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Robotic-assisted conservative excision of retrocervical-rectal deep infiltrating endometriosis: a case series

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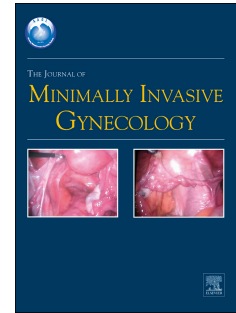
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1 TITLE PAGE

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3 TITLE

4 **Robotic-assisted conservative excision of retrocervical-rectal**  
5 **deep infiltrating endometriosis: a case series**

6

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22 Conflict of interest

23 All the authors (Alfredo Ercoli, Emma Bassi, Stefania Ferrari, Daniela Surico, Anna Fagotti,  
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25 interest and have nothing to disclose.

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## 42 PRECIS

43 The promotion of safe and less aggressive surgery with an aim to better spare organ function in the  
44 treatment of retrocervical-rectal endometriosis, by robotic conservative surgery

45

## 46 KEYWORD

47 Deep infiltrating endometriosis; Colorectal endometriosis; rectal nodulectomy; robotic-assisted  
48 laparoscopy

49

## 50 ABSTRACT

51 Deep infiltrating endometriosis (DIE) is a complex disease that impairs the quality of life and the  
52 fertility of women. Colorectal DIE accounts for 70% to 93% of all the intestinal endometriotic sites  
53 and frequently needs a surgical approach. However, the indications for the surgical management of  
54 this condition are still controversial. From March 2010 to June 2014, we scheduled 33 consecutive  
55 patients presenting with retrocervical-rectal DIE of any diameter not involving the mucosa nor  
56 producing rectal stenosis > 50% for laparoscopic robotic assisted nerve-sparing rectal nodulectomy  
57 (LRN). All patients were examined preoperatively, 3 and 6 months post-operatively and yearly  
58 thereafter. Dysmenorrhoea, dyschezia, dyspareunia and dysuria were evaluated with a 10-point  
59 visual analogue scale. 31 out of 33 (93.9%) enrolled patients fulfilled the selection criteria and were  
60 submitted to LRN. In 1 out of 31 (3.2%) available patients a segmental bowel resection was  
61 considered necessary for prudential purpose at the end of the nodulectomy procedure. No  
62 laparotomic conversion was performed in any case. A large variety of associated surgical  
63 procedures were performed in 25 out of 30 (83.3%) patients. No intraoperative complications were  
64 observed. We recorded one grade 3b and 2 grade 1 post-operative complications. The mean larger

65 axis of the excised nodules measured on the formalin fixed specimen was 26.4 mm. We found a  
66 significant improvement of patient symptoms at 3 months follow-up which persisted over the time.  
67 We observed 2 (6.7%) recurrences of intestinal endometriosis and one (3.3%) recurrence of chronic  
68 pelvic pain without clinical and/or radiological evidence of endometriotic lesions. The mean follow  
69 up time was 27.6 months. We believe that LRN is feasible, safe and show promising results in  
70 terms of radicality, anatomical recurrence rate and pain recurrence rate for treating isolated  
71 retrocervical-rectal DIE not involving the mucosa, without limiting this procedure to nodule smaller  
72 than 3 cm.

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74 TEXT

75

76 INTRODUCTION

77 Endometriosis is complicated by bowel involvement in 8-12% of affected patients (1), in particular  
78 the rectum and rectosigmoid junction together account for 70% to 93% of all intestinal  
79 endometriotic sites (2). Surgical treatment is often necessary because of the relatively high failure  
80 rate of hormonal treatment due to scar tissue caused by the fibrotic component of the lesions (3).  
81 However, the best surgical approach in case of deep infiltrating endometriosis (DIE) involving the  
82 rectum is still debated (4,5), with two different surgical attitudes confronting: the definitive  
83 approach, based on segmental colorectal resection and the conservative approaches that do not  
84 anticipate bowel resection (6). The conservative approaches include both the so called shaving  
85 procedure, which consists in the excision of the portion of the endometriotic nodule exceeding the  
86 linear profile of the intestinal wall, and the nodulectomy, which consists in the radical excision of  
87 the nodule along with the involved rectal wall with the consequent possibility of a full thickness  
88 resection of the rectal wall itself (7). Unfortunately, it is not possible to design adequate prospective

89 randomized trials for surgical management of DIE of the bowel because of the heterogeneity of this  
90 disease and its related symptoms.

