

Laparoscopic Cholecystectomy without Prophylactic Antibiotics in Low-Risk Patients: A Comparative Prospective Study

Authors:

Dr. Damini Kumari¹, Dr. Navdeep¹, Dr. Navneet Kumar Chaudhry², Dr. Kailash Chand Samota³, Dr. Parth Vinubhai Thummar⁴

¹Junior Resident, Department of General Surgery, Satguru Partap Singh Hospital, Ludhiana, Punjab, India.

²Senior Consultant, Department of General Surgery, Satguru Partap Singh Hospital, Ludhiana, Punjab, India.

³Junior Resident, Department of General Surgery, NIMS Medical College and Hospital, Jaipur, Rajasthan, India.

⁴Tutor, Department of Biochemistry, Sardar Patel Medical College and Research Centre (SPMCRC), Ahmedabad, Gujarat, India.

Corresponding Author:

Dr. Damini Kumari, Doctors Hostel, Satguru Partap Singh Hospital, Sherpur Chowk, Grand Trunk Road, Ludhiana, Punjab 141003, India.

DOI: <https://doi.org/10.5281/zenodo.23094097>

Received: 01 September 2026, Revised: 08 September, Accepted: 26 September 2026, Online First: 03 October 2026

ABSTRACT

Background: Elective laparoscopic cholecystectomy is a clean surgical procedure with a very low risk of surgical site infection. Despite this, prophylactic antibiotics are still routinely administered in many centres, leading to unnecessary antibiotic exposure. Rational antibiotic use is essential to reduce adverse drug reactions, limit antimicrobial resistance, and promote evidence-based surgical practice. **Objectives:** This study aimed to evaluate the need for antibiotic prophylaxis in low-risk patients undergoing elective laparoscopic cholecystectomy by comparing surgical site infection rates and postoperative outcomes, including wound healing, duration of hospital stay, and need for postoperative antibiotic administration in patients who received prophylactic antibiotics and in those who did not receive; and to support antimicrobial stewardship. **Methods:** This prospective, non-randomized comparative study included 100 patients aged 21 to 65 years who underwent elective laparoscopic cholecystectomy. Patients were divided into two equal groups. Group A did not receive prophylactic antibiotics, whereas Group B received intravenous cefuroxime (1.5 g) 10 to 60 minutes before incision. Demographic details, body mass index, operative duration, and length of hospital stay were recorded. The surgical site was assessed by the treating surgical team according to the CDC guidelines at 48 hours, 1 week, 30 days, and 90 days. **Results:** Baseline characteristics were comparable between the two groups. Operative time and hospital stay were slightly longer in Group A, but the differences were not significant. No surgical site infection occurred in Group A during 90 days of follow-up. One patient in Group B developed a superficial surgical site infection that resolved with conservative management. No deep or organ-space infections and no mortality were observed. **Conclusions:** Omission of prophylactic antibiotics did not increase postoperative infection rates in low-risk patients undergoing elective laparoscopic cholecystectomy. Routine antibiotic prophylaxis is unnecessary in such patients and should be reserved for high-risk situations to support rational antibiotic use.

Keywords: Laparoscopic cholecystectomy, Antibiotic prophylaxis, Surgical site infection, Antimicrobial stewardship

INTRODUCTION

Cholecystectomy is one of the most frequently performed surgical procedures worldwide, and laparoscopic cholecystectomy has become the gold standard for the management of symptomatic gallstone disease due to its clear advantages over open surgery. These advantages include reduced postoperative pain, shorter hospital stay, earlier ambulation, faster return to work, and improved cosmetic outcomes.^{1,2}

Surgical site infection remains one of the most important postoperative complications following abdominal surgery. Surgical antimicrobial prophylaxis refers to the administration of a short course of antibiotics, typically given within 30–60 minutes before surgical incision, to reduce the microbial burden at the operative site to a level that can be managed by host defense mechanisms.³ The concept of prophylactic antibiotic use was introduced in the early 1960s and became widely accepted, particularly for

clean-contaminated and contaminated surgical procedures.⁴

With the advent and widespread adoption of minimally invasive techniques, many traditional surgical practices have been re-evaluated. Laparoscopic surgery, including laparoscopic cholecystectomy, is associated with a significantly lower incidence of postoperative infective complications compared to open procedures.⁵ Large clinical studies have demonstrated that the overall infection rate following laparoscopic cholecystectomy is low, with surgical site infection rates reported at 0.4–1.1%.⁶

Despite this low risk, the routine use of prophylactic antibiotics in elective laparoscopic cholecystectomy remains common practice among surgeons. This variation persists despite several randomized controlled trials, meta-analyses, and international guidelines suggesting that antibiotic prophylaxis may offer little to no benefit in low-risk patients undergoing elective laparoscopic cholecystectomy. Unnecessary antibiotic use contributes to increased healthcare costs, adverse drug reactions, and the growing problem of antimicrobial resistance.

