

Lidocaine for Pain Control during Intrauterine Contraceptive Device Insertion: A Randomized Clinical Trial

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ABSTRACT

Background: Intrauterine contraceptive device (IUCD) is one of the most common contraception methods. In a survey of female Fellows of the American College of Obstetricians and Gynecologists, the prevalence of personal IUCD use was >20-fold higher than among women in the general population. In statistical terms, The IUCD is used by approximately 15% of reproductive-aged women in developing countries and 8% in developed countries.

Aim of work: To compare the safety and efficacy of different local lidocaine preparations (spray, cream and injection) for reducing pain associated with IUCD insertion.

Patients and Methods: This is a prospective randomized clinical trial. The study was conducted at Ain Shams University Maternity hospital at family planning outpatient clinic during the period between December 2017 and June 2018.

Results: Results proved that lidocaine 10% spray application to the cervix during IUCD insertion effectively reduce pain felt during stages of IUCD insertion and is good option for reduction of pain associated with IUCD insertion in compared with lidocaine injection or cream.

Conclusion: Our study demonstrated that local lidocaine spray 10% is effective in control of pain associated with IUCD insertion when compared with lidocaine cream or injection because its application is easy and rapid, while lidocaine injection can also reduce pain but injection itself is painful that makes it unfavorable method.

Keywords: Lidocaine – Intrauterine Contraceptive Device Insertion- Levonorgestrel Intrauterine System

INTRODUCTION

The intrauterine contraceptive device (IUCD) is the world's most widely used spacing method of reversible birth control, currently used by nearly 120 million women (about 10-15% of women in reproductive life⁽¹⁾).

This popularity of use has been gained primarily due to high long-term success rates and reversibility. Currently, there is established evidence about their safety and efficacy. Additionally, they exhibit superior contraceptive potential 20 times over traditionally used oral contraceptive pills that translates to lower rates of unintended pregnancies⁽²⁾.

However, the clinical use of IUCDs is largely limited by the associated pain during their insertion, which results in little preference of use as contraceptive method from the patient perspective, especially for

adolescents and young women. In their observational study, **Marions et al** found that out of 224 nulliparous women, 9% reported no pain, 17% reported severe pain and 72% reported moderate pain during insertion of a levonorgestrel intrauterine system (LNG-IUS)⁽³⁾.

IUCD insertion pain may be felt during various stages of the procedure, including the vaginal examination, placement of the speculum, tenaculum use, and traction of the uterus, hysteroscopy and insertion of the IUCD⁽⁴⁾.

Although being difficult to predict, factors affecting insertion related pain were highlighted explicitly in recent literature. **Danielsson et al.** reported that nulliparity, breastfeeding status and time since last pregnancy are the most influential predictors of insertion pain; of these factors, nulliparity is the strongest causal factor⁽⁴⁾.

Prevention and management strategies of IUCD insertion pain include both non-

pharmacologic and pharmacologic interventions. Non-pharmacological interventions include pre-insertion counselling, patient reassurance and distraction during the procedure, however, the evidence of efficacy has not established yet ⁽⁵⁾.

Pharmacologic therapies were largely studied for their efficacy to reduce IUCD insertion associated pain. Current pharmacological strategies include: pre-insertion therapy (oral analgesia, cervical ripening/priming and local anesthesia); therapy given during the procedure (local anesthesia administered reactively) and post-procedure therapy (non-steroidal anti-inflammatory drugs and opioid analgesia). Among pharmacologic therapies, amine-anesthetics, like lidocaine, have been shown to be the most effective for reducing pain during IUCD insertion. NSAIDS (Non-steroid anti-inflammatory drugs), which can be used either orally or topically, are common alternatives for reducing the pain felt during IUCD insertion, including topical agents like: sprays, gel creams or injectable preparations ⁽⁶⁾.

Pathways of IUCD pain can be textualized as pain sensation in the cervix is transmitted to the brain via pelvic splanchnic nerves running through the uterosacral ligaments. All types of lidocaine preparations stabilize the neuronal membrane by inhibiting ionic flow and preventing initiation and conduction of impulses ⁽⁷⁾.

