Paracervical Compared With Intracervical Lidocaine for Suction Curettage

A Randomized Controlled Trial

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OBJECTIVE: To estimate the efficacy of paracervical compared with intracervical administration of local anesthesia during first-trimester suction curettage.

METHODS: A double-blind, randomized controlled trial comparing paracervical with intracervical lidocaine was performed in women undergoing elective first-trimester suction curettage with conscious sedation. Pain was assessed at baseline, with dilation, and with curettage using a 10-cm visual analog scale (VAS). Assuming a minimal clinically important difference in pain score of 1.6 cm and a mean pain score (±standard deviation [SD]) of 4.7 (±2.9) cm for paracervical block, 120 patients would provide 80% power with an alpha of .05.

RESULTS: For the 132 women randomly assigned, no significant differences in VAS scores (mean±SD) were observed between paracervical and intracervical blocks during dilation (2.6±2.3 compared with 2.8±2.2, *P*=.72) or curettage (3.9±2.9 compared with 3.3±2.5, *P*=.16).

CONCLUSION: For women undergoing first-trimester suction curettage with conscious sedation, there was no clinically meaningful difference in pain relief between paracervical and intracervical lidocaine. Providers should feel confident that both techniques provide equally effective and acceptable analgesia.

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Dilation and curettage is one of the most commonly performed gynecologic procedures in the United States. According to the most recent Centers for Disease Control survey, more than 660,000 suction curettages were performed for first-trimester pregnancy termination in 2003.[1] Even with conscious sedation, the mean pain scores range from 3.4 to 4.9 of 10 cm on a visual analog scale (VAS) with dilation and from 3.8 to 7.1 cm with curettage.[2–5] General anesthesia is associated with higher rates of hemorrhage, uterine trauma, and death due to hypoventilation and loss of airway.[6] For these reasons, only 10% of clinics use general anesthesia, whereas 58% use local anesthesia with or without oral premedication and 32% use intravenous sedation with local anesthesia.[7] Because local anesthesia is almost always used in elective termination, either in combination with sedation or as the sole form of analgesia, it is important to identify the best techniques for administration.

During cervical dilation, pain signals are carried by parasympathetic fibers that accompany the uterine vessels and cardinal ligament, which presumably is why the original paracervical block for labor analgesia was injected at 3 and 9 o'clock.[8] In addition to pain with cervical dilation, contraction or cramping pain is transmitted by sympathetic fibers from the ovarian plexus and inferior hypogastric nerve, which travels in the uterosacral ligament and inserts into the cervix at the 5 and 7 o'clock positions. In theory, paracervical injections at 5 and 7 o'clock would be best for this cramping pain. Anesthetic administration at 4 and 8 o'clock requires the anesthetic to diffuse anteriorly and posteri-

orly but avoids the risk of injecting lidocaine directly into the uterine vessels. In contrast to the paracervical block, which is intended to be a peripheral nerve block, the intracervical block acts as an infiltrative anesthetic by distending the tissues, causing mechanical disruption of neural impulses. Theoretically, this requires a less precise injection than a nerve block and may be more reliable and reproducible.

There currently is a debate over the efficacy of these methods, and few data exist for the technique that provides the best analgesia. Thus, the aim of this study was to estimate the efficacy of intracervical compared with paracervical block on pain experienced during first-trimester suction curettage without the use of preoperative cervical ripening. Because of the theoretically improved reliability of stromal block, we hypothesized that intracervical block would produce lower pain scores than paracervical block at the time of cervical dilation.

MATERIALS AND METHODS

We designed a double-blind, randomized controlled trial comparing two techniques for local anesthesia—paracervical compared with intracervical block—in combination with a standardized conscious sedation protocol, with the paracervical block serving as the standard therapy control. The study was approved by the institutional review board at the University of California, San Diego. Participation in the study was offered to a convenience sample of women who presented to a single Planned Parenthood clinic in central San Diego for first-trimester surgical abortion between December 28, 2007, and February 8, 2008. Although the clinic was open 6 full days per week, women were enrolled 2 to 3 half days each week when the first author was available to provide informed consent to the participants. All participants gave written informed consent in English or Spanish. Exclusion criteria were gestation more than 12 weeks by ultrasonography, participant weight less than 98 pounds, known allergy to lidocaine, or known nonviable pregnancy.

