

Comparison of robotic versus conventional laparoscopy for the treatment of colorectal endometriosis: Pilot study of an expert center

Marjolaine Le Gac, Clément Ferrier, Cyril Touboul, Clémentine Owen, Alexandra Arfi, Anne-Sophie Boudy, Aude Jayot, Sofiane Bendifallah, Emile

Daraï

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1	Comparison of Robotic versus conventional laparoscopy for the treatment of colorectal
2	endometriosis: pilot study of an expert center
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4	Marjolaine Le Gac ¹ , Clément Ferrier ¹ , Cyril Touboul ^{1,2,3} , Clémentine Owen ¹ , Alexandra
5	Arfi ¹ , Anne-Sophie Boudy ¹ , Aude Jayot ¹ , Sofiane Bendifallah ^{1,2,3} , Emile Daraï ^{1,2,3} .
6	
7	1. Department of Gynecology-Obstetrics and Medicine of Reproduction, Hôpital Tenon,
8	Sorbonne University, Assistance Publique des Hôpitaux de Paris.
9	2. Groupe de Recherche Clinique in endometriosis (GRC-6 Sorbonne University), Centre
10	Expert En Endometriose (C3E).
11	3. UMRS-938 Sorbonne University
12	
13	
14	
15	
16	Corresponding Author
17	Professor Emile Daraï,
18	Department of Gynecology-Obstetrics, Hôpital Tenon, Sorbonne University, Assistance
19	Publique des Hôpitaux de Paris
20	4 rue de La Chine 75020 Paris France
21	e-mail : emile.darai@aphp.fr

22 Abstract:

Introduction: Surgical management of deep endometriosis with colorectal involvement remains an option after failure of medical treatments. Conventional laparoscopy is currently considered the standard approach for surgical treatment. Recently, assisted-robotic laparoscopy emerged as an alternative to conventional laparoscopy but with low evidence.

Methods: From March 2019 to September 2019, we conducted a prospective cohort study of 48 patients undergoing a surgical treatment for colorectal endometriosis (rectal shaving, discoid excision or segmental resection). The interventions were either performed by robotic or conventional laparoscopy. Patients' characteristics, operative and post-operative data were compared between the robotic and the conventional laparoscopic group.

32 Results: 48 patients were included, 25 in the conventional laparoscopy group and 23 in the 33 robotic group. Patients' characteristics and operative findings were similar between the two 34 groups, except for a trend in a higher incidence of associated surgical urinary or digestive 35 procedures in the robotic group (p=0.06). The mean total surgical room occupancy time and 36 operating time were longer in the in the robotic group $(281 \pm 97 \text{ min vs } 208 \pm 85 \text{ min})$; 37 p=0.008) and $(221 \pm 94 \text{ min vs } 163 \pm 83 \text{ min } (p=0.03)$, respectively. The mean intra operative 38 blood loss, the incidence of intra operative, post-operative complication (according to 39 Clavien-Dindo classification) rates and voiding dysfunction were similar in the two groups. The rate of grade III complication was higher in the robotic group (13% vs 0%) without 40 41 reaching a significance (p=0.17). The mean hospital stay was 8 ± 4.4 days in the robotic 42 group and 6.5 ± 2.6 days in the conventional laparoscopy group (p=0.18).

43 Conclusion: Despite our initial experience in robotic surgery, our results support that robotic
44 surgery is an adequate alternative to conventional laparoscopy for endometriosis colorectal
45 resection.

- 47 Keywords: Endometriosis; Colorectal endometriosis; Laparoscopy; Robotic surgical
 48 procedures.

52 INTRODUCTION

Endometriosis is a chronic disease, characterised by the presence of glands and endometrial stroma outside the uterus, affecting up to 10% of women ^{1 2 3}. Deep endometriosis (DE) is defined by the infiltration of anatomical structures and organs beneath the peritoneal surface by endometriotic tissue. DE with colorectal involvement is considered one of the most severe and complex form with an impact on the quality of life and fertility ^{4 5}.

