GYNECOLOGY

Self-administered vaginal lidocaine gel for pain management with intrauterine device insertion: a blinded, randomized controlled trial

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BACKGROUND: A major barrier to intrauterine device use is fear of pain during insertion. Trials exploring analgesic interventions for intrauterine device insertion have yielded mixed results, and no standardized pain management guidelines currently exist for this procedure. In an abortion-related study, self-administered lidocaine gel over a prolonged time interval showed promise as a method of pain control.

OBJECTIVE(S): The objective of the study was to assess pain control with intrauterine device insertion after patient-administered lidocaine gel compared with placebo.

STUDY DESIGN: We conducted a randomized, blinded trial of women undergoing levonorgestrel or copper intrauterine device insertion in an outpatient gynecology clinic between July 2016 and April 2017. Participants self-administered either 20 mL of 2% lidocaine gel or placebo gel vaginally at least 15 minutes prior to intrauterine device insertion. No other analgesics were administered. The primary outcome was pain during intrauterine device insertion, measured on a 100-mm visual analog scale (0 being no pain and 100 being worst pain imaginable). Secondary outcomes included anticipated and baseline pain and pain with speculum insertion and tenaculum placement. In a postprocedure questionnaire, participants reported acceptability of vaginal gel and willingness to wait for pain control. Median values were assessed because of the nonnormal distribution of visual analog scale scores using the Mann-Whitney *U* test. Predictors of intrauterine device insertion pain were assessed using a multiple linear regression.

RESULTS: In total, 220 women were randomized and 215 were included in analysis (108 in lidocaine gel, 107 in placebo gel groups). Median (range) time from gel administration to speculum insertion was 21 (14—74) and 20 (12—43) minutes in the lidocaine and placebo groups, respectively ($P = .13$). The median pain scores during intrauterine device insertion were not significantly different: 65 (1—99) mm in the lidocaine group and 59 (5—100) mm in the placebo group ($P = .09$). Among secondary outcome time points, only median pain scores at speculum insertion were significantly different between the lidocaine and placebo groups (7 [0—81] mm vs 11 [0—80] mm, respectively; $P = .046$). Anticipated pain and menstrual pain were both predictors of pain with intrauterine device insertion. The majority of women in both groups found the amount of vaginal leakage following gel insertion to be acceptable (>80%). Ninety-two percent of participants (n = 194) stated they would be willing to wait before intrauterine device placement for a potential analgesic effect.

CONCLUSION: Self-administered lidocaine gel at least 15 minutes before intrauterine device insertion does not appear to reduce pain compared with placebo but may help with speculum insertion. We found that women are willing to extend visit time to gain pain control. Self-administration of local anesthetic is acceptable to patients and should be considered in future research.

Key words: analgesia, intrauterine device, intrauterine device insertion, lidocaine

The intrauterine device (IUD) is a highly effective and safe method of contraception that is now recommended by the American College of Obstetricians and Gynecologists as a first-line contraceptive method for all women, including nulliparous and adolescent women.[1] While IUD acceptance rates in developed areas of the world have increased over time, this method remains underutilized, with only 12.7% of contracepting women electing for IUDs.[2]

A major barrier to IUD use is procedural discomfort and fear of pain during insertion.[3] Several components of the insertion process may cause pain, including tenaculum placement, uterine sounding,[4] IUD insertion through the cervical os, and contact with the uterine fundus.[5] There are currently no standardized pain management guidelines for IUD insertion, highlighting the need for research in this area, particularly to provide evidence-based clinical and program guidance. Reducing pain during IUD insertion also benefits providers; when a patient is more comfortable, the provider can likely perform the insertion more quickly and with fewer complications. Patients would also be expected to report higher overall satisfaction with the procedure,[6] and potentially the IUD itself.

