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Pain during Endometrial Sampling between Menstrual Regulator and Standard Uterine Curette

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Abstract : This study was designed to compare the level of pain of patients during endometrial sampling, using a menstrual regulator and a standard uterine curette. A randomized single-blind clinical trial was conducted on eighty women who had abnormal uterine bleeding and needed diagnostic fractional curettage at the Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital. They were randomly assigned to two groups. The uterine curettage was performed using a menstrual regulator in the first group and a standard curette in the second group. The pain scores before, during and after the curettage procedure were determined by a visual analogue scale. The time for the procedure was observed and the tissue was sent for pathological evaluation. The median pain scores during and 30 minutes after the procedure were lower in the menstrual regulator group compared to those in the standard curette group ($P<0.05$). The time in the menstrual regulator group was shorter ($P<0.05$) and the quality of tissue for diagnosis was better ($P<0.05$) than in the standard curette group. No serious complications were observed between both groups. Using a menstrual regulator for endometrial sampling can significantly reduce the pain, is easier to perform and yields better tissue quality compared to the standard curette.

Key words : uterine curettage, endometrial sampling, menstrual regulator, abnormal uterine bleeding

เรื่องย่อ : ความเจ็บปวดขณะเก็บเนื้อเยื่อโพรงมดลูกระหว่างการใส่เครื่องมือปรับประจำเดือน และเครื่องมือขูดมดลูกมาตรฐาน

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วัตถุประสงค์ : เพื่อเปรียบเทียบระดับความเจ็บปวดของผู้ป่วยขณะเก็บเนื้อเยื่อโพรงมดลูกระหว่างการใช้เครื่องมือปรับประจำเดือนและเครื่องมือดูดมดลูกมาตรฐาน รวมทั้งความยากง่ายในการใช้เครื่องมือและคุณภาพของชิ้นเนื้อที่ได้

ชนิดของการวิจัย : การวิจัยเชิงทดลองทางคลินิกโดยใช้วิธีสุ่มอำพรางฝ่ายเดียวในสตรีที่ตรวจพบว่ามีเลือดออกผิดปกติจากโพรงมดลูก และจำเป็นต้องได้รับการวินิจฉัยโดยการดูดมดลูกแบบแยกส่วน จำนวน 80 คน แบ่งกลุ่มตัวอย่างออกเป็นสองกลุ่ม กลุ่มละ 40 คนโดยวิธีสุ่ม กลุ่มแรกได้รับการดูดมดลูกโดยใช้เครื่องมือปรับประจำเดือน กลุ่มที่สองได้รับการดูดมดลูกโดยใช้เครื่องมือมาตรฐาน จับเวลาที่ใช้ในการดูดมดลูก และประเมินระดับความเจ็บปวด 3 ช่วงเวลาคือ ก่อน ระหว่าง และหลังดูดมดลูก 30 นาที โดยใช้วิธีชั่งแอนาลอกสเกล ส่งชิ้นเนื้อที่ได้จากการดูดมดลูกให้พยาธิแพทย์ประเมินคุณภาพ

ผลการศึกษา : ระดับความเจ็บปวดระหว่างเก็บเนื้อเยื่อโพรงมดลูกและหลัง 30 นาทีพบว่าในกลุ่มที่ใช้เครื่องมือปรับประจำเดือนมีค่าต่ำกว่ากลุ่มที่ได้รับการดูดมดลูกด้วยเครื่องมือมาตรฐานอย่างมีนัยสำคัญทางสถิติ ($P < 0.05$) เครื่องมือปรับประจำเดือนยังใช้เวลาในการดูดมดลูกน้อยกว่าและได้รับชิ้นเนื้อที่มีคุณภาพดีกว่าเครื่องมือมาตรฐานอย่างมีนัยสำคัญทางสถิติ ($P < 0.05$) ไม่พบภาวะแทรกซ้อนที่รุนแรงใดๆ ในผู้ป่วยทั้งสองกลุ่ม

