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Prospective randomized comparison of single-incision laparoscopic cholecystectomy with new facilitating maneuver vs. conventional four-port laparoscopic cholecystectomy

Konvansiyonel 4-port laparoskopik kolesistektomi ile yeni kolaylaştırıcı manevra ile uygulanmış tek-port laparoskopik kolesistektominin prospektif randomize karşılaştırılması

Recep Aktimur[1], Kerim Güzel[2], Süleyman Çetinkünar[3], Kadir Yıldırım[1], Elif Çolak[1]

ABSTRACT

Objective: We aimed to investigate the technical feasibility of single-incision laparoscopic cholecystectomy (SILC) with our new facilitative maneuver and to compare it with the gold standard four-port laparoscopic cholecystectomy (LC).

Material and Methods: Operation time, cosmetic score and incisional hernia rates between LC (n=20) and SILC-1 (first 20 consecutive operations with the new technique) and 2 (subsequent 20 operations with the new technique) were compared.

Results: The median operation time for LC, SILC-1 and SILC-2 were; 35 min (12-75), 47.5 min (30-70), and 30 min (12-80), respectively (p=0.005). The operation duration was similar in LC and SILC-2 (p=0.277) groups. Wound seroma rate was higher in SILC-1 (45%) and SILC-2 (30%) groups than LC (5%) group (p=0.010). Cosmetic score was similar between all the groups. Hernia rates were 15.8% and 5.3% in the SILC-1 and SILC-2 groups, respectively, while there was no hernia in the LC group.

Conclusion: SILC with new facilitating maneuver is comparable with classical four-port laparoscopic cholecystectomy in terms of ease, operation time, reproducibility and safety. Besides these advantages, the single-incision access technique must be optimized to provide comparable wound complication and postoperative hernia rates before being recommended to patients.

Keywords: Single-incision, conventional, laparoscopic, cholecystectomy, technique

ÖZ

Amaç: Bu çalışmada tek-port laparoskopik kolesistektomi (TPLK) için yeni bir cerrahi teknik olarak sunduğumuz manevranın uygulanabilirliğini değerlendirmek ve altın standart konvansiyonel laparoskopik kolesistektomi (LK) ile karşılaştırmak amaçlanmıştır.

Gereç ve Yöntemler: Laparoskopik kolesistektomi (n=20) ile TPLK-1 (yeni teknik ile yapılan ilk 20 operasyon) ve TPLK-2 (yeni teknik ile yapılan ikinci 20 operasyon), operasyon süreleri, kozmetik skor ve insizyonel herni oranı açısından karşılaştırılmıştır.

Bulgular: Laparoskopik kolesistektomi, TPLK-1 ve TPLK-2 için ortanca operasyon süreleri; sırası ile 35 dk (12-75), 47,5 dk (30-70) ve 30 dk (12-80) idi (p=0,005). Operasyon süresi LK ve TPLK-2 gruplarında benzerdi (p=0,277). Yara yeri seroması gelişme oranı, LK grubunda (%5), TPLK-1 (%45) ve TPLK-2 (%30) grubuna göre daha düşüktü (p=0,010). Gruplar arası kozmetik skor benzerdi. LK grubunda insizyonel herni görülmezken, TPLK-1 grubunda %15,8, TPLK-2 grubunda %5,3 oranda görüldü.

Sonuç: Uygulama kolaylığı, operasyon süresi, tekrar edilebilirlik ve güvenlik açısından yeni TPLK tekniği konvansiyonel LK ile karşılaştırılabilir düzeyde görünmektedir. Ancak bu avantajlarının yanında, hastalara tavsiye edilmeden önce, tek delikten giriş tekniğine bağlı gelişen yara yeri seroması ve postoperatif herni oranlarının azaltılması gereklidir.

