Is Single-Incision Laparoscopic Cholecystectomy Safe? A comparison between Single-Port and Multi-Port Laparoscopic Cholecystectomy. A Randomised controlled trial

Hany M S Mikhail[1] MD FRCS, Athar S M Elward MD, Tarek A. Awad[1] M.Sc MRCS, Mohamed H.A. Fahmy[1] MD., Ahmed Amr Mohsen[2] M.Sc
[1]Department of General Surgery, Faculty of Medicine, Cairo University, Egypt
[2]National Research Centre, Cairo, Egypt

ABSTRACT

Background: *Although the first single-incision laparoscopic cholecystectomy was described in 1997 by Navarra et al., this technique has spread slowly until most recent years. One of the main problems was concern about its safety specially regards CBD injuries. However, SILC holds the promise of improving the cosmetic results, reduce post-operative pain, allow early return to work resulting in greater patient satisfaction.* ***Patients and Methods:*** *Forty patients with chronic calcular cholecystitis underwent laparoscopic cholecystectomy. Twenty patients were subjected to SILC and were compared to the other twenty patients subjected to MILC concerning feasibility, operative time, occurrence of complications, degree of port-site pain, duration of hospital stay and finally, the aesthetic results.* ***Results****: At first, the operative time for SILC was considerably longer but later, it became almost comparable to that of MILC. CBD injury occurred in one case in the SILC group and the hepatic artery was injured in another case. Pain was significantly lower and this had resulted into lower analgesic demands and into shorter hospital stay. No port-site hernias were reported in the two groups. Finally, most of the cases in the SILC group were very satisfied with the aesthetic results.* ***Conclusion:*** *SILC was found to be safe, feasible, quite reproducible and had allowed early return to work through less pain and shorter hospital stay, and it had definitely resulted in better aesthetic results. However, SILC was found to be more expensive due to requiring single-use specialized instruments to complete the task safely.*

Key Words: *Single-port, Cholecystectomy, Laparoscopic, Scarless, Single-incision, Minimally Invasive.*

INTRODUCTION

Innovation in surgery is an important aspect of ensuring improvement in both quality of health care delivery and enhancement in surgical technology[1]. The development of laparoscopic surgery in the early 1990s has been heralded as one of the most important advances in surgery, providing patients with the benefits associated with reduced tissue trauma[2]. The important advantages of laparoscopy result from preservation of the integrity of abdominal wall, including less operative trauma and complications, thus, the incidence of wound infections and incisional hernias, of which especially obese patients are affected has decreased greatly. Furthermore, there is less postoperative ileus, allowing a faster postoperative feeding progress. After laparoscopic procedures, cosmetic results are much better compared with traditional operations. Postoperative pain is reduced, which results in faster mobilization and a lower number of immobilization-associated complications, such as venous thrombosis and pulmonary embolism[3,4]. Furthermore, less use of analgesics, and much shorter hospital stay characterize the laparoscopic procedures in general. Summarized, the benefit for the patient is faster recovery and better aesthetic result.

Several attempts have been made to reduce operative trauma further by decreasing the number and size of the trocars used in the procedure[5-14]. The use of three trocars instead of four, and the use of mini-instruments, is definitely a step in this direction[8,14]. Then came the introduction of natural orifice transluminal endoscopic surgery (NOTES)[15-17] and more recently, the introduction of single-incision laparoscopic surgery (SILS)[18-21]. With NOTES having major barriers that limit clinical

Corresponding Author: Hany M S Mikhail MD, FRCS, FEBS, FACS
E-mail: hanymikhail@kasralainy.edu.eg

application, such as spillage of gastric, urinary, or colonic contents within the abdomen, potential complications of leakage from a gastrotomy or colotomy, the difficult task of a viscerotomy closure, the difficulty maintaining spatial orientation[17,22] and the requirement of many special instruments[23], single-incision laparoscopic surgery holds the promise of advancing minimally invasive surgical techniques to the next frontier and is a step towards an even less invasive surgical procedures[24].

