Role of Prophylactic Antibiotics in Low Risk Elective Laparoscopic Cholecystectomy: A Randomized Controlled Study

Aryal Rishi Kant[1], Gautam Rakchhya[2], Shrestha Nabin[3]

ABSTRACT

Introduction: Elective laparoscopic cholecystectomy for symptomatic cholelithiasis has low risk of postoperative infective complications. Although antibiotics prophylaxis is routinely administered in laparoscopic cholecystectomy, its role is debatable. Our objective of this study was to explore the adequacy of anti-microbial prophylaxis in avoiding postoperative infective intricacies in low risk elective laparoscopic cholecystectomy patients.

Material and Methods: From June 2014 to Dec 2016, 300 patients were randomized into 138 in antibiotic group (ABG) and 162 in non antibiotics group(NABG). AG received single dose of injection Ceftriaxone 1 grm and ornidazole 500mg as prophylactic antibiotics(according to our institutional practice protocol) at the time of induction of anesthesia. NAG was given only intravenous fluids. Besides routine care in both groups age, gender, surgical duration, ASA classification, and duration of stay in hospital were documented. Patients were followed-up week by week for 4 weeks and rates of shallow surgical site contaminations and in addition intra-abdominal infections were assessed.

Results: Both groups were analogous in patient's clinico-demographic characteristics such as average Age (44.31 vs. 44.52 years) and sex (female 76.51% vs. 76.2%). Overall wound infection occurred in 4.33% (13/300). There was no significant difference observed in wound infections among the different groups (p =0.802): ABG 4.5% and NABG 4%.

Conclusion: Antibiotics prophylaxis is not needed for low risk laparoscopic cholecystectomy.

Keywords: Laparoscopic Cholecystectomy, Antibiotics

INTRODUCTION

Laparoscopic cholecystectomy(LC) is now considered the standard operation for symptomatic gallstones [1]. Perioperative antimicrobial prophylaxis is generally recommended for laparoscopic as well as open cholecystectomy as it results in a shorter hospital stay and thus reduces overall cost of treatment[2].Yet the routine use of prophylactic antibiotics is in dilemma in many centres. Scottish Scottish Intercollegiate Guidelines Network (SIGN) published its guidelines in 2000 that prophylactic antibiotics should not be prescribed for low risk elective LC [3]. LC is associated with smaller wounds and minimal tissue damage, which is the most probable reason for reduced infection rates[4]. From the available evidence, there appears to be no scientific basis for routine administration of antimicrobial prophylaxis to low-risk patients during LC.[5]

Prophylactic antibiotics use has been suggested by the CDC and Prevention. It is extensively used in clean-infected surgeries such as cholecystectomy to lessen post surgical site infections. In disparity, several studies have recently suggested that prophylactic antibiotic use is not acceptable in low-risk patients undergoing laparoscopic cholecystectomy.[4,5]

We conducted this study in our own teaching institute by keeping in mind the controversies existing regarding the injudicious use of antibiotic which adds to the expenses and enhances rise of multidrug resistance.

MATERIAL AND METHODS

This randomised controlled trial prospective study was conducted on 300 patients who underwent elective LC. Ethical permission was taken from Institutional Ethical Committee and informed written consent from the patients after explaining the study protocol was taken before the commencement of study. The randomization was done by coin toss method. Each patient routinely scheduled are given equal choice to choose the either side of one rupees coin. The photo side (head) was placed under NABG Group and the other side(tail) was placed under ABG group.

Patients with high danger of perioperative diseases, i.e., diabetes mellitus, utilization of immunosuppressive treatment, corticosteroids and and biliary hindrance, i.e., jaundice, alkaline phosphatase or direct bilirubin levels double the reference levels, anti-microbial intake 7 days preceding surgery, dynamic or intense cholecystitis 6 weeks before surgery and crisis cholecystectomy were excluded from study. After confirmation of the presence of gall stone using ultrasound (USG), all the patients were evaluated with haemogram, urea, creatinine, liver function test (LFT), blood sugar, electrocardiography (ECG) and chest radiography.

