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ORIGINAL ARTICLE

The effect of antibiotic prophylaxis on wound infections after laparoscopic cholecystectomy: A randomised clinical trial

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Abstract

The aim of this study was to determine whether the use of prophylactic antibiotics had any effects on the development of postoperative surgical wound infections between laparoscopic cholecystectomy patients. Patients who received a single dose of prophylactic antibiotics prior to surgery were included in the prophylaxis group, and those who did not receive preoperative and postoperative intravenous and/or oral antibiotics were included in the no prophylaxis group. A total of 206 patients who underwent laparoscopic cholecystectomy were examined; the infection rate in patients who received prophylaxis was 4.5%, while it was 4.2% in the non-prophylactic group. There was no statistically significant difference between the groups in terms of infection development rates ($P > .05$). We suggest that antibiotics should not be given for prophylaxis before low-risk laparoscopic cholecystectomy as there is no statistically significant difference in the rate of post-operative wound infection among patients who were either given or not given prophylaxis.

KEYWORDS
antibiotic prophylaxis, laparoscopic cholecystectomy, wound infection

1 | INTRODUCTION

A laparoscopic cholecystectomy (LC) is considered to be the gold standard for the treatment of symptomatic cholelithiasis. The most important advantages of an open surgery include a shortened hospital stay, faster resumption of daily life activities, less postoperative pain, and a lower risk of microbiological contamination.[1] Although there are potential problems associated with an LC, such as an extended hospital stay and a cost increase because of the development of a wound infections (WI), it is a minimally invasive technique, and therefore, the risk of infection is low.[2] Because of the small incision and less tissue damage when compared with an open cholecystectomy, WIs are less common in LC than in open surgeries.[3]

Numerous clinical studies have reported that, in LC surgeries in which an open cholecystectomy and prophylaxis are preferred, a single dose of cephalosporin should be used before the incision.[4] Cefazolin, which is a first-generation cephalosporin, should be the first choice for prophylaxis in gallbladder and biliary tract surgeries because of its sufficient distribution into the gallbladder wall, high concentration in the bile, wide antimicrobial spectrum, low toxicity, and low cost.[5]

There have been many studies arguing whether or not prophylactic antibiotics should be administered before an LC, as well as studies describing their effects on WI. However, in most meta-analyses, no statistically significant difference was found between the groups with and without prophylactic antibiotics.[6] It has also been reported that, currently, there is a tendency to abandon prophylactic antibiotic use in low-risk LCs.[7] However, because there is no consensus on this issue, most surgeons prefer to use prophylactic antibiotics before performing an LC.[8]

In this study, we aimed to determine whether the use of prophylactic antibiotics had any effects on the development of postoperative WI by examining whether or not there were any differences between LC patients who received prophylactic antibiotics and those who did not.

Key Messages

- the aim of this research was to evaluate and compare the effect of perioperative antibiotic prophylaxis on wound infections in those who underwent laparoscopic cholecystectomy
- antibiotic prophylaxis did not provide a significant advantage for postoperative wound infection

2 | METHODS

This study was conducted between September 2017 and May 2018 in patients who underwent LCs for cholelithiasis at our clinic. The patients were divided into two groups: those who were given preoperative prophylactic antibiotics and those who were not. Those patients who received a single dose of prophylactic antibiotics prior to surgery were included in the prophylaxis group, and those who did not receive preoperative and postoperative intravenous (IV) and/or oral antibiotics were included in the no prophylaxis group. Postoperatively, the wound sites were examined to determine whether or not an infection occurred.

The following items were recorded for each patient: age, gender, weight, diabetes and smoking histories, American Society of Anesthesiologists (ASA) score, history of a biliary colic attack in the last month, whether antibiotic prophylaxis was applied, any surgical findings (cholecystitis), operation time, drain use during the surgery, and development of a infection.

Preoperatively, 1 g of IV cefazolin was administered to all of the patients in the prophylaxis group. Those patients who had biliary colic attacks within 1 month of the operation were included in the study, and prophylactic antibiotics were administered to all of them. Those patients who were treated with antibiotics during the postoperative period because acute cholecystitis was detected during the operation were excluded from the study. All of the patients who were given antibiotics after the surgery, including those given an additional dose of IV antibiotics for any reason and those who were prescribed oral antibiotics at the time of discharge, were excluded from the study. Those patients who were not given prophylactic antibiotics but received a single dose of antibiotics during the surgery because of a gallbladder perforation were included in the prophylaxis group. Those patients with and without drains during the surgery were included in both groups. In both patient groups, all of the patients who underwent conversions from laparoscopic to open surgeries for any reason were excluded from the study. Those patients who were considered to be at risk of an infection (based on their history of diabetes, ASA score, and/or age) during the operation were treated with a single dose of antibiotics and included in the prophylaxis group. In both groups, those patients who were hospitalised for more than 1 day were excluded from the study.

