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Single-incision versus four-port laparoscopic cholecystectomy in an ambulatory surgery setting: A prospective randomised double-blind controlled trial

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Abstract

Background: Single-incision laparoscopic cholecystectomy (SILC) can be done as a day-case procedure and may have advantages over conventional laparoscopic cholecystectomy (LC). We present the results of our study looking at post-operative pain and post-operative recovery time. **Methods:** This was a single-institution randomised double-blind controlled trial. Seventy-three patients with symptomatic cholelithiasis were randomized to SILC (n = 37) or LC (n = 36). The primary endpoint was to compare post-operative pain. We also compared surgical time, procedural difficulty, adverse events, additional ports used and conversion rate, success of day surgery process, return to work, aesthetic satisfaction, quality of life and 4-year incisional hernia rate. **Results:** In the SILC group, post-operative analgesic requirements were lower on day 7, there was an earlier return to work and cosmetic satisfaction was significantly higher. The SILC procedure presented a higher technical difficulty. Operative time, surgical complications, post-operative pain, success of the day-case process, return to normal activity, quality of life scores and incisional hernia rates were similar for both the procedures. **Conclusions:** SILC has advantages over LC in terms of late post-operative analgesic requirements and aesthetic results; however, it is technically harder to perform. There was no benefit in terms of day surgery outcomes.

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Full Text

Introduction

Laparoscopic cholecystectomy (LC) is currently accepted as the gold standard for the treatment of gallstones as it reduces the invasiveness of open cholecystectomy. This leads to a shorter recovery time, decreased post-operative pain and an earlier return to work with better cosmetic results.

Single-incision laparoscopic cholecystectomy (SILC) was first described in 1997 by Navarra et al.[1] as a less-invasive alternative to conventional multiport laparoscopy, with the potential advantages of decreasing post-

operative pain and early return to normal daily activities. Several studies[2],[3],[4],[5],[6] published in the past few years have compared both techniques, but their outcomes were largely inconclusive regarding post-operative pain. There are very few studies that make a detailed analysis of post-operative pain in SILC cholecystectomy.

In 1990, Reddick and Olsen[7] reported the 1st day-case LC. This approach has the advantage of decreasing the risk of hospital-acquired infections, an early return to daily activities and a reduction in hospitalisation costs.

The objective of this single-institution randomised double-blind controlled trial is to compare the results of SILC with those of LC in an outpatient surgery setting.

Our hypothesis is that single-incision technique reduces post-operative pain, can be done as a day surgery procedure, might be associated with an early return to daily life and offers better cosmetic results.

Methods

The study protocol was developed at Hospital General de l'Hospitalet. It was approved by the hospital's ethics committee and followed the good clinical research practice.

The study is a single-centre, prospective randomised, double-blind controlled trial. The study design was reported according to the CONSORT guidelines [Figure 1] and was registered in www.clinicalTrials.gov (NCT02375529). {Figure 1}

Patients were prospectively recruited between May 2013 and June 2015. All patients who satisfied the inclusion criteria were offered the opportunity to participate and we obtained written informed consent. All eligible patients were randomised into two groups: one group underwent SILC and another one underwent four-port laparoscopic surgery (conventional LC). The randomisation procedure was centralised in the epidemiology department, which generated a list created before the beginning of the study.

Only three surgeons with significant experience in single port and conventional four-port LC participated as primary surgeons.

The inclusion criteria

The inclusion criteria for the study included age between 18 and 80 years, American Society of Anesthesiologists (ASA) Score of I or II, symptomatic gallstones and possibility of care by a responsible adult for 24 h after hospital discharge.

The exclusion criteria

The exclusion criteria included previous anaesthetic complications, body mass index (BMI) >35, previous history of acute cholecystitis, suspicion of Mirizzi's syndrome, common bile duct stones or malignancies, non-steroidal antiinflammatory drug allergies, history of psychiatric conditions incompatible with day-case procedures, previous open surgery, bleeding disorders and restrictive pulmonary disease.

