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Original article

Laparoendoscopic single-site hysterectomy with Ligasure is better than conventional laparoscopic assisted vaginal hysterectomy

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ABSTRACT

Objective: To determine an ideal route and device in hysterectomy by comparing laparoendoscopic single-site (LESS) hysterectomy with conventional laparoscopic-assisted vaginal hysterectomy (LAVH).
Methods: This is a computed clinical pathway based case–control study performed in the Buddhist Tzu Chi General Hospital, Hualien, Taiwan. Seventy-two patients (36 LESS hysterectomies and 36 LAVH) from May 2011 to August 2013 were included. The choice of route of hysterectomy and Ligasure use during the operation were made by the patient or by economic considerations. Perioperative outcomes, including postoperative visual analog scale for pain and analgesic pain-relief score were compared.
Results: Surgical time and length of hospital stay were shorter in LESS hysterectomy than in LAVH (126 ± 47.7 minutes vs. 158 ± 60.7 minutes and 4.7 ± 0.8 days vs. 5.4 ± 0.8 days, respectively). The visual analog scale pain scores at 0–2 hours and 24 hours postoperation were significantly lower in LESS hysterectomy than in LAVH (5.68 ± 2.11 vs. 8.14 ± 1.46 and 3.75 ± 1.61 vs. 5.04 ± 1.28, respectively). Overall, the pain score decreased by 30%, 26%, and 12% at 0–2 hours, 24 hours, and 48 hours, respectively, after the operation. The total pain-relief score was 38.2% lower in LESS hysterectomy than in LAVH (1.15 ± 0.44 vs. 1.86 ± 0.33; $p < 0.001$). There were comparable adverse events in both groups.
Conclusion: This study demonstrated that LESS hysterectomy with Ligasure is superior to conventional LAVH.

Introduction

Maturation in laparoscopic surgical techniques and improvement in laparoendoscopic single-site surgery (LESS) tools in the past decade have brought minimal invasive surgery towards a new era. In the past 5 years, gynecological LESS has developed quickly and continues to grow.[1–4] Surgeons perform procedures similar to those in traditional laparoscopic techniques, with the benefit of a single incision at the umbilicus, but, unlike a traditional multiport laparoscopic approach, LESS leaves only a single small scar.[2] This provides significant improvements in cosmetic value without any apparent difference in efficacy.[5–7] The positive acceptance of minimal invasive surgery among patients in Taiwan is reflected by the profound change in types of hysterectomy in the past 10 years, with increasing laparoscopic-assisted vaginal hysterectomy (LAVH) and decreasing total abdominal hysterectomy.[8,9]

Nonetheless, few articles discuss the optimal combination of route and tool use in hysterectomy. No research has declared that flexible laparoscopic equipment is better than conventional equipment in hysterectomy. Thus, the objective of this study is to compare the perioperative outcomes of LESS hysterectomy, with or without Ligasure, to LAVH and to determine the ideal combination of route and device in hysterectomy.

Materials and methods

A case–control study was conducted in the Buddhist Tzu Chi General Hospital, Hualien, Taiwan between May 2011 and August 2013. There were 81 laparoscopic hysterectomies performed during this period of study (Fig. 1). The exclusion criteria were: (1) age < 21

Conflicts of interest: All contributing authors declare no conflicts of interest.

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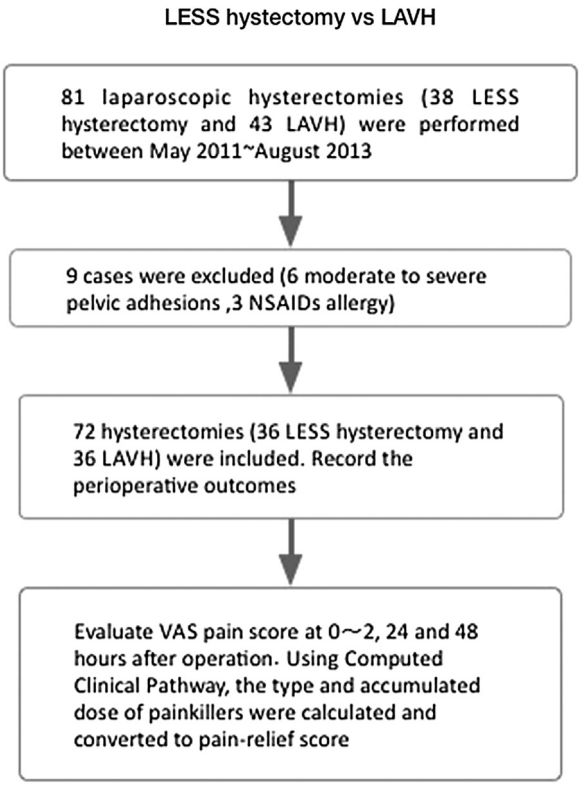

