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# A comparison of postoperative pain after transumbilical single-port access and conventional three-port total laparoscopic hysterectomy: a randomized controlled trial

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**Key words**
Postoperative pain, hysterectomy, single-port, multi-port, total laparoscopic hysterectomy, visual analogue scale

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**Conflict of interest**
The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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## Abstract

*Introduction.* The objective of this study was to compare postoperative pain between single-port access total laparoscopic hysterectomy (SPA-TLH) using a transumbilical single-port system and conventional multi (three)-port access total laparoscopic hysterectomy (MPA-TLH). *Material and methods.* A randomized controlled trial was conducted on 60 women who underwent SPA-TLH and MPA-TLH for benign gynecologic diseases between March 2014 and January 2015. Patients were randomly assigned to undergo SPA-TLH ($n = 30$) or MPA-TLH ($n = 30$). The variables measured included surgical outcomes and postoperative pain at 30 min and 1, 12, 24, and 48 h after surgery, assessed by the visual analog scale, bolus requirement of intravenous patient-controlled analgesia, and additional analgesic use. *Results.* The two study groups did not differ in terms of patient demographics or surgical outcomes except for operative time. The SPA-TLH group had a longer operative time ($p < 0.0001$) compared with the MPA-TLH groups. There were no differences in pain scores between the two groups. The SPA-TLH group had significantly more intravenous analgesia requests during the 12–24 h after surgery ($2.17 \pm 3.05$ vs. $0.79 \pm 1.99$; $p = 0.047$), more 24–48 h postoperative analgesics ($0.21 \pm 0.41$ vs. $0.03 \pm 0.19$; $p = 0.045$), and more total additional analgesics ($0.97 \pm 0.94$ vs. $0.45 \pm 0.87$; $p = 0.034$). *Conclusion.* SPA-TLH was feasible compared with MPA-TLH but the SPA-TLH group had a longer operative time. Although there is no difference in pain based on visual analog scale pain score, the SPA-TLH group required more analgesia to give the same postoperative pain control.

**Abbreviations:** IV-PCA, patient-controlled fentanyl-based intravenous analgesia pump; MPA-TLH, multiple-port access total laparoscopic hysterectomy; SPA-TLH, single-port access total laparoscopic hysterectomy; VAS, visual analog scale.

## Introduction

Since laparoscopic hysterectomy was first described by Reich et al., it has become one of the most commonly performed gynecologic surgeries (1). The major advantages of laparoscopy over laparotomy are less pain,

### Key Message

We compared postoperative pain between single-port and multi-port total laparoscopic hysterectomy; single-port surgery led to greater postoperative analgesic consumption.

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reduced recovery time, shortened length of hospital stay, and avoidance of a large operative scar (2). Because of patient demand for "scarless" surgery, surgical efforts have focused on maximizing the profits of minimally invasive surgery by reducing the number and size of abdominal wall incisions. From these efforts, single-port access surgery has emerged as a growing trend in minimally invasive surgery. These approaches result in clinical outcomes comparable to those of standard laparoscopic surgery, but with overall lower rates of major perioperative morbidity (3–8). Studies have shown that single-port surgery is expected to have multiple advantages over multi-port or open procedures, including shorter hospital stays, faster recovery times, better cosmetic outcomes, and reduced postoperative pain (9–11). However, most of these studies have demonstrated only the technical feasibility and better cosmetic results of single-port surgery. Moreover, the subjective cosmetic outcome is the only advantage of single-port access total hysterectomy that is clearly defined in the literature. Only a few studies have assessed pain after single-port or multi-port surgery based on analgesic dose and/or a visual analogue scale (VAS) pain score (11–17). Therefore, we conducted a prospective study comparing surgical outcomes and postoperative pain between a transumbilical single-port access total laparoscopic hysterectomy (SPA-TLH) and the conventional multi (three)-port access total laparoscopic hysterectomy (MPA-TLH).

