



Comparison between single-site and multiport robot-assisted myomectomy

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Abstract

Minimizing the number of port incisions during minimally invasive surgery is associated with improved outcomes and patient satisfaction. We designed this work to study the perioperative outcomes of robotic single-site myomectomy (RSSM) in comparison to robotic multiport myomectomy (RMM) in a certain subset of patients. The design of the study is a multicenter retrospective analysis (Canadian Task Force classification III). The setting was three university hospitals. Eighty patients with symptomatic uterine fibroids undergoing robot-assisted single-site myomectomy were selected for the study. These 80 consecutive RSSM patients were matched at the uterine fibroid tumor burden level with 95 consecutive RMM patients performed at the same institutions, by the same surgeons, within a similar time frame. The main outcome measures were estimated blood loss (EBL), operative time, overnight admission, and post-operative complications. Of the 175 women, 95 (54.2%) underwent RMM and 80 (45.7%) underwent RSSM. Single-site vs. multiport patient demographics differed significantly in mean age (39.1 vs. 35.6, $p < 0.001$), and BMI (25.3 vs. 27.5, $p < 0.04$). Pre-operative MRI fibroid characteristics were matched between the two cohorts. Fibroid size on imaging (5.8 cm vs. 5.9 cm, $p = 0.4$) and the number of fibroids removed (2.5 vs. 2.3, $p = 0.08$) were similar between the two groups. After adjustment for multiple covariates with regression models, single-site myomectomy and multiport myomectomy has comparable EBL (83.3 mL vs. 109.2 mL, $p = 0.34$), operative time (162.4 min vs. 162.4 min, $p = 0.99$), overnight admission (OR = 1.54, $p = 0.44$) and a post-operative complication (OR = 1.3, $p = 0.78$). In selected patients, robotic single-site myomectomy is equivalent to its multiport counterpart. Both surgical approaches are associated with low rates of intra-operative and post-operative complications.

Keywords Robotic myomectomy · Single-site surgery · Minimally invasive myomectomy · Single-site myomectomy

Abbreviations

RSSS Robot-assisted single-site myomectomy
RMM Robot-assisted multiport myomectomy
EBL Estimated blood loss
MRI Magnetic resonance imaging

BMI Body mass index
SD Standard deviation

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Introduction

Uterine fibroids are the most common tumor of the female genital tract [1, 2]. Leiomyomas are associated with abnormal uterine bleeding, bulk symptoms, recurrent pregnancy loss and subfertility [3]. Myomectomy allows a patient-centered approach to the surgical management of uterine fibroids for patients who desire fertility preservation or a uterine-sparing procedure [4].

With robust evidence suggesting that minimally invasive surgery is associated with reduced intra-operative blood loss, shorter hospital stay, faster recovery, fewer complications, decreased post-operative pain and enhanced post-operative cosmesis, we have seen a surge in the adoption of minimally invasive myomectomy [4–7]. However, in spite of the many demonstrated benefits, minimally invasive myomectomy remains underused given the technically demanding nature of the surgery which requires extensive tissue dissection and accurate multi-layer closure while maintaining adequate hemostasis [8]. Robotic surgery bypasses some of the inherent limitations of conventional laparoscopy with improved three-dimensional stereoscopic vision and magnification, articulating instrument, tremor-eliminating software, the ability to scale motion and the conferment of virtual ambidexterity [9, 10]. We still lack a well-designed randomized controlled trial comparing laparoscopic to robotic myomectomy; however, we have level III evidence [11] to suggest that tumor burden resection is superior using the robotic approach while maintaining comparable operative time, hospital length of stay, post-operative fertility and complications [4, 12].

