Single-Incision Hysterectomy Outcomes With and Without Robotic Assistance

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ABSTRACT

Objective: To evaluate the differences in operative time and postoperative complications for total laparoscopic hysterectomy (TLH) performed using conventional laparoendoscopic single-site surgery (LESS) versus a robotic-assisted LESS approach.

Methods: A retrospective study was conducted of all cases of conventional LESS TLH (n = 47) and robotic LESS TLH (n = 129) for benign gynecologic conditions performed from November 2014 to October 2017. Patient characteristics, operative time for hysterectomy, estimated blood loss, duration of hospitalization, and short-term postoperative complications were compared using appropriate parametric and nonparametric statistical tests.

Results: Conventional LESS TLH cases had a 16.36-minute longer mean operative time for hysterectomy ($P < .01$). No difference was found in uterine weight, estimated blood loss, hospitalization, or incidence of postoperative complications when LESS TLH was performed with or without robotic assistance. When comparing uterine weight < 100 g, conventional LESS TLH cases had significantly greater operative time than the robotic LESS TLH cases (78.10 ± 23.97 minutes vs. 59.97 ± 35.17 minutes, $P < .01$). When comparing uterine weight > 100 g, conventional LESS TLH cases again had significantly greater operative time than the robotic LESS TLH cases (98.73 ± 50.16 minutes vs. 80.00 ± 42.97 minutes, $P < .01$). There was no difference in postoperative complications.

Conclusion: Robotic single-incision laparoscopy can result in decreased operative time compared to a conventional LESS approach. Robotic-assisted and conventional LESS are similar in rate of postoperative complications, if performed by surgeons with abundant LESS experience.

Key Words: Operative time; Postoperative complications; Robotic-assisted surgery; Laparoendoscopic single-site surgery; Total laparoscopic hysterectomy.

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INTRODUCTION

Hysterectomy is the most common procedure in gynecology.[1,2] Benign indications include symptomatic leiomyoma, abnormal uterine bleeding, endometriosis, adenomyosis, and pelvic organ prolapse.[3] Hysterectomy can be performed abdominally, vaginally, or laparoscopically; laparoscopic approaches include total laparoscopic hysterectomy (TLH), laparoscopic-assisted vaginal hysterectomy, and robotic-assisted laparoscopic hysterectomy.[4] The American College of Obstetricians and Gynecologists advocates that a minimally invasive approach should be used whenever feasible, due to the well-documented advantages including smaller incisions, decreased blood loss, shorter hospitalization, faster recovery, and fewer surgical site infections.[5] TLH and laparoscopic-assisted vaginal hysterectomy comprise 60% of hysterectomies in both inpatient and day-surgery settings[6]; up to 82% of hysterectomies in an ambulatory setting may be performed laparoscopically.[2] The role of robotic-assisted hysterectomy is growing, accounting for 40%–45% of laparoscopic cases in 2012.[7]

Laparoendoscopic single-site surgery (LESS) is a novel approach that has been associated with reduced postoperative pain, improved cosmetic outcomes, avoidance of ancillary port complications, and faster recovery compared to multiport laparoscopy.[8–10] LESS is more technically challenging and requires coordination of multiple

instruments through one small incision.[11] To address this, a robotic single-site platform was developed to overcome ergonomic complexities.[12,13] Robotic LESS has been shown to be safe and feasible for laparoscopic hysterectomy.[14,15] Few studies exist comparing the outcomes of conventional and robotic-assisted LESS TLH.

The purpose of this study is to compare the operative time and postoperative complications of LESS TLH performed with or without a robotic platform assistance.

MATERIALS AND METHODS

Study Design

We conducted a retrospective cohort study with approval from the Baylor College of Medicine Institutional Review Board. All consecutive cases undergoing LESS TLH for benign gynecologic diseases (fibroids, abnormal uterine bleeding, pelvic pain, pelvic organ prolapse) between November 2014 and October 2017 at Baylor College of Medicine were included.

All cases were performed by a single, fellowship-trained surgeon (XG) with no residents or fellows involved in the cases; this surgeon began performing robotic-assisted LESS TLH in November 2014 and this cohort includes all cases performed up to October 2017. The LESS TLH approach (conventional or robotic assisted) was selected by the surgeon based on the anticipated uterine size and availability of the robotic console. Conventional LESS TLH was typically recommended for patients with a uterine size > 20 weeks' gestation during preoperative examination due to the limited range of motion of the robotic single-incision port and instrumentations as well as limited workspace.

