10% lidocaine spray for pain control during intrauterine device insertion: a randomised, double-blind, placebo-controlled trial

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ABSTRACT

Background Various medications have been investigated for their efficacy in pain reduction during intrauterine device (IUD) insertion, but there is currently no standard recommendation. This study aimed to investigate the efficacy of 10% lidocaine spray in reducing pain during copper-containing intrauterine device (Cu-IUD) insertion.

Methods This study was a randomised, double-blind, placebo-controlled trial. Reproductive-age women were randomised at a 1:1 ratio into 10% lidocaine spray or placebo spray group. A 10 cm visual analogue scale (VAS) was used to evaluate pain during several steps of the IUD insertion procedure, and after the procedure.

Results One hundred and twenty-four women were included and 62 women were randomised in each group. Baseline characteristics between groups were similar. The 10% lidocaine spray group demonstrated significantly lower median VAS immediately after IUD insertion than the placebo group (2.95 (IQR=1.00–5.63) vs 5.00 (IQR=3.35–7.00), respectively; p=0.002). Similarly, women receiving 10% lidocaine spray reported significantly lower median VAS than those receiving placebo during tenaculum use and uterine sounding. The maximum median VAS occurred immediately after Cu-IUD insertion. The proportion of women who reported VAS≥4 during uterine sounding and after IUD placement was significantly lower in the 10% lidocaine group than in the placebo group (p<0.05). Median change in VAS from baseline to IUD placement was significantly different between 10% lidocaine spray group and placebo group (1.85 (IQR=0.08–4.03) vs 3.6 (IQR=2.40–5.80), respectively; p=0.004).

Conclusion 10% lidocaine spray was found to be an effective local anaesthetic method for reducing pain during insertion of Cu-IUD.

Key messages

- There is no recommendation to reduce pain during intrauterine device (IUD) insertion. Few studies investigated the efficacy of 10% lidocaine spray for pain reduction during IUD insertion.
- Women who received 10% lidocaine spray reported significantly less pain than placebo during IUD insertion, especially during tenaculum placement, uterine sounding and after IUD placement.
- 10% lidocaine spray should be considered a safe, convenient and effective anaesthetic option for reducing pain during IUD insertion in both nulliparous and multiparous women.

Trial registration number Clinicaltrials.gov NCT03870711

INTRODUCTION

Copper-containing intrauterine device (Cu-IUD) is a highly effective long-acting reversible contraceptive method that was reported to have a 0.8% rate of unintended pregnancy during the first year of typical use.[1] Despite the advantages of this non-hormonal method of contraception, the rate of Cu-IUD use was estimated to be 14% among reproductive-age women worldwide, and its use varies widely among countries and regions.[2] One of the main limitations of Cu-IUD is patient concern about pain during the insertion procedure. Pain may occur during several steps of the procedure, including applying the tenaculum to the cervix, passing the uterine sound to measure the depth of the

Table 1 Baseline characteristics of participants (n=124)

	10% lidocaine spray (n=62)	Placebo spray (n=62)	P value*
Age (years)	31.2 ± 6.7	30.6 ± 6.3	0.6
Weight (kg)	60.2 ± 8.5	60.3 ± 11.1	0.938
Body mass index (kg/m^2)	24.0 ± 3.1	23.7 ± 3.6	0.556
Marital status			
Single	4 (6.5)	6 (9.7)	0.666
Married	57 (91.9)	54 (87.1)	
Separated	1 (1.6)	2 (3.2)	
Education			0.393
Less than high school	11 (17.7)	17 (27.4)	
High school degree or equivalent	17 (27.4)	17 (27.4)	
Bachelor degrees or higher	34 (54.8)	28 (45.2)	
Occupation			0.248
Unemployed/student	18 (29.0)	14 (22.6)	
Employee	26 (41.9)	27 (43.5)	
Government officer	5 (8.1)	12 (19.4)	
Business owner	13 (21.0)	9 (14.5)	
Income (Bath/month)			0.729
<10000	8 (12.9)	6 (9.7)	
10 000–50 000	42 (67.7)	41(66.1)	
>50 000	12 (19.4)	15 (24.2)	
Smoking	1 (1.6)	5 (8.1)	0.094
Nulliparous	4 (6.5)	2 (3.2)	0.68
History of vaginal delivery	39 (62.9)	37 (59.7)	0.712
Timing of IUD insertion			0.937
Delayed postpartum insertion	31 (50.0)	29 (46.8)	
Interval insertion	31 (50.0)	33 (53.2)	
Mode of delivery of the last child			0.811
Normal delivery	37 (63.8)	37 (61.7)	
Caesarean delivery	21 (36.2)	23 (38.3)	
Currently breast feeding	33 (53.2)	30 (48.4)	0.59
Dysmenorrhoea VAS≥4	16 (25.8)	21 (33.9)	0.326

