ACCEPTABILITY AND SAFETY OF POSTPARTUM INTRAUTERINE CONTRACEPTIVE DEVICE AMONG PARTURIENTS AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA

by

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Obstetrics and Gynecology of the Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by the Muhimbili University of Health and Allied Sciences in Dar es Salaam, a dissertation entitled**: ACCEPTABLITY AND SAFETY OF POSTPARTUM INTRAUTERINE CONTRACEPTIVE DEVICE AMONG PARTURIENTS AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA,** in partial fulfillment of the requirements for the degree of Master of Medicine (Obstetrics and Gynaecology) of Muhimbili University of Health and Allied Sciences.

…….....

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(SUPERVISOR)

Date……..

DECLARATION AND COPYRIGHT

I, **Rukiya Abdulwahab Mwinyi Ali**, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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I would like to extend my deepest thanks to my family for their encouragement, understanding, sacrifices and acceptance of my absence during the period of preparation of this dissertation.

DEDICATION

This dissertation is dedicated to my late mother, Aisha, my inspiring father, Abdulwahab, my loving husband, Mohammed and my lovely sons, Abubakar and Abdulwahab. You are all deeply loved and appreciated.

ABSTRACT

Background: In Tanzania the general use of modern methods of contraception is twenty seven percent with less than two percent of the women adopting the IUCD as a method of contraception. The modern IUCD is a highly effective, safe, private, long-acting, coitus independent and rapidly reversible method of contraception with few side effects. Intrauterine contraception is the most cost-effective method of contraception today. The postpartum insertion of an IUCD provides a convenient opportunity for the woman to receive IUCD services. This is particularly important for women who have limited access to medical care. The postpartum period is potentially an ideal time to begin contraception as women are more strongly motivated to do so at this time, which also has the advantage of being convenient for both patients and health-care providers.

Objectives: To assess acceptability and safety of immediate Postpartum Intrauterine Contraceptive Device (PPIUCD) among parturients at Muhimbili National Hospital (MNH).

Methodology: A prospective interventional analytical study was conducted from 1st August to 31st December 2011.Contraceptive counseling was given to 369 eligible parturients after delivery during their postpartum hospitalization. A pretested structured questionnaire was administered to all participants. Women who accepted the PPIUCD during their postpartum care were inserted with the device before discharge (within 48 hours). These women were followed up at 4 weeks for complications. The acceptance rate of PPIUCD and the percentage of actual insertions were recorded. The reasons for both acceptance and decline were also recorded.

Results: Of the 369 women counseled, a total of 102 (27.6%) were inserted with PPIUCD. Parturients who had a short duration from their last child birth (less than 2 years) were significantly associated with greater acceptance of the PPIUCD ($p \leq 0.05$). Parturients who had previously used the interval IUCD were significantly associated with greater acceptance of PPIUCD ($p = 0.005$). Preference to other methods of contraception mainly short acting methods, and the need to discuss with their partners were the most common reasons for

declining use of PPIUCD. More than half (55%) of the women whom PPIUCD was inserted did so due to its long term effect. Immediate PPIUCD was demonstrably safe due to its low rates of complications. The common complications at four weeks interval were expulsion (6.4%) and lost strings (5.3%).

Conclusion: Acceptance of PPIUCD was relatively high probably because of its 'newness' in the community. For these women, the best opportunity to receive information about contraception is during child birth when they are in contact with healthcare providers. It is also important to emphasize and educate women on long term methods of contraception as majority of the women preferred short term methods despite their future pregnancy desires of more than three years. Couple counseling should also be promoted. The government needs to develop strategies to increase public awareness of the PPIUCD through different media sources.

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ABBREVIATIONS

DHS	Demographic and Health Survey
DMPA	Depot Medroxy Progesterone Acetate
FP	Family Planning
Hb	Hemoglobin
IPPM	Intramural Private Practice Muhimbili
IUCD	Intrauterine Contraceptive Device
LAPM	Long Acting or Permanent Method
MCHIP	Maternal and Child Health Integrated Program
MNH	Muhimbili National Hospital
MMR	Maternal Mortality Rate
OCPs	Oral Contraceptive Pills
PI	Principal Investigator
PID	Pelvic Inflammatory Disease
PPFP	Postpartum Family Planning
PPH	Postpartum Hemorrhage
PPIUCD	Postpartum Intrauterine Contraceptive Device
PROM	Premature Rupture Of Membranes
RCTs	Randomized Controlled Trials
STD	Sexually Transmitted Disease
TDHS	Tanzania Demographic Health Survey

CHAPTER ONE

INTRODUCTION

Intrauterine Contraceptive Devices (IUCD) to prevent pregnancy are among the oldest methods of contraception. The modern IUCD is a highly effective, safe, private, long-acting, coitus independent and rapidly reversible method of contraception with few side effects. Intrauterine contraception is the most cost-effective method of contraception today. Many women also find the IUCD to be very convenient because it requires little action once it is in place.[1]

IUCD's have evolved through the Dalkon Shield produced in the 1970s to the Lippes Loop which are no longer in use. There are three categories of modern IUCDs: Copper IUCDs, Progestin-releasing IUCDs and Unmedicated (inert) IUCDs. The TCu380A (Paragard®) contains a T-shaped polyethylene frame with 380 A^0 (Armstrom units) of exposed surface consisting of fine copper wire wound around a vertical stem and copper collars on each of the horizontal arms. There is a 3 mm ball at the base of the stem to decrease the risk of cervical perforation. A white or clear polyethylene monofilament string is knotted through this ball. The frame contains barium sulfate to make it radiopaque. All copper-containing IUCDs have a number as part of their name. This is the surface area of copper (in square millimeters) the IUCD provides.[2] The device is latex-free and clinically relevant allergy to copper is extremely rare.[3]

The TCu380A is approved to remain in place for 10 years, but is effective for at least 12 years. With perfect use (in which the user checks the strings regularly to detect expulsion), the probability of pregnancy in the first year is 0.6 percent; with typical use, the first-year pregnancy rate is 0.5 to 0.8 percent.[4]

IUCDs work primarily by preventing fertilization, and do not act as abortifacients. When the uterus is exposed to an IUCD, a sterile inflammatory reaction occurs, which is toxic to sperms and impairs fertilization.[5] The production of cytotoxic peptides and activation of enzymes

lead to inhibition of sperm motility, reduced sperm capacitation and survival, and sperm phagocytosis.[6]

The IUCD is a safe and effective contraceptive option for postpartum women who wish to either space or limit subsequent births. IUCDs provide effective and reversible contraception for up to 12 years. Many women find the PPIUCD to be very convenient because it requires little action once it is in place.

Increasing numbers of women in the developing world are having their babies in hospitals. Many of these women welcome the opportunity to delay their next pregnancy. The postpartum insertion of an IUCD offers several advantages in such instances. For example, the delivery provides a convenient opportunity for the woman to receive IUCD services. This is particularly important for women who have limited access to medical care. Having just given birth, the woman is clearly not pregnant, and she may be very motivated to consider long-acting methods.[7]

Immediate postplacental insertion should only be done if there is adequate prenatal counseling. Ideally, choices of methods should be discussed during routine prenatal visits, allowing women to choose the most appropriate method at that point. In some cases, a woman in the early stages of labor could receive enough information after arriving at the labor ward to decide to have a postplacental insertion. Likewise, a woman could decide after delivery to have an IUCD inserted before leaving the hospital. A woman should never receive an IUCD immediately after delivery without having received adequate counseling and giving her informed consent. Counseling should be done once the emotional and physical stresses of labor have ended.[8]

Appropriate times for IUCD insertion in the postpartum periods include the postplacental IUCD insertion, the immediate postpartum IUCD insertion and the transcesarean IUCD insertion. The postplacental IUCD insertion is done within 10 minutes after expulsion of the placenta, following a vaginal delivery. The immediate postpartum IUCD insertion is done after the postplacental period, but within 48 hours of delivery and the transcesarean IUCD

insertion is when the insertion takes place following a cesarean delivery, before the uterus incision is sutured.[7]

Immediate postpartum IUCD insertion has a higher retention rate if the IUCD is inserted postplacentally, but the IUCD can be inserted safely at any time during the first 48 hours after delivery. IUCDs can also be inserted after the fourth week postpartum and after an abortion.

These periods are recommended because it is possible to use instruments or manual insertion as the cervix is open and limp and an IUCD can easily be placed high in the fundus, either manually or using forceps. Furthermore it continues to be possible to insert an IUCD with an instrument for up to 48 hours postpartum. After this period, the cervix is not open enough to allow for an easy and relatively painless instrument insertion.[7]

After birth, as the uterus returns to normal size (involution), uterine contractions expel retained placental tissues and blood clots and may have a similar effect on any foreign body introduced into the uterus. IUCDs inserted postplacentally have a much lower expulsion risk than those inserted later in the postpartum period, although the expulsion is still higher than for interval insertions (about 42 days after childbirth). However, the benefits of providing highly effective contraception immediately after delivery often outweigh the disadvantage of the higher postpartum expulsion rates. Pregnancy rates do not differ by timing of IUCD insertion.[7]

The risk of expulsion can be reduced significantly by properly inserting the IUCD. No increased risk of pelvic infection occurs with postpartum IUCD insertion. The risk of uterine perforation for postpartum IUCD insertion is low. There is no effect on breast milk quantity or quality.

