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Key Words

Office endometrial sampling, vacuum aspirator, MVA syringe, karman cannula, AUB, endometrial biopsy, cancer screening

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Benefits and Implementation of Office Endometrial Sampling Using Vacuum Aspirator in a New Medical College of a Low Middle Income Country

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Abstract

Endometrial biopsy as an office procedure serves as a helpful tool in the work-up of abnormal uterine bleeding (AUB), cancer screening, endometrial dating and infertility evaluation. Although office endometrial sampling using MVA syringe is simple, it is not being implemented effectively because of lack of knowledge, motivation and practice policy. The benefits of Vacuum Aspirator as an office endometrial sampling procedure in terms of feasibility, acceptability, pain scoring, sample adequacy, compliance and cost-effectiveness were analyzed. Measures to implement it for routine OPD care were improvised. A descriptive cross-sectional study was conducted. After a valid informed consent from the client, MVA syringe or sterile 20cc syringe with 4mm karman cannula and a connector was used for endometrial sampling in OPD in patients fulfilling inclusion criteria. A total of 50 patients were enrolled in the study after thorough counseling, detailed history, transvaginal ultrasound. Any minor complications were noted and addressed. Office endometrial sampling using Vacuum Aspirator is feasible, acceptable, practical approach with many benefits compared to traditional DC endometrial biopsy.

INTRODUCTION

Endometrial tissue sampling is one of the most common diagnostic procedures in gynaecology and the primary indication, by far, is the assessment of women with abnormal uterine bleeding^[3]. Histological examination of endometrial tissue remains the standard diagnostic procedure for uterine abnormalities^[3]. An accurate diagnosis facilitates the implementation of optimal treatment strategies. The safety, simplicity and acceptability of endometrial sampling methods influence the extent to which the techniques are employed. Since age old times, Dilatation and Curettage under anaesthesia in a dedicated operating room is being done for the patients needing endometrial sampling. Efforts to use the minimally invasive and feasible alternatives have been tried by many researchers since years. This study envisaged to implement one such method; i.e. office endometrial sampling using MVA syringe and analysed its benefits especially during the pandemic when providing optimal health care with minimal COVID exposure was one of the biggest challenge. Though, office hysteroscopy is the upcoming and effective approach, it needs skilled gynaecologist, OR technician, nursing staff and it is a costly affair especially for a new medical college of a low middle income country.

Aims and Objective:

Overall: To study the benefits of MVA Syringe as an office endometrial sampling procedure and its subsequent implementation during COVID-19 pandemic.

Specific:

- To analysed the feasibility, acceptability and practicability of the procedure.
- To analysed the overall benefits of this procedure with special interest to anaesthesia/analgesia requirement, pain scoring, adequacy of sample, procedure related complications, compliance, exposure risk to COVID and gross benefits in effect to cost.
- To implement MVA as office endometrial sampling procedure during COVID-19 pandemic.

MATERIALS AND METHODS

A total of 75 patients were included in this descriptive cross-sectional study over a period of 6 months (July'2020-December'2020) at DHGMCH, West Bengal and again for 6 months from August'2023-january'2023 at Primescan Imaging Intervention and Diagnostic Centre Pvt. Ltd., Patna. The walk-in patients were selected who attended the Gynaecology OPD and fulfilled the inclusion criteria. The patients with abnormal uterine bleeding, peri or postmenopausal bleeding, suspected endometrial neoplasia, abnormal

PAP smear with atypical cells favouring endometrial origin, screening for endometrial cancer in high risk patients, evaluation for subfertility were incorporated in the study. Initially, a detailed history was taken in case record form and patients were referred for transvaginal ultrasound. After incorporating all the pre-requisites, patients with endometrial thickness more than 4mm in postmenopausal and more than 10mm in reproductive age group were selected. Patients were counseled in detail and informed consent taken. Endometrial sampling was done in OPD couch without analgesia by the treating Gynaecologist using either reusable MVA Syringe or disposable 20cc syringe and 4mm Karman cannula by gently negotiating it through the cervix into the uterine cavity. Twirling the catheter while moving it in and out of the uterine cavity enhanced uptake of uterine tissue, which was aspirated into the catheter and removed^[2]. The specimen obtained was transferred to a specimen bottles containing formalin and normal saline respectively. The specimen was then sent for histopathological examination. In patients with suspected Genital TB, the sample was sent for TB PCR and Gene Xpert.

Immediate outcomes like acceptability, pain scoring using visual analogue scale wherein patients were asked to score on a scale from 0-10 and their facial expressions were analysed for pain experience and numbered from 0-5, analgesia requirement, procedure related complications if any were recorded in case record form. Final outcome in terms of feasibility, practicability, compliance, adequacy of sample, cost-effectiveness, COVID exposure, other merits and demerits if any and finally percentage implementation of the procedure were analysed by questionnaire, clinical assessment and follow up either physical or by teleconsultation. All the details were recorded in case record form. The results were analysed by standard statistical methods.

