A Reevaluation of Antibiotic Prophylaxis in Laparoscopic Cholecystectomy: A Randomized Controlled Trial†

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Abstract

Background : To assess the result of antibiotic prophylaxis in low-risk patients undergoing elective laparoscopic cholecystectomy with respect to the postoperative septic complications.

Method : One hundred and two low-risk patients were randomized into 1 of 2 treatment arms (1) cefazolin 1 g intravenously after induction of anesthesia (PA 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).

Results : 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.

Conclusion : Antibiotic Prophylaxis may not be necessary in low-risk patients undergoing elective laparoscopic cholecystectomy.

Key word : Antibiotic Prophylaxis, Septic Complications, Laparoscopic Cholecystectomy

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In laparoscopic cholecystectomy the global rate of septic complications was 3.6 per cent *vs* 12.6 per cent in open cholecystectomy; 2.4 per cent and 6.3 per cent wound infection respectively[1]. Open cholecystectomy has a significantly higher infection rate than laparoscopic cholecystectomy. Antibiotic prophylaxis reduces septic complications in open cholecystectomies [2-4]. The oveall septic complications following elective laparoscopic cholecystectomy are extremely low, but many surgeons still routinely use prophylactic antibiotics, though there are questions as to whether it is required or useful[5-6]. This prospective randomized trial was conducted to determine whether administration of prophylactic antibiotics is necessary during routine laparoscopic cholecystectomy in low-risk patients.

METHOD

From October 1999 to April 2000, all low-risk patients undergoing elective laparoscopic cholecystectomy at Rajavithi Hospital, Bangkok, Thailand were evaluated for the protocol. By block randomization, 51 patients received cefazolin 1 g intravenously after induction of anesthesia (PA group) and 51 patients received no prophylactic antibiotics (NONE group). Laparoscopic cholecystectomy was attempted in all cases. At surgery, the skin was cleansed with 10 per cent povidone-iodine solution. The allowed variables were number and location of port sites, intraoperative cholangiograms, port site used for gallbladder removal, and method of skin closure.

The following data were collected on each patient: sex, age, weight, American Society of Anesthesiologists patients classification score, operative time, surgical techniques, number of port sites, intraoperative cholangiograms, intraoperative gallbladder rupture, postoperative hospital stay and postoperative septic complications.

All patients were followed-up for 30 days after the procedure at the out-patient clinic or by telephone contact.

Septic complications were classified as superficial wound infection, deep surgical wound infection and distant. A superficial wound infection was defined as erythema and /or purulent drainage at the surgical site above the fascial layer. A deep surgical wound infection was defined as purulent material at or beneath the fascial layer. Distant infection was defined as any infection remote to the surgical site.

Inclusion criteria in the protocol were all patients scheduled for elective laparoscopic cholecystectomy aged between 15 and 80 years and meeting no exclusion criteria. Exclusion criteria were patients older than 80 years, pregnant or lactating women, beta-lactam or cephalosporin allergy, antibiotic therapy within 48 hours prior to surgery, evidence of acute inflammation, common bile duct obstruction, obstructive jaundice, gallstone pancreatitis, history of prosthetic valves, and immunocompromized host.

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). Multivariated analysis was carried out by using the septic complications as the dependent variable. $P<0.05$ was considered significant.

RESULTS

One patient in the PA group was lost to follow-up and one patient in the NONE group needed exploration for definite treatment of adenocarcinoma of the gallbladder after receiving the pathological report. Both were excluded. PA and NONE group included 50 patients each. One patient in the NONE group developed superficial wound infection on the fifth postoperative day. No organism was found from the discharge culture. Comparison of data showed no statistically significant difference between the groups. (Table 1) The multivariated analysis identified no factor significantly associated with the septic complication.

DISCUSSION

Many surgeons routinely use antibiotics to decrease the incidence of septic complications in biliary tract surgery. Several reviews have demonstrated a significant decrease in septic complications in open cholecystectomhy with the use of prophylactic antibiotics[2-4]. Laparoscopic cholecystectomy does not need antibiotic prophylaxis because it is associated with a low infection rate. However, this is not well documented and it is still controversial[7]. In this study we selected cefazolin 1 g intravenously as a single

Table 1. Demographic Data and Results.

