COMPARISON OF THE EXPULSION RATE OF INTRA UTERINE CONTRACEPTIVE DEVICE Cu 375 AND Cu T 380A AFTER POST PLACENTAL & EARLY POSTPARTUM INSERTION - A RANDOMIZED CONTROL TRIAL

THESIS

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AIIMS, JODHPUR

DECLARATION

I hereby declare that the thesis titled "**Comparison of the expulsion rate of Intrauterine contraceptive device Cu 375 and Cu T 380A after post placental & early postpartum insertion - A randomized control trial**" embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled "**Comparison of the expulsion rate of Intrauterine contraceptive device Cu 375 and Cu T 380A after post placental & early postpartum insertion - A randomized control trial**" is the bonafide work of **Dr.Nitesh C**, in the Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, Jodhpur.

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LIST OF ABBREVIATIONS	
AOR	Adjusted Odd's Ratio
CTRI	Clinical Trial Registry of India
CI	Confidence Interval
CPR	Contraceptive Prevalence Rate
EPI	Early postpartum insertion
GoI	Government of India
IEC	Information, Education, Communication
IIUD	Interval Intrauterine Device
ITA	Intention to treat
IUCD	Intrauterine contraceptive device
IUD	Intra Uterine Device
JSSY	Janani Shishu Suraksha Yojna
LARC	Long Acting Reversible Contraception
LNG	Levonorgestrel
NFHS	National Family Health Survey
PID	Pelvic inflammatory disease
PPA	Per Protocol Analysis
PPH	Post-Partum Hemorrhage
PPI	Post placental insertion
PPIUCD	Postpartum intrauterine contraceptive device
SD	Standard Deviation
SNOSE	Sequentially Numbered, Opaque, Sealed Envelope
SPSS	Statistical Package of the Social Sciences

TFR	Total Fertility rate
UNFPA	United Nations Population Fund
USG	Ultrasonography
WHO	World Health Organization

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SUMMARY OF THE PROJECT

Background:

Postpartum Intrauterine Contraceptive device (PPIUCD) placement provides safe and highly effective contraception at a time when women are accessing the medical care. However, the type and phenotype of IUCD like T shaped Cu T 380A or horseshoe-shaped Cu 375 with serrated edges have a role in increasing or decreasing the expulsion rate is still not proved. This study was therefore conceived with the aim to do a randomized control trial on these two types of IUCDs which are both supplied under family planning programs, and compare their expulsion rates at six weeks after post-delivery insertion.

Primary objective:

The primary objective was to see for the expulsion rates of both the types of Copper IUCDs (Cu 375 & CuT 380A) within or at 6 weeks after insertion.

Secondary objectives: These were to look for the expulsion rate of Cu IUCDS with the mode of delivery and timing of insertion and also to compare the complication rate between the two groups.

Methods:

It was a randomized control trial. A total of 396 pregnant women who delivered in our institute were recruited between March 2020 to August 2021. Out of these, 200 participants received Cu 375 and 196 participants received CuT 380A. Ultrasonography was done to look for the position of the IUCD at the time of discharge and at six weeks follow-up. Statistical analysis was done using the Independent samples *t*-test and Pearson Chi-square (χ^2) test, apart from mean, standard deviation and percentages for discrete variables.

Results:

Out of 396 participants, 365 participants were followed both clinically and telephonically. The attrition rate was 7.07% (28) due to COVID pandemic; three discontinued the study in the middle of the intervention. Overall, 22 PPIUCDs got expelled completely out of 365 acceptors who were followed at 6 weeks (modified intention to treat analysis [ITA]), 10 in the Cu 375

group (5.3%) and 12 in the CuT 380A group (6.7%) making an overall expulsion rate of 6.02%. The expulsion rate is more in the CuT 380A group as compared to Cu 375 group but this difference was not statistically significant.

When sonologically assessed partial expulsions were also considered, the overall total expulsion rate in both the groups (14.3% and 14.1% respectively by modified ITA and 15.5% and 16.4% by per protocol analysis) was found to be comparable.

As far as secondary outcomes are concerned, the expulsion rate was more in the vaginal delivery group (10.7%) than in the caesarean section (3.6%) group with a statistically significant difference (P=0.007).

Also, the expulsion rate was more in the early postpartum insertion group 12.3% than in the post placental insertion group 3.7% which was statistically significant (P= 0.002). The complication rate in both the groups of Cu IUD was comparable in terms of abdominal cramps, prolonged bleeding or spotting and missing CuT threads.

Conclusions:

The study concluded that the horseshoe shape of Cu 375 with serrated edges has effectively no role in decreasing the expulsion rate. The timing of insertion has an impact on the expulsion rates. Expulsion rates were significantly less if PPIUCD was inserted within 10 minutes of placental delivery because it is convenient for high fundal placement of IUCD with less discomfort to participants. In the early postpartum period (between 10 minutes and 48 hours) the uterus has more time for involution which makes it difficult for high fundal placement of IUCD. In the cesarean section, IUCD is inserted under vision directly into the fundus, hence high fundal placement of IUCD was achieved more in cesarean section than in vaginal delivery.

INTRODUCTION

Next to China, India is the second most populous country in the world with a current population of over 1.32 billion. The population curve is one which indicates a rising trend. Therefore, Family planning is a crucial area of concern not only for population stabilization, but also for improving maternal and new-born survival and health.

India has achieved a significant reduction in maternal mortality ratio, but it still contributes one- fifth of global maternal deaths, according to a 2017 World Bank, UNFPA, WHO report. Family planning can avert more than 30% of maternal deaths and 10% of child mortality if couples space their pregnancies more than two years apart. [(1)]

In 1952, the Government of India (GoI), in a first of its kind, launched a National Programme for Family Planning & this has evolved over the years with a shift in focus from merely population control to more critical issues of saving the lives and improving the health of mothers and new-borns. [(2)]

The aim of the Family planning programme is providing information to the couple for their unmet needs through a cafeteria approach so as to make an informed decision about what suits them the best. According to the National Family Health Survey (NFHS-4), the contraceptive prevalence rate (CPR) was 54 per cent in the currently married women aged 15-49 years.

Almost half (48%) of the currently married women used a modern method of contraception. However, only 15 per cent of those aged 15-19 years used a contraceptive method with hardly 10 per cent utilizing a modern contraceptive method. Among the sexually active, unmarried women aged 15-49, about one-third (34%) used a contraceptive method and almost all of them (32%) used a modern contraceptive method. [(3)]

Figure 1 shows the different contraceptive methods used by women of reproductive years as per NFHS-4.

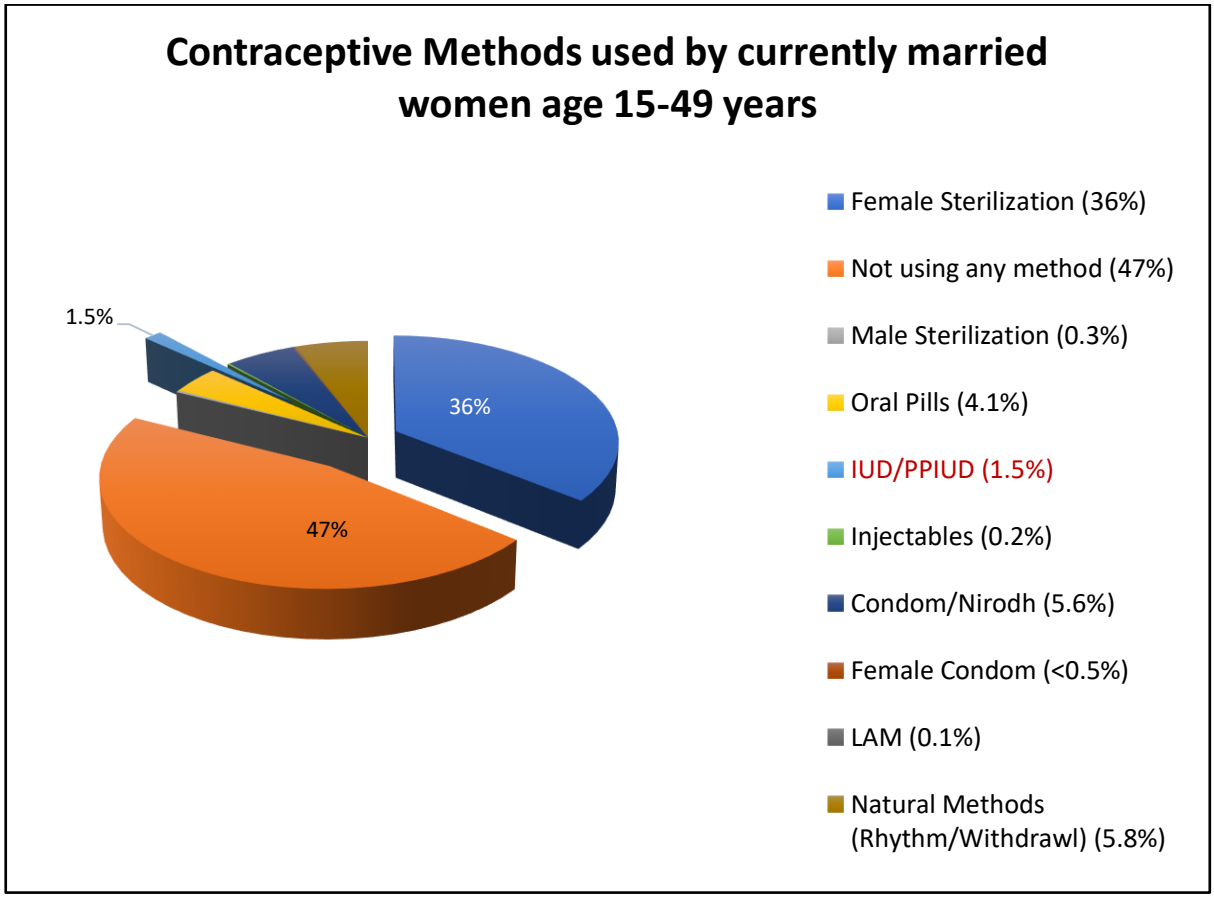

Figure 1: Contraceptive Methods used by currently married women age 15-49 years (NFHS-4)

In developing countries, follow up after delivery is almost unheard of. Hence, it is better to sensitize the women to contraceptive choices at the time of delivery. This concept led to the origin of post-partum contraceptive services & is continuously being evolved.

The last trimester of pregnancy is the best period of counselling, when the woman is the most receptive or in the immediate post-partum period. In India, discussing contraception is still a taboo. The purpose of discussing it antenatally is to make the woman aware of the available alternatives and also to avoid delay in discussing the issues at the last moment with other family members.

Among all post-partum contraceptive methods, intrauterine contraceptive device (IUCD) during the immediate postpartum period is a safe and effective method for spacing and limiting births. It provides advantages of easy insertion and, bleeding if any gets masked with the lochia of pregnancy. [4,5]

Rationale for Postpartum Family Planning

1. Ensuring healthy spacing between births
2. High unmet need for birth spacing
3. High chances of accidental or unplanned pregnancy
4. High acceptability and receptivity for various methods of contraception
5. Increased access to services

Globally, IUCD is a preferred method for birth control for 8.4% of couples. Utilization rates are undoubtedly inhomogeneous from country to country as IUCD use is high (8.6 %) in resource poor countries and low (7.2%) in more developed countries. [6]

In 2010, postpartum IUCD (PPIUCD) service was introduced in facilities with high case-load of deliveries. From 2010 till now, postpartum IUCD services are being hiked in a phased manner throughout the country. In 2012, the Cu IUCD 375 was introduced so that women could choose between Cu IUCD 380A with an efficacy of 10 years and Cu IUCD 375 of 5 years. [3]

Types of IUCD

There are three categories of IUCDs: Unmedicated (inert) IUCDs, Copper IUCDs and Progestin-releasing IUCDs.

Unmedicated (inert) IUCDs or Lippes Loop are inert devices made of polyethylene or other polymers, that appear in different shapes and sizes i.e. loops, spirals, coils, rings and bows. These are obsolete now. (Figure 2a)

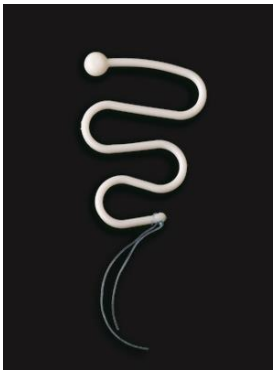

Figure 2a- Lippe's loop

he Cu T 380A (Paragard®) contains a T-shaped polyethylene frame with 380 A (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 round structure at the base of the stem to decrease the risk of uterine perforation. A white or transparent polyethylene monofilament string is knotted through this round ball like structure. Barium sulfate in the frame makes it radio opaque. All copper-containing IUCDs have a number as part of their name, which represents the surface area of copper (in square millimeters). The device is latex-free and clinically significant allergy to copper is an exceptionally rare complication. (Figure 2b)

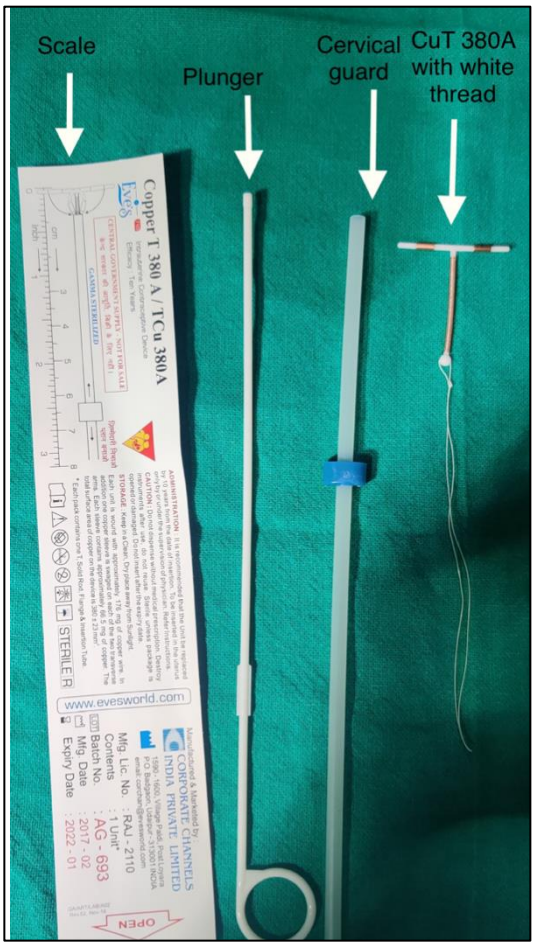

Figure 2b: Cu T 380A IUCD

Cu 375 IUCD is a horse shoe shaped device (Figure 2c)

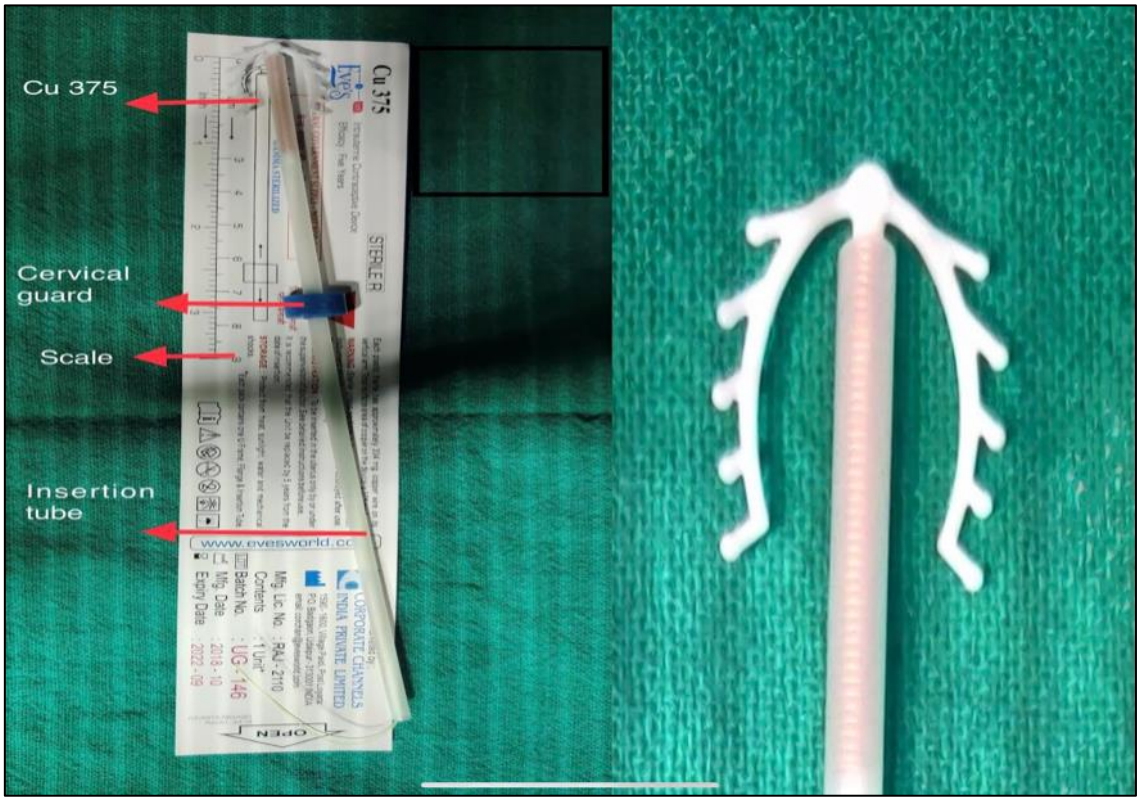

Figure 2c: Cu 375 IUCD

The difference between the two types of Cu-IUCD is shown in Table 1.

Table 1: Difference between Copper IUCD 380 A and Copper IUCD 375 [3]

Features	**Cu IUCD 380A**	**Cu IUCD 375**
Shape	T shaped device	Horse shoe shaped flexible arm
Material	Polyethylene impregnated with barium sulfate	Polyethylene impregnated with barium sulfate
Dimensions	3.6 cm long and 3.2 cm wide	3.5 cm long and 1.8 cm wide and 5 stubs on each side on the "U"
Copper bands/ Wire	Vertical stem and horizontal arms are wound with copper wire	Only vertical stem is wound with copper wire
Surface Area of Copper	380 sq. mm	375 sq. mm
Material of strings	Thin polyethylene strings	Monofilament nylon threads
Colour of string	White	Greyish green
Effectiveness Contraceptive	10 years from the day of insertion	5 years from the day of insertion
Content in the sterile packet	1. Cu IUCD 380 A 2. Insertion tube –Clear tube to guide the loaded IUCD through the cervical os into the uterus 3. Cervical guard/depth gauge on insertion tube – To set the appropriate measurement of the insertion tube corresponding to the length of uterus and to ensure that the arms of the T unfold in the proper direction (horizontal plane) when they are released from the insertion tube. 4. Measurement insert - It is used to set the blue length gauge to the appropriate measurement, obtained by sounding the uterus. 5. Plunger rod – White rod, which is put inside the insertion tube containing loaded IUCD and the tip of the rod remains just below the IUCD. The rod is held stationary while the insertion tube is pulled back to release the IUCD into the uterus (withdrawal technique)	1. Cu IUCD 375 2. Insertion tube – Clear tube to guide the IUCD through the cervical os into the uterus 3. Cervical guard/depth gauge on insertion tube – To set the appropriate measurement of the insertion tube corresponding to the length of uterus and to ensure that the IUCD is inserted as high in the fundus as possible without perforating the uterine wall. 4. Measurement insert – It is used to set the blue length gauge to the appropriate measurement, obtained by sounding the uterus.