Anahtar kelimeler: Tek-port, konvansiyonel, laparoskopik, kolesistektomi, teknik

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INTRODUCTION

Cholecystectomy is one of the most common operations performed by general surgeons. Since the introduction of video-laparoscopic cholecystectomy in 1987, laparoscopic cholecystectomy (LC) has become the gold standard treatment for benign biliary diseases. In daily practice, LC has improved general surgeon's familiarity with video-laparoscopic operations and has become the first step in evaluating other minimally invasive techniques, and in performing advanced laparoscopic operations. In order to move forward with the minimal invasive surgery concept of less surgical trauma and better cosmetic results, surgeons first reduced the number of incision and ports. Then the idea of totally eliminating skin incisions through the use of natural orifices was implemented in selected cases (1).

In theory, minimal incision should offer minimal postoperative pain and better cosmetic results. With the use of single incision laparoscopic cholecystectomy (SILC), this purpose is achieved in terms of cosmetic issues, but its effectiveness in providing minimal postoperative pain is still controversial (2-5). Recent

meta-analysis showed significantly favourable cosmetic benefits, comparable complication rates and length of hospital stay with SILC, but the mean operation time was significantly longer (6). At present, lack of a standardized operation technique, the need for specialized instruments, inability to apply safe cholecystectomy principles, the longer operation time, issues related to cost-effectiveness and advanced laparoscopic experience are still limiting factors for performing SILC.

The aim of this prospective randomised controlled trial is to compare the gold standard LC vs. SILC using our new facilitating maneuver. Our goal was to provide critical view of safety and safe cholecystectomy principles on SILC, improve operator ergonomics and shorten operation time while eliminating the need for specialized instruments.

MATERIAL AND METHODS

Patient Selection

CONSORT checklist, the protocol and the flow diagram for this trial are available as supplemental information; see Checklist, Protocol, Flow Diagram.

To calculate the sample size, we have conducted a pilot study with ten patients (five patients underwent LC, and the other five underwent SILC with new facilitating maneuver) who were planned to undergo laparoscopic cholecystectomy for symptomatic cholelithiasis, after approval by the local ethics committee (No: 2014/551). Sixty symptomatic cholelithiasis patients were enrolled in this prospective randomised study from January to April 2014 in Samsun Training and Research Hospital. An informed consent was taken from all patients before enrollment into the study. The subjects were divided into 3 groups of 20 patients each: LC (classical four port technique), SILC-1 (introduction of the new technique) and SILC-2 (experienced in the new technique) groups. The randomization was achieved by using consecutive allocation of patients into the groups regardless of demographic characteristics or predictors of surgical difficulty (BMI, concomitant diabetes mellitus, previous surgery in the upper abdominal region, presence of umbilical hernia, symptom duration and ASA score), by one author. The allocation flow chart for this study is shown in Figure 1.

The new facilitating maneuver was developed by one of the authors. One surgeon performed all of the operations. Our first goal was to provide critical view of safety, and to apply safe cholecystectomy principles. One of the authors recorded relevant patient data. At the end of the study, the data were analysed by two of the authors in a blinded manner to avoid bias.

The indication for surgery was symptomatic cholelithiasis diagnosed by ultrasound. Exclusion criteria were as follows: acute cholecystitis (diagnosed on ultrasound or elevated inflammatory serum markers), choledocholithiasis, patients <18 years old or American Society of Anesthesiologist (ASA) grade IV or V. A maximum age or body mass index (BMI) limitation was not specified. Demographic characteristics, BMI, concomitant presence of diabetes mellitus (DM), previous surgery in upper abdominal region, umbilical hernia, duration of symptoms, ASA grade, operation time, length of hospital stay (LOS), conversion to open cholecystectomy (OC) or LC and complications were recorded. Cosmetic results were assessed by visual

