

Evaluation of Safety, Efficacy and Continuation Rates of Postpartum Intrauterine Contraceptive Device (PPIUCD)

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Abstract: ***Objective:** To evaluate the safety, efficacy and continuation rates of postpartum intrauterine contraceptive devices (PPIUCD). **Methodology:** This is a prospective study done at the Department of Obstetrics and Gynaecology, Coimbatore Medical College Hospital from August 2014 to July 2015. After obtaining informed consent, 200 women who fulfilled the inclusion criteria underwent postpartum insertion of Cu T 380A. They were followed up at 6 weeks, 3 months and 6 months postpartum. **Results:** Out of the 200 women who underwent PPIUCD insertion, 41.5% were post placental, 20.5% immediate postpartum and 38% intracaesarian. The gross cumulative expulsion, removal and continuation rates were 5%, 6% and 78.5% respectively. There were no major complications noted. **Conclusion:** PPIUCD is a safe, very effective, long acting contraception with few side effects and no major complications.*

Keywords: Postpartum Intrauterine Contraceptive Device (PPIUCD), CuT 380A, Contraception, Expulsion, Continuation.

1. Introduction

India is the second most populous country in the world. In the year 2000, Indian population had crossed 1 billion and is projected to reach 1.53 billion by the year 2050. Family planning with adequate spacing between the pregnancies can prevent about 32% of maternal deaths and 10% of child mortality [1].

The recommended interval between 2 births is at least 3 years for a healthy pregnancy. 61% of the births in India have less than 3 years of spacing as per the third National Family Health Survey conducted in the year 2005-2006 [2]. Pregnancies with less than the recommended spacing result in spontaneous abortion, preterm labour, postpartum haemorrhage, SGA babies, fetal deaths and maternal deaths. In our country, the unmet family planning need is 65% in the first year of postpartum period [3] and FP methods are used by only 26% of the women during this period [4].

About 40% of the women resume sexual activity within 3 months postpartum and 90% of the women resume sexual activity within 10-12 months [5]. In countries like India, the only time a healthy woman contacts a health care provider is during delivery and many do not return for follow up. Also during this time the woman is very much motivated and receptive to family planning advice. Hence delay in initiating a birth control method puts them at increased risk of unplanned pregnancies. IUCD's are highly effective, safe, long acting, coitus independent, cost effective and fertility returns quickly as soon as it is removed.

According to the Medical Eligibility Criteria by World Health Organization, IUCD insertion within 48 hours after delivery is safe and highly effective [6]. In India, IUCD use is by only 2% of current contraceptive users [2]. At present the Copper T 380A is used by the government for immediate postpartum insertion.

With increase in institutional deliveries, the Government of India decided to introduce the PPIUCD in a phased manner. The clinical trainings were first started in 2009. A training centre at the national level was started at Safdarjung Hospital at New Delhi and 3 training centres at the regional level were started at Mumbai, Lucknow and Jabalpur in the year 2009-2010. Earlier studies have shown high expulsion rates of about 9-13%. Recent studies have shown that with better insertion techniques, the expulsion rates can be lowered.

As PPIUCDs are an emerging contraceptive choice in India, we still rely on international studies for follow-up data. Given the scale at which PPIUCD services are being introduced in India, it is important to generate country-based evidence about the PPIUCD. This would lead to an improved infrastructure with better trained health care personnel who provide evidence-based services.

2. Materials and Methods

This is a prospective study done at Department of Obstetrics and Gynaecology, Coimbatore Medical College Hospital from August 2014 – July 2015. Ethical approval for the study was obtained from hospital ethics committee prior to the commencement of the study. 200 women delivering in the hospital fulfilling the inclusion criteria were included in this study after obtaining informed consent.

Inclusion Criteria

- 1) All women delivering vaginally or by caesarean section, counselled for PPIUCD antenatally, in early labour or in the immediate postpartum period.
- 2) Provided informed written consent to participate in the study.
- 3) Parturients who are residing locally so that they can conveniently come for follow up.

Exclusion Criteria

- 1) Those who did not provide informed consent

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- 2) Postpartum haemorrhage
- 3) PROM > 18 hours
- 4) Chorioamnionitis
- 5) Active STD / other lower genital tract infection
- 6) Fever $\geq 38^{\circ}$ C during labour and delivery
- 7) Puerperal Sepsis
- 8) Uterine anomaly
- 9) HIV positive patients taking ART.

A questionnaire was used to collect data from the patients, which included socio demographic data, awareness about PPIUCD and obstetric history. Those women fulfilling the inclusion criteria underwent postpartum insertion of IUCD (Postplacental- within 10 minutes of placental delivery using Kelly's forceps, Immediate Postpartum- 10 minutes to 48 hours following delivery using Kelly's forceps, Intra-caesarean- During caesarean section, after removal of placenta, through uterine incision, IUCD is inserted manually).

