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Original Research Article

A Clinical Study to Compare the Efficacy of Single Dose Ceftriaxone Preoperatively with Multiple Dose Ceftriaxone Regimen Postoperatively for Laparoscopic Cholecystectomy in a Tertiary Care Hospital in Tezpur, Assam

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Conflict of interest: Nil

Abstract

Background: Surgical site infection (SSI) is a frequent postoperative complication that contributes to morbidity, prolonged hospitalization, and increased healthcare costs. Although antibiotic prophylaxis reduces the risk of SSI, prolonged regimens are often misused, particularly in low- and middle-income settings, increasing antimicrobial resistance.

Objective: To compare the efficacy of a single-dose versus multiple-dose ceftriaxone prophylaxis in preventing SSI in patients undergoing elective laparoscopic cholecystectomy.

Methods: This prospective, randomized study was conducted at Tezpur Medical College and Hospital between July 2024 to June 2025. A total of 100 patients scheduled for elective laparoscopic cholecystectomy were randomized into two groups: single-dose (SD, n=50) and multiple-dose (MD, n=50). The SD group received ceftriaxone 2 g intravenously at induction of anesthesia, while the MD group received the same preoperative dose followed by 1 g twice daily for two postoperative days. Patients were followed for 30 days, and SSI was assessed clinically.

Results: The overall incidence of SSI was 5% in the SD group and 4% in the MD group ($p>0.05$). Fever was more common in the MD group on POD 2, while wound discharge and port-site redness were observed in the SD group at 1 week. No infections occurred at 3 weeks.

Conclusion: Single-dose ceftriaxone prophylaxis is as effective as multiple-dose regimens in elective laparoscopic cholecystectomy, with advantages in antibiotic stewardship, cost reduction, and minimizing antimicrobial resistance.

Keywords: Surgical site infection, Antibiotic prophylaxis, Ceftriaxone, Laparoscopic cholecystectomy, antimicrobial stewardship.

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Introduction

Surgical site infections (SSIs) remain one of the most common healthcare-associated infections worldwide, accounting for approximately 20–30% of all hospital-acquired infections in surgical patients [1]. They are defined as infections occurring within 30 days of an operative procedure, involving either the incision, organ, or deep tissue at the surgical site [2]. SSIs are associated with increased morbidity, prolonged hospital stays, readmissions, higher healthcare costs, and in severe cases, increased mortality [3]. The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) emphasize SSI prevention as a major quality indicator of surgical care delivery [4]. In developing countries, the incidence of SSI is disproportionately higher,

ranging between 11–20% compared with 2–5% in high-income nations, largely due to variations in infection control practices, resource limitations, and antimicrobial misuse [5].

Antibiotic prophylaxis plays a pivotal role in reducing the risk of SSI by ensuring adequate serum and tissue drug concentrations during the perioperative period. The purpose is preventive rather than therapeutic, aiming to reduce the microbial load introduced at the time of surgery [6]. However, the rational use of prophylaxis requires adherence to strict guidelines regarding timing, spectrum, and duration [2]. The Surgical Infection Society (SIS), American Society of Health-System Pharmacists (ASHP), and WHO all recommend administration of a single preoperative dose of a suitable antibiotic, usually within 30–60 minutes before surgical incision [2,7]. Evidence consistently shows that prolonged postoperative antibiotic administration does not confer additional benefit and, conversely, increases the risk of antimicrobial resistance, *Clostridioides difficile* infection, and unnecessary costs [7].

Despite global consensus guidelines, antibiotic prophylaxis is often misused in LMICs [5]. In many hospitals, extended prophylaxis (often several days postoperatively) is considered routine, even for clean or clean-contaminated surgeries such as elective cholecystectomy [5]. This practice not only contributes to escalating antimicrobial resistance but also poses significant financial burden on patients and healthcare systems [8]. The irrational use of broad-spectrum antibiotics, frequently in combination regimens, has been documented as a major driver of resistance in pathogens such as *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* [5,8].

