# A Prospective Study Comparing No Antibiotic versus Antibiotic Prophylaxis in Patients Undergoing Elective Laparoscopic Cholecystectomy

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### **Abstract**

Laparoscopic cholecystectomy is one of the most common operations performed in general surgery. Elective laparoscopic cholecystectomy has a low risk for infective complications, and standard guidelines do not recommend prophylactic antibiotic use for low-risk cases. However, the use of antibiotic prophylaxis is very prevalent and the duration and dosage are inconsistent and varies widely among surgeons. This study is being done to assess the role of no antibiotic prophylaxis in the prevention of wound infection in a patient undergoing elective laparoscopic cholecystectomy.

**Study Design and Period:** The study was conducted in the Department of General Surgery at Christian Medical College, Ludhiana. This was an open labeled study conducted from the period of January 1, 2014, to December 31, 2014.

**Results:** 92 patients suffering from chronic calculous cholecystitis undergoing elective laparoscopic cholecystectomy were included in the study. Group A with 23 cases without prophylactic antibiotic. Group B with 69 cases with two doses of prophylactic antibiotics Inj. cefuroxime 1.5 gram 30 min prior to induction and after 6 h. The majority of our 81 patients (88.04%) were females. The male to female ratio was 1:8. 3 patients (3.27%) in Group B had associated comorbidities except for diabetes mellitus. The majority of patients 14 (60.86%) in Group A had taken 1-2 h of operative time while 58 patients (84.05%) patients in Group B with statistical insignificant P = 0.05. There was no fever in Group A patients while in Group B 2 patients (2.89%) had fever on second post-operative day which was not related to surgical site infection and that was due to superficial thrombophlebitis. In Group A 18 patients (78.26%) were discharged on second postoperative days while 46 patients (66.67%) patients in Group B were discharged on second postoperative days. There was no statistical difference in the duration of hospitalization between the two groups with P = 0.22. The overall incidence of postoperative infective complications were nil in both groups either with patients having no prophylactic antibiotic or those having prophylactic antibiotics.

**Key words:** Calculous cholecystitis prophylactic Antibiotics, Comorbidities, Infective complications, Laparoscopic cholecystectomy

### INTRODUCTION

Cholecystectomy is one of the most common surgeries done today and laparoscopic cholecystectomy is the gold standard procedure due to its advantages to the patient such as reduced pain, reduced hospital stay, lesser

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analgesics required, and earlier return to work and better cosmesis.<sup>[1,2]</sup>

Surgical antimicrobial prophylaxis refers to a very brief course of antimicrobial agent initiated 1/2 h before an operation begins. It is not an attempt to sterilize tissue, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that will not overwhelm host defense. <sup>[3]</sup> The concept of prophylactic antibiotics was introduced in the early 1960s. <sup>[4]</sup>

The success of laparoscopic surgery has led to the re-evaluation of many long-accepted surgical doctrines.

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A lower incidence of complication and a better postoperative outcome have been observed with laparoscopic surgery compared with conventional open operation.<sup>[5]</sup>

The infective complications following laparoscopic cholecystectomy are low, was further supported by study analysis of 1702 patients undergoing laparoscopic cholecystectomy and revealed an overall infections rate of 2.3% and surgical site infection rate 0.4%. [6] Observing the low incidence of infections following laparoscopic cholecystectomy, the need for prophylactic antibiotics is now frequently questioned. The overuse of antibiotics can result in rising frequency of adverse effects, emergence of drugresistant organisms, as well as excessive costs. [7] A number of studies and meta-analysis show different results in the context of surgical site infection in elective laparoscopic cholecystectomy and it ranges from 0.4% to 7.9%. [8-12]

Antibiotic prophylaxis includes the pre-operative administration of a wide spectrum antibiotic against the most frequent bacteria involved in surgical site infections, trying to get high tissue levels of the antibiotic at the surgical wound to avoid colonization and the growing of microorganisms.<sup>[13,14]</sup>

It is advisable to use prophylactic antibiotics to reduce the incidence of wound infection in laparoscopic cholecystectomy. <sup>[15]</sup> On the other hand, eliminating the unnecessary use of prophylactic antibiotics would result in a cost reduction; moreover, it would lower the risk of adverse reactions and reduce microbial resistance.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) provided a guideline for antibiotic prophylaxis as follows:

- 1. Antibiotics are not required in low-risk patients undergoing laparoscopic cholecystectomy
- Antibiotics may reduce the incidence of wound infection in high-risk patients (age >60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis)
- 3. If given, they should be limited to a single pre-operative dose given within 1 h of skin incision.

