นิพนธ์ต้นฉบับ • Original Article

การศึกษาเปรียบเทียบระหว่างการขูดมดลูกโดยใช้อุปกรณ์คาร์แมน แคนนูลากับอุปกรณ์ขูดมดลูกชนิดโลหะ

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Comparison between Karman Cannula and Metal Curette in Uterine Curettage

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วัตถุประสงค์:

1. เพื่อเปรียบเทียบระดับความปวดจากการขูดมดลูกระหว่างการใช้อุปกรณ์คาร์แมน แคนนูลา และอุปกรณ์ขูดมดลูกชนิดโลหะ

2. เพื่อเปรียบเทียบระยะเวลาที่เลือดออกภายหลังการขูดมดลูกระหว่างการใช้อุปกรณ์คาร์แมน แคนนูลา และอุปกรณ์ขูดมดลูกชนิดโลหะ

3. เพื่อเปรียบเทียบความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยา ระหว่างการใช้อุปกรณ์คาร์แมน แคนนูลา และอุปกรณ์ขูดมดลูกชนิดโลหะ

ระเบียบการวิจัย: Randomized controlled trial

สถานที่ศึกษา: โรงพยาบาลศรีนครินทร์ มหาวิทยาลัยขอนแก่น

กลุ่มตัวอย่าง: สตรีที่แผนกผู้ป่วยนอกนรีเวช ที่มีปัญหาเรื่องเลือดออกผิดปกติทางช่องคลอด และต้องได้รับการขูดมดลูก ตั้งแต่วันที่ 16 มิถุนายน พ.ศ. 2540 ถึง 20 มกราคม พ.ศ. 2541

วิธีการศึกษา: การขูดมดลูกด้วยอุปกรณ์คาร์แมน แคนนูลา หรืออุปกรณ์ขูดมดลูกชนิดโลหะ

ตัววัด

1. ระดับความปวดโดยใช้ visual analogue scale และ descriptive pain evaluation

2. ระยะเวลาที่เลือดออกภายหลังการขูดมดลูก โดยนับเป็นวัน

3. ความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยา

ผลการศึกษา: จากการศึกษาพบว่า จำนวนสตรีที่มีอาการปวดอยู่ในระดับรุนแรงมาก พบในกลุ่มที่ขูดมดลูกด้วยอุปกรณ์ชนิดโลหะมากกว่าในกลุ่มที่ขูดมดลูกด้วยอุปกรณ์คาร์แมน แคนนูลา ที่ความเสี่ยงสัมพัทธ์เท่ากับ 5 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 2.25-11.13) และ 7.25 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 2.71-

Objectives:

1. To compare severity of pain from endometrial curettage by Karman cannula and metal curette.

2. To compare duration of bleeding after endometrial curettage by Karman cannula and metal curette.

3. To compare adequacy of pathological specimen obtained by Karman cannula and metal curette.

Design: Randomized controlled trial study

Setting: Srinagarind Hospital, Khon Kaen University

Subjects: Women who attended gynecological outpatient clinic with abnormal uterine bleeding which required endometrial curettage from 16 June 1997 to 20 January 1998 were randomly allocated to either Karman cannula or metal curette group.

Intervention: Endometrial curettage by Karman cannula or metal curette

Main outcome measurement:

1. Level of pain by visual analogue scale and descriptive pain evaluation.

2. Duration of bleeding after endometrial curettage in day(s) by postcard questionnaire.

3. Adequacy of pathological specimen.

Results: The number of patients in the metal curette group who suffered from severe pain was more than that in the Karman cannula group, with relative risk of 5 (95% confidence interval 2.25-11.13) and 7.25 (95% confidence interval 2.71-19.36) in pain assessment by visual analogue scale and by descriptive pain evaluation, respectively. Duration of bleeding after curettage by Karman cannula was 2.93 ± 2.58 days and by metal curette was 2.50 ±

19.36) จากการประเมินด้วย visual analogue scale และ descriptive pain evaluation ตามลำดับ ส่วนระยะเวลาที่เลือดออกภายหลังการขูดมดลูก และความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยา พบว่าทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ โดยพบว่า ระยะเวลาเฉลี่ยที่เลือดออกในกลุ่มที่ขูดมดลูกด้วยอุปกรณ์คาร์แมน แคนนูลาเท่ากับ 2.93 ± 2.58 วัน ในขณะที่กลุ่มอุปกรณ์ขูดมดลูกชนิดโลหะเท่ากับ 2.50 ± 2.06 วัน และความเพียงพอของเนื้อเยื่อเพื่อการวินิจฉัยทางพยาธิวิทยาในกลุ่มอุปกรณ์คาร์แมน แคนนูลาเท่ากับร้อยละ 83.33 ในกลุ่มอุปกรณ์ชนิดโลหะเท่ากับร้อยละ 86.67

