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Transvaginal natural orifice transluminal endoscopic surgery-assisted versus transumbilical laparoendoscopic single-site ovarian cystectomy for ovarian mature cystic teratoma. A randomized controlled trial

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ABSTRACT

Objectives: Transvaginal natural orifice transluminal endoscopic surgery (vNOTES) and transumbilical laparoendoscopic single-site surgery (LESS) have shown the prospection as minimally invasive procedures. Here we aimed to compare ovarian cystectomy assisted by vNOTES and by LESS for ovarian mature cystic teratoma (OMCT).

Material and methods: A total of 81 premenopausal women with OMCT were randomized to undergo ovarian cystectomy assisted by either vNOTES (n = 41) or LESS (n = 40). The main outcome was the operative time. Secondary outcomes included the length of hospital stay, visual analog scale (VAS) pain scores, abdominal contamination by teratoma contents, and intraoperative and postoperative complications.

Results: There were no intergroup differences in age, body mass index, tumor size, or bilaterality of tumor. The operative time for the vNOTES group was significantly shorter than that for the LESS group (68.41 ± 20.92 min vs 85.05 ± 32.94 min, p = 0.008). The highest VAS pain score 24 hours postoperatively was 1.21 ± 0.48 in the vNOTES group and 2.43 ± 0.57 in the LESS group (p < 0.001). Twenty-four of the 40 patients in the LESS group experienced teratoma rupture intraoperatively, leading to abdominal contamination by the teratoma content, while 5 abdominal contamination was observed in the vNOTES group (p = 0.005). No significant differences between the two groups were observed in the other outcomes.

Conclusions: vNOTES assisted ovarian cystectomy has short operative time, fast recovery, no scarring, less pain, and low rate of abdominal contamination. Consequently, vNOTES might be superior to LESS for treating OMCTs.

Keywords: laparoendoscopic single-site surgery (LESS), transvaginal natural orifice transluminal endoscopic surgery (vNOTES), ovarian cystectomy, teratoma

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INTRODUCTION

Ovarian mature cystic teratoma (OMCT), one of the most common benign tumors, accounts for 25–40% of ovarian tumors [1, 2]. Ovarian cystectomy is a routine procedure for OMCT in premenopausal women and can be performed by laparotomy, laparoscopy, and through the vagina.

In the past decades, laparoscopic cystectomy has been the primary surgical approach because of its minimal invasiveness and clear vision compared to laparotomy or the transvaginal route. Today, with the increasing demand for less scarring and less invasiveness, transumbilical laparoendoscopic single-site surgery (LESS) and transvaginal natural orifice transluminal endoscopic surgery (vNOTES) have been developed based on conventional multi-port laparoscopic surgery (LAP) [3]. These three procedures, LAP, LESS, and vNOTES are considered safe and feasible in ovarian cystectomy for OMCT treatment [4, 5].

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However, there is limited clinical evidence comparing the differences between these procedures for OMCT removal, especially between LESS and vNOTES. Laparoendoscopic single-site surgery has distinct advantages, such as convenient specimen collection and cosmetic effects [5], but is relatively difficult to operate due to the loss of triangulation when compared to multi-port laparoscopy [6, 7]. Transvaginal natural orifice transluminal endoscopic surgery combines the advantages of NOTES and vaginal approach, which can help access and inspect abdominal cavity through the vagina [4]. Limited evaluations of LESS and vNOTES in ovarian cystectomy for teratoma have been performed. This prospective randomized controlled study was conducted to compare the intraoperative and postoperative outcomes between the two approaches (LESS vs vNOTES) for ovarian teratoma removal to provide evidence for clinical choices.

MATERIAL AND METHODS

Participants

The present study was designed as a randomized controlled study, conducted between March 2020 and March 2022 at a tertiary teaching school. The participant flow chart using CONSORT is summarized in Figure 1. The inclusion criteria were as follows: premenopausal women, preoperative imaging results indicating OMCT, tumor size measured by the largest diameter ranging between 5 cm and 10 cm, CA 125 and AFP within the normal range, and treatment through either LESS or vNOTES. The exclusion criteria were virginity, history of rectal surgery, suspected malignancy, active lower genital tract infection, pregnancy, mental illness impairing communication and follow-up, and failure to provide written informed consent.

