Original Article

Obstet Gynecol Sci 2018;61(2):261-266
https://doi.org/10.5468/ogs.2018.61.2.261
pISSN 2287-8572 · eISSN 2287-8580

Obstetrics & Gynecology Science

Postoperative outcomes of natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy and conventional laparoscopic-assisted vaginal hysterectomy: a comparative study

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Objective
The present study aimed to determine the differences in outcomes between natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy (NAVH) and conventional laparoscopy-assisted vaginal hysterectomy (LAVH).

Methods
We retrospectively reviewed the charts of patients who between July 2012 and September 2015, were diagnosed as having benign uterine disease such as uterine myoma, endometriosis, or adenomyosis and managed via NAVH or LAVH in a single-center (Eulji University Hospital). Data such as age, body weight, height, parity, operation time, intra/post-operative complications, and uterus weight were obtained from the clinical charts. NAVH and LAVH recipients were matched 1:3 in terms of baseline characteristics, and the 2 groups were compared regarding surgical outcomes.

Results
Of the 160 patients with benign uterine disease included in the present study. Forty received NAVH and remaining 120 received LAVH. There were significant differences between the groups regarding operation time and hemoglobin change. Notably, although the operation time was shorter for LAVH, hemoglobin change was lower for NAVH. Additionally, although maximum hospitalization duration was shorter for LAVH, the average length of hospitalization was similar between NAVH and LAVH. There were no significant differences between the groups in terms of other variables.

Conclusion
NAVH may become a new alternative surgical method of choice for hysterectomy, as it represents a clinically feasible and safe approach; moreover is superior to LAVH in terms of bleeding loss.

Keywords: Laparoscopy; Hysterectomy; Natural orifice endoscopic surgery; Postoperative complications

Introduction

Because of increasing concern regarding the cosmetic outcomes of surgery, minimally invasive surgery has received attention from surgeons in many areas. Minimally invasive surgery is valuable not only because it provides improved cosmetic outcomes, but also because it results in minimal surgical injury. Performing hysterectomy by using natural orifice transluminal endoscopic surgery (NOTES) is advantageous because it does not result in a surgery scar; moreover, the feasibility

Received: 2017.05.29. Revised: 2017.08.17. Accepted: 2017.08.17.
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and safety of NOTES hysterectomy have already been proven in several studies [1-5]. In study of 16 patients recruited between May and December 2010 in Taiwan, Su et al. [1] concluded that transvaginal NOTES has acceptable feasibility and safety for the treatment of benign uterine diseases. In another study involving 137 patients and conducted between May 2010 and August 2011 in Taiwan, Lee et al. [2] also confirmed that transvaginal NOTES is a feasible technique, and that it can be especially helpful in patients where the conventional vaginal approach is difficult to perform. And a meta-analysis conducted by Baekelandt et al. [3] in Belgium in 2017 demonstrated the feasibility of hysterectomy by NOTES compared to that of laparoscopy-assisted vaginal hysterectomy (LAVH). Whereas NOTES has received substantial attention worldwide, in Korea, a comparative study between NOTES-assisted vaginal hysterectomy (NAVH) and conventional LAVH has not been performed yet in clinical series.

Strictly speaking, NAVH is similar in some respects to other techniques of hysterectomy by using NOTES [1,4]. But unlike other type of hysterectomy by using NOTES, a wound retractor is inserted between intraperitoneal opening site in NAVH after trachelectomy. So, it can provide sufficient space and orientation, and solve the problem of CO_2 leakage.

The present study aimed to determine the differences in surgical outcomes between NOTES hysterectomy and conventional LAVH.

Materials and methods

The present study was reviewed and approved by the Institutional Review Board of Eulji University Hospital (IRB number: 2016-09-003). All patients who underwent surgery were given a written informed consent. This study was single-center, retrospective chart-review investigation enrolling patients who underwent NAVH or LAVH benign uterine disease, such as uterine myoma, adenomyosis, or endometriosis between July 2012 and September 2015. NAVH was performed in 40 patients, whereas the other patients underwent conventional LAVH. The 40 patients who received NAVH (NAVH group) were matched 1:3 to LAVH patients in terms of baseline characteristics (age, height, weight, body mass index). The following additional data were extracted from the medical charts: parity, diagnosis, first symptoms, previous operation history, type of operation, operation time, intraoperative/postoperative complications, and uterus weight. Hemoglobin change between preoperative and postoperative day 1 hemoglobin levels was also extracted from the medical charts to figure out the amount of bleeding loss during operation.

