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**Feasibility and safety of two different surgical routes for the eradication of recto-vaginal endometriosis with vaginal mucosa infiltration (Endo-Vag-r study)**

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**Conflicts of Interest statement**

None

## ABSTRACT

**Introduction:** Recto-vaginal endometriosis surgical management needing partial colectomy is a surgically challenging condition and has been associated with a notable risk of major postoperative complications. In the present study we sought to compare feasibility and safety of total laparoscopic (TL) and vaginal-assisted (VA) routes in women affected by symptomatic recto-vaginal endometriosis with vaginal mucosa infiltration scheduled for minimally invasive surgery.

**Material and methods:** Multi-centric, retrospective cohort study on medical records of consecutive reproductive age women submitted to complete macroscopic eradication of symptomatic recto-vaginal endometriosis with vaginal mucosa infiltration between March 2013 and November 2017. The two groups were compared in terms of preoperative data and surgical outcomes. **Results:** 84 women were included in the study (TL=57 and VA=27). The two groups were comparable in terms of preoperative, surgical and postoperative data. The major postoperative complications rate was 5.3% (three out of 57) in TL group and 7.4% (two out of 27) in VA group, without a significant difference. In the TL group we reported one case of bowel anastomosis dehiscence and two cases of pelvic abscess; in the VA group, one case of small bowel perforation after extensive adhesiolysis treated with ileal resection and one case of rectal sub-occlusion after segmental resection and mechanical anastomosis were noticed. **Conclusions:** In women affected by recto-vaginal endometriosis with vaginal mucosal infiltration, perioperative outcomes seem not to be influenced by the surgical route adopted.

## Keywords

rectovaginal endometriosis; laparoscopic route; vaginal-assisted route; minimally invasive surgery; endometriosis surgical treatment; usability

## Abbreviations

RVE: recto-vaginal endometriosis

TL: total laparoscopic

VA: vaginal-assisted

**Key Message:**

Comparison in terms of safety and feasibility of total laparoscopic and vaginal-assisted laparoscopic approach for recto-vaginal endometriosis treatment.

## **INTRODUCTION**

Endometriosis is defined as the presence of endometrial tissue outside the uterine cavity (1). It represents an important cause of morbidity in reproductive-aged women resulting in pelvic pain, pelvic masses and infertility (2;3). The most severe form of the disease is represented by deep infiltrating endometriosis, defined as endometriotic lesions infiltrating pelvic organ wall or retroperitoneal structures (4). Deep lesions are typically multifocal, involving most commonly uterosacral ligaments, upper third of posterior vaginal wall, bowel, bladder and ureters (4-6).

Vaginal endometriosis is defined as infiltration of vaginal wall by the disease. It can be isolated or more commonly associated with an adjacent posterior nodule in the recto-vaginal space and in some cases on the anterior surface of the recto-sigmoid tract (recto-vaginal endometriosis (RVE)) (4;7). RVE incidence is estimated from 3.8% to 37% among women with endometriosis (8;9). Vaginal lesions are characterized by visible red, blue, or hemorrhagic nodules at speculum examination or tender nodules and fibrosis at palpation of the upper third of vagina (10).

Hormonal therapy improves pain symptoms in around two-thirds of women with RVE (7).

However, surgical excision of endometriosis is required in case of pain symptoms resistant to hormonal therapy, complicated disease (bowel or urinary obstruction) or infertility after several assisted reproductive technology cycles. (6;11). Noteworthy, RVE surgical management needing partial colpectomy is a surgically challenging condition and has been associated with a notable risk of major postoperative complications, especially urinary (12) and colorectal ones (13).

RVE with vaginal mucosa infiltration can be isolated and excised using total laparoscopic (TL) or vaginal-assisted laparoscopic route (VA) (8;13-18). Although laparoscopy represents the gold standard for endometriosis treatment, there is no strong evidence to support the best approach in case of RVE.

