GYNAECOLOGY

Comparison of Efficacy between Manual Vacuum Aspiration and Sharp Curettage for the Treatment of Incomplete Abortion

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ABSTRACT

Objective: To compare the pain scores, duration of procedures, estimated blood loss, rate of complete evacuation, uterine perforation, and levels of satisfaction between sharp curettage and manual vacuum aspiration (MVA) for the treatment of incomplete abortion.

Study design: A randomized non-blind clinical trial.

Setting: Khon Kaen Regional Hospital.

Materials and Methods: Thirty-six patients with incomplete abortion, gestational age up to 12 weeks were included and randomized into two groups according to the method of treatment: sharp curettage and MVA. The pain scores were assessed in 4 time period, the procedure time and other complications were also recorded.

Main outcome: Pain level and procedure time for evacuation of intrauterine conceptive products **Results:** Mean pain scores at procedure and at discharge time for MVA versus sharp curettage were 6.39 vs 7.67 (p = 0.001) and 0.28 vs 1.00 (p = 0.01), respectively. The mean procedure duration of MVA was significantly shorter than sharp curettage group, 12.72 minutes and 15.67 minutes, respectively (p = 0.011). There were no significant difference of blood loss, hematocrit change, level of satisfaction between two groups. Rate of complete intrauterine evacuation was 94.4% for both groups. No uterine perforation was found in both procedures.

Conclusion: MVA is less painful, shorter duration and effective as sharp curettage for the treatment of incomplete abortion up to 12 weeks of gestation.

Keywords: sharp curettage, manual vacuum aspiration, incomplete abortion

Introduction

Abortion is one of the most frequent complications of pregnancy. The important problem public health is considered with consequences politics, economics and society. (1) Probably 67,000

women died each year, 10,000, suffering from long – term health consequences including infertility.⁽²⁾ In Thailand, there are about 10,000 abortion patients per year.⁽³⁾

Many factors influence abortion-related

mortality and morbidity such as gestational age, (4-5) the presence of infection in the reproductive tract during abortion, (6) underlying of maternal diseases, experience of physician, (7-8) and also the method used to evacuate the conceptive products from the uterus play a critical role. (9)

Incomplete abortion, expulsion of some but not all of the products of conception before 20 completed weeks of gestation, (10) is a major problem that should be effectively managed with safe and appropriate procedure. (11)

The preferred methods of abortion up to 12 completed weeks by World Health Organization are vacuum aspiration, or medical methods which had been shown effectiveness up to 9 completed weeks. Dilatation and curettage should be used only where none of the above methods are available. (2) Vacuum aspiration was associated with less pain, (11) shorter duration of procedure, (1,11) decreased blood loss, (1,11) and reducing health care cost⁽⁹⁾ when compared with those of sharp curettage. (11) Successful rate for complete evacuation of conceptive products by manual vacuum aspiration (MVA) was 95-100%. (1, 2,5,9,11) Other advantages of this method are the acceptability of doctors and, the satisfaction of the patients. (12-14) MVA was safe, effective and should be recommended for used in the management of incomplete abortion. (1,2,4,5,9,11,15,16)

Despite the advantages of vacuum aspiration, sharp curettage remains a widely used method for uterine evacuation in the treatment of incomplete abortion throughout the developing world⁽²⁾, and also many hospitals in Thailand. There are lacks of literatures that compare the MVA with the sharp curettage in the treatment of abortion in developing countries⁽¹⁾ and few existing data concern the use of this method in Thailand. Thus, the MVA studies should be performed with randomized control trial method to showed the expected good outcome, less complication and encourage the use of this good procedure for treatment of incomplete abortion in Thailand and developing world.

The objectives of this study were to compare the MVA with the sharp curettage in case of

incomplete abortion up to 12 completed weeks' gestation for pain scores (Visual Numerical Rating Scale),(17-18) procedure duration, amount of blood loss during the procedures, change in hematocrit level, efficiency to eliminate the remaining tissue of conceptive products, satisfaction of patients and physicians, and rate of serious complication (uterine perforation).

Materials and Methods

Between July 30, 2008, and August 28, 2008, we recruited 36 women with the diagnosis of incomplete abortion up to 12 weeks of gestation at Khon Kaen Regional Hospital. Informed consent was obtained after the procedures and methods were counseled. History and physical examination were taken and other important data were recorded using questionnaires such as demographic and socioeconomic details of patients.

