

## Original Research Article

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# A prospective study: role of prophylactic antibiotics versus no antibiotics in elective laparoscopic cholecystectomy

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## ABSTRACT

**Background:** Elective gallbladder surgery is the most common abdominal surgical procedure. Antibiotic prophylaxis is a common conduct in open cholecystectomy, but there is ambiguity about the use of prophylactic antibiotics in laparoscopic cholecystectomy. Some surgeons suggest that the elimination of prophylactic antibiotics in patients undergoing elective laparoscopic cholecystectomy increase the incidence of postoperative infective complications but not to a statistically significant degree. The aim of this study was to evaluate the role of prophylactic antibiotics in laparoscopic cholecystectomy.

**Methods:** A total of 100 patients were included and they were randomized in 2 groups of 50 each. Group A was given prophylactic intravenously (IV) antibiotic within 1 hour before surgery and group B was not given any antibiotics. Results were compared and data analyzed statistically using chi-square and t test. Complications in both the groups were compared.

**Results:** Rate of surgical site infections were 6% (n=3) and 4% (n=2) in group A and B respectively; and the difference between them was not found statistically significant. All infections which occurred in present study were superficial surgical site infection. There was no evidence of deep-seated infections and none of the patients developed distant infection. There was no derangement in any of the biochemical parameter in this study.

**Conclusions:** We were not able to demonstrate any significant benefit from addition of prophylactic antibiotics in elective laparoscopic cholecystectomy.

**Keywords:** Antibiotic, Elective, Cholecystectomy, Laparoscopic, Prophylactic

## INTRODUCTION

Although surgical science has come a long way since the barbaric operations performed in Babylonian times with a 100% morbidity rate, the utopia of infection free surgery still eludes us. Surgery can now be performed very safely mainly because of advancements in anaesthesia, improved surgical techniques, better post-operative care and potent and advanced anti-microbials. However, the post-operative wound infections still remain the most difficult and important problem of current surgical practices.<sup>1</sup> Surgical site infections (SSI), a significant post-operative complication, can lead to considerable

morbidity and mortality for the patient and strict asepsis is an ideal method to prevent post-operative infections which is hard to achieve because it's impossible to eliminate bacteria completely from the surgical environment. Another solution is the use of prophylactic antibiotics.<sup>2</sup> The basic principle is to provide adequate level of drug in the tissue prior to the procedure, during the procedure and to continue the use for shortest period of time post operatively to make the antibiotics reach the tissue before the multiplication of bacteria. The benefits of preoperative antibiotics are well known.<sup>3</sup> A study favoured the use of prophylactic antibiotics, which markedly reduced the rate of SSI.<sup>4</sup>

Open cholecystectomy was associated with a wound infection rate ranging from 1-21% which was reduced to 3-7% by the use of prophylactic antibiotics, thereby making its use a common practice.<sup>5</sup> Now laparoscopic cholecystectomy is accepted worldwide as the gold standard in treatment of symptomatic gall stone disease.<sup>6,7</sup> It has many advantages over open cholecystectomy including its association with smaller wounds and minimal tissue damage and, therefore, presumably a lower risk of wound infection as compared to open cholecystectomy.<sup>8-12</sup>

Bile in the gall bladder or bile ducts is normally sterile but mechanical hindrance to bile flow facilitates bacterial contamination or chances of bactibilia increases in presence of active inflammation.<sup>13</sup>

Antimicrobial prophylaxis for laparoscopic cholecystectomy, although somewhat so controversial, is, nevertheless a routine component of surgical care. Many surgeons still use and recommend the administration of prophylactic antibiotics, on the contrary, many authors believe that antibiotic prophylactic may not be necessary in low risk patients undergoing elective laparoscopic cholecystectomy.<sup>14-23</sup> According to a study, 79% of patients who had undergone laparoscopic cholecystectomy were given prophylactic antibiotics preoperatively.<sup>24</sup>

Since laparoscopic cholecystectomy now being considered a clean surgery, and various studies on elective laparoscopic cholecystectomy have shown a low risk for infective complications this routine practice of antibiotic prophylaxis needs to be re-evaluated since prophylactic antibiotics therapy is no substitute for careful surgical technique using established surgical principles and general use of prophylactic antimicrobial therapy is not in the best interest of the patients and also leads to microbial resistance.<sup>19,20,25,26</sup>

## METHODS

This was a Prospective, observational and comparative study carried out in the year 2016-2017 in the department of surgery, Rajindra Hospital, Patiala. Hundred (100) patients with symptomatic gall stone disease undergoing elective laparoscopic cholecystectomy were studied. Patients were randomly divided into 2 groups of 50 each; Group A and Group B. age of the patients vary between 10-60 years, with BMI  $\leq 30$ , with no medical comorbidities (e.g., diabetes, cardiovascular) and those with acute cholecystitis and cholangitis/obstructive jaundice, intra op gall bladder rupture were also excluded. The preoperative preparation of the wound area was same for both groups.

