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PROPHYLACTIC ANTIBIOTICS; ROLE STILL TO BE DEFINED IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY.

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ABSTRACT... Objectives: The purpose of this study was to find out the role of prophylactic antibiotics in preventing surgical site infections in patients underwent elective laparoscopic cholecystectomy. Study Design: Randomized control trail. Setting: Surgical Unit - III, Liaquat University Hospital Jamshoro. Period: 1st January 2015 to 31st December 2016. Materials and Method: All low risk patients those underwent laparoscopic cholecystectomy. Overall 150 cases were enrolled within the study as well as were categorized into A-Group (n=77), and B-Group (n=73). A-Group was offered prophylactic antibiotic's single dose at induction of anesthesia, and B-Group was offered without any antibiotic. Groups were recorded for, surgery duration, gender, age and hospital stay. All subjects were followed-up for one month on weekly basis and data was recorded regarding surgical site in addition to intra-abdominal infection. **Results:** There was no significant difference among both groups regarding duration of surgery, gender, age, and hospital stay, p-values guit insignificant. Complications in both the groups were compared. Rate of superficial infection was 6.49% and 6.84% respectively in group A and B. On statistical analysis these differences were not significant. No deep infection and seroma formation were observed among in both the groups. Conclusion: It was concluded that, the application of prophylactic antibiotics does not essential among low risk cases undergoing laparoscopic cholecystectomy.

Key words: Laparoscopic Cholecystectomy, Prophylactic Antibiotics, Surgical Site Infections.

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INTRODUCTION

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Elective laparoscopic cholecystectomy is a benchmark treatment for symptomatic gallstone disease since 1990.^{1,2} Laparoscopic approachs to cholecystectomy are linked to the decreases in postoperative pain and hospital stay, fast return to the normal activities and lower rate of morbidities and the mortality, and after its role as recognized for choice of the symptomatic cholelithiasis.^{3,4} Its reports amongs cases who had previously involved in acute pancreatitis due to gallstones, indicated as elevated operative risk and morbiditis, with increased rates of the conversion, prolonged hospital stay and high mortality.^{4,5} Now a days in centres where available laparoscopic surgeries, the open cholecystectomy has been almost replaced by the LC, because it has reduced unrequired and unneccesrary surgical traumas and unneccesrary cut of the the abdominal wall becauses it can be performed by small ports.^{6,7}

Major complication are very less frequent, however it is measured as the safe surgical technique not only for the elective surgery but also in the emergency as well. Though sometime among high risk patients it becomes necessary convert to open cholecystectomy in order to prevent the high risk and as only option for patient's safety.^{6,8}

The prevalence of infectious complication following laparoscopic cholecystectomy (LC) is significantly lesser contrasted to infection with open cholecystectomy^{6,9,10} as the wound in LC behave differently as compared to open cholecystectomy, because the wounds created are smaller and there is less tissue trauma as compared to the open surgery. The scheduled application of prophylactic antibiotic is routine in several centers, but its role in preventing infections of surgical site (SSIs) is yet debatable in elective LC.^{11,12-15} From the available evidence, no scientific base for regular antimicrobial prophylaxis' management to low-risk cases in the course of LC has been appeared and there is no added advantage of antimicrobial prophylaxis in terms of preventing infection. Current study was undertaken to assess the usefulness and effectiveness of prophylactic antibiotic in low risk LC during inducrion of anesthesia at tertiary care Hospital.

MATERIAL AND METHODS

This randomized control trial was carried out at Surgical Unit–III, Liaquat University Hospital Jamshoro from 1st January 2015 to 31st December 2016. On confirmation of the presence of gallstones on pre-operative ultrasound, all patients were evaluated for baseline investigations i.e. blood complete picture, liver function tests, serum creatinine, blood urea, chest x-ray and electrocardiography (ECG). All the high risk patients as elderly people and with co-existing illness were excluded. The subjects were randomly categorized into 2 groups. A-Group (n=77) was given single dose of injection Ceftriaxone 1gm at induction of general anesthesia, and B-Group (n=73) was offered no any antibiotic.

