Comparative Study on Single Dose Prophylactic Antibiotic in Laparoscopic Cholecystectomy Versus Conventional Post-operative Antibiotic Use Among Cholelithiasis Patients

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Abstract

Introduction: Cholelithiasis is one of the common health problems encountered in surgical practice worldwide. Laparoscopic cholecystectomy is the standard surgical management for cholelithiasis and it is preferably practiced everywhere. In many trials worldwide, it has been established that the single dose of prophylactic antibiotics is as effective as the multi-dose regimens. But still out of undue fear of surgical site infections the prophylactic antibiotics are being misused and continued for many days in postoperative period. This raises treatment costs for patients and contributes to the development of antibiotic resistance in microbes. The use of prophylactic antibiotics prior to laparoscopic cholecystectomy has led to reconsideration of the necessity for post-operative antibiotic therapy.

Objective: This study is aimed to compare complications related result of single dose prophylactic antibiotic with cefuroxime with conventional post-operative antibiotic use in laparoscopic cholecystectomy among cholelithiasis patients.

Methods: This observational case-control study was carried out in the Department of Surgery , Mymensingh Medical College Hospital between June 2019 and October 2020. Total 96 patients of diagnosed cholelithiasis were included. In group-I, there were 48 patients who were treated with single dose prophylactic intravenous cefuroxime and in group-II, there were also 48 patients treated with postoperative multiple dose conventional antibiotics. Surgical site infections following surgery were monitored in both groups.

Results: Total post-operative infection rate was 6.2% found in single dose prophylactic antibiotic group and 4.2% found in postoperative multiple dose antibiotic group, the difference of rates is statistically non-significant ($p = 0.646$).. Most of the infections were superficial. Almost no deep seated or distant infection was found in both groups.

Conclusion: There is no statistical difference ($p = 0.646$) between the rates of post-operative skin and soft tissue infection after prophylactic preoperative single dose cefuroxime (1.5 gm) intravenously and conventional multiple dose antibiotics in elective laparoscopic cholecystectomy. So, preoperative single dose of cefuroxime (1.5 gm) can be used safely as like as conventional multiple dose antibiotics in elective laparoscopic cholecystectomy.

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Introductio

Laparoscopic cholecystectomy is a commonly performed and well-established procedure for managing gallstone disease. It is now considered the first option and has become the “gold standard” in treating benign gallbladder disease.[1] The incidence of infectious complications after laparoscopic cholecystectomy is significantly lower than conventional open cholecystectomy.[2] The incisions made during laparoscopic cholecystectomy are smaller compared to those in open cholecystectomy. It results in lesser activation of the inflammatory response following the laparoscopic procedure.[3] SSI is a major post-operative complication associated with any surgery which will lead to increased hospital stay, loss of productive hours, hospital cost and patient morbidity and mortality. While antimicrobial prophylaxis is key in lowering the incidence of surgical site infections (SSIs), other elements—such as adherence to standard infection-control measures, the surgeon’s skill and method, and the length of the procedure, hospital and operating-room environments, instrument sterilization issues, preoperative preparation, perioperative management, and the underlying medical condition of the patient may have a strong impact on SSI rates. But, frequently, antibiotics are used irrationally for unduly long period in an attempt to reduce the SSI, which will increase the financial burden to the hospital and probable emergence of antibiotic resistance and antibiotic related adverse effects. A systematic predefined approach is to be followed to prevent it. Laparoscopic cholecystectomy is a minimally invasive procedure with a lower risk of contamination. There is no consensus on usage of prophylactic antibiotic in Laparoscopic Cholecystectomy.[4] The over-use of antibiotics can emerge antibiotic resistance and increases treatment cost.[3] Guidelines recommend the use of an antimicrobial drug that should be effective against the microorganism most likely to contaminate the surgical site, to be given in an appropriate dosage and at a time that will maintain sufficient levels in both plasma and tissues throughout the time when contamination risk is present. The antibiotic should have a strong safety profile and be used for the shortest duration necessary to reduce the risk of resistance and keep costs low.[4] In low-risk patients having elective laparoscopic cholecystectomy, antibiotic prophylaxis might not be required.[5,6,7] It being a clean contaminated surgery, use of prophylactic antibiotics (a brief course of an antimicrobial agent administered just before an operation) is mandatory to decrease the incidence of surgical site infections.[8] However, clinicians do not give up the tradition of using postoperative antibiotics despite recent evidences supporting single dose prophylactic antibiotic use over multiple doses of antibiotics during and after surgery.[9]