Cholecystectomy is one of the most commonly performed abdominal surgeries worldwide, indicated for symptomatic cholelithiasis, cholecystitis, and related conditions [9]. Laparoscopic cholecystectomy, in particular, is considered a clean-contaminated procedure, with SSI rates ranging between 1–5% in most series [10]. While routine antibiotic prophylaxis in low-risk laparoscopic cholecystectomy remains controversial, guidelines generally support its use in patients with risk factors such as advanced age, diabetes, immunosuppression, obesity, acute cholecystitis, or biliary obstruction [11]. In such cases, effective perioperative coverage can significantly reduce postoperative infectious complications [12]. Among available antibiotics, third-generation cephalosporins such as ceftriaxone are widely used for surgical prophylaxis due to their broad-spectrum activity against common biliary pathogens, including gram-negative bacilli (*E. coli*, *Klebsiella spp.*), gram-positive cocci (*Streptococcus*, *Staphylococcus aureus*), and some anaerobes [13]. Ceftriaxone's long half-life (6–8 hours) makes it particularly suitable for single-dose administration, maintaining adequate intraoperative tissue levels throughout most surgical procedures [13]. Randomized controlled trials and observational studies have compared single-dose ceftriaxone with multiple-dose regimens in abdominal surgeries, showing equivalent efficacy in SSI prevention, while minimizing costs, adverse drug reactions, and resistance selection pressure [10,11,13].

Given the rising threat of antimicrobial resistance, there is an urgent need to re-evaluate prophylactic strategies in common surgical procedures [5,7]. Cholecystectomy offers an ideal model for such evaluation, as it is widely performed and carries a low but significant risk of SSI [9,10]. The current study aims to compare the efficacy of a single preoperative dose of ceftriaxone versus multiple postoperative doses in patients undergoing cholecystectomy. Establishing non-inferiority of single-dose prophylaxis would support antibiotic stewardship initiatives, reduce healthcare costs, and prevent unnecessary antimicrobial exposure, aligning with global infection-prevention goals.

Materials and Methods

This prospective, randomized study was conducted at Tezpur Medical College and hospital in the department of general surgery between July 2024 to June 2025.The patients admitted for elective laparoscopic cholecystectomy were included in our study. patients with acute cholecystitis, associated choledocholithiasis, associated medical pathology like, diabetes mellitus, hypertension, cardiac /renal failure, ischemic heart disease, immunosuppression and converted to open surgery were excluded from this study. After admission, detailed history, clinical examination findings, routine blood investigation reports and ultrasonography report were noted in proforma sheet. Total of 100 patients were included in our study after obtaining their informed written consent.

Inclusion Criteria

1. Patient aged between 18-60 years belonging to both genders.
2. Patients undergoing elective cholecystectomy with no underlying co-morbid condition.
3. Patients who provided written informed consent for the study.

Exclusion Criteria

1. Age less than 18 years and more than 60 years
2. Patients with diabetes mellitus.
3. Patients on steroids, chemotherapy or immunosuppression.
4. Patients who had contaminated cavity like empyema gall bladder.

5. Patients with history of preoperative fever,cough and who were on antibiotics in last 7 days

The patients were randomly divided in two equal groups: single dose (SD) group and multiple dose (MD) group, comprising of 50 patients in each group. SD group was given ceftriaxone (1 gm) intravenously at the time of induction of anesthesia. Whereas MD group was given ceftriaxone (1 gm) intravenously at the time of induction of anesthesia followed by ceftriaxone (1gm) intravenously twice a day for two days post-operatively. Routine 4-port laparoscopic cholecystectomy was performed with all due aseptic precautions. All patients were followed up daily for two post-operative days and then 1-week and 3-week follow up was done for any SSI. Fever, tachycardia, leukocytosis, port-site redness and tenderness, wound discharge, wound gape and wound abscess were considered as SSI. Patients with fever and port-site redness and tenderness were given antipyretic and anti-inflammatory drugs respectively. In case of wound discharge, fluid swab was taken for microbial culture and antibiotic sensitivity and patients were given empirical antibiotic treatment. Data was analyzed using Chi-square test.

Results

Our study was completed with 100 patients between July 2024 to June 2025. The age range of the patients was from 18years to 60 years, the mean age being 43±6 years. Out of total study group, 46%were male and 54% were female patients. Demography and clinical features were comparable in both the groups studied.