The additional exclusion criteria were as follows: under 18 years old, over 75 years old, pregnant, previous abdominal surgery history, received antibiotics within 1 week prior to surgery, currently undergoing immunosuppressive treatment, on regular steroid therapy, choledocholithiasis, a common bile duct stone, obstructive jaundice, cholangitis, biliary pancreatitis, biliary surgery history, endoscopic retrograde cholangiopancreatography (ERCP) within 1 week prior to surgery, cephalosporin hypersensitivity, allergies, major thalassemia, and massive bleeding during surgery.

The patients were followed up in terms of the development of early and late postoperative wound infections. Any medical, interventional, or surgical treatments, if applied, were recorded.

3 | ETHICAL CONSIDERATIONS

This study was approved by the Ethics Committee of Alanya Alaaddin Keykubat University of Medical Sciences, and all of the subjects' parents were informed of the details of the study, and they signed a consent form.

4 | STATISTICAL ANALYSIS

The mean, SD, median lowest, median highest, frequency, and ratio values were used in the descriptive statistics of the data. The distribution of the variables was measured using the Kolmogorov-Smirnov test. The independent samples *t* test and Mann-Whitney *U* test were used for the analysis of the quantitative independent data. The paired samples *t* test and Wilcoxon test were used to analyse the dependent quantitative data. The χ^2 test was used for the analysis of the qualitative independent data, and Fisher's exact test was used when the χ^2 test conditions were not met. IBM SPSS Statistics for Windows version 22.0 (IBM Corp., Armonk, New York) was used for the statistical analysis.

5 | RESULTS

We started with 281 patients undergoing LC in our study. Conversion from LC to open surgery was carried out in 12 patients. Another 34 patients were excluded from the study because of postoperative administration of IV and/or oral antibiotic therapy for various reasons, and a further 29 patients were excluded because of hospitalisation for more than 1 day after the operation. Statistical analysis was performed on the remaining 206 patients. The gender distribution of the patients was 157 (76.2%) females and 49 (23.8%) males, with a mean age of 49 (21-80) years. Antibiotic prophylaxis was applied to 111 of these patients (53.9%) and not applied to the remaining 95 patients (46.1%).

There was a history of biliary colic in 51 patients (24.8%) in the last 1 month; 26 patients (12.6%) had diabetes, and 17 patients (8.3%) had a history of smoking. Forty-six patients (22.3%) had an ASA score of I, another 137 patients (66.5%) had an ASA score of II, and the remaining 23 patients (11.2%) had an ASA score of III. During surgery, cholecystitis was detected in 32 patients (15.5%). Operation times varied between 10 and 120 minutes. (average 30 minutes). Postoperative WI was seen in 9 (4.4%) of the 206 patients. This infection occurred in five patients (4.5%) who had received prophylaxis and in four patients (4.2%) who had not received prophylaxis. Table 1 presents the age, gender distribution, and risk factors included in the study and medical data of the patients.

The age of the patients did not differ significantly between the groups ($P > .05$). The rate of using prophylactic antibiotic in male patients was significantly higher than the females ($P < .05$). There was no significant difference in the ASA distribution between the groups ($P > .05$). The duration of surgery was significantly longer in the group that received antibiotics than in the group that did not ($P < .05$). A history of biliary colic, use of drains, and finding of cholecystitis during surgery were significantly higher in the antibiotic group ($P < .05$). Smoking did not differ significantly between the groups ($P > .05$). Table 2 presents the data of groups with and without antibiotic prophylaxis.

Age and gender distribution of the patients did not differ significantly between the groups with and without infection ($P > .05$). The weight of patients in the infection group was significantly higher than in the group without infection ($P < .05$). ASA distribution, diabetes, smoking, and biliary colic were not significantly different in the group with and without infection ($P > .05$). The duration of operation, the use of drains, and the rate of cholecystitis at the time of the operation did also not differ significantly ($P > .05$) between the infected and non-infected groups. Gallbladder perforations occurred in 32 cases, of which 18 patients were in the prophylactic group, and 14 patients were in the non-prophylactic group. These 14 patients received prophylactic antibiotics during surgery. Postoperative infection was not seen in any of these 32 patients. There was no statistically significant difference between the group that developed infection and the group that did not ($P > .05$). Table 3 presents the data of patients who developed WI and those who did not.

