Omission of Prophylactic Antibiotics in Elective Laparoscopic Cholecystectomy in Low Risk Patients

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ABSTRACT

Background: Despite elective laparoscopic cholecystectomy has a low risk for infectious complications, many surgeons' still use prophylactic antibiotics. Prophylactic antibiotics administration has been recommended by the centers for disease control and prevention and commonly used in clean-contaminated surgery such as cholecystectomy to reduce surgical site infections. In contrast, several meta-analyses have recently concluded that antibiotic prophylaxis is not necessary in patients undergoing laparoscopic cholecystectomy.

0bjectives

The goal of our study was to prove the safety of omission of prophylactic antibiotics regarding development of postoperative surgical site infection in patients undergoing laparoscopic cholecystectomy.

Patient and Methods: This is a cross sectional study of ninety four patients underwent laparoscopic cholecystectomy in Baquba teaching hospital during the period from February 2014 to October 2015. The patients were randomly placed into 2 groups: (group A) 47 patients received prophylactic cefotaxime 1g intravenously at the time of induction of anesthesia, and (group B) 47 patients were not given prophylactic antibiotics. Postoperatively the antibiotics were omitted in both groups. Exclusion criteria were patients older than 60 years; when antibiotics used 7 days before surgery; acute cholecystitis in the 4 -6 weeks before to the procedure; evidence of cholangitis and/or obstructive jaundice and biliary pancreatitis; regular corticosteroid therapy; pregnancy or lactation; previous biliary tract surgery or previous endoscopic retrograde cholangio pancreatography; American society of anesthesia higher than score II; diabetes mellitus; body mass index higher than 30; and conversion to open cholecystectomy. The development of surgical site infection postoperatively was investigated and compared in the two groups.

RESULTS

No significant differences were found between group A and B regarding gender, age, body weight, American society of anesthesia score, conversion to open surgery, duration of operation , number of intraoperative gallbladder perforations and spill of bile or stones, number of positive bile cultures, mean postoperative hospital stay, or number of infectious complications. Group A had 1 (2.17%) superficial SSIs in the epigastric port site. Group B had 2(4.44%) superficial SSIs in the epigastric port site (P>0.05). There was no significant association between intraoperative gallbladder rupture or positive bile culture and SSI. The rate of gallbladder rupture in groups A and B were (19.56%) and (13.33%) respectively (P>0.05).

CONCLUSION

Perforation of the gall bladder and possible positive bile culture do not increase SSI rates if the contaminated site was irrigated well. Antibiotic prophylaxis does not seem to affect the incidence of surgical site infection and is not necessary for elective Laparoscopic cholecystectomy in low-risk patients.

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

INTRODUCTION

Despite improved asepsis and surgical techniques, postoperative complications, such as surgical site infection and intra-abdominal abscess, still account for a significant morbidity. In the first 4 hours after a breach in an epithelial surface and underlying connective tissues made during surgery or trauma, there is a delay before host defences can become mobilised through acute inflammatory, humeral and cellular processes. This period is called the 'decisive period' and it is during these first 4 hours after incision that bacterial colonisation and established infection can begin. It is logical that prophylactic antibiotics will be most effective during this time.Following closure of the wound, local intravascular coagulation and the events of early inflammation that initiate wound healing seal its environment: this may explain why the postoperative administration of antibiotics is ineffective in preventing wound infection [1, 2].

Elective gallbladder surgery is the most common elective surgical procedure in the abdomen. Cholecystectomy is the universally accepted method to manage symptomatic uncomplicated gallstones and other benign gallbladder diseases because it can cure the disease and has low morbidity and mortality [3]

Gall stones are one of the most common abdominal diseases of adults. Although many patients are asymptomatic and gallbladder stones are an incidental finding during ultrasonography, 1% to 4% of patients have digestive complaints that compel a treatment [4, 6]. Furthermore, biliary dyskinesia and gallbladder polyps, although less frequent, are also indications of elective cholecystectomy [7,8].

The most frequent complication occurs in patients undergoing cholecystectomy is surgical site infection (SSI). Surgical site infection was reported in 10% to 23% of the patients who had been operated on before the routine use of antibiotic prophylaxis was introduced in 1960[9,10]. The surgical site infection increases length of hospital stay and costs and can cause considerable morbidity and mortality [11].

Since 1960, antibiotic prophylaxis has been considered as the best intervention to prevent surgical site infection in elective surgery. Antibiotic prophylaxis includes preoperative administration of wide-spectrum antibiotics against the most frequent bacteria involved in surgical site infection, trying to get high tissue levels of the antibiotic at the surgical wound in order to avoid colonization and growth of microorganisms [9,12,13].

It is accepted that antibiotic prophylaxis must be administered in all surgical procedures classified as clean-contaminated or in selected immune compromised patients undergoing clean surgery [14].

Cholecystectomy is considered a clean-contaminated operation on the basis that the biliary tract is entered without significant spillage during the procedure. Some randomized clinical trials have confirmed that antibiotic prophylaxis in open cholecystectomy is decreasing the risk of surgical site infection [15].

