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Original Article

Transvaginal endoscopic surgery-assisted versus conventional laparoscopic adnexectomy (TVEA vs. CLA): A propensity-matched study and literature review

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ABSTRACT

Objective: Natural orifice transluminal endoscopic surgery (NOTES) may be useful in gynecologic endoscopic surgery. This study evaluated the efficacy, safety, and perioperative outcomes of combined NOTES and vaginal approach, transvaginal endoscopic surgery-assisted adnexectomy (TVEA), for the surgical treatment of presumed benign ovarian tumors.

Materials and methods: Records were reviewed for 33 consecutive TVEA procedures performed between May 2011 and March 2014. Patient age, body mass index, parity, mass size, and mass bilaterality were used to select comparable patients who had undergone conventional laparoscopic adnexectomy (CLA). **Results:** A total of 236 patients were included in this study (203 CLAs and 33 TVEAs). No cases switched to abdominal laparotomy. Operating time and length of postoperative stay were significantly longer in the CLA group than in the TVEA group, while total hospital charges were higher in the TVEA group ($p < 0.001$). There was no difference in febrile morbidity between the two groups; while the estimated blood loss was higher in the TVEA group, the EBL was <30 mL in both groups.

Conclusion: TVEA can be safely performed for benign and large ovarian tumors. In addition, TVEA offers superior operative efficiency compared to CLA.

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Introduction

While ovarian tumors are common in women of all age groups, most are benign lesions identified during the reproductive years. Approximately 5%–10% of women require surgical treatment for adnexal masses [1]. Laparoscopy remains the gold standard for surgical investigation of presumed benign ovarian tumors [2]. However, laparoscopists face challenges including large tumor size, unexpected malignancy, specimen removal, and intraoperative spillage of tumor contents during surgery.

While transvaginal surgery has a long history, its use remains uncommon because of the limited field of vision. Although the reported advantages of pure transvaginal ovarian cystectomy

include shorter operating time and faster recovery [3,4], the restricted operative field is a challenge for surgeons. However, access via natural body orifices offers the potential for development of minimally invasive surgical techniques. Transvaginal extraction of ovarian tumors has very low risk of complications during transabdominal laparoscopic surgery. The method allows introduction of an endobag through the vagina wall while also minimizing intraabdominal spillage. The elastic distension of colpotomy incision makes removal of solid pathologies, such as teratomas or fibromas, faster and easier [5].

Natural orifice transluminal endoscopic surgery (NOTES) has attracted attention as a less invasive alternative to conventional laparoscopy. NOTES provides better cosmetic results, reduced postoperative pain, and less wound-related hernia formation [6]. Among the different NOTES approaches, the transvaginal route appears to be less complicated, permitting safe entry and simple closure. However, while general surgeons and urologists have

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extensively adopted transvaginal NOTES, few gynecologists have done so [7].

Gynecologist endoscopists at our tertiary referral medical center have used transvaginal NOTES for tubal sterilization, adnexal surgery, and hysterectomy since 2010 [8–10]. Recently, we reported successful transvaginal NOTES hysterectomy in 147 cases of non-prolapsed uteri [11]. Very few cases of adnexal procedures have been reported [8,12,13], and the safety, feasibility, and outcomes of transvaginal NOTES have not yet been established. The aim of the present study was to compare outcomes among patients who underwent transvaginal endoscopic surgery-assisted adnexectomy (TVEA) to those of patients who underwent conventional laparoscopic adnexectomy (CLA) for presumed benign ovarian masses. The outcomes included operative time, estimated blood loss, febrile morbidity, postoperative stay, and hospital charges.

