
GYNECOLOGY

Efficacy of Intravenous Sedation, Paracervical Block and Paracervical Block with Lidocaine Spray on Pain Relief during Uterine Curettage in First Trimester Incomplete Abortion: Randomized clinical trial

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ABSTRACT

Objectives: To evaluate efficacy of intravenous sedation, paracervical block (PCB) and PCB plus lidocaine spray for pain relief during uterine curettage in first trimester incomplete abortion.

Materials and Methods: Randomized trial included 121 participants with incomplete abortion at gestational age less than 14 weeks who underwent uterine curettage. They were randomly assigned into three groups: intravenous sedation (meperidine 50 mg and diazepam 10 mg), PCB (5 ml of 1% lidocaine injected at the 4 and 8 o'clock positions of cervix) and PCB plus 10% lidocaine spray 20 mg at the cervix. Pain score was measured using a numerical rating scale (0-10) before, during uterine curettage being undertaken, immediately and 30 minutes after the procedure. Adverse effects were observed and participants' satisfactions were evaluated.

Results: Pain score during the uterine curettage was significantly different across the three treatment groups (median score of 5 in intravenous sedation group, 5 in PCB group, 4 in PCB plus spray group, $p = 0.001$). Further pairwise comparisons found significantly greater benefits on pain relief during the uterine curettage in PCB plus spray than both PCB and intravenous sedation groups ($p = 0.001$ and 0.002 , respectively). Significant differences in pain scores across the three treatment groups were also observed immediately ($p = 0.025$), and 30 minutes after the procedure ($p = 0.003$). Satisfaction of pain relief was lower in the intravenous sedation than the PCB and PCB plus spray groups. The intravenous sedation group reported more nausea and dizziness, while the PCB group reported more symptoms of numbness than the other two groups.

Conclusion: Paracervical block plus 10% lidocaine spray had high efficacy in pain relief in incomplete abortion uterine curettage with fewer minor adverse effects of nausea and dizziness.

Keywords: incomplete abortion, uterine curettage, intravenous analgesia, paracervical block, lidocaine spray.

ประสิทธิภาพในการลดความเจ็บปวดระหว่างการขูดมดลูกในสตรีที่แท้งไม่ครบในไตรมาสแรก : การศึกษาแบบสุ่มเปรียบเทียบระหว่างการให้ยาลดปวดทางหลอดเลือดดำ การฉีดยาชาเฉพาะที่บริเวณปากมดลูก และการพ่นยาชาชนิดระเหยร่วมกับการฉีดยาชาเฉพาะที่บริเวณปากมดลูก

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บทคัดย่อ

วัตถุประสงค์: เพื่อประเมินประสิทธิภาพของการให้ยาลดปวดทางหลอดเลือดดำ การฉีดยาชาเฉพาะที่บริเวณปากมดลูก และการพ่นยาชาชนิดระเหยร่วมกับการฉีดยาชาเฉพาะที่บริเวณปากมดลูก ในการลดความเจ็บปวดระหว่างการขูดมดลูกในสตรีที่แท้งไม่ครบในไตรมาสแรก

วัสดุและวิธีการ: ทำการศึกษาแบบสุ่มในอาสาสมัคร 121 ราย ที่แท้งไม่ครบอายุครรภ์น้อยกว่า 14 สัปดาห์ ซึ่งเข้ารับการรักษาโดยการขูดมดลูก โดยสุ่มแบ่งเป็นสามกลุ่ม ได้แก่ กลุ่มที่ได้ยาลดปวดทางหลอดเลือดดำ (เมเพอริดีน 50 มิลลิกรัม และ ไดอะซีแพม 10 มิลลิกรัม), กลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูก (1% ลิโดเคน 5 มิลลิลิตร ที่ข้างปากมดลูกตำแหน่ง 4 และ 8 นาฬิกา) และกลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูกร่วมกับการพ่นยาชาชนิดระเหย (10% ลิโดเคนสเปรย์ 20 มิลลิกรัม) ประเมินระดับความเจ็บปวดโดยใช้ numerical rating scale (0-10) ก่อนทำหัตถการ ระหว่างทำหัตถการ หลังทำหัตถการทันที และหลังทำหัตถการ 30 นาที รวมถึงสังเกตผลข้างเคียง และสอบถามความพึงพอใจของอาสาสมัคร

