The Egyptian Journal of Hospital Medicine (April 2023) Vol. 91, Page 4110-4116

Lidocaine Spray 10% versus Oral Ibuprofen Tablets in Pain Control during Copper Intrauterine Device Insertion (A Randomized Controlled Trial)

Noha A. Sakna, Mohammed Ahmed Elkadi, Marina Ramsis Aziz Ghaly, Al Hassan Mohammad Khedr*
Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University
***Corresponding author:** Marina Ramsis Aziz Ghaly, **Mobile:** (+20) 01271869711, **E-Mail:** dr.marina_ramsis@yahoo.com

ABSTRACT

Background: The intrauterine contraceptive device (IUCD), which is a plastic T-shaped device with copper attached to it, is the most widely used type of reversible contraception in the world. It was developed more than 30 years ago and has since become the industry standard due to its long-term effectiveness, safety, and affordability.

Objective: To compare the effectiveness of oral ibuprofen versus 10% lidocaine spray as pain killers during the installation of copper intrauterine devices.

Patients and Methods: This prospective, randomized clinical study comprised 140 women who sought out the Family Planning Clinic at Ain Shams Maternity Hospital between December 2021 and June 2022 in order to have an IUCD inserted for the purposes of contraception. Two groups were created from the participants. Those in Group 1 were given four sprays (40 mg) of 10% lidocaine spray to be administered topically on the cervix uteri 3-5 minutes before to IUCD implantation, whereas those in Group 2 were given 400 mg of ibuprofen tablets orally to be taken at least 45 minutes before IUCD implantation.

Results: Failure of insertion statistically was non-significantly different among lidocaine spray and ibuprofen tablet groups. Vasovagal reactions statistically were non-significantly less frequent among lidocaine spray. Patients' pain perception statistically was significantly lower among lidocaine spray group. Moderate pain statistically was significantly less frequent among lidocaine spray. Need to analgesics statistically was significantly less frequent among lidocaine spray.

Conclusion: Pain from IUCD insertion may be effectively managed with 10% local lidocaine spray, which is more convenient than ibuprofen pills and takes action quickly. When deciding between ibuprofen pills and lidocaine spray for pain management following IUCD implantation, many women choose the latter.

Keywords: Lidocaine Spray 10%, Ibuprofen, Copper Intrauterine Device Insertion.

INTRODUCTION

A tiny, usually T-shaped contraceptive device that is put into the uterus, an intrauterine device (IUD) is also known as an intrauterine contraceptive device (IUCD) [(1)]. IUCDs are a kind of reversible, long-acting contraception (LARC). According to research, female family planning professionals are more likely to use LARC techniques (41.7% vs. 12.1% of the total population) [(2)].

The intrauterine contraceptive device (IUCD) is a plastic T-shaped framework that is implanted into the uterus. The copper variety is a coiled wire made of copper, which triggers an inflammatory response that is poisonous to sperm and eggs (ova), therefore inhibiting conception [(3)].

The copper intrauterine contraceptive device (IUCD) is very effective in preventing conception and contains no hormones. This makes it a viable choice for those who choose non-hormonal birth control or who cannot use hormonal methods due to medical conditions such as a history of blood clots (Deep venous thrombosis (DVT), pulmonary embolism (PE), stroke, or myocardial infarction (MI). To allay concerns concerning fertility, it has been proven that fertility returns to normal within a short time after the device is removed [(3)]. Women who used the Copper T IUCD (Cu-T380A) had a median delay to conception of three months from the time of removal[(4)].

Concerns about discomfort and difficulties with insertion are now the greatest obstacle to IUCD usage, despite the fact that the devices have been shown to be safe and effective. To lessen discomfort, non-steroidal anti-inflammatory medicines (NSAIDs) are often used before having an IUCD inserted. Ibuprofen 400 mg was the dose tested in the biggest NSAIDs study before IUCD implantation. Colposcopy and endometrial biopsies are not the only gynecologic procedures performed in an outpatient setting where NSAIDs are often prescribed as a pretreatment. Increasing IUCD uptake is possible after an effective strategy for minimizing insertion-related discomfort has been developed [(5)].

