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ORIGINAL RESEARCH ARTICLE

Comparison of perioperative outcomes between standard laparoscopic and robot-assisted approach in patients with rectosigmoid endometriosis

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Abstract

Introduction: Robot-assisted laparoscopic surgery (RALS) has gained widespread application in several surgical specialties. Previous studies on the feasibility and safety of RALS vs standard laparoscopy (S-LPS) for rectosigmoid endometriosis are limited and reported conflicting data. This study aims to compare S-LPS and RALS in patients with rectosigmoid endometriosis in terms of perioperative surgical and clinical data.

Material and methods: This is a multicentric, observational, prospective cohort study including 44 patients affected by rectosigmoid endometriosis referred to two tertiary referral centers for endometriosis from September 2018 to September 2019. Patients were divided into two groups: 22 patients underwent S-LPS, and 22 underwent RALS. Our primary outcome was to compare operative time (from skin incision to suture) between the two groups. Secondary outcomes included: operative room time (patient entry into operative room and patient out), estimated blood loss, laparotomic conversion rate, length of hospital stay, perioperative complications, and evaluation of endometriosis-related symptoms at 12-month follow up.

Results: The two groups were comparable regarding preoperative and surgical data, except for higher rates of hysterectomies and bilateral uterosacral ligament removal procedures in the RALS group. Also after adjusting for these discrepancies, operative time was similar between S-LPS and RALS. Operative room time was statistically longer in the RALS group compared with that of S-LPS. No statistically significant difference was found concerning other study outcomes. Pain and bowel symptoms improved in both groups at 12-month follow up.

Conclusions: If performed by expert teams, RALS provides similar perioperative outcomes compared with S-LPS in rectosigmoid endometriosis surgical treatment, except for longer operative room time.

Abbreviations: OT, operative time; RALS, robot-assisted laparoscopy; RSE, rectosigmoid endometriosis; S-LPS, standard laparoscopy.

KEYWORDS
endometriosis, laparoscopy, rectosigmoid endometriosis, robot-assisted laparoscopic surgery, surgical techniques

1 | INTRODUCTION

Deep infiltrating endometriosis is defined as endometrial glands and stroma infiltrating the peritoneum by >4 mm.[1,2] The rectum and rectosigmoid junction together account for 70%–93% of all deep infiltrating endometriosis lesions.[3] Rectosigmoid endometriosis (RSE) is the cause of debilitating symptoms, including constipation, diarrhea, dyschezia, painful bowel movements, rectal tenesmus and menstrual blood in stools.[4,5]

Hormonal therapy has been shown to be effective in treating pain, so surgery should be limited to complicated cases, and in case of failed medical therapy.[2] During the last decades, standard laparoscopic surgery (S-LPS) has proved to be the technique of choice for the treatment of endometriosis.[6]

Robot-assisted laparoscopic surgery (RALS) has gained interest among several surgical specialties, because of its technological advantages over S-LPS. Common RALS advantages include more degrees of freedom in instrument mobility, a three-dimensional view, and improved surgeon dexterity and comfort, in particular in patients with elevated body mass index.[7,8]

Although in several studies RALS has been advocated to be a safe, feasible, and effective alternative to S-LPS in RSE patients,[9-11] robust evidence regarding its clinical applicability is lacking.

This prospective study sought to compare RALS and S-LPS in patients affected by RSE in terms of operative time (OT), operative room time, blood loss, length of stay, laparotomic conversion rate, perioperative complications, and endometriosis-related symptoms at 12-month follow up.

Key message

Robot-assisted laparoscopic surgery can be considered as a valid alternative to standard laparoscopy in rectosigmoid endometriosis.

2 | MATERIAL AND METHODS

2.1 | Study design

This multicenter, observational, prospective, cohort study was performed at the Department of Gynecology at S. Orsola Academic Hospital in Bologna and at the Gynecology Unit of the University Policlinico of Modena.

