



Robot-assisted Vs Laparoscopic Sacrocolpopexy for High-stage Pelvic Organ Prolapse: A Prospective, Randomized, Single-center Study

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OBJECTIVE	To compare robot assisted to laparoscopic sacrocolpopexy, in terms of efficacy, in the treatment of high-stage pelvic organ prolapse.
METHODS	This was a noninferiority prospective randomized trial conducted in a tertiary Urology unit, comparing robot assisted and laparoscopic sacrocolpopexy in patients with symptomatic prolapse stage III and IV, according to the Pelvic Organ Prolapse quantification. All participants provided written informed consent at enrolment. The primary outcome was prolapse objective cure rate. Secondary outcomes included prevalence of urinary, anorectal and sexual symptoms, UDI-6, IIQ7 and FSFI scores, and maximum flow rate. Operative times, intraoperative blood loss, length of hospital stay, postsurgery pain, patient satisfaction as well as surgical and mesh complications were assessed. The Mann-Whitney and Wilcoxon tests for unpaired and paired data, respectively, were used to compare ordinal and nonnormally distributed continuous variables. Categorical data were analyzed by the McNemar, chi-square or Fisher exact test. Two-tailed $P < .05$ was considered significant.
RESULTS	One hundred patients were randomized. At a mean follow-up of 24.06 months the cure rate for the apical compartment was 100% with both approaches. There were no significant between-group differences in any of the secondary outcomes with the only exception of C/D point values, where results were significantly better in the robot-assisted group. Overall surgical procedure time was longer in the robot-assisted group. The main limitation of our study is the single-centre design and the inclusion of docking time in robotic-procedure surgical time calculations.
CONCLUSION	Robot-assisted sacrocolpopexy provides outcomes comparable to those of laparoscopic with 100% anatomic correction of the apical compartment. UROLOGY 134: 116–123, 2019. © 2019 Elsevier Inc.

Abdominal sacrocolpopexy has been considered for decades the gold standard for the treatment of vaginal vault prolapse, with good outcomes in long-term follow-up.¹ After the introduction of laparoscopy, it has been demonstrated that the minimally invasive laparoscopic approach is comparable to the abdominal procedure in terms of anatomic and functional results.² The advent of the robot-assisted approach in tertiary centers, and the relatively short learning curve

required for it, compared to laparoscopy, have increased the use of this technique in various urologic fields, including urogynecology. The robot-assisted surgical approach has been developed aiming to facilitate technically demanding procedures by improving the surgeon's vision and ergonomics. A systematic review of 27 studies found that robot-assisted sacrocolpopexy (RASC) is associated with objective and subjective cure rates in the range of 84%-100% and 92%-95%, respectively, with mesh erosion rates of 2%.³ Up-to-date minimally invasive, robot-assisted or laparoscopic (LASC), sacrocolpopexy has to a significant degree replaced the open approach. The majority of the available studies comparing laparoscopic and RASC are retrospective or prospective nonrandomized series, and there are only 2 randomized-controlled trials (RCTs).⁴⁻⁶ Unfortunately, these RCTs have relatively small sample sizes and short follow-up periods. Aim of the present randomized study was to compare RASC to LASC, in terms of efficacy and

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safety, in the treatment of female patients with pelvic organ prolapse (POP).

PATIENTS AND METHODS

This was a noninferiority RCT conducted in a tertiary, university affiliated, Urology unit, comparing RASC and LASC for POP repair in patients with symptomatic POP stage III or IV, according to the POP-quantification (POP-q).⁷ The trial was approved by local ethics committee (approval number: 2753/16) and registered on Clinical trials registry (NCT02852512). Patients included in the study provided written informed consent. Inclusion criteria were age above 18 years and symptomatic, stage III or IV POP. Exclusion criteria were: severe obesity (body mass index >35 kg/m²), heart failure (NYHA class III-IV),⁸ stage III-IV of chronic obstructive pulmonary disease,⁹ more than 2 previous abdominal surgical procedures and other contraindications to major surgery and/or general anesthesia. Preoperative evaluation included a medical and urogynecologic history, physical urogynecologic examination, a stress test (with and without prolapse reduction), and urodynamic testing. Even though urodynamics is not absolutely indicated, it is a minimally invasive test that could help in counseling the patient on micturition-related outcomes. Urinary, sexual, and anorectal symptoms were diagnosed according to current recommendations (International Urogynecological Association/International Continence Society terminology report definitions and Rome IV Criteria for Colorectal Disorders).^{7,10} With regards to urinary symptoms, patients were classified as having storage and/or voiding symptoms if they had at least one storage and/or at least one voiding symptom, without recording specific ones. Incontinence was the only single storage symptom that was specifically recorded. Sexual symptoms were evaluated with the Female Sexual Function Index (FSFI),¹¹ while urinary symptoms were quantified using the short forms of Urinary Distress Inventory -6 and Incontinence Impact Questionnaire-7.^{12,13} Patients were assigned to one of the 2 groups using a computer-generated block randomization sequence. Participants were intentionally allocated in equal numbers to each intervention (RASC and LASC) according to a block size of 4 (randomization ratio of 1:1 in each block) with randomization done at the time of scheduling for surgery. The allocation of this design was generated using StatsDirect, version 2.7.2, 2008 (StatsDirect, Altrincham, United Kingdom).