Group A was administered single dose of 2<sup>nd</sup> or 3<sup>rd</sup> generation antibiotic IV within 1 hour before surgery. Group B did not receive any antibiotic. After induction of anesthesia, the skin was disinfected with a 10% solution

of povidone iodine. Laparoscopic cholecystectomy was performed in all patients using a 4-port technique. If spill of bile or stones was encountered, spilled stones were retrieved whenever possible, and local peritoneal lavage with 1000 cc saline was performed. The gallbladder was removed through epigastric port. A drain wherever required was placed in Morison at the end of surgery. The postoperative course was monitored and any incidents, such as fever, tachycardia, and infection of the trocar site were recorded.

## Assessment

All patients were followed up daily till discharged, then after 2 weeks, 4<sup>th</sup> week and 8<sup>th</sup> week following surgery to evaluate the status of the surgical wound and to look for signs and symptoms suggestive of any deep-seated infections. Patients with symptoms or alteration of blood analysis were further subjected to abdominal ultrasound.

## RESULTS

Age of the patients in the study ranged from 10 years to 60 years. The majority of patients were between 30 years to 45 years age group. On applying Pearson Chi-square test the p value came to 0.309 (not significant), which signifies that both the groups were matching and were comparable with respect to age distribution (Table 1).

**Table 1: Age distribution of patients.**

Group	Age group (in years)		
	<30	30-45	>45
	N (%)	N (%)	N (%)
<b>Group A</b>	5 (10)	36 (72)	9 (18)
<b>Group B</b>	2 (4)	42 (84)	6 (12)
<b>Total</b>	7 (7)	78 (78)	15 (15)

Out of total 100 patients in the study 80 (80%) were females and 20 (20%) were males. On comparing the groups individually following results were obtained. Out of 50 patients in group B 39 were females and the rest of 11 were males (Table 2, Figure 2). On comparison of the two groups on sex distribution the two-tailed p value came to 0.8031. The test applied was Fisher's Exact test. The p value suggested that both the groups were comparable and there was no significant difference in the sex distribution.

**Table 2: Sex distribution.**

Group	Sex	
	Female	Male
<b>Group A</b>	41	9
<b>Group B</b>	39	11
<b>Total</b>	80	20

Mean duration of surgery was 37.87 minutes. In group A mean duration of surgery was 37.9 minutes and in group B it was 37.84 minutes with standard deviation of 7.265

and 6.798 respectively. On applying t test for equality of means the p value came 0.9661 which suggests no statistically significant difference between two groups for duration of surgery (Table 3).

**Table 3: Duration of surgery (in minutes).**

Group	Duration of surgery		
	Mean	Standard deviation	Standard error of mean
<b>Group A</b>	37.87	7.265	1.027
<b>Group B</b>	37.84	6.798	0.961

Out of 100 patient's bile spillages was present in 5 (5%) patients and stone spillage was present in only in 4 (4%). In Group A out of 50 bile spillages was present in 2 patients and stone spillage occurred in 2 whereas in Group B bile spillage occurred in 3 patients and stone spillage was present in 2 patients. On applying Chi-square test p value came 0.764 which was not significant and suggested both groups were comparable (Table 4).

**Table 4: Spillage.**

Group	Spillage		
	No spillage	Bile spillage	Stone spillage
	N (%)	N (%)	N (%)
<b>Group A</b>	46 (92)	2 (4)	2 (4)
<b>Group B</b>	45 (90)	3 (6)	2 (4)

On post-operative day one, none of the patients of both groups had any infection. So no test was applicable for any kind of comparison (Table 5A).

**Table 5A: Infections complications on post-operative day 1.**

Group	Infection/pain at wound site	No infection
<b>Group A</b>	0	50
<b>Group B</b>	0	50

**Table 5B: Infections complications on post-operative day 2.**

Group	Infection at wound site	No infection
<b>Group A</b>	3 (erythema)	47
<b>Group B</b>	2 (erythema)	48
<b>Total</b>	5	95

On post-operative day 2 out of total 100 patients 5 (5%) had some kind of infection. The infectious complications were described by three factors purulent/seroma discharge from the wound site, erythematous rash around local wound site and wound dehiscence. In group A out of 50 patients 3 (6%) had erythema whereas in group B out of 50 patients 2 (4%) on applying Chi-square test

p value come out 0.646 which is not significant (Table 5B).