Materials and methods

This study consisted of 33 women with ovarian masses (age range 40–79 years, mean 56.0 ± 8.3 years) clinically diagnosed as having a low probability of malignancy, who were scheduled to undergo TVEA performed by one of the authors (C.J.W.) at Chang Gung Memorial Hospital at Linkou between May 2011 and March 2014. Two hundred and three women undergoing CLA, performed by the same surgeon (C.J.W.), were also retrospectively studied to avoid specific clinical bias. Before TVEA, all patients underwent thorough clinical evaluation, including detailed medical histories and pelvic examinations. Sonography and computed tomography were used to assess mass characteristics. Low probability of malignancy was defined as the absence of ascites, absence of thick papillary projections, no reduced resistance index, no enlarged pelvic lymph nodes, and normal or only mildly elevated (<65 U/mL) serum cancer antigen 125 (CA125) concentrations. Exclusion criteria for TVEA included patients with history of abdominal–pelvic surgery with suspected severe adhesions, suspected severe endometriosis, and complete obliteration of the posterior Douglas pouch noted during pelvic examination. A history of cesarean section and nullipara were not considered contraindications for TVEA. Before the operation, the patients were informed of the risks and benefits of NOTES, including the potential need to switch to laparoscopy or laparotomy during the surgery and the risk of malignancy detected by frozen section. Written informed consent was obtained from all subjects. All women underwent bowel preparation on the morning of surgery. Intravenous cephalosporin prophylaxis was administered just before surgery.

Preoperative clinical and demographic characteristics including age, body mass index (BMI), and parity were obtained. Similarly, operating time, mass size and bilaterality of the mass, estimated blood loss (EBL), postoperative stay, and any perioperative complications (fever, bowel injury, or genitourinary tract injury) were recorded. Total hospital charges (not including the costs covered by National Health Insurance) were obtained from hospital financial records. The study was approved by the Institutional Review Board of Chang Gung Memorial Hospital.

CLA technique

Patients were placed in the dorsolithotomy Trendelenburg position with both legs protected by elastic bandages, and a Foley catheter was inserted for constant urinary drainage. After induction of general anesthesia, intravenous cephalothin (1 g) was administered as prophylaxis. CLA was performed following procedures as described by Nezhat et al. [14]. In brief, laparoscopic examination of the pelvis and lower abdomen was performed to determine the accessibility of the surgical field. Three or four trocars were used

according to the pelvis complexity. A disposable laparoscopic grasper, scissors, and suction-irrigator were used to perform various procedures such as holding, cutting, exploring, and dissecting. After identification of the tumor, traction was placed on the infundibulopelvic ligament and utero-ovarian pedicle; the adnexal pedicles were secured and coagulated with the bipolar electrocautery (Elmed, Addison, IL, USA) and cut with scissors. After the tubo-ovarian pathology was detached from the uterus, the specimens were removed from the abdomen using either a disposable endobag to avoid contaminating the abdominal wall or a posterior colpotomy due to the hard properties or solid components of the mass.

TVEA technique

Patient preparation, positioning and anesthesia were the same as for CLA [14]. All operations were performed with a similar technique, as described previously [8,15]. In brief, a posterior colpotomy was created using traditional vaginal surgical techniques. The colpotomy incision was extended laterally by digital pressure.

A wound retractor (Alexis, Small; Applied Medical Resources Corp., Rancho Santa Margarita, CA, USA) was then inserted transvaginally (Fig. 1A). A surgical glove was attached to the outer ring of the wound retractor. One 10-mm and two 5-mm sheaths were inserted through cut edges of the thumb, middle, and little finger tips, respectively, and tied with elastic bandage to prevent desufflation of the pneumoperitoneum (Fig. 1B). Once the single-port device placement was completed, a 0-degree, 10-mm laparoscope attached to a video camera and conventional rigid straight laparoscopic instruments were inserted and the procedures initiated (Fig. 1C). The energy source was a 5-mm LigaSure vessel sealer (Covidien, Mansfield, MA) designed for laparoscopy.

On entering the pelvic cavity, the uterus, bilateral adnexa, and ovarian mass were identified. After the mass was pulled into the cul-de-sac, the procedure was similar to the CLA procedure. For masses larger than 7 cm, controlled drainage was performed to permit adnexectomy. Simultaneously, the glove was detached, leaving the wound retractor in place. Under direct vision, volume reduction was achieved by the insertion of a needle connected to a suction apparatus, secured with a purse-string suture to prevent fluid leakage. After decompression, the suction tubing was withdrawn and the purse-string suture was tied. The deflated mass was returned to the cul-de-sac, the glove was re-attached, and pneumoperitoneum was reestablished. Before extraction of surgical specimens, all vascular pedicles were inspected to ensure hemostasis (Fig. 1D). Finally, the glove, surgical specimens, and wound retractor were removed and the colpotomy incision was closed with 2-0 polyglycolic acid sutures (Monocryl; Ethicon Inc., Somerville, NJ, USA).

