# COMPARISON OF EFFECTIVENESS OF COUNSELLING ONLY, SUPPOSITORY DICLOFENAC AND LIDOCAINE SPRAY AT INTRAUTERINE DEVICE INSERTION IN A TERTIARY HOSPITAL IN GHANA

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## Abstract

***Objective:*** Perception of pain at IUD insertion is one of the main barriers of its uptake. Several pharmacological and non-pharmacological interventions have been studied but currently there is no consensus on the pain management at IUD insertion. The study aim was to compare the effectiveness of counselling only, 10% lidocaine spray of the cervix and 100mg suppository diclofenac in reducing pain at IUD insertion.

***Methodology:*** A prospective study of 99 respondents were randomized into 3 study arms; suppository diclofenac, lidocaine spray and counselling only in a ratio of 1:1:1. All participants had a baseline counselling: while those in the diclofenac arm were given 100mg diclofenac suppository 30 minutes before the procedure, those in the 10% lidocaine spray arm were given 4 pumps on the cervix before the insertion. A 10cm- Visual Analog Scale was used to assess the pain experienced during and after IUD insertion. Chi-square test, one-way ANOVA and a Post-Hoc test were used for the statistical analysis. P value of < 0.05 and confidence interval of 95% were used.

***Results:*** Suppository diclofenac was superior to counselling only at speculum insertion, tenaculum application, uterine sounding, IUD placement, immediately and 5 minutes after procedure. Lidocaine spray of the cervix was also superior to counselling only throughout the procedure and up to 4 hours post procedure. Lidocaine spray of the cervix was superior to suppository diclofenac at 5 minutes and 4 hours after procedure.

***Conclusion:*** Lidocaine spray (10%) of cervix is more effective compared to 100mg Diclofenac Sodium and Counselling only in reducing pain at IUD insertion.

**Key words:** *Intrauterine Contraceptive Device, Lidocaine Spray, Suppository Diclofenac, Pain Experience*

## Introduction

Globally, about 100 million women of reproductive age are using intrauterine contraceptive device (IUD).The rate of IUD use in Africa is quoted at 0.5% and in developed countries such as France and Finland they are estimated at 21% and 18% respectively[1,2]. In Ghana, 25% of married and 30.6% of unmarried women between the ages of 15 to 49 use modern contraception. However, only 0.8% of married and 0.4% of unmarried women use IUD as a form of contraception ( GMHS 2017)[3].

Compared to other long-acting contraceptives, IUD has shown to be highly effective contraceptive method equal in efficacy to female tubal sterilization and is associated with lower discontinuation rates compared to other reversible methods. It also has several advantages such as long term effectiveness, no need for user interventions, reversible and immediate return to fertility once it is removed[2].

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It's use however, has continued to be low because of misperception by some health providers that IUD is associated with increased pelvic inflammatory disease (PID) and perceived technical challenges in its insertion for nulliparous women and user factors such as fear of having foreign body in the womb and fear of painful insertions[4]. The pain in IUD insertion has been attributed to the following processes: speculum placement, holding the cervix with tenaculum to straighten the uterus, sounding the uterus to determine the cavity depth, and IUD placement which causes irritation of the endometrium. Studies have shown that 17% of nulliparous[5] and 11% of parous[6] women experienced severe pain during IUD insertion. In a prospective study by Marions et al, 89% of women reported moderate to severe pain at IUD insertion[5]. Several studies have been done in the area of pain control during IUD insertions but currently there is no consensus on the most effective method of pain control at IUD insertion. Several pharmacological and nonpharmacological interventions have been used for such pain management. These include non-steroidal anti-inflammatory drugs (NSAIDs), anxiolytics and local anaesthetic agents. Examples of non-pharmacological interventions which have been used are pre-placement counselling and distractions during insertion[7]. Whilst some centres are using pharmacological agents such as analgesics and local



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anaesthetic agents for pain control, others like the Family Planning Unit of Korle Bu Teaching Hospital, Accra offer counselling only. A Cochrane review of all interventions aimed at reducing pain at insertion concluded that none of the interventions has been properly evaluated [8]. The aim of the study was therefore to compare the effectiveness of counselling only (standard of care), 10% lidocaine spray of the cervix and 100mg suppository diclofenac sodium in reducing pain at IUD insertion.