TABLE 1 The age, gender distribution, and risk factors included in the study and medical data of the patients

Variables	Descriptive statistics: Min.-Max.	Median	Mean ± SD	*n* (%)
Patient demographics				
Age (years)	21-80	49.0	49.8 ± 14.1	
Female				157 (76.2%)
Male				49 (23.8%)
Weight (kg)	47-110	70.0	71.0 ± 10.3	
Risk factors				
ASA scores				
I				46 (22.3%)
II				137 (66.5%)
III				23 (11.2%)
Diabetes				26 (12.6%)
Cigarette smoking				17 (8.3%)
Biliary colic				51 (24.8%)
Duration of operation (min)	10-120	30.0	32 ± 15	
Finding of cholecystitis at surgery				32 (15.5%)
Drain				161 (78.2%)
Prophylaxis				
Yes				111 (53.9%)
No				95 (46.1%)
Infection				9 (4.4%)

Abbreviation: ASA: American Society of Anesthesiologists score.

6 | DISCUSSION

One of major advantages of LC over open surgery is the lower risk of infection after surgery, and this has been reported in many previous studies.[3,9] In addition to the meta-analyses in which the rate of infection varied between 0.4% and 1.1%,[9] other studies have reported infection rates between 1.4% and 7.9%.[10-12] In our study, WI was seen in 9 of 206 patients (4.4%) who underwent LC.

TABLE 2 Data of groups with and without antibiotic prophylaxis

	Prophylaxis (−)			Prophylaxis (+)			
	Mean ± SD	**Median**	***n* (%)**	**Mean ± SD**	**Median**	***n* (%)**	***P***
Age	49.8 ± 13.8	49.5		49.7 ± 14.7	49		.962[a]
Female			103 (81.7%)			54 (67.5%)	**.019**[b]
Male			23 (18.3%)			26 (32.5%)	
Weight (kg)	70.4 ± 9.6	70		72.0 ± 11.3	70		.776[c]
ASA scores							
I			22 (23.1%)			27 (24.3%)	.061[b]
II			60 (63.1%)			76 (68.4%)	
III			13 (13.7%)			8 (7.2%)	
Diabetes			0 (0.0%)			26 (23.4%)	.000[c]
Cigarette smoking			2 (9.5%)			5 (6.3%)	.405[c]
Biliary colic			0 (0.0%)			51 (35%)	.000[c]
Duration of operation (min)	28.8 ± 11.8	30.0		37.9 ± 19.9	32.5		.000[c]
Finding of cholecystitis at surgery			0 (0.0%)			32 (40.0%)	.000[c]
Drain			83 (74.7%)			78 (82.1%)	.000[c]

Abbreviation: ASA, American Society of Anesthesiologists score.
[a]*t* test.
[b]χ^2 test (Fisher's test).
[c]Mann-Whitney *U* test.

TABLE 3 :Data of patients who developed infection and those who did not

	Infection (−)			Infection (+)			
	Mean ± SD	**Median**	***n* (%)**	**Mean ± SD**	**Median**	***n* (%)**	***P***
Age	49.6 ± 14.1	49.0		52.7 ± 15.0	56		.531[a]
Female			152 (77.2%)			5 (55.6%)	.137[b]
Male			45 (22.8%)			4 (44.4%)	
Weight (kg)	70.6 ± 10.2	70.0		79.1 ± 10.3	75.0		**.031**[c]
ASA score							
I			44 (22.3%)			2 (22.2%)	.688[b]
II			132 (67.0%)			5 (55.6%)	
III			21 (10.7%)			2 (22.2%)	
Diabetes			24 (12.2%)			2 (22.2%)	.317[c]
Cigarette smoking			16 (8.1%)			1 (11.1%)	.547[c]
Biliary colic			48 (24.4%)			3 (33.3%)	.542[c]
Duration of operation (min)	32.2 ± 15.2	30.0		35.6 ± 13.1	40.0		.373[c]
Finding of cholecystitis at surgery			32 (16.2%)			0 (0.0%)	.360[c]
Drain			152 (77.2%)			9 (100.0%)	.105[c]
Prophylaxis							
Yes			106 (53.8%)			5 (55.6%)	.918[c]
No			91 (46.1%)			4 (44.4%)	

Abbreviation: ASA, American Society of Anesthesiologists score.
[a]*t* test.
[b]χ^2 test (Fisher's test).
[c]Mann-Whitney *U* test.

LC surgeries are classified as clean, and antibiotic prophylaxis is only recommended for high-risk patients in these surgeries.[9] High-risk LC patients are identified as follows: patients over 60 years of age; those with a history of diabetes, immunosuppression, biliary stones and obstruction, cholangitis, or jaundice; patients with a history of colic within 30 days before surgery; patients with cholecystitis at the time of surgery; and patients with a history of previous biliary surgery.[2]