Lidocaine is an amide compound with aromatic group, 2, 6-xylidine, which is coupled to diethyl glycine via an amide bond. Lidocaine appears to be metabolized chiefly by the liver to 4-hydroxy-2,6-xylidine and this metabolite is excreted in urine over a 24-hour period and accounts for over 70% endogenous elimination of the administered dose of lidocaine ⁽⁸⁾. Lidocaine was shown to provide analgesia, by blocking both peripheral and central voltage-dependent sodium channels which results in halting the pain impulse initiation and transmission process in the axons ⁽⁹⁾.

It is generally safe to use topical lidocaine for anesthesia, and adverse reactions are rare. Minor side effects include flushing, redness of the skin, metallic taste and tinnitus ⁽¹⁰⁾. Topical lidocaine is contraindicated in patients with a history of hypersensitivity to

local anesthetics. Taken together, it is important to reduce the pain experienced during IUCD application. Topical lidocaine may be preferred for this purpose. However, there are different results in the literature regarding the efficacy of lidocaine use and degree of patient satisfaction during IUCD administration ⁽⁶⁾.

AIM OF WORK

To compare the safety and efficacy of different local lidocaine preparations (spray, cream and injection) for reducing pain associated with different steps of IUCD insertion.

PATIENTS AND METHODS

Study design: Prospective Randomized clinical trial.

Settings:

The study was conducted at Ain Shams University Maternity hospital at family planning outpatient clinic during the period between December 2017 and June 2018. **The study was approved by the Ethics Board of Ain Shams University and an informed written consent was taken from each participant in the study.**

Study Population:

- The study included 123 candidates at family planning clinic of Ain Shams University Maternity Hospital sought contraception using IUCD method.
- They were randomized to the 3 groups:
 - **Group 1:** (included 41patients) received lidocaine spray (Lidocaine topical aerosol ®, 10%, Arab drug co., Egypt) with a dose of four puffs (50 ml, 10 mg/puff) applied topically to the cervix.
 - **Group 2:** (included 41patients) received topical cream (Pridocaine ®, Global Napi, Egypt) with a dose of 2g lidocaine cream applied to the cervix via cotton swab.
 - **Group 3:** (included 41patients) received lidocaine injection (Debocaine®, 2%, Sigma-Tec, Egypt) with a dose of 80–200 mg equivalent to 10 ml lidocaine (20 mg/ml) injected at four and eight o'clock of the cervico-vaginal junction, and 2 ml to the area to be grasped with the tenaculum.

Method of randomization:

Computer generated randomization sheet using MedCalc^c version 13 was used for randomization.

Allocation and concealment:-

123 opaque envelopes were numbered serially and in each envelope the corresponding letter which denoted the allocated group was put according to randomization table. Then all envelopes were closed and put in one box. When the first patient arrived, the first envelope was opened and the patient was allocated according to the letter inside.

Inclusion criteria:

- Multiparous women.
- Over 18 years of age and eligible for IUCD insertion.
- Acceptance of IUCD as the method of contraception.
- Application of IUCD was done either if pregnancy test is negative or during menstrual period.

Exclusion criteria:

Subjects were excluded from the study for any of the following:

1. Null parity.
2. History of failed intrauterine device insertion (uterine perforation, acute expulsion).
3. Copper allergy.
4. Uterine anomaly.
5. Post-partum endometritis or septic abortion in the past three months.
6. Untreated cervicitis/vaginitis, including bacterial vaginosis.
7. Immunosuppression.
8. History of lidocaine, prilocaine allergy.
9. Analgesic or anxiolytic use within the last 24 hours before the procedure.
10. Wilson's disease.
11. Suspicion of pregnancy.

12. Untreated abnormal uterine bleeding.

Methods:

- A written consent was taken from each participant before recruitment in the study after explanation of the purpose and procedures of the study.
- A detailed medical history was obtained. Full personal, obstetric, menstrual and medical history was taken.
- All participants had complete clinical examination (General- Abdominal – pelvic).
- With the patient in the dorsolithotomy position, the provider conducted a pelvic examination to assess eligibility. The provider first did the bimanual examination and then inserted a speculum into the vagina to inspect the cervix. A standard 10% povidine iodine solution was used for local cleaning and preparation of the vagina and cervix was achieved. Then according to the patient group, each patient received either local lidocaine spray or cream or injection according to randomization table.
- All participants scored their pain at three different points during the procedure.

