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Research Article

HYSTEROSCOPIC MORCELLATION-ORIGIN AND FUTURE

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ABSTRACT

A morcellator is a surgical instrument used for division and removal of large masses of tissue. This procedure is designed to remove large masses of tissue through minimally invasive procedure. Initially morcellators were used primarily in laproscopic procedures but now the hysteroscopicmorcellators have been in vogue.

Newer hysteroscopic surgical technique especially morcellation allows us to remove not only polyps but also submucousmyomas and even retained products of conception. It also raises few if any concerns about spreading or upstaging an unsuspected malignancy , unlike laproscopicmorcellation. The use of hysteroscopic morcellation has been on rise since first hysteroscopy cmorcellator became available in US in 2005.

In this article we review the available literature to put into perspective the current status and position of morcellation in clinical practice. The evolution of hysteroscopic morcellation, its advantages and recent controversies and its future is discussed.

INTRODUCTION

Management and treatment of intrauterine pathologies have come a long way since the the introduction of uterine endoscopy by D.Commando. Pantaleoni in 1869[1]. However, at that time instruments were very elementary and as such hysteroscopy remained purely diagnostic endeavour until Neuwirth & Amin used a urological resectoscope to perform and report the first hysteroscopic resection of submucousmyoma in 1976[2]. Since then, the advancements in hysteroscopic instruments have facilitated the treatment of many intrauterine pathologies. These instruments include hysteroscopic scissors, snares, monopolar/ bipolar electrode, resectoscopes and more recently the hysteroscopic morcellators. Morcellation is a surgical technique involving fragmenting any surgical specimen into smaller pieces. Morcellators were being primarily used in laparoscopic surgeries making the retrieval of large tissue masses possible through laparoscopy. However, now a days morcellators are being used in hysteroscopic surgeries as well. Hysteroscopic morcellation allows us to remove not only polyps but also submucousmyomas and even retained products of conception. It raises few if any concerns about spreading or upstaging of an unsuspected malignancy, unlike laproscopic morcellation. The use of hysteroscopic morcellators has been on rise since first hysteroscopic morcellatorbecame available in US in 2005.

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HISTORY

Probably the earliest concept of morcellation came from the meat mincer. It is an appliance used for fine chopping of meat and similar food products. The meat is placed in a funnel on the top of the grinder, then it moves on to the horizontal screw conveyer that can be powered by a hand held or electric motor and 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. The earliest morcellator were thus based on this principle.

In 1977 Semmdeveloped the first ever 10mm morcellator for pelviscopic purpose[3,4]. This was followed by Serrated Edged Macro-Morcellator (SEMM set) in 1988in three sizes 10, 15 & 20 mm. Since then lots of models have flooded the market. Morcellators were thus used primarily in laproscopic surgeries. Using a modified prototype based on an orthopaedic arthroscopic tissue shaver, Dr Mark Hans Emanuel of Netherland was able to create a first generation device that used mechanical energy rather than electrical energy to resect intrauterine tissue. In 2005, the leap was taken when morcellators for hysteroscopic surgeries became available. Hysteroscopic resection is considered as a gold standard in treatment of intrauterine lesions[5,6] but hysteroscopic morcellation has been seen to be safe & effective alternative to conventional resectoscopy in both experienced and in experienced hands[7]. The TRUCLEAR hysteroscopic morcellator by Smith and Nephew was Food & Drug Adminstration (FDA) approved in 2005 as the first generation intra-uterine mechanical morcellator. It requires a dedicated fluid pump and has different instrument for

myomas and polyps. For myomas the instrument consists of a rotating tube that reciprocates within an outer 4mm tube. Both tubes have windows at the end with cutting edges. A vacuum connected to the inner tube provides controlled suction that pulls the tissue into the window on the outer tube and cuts it as the inner tube rotates at 1100 rpm. For polyps both inner and outer tubes have oscillating serrated edges on each window. Both instruments are used through 9mm off-set rod lenses with continuous flow hysteroscope[8].

