

Laparoendoscopic single-site surgery in gynecology: LESS is actually how much less?

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ABSTRACT

Gynecological surgery is evolving continuously. Laparoendoscopic single-site surgery (LESS) is the recent addition in this field that stands to benefit almost 40% of women in midlife who will eventually undergo adnexal surgery or hysterectomy. Carried out through a single umbilical incision, the potential benefit of single site surgery is improvement in operative morbidity and cosmesis. The safety, feasibility and efficacy of laparoendoscopic single site procedures have been established in studies over the last few years. In this article, we will review the nomenclature, instruments, and the evidence around the commonly performed gynecologic surgeries using the LESS procedure.

Key Words: Adnexal surgery, hysterectomy, laparoendoscopic single site procedure, single incision laparoscopic surgery, single port surgery

INTRODUCTION

Midlife is defined as the time between menopause and old age, the fifth, and sixth decades of life, when women are still relatively healthy and physically active.^[1]

This is unfortunately also the time when many women undergo surgeries due to myriad of gynecological problems. While a lot of concerted effort has been directed at avoiding surgery, gynecologists have also toiled towards reducing morbidity due to elective gynecological surgery. Laparoscopic surgery is one such innovation in the therapeutic armamentarium of the gynecologists.

Laparoscopic surgery has come a long way from its introduction in the early 20th century. Gynecologists have been at the forefront of introducing and popularizing newer techniques and innovations in laparoscopic surgery.^[2] Today most gynecological surgeries can be performed laparoscopically.

The focus of surgeons is now to reduce the duration of hospital stay, post-operative pain and improve cosmesis in laparoscopic procedures. One approach to this end has

been to reduce the number and size of ancillary surgical ports.^[3,4] Another important innovation has been to eliminate the ancillary ports altogether. This innovation is not novel to gynecologists who have been doing tubal ligations using single umbilical ports for decades.^[5] Of late the indications of single site surgery have expanded to include hysterectomy and adnexal surgeries. This has been possible due to technical advances in instruments, platforms for single site surgery and the enthusiasm of gynecological endoscopic surgeons. While there is enthusiasm for single site laparoendoscopic surgery in gynecology, there is concern regarding issues such as limited access, lack of triangulation, larger umbilical incision, and possibility of incisional hernia in the long-term.^[6,7]

In this article, we attempt to review the nomenclature, instruments, platforms, and the gynecological surgeries carried out using a single site access.

Search

Using the search terms laparoendoscopic single-site surgery (LESS), single port access, single port access surgery, pure

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single port access, combined single port access, single incision laparoscopic surgery, single port laparoscopy, single port laparoscopic surgery, single incision laparoscopy, one port umbilical surge (OPUS), embryonic natural orifice transluminal endoscopic surgery (NOTES)TM, Umbilical NOTESTM, and Gynecology, a search was made in MEDLINE and CENTRAL from 1990 to 2012. The relevant studies were selected and reviewed. Randomized controlled trials (RCT) on the subject were screened, and it was decided to do a meta-analysis if comparable data could be extracted from more than one RCT. If suitable RCTs were not available, a narrative review was carried out.

NOMENCLATURE

The nomenclature of LESS has been controversial and varied. It has been called single access/port/site/incision/trocar surgery, OPUS, and embryonic natural orifice transluminal endoscopic surgery (eNOTES).^[8] There is no consensus on the nomenclature in gynecology so far, and this hinders effective communication, comparison and search of literature on the topic. Urologic NOTES working group has recommended that LESS be designated the terminology of choice to define laparoendoscopic procedures performed through a single port, multiple port, and single multiport platform used via a single incision or location anywhere in the abdomen, flank or the back. They have suggested the term Umbilical laparoendoscopic single-site surgery (U-LESS) for similar procedures performed through the umbilicus.^[8] Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR) is an international multidisciplinary *ad hoc* organization made to advance the development of the necessary techniques, and technology to standardize the clinical outcomes in single site access laparoscopic surgery. In a white paper, they also proposed the term LESS.^[9] Most gynecological procedures described so far are performed through the umbilical incision using single incision or single multiport platform.

Devices/ports

Three types of access have been described in LESS procedure. Single umbilical incision with multiple fascial punctures, single incision with use of wound retractor and surgical glove; and use of multichannel ports.^[7,10-12]

In the first technique, a single umbilical skin incision 2-3 cm in length is given and three ports are introduced through different but adjacent fascial punctures through this incision.