We extracted the following data from inpatient and outpatient medical records: demographic characteristics (age, race, parity, body mass index, and body surface area), history of abdominal surgery, indication for surgery, type of LESS TLH (conventional versus robotic-assisted), estimated blood loss, operative time for hysterectomy, uterine weight, length of stay, and any short-term postoperative complications. Uterine weight was verified with the pathologist for any cases that appeared to be outliers. We included cases that had additional procedures performed, including salpingectomy, ovarian cystectomy, lysis of adhesions, resection of endometriosis lesions, sacrocolpopexy, etc., but we were interested only in the time specifically related to hysterectomy. As a result, total operative time was not assessed. Operative time for hysterectomy included two parts. The first part began at ligation

of the round and utero-ovarian ligaments and continued until complete uterus detachment from the vagina; the second part is duration of vaginal cuff closure. Each surgery was recorded on video and surgical time was meticulously recorded intra-operatively by the circulating nurse. Every patient was postoperatively followed for 1 year and all short-term postoperative complications noted in the electronic medical record were included.

The primary outcome was duration of hysterectomy. Secondary outcomes included estimated blood loss, length of stay, and frequency of postoperative complications. Statistical analysis was performed using SPSS software (IBM, SPSS Statistics for Macintosh, Version 24.0. Armonk, New York, USA). The normality assumption was assessed with the Kolmogorov-Smirnov test. Independent-samples t-test was used to evaluate continuous figures that was normally distributed, Mann-Whitney U test was used for discrete variables, and Pearson χ^2 was used for categorical data. Linear regression was used to calculate the correlation between operation time for hysterectomy and uterine weight. A two-tailed P-value with alpha set at 0.05 was considered statistically significant.

Surgical Techniques

Surgical instruments used in conventional LESS TLH were GelPOINT Mini advanced access platform (Applied Medical, Rancho Santa Margarita, California, USA), bipolar forceps, monopolar hook, Enseal® (Ethicon Inc., Somerville, New Jersey, USA), Harmonic® (Ethicon Inc., Somerville, New Jersey, USA), laparoscopic needle holder, and a suction-irrigation system. Instruments in robotic-assisted LESS TLH were the single-site port for Da Vinci® surgical system (Intuitive Surgical, Sunnyvale, California, USA), bipolar forceps, monopolar hook, needle driver, and a suction-irrigation system.

All patients received heparin 1 hour before the start of surgery. After general endotracheal anesthesia was induced, patients were placed in dorsal lithotomy position using Yellofins® stirrups (Allen Medical, Acton, Massachusetts, USA). A RUMI® II uterine manipulator was inserted (CooperSurgical, Trumbull, Connecticut, USA). A 15–20-mm skin incision was made vertically in the middle of the umbilicus. A multichannel port was inserted into the incision and the abdominal cavity was visually inspected. Lysis of any adhesions was performed with straight-stick laparoscopic instruments before docking the robotic system. For robotic-assisted LESS, two curved robotic cannulas were inserted into the multichannel port, accommodating robotic flexible laparoscopic instrument. Both

conventional and robotic-assisted LESS TLH were performed with identical steps, in the following manner.

To begin the hysterectomy, the left utero-ovarian ligament, fallopian tube, and round ligament were coagulated and transected. The left broad ligament was dissected anteriorly and inferiorly toward the bladder. The bladder was carefully dissected off the uterus. The anterior colpotomy was created by incising circumferentially along the uterine manipulator, while avoiding the uterine vessels laterally. The left uterine artery was skeletonized, coagulated, and transected. The left uterine artery pedicle was mobilized laterally and the colpotomy continued posteriorly. This process was repeated on the right side. The colpotomy was completed posteriorly, and this time point was recorded as the first part of hysterectomy end. The uterus was removed through the vagina or, if the uterus was too large to be easily removed vaginally, an umbilical tissue extraction was performed using cold-knife morcellation inside of the Alexis Contained Extraction System (Applied Medical, Rancho Santa Margarita, California, USA).[16,17] The

vaginal cuff was closed using a 2-0 V-Loc™ wound closure device in a continuous running fashion. Surgical time was meticulously noted in the intra-operative data record; surgical video was available for review if needed.

Postoperatively, patients were discharged from the hospital with an abdominal binder as well as acetaminophen-codeine 300 mg–30 mg and ibuprofen 600–800 mg for pain. The first postoperative clinic visit was scheduled for 3 weeks later and the surgeon was accessible to patients at any time for problems associated with surgery.

RESULTS

A total of 176 LESS TLH cases were included in our study: 129 cases with robotic assistance and 47 cases without robotic assistance. No differences existed in demographic characteristics, history of abdominal surgery, prior parity, and indication of hysterectomy between these 2 groups (**Table 1**).

