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ORIGINAL ARTICLE

Curative effect of laparoscopic-assisted vaginal radical trachelectomy combined with pelvic lymph node dissection on early-stage cervical cancer

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Summary

Purpose: *The purpose of this study was to explore the safety and feasibility of laparoscopic-assisted vaginal radical trachelectomy (VRT) combined with pelvic lymph node dissection in the treatment of early-stage cervical cancer.*

Methods: *Patients (N=136) with early-stage cervical cancer were divided into VRT group (laparoscopic-assisted VRT combined with pelvic lymph node dissection, n=68) and abdominal radical trachelectomy (ART) group (ART combined with pelvic lymph node dissection, n=68). The operation-related indexes, incidence of postoperative complications and fertility status were compared between the two groups, and the tumor recurrence status was recorded through follow-up. The factors related to recurrence of early-stage cervical cancer were analyzed by one-way analysis of variance and Cox multivariate regression analysis.*

Results: *VRT group had significantly less intraoperative blood loss and significantly shorter postoperative ventilation time than ART group. In VRT group, the length of vaginal resection and the width of parauterine tissue resection were significantly smaller than those in ART group. The pregnancy rate in VRT group (38.6%) was far higher than that in ART group (21.2%) (p=0.041), while the fertility rate had no statistically significant difference between the two groups (90.9% vs. 81.8%) (p=0.641). The results of univariate and multivariate analysis showed that the tumor diameter was an independent risk factor for the recurrence of early-stage cervical cancer (β=0.317, p=0.029, 95% CI=0.484-0.815).*

Conclusion: *VRT is safe and feasible in the treatment of early-stage cervical cancer, which can reduce surgical damage, facilitate postoperative recovery, and effectively preserve the fertility of patients. The tumor diameter is an independent risk factor for the recurrence of early-stage cervical cancer.*

Key words: *vaginal radical trachelectomy, pelvic lymph node dissection, cervical cancer, early stage, curative effect*

Introduction

Cervical cancer is the malignant tumor with a morbidity rate ranking 4th in women. Epidemiology shows that the average age of its onset has dropped by 5-10 years compared with that 10 years ago [1]. According to statistics, about 57.7% of cervical cancer patients in China are younger than 45 years old at the onset, and 42.4% of them have had one baby or have not given birth yet [2]. These patients will lose their fertility after traditional treatments such as extensive hysterectomy and/or radiotherapy [3]. Vaginal radical trachelectomy (VRT) refers to the transvaginal resection of the diseased cervix and parauterine tissues, and the anastomosis between isthmus of uterus and upper vagina, which preserves the fertility of patients with early-stage (Ia1, Ia2 or Ib1) cervical cancer while curing the tumor, and a certain proportion of patients can successfully conceive and give birth after operation [4-

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6]. In the present study, the efficacy and safety of laparoscopic-assisted VRT and abdominal radical trachelectomy (ART) combined with pelvic lymph node dissection were compared in the treatment of early-stage cervical cancer.

Methods

Objects of study

A total of 136 patients with early-stage cervical cancer were selected, and they were aged 24-49 years old, with a median of 35.96 years old. All patients were histopathologically diagnosed with early-stage (Ia1, Ia2 or Ib1) cervical cancer before operation. No tumor infiltration above the internal cervical orifice was found through vaginoscopy, and it was confirmed by preoperative examination that there was no pelvic lymph node or distant metastasis. Patients with adenocarcinoma underwent curettage to exclude endometrial cancer. Exclusion criteria were as follows: 1) patients with a history of pelvic/abdominal surgery or pelvic endometriosis that may cause severe adhesions, 2) those complicated with severe dysfunction in the heart, lung, liver or kidney, coagulation dysfunction, immune system disorders or infectious disease, 3) those complicated with other tumors, or 4) those with neurological dysfunction. According to different treatment methods, the patients were divided into VRT group (treated with laparoscopic-assisted VRT combined with pelvic lymph node dissection, n=68) and ART group (treated with ART combined with pelvic lymph node dissection, n=68). The baseline clinical data had no statistically significant differences between the two groups (Table 1) (p>0.05). All patients were informed of the study in line with the *Declaration of Helsinki*, reviewed by the Hospital Ethics Committee and signed the informed consent.