The Institutional Review Board of Chongqing Medical University approved the study (File No.: 20200901).The trail (A randomized controlled study of transumbilical and transvaginal single hole laparoscopy in the removal of ovarian teratoma) was registered in Chinese Clinical Trial Registry under www.chictr.org.cn (https://www.chictr.org.cn/bin/project/edit?pid=50016) on 2020-02-29. The registration number is ChiCTR2000030350.

vNOTES procedures

All surgical procedures were performed by one surgeon who started performing vNOTES and LESS in 2017 and had operated on over 500 patients before the study started. The surgeon performed vNOTES-assisted ovarian cystectomy in patients allocated to vNOTES group. The patient was placed in a lithotomy position under general anesthesia. After conventional disinfection, a posterior colpotomy was performed, and access to cul-de-sac was created. A wound retractor was inserted and rotated inward to expand the vaginal incision.

If the tumor could be seen directly after the retractor placement (Fig. 2A), a cystectomy was performed

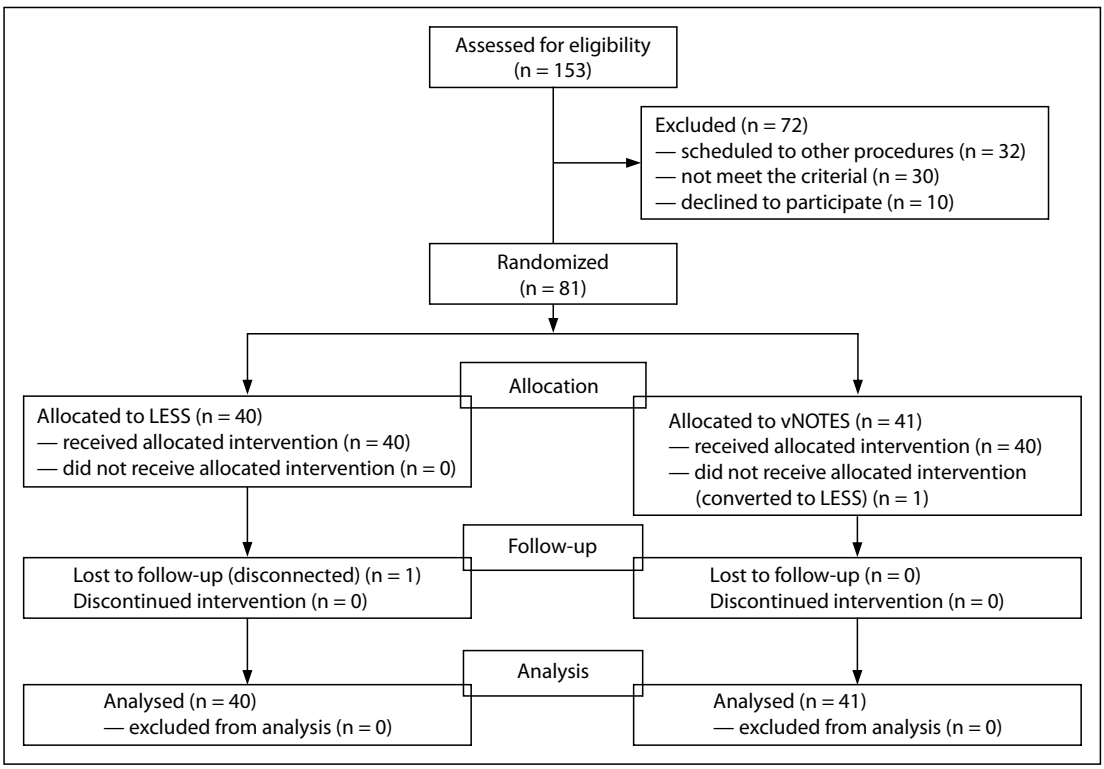

Figure 1. A summary of the study design; LESS — laparoendoscopic single-site surgery; vNOTES — transvaginal natural orifice transluminal endoscopic surgery

