

The Adequacy of Endometrial Sampling: Comparison between Manual Vacuum Aspiration and Metal Curettage Method

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Objective: To compare the adequacy of endometrium and the post-procedural pain between the manual vacuum aspiration (MVA) and metal curettage method.

Material and Method: The present research was a clinical experiment. A randomized controlled trial study was done with older than 35-year old females with abnormal intrauterine bleeding who attended the out-patient gynecology department of Maharat Nakhon Ratchasima Hospital between December 1, 2013 and April 30, 2014. Patients were allocated with simple randomization technique into two groups, the experimental group was using MVA and the control group was using conventional metal uterine curettage. Pain levels were assessed according to the visual analogue scale. All tissue samples were examined by pathologists. Statistics used were percentage and Chi-square.

Results: Percentages of tissue adequacy for pathological examination of control and experiment groups were 87.88 and 90.91, respectively. There was no significant difference between the two methods (p -value = 0.572). The patients with severe pain in the experiment group were less than that of the control group. The relative risk is 0.47 (95% CI = 0.30-0.72).

Conclusion: MVA caused less pain than the metal curette method, while both provided the same rate of adequacy of endometrial tissue sampling for pathological diagnosis. The MVA offered more humanized health care for gynecological patients who required such procedure. Further researches focusing on the cost-effectiveness or medical complications could benefit a practice guideline and the health care system for this patient group.

Keywords: Manual vacuum aspiration (MVA), Metal uterine curette, Endometrial adequacy, Pain

J Med Assoc Thai 2015; 98 (6): 523-7

Full text. e-Journal: <http://www.jmatonline.com>

Abnormal vaginal bleeding is a common medical problem⁽¹⁾. It may originate from various parts of female genital tract, e.g., cervix, vagina, uterine tube, the urethra, and ovarian hormones. However, the uterus is the most common cause. Besides the history taking, the physical examination, and the laboratory tests, the best method to diagnose the etiologies depends on the pathology of the endometrium especially in the patients⁽²⁾ older than 35-years-old in whom the endometrial carcinoma is to be differentiated⁽³⁾.

The uterine curettage using the uterine metal curette is considered the standard method for yielding adequate endometrial tissue for the microscopic diagnosis. However, its disadvantage is the pain⁽⁴⁾ that may be so severe that some patients need general anesthesia for relief, which 1 to 3% have anesthetic complications⁽⁵⁾. Other complications of the metal

curette are cervical tear, uterine rupture, visceral organ injury, infection, uterine adhesion, and mortality^(2,6).

New devices have been invented for collecting the endometrium. Most of them are made of flexible plastic small tube, e.g., Pipelle, Z-sampler, Vabra aspirator⁽⁷⁾. Their advantages are convenience and reduction of pain while their disadvantages are expensive and disposable. Moreover, they may yield inadequate tissue due to their small sizes. The rate of inadequate samples for diagnosis has been reported to be 2 to 60%⁽⁸⁾.

Manual vacuum aspiration (MVA) is the method to aspirate the endometrium using the vacuum manually created in the plastic cylinder connecting to the canula. This device has been used to aspirate the conceptive residual for the first trimester abortion worldwide for more than 30 years⁽⁹⁾. The size of plastic tube used depends on the gestational age. At present, the 3-mm diameter plastic tube is developed for collecting the endometrial sampling. Because of its flexibility and the small size of plastic tube, it is expected to cause less pain during the procedure of

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endometrial collection⁽¹⁰⁾. Furthermore, this device is more powerful from vacuum than other devices. Therefore, more tissue for diagnosis is expected⁽¹¹⁾. As a researcher, I am interested in studying the efficacy of the MVA and the metal uterine curette for collecting the endometrial specimen. The main objective of the present study is to compare the adequacy of the tissue for the pathological diagnosis between MVA and the metal uterine curette methods. The second objective is to compare the pain from the endometrial sampling between the two methods.

Material and Method

The present study was the clinical experimental research. It was approved by the Ethic Committee of Maharat Nakhon Ratchasima Hospital. Women, older than 35-years-old, who attended the gynecological out-patient department (OPD) of Maharat Nakhon Ratchasima Hospital due to abnormal uterine bleeding between December 1, 2013 and April 30, 2014, were recruited. All were treated with uterine curettage. The patients who had vaginal bleeding from abortion, abnormal pregnancy or coagulopathy, had allergy to pethidine, or refused to participate were excluded.

