



ROUTINE POST OPERATIVE ANTIBIOTIC PROPHYLAXIS IS UNNECESSARY TO PREVENT PORT SITE INFECTION IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY FOR LOW RISK GALL STONE DISEASE: A PROSPECTIVE RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Background: Cholecystitis is a global phenomenon prevailing more or less all over the world. One of the causes of increased morbidity after laparoscopic cholecystectomy has been port site infection. This study was carried out to compare the incidence of port site infections after elective laparoscopic cholecystectomy in patients receiving post op antibiotic prophylaxis to those receiving none. **Methods:** 100 patients undergoing elective laparoscopic cholecystectomy for low risk gall stone disease meeting the inclusion and exclusion criteria were divided into 2 groups. 50 patients allotted group I received post-operative antibiotic prophylaxis, while 50 patients in group II received none. Patients were followed postoperatively for wound infection on 10th to 14th day postoperatively.

Results: There was no significant difference in the incidence of wound infection following elective laparoscopic cholecystectomy in the two groups. 4 of 50 (8%) developed wound infection in group 1 while 2 of 50 (4%) developed wound infection in group 2. Moreover, the difference in the incidences of diabetes mellitus and intraoperative bile leak in the two groups was also found to be not significant. **Conclusion:** The use of post-operative antibiotic prophylaxis in patients undergoing elective laparoscopic cholecystectomy for low risk gall stone disease does not alter the risk of port site infection.

KEYWORDS: Laparoscopic cholecystectomy, antibiotic prophylaxis, port site infections.

INTRODUCTION

Cholecystitis is a global phenomenon prevailing more or less all over the world. Biliary tract disorders are one of the commonest abdominal conditions that the surgeons, gastroenterologists and radiologists encounter.

To come to a rational approach for management of a problem with such high prevalence such as Gall Bladder diseases, would decrease morbidity due to the disease. This will help in concluding to the most cost effective approach.^[1]

One of the causes of increased morbidity after laparoscopic cholecystectomy has been port site infection. Traditional safe practice of preoperative and post operative antibiotic prophylaxis long been employed

to prevent port site infections has been challenged recently. Use of unnecessary post operative antibiotic prophylaxis is now thought to contribute to development of resistant infections.

AIMS AND OBJECTIVES

To establish the unnecessity of post-operative antibiotic prophylaxis in elective laparoscopic cholecystectomy for low risk Gall stone disease to prevent port site infections by comparing the incidence in those receiving post op antibiotics to those receiving none.

METHODOLOGY

Place of study: The study was carried out from December 2015 to March 2016, in Ramakrishna Mission

Seva Pratishthan, Vivekananda Institute of medical sciences 99, SARAT BOSE Rd, Kolkata.

Ethical considerations: The study was conducted in accordance with the principles of Declaration of Helsinki for Biomedical Research involving Human subjects. Every effort was made to adhere to Indian Good Clinical Practice Guidelines. Written informed consent was mandatory for recruitment of study subjects. The study protocol, case report form and patients' informed consent were cleared by the institutional ethics committee.

Type of study: Study was a randomized, prospective study.

Target population: Residents of Kolkata and nearby areas of West Bengal.

Sample Size: 100 consecutive patients.

Subjects: patients attending surgical outpatient department of RMSP with diagnosis of gall stone disease established by ultrasound examination, meeting the following inclusion criteria but not excluded by the exclusion criteria.

Inclusion criteria: All patients of age 12 years or more and both sexes undergoing elective laparoscopic cholecystectomy successfully with or without intraoperative biliary spillage were included in the study.

Exclusion criteria: Presence of generalized peritonitis or grade 3 acute cholecystitis, conversion to open, complicated gall stones (cholangitis, choledocholithiasis, and pancreatitis)

Randomization: Computer generated randomization of subjects into two groups,
Group 1- Receiving post-operative antibiotic prophylaxis
Group 2- No postoperative antibiotic prophylaxis

Peri-Operative Methodology: All patients received one dose of 2nd generation cephalosporin at the time of

induction before as pre-op antibiotic prophylaxis and intra operative dose of 1g amikacin in case of any bile spillage from the gall bladder.

Thorough wash of the port site with normal saline was performed before port closure in all cases.

Gall bladder was removed from epigastric port without plastic packet in all cases.

