Efficacy and safety of robotic-assisted surgery in challenging hysterectomies – a single institutional experience

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Abstract. – **OBJECTIVE:** An increasing number of robotic hysterectomies are being performed and the most common indication is fibroids. Fibroid uterus is common indication for hysterectomy for enlarged uteri. The role of robotic approach for complex pathologies as enlarged uterus is still debatable. The study aimed to analyze the feasibility of robotic hysterectomy in patients with enlarged uteri and the impact of uterine weight on surgical outcomes and on operative time length.

PATIENTS AND METHODS: One hundred and thirty-eight patients who underwent robotic hysterectomy for benign indications at the 2nd Division of Obstetrics and Gynecology, Azienda Ospedaliero-Universitaria Pisana, University of Pisa were consecutively enrolled.

RESULTS: Data of patients undergoing robotic surgery for benign indications were collected. Patients were stratified in two groups based on their uterine weight, to analyze the effective impact of uterine weight and dimension on surgical performance, operative time and postoperative outcomes. Conversion rate was 0%. Median uterine weight was 615 g (range 400-1900 g). Median total operating time was 131 minutes (range 70-255 minutes). Increase in uterine weight significantly increased operative times (p=0.003) and morcellation time (p=0.001). On the other hand, operative time was just partially influenced by route for removal of the uterus (p=0.085) but significantly affected by uterine weight (p=0.008), previous surgeries (p=0.003) and BMI of the patient (p=0.005).

CONCLUSIONS: Robotic hysterectomy is feasible and safe for challenging cases as large uteri. This technique could enable patients with outsized uteri, not suitable for vaginal hysterectomy, to undergo minimally invasive surgery with excellent results. Larger studies to investigate and compare robotic with other surgical approaches for difficult hysterectomies are needed to confirm these data.

Key Words:
Minimally invasive surgery, Robotic surgery, Fibromatosis, Enlarged uteri.

Introduction

Hysterectomy is the most common major surgical procedure in gynecology worldwide[1]. Uterine fibroid is a common indication for benign hysterectomy[2,3], traditionally approached by vaginal, laparoscopic or laparotomic route[4-6].

The laparoscopic approach in case of complex benign pathology requires great expertise and can be associated with longer operative times, higher estimated blood loss (EBL) and higher conversion rate[7-9]. Despite of the increasing use of laparoscopy, complex laparoscopic hysterectomies for benign disease are usually performed in tertiary referral centers by trained surgeons, since the success of minimally invasive hysterectomy is strictly related to the volume of procedures performed in the center.

Robot-assisted technology could overcome the laparoscopic limitations by improving the surgeon's dexterity and, thanks to advanced 3D-imaging, by reaching a higher precision especially in narrow surgical fields[10]. In this way, robotic surgery allows more patients to benefit from a minimally invasive procedure and lowers the rate of laparotomies for complex hysterectomies.

Few data[9,11-15] concerning surgical outcomes of hysterectomy for large uteri treated by robotic approach are currently available in literature. All these studies concluded that in this subset of complex pathology, the robotic approach assures low postoperative morbidity, fast recovery and low conversion

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rate, but the real impact of the extraction time on overall operative time is still lacking.

The purpose of this study was to describe and validate our surgical technique and to assess the feasibility and the outcome of robotic hysterectomy in case of complicated benign pathology as large uteri.

Patients and Methods

Patients' Population

From January 2013 to May 2019, 138 patients with very enlarged uteri suitable for robotic hysterectomy due to benign pathology at the 2nd Division of Obstetrics and Gynaecology, Santa Chiara Hospital, Pisa, Italy were prospectively enrolled in the study.

Inclusion criteria were benign uterine diseases and patients' approval. Exclusion criteria were preoperative assessment suggestive for malignancy, uterine weight less than 400 g, concomitant procedure required other than hysterectomy with salpingectomy or adnexectomy.

