

Safety of Using Electrical Morcellation and Strategies to Reduce Incidental Diagnosis of Uterine Sarcoma

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Abstract

The use of power electric morcellation in gynecologic surgery may increase the risk of dissemination and recurrence as well as negatively impact on progression free survival in patients in which a sarcoma is incidentally diagnosed in the biopsy.

We reviewed our data regarding the use of electrical morcellation at our hospital, between May 2007 and May 2014. A total of 249 surgeries requiring morcellation were carried in that period. All cases underwent a peer-review discussion before assigning the surgical approach. No sarcoma was found in the biopsies; neither did any type of endometrial or uterine cervical cancer. Those cases suspicious of malignancy were discarded of using morcellation. In four of those cases, the final pathological report confirmed a uterine sarcoma.

Therefore, if patients are well selected based on a timely peer-review analysis, power electrical morcellation becomes a useful and safety tool for minimally invasive surgery.

Keywords: Morcellation; Uterine sarcoma; Laparoscopy; Myomectomy; Diagnosis; Safety

Introduction

In April 2014 the FDA emitted an alert about using electrical morcellation in laparoscopic subtotal hysterectomies and myomectomies [1]. They estimated, based in retrospective studies, an incidence of occult sarcoma of 1 in 350 among women undergoing surgery for presumed fibroid. So far, there is moderate evidence that morcellated sarcomas may worsen the prognosis of the patient, due to the dissemination of malignant tissue through the abdominal cavity [2,3]. Morcellation of sarcomas would also increase in more than three times the risk of recurrence and would significantly decrease the progression free survival.

In Chile electrical morcellation was introduced at least 15 years ago and since that date it has been widely used for piece reduction and removal during minimally invasive procedure in numerous public and private medical centers. It constitutes a very useful tool to expedite the removal of big pieces, either uterine body or fibroids, through 10 -12 mm ports during laparoscopic subtotal hysterectomies (when the uterine body is removed, leaving the cervix) and myomectomies, respectively [4]. To the best of our knowledge, there is no published data about the use of electrical morcellation, its complications or the prevalence of incidental uterine leiomyosarcomas in Latin America.

The objective of this article was to estimate the rate of the use of electrical morcellation during minimally invasive procedures, either during subtotal hysterectomy or myomectomy, in an university clinical center with a postgraduate obstetrics and gynecologic residence program. In addition we investigated the type and complication rate associated to electrical morcellation and the prevalence of diagnosis of incidental leiomyosarcomas. More importantly, we assessed the impact of using peer-review discussion to avoid misleading a malignancy and wrongly use morcellator in such a case as part of a laparoscopic approach.

Materials and Methods

We reviewed the electronic clinical records of all patients undergoing subtotal hysterectomy or myomectomy for benign conditions between May 2007 and May 2014 at the Clínica Universidad

Católica de Chile at the UC-Christus Health network. In all the cases a signed informed consent was obtained before carrying on the surgical procedure and the patients agreed for future clinical institutional review of their outcomes. The protocol was IRB approved.

To estimate the rate of the use of electrical morcellation in our center, all the patients undergoing any of these procedures (subtotal hysterectomy or myomectomy) for benign conditions were included. Only patients with incomplete clinical records were excluded, mainly due to pre-operative imaging studies performed out of the network. All the pathologic samples were studied at the pathology department of our institution, collected and retrieved from electronic institutional medical record whenever additional review was required.

A database was built up for clinical variables including age, the pre-operative diagnosis justifying the surgical indication (fibroid, repair of pelvic floor defect, endometriosis, so on), the type of surgical access (open or minimally invasive), intra or postoperative complications, surgical time, electrical morcellator use, time of hospital stay, and final pathological report.

The statistical analysis was carried out using JMP7 software (SAS Corporation, USA).