In the present study, we sought to compare feasibility and safety of the TL and VA routes in women affected by symptomatic RVE with vaginal mucosa infiltration scheduled for minimally invasive surgery.

## **MATERIAL AND METHODS**

## **Study design**

The present study is a multi-centric, retrospective cohort study. Medical records of consecutive reproductive age women submitted to complete macroscopic eradication for symptomatic RVE with vaginal mucosa infiltration between March 2013 and November 2017 were reviewed.

The population included women referring to Department of Gynecology at S.Orsola Academic Hospital in Bologna, Fondazione di Ricerca e Cura Giovanni Paolo II in Campobasso and Fondazione Policlinico Universitario A. Gemelli IRCCS in Rome.

Exclusion criteria were: women < 18 years and > 50 years; history of RVE surgical treatment or hysterectomy; previous or ongoing gynecological neoplastic pathology.

Before surgery, women demographic features and pain symptoms (chronic pelvic pain, dysmenorrhea, dyspareunia, dysuria, dyschezia) were assessed. Pain intensity was evaluated using a 10-cm visual analogue scale (VAS).

All women underwent bimanual and speculum examinations as well as transvaginal and transabdominal ultrasonography performed by skilled operators. When necessary, additional preoperative imaging methods, including multidetector computerized tomography enteroclysis urography or magnetic resonance imaging, were performed to plan surgery (19).

In all centers, women were followed up 30 days after surgery in order to evaluate their general health condition, post-operative pain scores and complications.

## **Surgical procedure**

Women under general anaesthesia were placed in a low dorsal-lithotomy position and a speculum examination was performed in order to identify any vaginal lesions. Adhesiolysis, excision of endometriotic peritoneal implants, ovarian cystectomy and temporary ovarian suspension, when needed, were all performed prior to deep endometriotic nodule removal, as previously published (20-21). The pelvis was examined to verify the presence of deep infiltrating endometriosis with bowel, urinary bladder, utero-sacral ligaments, parametrial or ureteral involvement. Recto-sigmoid endometriosis was removed using a conservative (shaving) or radical (segmental or discoid

resection) approach, as previously published (22). All patients were informed and counseled regarding the risk of bowel resection and the final decision made at time of surgery according to the depth of bowel involvement at macroscopic evaluation. Resections were classified as high/medium (>8 cm), low (5–8 cm), or ultralow (<5cm), according to distance from the anus. When the risk of major rectal complications was present according to intraoperative findings (i.e. low rectal resection associated to posterior colpotomy), a protective ileostomy was considered.

Bladder endometriosis was removed through a partial cystectomy with or without opening of the urinary bladder lumen. As previously stated (23;24), in case of ureteral involvement by endometriosis or surrounding fibrosis, conservative or radical procedures were performed.

All specimens were sent for routine histological examination. Endometriosis was considered histologically confirmed when endometrial glands and stroma were found in the examined specimens.

All surgical procedures were carried out by three surgeons (R.S., M.M., F.C.) with extensive experience on both techniques for the surgical treatment of RVE. Endometriosis severity was defined using the intraoperative classification revised by the American Society for Reproductive Medicine (rASRM) (25).

#### *Total-laparoscopic route*

Total laparoscopic (TL) consisted of complete removal of the RVE nodule, with or without bowel involvement, through laparoscopic approach (Figure 1). After development of pararectal and rectovaginal spaces, the RVE nodule was freed from any adhesions with the uterine cervix and isolated from the adjacent healthy tissue of the vaginal fornix through colpotomy. A pad of gauze wrapped in a surgical glove was placed inside the vagina to prevent loss of the pneumoperitoneum during the vaginal incision. After visual confirmation of vaginal free margins, the vaginal wall defect was closed laparoscopically or vaginally by interrupted or running sutures. In case of bowel involvement, the nodule left attached to the rectum was removed en-bloc through bowel segmental resection or conservative procedures, using the reverse technique according to Kondo et al. (13).