The primary endpoint of the study was to compare post-operative pain between SILC and LC group.

Secondary endpoints

Secondary endpoints studied were operative time, procedure difficulty, adverse events, number of additional ports used and conversions, success of daycase process, return to normal activity, return to work, cosmetic results, satisfaction scores, quality of life and incisional hernia rate. They were analysed in both techniques.

Surgical procedure

All the patients were placed in a supine position with spread legs.

Single incision laparoscopic cholecystectomy technique

The umbilicus was grasped, and a 2 cm vertical skin and fascial incision was performed. A multiport (TriPort + Olympus®) was inserted under direct vision and a pneumoperitoneum was insufflated to 12 mmHg. Semi-curved reusable instruments (Olympus® HiQ LS) and 30° laparoscope of 10 mm were used. The surgical technique was the same as that of traditional multiport cholecystectomy except that sutures could be used to retract the gallbladder fundus if deemed appropriate by the surgeon. Calot's triangle was dissected obtaining Strasberg's and Brunt Critical View of Safety[8] and 5 mm endoclips were placed before the transection of the cystic structures. The gallbladder was removed through the umbilical port. The rectus abdominis fascia was sutured with braided, absorbable sutures, and the skin was closed with subcuticular sutures.

Laparoscopic cholecystectomy

A 10 mm supraumbilical incision was made, and a pneumoperitoneum was insuflated using a Veress needle. Four ports were inserted: 2 of 10 mm in the supraumbilical region and left flank and 2 of 5 mm in the epigastric region and right flank. The gallbladder was removed through the umbilical incision with a retrieval bag. The rectus abdominis fascia and skin were sutured similarly to SILC technique.

All patients received general anaesthesia following the day-case protocol, and the use of morphine drugs was minimised to avoid nausea and vomiting. No prophylactic antibiotics were administered except in the event of gallbladder perforation during the procedure.

At the end of the operation, all patients in both the groups received 10 ml of 0.25% bupivacaine instilled in the subphrenic and subhepatic spaces through an aspiration probe, and 10 cc of 0.5% bupivacaine with adrenaline was injected in the skin around each incision.

Following the surgery, all patients were discharged to the recovery room and analgesics were administered according to a post-operative protocol (dexketoprofen + paracetamol ± metamizole). Oral intake was started 2 h postoperatively if it was tolerated, and patients were discharged to the day-case unit. They stayed in the unit for at least 8 h. Aldrete's criteria[9] were used to determine the time of discharge.

To prevent study bias, all patients had a dressing covering the whole abdomen immediately after surgery. Patients, study monitor and staff of the day-case unit were not aware to the technique to which they had been randomised for the first post-operative 3 days, assuming the dressing remained in place as instructed. After completion of the pain scale and social functioning (SF)-12 form at their 3-day appointment, patients were informed of the treatment when the dressing was removed.

A phone call was made the 1st day after surgery, and all of the patients were referred for hospital appointments on day 3, on day 7, and after 1 month.

Data were collected pre-operatively, intra-operatively and post-operatively by a study monitor, day-case unit staff, surgeons and patients. Immediately after each procedure, the surgeon recorded operative duration, findings and grade of difficulty. Pain scores were measured by a Visual Analogue Scale (VAS), where 0 represented no pain and 100 the maximum pain. Abdominal and shoulder pain were recorded in the recovery room 2, 4, 6 and 8 h after surgery while they were in the hospital and on 3rd, 7th and 30th days appointments.

Discharge timing, complications according to Dindo et al. classification[10] and hospital readmissions were also recorded.

All discharged patients were informed about the analgesic regime and they were provided with an explanatory document. They were also asked to fill out a chart with their daily medication needs.

Patient satisfaction with the cosmetic result was measured using a 0–10 scale. Satisfaction with the overall procedure was recorded on a scale of unsatisfied, satisfied or very satisfied the 1st and 30th days after surgery.

Post-operative pain and satisfaction with the day-case procedure were assessed by telephone at 24 h. Subsequently, patients were seen on day 3, day 7, and 1 month after surgery.