Data are mean±SD or n (%).
*A p value <0.05 indicates statistical significance.
IUD, intrauterine device; VAS, visual analogue scale.

uterus and insertion of the IUD inserter tube. Several studies have investigated pain during IUD insertion, and the reported results are variable.[3–5]

According to a 2015 Cochrane Review, lidocaine gel, some non-steroidal anti-inflammatory drugs and misoprostol were ineffective for reducing pain during IUD insertion, while some lidocaine preparations and naproxen decreased IUD insertion-related pain to some degree.[6] A recent meta-analysis concluded that lidocaine-prilocaine cream was the most effective medication for reducing pain at tenaculum placement and during IUD insertion.[7] However, there is currently no consensus or standard management recommendation to reduce pain during IUD insertion. 10% lidocaine spray is a form of local anaesthesia that is convenient with minimal side effect, and it is used in several medical procedures, including obstetric and gynaecological procedures. Few studies have investigated the efficacy of 10% lidocaine spray for pain reduction during IUD insertion.[8–10] Pain score was evaluated in only some steps of the procedure, and the results differ among studies. The objective of this study was to investigate the efficacy of 10% lidocaine spray for reducing pain immediately after Cu-IUD placement.

Table 2 VAS pain score and intrauterine insertion procedure-related variables

	10% lidocaine spray (n=62)	Placebo spray (n=62)	P value*
VAS			
Speculum placement	0 (0–1.53)	0.75 (0–1.68)	0.165
Tenaculum placement	0.75 (0–2.20)	2.40 (1.20–3.85)	<0.001
Uterine sound	2.30 (1.08–4.60)	4.10 (2.90–6.00)	<0.001
IUD insertion	2.95 (1.00–5.63)	5.00 (3.35–7.00)	0.002
5 min after IUD insertion	0 (0–2.03)	0.95 (0–2.93)	0.078
20 min after IUD insertion	0 (0–2.00)	0.55 (0–1.90)	0.688
Uterine position			0.464
Anteflex	35 (56.5)	39 (62.9)	
Retroflex	27 (43.5)	23 (37.1)	
Uterine sound (cm)	6.8±0.7	6.8±0.8	0.812
Duration of insertion (second)	62.1±24.3	67.0±41.3	0.42
Adverse drug effect			
Vaginal irritation	34 (54.8)	1 (1.6)	<0.001

Data are mean±SD, n (%) or median (IQR).
*A p value <0.05 indicates statistical significance.
IUD, intrauterine device; VAS, visual analogue scale.

METHODS

Study design

This randomised, double-blind, placebo-controlled trial was conducted during July 2018 to December 2019 at the Family Planning and Reproductive Health Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Written informed consent to participate was obtained from all women in the study.

The eligibility criteria were women aged 18–45 years with a body mass index of 18.5–30 kg/m^2 who requested Cu-IUD for contraception, and who were new Cu-IUD users. Women having one or more of the following were excluded: (1) presence of any contraindication to Cu-IUD based on Medical Eligibility Criteria for Contraceptive Use published by the WHO[11]; (2) inability to comprehend use of the 10 cm visual analogue scale (VAS); (3) previous history of local anaesthetic allergy or sensitivity to lidocaine spray; and/or (4) analgesics use during the 24 hours period before participating in the study.

Study participants were randomly assigned to the 10% lidocaine spray (Xylocaine; AstraZeneca, Sweden) group or the placebo spray group. Randomisation was performed using a random generator programme with block sizes of four at a 1:1 ratio. Previous studies reported the effective dose of 10% lidocaine spray in gynaecological procedures (including Cu-IUD insertion) to be 10–40 mg.[8 9 12] Participants in the treatment group received four puffs of 10% lidocaine spray (40 mg, 10 mg/mL/puff), and those in the control group received four puffs of sterile water spray (three puffs applied to the cervical surface, and one puff toward the cervical os). 10% lidocaine and sterile water were in identical spray bottles.

