based comparative observational study conducted in the department of surgery of Birat Medical College Teaching Hospital(BMCTH) from 27th November 2023 to 27th February 2024. Ethical approval for the study was obtained from the Institutional review committee of BMCTH (IRC–PA-353/2023).

Patients aged 18 years and above, with the symptomatic cholelithiasis and associated gallstone disease, confirmed with ultrasonography, American society of anaesthesiology(ASA) scoring<3, under medication with known history of diabetes, hypertension, hypothyroidism, chronic obstructive pulmonary disease and bronchial asthma, those undergoing elective laparoscopic cholecystectomy and willingness to participate were included for the study. The exclusion of the patients from participations was done for those who meet any of the given criteria i.e. ASA 3 or above, previous antibiotic treatment within the past 30 days prior to surgery, hypersensitivity to the prescribed antibiotics, pre-existing systemic infection or active infectious disease, liver disease, immunocompromised status, ongoing immunosuppressive therapy, requiring prolonged postoperative hospitalization due to other medical conditions unrelated to laparoscopic cholecystectomy and history of previous abdominal surgery infections.

Patients were divided in two groups namely: Group one as those who don't receive antibiotics and Group two as those who receive single dose (SD) preoperative antibiotics. Non-probability consecutive sampling technique was used to select 200 samples, 100 in each group, for the study. The first patient meeting the inclusion criteria was selected randomly by lottery method on no antibiotics group (i.e. group one). Thereafter, the samples meeting the inclusion criteria were enrolled on a roll basis consecutively in each group during the study period.

We administered self-developed questionnaires to collect data from patients in each group. The first part of the questionnaire includes patient's information on socio-demographic characteristics (age, sex),Body Mass Index(BMI) and any comorbid illness(controlled diabetes mellitus, hypertension, hypothyroidism, Chronic Obstructive Pulmonary Disease {COPD}, bronchial asthma). The second part of the questionnaire includes the presence of surgical site infection (SSI), intra-abdominal infection, fever, duration of hospital stay and follow-up complication.

Each patient was scheduled for elective laparoscopic cholecystectomy after obtaining written informed consent. The patients enrolled in group one (no antibiotic) did not receive any antibiotic prophylaxis. The patients enrolled in group two received single dose(SD) third generation cephalosporin (ceftriaxone), 1 gram intravenously(I/V) 30 minutes before the surgical procedure. Elective laparoscopic cholecystectomy was performed via routine 4-ports under aseptic condition and gallbladder was sent for histopathological examination. Aseptic dressing was applied for both groups. The postoperative course was monitored for both groups on the second postoperative day and every week till 30 days after discharge. Any incident, such as fever, surgical site infection or intra-abdominal collection of abnormal fluid was recorded.

SSI includes surgical port site redness, tenderness, pus discharge, wound gap, wound abscess and growth of microorganism on wound secretions, or iatrogenic opening of the incision.[6] Temperature measuring >99 degree Fahrenheit through digital thermometer was considered as fever.[7]

On the second postoperative day, patients were evaluated for any complication and advised for discharge on follow up till 4 weeks to rule out any complication. Upon discharge, patients were advised for a follow up visit after a week for suture removal, and immediately if any complication (SSI, fever) were present. Patients who didn't have follow-up visits were contacted via phone and asked for any complications and discomfort. Both groups were followed up via phone call weekly for the next 3 weeks and their findings were recorded. Patients presenting with signs of postoperative SSI were advised for further intervention and collected. The total duration of hospital stay was also recorded from both groups.

Collected data was entered in Microsoft excel sheet and transferred to Statistical Package for Social Science (SPSS) version 23. Frequency percentage, mean and standard deviation(sd) were calculated. Chi square test and Fisher exact test was applied to evaluate the statistical significant association among patients receiving no dose of antibiotics versus single dose preoperative antibiotics. P value <0.05 was considered statistically significant.

## RESULTS

A total of 200 patients were enrolled, 100 in each group (Group 1-no antibiotic versus Group-2 preoperative prophylaxis antibiotic) for the study. The age groups with the highest number of patients in the no preoperative group were 21-30 years and 41-50 years, each comprising 21 individuals (21%) respectively. Within the group receiving prophylactic antibiotics, the highest numbers 30 (30%) were within the 41-50 years age. Females constituted the predominant gender in both the no prophylaxis (68;68%) and prophylaxis-receiving groups (61;61%). Janajati ethnicity were majority in both the no prophylaxis group

(38;38%) and prophylaxis-receiving group (40;40%). More than half (51;51%) patients had normal BMI in no prophylaxis group and majority were overweight (54;54%) in prophylaxis-receiving group (Table 1).