Patients were followed up at 1, 3, 6, and 12 months postoperatively and then annually using the tests and evaluations of the preoperative assessment protocol. The follow-up was performed by examiners who had not been involved in the surgical procedures. Postoperative pain was assessed on the third postoperative day using the Visual Analogue Pain Scale.¹⁴ Patient's satisfaction with the operation was assessed at each visit with the Patient Global Impression of Improvement (PGI-I) questionnaire.¹⁵

Surgical Procedures

All operations were performed by one senior surgeon (E.C.). For LASC patients were positioned in the gynecologic position; a 4-trocar approach was used, including a primary umbilical 12 mm trocar for the 0-degree scope, a 10-mm trocar medial to the superior anterior iliac spine for the dominant hand, another 5 mm trocar medial to the superior anterior iliac spine on the contralateral side and a 5-mm trocar halfway between the symphysis and the umbilicus.²

For RASC Robot DaVinci Xi was used. The trocars were positioned in an inverted W plan. Optical trocar was placed above

the umbilicus. Two robotic arms were placed on the left side, the first 2 fingers above the anterior superior iliac spine and the second on the left paramedian line. Another robotic arm and the assistant's trocar were placed on the right side symmetrically to the left-side ones.

Surgical steps after entering the abdomen were the same for both approaches according to our standard practice for sacrocolpopexy,^{1,2} which has given very satisfactory long-term results. The anterior vaginal wall was dissected down to the bladder neck and the posterior vaginal wall was prepared down to the level of the levator ani. In cases of previous hysterectomy, 2 rectangular polypropylene meshes were attached to the anterior and posterior vaginal walls, respectively, using 4 absorbable sutures and then fixed to the sacral promontory with a nonabsorbable 0.0 polypropylene suture. In cases of uterus preservation, the anterior mesh was a Y-shaped, instead of a rectangular one, allowing the 2 arms of the mesh to be passed around the round ligament and then fixed to sacral promontory together with the posterior mesh. The peritoneal incision was reapproximated with a running absorbable suture.^{1,2}

It must be noted that our practice is to dissect both the anterior and posterior vaginal walls as far caudal as possible and place 2 pieces of mesh regardless of the relative degree or anterior/posterior compartment prolapse. We also never perform concomitant surgery such as anti-incontinence surgery or anterior repairs; we propose to our patients to treat incontinence at a later time in cases it persists postsacrocolpopexy.

Outcomes

The primary outcome of the study was prolapse cure rate. Cure was defined as prolapse stage $<II$ for all compartments, point C ≤ -5 and at least 7 cm for total vaginal length. Failure to correct to normal support (stage 0 or I) was considered persistence of prolapse and return to a higher stage following initial correction was considered a prolapse recurrence.

Secondary outcomes included prevalence of urinary, anorectal and sexual symptoms, Urinary Distress Inventory-6, Incontinence Impact Questionnaire-7 and FSFI scores, and maximum flow rate on uroflowmetry. Operative time was recorded as the time from first incision to last suture for the laparoscopic approach, and time from first incision to undocking for the robot-assisted approach. Intraoperative blood loss in millilitres and hospital stay in days were also recorded. Postsurgery pain was assessed by a visual analogue scale. Surgical complications were assessed by Clavien-Dindo classification,¹⁶ while the mesh complications were recorded according to Prosthesis/Graft Complication Classification.¹⁷ Patient satisfaction was assessed as PGI-I score.

