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Original research

Intraumbilical versus periumbilical incision in laparoscopic cholecystectomy: A randomized controlled trial

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HIGHLIGHTS

- The operative results of the intraumbilical (IU) incision and the periumbilical (PU) incision placed below the umbilicus were analyzed.
- 130 patients who received laparoscopic cholecystectomy were randomly allocated in to either the IU or PU groups.
- In the IU group, the operation time was shorter and the cosmetic survey score was higher than the PU group.
- There was no difference in complication rates between the two groups.
- The IU incision is a safe, feasible method that can reduce operation time.

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ABSTRACT

Introduction: An important issue in laparoscopic surgery is initial peritoneal access. An intraumbilical (IU) incision may be easier and faster to place, but due to concerns about wound complications, the periumbilical (PU) incision is still often used. A prospective randomized controlled study was performed to investigate the outcomes of the IU incision and PU incision in laparoscopic cholecystectomy.
Methods: Study subjects were patients who received laparoscopic cholecystectomy for acute or chronic cholecystitis, gallbladder polyp or adenomyomatosis, or porcelain gallbladder from June 2014 to January 2015. Enrolled subjects were randomly allocated to the IU incision group or the PU incision group. Demographic data, perioperative outcomes, and the results of a cosmetic satisfaction questionnaire were analyzed.
Results: A total of 130 subjects were analyzed (64 in the IU group, 66 in the PU group). There were no differences in patient demographics. The operation time was significantly shorter in the IU group (34.2 ± 14.6 vs 41.7 ± 21.3, $P = 0.020$). The cosmetic survey score was significantly higher in the IU group (36.8 ± 5.2 vs 33.2 ± 5.2, $P < 0.001$). There was no difference in the complication rates of the two groups.
Conclusions: The IU incision is a safe, feasible method of initial intraperitoneal access that can reduce the operation time and offer superior cosmetic effects to the patient.

1. Introduction

Laparoscopic surgery is being performed widely in many different fields. The advantage of laparoscopic surgery has been proven for procedures such as appendectomy, cholecystectomy, hernia repair, etc. [1–3] Current issues under debate are various methods of laparoscopy, rather than the issue of open versus laparoscopic surgery. Single incision surgery, a type of surgery performed through a single incision that is usually placed in the umbilicus, is method being used in many fields of surgery [4–6]. Another method that has been studied is reduced port surgery, in which a reduced number of ports are used compared to the conventional method. Although more than one port is used, advocates of this method claim that this method can reduce complications, with comparable operative outcomes [7,8]. There is also mini-laparoscopic surgery, in which laparoscopic instruments of a smaller caliber are used. Although the same number of ports is used, due to the smaller incisions required, further minimized access can be achieved [9,10].

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The methods described above are only several of the many methods being researched today. An issue that is important in all aspects of laparoscopic surgery is initial peritoneal access. The first incision used by a majority of surgeons is usually a vertical incision made inside the umbilicus, or a U shaped incision made beneath or above the umbilicus. Since the layers of the abdominal wall converge at the umbilicus, the intraumbilical (IU) incision may be relatively easier and faster to place, and also to close. But it seems many surgeons prefer the periumbilical (PU) incision, possibly due to concerns about complications such as wound infection or umbilical hernia.

The authors have reported a retrospective study comparing the outcomes of the IU incision and PU incision in laparoscopic appendectomy [11]. There were no differences in wound infection or umbilical hernia. This study was designed as a prospective randomized controlled study, studying patients on whom laparoscopic cholecystectomy was performed. Compared to laparoscopic appendectomy, when laparoscopic cholecystectomy is performed, the specimen sometimes requires extension of the umbilical wound. On one hand there may be less contamination of the wound, but more wound extension and manipulation may be required. We present the methods and the results of our study.

2. Materials and methods

2.1. Study design

This prospective randomized controlled study was approved by the Institutional Review Board (IRB) of Seoul St. Mary's Hospital (IRB protocol number: KC14EISI0149). The allocation ratio was 1:1. Randomization was performed using a random number table, in blocks of 5. JS Lee was in charge of generating the random allocation sequence, participant enrollment, and intervention assignment. The study period was June 2014 to January 2015. Study subjects were patients who received laparoscopic cholecystectomy for acute or chronic cholecystitis, gallbladder polyp or adenomyomatosis, or porcelain gallbladder during the study period. Patients who requested single port transumbilical surgery, patients in whom co-operation of other organs were performed, immunosuppressed patients, patients with a history of upper abdominal surgery, and patients converted to open surgery were excluded. No changes were made in the criteria after trial commencement.

