Effect of bag extraction to prevent wound infection on umbilical port site wound on elective laparoscopic cholecystectomy:

A prospective randomised clinical trial

Authors

Jordi Comajuncosas, M.D., Judit Hermoso, M.D., Ph.D., Jaime Jimeno, M.D., Ph.D, Pere Gris, M.D., Rolando Orbeal M.D., Antonio Cruz R.N., David Parés, M.D., Ph.D

Department and Institution

Department of General and Digestive Surgery. Parc Sanitari Sant Joan de Déu. Universitat de Barcelona. Sant Boi de Llobregat. Barcelona

Correspondence

Jordi Comajuncosas, M.D.

Department of General and Digestive Surgery.

Parc Sanitari Sant Joan de Déu. Universitat de Barcelona. Sant Boi de Llobregat. C/ Camí Vell de la Colònia 25. 08830 Sant Boi de Llobregat (Barcelona). Spain

Phone: +34 936615208 Fax: +34 936306175

E-mail: j.comajuncosas@pssjd.org

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Abstract

Background

Laparoscopic cholecystectomy is gold standard treatment for gallbladder stones. Complications due to laparoscopic procedure are rare but rate of wound infection in some studies is about 8 %.
From January 2007 to December 2008, 320 laparoscopic cholecystectomies were performed at our hospital, and in 4.7 % of them, wound infection of the umbilical trocar was identified.
We believe that this infection rate could be lower and that it is necessary to implement a new technique to reduce the wound infection. The aim of the study was to evaluate the benefits of bag extraction of gallbladder to prevent the wound infection.

Methods

2-arm, parallel, 1:1, randomized controlled trial (ISRCTN38095251). All patients suffering from symptomatic gallbladder stones of low risk were enrolled for this study and were divided into 2 groups in basics gallbladder extraction: with (80 patients) or, as usually, without bag (76 patients).
All patients with cholecystitis or accidental gallbladder perforation were excluded. We compared all the results to establish if meaningful differences were found.

Results

The final sample analysed (156 patients) consisted of 121 women and 35 men; there were 80 in the control group and 76 in the study group.
There were 15 (9.6 %) diagnosed wound infections, eight cases in the study group and 7 in the control group. There were no statistically significant differences.

Conclusions

The determinant of wound infection in elective laparoscopic cholecystectomy is not the direct contact of the gallbladder with the wound; therefore bag extraction is not necessary.

Key words

Laparoscopic cholecystectomy, wound infection, bag extraction, gallbladder, trocar site incisional hernia, laparoscopic complications.

Introduction

As we quoted in previously published studies[1] the introduction of laparoscopic cholecystectomy performed by Mouret[2] in 1987 and its widespread use in the past 20 years, has dramatically increased the number of patients undergoing this surgical approach. At present laparoscopic cholecystectomy has become the gold standard treatment for symptomatic cholelithiasis[3-4]. Any new technique is associated with the development of new complications, and trocar site incisional hernia (TSIH) is possibly the most common in laparoscopic cholecystectomy[5].

Several studies[1,6-12] suggested that wound infection was associated with the development of TSIH, therefore if we decrease the percentage of infections we will also reduce the number of TSIH.

The minimal tissue damage of laparoscopic cholecystectomy suggests a lower risk of wound infection but there are series[13] with an infection range of 8 %.

The aim of this study was to investigate the effect of the use of bag extraction on the occurrence of wound infection in the umbilical port site wound because there is no scientific consensus on the use of it.

Materials and Methods

Study design and Participants

This study (ISRCTN38095251) was approved by the institutional review board, ethical committee, of our institution and was a 2-arm, parallel, 1:1, randomized controlled trial. The inclusion criteria of the study were: patients older than 18 years with uncomplicated or low risk cholelithiasis who underwent elective laparoscopic cholecystectomy from March 2011 to June 2013 at our institution.

All participating patients signed informed consent of the study and were randomly allocated to the bag group (study group) or to the no bag extraction group (control group) with a computer based randomization system.

Exclusion criteria were patients who did not sign the informed consent of the study, patients with criteria for risk laparoscopic cholecystectomy (bile duct stones, previous surgery or obstruction of the bile duct, or recent cholecystitis)[14], use of antibiotics 7

days before or after the intervention (for a cause unrelated to the infection of the wound), finding of unexpected acute cholecystitis, accidental gallbladder perforation, and conversion to an open procedure. That is, all patients who had received prior antibiotic treatment, as well as those received following the findings before or during surgery, because our goal was to analyse a population as homogeneous as possible.
Final sample analyzed was 156 patients (76 at control group and 80 at study group).

