

Office/Ambulatory Hysteroscopic Tissue Retrieval System for Intrauterine Pathologies without Anesthesia: An Indian Study

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Abstract

Background: Abnormal uterine bleeding (AUB), the most common symptom of abnormal intrauterine pathologies is estimated to affect about 1/3rd of females in their fertile and postmenopausal age. Currently, diagnostic hysteroscopy can be performed in an office setup on a conscious patient without the use of anaesthesia. We used mechanical tissue removal system for the diagnosis as well as retrieval of intrauterine pathologies and evaluated feasibility and acceptance for intrauterine tissue retrieval system without anaesthesia.

Method: In this retrospective study, 84 patients underwent intrauterine tissue retrieval in office for 1 year (May 2019 to April 2020) in a private hospital post adequate counselling and obtaining informed consent by an experienced gynaecologist.

Statistical Analysis: Statistical analysis was performed using the R-statistical tool version 3.5.3 and Microsoft excel. P-Value < 0.05 was considered as statistically significant.

Results: Most patients underwent successful tissue retrieval with a median operative time of 4.05 minutes (0.66 - 15 minutes). None of them presented with postoperative complications such as per vaginal bleeding, pain, and fever. The procedure was equally good for polyps/fibroids/retained products of conception and endometrial hyperplasia.

Conclusion: This study represents the first clinical trial in a private hospital setting on an Indian cohort with such a large sample who underwent the procedure with safety and feasibility. Our study supports use of hysteroscopic tissue retrieval in an office setting for different endometrial pathologies with high precision, safety, and tolerability with minimal procedure time and patient satisfaction.

Keywords: Intrauterine Morcellator; Morcellation; Office Hysteroscopy; Tissue Retrieval

Introduction

Abnormal uterine bleeding (AUB)/ menstrual flow outside the normal volume, the most common symptom of abnormal intrauterine pathologies is estimated to affect about 1/3rd of females in their fertile and postmenopausal age [1,2]. Patients also present with excessive inter menstrual bleeding, irregular cycles, vaginal discharge, lower abdominal pain, backache, and pelvic pain. Hyperplastic overgrowth of the endometrial gland (endometrial polyps), uterine leiomyomas (fibroids or myomas) are the most observed intrauterine pathological abnormalities [3,4]. Apart from these, endometrial malignancies and retained products of conception (RPOC) resulting from miscar-

riage or termination of pregnancy can be the less common contributors to AUB [5,6]. Hysteroscopic resectoscopy is the most preferred treatment procedure for the removal of structural abnormalities, including endouterine polyps and fibroids since 1970 with satisfactory outcomes [7]. Office hysteroscopy is a powerful tool to visualize the cervical canal and the uterine cavity and serves as an excellent tool in treating endouterine pathologies as it serves the “see and treat” thought, wherein diagnosis, as well as treatment of most benign pathologies without any premedication or anaesthesia, can be done in the same setting [8]. The current trend of diagnostic hysteroscopy reflects it as a selective minor operative procedure that can be performed in an office setup on a conscious patient without the use of anaesthesia [9]. In comparison to transvaginal sonography (TVS), hysterosalpingography (HSG), and saline infusion sonography, hysteroscopy outstands as a gold standard protocol for uterine cavity assessment as it provides direct visualization and an opportunity for concurrent treatment of intrauterine pathologies [10]. TruClear™ 5C (Smith and Nephew; Operative Hysteroscope 5C) hysteroscopic tissue removal system facilitates the procedure of tissue retrieval. Simultaneous tissue cutting and aspiration may reduce the procedure time and steps required, while the window- lock feature optimizes the fluid flow.

In our present retrospective study, we have therefore analysed a large number of patients who underwent office Hysteroscopic tissue retrieval in our centre without the administration of anaesthesia or analgesic agents. We wished to assess the safety, feasibility of the procedure in our setting as well as the acceptance of the procedure among the Indian population.

Materials and Methods

Study design

In this retrospective study, we have analysed 84 patients who had undergone intrauterine tissue retrieval in office for 1 year (May 2019 to April 2020) in a private hospital which has an established outpatient hysteroscopic setup with expertise in office hysteroscopy. Before the procedure, informed written consent was obtained, and counselling of women was done in the outpatient department. Patients with abnormal uterine bleeding or those with the presence of abnormal intrauterine pathologies such as endometrial polyps and fibroids, retained products of conception diagnosed on ultrasound were included in the study. Patients with a suspicion of malignancy, vaginal infections, or who did not consent for office hysteroscopy were excluded from the study.

Office hysteroscopy procedure

Patient was placed in a lithotomy position with her buttocks jutting out of the table and no premedication, hysteroscopy was done using vaginoscopic approach without Sim’s speculum and Vollesellum (no-touch technique) wherein a rigid miniature scope with continuous flow irrigation was introduced in the vagina after separation of the labia majora [11]. Normal saline was the distension media of choice with a flow rate of a maximum 700 mL/min and 60 mm Hg pressure. The handpiece was connected to the control motor unit. Suction was connected to the handpiece and applied to the incisor blade which was inserted in the operative sheath of TruClear 5C scope. Fluid balance was closely monitored. All the material was collected in a collection bag in a canister and sent for histopathological evaluation. Following the introduction of the scope in the vagina, the anterior and posterior fornix was inspected.