Women with previous pelvic surgeries, history of pelvic inflammatory disease, high body mass index (BMI) and endometriosis were not excluded.

The observational cohort study was conducted in accordance with the World Medical Association Declaration of Helsinki. The study was approved by the appropriate Institutional Review Boards (Prot. No. 739). Written informed consent was obtained from all subjects.

All robotic operations were performed with da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA), models Si and Xi, with a three-port technique. All interventions were performed by the same skilled surgeon. After surgery the specimens were weighted using the same scale.

Complications after surgery were analyzed and reported according with Dindo classification[16].

Patients were reviewed 6 to 8 weeks after surgery. Clinical data regarding immediate and short-term postoperative outcomes were available from hospital and outpatient medical records. No patients were lost at follow-up.

Surgical Technique and Skills for Enlarged Uteri

After standard patients' preparation, positioning, evaluation and docking, cornerstones of our technique for robotic hysterectomy in case of large uteri are mainly two: standardized surgical steps and quadrant-approach, meaning the completion of the maximum number of surgical steps for each quadrant before moving to the next one. According to our quadrant-approach one round ligaments is coagulated and transected laterally and the Latzko pararectal space is developed, showing the ureter, the umbilical obliterated artery and the origin of the uterine artery. These structures are important anatomic landmarks, and their identification allows reducing damages and procedure-related complications. In order to devascularize the uterus and to reduce blood losses, one Hem-O-lok is applied at the origin of each uterine artery. If adnexectomy is required, after visualization of the ureter, three additional Hem-O-Lok are applied on each infundibulo-pelvic ligament, which is then cut with monopolar current. Otherwise, mono- or bilateral salpingectomy is performed. In the same quadrant, without need to move neither the scope nor the uterus, the posterior leaf of the broad ligament is cut up to the utero-sacral ligament. To accomplish this step, it is often necessary to flip the scope (up and down) of 180 degrees to enhance the visualization in this narrow space. Then, we move on the contralateral quadrant, where the same surgical steps are accomplished. Moving anteriorly the anterior leaves of the broad ligament are divided, the pubocervical fascia is identified, and then, the bladder is gently pushed down. Subsequently, the uterine vascular pedicles are skeletonized in order to obtain a better tissue effect of the bipolar forceps and to minimize the risk of lateral thermal spread to adjacent structures, such as the ureter. A little incision can be made in the fascia medially to the vascular pedicles to facilitate the penetration of one of the bipolar jaws, in order to bite the whole uterine vascular pedicle. This step is fundamental to reduce blood losses. Then, colpotomy with monopolar cut is started. The specimen is then inserted in an Endobag and extracted from the pelvis. If morcellation is needed, it can be performed in two ways: piecemeal morcellation of the uterus through the vagina, or morcellation through an abdominal minilaparotomy, as in case of a narrow vagina or a very large uterus. After specimen extraction a continuous suture with a slowly absorbable monofilament is used to close the vaginal cuff.

Statistical Analysis

Data were analyzed using SPSS Statistics 2020 (SPSS, Inc., Armonk, NY, USA). Given that all available data and all cases were included in this study, no sample size calculation was determined. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate and presented as incidence (n) and percent-

Table I. Operative variables in relation to uterine weight categories.

Variables	Overall (n=138)	<615 g (n=67)	≥615 g (n=71)	*p*-value
Operative Time, minutes (mean ± SD)	134.3 ± 37.7	123.2 ± 37.7	144.5 ± 35.0	**0.003**
Morcellation Time, minutes (mean ± SD)	25.9 ± 14.4	18.8 ± 12.8	32.4 ± 12.7	**0.001**
EBL, mL (mean ± SD)	70.1 ± 104.8	50.2 ± 43.7	88.6 ± 137.4	0.060
Postoperative complications, n (%)	11 (10.7)	6 (8.8)	5 (7.0)	0.761
Haemoglobin drop day 1 (mg/dL)	1.7 ± 1.4	1.5 ± 1.1	1.8 ± 0.7	0.070
Hospital stay, days (mean ± SD)	2.5 ± 1.0	2.4 ± 1.0	2.6 ± 1.1	0.340

age (%). Continuous variables were presented as mean ± standard deviation (SD). A receiver-operating characteristic (ROC) curve was used to assess the discriminative role of uterine weight during surgery in patients with larger uteri. The level of statistical significance was set at $p<0.05$.

