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Effect of laparoscopic cholecystectomy techniques on postoperative pain: a prospective randomized study

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Purpose: Minimally invasive surgical technics have benefits such as decreased pain, reduced surgical trauma, and increased potential to perform as day case surgery, and cost benefit. The primary aim of this prospective, randomized, controlled study was to compare the effects of single incision laparoscopic cholecystectomy (SILC) and conventional laparoscopic cholecystectomy (CLC) procedures regarding postoperative pain.

Methods: Ninety adult patients undergoing elective laparoscopic cholecystectomy were included in the study. Patients were randomized to either SILC or CLC. Patient characteristics, postoperative abdominal and shoulder pain scores, rescue analgesic use, and intraoperative and early postoperative complications were recorded.

Results: A total of 83 patients completed the study. Patient characteristics, postoperative abdominal and shoulder pain scores and rescue analgesic requirement were similar between each group except with the lower abdominal pain score in CLC group at 30th minute ($P = 0.04$). Wound infection was seen in 1 patient in each group. Nausea occurred in 13 of 43 patients (30%) in the SILC group and 8 of 40 patients (20%) in the CLC group ($P > 0.05$). Despite ondansetron treatment, 6 patients in SILC group and 7 patients in CLC group vomited ($P > 0.05$).

Conclusion: In conclusion, in patients undergoing laparoscopic surgery, SILC or CLC techniques does not influence the postoperative pain and analgesic medication requirements. Our results also suggest that all laparoscopy patients suffer moderate and/or severe abdominal pain and nearly half of these patients also suffer from some form of shoulder pain.

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INTRODUCTION

Conventional laparoscopic cholecystectomy (CLC) with three or more ports remains the 'gold standard' for cholecystectomy. Although the postoperative pain is generally less intense and lasts a shorter time than that following open cholecystectomy [1], postoperative pain and effective analgesic treatment after laparoscopic cholecystectomy has remained a clinical challenge [2]. Inadequate postoperative pain control can delay patient's recovery, lengthen the hospital stay and increase morbidity and costs [3-5].

Recently, single-incision laparoscopic cholecystectomy (SILC), which involves placing multiple instruments through a single umbilical access point, has emerged as a potential less-invasive alternative to CLC. The potential advantages of SILC include decreased scarring and decreased incisional pain [6]. Although there are some

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reports regarding decreased postoperative pain compared with the conventional approach [7,8], to date, the benefits of SILC have yet to be formally proven [9]. Recently, some systematic meta-analyses were presented that compare postoperative pain and complications after SILC and CLC. According to the results of these meta-analyses, the authors suggested that future randomized studies should be focused on elucidating subtle differences in postoperative pain [9,10].

The primary aim of this prospective, randomized, controlled study was to evaluate the effects of SILC and CLC procedures on postoperative pain.

MATERIALS AND METHODS

After institutional local ethical committee approval and informed consent, 90 consecutive patients with American Society of Anesthesiologists (ASA) physical status I-III undergoing elective laparoscopic cholecystectomy were included in the study. Exclusion criteria included body mass index of more than 30 kg/m^2, pregnancy, diagnosis of diabetes mellitus, cardiac or renal failure, mental disturbance, neurological disease, acute cholecystitis, previous abdominal surgery, preoperative indication for cholangiogram, ASA physical classification greater than III, ongoing peritoneal dialysis, and presence of an umbilical hernia. After meeting enrollment criteria, patients were randomly allocated to one of two groups with SILC and CLC using sealed envelopes.

Anesthesia procedure

Standard monitoring was applied to all patients including electrocardiogram, SpO_2 and noninvasive blood pressure after arriving in the operating room. Induction of general anesthesia was performed with propofol 2-2.5 mg/kg, rocuronium 0.5 mg/kg, and fentanyl 2 mg/kg. An orogastric tube was inserted into all patients after tracheal intubation and removed after the intervention. Anesthesia was maintained with sevoflurane in a mixture of 50% oxygen and 50% nitrous oxide. Ventilation was adjusted to maintain end-tidal carbon dioxide at 35-40 mmHg. Intravenous infusion of 1 g of paracetamol was given to all patients before the end of the operation.

