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# Analysis of feasibility, effectiveness and safety of transvaginal natural orifice transluminal endoscopic surgery(vNOTES) of ectopic pregnancy: a retrospective study

Shuo Zhang<sup>1</sup>, Dan Zhou<sup>1\*</sup>, Jin-bowen Yan<sup>1</sup>, Bo Zhang<sup>1</sup>, Qing-wei Meng<sup>1</sup> and Qiu-bo Lv<sup>1</sup>

# **Abstract**

**Background** vNOTES has been documented as a viable approach for conducting benign gynecologic surgery; however, its application in ectopic pregnancy cases remains relatively scarce. The principal objective of this investigation was to assess the practicability, effectiveness, and safety of vNOTES in surgical procedures related to ectopic pregnancy.

**Methods** Clinical data pertaining to patients diagnosed with ectopic pregnancy at Beijing Hospital between January 2018 and August 2023 were retrospectively collected (This study retrospectively registered with the China Clinical Trial Registry with the registration number ChiCTR2100052223 in September 22, 2021.). Based on the surgical technique employed, participants were categorized into two groups: the vNOTES group (29 cases) and the conventional laparoscopy (CL) group (34 cases). The baseline data, including age, body mass index (BMI), parity, and maximum diameter of pregnancy objects, were collected and analyzed, along with intraoperative indicators such as operation time and intraoperative blood loss, and postoperative indicators including postoperative exhaust time, hospital stays after surgery, and postoperative pain score at 24 h.

**Results** A total of 73 patients were included in this study, and all surgeries in both groups were performed according to the assigned procedures. There were no statistically significant differences observed in operation time, intraoperative blood loss, and hospital stays between the vNOTES group and the CL group (P > 0.05). However, the vNOTES group exhibited significantly lower postoperative exhaust time and 24-hour VAS scores compared to the CL group (P < 0.05).

**Conclusions** vNOTES proves to be a safe and effective approach for performing conservative tubal festration or salpingectomy in cases of tubal pregnancy. Furthermore, vNOTES offers a more minimally invasive surgical technique, resulting in reduced postoperative pain in patients.

**Keywords** Transvaginal natural orifice transluminal endoscopic surgery, Ectopic pregnancy, Salpingectomy, Salpingostomy

\*Correspondence: Dan Zhou zhoudan\_791124@163.com <sup>1</sup>Department of Obstetrics and Gynecology, Beijing Hospital, National Center of Gerontology, Institute of Geriatric Medicine, Chinese Academy of Medical Sciences, Beijing, P.R. China



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# **Background**

Ectopic pregnancy, which involves the implantation of spermatovum outside the uterine cavity, constitutes approximately 2% of all pregnancies [1]. The most prevalent form is tubal pregnancy, accounting for approximately 98% of cases, necessitating surgical intervention. Laparoscopic surgery is a crucial modality for both diagnosing and treating ectopic pregnancy, offering advantages such as prompt diagnosis, minimal surgical invasiveness, rapid postoperative recuperation, and limited occurrence of complications. Conventional laparoscopy (CL) is a traditional technique utilized in the treatment of ectopic pregnancy, involving the creation of 3 to 4 puncture holes in the lower abdomen to facilitate the completion of the operation [2]. The primary surgical interventions employed in this approach are salpingotomy and salpingectomy.

Additionally, vNOTES has been documented as a viable alternative for performing various benign gynecological procedures, such as adnexal surgery, ovarian cystectomy, myomectomy, and hysterectomy [3–6]. However, there are few studies on the application of vNOTES in tubal pregnancy. The primary aim of this study was to evaluate the feasibility, efficacy and safety of vNOTES in tubal pregnancy.

# **Methods**

Retrospective analysis was conducted on the medical records of 73 patients who underwent salpingectomy or salpingostomy for ectopic pregnancy at Beijing Hospital between January 1, 2018, and August 30, 2023(Clinical Trial Registry: ChiCTR2100052223). These patients were categorized into two groups based on the surgical technique employed: the vNOTES group (29 cases) and the CL group (34 cases). A total of 50 patients underwent salpingectomy, with 26 in the CL group and 24 in the vNOTES group. 13 patients underwent salpingostomy, with 8 in the CL group and 5 in the vNOTES group. Both groups' surgeries were completed successfully without the addition of other access routes or conversion to



Fig. 1 Tubal pregnancy tissue on the left side as viewed by vNOTES

alternative surgical methods. The diagnosis of ectopic pregnancy was established through clinical assessments, transvaginal ultrasound scans, and measurement of serum human chorionic gonadotropin (hCG) levels (7–8). Histopathological examination confirmed the presence of ectopic pregnancy in all cases.