All subjects had the following inclusion criteria: diagnosis of incomplete abortion (spontaneous or induced) up to 12 completed week's gestation by last menstrual period, bimanual pelvic examination of uterine size and transvaginal ultrasonography. The excluded patients were classified as either the following conditions: coagulopathy or any kind of bleeding disorders, psychogenic diseases or impairment of capacity for evaluating pain scores or satisfactory level from treatment, meperidine and/or diazepam allergies, and patient's uterus size and/or position can not be evaluated.

The patients were randomly assigned using simple randomization opaque sealed envelopes placed in a box from which only one envelop could be drawn at a time by the physician. Finally, eighteen patients for each group were included. Vital signs and conscious level were monitored and recorded before the procedure started. Samples of blood were collected for determining the baseline hematocrit level.

Injections of local anesthesia (paracervical block) were done skillfully. Therefore, we used meperidine 0.5 milligram per bodyweight (kilogram)

plus diazepam 0.2 milligram per bodyweight (kilogram) intravenously about 30 minutes before the procedures in both groups. In the present study, after the drugs were administered, the vital signs were monitored every 5 minutes, observed clinical signs for any possibility of drugs allergies, kept vein open with catheter for intravenous fluid and/or antidote, if needed.

Measurement of time spent in evacuation of conceptive products was started since the time devices were introduced to the cervical canal until the present signs of complete evacuation had been considered, as the generation of uterine harshness of which had the empty uterine socket, that the MVA also determined limitation of the movements of the cannula, its apprehension for the uterine wall, foaming presence of red blood. The procedure time was recorded by a nurse.

The materials for the intrauterine manual aspiration had consisted of a source of vacuum 60 milliliters of double valve, and flexible plastic cannulas in the size (external diameter) 4, 5, 6 ...12 millimeters with suction capacity of 610- 660 millimeters of mercury.

The evacuation procedures were performed by trained physicians (first, second and third year residents)

Pain level were assessed with Visual Numerical Rating Scale 0-10 by the patients during procedures, at 3 hours, 6 hours later, and at time of discharge from the hospital. In Visual Numerical Rating Scale, 0 = no pain, 1, 2, 3,..., and 10 = worstpain. (17,18) All patients were explained about Visual Numerical Rating Scale before the procedures were started. Additional drugs for pain relief, if occurred, would be recorded for types and doses. Hematocrit then was recorded at 6 hours after the procedures in both groups to detect the change of hematocrit level. Blood loss was assessed after completion of the procedures. Blood that contained in the syringe, vagina, and anywhere in the procedure field was absorbed with the cottons and measured with the weighing machine (weight of blood loss = weight of blood absorbed cottons minus total weight of the free

cottons used). In the present study, a free cotton weight was determined, during assessment, the amount of cottons used was counted to calculate the total weight of free cottons.

Specific gravity of blood was found to be 1.0621 (95% CI 1.0652-1.0590) at 4 Celsius degree and 1.0506 (95% CI: 1.0216-1.0193) at 37 Celsius degree, and these values are referred to the density of water,⁽¹⁹⁾ thus we interpreted the blood weight to the amount of blood loss (1 gram of blood weight was approximately represented for 1 milliliters). The weights of conceptive products were recorded in grams by nurses.

Uterine perforation usually caused by uterine sounding or during curettage, the diagnosis was suspected when the estimate depth of the uterine cavity by sounding were deeper than expected. (4) Uterine perforation is usually undetected and resolves without the need for intervention, (2) when uterine perforation is suspected, observation and antibiotics may be administration when necessary. Where available, laparoscopy is the investigative method of choice.

The levels of satisfaction of the evacuation methods were assessed by physicians and patients from 1 to 5, 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied. (20,21) All of the patients were repeated transvaginal ultrasonography in the next morning to document the complete evacuation. This study was approved by the Human Research Ethics Committee of Khon Kaen Regional Hospital.

Sample size calculation

The Visual Numerical Rating Scale was used to assess pain outcome for power analysis. The pilot study was performed in 10 patients at Khon Kaen Regional Hospital. We found the difference mean pain scores of the MVA(4.8) and sharp curettage (5.5) at procedure time was 0.067 and the standard deviation in each group was 0.75 and 0.54, respectively. We used a 95% confidence interval and 80% power. Under these conditions, 15 patients in each group would be needed to demonstrate a

significant difference (18 patients per group with added 20%).

Statistical analysis

Data was analyzed using SPSS version 16.0 (SPSS Inc. Chicago IL). The continuous variables were compared with the independent t- test and categorized variables with the Chi-square test. Results were reported as mean, standard deviation (SD) or percentage. The level of significance was considered at p value <0.05.