Treatment methods

In VRT group and ART group, 4 cases and 6 cases in stage Ia1 did not undergo pelvic lymph node dissection but directly received VRT, respectively. The remaining 64 cases and 62 cases in stage Ia2 and Ib1 underwent laparoscopic pelvic lymph node dissection first. The lymph nodes dissected were sent for rapid frozen pathological examination to confirm whether there is lymph node metastasis.

In VRT group, a circular incision was made in the vagina 2-3 cm below the cervix to form an incisal margin of the vaginal cuff, and the cervix was covered and intermittently sutured. The uterovesical space and rectal space were pushed open, the lateral bladder fossa was separated to expose the vesicocervical column, and the vesicocervical ligament was cut off. The exposed ureteral knee and descending branch of the uterine artery were carefully identified, and the cardinal ligament was cut off along the vaginal wall at 2 cm away from the cervix. The cervix was transected at the level of the descending branch of the uterine artery. The cervical tissues resected were sent for rapid frozen pathological examination, followed by suture after the incisal margin was confirmed to be negative. Later, the residual cervical canal was subjected to cerclage with non-absorbable micro line. A small urinary catheter was indwelt in the uterine cavity to prevent cervical adhesions. At last, the vaginal mucosal layer and the uterine serosal layer were intermittently sutured.

In ART group, the ureter was dissociated to the orifice, the lateral rectal fossa and the cervical rectal space

Table 1. Baseline demographic and clinical characteristics of the studied patients

	VRT group (n=68) *n (%)*	*ART group (n=68)* *n (%)*	*p*
Age (years old)	35.14±10.31	36.88±9.93	0.318
BMI (kg/m^2)	22.79±3.13	23.17±3.42	0.501
Pathological type			0.645
Squamous cell carcinoma	49 (72.1)	45 (66.2)	
Adenocarcinoma	11 (16.2)	14 (20.6)	
Adenosquamous carcinoma	8 (11.8)	9 (13.2)	
Tumor diameter (cm)	1.9±0.7	2.1±0.9	0.150
FIGO stage			0.354
Ia1	4 (5.9)	6 (8.8)	
Ia2	16 (23.5)	22 (32.4)	
Ib1	48 (70.6)	40 (58.8)	
Histological grade			0.672
G1	10 (14.7)	12 (17.6)	
G2	46 (67.6)	42 (61.8)	
G3	12 (17.6)	14 (20.6)	

VRT: Vaginal radical trachelectomy; ART: Abdominal radical trachelectomy; BMI: Body Mass Index; FIGO: Federation of gynecology and Obstetrics.

were separated, and the uterosacral ligament was dissociated. After that, the vesicocervical space was separated, the bladder was pushed downward to the external cervical orifice, and the uterine artery was dissociated and exposed. The ureteral tunnel was opened under the uterine artery, and the vesicocervical column was exposed, cut off and ligated. Then the bladder was pushed downward again to 3 cm below the external cervical orifice, followed by RT (the uterosacral ligament was cut off at 3 cm away from the cervix, the cardinal ligament was cut off at 3 cm next to the uterus, and the vaginal wall was circularly cut at 3 cm below the external cervical orifice). The cervix was cut out at 5-8 mm below the isthmus of uterus and sent for rapid frozen pathological examination. If there was no tumor invasion within 8 mm of the stump, routine cervical cerclage was performed after patch reinforcement, and a catheter was indwelt in the uterine cavity to prevent cervical adhesions. The vaginal and cervical stumps were anastomosed, and the cerclage patch was embedded to avoid exposure in the cervix and vagina. Finally, the cardinal and uterosacral ligaments were reinforced by patches, and the uterus was placed back.

Observation indexes

The operation time, intraoperative blood loss, number of pelvic lymph nodes dissected, hospital stay, postoperative exhaust time, length of cervical resection, length of vaginal resection, width of parauterine tissue resection, and the incidence of postoperative complications was recorded in the two groups.

The patients were followed up every 3 months within 2 years after operation, and every 6 months after 3 years until May 2020, as follows: The patients' complaints of discomfort were recorded, and pelvic examination was performed. Next, cytological screening was conducted for the new external cervical orifice, and the patients with abnormal results underwent colposcopic biopsy to exclude recurrence. Those suspected of recurrence next to the uterus or at other sites received MRI or positron emission tomography to exclude recurrence and metastasis. Those with no signs of recurrence after follow-up for more than 6 months were encouraged to conceive. Once successful, they needed reexamination in the pre-delivery high-risk clinic. Patients followed up for more than 1 year without pregnancy were transferred to the reproductive center for infertility diagnosis and treatment, and the corresponding techniques were used to assist pregnancy based on the diagnosis results. At last, the pregnancy rate and fertility outcome were compared between the two groups.

