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Original Article

Feasibility of Office-based Operative Hysteroscopy by a Tissue Removal System without Anesthesia

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ABSTRACT **Study Objective:** To investigate the feasibility of operative hysteroscopy by a hysteroscopic tissue removal system (HTRS) without anesthesia in women with endometrial polyps (EP) or retained products of conception (RPOC).

Design: Prospective observational cohort study.

Setting: University-affiliated Department of Obstetrics and Gynecology.

Patients: Consenting women aged >18 years diagnosed with EP or RPOC from 9/2022 to 8/2023 confirmed by a prior office hysteroscopy.

Interventions: Office-based vaginoscopic operative hysteroscopy without anesthesia using the Mini-Elite Truclear HTRS. Oral misoprostol was prescribed for cervical ripening. The patients rated intraoperative and 5-minute postoperative pain levels on a visual analog scale, with mild pain defined as a score of 0 to 4, moderate as 5 to 7, and severe as 8 to 10. A successful procedure was defined as complete removal of the pathology.

Measurements and Main Results: Fifty patients were included in this pilot study, and 47 (94.0%) procedures were completed successfully, including 21/24 (87.5%) cases of EP and all cases of RPOC (26/26, p = .06). No intra- or postoperative complications occurred. The intraoperative pain levels were rated as mild, moderate, and severe by 26 (52.0%), 16 (32.0%) and 8 (16.0%) patients, respectively. Severe intraoperative pain was more common in nulliparous women and those >10 years from their last vaginal delivery and was not associated with patient age, menopausal status, presence of abnormal uterine bleeding, or pathology size. Severe postoperative pain, reported by 5 (10.0%) patients, was significantly associated with removal of EP compared with RPOC, longer operative time, and nulliparity or >10 years from the last vaginal delivery. The procedure was considered acceptable by 46 (92.0%) patients, and 45 (90.0%) would recommend it to a friend/relative.

Conclusions: Office-based operative hysteroscopy by the HTRS is successful and well tolerated by most women, especially for RPOC removal. Journal of Minimally Invasive Gynecology (2024) 00, 1−7. © 2024 AAGL. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

Keywords: Hysteroscopy; Hysteroscopic tissue removal system; Endometrial polyp; Retained products of conception; Vaginoscopy

Hysteroscopy is the gold standard approach for the diagnosis and treatment of benign intrauterine pathologies, such as endometrial polyps (EP), submucosal fibroids, intrauterine adhesions, and retained products of conception (RPOC) [1]. Diagnostic hysteroscopy is usually performed as an office-based procedure by means of a vaginoscopic approach without cervical dilation or anesthesia. Operative hysteroscopy has been traditionally performed with large-diameter instruments in the operative room with the patient under general anesthesia [1]. The development of small-diameter hysteroscopic instruments (typically <5−6 mm in diameter) with an operative channel has enabled the performance of operative hysteroscopies by either mechanical instruments (scissors and grasper) or by a bipolar needle electrode in selected nonanesthetized patients [2]. These procedures, although mostly successful and well-tolerated, have still been limited by being unable to deal with

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relatively large sizes of the pathology (usually EP or RPOC) that need to be removed [3]. Thus, in the past, operative office-based procedures without anesthesia were offered mainly to selected patients with intrauterine pathologies measuring <2 cm in diameter [4].

The class of hysteroscopic tissue removal system (HTRS, formerly known as a hysteroscopic morcellator) has been used since 2005. These instruments simultaneously resect and aspirate the intrauterine lesions, allowing for more rapid removal of even relatively large intrauterine pathologies [5]. The miniaturized version of the HTRS, measuring 5 to 6.5 mm in diameter, can be introduced into the uterine cavity via vaginoscopy without cervical dilatation and used for office-based procedures in selected cases [6]. Indeed, successful office-based operative hysteroscopies (without anesthesia) by means of HTRS for EP and RPOC measuring >2 cm in diameter have been described in several reports [7−9]. However, patient characteristics in terms of the procedure's tolerability and successful completion have not been clearly delineated to date. The aim of the current study is to assess the feasibility of office-based operative hysteroscopy by HTRS without anesthesia and to investigate the demographic, obstetrical, gynecologic, and surgical factors associated with successful procedures.