First (baseline) assessment was carried out after speculum insertion and analgesic administration. After administration of analgesics, the speculum was removed in all groups and five minutes are taken to allow the analgesics to take effect.

The second pain assessment was made after the cervix was grasped with the tenaculum. In all participants, the cervix was grasped at 12 o'clock by closing only a single dent on the tenaculum.

The third pain assessment was performed after hysterometry and insertion of the IUCD.

To assess the perceived pain at these points, a 10-point visual analogue scale (VAS) score was used. Pain levels are categorized as none (0 point), mild (1–3 points), moderate (4–6 points) and severe (7–10 points).

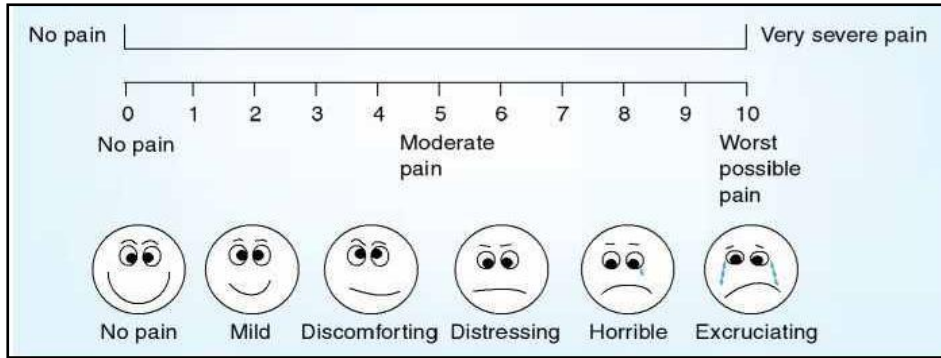


Figure (1): Visual Analogue scale (VAS).

Operationally a VAS is usually a horizontal line, 100mm in length, anchored by word descriptors at each end. The patient marked on the line the point that they felt representing their perception of their current state.

- All subjects were followed up for 6 hours for development of any side effects of lidocaine preparations. Patient satisfaction was assessed by asking the participants the question "Did you find inserting IUCD unpleasant?" if answer was no, they were further asked "Will you use lidocaine preparations for further future IUCD insertion?"

Study outcomes:-

Primary outcome:-

Pain scores assessed by 10-point VAS scale at three different points; baseline after application of speculum and analgesic administration, after grasping cervix with tenaculum, then following hysterometry and IUCD insertion.

Secondary outcome:

Patient satisfaction to IUCD insertion using different lidocaine formulations stratified to 2 levels; either "satisfied" or "not satisfied" and rate of adverse effects including: flushing, skin irritation and metallic taste 6 hours following use of lidocaine preparations during IUCD insertion.

Statistical analysis:

Descriptive statistics for measured variables were expressed as mean and SD for metric data, median and interquartile range for continuous non-normal data, number and proportions for categorical data. Normality of numerical data distribution was examined

using the Shapiro-Wilk test. Demographic data, and pain scores or secondary outcomes of the three study groups were compared using one-way ANOVA test for quantitative parametric measures, Kruskal-Wallis test for quantitative non-parametric measures, and χ^2 and Fisher's exact tests for categorical measures. A two-sided P value <0.05 was considered statistically significant. Pearson's correlation coefficient (for metric variables) and Spearman's correlation coefficient (for rank variables) were used to estimate association between variables. Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA) and IBM SPSS Statistics version 24 (IBM Corporation, Armonk, New York, USA) were used for data presentation and statistical analysis.

RESULTS

The current study was conducted at Ain Shams University Maternity Hospital at family planning clinic during the period between December 2017 and June 2018.

There were no significant differences between the three groups regarding age, BMI, Parity, abortions, Mode of delivery, Interval from LMP, dysmenorrhea and history of previous IUCD insertion denoting that the three groups were matched regarding factors that may influence pain sensation during the process of IUCD insertion.

The three groups then were compared regarding pain felt during speculum insertion and analgesic administration (baseline pain), during cervix grasping by tenaculum and during hysterometry & IUCD insertion using VAS score to detect the efficacy of the tested drug on decreasing pain sensation.