58 The rectum and the rectosigmoid junction are the most common locations representing over 80% of all bowel endometriosis ⁶ ⁷. Surgical management of DE with colorectal 59 involvement remains an option after failure of medical treatments ⁸⁻¹⁰. Colorectal resection for 60 61 endometriosis has demonstrated its efficacy on gynecological, digestive and urinary symptoms, fertility, as well as on quality of life ⁸ ⁹. However, colorectal resection expose 62 63 patients to the risk of severe complications such as rectovaginal fistula, anastomotic dehiscence, pelvic abscess and voiding dysfunction imposing a share making decision with 64 the patients according to their priorities $^{12-18}$. 65

66 Conventional laparoscopy is currently considered the standard for endometriosis 67 colorectal resection thanks to its advantages on intra and postoperative complications, hospital 68 stay and short recovery compared to open surgery ^{11,19-21}. Recently, assisted-robotic 69 laparoscopy emerged as an alternative to conventional laparoscopy although its superiority 70 remains questionable in gynecological surgery ¹⁰⁻¹¹. In the specific setting of colorectal 71 endometriosis, few small studies and case reports have been published to compare assisted-72 robotic to conventional laparoscopy ^{12 13}.

Therefore, the aims of the present pilot study from an expert center in endometriosis
were to evaluate and to compare safety, intra and postoperative complications and short

- 75 postoperative outcomes of robotic to conventional laparoscopy for endometriosis colorectal
- resection on a series of 48 patients operated on the short period of 6 months.

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79 MATERIEL AND METHODS

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81	From March 2019 to September 2019, we conducted a prospective cohort study of
82	patients undergoing a colorectal resection for endometriosis at Tenon University Hospital,
83	Expert Centre in Endometriosis (CE), Groupe de Recherche Clinique in endometriosis
84	Sorbonne University (GRC-6 SU), Paris, France.
85	Patients

The inclusion criteria were patients over 18 years-old, after failure of medical treatment or with infertility; with a preoperative diagnosis of DE with colorectal involvement confirmed by transvaginal ultrasonography, magnetic resonance imaging (MRI), and rectal echo endoscopy (REE) using previously published criteria ¹⁴⁻¹⁵, schedule for colorectal resection. Patients with DE without proved colorectal endometriosis or requiring an Assisted Reproductive Technique (ART) and refusing bowel surgery were excluded of the study. Patients with prior colorectal surgery were also excluded.

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94 <u>Surgical Procedure</u>

In February 2019, the hospital was equipped with the da Vinci Surgical System Si
(Intuitive Surgery). The two surgeons began to perform colorectal procedures in March 2019,
after being trained specifically in robotic surgery, between September 2018 and February
2019. The surgeons specific-procedure (conventional laparoscopy for rectal endometriosis)
volume per year is 40-50 cases.

100 During the study period, the interventions were either performed by robotic or 101 conventional laparoscopy depending on availability of robotic room without criterion to select

patients according to the extent of the lesions neither prior surgery for endometriosis as thesurgery was planned one year ago.

The surgery was performed under general anesthesia. An indwelling urinary catheter was 104 105 placed and an intrauterine manipulator. For robotic surgery, an umbilical incision was done 106 to create a pneumoperitoneum using a Veress needle. Then an 8 mm umbilical trocar was 107 placed for endoscope. On the same horizontal line, a 12 mm trocar was placed at the right side 108 for harmonic scapel or automatic stapler and an additional 8 mm trocar on right flank for 109 grasping forceps. On the left side an 8 mm trocar was placed for bipolar forceps and an 110 additional classic 5 mm trocar for suction/irrigator device. For conventional laparoscopy, surgery was performed as previously described ¹⁶. 111

112 All the robotic and conventional laparoscopic colorectal resections were performed by 113 surgeons (ED, SB) with an experience of at least 150 laparoscopic colorectal resections. All the robotic and conventional laparoscopic colorectal resections were performed with the 114 objective of complete resection, as previously described ¹⁶⁻¹⁷. Procedures included adnexal 115 116 surgery (ovarian cystectomy or salpingo-oophorectomy), uterosacral ligament, torus 117 uterinum, parametrium, partial colpectomy, hysterectomy, ureterolysis; and ureteral 118 reimplantation when required. The first step of the surgery consisted in exploring the 119 abdomen, mobilizing the colorectum to evaluate the size and extension of the bowel 120 endometriosis, identifying critical structures, and determining whether it was multicentric or 121 multifocal. For segmental resection, the ureter was identified crossing the pelvic brim and 122 mobilization was continued inferiorly to open the pararectal space. The mesocolon was then 123 opened and dissection extended down to the pararectal space. The space posterior to the 124 rectosigmoid mesocolon was opened. During this dissection the anterior branches of the 125 hypogastric plexus were identified, allowing a nerve-sparing surgery.