Materials and Methods

Study Cohort

This prospective observational cohort study was conducted in the Division of Minimally Invasive Gynecologic Surgery at the Shamir (Assaf Harofe) Medical Center from September 2022 to August 2023. Consecutive women >18 years of age with a hysteroscopic diagnosis of EP or RPOC (by office diagnostic hysteroscopy) who were considered appropriate for office-based operative hysteroscopy without anesthesia were invited to participate in the study. The exclusion criteria were consistent with the usual contraindications for operative hysteroscopy in the office setting (pregnancy, suspected pelvic infection, patient preference for general anesthesia, major cervical stenosis observed during diagnostic hysteroscopy, and vaginal bleeding precluding optimal hysteroscopic visualization) [10]. There were no limitations for study inclusion related to polyp number and size in cases of EP. In cases of RPOC, masses of up to 3 cm with grade 0 or 1 vascularity according to the Gutenberg classification were considered appropriate for this procedure [11]. A comprehensive medical, surgical, obstetrical, and gynecologic history was obtained at admission into the study.

Operative Hysteroscopy Procedure

All operative hysteroscopies were performed in an ambulatory hysteroscopic suite without the provision of any local, inhaled, or intravenous anesthesia. The participants had been prescribed misoprostol for cervical ripening (oral 400 mcg 12 hours before surgery). Operative hysteroscopy was performed via a vaginoscopic approach without the use of a speculum, a tenaculum, or cervical dilation. The Mini Elite 6 mm TruClear Tissue Removal System (Medtronic, Minneapolis, MN, USA) was employed at a setting of 1500 rounds-per-minute. A solution of 0.9% NaCl was used as the distension medium, and the pressure was set to 150 mmHg by means of an automatic pressure pump. A systematic hysteroscopic evaluation of the cervical canal and uterine cavity was performed to note the location, size, and number of uterine lesions, followed by removal of the lesions by means of the HTRS. Finally, the uterine cavity was inspected in order to verify that all lesions were completely resected in their entirety (see Supplemental Video). The specimens were collected in a specimen bag attached to the suction pump and sent for pathology examination. The procedure time (referred to as "operative time") was recorded from the beginning of the hysteroscope insertion (via vaginoscopy) to its removal. The procedure was defined as being successful if all lesions had been completely removed from the uterine cavity. The patients were discharged home after short observation period (10−30 minutes). Intraoperative complications were recorded (including uterine perforation, fluid deficit >2000 mL, and bleeding >50 mL), as were re-admissions occurring up to 30 days from the procedure. Postoperative antibiotics (oral amoxicillin-clavulanate, 875 mg twice daily for 3 days) were prescribed to women who underwent RPOC removal.

All operative procedures were performed by attending surgeons with prior experience (>50 cases) in using the HTRS in the operative room with the patient under general anesthesia but more limited experience (<10 cases) with the HTRS in an office setting.

Assessment of Intra- and Postoperative Pain

Shortly after the procedure, the study participants were requested to report their highest pain levels during the procedure ("intraoperative pain") and at 5 minutes after the procedure ("postoperative pain") on a digital visual analog scale (VAS). The VAS pain scores were categorized as mild (0−4), moderate (5−7), and severe (8−10). In addition, the participants were asked whether they found the procedure acceptable and tolerable and whether they would recommend it to a friend/relative.

Study End Points

The primary end points were the rate of successful procedures (defined as complete removal of the lesions) and the rate of patients experiencing severe intraoperative pain (defined as VAS ≥ 8). The secondary end points were rates

of severe postoperative pain (VAS ≥ 8 at 5 minutes after the procedure) and rates of intraoperative complications.

Ethics

This clinical trial was approved by the Institutional Review Board (#0004-22-ASF, approved on February 20, 2022) and registered in the clinicaltrials.gov registry (#NCT05722028). An informed consent form was signed by all participants.