Mechanism of Action of Copper-bearing IUCDs

Copper IUCD causes prevention of fertilization through a spermicidal type of cytotoxic inflammatory reaction. [7] In copper IUD users sperm motility is significantly inhibited by the high copper concentration in cervical mucus [8] Additionally, copper ions also result in considerable endometrial changes and thereby, affecting the sperm migration, quality and viability at the level of the endometrium. The primary mechanism by which the copper IUD provides contraception is this change in the endometrium milieu. [9]

However, evidence also suggests that the copper IUD also works by impairing implantation. This is why, placing a copper IUD, even in the early luteal phase, provides effective emergency contraception. [10]

Contraceptive Effectiveness

The Cu IUD is effective as soon as it is inserted. It is one of the most effective and long-acting reversible contraceptive methods (LARC) and its efficacy rates are comparable to female sterilization and male sterilization

.

Effective Lifespan

The Cu IUD 380A is effective for ten years and Cu IUD 375 is effective for five years of continuous use.

Removal or Replacement

♦ The Cu IUD needs to be replaced or removed once the full lifespan of IUD (ten years in case of Cu IUD 380A and five years in case of Cu IUD 375) is over, from the date of insertion.

♦ However, these can be removed any time when the woman wants, even before it reaches the date of expiry.

Return to Fertility

The woman's fertility returns promptly after an IUD is removed. [11] They should have another IUD inserted immediately after removal (if desired and appropriate) or immediately start another backup contraceptive method unless pregnancy is desired.

Advantages of Cu IUCD

♦ Offers long-lasting, highly effective reversible protection against pregnancy
♦ Is effective immediately after insertion
♦ Suitable for use by most women
♦ Can be used as an emergency contraceptive if inserted within five days of the first act of unprotected sexual intercourse
♦ It can be replaced, without any gap, as many times as desired, during the reproductive span
♦ Doesn't require special instructions regarding sexual intercourse or daily checking
♦ It's an outpatient (OPD) procedure and is cost effective
♦ Can be used by lactating women
♦ Does not have any drug interactions
♦ Prompt return of fertility is a crucial advantage

IUCD provides protection against ectopic pregnancy, thereby reducing the incidence of ectopic pregnancy in Cu IUCD users by 90% as compared to women using no contraceptives. If, however, a pregnancy occurs with an IUCD in place, there is a relatively high ratio of ectopic to intrauterine pregnancies, with approximately 6% of pregnancies among copper IUD users being ectopic. [12]

If an intrauterine pregnancy occurs with an IUCD in situ, the spontaneous abortion rate is estimated to be 40%–50%. If the pregnancy is continued and the strings are visible, removal can be attempted if it can be done without any uterine instrumentation. If the IUCD is successfully removed, the rate of spontaneous abortion is lowered to 20%. There is no evidence to support an increased risk of teratogenesis to infants born to women with an IUD in situ. [11]

Efficacy:

The failure rate is more in the first year after insertion. The pregnancy rate, both intrauterine and ectopic pregnancies, for the first year of use is low, between 0.5 and 1.0 per 100 women. [13-15] A large multinational study was conducted by the World Health Organization which reported that after 12 years of use, the cumulative pregnancy rate for the Copper T-380A was 2.2 per 100 women. [15]

Reasons for Contraception failure:

Failure of IUCD can be attributed to various reasons like abnormal uterine anatomy, intramural or sub-mucous fibroid and improper technique of insertion. However, in several studies, the efficiency of contraception is not altered by parity, uterine position and uterine size. [16,17] But malpositioned Cu IUD within the lower uterine segment or at the level of cervix increases the likelihood of contraceptive failure.

Contraindication for copper T

The contraindications for the use of Cu IUD include pelvic infections, pregnancy, uterine factors like submucous fibroid displacing the endometrial cavity or uterine malformations, gynecologic malignancies and history of adverse allergic reactions to copper.

Acceptability:

IUDs do not interfere with sexual intercourse, do not have cross reactions with drugs, have prompt return of fertility and they are not subject to forgetfulness or changes in medical supply. Hormone-related side effects & effect on lactation are nil. There is also no evidence to suggest that the copper IUDs are associated with weight gain, altered libido or mood changes. [18,19]

Cu IUDs as Postpartum Contraception

IUDs are a particularly useful method of birth spacing in situations especially where access to health care may be limited, as the contraceptive effect may last from 5 to 12 years depending on the type. Short birth-to-pregnancy intervals (18 months) are associated with poor perinatal outcomes like low birth weight, preterm birth, small-for-gestational-age, increased risk of neonatal and infant mortality and maternal health. [20] Thus, women and their children may benefit from improved access to immediate postpartum contraception, particularly to LARCs (long acting reversible contraceptives) such as intrauterine devices (IUDs).

Moreover, institutional (Hospital) deliveries are opted for by most women in developing countries nowadays. Women welcome an opportunity to delay their next pregnancy. The institutional delivery provides this convenient opportunity for the woman to receive IUCD services. This is particularly important for those who have limited access to medical care. Having just given birth, the woman may be extremely motivated to consider long-acting

methods. Further, this averts another visit for contraception to the health facility & thus has economic benefits too.

Based on the **timing of IUCD insertion** following delivery, IUCDs are classified into

1. Post placental
2. Early Post-partum
3. Intra caesarean.

The ***post placental IUCD*** (PPIUCD) insertion is done within ten minutes after expulsion of the placenta, following a vaginal delivery.

The ***early postpartum IUCD*** insertion is done after the post placental period, but within 48 hours of delivery and

The ***intra caesarean IUCD*** insertion is when the insertion takes place following a caesarean delivery, before the uterine incision is sutured. (Table 2) shows the basic differences between the different timings of insertion.

Table 2: Classification of PPIUCD according to the timing of insertion

Delivery type	**Type of insertion**	**Timing of Insertion**	**Method of Insertion**
Vaginal	Post placental	Within 10 min of placental delivery	High fundal placement in uterus is ensured by long curved Kelly forceps.
	Immediately postpartum	Between 10 min and 48 hours after placental delivery	The method of insertion is the same
	After 48 hours	>48 hours after delivery of placenta	Not recommended due to increased risks of complications
Caesarean	Intra operative/ Intra caesarean	Following delivery of placenta	Insertion is under direct vision through the uterine incision. Can be performed manually or using instruments

Post-partum insertion of Cu IUCDs is safe, convenient and can be inserted in the uterine cavity within 48 hours of delivery. Post-placental intrauterine Cu IUD insertions do not adversely affect the involution of uterus nor do they inadeptly multiply the risk of bleeding, sepsis, endometritis and uterine perforation. PPIUCD has no interference with breast-feeding and postpartum visit follow-up rates are low.

However, despite so many advantages, the expulsion rate of these IUCDs is variable, ranging from 3.6% to as high as 15 %. [21-27] When replacement IUCDs are not easily accessible, expulsions may compromise effectiveness. However, because many postpartum women do not return for a postpartum visit, therefore, the benefit of placing an IUD immediately or soon after delivery often outweighs the risk of expulsion. Government of India introduced Multiload Cu 375 and Cu 375 IUD in family welfare program which are a horse shoe shaped devices that come with lateral flexible plastic and serrated fins, to minimize the expulsion. [28]

Presently there is very limited data available on the clinical outcome of PPIUCD insertion comparing the CuT380A and Cu 375 IUD. Most of the studies are on CuT 380A and only few have compared the outcome (expulsion) with that of Cu 375 IUD or (multiload) with a slightly variable shape. Moreover, most of the studies are observational studies. Therefore, present study was planned as a randomized control trial to evaluate and compare the expulsion and continuation rates of CuT380A and Cu 375 inserted in the postpartum period.

At the same time, our study also aimed to evaluate and compare the continuation and expulsion rates in cases of different timings of insertion i.e. post placental and early post-partum insertion of Cu IUCDs and also to identify the factors affecting the expulsion rates.

AIM AND OBJECTIVES

AIM OF STUDY:

To estimate the difference in expulsion rates among women with postpartum intrauterine contraceptive device placement by Cu IUCD types, timing of insertion and delivery method.

OBJECTIVES:

PRIMARY OBJECTIVE:

To see for expulsion rates of both the types of Copper IUCDs (Cu 375 & Cu T380A) within/at 6 weeks of insertion.

SECONDARY OBJECTIVE:

1. To look for any difference in the expulsion rate of Cu IUCDs inserted after vaginal delivery and after caesarean section within/at 6 weeks.
2. To look for any difference in the expulsion rate of Cu IUCDs inserted post placental or early post-partum i.e. (within 48 hours of delivery) during 6 weeks follow up.
3. To see for the complications like pain, irregular bleeding or spotting per vagina, perforation, missing copper T threads or Pelvic inflammatory disease.

REVIEW OF LITERATURE

History

Tracing the history of contraception, stones were placed into the uteri of camels to prevent pregnancy during long treks across the sand dunes. This may represent the first ideation of intrauterine contraception. [29] The placement of contraceptive devices in the uterus to prevent pregnancy was first documented in scientific literature in the early 1900s. [30] Early intrauterine products started out as a metal ring with catgut or silk tied around the ring, and then evolved into variously shaped products that required the uterus to configure around the device. [29]

In the pre-World War II era, birth control was not only unpopular but was also considered against the law in many countries and led to the arrest of some of the originators of the IUD, including Dr. Grafenberg, Germany and Dr. Ota, Japan. [30]

In the 1960s there was evolution of the Modern-day intrauterine devices (IUDs) primarily in the form of inert, plastic IUDs- they were available in a wide variety of shapes and sizes including the Lippes Loop, Margulies Spiral, and SAf-T-Coil. In the mid-1970s and mid-1980s the newest IUD, the Dalkon Shield (A. H. Robins Company, Richmond, VA), became popular among physicians. This IUD later lost its prominence following reports of associated reproductive health problems (septic miscarriages, pelvic inflammatory disease), negative media reporting surrounding the device, and numerous legal issues. [29]

The development of the T-shaped product, which was a model that adjusted better to the natural shape of the uterus & further came with the addition of copper to the plastic device-improved contraceptive efficacy. The size was made smaller, which improved the ease of insertion and decreased some of its untoward side effects. The Cu T 380A or Cu 375 are now considered the best alternative to surgical sterilization for those who require long term pregnancy protection.

Post-placental IUCD insertion using Cu T 380A or Cu 375 is provided free of cost by the Government of India. The additional follow up visit is made to coincide with the newborn. It avoids outpatient service charges and transportation expenses & is thus cost effective.

The national family health survey (NFHS-3) documented that approximately 22% of couples required family planning services with 61% of women having the next child within a period shorter than three years indicating inadequate spacing. As per NFHS-4, TFR for India was

2.2. The NFHS-4 Survey showed 53.5% use of Contraceptives among married women (aged 15-49 years) and prevalence of modern method 47.8%. [2]

With the Government working specifically in this field, the data has been highly influenced. Presently, as per NFHS 5, the unmet need for spacing is only 5.7 %.

Post-Partum IUCD

Postpartum family planning is a prevention of unintended and closely spaced pregnancies in the first 12 months after delivery. There is a high chance of having unplanned pregnancy during the postpartum period, leading to adverse outcomes like abortion, premature labor, postpartum hemorrhage, low birth weight baby, fetal loss and maternal death. [31]

As per World Health Organization (WHO) recommendations, birth to pregnancy interval should be at least 24 months, [32] since short birth intervals are associated with adverse pregnancy outcomes.

Celen S *et al* [33] **(2004)** studied on the clinical outcomes of early post placental insertion of intrauterine contraceptive devices with the aim to assess the safety, efficacy, advantages and disadvantages of PPIUCD. Following both normal vaginal and caesarean deliveries, the Cu T was inserted via ring forceps within 10 minutes after removing the placenta along with its membranes in toto. Among the recipients, 74% delivered vaginally while 26% underwent caesarean sections. The acceptors were followed up before their discharge from the hospital and subsequently at 6 weeks, 6 months and one year respectively. 87.6% and 76.3% participants continued Cu T at the end of 6 months and one year respectively. The expulsion rate at the end of one year was 12.3%. Based on this study, it was concluded that the Cu T 380 A is a safe, effective and convenient method of contraception during the postpartum period.

Acceptance of PPIUCD

Numerous factors could contribute to low acceptance and utilization of immediate PPIUCD. **Hauck B *et al*** [34] **(2015) & Sharma A *et al*** [35] **(2017)** highlighted that poor awareness about the method, lack of trained providers, preference of short-acting contraceptive methods, spousal opposition and fears of complication were the main reasons for not accepting PPIUCD use.

Gebremedhin M *et al* [36] **(2021)** did a cross-sectional study on 452 participants and observed that 161 (35.6%) of the study participants accepted immediate PPIUCD (at 95% CI (31.0, 39.6)]. Multiparty (AOR = 2.33, 95% CI, [1.29, 4.20]), completed antenatal follow up (AOR = 3.65, 95% CI, [2.22, 5.99]), counselling (AOR= 8.38, 95% CI, [4.85, 14.48]) and prior discussion (AOR=2.57, 95% CI, [1.51, 4.36]) were the statistically significant predictors for better acceptance of this contraception.

They concluded that even though 58% of the mothers were counselled about PPIUCD during the important cascade of pregnancy and 53% of the mothers completed the antenatal service. Efforts are needed to improve antenatal care services and integrate counselling services through the whole cascade of pregnancy.

Gonie A *et al* [37] **(2018)** in their facility based cross-sectional study observed that the acceptance rate of PPIUCD immediately after delivery was 12.4%. Reasons stated for not accepting this method of contraception were the fear of complications and side effects related to IUCD (24.8%), myths or false beliefs (19.8%) and family or rather husband's denial (17.7%). Educated women accepted IUCD positively as compared to those without any formal education (AOR = 3, CI = 11.81, 53.91). Moreover, the acceptance rate was more among the booked cases as compared to the unbooked cases (AOR = 1.81, CI = 0.34, 0.85)

Geda YF *et al* [38] **(2021)** described in their study that PPIUCD utilization by working women was more as compared to the housewives. Respondents who had discussed postpartum family planning with their partners were 1.21 times more likely to utilize PPIUCD compared to those who never discussed it. On the contrary, 81% of respondents who needed partner approval were less likely to utilize PPIUCD compared to those who didn't need approval. Respondents who had been counselled about PPIUCD were 1.13 times (AOR = 1.13, 95%CI: 1.10, 2.21) more likely to utilize PPIUCD compared to those who were not counselled. Similarly, respondents who had good knowledge about PPIUCD were 7.50 times more likely to utilize PPIUCD compared to those who had poor knowledge.

In the study by **Muganyizi PS *et al*** [39] **(2018)**, it was noticed that out of 40,470 deliveries, PPIUD insertions were 5.8% (n=2347) and 43.2% (n=1013) women with a PPIUD returned for a follow-up visit. Midwives were the providers in 596 (58.8%) of these follow-up cases and clinicians in 417 (41.2%) cases. All PPIUD insertions by midwives were following vaginal delivery and amongst them, 43 (7.2%) had PPIUD-related complications by the end

of the sixth week. These complications included 16 (2.7%) cases of uterine infection, 14 (2.3%) IUD expulsions, 26 (4.4%) IUD removals, and 33 (5.5%) with overall method discontinuation.

Kanakuze CA et al [40] **(2020)** studied the prevalence and factors associated with the uptake of PPIUCD among postpartum women. They observed that the overall uptake of PPIUCD was 28.1% and the women who had spontaneous vaginal delivery were more likely to take up PPIUCD (Adjusted Odds Ratio (AOR) 2.623, 95% CI = 2.017–6.507 compared to those who had cesarean section; women who received PPIUCD counselling during the antenatal period were more likely to use PPIUCD ((AOR 2.072, 95% CI = 1.018–4.218) as compared to those who didn't receive any form of counselling; mothers who received spouse approval were more likely to use PPIUCD (AOR 2.591,95% CI = 1.485–4.492); as compared to those who didn't receive any spousal approval; women who had more than one child were more likely to use PPIUCD (AOR =2.265, 95% CI = 1.472–3.163) as compared to primi gravida.

Expulsion of PPIUCD

Dewan R *et al* [41] **(2017)** studied the clinical relevance of missing Copper-T string after post placental insertion of copper T 380 A and perception about missing Copper T string. The expulsion rate of Copper-T 380A for 1 year was calculated to be 2.3 % (8 cases expelled out of a total of 348 cases)

Gupta G *et al* [42] **(2014)** studied about the post placental insertion of CuT 380A using Kelly's forceps in normal vaginal delivery and analyzed the benefits and complications of PPIUCD. The expulsion rate was (14.3% at 6 weeks POG). However, there was no incidence of perforation or PID and the failure of contraception was at 6 weeks. Percentage satisfaction among users after 6 weeks was 91.7 %, at 3 months 92.9 % and at 6 months was 95.6 %.

Yadav V *et al* [43] **(2017)** studied and compared the two key outcomes of PPIUCD insertions expulsion and infection. In their study, 792 expulsion and 382 infection cases were seen out of 1041 cases. The expulsion rate was very high.

Singal S *et al* [44] **(2012)** in their study described the post placental Copper T 380A insertion in primiparous women undergoing caesarean section. Among 300 primiparous women who underwent postpartum intra caesarean insertion of Copper T 380A, the cumulative expulsion, removal, failure and continuation rates of IUCD were 5.33%, 7%, 0.67% and 91%, respectively.

Kumar S *et al* [25] **(2014)** conducted a large multicentric trial on post-partum Cu T use in an Indian scenario and observed an expulsion rate of only 3.6% with a high level of satisfaction among the acceptors.

Comparison between different types of IUCD

El Beltagy *et al* [21] **(2011)** conducted a randomized control trial in which three hundred women were randomized to CuT 380A (n = 150) and Multiload 375 (n = 150). The study revealed that the expulsion rate of Cu T380A was (8.1%) and Multiload 375 IUD was (5.4%) within 6 weeks of delivery after early postpartum insertion of CuT.

In a study by **Ragab A *et al*** [45] **(2015)**, comparison was done between the expulsion rate of Multiload 375, and Copper-T 380A intrauterine contraceptive devices (IUCDs) inserted during caesarean delivery after 1 year. At 1 year, the expulsion rate was reported to be 5% in the Multiload group and 13% in Copper T 380A. The Multiload 375 device showed a lower risk of displacement.

Jatlaoui TC *et al* [22] **(2018)** did a systematic review and meta-analysis on the absolute rates of IUCD expulsion between Cu containing IUCDs and levonorgestrel IUCDs and estimated relative risks for the timing of postpartum placement, delivery method, and IUCD type using a log-binomial multivariable regression model. They, however, did not include multi-load Cu 375 IUCD and concluded that the levonorgestrel intrauterine system was associated with a higher risk of expulsion compared with Cu T 380 A.