## Materials and Methods

An open- labelled, randomised controlled trial to test the efficacy of 10% Lidocaine spray of the cervix, 100mg suppository diclofenac, and counselling only (standard of care) in reducing pain at insertion of IUD was used. The period of study was (6) six months (1st October, 2020 – 31st March, 2021). The study was conducted at the Family Planning Unit of the Gynaecology Department, Korle Bu Teaching Hospital. The family planning unit operates as an Out Patient Department (OPD) and is opened from 8:00am to 5:00pm from Monday to Friday. The Copper-T IUD uptake for 2018 was 267 for first ever users, 4,083 for continuing clients making it about 22 new IUD acceptors per months. The sample size calculation for multiple comparisons using one-way ANOVA was used.

$$n = \frac{2(Z\alpha + Z1 - \beta)^2\delta^2}{\Delta^2}$$

Where;
n= sample per arm
Zα is 95% confidence level = 1.96
Z1-β is the power of the study (80% power) = 0.8416
And δ is the standard deviation (estimated within each group) = 1.8 (Karabayirli et al 2012). Δ is the difference in the effect size (the minimally clinical significant difference in 10cm-Visual Analog pain Score) = 1.3. The effect size of the visual analogue is the mean pain score change divided by standard deviation of baseline score. So, inputting the above into the sample size formula gave, n=30. Therefore, sample size, n =30 for each of the three groups making a total sample size of 90. Adjusting for 10% loss to follow up and incomplete or inconsistent data a sample of 33 in each group and a total sample size of 99 was obtained[14]. Women aged 18 years and above and those who accepted the IUD as a contraceptive method were included in the study.

The exclusion criteria included;

i. Contraindication to Copper IUD insertion from Medical Eligibility Criteria
ii. Presence of known uterine anomaly or fibroid distorting the uterine cavity
iii. Known cervical stenosis which requires dilatation.
iv. Systemic conditions or medications that will affect perception of pain.
v. Ever use of narcotics, e.g., pethidine/morphine
vi. Inability to understand how to score a 10cm- visual analog scale.
vii. Women who are allergic to diclofenac and lidocaine.
viii. Women with history of chronic pelvic pain.

The primary outcome was the assessment of the overall pain score at IUD insertion measured by 10cm-VAS. Secondary outcomes included mean pain scores during speculum placement, tenaculum placement, sound insertion, IUD placement, 5 minutes and 4hours post insertion. The other secondary outcomes were the need for additional analgesics and the side effects of the medications used. Patients who have received contraceptive counselling on the method mix and have chosen IUD were recruited into the study after the research methodology had been explained to them by the principal investigator or research assistant and written consent obtained. Participants were randomized into one of the three arms of the study; lidocaine spray, suppository diclofenac and counselling only (standard of care/control group) in ratio of 1:1:1. Ninety-nine (99) computer generated random numbers were obtained from Randomization .com and assigned to participants consecutively as and when they joined the study. The randomization blocks each containing 33 numbers were generated by the computer and used for the study.