## Material and methods

### *Patients*

This study was a randomized, controlled trial of surgeries performed at Daejeon St Mary's Hospital, a large teaching hospital in Korea, between March 2014 and January 2015. The Gynecology Department is highly experienced in minimally invasive surgery. Preliminary statistical power calculations (see below) showed that at least 30 patients per treatment arm would be required. The study prospectively enrolled 60 patients who had an indication for hysterectomy using a research protocol approved by our Institutional Review Board (approval date 28 March 2014, Reference number DC14EISI0026). Study conduct and data analysis were performed following the CONSORT criteria, and the study was registered in a clinical trials database (NCT02390804). This study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki. All enrolled patients were randomized into one of two groups using a computer-generated random number sequence: group 1 received a single-port total hysterectomy, and group 2 received a multi-port total hysterectomy. The randomization codes were placed into sealed, numbered envelopes and assigned to patients upon arrived in the operating room. All patients provided informed consent and underwent hysterectomy for benign disease. After surgery in all patients, three skin plasters were applied to the locations of the three ports used in multi-port surgery, even if there was only a single port. Therefore, the patients and the anesthesiology staff who measured the pain scores were blinded to the type of surgery. Figure 1 displays the progress of all participants throughout the study. The eligibility criteria for the patients were that they were 18 years or older and in an appropriate medical status for laparoscopic surgery (American Society of Anesthesiologists Physical Status 1–3). Exclusion criteria were suspicion of malignancy, the need for simultaneous interventions such as a prolapse repair, a uterine size greater than 18 weeks of gestation, ongoing peritoneal dialysis, and any disease associated with abdominal pain such as pancreatitis. We excluded the patient if we could not completely rule out the possibility of malignancy due to a secondary disease, such as an ovarian cyst with characteristics including ultrasonographic findings showing a multi-chambered cyst or an elevation in tumor marker CA 125. Such cases are likely to require frozen biopsy, possibly leading to prolonged operative times, thereby affecting the results. Patients with microinvasive cervical cancer were also excluded. Among the 32 patients who did not meet the inclusion criteria, 20 were thought to have a malignancy. Most of the remaining excluded patients needed a prolapse repair or had an overly large uterine size. One patient required peritoneal dialysis and one patient had a history of pancreatitis. Previous intestinal or pelvic surgery, midline incisions, an abnormal body mass index, or cervical intraepithelial lesions such as carcinoma in situ were not regarded as contraindications.

### *Surgical procedures*

*SPA-TLH.* All patients received general anesthesia and preoperative antibiotic prophylaxis. All surgeries were performed by one of three experienced gynecologic surgeons (Y.S.L., E.K.P., or I.C.J.). The surgeons did not use any articulating instruments for the single-port surgery. After partial eversion of the umbilicus, a 1.5- to 2.0-cm vertical transumbilical skin incision was made. Subsequently, rectus fasciotomy and peritoneal incision were performed. A transumbilical single-port system was fashioned using Octoport™ (Dalim, Seoul, Korea), which consisted of a retractor component and a cap component with a harbor mounted onto the retractor component and multiple channels permitting introduction of a scope and the laparoscopic instruments. After installation of the single-port system, carbon dioxide was infused to cause

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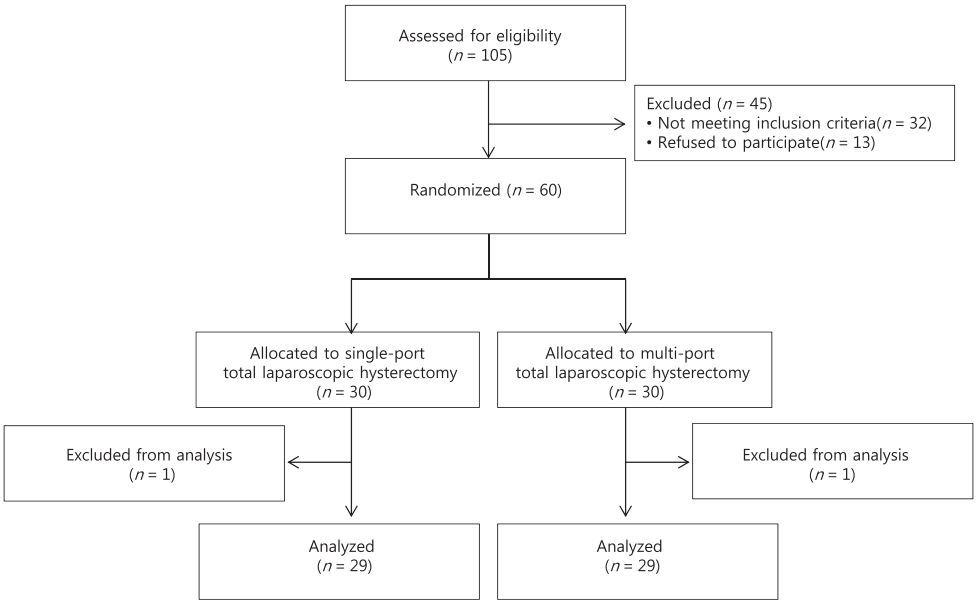


