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Comparison of Transvaginal and Transumbilical Laparoscopic Single-Site Surgery for Ovarian Cysts

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ABSTRACT

Background: Minimally invasive surgery is currently a preferred treatment for symptomatic ovarian cyst(s), with single-site techniques, such as transumbilical laparoendoscopic single-site surgery (TU-LESS) and transvaginal laparoendoscopic single-site surgery (TV-LESS), gaining increasing popularity. Although both methods have delivered positive outcomes, there is currently limited literature directly comparing TU-LESS and TV-LESS.

Objectives: This study had two primary objectives: (1) to evaluate the safety and feasibility of TV-LESS and TU-LESS for the treatment of ovarian cysts and (2) to compare the surgical and postoperative outcomes of the two procedures.

Method: This was a prospective observational clinical analysis of 81 patients with a diagnosis of benign ovarian cyst with indication for TV-LESS or TU-LESS. Surgeries were performed at a tertiary hospital between February 1, 2018 and January 31, 2020. Patients were divided into TV-LESS (n = 40) and TU-LESS groups (n = 40), with one excluded due to severe pelvic adhesive disease. Demographics, operation outcomes, and follow-up details were compared.

Results: All 80 patients underwent uncomplicated procedures. The two groups were demographically matched (except age), with no difference in operation time, intraoperative blood loss, hemoglobin loss, and hospitalization costs ($P > 0.05$). However, TV-LESS patients had significantly faster time to ambulation ($P < 0.001$), faster time to return of bowel function ($P < 0.001$), less postoperative pain level ($P < 0.001$), and shorter length of hospital stay ($P < 0.001$). The cosmetic scores at 1, 4, and 24 weeks after surgery were also higher for the TV-LESS group.

Conclusion: Our preliminary experience suggested that TU-LESS and TV-LESS are both feasible and safe for ovarian cystectomy and salpingo-oophorectomy. However, TV-LESS may provide three main advantages including: (1) fewer postoperative complications (i.e. incisional hernia); (2) less postoperative pain; and (3) improved cosmetic satisfaction.

Key Words: TV-LESS, Transvaginal natural orifice transluminal endoscopic surgery, Transumbilical single-port laparoscopy, Ovarian cysts.

INTRODUCTION

Ovarian cyst is a common benign gynecologic condition, with high incidence across all ages. Minimally invasive surgery is currently a preferred surgical option. Transumbilical laparoendoscopic single-site surgery (TU-LESS) has been accepted as a desirable surgical approach in the treatment of ovarian cyst.[1,2] The single-site method is generally associated with a concealed surgical scar (by the umbilicus' natural fold), less trauma, faster specimen removal time, and less postoperative pain compared to traditional multiport surgery.[3] Recently, transvaginal LESS (TV-LESS) has been evolving and shows promise as a less invasive approach with better cosmetic results than conventional laparoscopic methods.[4]

As suggested by the name, the technique specifically involves the use of a natural orifice of the human body, i.e. the vagina, as the entry route to the pelvic cavity.[4] TV-

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LESS not only avoids an abdominal surgical incision, but also has the advantages of less pain, faster recovery, and decreased complications, such as wound infections.[5] Previous publications have shown that TV-LESS is a safe and feasible method for hysterectomy and adenextomy; however, there is a need for more research using prospective clinical data with larger sample sizes to evaluate its effect against other minimally invasive procedures.[6–10] To our knowledge, there has been no study to date that directly compares TV-LESS with TU-LESS for treatment of ovarian cysts. A study with this focus may be very interesting for gynecologic surgeons since both methods are single-channel operations and require similar techniques.

We report on the first prospective observational clinical analysis of 80 patients who underwent TV-LESS or TU-LESS for ovarian cysts. Our study objective was divided into two parts: (1) to determine the feasibility and safety of the two procedures and (2) to compare their operative data and postoperative outcomes.

I. MATERIALS AND METHODS

1. General Material

We collected the prospective clinical data of all patients who underwent TV-LESS and TU-LESS ovarian cystectomy or salpingo-oophrectomy at a tertiary hospital from February 1, 2018 to January 31, 2020. The patients were grouped according to the surgical approach: TV-LESS and TU-LESS. The hospital's Institutional Review Board approved the study in 2017 and all patients provided written informed consents.