Comparison of surgical site infection

Table 1: Complications in SD group

Type of SSI	At POD 2	After 1wk	After 3 wk
Fever	2	0	0
Wound discharge	0	2	0
Wound gapping	0	0	0
Port site redness/tenderness	0	1	0
Wound abscess	0	0	0

Table 2: Complications in MD group

Type of SSI	At POD 2	After 1 wk	After 3 wk
Fever	3	0	0
Wound discharge	0	1	0
Wound gapping	0	0	0
Port site redness/tenderness	0	0	0
Wound abscess	0	0	0

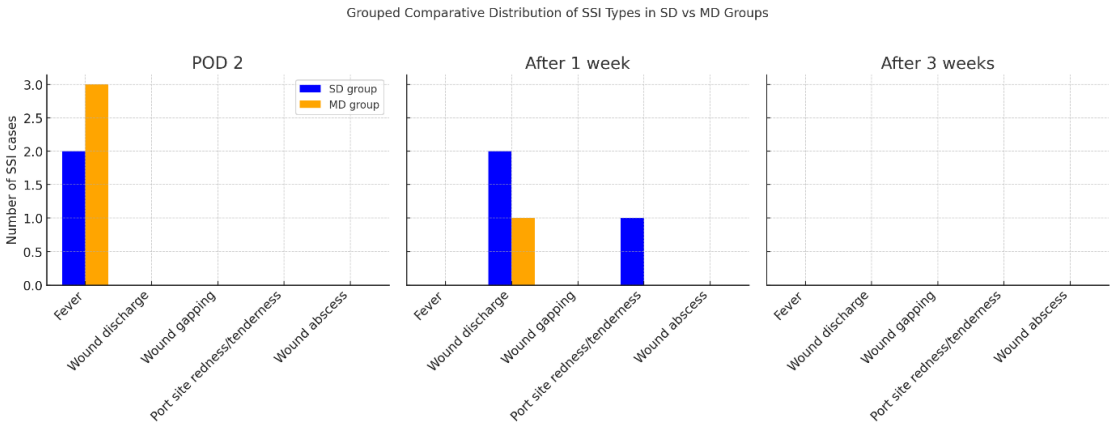

Figure 1: Grouped comparative distribution of SSI types at postoperative day (POD) 2, after 1 week, and after 3 weeks between the SD group and MD group

In the present study, the pattern of surgical site infections (SSI) varied between the single-dose (SD) and multiple-dose (MD) prophylaxis groups. At postoperative day (POD) 2, fever was the predominant manifestation, observed in 2 patients in the SD group and 3 patients in the MD group. At 1 week follow-up, wound-related complications were more evident in the SD group, with 2 patients developing wound discharge and 1 patient presenting with port site redness and tenderness,

whereas only 1 case of wound discharge was documented in the MD group. By the third postoperative week, no further infections were noted in either group, indicating complete resolution. These findings suggest that while the MD group exhibited a higher incidence of early postoperative fever, the SD group demonstrated a greater frequency of delayed wound complications, although both regimens were comparable in terms of overall infection clearance by the end of the observation period.

Table 3: SD group 1 (2%) patient developed post-operative fever and in MD group 2(4%) patients developed postoperative fever

Post-operative fever	SD group	MD group	Total
Absent	98	97	195
Present	2	3	5

Post-operative fever in SD group and MD group are not statistically significant.

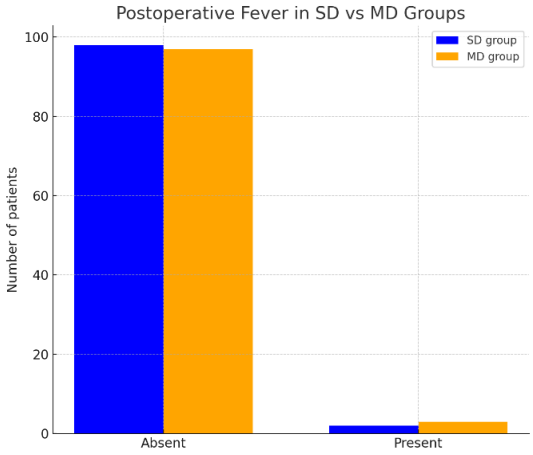

Figure 2: Distribution of postoperative fever among patients receiving single-dose (SD) and multiple-dose (MD) ceftriaxone prophylaxis

The bar graph shows that postoperative fever was absent in the majority of patients in both groups, with 98 in the SD group and 97 in the MD group remaining afebrile. Fever was observed in 2 patients in the SD group and 3 patients in the MD group. This indicates that the incidence of postoperative fever was low overall, with no significant difference between the two prophylactic regimens. In SD group 1 patient developed serous discharge and no patient developed purulent discharge and in MD group no patient developed serous discharge or purulent discharge.

Table 4: Comparison of post-operative wound discharge in SD and MD groups

Wound discharge	SD group	MD group
No discharge	99	99
wound discharge	1	1

Association between discharge from the wound between the SD and MD group are not significant.