2.2 | Inclusion and exclusion criteria

From September 2018 to September 2019, we enrolled symptomatic patients with clinical and sonographic diagnosis of RSE scheduled for surgery.

All patients enrolled were aged over 18 years and were asked to provide written informed consent. Exclusion criteria were: postmenopausal status, suspected gynecological malignancy, and medical diseases precluding a minimally invasive approach.

2.3 | Preoperative examination and study groups

In both hospitals, patients on the surgery list were called for a preoperative examination visit and surgery following a chronological order of listing, without any intervention on patient allocation. All patients were submitted to preoperative workup including an interview about endometriosis-related symptoms using an 11-point visual analog scale, bimanual clinical examination, transvaginal and renal ultrasound scan, and pelvic magnetic resonance imaging.

During the preoperative evaluation, patients meeting the inclusion criteria were counseled with informed consent about the possibility to undergo laparoscopic or robotic surgery.

During the study period, patients with RSE were divided into two study groups according to the surgical route performed. Patients underwent the robotic approach according to the availability of the robotic room.

2.4 | Surgical technique

All the procedures were performed under general anesthesia by two senior surgeons, one per center, experienced in endometriosis and minimally invasive surgery (RS and CA). In particular, they underwent a dedicated training and more than 25 robotic interventions for deep endometriosis before starting the study.

Careful inspection of the entire abdominal cavity was performed in order to stage disease. Endometriosis stage was defined according to the revised American Society for Reproductive Medicine classification. Deep endometriotic lesions of the posterior and anterior compartments were isolated and removed, as previously described.[12] Pararectal, rectovaginal, and retrorectal spaces were dissected using a nerve-sparing technique. During these steps, if necessary, the ureter was meticulously freed from the enclosing periureteral adhesions. If an actual ureteral nodule was isolated, a partial thickness resection of the adventitia/muscularis or partial ureterectomy was performed.[13,14]

When endometriosis extended laterally into the lateral parametrium, parametrectomy was performed after an uncrossing maneuver between the ureter and uterine artery.[15]

Shaving procedure was attempted first to treat RSE. If macroscopic residual disease was observed, discoid excision of the rectal wall using a transanal circular stapler or segmental resection using a linear stapler and direct mechanical anastomosis were carried out based mainly on the nodule extension and localization.[12]

Bowel segmental resections were all performed with the participation of a dedicated colorectal surgeon. A protective ileostomy was used when the risk of major rectal complications was present according to intraoperative findings.[16]

RALS was carried out using the Da Vinci Xi Surgical System and Da Vinci Si Surgical System (Da Vinci Surgical System®; Intuitive Surgical, Inc.).

In case of segmental resection, after linear stapler use and temporary robotic arm undocking, the affected bowel loop was cut through a suprapubic mini-laparotomy. Then, direct mechanical anastomosis was performed through a transanal circular stapler via robotic setting.

The surgical specimens were analyzed by the same pathological laboratory.

2.5 | Study outcomes and variables assessed

Our primary outcome was to compare OT (from skin incision to suture, including docking and undocking times in the RALS group) between the two groups. Secondary outcomes included: operative room time (patient entry into operative room and patient out), estimated blood loss, laparotomic conversion rate, length of hospital stay, perioperative complications, and evaluation of endometriosis-related symptoms at 12-month follow up.

Analyzed preoperative clinical data were as follows: age, body mass index, parity, number of previous abdominal surgical procedures for endometriosis, endometriosis-related symptoms (dysmenorrhea, dyspareunia, chronic pelvic pain, ovulation pain, dysuria, dyschezia, constipation, hematochezia, diarrhea), hormonal medical therapy within 3 months before surgery.

Operative data were as follows: operative time, operative room time, co-localizations of endometriotic lesions, type of surgical procedure performed per site, maximum diameter of RSE nodule, laparotomic conversion rate, estimated blood loss, perioperative complications according to the Clavien-Dindo Classification and need for re-intervention.