Use of a multichannel port or device is becoming commonplace. An endoscope and two instruments are introduced through the port and the procedure is

performed and completed through the single incision.^[6] A variety of ports have been manufactured and they can be classified as per type of access (through gel, multiple access or structural access) or as per retraction technology (gel, soft structural retraction or rigid structural retraction).^[13] GelPOINT[®] (Applied Medical, Rancho Santa Margarita, CA, USA) uses gel platform, which has minimum resistance to external mobility of instruments and maintains the pneumoperitoneum. Triport[®] and Quadport[®] (Advanced Surgical Concepts, Bray, Ireland) have multiple access channels and use a plastic sleeve for retraction. OCTO-portTM (Dalim Surgnet, South Korea) is also a multichannel port with sleeve retracting technology with a choice of one to four channels, X coneTM (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) is a reusable access port with three channels [Figure 1].

SILSTM (Covidien, Norwalk, CT, USA) is a disposable structural access port, which uses soft structural retraction and allows 5-12 mm trocars and instruments [Figure 2].

Use of a wound retractor and surgical glove is a viable and cheap alternative to expensive multichannel disposable ports [Figure 3].^[10,14-16]

Because the point of entry of these three instruments is close together, crowding and clashing of instruments is a major problem with LESS procedure. There is lack of triangulation and this requires modification in the technique of accessing the organs, dissection and endosuturing.^[12]

Standard telescopes are 30 cm in length and this exacerbates the problems in a crowded space. Use of longer bariatric telescopes is an alternative in LESS procedure. The light cable attaches at 90° to the axis of the telescopes in traditional telescopes. This causes more crowding and inhibits manipulation of the telescope. Use of a flexible digital endoscope, which obviates the need for a light cable and camera attachments, is an alternative in LESS procedures. The charged couple device (CCD) chip is at the tip of such a scope like EndoEYETM (Olympus Deutschland GmbH, Hamburg, Germany), which obviates the need of camera attachments [Figure 4]. Another innovation is the EndoCAMEleonTM (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany), a 10 mm rigid scope with a selection of viewing angles from 0° to 120°.

While traditional laparoscopic instruments are straight line, curved and roticulating instruments have been introduced for LESS procedures. Curved instruments allow the instrument tip and handle to come in the same line as in conventional laparoscopy. These allow triangulation and facilitate traction-counter traction, dissection, and suturing. Roticulating (wristed) instruments have maneuverability at



Figure 1: X cone by Karl Storz is a reusable working port with five channels

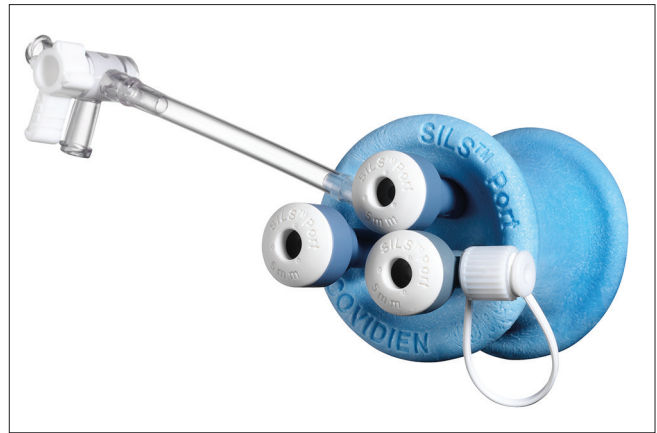


Figure 2: SILS port by Covidien is a single use multi access port with access channels for three cannula

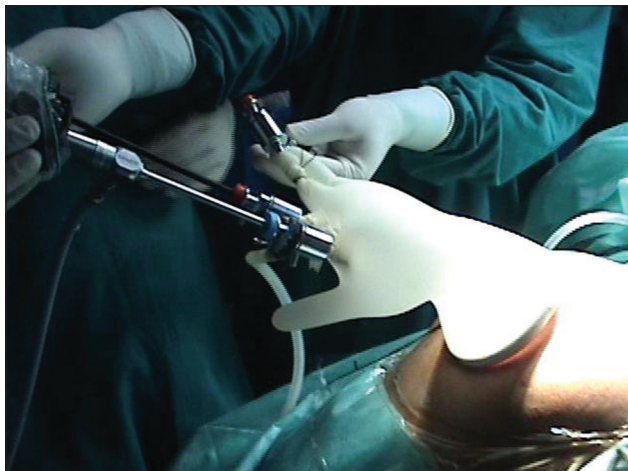


Figure 3: Use of a wound retractor with a surgical glove is an indigenous and cost effective way of gaining access in Laparoendoscopic single-site surgery procedures (Used with permission from Dr. B. Ramesh)

the tip and allow locking and 360° rotation of the tip. Use of multifunction instruments such as Ligasure™ (Valleylab Inc., Boulder, Colorado, USA), which allow coagulation, dissection and division of tissue also helps in LESS by reducing instrument changes.^[17]

LESS for adnexal diseases

Adnexal surgeries include a gamut of surgeries such as tubal ligation, salpingectomy, ovarian cystectomy, salpingoophorectomy for benign diseases like endometriosis and surgeries done for suspected malignancies in the adnexa. Risk reducing salpingoophorectomy is another