Statistical Analysis

A preliminary power analysis indicated that a sample size of 31 patients per group at $P < .05$ would have 80% power to reject the null hypothesis that RASC and LASC are not equivalent. Power calculation was performed using PS: Power and Sample Size ver.3.0, 2009 (<http://pspower-and-sample-size-calculation.software.informer.com/>). The Mann-Whitney and Wilcoxon tests for unpaired and paired data, respectively, were used to compare ordinal and nonnormally distributed continuous variables. Categorical data were analyzed by the McNemar, chi-square, or Fisher exact test. Two-tailed $P < .05$ was considered significant. All calculations were performed with IBM SPSS, version 22.0

RESULTS

Between March 2016 and October 2017, one hundred and fifty consecutive women with symptomatic, stage III or IV POP, were invited to participate. Fifty out of the 150 patients were not included: 27 did not meet all inclusion criteria and 23 refused to give consent. One hundred patients were randomized and included in the analysis as shown in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Fig. 1). There were no patients lost in follow-up. Forty-nine patients were operated with the robot-assisted approach and 51 with the laparoscopic. Baseline demographic and clinical characteristics showed no significant differences between the 2 groups (Tables 1 and 2). Thirty-six of the 51 women in the LASC group and thirty-five of the 49 women in the RASC group had previous hysterectomy for reasons not related to prolapse. No hysterectomy was performed in the 29 women who still had their uterus at the time of randomization: they all had a hysteropexy.

At a mean (range) follow-up of 24.06 (20.8-36.1) months the cure rate for the apical compartment was 100% with both approaches, as shown in Figure 2. Cure rates for the anterior and

posterior compartments were also not significantly different between groups (also shown in Fig. 2). Statistical improvements, compared to baseline, were shown for all POP-Q points in both groups without significant differences between them (Table 2). The only exception to this was C/D point values, where results were significantly better in the RASC group (median [range] -8 [-10 ; -6] for RASC vs -7 [-11 ; -6] for LASC, $P < .00001$).

Eight and four cases of low-stage persistent anterior and posterior prolapse, respectively, were found in the LASC group, while in the RASC group there were 4 in the anterior compartment and only one in the posterior (Fig. 2). All cases of prolapse persistence were asymptomatic, and none required reoperation. There were no cases of prolapse recurrence.

Urinary and anorectal symptoms improved in both groups without significant differences between them (Table 2). The improvement of voiding symptoms was mirrored by an improvement in uroflowmetry parameters, again without significant differences between LASC and RASC. Stress urinary incontinence (SUI) and urge urinary incontinence resolved in 50% of the patients (7/14 patients with SUI and 12/22 patients with urge

