

Laparoendoscopic Single Site Total Hysterectomy: Single Institution Initial Experience

Laparoendoskopik Tek Giriş Total Histerektomi: Tek Merkez Başlangıç Deneyimi

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ABSTRACT Objective: To compare the peri- and post-operative outcomes between the laparoendoscopic transumbilical single-site total hysterectomy (LESS-TH) and conventional three-port total laparoscopic hysterectomy (TLH). **Material and Methods:** A single institution retrospective review of patients operated on with LESS-TH (n= 24) and TLH (n=47) for benign uterine pathology or endometrial cancer with low-risk factors from March 2013 to March 2014. Patients underwent LESS-TH surgery through a single 2-3 cm transumbilical incision with a multi-channel SILS TM port (Covidien®, Mansfield, MA, USA). Patient demographics and peri-operative and post-operative variables were analyzed and compared between the groups. **Results:** There was one conversion to conventional laparoscopy and one conversion to laparotomy in the LESS-TH group, and no cases converted to laparotomy in the TLH group. Demographic characteristics such as age, body mass index (BMI), and indications were similar between the groups (p=0.497, 0.07, 0.594, respectively). Operation time was significantly longer in the LESS-TH group than in the TLH group (p=0.01). The other peri- and post-operative variables such as uterus length and width, estimated blood loss, post-operative Hb level drop, post-operative hospitalization time and analgesic management were found to be similar between the two groups. There were no major complications in either of the groups. **Conclusion:** With the exception of operative time, the surgical outcomes of the LESS-TH group were comparable to those of the conventional multiport TLH group.

Keywords: Endometrial neoplasms; laparoscopy; hysterectomy

ÖZET Amaç: Konvansiyonel 3 portla yapılan total laparoskopik histerektomi (TLH) ile Laparoendoskopik transumbilikal tek giriş total histerektominin (LESS-TH) peri ve postoperatif sonuçlarının karşılaştırılması. **Gereç ve Yöntemler:** Tek merkezde Mart 2013 ve Mart 2014 tarihleri arasında benign uterin nedenler ve düşük risk faktörlü endometrial kanser vakalarında yapılan LESS-TH (n=24) ile TLH (n=47) olguları retrospektif olarak değerlendirilmiştir. LESS-TH, tek bir 2-3 cm'lik transumbilikal insizyona uygulanan multi-channel SILS TM port (Covidien®, Mansfield, MA, USA) ile yapılmıştır. Hastaların demografik özellikleri, peri ve postoperatif özellikleri her iki grupta değerlendirilmiş ve karşılaştırılmıştır. **Bulgular:** LESS-TH grubundan bir hastada konvansiyonel laparoskopiyeye, bir vakada ise laparotomiye dönülmüştür. Yaş, beden kitle indeksi (BKİ) gibi demografik özellikler ve endikasyonlar her iki grupta da benzerdir (p=0,497, 0,07, 0,594, sırasıyla). LESS-TH grubunda operasyon süresi TLH grubuna göre belirgin yüksekti (p=0.01). Uterusun eni, boyu, tahmini kan kaybı, postoperatif Hb seviyesinde düşme, postoperatif hastanede kalış süresi, analjezik tedavisi gibi diğer peri ve postoperatif özellikler her iki grup arasında benzerdi. Her iki grupta da major komplikasyonumuz olmadı. **Sonuç:** Operasyon süresi dışında LESS-TH'in cerrahi sonuçları, konvansiyonel multiport TLH'ye benzerdir.

