Original Research

Hysteroscopic Morcellation Compared With Electrical Resection of Endometrial Polyps

A Randomized Controlled Trial

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OBJECTIVE: To evaluate whether hysteroscopic morcellation or bipolar electrosurgical resection is more favorable for removing endometrial polyps in an office setting in terms of feasibility, speed, pain, and acceptability.

METHODS: A multicenter, single-blind, randomized, controlled trial of office hysteroscopic morcellation compared with electrosurgical resection was conducted. A total of 121 women were randomly allocated to polyp removal by one of the two methods in an office setting. The outcomes assessed were time taken to complete the endometrial polypectomy, defined as the time from insertion to removal of vaginal instrumentation, completeness of polyp removal, acceptability, and pain measured on a 100-mm visual analog scale.

RESULTS: The median time taken to complete the procedure was 5 minutes and 28 seconds for morcellation compared with 10 minutes and 12 seconds for electrosurgical resection ($P<.001$). The polyps were completely removed in 61 out of 62 (98%) women assigned to morcellation compared with 49 out of 59 (83%) women treated with electrosurgical resection (odds ratio 12.5; 95% confidence interval [CI] 1.5–100.6; $P=.02$). The mean pain scores during the procedure favored morcellation by 16.1 points on average (35.9 compared with 52.0; 95% CI for difference, −24.7 to −7.6; $P<.001$). Overall, 99% of women found office polypectomy to be acceptable, with only one woman in the electrosurgical resection group considering the procedure unacceptable.

CONCLUSION: In comparison to electrosurgical resection during hysteroscopic polypectomy, morcellation was significantly quicker, less painful, more acceptable to women, and more likely to completely remove endometrial polyps compared with electrosurgical resection.

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LEVEL OF EVIDENCE: I

The miniaturization of hysteroscopes and ancillary instrumentation along with enhanced visualization have enabled hysteroscopic surgery to be performed in an office setting without the need for general anesthesia or hospital admission.[1] The most common operative hysteroscopic procedure is endometrial polypectomy,[2] and the feasibility of such approaches has been demonstrated.[3] A disposable miniature bipolar electrosurgical system has been developed to be used with standard operating hysteroscopes to cut away polyps, and the safety, acceptability, and feasibility of this approach has been reported.[3–5] However, retrieval of the detached polyp tissue from within the uterine cavity requires additional instrumentation, which may prolong the procedure and affect patient tolerability.

A new technology has become available called the hysteroscopic morcellation. This technology incorporates a disposable mechanical cutting device that simultaneously cuts and aspirates polyp tissue. The ability to both cut and retrieve polyps avoids the need for additional instrumentation of the uterine cavity and may also improve visualization during surgery by

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avoidance of bubble formation or the production of tissue fragments ("chips") associated with the electrosurgical approach.

Considering the development of hysteroscopic morcellation and potential advantages associated with this innovation, we designed a randomized controlled trial (RCT). The aim was to evaluate whether hysteroscopic morcellation or bipolar electrosurgical resection was more favorable for the removal of endometrial polyps in an office setting by comparing procedure speed, completeness of polyp removal, patient acceptability, and pain scores.

MATERIALS AND METHODS

A multicenter, single-blinded, parallel-group RCT comparing hysteroscopic morcellation compared with electrosurgical resection was conducted. Women were recruited from office hysteroscopy clinics within two large urban teaching hospitals, Birmingham Women's Hospital Foundation Trust and the Royal Hallamshire Sheffield Teaching Hospital. All women attending for an office hysteroscopy or who had a hysteroscopically diagnosed endometrial polyp and in who polypectomy was indicated[1] were approached to participate in the trial. Women were excluded from participation if they preferred the procedure under general anesthesia or were considered by the surgeon to be unable to tolerate an office hysteroscopic polypectomy based on their response to the office diagnostic hysteroscopy. Women with polyps suspected at hysteroscopy to be malignant were also excluded. The number and size of polyps were not exclusion criteria. All participating women gave written informed consent. A preoperative questionnaire was completed by all women before the procedure to collect demographic information and baseline pain scores. This trial was registered on clinicaltrials.gov (identifier: NCT01509313). The National Research Ethics Service, United Kingdom, granted ethical approval (identifier: 12/WM/0058). Research and Development approval was sought and granted at Birmingham Women's Hospital and Sheffield Teaching Hospital.