The above mentioned advantages argue a case for a study in PPIUCD with the aim of future inclusion of the method in the Tanzania Family Planning programme.

LITERATURE REVIEW

Maternal mortality in Tanzania is estimated at 454 per 100,000 live births in the 2010 survey, while many more women suffer long term morbidity from pregnancy complications.[9]

It is estimated that almost 115 million women worldwide have an unmet need for family planning— that is, they express a desire to limit or space future births, but they are not currently using a family planning method. The countries with the highest percentage of unmet need are in Sub-Saharan Africa ranging between 30 – 42%. The unmet need for contraception in Tanzania is 25.3% while the contraceptive prevalence is 29%. Injectables is the most commonly used method of contraception at 9 percent followed by the pill at 5 percent and male condoms at 4 percent.[10] Use of long-term methods such as intrauterine devices (0.6%) and implants (1.8%) are negligible. The appropriate spacing of births has been shown to have positive impacts on women's health and on their social and economic well-being. The postpartum period presents an excellent window of opportunity to provide family planning counseling and methods to women who may not otherwise received family planning services. Many family planning methods can be used immediately following childbirth and will help prevent subsequent mistimed or unwanted pregnancies.[7]

In a study done in Egypt, both the acceptance and actual insertion of IUCD in the postpartum period were low probably because the use of IUCD was a new concept in the community. For these women, the only opportunity to provide information about contraceptives is during childbirth when they are in contact with medical personnel. Hence, it was suggested that family planning should be integrated with maternal and child-care services in order to effectively promote the use of contraceptive devices in these women who otherwise would not seek the use of such a device.[11]

In the same study out of 3,541 clients, 1,024 (28.9%) accepted the use of IUCD after delivery. Acceptance was approximately the same during antenatal and postpartum counseling: 26.4 and 31.8%, respectively. Verbal acceptance was higher among women with formal education than among illiterate women. Planning another pregnancy in the near future,

preference for another contraceptive method, namely lactational infertility, and complications from previous use of IUCD were the most common reasons for refusing the use of IUCD. Of the 1,024 verbal acceptors, only 243 (23.7%) had the actual insertion of IUCD.[11]

The World Health Organization recently revised guidelines on postpartum and newborn care includes provision of family planning counseling as a core component of postpartum care. The postpartum period is potentially an ideal time to begin contraception as women are more strongly motivated to do so at this time, which also has the advantage of being convenient for both patients and health-care providers.

Contraceptive counseling has become an integral part of antenatal and postpartum programs as pregnant and postpartum women are generally motivated toward controlling their fertility either in spacing out their children or in stopping their fertility altogether. The time during pregnancy and that immediately after delivery may be the only time for the physician to connect with women who are poorly motivated to obtain routine health care, best described as 'crisis-oriented'.[11]

Nowadays, PPIUCD has been established as an effective and reliable method of contraception as it offers numerous advantages: easy insertion, no adverse impacts on breast-feeding, cost- effectiveness, relief of overcrowded outpatient facilities and protection against unwanted pregnancy and consequently abortion. In addition, insertion complaints caused by lochial blood and cramping are masked.[11]

Additionally, unintended pregnancies remain common. Clearly, the method of contraception must be tailored to meet the needs of the individual. Recent research has shown that women who choose contraceptive agents that do not require self-administration, periodic renewal, or daily pill-taking are better able to avoid unintended pregnancy than are women who use other contraceptive methods.[12]

Studies have shown that postpartum IUCD insertions, including those done immediately after placental delivery or cesarean section, are generally safe and effective. Compared with

interval insertions, postpartum insertions do not increase the risk of infection, bleeding, uterine perforation or endometritis, nor do they affect the return of the uterus to its normal size.[13] IUCDs inserted postplacentally and in the immediate postpartum period are more likely to be expelled than those inserted in the interval period. However, expulsion is less likely to occur with copper T IUCDs, postplacental insertions, high fundal placement, and clinicians trained and experienced in insertions. Over 90% of women are able to detect their own expulsions.[14]

In a Cochrane Collaboration review of nine Randomized Controlled Trials (RCTs) assessing the feasibility of immediate PPIUCD found out that expulsion rates were generally higher for the immediate postpartum than interval insertion. Overall the PPIUCD insertion was safe and effective, and these women require an early follow up to detect any spontaneous expulsions.[15]

Many countries with Postpartum Family Planning (PPFP) activities like Ghana, Liberia, Bolivia, Malawi, Guinea, Bangladesh, Indonesia, Nigeria and Albania promote PPIUCD use. PPFP is the provision of FP services for women during the first year after delivery. Return to fertility can occur prior to the onset of menses, especially when mothers introduce complimentary foods to their infants. When return to sexual activity occurs earlier than what was traditionally practiced, providers and mothers may not perceive the risk of another pregnancy. Many women wrongly assume that they are not at risk of pregnancy if they are breastfeeding, and couples may not admit to sexual activity during lactation due to the sexual taboo.[16]

Evidence-based interventions include: postpartum IUCDs; provision of FP counseling within the first 48 hours after birth; integrating FP messages at time of immunization; training MCH staff on PPFP methods compatible with breastfeeding, community involvement to promote the benefits of healthy spacing of pregnancies through FP. Any pregnancy that occurs within 24 months after the last birth increases the risks of adverse outcomes for the mother, her current baby and her new pregnancy.[8]

The very high efficacy of the CuT380A makes it the IUCD of choice and it can be considered as a potentially reversible, non-surgical alternative to sterilization for women requiring very long-term pregnancy protection.[15]

PPIUCD insertion can be cost-effective. A study conducted at a large hospital found that the costs of offering postpartum contraceptive services were significantly less than the costs of providing these services on an outpatient basis. In addition, providing postpartum contraceptive services helped to relieve overcrowded outpatient facilities, thus allowing more women to be served. It also eliminates transportation costs and service fees paid by women for making an additional visit for IUCD insertion beyond the postpartum period, if that visit does not coincide with infant care services.[16]

The main problem with postpartum insertions is that they generally result in higher expulsion rates than interval insertions. Risk of expulsion is lower for insertions done within 10 minutes of delivery than for those done between 10 minutes and hospital discharge. One multisite study found that after six months, the cumulative expulsion rate was 9 percent for immediate postplacental insertion, compared with 37 percent for insertions done between 24 and 48 hours after delivery. The risk of expulsion can be reduced substantially with appropriate training in postpartum insertion techniques.[17]

For interval insertions, the rate of expulsion after 12 months is about 6 percent. Expulsion rates can vary extensively, depending on the timing of insertion, the technique used, skill of the person doing the insertion, and the type of IUCD used. These factors are especially important in postpartum insertions.[18]

The enlarged postpartum uterus may contribute to the displacement of the IUCD. This has caused concern over possible increased risk of uterine perforation as uterine involution occurs. Family Health International has reported that the perforation risk at one month for immediate postpartum insertions was no greater than that associated with interval insertion, about 1 per 2000 insertions.

The risks of pelvic infection appear to be no greater with postpartum insertion than with insertion six weeks or longer post-delivery. For immediate postpartum insertions the cumulative six-month pelvic inflammatory disease (PID) rate was 1.4 to 2 per 100 women. Most cases of PID occurred within three months of insertion, and some were undoubtedly the result of endometritis associated with delivery rather than with the IUCD.[9]

The risk of PID is much lower than some providers believe. IUCDs alone do not cause PID. In the presence of an existing infection with Gonorrhea or Chlamydia, IUCDs can increase PID risk, primarily around the time of insertion.[20]

In a study conducted at the University of New Mexico, a chart review of women delivering at that hospital who indicated at discharge that they wanted an IUCD inserted at some point after discharge, only 60% received an IUCD. Barriers to insertion often include providers' advising against IUCD use based on outdated knowledge, providers' lacking skills in postpartum IUCD provision, and clients' having a difficult time in returning for a postpartum visit, resulting in early repeat unintended pregnancy.[7]

A recent FHI study in Africa showed the importance of training and experience. The study evaluated postpartum IUCD programs at the Provincial General Hospital of Nyeri, Kenya and the Maternité Hamdallaye of Bamako, Mali. In Kenya, 224 IUCD acceptors were interviewed at six weeks, three months and six months after insertion along with 185 non-acceptors. In Mali, a similar approach involved 110 acceptors and 273 non acceptors. The six-month cumulative expulsion rates in Kenya were 1 percent for postplacental IUCD insertions and 5 percent for immediate postpartum insertions, rates comparable to or even lower than interval insertions. These low rates might be attributable to the extensive training and experience of the Kenyan providers. In Mali, the six-month expulsion rates of 15 percent for postplacental insertions and 27 percent for immediate postpartum insertions were skewed by the high rates for one of the three providers, who had far less training and experience than the other two.[19]

The Technical Guidance Working Group, a panel of family planning experts from around the world organized by the U.S. Agency for International Development, recommends that

clinicians should not insert IUCDs unless they can follow basic infection prevention measures, including hand washing, preparation of the cervix, use of sterile IUCDs and equipment, decontamination of instruments and safe disposal of contaminated materials.