The preoperative protocol consisted of 800 mg of oral ibuprofen, a confirmatory ultrasound dating examination, and intravenous placement by clinic nurses. Immediately before the procedure, intravenous sedation consisting of 1 mg midazolam and 100 micrograms fentanyl was administered. Vital signs were monitored by the surgical assistants throughout the procedure. The surgeon then opened the sealed envelope and administered 20 mL of anesthetic by paracervical or intracervical block, according to the allocated treatment arm. The buffered lidocaine preparation for both block techniques consisted of 50 mL of 1% lidocaine, 5 units of vasopressin, and 5 mL of 8% sodium bicarbonate. The paracervical block was administered using a 5/8-inch, 25-gauge needle. A small amount was injected at the tenaculum site, and the remainder was distributed equally around the cervicovaginal junction at 3, 5, 7, and 9 o'clock. The depth was standardized at 5/8 inch by inserting the needle to the hub. The intracervical block was administered using a 1-inch, 20-gauge needle to overcome the increased resistance to injection caused by the cervical stroma. A small amount was injected at the tenaculum site and the remainder into the cervical stroma at 12, 3, 6, and 9 o'clock at a depth of 1 inches by inserting the needle to the hub (Fig. 1). The surgeon then performed serial cervical dilation with Denniston dilators (Ipas, Chapel Hill, NC), followed by suction curettage using an electrical vacuum aspirator in the usual fashion. No preoperative cervical ripening was used. Procedures were performed by experienced physicians employed by Planned Parenthood or by physicians in training under the direct supervision of Planned Parenthood faculty.

The primary outcome of pain was assessed using a 10-cm linear VAS at three time points: at baseline

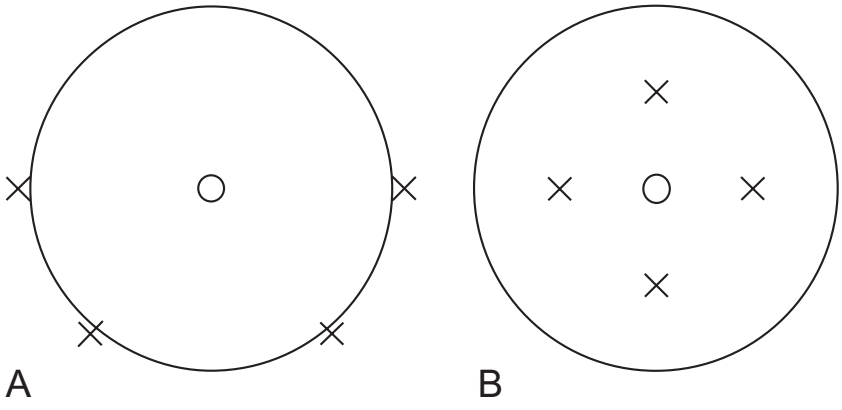

Fig. 1. Block types. **A.** Paracervical block. Each injection is 5/8″ deep and at the cervicovaginal junction. **B.** Intracervical block. Each injection is 1½″ deep and parallel to the long axis of the cervix. X, injection site.

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(before sedation), at completion of dilation, and at completion of curettage. Participants were instructed on the pain-scale administration before the procedure by the first author, and the scores were collected by a single surgical assistant who was blinded to the participant's study allocation. Details related to the procedure, including degree of dilation, size of largest curette used, and any complications, also were recorded. Data on participant demographics, pregnancy and delivery history, prior abortion experience, medical history, and gestational age were collected before the procedure.

Power calculations were based on previous reports identifying the minimal clinically important difference in pain score on a 10-cm VAS of 1.6 cm and a mean pain score (±standard deviation [SD]) of 4.7 (±2.9) cm for paracervical block with intravenous sedation.[3,9] Based on these data, we determined that 52 patients in each arm would provide 80% power with an alpha of .05 for detecting a significant and clinically important difference between the two groups. We aimed to recruit 60 participants per arm, or 120 total, to account for a 15% dropout rate.

Participants were randomly assigned to paracervical or intracervical local anesthesia based on a block randomization scheme in blocks of 10 using a random-numbers table. Sequentially numbered opaque sealed envelopes containing a description of the assigned block were prepared ahead of time. The random allocation sequence remained concealed until data analysis. Each participant was assigned a study number that correlated to the order in which she was enrolled by the first author. The corresponding envelope then was attached to the patient's record. The envelope was opened by the surgeon immediately before the procedure. Both the participants and the surgical assistants administering the pain scales were blinded to study assignment.

