Medicolegal Issues in Power Morcellation: Cautionary Rules for Gynecologists to Avoid Unfavorable Outcomes

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Precis: Adequate information must be provided to patients to obtain proper consent, based on awareness of the potential risks involved, such as occult malignancy spread.

ABSTRACT

Power morcellation in the context of laparoscopic surgery is a technology that enables specialists to carry out minimally invasive procedures such as hysterectomies and myomectomies by cutting the specimen into smaller pieces using a rotating blade and removing it through a laparoscope. Unexpected uterine sarcoma treated by surgery involving tumor disruption could be associated with worse prognosis. The current study aims to shed light on power morcellation from a medicolegal perspective: the procedure has in fact given rise to adverse outcomes, resulting in litigation and substantial compensation for plaintiffs. Studies have been published in various journals cited in PubMed-Medline, Cochrane Library, Embase, GyneWeb between 1995 and 2019. Considering claims following the US Food and Drug Administration (FDA) warnings on morcellation, the current study broadens the scope of research, including search engines, legal databases, and court filings (DeJure, Lexis Nexis, Justia, Superior Court of New Jersey, United States District Court of Minnesota). Trial records show that courts, especially under tort law statutes, often tend to place responsibility for unfavorable outcomes on doctors and facilities (finding malpractice, rather than complications, to have occurred). It is therefore essential to document adherence to safety protocols and specific guidelines, when available. Sound medical practice is tied to guidelines; adverse legal outcomes can be avoided if there are grounds to prove conformity with specific guidelines and the unpredictability of an event. Moreover, grey areas ought to be clarified. Well-defined best practices ought to be outlined, when missing, to defend health care operators from liability when unfavorable clinical outcomes do occur.

*Keywords***:** Leiomyosarcoma; Liability; Lawsuit; Malignancies

INTRODUCTION

Power morcellation is a practical technology that effectively enables specialists to carry out minimally invasive procedures such as hysterectomies and myomectomies by cutting the specimen into smaller pieces using a rotating blade and removing it through a laparoscope [1]. The ability to extract tissue through small abdominal incisions using morcellators revolutionized minimally invasive gynecologic surgery, which previously required open abdominal incisions to remove large uteri and fibroids [2,3]. In the absence of unsuspected malignancies, performing intracorporeal power morcellation may entail risks such as the dissemination of benign tissues (eg, leiomyoma, endometriosis, and rarely, parasitic fibroids) that may develop from morcellation remnants after laparoscopic myomectomy [4]. Dispersed tissue fragments could implant on abdominal organ surfaces and lead to inflammation, infection, and intestinal obstruction, which may in turn require additional surgery and treatments [5,6]. Power morcellation has nonetheless given rise to additional risks and complications associated with dissemination of benign as well as malignant tissues inside the abdominal cavity, particularly uterine leiomyosarcomas (LMS) a particularly aggressive, however rare, form of cancer. Based on reports of adverse events that led to worsened prognosis and even death, the US Food and Drug Administration (FDA) issued a discouraging statement in April 2014 on the use of power morcellators for the vast majority of patients undergoing hysterectomy or myomectomy, which caused a progressive, sharp decrease in the number of minimally invasive approaches over the following months and an increase of complications associated with open abdominal surgery [7]. Eventually, in February 2017, the Government Accountability Office (GAO) came into play, asserting that the FDA delay in warning the public was owing to research findings dating back to the 1990s (when the first power morcellator was greenlighted in 1991), which discounted the tissue dissemination risks, stating that only 1 in 10,000 women with uterine fibroids had undetected cancer [8]. As a response to these newly-asserted concerns, researchers have developed several containment systems aimed at averting the spread of tissue fragments during the morcellation of specimen (in-bag morcellation methods, however, need further improvement according to the FDA and major scientific societies)

[9-11]. Meanwhile, medicolegal implications are manifesting themselves, with individual and class-action lawsuits being filed and expected to grow, given that patients had not been warned prior to the FDA releases of the real risk associated with the use of power morcellation. Further, device makers may be blamed for breach of product liability statutes in the United States, as well as negligence, fraudulent misrepresentation, and failure to warn, test, and eventually recall their products, among other charges. The development of guidelines and new screening procedures to identify low-risk patients who may benefit from morcellation and the provision of thorough information to patients prior to any surgery are of utmost importance and represent the key to avoiding legal repercussions and unfavorable rulings.

OBJECTIVE

By virtue of the numerous lawsuits that have been filed with relation to the practice of morcellation and the restrictions that have been put in place, we have aimed to clarify the grounds upon which morcellation-related lawsuits had been filed. The assumptions that have been evaluated as possible causes of claims are failure to comply with recommendations, disregard of informed consent standards, unorthodox execution of the morcellation procedure, and incorrect indications relative to patient selection.