The aim of this study was to compare the efficacy of no prophylaxis with antibiotics prophylaxis with regard to post-operative infections in elective laparoscopic cholecystectomies performed in the Department of General Surgery at Christian Medical College, Ludhiana.

## **MATERIALS AND METHODS**

### **Study Setting**

The study was conducted in the Department of General Surgery at Christian Medical College, Ludhiana.

## **Study Design and Period**

This was an open labeled study conducted from the period of January 1, 2014, to December 31, 2014.

### **Study Population**

All patients undergoing elective laparoscopic cholecystectomy were included in the study as per inclusion and exclusion criteria after taking written informed consent for participation. To make it a statistically significant study with the expected difference of infection rate being 15% with alpha of 95% and power of 80%, with an unequal allocation ratio being 1:3, the sample size was calculated as 23 cases without antibiotic prophylaxis (Group A) and 69 cases with antibiotic prophylaxis (Group B).

- Group A: Patients in this group received no antibiotics prophylaxis
- Group B: Patients in this group received prophylactic antibiotic Inj. cefuroxime 1.5 g 30 min before induction and after 6 h.

#### Methods

A detailed history and general physical examination followed by routine investigations were done. Informed consent for laparoscopic/open cholecystectomy had taken. Group A patients had not received antibiotic prophylaxis before surgery. At the time of surgery, the site was cleaned with 10% povidone-iodine solution. Nasogastric tube was inserted after induction of anesthesia. Laparoscopic cholecystectomy was performed with standard four-port technique. The gallbladder was extracted through subxiphoid or umbilical port. The umbilical port sheath was closed with no.1 nylon. The skin incisions were closed with nylon 4–0.

Group B patients were received prophylactic antibiotic Inj. Cefuroxime 1.5 g 30 min before induction and after 6 h. All the patients received analysesic, steam inhalation, and nebulization postoperatively.

The patients were watched for infective complications which were defined as follows:

- 1. Pyrexia of >38°C (Excluding the 1st post-operative day)
- 2. Evidence of infections
  - Wound infections
    - Ervthema
    - Induration
    - Pus discharge and
  - Serous discharge with bacteriological evidence of infection.
  - b. Major infections
    - Intra-abdominal collections or abscess.

#### **Inclusion Criteria**

All patients undergoing elective laparoscopic cholecystectomy at the Department of General Surgery, Christian Medical College for chronic calculous cholecystitis were included in the study.

### **Exclusion Criteria**

The following criteria were excluded from the study:

- Age more than 60 years
- Antibiotic use within 48 h
- Diabetes mellitus
- H/O Steroid use
- Patients with acute cholecystitis
- Conversion to open cholecystectomy
- Cholangitis
- Intraoperative cholangiogram
- Jaundice
- Post-endoscopic procedure such as endoscopic retrograde cholangiopancreatography
- Patient getting antibiotics post-operative for any intervention
- Cardiac prosthesis
- Rheumatic heart disease.

### Follow-up

The patients were discharged 48–72 h postoperatively and were followed up in the outpatient department on 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> weeks postoperatively. The patients were examined to rule out any infective complications. If present, a wound swab from the infected site was taken to document the infection.

### **Statistical Analysis**

The results obtained were statistically analyzed using SPSS software version 16 and subjected to frequency, proportion, Chi-square, and *t*-test for significance.

## **RESULTS AND ANALYSIS**

Table 1 shows the mean age of patients and perioperative assessment of blood biochemistry of the patients in both groups. The mean age in Group A was 37.83 years with a standard deviation of 10.83 while in Group B the mean age was 42.80 years with a standard deviation of 10.75.

The mean hemoglobin was 12.01 g% with a standard deviation of 1.71 in Group A while the mean hemoglobin was 12.47 g% with a standard deviation of 1.58 in Group B with a statistically insignificant P = 0.241.