Proper fundal placement of the IUCD was confirmed by abdominal ultrasonography when the distance between the endometrium of the uterus at fundus and the upper part of the IUCD was less than 10 mm.

All women were advised to come for follow up at 6 weeks, 3 months and 6 months following IUCD insertion. A follow up card was given to all the women containing information regarding type of PPIUCD inserted, insertion date, date of expiry, date of follow up visits, principal investigator's telephone number. During follow up visits, data were collected regarding complaints, willingness to continue Cu T, request for removal. Clinical examination was done which included temperature, per abdomen examination for involution of uterus and supra-pubic tenderness, speculum examination to see if strings were visible and to look for any abnormal discharge. Women who expelled the IUCD or those with missing strings, transvaginal USG was done to confirm expulsion. IUCD endometrial distance was also measured during the follow up visits. IUCD endometrial distance was measured from the top of the vertical arm of the IUCD and the junction between the endometrium and uterine cavity in the longitudinal plane.

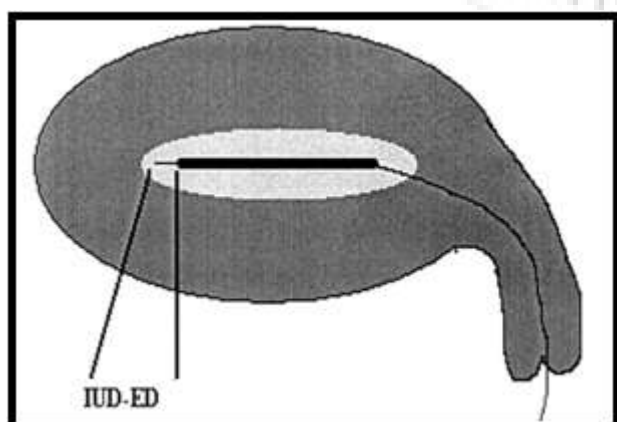


Figure 1: Measurement of IUCD endometrial distance

The collected data were analysed with SPSS (Statistical Package for the Social Sciences) 16.0 version and frequencies and percentages were calculated. To find the

significance in categorical data, Chi-Square test was used. In the above statistical tools the probability value <0.05 is considered as significant.

3. Results

This is a prospective longitudinal study in which 200 women fulfilling the inclusion criteria underwent postpartum insertion of Cu T 380A over a period of one year after obtaining informed consent. The safety, efficacy and continuation rates were analysed. The insertion was postplacental in 83 women (41.5%), immediate postpartum in 41 women (20.5%) and intra-caesarian in 76 women (38%).

Table 1: Socio demographic and obstetric characteristics

Characteristics	Number	Per cent
Age in years		
Up to 20	22	11.0
21-25	109	54.5
26-30	54	27.0
31-35	14	7.0
Above 35	1	0.5
Socioeconomic status		
Lower	108	54.0
Upper lower	77	38.5
Lower middle	13	6.5
Upper middle	2	1.0
Upper	0	0.0
Parity		
Primiparous	154	77.0
Multiparous	46	23.0

Majority of the women were aged between 21-25 years (54.5%), 54% belonged to lower socioeconomic status, 77% were Primiparous.

Table 2: Awareness of PPIUCD and literacy

Education	Awareness of PPIUCD			
	Yes (Number)	Yes (%)	No (Number)	No (%)
Illiterate	1	1.20	6	5.13
Primary school	5	6.02	50	42.74
Middle school	22	26.51	35	29.91
Secondary school	25	30.12	17	14.53
Higher secondary	21	25.30	8	6.84
Degree/Diploma	9	10.84	1	0.85

Highly significant by Pearson Chi square test (P-Value = 0.0005)

Awareness of PPIUCD increases with literacy rate. Among those aware of PPIUCD, majority of them (30.12%) studied up to secondary school and among those unaware of PPIUCD, majority (42.74%) had studied up to primary school.

Table 3: Follow up

Follow up	6 weeks N=200(%)	3 months N=182(%)	6 months N=172(%)	Total
Lost to follow up	6	6	9	21
Return for follow up	191	175	157	
Return for removal	3	1	6	10
Expulsion	9	3	-	12
Continuation	182 (91.0%)	172 (86.0%)	157 (78.5%)	

At the end of 6 months, out of the 200 women who were inserted PPIUCD, there were 10 removals, 12 expulsions with gross cumulative removal, expulsion and continuation rates of 5%, 6% and 78.5% respectively.

Table 4: Complications at follow up

Complications	6 weeks n=194	3 months n=176	6 months n=163
No complaints	166 (85.6%)	161 (91.5%)	152 (93.3%)
HMB	6 (3.1%)	8 (4.5%)	9 (5.5%)
Pain abdomen	7 (3.6%)	4 (2.3%)	2 (1.2%)
Missing strings	6 (3.1%)	-	-
Expulsion	7 (3.6%)	3 (1.7%)	-
Partial expulsion	2 (1.0%)	-	-

There was no case of perforation, pelvic infection and pregnancy with the IUCD *in situ*.