Multiport myomectomy is the most commonly used robot-assisted approach. However, this technique has the least desirable outcomes for cosmesis secondary to placement of multiple operative ports higher on the anterior abdominal wall [13, 14]. Robotic single-site surgery in the setting of hysterectomy and lymph node dissection has been shown to be as feasible as its multiport counterpart, with some evidence suggesting decreased post-operative pain, estimated blood loss (EBL), length of hospital stay and cost [15–18]. Prior studies on single-site laparoscopic myomectomy demonstrate a reduction in post-operative pain, post-operative complications, hemorrhage, all while maintaining the most cosmetically desirable scar pattern and better access for tissue extraction [13, 19–22]. Although single-site laparoscopic surgery offers the aforementioned advantages, adoption of this technique has been almost nonexistent because of the insurmountable ergonomic burdens and steep learning curve. Robotic technology has the potential to overcome the technical challenges of single-site conventional laparoscopy, thereby allowing

accurate uterine reconstructive surgery to be performed through a single operative site [23–25]. RSSM is still an emerging procedure with a lack of data comparing the perioperative outcomes of RMM to its single-site counterpart. Single-site robotic surgery has its own set of challenges. The semi-curved metallic ports used for the flexible instruments results in significant instrument crowding and limited visualization when working with larger pathology. In this article, we present the results of a multicenter retrospective analysis comparing operative variables and complications between RSSM and RMM patients when matched for uterine fibroid tumor burden.

Materials and methods

Design

A multicenter retrospective analysis of consecutive patients undergoing single-site and multiport robotic-assisted myomectomy between January 2011 and December 2016. Institutional review board approvals were obtained from the George Washington University (federal wide assurance number 00005945) on November 3rd, 2016, Brigham and Women's Hospital (federal wide assurance number 00000484) on October 30th, 2012, and Ajou University Hospital (AJIRB-MED-MDB-17-219) on November 24th, 2017.

Patient selection

Patients desiring a minimally invasive myomectomy were evaluated at the Brigham and Women's Hospital's Center for Infertility and Reproductive Surgery, the George Washington University Hospital's Division of Minimally Invasive Surgery, and the Ajou University Hospital in Korea. All patients underwent pre-operative MRI of the pelvis, with and without gadolinium enhancement, to rule out adenomyosis and to allow for accurate surgical planning based on precise three-dimensional mapping of the fibroid tumors. The inclusion criteria to perform RSSM included patients who had an MRI exam showing a total tumor load of < 5 fibroids and a maximum tumor diameter of < 8 cm. Patients who did not meet inclusion criteria based on fibroid characteristics were considered candidates for a RSSM if their overall uterine size was comparable to that of a gravid uterus at < 14 weeks gestation on pelvic exam. This was reserved for patients who had a large subserosal fibroid measuring > 8 cm or more than five small fibroids who were deemed acceptable candidates for a RSSM by their respective surgeons. We applied strict exclusion criteria on the RMM group. All patients who had a dominant fibroid measuring > 8 cm or who had more than five fibroids were excluded to ensure that the two groups were comparable at the uterine tumor burden level.

Patients were thoroughly counseled on all options of surgical management and were made aware of any “off-label” uses of robot-assisted technology planned for their operation. All surgeons were fellowship-trained gynecological surgeons, with extensive robotic surgery expertise (with a minimum of 500 robotic procedures performed as independent operator). Each surgeon was also proficient with robotic single-site surgery and had performed at least 15 procedures before the case collection was initiated. Patients who did not fit the criteria for a RSSM based on pre-operative MRI fibroid characteristics were offered a RMM, which is the standard of care at all three institutions.

RSSM surgical technique

All robotic surgeries were performed utilizing the Da Vinci single-site surgical platform, with wristed needle drivers. Additionally, an 8 mm assistant cannula for conventional laparoscopic instruments was utilized.

While under general anesthesia, patients were placed in the dorsal lithotomy position. The standard Veress needle entry technique was used, and a uterine manipulator was placed. Patients were placed in a 20° Trendelenburg position, and an 8 mm laparoscopic port was placed in the umbilical incision for an initial laparoscopic survey of the pelvis to assess the technical feasibility of the procedure. Given the satisfactory conditions, the laparoscopic port was removed, and the umbilical incision was extended to 2.5 cm. The robotic multi-channel single-port silicone device was then inserted through the umbilical incision. Our preferred method for robotic docking was midline placement. The sequence of trocar placement includes the dedicated 8.5 mm camera cannula, docked on robotic camera arm, then instrument cannulas to be docked on arm 2 and 1, followed by the assistant cannula. The assistant cannula was placed through the gel port or at a separate site based on surgeon preference and clinical scenario. The use of instruments and energy types varied slightly between the three hospitals. They included a combination of 5 mm flexible monopolar hook, fenestrated bipolar grasper, wristed needle drivers, and a 2 mm flexible CO₂ laser fiber as published previously [26, 27].