Given the low incidence of postoperative infections in elective laparoscopic cholecystectomy and the lack of consensus on prophylactic antibiotic use, further prospective studies are needed to determine whether omitting prophylactic antibiotics compromises patient safety. The present study was therefore undertaken to compare postoperative infective outcomes in patients undergoing elective laparoscopic cholecystectomy without prophylactic antibiotics.

SUBJECTS AND METHODS

Study Design

This was a prospective, non-randomised, comparative, hospital-based clinical study conducted to evaluate the incidence of postoperative SSI in low-risk patients undergoing elective laparoscopic cholecystectomy. Randomisation was not performed because perioperative antibiotic use was based on individual surgeons' preferences and routine surgical practice, which varied among operating surgeons within the institution. Allocation was done by convenient (non-random) sampling based on the operating surgeon's routine practice pattern. Eligible patients were assigned in a 1:1 ratio to 2 equal groups (n = 50 each): Group A (cases) received no prophylactic antibiotics, while Group B (controls) received prophylaxis with injection. Cefuroxime 1.5 g IV bolus was administered within 10 to 60 minutes before skin incision. This approach enabled comparison of SSI outcomes between the 2 management strategies under similar operative and demographic conditions.

Study Duration

The study was conducted over 18 months, from April 2024 to October 2025. This duration allowed adequate patient recruitment, follow-up, and data analysis.

Study Setting

The study was conducted in the Department of General Surgery at Satguru Partap Singh Hospital, Ludhiana, Punjab. The hospital is a tertiary-care teaching institute with advanced laparoscopic facilities and a structured infection-control system, ensuring standardized operative and postoperative care.

Sample Size Determination

Sample size was calculated using Cochran's formula: $n = (Z\alpha/2)^2 \times p \times q \div d^2$. For a 95% confidence level, $Z\alpha/2$ was 1.96. The expected proportion of surgical site infections after laparoscopic cholecystectomy was taken as 3.12% ($p = 0.0312$) from an Indian prospective study by Hajong R et al. (2021),⁷ so $q = 1 - p = 0.9688$. Absolute precision (d) was kept at 5% (0.05). After substituting the values, the estimated minimum sample size was $n \approx 46.45$, rounded to 47 patients. To account for dropouts and improve reliability, the final sample size was increased to 100 patients, divided into 2 equal groups: Group A (n = 50) without antibiotic prophylaxis and Group B (n = 50) receiving a single preoperative dose of cefuroxime 1.5 g IV, administered within 10 to 60 minutes before skin incision.

Patient Selection

Inclusion Criteria

Low-risk patients with ASA physical status I or II, without major comorbid illnesses, acute cholecystitis, biliary infection, or immunosuppressive conditions were included. These patients were expected to have an uncomplicated postoperative course and to be discharged early. Patients aged between 18 and 65 years scheduled for elective laparoscopic cholecystectomy for symptomatic gallstone disease were included.

Exclusion Criteria

Patients who had received antibiotics within 48 hours prior to surgery were excluded. Patients with comorbidities increasing infection risk, such as diabetes mellitus, immunosuppression, or steroid therapy, were excluded. Patients with acute cholecystitis, cholangitis, obstructive jaundice, conversion to open cholecystectomy, intraoperative complications such as bile or stone spillage, gallbladder perforation, intraoperative cholangiogram, prosthetic heart valves, rheumatic heart disease, or recent ERCP were also excluded.

Ethical Considerations

Institutional Ethics Committee approval was obtained before initiation of the study [DMS/SPS-I/2024/93]. Written informed consent was obtained from all participants. Patient confidentiality was maintained throughout the study. The study was conducted in

accordance with the Declaration of Helsinki (2013 revision).

Methodology
Preoperative Evaluation

All patients underwent detailed clinical history taking and physical examination. Baseline demographic and clinical parameters, including age, sex, body mass index, ASA score, comorbidities, and operative risk factors, were recorded. Standard preoperative investigations, including hemoglobin, total leukocyte count, random blood sugar, HbA1c, serum urea, creatinine, liver function tests, and abdominal ultrasonography, were performed. Pre-anesthetic fitness assessment was obtained for all patients.