Table 5: Expulsion and timing of insertion

Timing of insertion	Expulsion (Number)	Expulsion (%)
Post placental	3/83	3.61
Immediate postpartum	7/41	17.07
Intra caesarean	2/76	2.63

(P-value between immediate postpartum and intra caesarean IUCD= 0.009

P-value between immediate postpartum and post placental IUCD= 0.015)

Table 6: Parity and expulsion rate

Parity	Expulsion (Number)	Expulsion (%)
Primiparous	5/154	3.3
Multiparous	7/46	15.2

The expulsion rate is significantly higher in multiparous women compared to primiparous women (P-value=0.007).

Table 7: Reasons for Cu T removal

Reason	6 weeks	3 months	6 months
HMB	-	1	-
For permanent sterilization	1	-	5
Psychosocial causes	2	-	1

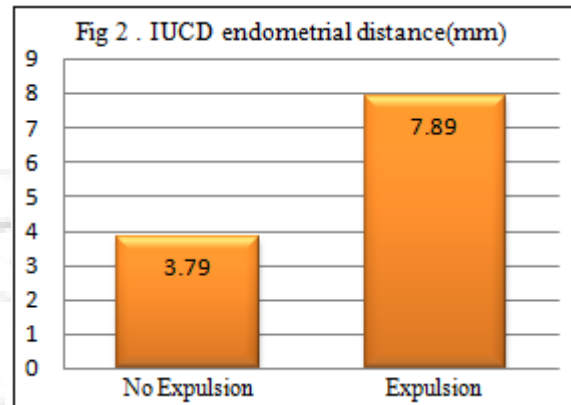
Table 8: IUCD endometrial distance in expulsion group

IUCD Endometrial Distance in mm	Expulsion	
	Number	Percentage
Before discharge		
0 – 2.5 mm	0	0
2.5 – 5 mm	0	0
5 – 7.5 mm	3	25
7.5 – 10 mm	6	50
At 6 weeks		
> 10 mm	3	25
Total	12	100

Table 9: IUCD endometrial distance in no expulsion group

IUCD Endometrial Distance in mm (Before discharge)	No Expulsion	
	Number	Percentage
0 – 2.5 mm	37	19.68
2.5 – 5 mm	116	61.70
5 – 7.5 mm	35	18.62
7.5 – 10 mm	0	0.00
> 10 mm	0	0.00
Total	188	100

Of the 9 women who expelled the Cu T at 6 weeks follow up visit, 6 women had IUCD endometrial distance (before discharge) ranging from 7.5- 10.0 mm and 3 women between 5.0- 7.5 mm respectively. 3 women who expelled the Cu T at 3 months follow up had IUCD endometrial distance of > 10.0 mm at 6 weeks follow up visit. Of the 188 women who had no expulsion, majority *i.e* 116 women (61.70%) had IUCD endometrial distance ranging from 2.5- 5.0 mm, 37 women (19.68%) between 0-2.5 mm and 35 women (18.62%) between 5.0-7.5 mm respectively. Mean IUCD endometrial distance before discharge in the no expulsion (n=188) and expulsion group (n=12) is 3.787 ± SD 1.5037 and 7.892 ± SD 1.2288 mm respectively.



Independent samples t-test showed that the IUCD endometrial distance before discharge is significantly higher in the expulsion group as compared to no expulsion group (p=0.0005).

4. Discussion

The PPIUCD is a highly effective, long acting reversible contraceptive choice in postpartum women in whom unintended pregnancies are common.

In this study, awareness of PPIUCD has a direct relation with women's education (p=0.0005). According to Ullah and Chakraborty [7], women's education was the most important determining factor for contraceptive use. According to Choudhary *et al.* [8] secondary and higher education influenced contraceptive usage.

In this study, the gross cumulative expulsion rate at the end of 6 months was 6%. All the expulsions occurred within three months following IUCD insertion. This is consistent with the study done by Kittur *et al.* [9] in 2012 in which the rate of expulsion was 5.23% and they also concluded that the expulsion rates could be minimized if the insertion was done by a trained person and proper fundal placement was ensured. According to Geetha Katheit *et al.* [10] (2013), the expulsion rate was 10.5% following post placental IUCD insertion and it was concluded that this was due to low placement of IUCD which resulted from lack of experience.

Another study by Raffat Sultana *et al.* [11] had 8% cumulative expulsion rate at 6 months. According to Anjum Afshan *et al.* [12] (2014), the expulsion rate was 5% and 6% at 6 weeks and 6 months respectively.