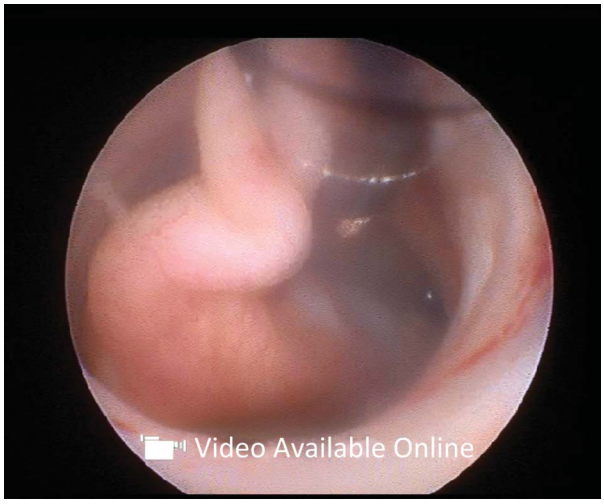
All surgical procedures were performed in the office setting without general anesthesia or conscious sedation. Three surgeons experienced in outpatient endometrial polypectomy performed all surgical procedures (T.J.C., M.E.C., P.S.). Participating surgeons were proficient in both methods of polypectomy, although all three had greater experience with the more established technique of electrical resection. Office polypectomy was performed immediately after diagnosis ("see and treat") or scheduled within 8 weeks of diagnosis, depending on local circumstances and patient preference. Vaginoscopy (ie, passage of the hysteroscope into the uterine cavity without the use of a vaginal speculum or instrumentation of the ectocervix) was the standard approach, with recourse to instrumentation of the lower genital tract when vaginoscopy failed. No cervical preparation was used before the procedure. Normal saline (0.9% w/v NaCl) was instilled from a 3-L bag within a pressure cuff set at 180 mm Hg, which was hung from a 180-cm stand to provide distension and irrigation of the uterine cavity. In line with departmental protocols, fluid deficit was not calculated for office polypectomy because procedures were short, limited to the endometrium, relatively avascular, and performed through small-diameter operating hysteroscopes.[1]

Polyp removal was performed under direct hysteroscopic vision using the TRUCLEAR 5.0 hysteroscopy system incorporating a 2.9-mm rotary-style hysteroscopic morcellator (see Video 1 online at http://links.lww.com/AOG/A479) or the VersaPoint disposable bipolar electrosurgical system. The latter electrode was placed through a 5-Fr operating channel within either the 3.5-mm ALPHASCOPE or the 5-mm Bettocchi operating hysteroscope. The hysteroscopic morcellator technology has been previously described; in short, it incorporates a disposable mechanical cutting device that simultaneously cuts and aspirates polyp tissue.[6] In contrast, electrosurgical resection requires the use of ancillary mechanical instruments to retrieve the specimens from the uterine cavity. These can be either hysteroscopic instruments (miniature grasping forceps, snares) or standard blind polyp forceps.[1] The use of local anesthesia (direct cervical block using 6.6 mL of 3% mepivacaine) was restricted to procedures when dilatation of the cervix was required to pass the hysteroscope through the endocervical canal or to facilitate retrieval of the polyp specimen from the uterine cavity.[1]

We evaluated the following outcomes: time taken to complete the endometrial polypectomy; completeness of polyp removal; and procedural pain and patient acceptability.

Time taken to complete the endometrial polypectomy was defined as the time from insertion to removal of vaginal instrumentation after randomization. In addition, the total time the hysteroscopic morcellator generator was activated according to the TRUCLEAR operating system was recorded at the Birmingham Women's Hospital site.

A complete endometrial polypectomy was defined as the detachment and retrieval of all visible polyp tissue (single or multiple polyps), such that no polyp remnants remained within the uterine cavity.



Video 1. A large fundal polyp is removed under direct vision using a hysteroscopic morcellator.

An incomplete procedure included any of the following: failure to detach any polyp tissue from the uterine wall; partial detachment of polyps from the uterine wall; and failure to retrieve the detached specimen from the uterine cavity.