Results

The average age of patients was 48 (range 37-61 years) and the average BMI was 25.6 (range 17.9-50.3 kg/m^2). Fifty-seven patients (41.3%) had a previous pelvic and/or abdominal surgery.

Indication to hysterectomy were fibromatosis (n=134; 97%) or adenomyosis/endometriosis with associated pelvic pain (n=4; 3%).

None of the 138 patients were pre-treated with gonadotropin-releasing hormone agonists. All patients underwent opportunistic salpingectomy, and some patients had mono or bilateral ovariectomy. Median follow up was 9 weeks (range 6-12 weeks).

No conversions to laparotomy were needed. Median uterine weight was 615 g (range 400-1900 g). Median total operating time was 131 minutes (range 70-255 minutes) and median extraction time (vaginal or by mini laparotomy) was 25 minutes (range 5-60 minutes). Median estimated blood loss was 30 mL (range 10-600 mL). No blood transfusions were administered, but intraoperative cell salvage procedures were adopted in two patients. The median length of the hospital stay (LOS) was 2 days (range 1-8 days). No intraoperative complications were recorded. More than 90% of the postoperatively (<30 days) diagnosed complications were mild (grade I) and just one required readmission and stenting (grade IIIa): 7 patients (5.07%) experienced vaginal cuff cellulitis but only 2 required inpatient treatment during the same hospitalization; 2 patients presented a vaginal cuff hematoma (1.44%); 1 patient presented a partial vaginal cuff dehiscence that did not require any surgical procedures (0.72%); 1 patients was readmitted for hydroureteronephrosis due to ureteral kinking (0.72%). All the histologic reports were benign except for one case of uterine leiomyosarcoma. In statistical analysis, patients were stratified in two groups considering median uterus weight: patients with uterus weighting <615 g (n=67) *vs.* patients with uterus ≥615 g (n=71) Increase in uterine weight influenced significantly operative times (p=0.003) and morcellation time (p=0.001), as exposed in Table I.

The median value of operation time was accepted as a critical value, and a cut-off point was calculated for uterine weight by using ROC curve analysis. A statistically significant positive relationship was found between uterine weight and operation time (r 0.176, $p<0.001$; Figure 1). The linear regression analysis showed a statistical significance (F 21.36 $p<0.001$). Operative time was just partially influenced by route for removal of the uterus (p=0.085). Contrarily, operative time was significantly influenced by uterine weight (p=0.008), previous surgeries (p=0.003) and BMI of the patient (p=0.005).

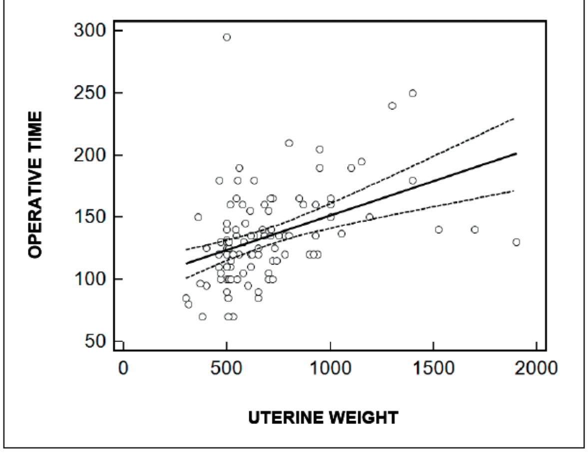

Figure 1. Relationship between uterine weight and operative time.