Now a day's laparoscopic cholecystectomy (LC) is considered the standard treatment for symptomatic gallstones. The incidence of occurrence of SSIs following LC is obviously lower compared with those following open surgery. The use of prophylactic antibiotics as a means of preventing SSIs in elective open cholecystectomy is clear, while it is still controversial in elective LC, which has a low risk for infectious complications [16].

Despite many authors believe that prophylactic antibiotics may not be necessary in patients undergoing elective LC [17_21], many other surgeons still use and recommend the administration of prophylactic antibiotics [22_26].

Aim of the study

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Patients and methods

This is a cross sectional study of ninety four patients underwent laparoscopic cholecystectomy in Baquba teaching hospital during the period from February 2014 to October 2015.

The patients were randomly placed into two groups: (group A) 47 patients received prophylactic cefotaxime 1g intravenously at the time of induction of anesthesia, and (group B) 47 patients were not given prophylactic antibiotics. Postoperative antibiotics were omitted in both groups. The development of surgical site infection postoperatively was investigated and compared in the two groups.

Exclusion criteria were patients older than 60 years; antibiotic used 7 days before surgery; acute cholecystitis in the 4 -6 weeks prior to the procedure; evidence of cholangitis and/or obstructive jaundice and biliary pancreatitis; regular corticosteroid therapy; pregnancy or lactation; previous biliary tract surgery or previous endoscopic retrograde cholangiopancreatography; presence of American society of anesthesiologists classification (ASA) higher than score II; evidence of diabetes mellitus; body mass index more than 30; and conversion to open surgery. Patients who do not have any of the above excluding criteria are considered low risk patients for developing SSI.

Patients in group A given cefotaxime (1g) administered intravenously during induction of anesthesia as a prophylactic antibiotic. In group B the patients do not given the prophylactic antibiotic. After induction of anesthesia, the skin was disinfected with a 10% solution of povidone-iodine. LC was performed in all patients by using a 4-trocar technique. A 10-mm trocar was placed with the open technique using an infraumbilical incision. The other 3 trocars were placed under direct vision. A 10-mm trocar was placed in the epigastrium, a 5-mm trocar on the midclavicular line, and a 5-mm trocar in the right flank in line with the gallbladder fundus.

If gallbladder perforated and spill of bile or stones were encountered, spilled stones were retrieved whenever possible, and local peritoneal lavage with 1 liter saline was performed. The gallbladder was removed through the epigastric port, without the use of an endobag but taking extreme care in avoiding soiling the site of exit of the extracted gallbladder (epigastric port site). If gallbladder perforation occurred with spillage of bile or stones, local irrigation of the peritoneum and irrigation of the site of extraction of the gallbladder from the epigastric port site wound is done. Secure hemostasis maintained and the drain was never placed. A sample of bile was removed by suction with a sterile syringe from the gallbladder immediately after its removal and sent to the microbiology laboratory for bacterial detection using a gram stain. Antithrombotic prophylaxis was not administered, and urinary catheter was not inserted. If a nasogastric tube needed to be inserted during surgery, it should be removed at the end of surgery.

The postoperative course was monitored, and any incidents, such as fever, infection of the trocar site, or intra abdominal collection of pus, were recorded. After discharge from the hospital, the patients underwent weekly clinical and laboratory postoperative monitoring for SSI for a 1 month period.

The following data were collected for each patient: age, gender, body weight, ASA classification, blood biochemical data, times of antibiotic administration, time of skin incision, gallbladder perforations, bile and/or spillage, positive bile culture, type of fascia and skin closure, duration of surgery, conversion to open surgery, bile and wound culture results, length of hospital stay, and number of septic complications. Postoperative superficial or deep incisional soft tissue SSI and intra abdominal abscess (organ/ space SSI) were defined according to published criteria. If local signs of inflammation or a pus collection were present, bacteriological swabs were taken from the wound site.

Statistical analyses were performed by using t- test, and Levene's test. All analyses were conducted using SPSS 10 software with a P-value < 0.05 considered as significant.

RESULTS

Three patients (1 patients from group A and 2 patients from group B) who were converted to open cholecystectomies were excluded from the original groups. After excluding the patients converted to open surgery, Groups A and B included 46 and 45 patients, respectively. The characteristics of the groups and number of infectious complications are presented in Table 1.

No significant differences were found between the 2 groups regarding gender, age, body weight, ASA score, conversion to open surgery, duration of operation, number of intraoperative gallbladder perforations and spill of bile or stones, number of positive bile cultures, mean postoperative hospital stay, or number of infectious complications. Group A had 1 (2.17%) superficial SSIs in the epigastric port site, 1 (2.17%) pulmonary infections, and 2(4.44%) urinary tract infections. Group B had 2(4.44%) superficial SSIs in the epigastric port site, 1 (2.17%) pulmonary infections, and 1 (2.17%) urinary tract infections. There was no significant association between intra operative gallbladder perforation or positive bile culture and SSI. The rate of gallbladder rupture in groups A and B were (19.56%) and (13.33%) respectively. SSI occurred in 1 of 15 patients who had a gallbladder perforation and in 2 of 91 patients without rupture (P>0.05). The positive culture rates of bile in patients in groups A and B were (15.22%) and (20%), respectively, and the difference was not significant.