### *Vaginal-assisted route*

The vaginal-assisted route (VA) consisted of the incision and isolation of the affected vaginal area through vaginal approach before laparoscopic entry (Figure 2) (14). In particular, vaginal fornices were exposed by two Breisky specula and the cervix was pulled ventrally by two tenacula. The vaginal wall was cut around the endometriotic nodule with disease free margins through the vaginal route. Then the vaginal nodule was isolated and pushed dorsally, in order to be subsequently removed together with the rectovaginal lesion through the laparoscopic route. The vaginal wall defect was closed vaginally by interrupted sutures.

The study population was divided into two groups, according to surgical approach used to isolate and remove RVE nodule: TL vs VA route. Preoperative, surgical and postoperative data were compared between the two groups. In particular, surgical outcomes included association with other endometriotic lesions, operative time, estimated blood loss, hospital stay, laparotomic conversion rate, number and type of associated surgical procedures and complication rate within 30 days from surgery. The evaluation of complications rate was carried out using the Clavien-Dindo Classification (26).

### **Statistical analyses**

Continuous data were expressed as mean  $\pm$  standard deviation (SD) or as median (range).

Categorical variables were expressed as absolute number and percentages. Univariate comparisons of continuous data were conducted with a 2-sample t test or the Mann-Whitney test for continuous data and a chi-square test or Fisher's exact test for categorical data, respectively. All reported P values were 2-sided, and a P value of less than .05 denoted a significant difference. Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) software version 24.0 (IBM Corp., Armonk, NY, USA).

### **Ethical approval**

The study was approved by the local Ethical Committees (CICOG-31-10-18/180 approved on 31/10/2018) and registered on ClinicalTrial.gov with the following ID number: NCT03744143.



## RESULTS

Eighty-four women meeting the inclusion and exclusion criteria were evaluated for study analysis. During preoperative diagnostic work-up, multidetector computerized tomography enteroclysis urography and magnetic resonance imaging were performed in 24 (28.6%) and 46 (54.8%) patients, respectively. In all cases, vaginal nodule involved the posterior fornix; while lateral vaginal infiltration was observed in 29 (29/84, 34.5%) women. We noticed a significant difference in terms of lateral vaginal infiltration between the two groups [24/52 (46.1%) in TL group vs 5/27 (18.5%) in VA group,  $p=0.03$ ]. Women were divided into two groups: in 57 (67.9%) of them the RVS nodule was removed using TL, while in the remaining 27 (32.1%) the VA approach was performed. The two groups were comparable in terms of demographic and preoperative clinical data (Table 1).

Surgical details are reported in Table 2. The two groups were similar in terms of operative time, estimated blood loss, and concomitant procedures. In only one case laparotomic conversion was needed due to severe adhesion syndrome. In the TL group, 46 women (81%) presented recto-sigmoid endometriosis. Out of them, 24 (52.2%) underwent segmental bowel resection, three (6.5%) underwent discoid resection and 19 (41.3%) shaving technique. Conversely, in the VA group, 20 (74.1%) women had bowel endometriosis requiring in 7 (35%) cases segmental bowel resection and in 13 (65%) shaving technique. There was no statistically significant difference between TL and VA groups concerning bowel surgical procedures adopted.

In all women submitted to VA approach, the vaginal wall defect was routinely closed through vaginal route. Instead, after TL approach, the vaginal wall defect was closed laparoscopically and vaginally in 26 (45.6%) and 31 (54.4%), respectively. In our vision, vaginal route for colporrhaphy was preferred in case of segmental or discoid resection or deep shaving with reinforcing sutures in order to avoid juxtaposition of the vaginal and rectal sutures.

Pathological examinations confirmed endometriosis in all women.

Postoperative data are shown in Table 3. In both groups pain symptoms' severity significantly decreased at one month follow-up. The two groups were comparable for length of hospitalization and postoperative complications. The major postoperative complications rate between TL and VA groups was similar: 5.3% (three out of 57 women) vs 7.4% (two out of 27 women), respectively.