Table (1): Comparison between 3 study groups regarding Pain scores (by VAS)

Pain assessment	VAS score	Group S (n=41)		Group C (n=41)		Group I (n=41)		χ^2	df	P-value*
		N	%	n	%	n	%			
Baseline (After application of speculum & analgesic administration)	Nil	39	95.1%	38	92.7%	0	0.0%	79.311	1	<0.001 (highly significant)
	Mild	2	4.9%	3	7.3%	9	22.0%			
	Moderate	0	0.0%	0	0.0%	30	73.2%			
	Severe	0	0.0%	0	0.0%	2	4.9%			
After grasping cervix with tenaculum	Nil	15	36.6%	3	7.3%	3	7.3%	9.797	1	0.002 (highly significant)
	Mild	19	46.3%	21	51.2%	22	53.7%			
	Moderate	6	14.6%	17	41.5%	16	39.0%			
	Severe	1	2.4%	0	0.0%	0	0.0%			
After hysterometry and IUCD insertion	Nil	10	24.4%	1	2.4%	1	2.4%	0.862	1	0.353 (NS)
	Mild	15	36.6%	10	24.4%	25	61.0%			
	Moderate	14	34.1%	28	68.3%	15	36.6%			
	Severe	2	4.9%	2	4.9%	0	0.0%			

Data are number (n) and percentage (%).

χ^2 = chi-squared statistic, df = degree of freedom,

*Chi-squared test for trend.

P-value > 0.05: Non-significant

P < 0.05: Significant

P < 0.01: Highly significant

As shown in table 1, regarding pain felt during speculum insertion and analgesic administration (measured by VAS), P value was less than 0.0001 which is statistically significant.

The table shows that baseline pain (after application of speculum & analgesic administration) was significantly higher in the lidocaine injection group than in the other groups; n=39 (95.2%) participants rated their baseline pain as mild to moderate.

Regarding pain felt during grasping cervix with tenaculum, P value was 0.002 which is statistically significant.

Lower tenaculum-related pain scores were observed in the lidocaine spray group; n=34 (82.9 %) participants described their

tenaculum-related pain as none or mild. In the spray group, tenaculum-related pain was lower than in the lidocaine cream and lidocaine injection.

As shown in table 1, regarding pain felt during hysterometry and IUCD insertion, P value was 0.353 which is statistically insignificant.

Regarding pain felt after hysterometry and IUCD insertion, Lidocaine injection was shown to reduce the pain associated with IUCD insertion; n=26(63.4%) participants rated pain as none or mild during this procedure of IUCD insertion. In the lidocaine injection group, insertion-related pain was lower than in lidocaine spray and lidocaine cream.

Table (2): Patient satisfaction in the three study groups

Patient satisfaction	Group S (n=41)		Group C (n=41)		Group I (n=41)		χ^2	df	P-value*
	n	%	n	%	n	%			
Dissatisfied	6	14.6%	11	26.8%	18	43.9%	8.706	2	0.013 (Significant)
Satisfied	35	85.4%	30	73.2%	23	56.1%			

Data are number (n) and percentage (%).

χ^2 = chi-squared statistic. df = degree of freedom,

*Pearson chi-squared test.

As shown in table 2, on comparing the 3 groups as regard patient satisfaction with each form of lidocaine preparations used during IUCD insertion, P value was 0.013 which is statistically significant.

Patient satisfaction was found to be the highest with the lidocaine spray group and the least with lidocaine injection group.

Table (3): Incidence of adverse effect in the three study groups

Adverse effect	Group S (n=41)		Group C (n=41)		Group I (n=41)		P-value*
	N	%	n	%	N	%	
Flushing	0	0.0%	0	0.0%	0	0.0%	NA
Redness of skin	3	7.3%	5	12.2%	0	0.0%	0.096
Metallic taste	0	0.0%	0	0.0%	0	0.0%	NA

Data are number (n) and percentage (%).

NA = test not applicable.

*Fisher's exact test.

As shown in table 3, on comparing the 3 study groups as regard incidence of adverse effects with each form of 3 lidocaine preparations, P value was statistically non-significant among 3 groups for flushing, redness of skin and metallic taste adverse effects.

No flushing or metallic taste adverse effects were observed in any of the 3 study groups; whereas n=3 (7.3%) participants reported redness of skin with lidocaine spray and n=5 (12.2%) participants with lidocaine cream.

