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A COMPARATIVE STUDY TO ASSESS THE NEED OF PROPHYLACTIC ANTIBIOTICS IN EARLY INFECTIVE COMPLICATIONS OF LOW RISK ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT **Background And Objectives:** Elective laparoscopic cholecystectomy has a low risk for infectious complications, but many surgeons still use prophylactic antibiotics. The aim of this study was to investigate the necessity and rationale for giving prophylactic antibiotics in early infective complications in low-risk laparoscopic cholecystectomy.

Study Design: Low-risk patients were randomly placed into 2 groups: 70 patients (group A) did not receive any prophylactic antibiotic and 70 patients (group B) received 1 g Ceftriaxone intravenously at the time of induction of anaesthesia. In both groups, incidence of infective complications were recorded and compared.

Results: In group A, there were 3 cases of post operative fever and 1 case of wound infection, while there were no cases of pulmonary infections and urinary tract infection. In group B, there were 2 cases of post operative fever and 1 case of wound infection, while there were no case of pulmonary infections and urinary tract infection. No significant difference existed in the incidence of complications between the groups. Prolonged duration of surgery and Bile or Stone spillage were statistically significant risk factors in determining post operative infective complications.

Conclusions: Use of prophylactic antibiotic does not affect the already low incidence of postoperative infective complications and surgical site infections. Hence, prophylactic antibiotic is not necessary in low-risk elective laparoscopic cholecystectomy.

KEYWORDS : Elective laparoscopic cholecystectomy . Prophylactic antibiotic . Surgical site infections . Infective complications .

INTRODUCTION

Gallstones is the most common biliary pathology. It is estimated that gallstones affect 10–15% of the population in Western societies. They are asymptomatic in the majority of cases. Approximately 1–2% of asymptomatic patients will develop symptoms requiring surgery per year, making cholecystectomy one of the most common operations performed by General surgeons.[1]

Surgical site infections (SSIs), a significant postoperative complication can lead to considerable patient morbidity. Preventing postoperative infection is an essential factor in improving the results of surgical procedures. One approach to preventing infection is the administration of prophylactic antibiotics.[2,3] Open cholecystectomy was associated with a wound infection rate ranging from 1-21%. The use of prophylactic antibiotics reduce this rate to 3-7% and so has become common practice.[3-6] Laparoscopic cholecystectomy is associated with smaller wounds and minimal tissue damage and, therefore, presumably a lower risk of wound infection. Many workers showed that the overall incidence of SSI in laparoscopic surgery is 0.5% and in open surgery it is 1.8% which is statistically significant ($p<0.01$).[3,5,7-9] Largely, laparoscopic techniques offer a lower incidence rate of SSI.

At present, Laparoscopic cholecystectomy (LC) is the standard treatment for symptomatic cholelithiasis. The use of prophylactic antibiotics as a means of preventing surgical site infections and other complications is still controversial in elective laparoscopic cholecystectomy which has low risk of infectious complications.

At present, there are 7 Meta analysis[10-16] and many randomised controlled trials[2,4,6-8] which suggest that antibiotic prophylaxis has no role in preventing SSI in low risk elective laparoscopic cholecystectomy. On the contrary, 4 recent Meta analysis [26-29] and certain randomised control trials[30,31] still find it beneficial to give antibiotic prophylaxis in preventing SSI in low risk elective laparoscopic cholecystectomy. Thus, controversy still surrounds the routine use of prophylactic antibiotics in elective laparoscopic cholecystectomy. So, present study was designed to evaluate the necessity and rationale of antibiotic prophylaxis in elective laparoscopic cholecystectomy.

Method -

Study is a randomized controlled prospective study comparing the two groups of randomly allocated patients undergoing elective laparoscopic cholecystectomy (n=70) in each group A and B. Informed written consent were taken from all the patients participating in the study. Inclusion criteria being adult patients (Age>18 years) who underwent Low Risk Elective Laparoscopic Cholecystectomy.[23] Low risk patients were defined as those without past or present objective evidence of biliary obstruction or recent severe acute infection. Exclusion Criteria[32] were (1) Conversion to open cholecystectomy (2) Partial cholecystectomy (3) High Risk Laparoscopic Cholecystectomy if patient had (a) Beta lactam allergy (b) Received any antibiotics within 7 days of the planned procedure (c) Temperature > 38°C (d) an elevated white blood cell (WBC) count (>12,500) (e) evidence of obstructive jaundice (dilated CBD, bilirubin level >3 mg/dl or preoperative choledocolithiasis) (f) a history of biliary tract surgery, pancreatitis, hepatic disease, or prosthetic valves (g) Parkland Grade 5[33] (h) Tokyo Grade 2 and 3.[34]

Computer generated random numbers were used for random allocation of patients into different group. GROUP A (70 patients) containing randomly enrolled patients, did not receive any prophylactic antibiotic. GROUP B (70 patients) containing randomly enrolled patients, received 1 g Ceftriaxone intravenously at the time of induction of anesthesia. After induction of anesthesia skin was disinfected with betadine. Elective Laparoscopic cholecystectomy was performed in all patients. Duration of surgery, Bile or Gall stone spillage, Length of hospital stay were also noted as per the case record form. The postoperative course was monitored for fever, surgical site infections[35], urinary tract infection, pulmonary infection and noted as per the case record form.

