ORIGINAL ARTICLE

ROLE OF PROPHYLACTIC ANTIBIOTICS IN LOW RISK ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY: IS THERE A NEED?

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Background: Elective cholecystectomy for symptomatic gall stone disease carries low risk of postoperative infective complications. Yet the routine use of prophylactic antibiotic is in vogue in many centres. The aim of this study was to find out the efficacy of antibiotic prophylaxis in preventing postoperative infective complications in low risk elective laparoscopic cholecystectomy patients. **Method:** Randomised controlled trial was carried out in our hospital from 1st Nov 2009 to 15th Oct 2011. A total of 350 patients were included in the study and were divided into Group A (n=177), and Group B (n=173). Group A was given single dose of injection Cefuroxime 1.5 gm as prophylactic antibiotic at the time of induction of anaesthesia, and Group B was not given any antibiotic. In both groups, age, sex, duration of surgery, American Society of Anesthesiologists classification, duration of surgery and length of hospital stay were recorded. Patients were followed-up weekly for 4 weeks and rates of superficial surgical site infections as well as intra-abdominal infections were recorded. **Results:** There were no significant differences in both groups in terms of age, sex, duration of surgery, length of hospital stay. Eight (4.5%) cases of superficial surgical site infection were noted in Group A and 7 (4.0%) in Group B which was insignificant statistically (p>0.05). **Conclusion:** In low risk patients antibiotic prophylaxis does not seem to affect the incidence of postoperative infective complications in elective laparoscopic cholecystectomy. The use of prophylactic antibiotics should be reserved for high risk patients undergoing laparoscopic cholecystectomy.

Keywords: Antibiotic Prophylaxis, Cholecystectomy, Laparoscopy

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INTRODUCTION

The Gold standard treatment for symptomatic gallstone disease is laparoscopic cholecystectomy (LC) since 1990.[1,2] Elective cholecystectomy for symptomatic gall stone disease carries low risk of postoperative infective complications.[3] Yet the routine use of prophylactic antibiotic is in vogue in many centres. LC is associated with smaller wounds and minimal tissue damage, which is the most probable reason for reduced infection rates.[4] Scottish Intercollegiate Guidelines Network (SIGN)[5] published its guidelines in 2000 that prophylactic antibiotics should not be prescribed for low risk elective LC. On the contrary, many randomised controlled trials[6,7], and a large meta-analysis[8] found significantly reduced incidence of postoperative infective complication with antibiotic prophylaxis (ABP) and recommended the use of prophylactic antibiotics in patients undergoing elective cholecystectomy and other biliary tract surgery. The aim of this study was to test the efficacy of ABP in preventing postoperative infective complications in low risk elective LC.

PATIENTS AND METHODS

This prospective randomised controlled trial was carried out on 350 patients who underwent elective LC from 1st Nov 2009 to 15th Oct 2011. After the hospital ethical committee approval, informed written consent after explaining the patient in detail about the procedure. Patients were randomly divided in to two groups. An exclusion criterion was patients with high risk of peri-operative infections, i.e., diabetes mellitus, use of corticosteroids and immunosuppressive therapy and evidence of biliary obstruction, i.e., clinical jaundice, alkaline phosphatase or direct bilirubin levels twice the reference levels, antibiotic intake 7 days prior to surgery, active or acute cholecystitis 6 weeks before surgery and emergency cholecystectomy. Group-A was given single dose of Inj. Cefuroxime 1.5 gm intravenously at the time of induction of anaesthesia, whereas group-B was not given any prophylactic antibiotic. Skin was prepared using 10% povidone-iodine solution. The nasogastric tube was placed at the beginning of surgery and removed at the end of procedure. LC was performed in both groups using the standard four ports. Gall bladder was taken out from the umbilical port and a sample for bile culture was taken at the time of gall bladder retrieval. Any blood or bile in the Calot's triangle and subhepatic space was mopped using suction and irrigation cannula. Wounds were stitched with 3/0 non-absorbable monofilament suture. Age, sex, ASA scoring, intra-operative findings, spillage of bile or gall stones in operative field, were recorded in each patient. Postoperative course of patients was followed. Any incident of fever was recorded and patients were investigated for presence of any intra abdominal collection in case of fever. Asymptomatic patients were discharged on 1st or 2nd postoperative day when taking and tolerating feed orally. Thereafter

patients were followed-up once a week for 4 weeks and any trocar site infection was recorded and investigated by wound swab culture and treated accordingly.

