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Evaluation of the Need for Prophylactic Antibiotics in Elective laparoscopic Cholecystectomy

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Abstract

Introduction: The primary aim of this prospective randomized study was to evaluate the necessity and impact of prophylactic antibiotics on postoperative infection complications in elective laparoscopic cholecystectomy. Our secondary aims included evaluation of comparison of cost of antibiotics, any need for readmission and reintervention.

Methods: At the time of induction of anaesthesia, group A patients (n = 20) received 1 g ceftriaxone with 0.5 g sulbactam, and group B patients (n = 40) received the same dose of antibiotics twice a day post-operatively for two days. Patients' characteristics and general operative outcomes were compared and analyzed.

Results: No significant difference in post-operative infectious complications was found between these two groups. Group B incurred four times the expenditure for antibiotics as compared to group A.

Conclusion: We do not recommend the use of prophylactic antibiotics in elective laparoscopic cholecystectomy as they will not decrease the already-low rate of postoperative infectious complications.

Keywords: Laparoscopic cholecystectomy, cholelithiasis, cholecystitis, surgical site infection, prophylactic antibiotics.

Introduction

Barely has any surgical procedure has had much a dramatic and altering impact on abdominal surgery as laparoscopic cholecystectomy[1]. Laparoscopic cholecystectomy is now the gold standard for the treatment of symptomatic cholelithiasis, particularly in elective setting and is the commonest laparoscopic operation performed worldwide[2,3,4]. Surgical site infections (SSIs) postoperatively may cause significant morbidity and mortality and are preventable in clean and clean-contaminated wounds by the using antibiotic prophylaxis[5,6,7]. However nowadays, routine use of antibiotics after clean LC is being equally questioned.[8,9,10,11,12,13]

Current consensus does not seem to advocate use antibiotics in patients undergoing LC for low-risk groups, due to the minimal risk of developing SSI as well as the added expense to the health-care system[14]. Simultaneously, there have been rising awareness to

reduce inappropriate antibiotic use with resultant multidrug microbial resistance and problems such as increasing rates of *Clostridium difficile* infection. Despite these recommendations, nearly 25% and 80% of patients undergoing LC running a low risk of SSI continue to receive antibiotics in various studies[15,16]

Hence, this study aims to find out if these recommendations are feasible in a sensitive Indian setting where finances and follow-up needs can impact treatment outcomes.

Aims and Objectives

The PRIMARY end-point is to compare the post-operative infectious complications i.e., surgical site infection between patients receiving post-operative antibiotic prophylaxis in addition to preoperative antibiotic and those not receiving the post-operative antibiotics.

The Secondary end-points are to compare:

1. Cost of treatment.
2. Readmissions.
3. Reinterventions.

Material and Methods

40 patients diagnosed as calculous cholecystitis who were admitted for undergoing laparoscopic cholecystectomy were included in the study. The patients were interviewed with due consent for a detailed clinical history, according to the proforma that had been specifically been prepared for the study. All patients were examined and underwent relevant investigations.

Study area: Chigateri General Hospital and Bapuji Hospital attached to JJM Medical College, Davanagere

Study period: 2 years (October 2018 to October 2020)

Study design: Prospective comparative study.

Inclusion Criteria

All cases above the age of 18 admitted for routine elective laparoscopic cholecystectomy. Inadvertent perforation of gall bladder and spillage of bile included.

Exclusion Criteria

1. Cholangitis, Obstructive jaundice.
2. Evidence of biliary pancreatitis.
3. History of oral/parenteral antibiotics in the past two weeks.
4. History of endoscopic retrograde cholangiopancreatography/endoscopy in the past one month.
5. Empyema of gall bladder.
6. Diabetes Mellitus.
7. Patients with HIV, HbsAg.

Investigations

- Complete blood count
- BT, CT
- RBS
- RFT
- ECG
- Chest X-ray
- USG-Abdomen
- HIV
- HbsAg
- LFT

Method of Operation

40 Patients were selected for this study. All patients received preoperative prophylactic dose of antibiotic, i.e., combination of Ceftriaxone 1 gm and Sulbactam 0.5 gm at the time of induction of anaesthesia.

Group A received only preoperative antibiotics and no post-operative antibiotics.

Group B continued with the same dose of antibiotics twice a day post-operatively for two days.

Post-operatively, the patient was assessed for development of post-operative infectious complications like surgical site infection, intra-abdominal abscess, readmissions, reinterventions, cost of treatment.

Patients were followed-up in OPD upto one month.

Surgical Procedure

All laparoscopic cholecystectomies were performed by experienced surgeons under general anaesthesia.