Researchers have looked at a variety of pain relief strategies for IUCD insertion. Non-steroidal anti-inflammatory medicines (NSAIDs) and medications that numb the cervix with local anesthetics are examples of these. Besides medication, other non-drug interventions, such as pre-insertion counselling, the procedure's location, or the provider's assurance, may change a woman's degree of anxiety, which in turn may affect her perception of pain and her experience [(6)].

Lidocaine spray, a local anesthetic often used in dentistry for oral mucosal anesthesia during small surgical operations, is a straightforward and practical option with few unwanted effects. It's possible that the spray version of lidocaine will be more user-friendly and well-received by patients than alternative delivery methods. Lidocaine produces local anesthetic effects by stabilizing neuronal membranes by blocking ionic

Received: 02/11/2022
Accepted: 04/01/2023

fluxes critical for impulse generation and transmission [7].

Because of its effective pain relief and fever reduction properties, ibuprofen is the most widely used and prescribed nonsteroidal anti-inflammatory drug (NSAID). It works by blocking the enzymes responsible for making prostaglandins, called cyclo-oxygenases (COX-1 and COX-2). Pain, inflammation, and fever may all be caused by prostaglandins [8-11].

The aim of this study is to compare the effectiveness of oral ibuprofen and 10% lidocaine spray as pain killers during the installation of copper intrauterine devices.

PATIENTS AND METHODS

This is a randomized controlled experiment with two treatment groups. One hundred and forty women participated in the research, with 70 women in each group. All of the participants were regulars at the Family Planning Clinic at Ain Shams Maternity Hospital.

Sample size justification:

Using G power program setting the alpha error 5% and power at 80%.

For a moderate effect size of 0.5 (Cohen d') on pain score, the needed sample is 70 cases per group with taking in consideration 10% drop out rate.

Methods:

In the lithotomy position, a speculum was used, and the vagina and cervix were washed with standard povidone iodine solution. The cervix was then lifted up with a tenaculum and straightened to the axis of the uterus. The next step was insertion, during which the uterine depth was assessed with a metal sound and the IUCD was inserted using the withdrawal technique by the supervisors. After IUCD insertion, patients were monitored for 30 minutes.

Study procedure:

During this randomized controlled experiment, we looked at 140 women who met the criteria for IUCD implantation based on their medical history and gynecological examination. All of the women were at least 18 years old and were either vaginally or surgically (cesarean section) delivered. Afterwards, they were split into 2 groups:

- **Group 1:** Seventy women were randomly allocated to have a 10% local lidocaine spray given onto the cervix. Each woman had four puffs (10 mg/puff). Before inserting the copper IUCD, we waited between three to five minutes for the anesthetic to take action after applying four puffs to the cervical surface and one puff of them directly towards the external cervical Os.
- **Group 2 (The control group):** Seventy women in the second group were randomly allocated to receive ibuprofen; those women were instructed to take 1 tablet (400 mg) of ibuprofen immediately, and then physicians waited at least 45 minutes before inserting the copper IUCD.

In all patients, a Copper T IUCD (Cu-T380A) was inserted on the 3rd–5th day of menstrual bleeding or was more than 6 weeks postpartum if recently pregnant.

Inclusion criteria:

Multiparity within third to fifth day of menstrual cycle. Presenting for intrauterine device implantation. Those women who did not take misoprostol or an analgesic in the 24 hours leading up to the insertion. Use of a tranquillizer or long-acting narcotic within 48 hours before to IUCD implantation was not permitted. It was safe to put an IUCD since there were no health risks involved.

Exclusion criteria:

If a female suspected with gynecological cancer, sexually transmitted disease (STD), pelvic inflammatory disease, or abnormal vaginal bleeding that hasn't been detected, should be excluded out of the trial. If pregnancy hypothesised. Ibuprofen and lidocaine allergies. IUCD-related copper allergy. Congenital malformations, endometrial lesions, adenomyosis, and submucous myoma were only few of the uterine conditions that might deform the uterine cavity. Changes in how one interpreted or experienced pain, as a result of a mental or neurological disease. Intrauterine system that releases levonorgestrel (LNG-IUS). Nulliparous women. Previous unsuccessful attempts to implant an intrauterine device (perforation of uterus, acute expulsion).

