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Single-port versus multi-port robotic sacrocervicopexy: Establishment of a learning curve and short-term outcomes

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ABSTRACT

Objectives: The purpose of this study was to compare the learning curves, surgical outcomes and complications of multi-port access robotic-assisted laparoscopic sacrocervicopexy (MP-RSC) to single-port robotic access (SP-RSC) for vaginal apex prolapse.
Methods: A retrospective study of the first 52 MP-RSC procedures compared with the first 52 SP-RSC procedures performed at one medical center. Primary outcomes were intraoperative bleeding, operative time, and hospitalization. Secondary outcomes were surgical complications.
Results: There was a statistically significant difference in mean operative times between the MP-RSC and SP-RSC procedures: 206.5 ± 39.4 and 187.8 ± 46.2, respectively, $P = 0.028$. The mean estimated intraoperative blood loss was 35 [20–87.5] ml and 20 [10–47.5] ml, respectively, $P = 0.008$. Respective mean operative times decreased from the first 15 to the subsequent 15 cases: in the MP-RSC group from 224.2 ± 43.2 to 198.4 ± 36.3 min, $P = 0.088$, and in the SP-RSC group from 222.4 ± 53.1 to 161.3 ± 28.2 min, $P < 0.001$. The subsequent 22 cases showed different trends. Hospitalization (days) and level of pain at 24 h postoperative, according to a 1–10 point visual analogue scale, did not differ. Adverse events were rare in both groups.
Conclusions: MP-RSC and SP-RSC are feasible and the short term outcomes and learning curves for both procedures are comparable.

Introduction

The “gold standard” surgical procedure for pelvic organ prolapse (POP) repair used to be abdominal sacrocervicopexy (ASC), with varying reported subjective success rates between 76–100%. [1–5] Nevertheless, estimated morbidity rates for ASC were approximately 17% [6,7], thus motivating surgeons to seek alternative feasible approaches.

Laparoscopic sacrocervicopexy (LSC) rose on account of this background as a popular alternative to ASC. [8] LSC carried many advantages compared to ASC, without compromising the high surgical success rates [7,9,10]. Among the advantages were shorter recovery and hospitalization times, reduced postoperative pain, and fewer cases of post-operative bowel ileus. Reported operative complication rates in LSC are 3–14%, most of which are minor [11–16].The published research to date, regarding LSC, demonstrated learning curves showing a decrease in mean operative times after the first 15–30 cases, performed by an experienced surgical team. The average operation time ranging between 2–3 hours reflects the highly technical aspects and demands of this surgical procedure [11–14].

Claerhout et al. defined completion of the LSC learning curve as a 90% success rate measured by a minimal complication rate and a satisfying anatomical outcome [13].

A similar number of cases, 15–30, is required to perform LSC or MP-RSC surgery efficiently in the hands of an ASC experienced surgical team. Mean operative times for both procedures is 265–317 minutes, [16,17] again, reflecting the high technical demands of this surgical procedure. MP-RSC and multi-port LSC have similar perioperative morbidity, anatomic and functional outcomes in 1-year post-surgical follow-up [18]. A substantial difference between the 2 surgical procedures is the higher pain levels at 3–5 weeks following RSC [19], thus requiring longer use of pain medication, mainly NSAIDs. This difference might be caused by the additional operating port required by the robotic system, the larger size and possibly different locations of robotic trocars, longer operating times, and the difference between robotic and manual trocar manipulation

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throughout the prolonged surgery. On the other hand, estimated blood loss was significantly lower in the RSC procedures, in addition to shorter hospitalization and shorter recovery time [16,17,20–26].

Single-port LSC has been described in several case reports, [27] with substantially longer mean operation times and a higher level of technical difficulty when compared to classic LSC. SP-RSC, the latest phase in sacrocolpopexy surgery evolution, is still undergoing implementation. This procedure holds promise as to be the next step in advancing minimal invasive surgery in the field of gynecology, with the potential for remarkable cosmetic results and reduced patient morbidity compared with MP-RSC surgery. Nonetheless, single-port surgical techniques are highly difficult to implement, which may bestow the explanation for their lesser popularity. The availability of RSC may help ease this difficulty, and thus aid in increasing the popularity of the procedure.

