Original Article

Evaluation of the Safety and Efficacy of Resection of Endometrial Polyps and Submucosal Fibroids in an Outpatient Setting in a Large District General Hospital in the UK

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Abstract

Background: Conventionally, endometrial pathologies of varying complexity have been surgically treated as inpatients under a general or regional anesthetic. **Aim:** In this paper, we evaluate the safety and efficacy of hysteroscopic morcellation of endometrial pathology in the form of endometrial polyps (EPs) and submucosal fibroids in an outpatient setting for both simple and complex lesions using the Myosure™ device. **Methods:** Two hundred and forty-nine hysteroscopic resections were performed in an outpatient setting at the < BLINDED FOR REVIEW > from May 2014 to March 2021. The median age of the patients was 54 years. More than half of the patients presented with postmenopausal bleeding; 64% were diagnosed with EPs and 24% with submucous fibroids (SMFs). The size, topography, extension, penetration, and wall classification system scoring system were used to grade them as simple (≤4) or complex (≥5) pathologies. **Results:** 90% of pathologies were simple (≤4), of which complete resection was carried out in 95% of patients; 10% of the pathologies were complex (≥5), of which 63% had complete resection. Two patients with complex pathologies returned for completion surgery as a two-step procedure. No procedure was abandoned due to the patient intolerance. The median intraprocedure pain score visual analog scale was 5/10 and immediate postprocedure pain score was 1/10. Notably, there was no intra- or post-procedure complications. **Conclusion:** Outpatient resection of endometrial pathology, both simple and complex, can be safely and effectively performed using hysteroscopic morcellator (Myosure™) and is accepted and well tolerated by patients.

Keywords: *Endometrial pathology, hysteroscopic morcellation, Myosure™, outpatient setting*

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Introduction

One in 4 women in the UK between the age of 30–50 years suffer from heavy menstrual bleeding.[1] Abnormal uterine bleeding (AUB) is a cause of significant morbidity to women and prompts referrals to secondary care for management. Endometrial pathologies such as endometrial polyps (EPs) and submucous fibroids (SMFs) can result in these symptoms.

EPs are focal outgrowths of the endometrium which are frequently found in both pre- and post-menopausal women. They are detected in approximately 20%–40% of women presenting with AUB.[2] Of the various types of fibroids, SMFs have the lowest prevalence, ranging from 5% to 10% of all fibroids.[3] However, they are more likely to cause hydroxymethylbutyrate (HMB) even when small.

Conventionally, EP and SMFs have been treated hysteroscopically in an inpatient setting using either

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blind avulsion or electrosurgical devices to resect the pathology, both of which can be associated with complications such as cervical trauma, uterine perforation, and fluid overload syndrome.[3]

With the advent of technology, the size of hysteroscopes have become smaller and newer mechanical hysteroscopic tissue retrieval systems have been introduced, leading to a shift towards successful treatment of these pathologies in the outpatient setting and reduction of the cervical trauma and electrosurgery risks. The advantage of newer second-generation mechanical morcellators, in addition to retrieving the tissues as they are morcellated, ensures that the field of vision remains clear as opposed to first-generation resectoscopes, where the debris would have to be repeatedly removed during the procedure to maintain clarity of the operative field, further increasing the risk of complications. Nationally, despite these advantages, majority of these pathologies are still being removed under anesthesia by either blind avulsion or with first-generation devices.

Of the various morcellation devices available, the Women's Health Center at the < BLINDED FOR REVIEW > have been using a second-generation mechanical hysteroscopic tissue removal system, Myosure™, in outpatient setting since 2014 to treat both simple and complex pathologies using the size, topography, extension, penetration, wall classification system (STEP-W) scoring system to classify the pathology. The aim of this article is to present an evaluation of the service and to highlight the safety and efficacy of performing hysteroscopic resections in the outpatient setting to treat both simple and complex endometrial pathologies.

Methods

Since the launch of the Myosure™ device in 2013 in the UK in the gynecology department at the <BLINDED FOR REVIEW>, it was initially trialed (2013–2014) in an inpatient setting to gain familiarity with the device. Since 2014, it has been used to treat EP and SMF exclusively in outpatient setting.