Results

Thirty-six women were enrolled into the study, 18 women in the MVA and 18 women in the sharp curettage treatment group. Baseline characteristics in both groups were comparable in age, gestational age, gravidity, level of education, underlying diseases (2 dyspepsia, 1 asthma patient in sharp curettage group, 2 dyspepsia and 1 migraine patient in MVA group), hematocrit level, pelvic infection status, and rate of spontaneous or induced abortion as shown in Table 1. In the induced abortion patients, all cases were performed outside the medical center (unsafe abortion). None of the patient was diagnosed of hypovolemic or septic shock. We did not find any uterine anomalies or myoma uteri by pelvic examination and transvaginal sonography. The

mean pain scores were assessed in 4 periods of time, during the procedure, 3 hours, 6 hours after the procedure and at discharge.

Our data demonstrated that the mean pain scores (range) of sharp curettage, at the procedure was 7.67 (6-10) and at discharge was 1 (0-3), were significantly higher than those of MVA 6.39 (5-8), 0.28 (0-2), p-value of 0.001 and 0.01, respectively. The average (range) time spent in sharp curettage was 15.67 (10-20) minutes, and 12.72 (8-19) minutes for MVA, with statistical significant (p-value 0.001).

There were no significant differences regarding the blood loss, hematocrit change, rate of complete evacuation and, conceptive products weight. Duration of hospital stay was less than 24 hours in all patients. In our study, blood transfusion, additional drugs for pain relief, diagnosed or suspected uterine perforation, cervical injury and anesthetic complications such as drugs allergies, respiratory depression were not found. There were no significant differences regarding the level of satisfaction in each procedure for both patients and physicians. There were two cases of incomplete evacuation, one in MVA and the other in the sharp curettage group; both cases were repeated evacuation by the same prior methods.

Table 1. Baseline characteristics of the two group patients

	Number (n)	Procedures		
		Sharp curettage n=18 (%)	MVA n=18 (%)	p value
Age (years) m*±SD**		27.78 <u>+</u> 6.86	27.94 <u>+</u> 7.86	0.946
Gestational age (weeks) m±SD		10 <u>+</u> 1.680	9.22 <u>+</u> 1.70	0.176
Gravida				
G1	13	7 (38.9)	6 (33.3)	0.723
G2	16	7 (38.9)	9 (50)	
G3	6	3 (16.7)	3 (16.7)	
G4	1	1 (5.6)	0 (0)	
Levels of education				
Primary	11	5 (27.8)	6 (33.3)	0.347
Secondary	12	8 (44.4)	4 (22.2)	

Tertiary	13	5 (27.8)	8 (44.4)	
Pelvic infections status				
No	29	16 (88.9)	13 (72.2)	0.206
Yes	7	2 (11.1)	5 (27.8)	
Types of abortion				
Induced abortion	19	9 (50)	10 (55.6)	0.738
Spontaneous abortion	17	9 (50)	8 (44.4)	
Underlying diseases				
No	30	15(83.3)	15 (83.3)	>0.05
Yes	6	3 (16.7)	3 (16.7)	
Baseline hematocrit(%) m±SD		33.50 <u>+</u> 3.05	31.78 <u>+</u> 2.52	0.73

^{*}m: mean

Table 2. Clinical outcomes of the two procedures

	Number (n)	Procedures		
		Sharp curettage n=18 (%)	MVA n=18 (%)	p value
Pain scores (0-10) m±SD				
At the procedure		7.67 <u>+</u> 0.97	6.39 ± 1.15	0.001*
3 hours		3.61 <u>+</u> 1.09	2.94 <u>+</u> 1.00	0.064
6 hours		1.78 <u>+</u> 0.55	1.39 <u>+</u> 0.78	0.92
At discharge		1.00 <u>+</u> 0.97	0.28 <u>+</u> 0.58	0.01*
Procedure time (min) m±SD		15.67 <u>+</u> 3.13	12.72 <u>+</u> 3.43	0.011*
Blood loss (ml) m±SD		65.83 <u>+</u> 14.98	55.17 <u>+</u> 17.82	0.06
Hematocrit change (%) m±SD		2.22 <u>+</u> 0.94	1.89 <u>+</u> 0.90	0.286
Complete evacuation				
No	2	1 (5.6)	1 (5.6)	> 0.05
Yes	34	17 (94.4)	17 (94.4)	
Levels of satisfaction				
Physicians				0.191
level 1	0	0 (0)	0 (0)	
level 2	3	3 (16.7)	0 (0)	
level 3	17	8 (44.4)	9 (50.0)	
level 4	16	7 (38.9)	9 (50.0)	
level 5	0	0 (0)	0 (0)	
Patients				0.486
level 1	0	0 (0)	0 (0)	
level 2	4	1 (5.6)	3 (16.7)	
level 3	21	12 (66.7)	9 (50.0)	
level 4	11	5 (27.8)	6 (33.3)	