Though robotic-assisted surgery has been aggressively marketed and widely adopted across numerous surgical specialties in many countries, our recent MEDLINE search identified very few clinical trials comparing MP-RSC with conventional LSC, and no completed clinical trials comparing MP-RSC with SP-RSC. The aim of this study was to compare the learning curve and short-term outcomes of MP-RSC with SP-RSC, as reflected by the first cases with each technique.

Materials and methods

Following institutional review board approval (0543-15-RMB, date: 20/1/2016), we reviewed the charts of the first 52 consecutive women who underwent MP-RSC and the first 52 who underwent SP-RSC for treatment of uterovaginal prolapse at the Female Pelvic Medicine and Reconstructive Surgery Service at our medical center.

The first MP-RSC procedures were performed from April 2011 to November 2012. The first SP-RSC procedures were performed from August 2015 to August 2017. The surgical team included the primary surgeon-uro-gynecologist, a resident with ample experience with laparoscopic surgeries, a resident/intern assistant between the patient`s legs and a team of 2 nurses designated by the medical center, for assistance in robotic surgery throughout various medical specialties. The whole team was highly competent at performing the procedures laparoscopically

Surgical technique

Of the 52 patients in the MP-RSC group, 47 underwent sacrocervicopexy and 5 underwent sacrocolpopexy for vault prolapse. Of the 52 patients in the SP-RSC group, 45 underwent sacrocervicopexy and 7 underwent sacrocolpopexy for vault prolapse. The sacrocervicopexy robotic procedures were performed using a similar technique via the da Vinci Surgical System. For the multi-port we used 5 tools overall and for the single-port only 3 tools.

The surgical procedure for treatment of uterovaginal prolapse has been described in previous publications [17]. The scope used was a 30-degree scope in all procedures. Differences between MP-RSC and SP-RSC included the number and location of the ports. For the multi-port RSC approach, an 8-mm port was placed, overall five ports in a shallow "W" formation: one supra-pubic 12-mm umbilical port for the laparoscope; one 10-mm port placed subcostally on the right lateral side of the rectus muscle, and three 8-mm robotic ports in bilateral lower quadrants, two at the left lower quadrant and one on the right lower quadrant. The robotic patient cart was docked in a 45-degree angle lateral to the patient's left leg. For the SP-RSC, one 25-mm incision was made over the umbilicus (Fig. 1). The robotic patient cart was docked between the patient's legs. At the end of the surgery, we performed a transurethral cystoscopy to control for possible urologic related complications, such as the passage of a polyester suture through the bladder wall, cystotomy, or possible damage to one or both ureters. An identical number of cervical sutures and presacral tacks were placed in both surgical groups. The same mesh type was utilized in both surgical groups.

All patients underwent preoperative multichannel urodynamic testing (model Duet Logic G/2; Medtronic, USA) in a standardized fashion, with patients seated in a birthing chair. Urodynamic definitions conformed to the standards recommended by the International Continence Society [1]. When presenting, stress urinary incontinence was treated by an additional procedure, which used an inside out transvaginal obturator suburethral tape (TVT O; Gynecare, Ethicon).

Primary and secondary outcomes and failure of treatment

The primary outcome was the surgical times as recorded in each procedure type. Secondary outcomes included blood loss, 3-month post-op POP-Q scores, pain scale assessment and use of post-op NSAIDs/Opioids. In addition, patient`s files were scanned for additional gynecological visits in the post-surgical years for complaints that may represent failure of surgery or recurrence of prolapse which were defined as a POP-Q score of 2 or higher at sequential follow-up visits or a need for repeated surgeries for POP repair. The follow up period was defined as the interval from the time of surgery up to the last documented gynecological follow-up examination.