Anahtar Kelimeler: Endometrial neoplaziler; laparoskopisi; histerektomi

A single-port approach has been used for hysterectomy and bilateral salpingo-oophorectomy by Pelosi and Pelosi since 1991, with the aim of reducing the invasiveness of conventional laparoscopy.¹ Ho-

wever, this approach initially did not gain popularity because of the technical limits of the laparoscopic transumbilical single-site (LESS) procedure. Recently, innovations in the technology such as multi-channel single-port, articulating instruments, and flexible endoscopes have allowed laparoscopic surgeons to perform increasingly complex gynecological and gynecologic-oncologic operations.²⁻⁷

A recent systematic review by Mencaglia et al. identified 65 studies (17 case reports, 32 case studies, 13 retrospective comparative studies and three randomized clinical trials) and reported that LESS is safe and feasible for most benign gynecologic surgeries.⁸ A randomized clinical trial that evaluated LESS compared to conventional laparoscopic-assisted vaginal hysterectomy reported significant decreases in post-operative pain and analgesic use in the LESS-assisted vaginal hysterectomy group.⁹ A comparative cross-sectional study on cosmetic outcomes after LESS and conventional laparoscopic gynecologic surgery reported that LESS offers better cosmetic and overall patient satisfaction.¹⁰ At the beginning, LESS is generally used with vaginal hysterectomy as an assisted procedure.⁹⁻¹² There are fewer studies in the literature on LESS-TH than on LESS-assisted vaginal hysterectomy.^{3,7,13}

In this study, we present our experience on total hysterectomy with LESS and make a retrospective comparative analysis of the surgical outcomes for LESS-TH and conventional TLH.

MATERIAL AND METHODS

We evaluated 24 patients who underwent LESS-TH and 47 matched patients who underwent conventional TLH for benign and malignant uterine pathology from March 2013 to March 2014. Patients were informed about the LESS-TH or conventional TLH and the conversion risk of multi-port laparoscopy or laparotomy. Informed consent was obtained from each patient. Patients were selected with following criteria: normal to moderately enlarged uterus (uterine size <12 weeks of gestation) with a diagnosis of benign endometrial and uterine pathology, low-risk premalignant and malignant endometrial pathology (endometri-

oid histology, FIGO grade 1 or 2, and no evidence of lymph node and/or adnexal and/or cervical involvement on high-resolution transvaginal ultrasonography or computerized tomography), no history of previous vertical incision, and a body mass index (BMI) \leq 35 and ASA score I-II. Patient demographic characteristics (age, BMI, parity, history of previous abdominal surgery and the presence of co-morbidities), operation time (min), estimated blood loss (EBL, ml), intra-operative complications (vascular injuries, bleeding [estimated blood loss >500 ml], urinary tract or bladder injury, gastro-intestinal injury), post-operative complications (bleeding, ileus, fever, infections of the port site or vaginal cuff, surgical re-evaluation, bladder dysfunction) post-operative hospitalization time (day), follow-up time (month), and analgesic type (classified as: 1- parenteral non-steroid anti-inflammatory drugs (NSAIDS), 2-parenteral opioids, 3- parenteral NSAIDS and opioids) were recorded. Operation time was defined as, the interval between incision start to skin closure. All patients received general anesthesia by the consultant anesthesiologist. In our clinic, we used the clindamycin and gentamycin antibiotherapy for the antibiotic prophylaxis of laparoscopic surgery for all patients. All patients with a diagnosis of endometrial biopsy as, complex atypical hyperplasia and endometrial cancer were evaluated with an intra-operative frozen section. The frozen section time was removed from the operation time. The patients with FIGO grade 1 or grade 2 endometrioid adenocarcinoma and less than 50% myometrial invasion only had extra-facial hysterectomy and bilateral salpingo-oophorectomy performed.

SURGICAL TECHNIQUES

All operations were performed by the same two surgeons (M.A.V, A.B.G). We have performed the laparoscopic hysterectomy at our gynecologic-oncology clinic since 2004. After general anesthesia and with the patient in the lithotomy position with both legs supported in stirrups, a 16 G Foley catheter was inserted into the bladder and an orogastric tube was inserted for all patients. The orogastric tubes were removed at the end of the

operation by an anesthesiologist, and the Foley catheter was removed on postoperative day one. A Clermont Ferrand (Karl-Storz™, Tuttlingen, Germany) uterine manipulator was placed in the cervical canal to manipulate the uterus at the beginning of the skin incision.

