GHANA COLLEGE OF PHYSICIANS AND SURGEONS

FACULTY OF OBSTETRICS AND GYNAECOLOGY

COMPARISON OF EFFECTIVENESS OF COUNSELLING ONLY, SUPPOSITORY DICLOFENAC AND LIDOCAINE SPRAY AT INTRAUTERINE DEVICE INSERTION

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DECLARATION

I hereby declare that with the exception of references from related research works which are duly acknowledged, this research proposal was put together by me under supervision.

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DEDICATION

I thank Almighty God for bringing me this far in my career. Lord, I am eternally grateful.

I dedicate this work to my late mother, Ekua Bentsiwah Yanney for her love, support, care and wise counsel which has brought me this far in life.

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LIST OF ABBREVIATIONS

ANOVA	-	Analysis of Variance
CNS	-	Central Nervous System
COVID-19	-	Coronavirus Disease
DMPA	-	Depo medroxyprogesterone acetate
EURAS	-	European Active Surveillance
FDA	-	Food and Drugs Authority
GDHS	-	Ghana Demographic Health Survey
GMHS	-	Ghana Maternal Health Survey
HIV	-	Human Immunodeficiency Virus
IUD	-	Intrauterine Device
KBTH	-	Korle Bu Teaching Hospital
LNG-IUD	-	Levonorgestrel Intrauterine Device
LNG-IUS	-	Levonorgestrel Intrauterine system
MEC	-	Medical Eligibility Criteria
Mg	-	Milligram
MPQ	-	McGill Pain Questionnaire
NAAT	-	Nuclear Amplification Test
NSAID	-	Non-Steroidal Anti-inflammatory Drug
OPD	-	Out-Patient Department
PIGF	-	Placental Growth Factor
PMT	-	Pain Measurement Tools
RH/FPU	-	Reproductive Health and Family Planning Unit
SARC	-	Short Acting Reversible Contraception
STI	-	Sexually Transmitted Infection
TCU	-	Copper ‘T’
UKMEC	-	United Kingdom Medical Eligibility Criteria
USMEC	-	United States Medical Eligibility criteria
VAS	-	Visual Analog Scale
VRS	-	Verbal Rating Scale
VSGF	-	Vascular endothelial Growth Factor

WHO	-	World Health Organization
WHOMEC	-	World Health Organization Medical Eligibility Criteria

ABSTRACT

Background

In Ghana, only 0.8% of married and 0.4% of unmarried women are on IUD. The perception of pain at IUD insertion is one of the main barriers of its uptake. Several pharmacological and non-pharmacological interventions have been studied. Despite these attempts, there is currently no consensus on the best form of pain management at IUD insertion. The aim of this 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.

Methodology

A prospective study involving women of reproductive age who presented at the Family Planning Unit, Korle Bu Teaching Hospital and had accepted IUD method of contraception was conducted. Clients who met the inclusion criteria were randomized into 3 arms; suppository diclofenac, lidocaine spray and counselling only arms in a ratio of 1:1:1. A calculated sample size of 99 participants, 33 in each arm was used.

All participants had a baseline counselling on the procedure and then those on diclofenac arm were given 100mg diclofenac sodium suppository 30 minutes whilst the 10% lidocaine spray arm were given 4 pumps on the cervix before the insertion.

Using a 10cm- Visual Analog Scale (VAS), the pain experienced at various stages of IUD insertion, the overall pain experienced after IUD insertion, 5 minutes and 4 hours post procedure were assessed. Mean pain scores were compared using a one way ANOVA and a Post-Hoc test used to compare which two groups were significantly different from each other. Categorical variables between groups were compared using a chi-square test. The statistical significance was set at $p < 0.05$ and confidence interval at 95%.

Results

Ninety nine participants were recruited for the study. The average age of the participants was 33.6$\pm$ 6.2 years whilst the average BMI was 29.5$\pm$ 5.7kg/m^2. There were 11/99 (11.11%) of respondents who were single, 3/99 (3.03%) who did not have formal education, 39/99 (39.39%) of them who had tertiary education; and 34/99 (34.34%) who were professionals. Traders and

artisans represented 31/99 (31.31%) each and majority 93/99 (93.94%) were Christians. Suppository diclofenac was superior to counselling only at pain control during speculum insertion, tenaculum insertion, uterine sound insertion, IUD placement, immediately after procedure and 5 minutes after procedure. Lidocaine spray of the cervix on the other hand, was superior to counselling only throughout the procedure and up to 4 hours post procedure. Again, Lidocaine spray of the cervix was found to be superior to suppository diclofenac at pain control 5 minutes after procedure (mean pain score 0.6 versus 1.5) and 4 hours after procedure (0.7 versus 0.9)

Conclusion

Lidocaine spray (10%) of cervix is more effective compared to 100mg Diclofenac Sodium in reducing pain at IUD insertion. The use of 10% lidocaine spray of cervix at insertion of IUD will therefore greatly enhance clients' satisfaction at IUD insertion and in the long run help to increase the uptake of the IUD, a highly effective long acting reversible contraceptive.

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

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 rate 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).

In spite of these merits, its use 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; holding the cervix with tenaculum to straighten the uterus, sounding the uterus to determine the endometrial depth, and IUD placement which causes the 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 anaesthetic agents for pain control, others like the Family Planning Unit of Korle Bu Teaching Hospital, Accra are still administering IUD without medications.

Meanwhile, Cochrane review of all interventions aimed at reducing pain at insertion concluded that none of the interventions have been properly evaluated (8).

1.2 Problem statement

From the 2014, Ghana Demographic and Health Survey (GDHS), though 59.7% of women of reproductive age have heard of IUD, only 0.8% use the method(9).

Pain experienced by women at IUD insertion can be distressing and may serve as a barrier for women using this method.

Studies have shown that perception of pain at insertion is one of the reasons IUD among women of reproductive age is not popular. In a study done in New York in 2014, 85% of the respondents cited fear of painful insertion as the reason they will avoid IUD as family planning method(10). This is corroborated by a 2018 study from United Kingdom where 55.8% of respondents of non-IUD users expressed pain at IUD insertion as their main concern(11).

Work done in Malawi and Northern Nigeria shows that perception of pain at IUD insertion is one of the main reasons for low uptake of IUD among Africans(12,13).

Moreover, studies elsewhere have shown that about 89% of women experience moderate to severe pain during IUD insertion(5). The proportion of Ghanaian women who experience significant pain at IUD insertion is not known.

Currently, at the Reproductive Health and Family Planning Unit of Korle Bu Teaching Hospital (RH/FPU, KBTH), there is no clear protocol for pain management at IUD insertions which are usually done without medication after counselling.

There is limited data and consensus on optimal analgesic, timing or route of their administration globally. However, few studies have been done to look at the effect of lidocaine and diclofenac at reducing pain at IUD insertion(8).

1.3 Justification

Currently, there is no consensus on pain management at intrauterine contraceptive device insertion.

Various methods of pain managements such as NSAIDS, opioids, local anaesthetic agents and pre insertion pain counselling have been used with mixed results.

Perception of pain at IUD insertion has been noted to be one of the important barriers to the uptake of IUD which is a long acting reversible contraception(8).

In Ghana, there is limited data on the extent of pain experienced by women at IUD insertion. Therefore, the results of the study comparing the use of medication (lidocaine spray or Suppository diclofenac sodium) to counselling only which is the routine practice at the RH/FPU will provide data which may help improve our current knowledge on the extent of the pain experienced by Ghanaian women at IUD insertion and the modality of pain management that maybe most helpful. This will in the long run help to increase uptake and continuation rate of intrauterine contraceptive device.

1.4 Aim of the study

The aim of the study is 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.

1.5 Objectives

1. To compare the effectiveness of 10% lidocaine spray of the cervix versus 100mg suppository diclofenac sodium in reducing pain at IUD insertion using 10cm-Visual Analog Score.
2. To compare pain control at IUD insertion using counselling only (standard of care) versus 10% lidocaine spray of cervix.
3. To compare pain control at IUD insertion using counselling only (standard of care) versus 100mg suppository diclofenac sodium.

Research questions

1. Is the use of 10% lidocaine spray of cervix more effective in reducing pain at IUD insertion compared to suppository diclofenac sodium?
2. Is the use of 10% lidocaine spray of cervix more effective in reducing pain at IUD insertion compared to the counselling only (standard of care)?
3. Is the use of suppository diclofenac sodium more effective in reducing pain at IUD insertion compared to the counselling only (standard of care)?

Hypothesis 1

Null hypothesis: The mean pain scores of women in the 10% lidocaine spray group would not be significantly lower than those of women in the 100mg suppository diclofenac sodium group using 10cm-VAS score at IUD insertion.

Alternate hypothesis: The mean pain scores of women in the 10% lidocaine spray group would be significantly lower than those of women in the 100mg suppository diclofenac sodium group using 10cm-VAS score at IUD insertion

Hypothesis 2

Null hypothesis: The mean pain scores of women in the 10% lidocaine spray group would not be significantly lower than those of women in the counselling only (standard of care) using 10cm-VAS score at IUD insertion

Alternate hypothesis: The mean pain scores of women in the 10% lidocaine spray group would be significantly lower than those of women in the counselling only (standard of care) using 10cm-VAS score at IUD insertion.

Hypothesis 3

Null hypothesis: The mean pain scores of women in the 100mg suppository diclofenac group would not be significantly lower than those of women in the counselling only (standard of care) using 10cm-VAS score at IUD insertion

Alternate hypothesis: The mean pain scores of women in the 100mg suppository diclofenac group would be significantly lower than those of women in the counselling only (standard of care) using 10cm-VAS score at IUD insertion .

CONCEPTUAL FRAMEWORK FOR COMPARISON OF EFFECTIVENESS OF COUNSELLING ONLY, SUPPOSITORY DICLOFENAC AND LIDOCAINE SPRAY AT INTRAUTERINE DEVICE INSERTION.

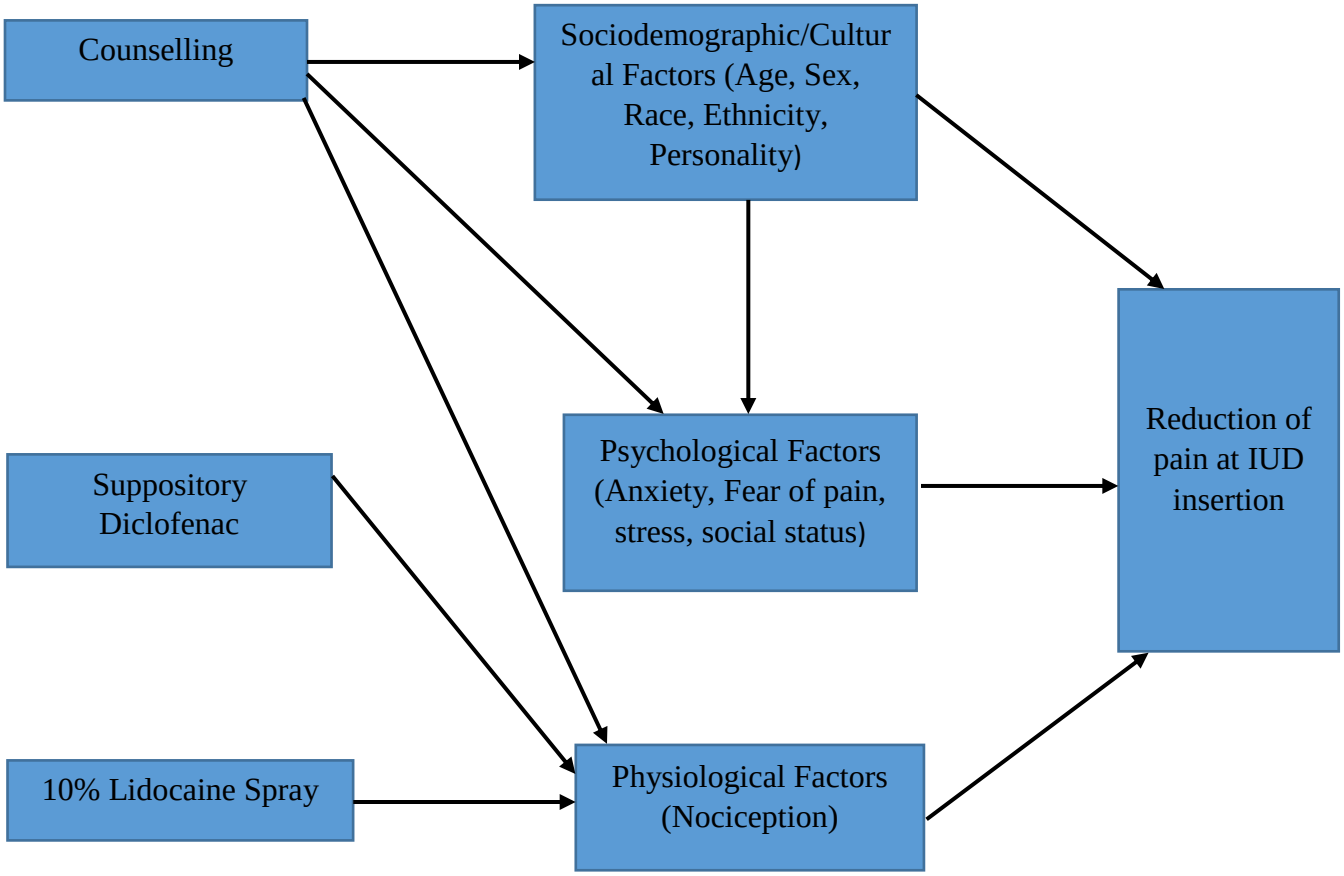

Figure 1.1.Conceptual Framework (Author's Own Construct)

1.6 Narrative of the Conceptual Framework for "Comparison of Effectiveness of Counselling only, Suppository Diclofenac and Lidocaine Spray at Intrauterine Device Insertion".

The intrauterine device (IUD) is one of the most effective reversible family-planning method globally. Nonetheless, the uptake of this family planning method continue to be low and one of the main reasons cited are pain at its insertion. Therefore, the main challenge to improving intrauterine contraceptive device uptake must include preventing pain at insertion and decreasing associated excessive menstrual bleeding, minimizing complications such as perforations and expulsions(7). Women's fear of pain during IUD insertion may lead them to reject this highly effective contraception. Several methods have been identified for reducing pain during IUD insertion, and these include administration of pharmacological and non-pharmacological agents. Examples of pharmacological agents used include nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac, local cervical anesthetic agents such as lidocaine, and cervical ripening agents such as misoprostol(14–16). The non-pharmacologic interventions include pre-insertion counselling, aromatherapy and delayed bladder emptying(17). Review of available literature have shown that none of the methods and drugs used during IUD insertion were superior (8).

Possible sources of pain during IUD insertion can be considered at three main levels, namely central nervous system (CNS) level, cervical level and the uterine level. The source of pain at the CNS level is mainly psychological and includes anticipatory anxiety, apprehension and fear of pain. At the cervical level, the source of pain is mainly from the clamping of the cervix with tenaculum and dilation of cervix during the IUD placement whilst at the uterine level the pain source is mainly due to cramping of the uterus once the IUD is placed in the uterine cavity. The non-pharmacological intervention such as counselling is mainly effective against CNS source of pain. The pharmacological agents such as lidocaine and diclofenac are mainly used to control cervical and uterine sources of pain.

Pain is believed to be a biopsychosocial phenomenon, which implies that the individual's experience and the assessment of pain are influenced by biological, social, psychological, cultural, environmental, spiritual, and other factors. Culture is defined as a set of values, beliefs, attitudes, experiences and learned patterns of behavior which is shared by the members of a

particular community. The attention paid to culture is often minimal even though culture plays an important role in the experience and expression of pain or pain related behavior(18).

There are differences in pain experience between individuals and also cultural groups. When individuals experience pain, usually the culture of the individual influences what is expected of them such as how to respond and what is acceptable response. Pain has specific social and cultural significance, and reactions to pain must be understood in light of this. A person's culture is important influence in the formation of individual reaction patterns to pain. Mental processes involving attention, anxiety, sociocultural learning, and experiences all influence pain experience(18).

It is known that individuals learn appropriate behavior and emotional responses by observing the actions of others who are socially or culturally similar to themselves. This originates from within the family as part of primary socialization processes. Various studies done among various ethnic groups give credence to biocultural hypothesis of pain. It is imperative to understanding cultural differences in pain perception, beliefs and expectations as this will help to accurately identify clients' needs and behaviors relative to one's own culture in order to offer appropriate pain assessment and pain management (18)

Every culture has a way for dealing with pain that may correspond to its own values and norms. In some cultures communication about pain may not be acceptable. For instance, the Irish would rather withdraw when in pain because they see this as bad form to show they were in pain. The North Americans on the other hand would prefer to see the doctor as soon as possible in order to describe their pain experience. Interestingly, the Italians, the Greeks, the Spaniards and the Portuguese express their pain loudly and clearly in order to get sympathy from others(18)

Health care providers need to be cultural competent by taking into account the clients' values, convictions, customs and habits and incorporate them into the treatment planning(18).