Kumar M *et al* [28] **(2017)** did a Prospective Randomized Comparative study on 300 women who delivered in the hospital and noticed that the expulsion of Cu T 380A was 14% while that for Multiload Cu 375 was 12%. The overall expulsion rate was 13% and the removal rate was 5%. The mean pain score during intrauterine contraceptive device (IUCD) insertion on the visual analogue scale was 2.93 in group A and 3.0 in group B and was not statistically different. There was no significant difference between the IUCDs regarding the safety, efficacy and complications such as expulsion, bleeding etc.

Kaneshiro B *et al* [30] **(2010)** did a comparative randomized control trial and reported expulsion rates of CuT 380A with other copper IUDs and concluded that the cumulative expulsion rates was 2.4-6.0 % after 1st year of use.

Kulier R *et al* [13] **(2007)** conducted a Cochrane Database Systematic review in which 34 trials were included, resulting in 16 comparisons of different IUDs. Cu T 380A was more effective than ML Cu375, ML Cu 250, Cu T 220 and Cu T 200. They also saw that changing the position of the copper on the arm of the IUD for Cu T 380S did not improve the efficacy of Cu T 380A. ML Cu375 was no more effective than Cu T 220 at 1 year, MLCu250 at 3 years or Nova T at 3 years. As compared to Cu T 380A, none of the IUDs showed any benefits in terms of bleeding or pain, or any of the other reasons for early discontinuation.

Timing of PPIUCD insertion on the rate of Expulsion

Letti Müller AL *et al* [46] **(2005)** in their observational study on transvaginal ultrasonographic assessment of the expulsion rate of intrauterine devices inserted in the immediate postpartum period after vaginal birth and caesarean section observed that the expulsion rates were statistically different between the two groups: after a vaginal birth, 50% (ultrasound only) + 27.8% (clinical examination); and post-caesarean section, 0% (P=0.001; OR 5.75, 95% CI 2.36 –14.01)

Lerma K *et al* [47] conducted a study in **2016** to evaluate the delivery-to-insertion interval for copper postpartum intrauterine devices (PPIUDs). IUDs were inserted within 48 hours of vaginal delivery (n=560), out of which 93 (16.6%) women received a post placental PPIUCD and 467 (83.4%) received an immediate PPIUCD. Complete expulsion at follow-up was 3.2% (n=3) in the post placental group and 7.5% (n=35) in the immediate postpartum group.

Averbach SH *et al* [48] **(2020)** in their study provided details about the IUCD expulsion rates and expulsion risk estimates among women with postpartum IUCD placement by the timing of insertion, mode of delivery and IUCD type. It was seen that complete IUCD expulsion rates varied by timing of placement: 10.2% (range 0.0-26.7) for immediate, 13.2% (3.5-46.7) for early inpatient, 0% for early outpatient, and 1.8% (0.0-4.8) for interval placements. Complete IUCD expulsion rates also varied by delivery type: 14.8% (range 4.8-43.1) for vaginal and 3.8% (0.0-21.1) for caesarean deliveries.

Suckak A *et al* [24] **(2015)** did a pilot study on 160 patients dividing them into three groups i.e. planned caesarean group, emergency caesarean group and vaginal deliveries and found that the cumulative expulsion rates were similar with a frequency of 8.7, 8.9 and 11.3% respectively in groups 1 to 3 ($P > 0.05$ in all pairwise comparisons).

Levi E *et al* [49] **(2012)** did a prospective cohort study of 90 patients undergoing cesarean delivery. After delivery of the placenta, a copper T380A IUD was inserted into the endometrial cavity through the incision. The study participants were followed up at 6 weeks and 6 months postpartum. They observed that forty-three (48%) returned for their 6-week follow-up and none of them had any expulsion. Forty-two (47%) were telephonically followed up at 6 months postpartum. They concluded that Immediate post placental IUCD insertion at the time of cesarean delivery is safe and acceptable.

Levi EE *et al* [50] **(2015)** did a non-blinded randomized trial to compare intrauterine device (IUD) use at 6 months postpartum among women who underwent IUCD placement during cesarean delivery versus women who were planned for interval IUCD placement at 6 or more weeks postpartum. They analyzed and reported that IUCD placement at the time of cesarean delivery leads to a higher proportion of IUCD use at 6 months postpartum when compared to interval IUD placement.

Other Factors associated with increased expulsion

Makins A *et al* [51] **(2018)** in their study described the factors associated with increased expulsion and absence of threads. Expulsion and removal rates were 2.5% and 3.6% respectively. Threads were not visible in 29%. It was also seen that expulsion rates were less likely after caesarean insertion (AOR 0.33; 95% CI, 0.26–0.41).

Singh R *et al* [52] **(2021)** conducted a prospective case control study on post-partum women who underwent vaginal delivery. They recruited the cases (n=292) in long inserter group and controls (n=301) where IUCD was inserted using conventional method. The patients were followed up at two weeks, six weeks and three months post insertion with sonographic assessment at each visit. Expulsion was seen in only one case in the long insertor group and five in the conventional group. They emphasized that the long inserter PPIUCD insertion is safe and convenient method. It facilitates high fundal placement and good thread visibility. Additionally, it has reduced risk of infections as compared to the conventional technique.

Paul D. Blumenthalet al [53] **(2018)**

Did a multicentric randomized controlled trial on 500 women and compared postpartum IUCD (PPIUCD) insertion using a newly developed dedicated PPIUCD inserter (inserter) with modified Kelly placental forceps (forceps). There were no perforations or insertion-related infections in both groups. Complete expulsion occurred in 19 (7.9%) in the inserter group and 13 (5.4%) in the forceps groups (p=0.28). It was seen that the inserter group had more partial expulsions (n=26, 10.8% versus n=12, 5.0%,) compared to the other group. They concluded that high fundal placement was similar between groups, with strings subsequently seen more frequently in the inserter group.

Role of Ultrasound in assessing expulsion

Singh S *et al* [54] **(2016)** studied 80 women who presented for PPIUD insertion and followed them up at 6 to 8 weeks post-insertion. USG was used to assess IUCD location. Complete expulsion was observed in 6 cases (7.5%), and asymptomatic partial expulsion in 8 cases (10%).

T. DIAS *et al* [55] **(2015)** conducted a prospective study on 91 participants in which ultrasound examination was done twice, one before discharge from hospital and one at six weeks follow up after delivery in women receiving PPIUCD. In both the groups ie PPIUCD insertion post vaginally and post caesarean, the distance from the internal os to the lower end of the IUD was measured at each examination and compared in unsuccessful and successful cases. The spontaneous expulsion/removal rate of IUCD was 22.4% after vaginal and 25.8% after caesarean delivery. Mean distance from the internal os to the lower end of the IUD on ultrasound examination immediately after insertion was significantly greater in successful cases than in those in which IUDs were subsequently expelled/displaced (mean difference after post vaginal insertion, 20.1 mm (P = 0.006); mean difference after post caesarean insertion, 10.3 mm (P = 0.05)). They concluded that Ultrasound examination after insertion of an IUD could be considered for predicting the success of IUD retention.

Gurney EP *et al* [23] **(2018)** did a prospective observational study on women who received a post placental Cu T 380 A IUCD at vaginal delivery and observed that amongst 160 enrolled patients, the complete expulsion rate was 8% and partial expulsion was seen in 16%. Of 25 (15.4%) malpositioned intrauterine devices, 14 were not at the fundus (8.6%; 95% confidence interval), and 11 were rotated within the uterus (6.8%; 95% confidence interval).

Goldthwaite LM *et al* [56] **(2017)** in their study analyzed the post placental intrauterine device expulsion by 12 weeks. They enrolled 123 women between aged 18-40 years. Participants were divided into two groups (68 in levonorgesteral (LNG) IUCD group and 55 in Copper IUCD group). Among the 96 women (78%) who came at 12-week follow-up, expulsion for Cu IUD users was 20% (OR; 2.55; 95% CI:0.99-6.55; p=0.05) as compared to 38% in LNG users. At 24 hours postpartum, there was no significant difference in median distance from the intrauterine device to the fundus between intrauterine device types or between those who did or did not experience expulsion. The only independent predictor of expulsion was IUD type.

Other Complications

Khurshid N *et al* [57] **(2020)** conducted a randomized controlled trial in which 238 patients were allocated to PPIUD group and 273 to IIUD (interval IUD) group. In the PPIUD group, there was no bleeding/spotting demonstrable as it was masked by the lochia. Mild pain at insertion was seen in only 11 patients in the PPIUD group. At 6 weeks, 6 months and 1 year follow up with regard to patients complaining of pelvic pain/dysmenorrhea, the difference between the two groups was not statistically significant.

It was also noted that the irregular bleeding or spotting was more in interval insertion than in the post-placental group. The difference in the two groups was statistically significant at 6 weeks and 6 months, but was not significant at 1 year. There was no case of perforation in either group. This study also found a statistically significant difference in expulsion after post-placental compared to delayed insertion. The difference between the two groups was statistically significant (P=0.006) for cumulative expulsion.

MATERIALS AND METHODS

Study Setting: The study was conducted in the Department of Obstetrics and Gynecology AIIMS, Jodhpur after ethical committee approval.

Study design: Randomized Control Trial.

Study participants: All pregnant females delivered at AIIMS Jodhpur and fulfilling the inclusion criteria and medical eligibility criteria for IUCD insertion.

Study Period: Recruitment started from March 2020 till August 2021

Ethical Justification

This study was undertaken after obtaining ethical clearance from the Institute's Ethics committee vide letter no. AIIMS/IEC/2020/2073. Patients were enrolled after obtaining their informed consent. The study was registered under the Clinical Trial Registry of India vide number CTRI/2020/07/026357.

Sample size:

Considering the number of deliveries in our institute in last six months from June 2019 to November 2019 to be average of 203 per month and the number of PPIUCD insertions from June 2019 to November 2019 to be average as 18 per month, average number of PPIUCD insertion for next 20 months was calculated to be around 360 insertions. Taking 10 % attrition rate (including patients failing to follow up), the final sample size calculated was around 396 with 198 cases in each group according to the feasibility. (Convenient Sampling)

Methodology

Inclusion criteria

1. All Postpartum women delivered in our institute either vaginally or by caesarean section who fulfilled the medical eligibility criteria for Cu IUD insertion. [58]
2. The women eligible for immediate postpartum copper IUD insertion with previous regular menstrual cycles for at least 6 months before current pregnancy
3. Those women who consented to participate in the study and willing to come for follow up

Exclusion Criteria

Following patients were excluded from the study

1. Women with history of Sexually transmitted diseases or pelvic inflammatory diseases, coagulation disorders, liver or renal dysfunction, Wilsons disease.
2. Intrapartum and recent antepartum fever (within 7 days), Past or current genital tract infections or history of multiple sexual partners, postpartum hemorrhage, rupture of membranes for greater than 18 hours prior to delivery.
3. Past history of ectopic pregnancy
4. Women with pre-existing gynecological cancers
5. Women with uterine anomalies or leiomyoma distorting the shape of uterine cavity.
6. Previous two LSCS

Women attending antenatal clinic, admitted in antenatal ward and in early labor (in labor room) were counselled about all postpartum family planning methods available, their advantages, limitations, effectiveness and side effects using suitable IEC material (Information, Education, Communication) and also for follow up. They were enrolled for the study only when they agreed to come for follow up visit at 6 weeks.

All subjects fulfilling the above-mentioned criteria and willing to participate were enrolled in the study. Patients were counselled and informed written consent was taken.

They were distributed into the two groups as per the randomization.

Group A including patients randomized to receive Cu 375 IUCD and

Group B who were randomized to receive Cu T 380A IUCD.

Method of randomization-

Block randomization in blocks of 10 was followed.

Computer generated Random sequences were generated by online software ***(https://www.sealedenvelope.com/simple-randomiser/v1/lists)*** by an individual not involved in enrolment, treatment and follow up of study.

Allocation Concealment: was done by Sequentially numbered, opaque, sealed envelope (SNOSE) technique.

Random sequences were used to make 400 identical, opaque, sealed envelopes in a serial order. These envelopes were made by a person not involved in enrolment, treatment and follow up of study. The envelopes were kept in the labor room.

Every time, the eligible patient consented for the study, one random closed envelop was picked by person not involved in the study. It was handed over to the investigator. According to the code written in the letter, patient was allocated in group A or group B.

Timing of Randomization: Randomization was done immediately after delivery and within the time frame of PPIUCD insertion (48 hours post-delivery) after excluding post-partum hemorrhage (PPH).

Procedure

Following normal delivery and active management of third stage of labor and after reconfirmation and written consent, with the patient in lithotomy position, under strict aseptic measures, uniform methodology for insertion using Kelly's forceps was adopted throughout our study. (Advantage of Kelly's forceps: This long curved instrument without locking feature allows not only fundal placement but also prevents the entanglement of IUD string while withdrawing the instrument.) (Figure 3,4)

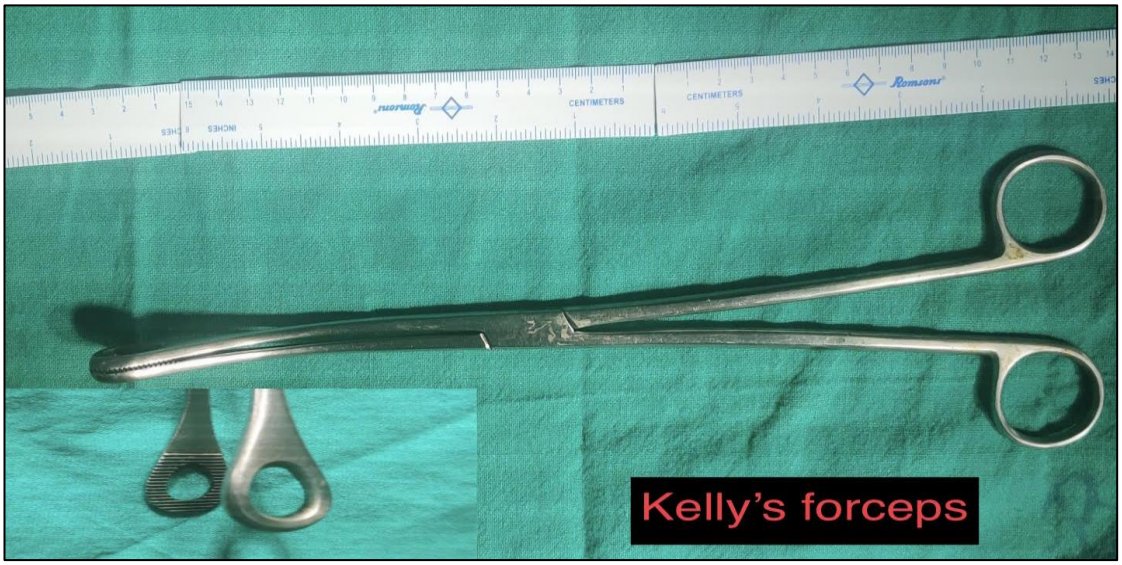

Figure 3: Kelly's Forceps

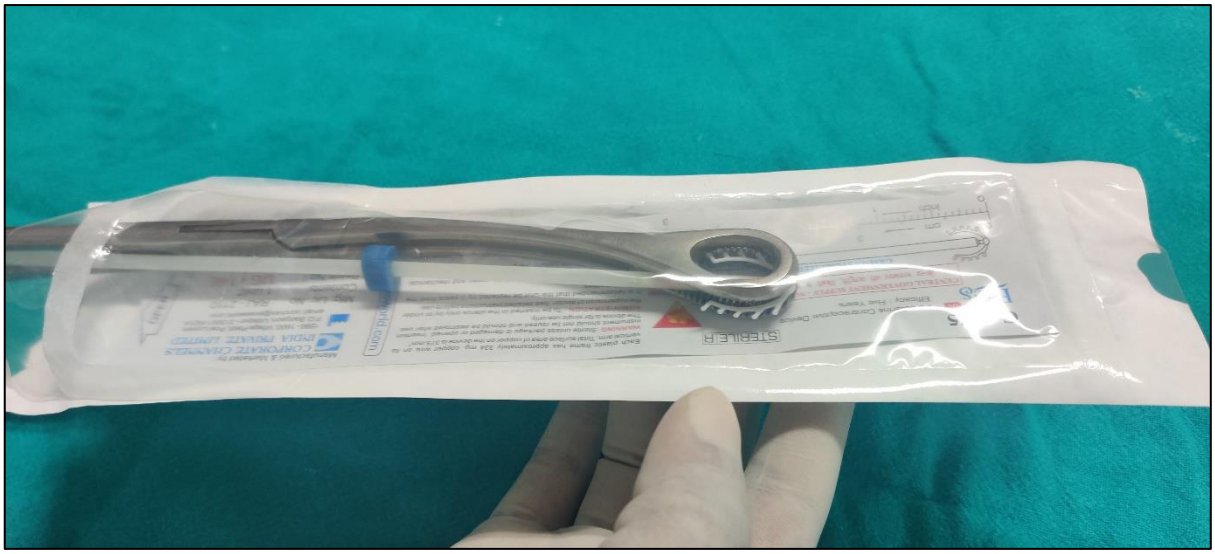

Figure 4: Method of insertion by No touch technique through Kelly's forceps

During vaginal delivery, the IUCD was held by kelly's forceps at the junction of horizontal and vertical limb by no touch technique as seen in figure 4 and inserted high upto the uterine fundus, leaving the IUCD there and gently sweeping the instrument along the lateral wall of the uterus.

However, during caesarean section, IUCDs were inserted high at the fundus through the lower-uterine segment incision immediately after delivery of the placenta using the inserter provided within the sterile packaging; the IUCD Plunger was not used. Following insertion adjacent to the fundus, the cylinder was gradually moved downwards across the threads, passed till cervical canal. This technique ensures that the threads are located within the vagina immediately after the operation and prevents their entanglement within the cervical canal or uterine cavity [12]. The uterine incision was then closed.

All the insertions were done by resident doctors who had received training in PPIUD insertion. Antibiotics were administered as per the hospital's protocol for caesarean section and women were observed for evidence of PPH or sepsis.

Ultrasound before discharge and at six weeks

Post insertion, within next 48 hours or before discharge from hospital, an ultrasound was performed to confirm the fundal placement of IUCD in uterine cavity. The distance between the endo-myometrial junction and the upper part of Cu IUD was noted. And same was repeated at 6 weeks follow up visit. The cut off distance of 10 mm was taken and any IUD

more than 10 mm from the endo-myometrial junction was considered as mal-positioned or displaced.