^{**}SD: standard deviation

level 5	0	0 (0)	0 (0)	
Conceptive products weight (grams)				
m <u>+</u> SD		61.61 <u>+</u> 17.69	56 <u>+</u> 16.70	0.344

^{*}Significant level was p-value < 0.05

Discussion

In our study, MVA consumed lesser procedure time than sharp curettage for the treatment of incomplete abortion up to 12 weeks of gestation. In addition, the group that treated with MVA had lesser pain during and after the procedure.

Piriera 2006⁽¹⁾ Mahomed 1994⁽⁹⁾ found that the necessary time for uterine evacuation has been pointed as significantly lesser in MVA, when compared with sharp curettage. In our study, the average time for the uterine evacuation by MVA was lesser than the group with sharp curettage. The result was concordant with other studies.

The previous study revealed that the accomplishment time of procedure and painful sensation told by the patients were inversely proportional to experience of the surgeon. (8) However, in our study, the difference in experience (first, second, and third year residents) was no statistically significant between MVA and sharp curettage group. All of the physicians were trained for MVA and sharp curettage procedure processes by the staffs of Khon Kaen Regional Hospital.

The difference in duration of time between the any two procedures (15 minutes in the sharp curettage group and 12 minutes in the MVA) did not have advantage, and the different between the lengths of stay for the two procedures were not difference. Although both groups of women were discharged relatively quickly after the procedures, MVA group tended to leave the hospital earlier.

MVA can also be performed on an outpatient basis (but not in this study), with analgesia and/or sedation administered as needed. Use of MVA allows women to be treated in a timely manner, rather than waiting for space in the operating room.

The sharp curettage procedure caused more pain as assessed by the patients, during the

procedure and at discharge compared with those experienced by the MVA group. Our data demonstrated that the mean pain scores of sharp curettage at the procedure and at discharge were significantly higher than those of MVA, which was similar to the previous study by Forna 2001.⁽¹¹⁾

The potency for use of minimal pain with MVA are an important advantage in developing- world settings where supplies of drugs are often inadequate or unavailable, (9) or lack of medical personnel. The MVA, with the advantage of the substitution of the general anesthesia for analgesics, or for paracervical blockage, it would contribute to the reduction of hospital cost.

In the previous studies^(1,9,11): the estimated blood loss was lesser for MVA compared with sharp curettage, but in our study, the hematocrit level did not change statistically significant difference between two groups. This may be due to small sample size to demonstrated the significantly difference.

Both MVA and sharp curettage had shown equal efficiency in the uterine evacuation, we found that, both MVA and sharp curettage were highly effective for complete evacuation of the retained conceptive product, which was concordant with the previous studies. (1,2,5,9,11)

No suspected or diagnosed case of uterine perforation was found in the present study. This may be, usually, uterine perforation is undetected, resolves without the need for intervention or too small sample size that this rare serious complication could occurred. Another reason was that MVA did not use any medical or surgical procedure for cervical dilatation, thus decreases the chance for cervical injury or uterine perforation.

The results of this study indicate that MVA is less painful and shorter duration than sharp curettage, and suggest that MVA is at least as effective as sharp curettage, if not more effective in the management of incomplete abortion.

There are several limitations in our study. First, the small sample size, which limited to identify the significant difference between the safety of the MVA with sharp curettage in estimating the blood loss and rate of uterine perforation. Second, the data of late complications such as pelvic infection, abnormal vaginal bleeding were not collected. Third, we did not calculate the cost of the procedure and admission. Fourth, in those two cases of incomplete evacuation, the pathological examination was not done, whether they were conceptive products or blood could not be finalized.

Nowadays, in the Khon Kaen Regional Hospital and many hospitals in Khon Kaen province, most of the method used for treatment of the incomplete abortion is the uterine evacuation by sharp curettage, under analgesia and tranquilizer agents (meperidine plus diazepam intravenous administration) or under general anesthesia. However, the present study indicate that MVA is an effective procedure which causes less pain, shorter duration, and no serious complications, concordant with previous studies. We suggest that the physicians should be trained and encouraged to use MVA as a preferable method for the treatment of incomplete abortion up to 12 weeks gestation.

