# **Efficacy and Safety of Paracervical Block in Reducing Intrauterine Device Insertion Related Pain : A Randomized Controlled Trial**

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# ABSTRACT

**Objective:** To assess the efficacy and safety of 20 ml of 1 % buffered lidocaine paracervical block to reduce pain during IUCD placement.

**Materials and Methods:** In randomized single blinded controlled trial, women were assigned to receive either a 20 ml buffered lidocaine or no block before IUCD insertion. Enrollment occurred at family planning clinic, Badr University Hospital. The primary outcome was pain measured with a 100-mm visual analogue scale in various steps of IUD insertion. **Results:** From January to july 2021, 138 women were enrolled and distributed randomly into two equal groups: group I (intervention group) included 70 women received paracervical block before IUCD insertion in form of lidocaine injection, and group II (no intervention) included 68 women. There were no differences in demographic characteristics of both groups. Women who received the paracervical block reported less pain with IUD insertion compared to women who received no block( median VAS score of 20.9 mm versus 37.4 mm, p < 0.001). Pain with tenaculum placement was less in intervention group (28.9mm versus 58.4mm, p < 0.001). Pain with paracervical block administration was higher for intervention group compared to the no paracervical block group (18.4mm versus 10.9mm, p < 0.001).

The mean pain intensity felt 5 minutes after IUD placement was (5.9mm versus 16.9mm, p < 0.001) which is statistically significant. The intensity of pain was similar and there was no statistically significant difference in the median VAS scores at baseline pain or pain with speculum insertion (51mm compared with 53.4 mm, p = 0.196).

**Conclusion**: 20 ml lidocaine 1% paracervical block prior to copper T380A IUD insertion significantly decrease the related pain perception when compared with no block group.

Key Words: Insertion, intrauterine device, pain, paracervical block.

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### **INTRODUCTION**

Unplanned pregnancy is a public health problem, which affects millions of women worldwide. Intrauterine contraceptive devices (IUCD) are long-acting reversible with the highest effectiveness and failure rate of less than 1% over 10 years of use.

The most common models in use worldwide are the CU T 380 A intrauterine device (cu\_iud) & levonorgestrelreleasing intrauterine system (LNG\_IUS), both types are safe, cost effective in long term and equal in efficacy to compare tubal sterilization but it still less commonly used compared with the less effective methods including condoms and pills<sup>[1]</sup>.

One barrier to IUCD use is the fear of pain during insertion. Several components of the insertion process may cause pain, including tenaculum placement, uterine sounding, IUD insertion through the cervical os and contact with the uterine fundus<sup>[2]</sup>.

The uterus has two distinct visceral pain pathways parasympathetic fibers (Frankenhauser plexus, S2 to S4) provide and sympathetic fibers (ovarian nerve plexus, T10 to L1) provide sensory innervation to the fundus of the uterus<sup>[3]</sup>.

IUCD insertion is usually associated with a variable degree of pain

Most women experience mild to moderate discomfort, rarely the pain is severe<sup>[4]</sup>.

Predictors of pain during IUCD insertion include nullipartity, age greater than 30 years, lengthier time since last pregnancy or last menses, and not currently breastfeeding. Reducing pain during IUD insertion not only provides satisfaction to patients but also benefits providers when the patient is more comfortable, the provider can likely perform the insertion more quickly and with fewer complications<sup>[5]</sup>.

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There are currently no standardized pain management guidelines for IUD insertion. Pain management modalities during IUD insertion commonly include non-steroidal anti-inflammatory drugs (NSAIDs), cervical ripening by preprocedural misoprostol, and local anesthesia in the form of intracervical gel, cervical and paracervical block<sup>[6]</sup>.

The administration of local anesthesia in gynecological procedures can be performed using different modalities: intrauterine, intracervical, paracervical, and topical applications.

Para cervical block is an anesthetic procedure used in obstetrics and gynecology for various procedures in which a local anesthetic is injected into between 2 to 6 sites at depth of 3-7 mm alongside the vagino portion of the cervix in the vaginal fornices<sup>[7]</sup>.

A randomized trial of paracervical blocks in a different but similar setting showed that the procedure significantly reduced pain related to cervical manipulation.

The concept of paracervical block is to anesthetize the nerve supplying the cervix by injecting local anesthetic  $agent^{[8]}$ .