Results

During the study period, a total of 1,515 patients underwent hysterectomies in our institution (an average of 216 per year). One hundred sixty six (10.9%) of them were laparoscopic subtotal hysterectomies (equivalent to almost 100% of subtotal hysterectomies carried out in that period). In addition, 295 myomectomies were carried out (83 by laparoscopic and 212 by open access). Therefore,

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Received June 29, 2015; **Accepted** July 09, 2015; **Published** July 16, 2015

Citation: Miranda VA, Pohlhammer DS, Viguera S, Cuello MA (2015) Safety of Using Electrical Morcellation and Strategies to Reduce Incidental Diagnosis of Uterine Sarcoma. Gynecol Obstet (Sunnyvale) 5: 304. doi:10.4172/2161-0932.1000304

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249 surgeries required the use of electric morcellation during this time period, estimating a rate of electrical morcellator use of 110 of 1000 hysterectomies and 281 of 1000 myomectomies at our institution (Figure 1).

Patient demographics are summarized in Table 1. Regarding the preoperative diagnosis for the subtotal hysterectomies, 36 were indicated for suspected adenomyosis, six for endometriosis, 40 for severe defect of pelvic floor (as part of a laparoscopic cervical- sacrocolpopexy), one for chronic pelvic pain, two for endometrial polyp, nine for abnormal uterine bleeding, and 72 for uterine fibroids (Figure 2).

In relation to intraoperative complications; there was 1 case of hematoma of the cervix with an estimated bleeding of 500 ml that required immediate blood transfusion of 2 units of red blood cells (Dindo II). Concerning post operative complications, 4 cases were identified: one ureteral injury leading to a subsequent uretero - vaginal fistula (Dindo III- b), one superficial thrombophlebitis (Dindo I), one re-admission for abdominal pain due to a fecaloma (Dindo II), and one patient with severe anemia who required blood transfusion (Dindo II). None of these complications were reported as intra- or post-operative complications attributable to the use of electrical morcellator. During this period no case was identified of parasitic myoma related to electrical morcellation.

In relation to the final pathological report, no case of incidental uterine malignancy or leiomyosarcoma was identified among the cases treated using electrical morcellation. The complete distribution of pathological diagnosis is shown in Figure 3.

From the total number of surgeries performed during this study period, there were only five cases of uterine sarcoma confirmed in the final pathological report. Thus, we can estimate a sarcoma incidence rate of 1 in 303 hysterectomies. Three of five (60%) corresponded to leiomyosarcoma. In four of five (80%) the diagnosis was hypothesized

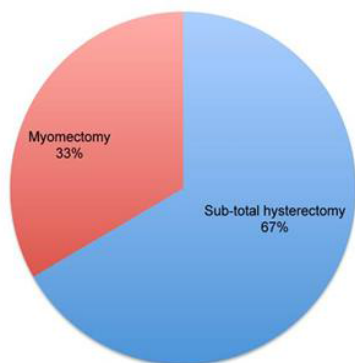


Figure 1: Distribution of minimally invasive surgeries with the use of electrical morcellation.

Variables	Subtotal Hysterectomy (n=166)	Myomectomy (n=83)
Age	48 (35-76) years	37 (26-70) years
OR Time	131 (35-300) min	105 (30-270) min
Hospital Stay	2,8 (1-8) days	2.1 (1-4) days
Conversion	1/166 (0,6%)	7/38 (8,4%)
Intra-operative Complications	1/166 (0,6%)	0
Post-operative Complications	5/166	2/83 (2,4%)

Table 1: Demographic characteristics of study population.

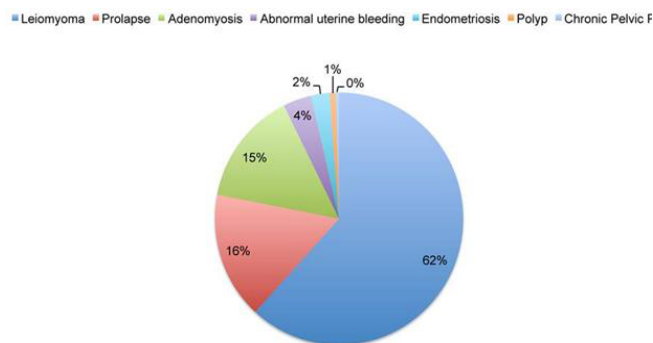


Figure 2: Distribution of pre-operative diagnosis in patients undergoing minimally invasive surgery with use of electrical morcellation (n=249).

