

Beyond the learning curve- Improving outcomes in Robotic Myomectomy compared to Laparoscopic Myomectomy

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Abstract

Uterine myomas are benign tumors frequently seen in women of reproductive age. Myomectomy remains a viable option for treating this condition in women who wish to preserve their uterus. We undertook this study to compare the peri-operative surgical outcomes of Robotic myomectomy (RM) with laparoscopic myomectomy (LM) in Indian patients of uterine myomas after the initial learning curve of RM was achieved. A retrospective chart review was performed for the patients who underwent RM or LM for the treatment of uterine myomas. A total of 177 patients; 116 in the RM group and 61 in the LM group were included in the study. The mean age in the RM and LM group was 34.31 ± 5.40 years and 33.54 ± 4.96 years respectively ($p = .355$). The mean total operative time was marginally more in RM group (127.37 ± 110.67 vs. 120.66 ± 44.27 , $p = .650$) but the difference was not statistically significant. Patients in the RM group had significantly less blood loss (115.43 ± 79.43 vs. 340.98 ± 453.9 ml, $p = <.0001$), hospital stay (1.28 ± 0.49 vs. 1.92 ± 1.05 days, $p = <.0001$), requirement of blood transfusion (93.97% vs. 81.97%, $p = .031$) and requirement of intravenous (IV) analgesia (41.38% vs. 34.43%, $p = .019$) as compared to the patients in the LM group. The Robotic myomectomy significantly reduces blood loss, the duration of hospital stay, and requirement of blood transfusions and IV analgesia as compared to the laparoscopic myomectomy.

Introduction

Uterine fibroids are a major public health concern and is documented in many young women. Underlying cause is still not clear and treatment options are limited. As fibroids are mostly asymptomatic, estimating its prevalence is difficult. In a recent systematic review, prevalence ranged from 4.5 to 68.6%, depending on study population and methodology [1].

A study from Telangana, India showed the prevalence rate of 37.2% and 57.3% for the women in the age groups of 20–39 years and 40–59 years respectively [2]. Symptoms associated with fibroids have a negative impact on the quality of life. Heavy menstrual bleeding leading to anaemia or dysmenorrhoea are the commonest symptoms [3–4]. Large fibroids can lead to “bulk” or “pressure” symptoms like abdominal mass, pelvic pressure; urinary frequency, urgency and constipation [5]. Fibroids can cause adverse reproductive outcomes. 10% of infertility cases are due to fibroids, and can cause spontaneous abortion, preterm delivery, and need for caesarean delivery [6].

Although hysterectomy is ultimately performed to relieve the symptoms, there is a need for myomectomy in younger women to preserve their fertility or to continue having their menstrual cycles. Depending on the size and location, myomectomy can be performed by laparotomy, laparoscopy or hysteroscopy. The techniques and results of abdominal myomectomy way first reported in the year 1931. Today, the gold standard for myomectomy is minimally invasive surgery, which can be performed using both traditional laparoscopy and Robotic platform. Laparoscopic myomectomy is not commonly performed by all surgeons as it is estimated that it takes a surgeon to perform about a 100 of laparoscopic myomectomies for optimal outcomes and reduced complication rates. [7]. We believe the Robotic

assistance can help bridge this gap and make the minimal access myomectomy accessible to larger population.

Materials And Methods

The study was conducted at the Minimal Access and Robotic Surgery Unit of the Department of Gynaecology at a tertiary care hospital. A retrospective chart review for the period February 2015 to March 2021 was performed for the patients who underwent LM or RM for the treatment of uterine myomas. The Robotic myomectomy was performed using Da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, CA, USA). A multiport technique with central 12 mm camera port, 8 mm secondary port on either side of abdomen and a 5 mm assistant port on left side was used. A 30 degree telescope, hot shears, fenestrated bipolar and mega needle driver was used to perform Robotic myomectomy. Laparoscopic myomectomy was performed with Storz (Spice HD system) with standard 2D vision. A central 10 mm port, two 5 mm ports on left side and if needed a 5 mm port on right side was placed. 30 degree laparoscope, harmonic scalpel, scissors, myoma screw and needle drivers were used. Reconstruction in both techniques was done using 1/0 VLoc sutures. Ethics committee approval was taken for this study.