Fig. 1. Flow chart of study. LESS = laparoendoscopic single-site surgery.

years or > 65 years; (2) moderate-to-severe pelvic adhesions; (3) previous history of radiation or pelvic inflammatory disease; (4) gynecologic malignancy; and (5) allergy to nonsteroidal anti-inflammatory drugs. The hospital's Research Ethics Committee approved the study (IRB100-137).

In conventional LAVH, one 10 mm trocar was inserted supra- or infraumbilicus, and two additional 5 mm ports were inserted through the lower lateral abdominal wall. The LESS hysterectomies were performed by a microsurgery team (D.C.D. and M.K.H.) in procedures as previously described.[2] Briefly, a 2.0–2.5 cm vertical incision wound through the umbilicus was made and a wound retractor (Alexis; Applied Medical, Rancho Santa Margarita, CA, USA) was inserted. A home-made adaptor composed of a surgical glove and trocars was connected to the wound retractor. The multiple fingers of the glove functioned as multiports for the laparoscopic instruments and camera. To optimize the range of motion and operation field, a rigid 5 mm laparoscope of 30° was used.

Otherwise, all hysterectomies were performed with the conventional laparoscopic straight tools or equipment, which included the: (1) bipolar (Karl Storz, Tuttlingen, Germany) or Ligasure (Valleylab Inc., Boulder, CO, USA); (2) grasper (Mansfield, MA, USA; Autonomy, Cambridge Endoscopic Devices, Framingham, MA, USA); and (3) scissors (Lagis, Taichung, Taiwan). Ligasure usage required extra cost, it was decided based on the patient's economic status or the patient's choice prior to the operation. After all of the procedures were completed, Vicryl 3-0 was used for subcutaneous closure of the skin wound in LAVH and coated Vicryl 0, 26 mm 5/8c (Ethicon, Somerville, NJ, USA) was used for closure of the fascia and subcutaneous skin in LESS hysterectomy.

Surgical time was defined as the time from skin incision to wound closure. Blood loss was calculated by subtracting the blood volume in the suction bottle from the irrigation fluid. The visual analog scale (VAS) for pain was used to rate the postoperative pain intensity at three different time points: 0–2 hours, 24 hours, and 48 hours postoperatively. To optimize the accuracy of pain estimation and minimize the mask effect of pain of analgesics used intra-operatively or painkillers used postsurgery, some adjustments were made in measuring the VAS pain score. Instead of evaluating the pain score right after the operation, when the patient was still relatively unclear, the first postoperative VAS pain score was defined as the highest score within 2 hours postoperatively, when operative analgesics were about to be eliminated. Second, if the patient used analgesics when the 24- and 48-hour pain scores were to be evaluated, then the VAS score at least 2 hours apart was recorded.

In the study hospital, the computed LAVH clinical pathway had been used for several years. In the clinical pathway, two kinds of intravenous analgesic were available: ketorolac 30 mg (Yung Shin Pharm. Ind. Co., Ltd, Taichung, Taiwan) and morphine 10 mg (Restricted Drug Factory of Food and Drug Administration, Ministry of Health and Welfare, Taipei, Taiwan). Two kinds of oral analgesic were also available: acetaminophen 500 mg (YungShin Pharm. Ind. Co., Ltd, Taichung, Taiwan) and naproxen 250 mg (China Chemical & Pharmaceutical Co., Ltd, Hsinchu, Taiwan). These were given based on the patient's need, although acetaminophen was usually given to a patient initially and then changed to naproxen if needed.

