SCIENTIFIC ARTICLE JSLS

To Morcellate or Not to Morcellate: A Cross-Sectional Survey Of Gynecologic Surgeons

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ABSTRACT

Background and Objectives: The inadvertent dissemination of uterine cancer cells with the power morcellator has received much attention in the press and a warning from the U.S. Food and Drug Administration. Many hospitals prohibit the use of the morcellator in gynecologic surgery. We conducted a survey in an attempt to assess gynecologic surgeons' beliefs regarding the intracorporeal power morcellation of fibroids in light of the risk of dissemination of malignancy in patients in whom the presence of cancer is unknown before surgery.

Methods: We conducted an Internet-based survey of 3505 members of the Society of Laparoendoscopic Surgeons (SLS) to assess demographics, current use of the intracorporeal power morcellator, and whether the recent negative press has affected gynecologic surgeons' use of the morcellator.

Results: Of the 3505 SLS members surveyed, 518 responded (response rate, 14.77%). Three hundred thirteen (61%) of the respondents were not using the intracorporeal power morcellator. Of those, 48% reported the reason was a hospital-wide ban, and an additional 17% reported lack of availability (not in stock). Senior attendings with >20 years of experience used the morcellator more often than junior attendings and fellows ($P = .007$). Furthermore, the morcellator was used significantly less among those with the belief that morcellation of occult malignancy affects survival ($P = .013$). Three hundred sixty-one (76%) of the participants currently perform laparotomy in fewer than a quarter of their cases; most those cases are still performed using laparoscopic and robot-assisted techniques.

Conclusion: The recent negative press suggesting that intracorporeal power morcellation can disseminate occult malignancy and affect survival has decreased the use of the morcellator. Despite the declining use of power morcellation, most practicing gynecologic surgeons have not converted their procedures to laparotomy.

Key Words: Fibroid tumor, Leiomyoma, Morcellator, Power morcellation.

INTRODUCTION

In 2013, as a result of a highly publicized case of disseminated uterine sarcoma after power morcellation, gynecologic surgery involving power morcellators came under great scrutiny by the media, the general public, and the United States Food and Drug Administration (FDA).[1–7] Historically, the minimally invasive laparoscopic hysterectomy or myomectomy were offered to patients with benefits that included less pain, shortened hospital stays, faster return to work, and improved cosmetic results when compared to laparotomy.[8–11] Integrating intracorporeal power morcellation to remove leiomyomas or large uterine specimens has changed the practice of gynecology by allowing surgeons to offer minimally invasive approaches to a larger number of patients who would otherwise have required a laparotomy. Although many patients have benefited from the use of power morcellation, some have suffered significant consequences. The morcellated particles of neoplastic tissue can disseminate throughout the abdominal cavity have the potential for seeding, in addition to dissemination of benign pathology.[2,3,12] Inadvertent dissemination of an occult uterine sarcoma by morcellation has been shown to worsen prognosis with poorer disease-free and overall survival rates.[13]

The incidence of uterine sarcoma is 3–7 per 100,000 women in the United States.[14] The FDA estimates that the

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Disclosures: none reported.

The authors thank Erin Moshier, MS, for all help with the statistical analysis.

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DOI: 10.4293/JSLS.2016.00092

incidence of occult uterine sarcoma in women undergoing myomectomy or hysterectomy is 1 in 350, and unsuspected leiomyosarcoma is 1 in 498.[15] Although the incidence is rare, iatrogenic dissemination of malignant tissue through power morcellation has serious clinical implications. In response to these concerns, the FDA issued a statement warning against the use of power morcellators for surgical removal of leiomyoma.[16] The FDA advised against the use of intracorporeal power morcellators for removal of tissue containing leiomyoma in peri- and postmenopausal women, in those in whom en block removal of tissue could be performed, and in women in whom a suspected or known malignancy is present.

With the FDA's warning against power morcellation, many hospitals have prohibited the use of the intracorporeal power morcellator. The impact on gynecologic practices with these mandates is unclear at this time. To assess the effects on surgical practices, we have conducted an international cross-sectional survey of gynecologic surgeons. Our purpose was to ascertain gynecologic surgeons' practices and attitudes regarding power morcellation of presumed benign leiomyoma, despite the risk of disseminated spread of occult sarcomatous malignancy.

METHODS

The Mount Sinai Roosevelt and Saint Luke's Institutional Review Board (IRB) approved this cross-sectional survey of 3505 members listed in the Society of Laparoendoscopic Survey (SLS) database. All participants identified themselves as gynecologists. No incentives were offered.