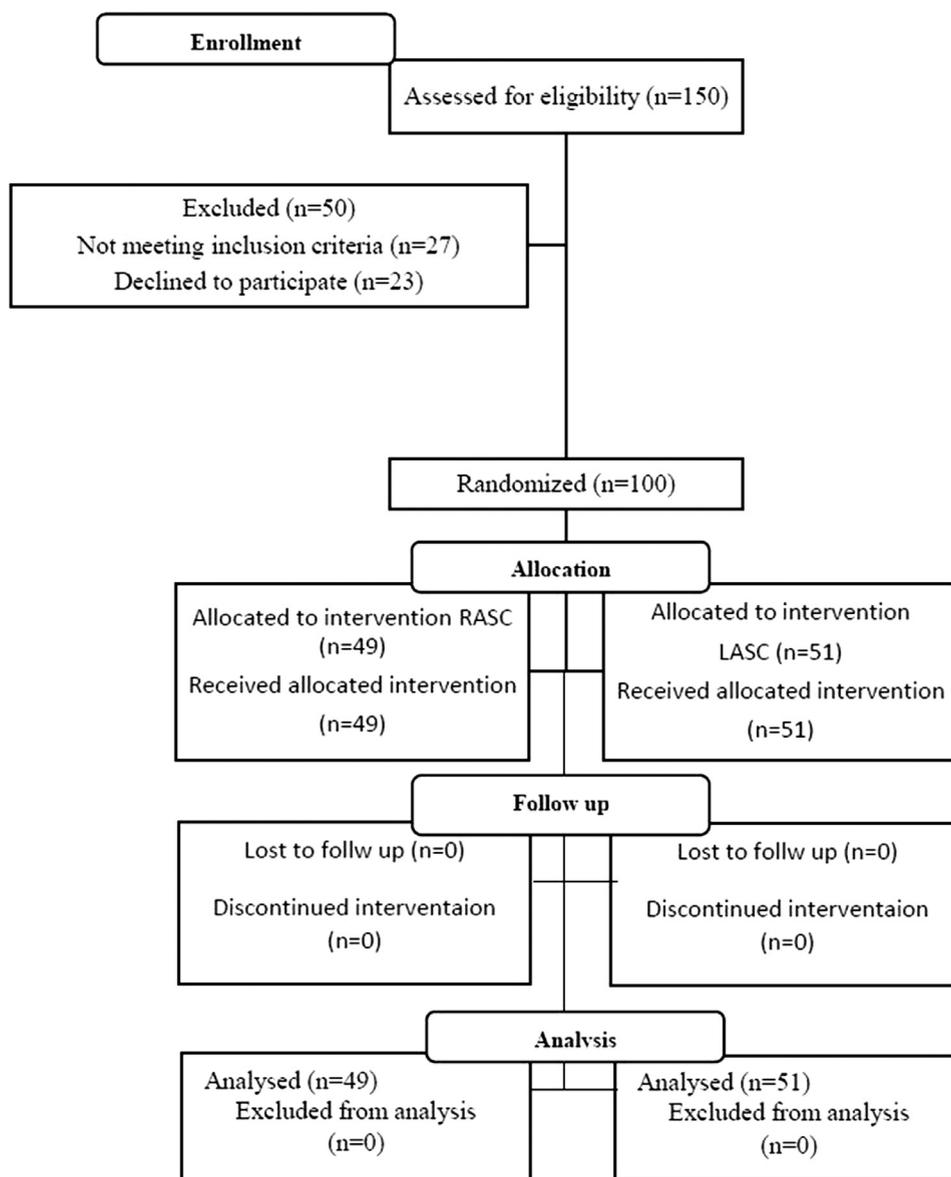


Figure 1. Consort flow diagram.

Table 1. Preoperative characteristics of the study population

Parameters	RASC (n = 49)	LASC (n = 51)	P Value
Age (years, mean ± SD)	60.2 ± 10.3	60.3 ± 8.6	.919
Body mass index (kg/m ² , mean ± SD)	25.74 ± 3.1	25 ± 3.0	.162
Weight of a baby at its birth (gr, median, range)	3500 (1750-5000)	3500 (2300-4300)	.696
Menopause (n, %)	36 (73.5)	43 (84.3)	.183
Previous prolapse or continence surgery (n, %)	13 (26.5)	15 (29.4)	.750
- Anterior colporrhaphy	11	12	
- Transobturator sling	2	3	
Previous hysterectomy (not prolapse related)	35	36	
History of recurrent urinary tract infections (n,%)	9 (18.8)	8 (15.7)	.686
Anxiety-depression syndrome	7 (14.3)	9 (17.6)	.647
Hypertension (n, %)	21 (42.9)	18 (35.3)	.438
Diabetes (n, %)	4 (8.2)	1(2.0)	.155
Thyroid disorders (n, %)	4 (8.2)	1(2.0)	.155
No. education level (n, %):			.409
Primary school	12 (24.5)	18 (35.3)	
Secondary school	20 (40.8)	13 (25.5)	
High school	11 (22.4)	13 (25.5)	
University	6 (12.2)	7 (13.7)	

urinary incontinence), with only 2 new cases of SUI in each group (Table 2). There were significant improvements in sexual function reflected in improvements in total FSFI scores in 69% of women in the RASC and 81% of women in the LASC group. Improvements were also noted in FSFI domain scores for desire, arousal, satisfaction, and pain. Many women sexually inactive before surgery resumed sexual activity postoperatively (Table 2). Sexual and urinary function questionnaire scores did not differ significantly between the RASC and LASC groups at mean follow-up of 24 months (Table 2).

Overall surgical procedure time was longer in the robot-assisted group compared to the laparoscopic technique (234.4 ± 50 vs 192.75 ± 65 min, $P < .001$). No statistically significant difference emerged between the groups in intraoperative bleeding (56.57 ± 34.57 vs 58.65 ± 32.33 mL, $P = .97$) and length of hospital stay (3.7 vs 4.1 days, $P = .98$).