Previous research into various pain management modalities has yielded mixed results. A 2015 Cochrane review assessing pain interventions for IUD insertion found that 2% lidocaine gel, misoprostol, and most nonsteroidal antiinflammatory drugs did not help reduce pain but concluded that certain lidocaine formulations (short-acting 4% gel, lidocaine-prilocaine cream, 10% spray, and 1% paracervical block) may be effective.[7] Ten percent lidocaine spray has continued to demonstrate efficacy but to date has been studied only in parous women.[8,9] Two recent trials examining 1% paracervical block in nulliparous women have demonstrated

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AJOG at a Glance

Why was this study conducted?

This study evaluated patient-administered lidocaine gel as a potential means of pain control for intrauterine device insertion.

Key findings

Twenty milliliters of 2% lidocaine gel self-administered vaginally at least 15 minutes before intrauterine device insertion did not reduce intrauterine device insertion pain compared with placebo but decreased pain with speculum insertion. The vast majority of participants found self-administration of gel to be acceptable and stated they would be willing to extend visit time for a potential analgesic effect.

What does this add to what is known?

At the dose and formulation studied, self-administered lidocaine gel was not an effective method of analgesia for intrauterine device insertion, but the application process is acceptable to women. Women are willing to extend visit time to gain pain control for this procedure.

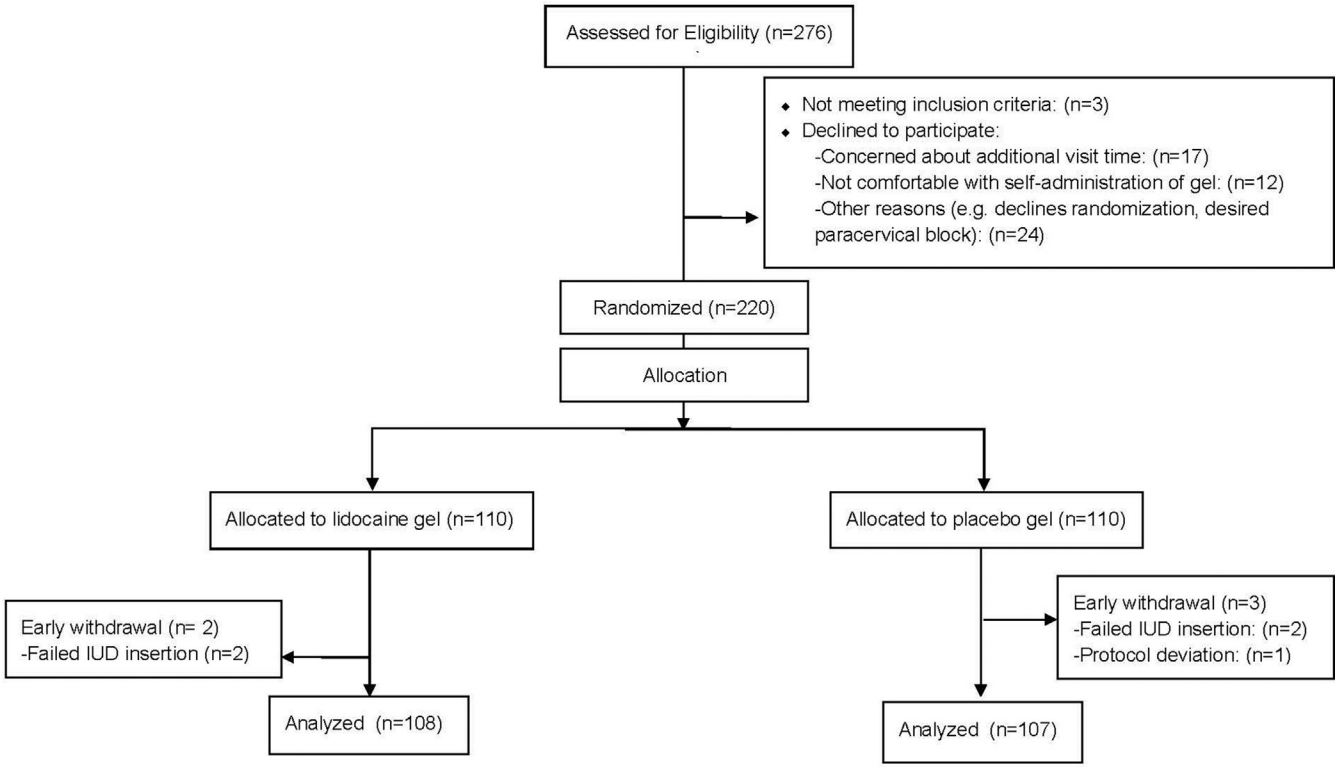
promising reductions in IUD insertion pain, although the block itself may be painful and associated with more adverse effects and higher procedure costs.[10,11]