Carbon dioxide was used to create pneumoperitoneum and standard four ports laparoscopic procedures were done carried in all the cases. On entering into peritoneal cavity, Calot's triangle identified. First the cystic duct, then cystic artery was clipped. Gallbladder dissected from liver bed and retrieved from umbilical port. A specimen of bile culture was taken in sterile syringe immediately from gallbladder on its retrieval from abdomen. By using suction and irrigation cannula, any bile or blood collection at liver bed and sub-hepatic space was mopped. On completion of the procedure, ports stitched with 2/0 vicryl suture.

The routine postoperative course was followed. Most of the patients were discharged on 1st and 2nd postoperative day. On discharge from hospital, the data were collected in both groups for each subject: gender, age, ASA classification, gallbladder rupture, surgery duration, bile or stone spillage, results of bile culture, prolomged hospital stay and frequency of the septic complications on weekly basis for 30 days and data was recorded regarding intra-abdominal infection and surgical site infection.

RESULTS

A total of 150 patients who experienced laparoscopic cholecystectomy were enrolled within current study, Groups A and B included 77 and 73 patients, respectively. There were 49(63.6%) females and 28(36.4%) males in ggroup A. 53(72.6%) were females and 20(27.4%) were males in ggroup A. Patients' mean age was 37.6 ± 17.8 years. There was no significant difference among both groups regarding surgery duration, sex, age, bile or stone spillage, hospital stay duration and are summarized in Table-I.

In Group A patients, the mean hospital stay was 1.50 ± 0.9 days while in Group B it was 1.50 ± 0.8 days, threwas no significant difference in mean Hospital stay, p-value 0.992. No patient in either group develops postoperative sub-hepatic /pelvic collection Table-I.

Group A had 5(6.49%) superficial infection at umbilical port, 4(5.19%) pulmonary infections, and 2(2.59%) urinary tract infection, for total rate of infection of 14.28%. Group B had 5(6.84%) superficial infection at umbilical port, 1(1.29%) superficial infection at epigastric port, 4(5.47%) pulmonary infections, and 2(2.73%) urinary tract infection, for total rate of infection of 15.0%, there was lower rate of infection and insignificant among both group, p-value 0.896 Table-II.

The bile's rates of positive culture among cases within B- and A-groups were 18.5% and 19.7% respectively with isignificant difference p-value 0.594. The microorganisms isolated from bile are summarized in Table-III.

DISCUSSION

Laparoscopic Cholecystectomy (LC) is prevalent and currently, is the "gold standard" surgical procedure for benign gallbladder pathologies especially gallstone disease.

Initially in 1987, it was described by Mouret, later

PROPHYLACTIC ANTIBIOTICS

Characteristics	Group A n=77	Group B n=73	p-value	
Age (years)	37.6±17.8	38.6±15.8	0.654	
Gender				
Male	28(36.4%)	20(27.4%)	0.239	
Female	49(63.6%)	53(72.6%)		
Bile / Gallstone Spillage	06 (7.8%)	09 (12.3%)	0.355	
Duration of Surgery (min)	70.3 ± 35.7	76.5±32.4	0.754	
Hospital Stay duration (d)	1.50±0.9	1.50±0.8	0.992	
Table-I. Patients' demographic characteristics n=150				

Infective Complication	Group A n=77	Group B n=73	p-value	
Umbilical Port (Superficial)	05 (6.4%)	05 (6.8%)		
Epigastric Port (Superficial)	00	01 (1.4%)	0.896	
Pulmonary Infections	04 (5.2%)	04 (5.5%)		
Urinary Tract Infections	02 (2.6%)	02 (2.7%)		
Table-II. Patients distribution according to infections n=150				
Organism	Group A	Group B	P-value	

Organism	n=77	n=73	P-value	
Esherichia Coli	7(9.1%)	9(12.3%)		
Enterococcus Species	4(5.2%)	4(5.5%)		
Pseudomonas Aeruginosa	3(3.9%)	5(6.8%)	0.594	
Klebsiella Species	2(2.6%)	1(1.4%)		
Enterobacter Aerogenes	0	2(2.7%)		
Table-III. Microorganism Isolated from Bile n=150				

followed and improved by Dubois. In this study out of total 150 patients, Groups A and B included 77 and 73 patients, respectively. There were females in majority in contrast to males among both groups. Patients' mean age was 37.6 ± 17.8 years, these findings were without significant difference among both groups. Other studies also found similar results, as in the study of Uludag M, et. al.¹⁶ mean ages of patients in group-A and group-B were 44.6 ± 23.4 and 42.5 ± 21.6 , respectively. The study of PASSOS MA, et. al.¹⁷ reported a mean age of 48 ± 13.63 years, However a small difference in mean age may be due to ethnicity difference of the population.