Clinical characteristics and demographic data were recorded from the patient's medical records. Symptoms at presentation, indication of myomectomy, diameter of largest myoma, number of removed myomas, weight of removed myomas, total operative time, console time, intraoperative blood loss, length of hospital stays, number of transfusion and requirement of post-operative IV analgesia were recorded. The total time was defined as the time taken from the placement of ports to closure of ports. All surgeries were performed by a single experienced surgeon.

Statistical analysis for categorical variables was summarized by the frequency and percentages. Discrete variables like symptoms at presentation, infertility, previous pregnancy, parity, abortion, blood transfusion, and intravenous analgesia were summarized by the numbers and the percentages. Continuous data were summarized by the arithmetic mean and standard deviation (SD) and analysed using the independent sample t-test whereas the categorical data were analysed using the chi-square test for independence. A two-sided $p < 0.05$ was considered significant. Statistical analysis was performed using SAS version 9.4 (SAS Institute Inc., North Carolina, USA).

Results

A total of 177 patients were included in the study. There were 116 patients in the RM group and 61 patients in the LM group. Baseline patient and fibroid characteristics for the two groups are presented in Table 1.

Table 1
Baseline Demographics and Fibroid Characteristics

Demographic and Fibroid Characteristics	RM (n = 116)	LM (n = 61)	p-value
Age, mean (SD), year	34.31 (5.40)	33.54 (4.96)	.355
BMI, mean (SD), kg/m ²	27.35 (4.54)	25.23 (4.17)	.003*
Symptoms, n (%)	68 (58.62)	16 (26.23)	.006*
Dysmenorrhoea	90 (77.59)	50 (81.97)	
Heavy Menstrual Bleeding	19 (16.38)	18 (29.51)	
Mass felt in abdominal examination	1 (0.86)	0 (0.0)	
Frequency of Urine			
Infertility, n (%)	48 (41.38)	23 (37.70)	.635
Infertility	68 (58.62)	38 (62.30)	
No Infertility			
Previous pregnancy, n (%)	67 (57.76)	30 (49.18)	.509
Nil	28 (24.14)	14 (22.95)	
1	17 (14.66)	14 (22.95)	
2	3 (2.59)	3 (4.92)	
3	1 (0.86)	0 (0.0)	
5			
Parity, n (%)	77 (66.38)	35 (57.38)	.687
Nil	20 (17.24)	14 (22.95)	
1	17 (14.66)	11 (18.03)	
2	2 (1.72)	1 (1.64)	
3			
Abortion, n (%)	100 (86.21)	53 (86.89)	.795
Nil	13 (11.21)	6 (9.84)	
1	1 (0.86)	0 (0.0)	
2	2 (1.72)	2 (3.28)	
3			
Number of fibroids, mean (SD)	2.38 (2.47)	1.97 (1.75)	.251

Demographic and Fibroid Characteristics	RM (n = 116)	LM (n = 61)	p-value
Size of largest fibroid, mean (SD), cm	9.13 (3.17)	9.20 (4.11)	.900
Fibroid weight, mean (SD), gm	382.53 (270.64)	418.38 (336.86)	.443

RM: Robotic-assisted laparoscopic myomectomy, LM: Laparoscopic myomectomy

*** Significant value**

Body mass index (BMI) was significantly more in the RM group. The patients who underwent RM were more symptomatic than the ones in LM group, especially for heavy menstrual bleeding and dysmenorrhoea and this difference was significant. Other demographic characteristics were not statistically different among the study groups. The mean age in the RM and LM group was 34.31 ± 5.40 years and 33.54 ± 4.96 years respectively ($p = .355$). Although the mean number of fibroids were more in RM group (2.38 ± 2.47) as compared to LM group (1.97 ± 1.75) the difference was not statistically significant ($p = .251$).

The comparison of the surgical outcomes between the two groups is enumerated in Table 2.

Table 2
Comparison of Surgical Outcomes

Surgical Outcomes	RM (n = 116)	LM (n = 61)	p-value
Docking Time, mean (SD), min	6.73 (1.88)	-	-
Console Time, mean (SD), min	93.88 (42.21)	-	-
Total Operative Time, mean (SD), min	127.37 (110.67)	120.66 (44.27)	.650
Blood Loss, mean (SD), ml	115.43 (79.43)	340.98 (453.09)	< .0001*
Hospital Stay (post-op), days, mean (SD)	1.28 (0.49)	1.92 (1.05)	< .0001*
Blood Transfusion, n (%)	109 (93.97)	50 (81.97)	.031*
Nil	5 (4.31)	3 (4.92)	
1	2 (1.72)	5 (8.20)	
2	0 (0.0)	2 (3.28)	
3	0 (0.0)	1 (1.64)	
5			
IV Analgesia, n (%)	48 (41.38)	21 (34.43)	.019*
Not required	65 (56.03)	31 (50.82)	
Required up to 24 hrs.	3 (2.59)	8 (13.11)	
Required up to 48 hrs.			