Good postpartum IUCD programs in hospitals need national and regional support. Clinicians need specialized insertion training, and prenatal clinics must give priority to contraceptive counseling. A variety of methods should be available to potential users. Also, the obstetric unit of the health-care center must work in close coordination with the family planning or maternal and child health unit. Only a few countries, including Mexico and Colombia, have committed major resources and programmatic attention to postpartum IUCD programs.[8]

STATEMENT OF THE PROBLEM

Despite the many advantages of the IUCD as a method of family planning, it generally suffers from unpopularity in Tanzania. In Tanzania less than two percent of women use the IUCD as their modern contraceptive method of choice (TDHS).[10] Recent studies estimate that the prevention of unplanned and unwanted pregnancies could help avert 20–35% of maternal deaths and as many as 20% of infant deaths. [7]

Countries with the highest percentage of unmet need are in Sub-Saharan Africa ranging between 30 – 42%. The unmet need for contraception in Tanzania is 25.3% while the overall contraceptive prevalence is 29%.[10] The reasons for non-use of contraception includes lack of awareness, non-availability of accessible family planning services, and limitations on women's mobility due mostly to cultural or geographical factors. For women with limited access to medical care, the time of delivery offers a unique opportunity to address their need for contraception if the delivery takes place in a health-care center.

Other countries like China, Egypt, Mexico and Turkey are enjoying the fruits of PPIUCD insertion by decreasing rates of unwanted pregnancies and fulfilling the Millennium Development Goal 5. In order to meet this target of improving maternal health by reducing our maternal mortality ratio of 454 per 100,000 live births by three quarters, it is important to achieve universal access to reproductive health. This can be achieved by increasing the contraceptive prevalence rate and decreasing the unmet need for family planning. One strategy would be to enhance our postpartum family planning services to ensure we meet this target by 2015 and also increase wider variety of FP methods.

RATIONALE OF THE STUDY

Factors affecting acceptability and safety of PPIUCD have not been studied in previous trials at MNH and Tanzania at large. A study was conducted 18 years ago at MNH to determine the safety of postplacental PPIUCD verses interval insertion with favorable outcomes but factors determining its acceptability were not explored.

This study will aid in increasing the contraceptive method mix coverage and will in return revitalize the use of this long acting reversible contraceptive in our set up of high unmet demand of family planning. The postpartum period is convenient for the woman as by the time she leaves the hospital she will have an effective and active method of FP.

This study will also enable to advise policy makers on strategies to enhance positive factors (e.g. to establish programs that are dedicated in educating parturients and promote PPFP) and remove negative factors that influence PPIUCD use (i.e. to adopt policies that dispel the parturient misbelieves), so as to increase contraceptive prevalence and ensure an increase in the PPFP choice of methods. Finally this will also work as a tool to decide on how to proceed with the PPIUCD skills training program.

OBJECTIVES

BROAD OBJECTIVE

To assess the acceptability and safety of immediate PPIUCD insertion among parturients at Muhimbili National Hospital.

SPECIFIC OBJECTIVES

1. To determine proportion of women accepting immediate PPIUCD insertion.

2. To describe the factors associated with acceptability of immediate PPIUCD insertion in women according to their socio-demographic and obstetrics characteristics, previous contraceptive use and future pregnancy desires.

3. To determine the rates of expulsion, pelvic infection, lost strings/displacement and uterine perforation following PPIUCD insertion among parturients at 4 weeks.

CHAPTER TWO

METHODOLOGY

Study Design

The study was a prospective interventional analytical study looking for acceptability and safety of PPIUCD use in women after delivery.

Study Setting

The study was conducted at the Muhimbili National Hospital (MNH), Antenatal Clinic and Postnatal Ward from 1st August to 31st December, 2011. The hospital is the largest Consultant and University teaching hospital in Tanzania and is a tertiary referral center for the Dar es Salaam municipal hospitals.

Maternity services are provided in the Maternity building that consists of seven wards. Four wards which serve as the antenatal and postnatal wards each have a capacity of 60 beds. The hospital's labour ward receives patients from three main municipal hospitals; Amana, Mwananyamala and Temeke and occasionally patients from nearby district hospitals like Kibaha and Mkuranga. Although the labour ward was designed for high risk patients referred from other centers, more than half of the women admitted are self-referred coming directly from home after attending antenatal care at other health levels. During a 24 hour period there are between 20 to 30 deliveries. Parturients with no intrapartum or postpartum complications are observed in the labour ward for approximately two hours before being transferred to the adjacent postnatal ward. At the postnatal ward these women are given health education on breastfeeding and nutrition, episiotomy care and general hygiene, cord care for the newborn and family planning. Their newborns are also immunized before discharge. Those women who delivered in the afternoon and over the night are discharged the following day in the afternoon while those who deliver during the early hours of the day discharged in the evening to ease up congestion in the ward. Those who encounter complications (e.g. Cesarean Section, Antepartum or Postpartum hemorrhage, Hypertensive disorders of pregnancy, poor neonatal

conditions) are transferred to the respective postnatal wards for further management while their newborns are admitted to the neonatal unit.

The postpartum family planning services offered are in the form of health education in group counseling sessions at the postnatal ward. These are done by well-trained FP counselors. Methods offered include OCP's (Oral Contraceptive Pills), DMPA (Depot Medroxy Progesterone Acetate), Implants, IUCD's and condoms.

Study period

The study was conducted from 1st August to 31st December, 2011.

Study Population

The study population included all women who delivered at MNH during the study period.

Sample Size

Sample size was obtained by the formula:

$n = z2 \times p \times (1-p)/d2$

where

n = sample size

z = 1.96 corresponding to 95% confidence interval

p = proportion of parturients accepting PPIUCD

d = margin of error set at 5%

The minimum sample size was estimated at

$$N = \frac{1.96^2 \times 28.9 \times 71.1}{5 \times 5}$$

N = 316

The minimum sample size was taken to be 316.

A study done by Safwat et al in Egypt showed acceptability of PPIUCD to be 28.9% therefore a sample size (n) of 369 was taken.

Inclusion Criteria

Parturients planning to stay in the area for at least a month postpartum therefore could conveniently return for follow up.

Exclusion Criteria

- fever during labor and delivery
- cesarean section delivery
- who had active STD or other lower genital tract infection or are at a high risk for STD
- known to have ruptured membranes for greater than 24 hours prior to delivery
- AIDS – Advanced stage, not well on antiretroviral therapy
- known uterine abnormalities e.g. uterine myomas
- manual removal of the placenta
- antepartum, intrapartum or postpartum hemorrhage or any evidence of postpartum uterine atony which necessitated use of oxytocic agents for control
- an allergy to copper

Training of Research assistants

Three Nursing Officers underwent a training program by the Principal Investigator. Two were from the postnatal ward and one from the labour ward. They were trained on the objectives of the study, on proper questionnaire filling, on counseling and identifying eligible parturients for the study purpose. The Principal Investigator had already undergone a training programme by PSI for PPIUCD insertion and was certified competent.

Pretest study

A two week pilot study was conducted at the postnatal ward. The flow of variables in the questionnaire and ease of obtaining information was assessed. Necessary changes and omissions were corrected.

Study tools

Instruments which were used in the study included a structured questionnaire, a check list and a PPIUCD follow up card.

A structured open ended questionnaire was used to extract important information from the parturient. The questionnaire was divided into four main areas; socio demographic information, antenatal, previous obstetric performance and future pregnancy desires; gynecological history including contraceptive history; awareness of PPIUCD; reasons of acceptance or decline and contraceptive preferences.

The checklist was used to counter check the eligibility of the parturient by the PI, to ensure that all the instruments required were set before insertion and to check any immediate complications.

A PPIUCD follow up card was given to all the parturients after insertion of the IUCD. This included instructions about recognizing expulsion for example through the string length or even vivid expulsion, postpartum warning signs i.e. bright red bleeding of which the woman needs to change her pad more than six times a day, unusual abdominal or pelvic pain (not after-birth pain) and unusual vaginal discharge or pain, or fever. The PPIUCD card also contained information on the date of insertion and follow up visit, type of IUCD inserted, date of expiry of the IUCD and the telephone number of the principal investigator.

DATA COLLECTION AND SAMPLING TECHNIQUE

General health education was done for all parturients who had normal vaginal deliveries during their postpartum hospitalization period in the postnatal ward.

During these sessions, postpartum contraception with IUCD was offered together with other options that include Implanon, DMPA and minipills suitable for breast feeding mothers. The

merits of each method, their common side effects and possible complications were explained to all the women. Each eligible woman was then counseled individually, during which PPIUCD was introduced. This approach was used to enable the woman to make a voluntary, informed and well-considered choice. The ultimate choice was respected. In all cases reasons for acceptance and refusals were recorded.

Counseling for postpartum family planning was offered every morning and afternoon before the parturient was discharged from the hospital. Counseling was done by the Research Assistants and the PI.