In TL group we reported one case of bowel anastomosis dehiscence and two cases of pelvic abscess; in VA group, one case of small bowel perforation after extensive adhesiolysis treated with ileal resection and one case of rectal sub-occlusion after segmental resection and mechanical anastomosis were noticed.

## **DISCUSSION**

In the present study, we observed no significant difference in terms of safety and feasibility between TL and VA routes for the surgical treatment of symptomatic RVE involving the posterior vaginal mucosa.

Up to date, several retrospective studies evaluated surgical outcomes in women treated for RVE involving vaginal mucosa with or without rectal involvement using a preferred technique (13-17). Chapron et al (15) described 29 women undergoing RVE plus rectal nodule removal using VA laparoscopic route. In particular, they started with laparoscopic route and isolated the RVE nodule from the anterior rectal wall through shaving procedure, leaving it attached to the posterior vaginal fornix (standard or traditional technique). Vaginal colpectomy was then performed including healthy vaginal tissue around the endometriotic nodule. No conversion occurred and they observed only one case (3.5%) of postoperative rectovaginal fistula.

Kondo et al (13) evaluated 75 women affected by RVE with bowel involvement and compared, in these women, surgical outcomes of standard and reverse laparoscopic techniques (35 and 40 women, respectively). During the reverse technique, after isolation of RVE nodule through colpectomy, the posterior nodule attached to the rectum was displaced cranially and removed through colorectal resection or shaving procedure. Authors concluded that the two approaches were similar in terms of operative time, blood loss, laparotomic conversion rate, major intraoperative complications, length of hospitalization, and minor post-operative complications. However, the major post-operative complications rate was significantly higher adopting standard

rather than reverse technique (22.9% vs 5% respectively,  $p=0.002$ ). Furthermore, they noted a restricted range of movements and working space using standard technique.

Possover et al (14) analyzed a group of 34 women undergoing RVE plus rectal nodule removal through VA laparoscopy using reverse technique. In all cases bowel segmental resection was performed. No laparotomic conversion neither major intraoperative complications occurred. Only two women suffered minor anastomotic leakage (5.8%), detected by sigmoidoscopy and healed spontaneously.

Zanetti-Dallenbach et al. (9) were the first to compare, in terms of surgical data, total abdominal/laparoscopic (18 patients) and VA routes (30 women) for RVE plus rectal nodule removal. In all cases the affected bowel was excised using segmental resection. Authors concluded that the combined approach significantly reduced complication rate (10% vs 38.9% respectively,  $p=0.03$ ), hospitalization time in days ( $13.7 \pm 2.7$  vs  $15.8 \pm 3.6$ , respectively,  $p=0.02$ ) and re-hospitalization rate (0 vs 22.2%,  $p=0.02$ ). Conversely, in our study we did not find these statistical differences between TL and VA approaches. These different findings can be explained by the inclusion of women scheduled only for laparoscopic surgery and without constant rectal involvement requiring a bowel resection.

The generalizability of results of the present study is limited by its retrospective design and tertiary center setting with experienced surgeons. Due to the lack of data comparing the two techniques for RVE eradication, in our study the choice of the approach has been essentially based on the surgeons' discretion and preference, case by case. We can hypothesize that lateral vaginal infiltration during speculum evaluation could have influenced surgical choice in favor of TL approach due to proximity to the ureters. However, no significant differences were reported in terms of associated surgical procedures and stages of disease at intraoperative evaluation.

Furthermore, being our study retrospective, it is difficult to directly link the surgical route adopted with iatrogenic complications. After a detailed revision of surgical charts, the surgical approach did not seem to be directly related to peri-operative complications detected during the study period, but to other surgical issues related to this complex multi-visceral surgery.

In our tertiary level centers, the presence of large bowel nodules with high rate of previous conservative rectal surgery and the need for low rectal resections justified the great number of segmental resections and ileostomies performed during the study period.