ผลการวิจัย: ระดับความเจ็บปวดระหว่างการขูดมดลูกมีความแตกต่างกันอย่างมีนัยสำคัญระหว่างกลุ่มการศึกษาทั้งสาม (ค่ามัธยฐานเท่ากับ 5 ในกลุ่มที่ได้ยาลดปวดทางหลอดเลือดดำ, 5 ในกลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูก และ 4 ในกลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูกร่วมกับการใช้ยาชาชนิดระเหย $p = 0.001$) การศึกษาเปรียบเทียบทีละคู่ พบว่าประสิทธิภาพในการลดปวดระหว่างการขูดมดลูกในกลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูกร่วมกับการใช้ยาชาชนิดระเหยดีกว่ากลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูก และกลุ่มที่ได้ยาลดปวดทางหลอดเลือดดำอย่างมีนัยสำคัญ ($p = 0.001$ และ 0.002 ตามลำดับ) และพบว่ามีความแตกต่างกันอย่างมีนัยสำคัญของระดับความเจ็บปวดระหว่างสามกลุ่มหลังหัตถการทันที ($p = 0.025$) และหลังหัตถการ 30 นาที ($p = 0.003$) ระดับความพึงพอใจต่อยาที่ได้รับในกลุ่มที่ได้ยาลดปวดทางหลอดเลือดดำน้อยกว่ากลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูก และกลุ่มที่ได้ฉีดยาชาเฉพาะที่บริเวณปากมดลูกร่วมกับการใช้ยาชาชนิดระเหย อีกทั้งกลุ่มที่ได้ยาลดปวดทางหลอดเลือดดำ มีคลื่นไส้และมีนงงมากกว่าในขณะที่กลุ่มที่ได้ฉีดยา

ชาเฉพาะที่บริเวณปากมดลูกพบว่ามีกรซามากกว่าอีกสองกลุ่ม

สรุป: การฉีดยาชาเฉพาะที่บริเวณปากมดลูกร่วมกับใช้ยาชาลิโดเคนชนิดละของฝอยมีประสิทธิภาพสูงในการลดความเจ็บปวดในหัตถการขูดมดลูกในสตรีแท้งไม่ครบโดยมีผลข้างเคียงคลื่นไส้และมึนงน้อยกว่า

คำสำคัญ: แท้งไม่ครบ, การขูดมดลูก, การให้ยาลดปวดทางหลอดเลือดดำ, การฉีดยาชาเฉพาะที่บริเวณปากมดลูก, การพ่นยาชาชนิดละของฝอย

Introduction

Incomplete abortion is one of the most common obstetric problems. Bureau of reproductive health, Thailand reported data of 1,415 spontaneous abortion in 2015 with high rate of complications such as requirement for blood transfusion due to excessive hemorrhage (5.0%) and hypovolemic shock (1.3%). Mortality rate from abortion in Thailand during 2005 to 2009 is about 0.06-0.09%⁽¹⁾.

Surgical curettage is considered an effective treatment for incomplete abortion with only 1% failure rate. This procedure is recommended for gestational age lower than 15 weeks⁽²⁾. This life-saving procedure is easy to perform in many settings such as in an operating room or an outpatient office⁽³⁾. However, this procedure causes undesirable pain for which adequate anesthesia is needed. A number of methods for pain relief have been used, including intravenous sedation with meperidine, local anesthesia with paracervical block (PCB)^(4, 5) and lidocaine spray in addition to PCB⁽⁶⁾. The patients who receive sedation with meperidine had more dizziness and nausea while the patients who receive PCB may experience more numbness⁽⁷⁾. While these methods have different adverse effects, evidence on which method is the most effective in pain relief remains inconclusive⁽⁷⁻⁹⁾. The primary objective of this study was to evaluate the efficacy of intravenous sedation, PCB and PCB plus lidocaine spray for pain relief during uterine curettage in first trimester incomplete abortion. The secondary objective was to evaluate adverse effects and satisfaction of the three methods.

