Excerpta Medica

The American Journal of Surgery

The American Journal of Surgery 191 (2006) 721–725
Clinical surgery—International

The impact of prophylactic antibiotics on postoperative infection complication in elective laparoscopic cholecystectomy: a prospective randomized study

Wen-Tsan Chang, M.D.[a], King-Teh Lee, M.D., Ph.D.[a,b,*], Shih-Chang Chuang, M.D.[a], Shen-Nien Wang, M.D.[a], Kung-Kai Kuo, M.D., Ph.D.[a,b], Jong-Shyone Chen, M.D., Ph.D.[a,b], Pai-Ching Sheen, M.D., Ph.D.[a,b]

[a]*Department of Surgery, Chung-Ho Memorial Hospital, Kaohsiung Medical University*
[b]*Department of Surgery, Faculty of Medicine, Kaohsiung Medical University, 100, Tz-You 1st Rd., Kaohsiung 80708, Taiwan*

Manuscript received June 30, 2005; revised manuscript January 8, 2006

Abstract

Background: The aim of this prospective randomized study was to investigate the necessity and impact of prophylactic antibiotics on postoperative infection complications in elective laparoscopic cholecystectomy.
Methods: At the time of induction of anesthesia, group A patients (n = 141) received 1 g cefazolin, and group B patients (control; n = 136) received 10 mL isotonic sodium chloride solution. Patients' characteristics and general operative outcomes were compared and analyzed.
Results: The overall rate of infection was 1.1% for total 277 patients (0.7% for group A patients and 1.5 % for group B patients). No significant difference in infection complications was found between these 2 groups. Also any risk factors contributing to infection complications could not be found.
Conclusions: We do not recommend the use of prophylactic antibiotics in elective laparoscopic cholecystectomy because they will not decrease the already-low rate of postoperative infectious complications.

Keywords: Cefazolin; Laparoscopic cholecystectomy; Prophylactic antibiotics; Surgical-site infection; Wound infection

Laparoscopic cholecystectomy (LC) carries an extremely low rate of postoperative infection compared with open cholecystectomy [1–3]: The average rate of wound infection was between 0.4% and 1.1% in three large meta-analyses of multiple centers retrospective cases studies [1,3,4]. Therefore, compared with open cholecystectomy, many investigators have suggested that antimicrobial prophylaxis is probably unnecessary for LC patients because the infection rate of LC is already low, and the use of prophylactic antibiotics does not decrease the rate of wound infections and other postoperative infection complications [3,5–9].

However, use of prophylactic antibiotics in LC is still popular, and many surgeons believe that prophylactic antibiotics will decrease the incidence of postoperative infection complications in LC [10–12]. McGuckin et al [3] showed that 79% of patients who had undergone LC procedures had received prophylactic antibiotics preoperatively, and 63% had received them postoperatively [3].

For its broad-spectrum antimicrobial effect, low toxicity, and low cost, the single-dose use of cefazolin has been recommended for patients undergoing open cholecystectomy and other biliary surgery [8,13], and it was recommended by the United States Centers for Disease Control and Prevention (CDC) as the general principle for prevention of postoperative surgical site infection (SSI) in open cholecystectomy [14,15].

Because there is still some controversy surrounding routine use of prophylactic antibiotics in elective LC, this current study was conducted according to the CDC guides and with the aim to clarify the impact and necessity of single-dose use of cefazolin as a prophylactic antibiotic in elective LC.

* Corresponding author. Tel.: +011-886-7-3208172; fax: +011-886-7-3216992.
E-mail address: ktlee@kmu.edu.tw

0002-9610/06/$ – see front matter
doi:10.1016/j.amjsurg.2006.01.050

Materials and Methods

Patient characteristics

From August 2000 to September 2002, 277 patients suffering from symptomatic gallbladder stones or polyps disease with or without acute cholecystitis who were candidates for elective LC were enrolled in this study consecutively. Patients were divided into 2 groups (A and B) by random numbers of operative schedule. At the time of induction of anesthesia, group A patients (n = 141) received 1 g cefazolin, and group B (control) patients (n = 136) received 10 mL isotonic sodium chloride solution. No additional doses of antibiotics in either intravenous or oral form were administered during or after surgery in either patient group. The use of antibiotic prophylaxis and normal saline was blinded to the patient. The Ethics Committee approved the study, and each patient gave signed informed consent before participating in the study.