Past trials of 2% lidocaine gel have involved short wait times of 1−3 minutes between gel administration and the procedure, which could have limited the effectiveness of this intervention.[12−15] A recent study by Rapkin et al[16] involving patient-administered 4 mL of 2% lidocaine gel in nulliparous women increased the wait time to 5 minutes and, unlike the other trials, noted pain reduction with tenaculum placement but not IUD insertion.

In an abortion-related study, 20 mL of 2% lidocaine gel self-administered 20−30 minutes prior to first-trimester surgical abortion was found to be noninferior to a 12 mL of 1% lidocaine paracervical block at reducing pain with cervical dilation.[17] In both of these studies, the vast majority of patients found the self-administered approach acceptable.[16,17]

In regard to safety, serum toxicity of intracervical lidocaine is thought to be around 5 μg/mL.[18] Serum lidocaine levels 10 minutes after paracervical injection of 20 mL of 1% lidocaine (200 mg) are associated with mean blood levels of 0.9−1.61 μg/mL[19] and serum lidocaine levels measured at various time

FIGURE 1
Consolidated standards of reporting trials flow diagram of subjects



The reporting trial period was from July 2016 to April 2017.

IUD, intrauterine device.

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TABLE 1
Demographic characteristics of participants

Variables	Lidocaine (n = 108)	Placebo (n = 107)
Age	28.9 (18–48)	27.0 (18–51)
BMI	22.8 (17.4–45.7)	23.6 (15.5–59.3)
Nulliparous (yes)	83 (76.9)	79 (73.8)
Previous cesarean delivery (yes)	11 (10.2)	6 (5.6)
Ethnicity		
Hispanic or Latino	14 (13.0)	15 (14.0)
Not Hispanic or Latino	93 (86.1)	90 (84.1)
Unknown/not reported	1 (0.9)	2 (1.9)
Race		
American Indian/Alaska Native	1 (0.9)	0 (0.0)
Asian	14 (13.0)	17 (15.9)
Native Hawaiian or other Pacific Islander	1 (0.9)	3 (2.8)
Black or African American	5 (4.6)	5 (4.7)
White	69 (63.9)	67 (62.6)
More than one race	9 (8.3)	6 (5.6)
Other	9 (8.3)	8 (7.5)
Highest level of education		
Less than high school	2 (1.9)	0
High school diploma or equivalent (GED)	5 (4.6)	10 (9.35)
Trade or vocational degree	2 (1.9)	1 (.93)
Associate degree	5 (4.6)	4 (3.7)
Some college, no degree	14 (13.0)	16 (15.0)
Bachelor's degree or equivalent	49 (45.4)	45 (42.1)
Master's degree or equivalent	17 (15.7)	16 (15.0)
Doctoral/professional degree or equivalent	14 (13.0)	15 (14.0)
Previous IUD (yes)	33 (30.6)	37 (34.6)

Data are presented in median (range) and n (percentage). Anyalysis was performed using a Mann-Whitney *U* test or a χ^2 test where appropriate.

BMI, body mass index; *GED*, general education degree; *IUD*, intrauterine device.

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points following 4 mL of 10% lidocaine spray (400 mg) prior to intracavitary vaginal brachytherapy found nontoxic levels in all patients studied.[20] We therefore determined that our predetermined 20 mL dose of 2% lidocaine vaginal gel (400 mg) would be a safe dose for pain control.