After enrolment, an unblinded research assistant opened the assignment code and prepared the appropriated trial medication for each patient. A Copper T-380A (Pregna; Pregna International Limited, Mumbai, India) was inserted in all participants on any day of the menstrual cycle after confirming that the patient was not pregnant. The same gynaecologic staff (NP) from the Family Planning and Reproductive Health Unit performed all IUD insertions. Each patient underwent a pelvic examination before the procedure. No cervical ripening agents were used. After administration of the assigned study formulation, the speculum was removed and 3 min was allowed for the lidocaine to take effect (as suggested by the manufacturer). After 3 min, the speculum was reinserted, and the cervix was grasped with a tenaculum and the uterine axis was aligned. The uterine depth was then measured using a metal uterine sound, and the Cu-IUD was inserted in the standard manner using the withdrawal technique.

Baseline demographic data and relevant medical history were collected. Pain assessment was performed by a research nurse using the 10 cm VAS. The patients, the research nurses performing VAS and the gynaecologist performing the procedure were blinded to the assigned medication. Other than any study group-related differences, there was no difference between groups relative to the treatment or care that patients received. Participants marked the 10 cm VAS to indicate their level of pain at six different points during and after the procedure. The first pain assessment was

Table 3 Comparison of the VAS scores

	10% lidocaine spray (n=62)	Placebo spray (n=62)	
	n (%)	n (%)	P value*
Speculum placement			0.477
0–3 (mild)	55 (88.7)	58 (93.5)	
4–6 (moderate)	6 (9.7)	4 (6.5)	
7–10 (severe)	1 (1.6)	0	
Tenaculum placement			0.261
0–3 (mild)	54 (87.1)	47 (75.8)	
4–6 (moderate)	6 (9.7)	12 (19.4)	
7–10 (severe)	2 (3.2)	3 (4.8)	
Uterine sound			0.004
0–3 (mild)	45 (72.6)	27 (43.5)	
4–6 (moderate)	10 (16.1)	24 (38.7)	
7–10 (severe)	7 (11.3)	11 (17.7)	
IUD insertion			0.042
0–3 (mild)	38 (61.3)	24 (38.7)	
4–6 (moderate)	14 (22.6)	22 (35.5)	
7–10 (severe)	10 (16.1)	16 (25.8)	
5 min after IUD insertion			0.445
0–3 (mild)	55 (88.7)	51 (82.3)	
4–6 (moderate)	7 (11.3)	11 (17.7)	
7–10 (severe)	0	0	
20 min after IUD insertion			0.329
0–3 (mild)	53 (85.5)	56 (90.3)	
4–6 (moderate)	9 (14.5)	5 (8.1)	
7–10 (severe)	0	1 (1.6)	

*A p value <0.05 indicates statistical significance.
IUD, intrauterine device; VAS, visual analogue scale.

performed immediately after speculum insertion at 3 min after applying the study medication. The second pain assessment was performed immediately after the anterior lip of the cervix was grasped with a single-dent tenaculum. The third pain assessment took place after hysterometry by metal uterine sound, and the fourth pain assessment was conducted immediately after insertion of the Cu-IUD and removal of the IUD insertion tube. The fifth and sixth pain assessments were performed at 5 and 20 min after IUD insertion, respectively.

Sample size calculation and statistical analysis

The sample size was originally calculated based on data from a study by Karasu *et al*[9] that 69.3% of participants in placebo group and 43.2% of participants in lidocaine spray group rated VAS≥4 during IUD placement. Using a significance level of 0.05 (two-sided) and an absolute precision error of 20%, a total of 56 women per group were calculated. Assuming a 10% dropout rate, the final number of participants was 62 women for each study arm. However, previous studies estimated the sample size for pain assessment during IUD insertion by using the difference on the VAS. A 15 mm to 20 mm difference on the VAS was suggested as clinically significant.[13–16] Hence, we also estimated a sample size based on mean VAS during IUD insertion of 50.9±30[5] and difference mean VAS of 20. We calculated that at least 36 participants per group would be required to demonstrate a clinically meaningful VAS difference of 2 cm difference on the VAS with 80% power with a type I error rate of 5%. Finally, we recruited 62 participants per group as we first calculated.

