Correlation between Manual Vacuum Aspiration and Endometrial Cell Sampler in Abnormal Uterine Bleeding

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ABSTRACT

Objective: Office endometrial biopsy using an endometrial cell sampler is an accepted method of obtaining endometrial tissue for histopathologic evaluation in women with abnormal uterine bleeding (AUB). Manual vacuum aspiration (MVA) is considered an alternative method, but data specific to the use of MVA is limited. This study aimed to evaluate the efficacy of MVA compared to endometrial cell sampler for diagnosing causes of AUB.

Materials and Methods: This prospective study enrolled women aged ≥35 years who presented with AUB during August 2015 to June 2016. For each patient, endometrial biopsy using an endometrial cell sampler was first performed followed by MVA. Correlation of endometrial histopathology between methods were analyzed using Kappa statistic. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were evaluated.

Results: Of the 162 patients enrolled, the data from 151 women were analyzed. Correspondence of histopathologic finding between tissue obtained from endometrial cell sampler and MVA was 72.8% (Kappa: 0.51). Correspondence of histopathologic finding between tissue obtained from MVA and the final most severe pathology used for treatment decision was 84.1% (Kappa: 0.72). MVA diagnosed all cases of malignancy, but endometrial cell sampler missed one case of malignancy. The overall sensitivity, specificity, PPV, and NPV of MVA was 84.5%, 100%, 100%, and 91.2%, respectively.

Conclusion: The histopathologic findings of MVA were in good agreement with those of endometrial cell sampler, and MVA had high accuracy for diagnosing endometrial pathology. MVA is suggested as a reliable alternative procedure for endometrial biopsy in women with AUB.

Keywords: Abnormal uterine bleeding; endometrial biopsy; endometrial sampling; manual vacuum aspiration
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INTRODUCTION

Abnormal uterine bleeding (AUB) is a common gynecologic problem that affects women of all ages, and that is responsible for a large proportion of visits in outpatient gynecologic practice.[1] AUB was reported as the most common gynecological endocrine abnormalities presenting among new patients in Siriraj Hospital.[2] Endometrial tissue for histopathologic evaluation is the standard investigation in indicated women with AUB, especially in women with risk factors for endometrial cancer. There are a number of techniques that can be employed to obtain endometrial tissue, including hysteroscopy, uterine curettage, and various endometrial sampling devices.[1,3,4]

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Uterine curettage has been a mainstay method for obtaining endometrial tissue for endometrial pathology evaluation in patients with AUB, but this technique has largely been replaced by the use of endometrial sampling devices, which achieve the same objective via a well-tolerated, less invasive, office-based procedure that has less complications. Endometrial sampling devices were reported to yield accuracy comparable to that of uterine curettage for diagnosis of endometrial pathology in patients with AUB.[1,5-10] However, some drawbacks of endometrial sampling devices had been reported as insufficient sample and limited capacity in diagnosis of focal endometrial lesion such as endometrial polyp.[11-15]

Manual vacuum aspiration (MVA), which is a procedure that employs the use of a manual vacuum aspirator, a cannula, and a vacuum syringe, is a widely used in obstetric procedure for termination of early pregnancy. Compared to the standard procedure (uterine curettage), MVA could provide several advantages such as less pain, fewer complications, less invasive, and office-based procedure. However, MVA is not yet widely used due to limitation of supporting data.[16,17] Previous studies found similar tissue adequacy and similar histopathologic finding between MVA and uterine curettage.[18-21] Moreover, MVA was reported to have 86.4-96% sensitivity and 100% specificity for diagnosing endometrial pathology.[19-23] MVA has, therefore, been proposed as an alternative technique for obtaining an endometrial biopsy in women with AUB.

Despite the fact that MVA and endometrial sampling devices are both noninvasive office-based techniques, few studies have compared diagnostic performance between the two methods. Two previous studies reported that the two techniques showed comparable tissue adequacy and diagnostic accuracy[17,23]; however, those studies did not compare the two procedures in the same woman. Moreover, the mechanism of MVA instrument may create a higher degree of negative suction pressure than endometrial sampling devices which could improve the limitation of these devices in sampling focal endometrial lesion. Accordingly, the aim of this study was to prospectively evaluate the diagnostic efficacy of MVA compared to endometrial cell sampler for investigating the causes of AUB.

MATERIALS AND METHODS

This prospective study was conducted during August 2015 to June 2016 at the Department of Obstetrics and Gynecology of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Ethical approval was obtained from the Siriraj Institutional Review Board (SIRB) (COA no. Si 237/2015), and written informed consent to participate was obtained from all study women.