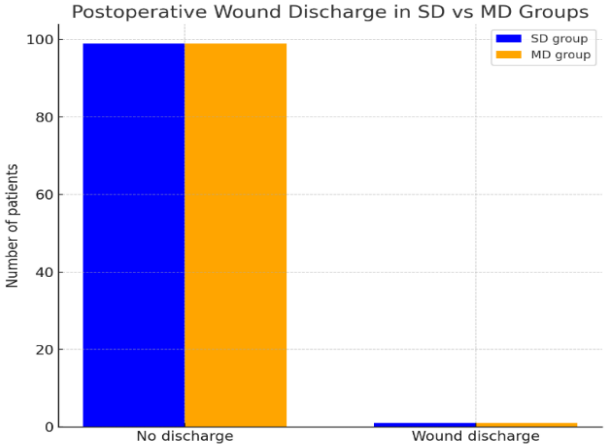

Figure 3: Distribution of postoperative wound discharge among patients receiving single-dose (SD) and multiple-dose (MD) ceftriaxone prophylaxis

The graph demonstrates that wound discharge was rare in both groups, with 99 patients in each group showing no discharge, and only 1 patient each in the SD and MD groups developing wound discharge. These findings suggest that the incidence of postoperative wound discharge was minimal and comparable between the two prophylactic strategies.

In both SD group and MD group no patient developed wound gapping, wound abscess, and lekocytosis.

Discussion

SSI is one of the most common post operative complications. The incidence of SSI varies considerably from 2.5% to 42%.The incidence is quiet less in clean contaminated surgeries compared to dirty contaminated wounds [14]. Cholecystectomy is one of the most common surgical procedures done worldwide including India. SSI is relatively more common in open cholecystectomy compared to Lap cholecystectomy [15]. Gall stone diseases are more common in females in compared to male [16].In our study also 41% patients were male and 59% patient were female. cholelithiasis is more common in 4 th decade of life [17]. In our study mean age of the patients was 43 years.

In our study, out of 100 patients who belonged to SD group, 5% patients developed post-operative complications. 2% of them were having post operative fever and 2% presented with wound discharge at first week follow up and 1 % was having port site redness/tenderness.

From the MD group 4% patient were having surgical infection.3 patient were having post operative fever and 1 patient were having wound discharge. The low overall incidence of SSIs in both groups aligns with the generally low risk of infection associated with laparoscopic cholecystectomy due to its minimally invasive nature. The infection rate of our study correlates with that of : Sutariya PK, Thekdi et al, where they found that the rate of SSI after LC is 3-5% [18]. Koirala et al conducted aprospective, single-blind study involved 200 patients undergoing elective laparoscopic cholecystectomy. Patients were randomly assigned to receive either a single 1g dose of ceftriaxone before induction of anesthesia or the same dose preoperatively followed by three additional postoperative doses over 24 hours. The incidence of surgical site infections (SSIs) was 4 in the single-dose group and 3 in the multiple-dose group, with no statistically significant difference (p=0.500) [19]. Yadav et al conducted a prospective study on 249 patients undergoing elective laparoscopic cholecystectomy were assigned to receive either a single 1g dose of ceftriaxone at induction or the same dose preoperatively followed by two additional doses over two days. The incidence of wound infections was 3.1% in the single-dose group and 2.5% in the multiple-dose group, with no statistically significant difference [20].

Vaghela et al conducted a randomized prospective study on 100 patients undergoing elective surgeries. Patients were randomly assigned to receive either a single 2g dose of ceftriaxone before induction of anesthesia or 2g ceftriaxone postoperatively for 3 days. The overall incidence of SSI in the study group was 9% and in the control group was 10% which is higher as compared to our study [21]. This is probably due to the fact that they have included open cholecystectomy and other clean contaminated elective surgeries. But we included only lap cholecystectomy and also excluded all patients with acute inflammation and any associated medical pathology, from our study.

Conclusion

The rate of post-operative SSI after single dose ceftriaxone (1 gm) intravenously at induction of anesthesia and multiple dose ceftriaxone (1 gm)intravenously post-operatively for two days with preoperative single dose ceftriaxone is comparable in elective laparoscopic cholecystectomy. Given the comparable outcomes, single-dose prophylaxis offers several advantages, including simplified antibiotic administration, reduced risk of antimicrobial resistance, lower healthcare costs, and improved adherence to surgical antibiotic stewardship principles. These findings support the adoption of single-dose ceftriaxone as a safe, effective, and efficient prophylactic strategy in routine laparoscopic cholecystectomy.

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