Service setup

Patients are referred to designated outpatient treatment clinics following confirmation of SMF/EP by diagnostic outpatient hysteroscopic assessment. Patients are sent a patient information leaflet regarding the procedure along with the appointment letter. They are encouraged to have a light meal and simple oral analgesia, either paracetamol and/or NSAIDS, 1 h before their procedure. Once in clinic, their observations and vitals are recorded preprocedure.

Procedure

Intraprocedurally, they are all given cervical blocks using 3% mepivacaine hydrochloride to facilitate a relatively painless dilatation along with "vocal local" by our nursing team.

Myosure™ device (Lite, Classic/Reach or XL) is chosen based on the pathology, size, location, penetration, extension, and number the type which determines the STEP-W score.

The device (Myosure™) comes as a separate hysteroscopic device which can be connected to an existing camera system. The operative scope and channel are available in two sizes, one for the Lite or Classic/Reach version, and a wider version for the XL to which any standard light lead and camera system can be connected. There are inflow and outflow channels on the outer sheath. It comes with a fluid management system called the "Aquilex system" which helps in keeping track of the fluid balance between the input and output which go through this system. In addition, one can also determine the time spent "cutting" or removing the tissue with the device using this system which is documented subsequently. Postprocedure, vast majority of patients feel well enough to directly go home, without the need for observation. A small number may need to lie down for 30–60 min before discharge. Details of the procedure are contemporaneously collected and entered into an Excel sheet immediately postprocedure in clinic by the operator to facilitate audit and service evaluation. The evaluation of this service and all the data from April 2014 to March 2021 has been retrospectively analyzed and is presented below.

Results

Since 2014, 249 procedures have been performed in the outpatient setting using the Myosure™ device.

The median age of our patients is 54 years (31–83 years). About 58% of our patients (145/249) presented with postmenopausal bleeding. 29% (73/249) presented with HMB and 5.2% (13/249) with mixed symptoms of HMB and intermenstrual bleeding. The remaining 7% (18/249) patients presented either as an incidental finding or with issues pertaining to subfertility, postcoital bleeding, irregular bleeding, or vaginal discharge.

69.08% (172/249) of patients had EP; 24.10% (60/249) had SMF; 6.82% (17/249) presented with both SMF and EP; 34.3% (59/172) presented with multiple EP (≥2); and 38.3% (23/60) presented with ≥2 SMF.

The STEP-W scoring system, originally used for stratifying the complexity of SMF, was extended to stratify both SMF and EP into simple (STEP-W score 0–4) and complex (STEP-W score 5–9) in our

series. Of the 249 cases, the STEP-W score was not documented in 7 cases, and they have been excluded from this part of the analysis. 90% of the cases had a STEP-W score of ≤4. Of these, 95% of cases had complete removal of pathology. The remaining 10% of the cases scored ≥5 (range 5–7), signifying an increasing complexity of presenting pathology; of which, complete morcellation was achieved in 62.5% of the cases [Figure 1]. Common reason for incomplete morcellation was obscuring of visual field by blood once the vascular pedicle of the SMF was breached. In one case, the fibroid was densely calcified preventing effective morcellation with the Myosure™ device.

In our series, in 20 out of 249 cases (8%), complete removal of the pathology was not achieved. Of these, two patients returned for a repeat procedure (0.8%). The first patient had a partially calcified fibroid with a STEP-W score of 6 which required two-step morcellation. The second patient presented with HMB secondary to a SMF with a STEP-W score of 5, 90% of the SMFs were morcellated in the first sitting and complete morcellation was achieved 4 months later following a course of ulipristal acetate (Esmya).

The average time taken for the entire procedure was 16.5 min (ranging from 2 min to 67 min). The time taken for resection when using each type of Myosure™ device has been separately calculated. The average cutting time to morcellate the pathology was 2.43 min (ranging from 0.02 to 25.85 min) [Table 1].

The blood loss was <10 ml in 99.5% of cases. One patient bled slightly more; however, she did not require any additional treatment. She was empirically given a prescription for a course of tranexamic acid postprocedure and discharged.