Procedural pain and patient acceptability data were collected using previously piloted self-completed questionnaires administered to participating women immediately after the procedure. Women were asked to complete the questionnaire before discharge from hospital to limit recall bias and to increase response rates. To assess acceptability, a 4-point ordinal scale was used with the following question and response categories: "would you describe the procedure as 'totally acceptable'; 'generally acceptable'; 'fairly acceptable'; or 'unacceptable.'" Pain was assessed using a 100-mm visual analog scale (0 for no pain and 100 for worst imaginable pain). Women were asked to assess their pain during the procedure and also their short-term postoperative pain just before discharge from hospital or after 15 minutes of completing the procedure, whichever came first.

Surgeons completed a standard form after the procedure to record technical aspects of the procedure, including time taken and perioperative or postoperative complications such as vasovagal reactions (defined clinically as patient unable to leave operating couch within 5 minutes of cessation of procedure because of feeling faint or dizzy or nauseous), uterine trauma, or bleeding.

The sample size for this trial was chosen to give high statistical power to detect a clinically important difference in the primary measure of time taken to complete the endometrial polypectomy. This size of difference was based on evidence reported from a randomized pilot study among residents in training evaluating the hysteroscopic morcellator with formal transcervical resection under traditional general anaesthesia.[7] The results here showed the mean operating time for morcellation to be 10.6 minutes compared with 17.0 minutes for resectoscopy, with a standard deviation of 9.5 minutes in both groups. This size of difference reflected an overall operating time reduction of approximately one-third, which we considered to be a clinically meaningful difference in the outpatient setting. To detect a difference of this size (6.4 minutes) with 90% power (P=.05) would require 48 participants per group, 96 in total. To account for attrition we aimed for 120 participants in total.

Women were allocated in a 1:1 ratio to either of the interventions through a telephone-based system managed by the Birmingham Clinical Trials Unit. The randomization blocks were kept centrally in the Birmingham Clinical Trials Unit and the sizes varied so that the allocation could not be deduced before randomization. Blocks were stratified by the location of polyp (fundal compared with nonfundal) to ensure we achieved balance between groups for this variable. Location was chosen because access to the base of fundal polyps can be problematic with standard mechanical or electrosurgical hysteroscopic instruments.[1] Women were not told which intervention they had been allocated to until after they had completed the postoperation questionnaire.

Analysis was performed by intention to treat. Mean differences and corresponding 95% confidence intervals (CIs) were calculated for treatment times and pain scores. A t test was used to assess statistical significance, although in the presence of some skewness of distribution for treatment times, a nonparametric Mann-Whitney U test was also performed. Logistic regression was used for dichotomous outcomes such as completeness of polyp removal. Odds ratios (ORs) and 95% CIs were derived with a χ^2 test used to assess statistical significance. Fisher exact test was used to compare treatment failure because sample sizes were small. Regression analysis was used to compare trends across the different responses to acceptability. All analyses were performed using SPSS software version 21.

Scan this image to view Video 1 on your smartphone.

RESULTS

In total, 121 women requiring removal of an endometrial polyps as part of their standard care were randomized from two hospitals over the course of 11 months between July 2012 and May 2013. There were 98 women recruited from Birmingham Women's Hospital and 23 women from Sheffield Teaching Hospital. Figure 1 summarizes the flow of participants through the trial in line with the recommendations of the consolidation standards of reporting trials (CONSORT) statement.[8] The majority of baseline variables were balanced between groups after randomization (Table 1). However, women randomized to hysteroscopic morcellation had more polyps on average than those randomized to electrical resection and proportionately more women were allocated to hysteroscopic morcellation in Sheffield Teaching Hospital compared with Birmingham Women's Hospital.

The median time taken to complete the polypectomy procedure was 5 minutes and 28 seconds for hysteroscopic morcellation compared with 10 minutes and 12 seconds for electrical resection ($P<.001$). Complete polyp removal was achieved in 61 out of 62 (98%) women for hysteroscopic morcellation compared with 49 out of 59 (83%) women who underwent electrosurgical resection (OR 12.5; 95% CI 1.5–100.6; $P=.02$) (Table 2). There was no singular reason why there were more failures in the electrosurgical resection group; reasons given were equally distributed between inability to locate polyps using blind instruments (ie, when removal under hysteroscopic vision had failed), inadequate visualization, and patient discomfort.