As this was a single-center study, all procedures were performed by the same surgical team. All patients enrolled in this study were fully informed regarding the surgical procedure and agreed to undergo the operations. Diagnosis was based on history taking, pelvic examination, and ultrasound examination. We excluded patients diagnosed with gynecological malignancy, as well as patients found to have severe pelvic adhesions and a fixed uterus. The surgical modality was decided by the operator.

Postoperative pain was managed via patient-controlled analgesia (intravenous fentanyl, 20 μg/kg). Patients who did not respond to this analgesic agent received additional parenteral analgesia (intramuscular dicknol, 90 mg). All patients were started on a soft diet and gradually switched to normal diet after the treating physician confirmed gas passing. In patients started on a soft diet, loxoprofen was permitted (60 mg orally, 3 times per day) for controlling postoperative pain until hospital discharge.

Patients were discharged when they had manageable pain, could ingest a normal diet, and had no postoperative complication such as fever or bleeding.

All baseline, peri-operative, and procedural details were extracted from the clinical charts. SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

1. Operative technique

The surgical modality was decided by the operator. In our previous study from 2014, we described NAVH technique [4]. And we performed NAVH in the same manner as previous study. The procedures of NAVH and LAVH are as in the following in brief.

Under general anesthesia, the patients were placed in the lithotomy and then Trendelenburg position. Foley catheter was inserted through the urethra for emptying the bladder, and vaginal retractors were used to expose the operative field. The operation (NAVH or LAVH) was performed using a 30°, 10-mm rigid laparoscope. Standard rigid laparoscopic 5-mm traumatic and atraumatic graspers were used. The energy source was a monopolar electrocoagulation system (Valleylab Force 2 electrosurgical unit; Valleylab, Boulder, CO, USA) or a 5- to 10-mm LigaSure vessel sealing system (Covidien, Valleylab).

1) NAVH

The uterine cervix was tracted using a tenaculum, and the circumferential incision of the vaginal mucosa around the cervix was made. The bladder was distracted from the anterior cervix, and the anterior fornix was opened. After opening the anterior fornix, the pouch of Douglas was also opened. Anterior and posterior colpotomies were complete as a result. A right-angle retractor was placed was placed under vaginal mucosa and bladder. Both uterosacral ligaments were clamped, cut, and ligated. The parametria were disconnected the same way along the uterus to the level of the uterine artery. A vasopressin analog (2 IU) was injected into the uterus to aid in hemostasis. The cervix was then amputated up to the lower portion of the uterus (trachelectomy) for transvaginal volume reduction. For NAVH, the Alexis wound retractor (Applied Medical, Rancho Santa Margarita, CA, USA) was inserted transvaginally into the opening site of the pelvic cavity after trachelectomy. A wound retractor was placed transvaginally, and the outer rim was draped with a surgical glove into which one 10-mm and two 5-mm cannulas were inserted through the fingers of the glove. The other laparoscopic instruments were inserted through remaining fingertips which edges were cut. Trocar or cannula was not used for inserting instruments. Next, CO_2 was insufflated to maintain an intra-abdominal pressure of 10 to 12 mmHg. NAVH was begun under the adequate pneumoperitoneum. The remaining lateral connections of the uterus containing the upper branches of the uterine vessels, the broad ligaments, and the round ligaments were secured and divided step by step using the LigaSure or monopolar electrode.

2) Conventional LAVH

For LAVH, we usually used 3 ports (one 12-mm trocar in the intraumbilicus and two 5-mm trocars in lateral abdominal wall). We insufflated CO_2 gas through trocar for making adequate pneumoperitoneum. All laparoscopic instruments were inserted through trocars. The ovarian ligaments, round ligaments, and broad ligament were dissected with a 45-mm EndoGIA (a single-use loading unit with titanium staples developed by Covidien) When the ligaments were dissected bilaterally and the bleeding was controlled, we begun the vaginal approach. After all procedures were completed, skin adhesive was used to close the abdominal wall.