Statistical analysis

Continuous variables were compared using Student's *t*-tests, while categorical values were compared using Pearson's χ^2 analysis and Fisher's exact tests. Multiple logistic regression was used to estimate the likelihood of undergoing a TVEA procedure for all patients based on age, BMI, parity, mass size, and mass bilaterality. The logistic model produces a propensity score from zero to one based on the predicted probability of undergoing TVEA versus CLA, which was dependent on differences in patient demographic and pre-operative clinical characteristics [16]. These propensity scores were then used to measure selection bias. Patients with low scores undergoing CLA would have been unlikely to undergo a TVEA and therefore were excluded from the comparative analyses.

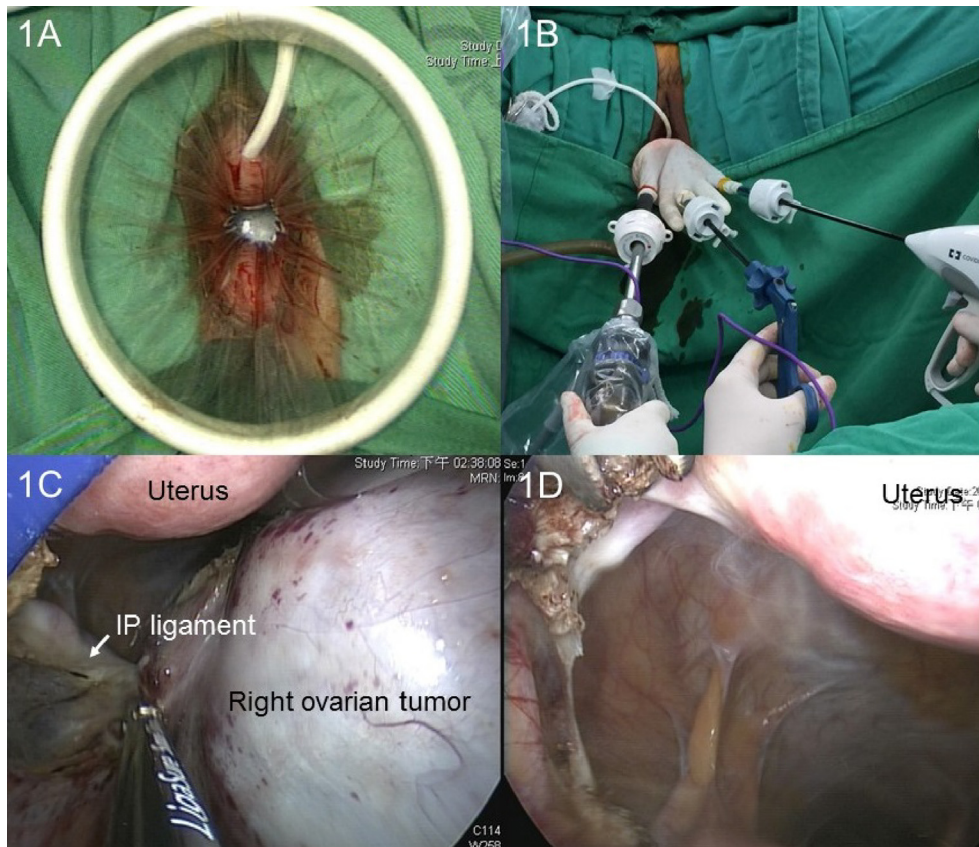


Fig. 1. A. Intraoperative images showing the transvaginal natural orifice transluminal endoscopic portal. The posterior colpotomy was protected using a small Alexis wound retractor. B. The outer rim of the wound retractor was draped with a disposable glove. An insufflating tube was connected to one of the cannulas to create a pneumoperitoneum. C. Endoscopic view of the right ovarian tumor and division of the right infundibulopelvic (IP) ligament. D. Endoscopic view of the post-right adnexectomy status.