Allocation and concealment:

The randomization table was used to assign subjects to one of the two groups, and the relevant letters were placed in numbered opaque envelopes. In order to assign a patient to a room, the first envelope was opened when the first patient arrived.

Primary Outcome Measures:

Self-reported pain score [Time Frame: after IUCD insertion]:

How many points on a visual analogue scale (VAS) participants reported feeling discomfort immediately after IUCD implantation. The severity of pain was rated using a VAS, which consists of a horizontal straight line with a 10-centimeter range (0 cm = no pain, 10 cm = extreme pain). On the visual analog scale (VAS), a score of 0 indicates no pain, 1-3 indicates moderate pain, 4-6 indicates medium discomfort, 7-9 indicates severe pain, and 10 indicates the most severe agony imaginable.

After having her IUCD inserted, the lady was asked by a study assistant standing by her to fill out a visual analogue scale (VAS) pain questionnaire (Figure 1).

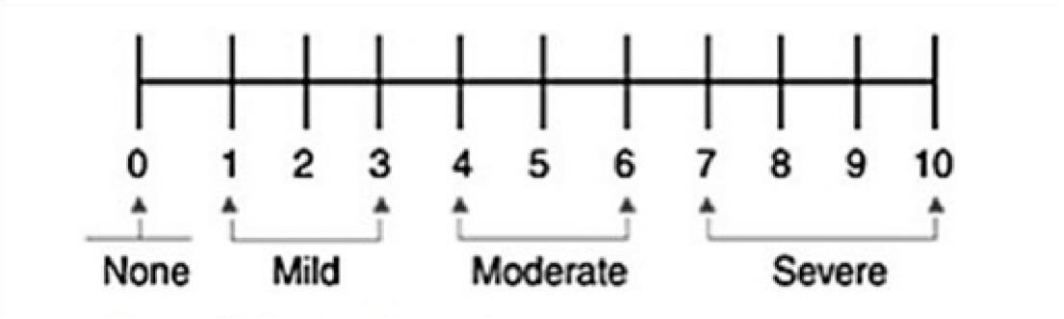

Figure (1): Visual analog scale.

Secondary Outcome Measures:

Immediate complications related to IUCD insertion [Time Frame: 30 minutes after insertion]:

The immediate complications related to IUCD insertion such as: Failure of insertion, vasovagal reaction, the number of women who needed analgesics after insertion.

Ethical consent:

The Institutional Review Board of the Faculty of Medicine at Ain Shams University gave its ethical approval to this study. All participants gave their written consent after being fully informed. In accordance with the Declaration of Helsinki, the study was carried out.

Statistical methods:

IBM SPSS Statistics (Statistical Package for the Social Sciences), Version 22.0, IBM Corp., Chicago, IL, USA, 2013 was used to analyse the data. Comparisons of means and standard deviations of normally distributed quantitative data were made using the independent t-test, whereas the median (1^{st}– 3^{rd} interquartile range) was used to characterize non-normally distributed data, which were compared by Mann-Whitne test. Qualitative data were presented as frequency and percentage and were compared using the Chi-square and Fisher's Exact tests. A p-value of less than 0.05 was considered statistically significant. **Intervention values was calculated as follows:** Rate elevation=Lidocaine Rate – Ibuprofen Rate. Efficacy= (Lidocaine Rate – Ibuprofen Rate) / Lidocaine rate. Relative Rate= Lidocaine Rate / Ibuprofen Rate. Number needed to treat = 1 / (Lidocaine Rate – Ibuprofen Rate).