As far as complications are concerned there were no statistical differences between RASC and LASC (Table 2). There were no intraoperative complications in either procedure. Ten patients in LASC group had postoperative nausea and vomiting, 3 women had fever (Grade 1), and 1 had blood loss requiring transfusion (Grade 2). In the RASC group, 1 patient had fever, 8 had nausea and vomiting, and 1 woman had a hematoma in the presacral space that did not require any procedure (Grade 1). There were 2 mesh exposures in the RASC group and 3 in the LASC group. All 5 exposures were discovered due to provoked pain on vaginal examination more than 12 months postoperatively, and, even though larger than 1 cm, they were relatively small located in the posterior vaginal wall (3B T4S2). All were asymptomatic and managed expectantly. Finally, there was no statistical difference in VAS pain scores and in PGI-I scores between the RASC and LASC groups (Table 2).

COMMENTS

This randomized trial demonstrates that RASC provides anatomic and functional outcomes as good as those of LASC, with excellent correction of the apical

compartment: the cure rate was 100% in both groups without apical recurrences.

Anatomic correction was also very good in the anterior and posterior compartments, with a statistical improvement for every POP-Q point without statistically significant differences between the 2 groups. In our study the only exception was point C/D, which was statistically better repaired in the RASC group, although this may not be of clinical relevance. Our results are in agreement with data from 2 previous RCTs. Both Paraiso et al in their RCT on 78 patients (38 in the LASC and 40 in RASC group)⁴ and Kenton et al in an RCT on 66 women (33 in the LASC and 33 in RASC group)⁵ demonstrated an improvement in all POP-Q point measurements at 12 months after surgery, without statistical difference between the 2 groups.

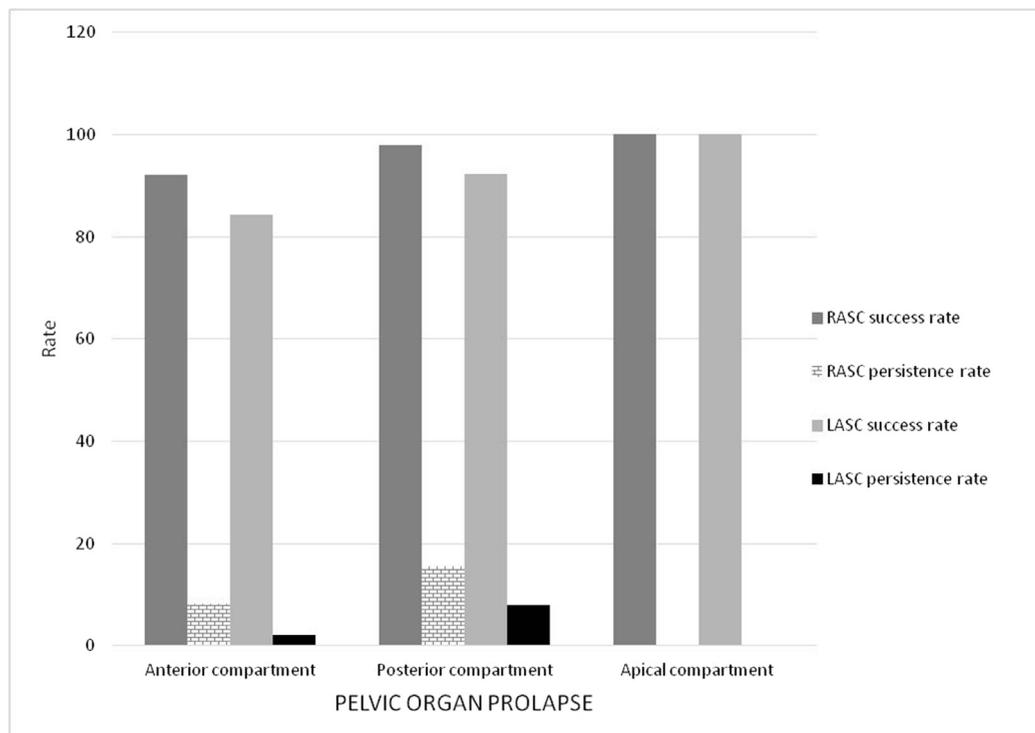
In our experience RASC had fewer, although not statistically significant, cases of anterior and posterior compartment prolapse persistence, compared to LASC, at a mean follow-up of 24.06 months after surgery. We can only hypothesize this result is due to the very nature of the robot-assisted technique, which allows a 3-dimensional vision, an ergonomic position of the surgeon, 8 degrees of freedom, and a filter for tremor leading to a better dissection of the vaginal walls, more efficient positioning of the mesh, and easier execution of the stitches fixing it to the sacral promontory.