Two clinical outcomes (EBL and perioperative complications) and three efficiency outcomes (operating time, postoperative stay, and hospital charges) were compared between the groups. We compared a propensity score-matched sample of 33 CLA patients with the 33 TVEA patients using a 'nearest neighbor' approach. In this approach, each TVEA patient was matched to the CLA patient with the closest propensity scores. Differences in outcomes by procedure type were tested by linear regression with log transformations or Mann–Whitney U rank tests when appropriate for skewed continuous outcomes, and logistic regression or Pearson's χ^2 analysis for categorical outcomes. All analyses were performed using PASW Statistics for Windows, version 18.0 (SPSS, Inc., Chicago, IL, USA).

Results

All procedures were completed successfully; no open conversion in both groups or laparoscopy conversions in the TVEA group were necessary. Table 1 shows the results of multiple logistic regression analysis of variables associated with case selection for TVEA. There was a trend toward more complex situations undergoing CLA. Patients with TVEA were more likely to have a presumed benign diagnosis and patients with preoperative suspicion of adhesions were 89% less likely to undergo TVEA. The propensity score model had a relatively high classification accuracy (c statistic = 0.7).

The propensity score matched analyses are shown in Table 2. Although the mean amount of blood loss was significantly less in the TVEA group than in the CLA group (14.0 ± 11.5 vs. 27.6 ± 30.0 mL; $p = 0.019$), both groups demonstrated that

adnexectomy for treatment of benign ovarian tumors was a bloodless operation. No major complications, such as ureter or bowel injury, occurred. No postoperative pelvic abscess formation was detected. No patient required blood transfusion, and no patient developed postoperative febrile morbidity. Regarding the efficiency outcomes, the mean operating time and postoperative stay were significantly lower in the TVEA group than in the CLA group. Mean hospital charges were almost twice as high for TVEA compared with CLA ($20,556.5 \pm 4856.1$ vs. $12,435.7 \pm 5890.0$ new Taiwan dollar; $p < 0.001$).

All ovarian lesions were benign. All patients underwent ultrasonographic follow-up 12 months after surgery, and no abnormal findings or recurrences of ovarian tumors were recorded.

Discussion

Transvaginal endoscopic surgery is a long-standing vaginal approach that has been merged with newly developed laparoendoscopic single-site surgery. Transvaginal access was first used for specimen retrieval after operative laparoscopy [17]. Development of single-site surgery made pure transvaginal endoscopic surgery feasible [18]. This technique not only results in an "invisible wound" for intraabdominal surgery, it also provides an appropriate operative working space. General surgeons and urologists have adopted the technique for cholecystectomy, sleeve gastrectomy, appendectomy, nephrectomy, adrenalectomy, and hernia repair [6]. Although its safety and feasibility for uterine adnexal procedures has been reported [8,12,13,15], extensive clinical experience and significant advantages have yet to be reported.

Table 1

Comparative patient characteristics for conventional laparoscopic adnexectomy versus transvaginal endoscopic surgery-assisted adnexectomy logistic regression results for propensity score model.

	CLA (n = 203)	TVEA (n = 33)	Odds ratio (95% CI)	p
Age (years)	48.3 ± 12.3 (9–79)	56.0 ± 8.3 (40–79)	1.03 (1.00–1.07)	0.091
Body Mass Index (kg/m ²)	24.6 ± 4.3 (16.9–45.7)	23.9 ± 3.9 (16.4–33.6)	0.98 (0.88–1.09)	0.680
Mass diameter (cm)	9.6 ± 5.1 (3–33)	7.6 ± 2.1 (4–13)	0.89 (0.78–1.03)	0.122
Bilaterality	31 (15.3)	0 (0)	1	
Nulliparae	38 (18.7)	1 (3.0)	0.28 (0.03–2.31)	0.236
Adhesion	79 (37.4)	2 (6.1)	0.11 (0.03–0.50)	0.004
Pathological diagnoses				0.013
Dermoid cyst or stroma ovarii	58 (28.6)	10 (30.3)		
Tubo-ovarian complex or abscess	34 (16.7)	0 (0)		
Benign Brenner tumor	4 (2.0)	0 (0)		
Endometrioma	10 (4.9)	0 (0)		
Fibroma or fibrothecoma	7 (3.4)	1 (3.0)		
Follicular cyst	9 (4.4)	0 (0)		
Mucinous cystadenoma	29 (14.3)	5 (15.2)		
Serous cystadenoma	37 (18.2)	9 (27.3)		
Simple cyst	15 (7.4)	8 (24.2)		

Significant at $p < 0.05$. Values are given as mean ± standard deviation (range) or number (%).