Thai women aged 35 years or more presenting with symptom of AUB at outpatient gynecology unit were eligible for inclusion. Women who were currently pregnant, who had known abnormal cervical cytology, or who were currently using any type of hormonal therapy were excluded. Any enrolled participant with a failed procedure, which was identified as failure to pass the instrument into the uterine cavity, was withdrawn from the study.

All procedures were performed in an outpatient setting by a single well-trained and experienced gynecologist (CS). Participants were placed in the dorsal lithotomy position after voiding. The perineum was prepped and draped using sterile technique. A sterile bivalve speculum was then gently inserted into the vagina. A Wallach® Endocell™ Endometrial Cell Sampler (Cooper Surgical, Inc., Trumbull, CT, USA) was then inserted through the endocervix and into the endometrial cavity. The entire endometrial cavity was sampled by gently moving the device in a 360-degree arc back and forth at least 2 times. That tissue was collected in a container. Finally, an MVA cannula ranging from No. 3 to No. 12 was titrated until the size of the cannula properly fit the size of the endocervical canal in order to create the proper negative pressure for each participant and to improve the effectiveness of MVA, and then the cannula was passed into the endometrial cavity. The number of the largest cannula used was recorded. Negative pressure or vacuum was generated using an Ipas MVA Plus® Aspirator (DKT Women Care Global, London, United Kingdom), and then the aspirator was connected to the cannula. The MVA was moved gently at least two complete 360-degree arcs back and forth within the endometrial cavity. The tissue obtained via MVA was then collected in a second container. Any complications that developed during any procedures were recorded.

The endometrial tissue collected by endometrial cell sampler and MVA was computer randomized into containers labeled 'Endometrium A' or 'Endometrium B' in order to blind the pathologist to the method of sampling. A single specialized gynecologic pathologist (MW) evaluated tissue adequacy and interpreted the histopathologic results. Endometrial glands and stroma both needed to be present in the endometrial tissue specimens as criteria for determining 'tissue adequacy'. In specimens from menopausal women, the term 'tissue adequacy' was substituted with the term 'atrophic endometrium'. The pathology results from endometrial cell sampler and MVA were compared. All specimens were classified

into 4 groups, including 1) inadequate specimen, 2) physiologic changes, 3) benign pathology, or 4) malignant pathology. 'Inadequate specimen' was defined as tissue presence with an absence of endometrial gland and/or endometrial stroma. 'Physiologic changes' was defined as the presence of inactive endometrium, proliferative endometrium, secretory endometrium, glandular and stromal breakdown, or atrophic endometrium. 'Benign pathology' was defined as the presence of endometritis or endometrial polyp. 'Malignant pathology' was defined as the presence of endometrial hyperplasia or endometrial cancer. The final diagnosis in each patient was the most severe pathology from either endometrial cell sampler or MVA. Further management was planned according to the most severe pathology.

Sample size calculation and statistical analysis

The sample size was calculated using data from a previous study that reported a Kappa statistic of 0.56 and a proportion of abnormal endometrial pathology of 35%.[20] Using a sensitivity of 87.7%, a specificity of 100%, and a level of confidence of 95%, the minimum number of enrolled patients was 137. Assuming a 10% dropout rate for any reason, the final number of participants to be recruited was 151.

All statistical analyses were performed using PASW Statistics version 21 for Windows (SPSS, Inc., Chicago, IL, USA). Descriptive statistics were used to summarize patient baseline characteristics. Agreement of endometrial pathology between endometrial cell sampler and MVA, and between MVA and the final most severe pathology was analyzed using Kappa statistic with a value closer to 1.0 indicating better agreement. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of MVA for diagnosis of the most severe pathology was calculated. A *p*-value less than 0.05 was considered to indicate statistical significance.

RESULTS

One hundred and sixty-two patients were prospectively enrolled in this study; however, 11 of those patients were withdrawn from the study due to failed procedure. The data from the remaining 151 patients were included in the final analysis. Baseline patient characteristics are shown in Table 1. The mean age and mean body mass index were 47.6±8.5 years and 26.0±4.5 kg/m^2, respectively. The most frequently used MVA cannula sizes were No. 3 (21.9%), No. 4 (34.4%), and No. 5 (33.8%).

Endometrial cell sampler and MVA obtained 95.4% and 86.8% tissue adequacy, respectively (p=0.002). Table 2 shows the histopathologic results compared between MVA and endometrial cell sampler. Correspondence of pathologic finding between methods was 72.8%, and pathological agreement was moderate (Kappa: 0.51). Pathologic results from MVA showed inadequate specimen in 15 cases of 'Physiologic change' pathology obtained from endometrial cell sampler. MVA diagnosed all malignant pathology (n=4), but endometrial cell sampler misdiagnosed 1 case of endometrial cancer

There was high correspondence of pathologic finding (84.1%) and substantial agreement (Kappa: 0.72) between MVA and the final most severe endometrial pathology that was used to guide management (Table 3). The accuracy of MVA for diagnosis of the final most severe endometrial pathology is shown in Table 4. The overall sensitivity, specificity, PPV, and NPV was 84.5% (95% confidence interval [CI]: 72.6-92.7), 100%, 100%, and 91.2% (95%CI: 83.9-95.9), respectively. No serious complication occurred in this study.