RESULTS

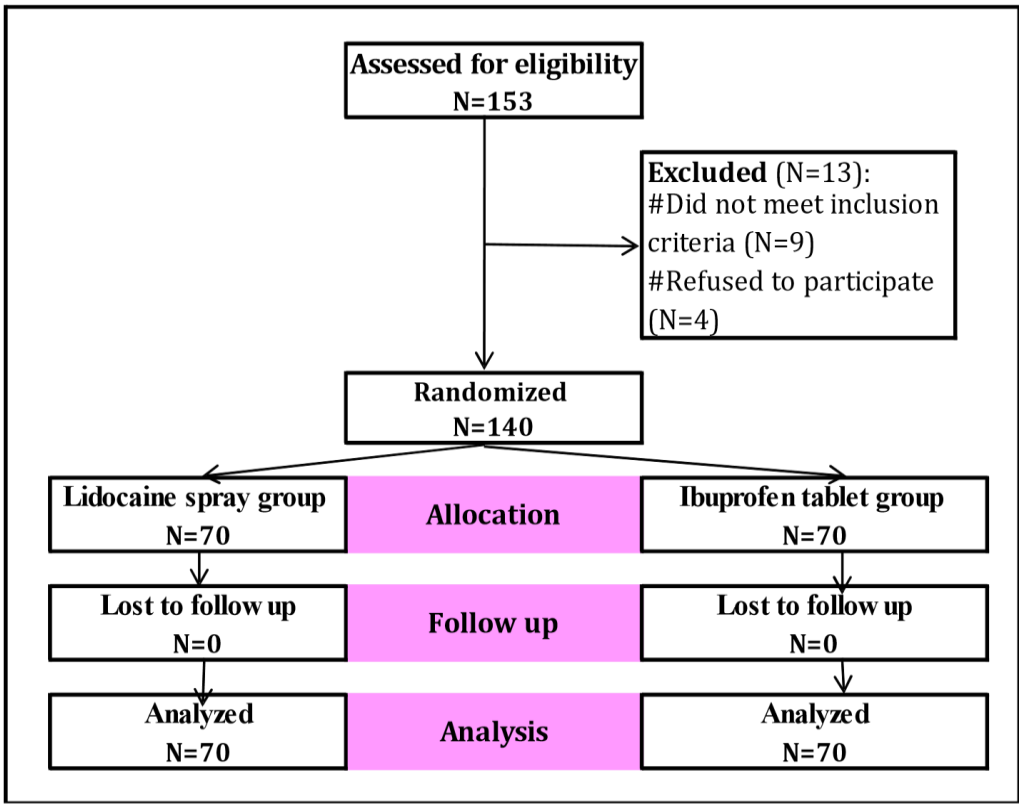

Figure (2): Flow chart of the studied cases.

Table (1) shows that: No significant difference between **lidocaine spray** and **ibuprofen tablet** groups regarding **age, BMI, parity and time after last delivery.**

Table (1): Baseline demographic characteristics among the study groups

Variables		Lidocaine spray (N=70)	Ibuprofen tablet (N=70)
Age (years)	**Mean±SD**	32.3±3.7	31.6±4.4
	Range	22.0–38.0	20.0–40.0
BMI (kg/m^2)	**Mean±SD**	26.1±2.0	25.9±2.1
	Range	21.4–30.1	20.2–29.8
Parity	**Median (1^{st}–3^{rd} IQ)**	1.0 (1.0–2.0)	1.0 (1.0–3.0)
	Range	1.0–4.0	1.0–3.0
Time after last delivery (weeks)	**Mean±SD**	11.7±2.5	12.3±2.4
	Range	6.0–17.0	6.0–16.0

SD: Standard deviation. BMI: Body mass index. IQ: Interquartile.

Table (2) shows that: **Failure of insertion** statistically was non-significantly different among **lidocaine spray** and **ibuprofen tablet** groups.

Table (2): Failure of insertion among the study groups

Findings	Lidocaine spray (N=70)	Ibuprofen tablet (N=70)	p-value
Failure	2 (2.9%)	3 (4.3%)	✷0.999
Success	68 (97.1%)	67 (95.7%)	
Value of Lidocaine spray relative to Ibuprofen tablet			
Items	**Value**	**95% CI**	
Rate reduction	1.4%	-4.7%–6.1%	
Efficacy	1.5%	-5.0%–6.1%	
Relative Rate	1.02	0.95–1.06	
Number needed to prevent	70.0	16.4–Infinite	

CI**:** Confidence interval. ✷: Fisher's Exact test.

Table (3) shows that: **Vasovagal reactions** statistically were non-significantly less frequent among **lidocaine spray**.