The levels of pain that women experience during IUCD insertion vary in published reports. Most women experience mild to moderate discomfort during IUCD insertion. Rarely, the pain is severe and associated with nausea and weakness and sometimes, pain may persist for a few days after insertion⁽¹³⁾.

The aim of our study is to compare the safety and efficacy of different local lidocaine preparations (spray, cream and injection) for reducing pain associated with IUCD insertion.

DISCUSSION

Intrauterine contraceptive devices (IUCDs) are one of the reversible contraceptives with a highest contraceptive effectiveness⁽⁵⁾.

In this Prospective randomized clinical trial, we enrolled a total of 123 women that came to Ain Shams maternity hospital, at the family planning clinic sought family planning by IUCD insertion during the period between December 2017 and June 2018.

One of the main reasons limiting the use of intrauterine contraceptive devices (IUCDs) is the fear of pain on the part of women and the difficulty of inserting the device on the part of healthcare professionals, which is more common in nulliparous women and in those with no previous vaginal deliveries⁽¹¹⁾.

The participants were divided into 3 groups; **Group 1** received lidocaine spray 10% with a dose of four puffs (40mg) topically to the cervix uteri, **Group 2** received 2g lidocaine cream topically to the cervix via a cotton swab & **Group 3** received 10 ml lidocaine injection injected at four and eight o'clock of the cervico-vaginal junction, and 2 ml to the area to be grasped with the tenaculum.

Components of the insertion procedure that may cause pain include the application of the tenaculum to the cervix to stabilize the uterus and provide traction for straightening the cervical canal, passing the uterine sound, inserting the IUCD in the inserter tube through the cervix, and irritation of the endometrial cavity with the device⁽¹²⁾, so this study was a trial to decrease pain during these steps during IUCD insertion.

In our study, there were no significant differences between the three groups regarding age, BMI, Parity, abortions, Mode of delivery, interval from LMP, dysmenorrhea, & history of previous IUCD insertion. Denoting that 3 groups were matched regarding factors that may influence pain sensation during the process of IUCD insertion.

The main outcome that was measured in our study as well as most of other studies was pain.

A standard 10 cm visual analogue scale (VAS) for pain scoring was used in our trial which was the same as **Karrasahin et al.**⁽¹⁹⁾ trial, **Aksoy et al.**⁽¹⁴⁾ trial, and **Hubacher et al.**⁽²²⁾ trial. This validated pain scale uses a 10 cm line to represent the continuum of 'no pain at 0' to 'worst imaginable pain at 10', on the other hand the **Allen et al.**⁽¹⁷⁾ trial, **Bednarek et al.**⁽²¹⁾ trial, **Farala et al.**⁽¹⁶⁾ and **Mody's et al.**⁽¹⁰⁾ trial used 1 to 100 pain scoring system, the same as standard VAS but numbered from 1 to 100 rather than from 1 to 10 with 'no pain at 1' and 'worst imaginable pain at 100'.

The results of our study on comparing the values of anticipated pain score after application of speculum and analgesic administration, pain score after grasping of cervix with tenaculum and pain score after hysterometry and IUCD insertion by VAS signify that lidocaine spray 10% decreases pain felt during the process of IUCD insertion and is good option for usage due to the ease of application in compared with lidocaine injection or cream.

Regarding pain felt after application of speculum and analgesic administration (measured by VAS), Baseline pain was significantly higher in the lidocaine injection group than in the other groups; n=39 (95.2%) participants rated their baseline pain as mild to moderate. On comparing the 3 study groups, the P value was <0.001 which was statistically significant.

Injection of lidocaine, when compared to the usage of topical lidocaine spray, is an invasive procedure, needs special needle and a well trained personnel, moreover, it carries the risk of nerve injury or accidental intravascular injection of the anesthetic while the main problem with lidocaine spray was that it was difficult to apply the spray directly into cervical canal but this difficulty could be overcome by applying the spray as close as possible to the cervical os and this seems to be effective in our study.

Regarding pain felt after grasping cervix with tenaculum (measured by VAS), The P value was 0.002 which was statistically

significant. Lower tenaculum-related pain scores were observed in the lidocaine spray group; n=34 (82.9 %) participants and described their tenaculum-related pain as none or mild. In the spray group, tenaculum-related pain was the lowest while it was the worst with the cream group.