We hypothesized that 20 mL of 2% lidocaine gel, self-administered vaginally and over a prolonged time interval of 15 minutes, would decrease pain with IUD insertion compared with placebo.

Materials and Methods

We conducted a randomized, blinded, placebo-controlled trial of women undergoing levonorgestrel or copper IUD insertion in an outpatient gynecology setting between July 2016 and April 2017. We received study approval from the Stanford University Institutional Review Board (IRB-32825) prior to the start of this project.

We approached patients 18 years of age or older who were undergoing IUD insertion, who were English or Spanish speaking, and who were able to give written informed consent. We excluded any participants who had an allergy to lidocaine, had a known uterine anomaly or history of cervical surgery, had taken misoprostol prior to their procedure, or who had elected for any additional oral or intravenous sedation or narcotics. We did not exclude participants who had taken ibuprofen or acetaminophen prior to their procedure because many patients routinely take these medications prophylactically to reduce postinsertion cramping, and this would increase external validity.

Participants were then 1:1 allocated to either the lidocaine gel or placebo gel group by block randomization and assigned a serial study identification number. We used sealed, opaque envelopes to conceal the intervention group until the time of enrollment. Both study participants and health care providers performing the IUD insertion were blinded to allocation. Because of the logistical barriers with needing to prepare the gel immediately prior to insertion, study coordinators responsible for enrolling and randomizing participants were not blinded to the identity of the gel.

Study coordinators prepared 20 mL of either 2% lidocaine gel (400 mg) or placebo gel (standard lubricating gel) in a sterile, 20 mL Luer-Lok syringe. The 2 gels had the same clear appearance and consistency, ensuring proper blinding. Study coordinators provided instructions to all participants in a standardized fashion. Participants were instructed to insert the full length of the syringe vaginally and administer the gel in a similar manner to inserting a tampon and were then shown a photograph of this method on a pelvic model.

We aimed for gel insertion to occur at least 15 minutes prior to speculum placement, allowing a window of time to account for real-life clinic practice and possible delays. Given that the 90–120 minute half-life of lidocaine gel[21], we believed a flexible insertion-to-procedure interval would be methodologically appropriate and provide the most clinically relevant results. No additional cervical anesthesia or narcotic

TABLE 2
Procedure data

Variables	Lidocaine (n = 108)	Placebo (n = 107)	*P* value
Provider type			.14
Attending	17 (15.9)	25 (23.2)	
Fellow	7 (6.5)	3 (2.8)	
Nurse practitioner	74 (69.2)	77 (71.3)	
Fourth-year resident	8 (7.5)	3 (2.8)	
Uterine position			.10
Anteverted	89 (82.4)	79 (73.8)	
Retroverted	13 (12.0)	11 (10.3)	
Midposition	6 (5.6)	15 (14.0)	
Type of IUD inserted			.5
Copper T380A (Paragard)	11 (10.2)	10 (9.4)	
LNG IUS 20 (Mirena)	71 (65.7)	74 (69.2)	
LNG20 (Liletta)	10 (9.3)	8 (7.5)	
LNG IUS 8 (Skyla)	9 (8.3)	7 (6.5)	
LNG IUS 9 (Kyleena)	7 (6.5)	7 (6.5)	
Did you take ibuprofen or acetaminophen, or the equivalent before your appointment? (yes)	45 (41.7)	47 (43.9)	.74
Time from gel insertion to speculum insertion, min	21 (14–74)	20 (12–43)	.13
Total procedure time, min	4 (1–65)	4 (2–23)	< .001
Uterine sound used (yes)	32 (29.6)	37 (34.6)	.44
Os finder used (yes)	8 (7.4)	9 (8.4)	.77
Provider: what was the ease of insertion?	9 (1–98)	9 (0–96)	.84

Data are presented in median (range) and n (percentage). Anyalysis was performed using the Mann-Whitney *U* test or the χ^2 test where appropriate.

IUD, intrauterine device.