Statistics

SPSS 22.0 software (IBM, Armonk, NY, USA) was used for statistical analysis. Measurement data were expressed as mean ± standard deviation, and t-test was performed for intergroup comparison. Enumeration data were expressed as rate (%), and x^2 test was performed for intergroup comparison. The survival curves were plotted using the Kaplan-Meier method, and log-rank test was performed for survival analysis. The related factors to recurrence were analyzed by one-way analysis of variance and Cox multivariate regression analysis. $p<0.05$ suggested the statistically significant difference.

Results

Comparison of operation-related indexes between the two groups

The operation time was (252.71±66.49) min and (261.83±76.38) min, the number of lymph nodes dissected was (16.16±2.51) and (15.87±2.63),

Table 2. Comparison of indicators related to surgery

	VRT group n=68	*ART group n=68*	*p*
Operation time (min)	252.71±66.49	261.83±76.38	0.459
Blood loss (ml)	284.52±215.49	406.44±239.27	0.002
Number of lymph nodes dissection	16.16±2.51	15.87±2.63	0.512
Length of hospital stay (d)	9.22±2.90	10.18±3.05	0.062
Postoperative ventilation time (d)	1.80±0.57	2.12±0.59	0.002
Cervical resection length (cm)	2.32±0.21	2.33±0.23	0.782
Vaginal resection length (cm)	2.63±0.50	2.89±0.41	0.001
Parametrium tissue resection width (cm)	2.40±0.39	2.72±0.36	0.001
Complications, n (%)			
Incision infection	1 (1.5)	2 (2.9)	0.559
Poor wound healing	1 (1.5)	3 (4.4)	0.238
Cervical stenosis	0 (0)	0 (0)	1.000
Stress incontinence	4 (5.9)	7 (10.3)	0.345
Ileus	4 (5.9)	8 (11.8)	0.227
Lymphocele	5 (7.4)	5 (7.4)	1.000

VRT: Vaginal radical trachelectomy; ART: Abdominal radical trachelectomy.

and the average postoperative hospital stay was (9.67±1.92) d and (10.69±2.02) d, respectively, in VRT group and ART group, showing no statistically significant differences (p=0.459, p=0.512, p=0.062). VRT group had significantly less intraoperative blood loss and significantly shorter postoperative ventilation time than ART group [(284.52±215.49) mL *vs.* (406.44±239.27) mL, (1.89±0.78) d *vs.* (1.97±0.71) d] (p=0.002). The length of cervical resection had no statistically significant difference between the two groups [(2.32±0.21) cm *vs.* (2.33±0.23) cm] (p=0.782). In VRT group, the length of vaginal resection and the width of parauterine tissue resection were significantly smaller than those in ART group [(2.63±0.50) cm *vs.* (2.89±0.41) cm, (2.40±0.39) cm *vs.* (2.72±0.36) cm] (p<0.001). The postoperative complications in the two groups mainly included incision infection, poor incision healing, stress urinary incontinence, intestinal obstruction and lymphatic cyst, and no cervical stenosis, external iliac vein injury and rectal dysfunction occurred. The incidence rate of postoperative incision infection was 1.5% (1/68) and 2.9% (2/68), that of poor incision healing was 1.5% (1/68) and 4.4% (3/68), that of stress urinary incontinence was 5.9% (4/68) and 10.3% (7/68), that of intestinal obstruction was 5.9% (4/68) and 11.8% (8/68), and that of lymphatic cyst was 7.4% (5/68) and 7.4%

Table 3. Comparison of Pregnancy rate and Pregnancy outcome between the two groups of patients

	VRT group (n=68) *n (%)*	*ART group (n=68)* *n (%)*	*p*
Pregnancy rate	22/57 (38.6)	11/52 (21.2)	0.041
Natural Pregnancy	19 (86.4)	9 (81.8)	
ART Pregnancy	3 (13.6)	2 (18.2)	
Pregnancy outcome			0.641
Abortion	2 (9.1)	2 (18.2)	
Premature delivery	6 (27.3)	3 (27.3)	
Full-term delivery	14 (63.6)	6 (54.5)	

VRT: Vaginal radical trachelectomy; ART: Abdominal radical trachelectomy; ART: Assisted reproductive technology.