Data was collected conveniently among the eligible parturients. Eligibility was sought by checking their files for the labour events and by asking the woman if she was planning to stay around the area for a month. Those women who were eligible for PPIUCD were identified and approached in the postnatal ward. A written informed consent was given to the parturients on their participation in the study. Questionnaires were filled by the PI and the three research assistants. By the use of the structured questionnaire, the following variables were collected: social demographic characteristics of the women studied, obstetric and gynecological characteristics, previous contraceptive methods used, source of information and awareness of the PPIUCD, reasons for acceptance or decline to PPIUD insertion and their future pregnancy desires. After contraceptive counseling and filling of the questionnaire, those who accepted the PPIUCD insertion had the IUCD inserted immediately. Reasons were sought for non-acceptance and other methods of postpartum family planning were advised. The IUCD was inserted in a side room adjacent to the postnatal ward.

Women in whom the PPIUCD was inserted were assessed before discharge and followed at four weeks after IUCD insertion. Upon discharge a PPIUCD follow up card was given which contained information of the date of insertion and follow up visit, type of IUCD inserted, date of expiry of the IUCD and the telephone number of the principal investigator. These women were also advised to phone or come back any time if she had any concern or experiences any warning sign or if the IUCD is expelled. The principal investigator crosschecked the checklist and questionnaire after every shift to ensure proper filling of information.

At four weeks interval those women whom the PPIUCD was inserted were reassessed by the PI at the examination room in the antenatal/postnatal clinic. The follow up checklist was filled by checking their oral temperature and an abdominal examination for suprapubic tenderness and involution of the uterus was done. A speculum examination was then performed to check if the strings were visible and any discharge noted. The visible IUCD strings were trimmed at approximately 3cms. A digital vaginal examination was then done to assess for cervical motion tenderness. Those women who had a pelvic infection were treated with antibiotics (Injection Ceftriaxone 250mgs stat followed by oral Erythromycin 500mgs 12 hourly and Metronidazole 400mgs 8 hourly for 2 weeks). Women who reported expulsion of the IUCD or those whom their strings were not visible had a pelvic ultrasound to confirm expulsion.

INSERTION TECHNIQUES

All necessary instruments (Copper T 380A, 2 ring forceps, Sim's speculum, head lamp, Povidone Iodine, Savlon, kidney dish and cotton swabs) were arranged on top of an auxiliary table covered with a sterile drape.

Insertion was performed by the PI using ring forceps. The patient was placed in a lithotomy position ensuring her buttocks were at the edge of the table. Aseptic techniques were used throughout the procedure.

The uterus was palpated to evaluate the height of the fundus and its tone. This is important to assess the size of the uterus as this will provide important information of whether to anticipate if the strings are likely to protrude through the cervix after insertion.
After performing the appropriate hand hygiene a pair of sterile gloves was worn. The perineum was cleaned with savlon then a clean sterile drape was kept underneath the woman's buttocks. The perineum, labia and vaginal walls were inspected for lacerations.

After moistening the Sim's speculum with savlon, it was gently inserted into the vagina to visualize the cervix. The cervix and the vaginal walls were cleaned twice with cotton swabs

soaked in Povidone Iodine solution. The anterior lip of the cervix was then gently grasped with ring forceps closing the forceps one notch only.

The IUCD was removed from the insertion sleeve and grasped with the second ring forceps using a no-touch technique. The IUCD was then inserted through the dilated cervix to the level of the uterine fundus, as confirmed by palpation with a hand placed on the abdomen overlying the fundus. The ring forceps were oriented so the arms of the IUCD lies parallel to the anterior and posterior walls of the uterus and then the forceps were opened to release the IUCD. The cervical os was then gently inspected with the Sims speculum for the strings. If the strings were visible then the IUCD was reinserted.
Before discharge, the patient was assessed for comfortability by the research assistants.

DATA ENTRY AND ANALYSIS

Data entry was done using Statistical Package for the Social Sciences (SPSS) version 17.0 for statistical analysis. Descriptive data were summarized as percentages or means. The Chi-square test was used to measure the strength of associations between variables, a p-value of <0.05 was considered to be statistically significant.

ETHICAL ISSUES

An informed choice was given by each client based on the client's full understanding of the method or procedure, including its characteristics, actions, and possible risks and side effects. In addition clients were informed on other alternative methods of contraception that are accessible to them.

The participants consent were sought and obtained after adequate information about all aspects covered by the study. Voluntary participation including the right to decline being in the study or to withdraw their participation at any time they wish to do so was emphasized. They were ensured of receiving the same care whether they agree to participate or not. A signed consent form was mandatory since an invasive procedure was performed to the participants.

Prior to insertion of the Cu T380A the principle investigator ensured that the parturient had received high-quality family planning counseling at the postnatal ward and also that the client was comfortable during the insertion procedure; and that the client knew about warning signs and needed follow- up.

Women were taught on how to detect expulsions and instructed to return for reinsertion or for another method.

Those parturients who declined PPIUCD insertion, other forms of postpartum family planning methods were advised or given according to availability.

ETHICAL CLEARANCE

Ethical clearance was obtained from the Research Ethics Committee of the Muhimbili University of Health and Allied Science and the Executive director of the MNH.

OPERATIONAL DEFINITIONS

Accept: Those parturients who agree insertion of the PPIUCD within 48hours of delivery.

Decline: Those women who refuse insertion of PPIUCD

Expulsion of the IUCD: When the stem of the IUCD or strings cannot be visualized or be sounded at the cervical canal. This also includes women who report visual expulsion of the IUCD. To confirm expulsion of the IUCD a pelvic ultrasound was done.

Pelvic infection: A definitive diagnosis of pelvic infection is made if the client had an oral temperature of 38^0C or higher before vaginal examination and suprapubic tenderness with guarding. Other criteria were cervical motion tenderness during vaginal examination or a unilateral or bilateral adnexal tenderness and/or palpable tender adnexal mass.

Lost Strings/Displacement: When the strings of the IUCD are not visualized despite confirming that the IUCD is in situ i.e. by sounding, X-ray or ultrasound.

Perforation: When the IUCD is diagnosed to be outside the uterine cavity by sounding, X-ray or ultrasound after the strings are not visible.

CHAPTER THREE

RESULTS

The total number of deliveries during the study period was 3158. Among these deliveries 887 women were eligible for PPIUCD insertion. A total of 369 women were approached. One hundred and two (27.6%) women accepted PPIUCD insertion while almost three quarters of them declined insertion. Those women whom the PPIUCD was inserted were followed up at four weeks. Eight women were lost to follow up, thus 94 were seen at four weeks after insertion of IUCD. Out of 94 women, 14 (14.9%) developed complications.

Figure 1: Recruitment of study participants

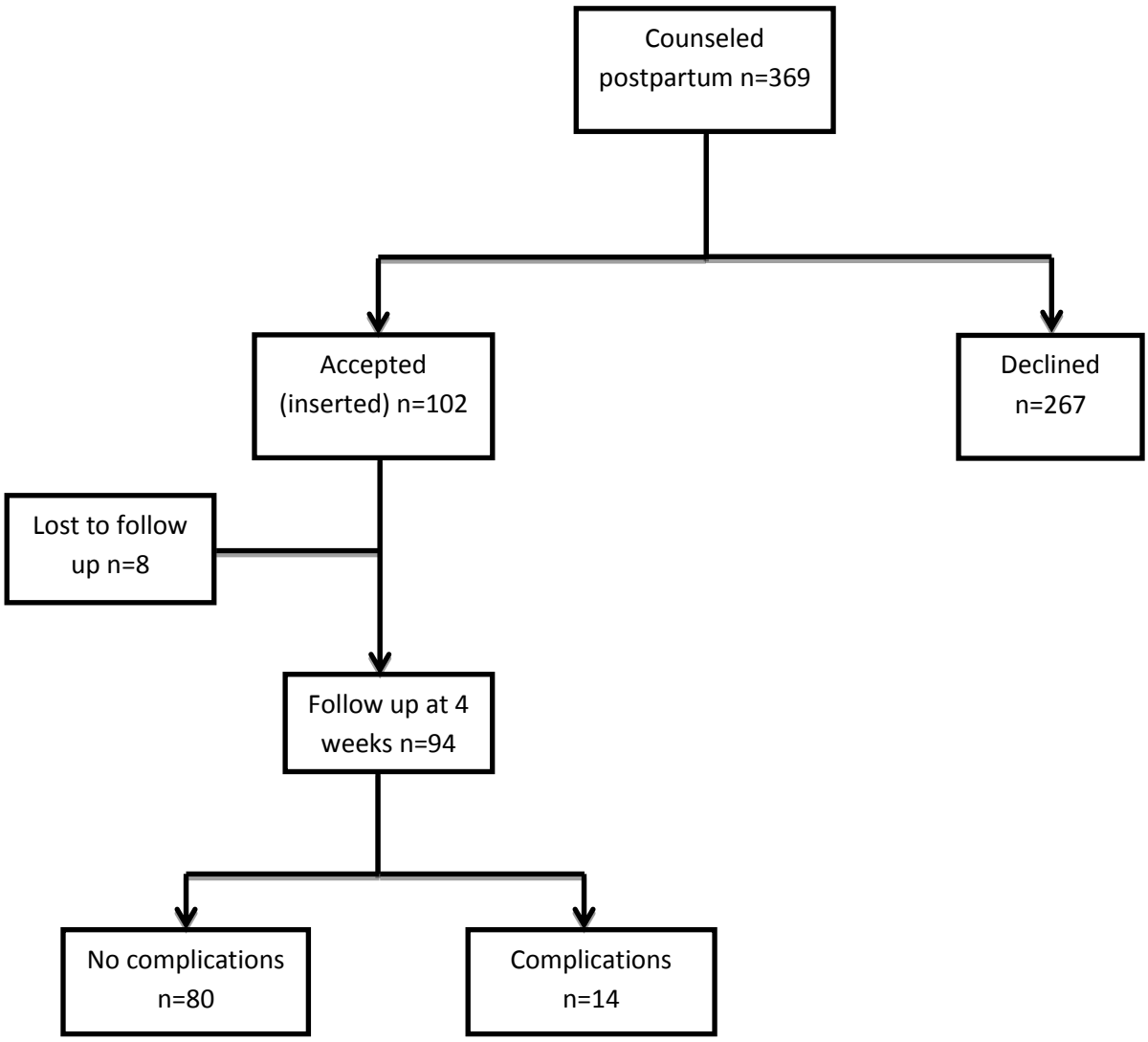

Table 1: Sociodemographic and obstetric characteristics of the parturients included in study (N=369)