PATIENTS AND METHODS

This is a Randomized Control Trial which was conducted on forty patients with chronic calcular cholecystitis presenting to Cairo University hospitals (kasr alainy) in the period between January 2018 to December 2018. Patients were randomized using closed envelope techniques. The study was approved by the Research Ethics Committee in January 2018. Unwilling patients, patients suffering from acute cholecystitis, patients with history of upper abdominal surgical procedures, morbidly obese patients, pregnant women, patients with difficulty achieving a regular follow up and patients with any medical conditions that may render surgery hazardus were excluded from this study. Patients were consented to a laparoscopic cholecystectomy. They were informed in great detail about the operative strategy of having a single incision in the abdomen with a possibility of several more incisions or a conversion to an open technique. No patients declined to undergo such a technique.

Twenty patients were subjected to SILC, the other twenty were subjected to MILC.

We compared both techniques Intra-operatively for feasibility, operative-time and for the development of intraoperative complications such as visceral injury.

Early post-operatively, we compared both techniques for the degree of pain, the requirement of analgesics, the development of early postoperative complications, and for the rate of clinical improvement and the duration of hospital stay.

As for the follow-up, our patients were followed up for a period of about four to six months to detect the development of any late complications as port-site hernia and wound infection and finally to assess the patient's satisfaction with the aesthetic results of the procedure.

Operative Technique regarding patients who underwent MILC:

Patients are placed supine in the reverse Trendelenburg position and rotated right side up. This ensures that the bowel and omentum fall down and medially, away from the operative site. The surgeon stands at the patient's left and the monitor is at the head of the bed. The cameraman (first assistant) is also on the left of the patient, the second assistant (facultative) is on the right, the nurse near the foot of the bed. For disinfection of the skin, iodopovidone is used. The abdomen is prepped and draped in the usual sterile fashion, with careful attention to the cleaning of the umbilicus.

A 12-mm paraumbilical skin incision is performed, the fascia and the peritoneum are incised in an open approach and a 12mm trocar is introduced. The pneumoperitoneum is maintained at 10-14 mmHg. A 10-mm 0° long scope is introduced. A 10-mm trocar is placed under optical control subxyphoidal on the right side of the falciforme ligament. This trocar is used for the dissection instruments. Additional 5-mm trocars are placed under optical control in the right midclavicular line subcostally and in the right anterior axillary line subcostally. These trocars are used for the endograspers to retain the fundus and the infundibulum.

Optimal exposure of the triangle of Calot is obtained and the critical view is achieved. The cystic artery and duct are first dissected and then separately clipped with a standard 5-mm clip applicator. The gallbladder is pushed upright and dissected free from the liver by means of the monopolar hook. Once the gallbladder is free from the adjacent tissues, an exploratory sweep is performed to ensure good hemostasis and then the gallbladder is extracted through the 10-mm epigastric port. The paraumbilical fascia and the epigastric fascia are closed using 2/0 absorbable Vicryl suture and the skin is closed using 3/0 subcuticular stitches.

Operative Technique regarding patients who underwent SILC:

Patients are placed supine in the French position with a 15° head up tilt and a left lateral tilt about 20° to ensure that the bowel and omentum fall down and medially away from the operative site. The surgeon stands between the

legs, the cameraman (first assistant) on the left of the patient, the nurse near the foot of the bed. For surgical disinfection of the skin iodopovidone is used. The abdomen is prepped and draped in the usual sterile fashion, with careful attention to the cleaning of the umbilicus.

Using an industrial Single-access Device:

Here, the technique followed to carry out the procedure no matter what single-access device is used is almost the same. The only main difference is with installing the access device. We have put to test the "SILS Port®" (Covidien Inc., USA) together with their Roticulator® line and their SILS Hand instrument® line, the "GelPoint®" (Applied Medical, USA) with their line of curved instruments, the "TriPort+®" (Advanced Surgical Concepts, Ireland), the "X-cone®" and the "S-Port®" (Karl Storz - Endoskope, Germany) together with their line of curved instruments also.

So, after installing the access device and establishing pneumoperitoneum which is maintained at 10-14 mmHg. A 5-mm 30° or 45° long scope is introduced through one of the openings in the Port-System. The fundus of the gallbladder is grasped and pushed cephalaid to expose the triangle of Calot. The infundibulum is laterally retracted via a Roticulator® grasper. Subsequently good exposure of the triangle of Calot is obtained and the critical view is achieved. The dissection is done using a monopolar hook and a Roticulator® Maryland. The cystic artery and duct are first dissected and then separately clipped with a standard 5-mm clip applicator. Then the gallbladder is pushed upright and dissected free from the liver by means of the monopolar hook. Once the gallbladder is free from the adjacent tissues, an exploratory sweep is performed to ensure good hemostasis and then the gallbladder is extracted together with the Port-System. The umbilical fascia is closed using 2/0 absorbable Vicryl suture, and the natural scar of the umbilicus is restored using 3/0 subcuticular stitches.