Results

Of the 160 patients enrolled in the study, 40 underwent NAVH, and the remaining 120 received LAVH. The NAVH and LAVH groups were well matched in terms of baseline characteristics such as age, weight, height, and body mass index, as well as in terms of parity, number of previous operations, and uterus weight (Table 1).

The mean age was 47.3 years in the NAVH group, 46.4 years in the LAVH group, with no significant difference (*P*=0.426).

All patients were diagnosed in a histopathological manner by a pathologist. Of the 120 patients who received LAVH, 36

Table 1. Demographics of women who underwent surgery-assisted vaginal hysterectomy

Characteristics	NAVH	LAVH	*P*-value
Age (yr)	47.3±6.1	46.4±4.7	NS
Body mass index (kg/m^2)	24.3±2.6	23.5±3.4	NS
Parity			
Median (range)	2 (0–3)	2 (0–4)	NS
0 (nulliparous)	2 (5)	8 (6.7)	NS
>1	38 (95)	112 (93.3)	NS
With vaginal delivery	29 (76.3)	85 (75.9)	NS
Without vaginal delivery	9 (23.7)	27 (24.1)	NS
Previous abdominal surgery	30 (75)	76 (63.3)	NS
Weight of uterus (g)	278.3±168.9	287.2±127.4	NS

Unless otherwise specified, data shown as mean±standard deviation or frequency (percentage).
LAVH, laparoscopic-assisted vaginal hysterectomy; NAVH, natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy; NS, not significant.

patients had adenomyosis, 37 patients had leiomyoma, and 46 patients had both adenomyosis and leiomyoma. Of 40 patients who underwent NAVH, 10 patients had adenomyosis, 12 patients had leiomyoma, and 17 patients had both adenomyosis and leiomyoma. Only 3 patients in the LAVH group were diagnosed with endometriosis, and it was not diagnosed unilaterally. Endometrial polyp was diagnosed in only one each group, and it was also not diagnosed unilaterally (Table 2).

One patient in the NAVH group had postoperative fever (body temperature ≥38℃), which resulted in prolonged hospitalization. In LAVH group, 2 patients had postoperative fever, but no substantial delay in hospital discharge was noted. Except for fever, there were no postoperative complications such as infection or bleeding in the NAVH group, whereas 2 cases of postoperative bleeding were noted in the LAVH group, resulting in prolonged hospitalization. Specifically, one LAVH procedure included vaginal wall repair and primary bladder repair because of injury to the anterior vaginal wall and bladder respectively, whereas an other LAVH included primary bowel repair because of bowel perforation. Nevertheless, no statistically significant differences between the groups were noted in terms of intraoperative or postoperative complications. There was only one case where the operation mode had to be changed. The hemoglobin change (differences between preoperative and postoperative day 1 hemoglobin levels) was significantly lower in the NAVH group than in the LAVH group (1.339±1.057 vs. 0.975±0.826 dL; *P*=0.049), but the mean operative time was significantly shorter in the LAVH group (*P*<0.001) (Table 3).

Table 2. Histopathological diagnosis

Characteristics	NAVH	LAVH
Adenomyosis only	36	10
Leiomyoma only	37	12
Adenomyosis with leiomyoma	46	17
Endometriosis	3	0
Endometrial polyp	1	1

LAVH, laparoscopic-assisted vaginal hysterectomy; NAVH, natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy.

Discussion

Because it does not result in surgical scar, NOTES has been receiving substantial attention from surgeons in many countries. NOTES was used not only for hysterectomy but also for adnexectomies [6-9], ectopic pregnancies [10,11], appendectomies [12-15], and cholecystectomies [16-18]. Recently, feasibility and technique for transvaginal NOTES liver resection was studied in a porcine model [19]. Nevertheless, NOTES is not widely performed and has not been extensively studied in Korea. As mentioned before, NOTES hysterectomy is different from NAVH. In our previous study from 2014, we described the use of wound retractor during NAVH to compensate for disadvantages commonly noted for transvaginal NOTES, such as CO_2 leakage. Uterine vessels ligation is performed via the vaginal approach in NAVH, but endoscopically in NOTES hysterectomy. To facilitate the removal of the specimen during NAVH, volume reduction techniques such as trachelectomy, morcellation, myometrial coring, bisection, vaginal myomec-

