Robotic Laparoscopic Myomectomy vs Abdominal Myomectomy and the Introduction of a New Annular Umbilical Incision(Hanafi AUI):

Clinical Evaluation and Cost Analysis.

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Introduction

Laparoscopic techniques are not surgically practical for patients with large fibroid tumors, tumors associated with endometriosis, severe bowel adhesions, and patients with short stature [1]. AUI technique is an option for the extraction of larger fibroid tumors and achieves an esthetically desirable post-operative outcome without the use of mechanical morcelator (controversial).

Previous studies demonstrate that at least 20% of women between ages 25-64 may require a hysterectomy for leiomyoma [2]. Seventy percent of Caucasian women and more than 80% of African-American women have uterine leiomyomata by age 50 [3]. Leiomyomata requires surgery when symptomatic [4]. Since 1931, myomectomy has been described as the gold standard surgical treatment of symptomatic leiomyomata for women desiring future fertility or uterine conservation [5]. Non-surgical options such as Uterine Fibroid Embolization [6] and Focused Ultrasonic Wave treatments [7] are available for patients who choose not to have surgery. AM is associated with higher morbidity, blood loss and adhesion formation rates [8-10]. Leiomyoma are treated with laparoscopic myomectomy which provides a minimally invasive surgery [11]. Although laparoscopy promotes faster post-operative recovery, improved cosmetics [12], other technical challenges, such as enucleating the leiomyomata and repairing the uterine incision with multilayer sutured closure, is overwhelming. Robotic surgery using the da Vinci® robotic surgical system has been proposed to overcome the limitations of the traditional laparoscopy while still benefiting from the advantages of the minimally invasive technique [13]. **The author has no conflicts of interest and no financial disclosure.**

Materials and Methods

This is a retrospective study for all consecutive myomectomy cases (n = 484) performed by the same surgeon (author) and assisted by a surgical assistant from January 1, 2009 to December 31, 2017, a period of 9 years. The cases were performed at Emory Saint Joseph's Hospital in Atlanta, GA. Patients' electronic medical records (office and hospital) were used to collect data on patient characteristics (age, BMI, ethnicity, parity, length of hospital stay, operative time, estimated blood loss [EBL], aggregate tumor weight and total hospital charges). Patient questionnaires were utilized to collect post-operative outcomes data (post-operative pain level, days until self-care, days of pain analgesic use, days until first bowel movement, weeks until returning to work, any post-operative complication and weeks until first intercourse). Each patient was given a letter of the research educational objective explaining the project and assuring respondents of the confidentiality of their personal data. Complete questionnaire data were obtained on 261 cases in the RLM group (62.3%) and 36 cases in the AM group (55.4%), seven patients refused to answer the questionnaires.

Patients had a pelvic examination and a trans-vaginal ultrasound to confirm the presence of the leiomyomata. MRI was done for larger fibroid tumors. The number, size, and location of the tumors were recorded. This information was brought to the operating room to guide the surgeon in locating the leiomyomata for excision. All statistical analyses were performed using *JMP 13.1.0* software (SAS Institute, Cary NC). Comparisons of the patient pre-operative and post-operative characteristics were performed using the Student's *t*-test. Variables with skewed distributions were analyzed using the Wilcoxon Signed Rank test. Statistical significance was set with an alpha level of 0.05.

Robotic Laparoscopic Myomectomy (RLM)

All patients received general anesthesia and were placed in lithotomy position. Hysteroscopy with fractional dilatation and curettage was performed as a part of the operation to diagnose and treat thickened endometrium, endometrial polyps, and submucosal leiomyoma (if present) and to visualize the cornual opening of each fallopian tube, especially for infertility patients.

A uterine manipulator with a proper cup size was fitted in the uterus. A Foley catheter was inserted in the bladder. Injection of bupivacaine 0.5% with epinephrine was performed subcutaneously in the trocar insertion sites. The skin of the center of the umbilicus was caught by Kocher clamp. A semicircular incision was made in the lower fold of the umbilicus with a knife blade size 15. In cases of larger fibroid tumors an annular umbilical incision (Hanafi AUI) was made in the upper fold of the umbilicus which increased the wound size significantly without compromising the esthetic appearance of the umbilicus after closure of the incision (Figure 1c.). An excision of a small portion of the skin (0.5-1.5 inches) was made, which allowed more space for retraction of the upper edge of the incision up to 2.5 inches above the umbilical fascia attachment to allow a small longitudinal fascia incision (1.5-2.0"above the umbilicus) for the laparoscopic camera trocar (Hasson trocar insertion). This is advantageous in these cases because it provides more space between the tip of the laparoscope (camera) and the tumors for easier excision and suturing. Retaining sutures were placed at each end of the slit in the fascia by size 0 VICRYL™ (Polyglactin-J329 by Ethicon Inc.) in a CT-1 needle, and the ends of the sutures were caught by hemostat for traction. Insertion of the Hasson trocar was anchored to the fascia with the sutures. CO_2 gas was insufflated with high pressure flow. The regular zero angle laparoscope was inserted. With visualization, small incisions were made in the mid-axillary line in each side just below the costal margins. A 12 mm SurgiQuest (Conmed Corporation, Utica, NY) trocar was inserted in the right mid-axillary line about one inch above the level of the umbilicus (Figure 1b.)