The inclusion criteria for patients who underwent TV-LESS were: (1) pre-operative imaging study suggesting benign ovarian cyst(s); (2) history of sexual intercourse and/or vaginal delivery; (3) physical examination showing good uterine mobility; (4) history of umbilical hernia repair or other contraindications for transumbilical surgery; and (5) no anesthesia or other surgical contraindications. The inclusion criteria for patients who underwent TU-LESS were: (1) pre-operative imaging study suggesting benign ovarian cyst(s); (2) history of pelvic floor dysfunction, hypertrophy, or other conditions causing narrow vaginal introitus; and (3) no anesthesia or other surgical contraindications. The exclusion criteria for TV-LESS and TU-LESS were similar: (1) suspected obliteration of cul de sac on imaging study or physical examination; (2) history of bowel surgery; and (3) conversion to open surgery for any reason. (See **Table 1** for details).

2. INTERVENTION METHOD

2.1 Surgical Instruments, Imaging Systems, and Operating Devices

For both TV-LESS and TU-LESS groups, the access platform was a disposable PanOport11(Kangji, Hangzhou, China), designed to accommodate 5 mm, 10 mm, and 12 mm instrumentation. The optical imaging system consisted of a 10 mm 30° endoscope at (Hopkinskarl Storz-Endoskope), with the following 45 cm operating devices: harmonic scalpel (Johnson & Johnson, USA), Maryland forceps, fenestrated bipolar, and needle driver.

2.2 Surgical Procedure

Patients in both groups received identical pre-operative and postoperative care, as detailed below. The surgical steps were also similar, with the main difference being the entrance site, which was the vagina for the TV-LESS group and umbilicus for the TU-LESS group.

Pre-operatively, for bowel preparation, patients were given a liquid diet 24 h before surgery and 200 ml carbohydrate-rich energy drinks 4 h before surgery. Up to 150 ml water was also allowed orally 2 h before surgery. The vagina and perineal area were sterilized with an iodophor solution and Ceftiofur sodium 1.5 g was given intravenously 30 min before surgery for bacterial infection prophylaxis.

Intra-operatively, the patients were administered general anesthesia and placed in a dorsal lithotomy position. The perineal region, vagina, and cervix were sterilized and a Foley catheter was placed for urinary drainage.

The surgical procedures were carried out as follows:

Entry into the Pelvic Cavity

For the TV-LESS group, a vaginal retractor is placed within the vagina and the cervix was visualized. The posterior lip of the cervix was grasped with an Allis forceps, and then pulled outwards superiorly to expose the posterior vaginal vault. The planned incision site on the posterior fornix was identified and two Allis clamps were used to demarcate the space. An incision about 2 – 3 cm in size was carefully made with tissue scissors horizontally to enter the pelvic cavity. After ensuring hemostasis, the vaginal wall and peritoneum were tagged with 2-0 silk sutures at both ends of the incision. A sterile port was then placed to allow for pneumoperitoneum. Full survey of the upper abdomen and bilateral ovaries were performed. A similar procedure was performed for the TU-LESS group, except

Table 1.
Clinical Characteristics of Patients in Transvaginal Laparoendoscopic Single-Site Surgery Group vs Transumbilical Laparoendoscopic Single-Site Surgery Group

Group	Case Number	Age (years, ± s)	Body Mass Index (kg/m^2, ± s)	Ovarian Volume (cm^3, ± s)	Previous Pelvic Surgery (Cases)	Sexual History	Childbirth History
TV-LESS	40	36.60 ± 8.80	23.03 ± 2.78	69.21 ± 11.57	8	40	40
TU-LESS	40	28.53 ± 7.88	22.27 ± 2.95	70.31 ± 9.80	12	29	13
P value		0.001	0.240	0.646	0.302	< 0.001	< 0.001

TV-LESS, transvaginal laparoendoscopic single-site surgery; TU-LESS, transumbilical laparoendoscopic single-site surgery.

a 3 cm vertical incision was made at the base of the umbilicus. Upon entering the abdominal cavity, the port was placed after suspending the fascia with 2-0 silk suture.

Ovarian Cystectomy

For both routes, cystectomy began with an incision made above the ovarian cyst with a harmonic scalpel, with care not to puncture the cyst. A combination of traction and blunt dissection was then performed with Maryland forceps along the ovarian cyst wall to completely separate the cyst from the ovary. The ovarian incision was then sutured with 3-0 barbed absorbable suture (Johnson & Johnson Ethicon).