Materials and Methods

This three-arm parallel-group randomized trial was conducted in Sanpasitthiprasong Hospital from July 2017 to August 2018 after approval of institutional ethical committee (048/2560). This project was registered at <http://www.thaiclinicaltrials.gov> (TCTR20180802002). All pregnant women, aged 15-45 years old who diagnosed incomplete abortion and required curettage at gestational age lower than 14 weeks were assessed for eligibility. The participants who had septic abortion, unstable vital signs, a history of hypersensitivity to lidocaine or meperidine, and those who were unable to communicate to evaluate pain score were excluded. After enrollment, the participants were randomized into 3 groups: Group 1 – to receive intravenous meperidine 50 mg and diazepam 10 mg and wait for 5 minutes before starting uterine curettage, Group 2 – to spray the cervix with 2 puffs of normal saline followed by PCB with 5 ml of 1% lidocaine solution using 23 gauge spinal needle at cervicovaginal junction 4 and 8 o'clock and wait for 2 minutes before starting the curettage, and Group 3 – to spray the cervix with 2 puffs of 10% lidocaine spray (20 mg) followed by PCB. Random numbers were computer-generated and put in opaque envelopes. After written informed consent was given, an independent research staff opened the envelopes according to the order that the participants enrolled into the study. Incomplete abortion was defined as bleeding that follows partial placental separation and dilation of the cervical os. Gestational age was calculated based on the date of the last menstrual period, in which there

was doubt, this gestational age was estimated by bimanual pelvic examination and/or an ultrasound examination. Standard uterine curettage procedure was performed in all participants. All participants were in lithotomy position. After cleaning of perineum with chlorhexidine solution, the speculum was inserted to expose the whole cervix. Pain relieving method was performed according to the assigned group. Anterior lip of the cervix was clamped at 2 and 10 o'clock with tenaculum. Sharp curettage was performed until uterine cry was heard. The tenaculum was removed, and then bleeding was checked and stopped. The speculum was removed. Doxycycline 100 mg oral twice daily was prescribed for 7 days in all participants.

Sample size was calculated by using the difference of mean pain score from previous study by Karasahin KE et al.⁽⁶⁾ and Allen RH et al.⁽¹⁰⁾ with power of 80% and a 2-sided type I error at 5%. With 10% addition for drop out, sample size per group was 55. Interim analysis was pre-planned at one year after recruitment.

Numerical rating scale (NRS) using to assess pain was defined as "0 is no pain" and "10 is the worst possible pain". Pain was evaluated at any point of time before, during, after procedure immediately and after procedure 30 minutes by the research staff who did not perform procedure. Data on adverse effects, requirement of additional intravenous analgesia, satisfaction to pain-relieving methods used during

procedures, overall satisfaction, and length of hospital stay were recorded.

An intention-to-treat analysis was used with SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were described using number (percentage), mean (standard deviation), and median (interquartile range). Comparisons in outcomes across the three treatment groups were performed using chi-square test, ANOVA and Kruskal-Wallis test for categorical, normally and non-normally distributed continuous variables respectively. Pairwise comparisons were done using chi-square test, student t test and Mann-Whitney-U test. A p-value of < 0.05 was considered statistically significant.

Results

During study period, there were 245 pregnant women presented with incomplete abortion and required curettage. After history review and physical examination, 9 cases were excluded due to unstable vital signs (n = 2), and septic abortion (n = 7). There were 115 pregnant women declined to participate. A pre-planned interim analysis at 12 months of enrollment showed that there was statistically significant different among treatment groups; therefore, the study was terminated. This resulted in a total of 121 pregnant women being enrolled and they were divided into three groups: 43 in the Intravenous sedation, 37 in the PCB and 41 in the PCB plus spray groups (Fig. 1).