Table II. Variables influencing operative time.

Variables	OR	Standard error	*p*-value	CI 95%
Morcellation time (mins)	0.69	0.32	0.432	0.276-1.733
Uterus weight (g)	3.36	1.54	**0.008**	1.369-8.280
BMI (kg/mq)	2.88	0.50	**0.005**	0.775-4.379
Previous abdominal surgery	2.94	16.17	**0.003**	1.224-6.280
Way of removal	0.14	0.16	0.085	0.016-1.305

OR: odds ratio; CI: confidence interval.

Discussion

In agreement with the literature[9-16], our results demonstrate that in patients with much enlarged uteri, the robotic hysterectomy can be a feasible and safe alternative with a satisfying perioperative outcome in terms of conversion rate, EBL, LOS and complications.

The increase of the skin-to-skin time for high-weight uteri is mainly attributable to a prolongation of the extraction time. The results showed in Table II confirm that the extraction time significantly increases with uteri heavier than 615 g, with a greater effect observed in case of uteri heavier than 1000 g.

The increase in patients' BMI determines a progressive increase in the operative time as for each unit of increase in BMI the operative time increased by 1.40 minutes. This implies that the difference in operative time should be of 14 minutes between a patient with a BMI of 25 and one with 35. On the other hand the increase in BMI has no impact on conversion rate nor on EBL.

Previous abdominal surgery is a factor that increases the operative time as well.

For uteri heavier than 615 g performing a morcellation through a minilaparotomy results less time-consuming than the vaginal morcellation. Another important result is that the minilaparotomy extraction time is shorter than the vaginal extraction time when uterine weight is greater than 615 g.

Of note, contrary to the study of Munetoshi et al[15], the rate of conversion and of perioperative complications did not change highlighting, not only the importance of a standardized surgical technique and a skilled operative team, but also the careful choice of the devices.

Our results suggest that the planning of the operative theatre should take into account not only the uterine size, but also the patient's BMI and history for previous abdominal surgery, in order to optimize operating room occupation time in the attempt to reduce costs. Moreover, the results suggest that the choice of the type of morcellation can be paramount in order to reduce the skin-to-skin time and consequently the cost of the procedure. Noteworthy, in spite of its positive impact on operative time, the BMI increase does not raise the conversion rate nor the EBL, confirming that this approach is extremely safe and recommended for obese patients[9-11].

Operative time enhancing with uterine weight could be explained by the difficult manipulation of very large uteri and by the consequently narrower surgical field.

Probably this protraction of operative time could be overcome by the use of the fourth robotic arm: further studies are needed to proof this hypothesis.

In future perspectives a new device for morcellation would be attractive in order to accelerate the extraction time and then to reduce skin-to-skin time and costs.

Even if this study is a single-center study and it has a limited number of patients, it has been accomplished prospectively. All robotic hysterectomies were performed and completed by the same trained surgical team in a high-volume center. This study represents the largest reported cohort of patients treated with robotic hysterectomy for enlarged uteri. We did not consider the effect of gonadotropin-releasing hormone agonists on robotic hysterectomies outcomes.

A considerable drawback of our study is that the precise uterine weight was known just after the surgery: it can only be esteemed preoperatively to predict the peri- and post-operative outcomes. Future studies should take into account sonographic parameters, such as the uterine dimension or the estimation of the uterine volume, which are usually known preoperatively.

In case of complex pathology, the robotic approach could replace laparoscopy, which is encumbered by a higher conversion rate even in tertiary referral centres[8,17-25]. The shorter learning curve of the robotic hysterectomy comparing to laparoscopic hysterectomy[25-28] favors the increasing utilization of robotic approach in challenging hysterectomies and correlates with decreasing rates of abdominal and laparoscopic hysterectomy[29]. The Da Vinci system provides technology that may improve the ability in performing minimally invasive hysterectomy, simplifying the approach in complex cases including those involving large uteri. Even if the main disadvantage of the robotic hysterectomy is the increased cost, a careful analysis by Lönnerfors et al[30] demonstrates in a randomized trial that when the robot is a preexisting investment a similar hospital cost can be attained for laparoscopic and robotic hysterectomy, with comparative perioperative outcomes in presence of experienced surgeon in a high-volume center.