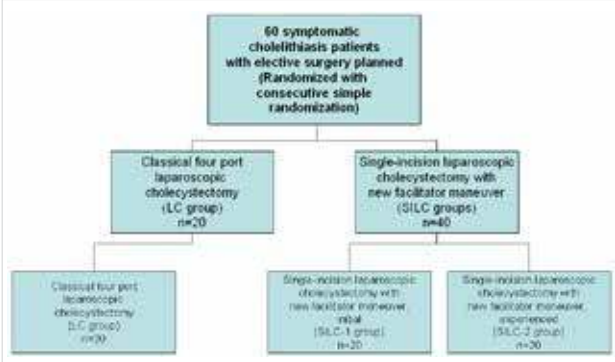

Figure 1. Study allocation flow chart

analog scale (VAS), in the first follow-up that was held on the 7th postoperative day and in the second follow-up on the 6th postoperative month. All patients were asked to evaluate an open cholecystectomy scar (Kocher incision) photo and compare it with their surgical scar on a VAS scoring chart, open cholecystectomy scar was accepted as 0 and the highest satisfaction with cosmetic appearance was rated as 10. Postoperative hernia development was assessed at postoperative sixth months by physical examination or ultrasonography in suspicious cases.

Surgical Procedures

The technique used for LC was the conventional four-trocar approach (10-mm optic at the umbilicus, 10-mm trocar in the epigastrium and two 5-mm trocars in the right upper abdomen).

For SILC, the patient was positioned supine on the operating table. Once the access was gained into the abdomen through an infraumbilical 2.5 cm incision from 12 o'clock to 6 o'clock, an OCTO™Port (Dalimsurg, Seoul, Korea) single-port device was introduced and the patient was re-positioned to reverse Trendelenburg and right tilt. The OCTO™Port is a multi-use single-port device that contains two 5-mm, one 10-mm and one 12-mm trocar within the same port. Pneumoperitoneum was created up to an abdominal pressure of 15 mm-Hg. A 10-mm, 30º scope (Karl Storz, Tuttlingen, Germany) was inserted through the inferiorly placed 10-mm port by the assistant who was standing on the patient's left side, and the peritoneal cavity was examined. The surgeon stood on the left side of the patient. First, the surgeon introduced an Endo Grasp™ (Covidien, Mansfield, MA, USA) with his left hand and elevated the gallbladder fundus to assess the mobility of the gallbladder infundibulum. In the presence of omental attachments, the gallbladder infundibulum was freed with monopolar hook device held by the surgeon's right hand. To provide safe dissection and ease, active fundus retraction was continued throughout the whole operation with the surgeon's left hand. After mobilization of the infundibulum, the next step of the operation was launched. A 2.0 multifilament straight atraumatic needle was inserted through a point to the left of the falciform ligament with simultaneous palpation of the abdominal wall for optimum insertion site (Figure 2a). The needle was grasped with a laparoscopic needle-holder operated by the surgeon's right hand, and the needle was passed through the Hartmann's pouch of the gallbladder at the lowest accessible point (Figure 2b). To allow infundibulum retraction, the passing suture with the needle was turned around the afferent suture creating a

"half-knot" (Figure 2c). Then, the needle was passed out of the abdominal wall from a point to the surgeon's left at the mid-clavicular line, with simultaneous palpation of the abdominal wall to provide optimum location (Figure 2d). After this point, an assistant or a nurse grasped both ends of the suspensory suture with clamps. With traction of the suspensory suture ends by the assistant's right or left hand with constant tension and active fundus retraction by the surgeon's left hand, the classical Hartmann's pouch retraction was provided similar to LC technique, which was previously defined as "puppeteer movement" (7, 8). Dissection of Calot's triangle and removal of the gallbladder from the liver bed were possible in almost all cases with the use of the aforementioned facilitating maneuver and a hook diathermy (Figure 3). In this study, this technique was used successfully for all non-selected patients, regardless of difficult anatomy, inflammation or impacted stone in the cystic duct or infundibulum (Figure 4).

The cystic duct and artery were identified, doubly clipped, and divided. Dissection of the gallbladder from the liver bed was performed with a hook diathermy by active traction-counter traction. The gallbladder was easily extracted from the abdominal cavity through OCTO™Port's wound protector. The abdominal wall fascia was closed using polydioxanone (Ethicon) suture, and the umbilical skin was closed with poliglecaprone 25 (Ethicon) suture.