The mean total leukocyte count was  $7713.04/\text{cm}^3$  with a standard deviation of 2489.12 in Group A while the mean total leukocyte count was  $7487.88/\text{cm}^3$  with a standard deviation of 2397.99 in Group B with a statistically insignificant P = 0.70.

The mean random blood sugar was 123 mg/dl with a standard deviation of 20.37 in Group A while the mean random blood sugar was 124.72 mg/dl with a standard

deviation of 23.02 in Group B with a statistically insignificant P = 0.75.

The serum creatinine was 0.66 mg/dl with a standard deviation of 0.19 in Group A while the serum creatinine

Table 1: Pre-operative assessment in both groups

Parameters	Group A	Group B	P value
Age			0.061
Sample size	23	69	
Mean±SD	37.87±10.83	42.80±10.75	
Median	37	44	
Min-max	18–60	22-60	
Interquartile range	30.25-47.5	33-51.25	
Hb			0.241
Sample size	23	69	
Mean±SD	12.01±1.71	12.47±1.58	
Median	12.4	12.5	
Min-max	8.1-15.2	9–17.6	
Interquartile range	11.125-13.150	11.275-13.525	
TLC			0.7
Sample size	23	69	
Mean±SD	7713.04±2489.12	7487.88±2397.99	
Median	7100	7200	
Min-max	3800-12400	64-14500	
Interquartile range	6025-9800	6025-8525	
RBS			0.75
Sample size	23	69	
Mean±SD	123±20.37	124.72±23.02	
Median	117	122	
Min-max	86–178	81-189	
Interquartile range	112-135.5	111.75-136.5	
Creatinine			0.067
Sample size	23	69	
Mean±SD	0.66±0.19	0.74±0.27	
Median	0.6	0.7	
Min-max	0.4-1.1	0.1-2.1	
Interquartile range	0.57-0.7	0.6–0.8	

SD: Standard deviation

Table 2: Age distribution of patients

Age	Gre	oup	Total (%)	P value
grouping	A (%)	B (%)		
18-20	1 (4.35)	0 (0.00)	1 (1.09)	0.121
21-30	5 (21.74)	10 (14.49)	15 (16.30)	
31-40	9 (39.13)	17 (24.64)	26 (28.26)	
41-50	5 (21.74)	21 (30.43)	26 (28.26)	
51-60	3 (13.04)	21 (30.43)	24 (26.09)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

χ²=7.299, df=4

Table 3: Comorbidities among the patients

Co morbidity	Group		Total (%)	P value
	A (%)	B (%)		
Bronchial asthma	0 (0.00)	1 (1.45)	1 (1.09)	0.793
HTN	0 (0.00)	1 (1.45)	1 (1.09)	
Hypothyroidism	0 (0.00)	1 (1.45)	1 (1.09)	
Nil	23 (100.00)	66 (95.65)	89 (96.74)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

 $\chi^2 = 1.034$ , df = 3

was 0.74 mg/dl with a standard deviation of 0.27 in Group B with a statistically insignificant P = 0.067.

Table 2 and Figure 1 shows the distribution according to the age of patients included in both the group separately. Nine patients (39.13%) were in the 4<sup>th</sup> decade and 5 patients (21.74%) were in the 5<sup>th</sup> decade of life in Group A, whereas 17 patients (24.64%) were in the 4<sup>th</sup> decade and 21 patients (30.43%) were in the 5<sup>th</sup> decade of life in Group B. There was no statistically significant difference between the two groups in terms of age distribution (P = 0.121).

Table 3 and Figure 2 in Group A, none of the patients have comorbidities while 3 patients (4.35%) in Group B have comorbidities. There was no statistically significant difference between the two groups (P = 0.793).