Psychological factors that are likely to affect pain perception and outcome are not usually considered by clinicians. However, this is critical for effective management of pain. For example, in the majority of individuals persistent pain naturally leads to emotional and behavioral consequence(19). Clients who are depressed or have a history of depression may have more difficulties in handling pain. It is also important to note that individuals have different

attitudes and beliefs about the origins of pain and their seriousness and how to react to pain. Personal expectations of pain, recovery and treatment benefits affect the course of pain. Have catastrophic thinking about pain is known to affect pain management outcomes. People who accept their pain and are prepared to self-manage their pain usually have better pain outcome(19).

Sociodemographic characteristics such as age, parity and educational level are known to affect individual's perception of pain. For example in a research by Shrestha et al in Nepal , almost half of the women in labor in the age group of 19 years or less described labor pain as severe as compared to women between 20-34years (30.4%) and 35years or more (20%). Among the nulliparous women in labor, 37% described it as severe compared to only 20.7% in women who have one or more children. For those with secondary or higher level education, 35.9% described labor pain as severe as compared to those women who had education up to primary level (26.9%) and up to secondary level (27.1%)(20).

A study by Guvenc et al in 2019 to investigate the effect of education and counselling on anxiety and pain in women undergoing hysterosalpingography as part of infertility treatment, the results were as follows; the mean pre-education and counselling anxiety scores of the intervention group and the control group were 47.13 ± 11.02 and 44.28 ± 10.14 respectively, with no statistical difference between the groups before the education and counselling ($t = -1.380$) ($p = .171$)(17). However, the post-test mean anxiety scores of the intervention group and control group were 34.75 ± 9.62 and 43.36 ± 10.28, respectively with statistically significant difference between the groups after the education and counselling ($t = 4.426$) ($p < .001$). Moreover, when intragroup comparisons were made in the two groups, the mean anxiety scores reduced in the post intervention period. However, in contrast to the control group, the intervention group experienced a statistically significant decrease in anxiety after the education and counselling ($z = 6.287$) ($p = .001$)(17). The mean pain score before the intervention was 7.13 ± 1.68 for the intervention group, and that of the control group was 6.77 ± 2.18. There was no statistically significant difference between the groups before the education and counselling ($t = .949$) ($p = .345$). Post education and counselling, the mean pain scores of the intervention group and the control group were 3.04 ± 2.38 and 6.40 ± 2.29, respectively. The difference of the pain score between the groups in the post-education and counselling period was statistically significant (t =

−7.348) ($p < .001$)(17). From the above counselling and education lead to a significant reduction in pain perception during the uterine procedure similar to the IUD insertion

The effect of lidocaine spray of cervix on pain reduction is due to the mechanism of action of the local anesthetic through reversible blockade of nerve impulse propagation. When infiltrated near a nerve, the drug enter the nerve by diffusion through the membrane and bind to the sodium channels causing a conformational change that prevents the transient influx of sodium and therefore depolarization. All potentially excitable membrane are blocked but more so the sensory fibres because they are thinner, unmyelinated and more easily penetrable. The onset of action is rapid and nerve blockade may last up to 5 hours when administered as a peripheral nerve block(21).

Diclofenac is a Non-Steroidal Anti Inflammatory Drug (NSAID and has anti-inflammatory, antipyretic and analgesic properties. Its main mechanism of action is believed to due to inhibition of prostaglandin synthesis by inhibition of cyclooxygenase-2 enzyme (cox-2) (22).

From the narrative, pain perception at IUD insertion are affected by sociodemographic and cultural factors such as age, sex, race and ethnicity, psychological factors such as personal attitudes, beliefs and personal expectations of pain and physiological process in the body through nociception. Diclofenac and Lidocaine work through the physiological factors i.e. blockage of nociceptors to cause reduction of pain at IUD insertion but counselling may act through the sociodemographic and cultural factors, psychological factors and physiological factors to bring about reduction of pain during IUD insertion.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Contraceptives are devices or methods for preventing pregnancy either by preventing the fertilization of the female egg by the male sperm or by preventing the implantation of the fertilised ovum.

Intrauterine contraceptive device is a long acting contraceptive device. It is a highly effective method equivalent to female tubal sterilization in efficacy with lower discontinuation rate of 5% compared to 29% for short acting hormonal contraceptives(23,24) .

Globally, 14.3% of women aged between 15 and 49 who are married or in union use IUD(25). There is however variations between continents. This rate is 27% for Asia, 17.1% for Europe, 15.4% for Africa and 4.8% for North America. In Asia 64% of IUD users live in China. For Africa, majority of IUD users are from North Africa (18.1%) with sub-Saharan Africa IUD use being less than 2%(25). Some of the reasons for low uptake of IUD in Sub-Saharan Africa include skewness of the method mix in favour of short acting hormonals (82% of all modern contraceptives), provider misconceptions and biases, limited provider training and perceived lack of demand by clients due in part to the mode of provision which is believed to be intrusive(26–28).

IUD insertion procedure has been associated with discomfort and pain. Due to concerns of this procedural pain, some health care providers selectively recommend less effective contraceptives methods which are not associated with pain or discomfort such as condoms(15).

Most studies report of mild to moderate pain at insertion(5). However, this pain can be severe enough to cause vasovagal reaction such as light-headedness, nausea, changes in pulse rate, syncope and even convulsions(8). It will therefore be of public health significance if an ideal agent can be found to eliminate or reduce pain at IUD insertion. This would have the ability to increase client satisfaction and consequently cause an increase in uptake of IUD and prevention of unintended pregnancy.

In light of this, various types of pain management at insertion of IUD have been proposed and these include NSAIDS, anxiolytics and local anaesthetic agents such as intracervical gels, cervical and paracervical blocks and cervical ripening agents such as Misoprostol(29).

Lidocaine spray has been demonstrated in a study to reduce significantly pain at IUD insertion(15). It is a simple and convenient topical anaesthetic agent with minimal side effect.

NSAIDS such as diclofenac on the other hand, decrease pain and inflammatory reaction by blocking cyclooxygenase enzyme and thereby blocking the formation of endogenous prostaglandins responsible for pain and inflammation(16).

In a study by Abass et al, oral diclofenac taken 30 minutes before IUD insertion reduced pain at insertion albeit slightly(16).

2.2 Intrauterine contraceptive device

Copper bearing IUDs were first discovered by Drs. Jaime Zipper and Howard Tatum in 1969. It is shaped like a capital ‘T’ because the uterine cavity of a contracted uterus assumes the shape of a ‘T’ and therefore the IUD in such a shape is less prone to expulsion(23). The other types of copper bearing IUDs include Fincoid-350 with curved horizontal arms and a copper coated

vertical stem and Gynefix also known as “frameless” IUD consisting of six (6) copper sleeves fixed in a length of semi-rigid suture thread (15).

The mechanism of action of intrauterine contraceptive devices is that they induce intense local sterile inflammatory reaction leading to lysosomal activation and other inflammatory changes which are spermicidal. This also works to prevent implantation of the developing embryo(23). The copper IUD releases free copper and copper salts that have both biochemical and morphologic impact on endometrium. They also produce changes in cervical mucus and endometrial secretions. It is important to note that the serum copper levels are not significantly increased during its use(23).

The CU-T380A is T- shaped device with a polyethylene frame holding 380mm^3 of exposed surface area of copper that provides contraception for up to 10 years. The copper wire is wound around the 36-mm stem which weighs 176mg and the copper sleeves on the horizontal arms weigh 66.5mg.

A polyethylene monofilament is tied through a 3mm ball on the stem which provides two white threads for detection and removal. The ball at the bottom of the stem helps reduce the risk of cervical perforation(30).

2.3 Indication for copper IUD use

The copper bearing IUD are mainly for women who are seeking reversible, effective and coitally independent method of contraception. It is also indicated for women who want their methods of contraception concealed from their partners, those concerned that they cannot remember to use a daily method, those who cannot use hormonal methods, breastfeeding women and following abortion or delivery(23).

Absolute contraindications are pregnancy, current pelvic inflammatory disease, cervicitis, chlamydial or gonorrhoeal infection and those with lifestyles with increased risk of sexually transmitted infection. Others include allergy to any of the constituents of the IUD and individuals with Wilson's disease(23).

2.4 Timing of Insertion of IUD

Ideally IUD insertion at the time of menses will provide the assurance that the women is not pregnant at the time of insertion. This is important to both health care provider and the client, however, this may not be practical all the time and may even be expensive to the woman. The timing of insertion at different times during the menstrual cycle has different effects on contraceptive continuation, effectiveness or safety of the IUD(31). There has been various studies to look at the insertion of IUD at different times during the menstrual cycle to evaluate how this might affect its use.

In a study of involving 9,904 women found that the rates of expulsion in the first two months after IUD insertion were highest among women with insertions on Cycle Days 1–5 (50.3 per 1000), with rates decreasing to 30.5 per 1,000 for insertion on Cycle Days 6–10, 24.0 per 1,000 for insertion on Cycle Days 11–17 and 22.0 per 1,000 for insertions on Cycle Day 18 or later ($p<0001$). Nonetheless, women coming for IUD removals due to pain and bleeding increased as day of the cycle increased, primarily for insertions after Day 17; removal rates were 20.9 per 1,000 for Cycle Days 1–5 and 20.6 per 1000 for Cycle Days 6–10, increasing to 27.2 for Cycle Days 11–17 and to 36.7 per 1000 for Cycle Day 18 and later ($p =0.01$). from the study the risk of pregnancy was noticed to increased with increasing cycle day of insertion, however this was not statistical significance ($p=.13$). It was postulated from the data that there would be nine (9) excess IUD discontinuations per every 1000 insertions before Cycle Day 11 due to expulsion,

pain and bleeding, or pregnancy than if insertions were done after Cycle Day 11. There were no observed trends for rates of expulsions, removals for pain and bleeding or pregnancy during the third and fourth months post-insertion(31).

Analysis of a similar study which examined a cohort of 2536 women found that continuation rates were highest among those who had IUD insertion insertion during menses or immediately after. In this study continuation of IUD use at 12 months was 92.0% for those who had theirs insertion during Cycle Days 1–3, 89.3% for those who had theirs at Cycle Days 4–7, 87.8% for insertions at Cycle Days 8–14, 88.3% for Cycle Days 15–21 and 84.8% for Cycle Days ≥22; no statistical comparison was reported(31). Number of women who reported for removals including those removals for bleeding, pain and for infection were highest among those with IUD insertions on Cycle Days 22 or more. The expulsion rates were highest among women who had their insertions on Cycle Days 8–14 (3.2%), compared with those with those women who their insertions on Cycle Days 1–3 (1.6%), Cycle Days 4–7 (1.9%), Cycle Days 15–21 (1.1%), or Cycle Days ≥22 (1.2%), however there was no statistical comparison reported. There was no differences in the pregnancy rates irrespective of the by timing of the IUD insertion(31).

There was yet another study which examined 867 women with IUD insertions occurring during or after menses and concluded that over 12 months, rates of continuation, expulsion, removal and pregnancy did not differ by timing of insertion. A different study assessed their risk of acquiring PID at different times during their menstrual cycle. They recruited 615 women for the study which included 156 HIV-positive women and 493 HIV-negative women. The result was that over four months, those women with IUD insertions during menses had similar rates of expulsion, removal and pelvic inflammatory disease (PID) as those with IUD insertions outside the menses. The disadvantage was that they did not report on the statistical significance of their

findings. There was also no pregnancies in either HIV-positive or HIV-negative groups. The calculated odds for any IUD complication was not significantly different among those with insertions outside menses as with those who had their insertions during menses [AOR= 1.65, 95% CI 0.21–12.91](31).

Several other studies have been done to look at the effects of timing of IUD insertion on insertion complications such as pain, bleeding and expulsion. In a subgroup analysis involving 29 nulliparous women who took part in a clinical trial of an analgesic agent concluded that the pain index which is the total amount of pain, discomfort and bleeding over 7 days post-insertion, was positively correlated with the day of the cycle on which the IUD was inserted (Spearmen rs=0.4559). In a study involving 84 nulliparous women, the conclusion was that immediate pain following IUD insertion was independent of day of the cycle. There was no further description of their findings. There was a clinical trial of prophylactic ibuprofen at IUD insertion which concluded that pain after IUD insertion measured by a visual analogue scale was highest among those with insertions day 11 or more since the start of last menstrual cycle and lowest among those with insertions 6–10 days since the start of last menstrual period ($p<05$, non-parametric Kruskal-Wallis test). Other researchers have attempted to compare the difference in pain at insertion during different type in a menstrual cycle. They found out that pain at the time of IUD insertion was more common among those with insertions outside menses than during menses (2.1% vs. 0%) and that rates of bleeding at the time of insertion were similar (1.6% vs. 1.8%), however there was no direct statistical comparisons which was reported(31). The rate of expulsion immediate post-insertion was more frequent among those with insertions during menses (7.0%) than those with insertions outside of menses (2.8%). The calculated odds for any IUD insertion complication among those with insertions outside versus within menses was non-

significant (adjusted OR=0.54, 95% CI 0.18–1.59)(31). From the above discussions, there is reasonable evidence to indicate that insertion of Cu-IUD at different times of the menstrual cycle has little effect on contraceptive safety, continuation or effectiveness(31).

2.5 Risks and complications of Copper IUD insertion

Like any surgical procedure, IUD insertion is associated with some complications. This includes uterine perforation which occurs in 1-2 per 1,000 insertions and contraceptive failure which accounts for 0.5 -1.0 per 100 woman- years of use in the first year(32). The most serious of these is uterine perforation which may lead to migration of the IUD into intra-abdominal cavity. Intra-abdominal IUD can led to intestinal obstruction and bowel perforation. Once recognised, the IUD should be removed either through laparoscopy or laparotomy(33). Even though uterine perforation is a potentially serious complication of intrauterine device contraceptive use, it is uncommon and usual are asymptomatic. In some of the perforations are not seen until months or years after insertion before they were identified. In one case series, the longest interval that had elapsed between insertion and diagnosis was 43 years. It is therefore important to know that they very seldom lead to harmful complications and hence do not affect the general excellent safety record of IUDs(34). It has been proposed that two mechanisms of uterine perforation exist;

1. Immediate traumatic perforation 2. Later "secondary" perforation caused by gradual erosion through the myometrium. In an analysis done in 1981 involving 356 cases, various types of perforations were identified. For example, a complete perforation is when the device pass through all uterine layers – endometrium, myometrium, and serosa – to lie freely in the peritoneal cavity or enveloped by omentum or move into other rarer locations. However in some few cases the IUD penetrates only into the myometrium, which then called partial perforation(34). It has generally been stated that missing the IUD threads do not necessarily

imply that a device is incorrectly located and on the other hand the threads may be visible when the device has perforated. In the sub-classification of partial perforation, three anatomical compartments are considered, and these include uterine cavity, myometrium and peritoneal cavity. A partially perforated device may be present in one, two, or all three anatomical compartments. A device with a perforation that is mainly situated in the uterine cavity (A1) will be easier to remove than one in which the IUD is mainly located in the myometrium (A2). As a matter of fact, removal of the IUD located in the myometrium can be difficult or even dangerous. In a type B perforation the IUD is located entirely within the myometrium and hence cannot be seen either through hysteroscopy or laparoscopy. For a type C perforation the device has protruded into the peritoneal cavity but is still fixed in the myometrium and for type D perforation, some portions of the device are situated in all three compartments and a detailed assessment will be needed to plan the mode of removal. Perforation type D2 will be more complex to remove laparoscopically than D1(34).

Partial perforations may remain as such or they may be converted into a complete perforation within a matter of days. The conversion to complete perforation is almost certainly due to uterine contractions pushing the device through the myometrium. The amount of force needed depends on the shape of the device. In a hospital-based study of the copper T-380A IUD in which the women were followed up for one year, they found an incidence of 2.2 per 1,000 insertions. Similar studies elsewhere could not be so certain of the denominator and hence have found lower perforation rates. For example in the Finnish study, they calculated an incidence of 0.4 per 1,000 sold intrauterine contraceptive devices. In one of the study they found a higher perforation rate in women using an IUD for the first time compared to women who had used the method previously(34,35). The rates of perforation by any IUD may in part be contributed by the

experience or the maintenance of skill of the health care provider. This idea was first brought up in a report from Singapore, in which more perforations were seen in insertions by junior doctors or general practitioners than by experienced gynaecologists. Results from a large prospective cohort study of a copper IUD indicated that doctors who had inserted fewer than 10 IUDs during the 10-year study period (73% of the sample) had significantly higher perforation rates than those who had inserted between 10 and 100. In a similar study called the European Active Surveillance (EURAS), showed a higher perforation rate in insertions performed by clinicians who inserted fewer than 50 devices per year compared to those inserting 50 or more per year. The implication of the above is that the more experience you are the less likely your IUD insertion will lead to a perforation.