Skin sutures were removed in the outpatient visit in the 1st postoperative week. Patients were invited to attend our outpatient clinics at the first week and at sixth months for detection of any complications, and the assessment of cosmetic satisfaction and port site hernia.

The primary outcome measure was the difference between operation times of LC and SILC-2. The secondary outcomes were as follows: 1) Conversion to OC, LC or insertion of additional port/ports. 2) Intraoperative complication rate. 3) Length of hospital stay (LOS). 4) Postoperative complication rate. 5) Patients' cosmetic satisfaction. 6) Port site hernia rate.

Statistical Analysis

According to the results of our pilot study, the mean±SD operation time for LC group was 24.8±8.2 min and was 60±14.1 min for SILC group (p=0.008). The target number of subjects per group was calculated according to the PS: Power and Sample Size Calculation software version 3.0.43, 2011 (http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize) using α level 0.05, and β level 0.1. Effect size calculation using the mean and standard deviation revealed an E=0.475. For the target number of 20, the effective size (power) was calculated as 0.976.

Continuous data were presented as median and range or mean±standard deviation (SD). Dichotomous and categorical data were expressed as numbers and percentages. Normally distributed continuous data were assessed with one-way ANOVA test. If the data were not normally distributed, continuous data were assessed with Kruskal-Wallis test for overall differences, and secondary analysis was conducted by using Mann-Whitney U test for differences between groups. The Chi-square test was used for categorical data. A two-tailed p value <0.05 was considered as statistically significant. Statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS Inc; Chicago, IL, USA), version 16.00.

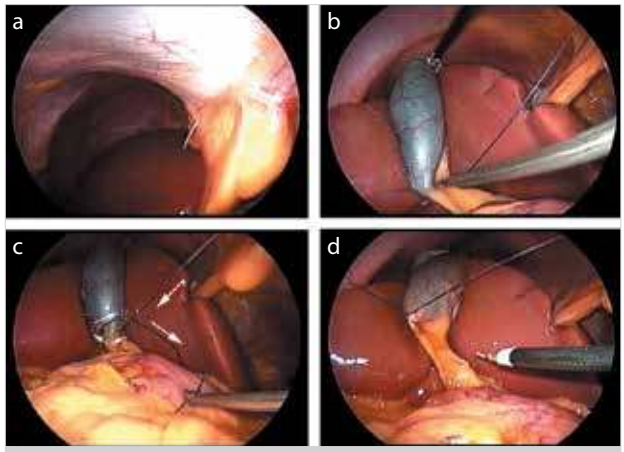

Figure 2. a-d. Providing "puppeteer movement" by using "Pick'n roll" technique. (a) Insertion of the needle into the abdominal cavity. (b) Passing through Hartmann's pouch. (c) Creating "half-knot". (d) Providing optimum view by "Pick'n roll" technique

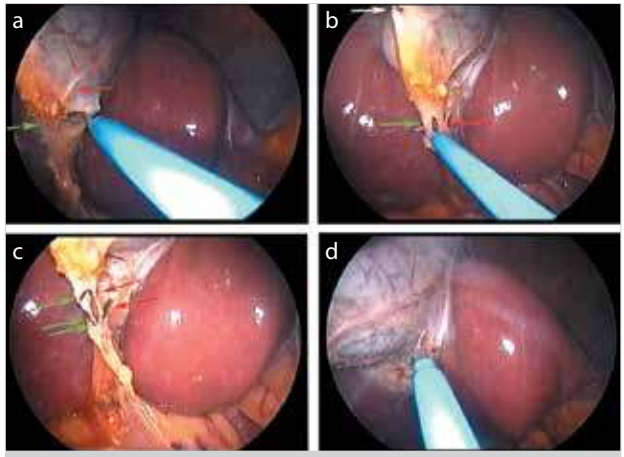

Figure 3. a-d. Providing critical view of safety by "Pick'n roll" technique and Calot triangle dissection. (a, b) Calot triangle dissection. (c) Synchronous clipping of the artery (red arrow) and the duct (green arrow). (d) Gallbladder dissection
White arrow: Hartmann's pouch suture for "Pick'n roll" technique