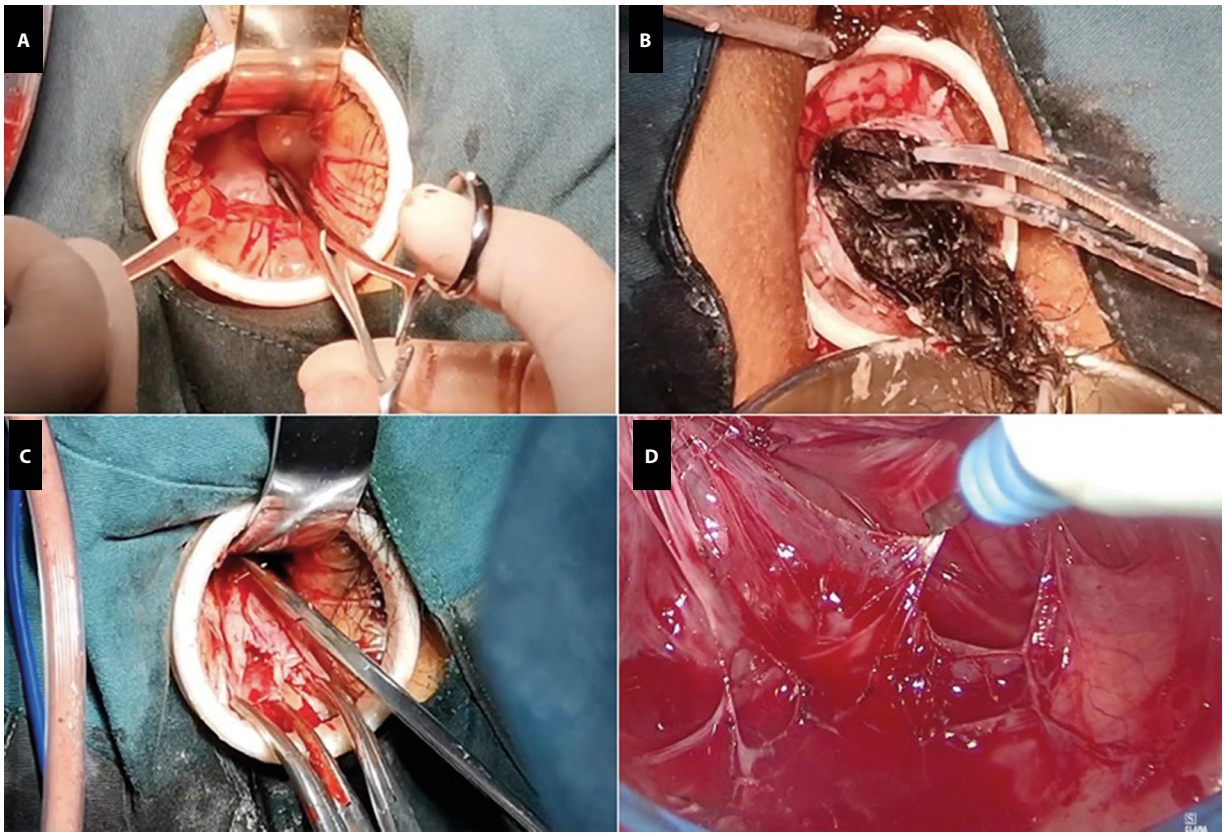

Figure 2. Ovarian cystectomy of ovarian mature cystic teratoma (OMCT) through transvaginal natural orifice transluminal endoscopic surgery (vNOTES); **A.** The teratoma was visible after opening the posterior fornix; **B.** Tumor removal in the vagina without abdominal contamination; **C.** Direct suturing of the ovary as in open surgery; **D.** Adhesiolysis under vNOTES

immediately in the vagina. Briefly, the tumor was pulled down with Allis clamps into the cul-de-sac or vagina. If the mass was too big to be removed intact, controlled drainage of the tumor was achieved by the insertion of a suction needle. If the mass was mainly solid, deliberate rupture of the tumor was performed with scissors or a scalpel. Spillage of the tumor content into the pelvic cavity was carefully avoided during the decompression process (Fig. 2B). Cystectomy and suturing (if necessary) were performed under direct vision as in open surgery in the cul-de-sac or vagina (Fig. 2C), followed by irrigation with saline.

If no tumor was visible in the cul-de-sac, a laparoscopic exploration was performed. A multiple-channel port was attached to the retractor with a pneumoperitoneum pressure of 12 mmHg, followed by laparoscopic exploration to observe the pelvic and abdominal cavity. A 10-mm rigid 30° laparoscope was used. Endoscopic instruments were used to release adhesions when pelvic adhesions were present (Fig. 2D). After the tumor was retracted into the cul-de-sac, the port was removed, and the wound retractor was left in place. A cystectomy was performed as described above.