The framed device type does not appear to be an important factor in the rate of perforations. The European cohort study (EURAS) found no clinically significant differences in perforation rates between copper IUDs and the Mirena® IUS (Bayer Schering Pharma, Turku, Finland). The other possible risk factors for perforation are as follows; Insertion by less experienced clinicians, lactation, postpartum insertion (within 6 months of delivery), lower parity and higher number of previous abortions. The age of the woman, history of dilation and curettage, and previous history of cesarean section have been found not to be associated with risk of uterine perforation(35).

The myometrium of the uterus is softer during pregnancy and puerperium, so is more vulnerable to being torn or punctured during instrumentation. The uterine involution starts immediately after delivery and is rapid during the first week and by 2 weeks postpartum the uterus is contained within the pelvis and by the 4th week it is close to normal size. The period of full breast-feeding is marked by very low oestrogen levels and the uterus is consequently small. Therefore IUD

insertion is less painful in lactating women. This may also be attributable to increased levels of β-endorphins. Uterine perforation during insertion at this time may be associated with little pain and may therefore be less likely to be noticed at the time of the perforation. Hence perforation in the postpartum period is generally rare(35).

In the 1960s a study was done in Singapore (in which 2,487 of 8,977 insertions were post placental, ie, within 48 hours of delivery) in which they recorded 93 perforations with the Lippes loop. In this study the perforation risk was perhaps high due both to its mode of release from its insertion tube and to its linear form if it did not conform to the shape of the uterine cavity. In another study from California where insertions were done between 4 and 8 weeks postpartum, there was zero perforation rate with copper-IUD. There was other study from Turkish of copper T380A insertions, no perforations were observed at up to 6 weeks postpartum, but there were some when insertions were done after 6 weeks. The possibility that women who are lactating are more susceptible to perforation of the uterus when an IUD is inserted was first raised in 1966 but it was first investigated in a USA in a case-control study(35). The key findings of the study was that there was a 10fold risk of perforation in women who were breastfeeding at the time of IUD insertion compared to women with at least one live birth who were not currently breastfeeding. In another multicentre 6-month follow-up study of involving 1,149 women who had copper-T 380A IUD insertion, there was no perforation in any of the women whether breast-feeding or not breast-feeding. There was another analysis of 50 perforations which was reported to a Swedish insurance scheme register which found that 27 of the women (54%) were breast-feeding at the time of insertion(35). A pharmacovigilance multicentre study found that 42% of women with IUD perforations were lactating at the time of insertion. The EURAS study, also showed a 6fold increase in risk of perforation associated with breast- feeding. From the ongoing deliberations, it

is difficult to take a position on whether breast-feeding increases the risk of perforation or not. Currently, professional guidance gives no restriction on eligibility for IUD insertion after 4 weeks postpartum, irrespective of whether or not a woman is breast-feeding. For the medical eligibility for IUD insertion between 48 hours and 4 weeks postpartum, the WHOMEC and UKMEC put them into category 3 (i.e. the risks generally outweigh advantages), but USMEC assigns category 2 (i.e. that the advantages generally outweigh risks)(35)

Uterine perforations with IUD can also occur through the fundus, especially if the uterus is in an axial orientation. It can also occur in the uterosacral ligament, the broad ligament, the fallopian tube, and the ovary. A case of IUD threads coming through the posterior fornix has been reported. In this case after failed localization at laparoscopy, the IUD was removed by colpotomy. In a rare case, an IUD was found within an ovarian carcinoma. Other very rare sites have been described such as the anterior abdominal wall. There is also one recorded case of sciatica after a posterior perforation. In most of the cases the perforated device is found free in the peritoneal cavity but usually they all become attached to an organ, the bowel, the mesentery, or most commonly the omentum(35). Occasionally, there may be adhesion formation as a result of the perforated device which may result in intestinal obstruction. Cervical perforation is very rare and they are usually asymptomatic. It is believed that some degree of malposition of the device which later resulted in the force exerted by the vertical stem with slow, repetitive uterine contractions which gradually propel the device through the cervical tissues. Removal is relatively easy and this is usually done by freeing the device initially by pushing it up toward the uterine cavity. Perforations of large and small bowel, appendix, and rectum have also been reported. Removal sometimes has to involve resection of a segment of bowel. There are some cases of successful removal of an IUD per rectum by proctoscopy or colonoscopy(35).

There is one reported case of a perforated frameless IUD which disappeared from the body and was assumed to have come out through the intestines.

The perforation with a modern T-shaped IUD has been observed to cause partial intestinal obstruction. In a Danish case report, there was a perforation next to the sigmoid colon which presented 5 years after insertion with thickening of the bowel wall causing acute abdominal pain. There is an exceedingly rare complication of fistula formation between different sections of bowel which has been reported. Also intestinal gangrene from the perforation of IUD has also been documented. There have been more than 70 cases of perforation involving the urinary tract reported in the literature. Perforation of IUD through to the bladder or ureter is an uncommon but regularly reported complication of IUD insertion(35). There have been reported cases of urinary calculus formation around the device .In one reported case IUD, was found in the urethra. Even cases of menouria (vesical menstruation) due to an uterovesical fistula and that of the formation of a colovesical fistula. Retroperitoneal location of a perforated IUD with fibrosis around the right pelvic ureter leading to right hydronephrosis has been reported in the literature. The IUD and the associated bladder calculi was removed cystoscopically(34)

Another important complication worth mentioning is the risk of expulsion. This occurs with 2-8% of IUD insertions within the first year of use. The expulsion rate is lower among older women (4.6%) compared with younger users (10.4%). Symptoms associated with expulsion includes lower abdominal pains and bleeding per vaginum(33).

There is also the complication of pregnancy with IUD in-situ which occurs in 0.20 per 1,000 woman-years(32). This usually occur when the IUD is not placed properly or there is displacement following placement. This carry with it the risk of miscarriage, preterm labour,

choriomnionitis and decreased likelihood of livebirth if left unremoved. Early removal is recommended but that also carries a high risk of spontaneous abortion.

There is also 3-9% risk that pregnancy occurring with IUD in situ could be an ectopic pregnancy (36). Intrauterine device insertion has also been associated with lower abdominal cramps in 43% of clients and this has been attributed to irritation of the endometrium after the IUD placement(33) Intrauterine device insertion has been associated with reduced risk of pre-eclampsia. In a meta-analysis done in 2016, the relative risk of pre-eclampsia between women who have used IUD either before pregnancy or during pregnancy and those who have never used IUDs was 0.74 (95% CI, 0.61-0.90), and no heterogeneity was detected ($I2 = 0$, $df = 1$) ($p=0.002$). This implies that compared to no IUD use, any use of IUD could reduce the risk of preeclampsia by 26%. Analysis was also done for patients who conceived with an IUD in situ and those who had IUDs removed early before pregnancy were analysed. The result was statistically insignificant ($P = 0.39$), indicating that there was no statistical difference between IUD in situ and IUD early removal. Further analysis showed that compared to no IUD use, early IUD removal could reduce the risk of preeclampsia by 24%(37). The key findings from the meta-analysis was that any use of IUDs could reduce the risk of preeclampsia by 26%. And that there was no statistically significant difference between IUD in situ and IUD early removal in the risk of developing preeclampsia. Comparing to conceiving with an IUD, pregnant women without an IUD suffer more risks. The analysis also showed that early removal of IUD can reduce the risk of preeclampsia compared to no IUD use(37). The proposed mechanism underpinning the effect of exposure to IUDs on the risk of preeclampsia may be the decreased risk of placenta hypoxia caused by relaxation of the vessels. The evidence is that in the placenta of patients diagnosed with preeclampsia, the circulating levels of two important indicators, i.e. sFlt-1 and PIGF, are

different from non-pre-eclampsia pregnant women. In this scenario, there is increased sFlt- 1 level and decreased PIGF level. The PIGF is released by placenta and functions as a vasorelaxation factor. This is a homolog of vascular endothelial growth factor (VSGF). However, sFlt-1 is an inhibitor of VSGF. Both copper-bearing and hormone-releasing IUD alter the cytokine profile of the endometrium. Hence the exposure to IUDs may decrease the level of sFlt-1 and raise PIGF level. Secondly, prostaglandins are known to have vasodilatory effect and therefore is able to increase the blood perfusions(38). Finally, the presence of IUD causes some endometrial damage which may be helpful for placentation however, the evidence showed that decidual injury may increase the potential of trophoblastic cell invasions to maternal spiral arteries which can remodel the arteries and provide the embryo with adequate vascular supply. The fetus is the able to access the oxygen and nutrients from the mother. When such process is disrupted, preeclampsia may occur(37,38).

Another important complication of IUD insertion is the risk of expulsion. In a multicentre retrospective study done in US in 2014 involving 2,523 adolescents and women between the ages of 13 and 35 who had IUD insertion during the study period, the overall rate of IUD expulsion after a mean follow-up of 37 months was 6% and increased. And this increased from 1% at 1 month of use to 4% at 12 months of use. There was no significant differences found between the expulsion rates among the age groups. But when IUD expulsion occurred, adolescents and young women between the ages of 13 and 19 years were more likely to have partial IUD expulsion (60%) as compared with the older cohorts(39). The commonest documented reasons for IUD expulsion were unknown (81%) and expulsion during menses (10%). Thirty four percent (34%) of patients elected to have a second IUD placed after expulsion. For those who had IUD inserted for the second time, the rate of expulsion was

14%(39). The failure rates with IUD contraception were 0.4% at 12 months and 1% after a mean follow-up of 37 months. Among the age groups, there were no significant differences in terms of contraceptive failure, and none of the pregnancies identified were extra uterine(40). Thirty-nine percent (39%) of failures occurred after a partial or a complete expulsion not previously identified by the patient or the health care provider. For those who conceived with an IUD in utero, 8 elected removal of the IUD at pregnancy diagnosis, whereas the remaining 6 females decided to continue the pregnancy with the IUD in utero(40). The overall rate of spontaneous abortions was 17%; this rate was the same in patients who had their IUD removed as well as the patients who elected to keep their IUD in utero. Of the 23 contraceptive failures, only one preterm delivery was noted. And this was in a patient who kept the IUD in utero(39).

From the study, IUD discontinuation rates were 19% at 12 months and 41% after a mean follow-up of 37 months. The commonest reasons for discontinuation, irrespective of age and IUD type, were pain (31%) and bleeding (24%). In spite of similar rates of IUD discontinuation between the various age groups at 12 months of use, teenagers and young women younger than the age of 20 years were more likely to request early discontinuation at the end of the total follow-up period. The rate of pelvic inflammatory disease was inversely related to age with a rate of 13% in the youngest age group. There was no significant difference noted in pelvic inflammatory disease rates (2%) based on age (39).

In all, 29% of IUD users reported pain and 30% reported abnormal bleeding. The adolescents and women aged 13–19 years were significantly more likely to report pain. In terms of uterine perforations 3 cases were identified, giving the overall rate of 0.3%. These perforations all occurred in parous women, between the ages of 20–24 years, who had their IUD inserted by nurse practitioners(40). When copper IUD was compared with hormonal IUD, the rate of IUD

expulsion was significantly higher in copper IUD users as compared with levonorgestrel intrauterine system users at all time intervals studied (2% compared with 1% at 1 month, 6% compared with 3% at 12 months, and 8% compared with 5% after a mean follow-up of 37 months, respectively(40). The IUD contraception failure rates were significantly higher in the study respondents who had a copper IUD insertion compared to those who had a levonorgestrel intrauterine system inserted (1.3% versus 0.2% at 12months and 3% versus 1% in the 37 months follow-up period, respectively)(40). There was a higher rate of discontinuation which was noted in copper IUD users (23%) compared to levonorgestrel intrauterine system users (18%) at 12 months(39). When the multiparous women were compared with nulliparous, there was no significant differences that were seen after a mean follow-up of 37 months in the rates of expulsion, contraceptive failure and premature discontinuation. But nulliparous women were more likely to report pain with IUD use as compared with multiparous women(39).

They also assessed the competence of the health care provider and the risk of discontinuation and found out that, women who had their IUD inserted by a gynaecologist were less likely to discontinue their IUD within the first year of use as compared with those with the IUD inserted by family physicians, nurse practitioners, and physician assistants. Adolescents and women who underwent IUD insertion by a non-gynaecologist provider did not experience a higher rate of complications such as expulsion(39).

The risk of PID among IUD initiators is elevated in the first weeks following placement; however, the absolute risk of PID is very low. US guidelines presently recommend that women should not have an IUD placed if they currently have purulent cervicitis, gonococcal or chlamydial (GC/CT) infection, or PID.

A secondary data analysis of a US prospective cohort study examined the rate of PID over 6 months among 4371 Cu-IUD or LNG-IUD initiators compared with 3240 non-IUD contraception initiators. All women were screened for gonorrhoea and chlamydia trachomatis at baseline with NAAT, and asymptomatic women initiated the IUD on the same day as screening. PID was assessed by self-report and confirmed through chart review. Among the 215 asymptomatic women testing positive for GC/CT at baseline, 1 of 91 women initiating an IUD developed PID compared to none of124 women who did not initiate an IUD (rates of 1.1 vs. 0.0, respectively; p=.42). Most of these women began antibiotics according to national guidelines within 2–3 weeks of enrolment. Across all women regardless of baseline GC/CT status, rates of PID were low but were significantly higher among IUD users at 6 months [0.46%; 95% confidence interval (CI), CI 0.26–0.66] compared with non-IUD users (0.09%; 95% CI, 0–0.20; p=.005). There was no significant difference in PID rates between 191 DMPA initiators and 194 IUD initiators after contraception initiation (2.1% vs. 2.2%, p=.97), although history of PID was more common at baseline among DMPA initiators compared with IUD initiators (4.7% vs. 0.5%, p=.01) [14]. Odds of STI were higher after contraception initiation among DMPA initiators compared with IUD initiators [adjusted odds ratio (OR), 2.67; 95% CI, 1.05–6.78, adjusted for several covariates](41).

In a systematic review of safety of intrauterine devices among women with HIV, the studies demonstrated that IUD placement in women with asymptomatic gonorrhoea and chlamydia trachomatis infection or at high risk of STIs did not increase the risk of PID compared to initiating other contraceptive methods. Historical concerns of higher PID risk among women at risk for STIs who use IUDs may not be relevant with modern devices and STIs. In conclusion, the limited evidence found no differences in infectious complications when comparing IUD

complication rates among women with varying levels of HIV disease severity. Studies generally found that IUD use was not associated with HIV transmission, infectivity, or disease progression, however there was little direct evidence to address potential differences related to HIV severity. The US MEC currently recommends that IUDs can generally be used by women with HIV but generally should not be inserted in women with severe disease(42)

2.6. Difficult Intrauterine Contraceptive Device Removals

Usually the removal of IUD because it has reached the licenced period of use or the contraceptor wants to switch to another method or wants to get pregnant is very simple. The standard technique used to remove IUDs is described as follows.

Patients maybe advised to take a dose of oral analgesic (ibuprofen 200– 400 mg or acetaminophen 325–650 mg) about an hour before the procedure. The procedure will be explained and verbal consent was obtained. With the patient placed in the dorsal lithotomy position, a speculum will be introduced gently into the vagina to expose the cervix. If the IUD thread visible outside the external os, traction will be applied to pull out the device. In majority of cases this will be the case. However, if the thread is not visible, an ultrasound examination in the consulting room or procedure room will be performed to determine the type and location of the IUD. The cervix will then be cleansed with an antiseptic solution and may be sprayed with a topical anaesthetic spray (e.g. 10% lidocaine spray). A uterine sound will be gently inserted into the endocervical canal to probe for the thread. If no thread was evident, the cervix would be gently dilated using a uterine sound. Occasionally, the cervix needed to be stabilized with a single- tooth tenaculum applied to the anterior lip of the cervix together with the help of a plastic os finder. Once the uterine cavity had been entered, the length and the direction of the cavity will be noted. An IUD removal hook will then be inserted inside the cavity to remove the IUD. If the

removal was unsuccessful, which may occur because the cervix is too stenotic, or the patient complained of unbearable pain, or the IUD was not obtainable despite using a hook in the uterine cavity, we may offer the patient the option of removal under general anaesthesia. In recent years, with the more popular use of misoprostol, patients would also be offered another attempt at office removal after administration of misoprostol (400 µg vaginally 3–4 hours before attempted removal) with or without paracervical block. Prophylactic antibiotics is usually not given routinely.