To compare postoperative pain objectively, the type and accumulated dose of analgesics used by each patient was calculated and converted to a pain-relief score according to number needed to treat (NNT) of the Oxford League Table of Analgesic Efficacy. The NNT is a system developed to compare the effectiveness of different analgesic drugs by providing an indication of how many analgesic had to be given to before one patients perceives 50% pain relief lasting for 4 hours. For the clinical sense and easier understanding by the general reader, the NNT of an analgesic was converted to the term "pain-relief score" and defined as [1/NNT]. Therefore, the pain-relief score of each ketorolac 30 mg/amp, morphine 10 mg/amp, acetaminophen 500 mg/tablet, and naproxen 10 mg/tablet were 0.294, 0.345, 0.286, and 0.323 respectively. As such, the total pain-relief score of a patient had during the 48 hours postoperation was equal to the sum of [number of NNT] × [1/NNT] of every single painkiller used. For example, during the period of 48 hours post-operation, Patient A used acetaminophen 2000 mg and 20 mg morphine but Patient B used acetaminophen 2000 mg and morphine 10 mg, so the pain-relief score of A = (2000/500) × 0.286 + (20/10) × 0.344 = 1.832; and B = (2000/500) × 0.286 + (10/10) × 0.344 = 1.488.

The Sample Size Calculator (G Power 3.1) was used to determine the appropriate sample size. Setting power to 0.8, type I error (α) to 0.05, and allocation ratio of each group to 1:1, a total of 72 cases were needed. Data are expressed as frequencies, proportions, or means ± standard deviations, depending on the characteristics of each item. Student t test was used to compare the means of continuous variables between different groups. Statistical significance was set at $p < 0.05$. All of the statistical analyses were performed using the SPSS software (version 17.0; SPSS Inc., Chicago, IL, USA).

Results

Of the 81 cases initially included, 9 were excluded due to moderate-to-severe pelvic adhesions or nonsteroidal anti-inflammatory drugs allergy (Fig. 1). Seventy-two patients were finally included (36 LAVH and 36 LESS hysterectomy), of whom 44% (33/75) were postmenopausal (Table 1). The mean body mass index was 26.6 ± 5.1 kg/m^2 (range, 20.5–38.8 kg/m^2). There was no significant difference in the patients' characteristics or additional

Table 1
Characteristics and perioperative outcomes of the study patients ($n = 72$).

Parameters	LESS hysterectomy ($n = 36$)	LAVH ($n = 36$)	p	Mean ± SD
Patient characteristics				
Age (y)	45.0 ± 4.47	45.0 ± 11.0	0.256	45.0 ± 8.0
BMI (kg/m^2)	25.4 ± 5.0	26.9 ± 8.0	0.421	26.6 ± 5.1
Mild pelvic adhesion	10 (27.7)	8 (20.5)	0.586	18 (25)
Operations				
Total hysterectomy alone	13 (36.1)	19 (48.7)		32 (42.7)
Total hysterectomy + BS	13 (36.1)	12 (30.7)		25 (33.3)
Total hysterectomy + BS + AD	10 (27.7)	8 (20.5)		18 (24)
Perioperative outcome				
Uterine length (cm)	10.2 ± 2.6	8.9 ± 4.7	0.259	10.6 ± 2.2
Uterine width (cm)	7.6 ± 2.2	6.5 ± 3.5	0.184	7.8 ± 1.8
Surgical time (min)	126 ± 47.7	158 ± 60.7	0.046*	139 ± 54
Blood loss (mL)	392 ± 355	316 ± 174	0.368	359 ± 288
Hospitalization (d)	4.7 ± 0.8	5.4 ± 0.8	0.004*	5.0 ± 0.8

Data are presented as mean ± standard deviation or n (%).
*$p < 0.05$ was considered statistically significant after the test.
AD = adhesiolysis; BMI = body mass index; BS = bilateral salpingectomy; LAVH = laparoscopic-assisted vaginal hysterectomy; LESS = laparoendoscopic single-site; SD = standard deviation.

operations between the two groups, including age, body mass index, uterine size, bilateral salpingectomy, and the number of mild pelvic adhesion. Ten patients (27.7%) in the LESS hysterectomy group and eight (20.5%) patients in the LAVH group had mild pelvic adhesion and received adhesiolysis during surgery.

The surgical time and length of hospitalization in the LESS hysterectomy group were significantly shorter compared to the LAVH group (126 ± 47.7 vs. 158 ± 60.7 min and 4.7 ± 0.8 vs. 5.4 ± 0.8 days, respectively). A total of 86.1% (31/36) patients in the LESS hysterectomy group and 48.7% (19/39) in the LAVH group used Ligasure. The estimated blood loss and uterine size were comparable in the two groups.

