

Comparison of Endometrial Pathology between Tissues Obtained from Manual Vacuum Aspiration and Sharp Metal Curettage in Women with Abnormal Uterine Bleeding

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Objective: To study the correlation of endometrial pathology, which were derived from manual vacuum aspiration (MVA) and sharp metal curettage (SMC).

Material and Method: Women aged over 35 years old who presented with abnormal uterine bleeding were enrolled. Endometrial biopsy using MVA and sharp metal curettage under paracervical nerve block were performed, respectively. Correlation of endometrial pathology from both methods and correlation between endometrial pathology from MVA and the most severe pathology were analyzed using Kappa statistics.

Results: One hundred and thirty two women were enrolled. Nine cases were drop out because of inability to pass the MVA's cannula through the cervical os. Mean age was 49.3 ± 8.5 years old. Mean BMI was 25.1 ± 4 kg/m². Pathological correspondence between tissue obtained from MVA and sharp metal curette was 64.2% and the Kappa agreement was 0.56 ($K_o = 0.56$, p -value < 0.05). Pathological correspondence between tissue obtained from MVA and the most severe pathology was 92.7% and the Kappa agreement was 0.86 ($K_o = 0.86$, p -value < 0.05). MVA could diagnose all cases of malignancy and endometrial hyperplasia.

Conclusion: Manual vacuum aspiration (MVA) can be used as an alternative diagnostic procedure in women with abnormal uterine bleeding.

Keywords: Manual vacuum aspiration, MVA, Curettage, Endometrial

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Women aged over 35 years old with abnormal uterine bleeding have a certain risk of endometrial abnormalities, including cancer^(1,2). These patients have to be further investigated to obtain endometrial tissue for a definite pathology. Other risk factors of endometrial cancer include history of chronic anovulation, obesity, metabolic syndrome, nulliparity, late menopause, diabetes mellitus, unopposed estrogen therapy, tamoxifen therapy, and Lynch II syndrome⁽³⁾. The gold standard for the diagnosis of endometrial pathology is endometrial tissue obtained from hysteroscopic biopsy or hysterectomy⁽⁴⁾. However,

these are invasive procedures, operating room and anesthesia dependence and require experience of operator.

Practically, there are many methods to obtain endometrial tissue in patients with abnormal uterine bleeding. Sharp metal curettage has been used traditionally as a method for diagnosis of endometrial pathology. However, previous studies reported many disadvantages, for example, operating room dependence, risk of anesthetic complication and complication of its own procedure such as uterine perforation and intrauterine infection⁽⁴⁻⁶⁾. Alternatively, previous study supported that the use of endometrial sampling, such as pipelle, is comparable to traditional fractional curettage. This method had high sensitivity and specificity for diagnosis of endometrial pathology^(2,7-9). Nevertheless, these instruments are still costly and disposable.

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Manual vacuum aspiration (MVA) is acceptable as an instrument using for removal of intrauterine contents. It contains only two main parts, an aspirator and a cannula, which is very simple, safe and portable. It is also reusable after disinfection. Its cannula varies in sizes from small to large diameter and can produce high negative pressure (610-660 mmHg) during suction⁽¹⁰⁾. In general practice, MVA has been used not only for termination of early pregnancy but also for endometrial sampling. Previous studies supported that MVA had comparative sensitivity and specificity with other methods⁽¹¹⁾. In addition, it can be used as outpatient procedure under local anesthesia⁽¹²⁾. Moreover, this procedure has more advantages than traditional sharp metal curettage because of its safety, less complication, and cost saving^(13,14). Therefore it could be argued that MVA is an appropriate method of endometrial biopsy for both diagnostic and therapeutic purpose.

Presently, at Siriraj Hospital, MVA was used mainly for termination of early pregnancy but not routinely used for gynecological purpose. Therefore, the objective of this study is to compare the accuracy of MVA with sharp metal curettage for the diagnosis of endometrial pathology in patients with abnormal uterine bleeding.