126 Depending on the evaluation of the size and extension of the bowel endometriosis, three 127 types of colorectal resection could be performed: rectal shaving, discoid excision or 128 segmental resection. Rectal shaving was performed for lesions with superficial serosal rectal 129 infiltration. A discoid excision was performed for lesions infiltrating the rectal muscularis less 130 or equal to 3 cm in length and involving less than 90° of the bowel circumference. Performed 131 either by standard laparoscopy or robotic surgery, the steps of a discoid excision procedure 132 were identical. Segmental resection was performed for colorectal endometriosis over 3 cm or 133 involving more than 90° of the bowel circumference or for multifocal lesions ¹⁸. Segmental 134 resections require a laparotomy step. The bowel is extracted through a supra-pubic mini-135 laparotomy incision, and resected. Then, a purse is created for the anvil and the colon is 136 reintroduced inside the peritoneal cavity before closing the supra-pubic incision. Rectal 137 anastomosis was performed by introducing an automatic stapler in the rectum. Except for the 138 skin incisions, trocars localization and the docking procedure in the robotic group, the 139 surgical steps were identical either performed by robotic or conventional laparoscopy.

Indication of laparotomic conversion were technical difficulties or major
intraoperative complication. The creation of ileostomy was performed for patients requiring
partial colpectomy when interposition of prevesical peritoneal was not feasible ¹⁹⁻²⁰.
Colorectal endometriosis was histologically confirmed in all the patients.

144 Statistical analysis

The following patient characteristics were recorded: age, body mass index (BMI),
parity, previous surgery, details of surgical procedure performed and preoperative symptoms.
The American Society for Reproductive Medicine score and Enzian score were systematically
calculated ²¹.

Postoperative complications were classified according to the Dindo-Clavien classification system as minor (grade I-II) or major (grade IIIA and IIIB-IV), and compared between the two surgical groups. Voiding dysfunction was defined by the need of intermittent bladder self-catheterization when postvoid residual urine volume was greater than 100 millilitres. Persistent voiding dysfunction is defined by urinary dysfunction lasting more than 1 month. The population was divided into two groups according to the surgical route i.e. robotic or conventional laparoscopy group.

156 Univariate analysis was performed using the Student's t test for normally distributed data

157 and Chi Square test for categorical data were used the Wilcoxon test for continuous variables

and the Fisher exact test for categorical variables. All reported p values were 2-sided.

159 Significant difference was denoted when p<05. All statistical analysis was performed using
160 commercially available software (Stata/IC 14.0).

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170 RESULTS

171 Epidemiologic characteristics of the study population

During the study period, 48 patients were included, 25 in the conventional laparoscopygroup and 23 in the robotic group.

174 No difference was found in epidemiologic characteristics between the groups Table 1. 175 The mean age was 36 ± 7 years in the robotic group and 37 ± 8 years in the conventional 176 laparoscopy group (p=0.60). No difference in the rate of prior surgery was found between the 177 groups (65% vs 52%, p=0.35). No difference in the rate of prior surgery for endometriosis 178 was found between the groups (43% vs 28%, p=0.26).

The mean ASRM score was 98 ± 49 in the robotic group and $86 (\pm 49)$ in the conventional laparoscopy group, respectively (p=0.39). The mean Enzian score was 0.9 in the robotic group and 0.8 in the conventional laparoscopy group for the A classification, 2.1 and 1.9 for the B classification, and 1.5 and 1.4 respectively for the C classification.

183 <u>Surgical findings and intra-operative complications.</u>

Characteristics of the surgical procedures are presented in the Table 2. There was no difference between the groups regarding the type of rectal procedure. In the robotic group, 8 patients (35%) underwent a shaving, 6 patients (26%) a discoid excision, and 8 patients (35%) a segmental resection. In the conventional laparoscopy group, 10 patients (40%) underwent a shaving, 4 (16%) a discoid resection and 11 patients (44%) a segmental resection. In the robotic group 6 (26%) underwent a hysterectomy and 11 (44%) in the conventional laparoscopy group. A trend for a higher incidence of associated procedures was noted in the robotic group (p=0.06) (i.e. 2 (9%) partial bladder resection, 1 (4%) ureteral resection and 2
ileo caecal resection (9%)).