Lidocaine is the most common local anesthetic agent used because of low cost, stability, and low risk of allergic or adverse reactions<sup>[9]</sup>.

Evaluation of pain as a symptom is difficult because it is subjective feeling and composed of sensory, emotional, and cognitive components.

A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. This validated pain scale uses a 10 cm line to represent the continuum of "no pain" to "worst imaginable pain".

# PATIENTS AND METHODS

The study was conducted at the family planning clinic obstetrics & gynecology department of Badr University Hospital during the period between January and July 2021

The study included 138 candidates attended the family planning clinic requesting contraception using IUCD methods and aged from 20 to 45 years. Exclusion criteria included pregnancy, cervical stenosis, active cervical infection, uterine or cervical anomaly, pelvic inflammatory disease, fibroid uterus, allergy to copper and lidocaine; they randomized and were distributed equally into two groups:

Group I (intervention group) included (70) women received paracervical block before IUCD insertion in form of lidocaine injection. Group II (no intervention) included (68) women

Randomization was performed using a block size of four with group assignment through sequentially numbered, opaque, sealed envelopes to ensure an equal distribution of participants who received and who not received a paracervical block

All eligible participants included in the study signed a written informed consent before recruitment in the study after explanation of the purpose and procedures of the study.

A full detailed personal, obstetric, menstrual and medical history was obtained.

All participants had complete clinical examination, pelvic ultrasound and pregnancy test.

Each patient had a case record form (CRF) in which the following data was recorded:

## Patient intials

Age, hight and weight

Parity, previous delivary and abortion

Medications and concomitant illness

Each participant was randomly assigned into one of two groups: group I: women who received a 20 cc buffered 1% lidocaine paracervical block (using syringe 25 gauge, and 3cm needle) prior to insertion, and group II: no paracervical block (a capped needle)

With the patient in the dorsolithotomy position, the provider conducted a pelvic examination to assess eligibility.

The provider performed the bimanual examination firstly then inserted speculum into the vagina to inspect the vagina, cervix and enterance to the cervical canal.

A standard 10% povidine iodine solution was applied to disinfect and preparation of the vagina and opening to the cervix

Then according to patient group, each patient received either 20ml of lidocaine or no according to randomization table.

For the intervention group, each patient received a 20ml paracervical block that consisted of 18ml of 1%lidocaine buffered with 2ml 8.4% sodium bicarbonate because the sodium bicarbonate decreases the burning sensation associated with lidocaine administration, without adding

epinephrine as IUD placements typically involve minimal risk for bleeding.

2ml was injected at the tenaculum site superficially at 12 o'clock on the anterior lip of the cervix and the cervix was grasped with the tenaculum to stabilize the cervix.

The remaining 18 ml was injected into the vaginal fornices in equal amount at the 4 and 8 o'clock positions. The injection was continuous from superficial to deep (3cm) to superficial (injecting with insertion and withdrawal).

For the no intervention group, pressure with applied at these sites with capped niddle.

Placement of the IUD (a copper T 380A Pregna International, Mumbai, India, DKT Egypt) took place after application of the paracervical block or no block.

All participants score their pain at different points during procedure as the following: Baseline pain just before the start of the procedure

Speculum insertion

Paracervical administration

Tenaculum placement

Uterine sounding

IUD placement

And 5 minutes after placement.

### Sample Size Calculation:

The required sample size has been calculated using the IBM<sup>©</sup> SamplePower<sup>©</sup> software version 3.0.1 (IBM<sup>©</sup> Corp., Armonk, NY).

The primary outcome measure is the pain score during IUD insertion in either study group.

A previous study reported that the mean  $\pm$  SD pain score during IUD insertion in patients receiving PCB was  $37.3 \pm 35$  compared with  $52.5 \pm 27.5$  in controls<sup>[2]</sup>.

So, we calculated that a sample size 69 patients in either study group would achieve power of 80% to detect

a statistically significant difference of 15.2 between both groups as regards the pain score during IUD insertion (corresponding to means of 37.3 and 52.5) and assuming a common SD of 31.5 (based on SD estimates of 35.0 and 27.5). These calculations used a two-sided unpaired t-test with type I error of 0.05.