Operative Technique

All procedures were performed by experienced general or gastrointestinal surgeons in accordance with a standardized protocol. A conventional four-port laparoscopic cholecystectomy technique was used with infraumbilical, epigastric, right subcostal, and right anterior axillary ports. Pneumoperitoneum was created using the closed Veress needle technique. A dissection was performed to obtain a critical view of safety. The cystic duct and cystic artery were individually clipped and divided. The gallbladder was dissected from the liver bed and retrieved. All specimens were sent for histopathological examination. Port site closure was done under strict aseptic precautions, with sheath and skin closure for ports of 10 mm or more and skin closure for 5 mm ports. Subhepatic drain placement was done selectively based on intraoperative judgment.

Postoperative Care and Follow-up

Both groups received identical postoperative care except for antibiotic prophylaxis. Wound inspection was performed daily during hospital stay to identify signs of surgical site infection, such as redness, pain, swelling, discharge, or induration. Follow-up visits were scheduled at discharge and at 1 week, 1 month,

and 3 months postoperatively. Surgical site infections were classified as superficial incisional, deep incisional, or organ or space infection according to CDC criteria.

Outcome Measures

The primary outcome measure was the incidence of surgical site infection in both groups. Secondary outcome measures included duration of hospital stay, need for additional antibiotics, readmission due to surgical site infection, and the association of operative factors, such as duration of surgery, bile spillage, and drain use, with infection rates.

Statistical Analysis

Continuous variables such as age, body mass index, and operative duration were reported as mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables, including sex, surgical site infection, and drain usage, were expressed as frequencies and percentages. Student’s t-test was used for normally distributed continuous variables, while the Mann-Whitney U test was used for non-parametric data. Categorical variables were analyzed using the chi-square test or Fisher’s exact test. A two-tailed p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 21.0.

RESULTS

A total of 100 low-risk patients undergoing elective laparoscopic cholecystectomy at the Department of General Surgery, Satguru Partap Singh Hospital, Ludhiana, were included in this prospective comparative hospital-based study conducted from April 2024 to October 2025. Patients were equally divided into two groups of 50 each, with Group A receiving no prophylactic antibiotics and Group B receiving intravenous cefuroxime 1.5 g within 10 to 60 minutes before incision.

Table 1. Demographic and clinical characteristics of Group A and Group B

Group	Group A		Group B		p-value
	n	%	n	%	
Age Group (years)					
20–29	6	12	8	16	0.315
30–39	20	40	11	22	
40–49	12	24	10	20	
50–59	7	14	11	22	
60–69	5	10	10	20	
Gender					
Male	12	24	13	26	0.97
Female	38	76	37	74	
BMI Category					
Underweight (<18.5)	0	0	0	0	0.263
Normal (18.5–24.9)	15	30	18	36	
Overweight (25–29.9)	25	50	23	46	
Obese I (30–34.9)	7	14	9	18	

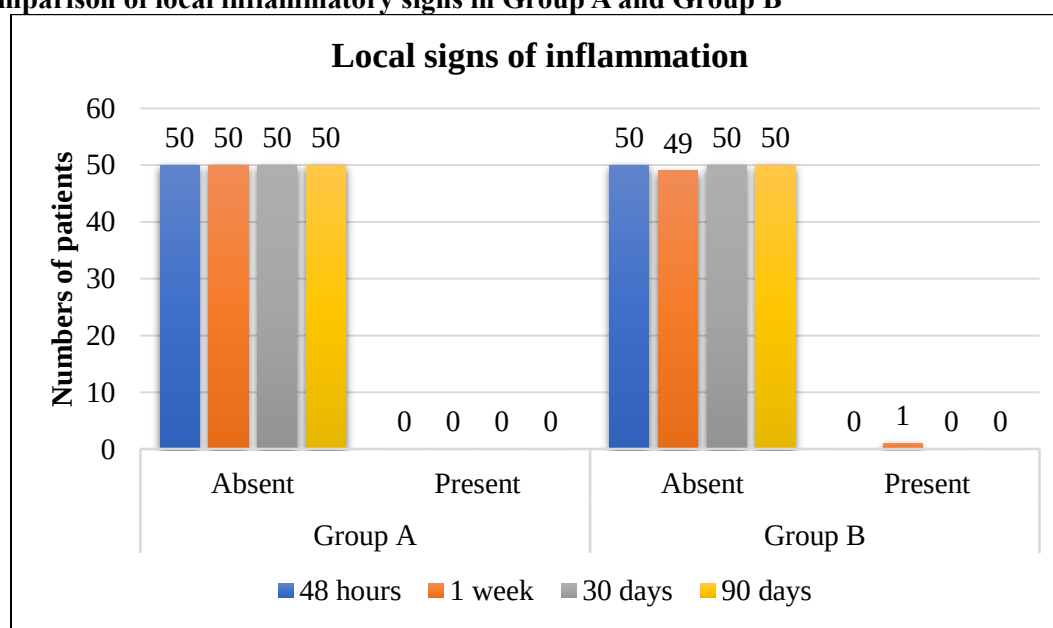
Obese II (35–39.9)	3	6	0	0	
Duration (minutes)					
40–49	11	22	23	46	0.046
50–59	17	34	19	38	
60–69	17	34	16	16	
70–79	4	8	0	0	
80–89	1	2	0	0	
Hospital Stay (days)					
2	6	12	8	16	0.0302
3	32	64	38	76	
4	12	24	4	8	
Total	50	100	50	100	