At the end of 2 weeks out of 100 patients 4 (4%) developed erythema. In group A out of 50 patients 2 (4%) developed erythema whereas in group B also out of 50 patients 2 (4%) developed erythema and on applying Chi-square test p value came out to be 0 which is not significant (Table 5C).

**Table 5C: Post-operative complications after 2 weeks of surgery.**

Group	De-hiscence	Seroma	Ery-thema	No infection
			N (%)	N (%)
<b>Group A</b>	0	0	2 (4)	48 (96)
<b>Group B</b>	0	0	2 (4)	48 (96)
<b>Total</b>	0	0	4 (4)	96 (96)

At the end of 4 weeks none of the patients of both the groups had any infection. So no test was applicable for any kind of comparison (Table 5D).

**Table 5D: Post-operative complications after 4 weeks of surgery.**

Group	Infection	No infection
<b>Group A</b>	0	0
<b>Group B</b>	0	0

At the end of 8 weeks none of the patients of both the groups had any infection. So, no test was applicable for any kind of comparison (Table 5E).

**Table 5E: Post-operative complications after 8 weeks of surgery.**

Group	Infection	No infection
<b>Group A</b>	0	0
<b>Group B</b>	0	0

Preoperative mean pulse for group A was 79.68 and for group B it was 82.08 with standard deviation of 5.227 and 2.586 respectively. Mean values calculated for both groups post-operative day 1, day 2 and 2<sup>nd</sup>, 4<sup>th</sup> and 8<sup>th</sup> week after surgery and comparison were made and data was analyzed by applying T test and all postoperative p values were  $>0.05$  which suggested that there was no significant change in pulse when compared between group A and group B after surgery (Table 6).

Preoperative mean total cell count were 7947.6 and 7538 for group A and group B respectively and mean calculated for all values of total cell count on post-operative day 1, day 2 and 2<sup>nd</sup>, 4<sup>th</sup> and 8<sup>th</sup> week after surgery and data was analyzed by applying T test and all p values came out to be more than 0.05 which was not significant (Table 7).

Mean value of preoperative total bilirubin in group A and group B was 0.948 and 0.95 with standard deviation of 0.28 and 0.27 respectively on comparing all the data of

post-operative day 1, day 2 and 2<sup>nd</sup>, 4<sup>th</sup> and 8<sup>th</sup> week after surgery with applying T test all p values were >0.05 which were not significant (Table 8).

**Table 6: Pulse (preoperative to 8 weeks after surgery).**

Pulse	Group	Number	Mean	Std. deviation	Std. error mean	P value
Pre-operative	A	50	80.88	4.024	0.575	0.0792
	B	50	82.08	2.586	0.369	
Day 1	A	50	81.72	4.199	0.593	0.4016
	B	50	80.96	4.802	0.679	
Day 2	A	50	80	5.421	0.766	0.3314
	B	50	80.96	4.356	0.616	
Week 2	A	50	80.6	3.386	0.479	0.4024
	B	50	79.84	5.419	0.766	
Week 4	A	50	81.8	2.864	0.409	0.1455
	B	50	80.88	3.384	0.483	
Week 8	A	50	82.08	2.586	0.369	0.0532
	B	50	80.64	4.304	0.615	

**Table 7: Total cell counts (preoperative to 8 weeks after surgery).**

WBC count	Group	Number	Mean	Std. deviation	Std. error mean	P value
Pre-operative	A	50	7947.6	1347.6	192.58	0.1855
	B	50	7538	1703.9	243.36	
Day 1	A	50	7792	1557.6	222.47	0.1936
	B	50	8173.8	1352.6	193.23	
Day 2	A	50	7572	1669.5	238.46	0.3924
	B	50	7848	1540.0	220.19	
Week 2	A	50	7356	1607.1	229.71	0.9431
	B	50	7380	1740.3	248.61	
Week 4	A	50	7616	1425.9	203.59	0.8869
	B	50	7572	1652.1	236.01	
Week 8	A	50	7398	1438.1	205.55	0.2502
	B	50	7762	1697.6	242.58	

