



Laparoscopic Hysterectomy and Tissue Morcellation

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Abstract

In order to avoid larger abdominal incisions or colpotomy uterine power morcellation has been a challenging field of discussions also at hysterectomies with many contradictory issues. Morcellation is defined as division and removal in small pieces in the Merriam Webster dictionary. When laparoscopic or hysteroscopic operations are performed today frequently electromechanical morcellation is used, which allows removal of uterine fibroids and uterine tissue through port sites. However, morcellation procedures can potentially cause intra operative dissemination of pathological uterine tissue into the abdominal cavity, especially in unsuspected malignant cases, which may lead to a spreading of the disease and may have negative clinical consequences. The purpose of this editorial dealing with hysterectomies for benign cases is to evaluate dangers of power morcellation.

Morcellators

The Serrated Edged Macro Morcellator, developed in 1991 as manual morcellator by SEMM and METTLER worked by punching out tissue cylinders of, 1 cm, 1.5 cm and 2 cm in diameter, in length measuring up to 10 cm to 20 cm specimen particles. Only up 3 times reusable metal serrated edged cylinders were used to cut the tissue, grasped with a big claw forceps. Working only with manual power the technique was time consuming and difficult for the surgeon. SEMM later added battery power and finally electric power to his SEMM, which was produced by WISAP, Germany. Different types of electro-mechanical morcellators were introduced into the market after 1995. The Steiner morcellator was the first one to be FDA approved. He used a rotating knife driven by an electric micro engine, controlled via a foot pedal. The cutting cylinder, which was 13mm in diameter and 25cm long, was placed in a 14 mm trocar sleeve and protruded a few millimeters past the sleeve of the trocar into the abdomen. Carter JE, et al. [4] published a time and cost analysis of power vs. manual morcellation in 1997. He demonstrated that electromechanical morcellation reduced the average time for extraction of specimen <100g by 15 min and of specimen weighing 401 g – 500 g by 150 min. To everybody's understanding this also led to a significant cost reduction despite the more expensive nature of the electromechanical morcellators [1-4]. The general engineering of the modern electromechanical morcellators is similar to that described by Steiner. The ideal morcellator is easy to handle, ergonomic, maintains pneumoperitoneum, and enables constant visualization of the rotating knife with minimal operator effort.

The Morcellator Knife was developed in 2000. It was a classic lancet with an interchangeable blade that was inserted through at 10mm trocar and used to cut a specimen as it was held between two forceps. A posterior culdotomy was made to remove the small pieces of the specimen. The Sawalhe morcellator, developed by Karl Storz, modified the Steiner model and enabled removal of morcellated tissue from the abdominal cavity via the sleeve, obviating the need for a posterior culdotomy that was necessary with the Morcellator Knife. Karl Storz then developed an even more competitive morcellator in 2007 called the Rotocut G1 morcellator. In comparison to the existing Sawalhe model in a study published in 2007, the Rotocut G1 device accomplished significantly shorter morcellation time, operative time and duration of anesthesia. Fewer and longer pieces of tissue due to a more effective power output and drive transmission gave a faster removal time. In this model, the generator is located in the hand piece and is activated by a foot pedal. The Gynecare Morcellex tissue morcellator developed by Ethicon, Inc. is another popular power morcellator. Unlike the Rotocut G1, the Gynecare Morcellex does not require a foot pedal. In 2009, a randomized controlled trial was initiated to compare the two popular models, the Gynecare Morcellex and the Rotocut G1. There was no statistical difference between the two groups in regards to operative time, morcellation time, weight of excised pieces, blood loss/blood transfusion, intra or post operative complications, post operative pain, hospitalization or time to return to full working activity. TBy using using a VAS score ranging from 0 (low handling, easy) to 10 (high handling, difficult) the 2

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morcellators were evaluated. There was a significant difference in ease of use, with the Gynecare Morcellex having a higher handling score (average 7.0 for supracervical hysterectomy and 7.2 for myomectomy) [5,6]. In July 2014 the Gynecare Morcellex was withdrawn from the market by Johnson and Johnson after a statement discouraging the use of power morcellators was released by the FDA. See "Updated FDA Recommendations" [7].

Transcervical Morcellation

The steps are essentially the same; however, instead of extending an abdominal wall incision by dilation, the cervical canal is dilated until the morcellator cannula can be inserted. We used this technique a lot for morcellation after the LSH procedures. A longer cannula and blade must be used to traverse the vaginal canal. Morcellation is then completed in the same manner and the dilated cervical os may be closed using a single stitch laparoscopically. This technique allows the surgeon to avoid making a large abdominal wall incision and thus decreases the risk of future herniation. Details were nicely described in the literature by Rosenblatt et al. [8].