Participants were examined sonographically on USG machine MINDRAY ((Figure 5) to see the correct position of IUCD. (Figure 6,7)

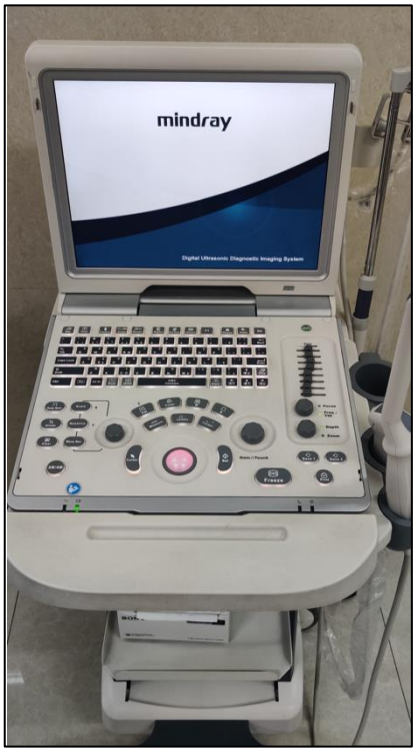

Figure 5: Mindray Ultrasonographic machine

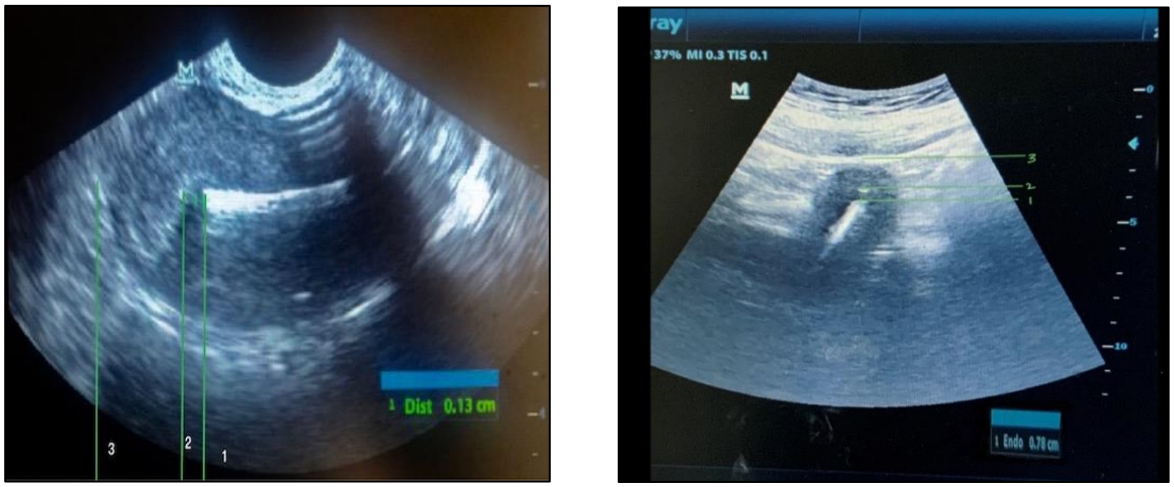

Figure 6: Transvaginal USG and Trans abdominal USG at 6 weeks showing distance of Cu IUCD from uterine fundus (Endo-myometrial junction)

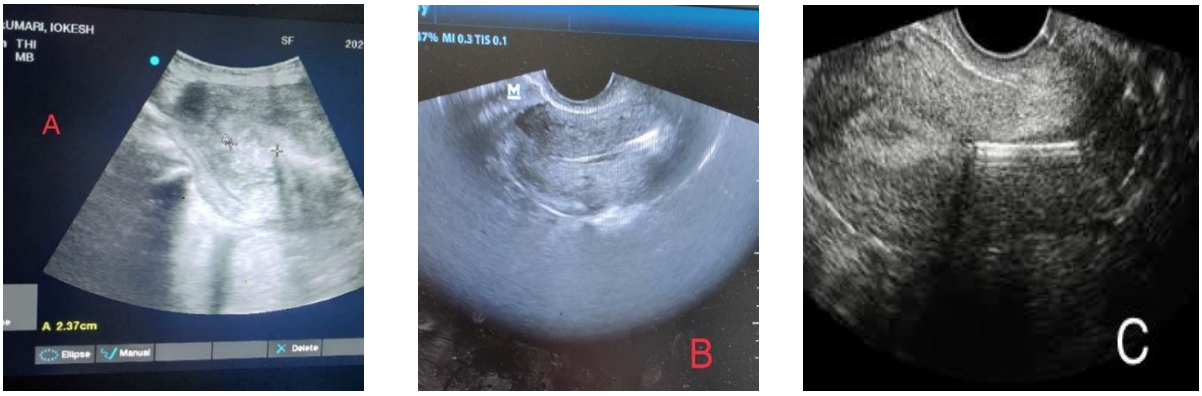

Figure 7: USG showing different positions of Cu IUCD in uterine cavity

The acceptors of post placental intrauterine device were followed up routinely at six weeks on outpatient basis. The recipients were instructed about the possible side effects and advised to report to the hospital if they experienced abdominal pain, bleeding or foul-smelling vaginal discharge or if there was history of expulsion of IUCD. Position of IUCD was verified by per speculum and vaginal examination. If the threads were not seen, a check pelvic ultrasound or radiography of pelvis was done.

However, due to COVID Pandemic, few women were not able to come for 6 weeks sonography. They were interviewed telephonically about the expulsion and other complaints.

The Operational terminologies used were:

Expulsion: When the strings of Cu IUD cannot be seen. Some may even notice the fall of IUCD and in such patients, speculum examination, bimanual pelvic examination and a pelvic ultrasound confirms the diagnosis.

Partial Expulsion or displacement: is defined as an intra-uterine device protruding from the external cervical OS or a transvaginal ultrasound showing the distal end of the intrauterine device below the internal OS of the cervix or when the IUCD was more than 10 mm away from the fundus but still totally within the uterine cavity, or a rotated device.
The distance from the top of the IUCD to the top of the endometrial verge (endo-myometrial junction) was measured. An IUCD at the endometrial verge was defined as being at the fundus or more than 90 % of the distance to the uterine fundus from the cervix.

Lost/Missed Strings: When the IUCD thread is not seen, despite confirming the presence of it within the uterine cavity by means of X ray or ultrasound, in such a scenario it is referred as missing strings.

Perforation: When the IUCD thread is not seen associated with the presence of Cu T outside the uterine cavity confirmed by X ray or ultrasound.

Post placental IUCD insertion means insertion within 10 mins after placental expulsion.

Early postpartum IUCD insertion means insertion after 10 mins of placental expulsion and within 48 hours following delivery and before hospital discharge.

Removal of IUCD is defined as any removal carried out by the service provider owing to maternal request, dislocated or partially expelled IUCD, presence of uterine infection, or accidental removal while retrieving the strings.

IUCD discontinuation is defined as the woman's or provider's decision not to continue with an IUCD at the 6-week follow-up visit following spontaneous expulsion or removal.

The outcome for this analysis was a composite variable of PPIUCD expulsion and complications experienced by the woman since the time of insertion to the day of follow-up, which is defined by the presence of any of the following specific outcome variables: uterine infection, confirmed expulsion of IUCD, and removal of IUCD.

A significant clinical symptom was defined as a complaint given by the woman that was attributed to PPIUCD insertion, including severe abdominal pain and abnormal vaginal discharge in terms of amount, color, and smell. The presence of any of these, or both, with or without fever, was interpreted as uterine infection.

Women who opted for re-insertion at the follow-up visit and received this were not counted as discontinuation.

Transvaginal ultrasound with a 5-MHz transducer was performed at 6 weeks after delivery, preferably by the same investigator, and the tests results were reported as IUCD in situ (inside the uterine cavity or lower segment), completely expelled (empty uterine cavity, IUCD located in the cervical canal) or IUCD outside the uterus (in the vagina or outside the patient body).

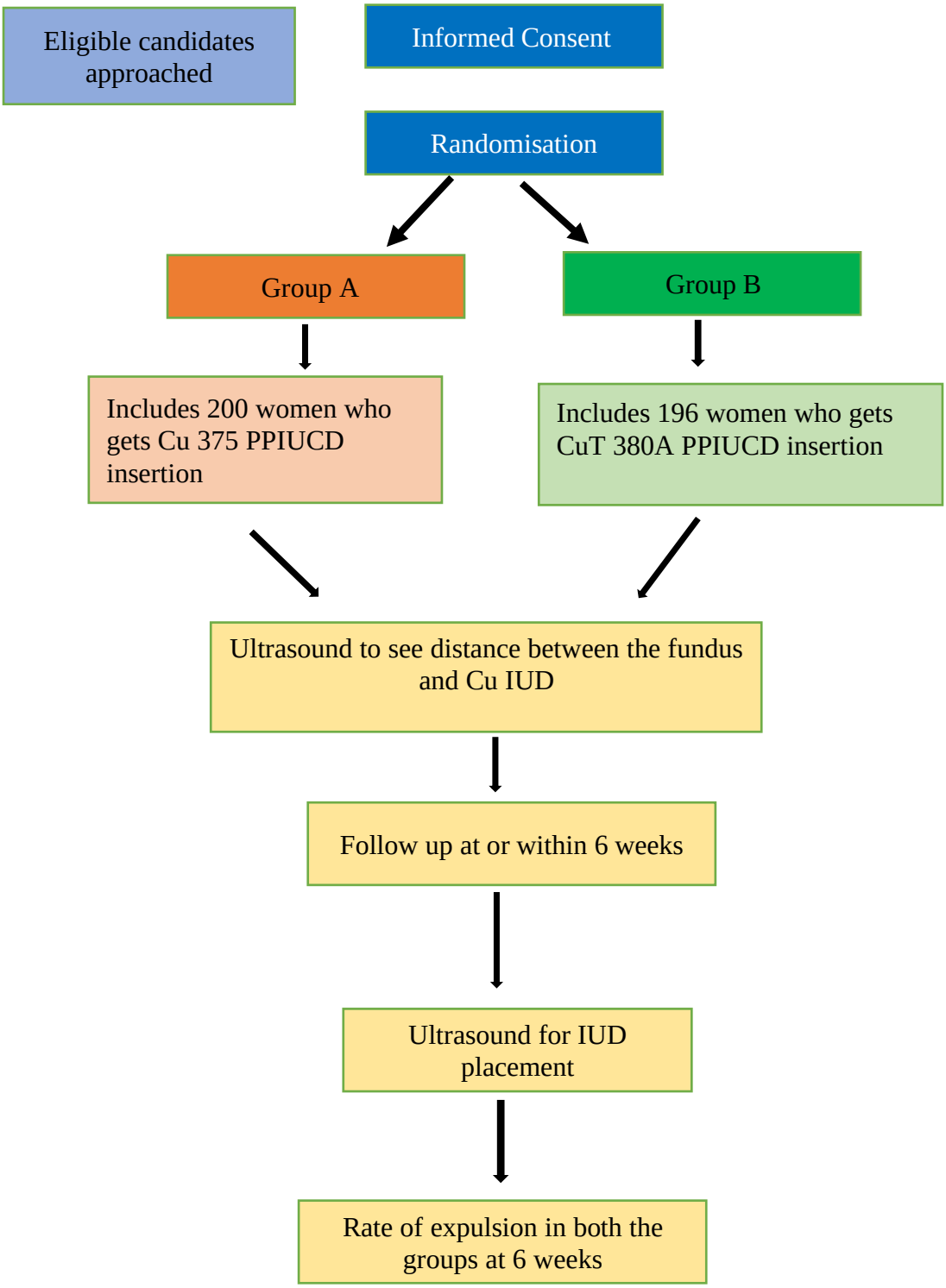

Figure 8: Work Flow

Statistical Analysis

Data were collected, coded, and then entered into an IBM compatible computer, using SPSS (Statistical Package of the Social Sciences) version 23 for Mac. Entered data were checked for accuracy and for normality. Qualitative variables were expressed as numbers and percentages, while quantitative variables were expressed as means and standard deviations.

The following statistical tests were used:

a. Independent samples *t*-test as a parametric test of significance for comparison between two sample means, after performing the Leven's test for equality of variance.
b. Pearson Chi-square (χ^2) test for paired comparison of dichotomous variables.
c. Fisher's exact test.

Level of significance equal to 0.05 was required for statistical significance.

RESULTS

During the study period from March 2020 to August 2021, an average of nearly 200 deliveries per month occurred in the institute with ups and downs due to the COVID pandemic. After considering the inclusion and exclusion criteria, nearly 960 eligible pregnant women were approached for counseling regarding IUCDs. 396 pregnant women consented to be part of the study and were accepted for PPIUCD insertion. Counseling was initiated during the antenatal period, whereas unbooked patients were counseled as and when feasible.

Out of 396 postpartum women randomized into two groups for PPIUCD insertion, 200 women were included in Cu 375 (Group A) and 196 women in Cu T 380A (Group B). Figure 9 shows the Consort Chart for the recruited subjects.

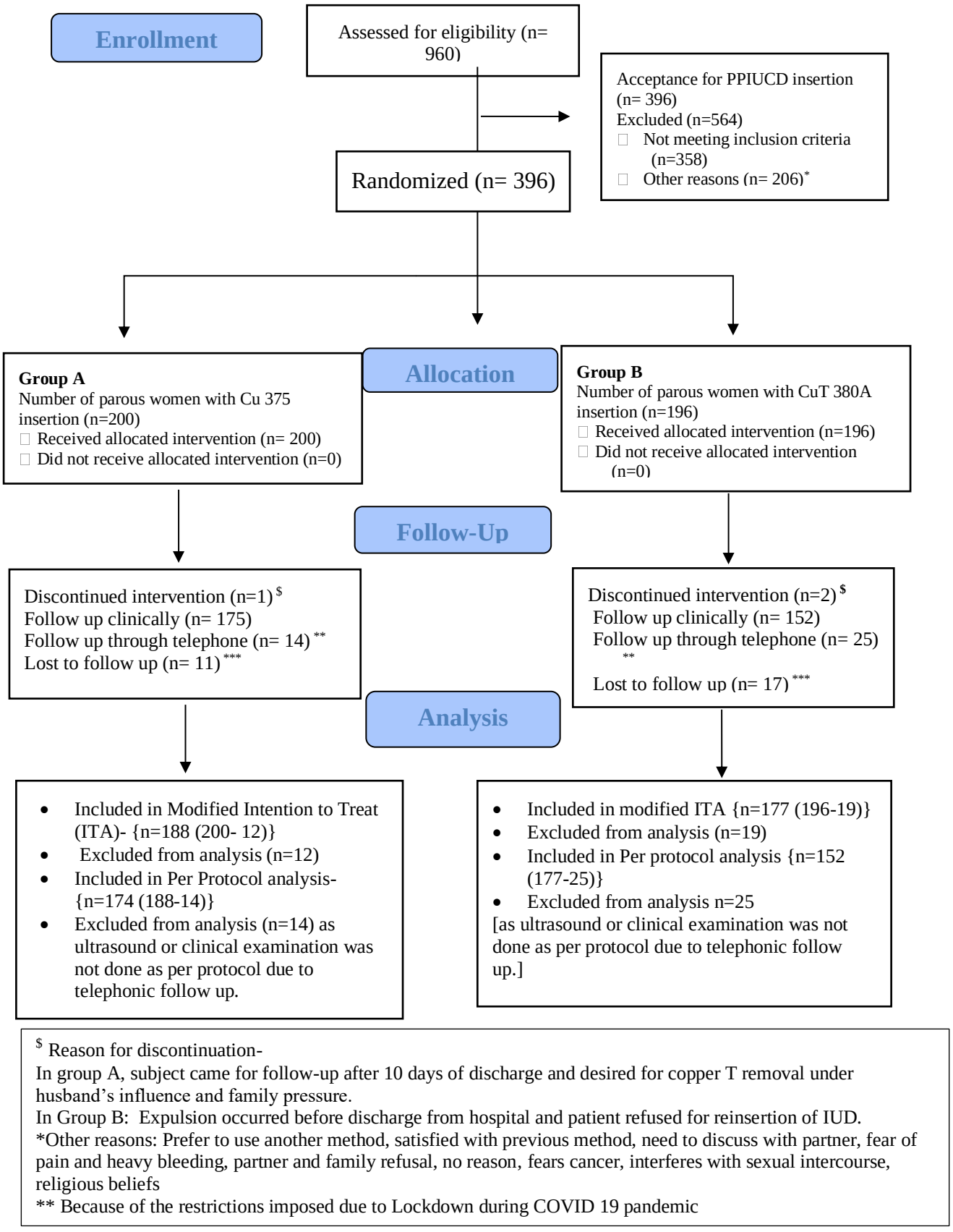

Figure 9: CONSORT Flow Chart

1. DEMOGRAPHIC VARIABLES

1.1 Age Distribution

The age of the subjects in both the PPIUCD groups was normally distributed as confirmed by normality tests.

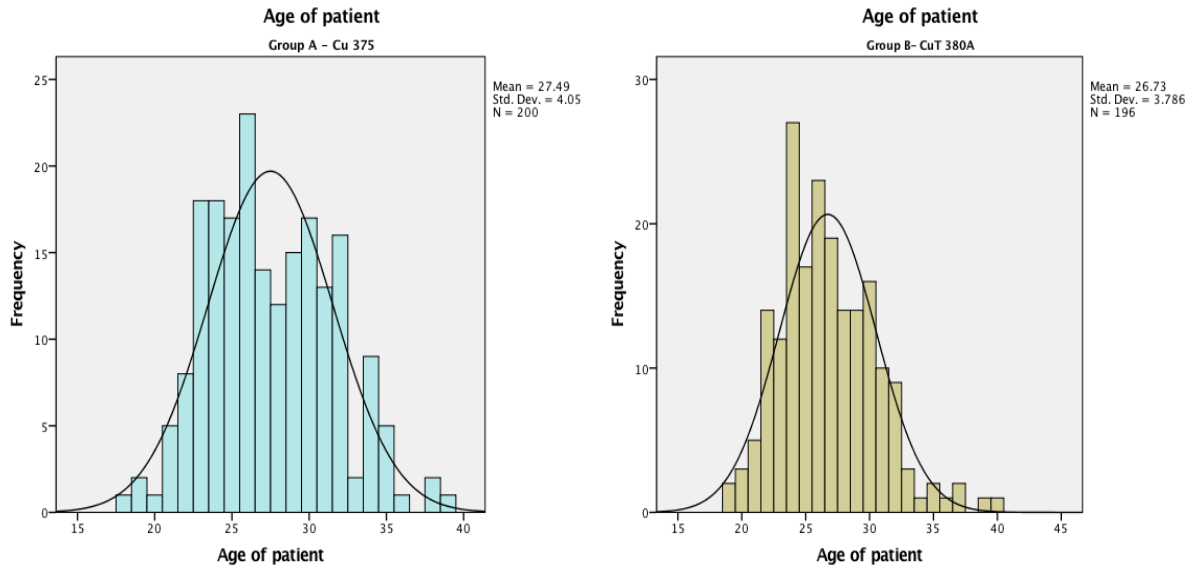

Figure 10: Distribution of age in the study population

Figure 10 shows a bell-shaped curve, which means that the age is uniformly distributed among the two groups.

Table 3- Comparison of Age between the two Study groups

	Multiload Cu 375 (Group A) N=200	**CuT 380A (Group B) N=196**	**P-value**
Min-Max (years)	18-39	19-40	
Mean ± 2 SD† (years)	27.49±4.050	26.73 ±3.786	0.054^{NS}

†Standard Deviation; ^{NS} Not Significant

The mean age of the women in group A is 27.49±4.050 years and in the group, B is 26.73 ±3.786 years. The difference in the mean age between the two groups as assessed by the independent students' t-test was not statistically significant.