Material and Method

After approval from Siriraj Institutional Board Review (SIRB), the study was performed between October 2012 and November 2013. Inclusion criteria included women aged over 35 years old who complained of abnormal uterine bleeding and attended at gynecological outpatient unit, Siriraj Hospital. They must be able to read and write Thai language and also volunteer to be subjects in the study. Those who were currently pregnant or had known abnormal Pap smear, pelvic pathology or current hormonal use for endometrial pathology were excluded.

The sample size was calculated from data of previous study using Kappa statistic of 0.59 and the proportion of the abnormal endometrium was 30%. With the null hypothesis agreement, $K_0 = 0.59$, alternative agreement, $K_1 = 0.85$, the level of confidence at 95%, the power at 90%, we used the nQuery Advisor to calculate the number of population including 10% of error which is equal to 132 patients.

After completion of a process of informed consent, a participant was moved to minor operating room and placed in dorsal lithotomy position. Vital signs and pulse oximetry were recorded continuously. The

perineum was prepped and draped with sterile technique. Urinary bladder was emptied and pelvic examination was then performed. Gentle sterile speculum was placed in the vaginal canal. Paracervical nerve block was performed carefully by injection 5 mL of 1% xylocaine with adrenaline to each side. Ten minutes after complete paracervical nerve block, endocervical curettage was performed and tissue was collected in the container named as "endocervix". Next, each MVA's cannula ranged from No. 3 to No. 12 was titrated until it fitted with the endocervical canal and passed into endometrial cavity. Number of the largest cannula and the depth of intrauterine cavity were recorded. After that, negative pressure of the MVA's aspirator was generated and the aspirator was then connected to the cannula. MVA was moved gently around the entire endometrial cavity.

Following MVA, sharp metal curettage was performed thoroughly within intrauterine cavity. If the smallest cannula (No. 3) couldn't be passed through internal cervical os, there would be no further dilation procedure of the cervix and the patient was appointed to perform fractional curettage under narcosis. These groups of patients would be recorded as "Failed". If the patient couldn't tolerate the procedure due to severe pain, 50 mcg of intravenous Fentanyl, also called rescue dose medicine, would be prescribed.

The tissue collected from either MVA or sharp metal curette was computerized randomly into the containers named as "Endometrium A" or "Endometrium B". Then three containers included "Endocervix", "Endometrium A" and "Endometrium B" were sent to a pathologist for evaluation of the adequacy and histopathology of the specimens. Both endometrial glands and stroma needed to be presented in the pathological specimens to determine "tissue adequacy" with the only exception that in case of the menopausal specimens this "tissue adequacy" would be replaced with the term of "atrophic endometrium".

Endometrial tissue from MVA and sharp metal curette were compared. The specimens were classified as "inadequate", "physiological change", "benign pathology" or "malignant pathology". "Inadequate" included tissue that neither perceived endometrial gland nor endometrial stroma. "Physiological change" included inactive endometrium, proliferative endometrium, secretory endometrium, atrophic endometrium. "Benign pathology" included endometritis, endometrial polyp. "Malignant pathology" included endometrial hyperplasia, endometrial cancer. The final diagnosis in this study

defined as the most severe pathology either from MVA or sharp metal curette. Total operative time, pre- and post-operative vital signs and complications after procedure were recorded.

After complete observation for 2 hours after the procedure, patients could be discharged. Prophylactic antibiotic with penicillin or erythromycin was prescribed. They were all followed-up on the next 2 weeks. On the day of follow-up, patients were interviewed about limitation of their daily activity, duration of pelvic pain after procedure and duration of analgesia dependence. Further management of the patient was depended on the most severe pathological result.

Descriptive statistic was used for analysis of baseline characteristic of study population,

Table 1. Characteristic of overall study population (n = 132)

| | Mean (SD) |
|--|------------|
| Age (year) | 49.3 (8.5) |
| Body mass index (BMI) (kg/m ²) | 25.1 (4.0) |
| | n (%) |
| Age group | |
| 35-40 | 18 (13.6) |
| 41-50 | 69 (52.3) |
| 51-60 | 33 (25) |
| >60 | 12 (9.1) |
| Menopausal status | |
| Premenopause | 95 (72) |
| Postmenopause | 37 (28) |
| BMI | |
| Underweight (<18.5 kg/m ²) | 3 (2.3) |
| Normal weight (18.5-23.5 kg/m ²) | 53 (40.2) |
| Overweight (23.5-27 kg/m ²) | 36 (27.3) |
| Obesity (>27 kg/m ²) | 40 (30.3) |
| Parity | |
| Nulliparous | 19 (14.4) |
| multiparous | 113 (85.6) |
| Marital status | |
| Single | 5 (3.8) |
| Marriage | 107 (81.1) |
| Divorce/separate | 20 (15.1) |
| education | |
| ≤secondary | 68 (51.5) |
| >secondary | 64 (48.5) |
| Income | |
| ≤15,000 baht | 37 (28) |
| >15,000 baht | 95 (72) |

