



# SURGICAL SITE INFECTION; PROPHYLACTIC ANTIBIOTICS IN LAPAROSCOPIC CHOLECYSTECTOMY TO REDUCE SURGICAL SITE INFECTION

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**ABSTRACT... Objectives:** To compare antibiotic prophylaxis in preventing frequency of postoperative surgical site wound infection rate in low risk laparoscopic cholecystectomy with controls. **Study design:** Randomized Controlled Trial. **Setting:** Department of Surgery, Combined Military Hospital, Rawalpindi. **Duration of study:** This study was conducted from 11-07-2015 to 10-01-2016. **Subjects and methods:** A total of 650 patients (325 in each group) were included in the study. Patients in group-A received antibiotic prophylaxis whereas patients in group-B did not receive any antibiotic prophylaxis. **Results:** Mean age of the patients was  $44.91 \pm 13.37$  and  $42.28 \pm 13.76$  years in group-A and B, respectively. In group-A there were 152 patients (46.7%) and in group-B 148 patients (45.5%) were males. In group-A 173 patients (53.3%) and in group-B 177 patients (54.5%) were females. In group-A, superficial site infection was seen in 4 patients (1.2%) and in group-B superficial site infection was observed in 13 patients (4.0%). The difference between two groups was statistically significant ( $p=0.027$ ). Mean duration of symptoms was  $5.75 \pm 0.50$  and  $5.77 \pm 0.92$  days in group-A and B, respectively. Stratification with regard to age, gender and duration of symptoms was carried out. **Conclusion:** In conclusion, we recommend the use of pre-operative prophylactic antibiotics for patients who are undergoing elective low-risk laparoscopic cholecystectomy in order to prevent post-operative infectious complications.

**Key words:** Laparoscopic Cholecystectomy, Antibiotic Prophylaxis, Surgical Site Infection.

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## INTRODUCTION

Laparoscopic cholecystectomy is carried out through small incisions, hence the chances of getting surgical site infection are minimal. The Center for Disease Control and Prevention recommends the use of prophylactic antibiotics in clean-contaminated surgery like cholecystectomy to in order to minimize the risk of surgical site infections (SSI).

The third most common healthcare-associated infection is SSI, accounting for 14% to 16% of infections.<sup>1</sup> Bile may contain multiple aerobic as well as anaerobic bacteria thus increasing the risk of SSI.<sup>2</sup> Some newly developed guidelines do not support the use of prophylactic antibiotics in routine laparoscopic cholecystectomy (LC).<sup>3</sup> Similarly, a Cochrane review on the subject finds

no evidence to support the use of antibiotic prophylaxis in routine LCs.<sup>4</sup> On the other hand if we look at the current practice, most of the centres are still using prophylactic antibiotics during LC.<sup>5</sup>

The rationale for this study is to determine whether the use of routine antibiotic prophylaxis during laparoscopic cholecystectomy is really helping or only the need of our ongoing practice.

## Materials and methods

This study was conducted at the department of surgery, Combined Military Hospital, Rawalpindi over a period of six months from 11-07-2015 to 10-01-2016. Clearance was obtained from institutional ethical committee before start of the study and informed written consent was obtained from every individual. Calculation of the

sample size was done by using WHO sample size calculator having level of significance as 5 %, power of test as 80%, anticipated population in group -A 0.8 % and anticipated population in group-B 3.7%<sup>8</sup> (total sample size 325 in each group). Sampling technique was non-probability consecutive sampling. All symptomatic LC patients of ASA I or II were defined as low risk laparoscopic cholecystectomy, were included in this study. Patients with diabetes mellitus, peritoneum involvement in malignancy, in whom ascites was noted per-operatively, previous history of abdominal surgery, complicated gallstones (cholangitis, choledocholithiasis and pancreatitis), cases converted to open cholecystectomy and patients of acutely inflamed gallbladders with leukocytosis (>11,000) and a temperature of >100<sup>o</sup>f prior to surgery were excluded. Patients were divided into intervention group (Group-A) and control group (Group-B). Patients were allocated to any of the two groups by lottery method. In group-A patients received antibiotic prophylaxis, whereas in group-B patients did not receive any antibiotic prophylaxis. A single dose of cefuroxime 1.5 gram was administered before induction of anaesthesia. All LC were carried out under GA by same surgical team. In both groups subcutaneous fat was approximated with interrupted vicryl 3/0 sutures and skin was closed with staples. Post-operative monitoring was carried out postoperatively as per our existing protocols. After 4 hours of surgery the patient was allowed to take sips of water. Infusion of intravenous fluids was stopped 6 hours after surgery however, the cannula was not removed. Those patients who had a smooth recovery on first post-operative day and tolerated orally were discharged. They were followed up in surgical OPD within seven days and then weekly for the next 3 weeks. Status of wound (normal, inflamed or pus) was recorded. Inflammation was managed with ciprofloxacin 500mg twice daily, purulent discharge was managed by dressings or laying open the wound. Patients' demographics and clinical characteristics, including perforation of the gallbladder and spillage of bile or calculi at surgery, were also noted down. Data so obtained was entered and analyzed using computer software, statistical package for social sciences