In many trials worldwide, it has been established that the single dose of prophylactic antibiotic is as effective as the multidose postoperative regimens. But still due to fear of surgical site infections, single dose prophylactic antibiotic is not practiced routinely; rather multiple doses postoperative antibiotics are continued for many days that increases cost burden and possibility of antibiotic resistance in the microorganisms.[10]

Methods

It was an observational case-control study. The study was carried out in the Departmet of Surgery, Mymensingh Medical college Hospital, Bangladesh from June, 2019 to October, 2020 (seventeen month duration). The study population consisted of patients diagnosed with cholelithiasis who were admitted to the Surgery Department at MMCH during the study period and met the inclusion and exclusion criteria. Total sample population was 96. There were 48 patients in group-I who were treated with single dose prophylactic intravenous cefuroxime and 48 patients in group-II who were treated with multiple doses of postoperative conventional antibiotics. Outcome in terms of surgical site infections was assessed in day 3 and day 7. By following standard procedure, the principal investigator entered, checked, rechecked and scrutinized all data. Data were analyzed by SPSS version 21. A p-value below 0.05 ($p < 0.05$) was used to determine statistical significance. Results were presented by choosing of variables in the form of tables, graph, percentage, frequency, chart etc. Statistical analyses were done by using appropriate statistical tool. Data were expressed in means with standard deviations for continuous variables and categorical variables were presented as frequency.

Results

Total sample population was 96. There were 48 patients in group-I treated with single dose prophylactic intravenous cefuroxime before laparoscopic cholecystectomy and 48 patients in group-II treated with postoperative multiple doses of conventional antibiotics.

Table I: Distribution of age group among study population (n = 96)

Age	Antibiotic given				p value
	Prophylactic n=48		Conventional n=48		
	Frequency	%	Frequency	%	
<30	12	25.0	8	16.7	0.549
31-40	17	35.4	14	29.2	
41-50	12	25.0	14	29.2	
51-60	5	10.4	6	12.5	
61-700	2	4.2	4	8.3	
>70	0	0.0	2	4.2	
Total	48	100	48	100	
Mean ± SD	40.46±11.73		44.21±14.18		0.161

Unpaired t-test was done to analyse difference in mean age in two groups.
$P < 0.05$ is considered significant difference and $p > 0.05$ is non-significant.

Table I shows age distribution of study population. Majority of patients were in the age range of 30 – 50 years in group-I & group II. The mean age of group-I was 40.46 ± 11.73 years and group-II was 44.21 ± 14.18 years. Analysis revealed statistically non-significant ($p > 0.05$) mean age difference between the study groups.