91 Interestingly, in a recent review by De Cicco et al. the authors reported that among 612 bowel  
92 specimens from segmental resections for colorectal DIE, 23% had infiltration of the submucosa, 6%  
93 had mucosal infiltration while in the remaining 71% the infiltration was limited to the muscularis  
94 and serosa (8). These data suggest that the vast majority of the patients with rectal DIE without  
95 mucosal involvement could be radically treated with nodulectomy with a minimal risk of  
96 complications assuming that the submucosal layer is respected. In fact, the integrity of the  
97 submucosa is the main determinant for avoiding post-operative rectal perforation and fistulization  
98 which are the most dangerous and disappointing complications, for both surgeon's and patients, in  
99 this type of surgery (9). Our previous experience (10) in the laparoscopic robotic treatment of  
100 colorectal DIE showed us the potential of this approach to perform a precise excision of  
101 endometriotic lesions from the rectal wall aided by the 3-D view and the possibility of modulating  
102 the axis of the robotic instruments. Based on these observations and our previous experiences, we  
103 developed a surgical technique to performing a laparoscopic robotic-assisted nerve-sparing  
104 nodulectomy (LRN) intended to completely remove the endometriotic lesion and the muscular  
105 layers of the rectal wall involved respecting the integrity of the rectal mucosa. We then decided to  
106 propose LRN to those patients presenting retrocervical-rectal DIE nodule of any diameter involving  
107 the muscular portion of the rectal wall but not the mucosa in the pre-operative evaluation and we  
108 prospectively evaluated the perioperative results and the clinical outcome.

109 In this paper we analysed the feasibility and the results obtained in the first 33, consecutive, selected  
110 patients presenting the above mentioned characteristics and scheduled for LRN and removal of all  
111 other sites of superficial and/or deep infiltrating endometriosis eventually associated with a median  
112 follow-up exceeding 30 months.

113 MATERIALS AND METHODS

114 From March 2010 to June 2014 all patients with suspected retrocervical-rectal DIE candidate to  
115 surgery admitted to the Department Gynecologic Surgery of the Policlinico Abano Terme and to the  
116 Division of Gynecologic Oncology of the Catholic University of the Sacred Heart were routinely  
117 submitted to standard preoperative evaluation including: bimanual clinical examination, interview  
118 about endometriosis-related symptoms, transvaginal ultrasound scan, pelvic MRI with rectal  
119 opacification with ecographic gel and fecal occult blood test. Endometriosis-related symptoms  
120 including: dysmenorrhea, dyschezia, dyspareunia and dysuria were evaluated with a 10-point visual  
121 analog scale (0 absent, 10 unbearable) and gastrointestinal symptoms were assessed as well.  
122 Additional double contrast barium enema and rectocolonoscopy were performed in case of rectal  
123 stenosis or suspicious sigmoid stenosis at MRI and in case of positive fecal occult blood test,  
124 respectively. Patients with rectal mucosal involvement at rectocolonoscopy and patients with rectal  
125 stenosis > 50% or simultaneous rectal and sigmoid stenosis of any degree at double contrast barium  
126 enema were candidate for colorectal segmental resection and were excluded from the study. From  
127 March 2010 to June 2014, 33 consecutive patients presenting rectal endometriotic nodules not  
128 involving the mucosa nor producing rectal stenosis > 50% as the only preoperative evidence of  
129 intestinal endometriosis out of 112 (29%) examined were scheduled for LRN and radical removal of  
130 all other sites of superficial/deep infiltrating endometriosis.