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analgesia was administered prior to the procedure. Following gel insertion, study coordinators administered a pre-procedure questionnaire to collect sociodemographic characteristics, obstetric history, and menstrual history.

Attending physicians, family-planning fellows, fourth-year obstetrics and gynecology residents, and nurse practitioners placed the IUDs. Subjects were asked to report their pain levels throughout the procedure using a 100 mm unmarked visual analog scale (VAS), with 0 mm being no pain and 100 mm being the worst pain imaginable.

Our primary outcome was pain at time of IUD insertion, as measured by VAS level immediately after speculum removal; study coordinators asked, "How was pain with insertion?" in a standardized fashion. Secondary outcomes included anticipated pain (measured immediately after gel insertion), baseline pain (measured immediately prior to start of the procedure), pain with speculum insertion, and pain after tenaculum placement.

The study coordinators recorded all the procedural data, including IUD type, uterine position, additional cervical manipulation (ie, with uterine sound or os finder), and total procedure time. Providers rated ease of insertion on a 100 mm VAS, with 0 mm being very easy and 100 mm being very difficult. In a post-procedure questionnaire, participants reported their overall pain score, global satisfaction of the procedure, acceptability of the vaginal gel, and the amount of IUD insertion pain they would be willing to tolerate to avoid waiting for pain medication.

Prior pain studies have established a clinically significant reduction in pain as a reduction of 13–20 mm on a 100 mm VAS,[22–24] and the standard deviation for IUD insertion pain in prior studies is cited as 32 mm.[12] To detect at least a 15 mm mean difference on a 100 mm VAS with 90% power and a significance level of .05, a total of 192 participants was required. We added approximately 15% to the number of participants to account for participant withdrawal and protocol deviations, resulting in a sample size of 220 (110 per group).

We recorded all participant information and VAS scores on an electronic tablet using REDCap electric data capture tools hosted at the Stanford Center for Clinical Informatics.[25] IBM SPSS Statistics, version 25.0 (IBM Corp., Armonk, NY) was used for data analysis. We compared sociodemographic and clinical characteristics between the lidocaine and placebo gel groups using either χ^2 tests or Mann-Whitney *U* tests where appropriate.

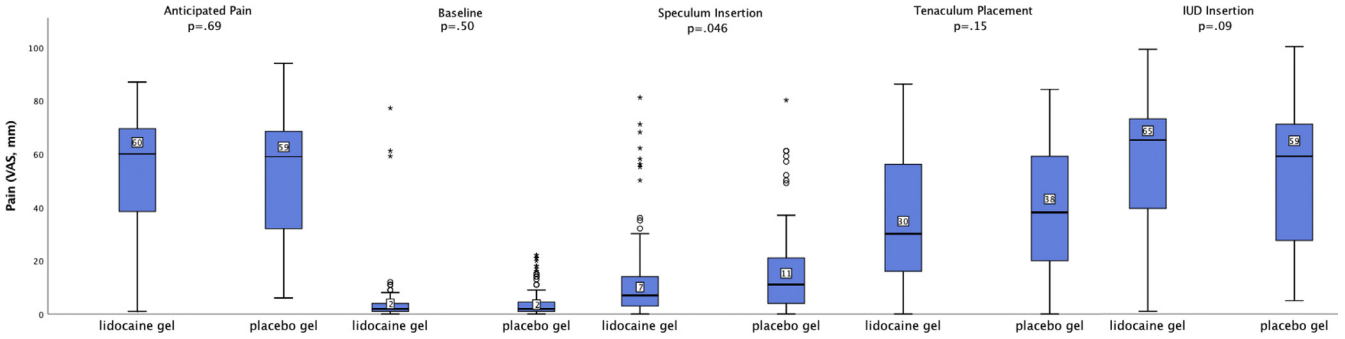
Mean VAS scores were analyzed using Student *t* tests. Because of the non-normal distribution of VAS scores, medians were also assessed using the Mann-Whitney *U* test. We then conducted a multiple linear regression to assess predictors of IUD insertion pain.