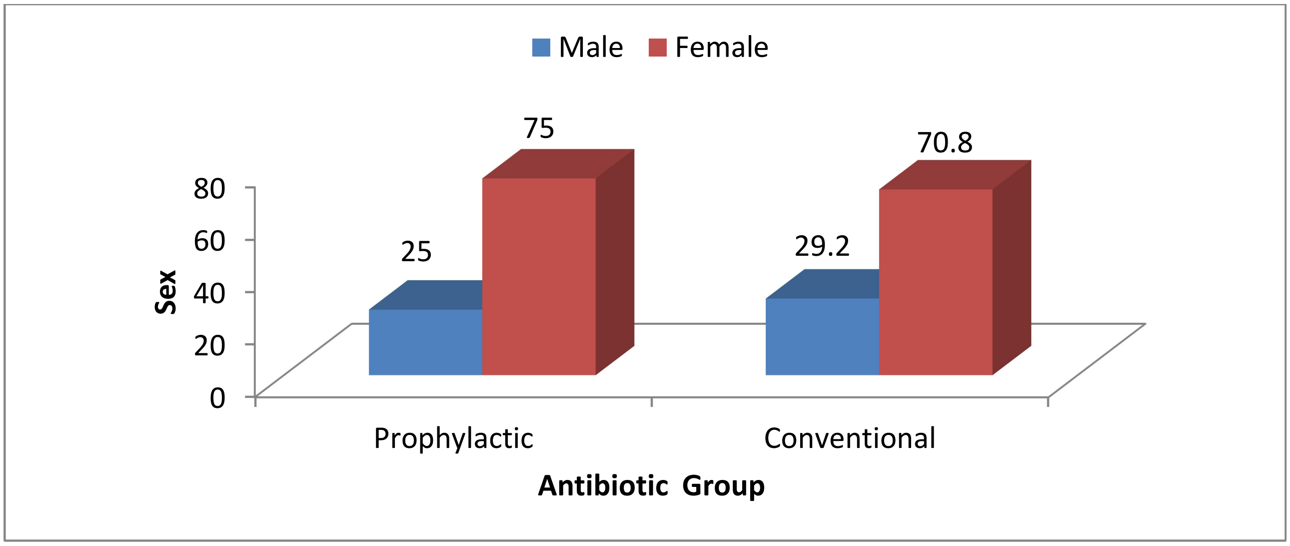

Figure 1. Multiple bar diagram showing distribution of sex in percentage among study population.

Figure 1 shows sex distribution of the study population. In group-I, 12 (25.0%) were male & 36 (75.0%) were female. In group-II, 14 (29.2%) were male and 34 (70.8%) were female.

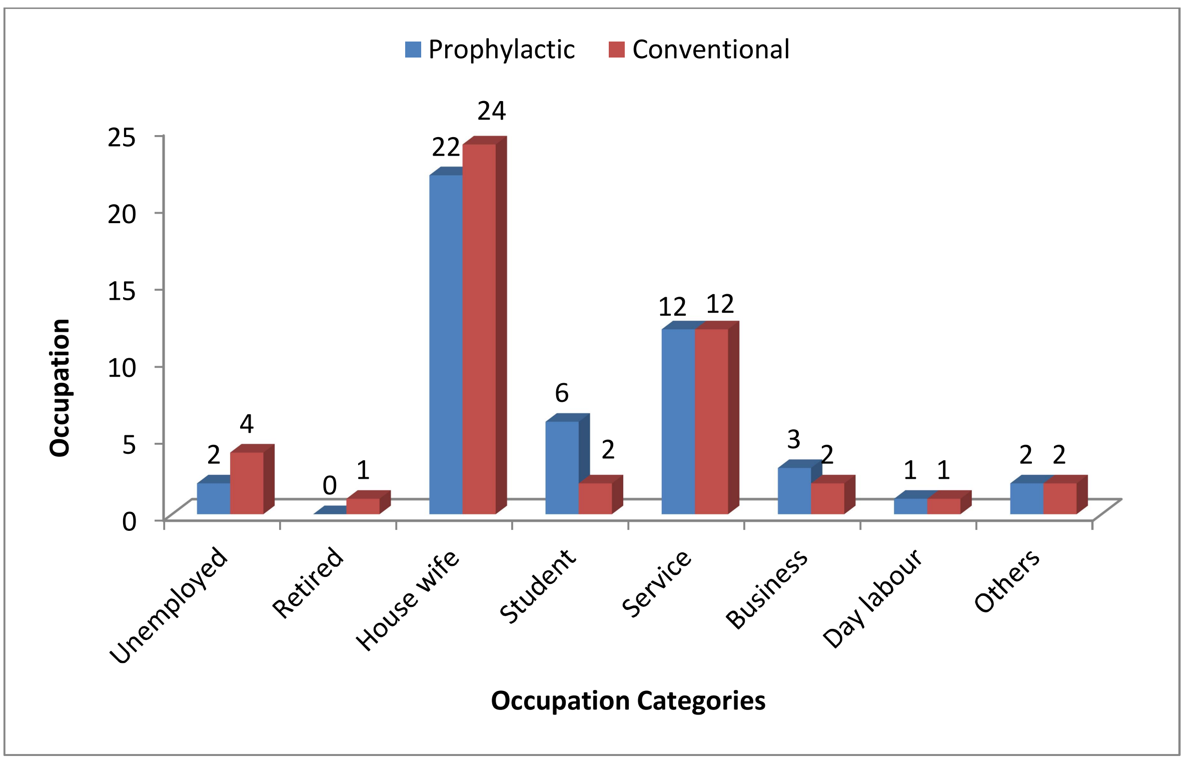

Figure 2. Multiple bar diagram showing occupation status of the study population.