**Table 1: Baseline Characteristics of the patients**

| Socio-demographic profile | No Pre -operative and postoperative antibiotics group (n=100) n (%) | Prophylaxis antibiotics-group(n=100) n (%) |
|---|---|---|
| **Age Ranges in years** | | |
| <20 | 2(2) | 2(2) |
| 21-30 | 21(21) | 20(20) |
| 31-40 | 17(17) | 18(18) |
| 41-50 | 21(21) | 30(30) |
| 51-60 | 18(18) | 14(14) |
| 61-70 | 16(16) | 10(10) |
| 71-80 | 16(16) | 6(6) |
| **Sex** | | |
| Male | 32(32) | 39(39) |
| Female | 68(68) | 61(61) |
| **Ethnicity** | | |
| Brahmin/Chhetri | 36(36) | 31(31) |
| Dalit | 2(2) | 4(4) |
| Janajati | 38(38) | 40(40) |
| Madhesi | 21(21) | 25(25) |
| Muslim | 3(3) | 0(0) |
| **BMI ( Body Mass Index)** | | |
| Normal | 51(51) | 43(43) |
| Overweight | 47(47) | 54(54) |
| Obese | 2(2) | 3(3) |

**Table 2: Comparison of outcome between patient receiving preoperative prophylactic antibiotics versus patients with no antibiotics(n=200)**

| Categories | Fever n(%) | SSI n(%) | Intra Abdominal infection | Mean duration of hospital stay |
|---|---|---|---|---|
| Prophylactic antibiotics (n=100) | 8(8) | 5(5) | 0(0) | 3.08 |
| No antibiotics(n=100) | 8(8) | 3(3) | 0(0) | 3.14 |

SSI: surgical site infection

The overall incidence of SSI was 4(4%). SSI occurred more frequently among patients receiving preoperative antibiotic prophylaxis, with 5 cases (5%), compared to those not receiving it, where there were 3 cases (3%). Fever was equally prevalent 8 cases (8%) each Top of Form Group (Table 2).

There was no statistical significant association between preoperative antibiotic prophylaxis receiving versus non-receiving groups in terms of sex, comorbidities and body mass index with the occurrence of postoperative fever and SSI (Table 3).

**Table 3: Association of complications present with different factors(n=200)**

| Categories | | Fever | | | SSI | | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | P value | Yes | No | P value |
| Prophylactic antibiotics | Yes | 8(8) | 92 (92) | 1.000 | 5 (5) | 95(95) | 0.721* |
| | None | 8(8) | 92 (92) | | 3 (3) | 97(97) | |
| Sex | Females | 10(7.8) | 119 (92.2) | 0.862 | 4 (3.1) | 125(96.9) | 0.458* |
| | Male | 6(8.5) | 65 (91.5) | | 4 (5.6) | 67(94.4) | |
| Comorbidities | Yes | 1(4.8) | 20 (95.2) | 1.000* | 1 (4.8) | 20(95.2) | 0.595* |
| | No | 15(8.4) | 164 (91.6) | | 7 (3.9) | 172 (96.1) | |
| Body Mass Index | Normal | 43 (45.7) | 51 (54.3) | 0.321 | 3 (3.2) | 91(96.8) | 0.725* |
| | Overweight and obese | 57 (53.8) | 49(46.2) | | 5 (4.7) | 101 (95.3) | |

SSI: Surgical site infection, P value <0.05 was considered statistically significant. *Fishers' exact test was applied.

## DISCUSSION

This study investigated the comparative effectiveness of preoperative prophylactic antibiotics versus no antibiotics in elective laparoscopic cholecystectomy, shedding light on a crucial aspect of perioperative care. Our findings contribute to the ongoing discourse surrounding antibiotic stewardship in surgical settings, particularly in the context of elective cholecystectomy.