Any abdominal and/or pelvic adhesions were dissected with the use of hydrodissection and monopolar shears. Chromopertubation with indigo carmine dye (5cc) diluted in 150cc of saline solution was performed before and after myomectomy in all patients especially those who desire future fertility, was performed. The dye solution was injected through the uterine manipulator.

Da Vinci® SI or XI robotic equipment was docked. Any suspicious operative appearance of malignancy of any fibroid tumors intra-operative biopsies were obtained for frozen section for pathological evaluation. The hot shears (Monopolar Curved Scissor, with 30-40 volts setting) was inserted in the right 8mm trocar, and the Cadiere forceps (or pro-grasp) was inserted in the left 8mm trocar. All instruments were inserted in the abdominal cavity with visualization. Diluted vasopressin solution (20 units of vasopressin in 100cc of injectable saline) was injected very carefully around the visualized leiomyomata in sessions by the use of a long needle with visualization. The duration of the effect of vasopressin is about 20 minutes. An incision was made in the seromuscular layer covering the tumor. The incision was designed in the uterine wall according to the tumor size, location, and its correlation to the fallopian tubes. The tumors were enucleated by traction and counter-traction by the use of instruments of the surgeon's choice like the Tenaculum, Davis and Geck grasper, and the tip of the suction irrigator. Cutting of all adherent tissue surrounding the tumor was done using monopolar hot shear scissors. The uterine wound edges were trimmed with the hot shears and sutured in two layers by PDS®II size 0 (Polydioxanone Z340H by Ethicon Inc.) in CT-1 needle or V-Loc™ size 0 (by Covidien). The uterine incision close to the insertion of the fallopian tube was sutured by polyglactin 3-0 in SH (small-half circle) needle in an interrupted superficial fashion or 3-0 V Loc™ in a continuous suture to avoid interruption of the tubal patency. The tumors were sutured together with V-Loc™ size 0 sutures for identification and removal through the extended midline fascial incision and Hanafi AUI. After the robotic portion of the excision of the myomas, the uterine incisions were sutured and each tumor marked with sutures for easy identification and extraction. The opening of the parietal peritoneum was closed by polyglactin size 0 in CT1 needle in a continuous fashion. The fascial midline incision was closed securely with PDS®II size 0 with multiple figure of eight sutures to avoid any herniation. All the incisions were closed per routine after the CO_2 gas was released and covered with topical skin adhesive. The AUI subcutaneous tissue was closed in two layers. The deep layer was closed with interrupted figure of eight multiple polyglactin size 0 in CT1 needle sutures anchored to the fascia, after excision of the excess fat, tailored to approximate the upper and lower edges of the skin incision to accomplish an esthetically acceptable smooth wound. The superficial layer is sutured by Monocryl dyed sutures 4-0 in a PS-2 needle, which is used to close the skin in a continuous subcuticular or interrupted superficial skin suture. The VCare® uterine manipulator was removed.

Abdominal Myomectomy (AM) – Figure 1d.

Hysteroscopy with fractional dilatation and curettage was performed for all the patients to thoroughly evaluate the endometrial cavity and to excise any endometrial polyps and/or submucous fibroid tumors. A Pfannenstiel transverse abdominal incision was made after the patient was given general anesthesia and placed in lithotomy position. A self retaining retractor was placed after the peritoneal cavity was opened. Chromopertubation, for patients who were trying to conceive before and after myomectomy, was done through a Foley catheter size 12 placed in the uterine cavity. Diluted solution of vasopressin in injectable saline (20 units of vasopressin in 100 cc of saline) was injected in the myometrium surrounding the leiomyomata. Incisions were made in the seromuscular layer over the leiomyomata with the goal of removing the most tumors with the least numbers of incisions in the uterine wall as possible. Suturing of the uterine incisions was performed in two layers using V-Loc™ size 0 (by Covidien) in CT-1 needle. The abdominal wall was closed in layers as routine. The skin was closed by 3-0 polyglactin ™ in a Keith straight needle. 30 cc of bupivacaine 0.5% with epinephrine was injected subcutaneously and in the rectus fascia to reduce the immediate post-operative pain. Topical skin adhesive was placed over the abdominal incision. A pressure abdominal dressing was placed to avoid any post-operative wound hematoma when mini-abdominoplasty was performed. Mini-abdominoplasty was frequently performed by the gynecologist, in patients with large fibroid tumors for the purpose to reduce the redundancy of the abdominal wall and increase the patient cosmetic appearance post-operatively.