Inclusion Criteria:

- All woman attending Gynaecology OPD and having indications for endometrial sampling both primary and follow-up like:
- Assessment of Abnormal Uterine Bleeding
- Evaluation of peri and post-menopausal bleeding
- Evaluation of Dysfunctional uterine bleeding not/sub-optimally responding to medical management
- Suspected endometrial neoplasia
- Evaluation and follow up of endometrial hyperplasia
- Screening for endometrial cancer in high risk patients
- Abnormal Pap smear with atypical cells favouring endometrial origin

- Evaluation for subfertility
- In conjunction with LNG IUS insertion
- Chronic endometrial infections

Exclusion Criteria:

- Pregnancy
- Acute pelvic inflammatory disease
- Clotting disorders (coagulopathy)
- Acute cervical or vaginal infections
- Cervical cancer
- Severe cervical stenosis

RESULTS AND DISCUSSIONS

The procedure was accepted by 69 patients, six patients wanted the procedure under anaesthesia because of anxiety and underlying cardiac morbidities. The mean age of population was 41yrs with age range between 35-55yrs. 20 patients had mild pain (1-3), 28 patients had moderate pain (4-5), 12 patients had severe pain (6-7), 7 patients had very severe pain (8-9), 2 patients had excruciating pain and procedure couldn't be done in these patients(10). (Mean 4.72, SD 2.35, SEM 0.34, 90%CI:4.15-5.3, 95%CI: 4.03-5.4, 99%CI: 3.8-5.6). The patients with score more than 5 (27.4%) needed oral analgesia following the procedure while the ones with score more than 9 (2.8%) had to be administered injectable anaelgesics. Only 5 patients had slightly increased bleeding PV which was controlled with IV tranexamic acid 500mg. The procedure was feasible for all the patients enrolled. The sample was adequate in 61 patients while remaining 6 patients needed repeat endometrial biopsy under hysteroscopic guidance as the sample obtained via aspiration was not satisfactory to comment as per the pathologist. The procedure was cost-effective for almost all the patients as it alleviated the need for indoor admission and anaesthesia. Thereby the recruited patients and their attendants didn't have to face loss of wages for absent from work. The procedure proved to be a boon during COVID times alleviating the need for multiple travels, hospital admission and thereby COVID exposure. The procedure was effective to reduce bleeding in acute AUB patients. The histopathology report of majority of patients came as either secretory endometrium or endometritis. Only 10 patients had endometrial hyperplasia, of which only 3 patients had atypical endometrial hyperplasia while remaining 7 patients didn't have atypia. 2 patients were diagnosed with Carcinoma Endometrium. 80 percent increase in implementation of Office Endometrial sampling was noted from baseline over the course of time due to the ease of procedure, various merits and cost-effectiveness of the procedure.

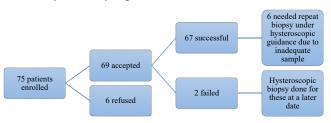
Histological examination of endometrial tissue remains the standard diagnostic procedure for uterine abnormalities^[3]. Endometrial tissue sampling is one of

the most common diagnostic procedures in gynaecology and the primary indication, by far, is the assessment of women with abnormal uterine bleeding^[3]. Accurate diagnosis facilitates the implementation of optimal treatment strategies. The safety, simplicity and acceptability of endometrial sampling methods influence the extent to which the techniques are employed. Endometrial sampling began with the introduction of dilatation of cervix and curettage of uterus (D and C) in the 19th century^[5]. In 20th century it was gradually recognised that therapeutic effectiveness of D and C outside of early-pregnancy was limited, but that D and C could provide endometrial tissue to enable histological diagnosis. The later part of 20th century saw the usefulness of D and C being questioned as a diagnostic tool both in terms of accuracy and tissue yield5. This coincided with the development of miniature devices capable of obtaining tissues samples for histological diagnosis, avoiding the need for anaesthesia and inpatient hospital stay. The routine application of D and C in abnormal bleeding disorders was thus reappraised in light of these advances and recommendation to limit its use was made [6,7]. This has resulted in less invasive and cheaper outpatient biopsy devices becoming established in gynaecology practice^[8].

The procedure is rapid with less than 10% woman complaining excruciating pain^[9]. The overall failure rate of outpatient biopsy procedure is 2.8% (95% CI 5-8%) of all attempted biopsies. Histologically inadequate samples occur in 6% (95% CI 12-17%) of samples overall and in 8.9% (95%CI 10-16%) of vacuum aspirator. Failure rates and inadequate sampling rates are higher among postmenopausal being around 12(95%CI 9-15%) and 22% (95%CI 18-26%) respectively.



Fig. 1: 4mm Karman cannula with connector and 20cc disposable syringe



Flowchart 1: Results of patients enrolled in the study

Table: Pain score and their percentage in the study population (N=69)

Pain Score	1-3	4-5	6-7	8-9	10
Number of patients (N=69)	20	28	12	7	2
Percentage of cases	28.9	40.5	17.3	10.1	2.8

The cumulative cost of this procedure is between 1 to 1.5 USD against 60-70 USD for a traditional D and C and 90-100 USD for Office Hysteroscopy. This method is a boon to the overhauling medical colleges in a low middle income country where we can help maximum number of patients at an affordable cost and with limited resources without burdening the already over-burdened health system. Although the office endometrial sampling using Vacuum Aspirator is very simple, safe, easy, cost-effective still it is not being implemented effectively because of lack of knowledge, motivation and practice policy.

CONCLUSION

Vacuum aspiration is a simple, safe technology that can be used for endometrial sampling, as an alternative to sharp curettage or dilation and curettage (D and C), a surgical procedure that requires facilities with operating rooms4. Using vacuum aspiration offers advantages for both the patient and provider. A vacuum aspiration procedure, an ambulatory procedure, performed in an office (OPD), increases accessibility as well as acceptability for most women. By contrast, D and C requires an operating room which increases the cost of care; furthermore, the woman usually receives general anaesthesia, increasing both her risk and recovery time and hence risk of contracting COVID. Moreover, during this pandemic when COVID testing of every patient was mandatory before any elective operative procedure, it was burdening the already overburdened COVID laboratory, long waiting time and inability of multiple hospital visits due to lockdown and travel restrictions for patients, this technique enabled to provide optimal timely health care.

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