The sample size was calculated to be 60 per group by comparing the rate of adequacy of the endometrial tissues obtained from 15 patients of each methods in a pilot study. The type I and type II errors were proposed to be 0.05 and 0.20, respectively. If the rate of procedure failure, which was about 10%, was compensated, the sample size needed to be 66 per group. After all 132 patients had signed the informed consent, they were allocated into two groups using simple random sampling technique. Group 1, the MVA group, using Ipas MVA Plus@ (Ipas 3 mm) manufactured by Ipas protecting women's health, USA. The tube diameter was 3 mm. Group 2 was the metal curette group. Before the procedure was started, demographic data were collected and the patients were facilitated to understand the visual analogue scale (VAS) evaluation by the only one nurse thorough the study period. Pethidine 1 mg/kg (maximum 50 mg) was intravenously administered 15 to 30 minutes before the procedure was started. The patients would not know in which group they were. All patients were treated by only one doctor. All standard steps of procedures were strictly followed in both groups. Pain was evaluated using the VAS (interpretation: score 0 = no pain, 1-6 = pain, 7-10 = severe pain). After the procedure, the tissue samples obtained from both groups were sent to pathologists. If the pathologists,

who did not know to which group each tissue sample belonged, could identify the endometrial epithelium, gland, and stroma, and make diagnosis, such sample would be defined as adequate tissue. All data were described using mean, percentage, and analyzed with Chi-square for comparison of the rate of adequate tissue and pain level from both groups. The *p*-value <0.05 was considered statistically significant.

Results

General characteristics of patients from both groups were similar shown in Table 1. Mean age in group 1 (MVA) and in group 2 (metal curette) were 43.17±7.20 (range 35-70 years) and 43.20±6.67 (range 35-61 years), respectively.

The endometrial tissues sent to pathologists were found adequate 58 (87.88%) in MVA group, and 60 (90.91%) in metal curette group. There was no statistically significant difference between both groups (*p*-value = 0.57).

The various pathological findings of the endometrial tissues were shown in Table 2.

The level of pain was evaluated according to the VAS, no one was found in "no pain", "pain" classes were MVA 49 (74.24), metal curettage 27 (49.91). There were 17 patients (25.76%) in MVA group and 39 patients (59.09%) in metal curette group, having "severe pain". These data were shown in Table 3.

Table 1. General characteristics of the patients from 2 groups

| Characteristics | MVA (n = 66) | Metal curettage (n = 66) |
|----------------------------|-----------------|-----------------------------|
| Mean age (year), mean ± SD | 43.17±7.20 | 43.20±6.67 |
| Median parity | 2 (0-4) | 2 (0-5) |
| Having offspring, n (%) | 54 (81.82) | 58 (87.88) |
| Previous curette, n (%) | 8 (12.12) | 6 (9.09) |

MVA = manual vacuum aspiration

Table 2. The pathological findings of the endometrium yielded from both methods

| Histology | MVA n (%) | Metal curettage n (%) | <i>p</i> -value |
|----------------|--------------|--------------------------|-----------------|
| Adequate | 58 (87.88) | 60 (90.91) | 0.57 |
| Proliferative | 19 (28.79) | 18 (27.27) | 0.85 |
| Secretory | 17 (25.76) | 20 (30.30) | 0.56 |
| Hyperplasia | 1 (1.52) | 3 (4.55) | 0.62 |
| Carcinoma | 1 (1.52) | 1 (1.52) | 1 |
| Other (benign) | 20 (30.30) | 18 (27.27) | 0.70 |

* *p*-value <0.05

Table 3. The level of pain from the uterine curettage compared between MVA and metal curette methods

| Pain level | MVA n (%) | Metal curettage n (%) | RR (95% CI) |
|-------------|--------------|-----------------------------|-------------------|
| Pain | 49 (74.24) | 27 (49.91) | 1 |
| Severe pain | 17 (25.76) | 39 (59.09) | 0.47 (0.30-0.72)* |

RR = relative risk

* *p*-value <0.05

Discussion

In the present study, 132 women who had abnormal uterine bleeding and needed uterine curettage were recruited and equally allocated into two groups, 66 patients/group and the basic characteristics from both groups were similar.

The rate of adequacy of endometrial specimen for pathological diagnosis was not different between both groups, which is consistent with previous study⁽¹¹⁾. However, this study recruited the patients and collected the endometrial specimen at OPD and used analgesic whereas the former study collected the specimen in the operative room under general anesthesia. The rate of the adequacy of endometrial specimen in MVA group is 87.88%, which was close to 88.90% of the former study. Due to the vacuum principle used by the device, the specimen was successfully obtained and enough material for diagnosis.

When the level of pain was evaluated according to the VAS, the numbers of patients with “severe pain” in MVA group were less than that of the metal curette group with statistical significance, the relative risk (RR) is 0.47 (CI: 0.31-0.72). This finding is compatible with the study of Boonyarangkul and Leksakulchai⁽¹⁰⁾ who found that uterine curettage using MVA had lower degree of pain than using the metal curette. However, the pre-operative preparations in two studies were different. In this study, pethidine alone was used while in the previous study, they used a combination of diclofenac, an analgesic, a paracervical block, and misoprostol, the medical cervical dilator.