Therefore, the FDA warnings, documentation, official positions, and recommendations from national and international health care and medical societies in the field have been taken into account. Various statements that seem to back up the recommendations of the FDA, among which, the American Association of Gynecologic Laparoscopists, the American College of Obstetricians and Gynecologists, the British Society for Gynaecological Endoscopy, the European Society for Gynaecological Endoscopy, the European Society of Gynecological Oncology, the National Institute For Health And Care Excellence, the Italian Society of Gynecological Endoscopy, the Italian Association of Hospital Obstetricians and Gynecologists, the German Society for Gynecology and Obstetrics, and the Society of Gynecologic Oncology. Moreover, searches in Medline/PubMed and Cochrane Library, Embase, GyneWeb for publications between 1995 and 2019 have been conducted using keywords “uterine fibroids”, “morcellation”, “laparoscopy”,

104 “hysterectomy”, “myomectomy”, and “uterine sarcoma.” For medicolegal aspects to be optimally
105 highlighted, major legal databases have been searched: DeJure, Lexis Nexis, Justia, and Court
106 filings have been perused from all available sources (ie, Superior Court of New Jersey, United
107 States District Court of Minnesota), taking into account all relevant cases that saw uncontained
108 power morcellation as the centerpiece of the claims. Professional medical societies and
109 associations are predominantly in favor of keeping power morcellation available, though with
110 caveats, for patients to be able to benefit from the well-documented advantages inherent to
111 minimally invasive procedures, in light of the low incidence of undetected malignancies being
112 spread (Table 1) [12-22].

113 In 2015, the GAO began investigating the FDA and power morcellators at the request of US
114 House Representatives Mike Fitzpatrick, Louise Slaughter, and others over concerns the device
115 could spread uterine cancer. Failures in the reporting system may have played a role as well. The
116 GAO February 7, 2017 report found doctors, hospitals, and individuals did not properly report
117 morcellator problems to the FDA through its adverse event reporting system, causing a delay in its
118 action to warn the public. The GAO report said that the FDA knew power morcellators could
119 spread potentially cancerous tissue in the body as early as 1991, before receiving the first adverse
120 event reports describing the spread of cancerous tissue after the use of a power morcellator to
121 treat uterine fibroids, when it allowed the first morcellator on the market. This awareness was
122 reflected in the labeling of 12 of the 25 devices cleared by the FDA. Yet, the agency believed the
123 threat of spreading cancer was low—between 1 in 500 and 1 in 10,000 [7], as mentioned above. In
124 fact, the labeling for these power morcellators recommended [23] the use of a bag when cutting
125 cancerous (diagnosed or suspected) tissue and any other tissue that may be considered harmful if
126 spread, even though available data regarding the performance, safety, and effectiveness of bags
127 during laparoscopic morcellation of tissue are limited, according to the FDA. To arrive at those
128 conclusions, the GAO looked at 25 power morcellators, nearly all of them indicated for gynecologic
129 surgery, that the FDA approved from 1991 through 2014. There were no clinical trials to assess
130 their safety or efficacy because they were all greenlighted through the FDA 510(k) premarket
131 approval process. Under 510(k), a manufacturer need only demonstrate that the product is

substantially the same as one already on the market (called predicate). In the case of the first power morcellator approved in 1991, the predicate product was an electromechanical device for cutting tissue in orthopedic procedures. The 24 morcellators that followed piggy-backed on that previously approved morcellator [23]. Professional societies interviewed by GAO offered guidance to physicians on the proper use of power morcellators, while manufacturers provided instructions and some technical training. It became apparent that currently there are no clearly defined professional standards for use of power morcellators, but some guidance and educational resources are available for surgical procedures to treat uterine fibroids for which the devices may be used. Training activities for physicians using power morcellators routinely take place at hospitals to supply physicians with suitable experience and abilities.

Manufacturers provide instructions for use, and some offer technical training relative to the device structural characteristics, functional traits, and its necessary cleaning (Table 2) [7, 9,10, 23]. Original studies, meta-analyses and reviews have been looked into: such probes have shown that the prevalence of unsuspected uterine sarcoma in patients undergoing hysterectomy or myomectomy for presumed benign leiomyoma is 1 in 352 and the prevalence of unsuspected uterine LMS is 1 in 498 [24]. The risk ratio of unsuspected uterine sarcoma has been found to be 0.14% or 1 in 700 [25]. Differences have been observed with a significant degree of variation (from 0.49 %, or 1 in 204 [14], to 0.056 % or 1 in 1,788 [26]). On average, papers that have reported on power morcellators and myomectomy specimens pointed to a lower risk (though by a mere .08%, or 1 in 1,306) compared with those that looked at hysterectomy specimens and found the overall pooled risk to be 0.15%, or 1 in 650. There seems to be an undisputable age correlation in those rates; the risk has been observed to be lower in patients under 45 [27]. Of the 234 sources found, 31 were ultimately deemed to be suitable for the paper's objective[1-6, 8, 24-33, 52, 54-64, 67, 68]. As for the Court cases herein expounded upon, they have been selected out of a 54-case pool, among which 9 involved morcellation as a determining factor in giving rise to the claim. Court cases where morcellation did occur but was not the determining factor in terms of causing the alleged damage have been disregarded. After the FDA statement, studies showed decreased rates of minimally invasive surgery and increased rates of open abdominal hysterectomy. A