Another hysteroscopic morcellator called MYOSURE Tissue Removal System by Hologic was US FDA approved in 2009. Like the first generation TRUCLEAR, the second generation MYOSURE SYSTEM also relies on suction based mechanical energy and rotating tubular cutter system rather than the high frequency electrical energy historically used by the resectoscopy systems. The MYOSURE SYSTEM has a 2.5mm inner blade that rotates and reciprocates within a 3mm outer tube at a speed as high as 6000rpm and presents an outer bevel on a rotating blade edge[9]. The blade and a handpiece are combined into a single use device that is then attached to suction and a motor control unit. The device is introduced into the uterus through a 6.25mm offset lens, 0^0, custom designed continuous flow hysteroscopethat is compatible with all currently available fluid management systems. The smaller diameter of MYOSURE hysteroscope (6.25mm) compared to the TRUCLEAR hysteroscope (9.0mm) makes the MYOSURE device more compatible with local anaesthesia protocols and therefore amenable to office based treatments.

DISCUSSION

Many intra-uterine pathologies like polyps, fibroids and retained products of conception are amenable to hysteroscopic removal. Endometrial polyps are one of the most common intra-uterine lesions associated with abnormal uterine bleeding. Polyps are found in 10-40% of asymptomatic women and upto 12% of symptomatic women[10]. The majority of symptomatic polyps occur in premenopausal women with highest incidence in 5^{th}decade of life[11]. Asymptomatic polyps <2mm in premenopausal women may be monitored. However in patients with risk of endometrial neoplasia any lesion should be removed and sent for histopathological examination. It has been reported that polypectomy results in improvement of symptoms in 75-100% of symptomatic women[12].

Leiomyomas are found in upto 70-80% of women[13]. Risk factors include early menarche, black race and parity[13, 14]. Myomas in the submucosallocation, specifically may cause abnormal uterine bleeding or subfertility. The European Society of Gynaecological Endoscopy (ESGE) classifies submucosalmyomas as Type-0, Type-I and Type-II. Type-0 if the entire lesion is intercavitory, Type-I if <50% extends into myometrium and Type-II if >50% extends into myometrium[15]. A co-relation has been found between the depth of myometrial involvement and the rate of complete resection at the time of hysteroscopy; Type-II myomas have the lowest rate of complete resection at 61-83%[15]. Another factor determining the rate of complete resection and recurrence is the size of myoma. The myomas larger than 4cm often requiring repeat procedures[16] and myomas larger than 6cm demonstrating both high recurrence and high complication rates[17].

Another pathological entity that is amenable to hysteroscopic removal is retained products of conception particularly in cases were conventional treatment options have failed. There are well documented risks associated with repeated dilatation and curettage procedures, even if done under ultrasound guidance.

Many treatment options exist for the management of these intrauterine pathologies. Dilatation and curettage, a blind procedure may be used as adiagnostic procedure for obtaining tissue for pathological examination or as a treatment of abortion and retained products of conception. For endometrial polyps, hysteroscopic guided polypectomy has been demonstrated to have better efficacy compared to blind curettage[18]. Although hysteroscopic loop electrode resectoscopy provides a reliable method for removing intrauterine pathology for many decades, the distension media issues, risk of perforations, visual field limitation created by resected chips all combine to encourage the development of alternate treatment methods. One such alternative is hysteroscopic morcellation.

Hysteroscopic morcellation is a novel technique of removal of intra uterine polyps, myomas and placental tissue. It raises few if any concerns about spreading and upstaging unsuspected leiomyosarcoma. In this respect the controversy over laparoscopic power morcellation does not extend to hysteroscopic morcellation. Such a distinction was made during opening remarks at a meeting in June 2014 of Obstetric and Gynaecology devices panel of the Food and Drug Administration Medical Devices Advisory Committee which was charged with addressing such concerns. It was said that in hysteroscopic morcellation tissue is contained and delivered through the morcellation system into a trap or collecting pouch. This allows for a complete capture and histopathological assessment of all fragments extracted from the uterine cavity[19].

Hysteroscopic morcellation is thus an excellent method for removal of endometrial polyps, fibroids as well as retained products of conception. It has been found to be an effective, fast and safe alternative to resectoscopy. It withholds some technical advantages over resectoscopy.