At 12-month follow up, pelvic examination, clinical interview regarding endometriosis-related symptoms, and pelvic/abdominal ultrasound were performed.

2.6 | Statistical analysis

To determine the minimum sample size, we assumed that the mean OT of standard laparoscopic surgery was 160 ± 54 min.[12] We determined that 20 women in each group were needed to detect a difference of 30% in OT between conventional laparoscopic and robotic surgery for endometriosis, with 80% power and a significance level of 0.05.

Numerical variables were summarized as mean ± SD or as median (range or interquartile range), according to their distribution; categorical variables were summarized as counts and percentages. Chi-squared test, Fisher's exact test, two-sample *t* test and Mann-Whitney test were used for comparison of categorical and numerical variables, where appropriate. A $p < 0.05$ was considered statistically significant for all tests. All analyses were performed using the Statistical Package for the Social Sciences software v. 25 (IBM SPSS).

2.7 | Ethical approval

The study was approved by the local research ethics committee (protocol number: 290/2017/o/sper) on December 19, 2017, before enrollment.

3 | RESULTS

During the study period, 44 patients with RSE respecting inclusion criteria were divided into two study groups: 22 underwent S-LPS, and 22 underwent RALS.

Preoperative characteristics are resumed in Table 1. Body mass index, age, parity, and history of previous medical therapy and pelvic surgery for endometriosis were similar between the two groups.

Surgical procedures and immediate post-operative data are illustrated in Table 2, while operative and operative room times are resumed in Table 3.

RALS group required a higher number of hysterectomies (8 [36%] in RALS group vs. 1 [5%] in S-LPS group, $p = 0.021$] and bilateral uterosacral ligament removal procedures (14 [64%] in RALS group vs. 5 [23%] in S-LPS group, $p = 0.022$) compared with the control group. No statistical difference was found regarding other surgical procedures performed.

The two groups presented similar OT, length of stay, estimated blood loss, laparotomic conversion rate, and perioperative complications. In particular, the mean OTs for RALS and S-LPS were 207 ± 79 min vs. 177 ± 63 min, respectively. This result was confirmed after adjusting for hysterectomy and bilateral uterosacral ligament removal procedure (+27 min; 95% CI −24 to 79; $p = 0.292$).

Subgroup analyses for type of rectosigmoid surgery (shaving, discoid, and segmental resection) did not shown any statistical difference in terms of OT between RALS and S-LPS groups.

Operative room time was statistically longer in the RALS group than in the S-LPS group (296 ± 80 min vs. 241 ± 72 min; $p = 0.020$).

One patient (5%) in the RALS group experienced a mechanical lesion of the internal iliac vein needing conversion to laparotomy. No intraoperative complication was observed in the S-LPS group. Four patients (18%) in the robotic group reported post-operative

TABLE 1 Preoperative characteristics

	RALS (*n* = 22)	S-LPS (*n* = 22)	*p* value
Age (years), mean ± SD	38 ± 7	36 ± 5	0.309
BMI (kg/m^2) median (interquartile range)	24.5 (21–27)	22.5 (21–24)	0.322
Parity, *n* (%)			
Nulliparous	14 (64)	19 (86)	0.165
1	3 (14)	2 (9)	
≥2	5 (23)	1 (5)	
Last medical therapy, *n* (%)			
COC	5 (23)	10 (45)	0.258
POP	10 (45)	8 (36)	
LNG-IUD	0 (0)	0 (0)	
Previous surgical therapy for endometriosis, *n* (%)			
Ovarian endometriosis	3 (14)	4 (18)	0.800
DIE	2 (9)	3 (14)	
Preoperative pain symptoms using VAS, median (interquartile range)			
Dyspareunia	5.5 (3–7)	5 (0–7)	0.676
Chronic pelvic pain	3 (0–5)	3.5 (0–5)	0.548
Dysmenorrhea	7.5 (4–9)	8 (6–10)	0.211
Ovulation pain	1.5 (0–5)	4 (0–5)	0.430
Dysuria	0 (0–0)	0 (0–3)	0.200
Dyschezia	5 (2–5)	4.5 (0–8)	0.726
Constipation, *n* (%)	9 (41)	11 (50)	0.545
Diarrhea, *n* (%)	2 (9)	4 (18)	0.664
Hematochezia, *n* (%)	1 (5)	1 (5)	1.000

