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REVIEW ARTICLE

Morcellation: Its Origin and Where It is heading to?

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ABSTRACT

A morcellator is a device used to cut, grind and extract tissue. This minimally invasive procedure is designed to help patient heal faster while removing the tissue that is causing the problems. The Food and Drug Administration (FDA) gave its approval for this device in 1993. Since then, nearly two dozen similar devices have hit the market.

The authors review the available literature in order to put into perspective current status and position of morcellation in clinical practice. The evolution of morcellation over the course of years, its advantages and recent controversies and various other methods of specimen retrieval their advantages and disadvantages are discussed. Morcellation being one of the techniques, has been in the news with FDA discouraging the use of these devices as they can lead to spread of cancerous tissue or they can lead to dissemination of undiagnosed cancer.

We also discussed the recent innovations in morcellators and its techniques and through this topical discussion try to come to some conclusion.

Keywords: Endobag, Morcellator, Review.

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INTRODUCTION

The extraction of large tissue masses from abdominal cavity during laparoscopic surgery is a time consuming and complicated process since the start of laparoscopic surgeries. Morcellation is any surgical technique involving fragmenting any surgical specimen into smaller pieces. For this, a new device was introduced and the device used for this purpose was called morcellator. Electromechanical morcellation (EMM) (also known as 'electronic morcellation', 'electric-generated morcellation' and 'power morcellation') is a specific subtype of morcellation in which tissue is mobilized through a spinning blade to cut into smaller strips.

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HISTORY

Laparoscopic myomectomy was first reported by Kurt Semm in 1979. Laparoscopic hysterectomy, introduced by Reich et al in 1988 has been proven to be an effective alternative to abdominal and traditional vaginal hysterectomy.[1] Retrieval of the tissue from abdominal cavity was the major obstacle in this surgery. The following routes were used:[2]

- Through the abdominal incision after widening the incision.
- Through vagina after opening the posterior fornix.
- The simplest method though not elegant was through the trocar by using powerful forceps.
- Through the umbilical incision route.

Necessity being the mother of any invention, the need of an instrument which could cut, grind and extract the specimen through the laparoscopic incision came into picture.

Meat mincer is an appliance used for fine chopping of meat and similar food products. The meat is place in a funnel on the top of the grinder, then it moves on to horizontal screw conveyor that can be powered by a hand held motor or electric motor, there is a knife to chop it and finally minced meat comes out of the machine. The fineness depends on the size of the holes in the plate. Probably, earlier inventors of morcellator were inspired by it, and morcellator was invented based on this principle (Fig. 1).

In 1977, Semm developed a 10 mm morcellator for pelviscopy purposes. However, this instrument was not very effective. In 1988, the manually operated serrated-edge macro-morcellator (SEMM) of 15 to 20 mm was introduced (Fig. 2).

This was a breakthrough in history of laparoscopy and morcellation. It consisted of a cylinder with a coning knife at its intra-abdominal end which is placed inside the trocar sleeve and was rotated by an electrical microengine attached to the trocar. Cylindrical tissue blocks are cut step by step out of the main specimen and removed from the peritoneal cavity through the sleeve by a grasping forceps.

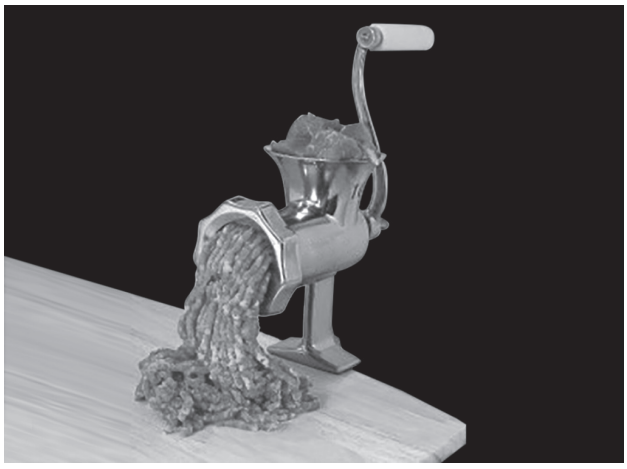

Fig. 1: Meat mincer

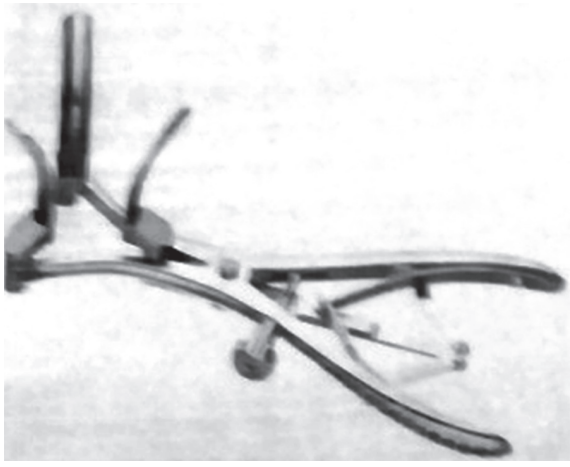

Fig. 3: Endobag retractor[5]