The primary outcome was VAS immediately after Cu-IUD placement. The secondary outcomes were VAS at the other different points of the procedure, the difference in VAS at each time point from baseline and the side effects of the medication. Statistical analysis was performed using PASW Statistics V.21 for Windows (SPSS, Inc, Chicago, Illinois, USA). Demographic data were summarised using descriptive statistics. Data were presented as mean±SD, median and IQR or number (n) and percentage. Pearson's χ^2 test or Fisher's exact test was used for comparing categorical data, and t-test or Mann-Whitney U test was used for comparing continuous data as appropriated. A p value <0.05 was considered to be statistically significant.

Patient and public involvement

There was no direct patient and public involvement in the design of the study.

RESULTS

Of the 178 women who were assessed for eligibility, 124 women were included and randomised (online supplementary figure 1). All procedures were successfully completed without complications. Baseline characteristics between groups were similar (table 1). The

Table 4 VAS median change from baseline

	10% lidocaine spray	Placebo spray	
	(n=62)	(n=62)	P value*
Tenaculum placement	0 (0 to 1.38)	1.4 (0.20 to 2.13)	<0.001
Uterine sound	1.6 (0 to 3.05)	2.9 (2.18 to 4.50)	<0.001
IUD insertion	1.85 (0.08 to 4.03)	3.6 (2.40 to 5.80)	0.004
5 min after IUD insertion	0 (−0.03 to 1.0)	0 (−0.83 to 2.03)	0.784
20 min after IUD insertion	0 (−0.20 to 1.23)	0 (−0.93 to 0.83)	0.3

Data are median (IQR).
*A p value <0.05 indicates statistical significance.
IUD, intrauterine device; VAS, visual analogue scale.

mean age of patients was 31.2±6.7 years in the study group, and 30.6±6.3 years in the placebo group. The number of patients who underwent Cu-IUD insertion during the delayed postpartum period (within 6–8 weeks after delivery) was similar (50% in the 10% lidocaine spray group and 46.8% in the placebo group).

Pain score evaluation by VAS during the various steps of IUD insertion and IUD insertion procedure-related variables are shown in table 2. During IUD insertion, women in the 10% lidocaine spray group had a significantly lower median VAS than those in the placebo group (2.95 (IQR=1.00–5.63) vs 5.00 (IQR=3.35–7.00), respectively; p=0.002). Pain during tenaculum placement and during uterine sounding was significantly lower in the 10% lidocaine spray group than in the control group (both p<0.001). The maximum median VAS was observed during IUD placement. The total procedure time from speculum insertion to removal of the IUD insertion tube was not significantly different between groups (62.1±24.3 vs 67.0±41.3 s, respectively; p=0.42). Uterine position and uterine sound length were not significantly different between groups. Significantly more women in the 10% lidocaine group reported vaginal irritation side effect than women in the placebo group (34 (54.8%) vs 1 (1.6%), respectively; p<0.001). No participant needed for additional analgesia during or immediately after the procedure. No serious adverse effect related to 10% lidocaine spray, and no case of uterine perforation or vasovagal reaction was observed in either group.

The proportion of women who reported VAS≥4 during uterine sounding and immediately after IUD placement was significantly lower in the 10% lidocaine group than in the placebo group (table 3).

The median changes in VAS at each time point from baseline (speculum placement) are shown in table 4. Median change in VAS from baseline to IUD placement was significantly different between 10% lidocaine spray group and placebo group (1.85 (IQR=0.08–4.03) vs 3.6 (IQR=2.40–5.80), respectively; p=0.004). Similarly, the median change of VAS from baseline to tenaculum placement and uterine sounding was significantly lower in the 10% lidocaine spray group than in the control group.

