

Anesthesia-free In-office Hysteroscopic Morcellation for Endometrial Polyps: A Prospective Study

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Abstract

Objectives: The objective of the study was to evaluate the feasibility and quality of anesthesia-free in-office hysteroscopic morcellation for the treatment of endometrial polyps.

Materials and Methods: A prospective, single-center, open-label, single-arm clinical trial was conducted to evaluate the efficacy of hysteroscopic morcellation for endometrial polyps or retained products of conception. All surgical procedures were performed using the TruClear™ 5C system in the office setting without anesthesia. The primary endpoint was the success rate of surgery, defined as the completion of the operation. The secondary endpoints were operating time, fluid deficit, adverse events, pain evaluated by Visual Analog Scale (VAS) scores, and recurrence rate.

Results: Ninety-five patients underwent hysteroscopic morcellation without anesthesia and received the treatment. The success rate of surgery was 100% (95/95), and the mean operating time was 7.3 min. Adverse events occurred in only 2.1% (2/95), with vasovagal reflex. The mean VAS scores during the procedure ranged from 2.4 to 3.1, and the recurrence rate after 6 months was 2.1% (1/47), with a pregnancy rate of 33% (11/33). When comparing nulliparous and parous patients, the success rate and the operating time were equivalent, and the mean VAS scores during the procedure were both within tolerable levels but significantly higher in nulliparous patients (3.3–4.5 vs. 1.6–1.9, $P < 0.001$).

Conclusion: This study demonstrated that anesthesia-free in-office hysteroscopic morcellation for endometrial polyps can be safely performed with feasible quality and only tolerable pain. This less-invasive procedure is expected to become more widespread in future.

Keywords: Endometrial polyp, endometrial polypectomy, hysteroscopic morcellation, in-office surgery, without anesthesia

INTRODUCTION

Endometrial polyps are a common gynecological disease that often causes abnormal uterine bleeding or infertility and requires surgical treatment.^[1,2] Hysteroscopic polypectomy is the treatment, but electrical resectoscopes are often difficult and painful, requiring general anesthesia.^[3] The hysteroscopic morcellation system, such as TruClear™ 5C system, has shown superior outcomes and allows for in-office day surgery, but complications related to anesthesia and sedation remain a concern.^[4-15] This study aims to investigate the feasibility and pain level of anesthesia-free in-office hysteroscopic surgery

using a morcellation system, which has been infrequently reported, with no report in Asia.^[3,16-18]

MATERIALS AND METHODS

Study design

A prospective, single-center, open-label, single-arm clinical trial was conducted to evaluate the effectiveness of hysteroscopic morcellation for endometrial polyps or retained products of conception (RPOC). The target sample size was

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75, comprising endometrial polyps and RPOC, and written informed consent was obtained from all participants before they were enrolled in the study (approval number: 20-058). The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Teikyo University (approval number: 20-058, UMIN-CTR identifier: UMIN000041338).

Patients

All women with indications for endometrial polypectomy or removal of RPOC were screened for eligibility, and those who declined to participate were excluded. Eligibility was determined based on a diagnostic office hysteroscopy, and exclusion criteria included patients with uterus bipartitus, intrauterine adhesion, endometrial carcinoma or suspected endometrial carcinoma, the experience of vasovagal reflex due to intrauterine procedure, endometrial polyps larger than 3 cm in diameter, or those who were judged ineligible by the principal investigator or subinvestigators. The number of polyps was not a criterion for exclusion. All enrolled participants were allocated to receive in-office hysteroscopic morcellation without anesthesia.

Surgical procedures and postoperative follow-up

All surgical procedures were performed in the office setting without the use of general anesthesia or conscious sedation. The operations were performed or directly supervised by A.T., who is a highly skilled hysteroscopic specialist and is accredited by the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Surgery. Hysteroscopic morcellation was performed using the TruClear™ 5C system, with a 0° optic and a 5.7-mm sheath, and a 2.9-mm rotary morcellator. The surgical procedure flowchart is presented in Figure 1. Before the operation, a 50 mg diclofenac suppository was administered 30 min before the operation.