Table 1 shows that the two groups were comparable with respect to baseline demographic and clinical characteristics. There was no statistically significant difference in age distribution between the groups, and both had a predominance of female patients. Body mass index profiles were also similar, with most patients being overweight or obese, and no significant difference in mean body mass index was observed between the groups. Overall, these findings indicate that the study groups were well-matched at baseline.

Operative characteristics differed between the groups. The mean operative duration was longer in Group A (55.51 minutes) than in Group B (47.80 minutes), indicating that procedures without prophylactic antibiotics were longer. Despite this, the difference did not translate into adverse clinical outcomes.

Most patients were discharged within 2 to 3 days after surgery. However, the mean hospital stay was slightly longer in Group A (3.14 days) than in Group B (2.92 days).

Figure 1. Comparison of local inflammatory signs in Group A and Group B



As shown in Figure 1, local inflammatory signs such as erythema, local warmth, swelling or induration, tenderness, discharge, and wound gaping were almost entirely absent in both groups throughout follow-up. In Group A, none of the 50 patients had any local inflammatory signs at 48 hours, 1 week, 30 days, or 90 days. In Group B, no patient had local inflammation at 48 hours, 30 days, or 90 days, while 1 patient (2%) developed inflammatory changes at the epigastric port site at 1 week. The difference between groups at 1 week was not significant (Fisher's exact test, $p = 0.98$), indicating comparable wound responses.

Wound culture and sensitivity testing were not required and therefore were not performed in any patient in either group during follow-up. No patient in either group developed a deep or organ-space surgical site infection. Superficial surgical site infection was not observed in Group A, while 1 patient (2%) in Group B developed a superficial infection limited to local inflammatory changes at the port site, which was managed conservatively with daily dressings. There was no mortality in either group, and all 100 patients completed the planned 90-day follow-up.

DISCUSSION

Overview of study findings

This prospective comparative study evaluated 100 low-risk patients undergoing elective laparoscopic cholecystectomy, equally divided into two groups. Group A did not receive prophylactic antibiotics, whereas Group B did. Both groups were comparable with respect to age, gender distribution, and body mass index, allowing valid comparison of postoperative outcomes.

During the 90-day follow-up period, only one superficial surgical site infection was observed, occurring in Group B. This patient developed local inflammatory signs at the port site within the first postoperative week, which resolved with conservative management. No patient in either group developed a deep, organ, or space surgical site infection. Wound culture and sensitivity testing were not required in any case, and no mortality was recorded. Although operative time and hospital stay were slightly longer in Group A, these differences were small and did not translate into increased wound complications. Overall, the findings suggest that omission of prophylactic antibiotics does not increase early or late postoperative morbidity in low-risk elective laparoscopic cholecystectomy.

Surgical site infection in elective laparoscopic cholecystectomy

Elective laparoscopic cholecystectomy is generally classified as a clean-contaminated procedure with a very low risk of surgical site infection. Reported infection rates in low-risk patients typically range from 0.4% to 1.1%.^{5,8-10} Modern database studies have also shown infection rates of approximately 1%, comparable to those seen in clean general surgical procedures.^{10,11} In the present study, the absence of infection in Group A and the occurrence of only one superficial infection in Group B reinforce the inherently low infection risk associated with uncomplicated elective laparoscopic cholecystectomy.