**Figure 1.** Flowchart of the trial population.

pneumoperitoneum. A rigid 0° 5-mm or 30° 10-mm laparoscope was used at the surgeon's discretion. The uterus was manipulated using a Karl Storz Clermont-Ferrand uterine manipulator (Karl Storz, Tuttlingen, Germany). All vascular pedicles were secured by bipolar coagulation and sectioned using scissors. All specimens were removed through the vagina by manual morcellation so as to not cause pain at the trocar. Vaginal cuff suturing was performed laparoscopically with three figure-eight sutures of 0 Polysorb (Syneture, Mansfield, MA, USA), using extracorporeal knot tying. Before finishing surgery, saline at 37°C was irrigated under the diaphragm at 25 mL/kg of body weight.

*MPA-TLH.* Two 5-mm trocars were inserted into the 11-mm camera port at the umbilicus. A 5-mm port was placed in both the left lower and the right lower quadrants of the abdomen. All other procedures were similar to the SPA-TLH.

### *Postoperative pain management*

Pain was assessed using a VAS (0 = no pain; 10 = worst pain imaginable), for which patients were asked to evaluate the maximal degree of pain. Pain scores were recorded at 30 min and 1, 12, 24, and 48 h after surgery. Postoperative pain was measured by two independent anesthesiology staff members (J.H.C., K.D.C., and H.T.C.). To accurately compare the intensity of the postoperative pain, all the participants received the same mode of anesthesia. Postoperative pain was managed by a patient-controlled fentanyl-based intravenous analgesia pump (IV-PCA; Baxter Healthcare Corporation, Deerfield, IL, USA: bolus dose 0.12 mg/kg of fentanyl, lockout interval of 5 min, basal infusion 0.02 mL/kg). Patients were instructed to press the IV-PCA bolus button when pain was 3 or higher on the VAS. A patient under IV-PCA whose VAS pain was >5 received 50 mg of Tridol intravenously. The IV-PCA was removed 48 h after surgery unless a patient specifically asked to retain it. Data were analyzed by assessing the number of IV-PCA bolus requests over time, the total amount of fentanyl administered, and the number of additional Tridol administrations.

### *Surgical outcomes*

Patient age, body mass index, parity, previous abdominopelvic surgery, and indication of hysterectomy were recorded. Total blood loss was calculated from the blood loss in suction, gauzes, and drapes. Operation time was recorded from the first incision to the completion of the final skin suture. The weight of the uterus was determined by a pathologist. Operative complications were defined as injuries to the bowel, bladder, ureter, or major vessel, incisional herniation, intra-abdominal bleeding, and wound infection.

### *Statistical analysis*

To compare the SPA-TLH and MPA-TLH groups, sample sizes were calculated based on the relation of the two

groups and VAS, as described in a reference document (18). The number of patients required for the study was calculated on the basis of a 90% power to detect a significant difference in a major end-point such as decrease in postoperative VAS scores at the 5% significance level. With a type I error of 0.05 and a type II error of 0.10, the necessary sample size would be 52 patients (26 patients in each group). Assuming a dropout rate of 15%, we recruited 30 participants per group ($26 \times 1.15 = 30$); hence, a total of 60 participants were recruited. This sample size was calculated using PASS (version 11.0, Kaysville, UT, USA) software (19,20). A folded *F* test was conducted on the continuous variables to determine the homogeneity of variances. When the variances were equal, a Student's *t*-test was carried out, while unequal variances were analyzed with the Welch *t*-test. Categorical variables were analyzed by using a chi-squared test or Fisher exact test. All statistical analyses were performed with SPSS version 18.0 (SPSS Inc., Chicago, IL, USA) at a 0.05 significance level.