There are definitely advantages of using hysteroscopic morcellation for removal of intrauterine pathologies which include:

- Morcellators use a blade and suction tube to simultaneously cut and remove the tissue which improves visibility, reduces the risk of perforation and gas embolus that are more likely with multiple equipment insertions.
- Morcellators are based on mechanical energy rather than high frequency electrical energy. There is no risk of generation of stray currents and risk of thermal injury.
- It has been seen that the operating time is much less with morcellators.
- All the tissue removed is available for histopathological examination.
- No risk of spreading or upstaging the unsuspected leiomyosarcoma
- Can be used with saline so less chances of fluid overload.
- With hysteroscopic morcellator there is no gas bubble formation unlike resectoscopy. Lethal complications have

been described using hysteroscopic electro-surgery causing air bubbles and consequent air embolism[20]

Emanuel and collegues showed a significant reduction in operating time when removing polyps and Type-0 or Type-I submucousmyomas. Polyps were removed with a 72% reduction in operating time with a morcellator as compared to a resectoscope (8.7min vs 30.9min) whereas Type-0 and type-I myomas were removed in 61% less time (16.4min vs 42.2min) respectively[21]. Another study by van Dongen and associates in 2008, also demonstrated 38% reduction in operating room time (17min vs 10.6 min) as well as 32% reduction in distension media used (5050ml vs 3413ml) the study also demonstrated a marked reduction in the number of insertions and reinsertions of the hysteroscope to remove tissue chips when morcellator was used (Number of insertions - 1) compared to resectoscope (number of insertions-7)[7]. Miller and co-workers using a newer MYOSURE device reported average polyp morcellation time of 37 sec and average myomamorcellation time of 6.4min with a mean diameter of 31.7mm[22]. These data were further validated by a study by Lukes, who using the MYOSURE device to remove 6 myomas (<3cm) and 20 polyps in 13 women with a mean resection time of 84 seconds. All procedures were performed in an office setting using local anaesthesia[23]. In 2008 a study by Greenburg JA *et al* compared a working MYOSURE device with TRUCLEAR device to assess tissue resection speed. The study demonstrated that although both devices are capable of resecting submucousmyomas 3cm in diameter in 15min or less but MYOSURE device was consistently faster at tissue removal at every time interval despite its smaller diameter[24]. Similar findings were confirmed by another study in 2011 by Cohen S *et al*; demonstrating a shorter cutting time with MYOSURE system[25].

There are few disadvantages that have been seen with the use of hysteroscopic morcellator which include:

- First and the foremost is the inability to coagulate the blood vessels during surgery[26]. However, in a study by Sardo ADS *et al* in 2008 no significant intra-operative or post-operative bleeding was noted[6]. Another study by TjalinaHamerlynck *et al* in 2011 showed same results[27]
- Hysteroscopic morcellator has a limited utility in case of Type II myomas[6]
- In case of larger myomas the use of morcellator becomes time consuming.
- The cost of disposables needed to perform the hysteroscopic morcellation procedure is high
- Finally regional/general anaesthesia is mandatory for hysteroscopic morcellation procedure esp. if TRUCLEAR is used[27].

Another important use of hysteroscopic morcellation is in the management of retained products of conception where standard treatment options have failed. Retained products of conception are a relatively common occurrence and are estimated to complicate 1% of pregnancy[28]. They most commonly present following miscarriages and termination of pregnancy and less commonly following spontaneous vaginal delivery and caesarian sections. Standard treatment options include conservative, medical or surgical management with varying documented success rates between 13-96%[29,30,31,32].

However in cases were standard management options have failed, subsequent management of persistent retained products of conception can be problematic with significant complications like bleeding, infection, adherent tissue and intra-uterine adhesion formation[33]. An alternative to blind curettage is direct visualisation by hysteroscopy and resection using monopolar or bipolar energy. However, resection does have its limitations in management of retained products of conception like the need for theatre setting, anaesthetic risks, cost implications of in-patient stay, uterine perforation and fluid overload. Hysteroscopic morcellation confers the benefit of direct visualisation of uterine cavity while avoiding many of the risks associated with standard resectoscopy. Hamerlynck *et al* first described the use of hysteroscopic morcellation in management of placental remanants in 2013[34]. Since then many studies have confirmed the advantages. Another study by Mallick R *et al* confirm the complete removal of retained products of conception with restoration of a normal uterine cavity in 100% of cases with histological confirmation in 89% of cases. The procedure was well tolerated with average pain-score of 2.67 out of 10 and a mean procedure time of 5.78 minutes with no intra- or post-operative complication. The patients were managed on out-patient bases using 6mm MYOSURE hysteroscope[35]. Thus hysteroscopic morcellation appears to be an efficacious and safe alternative treatment option.