The fluid deficit was calculated to be an average of 416 ml of normal saline (range of 4–2800 ml) for 207 patients. The median fluid deficit was 300 ml. In 7 cases, the fluid deficit was not recorded, and these cases have been excluded from this analysis. One case had a fluid deficit of 2800 ml but was clinically asymptomatic for fluid overload. It is likely that fluid deficit was not calculated accurately and probably overestimated as there was a lot of fluid leakage onto the floor that was not entirely accounted for. A new setup is being trialed since January 2020 called the "easy set up" which is less complicated to use as compared to the traditional "Aquilex" set up with the device, however, the drawback is that the machine does not give an accurate fluid deficit – and this has to be estimated – which was <500 ml in the 35 patients that it was used.

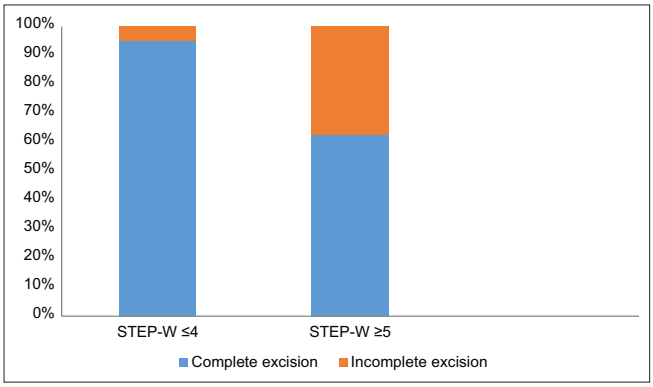

Figure 1: Cases comparing complexity of pathology (using STEP-W score) and completeness of resection. STEP-W: Size, topography, extension, penetration, wall classification system

Two of the 249 procedures had to be abandoned (0.8%). One was abandoned as the fibroid was too calcified to be morcellated, and the other case had to be abandoned after 80% was already morcellated due to faulty equipment. As 80% of the SMFs had already been morcellated in the second case, she was discharged back to the GP with the caveat that she would return for a second resection if still symptomatic. We assume she was asymptomatic as she did not return.

Intra- and post-procedure pain scores were enquired from patients using a visual analog scale, ranging from 0 (no pain) to 10 (most painful), by each operator and were entered after the procedure. However, this data has only been collected from January 2019, and therefore, includes only 103 patients. In this dataset, the median intraoperative pain score was 5 (0–10) and immediately (within 10 min) postprocedure was 1 (0–8). Despite being a small subset, none of the patients prior to or since January 2019 have had procedures abandoned due to pain or intolerance.

There were no complications such as perforations or vasovagal reaction which required admission and monitoring.

Table 1: Procedure and morcellation timings with comparison with size, topography, extension, penetration, wall classification system score and size of Myosure™ device

	XL	Classic	Lite
Average cutting time (min)	4.2	2.8	0.9
Range	0.13-25.85	0.03-21	0.02-5
Median STEP-W score	3.5	3	3
Range	1-7	0-6	0-5
Average procedure time (min)	16.91	16.63	16
Range (min)	3-45	1-67	2-50

STEP-W: Size, topography, extension, penetration, wall classification system

Discussion

HMB or AUB, especially when associated with endometrial pathologies, such as polyps and SMFs, are treatable with compelling evidence that doing so improves symptoms.[4] Operative hysteroscopy is still commonly performed in an inpatient theatre setting, especially when one anticipates a complex lesion, which we will define here as having a STEP-W score of ≥5. With the advent of outpatient hysteroscopy, vast majority of these can be successfully treated in outpatient setting.

Advantages of outpatient treatments are numerous, including the avoidance of risks associated with an anesthetic with its economic benefit for both the patient and the hospital. The risks associated with electrosurgical devices can also be avoided using mechanical morcellators like Myosure™. Outpatient treatments for EP was compared with the traditional day case surgery model using electrosurgical resection currently employed in the UK by Marsh *et al*. They found that the women who underwent the procedure as an outpatient had slight or no discomfort from the procedure the following day (as opposed to only 41% of patients in the daycase model), returned to preoperative fitness quicker, spent less time away from home and required less analgesia than the day case cohort.[5]

