

## Invited Commentary

# The Dilemma of Myomectomy, Morcellation, and the Demand for Reliable Metrics on Surgical Quality

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In late 2013, a public awareness campaign was initiated after electromechanical morcellation (EMM) of a uterus with presumed benign leiomyoma, which in fact was leiomyosarcoma (LMS). Over the past year, the focus of the medical community has been



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on the incidence of occult LMS, specifically related to EMM. The risk of intracorporeal tissue dissemination by EMM resulted in some manufacturers halting sales of the EMM device, various hospitals banning the procedure, and ultimately a black box warning from the US Food and Drug Administration (FDA) for electromechanical morcellators.<sup>1</sup>

This type of issue is not new in medicine. In the 1950s and early 1960s, laparoscopic surgery was banned in Germany owing to electrosurgical complications during laparoscopic sterilization.<sup>2</sup> This led to greater understanding of sparking, capacitation, and coupling related to electrosurgery during laparoscopy; subsequent technological improvements and surgeon education resulted in electrosurgery being an integral part of minimally invasive surgery today. Albert Einstein defined insanity as doing the same thing over and over again and expecting different results. As with electrosurgery, EMM needs reassessment and improvement in technique and instrumentation for proper use.

Systematic literature reviews,<sup>3</sup> reports from multispecialty centers,<sup>4</sup> and large group studies<sup>5</sup> have mainly focused on hysterectomy patients with estimations of uterine sarcoma relating primarily to symptomatic women requiring hysterectomy. This methodology overlooks a large data set of patients undergoing myomectomy to restore anatomy and preserve and enhance fertility.<sup>6</sup> Worldwide, thousands of myomectomies are performed vaginally or by minilaparotomy, conventional laparotomy, laparoscopy, or hysteroscopy, primarily in women of reproductive age for subfertility. While EMM is used mostly during laparoscopic myomectomies, with or without robotic assistance, the impact and outcome of tissue disruption at the time of myomectomy by any method, including laparotomy, carries a small risk of intraperitoneal dissemination of occult malignant tissue.

In this issue of *JAMA Oncology*, Wright and colleagues<sup>7</sup> report their analysis concerning the prevalence of undetected cancer and precancerous changes in women who underwent myomectomy with and without EMM. In light of the limited data regarding safety and risks in women undergoing myomectomy with EMM, this report broadens the focus on this matter. Owing to lack of information regarding the risk of occult uterine malignant neoplasms in reproductive-age women and possible tumor dissemination during myomectomy, with or without morcellation, the magnitude of harm is unknown. Consequently, not only morcellation, but the prevalence of ma-

lignant and premalignant uterine lesions in younger patients, calls for investigation.<sup>8</sup>

En bloc removal of all myomas translates to total hysterectomy, which is inappropriate; myomectomy remains the surgical treatment of choice in reproductive-age women with symptomatic uterine fibroids. Patients prefer minimally invasive surgery because the benefits outweigh the risks when performed appropriately. The FDA black box warning on power morcellators must not cause a reversal to laparotomy or increase in the number of hysterectomies for uterine tumors.

The demand for reliable metrics of surgical quality is at an all-time high, calling for a more systematic and rigorous approach to quality improvement. Since there are no clinical registries for measuring surgical quality during myomectomy, the report by Wright et al<sup>7</sup> opens the door to the use of administrative data. However, there are significant differences between administrative data and clinical registries to measure outcome and surgical quality. Administrative data are pulled from claims provided to insurers, while clinical registries contain data collected from medical records, which questions the completeness and reliability of administrative data. In an analysis of clinical-based data, Graebe et al<sup>4</sup> found that morcellation was associated with substantially higher risk of abdominopelvic recurrence and lower disease-free survival, placing a greater emphasis on the magnitude of the problem, not merely the incidence.

Comparison between administrative data and clinical registries conducted for predicting surgical results revealed significant differences in both recording and outcomes.<sup>9</sup> Creating and maintaining a prospective registry is prohibitively costly and time consuming compared with gathering administrative data, which is inexpensive and readily available electronically. However, clinical data such as final pathology reports and long-term results supplemented with reliable administrative data is ideal for surgical quality improvement.

Improved and individualized patient care is dependent on accurate data collection (both clinical and administrative), research, and innovation. "Although data are being collected to quantify and understand these risks more clearly, a minimally invasive alternative to unenclosed intracorporeal morcellation is favored when available. It is incumbent on surgeons to communicate the risks of practices and devices and to advocate for continued improvement in surgical instrumentation and techniques."<sup>8(p790)</sup> This dilemma requires retrospective analysis and research toward safer solutions, including alternatives to unprotected intracorporeal morcellation. In addition, developing strategies to optimize data collection and gathering accurate and reliable information will allow clinicians to counsel patients based on scientific research to make educated decisions rather than on fear of the unknown.

## ARTICLE INFORMATION

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