Those on diclofenac (100mg Voltarol suppository, Novartis Pharmaceutical, UK) were instructed to administer 1 hour before IUD insertion. Those on the lidocaine arm had speculum placement and then received 4 pumps (about 40mg) of 10% lidocaine spray (xylocaine 10% pump spray, 100mg/ml, Astra Zeneca) and waited for 3minutes (as suggested by the manufacturer) to allow for the anaesthetic effect to take place before IUD insertion. All participants in the study had a baseline counselling on the procedure and what to expect at each stage of the intervention. Before the IUD insertion, baseline data was collected with a questionnaire. The standard 10cm-VAS was then explained to the participants. The severity of the pain was quantified with 0 = no pain and 10 = worst possible pain imaginable. Each woman received copper T380A safe load IUD (Pregna International Limited, Dabhel, Daman, India). The IUD was inserted by an experienced Nurse using the standardized manufacturer approved technique. Medium size Cusco's bivalve speculum was used for all the participants. The tip of the speculum was dipped in sterile aqua for lubrication. The visual analog scale is a unidimensional measure of pain intensity. It is presented as a 10-cm or 100-mm line which is anchored by verbal descriptors such as "no pain" and "worst pain imaginable". The patient is asked to make a mark on the 100mm line to indicate pain intensity. The pain score is measured from zero to the patient's mark. Using the 100-mm scale, there are 101 levels of pain intensity.
The visual analog scale (chart) was shown to all the respondents and the explanation given. No pain was illustrated by a particular picture and maximal pains by



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a different picture. The chart also had a numerical rating scale on it with no pain corresponding to zero and that of maximal pain corresponding to 10cm. Therefore, during phone calls, respondents scored their pain out of 10 using the combination of the analog score and the numerical rating. Each step of the procedure was explained to the participants and then the pain scored immediately after. This was done by a research assistant who was blinded to the interventions received by participants, who asked the participants to rate the intensity of pain at 6 consecutive steps; at speculum insertion, at tenaculum placement, at metal sound insertion, at IUD insertion, 5minutes and 4 hours after insertion using the same 10cm- VAS with different sheet of paper at every point (0=no pains, and 10=the worst possible experienced pain). To prevent the pain of one step fading into the next step, participants were given one minute to recover from their pain after each step before proceeding onto next step. Immediate complications of IUD insertion such as uterine perforation, failure of insertion, and vasovagal reaction were recorded. Participants were contacted 4 hours and 24 hours after IUD insertion by phone to query about post insertion pain and any adverse effects of diclofenac and lidocaine such as nausea, vomiting, dizziness, dyspepsia, skin reaction and allergic reaction.

### *Data Management and Analysis*

Data analysis was by intention-to- treat. Data collected was entered into an excel spread sheet and exported to IBM SPSS- Version 23 for analysis. Continuous demographic data was described using means and standard deviation while categorical ones was described using frequencies and percentages. Mean pain scores were compared using a one-way ANOVA and a Post-Hoc test used to compare which two groups are significantly different from each other. The Fisher's Least Significant Difference Post-Hoc test was used because it is relatively easy to calculate and interpret. It also has a good power to detect differences between means even when small sample sizes are used. It is relatively conservative, which means that it is less likely to find a significant difference when there is none.

Categorical variables between groups were compared using a chi-square test. The Fisher's Exact test was used instead of chi-square test when expected frequency in any cell was less than 5. Multivariate analysis was used to test for preferential effect of different variables on 10cm- VAS pain score during IUD insertion. The preferential effect had to do with the effect of various variables such as parity, type of analgesia used etc. on pain experienced by respondents during speculum insertion, tenaculum application to the cervix and IUD insertion into the uterine cavity. This was indicated by the pain score on the visual analog scale. The data was analysed using ANOVA and Fisher's Least Significant Difference Post-Hoc test. In all statistical tests, a p-value of less than 0.05 at a confidence interval of 95% was considered statistically significant.

## Ethics Approval

Ethical clearance for the study was obtained from Korle Bu Teaching Hospital Institutional Review Board with identification number KBTH-IRB 00050/2020. Permission from the Obstetrics and Gynaecology Department of Korle Bu Teaching Hospital was sought for the study. The reason for the study, the benefits, the right of the participant and the procedure were explained to the participants and informed consent obtained from each participant. Participation was voluntary and patients were assured that there was no penalty for refusing to participate. Participants were also assured that their personal information were to be handled in a confidential manner and that there was safety and monitoring board comprising statistician, physician specialist and a pharmacist who in the event of adverse drug reaction were to be referred to for care at no cost to them.

