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Original Article

Single Dose Prophylactic versus Multiple Dose Antibiotics for Reducing Surgical Site Infection in Elective Laparoscopic Cholecystectomy

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Abstract

Background: *Surgical Site Infection (SSI) is a less commonly encountered condition in Laparoscopic Cholecystectomy (LC). Whether prophylactic use of antibiotics in elective LC can reduce the incidence of SSI remains inconclusive. Prophylactic multiple dose antibiotic therapy after surgery is a common practice in our country to combat SSI. The study aimed to compare the incidence of SSIs after elective LC with single dose antibiotic and conventional multi doses prophylaxis antibiotic regimen.*

Materials and methods: *This prospective randomized study was conducted during the period September 2019 to August 2020. A total of 100 patients who were admitted for elective LC in the Department of Surgery, Chittagong Medical College Hospital were included in this study. Patients were randomly allocated into two equal groups based on antibiotic prophylaxis: Single Dose Group (SDG) and Multiple Dose Group (MDG). SD group was given Cefuroxime axetil (750 mg) intravenously at the time of induction of anaesthesia and MD group was given Cefuroxime axetil (750 mg) intravenously at the time of induction of anaesthesia, followed by Cefuroxime (500 mg) orally twice daily for 7 days. Patients were followed up till 30th post-operative day to assess postoperative outcome in terms of SSI and other complications.*

Results: *Both the groups were similar in terms of their demographic characteristics. The mean duration of postoperative hospital stay was 1.44±0.57 and 1.5±0.61 days in SDG and MDG, respectively. Grade I (Normal healing with mild bruising or erythema according to Southampton Wound Grading System) was found 3(6.0%) and 5(10.0%) in SDG and MDG, respectively (p=0.461).*

Conclusion: *As there is no statistical difference between use of single dose antibiotic before and use routine multi doses antibiotic before and after elective LC, it could be concluded that preoperative single dose antibiotic is comparable to conventional multi doses prophylaxis antibiotic regimen in elective LC.*

Key words: Elective laparoscopic cholecystectomy; Perioperative; Prophylactic antibiotics; Surgical site infection.

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INTRODUCTION

Surgical Site Infection (SSIs) are the leading cause of health care-associated infections and the development of SSI results in prolonged hospital stay, extra costs, and increased morbidity and mortality.[1,2] Antibiotic prophylaxis to prevent SSI is one of the most widely accepted practices in surgery.[3]

LC is the gold standard surgical technique for the treatment of symptomatic gallbladder stones and particular benign gallbladder diseases.[4,5] Studies have shown that the incidence of SSI following LC is approximately 0.4–1.13%, which is significantly lower than that of open cholecystectomy by 3–47%.[6-8] The possible

reason is that the LC incision is smaller, and the chance of wound exposure and contamination using a trocar is lower, significantly reducing the incidence of surgical site infections.[9,10] Due to the low incidence of SSIs and unnecessary high medical costs, current guidelines do not support the routine use of prophylactic antibiotics in elective LC.[11] On the other hand, a recent meta-analysis demonstrates that the perioperative use of antibiotics in LC is effective in low-risk patients, possibly reducing the incidence of SSIs.[12]

Prolonged use of antibiotics in postoperative period is common in surgical practice in Bangladesh. Most of the surgeons traditionally practice multiple dose regimens for 7 days postoperatively in absence of infection. Due to undue fear of SSIs, there is misuse of antibiotics, which can result resistance of antibiotics to microorganism as well as increased cost.[13] So, this study aimed to investigate whether single dose prophylactic antibiotics in case of elective LC is as effective as multiple dose antibiotics to reduce SSIs.

MATERIALS AND METHODS

This prospective randomized study was conducted at Chittagong Medical College Hospital, Chattogram, Bangladesh from September 2019 to August 2020. Study protocol was approved by the Ethical Review Committee of Chittagong Medical College. A total of 100 patients were included in this study after obtaining written informed consent from individual patients.

Patients age between 18- 60 years, admitted to the surgery ward for elective LC were included in this study. Patients with common bile duct stone, acute cholecystitis, empyema and mucocele of gallbladder, jaundice or abnormal liver function test, diabetes mellitus, immunosuppression state, having features peritonitis or cholangitis, and pregnant women were excluded from this study.

After admission, detailed history, clinical examination findings, routine blood investigation reports and ultrasonography report were noted in proforma sheet. Patients were randomly allocated into two equal groups based on antibiotic prophylaxis: Single Dose (SD) group and Multiple Dose (MD) group comprising 50 patients in each group. SD group was given Cefuroxime axetil (750 mg) intravenously at the time of induction of anaesthesia and MD group was given Cefuroxime axetil (750 mg) intravenously at the time of induction of anaesthesia, followed by Cefuroxime (500 mg) orally twice daily for 7 days.