The mean pain scores for morcellation compared with electrosurgical resection were significantly lower during the procedure and at 15 minutes after the procedure (Table 3). Overall, more than 99% of women found office polypectomy to be at least "fairly acceptable" (Table 4), with only one woman in the electrosurgical resection group reporting the procedure as unacceptable. There was a significant trend toward increased acceptability in women receiving morcellation rather than electrosurgical resection ($P=.009$). There was also a significant difference

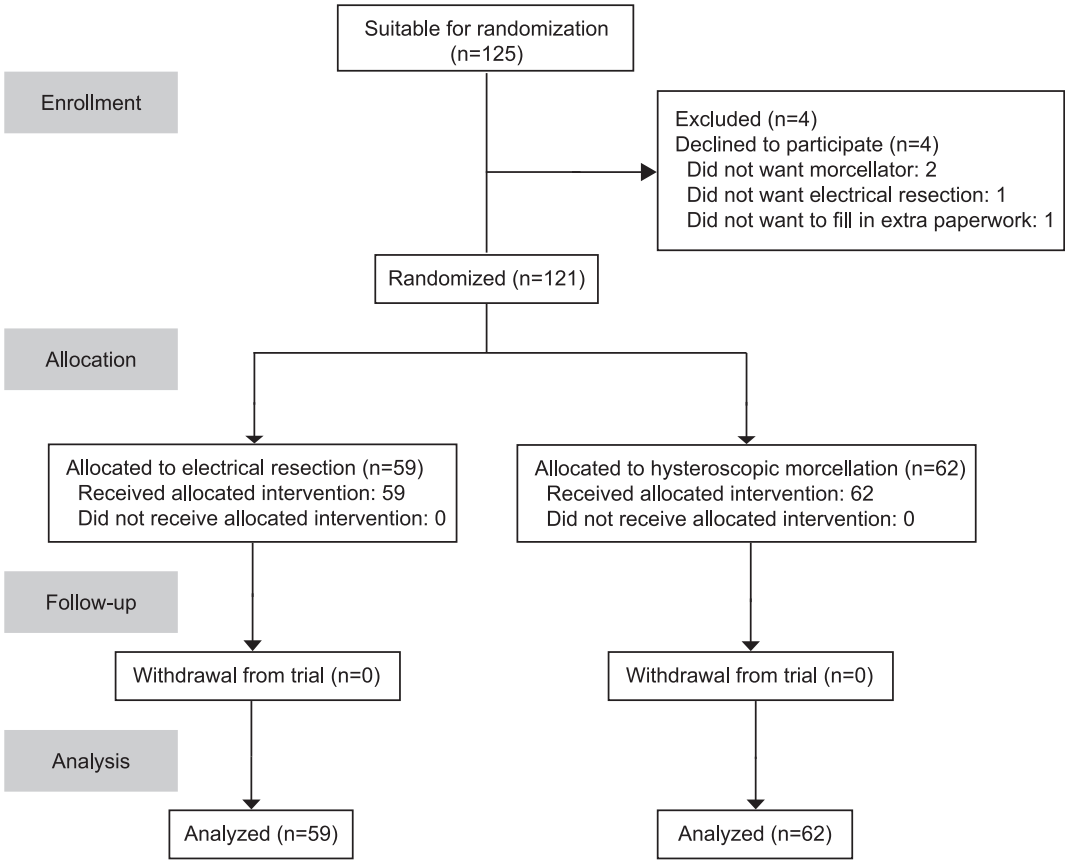


Fig. 1. Consolidation standards of reporting trials flow diagram.
Smith. Morcellation vs Electrical Resection Trial. Obstet Gynecol 2014.

Table 1. Baseline Characteristics of Trial Participants

Characteristic	Hysteroscopic Morcellation (n=62)	Electrical Resection (n=59)
Age (y)	54.3±12.7*	54.9±14.2†
BMI (kg/m²)	31.7±6.6‡	31.5±8.4§
Parity	1.9±1.6	2.2±1.8
Previous cesarean delivery		
Yes	5 (8)	4 (7)
No	57 (92)	55 (93)
Menopausal status		
Premenopausal	26 (42)	28 (47)
Postmenopausal	35 (56)	31 (53)
Missing	1 (2)	0
Indication		
Bleeding	51 (82)	52 (88)
Fertility	1 (2)	4 (7)
Dysmenorrhea	0	2 (3)
Incidental radiology	3 (5)	1 (2)
Vaginal discharge	1 (2)	0
Missing	6 (10)	0
No. of polyps	1.8±0.9 (1, 4)	1.2±0.5 (1, 3)
Polyp size (cm)	1.5±1.0 (0.3, 4.0)	1.7±1.3 (0.5, 7.0)
Polyp location		
Fundal	19 (31)	16 (27)
Nonfundal	43 (69)	43 (73)
Surgeon		
M. Connor	17 (27)	6 (10)
J. Clark	12 (19)	17 (29)
P. Smith	33 (53)	36 (61)
Center		
BWHCT	45 (73)	53 (90)
STH	17 (27)	6 (10)