Anastomotic leakage diagnosed by leak test was observed in two patients (9%) in the robotic group requiring an immediate second rectal resection and anastomosis (none in the conventional laparoscopy group). Intraoperative complications occurred in two cases in the robotic group consisting in one vaginal opening and one incomplete resection by discoid excision requiring a segmental resection and one bladder injury in the conventional laparoscopy group (p=0.5).

An ileostomy was performed in three cases (13%) in the robotic group for colpectomy in two cases and rectal and ileocecal resection in one case. Ileostomy was required in six cases (24%) in the conventional laparoscopy group for low rectal anastomosis in two cases, colpectomy in two cases, excision of the Douglas pouch peritoneum and double resection in one case each. No difference in ileostomy was noted between the groups.

204 The mean total surgical room occupancy time were 281 ± 97 min in the robotic group 205 and 208 ± 85 min in the conventional laparoscopy group (p=0.008). For the robotic group, 206 mean docking time was 18 min. The mean total operating time were 221 ± 94 min in the 207 robotic group and 163 ± 83 min in the laparoscopic group (p=0.03). The mean intra operative 208 blood loss was 130 ± 86 ml and 108 ± 99 ml in the robotic and in the conventional laparoscopy group, respectively (p=0.43). None of the patients required transfusion during or 209 210 after the surgery. No conversion to laparotomy was needed. In the robotic group, no 211 conversion to conventional laparoscopy was needed.

212 Postoperative complications

213 The mean hospital stay was 8 ± 4.4 days in the robotic group and 6.5 ± 2.6 days in the 214 conventional laparoscopy group (p=0.18). Postoperative complications occurred in 6 cases in 215 the robotic group, with three major complications requiring a radiological or surgical 216 treatment (grade III complication according to Clavien-Dindo classification): one recto-217 vaginal fistulae treated by ileostomy with spontaneous healing, one deep pelvic abscess and 218 one parietal evisceration. No major complications occurred in the conventional laparoscopy 219 group. Immediate postoperative voiding dysfunction was noticed in one case in the robotic 220 group and four cases in the conventional laparoscopy group (p=0.22). Voiding dysfunction 221 requiring a bladder self-catheterization more than 1 month after surgery was noticed in one 222 case in each group. The proximal and distal margins of the resection were confirmed to be in 223 sano in 14/15 patients (93%) in the robotic group and in 12/15 (80%) in the conventional 224 laparoscopy group (p=0.27).

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228 DISCUSSION

The results of the current pilot study support that robotic surgery is a reliable alternative to conventional laparoscopy for the surgical treatment of colorectal endometriosis. Although no difference in intra and postoperative complications were noted between the groups, operating time was higher in the robotic group.

233 To our knowledges, no data comparing robotic to conventional laparoscopy for the 234 surgical treatment of deep endometriosis with colorectal involvement are available. In the 235 present pilot study, most patients underwent a conservative surgery consisting in a rectal 236 shaving or discoid resection (58%) while a radical surgery consisting in a segmental resection 237 was required in 42% of cases without difference between the groups. Although the current 238 study is not randomized, it is important to note that no selection for robotic or conventional 239 laparoscopy was done on preoperative characteristics as the route was based on the assess to 240 the robotic room. Indeed, for the department of gynecology, robotic room was reserved once a 241 week and twice a week every other week for the patients who were previously scheduled for 242 colorectal surgery at one year. Finally, none of the patients refused a robotic approach.

243 Only few previous studies with small sample sizes, long periods of inclusion and high heterogeneity in endometriosis are available ^{3 22 23 24 25}. In a cohort of patients with severe 244 245 endometriosis, Nezhat et al. observed longer operating time for robotic compared to 246 conventional laparoscopy (251 min vs 173 min; p=0.0005) but without difference in intra and postoperative complications and in hospital stay ²⁶. In our study, patients in the robotic and in 247 248 the conventional laparoscopy groups had similar epidemiological characteristics (age, BMI, 249 prior surgery for endometriosis) and similar extent in endometriosis as proved by the values of ASRM and ENZIAN scores. However, a trend for a higher rate of associated surgical 250

procedures was noted in the robotic group (p=0.06) including ileocecal resection, partial
bladder resection or ureteral resection.