The ineffectiveness of the lidocaine cream could be related to the delayed absorption of this form or we might use a lower dose of lidocaine cream as much of it was soaked by cotton swab and contaminated outside the intended area. Pain caused by the injection itself could be the reason for this finding, as stress induced by the injection might have resulted in a relatively high pain scores in this group. The main factor underlying improved pain scores with lidocaine spray may be the relaxing effect of not feeling pain during application of the drug.

Regarding pain felt after hysterometry and IUCD insertion, Lidocaine injection was shown to reduce the pain associated with IUCD insertion; n=26(63.4%) participants rated pain as none or mild during this procedure of IUCD insertion. In the lidocaine injection group, insertion-related pain was lower than in lidocaine spray and lidocaine cream.

Analysis of data revealed that lidocaine 10% spray application to the cervix during IUCD insertion effectively reduce pain felt during stages of IUCD insertion and is good option for reduction of pain associated with IUCD insertion in compared with lidocaine injection or cream.

There are different results in the literature regarding the efficacy of lidocaine use during IUCD insertion.

Most of the previous studies on this topic had compared a single method with either a control group or placebo as seen in the studies of^(14- 20); however the aim of our study was to compare the effects of 3 different forms of topical lidocaine applied prior to IUCD insertion.

Unlike other studies, a baseline pain assessment was made after lidocaine application to see whether the application itself was painful or not. One major point for which our study differs from others is that we evaluated whether the procedures aimed at reducing pain were themselves a cause of increased pain sensation.

Askoy et al.⁽¹⁴⁾ concluded that significant pain reduction during IUCD insertion can be achieved by using 10% lidocaine spray alone. He had used lidocaine 10% spray in a dose of 40 mg (the same dose we used). A total of 200 patients were included in the study & divided into 2 groups: lidocaine spray (n=100) & placebo (n=100), the patients were asked to mark their pain only before speculum placement (pain expectancy) & immediately after IUCD insertion. The mean pain score during the procedure was 1.01 ± 1.20 in the lidocaine spray group and 3.23 ± 1.60 in the placebo spray group ($p < 0.001$). Lidocaine spray treatment significantly lowered the overall procedural pain score compared with placebo. Results of this study are consistent with our study.

The differences between **Askoy et al.**⁽¹⁴⁾ study and our study are that he used a larger number of participants (n=200) but we used 123 participants instead. In our study, we didn't use a placebo but we compared lidocaine spray with injection and cream. In our study, pain was assessed during analgesic administration and speculum insertion, during tenaculum attachment, and during hysterometry & IUCD insertion but he assessed pain before speculum placement (pain expectancy) and immediately after IUCD insertion. Also Askoy had used lidocaine 10% spray in a dose of 40 mg (the same dose we used).

We should state here that we didn't assess pain expectancy of participants as a psychological factor that may influence the process of IUCD insertion.

Mody et al.⁽¹⁰⁾ concluded that Compared with no anesthetic, a 1% lidocaine paracervical block did not result in a statistically significant decrease in perceived pain with IUCD insertion. 50 patients were enrolled in the study, 26 women were assigned to the paracervical block group & 24 women were assigned to no local anaesthetic group. Women who received the paracervical block reported a median VAS score of 24.0 mm with IUCD insertion, and women who did not receive local anesthetic reported a median VAS score of 62.0 mm with IUCD insertion; $p = 0.09$. Results of this study are consistent with our study because it was found that overall reduction of pain with the use of

lidocaine injection was not significantly noticed as it can reduce pain during the procedure of IUCD insertion but injection itself was painful that makes it unfeasible method for reducing pain during IUCD insertion.

The differences between **Mody et al.**⁽¹⁰⁾ study and our study are that we used larger number of participants and we didn't use a placebo but we compared lidocaine injection with cream and spray. In our study, we used 12ml of lidocaine injection 2% but **Mody et al.**⁽¹⁰⁾ used 10 ml 1% lidocaine paracervical block. Also, **Mody et al.**⁽¹⁰⁾ used a 100 mm VAS to assess pain but we used a 10 mm VAS instead.