## Results

The average age of the participants was 33.8$\pm$ 6.2 years whilst the average BMI was 29.6$\pm$ 5.9kg/m$^2$. In all, 11/103 (10.68%) of the respondents were single. The rest were either married or cohabiting. Only 3/103 (2.91%) of the participants did not have formal education, the rest had some form of formal education. There were 42/103 (40.78%) of them who had tertiary education. In terms of occupation, 37/103 (35.92%) of the respondents were professionals. Traders and artisans represented 32/103 (31.07%) each. For the religious affiliations of respondents, only 6/103 (5.83%) were Muslims, the rest were Christians. There was no significance difference in the pain experience by respondents during speculum placement among the counselling only and suppository diclofenac (p=0.06). However, there was significant difference in the pains experience by respondents at tenaculum insertion (p=0.005), uterine sound (p=0.046), during IUD placement (p=0.002) and immediately after procedure (p=0.008) using counselling only, suppository diclofenac and lidocaine spray. Moreover, pain experience by respondents after 5 minutes and 4 hours after procedure in all the three arms of the study was also significant, p< 0.001 for both. The pain score at speculum insertion for lidocaine spray was omitted because lidocaine spray of the cervix could only be done after the insertion of the speculum.

### *Counselling only versus suppository diclofenac during IUD insertion*

There was significant difference between counselling only and suppository diclofenac at tenaculum insertion (p= 0.006), uterine sound insertion (p= 0.037), IUD placement (p= 0.003), over all pain immediately after the procedure (p= 0.002) and 5 minutes after the procedure (p=0.004). However, there was no significance difference in pain experienced by respondents who had counselling only compared to



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those who had suppository diclofenac 4 hours after procedure (p=0.06).

Since the mean pain score for suppository diclofenac was lower than counselling only at tenaculum insertion (3.6 versus 4.9), Suppository diclofenac was better at pain control at tenaculum insertion compared to counselling only. Again, suppository diclofenac was superior to counselling only in pain control during uterine sound insertion (3.1 versus 4.1), IUD placement (2.2 versus 3.4), immediately after procedure (p= 2.2 versus 3.5) and 5 minutes after procedure (1.4 versus 2.4).

***Counselling only versus lidocaine spray.***

The difference between the pain experienced by respondents at counselling only and lidocaine spray at tenaculum insertion (p= 0.04), uterine sound (p= 0.028), IUD placement (p= 0.001), over all pain immediately after the procedure (p= 0.041), 5 minutes after the procedure (p< 0.001) and 4 hours after the procedure (p< 0.001) were significant. Lidocaine spray of the cervix was superior in pain control compared to counselling only during tenaculum insertion (3.5 versus 4.9), uterine sound (3.1 versus 4.1), IUD placement (2.1 versus 3.4), immediately after procedure (2.7 versus 3.5), 5minutes after procedure (0.6 versus 2.4) and 4 hours after procedure (0.1 versus 1.3).

***Suppository Diclofenac versus Lidocaine spray***.

There was no significant difference between suppository diclofenac and lidocaine spray of the cervix at tenaculum insertion (p= 0.850), uterine sound (p= 0.920), IUD placement (p= 0.774) and immediately after the procedure (p= 0.299). However, there was significant difference in pain experience at 5 minutes after procedure (p= 0.011) and 4 hours after procedure (p= 0.004).

Lidocaine spray of the cervix was superior to suppository diclofenac at pain control 5 minutes after procedure (mean pain score 0.6 versus 1.4) and 4 hours after procedure (0.1 versus 0.8). The study intended to compare the 3 arms at post-Hoc and since lidocaine spray could only be done after speculum insertion, pain score at speculum insertion was omitted at post-Hoc analysis.