RESULTS

The forty patients included in our study were divided into two groups. Group A included the 20 patients subjected to SILC and Group B included the other 20 patients subjected to MILC. Regarding the patient's demographics, there was no significant difference between the two groups that may interfere with our results in the end.

Concerning the operative time, in the beginning of the learning curve, it was considerably longer but as the learning progressed, the curve sloped down and the operative time decreased till a plateau had almost been reached by the eighth case and it became almost comparable to MILC. Statistically however, there wasn't a significant difference regarding the operative time between the two groups (p value = 0.089).(Fig1)

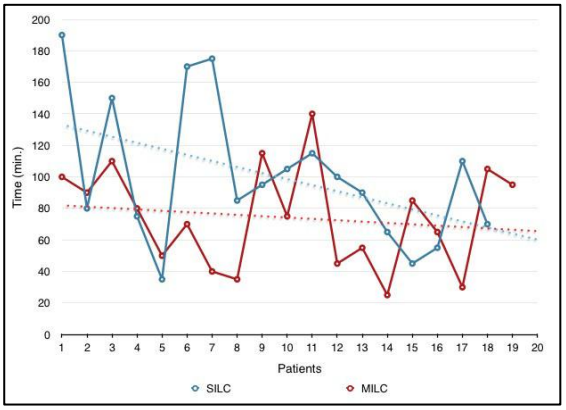

Fig 1: Operative time

Concerning structural injuries, as regards the CBD, it occurred in one case in the SILC group as well as in the MILC group. As for the vascular injuries, the hepatic artery was injured in one case in the SILC group (5%). On the contrary, no vascular injuries occurred in the MILC group however, that was statistically insignificant (p value for vascular injuries = 1.000). (Fig 2)

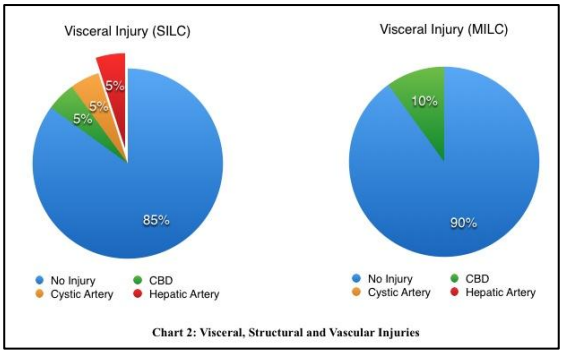

Fig 2: Visceral, structural and vascular injuries

Regarding the outcome, in the SILC group, the failure rate was 10% (two cases), one was due to hepatic artery injury and one was due to the occurrence of an uncontrolled gas leak from the used access device. On the other hand, the failure rate in the MILC group was 5% (one case), due to CBD injury. However, that was found to be statistically insignificant (p value = 1.000).

For monitoring and comparing the pain intensity, a visual analog scale (VAS) with a 10cm vertical score ranging from ‘‘no pain’’ (score 0) to ‘‘worst possible pain’’ (score 10) was used. Pain score analyses showed significant differences regarding pain, both, early (p value = 0.000) and late (p value = 0.000). Patients in the SILC group usually reported lower pain scores. (Fig 3,4)

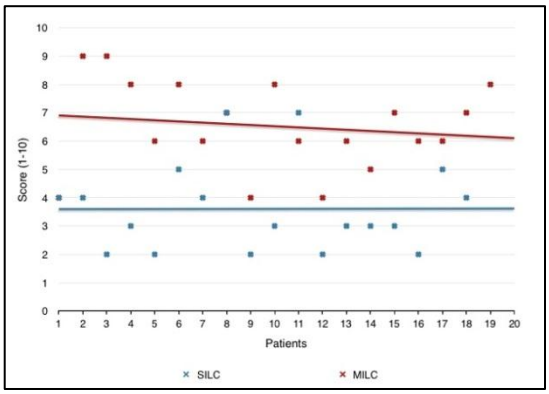

Fig. 3: Post-site pain (Early postoperative) Score (1-10)