Characteristics		PPIUCD insertion		
	Total N = 369	Accepted (N=102)	Declined (N=267)	P-value
	n (%)	n (%)	n (%)	
Age				
≤19	23 (6.2)	7 (6.9)	16 (6.0)	0.511
20 – 29	211 (57.2)	53 (52.0)	158 (59.2)	
30 – 39	131 (35.5)	40 (39.2)	91 (34.1)	
≥40	4 (1.1)	2 (2.0)	2 (0.7)	
Educational Status				
No formal education	12 (3.3)	4 (3.9)	8 (3.0)	0.083
Primary	181 (49.1)	39 (38.2)	142 (53.2)	
Secondary	123 (33.3)	42 (41.2)	81 (30.3)	
Higher education	53 (14.4)	17 (16.7)	36 (13.5)	
Marital Status				
Single	83 (22.5)	23 (22.5)	60 (22.5)	0.763
Married	286 (77.5)	79 (77.5)	207 (77.5)	
Religion				
Christian	205 (55.6)	52 (51.0)	112 (41.9)	0.129
Muslim	164 (44.4)	50 (49.0)	155 (58.1)	
Occupation				
Housewife	152 (41.2)	34 (33.3)	118 (44.2)	0.051
Businesslady	131 (35.5)	46 (45.1)	85 (31.8)	
Employed	86 (23.3)	22 (21.6)	64 (24.0)	
Parity				
1	159 (43.1)	40 (39.2)	119 (44.5)	0.593
2	113 (30.6)	30 (29.4)	83 (31.1)	
3	52 (14.1)	17 (16.7)	35 (13.1)	
4	28 (7.6)	8 (7.8)	20 (7.5)	
≥5	17 (4.6)	7 (6.9)	10 (3.8)	
Last Child Birth				
0 – 2	163 (44.2)	37 (36.3)	126 (47.2)	0.004*
2 – 3	45 (12.2)	22 (21.6)	23 (8.6)	
3 – 4	53 (14.4)	17 (16.7)	36 (13.5)	
≥5	108 (29.3)	26 (25.5)	82 (30.7)	
Future Pregnancy desire				
1 – 2yrs	8 (2.2)	3 (2.9)	5 (1.9)	0.248
3 – 5yrs	145 (39.3)	38 (37.3)	107 (40.1)	
>5yrs	73 (19.8)	26 (25.5)	47 (17.6)	
Not Sure	84 (22.8)	17 (16.7)	67 (25.1)	
No intention	59 (16.0)	18 (17.6)	41 (15.4)	

*$p \leq 0.05$ statistically significant

Table 1 shows of the parturients studied, majority were in the age range 20 -29 (57.2%). Their mean age was 27.6 (SD ± 5.68). Most of the study population had at least a primary level of education (96.7%). Median parity was 2 (Range: 0 – 7). Grand multipara made up a small percentage (4.6%) of the study sample while the majority (43.5%) were primiparous. Majority of the women (44.2%) had their last child birth less than 2 years ago. The duration since the last child birth was statistically significantly associated with acceptance of PPIUCD (p=0.004).

Table 2: Previous contraceptive method used (N=369)

Methods Used	PPIUCD Insertion		Total	*p* value
	Accepted (N=102) n (%)	Declined (N=267) n (%)	N=369	
DMPA	34 (33.3)	76 (28.5)	110 (29.8)	0.360
OCPs	27 (26.5)	56 (21.0)	83 (22.5)	0.258
Natural	22 (21.6)	48 (18.0)	70 (19.0)	0.431
Male Condoms	19 (18.6)	37 (13.9)	56 (15.2)	0.253
Interval IUCD	8 (7.8)	4 (1.5)	12 (3.3)	0.005*
Implants	5 (4.9)	6 (2.2)	11 (3.0)	0.185
Spermicidal Agents	2 (2.0)	1 (0.4)	3 (0.8)	0.186
Never used	25 (24.5)	95 (35.6)	120 (32.5)	0.042*

* $p < 0.05$ statistically significant
The percentages are more than 100% as there were multiple responses.
DMPA – Depot Medroxy Progesterone Acetate
OCPs – Oral Contraceptive Pills
IUCD – Intrauterine Contraceptive Device

Out of the total women studied, 249 (67.5%) had used at least one method of contraception. The most common method of contraception used previously by parturients was DMPA (44.2%). Interval IUCD was among one of the least used methods (3.3%). Previous interval IUCD use and parturients who had never used contraception were statistically significantly associated with acceptance of PPIUCD ($p < 0.05$).

Table 3: Source of Information for the parturients who were aware of PPIUCD (N=96)

Source	PPIUCD Insertion		Total **N=96**
	Accepted N = 25 n (%)	Declined N = 71 n (%)	n (%)
Antenatal Clinic	17 (68.0)	55 (77.5)	72 (75.0)
Family Planning Clinic	5 (20.0)	9 (12.7)	14 (14.6)
Relative/Friend	3 (12.0)	7 (9.8)	10 (10.4)

A quarter of the parturients were aware of the PPIUCD. Among 96 of the parturients who were aware of PPIUCD, majority (75.0%) had the antenatal clinic as their source of information. None of them had the media (radio, TV or newspapers) as their source of information (Table 3).

Table 4: Reasons for Declining PPIUCD among parturients (N=267)

Reason	**n**	**%**
Prefer to use another method	81	30.3
Satisfied with previous contraceptive method	46	17.2
Need to discuss with my partner	45	16.9
Fear of pain and heavy bleeding	28	10.5
Partner refusal	24	9.0
Don't want contraception immediately	21	7.9
No reason	9	3.4
Not enough knowledge about PPIUCD	6	2.2
Fears cancer	4	1.5
Interferes with sexual intercourse	2	0.7
Religious beliefs	1	0.4

*the percentages are more than 100% as there were multiple responses

A total of 267 parturients (72.5%) declined the use of PPIUCD. Among those parturients who declined the PPIUCD, majority of them were due to their other preferences of other forms of contraception (30.3%). (Table 4)

Table 5: Reasons for Acceptance of PPIUCD among parturients whom IUCD was inserted (N=102)

Reason	n	%
Long term	56	55.0
Safe	36	35.3
Fewer Clinic visits	16	15.7
Non hormonal	12	11.8
No Remembrance once inserted	10	9.8
Reversible	9	8.8
No interference with breast feeding	3	2.9

*the percentages are more than 100% as there were multiple responses

Table 5 shows that more than half (55.0%) of those women who accepted PPIUCD were due to the reason of its long term effect.

Table 6: Parturients preferences for other forms of contraception, among those declining PPIUCD insertion (N=267)

Method	n	%
DMPA	99	37.1
Natural	54	20.2
None	36	13.5
OCP	33	12.4
Interval IUCD	18	6.7
Male condoms	15	5.6
Implants	8	3.0
BTL	4	1.5

The above table shows that among those who declined the PPIUCD majority (37.1%) preferred to use DMPA while the least preferred method was BTL (1.5%).

Table 7: Complications at 4 weeks after PPIUCD insertion (N=94)

Complications	n	%
Expulsion	6	6.4
Lost Strings	5	5.3
Pelvic Infection	3	3.2

Out of 94 parturients who were followed up after PPIUCD was insertion, 14 (15%) developed complications. The commonest complication was expulsion of IUCD (6.4%). There was no parturient who had uterine perforation (Table 7)

CHAPTER FOUR

DISCUSSION

In this study, the proportion of parturients accepting PPIUCD and their socio-demographic and obstetric characteristics was determined. Majority of the women (96.7%) in the study population had at least a primary level of education. Acceptance of the use of PPIUCD was higher among women with secondary education (41.2%), than those with no formal education (3.9%). This could be reasoned out that educated women are high achievers and have greater labor market opportunities than the less educated women. This was similar to a study done in Egypt by Safwat et al where women with no formal education had an acceptance of 9.4% while those with formal education was 19.4%.[11] Education has a positive effect on modern contraceptive use as shown in a study done in Zimbabwe. It was only apparent among women who completed secondary education (12 years or more). Women who completed secondary school were about twice as likely to use modern contraceptive methods as women who did not complete primary education. [21]

The duration since the parturients last child birth was significantly associated with acceptance of PPIUCD. More than a third of the parturients (36.3%) who had the PPIUCD inserted had their last childbirth less than two years ago. This could be explained that women who had a short pregnancy interval to the index pregnancy felt they required a long acting and reliable method of contraception. This also has the added advantage of giving the mother enough time to recover from the physical stress of one pregnancy before moving on to the next and gives enough time for lactation. In a report released by WHO in 2006, healthy timing and spacing of pregnancies has a positive effect on maternal health and newborn outcomes.