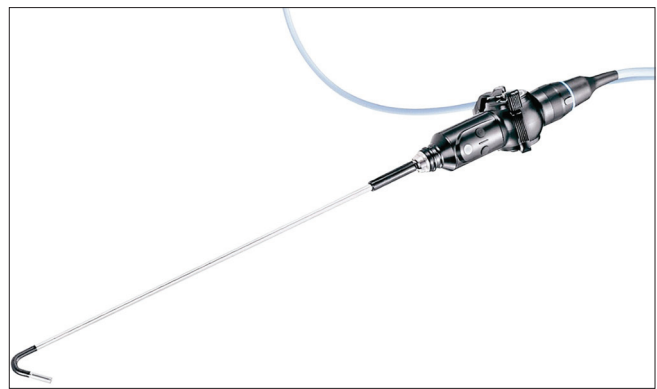


Figure 4: Flexible 5 mm telescope with charged couple device chip at the tip (Olympus EndoEye)

adnexal surgery indicated for women at high-risk of ovarian and breast cancer.^[18,19] Adnexal surgeries are said to be eminently suitable for LESS compared to other intraperitoneal diseases such as appendicitis or gall bladder disease, because a uterine elevator through another natural orifice, vagina, permits mobilization of the adnexal tumor.^[20]

The first report of use of single site surgery for adnexal tumors was by Fagotti, *et al.*, in 2009. In this case series of three cases, the authors used a single trocar with a combination of standard (36 cm) and long (42 cm) laparoscopic instruments and a 5 mm 30° laparoscope. The mean operative time was 79.6 min and estimated blood loss was 20 ml. There were no complications or conversion to conventional laparoscopy. This was followed by retrospective case series from Cleveland Clinic by Escobar, *et al.*^[21] Nine cases of benign adnexal masses or endometrioma were operated and the procedure could be completed through a single port in eight cases. The same group reported the feasibility of single site laparoendoscopic surgery in carefully selected cases in gynecological oncology.^[17] In this case series, nine cases were performed laparoscopically

and four by robotic single site surgery. The authors used articulating instruments, flexible 5 mm 30° laparoscope and multi-functional 5 mm instruments, which allow tissue fusion/vessel sealing, spot coagulation and endoscissors together, which allows surgery to proceed with minimum instrument changes and crowding. The procedures performed were varied and included endometrial cancer staging, ovarian cancer staging, retroperitoneal pelvic lymph node dissection, risk-reducing extrafascial hysterectomy/bilateral salpingo-oophorectomy and (BSO) alone, ovarian cystectomy and BSO for complex adnexal masses. Subsequently, a case series of 58 patients who were BRCA mutation carriers and women at high risk for breast and ovarian cancers undergoing risk-reducing salpingo ophorectomy (RRSO) was published in 2009.^[22] This is the largest case series reported so far for LESS for adnexal surgeries. The mean operative time was 38.1 min. A multivariate linear regression analysis showed that the only factor affecting operative time was the number of cases performed by the operator. The authors concluded that surgical proficiency in LESS RRSO could be attained after 10-15 cases.^[22]

All these reports were retrospective in nature and designed as feasibility studies. The number of patients was less and objective pain assessment by use of validated scales was not done in some of them. These were followed by case control studies, which compared conventional laparoscopy to LESS in adnexal surgery.^[23,24] Lee, *et al.*, used an access port made using a wound retractor and surgical glove to perform oophorectomy or cystectomy. This is an important surgical innovation as commercial ports are expensive and disposable. This has been used in other studies and has the advantage of being accessible, cheap, and disposable.^[11] They found comparable operative outcomes including operative time, analgesia requirement, hospital stay, and mean drop in hemoglobin in the two groups.^[24] Yoon, *et al.*, used a similar access platform made of wound retractor and surgical glove and published a case control study in 2010.^[14] They performed salpingectomy in women with tubal ectopic pregnancies by single port access in 30 patients and compared the surgical outcome with 30 women undergoing conventional four port laparoscopic salpingectomy. There was no difference in operative time, hospital stay and complication rates between the two groups. This study did not look at post-operative pain or patient satisfaction with the new technique.

These studies prove that LESS is acceptable, feasible and safe with a learning curve of 10-15 cases for surgeons already performing conventional laparoscopic procedures and paved the way for RCT.