Long-term incisional hernia: patients were called 1 year and 4 years after surgery and were asked about the presence of a port hernia. If a hernia was suspected, the patient was called for examination and an ultrasonography of the abdominal wall was performed.

Categorical variables were compared among the groups using the Chi-square test or Fisher's exact test and continuous variables were compared using Student's t-test or the Mann–Whitney U-test was used for non-parametric variables.

Results

A total of 73 patients entered the study and were randomised to SILC (n = 37) or LC (n = 36). There were no significant differences between the study arms with respect to age, sex, BMI or ASA risk [Table 1].{Table 1}

Pain scores were obtained 2, 4, 6 and 8 h after surgery during hospital stay using a VAS [Table 2]. There were no significant differences between the groups.{Table 2}

The operative time was similar for SILC (mean ± standard deviation, 57.1 min ± 20.67) and LC (53.89 min ± 28.05) with no statistical differences. Subjective difficulty was assessed after surgery on a scale from 0 to 10 and was significantly greater (P = 0.027) in the SILC group (3.17) compared to the LC group (1.94).

One patient in four-port group was diagnosed with choledocholithiasis during the surgery. An intraoperative cholaniography was done and a therapeutic ERCP was performed 48 h after cholecystectomy. The patient was not excluded because there was no impact in the surgical technique.

Additional ports were required in three patients in single-incision group (8%). There were no conversions to open surgery in either group. No complications were detected during the immediate post-operative period.

A total of 6 patients (8%) required admission to hospital beyond day surgery standards: 3 because of pain; 1 patient because of vomiting; 1 because of social problems and 1 because of choledocholithiasis. The day-case process was successful in 67 patients (92%). There were no statistical differences in either group in terms of hospitalisation needs.

No major complications were detected during the first 30 post-operative days. Post-operative complications (Grade I of Clavien–Dindo Classification) were registered in 6 patients (8%) with no differences between the groups.

Information about analgesic use after surgery was collected after 7 days. The analgesic requirements (number of tablets) were lower every day in the SILC group than in the LC group, but the difference was statistically significant only on the 7th day [Table 3].{Table 3}

The cosmetic evaluation at day 30 showed that the SILC group had better results than the LC group on a 0–10 point scale (9.86 ± 0.58 vs. 7.78 ± 1.50; $P < 0.001$).

There were no differences between the groups regarding return to normal daily activity, although return to work after 2 weeks was more frequent in the LC group (n = 14) than in the SILC group (n = 7) ($P = 0.014$).

Patients were asked to complete SF-12 quality of life questionnaire, which showed no statistical differences between the groups [Figure 2].{Figure 2}

Regarding patient satisfaction level with the overall procedure (on a scale of unsatisfied, satisfied and very satisfied) on the 1st day after surgery, 46 patients were very satisfied (63%) with day-case procedure and 27 patients were satisfied (37%). No one was unsatisfied. On the 30th day after surgery, 51 patients were very satisfied (70%) with the overall procedure and 22 patients were satisfied (30%) with no differences between groups.

Port-site hernia occurred in two patients in the single-incision group and in two patients in conventional laparoscopic surgery group (5%) after 4 years of the surgical procedure. They were diagnosed by physical examination and ultrasonography. In all of them, the incisional hernia was repaired.

Two patients in SILC arm and six patients in LC arm were lost to follow-up at 1-year follow-up.

At 4-year follow-up, a total of 15 patients were lost to follow-up (20.5%): five patients in the SILC group and 10 in the LC group.

Discussion

LC is a low morbidity procedure. In a Cochrane review,[11] day-case procedures seem to be as safe as overnight stay surgery and there are no differences in terms of pain, time of return to usual activity, adverse events, mortality and readmissions.