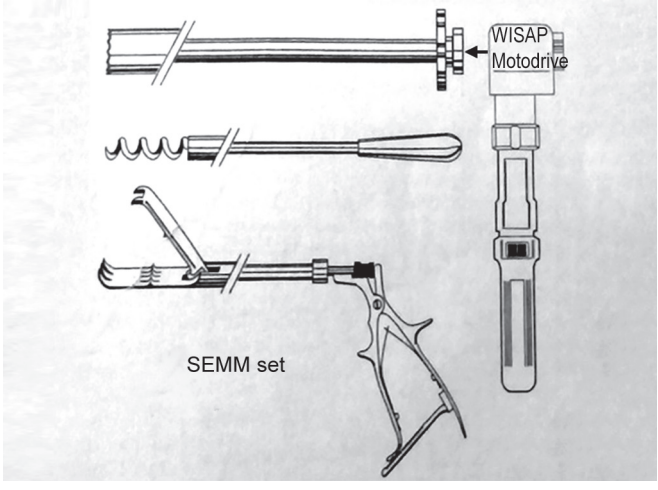

Fig. 2: Serrated-edge macro-morcellator[3]

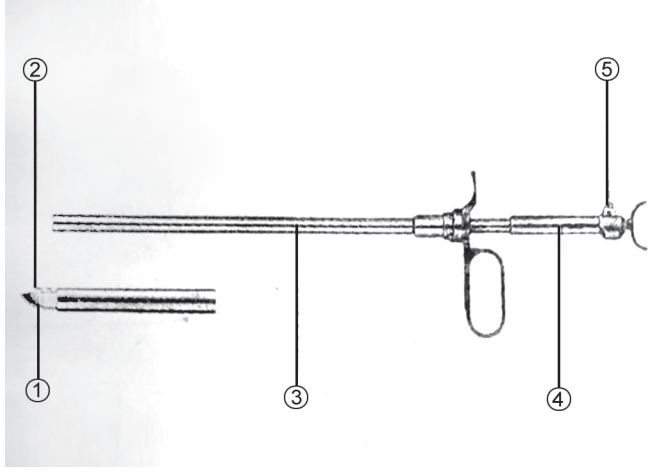

Fig. 4: The morcellator knife consists of a number 10 blade (1), knife insert (2), 10 mm diameter outer tube (3), handle with a retraction system (4) and locking button (5) (endoscalpel/morcellator knife[4])

Another instrument called calibrated uterine resection tool (CURT) allowed removal of uterus from partially closed abdominal cavity after morcellation without colpotomy[3] 1977. A hand held tissue puncher was introduced but was very tiresome and, therefore, only of little help in removal of larger volume of tissues (1978). Cutting the cervix, morcellation and extraction of the uterus and myoma remained a major problem in endoscopic surgery. So, a morcellator knife (Fig. 3) which is a classic lancet with interchangeable blade, transformed into an endoscopic instrument that could be inserted easily through a 10 mm diameter trocar was introduced (1982).[4]

Intra-abdominal masses are removed during laparoscopy using different types of endobags. However, in many cases, the specimens are larger than the trocar or incision in the abdomen, with a potential risk of endobag rupture. Hence, endobag retractor (Fig. 4) was developed which did not need the conventional minilaparoscopy. This instrument had three removable diverging blades that symmetrically enlarged the operative canal in the abdominal wall if spread after extension of the incision. Whole endobag could be withdrawn through the canal without the risk of endobag rupture during tissue retrieval and was reusable making it cost-effective. It was introduced in 1999.[5]

Food and drug administration (FDA) gave its approval for the use of morcellators in the year 1995. Since then, two dozen models have flooded the market. Laparoscopic morcellation is a technique used in gynecological surgeries, such as hysterectomy and myomectomy, to remove uteri and uterine fibroids through small abdominal incision. Current morcellators use blades or bipolar energy to cut tissue into small pieces that are then removed through laparoscopic ports in a piecewise manner.