Figure 2 shows occupation status of the study population. In both group-I and group-II most of the patients are house wife and in service.

Table II: Status of BMI and obesity among study population (n = 96)

BMI	Antibiotic given			
	Prophylactic n=48		Conventional n=48	
	Frequency	%	Frequency	%
≥ 25 (Obese)	25	52.1	23	47.9
< 25 (Non-obese)	23	47.9	25	52.1

Table II shows status of BMI and obesity among study population. In group-I, 52.1% (n = 25) patients were obese (BMI ≥ 25) and 47.9% (n = 23) were non-obese (BMI < 25). In group-II, 47.9% (n = 23) patients were obese (BMI ≥ 25) and 52.1% (n = 25) were non-obese (BMI < 25).

Table III: Mean BMI among study population (n = 96)

	Antibiotic given	
	Prophylactic (n=48)	Conventional (n=48)
Mean BMI	25.53 ± 3.29	25.03 ± 3.60

Table III shows the status of mean BMI among study population. Mean BMI in group-I and group-II were 25.53 ± 3.29 and 25.03 ± 3.60 respectively.

Table IV: Outcome in day 3 (n = 96)

Outcome		Antibiotic given				p value
		Prophylactic (n=48)		Conventional (n=48)		
		Frequency	%	Frequency	%	
Any sign of surgical site infection	Yes	3	6.2	2	4.2	0.646
	No	45	93.8	46	95.8	
Superficial	Yes	3	6.2	2	4.2	0.646
	No	45	93.8	46	95.8	
Distant	Yes	-	-	-	-	
	No	48	100.0	48	100.0	
Deep seated	Yes	-	-	-	-	
	No	48	100.0	48	100.0	
Fever	Yes	1	2.1	0	0.0	0.315
	No	47	97.9	48	100.0	
Port-site redness / tenderness	Yes	3	6.2	2	4.2	0.646
	No	45	93.8	46	95.8	
Wound discharge	Yes	2	4.2	2	4.2	1.00
	No	46	95.8	46	95.8	
Wound gap	Yes	-	-	-	-	
	No	48	100.0	48	100.0	
Wound abscess	Yes	-	-	-	-	
	No	48	100.0	48	100.0	

Chi-square test was done.
P < 0.05 is considered significant difference and p > 0.05 is non-significant.

Table IV shows outcome in day-3 among study population. In group-I, 6.2% (n = 3) patients developed surgical site infection and in group-II, it was 4.2% (n = 2). In group-I and group-II, superficial surgical site infection developed in 6.2% (n = 3) and 4.2% (n = 2) patients respectively, fever developed in 2.1% (n = 1) and 0% (n = 0) patients respectively, port-site redness/tenderness developed in 6.2% (n = 3) and 4.2% (n = 2) patients respectively, wound discharge developed in 4.2% (n = 2) and 4.2% (n = 2) patients respectively. In all the instances, there is no significant statistical difference among two groups (p > 0.05). None of the patient in both groups developed distant or deep seated infection, wound gap, wound abscess.

Table V: Outcome in day 7 (n = 96)

Outcome		Antibiotic given				p value
		Prophylactic (n=48)		Conventional (n=48)		
		Frequency	%	Frequency	%	
Any sign of surgical site infection	Yes	3	6.2	2	4.2	0.646
	No	45	93.8	46	95.8	
Superficial	Yes	3	6.2	2	4.2	0.646
	No	45	93.8	46	95.8	
Distant	Yes	-	-	-	-	
	No	48	100.0	48	100.0	
Deep seated	Yes	-	-	-	-	
	No	48	100.0	48	100.0	
Fever	Yes	1	2.1	1	2.1	1.0
	No	47	97.9	47	97.9	
Port-site redness / tenderness	Yes	3	6.2	3	6.2	1.0
	No	45	93.8	45	93.8	
Wound discharge	Yes	1	2.1	2	4.2	0.557
	No	47	97.9	46	95.8	
Wound gap	Yes	0	0.0	1	2.1	0.315
	No	48	100.0	47	97.9	
Wound abscess	Yes	-	-	-	-	
	No	48	100.0	48	100.0	

Chi-square test was done.
P < 0.05 is considered significant difference and p > 0.05 is non-significant.

