

Prevalence of Occult Malignancy Within Morcellated Specimens Removed During Laparoscopic Sacrocolpopexy

Vaneesha Vallabh-Patel, DO, Cristina Saiz, MD, Charbel Salamon, MD, MS, Amanda Francis, DO, Jennifer Pagnillo, RN, BSN, and Patrick Culligan, MD

Objective: This study aimed to determine the prevalence of occult malignancy found in morcellated specimens removed in the context of pelvic organ prolapse repair operations.

Methods: A total of 786 cases were reviewed from a single health system between October 2006 and July 2015. Thorough chart reviews were performed to include pathological specimens. Demographic, perioperative, and postoperative data were collected.

Results: Four occult malignancies were identified including 3 endometrial adenocarcinomas of the uterus and 1 papillary serous carcinoma of the uterus. The overall prevalence of occult malignancy within morcellated specimens was 0.5% (4 of 786). On adopting universal screening with endometrial biopsy, 5 malignancies were identified (5 of 176) before morcellation and no postoperative malignancies in the remaining patients.

Conclusions: Power morcellation is a low-risk procedure with laparoscopic supracervical hysterectomy and sacrocolpopexy. Universal screening is highly effective in detecting occult malignancy and in our small series eliminated the risk; studies in multiple institutions will be needed to determine its effectiveness in other hospital systems.

Key Words: occult malignancy, morcellation, morcellated specimens, laparoscopic sacrocolpopexy

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The first laparoscopic power morcellator was described by Steiner et al¹ in 1993 and, in 1995, a very similar version was cleared by the US Food and Drug Administration (FDA) as a way to remove large tissue specimens through laparoscopic ports. During the subsequent 18 years, power morcellation became increasingly popular among general gynecologic surgeons wishing to remove large fibroid uteri laparoscopically. In 2013, however, the safety of morcellating these large uteri was called into question after a widely publicized case in which this technology was used to remove (and thereby possibly disseminate) a leiomyosarcoma. The FDA released its 2014 safety communication recommending against the use of laparoscopic power morcellation for the removal of leiomyomas.² In response to this FDA document, most hospitals in the United States banned laparoscopic power morcellation outright (ie, not just for removal of fibroid uteri) until further information regarding its risks and benefits is known.

In response to this kind of wholesale banning of the technology, several prominent surgical societies including the AUGS (American Urogynecology Society) released statements calling for continued availability of power morcellation at the discretion of individual surgeons after proper informed consent.^{3–7} The AUGS position statement declared that the decision to perform

power morcellation in benign cases as part of a laparoscopic sacrocolpopexy is still a reasonable procedure. This statement was meant to support the many urogynecologists who—based on evidence that sacrocolpopexy mesh exposure rates increase when concomitant total hysterectomy is performed⁸—routinely use power morcellation to remove normal-sized uteri as part of their laparoscopic supracervical hysterectomy/sacrocolpopexy procedures. Given that our group has routinely used this technique since 2006, the objective of our study was to determine the prevalence of occult malignancy found in morcellated specimens removed in the context of these pelvic organ prolapse repair operations.

MATERIALS AND METHODS

This was a retrospective study including all women who underwent a supracervical hysterectomy with laparoscopic power morcellation as part of a robotic-assisted laparoscopic supracervical hysterectomy and sacrocolpopexy at our institution from October 2006 through July 2015. Approval was obtained from the Atlantic Health Systems Institutional Review Board (no. 713532-1).

Study subjects were identified from the case logs maintained by each attending surgeon and also by query of the Atlantic Health System billing system. The hospital records of all potential study subjects were reviewed to verify their eligibility for inclusion. Baseline demographic information and key perioperative details were recorded for each study subject. Demographic data included age at the time of surgery, body mass index (BMI; in kilograms per square meter), patient history of diabetes, family history of malignancy, and (for patients who were breast cancer survivors) any use of tamoxifen. The recorded perioperative pathology data included results from preoperative endometrial biopsies (when applicable), weight of surgical pathology specimens, pathologic evidence of leiomyomas, and pathologic diagnoses of malignancy. The recorded perioperative data included estimated blood loss, whether or not a concomitant sling procedure was performed, details of any intraoperative complications; length of hospital stay, readmissions to the hospital, and whether or not patients were voiding spontaneously when discharged.

For any patient diagnosed as having an occult malignancy in the morcellated specimen, all subsequent/resultant treatments were recorded. In addition, each of these patients was interviewed by her attending surgeon to verify her survival as well as to identify any continued surveillance protocols she may be following.

During the study period, our group's practice patterns regarding preoperative screening for malignancy changed. Before November 2013, we performed only selective screening with endometrial biopsy for those patients deemed at risk for occult malignancy based on medical history or symptoms of postmenopausal bleeding. After November 2013, any patient for whom morcellation was planned received an endometrial biopsy and a pelvic ultrasound regardless of her history or risk factors. In response to the FDA warning, our hospital system banned morcellation for any patient whose preoperative pelvic ultrasound demonstrated fibroids of any size.

