

## A study to assess the safety, efficacy of PPIUCD in a tertiary care centre in a hilly region of South India

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### Abstract

**Background:** In India 65% of women have unmet need for family planning during the first year post-partum, Insertion of PPIUCD appears appealing because, High unmet need for contraception during the first post-partum period, increasing rate of institutional delivery, Long term and reversible method, it requires only once motivation, Highly effective, Long-term benefits of reducing maternal mortality burden, hence in recent past PPIUCD as a method of contraception has evolved.

**Objectives:** To assess the safety and efficacy of PPIUCD.

**Materials and methods:** This is an observational study from June 2019 to May 2020, conducted in department of OBG, Kodagu Institute of Medical Sciences to assess the safety and efficacy of CuT380A when inserted within 10 mins of placental expulsion up to 48 hours after delivery. During this period total number of deliveries were 3293. Among them 833 women had PPIUCD insertion. Counselling of PPIUCD was done during their antenatal visit, early labour, immediate postpartum and while preparing for the scheduled caesarean delivery. Post-abortal and 6 weeks postpartum IUD insertion were excluded from study.

**Results:** Of 3293 total deliveries, women who had PPIUCD insertion were 833(25.9%). Among them Post placental 165(19.8%), Primary cesarean delivery 550(66%) and repeat cesarean delivery 24(2.88%). PPIUCD counselling were done during antenatal period in 211 (25.3%), during early labor in 528 (63.3%) and during postpartum period 94 (11.2%). Acceptance of PPIUCD insertion was found to be 526(63.14%) among women of age 20-25 years, primipara 651(67.34%), who had at least primary education 249(29.9%). 812 women attended follow up. 651(80.17%) had no complaints, continued counselling helped. Complications like string problem (5.91%), expulsion rate (2.83%), pain abdomen (6.4%), bleeding P/V (3.94%). PPIUCD was found to be safe as there was no evidence of perforation or failure rate. 10 women insisted for removal of PPIUCD, one of the main reasons was social factor.

**Conclusion:** The acceptance of PPIUCD was high in Primipara. PPIUCD was demonstrably safe with low expulsion rate and more retention rate, thus more effective. To improve acceptance and to remove misconceptions regarding PPIUCD, Community should be educated.

**Keywords:** Cu T 380A, safety, bleeding, PPIUCD, maternal morbidity

## Introduction

According to WHO, after one delivery the recommended interval before attempting next pregnancy should be at least 24 months in order to reduce the risk of adverse maternal, perinatal and infant outcomes <sup>[1]</sup>. When pregnancy occurs less than 24 months of a previous birth there is a higher risk of adverse outcomes like abortions, premature labor, post-partum hemorrhage, low birth weight babies, fetal loss and maternal death <sup>[1]</sup>. In India 65% of women have unmet need for family planning during the first-year post-partum and only 25% of women are using any form of contraception during first post-partum year and only 8% of women desire to have another child within the next two years after giving birth and are vulnerable to risk of pregnancy <sup>[2]</sup>.

Newer understanding of IUCD in terms of acceptability, low expulsion when inserted with proper technique, cost effectiveness, safety and feasibility of inserting immediately after child birth <sup>[3]</sup>.

The contraceptive prevalence rate (CPR) among married women in India is 56.3% i.e. more than 40% of women are not using any method of contraception. Contraceptive use constituted predominance of sterilization, particularly female sterilization accounting for 85% of all the modern contraceptive methods used. Three out of four rely on sterilization method of family planning in India. Less than 7% of currently married women use officially sponsored spacing methods (pills, IUCD and condoms) <sup>[5]</sup>.

Long term benefits of reducing maternal mortality burden. Hence in recent past PPIUCD as a method of contraception has evolved.

## Aims and objectives

1. To assess the safety and efficacy of PPIUCD.
2. To study the patient compliance after PPIUCD insertion.

## Materials and Methods

The present Longitudinal study was done by the department of the OBG at Kodagu Institute of Medical Sciences, Madikeri from June 2019 to May 2020.

