Contraception: *Original Research*

# Paracervical Block for Intrauterine Device Placement Among Nulliparous Women

## *A Randomized Controlled Trial*

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**OBJECTIVE:** To investigate whether a 20-mL buffered 1% lidocaine paracervical block decreases pain during intrauterine device (IUD) placement.

**METHODS:** In a randomized, single-blind, placebo-controlled trial, women were assigned to receive either a 20-mL buffered 1% lidocaine paracervical block or no block before IUD placement. The primary outcome was pain with IUD placement measured on a 100-mm visual analog scale. Our sample size had 80% power ($\alpha=0.05$) to detect a 20-mm difference in visual analog scale scores with a SD of 28 mm. Secondary outcomes included pain with speculum placement, paracervical block administration, tenaculum placement, 5 minutes postprocedure, and overall pain perception.

**RESULTS:** From October 7, 2014, through October 26, 2017, 64 women were enrolled and analyzed (33 in the paracervical block arm, 31 in the no-block arm). There were no differences in baseline demographics between the groups. Women who received the paracervical block reported less pain with IUD placement compared with women who received no block (median visual analog scale score of 33 mm vs 54 mm, $P=.002$). Pain was significantly less in the intervention group for uterine sounding (30 mm vs 47 mm, $P=.005$), 5 minutes after placement (12 mm vs 27 mm, $P=.005$), and overall pain perception (30 mm vs 51 mm, $P=.015$). Participants who received the paracervical block experienced more pain with block administration compared with placebo (30 mm vs 8 mm, $P=.003$). There was no perceived pain difference for speculum insertion (10 mm vs 6 mm, $P=.447$) or tenaculum placement (15 mm vs 10 mm, $P=.268$).

**CONCLUSION:** A 20-mL buffered 1% lidocaine paracervical block decreases pain with IUD placement (primary outcome), uterine sounding (secondary outcome), and 5 minutes after placement (secondary outcome). Although paracervical block administration can be painful, perception of pain for overall IUD placement procedure is lower compared with no block.

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Intrauterine devices (IUDs) are long-acting reversible contraceptives with a failure rate less than 1%.[1] Although IUD use is increasing, it is still less commonly used compared with less effective methods including pills and condoms.[2,3] Although IUD placement is an office procedure, fear of pain can be a barrier. This is especially a concern for nulliparous women, who experience more pain with placement compared with multiparous women.[4,5]

Currently, there is no standard of care for pain management with IUD placement among adult nulliparous women. The majority of randomized controlled trials of oral and local anesthetics have not demonstrated a reduction in pain scores with IUD

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placement.[4–15] If effective, use of a local anesthetic during the IUD placement would be convenient because it would not interrupt clinic flow.

Health care providers often suggest a paracervical block with IUD placement among nulliparous women. A previous trial evaluating a 10-mL 1% lidocaine block did not demonstrate a decrease in pain with IUD placement.[4] However, the 10-mL block may not have been a sufficient dose, because studies for other types of gynecologic procedures have shown efficacy of a 20-mL block.[16,17] A trial using a 10-mL 1% lidocaine block demonstrated a decrease in pain with IUD placement among nulliparous adolescents and young women (14–25 years old) receiving the levonorgestrel 13.5-mg IUD.[18] The levonorgestrel 52-mg and copper IUDs have slightly larger applicators, so it is difficult to extrapolate these results. This study evaluates whether a 20-mL buffered 1% lidocaine paracervical block will decrease pain with IUD placement.