RM: Robotic-assisted laparoscopic myomectomy, LM: Laparoscopic myomectomy

* Significant value

The mean total operating time was marginally more in RM group and this difference was not statistically significant ($p = .650$). Patients in the RM group had significantly less blood loss (115.43 ± 79.43 vs. 340.98 ± 453.9 ml, $p = < .0001$) along with the significantly lesser requirement of blood transfusion. 93.97% of patients in the RM group required no blood transfusion as compared to 81.97% of patients in the LM group. The hospital stay was significantly less in RM group as compared with LM group (1.28 ± 0.49 vs. 1.92 ± 1.05 days, $p = < .0001$). Further, the requirement of IV analgesia was also significantly less for patients in the RM group as compared to the patients in the LM group ($p = .019$).

Discussion

A survey of current practices and opinions amongst surgeons on fibroid management published by R Fusun Sirkeci et al, reported that 81% surgeons perform some type of myomectomy [8]. Of these, open myomectomy, hysteroscopic procedures and laparoscopic myomectomy was performed by 74%, 56%

and 32% of the respondents respectively [8]. Although laparoscopy has been advocated for gynecological procedures since 1979 [9] there is still a lot of gap in availability of laparoscopic myomectomy as an option to women seeking conservative treatment for fibroids. This gap is primarily due to steep learning curve, limited degree of freedom of the instruments and the difficulty in performing sutures in narrow pelvic spaces by surgeons. The Robotic technology is more intuitive than standard laparoscopy. It exactly simulates the surgeon's movements performed at the masters on the console and perfectly translates it on to the patient's pelvis. The ten times magnification with 3-D vision, wrist like movements and the physiologic tremor filtration are key features of Robotic technology. These features can help surgeon reduce their learning curve. A recent publication on learning curve for gastrectomy by Kim M et al [10], reported that twenty-five cases were needed to gain proficiency and additional 23 cases were needed to progress from proficiency to mastery.

The first Robotic-assisted myomectomy was reported by Advincula et al in the year 2004 [11]. In India, there is a paucity of data on the surgical outcomes of laparoscopic, and Robotic myomectomy. To the best of our knowledge, the present study is the first study from a tertiary care centre in India that has compared the outcomes of these two surgical techniques in patients with uterine myomas. The general criticism is that Robotic myomectomy takes more time and does not give superior clinical outcomes when compared to laparoscopic myomectomy. This study is mainly to focus in comparing these two procedures once the learning curve of Robotic myomectomy was achieved at our centre.

In a study by Göçmen et al the mean age reported for the Robotic and laparoscopic groups was 34.20 ± 5.65 years and 35.65 ± 6.13 years ($p = .202$) respectively [12]. In another study comparing the surgical outcomes of Robotic-assisted, laparoscopic, and abdominal myomectomy from a total of 575 myomectomies the mean age reported for the Robotic and laparoscopic groups was 37.00 ± 5.19 years, 38.00 ± 6.67 years and 37.00 ± 5.93 years respectively [13]. Pluchino et al reported the mean age of 34.72 ± 5.95 years and 36.40 ± 7.14 years respectively for the Robotic and laparoscopic groups [14]. In our study, mean age of 34.31 ± 5.40 years and 33.54 ± 4.96 years respectively for the RM and LM group ($p = .355$) was comparable. The women needing myomectomy are of similar ages across multiple studies and countries.

It is reported across specialities that robot gives an advantage in performing surgery in obese patients. Similar to this, in our study, patients in the RM group had a significantly higher mean BMI as compared to the LM group (27.35 ± 4.54 kg/m² vs. 25.23 ± 4.17 kg/m², $p = .003$). Both Gocmen and Chen in fact reported the opposite findings and their LM group had higher BMI than the RM group although the difference was not statistically significantly [12,15]. However, Geppert et al concluded that Robotic hysterectomy in obese women (BMI > 30) was associated with similar operating time when compared with the abdominal hysterectomy once the learning curve was over [16]. An interesting study by Moss EL et al, recorded the real-time information on the muscle movement/activity in surgeons to perform exercises in simulated in normal and high BMI models. They found that the time to complete all exercises was significantly lower for Robotically assisted surgery as compared with straight-stick laparoscopy ($p < 0.05$ or better). Further, the movement of the surgeons' core and muscle usage was significantly greater in

high BMI straight-stick laparoscopy as compared to the Robotically assisted surgery [17]. Our study was not a randomised trial, but it did suggest that Robotic surgery is offered more to obese women as pelvic surgery is easy with robot in such women. This may be attributed to the fact that in morbidly overweight patients, Robotic myomectomy can be a safe and effective minimally invasive method.