Although women with parity greater than five made a small proportion (6.9%) of the study sample when compared to other parity groups, acceptance of the PPIUCD was higher among grand multiparous (41.2%) compared to primiparous (25.2%). Similar findings were reflected in the study done by Safwat et al in Egypt, where 16% of primiparous accepted the use of

PPIUCD compared to one third of grand multiparous.[11] This simply reflects that women with higher parity required long-term contraception.

The common methods of contraception previously used by the study sample were DMPA (29.8%), OCPs (22.5%) and natural methods (19%). All were short term methods. Interval IUCD (3.3%) was among the least used method of contraception but among acceptors of PPIUCD, majority (66.7%) of the women had previously used interval IUCD. This was statistically significant. This could probably be due to the fact that women who had previously used the IUCD had already experienced its favorable effect (i.e. the IUCD was not new to them) and felt comfortable with insertion of the PPIUCD. In the study done by Safwat et al, among the acceptors 49.2% of the women used IUCD in the past. The most widely used modern methods of contraception among all women in Tanzania (DHS 2010) are injectables (9.0%), pills (5.0%) and male condoms (4.0%) while IUCDs (0.4%) are the least used.[10] This similar trend was reflected in this study.

Majority (74%) of the study population were not aware of the PPIUCD. Among women who had the PPIUCD inserted, 68% have ever heard about the PPIUCD from the antenatal clinic. This could be because the PPIUCD is a relatively new method of contraception in this community. In a WHO report released in 2010, on unmet need for family planning, one of the common reasons for non-use of contraception included lack of awareness. Another possible explanation for this would be that only the health care workers in the antenatal clinics and postnatal wards were aware of PPIUCD.

Among women whom PPIUCD was inserted, more than half (55%) accepted due to its long term effect, 35.3% due its safety and 15.7% due to fewer clinic visits. This shows that postpartum women need a contraceptive method which is long acting, safe and convenient.

Among those women who declined the PPIUCD (72.4%), a third of them preferred to use other contraceptive methods (mainly DMPA 37.1% and natural methods, 20.2%); 16.9% of them needed to discuss with their partners and 17.2% were satisfied with previous

contraceptive methods used. In a study done in Egypt, among the 71.1% women who refused the IUCD, planning another pregnancy in the near future (34.3%) was the most common reason followed by preference of interval IUCD (30.2%) and lactational amenorrhoea (9.3%). Complications from previous use of IUCD (9.7%) or absence of husbands (3.4%) were some other reasons. The possible explanation for this would be that these women in our set up lacked awareness of long acting contraceptive methods or were satisfied with previous methods of contraception. Furthermore, contraceptive provision in many Sub-Saharan African countries has relied predominantly on short-term methods, such as oral pills, condoms and injectables which were also reflected in this study.[22]

A significant number of women declined the PPIUCD because of non partner involvement. This reveals the importance of partner involvement during counseling and decision making. Many studies have shown that when the partner is involved in contraceptive counseling and decision making, the acceptance and continuation rates were higher. Unfortunately in our setup women who visit the antenatal clinic are usually not accompanied by their partners and therefore couple counseling is lost during this period. Furthermore, during the short postpartum care partners usually come in contact with their spouses during discharge which is not appropriate for counseling. If the partners fail to agree on the method, or do not know how to use it well, even highly effective method will not be used well. Therefore, this is a good reason for including both partners when helping a couple to choose a contraceptive method which will also increase the compliance. In the Africa postpartum study done by FHI, husbands' desires for IUCD removals was a significant reason for removal, emphasizing the importance of involving the husband in prenatal counseling.[23]

Overall acceptance of PPIUCD was generally good (27.6%) despite a very low usage of the interval IUCD in Tanzania. A plausible explanation of the relatively high acceptance of PPIUCD was the newness of the immediate postpartum IUCD in the community. Across the region, only 2% of users of any contraceptive method use the interval IUCD, in spite of its

low cost and effectiveness.[24] Healthcare providers trained in PPIUCD insertion could be biased to the PPIUCD as they are aware of and are competent to this method.

Majority (37.3%) of the women who were inserted with the PPIUCD had their future pregnancy desire of 3 to 5 years. In a quarter of them the period was more than five years. This was due to its long acting and reversible effect. Eighteen percent of these women wanted to limit their pregnancies but accepted the PPIUCD. The PPIUCD is especially good for women who think they do not want any more children, but want to delay sterilization until they are certain.[25]

It should be noted that there were no serious complications in this study. Expulsion rates of the immediate PPIUCD at 4 weeks interval was 6.4%. This was similar to a multi country study done in Belgium, Chile and Philippines which showed the rate of expulsion at 1 month ranging from 4.6 – 16.0%.[9] Expulsion rate of immediate PPIUCD in a study done in China by Chi et al, 1994, was 25 – 37% while post placental was 9.5 – 12.5%. Expulsion of PPIUCD usually occurs in the first few months after insertion. In a multicenter study done by Tatum et al, the expulsion rates of PPIUCD was similar at one and 12 months in Belgium (4%) and Chile (7%), while in the Philippines expulsion increased from 19% at one month to 28% at 12 months follow up. [26]

In this study, pelvic infection (3.2%) was slightly high compared to a study done in Kenya and Mali which indicated a rate of less than 2%. A study done in Ethiopia revealed that lower genital tract infections are very common among apparently healthy looking pregnant women with an overall prevalence of 40-54%.[27] This higher incidence of untreated reproductive tract infection increases the risk of pelvic infection after immediate PPIUCD insertion.

Five women (5.3%) among those inserted with PPIUCD had lost strings at four weeks. An ultrasound confirmed that the IUCD was in situ. This indicated possible retraction or curling of the strings into the endocervical canal or uterine cavity.[28] Absence of uterine perforation with extremely low rates of expulsion (6.4%), pelvic infection (3.2%) and lost strings (5.3%)

are strong indicators of safety. There were no terminations of PPIUCD on medical grounds (e.g. severe pelvic pain or heavy bleeding).

LIMITATIONS

This study was conducted in a tertiary centre therefore the findings may not adequately reflect the entire Dar es Salaam region.

Lost to follow up as observed in the study was a limitation of the study. This made it difficult to draw a clear conclusion as what happened to those who did not complete their follow up schedule.

CONCLUSION

The acceptance of PPIUCD was high in the parturients studied but comparable to other studies done globally. Awareness of the PPIUCD among these women was very poor despite high acceptance. Majority of the women had heard about the PPIUCD from the antenatal clinics. Parturients who had a short duration from their last child birth (less than 2 years) had greater acceptance of the PPIUCD. Acceptance was higher among women who had previously used the interval IUCD and among those who had never used any form of contraception. These women preferred to use short acting methods of contraception despite a majority of them having their future pregnancy desires of more than three years. The PPIUCD was demonstrably safe, having no reported incidence of perforation with low rates of expulsion, pelvic infection and lost strings.

RECOMMENDATIONS

The provision of PPIUCD is feasible and safe, and can increase contraceptive use in Tanzania.

The education and awareness of PPIUCD should be targeted to all stakeholders including husbands.

It is important to ensure high fundal IUCD placement in order to reduce expulsion rates. It is also important to consider screening for lower genital tract infection among women who accept PPIUCD or give prophylactic antibiotics post insertion.

With the high level of acceptance despite low levels of awareness, the government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange for training on PPIUCD in order to increase knowledge and skills among healthcare providers. This will also further promote PPIUCD use and aid in reduction of the expulsion rates.

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APPENDIX I: INFORMED CONSENT FORM

Thank you for your time and agreeing to listen/read this. My name is Rukiya Abdulwahab M Ali, a postgraduate student in the department of Obstetrics and Gynecology from Muhimbili University of Health and Allied Sciences. I would like to conduct the following study as part of the requirement for fulfillment of my post graduate studies.

Title of the study:

Acceptability and safety of immediate postpartum IUCD insertion in parturients at Muhimbili National Hospital, Dar es Salaam.

Purpose of the study:

The aim of the study being conducted is to assess reasons of acceptance and non-acceptance of immediate postpartum IUCD insertion and its safety. The main focus of this study is to create awareness of postpartum IUCD insertion as one of the methods of postpartum family planning and to evaluate its safety. This will help prevent unwanted and unplanned pregnancies and hence decrease maternal deaths.

What participation involves:

After receiving contraception counseling by well trained counselors you will be required to fill in a questionnaire with the help of the principal investigator or a research assistant which will consume your time from 10 to 15 minutes. Questions will be more directed on your reproductive health history. After counseling if you wish to have a Copper T380A IUCD inserted within 48hours of delivery you will have to be evaluated whether you are eligible or not after fulfilling the inclusion or exclusion criteria. Insertion will be done at a side room near the postnatal ward and assessed immediately of proper placement and a follow up 4 weeks later to check for expulsion of IUCD, pelvic infection, lost strings and perforation.