characteristic of MVA procedure and clinical data on the day of follow-up. Agreement of endometrial pathology between MVA, sharp metal curettage and the most severe pathology were further analyzed using Kappa statistic (K_0). Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were also calculated in this study. The *p*-value of less than 0.05 indicates statistically significance.

Results

One hundred and thirty two patients were enrolled in this study. Mean age and BMI were 49.3±8.5 years old and 25.1±4 kg/m², respectively. Table 1 showed baseline characteristic of study population. Nine cases were excluded during study because the instruments, both MVA cannula and sharp metal curettage, could not pass through internal cervical os (6.8%).

Table 2 showed characteristic of remaining study population during MVA procedure and clinical follow-up data. The most frequently used cannula sizes

Table 2. Characteristic of remaining study population during MVA procedure and clinical follow-up data (n = 123)

| | Mean (SD) |
|---------------------------------------|-----------|
| Uterine depth (cm) | 8.1 (1.3) |
| | n (%) |
| Size of cannula (number) | |
| 3 | 9 (7.3) |
| 4 | 33 (26.8) |
| 5 | 32 (26) |
| 6 | 22 (17.9) |
| 7 | 14 (11.4) |
| 8 | 8 (6.5) |
| >8 | 5 (4.1) |
| Days with limited daily activity | |
| 0 | 99 (80.5) |
| 1-3 | 20 (16.3) |
| >3 | 4 (3.2) |
| Days with pelvic pain | |
| 0 | 74 (60.2) |
| 1-3 | 41 (33.3) |
| >3 | 8 (6.5) |
| Days with analgesic drugs requirement | |
| 0 | 71 (57.7) |
| 1-3 | 43 (35) |
| >3 | 9 (7.3) |

were between No. 4 and No. 6 (70.7%). The mean uterine depth was 8.1±1.3 cm. Although pelvic pain was common after procedure, interview data on the day of follow-up showed that majority did not have persistent pelvic pain and had no limitation of daily activity after procedure. Postoperative analgesic drug dependence was no more than 3 days in most subjects (92.7%). No requirement of rescue medicine and complication after procedure were reported.

Table 3 showed comparison between pathology obtained from MVA and sharp metal curettage. The pathological correspondence of both methods was 64.2% and pathological agreement was significant ($K_0 = 0.56, p\text{-value} < 0.05$). Similarly, both MVA and sharp metal curettage could diagnose all 6 cases of “malignant pathology”, including 4 cases of endometrioid adenocarcinoma of endometrium, 1 case of uterine sarcoma, and 1 case of simple endometrial hyperplasia without atypia.

However, MVA misdiagnosed some physiologic change and benign endometrial pathology. MVA pathology showed inadequate specimen in 3 cases of “physiologic change” including inactive, proliferative, and atrophic endometrium obtaining from sharp metal curettage. On the other hand, sharp metal curettage could diagnose 7 cases of “benign pathology” including 6 cases of endometrial polyp and 1 case of endometritis, whereas MVA diagnosed these cases as “Physiologic change”.

Regarding to the most severe pathology, Table 4 showed pathological correspondence between MVA and final pathology that was used for management decision. There were high pathological correspondence and almost perfect pathological agreement (92.7% correspondence and $K_0 = 0.86, p\text{-value} < 0.05$) between them.

Accuracy of MVA for the diagnosis of final endometrial pathology was shown in Table 5. Overall sensitivity was 87.7% (95% CI 75.8-94.3), specificity was 100%, positive predictive value of 100%, and negative predictive value of 92.5% (95% CI 84.6-96.5).