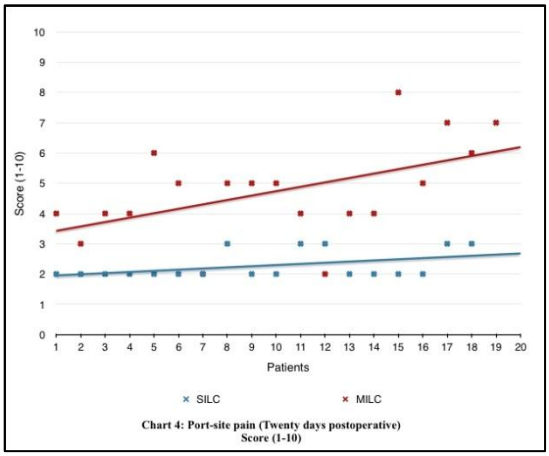

Fig. 4: Port-site pain (Twenty days postoperative) score (1-10)

This had been translated into lower analgesic demands for the SILC patients, early postoperatively (p value for the I.V. analgesic demand = 0.013) and during the follow up (p value for the Oral analgesic demand = 0.035). (Fig 5,6)

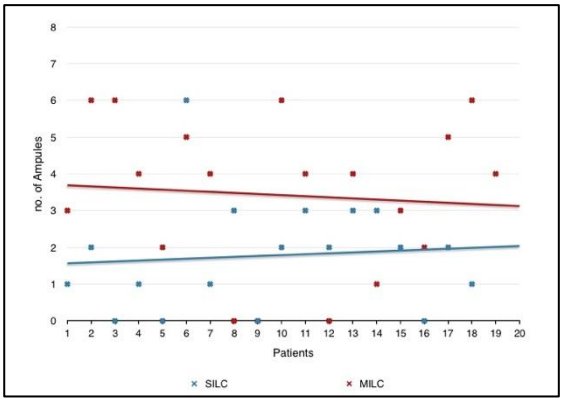

Fig. 5: Postoperative I.V. analgesic requirements

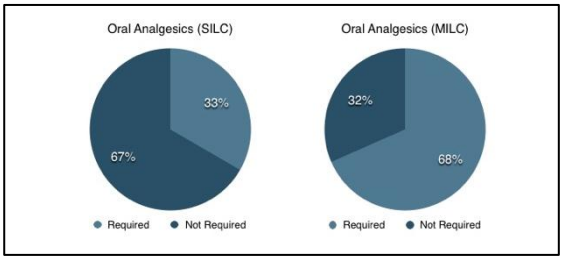

Fig. 6: Postoperative Oral analgesic requirements

As for the postoperative Ileus, the difference between the two groups was not statistically significant (p value = 0.179) with most of the patients restoring the bowel movement within the first 24 hours post operatively. The less postoperative pain together with the rapid restoration of bowel motility had resulted into a quicker recovery and had been ultimately translated into a shorter hospital stay for the SILC patients but not with a big difference, (p value = 0.065). (Fig 7,8)

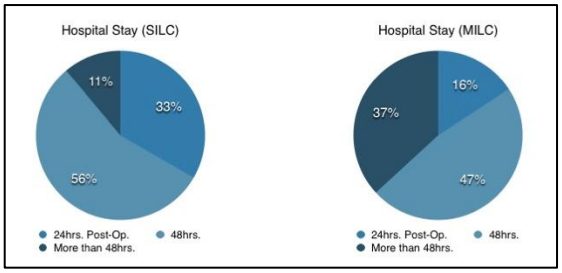

Fig. 7: Postoperative Hospital stay duration (1)

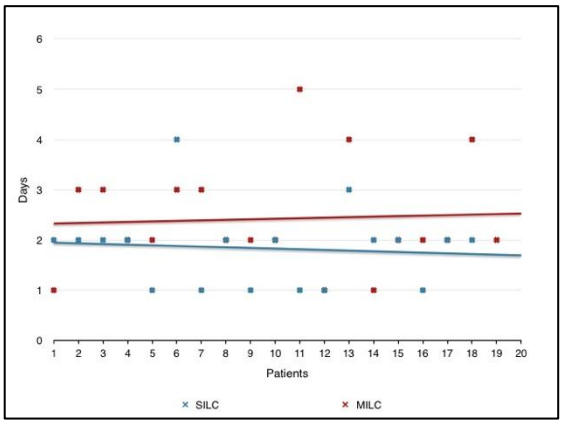

Fig. 8: Postoperative Hospital stay duration (2)

As for the late parameters, no port-site hernias were reported in the two groups during the follow up.