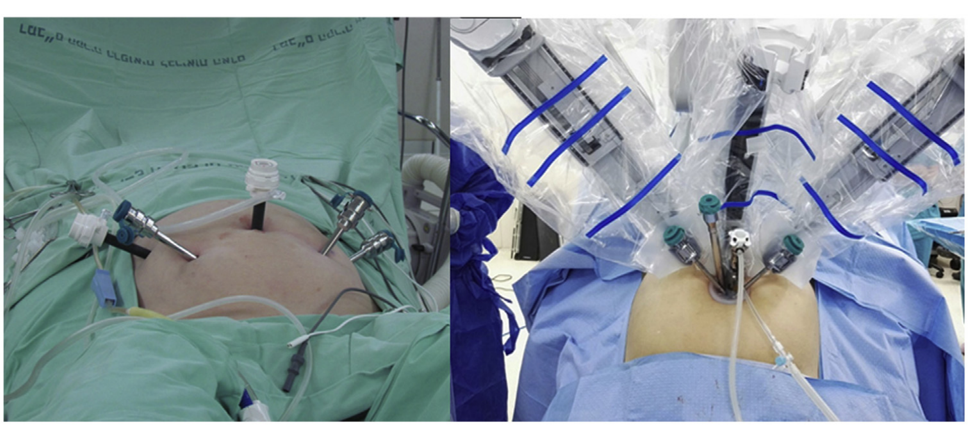

Fig. 1. Trocar placement in multiple-port versus single-port RSC.

Data collection

Sociodemographic data, preoperative and 3-month postoperative standardized prolapse assessment according to the pelvic organ prolapse quantification (POPQ) system, [24] medical history, and operative parameters, including time from initial incision to skin closure for all procedures (total operative time), time for specific stages of the procedure including robotic cart docking, hysterectomy + bilateral salpingo-oophorectomy, mesh suturing and peritonization time, perioperative complications (intra-operative and during hospitalization), and estimated blood loss, were retrieved from patients' electronic charts:

Pain level was assessed according to a 1–10-point visual analog scale (VAS) 24 h after surgery and during hospitalization. The use of pain medication including narcotics and nonsteroidal anti-inflammatory drugs (NSAIDs) during the hospitalization was also retrieved.

SPSS for Windows version 18 (SPSS, Inc, Chicago, IL) was used for data management and statistical analysis. The independent *t*-test was used for comparison between independent groups of continuous variables and Chi square of association for categorical parameters. All tests were considered significant at the 0.05 level. All tests were two-sided.

Results

Demographic and peri-operative anatomic and functional data showed no statistically significant differences according to procedure type (Table 1). Nor were there statistically significant differences in the POP-Q staging of patients who underwent MP-RSC compared with SP-RSC surgery (Table 1).

Rates of supra-cervical hysterectomy were similar for both procedures (Table 1), but rates of bilateral salpingo-oophorectomy were significantly higher in the single-port group (90.4% vs. 67.3%), P = 0.007. There was a statistically significant difference in mean operative times between the MP-RSC and SP-RSC procedures: 206.5 ± 39.4 and 187.8 ± 46.2, respectively, P = 0.028 (Table 2). In addition, there was a statistically significant difference in docking times between the two groups (the mean MP-RSC was 3 min longer, P = 0.001 (Table 2).

For both MP-RSC and SP-RSC, duration of surgery was decreased from the first 15 to the subsequent 15 surgeries from 224.2 ± 43.2 to 198.4 ± 36.3 min and remained stable over the subsequent 22 surgeries 199.9 ± 36.3, P = 0.12 and from 222.4 ± 53.1 to 161.3 ± 28.2 min increasing to 182.3 ± 37.2, P < 0.0001/P = 0.014, respectively (Tables 3 and 4). Reduction in duration of surgery time is attributed mainly to the steady decrease in console time. Console time in the MP-RSC group decreased from the first 15 to the subsequent 15 surgeries from 163.8 ± 35.5 to 125.5 ± 23.9 min and increased in the subsequent 22 surgeries to 143.7 ± 28.3, P = 0.01. In the SP-RSC group, console time decreased from the first 15 to the subsequent 15 surgeries from 173.9 ± 59.9 to 115.2 ± 19.3 min and increased in the subsequent 22 surgeries to 140.7 ± 31.9, P = 0.001/ P = 0.053(Tables 3,4).

Table 2
Surgical time parameters for multi-port and single-port robotic sacrocervicopexy/ sacrocolpopexy. Data are presented as means and standard deviations.