Demographic data were tabulated, but no hypothesis testing was used to compare data between groups. Student *t* tests were used to estimate mean VAS scores and other outcomes such as mean dilation, cannula size, estimated blood loss, and length of time for the procedure. Fisher exact test was used to compare the experience level of the physicians preforming the procedures as well as the complication rates between groups. Repeated measures analysis of variance was used to estimate the interaction of VAS scores over time. Statistical analyses were performed with SPSS 16.0 (SPSS Inc., Chicago, IL).

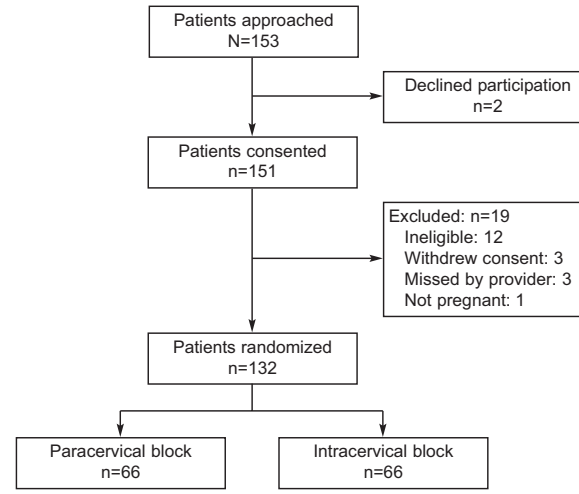

Fig. 2. Trial recruitment and flow.
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RESULTS

Of 818 women who underwent first-trimester abortion, a total of 153 patients were screened and 151 consented to participate. Nineteen participants were excluded before randomization: 12 because of gestational age more than 12 weeks, three for personal reasons, three because the provider forgot to open the study envelope, and one because she was not pregnant (Fig. 2). The remaining 132 enrolled participants were randomly assigned, with 66 in each arm. Six participants had incomplete pain scores, one in the paracervical group and five in the intracervical group. Three patients were missing VAS scores at dilation, two were missing VAS scores at curettage, and one was missing both scores. Because this was an intention-to-treat analysis, they were included in the analysis in their respective groups. In addition, one participant in the intracervical group who was 13 weeks pregnant and received misoprostol for cervical ripening should have been excluded before randomization but was not and remained in the analysis. Secondary analysis excluding those with incomplete data or misoprostol administration did not change the conclusions (data not shown).

As stated earlier, patients were recruited from December 28, 2007, to February 8, 2008. All study data were collected on the day of enrollment. There were no long-term follow-up data collected. Table 1 demonstrates that there were no clinically significant differences between groups with respect to age, gravidity, parity, prior abortions, race, marital status, education, or history of depression, anxiety, dysmenorrhea, or chronic pain disorders.

Table 1. Demographics by Treatment Arm

	Paracervical (n=66)	Intracervical (n=66)
Age (y)	26±6	26±6
Race/ethnicity		
White	19 (29)	23 (35)
Hispanic	33 (50)	26 (39)
African American	10 (15)	6 (9)
Asian/Pacific Islander	4 (6)	9 (14)
Other	0	2 (3)
Marital status		
Married	9 (14)	7 (11)
Divorced	8 (12)	6 (9)
Living together	20 (30)	21 (32)
Separated	5 (8)	10 (15)
Never married	24 (36)	22 (33)
Education		
Elementary only	1 (2)	1 (2)
Some secondary	5 (8)	5 (8)
Secondary/GED	20 (30)	15 (23)
Some college/trade school	31 (47)	34 (52)
Bachelor's degree	8 (12)	9 (14)
Some postgraduate	1 (2)	2 (3)
Past medical history		
Depression	3 (5)	4 (6)
Anxiety	6 (9)	8 (12)
Dysmenorrhea	7 (11)	8 (12)
Chronic pain	0	0
Low pain tolerance	2 (3)	2 (3)
Gravidity	2 [7]	3 [7]
Parity	0 [6]	1 [5]
Vaginal	0 [5]	1 [5]
Cesarean	0 [2]	0 [2]
Abortions		
Spontaneous	0 [1]	0 [3]
Medical	0 [1]	0 [1]
Surgical	0 [3]	1 [6]
Prior D&C	0 [4]	0 [6]
Prior pelvic exam	58 (88)	63 (95)
Gestational age (d)	60±13	61±12

GED, general equivalency diploma; D&C, dilation and curettage. Data are mean±standard deviation, n (%), or median [range].