Table 4 and Figure 3 shows that 3 patients (13.04%) required <1 h, 14 patients (60.87%) required 1–2 h, and 6 patients (26.09%) required more than 2 h of operative

**Table 4: Duration of operation** 

		·		
Duration of	Group		Total (%)	P value
operation (h)	A (%)	B (%)		
<1	3 (13.04)	5 (7.25)	8 (8.70)	0.054
1–2	14 (60.87)	58 (84.06)	72 (78.26)	
>2	6 (26.09)	6 (8.69)	12 (13.04)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

 $\chi^2=5.852$ , df=2

Table 5: Distribution of patients according to post-operative hospital stay

Duration of hospital	Group		Total	P value
days (days)	A (%)	B (%)	No (%)	
1	5 (21.74)	15 (21.74)	20 (21.74)	0.22
2	18 (78.26)	46 (66.67)	64 (69.57)	
3	0 (0.00)	8 (11.59)	8 (8.69)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

Table 6: Distribution of wound complication in both groups

Complications	Group A	Group B
Fever		
Present	00	02
Absent	23	67
Erythema		
Present	00	00
Absent	23	69
Induration		
Present	00	00
Absent	23	69
Discharge (Pus/serous)		
No discharge	23	69

time in Group A while in Group B 5 patients (7.25%) required <1 h, 58 patients (84.06%) required 1–2 h, and 6 patients (8.69%) required more than 2 h of operative time. There was no statistically significant difference between the two groups with P = 0.054.

Table 5 and Figure 4 shows that 5 patients (21.74%) were discharged on 1<sup>st</sup> post-operative day while 18 patients (78.26%) were discharged on 2<sup>nd</sup> post-operative day in Group A whereas 15 patients (21.74%) discharged on 1<sup>st</sup> post-operative day, 46 patients (66.67%) were discharged on 2<sup>nd</sup> post-operative day, and 8 patients (11.59%) were discharged on 3<sup>rd</sup> post-operative day in view of high drain output in Group B. The difference was not statistically significant with P = 0.22.

Table 6 shows that there was no fever in Group A patients whereas 2 patients (2.89%) in Group B had a fever on the 2<sup>nd</sup> post-operative day due to superficial thrombophlebitis and were cured with antipyretic. No any

Table 7: Distribution of wound complications in both groups

Complications with time duration	Group A	Group B
Bacteriological evidence of infection		
Absent	23	69
Infection at other site		
Absent	23	69
Infection at the surgical site		
1 <sup>st</sup> week		
Absent	23	69
2 <sup>nd</sup> week		
Absent	23	69
4 <sup>th</sup> week		
Absent	23	69

Table 8: Status of the wound in the two groups

Status of wound	Gro	oup
	A (%)	B (%)
Healed	23 (100)	69 (100)
Wound complication	0	0

Table 9: Infection at the surgical site after discharge

Infections		Group		Total (%)
		A (%)	B (%)	
Infection at surgical site 1st week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Infection at surgical site 2 <sup>nd</sup> week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Infection at surgical site 4 <sup>th</sup> week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Total		23 (100.00)	69 (100.00)	92 (100.00)

other wound complication noticed in both groups. There is no statistically significant difference noticed between the two groups.

Table 7 shows that there is no bacteriological evidence of infection in both groups as well as there is no infection at other site in both groups. Following follow-up at 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> weeks, there was no evidence of infection at the surgical site in both groups.

Table 8 and Figure 5 shows that there were no wound complications noticed in both groups and all patients had completely healed the wound in both groups.

Table 9 and Figure 6 shows no evidence of infection at the surgical site after discharge on follow-up.

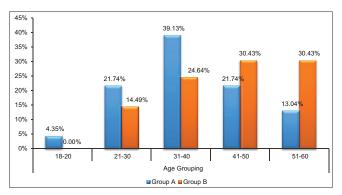


Figure 1: Age distribution

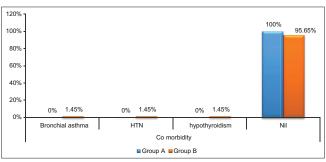


Figure 2: Comorbidities

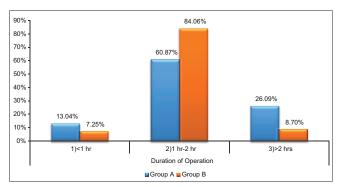


Figure 3: Duration of operation \* group

## **DISCUSSION**

Laparoscopic cholecystectomy is now considered as the "gold standard" treatment for symptomatic cholelithiasis. <sup>[16]</sup> The infective complication following this procedure is significantly less compared to open cholecystectomy. <sup>[17-19]</sup> It has been shown to be associated with decreased pain, shorter hospital stay, reduced pulmonary complications, decreased wound infection, and faster recovery. <sup>[1,2]</sup> The systemic immune response for surgery, in general, may not apply to laparoscopic surgery. The body response to laparoscopy is one of lesser immune activation as opposed to immunosuppression. <sup>[20]</sup> The smaller biological impact induced by laparoscopy is followed by greater preservation of the immune response, than that after the