During the study period a total of 3293 deliveries were conducted in the study center and 833 of them had Post-Partum Intrauterine Copper Device insertion.

The IUD was inserted was CuT 380 A within 10 minutes of Placental expulsion to 48 hours after Delivery.

Counselling of PPIUCD was done during their antenatal visit, early labour, immediate postpartum and while preparing for the scheduled caesarean delivery.

Post abortal and 6 weeks postpartum IUD insertion were excluded from study.

## Timing of insertion <sup>[6]</sup>

Following birth of baby, insertion of PPIUCD can be done at

- **Post placental:** Immediately following delivery of placenta within 10 minutes of placental expulsion

- **Intra caesarean:** During caesarean section
- **Immediate postpartum:** Within 48 hours after the birth of baby and prior to discharge from post-partum ward
- **Delayed postpartum:** After 6 weeks postpartum.
- **Post abortion:** Following abortion especially first trimester.

IUCD should NOT be placed from 48 hours to 6 weeks following delivery because there is increased risk of infection and expulsion <sup>[7]</sup>.

Retention of IUCD following delivery is not affected by active management of third stage of labor. All women regardless of whether they accept PPIUCD or not, should be managed with active management of third stage of labor. These periods are recommended because it is possible to use instruments or manual insertion as the cervix is open and limp and an IUCD can easily be placed high in the fundus, either manually or using forceps. Furthermore, it continues to be possible to insert an IUCD with an instrument for up to 48 hours postpartum. After this period, the cervix is not open enough to allow for an easy and relatively painless instrument insertion <sup>[7]</sup>.

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

### Post insertion counseling

Following insertion of PPIUCD, counseling should be done regarding side effects and normal post-partum symptoms to allay her anxiety and to cope up with minimal side effects. Fact that IUCD does not affect breast feeding; women should be encouraged to breast feed exclusively, also explaining her to return for follow up at 6 weeks or return anytime if any concern/experiences any warning sign of suspected pregnancy/IUCD expelled.

### Statistical analysis

Data will be entered into Microsoft excel data sheet and will be analyzed using SPSS 22 version software. Categorical data will be represented in the form of Frequencies and proportions. Chi-square will be used as test of significance. Continuous data will be represented as mean and standard deviation. p value <0.05 will be considered as statistically significant

### Results

Out of 833 women, 63.14% of them were belonging to age of 20-25 years.

**Table 1:** Distribution of study subjects based on the Age group

Age	Numbers	Percentage
Below 19 years	106	12.72%
20-25 years	526	63.14%
26-30 years	143	17.16%
Above 31 years	58	6.96%

**Table 2:** Distribution of study subjects based on Socio-Economic status distribution

SES	Numbers	Percentage
Lower	427	51.26%
Middle	192	23.04%
Upper	214	25.69%

In the present study nearly 51.26% of them were from lower SES, 23.04% were from Middle and 25.69% were from Upper SES.

**Table 3:** Distribution of study subjects based on Education

Education	Numbers	Percentage
No Formal Education	44	5.28%
Primary	249	29.89%
Secondary	168	20.16%
Senior secondary	198	23.76%
PUC	108	12.96%
Degree	66	7.92%

In our study nearly 29.89% of them had Primary education, 20.16% had secondary education, 23.76% had Education till SSLC, 12.96% of them were educated till PUC and 7.92% of them had studied till Degree.

**Table 4:** Distribution of study subjects based on the time of counselling for IUD insertion

Counseling	Number	Percentage
ANC	211	25.33%
Early Labour	528	63.38%
Postpartum	94	11.28%

In the present study the counselling for the mothers for the IUD insertion was done in ANC period only in 25.3%, 65.38% in Early Labour and 11.28% in Post-partum period.