The primary endpoint of this study was the wound complication rate of the umbilical incision. The secondary endpoint was the cosmetic satisfaction score. The hypothesis was that the IU incision would not be inferior to the PU incision in terms of wound complications. There was no change in endpoint after trial commencement.

The study was explained to the patients in detail. Written informed consent was obtained for every subject. Each patient was allocated to either the IU group or the PU group, using a random number table. The patients were blinded to the allocated group, and the surgeon was also blinded to the allocated group until beginning of the operation. Data collection and analysis was performed by an independent researcher.

2.2. Outcome measurement

Demographic data such as age, sex, body mass index (BMI), comorbidity, gallbladder pathology, and cholecystitis severity were collected. The Tokyo guidelines for the management of acute cholecystitis (TG13) were used to assess the severity of cholecystitis [12]. Perioperative data such as operation time, estimated blood loss, postoperative complications, pain score, pain control medication requirement, return to diet, and postoperative hospital stay were collected.

At the outpatient clinic visit scheduled one week after discharge, each patient was asked to fill out a body image questionnaire (BIQ). The BIQ was devised by Dunker et al. [13], and has been used to assess the patient satisfaction of the cosmetic effect of surgery. It consists of a total of ten items, asking a range of questions such as the patients' perception of their own body, the patients' satisfaction with the surgical scar, and the patients' self-confidence before and after surgery. The BIQ score ranges from 0 to 44, and a higher score corresponds to a higher body image.

2.3. Surgical technique

After general anesthesia, the umbilicus was prepared by removing all debris using gauze, cotton swabs, and alcohol. Either an IU incision or a PU incision was placed for initial intraperitoneal access, using a method described previously [11]. A 10 mm trocar was inserted, and pneumoperitoneum was achieved by carbon dioxide (CO_2) insufflation, up to a pressure of 12 mmHg. The epigastric trocar was placed about 5 cm below the xiphoid process, and the lateral trocar was placed in the anterior axillary line, at a level slightly above the umbilicus. A grasper was inserted through the lateral trocar, the infundibulum of the gallbladder was retracted to expose the Calot's triangle, and a working instrument inserted through the epigastric trocar was used to dissect the cystic duct and artery. After identification of the cystic duct and artery, the structures were ligated with clips and divided with endoscissors. The gallbladder was dissected off the liver bed, and placed inside a vinyl bag. The bag was removed through the initial incision. After removal of the gallbladder, the incisions were closed. In case of the IU incision, only a single full layer suture was required for closure. Skin closure or subcutaneous fat layer closure were unnecessary. Closure of the PU incision was performed in a layer-by-layer fashion.

2.4. Statistical analysis

Data analysis was performed using SPSS statistical package software version 20.0 for Windows (SPSS Inc., Chicago, IL, USA). Comparison of categorical variables were performed with the chi-square test of Fisher's exact test. Comparisons of continuous variables were performed using Student's t-test. All tests were two-sided, and a P value ≤ 0.05 was regarded as significant.

3. Results

A total of 140 patients were enrolled in the study. Seventy-one patients were allocated to the IU incision group (IU group), and 69 patients were allocated to the PU incision group (PU group). In the IU group, 7 patients were excluded, and 64 patients were analyzed. Among the 7 excluded patients, 5 patients were excluded due to previous upper abdominal surgery, and 2 patients were excluded due to the patient requesting single incision surgery. In the PU group, 3 patients were excluded, and 66 patients were analyzed. All 3 patients were excluded due to previous upper abdominal surgery.

Table 1 shows the patient demographics. There were no significant differences in age, gender, BMI, comorbidities, pathologic findings, or cholecystitis severity between the two groups. Mean age was 52.1 ± 14.5 in the IU group, and 55.7 ± 17.4 in the PU group. The number of male subjects were 29 (45.3%) in the IU group and 36 (54.5%) in the PU group.

Surgical outcomes are shown in Table 2. The operation time was significantly shorter in the IU group (34.2 ± 14.6 vs 41.7 ± 21.3, $P = 0.020$). There were no significant differences in estimated blood loss, start of diet, length of postoperative hospital stay, Visual Analogue Scale (VAS) score during convalescence, or required