Furthermore, LC has been shown to have important advantages over open surgery and it has been established as the gold standard technique.[12],[13]

Some reviews have been unable to demonstrate these benefits in SILC and some reports have suggested that the complexity of the technique may lead to severe intraoperative complications.[14]

Two meta-analyses have compared SILC to LC.[15],[16] Pisanu et al.[15] assessed the feasibility and safety of SILC and LC. There were significant differences in operating time (longer with SILC) and in satisfaction scores which favoured SILC, without significant differences in post-operative pain and hospital stay. Trastulli et al.[2] demonstrated a higher failure rate in SILC because more additional ports were needed during the procedure. SILC was associated with greater intraoperative blood loss, although it provided better aesthetic results.

Our study shows that LC was suitable as a day surgery procedure in 92%, which was higher than in other outpatient LC studies.[17],[18] There were no significant differences between SILC and LC groups.

In our experience, all of the registered measurements of post-operative period were lower for the SILC group than for the LC group and analgesic requirements were lower in the SILC group than in the LC group, but there

was a statistical difference only at day 7 measurement (P = 0.018).

The operative time was similar between both the groups and the overall post-operative outcomes in both the groups were similar with no severe complications (blood loss, bile duct injury or leaks) in either group. These results are significant, as they suggest that, in experienced hands, SILC can be done with low morbidity, similar operating time and better cosmesis.[19],[20],[21],[22]

SILC has not been widely accepted by all surgeons and conventional LC remains the gold standard.[23] Semi-curved instruments and current laparoscopes improve triangulation and visualisation of the operative field; however, a single port is still technically challenging when compared to conventional approaches. In our opinion, this technique should be carried out by experienced surgeons. The development of better-designed instruments will allow SILC to become more widespread. Improved visualisation and the ability to perform a fluorescence cholangiography should reduce the risks of cholecystectomy to a level that has not yet been achieved with conventional laparoscopy. Advanced simulation technology for robotic surgery and new single-site robotic platforms have the potential to further revolutionise this technology and lead to a better patient satisfaction.[24] Robotic single-port cholecystectomy is feasible but hindered by technical challenges due to the inadequate length of non-wristed robotic instruments as well as cost. On the other hand, high incidence of gallbladder rupture and trocar-site hernias may limit its application.[25]

Recently, a systematic review and meta-analysis[26] analysed the advantages of single-incision robotic cholecystectomy (SIRC) versus SILC in six comparative studies (n = 633 patients). The data showed that SIRC and SILC had equivalent outcomes for operative time, intraoperative complications, post-operative complications, hospital stay, readmissions rate, and conversion rate, but the total cost of SIRC was significantly higher than SILC. Therefore, to date, SILC remains the least expensive and accessible alternative to LC.

Lurje et al.[27] reported that cosmetic satisfaction, post-operative pain and quality of life were better in SILC group. Our results confirm these findings.

Only a few studies have assessed long-term complications of the two techniques, especially regarding incisional hernia.[28],[29],[30] A multicentre study has observed an increased incidence of incisional hernia in SILC with rates of 8.4% at 1-year post-procedure.[29] Recently, two studies about incisional hernia after single-incision surgery have been published[29],[30] with divergent results in terms of incidence. A Danish study did not present differences, but a meta-analysis showed statistically significant differences: 2.2% in single port group and 0.7% in LC. In our study, we have recorded an incidence of 2.7% of incisional hernia in both the groups during 1 year of follow-up and an incidence of 5.4% in 4 years.

One of the limitations in our study is that we lost 20.5% patients in follow-up at 4 years, which makes it difficult to draw definitive conclusions regarding long-term incisional hernia incidence.

The study by Arezzo et al.[22] presents similar results to ours, without significant differences in incisional hernia rate and with a loss of control of 25% per year. We believe that a 12-month follow-up may be too short to determine the true differences between SILC and LC in terms of risk of hernia development. In our series, the 4-year follow-up suggests that the risk of port-site hernia is not higher than in the LC technique.

Conclusions

SILC is a feasible and safe technique that can be performed as a day case and gives better cosmetic results than LC. Post-operative pain and analgesic requirements are lower in the SILC group, but differences were only statistically significant on post-operative day 7. In experienced hands, the outcomes are similar to those of multiport LC.

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Conflicts of interest

There are no conflicts of interest.

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