Advantages are: (A) Allows quick removal of larger sizes of the tissue, (B) smaller incision hence cosmetically better, (C) quick recovery and shorter stay in hospital, (D) commonly used monopolar electrodes or laser beams produced large amount of smoke and carry the risk of distant electric injury. This is absent in morcellators and (E) no vaginal contamination of the tissue.

Disadvantages being (A) time consuming as the tissue must be manually removed over the devices during the cutting step and removal piecewise, (B) can

lead to accidental injuries to surrounding structures, (C) do not provide safe containment of tissue during the morcellation process which can lead to seeding of benign or potentially cancerous tissue and (D) tissue looses its anatomical form and likely chances of missing out the diseased lesion for histopathological examination.

Contraindications of morcellators are being suspected cancer of cervix, endometrium or fibroids, larger fibroids with very rapid increase in size, fibroids in women greater than 50 years of age, without any preoperative workup to exclude carcinoma and without any informed consent for the procedure.

RECENT CONTROVERSIES

The food and drug administration has recently discouraged the use of power morcellation as the procedure can spread occult cancerous tissue and also upstage the grade of the tumor. It has given various suggestions to the manufacturers to revise the labeling.

Here is a summary of major events leading up to the FDA announcement as follows:

- *1995*: The FDA approves the first laparoscopic power morcellator with a gynecologic indication for use through its 510(k) process. Since then, the agency has cleared about two dozen such devices for use in gynecology.
- *2009*: The American College of Obstetricians and Gynecologists (ACOG) issues a statement recommending vaginal hysterectomy as the best route of removal in most cases of benign disease. According to the statement, 'Evidence demonstrates that, in general, vaginal hysterectomy is associated with better outcomes and fewer complications than laparoscopic or abdominal hysterectomy.'

The American College of Obstetricians and Gynecologists reaffirms this statement in 2011.

- *2012*: Researchers review the medical records of 1091 women who underwent morcellation for uterine masses presumed to be fibroids at Brigham and Women's Hospital in Boston from 2005 to 2010. The results published, show the rate of unexpected leiomyosarcoma to be 0.09%, nine-fold higher than the 1-in-10,000 rate typically quoted to patients during their preprocedure briefings.

'These data suggest the uterine morcellation carries a risk of disseminating unexpected malignancy with apparent associated risk of mortality much higher than appreciated currently,' they write.

- *October 2013*: Boston-based anesthesiologist Amy Reed undergoes minimally invasive surgery with power morcellation at Brigham and Women's Hospital. She later finds out that the mass is cancerous.

Dr Reed's husband, cardiothoracic surgeon Hooman Noorchashm, launches a campaign against morcellation.

- *December 2013*: The Wall Street Journal publishes its first article about Dr Reed's case, igniting a debate about the true risk-benefit profile of power morcellation. Robert Barbieri, MD, the chair of obstetrics and gynecology at Brigham and Women's, tells the WSJ that Dr Reed's case and another in the past 14 months have prompted discussions at the hospital's top levels. He says the hospital issued a note to medical staff in early December warning that morcellation of an occult tumor may occur in 1 in 400 to 1 in 1000 women who have this procedure.

The Society of Gynecologic Oncology (SGO) publishes a statement that says morcellation should not be performed in patients with premalignant conditions and that patients should be informed of the procedure's risk prior to surgery.

The FDA begins to review data on morcellators used in gynecology.

- *January 2014*: In a letter to members, the medical society AAGL: Advancing Minimally Invasive Gynecology Worldwide (formerly known as the American Association of Gynecologic Laparoscopists) announces that it is creating a task force to examine the risks involved in power morcellation. The letter asks members to submit descriptions of tissue extraction methods.
- *February 2014*: Temple University Hospital, Philadelphia, US, requires that a bag be used during morcellation and that fibroids larger than 7" must be removed through a large incision.

The Lancet published an editorial calling the SGO's position on morcellation 'soft.' 'This problem needs urgent attention, not only because hysterectomy is extremely common and a 1 in 400 risk of morcellating an occult tumor is unacceptable, but also because these techniques are used in a wide range of settings,' the editorial states.

- *March 2014*: Brigham and Women's Hospital and Massachusetts General Hospital tell their surgeons they will only be allowed to use power morcellators inside a surgical bag.

DISCUSSION

Morcellator is used to cut, grind and extract tissues. Currently, there are three general categories of uterine morcellation: (1) Vaginal morcellation with scalpel through culdotomy or colpotomy, (2) minilaparotomy/laparoendoscopic single site (LESS) morcellation with scalpel and (3) electromechanical morcellation.

