Role of prophylactic antibiotics in laparoscopic cholecystectomy in the prevention of skin and skin structure infections

Nisar Ahmed, Saqib Saleem Afridi, Mohammad Ziaulhaq, Mahmud Aurgangzeb, Muhammad Muslim, Mohammad Zarin

Abstract:
Objective: To compare the frequency of skin and skin structure infections in patients undergoing laparoscopic cholecystectomy with and without prophylactic antibiotics.
Study Design: Randomized controlled Trial
Place and Duration of Study: Surgical B Unit, Department of Surgery, Khyber Teaching Hospital, Peshawar
Methodology: A total number of 144 patients randomized into two equal groups; A and B were included. Group A received prophylactic cefuroxime 1.5 g diluted into 10 ml solution while Group B received 10 ml normal saline before the induction of anaesthesia, no antibiotics were administered thereafter to either group. The frequency of skin and skin structure infection (SSI) were compared in both groups.
Results: In Group A 3 (4.1%) patients developed skin and skin structure infection, while in Group B 2 (2.7%) patients developed skin and skin structure infection. The difference between the two groups was not statistically significant (p=1.000).
Conclusion: Administration of prophylactic antibiotics does not reduce the frequency of skin and skin structure infections in patients undergoing laparoscopic cholecystectomy.

Keywords: Prophylactic antibiotics, Laparoscopic cholecystectomy, Skin and Skin Structure Infections

Introduction:
Laparoscopic Cholecystectomy (LC) has become the preferred procedure for gallstone disease. Out of the several advantages over open cholecystectomy (OC), an important benefit is low risk of infective complications i.e. 0.4 to 1.7%, mostly at the umbilical port site.1-4

Owing to the very low risk of infection, there has been a debate on whether prophylactic antibiotics are necessary. Regarding risk of infective complications, gallstone diseases have been classified into low and high risk groups.5 Those falling in the high risk group have one or more of the following; diabetes mellitus, age > 60 years, history of biliary colic in past 30 days, presence of jaundice, or history of acute cholangitis or acute cholecystitis.5 Regarding the low risk group that comprises the main bulk of patients with gallstone disease, there have been various studies done on whether prophylactic antibiotics are necessary or not.3, 6, 7, 8 The present study was designed to evaluate the importance of antibiotic prophylaxis in laparoscopic cholecystectomy.

Patients and methods:
This randomized controlled trial was carried out at Surgical B Unit, Khyber Teaching Hospital, Peshawar over a period of 6 months from January 2011 to June 2011. The study design was approved by the ethical committee of the hospital. Informed and written consent was obtained from all the patients scheduled to be included in the study.

All the patients scheduled for elective laparoscopic cholecystectomy were considered for
inclusion in the study. The exclusion criteria included: presence of diabetes mellitus, age > 60 years, history of acute cholangitis or cholecystitis, history of biliary colic in past 30 days and presence of jaundice clinically or biochemically. Routine preoperative workup included, assessment of ASA (American Society of Anesthesiologists) status, body weight, complete blood picture (CBC), liver function tests and ECG and chest x ray where indicated.

After inclusion in the study, the patients were randomized into two groups A and B by a method of random numbers. Both the patient and the surgeon were blinded to the groups. Group A received Cefuroxime 1.5 g diluted in 10 ml distilled water and group B received 10 ml of isonic saline intravenously before the induction of anaesthesia.

After induction of anaesthesia, the skin was prepared with 10% povidone iodine solution. Laparoscopic cholecystectomy was done by 3 ports technique, a fourth port was used whenever necessary. After completion of the procedure, the gallbladder with stones was extracted through the umbilical port site. Patients were kept nil by mouth for the next 6 hours.

All the patients were encouraged to be discharged from hospital on the next day. They were followed for the next two weeks and monitored for the development of skin and skin structure infections (SSIs), defined as redness or erythema around the wound, purulent discharge or microbiologically confirmed infective discharge from the wound. Infective complications in terms of SSI were compared between the two groups. The statistical analysis was done with the help of SPSS® v 10.0 for windows.

Results:
Out of total 163 patients scheduled for LC, 144 (111 females, 33 males) fulfilled the inclusion criteria. After randomization, each group received 72 patients. The preoperative demographic statistics were compared between the two groups with no statistically significant difference (Table 1). Similarly the operative variables such as duration of surgery, gallbladder rupture, bile spillage, stone spillage and postoperative hospital stay were compared with no significant difference between the two groups (Table 2).

In Group A, total number of 3 (4.1%) patients developed SSI, 2 at the umbilical port site and 1 in the epigastric port site. In Group B 2 (2.7%) patients developed SSI, both at the umbilical port site. No significant statistical difference was found between the two groups (p value=1.000).

Discussion:
With the advent of laparoscopic surgery, the outcomes of surgery have improved viz. less hospital stay, less perioperative pain, early recovery and return to work. As antibiotic prophylaxis has played a major role in prevention of septic complications in open surgery, its role has to be re-evaluated in laparoscopic surgery owing to its less morbidity as compared to open surgery.