In current study, in Group A patients, the mean hospital stay was 1.50 ± 0.9 days while in Group B it was 1.50 ± 0.8 days. No patient in either group develops postoperative sub-hepatic / pelvic collection. On the other hand, Naqvi MA, et. al.¹ reported that in their study mean hospital stay in group-A and group-B were 1.36 ± 0.8 days and 1.49 ± 0.8 days, respectively, and they found no case of deep infection/sub-hepatic abscess

in both groups. Higgins et al¹⁸ as well carried out a similar study, where he contrasted single dose prophylactic antibiotics with no antibiotics and also had similar results. Illeg et al¹⁹ in thier study contrased three doses of the antibiotics with no antibiotics and reported that there was no significant difference in postoperative infection rate. McGuckin et al²⁰ and Tocchi et al¹¹ reported that the application of prophylactic antibiotic is only required for those cases who are at high risk in infection development, such as, diabetic population or individuals with increased risk of bactobilia.

In this study, Group A had 5(6.49%) superficial infection at umbilical port, 4(5.19%) pulmonary infections, and 2(2.59%) urinary tract infection, for total rate of infection of 14.28%. Group B had 5(6.84%) superficial infection at umbilical port, 1(1.29%) superficial infection at epigastric port, 4(5.47%) pulmonary infections, and 2(2.73%) urinary tract infection, for total rate of infection of 15.0%. In contrast, Uludag M, et. al.,¹⁶ found that Group-A had superficial surgical site infections

3

at umbilical port site, pulmonary infections, and urinary tract infections, in the order of 3(4.41%), 3(4.41%) and 1(1.47%) respectively, for an overall infection rate of 10.29%. Group-B had superficial surgical site infections at umbilical port site, pulmonary infections, and urinary tract infections, in the order of 2(2.63%), 2(2.63%), and 3(3.95%) respectively, for an overall infection rate of 9.21%.

In our study, the bile's rates of positive culture among cases within B- and A-groups were 18.5% and 19.7% respectively. Uludag M, et. al.,¹⁶ reported that bile's rates of positive culture among cases within B- and A-groups were 13.2% and 17.1%, respectively. While on the other hand positive bile culture rate among cases with gallbladder stones has been from 10% to 42.5% in earlier studies.^{11,13,14,21} The main advantages of LC over open cholecystectomy includes a smaller amount of postoperative discomfort, smaller hospital stay, lower mortality and morbidity, less expenses and a lesser rates of surgical site and postoperative infection. Despite many benefits over open cholecystectomy, a significant benefit is the low rates of infective complication (0.4% to 1.1%)¹¹⁻¹⁵ Due to low incidence of infections, there have been several arguments and studies on the necessity of prophylactic antibiotics as one must consider that their mismanagement elevates the rates of infections and carries excessive financial burden on patient. It is evidenced that antibiotic is not indicated in surgeries where the risk of infection for surgical sites is around 5%. Several prospective studies also been conducted and concluded on results that the prophylactic antibiotics' application in low-risk subjects experiencing LC is unnecessary.22-24 In general terms, antibiotic prophylaxis usually restricted undergoing cholecystectomy to patients with associated risk factors and co-morbids like choledocolithiasis, cholangitis, age over 70 years, duration of intervention over 70 minutes, prior biliary instrumentation, immune compromise patients.^{11,25,26,27} As in results of this study, prophylactic antibiotic does not appear to reduce the rate of complications of postoperative infections significantly. On completion of this study, the policy adopted in our unit not to administer prophylactic antibiotics in uncomplicated and

low risk cases underwent LC. In the rational of social structure and socioeconomic conditions of our country and other developing countries, the findings of this study will definitely help the society.

CONCLUSION

In laparoscopic cholecystectomy, the application of antibiotic prophylaxis has no advantage in lowering the prevalence of surgical site infections as well as is unnecessary for elective laparoscopic cholecystectomy in low-risk cases.

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