P- value	Single-port	Multi-port	Time parameter
0.028	187.8 ± 46.2	206.5 ± 39.4	Duration of surgery, min[a]
0.001	7.4 ± 4.3	10.4 ± 4.7	Duration of docking, min[a]
0.96	142.9 ± 45.2	142.6 ± 31.8	Console time, min[a]
0.14	248.7 ± 47.0	261.5 ± 41.1	Duration of anesthesia, min[a]

[a] Independent *t*-test.

There was no statistically significant difference in the length of hospital stay between the MP-RSC and SP-RSC patients (Table 5). In addition, there was no statistically significant difference in the level of pain, according to the VAS scores between the 2 groups (Table 5). Pain management treatment did not differ for the 2 procedures. Following MP-RSC, 90% of the patients managed the postoperative pain with NSAIDs alone; the remaining 10% required more aggressive pain management with opioids. Following SP-RSC, 97% managed the postoperative pain with NSAIDs alone; 3% required more aggressive pain management with opioids.

Complications

Following the MP-RSC procedure, one patient had a postoperative myocardial infarction, one developed a hernia in one of the surgical incision sites, and one had a postoperative surgical site hematoma. Following the SP-RSC, two patients had postoperative surgical site hematomas.

Three-month follow up visit

In three months follow-up, there were no documented surgical failures as measured by a POP-Q score of 2 or higher. The patients themselves had no subjective complaints either.

There were no conversions to classical laparoscopic surgery in either surgical group.

Table 1
Sociodemographic data and clinical history of women who underwent multi-port and single-port robotic sacrocervicopexy/sacrocolpopexy.

P- value	Single-port (2)	Multi-port (1)	Characteristic
0.77	58.4 ± 7.7 (35-74)	58.8 ± 7.8 (45-77)	Age, mean and range, years[a]
0.82	27.8 ± 3.8 (20.6-38.7)	27.6 ± 4.1 (18.3-34.9)	BMI, mean and range[a]
0.42	18 (34.6%)	20 (38.5%)	Hyperlipidemia, number (%)[b]
0.51	16 (30.8%)	12 (23.1%)	Hypertension, number (%)[b]
0.36	8 (15.4%)	4 (7.7%)	Diabetes, number (%)[b]
1.00	4 (7.7%)	3 (5.8%)	Cardiac disease, Number (%)[b]
0.76	45 (86.5%)	47 (90.4%)	SCH, number (%)[b]
0.007	47 (90.4%)	35 (67.3%)	BSO, number (%)[b]
0.13	12.8 ± 1.07 (12.9)	12.5 ± 1.2 (12.5)	Hemoglobin pre-op, gr/dl[a]
P = 0.004			Preoperative POP-Q[a] Score
	2 (3.8%)	5 (9.6%)	2
	33 (63.5%)	43 (82.7%)	3
	17 (32.7%)	4 (7.7%)	4

SCH: Supra cervical hysterectomy, BSO: Bilateral salpingooopherectomy, TVT: Tension-free vaginal tape, BMI-Body Mass Index, POP-Q- Pelvic Organ Prolapse Quantification.
[a] Independent *t*-test.
[b] Chi square of association.

Table 3
Surgical time parameters for the first 15 cases followed by the subsequent 15 cases and the subsequent 22 cases of single/multi-port robotic sacrocervicopexy/sacrocolpopexy. Data are presented as means and standard deviations.

P- value	Multi-port- Last 22 cases	Multi-port- subsequent 15 cases	Multi-Port- first 15 cases	Time parameter
0.12	199.9 ± 36.3	198.4 ± 36.3	224.2 ± 43.2	Duration of surgery, min[a]
0.008	[2]8.5 ± 2.8	10.3 ± 2.2	[2]14.0 ± 6.8	Duration of docking, min[a]
0.01	143.7 ± 28.3	[1]125.5 ± 23.9	[1]163.8 ± 35.5	Console time, min[a]
0.50	259.9 ± 33.9	254 ± 40.7	271.4 ± 50.9	Duration of anesthesia, min[a]

Statistically significant with Bonferroni adjustment:
P[1]: first 15 cases vs. subsequent 15 cases.
P[2]: first 15 cases vs. last cases.
P[3]: subsequent 15 cases vs. last 22 cases.
[a] Independent *t*-test.

