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## **PPIUCD in private sector: Prospective study to assess acceptability, safety and expulsion rate of Cu T 380 A in immediate postpartum period**

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**Abstract**--PPIUCD is preferably inserted within 10 minutes of placenta delivery, intracaesarean, or 48 hours of delivery. In India, 65 percent of women have unmet family planning needs. The goal of this prospective study was to assess the acceptability, safety, and expulsion rate of Cu T 380 after 6 weeks of insertion. The research was conducted at St. Stephen's Hospital in Delhi, a tertiary care facility, in the Department of Obstetrics and Gynecology. For a year, 150 patients of various ages were implanted with PPIUCD. Patients were monitored for 6 weeks to assess- 1) Expulsion rate 2) Safety within Within 6 weeks of insertion, there was no evidence of abdominal pain, foul-smelling vaginal discharge, bleeding, or perforation. 3). Removal reasons In our study, we found that the overall complication rate was 9.29 percent, with infection rate 0.7 percent, prolonged lochia rate 2.1 percent, persistent bleeding rate 3.6 percent, and pain abdomen 1.4 percent. The study's removal rate was 5.0 percent. The rate of expulsion was 2.86 percent. The satisfaction rate was 80%. Based on the findings of this study, we believe that postpartum IUCD should be widely used as a contraceptive.

**Keywords**--postpartum IUCD, family planning, complication.

## **Introduction**

PPIUCD is preferably inserted within 10 minutes of delivery of placenta, intracaesarean, < 48 hours of delivery [2]. The presence of the IUCD in the uterine cavity creates a local inflammatory reaction that prevents sperm from reaching the fallopian tubes. Cellular and humoral components of this inflammation lead to decreased sperm and egg viability. In India 65% of women have an unmet need for family planning. Only 26% of women use any method of family planning during first year postpartum and 61% of births in India occur at intervals shorter than 36 months [3]. WHO recommends interval between attempting the next pregnancy should be at least 24 months [4]. Insertion of postpartum IUCD has several advantages over other methods of contraception i.e. commencement of ovulation is unpredictable after delivery, delivery may be the only time when healthy women come in contact with health care providers, women are likely to be highly motivated for accepting contraception during postpartum period, and the setting is convenient since procedure is carried out by expert hands and women remain under professional care post delivery.

Also, there is newer understanding about IUCD in terms of acceptability and low expulsion when inserted with proper technique. However it is associated with increased risk of expulsion, perforation and infection as compared to interval IUCD insertion due to physiological changes in uterine anatomy during pregnancy. WHO introduced its MEC (medical eligibility criteria) [2] for postpartum and postabortal IUCD insertion and revised them in 2009 and placed Postpartum IUCD insertion in category 1 (no restriction to use). In Nov 2010, Ministry of Health & Family Welfare introduced guidelines for all health facilities to provide good quality postpartum (post placental as well as early postpartum and intracaesarean) IUCD services to deal with the unmet need of contraception. PSI (Population Services International) and FOGSI (Federation of Obstetric and Gynaecological Societies of India) [5] have introduced Pehel women health programme to promote women health and increase the use of IUCD and promoting Postpartum IUCD insertion (post placental and early postpartum < 48 hours). Hence this study is being conducted to assess acceptability, safety and expulsion rate of postpartum IUCD (Cu T 380A) in St. Stephen's Hospital, New Delhi.

## **Methods and Materials**

### **Study population**

Women delivered in St. Stephen's hospital from 1st December 2014 to 31st November 2015.

### **Study design**

Prospective study

**Sample size**

The sample size of this study is 150. With precision error of estimation ( $d$ ) = 0.05 (or 5%), and  $\alpha = 0.05$ , a sample size of minimum 150 postnatal women is needed. Sample size was calculated using the formula for study  $(z^2 \times p \times q) / d^2$

**Inclusion criteria**

- All postnatal women delivering vaginally (within 48 hours of delivery)
- Prior consent obtained for PPIUCD after counselling
- Willing to have IUCD inserted and follow up

**Exclusion criteria:**

- Patient's refusal
- Patients with chorioamnionitis and puerperal sepsis
- Postpartum hemorrhage traumatic & atonic
- Fibroid uterus & Uterine malformation
- Rupture of membranes >18 hours

**Methodology**

All patients willing for spacing of childbirth were counselled during antenatal period or in early labour about PPIUCD in a structured format. Patients motivated for immediate postpartum IUCD insertion were assessed for eligibility and those meeting the inclusion criteria after obtaining written informed consent were included in the study.

**Post-placental IUCD insertion**

IUCD was placed within 10 minutes of placental expulsion after vaginal delivery. Episiotomy, cervical, vaginal tears were repaired after IUCD insertion.

**Early post partum insertion**

IUCD was inserted up to 48 hours post delivery.

**Steps of IUCD insertion**

- Informed and written consent taken.
- After delivery and active management of third stage of labour, willingness of PPIUCD is reconfirmed.
- Perineum is inspected for lacerations.
- Cervix visualised using Sim's speculum (held by assistant) and anterior vaginal wall retractor.
- Cervix and vagina cleaned twice with sterile swabs.
- Anterior lip of cervix is grasped with sponge holding forceps.
- CuT 380 a is held with Kelley's forceps or sponge holding forceps in sterile packet at junction of horizontal & vertical arms.