Table-V shows outcome in day-7 among study population. In group-I, 6.2% (n = 3) patients developed surgical site infection and in group-II, it was 4.2% (n = 2). In group-I and group-II, superficial surgical site infection developed in 6.2% (n = 3) and 4.2% (n = 2) patients respectively, fever developed in 2.1% (n = 1) and 2.1% (n = 1) patients respectively, port-site redness/tenderness developed in 6.2% (n = 3) and 6.2% (n = 3) patients respectively, wound discharge developed in 2.1% (n = 1) and 4.2% (n = 2) patients respectively, wound gap developed in 0% (n = 0) and 2.1% (n = 1) patients respectively. In all the instances, there is no significant statistical difference among two groups (p > 0.05). None of the patient in both groups developed distant or deep seated infection, wound abscess.

Discussion

The majority of patients in both groups fell within the 30 to 50-year age range in this study. The mean age was 40.46 ± 11.73 years in group-I and 44.21 ± 14.18 years in group-II. Analysis revealed statistically non-significant ($p > 0.05$) mean age difference between the study groups. Comparable results were reported by Sharada B et al. in 2017, indicating "a higher occurrence of cholelithiasis during the fifth and sixth decades of life, with a peak in the fifth decade".[11] Present study shows in both groups, there was female predominance. In group I, 25.0% (n=12) of the participants were male and 75.0% (n=36) were female, whereas in group II, males accounted for 29.2% (n=14) and females for 70.8% (n=34). The difference of distribution of sex in both groups was statistically non-significant ($p > 0.05$). In most of the studies worldwide it was shown that gall stone disease is more commonly occurred in females. Sharada B and Srinivas D showed in there study that gallstone disease is a common problem in female population.[11] In a Bangladeshi study by Saha M, et al., 14 patients were males and 47 patients were females with gall stone disease.[11] Current study reveals in both group-I and group-II, most of the patients were house wife and in service. In a Bangladeshi study by Saha M, et al., gallstone disease was found more commonly among housewives and middle class people.[12] In this study, in group-I, 52.1% (n = 25) patients were obese (BMI ≥ 25) and in group-II, 47.9% (n = 23) patients were obese (BMI ≥ 25). Analysis revealed statistically non-significant ($p > 0.05$) BMI difference between the study groups. By many studies worldwide, it is established that gall stone disease is strongly associated with obesity. Su P, et al., in 2019, in a retrospective, cross-sectional study involved 3190 participants showed that there is an increased association of gallstones in younger people (< 50 years old) with metabolic syndrome and obesity.[13] Total post-operative infection rate was found in single dose antibiotic group was 6.2%and that in multiple dose groups was 4.2%. Most of the infections were superficial. Almost no deep seated or distant infection was found in both groups. A 2016 study conducted in India by Sutariya PK et al. reported comparable findings. "Among 90 patients who received a single dose of antibiotics, follow-up at one week showed that 2 (2.2%) developed redness and tenderness at the umbilical port site, which resolved with anti-inflammatory medication, and 1 (1.1%) experienced wound discharge. In multiple dose antibiotic group, at one week follow up, 2 (2.2%) patients were having port-site redness and tenderness."[14] Chaudhary R, et al., in 2015, in their study also showed that prophylactic antibiotic just before laparoscopic cholecystectomy is sufficient to prevent post-operative surgical site infections.[10]

Conclusion

There is no statistical difference ($p = 0.646$)between the rates of post-operative skin and soft tissue infection after prophylactic preoperative single dose cefuroxime (1.5 gm) intravenously and conventional multiple dose antibiotics in elective laparoscopic cholecystectomy. So, preoperative single dose of cefuroxime (1.5 gm) can be used safely as like as conventional multiple dose antibiotics in elective laparoscopic cholecystectomy.

Limitations of the Study

The sample size of this study was only 96. The study population was selected from a single hospital in Bangladesh, so the results may not reflect the exact scenario of the whole country. Sterility of the operation theatre is not properly assessed that can be a factor for surgical site infection.

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