**Table 1: The Socio-demographic characteristics of the respondents**

| Characteristics | Counselling only group (N=33) | Suppository Diclofenac Group (N=33) | Lidocaine Spray Group (N=33) | Total (N=99) | P-Value |
|---|---|---|---|---|---|
| **Marital status** | | | | | 0.052 |
| Single | 1 (9.1) | 3 (27.3) | 7 (63.6) | 11 (100.0) | |
| Married | 26 (41.3) | 18 (28.5) | 19 (30.2) | 63 (100.0) | |
| Cohabiting | 6 (24.0) | 12 (48.0) | 7 (28.0) | 25 (100.0) | |
| **Educational level** | | | | | 0.570 |
| No formal education | 1 (33.3) | 1 (33.3) | 1 (33.3) | 3 (100.0) | |
| Primary | 2 (22.2) | 4 (44.4) | 3 (33.3) | 9 (100.0) | |
| JHS | 7 (46.7) | 4 (26.7) | 4 (26.7) | 15 (100.0) | |
| SHS | 10 (30.3) | 15 (45.5) | 8 (24.2) | 33 (100.0) | |
| Tertiary | 13 (33.3) | 9 (23.1) | 17 (43.6) | 39 (100.0) | |
| **Occupation** | | | | | 0.436 |
| Professional | 10 (29.4) | 9 (26.5) | 15 (44.1) | 34 (100.0) | |
| Artisan | 19 (29.0) | 11 (35.5) | 11 (35.5) | 31 (100.0) | |
| Trader | 13 (41.9) | 11 (35.5) | 7 (22.6) | 31 (100.0) | |
| Unemployed | 1 (33.3) | 2 (66.7) | 0 (0.0) | 3 (100.0) | |
| **Religion** | | | | | 0.203 |
| Christian | 29 (31.2) | 32 (34.4) | 32 (34.4) | 93 (100.0) | |
| Muslim | 4 (66.7) | 1 (16.7) | 1 (16.7) | 6 (100.0) | |



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**Table 2: Visual Analog Score (VAS) of pain experience by respondents during and after IUD insertion using counselling only, Suppository Diclofenac and Lidocaine spray.**

| Procedure | Treatment | N | VAS (Mean) | Standard Deviation | P-value |
|---|---|---|---|---|---|
| Pain estimated at speculum insertion | Counselling only | 33 | 5.1 | 2.2 | 0.041 |
| | Suppository diclofenac | 33 | 4.9 | 2.0 | |
| | Total | 66 | 5.0 | 2.1 | |
| Pain estimated at tenaculum placement | Counselling only | 33 | 4.9 | 2.0 | 0.010 |
| | Suppository diclofenac | 33 | 3.7 | 1.9 | |
| | Lidocaine spray | 33 | 3.5 | 1.9 | |
| | Total | 99 | 4.0 | 2.0 | |
| Pain estimated at uterine sound insertion | Counselling only | 33 | 4.1 | 2.1 | 0.049 |
| | Suppository diclofenac only | 33 | 3.2 | 1.4 | |
| | Lidocaine spray only | 33 | 3.0 | 2.3 | |
| | Total | 99 | 3.4 | 2.0 | |
| Pain estimated during IUD insertion | Counselling only | 33 | 3.4 | 2.0 | 0.004 |
| | Suppository diclofenac only | 33 | 2.2 | 1.3 | |
| | Lidocaine spray only | 33 | 2.1 | 1.7 | |
| | Total | 99 | 2.6 | 1.8 | |
| Overall pain estimated immediately after procedure | Counselling only | 33 | 3.5 | 2.1 | 0.013 |
| | Suppository diclofenac only | 33 | 2.2 | 1.3 | |
| | Lidocaine spray only | 33 | 2.7 | 1.7 | |
| | Total | 99 | 2.8 | 1.8 | |
| Pain estimated 5 minutes after procedure | Counselling only | 33 | 2.4 | 1.9 | <0.001 |
| | Suppository diclofenac only | 33 | 1.5 | 1.2 | |
| | Lidocaine spray only | 33 | 0.6 | 0.7 | |
| | Total | 99 | 1.5 | 1.5 | |
| Pain estimated 4 hour procedure by telephone | Counselling only | 33 | 1.2 | 1.5 | <0.001 |
| | Suppository diclofenac only | 33 | 0.9 | 1.0 | |
| | Lidocaine spray only | 33 | 0.1 | 0.2 | |
| | Total | 99 | 0.7 | 1.2 | |