Table 4. Univariate analysis of predictors for recurrence rate of patients with early-stage cervical cancer

	Cases n=136 *n (%)*	*Recurrence rate (%)* *n (%)*	*x^2 value*	*p*
Age, years			1.716	0.190
≤30	49 (36.0)	8.2%		
>30	87 (64.0)	16.1		
Pathological type			3.662	0.160
Squamous cell carcinoma	94 (69.1)	9.6		
Adenocarcinoma	25 (18.4)	20.0		
Adenosquamous carcinoma	17 (12.5)	23.5		
Tumor diameter (cm)			15.855	0.001
≤2	81 (59.6)	3.7		
2-4	55 (40.4)	27.3		
FIGO stage			5.504	0.033
Ia1	10 (7.4)	0		
Ia2	38 (27.9)	5.3		
Ib1	88 (64.7)	18.2		
Histological grade			31.052	0.001
G1	22 (16.2)	0		
G2	88 (64.7)	6.8		
G3	26 (19.1)	46.2		
Operation method			1.081	0.449
VRT	68 (50.0)	10.3		
ART	68 (50.0)	16.2		

(5/68), respectively, in VRT group and ART group, displaying no statistically significant differences (p>0.05) (Table 2).

Comparison of postoperative fertility status between the two groups

Among 68 patients successfully undergoing VRT, 1 case received radiotherapy due to recurrence at 3 months after operation and she was unable to give birth, and 10 unmarried or divorced cases had no demand for fertility. Among 57 patients followed up for ≥6 months with a demand for fertility, 22 cases successfully conceived, and the pregnancy rate was 38.6%, including 3 cases using assisted reproductive technique and 19 cases of natural pregnancy. A total of 20 patients gave birth to 20 newborns, including 2 cases of early abortion, 6 cases of premature birth, and 14 cases of full-term birth. All of the 20 newborns were delivered by cesarean section, and they all survived healthily, with a fertility rate of 90.9%. Besides, among 52 patients followed up for ≥6 months with a demand for fertility in ART group, 11 cases successfully conceived, and the pregnancy rate was 21.2%, including 2 cases using assisted reproductive technique and 9 cases of natural pregnancy. A total of 9 patients gave birth to 9 newborns, including 2 cases of early abortion, 3 cases of premature birth, and 6 cases of full-term birth. All of the 9 newborns were delivered by cesarean section, and they all survived healthily, with a fertility rate of 81.8%. It was found that the pregnancy rate in VRT group was far higher than that in ART group, with a statistically significant difference (p=0.041), while the fertility rate had no statistically significant difference between the two groups (p=0.641) (Table 3).

Analysis of recurrence status and influencing factors for recurrence in the two groups

As of May 2020, all patients were followed up for 6-36 months, with a median of 29.6 months. There were 7 cases and 11 cases of recurrence, respectively, in VRT group and ART group, with a recurrence rate of 10.3% and 16.2%, showing no statistically significant difference between the two groups (p=0.449).

Age, pathological type, tumor diameter, FIGO stage, histological grade and operation method were included in the univariate analysis of recurrence status. The results showed that the recurrence of early-stage cervical cancer was related to tumor diameter, FIGO stage and histological grade (p<0.05), but it had no correlation with age, pathological type and operation method (p>0.05) (Table 4). The results of multivariate analysis manifested that the tumor diameter was an independent risk factor for the recurrence of early-stage cervical cancer (β=0.317, p=0.029, 95% CI=0.484-0.815).

Discussion

In 1994, Dargent and Maththevet reported and performed VRT for the first time. Then VRT + laparoscopic pelvic lymph node dissection was gradually accepted by patients with early-stage cervical cancer around the world [7]. In 1997, some scholars proposed ART + pelvic lymph node dissection, in which pelvic lymph nodes were dissected first, and then the cervical and parauterine tissues were extensively resected [8]. Relatively speaking, in addition to higher technical requirements for the surgeon and longer learning time, VRT requires good vaginal surgery and laparoscopic techniques, and the parauterine tissue resection is limited and restricted by vaginal anatomy, thus restricting its application. On the contrary, ART is closer to the standard extensive hysterectomy in terms of anatomy, surgical procedures and scope of resection, which can well dissect and push the ureter and dissect parauterine tissues more extensively. Einstein et al. [9] compared the scope of resection between 28 cases of VRT and 15 cases of ART, and found that the average width of parauterine tissue resection was 1.45 cm in VRT and 3.97 cm in ART, showing a statistically significant difference (p<0.01). In this study, it was found that the length of vaginal resection and the width of parauterine tissue resection in ART group were both larger than those in VRT group, consistent with the above conclusions. Therefore, ART has broader indications than VRT and is suitable for larger tumors [10].