We attempted to reach the uterine cavity by vaginoscopy. If it was difficult to reach the uterine cavity, the sheath was removed. Cervical dilation was not performed, and a vaginal speculum was not used unless the scope could not access the uterine cavity by vaginoscopy. If the pain during the procedure was intolerable, 30 mg of pentazocine was administered intravenously. The hysteroscopic morcellation technique was performed as previously described.^[4,12] Normal saline was used for irrigation with a pressure of 70 mmHg without a specific pump. After introducing the hysteroscope, we thoroughly examined the uterine cavity, then conducted polypectomy, and finished the procedure after confirming the complete removal of the endometrial polyps. All hysteroscopic procedures were recorded on hard disk drives (HDDs). After the operation, patients rested for 30 min and completed a questionnaire document containing 10 cm Visual Analog Scale (VAS) scores of pain (0 for no pain and 10 for the worst imaginable pain). Patients recorded the VAS score of the maximum pain during menstruation and the scores before the surgery, during insertion (vagoscopy), after insertion, during morcellation, and after the surgery. Transvaginal ultrasound sonography was conducted after 2 and 6 months, and symptoms were assessed to determine recurrence.

Endpoints

The primary endpoint was the success rate of surgery, defined as the completion of the operation. The secondary endpoints were (1) operating time, (2) fluid deficit, (3) adverse events, (4) patient-evaluated pain, and (5) recurrence rate by transvaginal ultrasonography. Operating time was divided into vagoscopy time and insertion time. The vagoscopy time was defined as the time from the visual introduction by the scope until the time the scope reached the uterine cavity, and the insertion time was defined as the time from

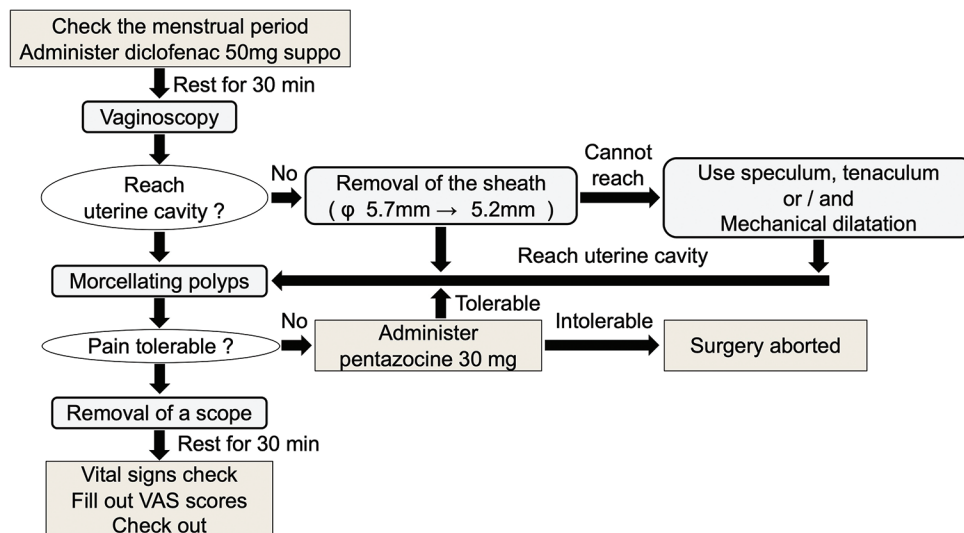


Figure 1: The flowchart of the surgical procedure

the time the scope reached the uterine cavity to the time of the completion of the procedure. Therefore, the operating time was equal to the vaginoscopy time plus the insertion time. Furthermore, to further evaluate the sustainability of in-office surgery without anesthesia, we divided the patients into two groups: nulliparous and parous and compared them.

Statistical analysis

The statistical analyses were conducted according to the principles of intent-to-treat. The statistical significance of the observed continuous values was assessed using the Welch’s *t*-test, whereas dichotomous variables were compared using the Fisher’s exact test. Statistical significance was considered at *P* < 0.05. The statistical analyses were performed using the JMP 12.0 software (SPSS, Chicago, IL, USA) for Windows. A sample size of 75 patients was determined to achieve an acceptable alpha value of 0.05, a beta value of 0.2 with an expected validity probability of 0.95, and a threshold validity probability of 0.85, based on the previous report where the success rate of surgery was 96%.^[18]

RESULTS

Patient characteristics and endpoints

A total of 291 patients were assessed for eligibility for this study, and 95 patients were enrolled in this study from August 2020 to February 2022. All 95 patients received hysteroscopic morcellation without anesthesia. Seventy-three patients received a 2-month follow-up and 47 received a 6-month follow-up [Figure 2]. Table 1 shows the patient characteristics, whereas surgical data and postoperative course are shown in Table 2. All patients achieved complete resection without any adverse events including blood loss, infection, or uterine perforation, except for vasovagal reflex in two patients. The success rate of surgery was 100% (95/95). Six patients needed to remove the sheath, and one needed a vaginal speculum. The average operating time was 7.3 ± 3.9 min and the average amount of the used fluid was 668 ± 372 ml, with a deficit of 128 ± 83 ml.

