

To Determine The Role Of Prophylactic Antibiotics In High-Risk Patients Undergoing Laparoscopic Cholecystectomy

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Abstract

Aim: To determine the role of prophylactic antibiotics in high-risk patients undergoing laparoscopic cholecystectomy.

Method: The Department of General Surgery performed a randomized controlled trial study. Patients hospitalized for laparoscopic cholecystectomy were randomly assigned to one of two groups: A (who did not receive prophylactic antibiotics) or B (who did) (those who received antibiotics). The research comprised 100 patients who were evenly split into two groups. There were 50 patients in categories A and B, respectively. Both groups had identical baseline demographic parameters and preoperative reasons for cholecystectomy. Intra-operative details did not vary significantly between the two groups.

Results: There was no statistically significant difference in the risk variables between the study and control groups. Surgical site infection occurred in six and four patients, respectively, in the study and control groups. All of the SSIs were superficial and only responded to cautious care. There was no need for intravenous treatment or hospitalisation for any of the affected individuals. The mean length of hospital stay among patients who did not get prophylactic antibiotics (Category A) neared significance ($p=0.06$), despite the fact that the range (in days) was the same in both groups.

Conclusion: Prophylactic antibiotics had no function in preventing SSI in high-risk patients having laparoscopic cholecystectomy. The aseptic minimally invasive procedure, as well as the essential peritoneal lavage and drainage during LC, are critical in avoiding postoperative infection.

Keywords: High-risk, laparoscopic cholecystectomy, antibiotic prophylaxis.

Introduction

When compared to open cholecystectomy, laparoscopic cholecystectomy (LC) has an extremely low rate of postoperative infection.¹ In the literature, the average rate of SSIs for LC has been reported to be between 0.4 and 6.3 percent, which is lower than rates reported for open cholecystectomy.¹⁻³ Unlike open cholecystectomy, many researchers believe that antimicrobial prophylaxis is probably unnecessary for LC patients since the infection incidence is already low, and prophylactic

antibiotics do not reduce the likelihood of wound infections or other postoperative infection problems.⁴⁻⁸ Furthermore, recent meta-analyses and systematic reviews revealed that prophylactic antibiotics for elective LCs are ineffective in low-risk patients, while there were no outcomes in high-risk patients.⁹ Despite these data, many other surgeons continue to use and suggest prophylactic antibiotics for LC in low-risk patients. Preoperative single-dose cefazolin as a prophylactic antibiotic has been extensively

suggested and utilized to minimize SSI in clean-contaminated operations such as cholecystectomy and biliary surgery.¹⁰

Materials and methods

After receiving clearance from the protocol review committee and the institutional ethics committee, a randomized controlled trial investigation was carried out in the Department of General Surgery.

Criteria for inclusion:

- Cholelithiasis diagnosis with any high-risk factor
- >18 years old

Criteria for exclusion:

- Pregnant and lactating women
- Patients in need of antibiotics for any other reason
- Immunocompromised individuals
- Probable active cholangitis/pancreatitis
- Infirm patients

Methodology

Total 100 patients on the basis of computer-generated randomization tables, hospitalised for LC from surgical outpatient or emergency departments were divided into two groups: A and B. Antibiotics were not administered to Category A patients prior to surgery. Only oral analgesics, proton pump inhibitors, and supportive care were prescribed in typical dosages, and these patients were monitored throughout their hospital stay. If antibiotics were required (because to clinical or laboratory suspicion), they were not withheld, but the patient was then excluded from the trial. Within 60 minutes after the procedure, Category B patients got a single intravenous antibiotic (first generation Cephalosporin- intravenous Cephazolin 1-2 grams/day). These individuals, like Category A patients, got postoperative treatment.

Aseptically obtained culture from the probable location of infection. The surgical wound was cleansed with 70% ethyl alcohol, and the exudate was collected from the depth of the incision using two sterile cotton swabs, one for

Gram stain and the other for culture. To avoid contamination of the swab by endogenous resident organisms, extreme caution was taken not to contact the surrounding tissues.

The obtained samples were promptly submitted to the laboratory for processing to minimise desiccation and to prevent the development of certain species at room temperature, which might negate the discovery of genuine infections.

Statistical evaluation

Data were collected using a pre-designed, standardised data collection form, which was then input into a Microsoft Excel 2013 sheet. It was evaluated using the statistical programme SPSS 24.0. (SPSS Inc. Chicago, IL, USA).

Results

This research comprised 100 patients who were evenly split into two groups. There were 50 patients in categories A and B, respectively. Both groups had identical baseline demographic parameters (Table 1) and preoperative reasons for cholecystectomy (Table 2). Intra-operative details did not vary significantly between the two groups. (Table 3). Because our research included patients who had one or more preoperative risk factors for the development of SSI, we performed a comprehensive examination of risk factor status. There was no statistically significant difference in the risk variables between the study and control groups. (Table 4) Surgical site infection occurred in six and four patients, respectively, in the study and control groups. (Table 6) All of the SSIs were superficial and only responded to cautious care. There was no need for intravenous treatment or hospitalization for any of the affected individuals. The mean length of hospital stay among patients who did not get prophylactic antibiotics (Category A) neared significance ($p=0.06$), despite the fact that the range (in days) was the same in both groups. All patients acquired epigastric port superficial SSI (Gall bladder extraction port).