Discussion

In cases of abnormal uterine bleeding over the age of thirty five, further investigation of abnormal endometrial pathology is recommended^(1,2). Theoretically, the gold standard for diagnosis of endometrial pathology comes from hysteroscopic resection of endometrial tissue or tissue from hysterectomy specimen⁽⁴⁾. However, Aston and Weaver reported in 2014 that the procedure such as

Table 3. Comparison between pathology obtained from manual vacuum aspiration (MVA) and sharp metal curettage (SMC) (n = 123)

| MVA pathology | SMC pathology | | | | | | | Total | | |
|---------------|---------------|----------|---------------|-----------|----------|--------------|-------|-------|-------------|--------|
| | Inadequate | Inactive | Proliferative | Secretory | Atrophic | Endometritis | Polyp | | Hyperplasia | Cancer |
| Inadequate | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 4 |
| Inactive | 5 | 16 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 24 |
| Proliferative | 3 | 3 | 26 | 0 | 1 | 0 | 4 | 0 | 0 | 37 |
| Secretory | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 5 |
| Atrophic | 0 | 0 | 1 | 0 | 10 | 0 | 0 | 0 | 0 | 11 |
| Endometritis | 1 | 1 | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 7 |
| Polyp | 1 | 2 | 9 | 1 | 6 | 0 | 10 | 0 | 0 | 29 |
| Hyperplasia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Cancer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 5 |
| Total | 11 | 23 | 37 | 6 | 18 | 6 | 16 | 1 | 5 | 123 |

$K_0 = 0.56, p\text{-value} < 0.05$

Table 4. Comparison between pathology obtained from manual vacuum aspiration (MVA) and the most severe pathology (final diagnosis) (n = 123)

| MVA pathology | Final pathology | | | | Total |
|---------------------|-----------------|--------------------|------------------|---------------------|-------|
| | Inadequate | Physiologic change | Benign pathology | Malignant pathology | |
| Inadequate | 1 | 3 | 0 | 0 | 4 |
| Physiologic change | 0 | 70 | 6 | 0 | 76 |
| Benign pathology | 0 | 0 | 37 | 0 | 37 |
| Malignant pathology | 0 | 0 | 0 | 6 | 6 |

Table 5. Accuracy of MVA for diagnosis of final pathology (n = 123)

| MVA pathology | Final pathology | |
|----------------------------|------------------------|----------------------------|
| | Pathological histology | Non-pathological histology |
| Pathological histology | 43 | 0 |
| Non-pathological histology | 6 | 74 |

hysteroscopic diagnosis is still costly and has low rate of positive findings⁽¹⁵⁾.

To find the optimum way, the endometrial sampling can be done by various kinds of instruments such as Pipell, Wallach Endocell or even Karman endometrial vacuum aspiration. All of these techniques have an accepted sensitivity and specificity in detecting abnormal endometrial pathology, as well as they can be done with less pain, more saving and less surgical skill. Moreover, they can be done as the office procedure, too^(14,16-18). However, there is remaining question about these minor procedures, such as Kazandi reported in 2012 about the limitation in diagnostic accuracy of the Pipelle biopsies in focal pathology⁽¹⁹⁾.

In Thailand, sharp metal curettage and endometrial sampling are also common procedures and acceptable for obtaining endometrial tissue. These methods have both advantages and disadvantages. Practically, management of abnormal uterine bleeding is however based on the most severe pathology obtained from any endometrial biopsy methods; MVA, endometrial sampling or sharp metal curettage.

Manual vacuum aspiration (MVA) provides benefit for termination of early pregnancy and is acceptable to use as an alternative method for endometrial biopsy. It has fewer complications than sharp metal curettage and comparable accuracy in cases

of abnormal uterine bleeding^(17,18). In 2000, Suarez et al reported that, regard to diagnose of endometrial hyperplasia and carcinoma, sensitivity of MVA with Karman cannula was 71% and specificity was 93%. They also claimed that this instrument was proper for diagnosis of endometrial polyp because it could detect 86.9% of the cases⁽²⁰⁾. In addition, Tansathit et al reported in 2005 that sensitivity and specificity of Karman aspiration in diagnosis of abnormal endometrium was 89.6% and 100%, respectively. However, using old version Karman cannula, they reported one missing case of endometrial cancer due to the failure to create negative pressure in the uterus⁽¹¹⁾. There are nine cases (6.8%), which were excluded during study because the instruments could not be passed into the uterine cavity. These sampling processes can be reported as the technical failure. Visser et al also reported in 2013 that the prevalence of failed endometrial sampling is up to 20.8% and can be found higher in nulliparity and advanced age women⁽²¹⁾.