Operative procedure

All operations were performed by one of three surgeons. The abdomen was prepared sterilely with careful attention to the cleaning of the umbilicus. Patients were positioned in the supine position at 30 degrees head up and right side up. At this time, the study envelope was opened, and the procedure was continued according to the randomization card.

CLC surgical technique

The surgeon positioned to the left of the patient, with the surgeon guiding the camera on the left side and the monitor at the right shoulder of the patient. Laparoscopic cholecystectomy was performed using a four-trocar technique with four incisions of 1 cm each. Pneumoperitoneum was established either by puncture in "Veress" technique. Intra-abdominal pressure was elevated to 12 mmHg with insufflation. A 10-mm 30-degree optic was used. Dissection of Calot's triangle was performed with an atraumatic monopolar dissecting forceps. Artery and cystic duct were clipped with a medium clip through an 11-mm trocar. The gallbladder was separated via a hook cautery and removed from the subxiphoidal incision. At the subumbilical port site, the fascia was not routinely closed.

SILC surgical technique

The surgeon stood between the patients' legs. A camera assistant stood to the patients' left. Skin and subcutaneous tissues were passed with a 2-cm transvers incision in the umbilicus. Fascia was slinged with notched clamps and the abdomen was entered with a transvers fascia incision. A port manufactured for single-incision laparoscopic surgery (SILS port, Covidien, Mansfield, MA, USA) was placed. Intra-abdominal pressure was elevated to 12 mmHg with insufflation. The abdomen was entered above the specific port with 2 (5 mm) and 1 (12 mm) trocars. A 5-mm 30-degree laparoscope was used. The gallbladder was suspended by the grasper. With special care, a dissection of the cystic duct and cystic artery was done. Relation between the common bile duct and cystic duct was displayed. The artery and cystic duct were clipped with a medium clip through a 12-mm trocar. The artery and cystic duct were divided with endoscopic scissors. The gallbladder was separated from the liver via a hook cautery. After removing port and releasing the residual carbon dioxide, the fascia defect was closed with loop prolene. Skin was sutured in an intradermic fashion using rapid Vicryl.

Outcome measurements

A verbal rating scale (VRS) (0, no pain; 1, mild pain; 2, moderate pain; 3, intense pain; 4, extremely intense pain) was chosen for pain intensity measurement. Before surgery the patients were instructed to use a VRS for shoulder pain and abdominal pain (trocar wound and deep visceral pain) and assessed at 30-minutes and at 1-, 2-, 6-, 12-, and 24-hours intervals after operation by a staff nurse who was blinded from the patient group assignment.

Rescue analgesics (20 mg of tenoxicam, intravenous) were given at the request of the patient or if the VRS score moderate or more intense. If pain continued despite use

of tenoxicam, intravenous tramadol (1 mg/kg) was used. Intravenous ondansetron at 4 mg was administered to patients suffering from postoperative nausea and vomiting and was repeated if necessary. Patient characteristics, perioperative data, intraoperative complications (including liver bed injury, spilled gall stones, vascular injury, biliary leak, and bowel injury), early postoperative complications, abdominal and shoulder pain, and postoperative rescue analgesic use were recorded.

All patients were admitted to the hospital on the morning of surgery and were discharged after a 48–72 hour hospital stay depending on their status. Follow-up control was at the 7th day after surgery.

Statistical analysis

To achieve a 20% difference between the two groups regarding pain scores with a significance value of 0.05 and power of 0.95, the necessary sample size of patients to be included is a minimum 29 for each group. Continuous variables were compared by using the Mann-Whitney U test. Categorical variables were compared by using chi-square test. The level of significance was set at 0.05.