Table 1 Demographic of the patients

	Category A	Category B
Gender		
Male	23	26
Female	27	24
Age in years		
Below 30	14	10
30-50	26	30
Above 50	10	10

Table 2 Indications of cholecystectomy

	Category A	Category B
Chronic cholecystitis with cholelithiasis	16	25
Acute cholecystitis with cholelithiasis ± sequelae (mucocoele/ empyema gall bladder/ gangrene)	24	14
Polyp	3	3
Post pancreatitis	3	4
Post ERCP (Endoscopic Retrograde CholangioPancreaticography)	4	4

Table 3 Intra-operative details

	Category A	Category B	P value
Bile spillage	14	16	0.74
Drain insertion	22	21	0.77
Duration of surgery			
Difficult dissection (>30 mins for Callots dissection)	10	11	0.59
Previous upper abdominal surgery	4	2	0.44

Table 4 Risk factors

Risk factors	Category A	Category B	P value
Bile spillage	13	13	0.74
Drain insertion	26	25	0.69
Duration of surgery			
Difficult dissection (>30 mins for Callots dissection)	9	10	0.55
Previous upper abdominal surgery	2	2	0.41

Table 5 Numbers of risk factor

	Category A	Category B
One risk factor	24	26
Two risk factors	21	20
Three risk factors	4	3
Four risk factors	1	1

Table 6 Post-operative outcomes

	Category A	Category B	P value
SSI	4	2	0.55
Hospital stay (days) mean \pm SD	2.51 \pm 0.74	2.41 \pm 0.66	0.061

Discussion

SSIs are a standard performance indicator used to evaluate health-care quality. Based on findings from a range of surgical fields, the Centers for Disease Control and Prevention (CDC) has suggested that patients having clean-contaminated surgeries get just a single dose of preoperative antibiotics. Laparoscopic cholecystectomy is one such operation, and we wanted to test whether a single dosage was also required. This was done because the widespread and indiscriminate use of antibiotics exacerbated the threat of antibiotic resistance and its repercussions.¹¹ Previously, studies looked examined the use of prophylactic antibiotics in different organ system procedures.¹²⁻¹⁴ in other biliary procedures¹⁵⁻¹⁸, the role of single vs numerous doses¹⁰, and the timing of antibiotic delivery¹⁹⁻²¹ To the best of our knowledge, no research evaluating the usefulness of preventive antibiotics in LC

patients has included all patients with risk factors.

This study included 100 patients with high-risk factors, 50 of whom did not receive any prophylactic antibiotics, in contrast to a recently published study⁸ in which prophylactic antibiotics were not given to only 50 patients, with no mention of the presence or absence of high-risk factors in these 50 patients.

The study population randomized to receive or not receive prophylactic antibiotics in our research had identical demographic, preoperative, and intraoperative information (as shown by non-significant p values), indicating homogeneity in baseline characteristics.

Because SSI occurred in only 6 (6%) of patients, a multivariate logistic regression analysis (as intended previously) to determine the influence of each risk factor on the development of SSI was not performed.

In our investigation, the incidence of SSI was shown to be low in the groups that had received preventive antibiotics. Similar findings have been reported in other investigations.²²

In our current investigation, 14 patients in the study group and 16 patients in the control group experienced bile leakage, which included both bile spilling after surgery, i.e. iatrogenic, and bile spillage owing to primary disease, such as gangrenous/perforated gall bladder. We did not do bile cultures as a routine since this procedure does not ensure preoperative identification of which individuals have bactibilia. Our findings are consistent with the previously published paper by Hui TT et al.²³, who found no SSI in gall bladder perforation.

In the twentieth century, prophylactic antibiotics were suggested for all patients having cholecystectomy²⁴, as well as those over the age of 60 or with a history of past bouts of acute cholecystitis.²⁵ However, further research has shown that preventive antibiotics, even if just a single dosage⁸, reduce the incidence of SSI following laparoscopic cholecystectomy.²⁶ However, none of these studies included all individuals who had one or more of the other risk factors. The mean length of hospital stay in patients who did not receive prophylactic antibiotics (Category A) neared statistical significance ($p=0.06$). This could only be by accident since the range of hospital stay time (in days) was the same in both groups. The patient was often released the next day after surgery. However, in the majority of situations, it is the patient's mental state that he is unwell and needs further hospitalization that leads to a substantially prolonged length of stay, rather than surgical reasons. In terms of hospital stay, our findings are comparable with the meta-analysis done by Choudhary A et al.²⁷

Conclusion

Prophylactic antibiotics had no role in preventing SSI in high-risk patients having laparoscopic cholecystectomy. The aseptic minimally invasive procedure, as well as the essential peritoneal lavage and drainage during LC, are critical in avoiding postoperative infection.

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