Statistical analysis of quantitative data was summarized as mean and Standard deviation (SD) whereas nominal/ categorical variables were expressed as percentage (%). Unpaired student t-test was used for comparison of quantitative data between groups while Chi-square test and Fischer's Exact test were used for nominal/categorical analysis. Fisher's exact test is a statistical significance test used in the analysis of contingency tables. P-value < 0.05 was taken as significant.

RESULTS

There was no significant difference in the mean age among the groups : Group A (45.85 ± 12.94 years) and Group B (46.12 ± 13.37 years) with p value of 0.451. In each group, 35.71% cases are males and 64.29% cases are females, rendering Male : Female ratio to be 1:1.8. Distribution of cases as per parkland grades is similar in both groups with p value of 0.85 which is statistically not significant. In both groups, maximum cases are of Parkland Grade 3 and minimum of Grade 4.

Incidence of SSI in both groups is very low (1.43%) and comparable to each other. In the group A, mean duration of surgery was 58.03 ± 25.6 mins, while in the group B it was 56.09 ± 24.02 mins (p-0.322) which was statistically not significant. Mean length of hospital stay in Group A is 1.77 ± 0.78 days and in Group B is 1.99 ± 0.86 days with p value of 0.063 which is statistically insignificant. Incidence of bile or stone spillage in Group A is 15.71% and in Group B is 28.57 % with a p value of 0.067 which is statistically not significant.

Both the cases of SSI had duration of surgery more than 2 hours because of dense omental adhesions, inflammed thickened gall bladder and Parkland Grade 4. While in non SSI patients, only 2 out of 138 patients had duration of surgery more than 2 hrs. The Fischer exact test statistic value is 0.0006. Hence, it is statistically significant. Both the cases of SSI had intraoperative bile or stone spillage while in non SSI patients, only 29 out of 138 patients had bile or stone spillage. The Fischer exact test statistic value is 0.0478. Hence, it is statistically significant.

Incidence of post operative fever (indicative of infection) in Group A is 4.29% and in Group B is 2.86 % with a p value of 0.649 which is statistically not significant.

Table No. 1 Incidence Of SSI In Both Groups

SSI	GROUP A		GROUP B	
	No.	%	No.	%
PRESENT	1	1.43	1	1.43
ABSENT	69	98.57	69	98.57

Table No. 2 Evaluation of Duration of Surgery as an independent risk factor for SSI

Duration of Surgery as an independent risk factor for SSI		
Duration of Surgery	SSI present	SSI absent
<2 hr	0	136
> 2 hr	2	2

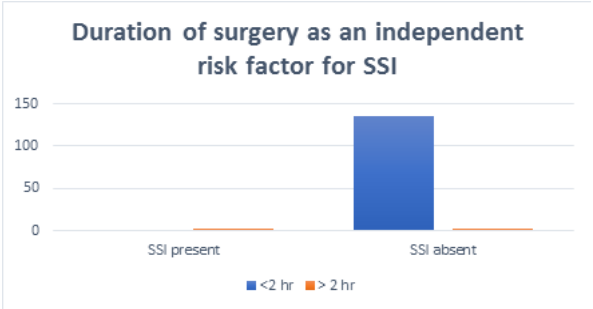
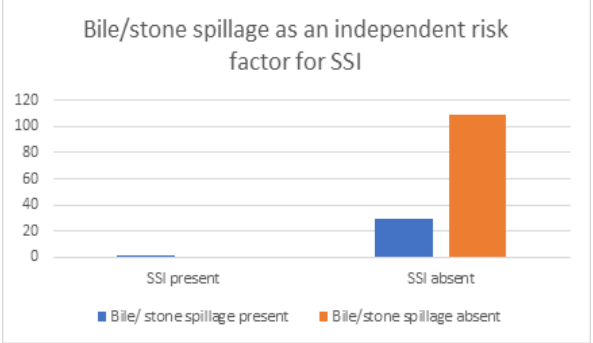


Table No. 3 Evaluation Of Bile Or Stone Spillage As An Independent Risk Factor For SSI

Bile/stone spillage as an independent risk factor for SSI		
	SSI present	SSI absent
Bile/ stone spillage present	2	29
Bile/stone spillage absent	0	109



DISCUSSION

This was a randomized, prospective, comparative study. Patients undergoing elective laparoscopic cholecystectomy were divided into 2 randomised groups by random sequence generated by computer. Patients with Tokyo Grade 3 acute cholecystitis and Parkland grade 5 cholecystitis were excluded from the study. Group B patients received 1gm Ceftriaxone at the time of induction as prophylactic antibiotic and Group A patients didn't receive any prophylactic antibiotic. Incidence of SSI and other deep infections were recorded in patients and then compared between 2 groups.