Comparison with randomised controlled trials

Multiple randomised controlled trials have compared antibiotic prophylaxis with placebo or no antibiotics in low-risk elective laparoscopic cholecystectomy. Higgins et al. reported no significant difference in infection rates among patients receiving cefotetan, cefazolin, or placebo.⁵ Passos and Portari Filho observed equal infection rates in antibiotic and non-antibiotic groups.⁹ Similar findings were reported by Mirani et al.⁸ and Ahmed et al.,⁹ who demonstrated no increase in postoperative infectious complications when prophylaxis was omitted. Smith et al.,¹⁰ using a quality-improvement approach, also concluded that routine prophylaxis was unjustified, even when some higher-risk patients were included. The findings of the present study are consistent with these trials,

confirming that the absolute benefit of prophylactic antibiotics in low-risk patients is minimal.^{5,8-10,12}

Comparison with meta-analyses and systematic reviews

Meta-analyses have largely supported these observations. Choudhary et al. found no significant reduction in infectious complications with prophylactic antibiotics in low-risk patients.¹³ Gomez Ospina et al. similarly reported no difference between prophylaxis and placebo or no treatment.¹⁴ Although some analyses have suggested small reductions in superficial infections, the absolute benefit remains limited, and the quality of evidence is moderate to low.^{11,15} When baseline infection rates are already very low, the clinical relevance of such marginal reductions is questionable.

Guidelines and contemporary practice

Current evidence indicates that patient-related factors such as diabetes, obesity, higher ASA class, smoking, and prolonged operative duration have a greater influence on infection risk than antibiotic prophylaxis itself.^{10,11} International guidelines advocate selective use of prophylactic antibiotics and discourage routine administration in low-risk cases due to concerns regarding adverse drug reactions, Clostridioides difficile infection, and antimicrobial resistance.¹⁶⁻¹⁹ The present study supports this stewardship-oriented approach.

Operative time and hospital stay

Although operative time and hospital stay were statistically longer in the no-antibiotic group, the absolute differences were small and clinically insignificant. Similar findings have been reported in previous trials and meta-analyses without any corresponding increase in infection rates.^{5,10-13}

Strengths and limitations

The strengths of this study include its prospective design, equal group allocation, standardized follow-up, and clinically relevant endpoints. Limitations include the modest sample size and single-centre setting, which may limit generalisability. Nevertheless, the study reflects real-world practice in low-risk elective cases.

Implications for practice and future research

These findings provide further evidence that routine prophylactic antibiotics are unnecessary in low-risk elective laparoscopic cholecystectomy. Antibiotics should be reserved for patients with clear risk factors such as acute cholecystitis, biliary infection, obstructive jaundice, perforation, or immunosuppression.^{16-18,20} Future multicentre studies with larger sample sizes may help refine risk-based antibiotic policies.

CONCLUSION

This prospective comparative study demonstrates that routine prophylactic antibiotics are not required in low-risk patients undergoing elective laparoscopic cholecystectomy. The very low incidence of surgical site infection, absence of deep or organ or space infections, and lack of mortality highlight the safety of omitting antibiotics in selected patients. Minor differences in operative time and hospital stay were clinically insignificant and unrelated to infection risk. These findings support a selective, evidence-based approach to antibiotic prophylaxis and reinforce antimicrobial stewardship in modern surgical practice.

DECLARATIONS

Ethics Approval and Consent to Participate

The study was approved by the Institutional Ethics Committee of Satguru Partap Singh Hospital, Ludhiana, Punjab, India (Approval No. DMS/SPS-I/2024/93). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki (2013 revision).

Consent for Publication

Not applicable. No individual patient-identifiable information or images are included in this manuscript.

Funding

No external financial support was received for this study. The study was supported by institutional resources.

Competing Interests

The authors declare that they have no competing interests or conflicts of interest related to the publication of this study.

Authors' Contributions

All authors contributed to the study conception, clinical data collection, analysis and interpretation of the results, manuscript preparation, and critical revision of the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

Acknowledgements

The authors acknowledge the support of the Department of General Surgery, Satguru Partap Singh Hospital, Ludhiana, Punjab, India, for providing the clinical and institutional facilities required to conduct this study.

AI Use Disclosure

The authors declare that no generative artificial intelligence tools were used to generate or substantially modify the scientific content of this manuscript.