There have been numerous studies in this aspect of biliary laparoscopic surgery. In a meta-analysis by Choudhary et al. in which 9 randomized control trials were selected for evaluation out of 133 articles, it was concluded that prophylactic antibiotics did not confer any benefit to patients undergoing laparoscopic cholecystectomy in terms of prevention of total infection, superficial infections, major infections, distant infections and reduction of hospital stay.

In a prospective randomized control trials by Tocchi et al. conducted in Italy that included 84 patients divided into two groups i.e., antibiotics group and control group. It was found that no benefit was conferred by antibiotic prophylaxis. In this study diabetic patients, patients with history of renal colic, previous endoscopic intervention and history of cholangitis were excluded. The same criteria was adopted in our study. Another RCT by Koc et al. also yielded the same results.

In another meta analysis by Yan et al in which 12 RCTs were selected from 156 articles, it was concluded that antibiotic prophylaxis does not confer protection from infective complications,
Role of prophylactic antibiotics in laparoscopic cholecystectomy in the prevention of skin and skin structure infections

The risks of infections in biliary surgery have been identified as history of acute cholangitis, presence of jaundice, history of renal colic. All of these conditions lead to increase in the intra luminal pressures of common bile duct, which leads to initiation of sepsis process. Thus performing surgery in such situations is associated with definite risk of infections. It is therefore imperative to prophylactically cover these patients with antibiotics especially when some intervention is being sought.

Diabetics, apart from being an independent risk factor for infective complications, renders the biliary tract susceptible to infections because it alters the motility of bile duct musculature. For this reason, diabetic patients were excluded from the protocol.

As it has been a proven phenomenon by several RCTs that micro-organisms are present in the aspirated bile during LC contains like E.coli, Klebsiella etc. but they do not alter the outcome in terms of antibiotic prophylaxis, therefore, doing bile cultures was excluded. In a study by Sattar I et al, conducted at Jinnah Postgraduate Medical Center, the frequency of infected bile was 36% whereas the frequency of wound infection was only 4%, meaning that the presence of infection does not necessarily mean that the wound will get infection. For this reason doing bile cultures were excluded from our study. This finding has been described by Koc M et al.

In the present study we have studied the infective complications in low risk patients. The role of prophylactic antibiotics needs to be evaluated in high risk patients as well. But keeping in view the nature of the disease, the problem of ethical perspective of this issue needs to be thrown light upon because not giving antibiotics to the high risk group might put the patient's outcome at stake. For this reason, in the international literature this question has seldom been asked and there is almost unanimous agreement that prophylactic antibiotics to the high risk group should be given.

In summary, the risks of infective complications in laparoscopic cholecystectomy are lower as compared to open cholecystectomy and for this reason the issue of use of prophylactic antibiotics has been thoroughly evaluated in many centers and meta analyses; much of the agreement is on the conclusion that prophylactic antibiotics do not reduce the chances of infective complications, whereas, their use is directly associated with increase in cost and might be indirectly associated with making the patient vulnerable to several side effects of the drugs used.

Table 1: Preoperative Demographics of the patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (n=72)</th>
<th>Group B (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (mean±SD)</td>
<td>49.2±7.6</td>
<td>52.3±6.3</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>22/50</td>
<td>18/54</td>
</tr>
<tr>
<td>ASA Score (n=%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>40 (55.55)</td>
<td>39 (54.16)</td>
</tr>
<tr>
<td>II</td>
<td>28 (38.88)</td>
<td>22 (30.55)</td>
</tr>
<tr>
<td>III</td>
<td>4 (5.55)</td>
<td>11 (15.27)</td>
</tr>
<tr>
<td>BMI (mean±S.D.)</td>
<td>24.3±4.3</td>
<td>24.9±5.1</td>
</tr>
</tbody>
</table>

Table 2: Operative variables of both groups.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (n=72)</th>
<th>Group B (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of surgery in minutes (mean±SD)</td>
<td>52.3±23.5</td>
<td>48.5±18.6</td>
</tr>
<tr>
<td>Gallbladder rupture, n(%)</td>
<td>4 (5.55)</td>
<td>7 (9.72)</td>
</tr>
<tr>
<td>Bile Spillage, n(%)</td>
<td>16 (22.2)</td>
<td>14 (19.44)</td>
</tr>
<tr>
<td>Stone Spillage, n(%)</td>
<td>17 (23.61)</td>
<td>13 (18.05)</td>
</tr>
<tr>
<td>Drain placement, n(%)</td>
<td>5 (6.94)</td>
<td>4 (5.5)</td>
</tr>
<tr>
<td>Use of 4th port, n(%)</td>
<td>5 (6.94)</td>
<td>7 (9.72)</td>
</tr>
</tbody>
</table>

Conclusion:
Prophylactic antibiotics do not reduce the risk of infective complications in patients undergoing laparoscopic cholecystectomy in low risk group of patients. In high risk group i.e. Patients having diabetes, age>60 years, history of cholangitis, presence of jaundice and a history of biliary colic in previous 30 days; needs to be evaluated in proper randomized controlled trials.

References:
2. Chuang SC, Lee KT, Chang WT, Wang SN, Kuo KK, Chen JS,