Laparoscopic Cholecystectomy

Laparoscopic cholecystectomy was performed by operating surgeon on the left side of the table. Pneumoperitoneum was created by using Verses needle and by Hassan's technique in some of the cases. This involved two 10 mm and two 5mm trocars. Peritoneal cavity was visualized. Any adhesions if present were released. Upon visualization of Calot's triangle, dissection was done using electro-cautery and the cystic duct and cystic artery were secured with titanium clips. After the successful completion of surgery, patients were shifted to recovery room for observation and were later shifted to post-op ward and monitored. Patients were monitored for development of any post-operative complications during the duration of their stay at the hospital as well as upto 4 weeks after being discharged. The histopathology of specimen sent was also noted.

The total cost incurred during the duration of hospital stay was evaluated. This included cost of investigations, surgery and medications.

Result Analysis

Twenty patients were randomized to each group i.e Group A and Group B. The results were as follows:

Patient Demographics

Table 1A: Age distribution in two groups

Age in years	Gr A		Gr B		Total
	No.	%	No.	%	
22-30	4	20.0	5	25.0	9
31-40	9	45.0	8	40.0	17
41-50	2	10.0	4	20.0	6
51-60	3	15.0	2	10.0	5
61-73	2	10.0	1	5.0	3
Total	20	100.0	20	100.0	40

Fig. 1B: comparison of mean age between two groups

Variable		Gr A	Gr B	Gr A vs Gr B	
				t value	P value
Age (yrs)	Mean±SD	41.9±13.3	39.2±11.5	0.7	0.49, NS
	Range	24 - 73yrs	22 - 65yrs		

Unpaired t-test

Table 2: Sex distribution of cases in two groups					
Sex	Gr A		Gr B		Total
	No.	%	No.	%	
Male	8	40.0	9	45.0	17
Female	12	60.0	11	55.0	23
Total	20	100.0	20	100.0	40

$X^2 = 0.10$, P = 0.75, NS

Table 3: Clinical diagnosis in two groups					
Diagnosis	Gr A		Gr B		Total
	No.	%	No.	%	
Acute Cholecystitis	2	10.0	17	85.0	19
Chronic cholecystitis	18	90.0	3	15.0	21
Total	20	100.0	20	100.0	40

Table 4: USG Findings in two groups					
Findings	Gr A		Gr B		Total
	No.	%	No.	%	
Single stone	11	55.0	12	60.0	23
Multiple stones	9	45.0	8	40.0	17
Total	20	100.0	20	100.0	40

$X^2 = 0.10$, P = 0.75, NS

Table 5: Incidence of SSI					
SSI	Gr A		Gr B		Total
	No.	%	No.	%	
None	20	100.0	20	100.0	40

Table 6: Cost of Antibiotics					
Cost (Rs)	Gr A		Gr B		Total
	No.	%	No.	%	
Rs.160/-	20	100.0	0	0.0	20
Rs.640/-	0	0.0	20	100.0	20
Total	20	100.0	20	100.0	40

Fisher's Exact test P < 0.001, High Sig.

No difference between two groups

Table 7: Readmission / Reinterventions					
Readmission/ Reinterventions	Gr A		Gr B		Total
	No.	%	No.	%	
None	20	100.0	20	100.0	40

No difference between two groups

Statistical Analysis

Results are presented as Mean ± SD and range values for continuous measurements and frequencies as number and percentages. Unpaired t test was used to compare means of two groups. Categorical data was analyzed by Chi-square test /Fisher's exact test. A P value of 0.05 or less was set for statistical significance. SPSS (Version 17) software was used for data analysis.

Discussion

Laparoscopic Cholecystectomy (LC) is the gold standard for symptomatic gallstones. The role of prophylactic antibiotics in ameliorating surgical outcome is a belief that is held since the era prior to introduction of minimal invasive LC two decades ago. LC is an elective clean operation with low post-operative wound infection rate.

The main aim of our study was to evaluate the efficacy of single dose versus multiple doses of antibiotics in prevention of post-operation SSI in elective LC.

The mean age in our study was 41 years for patients receiving single dose antibiotics and 39 years in patients receiving multiple doses of antibiotics.

Incidence of gallstone peaks in the fourth decade of life. In our study, none of the patients in either group developed any intra-abdominal or systemic infection post operation. Earlier study by Vikram Singh Chouhan et al showed overall infection rate of 2.3% in patients with single dose intraoperative antibiotic, which compares favourably with our study. Other studies have opined that prophylactic antibiotics neither affect the development nor the course of infectious complications following LC as the infection rate is very low.