สรุปผลการศึกษา: การขูดมดลูกโดยใช้อุปกรณ์คาร์แมน แคนนูลาก่อให้เกิดอาการปวดน้อยกว่าอุปกรณ์ขูดมดลูกชนิดโลหะ ในขณะที่การใช้อุปกรณ์ทั้งสองชนิดสามารถเก็บเนื้อเยื่อเพื่อวินิจฉัยทางพยาธิวิทยาได้ไม่แตกต่างกัน และระยะเวลาที่เลือดออกภายหลังการขูดมดลูกก็ไม่แตกต่างกัน

2.06 days and there was no significant difference in duration of bleeding between the two procedures. Adequacy of pathological specimen was 86.67% in metal curette group and 83.33% in Karman cannula group which was not significantly different.

Conclusion: Endometrial curettage by Karman cannula is less painful than curettage by metal curette and there is no significant difference in both duration of bleeding after the procedure and adequacy of pathological specimen.

Key words: Karman cannula, metal curette, endometrial curettage, pain, bleeding

ศรีนครินทร์เวชสาร 2543; 15(1), 18-22 • Srinagarind Med J 2000; 15(1), 18-22

In Thailand, endometrial curettage by metal curette is a common procedure in management of abnormal uterine bleeding, especially in elderly women. Although it is very effective to stop bleeding and to get adequate endometrial tissue for diagnosis, a large number of patients suffer from severe pain during the operation. Paracervical nerve block immediately performed before curettage can only partially relieve the pain in some cases.[1],[2]

Currently, there are many instruments such as Masterson endometrial biopsy system, Pipelle, and Tis-U-Trap which can be used to collect endometrial tissue without significant pain.[3-6] However, these instruments are not available in most hospitals in Thailand including Srinagarind Hospital.

Karman cannula is the instrument originally designed for menstrual regulation and is widely used in most hospitals in Thailand. Some studies showed that the amount of endometrial tissue obtained from curettage by Karman cannula was comparable to curettage by metal curette.[5],[7] However, there has been no randomized controlled trial to compare the level of pain and efficacy to stop bleeding between these two instruments.

Materials and Methods

This study consisted of 120 women who had abnormal uterine bleeding which required endometrial curettage at Srinagarind Hospital, Khon Kaen University from 16 June 1997 to 20 January 1998. The exclusion criteria were below 20 years of age, abortion, coagulopathy and being given other kinds of analgesia besides paracervical nerve block. Consent form was obtained after proper counseling. One hundred and twenty patients were randomized into two groups, using sealed envelop technique, 60 in each, for endometrial curettage either by Karman cannula or metal curette.

The metal curettes, scoop-shaped instruments, used in this study had different sizes (2 to 15 mm) and were shown in figure 1. The Karman cannula with syringe consisted of a flexible plastic suction cannula and a syringe as a source of vacuum (figure 2). The cannula, made in 4-, 5- and 6-mm diameters, had two opposing ports near the distal end. The 50-ml plastic syringe features a self-retaining cannon plunger to maintain negative pressure suction during curettage. These instruments, metal curette and Karman cannula, can be reused after proper sterilization.

Endometrial curettage technique by metal curette was not different from general practice and by Karman cannula was the same technique as doing menstrual regulation. Upon completion of the endometrial curettage, the obtained tissue was placed in formalin and sent for pathological study. All curettages were performed by gynecologic residents. Pathological evaluation was done by a pathologist who was blinded to the types of curettage.

Data collected included age of patient, parity, type of bleeding, uterine size, pathological diagnosis, level of pain during and immediately after the operation, and duration of postcurettage bleeding.