Since the introduction of laparoscopic cholecystectomy, role of prophylactic antibiotics have been questioned because of low infection rates. Most of the randomized trials and their meta-analysis have concluded that low risk elective laparoscopic cholecystectomy does not require prophylactic antibiotics.[2,4,10-16] However, a few recent meta analysis have shown that prophylactic antibiotics in elective laparoscopic cholecystectomy is beneficial in reducing the incidence of SSI.[26-29] These mixed results warrant further study of role of prophylactic antibiotics in elective laparoscopic cholecystectomy.

In this study, we observed that there was no significant difference in population demographics of both groups viz mean age of patients , sex ratio of patients (female predominance in both groups) and distribution of parkland grading. In both groups, maximum cases were of Parkland Grade 3 and minimum of Grade 4.

In this study, we found that in both Group A and Group B, 1 case of SSI (Surgical site infections) was present in each group. Hence, incidence of SSI in both groups was low and same viz 1.43 %. **(Table 1).** Both were superficial SSI and were treated by oral antibiotics for 5 days and were resolved. There was no incidence of Deep or Organ/Space SSI in either group. Thus, no significant difference was observed amongst both groups regarding SSI. These results were corroborate to other workers suggested that there was no statistical significant difference in incidence of SSI in both groups and that prophylactic antibiotics doesn't help in reducing incidence of SSI amongst elective laparoscopic cholecystectomy.[2,12,14,21-25,36] Albeit, other workers have shown that prophylactic antibiotics in elective laparoscopic cholecystectomy is beneficial in reducing the incidence of SSI.[26-29] Therefore, we can infer that in our Center no difference in incidence of SSI was found in both groups, hence prophylactic antibiotics doesn't further decrease already low incidence of SSI in elective laparoscopic cholecystectomy. Moreover, they increase the cost of procedure, increase antibiotic resistance and expose patients to potential harmful adverse reactions of antibiotics.

Mean duration of surgery was similar in both groups and statistically insignificant. These results were comparable to other workers.[2,18,21,22,32,36] Although, in the study by Kim H J et al[23] duration of Surgery was found to be significantly lower in no antibiotic group compared to antibiotic group. Evaluation of prolonged duration of surgery as an independent risk factor in our study was statistically significant as both cases of SSI had duration of surgery more than 2 hours because of dense omental adhesions, inflammed thickened gall bladder and Parkland Grade 4. **(Table 2)** Similar results were obtained by other workers which concluded that prolonged duration of operation is an independent risk factor for SSI in laparoscopic cholecystectomy.[37-39] Hence, we gather that it is safe and rational to give prophylactic antibiotic in elective laparoscopic cholecystectomy if prolonged duration of operation is expected.

In our study, mean duration of hospital stay in Group A was 1.77 days and in Group B was 1.99 days which were comparable and p value was 0.063. These results were corroborate to studies by other workers.[12,22,36] But, Yan R C et al[15]and Liang Bet al[27] studies showed that length of hospital stay in those patients who received prophylactic antibiotic was significantly less as to those who didn't receive any antibiotic. So, we conclude that in hospital setting prophylactic antibiotic before elective laparoscopic cholecystectomy didn't significantly reduce hospital stay.

Incidence of bile or stone spillage in both groups was found similar. In Group A, it was 15.71% and in Group B is 28.57 % with no statistically significant difference. Many studies also showed similar data.[12,23,30,32,36] Evaluation of bile or stone spillage as an independent risk factor in our study was statistically significant as both cases of SSI had duration of surgery more than 2 hours. **(Table 3)** Similar results were obtained by other workers which concluded that bile or stone spillage is an independent risk factor for SSI in laparoscopic cholecystectomy.[40-44] Hence, we conclude that if bile or stone spillage occurs during elective laparoscopic cholecystectomy , it should not be ignored and aspiration along with thorough lavage should be done.

In our study, Incidence of post operative fever (indicative of infection) in Group A is 4.29% and in Group B is 2.86 % with a p value of 0.649

which were statistically insignificant. These results were comparable to Gaur A et al[45] and Kumar V et al[25] studies.

There were no incidences of UTI or Pulmonary infection in either Group A or B in our study. Therefore, we conclude that a larger sample size and a longer follow up is required for evaluating such rare infective complications.

CONCLUSION

In our study, it was observed that low risk elective laparoscopic cholecystectomy has a very low incidence of infective complications (~1.43%) which is at par with clean cases. Also, single dosage of prophylactic antibiotic doesn't reduce the incidence of SSI in low risk elective laparoscopic cholecystectomy and neither does it significantly affect length of hospital stay. Prolonged duration of operation (>2 hr) and bile or stone spillage emerged out to be statistically significant independent risk factors for SSI in laparoscopic cholecystectomy.

So, we conclude that there is no necessity and rationale in giving prophylactic antibiotic in case of low risk elective laparoscopic cholecystectomy. This practice may help in reducing the development of antibiotic resistance, save the patient from potential side effects of antibiotics and helps in reducing the cost of operation.

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