สรุป : การเก็บเนื้อเยื่อโพรงมดลูกโดยใช้เครื่องมือปรับประจำเดือน มีความเจ็บปวดน้อยกว่าเป็นหัตถการที่ทำได้ง่ายกว่าและได้รับชิ้นเนื้อคุณภาพดีกว่าเมื่อเปรียบเทียบกับดูดมดลูกโดยใช้เครื่องมือมาตรฐาน

INTRODUCTION

Abnormal uterine bleeding is a frequent gynecological problem. Usually a history and physical examination, including a pelvic exam, cannot determine the causes, if there is no obvious tumor. Uterine curettage is the standard procedure to collect endometrium for a pathologic exam. This procedure causes a lot of pain and generally general anesthesia is needed.

Suction curettes such as the Pipelle suction curette and the Vabra aspirator were widely studied. These devices produce minimal pain and yield sufficient endometrial tissue for pathological study¹⁻³. The procedure can be performed at an outpatient department. But these devices are not available in most clinics and hospitals.

The menstrual regulator (MR), which has been used in family planning units for a long time, has a suction mechanism like the suction curette. The MR is composed of a 60 ml - negative - syringe and a small catheter. This study was conducted to compare pain, difficulty and tissue quality for pathological exams between the MR and the standard curette.

MATERIAL AND METHODS

A randomized single-blind clinical trial was done on women who were presented with abnormal uterine bleeding and required fractional uterine curettage at the Minor Operating Room, Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital. Exclusion conditions were suspected pregnancy, general anesthesia need, medical diseases (eg. heart disease, hypertension) and heavy bleeding with unstable vital signs.

The main objective was to compare pain during procedure between MR and standard metal curettes. The secondary objectives were quality of endometrial tissue obtained for pathologic study, pain at 30 minutes after procedure and complication.

The pain was evaluated by a visual analogue scale. The sample size was calculated and required 40 cases for each groups.

The patients were informed about the detail of the study and signed consent forms. They were informed about how to score the pain during and 30 minutes after the procedures by the Visual Analogue scale. They were randomized in 2 groups.

A paracervical block and endocervical curettage were performed on both groups. The catheter, attached with a suction syringe, was introduced into the uterine cavity in the MR group. When the valve was opened, the tissue and blood were suctioned and the device was rotated and withdrawn simultaneously. In the standard curette group, the metal curette was used to collect tissue. Hegar dilators were used when the devices could not pass the cervix in both groups.

Pain was evaluated immediately after the procedure and 30 minutes later. The tissue collected was sent for a pathological exam. The patients were scheduled 1 week later for a pathologic report and

had further appropriate management. The pathologist didn't know the methods selected. The quality and quantity data were analysed by Chi-Square and Student t-test. The pain score was analysed by Mann Whitney U test.

RESULT

From Table 1, the mean age of the patients was 40.1 ± 8.2 years; 87.5% were married, 12.5% separated, and 86.3% with vaginal delivery. There were no differences in age, marital status, education, occupation, income and vaginal delivery between both groups.

Table 1. Age, marital status, education, occupation, income and vaginal delivery in both groups.

Data	MR	Standard curette	P value
Age (yr) (mean \pm SD)	39.75 \pm 7.39	40.42 \pm 9.00	0.715**
Marital status	No (%)	No (%)	
Married	37 (92.5)	33 (82.5)	0.18*
Separated	3 (7.5)	7 (17.5)	
Education			
\leq Junior high school	27 (67.5)	29 (72.5)	0.32*
Senior high school / Vocational certificate	7 (17.5)	9 (22.5)	
Higher vocational certificate	3 (7.5)	-	
\geq Bachelor degree	3 (7.5)	2 (5.0)	
Occupation			
Housewife	6 (15)	9 (22.5)	0.44*
Farmer	2 (5)	5 (12.5)	
Official	5 (12.5)	2 (5.0)	
Merchant	11 (27.5)	12 (30)	
Worker	16 (40)	12 (30)	
Income (Baht)			
\leq 5,000	11 (27.5)	13 (32.5)	0.59*
> 5,000 - 10,000	11 (27.5)	14 (35)	
> 10,000 - 20,000	8 (20)	4 (10.0)	
> 20,000	10 (25)	9 (22.5)	
Vaginal delivery			
No	4 (10)	7 (17.5)	0.3.*
Yes	36 (90)	33 (82.5)	

*Chi-square test, **Student t-test

From Table 2, the position of the uterus, cervical dilatation need and uterine length were not different. The procedure time for the MR (2.8 ± 1.4 minutes) was less than that of the standard curette (5.5 ± 4.2 minutes).