Results

Between July 2016 and April 2017, we assessed 276 women for eligibility and enrolled 220 in the study and included 215 in the analysis (Figure 1).

There were no significant differences in baseline characteristics between groups, including age, race and ethnicity, education level, and parity (Table 1). Median time from gel insertion to speculum placement was 21 minutes (14–74) for the lidocaine gel group and 20 minutes (12–43) for the placebo gel group ($P = .13$). Median procedure time,

FIGURE 2
Boxplots of median pain scores measured by visual analogue scale



Boxplots of median pain scores at several time points during the intrauterine device insertion procedure are shown.

IUD, intrauterine device.

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measured from the speculum placement to speculum removal, was 4 minutes (1−65) for the lidocaine gel group and 4 minutes (2−23) for the placebo gel group ($P < .001$). There was no significant difference between groups with regard to the uterine evaluation, such as the use of uterine sound or os finder (Table 2). Provider-rated ease of insertion was similar between the groups ($P = .84$) (Table 2).

For the primary outcome, pain with IUD insertion, mean and median pain scores were not significantly different between groups (mean, 58.1 ± 23.2 mm lidocaine vs 52.3 ± 25.2 mm placebo, $P = .08$; median: 65 (1−99) mm lidocaine vs. 51 (2−99) mm placebo, $P = .09$).

Pain with speculum insertion did vary between groups; the median pain score for the lidocaine group was 7 mm (0−81 mm) compared with 11 mm (0−80 mm) for the placebo group ($P = .046$). The median pain scores for baseline, tenaculum placement, and overall pain experience scores did not differ between groups (Figure 2, and Table 3).

We performed a linear regression to predict IUD insertion pain from study group, parity, body mass index, anticipated pain (100 mm VAS), pain experienced from menstrual period pain in the last 3 months (100 mm VAS), provider type, premedication (ibuprofen or acetaminophen), and IUD type. Anticipated pain and menstrual pain were found to be significant contributing predictors of IUD insertion pain ($P = .001$ and $P = .002$, respectively).

In the postprocedure questionnaire, when the participants were asked how much pain they would be willing to tolerate to avoid waiting for pain medication, these theoretical median pain scores did not differ significantly between groups (21 [0−77] mm lidocaine vs 22 [0−97] mm placebo, $P = .75$). The majority of women in the lidocaine group (81.5%, n = 91) and the placebo group (87.5%, n = 88) either agreed or strongly agreed that the amount of vaginal leakage following gel insertion was acceptable.

Of all participants, 92% (n= 194) stated they would somewhat or strongly prefer to wait 15 minutes before IUD placement for a potential analgesic effect. When, based on their pain control experience, subjects were asked how likely they would be to recommended IUD insertion to someone who wanted the method, median VAS scores were 87 (33−100) and 83 mm (9−100) for the lidocaine and placebo groups, respectively $P = .64$; 0 being strongly not recommend and 100 being strongly recommend).

TABLE 3
Pain with intrauterine device insertion measured by visual analogue scale

Variables	Lidocaine (n = 108)	Placebo (n = 107)	*P* value
Anticipated pain (at the time of vaginal gel insertion)	60 (1−87)	59 (6−94)	.69
Baseline, before procedure	2 (0−77)	2 (0−22)	.50
Speculum insertion	7 (0−81)	11 (0−80)	.046
Tenaculum placement	30 (0−86)	38 (0−84)	.15
IUD insertion	65 (1−99)	59 (5−100)	.09
How was your overall pain experience?	59.5 (1−92)	58 (2−100)	.63

Data are presented in median (range) and n (percentage). Anyalysis was performed using the Mann-Whitney *U* test or the χ^2 test where appropriate.

IUD, intrauterine device.