The most commonly isolated microorganisms are summarized in **Table 2**. SSI occurred in 1 of 16 patients who had a positive bile culture and in 2 of 75 patients who had a negative bile culture (P>0.05). In group A the wound culture from the one patient who developed SSI was associated with negative bile culture; while in group B the wound culture from the two patients who developed SSI were associated with one negative and one positive bile culture. In the 1 of 3 patients who had a negative bile culture, coagulase-negative *Staphylococcus spp.* and *Staphylococcus aureus* were isolated on culture from the wounds. All SSIs were superficial SSIs.

DISCUSSION

The data of present study show that the incidence of SSI in patients was 3% for the total study group, 2.17% for group A, and 4.44% for group B, there was no significant difference in infection rate between the two groups and this is in agreement with studies done by Chang WT, et al., Koc M, et al. , Mahatharadol V. and Tocchi A, who all showed that antibiotic prophylaxis is not required in elective LC, because the infection rate of LC is already low and the use of prophylactic antibiotics does not decrease the incidence of SSIs and other postoperative infection complications[17_20].

Another study done by Goldfaden and Birkmeyer also showed the same results as ours; they reviewed the perioperative treatment of patients with laparoscopic interventions in 98 randomized studies on antibiotic prophylaxis since 1990. They stated that routine antibiotic use in LC is likely unnecessary for low-risk patients [27].

In our study, we detected that the overall rate of SSI did not correlate with the presence of bacteria in the bile, gallbladder rupture or spillage of gallbladder stones. Many other studies have also indicated that SSIs are not related to bile culture, or bile spillage [16,17,19,21,27,28].

In a study done by Mahatharadol V, One hundred and two low-risk patients were randomized into 1 of 2 treatment arms (1) cefazolin 1 g intravenously after induction of anesthesia (prophylactic group) and (2) no prophylactic antibiotics (NONE group). Laparoscopic cholecystectomy was attempted in all cases. The patients were followed-up for postoperative septic complications for at least 30 days at the out-patient clinic or by telephone contact. In both groups, sex, age, weight, American Society of Anesthesiologists patient classification score, operative time, surgical techniques, number of port sites, intraoperative cholangiograms, intraoperative gallbladder rupture, postoperative hospital stay, and postoperative septic complications were compared. The statistical analysis of data performed by computer program SPSS 10.0 for Windows was based on the Independent-Samples T Test or the Pearson Chi-Square (2-sided).

In this study there was only one minor problem of superficial wound infection in the NONE group. Comparison of data showed no statistically significant difference between the groups. [19]

Conclusion

Intraoperative gallbladder perforation and possible positive bile culture do not increase the rate of SSI. Local irrigation of the peritoneum and irrigation of the site of extraction of the gallbladder from the epigastric port site wound is sufficient in managing this problem. For this reason, we concluded that antibiotic prophylaxis does not seem to affect the incidence of SSIs and is not necessary for elective LC in low-risk patients.

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Table 1. Distribution of variables related to the patients, surgery and the development of SSI

Characteristics	Group A n _ 46	Group B n _ 45	P- Value
Gender (M/F)	3/43	4/41	(P>0.05)
Mean age (y)	23.4_44.6	21.6_42.5	(P>0.05)
Body weight (kg)	7.61_73.3	7.73_74.1	(P>0.05)
ASA score (I/II)	44/2	44/1	(P>0.05)
Conversion n (%)	1 (2.13)	2 (4.26)	(P>0.05)
Infected bile n (%)	7(15.22)	9 (20)	(P>0.05)
Bile or gallstone spillage	9 (19.56)	6 (13.33)	(P>0.05)
Duration of surgery (min)	31.2_52.4 (average 41.8)	29.6_45.1(average 37.35)	(P>0.05)
Length of hospital stay (Day)	0.75_1.11 (average 0.93)	0.75_1.21 (average 0.98)	(P>0.05)
SSI (superficial) n (%)	1 (2.17)	2(4.44)	(P>0.05)
Urinary tract infection n (%)	2 (4.44)	1 (2.17)	(P>0.05)
Pulmonary infection n (%)	1 (2.17)	1 (2.17)	(P>0.05)

* P- Value > 0.05 non-significant

* P- Value < 0.05 significant

Table 2. Microorganisms isolated from gallbladder bile

Microorganism	Group A (n _46)	Group B (n _45)	P- Value
Esherichia coli	3	5	(P>0.05)
Enterococcus species	2	1	(P>0.05)
Klebsiella species	1	1	(P>0.05)
Pseudomonas aeruginosa	1	2	(P>0.05)
Staphylococcus species	1	1	(P>0.05)
Enterobacter aerogenes	0	1	(P>0.05)
Monobacterial	6	7	(P>0.05)
Mixed flora	1	2	(P>0.05)
Total bile culture	7	9	(P>0.05)

* P- Value > 0.05 non-significant

* P- Value < 0.05 significant