If you do not wish to have a Copper IUD inserted then reasons will be sought and other method of family planning will be advised.

Risks and discomforts:

No added risk is directly anticipated in this study.

Benefits:

No personal benefits will be gained from participating in this study, but the results may help nurses, midwives and doctors to improve postpartum contraceptive counseling/services, awareness and safety of immediate postpartum IUD insertion.

Confidentiality:

The medical information produced by this study will become part of your hospital record and will be subject to confidentiality. Information of sensitive personal nature will not be part of the medical record, but will be stored in the investigator's research file. If the data are used for publication in the medical literature or for teaching purpose, no names will be used.

Right to participate:

Your participation is voluntary and you may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice. You can have the IUCD removed anytime you wish to.

Injury statement:

In the unlikely event of injury resulting directly from your participation in this study, then appropriate treatment will be provided. No further compensation will be provided by the hospital. By agreeing to participate in this study you will not be waiving any of your legal rights.

Contact person in case of any questions:

If you have any questions about this study you are free to contact the principal investigator Dr. Rukiya Ali, telephone number 0653400413 or email: daktura75@gmail.com.

If you have any questions about your right as a participant, you may call Prof. M. Aboud, Chairman of the Senate Research and Publications Committee, P.O.Box 65001, Dar-es-salaam. Tel 2150302-6.

If you agree to participate in the study, please sign this consent form.

I ……, have read/ have been told about the contents of this form and understood everything explained/written. I therefore agree to participate in the study.

Participant's signature: _____ Date_____

Investigator's signature: _____ Date _____

APPENDIX II: FOMU YA RIDHAA (CONSENT FORM) – SWAHILI VERSION

Asante kwa muda wako na kukubali kusoma hii fomu. Jina langu ni Rukiya Abdulwahab M Ali, na ni daktari kwenye masomo ya uzamili katika idara ya magonjwa ya kina mama kutoka Chuo Kikuu cha Tiba na Sayansi za Jamii Muhimbili.

Madhumuni ya utafiti

Madhumuni ya utafiti huu ni kutazama sababu za akina mama kukubali na kutokubali kuekewa au kutumia kitanzi cha uzazi wa mpango mara tuu baada ya kujifungua. Lengo kuu la utafiti huu ni kujenga ufahamu wa uwepo wa kitanzi cha kizazi baada ya kujifungua kama moja za mbinu ya uzazi wa mpango, na kufanya tathmini ya usalama wake. Hii itasaidia kuzuia mimba zisizotarajiwa na hivyo kupunguza vifo vya wazazi.

Nini ushiriki inahusisha:
Baada ya kupokea ushauri wa uzazi wa mpango utahitajika kujaza dodoso ambao utatumia dakika 10 hadi 15. Maswali ya katika dodoso yatahusikana zaidi na historia ya afya ya uzazi. Baada ya ushauri, na kama unakubali kuwekewa kitanzi katika kipindi cha masaa 48 baada ya kujifungua, utapimwa na daktari kuangalia kama hali yako ya kiafya inaruhusu kuekewa kitanzi hicho.
Baada ya kuekewa kitanzi hicho utahitajika kuonana na daktari baada ya wiki nne kutazama ama kuangalia maendeleo yako.

Kama hupendi kuekewa kitanzi hicho utashauriwa aina nyengine ya mpango wa uzazi.

Hatari na madhara:
Hakuna athari yeyote inaotegemewa kutokana na utafiti huu.

Faida:
Utafiti huu unakusaidia wewe kupata njia ya uzazi wa mpango lakini itasaidia wahudumu wa afya kupata ujuzi zaidi kuhusu matumizi ya kitanzi hiki.

Usiri:

Taarifa zote zinayotokana na utafiti huu zitakuwa ni sehemu ya kumbukumbu za hospitali na zitatunzwa kama siri.

Haki ya kushiriki kwenye utafiti

Uko huru kuchagua kushiriki au kutoshiriki. Uko huru kujibu maswali jinsi utakavyo wewe ili mradi uwe na amani. Kama hutajisikia kujibu maswali uko huru kuacha majadiliano wakati wowote utakaotaka.Kitanzi utachowekewa kinaweza kuondolewa wakati wowote ukitaka.

Kama utapata matatizo yeyote kutokana na ushiriki wako katika utafiti huu, utapewa matibabu sahihi kutoka kwa hospitali kuu ya Muhimbili.

Mawasiliano na mtu katika kesi ya maswali yoyote:

Kama una maswali yoyote kuhusu utafiti huu uwe huru kuwasiliana na mkuu wa uchunguzi Dk Rukiya Ali, simu namba 0653400413 au barua pepe: daktura75@gmail.com. Kama una maswali yoyote kuhusu haki yako kama mshiriki, unaweza wasiliana na Prof M. Aboud, Mwenyekiti wa Utafiti wa Seneti na Kamati ya Machapisho, SLP 65,001, Dar-es-salaam. Tel: 2150302-6

Kama umekubali kushiriki katika utafiti, tafadhali weka saini katika fomu hii ya ridhaa.

Mimi _____, nimesoma / nimeambiwa yaliyomo katika fomu hii na kuelewa kila kitu kilichoelezwa / kilichoandikwa. Kwa hiyo nakubali kushiriki katika utafiti.

Sahihi ya mshiriki : _____ Tarehe_____

Sahihi ya mtafiti: _____ Tarehe_____

Appendix III: QUESTIONNAIRE (ENGLISH VERSION)

Questionnaire to Assess Acceptability of Postpartum IUCD in Parturients at MNH

Interviewer: circle the selected answer(s).Do not read responses.

1. **Identification**

Hospital Registration No: _____

Name: _____

Age: _____

Date: _____

Address: _____

Telephone no: _____

2. **Educational Status:**
   - No formal education
   - Primary
   - Secondary
   - College
   - University

3. **Marital Status:**
   - Single
   - Married
   - Cohabiting/Divorced

4. **Occupation:**
   - Housewife
   - Employed
   - Self employed
   - Other, Specify? _____

5. Religion: Muslim

Christian

Other, Specify? _____

6. Obstetric history:

Gestational Age: _____ (weeks)

Gravidity: _____ (number)

Last Child Birth: _____ (years/months)

Total number of deliveries (pregnancies ended at 28 wks or more) _____

Number of abortions (pregnancies terminated before 28wks) _____

Mode of deliveries: SVD _____

Instrumental (forceps/vacuum) _____

Caesarean section _____

Any history of PPH: Yes _____

No _____

7. Gynecological history:

Menarche _____

Duration of Menstrual bleeding (days) _____

Length of Menstrual cycle _____

Amount of Flow: Heavy _____

Normal _____

Scanty _____

Any history of puerperal or post-abortal PID: Yes _____

No _____

8. Have you heard about family planning? Yes ____

No ____

9. If yes, which methods of contraception are you aware of:

Contraceptive pills_____

Male Condoms _____

Female Condoms _____

LARC – IUCD_____

– Implants_____

– Depot _____

Natural– Withdrawal (Coitus Interruptus)

– Calendar/ Safe days

Spermicidal Agents

Lactational Amenorrhoea (LAM)

Tubal Ligation

None

Others, specify _____

10. Have you ever used any method of family planning in the past?

Yes _____

No _____

11. If yes, which methods of contraception have you used in the past?

Contraceptive pills_____

Male Condoms _____

Female Condoms _____

LARC – IUCD_____

– Implants_____

– Depot _____

Natural– Withdrawal (Coitus Interruptus)

– Calendar/ Safe days

Spermicidal Agents

LAM

None

Others, specify _____

12. Were you on any method of family planning prior to the current pregnancy?

Yes _____

No _____

13. If yes, were you satisfied by the FP method you were using prior to current pregnancy?

Yes _____

No _____

14. Was this pregnancy planned/unplanned?

Planned _____

Unplanned _____

15. Have you heard about PPIUCD insertion?

Yes ____

No ____

16. If yes, how?

From the media (radio, TV, Newspapers)

In the Antenatal Clinic

In the Family Planning Clinic

From a relative/friend

Others, Specify……..

17. Are you interested in insertion of postpartum IUCD insertion?

Yes _____

No _____

18. If no, why?

Don't want contraception immediately (later)

I need to talk to my partner

Prefer to use other methods

Satisfied with the method I was using before

Complications of IUCD e.g. bleeding, pain, expulsion, infections

Husband doesn't want

Religious beliefs

Interferes with sexual intercourse

No knowledge about PPIUD

No particular reason

Others, Specify_____

19. If no, what method of family planning will you prefer?

Contraceptive pills_____

Male Condoms _____

Female Condoms _____

LARC – IUCD_____

– Implants_____

– Depot _____

Natural– Withdrawal (Coitus Interruptus)

– Calendar/ Safe days

Spermicidal Agents

Tubal ligation

LAM

None

Others, specify _____

20. If yes, reasons of preference to PPIUCD

Safe

Long acting method

Reversible method

Don't need to remember once inserted (unlike the pill)

Doesn't interfere with breast feeding

No hormone-related side effects

Fewer routine clinic visits required

Others, specify _____

21. Do you intend to deliver again? YES _____

NO _____

22. If yes, when do you intend to deliver? 1 – 2years

3 – 5 years

After 5 years

Not sure

Appendix IV: SWAHILI VERSION QUESTIONNAIRE

Dodoso Kwa Kukubali Kuekewa Kitanzi Katika Kizazi Mara Tuu Baada Ya Kujifungua Katika Hospitali Kuu Ya Muhimbili

Maelekezo: Zungushia nambari ya jibu litakalotajwa, usisome majibu.