Pain level was assessed by descriptive pain evaluation (nonsevere and severe) and visual analogue scale (0-6 = nonsevere, 7-10 = severe). Statistical analyses were chi-square test for comparing pain level and adequacy of pathological specimen between two

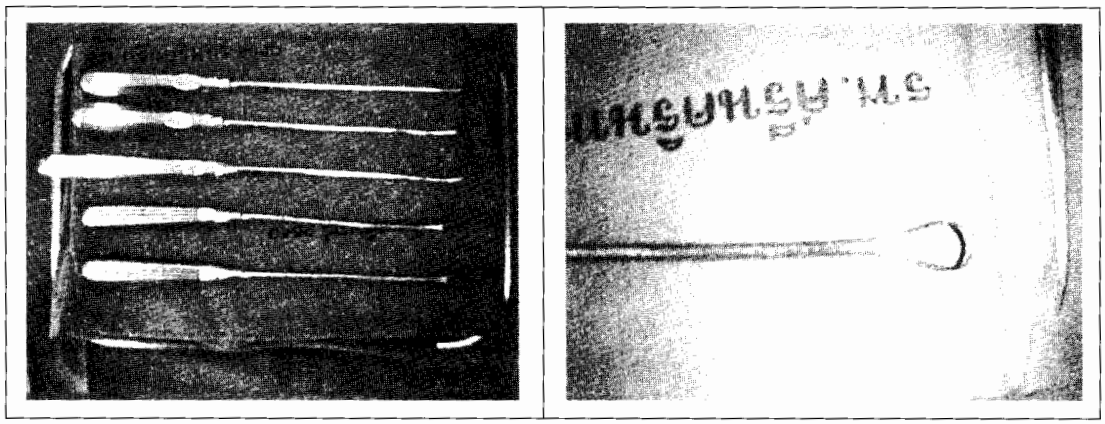

Figure 1. Metal curette

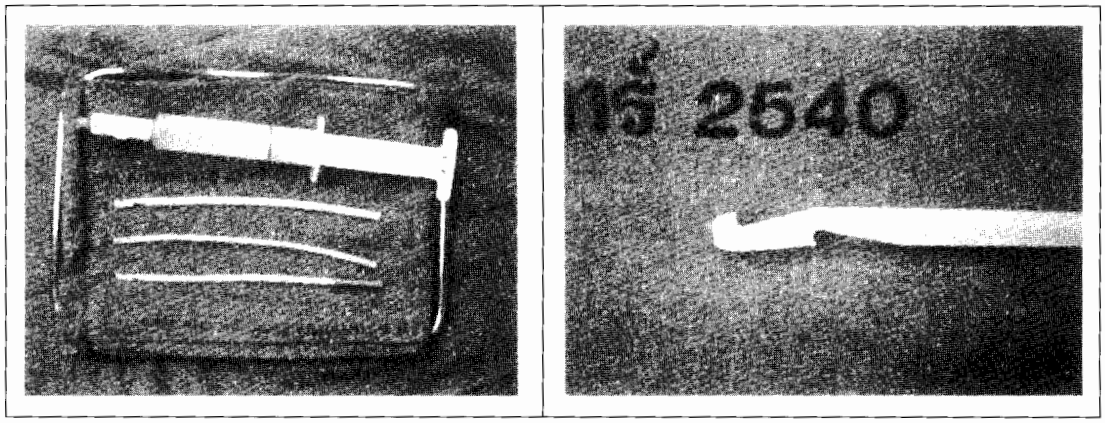

Figure 2. Karman cannula curette

types of curettage and t-test for comparing duration of bleeding in day(s) after curettage. The level of statistical significance was $P < 0.05$. This study was approved by the Ethics Committee of Faculty of Medicine, Khon Kaen University.

Results

Table 1 revealed basic characteristics of patients in this study which were similar in both groups. Using visual analogue scale pain assessment, 30 out of 60 patients (50%) in the metal curette group suffered from severe pain while only 6 out of 60 patients (10%) in the Karman cannula group suffered from severe pain, with a relative risk of 5 (95% confidence interval 2.25-11.13). Descriptive pain evaluation demonstrated very similar results, 48.33% and 6.67% in metal curette and Karman cannula group, respectively, with a relative risk of 7.25 (95% confidence interval 2.71-19.36). The overall correlation of pain level assessment by visual analogue scale and descriptive pain evaluation was high (Kappa value at 0.92).

Table 1. Basic characteristics of patients

Characteristics	Metal curette	Karman cannula
1. Mean age (yr)	44.72 ± 1.15	43.90 ± 0.99
2. Median parity	2 (1-8)	2 (0-10)
3. Mean uterine size (cm)	7.90 ± 1.15	8.39 ± 1.26

Among the 96 patients contacted by postcard after the operation, 50 in metal curette group and 46 in Karman cannula group, duration of bleeding ranged from 1 to 12 days. The duration of bleeding in metal curette group was 2.50 ± 2.06 days and that in Karman cannula group was 2.93 ± 2.58 days. The difference was not statistically significant.