The present, MVA showed moderate pathological correspondence (64.2%) and significant agreement ($K_0 = 0.56$) comparable to sharp metal curettage. Regarding to the most severe pathology, MVA showed almost perfect agreement ($K_0 = 0.86$). Overall sensitivity, specificity, PPV and NPV of MVA for diagnosed endometrial pathology was not difference from the previous study performed in

Thailand. It could also diagnose 29 cases of endometrial polyp out of total 35 cases (82.9%). As a result, it could be concluded that MVA was an acceptable tool for diagnosis of endometrial polyp, endometrial hyperplasia and endometrial cancer.

None of serious complication occurred in the present. There was no immediate complication such as cervical laceration or uterine perforation. This could be explained that cervical dilatation was not attempted in cases of cervical stenosis and high experience of the performing physicians. Moreover, because of sterile technique and appropriate antibiotic prophylaxis, there were no cases of pelvic infection on the follow up appointments. Because of this saving technique, MVA could also be introduced to the new graduates for management as the front-line doctor, too⁽²²⁾.

In this present, it has some interesting aspects of methods and outcomes. Firstly, a newer version of MVA (Ipas MVA plus[□]) was used. During procedure, vary sizes of cannulas, from smaller to larger diameters, were titrated during procedure until fit to endocervical canal. It could be claimed that this technique improves an effectiveness of endometrial tissue biopsy because the use of the largest diameter of cannula provides the highest suction capacity. Secondly, it could be recommended that paracervical nerve block with 1% xylocaine is adequate for pain control during procedure because none required rescue medicine during procedure and most of the subjects had no limitation of their activity after procedure. Lastly, compared to sharp metal curettage, MVA could diagnose all malignant pathology, including endometrial hyperplasia and cancer. Unfortunately, MVA missed some benign pathology in seven cases include 6 cases of endometrial polyp and 1 case of endometritis. It could be assumed that these pathologies located as a focal lesion in the endometrial cavity and was not obtained by MVA.

In conclusion, endometrial biopsy using MVA is comparable to sharp metal curettage in diagnosis of endometrial pathology. Pain control with paracervical nerve block was appropriate. We recommend the operator to titrate MVA's cannulas until it fits with the endocervical canal to create optimal negative pressure. Regarding to operating room dependence, need for complicated anesthesia, and cost of hospitalization, MVA is acceptable as an alternative tool for diagnosis of endometrial pathology in patients with abnormal uterine bleeding.

Conclusion

Manual vacuum aspiration (MVA) can be used

as an alternative diagnostic procedure in women with abnormal uterine bleeding.

What is already known on this topic?

Up to the present day, many reports about the efficiency of the various endometrial sampling methods have been published. However, the innovation for the better medical instrument has also been continued and the latest version of the Ipas MVA Plus and Ipas Easy grip Cannulae are introduces⁽¹⁰⁾.

At least two publications about the Ipas MVA Plus are also reported in 2015, but both studies allocated the patients into two groups in order to receive different method of endometrial sampling^(17,18). The result shows that the Ipas MVA Plus is comparable to sharp metal curettage and Wallach Endocell in terms of tissue adequacy.

What this study adds?

In this present, the study aims to use the latest version of the Ipas MVA Plus and Ipas Easy grip Cannulae, as well as to compare Ipas MVA Plus with the sharp metal curettage, which is the traditional and the gold standard for endometrial sampling in Thailand. In order to reduce the bias between the study groups, so in this study, the endometrial tissue for pathologic examination has been collected from the same study patient. And the final result can be stated that the endometrial biopsy using the Ipas MVA Plus is comparable to sharp metal curettage in diagnosis of endometrial pathology.

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Potential conflicts of interest

None.