At the end of 6 months, there were 12 expulsions out of which 3 (3.61%) were in post placental insertions, 7 (17.07%) in immediate postpartum insertions and 2 (2.63%) in intra-caesarean insertions. The expulsion rate is significantly higher in immediate postpartum insertions compared to post placental insertion ($P = 0.015$). The expulsion rate in intra-caesarean insertion is significantly lower than that of immediate postpartum insertions ($P = 0.009$). There is no statistical significance in the expulsion rate between post placental and intra-caesarean insertions. The low expulsion rate in intra-caesarean insertions may be due to the direct fundal placement of the IUCD. According to Gupta *et al.* [13] (2013) the expulsion rate following vaginal PPIUCD (6.6%) was significantly higher than that of intra-caesarean insertions (2%) ($p < 0.05$). According to Raffat Sultana *et al.* [11] (2015), the expulsion rate following intra-caesarean insertion was significantly less than that following vaginal PPIUCD (6.6% vs 1.8%).

In this study, 5 (3.3%) expulsions were in primiparous women and 7 (15.2%) in multiparous women. The expulsion rate is significantly higher in multiparous women compared to primiparous women (P -value=0.007). The higher expulsion rate in multiparous women may be due to parous cervix. According to Gupta A *et al.* [13] expulsion rate was significantly higher in multiparous women compared to primiparous women following both vaginal PPIUCD insertions (4.67% vs. 2%) as well as intra-caesarean insertions (0% vs. 2%).

In this study, heavy menstrual bleeding was present in 6 (3.1%) at 6 weeks, 8 women (4.5%) at 3 months and 9 women (5.5%) at 6 months. Pain abdomen was present in 7 women (3.6%) at 6 weeks, 4 women (2.3%) at 3 months and 2 women (1.2%) at 6 months. Missing strings were complained by 6 women (3.1%) at 6 weeks in whom speculum examination and ultrasound was done which confirmed that the IUCD was *in situ* and they were reassured. There was no case of infection, perforation or unplanned pregnancy. According to a study by Rekha G. Daver *et al.*, [14] 7 (8%) had menstrual complaints at 6 months, pain abdomen was present in 11(10%), 5 (5%), 2 (2%), at 6 weeks, 3 months and 6 months respectively. 4 (5%) women could not feel the threads at 6 months. There were no major complications noted. According to a study, Farhat Arshad *et al.*, [15] menstrual problems were present in 30 women (11.6%) and 17 women (10.24%) at 6 weeks and 3 months respectively. Pain abdomen was present in 25 (14.20%), 22 (13.25%) and 24 women (15%) at 6 weeks, 3 months and 6 months respectively and vaginal discharge was present in 22 (12.5%), 20 (12%) and 21 women(13.12%) respectively. No case of PID or perforation was noted. 9 (5.1%) had string problems at 6 weeks and USG confirmed that the IUCD was *in situ*.

In this study, Cu T removal was done in 10 women (5%). 1 woman wanted removal for heavy menstrual bleeding not responding to medical treatment, 6 women wanted removal for permanent sterilization, 3 women wanted removal for psychosocial causes. According to a study conducted by Rekha G. Daver *et al.* [14] Cu T removal was done in 20 of 107 patients (19%) of which 12 were due to displacement, 2

for heavy menstrual bleeding, 5 for abdominal pain and 1 for personal reasons.

In this study, the continuation rates at 6 weeks, 3 months and 6 months postpartum were 91%, 86% and 78.5% respectively. This is consistent with a study conducted by Raffat Sultana *et al.* [11] (2015) who reported continuation rates of 94%, 92% and 82.6% at 1 week, 6 weeks and 6 months postpartum respectively. According to a study conducted by Anjum Afshan *et al.* [12] (2014) the continuation rates at 6 weeks and 6 months were 90% and 84% respectively. Sahaja Kittur *et al.* [9] (2012) reported continuation rate of 86.19% at 6 weeks follow up.

Independent samples t-test showed that the IUCD endometrial distance before discharge is significantly higher in the expulsion group as compared to no expulsion group ($p=0.0005$). According to a study conducted by N.S. El Beltagy *et al.*, [16] there is a direct correlation between the expulsion rate and the IUCD endometrial distance at the uterine fundus using a cut off of 10 mm.

5. Conclusions

Postpartum intrauterine contraceptives device (PPIUCD) provides a safe, effective and long lasting reversible contraception for women before discharge from the hospital in low resource settings. During the postpartum period women are highly motivated and receptive to family planning advice and an additional visit to the hospital is not required. Although the expulsion rates are high compared to interval Cu T insertion, they can be reduced by training of health care providers and by proper fundal placement. Increased IUCD endometrial distance measured by ultrasound is associated with increased expulsion. Ultrasound measurement of IUCD endometrial distance can be used to detect risk of expulsion.

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