CLA = conventional laparoscopic adnexectomy; TVEA = transvaginal endoscopic surgery-assisted adnexectomy.

Table 2

Propensity score 1-1 matched comparison of outcomes after conventional laparoscopic adnexectomy versus transvaginal endoscopic surgery-assisted adnexectomy.

	CLA (n = 33)	TVEA (n = 33)	p
Clinical outcomes			
Blood loss (mL)	27.6 ± 30.0 (2–100)	14.0 ± 11.5 (3–50)	0.019
Febrile morbidity	0 (0)	0 (0)	
Efficiency outcomes			
Operating time (minute)	51.9 ± 22.5 (20–110)	39.2 ± 18.5 (20.0–120.0)	0.015
Postoperative stay (day)	2.1 ± 0.9 (1–6)	1.4 ± 0.5 (1–2)	0.001
Hospital charges (NTD)	12,435.7 ± 5890.0 (5849–29851)	20,556.5 ± 4856.1 (7377–32272)	<0.001

Significant at $p < 0.05$. Values are given as mean ± standard deviation (range) or number (%).

CLA = conventional laparoscopic adnexectomy; NTD = new Taiwan dollar; TVEA = transvaginal endoscopic surgery-assisted adnexectomy.

Few cases of successful transvaginal endoscopic surgery or laparoscopic-assisted vaginal approach for adnexal lesions have been reported (Table 3) [8,12,13,15,19–23]. A review of the English-language literature revealed several potential complications,

including cervical laceration, infection, and conversion to laparotomy or conventional laparoscopy. Furthermore, the main obstacles for transvaginal surgery are a limited visual field and the inability to directly manipulate target lesions. In addition, adhesions in the

Table 3

A review of published reports of laparoscopic assisted vaginal surgery on the adnexa.

Reference	Operative method	No. of patient	Mass size, cm (range)	Operating time, min (range)	Blood loss, mL (range)	Postoperative stay, day (range)	Complication
Pardi et al. [20]	2 suprapubic puncture used for adhesiolysis & placement then colpotomy for manual adnexal procedure	19	(4–11)	60 ^a (40–100)	<50	2 ^a (1–3)	Switch to laparotomy in 1 case
Teng et al. [21]	Conventional laparoscopic inspection then colpotomy for manual adnexal procedure	14	10 ^a (5–17)	81 ^a	100 ^a	<1	Cervical laceration
Wang et al. [22]	3 abdominal puncture used for adhesiolysis & placement then colpotomy for manual adnexal procedure	10	15.5 ^b (10–27)	62 ^b (31–110)	50 ^b (10–150)	2 ^b (1–4)	Postoperative fever in 1 case
Bae et al. [19]	Transvaginal 2.9 mm endoscopy inspection filled with Ringer lactate solution then colpotomy for manual adnexal procedure	140	6 ^a (3–20)	35 ^b (15–110)	38 ^b (10–80)	<1	Switch to conventional laparoscopy in 4 cases
Ahn et al. [12]	Colpotomy then transvaginal single-port with multiple channels	10	6 ^b (2.9–8)	62.5 ^b (55–70) the first 5 cases 55 ^b (50–65) the last 5 cases	NA	1–2	None
Lee et al. [8]	Colpotomy then transvaginal wound retractor with a surgical glove	10	4.5 ^b (4–6)	64 ^b (18–162)	30 ^b (2–2000)	2 ^b (0–2)	Switch to conventional laparoscopy in 1 case
Yang et al. [13]	Colpotomy then transvaginal wound retractor with a surgical glove	7	6 ^b (3.7–6.7)	45 ^b (40–80)	(5–300)	2 ^b (1–3)	None
Xu et al. [23]	Colpotomy then fixed cannulas and port by purse-string suture. Then double-channel endoscopy inserted	18	NA	53.33 ^a	<50	2.2 ^a	None
Wang et al. [15]	Colpotomy then transvaginal wound retractor with a surgical glove	34	7.6 ^a (5–12)	38.1 ^a (29–65)	31.6 ^a (5–100)	1.4 ^a (1–3)	None

NA = not available or report.