To minimize blood loss, 5–10 units of dilute vasopressin were injected into the myometrium. Depending on myoma location and type [28], either a transverse or elliptical uterine incision was made to allow for more ergonomic enucleation of the fibroid and repair.

Fibroid enucleation was achieved with steady traction from a 5 mm single tooth tenaculum from the assistant cannula. Once fibroid enucleation was complete, each uterine incision was repaired in multiple layers, as per standard microsurgical technique, using an absorbable unidirectional barbed suture. Deep running suturing was performed. The

most superficial layer was closed in a hemostatic baseball stitch fashion to minimize barbed suture exposure and subsequent adhesions. After adequate hemostasis was noted the robot was undocked, and the single-site silicone port was removed from the umbilical incision. A flexible self-retaining retractor was then secured within the umbilical incision, and an endoscopic specimen extraction pouch was inserted through the retractor into the abdomen. A gel cap was placed over the self-retaining retractor, and conventional laparoscopic instruments were utilized to place the specimens within the endoscopic pouch. The edges of the pouch were then brought up through the incision, and the retraction device was placed within the bag to enhance visualization and protection of the umbilical incisions. The enucleated fibroids were extracted from the endoscopic pouch at the umbilical incision site via steady traction and precise cold-knife coring technique.

RMM surgical technique

The multiport protocol required a 12 mm camera trocar at the umbilical site, and at least two 8 mm lateral robotic trocars, with or without an assistant port. The umbilical port was enlarged to allow similar tissue extraction methods. With the exception of the mentioned differences, the two procedures followed similar surgical techniques.

Statistical analysis

Data extracted from the medical record included age, race, body mass index (BMI), history of smoking, history of previous pelvic surgery, pre-operative diagnoses, post-operative diagnoses, pre-operative hematocrit, pre- and post-operative complications, operative time, fibroid characteristics, length of hospital stay and EBL. Operative time was defined as time from skin incision to time of completed skin closure, including robotic docking time but excluding time to assemble to robot, which was performed pre-operatively.

Differences among demographic and clinical characteristics between cohort arms was determined using the Student's *t* test for continuous variables and Pearson's Chi square or Fisher's exact test for categorical differences depending on sample size. Comparison of surgical outcomes (including EBL, operative time, length of hospital stay, and operative complications) were evaluated using a Wilcoxon test for non-normally distributed continuous variables and Fisher's exact test for categorical variables.

Generalized linear models were utilized to analyze the relationship of clinical outcomes to single-site vs. multiport surgical approaches. The models were adjusted to account for all significant differences among demographic and clinical variables.

Odds ratios were calculated using logistic regression to analyze for differences in the length of hospital stay and post-operative complications between RMM and RSSM. Adjustments were made for statistically significant variables including relevant demographic characteristics, clinical variables and prior cesarean history, fibroid weight and the number of fibroids removed. It was not possible to calculate an odds ratio for intra-operative complications because of sample size limitation.