## MATERIALS AND METHODS

Approval was obtained from the institutional review board at University of California, San Diego. Nulliparous women 18–45 years of age presenting for an IUD placement for contraception or treatment of abnormal uterine bleeding were approached to participate in this study. Exclusion criteria included pregnancy, any diagnosed chronic pain issues (fibromyalgia, endometriosis, dysmenorrhea, irritable bowel syndrome, interstitial cystitis), use of pain medication (eg, aspirin, nonsteroidal antiinflammatory drugs) within 6 hours of enrollment, misoprostol administration within 24 hours of enrollment, history of prior IUD placement, or known contraindications to IUD placement. Written informed consent was obtained. Each participant was randomly assigned to receive either a 20-mL buffered 1% lidocaine paracervical block or no paracervical block. We chose this buffered lidocaine because the sodium bicarbonate decreases the burning sensation associated with lidocaine administration.[19] We did not add vasopressin or epinephrine because IUD placements typically involve minimal risk for bleeding. Also, not including vasopressin or epinephrine makes the results more generalizable to clinics where these agents may not be available. Randomization was performed using a block size of four with group assignment through sequentially numbered, opaque, sealed envelopes. Given our smaller sample size, we chose a block size of four to ensure an equal distribution of participants who received the paracervical block and who did not receive the paracervical block. This study was single-blinded to the participants. After group allocation, the clinician was informed to administer either the paracervical block or no paracervical block (a capped needle).

For the intervention group, we administered a 20-mL paracervical block that consisted of 18 mL of 1% lidocaine buffered with 2 mL 8.4% sodium bicarbonate. This block is most commonly reported in the literature.[20–22] After speculum insertion, 2 mL was injected at the tenaculum site superficially at 12 o'clock on the anterior lip of the cervix.[23,24] The tenaculum was placed at 12 o'clock. The remaining 18 mL was injected into the vaginal fornices equally at the 4 and 8 o'clock positions. The injection was continuous from superficial to deep (3 cm) to superficial (injecting with insertion and withdrawal).[21,22,25,26] In the nonintervention group, the clinician performed a sham paracervical block as follows: 2 mL of buffered lidocaine was injected at the tenaculum site superficially at 12 o'clock on the anterior lip of the cervix followed by tenaculum placement. Over 60 seconds, without moving the tenaculum, a capped needle gently touched the vaginal sidewall at the level of the external os at 4 and 8 o'clock. All participants were counseled during the no block or paracervical block and tenaculum placement using standardized language, for example, "You may or may not feel something" to promote blinding. Placement of the IUD took place after application of the paracervical block or no block. The performing clinicians were obstetrics and gynecology attending physicians, resident physicians, and advance practice clinicians. We chose not to include a saline placebo block because the saline can distend the paracervical nerves and cause relief; therefore, it is not a true placebo. The capped needle approach is the same approach used by other paracervical studies.[4,16,17]

The outcome of interest was the participant's pain on a visual analog scale (VAS) from 0 mm (no pain) to 100 mm (worst pain imaginable) at various steps during the IUD placement. Participants marked the VAS scale for anticipated and baseline pain, pain during speculum insertion, sham or paracervical block administration, tenaculum placement, uterine sounding, IUD placement, 5 minutes after placement, and overall pain. Visual analog scale scores for anticipated and baseline pain were obtained just before the start of the procedure. Visual analog scale scores for speculum insertion, sham or paracervical administration, tenaculum placement, sounding, and IUD placement were obtained immediately after that step of the procedure. Participation concluded with a survey that included questions asking overall satisfaction with IUD placement and whether they would recommend IUD placement to a friend using the same pain

control (Box 1). This survey was used in prior pain control for IUD placement studies.[4,14] Participants were offered acetaminophen or ibuprofen at 5 minutes after the procedure. Participants received a $10 gift card for participating.

The calculation of the sample size was based on previous studies involving pain control for IUD placement using a 100-mm VAS.[4,5,15] The SD for pain with IUD placement was 23–35 mm in previous studies in the United States.[4,12] Our sample size calculation used a SD of 28 mm. Prior studies have reported a range of 9–20 mm as clinically significant differences in VAS pain scores. We defined a 20-mm difference on the VAS as clinically significant. We chose the 20-mm difference to demonstrate a large enough difference to change clinical practice. Using these parameters, we calculated that 64 participants would be required to achieve 80% power with a type I error ($\alpha$) rate of 5% to detect this difference.[27] We planned recruitment of 67 participants to account for a 5% dropout rate.