Table 4- Comparison of Age by categories between the two Study groups

Age group (years)	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
18-24	53	26.5	63	31.63
25-34	138	69	126	64.29
≥35	9	4.5	7	4.08
Total	200	100	196	100

χ2 =1.617 P=0.445 ^{NS}

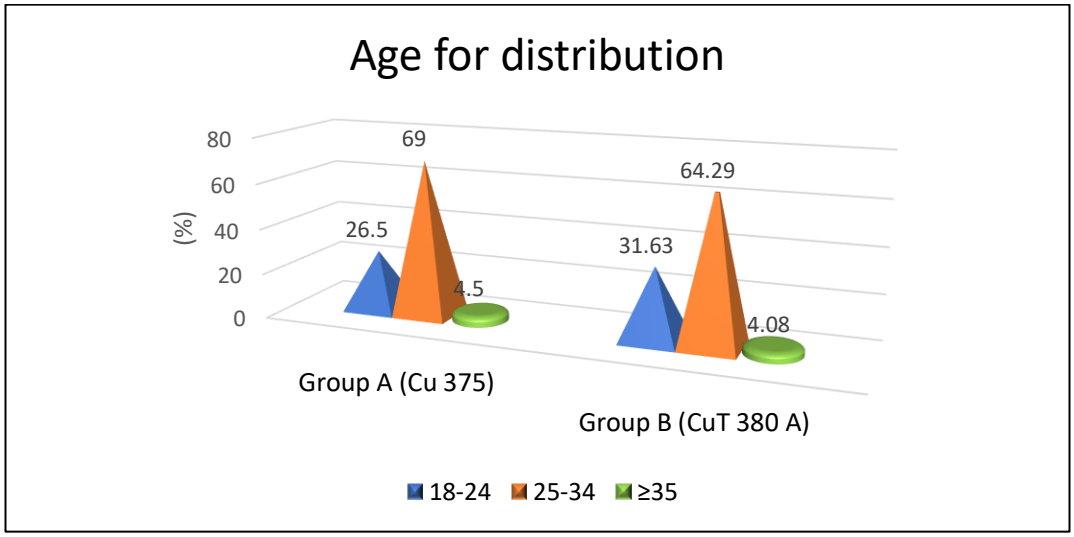

Figure 11: Comparison of Age by categories between the two Study groups

Table 4 and Figure 11 shows that the majority of the pregnant women who accepted PPIUCD were in the early reproductive age group of 25-34 years accounting for 69 % in the Cu 375 (Group A) and 64.29 % in the CuT 380A Group B. The P value is 0.445, not statistically significant

1.2 Socioeconomic status

Table 5: Distribution of study groups by Socioeconomic status

Socioeconomic Status	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Lower middle	59	29.5	43	21.94
Upper middle	93	46.5	109	55.61
Upper	48	24	44	22.45
Total	200	100	196	100

χ^2 =3.911, P=0.14 ^{NS}

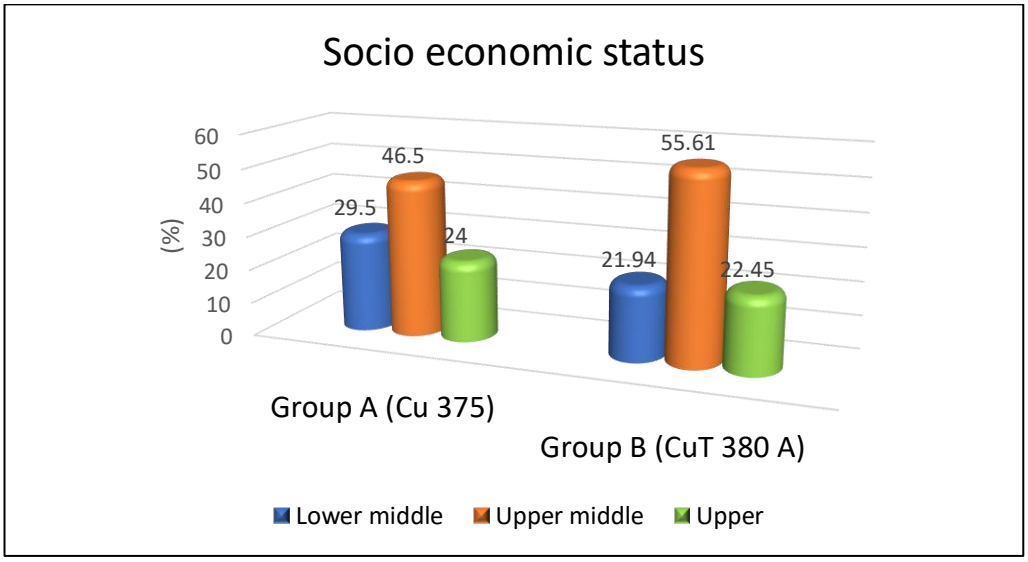

Figure 12: Distribution of Study groups by Socioeconomic status

Majority of the subjects belong to upper middle class, 46.5 % in the Cu 375 (group A) and 55.61 % in the CuT 380A (group B). The p value is 0.14, not statistically significant.

1.3 Occupation

Table 6: Distribution of study groups by Occupation

Occupation	Group A (Cu 375) N=200		Group B (CuT 380 A) N=196	
	N	%	N	%
Housewife	170	85	174	88.8
Working	30	15	22	11.2
Total	200	100	196	100

χ2 =1.237, P=0.299 NS

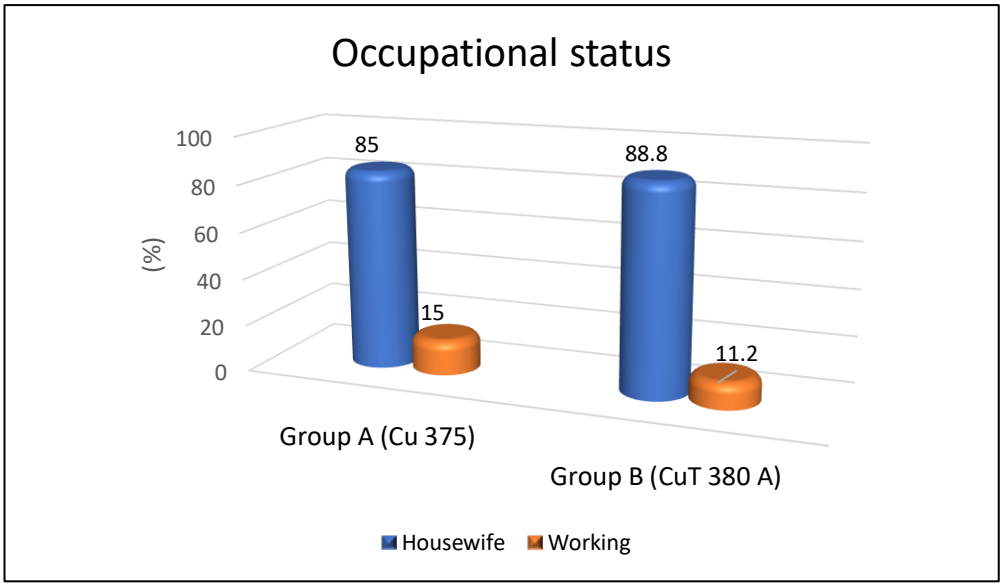

Figure 13: Distribution of study groups by Occupation

Table 6 and Figure 13 demonstrates that among the two PPIUCD groups, the majority of the subjects were housewives, 170 (85 %) in Group A (Cu 375) and 174 (88.8%) in the CuT 380A group. The p-value is 0.299 which is not statistically significant, as shown in Table 6 and Fig 13.

1.4 Education

Education plays an important role in deciding the choice of contraception as it helps in better understanding about the importance of family planning.

Table 7- Distribution of study groups by Education

Education	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
No formal education	26	13	25	12.8
Primary education	49	24.5	40	20.4
Secondary	52	26	54	27.6
Graduate and above	73	36.5	77	39.3
Total	198	100	198	100

χ2 = 1.034, P=0.793 NS

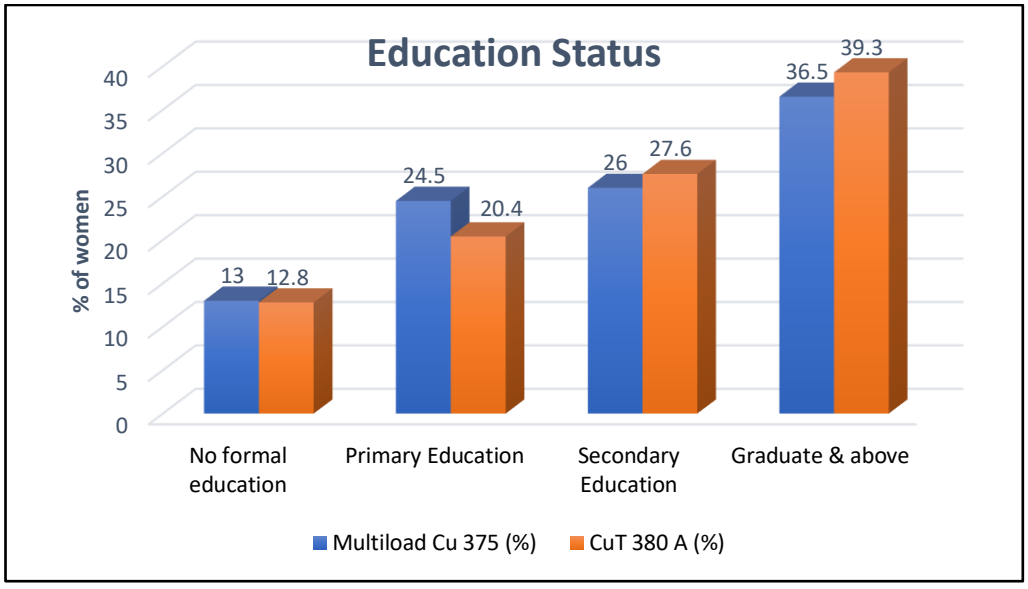

Figure 14: Distribution of study groups by Education

Table 7 and figure 14 show that the majority of the participants were graduate and above; 73 (36.5%) in the Cu 375 (group A) and 77 (39.29 %) in the CuT 380A (group B). This difference is not statistically significant (*P*= 0.793).

1.5 Residential status

Table 8- Distribution of Study groups by Residential status

Residence	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Urban	110	55	119	60.7
Rural	90	45	77	39.3
Total	200	100	196	100

$\chi 2 = 1.325$, $P=0.264$ ^{NS}

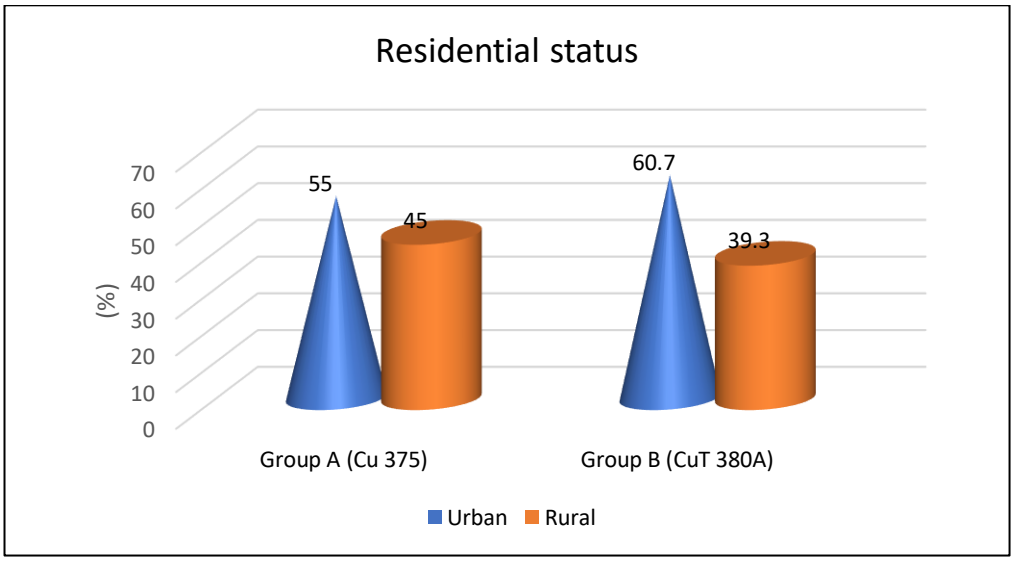

Figure 15: Distribution of study groups by Residential status

As seen in figure 15, the majority of the subjects were from urban background; 110 (55%) in group A and 119 (60.71%) in group B. This distribution was comparable in both the groups. The urban population is much more aware about the current family planning methods. Moreover, a larger number of urban population visit a tertiary care center like AIIMS.

Table 9: Composite Baseline Characteristics of the Study Groups

Baseline Characteristics	Group A (Cu-375)	Group B (Cu T 380A)	Significance
Age			
(Mean ± 2SD) years	27.49±4.050	26.73 ±3.786	*P= 0.054*^{NS}
Min-Max (years)	18-39	19-40	
18-24 years	53 (26.5)	63(31.63)	
25-34	138 (69)	126 (64.29)	
≥35	9 (4.5)	7 (4.08)	
Socioeconomic Status			
Lower middle	59 (29.5)	43(21.94)	*χ2 =3.911, P=0.14* ^{NS}
Upper middle	93 (46.5)	109 (55.61)	
Upper	48 (24)	44 (22.45)	
Occupation			
Housewife	170 (85)	174 (88.8)	*χ2 =1.237, P=0.299* ^{NS}
Working	30 (15)	22 (11.2)	
Education			
No formal Education	26 (13)	25 (12.8)	*χ2 = 1.034, P=0.793* ^{NS}
Primary	49 (24.5)	40 (20.4)	
Secondary	52 (26)	54 (27.6)	
Graduate & Above	73 (36.5)	77 (39.3)	
Residence			
Urban	110 (55)	119 (60.7)	
Rural	90 (45)	77 (39.3)	
Mode of Delivery			
Vaginal	64+1 (32.5)	70+1 (36.2)	*χ2 =0.609, P=0.435* ^{NS}
Caesarean	135 (67.5)	125 (63.8)	
Number of living Children			
One	56 (28)	69 (35.2)	*χ2 =6.509, P=0.039**
Two	118 (59)	115 (58.7)	
Three or more	26 (13)	12 (6.1)	

2. ACCEPTANCE OF PPIUCD

2.1 Mode of Delivery

Table 10: Acceptance of PPIUCD according to the Mode of Delivery in both the Study groups

Mode of delivery	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Vaginal Delivery	64+1†	32.5	70+1†	36.2
Caesarean Section	135	67.5	125	63.8
Total	200	100	196	100

χ2 =0.609, P=0.435 ***NS***

†There was one instrumental delivery each in both the groups which have been added in vaginal delivery

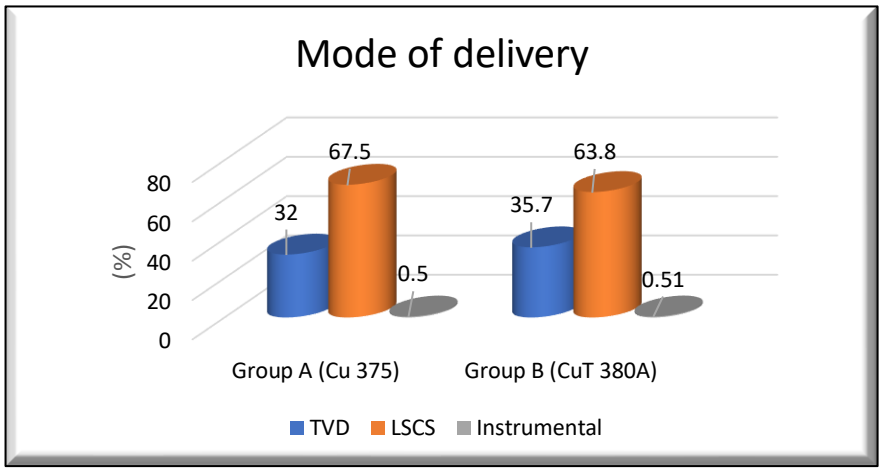

Figure 16: Acceptance of PPIUCD according to the Mode of Delivery in both the Study groups

As depicted in figure 16, the majority of the acceptors for PPIUCD insertion during the study period were those who were planned for caesarean section or had an emergency caesarean as majority of High risk and referred patients are treated in AIIMS; 135(67.5%) in the Cu 375 (group A) and 125 (63.8%) in the CuT 380A (group B). The P value is 0.435, and the difference was not statistically significant. This suggests that more importance is given for birth spacing after caesarean birth.

2.2 Number of living children

Table 11: Acceptance of PPIUCD according to the Obstetric History in both the Study groups

No of living children	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
One	56	28	69	35.2
Two	118	59	115	58.7
Three or more	26	13	12	6.1
Total	200	100	196	100

χ2 =6.509, P=0.039*(Significant)

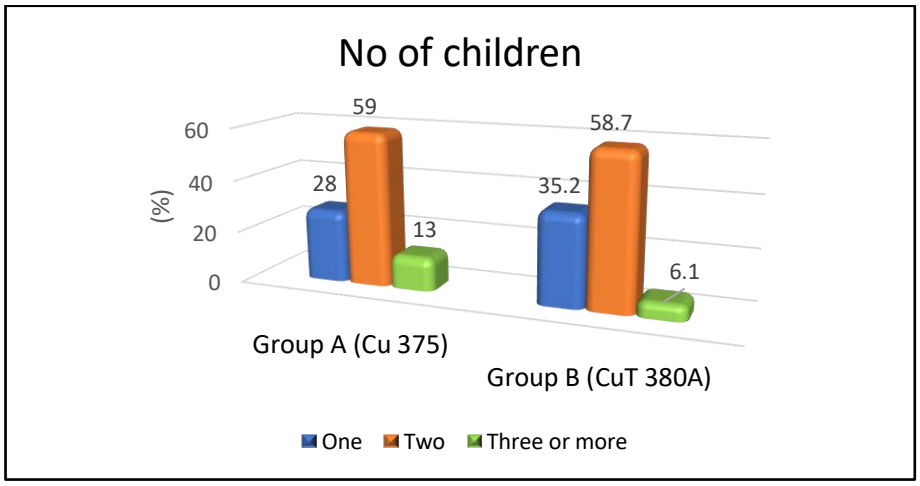

Figure 17: Acceptance of PPIUCD according to the Obstetric History in both the Study groups

Among two PPIUCD groups, the majority of the subjects opted for PPIUCD insertion after having two living issues following the slogan (HUM DO HAMARE DO; 118 (59%) in group A and 115 (58.7%) in group B. This was also comparable in both the groups.

2.3 Influence of the sex of the child for PPIUCD acceptance

Table 12: Influence of the sex of the child on PPIUCD acceptance

Sex of the child	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Girl	97	48.3	95	48.2
Boy	104	51.7	102	51.8
Total	201[#]	100	197[#]	100
χ2 =0.000, P=0.994 NS				

[#]*There were two twins one in each group, hence the total count is 398(201+197)*

As shown in the above table, the acceptance for PPIUCD insertion after the birth of a boy child is seen to be more as compared to that after the girl child. However, there was no statistically significant difference between the two groups.