retrospective cohort study, published in 2018, included 75,487 patients (mean [SD] age 47.8 years)[28] who underwent hysterectomy for benign conditions. The study was based on the National Surgical Quality Improvement Program and that included 603 hospitals. 32,186 (42.6%) patients were treated before the FDA warning regarding power morcellation and 43,301 (57.4%) were treated after the warning. The population included mainly non-Hispanic white women (59.4%) and African American women (15.1%). While the overall rate of major and minor complications remained similar both before and after the FDA warning, in a subgroup of patients undergoing hysterectomy for uterine fibroids (25,571 patients or 33.9% of the total population), the study found a significant increase in major complications following the warning (from 1.9% to 2.4%) as well as a rise in minor complications (from 2.7% to 3.3%). This group reported higher rates of abdominal hysterectomy (from 37.2% to 43.0%) and lower rates of minimally invasive hysterectomy (from 56.1% to 49.7%). In light of those findings, it is undeniably of utmost importance to outline a thorough risk-benefit analysis, by which surgeons should appropriately advise patients on both the risks and potential benefits connected to power morcellation during minimally invasive hysterectomy. The decision should be a shared decision between patient and surgeon, and all patients should be adequately informed before surgery. It is of utmost importance to pursue a substantial improvement of these alternative techniques of uterine morcellation and a more effective identification process of patients who can benefit from minimally invasive procedures [29-30].

Following the FDA advisory panel concerns regarding a surgical device commonly used in hysterectomies and to remove fibroids, a July 29, 2014 *Journal of the American Medical Association* briefing noted “We may have underestimated the risks of morcellation,” on the basis of a study that showed patients with undetected cancer that unintentionally spread [31]. Following the publication, Ethicon (a Johnson & Johnson subsidiary), the manufacturer of nearly three-quarters of laparoscopic power morcellators on the US market, started a voluntary recall of the device [32]. Such developments have given rise to far-reaching medicolegal ramifications associated with power morcellation and possible adverse outcomes. Considering that research noting the possible risks of morcellation has been publicly available since 1990 before power morcellators were even

released, plaintiffs cite these studies to support their claims that manufacturers should have known about the serious cancer-spreading risks of their products and yet did not take appropriate action [33]. In the US, the first such lawsuit was filed in March 2014 (Burkhart vs. LiNA Medical); since then, more than 300 suits have been filed [34-36] against morcellator manufacturers on the heels of FDA warnings, of which those that were made public are summarized in Table 3 [37-47] . Johnson & Johnson has reportedly paid $100,000 to $1 million [48]per case to settle power morcellator lawsuits behind the scenes, and it is expected that the manufacturer will pay millions to settle future claims. According to attorneys, Johnson & Johnson is already in talks to settle more of its morcellator lawsuits, including those in state courts throughout the country, and more cases are expected to be filed [49]. According to court transcripts, plaintiff attorney Sean Tracey said he had "another 40 morcellator cases" ready to be filed. Companies often settle lawsuits confidentially to prevent damaging information from coming to light [50]. The Wall Street Journal reported in March 2016 that Johnson & Johnson has settled nearly 70 of the estimated 100 legal claims that the devices harmed patients by spreading undetected cancer. Plaintiffs also state that device makers were aware or should have known of the dangers of morcellators but continued to profit from their sales, disregarding the blatant consumer risk posed by their conducts, and should have stopped selling them because of the potential harm they can cause, but they failed to recall or remove the products from the market [51]. Singh et al reported that Canadian guidelines in 2015 stated that morcellation should be discouraged in patients in menopause or older and in patients with a history of pelvic cancer because their cancer risk is higher [52]. Meanwhile, major insurers in the United States, such as Aetna, UnitedHealth, Highmark, Blue Cross Blue Shield of Massachusetts, and AmeriHealth Caritas are among payers who have ceased coverage of procedures that use a morcellator. Among major insurers, UnitedHealth and Anthem require prior authorization for morcellator use. Vice President of Medical Affairs at the University of Pittsburgh Medical Center said that reimbursement for morcellation procedures was being discontinued to "protect patient safety," while University of Pittsburgh Medical Center spokeswoman Gloria Kreps called the policy decision "an appropriate and prudent course of action [53]."