Data were analyzed with an intention-to-treat analysis. Visual analog scale pain scores were tested for normality using the Shapiro-Wilk test. The majority of VAS scores had a nonnormal distribution; therefore, median pain scores were compared using the Wilcoxon rank-sum test. For demographics and questionnaires, $\chi^2$ or Fisher exact tests were used to compare categorical variables and the *t* test or Wilcoxon rank-sum tests were used to compare continuous variables. Statistical analyses were completed using SAS 9.4.

**Box 1. Postintrauterine Device Insertion Patient Survey**

1. Did you experience any of the following side effects from the paracervical block? (circle all that apply)
   a. Nausea
   b. Vomiting
   c. Dizziness
   d. Injection site pain? Please describe: _____
2. How would you describe the injection site pain?
   a. No injection pain
   b. Not as bad as the IUD placement
   c. Just as bad as the IUD placement
   d. Worse than the IUD placement
   e. Much worse than the IUD placement
3. How did the pain with IUD insertion compare with the expected pain?
   a. No pain with IUD insertion
   b. Not as bad as the expected pain
   c. Just as bad as the expected pain
   d. Worse than the expected pain
   e. Much worse than the expected pain
4. Are there are some things about the pain control you received that could be better?
   a. Yes
   b. No
   c. Not sure
5. Would you choose the same pain control method for a future IUD insertion?
   a. Yes
   b. No
   c. Not sure
6. Would you recommend this pain control method to a friend for IUD insertion?
   a. Yes
   b. No
   c. Not sure

IUD, intrauterine device.

## RESULTS

Recruitment occurred from October 2014 to October 2017 at the University of California, San Diego and Planned Parenthood of the Pacific Southwest. A total of 67 women were enrolled and 64 of those women completed the study. Three participants dropped out of the study because they were unable to tolerate the pelvic examination and did not want to proceed with IUD placement (Fig. 1). There was no difference in baseline demographics including age, race or ethnicity, body mass index, or level of education between the two groups. There were six women in the paracervical block group and one in the no paracervical block group with prior abortions that were specified as terminations. None of the participants had more than one prior pregnancy. We do not have information on the type of termination (medical or surgical) or the trimester. No participants reported prior cervical procedures such as conization (Table 1).

For the primary outcome of VAS score for IUD placement, the median pain score was less for the paracervical block group compared with the no paracervical block group (33 mm vs 54 mm, $P$=.002). Median pain scores were also less for the secondary outcomes of uterine sounding (30 mm vs 47 mm, $P$=.005), 5 minutes after IUD placement (12 mm vs 27 mm, $P$=.005), and overall pain perception for the procedure (30 mm vs 51 mm, $P$<.05). Pain with paracervical block administration was higher for the intervention group compared with the no paracervical block group (30 mm vs 8 mm, $P$=.003). There was no difference in baseline pain, anticipated pain, or pain with speculum or tenaculum placement (Table 2).

There was no difference in patient-reported adverse effects. Participants in the no paracervical block group more often reported that IUD placement

**Table 1. Demographics of Study Participants**

| Demographic | No Paracervical Block (n=31) | Paracervical Block (n=33) | *P* |
|---|---|---|---|
| Age (y) | 24.8±3.4 | 26.1±3.9 | .458* |
| BMI (kg/m$^2$) | 24.0±5.9 | 24.5±4.4 | .089* |
| Ethnicity | | | .556† |
| Non-Hispanic | 23 (74.2) | 26 (81.3) | |
| Hispanic | 8 (25.8) | 6 (18.8) | |
| Race | | | .289† |
| Caucasian | 20 (64.5) | 21 (67.7) | |
| Black or African American | 0 (0) | 2 (6.5) | |
| Asian or Pacific Islander | 5 (16.1) | 6 (19.4) | |
| Native American or Alaska Native | 0 (0) | 0 (0) | |
| Other or multiracial | 6 (19.4) | 2 (6.5) | |
| Highest level of education completed | | | .939† |
| High school graduate | 0 (0) | 0 (0) | |
| Some college | 7 (22.6) | 7 (21.1) | |
| College degree | 18 (58.1) | 21 (63.6) | |
| Graduate degree | 6 (19.4) | 5 (15.2) | |
| Prior abortion | 1 | 6 | .106† |
| History of LEEP or conization | 0 | 0 | 1.000† |