National Institute for Health and Care Excellance -NICE have issued a guidance report first in April 2014 and then in June 2015regarding the use of hysteroscopic morcellators. NICE recommends that the current evidence on the efficacy of hysteroscopic morcellation of uterine leiomyomas (fibroids) is limited in quality and quantity. Evidence on safety shows potential for serious complications, and the incidence of these is unknown. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. They also recommend that the clinician wishing to do hysteroscopic morcellation should explain the options for treatment and the reasons for considering hysteroscopic morcellation to the patients. Hysteroscopic morcellation of uterine leiomyomas (fibroids) should only be carried out by clinicians with specific training in this technique. NICE encourages further research into hysteroscopic morcellation of uterine leiomyomas (fibroids) which include data collection with publication of findings particularly of safety outcomes and complications. Patient selection should be clearly described. Regarding the indications and current treatments NICE recommends that uterineleiomyomas (fibroids) are benign tumours of the uterine wall. They can be asymptomatic or cause symptoms including menorrhagia, intermenstrual bleeding, pelvic pressure or pain, and urinary incontinence. They can be associated with subfertility and miscarriage. Treatment depends on whether the leiomyomas cause symptoms, and on the woman's desire for future childbearing. For symptomatic leiomyomas, treatment options include hysterectomy, myomectomy, uterine artery embolisation and endometrial ablation techniques. Smaller submucousleiomyomas can be removed by hysteroscopic resection. The procedure aims to remove uterine leiomyomas (fibroids) during a single insertion of a hysteroscope into the uterus. This contrasts with traditional hysteroscopic resection of leiomyomas, in which the instrument is reinserted into the uterus multiple times. Hysteroscopic morcellation is intended to reduce the risk of