In a 10 year study from China involving 491 women, the key findings were as follows;

Of the 314 women using Chinese IUDs, 227 (72.3%) had the device removed successfully in the office setting; in contrast, successful removal occurred in 137 (95.8%) of the 143 women who had their IUD inserted in Canada (P<0.001). Most women whose IUD had been inserted in Canada had a visible thread seen outside the cervix (93.7%), which likely contributed to the ease of removal; in contrast, only 13.4% of women using Chinese IUDs had a visible thread, P<0.001). The mean age and mean parity of patients with IUDs fitted in Canada (39.9±6.1 years and 1.2±0.8, respectively) were similar to those of women using Chinese IUDs. Of all IUDs inserted in Canada 98.6% (141 out of 143) were copper T IUDs, with the exception of 2 that were which were Mirena IUDs. The mean duration of placement of IUDs inserted in Canada was significantly shorter than that of the IUDs inserted in China (3.5±1.9 vs 9.4±5.3 years, respectively; Pb0.001). A total of 279 Chinese IUDs were removed (from the office setting and the operating room). Of the 88 women with a failed first attempt at IUD removal in the office setting, 2 women had a second attempt after using misoprostol administration and removal was successful in 1 woman. A total of 28 women (including 1 with a failed attempt at removal after using misoprostol) decided to keep their IUD in place without further intervention. A total of 59 women had their IUD successfully removed under general anaesthesia. All in-hospital IUD

removals were performed under general anaesthesia (less than 15 minutes) with cervical dilatation up to 6–7 mm and removal of the IUD using the hook or the uterine curette. In 12 (20.3%) women, hysteroscopy examination was performed to locate the IUD before removal under anaesthesia. Intraoperative ultrasound-guided IUD removal was not a usual practice.

No post-removal infection was reported in women with an attempted and successful IUD removal. Only 1 woman in this series had a partially embedded IUD, which required removal under general anaesthesia. Difficult removal was associated with absence of a visible thread outside the cervix, no previous vaginal birth and older women especially during their menopause. The type of IUD and duration of placement did not affect the ease of removal(43)

In another study where difficult removal was defined as a situation in which the IUD was known to be in the uterine cavity but was unable to be removed in an office setting, and the patient was taken to the operating room; the key findings were as follows, there were 157 difficult removals out of 1169 IUD removals (13.43%). The age of women who experienced a difficult removal of an IUD was (mean ± S.D.) 32.9±9.6 years. Fifty (31.9%) of the IUDs were thought to be embedded at the time of preoperative imaging; however, only 15 (9.6%) were truly embedded at the time of operative removal. Hysteroscopy was employed to facilitate removal in 38.2% (n=60) of cases. The IUD types associated with difficult removals were as follows: 37.6% (n=59) were with the Copper-T 380A; 20.4% (n=32) were with the Copper 7; 24.8% (n=39) were with the LNG-IUS and 17.3% (n=27) were other types of IUDs. Obstetrician/Gynecologists performed the majority of cases (n=137, 93.2%). The rest were performed by Family Practice Physicians (n=8, 5.4%) or General Surgeons (n=2, 1.4%). Surgery for 36 of 157 (22.9%) occurred in a tertiary care hospital; 121 (77.1%) occurred at a community hospital(44).

Evaluation of the cases revealed that 42 of the women became pregnant with IUD in place and were taken to the operating room for management. The mean patient age was 28.5±5 years. Of note, these numbers do not take into account those women with an IUD in place who had an ectopic pregnancy treated with methotrexate. Twenty-three of the pregnancies identified were ectopic (54.8%). The LNG-IUS was identified in 16 of the pregnancies (38.1%); the Copper T 380A, in 15 (35.7%); the Copper 7, in 6 (14.3%); other IUDs were identified in 5 (11.9%). Treatment modalities differed for patients in this group. Twenty-two of the cases (95.6%) were managed using laparoscopy and 3 cases (13%) were managed via laparotomy. Some women received multiple procedures. For example, one laparoscopy was converted to exploratory laparotomy due to bleeding, and one laparoscopy was converted to mini-laparotomy for visualization(44).

2.7 Barriers to Intrauterine Contraceptive Device Uptake

Medical barrier to contraception is defined as "obstacles that present themselves once an individual is within the premises of the service provider"(45).

Medical barriers can be present at various levels such as the national regulatory or policy level, at the program or facility level and at the individual level. Bertrand and colleagues noted that there were seven types of medical barriers to contraceptive method utilization. These were (i) regulatory barriers (ii) eligibility barriers (iii) contraindications (iv) service provider qualifications (v) provider bias (vi) inappropriate management of side effects and (vii) process and scheduling hurdles(45).

However other researchers have classified the medical barriers into individual level barriers, health facility level barriers and community level barriers(46,47).

The individual level barrier to contraceptive utilization includes risk perception of family planning methods, lack or insufficient knowledge about the family planning methods needed to make the desired decision, disapproval from male partner, geographic and economic inaccessibility to the service facility(46). For instance, in a study involving 252 women aged 14 – 27 presenting to a Family Planning clinic, 55% had not heard of IUDs. The parous women were 4.4 times more likely to be interested in IUD compared to nulliparous women. If a woman had been educated about IUDs by their health care provider, she was 2.7 times more likely to be interested in using one of these(48).

In another study of 144 women aged 14 – 24 who were given a knowledge survey prior to a three-minute educational intervention, 60% had not heard of IUDs before the teaching. Of those who have heard of the method, only 37.5% had a positive attitude before the intervention. After the education, 53.5% had a positive attitude about IUDs and the participants particularly liked the fact that the method was long acting and very private(48). In a study in which 40 women were asked more detailed questions about intrauterine contraception, it was found out that the women had pregnancy concerns and had fears about letting a foreign body be put inside their uterus(48). The participants also believed that an IUD was use when other FP methods had failed. The women in this study reported a lack of discussion and information about IUDs from their providers, in the media or from other sources. Study from Australia where women were interviewed when they presented to family planning clinics for IUD insertion, 16% of respondents (51/318) had not found it easy to obtain IUD-related information, and almost a fifth (58/318) had been told it was not a suitable method for them by either a health care provider or a friend or family member (or both), in spite of these women meeting the medical eligibility criteria(48).

Irregular bleeding pattern is one of the commonest reasons that women discontinue their contraceptive method. It is a known fact that copper-IUD may increase the quantity of blood flow.In one study, there was a higher discontinuation rates for 'bleeding problems' in copper device (Nova T) users compared with LNG-IUD. In a more recent study of 136 adolescents, 7.4% had the device removed within the first year as a result of bleeding-related problems, with no difference in rate by IUD type. Therefore women need to be educated about the bleeding changes to be expected with an IUD, so that they are able to select the method that is best for them(48).

Health facility level barrier comprise of issues such as commodity stock out, limited provider skills for insertion and removal of IUD and limited number of family planning methods(46).

In some countries, IUD use are dictated by guidelines, package inserts or product labelling that recommend IUDs to be used for multiparous women. For example, in 2005, the US Food and Drug Administration (FDA) approved the package insert for the CuT380A IUD in which the requirement for the device to be used in women with one or more children had been removed. However, at the time the LNG-IUD had still not received the FDA approval for use in nulliparous women, making its use in this group an 'off label'. Because of the medico-legal environment in the USA, this may prevent providers from inserting a LNG-IUD in nulliparous women(48). Many health care providers working for large organisations such as Planned Parenthood often have to practise within regulations related to package inserts and, therefore, are not allowed to insert a LNG-IUD in a nulliparous women even if they believe it is safe. Therefore it was not surprising that a survey about use of IUDs among American gynaecologists, showed that 16% felt that inserting IUDs would lead to law-suits against them(48).

An example of health care provider bias against IUD resulted from the 1970s class action lawsuits against the manufacturers of the Dalkon Shield in the USA who was the manufacturer of IUD at the time which was linked to pelvic infection, infertility, and even death from sepsis(48). Even though currently there is no evidence that modern devices carry the same risks, this outdated information about the benefit and risks of IUDs persist and has resulted in unwillingness among Health Care Providers to recommend an IUD, and for women to take up these methods despite the international guidelines to the contrary. The risk inherent with IUD use ectopic pregnancy is poorly understood. Some heal care providers tend to overestimate the risk of ectopic pregnancy and believe that a past history of ectopic pregnancy is a contraindication to the use of IUD(48). The fact is that a pregnant with an IUD in situ has a 10.6-fold increased chance that the pregnancy will be ectopic compared to a pregnant not using IUD. It must be noted that generally women on contraception have very low risk of pregnancy and hence ectopic compared to the non-contraceptive users(48).

Health care providers have been known to refuse to insert an IUD for nulliparous women because of the perceived technical challenges(45,48). Even though some studies do suggest an increased rate of insertion problems in nulliparous women the majority of women will have an IUD inserted with ease irrespective of parity. There is several evidence for insertion success in nulliparous women comes from case series. In a Swedish non-interventional study of LNG-IUD insertions involving 224 nulliparous women, only six insertions were unsuccessful and more than 70% were regarded as ‘ easy ’ by the inserting clinician(5). Another study comparing the LNG-IUD with oral hormonal contraceptives in young nulliparous women in Finland and Sweden, it was reported that insertion of the LNG-IUD was ‘easy’ in 85% of cases (80/94 insertions) and only two of the 94 attempted insertions failed. In another retrospective study

done in Brazil comparing LNG-IUS insertions in nulliparous versus multiparous women, only one of 159 insertions in nulliparous women was unsuccessful(49). Few data directly comparing insertion-related pain in nulliparous women versus multiparous women exist, but the evidence suggests that it is likely to be greater in nulliparous women. A higher pain score for the insertion of the CuT380A in nulliparous versus multiparous women (mean of 2.7 cm vs. 1.9 cm on a 10-cm visual analogue scale) has been reported, although neither score was particularly high(48). In the Swedish study of LNG-IUD insertions in nulliparous women, moderate to severe pain was experienced by almost 90% of all participants at the time of insertion(5). Misoprostol (a prostaglandin analogue and cervical ripening agent) has been used to help with the insertion in nulliparous women(48).

Health care providers perceive nulliparous women to be at increased risk of uterine perforation, although the data about perforation are likely to underestimate the true incidence of perforation because of insufficient length of follow-up, loss to follow-up and unrecognised cases. There is some evidence that the risk is indeed higher in nulliparous women, or have had an abortion, but is probably greatest for women in the post-partum period(48). In a European study of IUD insertions involving 8343 women, the rate of uterine perforation was 2.2 per 1000 women. It was found by the authors found that higher parity decrease the risk (odds ratio [OR]: 0.04, CI: 0.01 – 0.1) whereas a greater number of pregnancy terminations increased the risk (OR: 2.1, CI: 1.2 – 3.6). However, the greatest risk was observed in women who were 0 - 3 months post-partum (OR: 11.7, CI: 2.8 – 49.2) and those 4 – 6 months post-partum (OR: 13.2, CI: 2.8 – 62)(48). This finding was supported by an earlier study which showed that 90% of women with IUD perforations had the device inserted within 12 months of a full-term pregnancy and 62% had

been within 12 weeks, suggesting the softer post-pregnancy uterine wall was predisposed to perforation(48).

Some health care providers were of the opinion that IUDs in nulliparous women may have a higher risk of expulsion. However, the available data do not support this assertion. In a study from Holland evaluating complications of IUDs according to parity, the expulsion rate for Cu-IUDs was 0– 2.8% per year among 142 nulliparous women versus 0–1.4% per year among 443 multiparous women; however this difference was not statistically significant. In a study from Brazil comparing use of the LNG-IUD in nulliparous and multiparous women, the expulsion rate within the first year after insertion was similar (4%) in both groups(49). From the US-based Contraceptive CHOICE Project, the one-year Cu-IUD/LNG-IUD expulsion rate among 437 nulliparous women was 2.5%, compared with 5.6% among multiparous women(50).

Health care providers who are competent in IUD insertion may be unwilling to have more providers gain those skills, because of the discomfort that they may lose an important source of income(48).

For some health care systems, referral systems may make it more make more sense to the health care provider and therefore the women are sent elsewhere for IUD placement instead of spending the time and money to provide this care themselves. In a US survey analysing IUD insertions found out that that for the health care providers not providing IUDs, 47% did that because of lack of reimbursement as a reason for not performing insertions. In both of the above cases these perceptions lead to inadequate trained health care providers(48).

The community level barriers included men's attitude towards family planning and fertility preference(46). Also because there is an intersection between personal beliefs, attitudes and

community norms, personal health seeking behaviour like contraceptive utilization can be influence by others in the community(47).

Individuals and communities apprehension about the mechanism of action of copper IUDs has prevented health care providers from providing IUD services and women from using IUDs. For many years it was believed that IUDs main mechanism of action was by preventing implantation of a fertilised egg. For many people who believed that life begins at conception, IUD use was considered morally unacceptable. There has been several studies which have confirmed that the main mechanism of action is what happens before fertilisation. And that is IUDs create a sterile inflammatory response that immobilises sperm, and hence women with one of these devices in their uterus have considerably fewer fertilised ova in their fallopian tubes than women not using contraception(48). Other research had utilised a highly sensitive immunoradiometric assay for hCG in user and non-users of IUDs in order to detect the earliest possible evidence of an embryo. For over 100 cycles in IUD users, they detected only one case of transient hCG elevation while their controls had four transient rises in 89 cycles. Their conclusion was that IUD interferes with the reproductive process before the embryo produces enough hCG to be detected in the maternal body fluids(48). In a comprehensive review from 2007 which cited the previous papers and several others, it was stated that the common thought that the mechanism of action of IUDs in women is destruction of embryos in the uterus is not supported by empirical evidence. The LNG-IUD, in addition to the above mechanism causes thickening of the cervical mucus, which impedes transport of sperm through the cervix(48).

At the national level because the up-front costs of intrauterine contraception are high in some countries, it may be perceived as being an expensive option. However, once inserted an IUD is effective for several years and over time becomes more cost-effective. The Cu-IUD, the LNG-

IUD and vasectomy were the three most cost-effective methods of contraception over five years of use in a US-based analysis. Even though the health care system as a whole will profit from this by preventing the costs of unplanned pregnancy, a particular payer may not. This can be true in a system with private insurers, but can also affect a national health care system where the different budgets have no crossover, as is what happens in the United Kingdom(48).

In an analysis from Africa on IUD underutilization, it was found that providers often impose unnecessary age and parity eligibility restrictions on client based on personal bias, outdated guidelines, lack of knowledge of method risks and misperception of method risks(51). There was a high rate of method denial for non-menstruating clients in countries such as Kenya, Senegal and Ghana. The long term protection afforded by IUD led in the past to providers giving it to mainly women who have completed their family but were denied to those who were seeking to space their births. The extra effort required for insertion also leads to some providers to favour short acting hormonal methods such as pills and injectables(51).

2.8 Physiology of pain at IUD placement

Pain is defined as unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in such terms (International Association for the Study of Pain, 2011)(52).

Pain is also termed as nociceptive which implies something sensitive to noxious stimuli. Noxious stimuli on the other hand refers to stimuli which elicit tissue damage and activate nociceptors.

Nociceptors are unspecialized, free, unmyelinated nerve endings that convert variety of stimuli into nerve impulses which the brain interpret to produce the sensation of pain. The nerve cell bodies are located within the dorsal root ganglia or for trigeminal nerve in the trigeminal ganglia.

They send one nerve fibre branch to the periphery and another into the spinal cord or brain stem(53).

There are two types of pain nerve fibres; the small diameter, unmyelinated nerve fibre which conduct the nerve impulse slowly (2m/sec= 7.2km/hour) which are called the c-fibres and the larger diameter, lightly myelinated nerve fibre which conduct nerve impulse faster (20m/sec= 72km/hour) which is termed as Aσ fibres.

The c- fibre nociceptive respond polymodally to thermal, mechanical and chemical stimuli whereas the Aσ fibres respond to thermal and mechanical stimuli. The sensation of pain is made up of categories. The initial fast and sharp ('epicritic') pain and later slow dull long lasting ('protopathic') pain. This pattern of pain conduction is explained by the way the two nerve fibres conduct pain with the fast Aσ fibres conducting the sensation of sharp, fast pain whilst the slower c- fibres producing the sensation of the delayed dull pain.

The spinothalamic and trigeminal pathways are the two major nerve routes for the transmission of pain and normal body temperature from the body to the brain(54).

Pelvic pain on the other hand, can be somatic or visceral. Pelvic somatic pain is innervated through iliohypogastric, ilioinguinal, lateral femoral cutaneous, and genitofemoral nerves originating from T_{12} to L_3. The nerve to the levator ani and pudendal nerves originates from S_2 to S_5(53).

Visceral organs such as the uterus have only c-fibre nociceptive nerves and therefore have no reflex action from visceral organ pain.

The uterus has two distinct visceral pathways. The parasympathetic fibres (Frankenhauser plexus, s_2 to s_4) which provides sensory innervation to the cervix and lower portion of the uterus

and sympathetic fibres (ovarian nerve plexus, T_{10} to L_1) which provides sensory innervation to the fundus of the uterus(55).

2.9 Methods of pain assessment

Pain assessment is an important feature in the study of pain in many health care disciplines such as medicine, psychology, nursing and public health(56). Assessment of pain is important for the management of pain as it helps understand the cause of the pain and therefore the best treatment options. It also helps to determine whether the underlying disease or disorder is improving or worsening. Finally, pain assessment is critical because it is an important emerging area in applied research. Examination of various literature has shown that there are over 200 pain assessment tools currently available(56). However the prominent among these methods are the Visual Analogue Scale, the Health Assessment Questionnaire, the Numerical Rating Scale, Brief Pain Inventory, the McGill Pain Questionnaire, the Hospital Anxiety & Depression Scale, the SF-36 Health Survey, the Pittsburgh Sleep Quality Index, and the PROMIS.

