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Original research

A randomized controlled trial comparing single-incision laparoscopic cholecystectomy using a novel instrument to that using a common instrument

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ABSTRACT

Background: To evaluate the safety and feasibility of single incision laparoscopic cholecystectomy (SILC) using a novel instrument.

Materials and methods: From September 2011 to June 2012, eligible patients (150 cases) were divided randomly into three groups: group A, SILC using a novel instrument; group B, SILC using a conventional instrument; and group C, conventional laparoscopic cholecystectomy (LC). Operative and postoperative outcomes were analyzed.

Results: The operative times for Group A [mean 40 min; rang 30–50 min] and Group B [mean 37.5 min; rang 25–50 min] demonstrated no significant differences ($P = 0.610$), but both times were longer than that in Group C [mean 25 min; rang 20–35 min] ($Z = 25.165$, $P = 0.000$; $Z = 16.184$, $P = 0.000$). There was no significant difference between the level of blood loss in Group A [mean 10.0 ml; range 5.0–20.0 ml] and Group B [mean 10.0 ml; range 5.0–20.0 ml] ($P = 0.989$), but the level in both groups was higher than that in Group C [mean 7.5 ml; range 5.0–10.0 ml] ($Z = 12.571$, $P = 0.002$; $Z = 13.619$, $P = 0.001$). There were no significant differences in patient satisfaction and pain scores ($P = 0.519$; $P = 0.691$) among the three groups. Complications occurred in 4 cases, including 1 case of bile injury and 3 cases of bile leakage. There were no complications in SILC with a novel instrument.

Conclusions: SILC require a longer operative time and more blood loss without benefit of patient satisfaction and pain scores. However, SILC with a novel instrument has fewer complications and a tendency to safer than SILC with a conservative instrument, and it could be a possible alternative in cholecystectomy.

1. Introduction

Since the advent of single-incision laparoscopic cholecystectomy (SILC) in 1997 [1], there has been controversy concerning the possible disadvantages, such as conflicting instruments and operative triangle loss, according to retrospective reports [2,3]. Most of the reports [4] have focused on the feasibility and safety of SILC, as well as the above mentioned disadvantages, as important factors. Meanwhile, the instrumentation innovation is trying to keep pace with the concept of single-incision laparoscopic surgery (SILS). Several specifically designed instruments, such as curved laparoscopic instruments, have been introduced in an attempt to solve the aforementioned problems. However, the advantages of a novel instrument must be validated through a randomized controlled trial (RCT), which has rarely been reported. In this study, we reported our RCT of SILC using a novel laparoscopic instrument with an adjustable and rotatable wrist [5].

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2. Material and methods

2.1. Study design

We conducted this randomized trial from September 2011 to June 2012, and 150 consecutive patients underwent elective laparoscopic cholecystectomy by one experienced surgeon who has performed more than 200 LCs and 50 SILCs before this randomized control trail. There were 51 males and 99 females, ranging from 18 to 65 years old. The patients were randomly assigned to one of three groups: Group A (SILC with a novel instrument), Group B (SILC with a conventional instrument) or Group C (conventional laparoscopic cholecystectomy).

This randomized trial included patients indicated for LC. The study protocol was approved by the Ethics committee of Harbin Medical University. The protocol was designed and conducted by the authors of this manuscript. The authors confirm the fidelity of this report to the protocol, the accuracy and completeness of the data and the analyses.

In this study, the experience of the patients including the pain and satisfaction scores, was listed as an importance index for evaluation. The pain scores were evaluated using a standard 10-point visual analog scale (VAS). Patient satisfaction scores were rated using a self-assessed satisfaction questionnaire obtained at the time of discharge. Five issues were evaluated: number of incisions, postoperative pain, hospitalization duration, ambulation and scarring. Each issue was rated with 1–5 points. The patients were assured that the scores would not be revealed to the surgeons. The survey process required approximately 10 min to complete.