RESULTS

Ninety patients were randomized to either SILC (n = 45) or CLC (n = 45). A total of 83 patients were completed the study. Seven patients were excluded because of conversion to open cholecystectomy (n = 2, 1 for SILC group and for CLC group), accidental analgesic injection (n = 1 for CLC) and losing of study data on the follow up (n = 4, 3 for CLC and for SILC). Demographic and operative data of patients are given in Table 1. The two groups were similar with respect to demographic data.

Postoperative abdominal and shoulder pain scores of each group and number of patients who needed rescue analgesic are detailed in Table 2. There was no statistically significant difference between groups regarding pain scores except with the lower abdominal pain score in CLC group at 30 minutes (P = 0.04).

Nausea occurred in 13 of 43 patients (30%) in the SILC group and 8 of 40 patients (20%) in the CLC group, but no significant difference was observed between the two groups (Table 2). Number of patients who received ondansetron was 6 and 7 in SILC and CLC groups, respectively. Despite ondansetron treatment, 6 patients in SILC group and 7 patients in CLC group vomited. Intraoperative and early postoperative complications such as bile leak, bile duct injury and deep venous thrombosis did not occur in any patients. Wound infection was seen in 1 patient in each group.

DISCUSSION

Minimally invasive surgical technics have gained popularity with the desire of benefits such as decreased pain, reduced surgical trauma, and increased potential to perform as day case surgery, and cost benefit. A laparoscopic procedure such as SILC is a good example of minimally invasive techniques.

Table 1. Demographic and operative data of patients

Variable	SILC (n = 43)	CLC (n = 40)	P-value
Age (yr)	48.5 ± 12.0	51.0 ± 9.0	NS
Sex			
Female/male	34/9	27/13	NS
Body mass index (kg/m^2)	24.2 ± 4.0	23.3 ± 3.0	NS
ASA score			NS
I/II/III	8/30/5	2/33/5	
Duration of operation (min)	34.6 ± 15.0	39.3 ± 11.0	NS

Values are presented as mean ± standard deviation.
SILC, single incision laparoscopic cholecystectomy; CLC, conventional laparoscopic cholecystectomy; NS, nonsignificant; ASA, American Society of Anesthesiologists.

Table 2. Data about pain and nausea-vomiting

Variable	SILC (n = 43)	CLC (n = 40)	P-value
Abdominal pain score (VRS)			
At 30 min after operation	3.23 ± 0.75	2.95 ± 0.90	0.044
At 2 hr after operation	1.83 ± 1.32	1.6 ± 1.23	NS
At 4 hr after operation	1.25 ± 1.27	1.17 ± 1.08	NS
At 12 hr after operation	0.65 ± 0.78	0.7 ± 0.96	NS
At 24 hr after operation	0.18 ± 0.45	0.07 ± 0.34	NS
Shoulder pain scores (VRS)			
At 30 min after operation	1.06 ± 1.35	0.5 ± 1.03	NS
At 2 hr after operation	0.65 ± 1.08	0.5 ± 0.96	NS
At 4 hr after operation	0.58 ± 1.09	0.2 ± 0.51	NS
At 12 hr after operation	0.27 ± 0.7	0.17 ± 0.44	NS
At 24 hr after operation	0.18 ± 0.58	0	NS
Patient with abdominal pain	43 (100)	40 (100)	NS
Patient with shoulder pain	23 (53)	19 (47)	NS
Patient who received tenoxicam	43 (100)	40 (100)	NS
Patient who received tramadol	7 (16)	9 (22)	NS
Patient with nausea / vomiting	13 (30) / 6 (13)	8 (20) / 7 (17)	NS
Patient who received ondansetron	6 (13)	7 (17)	NS

Values are presented as mean ± standard deviation or number (%).
SILC, single incision laparoscopic cholecystectomy; CLC, conventional laparoscopic cholecystectomy; NS, nonsignificant; VRS, visual rating score (0, no pain; 1, mild pain; 2, moderate pain; 3, intense pain; 4, extremely intense pain).

Since Navarra et al. [11] first performed SILC in 1997, certain results could not be obtained from the literature to make an evidence-based determination for the real benefits of this technique when compared with CLC [12].