## Results

### *Clinicopathological characteristics*

A total of 105 patients scheduled for elective TLH were screened for inclusion in this study. Among them, 32 patients failed to meet the inclusion criteria and 13 declined to participate. The remaining 60 patients were randomly assigned to one of two study groups so that each group consisted of 30 people. After enrollment, one patient in the MPA-TLH group stopped PCA administration early because of severe postoperative nausea and vomiting, and one patient in the SPA-TLH group did not use PCA because of an error. If PCA was stopped, not only patient-controlled bolus dose but also basal infusion would be halted, and the amount of analgesic injected into a patient would sharply decrease, consequently affecting VAS or additional analgesic use data. To prevent this, we used per-protocol analysis instead of intention-to-treat analysis. Hence, data for these two patients were excluded, leaving data from 58 patients to be analyzed. There were no cases of operative failure, defined as a need for an additional port or conversion to laparotomy. Patient characteristics are presented in Table 1. There were no significant differences in age, body mass index, American Society of Anesthesiologists grade, parity, or diagnosis between the two groups.

**Table 1.** Clinical characteristics of 58 patients who underwent total laparoscopic hysterectomy.

| | SPA-TLH ($n$ = 29) | MPA-TLH ($n$ = 29) |
|---|---|---|
| Age (years), mean ± SD | 47.45 ± 6.60 | 47.03 ± 6.44 |
| Body mass index (kg/m$^2$), mean ± SD | 24.74 ± 3.84 | 24.07 ± 2.61 |
| Parity, median (range) | 2 (0–5) | 2 (1–3) |
| Menopause, *n* (%) | 3 (10.3) | 6 (20.7) |
| ASA grade, *n* (%) | | |
| 1 | 19 (65.5) | 23 (79.3) |
| 2 | 10 (34.5) | 6 (20.7) |
| Previous abdomino-pelvic surgeries, *n* (%) | | |
| Adenexal operation | 1 (3.5) | 1 (3.5) |
| Appendectomy | 2 (6.9) | 2 (6.9) |
| Cesarean section | 0 (0.0) | 2 (6.9) |
| Cesarean section * 2 | 2 (6.9) | 6 (20.7) |
| Cesarean section * 3 | 0 (0.0) | 2 (6.9) |
| Other | 2 (6.9) | 1 (3.5) |
| Total | 5 (17.2) | 12 (41.4) |
| Preoperative diagnosis, *n* (%) | | |
| Myoma | 16 (55.2) | 16 (55.2) |
| Adenomyosis | 6 (20.7) | 5 (17.2) |
| Endometriosis | 3 (10.3) | 0 (0.0) |
| Endometrial hyperplasia | 0 (0.0) | 1 (3.5) |
| Clervical intraepithial neoplasia stage 2,3 | 1 (3.5) | 4 (13.8) |
| Myoma + Adenomyosis | 4 (13.8) | 3 (10.3) |
| Myoma + Ovary cyst | 1 (3.5) | 1 (3.5) |
| Adenomyosis + Ovary cyst | 1 (3.5) | 0 (0.0) |

ASA, American Society of Anesthesiologists; MPA-TLH, multi-port access total laparoscopic hysterectomy; SPA-TLH, single-port access total laparoscopic hysterectomy.

### *Surgical outcomes*

Operative data are summarized in Table 2. Patients in the SPA-TLH group experienced a longer operative time than those in the MPA-TLH group ($p < 0.0001$). Blood loss during surgery, perioperative hemoglobin changes, and uterine weight were not significantly different between the two groups. There were no complications during surgery, such as bleeding or injury, and none of the patients underwent a drainage procedure. All patients were discharged from the hospital on postoperative day 2 or 3, as they chose, without complication. One case of vaginal stump dehiscence occurred in the SPA-TLH group on postoperative day 20 after early coitus, which was repaired laparoscopically without any complications.

### *Postoperative pain assessment*

A comparison of postoperative pain scores between the two groups (SPA-TLH vs. MPA-TLH) is shown in Table 3. There were no differences in VAS scores at 30 min, 1, 12, 24, or 48 h postoperatively, between the two groups. The total amount of fentanyl consumption did not vary in relation to the laparoscopic method. In

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**Table 2.** Operative data of 58 patients who underwent total laparoscopic hysterectomy.