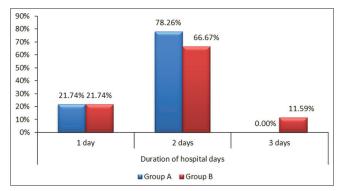


Figure 4: Duration of hospital days \* group

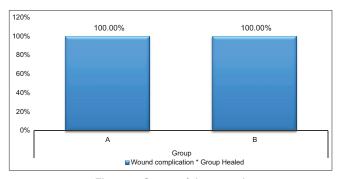


Figure 5: Status of the wound

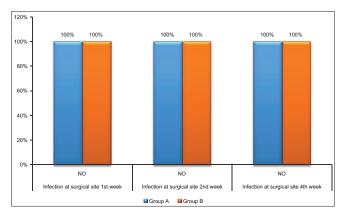


Figure 6: Infection at the surgical site after discharge

open operation, consequently lowering the incidence of infectious complications.<sup>[5]</sup>

Antibiotic therapy has played a major role in the treatment of general and biliary septic complication in biliary surgery. The administration modalities of these drugs have progressively been changed, with pre-operative prophylaxis preferred to post-operative treatment, based on a number of studies that documented the efficacy of the former in controlling septic complications.<sup>[21]</sup>

It is well documented that prophylactic antibiotic coverage of most clean-contaminated surgical procedure can significantly prevent infectious complications, including wound infection, thereby affecting the overall rates of morbidity and mortality. However, the benefit of antibiotic prophylaxis in other clean surgical procedure such as laparoscopic cholecystectomy has been considered questionable.[22] The low rate of wound infections and the straight forward treatment, if they occur at all are the main arguments against routine antibiotic coverage during laparoscopic cholecystectomy. Laparoscopic cholecystectomy is an elective clean operation and the post-operative wound infection rate been shown to be of value in other areas of surgery such as trauma<sup>[23]</sup> and vascular surgery, [24,25] but in laparoscopic cholecystectomy, its benefits remain uncertain. [22] Due to the unknown impact on bacterial resistance, Waldvogel et al. suggested that the routine use of antibiotic prophylaxis should be discouraged. [26] SAGES also advocate no prophylactic antibiotics in low-risk patient undergoing laparoscopic cholecystectomy.

We have carried out a prospective open labeled study which included patients with an unequal allocation ratio being 1:3, considering statistically significant study with the expected difference of infection rate being 15% with alpha of 95% and power of 80%. The sample size was calculated as 23 cases without antibiotic prophylaxis (Group A) and 69 cases with antibiotic prophylaxis (Group B).

Patients in Group A not received prophylactic antibiotic while patients in Group B received prophylactic antibiotic intravenous Cefuroxime 1.5 g, 30 min before induction and after 6 h.

## Comparison of mean age in our study with other studies

Study	Mean age (years)
Peters and associates[27]	46
Gordan and associates[28]	47
Lipman and associates[29]	45
Present study	45.5

The mean age in our study (45.5 years) is consistent with the mean age in the above-mentioned studies.

## Comparison of % of female in our study with other studies

Study	% of females
Kambouris and associates[30]	72.6%
Schirmer and associates[31]	78.2%
Bailey and associates[32]	80.7%
Present Study	88.04%

The percentage of females in our study 88.04% is consistent with the percentage of females in the abovementioned studies.

Thus, the mean age at presentation (45.5 years) and female preponderance obtained in our study are similar to most of the other studies, thereby implying that symptomatic cholelithiasis most commonly presents in the 5<sup>th</sup> decade of life, with a significant female preponderance.

## **Presenting Symptoms**

In this study, pain abdomen associated with chronic calculous cholecystitis was 72.83% of patients.