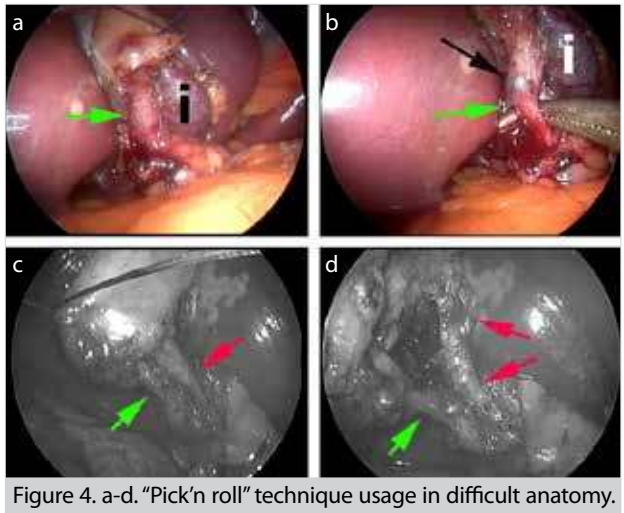

Figure 4. a-d. "Pick'n roll" technique usage in difficult anatomy. (a, b) Impacted stone (black arrow) on cystic duct (green arrow) and atypical localization of gallbladder infundibulum (i). (c, d) Preservation of right hepatic artery branch (red arrow) during Calot triangle dissection

Table 1. Patient demographics

	LC	SILC-1	SILC-2	p
Number of patients	20	20	20	
Age (years), mean±SD	54±16.1	48.5±18.4	44.1±11.9	0.150
Gender (%)				
Female	15 (75)	14 (70)	10 (50)	0.215
Male	5 (25)	6 (30)	10 (50)	
BMI (kg/m^2), mean±SD	30.4±6.9	29.8±4.8	29.3±3.3	0.984
Previous upper abdominal surgery (%)	1 (5)	1 (5)	-	0.999
Umbilical hernia (%)	-	1 (5)	3 (15)	0.310
DM (%)	5 (25)	1 (5)	2 (10)	0.246
Symptom duration (%)				
0-6 months	19 (95)	17 (85)	20 (100)	0.310
6-12 months	1 (5)	3 (15)	-	
ASA grade (%)				
I	17	18	18	
II	2	1	1	0.999
III	1	1	1	

LC: laparoscopic cholecystectomy; SILC: single incision laparoscopic cholecystectomy with new facilitating maneuver; SILC-1: initial; SILC-2: experienced; BMI: body mass index; DM: diabetes mellitus; ASA: American Society of Anesthesiologist

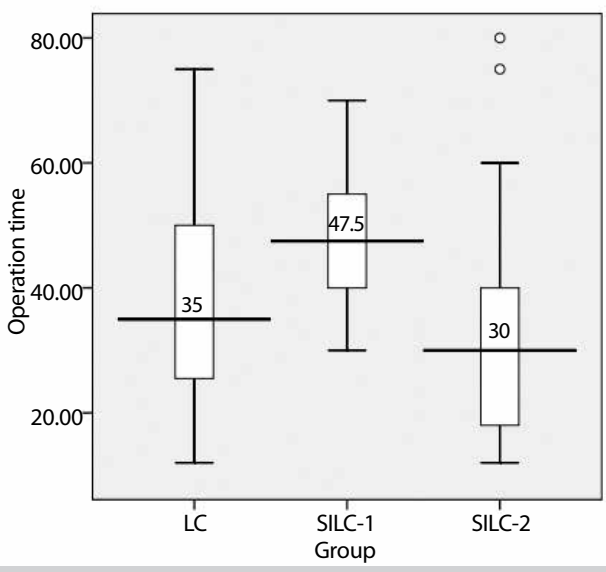

Figure 5. Duration of surgery according to surgical technique

RESULTS

During the study period, one surgeon operated 60 consecutive symptomatic cholelithiasis patients: 20 LC, 20 SILC-1 and 20 SILC-2. Demographic characteristics are shown in Table 1. Age, gender, BMI, previous upper abdominal surgery, presence of umbilical hernia, DM, symptom duration and ASA grade were statistically similar in all groups.