	PA group (n = 50)	NONE group (n = 50)	P
Sex, M/F	13/37	10/40	0.47
Age, y	52.2 ± 14.4	51 ± 15.7	0.42
Weight, kg	57.5 ± 9.4	59.9 ± 13.1	0.29
Hypertension	12	9	0.46
Diabetes	5	3	0.46
ASA score			
1	34	37	
2	14	13	0.34
3	2		
Operative time, m	109 ± 30.7	102.6 ± 31.3	0.75
Operative Technique			
No of ports 3/4	13/37	9/41	0.06
IOC	3	4	0.69
Intraoperative	4	6	0.50
Gallbladder rupture			
Postoperative stay, day	2.6 ± 1.0	2.8 ± 1	0.78
Wound infection	0	1	0.31

injection as it was recommended for likely pathogens (Enteric gram negative bacilli, enterococci, clostridia)[8]. This study demonstrated no reduction of septic complications with a single dose of prophylactic antibiotics in elective low-risk laparoscopic cholecystectomy. Illig et al[9] had similar results in a prospective randomized study. They compared the use of 3 perioperative doses of cefazolin with no use of antibiotics in elective laparoscopic cholecystectomy. Frantzides and Sykes[10] had similar results in a prospective nonrandomized study comparing preoperative cefotetan with preoperative chlorhexidene gluconate scrub without preoperative antibiotics. Tocchi et al[11] had similar results in a prospective randomized study. They compared the use of cefotaxime with placebo.

Some antibiotics are very expensive and are no more effective than less expensive antibiotics. Obviously, if all low-risk patients under going laparoscopic cholecystectomy stop getting antibiotics, there is a big potential reduction in cost as well as avoidance of a variety of antibiotic problems. Many surgeons, thinking that drugs are totally safe, use antibiotics when the chance of an adverse effect from the drug is greater than the chance of infection in the patient.

Antibiotic prophylaxis may be not necessary in low-risk patients undergoing elective laparoscopic cholecystectomy.

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การใช้ยาปฏิชีวนะแบบป้องกันไม่ลดภาวะแทรกซ้อนจากการติดเชื้อในการผ่าตัดถุงน้ำดีโดยใช้กล้อง†

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ผู้ทำการวิจัยได้ศึกษาภาวะแทรกซ้อนจากการติดเชื้อในการผ่าตัดถุงน้ำดีโดยใช้กล้องในผู้ป่วยที่มีความเสี่ยงต่ำ 102 ราย ที่โรงพยาบาลราชวิถี ตั้งแต่เดือนตุลาคม 2542 - เมษายน 2543 แบ่งผู้ป่วยเป็นสองกลุ่มโดยวิธีการสุ่มตัวอย่าง กลุ่มที่หนึ่งจำนวน 51 ราย ให้ยาปฏิชีวนะ cefazolin 1 กรัมฉีดเข้าเส้นเลือดดำหลังดมยาสลบ กลุ่มที่สองไม่ให้ยาติดตามผู้ป่วยทั้งหมดอย่างน้อย 30 วันหลังผ่าตัด ทั้งสองกลุ่มไม่มีความแตกต่างกันทางสถิติในเรื่องเพศ อายุ น้ำหนัก American Society of Anesthesiologists patient classification score ระยะเวลาผ่าตัด เทคนิคการผ่าตัด การรั่วของถุงน้ำดีระหว่างผ่าตัด และระยะเวลาที่อยู่โรงพยาบาลหลังผ่าตัด พบว่ามีการติดเชื้อแบบตื้นที่แผลผ่าตัดเพียง 1 รายในผู้ป่วยกลุ่มที่ไม่ได้ยาซึ่งไม่มีนัยสำคัญทางสถิติ (p=0.31) การศึกษานี้สรุปได้ว่าการใช้ยาปฏิชีวนะ แบบป้องกันไม่ลดภาวะแทรกซ้อนจากการติดเชื้อในผู้ป่วยที่มีความเสี่ยงต่ำในการผ่าตัดถุงน้ำดีโดยใช้กล้อง

คำสำคัญ : การใช้ยาปฏิชีวนะแบบป้องกัน, ภาวะแทรกซ้อนจากการติดเชื้อ, การผ่าตัดถุงน้ำดีโดยใช้กล้อง

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