# Comparison of % of patients with pain abdomen in our study with other studies

Study	% of patients with pain abdomen
McMahon and associates[33]	32-82%
Singh and associates[34]	40%
Present study	72.83%

Pain abdomen associated with chronic calculous cholecystitis is the most common presenting symptoms in our study, which is consistent with the result obtained in the abovementioned studies.

#### **Associated Comorbidities**

In this study, 3 patients in Group B has associated comorbidities, but none of them are significantly associated with an increased incidence of infective complications following elective laparoscopic cholecystectomy.

### **Duration of Hospitalization**

In our study, all patients in Group A were discharged within the 1<sup>st</sup> week of operation, maximum within 2 days (78.26%). As similar, all patients in Group B were discharged within the 1<sup>st</sup> week of operation, maximum within 2 days (66.67%). The corrected P = 0.22 which is statistically insignificant.

Our study is comparable to a study conducted by Tocchi *et al.*, [10] in which all 84 patients were discharged within the 1<sup>st</sup> week of surgery.

### **Post-operative Wound Status**

In our study, 23 out of 23 patients (100%) in Group A had completely healed wound postoperatively without any evidence of surgical site infections. In Group B, 69 patients out of 69 also had completely healed wound postoperatively without any evidence of surgical site infections. This illustrates that patients in Group A without antibiotic prophylaxis and patients in Group B with antibiotic prophylaxis have no difference in outcome in terms of surgical site infections.

Elective laparoscopic cholecystectomy has a low risk of infective complications. [8] In a randomized controlled trial on 417 patients undergoing laparoscopic cholecystectomy, conducted by Gaur and Pujaharr, they reported an overall infection rate of 2.2%, which is consistent with the results obtained in our study. [35]

Chang *et al.* conducted a prospective randomized study to demonstrate the impact of prophylactic antibiotics on post-operative infective complications in elective laparoscopic cholecystectomy. They demonstrated that no prophylactic antibiotics are necessary after wound closure, i.e., postoperatively in an effort to decrease the incidence of superficial wound infections in elective laparoscopic cholecystectomy.<sup>[36]</sup>

Kuthe et al. carried out a prospective study to define the role of prophylactic antibiotics in elective laparoscopic cholecystectomy to prevent post-operative infection. Ninety-three patients were randomly placed in two groups. Group A comprised 40 while Group B consisted of 53 patients. Patients in Group A received 1.5 g of second generations cephalosporin (cefuroxime sodium) diluted in 100 ml of normal saline, at the time of induction of anesthesia. Group B patients received an equal volume of normal saline only. In Group A, one patient (2.5%) had post-operative wound infection and in Group B, two patients (3.8%) had post-operative infections which were statistically similar (P > 0.1). Therefore, the study concluded that prophylactic antibiotic did not have a significant role to play in the prevention of post-operative wound infection in elective laparoscopic cholecystectomy this result is consistent with the results obtained in our study.[37]

Mehmet *et al.* conducted a double-blind prospective, randomized, controlled study comparing the prophylactic use of cefazolin (Group 1) versus placebo (Group 2). One hundred fifty patients undergoing elective laparoscopic cholecystectomy were selected for study. After all exclusion Groups 1 and 2 included 68 and 76 patients, respectively. The study showed that the incidence of SSI in patients was 3.47% for the total study group. Nearly 4.41% for Group 1 and 2.63% for Group 2 and there was no

significant difference in infection rate between the groups. They concluded that antibiotic prophylaxis did not seen to affect the incidence of SSI and is not necessary for elective laparoscopic cholecystectomy in low-risk patients which is consistent with our study too.<sup>[38]</sup>

Qahtani carried out a study to determine the necessity of a single dose prophylactic antibiotic in preventing the post-operative infective complications in patients undergoing elective laparoscopic cholecystectomy. Patients who were included in this study were prospectively randomized into two groups, those receiving single dose of intravenous cefuroxime 1.5 g, 30 min before surgery (Group A) and those not receiving any pre-operative antibiotic (Group B). One hundred two patients in Group A received antibiotic and 109 patients in Group B did not received any antibiotics. In this study, the overall post-operative infective complications were 3.62% (2.7% in Group A and 4.6% in Group B) with no significant statistical difference between the two groups.<sup>[39]</sup>

They concluded that elimination of prophylactic antibiotics in patients undergoing elective laparoscopic cholecystectomy increases the incidence of post-operative infective complications but not to a statistically significant degree. In our study, the post-operative wound infections in both groups were statistically not significant.