253 As previous studies, we observed a higher operative time in the robotic group (281 254 min versus 208 min; p=0.008). Even when excluding the docking time (18 minutes on 255 average), the robotic route was longer with a mean difference in operating time of 40 minutes. 256 Our results are in agreement with those of a Cochrane review showing that robotic 257 gynecologic procedures (hysterectomy and sacrocolpopexy) were 40 minutes longer than 258 conventional laparoscopy but including the docking time ¹² ²⁷. Therefore, a better criterion is 259 probably the total surgical room occupancy time that was also higher for the robotic group 260 (281 min vs 163 min, p=0.03). However, in the current study, the difference in both operating 261 and surgical room occupancy time could be also explained by different parameters. First, a 262 trend for a higher rate of associated surgery in the robotic group. Second, the initial 263 experience of the two operators in robotic surgery. Indeed, using the CUSUM methods on 264 operating time, a previous study on robotic rectal resection for cancer showed that the phase 3, representing the mastery phase, was achieved after 25 cases 28 . 265

266 Except operating time, the crucial criterion to compare robotic and conventional 267 laparoscopy is the incidence of complications. Using the Clavien-Dindo classification, the 268 intra and postoperative complication rates were similar between the groups. However, a 269 higher rate of grade III complication was found in the robotic group although not reaching 270 significance (13% versus 0%). As for operating time, this could be explained by both the rate 271 of associated procedures and the limited experience of surgeons in robotic with subsequent 272 trend for a slight increase in hospital stay (8.0 versus 6.5 days) and in rehospitalization (9% 273 versus 0%). Moreover, our complications rate is in agreement with those of a recent meta-274 analysis on laparoscopic colorectal resection for endometriosis involving 38 series with 3079 275 patients ²⁹. Finally, our rate of voiding dysfunction, that is one of the most frequent postoperative complication not taken into account by the Clavien-Dindo classification, was
particularly low in the robotic group (4%) compared to previous studies affecting up to 20%
of the patients underlying the feasibility of robotic nerve sparing surgery ^{16 30 31}.

279 Many advantages of the robotic techniques were already underlined: greater view with the 280 three-dimensional visual system, motion range allowed by the articulated instruments, filtration of any natural tremor of the surgeon ^{32 33}. Then, we won't attribute the higher 281 282 proportion of associated procedure in the robotic group to the better 3D visualisation. 283 Moreover, robotic procedure confers ergonomic advantages and the ability to sit. Robotic 284 procedures appear to be associated with less fatigue for surgeons. However, advantages on 285 intra- and postoperative complications, quality of life, patient's satisfaction on incisions and 286 medico-economic have to be evaluated. In our population, all the associated procedures were 287 planned before the surgery.

288 Some limits of the current pilot study deserve to be underlined. First, our data 289 corresponded to the initial experience in robotic of two experienced surgeons in laparoscopic 290 colorectal resection for endometriosis that might be a source of bias especially concerning 291 operating time and complication rate. Second, the number of patients included in the two 292 groups was relatively low but on a short period reflecting the recruitment of an expert centre 293 operating on severe forms as proved by the high rate of associated procedures to colorectal 294 endometriosis. Graham et al reported their experience on robotic colorectal resection for 295 endometriosis on 15 patients operated on a period of three year with an incidence of severe complications in one-third of the population ³⁴. Similarly, on a series of 10 cases of robotic 296 297 colorectal resection for endometriosis on a period of two years, Morelli et al reported similar complication rate³. However, a recent study by Bendifallah and al underlined that the risk of 298 299 complications after colorectal resection for endometriosis by conventional laparoscopy was higher for center with an hospital volume of less than 20 cases per year and for surgeons with
less than 8 procedures per year ³⁵. Third, despite the small sample size, the advantage of the
current study is offering data for power calculation for further trials. Finally, due to the short
follow-up, it was not possible to evaluate according to the groups changes in symptoms,
quality of life, sexual function and fertility outcomes.

305 Despite the limits of the present pilot study, our results support that robotic surgery is 306 an adequate alternative to conventional laparoscopy for endometriosis colorectal resection. 307 Further studies are required to explore the non-inferiority of robotic surgery regarding 308 postoperative complications. Moreover, potential benefit for the patient should be 309 investigated.