Table (3): Vasovagal reactions among the study groups

Findings	Lidocaine spray (N=70)	Ibuprofen tablet (N=70)	p-value
Reactions	5 (7.1%)	8 (11.4%)	¤0.382
No reactions	65 (92.9%)	62 (88.6%)	
Value of Lidocaine spray relative to Ibuprofen tablet			
Items	**Value**	**95% CI**	
Rate reduction	4.3%	-6.2%–12.8%	
Efficacy	4.6%	-7.1%–13.2%	
Relative Rate	1.05	0.93–1.15	
Number needed to prevent	23.3	7.8–Infinite	

CI**:** Confidence interval. ¤: Chi square test.

Table (4) shows that: **Patients' pain perception** statistically was significantly lower among **lidocaine spray** group.

Table (4): Patients' pain perception (VAS-10) among the study groups

Measures	Lidocaine spray (N=70)	Ibuprofen tablet N=70)	P-value
Mean±SD	2.6±0.9	4.1±1.1	⌂ **<0.001**✣
Range	1.0–4.0	2.0–6.0	
Value of Lidocaine spray relative to Ibuprofen tablet			
	Mean±SD	**95% CI**	
Pain difference	-1.5±0.2	-1.8–-1.2	

SD: Standard deviation. CI: Confidence interval. ✣: Significant. ⌂Independent t-test.

Table (5) shows that: **Moderate pain** statistically was significantly less frequent among **lidocaine spray**.

Table (5): Perceived pain grade among the study groups

Grade	Lidocaine spray (N=70)	Ibuprofen tablet (N=70)	p-value
Moderate	15 (21.4%)	45 (64.3%)	¤ **<0.001✣**
Mild	55 (78.6%)	25 (35.7%)	
Value of Lidocaine spray relative to Ibuprofen tablet			
Items	**Value**	**95% CI**	
Rate reduction	42.9%	25.6%–57.2%	
Efficacy	54.5%	36.7%–66.7%	
Relative Rate	2.20	1.58–3.00	
Number needed to prevent	2.3	1.7–3.9	

✣: Significant. CI**:** Confidence interval. ¤: Chi square test.

Table (6) shows that: **Need to analgesics** statistically was significantly less frequent among **lidocaine spray**.

Table (6): Need to analgesics among the study groups

Findings	Lidocaine spray (N=70)	Ibuprofen tablet (N=70)	p-value
Needed	24 (34.3%)	58 (82.9%)	¤ **<0.001✣**
Not needed	46 (65.7%)	12 (17.1%)	
Value of Lidocaine spray relative to Ibuprofen tablet			
Items	**Value**	**95% CI**	
Rate reduction	48.6%	31.8%–61.8%	
Efficacy	73.9%	55.5%–85.5%	
Relative Rate	3.83	2.25–6.90	
Number needed to prevent	2.1	1.6–3.1	

✣: Significant. CI**:** Confidence interval. ¤: Chi square test.

DISCUSSION

Between December 2021 and June of 2022, we included 140 women who sought IUCD insertion as a method of birth control at the family planning clinic of Ain Shams Maternity Hospital. Participants were randomly assigned to either Group 1 (lidocaine spray 10% with a dosage of four puffs; 40 mg) or Group 2 (ibuprofen tablets 400 mg orally 45 minutes before to IUCD implantation).

Our study concluded that:

No significant difference between **lidocaine spray** and **ibuprofen tablet** groups was found regarding **age, BMI, parity and time after last delivery.** Patients' pain perception statistically was significantly lower among lidocaine spray group with mean pain score 2.6±0.9 and 95% Confidence interval (-1.8– -1.2) but among ibuprofen tablets group showed mean pain score 4.1±1.1 (P<**0.001)**. Moderate pain statistically was significantly less frequent among lidocaine spray as 21.4 % showed moderate pain, but in ibuprofen tablets group 64.3% showed moderate pain.

Nevertheless, the research on the topic of the effectiveness of lidocaine for IUCD implantation is mixed. Most previous research on this subject only compared one technique against a placebo or control group.