On the other hand, **Goldthwaite et al.**⁽¹⁵⁾ compared lidocaine injection and lidocaine gel for tenaculum application and found that the injection was more effective. A total of 74 women were enrolled and randomized; 35 subjects in each group met criteria for analysis. Women who received the injection had lower mean pain levels at tenaculum placement [12.3 mm (S.D. 17.4 mm) versus 36.6 mm (S.D. 23.0 mm), $p < 0.001$]. Results of this study are inconsistent with our study.

The differences between **Goldthwaite et al.**⁽¹⁵⁾ study and our study are that we used larger number of participants and we didn't use lidocaine gel but we used 3 different forms of local lidocaine preparations (cream, spray & injection). In our study, we assessed pain during 3 different stages of IUCD insertion not during tenaculum placement only. He used a 100-mm VAS to assess pain but we used 10mm VAS instead.

Farala et al.⁽¹⁶⁾ concluded that 20 cc 1% lidocaine paracervical block decreases pain with IUCD placement, uterine sounding, 5 minutes after placement and overall pain perception. A total of 64 women were enrolled and analyzed (33 in the paracervical block arm, 31 in the no-block arm). Women who received the paracervical block reported less pain with IUCD placement compared with women who received no block (median visual analog scale score of 33 mm vs 54 mm, $P = 0.002$). Pain was significantly less in the intervention group for uterine sounding (30 mm vs 47 mm, $P = 0.005$), 5 minutes after placement (12 mm vs 27 mm, $P = 0.005$), and overall pain perception (30 mm vs 51 mm, $P = 0.015$). Participants who received the

paracervical block experienced more pain with block administration compared with placebo (30 mm vs 8 mm, $P=0.003$). There was no perceived pain difference for speculum insertion (10 mm vs 6 mm, $P=0.447$) or tenaculum placement (15 mm vs 10 mm, $P=0.268$). Results of this study is inconsistent with our study as regard paracervical block reduces overall pain perception during IUCD insertion, although we both agreed that lidocaine injection is painful during administration and is effective for reduction of pain during the step of IUCD insertion, but has no effect on tenaculum-related pain. The differences between **Farala et al.**⁽¹⁶⁾ study and our study are that he used 100mm VAS to assess pain, he used less number of participants and he compared paracervical block with no method but we compared lidocaine injection with spray and cream.

Our secondary outcomes were patient satisfaction to IUCD insertion using different lidocaine formulations and and rate of adverse effects including: flushing, skin irritation and metallic taste 6 hours following use of lidocaine preparations during IUCD insertion.

The results of our study showed that patient satisfaction was found to be the highest with the lidocaine spray group and the least with lidocaine injection group.

That was in contrast with **Farada et al.**⁽¹⁶⁾, Patient satisfaction was found to be 78.1% with usage of paracervical block method versus 51.6% with no method used. Also, **Goldthwaite et al.**⁽¹⁵⁾ found that satisfaction with tenaculum placement was similar for both lidocaine gel group and injection group. However in our study, Satisfaction was 85.4% with spray group, 73.2% with cream group and 56.1% with injection group.

In our study, all procedures were successfully completed without severe complications or serious adverse reactions. No flushing or metallic taste adverse effects were observed in any of the 3 study groups; whereas only 3 participants reported redness of skin with lidocaine spray and 5 participants with lidocaine cream.

That was in agree with **Askoy et al.**⁽¹⁴⁾ in which there were no severe complications

or serious adverse reactions observed. There were only five mild complications associated with vasovagal reaction such as nausea, vomiting and dizziness, but for which no treatment was needed. Of these, two were in the control group. Systemic side effects associated with 10% lidocaine spray were not observed. In contrast to our study, **Farala et al.**⁽¹⁶⁾ study showed that out of 33 participants receiving paracervical block with lidocaine, there were 3 participants reported nausea and 10 participants with dizziness and 19 participants with injection site pain after 5 minutes of IUCD placement. There are different studies about usage of another different form of lidocaine preparations and different techniques of application that we didn't use in our study

Allen et al.⁽¹⁷⁾ concluded that 2% lidocaine gel placed on the anterior lip of the cervix and at the internal os did not reduce pain with tenaculum placement and IUCD insertion compared to placebo gel. 150 women were enrolled in the study, 73 women received placebo gel & 72 women received 2% lidocaine gel on the anterior cervical lip & inside the cervical canal. Allen's trial is similar to **Maguire's et al.**⁽¹⁸⁾ trial except that Allen used a higher dose of lidocaine gel (6%).