2.2. Patient selections and instrumentation

In this study, 150 consecutive patients were enrolled. This investigator-initiated RCT was approved by the Chinese Clinical Trial Register and performed at the Fourth Hospital of Harbin Medical University between Sep 2011 and June 2012 (*Registration Clinical Trial number: ChiCTR-TRC-11001448,* http://www.chictr.org.cn/showproj.aspx?proj=8091). All subjects included in the study provided written informed consent. The study inclusion and exclusion criteria are shown in Table 1. All patients were diagnosed based on clinical, laboratory and radiological findings. In group A, the novel instruments used were a series of rotatable laparoscopic instruments that primarily included laparoscopic graspers and laparoscopic forceps. The instrument was primarily designed to overcome the limitation by introducing 2 simultaneously rotatable wrists rather than a fixed curved tip. The length of the novel instrument was 5 cm longer than the conventional one, due to its seven-degree-of-freedom rotatable wrist. With its adjustable and rotatable wrist, the new instrument transmits the movements of the surgeon's wrist simultaneously, the wrists were divided into two types in terms of the relation of the directions of both the wrist at the surgeon's hand side and the instrument's tip, ie. the syntropic and adverse wrist. As shown in Fig. 1, when the manipulator wrist (outside the abdomen during surgery) is curved to a certain direction, the tip of the wrist will be curved to the opposite/same direction.

2.3. Randomization and ethics

The study protocol was approved by the Ethics Committee at the Fourth Hospital of Harbin Medical University. Eligible patients were randomly (1:1:1) assigned to Group A (SILC with a novel instrument), Group B (SILC with conventional instrument) or Group C (LC) using a random number table. The intraoperative conversion from SILC to LC or open cholecystectomy were indicated for any given circumstance in which a safe procedure could no longer be confirmed by the operator.

2.4. Surgical methods

SILC: The patients were placed in the Trendelenburg position, with the pneumoperitoneum induced and maintained at 14 mmHg with carbon dioxide (CO_2) under routine general anesthesia. A 20-mm single curved transumbilical incision was made through the skin and the subcutaneous layer. Then, a 10-mm Trocar (Johnson & Johnson Investment Co., Ltd., USA) was introduced through the middle of the incision, and the abdominal cavity was explored with a 10-mm, 30°scope (Storz Co., Ltd. Germany). Then, the second and third 5-mm Trocar were introduced via same incision to the upper left and upper right of the 10-mm Trocar to form a "▽" shape (Fig 2). Firstly, Calot's triangle was explored. The surgical procedures were similar in all the three groups, except that in group A, the exposure and dissection of Calot's triangle could be facilitated by moving the tip of the laparoscopic instrument by manipulating its flexible and rotatable wrist which improved the scale of movement of the tip and avoided conflicts with the laparoscopic instruments outside of the single incision. In group B, the novel instrument was not used; the laparoscope was adjusted to facilitate the angle of observation to avoid the chopsticks effects and to avoid

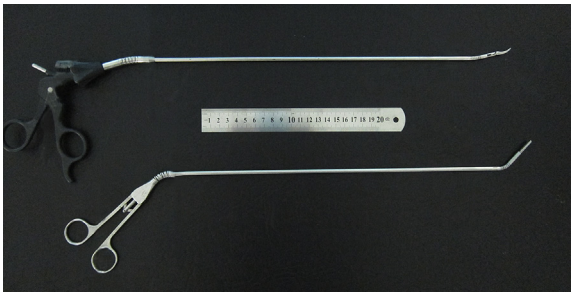

Fig. 1. The novel laparoscopic instrument, which has an adjustable and rotatable wrist.

Table 1
In- and exclusion criteria for eligibility for participation in the study.

Inclusion criteria	Exclusion criteria
Age≥18 and ≤ 65	Age≤18 and ≥ 65
BMI[a]≤35 kg/m^2	BMI > 35 kg/m^2
Benign gallbladder disease	Malignant gallbladder disease
Cholecystitis (acute and chronic)	Intrahepatic or extrahepatic bile duct stone
Cholecystolithiasis	Acute cholangitis
Polyp of gallbladder	Pregnancy
Adenomyomatosis gallbladder	Refusal of laparoscopy-assisted surgery
	With underlying diseases who can not tolerate an operation or have absolute contraindication to surgery

[a] BMI: Body Mass Index.