# Statistical analysis:

Statistical analysis was done using Data were analyzed using IBM<sup>®</sup> SPSS<sup>®</sup> Statistics version 26 (IBM<sup>®</sup> Corp., Armonk, NY) and MedCalc<sup>®</sup> Statistical Software version 20 (MedCalc Software Ltd, Ostend, Belgium; https://www. medcalc.org; 2021).

Categorical variables are presented as counts and percentages and intergroup differences are compared using the Pearson chi-squared test. Ordinal data are compared using the chi-squared test for trend.

Numerical variables are presented as mean and standard deviation and intergroup differences are compared with the independent-samples t-test.

Serial measurement analysis is used to calculate summary measures for the pain scores using the methods described by<sup>[10]</sup>. The area under the time-VAS curve (AUC), time-weighted average TWA) and minimum and maximum VAS scores are calculated and compared between groups using the unpaired t-test.

Repeated measures analysis of variance (ANOVA) is used to examine between-subjects and within-subjects effects as regards the change in pain scores.

*P-values* < 0.05 are considered statistically significant.

#### RESULTS

A total 150 women were evaluated for eligibility. 12 of them were excluding: 5 refused to participate in the study and 7 who did not meet inclusion criteria. 138 women were enrolled and completed the study. All procedures were successfully completed without severe complications or serious adverse reactions. No statistically significant difference was found between the two groups in term of mean age, body mass index, gravidity or parity, abortions, mode of delivery, and time since last menstrual period. (Table 1, 2).

	Intervention g	roup (n=70)	Control g	roup (n=68)	Diffe	erenc	95%	6 CI	
Variable	Mean	SD	Mean	SD	Mean	SE	Lower	Upper	P value†
Age (years)	30.4	6.1	29.8	5.0	0.576	0.949	-1.300	2.453	0.544
Weight (kg)	74.5	11.2	74.7	10.6	-0.234	1.863	-3.918	3.450	0.900
Height (cm)	164.7	3.9	164.5	3.6	0.186	0.636	-1.072	1.444	0.770
BMI (kg/m <sup>2</sup> )	27.3	3.6	27.5	3.4	-0.2610	0.5942	-1.4360	0.9140	0.661

 Table 1: Demographic characteristics of both groups

<sup>†</sup>. Independent-samples t-test.

SD = standard deviation, SE = standard error, 95% CI = 95% confidence interval.

The *p* value for age is 0.544 which is statistically insignificant The *p* value of BMI is 0.661 which is statistically insignificant

Table 2: Obstetric history in both groups

		Interventio	n group (n=70)	Control g	group (n=68)	
Variable		N	%	Ν	%	P value†
Parity	P1	27	38.6%	28	41.2%	0.646‡
	P2	22	31.4%	21	30.9%	
	P3	17	24.3%	17	25.0%	
	P4	3	4.3%	1	1.5%	
	P5	1	1.4%	1	1.5%	
Previous abortion	-	48	68.6%	48	70.6%	0.797
	+	22	31.4%	20	29.4%	
Past labors	NVD	13	18.6%	17	25.0%	0.657
	CS	49	70.0%	44	64.7%	
	NVD & CS	8	11.4%	7	10.3%	
Frequency of previous CS	Nil	14	20.0%	16	23.5%	0.076‡
	1 CS	22	31.4%	27	39.7%	
	2 CS	19	27.1%	19	27.9%	
	3 CS	13	18.6%	6	8.8%	
	4 CS	2	2.9%	0	0.0%	

<sup>†</sup>. Pearson chi-squared test unless otherwise specified.

‡. Chi-squared test for trend.

Table 3: Uterine position and length and timing of IUD insertion in both groups

Variable	Intervention group (n=70)	Control group (n=68)	P value
Uterine length (cm), mean $\pm$ SD	$7.6 \pm 0.9$	$7.6 \pm 1.0$	0.670†
Uterine position, n (%)			0.412 <i>‡</i>
AVF	56 (80.0%)	58 (85.3%)	
RVF	14 (20.0%)	10 (14.7%)	
Timing of IUD insertion, n (%)			0.368‡
LMP	56 (80.0%)	50 (73.5%)	
Post-abortion	14 (20.0%)	18 (26.5%)	

†. Independent-samples t-test.‡. Pearson chi-squared test.

There was no difference in participants in uterine length, position or timing of insertion between both groups (Table 3).