We developed an 11-item questionnaire that assessed demographics, current use of the morcellator, changes in the use of the morcellator after the FDA warning, beliefs that morcellation affects survival, and percentages of operations performed by traditional laparoscopy, robot-assisted laparoscopy, and laparotomy.

An initial e-mail was sent to all the database members describing the survey and containing a link to the web-based survey on January 15, 2015. A second e-mail was sent March 12, 2015 to increase the number of respondents. Internet protocol (IP) addresses were the only identifying information attached to the respondents' completed surveys. The survey was conducted through a Wufoo online survey form (www.wufoo.com).

As this was a descriptive study, percentages were used to detail the answers to the questionnaire. Chi square and Fisher's exact test were used to analyze the categorical variables and differences in proportions.

RESULTS

The survey was sent to 3505 SLS database gynecologists; of those, 518 responded (a response rate of 14.77%). Sixty-four percent of respondents were from the United States, and the remaining 36% were international. Forty-seven percent of respondents identified themselves as senior attendings with >20 years' experience, 41% as attendings, and 12% as fellows.

A total of 313 (61%) of the respondents were not using the intracorporeal power morcellator (**Tables 1** and **2**) at the time of the survey. Of those who did not use it, 48% reported that was because the morcellator was banned by their hospital, and an additional 17% stated that their hospitals did not stock the equipment.

Senior attendings with >20 years' experience used the morcellator more than junior attendings and fellows (P = .007; **Table 3**). Use of the morcellator was significantly less among those who believe that morcellation of occult malignancy affects survival (P = .013). Of those who believe morcellation disseminates benign disease, there was no difference in the use of the morcellator (P = .191). Of the respondents, 361 (76%) performed laparotomy in fewer than 25% of their cases; most cases were still performed with laparoscopic and robot-assisted techniques.

DISCUSSION

This survey identified gynecologic surgeons' beliefs and practices of intracorporeal power morcellation after the FDA's warning on its use. The warning prompted many national gynecologic societies to take a stand on power morcellation. In May 2014, the American Congress of Obstetricians and Gynecologists (ACOG) released a bulletin emphasizing appropriate patient selection and informed consent. However, it stated that it was still important to maintain access to morcellation for women who would benefit from its use.[17] The American Association of Gynecologic Laparoscopists (AAGL) stated, "power morcellation with appropriate informed consent should remain available to appropriately screened, low risk women." The AAGL also estimates that converting all hysterectomies that would otherwise use the power morcellator to laparotomy would result in an annual increase of 17 more women dying from surgery each year.[18] Even before the FDA's warning in December 2013, the Society of Gynecologic Oncologists (SGO) stated that the use of power morcellation should be contraindicated in cases where malignancy is highly suspected.[19] The general terms used in these statements allow room for interpre-

Table 1.
Survey on Intracorporeal Power Morcellators

1. Age:
   - o Please choose one:
   - o 20–30
   - o 31–40
   - o 41–50
   - o 51–60
   - o 60+
2. What is your current level of training?
   - o Fellow
   - o Attending
   - o Senior attending (20+ years)
3. Do you use an intracorporeal power morcellator currently?
   - o Yes
   - o No
4. If you do NOT use a power morcellator currently, what is your reason for not using it?
   - o I do not feel comfortable using it
   - o My hospital does not keep a morcellator in stock
   - o My hospital has banned the use of the morcellator
   - o Not applicable
5. Does your hospital or hospital system have a policy about the use of morcellation?
   - o Yes
   - o No
   - o I don't know
6. Have you heard about the recent press concerning dissemination of occult uterine malignancy after power morcellation?
   - o Yes
   - o No
7. Will the risk of disseminated disease make you stop using the morcellator?
   - o Yes
   - o No
8. Do you think intracorporeal morcellation of occult malignancy affects survival?
   - o Yes
   - o No
9. Do you think intracorporeal morcellation can disseminate benign pathology, including endometriosis and fibroids?
   - o Yes
   - o No

Table 1.
Continued

10. Have you personally seen a uterine sarcoma diagnosed, which was not suspected preoperatively?
    - o Yes
    - o No
11. What percent of your cases are performed open, laparoscopic, robotic, or MIS with mini-incision for tissue extraction?

	<10%	10–25%	25–49%	50%	51–75%	75–90%	>90%
Open	o	o	o	o	o	o	o
Laparoscopic	o	o	o	o	o	o	o
Robotic	o	o	o	o	o	o	o
MIS with mini-incision	o	o	o	o	o	o	o

tation and do not necessarily guide the practicing gynecologist. The dilemma with sarcomatous uterine malignancy is that it often cannot be diagnosed, or even highly suspected, before surgery. Advanced age is one of the only identifiable risk factors.[6,7] Thus, selecting "appropriate patients" for power morcellation can be challenging.