**Table 3: The Post Hoc analysis of pain experience at IUD insertion using counselling only, suppository diclofenac and lidocaine spray.**

| Dependent Variable | (I) Group | (J) Group | Mean Difference | Std. Error | P-value |
|---|---|---|---|---|---|
| Pain estimated at tenaculum placement | Counselling only | Suppository diclofenac | 1.303* | 0.473 | 0.007 |
| | | Lidocaine spray | 1.455* | 0.473 | 0.003 |
| | Suppository diclofenac | Counselling only | -1.303* | 0.473 | 0.007 |
| | | Lidocaine spray | 0.152 | 0.473 | 0.749 |
| | Lidocaine spray | Counselling only | -1.455* | 0.473 | 0.003 |
| | | Suppository diclofenac | -0.152 | 0.473 | 0.749 |
| Pain estimated at uterine sound insertion | Counselling only | Suppository diclofenac | 1.182* | 0.470 | 0.014 |



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| | | | | | |
|---|---|---|---|---|---|
| | | Lidocaine spray | 1.242* | 0.470 | 0.010 |
| | Suppository diclofenac | Counselling only | -1.182* | 0.470 | 0.014 |
| | | Lidocaine spray | 0.061 | 0.470 | 0.898 |
| | Lidocaine spray | Counselling only | -1.242* | 0.470 | 0.010 |
| | | Suppository diclofenac | -0.061 | 0.470 | 0.898 |
| Pain estimated during IUD insertion | Counselling only | Suppository diclofenac | 1.212* | 0.395 | 0.003 |
| | | Lidocaine spray | 1.515* | 0.395 | <0.001 |
| | Suppository diclofenac | Counselling only | -1.212* | 0.395 | 0.003 |
| | | Lidocaine spray | 0.303 | 0.395 | 0.445 |
| | Lidocaine spray | Counselling only | -1.515* | 0.395 | <0.001 |
| | | Suppository diclofenac | -0.303 | 0.395 | 0.445 |
| Overall pain estimated immediately after procedure | Counselling only | Suppository diclofenac | 1.364* | 0.421 | 0.002 |
| | | Lidocaine spray | 1.061* | 0.421 | 0.013 |
| | Suppository diclofenac | Counselling only | -1.364* | 0.421 | 0.002 |
| | | Lidocaine spray | -0.303 | 0.421 | 0.473 |
| | Lidocaine spray | Counselling only | -1.061* | 0.421 | 0.013 |
| | | Suppository diclofenac | 0.303 | 0.421 | 0.473 |
| Pain estimated 5 minutes after procedure | Counselling only | Suppository diclofenac | 1.000* | 0.334 | 0.003 |
| | | Lidocaine spray | 1.879* | 0.334 | <0.001 |
| | Suppository diclofenac | Counselling only | -1.000* | 0.334 | 0.003 |
| | | Lidocaine spray | .879* | 0.334 | 0.010 |
| | Lidocaine spray | Counselling only | -1.879* | 0.334 | <0.001 |
| | | Suppository diclofenac | -.879* | 0.334 | 0.010 |
| Pain estimated 4 hour procedure by telephone | Counselling only | Suppository diclofenac | 0.515 | 0.266 | 0.055 |
| | | Lidocaine spray | 1.303* | 0.266 | <0.001 |
| | Suppository diclofenac | Counselling only | -0.515 | 0.266 | 0.055 |
| | | Lidocaine spray | .788* | 0.266 | 0.004 |
| | Lidocaine spray | Counselling only | -1.303* | 0.266 | <0.001 |
| | | Suppository diclofenac | -.788* | 0.266 | 0.004 |

*represents significant differences. The (I) represent the treatment group in the first column whilst the (J) represents the other treatment groups being compared to (I) in the second column.