Pain is a subjective sensation that can be described by several important attributes such as quality, location, intensity, evasiveness, emotional impact and frequency. Of these attributes, intensity is recognized as one of the most important clinical dimension of the pain experience(56). Since pain is a subjective experience, there is no objective method to measure it. However, pain intensity can be measured in patients in a reliable and valid way by recording the self-rating of the sensation on different types of scales. In clinical research, it is important that the selected tool for pain measurement is valid and appropriate to the patient population and the study design. Pain Measurement Tools (PMT) are divided into unidimensional and multidimensional. Unidimensional PMT measure only the pain intensity and the three (3) commonest methods here are Visual Analogue Scales (VAS), categorical Verbal Rating Scales

(VRS), and categorical Numerical Rating Scales (NRS). All of these approaches are commonly used to measure pain relief. There are many verbal rating scales in use in different languages(56). The verbal 15-level scale developed by Gracely et al. for rating experimental pain can be considered a ratio scale(56,57). After many discussions on the translational validity of verbal rating scales, the Expert Working Group recognized that a simple intensity scale of "none, mild, moderate, and severe" is the most widely used in the clinical context. Also scales with a larger number of intervals were more desirable, both in research and in clinical practice, because of higher sensitivity to treatment effects. An example is a 6-level VRS (none, very mild, mild, moderate, severe and very severe) to a question "how much bodily pains have you had in the past 4 weeks"(56).

The Visual Analogue Scale (VAS) has been widely studied and is often seen as the ideal scale. Since it is continuous, it approximates a ratio scale, and it is more independent from language than verbal scales. Its validity however depends greatly on the type of administration method and the instructions given to the study subjects and hence it is more difficult to use than other scales(18,56).

Generally, Numeric Rating Scales (NRS) are easier to use and are associated with better compliance than the VAS. The standard 0–10 numeric rating scale and 100-mm visual analogue scale can be used interchangeably and scales are administered with pen and paper. Modern valid approaches include the use of touch screens for both VAS and NRS(56).

Pain intensity and pain relief can be measured during interventional studies. For example, pain relief can be measured by asking the patients to compare their pain experience now with that of previous pain experiences. It is important to note that pain relief measurement validity is limited

to short-term interventional studies (24 hours or less). For chronic pain studies, its validity has been seriously questioned(56).

The commonest multidimensional scales are the McGill Pain Questionnaire, the Brief Pain Inventory, and the Memorial Pain Assessment Card. There are Short form of the Brief Pain Inventory or the McGill Pain Questionnaire currently in use. These tools are well validated in multiple languages and hence suitable for worldwide application. The problem with the Memorial Pain Assessment Card is that it is not validated in any languages apart from English. Therefore it has a limited use in non-English speaking countries(56).

The Brief Pain Inventory (BPI) is a simple and easy to administer tool which provides information about the history, intensity, location, and quality of pain. It has a numeric scales (range 0 to 10) which indicates the intensity of pain in general, at its worst, at its least, and right now. A percentage scale on the other hand quantifies pain relief from current therapies(56). A picture representing the human body is given to the patient to shade the area corresponding to his or her pain. There are seven (7) questions which are asked to determine the degree to which pain interferes with function, mood, and enjoyment of life. The BPI is self-administered and easily understood, and has been translated and validated in many different languages. It is can also be used for repeated evaluation of pain such as weekly or bi-weekly pain assessments(56).

The McGill Pain Questionnaire (MPQ) is a self-administered questionnaire that provides global scores and subscale scores which reflects the sensory, affective, and evaluative dimensions of pain. It has been validated in cancer pain. A short form of the MPQ (SF-MPQ) has been developed for use in research settings. This SF-MPQ consists of 15 representative words from the sensory (n = 11) and affective (n = 4) categories of MPQ(56).

The Present Pain Index, verbal rating scale, and a visual analogue scale (VAS) measuring pain intensity is included in the MPQ. The 15 words are scored using a 4-point verbal rating scale, ranging from none, mild, moderate, to severe pain. The advantage is that SF-MPQ correlates highly with the MPQ but the disadvantage is that whilst MPQ is available in many languages, the SF-MPQ is not. For all the above pain measurement tools, the visual analogue scale remains the gold standard for unidimensional measurement for pain(56).

2.10 Visual analogue scale

Pain measurement in humans is complex as this can be affected by emotional and psychological factors. Self-report pain scales such as The Verbal Rating Scale, The Numerical Rating Scale and Visual Analog Scale (VAS) help patients to communicate their pain intensity and afford the physicians with the means to track it. Pain measurement is also important for effective pain management. The VAS is reported to be the most standardized, validated and easy to understand self-report pain assessment instrument (58).

The visual analog scale is a unidimensional measure of pain intensity which has been used in diverse populations. Since the 1960s, VAS have been used frequently both as a clinical and research tool. The VAS is simple to use and can be used in different research settings with ease(59).

The instrument 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(60).

In a study by Collins et al in 1997, a score of approximately 30mm on a 100-mm scale corresponded with moderate pain and that of 54mm or more with severe pains. The advantages of VAS are that it is simple and quick to construct; it is quick and easy to administer and score; it is easily understood by participants; it is very sensitive with discriminatory capacity superior to other scales; it requires little motivation for completion by participants and allow the use of numerical values which is suitable for statistical analysis(61).

Its limitations are that it must be administered on paper or electronically; photocopying can affect the length of the paper and therefore the scale and lead to significant changes; it has a ratio properties and is linear but not always normally distributed; patients with cognitive impairments cannot reproduce VAS scores consistently; and errors may increase and sensitivity decrease when used in certain populations such as the elderly because their ability think in abstract terms may be deteriorating with age (59).

However, a study done in Ghana by Hamzat et al in 2009 comparing the original VAS with a Twi (widely used language in Ghana) version of VAS, there was an excellent correlation. Therefore the VAS as an instrument has been validated among the Ghanaian Populace(58).

2.11 Pain relief at IUD insertion

Several NSAIDs such as ibuprofen, mefenamic acid, and naproxen have been used to relieve pain at IUD insertion; however, not all of them have been demonstrated to be effective(8).

In the study of the use of ibuprofen, there was no difference between those women who had the treatment and the controls ($p>0.06$). On the other hand, naproxen has been shown to reduce pain at insertion(62).

The use of diclofenac potassium has been demonstrated by Abbas et al in 2018 to significantly lower the mean pain score during speculum and tenaculum placements. In the above study, 50mg oral diclofenac potassium was given 30minutes before the IUD insertion. There was a lower ease of Insertion and duration of IUD insertion was significantly shorter(16). Suppository diclofenac has been demonstrated to be effective for management of perioperative pain. For instance, preoperative use of suppository diclofenac in cleft palate repair in children was shown to be effective and reduces significantly the use of opioids postoperatively compared to controls (1.67 versus 6.08; $p<0.001$)(63).

Several local anaesthetic agents have been used for pain management at IUD insertion with mixed results. The commonest local anaesthetic agent used has been lidocaine and has come in different formulations such as cream, gel, injection and spray. The main route of administration investigated included topical, intracervical and paracervical(8).

Karasu et al in 2017 compared different formulations of lidocaine anaesthetic agents (lidocaine spray of the cervix, lidocaine gel and lidocaine injection of the cervix) for pain control at IUD insertion involving 200 study participants. The overall pain score was significantly higher in the lidocaine injection group than the other groups ($p <0.001$). The tenaculum related pain score was lowest in the lidocaine spray group ($p <0.01$) than in the lidocaine gel group ($p=0.001$), lidocaine injection group ($p=0.01$) and the control group ($p= 0.01$). When the lidocaine gel was compared with the controlled group, there was no significant reduction in pain experience during the tenaculum use or IUD insertion ($p=0.657$ and $p= 0.894$ respectively). However, lidocaine injection was associated with reduction in pain score during IUD insertion ($p= 0.011$) but no effect on tenaculum related pains ($p= 0.082$). More respondents in the lidocaine spray arm

(25.5%) reported no pain compared to the lidocaine injection arm (2.1%) during the IUD insertion (64)

In a Cochrane review, one study suggested that 2% lidocaine gel may reduce pains associated with IUD insertion and warranted further investigation(8). There was another from Egypt comparing lidocaine gel, spray and injection. In a recent study of use of lidocaine spray from Turkey, the median pain score during IUD insertion was 3.0 for controls compared to 1.0 for the treatment arm($p < 0.001$)(15). Lidocaine spray is a simple and convenient local anaesthetic agent with minimal side effect and is widely used in dentistry for oral mucosal anaesthesia. It provides for easy application and better patient acceptance than other forms of lidocaine agent(15)

2.12 Pharmacology of Lidocaine

Lidocaine is found on the World Health Organization(WHO) essential drug list and considered as very efficacious, safe and cost effective for any healthcare system(65).

It is an amide local anaesthetic and a class 1b antiarrthymic agent (66). It is a stable crystalline, colourless solid whose hydrochloride salt is water soluble. Solutions for injection are available with or without adrenaline. Lidocaine injection should be protected from light and maintain at room temperature of about 25^{o}celcius(67) .

It can be used for local, neuraxial, regional or peripheral anaesthesia and is administered mainly through infiltration, block or topical application. It is also used for prophylaxis or treatment of ventricular arrhythmias. Lidocaine has a long history of use for chronic and neuropathic pain. Currently, it is being used for post-operative analgesia and for surgery recovery through intravenous infusion(67).

The mechanism of action for local or regional anaesthesia is through reversible blockade of nerve impulse propagation. When infiltrated near a nerve, some of it is removed through tissue binding and through blood circulation. The rest of the drug enter the nerve by diffusion through the membrane and bind to the sodium channels. This causes a conformational change that prevents the transient influx of sodium and hence depolarization. Every potentially excitable membrane is blocked but more so the sensory fibres because they are thinner, unmyelinated and more easily penetrable. The onset of action is rapid and nerve blockade may last up to 5 hours when administered as a peripheral nerve block(21).

2.13 Antiarrthymic effect of lidocaine

This effect is mediated by direct effect of lidocaine on purkinje fibres of the heart. It does this by decreasing the slope of phase 4 and changing the excitability threshold and thereby reducing the automaticity. The PR interval, QRS complex and QT durations are not affected(68).

Antinociceptive effect of lidocaine

This is believed to be due to the blockade of neuronal sodium channels and potassium currents and presynaptic muscarinic and dopamine receptors(69).

2.14 Pharmacokinetics of Lidocaine

The onset of action of lidocaine is 1-5 minutes after local infiltration and 5-15minutes after peripheral nerve block. The peak serum concentration occurs at 20-30minutes following injection. The addition of adrenaline (1:200,000) to the solution reduces the peak serum levels and delay the rate of absorption. It is 60%-80% protein bound at a concentration of between 1-4mcg/ml and has been shown to cross the placenta and the blood brain barrier by simple diffusion(21).

It is de-alkylated in the liver by the cytochrome p450 system into numerous metabolites. Lidocaine and its metabolites are mainly excreted through the kidneys.

The maximum dose of lidocaine for infiltration and regional block technique is 300mg (approximately 4.5mg/kg) or 500mg (approximately 7mg/kg) if used with adrenaline (1:200,000)(21)

Lidocaine toxicity may occur when the correct dose is given accidently through intravenous route or when the correct doses are given by the correct route in excessive manner(70). Factors which affect the severity of lidocaine toxicity includes vascularity of the injection site, the speed with which the injection is given, acid-base status of the individual and underlying hepatic or renal impairment. As plasma levels continue to increase, all pathways are suppressed resulting in respiratory arrest, cardiovascular collapse and coma. This usually occur at a concentration of about 5mcg/ml(70).

2.15 Pharmacology of diclofenac

Diclofenac is a potent Non-Steroidal Anti Inflammatory Drug (NSAID). It has been available for more than 40 years(71). The main mechanism for its anti-inflammatory, antipyretic and analgesic action is believed to due to inhibition of prostaglandin synthesis by inhibition of cyclooxygenase-2 enzyme (cox-2). Diclofenac inhibits cox-2 with 20 times more potency than cox-1 and has lower incidence of gastrointestinal complaints. It is more than 99% protein bound and metabolize mainly by the liver. It has elimination half-life of 1-2 hours and excreted 60% in the urine and 40% through biliary route(22).

They mostly come in sodium and potassium formulations. The diclofenac sodium available on the market come in enteric coated form which helps it to avoid dissolution in the low PH

environment in the duodenum. Its release is also slow and hence used for chronic painful conditions. The diclofenac potassium on the other hand is formulated for rapid release and absorption in the stomach. It achieves peak concentration within 45minutes and therefore ideal for acute painful conditions(22).

The rectal route is preferable over the oral because half of the drug which is absorbed by the rectum will bypass the liver and hence not metabolized compared with a higher proportion of hepatic first-pass metabolism with oral intake. This leads to rapid pain relief and prolonged action of treatment. Whereas oral administration of diclofenac has a terminal half-life of 1-2 hours, after rectal route the half-life is longer and absorption is complete within 40 minutes. It is less secreted in breast milk and as it is almost completely bound to protein. This makes it suitable even to breastfeeding women(72).

2.16 Intrauterine device insertion and pain

Intrauterine device uptake has clear advantages such as long term effectiveness, no need for user intervention, low failure rate and reversibility. However, its uptake continue to be low. Several studies have shown among other causes that pain associated with IUD insertion is one of the major barriers(73).The severity of pain women feel during IUD insertion is different in various studies but mostly range from moderate to severe pains. The severity of pain also varied with the women's age and circumstances(5). Globally, about forty(40) million women who are undergoing IUD insertion experience significant pain and therefore management of pain during IUD insertion cannot be overemphasized(2). The IUD insertion pain occur at the various steps of the procedure. For instance the pain is felt when tenaculum is applied to the cervix in order to

straighten the uterus; doing intrauterine sounding with hysterometer to measure the length of the uterus; insertion and placement of IUD in the uterus itself(2).

There is the likelihood that if IUD insertion was made painless, more women would be willing to choose this method as a means of contraception.

In a study by Seamark et al in 1993 in which pain during IUD insertion at various stages of the procedure was scored, pain at tenaculum insertion was scored at 8, IUD placement was 5, speculum insertion was 4 and the overall procedure was 3. Implication of the study was that though the women believed the overall procedure was not as painful, pain at tenaculum was very severe(2). In a prospective study by Marions and fellow researchers, majority of women undergoing IUD insertion reported moderate to severe pains(5)

Again, in a study by Oloto et al, the overall pain score at IUD insertion was 6(2). There have also been other studies which have shown that psychological preparation before IUD insertion can considerably reduce pain at the insertion. Here, the women were taught about what to expect such as abdominal cramps, and pain at insertion. Their pain scores were considerably lower compared to the controls(74).

2.17 Factors which affect pains at IUD insertion

A study by Chi et al showed that in developing countries factors which may be associated with increased pain at IUD insertion are higher education level(7 years or more), low parity(2 or less), the longer the distance between first pregnancy and IUD insertion(13months or more) and lack of breastfeeding(75). In other studies, nulliparous and non-lactating women were noted to experience significantly higher pain at IUD insertion compared to parous and lactating women respectively(76,77). It was also noted from the study that those whose pregnancy ended within 3

months experienced less pain compared to those whose last pregnancy ended at least 6 months ago($p<0.05$)(76). In a prospective cohort study of pain with IUD insertion among women with and without vaginal delivery, variables that predicted greater pain were: higher expected pain; lower self-reported pain tolerance; interval compared with postpartum insertion; no history of vaginal delivery; and the provider rating the insertion as difficult compared with an easy procedure. Pain tolerance was correlated with expected pain(78). Past history of vaginal delivery predicted a mean pain score of 15.5mm points less than those without a history of vaginal delivery ($p=0.01$). Expected pain remained significant with a 5-point increase in procedure pain for every 10-point increase on the 0 – 100 mm VAS measuring expected pain ($p=0.0002$)(78). Procedure difficulty also remained significant, with average difficulty predicting an 18-point increase in pain compared with easy, and a difficult rating predicting a 22-point increase in pain compared with easy(77). From other researchers, the predictors of significant pain at IUD insertion included lower parity and younger age. The age and experience of the health provider in years, the presence of menses on day of insertion and procedure time were not associated with significant pains at IUD insertion(77).

Stress and fear of IUD insertion have also been shown to increase pain at insertion. This has been corroborated by a study by Brockmeyer et al in which in over 30% of women, the actual pain at insertion was lower than expected(79). In a study from Turkey on the relationship between pain during IUD insertion and anxiety, negative perceptions of IUD and previous mode of delivery in parous women, the result was that whilst caesarian delivery and pre-procedure anxiety were associated with higher pain scores, it was the presence of negative perception of IUD which was the most significant predictor of pain at IUD insertion ($P<0.001$). Conversely, women who have had vaginal delivery under epidural analgesia had lower pain scores at IUD insertion ($p<0.001$).

Using the Beck Anxiety Inventory (BAI) to measure the effect of pre-procedure anxiety on pain at IUD insertion, women with mild anxiety (BAI 8-15) had higher visual analog score compared to those with minimal anxiety (BAI <7)(80).