Choudhary *et al.* in their meta-analysis to evaluate the efficacy of prophylactic antibiotics in low-risk patients undergoing laparoscopic cholecystectomy concluded that prophylactic antibiotics before laparoscopic cholecystectomy resulted in no statistically significant benefit for wound infection. This difference, though, can be attributed to the exclusion criteria used by Choudhary *et al.*, who excluded all patients with cholelithiasis or cholangitis from their study. They went onto state that future multicenter randomized controlled trials with adequate statistical power and involving a higher number of patients, particularly those at high risk for infections are needed to complete the evaluation of prophylactic antibiotics before laparoscopic cholecystectomy. [40]

In another study conducted by Mahmoud *et al.* to assess the role of antibiotic prophylaxis in elective laparoscopic cholecystectomy, they stated that antibiotic prophylaxis does not prevent wound infection in elective laparoscopic cholecystectomy. This is probably due to the fact that Mahmoud *et al.* excluded all patients with associated comorbidities, such as diabetes mellitus and hypertension from their study.<sup>[410]</sup>

They also concluded that the use of antibiotic prophylaxis is preferred to be restricted to high-risk patients such as patients with associated comorbidities like diabetes mellitus.

The rate of post-operative wound infection in our study was nil in both groups and there is no difference in surgical site infections in patients those who received no prophylactic antibiotics versus those who received prophylactic antibiotics.

This can be attributed to the following reasons:

- Proper selection of patients
- Strict adherence to aseptic precautions
- Good surgical technique
- Better handling of tissues
- Experienced laparoscopic surgeons.

### **SUMMARY AND CONCLUSIONS**

This was an open label prospective study and has been conducted in the Department of General Surgery, Christian Medical College, Ludhiana, Punjab. Ninety-two patients suffering from chronic calculous cholecystitis undergoing elective laparoscopic cholecystectomy were included in the study.

- Ninety-two patients underwent elective laparoscopic cholecystectomy for chronic calculous cholecystitis
- Patients were randomized with an unequal allocation ratio of 1:3 into two groups
- Group A with 23 cases without prophylactic antibiotic
- Group B with 69 cases with two doses of prophylactic antibiotics Inj. cefuroxime 1.5 g 30 min before induction and after 6 h
- Laparoscopic cholecystectomy was done by the standard four port technique
- Patients were discharged between 48 and 72 h postoperatively and were followed on 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> weeks for the development of infective complications
- Maximum incidence of cholelithiasis was found in between 4<sup>th</sup> and 5<sup>th</sup> decade of life, 38 patients (56.52%).
   The mean age of our patients was 40.33 years with a range from 18 to 60 years
- The majority of our 81patients (88.04%) were females. The male to female ratio was 1:8
- Three patients (3.27%) in Group B had associated comorbidities except for diabetes mellitus
- The majority of patients 14 (60.86%) in Group A had taken 1–2 h of operative time while 58 patients (84.05%) patients in Group B with statistical insignificant P = 0.05
- There was no fever in Group A patients while in Group B 2 patients (2.89%) had a fever on 2<sup>nd</sup> post-operative day which was not related to surgical site infection and that was due to superficial thrombophlebitis
- In Group A, 18 patients (78.26%) were discharged on 2<sup>nd</sup> post-operative days while 46 patients (66.67%)

- patients in Group B were discharged on the 2<sup>nd</sup> postoperative day. Eight patients (11.59%) in Group B were discharged on 3<sup>rd</sup> post-operative days
- There was no statistical difference in the duration of hospitalization between the two groups with P = 0.22.
- The overall incidence of post-operative infective complications was nil in both groups either with patients having no prophylactic antibiotic or those having prophylactic antibiotics
- There was no statistical difference in the incidence of post-operative infective complications in lowrisk patients underwent elective laparoscopic cholecystectomy with or without prophylactic antibiotics.

## **CONCLUSION**

Based on the finding of our study, it may be concluded that not giving prophylactic antibiotic does not increase the post-operative infective complications. Prophylactic antibiotic is not necessary for low-risk patients undergoing elective laparoscopic cholecystectomy.

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