Infectious complications were defined as pyrexia with a body temperature higher than 38 °C twice a day (excluding the first postoperative day) and culture findings positive for pathogens from infectious sites such as trocar wounds and the abdominal cavity.[9]

Statistical analyses were performed using Chi-square test, Fisher's exact test, and Mann-Whitney U-Test. All analyses were done using SPSS-10 with $p<0.05$ considered as significant.

RESULTS

A total of 350 patients underwent LC in the study period; 176 patients were in Group-A and 173 were in Group-B. There were 252 (72%) females and 98 (28%) males. Mean age of the patients was 45.8±10.6 years. Both groups were homogeneous for sex, age, ASA score. Mean duration of surgery in Group-A was 42.2±9.7 minutes and in group-B was 42.68±9.8 minutes (p=0.683). Mean length of hospital stay in group-A was 1.36±0.8 days where as in 1.49±0.8 days (p=0.274). There was no case of sub-hepatic abscess/deep infection was seen in either group (Table-1). Eight (4.5%) cases of superficial surgical, i.e., trocar site infection were noted in group-A and 7 (4.0%) in group-B (p=0.652) (Table-2). The most common site of infection was umbilical trocar site in both the group, 5 (71.4%) cases in group-A and 4 (57.14%) cases in group-B. Hence there was no statistical difference between two groups in superficial and deep infection rates.

Table-1: Incidence of deep seated infection in the study population

Prophylactic antibiotic given	Deep abscess		Total
	Yes	No	
Yes	0	177	177
No	0	173	173
Total	0	350	350

Table-2: Incidence of superficial surgical site infection

Prophylactic antibiotic given	Superficial surgical site infection		Total
	Yes	No	
Yes	8	169	177
No	7	166	173
Total	15	335	350

DISCUSSION

The role of ABP is well established in prevention of infective complications in general as well as elective surgery.[10] Many studies have also demonstrated the role of ABP in open cholecyctectomy[6–11] LC is now the recommended procedure of choice for treatment of symptomatic gall stone disease.[1] The main advantages of LC is less postoperative pain, shorter hospital stays, a rapid return to work, and a significant decrease in perioperative septic complications.[2,12] Even in the presence of these guidelines and evidences, the same criteria of antibiotic prophylaxis previously applied to conventional surgery are routinely used for laparoscopic surgery as well.[13] Illeg *et al*[14] compared three doses of prophylactic antibiotics with no antibiotic in his study and did not find any difference in postoperative infective complication rate. Higgins *et al*[15] also performed a similar study in which he compared single dose prophylactic antibiotics with no antibiotics and also had identical results. McGuckin *et al*[16] and Tocchi *et al*[17] identified that the use of prophylactic antibiotic is only recommended for those patients who are at high risk for developing infective complications, e.g., diabetic population or people with increase risk of bactobilia. Frantzides and Sykes[18] performed a prospective nonrandomised study comparing preoperative antibiotic prophylaxis using single dose intravenous Cefotetan with preoperative chlorhexidine gluconate scrub without induction antibiotics. They demonstrated that a well-performed surgical scrub or giving induction ABP has equal incidence of post operative infective complication rates. Our study also verified that number of post operative infective complications were similar in both the groups whether ABP is used or not. It is well known that bactibilia is a common finding in high-risk individuals with complicated gallstone disease, including those with age >70 years, acute cholecystitis, biliary obstruction, non-functioning gallbladders, common bile duct stones, and cholangitis.[19,20] So there is an increase incidence of postoperative complications in high risk patients and use of prophylactic antibiotics in patients is therefore recommended for such patients.

CONCLUSION

In patients undergoing low risk elective laparoscopic cholecystectomy, antibiotic prophylaxis seems justified only for high risk patients. In all the other cases, antibiotic prophylaxis does not affect the incidence of postoperative infections and is therefore not recommended.

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