(SPSS) version 16.0. Mean and standard deviation was calculated for quantitative variables like age of patient. Frequency and percentages were calculated for qualitative variables like gender of patient and SSI. Effect modifiers like age, gender and duration of symptoms was controlled by stratification. Post-stratification chi square test was applied. P value of <0.05 was considered as significant.

## RESULTS

A total of 650 patients (325 in each group) were included in this study. Patients in group-A received antibiotic prophylaxis whereas patients in group-B did not receive any antibiotic prophylaxis. Patients ranged between 20-70 years of age. Mean age of the patients was 44.91±13.37 and 42.28±13.76 in group-A and B, respectively. In group-A 152 (46.7%) while in group-B 148 patients (45.5%) were males. In group-A, superficial site infection was seen in 4 patients (1.2%) and in group-B superficial site infection was observed in 13 patients (4.0%). The difference between two groups was statistically significant (p=0.027) as shown in Table-I. Mean duration of symptoms was 5.75±0.50 and 5.77±0.92 days in group-A and B, respectively.

Stratification with regard to age, gender and duration of symptoms was carried out and presenting in Tables which showed p value more than 0.05.

Superficial site infection	Group-A (Antibiotic prophylaxis)		Group-B (Without antibiotic prophylaxis)	
	No.	%	No.	%
Yes	4	1.2	13	04.0
No	321	98.8	312	96.0
Total	325	100.0	325	100.0

**Table-I. Distribution of cases by superficial site infection**

Chi Square = 4.893 P value = 0.027

## DISCUSSION

Surgical site infection is considered to be the third most common healthcare related infection. It prolongs the cure, thus leading to morbidity and increasing the cost of treatment many folds.<sup>1</sup>

In the literature the incidence of surgical site infection is about 3-4%.<sup>6,7</sup>

The use of single dose antibiotic prophylaxis during LC still lacks definitive evidence. The Department of Surgery, Kansai Medical University carried out an RCT on the subject with an adequate sample size. It showed a significantly low incidence of SSI in the group treated with prophylactic antibiotics (0.8 Vs 3.7%,  $p=0.001$ , OR 0.205 (95% CI: 0.069 to 0.606).<sup>8</sup> On the other hand Hassan AM et al<sup>9</sup> revealed that as for surgical site infection is concerned post-operatively there is no statistically significant difference when we compare both the groups after using ceftazidime as single dose. To prevent SSI post LC different combinations of antibiotics have also been tried but there has been no difference.<sup>10</sup> We have also published our data based on the culture of bile in open cholecystectomies.<sup>11</sup>

Recently a trend is developing against the use of antibiotics in LC especially in non-complicated cases. The rationale behind not using any antibiotics is two folds; it reduces the cost of surgery as well as the emergence of resistant bacteria is also minimized. A meta-analysis on the subject has also concluded that prophylactic antibiotics are not required in low risk LC.<sup>12</sup> But a recent comment regarding these meta-analyses has highlighted a problem that the included randomized trials were having small sample sizes therefore, underestimating the actual occurrence of surgical site infection postoperatively.<sup>13</sup> Similarly, many trials which comprise these meta-analyses also suggest that in order to get a statistically significant difference, large sample sizes are required because these complications are few and far between.<sup>14,15,16,17</sup>

If we look at our results, it is clear that the infectious complications are higher in the non-prophylactic group. This is in contrast to most of the previously carried out studies. We think that these trials were carried out using small sample size which might have underpinned the statistical power of these trials. If we look at our study the infection rate is less than 7%, as in our study, therefore, a large sample size would be required to detect

the difference. Similarly most of the patients were discharged within a few days and lacked proper follow up for a few weeks to detect these complications. We could find only one trial<sup>18</sup> where proper follow up has been reported. Therefore, we conclude that the large sample size as well as the proper follow up of our patients may have resulted in significant post-operative infectious complications in the non-antibiotic group.

## CONCLUSION

In conclusion, this study has shown that antibiotics administered as prophylaxis has prevented postoperative infectious complications in elective low-risk laparoscopic cholecystectomy and we recommend a single dose pre-operatively.

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### AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Syed M. Nauman	Research work	
2	Yousaf Haroon	Supervision	
3	Asrar Ahmad	Data analysis	
4	Irum Saleem	Literature search	