Note: Data were analyzed using chi-squared test, Fisher's exact test, two-sample *t* test and Mann-Whitney test for comparison of categorical and numerical variables, where appropriate.

Abbreviations: BMI, body mass index; COC, combined oral contraception; DIE, deep infiltrating endometriosis; LNG-IUD, levonorgestrel intrauterine device; POP, progestogen-only pill; RALS, robot-assisted laparoscopic surgery; S-LPS, standard laparoscopy; VAS, visual analog scale.

TABLE 2 Perioperative data

	RALS (*n* = 22)	S-LPS (*n* = 22)	*p* value
rASRM stage, *n* (%)			
III	1 (5)	5 (23)	0.185
IV	21 (95)	17 (77)	
Conversion to laparotomy, *n* (%)	1 (5)	0 (0)	1.000
Blood loss (mL), mean ± SD	184 ± 214	144 ± 101	0.425
Surgical procedures, *n* (%)			
Hysterectomy	8 (36)	1 (5)	0.021*
Endometrioma removal			
Monolateral	8 (36)	7 (32)	0.627
Bilateral	3 (14)	6 (27)	
Ovariectomy			
Monolateral	5 (23)	1 (5)	0.185
Bilateral	0 (0)	0 (0)	
Uterosacral ligaments			
Monolateral	3 (14)	8 (36)	0.022*
Bilateral	14 (64)	5 (23)	
Rectovaginal septum	13 (59)	12 (55)	0.761
Vagina	7 (32)	4 (18)	0.296
Lateral parametrium			
Monolateral	5 (23)	7 (32)	0.840
Bilateral	4 (18)	3 (14)	
Bladder	2 (9)	5 (23)	0.412
Ureteral surgery			
Monolateral ureterolysis	8 (36)	6 (27)	0.794
Bilateral ureterolysis	4 (18)	6 (27)	
Nodulectomy	0 (0)	0 (0)	
Ureteral reimplantation	0 (0)	1 (5)	
Bowel surgery			
Rectal shaving	13 (59)	10 (45)	0.722
Discoid resection	4 (18)	5 (23)	
Segmental resection	5 (23)	7 (32)	
Appendectomy	2 (9)	2 (9)	1.000
Protective ileostomy	1 (5)	3 (14)	0.607
Maximum diameter of bowel nodule (mm), mean ± SD	30 ± 13	31 ± 15	0.857
Distance from anus (mm), median (interquartile range)	7 (7–8)	8 (7–9)	0.461
Length of hospital stay (days), mean ± SD	8 ± 7	6 ± 2	0.291
Surgical complications according to Clavien-Dindo classification, *n* (%)			
Total	4 (18)	1 (5)	0.345
Grade I	1/4	1/1	
Grade II	1/4	0	
Grade IIIa	1/4	0	
Grade IIIb	1/4	0	

(Continues)

complications, as follows: one required antibiotic therapy for hyperpyrexia for low urinary tract infection, one blood transfusion for anemia, one mechanical dilatation of bowel anastomosis stenosis and one re-intervention for bowel anastomosis leakage. Only one patient (5%) in the S-LPS group experienced hyperpyrexia because of low urinary tract infection during the post-operative period.

All patients in both groups reported an improvement of pain and bowel symptoms after surgery at 12-month follow up (Table 4).