^a Mean.

^b Median.

pelvic cavity make it more difficult to access the route and restrict adnexal motility. Thus, selecting appropriate patients for TVEA surgery is crucial for successful outcomes.

The primary indication for laparoscopic adnexal surgery is presumed benign lesions. The role of the minimally invasive surgery for adnexal malignancies remains to be determined. Although the rate of unexpected malignancy during laparoscopic surgery is low, it has been reported in 0–2.5% of cases [24]. The complications of unexpected malignancy include upstaging the disease and potential port site metastasis. The TVEA approach offers the advantage of localized drainage of ovarian tumors with a purse-string suture to prevent fluid leakage into the abdominal cavity. In addition, the use of a wound retractor theoretically further prevents the specimen from “contaminating” the working platform.

The key to transvaginal access is successful culdotomy. Most cases of failed transvaginal route access were attributed to pelvic adhesions obliterating the posterior Douglas pouch [8,19,20]. Thus, patients suspected of having pelvic adhesions based on history or pelvic examination findings should be contraindicated for TVEA surgery. Contrarily, patients with previous cesarean section with common adhesions at the anterior uterine wall should not be excluded [11]. Vaginal access in nulliparous women is relatively narrow, but not unreachable [15]. The wound retractor in our system also helps to expand the operative field. With use of flexible surgical gloves, our working system provides an optical range of motion for the instruments and decreases clashing while handling.

Ovarian tumor size is of primary concern during conventional laparoscopic surgery. Larger tumors make it more difficult to insert trocars, manipulate surgical equipment, prevent tumor rupture, and extract specimens [25]. The usefulness of TVEA for large ovarian tumors remains undetermined. In our study, there were no differences in ovarian tumor size between the CLA and TVEA groups. We found that isolation of large ovarian tumors in the cul-de-sac during the TVEA approach offered several advantages. Tumors were visible immediately after the posterior colpotomy. The surgeon could avoid tumor rupture while setting up the working system. Alternatively, if needed, the surgeon could easily decompress the tumor in situ without spillage into the intraabdominal cavity.

The overall complication rate for transvaginal endoscopy in general surgery ranges from 6.9 to 9.8% [26]. Theoretical complications related to access port insertion include rectal or bladder injury and postoperative pelvic infection. The clinically reported incidence is relatively low. Culdotomy is a traditional procedure that provides safe entry to the intraperitoneal cavity [27]. Recognition of the anatomic landmarks such as the “triangle of safety”, helps minimize the risk of injury to adjacent structures [28]. Other complications have been reported, such as transient urinary retention, transient brachial plexus injury, and vaginal wound granulation [26]. The patients who underwent TVEA surgery in our study had none of these complications.

In our study, the TVEA group had better surgical outcomes other than hospital charges. The TVEA group had significant shorter operating time, less blood loss, and shorter postoperative stay. The higher charges in the TVEA group were mainly attributed to the costs of disposable devices (Alexis wound retractor and LigaSure vessel sealer) because of the relatively low cost of hospitalization in the Taiwan National Insurance System. Neither group had major intraoperative complications or postoperative febrile episodes.

The limitations of the present study include the small number of cases and the associated selection bias. Women with a low risk of pelvic adhesions and with more complicated situations tended to undergo TVEA and CLA surgeries, respectively. This study did not score postoperative pain. The nature of retrospective observational

studies makes it difficult to compare these two surgical procedures accurately.

In conclusion, this report on our experiences shows that transvaginal NOTES for presumed benign and large tumors is a feasible and effective surgical technique in well-selected patients. Surgeons should be aware of the limitations of this technique, including the skills of colpotomy, the upside-down orientation of the pelvis, the difficulty of precise differential diagnosis of the mass, and awareness of the potential for unexpected malignancies. Despite our small sample size, we believe it is worthwhile to report these preliminary results.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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