310

С	Robotic group (n=23)	Conventional	p-value
		Laparoscopy group	
		(n=25)	
Age, years mean (± SD)	36 ± 7	37 ± 8	0.60
BMI,kg/m2 mean (± SD)	25 ± 3	25 ± 4	0.91
Prior abdominal surgery, n	15 (65%)	13 (52%)	0.35
(%)			
Prior surgery for	10 (43%)	7 (28%)	0.26
endometriosis, n (%)			
Pregnancy before surgery, n	9 (39%)	11 (44%)	0.73
(%)			
Live birth before surgery, n	6 (26%)	9 (36%)	0.46
(%)			
Infertility, n (%)	9 (39%)	9 (36%)	0.82
-MRI	23 (100%)	25 (100%)	1
-Rectal endoscopic sonography	13 (57%)	9 (38%)	0.19
-Entero MRI	10 (43%)	8 (32%)	0.41
-Cystoscopy	3 (13%)	1 (4%)	0.26
MRI ENZIAN classification			
A, mean	0.9	0.8	0.92
B, mean	2.1	1.9	0.51
C, mean	1.5	1.4	0.75
Indication for surgery, n (%)			0.77
-Pain	14 (61%)	15 (60%)	
-Infertility	2 (9%)	1 (4%)	
-Pain and infertility	7 (30%)	9 (36%)	

313 Table 1: Epidemiologic and imaging characteristics of the study population

	Robotic group (n=23)	Conventional	p-value
		Laparoscopic group	
		(n=25)	
ASRM score	98 (±49)	86 (±49)	0.39
Rectal procedure			0.69
-Shaving	8 (35%)	10 (40%)	
-discoid resection	6 (26%)	4 (16%)	
-Segmental resection	9 (39%)	11 (44%)	
Size of digestive resections			
cm			
-Discoid resection	4 (±1)	4.8 (±1.3)	0.69
-Segmental resections	12 (±4,1)	11 (±4,7)	0.60
Free-margins digestive	14/15 (93%)	12/15 (80%)	0.27
resections			
Sigmoid resection	3 (13%)	3 (12%)	0.91
Ureterolysis	23 (100%)	25 (100%)	1
Torus resection	21 (91%)	25 (100%)	0.74
Uterosacral ligament	21 (91%)	25 (100%)	0.74
resection (uni or bilateral)			
Hysterectomy	6 (26%)	11 (44%)	0.20
Parametrium resection (uni	11 (48%)	15 (60%)	0.40
or bilateral)			
Salpingectomy (unilateral or	4 (17%)	3 (12%)	0.57
bilateral)			
Urinary and/or digestive	5 (22%)	1 (4%)	0.06
associated procedures			
- Cecal resection	1 (4%)	1 (4%)	0.95
- Ileocecal resection	2 (9%)	0	0.13
- Partial bladder	2 (9%)	0	0.13
resection			
- Ureteral resection	1 (4%)	0	0.29
Partial colpectomy	6 (26%)	4 (16%)	0.39
Endometrioma fenestration	9 (39%)	13 (52%)	0.42
Protective ileostomy	3 (13%)	6 (24%)	0.30

319 Table 2: Surgical characteristics according to robotic and conventional laparoscopy groups

- 325 Table 3: Intra operative and postoperative complications and voiding dysfunction according
- 326 to robotic and conventional laparoscopy groups.

	Robotic group	Conventional	p-value
	(n=23)	laparoscopic group	
		(n=25)	
Operative outcomes			
-Total surgical room occupancy time	281 ± 97	208 ± 85	0.008
(min)	221 ± 94	163 ± 83	
-Total operating time (min)	0	0	0.03
-Conversion for laparotomy	2 (9%)	1 (4%)	1
-Unsatisfying leak test requiring a second			0.50
resection-anastomosis.	130 ± 86	108 ± 99	0.43
-Blood loss (ml)	0	0	1
-Transfusion			
Post-operative outcomes			
-Hospital stay (day)	8.0 ± 4.4	6.5 ± 2.6	0.18
-Post-operative complication	6 (27%)	4 (15%)	0.31
Grade of complications (Clavien-Dindo			
classification)			0.43
I	1 (4%)	1 (4%)	
П	2 (9%)	3 (12%)	
IIIa	1 (4%)	0	
Шь	2 (9%)	0	
IV	0	0	
-Rehospitalization	2 (9%)	0	0.13
-Voiding dysfunction requiring bladder	1 (4%)	4 (16%)	0.22
self-catheterization			
<1 month	0	3 (12%)	
>1 month	1 (4%)	1 (4%)	

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