4 | DISCUSSION

Over time RALS has gained importance in gynecologic surgery, both for malignant and benign conditions, including deep infiltrating endometriosis.[17,18] Despite RALS having several technological

TABLE 2 (Continued)

	RALS (*n* = 22)	S-LPS (*n* = 22)	*p* value
Days needed to urinate, median (range)	1 (1–1)	1 (1–1)	/
Days needed to pass wind, median (range)	1 (1–3)	1 (1–3)	0.822
Days needed to pass stool, median (range)	4 (2–9)	6 (2–9)	0.410

Note: Data were analyzed using chi-squared test, Fisher's exact test, two-sample *t* test and Mann-Whitney test for comparison of categorical and numerical variables, where appropriate.

Abbreviations: NA, not applicable; RALS, robot-assisted laparoscopic surgery; r-ASRM, revised-American Society for Reproductive Medicine; SD, standard deviation; S-LPS, standard laparoscopy.

*Significant at the 5% level.

TABLE 3 Operative times and operative room times

	RALS (*n* = 22)	S-LPS (*n* = 22)	*p* value
Operative time (min), mean ± SD	207 ± 79	177 ± 63	0.171
Docking time (min), mean ± SD	6 ± 1	NA	/
Undocking time (min), mean ± SD	3 ± 1	NA	/
Operative time according to the type of rectosigmoid surgery (min), mean ± SD			
Shaving	211 ± 74	169 ± 63	0.092
Discoid resection	166 ± 63	182 ± 64	0.717
Segmental resection	230 ± 102	227 ± 51	0.949
Operative room time (min), mean ± SD)	296 ± 80	241 ± 72	0.020*

Note: Data were analyzed using chi-squared test, Fisher's exact test, two-sample *t* test and Mann-Whitney test for comparison of categorical and numerical variables, where appropriate.

Abbreviations: NA, not applicable; RALS, robot-assisted laparoscopic surgery; SD, standard deviation; S-LPS, standard laparoscopy.

TABLE 4 12-month follow-up data

	RALS (*n* = 22)	S-LPS (*n* = 22)	*p* value
Postoperative pain symptoms using VAS, median (interquartile range)			
Dyspareunia	0 (0–3)	0 (0–0)	0.322
Chronic pelvic pain	0 (0–0)	0 (0–0)	0.560
Dysmenorrhea	1 (0–3)	0 (0–1)	0.268
Ovulation pain	0 (0–2)	0 (0–0)	0.576
Dysuria	0 (0–0)	0 (0–0)	0.184
Dyschezia	0 (0–0)	0 (0–2)	0.210
Constipation, *n* (%)	6 (27)	11 (50)	0.122
Diarrhea, *n* (%)	1 (5)	6 (27)	0.095
Post-operative therapy, *n* (%)			
COC	3 (13)	10 (45)	0.071
POP	8 (36)	8 (36)	
LNG-IUD	1 (5)	0 (0)	
GnRH analogs	1 (5)	0 (0)	

Note: Data were analyzed using chi-squared test, Fisher's exact test, two-sample t-test and Mann-Whitney test were used for comparison of categorical and numerical variables, where appropriate.

Abbreviations: COC, combined oral contraception; GnRH, gonadotropin-releasing hormone; LNG-IUD, levonorgestrel intrauterine device; POP, progestogen-only pill; RALS, robot-assisted laparoscopic surgery; S-LPS, standard laparoscopy; VAS, visual analog scale.

advantages and theoretically improving surgeon gesture, comfort, and performance, evidence of its applicability for complex deep infiltrating endometriosis surgery is limited.[9]

Previous comparative studies on RALS and S-LPS approaches for pelvic endometriosis reported controversial data regarding OT. A recent systematic review and meta-analysis reported that patients in the RALS group have a longer OT than those in the S-LPS group, despite having eliminated the docking time.[17] However, this review considered for analysis mostly low-quality retrospective studies covering long periods with a different learning curve and types of robotic platforms and included patients with different endometriosis stages and disease localizations.