BMI, body mass index; BWHCT, Birmingham Women's Hospital Foundation Trust; STH, Sheffield Teaching Hospital.
Data are mean±standard deviation, n (%), or (minimum, maximum).
* Four values missing.
† Three values missing.
‡ Eleven values missing.
§ Twelve values missing.

between techniques when we dichotomized the acceptability response to totally acceptable or generally acceptable compared with fairly acceptable or unacceptable.

The only surgical complications observed in either treatment group were vasovagal reactions occurring in 1 out of 62 (2%) and 6 out of 59 (10%) hysteroscopic morcellation and electrosurgical resection procedures, respectively (P=.08) (Table 2). One serious adverse event occurred. This was in a woman treated in the morcellation group who was admitted 2 weeks after treatment because of vaginal bleeding and pain. Endometritis was diagnosed and treated with broad-spectrum antibiotics.

DISCUSSION

This RCT provides strong evidence to suggest that hysteroscopic morcellation is quicker to perform, more successful at completing polyp removal, less painful, and more acceptable to women than traditional electrosurgical resection for the removal of endometrial polyps. The improved performance of morcellation relative to electrosurgical resection may reflect its ability to simultaneously cut and extract polyp tissue under vision. In addition, acquiring proficiency with the hysteroscopic morcellator is rapid,[7] and this relative ease of use also may have contributed to obtaining favorable outcomes.

We used a rigorous definition of what constituted a successfully completed procedure. Data from this trial suggest that the increased success of morcellation compared with electrosurgical resection arises from a combination of factors. First, failures attributable to inadequate visualization were reduced. Although this trial did not evaluate reasons behind enhanced visualization, it may have arisen because steam bubble formation from electrically heating saline was avoided. Alternatively, it may have reflected better continuous irrigation because the morcellator system used a larger-diameter hysteroscope with greater inflow of saline and the disposable morcellator provided suction when activated. Second, failures because of inability to blindly locate specimens within the uterine cavity were avoided because simultaneous tissue cutting and extraction under direct hysteroscopic vision from the uterine cavity were integral to the morcellation system.

Third, failures attributable to patient discomfort were circumvented. Conventional mechanical or electrical instruments necessitate additional hysteroscopic or blind mechanical instrumentation of the uterus to retrieve resected polyp tissue via the narrow endocervical canal. It is likely that the need for these further maneuvers contributed to prolongation of the electrosurgical resection procedure and increased perioperative pain compared with morcellation. Although the clinical significance of the differences in procedural pain is uncertain without further qualitative research, the findings appear consistent with the observed increase in acceptability with morcellation. The integration of cutting and aspiration with

Table 2. Surgical Technique and Complications

Surgical Technique and Complications	Hysteroscopic Morcellation (n=62)	Electrical Resection (n=59)	OR (95% CI)	*P*
Surgical technique				
Speculum used	28 (45)	37 (63)	0.5 (0.2–1.0)	.05
Cervical dilatation	30 (48)	31 (53)	0.8 (0.4–1.7)	.8
Cervical anesthesia	31 (50)	34 (58)	0.7 (0.4–1.5)	.4
Removal success				
Total removal	61 (98)	49 (83)	12.4 (1.5–100.6)	.02
Partial removal	0	7 (12)*		
Failed removal	1 (2)†	3 (5)*		
Complications				
Vasovagal reactions	1 (2)	6 (10)	0.1 (0.0–1.2)	.08
Others	0	0		

OR, odds ratio; CI, confidence interval.
Data are n (%) unless otherwise specified.
* Partial removal or failed removal reasons: unable to locate blindly (n=4); patient discomfort (n=3); inadequate visualization (n=3).
† Partial removal or failed removal reasons: inadequate visualization (n=1).

morcellation may also explain why the needs for cervical dilatation and local anesthesia were comparable between interventions, despite the larger diameter of the hysteroscopic morcellator. The size and number of polyps did not seem to affect the success of morcellation, although the study was not powered to provide adequate analysis of these subgroups.