In the intention-to-treat analysis, there were no statistically or clinically significant differences between the two groups with respect to pain with dilation or curettage (Fig. 3). The mean pain score (±SD) with cervical dilation was 2.6 (±2.3) cm in 66 participants in the paracervical group and 2.8 (±2.2) cm in 66 participants in the intracervical group (*P*=.72). The mean pain score (±SD) with curettage was 3.9 (±2.9) cm in the paracervical group and 3.3 (±2.5) cm in the intracervical group (*P*=.16). There was a slight difference in preoperative pain scores that neared statistical significance, with the paracervical group scoring 0.2 cm lower than the intracervical group (*P*=.06). Therefore, the analysis was repeated using change-in-pain scores from baseline. Again,

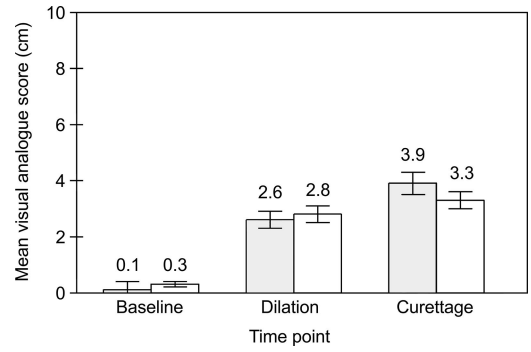

Fig. 3. Degree of pain with procedure by treatment arm. *Gray bars,* paracervical block; *white bars,* intracervical block. Student *t*-testing not significant for visual analog scores at baseline (*P*=.06), with dilation (*P*=.72) or curettage (*P*=.16). Repeated measures analysis of variance using Wilks' lambda not significant (*P*=.10).

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there were no differences in pain with dilation, but there was a trend toward lower pain scores in the intracervical group during curettage. The mean change-in-pain score (±SD) from baseline with cervical dilation was 2.5 (±2.3) cm in the paracervical group and 2.4 (±2.1) cm in the intracervical group (*P*=.89). The mean change-in-pain score (±SD) from baseline with curettage was 3.8 (±2.8) cm in the paracervical group and 2.9 (±2.6) cm in the intracervical group (*P*=.07). This difference of 0.9 cm, although almost statistically significant, is not clinically meaningful because it does not meet the standard for a minimal clinically meaningful difference of 1.6 cm. Furthermore, repeated measures analysis of variance testing of VAS over time by block type revealed no significant difference between groups using Wilks' lambda (*P*=.10).

Additionally, there were no statistically significant differences between groups with respect to degree of dilation, cannula size used, estimated blood loss, length of time of the procedure, or skill of the provider, with 92% of procedures performed by the attending physician (Table 2). There were also no significant differences in adverse events. There was one patient with a vasovagal episode in the paracervical group and one patient with nausea and vomiting in the intracervical group. There were no reported hemorrhages or toxic events.

DISCUSSION

In this population of women undergoing first-trimester termination with conscious sedation, we found that there was no difference in pain scores with cervical dilation between paracervical and intracervical

Table 2. Procedure Data and Adverse Events by Treatment Arm

	Paracervical (n=66)	Intracervical (n=66)	*P*
Dilation (cm)	9.5±1.8	9.5±1.7	.80*
Cannula (cm)	8.7±1.6	8.8±1.6	.83*
Estimated blood loss (mL)	26±8	27±7	.56*
Time (min)	6.6±2.9	7.2±2.6	.30*
Provider			.32†
Resident	3 (5)	7 (11)	
Attending	63 (95)	59 (89)	
Complications	1 (2)	1 (2)	1.00†

Data are mean±standard deviation or n (%).
* *t* test.
† Fisher exact test.

blocks. Although pain with curettage demonstrated a trend toward lower pain scores in the intracervical group, this did not meet our standard for a minimal clinically important difference.

Overall, mean pain scores with dilation and curettage were low with both types of local anesthesia when compared with other studies. Mean pain scores with paracervical block and intravenous sedation have been reported in the literature previously, ranging from 3.4 cm to 4.9 cm with dilation and from 3.8 cm to 7.1 cm with curettage.[2–5] In our study, the mean pain score in the paracervical group was 2.6 cm with dilation and 3.9 cm with curettage, and in the intracervical group 2.8 cm with dilation and 3.3 cm with curettage. Thus, our pain scores with dilation are lower than average and for curettage are on the lower end of what has been reported previously.