At the end of the surgery, laparoscopic exploration was performed to ensure the absence of bleeding or other abnormalities. Hemostasis was performed with bipolar when necessary. Then the port and retractor were removed, and the vaginal incision was closed. A catheter was used to empty the bladder, which was then removed. No drainage or indwelling catheter were used. A gauze and a wound dressing were attached to the umbilicus for blinding.

LESS procedures

In the patients assigned to the LESS group, the surgeon performed LESS cystectomy. A 2–2.5 cm vertical umbilical incision was made, followed by the insertion of a wound retractor and placement of a multiple-channel port at the umbilicus. A laparoscope and instruments were inserted through the channels. After abdominal exploration, an ovarian cystectomy and suture (if necessary) were performed, as typical in multi-port laparoscopy. Intraoperative tumor rupture and abdominal contamination were tried to avoid. Additional trocars would be added in cases with intraoperative challenges, such as severe pelvic adhesions. The umbilical incision was closed as described by Park et al. [8]. A catheter was used to empty the bladder and no indwelling urinary catheter was placed, and the umbilical site was covered with the same gauze and wound dressing as that in the vNOTES group.

The baseline characteristics, the intra- and postoperative outcomes and complications were recorded. All the patients underwent routine follow-ups at 1 week, 1 month, and 3 months postoperatively at the outpatient department or by telephone (implemented due to the COVID-19 pandemic).

Outcome measurements

The primary outcome was the operative time, defined as the time from umbilical or vaginal incision to closure. The second outcomes included the length of hospital stay, the highest pain score by visual analog scale (VAS) 24 h postoperatively, abdominal contamination by the teratoma contents (spillage of tumor contents into peritoneal cavity), blood loss, conversion (vNOTES to other access, LESS to additional trocars or other access), passage of flatus reported by patients, and perioperative complications.

Eligible patients were allocated to the vNOTES and LESS groups by random number assignments (0 or 1) generated via an interactive web-based response system (www.randomization.com). Sequentially numbered, sealed envelopes were used to ensure allocation concealment.

To ensure the blinding of participants, care unit personnel, and outcome assessors, identical wound dressings were attached at the umbilical site for all patients in the vNOTES group and the LESS group. For patients with LESS who required additional trocars, the blinding was revealed given the additional incisions. The intraoperative and postoperative care were standardized to avoid potential bias.

Sample size calculation

The present study hypothesized that the operative time for vNOTES is shorter than for LESS. The surgeons' data were retrospectively reviewed. In the LESS group comprising 25 patients, the mean operative time was 91.5 ± 19.7 min, similar to the previous report by Park et al., which was 89.0 ± 30.9 min [9]. The operative time for 22 patients with vNOTES was 78.0 ± 19.2 min, without any prior reports evaluating the same parameter. The estimated sample size was 36 cases to demonstrate the superiority of vNOTES over LESS for the primary outcome (alpha error, 0.05; power, 80%). Considering a potential loss to the follow-up rate of 10%, a minimum of 40 cases should be included in each group.

Statistical analysis

The baseline characteristics and intra- and postoperative outcomes were compared between the two groups. The student's t-test or Mann–Whitney U test was used for normally or non-normally distributed continuous variables, respectively. The Pearson's chi-squared test or Fisher's exact test was used for dichotomous data.

All analyses followed the intention-to-treat principle, in which all the available data were used as initial allocation, irrespective of the level of attendance. All tests were two-tailed, and the significance level of primary outcome was set at $p < 0.05$. The analyses were performed using SPSS version 18.0 software (IBM Corporation, Armonk, NY, USA).