CONCLUSION

Informed consent is eminently relevant when it comes to risky surgical practices such as morcellation and should be viewed as a process, not as a mere form, involving ongoing, interactive dialogue between medical staff and prospective patients.

In particular, during patient counseling, the surgeon should stress how current scientific evidence reinforces the use of a minimally invasive approach to myomectomy [54]. The surgical approach should be tailored according to the individual characteristics of the patient (such as size, location, and number of fibroids) and to surgeon expertise [55]. All patients undergoing myomectomy should be aware of the low prevalence of malignancy in a presumed fibroid [56]. According to the FDA, the overall risk is 1 in 350, seemingly an overestimation. An overall risk of malignancy in a presumed benign uterine fibroid of less than 1 in 500 has been reported, lower in some cohorts (down to 1 in 7,400) [57]. Age is an important factor when considering the risk of inadvertent LMS, with a prevalence in women under 40 years being less than 1 in 1,000 [58].

Myomectomy is a surgical procedure usually performed in younger patients who are interested in preserving their fertility [59], in place of hysterectomy. Patients should also clearly understand that it is not possible to completely rule out malignancy through preoperative imaging modalities, although certain morphological characteristics may be highly suspicious [60]. In case of inadvertent LMS during a myomectomy for a presumed fibroid, the non en-bloc dissection performed through the use of morcellation carries a poorer prognosis. In bag morcellation has been proposed to reduce the risk of malignancy spread in case of occult LMS, nonetheless the evidence in its favor is scant. The increased risk of vascular or visceral damage when using such a device has been noted [61]. Consensus and evidence-based guidelines should always be consulted when choosing the best surgical route for the patient and during the selection for appropriate morcellation candidates. A standard preoperative workup that excludes malignancy is important and should include cervical cytology, pelvic imaging, and possibly endometrial assessment [62]. During the selection process, patient age should be evaluated as well as menopausal state, uterine dimensions, rapid growth of the fibroid, treatments (eg, tamoxifen) and genetic conditions (eg, Lynch syndrome) [63].

In addition to a thorough informed consent process and proper assessment of risk factors and patient individualities, it is worth considering that a court of law (particularly in tort law) tends to place responsibility and blame on doctors and facilities (finding malpractice, rather than complications, to have occurred) if the informed consent documentation process and patient medical records are lacking in any way; such inconsistencies may contribute to poor outcomes, that can be viewed by a court as stemming from negligence rather than typical complications. In broader terms, any failure to abide by surgical safety protocols or properly produce documentation reflecting adherence to those rules will most commonly lead to unfavorable rulings against health care providers and facilities. It is imperative to standardize clearly-defined best practices to shield health care professionals from arbitrary judicial rulings as well as to protect patients. Adverse legal outcomes can be avoided if conformity specific guidelines can be proven as well as the unforeseeable nature of the mishap. Virtually all litigation that has been singled out and delved into by the authors [37-47] related to morcellation stemmed from the dissemination of unsuspected malignancies in the pelvic cavity. Thus, it is incumbent upon specialists to put in place more reliable selection criteria for patients eligible to undergo these procedure. To reduce the risk of adverse outcomes and legal claims, only patients of fertile age should undergo power morcellation (ie, patients with a small likelihood of having an occult malignancy). The increasing prevalence of LMS with advancing age (menopause or perimenopause status), could warn this patient population to avoid procedures involving morcellation. ~~However, adequate and thorough information must be provided to such patients, to acquire a solidly grounded consent, based on awareness of the risks involved, including those relative to the spreading of occult malignancies.~~

Morcellation-targeted consent forms have been developed, such as the one recently released by the Royal College of Obstetricians and Gynecologists [64]. The essential nature of the consent process has been reinforced by the support of the American College of Obstetricians and Gynecologists as well [65]. It is important to note the potential risks associated with power morcellation, even those completed within a containment system [66-68]. ~~It is therefore necessary for patients to be made aware of the fact that by consenting to undergo power morcellation, they will be exposed to a risk, however low, of upstaging unsuspected cancer and resulting in a worse~~

~~prognosis.~~ The information may well act as a dissuading factor for patients, even leading them to opt for open surgery instead, which, however, entails no less risk, from the standpoints of surgery and anesthesia. As several studies have shown, awareness of the risks associated with power morcellation will likely lead to a decrease in the rates of minimally invasive surgery overall, since fewer patients are willing to take those chances.

Furthermore, medical insurance providers have been pulling out of covering power morcellation in their policies, on account of its controversial nature. A more clearly defined stance by scientific societies and health care organizations worldwide may validate morcellation and its undeniable benefits as a minimally invasive surgical practice, at least in strictly select patients that would make it possible for minimally invasive practices to grow, rather than be abandoned for defensive medicine reasons.

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