Conclusion

This study showed that MVA is an effective procedure for the treatment of incomplete abortion up to 12 weeks gestation.

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ประสิทธิผลของกระบอกดูดสุญญากาศเปรียบเทียบกับการขูดมดลูกในการรักษาภาวะแท้งไม่ครบ

อัมรินทร์ สุวรรณ, นฤมิต วงศ์ลิขิตปัญญา

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบระดับความเจ็บปวด ระยะเวลาในการทำหัตถการ ปริมาณการเสียเลือด อัตราความสำเร็จของ การนำชิ้นส่วนของการตั้งครรภ์ออกจากโพรงมดลูก ภาวะมดลูกทะลุ และระดับความพึงพอใจของแพทย์และผู้ป่วยจากการรักษา ภาวะแท้งไม่ครบด้วยการขุดมดลูกและกระบอกดุดสุญญากาศ

ชนิดของการวิจัย: การศึกษาทางคลินิกแบบสุ่มที่มีกลุ่มเปรียบเทียบ

สถานที่ทำการวิจัย : โรงพยาบาลศูนย์ขอนแก่น

วัสดุและวิธีการ: สตรีตั้งครรภ์ อายุครรภ์น้อยกว่า 12 สัปดาห์ที่ได้รับการวินิจฉัยภาวะแท้งไม่ครบจำนวน 36 รายถูกสุ่มเป็น 2 กลุ่ม ได้แก่ กลุ่มที่ได้รับการรักษาโดยการขูดมดลูกและกลุ่มที่รักษาโดยใช้กระบอกคูดสุญญากาศ ระดับความเจ็บปวดถูกประเมินใน 4 ช่วง เวลา บันทึกระยะเวลาในการทำหัตถการและประเมินภาวะแทรกซ้อนอื่นๆ ระหว่างการทำหัตถการ

ตัวชี้วัดสำคัญ: ระดับความเจ็บปวดและระยะเวลาของการทำหัตถการ

ผลการศึกษา : กลุ่มที่ได้รับการรักษาด้วยกระบอกดูดสุญญากาศพบระดับความเจ็บปวดระหว่างการทำหัตถการและขณะจำหน่าย ผู้ป่วยออกจากโรงพยาบาลน้อยกว่ากลุ่มที่ขูดมดลูกอย่างมีนัยสำคัญทางสถิติ โดยค่าเฉลี่ยคะแนนเท่ากับ 6.39 เทียบกับ 7.67 (p < 0.001) และ 0.28 เทียบกับ 1 (p < 0.01) ตามลำดับ นอกจากนี้ค่าเฉลี่ยระยะเวลาของการทำหัตถการพบน้อยกว่าอย่างมีนัยสำคัญ ทางสถิติ คือ 12.72 นาที เทียบกับ 15.76 นาที (p < 0.001) อย่างไรก็ตามไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของปริมาณ การเสียเลือด การเปลี่ยนแปลงระดับความเข้มข้นของเลือด และระดับความพึงพอใจจากการรักษาทั้ง 2 วิธี อัตราความสำเร็จของ การนำชิ้นส่วนของการตั้งครรภ์ออกจากโพรงมดลูกเท่ากับร้อยละ 94.4 ทั้ง 2 วิธี และไม่พบภาวะมดลูกทะลุในการศึกษาครั้งนี้ **สรุป** : จากการศึกษาครั้งนี้พบว่าการรักษาภาวะแท้งไม่ครบในอายุครรภ์ไม่เกิน 12 สัปดาห์โดยการใช้กระบอกดูดสุญญากาศก่อให้

สรุป : จากการศึกษาครั้งนี้พบว่าการรักษาภาวะแท้งไม่ครบในอายุครรภ์ไม่เกิน 12 สัปดาห์โดยการใช้กระบอกดูดสุญญากาศก่อให้ เกิดความเจ็บปวดน้อยกว่า ใช้ระยะเวลาในการทำหัตถการสั้นกว่า เปรียบเทียบกับการขูดมดลูก การนำชิ้นส่วนของการตั้งครรภ์ออก จากโพรงมดลูกโดยการใช้กระบอกดูดสุญญากาศได้ผลสำเร็จเท่ากับการขูดมดลูก