Table 4
Surgical time parameters for the first 15 cases followed by the subsequent 15 cases and the subsequent 22 cases of single-port robotic sacrocervicopexy/sacrocolpopexy. Data are presented as means and standard deviations.

P- value	Single-port- Last 22 cases	Single-port- subsequent 15 cases	Single-Port- first 15 cases	Time parameter
[1]<0.0001 [3]0.014	[3]182.3 ± 37.2	[1]161.3 ± 28.2	[1,3]222.4 ± 53.1	Duration of surgery, min[a]
0.002 <0.0001	[3]5.5 ± 2.1	[1]6.4 ± 2.7	[1,3]11.2 ± 5.4	Duration of docking, min*
0.001 0.053	[3]140.7 ± 31.9	[1]115.2 ± 19.3	[1,3]173.9 ± 59.9	Consol time, min[a]
0.003	252.9 ± 41.7	[1]218.4 ± 28.1	[1]272.7 ± 55.1	Duration of anesthesia, min[a]

Statistically significant with Bonferroni adjustment:
P[1]: first 15 cases vs. subsequent 15 cases.
P[2]: first 15 cases vs. last cases.
P[3]: subsequent 15 cases vs. last 22 cases.
[a] Independent *t*-test.

Table 5
Post-operative parameters for women who underwent multi-port and single-port robotic sacrocervicopexy. Data are presented as numbers and (percentages) or as means and standard deviations.

P- value 0.9	Single-port 1 (0-2)	Multi-port 1 (0-2)	Characteristic Post-operative POP-Q[a] Score
0.91	2 (7%)	1 (3.5%)	Post-operative hematoma formation, number (%)[b]
0.86	11.4 ± 1.2	11.5 ± 1.1	Hb post-op, gr/dl[a]
0.12	37.6 ± 51.3	54.3 ± 58.6	Estimated blood loss, ml[a]
0.21	2.7 ± 0.86	2.4 ± 1.1	Hospitalization time, days[a]
0.17	1.5 ± 0.93	2.0 ± 1.2	Mean postoperative pain during first 24 h, visual analogue scale (1-10)[a]

[a] Independent *t*-test.
[b] Chi square of association.

Discussion

This study showed comparable learning curves for both MP-RSC and SP-RSC, performed by the same surgical team as appreciated based on surgical time and blood loss improvement. As expected, for both procedures, the operative time was significantly shorter for the sequential 15 operations (procedures 16–30) than for the first 15 procedures. For both RSC procedures, all the surgical time parameters improved after the first 15 surgeries. Postoperative failure rates as measured 3 months post-op by patients` POP-Q scores were zero for both procedures.

Based on our experience, about 15 cases are necessary to improve the skills and technique in both MP-RSC and SP-RSC. The learning curves we report are similar to those that have been reported for MP-RSC, with decreased operative times following 10–15 cases. [17] For SP-RSC, reduction in total operative time resulted not only from shortening of console time by the primary surgeon, but from the improvement by the entire team in preparation of the patient before docking, and of team work toward the end of the surgery following undocking. This improvement in the SP-RSC compared to the MP-RSC procedures may be due, at least in part, to the surgical team's accumulated experience in the RSC field. In addition, whereas the performance of MP-RSC depends almost completely on the skills of the primary surgeon, in SP-RSC, it is our experience that both the assistant surgeon and nurse must be highly familiar with the procedure, as their experience is key to it`s success. This crucial anecdote is strengthened by the results of the sequential 22 patients (procedures 31–52) in each surgical procedure group that demonstrates that while the first 52 surgeries performed in the MP-RSC group were all performed by the same exact surgical team, in the SP-RSC group, the first 30 surgeries were performed by the same surgical team and the sequential 22 surgeries were performed by the same primary surgeon but a random selection of assistants, with far less experience in RSC surgery. This further supports the notion that surgeon familiarity with the RSC procedure is a crucial point for surgical efficiency. Our findings are supported by Geller et al.'s study, which demonstrated improvement in multi-port robotic efficiency over a short learning period, with the most prominent improvement over time in intra-corporeal sutures and overall surgical times [15,16].