Table 1. The patients' characteristics

Characteristics	LESS (n = 40)	vNOTES (n = 41)	p value
Age [year]	29.35 ± 7.00	29.85 ± 7.122	0.749
Body mass index [kg/m^2]	22.58 ± 3.70	22.73 ± 2.97	0.841
Side			
Left	16 (40.0)	13 (31.7)	0.465
Right	17 (42.5)	23 (56.1)	
Bilateral	7 (17.5)	5 (12.2)	
History of deliveries			
None	26 (65.0)	23 (56.1)	0.681
Caesarean section	7 (17.5)	8 (19.5)	
Vaginal	7 (17.5)	10 (24.4)	
Tumor size [cm]	6.80 ± 1.62	6.54 ± 1.52	0.467

The values are expressed as the mean ± standard deviation or numbers (percentage); LESS — laparoendoscopic single-site surgery; vNOTES — transvaginal natural orifice transluminal endoscopic surgery

RESULTS

A total of 153 patients were assessed for eligibility and 81 patients were eligible for the study and underwent either vNOTES or LESS (Fig. 1). Forty patients were randomized to the LESS group, with one lost in the third-month follow-up. The rest were assigned to the vNOTES group (n = 41) without loss during follow-up. There was no missing data on the primary outcome for any of the patients.

The baseline characteristics are summarized in Table 1. There were no differences between the two groups regarding age, body mass index, delivery histories, tumor size or bilaterality.

The main outcomes of this study are summarized in Table 2. The mean operative time of the vNOTES group was 68.41 ± 20.92 min, significantly shorter than the LESS group [85.05 ± 32.94 min ($p = 0.008$)]. In terms of the intraoperative conversions, one patient initially undergoing vNOTES converted to LESS because of severe pelvic adhesions. In the LESS group, two patients required additional trocars, one had severe pelvic adhesions, and the surgeon had difficulties while suturing in the other. Conversion to open surgery was not observed in either group. The estimated blood loss and postoperative passage of flatus were similar between the two groups. For abdominal contamination, 24 of 40 patients (60.0%) in the LESS group experienced intraoperative teratoma ruptures, which led to abdominal contamination by the teratoma content. In the vNOTES group, teratoma

Table 2. A summary of the main outcomes

Characteristics	LESS (n = 40)	vNOTES (n = 41)	p value
Operative time [minutes]	85.05 ± 32.94	68.41 ± 20.92	0.008
Blood loss [mL]	41.38 ± 43.34	33.17 ± 29.107	0.319
Conversion	2 (5.0)	1 (2.4)	0.616
Abdominal contamination			0.005
No	16 (40.0)	36 (87.8)	
Yes	24 (60.0)	5 (12.2)	
Passage of flatus [hours]	19.44 ± 9.01	15.58 ± 7.57	0.075
VAS pain score 24 hours postoperatively	2.43 ± 0.57	1.21 ± 0.48	0.000
Highest temperature postoperatively ≥ 37.5°C	1 (2.5)	1 (2.4)	0.986
Postoperative complications			0.116
Gastritis	1 (2.5)	0 (0.0)	
Wound infection	2 (5.0)	0 (0.0)	
Length of hospital stay (days)	2.63 ± 0.90	1.71 ± 0.81	0.000

The values are expressed as the mean ± standard deviation or numbers (percentage); LESS — laparoendoscopic single-site surgery; VAS — visual analog scale; vNOTES — transvaginal natural orifice transluminal endoscopic surgery

ruptures happened unintentionally in 5 patients (12.2%) in the cul-de-sac, which led to abdominal contamination. LESS group had higher rate of abdominal contamination by the tumor content than the vNOTES group (p = 0.005). The vNOTES group had lower VAS pain score 24 h postoperatively, and shorter hospital stay than the LESS group. One patient in the LESS group had gastritis, and one had a fever, while one patient in the vNOTES group had a fever.

During follow-up, two patients from the LESS group had incisional site infection and were treated and recovered within one month postoperatively. No patients in either group reported abnormal vaginal bleeding, or dyspareunia at the 1-month and 3-month follow-ups. One patient in the LESS group could not be contacted by telephone at the 3-month follow-up.

DISCUSSION

In the present study, we compared vNOTES and LESS cystectomy for OMCT. To the best of our knowledge, this is the first randomized study comparing vNOTES with LESS in the patients with OMCT. We found that vNOTES assisted ovarian cystectomy was associated with shorter operative time and faster postoperative recovery. Additionally, vNOTES was superior to LESS in terms of postoperative pain and abdominal contamination by the content of teratoma.