External os localized; the scope was moved forward and aligned with internal os keeping the internal os in the centre of the screen as the scope was 0 degree. Upon entering the cavity, a proper and systematic evaluation of uterine cavity was done. At the end of the evaluation, closure of the inflow and reduction of the pressure was done to rule out subtle intrauterine lesions, thus preventing a negative hysteroscopy.

Following the diagnostic hysteroscopy, the incisor blade (2.9 mm disposable) of TruClear 5C intrauterine morcellator was moved ahead under direct vision and window of the blade placed on the pathology and morcellation started at speed of 800 revolutions per minute (rpm). All the morcellated specimen was sent for histological assessment. The age, parity, and other surgical indications were col-

lected, and data were statistically analysed.

The patient was observed for 30 minutes for any pain or discomfort or any other complications after the procedure and was discharged. Patients were called for follow up after 5 days or could contact the doctor in case of any complaints.

The study was approved by the Institution Review Board (IRB) and was in accordance with the code of ethics of World Medical Association (Declaration of Helsinki).

Statistical analysis

Outcomes were presented using descriptive statistics. The Kolmogorov Smirnov test was used to access the normality of data. Continuous data were expressed as mean \pm SD and skewed data by the median and Inter-quartile range (IQR), categorical data as numbers, and percentage. Student's T-tests and ANOVA Test analysis of variance will use to compare the operative time with the various surgical indications. P-Value < 0.05 will consider as statistically significant. All statistical analyses were performed using the R-statistical tool version 3.5.3 and Microsoft excel.

Results

A total of 84 cases with abnormal intrauterine pathologies were enrolled in the study. The average age of the cohort was 32.82 ± 8.74 years, and most of the patients were premenopausal (90.47%). The mean pathological size was noted to be 2.95 CM (SD ± 1.92). About 71.43% were parous with single or more pregnancies. The remaining 28.57% of patients were nulliparous (Table 1). A correlation analysis was done between the age of the patient and mean operative time taken and the results show a positive correlation between the two parameters with a correlation coefficient, $r = 0.216$ ($P = 0.048$). The results indicate that with an increase in age there is also a significant increase in the time taken for the procedure.

Characteristics	Mean \pm SD/%
Age of patient	32.82 \pm 8.74
% Nulliparous	24 (28.57%)
% Parous	60 (71.42%)
Pathology size	2.95 CM \pm 1.92
Menopausal Status	
Pre-menopausal	76 (90.47%)
Post-menopausal	8 (9.53%)
Median time taken (Minutes)	4.05 (0.66 - 15)

Table 1: Baseline characteristics of patients that utilized intrauterine morcellator.

All patients underwent preoperative imaging by ultrasonography before the procedure, with the majority undergoing saline infusion sonography. The various abnormal intrauterine pathologies as observed by the TruClear 5C device were as follows: endometrial polyps, fibroids, retained products of conception (RPOC), and endometrial hyperplasia. The results are as shown in table 2. Since most of the patients were pre-menopausal, the diagnosis was further subdivided based on the menopausal status. There was no significant statistical difference between the groups and the results are as represented in table 3.

Indications	N (Percentage)
Endo polyp/polyp	29 (34.53%)
SB fibroid/fibroid	8 (9.52%)
RPOC	35 (41.67%)
Diffused Pathologies (Hyperplasia)	12 (14.67%)

Table 2: Surgical indications for patients that used the intrauterine morcellator.

Diagnosis	Menopausal status (n(%))	
	Pre-menopausal	Post-menopausal
1	23	6
2	7	1
3	35	0
4	11	1
P-value	0.117	

Table 3: Distribution of Intrauterine pathologies based on menopausal status.

All patients underwent the procedure without the use of anaesthetic agents. We used the “vocal local” technique wherein a female attendant was providing verbal support to the patient throughout the procedure [11].

The operative start time was defined as the time of introduction of the hysteroscope into the vagina and the operative closure time was defined as the time when the device was removed from the vagina. The median operative time was 4.05 minutes (range; 0.66 - 15). The minimum time taken was 0.66 minutes for removal of an endometrial polyp of 1.2 CM in size and the maximum time taken was of 15 minutes for retrieval of fibroid about 2.9 CM in size. The average operative time was based on the age, menopausal status, and the surgical diagnosis was calculated, and results are as shown in table 4. There was a statistically significant difference in the mean operative time between the various intrauterine pathologies ($P = 0.0001$) as determined by the ANOVA test. The pain score during the office hysteroscopic procedure was measured in terms of visual analog score (VAS). Most of the patients did not complain of any form of pain during the procedure, while the few who experienced pain was within the tolerability limit (mild) (Table 5).