**Inclusion criteria** ①Stable vital signs, pelvic ultrasound indicating cul-de-sac fluid < 5 cm. ②No analgesic drugs were used postoperatively. ③History of sexual activity. ④Signed informed consent form.

**Exclusion criteria** ①History of more than two pelvic surgeries. ②History of chronic pelvic inflammatory disease. ③History of endometriosis. ④Bimanual pelvic examination suggesting vaginal stenosis. ⑤Recto-vaginal abdominal examination suggesting recto-uterine adhesion. ⑥Refusal of surgical treatment.

To reduce the bias in outcomes caused by the surgeon, all surgeries in our study group's enrolled cases were performed by two chief physicians. Both doctors have many years of experience in traditional laparoscopic surgery and have independently completed 50 vNOTES surgeries each. The surgical technique for CL involves the insertion of trocars through the umbilical incision and the subsequent insertion of a laparoscope. During the procedure, a 1 cm incision is made 3 cm medial to the left and right anterior superior iliac spines, and trocars measuring 5 mm and 10 mm are placed into the abdominal cavity. Patients in the CL group had their subcutaneous tissue at the umbilicus sutured with absorbable suture in a purse-string fashion, and the epidermis of all ports was sealed with glue. In contrast, the surgical approach for vNOTES entails making an incision of approximately 2-3 cm on the posterior vaginal fornix mucosa. After confirming that the bowel was not damaged, a single-port laparoscopic port (Kangji, Hangzhou, China) was inserted, and then a laparoscope and operating instruments were inserted through it to complete the operation (Fig. 1). Endovascular surgery procedures were essentially the same as standard laparoscopy procedures. The excised specimens were placed in self-made specimen bags (Kangji, Hangzhou, China) and were removed entirely through the enlarged posterior vaginal fornix incision. Patients in the vNOTES group had continuous absorbable sutures used to close the posterior fornix of the vagina (Fig. 2).

Baseline characteristics including patients' age, body mass index (BMI), gravidity, parity, preoperative hCG level, and the maximum diameter of the gestation, as well as perioperative data such as operation time and intraoperative blood loss, and postoperative data including postoperative exhaust time and visual analogue scale (VAS) 24 h after surgery, were collected. Furthermore, the hCG

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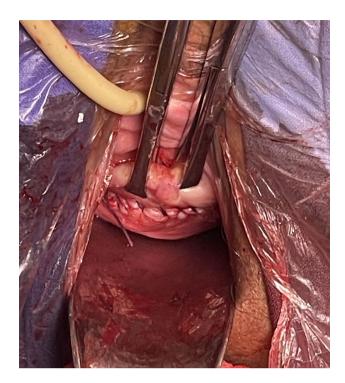


Fig. 2 Postoperatively sutured posterior fornix incision

level at 1 month after surgery was also recorded and collected.

Statistical analysis was performed using SPSS 25.0 software. Measurement data were expressed as  $(x \pm s)$  and an independent sample T test was utilized. Counting data were compared by Chi-square test or Fisher exact probability test, using two-sided test. P < 0.05 indicated significant difference.

# **Results**

There was no significant difference in age, BMI, gravidity, parity, type of delivery, previous pelvic surgery, preoperative hCG level and maximum diameter of pregnancy in vNOTES group compared with CL group(P > 0.05) (Table 1).