In six different meta-analyses, 58 randomised clinical trials and 9872 patients' data were analysed to evaluate the effect of prophylactic antibiotics on infection development in low-risk LC cases. All of these meta-analyses reported that there was no difference between the prophylactic group and the non-prophylactic group in terms of infection and that it was therefore not necessary to apply prophylaxis before low-risk LC.[1,13-17] In another study where LC was performed on 102 patients and prophylactic antibiotics were not applied, it was concluded that prophylactic antibiotic use before low-risk LC was not necessary.[18] A study conducted on 277 patients undergoing LC[19] and another study that examined 1037 patient[6] reported that there was no statistically significant effect of prophylactic antibiotic use prior to low-risk LC on the development of postoperative infection. In a study of 429 patients who underwent low-risk LC, the rate of infection was 1.7% and 2.1% in 182 patients with prophylaxis and 247 patients without prophylaxis, respectively; however, no statistically significant difference was found.[8] In our study, 206 patients who underwent LC were examined, and preoperative prophylaxis was given to 111 patients, while 95 low-risk patients did not receive prophylaxis. The WI rate in patients who received prophylaxis was 4.5% (five patients), while it was 4.2% (four patients) in the non-prophylactic group. There was no statistically significant difference between the groups in terms of WI development rates ($P > .05$).

Although many studies have reported no effect on postoperative infection, other studies indicate that the use of prophylactic antibiotics decreases the rate of postoperative infection. In a meta-analysis on this subject, the data from 21 comparative studies involving 5207 patients on the use of antibiotic prophylaxis in LC were examined. Single-dose antibiotics were administered in 15 of these studies, two doses were administered in 2 studies, three doses were administered in 3 studies, and two different antibiotics were administered in the final study. This meta-analysis concluded that antibiotic prophylaxis prior to low-risk LC reduces the number of infections that occur during hospitalisation and after discharge and that the use of two or more antibiotics reduces the incidence of postoperative infections compared with a single dose of antibiotics.[20] However, it is also reported that the overuse of prophylactic antibiotics may increase bacterial resistance, alter normal bile flora, increase cost, and increase the development of opportunistic nosocomial infection and surgical site infection.[21]

Some risk factors may affect the development of post-LC infection. One of these is the age of the patient. Studies report that prophylactic antibiotic administration can reduce the frequency of infection in patients over 60 years of age, and so, the administration of antibiotics to this age group is recommended.[12,21] It has also been reported that a history of biliary attack in the last month prior to surgery, the ASA score, and a diagnosis of diabetes or obesity are risk factors for developing an infection after LC.[8,12] Local complications after LC can increase in overweight male patients (70 kg and over), while infection and local complications after LC are especially high in patients who weigh 90 kg or more.[22] In a study conducted on 570 patients on the development of post-LC infection, no association was found between post-LC infection and age (over 60 years), diabetes, smoking, and ASA scores.[23] In our study, the mean age of patients who developed infection after LC was 56 years, while the mean age of patients without infection was 49 years. Five of the nine patients who developed infection were female, four of them were male, two of them had diabetes, and one had a history of smoking. The ASA score was I in two of the nine patients with infection, the score was II in five of the patients, and it was III in two of the patients. Three patients had a history of biliary colic. No statistically significant difference was found between the groups in terms of gender diabetes and a history of smoking, ASA scores, drain use, and a history of biliary colic on postoperative infection ($P > .05$). However, patient weight was significantly higher in the group with infection ($P < .05$).

Whether gallbladder perforation during LC has an impact on the development of postoperative infection is controversial. The incidence of positive bile culture varies between 10% and 20% in gallbladder stones.[24] It is reported that gallbladder perforation occurs during surgery in 11% to 35% of cases and that this usually happens during the stages of dissection, traction, and gallbladder removal from the liver.[12,19,25] Some studies report that there is no relationship between gallbladder perforation and the development of postoperative infection,[20] while other studies suggest that gallbladder perforation during surgery is a risk factor in the development of infection.[8,26,27] It is therefore recommended that prophylactic antibiotics should be administered in cases of gallbladder perforation during surgery.[4] Gallbladder perforation occurred during surgery in 32 of our patients (15.5%), and a single-dose prophylaxis was applied during surgery to 14 patients who had not received preoperative prophylaxis. No postoperative WI was seen in any of the 32 patients with perforated gallbladders.

In conclusion, although the use of prophylactic antibiotics before low-risk LCs to prevent postoperative WI is a controversial issue, many studies suggest that it is not necessary to use prophylactic antibiotics prior to those LCs that are classified as clean surgical interventions. Recently, some surgeons have tended to abandon prophylactic antibiotic use prior to low-risk LC, while others still prefer to continue using prophylaxis. As a result of our study, we suggest that antibiotics should not be given for prophylaxis before low-risk LC as there is no statistically significant difference in the rate of postoperative WI among patients who were either given or not given prophylaxis. We believe that antibiotic use should be minimised to reduce or prevent bacterial resistance and development of opportunistic nosocomial infections and to avoid high costs.

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CONFLICT OF INTEREST

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