Likewise, robotic approach as to be recommended just in referral centers as multidisciplinary skilled team can manage possible intraoperative and postoperative complications.

Conclusions

To our knowledge, this is the first study assessing the feasibility of robotic route in patients with large uteruses and the impact of uterus weight on robotic operative time.

Study results demonstrated that robotic surgery was associated with a favorable short-term surgical outcome in performing hysterectomies in patients with large uteri.

Operating times and morcellation time increased significantly with increasing uterine size, and there was no significant relationship between complications and uterine weight.

Higher BMI, more need for adhesiolysis possibly imply the more challenging nature of women who underwent TRH in the presence of large uterus.

Robotic approach for removing large uteri demonstrated to be safe, feasible and may be the most cost-effective surgical technique. In light of our clinical experience, uterine weight did not affect the complication rate, estimated blood loss and length of hospital stay in TRH operation.

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Conflict of Interests

The authors declare they have no conflict of interest.

References

1) Lefebvre G, Allaire C, Jeffrey J Allaire C, Jeffrey J, Vilos G, Arneja J, Birch C, Fortier M, Clinical Practice Gynaecology Committee and Executive Committeee and Council, Society of Obstetricians and Gynaecologists of Canada. SOGC clinical guidelines. Hysterectomy. J Obstet Gynaecol Can 2002; 24: 37-61.
2) Merrill RM. Hysterectomy surveillance in the United States, 1997 through 2005. Med Sci Monit 2008; 14: CR24-31.
3) Stang A, Merrill RM, Kuss O. Nationwide rates of conversion from laparoscopic or vaginal hysterectomy to open abdominal hysterectomy in Germany. Eur J Epidemiol 2011; 26: 125-133.
4) Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R, van Voorst S, Mol BW, Kluivers KB. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009; 3: CD003677.
5) Moon AS, Garofalo J, Koirala P, Vu MT, Chuang L. Robotic Surgery in Gynecology. Surg Clin North Am 2020; 100: 445-460.
6) Committee Opinion No 701: Choosing the Route of Hysterectomy for Benign Disease. Obstet Gynecol 2017; 129: e155-e159.
7) AAGL Advancing Minimally Invasive Gynecology Worldwide. AAGL position statement: route of hysterectomy to treat benign uterine disease. J Minim Invasive Gynecol 2011; 18: 1-3.
8) Payne TN, Dauterive FR. A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: surgical outcomes in a community practice. J Minim Invasive Gynecol 2008; 15: 286-291.
9) Boggess JF, Gehrig PA, Cantrell L, Shafer A, Mendivil A, Rossi E, Hanna R. Perioperative outcomes of robotically assisted hysterectomy for benign cases with complex pathology. Obstet Gynecol 2009; 114: 585-593.
10) Visco AG, Advincula AP. Robotic gynecologic surgery. Obstet Gynecol 2008; 112: 1369-1384.
11) Payne TN, Dauterive FR, Pitter MC, Giep HN, Giep BN, Grogg TW, Shanbour KA, Goff DW, Hubert HB. Robotically assisted hysterectomy in patients with large uteri: outcomes in five community practices. Obstet Gynecol 2010; 115: 535-542.
12) Silasi DA, Gallo T, Silasi M, Menderes G, Azodi M. Robotic versus abdominal hysterectomy for very large uteri. JSLS 2013; 17: 400-406.
13) Lim PC, Crane JT, English EJ, Farnam RW, Garza DM, Winter ML, Rozeboom JL. Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications. Int J Gynaecol Obstet 2016; 133: 359-364.
14) Moawad GN, Abi Khalil ED, Tyan P, Shu MK, Samuel D, Amdur R, Scheib SA, Marfori CQ. Comparison of cost and operative outcomes of robotic hysterectomy compared to laparoscopic hysterectomy across different uterine weights. J Robot Surg 2017; 11: 433-439.
15) Akazawa M, Lee SL, Liu WM. Impact of uterine weight on robotic hysterectomy: Analysis of 500