As regard uterine length, p value was 0.670<sup>†</sup> which is statistically insignificant.

As regard uterine position, p value was 0.412 which is statistically insignificant.

As regard timing of IUD insertion, p value was 0.368 which is statistically insignificant.

		Intervention group (n=70)		Control group (n=68)		Difference		95% CI			
Variable	Time	Mean	SD	Mean	SD	Mean	SE	Lower	Upper	P value†	
VAS	Speculum insertion	51.0	10.1	53.4	11.4	-2.4	1.8	-6.0	1.2	0.196	
	Paracervical administration	18.4	5.8	10.9	2.9	7.5	0.8	6.0	9.1	<0.001	
	Tenaculum placement	28.9	6.5	58.4	10.3	-29.5	1.5	-32.4	-26.6	<0.001	
	Uterine sounding	28.0	5.3	47.8	10.5	-19.8	1.4	-22.6	-17.0	<0.001	
	IUD placement	20.9	7.4	37.4	9.2	-16.4	1.4	-19.2	-13.6	<0.001	
	5 min after IUD insertion	5.9	5.5	16.9	6.5	-11.0	1.0	-13.0	-9.0	<0.001	

<sup>†</sup>. Independent-samples t-test.

SD = standard deviation, SE = standard error, 95% CI = 95% confidence interval.

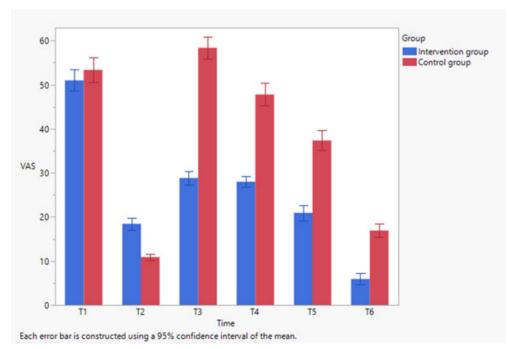
[Table 4] shows that the primary outcome of VAS score for IUD placement, the median pain score was less for the paracervical block group compared to the no intervention group (20.9mm versus 37.4 mm, p < 0.001) which is statistically significant.

Median pain score was also less for uterine sounding (28mm versus 47.8mm, p < 0.001), which is statistically significant.

Pain with tenaculum placement was less in intervention group (28.9mm versus 58.4mm, p < 0.001), the mean pain

intensity felt 5 minutes after IUD placement was (5.9mm versus 16.9mm, p < 0.001) which is statistically significant. Pain with paracervical block administration was higher for intervention group compared to the no paracervical block group (18.4mm versus 10.9mm, p < 0.001).

The intensity of pain was similar and there was no statistically significant difference in the median VAS scores at baseline pain or pain with speculum insertion. (Table 4).



**Fig. 1:** Mean pain scores in both study groups. Error bars represent 95% confidence intervals (95% CI). T1 = Speculum insertion, T2 = Paracervical administration, T3 = Tenaculum placement, T4 = Uterine sounding, T5 = IUD placement, T6 = 5 min after IUD insertion. Differences between both groups starting from paracervical placement till 5 minutes after IUD insertion are all statistically significant at the P < 0.001 level.

Figure 1 shows between-group differences in the VAS scores at each procedural step. VAS scores were significantly higher in control group (no block group)

compared with the intervention group at all subsequent procedural steps except para cervical administration which is higher in intervention group.

VAS	Group	N	Mean	SD	Difference	95% CI	P-value†
	Intervention group	70	124.7	23.3		55.1 to 74.6	
AUC	Control group	68	189.6	33.8	64.9		0.0001
TT 1 1	Intervention group	70	24.9	4.7	12.0	11.0 to 14.9	0.0001
TWA	Control group	68	37.9	6.8	13.0		0.0001
Minimum	Intervention group	70	5.9	5.5	4.7	3.1 to 6.2	0.0001
	Control group	68	10.6	3.4	4./	5.1 10 0.2	0.0001
Maximum	Intervention group	70	51.0	10.1	9.4	(0 + 12 0	0.0001
	Control group	68	60.4	10.4	9.4	6.0 to 12.9	0.0001

**Table 5**. Serial measurement analysis for the change in pain scores

†. Unpaired t test. AUC = area under the time-VAS curve, TWA = time-weighted average.