In a recently completed multicenter RCT in the United Kingdom (Office Polypectomy Trial, ISRCTN65868569; http://www.opt.bham.ac.uk), bipolar electrosurgical resection was the most commonly adopted modality, but recruitment to this trial predated widespread commercial availability of the hysteroscopic morcellator. Treatment times and failure rates for electrosurgical resection were comparable to those noted in the current study (personal communication, T.J. Clark, 2013). Moreover, the results presented here are consistent with data from two trials comparing the morcellator to electrosurgical resection using a resectoscope under general anesthetic;[6,7] both of these trials found the morcellator to be quicker. In keeping with these data, our trial supported the apparent safety of office polypectomy, with adverse events limited to self-limiting vasovagal episodes affecting a minority of women. One postoperative complication was observed in a woman with development of endometritis after morcellation, which resolved with oral antibiotics. All retrieved specimens underwent histopathologic examination and a diagnosis was provided in all cases, consistent with another study.[9] Thus, concerns over the ability to histologically analyze morcellated tissue specimens seem unfounded.

The strengths of our trial include strict randomization, the multicenter design, and full completeness of data collection both before and after treatment. Although we did not collect longer-term clinical follow-up data, a retrospective cohort study comparing morcellation with electrosurgical resection found that morcellation may be associated with lower recurrence of endometrial polyps, although the incidence of recurrent abnormal uterine bleeding was unaffected by the technique used.[10] The soon-to-be-published Office Polypectomy Trial (ISRCTN65868569; http://www.opt.bham.ac.uk) should also provide data pertaining to longer-term outcomes after endometrial polypectomy for abnormal uterine bleeding. Our trial does have some limitations. Randomization did not equally distribute the potential confounders of polyp number and surgical site. However, the distribution of these confounders would be expected to bias against hysteroscopic morcellation by prolonging treatment time because women randomized

Table 3. Pain Scores Measured on a 100-Point Visual Analog Scale

Pain Score	Hysteroscopic Morcellation	Electrical Resection	Mean Difference (95% CI)	*P*
Baseline	8.1±9.4 (60)	5.1±9.7 (58)	−3.0 (−6.4 to 0.5)	.1
During procedure	35.9±23.5 (60)	52.0±23.5 (58)	16.1 (7.6–24.7)	<.001
After procedure	23.9±21.2 (60)	31.0±23.9 (59)	7.1 (−1.1 to 15.3)	.09

CI, confidence interval.
Data are mean±standard deviation (n) unless otherwise specified.

Table 4. Patient Acceptability Measured on a 4-Point Likert Scale

Patient Acceptability	Hysteroscopic Morcellation (n=61)	Electrical Resection (n=58)	*P**
Totally acceptable	44 (72)	33 (57)	.009
Generally acceptable	15 (25)	12 (21)	
Fairly acceptable	2 (3)	12 (21)	
Unacceptable	0	1 (2)	

Data are n (%) unless otherwise specified.
* Using a logistic regression test for trend.

to morcellation had slightly more polyps and were more likely to have undergone treatment at Sheffield Teaching Hospital, where there was an overall longer procedure time than there was at Birmingham Women's Hospital (5 minutes and 7 seconds). Another potential source of bias was inability to blind the surgeon from the intervention. Although every effort was made to blind the patient from the allocated intervention, it is probable that some women would have been aware of the treatment they received given that they were awake and had received thorough pretrial patient information that included a description of morcellation and electrosurgical resection.

The economic advantages of the office compared with the traditional inpatient setting for polypectomy are primarily driven by the avoidance of expensive inpatient bed and theater facilities.[11,12] We did not conduct a cost-effectiveness evaluation in this RCT because symptom outcome data were not collected (these soon-to-be-published data have been collected in the larger Office Polypectomy Trial). In addition, the known wide variation in costs between different health care systems would limit the transferability of findings from such an economic evaluation. Despite these caveats, it is likely that the use of hysteroscopic morcellation will be more cost-effective compared with electrical resection in terms of successfully removing polyps given the magnitude of the observed OR in favor of morcellation.

Although advances in technology are increasingly allowing more gynecologic procedures to be performed in the office setting, it is important to critically appraise new technologies such as hysteroscopic morcellation before they become more widely embedded into clinical practice. Assessments of larger patient cohorts are required to more reliably assess the relative safety of hysteroscopic morcellation in the wider population.

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