BMI, body mass index; LEEP, loop electrosurgical excision procedure.
Data are mean±SD or n (%) unless otherwise specified.
Percent totals may not add up to 100 because of rounding.
* *P* value obtained from a *t* test.
† *P* value obtained from a Fisher exact test.

pain was worse than expected pain (1.6% vs 14.1% for the paracervical vs no paracervical block group), whereas participants in the paracervical group more often reported no pain (10.9% vs 1.6%) or pain not as bad as expected (29.7% vs 18.8%) compared with the no paracervical block group (Table 3). There was no difference in the health care provider type, type of IUD inserted, purpose of IUD placement, uterine position, need for cervical dilation, or major complications reported by health care providers. There was also no difference in participants taking postprocedural ibuprofen or acetaminophen before leaving the office (Table 4). Of note, we were not powered to detect differences in these outcomes.

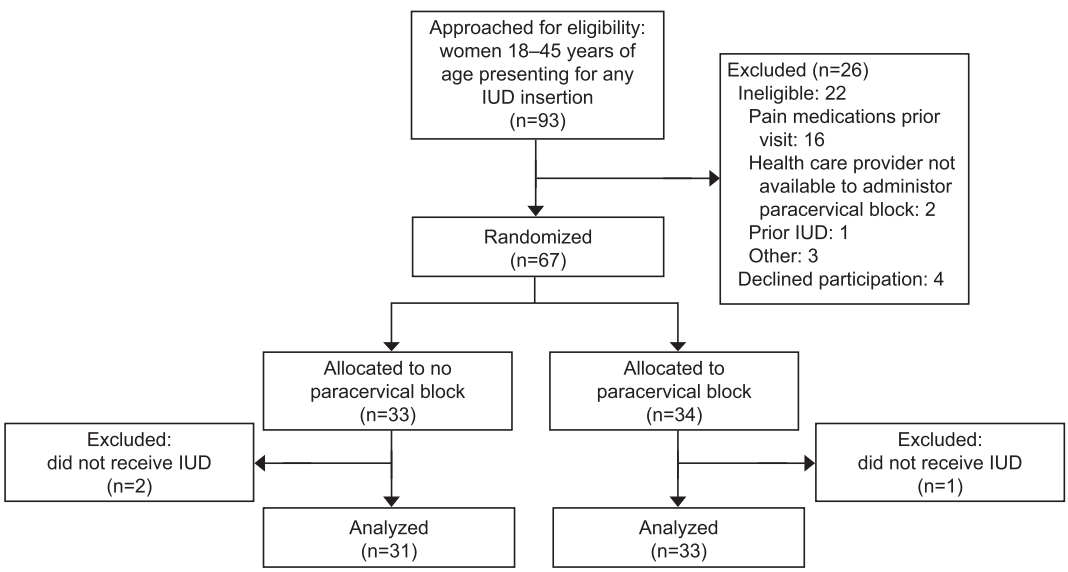


**Fig. 1.** Patient flow chart. IUD, intrauterine device.
*Mody. Paracervical Block for IUD Placement. Obstet Gynecol 2018.*

**Table 2. Median Pain Scores for All Time Points**

| All Participants | No Paracervical Block (mm) (n=31) | Paracervical Block (mm) (n=33) | Difference in Pain Scores | P* |
|---|---|---|---|---|
| Anticipated pain | 51 (30–70) | 58 (48–68) | +7 | .419 |
| Baseline pain | 0 (0–2) | 0 (0–2) | 0 | .377 |
| Speculum insertion | 6 (2–20) | 10 (4–14) | +4 | .447 |
| Capped needle or PCB | 8 (2–20) | 30 (17–47) | +22 | <.001 |
| Tenaculum placement | 10 (4–19) | 15 (6–24) | +5 | .268 |
| Uterine sounding | 47 (24–65) | 30 (8–43) | −17 | .005 |
| IUD placement† | 54 (33–75) | 33 (10–56) | −21 | .002 |
| 5 min after IUD placement | 27 (15–50) | 12 (6–27) | −15 | .005 |
| Overall pain | 51 (21–65) | 30 (16–48) | −21 | .015 |