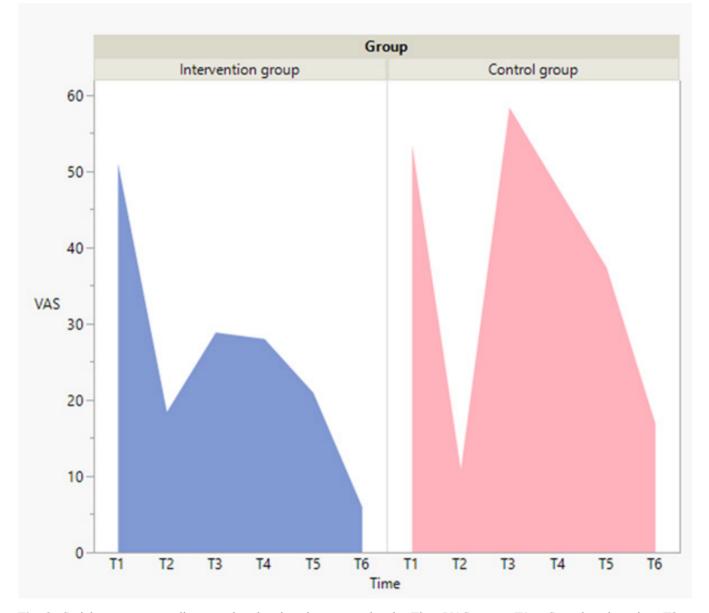


Fig. 2: Serial measurement diagram plot showing the area under the Time-VAS curve. T1 = Speculum insertion, T2 = Paracervical administration, T3 = Tenaculum placement, T4 = Uterine sounding, T5 = IUD placement, T6 = 5 min after IUD insertion. Area under the time-VAS curve (AUC), time-weighted average VAS, and minimum and maximum VAS are all significantly lower in the intervention group compared with the control group (P values < 0.0001).

Table 6: Repeated measures analysis of variance (ANOVA) for the change in pain scores

Sphericity					
Method	Epsilon				
Greenhouse-Geisser	0.802				
Huynh-Feldt	0.829				
Test	of Between-Subjects Effe	ects			
Source of variation	Sum of Squares	DF	Mean Square	F	P value
Groups	29441.1	1	29441.1	143.55	< 0.001
Residual	27892.12	136	205.089		
Tes	t of Within-Subjects Effec	cts			
Source of variation	Sum of Squares	DF	Mean Square	F	P value
Time	180526.6	5	36105.32	1003.82	< 0.001
Group * Time interaction	29767.67	5	5953.533	165.52	< 0.001
Residual	24458.18	680	35.968		

DF = degree of freedom. F = F statistic

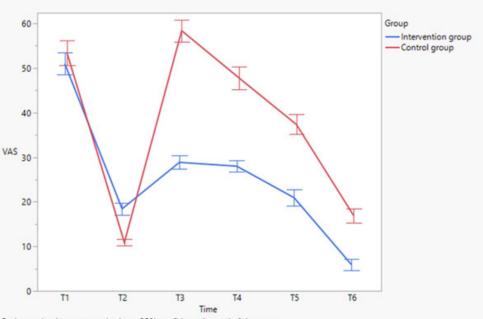
### Comment

The results of repeated measures analysis of variance (ANOVA) for the change in pain scores is shown in (Table 6).

The assumption of sphericity is not violated (Greenhouse-Geisser epsilon = 0.802, Huynh-Feldt epsilon = 0.829), so no correction was done for the degrees of freedom.

Test of between-subjects effects shows a statistically significant difference between groups (F = 143.55, df = 1, 136, P value < 0.001).

Test of within-subjects effects shows a statistically significant effect of time (F = 1003.82, df= 5, *P* value < 0.001) with a statistically significant Group \* Time interaction (F = 165.52, df= 5, *P* value < 0.001).





**Fig. 3:** Mean pain scores in both study groups. Error bars represent 95% confidence intervals (95% CI). T1 = Speculum insertion, T2 = Paracervical administration, T3 = Tenaculum placement, T4 = Uterine sounding, T5 = IUD placement, T6 = 5 min after IUD insertion. Test of between-subjects effects shows a statistically significant difference between groups (F = 143.55, df = 1, 136, *P value < 0.001*). Test of within-subjects effects shows a statistically significant effect of time (F = 1003.82, df= 5, *P value < 0.001*) with a statistically significant Group \* Time interaction (F = 165.52, df= 5, *P value < 0.001*).