Elective LC was done after overnight fasting in the hospital. All surgeries were done under general anaesthesia (GA). ABG group was given single dose of Inj. Ceftriaxone 1 gm + ornidazole 500mg intravenously at the time of induction of anaesthesia, whereas NABG group was given only intravenous fluids. Skin was readied utilizing 10% povidone iodine arrangement. The nasogastric tube was set toward the start of surgery and evacuated toward the completion of procedure. LC was performed in both gatherings utilizing the standard four ports. Gall bladder was taken out from the umbilical port and a specimen for bile culture was taken at the time of gall bladder recovery. Any blood or bile in the Calot's triangle and subhepatic space was wiped utilizing suction and water system cannula. We considered bile spillage when there was leak from the puncture site, gallbladder side, cystic duct or gallbladder perforation during dissection. Any

[1]Assistant Professor, [2]Lecturer, [3]Consultant Surgeon, Department of Surgery, Devdaha Medical College, Rupendehi, Nepal

Corresponding author: Dr. RK Aryal, Assistant Professor, Department of Surgery, Devdaha Medical College, Bhaluhi-9, Rupendehi, Nepal

How to cite this article: Aryal Rishi Kant, Gautam Rakchhya, Shrestha Nabin. Role of prophylactic antibiotics in low risk elective laparoscopic cholecystectomy: a randomized controlled study. International Journal of Contemporary Medical Research 2017;4(6):1306-1308.

drop of stone to the peritoneal cavity was termed 'stone spill' wherein irrigation suction was done after retrieval of stones. Subhepatic drain was used only selectively in long and difficult surgery where the chance of missed injury was high. Wounds were sutured with 3/0 non-absorbable monofilament suture. Age, sex, intra-operative observations, ASA scoring, spillage of bile or gall stones in operative field, were documented in every patient. Postoperative course of patients was taken after.

Protocol based post operative management in the form of intravenous fluids for six hours, injection diclofenac sodium, ondansetron and pantoprazole were used for one day. Fluid diet was advised for one day followed by normal diet. Any occurrence of fever was recorded and patients were explored for presence of any intra abdominal collection if there is a rise of an occurrence of fever. Asymptomatic patients were released on first or second postoperative day when taking and enduring food orally. USG of abdomen was done in all symptomatic patients and at least once during the 30 days postoperative period of all other cases.

STATISTICAL ANALYSIS

The SPSS 16.0 and Windows Excel were used for the analysis of the data. Chi square test was done for large size samples and Fisher's exact test used to test the frequency distribution of study parameters between ABG and NABG. Student 't' test has been used to test the significance of mean values between ABG and NABG in univariate analysis.

RESULTS

A total of 300 patients underwent LC in the study period; 132 patients were in antibiotic group (ABG gr) and 168 were in non-antibiotic group(NABG gr). There were 229 (76.33%) females and 71(23.66%) males. Mean age of the patients was 44.31±13.79 and 44.52+_13.32 years in either group. Both groups were homogeneous for sex and age (Table-1) and ASA score. Mean duration of surgery in ABG gr was 42.2±9.7 minutes and in NABG gr was 42.68±9.8 minutes (p=0.683). Mean length of hospital stay in ABG gr was 1.36±0.8 days where as NABGgr in 1.49±0.8 days (p=0.274). Perforation and spillage of bile occurred in 16 cases and 10 also had dismissal of stones. Spilled stones were selected and irrigated with normal saline until there was clear aspiration. Distended gall bladder leading to difficulty in grasping and dissection were aspirated. 56 patients were categorized as difficult surgery which took more time for dissection of calots triangle (Table-2). There was no case of sub-hepatic abscess/deep infection was seen in either group (Table-3). 6(4.5%) cases of superficial surgical, i.e., trocar site infection were noted in ABG gr and 7(4.0%) in non-antibiotic group(NABG gr) (Table-3). The most common site of infection was umbilical trocar site in both the group. Both the groups had almost similar number of postoperative fever cases. (Table-3). In 9 cases fever subsided on the next day. Therefore, no statistical difference was observed among both the groups in deep and superficial infections.