TLH: A 10 mm, vertical intra-umbilical incision was made after the appropriate CO₂ pneumoperitoneum by veres needle. A 10 mm trocar was inserted bluntly through the umbilicus. A rigid 0°, 10 mm laparoscope was introduced. Two ancillary 5 mm trocars were inserted at the McBurney and counter McBurney point through direct visualization with a Trendelenburg tilt. A careful inspection of the entire abdominal cavity was performed as the first surgical step to identify any suspicious peritoneal lesions. Peritoneal washing was not routinely performed. The round ligaments were ligated bilaterally by 5 mm Ligasure Advance™ (Covidien®, Mansfield, MA, USA) and after identification of the ureters, the infundibulopelvic ligaments were ligated. A bladder flap was developed by using scissors with mono-polar energy and ecarted the cervix. The bilateral uterine arteries were identified and ligated by ligasure. The bilateral sacrouterine and cardinal ligaments were ligated and circumferential colpotomy was performed using the monopolar L-hook. After the specimen was removed through the vagina, the vaginal cuff was closed through the vaginal route using 1.0 absorbable suture material (Vicryl™, Ethicon, USA) with continuous locking sutures. After the hemostasis, the trocars were removed with direct visualization. The skin was closed subcutaneously by no: 2.0 absorbable suture material (Biosyn™, Covidien, USA).

LESS-TH: A single 2-3 cm vertical transumbilical incision was performed by an open technique. The SILS™ port (Covidien®, Mansfield, MA, USA) was used for all cases in this group (Figure 1). After insertion of the port and insufflation of the abdomen with CO₂ gas, a blunt 5 mm trocar was inserted through the most cephalad channel and 0°, 10 mm laparoscope was introduced. Two additional 5 mm trocars were inserted for using the flexible laparoscopic devices through the other two



FIGURE 1: SILS port application.

other channels. The procedures of the hysterectomy were same the as the TLH. We used the two flexible devices at the same time for LESS-TH in the first five cases, but one flexible device and one rigid device were used for the other LESS-TH cases. The flexible device was a grasping forceps and the rigid devices were a ligasure and scissors in all of the cases. All of the procedures were performed using CO₂ pneumoperitoneum with a maximum of 15 mmHg intra-abdominal pressure. The vaginal cuff was repaired as described above. After completing the procedure, the SILS port was removed and the umbilical fascia was sutured by no: 1.0 absorbable suture material using the retractors. The skin was closed subcutaneously using no: 2.0 absorbable suture materials (Biosyn™, Covidien, USA).

Statistical analysis was performed with SPSS version 20. The Student's t test and the Mann-Whitney U test were used for the parametric and non-parametric variables, respectively. Comparison of the categorical variables between the groups was performed using the Chi-Square test. A P value of less than 0.05 was regarded as significant.

RESULTS

A total of 71 patients were included in this study. Two patients in the LESS-TH group were removed from this analysis because one of them was converted to multi-port laparoscopy with technical difficulty, and the other was converted to laparo-

tomy because of the necessity of the surgical-staging procedures and frozen section evaluation results. The results of the 69 patients were included in the analysis; 22 patients in the LESS-TH group and 47 patients in the conventional LTH group.

Age, BMI, parity, previous abdominal surgery, and the presence of co-morbidities such as hypertension or diabetes mellitus were not different between the groups ($p=0.497$, 0.07 , 0.579 , 0.431 , respectively). The indications for hysterectomy were not significantly different between the groups ($p=0.594$). The demographic characteristics and operation indications are presented in Table 1. The intra-operative and post-operative variables and the comparison of these two variables are presented in Table 2. The only significant difference was in the median operative time between the groups. The LESS-TH group had a significantly longer operation time than the TLH group ($p=0.01$). One of the patients received a blood transfusion (two erythrocyte suspensions) intra-operatively because the pre-operative Hb value was 7.4 g/dl. Two patients in both groups had pelvic adhesions, but this factor did not change the management of the operation.