2.4 Booking /Registration

Table 13: Acceptance of PPIUCD according to the Booking Status in both the Study groups

Booking status	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Booked	161	80.5	163	83.2
Unbooked	39	19.5	33	16.84
Total	200	100	196	100

χ2 =0.472, P=0.492 NS

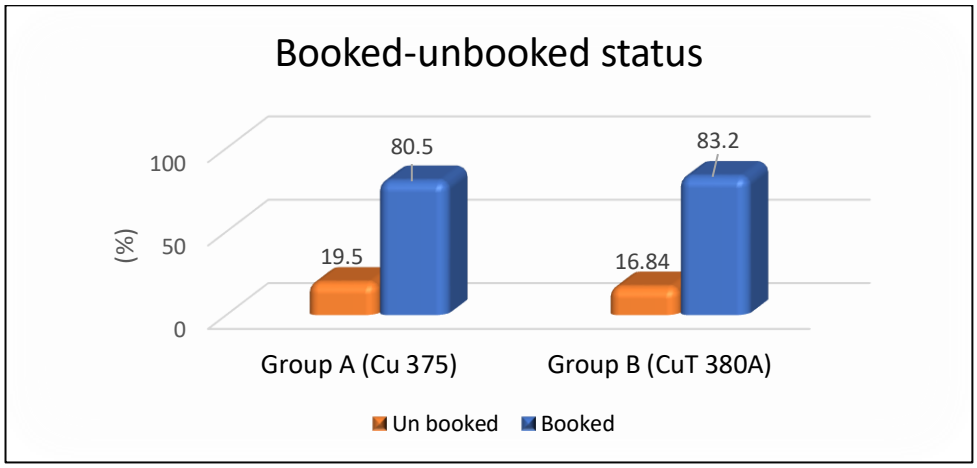

Figure 18: Acceptance of PPIUCD according to the Booking Status in both the Study groups

In a tertiary center like AIIMS, the majority of the antenatal women have their first visit at early trimesters and this helps in early counseling about family planning methods. Therefore, the acceptance rate in booked patients was better as compared to unbooked patients in both the groups as shown in table 13 and figure 18. The p-value is 0.49, not statistically significant.

2.5 Timing of counseling

Table 14: Acceptance of PPIUCD according to the Timing of Counseling in both the Study groups

Timing of counseling	Group A (Cu 375) N=200		Group B (CuT 380A) N=196	
	N	%	N	%
Antenatal visits	62	31	57	29.1
Intrapartum (Early labor)	132	66	131	66.8
Early postpartum	6	3	8	4.1
Total	200	100	196	100

$\chi 2$ =0.459, P=0.795 NS

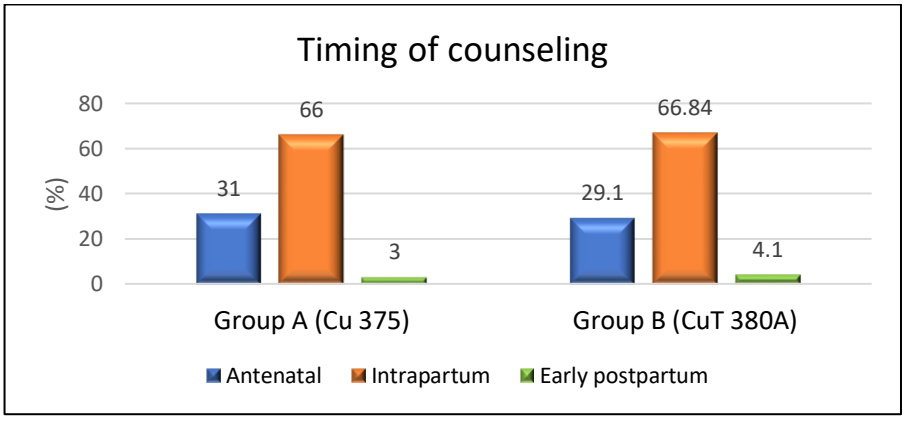

Figure 19: Acceptance of PPIUCD according to the Timing of Counseling in both the Study groups

Among the two groups, it was observed that there was a positive approach towards acceptance of PPIUCD during the latent phase of intrapartum period; 132 (66 %) consented for IUD placement after delivery in group A and 131(66.84 %) in the group B. This proportion was almost similar in both the groups.

2.6 Ultrasonography result at the time of discharge

The position of PPIUCD in the uterine cavity is one of the key factors effective for retention of IUCD. USG has better sensitivity than clinical examination for identifying the malposition.

Table 15 depicts that on USG at the time of discharge, two participants already had complete expulsions of IUD in Group B owing to post-partum hemorrhage.

There were three participants who had malpositioned IUCDs in their uterine cavity at the time of discharge, one in Group A and two in Group B

Table 15: Ultrasound result at the time of discharge in both the Study groups

USG result	**Group A (Cu 375) N=200**		**Group B (CuT 380A) N=196**	
	N	%	N	%
CuT within a cavity in the correct position	199	99.5	192	98
Complete expulsion	0	0	2	1
Malposition	1	0.5	2	1
Total	200	100	196	100

3. PRIMARY OUTCOME

3.1 Type of follow Up at Six weeks

The majority of the PPIUCD acceptors came for follow-up clinically, as they also wanted to get their babies vaccinated at around 6 weeks. They were equally concerned about the IUCD. However, due to the lockdown imposed due to the COVID pandemic and fear of acquiring infection, few participants could not come for follow-up physically, but they were interviewed telephonically about the expulsion and other complications. Table 16 shows the distribution of participants regarding their mode of follow up.

Table 16: Type of follow up of Study Participants at 6 weeks in both the groups

Type of follow-up	**Group A (Cu 375) N=200**		**Group B (CuT 380A) N=194**	
	N	%	N	%
Clinical/ USG based	175	87.5	152	77.6
Telephonic (due to COVID pandemic)	14	7.0	25	12.8
Lost to follow-up	11	5.5	17	8.7
Total	200	100	194	100

$\chi 2$ =6.06, P=0.48^{NS}

The overall attrition in our study was 7.07% (28/396) lesser than what was expected. As shown in table 16, in Group B 194 parous women were followed out of 196 as two women already had expulsion of IUCD at the time of discharge and they refused for reinsertion. Hence these two cases were followed as other post-partum patients and not according to the study protocol.

Table 17: Follow up of Study Participants at 6 weeks in both the groups

At 6 weeks follow up	Group A (Cu 375) N=200		Group B (CuT 380A) N=196		P-value
	N	%	N	%	
IUCD sonographically in the correct position	147	73.5	127	64.7	0.63 (NS)
Complete Expulsion of IUCD (a)	10	5.0	12	6.1	0.69 (NS)
Malpositioned IUCD (Partial Expulsion) (b)	17	8.5	13	6.6	0.48 (NS)
Discontinued*	1	0.5	4(2+2)*	2.04	0.55 (NS)
Lost for follow up (c)	11	5.5	17	8.7	0.22 (NS)
Telephonic Follow up (No Clinical or USG based assessment) (d)	14	7.0	25	12.8	-
Total	200	100	196	100	
	χ^2 =4.371, P=0.497				

***Discontinued at the middle of the intervention; 2+2 in group B= 2 early expulsion and 2 requested removal at 6 weeks**

There was one patient in Group A (Cu 375) who had discontinued CuT in the middle of the intervention due to family pressure and two patients in Group B (CuT 380A) had PPH few hours after delivery due to which the CuT was expelled. These two women refused for reinsertion. Another two patients requested for removal at 6 weeks follow up due to prolonged bleeding but did not opt any modern methods of contraception.

1.2 Expulsion Rate at Six weeks

Overall, 22 PPIUCDs got expelled completely out of 396 acceptors by 6 weeks, ten in the Cu 375 group (5%) and 12 in the CuT 380A group (6.1%) making an overall expulsion rate of 5.55%. However, on excluding the attrition rate, the expulsion rate in our study turned out to be 6.02%. The expulsion rate is more in the CuT 380A group as compared to Cu 375 group but this difference was not statistically significant.

Table 18: Complete Expulsion Rate in Study Participants at 6 weeks in both the groups

Analysis Approach	**Expulsion Rate (Complete Expulsion)**		*P*
	Group A (Cu 375) N=200	Group B (CuT 380A) N=196	
	No. of patients with event/ total number (%)		
Modified Intention to Treat [(a) / (N-c)]	10/188 (5.3)	12/177 (6.7)	$\chi 2 = 0.133$, $P = 0.71^{NS}$
Per Protocol [(a) / N-(c+d)]	10/174 (5.7)	12/152 (7.8)	$\chi 2 = 0.302$, $P = 0.58^{NS}$

In group A, 11 patients and in group B 17 patients did not come back for follow-up visits at 6 weeks, nor did they have any telephonic contact. Hence, they were excluded from the primary analysis, and the expulsion rate was calculated as per modified intention to treat analysis for only those patients who were followed. Table 18 shows that on considering modified ITA, the expulsion rate was more in group B (6.7%) as compared to Group A (5.3%), however, the difference was not statistically significant.

The telephonic follow-up was done in 14 cases in group A and 25 cases in group B. Hence these patients could not be evaluated clinically or sonographically as per the protocol. Therefore, these cases were excluded from per-protocol analysis still making no significant difference in expulsion rate. (Table 18)

Ultrasound is a useful tool for the detection of the exact position of IUCD in the cavity. Its sensitivity to detect any alteration from the correct position is high and is believed to be one of the contributing factors in future expulsion. 17 (8.5%) subjects had malpositioned Cu IUD (i.e. presence of IUD beyond 10mm range from uterine fundus or inverted or misaligned or rotated) in Group A and 13 (6.6%) in Group B. This percentage was considered as partial expulsion.

Table 19: T+otal Expulsion rate (Complete & Partial) in Study Participants at 6 weeks in both the groups

Analysis Approach	Total Expulsion Rate (Complete + Partial Expulsion)		*P*
	Group A (Cu 375) N=200	Group B (CuT 380A) N=196	
	No. of patients with event/ total number (%)		
Modified Intention to Treat [(a+b) / (N-c)]	27/188 (14.3)	25/177 (14.1)	$\chi 2 = 0.004$, $P = 0.94^{NS}$
Per Protocol [(a+b) / N-(c+d)]	27/174 (15.5)	25/152 (16.4)	$\chi 2 = 0.052$, $P = 0.81^{NS}$

Table 19 shows that even on adding this number to the complete expulsion, the overall expulsion rate in both the groups was also comparable (14.3% and 14.1% respectively by modified ITA and 15.5% and 16.4% by per protocol analysis).

4. SECONDARY OUTCOMES

4.1 Timing of PPIUCD insertion

Table 20: Distribution of the Study participants according to Timing of PPIUCD insertion

Time of Cu IUD insertion	Group A (Cu 375) N=200		Group B (CuT 380A) N=196		Total
	N	%	N	%	
Post placental insertion	147	73.5	142	72.4	289
Early postpartum insertion	53	26.5	54	27.6	107
Total	200	100	196	100	396

χ2 =0.05, P=0.814 NS

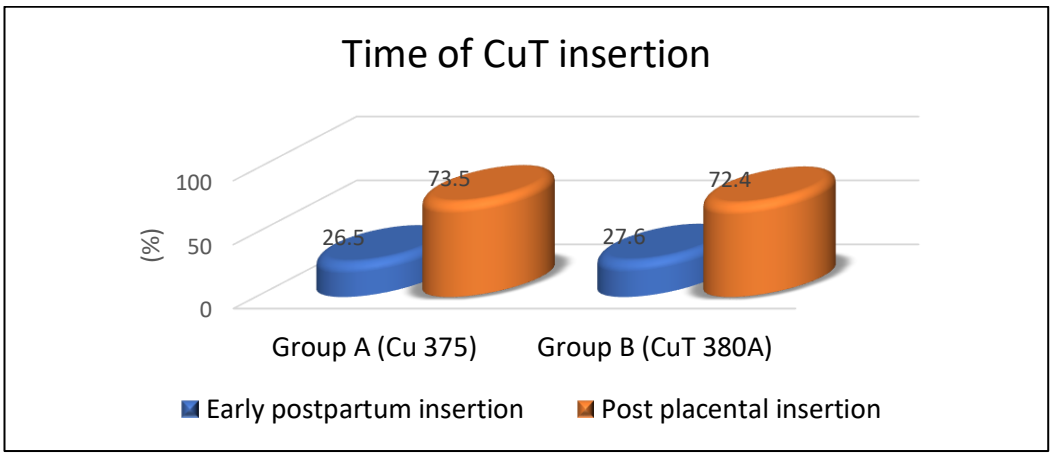

Figure 20: Distribution of the Study participants according to Timing of PPIUCD insertion

As shown in Table 20 and figure 20, in the majority of the subjects who accepted PPIUCD for contraception, the insertion was done immediately after the delivery i.e post placental (within 10 minutes of the expulsion of the placenta) after excluding any post-partum hemorrhage or cervical tear. There were 147 (73.5 %) post placental PPIUCD insertion in group A and 142 (72.4 %) in group B which is comparable.

4.2 Expulsion rate according to the timing of PPIUCD insertion

Table 21: Follow up of Study participants at 6 weeks according to the timing of PPIUCD insertion

After 6 weeks	Early postpartum Insertion (EPI) N=107		Post placental insertion (PPI)N=289		P-value
	N	%	N	%	
Continued IUCD	83	77.5%	258	89.2	**0.00 (S)**
Complete Expulsion (a)	12	11.21	10	3.48	**0.002 (S)**
Malposition (Partial Expulsion) (b)	7	6.6	23	8.0	0.63^{NS}
Discontinued*	1+ $2^{\dagger}$=3	2.8	2	0.69	
Lost for follow up (c)	9	8.4	19	6.6	0.99^{NS}
Telephonic Follow up (d)	10	9.3	29	10.03	
Total	107	100	289	100	

*Discontinued in the middle of intervention; $2^{\dagger}$ requested for removal of IUCD at 6 weeks and discontinued; *(S)= P <0.05 statistically significant*; ^{NS} not significant

At 6 weeks follow up, where the complete expulsion rates are higher in the early postpartum insertion (EPI) group as compared to the post placental insertion (PPI) group, 12 (11.21 %) and 10 (3.48 %) with P-value – 0.002 which is significant, the malposition (Partial expulsion) rates are comparable between the 2 groups [seven in EPI (6.6% [ITA] & 7.2% [modified ITA]) and 23 (8.0% [ITA] & 8.6% [modified ITA]) in PPI, statistically not significant.

The continuation rate of IUCD was significantly more in the PPI group, 258 (89.2 %) than EPI -83 (77.5 %) with P-value of 0.002. (Table 21 and Figure 21)

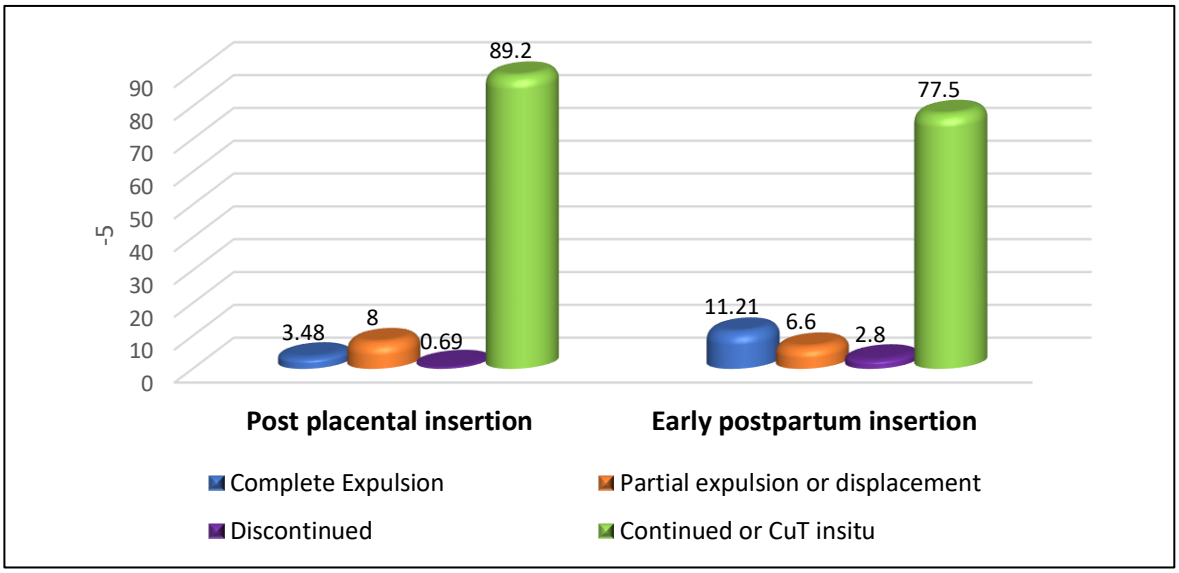

Figure 21: Follow up of Study participants on the basis of timing of insertion

Table 22: Expulsion Rate (Complete Expulsion) at six weeks with respect to the timing of insertion of IUCD in Study Participants

Analysis Approach	Expulsion Rate (Complete Expulsion)		*P*
	Early postpartum Insertion (EPI) N=107-1	Post placental insertion (PPI)N=289 N= 289-2	
	No. of patients with event/ total number (%)		
Modified Intention to Treat [(a) / (N-c)]	12/ 97 (12.3)	10/268 (3.7)	*$\chi 2$ =9.386,* ***P=0.002 (S)***
Per Protocol [(a) / N-(c+d)]	12/ 87 (13.79)	10/239 (4.18)	*$\chi 2$ =9.358,* ***P=0.002 (S)***

(S)= P <0.05 statistically significant

Table 22 shows that there was a statistically significant difference in the expulsion rate as per modified intention to treat and per protocol analysis in post placental IUCD insertion and Early post-partum insertion.

Table 23: Total Expulsion Rate (Complete + Partial Expulsion) at 6 weeks with respect to the timing of insertion of IUCD in Study Participants

Analysis Approach	Total Expulsion Rate (Complete + Partial Expulsion)		*P*
	Early postpartum insertion (EPI) N=107-1=106	**Post placental insertion (PPI) N= 289-2=287**	
	No. of patients with event/ total number (%)		
Modified Intention to Treat Analysis [(a+b) / (N-c)]	19 / 97 = 19.58%	33 / 268 = 12.31%	$\chi 2 = 3.08, P = 0.08^{NS}$
Per protocol Analysis- [(a+b) / N-(c+d)]	19/87= 21.83%	33/239 =13.8%	$\chi 2 = 3.06, P = 0.08^{NS}$

In the subgroup analysis, nine patients in the EPI group and 19 patients in the PPI group did not come back for follow-up visits at 6 weeks, nor did they have any telephonic follow-up. Hence, they were excluded from analysis, and the expulsion rate was calculated as per modified intention to treat analysis. Table 23 shows that the expulsion rate was more in the EPI group (19.58%) as compared to the PPI group (12.31%). However, the difference was not statistically significant.

The telephonic follow-up was done in ten cases in the EPI group and 29 cases in the PPI group. Hence these patients could not be evaluated clinically or sonographically as per the protocol. Therefore, these cases were excluded while doing per-protocol analysis, still making no significant difference in expulsion rate.