In our study population no recurrences of prolapse were seen in any compartment, with either of the evaluated approaches. This result further supports data in the literature for low recurrence rates with both the robotic and laparoscopic procedures. Chan et al in a retrospective study¹⁸ showed a 7% rate of anterior or posterior recurrence (stage II) in RASC group and 5% in LASC group. Nevertheless, statistical significance was not specified in the manuscript. Seror et al in a prospective study on 68 women (20 in the RASC and 47 in LASC group)¹⁹

Table 2. Preoperative and postoperative POP-Q, functional results, patient's satisfaction, and complications

	RASC Preop	LASC Preop	P Value	RASC Postop	LASC Postop	P Value
Follow up (months, mean ± SD)				25.71 ± 7.1	25.06 ± 2.36	.631
Aa (median,range)	3 (-3;3)	3 (-3;+3)	.07	-2 (-3;-1)	-2.5 (-3;-1)	.59
Ba (median,range)	4 (-2;+6)	4 (-3;+6)	.13	-3 (-5;-0.5)	-2.5 (-4;-1)	.81
Ap (median,range)	1.5 (-3;+3)	1.5 (-3;+3)	.94	-2 (-3;-1)	-2.5 (-3;-2)	.06
Bp (median,range)	2 (-3;+5)	3 (-3;+3)	.19	-3 (-3;-1)	-2.5 (-3;+3)	.7
C/D (median,range)	-2 (-10;+7)	-3 (-10;+6)	.1	-8 (-10;-6)	-7 (-11;-6)	<.0001
Total vaginal length (cm)	8.2 (7.1-12.4)	8.2 (7-12.3)	.9	7.1 (7.0-11.2)	7.1 (7-11)	.9
Voiding symptoms(n,%)	40 (81.6)	42 (82.4)	.925	4 (8.2)	4 (7.8)	.95
Storage symptoms(n,%)	34 (69.4)	31 (60.8)	.367	6 (12.2)	1 (2.0)	.05
Sexually active (n,%)	20 (40.8)	21 (41.2)	.971	21 (42.9)	31 (60.8)	.07
Sexual dysfunction (n,% of sexually active)	13 (65)	16 (76.2)		4 (8.2)	5 (9.8)	
Anorectal dysfunction symptoms (n,%)	17 (34.7)	22 (43.1)	.387	6 (12.2)	4 (7.8)	.46
Stress urinary incontinence (n,%)	14 (28.6)	22 (43.1)	.129	7 (14.3)	10 (19.6)	.47
De Novo case (n,%)				2 (4.1)	2 (3.8)	
Urgency urinary incontinence (n,%)	9 (18.4)	8 (15.7)	.721	4 (8.2)	4 (7.8)	.95
Qmax (ml/s) (mean ± SD)	13.34 ± 1.56	13.37 ± 1.59	.96	21.76 ± 1.98	21.90 ± 1.50	.63
Post void residue >30% of volume (n,%)	35 (71.4)	38 (74.5)	.72	0	0	-
FSFI score (median,range)	3 (1.2-19.2)	4.3 (1.3-32.2)	.064	26.5 (13-30)	22 (2-33)	.097
IIQ7 score (median,range)	8 (0-23)	7 (0-17)	.707	0 (0-12)	0 (0-12)	.259
UDI 6 score (median,range)	7 (0-18)	8 (0-16)	.68	0 (0-11)	0 (0-12)	.25
PGI-I score						
1				20	27	
2				20	20	
3				9	4	
VAS score				1 (1-3)	1 (1-3)	.14
Mesh erosion				2 (4.1)	3 (6)	.68
Clavien-Dindo postop complications: (n,%)						
Grade 1				10 (20.4)	13 (25.5)	.546
Grade 2				0	1 (2)	.325
Grade 3				0	0	

Abbreviations: FSFI, Female Sexual Function Index; IIQ, Incontinence Impact Questionnaire; UDI, Urinary Distress Inventory.

**Figure 2.** Prolapse cure and persistence rates for robot-assisted (RASC) and laparoscopic (LASC) sacrocolpopexy.

showed only 1 prolapse recurrence in RASC group at 16 months of follow-up, but the authors did not specify the compartment involved and the prolapse stage.