Results

A total of 484 of myomectomy cases, 419 RLM and 65 AM cases were reviewed. Age, BMI, gravidity, parity, operative time and hospital charges did not differ significantly between AM and RLM groups. AM group had a significantly higher hospital stay (2.3 days) than RLM group (1.4 days) *P* <.001. Estimated blood loss was significantly higher in AM (178.5 mL) than RLM (105.9 mL) *P* <.001. The mean aggregate weight of Leiomyomata removed in AM group (525.1 g) was significantly greater than RLM group (76.4g) *P* <.001. RLM group had significantly less number of weeks to return to work (4.2) than AM group (5.7) p=.010. AM group had significantly greater number of days until first bowel movement (5.2) than RLM group (2.7) *P* =.008. RLM group had significantly fewer number of weeks until resuming sexual activity (7.7) than AM group (10.4) p=.007.

Table 1. Comparative Table of Pre-Operative and Post-Operative Characteristics (n=484)

	Mean		
Characteristics	**RLM (n= 419)**	**AM (n= 65)**	**P-Value**
Age	40.0	41.7	.052
BMI	31.0	29.3	.065
Gravidity	1.7	1.4	.249
Parity	0.9	0.6	.076
Operative time	185.9	189.4	.722
Total Hospital days	1.4	2.3	<.001*
Blood loss (ml)	105.9	178.5	<.001*
Weight of Tumor (gm)	76.4	525.1	<.001*
Surgery Cost (dollars)	31208.2	32083.2	.591

RLM= Robotic Laparoscopic Myomectomy, AM= Abdominal Myomectomy.
*p<.05 was considered statistically significant

Table 2. RLM Mean Operative Time vs. Year of Surgery

Year	Mean Operative Time (minutes)
2009	217.0
2010	201.6
2011	194.1
2012	196.4
2013	186.0
2014	174.7
2015	174.2
2016	171.8
2017 (n=55)	174.9
2018 (n=36)	167.9

RLM= Robotic Laparoscopic Myomectomy

Table 3. Summary of Questionnaire Results

	Mean		
Characteristics	**RLM** n= 261/419 (62.3%)	**AM** n= 36/65 (55.4%)	**P- Value**
Post-operative pain level	6.1	7.0	.098
Days of analgesic use	9.8	11.2	.469
Days until self-care	7.7	10.4	.007*
Weeks until work	4.2	5.7	.010*
Days until first bowel movement after surgery	2.7	5.2	.008*
Weeks until intercourse after surgery	7.1	11.2	.014*

RLM= Robotic Laparoscopic Myomectomy, AM= Abdominal Myomectomy.
*p<.05 was considered statistically significant

Figure 1b. Placement of abdominal trocars in RLM

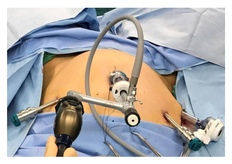


Figure 1c. Post-operative AUI-RLM patient.

Figure 1d. Mini-Abdominaloplasty Incision Post-operatively in AM Case.