### DISCUSSION

Although IUCD is represented as one of the most effective birth control options, it is still less commonly used compared with less effective methods including pills and condoms<sup>[11]</sup>.

Fear of pain during the insertion procedure presents a reason beyond the decline of women to use IUCD for family planning<sup>[2]</sup>.

The level of pain that women experience during IUD insertion vary in published reports, Most women experience mild to moderate discomfort, rarely the pain is severe<sup>[4]</sup>.

Several components of the insertion process may cause pain, including tenaculum placement, uterine sounding, IUD insertion through the cervical os, and contact with the uterine fundus<sup>[12]</sup>, so this study was a trial to decrease pain during these steps of IUCD insertion.

The aim of the current study is to assess the efficacy and safety of 20ml of 1% buffered lidocaine paracervical block to reduce pain during IUCD insertion.

In this randomized controlled double blinded clinical trial we enrolled a total of 138 women that come to Badr University Hospital, at family planning clinic sought family planning by IUCD insertion. After ensuring the eligibility for the trial and having a written consent, they were randomized into two groups; group I received 20 ml of lidocaine 1% paracervical block, and group II no intervention, then the steps of IUCD insertion were completed.

In the current study, there were no significant differences between the two groups regarding age, parity, abortions, mode of delivery, interval from LMP denoting that both groups were matched regarding factors that may influence pain sensation during the process of IUD insertion.

The primary outcome was the participant's pain on visual analog scale (VAS) from 0mm (no pain) to 100mm (worst imaginable pain) at various steps during IUD placement.

A median 100mm visual analogue scale (VAS) for pain scoring was used in our study which was the same as<sup>[6,13,2]</sup>. This pain scale used 1 to 100 pain scoring system numbered from 1 to 100 with no pain at 1 and worst pain at 100.

In this study we found that the *p value* for the pain felt during speculum insertion measured by VAS was 0.196 which is statistically insignificant.

Regarding pain felt after grasping cervix with tenaculum (measured by VAS) the *p* value was <0.001 which was statistically significant.

Lower tenaculum related pain scores were observed in lidocaine block group than in no-intervention group (28.9mm versus 58.4mm).

As regard pain during paracervical block administration, the *p* value was < 0.001 which is statistically significant.

Regarding pain during uterine sound, the *p* value was <0.001 which is statistically significant.

As regard pain felt during IUCD insertion, the *p* value was < 0.001 which is statistically significant. In the lidocaine block group, insertion related pain was lower than in no block group (20.9mm versus 37.4 mm).

Regarding pain felt 5 minute after IUD placement, the *p value* was <0.001 which is statistically significant.

The median pain reported during the procedure was significantly less in lidocaine block group compared with the non-block group at various steps of the procedure. The VAS scores were lower in lidocaine block group compared with the non-block group.

Finally, the analysis of data revealed that injection of 1% lidocaine paracervical block before IUD insertion effectively reduce pain felt during steps of IUD insertion and good option for reduction of IUD insertion related pain compared with no block.

By reviewing online published trials, there are articles published in ELSEVIER 2012, Indian Journal and review published in The Cochrane Library 2015, reviewing intervention for pain with intrauterine device insertion.

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

Akers *et al.*<sup>[4]</sup> concluded that a 10ml 1 % lidocaine paracervical nerve block reduces pain during IUD insertion in adolescents and young women compared with a sham block. 95 participants enrolled in the study and divided into two groups 47 lidocaine group & 48 sham block group. The median VAS score after IUD insertion was 30.0 in the lidocaine block group and 71.5 in the sham block, *p value* <0.001.their results were in agreement with those of the current study.

The difference between the Akers *et al.*<sup>[4]</sup> study and the current study are that they focused on adolescents and young nulliparous women.