Hubacher and MacGuire found out that in addition to the above, older age and younger age were also associated with increased pain at insertion(76,77).

In the McGuire study, women who had history of dysmenorrhea were noted to have more pains at IUD insertion. However, insertion immediately after menses (6-10 days since start of last menstrual period) was associated with less pain than insertion at other time of the cycle(77)(77). In another study from Los Angeles, USA aimed at finding the effect of dysmenorrhea on IUD insertion pain involving 188 participants, the findings were that women with severe dysmenorrhea has a higher visual analog score in all the steps of IUD insertion including speculum placement, insertion of tenaculum and IUD placement compared to individuals with history of mild to no dysmenorrhea(81).

2.18 Benefits of Use of intrauterine contraceptive device

Improvement in the uptake of contraception will lead to demographic, socioeconomic and health benefits to any community or country(77).

The use of contraceptive alone prevent more than 230 million births annually and family planning is basically the primary strategy for prevention of pregnancy. Family planning has been used as a public health intervention to reduce maternal and infant morbidity and mortality(82). From various studies it has been projected that spacing of child birth alone can reduce under 5 years mortality by 10% and pregnant women by 32%(82,83).

If all women of child bearing age who want to prevent pregnancy were put on modern contraception, unplanned pregnancies will reduce by 70%, maternal deaths will fall by 67%, neonatal mortality will fall by 77% and transmission of HIV from mother to child will almost be eliminated(84).

There are other non-contraceptive health benefits associated with the use of contraceptives. For instance, the hormonal contraceptives are protective against uterine and ovarian cancers, PID, benign cysts of the breasts and ovaries. Contraceptive pills can also reduce menstrual flow, dysmenorrhoea and prevalence of iron deficiency anaemia(84,85).

Planned pregnancies are known to be safer for both the mother and baby compared to unplanned pregnancies. It is more expensive to manage unwanted birth compared to the prevention of unwanted pregnancy (84).

The socioeconomic benefits of contraceptive use include small family sizes, improvement in child survival and reduction of sibling competition for scarce family and maternal resources at the family level. At the national level, the decrease in the national population growth will reduce the strain on the environment, natural resources, health care and education(82,86)

Widespread use of contraceptive will allow individuals and couples realise their full potential as the women are able to play their roles as a wives, mothers, wage earners and productive community members. The men will be able to better expand their roles as a husbands, fathers and home providers(86).

2.19 Factors which promote the use of intrauterine contraceptive device

Until the International Conference on Population and Development at Cairo in 1994, success of family planning programs were measured by the increased contraceptive prevalence and hence decreased total fertility rate (87), but there is a new paradigm shift and the focus now is on the

protection of women's right to have the number of children she wants, and when she wants them(88). It is therefore important that the individual is provided with all the necessary information and education to exercise this right. Contraceptive knowledge, method mix, and sociodemographic characteristics have been cited as factors which affects contraceptive choice(89).

With the modern contraceptive methods, the long-acting reversible contraceptives i.e. implants and Intra Uterine Contraceptive Device (IUCD) are among the highly effective family planning methods and are rated to be one of the top tier methods by the World Health Organization. Comparing them with short-acting reversible contraceptives (SARCs), long-acting reversible contraceptives (LARCs) are very effective in preventing unwanted pregnancy and its consequences(89,90). They are also known to be safe, with excellent continuation rates and are relatively cheap. They have therefore become the first-line contraceptive choices for all age groups including adolescents and women with chronic illness as HIV/AIDS and cardiovascular diseases. Long Acting Reversible Contraceptives once they have been administered, the clients do not have to visit health care providers repeatedly. Various studies have also shown that LARCs have failure rates of less than one percent which is comparable to that of bilateral tubal ligation and vasectomy(90,91). They are therefore considered as a means of chemical sterilization and may eventually replace permanent methods. The widespread use of LARCs which are easily reversible, will prevent post-sterilization regret. As opposed to the very low failure rates of LARCs, the failure rate for short acting contraceptives among ideal users is between 0.2%-18% and the typical user failure rate is 6% to 28%(91).

Utilization of LARC worldwide among sexually active reproductive-age women is lower compared to the short acting methods. Determinants of LARC utilization are multidimensional

and they include socio-demographic characteristics such as older age, higher level of education, high socioeconomic status and place of residence(90). Also client factors such as higher parity, history of unwanted pregnancy, history of smoking, and misconception towards LARCs, lack of knowledge, negative attitude and fear of side effects affect LARC utilization affect their utilization. Other factors such as health level of care, availability of the contraceptive methods, spousal influence all affect LARC use. Health provider related factors such as level of training, competency of providers, and attitudes of providers may affect LARC utilization(90,92).

In an institutional based study by Gashaye et al in 2019 on determinants of Long Acting Reversible Contraception utilization in North West Ethiopia, the main determinants were wealth status, history of abortion, desire to limit child bearing, knowledge about LARC, convenience of the method of choice, perceived ease of reversibility of the method, easy availability of the method of choice, less frequent visits, advise by health professionals, husband/partner approval, and favorable attitude towards LARC, as each was significantly associated with LARC utilization(89). In the study women who chose LARC were 13 times more likely to have favorable attitude towards LARCs than short acting contraceptive users [AOR: 13.0, 95% CI (8.6, 19.7)] and LARC users were more than 10 times more likely to choose their method due to the advice of health care professionals than short acting contraceptive users [AOR: 10.7, 95% CI (3.3, 34.9)]. Also LARC users were 1.5 times more likely to choose their method due to its ease of reversibility compared to short acting contraceptive users [AOR: 1.5, 95%CI (1.0, 2.2)]. On the other hand LARC users were 90% less likely to choose their method due to its ease of availability than short acting contraceptive users and they are 77% less likely to choose their method due to its convenience than short acting contraceptive users(89). In another study from 6 public hospitals in the Mbarra district of Uganda on factors influencing use of LARCs and Short

Acting Reversible Contraception (SARC) among women of reproductive age in a low resource-limited setting, the findings were as follows; the most common reasons for choosing a LARC method was longer protection, followed by better choice for child spacing, effectiveness, and wanting a method that does not require daily application. For those using SARCs, the most common reasons for not using a LARC method included wanting a client-controlled method and intending to conceive in the near future. Urban clients were less likely to opt out of a long term method due to opposition from partners (P = 0.039); rural clients' were more likely to indicate lack of awareness as the reason for not using long-acting methods (P = 0.04)(90)

Among the same participants, the most common reasons for choosing short-acting methods were: accessibility; lower cost; privacy; and freedom to stop use without first seeing a health care worker. Compared to rural clients, urban clients were more likely to choose a short term method because of cost (P = 0.01) and because they could easily stop it without involving a provider(90). In both the urban and rural setting, the proportion using LARC methods appeared to increase with age. Larger proportion of those with more than 1 child had ever used LARC methods. Although urban clients seemed to suggest that they were less likely to opt out of using a LARC due to partner opposition, a larger proportion of urban clients with supportive partners had ever used LARC methods. Among clients in the urban setting, proportions using LARC methods increased with education levels (14% in those with primary or no education, 16% in those with secondary education, and 40% in those with tertiary education)(90).

CHAPTER THREE

METHODOLOGY

3.1 Study design

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 the insertion of IUD was used.

3.2 Study period

The period of study was (6) six months (1st October, 2020 – 31st March, 2021).

3.3 Study site and setting

The study was conducted at the Family Planning Unit of the Gynaecology Department, Korle Bu Teaching Hospital.

Korle Bu Teaching Hospital is advance tertiary centre located in the capital Accra. 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 OPD attendance for 2018 was 56,691(Korle Bu Teaching Hospital Annual Report, 2019). This includes the new Acceptors (13,851), the Continuing Clients (33,210) and the Follow-up visits (9,630). This gives new acceptance rate for 2018 to be 244 per 1,000. The unit offer all the contraceptive method mix which includes combined and progestin only contraceptive oral pills, hormonal implants, intrauterine contraceptive devices including intrauterine system (IUS), injectables, and fertility awareness based methods, and male and female sterilization.

Services such as comprehensive abortion care, cervical cancer screening and gynaecologic office procedures such as colposcopy and endometrial biopsy are available in the unit.

The unit has one operating theatre where vasectomy and bilateral tubal ligations are performed.

The copper-T IUD acceptance for 2018 was 267 for first ever users, 4,083 for continuing clients making it about 22 new IUD acceptors per months.

The unit is manned by 4 consultant obstetricians/gynaecologists, 3 senior residents, midwives and family planning nurses.

3.4 Study population

Sample size calculation for one way ANOVA.

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

where;

n= sample per arm

Zα is 95% confidence level = 1.96

Z1-β is the power of the study = 0.8416

And δ is the standard deviation (estimated) = 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

Substituting values into the formula above gives a sample size of 30 for each of the three groups making a total sample size of 90

Calculating for an anticipated 10% loss to follow up and incomplete or inconsistent data, 3 + 30 = 33 in each group and a total sample size of 99(93).

3.5 Inclusion criteria

i. Women aged 18 years and above
ii. Women who accept the IUD as a contraceptive method

3.6 Exclusive criteria

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. Past or current history of illegal drug or narcotic use
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 and vulvodynia

3.7 Data collection

1. The primary outcome was the assessment of the overall pain score at IUD insertion measured by 10cm- VAS
2. Secondary outcomes included mean pain scores during speculum placement, tenaculum placement, sound insertion, IUD placement, 5 minutes and 4hours post insertion. Also the need for additional analgesics and the side effects of the medications used
3. Patients who have received contraceptive counselling on the method mix and have chosen IUD were recruited into the study after the research methodology has been explained to them by the principal investigator or research assistant and written consent obtained. The counselling was done by an experienced midwife who has been trained on contraceptive counselling
4. 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 join the study. The randomization blocks each containing 33 numbers were generated by the computer and are as shown below.

1. counselling_____
2. lidocaine_____
3. lidocaine_____
4. counselling_____
5. counselling_____
6. counselling_____
7. diclofenac_____
8. diclofenac_____
9. diclofenac_____
10. counselling_____
11. counselling_____
12. lidocaine_____
13. lidocaine_____
14. lidocaine_____
15. diclofenac_____
16. counselling_____
17. lidocaine_____
18. counselling_____
19. counselling_____
20. diclofenac_____
21. diclofenac_____
22. diclofenac_____
23. counselling_____
24. lidocaine_____
25. lidocaine_____
26. counselling_____
27. diclofenac_____
28. diclofenac_____
29. diclofenac_____
30. lidocaine_____
31. lidocaine_____
32. diclofenac_____
33. lidocaine_____

34. counselling_____
35. lidocaine_____
36. diclofenac_____
37. lidocaine_____
38. lidocaine_____
39. lidocaine_____
40. lidocaine_____
41. counselling_____
42. lidocaine_____
43. diclofenac_____
44. counselling_____
45. counselling_____
46. counselling_____
47. counselling_____
48. lidocaine_____
49. lidocaine_____
50. diclofenac_____
51. counselling_____
52. counselling_____
53. counselling_____
54. diclofenac_____
55. counselling_____
56. diclofenac_____
57. diclofenac_____
58. lidocaine_____
59. counselling_____
60. diclofenac_____
61. lidocaine_____
62. diclofenac_____
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66. diclofenac_____

67. diclofenac_____
68. diclofenac_____
69. diclofenac_____
70. lidocaine_____
71. lidocaine_____
72. counselling_____
73. lidocaine_____
74. counselling_____
75. counselling_____
76. lidocaine_____
77. counselling_____
78. lidocaine_____
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87. lidocaine_____
88. lidocaine_____
89. counselling_____
90. lidocaine_____
91. diclofenac_____
92. counselling_____
93. counselling_____
94. diclofenac_____
95. diclofenac_____
96. counselling_____
97. lidocaine_____
98. diclofenac_____
99. lidocaine_____

5. Those on diclofenac (100mg Voltarol suppository, Novartis Pharmaceutical, UK) were instructed to administer 1 hour before IUD insertion and the lidocaine arm will 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 insertion.

6. All participants in the study had a baseline counselling on the procedure and what to expect at each stage of the intervention

7. 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.

8. 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.

9. IUD insertion: in the lithotomy position, a bimanual examination was done and a water-lubricated, single- use speculum is placed in the vagina, the vagina and cervix was cleansed with povidone iodine solution. Traction was then applied on the cervix using the tenaculum. Uterine depth was measured with a metal sound and the IUD inserted using the Withdrawal method.

10. 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.

11. Immediate complications of IUD insertion such as uterine perforation, failure of insertion, and vasovagal reaction were recorded.

12. 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.

13. Participants satisfaction level with the procedure was recorded as follows;
    a) 1- Very pleasant
    b) 2- Pleasant
    d) 3- Unpleasant
    d) 4- very unpleasant

14. To prevent contamination if more than one client presented, each client was counselled privately. Also, following the procedure each client was taken separately to a consulting room where the post procedure questionnaire was administered

Stopping Rules:

If sequential study participants who receive the intervention were shown to have severe adverse effect like drug reaction, then the study was halted prematurely.

Management of participants with adverse effect from the intervention (use of 100mg diclofenac sodium and 10% lidocaine spray):

There was the formation of data safety and monitoring board that comprised of statistician, physician specialist and a pharmacist. In the event of drug reaction, the participant were made to see the physician specialist and the cost of care was borne by the principal investigator. In this study the severe adverse event was defined as any untoward medical event that was life threatening or required hospitalization.

3.8 Data Management and Analysis

To ensure data quality, there was a meeting with the research assistants every week to examine the data and account for missing data or poorly collected data.

Data analysis was by intention-to- treat. This enabled a full set of analysis to be done so that treatment groups remain unchanged and the potential bias due to exclusion of patient was avoided.

Data collected was entered into an excel spread sheet and exported to SPSS-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 was compared using a one way ANOVA and a Post-Hoc test used to compare which two groups are significantly different from each other. Categorical variables between groups was 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.
All statistical tests were carried out using a 5% significance level.

3.9 Dissemination of results

The final report would be made available to the staff of Department of Obstetrics and Gynaecology Korle Bu Teaching Hospital. It will also be presented to the Faculty of Obstetrics and Gynaecology, Ghana College of Surgeons in partial fulfilment of the requirements for the award of the Fellowship of Ghana College of Surgeons. The report will also be submitted for peer reviewed scientific journal for consideration for publication and will be presented at various scientific gatherings.

3.10 Ethical Considerations

Ethical clearance for the study was obtained from Korle Bu Teaching Hospital Institutional Review Board. Permission from the Obstetrics and Gynaecology Department of Korle Bu Teaching Hospital were sought in order for the study to be carried. 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 participants. Participation was by voluntary basis 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. Whenever necessary an interpreter was used and participants were required to sign or thumbprint a consent form. The questionnaire was translated and back translated into Twi and Ga, the two dominant languages in Accra to allow for participant who did not understand English to partake in the study.

Due to the ongoing covid-19 pandemic, the following measures were put in place,

Protection of study participants

a. All participants underwent hand washing with soap and running water or sanitized their hands with alcohol-based hand sanitizer.
b. Participants were taught how to wear, remove and care for the reusable facemasks. All participants without a face mask upon arrival at the study site were provided with one and also advised to keep it on until they got home and to properly dispose of it at home.
c. The facemasks were provided to all participants at no cost to them.
d. Physical distancing of 2 meters was maintained at all time during the study period.

The research assistants were taken through a 3-day training on the questionnaire and its administration and the questionnaire was pretested at Mamprobi Polyclinic.

The research assistants were also taken through public health hygiene protocols to observe in order to prevent the spread of covid-19.

CHAPTER FOUR

RESULTS

4.0. Introduction

In this chapter, the results of the study on comparison of efficacy of counselling only, suppository diclofenac and lidocaine spray at intrauterine device insertion are presented. This chapter contains six sections. Section one presents the socio-demographic characteristics of the respondents. Section two shows the obstetrics, gynecologic and medical characteristics of the respondents, section three the contraceptive history of the respondents and section four the results of Visual Analog Scale assessment of pain at IUD insertion using counselling only, suppository diclofenac and lidocaine spray. Section five shows the Post Hoc Analysis of pain experienced at IUD insertion. The sixth section shows the comparison of respondents' satisfaction with IUD insertion using counselling only, suppository diclofenac and lidocaine spray.

One hundred and three (103) women were assessed for study eligibility out of which 99 were enrolled. All the 4 women excluded declined to participate in the study citing their lack of interest in the study as their main reason.