Table 2 revealed pathological diagnoses of the endometrial specimens. Both types of curettage had comparable inadequate tissue for diagnosis, 8 cases (13.33%) in metal curette group and 10 cases (16.66%) in Karman cannula group. The difference was not statistically

Table 2. Pathological diagnoses

Histology	Metal curette (N = 60)	Karman cannula (N = 60)	Total (N =120)
Proliferative	18	18	36
Secretory	19	16	35
Hyperplasia	2	6	8
Carcinoma	1	0	1
Inadequate	8	10	18
Others (Benign)	12	10	22

significant. One case of endometrial carcinoma was diagnosed, while the remaining 101 cases revealed benign conditions.

Discussion

Of all 120 patients underwent endometrial curettage, 60 cases by metal curette and the other 60 cases by Karman cannula, the number of patients who had severe pain in the metal curette group was more than that in the Karman cannula group with relative risk of 5 (95% confidence interval 2.25-11.13) and 7.25 (95% confidence interval 2.71-19.36) in pain assessment by visual analogue scale and by descriptive pain evaluation, respectively. However, postcurettage duration of bleeding (metal curette group = 2.50±2.06 days, Karman cannula group = 2.93±2.58 days) and adequacy of pathological specimen (metal curette group = 86.67%, Karman cannula group = 83.33%) showed no significant difference between these two groups.

The study of Suarez RA *et al.*[5] in 1980 showed that pain from Karman cannula curettage was lower than that from metal curettage and most of this pain severity were comparable to pain caused by venepuncture. This was agreed with the result found in our study.

No definite study regarding postcurettage bleeding by Karman cannula or metal curette has been reported, however we found no significant difference in duration of bleeding between these two groups.

The study of Suarez RA *et al.* also found that adequacy of pathological specimen obtained from Karman cannula was 82% which was close to what was found in our study while adequacy from metal curette was only 76%.[5] Grimes DA[8] reported in 1988 that metal curette could get adequate endometrium in 77%-94% of patients. The adequacy of pathological specimen in our study was higher than that in the study of Suarez RA *et al.*, probably because in the study of Suarez RA *et al.*, they performed endometrial curettage by Karman cannula first and followed by metal curette in the same patient.

In Thailand, Vijatrasil S *et al.*[9] and Kamwilaisak R *et al.*[2] reported 85.7% and 83.9% adequacy of endometrial specimens from metal curette, respectively. The endometrial curettage procedures in Thailand are generally performed in an outpatient basis using similar techniques including paracervical block for pain relief. This probably explains why the adequacy of endometrial specimen from our study was not so different from the results reported by Vijatrasil S *et al.* and Kamwilaisak R *et al.*

The study design of our study was randomized controlled trial so it was suitable for all three objectives. However, our sample size might be too small for the study of adequacy of endometrial specimen. This might not be strong enough to verify the result of adequacy of tissue obtained. Regarding the reliability of our study, the duration of bleeding and the adequacy of endometrial specimen were determined by the patients and the pathologist, respectively. Both evaluators were not aware of the methods of curettage being performed in each case, we thus considered our study reliable in these aspects. In the aspect of pain evaluation, however, we assigned an assistant involving in the curettage procedures to record pain severity. This evaluator, therefore, was not blinded to the method of curettage being used in each case. The limitation was due to the availability of only one official at the time. The reliability concerning pain evaluation, however, was enhanced by using two methods of pain evaluation, descriptive pain evaluation, and particularly, visual analogue scale.

Wongwisetsirikul P and colleagues[9] studied the correlation between pain severity and suffering during curettage and various factors including age of patient, experience of patient related to previous curettage, and duration of curettage procedure and found that duration of curettage was the only factor relating to pain severity. In our study, we did not record duration of curettage in both methods so this might be a confounding factor for the pain evaluation.

We concluded that endometrial curettage by Karman cannula caused less severe pain than metal curette did. Postcurettage duration of bleeding and adequacy of endometrial specimen obtained from these two methods were within comparable ranges. This can be clinically applicable because Karman cannula is widely available in Thailand. It can improve the quality of medical service and possibly receive more acceptability from the patients.

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