Among hysteroscopic procedures, resection of SMF has been found to have the highest complication rate. Complications typically associated are uterine perforation, injury to adjacent organs, excessive bleeding, and fluid overload. In rare cases, excessive fluid absorption can cause pulmonary edema or death.[6] Conventionally, the most widely used classification – the European Society of Gynaecological Endoscopy – classification has been used to describe and classify SMF based on the degree of penetration of the fibroid into the myometrium; however, it does not provide a good degree of correlation with the difficulty anticipated at the time of the surgical procedure with regards to the time required and the possibility of doing the resection in two stages [Table 2].[6]

A new classification, the STEP-W classification, developed by Lasmar *et al*.,[6] is a much more comprehensive classification which helps to anticipate and predict difficulties to be expected at the time of surgical removal, in terms of time required, prediction of complete myoma removal, fluid balance, possibility of needing a 2-step procedure and surgical complications [Figure 2]. The STEP-W system, in addition to considering the degree of penetration of the myoma into the myometrium, also considers the size, topography, extension, and presence of the pathology on the lateral walls. The sum of these five parameters helps score the degree of complexity or simplicity of SMF [Table 3].[6] We have tried to extrapolate the same criteria to EPs to help stratify their complexity – allowing us to choose the appropriate sized Myosure™ device. Although not formally validated, looking at the results, we feel that this is a promising avenue worth looking into for the future. Pathologies scoring 0–4 are generally considered simple and easier to remove with the smaller Myosure™ devices (Lite/Classic) and can be completed within seconds. EP/SMF scoring ≥5 are generally considered complex. These generally benefit from the larger Myosure™ device (XL) as they will generally take longer to resect.

In our series, 20 patients had incomplete resections in their first sitting, the most common reason being, either significant calcification or bleeding with the larger SMF. Evidence suggests that when mechanical morcellation is used, unlike with thermal coagulation, hemostasis occurred through spontaneous myometrial contraction. According to Scheiber and Chen in cases of incomplete excision, the tissue left behind spontaneously regressed in >50% of the cases, predominantly in the first 3 months after intervention.[4] This would be expected to lead to normalization of the endometrial morphology, even in women with limited residual tissue,[4] which is probably why only 2 out of the 20 patients needed to come back for a second sitting for complete excision of their fibroid.

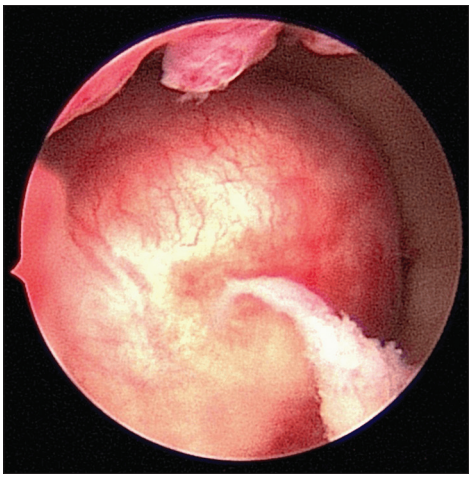

Figure 2: An image of a submucosal fibroid (obtained from Google)

Table 2: ESGE Classification of submucous fibroids(SMF)

Type 0	Entirely within endometrial cavity No myometrial extension (pedunculated)
Type 1	< 50% myometrial extension (sessile) < 90 - degree angle of myoma surface to uterine wall
Type 2	≥ 50% myometrial extension (sessile) ≥ 90-degree angle of myoma surface to uterine wall

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Table 3: STEP-W* classification system score[6]

Score	Size	Topography	Extension of the base	Penetration (%)	Lateral wall	Total
0	<2	Low	<1/3	0	+1	
1	>2-5	Middle	1/3-2/3	<50		
2	>5	Upper	>2/3	>50		

*STEP-W: Size, topography, extension, penetration, wall classification system

As the surgeons' proficiency in performing these procedures has increased over time, we have also started successfully treating complex lesions (EP and SMF) with a score of ≥5 according to the STEP-W system, as reflected in our data set. Women have been able to tolerate these procedures without any complications or adverse events. The feasibility of the use of Myosure™ has been previously validated for use in an outpatient setting,[7] with our results validating the same.