On the other hand, high volume providers (tertiary hospitals and skilled surgeons) for colorectal surgery for endometriosis are associated to lower incidence of perioperative complications rather than facilities with low volume of activity (27). Feasibility and safety of posterior DIE surgery are strictly related to skills and experience of surgeons.

Lastly, due to limited follow-up time we could have missed delayed major complications. Future randomized controlled trials with long-term follow-up are needed to investigate any differences between the two routes for RVE surgical treatment.

## **CONCLUSION**

In symptomatic women affected by RVE with vaginal mucosal infiltration requiring surgery, total laparoscopic and vaginal-assisted routes were comparable in terms of safety and feasibility.

Women with RVE should be adequately counseled on potential complications associated with this challenging surgery.

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## Tables

Table 1. Preoperative data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach.

Table 2. Surgical data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach.

Table 3. Postoperative data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach.

## Figures

Figure 1. Total-laparoscopic approach: A. Colpotomy via laparoscopic approach; B. RVE nodule removal via laparoscopic route

Figure 2. Vaginal-assisted approach: A. Colpotomy via vaginal route; B. RVE nodule removal via laparoscopic route.



Table 1. Preoperative data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach

	TL (57)	VA (27)	p value
Age (years old), mean $\pm$ SD	36.1 $\pm$ 4.9	34.2 $\pm$ 7.2	0.1
Body mass index (kg/m <sup>2</sup> ), mean $\pm$ SD	22.4 $\pm$ 3.1	21.9 $\pm$ 3.1	0.1
Parity $\geq$ 1, n (%)	3 (5.3)	3 (11.1)	0.8
Previous surgery for endometriosis, n (%)	22 (38.6)	12 (44.4)	0.6
- Ovarian endometriosis	17/22 (77.3)	9/12 (75.0)	0.8
- Deep infiltrating endometriosis	5/22 (22.7)	3/12 (25.0)	
Stage of disease according to rASRM, n (%)			
- Stage III	10/57 (17.5)	9/27 (33.3)	0.1
- Stage IV	47/57 (82.5)	18/27 (66.7)	
Preoperative pain symptoms assessed with VAS, median (range)			
- Dysmenorrhea	8 (2-10)	8 (4-10)	0.9
- Dyschezia	6 (2-10)	4 (2-10)	1
- Dysuria	0 (0-9)	0 (0-10)	0.2
- Dyspareunia	7 (0-10)	7 (2-10)	0.4
- Chronic pelvic pain	8 (1-10)	7 (1-10)	0.4

Preoperative medical therapy, n (%)	46 (80.7)	18 (66.7)	0.1
- Estro-progestinic	30/46 (65.2)	15/18 (83.3)	0.3
- Progestinic	14/46 (30.4)	2/18 (11.1)	
- GnRH agonist	2/46 (4.3)	1/18 (5.6)	

n: number

rASRM: revised American Society for Reproductive Medicine

SD: Standard Deviation

VAS: Visual Analogue Scale

GnRH agonist: Gonadotropin-releasing Hormone Agonist

Table 2. Surgical data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach

	TL (57)	VA (27)	p-value
Operative time (minutes), mean $\pm$ SD	197 $\pm$ 83.4	191.3 $\pm$ 92	0.5
EBL (ml), mean $\pm$ SD	143.9 $\pm$ 66.2	177.8 $\pm$ 78.2	0.8
Laparotomic conversion, n (%)	1 (1.7)	0 (0.0)	1.0
Adenomyosis, n (%)	26 (45.6)	13 (48.1)	1.0
Associated surgical procedures, n (%)			
- Adhesiolysis	57 (100.0)	26 (96.3)	0.1
- Hysterectomy	2 (3.5)	0 (0.0)	1.0
- Excision of endometrioma	25 (43.9)	12 (44.4)	0.5
- Monolateral	16/25 (64.0)	10/12 (83.3)	0.4
- Bilateral	9/25 (36.0)	2/12 (16.7)	
- Salpingectomy	13 (22.8)	6 (22.2)	0.7
- Monolateral	7/13 (53.8)	2/6 (33.3)	0.7
- Bilateral	6/13 (46.2)	4/6 (66.7)	
- Excision of peritoneal endometriosis	36 (63.2)	12 (44.4)	0.1
- Uterosacral ligament nodule removal	32 (56.1)	10 (37.0)	0.1
- Monolateral	18/32 (56.3)	8/10 (80.0)	0.3