Table 8: Comparison of SSI in similar studies

Sn.	Studies Conducted	SAMPLE SIZE (group A/group B)	SSI in Group A (number of patients) –SD of antibiotic	SSI in Group B (number of patients)—MD of antibiotic
1.	Vikram Singh et al	210 (112/98)	2	3
2.	Eun Young et al	200 (100/100)	7	8
3.	Loozen et al	150 (75/75)	3	3
4.	Sagun Bahadur et al	240 (118/112)	5	4
5.	Martin Santibanes et al [CHART]	104 (double blind, randomized trial)	6	6
6.	Current study	40 (20/20)	0	0

There are some limitations in this study; we did not include patients with empyema or gangrenous gall bladder or diabetic patients for this study. Thus, these findings cannot be applied to all patients who undergo surgery for acute cholecystitis. This will require a separate study.

We chose injection ceftriaxone with sulbactam instead of injection cefazolin as described in almost all studies, as it is more easily available and has a more extended spectrum. We chose to administer pre-operative antibiotic at the time of induction of anaesthesia as it aids the host immune system in tiding over the most likely period of infectious complications, rather than completely eliminating pathogens, and strike a balance between 'no antibiotics at all' and 'prolonged antibiotic administration.'

Hence, none of the patients in our study group needed any readmission or reintervention. It was also observed that patients who received post-operative antibiotic prophylaxis (Group B) incurred four times the expenditure as compared to Group A, which received only single- dose antibiotic at the time of induction of anaesthesia.

Table 9: Comparison of outcomes of similar studies

Sn.	Studies Conducted	Remarks	Sample Size (Group A/Group B)	Antibiotic Used	Conclusion
1.	Vikram Singh et al	Single dose versus 4 doses	210 (112/98)	Ceftriaxone	Favourable
2.	Eun Young et al	Single dose versus 6 doses	200 (100/100)	Cefoxitin	Favourable
3.	Loozen et al	Single dose versus 6 doses	150 (75/75)	Cefazolin	Favourable
4.	Sagun Bahadur et al	Single dose versus 4 doses	240 (118/112)	Amikacin	Favourable

5.	Martin Santibanes et al [CHART]	Placebo versus 10 doses	104 (double blind, randomized trial)	Amoxicillin-clavulanic acid	Favourable
6.	Current study	Single dose versus 4 doses	40 (20/20)	Ceftriaxone-Sulbactam	Favourable

Our current study confirms the findings of the earlier studies as mentioned above, hence, there can be a favorable case made for recommending single dose antibiotic at the time of induction as the most practical and effective choice of prophylactic protocol.

Conclusions

40 patients diagnosed as calculous cholecystitis admitted for undergoing laparoscopic cholecystectomy in Chigateri General Hospital and Bapuji Hospital attached to JJM Medical College, Davanagere were included in the study. All patients received preoperative prophylactic antibiotic. However, only 20 patients received post-operative prophylactic antibiotic as well. Patients were evaluated based on occurrence of any post-operative complications, cost of antibiotics, any need of readmissions and reinterventions.

Despite not receiving post-operative prophylactic antibiotics, no post-operative surgical site infections were reported. Patients in neither group showed any need for any readmissions or reinterventions.

Elective Laparoscopic Cholecystectomy has low risk of post-operative infectious complications, yet most clinicians persistently use post-operative prophylactic antibiotics either out of habit, tradition or simply as a defensive practice, in order to avoid evolving medico-legal implications of a large number of surgeries showcased as daycare or next-day discharge procedures. Our study was a randomized prospective trial done to test the need for such prophylaxis in cases of elective LC in a rural/semi-urban setting.

Surgical site infections post-operatively can cause significant morbidity and mortality and are prevented in clean clean-contaminated wounds by using antibiotic prophylaxis. Although Centre for Disease Control and Prevention recommends the use of prophylactic antibiotics in clean and clean-contaminated surgery such as LC to reduce SSI, most recent meta-analysis concluded that antibiotic prophylaxis is unnecessary in low-risk patients undergoing LC.[58]

Our study shows that risk of SSI in LC is low and does not seem to be affected by usage of routine prolonged course of post-operative antibiotic prophylaxis for uncomplicated cases. In addition to this, there is a very real risk of adverse reactions to antibiotic usage that may cause significant morbidity and financial burden.

In view of the above findings, we found that a single dose antibiotic at induction is most practical and effective choice of prophylactic protocol. However, to make a recommendation on the basis of these results, it needs to be performed using a larger sample size at multiple locations.

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