DISCUSSION

Endometrial tissue biopsy is an investigation that is employed to evaluate for endometrial pathology in indicated women with AUB. Outpatient endometrial sampling devices have become a method of choice for this purpose. Thus, endometrial cell sampler, Wallach® Endocell™ Endometrial Cell Sampler, was considered to be the standard procedure in this study. MVA is considered to be an alternative and effective endometrial biopsy method. However, few studies have investigated the efficacy of endometrial tissue collection for evaluation of endometrial pathology compared between MVA and endometrial cell sampler, and no study has compared these two biopsy collection modalities in the same woman. In this study, we directly compared the diagnostic efficacy of an endometrial sampling device (i.e., Wallach® Endocell™ Endometrial Cell Sampler) and MVA. Our results demonstrated MVA to have high accuracy for diagnosing endometrial pathology, and showed high correspondence of pathologic findings between MVA and endometrial cell sampler.

In our study, tissue adequacy identified by pathologist was 95.4% from endometrial cell sampler and 86.8% from MVA, which was statistically significantly different between methods. Previous studies reported 85-98% tissue adequacy from endometrial sampling devices[5-7,10,14,17,23] and 81-99% from MVA.[17-19,23,26] This difference in tissue adequacy between methods among studies could result from different factors, such as study design, the types of devices used, the characteristics of study participants, and differences in the level of operator experience. In contrast to the finding of the present study, the previous

TABLE 1. Baseline characteristics of the study population (N=151).

Characteristics	Mean ± SD or n (%)
Age (years)	47.6±8.5
Body mass index (kg/m^2)	26.0±4.5
Parity	
0	42 (27.9%)
≥1	109 (72.1%)
Menopausal status	
Premenopause	112 (74.2%)
Menopause	39 (25.8%)
Education	
Primary school	34 (22.5%)
High school	43 (28.5%)
Bachelor's degree or higher	74 (49.0%)
Occupation	
Housewife/unemployed	34 (22.5%)
Employee	29 (19.2%)
Government officer	33 (21.9%)
Private business owner	32 (21.2%)
Other	23 (15.2%)
Presence of family history of cancer	
Breast cancer	14 (9.3%)
Colorectal cancer	12 (7.9%)
Ovarian cancer	1 (0.7%)
Other type of cancer	28 (18.5%)
MVA cannula number	
3	33 (21.9%)
4	52 (34.4%)
5	51 (33.8%)
≥6	15 (9.9%)

Abbreviations: SD, standard deviation; MVA, manual vacuum aspiration

TABLE 2. Histopathology obtained from MVA and endometrial cell sampler (N=151).

		Endometrial Cell Sampler				
		Inadequate pathology	Physiologic change	Benign pathology	Malignant pathology	Total
MVA	Inadequate pathology	5 (3.3%)	15 (9.9%)	0 (0.0%)	0 (0.0%)	20 (13.2%)
	Physiologic change	2 (1.3%)	71 (47.0%)	9 (6.0%)	0 (0.0%)	82 (54.3%)
	Benign pathology	0 (0.0%)	14 (9.3%)	30 (19.9%)	0 (0.0%)	44 (29.1%)
	Malignant pathology	0 (0.0%)	0 (0.0%)	1 (0.7%)	4 (2.6%)	5 (3.3%)
	Total	7 (4.6%)	100 (66.2%)	40 (26.5%)	4 (2.6%)	151 (100%)

Abbreviation: MVA, manual vacuum aspiration

TABLE 3. Histopathology obtained from MVA and the final most severe endometrial pathology (N=151).

		The final most severe endometrial pathology				
		Inadequate pathology	Physiologic change	Benign pathology	Malignant pathology	Total
MVA	Inadequate pathology	5 (3.3%)	15 (9.9%)	0 (0.0%)	0 (0.0%)	20 (13.2%)
	Physiologic change	0 (0.0%)	73 (48.3%)	9 (6.0%)	0 (0.0%)	82 (54.3%)
	Benign pathology	0 (0.0%)	0 (0.0%)	44 (29.1%)	0 (0.0%)	44 (29.1%)
	Malignant pathology	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (3.3%)	5 (3.3%)
	Total	5 (3.3%)	88 (58.2%)	53 (35.1%)	5 (3.3%)	151 (100%)

Abbreviation: MVA, manual vacuum aspiration

TABLE 4. Accuracy of MVA for diagnosis of the final most severe endometrial pathology (N=151).