Two patients in the LC group, one patient in the SILC-1 group and one patient in the SILC-2 group did not accept our invitation for a hospital visit in postoperative sixth months. These patients were excluded from cosmetic and hernia assessments.

The median time to perform a LC was 35 min (range 12-75 min), 47.5 min (range 30-70 min) for SILC-1, and 30 min (range 12-80 min) for SILC-2 (p=0.005) (Figure 5). The operation time was significantly different between LC and SILC-1 groups, as well as SILC-1 and SILC-2 groups (p=0.020, and 0.002, respectively). No difference was observed between LC and SILC-2 groups in terms of operation time (p=0.277).

All of the operations were performed without conversion to LC or OC. Critical view of safety was provided in all patients without any additional trocar placement. No intraoperative complication was seen, and an intraoperative cholangiography was not required for any of the patients. Patients were generally discharged on the first postoperative day. There were no statistical difference between groups in terms of LOS (p=0.164).

Overall, wound complication rate was 28.3%. Wound seroma was observed in one patient (5%) in LC group, 9 patients (45%) in SILC-1 and 6 patients (30%) in SILC-2 group (p=0.01). Wound infection was seen in one patient (5%) in the SILC-2 group. Perioperative complication rates according to the surgical techniques were shown in Figure 6. Perioperative outcomes according to surgical techniques were shown in Table 2.

Patient satisfaction score on the postoperative 7th day and 6th month did not show any difference between the groups (p=0.776 and 0.08, respectively) (Table 3). When we aimed to assess the effect of wound complications on cosmetic score, we found a correlation between postoperative wound seroma development and lower cosmetic score on postoperative day 7 only in the SILC-1 group (p=0.007). The postoperative sixth month cosmetic scores and other group's results were found to be similar.

Port site hernia was assessed on the postoperative sixth month outpatient visit. We did not detect any port site hernia in the LC group, (n=18), while port site hernias were detected in 3 patients in the SILC-1 group (n=18, 15.8%) and in 1 patient in the SILC-2 group (n=18, 5.3%). In the SILC-1 group, all port site hernias were seen in patients who experienced wound seroma, but in the SILC-2 group, the one detected port site hernia was seen in a non-complicated patient. Among patients with wound infection, port site hernia was not detected.

DISCUSSION

Classical four port LC has been widely used due to its several advantages such as sufficient exposure of the gallbladder and related structures, safe dissection of Calot's triangle and good surgeon ergonomics. Despite all improvements in instrumentation, the application of SILC is still limited mainly because of the aforementioned reasons. In addition to these, lack of a standardized technique, requirement for specialized instruments, longer operation time and cost-effectiveness are well-known barriers. An ideal SILC technique must provide critical view of safety and safe dissection of Calot's triangle in almost all cases (including difficult anatomy, inflammation, impacted stone in the infundibulum) without compromising from good surgeon ergonomics, comparable operation time and cost, and must use more familiar (preferably conventional) instru-