In our study urinary, sexual, and anorectal symptoms improved in both groups, without differences between them. Voiding symptoms disappeared in 73.4% and 74.6% after RASC and LASC, respectively. These results were confirmed by uroflowmetry data demonstrating excellent functional outcomes. The storage symptoms disappeared in 57.2% and 58.8% of women after RASC and LASC, respectively. These findings are in agreement with data from previous studies by Seror et al,¹⁹ Paraiso et al⁴ and Anger et al.⁶ The restoration of continence in 7 out of 14 patients with stress incontinence may be explained by the restoration of anatomy with sacrocolpopexy: the development of the anterior vaginal wall down to the level of the bladder neck, its reinforcement with a mesh and its suspension from a fixed point, restore the function the urethral support mechanism that according to Delaney's hammock theory plays a key role in continence.

Intraoperative bleeding and length of hospital stay did not show statistically significant differences between the 2 groups, confirming data from previous studies.^{5,17-19} Hospital stay in our study is somewhat longer than reported in the literature, but this is partly due to local hospital admission and discharge policies. The operative time was longer for RASC compared to LASC. We have not recorded docking time separately, so the longer time in RASC group may be attributed to both time docking the robot and console time. It is not possible to compare our results with the ones of the Seror et al¹⁹ study because they evaluated the "strict operating time" (excluding the docking and undocking time) and the "overall operating time" (total time in operating theatre, including anesthesia time) reporting a shorter strict operative time in the RASC group (128 min in RASC group vs 231 min in LASC group [$P < .0001$]). The fact that RASC was a median of 100 min quicker than LASC was explained by the greater simplicity of performing sutures with the robot, according to the authors. This opinion is not supported by Paraiso et al⁴ who evaluated the sacrocolpopexy suturing time (time from start of suturing mesh on the vagina to closure of the peritoneum over the mesh) and found longer robotic than laparoscopic sacrocolpopexy suturing time (98 min vs 68 min, $P < .0001$). To our opinion such variations can also be explained by differences in the experience of surgeons involved in the studies. The extensive dissection of the vaginal walls we routinely perform before mesh placement may somewhat increase time measurements in our study, but this may be offset by putting just 4 sutures to secure it on each vaginal side. Furthermore, inclusion of time to dock and undock the robot in time calculations in various studies should also may be taken into consideration as, Paraiso et al estimated that it can be as long as 20 minutes.

In our experience surgical complications and mesh erosion rates did not differ statistically between the 2 approaches. Paraiso et al⁴ and Seror et al¹⁹ have presented

similarly low erosion rates, while Chan et al¹⁸ did not detect mesh erosion during the vaginal examination. In our study, mesh erosions were small and asymptomatic. As in our past experience small (smaller than 1 cm), completely asymptomatic, and noninfected erosions tend to remain asymptomatic over time and given the lack of evidence in the literature regarding the treatment of such erosions we have decided to defer treatment after informing the patient on the advantages and disadvantages of mesh revision excision. We, nevertheless, followed them up every 3 months after diagnosis for the first year and then every 6 months with measurement of the size of the exposure and evaluation of symptoms. In this study no surgical intervention was required.

A cost effectiveness comparison of RASC and LASC was beyond the aims of our study. Nevertheless, RASC is known to be more expensive than LASC (longer operative time and higher operating room costs).⁴ This in combination with training and equipment availability issues make the benefit of the robot-assisted approach over the laparoscopic in terms of surgeons' view, ease, and ergonomics⁶ less obvious to hospital administrations and even surgeons themselves.

Strengths of our work are the prospective, randomized design, the long median follow-up, the longest in the literature, and the large, in comparison to other RTCs, number of patients included. The main limitation of this study is the single-centre, single-surgeon design. This may explain the high objective success rate and 100% patient compliance to follow-up. To reduce assessment bias follow-ups were performed by physicians that were not involved in the trial. Nevertheless, they could not be blinded to the treatment arm because of the number of trocar wounds for each procedure. Another limitation is the inclusion of docking and undocking time in the evaluation of operative time for the robotic-assisted technique.

CONCLUSION

RASC provides outcomes as good as those of LASC with 100% anatomic correction of the apical compartment. Although differences in cure rates for the anterior and posterior compartment repair were not clinically significant, RASC was somewhat more efficient and associated with fewer cases of persistent prolapse. Patients were satisfied with both procedures. These data enable us to state that RASC, when available, can be considered a good alternative in the treatment of symptomatic, stage III or IV, and POP.

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objective and subjective outcome criteria for pelvic support, incontinence, and sexual function, is a plus. Not surprisingly, the anatomic outcomes at a mean of 2 years are excellent and symptomatic improvements have followed suit.