The overall rate of SSI was 4(4%) in our study. Five out of 100 patients who received prophylactic and 3 out of 100 patients who did not receive antibiotics developed infection. However, the difference was not statistically significant. Similar findings were observed in a randomized control trial (RCT) study, which explained

that there were no differences in the outcome between either group.[3,8] Studies reported that Laparoscopic cholecystectomy (LC) carries an extremely low rate of postoperative infection compared with open cholecystectomy (range of 0.4% and 6.3%)[9,10]. Given the lower infection rate, several other studies suggest that antibiotic prophylaxis is unnecessary for LC patients and the use of prophylactic antibiotics does not necessarily decrease the rate of postoperative infection complications.[8,11-13] The findings from meta-analysis and systematic reviews also concluded similar findings mentioned above. [14,15]

Our study findings did not have significant differences in mean duration of hospital stay among groups receiving prophylactic antibiotics and those who do not. Sex, comorbid illness, BMI also did not have any statistically significant differences for the presence of postoperative infection in our study. Similar finding was observed in another study which stated no statistical significant difference while comparing both group's gender and hospital stay.[2] Since limited evidence is found to conclude the significant association further research need to be conducted.

However, a systematic review and meta-analysis explained that antibiotic prophylaxis significantly reduced the incidence of surgical site infections, global infection after discharge and postoperative length of hospital stay which is contrast to the finding of our study. [16]

Considering the healthcare cost associated with the management of SSI, prophylactic antibiotics have benefits. However, the unnecessary use of prophylactic antibiotics increased risk of antibiotic resistance and the cost of health care. Moving forward, a cautious approach to antibiotic prophylaxis tailored to individual patient characteristics and surgical risk factors is warranted to optimize patient care while minimizing the risks of antimicrobial resistance.[17,18] Our study findings and similar findings from other studies mentioned collectively underscore the notion that antibiotic prophylaxis may not confer significant additional benefits in terms of preventing SSIs or reducing postoperative morbidity in laparoscopic cholecystectomy patients especially in patients with low risk.[19] Furthermore, our study adds to the growing body of evidence highlighting the potential risks associated with routine antibiotic use in surgical practice. Antibiotic resistance is a global concern, and the overuse or misuse of antibiotics in surgical prophylaxis contributes to the proliferation of resistant pathogens.[20] By demonstrating comparable outcomes between the antibiotic and non-antibiotic groups, our study suggests that withholding antibiotics in selected cases of elective laparoscopic cholecystectomy may be a viable strategy for reducing antimicrobial pressure and mitigating the risk of antibiotic resistance.

The absence of statistically significant associations between preoperative antibiotic prophylaxis and outcomes such as SSI and fever underscores the study's ability to provide nuanced insights into the efficacy of antibiotic use in elective laparoscopic cholecystectomy.

## CONCLUSIONS

Our study comparing preoperative prophylactic antibiotics versus no antibiotics in elective laparoscopic cholecystectomy patients reveals no significant association between antibiotic use and outcomes such as surgical site infections and fever.

**RECOMMENDATIONS** It is recommended to exercise caution in routinely administering preoperative antibiotic prophylaxis for elective laparoscopic cholecystectomy based on our findings. Given the absence of significant associations between antibiotic use and outcomes such as surgical site infections and fever, a selective approach to antibiotic administration should be considered. Clinicians should assess individual patient risk factors, surgical complexity, and local antimicrobial resistance patterns when determining the need for prophylactic antibiotics. Additionally, further research is warranted to explore the long-term implications of antibiotic prophylaxis and its impact on antimicrobial resistance. Multicenter randomized controlled trials with standardized protocols are needed to elucidate optimal antibiotic strategies in this surgical population.

**LIMITATION OF THE STUDY** A limitation of our study is its single-center design, potentially limiting the generalizability of findings to broader healthcare settings. Additionally, the study primarily focuses on immediate postoperative outcomes, such as SSI and fever, without considering long-term complications or antibiotic resistance patterns. The lack of randomization may introduce selection bias, affecting the comparability of study groups. Furthermore, the study does not account for variations in surgical technique or specific antibiotic regimens, which could influence outcomes. Future research should address these limitations through multicenter studies, longer follow-up periods, and randomized controlled trials incorporating standardized protocols for antibiotic administration.

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**CONFLICT OF INTEREST** None

**FINANCIAL DISCLOSURE** None

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