Surgical technique

No antimicrobial prophylaxis was used. Operative site preparation always consisted of a povidone iodine scrub. Five surgeons, proficient in laparoscopic cholecystectomy (more than 50 cases per year), performed in all cases same surgical technique: At the beginning of surgery, a supraumbilical transverse skin incision followed by an open technique with a vertical incision along the midline was performed. Next, a 12-mm Hasson trocar was inserted and an additional 2 or 3 more bladeless trocars (5 mm at the lower right quadrant, 10 mm at the upper left quadrant, and 5 mm, if required, at the epigastrium) were introduced. Only the umbilicus and the upper left quadrant incisions were closed in all cases with same technique: a hand-sewn interrupted suture with a variable number of stitches according to length of the incision. A medium-term absorbable synthetic polyglycolic acid polymer (size 0), using a 30-mm atraumatic hook needle, including all layers of the abdominal wall was used. In cases in which umbilical incision needed to be enlarged, the closure technique was the same. Skin closure was performed using metallic staplers in all cases. In all patients the gallbladder was removed through the umbilical incision with (study group) or without a protection bag (control group) depending on whether patients belonged to one group or the other. The surgeon did not know which group the patient belonged to until the exact moment of the removal. The bag used was Endopocket Unimax©. Management of the wound included the use of a pad that was removed in all the cases within first 24 hours. The same instructions to manage the wound were given to all patients in both groups.
Once a week a surgeon checked inclusion criteria of the patients, signed informed consent and operative reports confirming surgeons adherence to the protocol.

Study variables

The primary variable of the study was the occurrence of wound infection in the umbilicus port site, defined according to the internationally accepted definition of the Center for Disease Control and Prevention[15] and attending to 2 criteria: a positive culture and/or a finding of infection in the surgeon's opinion. All the patients of the study were followed-up by an independent observer.

The following variables were also recruited prospectively: age, gender, comorbidities (diabetes mellitus), corticosteroid treatment, smoking, chronic obstructive pulmonary disease, obesity (body mass index [BMI] > 30 kg/m2), fascial incision enlargement to remove the gallbladder from the abdomen, and the preexistence of an umbilical hernia.

Follow-up

In all patients, a thorough physical examination was performed by a surgeon, who did not know to which group the patient belonged, checking specifically for signs suggestive of a wound infection at day 7 and 1 month. He was unaware of the method of gallbladder extraction used. If wound infection was found, bacteriological study and clinical management was at the discretion of the doctor seeing the patient. All patients received instructions on the clinical signs of wound infection and were told to contact the team if they developed these signs outside the follow-up schedule described.

Sample size calculation

We planned a study of independent cases and controls with 1 control per case. Prior data indicate that the infection rate among control was 18% (Comajuncosas et al. American Journal of Surgery 2014). If the infection rate for study subjects was to be 5% we estimated the need for a minimum of 50 cases per group with a power of 90%. The type I error probability associated with this measure of this null hypothesis was considered 0,05.

Statistical analysis

All results and variables were introduced in a specially designed database. Continuous variables are presented as mean and standard deviation and ranges and categorical variables as absolute numbers or percentages. Chi-square tests were used to compare differences in categorical variables (Fisher's exact tests were used as needed), and Student's t tests were used for continuous variables.

Univariate analysis and multivariate logistic regression analysis were performed to identify independent predictive causal factors for the development of wound infection. Adjusted odds ratios (ORs) were calculated using logistic regression. Variables achieving statistical significance in the univariate analysis were considered for multivariable analysis. ORs with 95% confidence intervals (CIs) are presented for each studied variable.

Differences were considered to be significant at the 5% level. All P values reported are 2 sided. Statistical analyses were performed using SPSS version 19.0 (SPSS, Inc, Chicago, IL).

Results

Demographical values and study variables findings

From March 2011 to June 2013, a total of 274 patients with cholelithiasis were considered eligible for the study. All underwent laparoscopic cholecystectomy, but 112 were excluded during the intervention for the following reasons: in 93 cases the gallbladder was accidentally perforated, conversion to laparotomy was required in 11 because of technical difficulties, and acute cholecystitis was unexpectedly found in 8 patients. Of the remaining 162 patients randomly allocated to one of the study groups, 6 were postoperatively excluded (2 of them underwent reoperation within a month, 3 received antibiotherapy for a cause unrelated to the infection of the wound and 1 patient was lost to follow-up) (Figure 1).