Complications

Morcellator related injuries have also increased. These injuries range from direct surgical risks resulting in immediate complications to sequelae of morcellated tissue fragments and morcellation of preoperatively undiagnosed malignancy resulting in possibly more long term complications. Long term complications of morcellation include retained or parasitic tissue, leiomyomatosis or dissemination of undiagnosed malignancy. The term "iatrogenic parasitic myoma" has been developed to describe the formation of new myomas that are not attached to the uterus presenting after uterine or myoma morcellation. When fragments of myomas are left behind following morcellation and become implanted in normal tissue in the abdominal cavity uterine myomatosis may occur. Iatrogenic endometriosis has been reported to occur after uterine morcellation, but not all of the literature is consistent. A case report by Sepilian demonstrated widespread endometriosis and symptoms of cyclic pelvic pain six months following morcellation after a supracervical hysterectomy performed for uterine fibroids with an absence of endometriosis [9].

The Malignancy Potential at Tissue Dissemination

The biggest concern in regards to dissemination of tissue during morcellation is the inadvertent dissemination of malignancy, which occurs in the moment of any enucleation, resection and extraction.

Endometrial adenocarcinoma

Morcellation of endometrial adenocarcinoma can cause cancerous tissue to be spread throughout the abdomen and lead to possible upstaging of an existing malignancy this does appear as a maximal threat. Morcellation of endometrial adenocarcinoma can usually be avoided by appropriate pre-operative evaluation with endometrial biopsy or dilation and curettage; however, this is not always accurate.

Leiomyosarcoma

Since the beginning of introducing tissue morcellation into gynecology it was strongly advised to exclude any case of unclear preoperative pathology from morcellation. Of greatest concern is the inadvertent morcellation of a leiomyosarcoma [10] representing 1% - 2% of all uterine malignancies. It is an aggressive malignancy with 5-year survival rates of 18.8% to 65%. Particularly women in

the perimenopausal years are affected. Their median age of 52 years and sarcomas are very rare in women below the age of 40 years. Mostly this malignancy reveals a rapidly growing uterus; however, because it is uncommon, only 0.23% of patients with this finding will have leiomyosarcomas. Preoperative LDH increased measurements correlated with these sarcomas. When LDH was combined with MRI, the specificity, positive predictive value and negative predictive value were all 100% in this particular study [11]. MRI and LDH should be performed in all slightly unclear preoperative evaluations if power morcellation stands up for discussion. There are currently many studies in the literature on unsuspected leiomyosarcomas in patients who had a hysterectomy or myomectomy for presumed benign disease [12].

The rate of leiomyosarcoma in these studies ranges from 0% to 0.49% with the average being 0.18% [169]. The FDA recently released a statement quoting the incidence to be 1 per 350 or 0.29% [13-16]. This incidence has been challenged by Elizabeth Pritts, et al. [17] at the FDA meeting. Her more extensive evaluation of the literature was correlated to a much lower risk of leiomyosarcoma. Morcellating these unsuspected malignancies can result in upstaging and a worse prognosis. Due to these controversial findings and reports, the FDA put out a statement discouraging the use of power morcellators, citing safety concerns, mostly the inadvertent dissemination for occult uterine cancer in patients undergoing hysterectomy and myomectomy for presumed leiomyomata. They quote other options to intracorporeal morcellation including removing the uterus through a mini- laparotomy or morcellating the uterus inside a laparoscopic bag. The AAGL states that when comparing the risks involved in open hysterectomy versus those of power morcellation, gynecologists should improve but not abandon power morcellation, and that power morcellation with appropriate informed consent should remain available to appropriately screened, low risk women.

Contained morcellation - does it diminish the risk? Fibroid tissue morcellation within a bag is also called contained morcellation. Cohen et al. [18] came out with a feasibility study in September 2014 reporting 73 successful cases of morcellation of uteri or myomas with and insufflated bag. There were no complications in this report and no visual evidence of tissue dissemination outside of the isolation bag. The bag used in this case was developed by one of the authors specifically for this use. Different forms of these bags are presently being evaluated. We work on a technique homogenizing the tissue in a bag to powder, to be extracted by a catheter technique to be later evaluated for malignancy by genetic technology. Despite all these reports on the danger of spreading malignant disease at morcellation, many of these data are still limited and controversial. In a systematic review of 6 studies, data seemed to be highly biased and of poor quality, resulting in the author's conclusion that there is no reliable evidence that morcellation significantly results in tumor upstaging or in poorer patient outcome. There is also no evidence from these studies that power morcellation affects patient outcomes differently than any other type of morcellation, or even simple myomectomy. Already a myoma enucleation, the opening of the pseudo capsule in a case of an adenomatoid tumour or a sarcoma may have the same risk potential than a careful morcellation.

Laparoscopic Subtotal Hysterectomies (LSH) and Laparoscopic Total Hysterectomies (LTH)

Both technologies are applied in Kiel for hysterectomies besides

vaginal and open abdominal hysterectomies in benign cases. Laparoscopic conventional and robotic technologies are applied according to the demand. Particularly in cases of uterine and genital malignancies we prefer the robotic laparoscopic approach. Laparoscopic Subtotal Hysterectomies (LSH) and Laparoscopic Total Hysterectomies follow the same 10 step pattern of the procedure and vary only in steps 4 -7.