As regards wound infection, in the MILC group, 6 cases (32%) came presenting with wound infection during the follow up. Four of them were at the epigastric port-site but on the other hand, no wound infections were reported in the SILC group. That finding was of a high significance (p value = 0.020). (Fig 9)

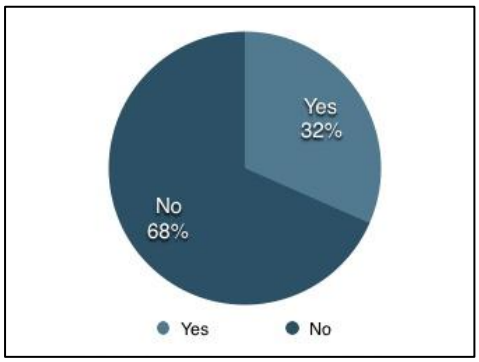

Fig. 9: Wound Infection in the MILC group

Finally, the aesthetic results, for reporting and comparing the patients' satisfaction with the results of both procedures, a visual analog scale with a 10cm vertical score ranging from "very dissatisfied'' (score 0) to "very satisfied'' (score 10) was used. Scar satisfaction analyses showed a significant differences regarding the aesthetic results between the two groups (p value = 0.000). Where most of the cases in the SILC group were highly satisfied with the aesthetic results while, on the other hand, many of the cases in the MILC group were some what dissatisfied with the aesthetic results. (Fig 10)

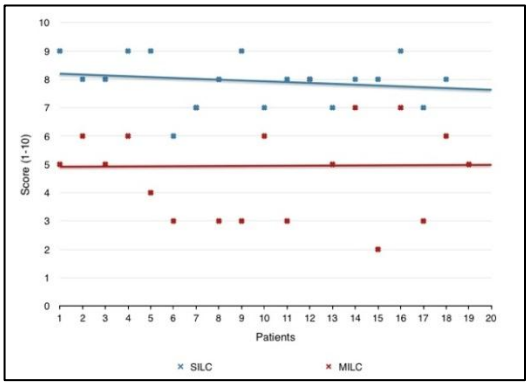

Fig. 10: Scar Satisfaction Score (1-10)

DISCUSSION

The SILS technique holds the promise of taking surgical practice to the next level. Our study aims at exploring that new innovative field, experience its feasibility, and construct an idea regarding its benefits and limitations.

Concerning the feasibility of the SILS technique, operative time and the learning curve; various studies have demonstrated difficulties in the acquisition of SILS skills with impaired performances compared to standard laparoscopic surgery. These studies revealed significantly longer learning curves for SILS compared to standard laparoscopic surgery. A review by Pucher et al.[26] in 2013 assessed the evidence for training in SILS and showed that laparoscopic expertise did not necessarily translate to SILS proficiency. The review elucidates the presence of a significant learning curve for the surgeons adopting SILS with greater operative time and increased rate of conversion to multi-port laparoscopy in their initial cases. A "SAGES" learning center study in 2011 showed that the

performance in a basic peg transfer task was significantly worse for SILS compared to conventional laparoscopy. Also, SILS with articulating instruments was shown to be even more difficult compared to SILS with straight instruments[27]. Montero et al.[28] (2011) showed that the performance in a peg transfer simulation model is better using standard laparoscopy compared to SILS. However, performance improved when angulated instruments were used. Also in 2011, Rieder et al.[29] observed a greater mental strain in surgeons using a single-incision approach. A high percent of the surgeons reported occasional or frequent problems with eyesight, traction, triangulation and interference with the other members of the surgical team.

In our study, SILC was found to be very challenging in the beginning. Even our expert surgeons found it difficult to perform. This could be partly attributed to the fact that at first we used standard laparoscopic instruments not designed for SILS and this demanded the operating surgeon to use the "cross-handed technique" which had burdened the surgeon with a huge physical and mental toll and this had been translated into prolongation of the operative time remarkably. But, when we started to use the correct instruments, ergonomics improved, and so did our time.