**Table 5:** Distribution of the study subjects based on time of insertion after the delivery

Time	Number	Percentage
With In 10 Minutes	165	19.80%
With In 48 Hours	94	11.28%
Cesarean Delivery	574	68.90%

In nearly 68.9% of the subjects the insertio was done during the cesarean delivery, 19.8% of them had insertion within 10 minutes of delivery.

**Table 6:** Distribution of the study subjects based on the time of follow up

Weeks	Number	Percentage
3 Week	297	37.54%
6 Week	491	62.07%
6 Month	24	3.03%
Drop Out	21	2.65%

Nearly 62.07% of them were followed up for nearly 6 weeks after the delivery, 37.5% of them till 3 weeks, 3.03% till 6 months after delivery and 2.65% of them were drop outs who never returned for the follow up.

**Table 7:** Distribution of the study subjects based on the Complaints during follow up

Complaints	Numbers	Percentage
Pain Abdomen	52	6.40%
Bleeding Pv	32	3.94%
String Problem	48	5.91%
Expulsion	23	2.83%
White Discharge	6	0.73%
No Complaints	651	80.17%
Total	812	100%

In the present study 80.17 % of them had no complaints of any discomfort after the insertion of IUD, 6.4% had pain abdomen, 5.91% had string problem, 3.94% had bleeding PV, 2.83% had expulsion, 0.73% had white discharge.

## Discussion

The PPIUCD is a highly effective, long acting, reversible, cost effective and easily accessible family planning method that is safe for use by most postpartum women including those who are breast feeding <sup>[8]</sup>.

Across the world, particularly in developing countries, the use of long-acting reversible forms of contraceptive methods, especially PPIUCD, is being promoted largely in the postpartum period. Most women are sexually active by six weeks postpartum, and women who deliver by cesarean section may be more likely to resume sexual activity earlier than women who had vaginal deliveries <sup>[9-11]</sup>.

In the present study of 833 women delivered in our hospital, majority of them belonged to 20-25 years of age with a 63.14% of them accepting the PPIUCD.

There was high acceptance rate among primigravida accounting for 67.34% (n=561), Women having primary education (29.89%), Women belonging to rural areas (73.22%), women who belonged to lower socioeconomic status (51.26%), women with Lower segment uterine section accounting for total of 68.90% (n=574), women who had 6 week follow up (62.07%) with a dropout rate of 2.65% which was low to the findings of a study done by Pulwasha PM *et al.* <sup>[12]</sup>.

Among 833 women, 528 women were counselled for PPIUCD insertion at the time of Early labour accounting for 63.38%. Around 211 with 25.33% women were counselled at ANC and 94 with 11.28% women were counselled in Postpartum period.

A cumulative 6.40% of women had complaints of pain abdomen, 5.91% of women had string problem and 3.94% of women had bleeding pv. The expulsion rate in our study was found to be 2.83% which is low as compared with other studies namely Turkey, Celen *et al.* <sup>[13]</sup> and Thiery *et al.* <sup>[14]</sup> from Belgium.

A total of 10 women had their PPICUD removed due to social factors, sterilization and pain abdomen accounting for 0.61%, 0.36% and 0.24% respectively.

The results of our study were similar to Mishra *et al.* <sup>[15]</sup> and Barala S *et al.* <sup>[16]</sup> but contradictory to a similar study done by Gujju *et al.* <sup>[17]</sup>, Sharma A *et al.* <sup>[18]</sup> and Deshpande *et al.* <sup>[19]</sup> where they found a higher acceptance in multiparous women.

There were no cases of Endometritis, PID or any perforations reported in our study which was in accordance with the study done by El Shafei MM *et al.* <sup>[20]</sup> and Ricalde *et al.* <sup>[21]</sup>.

## Conclusion

With our present study, we concluded that the acceptance of PPIUCD were high in primipara and PPIUCD was demonstrably safe with low expulsion rate and more retention rate,

thus simpler. The continued practice of PPIUCD will play a good role in accepting contraception in our country thus playing an important role in family planning.

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