Table 3. Perioperative outcomes of surgery-assisted hysterectomy

Characteristics	NAVH	LAVH	*P*-value
Operative time (min)	75.4±25.1	58.3±28.2	<0.001
Hemoglobin change (g/dL)	1.339±1.057	0.975±0.826	0.049
Intraoperative complications	0 (0)	2 (1.7)	NS
Additional operation	0 (0)	2 (1.7)	NS
Conversion of operative method	1 (2.5)	0 (0)	NS
Hospitalization duration (day)	5.3 (4–7)	5.2 (4–17)	-
Fever after operation	1 (2.5)	2 (1.7)	NS
Postoperative bleeding	0	2 (1.7)	NS

Data shown as mean±standard deviation, frequency(percentage), or median (range).
LAVH, laparoscopic-assisted vaginal hysterectomy; NAVH, natural orifice transluminal endoscopic surgery-assisted vaginal hysterectomy; NS, not significant.

tomy, or wedge resection can be performed transvaginally. These techniques can be helpful to secure the operative field and remove the uterus more easily. If necessary, NAVH can easily be converted to vaginal hysterectomy.

In our 2014 study, we compared the perioperative outcomes between NAVH and single-port LAVH (SP-LAVH), and found that NAVH was feasible and safe, and moreover had shorter operative time and postoperative hospitalization duration compared with those of SP-LAVH. Nevertheless, it should be noted that, compared to LAVH, SP-LAVH provides limited mobility of the endoscope because it uses only one port. To our knowledge, the outcomes of NAVH and LAVH have not been compared to date.

Wang et al. [5] performed a comparative study between transvaginal NOTES hysterectomy (tVNOTEH) and LAVH, and concluded that operation time, estimated blood loss, requirement for blood transfusion, and postoperative hospitalization duration were significantly lower for tVNOTEH than for LAVH. Also, in a meta-analysis conducted by Baekelandt et al. [3], the operative time and the length of stay in women treated by NOTES were shorter compared to LAVH. On the contrary, in present study, we found that operation time was significantly lower for LAVH, whereas hemoglobin change was significantly lower for NAVH. We believe this discrepancy originates from the fact that, NAVH is not routinely performed in Korea, unlike LAVH. Therefore, we expect that the operation time for NAVH will decrease as the frequency of NAVH increases and the surgeons gain more experience with this technique. As we mentioned in our previous report, it is difficult to explore the entire pelvic area because of the lack of appropriate endoscope instruments, which represents a major limitation of NAVH. Therefore, we expect that NAVH outcomes will improve with the development of instruments suitable for exploring the pelvic cavity. To overcome the limitation of our previous study, we enrolled a higher number of NAVH patients in the present study (16 vs. 40 patients). Moreover, all operations were performed by the same team, which consisted of operators with similar expertise and experience as our present study. To reduce bias, patients with the same criteria were selected and patients in the LAVH group were randomly chosen for comparison with the 40 patients of NAVH group. There were no significant differences in the basic characteristics of the 2 groups. Although we tried to reduce selection bias, but it was difficult to do because of the retrospective design of the study. Hence, it is one of the limitations of our present study. Future studies should involve large, prospective, randomized controlled trials focused on comparing the cosmetic outcomes of NAVH and LAVH.

Manual hand scrubbing was performed thoroughly before operation to prevent surgical site infection. And a sterile operation field and the skin were prepared; surgical drapes were used. The patients were given antibiotic prophylaxis just before the operation.

Our present study indicates that NAVH can become the surgical method of choice for hysterectomy. The feasibility and safety of NAVH were proven in this study by comparison against those of conventional LAVH. The surgical outcomes of NAVH were not different from those of LAVH. Instead, hemoglobin change was substantially lower for NAVH than for LAVH. With the development of proper instruments, NAVH can become a new alternative surgical method for the management of benign uterine diseases. Future, large, prospective, randomized controlled studies are warranted.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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