The mechanism of pain perception⁽¹²⁾ begins when the noxious stimuli trigger the primary afferent nociceptor and the action potential is propagated. Such stimuli may be either chemical or physical. The pain due to the uterine curettage is the physiological process that is associated with somatic nervous system, from scraping the endothelium inside the uterine cavity with a pressing force, the tension of the muscle by the device

usage, and the dilatation of the cervix and of the vagina during the procedure. The MVA device is a small, flexible canula that is used to insert into the uterine cavity for suctioning the endothelium by vacuum force, not pressing force. This study used the 3-mm diameter canula, the small tube. There was no need for cervical dilatation and there was no uterine injury, resulting in less pain than using the metal curette. In the study of the association of various factors and the level of pain severity from uterine curettage by Wongwisetsirikul and Chareonpol⁽⁴⁾, the duration of time of procedure was associated with the level of pain but it was not explored in the present study, although it may affect the interpretation of level of pain. Further studies should consider various relating factors thoroughly.

Conclusion

The uterine curettage is an important procedure for obtaining the endometrial sample for pathological diagnosis in case of abnormal uterine bleeding. The MVA device is small and reusable causing less pain as compared to the metal curettage. Furthermore, the effectiveness of tissue yielding for diagnosis is no different. Therefore, MVA is a good alternative for patients who need the examination for good quality of life and holistic service. Additional studies to compare other factors relating to pain, health economics, and medical complications between both methods should be further performed. They will be useful for improving the guideline of diagnosis and treatment of gynecological patient group.

What is already known on this topic?

Manual vacuum aspiration (MVA) has been used to aspirate the conceptive residual for the first trimester abortion worldwide for more than 30 years. At present, a 3-mm diameter plastic tube is developed for collecting the endometrial sampling. The objective of this study was to compare the adequacy of the tissue for the pathological diagnosis between using MVA and the metal uterine curette methods. A former study collected the specimen in the operative room under general anesthesia.

What this study adds?

The present study compared the adequacy of the tissue for pathological diagnosis between using MVA and the metal uterine curette methods from recruited patients, and collected the endometrial specimen at outpatient department. It used only

intravenous analgesic. The procedure in the present study is simpler and cost less than the other method.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยาระหว่างการดูดมดลูกโดยใช้ *manual vacuum aspiration (MVA)* กับอุปกรณ์ดูดมดลูกชนิดโลหะ

สิริยา กิติโยดม

วัตถุประสงค์: เพื่อเปรียบเทียบความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยาและระดับความปวดจากการดูดมดลูกระหว่างวิธี *MVA* และการใช้อุปกรณ์ดูดมดลูกชนิดโลหะ

รูปแบบการศึกษา: การศึกษาเชิงทดลองทางคลินิก

วัสดุและวิธีการ: เป็นการศึกษาในสตรีอายุมากกว่า 35 ปี ที่มาตรวจที่แผนกผู้ป่วยนอกนรีเวชโรงพยาบาลมหาราชวิทยาลัยด้วยภาวะเลือดออกผิดปกติจากโพรงมดลูก และได้รับการดูดมดลูกเพื่อวินิจฉัย ระหว่างวันที่ 1 ธันวาคม พ.ศ. 2556 ถึง 30 เมษายน พ.ศ. 2557 แบ่งผู้ป่วยเป็นสองกลุ่มโดยการสุ่ม ผู้ป่วยกลุ่มทดลองได้รับการดูดเยื่อโพรงมดลูกด้วยวิธี *MVA* และกลุ่มควบคุมได้รับการดูดมดลูกด้วยอุปกรณ์ดูดมดลูกชนิดโลหะ เนื้อเยื่อจากทั้งสองวิธีถูกส่งตรวจทางพยาธิวิทยาเพื่อการวินิจฉัย ผู้ป่วยทั้งสองกลุ่มได้รับการประเมินความปวดด้วย *visual analogue scale* ทำการวิเคราะห์ข้อมูลโดยใช้สถิติร้อยละ และ *Chi-square*

ผลการศึกษา: จากการศึกษาพบว่า ความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยาในกลุ่มทดลองไม่แตกต่างจากในกลุ่มควบคุม (ร้อยละ 87.88 และ 90.91 ตามลำดับ $p\text{-value} = 0.572$) จำนวนสตรีในกลุ่มทดลองมีอาการปวดอยู่ในระดับปวดมากน้อยกว่ากลุ่มควบคุม มีความเสี่ยงสัมพันธ์เท่ากับ 0.47 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 0.30-0.72)

สรุป: การดูดมดลูกโดยวิธี *MVA* มีประสิทธิภาพไม่แตกต่างกับการดูดมดลูกโดยอุปกรณ์โลหะ ในแง่ของความเพียงพอของชิ้นเนื้อเพื่อการวินิจฉัยทางพยาธิวิทยา แต่ก่อให้เกิดอาการปวดน้อยกว่า การศึกษาเปรียบเทียบเพิ่มเติมในปัจจัยอื่นๆ ที่สัมพันธ์กับความปวด การศึกษาด้านเศรษฐศาสตร์สาธารณสุขและภาวะแทรกซ้อนทางการแพทย์ระหว่างทั้งสองวิธี จึงน่าจะเป็นประโยชน์ในการพัฒนาแนวทางการตรวจวินิจฉัยและรักษาผู้ป่วยนรีเวชกลุ่มนี้ต่อไป