- Bilateral	14/32 (43.8)	2/10 (20.0)	
- Ureteral surgery	54 (94.7)	25(92.6)	0.9
- Ureterolysis	33/54 (61.1)	20/25 (80.0)	0.2
-Monolateral	5/33 (15.2)	2/20 (10.0)	0.9
-Bilateral	28/33 (84.8)	18/20 (90.0)	
- Nodule removal	21/54 (38.9)	5/25 (20)	
-Monolateral	19/21 (90.5)	5/5 (100.0)	1.0
-Bilateral	2/21 (9.5)	0 (0.0)	
- Recto-sigmoid nodule removal	46 (80.7)	20 (74.1)	0.4
- Shaving	19/46 (41.3)	13/20 (65.0)	0.2
- Discoid resection	3/46 (6.5)	0 (0.0)	
- Segmental resection	24/46 (52.2)	7/20 (35.0)	
- high/medium	17/24 (70.8)	5/7 (71.4)	1.0
-low/ultra-low	7/24 (29.2)	2/7 (28.6)	
- ileo-cecal resection	1 (1.8)	0 (0.0)	1.0
- ileostomy	9 (15.8)	3 (11.1)	0.7
- Omental flap	2 (3.5)	0 (0.0)	1.3
- Partial cystectomy for urinary bladder nodule	8 (14.0)	3 (11.1)	0.7
- with opening of the urinary	3/8 (37.5)	1/3 (33.3)	0.6

bladder lumen			
- without opening of the urinary bladder lumen	5/8 (62.5)	2/3 (66.7)	
- Lateral parametrial nodule	26 (45.6)	8 (29.6)	0.9
- Monolateral	26/26 (100.0)	7/8 (87.5)	0.2
- Bilateral	0 (0.0)	1/8 (12.5)	
Maximum size of vaginal nodule (cm), mean $\pm$ SD	2 $\pm$ 0.6	2.1 $\pm$ 0.9	0.5
Maximum size of posterior deep nodule (cm), mean $\pm$ SD	4.1 $\pm$ 0.7	4.5 $\pm$ 0.8	0.2

Legend:

n: number

EBL: Estimated Blood Loss

SD: Standard Deviation

Table 3. Postoperative data of the study groups: total-laparoscopic (TL) and vaginal-assisted (VA) approach

	TL (57)	VA (27)	p-value
Hospital stay (days), mean $\pm$ SD	7.2 $\pm$ 3.6	6.9 $\pm$ 3.1	0.4
Complications (Clavien-Dindo classification), n (%)	9 (15.8)	5 (18.5)	0.8
- Grade I	3/9 (33.3)	2/5 (40.0)	0.9
- Grade II	3/9 (33.3)	1/5 (20.0)	
- Grade IIIa	0 (0.0)	0 (0.0)	
- Grade IIIb	3/9 (33.3)	2/5 (40.0)	
Pain symptoms assessed with VAS at 1-month follow-up, median (range)			
- Dysmenorrhea	0 (0-9)	0 (0-8)	0.9
- Dyschezia	0 (0-9)	0 (0-8)	0.9
- Dysuria	0 (0-2)	0 (0-4)	0.6
- Chronic pelvic pain	0 (0-7)	0 (0-7)	0.9

Legend:

n: number

SD: Standard Deviation

VAS: Visual Analogue Scale



Figure 1



Figure 2

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