10 steps for Laparoscopic Total (LTH) and Subtotal Hysterectomy (LSH) – Both procedures are only in steps 4-7 different. (Alkcout, I and L. Mettler Hysterectomy- A Comprehensive Surgical Approach, Springer, 2017).

- Introduction of trocars, surgical site recognition, preparation of round ligaments/adnexae
- Opening of the bladder peritoneum
- Dissection of Broad ligament leafs
- Coagulation and dissection of uterine vessels
- Coagulation and dissection of ascending branches of uterine vessels
- Dissection cervix from vagina on a ceramic cup
- Dissection of cervix from uterine body with a cutting loop
- Vaginal extraction of uterus – supported my morcellation
- Coagulation of cervical canal with bipolar forceps
- Closure of vaginal stump with sutures
- Morcellation and extraction of uterus
- Closure of the visceral peritoneum
- Reconstruction of pelvic floor, if indicated
- Closure of trocar entry points

Kiel evaluation

To evaluate the frequency of unsuspected cases of uterine sarcoma in patients undergoing myomectomies and hysterectomies by laparoscopy or laparotomy for presumed benign uterine fibroids and to assess the incidence of uterine sarcoma among patient undergoing surgery for benign uterine fibroid we performed a retrospective single-center study at our university hospital. The records of patients with uterine fibroids and uterine sarcoma from 2003 to 2015 were reviewed. Descriptive statistics were used to analyze demographic and clinical characteristics. To calculate Confidence Intervals (CIs), the exact Clopper-Pearson method was applied. Material and results: A total of 2,275 patients were included. Preoperatively, 2,269 patients had presumed benign uterine fibroids, and 6 patients had suspected uterine sarcoma. Among the 2,269 patients who underwent surgery for presumed uterine fibroids, only one patient (0.044%, 95% CI: 0.001% - 0.25%) histopathologically revealed Endometrial Stromal Sarcoma (ESS) after Laparoscopic Subtotal Hysterectomy (LSH) with morcellation. Six patients were diagnosed with uterine sarcoma preoperatively and underwent a direct open conventional cancer treatment. Histopathological analyses confirmed four cases of Uterine Leiomyosarcoma (ULMS), one High-Grade Undifferentiated Uterine Sarcoma (HGUS), and one Embryonal Rhabdomyosarcoma (ERMS). Altogether, seven of the 2,275 women (0.31%, 95% CI: 0.12% to 0.63%) were diagnosed with uterine sarcomas over this twelve-year period. The frequency of unsuspected uterine sarcoma was 1/2,269

(0.044%) among the women who underwent myomectomies and hysterectomies to treat presumed benign uterine fibroids. The total incidence of uterine sarcoma was 7/2,275 (0.31%) among the women who had presumed uterine fibroids or a suspected uterine sarcoma before undergoing the surgical procedures [19,20].

Conclusion

The female uterus as the cradle of human development prior to birth serves many good purposes, but sometimes requires also complex surgical procedures and has to be resected out of its unique localization within the female pelvis. Extended hysterectomy procedures cannot be separated from pre- and post-surgical aspects or from procedures on the internal genital organs or those involving the anatomical and functionally relevant surrounding area. The most advanced diagnostic and treatment concepts of our time involve a cooperation of medical technical industry, imaging, genetics, anatomic knowledge and surgical skills. Global demands of unlimited exchange give access to the worldwide community interested in this topic and contribute to the global improvement of healthcare for women. Following the 10 steps involved in a laparoscopic conventional or robotic hysterectomy basic features as exposure, traction, optical clear vision, augmentation, temperature, haemostasis, anatomic knowledge, the application of grasping and cutting instruments, pneumoperitoneum, suction, irrigation, contained removal, suturing go hand in hand with surgical skills and medical knowledge., protection and the wish for positive outcome. The leading force for every player in the “health game” is the patient’s health improvement and happiness. Morcellation has to be performed with great care and requires us to use all possible malignancy exclusion mechanisms prior to the decision for any morcellation performing Laparoscopic Subtotal Hysterectomies (LSH) or Laparoscopic Total Hysterectomies (LTH). Laparoscopic power morcellation for tissue extraction should be performed only in cases where any malignancy potential can be most likely excluded (MRI; ULTRASOUND and LDH measurements. All patients who undergo laparoscopic or hysteroscopic surgery for myoma enucleation or hysterectomy and face morcellation during their surgery should be informed about the possible risks of morcellation in cases of difficult to diagnose and rare cases of unexpected malignancies. Special attention is advised in patients over the age of 50 for morcellation, as most of observed preoperatively not suspected rare sarcoma cases were in females beyond the age of 50 years. The final advice concerning myomectomy along with “power-morcellation”, “contained morcellation” or “open surgery” to avoid unprotected spread by morcellation is still outstanding. Most likely even myomectomy at open or vaginal surgery does carry the same risks as we are discussing for laparoscopic morcellation.

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