Group 1 received 2 intravenous doses of 2nd generation cephalosporin postoperatively at 12 hour interval followed by oral doses at same intervals for 3 days.

Group 2 did not receive any post-operative doses of antibiotic.

All patients discharged on 3rd post op day. Patients in each group were given the same set of instructions to return to normal activity and to work as soon as possible.

Follow up: Discharged patients will be followed up in the Out Patient department on 10th – 14th post op day for collections or wound infections. A wound complication means redness or discharge from wound site.

RESULTS AND OBSERVATIONS

7 of 50 (14%) of patients were diabetic in group I, while 5 of 50 (10%) were diabetic in group II. This difference was found to be not significant. [Table 1]

Intra operative bile leak from the gall bladder occurred in 18/50 (36%) cases in group I, while in 21/50 (42%) cases in group II. This difference was found to be non significant. [Table 2]

4 of 50 (8%) developed wound infection in group 1 while 2 of 50 (4%) developed wound infection in group 2. This difference was found to be non- significant. [Table 3]

Table 1: Showing distribution of patients with Diabetes Mellitus amongst two groups.

		Group		Total	p Value	Significance
		Group I	Group II			
DM	NO	43(86)	45(90)	88(88)	0.538	Not Significant
	YES	7(14)	5(10)	12(12)		
Total		50(100)	50(100)	100(100)		

Table 2: Showing distribution of intraoperative biliary spillage amongst the two groups.

		Group		Total	p Value	Significance
		Group I	Group II			
Intraop spillage	ABSENT	32(64)	29(58)	61(61)	0.539	Not Significant
	PRESENT	18(36)	21(42)	39(39)		
Total		50(100)	50(100)	100(100)		

Table 3: Showing incidence of port site infections amongst the two groups.

		Group		Total	p Value	Significance
		Group I	Group II			
Wound Infection	N	46(92)	48(96)	94(94)	0.400	Not Significant
	Y	4(8)	2(4)	6(6)		
Total		50(100)	50(100)	100(100)		

DISCUSSION

In our study carried out on patients undergoing elective laparoscopic cholecystectomy for uncomplicated gall stone disease in Ramakrishna mission seva pratishtan from a period of dec 2015 to march 2016, we compared the incidence of development of wound infection amongst two groups, group 1 being those receiving routine post operative antibiotics, and group 2 being those receiving not post op antibiotics.

We found out that by the first post-operative opd visit, 8% of those belonging to group 1 developed wound infection while only 4% belonging to group 2 suffered from the same. This difference was though statistically insignificant. The treatment of these wound infections was variably complex involving adequate drainage along with empirical antibiotic therapy for 3 days followed by switching to specific antibiotics according to culture sensitivity report when available. Our results were comparable to reported studies^[2,3,4,5]

There were no significant differences in the distribution of patients with Diabetes Mellitus and the incidence of biliary spillage amongst the two groups, hence eliminating the above as confounding factors.

We did not include body mass index (BMI) as a possible variable to influence wound infection in open surgery, because BMI is not considered a risk factor in minimal invasive LC with small incision.

Iatrogenic gallbladder perforation in LC occurs in 2-25% of cases^[6,7,8,9] In the present study, we had higher incidence of bile leakage spillage (39%). Possible cause of this higher incidence could be different levels of operating surgeons and including all acute cases in the study.

Findings of this study does not support the general perception that bile leak increases the SSI. Out of 18 bile spillage in Group 1 (50 LC), only one port site infection was out of those that had spill during surgery. Similarly in Group 2 (50 LC), there were 21 bile spills, but here both the port site infections had history of bile spill. Other studies have reported similar findings^[8,9]

Risk of port site infections in Laparoscopic cholecystectomy is low and does not seem to be reduced by the routine use of post operative antibiotic prophylaxis in uncomplicated cases, as we found in this study. Based on recent published evidences and after the completion of our own study, we have now adopted the policy of not

administering routine post op antibiotics in uncomplicated cases of LC.

We hope that being conducted in a local scenario this study will help other institutions in developing countries like ours.

CONCLUSION

The use of post operative antibiotic prophylaxis in patients undergoing elective laparoscopic cholecystectomy for low risk gall stone disease does not alter the risk of port site infection. Thus, administration of routine post operative antibiotics in elective setting is unnecessary.

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