Group	ABG gr	NABG gr
Total	132	168
Age range (yrs)	24-73	25-72
Mean age	44.31±13.79	44.52±13.32
Male:Female	31:101	40:128

Table-1: Age and sex distribution

Procedure related events	ABG Gr (n=132)	NABG Gr (n=168)	p-value
Bile spillage	7(5.3%)	9(5.35%)	0.533
Stone spillage	4(3%)	6(3.5%)	0.503
GB aspiration	37(28%)	50(29%)	0.703
Difficult Surgery (>1hr)	27(20.4%)	29(17.3%)	0.523
ABG gr:Antibiotics group; NABG gr:No antibiotics groups			

Table-2: Procedure related events

Complications	ABG gr (%)	NABG gr (%)	p-value
N	132	168	0.721
Postoperative fever	4(3%)	7(4%)	0.546
Deep abscess	0	0	
SSSI	6(4.5%)	7(4%)	0.892
n = numbers of patients; SSSI - Superficial surgical site infection			

Table-3: Postoperative events

DISCUSSION

LC is associated with a lower risk of wound sepsis than open cholecystectomy[6]. The position of ABP is well recognized in anticipation of infective barriers in surgeries[7]. The main benefits of LC is less postoperative pain, shorter hospital stays, a rapid come back to work, and a decrease in perioperative infections.[8] Even in the light of these guidelines and documentations, the same basis of prophylactic antibiotic use previously applied to conventional surgery are routinely used for laparoscopic surgeries as well.[9]

Antibiotic prophylaxis in LC is not only unnecessary but also increases the overall cost of surgery and hospitalization[3]. It is important to follow the guidelines for antibiotic prophylaxis for cholecystectomy in coordination with infection control policy of the hospital. This will result in a more suitable utilisation of the prophylactic agents[10]. Higgins et al [11] also conducted a identical study where they did comparative evaluation of single dose prophylactic antibiotics with no antibiotics and also had similar kind of results. McGuckin et al[12], Tocchi et al[13] recognized that the use of prophylactic antibiotic is only suggested for those patients who are at higher risk for developing infective problems, e.g., diabetic people with increased chances of bactobilia.

Frantzides and Sykes[14] carried out a comparative study among preoperative antibiotic prophylaxis using single dose intravenous Cefotetan with preoperative chlorhexidine gluconate scrub without induction antibiotics. They verified that a well-executed surgical scrub or providing induction antibiotic prophylaxis has equivalent incidence of post operative infective complication rates. Our study also confirmed that number of post operative infective complications were analogous to both the groups whether antibiotics prophylaxis is used or not. As in our study, others have also reported umbilicus as the commonest site for sepsis[15]. This may be because the deep umbilical depression is sometimes difficult to clean. In our study, one patient had erythema and three had umbilical discharge with no growth in culture. Positive bile culture is found in 25% of simple gall stone disease and it goes up to 47% after an acute attack[16]. In our study 37 (28%) cases in ABG and 50(29.7%) cases in NABG with resolving acute cholecystitis and mucocele with distended

gall bladder were aspirated. However culture positivity was seen in only 19 (21.83%) cases, almost equally distributed in both the groups. Even though most studies have found no role of antibiotics in elective LC, they still recommend larger studies[17]. Prophylactic antibiotic use is defensible only in patients at high risk undergoing elective LC[18].It is well known that bactibilia is a common finding in high-risk individuals with complicated gallstone disease, including those with age >70 years, biliary obstruction, non-functional gall bladders, acute cholecystitis, common bile duct stones, and cholangitis[19]. 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

It may be concluded that antibiotic prophylaxis is not recommended in all elective LC. However, the hospital infection control policy and merits of individual case may dictate otherwise. Larger trials will give further evidence and help formulate guidelines for universal acceptance.

ACKNOWLEDGMENTS

We are thankful to operating-room nurses for helping in randomization and administration of Ant.ibiotics

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 18-05-2017; **Accepted:** 27-06-2017; **Published:** 04-07-2017