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***Counselling only versus lidocaine spray.***

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Lidocaine spray of the cervix was superior to suppository diclofenac at pain control 5 minutes after procedure (mean pain score 0.6 versus 1.4) and 4 hours after procedure (0.1 versus 0.8). The study intended to compare the 3 arms at post-Hoc and since lidocaine spray could only be done after speculum insertion, pain score at speculum insertion was omitted at post-Hoc analysis.

## Discussions

As shown in table 1, there was no difference in the sociodemographic characteristics of the respondents of all the three arms of the study. The key findings from the work were that 10% percent Lidocaine spray was more effective compared to 100mg Diclofenac Sodium in reducing pain at IUD insertion and both 10% lidocaine spray of the cervix and suppository diclofenac were superior to counselling only (standard of care).

From this study the level of pain experienced by respondents were significant during speculum placement among the counselling only compared to suppository diclofenac (mean VAS 4.9 versus 5.1, p=0.041). This is shown in table 2. This may be because after one hour administration of the suppository diclofenac, its analgesic effect would have started and therefore those in the suppository diclofenac arm of the study had less pain during speculum passage compared to those in the counselling only arm.

There was also significant difference in the pain score experienced by respondents at tenaculum placement (4.9 $\pm$ 2.2; 3.7 $\pm$ 1.4; 3.5 $\pm$ 1.9; p=0.010), uterine sounding (4.1 $\pm$ 2.1; 3.2 $\pm$ 1.4; 3.0 $\pm$ 2.3; p=0.049), IUD placement (3.4 $\pm$ 2.0; 2.2 $\pm$ 1.3; 2.1 $\pm$ 1.7; p=0.004) and immediately after procedure (3.5 $\pm$ 2.1; 2.2 $\pm$ 1.3; 2.7 $\pm$ 1.7; p=0.013) using counselling only, suppository diclofenac and lidocaine spray. From the study by Collins et al, the mean VAS of less than 3.0cm corresponds to mild pain , 3.0cm to 5.3cm corresponds to moderate pain and 5.4cm or more represents severe pain[24]. It is therefore obvious that whilst respondents who had counselling only had moderate to severe pains during the procedure, the diclofenac and lidocaine arms of the study only experienced mild to moderate pains. Generally, the mean pain score for 10% lidocaine spray was smaller at each point of the procedure, implying that 10% lidocaine was better at pain control compared to suppository diclofenac and counselling only. Moreover, at 4 hours the mean pain score for both suppository diclofenac and 10% lidocaine spray were below 1.0 which implied that respondents had mild to no residual pain 4 hours after the procedure. Pain assessment at 5minutes and 4 hours after the procedure evaluated the delayed prostaglandin related cramping pain that is experienced after IUD insertion. Therefore, it was expected that since diclofenac, an NSAID reduce pains and inflammation by blocking cyclooxygenase enzyme activity and consequently the formation of endogenous prostaglandins, it would have had lower mean VAS than lidocaine but the opposite effect was observed.