TABLE 1: Patients demographics and indications of hysterectomy.

	LESS-TH (n=22)	TLH (n=47)	
	Mean±SD	Mean±SD	
	Median	Median	
	Min-max	Min-max	p
Age (year)	53.7±7.8	52.3±8.2	0.497
	52	51	
	43-78	40-78	
BMI	28.9±3.7	30.0±3.5	0.07
	29	30	
	20-35	21-35	
Nulliparity	2	1	0.09
Previous abdominal surgery	7	12	0.579
Co-morbidity	7	21	0.431
Indication			
Myoma uteri	4	12	0.594
Endometrial hyperplasia	8	20	
Prophylactic	3	2	
Endometrial carcinoma	7	13	

BMI: Body-mass index.

There were no intra-operative complications for the included patients, but two post-operative complications occurred: one was vaginal cuff cellulitis, and the other was post-operative febrile morbidity with urinary tract infection. Both of the patients were in the TLH group and were hospitalized and then discharged after healed. None of the patients underwent surgical re-exploration for complications.

DISCUSSION

LESS-TH was developed with the aim of reducing post-operative pain and providing better cosmetic results. However, this technique has not gained popularity among surgeons for the main reason that it is more difficult than conventional laparoscopy, particularly because of the limited movement of the surgical devices, and the required technological equipment such as a multi-channel single port and articulated instruments. Technological innovation resulted in the increased use of LESS-TH, not only for benign gynecologic surgery but also for endometrial cancer surgery and lymphadenectomy.^{2,4,6} Our results showed no significant differences in terms of estimated blood loss, post-operative Hb drop and post-operative hospitalization time between the LESS-TH group and the conventional multi-port TLH group, and this finding is consistent with previous study.³ However, the operation time was longer in the LESS-TH group. Longer operation times with the LESS-TH procedure were reported in some studies however, there were similar results in some others.^{13,14}

LESS-TH in gynecologic oncology was first reported in 2009 as a single-institution retrospective review by Fader and Escobar on 13 gynecologic oncology cases.⁶ Fanfani then reported the LESS-TH surgery results of twenty patients with low-risk endometrial cancer.² Not only extra-facial hysterectomy but also pelvic and para-aortic lymphadenectomy and also bulky lymphadenectomy were reported in the literature by single port robotic technique.⁴ The authors of these studies concluded that LESS-TH surgery for endometrial carcinoma is feasible when compared with conventional la-

TABLE 2: Peri- and post-operative outcomes of the patients and comparison of the groups.

	LESS-TH (n=22) Mean±SD Median Min-max	TLH (n=47) Mean±SD Median Min-max	p
BSO	22	44	0.226
Pelvic adhesion	2	2	0.587
Operation time (min)	79.3±35.6 70 30-180	58.4±18.7 60 24-100	0.01
EBL (ml)	94.0±103 50 20-400	54.2±37.8 50 10-200	0.075
Drop in Hb level (g/dl)	0.96±0.8 0.85 0-3	0.68±1.2 0.3 0-3	0.325
Post-operative Hospitalization time (day)	2.1±0.8 2 1-5	2.8±2 2 1-13	0.141
Uterus length (cm)	9.7±4 8.5 3.5-15	10.1±4.2 9 3-16	0.556
Uterus width (cm)	6.5±2.3 6 3-12	7.2±3.2 7 3-12	0.394
The management of analgesia			
1-NSAID	1	1	0.823
2-Opioids	1	3	
3-NSAID+Opioids	20	43	
Post-operative complications	0	2	1
Post-operative follow-up	16	36	0.708

BSO: Bilateral salpingo-oophorectomy, EBL: Estimated blood loss, NSAID: Non-steroidal antiinflammatory drugs.

paroscopy and robotic surgery. In these studies, the majority of the patients had low-risk factors. We performed the LESS-TH in seven patients with low-risk endometrial cancer. However, there is still a lack of data on any cost-benefit analysis and more importantly on long-term oncologic results.