Intraoperative VAS scores ranged from 2.4 to 3.1 points, and the postoperative score showed 0.5 ± 1.0 [Table 3]. Only one patient required the injection of pentazocine. Seventy percent (63/90) of the patients felt less pain during operation than menstruation. The recurrence rate after 2 months was 0.0% (0/73) and after 6 months was 2.1% (1/47), with an accumulated pregnancy rate of 33% (11/33).

Table 1: Patient characteristics

	All patients (n=95)	Nulliparous (n=46)	Parous (n=49)	P
Age (years)	39.0±6.6	36.9±6.1	42.1±6.2	<0.001
BMI (kg/m ²)	21.0±3.3	20.9±2.8	21.6±3.7	0.359
Height (cm)	159.2±5.2	160.1±5.6	158.4±4.7	0.114
Weight (kg)	53.9±8.7	53.6±7.6	54.1±9.7	0.808
Number of parity	0.8±0.9	0	1.6±0.7	NA
Postmenopause	3 (3.1)	1 (2.1)	2 (3.5)	0.130
Symptoms				
Bleeding	26 (27)	11 (16)	15 (30)	0.470
Dysmenorrhea	58 (61)	31 (70)	27 (63)	0.224
Hypermenorrhea	49 (51)	22 (45)	27 (48)	0.483
Infertility	44 (46)	29 (62)	15 (33)	0.001
Number of polyps	2.1±1.3	2.3±1.4	2.0±1.3	0.307
Polyp size (mm)	10.9±3.5	10.3±3.3	11.6±3.7	0.079
Polyp weight (g)	0.33±0.52	0.22±0.23	0.45±0.69	0.032

Values are presented as mean±SD or *n* (%). SD: Standard deviation, NA: Not available, BMI: Body mass index

Table 2: Clinical outcomes of hysteroscopic morcellation

	All patients (n=95)	Nulliparous (n=46)	Parous (n=49)	P
Complete resection	95 (100.0)	46 (100.0)	49 (100.0)	NA
Total operating time (min)	7.3±3.9	7.3±3.9	7.3±3.9	0.997
Vaginoscopy time (min)	2.2±2.2	2.8±2.8	1.6±1.2	0.006
Insertion time (min)	5.1±3.3	4.4±2.5	5.7±3.9	0.067
Diclofenac suppository used	92	44	48	0.949
Pentazocine used	1	0	1	0.335
Speculum used	1	1	0	0.305
Tenaculum used	1	1	0	0.305
Cervical dilator used	0	0	0	NA
Sheath removed	6	6	0	0.009
Fluid used (mL)	668±372	631±315	743±417	0.146
Fluid deficit (mL)	128±83	137±92	120±74	0.381
Adverse event				
Vasovagal reflex	2 (2.1)	1 (2.1)	1 (2.0)	0.965
Other events	0	0	0	NA
Recurrence				
2 months (n=73)	0	0	0	NA
6 months (n=47)	1 (2.1)	1 (5.3)	0	0.229
Pregnancy rate (n=33)	33.3 (11/33)			
Postoperative use of NSAIDs	14 (14)	6 (13)	8 (16)	0.662

Values are presented as mean±SD or *n* (%). NSAIDs: Nonsteroidal anti-inflammatory drugs, SD: Standard deviation, NA: Not available

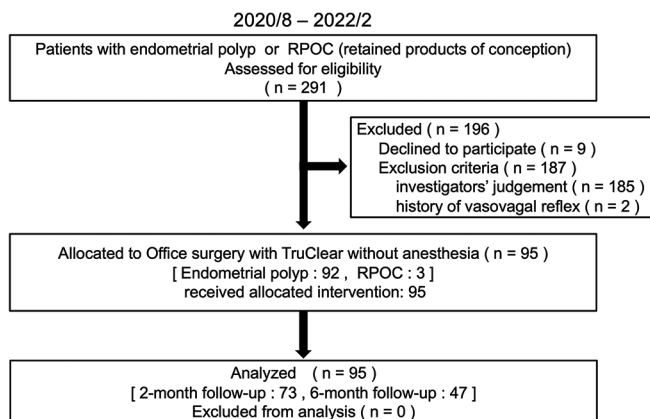


Figure 2: The flow diagram of the reporting trial

Table 3: Evaluation of pain using Visual Analog Scale scores during hysteroscopic morcellation