Statistical Analysis

The statistical analysis was performed with the SPSS software (version 26, IBM Corp.). Continuous variables (means or medians) were compared with the student's *t* test, the one-way analysis of variance test, or the Wilcoxon rank test. Categorical variables were compared with the $\chi 2$ test or the Fisher-exact test, as appropriate. A 2-sided p-value <.05 was considered statistically significant. Because this was a pilot study, a sample size calculation was not performed.

Results

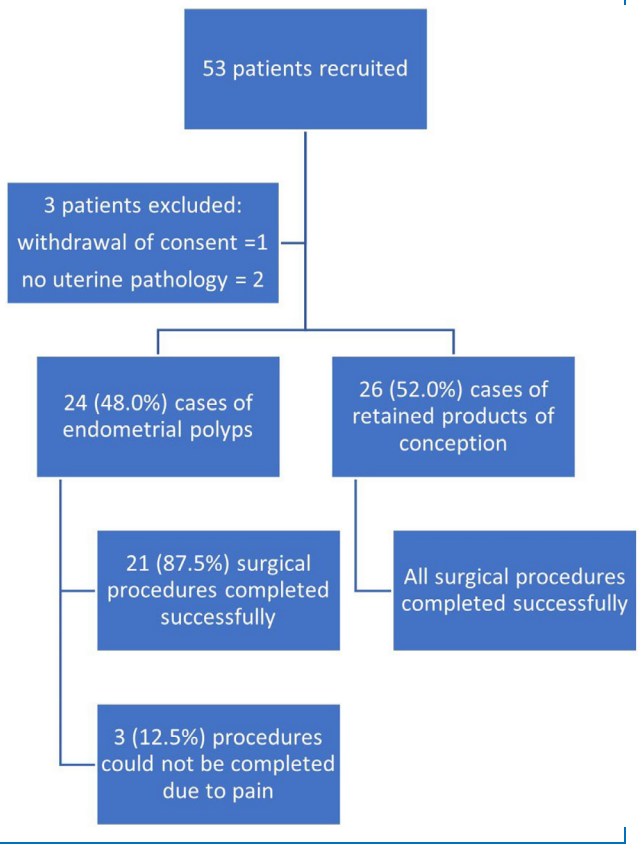
Fifty-three women were recruited into the study, and 50 of them completed the procedure and the pain questionnaire, including 26 cases of RPOC (52.0%) and 24 cases of EP (48.0%) (flow chart, Fig. 1). Their demographic, obstetrical, gynecologic, and clinical characteristics are shown in Table 1. Women with EP were significantly older and had a higher mean body mass index compared to women with RPOC. As could be expected, there was also a higher proportion of women with EP who were postmenopausal. However, the obstetrical history, including gravidity, parity, nulliparity, and history of vaginal delivery or cesarean section, were similar between the 2 groups (Table 1).

The surgical characteristics of the study cohort are listed in Table 2. Forty-seven (94.0%) procedures were completed successfully, including 21/24 (87.5%) cases of EP and all cases of RPOC (26/26) (p = .06). The remaining 3 patients could not tolerate the insertion of the hysteroscope through the cervical canal due to severe pain and the procedure was discontinued. The mean surgical time was similar for the EP and RPOC groups (2.9 ± 1.9 minutes versus 2.5 ± 1.0 minutes, respectively, p = .4). All other examined surgical characteristics, including uterine position, pathology size, and pathology location within the uterine cavity, were similar for the EP and RPOC groups (Table 2). There were no intraoperative complications, and all patients were discharged as planned after a short period of observation. There were no re-admissions and no postoperative infections. Operative hysteroscopy under general anesthesia was subsequently performed without incident at a later date in the 3 unsuccessful cases.

The EP were solitary in 20 (83.3%) cases and ≥ 2 in 4 (8.0%) cases. The polyp anatomy was described as wide-based in 16 (66.7%) cases and as pedunculated in 8 (33.3%) cases. The success rate of removal was similar for the solitary and multiple polyps (85.0% versus 100.0%, respectively, p = .6), as well as for wide-based and pedunculated polyps (86.7% versus 88.9%, respectively, p = .7).

Fig. 1

Flow chart of the study.



The postoperative pathology findings of EP cases confirmed benign polyps in 22 (91.7%) cases and polyps with nonatypical hyperplasia in 2 (8.3%) cases. For the RPOC cases, chorionic villi were confirmed on pathology in 19 (73.1%) cases.