Two RCT comparing conventional laparoscopic adnexal surgery with LESS adnexal surgery are available.^[25,26]

Fagotti, *et al.*, compared post-operative pain scores and cosmetic outcome in patients undergoing LESS adnexal surgery with conventional multiport laparoscopy. They found significantly less pain scores in women undergoing LESS compared to conventional laparoscopy. They found a higher rate of satisfaction in the patients as well as surgeons in the LESS than in the conventional LPS group. The second RCT on this subject was carried out in Norway.^[26] The primary outcome measure was post-operative pain score at 24 h post-op. Other outcomes were post-operative pain 6 h after surgery, shoulder tip pain, and satisfaction with cosmetic result, which was self-reported and based on the Manchester scar scale. Contrary to the study by Fagotti, *et al.*, they found similar pain scores at 6 h and 24 h in the two groups. Women who underwent LESS reported a higher rate of post-operative shoulder pain, which was statistically significant. In this study, in contrast to the study by Fagotti, *et al.*, the operative time was significantly longer in LESS group and the satisfaction rate with the surgical scar were similar in both groups.

The most important outcomes to the patient are post-operative pain and cosmesis. The two RCT have contradictory results in both these outcome measures. Unfortunately, they could not be combined into a meta-analysis due to methodological variations such as the time of measuring pain score in both the trial. Both RCTs had a-priori sample size calculation, central randomization, and adequate allocation concealment. In both the studies, the participants and outcome assessors were not blind to the type of surgery performed. The apparently contrary conclusions of these two RCTs cannot be explained on the basis of surgeon experience alone. There is a need for a well-designed RCT, preferably multi-centric and powered to detect a difference in patient satisfaction rate among other outcomes. An economic analysis is important as the cost of ports and instruments could be significantly high and might offset any benefit in terms of reduced hospital stay.

LESS for hysterectomy

Hysterectomy is one of the most common surgeries performed on women. It is estimated that almost one third of the women undergo a hysterectomy by the age of 60 in the United States.^[27] Laparoscopic approach to hysterectomy has several advantages over abdominal hysterectomy such as quicker return to normal activities, less post-operative pain, fewer wound or abdominal wall infections, fewer febrile episodes or unspecified infections, smaller drop in hemoglobin, earlier discharge from hospital, and improved quality of life.^[28] Use of a single umbilical puncture for laparoscopic hysterectomy has been described as early as 1992.^[22] Reducing the number of punctures might reduce potential morbidity from bleeding, port-site hernias, and internal organ damage and have cosmetic benefits.^[29]

Retrospective study has shown that single port access laparoscopically assisted vaginal hysterectomy (LAVH) had comparable surgical outcomes to conventional LAVH with lower post-operative pain in the single port access group.^[30] An RCT from Taiwan also showed significantly lower post-operative pain in single port LAVH compared to conventional LAVH.^[31] However, the use of vaginal approach precludes accurate comparison between the laparoscopic access techniques of LESS and conventional multiport access in these studies. Jung, *et al.*, in 2010 reported their case series of 30 patients who underwent LESS total laparoscopic hysterectomy (TLH) using a wound retractor and surgical glove. There were no conversions to traditional laparoscopy with a mean operative time of 100 min (10-400 ml) and no operative complications.^[32] A case control studies comparing single port with multiport traditional TLH showed a significantly longer operative time with the single port approach. The authors mentioned that vault suturing was particularly difficult with single port access, but the time taken to suture the vault reduced with experience. After performing five cases of LESS TLH, the operative time to suture the vault improved significantly.^[29]

An RCT comparing LESS TLH with conventional TLH did not find a significant difference in pain scores in the two groups.^[33] However, the confounding factor was that women in LESS group requested analgesia more often than women who underwent conventional TLH. Another RCT from China compared LESS TLH with conventional TLH.^[15] This study showed significantly shorter duration of immobilization, lower port site infection and higher patient satisfaction rate with LESS TLH. However, the duration of surgery was significantly longer in the LESS TLH group than the conventional laparoscopy group. Interestingly, the duration of surgery in LESS TLH reduced significantly after first 25 cases. This study was not adequately randomized (patients assigned as per admission sequence); there was no allocation concealment or blinding of participants or outcome assessors.

To summarize, retrospective case control studies show comparative operative outcomes and longer operative times in LESS TLH group. Of only two RCT, one had methodological flaws and did not measure post-operative pain scores.^[15] The other RCT did not show any significant difference in pain scores between LESS TLH and conventional TLH.

There are no studies that evaluate cosmesis, body image, and long-term outcomes like port site hernia in patients undergoing LESS TLH. Furthermore, there is no economic analysis of LESS TLH, which is a significant factor in decision-making.

CONCLUSION

The procedure of LESS in gynecological adnexal surgeries and hysterectomy is still evolving. Case series and case control studies have established that it is feasible and safe with a significant but surmountable learning curve. There are very few RCT and these show that LESS is comparable to conventional laparoscopic surgery. There remain areas like economic impact of using disposable ports and special instruments, longer operative time and higher post-operative pain scores that need to be addressed prior to widespread uptake of the technique.

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