PCB, paracervical block; IUD, intrauterine device.
Data are median (interquartile range [25–75%]).
Pain scores reported in millimeters on a 0–100 mm visual analog scale.
* *P* value obtained from a Wilcoxon rank-sum test.
† Primary outcome; all others are secondary outcomes.

## DISCUSSION

This study demonstrates that lidocaine administered locally through a paracervical block decreases pain with placement of the most commonly used IUDs, levonorgestrel 52 mg (Mirena) and CuT380A. The study by Akers et al[18] showed a decrease in pain with a 10 mL 1% lidocaine block, but had used the smaller levonorgestrel 13.5-mg IUD with adolescent and young adult

**Table 3. Results of the Participant Survey Completed 5 Minutes After Intrauterine Device Placement**

| | No Paracervical Block (n=31) | Paracervical Block (n=33) | P* |
|---|---|---|---|
| Side effects | | | |
| Nausea | 4 (6.3) | 3 (4.7) | .625 |
| Vomiting | 0 (0) | 0 (0) | 1.000 |
| Dizziness | 8 (12.5) | 10 (15.6) | .689 |
| Injection site pain | 11 (17.2) | 19 (29.7) | .077 |
| Injection site pain | | | .128 |
| None | 10 (32.3) | 9 (27.3) | |
| Not as bad as the IUD placement | 16 (51.6) | 12 (36.4) | |
| Just as bad as the IUD placement | 4 (12.9) | 3 (9.1) | |
| Worse than the IUD placement | 1 (3.2) | 8 (24.2) | |
| Much worse than the IUD placement | 0 (0) | 1 (3.0) | |
| Pain with IUD placement vs expected pain | | | .002 |
| No pain with IUD placement | 1 (3.2) | 7 (21.2) | |
| Not as bad as expected pain | 12 (38.7) | 19 (57.6) | |
| Just as bad as expected pain | 5 (16.1) | 6 (18.2) | |
| Worse than expected pain | 9 (29.0) | 1 (3.0) | |
| Much worse than expected pain | 4 (12.9) | 0 (0) | |
| Choose the same pain control method for a future IUD | | | .479 |
| Yes | 15 (48.4) | 20 (60.6) | |
| No | 7 (22.6) | 4 (12.1) | |
| Not sure | 9 (29.0) | 9 (27.3) | |
| Recommend this pain control method to a friend for IUD placement | | | .078 |
| Yes | 16 (51.6) | 25 (78.1) | |
| No | 6 (19.4) | 2 (6.3) | |
| Not sure | 9 (29.0) | 5 (15.6) | |

IUD, intrauterine device.
Data are n (%) unless otherwise specified.
Percent totals may not add up to 100 because of rounding.
* *P* values are derived from the $\chi^2$ test.