		The final most severe endometrial pathology		
		Benign or malignant pathology	Inadequate pathology or physiologic change	Total
MVA	Benign or malignant pathology	49 (32.5%)	0 (0.0%)	49 (32.5%)
	Inadequate pathology or physiologic change	9 (6.0%)	93 (61.6%)	102 (67.5%)
	Total	58 (38.4%)	93 (61.6%)	151 (100%)

Abbreviation: MVA, manual vacuum aspiration

2 studies that compared endometrial sampling devices and MVA[17,23] found no significant difference in tissue adequacy between methods. One possible explanation for our significantly different tissue adequacy between groups may be that we directly compared both methods in each woman, whereas previous studies did not directly compare both techniques in the same participant. In our study, endometrial cell sampler was used before MVA, so it could be argued that normal and pathologic endometrial tissue is more available and easier to harvest during the endometrial cell sampler procedure, with less tissue being available for harvest during MVA.

Our results showed 72.8% correspondence of pathologic finding with moderate pathologic agreement between endometrial cell sampler and MVA. Moreover, MVA showed 84.1% correspondence of pathologic finding between MVA and the final most severe endometrial pathology used to guide the treatment, which is considered a high level of correspondence. Our result indicates that MVA has comparable efficacy to endometrial cell sampler for investigation and diagnosis of the cause of AUB. Previous studies compared the concordance of pathologic results between either endometrial sampling devices or MVA with uterine curettage or hysterectomy. Tissue obtained from endometrial sampling devices showed 86-94% concordance of pathologic results with uterine curettage[7,9,14], while tissue obtained from MVA showed 63-64% concordance of pathologic finding with uterine curettage or hysterectomy.[20,21,26]

No previous study has directly compared diagnostic accuracy between MVA and endometrial sampling devices. Only one study compared efficacy between MVA and endometrial sampling device, but it did not directly compare both procedures in the same woman. The result of that previous study showed comparable sensitivity and specificity between the two evaluated methods, and the diagnostic efficacy of MVA was 86.4% sensitivity and 96% specificity, which was comparable to our result.[23] Several studies had previously compared the diagnostic efficacy of either MVA or endometrial sampling devices with uterine

curettage. Endometrial sampling devices were reported to have high sensitivity and specificity for diagnosing various endometrial pathologies, such as endometrial hyperplasia, endometrial carcinoma, endometritis[5-7,9], and MVA demonstrated high sensitivity and specificity for diagnosing several endometrial pathologies[19-22], which is consistent with our result. Our study also showed high accuracy of MVA for diagnosing endometrial cancer, while endometrial sampling device misdiagnosed one case of malignancy. However, we could not evaluate the efficacy of MVA for diagnosing endometrial hyperplasia due to there being no endometrial hyperplasia cases in our study.

MVA could produce higher degree of negative suction pressure in the cannula and syringe compared to office endometrial sampling devices. This higher vacuum may lead to more effective tissue retrieval compared to endometrial sampling devices, especially in focal endometrial lesion, and this was reported to be a limitation of endometrial sampling devices.[12,27] Moreover, we used the titration technique and selected the MVA cannula with the best fit to the endocervical canal in order to create the proper negative pressure for each participant and to improve the effectiveness of MVA.

Study strengths and limitations

The strengths of this study include its prospective design, direct comparison of the histopathologic diagnosis from both methods in each woman. All procedures were performed by one gynecologist, and all endometrial specimens were evaluated by one gynecologic pathologist. In addition, the gynecologic pathologist was blinded to the specimen collection method, which reduced bias of histopathology assessment.

This study also has some mentionable limitations. First, the study design may not fully reflect the effectiveness of MVA because MVA was performed following endometrial cell sampler, which was considered to be the standard procedure in this study. Second, we had a small number of endometrial carcinoma and no cases of endometrial hyperplasia. Further study regarding the cost-effectiveness of MVA should be investigated to support the benefit of using MVA as an alternative outpatient endometrial biopsy method in women with AUB in low-resource settings.

CONCLUSION

MVA had high correspondence of pathologic findings with endometrial cell sampler and with the final most severe endometrial pathology that was used to guide management. The results of this study suggest MVA as a reliable alternative minimally invasive outpatient procedure for obtaining an endometrial biopsy in women with AUB.

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Conflict of interest declaration

All authors declare no personal or professional conflicts of interest, and no financial support from the companies that produce and/or distribute the drugs, devices, or materials described in this report.

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