- Forceps with IUCD inserted through cervix to lower uterine segment without touching the vagina.
- Place the left hand on sterile drape over the fundus of uterus
- IUCD with forceps is advanced upwards following the contour of uterus until it can be felt at fundus
- Keeping the tongs open forceps swept to sidewalls of uterus and slowly removed.
- Uterus stabilized until forceps are out.
- Proper placement confirmed by non-visibility of strings through cervix, if strings are visible, it was placed too low and it was removed and reinserted.
- Other instruments were removed.

### **Before discharge**

patient was explained about:

- rest, nutrition and hygiene.
- the warning signs that warrant medical care: excessive bright red bleeding for which patient needs to change her fully soaked pad > 6 times a day
- follow up at 6 weeks to assess expulsion, infection, missing threads, any other complications and reason for removal if any.

### **Follow up visit at 6 weeks**

- Detailed history and physical examination
- Unusual abdominal or pelvic pain (not after birth pain)
- Unusual vaginal discharge or pain, or fever.
- Discomfort of strings.
- Expulsion of IUCD.
- Per speculum/ per vaginal examination
- Check strings, shorten them check for signs of infection and excessive bleeding
- Evaluate for: expulsion: by history, physical examination and USG if indicated side - effects: bleeding, pain, signs / symptoms of infection
- Women explained how to feel for thread and report back in case of missing thread or any warning sign or missed period.

### **Outcome Measures**

- **Primary outcome measures** - expulsion rates
- **Secondary outcome measures** -complications at 6 weeks postpartum removal rates for pain, bleeding, foul smelling discharge Failure rates

### **Statistical Methods**

Descriptive statistics will be analyzed with spss version 17.0 software. Continuous variables will be presented as mean +SD. Categorical variables will be expressed as frequencies and percentages. Nominal categorical data between the groups will be compared using chi-square test or fisher's exact test as

appropriate. A p value < 0.05 will be taken to indicate a significant difference.

## Results

Of the 578 people counselled, 186 patients were willing to participate in the study. They were assessed for eligibility criteria, 16 patients underwent cesarean section, 6 excluded due to PPH during delivery, 8 had prolonged prelabour rupture of membranes > 18 hours, 6 declined IUCD post delivery. Remaining 150 patients underwent Cu T 380 A insertion and were followed up at 6 weeks.

- Majority of the patients belonged to 26 – 30 years age. Mean age of enrolment was  $28.71 \pm 3.62$ . (Table 1)
- A large proportion of literate women adopted IUCD, highest seen in graduate women. (Table 2)
- Maximum number of patients belonged to upper middle (30%) and upper lower class (30.7%) (Table 3)
- Follow up rate of the study at 6 weeks was 93.3%.
- At 6 week 6.7 % (n = 10) patients were lost to follow-up. 4 patients out of 140 who came for follow up at 6 weeks had their IUCD expelled. This makes the expulsion rate to be 2.86 %. Continuation Rate: At 6 week follow up 92.14% (129 patients out of 140 followed up patients) were willing to continue the PPIUCD. Removal Rates: At 6-week follow up was 5.0% (n = 7) (Table 4)
- A total of 13 (9.29 %) had complications. Constant pressure by family members for discontinuation of Cu T was also included in complication. Most common complication encountered was persistent bleeding. (Table 5)
- Out of 5 patients who presented with persistent bleeding as complication 60% (n = 3) continued after medical management and 40% (n = 2) underwent removal. 2 patients had constant pain abdomen out of which 50% (n = 1) underwent removal, and 1 was managed medically. 1 patient had PID managed conservatively. 3 patients had prolonged lochia, 66.7% (n=2) underwent removal. 2 patients got their IUCD removed due to disapproval and discouragement by family members.
- p value of <0.001 observed reflecting a significant effect of complications on removal rate. (Table 5)
- Patients were asked to share their experiences of IUCD after 6 weeks. Women satisfied with PPIUCD were 80%.
- Different complications were assessed according to different age groups, literacy status and socioeconomic status, there was no statistically significant relationship with p value 0.972, 0.065, 0.189 respectively.
- Complications increased with increasing parity. There was significant difference observed with p value = 0.011. (Table 6)

Table 1  
Distribution of patients according to age in years

Age	Frequency	%
21 - 25	27	18.0%
26 - 30	78	52.0%

31 - 35	41	27.3%
36 - 40	4	2.7%
Total	150	100%
Mean $\pm$ SD	28.71 $\pm$ 3.62	
Min - max	21 - 38	

Table 2  
Distribution of patients according to Literacy level:

Literacy Status	Frequency	%
Illiterate	4	2.7%
Primary	26	17.3%
Secondary	42	28.0%
Higher secondary	34	22.7%
Graduate	44	29.3%
Total	150	100%