REFERENCES

1. Darbar R, Mujalde VS, Singh RP, Rathore AK. Study the postoperative abdominal complications in cholecystectomy patients. *Res J Med Sci.* 2023;17(4):498-502. doi:10.59218/makrjms.2023.498.502.
2. O'Connell PR, McCaskie AW, Sayers RD, editors. *Bailey and Love's Short Practice of Surgery.* 28th ed. Boca Raton: CRC Press; 2023. p. 50-57.
3. Verma R, Mittal SK, Singla NK. Role of prophylactic antibiotics versus no antibiotics in elective laparoscopic cholecystectomy: A prospective study. *Int Surg J.* 2020;7(5):1580-6.
4. Agrawal VP, Akhtar M. Evaluation of antibiotic prescription practices among general surgeons in Nagpur. *Sch J App Med Sci.* 2015;3(6D):2437-2440.
5. Higgins A, London J, Charland S, Ratzer E, Clark J, Haun W, Maher DP. Prophylactic antibiotics for elective laparoscopic cholecystectomy: Are they necessary? *Arch Surg.* 1999;134(6):611-614.
6. Kumar V, Singh JP, Upadhyaya S, Chaudhry NK. A prospective study comparing no antibiotic versus antibiotic prophylaxis in patients undergoing elective laparoscopic cholecystectomy. *Int J Sci Study.* 2019;7(3):54-59.
7. Hajong R, Dhal MR, Newme K, Moirangthem T, Boruah MP. A cross sectional study of risk factors for surgical site infections after laparoscopic and open cholecystectomy in a tertiary care hospital in North East India. *J Family Med Prim Care.* 2021 Jan;10(1):339-342.
8. Mirani AJ, Idrees S, Younus SM, et al. Use of antibiotic prophylaxis in low-risk laparoscopic cholecystectomy is unnecessary: A clinical trial. *Pak J Med Health Sci.* 2014;8(3):713-716.
9. Ahmed H, Elgarf S, Gamal IM, Hosam BB, Swelam M. Prophylactic antibiotic in elective laparoscopic cholecystectomies: Is it mandatory? *Med J Cairo Univ.* 2022;90(9):1407-12.
10. Smith JP, Samra NS, Ballard DH, Moss JB, Griffen FD. Prophylactic antibiotics for elective laparoscopic cholecystectomy. *Am Surg.* 2018;84(4):576-80.
11. Kim SH, Yu HC, Yang JD, Ahn SW, Hwang HP. Role of prophylactic antibiotics in

elective laparoscopic cholecystectomy: a systematic review and meta-analysis. *Ann Hepatobiliary Pancreat Surg.* 2018;22(3):231–47.

12. Passos MAT, Portari-Filho PE. Antibiotic prophylaxis in laparoscopic cholecystectomy: is it worth doing? *ABCD Arq Bras Cir Dig.* 2016;29(3):170–2.

13. Choudhary A, Bechtold ML, Puli SR, Othman MO, Roy PK. Role of prophylactic antibiotics in laparoscopic cholecystectomy: a meta-analysis. *J Gastrointest Surg.* 2008;12(11):1847–53.

14. Gomez-Ospina JC, Zapata-Copete JA, Bejarano M, Garcia-Perdomo HA. Antibiotic prophylaxis in elective laparoscopic cholecystectomy: a systematic review and network meta-analysis. *J Gastrointest Surg.* 2018;22(12):1960–72.

15. Yang J, Gong S, Lu T, Tian H, Jing W, Liu Y, et al. Reduction of risk of infection during elective laparoscopic cholecystectomy using prophylactic antibiotics: a systematic review and meta-analysis. *Surg Endosc.* 2021;36(6):4281–93.

16. Bailey & Love's Short Practice of Surgery. 28th ed. O'Connell PR, McCaskie AW, Sayers RD, editors. Boca Raton: CRC Press; 2023. p. 50–66.

17. Redmond HP, Razzaq Z. Surgical infection. In: O'Connell PR, McCaskie AW, Sayers RD, editors. Bailey & Love's Short Practice of Surgery. 28th ed. Boca Raton: CRC Press; 2023. p. 50–66.

18. Therapeutic guidelines: antimicrobial prophylaxis in surgery. *Am J Health Syst Pharm.* 2013;70:734–52.

19. Allegranzi B, Bischoff P, de Jonge S, et al. New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis.* 2016;16(12):e276–87.

20. de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. *Am J Infect Control.* 2009;37(5):387–97.