cases in a single institute. Int J Med Robot 2019; 15: e2026.
16) Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004; 240: 205-213.
17) Klauschie J, Wechter ME, Jacob K, Zanagnolo V, Montero R, Magrina J, Kho R. Use of anti-skid material and patient-positioning to prevent patient shifting during robotic-assisted gynecologic procedures. J Minim Invasive Gynecol 2010; 17: 504-507.
18) Ghomi A. Robotics in practice: New angles on safer positioning. Contemporary Ob/Gyn 2012; 57: 26.
19) Greenberg JA. The Pink Pad—Pigazzi Patient Positioning System™. Rev Obstet Gynecol 2013; 6: 97-98.
20) Neugebauer EAM, Sauerland S, Fingerhut A, Millat B, Buess G. EAES Guidelines for Endoscopic Surgery: Twelve Years Evidence-Based Surgery in Europe, 2006. Available at: https://link.springer.com/book/10.1007/978-3-540-32784-4.
21) Einarsson JI, Hibner M, Advincula AP. Side docking: an alternative docking method for gynecologic robotic surgery. Rev Obstet Gynecol 2011; 4: 123-125.
22) Varghese A, Doglioli M, Fader AN. Updates and Controversies of Robotic-Assisted Surgery in Gynecologic Surgery. Clin Obstet Gynecol 2019; 62: 733-748.
23) Long E, Kew F. Patient satisfaction with robotic surgery. J Robot Surg 2018; 12: 493-499.
24) Seracchioli R, Venturoli S, Vianello F, Govoni F, Cantarelli M, Gualerzi B, Colombo FM. Total laparoscopic hysterectomy compared with abdominal hysterectomy in the presence of a large uterus. J Am Assoc Gynecol Laparosc 2002; 9: 333-338.
25) Wattiez A, Soriano D, Fiaccavento A, Canis M, Botchorishvili R, Pouly J, Mage G, Bruhat MA. Total laparoscopic hysterectomy for very enlarged uteri. J Am Assoc Gynecol Laparosc 2002; 9: 125-130.
26) Uccella S, Casarin J, Marconi N, Cromi A, Morosi C, Gisone B, Pinelli C, Ghezzi F. Laparoscopic Versus Open Hysterectomy for Benign Disease in Women with Giant Uteri (≥1500 g): Feasibility and Outcomes. J Minim Invasive Gynecol 2016; 23: 922-927.
27) Bell MC, Torgerson JL, Kreaden U. The first 100 da Vinci hysterectomies: an analysis of the learning curve for a single surgeon. S D Med 2009; 62: 91, 93-95.
28) Woelk JL, Casiano ER, Weaver AL, Gostout BS, Trabuco EC, Gebhart JB. The learning curve of robotic hysterectomy. Obstet Gynecol 2013; 121: 87-95.
29) Smorgick N, Patzkowsky KE, Hoffman MR, Advincula AP, Song AH, As-Sanie S. The increasing use of robot-assisted approach for hysterectomy results in decreasing rates of abdominal hysterectomy and traditional laparoscopic hysterectomy. Arch Gynecol Obstet 2014; 289: 101-105.
30) Lönnerfors C, Reynisson P, Persson J. A randomized trial comparing vaginal and laparoscopic hysterectomy vs robot-assisted hysterectomy. J Minim Invasive Gynecol 2015; 22: 78-86.