Power morcellation allows minimally invasive surgery to be performed on a large number of patients who would otherwise undergo laparotomy. The literature supports a minimally invasive approach performed in place of a laparotomy with decreased morbidity and faster recovery for patients.[8–11] The occurrence of occult malignancy in women who undergo surgery with a minimally invasive approach for fibroids is rare, but the consequences when cancer is present are severe. As to whether banning the power morcellator does more harm than good, that remains to be seen.

There is a risk of spreading occult malignancy. In 2011, Park et al[13] published a retrospective study comparing leiomyosarcoma with and without tissue morcellation. They noted an increased risk of disseminated disease (44% vs 12%), a decrease in 5-year disease-free survival (40% vs. 65%), and a decrease in 5 year overall survival (46% vs. 73%) in those in whom tissue morcellation was used, compared with those in whom it was not used. Although it is difficult to confirm dissemination other than second-look surgery or at time of autopsy, small studies have been published confirming spread after power or hand morcellation. Oduyebo et al[20] evaluated findings from second-look surgery after use of tissue morcellation

Table 2.
Survey Responses

Item	n (%)
Country	19 Missing
USA	317 (64)
Other	182 (36)
Q1. Age	78 Missing
20–30	6 (1)
31–40	74 (17)
41–50	132 (30)
51–60	147 (33)
61+	81 (18)
Q2. Level of training	6 Missing
Attending	209 (41)
Fellow	61 (12)
Senior Attending (20+ years)	242 (47)
Q3. Use intracorporeal power morcellator	5 Missing
No	313 (61)
Yes	200 (39)
Q4. Reason for not using power morcellator	1 Missing
Not comfortable	61 (20)
Hospital does not keep in stock	53 (17)
Hospital banned morcellator	149 (48)
NA	49 (16)
Q5. Hospital have policy about morcellation	6 Missing
DK	31 (6)
No	207 (40)
Yes	274 (54)
Q6. Heard about press concerning dissemination of occult uterine malignancy after morcellation	4 Missing
No	19 (4)
Yes	495 (96)
Q7. Will risk of disseminated disease make you stop using morcellator	6 Missing
No	339 (66)
Yes	173 (34)
Q8. Does morcellation of occult malignancy affect survival	7 Missing
No	204 (40)
Yes	307 (60)
Q9. Can morcellation disseminate benign pathology, including endometriosis and fibroids	4 Missing
No	160 (31)
Yes	354 (69)
Q10. Personally seen uterine sarcoma diagnosed not suspected pre-op	4 Missing
No	268 (52)
Yes	246 (48)
Q11. What percent of your cases are performed open, laparoscopic, robotic, or MIS with mini-incision for tissue extraction?	
Open	41 Missing
<10%	286 (60)
10–25%	75 (16)
25–49%	41 (9)
50%	31 (6)
51–75%	17 (3)
75–90%	14 (3)
>90%	13 (3)
Laparoscopic	30 Missing
<10%	45 (9)
10–25%	65 (13)
25–49%	72 (15)
50%	53 (11)
51–75%	67 (14)
75–90%	89 (18)
>90%	97 (20)
Robotic	141 Missing
<10%	195 (51)
10–25%	33 (9)
25–49%	44 (12)
50%	12 (3)
51–75%	34 (9)
75–90%	30 (8)
>90%	29 (8)

with malignant pathology, and found disseminated disease in 2 of 7 cases of leiomyosarcoma. In addition, 1 of 4 patients with smooth muscle tumor of unknown malignant potential (STUMP) had disseminated disease. Although retrospective, these studies shed light on the relation of tissue morcellation to disseminated disease and its affects on patients' survival.

Table 3.
Cross-tabulations With Use of Power Morcellator

	Use Power Morcellator Currently		*P*
	No	Yes	
	n = 313	n = 200	
Q2. Level of training	4 Missing	1 Missing	**0.0076**
Attending	143 (69)	65 (31)	
Fellow	35 (59)	24 (41)	
Senior attending (20+ years)	131 (54)	110 (46)	
Q6. Heard about press concerning dissemination of occult uterine malignancy after morcellation	1 Missing	2 Missing	0.3276
No	13 (72)	5 (28)	
Yes	299 (61)	193 (39)	
Q7. Will risk of disseminated disease make you stop using morcellator?		2 Missing	
No		174 (88)	
Yes		24 (12)	
Q8. Does morcellation of occult malignancy affect survival?	2 Missing	4 Missing	**0.0132**
No	110 (55)	91 (45)	
Yes	201 (66)	105 (34)	
Q9. Can morcellation disseminate benign pathology, including endometriosis and fibroids?	1 Missing	1 Missing	0.1906
No	91 (57)	69 (43)	
Yes	221 (63)	130 (37)	
Q10. Personally seen uterine sarcoma diagnosed not suspected pre-operatively?	1 Missing	1 Missing	0.2169
No	155 (58)	110 (42)	
Yes	157 (64)	89 (36)	

Probabilities in bold indicate significant results.