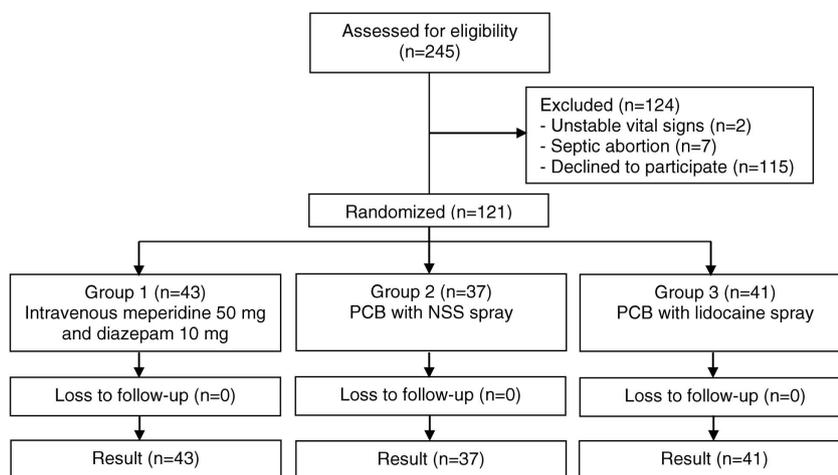


Fig. 1. Enrollment, randomization, and follow-up of the study participants.

The three treatment groups were similar regarding their age, gestational age at enrollment, parity, occupation, education, and body mass index (Table 1).

Table 1. Baseline characteristics of the pregnant women presented with first trimester incomplete abortion, overall and by treatment groups.

	Total (n=121)	Intravenous sedation (n=43)	Paracervical block (n=37)	Paracervical block plus lidocaine spray (n=41)	p value
Age	29 (24,37)	28 (24,37)	29 (21.5,37)	30 (26,36)	0.745
BMI	22.0 (19.1,25.6)	21.8 (18.0,25.0)	23.2(19.1,25.9)	21.6 (19.5,25.0)	0.308
Occupation					0.295
- Housewives	34 (28.1%)	11 (9.1%)	16 (13.2%)	7 (5.8%)	
- Employee	34 (28.1%)	12 (9.9%)	8 (6.6%)	14 (11.6%)	
- Student	7 (5.8%)	4 (3.3%)	2 (1.7%)	1 (0.8%)	
- Government officer	10 (8.3%)	3 (2.5%)	2 (1.7%)	5 (4.1%)	
- Farmer	11 (9.1%)	2 (1.7%)	4 (3.3%)	5 (4.1%)	
- Self-emplo	25 (20.7%)	11 (9.1%)	5 (4.1%)	9 (7.4%)	
Education					0.538
- Primary school	17 (14.0%)	5 (4.1%)	8 (6.6%)	4 (3.3%)	
- Secondary school	58 (47.9%)	20 (16.5%)	18 (14.9%)	20 (16.5%)	
- High Vocational Certificate	18 (14.9%)	7 (5.8%)	6 (5%)	5 (4.1%)	
- Bachelor's degree	24 (19.8%)	10 (8.3%)	5 (4.1%)	9 (7.4%)	
- Master's degree	4 (3.3%)	1 (0.8%)	0 (0%)	3 (2.5%)	
Underlying disease					0.518
- Diabetes mellitus	2 (1.7%)	0 (0%)	1 (0.8%)	1 (0.8%)	
- Thyroid disease	1 (0.8%)	0 (0%)	1 (0.8%)	0 (0%)	
- Hypertension	1 (0.8%)	1 (0.8%)	0 (0%)	0 (0%)	
- Others	1 (0.8%)	0 (0%)	0 (0%)	1 (0.8%)	
Gravidity	2 (1,3)	2 (1,3)	2 (1,3)	2 (1,2)	0.030
Parity	1 (0,1)	10 (0,1)	1 (0,2)	1 (0,1)	0.340
Gestational age	10.3 (9.0,12.0)	10.7 (9.0,12.0)	10.0 (8.4,11.0)	10.4 (9.0,12.0)	0.165
Previous vaginal delivery	59 (48.8%)	23 (19%)	18 (14.9%)	18 (14.9%)	0.680
Previous uterine curettage	10 (8.3%)	6 (5%)	3 (2.5%)	1 (0.8%)	0.159
Prostaglandins used	41 (33.9%)	16 (13.1%)	10 (8.3%)	15 (12.4%)	0.571
Operators					0.061
- 1 st year resident	23 (19.0%)	12 (27.9%)	5 (13.5%)	6 (14.6%)	
- 2 nd year resident	75 (62.0%)	19 (44.2%)	27 (73.0%)	29 (70.8%)	
- 3 rd year resident	23 (19.0%)	12 (27.9%)	5 (13.5%)	6 (14.6%)	

Note: Data in the table are given as or number (percentage) and median (interquartile range) for categorical and continuous variables respectively.