While randomized comparisons confirming solid anatomic and subjective outcomes are welcome with open arms, analyses such as this one inevitably raise several questions going forward. First, can the results of this study be applied to a typical, tertiary referral population with recurrent prolapse, especially since the current cohort is a highly selective one (ie, thin, healthy, and having little previous pelvic surgery)? Second, does uterine preservation in 30% of the current cohort represent an unaccounted confounding factor in this study where the authors have done a terrific job of recruiting a relatively “pure” population? Third, do surgical nuances, which admittedly vary from study to study, influence long-term outcomes? In particular, does anchoring mesh to the sacral periosteum rather than the anterior longitudinal ligament increase the possibility of osteomyelitis? Likewise, does performing an extended dissection between bladder and vagina to the level of the bladder neck increase the chance for unrecognized, or recognized, organ injuries in the hands of a less-experienced surgeon? Finally, and this is more an observation rather than a question, the handling of overt preoperative stress urinary incontinence (SUI) is somewhat puzzling to me. As it appears, none of the women in this study was offered a concomitant anti-incontinence procedure, which has the potential benefit of addressing preoperative SUI in the same setting without significant attendant increase in morbidity. Fortunately, in this population, the rate of SUI resolution after the prolapse procedure alone was high and the appearance of new-onset, overt SUI was quite low.

With emerging outcomes such as those in the current study, several conclusions can be drawn. In experienced hands, robotic- and laparoscopic-assisted sacral colpopexies are associated with similarly solid anatomic outcomes. Robotic procedures are associated with greater costs and may take longer to perform (at least initially), while laparoscopic procedures require specialized expertise. Robotic procedures are also useful because surgeons trained in the open approach can often transition to robotic surgery directly without undergoing specialized laparoscopic training. Finally, as the outcomes are relatively immature, durability should be monitored closely.

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EDITORIAL COMMENT



There is a lot to like about this well-designed, prospective RCT comparing robot-assisted and laparoscopic sacral colpopexy by a high-volume, experienced surgeon. Compared to 2 previous similar RCTs,^{1,2} the current paper offers a longer mean follow-up period and a higher number of recruited patients. The use of standardized questionnaires, as well as the utilization of both

AUTHOR REPLY

We would like to thank you for your positive critique and the opportunity to further discuss the implications of our results.



As you have pointed out the main conclusion drawn from our data is that, for the time being, the choice between laparoscopic and robot-assisted surgery can only be based on cost, time, and training requirements, since there is consistently no difference in efficacy and safety in available trials. When longer follow-up becomes available, durability of results could be compared and further guide our choice.

Randomized trials are essential in giving high quality information but also have inherent flaws. The need to have 2 balanced and comparable arms at randomization imposes certain exclusion criteria such as obesity. Very severe obesity is not common in our referral area and the inclusion of such patients randomly in one of the arms would have made our groups not balanced. As far as excluding patients with comorbidities is concerned, it did not significantly change the characteristics of our sample: in our practice we advise patients with comorbidities, especially respiratory ones, to undergo vaginal and not abdominal surgery. The results of this study can be applied to a typical, tertiary population with recurrent prolapse. Without a doubt, the factor that makes the difference is the surgical expertise that is expected, but not always guaranteed, in tertiary centers as you have pointed out.

As far as dissection of tissues before mesh placement is concerned, it goes without saying that the wider the dissection the more the adjacent organ injuries, especially in inexperienced surgeon's hands. This issue probably calls for an improvement in the quality and supervision of young surgeons' training more than for a modification of the surgical technique: we have associated this particular step in prolapse repairs with a significant improvement in outcomes such as degree and duration of anatomical correction and resolution of preexisting stress incontinence,¹ and we feel that a slightly increased risk of minor intraoperative complications is justified. The issue of adding or not a concomitant anti-incontinence procedure is still not resolved in the literature, but the widely accepted idea to adopt a 2-step approach is further supported by the resolution of stress incontinence in our series.

Uterus preservation during prolapse surgery has been a significant trend in recent years as an increasing number of women, especially the younger ones, consider the uterus an integral part of their self/body image and a testament to their femininity. This is particularly relevant in our referral area and is supported by

evidence of very good prolapse-repair results, both anatomic and functional, with uterous preservation.²⁻⁴ Consequently a high percentage of women with the uterus in situ in our population is not so much the result of selection.

Anchoring of the sacral end of the mesh on the sacral is a very commonly adopted approach⁵ and has never been a relative safety issue.

We believe that long-term follow-up will confirm our initial ideas and observations.

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