The VAS pain score was significantly lower in the LESS hysterectomy group than in the LAVH group at 0–2 hours and 24 hours postoperatively (5.68 ± 2.11 vs. 8.14 ± 1.46 and 3.75 ± 1.61 vs. 5.04 ± 1.28, respectively; Table 2; Fig. 2A). The difference in VAS pain score between the two groups was greatest at 0~2 hours postoperatively and gradually decreased at 24 hours and 48 hours (Table 2, Fig. 2B). Overall, the VAS pain score of the LESS hysterectomy group at 0–2 hours, 24 hours, and 48 hours after surgery decreased by 30%, 26%, and 11.9%, respectively, compared to the LAVH group. The total pain-relief score was 38.2% less in the LESS hysterectomy group (1.15 ± 0.44) than in the LAVH group (1.86 ± 0.33; $p < 0.001$).

Adverse events

The adverse events in the two groups were comparable. There was a total of 13 intra- or postoperative adverse events (Table 3), including two bladder injuries, three blood loss >1000 mL, two poor wound healing, and six postoperative shoulder pain. In general, there was no significant difference in complication rate between the two groups (6 of 36, 1.66% vs. 7 of 36, 1.94%). Three cases of massive blood loss were noted in this study (2 in the LESS hysterectomy group and 1 in the LAVH group). One was a case of enlarged uterus (about 18 cm × 14 cm) with a large leiomyoma (about 10 cm in diameter, weight 750 g) over the posterior uterine wall. The other two were also cases of enlarged uterus with adenomyosis and severe chronic anemia—one had intestinal adhesion and the other had a history of multiple previous cesarean deliveries.

The LAVH group had more cases of postoperative shoulder pain compared to LESS hysterectomy group (4 cases vs. 2 cases, respectively), which might be due to the longer surgical time. There was one case of bladder injury and one case of poor healing trocar wound with some aseptic discharges in both groups. The bladder injury was sutured with chromic 0 and maintained normal bladder function on follow-up, whereas the trocar wounds were managed by wet dressing. These wounds healed about 10 days after surgery.

Table 2
Comparison of postoperative pain.

	Time	LESS hysterectomy	LAVH	p
VAS pain score	0–2 h	5.68 ± 2.11	8.14 ± 1.46	<0.001*
	24 h	3.75 ± 1.61	5.04 ± 1.28	<0.001*
	48 h	2.25 ± 1.59	2.51 ± 1.37	0.452
Pain-relief score		1.15 ± 0.44	1.86 ± 0.33	<0.001*

* Pain score and pain-relief score difference between groups is significant ($p = 0.01$) with t test.
LAVH = laparoscopic-assisted vaginal hysterectomy; LESS = laparoendoscopic single-site.

Discussion

This study demonstrates that LESS hysterectomy with Ligasure is superior to LAVH in terms of shorter surgical time and hospitalization, less postoperative pain, and less use of analgesics. Unlike a traditional multiport laparoscopic approach, LESS leaves only a single small scar that becomes "scarless" when healed, which is also cosmetically more appealing. Based on these advantages, LESS hysterectomy with Ligasure is one of the ideal combinations of route and device in hysterectomy and it may become the most popular route and tool in hysterectomy in the near future.[10]

There is anatomic and histologic fundamental evidence supporting the findings of less postoperative pain and faster recovery in LESS.[11–13] The umbilicus is avascular and is also the thinnest area of the abdominal wall. Thus, it is the best place to introduce the trocar of laparoscopy. Moreover, the nerve innervation at the abdomen wall and umbilicus originate from the lumbar spinal cord and extend via the abdominal wall bilaterally to the abdominal midline. As such, the midline of the abdomen or umbilicus is the area where it is most insensitive to pain. Nonetheless, a vertical umbilical incision is recommended rather than a transverse one in order to achieve the goals of minimal invasiveness and less postsurgical pain. In LAVH, two more trocars have to be introduced over the bilateral site of the lower abdomen where injury to the muscle and fascia is inevitable. All of this can explain why LESS hysterectomy gives significantly less pain than LAVH at different time points postoperatively.[1,14]

In this study, the difference in postoperative pain is the greatest within 2 hours after the operation, and then decreases gradually thereafter. This finding is totally different from a previous study in which the difference in pain is smallest 12 hours postoperatively and then gradually increases at 24 hours and 48 hours postoperatively.[1,14] This unexpected finding may due to the difference in study design. In this study, the masking effect of operative analgesics on VAS pain score has been considered. The first postoperative VAS pain was evaluated by asking about the maximum pain within 2 hours postoperatively, when operative analgesics were about to be totally eliminated and the consciousness of patient was relatively clearer.