Also, one of the major factors that had affected our operative times is the surgeon's experience. At first, unfamiliarity with the ergonomics of this technique, had crippled our performance and prolonged our times up to 190 minutes. But as our experience grew, our operative times started to improve. the operative time continued to drop until they became very comparable to those of the conventional technique, scoring a minimum of thirty-five minutes. The mean operative time for our SILC cases was 100.5 minutes while that for our MILC cases was 74.2 minutes.

The mean operative time for the first case series of thirty patients published by G. Navarra in 1997 was 123 minutes[30]. Cuesta et al.[31] reported a series of ten patients in 2008 with an average operative time of seventy minutes. Also in 2008, Rao et al.[32] performed twenty SILS cholecystectomies using the "TriPort+®". They reported an average operative time of forty minutes. In 2009, Merchant et al.[33] have reported the completion of twenty one SILC cases using the "GelPoint®". The operative times ranged from forty-five to ninety minutes however, the average time per procedure was not reported. Another series by Rivas et al.[34] in 2010 investigated 100 patients undergoing SILC. Their operative times were initially longer but improved over time, with an average operative time of fifty-one minutes. Hirano et al.[35] performed a review of all case series of SILC published in 2010 and reported longer operative times compared with the standard approach.

As for safety and conversion rate; safety should and must always be the corner stone for assessing and judging any new emerging technique. Giuseppe Navarra[50] in his series of thirty patients had reported the occurrence of one wound complication only. While Piskun et al.[38] presented a series of ten patients in 1999 and they reported the occurrence of no complications. And of the twelve patients who underwent this operation in the study by Tacchino et al.[24] (2008), two complications were observed (16.6%). In one case, the patient sustained trauma to the abdominal wall due to the multiple trocars inserted at the single umbilical incision and developed a subcutaneous hematoma that required evacuation. Another patient experienced persistent postoperative abdominal pain secondary to an intra-abdominal collection that most likely occurred due to bleeding from the liver which spontaneously resolved but extended the patient's hospital stay to seven days. In 2009, Zhu et al.[18] performed six SILS cholecystectomies. They were able to successfully remove the gallbladder using this technique in all but one case which needed conversion for uncontrolled bleeding. In 2010, Roberts et al.[39] reported on fifty six SILS cholecystectomies. They reported three complications including a gallbladder fossa abscess, a duct of Luschke bile leak, and a retained common bile duct stone. In their series in 2010, Rivas et al.[34] had also reported that the complications were similar in number and nature to those of MILC. In their review in 2010, Hirano et al.[35] had reported a rate of 5.6% for conversion to MILC as well as a 1.9% complication rate.

In our study, concerning structural Injuries, as regards the CBD, it occurred only in one case in our SILC series but that did not require conversion for the injury was minimal and the operating surgeon was able to deal with it. As

regards the vascular injuries, the hepatic artery was injured in one case in the SILC series and required conversion to open surgery and the case was considered a failure.

Regarding the outcomes, in the SILC series, the failure rate was 10% (two cases), where one case was converted from SILC to MILC for uncontrolled gas leaks continued to occur from the access port rendering the procedure extremely difficult and that increased the risk of injury, and the other case was converted from SILC to open laparotomy due to the seriousness of the injury inflicted where the hepatic artery was injured in that case and that resulted in massive bleeding.

Concerning the postoperative pain, hospital stay and the rate of clinical improvement; less pain, decreased use of pain medication, and faster return to work have been also shown with SILC helping achieve the concept of one-day surgery. A report from Bresadola et al.[38] back in 1999 had also demonstrated lower pain scores in their single-port group.

In our study, pain score analyses showed significant differences regarding port-site pain, both, early and late. Patients in the MILC group usually reported higher pain scores, for almost all of them complained of severe pain at the "epigastric port-site".

As regards the requirements of analgesics; lower analgesic demands were recorded in the SILC group both, early postoperatively and during the follow up and this goes in line with the port-site pain intensity that the two groups had experienced.