Table 3  
Distribution of patients according to socio-economic status

Socio Economic Status	Frequency	%
Upper	15	10.0%
Upper Middle	45	30.0%
Lower Middle	31	20.7%
Upper Lower	46	30.7%
Lower	13	8.7%
Total	150	100%

Table 4  
Continuation/Expulsion/Removal rates

6 Weeks Follow-up	Frequency	%
Continued	129	92.14%
Expelled	4	2.86%
Lost to FU	10	6.7%
Removal	7	5.0%
Total	150	

Table 5  
Relationship between complications and frequency of continuation and removal

Complications	Total Cases	6 Weeks Followup			P Value
		Continued	Expelled	Removal	
		Frequency(%)	Frequency(%)	Frequency(%)	
None	127	123 (96.9%)	4 (3.1%)		<0.001
Bleeding	5	3 (60%)		2 (40%)	
Family pressure	2			2 (100%)	
Pain abdomen	2	1 (50.0%)		1 (50.0%)	
PID	1			1 (100%)	
Prolonged lochia	3	2 (66.7%)		1 (33.3%)	
Total	140	129 (92.9%)	4 (2.9%)	7 (5.0%)	

Table 6  
Relationship of complications with parity:

Parity	Total cases	Complications						P value
		None	Bleeding	Family pressure	Pain abdomen	PID	Prolonged lochia	
		Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	
1.00	10	8 (80%)	1 (10%)	1 (10%)				0.011
2.00	98	93 (94.9%)	1 (1.0%)			1 (1.0%)	3 (3.1%)	
>2	32	26 (81.3%)	3 (9.4%)	1 (3.1%)	2 (6.3%)			
Total	140	127 (90.7%)	5 (3.6%)	2 (1.4%)	2 (1.4%)	1 (0.7%)	3 (2.1%)	

## Discussion

Postpartum insertion of IUCD in India dates back to 1988 reported by Ananthasubhranium et al. [6] It is because of the high expulsion rates and limited data that PPIUCD has not been utilized to its maximum. The Mean age of participating women was  $28.71 \pm 3.62$  years comparable to population in studies by Xu et al ( $24.55 + 3$  years), Celen et al (24.7 years) [7,8]. The age composition depends on age at marriage, parity of the women in chosen population eg primiparity in Chinese population and multiparity and early age of marriage in Indian context may determine the age composition of the study. There were only 7.3 % primiparous women accepting IUCD in the study; different from Eroglu et al 35.1% Celen et al 31%. However in a study by Xu-JX et al 97.7 % of the enrolled 910 women were primiparous possibly because of the state's one child

policy. [7,8,9].The literacy level in our study was higher (Illiterate 2.7%, Primary 17.3%, Secondary 28.0%, higher secondary 22.7%, graduate 29.3 %) similar to Eroglu study (1.9% just literate and 51.2% primary pass).

Socio-economically our population predominately belonged to upper middle (30%) and upper lower class (30.7%) (According to modified kuppuswamy scale). This could possibly be explained by the fact that the place of study is a private hospital with delivery packages accessible to these strata of population. Expulsion rates at 6 weeks (2.86%) were lower as compared to similar studies in CuT 380 A. Expulsion rate at 6 week reported by Kumar S et al was 3.6%, Kittur S 5.23% [11,12]. Celen S et al [9] reported expulsion rate of 12.3% at 1 year. Grimes D. et al [10] had 23.5% in immediate group vs 4.4% in delayed insertion. Cochrane database review by Greimes et al [10] and Kapp & Curtis [13] on IUCD shows the expulsion rate depends on timing, method, skill, type of IUCD inserted. Though interval insertion has least expulsion rate, the benefit and convenience of postpartum IUCD insertion with acceptable expulsion rates outweighs it. The overall complication rate in this study was 9.29%, with infection rate (PID) 0.7%, prolonged lochia 2.1%, persistent bleeding 3.6%, pain abdomen 1.4 %.

Out of which 5 patients wanted removal due to complications (bleeding, PID, prolonged lochia, pain abdomen) and 2 due to discouragement by family members. Hence the removal rate for the study was 5.0 %. Two women had heavy bleeding post insertion in Xu et al study compared to this study where lochia was prolonged in 3 patients. This data reconfirm that IPPI is safe and can be promoted in maternity hospitals. In the study by Xu et al no uterine perforations or pelvic sepsis were noted. Similarly there was no case of perforation or pregnancy with IUCD in situ in this study. [7] It was observed that there was higher number of complications in multiparous women compared with primiparous women with  $p < 0.01$ . Follow up rates in the study was 93.3%. The lower loss to follow-up rate was attributed to the fact patients full details with complete address and contact number were well . There were 80 % women satisfied with PPIUCD insertion. Patient satisfaction though no author has studied was important determinant in uptake of this as a contraceptive.

### **Conclusion**

Although WHO, and Govt. of India recommend postpartum IUCD under standard regimen, it is under practiced possibly due to high concerns of expulsion rates, lack of awareness and limited data available on safety in our set up and other private institutions in India. This study showed high satisfaction rate among patients, with minimal complications and no perforation. Therefore should be practiced more widely in private institutions.

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