| | Single-port group ($n$ = 29) | Multi-port group ($n$ = 29) | $p$-value |
|---|---|---|---|
| Surgery performed, *n* (%) | | | |
| TLH | 21 (72.4) | 22 (75.8) | 0.837 |
| TLH with unilateral adnexal surgery | 2 (6.9) | 1 (3.45) | |
| TLH with bilateral adnexal surgery | 6 (20.7) | 6 (20.7) | |
| Operation time (minutes), mean ± SD | 170.10 ± 49.97 | 114.93 ± 27.73 | <0.0001 |
| Blood loss (mL), mean ± SD | 197.59 ± 153.38 | 168.28 ± 126.32 | 0.430 |
| Haemoglobin (g/dL), mean ± SD | | | |
| Preoperative | 11.95 ± 1.60 | 11.83 ± 2.47 | 0.821 |
| Postoperative | 10.10 ± 1.29 | 10.52 ± 1.51 | 0.262 |
| Haemoglobin change between preoperative and postoperative, mean ± SD | 1.85 ± 1.11 | 1.66 ± 0.75 | 0.440 |
| Transfusion, *n* (%) | 1 (3.5) | 0 (0.0) | >0.999 |
| Complication, *n* (%) | 1 (3.5) | 0 (0.0) | >0.999 |
| Specimen weight (mg), mean ± SD | 307.34 ± 150.34 | 384.66 ± 464.61 | 0.398 |
| Single-port incision length (mm), mean ± SD | 18.45 ± 4.45 | | |

TLH, total laparoscopic hysterectomy.

**Table 3.** Comparison of postoperative pain scores according to type of surgery.

| | SPA-TLH ($n$ = 29) | MPA-TLH ($n$ = 29) | $p$-value |
|---|---|---|---|
| Pain score (VAS score) postoperatively | | | |
| Initial (in the recovery room) | 5.52 ± 1.94 | 5.21 ± 1.57 | 0.505 |
| 1 h | 3.41 ± 1.38 | 3.97 ± 1.95 | 0.219 |
| 12 h | 2.52 ± 1.02 | 2.76 ± 1.06 | 0.381 |
| 24 h | 2.10 ± 0.67 | 2.24 ± 0.64 | 0.426 |
| 48 h | 1.76 ± 0.44 | 1.83 ± 0.38 | 0.525 |
| Number of IV-PCA bolus requests | | | |
| Initial to 1 h | 1.00 ± 1.04 | 0.93 ± 1.03 | 0.800 |
| 1–12 h | 6.07 ± 6.09 | 5.45 ± 9.47 | 0.768 |
| 12–24 h | 2.17 ± 3.05 | 0.79 ± 1.99 | 0.047 |
| 24–48 h | 1.38 ± 2.38 | 0.62 ± 1.40 | 0.146 |
| Total | 10.62 ± 9.98 | 7.79 ± 10.70 | 0.303 |
| Total amount of fentanyl consumption (μg) | 321.02 ± 139.83 | 305.53 ± 85.79 | 0.614 |
| Number of additional dose of analgesic | | | |
| Initial to 1 h | 0.48 ± 0.63 | 0.24 ± 0.51 | 0.116 |
| 1–12 h | 0.07 ± 0.26 | 0.10 ± 0.31 | 0.647 |
| 12–24 h | 0.03 ± 0.19 | 0.03 ± 0.19 | >0.999 |
| 24–48 h | 0.21 ± 0.41 | 0.03 ± 0.19 | 0.045 |
| >48 h | 0.17 ± 0.38 | 0.03 ± 0.19 | 0.090 |
| Total | 0.97 ± 0.94 | 0.45 ± 0.87 | 0.034 |

Values are expressed as mean ± SD.
IV-PCA, patient-controlled fentanyl-based intravenous analgesia pump; MPA-TLH, multi-port access total laparoscopic hysterectomy; SPA-TLH, single-port access total laparoscopic hysterectomy; VAS, visual analogue scale.

contrast, the number of IV-PCA bolus requests and the number of additional analgesic injections were higher in the SPA-TLH group. Specifically, those in the SPA-TLH group displayed statistically more bolus requests during the 12–24-h period after surgery ($p = 0.047$), more postoperative additional analgesics during the 24–48-h period ($p = 0.045$), and more total additional analgesics ($p = 0.034$).

In addition, we performed regression analysis to assess whether operative time, preoperative hemoglobin change, and specimen weight affected pain intensity and found that these factors did not influence the VAS scores at any time-point.