Table 1.
Baseline Characteristics

	Conventional LESS (n = 47)	Robotic-Assisted LESS (n = 129)	P-Value
Age (years)	44.8 ± 7.8 (24–66)	44.9 ± 10.0 (25–73)	.98
Race/ethnicity			.07
Caucasian	24, 51%	59, 46%	
African	18, 38%	33, 26%	
Hispanic	3, 6%	15, 12%	
Asian	2, 4%	22, 17%	
BMI (kg/m^2)	30.1 ± 8.1 (18.2–59.3)	29.0 ± 7.6 (16.8–59.9)	.45
Body surface area (m^2)	1.9 ± 0.2 (1.5–2.5)	1.9 ± 0.3 (1.3–2.9)	.62
Previous abdominal surgery	1 (0–5)	1 (0–5)	.31
Gravidity	2 (0–5)	2 (0–8)	.86
Parity	2 (0–5)	2 (0–7)	>.99
Benign indication			.11
Fibroids	30, 64%	51, 40%	
Pelvic pain	10, 21%	41, 32%	
Abnormal uterine bleeding	4, 9%	18, 14%	
Postmenopausal bleeding*	2, 4%	10, 8%	
Pelvic organ prolapse	1, 2%	5, 4%	
Abnormal cervix*	0, 0%	4, 3%	

BMI, body mass index; LESS, laparoendoscopic single-site surgery.

Data presented as mean ± SD (range); median (range); or N, %.

*Pathology showed no malignant cell.

Conventional LESS TLH cases had a 16.36-minute-longer mean operative time for hysterectomy compared to robotic-assisted LESS TLH (91.42 vs 75.06 minutes, $P < .01$, **Table 2**). There were no differences in uterine weight, or estimated blood loss for conventional LESS compared to robotic-assisted LESS. Robotic-assisted LESS cases more often had a concurrent procedure performed. Total length of stay did not differ between approaches.

With three times as many cases using the robotic-assisted approach, statistical analysis could also be skewed. So the cases were randomly assigned in a 3:1 case-control manner per each category (< 100 g and > 100 g) (**Table 2**). When comparing uterine weight < 100 g, conventional LESS TLH cases had significantly greater operative time than the robotic LESS TLH cases (78.10 ± 23.97 minutes vs. 59.97 ± 35.17 minutes, $P < .01$). When comparing uterine weight > 100 g, conventional LESS TLH cases

again had significantly greater operative time than the robotic LESS TLH cases (98.73 ± 50.16 minutes vs. 80.00 ± 42.97 minutes, $P < .01$) (**Table 2**).

All patients attended their 1-year postoperative follow-up appointment. There was one adverse postoperative outcome in the conventional LESS group and three in the robotic-assisted LESS group, which was not statistically different ($P = .94$, **Table 2**). A pelvic abscess presented 6 weeks after surgery with right-sided pelvic pain, night sweats, and fevers. After the abscess was identified and removed surgically, the patient recovered well. An umbilical hernia presented 5 months after surgery with peri-umbilical discomfort; ultrasound confirmed a hernia, which was repaired by general surgery. The mild wound separation presented 10 days after surgery with discharge from her umbilicus; a small separation at the inferior wound border and granulation

Table 2.
Operative Times and Postoperative Complications

	Conventional LESS (n = 47)	Robotic-Assisted LESS (n = 129)	P-Value
Uterine weight (g)*	327 ± 413 (34–1,674)	182 ± 158 (18–1,248)	.18
0–100g	15, 37%	40, 31%	.909
>100g	32, 63%	89, 69%	
Hysterectomy time (minutes)†	91.42 ± 43.88 (29–187)	75.06 ± 42.08 (20–195)	.00
0–100g	78.10 ± 23.97 (36–114)	59.97 ± 35.17 (21–148)	.00
>100g	98.73 ± 50.16 (29–187)	80.00 ± 42.97 (20–195)	.00
Concurrent procedure			
BUSS	18, 38%	64, 50%	.18
Lysis of adhesion	6, 12%	35, 27%	.46
Ovarian cystectomy	2, 4%	41, 32%	<.01
Resection of endometriosis	1, 2%	21, 16%	.01
Sacrocolpopexy	0, 0%	6, 5%	—
Urethral surgery	0, 0%	1, 1%	—
Length of stay (days)	1.2 ± 0.9 (1–7)	1.1 ± 0.3 (1–3)	.77
Post-operative complications	1, 2%	3, 2%	.94
Pelvic abscess	1	0	
Umbilical hernia	0	1	
Wound separation	0	1	
Skin allergy to wound closure strip	0	1	

BUSS, bilateral uterosacral ligation suspension; LESS, laparoendoscopic single-site surgery.