Although this study did not show a clinically meaningful difference between paracervical and intracervical lidocaine, we believe that this is an important finding. In our experience, intracervical block is an easier technique to teach. Paracervical injection techniques vary in location, depth, and number of injection sites.[10–14] Hence there is no standard paracervical block, which can be confusing for new learners. To our knowledge, there has been only one intracervical block injection technique described in the literature (Fig. 1). It is performed by injecting 5 mL of lidocaine at the 12, 3, 6, and 9 o'clock positions, where the needle is placed at a depth of 1 to 1 inches, parallel to the long axis of the cervix and halfway between the os and the periphery.[15] This is a simple technique to explain, perform, and supervise. Hence, if there is no benefit to performing a paracervical block over an intracervical block, perhaps more widespread use of an intracervical block is a reasonable technique, especially in the university setting while supervising resident education.

The efficacy of local anesthesia for suction curettage has been studied as it relates to the depth of injection, speed of injection, effect of waiting between injection and procedure, concentration of anesthetic, and the actual medication injected. Deep injections have been shown to be more effective than superficial injections.[16,17] Injecting slowly has been shown to be less painful than injecting quickly,[18] but there is no benefit in waiting between injection and procedure.[5] There is also no difference with respect to the concentration of the anesthetic.[16] Furthermore, there is no evidence that any one local anesthetic agent is superior to another. Bupivacaine has been shown to be equivalent to lidocaine.[18] Even bacteriostatic saline (0.9% benzyl alcohol) was found to be no different than 1% buffered lidocaine.[4] However, bacteriostatic saline should not be regarded as a placebo because benzyl alcohol is an active anesthetic agent.[19]

With so many factors shown not to affect pain scores, the astute reader may wonder, "Is local anesthesia needed at all?" In fact, local anesthesia has been shown to improve pain with suction curettage when compared with placebo[20,21] and, when used in combination with systemic medications, is superior to systemic anesthesia alone.[22] In the current literature, only one study has evaluated the two techniques of intracervical and paracervical anesthesia.[2] In that study, 134 women seeking first-trimester surgical abortions were randomized into three groups. Group A received a 2-point paracervical block at 4 and 8 o'clock, group B received a 2-point intracervical block at 4 and 8 o'clock, and group C received no local anesthetic. All patients received preoperative vaginal misoprostol and conscious sedation. Only 30% of patients in that study required cervical dilation, presumably owing to the use of misoprostol. Our study differs in that we did not use misoprostol. Similar to our study, no differences in pain scores were seen between groups, although overall pain scores were higher than described in other studies. Mean VAS scores with curettage were 7.1 cm in the paracervical group, 6.5 cm in the intracervical group, and 8.0 cm in the no-local group. These are much higher than in our study, which found VAS scores with curettage of 3.9 cm in the paracervical group and 3.3 cm in the intracervical group. This difference may be related to the amount of anesthetic used (10 mL of anesthetic administered at two sites rather than 20 mL at four sites). Alternatively, it may be related to a different sedation protocol (2 mg intravenous midazolam and 25 micrograms intravenous fentanyl compared with 1 mg intravenous midazolam and 100 micrograms intravenous fentanyl).

Our study has several strengths. To our knowledge, this is the first double blind, randomized controlled trial comparing paracervical with intracervical anesthesia without the use of preoperative misoprostol. Both the participant and the outcome assessor were blinded to the intervention arm. A sufficiently large number of patients were recruited in a short period of time, and we used standardized techniques and drug dosing. A diverse patient population was included, increasing the external validity of our findings.

The main limitation of this study was the use of intravenous sedation, which may have blunted the difference between the two groups. We chose this design because it reflected the most common practice for surgical pregnancy terminations performed in this country.[7] Furthermore, the use of conscious sedation has not been shown to affect pain scores, although it does improve overall patient satisfaction.[23] We are currently enrolling patients in a similar study without the use of conscious sedation to determine whether the results are similar. Another criticism may be that we did not include a placebo arm for this study; however, local anesthesia has been shown to be superior to placebo.[20,21] We felt that a study including a placebo arm would have been unethical. Finally, our study may be criticized for stopping the evaluation of pain at the completion of the procedure. However, other studies have established that pain scores 30 to 60 minutes after the procedure are low[2,5,23] and, therefore, not likely to show a difference between groups.

In conclusion, for patients undergoing elective first-trimester suction curettage for pregnancy termination with conscious sedation, intracervical and paracervical blocks have comparable effects on pain with abortion. Providers should feel confident that both administration methods of local anesthesia are acceptable and equally effective.

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