## Discussion

Severity of postoperative pain may have a large influence on the choice of an operative method. Although reduced postoperative pain is one of the advantages of laparoscopy compared with laparotomy, most patients who have laparoscopic surgery still need postoperative pain control, particularly during the immediate postoperative period (21). Accordingly, various attempts to reduce post-laparoscopy pain have been made (22–25). Single-port surgery requires a smaller numbers of incisions than conventional laparoscopy. Importantly, the single port is often installed in the umbilical area where there are no muscles so this technique minimizes abdominal muscle injury and the associated postoperative pain (11,13,14). Research on these aspects of postoperative pain reduction of single-port surgery in comparison with multi-port surgery has been performed in various surgical fields, but the results are still controversial. Some researchers have reported that postoperative pain was eased with single-port surgery (11–13), whereas others reported an increase in pain (14), or have found no significant differences (16,17,26). To date, only a few gynecological studies have

compared the degree of postoperative pain of single-port surgery using objective indicators such as a VAS score. Moreover, many of these studies were preliminary and did not distinguish between adnexal surgery and uterine surgery. Randomized trials of hysterectomy are especially rare. Unlike adnexal surgery, hysterectomy inevitably includes a vaginal incision accompanied by widespread damage to pelvic structures. Therefore, the effects of single-port vs. multi-port surgery on postoperative pain from hysterectomy may be different from those of other abdominal procedures. There have been several prospective studies on the postoperative pain of single-port laparoscopic hysterectomy compared with multi-port surgery. Jung et al. reported no difference between the two procedures (16), while Angioni et al., Chen et al., and Kim et al. found that single-port surgery involved less postoperative pain (11,13,14). Eom et al. reported no difference in hysterectomy patients, although pain intensity did differ between the hysterectomy group and the group that underwent gynecologic operations other than hysterectomy (17). A meta-analysis of six randomized, controlled trials on single-port vs. multi-port gynecologic surgery concluded that potential advantages such as better cosmetic result and less pain, have not yet been established (27). We prospectively compared single-port and multi-port hysterectomy in the first study to compare three-port and single-port hysterectomies. The TLH in the present study was performed in the same manner in both sample groups, with the only exception being the number of ports. Therefore, operative wound pain was the main contributor to postoperative pain in this study. This study was double-blinded considering the patients and the study personnel who carried out the postoperative pain assessment. In an effort to improve objectivity, we measured pain with two indicators: VAS and analgesic dose.

We found that the VAS pain scores were not significantly different between the SPA-TLH and MPA-TLH patient groups, but the SPA-TLH group showed significantly more 12–24-h postoperative PCA bolus requests, more 24–48-h postoperative additional analgesics, and more total additional analgesic injections. This indicates that the SPA-TLH group experienced more severe postoperative pain during the 48 h after surgery. In the case of single-port surgery, the length of the single fascial incision tends to be longer than those made during multi-port surgery, and the length of the incision is closely associated with postoperative wound pain. According to the existing literature on hysterectomy, the length of a single umbilical incision is usually 15–20 mm (13,14,16), which was similar to the length of the single incision used in this study. The SPA-TLH group had a longer operative time. A longer operative time may result in increased stretching of the single umbilical wound, and hence more postoperative pain. However, our results show that operative time did not influence VAS scores at any time point. In fact, compared with our previous study, the operative time of SPA-TLH in this study was less than those of the previously performed operations (170.1 min vs. 188.3 min, respectively) (28). However, the operative time of SPA-TLH was still longer than the operative time of MPA-TLH. Lee et al. reported no difference in operation time between conventional and single-port laparoscopically assisted vaginal hysterectomy (29). In contrast, our previous study showed that SPA-TLH had a longer time of operation, which was in agreement with Choi et al., who reported that laparoendoscopic single-site surgery required more time because of the installation of the single-port system and difficulties in intra-abdominal manipulation resulting from a loss of triangulation (30). In this study, we did not analyze the cost difference between the two groups because there was little difference in the cost of trocars used for the SPA-TLH and MPA-TLH group (US $257 vs. US $265). However, considering that the SPA-TLH group experienced longer operative time, which is one of the main determinants of total surgical cost, the SPA-TLH group might be associated with a higher surgical cost.

In conclusion, SPA-TLH was feasible but had a longer operative time. Although there were no differences in pain scores between the two groups, the SPA-TLH group requires more analgesia to give the same postoperative pain control. Although the SPA-TLH group may have experienced superior cosmetic results, this technique may not always be advised for patients undergoing hysterectomy. An individualized decision should be made after careful consideration of patient needs.

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