Our study was in concordance with:

It has been determined by **Aksoy *et al.*** [7] that the use of 10% lidocaine spray alone may significantly reduce discomfort during IUCD implantation. This dosage of 10% lidocaine spray, which was 40 mg, had worn off (the same dose we used). Two hundred women participated in the trial and were randomly assigned to receive either lidocaine spray (n=100) or a placebo (n=100) before to speculum insertion (pain expectancy) or immediately after IUCD implantation. The average pain rating for those who were given lidocaine spray was 1.01±1.20, whereas those who were given a placebo spray had 3.23±1.60 (p<0.00l).

Similarly, **Karasahin *et al.*** [12] found that using a topical lidocaine spray prior to the HSG treatment reduced pain perception ratings. The doctor randomly divided 81 people into three groups, giving some a spray containing 10 milligrammes of lidocaine hydrochloride (10%), others 20 milligrammes, and the rest a dummy drug called a placebo. The average AP score in Group1 was 64.5 ±12.62. The average AP score for members of Group 2 was 66.44±12.02. The average AP score for the third group was 61.81±18.5.

In this analysis, a 10 mg dosage was shown to be helpful in reducing pain just as well as a 20 mg dose, with fewer adverse effects and more cost-effectiveness.

In contrast to our study

Preventative dosing with 400 mg of ibuprofen at least 45 minutes before to IUCD implantation did not reduce participants' reported levels of pain in a clinical investigation by **Hubacher *et al.*** [13]. The average pain score was 1.8 on a 10-centimeter visual analogue scale in the ibuprofen group, and 2.0 in the control group (95% CI: -0.41 to 0.01).

Although recruiting 202 women and randomly allocating 101 to each group, **Bednarek *et al.*** [9] found no effect on pain after administration of 800 mg Ibuprofen prior to implantation (Ibuprofen or placebo). Before (at baseline) and after (immediately) IUCD injection, pain was measured using a 100 millimeter visual analogue scale (VAS). The placebo group had a median pain level of 41.5 mm after IUCD implantation, whereas the ibuprofen group experienced a score of 38.0 mm (p=0.50).

Nelson and Fong [14] showed that IUCD insertion pain ratings were not significantly reduced when 2% lidocaine was administered through endometrial aspirator. Forty women undergoing IUCD insertion participated in the experiment, and those who had received either 1.2 mL of 2% lidocaine or normal saline infused 3 minutes before to IUCD insertion had their pain evaluated on a 0-9 point scale.

Women who received an infusion of lidocaine during IUCD insertion reported significantly less discomfort than those who received a saline infusion (mean pain score: lidocaine: 2.95; saline: 3.75; p=0.37. Considerable variation in pain scores was noted; 46% of subjects had pain scores ≤ 2 while 33% had pain scores ≥ 5.

Our secondary outcomes were a- Failure of insertion: the results of our study showed that failure of insertion statistically was non-significantly different among lidocaine spray (2.9%) and ibuprofen tablet (4.3%) groups.

Vasovagal reaction: the results of our study showed vasovagal reactions statistically were non-significantly less frequent among lidocaine spray (7.1%). That was in agreement with **de Oliveira *et al.*** [15]**,** who found that the only complication observed during insertion was vasovagal-like reactions (7%).

Need to analgesics statistically was significantly less frequent among lidocaine spray as (34.3%) needed analgesic but in ibuprofen tablets (82.9%) needed analgesic after IUCD insertion.

As reported by **Aksoy *et al.*** [7], no life-threatening complications or adverse reactions were seen. Just five patients had symptoms consistent with a vasovagal response, including nausea, vomiting, and dizziness, although none of these conditions required medical attention. Lidocaine spray at a 10% concentration was not related with any systemic adverse effects.

Our experiment employed the same 10-centimeter VAS for measuring pain as the trials conducted by **Aksoy *et al.*** [7], **Hubacher *et al.*** [13] and **Karasahin *et al.*** [16]. While the traditional visual analogue scale (VAS) employs a 10-cm line with "no pain" at 0 and "worst possible agony" at 10, some studies, like the **Bednarek *et al.*** [9] and the **Allen *et al.*** trial [17], have employed a 1-to-100 pain grading system.

