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Impact of FDA Power Morcellation Ban on Perioperative Outcomes for Robotic Sacrocolpopexy

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Abstract

Objective: Uterine power morcellation has been under scrutiny following statements by the Food and Drug Administration (FDA) concerning dissemination of a possible occult malignancy. The impact of these warnings on women with pelvic organ prolapse and low suspicion for malignancy are not well documented in the medical literature. This study aims to compare the perioperative outcomes of patients undergoing Robotic-Assisted Sacrocolpopexies with Supracervical Hysterectomies (R-ASCP+SCH) by mechanical *vs*. manual morcellation.

Methods: Cases of R-ASCP+SCH with contained manual morcellation were compared to controls using mechanical power morcellation. The primary outcome is operative time (minutes) from robotic patient cart undocking to the end of the surgical case and total narcotic medication requirements as measured by Morphine Milligram Equivalents (MME). Secondary outcomes assessed included estimated blood loss (cc), recovery time in the PACU (minutes), length of stay (days), incidence of malignancy on surgical pathology report, and percentage of patients who return for evaluation of post-operative complications.

Results: A total of 162 women were identified. Cases of manual morcellation (n=131) were compared to mechanical morcellation controls (n=31). A total of 5 cases of malignancy were identified. Cases required approximately 9 additional minutes of operative time (49.5 min vs. 40.3 min, $p<0.05$). Cases additionally required more narcotic medications during recovery compared to controls (24.9 MME vs. 15.3 MME, $p<0.05$). The estimated blood loss, length of stay, and percentage of patients with post-operative wound complications were not statistically different.

Conclusion: Uterine malignancy may be found in asymptomatic postmenopausal women presenting for pelvic organ prolapse repair. Manual morcellation during pelvic organ prolapse repair is a safe and effective approach without increased operative morbidity or complications.

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Introduction

The American Association of Gynecologic Laparoscopists (AAGL) in 2014 released a position statement on the use of mechanical morcellation for uterine tissue extraction [1]. Uncontained tissue retrieval may unknowingly disseminate mullerian malignancy within the abdomen. The risk of upstaging undiagnosed Leiomyosarcoma (LMS) and uterine cancer as presented by the Society of Gynecologic Oncology (SGO) may vary between 1:400 patients to 1:1000 patients [2]. A multitude of investigations has since taken place to identify this true risk, while optimal methods of extraction has continued to be addressed in the AAGL's recent practice guidelines as of 2018 [3].

Postmenopausal women may ultimately require a sacrocolpopexy with concomitant hysterectomy in order to treat symptomatic pelvic organ prolapse. The clinical work-up of the urogynecologic patient juxtaposes women presenting for oncological evaluation due to the absence of risk factors typical of uterine and leiomyomatous cancer. Concomitant supracervical hysterectomies that retain a cervical stump have been performed in order to decrease the likelihood of vaginal mesh erosion [4]. This necessitates removing the specimen through a small abdominal incision, raising concern for potentially unsuspected occult seeding of malignancy within the abdomen when tissue is morcellated in an open and uncontained abdomen.

Evidence surrounding operative outcomes following the 2014 Food and Drug Administration's (FDA) recommendations against mechanical morcellation for low-risk populations is still

forthcoming. Further analysis is necessary to detail the benefits of minimally invasive surgery while minimizing the risks of potential malignancy dissemination. This study aims to compare perioperative outcomes of mechanical *vs.* contained-manual morcellation amongst patients treated for pelvic organ prolapse with Robotic-Assisted Sacrocolpopexy (R-ASCP) and Supracervical Hysterectomy (SCH).

Materials and Methods

After obtaining approval from the University at Buffalo (Buffalo, New York, USA) Institutional Review Board, a retrospective cohort study was performed between January 2013 and January 2017 by identifying all women with pelvic organ prolapse who had undergone surgical repair *via* a R-ASCP with concomitant SCH at Millard Fillmore Suburban Hospital (Williamsville, New York, USA). This was done by identifying those women with the appropriate diagnosis code (ICD-10 N81.9 for female genital prolapse, unspecified) and respective surgical procedural codes (CPT57425 for laparoscopic colpopexy, CPT58542 for supracervical hysterectomy with bilateral salpingo-oophorectomy). Patients were separated as cases of contained manual morcellation *vs.* controls of open mechanical morcellation *via* Gynecare Morcellex® tissue morcellator device as registered-trademark by Johnson and Johnson for extraction of uterine tissue.