DISCUSSION

Cu-IUD is a highly effective long-acting reversible contraceptives method. However, some women opt out to use Cu-IUD due to a fear of pain during insertion. It was reported that some medications may effectively reduce IUD insertion-related pain.[6] In the present study, women who received 10% lidocaine spray reported significantly less pain than those receiving placebo during the IUD insertion procedure, especially during tenaculum placement, uterine sounding and immediately after IUD placement. Median changes at tenaculum placement, uterine sounding and IUD placement from baseline were also significantly lower in 10% lidocaine spray group than in the placebo group. Moreover, the proportion of women who reported VAS≥4 was significantly greater in the placebo group than in the 10% lidocaine group during uterine sounding and immediately after IUD placement. Pain may occur during various steps of the IUD insertion.[6] Cervical pain is mediated by the S2 to S4 parasympathetic nerves, which enter the cervix at 03:00 and 09:00, whereas the uterine fundus is innervated by T10 to L2 sympathetic fibres.[17] Several preparations of lidocaine have been investigated for their efficacy in reducing pain during IUD insertion.[18–20] 10% lidocaine spray is a form of local anaesthetic that has been used for pain reduction in several medical procedures, including IUD insertion. Its mechanism of action is stabilisation of the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses. A Cochrane Review concluded that some lidocaine preparations may effectively decrease IUD insertion-related pain.[6]

Karasu *et al*[9] used lidocaine spray and reported a significant reduction in pain related to tenaculum use and IUD insertion, and a study by Aksoy *et al*[8] found a significantly lower pain score during IUD insertion in the lidocaine spray group. Another study by Elsafty *et al*[18] used lidocaine spray with different dose and different duration to allow the analgesics to take effect compared with our study and demonstrated decreased pain associated with tenaculum use. The results of our study showed significantly lower pain scores during tenaculum placement, uterine sounding and immediately after IUD placement in the lidocaine spray group as compared with the placebo group which are similar to the results reported from those previous studies. Torky *et al*[10] included women with and without history of vaginal delivery, and they found that women who received lidocaine spray did not reduced pain during IUD insertion compared with no local anaesthetic use, which is inconsistent with our result. However, that study did not mention the dose of lidocaine spray, which is a factor that would be expected to affect pain, so this is a possible explanation why their result differs from our result. Additionally, we grouped VAS responses into mild, moderate and severe. Our findings are consistent with previous studies that showed lower proportion of women with VAS≥4 during tenaculum placement and immediately after IUD insertion in lidocaine spray group.[8 9] Prior studies have typically reported clinically relevant changes in VAS of a range of 15–20 mm.[13 16] Recent review suggested that using a median effect size of ≥17 mm as a benchmark was shown to achieve clinically relevant reductions in pain at the time of IUD insertion when compared lidocaine preparations including lidocaine spray with placebo in several previous studies.[21] Although median VAS changes at tenaculum placement, uterine sounding and IUD placement from baseline met statistical differences when comparing lidocaine spray and placebo

groups in this study, only median VAS changes at IUD placement achieved clinical significance. In the current study, we included both women with and without history of vaginal delivery. History of vaginal delivery was reported to be a factor significantly associated with decreased pain during IUD insertion.[3 22 23] Thus, studies focus on women without history of vaginal delivery could yield more evidence of clinically relevant changes in the VAS.

The strength of the present study is its randomised, double-blind, placebo-controlled design. Additionally, all IUD insertion procedures were performed with single experienced physician, and VAS was assessed in all steps of the Cu-IUD insertion procedure, and after Cu-IUD insertion. Lastly, we included women with and without history of vaginal delivery, so the results of our study can be generalised to both groups. This study has some mentionable limitations. First, we did not evaluate some factors that might affect pain during the insertion procedure, such as anticipated pain, participant anxiety and the easiness score of insertion. Second, we evaluated only one type of IUD in this study (Copper T-380A IUD), so our findings may not be generalisable to other types of IUD.

Our result suggests that 10% lidocaine spray is an effective anaesthetic option for improving pain during IUD insertion. 10% lidocaine spray should be considered a safe and effective anaesthetic method for reducing pain during the Cu-IUD insertion process due to the fact that significant decrease in pain was found during the Cu-IUD insertion procedure, and that only minimal side effect of lidocaine spray was observed. The only disadvantage of using 10% lidocaine spray is that it requires 3 min to allow the analgesics to take effect. Further studies comparing 10% lidocaine spray with other medications should be conducted to identify the best method for alleviating Cu-IUD insertion-related pain.

CONCLUSIONS

10% lidocaine spray prior to Cu-IUD insertion effectively reduced pain during IUD insertion, specifically during the steps of tenaculum placement, uterine sounding and immediately after IUD placement.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval Ethical approval was obtained from the Siriraj Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University (COA No. Si 240/2018), and this study complied with the principles set forth in the Declaration of Helsinki and all of it subsequent amendments.

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