Transvaginal natural orifice transluminal endoscopic surgery combines the advantages of vaginal access and the endoscopic approach resulting in no visible scars, complete exploration of the peritoneal cavity, and constant visual control of the adjacent structures. [10–12]. Studies have revealed the advantages of vNOTES, including less postoperative pain and faster postoperative recovery than conventional laparoscopic surgery in adnexectomy, ovarian cystectomy and hysterectomy[13–15]. In the NOTABLE trial by Baekelandt et al. [15], it is reported that vNOTES was associated with shorter operative time and less postoperative pain in adnexectomy when compared with mulitiport laparocopy. Wang et al. [16] reviewed the records of ovarian cysterectomy between vNOTES and mulitiport laparocopy in a case-matched study and found the mean operative time and hospital stay were significantly less for vNOTES group than for laparocopy group. The comparison between vNOTES and LESS was limited. Zhang et al. reported that vNOTES had less postoperative pain and shorter length of hospital stay than LESS for ovarian cystectomy and salpingo-oophorectomy [17]. In addition to the postoperative pain and recovery, the present study is the first to demonstrate the superiority of vNOTES to LESS for ovarian cystectomy in terms of operative time. The creation and closure of colpotomy incisions is relatively easier than an umbilical incision for most gynecologists, as stated by Wang et al. [16] The closure of the posterior fornix usually requires one layer of suture, which could be timesaving compared to LESS, in which at least two layers of sutures are performed for umbilical closure. Cystectomy and the suturing of ovaries is much faster under direct vision than by using laparoscopic instruments. LESS procedures are time-consuming because of the relatively difficult manipulation through one incision, and the suture technique is the most difficult to handle [6, 7]. Extra time is also required to clean up cyst spillage and flush the peritoneum in LESS. All these factors could explain the shorter operative time in the vNOTES group.

Transvaginal natural orifice transluminal endoscopic surgery could act as a "rescue" for vaginal surgery [18, 19].

In the vNOTES group, six patients had pelvic adhesions, which made the tumor unreachable and immobile. It was a common difficulty in traditional vaginal surgeries. Adhesiolysis under vaginal laparoscopy was conducted in these patients. Furthermore, inspection of the abdominal cavity and hemostasis with bipolar under vNOTES also expand the application of vaginal surgery.

Additionally, vNOTES is advantageous for decreasing abdominal contamination compared to LESS or other abdominal laparoscopy [16]. The consequences of benign cyst or tumor spillage remain disputed. Some studies revealed that it was not associated with short- or long-term outcomes [20, 21]. The present study did not find any abnormal outcomes in the patients with tumor rupture. However, a meta-analysis indicated that abdominal contamination by teratoma contents might be related to tumor recurrence [22]. In clinical practice, surgeons should try to avoid abdominal contamination by the tumor content, whether benign or malignant. This is an advantage of vNOTES procedure in the treatment of teratoma. Firstly, cystectomy was performed vaginally under direct vision as in open surgery, which could lower the incidence of tumor rupture, when compared to LESS procedure with laparoscopic instruments. Secondly, with the application of the wound retractor the cystectomy was performed in the cul-de-sac or in the vagina. The teratoma contents were directly removed out of the pelvis, which could minimize abdominal contamination under careful operation.

This study has several limitations. First, this was a single-center trial, and all procedures were performed by one surgeon, thereby restricting the generalizability of the study findings. Second, although the small sample size of the study had reached statistical significance, studies with multiple centers and larger sample size are needed before robust conclusions can be drawn. Finally, the study focused on OMCT, the results of which cannot be extrapolated to other diseases or procedures.

CONCLUSIONS

Aside from leaving no visible scars and being a safe process, vNOTES-assisted ovarian cystectomy is a quicker procedure associated with less pain and better recovery than LESS in patients with OMCT. The positive findings of the present study provide a basis for further multicenter RCTs to establish the benefits of vNOTES compared to traditional laparoscopic surgery or vaginal procedure.

Article information and declarations

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics statement

The study was approved by the ethics committee of Chongqing Medical University.

The trail was registered in Chinese Clinical Trial Registry under www.chictr.org.cn. The registration number is ChiCTR2000030350. Informed consent was obtained from all individual participants included in the study.

Author contributions

Yulin Zhang — data collection and analysis, patients' follow-up;Ying Jia — data collection and analysis, patients' follow-up; Xuelin — conception, data collection and nurse work; Fulan Wang — conception; Yao Gong — conception, surgeon and manuscript writing.

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Conflict of interest

The authors declare there is no conflict of interest.

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