traumatic injury to the uterus and the risk of inadvertent fluid overload associated with traditional procedures (because the procedure may be completed more rapidly). An intended advantage of the procedure over thermal ablation techniques is avoiding the risk of thermal injury. Hysteroscopic morcellation of uterine leiomyomas is usually done with the patient under general or spinal anaesthesia, typically as a day-case procedure. A hysteroscope is inserted into the uterus through the cervix and saline is pumped through a small channel in the hysteroscope to distend the uterus. A specially designed morcellator is introduced via the hysteroscope and used to cut and simultaneously aspirate the leiomyoma tissue. The aspirated tissue can be collected for histological analysis. NICE have described efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. A non-randomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported that all patients were symptom free at 3-month follow-up.Another randomised controlled trial of 60 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean operating times of 11 and 17 minutes respectively (p=0.008). The nonrandomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean operating times of 16 minutes (95% confidence interval [CI] 13 to 20) and 42 minutes (95% CI 40 to 45) respectively (p value not stated).The randomised controlled trial of 60 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean total fluid deficits (the amount of distending fluid infused during a procedure minus the amount of fluid recovered) of 409 and 545 ml respectively (p=0.224). The non-randomised comparative study of 200 patients treated by hysteroscopic morcellation or conventional hysteroscopic resection reported mean fluid deficits of 660 ml (95% CI 419 to 901) and 742 ml (95% CI 646 to 838) respectively (p value not stated). The specialist advisers have listed key efficacy outcomes as: proportion of leiomyoma (fibroid) removed by morcellator at first procedure; need for repeat procedures to remove leiomyoma remnants; relief of symptoms (such as reduction in menstrual blood loss and reduction or stopping of intermenstrual bleeding); need for further treatment (including surgery) to manage initial symptoms; reduction in incidence of miscarriage; duration of pregnancy; and live birth rate. Regarding the safety concerns the Committee have recommended the report based on the Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE) database. The review estimated that approximately 180,000 hysteroscopic procedures have been done during the study period ,with an over all reported adverse event rate of less than 0.1%which include bowel damage in 12 patients; fluid overload needing treatment by intubation and admission in intensive care unit in 11 patients; incomplete procedure in 1 patient; conversion to hysterectomy in 6 patients; uterine perforation in 28 patients; device failure in 25 patients; pelvic infection in 4 patients; post operative bleeding in 6 patients and death due to pulmonary embolism and comorbitidies in one patient. The Committee noted that laparoscopic morcellation for the treatment of fibroids is the subject of a safety communication from the US Food and Drug Administration (FDA). In this communication, the FDA discourages the use of laparoscopic power morcellation during hysterectomy myomectomy for the treatment of women with uterine fibroids because concerns have been raised about the risk of spreading unrecognised malignant tumours. In light of this, the Committee sought advice from a number of specialists and was advised that: • Laparoscopic morcellation is a different procedure from hysteroscopic morcellation, and has a different risk profile. Laparoscopic morcellation involves inserting a morcellator device through a small incision in the patient's abdomen, and the morcellation of fibroid tissue takes place within the peritoneal cavity. In hysteroscopic morcellation, the morcellator device is inserted into the uterus through the vagina, and the fibroid tissue is morcellated within the uterus. • It is theoretically possible that unrecognised malignancy could be spread into the peritoneal cavity by hysteroscopic morcellation in a woman with patent fallopian tubes, but advisers considered this would be very unlikely. To date, this has not been reported in the peer reviewed research literature. The Committee noted that the use of morcellation is contraindicated when malignancy is suspected. The Committee also noted that leiomyosarcoma is very rare in premenopausal women. In addition, the Committee noted that unexpected malignancy has been diagnosed as a result of histologic analysis of tissue removed by hysteroscopic morcellation and then successfully treated.The Committee was advised that hysteroscopic morcellation is most useful for small or pedunculated leiomyomas. The Committee noted that available publications contained very little information about symptom relief, quality of life or fertility.

Recent Advances and Future

The need to improvise the existing systems of morcellation is always there. Many companies have come up with some novel innovations.

- Smith and Nephew have recently introduced a smaller set of instruments including a 2.9mm blade for removal of polyps through a 5.6mm continuous flow hysteroscope.
- G Bigatti in conjunction with KARLSTORZ have developed a new morcellation system called Integrated Bigatti Shaver (IBS) system. This shaver system is inserted through the working channel of a wideangle telescope with parallel view and permits most operative procedures in hysteroscopy such as polypectomies or myomectomies. The IBS consists of 6^{o} angled telescope with an integrated sheath and working channel within a rigid shaver system. The outer diameter of the sheath is 8mm. Recent developments have made it possible to simplify the shaver system design. The irrigation connection of the sheath is connected to the HYSTEROMAT E.A.S.I, a double roller pump to maintain distension inside the uterine cavity. Another tubeconnector between the DRILLCUT-X IIGYN handpiece and the HYSTEROMAT E.A.S.I ensures good visibility and continuous suction. The rigid shaver system consists of two hollow and reusable metal tubes that fit into each other. The inner tube oscillates within the outer tube and is connected to a handpiece and a motor control unit as well as a double roller pump which is activated by a one pedal foot switch. The foot switch simultaneously activates the movement of the shaver tip and aspiration of the double roller pump to allow

continuous suction of irrigation fluid and tissue through the hollow shaver blade[36].

CONCLUSION

It is our opinion that all the existing methods of hysteroscopic tissue removal have risks as well as benefits which must be balanced and tailed according to the patients' profile. A good pre-operative workup which includes the type of pathology and the degree of extent into the myometrium needs to be carefully evaluated. Informed consent is of prime priority. Training and education of surgeons in safe and appropriate use of all methods of tissue resection should be done.

As a novel method of tissue resection i.e., Integrated BigattiShaver System has been developed but there are limited statistics regarding its advantages, disadvantages and safety profile. So long term trials need to be done to assess how much this technique deserves to be labelled risk free.

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