Results

The study population included 175 women, 95 (54.2%) of whom underwent RMM and 80 (45.7%) of whom underwent RSSM. Demographic and surgical characteristics are listed in Table 1. Statistically significant differences were noted in age, BMI, race, smoking history, pre-operation hematocrit, history of cesarean section, and history of adnexal surgery. Subjects in the RSSM cohort had a higher mean (\pm SD) age (39.1 ± 6.1 years vs. 35.6 ± 5.6 years, $p < 0.001$), had a more frequent history of cesarean delivery (14.1% vs. 3.2%, $p = 0.012$) and adnexal surgery (8.8% vs. 0%, $p = 0.004$). Patients in the RMM group had a higher mean (\pm SD) BMI (27.5 ± 6.6 vs. 25.3 ± 5.1 , $p < 0.04$), and higher rates of smoking (12.6% vs. 2.5%, $p = 0.02$). Pre-operative MRI fibroid characteristics were matched between the two cohorts. Compared to the RSSM cohort, the RMM cohort included patients with greater fibroid weights (176.4 g vs. 85.2 g, $p < 0.0001$). Estimated fibroid size on imaging (5.8 cm vs. 5.9 cm, $p = 0.4$) and number of fibroids removed (2.5 vs. 2.3, $p = 0.08$) were similar between the two groups (Table 2).

In the linear regression analysis, after adjusting for differences in patient demographics, surgical history, hospital site, and fibroid characteristics, RSSM had comparable EBL (83.3 mL vs. 109.2 mL, $p = 0.34$) and operative time (162.4 min vs. 162.4 min, $p = 0.99$) compared to RMM (Table 3).

In the logistic regression analysis, after adjusting for demographics, surgical history and fibroid characteristics, the risk of an overnight admission (OR = 1.54, $p = 0.44$) and a post-operative complication (OR = 1.3, $p = 0.78$) were both higher in the RSSM group, however, neither of these findings achieved statistical significance (Table 4). It was not possible to calculate the risk of intra-operative complications between groups, because no complications occurred in the single-site group.

Discussion

Robot-assisted myomectomy has been well-established as a safe minimally invasive option for management of uterine fibroids; however, use of single-site technology for this surgery is a more recent approach, for which safety data from large studies is still lacking. Potential advantages of umbilical single-site myomectomy include improved post-operative cosmesis with demonstrated higher patient acceptability, lower blood loss, decreased post-operative pain and complications, and shorter operating time [13, 14, 18, 29]. Limited studies have already demonstrated the feasibility and reproducibility of RSMM [22, 30, 31]. This study is the first attempt to compare the efficacy and safety of RSSM to the standard RMM in a carefully selected comparable cohort of patients.

Table 1 Patient demographics and surgical characteristics

Characteristic	Multiport ($N=95$)	Single-site ($N=80$)	p value
Age (years), mean (SD)	36.1 (5.7)	39.1 (6.05)	<0.001
BMI (kg/m^2) (SD)	27.9 (6.27)	25.3 (5.05)	<0.001
Race/ethnicity			<0.001
Black/African American	163 (56.6%)	19 (23.8%)	
White	74 (25.7%)	21 (26.3%)	
Asian	21 (7.3%)	37 (46.3%)	
Other/unknown	30 (10.4%)	3 (9.8%)	
History of smoking	35 (12.2%)	2 (2.5%)	0.01
Pre-operation hematocrit (%) (SD)	37.1 (4.03)	38.2 (3.64)	0.027
Prior surgical history			
Unspecified laparoscopy	32 (11.1%)	12 (15.0%)	0.343
Cesarean delivery	16 (5.7%)	11 (14.1%)	0.012
Myomectomy	28 (9.9%)	4 (5.1%)	0.192
Adnexal surgery	6 (2.1%)	7 (8.8%)	0.004
Unspecified laparotomy	22 (7.6%)	3 (3.8%)	0.221
Endometriosis excision	14 (4.9%)	3 (3.8%)	0.675