All identified patients were later further stratified based on the presence of additional concomitant surgical procedures, with codes including a) placement of a Transobturator Tape (TOT) midurethral sling (CPT57288) and b) perineorrhaphy (CPT57250). Patients who underwent total laparoscopic hysterectomy were excluded from the study, and all other patients with unaccompanied or concomitant procedures not listed as aforementioned above were likewise excluded. Patient data was extracted individually, with every fifth entry reviewed by a separate physician to ensure accuracy of data extraction and entry within the database spreadsheet.

Primary outcomes included operative time (minutes) from robotic patient cart undocking to incisional closure as surrogate marker of specimen removal time, and narcotic medication utilization as measured by Morphine Milligram Equivalents (MME) both in the Post-Anesthesia Care Unit (PACU) and during the entire hospital stay until discharge. Secondary outcomes assessed included total operative time (minutes), total robotic operative time (minutes), estimated blood loss (cc), recovery time in the PACU (minutes), length of stay (days), and percentage of patients who return to the hospital or outpatient office for surgical wound complications. Uterine weight (grams) and incidence of malignancy as diagnosed by surgical pathology report were also recorded, as were patient demographics including age (years), body mass index (kg/m^2), gravidity, parity, and history of abdominal surgery.

The Shapiro-Wilk test was initially performed on all continuous variables, with a univariate approach employed to compare variables across cases and controls. For categorical variables the Chi-Square Test of Independence was used and for continuous non-normal variables both the Mann-Whitney and Wilcoxon Rank-Sum tests were applied redundantly. Correlation coefficients were determined between exposures and the significant outcome variables to establish monotonicity of relationships between variables, and the Kendall tau coefficient was used to determine perfect positive, perfect negative, or no correlation between variables. Regression models were implemented and two multiple regression models were developed for cases and controls, both incorporating the relevant exposures simultaneously.

Operative techniques

Robotic-assisted sacrocolpopexy (R-ASCP): At our institution, we have a standard approach to the robotic-assisted laparoscopic sacrocolpopexy. The procedure for the purpose of this study takes place following entrance into the abdomen with removal of the uterus *via* supracervical hysterectomy using a robotic surgical system platform. Potential spaces of the pelvis are systematically opened by blunt dissection with traction countertraction and short bursts of electrocautery. These include: the vesicovaginal space caudad to the level of the urethrovesical junction, the rectovaginal space caudad to the dorsal perineal membrane, and the presacral space for exposure of the anterior longitudinal ligament at the level of the sacrum at S1 and S2 vertebral bodies.

Thereafter, a Y-shaped wide pore (>75 μm) polypropylene mesh is secured to the anterior and posterior vaginal walls, with the long arm of the mesh secured to the anterior longitudinal ligament of the sacrum at the exposed S1 and S2 vertebral bodies. The peritoneum is then closed over the mesh with running absorbable suture to minimize bowel adhesions in the pelvis. The robot is undocked and attention is then turned to specimen extraction.

Mechanical morcellation: Mechanical morcellation was accomplished using the Gynecare Morcellex® tissue morcellator device as registered-trademark by Johnson and Johnson. A trocar port site is extended to approximately 15 millimeters in total length to allow insertion of the morcellator. Under direct visualization, the tenaculum is passed through the morcellator to retrieve and retract the specimen within the opening of the morcellator. The morcellator is subsequently activated and rotary blades cut long continuous pieces of the specimen which are extracted through the morcellator lumen. Tissue is extracted piecemeal until the whole specimen is removed. Prior to the FDA recommendations of 2014, mechanical morcellation was performed intraperitoneally without containment system technology to prevent tissue dissemination as this was previously unavailable at the time. In the typical postmenopausal female preventing for pelvic organ prolapse repair, small uteri <250 grams required an average of ten minutes in order to mechanically morcellate the uterus and adnexa. Following, the extended trocar port site is closed with the use of a fascia closure assistance device and the skin closed with overlying sutures.

Manual morcellation: At the time of specimen extraction, a containment bag is introduced through a previous robotic trocar port site preferably at the umbilicus. The specimen in whole is placed within the containment bag and the edges are lifted and exteriorized with the specimen completely contained. A minilaparotomy is then created by extending the midline umbilical port site to a size of approximately 2.5 cm to 3.0 cm. Careful attention is given to not pierce the containment bag. With use of cold-knife scalpel, "paper-roll" coring technique is done to remove the specimen [5]. The bag is checked for integrity and the fascia is then closed with a direct closure using running absorbable suture, followed by the skin.

Results

A total of 162 women were identified during the study period. Cases of R-ASCP with SCH that used a contained-manual morcellation approach [manual group] (n=131) were compared

Table 1: Patient demographics.