Oophorectomy

If oophorectomy was indicated for either route, the following procedures were performed. First, the ipsilateral ureter was identified. The fenestrated bipolar forceps was used to cauterize and transect the infundibulopelvic ligament.

Closure of Vaginal or Umbilical Incision

The excised cyst(s) (and ovary, in some cases) was removed directly through the trocar or, for larger specimens, in a retrieval bag. A 2-0 absorbable suture was then used to continuously suture the vaginal or umbilical (TU-LESS) incision. Ceftiofur sodium 1.5 g was administered for prophylactic treatment 24 h after surgery, and patients were recommended to refrain from sexual activity for 6 to 8 weeks.

2.3 Data Collection

The baseline demographic data recorded included: age, body mass index (BMI), and history of surgery. The perioperative outcomes recorded included: ovarian volume, estimated blood loss, time to ambulation, time to return of bowel function, pathological results, surgical complications, length of hospital stay, visual analogue scale (VAS) of pain at 12 h after operation,[12] validated cosmetic score at 1, 4, and 24 weeks after surgery;[13] and postoperative recovery.

Ovarian cyst volume was determined using transvaginal Doppler by measuring ovarian length (L), width (W), and height (D), and then the volume (L * W * H) was computed. The change in hemoglobin (HGB) level was calculated as the pre-operative hemoglobin level 1 day before surgery minus the hemoglobin value 1 day after surgery. The operation time was defined as the time between opening to the closure of the incision, which was the posterior vaginal fornix incision for the TV-LESS group and umbilical incision for the TU-LESS group. The time to return of bowel function was calculated from after surgery to the event of the first conscious passage of flatus. The length of hospital stay was calculated from the time of patient admission to discharge. The VAS for postoperative pain assessment was calculated from the average of two pain scores obtained from patients, with assistance by two qualified nurses. (Pain scale was defined as: no pain = 0, mild pain = 1 – 3, moderate pain = 4 – 6, and severe pain = 7 – 10.) A body image questionnaire was used to evaluate cosmesis.[13] With the assistance of two nurses, patients were asked to subjectively evaluate their satisfaction with the incision, either vaginal or umbilical, and the average of two cosmetic scores at 1, 4, and 24 week(s) postoperatively were recorded. The score scale ranged from zero (very dissatisfied) to 24 (very satisfied) points.

Postoperatively, patients were followed up in the outpatient clinic at 1 and 4 weeks. In addition to the general screening and imaging examination, both groups were also evaluated for abnormal vaginal discharge, incisional complications, abdominopelvic hematoma, and infection. At 24 weeks after surgery, all patients were contacted via telephone to evaluate for symptoms of dyspareunia.

3. STATISTICAL ANALYSIS

The data analysis was conducted by the SPSS 25.0 software, and the collected data were expressed as mean and standard deviation ($\bar{x} \pm s$). The intergroup data met the normal distribution, and independent sample t test and χ^2 test were performed. The difference was statistically significant when $P < .05$ and $\alpha = 0.05$.

RESULTS

II. Comparison of Surgical Outcomes

During the study period, a total of 81 patients presented with pre-operative presumptive diagnosis of benign ovarian cyst(s) and underwent either TV-LESS or TU-LESS. One patient did not meet inclusion criteria due to severe pelvic adhesive disease and need for operative conversion. Forty patients were included in each group, with 8 patients in the TV-LESS group and 12 patients in the TU-LESS group with history of pelvic surgery.

There was no statistical difference between the two groups in terms of previous pelvic surgery history, BMI, and ovarian volume (**Table 1**). However, there is a significant difference in age between the two groups: 36.6 ± 8.8 years for the TV-LESS group and 28.53 ± 7.88 for the TU-LESS group ($P < .01$). All 80 patients had uncomplicated surgeries, and the postoperative pathological examination suggested benign ovarian lesions. In the TV-LESS group, there were 31 cases of ovarian cystectomy and 9 cases of salpingo-oophrectomy. In the TU-LESS group, there were 38 cases of ovarian cystectomy and 2 cases of salpingo-oophrectomy.