Table 2 Clinical outcomes

Clinical outcomes	Multiport N=95	Single-site (N=80)	p value
Estimated blood loss (mL), mean (SD)	163.9 (198.10)	64.25 (86.99)	<0.001
Operative time (min), mean (SD)	153.1 (64.96)	131.4 (58.54)	0.02
Length of stay (days), mean (SD)	0.28 (0.58)	1.09 (1.13)	<0.001
Any operative complications	8 (8.6%)	4 (5%)	0.388
Any intra-operative complications	3 (3.3%)	0	0.249
Organ injury	0	0	1
Estimated blood loss > 1000 cc	1 (1.1%)	0	1
Transfusion	3 (3.3%)	0	0.251
Conversion to laparotomy	0	0	1
Any post-operative complications	7 (7.4%)	4 (5%)	0.756
Reoperation	1 (1.1%)	0	1
Transfusion	2 (2.1%)	2 (2.5%)	1
Readmission	2 (2.1%)	0	0.501
Antibiotic treatment	2 (2.1%)	0	0.501
Urinary tract infection	1 (1.1%)	0	1
Urinary retention	1 (1.1%)	0	1
Bowel obstruction	0	0	1
Incision seroma/cellulitis/hematoma/separation/hernia	2 (2.1%)	2 (2.5%)	1
Fibroid characteristics			
Fibroid weight (g)	342.8 (325.80)	85.2 (75.70)	<0.001
Estimated size on imaging (cm)	8.3 (3.85)	5.9 (2.02)	<0.001
Number of fibroids removed	4.7 (4.11)	2.4 (2.05)	<0.001

p values for continuous variables are calculated using a Wilcoxon test (because they are non-normal). Categorical variables are compared using Fisher's exact test as appropriate (when $n \leq 5$)

Table 3 Linear regression results of estimated blood loss and operative time, comparing multiport and single-site robotic myomectomy

Clinical outcome	Multiport (SE)	Single-site (SE)	Difference (95% CI)	p value
Estimated blood loss (mL) ^a	110.3 (30.84)	87.96 (35.47)	22.33 (−27.31, 71.97)	0.375
Operative time (min) ^{ab}	148.5 (10.42)	147.9 (12.0)	0.58 (−16.31, 17.46)	0.946

^aAdjusted for age, body mass index, race/ethnicity, hospital site, smoking history, pre-operation hematocrit, prior non-specified laparotomy, previous myomectomy, fibroid weight, and total surgery time

^bAdjusted for age, body mass index, race/ethnicity, hospital site, smoking history, pre-operation hematocrit, prior non-specified laparotomy, previous myomectomy, fibroid weight, and estimated blood loss

Table 4 Logistic regression results of overnight admission and complications of multiport comparing multiport to single-site robotic myomectomy

Clinical outcome	Odds ratio (95% CI)			Adjusted odds ratio (95% CI)		
	Multiport	Single-site	p value	Multiport	Single-site	p value
Overnight admission ^a	Ref	3.58 (1.87, 6.86)	<0.001	Ref	2.69 (0.704, 10.27)	0.879
Any complication ^b	Ref	0.56 (0.16, 1.93)	0.358	Ref	1.53 (0.230, 10.130)	0.662

^aAdjusted for age, BMI, race/ethnicity, hospital site, preoperation hematocrit, smoking history, prior myomectomy, prior non-specified laparotomy, fibroid weight, estimated blood loss, total surgery time

^bAdjusted for age, race, preoperation hematocrit, estimated blood loss, total surgery time, fibroid weight

Multiple robotic approaches are described for myomectomy including the standard RMM, the RSSM and the “Reduced Port Robotic Myomectomy”. Each of these

methods has its set of benefits and limitations. Optimal use of the robotic platform is likely obtained by carefully tailoring the selected approach on a patient-by-patient basis.

Known limitations of current techniques of RSSM include a limited range of motion, limited triangulation, semi-rigid instruments that limit the traction that can be applied to tissue, sub-optimal smoke evacuation and finally lack in the armamentarium of available instruments. Those limitations prompted us to select a patient population that had a less significant tumor burden as candidates for the RSSM.

Pelvic MRI is the most accurate imaging modality for fibroid localization and was a standard component of the pre-operative testing for robot-assisted myomectomy at all three participating centers at the time this study was conducted. We carefully set our inclusion criteria based on MRI leiomyoma description. We established the tumor burden limit for RSSM at a maximum number of 5 fibroids, a maximum diameter of 8 cm per fibroid and/or a uterine volume of 14 weeks.