The former two approaches have been used for decades, but it is not known at this time if they share equivalent risks as EMM regarding dissemination of

an occult malignancy. Each technique outlined above can be performed within a specimen retrieval bag. The specifics are not yet fully delineated in the literature, but various other methods may have inherent risk profile. The technique under question by the FDA is EMM or (power morcellation).

The AAGL which is committed to advancing safe minimally invasive procedures for the benefit of women recognizes the role of FDA in regulating the use of medical devices and in protecting the interests of patients. The benefit of minimally invasive surgery are well known and includes decreases in numerous highly morbid postoperative complications including deep vein thrombosis, pulmonary embolism, infection and sepsis, fascial dehiscence and bowel obstruction.

The American Association of Gynecologic Laparoscopists state that mortality related to power morcellation in laparoscopy is lesser than open hysterectomies which are 0.077 and 0.085% respectively.

Investigators are examining the safety and feasibility of using EEM within a specimen containment system, but current data is limited. Variability in size, shape and weight of uterine tissue makes placing the specimen into the bag challenging. Puncturing the bag in some cases of multiport laparoscopy can be a risk. Visualization of the mass within the bag maybe suboptimal and vision of vital structures external to the bag maybe obscured. Advanced laparoscopic skills are required to avoid complications performing EMM inside a bag.

A variety of specimen retrieval pouches are available on the market. Although this approach makes intuitive sense from patient safety perspective, there is no evidence to date that EMM within a bag improves prognosis in the setting of unsuspected malignancy. Use of a containment system in vaginal and abdominal cases is being entertained as well. A recent study of 12 endometrial cancer patients whose uteri (mean weight 291 ± 80 gm) were morcellated vaginally in a bag after laparoscopic hysterectomy demonstrated no evidence of local or distant recurrence at median follow-up of 18 months; these cases were not stratified by grade.[6] Another report on similar technique described successful outcomes for endometrial cancer patients with mean uterine weight of 255 gm.[6] Contained vaginal morcellation of pre invasive specimens appears to permit rapid uterine extraction any may avoid unnecessary laparotomy in women with larger uteri. However, it remains uncertain whether this technique maintains the architectural integrity to facilitate adequate pathologic analysis or preserves oncologic outcomes, both of which must be confirmed in larger studies.

Stress upon the need of proper preoperative work up, proper counseling and appropriate consent before taking up the patient for power morcellation in an endobag. While it is paramount interest that our patients are counseled appropriately about dissemination risks associated with intracorporeal morcellation, specifically, and tissue extraction in general it is also important for our patients and public to recognize the benefits of minimally invasive surgery. It is therefore the responsibility of both the doctor and patient to weigh the risks of alternative approaches to surgeries based on individual circumstances.

On 6th May, 2014, the AAGL released 'Morcellation during Uterine Tissue Extraction' task force report. The conclusion states that all existing methods of tissue extraction have benefits and risks, which must be balanced. The American Association of Gynecologic Laparoscopists report does not believe that there is a single method that can protect all patients. Therefore, all current methods of tissue extraction should remain available (i.e. mechanical morcellation, vaginal morcellation or culdotomy). American Association of Gynecologic Laparoscopists's recommendations are as follows:

- Morcellation should not be used in the setting of known malignant or pre malignant conditions.
- Morcellation should be considered in patients if the appropriate evalution of the myometrium (with or without fibroids) is reassuring and appropriate evaluation of the cervix and endometrium is also reassuring.
- For patients in whom preoperative evaluation results in an increased suspicion for malignancy, alternatives to morcellation should be employed, including laparotomy.
- As the risk of malignancy is increased in post-menopausal women, alternatives to morcellation should be employed.
- When electromechanical morcellation (EMM) is planned or considered likely, the specific risks of encountering an undetected malignancy and likelihood of worsening the patient's prognosis should be discussed in a patient centered manner as part of the informed consent process so that the patient can actively be involved in the decision whether to use EMM. Patient autonomy must be respected.
- The use of morcellation within specimen retrieval pouches for containment of benign or malignant uterine tissue requires significant skill and experience and the use of specimen retrieval pouches should be investigated further for safety and outcomes in controlled setting.

The need of the hour is not to panic and abandon the procedure but follow certain guidelines. They are: (A) Do a good preoperative workup to rule out any carcinomatous changes, (B) informed consent, (C) Gd-DTPA

enhanced MRI along with LDH3 isoenzyme measurements gives promising results to differentiate leiomyoma from leiomyosarcoma,[7] (D) vaginal morcellation better than abdominal morcellation whenever possible and (E) use of endobags during morcellation to prevent spillage and dissemination of the specimen.