The intraoperative pain levels were reported as mild (VAS 0−4) by 26 (52.0%) patients, moderate (VAS 5−7) by 16 (32.0%) patients, and severe (VAS 810, including the 3 unsuccessful procedures) by 8 (16.0%) patients. Comparisons of the demographic, clinical, gynecologic, and surgical characteristics of patients with mild, moderate, and severe intraoperative pain are shown in Table 3. A significantly higher rate of nulliparous, and patients >10 years from their last vaginal delivery reported severe pain. Postmenopausal patients and those who operated for EP also reported higher rates of severe pain, but the differences did not reach a level of significance (Table 3). There were no differences between intraoperative pain groups in terms of gravidity, uterine position (i.e., anteverted or retroverted), or the location of the pathology on the uterine walls (data not shown).

Table 1

Comparison between the demographic, obstetrical, gynecologic, and clinical characteristics of the study participants with EP and those with RPOC

Characteristic	Entire cohort (*N* = 50)	EP (*N* = 24)	RPOC (*N* = 26)	p value
Age (yr)	40.4 ± 12.9	49.1 ± 13.6	32.4 ± 3.9	< .01*
Body mass index (kg/m^2)	26.6 ± 6.1	28.7 ± 7.2	24.5 ± 4.0	.02*
Gravidity	3 (0−11)	3 (0−11)	3 (1−7)	.4
Parity	2 (0−9)	2 (0−9)	2 (06)	.2
History of vaginal delivery	42 (84.0)	19 (79.2)	23 (88.5)	.4
History of cesarean section	7 (14.0)	3 (12.5)	4 (15.4)	.8
Nulliparous	5 (10.0)	4 (16.7)	1 (3.8)	.2
>10 years from the last delivery	16 (32.0)	15 (62.5)	1 (3.8)	<.01*
Postmenopausal	12 (24.0)	12 (50.0)	0	<.01*
Abnormal uterine bleeding	22 (44.0)	13 (54.2)	9 (34.6)	.2

EP = endometrial polyps; RPOC = retained products of conception.
Data are given as mean ± SD, median (range), or number (%).
* Significant p value.

Table 2

Comparison of the surgical characteristics of the study participants with EP and those with RPOC

Surgical characteristic	Entire cohort (*N* = 50)	EP (*N* = 24)	RPOC (*N* = 26)	p value
Successful procedure	47 (94.0)	21 (87.5)	26 (100.0)	.06
Operative time (min) (range, min−max)	2.7 ± 1.5 (1.5−7.0)	2.9 ± 1.9 (1.5−7.0)	2.5 ± 1.0 (1.5−5.0)	.4
Uterine position				
Anteverted	37 (74.0)	18 (75.0)	19 (73.1)	.9
Retroverted	13 (26.0)	6 (25.0)	7 (26.9)	
Pathology location				
Anterior/fundal uterine wall	14 (28.0)	8 (33.3)	6 (23.1)	.1
Posterior uterine wall	22 (44.0)	7 (29.2)	15 (57.7)	
Lateral walls	14 (28.0)	9 (37.5)	5 (19.2)	
Largest lesion diameter (mm)	1.8 ± 0.6	1.8 ± 0.8	1.8 ± 0.6	.8
Largest lesion diameter >20 mm	29 (58.0)	12 (50.0)	17 (65.4)	.4

EP = endometrial polyps; RPOC = retained products of conception.
Data are given as mean ± SD or number (%).

The 5-minute postoperative pain levels were reported as mild (VAS 0−4) by 40 (80.0%) patients, moderate (VAS 5−7) by 5 (10.0%) patients, and severe (VAS 8−10, including the 3 unsuccessful procedures) by 5 (10.0%) patients. The comparisons of the postoperative pain scores according to the participants' demographic, clinical, gynecologic, and surgical characteristics are shown in Table 4. Nulliparity or >10 years from the last vaginal delivery, removal of EP compared with RPOC, and longer operative time were associated with severe pain, while menopausal status, pathology size, body mass index, history of cesarean section, or presence of abnormal uterine bleeding were not (Table 4). In addition, gravidity, uterine position, and location of the uterine pathology were not correlated with postoperative pain (data not shown).