Data presented as mean ± SD (range); or N, %.

*Weight determined by pathology evaluation of specimen.

†Operative duration of hysterectomy was not available for 9 cases for conventional LESS (n = 38).

tissue along the length of the incision were identified—granulation tissue was excised and the wound was repaired with suture. Lastly, the wound skin allergy presented with 10 days after surgery with pruritus, an overlying blister, and a maculopapular rash extending from the umbilicus to the bilateral flanks, groin, and nipples. The patient was treated with neomycin-poly-myxin-bacitracin and hydrocortisone ointment.

DISCUSSION

Our study demonstrates that conventional single-incision laparoscopy required more time for hysterectomy than a robotic-assisted approach in cases with uteri < 100 g or uteri > 100 g. However, there were no differences in blood loss, length of stay, and postoperative complications between the two approaches.

One previous study has compared outcomes between robotic-assisted and conventional LESS TLH approaches[15]; 25 robotic-assisted cases were propensity-score matched to 100 conventional LESS cases to account for age, body mass index, previous abdominal surgery, pelvic adhesions, and uterine size. Duration of hysterectomy was longer in the robotic-assisted LESS group (81.8 vs. 56.3 minutes, *P* = .02). In comparison, our study has a much larger sample of robotic-assisted LESS cases and overall, the mean duration of hysterectomy was shorter for robotic-assisted LESS TLH approach. The sample size of robotic approaches may due to the preference of our surgeon. At the beginning of the surgeon's learning curve, the operative time was potentially longer than the surgeries were performed later on. His techniques have been gradually perfected using the robotic-assisted approach and this may account for the faster operative time.

Success with single-incision TLH depends on the surgeon's experience and the patient's anatomy, including uterine size. As the curved trocars in the robotic platform reduce the effective surgical space in the abdomen and pelvis, it can become more difficult to access all anatomy surrounding large uteri and the operative time subsequently increases. However, similar to our findings, previous studies suggest that the robotic-assisted approach can overcome technical challenges associated with LESS—providing benefits such as improved visualization and dexterity, improved ergonomics, reduced instrument crowding, reduced single-site confusion (due to software reassociating user's hands with instrument tips after crossing at the fascia level), and easier intra-corporeal vaginal cuff closure.[8,14]

Studies evaluating oncology patients have suggested that robotic surgery can be cost beneficial for both payers and society in the long run when optimal physiologic and quality-of-life outcomes occur.[18] For benign TLH, robotic-assisted multiport TLH was associated with an increased cost of $2189 (95% CI, $2030 to $2349) compared to conventional multiport TLH.[19] No studies to date compare costs for LESS in benign TLH. While our study does not compare costs, we demonstrate that expertise can result in noninferiority of operative time for the hysterectomy portion of TLH performed with LESS. This is a necessary first step for robotic-assisted LESS to potentially become cost effective or cost advantageous for performing TLH for benign indications.

Our study has a few strengths and limitations. The major strength of our study is the larger sample size compared to previous studies, especially the participants undergoing robotic-assisted LESS (n = 129)—far more than in previous studies.[14,15] The first limitation includes the retrospective manner. All the cases were performed by the same surgeon who has completed over 400 cases of LESS; thus, our findings may not be reproducible in another surgeon with less training and experience in LESS. Additionally, patients were not randomized to the approach, as the surgeon prefers a robotic approach for its technical advantages which limits the interpretation of our findings regarding outcomes. Our study did not assess total operative time due to the variable inclusion of additional surgical procedures (lysis of adhesion, resection of endometriosis, urethral surgery etc.), and we did not assess outcomes such as total time in the operating room (to account for time required for robot docking). Lastly, events such as incisional hernia or vaginal cuff dehiscence are rare after laparoscopic surgery (0.5&−0.94%[20−23] and up to 7.5%,[24,25] respectively). While our outcomes were consistent with the literature (one incisional hernia [0.57%] and no cuff dehiscence), our study has insufficient power to detect differences in complications between the two LESS approaches. As more cases of LESS are performed, future studies should assess these complications.

In conclusion, selecting an approach for LESS TLH may depend on facility resources and physician expertise. Among physicians with experience performing LESS for benign TLH, the robotic-assisted approach may be more efficient compared with the conventional approach for the hysterectomy and vaginal cuff closure portions of the case, and does not appear to result in any increase in complications. Next step, we are planning to design a randomized, multiple-centers research to compare robotic-assisted LESS and conventional LESS. Continued spread of the LESS approach (conventional or robotic-assisted) for benign TLH in those gynecologists

with minimally invasive surgery training can provide reduced pain, improved cosmetic outcomes, and faster recovery for patients.

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