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Comment

In this blinded, randomized controlled trial, we found no difference in mean or median pain scores with our primary outcome, IUD insertion, between a self-administered 2% lidocaine gel and placebo. Although there was a statistically

significant between-group difference (difference, 4 mm) in median pain scores associated with speculum insertion, with insertion being less painful in the lidocaine gel group, this finding may not be clinically important for a general population of IUD initiators. However, it could have some importance for women with a history of sexual trauma or anxiety around speculum insertion, in general.

Unlike Rapkin et al,[16] we did not observe a statistically significant reduction in tenaculum pain, despite increasing the time from self-administration of gel to speculum placement from 5 to at least 15 minutes and increasing the volume of gel from 4 mL to 20 mL. The reason for this discrepancy is unclear but may be related to variability in method of tenaculum placement. Furthermore, because neither study involved direct application of gel to the cervix, it is possible that differences in applicator type or method of insertion caused variable amounts of gel to reach the tenaculum site.

The need for further studies examining adequate and reliable pain relief with IUD insertion is evident. While women overwhelmingly agreed that they would recommend the IUD insertion procedure to others, overall median pain scores were still 59.5 mm and 58 mm for the lidocaine and placebo groups, respectively. These scores are nearly double the median values that women indicated they would be willing to tolerate to avoid waiting for pain medication to take effect, signifying that there is a large gap between acceptable and realized pain and ample room for more reliable methods of pain relief.

Of note, the median overall pain scores were similar to the median anticipated pain scores, indicating that women come into the procedure with a reasonable understanding of the degree of pain they will experience, be it from personal research or shared experiences from friends. Prophylactic use of nonnarcotic pain medication such as ibuprofen or acetaminophen, as reported by 43.9% of the placebo group (n = 47) and 41.7% of the lidocaine group (n = 45), also supports the idea that women prepare themselves ahead of time for what will be a painful procedure, as evidenced by several IUD trials quantifying pain.[3,5–10,12–16,26,27]

Strengths of this study include its blinded, randomized, placebo-controlled design. We included both nulliparous and parous patients receiving all 5 types of IUDs currently approved by the Food and Drug Administration for use in the United States. Furthermore, the majority of IUDs were inserted by specialized nurse practitioners, limiting variability in skill among providers.

Limitations of this study include its potential generalizability; the majority of enrolled participants were white, nulliparous, and highly educated, having received a bachelor's degree or higher. Another limitation of our study is the lack of blinding of study coordinators responsible for collecting participant data.

It is noteworthy that the majority of women in this study indicated that the vaginal leakage associated with self-administered gel was acceptable, consistent with a previous abortion-related study that examined self-administered lidocaine gel for pain relief.[13] More importantly, the vast majority of participants in this study indicated they would be willing to extend visit time to gain pain control. Self-administration of gel may allow for longer medication exposure time without the need for prolonged speculum placement.

Our results support continued research into self-administered local anesthetics as a method of analgesia, especially as alternative formulations are showing promising results for pain control during different time points of the IUD insertion procedure.[26,27] One recent trial demonstrated significant reductions in pain with copper IUD insertion after cervical application of lidocaine-prilocaine cream, an oil/water emulsion with rapid absorption when applied to mucosal membranes; notably, however, the study protocol required women to lie with a speculum in place for 7 minutes after anesthetic application.[26]

In another study, self-administration of a newly developed lidocaine dual-responsive in situ gel reported similar reductions in pain.[27] In contrast to the paracervical block, which has recently demonstrated benefit for IUD insertion pain among nulliparous women,[10,11] these topical analgesics maintain the benefit of being noninvasive and therefore warrant further study.

While this randomized trial did not demonstrate a reduction in IUD insertion pain with self-administered 2% lidocaine gel, achieving pain relief for IUD insertion should continue to be an important area of research. Future studies exploring alternative local anesthetic formulations for IUD insertion pain should continue to consider a patient-administered approach. ■

Acknowledgment

The study was registered at ClinicalTrials.gov with the identifier of NCT02738203 (https://clinicaltrials.gov/ct2/show/NCT02738203); the date of registration was April 14, 2016, and initial enrollment July 1, 2016.

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