The female uterus is at the midline of the pelvis and the procedures involved in laparoscopic hysterectomy do not need wide angulations. As such, the approach via LESS is easier. The use of Ligasure further fastens the laparoscopic part in hysterectomy either via LESS or conventional LAVH.[15] The surprising advantage of shorter surgical time in LESS hysterectomy is actually due to the use

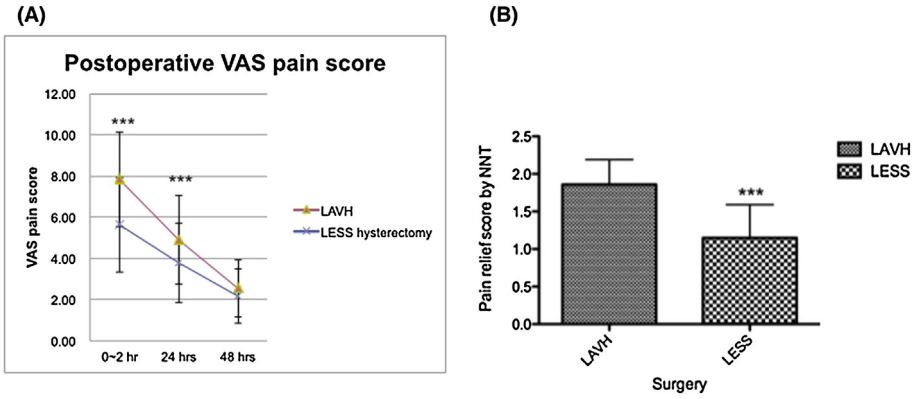

Fig. 2. Postoperative pain score. (A) Visual analog scale (VAS); (B) Pain-relief score. LESS = laparoendoscopic single-site surgery. ***$p < 0.001$.

of Ligasure intraoperatively (86.1% in LESS hysterectomy and 48.7% in LAVH). However, this advantage disappears in LESS adnexal surgeries, including salpingo-oophorectomy and cystectomy, compared to laparoscopic adnexal surgeries (data not shown). There was no difference between groups in terms of pain relief score and postoperative VAS pain score.

This study had some strengths. First, the computed clinical pathway provides a fair fundamental condition for the comparison of analgesic use after surgery. All patients have been given analgesics as needed. Second, postoperative pain is evaluated in a subjective and objective manner. Considering the pain-masking effect and altered cognitive function by analgesic use during surgery, the VAS pain score was evaluated within 2 hours postoperatively by asking the patient with a maximum pain score within these 2 hours. The type and accumulated dose of analgesics use in every patient were recorded and converted to the pain-relief score. Moreover, the data on the pain-relief score were highly confidential and could objectively reflect the pain condition of patients after operation.

Nonetheless, this study also has some limitations. For one, it is not a randomized trial. The surgeries were not conducted by the same surgeon and concomitant surgery might have an effect on the evaluation of pain. Concomitant surgeries may increase the postoperative pain, but this bias is considered minimal because the distributions of concomitant surgeries are balanced in the two groups.

This study demonstrates that LESS hysterectomy with Ligasure provides advantages for patients who are indicated for hysterectomy.[16] When patients can return to work a shorter time after operation, this can improve productivity and help in social economics. This is especially valuable in many countries that lack health personnel. The lower analgesic use and shorter hospitalization will also save medical resources. In addition, under the diagnosis-related global budget medical payment system in Taiwan, less hospitalization will result in more profit for the hospital. From the patient's viewpoint, reduced pain and faster recovery from surgery will definitely improve their satisfaction.

Table 3
Perioperative adverse events.

Adverse event	LESS hysterectomy	LAVH
Bladder injury	1	1
Blood loss >1000 mL	2	1
Wound poor healing	1	1
Postoperative shoulder pain	2	4
Total	6	7

LAVH = laparoscopic-assisted vaginal hysterectomy; LESS = laparoendoscopic single-site.

Based on these analyses, it is reasonable to predict that another trend of hysterectomy is starting and that LESS hysterectomy with or without Ligasure will most probably become a popular surgery in the next 10 years, especially in Taiwan.

Conclusion

In conclusion, LESS hysterectomy with Ligasure is superior to conventional LAVH in terms of shorter surgical time and hospitalization, less postoperative pain, less analgesic use, and a “scarless” wound. It is an ideal combination of route and device in hysterectomy.

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