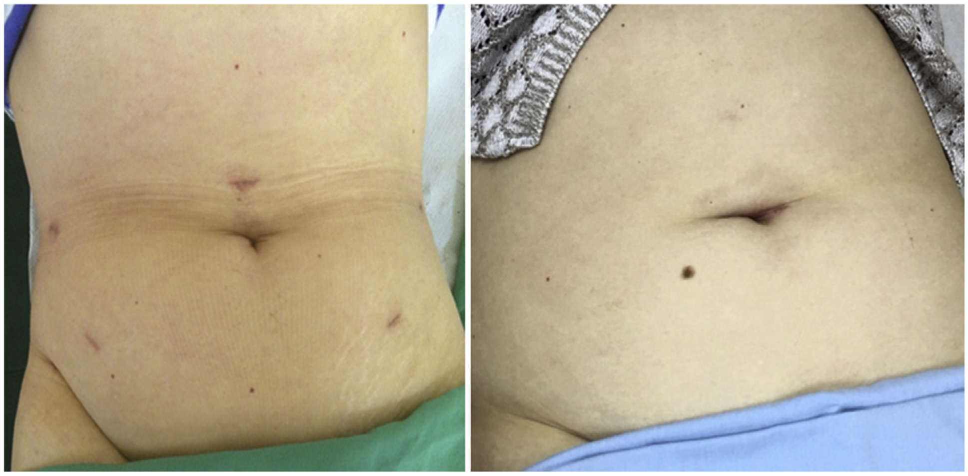

Fig. 2. Comparison of surgical scar in multiple-port versus single-port RSC.

In the current study, the complication rate was low for both RSC surgical procedures, and all complications were minor, except for a postsurgical myocardial infarction in one patient who underwent MP-RSC surgery.

Preoperative POP-Q staging was performed for all patients and was similar for the two procedures. No surgery failure (POPQ > 1) was reported during the 3-month follow-up or later during long term patients` electronic files follow-up (5–6 years in the MP-RSC group and 1–3 years in the SP-RSC group).

To upgrade surgical performance and as a part of our learning curve we made several modifications in our single-port surgical technique, during the course of the first 15 surgical procedures. These upgrades may have contributed to shortening duration of surgery. The modifications included:

1 Step by step fixation of mesh; the posterior sheet of the mesh was fixated first, followed by the anterior sheet of the mesh, after which approximation and fixation of both sheet was performed over the promontorium. This modification enabled posterior mesh suturing without having to remove the anterior sheet and the long arm of the mesh from the surgical field.
2 The sigmoid was fixated against the abdominal wall in order to remove it from the surgical field.
3 One of the most challenging parts of the surgery was the exposure of the posterior vaginal wall, for more accessible mesh suturing. Using the single-port accessory port was not always feasible as it often conflicted with the robotic arms. After 10 cases, we began using a straight needle with a prolene suture for cervical stump fixation to the abdominal wall, allowing the second assistant to demonstrate the posterior vaginal wall with the EEA™ sizer in an ideal fashion, thus facilitating suturing.

Improving quality of life and self-esteem are important goals of urogynecology surgeries. The single-port technique, which entails operating through one small abdominal incision, facilitates improved cosmetic results (Fig. 2).

Surgical outcome, costs and patient satisfaction are important factors that require further evaluation, though they are beyond the scope of the current study. An ongoing study is currently evaluating these factors in a longer post-operative follow-up.

Study limitations included:

1 The comparison of procedures performed during two different time periods. However, since the implementation of procedures did not occur in parallel, as is often the case regarding procedure implementation, a retrospective study design was necessary.
2 The apparent cosmetic advantage was not recorded with a subjective measure and is therefore not reported.
3 Long term follow-up is not available, thus limiting the evaluation of both long-term complications and long term surgical success.

Conclusion

Both MP-RSC and SP-RSC procedures are feasible, and their learning curves are comparable. Long term follow-up is needed to evaluate differences in outcomes between the surgical approaches.

Disclosure statement

The authors report no conflict of interest.

Consent

Written informed consent was obtained from the patient for publication of these images.

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