

Role of Prophylactic Antibiotics on Surgical Site Infection in Elective Laparoscopic Cholecystectomy

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Abstract

Objective: To compare the frequency of post-operative surgical site infection in patients receiving prophylactic antibiotics and without prophylactic antibiotics after elective laparoscopic cholecystectomy.

Method: Randomized Controlled Trial carried out at Surgical Unit-1, Holy family Hospital, Rawalpindi. Duration of this was 1st May 2019 to 31st Oct 2019.

Total 218 patients were enlisted according to the inclusion criteria of the study. Patients were randomly divided into two equal groups. Group A was given prophylactic antibiotic before surgery and Group B was considered as placebo. Outcomes were measured in terms of frequency of postoperative surgical site infection in patients of both groups. A p-value of 0.05 was considered statistically significant.

Results: Mean age (years) in the study was 45.62±12.66 whereas there were 128 (58.1%) male and 90 (41.3%) female patients. Frequency and percentage of post-operative surgical site infection in patients among both the groups was 9 (8.3%) and 2 (1.8%) respectively which was statistically significant (p-value 0.03).

Conclusion: The study concluded that there is a difference in frequency of surgical site infection in patient receiving prophylactic antibiotics and those with not receiving antibiotics, undergoing laparoscopic cholecystectomy. This is likely to be happen because of the overuse of antibiotics which are the key factors contributing to antibiotic resistance. Hence, it would be advisable that general public and doctors should play a role in order to avoid unnecessary exposure of antibiotics to the patient which don't play any significant role on post-operative surgical site infection.

Keywords: Antibiotics, laparoscopic cholecystectomy, Prophylactic, Surgical site infection.

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Introduction

For decades surgical site infection (SSI) has contributed a major burden in increasing morbidity and mortality over the surgical floor. According to studies, incidence of SSI is approximately 3-4%.¹ In order to improve the outcomes of surgery, prevention of such infection is the key factor. One way to decrease the incidence of

SSI is the use of prophylactic antibiotics. In clean contaminated and contaminated procedures, preoperative antibiotics significantly reduce bacterial contamination and thus SSI.⁴

Nowadays, laparoscopic cholecystectomy (LC) is the procedure of choice for symptomatic gallstones. Although it is minimal invasive but laparoscopic cholecystectomy has incidence of SSI, correlating with intraoperative findings and comorbidities of the patient². Studies have proved that infection rate after LC is far lesser than open cholecystectomy.^{1,6,7} Most occurring infective complications after open cholecystectomy are seroma formation, wound infection and wound dehiscence. Therefore, prophylactic antibiotics are routine practice

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at most surgical departments.^{2,3}

In elective LC, studies suggest that antibiotics should be given prior to surgery in high risk patients⁶. But the benefit of prophylactic antibiotics in low risk cases is still a subject of debate. Recent studies now suggest that low-risk patients do not require antibiotics before surgery.²⁻⁵

The aim of this research proposal is to compare the frequency of post-operative surgical site infection in patients receiving prophylactic antibiotics and without prophylactic antibiotics after elective laparoscopic cholecystectomy. The rationale of this proposal is that although antibiotics decrease morbidity postoperatively but overuse has aggravated the problem of drug-resistance, the accurate measure of magnitude and frequency of drug resistance needs further studies. Hence, by implementing this study in our routine practice, it will prevent patient from unnecessary exposure of antibiotics and it would be cost effective as well. This study will help a lot to avoid unnecessary exposure of antibiotics to the patient which don't play any significant role on post-operative surgical site infection.

Materials and Methods

Ethical committee approval received for the study and a Randomized Controlled Trial was done in Surgical Unit-1, Holy family Hospital, Rawalpindi of six months duration i.e. 1st May 2019 to 31st Oct 2019. Sampling Technique was consecutive non probability sampling. There were 109 patients in each group with a total of 218 patients.

Both male and female patients aged 18-60 years undergoing elective Lap cholecystectomy.

Acute cholecystitis, Empyema GB, Contaminated surgery, Body mass index ≥ 30 , Diabetes mellitus; BSR >200 mg/dl, Use of antibiotics within one week of the planned LC (As it may create a bias in one group) current study. All the patients has been fulfilling the selection criteria presenting at surgical unit – I, Holy Family Hospital, Rawalpindi were acknowledged about the study and written informed consent was taken. A random number list was generated for 218 patients randomly assigned them group A or Group B (109 patients each) using SPSS software. Every patient fulfilling the selection criteria was assigned study ID number in chronological order and after corresponding to the ID number of mentioned study group SPSS generated random

number list was allocated to the patient. The surgical procedural elements and the surgeon performing procedures was standardized to eliminate any potential confounding effect. All surgeries were done by consultant having >1 year post fellowship experience.

Group A was given prophylactic antibiotic 1gram ceftriaxone 30 minutes before surgery and group B was given 0.9% normal saline 5 ml (placebo). Postoperative surgical site infection was recorded as per operational definition on the day 7, 14 and 28 days follow up after surgery. All the information of patients were recorded.

Data was entered and analyzed in SPSS version 26. Qualitative variables like wound infection, gender and previous history of acute cholecystitis were measured as frequency and percentage. Quantitative variables like age, BMI were presented as mean+standard deviation. Surgical site infection in the two study groups were analyzed using chi square test. P-value of <0.05 would be considered statistically significant. For effect modifier like age, gender and previous history of acute cholecystitis, BMI stratification were done and post stratification chi square test was applied at 5 % level of significance.