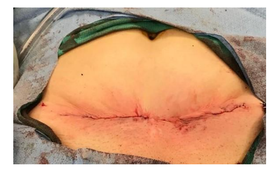


Figure 2. Surgery Method vs. Mean Operative Time p <.722

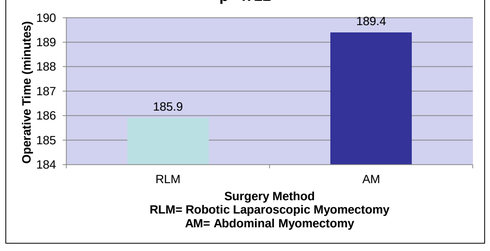


Figure 3. Surgery Method vs. Mean Total Hospital Charges p =.591

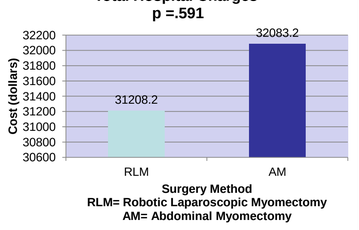


Figure 4. Surgery Method vs. Mean Length of Hospital Stay p <.001

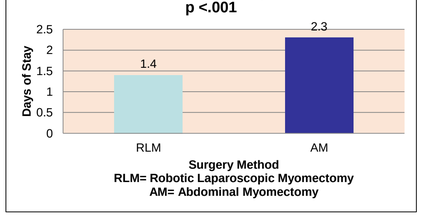


Figure 5. Surgery Method vs. Mean Estimated Blood Loss p <.001

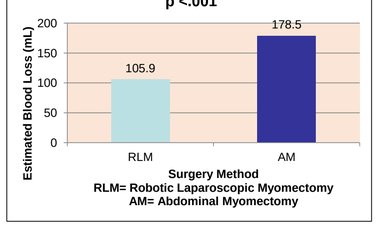


Figure 6. Surgery Method vs. Mean Tumor Weight p <.001

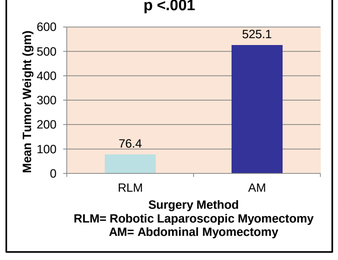


Figure 7. RLM Mean Operative Time vs. Year of Surgery

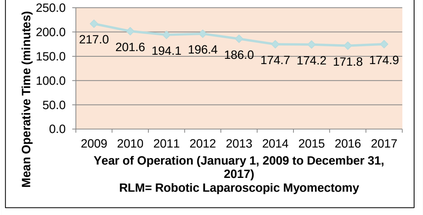


Figure 8. Surgery Method vs. Weeks Before Returning to Work

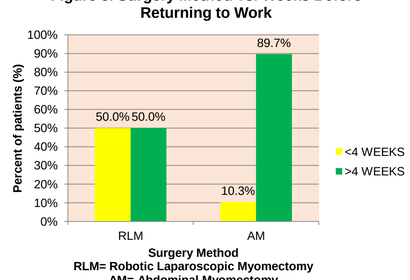


Figure 9. Surgery Method vs. Bowel Movement Within First Post-Operative Day p=.008

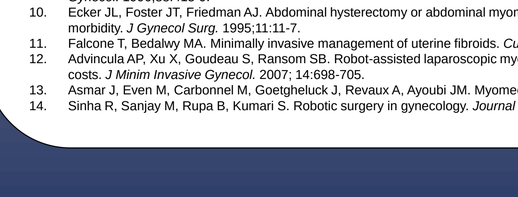
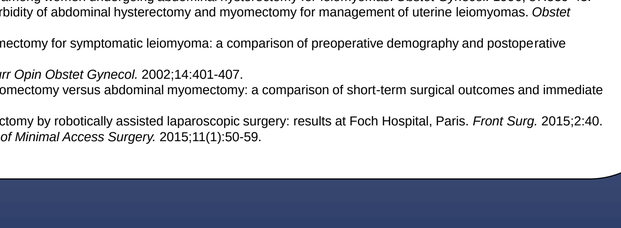


Figure 10. Surgery Method vs. Weeks Before Resuming Sexual Activity p=.014



Conclusions

This study demonstrated some advantages of RLM includes a shorter hospitalization (most patients were discharged within 1-2 days of surgery), less estimated blood loss and resumption of normal activities within 1-2 weeks, less days before having the first post-operative BM, self care and sexual activities. There are some limitations of robotic assisted laparoscopic myomectomy (i) Limited angles for trocars insertion for instruments; (ii) Loss of haptic and force feedback which makes it difficult to identify smaller intra-mural fibroid tumors and challenges the ability to tie suture knots. (iii) Reduced field of vision [14]. Many of these limitations can be overcome by surgeon training and partially compensated for by the 3D visual feedback. In addition, collision of the robotic arms is less of a problem when using the da Vinci® robotic Xi. Placement of the 8-mm trocars at the level of the anterior axillary lines bilaterally with the da Vinci® robotic Xi will give the articulated arms a wider range of motions and less collision. The scars of these incisions are less noticeable and more esthetically acceptable by the patients. Utilizing smaller operative incisions, as in RLM, the use of narcotic pain management is reduced.

The use of AUI for larger fibroid tumors has the following advantages:

Wider skin, rectus fascia and peritoneal wound space, better visualization of the pelvic organs including the fibroid tumors, before, during, and after the tumor's excision. This is due to the longer distance between the tip of the laparoscope and the pelvic organs. Better control of bleeding. Facilitate suturing, traction and counter traction of tumors from the uterus, chromopertubation procedure and localization of the extracted tumors. Facilitates tissue extraction without the use of mechanical morcelator (which is controversial).

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