Timing	All patients (n=95)	Nulliparous (n=46)	Parous (n=49)	P
Before surgery	0.0±0.0	0.0±0.0	0.0±0.0	0.335
During insertion	2.4±2.5	3.3±2.5	1.6±2.2	<0.001
After insertion	2.7±2.4	3.8±2.3	1.6±1.9	<0.001
During morcellation	3.1±2.6	4.5±2.2	1.9±2.3	<0.001
After surgery	0.5±1.0	0.6±1.1	0.4±0.8	0.346
Menstrual pain	5.3±2.2	5.7±2.0	4.8±2.3	0.065

Values are presented as mean±SD or n (%).SD: Standard deviation

Comparison between nulliparous and parous patients

To assess the sustainable strategy for in-office surgery without anesthesia, the patients were divided into nulliparous and parous groups. Table 1 shows the patient characteristics, and the average age of nulliparous patients was 5.2 years younger than that of the parous group (36.9 ± 6.1 vs. 42.1 ± 6.2 , $P < 0.001$), with a higher rate of infertility (62% vs. 33%, $P = 0.001$) in the nulliparous group. Surgical data and postoperative course are shown in Table 2. There were no significant differences in operating time (7.3 ± 3.9 vs. 7.3 ± 3.9 min, $P = 0.997$), but the vaginoscopy time was significantly longer in the nulliparous group (2.8 ± 2.8 vs. 1.6 ± 1.2 min, $P = 0.006$), and all six cases of sheath removal were nulliparous ($P = 0.009$). Figure 3 and Table 3 describe and compare the VAS scores for the evaluation of pain at each step. The intraoperative VAS scores were significantly higher in the nulliparous group (3.3–4.5 vs. 1.6–1.9, $P < 0.001$), whereas postoperative pain was at the same level between nulliparous and parous groups (0.6 vs. 0.4, $P = 0.346$).

DISCUSSION

In this prospective study, in-office hysteroscopic surgery using a morcellation system could be performed without anesthesia. All patients enrolled were able to complete the procedure without anesthesia, with good clinical outcomes including operating time and recurrence rate. The pain was within the level of tolerance, but it tended to be more severe in the nulliparous group than in the parous group. This report suggests that anesthesia-free in-office hysteroscopic morcellation is feasible and may become the primary treatment strategy for endometrial polyps in future.

The success rate of surgery, the primary endpoint of this study, was 100% (95/95), which is equal to or superior to the 90% rate reported by others.^[3,16-18] Concerning secondary endpoints, (1) the operative time was 7.3 min, of which 2.2 min was required for insertion by vaginoscopy and 5.1 min for morcellation after insertion; (2) the operative time was comparable to 4–10 min in other reports;^[3,16-18] (3) the fluid deficit was only 128 ml; (4) adverse events were

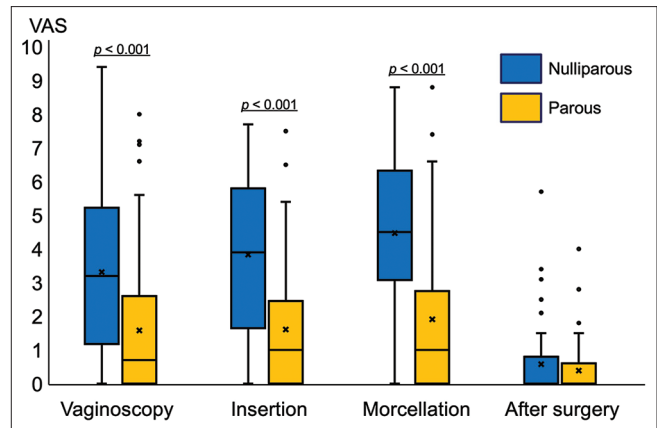


Figure 3: The comparison of Visual Analog Scale scores between nulliparous and parous patients by boxplots

only 2.1% of vasovagal reflex, which is mainly caused by pain;^[19] and (5) the recurrence rate was 2.1% (1/47) with a pregnancy rate of 33% (11/33), indicating that high-quality treatment was achieved even without anesthesia.^[20] The patient with recurrence (1/47) had ovulation disorder with polycystic ovaries, which might be a risk factor for recurrent endometrial polyps. The resected polyp was a pedunculated polyp (20 mm), and the recurrence was only one 10 mm polyp without any symptoms. Previous reports have demonstrated that narrower diameters and morcellation reduce pain,^[10,11,21] and the use of a 5.7 mm morcellation system was probably the most important factor in achieving a high completion rate and quality in this anesthesia-free in-office surgery.