Results

Mean age (years) in the study was 45.62 ± 12.66 years. There were 128 (58.1%) male and 90 (41.3%) female patients. Mean body mass index in the study was 28.36 ± 5.35 kg/m². There were 30 (27.5%) patients who were presented with history of acute cholecystitis. Frequency and percentage of post-operative surgical site infection in patients receiving prophylactic antibiotics and without prophylactic antibiotics after elective laparoscopic cholecystectomy was 9 (8.3%) and 2 (1.8%) respectively which was statistically significant (p-value 0.030) as shown in Table-1

Table 1: Comparison of Post-operative surgical site infection in patients among both the groups

Parameters	Two Groups		Total N (%)	P- value	
	Group A (antibiotics)	Group B (placebo)			
	N (%)	N (%)			
Surgical Site Infection (post operatively at day 28)	Yes	9 (8.3%)	2 (1.8%)	11 (5%)	0.03
	No	100 (91.7%)	107 (98.2%)	207 (95%)	
Total		109	109	218	

Table 2: Effect modifiers stratification with Comparison of Post-operative surgical site infection in Acute Cholecystitis patients among both the groups

Parameters	Surgical Site Infection (post operatively at 28 day)	Group-A (n=35)		Group-B (n=35)		P value
		n = 109	%	n=109	%	
Age (years)	18 - 40	Yes	5	13.2%	2.7%	0.095
		No	33	86.8%	97.3%	
	41 - 65	Yes	4	5.6%	1	0.167
		No	67	94.4%	71	
Gender	Male	Yes	4	5.7%	1	0.246
		No	66	94.3%	57	
	Female	Yes	5	12.8%	1	0.041
		No	34	87.2%	50	
BMI	< 23	Yes	2	7.1%	0	0.165
		No	26	92.9%	26	
	> 23	Yes	7	8.6%	2	0.08
		No	74	91.4%	81	
Previous history of acute Cholecystitis	Yes	Yes	8	26.7%	0	0.549
		No	22	73.3%	1	
	No	Yes	1	1.3%	2	0.753
		No	78	98.7%	106	

For effect modifier like age, gender, BMI and previous history of acute cholecystitis, stratification was done and compared with the frequency of post-operative surgical site infection in patients receiving prophylactic antibiotics and without prophylactic antibiotics after elective laparoscopic cholecystectomy as shown in Table-2

Discussion

The purpose of using prophylactic antibiotics is controversial in low-risk cases. Many studies strongly believe on the efficacy of preoperative antibiotics in low-risk patients.¹³⁻¹⁷ On the other hand, many research proposals discourage the use of antibiotics preoperatively undergoing laparoscopic cholecystectomy.⁸⁻¹² Furthermore, decline in infectious complications was the main reason of antibiotic use in such patients¹⁴⁻¹⁷. But the recent studies and clinical trials now conclude that rate of infection is very low in low-risk patients, so it does not alter the rate of postoperative SSI.⁸⁻¹²

In a study by Jae Do Yang, five hundred and nine laparoscopic cholecystectomies were performed on low-risk patients. It was observed that antibiotics given before the procedure did not alter the rate of infection post-operatively.³

In a study conducted by Pankaj Kumar, patients were divided into two groups. First group received antibiotics

before the procedure while second group received placebo (saline injections). It was observed that the rate of SSI was equal in both groups. It was also observed that SSI rate was not related to spillage of bile during the procedure. So antibiotics are not required in low-risk cases.⁴

Similarly, Chong ju, described in his study that four hundred and seventy-one patients underwent LC and the rate of SSI was 1.69%. The incidence of SSI was comparable for patients 5 out of 279 (1.79%) in group 1, who received second generation cephalosporin 1 gram I/V before surgery and 3 of 192 patients (1.56%) in group 2 (p=0.973), who were not given prophylactic antibiotic.⁵

Spaziani E study showed that preoperatively patients were divided into three groups. Group 1 patients (n=41) were given ampicillin-sulbactam; Group 2 patients (n=40) received ciprofloxacin while Group 3 patients (n=53) received no antibiotic. It was observed that there was infection in total 11 patients (8.2%) in all groups. Six patients developed infection in Group1 and Group 2 (three in each group 7.3%) while five patients (9.4%) developed infection in Group 3 (p=0.916).⁸

The impact of biliary spillage during LC on the frequency of SSI is also a matter of discussion in many studies. One group of authors mark bile spillage and bactibilia as an important factor in causing wound infection in low-risk patients.¹⁵ So they suggest antibiotic use pre-

operatively. Anderson DJ concluded in his study that third generation cephalosporin decrease bactibilia and thus postoperative infection¹⁴. In our study, we concluded that the rate of SSI is not influenced by the presence of bacteria in bile or perforation of gallbladder causing spillage.

Study conducted by Chong Ju⁷ showed that average age of patients in his study were 44.6+23.4 with gender distribution 15% and 85% respectively, the study showed that surgical site infection among both the groups was 4.41% and 2.63% respectively showing that the rate of postoperative SSI is not altered by giving antibiotics preoperatively and thus not an essential component in low-risk patients of LC.

Conclusion

The study concluded that there is a difference in frequency of surgical site infection in patient receiving prophylactic antibiotics and those with not receiving antibiotics, undergoing laparoscopic cholecystectomy. Hence, it would be advisable that patient should be prevent from unnecessary exposure of antibiotics which will be cost effective. Thus, general public and doctors should play a role in order to avoid unnecessary exposure of antibiotics to the patient which don't play any significant role on post op surgical site infection.

Conflict of Interest

None

Funding Source

None

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Authors Contribution

SS: Conceptualization of Project

SS, SA: Data Collection

SMD: Literature Search

UQ: Statistical Analysis

JSK: Drafting, Revision

SMD: Writing of Manuscript