131 Patients ate a fiber-free diet for 3 days before surgery. The day before surgery, all patients received  
132 a mechanical bowel preparation with 3 L of polyethylene glycol. Prophylactic antibiotic therapy  
133 with cefazolin 2 g was given at the beginning of the operation and was maintained for 1 to 3 post-  
134 operative days according to surgeon discretion. The operation time was calculated from skin  
135 incision to the last stitch applied, and estimated blood loss was calculated by measuring aspirated  
136 blood volume.

137 In the post-operative period, the patients had clear fluids for 12 h and started eating a fiber-free diet  
138 24 h after the procedure. We recorded the day of first bowel movements with evacuation and the  
139 day of valid spontaneous voiding (with 2 consecutive post void residual < 50 cc) after surgery. Peri-

140 operative complications were recorded according to Dindo's classification (11). Post-operative  
141 hormonal therapy, consisting of continuous low-dose monophasic oral contraceptives (choice at the  
142 discretion of the surgeon), was prescribed in all cases with the exception of 5 patients seeking  
143 pregnancy. We collected the follow up for all patients at 3 and 6 months post-operatively and yearly  
144 thereafter with pelvic examination, a clinical interview regarding symptoms and a pelvic ultrasound  
145 scan. In case of clinical and/or instrumental suspicion of DIE relapse (defined as a symptomatic  
146 pelvic nodule), a pelvic MRI with and without contrast was planned.

147 LRN technique

148 The robotic-assisted procedure was performed with the patient in a gynecologic position under  
149 endotracheal general anesthesia. A bladder catheter was placed to empty the bladder and control the  
150 urine output, and a uterine manipulator was placed through the cervix to manipulate the uterus. All  
151 the procedures were performed through open laparoscopy technique through an umbilical access.  
152 After induction of pneumoperitoneum and insertion of the robotic videolaparoscope, we explored  
153 the entire abdominal cavity to evaluate the extension of endometriotic lesions and then two robotic  
154 trocars (8 mm) and two assistant trocars (5 and 12 mm) were introduced (Fig. 1). Then robot  
155 docking was performed with the primary surgeon controlling the robot remotely from the console.  
156 The robotic instruments used during the procedure included monopolar scissors or a hook, a bipolar  
157 forceps and one large needle holder. All the procedures were performed with a nerve-sparing  
158 approach mediated by our previous studies on female pelvic surgical anatomy and radical pelvic  
159 surgery for neoplasia (12-13).

160 The surgical approach to the retrocervical-rectal nodule started with the identification of the  
161 presacral fascia containing the hypogastric nerves just caudal to the sacral promontory and their  
162 dissection from the rectal fascia and the uterosacral ligaments up to the cross with the uterine  
163 arteries and, if necessary, the deep uterine veins so as to bilaterally develop the Okabayashi  
164 pararectal spaces. In this way the fibrous component of the uterosacral ligaments were exposed in



165 their portion in proximity of the uterus and they could be resected along with the rectal nodule in a  
166 nerve sparing fashion, if necessary. At this point, we entered into the rectal fascia cranial to the  
167 endometriotic nodule on both sides of the rectal wall and we dissected the lateral rectal walls from  
168 the nodule up to completely expose the dorsal vaginal wall caudal to the nodule itself, so as to leave  
169 the latter attached to the uterus and vagina only in its retrocervical area (Fig. 2A). Then, we  
170 separated the ventral rectal wall from the endometriotic nodule by the monopolar scissors or the  
171 hook, with and without energy, following the edges of the nodule paying attention to remove the  
172 macroscopically infiltrated muscular portion of the rectal wall but leaving intact the mucosa (Fig.  
173 2B). Different types of rectal probes have been useful to keep the rectum in tension during the latter  
174 action. When the rectum was completely freed, the endometriotic nodule was resected en bloc with  
175 the uterosacral ligaments and/or the vagina, if necessary; the resection was performed through the  
176 monopolar scissors or the hook (Fig. 2C) and extracted by the vagina or into a bag through the optic  
177 trocar. At the end of the LRN procedure, cold knife biopsies at 12, 3, 6 and 9 o'clock of the edges  
178 of the excised rectal wall were performed in selected cases in order to verify the absence of  
179 microscopic residual endometriotic tissue. In the end, one or two layers of 00 vycril interrupted  
180 sutures placed in the same direction of rectal axis were put to reinforce the rectal wall and ensuring  
181 the hemostasis.