Garuti *et al.* found that the removal of EP in outpatient setting using operative hysteroscopy was effective in removing the pathology in 81% of cases, with the success declining as the size of the polyp got bigger.[8] A prospective multicenter study in 2016 by Scheiber and Chen looked at a combination of EP and SMF that were resected in both inpatient and outpatient settings using mechanical morcellation. The mean diameter of the polyps removed was 1.3 ± 1.0 cm, and the mean diameter of SMF was 2.2 ± 1.2 cm (which would score a 1 on the size component of the STEP-W score). The success rate of complete removal of pathology was 95.4%.[4] Another paper by Lasmar *et al.*, which considered treatment of only SMF using the STEP-W score, showed a success rate of 100% for pathologies scoring ≤4 using STEP-W score and that of 76.9% for STEP-W ≥5.[6] As Lasmar *et al.* did not clarify whether their cases were performed in an office setting or under an anesthetic, we find our rates of complete resection of both EP and SMF, 95% and 62.5%, respectively, are comparable as these were all exclusively performed in an outpatient setting.

Our data on pain score, albeit small (n = 103 patients), showed that women tolerate resections in the outpatient setting using Myosure™ well, with a median intraprocedure pain score of 5/10 (0–10) and an immediate (10 min) postprocedure pain score of 1/10 (0–8). None of the procedures were abandoned due to pain. Completion of resection and procedure abandonment was no different for the procedures undertaken before January 2019, when the pain score data were not collected. The average pain scores from January 2019 onward can therefore be safely extrapolated to the entire dataset.

Looking at our data, we feel that for an initial review, the sample size that we have is adequate to draw conclusions. A strength of our study is the addition of the pain relief scores and patient questionnaires that were included, which is the goal of any outpatient procedure – patient satisfaction while maintaining patient safety and minimizing risks. Limitations of our study were that the data looking at the pain scores of the patients were subsequently introduced and were not as large a sample size as the complete cohort of patients undergoing treatment; the relatively smaller cohort of women undergoing their procedure for a complex pathology (EP or SMF) as compared to women with simple pathology. Although the STEP-W score has not been validated for the use of stratification of complexity of EPs, our study shows promising results in the ability for the scoring system to be used such; this can be an avenue for the future to conduct a larger study to validate the application of the STEP-W score to the stratification of complexity of EPs as well.

Conclusion

Hysteroscopic morcellation of EP and SMF in an outpatient setting for both simple and complex pathologies is safe and effective, well-tolerated, and not associated with complications or a higher incidence of failed or repeat treatments. In addition, we feel that these results can be extrapolated to various other hysteroscopic morcellation devices as well for their use in an outpatient setting.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. The Royal College of Obstetricians & Gynaecologists (RCOG) National Heavy Menstrual Bleeding Audit, Final Report; July, 2014.
2. Cooper NA, Clark TJ, Middleton L, Diwakar L, Smith P, Denny E, *et al.* Outpatient versus inpatient uterine polyp treatment for abnormal uterine bleeding: Randomised controlled non-inferiority study. BMJ 2015;350:h1398.
3. Yin X, Cheng J, Ansari SH, Campo R, Di W, Li W, *et al.* Hysteroscopic tissue removal systems for the treatment of intrauterine pathology: A systematic review and meta-analysis. Facts Views Vis Obgyn 2018;10:207-13.
4. Scheiber MD, Chen SH. A prospective multicenter registry of patients undergoing hysteroscopic morcellation of uterine polyps and myomas. J Gynecol Surg 2016;32:318-23.
5. Marsh FA, Rogerson LJ, Duffy SR. A randomised controlled trial comparing outpatient versus daycase endometrial polypectomy. BJOG 2006;113:896-901.
6. Lasmar RB, Lasmar BP, Celeste RK, da Rosa DB, Depes Dde B, Lopes RG. A new system to classify submucous myomas: A Brazilian multicenter study. J Minim Invasive Gynecol

2012;19:575-80.

7. Georgiou D, Tranoulis A, Jackson TL. Hysteroscopic tissue removal system (MyoSure) for the resection of polyps, sub-mucosal leiomyomas and retained products of conception in an out-patient setting: A single UK institution experience. Eur J Obstet Gynecol Reprod Biol 2018;231:147-51.
8. Garuti G, Cellani F, Colonnelli M, Grossi F, Luerti M. Outpatient hysteroscopic polypectomy in 237 patients: Feasibility of a one-stop "see-and-treat" procedure. J Am Assoc Gynecol Laparosc 2004;11:500-4.