This study's characteristics include (1) the average age of the patients, (2) the detailed evaluation of pain using VAS scores, (3) the parity of the patients, and (4) the fact that the patients were Asian. (1) Like our past report in 2018,^[12] the patients' average age was 39 years old, and only 3% were postmenopausal, compared to other previous reports where the average age was in the 50s and over 40% were treated for postmenopausal bleeding.^[3,16-18] It is assumed that treating younger patients raises the risk of recurrence due to high endometrial proliferative capacity and abundant blood flow in the uterus. However, the recurrence rate was 2.1% (1/47), indicating that the surgical quality was enough and the short-term prognosis was excellent. (2) Overall, VAS scores were similar to or lower than other reports.^[3,16-18] In addition, we evaluated VAS scores at each step. Pain and insertion difficulty were the main causes of surgical discontinuation in previous reports,^[16] and in addition to vaginoscopy without a vaginal speculum, cervical dilation with drugs and paracervical block have been reported.^[17,22] However, in the present study, the VAS score during insertion by vaginoscopy was only 2.4 and was not significantly different from that immediately after insertion. The fact that the VAS scores during operation were lower than the maximum pain

of menstruation in 70% of the patients also shows the pain during the procedure was usually tolerable. We believe that analgesia with diclofenac alone was sufficient to perform the procedure with the same or better invasiveness than in other reports. The fact that the VAS score after surgery was almost the same as before surgery also indicates the ease of returning to daily life. (3) While the percentage of parous patients was higher in other reports,^[3,16-18] this study had almost half nulliparous and half parous patients. In the analysis comparing nulliparous and parous patients, the VAS scores were higher in the nulliparous group throughout the operation, except for pre- and postoperation. This is probably due to the narrower and stiffer cervix. The insertion time was significantly prolonged in the nulliparous group, and the removal of sheaths was necessary in six cases (6/46 vs. 0/49, $P = 0.009$) for the same reason. However, since there was no difference in operating time, completion rate, or recurrence rate between the two groups, anesthesia-free in-office hysteroscopic surgery is feasible, regardless of parity. On the other hand, in individual cases, it may be worthwhile to consider providing options such as paracervical block, misoprostol (uninsured in Japan), and shallow sedation for nulliparous women. (4) This is the first report about anesthesia-free in-office hysteroscopic morcellation in Asia. Considering the racial differences, this prospective study is significant for Asian countries.

This study has some limitations. First, this is a single-arm study. In-office hysteroscopic surgery was initiated simultaneously with the introduction of the TruClear™ 5C system in 2020. Due to a shortage of space in the outpatient area and difficulty in prolonged bed rest caused by sedation, a single-arm trial was conducted. In future, a randomized clinical trial of anesthesia-free in-office hysteroscopic surgery should be conducted in Asia. Second, there is a selection bias. In this study, cases expected to be difficult to perform in-office were excluded based on the evaluator's judgment, which may have resulted in the selection of only those cases that were easy to treat. To make this treatment more widely used in future, the most effective analgesia or sedation for each patient based on their background and medical history should be evaluated and confirmed. Third, some patients were lost to follow-up because most of the infertility patients were referred by other infertility clinics, and after surgery, we usually refer the patients back to their original clinics. Hysteroscopic diagnosis of endometrial polyps has been found in 4% of women with unexplained infertility, and polypectomy increases pregnancy rates,^[23] so further study on pregnancy rates after anesthesia-free in-office surgery will be beneficial for more accurate recurrence and pregnancy rates.

CONCLUSION

In-office hysteroscopic morcellation surgery can be completed safely and with high therapeutic efficacy without anesthesia. This is the first report of anesthesia-free in-office hysteroscopic surgery in Asia. The use of in-office hysteroscopic surgery is expected to expand in future. Since nulliparous patients are more likely to experience pain, adding analgesia is a possibility for them.

Author contributions

DH and AT collected the data. DH analyzed the data. DH, AT, AF, and ON discussed and interpreted the results. DH drafted the manuscript. AT supervised the study. All authors read and approved the final manuscript.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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