## 182 Statistical analysis

183 The data analysis was done on surgical details including operative time, estimated blood loss and  
184 days of hospitalization as well as on intraoperative and post-operative complications, pathological  
185 details and follow-up records. Student t-test was used to compare the outcomes regarding evaluation  
186 symptoms after checking the normal distribution of values. A p-value <0.01 was used to assess  
187 statistical significance. Data analysis was performed using MedCalc 12.5 (MedCalc Software,  
188 Ostend, Belgium).

## 189 RESULTS

190 The mean age and BMI of the 33 enrolled patients were 37 years (SD 4.91) and 21.9 (SD: 2.18),  
191 respectively. The study population was homogeneous also for the other parameters, as parity, race,  
192 previous therapy and previous surgery (data non shown). Eight (24.2%) of these patients had  
193 previous pelvic surgery for endometriosis (only cystectomies or peritoneum biopsies for mild  
194 endometriosis). At preliminary surgical abdominal exploration, 31 out of 33 (93.9%) enrolled  
195 patients fulfilled the selection criteria and were submitted to LRN and eradication of others, non  
196 intestinal sites of DIE as planned preoperatively, while 2 (6.1%) patients showing additional, not  
197 radiologically detected, endometriotic nodules involving the sigmoid were excluded from the  
198 following analysis. In 1 out of 31 (3.2%) patients (with nodule of 32 mm), a segmental bowel  
199 resection was considered necessary at the end of the nodulectomy procedure because of the  
200 extensive devascularization of the rectal wall. This patient was excluded from the following  
201 analysis. Table 1 shows the surgical data concerning the 30 patients submitted to LRN. No  
202 laparotomic conversion was performed. A large variety of associated surgical procedures were  
203 performed in 25 out of 30 (83.3%) patients; in particular we performed 11 (42.3%) extensive  
204 ureterolysis and 8 (26.6%) full thickness vaginal resection (Table 1). No intraoperative  
205 complications were observed and, in particular, we did not have any case of inadvertent rectal  
206 perforation during the LRN procedure. None of the patients had temporary ileostomy or colostomy.  
207 None of the patients required blood transfusion either intra and/or post-operatively (data not  
208 shown). Table 2 shows the main peri-operative clinical data. The mean larger axis of the excised  
209 nodules measured on the formalin fixed specimen was 26.6 mm (SD: 9.43). In 9 (33%) patients 4-  
210 quadrants cold knife biopsies were performed on the rectal wall edges at the end of the LRN  
211 procedure at the beginning of our experiences; all of the performed biopsies resulted negative for  
212 endometriosis. In particular, we recorded one grade 3b complication consisting of a case of  
213 hemorrhage with hemoperitoneum due to the partial rupture of one uterine artery in the second day  
214 post-surgery, which required a second laparoscopic surgery for assuring effective hemostasis and

215 performing a pelvic-toilette, and 2 grade 1 complications consisting of a periumbilical hematoma of  
216 30 mm of diameter and one case of paralytic ileus, resolved in 2 days with medical treatment.

217 During the follow-up time (mean: 27.6 months, range: 10-48, SD: 16.69) we observed 3 treatment  
218 failures out of the 30 (10%) treated patients, consisting of 2 (6.7%) recurrences of intestinal  
219 endometriosis, one of which with recurrent pelvic pain and dyspareunia, and one (3.3%) with  
220 recurrence of chronic pelvic pain and with clinical and radiological evidence of endometriotic  
221 lesions (nodule of uterosacral ligament of 18 mm). All these recurrences occurred after at least 12  
222 months from surgery, in patient with original endometriotic nodule of 24.6, 26.6 e 31.2 mm,  
223 respectively. One additional patient (3.3%) developed an asymptomatic “de novo” bladder  
224 endometriotic nodule of 20 mm of larger axis 12 months after surgery. In the remaining 26 (86.7%)  
225 patients we found a significant improvement of symptoms at 3 months follow-up which persisted  
226 over the time for all the investigated parameters (Table 3).