The lidocaine group reported a mean pain score with tenaculum placement of 37.5 (median: 39) compared to the placebo group of 41.6 (median: 37) ($p=0.4$). Similarly, pain with IUCD insertion was no different with a mean pain score of 35.2 (median: 34) in the lidocaine group and 36.7 (median 36) in the placebo group ($p=0.8$). Unlike our study, we didn't use lidocaine gel but we compared 3 other different forms of lidocaine preparations.

Karashin et al.⁽¹⁹⁾ concluded that topical lidocaine spray is a practical and effective analgesic for decreasing pain perception scores during HSG procedure. A total of 81 patients were randomly assigned to three groups: Group 1, 10 mg lidocaine hydrochloride 10% spray; Group 2, 20 mg lidocaine hydrochloride 10% spray; and Group 3, Placebo. A 10 mg dose is comparable to a 20 mg dose in pain reduction with less chance of side effects and better cost-effectiveness in **Karashin** study.

The differences between **Karashin et al.**⁽¹⁹⁾ study and our study are using lidocaine during

the procedure of HSG rather than IUCD insertion and we used a dose of 40mg dose instead of 10 mg and 20 mg. In our study, we used larger number of participants and we didn't use a placebo but we compared lidocaine spray with injection and cream. **Nelson et al.**⁽²⁰⁾ concluded that Use of 2% lidocaine administered through an endometrial aspirator did not significantly reduce IUCD insertion pain scores. 40 women undergoing IUCD insertion were enrolled in the study, pain scores of women receiving 1.2 mL 2% lidocaine versus normal saline (1:1) infused 3 min prior to IUCD insertion were measured using a 0–9-point scale. Pain at tenaculum placement was similar between both groups. There was no difference in mean pain scores during IUCD insertion of women infused with lidocaine (2.95) versus normal saline (3.75), $p=0.37$.

In our study, we used 3 different forms of a local anaesthetic agent (lidocaine) to give the least chance of systemic side effects unlike other studies that used oral analgesia as a method of reduction of pain associated with IUCD insertion.

Bednarek et al.⁽²¹⁾ had evaluated the effect of maximum dose of Ibuprofen (800mg), 202 women were enrolled with 101 randomized to each group (Ibuprofen or placebo), **Hubacher et al.**⁽²²⁾ used Ibuprofen 400mg but on a large number of women (2019 participants). The strength in **Bednarek et al.**⁽²¹⁾ study was its power to evaluate effect for both nulliparous & multiparous women also, the use of 2 different types of IUCD determining whether there are factors related to type of IUCD as regard pain felt during its insertion or not, but in our study we only used T Cu- 380 A with all participants.

Bednarek et al.⁽²¹⁾ failed to find an effect on pain with administration of 800mg Ibuprofen prior to insertion. The median pain score with IUCD insertion was 41.5 mm in the placebo group and 38.0 mm in the Ibuprofen group ($p=0.50$).

Also, prophylactic administration of 400 mg of Ibuprofen at least 45 minutes prior to IUCD insertion had no effect of pain in a Chilean trial **Hubacher et al.**⁽²²⁾. Mean pain scores were 1.8 in the Ibuprofen arm and 2.0 in the control arm on a 10 cm visual analog scale (mean difference -0.20; 95% CI -0.41 to

0.01). Ibuprofen takes longer time to do its effect when compared to lidocaine (the waiting time after giving Ibuprofen in that study was 30–45 min while in our study it was only 5 minutes after giving each local lidocaine form).

One of the major strength points in our study is:

- It is a Prospective randomized clinical trial study.
- The waiting time after application of lidocaine preparation and before continuation of cervical manipulation was 5 minutes which is the time required for local anesthetics to reach its effect.
- Type of IUCD used was T 380 A which is the most popular type of IUCD and most available one in Egypt and worldwide.
- Analysis of pain was done using the standard VAS which is the most reliable tool for assessment of pain.
- This trial was non-invasive, the drug used works locally which gives the least chance of side effects.

CONCLUSION

Our study demonstrated that local lidocaine spray 10% is effective in control of pain associated with IUCD insertion when compared with lidocaine cream or injection because its application is easy and rapid, while lidocaine injection can also reduce pain but injection itself is painful that makes it unfavorable method.

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