Comparison of Perioperative Evaluation Indicators

No significant difference ($P > .05$) was detected between the two groups in terms of: operation time (TV-LESS 89.93 ± 19.69 min; TU-LESS 87.63 ± 15.18 min), estimated blood loss (TV-LESS 15.00 ± 4.03 ml; TU-LESS 13.90 ± 3.48 ml), change in hemoglobin level (TV-LESS 6.13 ± 2.67g/L; TU-LESS 5.95 ± 2.68g/L), and hospitalization costs (TV-LESS 0.32 ± 0.009 million dollars; TU-LESS 0.34 ± 0.011 million dollars).

However, the two groups had significant difference ($P < .05$) for the following variables: length of hospital stay (TV-LESS 3.43 ± 0.71 d; TU-LESS 4.88 ± 0.72 d), time to return of bowel function (TV-LESS 13.28 ± 2.62 h; TU-LESS 15.92 ± 3.13 h), time to ambulation (TV-LESS 10.90 ± 1.59 h; TU-LESS 16.12 ± 2.63 h), and VAS at 12 h postoperatively (TV-LESS 1.75 ± 0.78 points; TU-LESS 2.68 ± 0.73 points). In addition, the cosmetic score in the TV-LESS group was 21.85 ± 0.66 points, 22.88 ± 0.69 points, and 23.55 ± 0.80 points at 1 week, 4 weeks, and 24 weeks after operation, respectively. In the TV-LESS group, the cosmetic score was higher than that of the TU-LESS group, with statistical significance ($P < .05$). Refer to **Table 2** for more details.

Postoperative Short-Term and Long-Term Complications

No peri-operative complications occurred in either group. All 80 patients had follow-up at 6 months and underwent data collection at the follow-up visit. At follow-up, no abnormal vaginal discharge or abdominopelvic pain was reported in the TV-LESS group, and all patients exhibited appropriate healing of posterior vaginal fornix incision. The patients also reported no sexual discomfort or pain during telephone follow-ups.

DISCUSSION

With improvements in technology, gynecological laparoscopic surgery has been continuously evolving. As single-port laparoscopic surgery has many advantages, including a single incision, less trauma, cosmetic surgical scar, and easy specimen removal. Due to these advantages, it has been adapted to treat more gynecological conditions, such as benign ovarian tumors, uterine fibroids, ectopic pregnancy, and early endometrial cancer surgery.[14] Over time, surgeons have developed deeper insight into the concept of minimally invasive surgery and demonstrated that natural orifice like the vagina (TV-LESS) could be used for surgical entry, thereby eliminating the need to make an abdominal incision.[9] This surgical technique effectively combines traditional vaginal surgery and single-port laparoscopic surgery, and provides the advantages of better visualization, pain reduction, no abdominal incision, and faster recovery after surgery.

The application of TV-LESS for adnexal surgery is still in the exploratory stage with lingering uncertainties regarding its efficacy and safety, as limited by the steep learning curve and need for improved surgical instruments.[15–16] One study by Lee et al. in 2012, examined 10 cases of natural orifice adnexal surgery.[7] Of these cases, nine patients underwent successful surgery and one patient was converted to traditional laparoscopic surgery. In another study, Ahn et al.[16] conducted a preliminary exploratory

Table 2.
Comparison of (A) Intraoperative and (B) Postoperative Conditions in Transvaginal Laparoendoscopic Single-Site Surgery Group and Transumbilical Laparoendoscopic Single-Site Surgery Group ($\bar{x} \pm s$)

(A)

Group	Number	Operation Time (min)	Bleeding Amount (ml)	HGB Decrease (g/L)	LOS (d)	Return of Bowel Function Time(h)	Hospitalization Costs (Ten Thousand RMB)
TV-LESS	40	89.93 ± 19.69	15.00 ± 4.03	6.13 ± 2.67	3.43 ± 0.71	13.28 ± 2.62	2.11 ± 0.06
TU-LESS	40	87.63 ± 15.18	13.90 ± 3.48	5.95 ± 2.68	4.88 ± 0.72	15.92 ± 3.13	2.19 ± 0.07
P value		0.560	0.195	0.771	<0.001	<0.001	<0.001

TV-LESS, transvaginal laparoendoscopic single-site surgery; TU-LESS, transumbilical laparoendoscopic single-site surgery; HGB, hemoglobin; LOS, length of stay; RMB, Renminbi.