We found no significant differences between techniques in terms of EBL, operative time, overnight admission or surgical complications. Due to the absence of intra-operative complications in the single-site arm, the risk of intra-operative complications between groups could not be calculated. No conversions were reported in either of the groups. These findings demonstrate that RSSM does not offer any disadvantages in comparison to the multiport approach in carefully selected patients. Overall, this study is in line with previously published data and confirms equivalence in patient safety and surgical outcomes of robotic single-site gynecologic surgery.

Much of the previously stated concerns regarding use of single-site access included longer operative times, largely due to ergonomic challenges that stem from loss of extracorporeal triangulation in the setting of semi-rigid, non-wristed robotic instruments [31, 32]. Recent advances in robotic technology include development of wristed instruments for the robotic single-site platform, the safety and feasibility of which were demonstrated in several case studies [33, 34]. This newly designed technology in RSSM has been reported to enhance the ease of intracorporeal suturing, a notable outcome for suture-intensive procedure such as myomectomy [35]. Use of this wristed technology was employed at our study sites and did not demonstrate any disadvantages in surgical time. In fact, RSSM had significantly shorter surgical time compared to the multiport group, as mentioned above.

This study has some limitations. A retrospective study design, particularly one that evaluates surgical outcomes in selected patients, includes patient selection bias by its own design. In this cohort, all patients were referred to (or independently sought) minimally invasive surgery specialists for evaluation of their symptomatic fibroids, because of their stated preference for a minimally invasive surgical management. Therefore, the patient population in our study may not be representative of all women seeking treatment for symptomatic fibroids. Further, our inclusion

criteria for RSSM only allowed patients with less than 5 fibroids, with the largest tumor diameter of less than 8 cm, or an overall uterine size of less than 14 weeks, to undergo the single-site operation. This clearly prevents generalizability of our findings to women with larger and more numerous tumors. Also notable were some significant differences in our patient demographic and surgical baseline data. However, all such differences were adjusted for in our assessment of safety and surgical outcomes. The absence of complications in the RSSM group limits the ability to determine significant differences among groups in that respect. A strength of this study is its multicenter design in which surgeries were performed by multiple surgeons from different institutions, thus, our results may be generalizable to the larger surgical community. Further, some evidence has shown that, where single-site minimally invasive surgery is desired, robotic surgery allows shorter learning curves when compared to conventional laparoscopy [24, 36].

Future studies are needed to further evaluate additional potential benefits and long-term outcomes of robotic single-site gynecologic surgery. One potential benefit is the use of single-site technology in overweight and obese patients who represent a significant percentage of patients undergoing fertility and reproductive surgery, and who are at an increased risk of complications from open techniques [31]. Our study demonstrated good outcomes for both overweight and obese patients, as the average BMI of the single-site and multiport groups were 25.3 ± 5.1 kg/m² and 27.5 ± 6.63 kg/m², respectively. Further, based on data from conventional single-site laparoscopic surgery, the advantages of this technique include a decreased risk of incisional hernias and surgical adhesions compared to surgeries requiring multiple incisions [30, 31]. One retrospective study demonstrated minimal risk of 0.05% of umbilical herniation in women undergoing laparoscopic single-site surgery [37]. Other potential benefits that require further evaluation include enhanced cosmetic outcomes due to the hidden scar within the umbilicus in appropriately selected patients, as well as enhanced ease of contained extracorporeal tissue extraction. In our view, the wider umbilical incision used in the single-site access represents an ideal and ready point of removal of tissue through an endoscopic pouch [38].

Our study demonstrates that, in appropriately selected patients, single-site robotic myomectomy is feasible and safe, and has surgical outcomes comparable to those of standard multiport robotic myomectomy. Both techniques are associated with low blood loss, low rates of surgical complications and short lengths of post-operative hospital stay. Moreover, neither one of the techniques was associated with a conversion to open surgery. Larger cohorts or randomized controlled prospective studies with long-term follow-up periods are needed to confirm our findings and

further evaluate the long-term outcomes of robot-assisted approaches to myomectomy.

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Compliance with ethical standards

Conflict of interest Doctors Tyan, Paek, Tappy, Park, Chousein, Srouji, and Gargiulo declare that they have no conflict of interest. Dr. Moawad is a speaker for Intuitive Surgical.

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