In the literature, there are only two randomized controlled trials and some retrospective cohort studies related with the LESS-TH procedure. In one of these studies, LESS-TH was performed in en-

dometrial cancer cases.^{3,7,13,15-18} In another study, the same procedure was used for the treatment of benign and malignant uterine pathologies. Jung et al. reported that the mean operation time was 89 min. in the LESS-TH group, and was 80 min. in the four-port TLH group (p=0.175).¹⁶ They were no differences found between the groups for peri-operative and post-operative outcomes except the total analgesics request. Higher total requests for analgesics were observed in the LESS-TH group in this study. Li et al. reported that operative time was longer in LESS-TH group than multiport TLH group (130 min. versus 112 min.).¹⁵ The mean operative time was 93.5 min. in another study.³ A longer operative time (175 min) was reported by Fagotti et al. which included the patients with endometrial cancer.¹⁸ The time was 105 min. in the Fanfani et al. study, which included the patients with benign and malignant uterine pathology.¹⁷ These results are longer than our mean operative time (79.3 min). This difference was explained by the closure technique of the vaginal cuff. The vaginal cuff was sutured laparoscopically in all of these studies, however we repaired the vaginal cuff vaginally. The authors of the presented studies reported that the most difficult procedure was the vaginal vault suture with the laparoscopic suture techniques. The longer operative time was explained by the technical difficulties, especially the relatively restricted placement of the surgeon's hand within a fairly narrow field, the limited range of motion, the interference of instruments and of course, changes according to indication. We had a learning curve for LESS-TH; therefore, the longer operation times in LESS-TH group were expected. In the first five cases, we used two flexible laparoscopic devices at the same time for both of the 5 mm trocars. One of these instruments was a grasping forceps or a bipolar forceps and the other was scissors. However, because of the difficulty of using two flexible instruments at the same time, we have changed our operative technique after our fifth case. Moreover, we used one flexible and one rigid device simultaneously for the other LESS-TH cases thereafter. Thus, the time of surgery was shortened

and the operations have become easier for us. However, this technical detail is only an opinion arising from our experience and is open for discussion. In our experience, this technique may not be recommended yet. A recent meta-analysis on LESS-TH demonstrated that the only difference in operative outcomes of the LESS-TH was longer operative time than multiport TLH.¹⁹ In this study concluded that LESS-TH for benign hysterectomy is feasible, safe, and equally effective compared to the conventional technique but the clinical benefits have not been clearly demonstrated.

Our study has limitations, as do all retrospective studies. One serious limitation was the susceptibility to bias of the selection of patients for surgery types. However, we attempted to minimize any significant difference between the groups by matching the patients in the TLH group according to age, BMI, indication and the risk factors of the patients with endometrial cancer. Our study has a

relatively small number of cases in the LESS-TH group, but this report is our initial LESS-TH experience for hysterectomy.

Our preliminary results showed that LESS-TH is a feasible method for hysterectomy with comparable peri-operative surgical outcomes. LESS-TH requires more time and effort to acquire the necessary skills than conventional multi-port TLH but is feasible and acceptable. In conclusion, the oncologic outcomes of these laparoscopic techniques should be investigated by randomized controlled studies.

Conflict of Interest

Authors declared no conflict of interest or financial support.

Authorship Contributions

Concept-Design: Mehmet Ali Vardar, Ahmet Barış Güzel, Ümran Küçükgöz Güleç. **Data Collection:** Ümran Küçükgöz Güleç; **Analysis, Writing:** Ümran Küçükgöz Güleç, Mete Sucu, Ghanim Khatib, **Supervision, Consultancy:** Mehmet Ali Vardar, Ahmet Barış Güzel.

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