The majority of the respondents (61%) are not currently using the morcellator, mainly because it was banned by their hospital or their hospital did not keep it in stock. This implies that discontinued use of the power morcellator is not by choice, but rather by a policy imposed on surgeons. However, beliefs about the morcellator and its implications in possibly disseminating occult malignancy also play a role. Use of the morcellator was significantly less among those who believe disseminated malignancy adversely affects survival.

Three hundred sixty-one (76%) of the participants stated that they perform laparotomy in fewer than 25% of their cases. This result implies that despite the decreasing use of power morcellation, most of these gynecologic surgeons have not converted their procedures to laparotomy and are still operating using conventional and robot-assisted laparoscopic techniques. This is still the case, even though some gynecologic societies believe that banning the use of the power morcellator would result in an increase in laparotomies and therefore increase the death rate in women undergoing open hysterectomies.[18]

Mandato et al[21] recently published a study similar to ours, looking at the impact of the FDA's warning on the use of power morcellation use, specifically in Italian gynecology practices. This study was different from the current one in

several ways. Most respondents practiced daily gynecologic oncology, which is not likely to be the case with our study, as members of SLS are typically general gynecologists. The respondents also performed a higher percentage of laparotomies, whereas our study included mostly experienced laparoscopists. The Italian study was focused on the FDA statement and its sequelae, and touched upon medicolegal implications. Our study focused more on power morcellation and how the negative press would affect the use of intracorporeal power morcellation.

Several other studies looked at the implication of FDA warning statement. Barron et al[22] performed a time series analysis, looking at all gynecological surgical cases performed at 6 hospitals before and after the FDA statement. They found that there was a significant decrease in the proportion of minimally invasive hysterectomies and myomectomies after the FDA warning statement, as well as a larger percentage of minimally invasive supracervical hysterectomies converted to open procedures. Lum et al[23] surveyed AAGL as well as the American College of Obstetricians and Gynecologists Collaborative Ambulatory Research Network (ACOG CARN) members and found a decrease in the use of power morcellation, as well as an increase in the rate of laparotomy. The discrepancy noted in the rate of laparotomy between the current study and the aforementioned studies may be explained by the recall bias of the responders.

Another limitation of our survey is the potential for bias toward minimally invasive techniques when surveying gynecologists through a laparoscopic society. Although we chose a laparoscopic society to ensure respondents' use and familiarity with the power morcellator, it may also introduce a bias in their responses. Another limitation of our survey is that the surgeons were not asked to disclose the techniques used in place of the power morcellator. Removing uterine tissue through the vagina or minilaparotomy, with or without a self-containing retractor, allows for less risk of dissemination, while maintaining the benefits of a minimally invasive surgery.[24,25] There is also the possibility of using intracorporeal power morcellation in an insufflated bag to prevent seeding of malignancy or benign disease.[24,25] A follow-up study may be warranted to stay abreast of adjustments in surgeons' techniques in place of the power morcellator. Last, the nonresponse rate was high, resulting in a large bias.

This is the first study to assess international and national gynecologic surgeons' beliefs and practices regarding intracorporeal power morcellation and the concern for dissemination of occult malignancy. Despite increasing negative publicity, 39% of respondents are still using the power morcellator. Although most respondents do not use it, the majority are still using a minimally invasive approach in gynecologic operations.

To compensate for the absence of power morcellation, gynecologists have started developing different techniques and devices for tissue extraction, such as contained power morcellation.[26,27] One such device is the Pneumo-Liner (Advanced Surgical Concepts, Wicklow, Ireland). The FDA has approved the marketing of this first-of-its-kind tissue containment system for use with certain laparoscopic power morcellators in select patients.[27] Although the device is not currently available on the market, it has not been shown to reduce the risk of spreading cancer during the procedure.

We urge more minimally invasive surgeons to publish their success with other techniques to support the continued benefit of the minimally invasive approach for patients. Although use of the power morcellator has been scrutinized by the press and governing agencies, it has not completely fallen out of favor and continues to play a role in gynecologic surgery, especially with containment morcellation.

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