**Table 8: Total serum bilirubin (preoperative to 8 weeks after surgery).**

T. bilirubin	Group	Number	Mean	Std. deviation	Std. error mean	P value
Pre-operative	A	50	0.948	0.28	0.039	0.9711
	B	50	0.95	0.27	0.039	
Day 1	A	50	0.936	0.27	0.038	0.7676
	B	50	0.92	0.268	0.038	
Day 2	A	50	0.906	0.23	0.032	0.2050
	B	50	0.97	0.27	0.038	
Week 2	A	50	0.926	0.25	0.036	0.9120
	B	50	0.92	0.28	0.040	
Week 4	A	50	0.914	0.23	0.033	0.894
	B	50	0.92	0.223	0.032	
Week 8	A	50	0.902	0.24	0.034	0.497
	B	50	0.87	0.231	0.033	

## DISCUSSION

The age of the patients in our study, ranged from 10-60 years with median age of presentation being 37.00 years

of the patients were in 30 years to 45 years age group which was similar to other studies.<sup>27,28</sup>

Women are three times more likely to develop gall stones than men.<sup>29</sup> In present study 80% were females and 20%

were males. This discrepancy may be due to small sample size.

The mean duration of surgery was 37.87 minutes with standard deviation of 7.265 in group A and in group B it was 37.84 minutes with standard deviation of 6.798. On applying T test, both the groups were comparable. Whereas in other study, the mean operating time was 41.6 minutes.<sup>30</sup>

Perforation during gall bladder surgery is attributed to traction, grasping, dissection, and removal of the gall bladder and occurs in 11% to 35% of laparoscopic cholecystectomy.<sup>15,18,19,23</sup> In present study we excluded such cases.

The effect of bile or stone spilling due to perioperative gallbladder perforation on the occurrence of surgical site infection is still controversial. A study stated that both positive bile culture and intraoperative gall bladder rupture were strongly associated with development of surgical site infection whereas many other studies have indicated that surgical site infections are not related to bile culture, rupture of gall bladder, or spillage of gallbladder stones or bile.<sup>17,19-23</sup> In present study out of 100 patients bile spillage was present in 5 (5) (2 in group A, 3 in group B) patients and stone spillage was present only in 4 (4) (2 in each group). On applying Chi-Square Test p value came 0.764, so there was no significant difference in spillage rate between two groups. And no infection occurred in any of these 9 patients in whom spillage occurred so it suggests that stones and bile spillage are not associated with surgical site infection and many other studies support this.

Post-operative stays and outcome in all 100 patients was uneventful and all patients discharged from hospital on post op day 1 or day 2 without developing any major complications or fever.

The results of role of antibiotic prophylaxis in elective laparoscopic cholecystectomy, analysed in several studies during past are conflicting. Several studies concluded that their use in laparoscopic cholecystectomy leads to a significant decrease in infectious complications.<sup>15-18,31-33</sup> Conversely, many studies have suggested that antibiotic prophylaxis is probably not required in elective laparoscopic cholecystectomy, since the infection rate of laparoscopic cholecystectomy is already low and the use of prophylactic antibiotics does not decrease the incidence of surgical site infections and other postoperative infectious complications.<sup>19-23,34-38</sup>

The average rate of surgical site infections for laparoscopic cholecystectomy has been reported in the literature to be between 0.4% and 6.3%.<sup>16,19,21,26,39</sup>

## CONCLUSION

Present study was for the assessment of any benefit of prophylactic antibiotics in elective laparoscopic cholecystectomy. For this we divided 100 patients into 2 groups of 50 each. Fifty patients were included in group A who received antimicrobial prophylaxis and fifty were included in group B who did not receive any antimicrobial prophylaxis. It has been concluded by the present study that there is no significant difference in infection rate between the two groups whether antibiotics were given or not. In present study all infections were superficial surgical site infections with no evidence of deep seated and distant infection. Post-operative stay and outcome in all 100 patients was uneventful and all patients were discharged from hospital on post op day 1 or day 2 without developing any major complications or fever.

We were not able to demonstrate any advantage of routine antibiotic prophylaxis as a part of elective laparoscopic cholecystectomy. Therefore, we do not recommend the use of antibiotic prophylaxis in elective laparoscopic cholecystectomy as it may prevent the chance of development of bacterial resistance and will make laparoscopic surgery more economical, thus saving a lot of revenue.

However, a much larger study is needed to confirm this and some other factors which were not included in our study should be assessed like intraoperative gall bladder rupture, intraoperative bile culture, low and high-risk groups should be properly defined.

In the end;

“It is the surgeon’s technique and proper sterilization that are superior to any antibiotic for a successful surgical outcome.”

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