**Table 2** Perioperative data and Postoperative data

	vNOTES group(n = 29)	CL Group(n=34)	<i>P</i> value (95%c.i.)
Operative time(h)	65.93 ± 27.87	65.73 ± 23.95	0.282(13.37,12.96)
Intraoperative blood loss(ml)	36.38±31.65	31.47 ± 30.76	0.819(20.67,10.85)
Hospital stays after surgery(d)	1.94±0.98	$2.52 \pm 3.56$	0.107(1.86,0.70)
Postopera- tive exhaust time(h)	21.48±2.53	31.29 ± 14.68	< 0.001(4.28,15.34)
VAS scores(points)	0.48±0.83	5.53 ± 1.80	< 0.001(4.32,5.77)

There were no statistically significant differences observed in operation time, intraoperative blood loss, and hospital stays following surgery between the vNOTES group and CL group (P > 0.05). However, the vNOTES group exhibited significantly lower postoperative exhaust time and 24-hour Visual Analog Scale (VAS) scores compared to the CL group (P < 0.001). Additionally, both groups demonstrated negative hCG results one-month post-surgery (Table 2).

## Discussion

Conventional laparoscopy (CL) is widely used in clinic as a classic operation for the treatment of ectopic pregnancy. Because of the potential risks of bleeding, infection, nerve damage, and hernia formation associated with each puncture in CL, people try to reduce the number of puncture holes [9]. The advancement of contemporary medical technology and the widespread adoption of minimally invasive approaches have prompted surgical treatment endeavors to prioritize reduced trauma, diminished pain, and expedited recovery post-surgery [10]. CL is commonly employed in clinic as a traditional procedure for managing ectopic pregnancy. Due to the potential hazards of bleeding, infection, nerve damage, and hernia

**Table 1** Baseline characteristics

	vNOTES	CL	<i>P</i> value(95%c.i.)
	group (n=29)	group (n=34)	
Age(years)	$33.10 \pm 4.42$	33.29 ± 3.94	0.585(1.92,2.30)
BMI (kg/m2)	$22.44 \pm 3.22$	$22.27 \pm 2.86$	0.348(1.79,1.44)
Gravidity(times)	$2.69 \pm 1.73$	$2.15 \pm 1.73$	0.357(1.39,0.31)
Parity(times)	$0.69 \pm 0.85$	$0.68 \pm 0.68$	0.517(0.40,0.40)
Type of delivery (count)			
Nulliparity	14	15	0.109(0.313,2.286)
Natural birth	12	12	0.246(0.467,3.590)
Cesarean section	3	6	0.682 (0.161,2.365)
Previous pelvic surgery (count)	4	7	0.501(0.161,2.365)
Preoperative hCG level(U/L)	4660.68 ± 10250.53	4806.83 ± 611.74	0.097(5606.25,1898.56)
Maximum diameter of the gestation(cm)	$3.20 \pm 0.87$	$2.40 \pm 0.98$	0.514(1.26,0.32)

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formation linked to each puncture in CL, efforts are made to minimize the number of puncture sites. The notion of enhanced recovery after surgery has gained widespread acceptance and is considered the prevailing direction of advancement among surgical professionals [11]. Given its distinctive anatomical structure, the vNOTES approach presents a relatively optimal option for female endoscopic surgery. Consequently, vNOTES may offer several advantages as a surgical approach. The findings of a randomized controlled study conducted by the author demonstrate the safety and feasibility of utilizing vNOTES for gynecological adnexal surgery [12].

Within the vNOTES group, a total of 29 cases were successfully completed without the need for conversion to CL or open surgery. Furthermore, one-month post-surgery, both groups exhibited a 100% negative conversion rate of hCG, indicating the effective removal of ectopic pregnancy through vNOTES surgery. The findings of this study indicate that there was no statistically significant disparity in operation time, intraoperative blood loss, and hospital stays following surgery between the vNOTES group and the CL group (P > 0.05). These results align with the outcomes observed in eight cases of ectopic pregnancy salpingectomy conducted via transvaginal single-hole laparoscopic surgery in 2018 [13]. By combining vaginal and laparoscopic techniques, vNOTES addresses the limitations associated with vaginal surgery, such as restricted operating space and unclear operative field [14]. Nevertheless, it is important to note that surgeons undertaking vNOTES surgery must undergo specific training, encompassing both traditional multi-port laparoscopy experience and proficiency in transvaginal surgery. The anatomical positioning of pelvic organs and adjacent structures as observed through the laparoscopic lens of vNOTES differs from that of traditional laparoscopy, necessitating a specific adaptation process. A study [15] on vNOTES attachment surgery showed that after about 20 cases of vNOTES attachment surgery, the basic operation time tended to be stable, about 40 min. The average duration of the vNOTES procedure in this particular study was recorded as [(65.93 ± 27.87) min]. We considered that it might be related to the repeated intraoperative flushing of the abdominal cavity to remove the accumulated blood, resulting in a longer operation time than ovarian cystectomy or oophorectomy with vNOTES. Furthermore, the average operative time did not exhibit a significant difference when compared to CL. It should be noted that the time required for vNOTES is either equivalent to or even shorter than that of CL, provided a certain level of surgical proficiency has been attained. In this study, the postoperative hCG levels did not exhibit a statistically significant difference between the two groups, suggesting that the efficacy of vNOTES surgery was comparable to that of CL.