Various work on the use of NSAIDs and Lidocaine for pain control at IUD insertion has been done but this is the first time Suppository diclofenac, lidocaine spray of the cervix and counselling only has been compared in one study. In the study by Abbas et al comparing the use of oral diclofenac and buscopan prior to insertion of copper IUD, the diclofenac was superior to buscopan in pain reduction at speculum placement (1.73 versus 2.13, p=0.044) and tenaculum insertion (1.85 versus 2.3, p=0.033)[20]. In another study by Chor et al, comparing ibuprofen and control in IUD insertion, there was no difference in pain score during tenaculum insertion (3.81 versus 3.86; p=0.90) and IUD placement (3.34 versus 3.69; p=0.91) between the Ibuprofen and control[26]. From the above studies, NSAIDs have generally given consistently low VAS compared to controls at IUD insertion which was consistent with our current study.

The probable explanation is that irrespective of the route of administration of NSAIDs, the mechanism of action is the same. In other studies, where suppository diclofenac has been used, its analgesic effect has been proven. For instance, preoperative use of suppository diclofenac in cleft palate repair in children have been shown to be effective and reduces significantly the use of opioids postoperatively compared to controls (1.67 versus 6.08; p<0.001)[27].

In a recent randomized, double-blind placebo-control study by Aksoy et al, 10% Lidocaine spray of the cervix during IUD insertion was associated with significant reduction in pain perception immediately after the procedure compared to the controlled group (1.01 versus 2.23, p <0.001)[28]. This is comparable to our study where mean pain score immediately after the procedure was lower for the lidocaine group than those of the control

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(2.7±1.7 versus 3.5±2.1, p=0.013). In both of the studies 4 pumps of lidocaine spray (40mg) were used; however, in the study by Aksoy et al, nulliparous women were not included in their study and the control group were given isotonic saline spray of the cervix. This might have accounted for the differences in the mean pain scores between the two studies.

In contrast to our study where both parous and nulliparous women were included, the study by Aksoy et al did not include any nulliparous woman. Meanwhile, parity has been shown to be associated with pain perception at IUD insertion[15]. In the current study, both 10% lidocaine spray and suppository diclofenac were superior to counselling only at pain control during tenaculum insertion, uterine sound use, IUD placement and immediately after procedure but there were no significant differences between them. This is demonstrated in table 3. However, 10% lidocaine spray was superior to suppository diclofenac at pain control 5minutes ($p<0.001$) and 4 hours ($p<0.001$) after the procedure. Since the terminal half-life of diclofenac is 1-3 hours and that of lidocaine is 10 – 15 minutes[31,32], it was expected that suppository diclofenac would be superior at pain control hours after the procedure. However, the above observation maybe due to the fact that lidocaine acts locally on the nociceptors, and once they were blocked, they gave a longer lasting pain control compared to the diclofenac which acts systemically.

There were no medical complications recorded in the study with the use of lidocaine spray and suppository diclofenac and the two (1 nausea, 1 dizziness) that were reported by respondents after 4 hours of the procedure were associated with the counselling only arm of the study. In both cases, the symptoms were mild and transient and had resolved without any intervention when the 4 hour-call was made.

## Strength of the study

This is one of the first few comparative studies evaluating the effectiveness of pain control at IUD insertion using 10% lidocaine spray of the cervix, suppository diclofenac and counselling only. The participants were randomized and the intervention (lidocaine spray and suppository diclofenac administration) and IUD insertion was done by an experienced nurse who was different from the research assistant who did the pain scoring using the Visual Analog scale. The Visual Analogue score was done in Korle Bu Teaching Hospital by one person (research assistant) to avoid inter assessor variations in the VAS estimations.

## Study limitation

This is an institution-based study which was done in Korle- Bu Teaching Hospital, in the Accra Metropolitan area which is a tertiary referral Centre and therefore this places a limitation on the generalization of the findings.

However, it is worth noting that the hospital receives varied clients from different parts of the Greater Accra and other regions of the country. The study involved the use of Visual Analogue Scale for pain assessment which is noted to be associated with subjectivity in the reporting of pain, however this is a widely accepted and validated instrument for pain assessment[18].

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## Data availability

The datasets generated during the current study are available from the corresponding author on reasonable request.

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