## 227 DISCUSSION

228 In this paper we report the surgical technique and the peri-operative and long term results of LRN in  
229 a large, homogeneous series of consecutive patients with retrocervical-rectal endometriotic nodule  
230 of any volume not involving the mucosa nor producing rectal stenosis > 50% associated or not, with  
231 other non intestinal localizations of DIE. Our results show that in this specific patient’s setting,  
232 LRN is feasible, without major complications and show promising results. First of all, the fact that  
233 the procedure was performed in all but one enrolled patients independently from previous surgery  
234 for endometriosis, clearly demonstrates the feasibility of this technique. Only in 1 out of 31 (3.2%)  
235 cases, at the beginning of our experience, we decided to perform a segmental rectal resection at the  
236 end of the LRN procedure because of the extensive devascularization of the rectal wall, but is  
237 independent from the large axis of nodule (32 mm). Interestingly, our results showed that LRN was  
238 feasible in all patients enrolled independently from the dimension of the nodule. It has been  
239 suggested by several authors the necessity for segmental rectal resection in rectal nodules larger

240 than 3 cm in order to avoid significant distortion of the bowel axis and subsequent stricture (14).  
241 However, in our experience we found that LRN was always feasible independently from the  
242 dimensions of the nodule obtaining endometriosis-free margins without significant complications.  
243 So we obtained a radical treatment with a more conservative approach, and this is desirable in the  
244 treatment of endometriosis. These results could be obtained in our opinion thanks to the high  
245 surgical precision obtainable by combining the three dimensional vision with the freeness of  
246 movement of robotic instruments. The safety of the technique is suggested by the median operative  
247 time, the median time of hospitalization and the low perioperative complications rate we observed  
248 in our series of patients that are similar to those reported for rectal shaving surgery using  
249 conventional laparoscopy which nowadays is reputed as the correct approach to rectal  
250 endometriosis with the lower complications rate (15-16). It is of particular relevance the absence, in  
251 our series, of complications related to rectal surgery such as perforations, abscesses and/or fistulas  
252 considering the high rate of vaginal resections (27%) and ureterolysis (43%) in our series, which are  
253 well recognized risk factors for these complications when performed along with rectal surgery (17).  
254 Indeed, the absence of bladder and/or rectal postoperative dysfunctions demonstrate the substantial  
255 preservation of pelvic innervation. It is our belief that the highly precise surgery obtainable by  
256 robotic assistance could be the main determinant for achieving these excellent results in terms of  
257 safety of the procedure as we hypothesized in the first place to explain the feasibility of LNR.  
258 As far as the effectiveness of this approach is concerned, from an anatomico-pathological point of  
259 view, we observed that the macroscopic appearance of radical nodule excision always corresponded  
260 to microscopical absence of endometriotic tissue in the biopsies performed at the 4 cardinal edges  
261 of the excised lesion in all patients we tested. Supporting these data there is the low rate of  
262 anatomical intestinal DIE recurrence (6.7%) we found during the long follow-up time in the studied  
263 population. From the point of view of patient's symptoms, we found a significant improvement of  
264 all the parameters investigated at 3 months follow-up which persisted during the follow-up time.  
265 Severe pelvic pain recurrence was observed in only 6.7% of the cases. This data matches the

266 outcome of bowel resection for intestinal DIE reported in literature to range from 6 to 24% (8).  
267 These favorable results in terms of both anatomical recurrence and pain recurrence rates may be  
268 explained, in our opinion, by the preservation of the nerves during the nodule excision and by the  
269 radical resection of the endometriotic lesions.