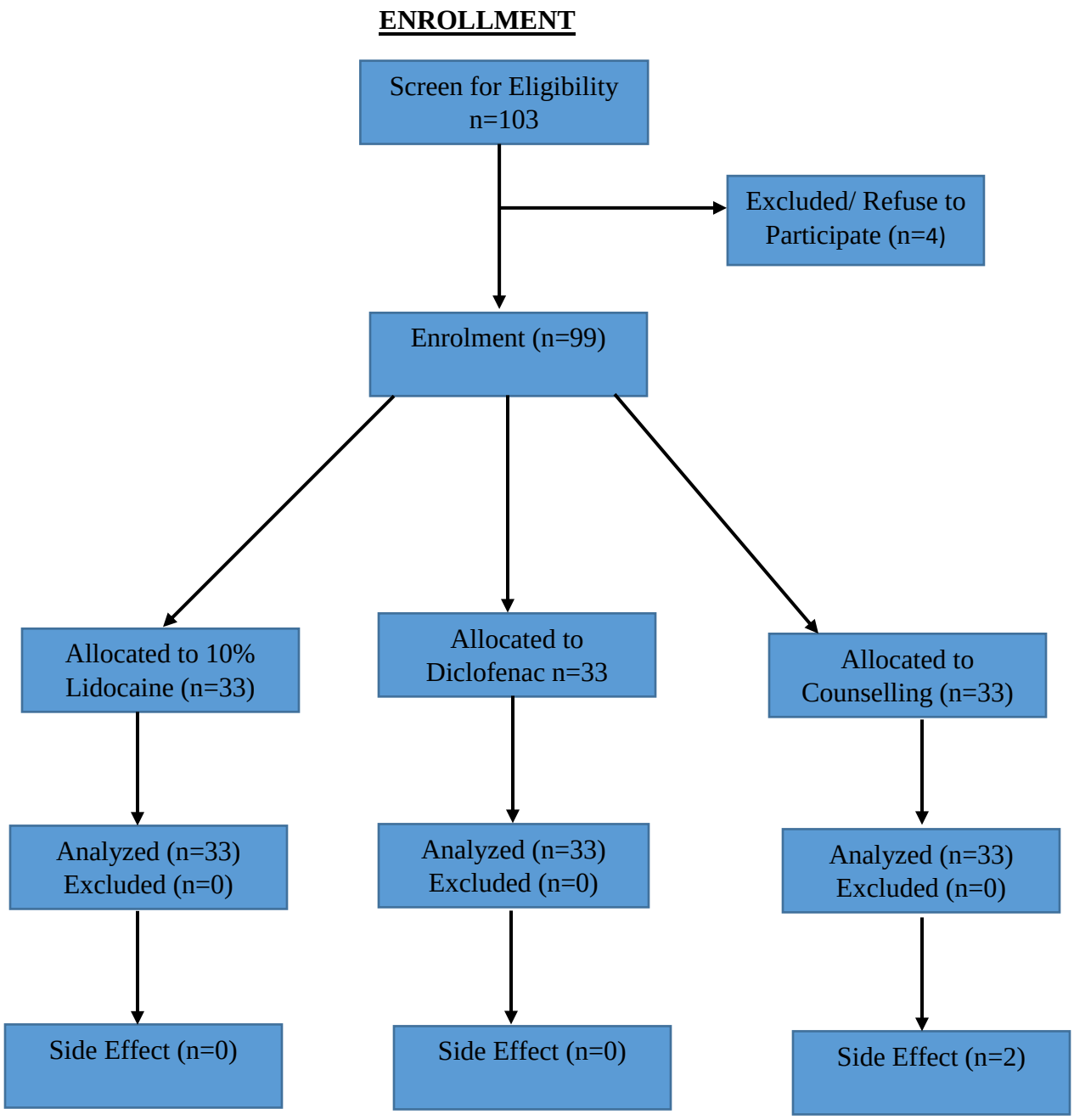

Figure 4.1 Study flow diagram of participants.

4.1. Socio-demographic Characteristics of Respondents

A total of 99 participants were recruited for the study. The socio-demographic characteristic of the study participants is as presented in table 4.1. There was no differences in the sociodemographic characteristics of all the three arms of the study.

The age range of the participants was between 19 and 49 years and the average was 33.6$\pm$ 6.2 years whilst the average BMI was 29.5$\pm$ 5.7kg/m^2. In all, 11/99 (11.11%) of the respondents were single. The rest were either married or cohabiting. Participants who did not have formal education were 3/99 (3.03%), the rest had some form of formal education. There were 39/99(39.39%) of them who had tertiary education.

Thirty four out of ninety nine (34.34%) of the respondents were professionals. Traders and artisans represented 31/99 (31.31%) each. For the religious affiliations of respondents, 6/99 (6.06%) were Muslims, the rest were Christians.

Table 4-1: 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
Age group					0.999
<20	0 (0.0)	1 (3.0)	0 (0.0)	1 (1.0)	
20-29	7 (21.2)	6 (18.2)	9 (27.3)	22 (22.2)	
30-39	19 (57.6)	23 (69.7)	18 (54.5)	60 (60.6)	
40+	7 (21.2)	3 (9.1)	6 (18.2)	16 (16.2)	
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)	

4.2 Obstetrics History of the Respondents

The obstetrics history of the respondents is as shown on table 4-2

There were 91/99 (91.92%) participants who were multiparous. The rest were nulliparous. The commonest mode of delivery was spontaneous vaginal delivery, 68/91 (74.73%). Currently breastfeeding mothers represented 24/99 (24.24%) of the participants. There were 30/99 (30.30%) of the women had a history of previous miscarriage.

Table 4-2: Obstetrics History of the Respondents

Characteristics	**Counselling Only Group N=33**	**Suppository Diclofenac Group N=33**	**Lidocaine Spray Group N=33**	**Total N=99**	**P-value**
Parity					0.386
Nulliparous	3 (37.5)	4 (50.0)	1 (12.5)	8 (100.0)	
Multiparous	30 (33.0)	29 (31.9)	32 (35.2)	91 (100.0)	
Prev. mode of delivery					0.364
SVD	20 (29.4)	24 (35.3)	24 (35.3)	68 (100.0)	
CS	10 (43.5)	5 (21.7)	8 (34.8)	23 (100.0)	
Currently breastfeeding					0.610
Yes	9 (37.5)	6 (25.0)	9 (37.5)	24 (100.0)	
No	24 (32.0)	27 (36.0)	24 (32.0)	75 (100.0)	
Previous miscarriages					0.563
Yes	10 (33.3)	12 (40.0)	8 (26.7)	30 (100.0)	
No	23 (33.3)	21 (30.4)	25 (36.2)	69 (100.0)	

4.3 Gynecologic and Drug History of Respondents

The gynaecologic and the drug history of the respondents are shown on table 4-3. There were 12/99 (12.12%) participants who had a history of dysmenorrhea. There were 5/99 (5.05%) of participants who had a history of previous pelvic inflammatory disease. There were 10/99 (10.10%) of the respondents who were on medication for chronic illness.

Table 4-3: Gynecologic and Drug History of Respondents

Characteristics	Counselling Only Group (N=33)	Suppository Diclofenac Group (N=33)	Lidocaine spray Group (N=33)	Total (N=99)	P-Value
History of dysmenorrhea					0.999
Yes	4 (33.3)	4 (33.3)	4 (33.3)	12 (100.0)	
No	29 (33.3)	29 (33.3)	29 (33.3)	87 (100.0)	
History of PID					0.065
Yes	1 (20.0)	0 (0.0)	4 (80.0)	5 (100.0)	
No	32 (34.0)	33 (35.1)	29 (30.9)	94 (100.0)	
On medication for Chronic Illness					0.895
Yes	3 (30.0)	4 (40.0)	3 (30.0)	10 (100.0)	
No	30 (33.7)	29 (32.6)	30 (33.7)	89 (100.0)	

4.4. Contraceptive History of the respondents.

The contraceptive history of the respondents is as depicted in table 4-4.

For 22/99 (22.22%) of the respondents, this was their first family planning method. For 22/99 (22.22%) of the respondents, this was their first family planning method they have ever used.

Of those with history of family planning method use, injectable accounted for the most method use, 40/91 (43.96%) and the average duration of use of a method ranged between 2.5 -68.7 months (mean=35.7 months).

The two commonest source of information on IUD were from health care providers, 61/99 (61.62%) and relations, 28/99 (28.28%). Majority of the respondents, 82/99 (82.83%) had no history of previous IUD use. There were 17/99 (17.17%) of respondents who had previously used IUD.

Table 4-4: Contraceptive History of the respondents

Characteristics	Counselling Only Group	Suppository Diclofenac Group	Lidocaine Spray Group	Total	P-Value
First Time Family Planning Acceptor					0.664
Yes	7 (30.8)	6 (27.1)	9 (40.9)	22 (100.0)	
No	26 (33.8)	27 (35.1)	24 (31.2)	77 (100.0)	
Previous Family Planning Method Used					
Condom	2 (40.0)	1 (20.0)	2 (40.0)	5 (100.0)	0.810
Pills	8 (42.1)	7 (36.8)	4 (21.4)	19 (100.0)	0.429
Implants	4 (28.6)	6 (42.4)	4 (28.6)	14 (100.0)	0.717
IUD	4 (30.8)	2 (15.4)	7 (53.8)	13 (100.0)	0.186
Injectables	11 (27.5)	16 (40.)	13 (32.5)	40 (100.0)	0.451
Length Of Family Planning Method Use (Months)	31.0 ±28.4	42.9 ±42.9	32.3 ±24.4	35.7 ±33.2	0.370
Source Of Information On IUD					0.206
Health provider	17 (27.9)	21 (34.4)	23 (37.7)	61 (100.0)	
Print media	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)	
Radio/ television	4 (57.1)	1 (14.3)	2 (28.6)	7 (100.0)	
Relations	12 (42.9)	10 (35.7)	6 (21.4)	28 (100.0)	
Social media	0 (0.0)	0 (0.0)	2 (100.0)	2 (100.0)	
Previous IUD insertion					0.397
Yes	5 (29.4)	4 (23.5)	8 (47.1)	17 (100.0)	
No	28 (34.1)	29 (35.4)	25 (30.5)	82 (100.0)	

4.5. Visual Analog Scale (VAS) assessment of pain at IUD insertion using Counselling only, Suppository Diclofenac and Lidocaine spray

The level of pain experience by respondents during and after IUD insertion using counselling only, Suppository Diclofenac and Lidocaine spray is presented on table 4-5.

There was a significance difference in the pain experience by respondents during speculum placement among the counselling only and suppository diclofenac (p=0.041). Moreover, there was significant difference in the pains experience by respondents at tenaculum insertion (p=0.010), uterine sound (p=0.049), during IUD placement (p=0.004) and immediately after procedure (p=0.013) 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.

Table 4-5: 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	

4.6. Post Hoc Analysis of pain experience at IUD insertion.

The Post Hoc analysis of pain experience at IUD insertion as shown on table 4-6

4.6.1. Counselling only versus suppository diclofenac during IUD insertion

There was significant difference between counselling only and suppository diclofenac at tenaculum insertion (p= 0.007), uterine sound insertion (p= 0.014), IUD placement (p= 0.003), over all pain immediately after the procedure (p= 0.002) and 5 minutes after the procedure (p=0.003). However, there was no significance difference in pain experienced by respondents who had counselling only compared to those who had suppository diclofenac 4 hours after procedure (p=0.055).

Again, suppository diclofenac was superior to counselling only in pain control during uterine sound insertion (3.2 versus 4.1), IUD placement (2.2 versus 3.4), immediately after procedure (p= 2.2 versus 3.5) and 5 minutes after procedure (1.5 versus 2.4).

4.6.2. 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 (3.0 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 1.2).

4.6.3. Suppository Diclofenac versus Lidocaine spray.

There was no significant difference between suppository diclofenac and lidocaine spray of the cervix at tenaculum insertion (p= 0.740), uterine sound (p= 0.898), IUD placement (p= 0.445) and immediately after the procedure (p= 0.473).

However, there was significant difference in pain experience at 5 minutes after procedure (p= 0.010) 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 1.5) and 4 hours after procedure (0.1 versus 0.9).

Table 4-6: 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 (I-J)	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
		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

4.7. Comparison of respondents' satisfaction with IUD insertion using counselling only, suppository diclofenac and lidocaine spray.

Below is table 4-7 showing respondents' satisfaction with IUD insertion using counselling only, suppository diclofenac and lidocaine spray of the cervix.

Over all, majority of the respondents had a pleasant experience with the IUD insertion; 26/33(78.79%) of counselling only, 31/33(93.94%) of suppository diclofenac and 30/33 (90.91%) of lidocaine spray. Out of 12/99 (12.12%) respondents who had very unpleasant experience, 7/13 (53.85%) were in the counselling only group, 2/13 (15.38%) were in the suppository diclofenac group and 3/13 (23.08%) were in the lidocaine spray group. There was a significance difference in the ease of insertion between the 3 arms of the study (p=0.008). Out of 15 difficult insertions, 11/15 (73.33%) were from the lidocaine group, 2/15 (13.33%) were from diclofenac group and from counselling only respectively.

Majority of the respondents, 90/99 (90.91%) said they would recommend IUD insertion procedure to another woman. However, out of the 9/99(9.09%) who said they would not recommend IUD procedure to anyone, 5/9(55.56%) from counselling only or the control group and 4/9(44.44%) were from the suppository diclofenac group. All the respondents in the lidocaine spray group said they would recommend the IUD to anyone.

Table 4-7: Comparison of respondents' satisfaction with IUD insertion using counselling only, suppository diclofenac and lidocaine spray of the cervix

Variables	Counselling Only Group (N=33)	Suppository Diclofenac Group (N=33)	Lidocaine Spray Group (N=33	Total (N=99)	P-Value
Overall satisfaction					**0.037**
Very Pleasant	1(12.5)	1 (12.5)	6 (75.0)	8 (100.0)	
Pleasant	25 (31.6)	30 (38.0)	24 (30.4)	79 (100.0)	
Unpleasant	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)	
Very Unpleasant	3 (42.9)	1 (14.3)	3(42.9)	7 (100.0)	
Would you recommend this procedure					**0.077**
Yes	28 (31.1)	29 (32.2)	33 (36.7)	90 (100.0)	
No	5 (55.6)	4 (44.4)	0 (0.0)	9 (100.0)	
Ease of insertion					**0.008**
Very easy	1 (25.0)	1 (25.0)	2 (50.0)	4 (100.0)	
Easy	30 (37.5)	30 (37.5)	20 (25.0)	80 (100.0)	
Difficult	2 (13.3)	2 (13.3)	11 (73.3)	15 (100.0)	

CHAPTER FIVE

DISCUSSION

5.1 Introduction

This chapter compares and contrasts the findings from Comparison of Effectiveness of Counselling Only, Suppository Diclofenac and Lidocaine Spray at Intrauterine Device Insertion and other similar studies.

The main objective of the study was to compare the effectiveness of counselling only (standard of care/control group), 10% lidocaine spray of the cervix and 100mg suppository diclofenac sodium in reducing pain at IUD insertion with the specific objectives been to compare the effectiveness of 10% lidocaine spray of the cervix versus 100mg suppository diclofenac sodium in reducing pain at IUD insertion using 10cm-Visual Analog Score, to compare pain control at IUD insertion using counselling only (standard of care) versus 10% lidocaine spray of cervix and to compare pain control at IUD insertion using counselling only (standard of care) versus 100mg suppository diclofenac sodium.

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).

5.2 Background characteristics of Respondents

From the study, the average age of the participants was 33.6± 6.2 years which is comparable to the mean age of 29.4 ± 6.69 years found by Rominski et al, 2018 study titled 'Contraceptive method preferences among Women in Two Ghanaian cities' (88).

In a Nigerian study of 2019, 99% of IUD acceptors were married and 53.7% had secondary and 24.1% had tertiary education(94). However, from our study, 88/99 (88.89%) of the respondents were married or cohabiting, 96/99 (96.67%) of the respondents had some formal education with 39/99 (39.39%) of them having had tertiary education. It appears that generally more educated and married women were more likely to opt for the IUD. This is in line with a study done by

Rominski et al which found out that the older, married women with higher level of education were more likely to accept the IUD as a form of contraception(88). The probable reason is may be that IUD unlike the other methods of contraception is invasive and may invade the woman's privacy and therefore requires a lot more of education before reaching a decision point. Higher education therefore may influence that choice. Moreover, the more educated the woman the more likely she is emancipated and has control over her own body.

There were no differences in the obstetrics, gynaecologic and medical history of the respondents in the counselling only, suppository diclofenac and lidocaine arms of the study.

In the current study, 8.08% of the IUD acceptors were nulliparous. This is consistent with a case control study from Ethiopia in 2016 in which 7.5% of IUD acceptors were nulliparous(28). Another study found this to be 9.2%(95). This may be attributable to the fact that the more children a woman has the likely she is to accept the IUD as a method of contraception. Other probable explanation for low uptake of IUD by nulliparous women may have arisen from provider bias, myths and misconceptions about IUD use in nulliparous populations. Some health care workers have the wrong perception that there is increased risk of perforation, expulsion and non-existent expectations of difficult IUD insertions in the nulliparous women and therefore may not bring up IUD when counselling a nulliparous woman for contraception. There is also the myth that IUD causes pelvic inflammatory diseases and infertility and hence nulliparous women may not readily accept IUD for contraception. There is this persistent misconception that IUD causes an increased ectopic gestation among users and this may explain why nulliparous women may not take IUD for contraception(48).