Postoperative laparoscopic cholecystectomy pain has two major components including abdominal pain and shoulder pain. In three meta-analyses reported by Markar et al. [9], Trastulli et al. [10], and Garg et al. [13], which compare SILC with CLC techniques, SILC did not confer any benefit in postoperative pain as compared to CLC. When the studies in these meta-analyses are examined carefully, heterogeneity can be seen regarding both evaluation timing and localization of the pain. In previous meta-analyses [9,10,13], with a total of 15 studies investigated, the shoulder tip pain was assessed in only two of them [14,15] and assessed separately from abdominal pain only in one of them [15]. And the first time of pain evaluation was at the 2nd hour after the operation [14]. As a result of these meta-analyses, the authors concluded that future randomized controlled studies are required to elucidate differences in postoperative pain associated with SILC and CLC.

In the current study, treatment modalities for pain after laparoscopic cholecystectomy includes preoperative single dose of Dexamethasone, infusion of local anesthetics into incision site (at the beginning or at the end of operation, depending on preference), and regular use of nonsteroidal anti-inflammatory drugs or COX-2 inhibitors combined during the first 3-4 postoperative days, including the day of surgery [16]. Short-acting opioids should be used only on demand when other analgesic techniques fail [17]. In the present study all patients received tenoxicam as a rescue analgesic as they suffered moderate or severe abdominal pain at 30 minutes after the operation despite routine use of intravenous paracetamol during the operation. The number of patients who received tramadol as a rescue analgesic despite tenoxicam treatment were 7 (16%) and 9 (22%) in the SILC and CLC groups, respectively.

Previous published studies showed conflicting results in terms of postoperative pain with SILC when compared to CLC. Most of them reported no difference between single port and conventional multiport techniques except two of them found less pain in the favor of SILC technique [14,18] and one of them found less pain in the favor of CLC technique [19]. In the present study, the only significant difference between the groups regarding primary and secondary outcome measures was higher abdominal pain score at 30 minutes after operation in the SILC group (P = 0.04). There is a difference between present study and previous studies regarding assessment timing of pain. In our study, pain assessment was started from 30 minutes after operation while among the previous studies there was various follow-up times of abdominal and shoulder pain with the earliest one at 2 hours after operation. Even with this difference, pain scores of this study were similar with previous randomized controlled studies [20,21].

Shoulder pain is frequent and distressing, with a reported incidence of 31-80% after laparoscopic cholecystectomy [22]. In our study, the incidences of shoulder pain were similar between SILC and CLC groups with 53% and 47% respectively. Although the exact mechanism of the shoulder pain is not clear, the resultant irritation or injury of the phrenic nerve at the diaphragm surface during CO_2 pneumoperitoneum seems to provoke the pain [23,24]. The level of the CO_2 pneumoperitoneum pressure can affect the intensity of pain [25]. In our study the level of this pressure was limited to 12 mmHg. Level of the pneumoperitoneum pressure was not stated in most of the studies that compare the SILS and CLC, and it varies between 10-15 mmHg in the rest of the studies [14,26].

There are some limitations to this study. Acute cholecystectomy or complicated surgery may increase deep intra-abdominal pain by complicating the surgical technique and increasing operative time. In this study all patients were ASA I-III and they all had uncomplicated cholelithiasis which were treated with the same surgical technique. Patients with more complex biliary pathology and premorbid status (ASA IV grade and obesity) may exhibit more realistic and reliable results. Another limitation of this study is lack of long-term follow-up of pain assessment and postoperative complication, and we think that further investigations that present more satisfactory and evidence-based results need to be done.

In conclusion, in patients undergoing laparoscopic surgery, SILC or CLC techniques do not influence the postoperative pain and analgesic medication requirements. Our results also suggest that all laparoscopy patients suffer moderate and/or severe abdominal pain and nearly half of these patients also suffer from some form of shoulder pain. Therefore, a multimodal management strategy should be considered for the management of pain in laparoscopic cholecystectomy.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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