270 In conclusion, our results suggest that LRN could represent an adequate approach for treating  
271 isolated retrocervical-rectal DIE not involving the mucosa without limiting this procedure to nodule  
272 smaller than 3 cm. We think that additional researches in larger series of patients are needed in  
273 order to define the role of LRN in the treatment of bowel endometriosis.

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322

323 Figure legend

324

325 Fig 1 Trocars Position

326 ● 10-12 mm trocars    ▲ 8 mm robotic trocars;    ■ 5 mm trocar

327

328 Fig. 2: Surgical approach:

329 (A) Left Okabayshi pararectal space and left lateral rectal wall dissections; (B): Dissection of  
 330 the nodule from the ventral rectal wall; (C): Resection of the nodule from the retro-cervical area.

331 - - - - Endometriotic nodule; □ Uterosacral ligament partially resected; ■ Uterosacral ligament;  
 332 + Presacral fascia; ● Mesorectum; → Rectum; U Ureter; § Dorsal vaginal wall; ----- Nodule  
 333 attached to uterosacral ligament

334

Table 1: Surgical data

| <b>Variable</b>                                       |                |
|---|----------------|
| Operative time, min: mean (SD)                        | 189.83 (42.21) |
| Docking time, min: mean (SD)                          | 23.83 (7.4)    |
| Estimated blood loss, ml: mean (SD)                   | 169 (80.74)    |
| Additional surgical procedures, n (%)                 | 25 (83.3)      |
| Full thickness vaginal resection, n (%)               | 8 (26.6)       |
| Ureterolysis, n (%)                                   | 11 (42.3)      |
| Monolateral salpingo-oophorectomy, n (%)              | 5 (16.6)       |
| Mono-bilateral ovarian cystectomy, n (%)              | 16 (53.3)      |
| Adenomyosis nodule resection, n (%)                   | 2 (6.6)        |
| Myomectomy, n (%)                                     | 3 (10)         |
| Mono-bilateral uterosacral ligaments resection, n (%) | 25 (83.3)      |