They were also similar according to medical history, including previous history of vaginal delivery, previous history of uterine curettage, history of prostaglandin use and underlying diseases. The only difference between the treatment groups was in gravidity and the difference was very small. Before receiving uterine curettage, participants in the three treatment groups reported similar pain scores (Table 2).

Comparison of pain scores across three treatment groups is shown in Table 2. Pain score during undertaking uterine curettage was significantly different across the three treatment groups (median score of 5 in Intravenous sedation group, 5 in PCB group, 4 in

PCB plus spray group, $p = 0.001$). The differences in pain scores across the three treatment groups remained significant both at immediately and 30 minutes after therapeutic curettage ($p = 0.025$ and 0.003 respectively). Pairwise comparisons found the PCB plus spray group had a lower pain score during the therapeutic curettage than PCB ($p = 0.001$) and Intravenous sedation group ($p = 0.002$). Similar findings on pairwise comparison both at immediately and 30 minutes after therapeutic curettage were also observed.

Fig. 2. shows changes in pain scores at different time points by treatment groups. No additional intravenous analgesia was given in all treatment groups.

Table 2. Comparison of pain score among groups before, during, immediately and 30 minutes after uterine curettage.

	Total (n=121)	Intravenous sedation (n=43)	Paracervical block (n=37)	Paracervical block plus lidocaine spray (n=41)	p value
Before procedure	1 (0, 5)	0 (0, 5)	2 (0, 5)	0 (0, 3)	0.098
During procedure	5 (4, 7)	5 (5, 8)	5 (5, 7)	4 (3, 5)	0.001
		p = 0.800		p = 0.001	
		p = 0.002			
After immediately	2 (0, 4)	3 (1, 5)	2 (0, 5)	1 (0, 3)	0.025
		p = 0.144		p = 0.292	
		p = 0.006			
After 30 minutes	0 (0, 0)	0 (0, 2)	0 (0, 1)	0 (0, 0)	0.003
		p = 0.242		p = 0.020	
		p = 0.001			

Note: Values in the table are given as median (interquartile range) and Kruskal-Wallis test was used for comparison across treatment groups.

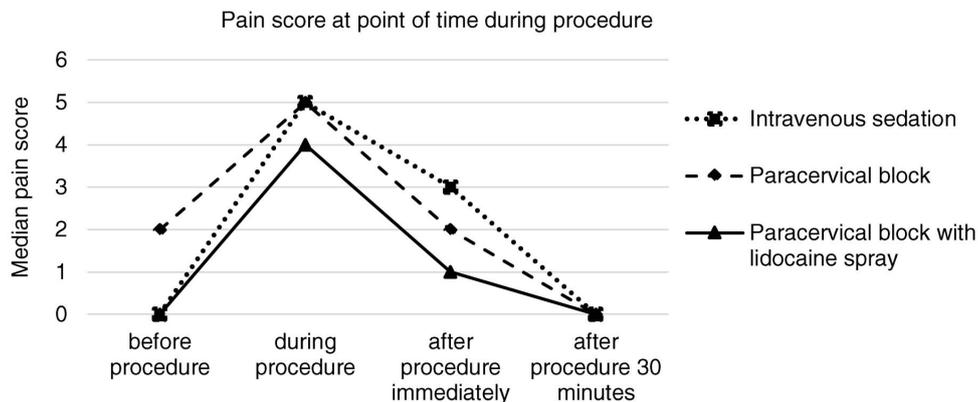


Fig. 2. Pain score at point of time during procedure.

Adverse effects and complications are shown in Table 3. Nausea and dizziness were significantly different across treatment groups, with the Intravenous sedation group reporting considerably more frequent than the other two groups ($p < 0.001$). Numbness was significantly different across treatment groups, with

highest occurrence in the PCB group. There were a few participants having vomiting, tinnitus and feeling metallic taste, and there was no difference in these adverse effects between treatment groups. No serious complication such as uterine perforation was reported in either group.