The current study is in agreement also with Mody et al.[13] they concluded that 20 cc 1% lidocaine paracervical block decreases pain with IUD placement, uterine sounding, 5 min after placement and overall pain perception. A total 64 women were enrolled and analyzed (33 in paracervical arm, 31in the no-block arm). Women who received paracervical block reported less pain with IUD placement compared with women who received no block (33mm versus 54mm, p=0.002). Pain was significantly less in the intervention group for uterine sounding (30mm versus 47mm, p=0.005), 5 minute after placement (12mm versus 27mm, p=0.005). Participants who received the paracervical block experienced more pain with block administration compared with placebo (30mm versus 8mm). There was no perceived pain difference for speculum insertion (10mm versus 6mm, p=0.447) or tenaculum placement (15mm versus 10mm, p==0.268). The results of this study is in agreement with the current study as regard paracervical block reduces pain perception during every step of IUD insertion, but differ as regard tenaculum- related pain. In current study there was Lower tenaculum related pain scores were observed in lidocaine block group than in no-intervention group (28.9mm versus 58.4mm, p=0.001), and also in our study we used a larger number of participants .

Also, Goldthwaite *et al.*,<sup>[14]</sup> 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 mean pain levels at tenaculum placement (12.3mm versus 36.6mm, p=0.001). result of this study are consistent with our study but the difference between Goldthwaite *et al.*<sup>[14]</sup> study and the current study are that we did not use lidocaine gel and we assess pain during various steps of IUCD insertion not during the tenaculum placement only.

Results of CIrIk DA *et al.*<sup>[15]</sup> demonstrated significantly lower pain perception in paracervical block group when compared to placebo and no treatment groups. A total 95 women were enrolled and randomized to paracervical lidocaine injection (n=34), placebo (n=30) and no treatment (n=31) arms before IUD insertion and compared pain perception during tenaculum and IUD application and 5 minutes after the procedure. Pain score were found to be lower in para cervical group (p=0.00).this study was in agreement with the current study with difference in the randomization as our study randomized two group and did not use placebo.

Also, Allen *et al.*,<sup>[6]</sup> concluded that 2% lidocaine gel placed on the anterior lip of the cervix and at the internal os did not reduce pain with tenaculum pacement and IUD insertion compared to placebo gel (mean pain score 37.5mm versus 41.6mm, p=0.4).

In the study by Karasu *et al.*,<sup>[16]</sup> use of lidocaineprilocaine cream did not lead to lower pain scores at either tenaculum or IUD placement when compared with controls (no anesthesia).

In contrast to Abbas *et al.*,<sup>[17]</sup> that investigated the analgesic effect of cervical lidocaine prilocaine (LP) cream in alleviating pain during copper T380A IUD insertion among parous women. Women received 2 ml of LP cream or placebo to the anterior cervical lip, followed by 2 ml placed in the cervical canal using a Q- tip applicator. LP cream reduces the median VAS pain scores during tenaculum placement (2 vs 4), sound insertion (3 versus 6) and IUD insertion (3 versus 6.5) with p = 0001 at all steps. A lower ease of insertion score was also determined among LP women.

Wong *et al.*,<sup>[18]</sup> found no benefit using lignocaine gel applied on the cervix before the procedure, whereas, Soriano *et al.*,<sup>[19]</sup> demonstrated substantial reduction in pain associated with the use of lidocaine spray.

The strengths points of the current study include that it was a randomized control trial, the relatively large number of participants. Also, we included different educational levels of women, as this could affect the perception of pain, so our results could be generalizable to different women in our community.

The study has its limitations including that the study focused on one type of IUD and the data are applied only for copper T380A which is the most popular type of IUCD and most available one in Egypt and worldwide. A second limitation was the subjectivity in reporting pain through VAS score, as there no objectives parameters to evaluate pain. Furthermore, none of the included women were nulliparous because IUD insertion is not requested by this group in Egypt. Finally the limiting factor that may interfere with the results is pain threshold difference between the patients.

# **CONCLUSION & RECOMMENDATIONS**

Use of lidocaine 1% paracervical block is a good option for reducing IUCD insertion related pain when compared with no block.

Further studies are needed to explore its effectiveness in women at high risk for experiencing severe pain during IUD insertion such as nulliparous women or those who only delivered by cesarean section.

Further studies are recommended to focus on refinement of the paracervical technique.

Further studies are recommended to assess the effectiveness and safety of different doses and forms of lidocaine.

### **CONFLICT OF INTEREST**

There are no conflicts of interests.

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