Routine 4 ports LC was performed by trained general surgeons under general anesthesia. All patients were followed-up at 3rd POD, 7th POD and 30th POD (Final follow up) for any SSIs or other complications. Primary outcome measure was SSI. SSI was defined as an infection related to operative procedure that occurs at or near the surgical incision within 30 days of procedure and Southampton Wound Grading System (Grade 0 – normal healing, Grade I–normal healing with mild bruising or erythema, Grade II –erythema plus other signs of inflammation, Grade III–clear or hemoserous discharge, Grade IV- pus formation, Grade V- deep or severe wound infection with or without tissue breakdown, hematoma requiring aspiration) was followed to grade SSIs.[14]

Data analysis was performed using the SPSS (Statistical Package for the Social Sciences) software, version 23.0. The data were expressed as mean (Standard Deviation–SD). Unpaired t test was applied to examine statistically significant differences between the two groups for age, duration of operation and length of postoperative hospital stay. Categorical variables were presented as number (Percentage) and compared between groups by Chi square or Fisher exact test as appropriate. p value <0.05 was considered to as statistically significant.

RESULTS

A total of 100 patients were included (50 in each group). Age ranged between 22-60 years and 78% were female with a female to male ratio of 3.5:1. Table I shows that both the groups were comparable in terms of their baseline age and sex distribution.

Table I Distribution of demographic characteristics of the study patients

Age (In years)	SD Group (n=50)		MD Group (n=50)		p value
	n	%	n	%	
Age, (Mean ±SD) years	39.74±10.49		40.72±9.84		0.631*
Sex					
Male	15	30.0	11	22.0	0.362†
Female	35	70.0	39	78.0	

SD: Single dose prophylactic antibiotic, MD = Multiple dose prophylactic antibiotic, *Unpaired t-test, †Chi-square test.

The mean duration of operation is 42.6±7.91 min in Group I and 40.2±9.31 min in Group II. The difference is statistically not significant (p>0.05) between two groups. The mean duration of postoperative hospital stay is 1.44±0.57 days in Group I and 1.5±0.61 days in Group II. The difference is statistically not significant (p>0.05) between two groups (Table II).

Table II Comparison of mean duration of operation and duration of hospital stay between two groups

Variabels	SD Group (n=50)	MD Group (n=50)	p value
Duration of operation, in minutes	42.6±7.91	40.2±9.31	0.168*
Length of hospital stay, days	1.44±0.57	1.5±0.61	0.245*

SD: Single dose prophylactic antibiotic, MD = Multiple dose prophylactic antibiotic, Data were expressed as mean ±SD, *Unpaired t-test.

Table III shows that in all (100.0%) patients, Grade 0 is found on 3rd POD in both groups. In majority (94.0%) of patients, Grade 0 is found on 7th POD in Group I and 45(90.0%) in Group II. 3(6%) patients and 5 (10%) patients show Grade I in Group I and II respectively. All (100.0%) patients show Grade 0 in 30th POD in both groups. The difference is not statistically significant (p>0.05) between two groups.

Table III Distribution of the study patients by evaluation of SSI by Southampton Wound Grading System (n=100)

Evaluation of SSI by Southampton wound Grading system	SD Group (n=50)		MD Group (n=50)		p value
	n	%	n	%	
3rd POD					
Normal healing	50	100.0	50	100.0	NA
7th POD					
Normal healing	47	94.0	45	90.0	0.461†
normal healing with erythema	3	6.0	5	10.0	
30th POD					
Normal healing	50	100.0	50	100.0	NA

SD: Single dose prophylactic antibiotic, MD = Multiple dose prophylactic antibiotic, NA: Not applicable, †Chi-square test.

DISCUSSIONS

Cholelithiasis is more common in females in their 4th decade of life. In the current study, 78% of the patients were females and male to female ratio was 1:3.5 and the mean age of the patients was around 40 years, which coincide with the findings of other similar studies.[15-17]

In this current study, it is observed that the mean duration of operation is 42.6±7.91 min in SD Group and 40.2±9.31 min in MD Group and the difference was not statistically. Our study findings agreed with the findings of Thapa et al. study, where the mean duration of operation were 42.84±28.66 min and 40.12±24.67 min in SD and MD group, respectively.[17]

In this present study, mean duration of hospital stay was also comparable between two groups. In Thapa et al. study, there was longer length of hospital stay in multiple dose group.[17] The investigators found that mean length of hospital stay was 2.02±0.13 days and 3.15±0.36 days in single dose antibiotic prophylaxis and multiple dose group respectively.

In this current study, only wound erythema was seen in both groups but the difference was not significant statistically. It was observed that 100.0% patients have Grade 0 (According to Southampton Wound Grading System) in 3rd pod in both groups. Grade I are found 6.0% and 10.0% in SD and MD Group, respectively during 7th POD. In 30th POD, normal healing was observed in all studied patients irrespective of the study group. In Thapa et al. the SSI was slightly higher in SD group but it was not significantly different, which was comparable with other studies.[17,16,18,19] This suggested that single dose antibiotic was found effective as multiple dose antibiotics in terms of rate of post-operative SSI.

LIMITATIONS

Sample size was small and included from a single tertiary level hospital. Moreover, study included a highly selective low-risk group of patients.

CONCLUSION

In conclusion present study findings suggested that during elective LC in a low-risk group of patients, single preoperative Cefuroxime axetil injection was equally effective in preventing SSIs as multiple dose pre and postoperative intravenous and oral Cefuroxime axetil.

RECOMMENDATIONS

Based on the study findings, single dose of Cefuroxime axetil (750 mg) could be safely use in elective LC as prophylactic antibiotic for SSIs. However, considering the limitations, a larger sample, with multi-center RCTs with sufficient statistical power is still required to further demonstrate the difference in postoperative infection rates in high-risk patients.

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DISCLOSURE

The authors declared no conflicts of interest.

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