In this study, the intraoperative blood loss in VRT group was obviously less than that in ART group, consistent with the report results in most literature. There were no significant differences in operation time and postoperative hospital stay between the two groups. In a study on intraoperative complications of 137 patients undergoing VRT, including 9 cases of bladder injury, 1 case of bowel injury, 1 case of vascular injury and 1 case of ureteral injury, the incidence rate of intraoperative complications is slightly higher than that during extensive hysterectomy [11]. In this study, the incidence rate of complications had no statistically significant difference between the two groups (p>0.05), and no cervical stenosis, external iliac vein injury and rectal dysfunction occurred. Cervical canal stenosis and adhesion is the main complication after RT, with an incidence rate of 27% [12], which can block the passage of sperm after operation, greatly affecting the patient's fertility. According to reports

in foreign literature, this complication can be prevented by intraoperative placement of intrauterine catheters [13]. However, the catheter is highly prone to slipping off and falling off. Therefore, the technique has been improved continuously by Chinese scholars. For example, the tailed T-type intrauterine device was intraoperatively placed in the uterine cavity of patients undergoing ART in Fudan University Shanghai Cancer Center, which can effectively prevent the occurrence of cervical canal stenosis and adhesion [14].

In a report covering 621 patients undergoing VRT, there were 186 cases of pregnancy for a total of 300 times, and the pregnancy rate was about 30% (186/621). The 186 pregnant women gave birth to 190 newborns, obtaining satisfactory results [15]. In another study, there were 35 times (14.9%) of pregnancy among 221 patients undergoing ART [16,17]. It can be confirmed that the pregnancy rate of patients after ART is lower than that after VRT, and the reason may be cervical factors. The residual cervix of patients undergoing ART is shorter than that of patients undergoing VRT, so there is less cervical mucus, easily leading to ascending infection and premature rupture of membranes after pregnancy. In addition, the scope of resection in ART is larger than that in VRT, which may cause the loss of mechanical support around the uterus, thereby resulting in abortion and premature delivery. Moreover, some doctors cut off the uterine artery when performing ART, affecting the blood supply of the uterus and fetal placenta, and some clinicians recommend pregnancy in 2 years. The above factors may be the reasons for the low pregnancy rate and relatively poor fertility after ART.

Dursun et al. [18] retrospectively analyzed the clinical data of 520 patients undergoing RT, and found that the recurrence rate was 5.1% and the mortality rate of patients was 2.8%. Beiner et al. [19] reported that the recurrence rate and the mortality rate after RT were 5.1% and 3.1%, respectively, similar to those after extensive hysterectomy. Therefore, the effect of RT on early-stage cervical cancer is credible. It is currently believed that the tumor diameter is one of the high-risk factors for tumor recurrence. Plante et al. [20] reported that the tumor diameter >2 cm is a high-risk factor for recurrence. Combined with the literature, Beiner and Covens summarized the clinical data of 548 patients, and found that the recurrence rate was 17% in patients with a tumor diameter ≥2 cm, and 2% in those with a tumor diameter <2 cm [19]. In this study, the results of univariate and multivariate analysis manifested that the tumor diameter was an independent risk factor for the recurrence of early-stage cervical cancer (β=0.317, p=0.029, 95% CI=0.484-0.815), consistent with previous reports.

As a retrospective study, this study had certain limitations. The pregnancy rate and fertility status are affected by the patient's own psychological factors, family and social factors, the sample size was small, and the follow-up period was short. Therefore, the fertility status of patients with early-stage cervical cancer after RT remains to be confirmed by large-sample long-term follow-up. The tumor diameter, patient's age and fertility demand should be taken into account when the operation method is selected for patients with early-stage cervical cancer.

Conclusions

VRT is safe and feasible in the treatment of early-stage cervical cancer, which can reduce surgical damage, facilitate postoperative recovery, and effectively preserve the fertility of patients. The tumor diameter is an independent risk factor for the recurrence of early-stage cervical cancer.

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Conflict of interests

The authors declare no conflict of interests.

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