From the Atlantic Health System, Division of Urogynecology and Reconstructive Pelvic Surgery, Morristown, NJ.

Reprints: Vaneesha Vallabh-Patel, DO, Atlantic Health System, Division of Urogynecology and Reconstructive Pelvic Surgery, 435 South St, Suite 370, Morristown, NJ 07960. E-mail: Vaneesha.Vallabh-Patel@atlantichealth.org.

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In an effort to determine the ramifications of this policy change, we collected and reviewed the results of all endometrial biopsies performed by our division during the entire study period. Further analysis was completed to determine the number of occult malignancies found after that policy change. Descriptive statistics were used for all data analyses.

RESULTS

Between October 2006 and July 2015, 786 women underwent robotic-assisted laparoscopic supracervical hysterectomy and sacrocolpopexy plus power morcellation through our division and were therefore included in our study. Demographic and operative pathology data are illustrated in Tables 1 and 2, respectively.

Among these 786 cases, 4 occult malignancies were identified, including 3 endometrial adenocarcinomas of the uterus and 1 papillary serous carcinoma of the uterus. All 3 adenocarcinoma cases were FIGO (International Federation of Gynecology and Obstetrics) grade 1 stage 1. The overall rate of occult malignancy within morcellated specimens was 0.5% (4 of 786). None of these patients had undergone a preoperative screening endometrial biopsy because they did not have any identifiable risk factors for occult malignancy. In other words, all 4 cases occurred before our policy change in favor of universal screening; after that policy change, no occult malignancies were found in morcellated specimens.

By way of subsequent cancer treatments and/or operations, the patient with papillary serous carcinoma underwent laparoscopic BSO (Bilateral Salpingo-oophorectomy), trachelectomy, and partial removal of mesh, as well as chemotherapy (Carbotaxol), and has remained cancer-free for 2.5 years since her diagnosis as of the conclusion of this study. Of the 3 patients identified with endometrial adenocarcinoma, one had a subsequent prophylactic laparoscopic bilateral salpingo-oophorectomy without incident, another had a subsequent trachelectomy with pelvic washings and appendectomy, and the third was followed with only pelvic examinations and endocervical curettage. All 3 of these patients have remained cancer-free for more than 5 years as of the completion of this study.

Before adopting the policy of universal preoperative screening, only 18.3% (124 of 679) of our surgical patients underwent endometrial biopsy. Among these 124 patients, 4 malignancies were discovered (3.2%). Those 4 patients were subsequently cared for by our Gyn Oncology service. Among the remaining 120 patients with negative preoperative endometrial biopsies, none was found to have occult malignancies within her morcellated specimens.

Since adopting our practice of universal screening, we have performed 176 preoperative endometrial biopsies, and 107 of those patients went on to choose morcellation for their tissue extraction method. Of the remaining 69 patients, 61 underwent planned prolapse surgery but declined power morcellation during

TABLE 1. Demographics

	All Patients (N = 786)
Mean age ± SD, y	57 ± 9.9
Mean BMI ± SD, kg/m ²	26.1 ± 4.80
History of diabetes mellitus, n (%)	22 (2.7)
Family history of cancer, n (%)	
Endometrial	13 (1.6)
Ovarian	11 (1.3)
Colon	27 (3.4)
Breast	78 (9.9)
History of tamoxifen use, n (%)	18 (2.2)

TABLE 2. Operative Pathology

	All Patients (N = 786)
Median uterine weight (range), g	55 (16–610)
Leiomyomas, n (%)	344 (43.7)
No leiomyomas, n (%)	442 (56.3)
Endometrial hyperplasia, n (%)	4 (0.5)
Endometrial cancer, n (%)	4 (0.5)
Fallopian tube cancer	0
Ovarian cancer	0

the informed consent process, and 8 were screened out because of abnormal pathology on endometrial biopsy. Of those 8, 5 patients were positive for malignancy and therefore did not undergo planned prolapse repair. The remaining 3 patients had endometrial hyperplasia and therefore underwent total hysterectomy along with their prolapse repairs. Therefore, none of the 171 patients who had universal screening and went on to have prolapse repair ultimately had occult malignancy.