	Age (years)	BMI (kg/m²)	Gravity	Parity
Mechanical Morcellation (n=31)	60.61	28.67	2.83	2.41
Manual Morcellation (n=131)	64.58	28.2	3.14	2.72
p-value	<0.05	0.75	0.2	0.16

*Variables compared across groups using Mann-Whitney and Wilcoxon Rank-Sum, or Chi-Square test
BMI: Body Mass Index

Table 2: Perioperative outcomes among mechanical *vs.* contained-manual morcellation.

	Morcellation Time (min)	Estimated Blood Loss (cc)	PACU Recovery Time (min)	PACU Narcotic Requirement (MME)	Total Narcotic Requirement (MME)	Length of stay (days)
Mechanical Morcellation (n=31)	40.31	4.84	107.77	2	15.25	1.13
Manual Morcellation (n=131)	49.53	0.38	122.72	2.67	24.85	1.21
p-value	<0.05	0.22	0.08	0.14	<0.05	0.36

*Variables compared across groups using Mann-Whitney and Wilcoxon Rank-Sum
PACU: Post Anesthesia Care Unit; MME: Morphine Milligram Equivalents

Table 3: Intraoperative variables and procedures among mechanical *vs.* contained-manual morcellation.

	Morcellation Time (minutes)	Uterine Weight (grams)	Midurethral Sling Performed	Perineorrhaphy Performed
Mechanical Morcellation (n=31)	40.31	51.6	15	1
Manual Morcellation (n=131)	49.53	53.49	102	54
p-value	0.03	0.97	<0.05	<0.05
Additional Adjusted Operative Time (minutes)	-4.64**	0.12	14.99	3.22
Adjusted Operative Time p-value	0.11	<0.05	<0.05	0.18

*Variables compared across groups using Mann-Whitney and Wilcoxon Rank-Sum; **Time adjusted per gram per minute

to matched mechanical morcellation controls [mechanical group] (n=31) in 4:1 ratio. The data was analyzed with a PhD data scientist. Patient demographics are described in Table 1. Mean age at the time of surgery was 64.6 years and 60.6 years among cases and controls, respectively, with a mean body mass index of approximately 28 kg/m² to 29 kg/m² between groups. Patients among cases and controls had similar gravidity and parity - 3.14 and 2.72 with 2.83 and 2.41, respectively.

Perioperative data comparing R-ASCP with SCH using contained-manual morcellation *vs.* mechanical morcellation are presented in Table 2. The total operative time was 9 minutes longer on average for cases *vs.* controls (49.53 min *vs.* 40.31 min, p<0.05) with a similar estimated blood loss between groups (0.38 cc *vs.* 4.84 cc, p=0.22). Both cases and controls spent a similar time recovering in the PACU (122.72 min *vs.* 107.77 min, p=0.08), with similar narcotic requirements during PACU recovery (2.67 MME *vs.* 2.00 MME, p=0.14). Cases of contained-manual morcellation required more narcotic pain medications than did controls (24.85 MME *vs.* 15.25 MME, P<0.05) during the entire hospital stay. Length of stay between cases and controls were similar (1.21 days *vs.* 1.13 days, p=0.36). Among this study population, none developed a postoperative wound complication at the site of the specimen extraction, which was the wound of interest in this study.

A subgroup analysis was performed amongst peri-operative variables comparing operative time for specimen morcellation. Multiple regression modeling was performed for concomitant procedures, uterine weights, and morcellation method. This analysis is illustrated in Table 3. The addition of a midurethral sling procedure increased operative time for approximately 15 min (p<0.05). A perineorrhaphy was seen to increase operative time for approximately 3 min (p=0.18). For every additional gram of uterine weight, operative time was increased by approximately 6 sec (0.12 min, p<0.05). Contained-manual morcellation as compared to mechanical morcellation experienced longer operative time per gram per minute (4.64 min/gram, p=0.11).

Table 4: Surgical pathology reports, n=162.

Pathology	N	Percentage (%)
Benign*	155	95.7
Premalignant		
Focal Simple Hyperplasia	4	2.5
Focal Complex Hyperplasia without Atypia	1	0.6
Focal Complex Hyperplasia with Atypia	1	0.6
Malignant		
Tubal High Grade Serous Carcinoma	1	0.6

*Benign pathology includes inactive, atrophic, proliferative, and secretive endometrium, benign endometrial polyps, leiomyomas, adenomyosis, and endometriosis

Among all patients who underwent R-ASCP with SCH, 95.7% were found to have uteri with benign pathology (atrophic/proliferative endometrium, endometrial polyp, adenomyosis, and leiomyoma), 3.7% of patients were found to have premalignant tissue pathology including simple and complex hyperplasia, with and without atypia. One patient, comprising 0.6% of the total study population was found to have malignant pathology. This patient was found to have tubal high grade serous carcinoma and subsequently was referred to a gynecologic oncologist.