That of course had translated into a shorter hospital stay for the SILC patients. The mean postoperative hospital stay for the SILC patients in our study was 1.8 days while that for the MILC patients was 2.4 days. This reflects the fact that the rate of clinical improvement after SILC is quite faster than that after MILC. What does this has to do with costs, yet requires further investigation and study.

Navarra[50] in his case series reported that the mean postoperative hospital stay was 1.8 days which was similar to our results and Piskun et al.[36] reported in their case series in 1999 that all patients were discharged within the first 24 hours post operatively.

As for the port-site Hernias; one of the clear benefits of multiport laparoscopy has been the reduction of large incisional hernias that used to occur with open surgery. However, early in the experience of laparoscopy, we saw some reports surface that addressed port-site hernias. Two lessons became clear back then: increased port size results in a higher incidence for hernia to occur, and the most likely port site to result in a hernia is the paraumbilical area. Whether this is due to the larger trocars being inserted in this position or the inherent weakness of the muscles at this site is not clear. Regardless of the reason, we absolutely need to follow closely the possible increased incidence of hernia formation rate that we might see with the use of larger access devices with SILS.

In 2011, Gangl et al.[39] and Krajinovic et al[42] showed that the frequency of incisional hernias after SILS surgery amounted to 1.9 - 2.0%. By adequate closure of the abdominal fascia, the incidence of incisional hernia is not increased after SILS.

In our study, no port-site hernias were reported in the two groups during the four to six months period of the follow up. This probably could be attributed to the close attention payed to the fascial closure done for all patients of both groups.

As regards wound infection; in the MILC group, six cases (32%) came presenting with wound infection during the follow up. Four of them were at the epigastric port-site. This could be attributed to that no "Retrieval Bags" were used for the retrieval of the gall bladder through the epigastric port-site in the MILC series and that may have caused the contamination of the wound and the occurrence of wound infection later on. This could also be attributed to patients' self-hygiene and wound care. On the other hand, no wound infections were reported in the SILC group. This could be attributed to that most of the single-access devices used has a built in wound protector/retractor as a part of their design and this could have guarded against wound contamination.

Finally for the aesthetic results, many have mentioned that improved cosmesis is the strong foothold of this technique, where the careful reconstruction of the umbilicus leaves the abdominal wall virtually with no scars. Studies by both, Aprea et al.[43] and Bucher et al.[40] in 2011 has shown improved cosmesis for patients undergoing SILC, as shown by postoperative surveys.

In our study, great care had been payed to the reconstruction of the umbilicus by the end of the procedures and scar satisfaction analyses later on had shown a significant difference between the two groups. Where most of the cases in the SILC group were highly satisfied with the aesthetic results of the single-access approach. on the other hand many of the cases in the MILC group were some what dissatisfied with the aesthetic results of the conventional approach.

CONCLUSION

So, SILC is safe, feasible, and quite reproducible. Furthermore, with progressive experience, more complex patients may be suitable candidates for this technique. The outcomes are comparable with those for conventional endoscopic techniques, with similar minimal morbidity and no mortality.

Also, patients who underwent SILC had experienced less pain and that had been translated into shorter hospital stay. Also, they had acknowledged enjoying better aesthetic results.

However, SILC was found to be more expensive because of a slightly prolonged operating time and the single-port device and instruments, which in most cases are not reusable. Also, SILS is accompanied by musculoskeletal problems and technical difficulties for the surgeons. Although devices to facilitate single port procedures are becoming available, the development of new devices and instruments and the refinement and standardization of surgical techniques, will help reduce these issues and may allow for the wide dissemination of these techniques.

Finally, clinical trials are warranted before this procedure is adopted universally. Wide adoption of this technique should be carefully implemented, with continuous medical education and training. This is not only mandatory but also ethical.

List of Abbreviations:

SILS: Single-Incision Laparoscopic Surgery.
SILC: Single-Incision Laparoscopic Cholecystectomy.
MILC: Multi-Incision Laparoscopic Cholecystectomy.
MIS: Minimally invasive surgery.
NOTES: Natural Orifice Transluminal Endoscopic Surgery
SIMPLE: Single-incision multiport laparoendoscopic surgery
CBD: Common Bile Duct.
HMP: Home made port.
SHI: SILS Hand Instruments®.
VAS: Visual Analog Scale.
CCC: Chronic Calcular Cholecystitis.

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