Perioperative details and postoperative characteristics for the entire study group are listed in Table 3. Details regarding any patients whose hospital stay was longer than 24 hours are listed in Table 4. Of the 786 patients, 97% (761 of 786) passed their voiding trial on postoperative day 1 and were discharged without a catheter. Our specific postoperative catheter management protocol has been previously published.⁹

DISCUSSION

The perceived benefits of cervical preservation during laparoscopic hysterectomy/sacrocolpopexy cases include decreased rates of significant blood loss, mesh exposure, and lower urinary tract injury.¹⁰ When supracervical hysterectomy is chosen for these reasons, the next decision has to do with removal of the specimen. One may either use a laparoscopic power morcellator through one of the trocar sites or enlarge one of the incisions and remove the specimen by hand. The obvious benefits of morcellation have to do with decreased incision size and therefore decreased morbidity. Therefore, the population of patients who would benefit from use of power morcellation would be those

TABLE 3. Operative and Postoperative Characteristics

	All Patients (N = 786)
Median estimated blood loss (range), mL	50 (3–700)
Concomitant suburethral sling, n (%)	601 (76.4)
Intraoperative complications, n (%)	1 (0.1)
Bowel injury	1 (0.1)
Bladder injury	0
Ureteral injury	0
Postoperative complications, n (%)	3 (0.4)
DVT/PE	0
Blood transfusion	0
Postoperative ileus	1 (0.1)
Postoperative bowel obstruction	1 (0.1)
Pain	0
Mesh erosion	0
Postoperative fever	0
Operative site infection	1 (0.1)
Neurological injury to extremities	0

TABLE 4. Hospital Days

	All Patients (N = 786)
Discharges POD 1, n (%)	770 (98)
Discharged POD 2, n (%)	14 (1.8)
Pain	5
PO intolerance	5
Cardiac symptoms	3
Neurologic symptoms (not including extremities)	1
Discharge POD 3—Cardiac symptoms, n (%)	1 (0.1)
Discharge POD 4—Concomitant rectopexy, n (%)	1 (0.1)

POD, postoperative day.

patients who would require an extension of an incision to remove the uterus if power morcellation was not applied. The obvious risks of power morcellation have to do with potential upstaging of occult malignancies.

Several groups have reported rates of occult malignancy among gynecologic specimens removed either with or without morcellation. Mahnert et al¹¹ found occult malignancy within 2.7% of nearly 7500 cases, but the majority of these patients received their surgery for conditions other than pelvic organ prolapse. Of the 670 patients in their cohort who had undergone prolapse surgery, they found 4 malignancies for a prevalence of 0.6%. In a study of nearly 35,000 morcellated specimens removed for a variety of benign indications, Wright et al¹² found 0.27% occult malignancies. That rate was similar to both our reported occult malignancy rate of 0.5% and the rate of 0.3% estimated by the FDA for occult malignancies found within morcellated specimens derived from the treatment of myomas.²

Only one other published series focused exclusively on prolapse patients who received supracervical hysterectomy, morcellation, and sacrocolpopexy. In that study, Hill et al¹³ reported an occult malignancy rate of 3.2% among just 63 cases. They note that all diagnosed patients were asymptomatic and hence did not receive preoperative endometrial evaluation. Although their inclusion criteria were very similar to ours, we feel that our higher number of study patients lends credibility to our findings. Based on our experience, one could also argue that performing universal screening will increase the number of abnormal pathology identified in asymptomatic patients, giving the surgeon the option of referring the patient to gynecology or changing the surgical procedure in the best interest of the patient.

Frick et al¹⁴ performed a study that primarily focused on the risk of unanticipated abnormal gynecologic pathology at the time of reconstructive pelvic surgery when power morcellation was not applied. During a 3.5-year period, they concluded that premenopausal women with uterovaginal prolapse with a regular bleeding pattern or a negative endometrial biopsy had a minimal risk of abnormal pathology. They also concluded that, in asymptomatic postmenopausal women, the risk of unanticipated pathology is 2.6% but may be reduced with preoperative endometrial evaluation.

However, even the very low rates of occult malignancy described by our group and others beg the question, “why morcellate at all—given any risk of upstaging cancer?” We feel that patients deserve the right to make the choice of whether they undergo morcellation as long as it is done through a proper informed consent process. Since we began screening all patients before offering morcellation, we have not found a single case of occult malignancy.

Although the discovery of occult malignancy within a morcellated specimen usually results in at least 1 subsequent surgery, other more common scenarios such as mesh exposure, incisional hernias, and recurrent prolapse can also result in subsequent surgery. Furthermore, at least for the patients with occult malignancy in our study, there seem to have been no ramifications. However, we do not believe that this can be inferred for all populations and should be addressed on an individual patient basis. The relatively small uterine size among our study group seems to decrease the chances of leaving behind intraperitoneal fragments after morcellation.

The strengths of our study include the large sample size, the homogeneous nature of the surgical techniques we used, the inclusion of all patients who ever underwent morcellation through our practice, and the fact that we actually contacted the 4 patients with occult malignancies to determine how they are currently doing. Another strength of our study was our inclusion of background information about every endometrial biopsy performed by our practice for any reason during the study period.

The limitations of our study include its retrospective nature as well as potential lack of generalizability inherent in any single-center study. Our study group may simply be at a lower risk for uterine cancer given its relatively low BMI.

These limitations notwithstanding, we believe that it is reasonable to offer patients power morcellation when performing laparoscopic supracervical hysterectomy and sacrocolpopexy as long as patients are screened with endometrial biopsy and pelvic ultrasound.

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