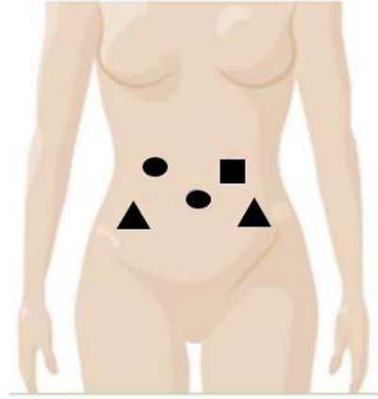


Table 2: Post-operative findings

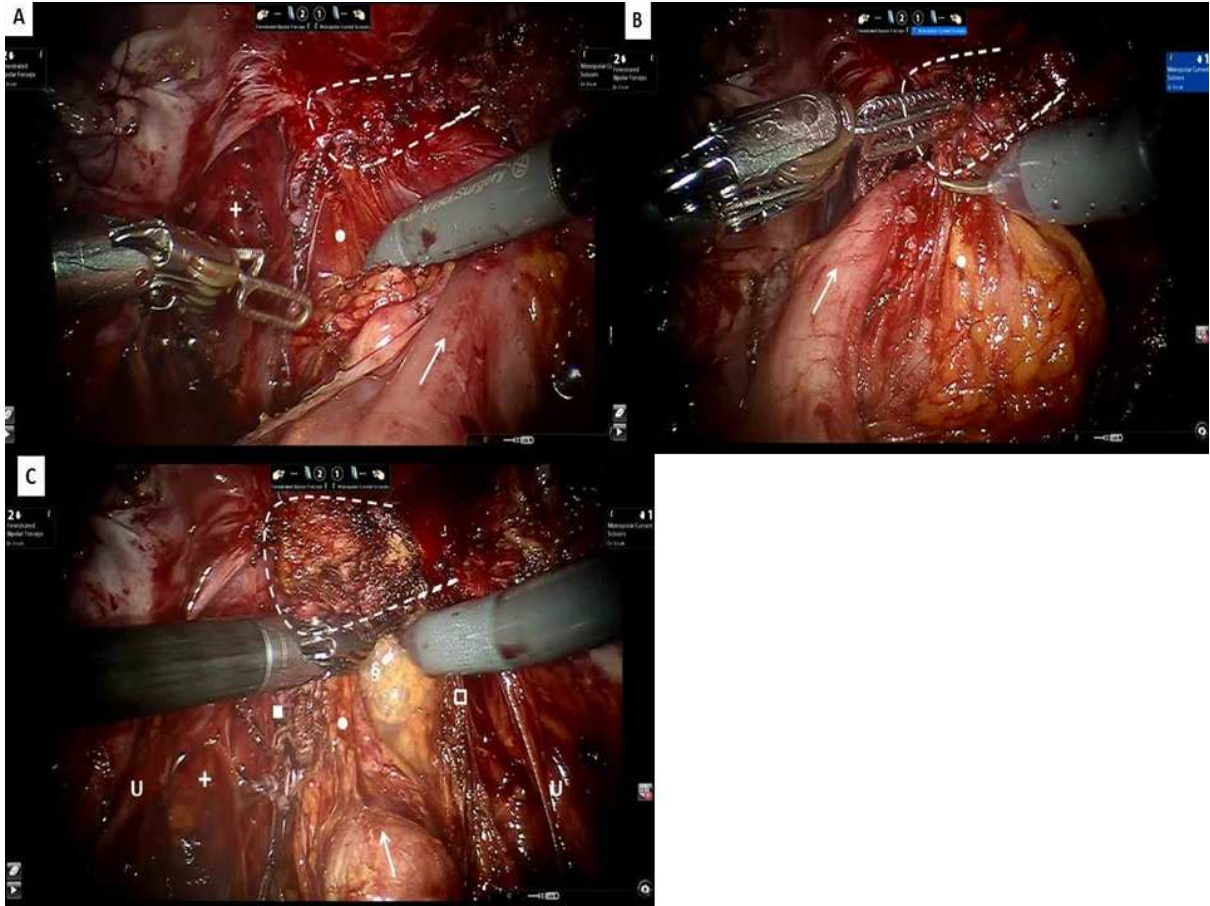
| <b>Variable</b>                                  |                                 |
|--|---------------------------------|
| Hospital stay, days: mean (SD)                   | 4.43 (2.06)                     |
| Time to resume urinary function, days: mean (SD) | 1.3 (0.47)                      |
| Time to resume bowel function, days: mean (SD)   | 3.33 (1.18)                     |
| Perioperative complications                      |                                 |
| ≥ grade 3, n (%)                                 | 1 (3.3)                         |
| type of complication                             | hemoperitoneum                  |
| grade 1, n (%)                                   | 2 (6.7)                         |
| type of complication                             | (1 hematoma, 1 paralytic ileus) |

Table 3: Pre and Post-operative symptoms at last follow-up (mean: 27.6 months) on 10-point analog rating scale.

| <b>Symptom</b>                 | <b>Pre-op</b> | <b>Post-op</b> | <b><i>P</i></b> |
|--------------------------------|---------------|----------------|-----------------|
| Dysmenorrhea, mean (SD)        | 7.63 (2.49)   | 2.4 (2.42)     | < 0.01          |
| Deep dyspareunia, mean (SD)    | 6.26 (2.93)   | 2.76 (3.21)    | < 0.01          |
| Dyschezia, mean (SD)           | 4.73 (3.05)   | 1.1 (1.34)     | < 0.01          |
| Dysuria, mean (SD)             | 2.06 (2.7)    | 0.66 (0.8)     | < 0.01          |
| Chronic Pelvic Pain, mean (SD) | 4.5 (2.4)     | 1.63 (2.15)    | < 0.01          |



ACCEPTED MANUSCRIPT



PRECIS

The promotion of safe and less aggressive surgery with an aim to better spare organ function in the treatment of retrocervical-rectal endometriosis, by robotic conservative surgery

ACCEPTED MANUSCRIPT