In the Ethiopian study by Dejere et al, 21.10% of the IUD acceptors had a history of abortion(95). However, in our study 30/99 (30.30%) of the respondents had a history of abortion. From Ghana Maternal survey 2017, 23.6% urban and 14.8% rural women aged between 15-49 years have had an abortion(3). This could explain why our findings were high because the respondents were mainly from Accra Metropolitan area and the adjoining suburbs. The other reason for high percentage of respondent with past history of abortion is that such individuals are likely to have come in contact with family planning providers and may have been told of the efficacy and the long acting reversible nature of IUD.

In a randomized control trial from Egypt comparing the use of oral diclofenac and hyoscine for pain control at IUD insertion, 19.05% had a history of dysmenorrhea which is comparable to the number of respondents in our study who had dysmenorrhea (13.59%)(16).

5.3 Contraceptive History of Respondents

From the Ghana maternal health survey of 2017, the three commonest modern family planning method used by married couple were injectable (8.0%), implants(7.0%) and pills (4.0%)(3). Again from the 2019-2020 annual progress report of Ghana FP2020, the most used methods were injectable (38.4%), pills (24.3%) and implants (21.6%)(96). In our study the three commonest methods mentioned were injectables (48.35%), pills (20.88%) and implants (15.38%). Our findings were consistent with the findings of the 2017 Ghana Maternal Health Survey. The injectable contraceptive is seen as private and long acting family planning method and hence in conservative societies in Subsaharan Africa where women using contraceptives are viewed as being promiscuous, its use continue to be appropriate since it can be used without being exposed. There is also a deliberate national policy to increase the uptake of long acting reversible contraception such as implants among the populace by the family health division of the Ghana Health Service and this may partially explain the increase uptake of implant in the study. The contraceptive oral pills is the third most used method among the women of reproductive age because it is generally very cheap, easily available. However, unlike the Maternal Survey where less than 1% of the women of reproductive age were using IUD(3), in our study 17.17% of the respondents had previously used IUD. This is probably because the study was assessing IUD users and most of them comparatively may have used IUD and had been satisfied and hence opting to use it again. It was also found out that the two commonest source of information on IUD were from health care providers, 61/99 (61.61%) and relations, 28/99 (28.28%). This is in contrast with a recent study by Asiedu et al in Ashaiman Municipality of Greater Accra Region of Ghana in which the commonest sources of information on contraception were television (99.7%), radio (96.7%) and healthcare providers (93.1%)(97) but were consistent with a Nigerian study of 2017 in which the commonest sources were healthcare providers (94.6%), mass media (5.0%) and friends and relatives (0.5%)(98). Even though the knowledge of modern contraceptive is universal, that for IUD which is an invasive method and involve pelvic examination was less than 60% in the GMHS 2017 because probably the women

want to learn about IUD from trusted sources such as their Health care providers. This may be the likely reason why 94.5% of our respondents cited the health care providers as their source of information on IUD.

5.4 Visual Analog Scale (VAS) assessment of pain at IUD insertion using Counselling only, Suppository Diclofenac and Lidocaine spray

From this study the level of pain experience by respondents were significant during speculum placement among the counselling only and suppository diclofenac (Mean VAS 4.9 versus 5.1, p=0.041). 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 or control arm. It is also important to note that in the lidocaine arm of the study, the intervention was started after the placement of the speculum, i.e. lidocaine spray of cervix. Therefore the comparison of pain experience at the speculum placement was between counselling only and suppository diclofenac.

There was also significant difference in the pain score experienced by respondents at tenaculum insertion (4.9 $\pm$ 2.2; 3.7 $\pm$ 1.4; 3.5 $\pm$ 1.9; p=0.010), uterine sound (4.1 $\pm$ 2.1; 3.2 $\pm$ 1.4; 3.0 $\pm$ 2.3; p=0.049), during 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 pains(61). 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. Also, pain experience by respondents at 5 minutes after placement of IUD was lowest in the 10% lidocaine spray group (0.6$\pm$0.7) compared to the suppository diclofenac(1.5$\pm$1.2) and counselling only group (2.4$\pm$1.9). This was statistically significant with $p<0.001$. The same pattern of mean pain score was noticed 4 hours after procedure among the three arms of the study. This was also significant, $p< 0.001$. 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.

5.5 Post Hoc Analysis of pain experience at IUD insertion using Counselling only, Suppository Diclofenac and Lidocaine spray.

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)(16). In a study from Turkey titled "comparison of the analgesic effect of oral tramadol and naproxen sodium on pain relief during IUD insertion", the pain score in naproxen arm was significantly lower than the control group (p=0.001). However, the pain score in tramadol group, 2.31 (0.60; 2.09-2.53) was found to be significantly lower than in the naproxen group, 2.94 (0.70; 2.69-3.18)(62). 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(99). 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)(63).

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)(15). 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 (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 the work done by Karasahim et al to evaluate whether 10% lidocaine spray of the cervix will be effective in pain control during hysterosalpingogram, 10mg and 20mg lidocaine spray was compared with a placebo using a standard 10cm VAS for pain scoring. A total of 81 participants were recruited (n=27 in each arm). In the 10mg lidocaine group, the tenaculum related pain score was 5.75± 1.13 and that for 20mg lidocaine was 4.80± 1.34 and the placebo was 5.95± 1.5. There was no statistical difference which was observed between the 10mg and 20mg lidocaine spray(100). In our study 40mg lidocaine was used and the mean pain score at tenaculum insertion was 3.5±1.9 compared to 4.9±2.2 of the control group. The higher doses used in our study explain why the mean VAS was lower in our study. Karasu et al in 2017 compared different formulations of lidocaine anaesthetic agents (lidocaine spray of the cervix, lidocaine gel and lidocaine injection of the cervix) for pain control at IUD insertion involving 200 study participants. The overall pain score was significantly higher in the lidocaine injection group than the other groups (p <0.001). The tenaculum related pain score was lowest in the lidocaine spray group (p <0.01) than in the lidocaine gel group (p=0.001), lidocaine injection group (p=0.01) and the control group (p= 0.01). When the lidocaine gel was compared with the controlled group, there was no significant reduction in pain experience during the tenaculum use or IUD insertion (p=0.657 and p= 0.894 respectively). However, lidocaine injection was associated with reduction in pain score during IUD insertion (p= 0.011) but no effect on tenaculum related pains (p= 0.082). More respondents in the lidocaine spray arm (25.5%) reported no pain compared to the lidocaine injection arm (2.1%) during the IUD insertion. Moreover, the injection itself is painful and therefore makes it less practical to be used for pain reduction in IUD insertion(64). In the above study, 40mg lidocaine spray of the cervix and the control groups were counselled only

which is similar to the current study but the pain scores were done at tenaculum insertion and IUD placement only. The mean pain scores were however categorized into none (VAS 0), mild (VAS 1-3), moderate (4-6) and severe (7-10) and therefore the results for 10% lidocaine spray and the controls were difficult to compare with our study.

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. 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(65,68), 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.

5.6 Comparison of respondents' satisfaction with IUD insertion using counselling only, suppository diclofenac and lidocaine spray

Out of 5/103 (4.85%) respondents who had unpleasant experience, 4/5 (80.00%) were in the counselling only group and 1/5 (20.00%) in the suppository diclofenac group. This was in line with the work done by Karabayirli et al., where out of 37/103 (35.92%) of the respondents who had unpleasant experience 30/37 (45.45%) were in the control group and 5/37 (13.51%)were in the naproxen group(62). This is probably because naproxen, like diclofenac is proven to be effective at pain control during IUD insertion and hence the similarities in the level of satisfaction. There was no unpleasant experience in the lidocaine group during the IUD insertion.

Even though there was significant difference in the ease of insertion between the 3 arms of the study ($p=0.008$), there was no correlation between ease of insertion of the IUD and level of satisfaction from the study. For example, out of 15 difficult insertions, 11/115 (73.33%) were from the lidocaine group and 2/15 (5.33%) were from diclofenac and counselling group respectively. However, 80.00% of respondents who had unpleasant experience were in the control group. This is probably because the assessment of satisfaction by the respondents were affected by the level of pain control i.e. the better the pain control the higher the level of

satisfaction. However, the assessment of ease of insertion by the provider was probably determined by the skill of the provider and the anatomy of the cervix and once pain control was adequate did not affect the level of satisfaction by the respondents.

Majority of the respondents, 90/99 (90.91%) said they would recommend IUD insertion procedure to another woman which is consistent with the high level of satisfaction of insertion of the IUD among the study participants. This implies that women who receive IUD are generally satisfied and therefore more effort should be made to improve on our primary IUD uptake. Women with history of IUD use could also be used to dispel myths associated with IUD insertion.

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.

5.7 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.

5.8 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 a widely accepted and validated instrument for pain assessment.

CHAPTER SIX

CONCLUSION AND RECOMENDATIONS

6.1 Conclusion

Ten percent Lidocaine spray of cervix is more effective compared to 100mg Diclofenac Sodium in reducing pain at IUD insertion. Compared to counselling only, 10% lidocaine spray of cervix offers better pain control at IUD insertion and finally when counselling only was compared to 100mg diclofenac suppository, the 100mg suppository was better at pain control at IUD insertion.

The use of 10% lidocaine spray of cervix at insertion of IUD will therefore greatly enhance patients' satisfaction at IUD insertion and in the long run help to increase the uptake of the IUD, a highly effective long acting reversible contraceptive.

6.2 Recommendation

From the findings of the study, the following recommendation can be made;
Even though both 10% lidocaine spray of the cervix and suppository diclofenac were shown to be better at pain control during IUD insertion compared to counselling only which is the standard of care in Korle Bu Teaching Hospital, 10% lidocaine spray is cheap, has rapid onset of action and is easily available and hence may be considered as one of the first line for pain control at IUD insertion.

It is recommended that the Family Planning Unit of Korle Bu Teaching Hospital should start the use of 10% Lidocaine spray of cervix for pain control during IUD insertion.

A multicenter study by the Ministry of Health and Ghana Health Service to compare 10% lidocaine spray of cervix, 100mg suppository diclofenac and counselling only for pain control at IUD insertion will help remove the possibility of selection bias in this study which was carried out in a single tertiary referral facility.

Further studies should be conducted by the Ministry of Health and Ghana Health Service to ascertain the magnitude of pain experienced by women during IUD insertion and the part this play as a barrier to IUD insertion.

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APPENDIX I: INFORMATION LEAFLET FOR PARTICIPANTS

RESEARCH TOPIC: COMPARISON OF EFFICACY OF COUNSELLING ONLY, SUPPOSITORY DICLOFENAC AND LIDOCAINE SPRAY AT INTRAUTERINE DEVICE INSERTION.

Background information

I am a resident in the Department of Obstetrics and Gynaecology of the Korle Bu Teaching Hospital (KBTH) under Ghana College of Surgeons. My assistants and I are undertaking a study to find out whether inserting Intrauterine contraceptive device into the womb causes pain. We are also interested in how much pain this may cause and whether giving some medications can help reduce the pain during insertion of the device.

We are very glad to invite you to take part in the study. We would be grateful if you could kindly read the leaflet or let someone read it to you so that you can decide whether to take part or not.

Purpose of the study

The purpose of the study is to determine if Lidocaine spray of the cervix or administration of diclofenac significantly reduce pain at IUD insertion

Study procedure, benefits and costs

Participation in this research will involve answering some questions which will last about 30 minutes and rating the level of pain experienced during IUD insertion using 10cm- Visual analog scale. Information that will be required from you will include your demographic data, obstetric history as well as the outcome of the pregnancies (vaginal birth or caesarean section). Other information will be extracted from your family planning record books. The information obtained from this research may help improve on the family planning services that will be provided to women in future. There are no costs involved in your part in participating in this research. The study will not pose no risk at all to you except the discomfort in the insertion of the IUD.

Confidentiality

The researcher and his team guarantee that all information obtained will be kept in the strictest confidence. Your name and identity is not needed for the study. However, the information you will provide is going to be identified by a special code number and would be treated with strict

confidentiality. We assure you that your name will not appear or be mention in any report that might come out from this study.

Voluntariness and Autonomy

Your participation in this study is entirely voluntary. We will be grateful if you take part, however we are assuring you that you will not suffer or be affected if you decide not to take part in the research. If you decide to take part in the research, you will not have to answer every question and you may withdraw whenever you wish.

This study has been reviewed and approved by the Ethical Review Committee of the University of Ghana Medical School whose task is to make sure that research participants are protected from harm and their rights respected.

If you have any questions or concerns, we will be happy to answer or address them now or later.

You may contact the principal investigator:

Dr .Henry Ekow Yanney,
Department of Obstetrics and Gynaecology,
Korle-Bu Teaching Hospital. P.O. Box KB77. Korle-Bu,
Accra.
Email: yanney146@gmail.com
Cell phone: 0242216552

Participant's Consent Form

I confirm that I have read thoroughly through the foregoing information or it has been explained to me and that I understand the information about the study as provided in the Participant Information Sheet that was provided to me.

I am aware that participating in this study is voluntary and that I can withdraw my participation any time from the study without having to give reason and without suffering any consequences.

I confirm that my concerns have been fully addressed to my satisfaction and I am not expecting any financial rewards.

Name of Participant……

Signature/thumbprint of Participants ---------- Date----------

Name/Signature of interviewer…… Date……

APPENDIX II: QUESTIONAIRE

TITLE: COMPARISON OF EFFICACY OF COUNSELLING ONLY, SUPPOSITORY DICLOFENAC AND LIDOCAINE SPRAY AT INTRAUTERINE DEVICE INSERTION.

Identification and sociodemographic characteristics:

1. Participant ID No: _____

2. Folder No: _____

3. Date form completed: _____

4. (i) Age: _____ years, (ii) maternal height_____

   (iii) Maternal weight _____

5. House No/Location: _____

6. Marital status: [0] married [1] single [2] cohabiting

   [3] Others, specify: _____

7. Educational level: [0] No formal education [1] Primary [2] JHS [3] SHS

   [4] Tertiary, specify: _____

8. Occupation :_____

   [3] others, specify: _____

9. Religion: [0] Christian [1] Moslem [2] Others, specify_____

Obstetric history

10. How many previous deliveries have you had? _____

11. What is/are your previous mode(s) of delivery? _____

12. When was your last delivery? _____

13. Are you currently breastfeeding? [0] Yes [1] No

14. If yes, how long have been breastfeeding? _____

15. Have you had any miscarriage(s) in the past? [0] Yes [1] No

16. If yes, how many? _____

17. When was your last normal menstrual period (LMP) _____

18. Any history of dysmenorrhoea? [0] Yes [1] No

19. Do you have a past history of pelvic inflammatory disease? [0] Yes [1] No

Medical history

20. Are you on medications for any chronic illness? [0] Yes [1] No

21. If yes, specify (name of drug) _____

22. Are you taking any medications for chronic pains? [0] Yes [1] No

23. Have you used narcotic or illegal drugs in the past? [0] Yes [1] No

24. State any medical condition identified (Tick as appropriate)

[0] Hypertension [1] Renal disease [2] Urinary Tract Disease [3] Retroviral infection [4] Vulvar heart disease [5] Peptic Ulcer disease [6] Uterine Fibroids.

[7] Others, specify _____

Contraceptive History

25. Is this your first family planning method? [0] Yes [1] No

26. If no, previous method used_____

Duration of use----------

Reasons for stoppage/ change to other method----------

27. Where did you hear about the intrauterine contraceptive device from? [0] health provider [1] pharmacy [2] radio/television [3] print media [4] social media [5] others_____

Specify _____

28. Have you had IUD insertion before? [0] Yes [1] No

29. If yes, how long ago_____

Thank you for taking part in this study. Completed by: _____

APPENDIX III: DATA COLLECTION TOOL

(To be used by the researcher for data collection)

1. Bimanual examination

   a. Uterine position (Anteverted/ retroverted)
   b. Uterine size-------

2. Pain estimated by patient using the 10cm- VAS score

   a. During speculum insertion_____
   b. During tenaculum placement_____
   c. Uterine sound insertion_____
   d. During IUD insertion_____

3. Overall pain estimated by patient immediately after procedure_____

4. Pain estimated 5 minutes after procedure _____

4. Pain estimated 4 hours after procedure (by telephone) _____

5. Patient overall satisfaction after procedure

   a. 1-Pleasant
   b. 2-Very pleasant
   c. 3-Not very unpleasant
   d) 4- Unpleasant
   e) 5- Very unpleasant

6. Would you recommend the procedure to another woman?

   a. Yes
   b. No.

      If No, why ----------

7. Immediate IUD insertion complications

   a. Nil
   b. Vasovagal attack
   c. Failure of insertion
   d. Uterine perforation

8. Adverse reaction of the drugs 24 hours after procedure (by telephone)

   a. Nil
   b. Nausea
   c. Dizziness
   d. Heartburns
   e. Skin reaction
   f. Allergic reaction

9. Ease of insertion (as reported by the experienced nurse doing the insertion)

   a. Difficult
   b. Easy
   c. Very easy