Table 3. Comparison of adverse effects among treatment groups.

	Total (n=121)	Intravenous sedation (n=43)	Paracervical block (n=37)	Paracervical block plus lidocaine spray (n=41)	p value
Nausea	22 (18.2%)	17 (14.0%)	2 (1.7%)	3 (2.5%)	< 0.001
Vomiting	1 (0.8%)	1 (0.8%)	0 (0%)	0 (0%)	0.401
Dizziness	26 (21.5%)	20 (16.5%)	4 (3.3%)	2 (1.7%)	< 0.001
Tinnitus	7 (5.8%)	2 (1.7%)	3 (2.5%)	2 (1.7%)	0.767
Numbness	5 (4.1%)	0 (0%)	4 (3.3%)	1 (0.8%)	0.043
Metallic taste	1 (0.8%)	0 (0%)	0 (0%)	1 (0.8%)	0.374

Note: values in the table are given as number (percentage).

Overall satisfaction was not significantly different among the three treatment groups (Table 4). Satisfaction of pain-relieving methods significantly

differed across treatment groups ($p = 0.010$). Unsatisfaction was exclusively reported in 3.3% of the participants in the Intravenous sedation group.

Table 4. Levels of overall and anesthesia-related satisfaction of participants in three treatment groups.

	Total (n=121)	Intravenous sedation (n=43)	Paracervical block (n=37)	Paracervical block plus lidocaine spray (n=41)	p value
For pain-relieving methods					0.01
- Unsatisfied	4 (3.3%)	4 (3.3%)	0 (0%)	0 (0%)	
- Neutral	6 (5%)	1 (0.8%)	1 (0.8%)	4 (3.3%)	
- Satisfied	55 (45.5%)	15 (12.4%)	24 (19.8%)	16 (13.2%)	
- Very satisfied	56 (46.3%)	23 (19%)	12 (9.9%)	21 (17.4%)	
Over all					0.15
- Unsatisfied	2 (1.7%)	2 (1.7%)	0 (0%)	0 (0%)	
- Neutral	7 (5.8%)	3 (2.5%)	1 (0.8%)	3 (2.5%)	
- Satisfied	55 (45.5%)	16 (13.2%)	23 (19.0%)	16 (13.2%)	
- Very satisfied	57 (47.1%)	22 (18.2%)	13 (10.7%)	22 (18.2%)	

Note: values in the table are given as number (percentage)

Discussion

In this three-arm parallel-group randomized control trial, PCB with lidocaine spray had higher efficacy in pain relief during, immediate and at 30 minutes after uterine curettage compared to PCB alone and intravenous sedation, with minimal adverse effects reported. From the patient perspectives, PCB plus lidocaine spray was among the most satisfactory anesthetic methods.

The different mechanisms to pain relief of intravenous sedation and PCB with and without lidocaine spray may explain our key results. In term of mechanisms to relieve pain during curettage procedure, intravenous opioid binds to opioid receptors in the central nervous system, inhibits ascending pain pathways, and alters the perception and response to pain. This central acting mechanism of intravenous sedation method causes adverse effects such as nausea, vomiting⁽¹⁰⁾. Paracervical block is another proven method of pain relief during this procedure⁽⁵⁾. The anesthetic mechanisms of lidocaine in paracervical block are mechanical distention of tissue and peripheral nerve block⁽¹¹⁾. However, paracervical block alone may not provide adequate analgesia⁽¹²⁾. Our study clearly demonstrated efficacy of lidocaine spray added on PCB over PCB alone and intravenous sedation method in pain relief during and immediately after curettage procedure which support previous study⁽⁶⁾. Of note, it seems that local anesthetic methods are at least not inferior to systemic central-acting anesthetic methods in pain relief in uterine curettage, with suggestively reduced adverse effects.