Variables	Total	Time Taken (Minute)			P-value
		Mean	SD	Median	
Age Group					
20 - 29	44	4.00	1.93	4.00	0.073
30 - 39	19	5.04	3.06	4.63	
40 - 49	16	5.99	3.97	4.50	
50+	5	4.23	0.32	4.00	
Menopausal status					
Pre-menopausal	76	4.08	0.53	4.00	0.56
Post-menopausal	8	4.68	2.93	4.10	
Diagnosis					
Endo polyp/ polyp	29	3.76	2.47	NA	0.0001
SB fibroid/ fibroid	8	8.56	4.47		
RPOC	35	4.48	2.13		
Hyperplasia/ endo hyperplasia	12	4.53	0.56		

Table 4: Comparison of mean operative time taken for intrauterine morcellator.

Pain Intensity/ Score	No of patients, N (%)
None	69 (76.67)
Mild (1 +/- 3)	20 (22.22)
Moderate (4 +/- 7)	1 (1.11)
Severe (8+/-10)	0 (0.00)

Table 5: Visual analog score (VAS).

Discussion

Office hysteroscopy is a minimally invasive procedure that is highly accurate in diagnosing abnormalities of the endometrial cavity and the endocervical canal.

It allows direct visualization of the uterine pathology without the need for general anaesthesia and the use of an operating room, generating cost savings and greater compliance among patients. The advent of small diameter hysteroscopes, the use of saline solution as a distension media, as well as the vaginoscopic technique have widely contributed to the diffusion of this technique worldwide, and currently, it can be considered the gold standard for the examination of the uterine cavity. The improved technology has also enabled surgeons to perform many operative procedures in an ambulatory setting without significant patient discomfort.

With the development of miniaturized operative hysteroscopes and mechanical instruments, many surgical interventions on the uterine cavity can be performed safely and effectively in the office-based setting, introducing the concept of “see and treat hysteroscopy” [12].

Hysteroscopic tissue removal system aids in the removal of polyps or fibroids without making incisions or use of electricity in the uterus [13].

The first report on the use of an intrauterine morcellator was reported by Emanuel, *et al.* in 2005 on 55 patients with endouterine abnormalities under anaesthesia. In this study, it was observed that the operative time for both endometrial polyps and fibroids was significantly lower for intrauterine morcellator when compared to the use of monopolar high frequency resectoscopy [14]. The operative time was similar to our study which was within an average of 5 to 15 minutes.

Since then a lot of randomized controlled studies have been done to compare the conventional resectoscopy with other techniques. There are mainly four different Tissue removal systems: TruClear™, Myosure, IBS® Integrated Bigatti Shaver, and Symphion™ currently available *in vitro* direct hysteroscopy [15].

In a study by Smith, *et al.* [16] and Pampalona, *et al.* [17] the authors have compared the operative time in office setting between TruClear 5C and bipolar electrosurgical system and in both the studies the operative time was significantly shorter for those who underwent TruClear polyp morcellation.

Since TruClear tissue retrieval is a well-established technique, we did not intend to compare the superiority of the various HTRs. In a retrospective multi-centric study on 146 women undergoing office hysteroscopy for large endometrial polyps (≥ 20 mm), it was observed that the size of the polyp was not related to the overall procedure time [18]. Whereas, in our study, there was a statistical difference in the operative time for different endouterine abnormalities based on their size or pathology ($P = 0.0001$).

In a study by Capmas P, *et al.* of office hysteroscopy on 2402 patients, the mean pain score was 3.57 out of 10 (3.48 - 3.66) and most of the women appreciated the convenient “see and treat” procedure with less time requirement and reduced cost and loss of income [19].

Similarly, in our study, most of the patients (69 cases) did not complain of any pain and very few patients (20 cases) reported mild pain as measured by the visual analog score. In yet another observational clinical study on 4863 patients who underwent office hysteroscopy, the results showed excellent patient satisfaction with 71 - 92% women underwent the procedure without discomfort except for those with large polyps [20].

Most of the patients in our study were diagnosed with RPOC (41.67%) followed by endometrial polyp (34.53%). In this study, the RPOC was successfully removed with a mean operative time of 4.48 minutes without any further complications. The average time taken for the removal of other intrauterine pathologies are as follows: endo polyps- 3.76 minutes, fibroids- 8.56 minutes, and visual D and C- 4.53 minutes.

Despite the introduction of hysteroscopic tissue retrieval techniques, their widespread use among surgeons as well as their implementation for retrieval of pathologies in an office setting is limited. Data available for the “see and treat” philosophy for hysteroscopic tissue retrieval using TruClear morcellator is scanty and thus larger number of studies are required to validate their use on a larger scale.

The major limitations of our study included the removal of uterine pathologies of no greater than 2.95 CM (mean pathological size). For pathologies greater than 3 CM, general anaesthesia, resectoscopy or TruClear 8C were advised.

Conclusion

In office settings, the patient acceptability and procedural pain are directly linked to the time taken for the hysteroscopic surgery as well as the mechanical instrument and pressure setting used for tissue retrieval. Our study supports the use of intrauterine tissue retrieval in an office setting for intrauterine morcellation with different endometrial pathologies with high precision, safety, and tolerability even for large polyps upto 3.5 cm with minimal procedure time and patient satisfaction. In the case of endometrial polyps, a six-month follow can be further taken into consideration to evaluate their recurrence.

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