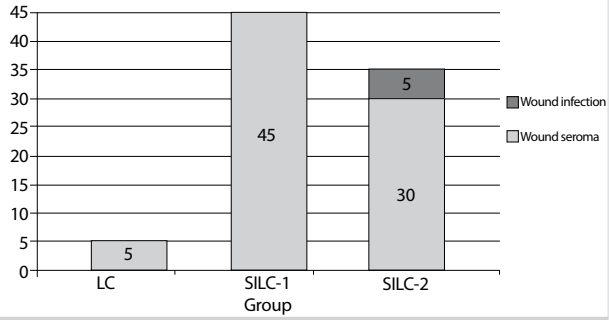

Figure 6. Perioperative complication rates according to surgical techniques

Table 2. Perioperative outcomes according to surgical techniques

	LC	SILC-1	SILC-2	p
Number of patients	20	20	20	
Operation time, mean±SD	37.9±16.4	48.2±12.6	33.4±19.3	0.005
LOS, mean±SD	1.1±0.4	1.3±0.5	1.0±0.2	0.164
Complication (%)				
Wound seroma	1 (5)	9 (45)	6 (30)	0.010
Wound infection	-	-	1 (5)	

LC: laparoscopic cholecystectomy; SILC: single incision laparoscopic cholecystectomy with new facilitating maneuver; SILC-1: initial; SILC-2: experienced; LOS: length of hospital stay

Table 3. Patient cosmetic scores on postoperative day 7 and sixth months and port site hernia rates according to groups

	LC	SILC-1	SILC-2	p
Number of patients on postoperative day 7	20	20	20	
Postoperative day 7 VAS score, mean±SD	8.3±1.6	8.2±1.6	8.6±1.5	0.776
Number of patients on postoperative 6 months	18	19	19	
Postoperative 6 months VAS score, mean±SD	9.5±1.1	9.9±0.2	9.9±0.2	0.080
Port site hernia on postoperative 6 months, n (%)	-	3 (15.8)	1 (5.3)	0.307

LC: laparoscopic cholecystectomy; SILC: single incision laparoscopic cholecystectomy with new facilitating maneuver; SILC-1: initial; SILC-2: experienced; VAS: visual analog scale

ments. In this study, with the use of a simplified SILC technique, the operation times were similar between LC and SILC-2 (experienced) groups, without any conversion, or port related and other intraoperative complication.

In a recent meta-analysis comparing LC vs. SILC, 11 randomized controlled trials with 858 patients were analyzed (9). Postoperative pain, complications, LOS, cosmetic score, conversion rate, need for additional port placement, and time to return to normal activities were found to be similar in both groups, while SILC was associated with significantly longer operation times. They concluded that the advantages related to postoperative pain and better cosmetic results were thought to be two main factors to perform a SILC, but SILC did not offer any advantage over LC. In the present study, we did not show a cosmetic benefit of the new SILC technique over LC on the 7th postoperative day and 6th months. In addition, there was no difference in cosmetic scores of the patients who experienced wound complications, except the significantly lower cosmetic score on the 7th postoperative day in the SILC-1 group patients with wound seroma. In another meta-analysis investigating wound-related complication rates between LC and SILC, the incidence of such complications was reported to be higher in SILC than in LC (4.6% vs. 2.6%), though not statistically significant (6). The wound complication rates in our study were higher when compared to previous trials (6). Although our wound-related complication rate for LC was comparable with previous trials, wound seroma rates were quite high in SILC-1 and SILC-2 groups, 45% and 30%, respectively. The wound seromas in our series were conservatively observed with basic wound dressing up to one week without any additional intervention, and all of them recovered quickly. The high seroma rates may be attributed to various reasons. First, our definition of wound seroma was broad including any serous discharge from the wound. Second, our inexperience at single incision access technique and excess usage of electrocautery could have affected wound complications. In the experienced arm of study, the rate of seroma decreased markedly but it was still high for recommending the single-port access technique to a patient. On the other hand, despite the higher seroma rates, the hernia rate in the experienced group (5.3%) were in concordance with the reported rates (0.3%-8.4%) (10-12). Our incisional hernia rates showed a marked decrease with experience just like wound seromas, this finding was considered as a supporting data for our comment about the need for optimization of the single-incision access technique.