RECENT ADVANCES

An improved device would need to eliminate the major safety issue present in current devices and decrease morcellation time. Based on the functional requirements, the strategy of enclosing the tissue in a bag and using a cutting mechanism to safely morcellate the tissue in a protected manner should be done. The three most promising concepts which emerged from are (Fig. 5): (1) altering the current morcellator by attaching a protective blade cover along with a bag to its distal end, (2) using a whisk in a bag for rotator cutting and (3) using a mesh in a bag for linear radial cutting. These are in the experimental stage.

Since the present morcellator have limitations like: Time consuming can lead to accidental injury of surrounding structures and they do not provide a safe containment of tissue during morcellation process which can lead to seedling a new laparoscopic morcellator using an actuated wire mesh and bag[8] is undertrial by Alexander Isakov and Murdaugh KM et al at Havard University since 2013.

This laparoscopic morcellator overcomes the limitations of through a new design that is based on an enclosed, motor activated mesh that applies only an inward—directed cutting force to the tissue after it has been loaded into the protective mesh and the bag. The cutting system consists of wire mesh and a supporting rod. The bag has a diameter of 14 cm and a length of 28.2 cm and volume of 3000 ml. The bag dose not experience forces of a magnitude that would cause tearing using the proposed devices thus preventing tissue or fluid leakage during surgery. The rod is a steel tube with an outer diameter of 1.4 cm and wall thickness of 0.89 mm hence can fit through a standard 1.5 cm trocar or similar size incision and prevent seeding and accidental damage to nearby healthy tissues. It is more efficient for procedures currently requiring over 15 minutes of morcellation time. It also maintains tissue structure required for pathological analysis by producing intact pieces of tissues and has comparable costs to current disposable devices. It removes tissue up to 12 cm in diameter.

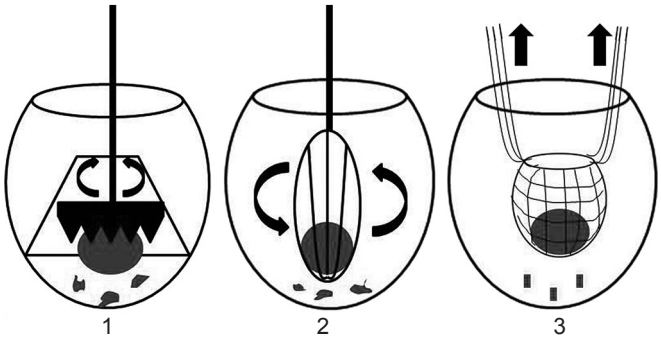

Fig. 5: Innovative morcellator currently in experimental stage within a bag[8]

Another concept morcellation within an insufflated endobag irrespective of single port or multiport laparoscopic surgeries has been the talk of the year. A standard size endobag 18 × 18" in multiport with large specimens and 50 × 50 cm bag for single port is used. Specimen is retrieved into the endobag which is inserted into the abdominal cavity through primary port site. Bag is insufflated as artificial pneumoperitoneum within the large isolated bag not only provides room for containment of the specimen but also creates a safe working space. Lateral trocars are then inserted into the insufflated bag. Specially designed trocars with endo cuff/balloon tipped trocars are used to prevent leakage of the gas. Bags should be tough enough to withstand the stress of distenstion. Till date, no company has marketed any such bag. Good training of all gyne endoscopists for this procedure is a must.

CONCLUSION

It is our opinion that all the existing methods of tissue retrieval have the risks and benefits, which must be balanced and tailored according to the patient's profile. A good preoperative workup to exclude any genital malignancy and a proper informed consent is mandatory. Methods of tissue retrieval are bagged or un-bagged approaches in minilaparotomy or the vaginal route, laparoscopically via power morcellation or through Laparotomy incisions. Individual patient care to provide the maximum benefits to achieve best outcome is of prime priority. Training and educating of surgeons in safe, appropriate use of all methods of tissue extraction and encourage future research and development in this regard should be done.

As novel methods of specimen retrieval are being developed, we are eagerly awaiting them to hit the market. But, anything new has to be accepted with a pinch of salt. As there is only limited statistics about endobag morcellation, its advantages, disadvantages and side effects, only a long-term (preferably randomized) trial can access how much this technique deserves to be labeled 'risk free'.

We hope, the tongue firmly in cheek, that the newer instruments being developed further enhance the positivity related to minimally invasive surgeries in any branch of surgery and do not complicate the issues and confuse us further!

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