4.3 Expulsion rate depending on the route of delivery

Table 24: Follow up at 6 weeks with respect to mode of delivery

After 6 weeks	Caesarean N= 260		Vaginal N=134+2*		P-value
	N	%	N	%	
Continued	234	90	107	78.67	0.08^{NS}
Complete Expulsion (a)	9	3.46	13	9.55	**0.03(S)**
Malposition (Partial expulsion) (b)	22	8.46	8	5.88	0.62^{NS}
Lost for follow up (c)	15	5.76	13	9.55	0.32^{NS}
Telephonic Follow up (d)	28	10.76	11	8.08	
Total	260	100	134+2	100	

*2 patients underwent instrumental delivery considered under vaginal delivery; *(S)= P <0.05 statistically significant*

As shown in Table 24, On comparing the expulsion rate of PPIUCD with mode of delivery, the expulsion rate is more in the vaginal delivery group (9.55%) than in the cesarean section group (3.46%) which is statistically significant with a P-value of 0.03.

Table 25: Expulsion rate at 6 weeks according to the mode of delivery

Analysis Approach	Complete Expulsion		*P*
	Caesarean N= 259 (260-1)	**Vaginal including Instrumental N=134 (136-2)**	
	No. of patients with event/ total number (%)		
Modified Intention to Treat [(a) / (N-c)]	9/244 (3.68)	13/121 (10.7)	*$\chi 2$ =7.1085,* ***P= 0.007(S)***
Per protocol analysis [(a) / N-(c+d)]	9/216 (4.16)	13/110 (11.81)	*$\chi 2$ =6.780,* ***P=0.009(S)***

(S)= P <0.05 statistically significant

Table: 26 Total expulsion rates at 6 weeks according to the mode of delivery

Analysis Approach	Total Expulsion Rate (Complete + Partial Expulsion)		*P*
	Caesarean N= 259 (260-1*)	**Vaginal (N=134) Instrumental (N=2) (136-2*)**	
	No. of patients with event/ total number (%)		
Modified Intention to Treat [(a+b) / (N-c)]	31/244 (12.7)	21/121 (17.35)	$\chi^2 = 1.431$, $P = 0.231^{NS}$
Per protocol analysis [(a+b) / N-(c+d)]	31/216 (14.3)	21/110 (19.09)	$\chi^2 = 1.22$, $P = 0.269^{NS}$

4.4 Complications:

Table 27: The complication rate of PPIUCD in both the study groups (Intention to Treat)

Complications	Group A (Cu 375) N=200			Group B (CuT 380A) N=196			
	Total (%)	TVDs (%)	C-section (%)	Total	TVDs	C-section	P-value
Crampy abdominal Pain	13 (6.5%)	2 (1%)	11 (5.5%)	15 (7.6%)	5 (2.55%)	10 (5.1%)	0.65 NS
Bleeding PV or Spotting PV	19 (9.5%)	5 (2.5%)	14 (7%)	10 (5.1 %)	3 (1.53%)	7 (3.57%)	*0.093 NS*
Missing CuT threads	14 (7%)	4 (2 %)	10 (5%)	13 (6.6%)	2 (1.06 %)	11(5.6%)	*0.88 NS*
Foul-smelling discharge /Fever/ PID	1(0.5%)	0 (0%)	1(0.5%)	-	-	-	*0.32 NS*
Perforation	-	-	-	-	-	-	-

TVDs- Term vaginal delivery, C-section- caesarean section

Table 27 shows a comparison of the composite complications between the two groups. None of the patients had perforation in both the groups. The most common complication was bleeding per vaginum.

DISCUSSION

The PPIUCD services in India started in 2009 and rapid expansion took place in 2012. The Government policy in India is mainly focusing on spacing methods. [59] The significance of healthy spacing of pregnancy in India is emphasized by the fact that approximately 27% of births occur in less than 24 months after a previous birth. Nearly 61% of births occur within the recommended birth to a birth interval of 36 months. The intrauterine device is an effective, long-lasting, and reversible method of birth control. [56,60,61] Current guidelines recommend that asymptomatic IUD users should return for a follow-up visit after 3-6 weeks of insertion. Hence, this study was planned to see the expulsion rate at six weeks after delivery when minimum attrition is expected.

Age:

In our study, the majority of the IUD acceptors were between 25-34 years. This represents the most fertile and reproductive age group. Additionally, our study population was mostly urban where women get married at a later age.

Our findings are consistent with the findings of some of the studies done abroad. [38,56] However, in few Indian studies from Rajasthan as by Xess S et al and Jakhar et al**,**
nearly half of the study group belongs to < 25 years of age. The reason could be that the rural Indian population gets married at an early age and there is a short interval between marriage and childbirth. Table 28 shows the mean age of PPIUCD acceptors. [62,63]

Table 28: Comparison of various studies in terms of Mean Age

Studies	**Place of Study**	**Mean age in years ±2SD**
Jakhar & Singhal[63] (2019)	India (Rajasthan)	24.87 ± 3.85
Yadav V *et al* [43] (2016)	India (Rajasthan)	24.2 ± 3.3
Goldthwaite LM *et al*[56] (2017)	Aurora, Colorado	27.4 ±5.4
Geda *et al* [38] (2020)	Addis Ababa, Ethiopia.	28.0 ± 4.69
Index study (2021)	Rajasthan	27.11±3.93

Area of Residence:

In our study, the majority of women are from urban background in both the study groups (55% and 60.71% respectively) similar to other Indian studies accounting to 96.8% and 79.7% respectively. [59,64] The reason might be that most of the urban women are educated and, getting the proper information and motivation about family planning methods leads to high acceptance of PPIUCD. Contrary to our finding, the two studies from Rajasthan again had 57.3% and 54.5% of the study population from rural background. This shows that the implementation of Janani Shishu Suraksha Yojna (JSSY) in Rajasthan attracts the beneficiaries from rural backgrounds. [62,63]

Religion:

In our study, the majority of the participants (80%) were Hindus similar to a study done in Maharashtra (78.6%) and the other two studies from Rajasthan (75.9% and 87.5%). [59,62,63] The demographic profile of Rajasthan is a Hindu dominant state. However, if given privacy, anonymity, and proper counseling, Muslim women too are as likely to accept PPIUCD as their Hindu counterparts. Muslims have some social barriers to contraception that need to be sorted out amicably.

Socioeconomic status:

In our study, the major proportion of the study population belonged to the Upper middle class (46.5% and 55.61%) in both the groups respectively. One of the reasons could be that women belonging to upper-middle-class families had better knowledge about family planning and understood better at the time of counseling by the doctors and caregivers.

In the Study done by Dewan R *et al* and Xess S *et al,* the majority of the study population belonged to the lower middle class. [41,62]

Education:

In our study majority of the study participants were educated till graduation and/or above, and they stand on their thinking capacity, not getting influenced by the family members during the time of family planning counseling. This finding confirms the importance of education in deciding and planning for future pregnancy. IUCDs are a 'USE AND FORGET' type of method for contraception thereby, it is a good choice for the illiterate population also. There were two similar studies in Rajasthan in which the majority of the women (95.98% and 98.7%) had at least a primary level of education. [62,65]

Parity:

The current study witnessed that the majority of the pregnant women who accepted PPIUCD were 2nd gravida where most of them had at least one child and after delivery currently had two live issues. These findings were also in concordance with the literature including the Cochrane Database of systematic reviews where they found that most of the PPIUCD acceptors were multiparous clients. [56,60,66]

Healthy timing and spacing of pregnancies have a positive effect on maternal health and newborn outcomes. The importance of having a healthy spacing of pregnancy in India is emphasized by the fact that approximately 27% of births occur in less than 24 months of previous birth.

Contrary to our study Xess S *et al* [62] and Gautam *et al* [61]**,** found an acceptance rate of 40.9% and 44.9% respectively in primipara i.e. after one live issue. They hypothesized that parity increases the risk of IUD expulsion regardless of the mode of delivery. The authors commented that uterine involution was more prominent in primiparous women [24] thereby decreasing the expulsion rate.

Acceptance of PPIUCD

In our study it was observed that majority of the participants in both the groups (80.5% and 83.2%) had early booking and they received counseling right from the antenatal period. This has a lasting effect as many patients were themselves motivated to receive contraception and they were very much concerned at the time of delivery regarding insertion of IUCD. Moreover, early antenatal counseling helps to provide positive information regarding PPIUCD by eliminating false belief and also provide time for couples to discuss and opt for suitable family methods and increase PPIUCD insertion rate and continuation. However, practically most patients are counseled and re-counseled in the early intrapartum period as they are most receptive at that time and most of the family members are also with them to support their decision. Table 29 shows various studies where predominantly intrapartum counseling was received.

Table 29: Comparing the various studies in terms of counseling.

Studies	Place of Study	Time of counseling	Cu 375 group	CuT 380A group
Divya *et al*[67] (2018)	New Delhi	Intrapartum	70%	69%
Lerma *et al* [47] (2020)	5 states within India	Intrapartum	228 (48.8%)	68 (73.1%)
Index Study (2022)	Rajasthan	Intrapartum	131 (66.84)	132 (66%)

Hence, early and repeated counseling during each antenatal visit and at the time of admission to the labor room is highly required along with public awareness through different media sources to increase not only the acceptance but also the continuation rate in a situation of limited access to postpartum care.

In our study, the attrition rate was 7.07% (28/396), with 9.8% of women followed telephonically in view of COVID pandemic. The clinical follow up in our study was more than that in other studies as seen in table 30. This signifies the result of good counseling and participants' concern about PPIUCD.

During physical or clinical follow up the expulsion was diagnosed using standard protocol of per speculum examination to see the thread through os or by ultrasound to see the presence of IUCD in cavity and at right position. Whereas in case of telephonic follow up, the investigator made the diagnosis of expulsion based on self-report of the participant.

In most low-resource countries, women are discharged rapidly after delivery and seldom return for a postpartum visit. In India, for example, an average of 30% of women do not return for a postpartum visit (based on 2015–2016 data) and consequently may not receive the contraception that they desire. [47]

In a large case control multicentric study by Yadav V. *et al* [43], telephonic follow up was 26.2% as compared to 9.8% in the index study. Table 30 elaborates the type of follow up in various studies.

Table 30: Comparison of Follow up rates in different studies

Studies	Place of Study	Clinical Follow up	Telephonic follow up	Attrition
Jakhar and Singhal [63] (2019)	Jodhpur, Rajasthan	(151 out of 200) 75.5%	(40/200) 20%	(9/200) 4.5%
Levi E *et al* [49] (2012)	Abroad	43 out of 90 (47.7%)	11 out of 90 (12.2 %)	36 out of 90 (40%)
Index study	Rajasthan	327 out of 394 (82.9%)	39 (9.8%)	28 (7.07%)

Expulsion rate:

In the current study, overall, 22 PPIUCDs got expelled completely out of 365 acceptors (after excluding the lost to follow up cases and early discontinuation) by 6 weeks; ten in the Cu 375 group (5.3%) and 12 in the CuT 380A group (6.7%) making an overall expulsion rate of 22 out of 365 i.e 6.02 %. This expulsion rate was more in the CuT 380A group as compared to Cu 375 group but the difference was not statistically significant (P=0.71)

In a study done by Goldthwaite L M *et al*[56] *and* Kumar M *et al*[28], the expulsion rate was significant because they followed the patients for longer duration (one year). The hypothesis that serrated wings in the curved arm of Cu 375 helps to prevent expulsion of the IUCD from a uterine cavity, is partially acceptable in the parous uterus. Table 31 shows the expulsion rate in various studies.

Table 31: Comparison of expulsion between the two types of Cu IUCDs in various studies

Studies	Time of Follow up and Place of study	Cu IUD 375	CuT 380A	P-value
Xess S et *al*[62] (2017), *(n=220)*	At 6 weeks, Rajasthan	3.7%	1.8%	0.28[NS]
Jakhar & Singhal[63] (2019), *(n=200)*	Jodhpur, Rajasthan		5/200 (2.5%)	0.825 [NS]
Beltagy EL *et al* [21] (2011) *(n=300)*	at 6 weeks, Egypt	(9/150) 6.7%	(8/150) 6%,	0.814 [NS]
Kumar M *et al*[28] (2017), (n=300)	at 1-year, New Delhi,	(18/150) 12%	(21/150) 14%	**0.028 S**
Ragab *et al* [45] (2015), *(n=80)*	at 6 weeks, Egypt	(2/40)5%	(5/40)13%	0.435[NS]
Lara Ricalde R *et al* [26] (2006)	At 1 year	10.4%	7.7%	NS
Goldthwaite LM *et al* [56] (2017), *(n=123)*	3 months, compared with LNG IUS, Aurora, Colorado	(8/41) 19.5%		**0.05 S**
Divya *et al* [67] (2018),	12 months New Delhi	(10/150) 2%	(6/150) 0.7%	0.875 [NS]
Index Study (2021) *(n=396)*	Rajasthan	14.3%	14.12%	0.91 [NS]

Ultrasound is currently considered the best follow-up technique for IUD localization. It has been demonstrated that the contraceptive efficacy of an IUD is associated with its fully intrauterine location.

Our study is unique as it includes not only the clinical follow up but also the sonographic follow up. USG was done twice, one before discharge from hospital and one at 6 weeks to look for malpositioned and partially expelled CuT, which was missed in most other studies.

The proportion of women who had malpositioned Cu IUCD in our study was 8.5% and 6.6% in both the groups by taking a cut off of 10 mm. However, in a study by Kumar M *et al* [(28)] a higher proportion of women presented with malpositioned Cu IUCD i.e. 30.6% and 18.6% respectively in both the groups. In a study done by Gurney *et al,* [(23)] amongst 160 enrolled patients, the complete expulsion rate was 8% and partial expulsion was seen in 16%. Of 25 (15.4%) malpositioned intrauterine devices, 14 were not at the fundus (8.6%) and 11 were rotated within the uterus (6.8%). These women are more prone for future expulsion of IUCD and this affects the efficacy of the contraception.

In most of the studies that utilized ultrasound for ruling out any displacements, the distance between the horizontal limb of IUCD and endomyometrial junction was taken but Dias T *et al* measured the distance between the internal os and lower end of vertical limb of IUCD. They concluded that higher the distance of IUCD from internal os, better is the retention of IUCD. [(55)]

The various studies that used sonography for assessing the expulsion are shown in the table 32.

Table 32: Comparison of expulsion on the basis of ultrasound in various studies

Studies	Study place	Variables	Cu 375	CuT 380A	P-value
Divya *et al* [67] (2018)	*New Delhi*	Complete Expulsion	3 (2%)	1 (0.7%)	0.77^{NS}
		Partial expulsion	3 (2%)	1 (0.7)	0.85^{NS}
		Discontinued	5 (3.3%)	1 (0.7%)	
		Continued	139 (92.6%)	147(98%)	0.85^{NS}
Ragab *et al* [45] (2015) (n=80)	*At 6 weeks Egypt*	Complete expulsion	2 out of 40 (5%)	5 out of 40 (13%)	0.435^{NS}
		Partial expulsion or displacement	2/40 5%	9/40 22.5%	
Kumar M *et al* [28] (2017)	*New Delhi, India.*	Complete expulsion	21 out of 150 (14%)	18 out of 150 (12%)	$>0.05^{NS}$
		Partial expulsion	35out of 139 (13.6%)	22 out of 137 (18.6%)	**0.013 (S)**
Index study (2021)	Rajasthan	Complete expulsion	10 (5.3%)	12(6.7%)	0.69^{NS}
		Partial expulsion	17(8.5%)	13(6.6%)	0.48^{NS}
		Discontinuation	1 (0.5%)	4 (2.04%)	-
		Continuation	178 (89%)	163 (83.1%)	0.09^{NS}

The discontinuation rate in our study was 0.5% and 2.04% respectively in both the groups. One patient in Cu 375 group discontinued IUCD due to family pressure and husband influence in the middle of intervention, and the other two patients in the CuT 380A group requested the removal of IUCD owing to prolonged bleeding and crampy abdominal pain at her follow up visit at 6 weeks. Two cases who had PPH after delivery got their IUCD expelled on the same day of insertion and they discontinued because of fear of having heavy bleeding again. Hence, overall discontinuation in our study was 1.35% (5/368) as per modified intention to treat analysis.

In a study done by Muganyizi PS *et al* (39) 33 out of 2347 (5.5%) discontinued IUCD due to PID, husband influence, change in mind, prolonged bleeding PV.

Comparison of IUCD expulsion with respect to the mode of delivery

In our study, the expulsion rate of the IUCD was more in the vaginal delivery (10.7%) than in cesarean section (3.6%). The findings are consistent with the findings observed by Averbach *et al* [48] in their systematic review and meta analysis of different studies, where they observed that complete IUCD expulsion rates was higher in vaginal delivery;14.8% (range 4.8-43.1) as compared to 3.8% (0.0-21.1) for caesarean deliveries. Table 33 illustrates the various studies related to the expulsion on the basis of mode of delivery. It is assumed that in vaginal delivery, the blind insertion of IUCD using Kelly's forceps whereas in cesarean section direct fundal placement of IUCD under vision might be responsible for the difference in expulsion rate. However, Dias T *et al* noticed a contradictory finding as the spontaneous expulsion/removal rate of IUCD was 22.4% after vaginal and 25.8% after caesarean delivery. [55]

Table 33: Comparison of IUCD expulsion with respect to the mode of delivery in various studies

Studies	Place of study & Timing of Follow up	Vaginal Delivery	Caesarean Delivery	P-value
Divya *et al* [67] (2018) (n=300)	12 months, New Delhi		(16/300)5.33%	>0.05^{NS}
Agarwal and Singh [68] (2020) (n=232)	6 weeks, Rajasthan	(10/114)1.69%	3/118 0%	0.12 ^{NS}
Sucak *et al* [24] (2015) (n=160)	12 months Ankara, Turkey,	9.7%	4.3 and 6.7 % (in elective and emergency)	>0.05^{NS}
Mehta et *al* [60] (2019) (n=112)	Ahmedabad.	8.8%	4.6%	> 0.05^{NS}
Dias T *et al* [55]	London, UK	22.4%	25.8%	-
Kumar *et al*[28] (2017), (n=300)	At 12 months, New Delhi,	38/240 15.83%	1/60 (1.66%)	NS
Index study (2021)	Rajasthan	(13/121)10.7%	(9/244)3.6%	**0.007 (S)**

Table 34: Comparison of expulsion rate of Cu IUD with the timing of insertion in various studies

Studies	Place of Study	Variables	PPI (post placental insertion) Group	EPI (early postpartum Group)	P-value
Mehta *et al*[60] (2019)	*Ahmedabad*	Expulsion	3(4.6%)	3 (11.1%)	0.204[NS]
		Missing CuT threads	7(10.7%)	2(7.4%)	0.046NS
		Bleeding PV	2 (3.07%)	2(7.4%)	-
		Removal	6 (9.2%)	5(18.5%)	0.205[NS]
Lerma *et al* [47] (2020)	*5 states within India*	Complete expulsion	3 (3.2%)	35(7.5%)	0.435[NS]
		Removed	8(8.6%)	28(6%)	
		Accidental self-removal	0 (0%)	5(1.1%)	-
		Partial expulsion	5(5.4%)	41 (8.8%)	-
		Retained	77 (82.8%)	358 (76.67)	-
Erogˇlu *et al* [69] (2006)	*Turkey*	Complete expulsion	9 out of 82(11%)	6 out of 46(14%)	0.033[*]
		Partial expulsion	13 out of 82(15.9%)	16 out of 46(37.2%)	-
		Continuation	59 out of 82(72%)	21 out of 46(48.8%)	-
Singh S *et al* [54] (2016)	*2 public-sector, Govt. hospitals in Delhi and Lucknow*	Complete expulsion		7.5%	>0.05[NS]
		Partial expulsion		10%	-
Index study (2021)	Rajasthan	Complete expulsion	10 (3.7%)	12 (12.3%)	0.002[*]
		Partial expulsion	23(8.6%)	7(7.2%)	0.63[NS]
		Discontinuation	2 (0.74)	3 (3.09%)	-
		Continuation	83(77.5%)	258(89.2%)	0.00[*]

In our study Post placental (PP) insertion of IUCD has a lower expulsion rate than Early postpartum insertion (EPI) with a statistically significant p-value. The findings are consistent with the findings observed by Erogˇlu *et al* [69] with significant results.