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การเปรียบเทียบผลทางพยาธิวิทยาระหว่างการใช้เครื่องดูดสุญญากาศด้วยมือและการขูดมดลูกด้วยอุปกรณ์ชนิดโลหะในสภาวะที่มีเลือดออกผิดปกติจากมดลูก

กรกฎ สิริมัย, ตรีภพ เลิศบรรณพงษ์, กิตติ มาลากร, มาลี วรรณิสสร

วัตถุประสงค์: เพื่อศึกษาความสัมพันธ์ของผลตรวจทางพยาธิวิทยาของเยื่อบุโพรงมดลูก ที่เก็บได้จากการใช้เครื่องดูดสุญญากาศด้วยมือ และการขูดมดลูกด้วยอุปกรณ์ชนิดโลหะในสตรีที่มีสภาวะเลือดออกผิดปกติจากมดลูก

วัสดุและวิธีการ: สตรีอายุมากกว่า 35 ปีที่มีสภาวะเลือดออกผิดปกติจากมดลูก และจำเป็นต้องรับการเก็บเยื่อบุโพรงมดลูกเพื่อส่งตรวจทางพยาธิวิทยา ได้รับการชักชวนให้เข้าร่วมการศึกษาวินิจฉัย การเก็บเยื่อบุโพรงมดลูกทำได้โดยการใช้เครื่องดูดสุญญากาศด้วยมือและการขูดมดลูกด้วยอุปกรณ์ชนิดโลหะ ร่วมกับการระงับความรู้สึกโดยการฉีดยาชาบริเวณข้างปากมดลูก จากนั้นหาความสัมพันธ์ของผลตรวจทางพยาธิวิทยาของเยื่อบุโพรงมดลูกที่เก็บได้ จากการใช้เครื่องดูดสุญญากาศด้วยมือกับการขูดมดลูกด้วยอุปกรณ์ชนิดโลหะ และความสัมพันธ์ของผลตรวจทางพยาธิวิทยาของเยื่อบุโพรงมดลูก ที่เก็บได้จากการใช้เครื่องดูดสุญญากาศกับความผิดปกติทางพยาธิวิทยาที่รุนแรงที่สุดโดยใช้วิธีการทางสถิติ Kappa statistics

ผลการศึกษา: สตรีจำนวน 132 คนได้เข้าร่วมโครงการวิจัย มีสตรีจำนวน 9 รายที่ต้องออกจากกรวิจัย เนื่องจากไม่สามารถใส่เครื่องมือตรวจได้ อายุเฉลี่ยของผู้ร่วมวิจัย 49.3 ± 8.5 ปี ค่าดัชนีมวลกายเฉลี่ย 25.1 ± 4 กก./ตร.ม. ความสัมพันธ์ของผลตรวจทางพยาธิวิทยาของเยื่อบุโพรงมดลูก ที่เก็บได้จากการใช้เครื่องดูดสุญญากาศด้วยมือกับการขูดมดลูกด้วยอุปกรณ์ชนิดโลหะเท่ากับร้อยละ 64.2 โดยมี Kappa agreement 0.56 และความสัมพันธ์ของผลตรวจทางพยาธิวิทยาของเยื่อบุโพรงมดลูกที่เก็บได้จากการใช้เครื่องดูดสุญญากาศด้วยมือกับความผิดปกติทางพยาธิวิทยาที่รุนแรงที่สุดเท่ากับร้อยละ 92.7 โดยมี Kappa agreement 0.86 การเก็บเยื่อบุโพรงมดลูกเพื่อส่งตรวจทางพยาธิวิทยา โดยการใช้เครื่องดูดสุญญากาศด้วยมือสามารถวินิจฉัยภาวะมะเร็งและเยื่อบุโพรงมดลูกหนาตัวได้ทั้งหมด

สรุป: การเก็บเยื่อบุโพรงมดลูกเพื่อส่งตรวจทางพยาธิวิทยาในสตรีที่มีสภาวะเลือดออกผิดปกติจากมดลูก โดยการใช้เครื่องดูดสุญญากาศด้วยมือสามารถใช้เป็นวิธีตรวจทางเลือกที่เชื่อถือได้