(B)

				Cosmetic Score (Points)		
Group	Number	Ambulation Time (h)	Postoperative 12-Hour Pain VAS	1 Week Post-Surgery	4 Weeks Post-Surgery	24 Weeks Post-Surgery
TV-LESS	40	10.90 ± 1.59	1.75 ± 0.78	21.85 ± 0.66	22.88 ± 0.69	23.55 ± 0.80
TU-LESS	40	16.12 ± 2.63	2.68 ± 0.73	19.05 ± 1.32	19.93 ± 1.32	20.93 ± 1.97
P value		<0.001	< 0.001	<0.001	<0.001	<0.001

TV-LESS, transvaginal laparoendoscopic single-site surgery; TU-LESS, transumbilical laparoendoscopic single-site surgery; VAS, visual analog scale.

study on the treatment of six different benign adnexal diseases with TV-LESS in 10 patients: oophorectomy (n = 4), salpingostomy (n = 2), salpingectomy (n = 2), ovarian cystectomy (n = 1), paratubal cystectomy (n = 1), and ovarian wedge resection (n = 1). All 10 surgeries were successful and follow up conducted for 2 months demonstrated satisfactory therapeutic results. A few preliminary studies using TV-LESS for the treatment of ovarian cysts have also been conducted.[5,15,20] However, they were single-center prospective cohort studies, with a limited number of cases, so there remains a need to improve the level of evidence in support of TV-LESS. At present, there is no study which effectively evaluates the feasibility and safety of TV-LESS for treatment of ovarian cysts or against other single-site methods (i.e. TU-LESS).[9,10,17] In an attempt to fill this gap, we focused our research on comparing TV-LESS with TU-LESS to determine the safety and feasibility of both methods and to assess whether TV-LESS offers any advantages over TU-LESS.

In this paper, we present 40 patients with benign ovarian cysts who were successfully treated by either TV-LESS or TU-LESS. Age was different in two groups due to the fact that the vaginal route was not an option for patients without a history of sexual intercourse and the average age for losing virginity is higher in China.[21] Compared with TU-LESS, TV-LESS showed several advantages for patients, including faster time to ambulation, faster time to return of bowel function, and shorter length of hospitalization ($P < .05$); however, three were most notable. First, TV-LESS has reduced incidence of postoperative complications, such as incisional hernia. Because TU-LESS requires making a 2.5 – 3.0 cm incision at the umbilicus, the method is associated with a relatively high incidence of incisional hernia, with some studies reporting an incidence of 2.2% ~ 5.51%.[3] This risk is absent for TV-LESS, which is performed directly through the natural vaginal orifice. At the 6 months postoperative visit, no complications were reported in all 40 patients. Second, TV-LESS is associated with less postoperative pain compared to both TU-LESS and multiport methods.[15,18,19] Our results found that the 12-hour pain score of the TV-LESS group was significantly lower than that of the TU-LESS group. This

is likely due to the fact that the transvaginal approach does not require an abdominal incision and vaginal visceral nerves are less sensitive.[15] In turn, less postoperative pain can help patients ambulate and pass flatus earlier. Third, cosmetic scores at 1, 4, and 24 weeks post-surgery in the TV-LESS group were also statistically higher than those of the TU-LESS group ($P < .05$).

Although significant findings are reported in this study, there are also several limitations. With the relatively small sample size, nonrandomized trial, and focus on a single institution, it is possible that our findings may not be widely applicable. Also, we recognize that it is difficult to compare a transumbilical (skin) with a transvaginal (internal organ) incision. Hence, we used a cosmetic score that is entirely based on the patient's subjective assessment of their body image after the surgery. Additionally, we only directly compared TV-LESS with another single site method and did not incorporate more commonly used multiport methods into our design. Therefore, we recommend that multicenter, large-sample, and prospective randomized controlled trials; involving TV-LESS, TU-LESS, and multiport laparoscopic procedures, be conducted to supplement our clinical data and provide more favorable evidence for clinical treatment in the future.

In summary, our results supported that TU-LESS and TV-LESS adnexal surgeries are both effective and safe. In addition, our data demonstrated that TV-LESS provides three major benefits compared to TU-LESS: (1) fewer postoperative complications, including no risk of umbilical hernia; (2) less postoperative pain resulting in earlier return of bowel function and ambulation and shorter hospitalization stay; and (3) higher cosmetic satisfaction. Therefore, in the appropriate cases, TV-LESS may be considered in the treatment of benign ovarian cysts and has practical advantages over TU-LESS.

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