The final sample analysed (156 patients) consisted of 121 women and 35 men, with a mean age of 51.70 years (range, 18 to 89 years). There were 80 in the control group and 76 in the study group. The patients characteristics are shown in table 1: 9 patients (5.8%) had diagnoses of diabetes mellitus (5 of them insulin dependent), 36 patients (23.1%) had BMI > 30 kg/m2, 35 patients (22.4%) required incision enlargement to remove the gallbladder from the abdomen and 16 patients (10.3%) had pre-existing umbilical hernia. There were no significant differences in the characteristics between two groups (Table 1). Table 2 presents the percentages of wound infection according to studied variables.

Wound infection

There were 15 (9.6 %) diagnosed wound infections, all of them in the umbilical port site wound, eight cases in the study group and 7 in the control group. There were no statistically significant differences in the occurrence of an infection for using or not using an extraction bag (p = 0.789).

Bacteriological studies were available in 11 cases and the microorganisms isolated were: 5 cases of likely commensal (Corynebacterineae, coagulase-negative Staphyloccus spp and Streptococcus pyogenes) and one case of E. Coli in the control group, and 5 cases of likely commensal in the study group. There were no other septic complications.

In the univariate analysis to study if any factor influenced the presence of wound infection only BMI > 30 kg/m2 was a statistically significant risk factor for the development of wound infection. Diabetes mellitus, fascial incision enlargement, corticosteroid treatment, smoking, chronic obstructive pulmonary disease (COPD) and pre-existing umbilical hernia were not significant (Table 3)

Obesity, defined as a BMI > 30 kg/m2, was a significant risk factor in both univariate and multivariate analysis (p =0.03).

Discussion

In view of our results the determinant of wound infection in elective laparoscopic cholecystectomy is not the direct contact of the gallbladder with the wound, therefore bag extraction is not necessary.

The association of laparoscopic cholecystectomy with smaller wounds and minimal tissue damage suggest a lower risk of wound infection and while it is stated that the acceptable infection rate ranged between 0.4 and 1.1 %[16,17], the fact is that there are series that have come to rate almost 8%[13]. Maybe that's why there are many surgeons who still believe that the use of prophylactic antibiotics decreases the incidence of surgical wound infection, and still continue administering them preoperatively[7].

It is from 1997 when studies began to appear in order to establish the role of antibiotic prophylaxis in wound infection and although the first results of this small series suggest that decreased the rate of infection[18-20], more recent studies with a larger number of cases have concluded that there are no significant differences between administering or not administering antibiotic prophylaxis in elective laparoscopic[21-23] low risk patients[24].

Therefore we have reached 3 conclusions: 1) preoperative prophylaxis is not indicated in uncomplicated or low risk cholelithiasis, 2) there is no clear consensus on the need for the extraction bag and 3) the exact physiopathology of these infections is unknown. It seems that the surgical community worldwide accept high infection rates.

Based on these conclusions we performed this study to investigate if the determinant of the infection was the direct contact of the gallbladder with the wound or if other factors could be involved. We believe that a knowledge of these factors allow us to reduce the rate of infections in laparoscopic cholecystectomy.

The postoperative wound infection rate in this study was 9.6 % and was equally distributed between the control and study group and in view of these results we can conclude that direct contact of the gallbladder with the wound is not the cause of infection.

Also there is another finding that rejects the link between the two: in all cases, except one (E. coli), organisms isolated from the wound sites of those patients that developed postoperative infections were skin commensals (Corynebacterineae, coagulase-negative Staphyloccus spp and Streptococcus pyogenes).

In previous and recent studies[25-32] similar results were obtained with no correlation between gallbladder organisms and wound infection.

The wound infections of our study have been caused by skin commensal bacteria and therefore we must analyse what has been the cause of it, possibly incorrect skin antisepsis or insufficient drying time have played a role.

About potential factors that could influence the onset of infection (obesity, diabetes mellitus, fascial incision enlargement, pre-existing umbilical hernia, corticosteroid treatment, smoking and chronic obstructive pulmonary disease) only obesity (BMI > 30 kg/m2 was a significant risk factor in both univariate and multivariate analysis.

We think that the importance of our study is that it is the first clinical trial that has analysed this in a population with uncomplicated or low risk cholelithiasis. On the other hand the only objection is the high number of patients excluded because our goal was to analyse a population as homogeneous as possible.

Further studies are needed to determine what other factors are involved and what measures should be taken in order to reduce the high rate of infection.

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Compliance with ethical standards

Disclosures

No conflict of interest has been declared by Jordi Comajuncosas, Judit Hermoso, Jaime Jimeno, Pere Gris, Rolando Orbeal, Antonio Cruz and David Parés.

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