The following data were collected for each patient: age; sex; body height and weight; catalogs of gallbladder diseases (stone or polyp); presence of diabetes mellitus (DM); blood biochemical data; presence of jaundice; preoperative retrograde cholangiopancreatography or percutaneous transhepatic cholangiography (PTC); episodes of colic within 30 days before surgery; fever (>38°) or chills within 1 week before surgery; American Society of Anesthesiologists score; duration of operation; length of postoperative hospital stay; gallbladder rupture, bile, and/or stone spillage; histologic finding of gallbladder; presence or not of subhepatic drain; result of bile culture; number and kinds of infection complications; and organisms cultured from the SSI.

One hundred eighty-six patients were not eligible because they met 1 of the following 6 exclusion criteria: (1) antibiotics use within 7 days of the planned LC for 62 patients; (2) cephalosporin or B-lactam allergy, sensitivity, or anaphylaxis for 6 patients; (3) concomitant choledocholithiasis, intrahepatic duct stones, or gallstone pancreatitis for 43 patients; (4) previous biliary surgery for 20 patients; (5) acute and emergent intervention for 37 patients; and (6) conversion to open cholecystectomy for 18 patients.

Treatment protocol and surgical procedure

Skin preparation, aseptic procedure, and LC were performed as the standard procedure [16]. Cefazolin (1 g) or normal saline was administered intravenously by anesthesia personnel in the operative suite at induction. Gallbladders were extracted through the opening of the trocar-made extraction hole located in the umbilical region. A sample of bile was removed with a sterile syringe from the gallbladder immediately after its removal and sent to the micrology laboratory for bacteria detection. Any ruptured gallbladder with severe inflammation and friability was removed by a plastic bag (Endo-Bags, LiNA, Glostrup, Denmark). Local peritoneal irrigation was done when gallbladder rupture and spill of bile or stone was encountered. One Jackson-Pratt drainage tube was placed in the subhepatic space if a there was a complicated and difficult gallbladder removal or if spillage of bile or gallbladder stone was encountered. The umbilical incision was closed with 2-0 nonabsorbable monofilament suture, and the other incisions were closed with 3-0 nonabsorbable monofilament sutures.

Definition of infection

The postoperative course was monitored during admission, and patients were followed-up 1, 2, 3, and 4 weeks after discharge. Infectious complications were defined as pyrexia with a body temperature >38°C (temperature taken twice a day, excluding the postoperative day 1) or purulent drainage from the surgical sites, with or without positive cultures for infectious sites such as wounds, urinary or respiratory tract, and abdominal cavity, according to the definition of the CDC [5,6,15,17]. In this study, wound infections were further classified into superficial or deep incisional SSI, and abdominal cavity infection was defined as organ/space SSI [15,17]. If an SSI was encountered, antibiotics were given until there was no evidence of SSI or persistent signs of sepsis.

Statistical analysis

Data were analyzed using SPSS 11.0 statistical package (SPSS, Chicago, Illinois). All categoric variables were assessed by Chi-square test with Yates correction, and analysis of risk factors contributing to SSI was performed with Fisher's exact test for small cell sizes. Continuous variables were compared using a 2-tailed unpaired Student *t* test. $P < .05$ was considered statistically significant.

Results

Patient's characteristics and perioperative data

Fifty male and 91 female patients (mean age 50.3 years) were enrolled in group A, and 55 male and 81 female patients (mean age, 52.9 years) were enrolled in group B. Between group A and B patients, there was no difference in characteristics of patients and surgical outcomes (Table 1).

Postoperative infection complications

Overall rate of SSI was 1.1% for 277 patients. No difference in infection complications was found in either group. The use, or not, of prophylactic antibiotics did not correlate with SSIs ($P = .148$, Table 1). In group A, 1 patient (.7%) who received PTC before LC developed subphrenic purulent fluid accumulation (space SSI) and fever up to 39° discovered 2 days after discharge; however, there initially was no drain left in the subhepatic space after