Patient satisfaction was evaluated by a digital questionnaire that was filled in several minutes after the procedure. Forty-six (92.0%) patients were satisfied with the procedure, and 45 (90.0%) would recommend it to a friend/relative. Low satisfaction was significantly associated with severe intra- and postoperative pain (in 50.0% and 60.0% of patients, respectively, compared with 0% and 2.2% of patients with mild or moderate intra- and postoperative pain, p <.001).

Discussion

The relatively new class of operative hysteroscopes, the tissue removal device, enables the extraction of

Table 3

Relationship between selected demographic, clinical, gynecologic, and surgical characteristics and intraoperative pain scores

Characteristic	Mild pain* (*N* = 26)	Moderate pain* (*N* = 16)	Severe pain* (*N* = 8)	p value
Age (yr)	40.5 ± 13.4	41.4 ± 13.3	46.4 ± 16.1	.7
Body mass index (kg/m^2)	27.4 ± 4.4	24.3 ± 5.4	29.5 ± 11.7	.1
Uterine pathology				
Polyp	10 (38.4)	8 (50.0)	6 (75.0)	.2
RPOC	16 (61.6)	8 (50.0)	2 (25.0)	
History of cesarean section	5 (19.2)	1 (6.2)	1 (12.5)	.4
Nulliparous or >10 years since the last vaginal delivery	7 (26.9)	8 (50.0)	6 (75.0)	.04†
Menopausal status				
Premenopausal	21 (80.8)	12 (75.0)	5 (62.5)	.6
Postmenopausal	5 (19.2)	4 (25.0)	3 (37.5)	
Abnormal uterine bleeding	9 (34.6)	9 (56.2)	4 (50.0)	.3
Largest lesion diameter (mm)	1.8 ± 0.7	1.8 ± 0.6	2.0 ± 0.3	.8
Operative time (minutes)	2.4 ± 1.2	2.8 ± 1.7	3.6 ± 2.3	.3
(range, min to max)	(1.5–5.0)	(1.5–7.0)	(2.0–7.0)	

RPOC = retained products of conception.
Data are given as mean ± SD or number (%).
* Pain scores were defined as mild for a visual analog scale of 0–4, moderate for a VAS of 5–7, and severe for a visual analog scale of 8–10 (the latter including the 3 patients whose procedure was unsuccessful).
† Significant p value.

Table 4

Comparison of the 5-minute postoperative pain scores with selected demographic, clinical, gynecologic, and surgical characteristics

Characteristic	Mild pain* (*N* = 40)	Moderate pain* (*N* = 5)	Severe pain* (*N* = 5)	p value
Age (yr)	39.5 ± 11.5	43.5 ± 19.0	68.0 ± 11.0	.1
Body mass index (kg/m^2)	26.5 ± 5.9	28.2 ± 7.4	25.7 ± 9.6	.8
Uterine pathology				
Endometrial polyp	16 (40.0)	3 (60.0)	5 (100.0)	.03†
RPOC	24 (60.0)	2 (40.0)	0	
History of cesarean section	5 (12.5)	0	2 (40.0)	.2
Nulliparous or >10 years from the last vaginal delivery	13 (32.5)	3 (60.0)	5 (100.0)	.01†
Menopausal status				
Premenopausal	32 (40.0)	4 (80.0)	2 (40.0)	.1
Postmenopausal	8 (20.0)	1 (20.0)	3 (60.0)	
Abnormal uterine bleeding	18 (45.0)	2 (40.0)	2 (40.0)	.9
Largest lesion diameter (mm)	1.8 ± 0.7	2.1 ± 0.6	2.2 ± 0.3	.8
Operative time (min)	2.5 ± 1.4	3.1 ± 1.4	6.0 ± 1.4	.004†
(range, min–max)	(1.5–7.0)	(2.0–5.0)	(5.0–7.0)	