Fig. 3 The vaginal wound recovered well 3 months after surgery

vNOTES demonstrated notable benefits in terms of postoperative pain management [16, 17]. In this study, the postoperative VAS scores of the vNOTES group [ $(0.48 \pm 0.83)$  points] was significantly lower than that of the CL group  $[(5.53 \pm 1.80)]$  points, and the difference was significant (P<0.01). Additionally, the surgical site for vNOTES was situated within the pelvic cavity, resulting in limited carbon dioxide gas entry into the abdominal cavity due to uterine occlusion. Consequently, this had minimal impact on intestinal function, leading to a faster recovery compared to the CL group. The duration of postoperative exhaust time in the vNOTES group was found to be significantly lower compared to that in the CL group (P<0.05). The reduced occurrence of severe pain following surgery enables quicker patient discharge, making partial vNOTES a viable option for day surgery. vNOTES also showed an advantage in post-operative wound recovery. And a prospective cohort study showed that the rate of postoperative improvement was higher in the vNOTES group than the CL group at the postoperative first week (87.5% vs. 68.2%, p < 0.05) [18]. The patient underwent a postoperative follow-up examination at the three-month mark, during which it was observed that the vaginal wound had successfully healed and had no discernible impact on her quality of life (Fig. 3). However, it is important to note that there is currently a dearth of comprehensive, multi-center prospective clinical data on the incidence rate of vNOTES manual complications. Compared with CL, vNOTES requires special attention for the following complications: Dinfection, includes incision of the hand, pelvic secondary infection, abdominal abscess and urinary tract infection; 2Adjacent organ damage, mostly bladder and rectum damage. Given that vNOTES involves a retrograde process from bottom to top, it is imperative to adapt the surgical thinking mode to accommodate these changes. The incidence of the aforementioned complications is frequently associated with the operator's expertise, the technical proficiency of single-hole laparoscopic procedures, and the ability to identify retrograde anatomical structures. Particular

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attention should be paid to the exclusion of pelvic adhesions using rectovaginal examination and ultrasonography before confirming the surgical approach, to prevent any adverse impact on patient surgical safety.

## **Conclusions**

In conclusion, transvaginal natural orifice transluminal endoscopic surgery (vNOTES) is a viable option for managing ectopic pregnancies.

#### Abbreviations

vNOTES Transvaginal natural orifice transluminal endoscopic surgery

CL Conventional laparoscopy

BMI Body mass index

hCG Human chorionic gonadotropin

VAS Visual analogue scale

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Not applicable.

#### **Author contributions**

Conceptualization, D.Z. and S.Z.; data curation, S.Z.; writing—original draft preparation, S.Z.; writing—review and editing, D.Z.; investigation, J.Y., B.Z., Q.M., Q.L. All authors reviewed the manuscript.

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## Data availability

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy/ethical restrictions.

## **Declarations**

## Ethical approval and consent to participate

This study was approved by the Ethics Committee of Beijing Hospital (Approval Letter No.2019BJYYEC-250-02). All patients or their legal guardians provided written informed consent for this retrospective study. All methods were carried out in accordance with relevant guidelines and regulations. All experimental protocols were approved by a licensing committee.

## Consent for publication

Written informed consent has been obtained from the patient to publish this paper.

## **Competing interests**

The authors declare no competing interests.

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