CONCLUSION

A 10% local lidocaine spray, which was shown to be helpful in our trial despite being statistically non-significant; it is preferable rather than ibuprofen pills for the management of pain after IUCD insertion. When deciding between ibuprofen pills and lidocaine spray for pain management following IUCD implantation, many women choose the latter.

Supporting and sponsoring financially: Nil.
Competing interests: Nil.

REFERENCES

1. **BetterHealth Channel (2014):** IUD (Intrauterine Device). Contraception Guide: NHS Choices. The intrauterine device, or IUD (sometimes called a coil). https://www.betterhealth.vic.gov.au/ health/ healthyliving/contraception-intrauterine-devices-iud
2. **Winner B, Peipert J, Zhao Q *et al.* (2012):** Effectiveness of long-acting reversible contraception. New England Journal of Medicine, 366(21): 1998-2007.
3. **Gillian D, Bimla S (2011):** Intrauterine contraceptives (IUCs). In: Robert A, James T, Anita L *et al.* (eds.). Contraceptive technology (20th ed). New York: Ardent Media. pp. 147–191. https://bmjopen.bmj.com/content/bmjopen/11/10/e045819.draft-revisions.pdf
4. **Belhadj H, Sivin I, Diaz S *et al.* (1986):** Recovery of fertility after use of the levonorgestrel 20 mcg/d or copper T 380 Ag intrauterine device. Contraception, 34(3): 261–267.
5. **Lopez L, Bernholc A, Zeng Y *et al.* (2015):** Interventions for pain with intrauterine device insertion. Cochrane Database Syst Rev., 7:CD007373. doi: 10.1002/14651858.CD007373.pub3.
6. **Gemzell-Danielsson K, Mansour D, Fiala C *et al.* (2013):** Management of pain associated with the insertion of intrauterine contraceptives. Human Reproduction Update, 19(4): 419-27.
7. **Aksoy H, Aksoy Ü, Ozyurt S *et al.* (2016):** Lidocaine 10% spray to the cervix reduces pain during intrauterine device insertion: a double-blind randomised controlled trial. Journal of Family Planning and Reproductive Health Care, 42(2): 83-7.
8. **Suleyman H, Demircan B, Karagoz Y (2007):** Anti-inflammatory and side effects of cyclo-oxygenase inhibitors. Pharmacological Reports, 59(3): 247-58.
9. **Bednarek P, Creinin M, Reeves M *et al.* (2015):** Prophylactic Ibuprofen does not improve pain with IUD insertion: a randomized trial. Contraception, 91(3): 193-7.

10. **Potter J, Rubin S, Sherman P (2014):** Fear of intrauterine contraception among adolescents in New York City. Contraception, 89: 446-450.
11. **Grimes D, Lopez L, Schulz K *et al.* (2010):** Immediate post-abortal insertion of intrauterine devices. Cochrane Database Syst Rev., 6: CD001777. doi: 10.1002/14651858.CD001777.pub3.
12. **Karasahin K, Alanbay I, Keskin U *et al.* (2009):** Lidocaine 10% spray reduces pain during hysterosalpingography: a randomized controlled trial. J Obstet Gynaecol Res., 35: 354–358.
13. **Hubacher D, Reyes V, Lillo S *et al.* (2006):** Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. Am J Obstet Gynecol., 195: 1272–1277.
14. **Nelson A, Fong J (2013):** Intrauterine infusion of lidocaine does not reduce pain scores during IUD insertion. Contraception, 88: 37–40.
15. **de Oliveira E, Baêta T, Brant A *et al.* (2021):** Use of naproxen versus intracervical block for pain control during the 52-mg levonorgestrel-releasing intrauterine system insertion in young women: a multivariate analysis of a randomized controlled trial. BMC Women's Health, 21(1): 1-7.
16. **Karasahin K, Alanbay I, Ercan C *et al.* (2011):** Lidocaine spray in addition to paracervical block reduces pain during first-trimester surgical abortion: a placebo controlled clinical trial. Contraception, 83: 362–366.
17. **Allen R, Goldberg A, Grimes D (2009):** Expanding access to intrauterine contraception. American Journal of Obstetrics and Gynecology, 201(5): 451-456.