To the best of our knowledge, our study revealed one of the shortest operation times for SILC and LC (13). In the experienced group, the median time to perform a SILC with the new facilitating maneuver was 30 min (range 12-80 min), and was 35 min (range 12-75 min) for LC. In our opinion, this operation time advantage was directly related to the simplified operative technique. Our new facilitating maneuver simplified SILC operation with regard to the principles of safe cholecystectomy in conventional LC. With the use of classical laparoscopic instruments and a new method to achieve active retraction of Hartmann's pouch via manipulation of suspensory suture ends, the operation becomes safer, easier and shorter. Providing easy access to the Calot's triangle, shorter surgeon adaptation time and suitability to safe cholecystectomy principles make our facilitating maneuver for SILC a reproducible technique for the surgeons. Nevertheless, higher wound complication and hernia rates due to single-incision access technique must be further optimized.

Until now, several authors have described different operations to standardize the SILC technique and provide ease of application, and a lot of facilitating technical maneuvers have been proposed in the social media (2-5, 14-16) few articles compare single-incision data with traditional LC. In most of these techniques, specific instruments were used such as 5-mm long and/or articulated scopes and articulated laparoscopic instruments. In addition, numerous gallbladder retraction

techniques were described; such as fundal traction technique, gallbladder-abdominal wall suture technique, fundus and infundibulum suture and Veress needle retraction technique (7, 8, 17). In our opinion, the key factor to perform a safe and easy SILC is to use an easy, two-side controllable, and reproducible single maneuver for retraction of the fundus and infundibulum. Our new facilitating maneuver provides constant and active fundal retraction and two-side controllable infundibulum retraction. Two articles described a suture triangulation method, i.e. "puppeteer maneuver", similar to our technique (18, 19), albeit significant differences. The first technique requires articulated instruments, triangulated infundibulum passing suture and two-side titanium clips, while the second technique included 5-mm scope and triangulated infundibulum passing suture with two needle pass from the infundibulum. With the help of logical combination of instruments that surgeons are more familiar with, and a minimal maneuver to provide the "puppeteer movement" our technique seems to be simpler.

Study Limitations

The relatively small size of our study may have affected our results, especially regarding rare complications of cholecystectomy such as common bile duct injury and stricture. In addition, the short follow-up period may have not reflected the actual postoperative hernia rate with the new technique. In this study, we did not perform a cost analysis, since conventional instruments were used except a commercially available single port device. Although, this device has the advantage of ease of application, an E.K. glove port might have been used for single-incision access to further decrease costs (20).

CONCLUSION

Currently, SILC is generally accepted as a more satisfactory method for patients with better cosmetic results. Nevertheless, there are several limiting factors for performing SILC such as poor surgeon ergonomics and fear of inability to perform a safe cholecystectomy. Our simplified SILC technique has the potential to overcome these limitations, with the advantage of ease, simplicity, short learning period, safety and reproducibility. Beside these advantages, the single-incision access technique must be optimized to provide comparable wound complication and postoperative hernia rates before being recommended to patients.

Ethics Committee Approval: An approval was obtained for this study from the ethics committee of Samsun Training and Research Hospital (No: 2014/551).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - R.A.; Design - R.A., K.G.; Supervision - E.Ç.; Resources - S.Ç., K.Y.; Materials - K.Y.; Data Collection and/or Processing - R.A., K.Y.; Analysis and/or Interpretation - R.A., K.G., S.Ç., K.Y., E.Ç.; Literature Search - R.A., D.Ç., E.Ç.; Writing Manuscript - R.A.; Critical Review - R.A., K.G., S.Ç., K.Y., E.Ç.; Other - R.A., K.G., S.Ç., K.Y., E.Ç.

Conflict of Interest: No conflict of interest was declared by the authors.

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Etik Komite Onayı: Bu çalışma için etik komite onayı Samsun Eğitim ve Araştırma Hastanesi'nden (No: 2014/551) alınmıştır.

Hasta Onamı: Bu çalışmaya katılan hastalardan yazılı hasta onamı alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

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