Table 2. Uterine position, cervical dilatation need, uterine length and procedure time in both groups.

Data	MR No (%)	Standard curette No (%)	P value
Uterine position			
Anteflexion	16 (40.0)	12 (30.0)	0.53*
Mid position	5 (12.4)	4 (10.0)	
Retroflexion	19 (47.6)	24 (60.0)	
Dilator			
Needed	2 (5.0)	6 (15.0)	0.14*
Not need	38 (95.0)	34 (85.0)	
Uterine length (cm) mean \pm SD	6.87 \pm 0.76	7.00 \pm 1.04	0.54**
Procedure time (min) mean \pm SD	2.84 \pm 1.40	5.51 \pm 4.27	<0.01**

* Chi-square test, **Student t-test

From Table 3, pain scores during MR and standard curettes were 2.25 and 7.35, respectively. Pain scores 30 minutes after was 0 and 1.6, respectively and the pain scores during and after procedure were statistically different ($p < 0.05$).

Table 3. Mean pain scores before, during and after procedure in both groups.

Pain score	MR Median (min-max)	Standard curette Median (min-max)	P value
Before	0.00 (0-6.5)	0.00 (0-1.2)	0.22*
During	2.25 (0-10)	7.35 (2.5-10)	<0.01*
After 30 min	0.00 (0-5.6)	1.60 (0-10)	<0.01*

From Table 4, the MR group has good tissue quality (92.5%) significantly, more than that in the standard curette group (72.0%).

Table 4. Tissue quality of endometrium assessed by the pathologist in both groups.

Tissue quality	MR No (%)	Standard curette No (%)	P value
Poor	3 (7.5)	11 (27.5)	0.02*
Good	37 (92.5)	29 (72.5)	

*Chi-square test

DISCUSSION

The standard uterine curettage has been used for diagnosing the causes of bleeding but it requires anesthesia such as the paracervical block or general anesthesia for pain control. Many endometrial suction devices have been developed; they produce less pain and more convenience^{4,6}. The devices were acceptedly used instead of the standard curette, but the common devices (eg. the Pipelle suction and the Vabra aspiration) were not available in most clinics.

The MR which was used in family planning clinics had a mechanical function as a suction device. The MR could not collect endocervical tissue separately so an endocervical curettage was done first. Nevertheless, this study did not compare endocervical tissue collection.

This study was a randomized single-blinded-clinical trial; the patients and the pathologist didn't know what method was used. The characteristics of both groups, such as age, married status, education, occupation, income, vaginal delivery, position of uterus and necessity of cervical dilatation were not different. The resulting pain from MR during and 30 minutes after procedure was significantly less than that from the standard curette. The procedure time was significantly shorter in the MR group so the MR should be easily performed.

Pathological quality was evaluated by only one pathologist, so there would be no personal variation. The result showed the MR group had good tissue quality 92.5%, while the standard curette group had 72.5%. This difference was significant. The MR was able to suck most of the tissue from the cavity but some endometrial tissue might be retained inside the uterus, in the endocervical canal or in the gauze in standard curette group. Since the endometrial thickness was not measured before the endometrial sampling in this study, it may have effect in pathological quality. But the randomization should minimize this effect. And the pain which was more in the standard curette, may make the procedure shortened and procedure may not be completely done.

This study showed that the menstrual regulator could be used for endometrial sampling and yield a better pathological report.

CONCLUSION

Pain was significantly less in the MR group. The MR was performed simply and had a better quality of endometrial tissue. The MR could be applied generally instead of the diagnostic uterine curettage.

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