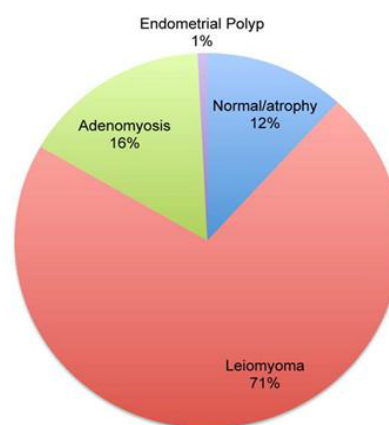


Figure 3: Distribution of diagnosis in uterine pathology reports.

pre-operative based on alarm signs (age of presentation, abnormal uterine bleeding and growth rate). In all the cases, the peer-review advised against laparoscopic approach and morcellation.

Discussion

The term “morcellation” refers to the surgical technique used to reduce the size of solid tissues (surgical pieces) allowing its removal through small incisions or minimally invasive access routes. This technique has been used since a long time ago for reducing and removing large size fibroids or complete uterus either through abdominal or vaginal access [4,5]. It was carried out using cold or electro-surgical knife. Since the introduction of laparoscopy, morcellation became a major issue to successfully treat and remove fibroids and uterine bodies during myomectomy and subtotal hysterectomy using this technique. Initially, surgeons developed alternative ways to remove the piece respecting the principle of minimally invasive procedure [6]. Consequently and with improvement in laparoscopic instrumentation and surgical skills, morcellation was carried using laparoscopic cold knife or scissors. Despite being effective, this approach was time consuming prolonging the surgical time. With the invention and introduction of electrical morcellation it was feasible to perform in a timely fashion the piece removal.

It is a fact that morcellation has risks associated to its use. In particular, the chance of dispersing fragments of tissue in multiple directions in both benign and malignant conditions [7,8]. That risk is independent of the form in which morcellation is carried out.

Recently, a review was published about the morbidity associated with electrical morcellation. In this review, only 55 complications were reported, including vascular, bowel, bladder, ureteral, fallopian tube and omental lesions, in period above 20 years of instrument use. Based on this compilation, it was possible to estimate a complication rate of 0.02 to 0.007% with electrical morcellation [9]. Despite the very low risk of adverse effect all the complications; a major concern was raised in relation with a long-term risk, the intraperitoneal dissemination of benign tissue or 'worse fabric' with elements of a malignancy [10].

Based on this risk the FDA emitted an alert about the insecurity of using electrical morcellation in gynecologic surgery based on the risk of disseminating pieces of a misdiagnosed leiomyosarcoma or other uterine malignancies [1]. All the guilty were assigned first to the morcellator, secondly to the manufacturer, and barely to the surgeon who chose to use it. As a consequence, a useful tool was discarded or put out of market by the clinics and manufacturer to avoid lawsuits. However, nobody demonstrated if the increase in disseminated leiomyosarcomas indeed was increased compared to previous decades when the large size fibroids were removed using cold knife of mechanical morcellation. In addition, nobody critically reviewed whether the increased risk was due to inadequate preoperative study and wrong diagnosis of an underlying cancer.

To explore the safety of using electrical morcellation we decided to carry out a retrospective review of all cases in which our group decided to use this technique. We have postulated that the risk of disseminating a leiomyosarcoma or other uterine malignancies is not related to the type of instrument chosen to make it (i.e. electrical or cold knife morcellation). The risk is more likely associated to the wrong patient selection. Promoting a widespread use of morcellation will be always risky when an incomplete and single surgeon decision-making is taking as policy to decide the surgical approach. This fact is particularly relevant when signs of alarm for leiomyosarcoma are present and not taking in account for the surgeon.

It has been an institutional policy to review in a weekly base all the cases planned to be scheduled for surgery the near days. As a teaching center, residents and trainees present patient clinical histories, their laboratory and radiological exams, propose and discuss potential diagnosis and surgical alternatives to treat their conditions. In terms of laparoscopic or minimally invasive approach, the goal is to properly balance the benefits of this approach both in quality of life, shorter hospital stay, risk of bleeding and less postoperative pain versus the disadvantages associated to potential higher costs [11], limited access to certain anatomical sites in same patients (i.e. obese patients), and wrongly manage and favor the spread of an undiagnosed cancer.