RPOC = retained products of conception.
Data are given as mean ± SD or number (%).
* Pain scores were defined as mild for a visual analog scale of 0–4, moderate for a VAS of 5–7, and severe for a visual analog scale of 8–10 (the latter including the 3 patients whose procedure was unsuccessful).
† Significant p value.

comparatively large pathologies, such as EP or RPOC, in a relatively short operative time and with the use of small-diameter instruments. In some cases, the small diameter of the instruments also allows for performing these procedures in the office setting and without anesthesia. However, office-based operative hysteroscopies are not suited to all patients, and intra- and postoperative pain (mostly caused by the introduction of the hysteroscope through the nondilated cervical canal) remains a critical barrier for some women. In this study, we demonstrated that this procedure may be performed without considerable pain or discomfort in most cases among preselected patients. It emerged that

some patients, particularly those with EP who are nulliparous or >10 years from their last vaginal delivery, may opt for operative hysteroscopy under general anesthesia or sedation. Similarly, longer procedures (mainly due to the extended time required for the introduction of the hysteroscope into the uterine cavity) were associated with severe postoperative pain. Surprisingly, other obstetrical and gynecologic factors, such as a history of cesarean section and the position of the uterus, were not correlated with severe intra- or postoperative pain among any of our study participants.

The size and the number of uterine pathologies had been thought to represent the main criteria for acceptability of office-based operative hysteroscopy. Gambadauro et al [3] recommended performing office-based uterine polypectomy for polyps < 2 cm when using miniaturized hysteroscopic instruments (i.e., scissors, bipolar needle electrodes, and graspers). However, that restriction did not appear to determine the success or failure of office-based HTRS procedures in our experience. Our findings showed similar success rates and pain scores for EP and RPOC masses of <2 cm and >2 cm, as well as no differences in the successful removal of solitary versus multiple EP. Thus, we consider that the preoperative evaluation of patients who are candidates for office-based HTRS procedures without anesthesia should focus on evidence of cervical stenosis and less so on the number and size of their EP.

RPOC is particularly suited for outpatient removal without anesthesia when using the HTRS, given the relatively greater softening and dilation of the cervical canal in these patients. It should be noted, however, that vascular RPOC are not suitable for office-based HTRS procedures because of the risk of uncontrolled bleeding, which cannot be well managed in this setting [12]. This caveat mandates a preoperative evaluation of patients with RPOC that includes the performance of ultrasonography with color Doppler flow. The Gutenberg classification may be used to determine the degree of vascularization and the ability to schedule the appropriate therapeutic approach: Alonso Pacheco et al [11] recommended that RPOCs classified as types 0 or 1 may be managed in the office setting, while types 2 or 3 are more suited for operative room settings.

Several strategies for pain management during office-based operative hysteroscopies have been suggested, ranging from preoperative oral analgesia, inhaled analgesia (nitrous oxide), local intracervical or intramyometrial anesthesia, paracervical blocks, and intravenous sedation [6,13]. Each of these strategies has advantages and disadvantages, and no pain strategy has thus far been considered as being superior or optimal [14]. For example, although paracervical blocks may slightly decrease intraoperative pain scores, they are associated with considerable discomfort during the injection [6]. As a result, many practitioners opt for level 1 pain management (i.e., no medications or oral nonsedative medications), similar to the management in our study. Future studies to identify the optimal pain management strategy for office-based operative hysteroscopy are warranted.

This study is limited by its small number of cases, a factor that could contribute to the lack of significant differences due to insufficient statistical power. In addition, our study is limited by a selection bias because we preselected patients by performing a diagnostic office hysteroscopy to assess their cervical and uterine anatomy and their presumed compliance, which could have influenced our high success rate and may have affected the reproducibility and generalizability of our results. These rates could be lower in a nonselected patient group. In addition, our study is limited by a recall bias because patients were asked about their intraoperative pain levels shortly after the procedure.

In conclusion, office-based operative hysteroscopies by means of the HTRS are successful and well tolerated in most women, particularly for RPOC removal. Women with EP who are nulliparous and those who had delivered >10 years earlier may be offered operative hysteroscopy under sedation or general anesthesia because of higher rates of severe intra- and postoperative pain associated with the office-based procedure.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.jmig.2024.05.005.

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