Discussion

With the advent of minimally invasive and robotic surgery, many previously open-abdominal procedures are transitioning to a laparoscopic approach. Minimally invasive surgery has been associated with decreased blood loss, decreased pain, shorter hospital stay, faster recovery time, and fewer postoperative complications

[6-8]. Morcellation has been a controversial issue of technique and technological advancement recently under scrutiny by the Food and Drug Administration (FDA) as well as the American Association of Laparoscopic Gynecologists (AAGL) [1-3]. Initial studies following the restriction of morcellation devices reveal longer operative time for contained morcellation and an unknown true risk of LMS and uterine cancer dissemination [9]. Thus, extraction of specimens from laparoscopic ports has transitioned from prior open-mechanical to contained-manual and contained-mechanical morcellation.

When pelvic organ prolapse requires surgical correction, oftentimes a sacrocolpopexy is performed to resolve patients' symptoms. For women who have retained their uterus until the time of surgery, a concomitant hysterectomy may be required for optimal apical restoration. This presents as a unique challenge because clinical risk factors between urogynecologic and general gynecologic and oncologic practice populations vary as are their potential for discovering malignancy. In this study we discuss the perioperative findings associated with open mechanical and contained manual morcellation after the FDA ban. We also highlight the incidence of malignancy among women with pelvic organ prolapse undergoing repair by R-ASCP+SCH.

Cases of contained-manual morcellation required an approximate 9 additional minutes of procedural time as compared to mechanical morcellation. This statistically significant finding represents an average 25% increase in operative time after undocking the robotic console, namely due to insertion of the specimen bag and retrieval, the extension of the umbilical laparoscopic fascial port site incision, subsequent coring technique for specimen retrieval, and closure of the fascia with the enlarged incision [5]. This time may in theory incur real operative costs beyond the scope of this study. Subgroup analysis was performed based on concomitant procedures in order to stratify for possible confounding from the time of robotic console undocking to the end of the surgical case. A midurethral sling added on average 15 min of operative time, and perineorrhaphy with an additional 3 min. Specifically, correlation regressions were made between operative time and uterine weight, and noted a statistically significant increase in procedure time of 6 sec per added gram of tissue for extraction between cases and controls.

Patients who underwent contained-manual morcellation were also seen to require more narcotic medications as measured by an extra 9 MMEs in the post-operative period than mechanical controls. This may again be due to the extensive manipulation and fascial extension required during tissue extraction in the case of contained-manual morcellation. This statistically significant finding illustrates greater than a 50% increase in MME (15.25 *vs.* 24.85, $p<0.05$) used by patients in the post-operative course. Cases had a propensity towards increased time for recovery in both the immediate PACU as well as the entire hospital length of stay; however this was not statistically significant. All demographics and other comparative variables were similar between both methods of morcellation. Postoperative wound complications involving the extraction site were absent in both groups.

Review of the pathology reports from all patients in this study population revealed that the majority of women who underwent supracervical hysterectomy during pelvic organ prolapse repair had benign pathology (95.7%) that included: inactive, atrophic, proliferative, and secretive endometrium, benign endometrial polyps, leiomyomas, adenomyosis, and endometriosis (Table 4). However, in 4.3% of the study population, both uterine and adnexal pathology was found. This ranged from simple hyperplasia to complex atypical hyperplasia to a case of tubal high grade serous carcinoma. Patients were appropriately referred to a gynecologic oncologist for follow up surgery and appropriate staging procedures as indicated. Limitations of this study include the retrospective nature of our cohort study and small sample sizes for comparison which may decrease the intended power and generalizability of our results and conclusions. However, given the lack of medical literature pertaining to morcellation risk in the urogynecologic patient, this pilot study may serve as further evidence into the potential risks of uncontained mechanical morcellation, and rationale for its guarded use, even in those without clinical risk factors for malignancy. Future inquiry aimed at various contained-morcellation approaches *vs.* uncontained mechanical morcellation in a larger study population is needed to expand our knowledge and evidence-based selection for optimal and efficient tissue extraction in gynecologic patients.

Conclusion

Extracting tissue *via* contained manual morcellation in urogynecologic patients is safe and effective. With the exception of increased procedural time and pain MME, there is no significant increase in morbidity. Investigating a safe and efficient means for morcellation in the urogynecologic patient is warranted as undiagnosed LMS, endometrial cancer, and other malignancies may still be found in postmenopausal women without typical clinical presentations. Additional research is needed to evaluate morcellation techniques as they continue to develop and evolve.

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