Although not statistically significant, in our study the mean number of fibroids removed were more in RM group as compared with LM groups (2.38 ± 2.47 vs. 1.97 ± 1.75 respectively, $p = .251$). This observation is consistent with the findings (2.73 ± 3.10 vs. 2.09 ± 1.85 , $p = .573$) of Gocmen et al [12]. Further, in our study, the mean size of the largest fibroid for the RM and LM groups was 9.13 ± 3.17 cm and 9.20 ± 4.11 cm respectively ($p = .900$). The mean size of the largest fibroid in our study was way higher than the previously published report by Gocmen et al (6.00 ± 1.50 cm vs. 5.53 ± 1.40 cm, $p = .307$), Barakat et al (7.7 ± 0.73 cm vs. 6.7 ± 0.93 cm), Pluchino et al (4.76 ± 1.71 cm vs. 4.2 ± 2.38 cm) and Hsiao et al (6.3 ± 0.23 cm vs. 6.4 ± 0.33 cm) respectively [12–14, 18]. The mean fibroid weight for the RM and LM groups (382.53 ± 270.64 gm vs. 418.38 ± 336.86 gm, $p = .443$) in our study was higher than the previously published report by Bedient et al (210 ± 270 gm vs. 350 ± 330 gm, $p = .13$) [19]. This is again consistent with the observation that robot assisted surgery is useful in performing more complex myomectomies and can be instrumental in preventing open myomectomies.

The mean total operative time reported in our study was slightly more for the RM group when compared with the LM group (127.37 ± 110.67 min and 120.66 ± 44.27 min respectively ($p = .650$). This difference is not statistically significant. We consider this as an important finding as it contradicts the previously reported studies showing significantly higher operative time in Robotic myomectomies. An increase of surgical time (coefficient = 51.9 min, $P < .001$) was reported by Chen et al [15]. Wang et al reported a significantly prolonged operative time (weighted mean difference 84.88, $p < .00001$) in RM cases when compared to abdominal myomectomy cases [20]. This is an important conclusion of our study, that beyond the initial learning curve, there is no difference in the operative time between LM and RM cases. However, Robotic surgery can help in better operative outcomes as discussed further in this study.

A multiple regression analysis was performed on log operative time considering all the variables as independent variables. The regression model had the number of fibroids and the size of the fibroids as significant predictors. The result revealed that the total operative time was significantly affected by the number of fibroids ($P < .0001$) and the size of the fibroids ($P = .005$) without any significant association with the type of surgery ($P = .953$). The model power was low so we performed the stepwise regression where we found the same two variables as significant ($P < .0001$) but with the higher power. Considering that no significant difference is seen by adding additional independent variables the number of fibroids and the size of the fibroids turn out to be significant in the regression model at a 1% level of significance. To confirm this, we also performed the analysis of covariance in order to see if there is any effect of covariates on the dependent variable and again, we found that the type of surgery was not significant although the dependent variable was significant at a 1% level of significance.

In our study, mean blood loss was significantly less in the RM group as compared to the LM group (115.43 ± 79.43 vs. 340.98 ± 453.09 ml, $p = < .0001$). Four previous studies by Gocmen et al (101.33 ± 39.84 ml vs. 119.78 ± 43.70 ml), Barakat et al (100 ± 120.4 ml vs. 150 ± 74.1 ml), Pluchino et al (138.42 ± 67.66 ml vs. 232.74 ± 183.14 ml), and Qin et al (68.2 ± 28.9 ml vs. 102 ± 25.7 ml) have reported similar observations [12–14, 21]. Among all these studies, the mean blood loss in the RM group was lowest in the study by Qin et al whereas the same for the laparoscopic group was highest in our study. Reduction in total blood loss and the need for lesser IV analgesia in the post op periods has significant impact on post-operative recovery. This further contributed in reducing the length of stay even allowing patient to undergo this procedure as day care.