**Table 4. Results of the Health Care Provider Survey Completed After Completion of Intrauterine Device Placement**

| | No Paracervical Block (n=31) | Paracervical Block (n=33) | P* |
|---|---|---|---|
| Clinician type | | | .557 |
| Resident | 2 (6.5) | 3 (9.1) | |
| Attending at UCSD | 21 (67.7) | 18 (54.6) | |
| Nurse practitioner at PPPSW | 8 (25.8) | 12 (36.4) | |
| IUD type | | | .447 |
| LNG 52 mg (Mirena) | 24 (77.4) | 21 (63.6) | |
| CuT380A (Paragard) | 6 (19.4) | 11 (33.3) | |
| LNG 13.5 mg (Skyla) | 1 (3.2) | 1 (3.0) | |
| Purpose of IUD | | | 1.000 |
| Contraception | 31 (100) | 33 (100) | |
| Abnormal uterine bleeding | 0 (0) | 0 (0) | |
| Position of the uterus | | | .205 |
| Anteverted | 24 (77.4) | 20 (60.6) | |
| Retroverted | 2 (6.5) | 7 (21.2) | |
| Midpositioned | 5 (16.1) | 6 (18.2) | |
| Need for cervical dilation | | | .108 |
| No | 25 (80.7) | 31 (93.9) | |
| Yes | 6 (19.4) | 2 (6.1) | |
| Unable to complete IUD placement | | | 1.000 |
| No | 31 (100) | 33 (100) | |
| Yes | 0 (0) | 0 (0) | |
| Significant bleeding (greater than 5 min) | | | .329 |
| No | 31 (100) | 32 (96.7) | |
| Yes | 0 (0) | 1 (3.0) | |
| Major complications | | | 1.000 |
| No | 31 (100) | 33 (100) | |
| Yes | 0 (0) | 0 (0) | |
| Ibuprofen or acetaminophen before leaving the office | | | .068 |
| No | 19 (61.3) | 27 (81.8) | |
| Yes | 12 (38.7) | 6 (18.2) | |

UCSD, University of California, San Diego; PPPSW, Planned Parenthood of the Pacific Southwest; IUD, intrauterine device; LNG, levonorgestrel.
Data are n (%) unless otherwise specified.
Percent totals may not add up to 100 because of rounding.
* *P* values were derived from the $\chi^2$ test.

participants who were 14–25 years old. A phase II trial of lower-dose levonorgestrel IUDs demonstrated less pain associated with insertion of these smaller framed IUDs compared with the levonorgestrel 52-mg IUD.[28] Our study includes nulliparous women 18–45 years old receiving mostly the larger framed levonorgestrel 52-mg and CuT380A IUDs, which are the most commonly used IUDs in the United States. Most of the IUDs included in our study provide the longer duration of use compared with the smaller, lower dose IUDs. In addition, the levonorgestrel 52-mg IUD provides the highest likelihood of amenorrhea compared with the lower dose levonorgestrel IUDs.

Our sample size is powered to detect a 20-mm difference in VAS pain scores, which is consistent in being a clinically significant difference. This study provides more information for counseling about using a lidocaine paracervical block and counseling nulliparous patients about pain and IUD placement. For example, the patient may be informed during counseling that the paracervical block typically does cause some pain (30 mm on a 100-mm scale), but that the paracervical block reduces pain with IUD placement, pain 5 minutes after the procedure, and perceived pain for the overall procedure.

Limitations of this study include the lack of diversity in age, race, and education level. The study had an underrepresentation of African American participants compared with the national population, although representative of local demographics. Participants also tended to have higher education levels and were younger compared with the population of nationwide IUD recipients. These factors may limit the generalizability of the results. We also acknowledge that adding sodium bicarbonate may add a level of complexity to incorporating the results of this study into

clinics that do not typically buffer the lidocaine. Another weakness of the study is that it did not include the newer levonorgestrel 52-mg IUD (Liletta) that is now widely used. Although the levonorgestrel 52-mg IUD was introduced nationally during the study period, it was not routinely offered at the study institutions during the recruitment period.

Recruitment for this study took 3 years. A major challenge in recruitment was the exclusion criteria of ibuprofen and other pain medication use before IUD placement. Although the literature does not support ibuprofen as effective analgesia for IUD placement, this study excluded women who used ibuprofen within 6 hours of study enrollment to eliminate any possible confounding effect of pain medications. However, because women are often told to take ibuprofen by nurses or friends, this screened out many potential participants from the study.

Major strengths of this study include that it is a randomized controlled trial, use of the VAS, and use of a paracervical block technique comparable with other IUD placement pain studies. This allows better comparison with other studies evaluating pain studies with IUD placement. We included both an academic site and the Planned Parenthood site to increase diversity of the participants. We also included a variety of clinician types including advance practice clinicians, residents, and obstetrics and gynecology attendings. This is one of the few studies to demonstrate an intervention that helps decrease pain with IUD placement and which could be offered to nulliparous women presenting for IUD placement.

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