1. **Kitambulisho**

Namba ya usajili:

Jina:

Umri:

Tarehe:

Anwani:

Namba ya simu:

2. **Elimu**
   Sina elimu rasmi
   Msingi
   Sekondari
   Chuo

3. **Hali ya ndoa**
   Sijaolewa
   Nimeolewa
   Nimetengana na mume

4. **Shughuli**
   Mama wa nyumbani
   Nimejiajiri
   Nimeajiriwa
   Nyengine, taja? _____

5. **Dini**
   Mwislamu
   Mkristo
   Mengine, taja? _____

6. Historia Ya Uzazi

Umri wa uja uzito: _____ (wiki)
Mimba ya ngapi: _____(idadi)
Umri wa mtoto wa mwisho: _____ (miaka)
Jumla ya mimba ulizojifungua baada ya wiki 28: _____
Idadi ya mimba ziloharibika kabla ya wiki 28: _____

Namna ya kujifungua: Njia ya kawaida _____
Kusaidiwa kwa mtoto kuvutwa _____
Upasuaji _____

Historia yoyote ya kutokwa na damu nyingi baada ya kujifungua: Ndiyo_____
(iliohitaji kuengezwa damu au maji/drip) Hakuna _____

7. Historia ya hedhi na uambukizi wa kizazi

Kuvunja Ungo: _____
Siku za hedhi:_____
Mzunguko wa hedhi: _____
Wingi wa damu ya hedhi: Nyingi_____
Kawaida _____
Kidogo _____
Historia ya kuambukizwa magojwa ya kujamiana: Ndiyo_____
Hapana _____

8. Je unao fahamu kuhusu uzazi wa mpango? Ndio ____
Hapana ____

9. Kama ndio, taja: Vidonge _____
Kondomu za kiume _____
Kondomu za kike _____
Kitanzi _____
Vipandikizi ____
Sindano _____
Kumwaga nje _____
Siku za usalama _____

Kemikali za kutumbukiza ukeni
Kunyonyesha kuzuia kushika mimba
Kufunga mirija ya kizazi
Hakuna
Nyengine, taja _____

10. Je, ushawahi kutumia njia yoyote za uzazi wa mpango?

Ndio _____
Hapana _____

11. Kama ndio, njia gani za uzazi wa mpango ulizotumia nyuma?

Vidonge _____

Kondomu za kiume _____

Kondomu za kike _____

Kitanzi _____

Vipandikizi ____

Sindano _____

Kumwaga nje _____

Siku za usalama _____

Kunyonyesha kuzuia kushika mimba

Kemikali za kutumbukiza ukeni

Kufunga mirija ya kizazi

Hakuna
Nyengine, taja _____

12. Je, kabla ya mimba hii ulikua unatumia uzazi wa mpango?

Ndio _____
Hapana ___

13. Kama ndio, umeridhika na njia hio?

Ndio _____
Hapana ____

14. Je, uja uzito huu ulipanga?

Nilipanga _____
Bila ya mpango _____

15. Je, umewahi kusikia kuhusu kitanzi kinachowekwa mara tuu baada ya kujifungua?

Ndio _____
Hapana ____

16. Kama ndio, ulisikia wapi?

Kutoka kwenye viombo vya habari
Katika kliniki ya waja wazito
Katika kliniki ya Uzazi wa Mpango
Kutoka kwa rafiki/jamaa
Wengeni, taja _____

17. Je, utaridhika kuwekewa kitanzi mara tuu baada ya kujifungua?

Ndio _____
Hapana _____

18. Ikiwa hapana, sababu?

Sipendi kuzuia mimba kwa sasa
Nataka kushauriana na mwenzangu
Napenda kutumia mbinu nyengine
Nimeridhishwa na utaratibu niliokuwa nikitumia kabla

Naogopa maumivu, kutokwa na damu nyingi

Mume wangu hataki

Dini yangu hairuhusu

Huathiri tendo la ngono

Sina ufahamu kuhusu kitanzi hiki

Hakuna sababu
Nyengine, taja _____

19. Ikiwa hapana, unatarajia kutumia uzazi wa mpango gani?

Vidonge _____

Kondomu za kiume _____

Kondomu za kike _____

Kitanzi _____

Vipandikizi ____

Sindano _____

Kumwaga nje _____

Siku za usalama _____

Kemikali za kutumbukiza ukeni

Kufunga mirija ya kizazi

Kunyonyesha kuzuia kushika mimba

Hakuna

Nyengine, taja _____

20. Ikiwa ndio, toa sababu za kupendelea kutumia kitanzi kinachowekwa mara baada ya kujifungua

Ni salama

Kinafanya kazi kwa mda mrefu

Ukitoa kitanzi unaweza kushika mimba bila shida

Huna haja ya kukumbuka ukisha wekewa (tofauti na vidonge)

Haina madhara kwa konyonyesha

Haina matatizo ya homoni

Hakuna haja ya kurudi kliniki mara kwa mara

Nyengine, taja _____

21. Je, unataraji kushika mimba nyengine baadae?

Ndio _____

Hapana _____

22. Kama ndio, lini unatarajia kubeba mimba tena?

1 – 2 miaka

3 – 5 miaka

Baada ya miaka 5

Sina uhakika

Appendix V: CHECKLIST BEFORE PPIUD INSERTION

Serial No: _____

IDENTIFICATION

Hospital Registration No: _____

Name: _____

Age: _____

Date: _____

Address: _____

COUNSELLING PROVIDED: Antenatally _____

Immediate Postpartum _____

ANY RISK OF STI?

ANY H/O OF DM, VALVULAR HEART DIS.or COAGULOPATHIES?

WRITTEN CONSENT _____

LABOUR ONSET Spontaneous _____

Induced _____

RUPTURE OF MEMBRANES: Time _____

Artificial _____

Spontaneous _____

Liqour state(C/M) _____

DURATION OF LABOUR (after rupture of membranes) _____ hours

THIRD STAGE OF LABOUR (amount of blood loss)	<500ml _____
	>500ml _____
TOTAL DURATION OF LABOUR	_____ hours
BODY TEMPERATURE	_____ ^{0}C
EQUIPMENTS	Sterile gloves _____
	Sterile drapes _____
	Sterile guaze _____
	Povidone iodine _____
	Cu T 380A IUCD _____
	Sponge holding forceps _____
	Sims Speculum _____
IMMEDIATE COMPLICATIONS (YES/NO)	Severe Abdominal cramps _____
(before discharge)	Heavy P/V bleeding _____
	Pyrexia _____
	Perforation _____
	Expulsion_____

Appendix VI: FOLLOW UP CHECK LIST

Serial No:

Date of IUD insertion:

Follow up	**4 WEEKS**
Date of visit	
Duration from insertion	
Duration of blood flow	
Lower abdominal pain	
Pyrexia	
Foul vaginal discharge	
Can you feel the strings?	
Suprapubic tenderness	
Uterus involuted	
State of cervix	
Perforation	
IUD Strings visualized	
IUCD expulsion	
Cervical excitation test	
Are you satisfied with the PPIUCD?	

Appendix VII: PPIUCD Follow up Card

POSTPARTUM IUCD CARD

NAME	
REG NO	
TYPE OF IUCD	
DATE OF INSERTION	
DATE OF REMOVAL/REPLACEMENT	
DATE OF POSTPARTUM FOLLOW UP VISIT	

INCASE OF ANY PROBLEM/QUESTION
CALL DR RUKIYA ALI – 0653400413

Please return to Muhimbili National Hospital when you develop the following;

- Missed periods
- Excessive vaginal bleeding which is not normal
- Excessive abdominal pain
- Abnormal vaginal discharge (foul smelling, increased amount, discoloured)
- Fever or chills
- Lost strings

Appendix VIII: FOLLOW UP CARD (SWAHILI VERSION)

KADI YA MTEJA WA KITANZI

JINA	
NAMBA YA USAJILI	
AINA YA KITANZI	
TAREHE YA KUEKA KITANZI	
TAREHE YA KURUDI KUTOA KITANZI	
TAREHE YA KURUDI MARA PILI KWA UANGALIZI	

KAMA UNA TATIZO LOLOTE AU SWALI PIGA SIMU

NAMBA YA DK RUKIYA ALI 0653400413

Rudi kwa Hospitali kuu ya Muhimbili wakati wowote utakapoona zifuatazo:

- Ukikosa/kuvuka siku za hedhi
- Kutoka damu kusiko kawaida
- Maumivu ya tumbo
- Kutoka maji ukeni kusiko kawaida (Mengi, Harufu mbaya, Yenye rangi)
- Haujiskii vizuri, homa au baridi kali
- Kama ukihisi uzi umepotea