The duration of hospital stay in our study was significantly less for patients in the RM group as compared to the patients in the LM group (1.28 ± 0.49 vs. 1.92 ± 1.05 days, $p = < .0001$). This observation is consistent with the findings of the previously published reports by Gocmen et al (1.67 ± 0.58 days vs. 1.87 ± 0.67 days) and Barakat et al (1 ± 0.001 days vs. 1 ± 0.67 days) [12–13]. Two other studies by Pluchino et al (2.03 ± 1.08 days vs. 1.94 ± 0.37 days) and Qin et al (3.12 ± 0.82 days vs. 4.98 ± 0.83 days) have reported a higher duration of hospital stay as compared to our study but the difference between the RM and LM group in these studies also was statistically significant [14–21]. A meta-analysis reported no statistical significance for the length of hospital stays between RM and LM group (OR 0.04, 95% CI, 0.09–0.18, $p = .56$) [22].

In our study, 93.97% of patients in the RM group required no blood transfusion as compared to 81.97% of patients in the LM group ($p = .031$). Two previous studies by Pluchino et al (97.67% vs. 90.7%) and Bedient et al (95% vs. 95.12%) reported a relatively higher percentage of patients that require no blood transfusion in both RM and LM groups [14, 19]. The number of blood transfusions in the RM group of our study was significantly less than the LM group (6.03% vs. 18.03%) and the finding is contrary to the observations of a pooled analysis of 6 studies [20] where there was no significant difference in the number of transfusions between RM and LM group (OR 1.16, 95% CI, 0.61–2.18, $p = .66$). Another meta-analysis comprising eight studies of Robotic versus laparoscopic myomectomy reported no statistical significance for the transfusion needed between RM and LM group (OR 1.13, 95% CI, 0.42–3.07, $p = .15$) [22].

Post-operative pain felt by the patient is important criteria to determine early discharge and less dependence on IV analgesia can help achieve this. In our study, 41.38% of patients in the RM group, and 34.43% of patients in the LM group did not require any IV analgesia ($p = .368$) once they were out of the operating room. Further, 56.03% and 2.59% of patients in the RM group and 50.82% and 13.11% patients in the LM group required IV analgesia for up to 24 hrs. ($p = .509$) and 48 hrs. ($p = .006$) respectively. The requirement of IV analgesia was significantly less for patients in the RM group as compared to the LM group ($p = .019$). This significant difference in IV analgesia requirement helped in reducing the length of stay in our study population. A previous study by Mangalath AS et al comparing the analgesic requirements in robot-assisted versus conventional laparoscopic abdominal surgeries also reported the similar finding [23].

In our study, the symptoms (dysmenorrhoea, heavy menstrual bleeding, abdominal mass, and frequency of urine) were significantly higher in the RM group as compared to the LM group ($p = .006$). A study by Chen YC et al, also reported higher symptoms (mass effect, bladder symptoms, dysmenorrhea, pelvic pain and abnormal uterine bleeding) in the RM group as compared to the LM group although the difference was not statically significant [24].

Conclusion

The RM significantly reduces blood loss, the duration of hospital stay and requirement of blood transfusions as compared to the laparoscopic myomectomy. Further, the requirement of IV analgesia in the immediate post-operative period and up to 72 hours post-operatively is important in achieving early discharge. Beyond the learning curve of the surgeon, RM is comparable if not better than LM in clinical practice.

Strengths And Limitations

A relatively small number of patients in each group as well as retrospective design may be regarded as a limitation but statistically significant improvement in most of the surgical outcomes by the Robotic myomectomy clearly offsets the limitations of the study. A prospective study on Indian population evaluating the long-term outcomes such as pain control, fertility, pregnancy rates and recurrence rates after Robotic myomectomy seems warranted.

Declarations

CONFLICT OF INTEREST: The authors report no conflicts of interest in this work. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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Ethics Approval: This study was performed in line with the principles of the Declaration of Helsinki and the applicable guidelines for good clinical practice (GCP). The approval was granted by the Institutional Ethics Committee – Biomedical Research of Apollo Hospitals, Hyderabad (Date: 26th April 2021/IEC Application No: AHJ-ACD-045/04-21)

Consent to Participate: Being a retrospective data collection study, the study data was collected in an anonymized fashion. Hence waiver of informed consent was applicable as per the regulatory guidelines.

Consent to Publish: Not applicable

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