This result can be related to the higher fundal placement of IUD during PP insertion. The uterine wall is thick after delivery; thus, uterine perforation during PP insertion is unlikely to occur, but as involution begins the uterus becomes small and the uterine wall becomes thin, leading to an increased risk of uterine perforation during insertion. The 10-minute insertion window is a barrier to uptake and should be reassessed for inclusion in service delivery guidelines. Post placental IUD placement, within 10 minutes of delivery, is safe and effective as well as convenient for providers and patients with less pain perception compare to early postpartum insertion.

As far as complications are concerned, in our study, there were no significant complications after PPIUCD insertion thereby documenting its safety. There was no incidence of perforation in either group. The findings are consistent with the findings observed by other researchers. [67,68] The possible reason for the low perforation rate in post placental insertion is due to the thick uterine wall and inserter's expertise.

Xess S *et al* and Divya *et al* [62, 67] in their study observed no significant difference between CuT380A IUCD users and Multiload 375 IUCD users at 6 weeks of follow-up regarding bleeding abnormalities, pelvic pain, or excessive vaginal discharge.

The missing CuT threads in our study was 3.8 % as compared to 38.3% in another study. [67] The Visibility of strings is important as it aids the removal of IUDs and non-visibility may therefore pose a problem for service providers when removal of an IUD is required. Non-visibility of the CuT strings at the time of insertion reassures the provider about the fundal placement of IUD.

Table 35 shows the comparison of complication rates in various studies.

Table 35: Comparison of complications between Cu 375 and CuT380A in various studies

Studies	Complications	Total	Cu 375	CuT 380A	P-value
Xess S et *al* [62] (2017)	Pain abdomen	23.1 %	22.2 %	25%	0.066^{NS}
	Bleeding PV	38.4%	50%	33.4%	
	Discontinued	5.9%	3.63%	8.18%	
	Continued	90.4%	94.6%	86.7 %	
Divya *et al*[67] (2018)	Fever	6/300(2%)	3/150 (2%)	3/150 (2%)	$>0.05^{NS}$
	Bleeding PV	39/300(13%)	18/150 (12%)	21/150(14%)	
	Abdominal pain	38/300(12.6%)	15/150(10%)	23/150(15.3%)	
	Missing CuT threads	115/300(38.3%)	42/150 (28%)	73/150(48.7%)	
Index study	Abdominal cramps	28(7%)	13(6.1%)	15(7.6%)	0.65^{NS}
	Bleeding/Spotting PV	29(9.7%)	19(9.5%)	10(5.1%)	0.093^{NS}
	Missing CuT threads	27(6.8)	14(7%)	13(6.6%)	0.88^{NS}
	Fever	1(0.5%)		-	0.32^{NS}
	Perforation	-	-	-	

In overpopulated countries like ours where there is lack of awareness of family planning measures, institutional delivery can be considered as ideal time to offer contraception. PPIUCD can be inserted within 10 minutes of delivery thus, not prolonging hospital stay and not imposing any additional financial burden making it affordable, especially in low socio-economic group. The expulsion rate was not high in our study, which can be further minimized with technical expertise. Any type of Cu IUCD that is available in the facility can be used as PPIUCD with equivalent safety and efficacy.

STRENGTH AND LIMITATIONS OF THE STUDY

STRENGTH

- The biggest strength of the index study is that it is a randomized controlled trial.
- Despite COVID pandemic and decreased number of deliveries for a considerable period of time, the sample size was achieved.
- Besides clinical follow up, ultrasonographic assessment was also done which makes it unique.
- Total expulsion rate (complete & partial) was also considered in this study which is lacking in majority of the studies.

LIMITATIONS

- The COVID Pandemic and the subsequent lockdown imposed by the authorities hampered the clinical follow up and ultrasound assessment.
- The duration of follow-up was 6 weeks in our study, which is not enough to look for the complications related to menstruation and is also insufficient to comment upon continuation.
- As Ultrasonography is not cost- or resource-effective, particularly in low-income settings where it is probably not accessible or feasible in most facilities, its use as a routine for deciding partial expulsion is not justifiable and is limited in research setting.

CONCLUSION

- This was a randomized controlled trial comparing the expulsion rate of Cu 375 IUCD and CuT 380A IUCD after post placental and early postpartum insertion at 6 weeks after delivery.

- The clinical trial was conducted at All India Institute of Medical Sciences, Jodhpur in the department of Obstetrics and Gynecology from March 2020 to August 2021 after ethical approval and registration at Clinical Trial Registry of India (CTRI).

- All consenting women irrespective of mode of delivery were included in the study.

- A total of 396 patients were randomized into two groups of Cu375 IUCD (200) and Cu T 380A IUCD (196). However, three participants discontinued the intervention. All participants were matched in terms of age, education and other demographic variables.

- Ultrasonography was done to look for the position of the Cu IUCD before discharging the participants and they were called for follow-up at six weeks, when again the sonography was done to ensure the exact location of IUCD.

- The Complete expulsion rate in both the Cu IUCD groups was comparable at 6 weeks follow-up. Overall the expulsion rate was 22/365 (6.02%). On doing modified intention to treat analysis, the expulsion rate in both the groups was 5.3% and 6.7% while on Per protocol analysis, the expulsion rate was 5.7% and 7.8%. This difference was comparable in both the groups, thereby, reaching a conclusion that the type of IUD does not affect the expulsion rate. However, further research is needed for prolonged follow up to generalize this finding.

- This study also utilized the ultrasonography to assess the rate of partial expulsion which was 8.5% in group A and 6.6% in group B and found that the total expulsion rate including both complete and partial, was higher in both the groups, (14.3% and 14.1% according to modified intention to treat; and 15.5% and 16.4% according to Per protocol analysis.

- As far as secondary outcomes were concerned, it was observed that the expulsion rate was more in the vaginal delivery group (10.7%) than in caesarean section (3.68%) group with a statistically significant difference (P- 0.007). Thus, concluding that in caesarean sections,

since IUCD is inserted under vision directly upto the fundus whereas in vaginal delivery, the blind insertion of IUCD using Kelly's forceps might be a hindrance for near fundal placement. Hence the high fundal placement of IUCD was achieved more in cesarean section than in vaginal delivery.

- The study also concluded that the expulsion rate was more in the early postpartum insertion group 12.3% than in the post placental insertion group 3.7 % which was statistically significant (P- 0.002). Since the majority of the post placental insertion was done during the time of cesarean section under direct vision higher fundal placement of IUD was achieved. Additionally, the continuation rate of IUCD was significantly higher in the PPI group as compared to EPI group (P= 0.002).

- The complication rate in both the groups of Cu IUD was comparable in terms of abdominal cramps, prolonged bleeding or spotting and missing CuT threads, thereby, concluding that both types of Cu IUDs are equally safe and effective. There was no case of perforation in either of the groups. The discontinuation rate in Cu 375 group and CuT 380A group was 0.5% and 2.04 % respectively.

- From the index study, we conclude that the horseshoe shape of Cu 375 with serrated edges has effectively no role in decreasing the expulsion rate. The timing of insertion has an impact on the expulsion rates. Expulsion rates were significantly less if PPIUCD was inserted within 10 minutes of placental delivery because it is convenient for high fundal placement of IUCD with less discomfort to participants. In the early postpartum period (between 10 minutes and 48 hours) the uterus has more time for involution which makes it difficult for high fundal placement of IUCD. In the cesarean section, IUCD is inserted under vision directly into the fundus, hence high fundal placement of IUCD was achieved more in cesarean section than in vaginal delivery.

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Ethical Clearance Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2073 Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/947**

Project title: **"Comparison of the expulsion rate of intra uterine contraceptive device Cu T 375 and Copper T 380 A after post placental and early postpartum insertion - A randomized control trial"**

Nature of Project:	**Research Project**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr.Nitesh C.**
Guide:	**Dr.Charu Sharma**
Co-Guide:	**Dr.Shashank Shekhar, Dr.Pratibha Singh, Dr.Manisha Jhirwal & Dr.Meenakshi Gothwal**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Enclose:
1. Annexure 1

Basni Phase-2, Jodhpur, Rajasthan-342005, **Website:** www.aiimsjodhpur.edu.in, **Phone:** 0291-2740741 Extn. 3109
Email: ethicscommittee@aiimsjodhpur.edu.in

Annexure 1

Institutional Ethics Committee
All India Institution of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on **23-12-2019 at 10:00** AM at Committee Room, Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	**Chairman**
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary

Dr. Praveen Sharma
Member Secretary
Institutional Ethics Committee
AIIMS, Jodhpur

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

(Department of Obstetrics & Gynecology)

PROFORMA FOR DATA COLLECTION: -

Name of the patient Age: REG.ID:

Education: Occupation:

Mobile No. Socio economic status:

BMI (Kg/m^2)

Urban /Rural:

Parity Religion

Mode of Delivery- Vaginal /Instrumental /Caesarean

Sex of baby delivered

Number of children

Decision taken by

Patient herself/ Husband /Mother in law

Any hurdles in decision making – Yes /No

If Yes -Specify

No. of antenatal visits

Booked /Unbooked

Timing of counselling- Antenatal clinic, Early labor/ After delivery

Membrane status

Date and Time of insertion after delivery: Postplacental / Early postpartum insertion.

Previous H/O IUD use and intolerance to the device: YES / NO

Ultrasound before discharge-

IUD in situ (inside the uterine cavity or lower segment)

IUD outside the uterus (in the vagina or IUD located in the cervical canal).

Completely expelled (empty uterine cavity, outside the patient body)

Distance of horizontal limb of IUCD in mm from endometrial lining of fundus of uterus _____

Follow up

Breastfeeding habits

Expulsion -Yes/No

Timing of expulsion in days/ weeks_____

If No – Ultrasound

Distance of horizontal limb of IUCD in mm from endometrial lining of fundus of uterus_____

Any other complications

Foul smelling discharge, Excessive Bleeding / spotting per vaginum

Any signs and symptoms of infection like fever or chills, myalgia, body ache, discharge P/V

Unusual vaginal discharge or pain lower abdomen.

Resumption of menstruation:

Menstural irregularities: Menorrhagia / Dysmenorrhea

Missing CuT thread (strings) or elongated CuT thread

Discontinuation

Expulsion

Ask her if she felt the hard plastic of an IUD that has partially come out

Questionaire at follow up visit

1. Discontinued under husband influence?
2. Are you satisfied with your CuT? Yes/No
3. Would you recommend it to others?
4. If you have any additional Suggestions, please let us know
5. Currently used method if PPIUD was discontinued were enquired.

Thank you for your participation.

PPIUCD FOLLOW UP CARD: [For any querries contact:Dr Nitesh C (9900906959)]

Alloted case No. _____

1. NAME 2. REG NO
2. DATE and TIME OF INSERTION
3. DATE OF POSTPARTUM FOLLOW UP VISIT
4. LOCAL EXAMINATION
5. PER SPECULUM EXAMINATION
6. USG

Checklist

1. Date of visit
2. Duration from insertion
3. Duration of blood flow
4. Lower abdominal pain
5. Pyrexia
6. Foul smelling vaginal discharge
7. Supra pubic tenderness
8. Uterus involuted
9. State of cervix
10. Perforation
11. IUCD strings visualized
12. IUCD expulsion
13. Satisfaction with PPIUCD

All India Institute of Medical Sciences

Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation : **Comparison of the expulsion rate of intra uterine contraceptive device Cu 375 and CuT 380A after post placental and early postpartum insertion- A randomized control trial**"

Name of PG Student : Dr. Nitesh C Tel. No. 9900906959

Patient/Volunteer Identification No. : _____

I,_____S/o or D/o_____

R/o_____

give my full, free, voluntary consent to be a part of the study "**Comparison of the expulsion rate of intra uterine contraceptive device Cu 375 and CuT 380A A after post placental and early postpartum insertion- A randomized control trial**", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I had opportunity to ask the questions. I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from **AIIMS Jodhpur** or from regulatory authorities. I give permission for these individuals to have access to my records.

Date : _____ _____

Place : _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date : _____ _____

Place : _____ Signature of PG Student

1. Witness 1

   _____

   Signature

   Name: _____

   Address : _____

   _____

2. Witness 2

   _____

   Signature

   Name: _____

   Address : _____

   _____

अखिल भारतीय आयुर्विज्ञान संस्थान

एम्स जोधपुर

सूचित सहमति पत्र

थीसिस / निबंधका शीर्षक: पोस्ट प्लेसेंटल और अर्ली पोस्टपार्टम इंसर्शन के बाद गर्भाशय में डाली गयी गर्भ निरोधक कॉपर 375 और कॉपर T 380A के निष्काशन दर की तुलना - एक यादृच्छिक नियंत्रण परीक्षण

पीजी छात्र का नाम: डॉक्टर नितेश सी

दूरभाष संख्या: 9900906959

रोगी / स्वयं सेवक पहचान संख्या: _____

मैं, _____ पत्नी/ पुत्री _____आर / ओ _____

अध्ययन"पोस्ट प्लेसेंटल और अर्ली पोस्टपार्टम इंसर्शन के बाद अंत: गर्भाशय गर्भ निरोधक कॉपर 375 और कॉपर T 380A निष्काशन दर की तुलना - एक यादृच्छिक नियंत्रण परीक्षण" का एक भाग बनने के लिए मेरी पूर्ण, स्वतंत्र सहमति देती हूँ जिसकी प्रक्रिया और प्रकृति मुझे अपनी पूरी संतुष्टि के लिए अपनी भाषा में समझाई गई है।मै पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझती हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को अखिल भारतीय आयुर्विज्ञान संस्थान या विनियामक प्राधिकरणों से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन लोगों के लिए मेरे रिकॉर्डों तक पहुंचने की अनुमति देती हूं।

तारीख : _____

जगह: _____ हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है।

तारीख : _____

जगह: _____ पीजी छात्र के हस्ताक्षर

1. गवाह 1 2.गवाह 2

Patient Information Sheet

Part-1

You are invited to take part in this study entitled "**Comparison of the expulsion rate of intra uterine contraceptive device Cu 375 and CuT 380A after post placental and early postpartum insertion- A randomized control trial**."

It is informed that it is entirely voluntary and you may refuse to take part or discontinue at any time without losing your right to adequate clinical care.

This research is aimed at studying the outcome of post-partum IUCD placement. If the outcomes after post-partum IUCD insertion are better, it will give wider choice of contraception to post-partum women and will be a valuable addition to National Family Planning program.

No extra test or Investigations are needed as a part of the study. The IUCD will be applied free of cost. You will be randomly divided into two groups after your consent. In Group A Cu 375 and in group B Cu T 380A will be applied. You are expected to come for follow up at 6 weeks which will coincide with your baby's vaccination.

All the records will be kept confidential.

You have the right to ask for any further information that you require.

In case of any doubt regarding the study you are welcome to contact the undersigned personally or telephonically.

Part-2

Investigator's statement

I have explained the purpose, procedures, benefits and harms of the study in detail to the patient/ patient's relative.

All information regarding the study has been disclosed.

Enough Time and Opportunity for asking questions regarding the study was given to the patient/ patient's relative.

Investigator signature: - Witness signature:-

Phone no.

रोगी सूचना पत्र

आपको इस अध्ययन में भाग लेने के लिए आमंत्रित किया गयाहै "पोस्ट प्लेसेंटल और अर्ली पोस्टपार्टम इंसर्शन के बाद गर्भाशय में डाली गयी गर्भ निरोधक कॉपर 375 और कॉपर T 380A के निष्काशन दर की तुलना - एक यादृच्छिक नियंत्रण परीक्षण" यह सूचित किया जाता है कि यह पूरी तरह से ऐच्छिक है और आप देखभाल के अपने अधिकार को खोए बिना किसी भी समय हिस्सा ले सकते हैं या बाहर निकल सकते हैं।

इस शोध का उद्देश्य पोस्ट-पार्टुम IUCD प्लेसमेंट के परिणाम का अध्ययन करना है। यदि पोस्ट-पार्टम आईयूसीडी डालने के बाद परिणाम बेहतर हैं और निष्काशन दर काम होती है, तो यह पोस्ट-पार्टुम महिलाओं को गर्भनिरोधक का व्यापक विकल्प देगा और राष्ट्रीय परिवार नियोजन कार्यक्रम के लिए एक मूल्यवान उपाय होगा।

अध्ययन के इस हिस्से के रूप में कोई अतिरिक्त परीक्षण या जांच की आवश्यकता नहीं है। आईयूसीडी को नि: शुल्क लगाया जाएगा। आपकी सहमति के बाद आपको यादृच्छिक रूप से दो समूहों में विभाजित किया जाएगा। समूह I में CuT 380 A और समूह 2 में Cu 375 लगायी जाएगी । आपसे 6 सप्ताह पर आने की उम्मीद है जो आपके बच्चे के टीकाकरण के साथ मेल खाएगा।

अगर आप इस अध्ययन में भाग लेने से इनकार करते हैं तो जांच और उचित उपचार नियमित प्रोटोकॉल के रूप में किया जाएगा।

इस अध्ययन में आपकी भागीदारी अपेक्षित अवधि छः सप्ताह होगी।

अध्ययन के कारण कोई विशिष्ट नुकसान नहीं है। सभी रिकॉर्ड गोपनीय रखें जायेंगे। आपके पास किसी भी प्रकार की अधिक जानकारी लेने का अधिकार है। अध्ययन के बारे में किसी भी संदेह की स्थिति में आपका व्यक्तिगत रूप से या टेलीफ़ोनिक रूप से संपर्क करने के लिए स्वागत है।

<u>जांचकर्ता का बयान</u>

मैंने अध्ययन के उद्देश्य, प्रक्रियाओं, लाभ और हानि को रोगी / रोगी के रिश्तेदार को विस्तार से समझाया है।

अध्ययन के बारे में सभी जानकारी का खुलासा किया गया है।
अध्ययन के संबंध में प्रश्न पूछने के लिए पर्याप्त समय और अवसर रोगी / रोगी के रिश्तेदार को दिया गया था।

जांचकर्ता हस्ताक्षर: - साक्षी हस्ताक्षर:

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