PCB plus lidocaine spray has been reported to be effective in pain relief for patients receiving uterine curettage. A 4-arm double-blind randomized control trial by Aksoy H et al.⁽¹³⁾ found significant difference in pain relief for intra-procedural and 30-minute post-procedural periods across treatment groups without reporting pairwise comparison between two groups. In contrast, in addition to differences in outcomes across the three treatment groups our study was able to demonstrate the beneficial effects of PCB plus lidocaine spray over PCB alone. This suggests that

lidocaine spray might have some potential incremental benefits in pain relief for intrauterine operative procedures. However, such benefits have been inconsistently documented in previous literature. A previous trial examining the effect of lidocaine spray on pain relief during endometrial biopsy⁽¹⁴⁾ compared to placebo normal saline spray found that lidocaine spray did not help reduce pain. This is different from our findings. This may be explained by the differential complexity and duration of the two procedures.

Many factors may affect pain during and after uterine curettage such as age, education, uterine position, gestational age, psychosocial, a history of prior vaginal delivery and operators of uterine curettage⁽¹⁵⁻¹⁷⁾. Since the design of this study was randomized control trial, the effects of these factors on study outcomes were cancelled out. This was clearly supported by comparable levels of these factors in the three treatment groups as demonstrated in Table 1.

In term of adverse outcomes, our study found significantly higher nausea and dizziness in intravenous sedation group than PCB groups, which is different from a previous study by Allen RH et al.⁽¹⁰⁾ This may be explained by different drugs used for intravenous sedation between the two studies. Meperidine combined with diazepam used in our study is essentially more potent and have longer half-life than fentanyl, with or without midazolam for antiemetic effect in Allen's. However, the proportion of nausea was similar in both studies (14% in our study compared with 15.9% mild nausea and 4.5% severe nausea in previous study).

Our study showed lower levels of patient dissatisfaction than previous studies investigating benefits of intravenous or systemic sedation. In our study, only a small proportion of participants reported dissatisfaction in all treatment groups (3.3%, 0%, 0% in intravenous sedation, PCB, PCB plus spray group, respectively). A study in USA⁽¹⁰⁾ found that considerably higher proportions of participants reported dissatisfaction during uterine curettage (5.8%, 24.3%, 16.0% and 9.1% for the PCB alone, PCB plus sublingual lorazepam, PCB plus low-dose intravenous

sedation of fentanyl and midazolam and PCB plus moderate-dose intravenous sedation groups respectively). There may be a number of reasons for such the difference between the two studies. First, participants in the two studies may be different regarding a number of factors possibly affecting satisfaction outcomes such as a history of vaginal delivery, previous experience of uterine curettage. Significant proportion of participants in our study had experience of vaginal delivery (median parity of 2), and a previous history of uterine curettage (8.3%), while almost two-thirds of participants in the US study was nulliparous and half had bad impression from prior induced abortion. Additionally, different study designs may explain the disparity in satisfaction/ dissatisfaction levels between both studies. The US study was observational prospective study, while ours was randomized controlled trial. It is possible that participants in the trials were highly selected and different from those enrolled in observational studies regarding expectation and hence satisfaction.

Our study was a three-arm parallel-group randomized control trial with standardized outcomes ascertainment and intention-to-treat analysis. Together these allowed us to be able to control for possible confounding, and hence high study internal validity was achievable. This study was among the first to compare the effect of intravenous sedation with meperidine and diazepam to widely used anesthetic methods such as PCB. Comparable effects on pain relief of meperidine plus diazepam and PCB alone suggest potential use of meperidine plus diazepam instead of PCB alone in resource-constrained healthcare settings. However, our study has some limitations. First, blinding of patients and operators regarding treatment arms (PCB procedure and/or intravenous sedation) was not done in this study, so there might be the possibility of biases that the realization of these therapeutic procedures might have influenced physicians' performance and patients' responses on pain relief, adverse effects and satisfaction. It was also possible that adverse effects of meperidine and diazepam, particularly drowsiness

and dizziness, may have effects on the ways that the participants felt and reported their pain levels.

Conclusion

PCB plus 10% lidocaine spray was effective in pain relief with fewer adverse effects for incomplete abortion uterine curettage procedure compared to PCB alone or intravenous sedation. This might suggest the potential use of a combined treatment of PCB plus lidocaine spray in these groups of patients.

Potential conflicts of interest

The authors declare no conflict of interest.

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