The process is led by a senior staff that is seconded for members of the teams from different sub-specialties (i.e. gynecologic oncology, human reproduction, urogynecology, endocrinology, gynecologic imaging, so on). After discussion, recommendations are given to the surgeon in charge and the trainees. This peer-review process has allowed us choosing the best surgical approach for a particular case and offering assistance or deriving complicated cases to our expert team. In those cases still in doubt, further studies are requested to carry out before a final decision-making. For example, when the committee considers that a bleeding history is not typical or unclear, an office endometrial aspiration sampling or hysteroscopy is conducted before surgery. Additional imaging (i.e. MRI) is requested if transvaginal ultrasound imaging is not clear in defining the endometrium-myometrium interphase or the fibroid imaging is not characteristic or present abnormal vasculature at Doppler color. In 2009, our group

published an extensive and comprehensive review of about 5500 hysterectomies carried out in 15-year period. By using this peer-review protocol we have been able to reduce the incidental gynecologic cancer rate to less than 1% [12].

In the present study, there was no complication attributable to the use of electrical morcellator. No parasitic fibroid has been found so far, among cases of morcellation in this cohort. In terms of malignancy, five cases of sarcoma were identified. Based on these cases, our incidence of uterine sarcomas was 1 in 300 hysterectomies. In four of five the leiomyosarcoma was suspected pre-operative based on signs of alarm (peri- or post-menopausal age of presentation, abnormal uterine bleeding, and rapid growth). In all the cases, the committee advised against using laparoscopic approach or morcellation. All were managed by abdominal open approach. No case of leiomyosarcoma was found among laparoscopic or open myomectomies. Only one case was not suspected previous to surgery. The estimate for incidental or undiagnosed uterine sarcoma was 1 in 1500 hysterectomies (0,07%). Our estimate is similar to that reported by others, Seidman et al found an unsuspected malignancy rate of 1,2% and 0,09% of unsuspected leiomyosarcoma, respectively, in about 1000 morcellations. These authors based on these estimates concluded that morcellating a leiomyosarcoma would increase the risk of recurrence and decreased the progression-free survival [13]. Similarly, Tan-Kim et al reported an incidence rate of 0,6% in about 900 morcellations. They were not able to identify any useful predictor of unsuspected sarcoma. Therefore, they recommended careful counseling to patients about the potential risk of using morcellation but they did not advise against it [14]. Despite the lower number of sarcomas in our series, we agree with this recommendation and we feel confident of continuing using electrical morcellation in well-selected benign cases, particularly fibroids. By reviewing our historical series [12] and the present we were not able to identify differences in terms of incidence of unsuspected sarcoma, surgical stage distribution, recurrence or progression-free survival to justify the contraindication of electrical morcellation in well-selected benign cases.

Since uterine sarcoma will remain as a diagnosis challenge compared to endometrial cancer (i.e. aspiration uterine sampling has detection rate of 99.6% and 91% in pre- and post- menopausal patients, respectively) [15], despite incorporating more sensitive imaging studies (i.e. MRI), the FDA contraindicates the use of morcellators in patients with peri- or post-menopausal fibroids. We agree with this recommendation but we also add the need of careful peer-review of suspicious cases, independently of age of presentation. In doubt, it is better to choose alternative accesses for surgery.

Thanks to peer-reviewed discussion, we did not identify cases of leiomyosarcoma in the group managed with electrical morcellator. Even though, our number of patients may be limited to diagnose a relatively rare disease, we believe that in well-selected patients, with an adequate preoperative study, and peer-review discussion before scheduling surgery, morcellation would be a safe technique for conservative management of fibroids or uterine corpus removal in patients undergoing laparoscopic subtotal hysterectomy for benign conditions.

Any time morcellation comes into consideration, a critical peer-review discussion should carry out before decision-making.

Independently of a wise decision-making, we also recommend to morcellate and remove solid tumors within plastic bags, to reduce the risk of dissemination either of benign or malignant tissues. Even when

removing a solid tumor through a small laparotomy we recommend using a plastic bag to exteriorize the tumor sample.

Finally we can conclude that choosing a minimally invasive approach and using electric morcellator constitute essential tools for successful surgical management of benign gynecological diseases. However it is not exempt of risks, which may be minimized by making a correct selection of our patients. Nevertheless, all patients should be always warned of possible risks associated with morcellation.

Acknowledgment

The authors thank all the current and previous members of our division for their weekly-based participation in the peer-review clinical committee.

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