Two large retrospective cohort studies on patients affected by stage III–IV endometriosis reported longer mean OT in the RALS group compared with the S-LPS group.[10,18] However, Magrina et al,[18] after adjusting their findings for age, blood loss, and number of procedures per patient, showed that an RALS approach resulted in 16.2% shorter OT than S-LPS.

Finally, Soto et al,[19] in a recent randomized clinical trial enrolling 73 patients with suspicion of pelvic endometriosis, showed a similar OT between RALS and S-LPS (mean ± SD, 107 ± 48 min vs. 102 ± 63 min) when adjusted to the stage of disease. According to Soto et al,[19] our study showed no significant difference between the two groups regarding OT.

In particular, we observed a mean OT in the RALS group of 207 ± 79 min. In line with our study, Collinet et al[20] and Abo et al[9] in two multicentric non-comparative single-cohort retrospective studies on RSE patients requiring mostly shaving technique reported mean OTs of 188 ± 76 min and 207 ± 67 min, respectively. Also Ercoli et al[10] in a series of 30 patients with RSE treated with only discoid technique with a transanal circular stapler showed a mean OT of 190 ± 42 min.

Recently, Le Gac et al[21] performed a prospective non-randomized comparative study on RSE patients and reported higher OT in the robotic group than in the group using standard laparoscopy. Notably, the RALS group required more urinary and digestive surgical procedures compared with the control group, even if these differences did not reach statistical significance. In addition, despite the two surgeons who performed all laparoscopic and robotic procedures in the study receiving specific formation before the start of the study, no mention was made of the number of robotic procedures performed

per surgeon before study enrollment period. As hypothesized by the same authors, learning curve could have influenced docking and operative times as well as complication rate in the robotic group.

Regarding perioperative surgical complications, we experienced more complications in the RALS group compared with S-LPS (18% vs. 5%), even if statistical significance was not reached, likely due to unpowered sample size for this issue. In accordance with our data, Restaino et al,[17] analyzing five comparative studies, demonstrated no difference between RALS and S-LPS in terms of intra-operative and post-operative complications. However, the included studies showed different results in terms of surgical complications, possibly related to different surgical complexity between the two groups and learning curve effect.

In our study the robotic approach seemed to increase the operative room time. This latter aspect could be due to deep neuromuscular block usually being required during robotic procedures and the occurrence in the RALS group of a major intraoperative complication requiring intensive anesthesiologic monitoring in the operative room.

Strengths of our study are its multicenter and prospective design. However, this study has several limitations: the need for expertise in endometriosis and minimally invasive techniques and the number of surgeons may limit the reproducibility of our results. On the other hand, this complex surgery must be performed in tertiary care and referral centers by highly skilled surgeons to reduce morbidity. Moreover, long-term follow up and larger study populations are needed to evaluate and compare the efficacy and efficiency of the two approaches. Finally, selection bias related to observational study design could have influenced our findings, which must be confirmed by randomized controlled studies. On the other hand, in both hospitals, patients in the elective schedule underwent robotic or laparoscopic surgery following a chronological order of listing, which limits this type of bias.

5 | CONCLUSION

If performed by expert teams, RALS provides similar perioperative outcomes compared with S-LPS in RSE surgical treatment, except for operative room time.

Further prospective studies with larger sample size are needed to evaluate perioperative complications, long-term clinical and functional outcomes, and cost-effectiveness analysis of the two approaches.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

DR contributed to conception and design of the study, and for women recruitment; CA contributed to conception and design of the study, for women recruitment, and is one of the responsible surgeons; BO contributed to conception and design of the study, the statistical analysis, and the manuscript preparation; ACA and AF contributed to manuscript preparation; MM, VS, and MM contributed to data collection; AA and SDF contributed to data analysis and interpretation; MP contributed to design of the study; RS is one of the responsible surgeons.

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