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Original Research Article

A study to evaluate safety and efficacy of immediate postpartum postplacental IUCD insertion

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ABSTRACT

Background: The postpartum period is an important time in a woman's life to promote the health of the newborn and the mother. In INDIA, the unmet need for contraception in the first year postpartum is as high as 65%. Hence, this study aims to evaluate the safety and efficacy of immediate postpartum intrauterine contraceptive device (PPIUCD) as a method of contraception.
Methods: The study was undertaken in KIMS Hospital and Research Centre, Bangalore. A total of 60 patients were recruited following complete evaluation. 30 patients had immediate postpartum post placental insertion and 30 patients had intracesarean insertion of Cu T 380A.
Results: The patients who accepted PPIUCD mostly belonged to the age group 19-24 years, multigravida with one living issue. Insertion of IUCD was easy in 96.7% of the patients. Only 8.3% of the patients were anxious post insertion. 20% of the patients had minor complications, most commonly, bleeding and pain. There was only one case (1.7%) of infection (vaginitis). There were 23.3% of cases with missing strings but in all these cases IUCD was found in-situ on ultrasonography. Removal rate and expulsion rate were 6.7% and 5% respectively. Continuation rate was 88.3%.
Conclusions: We can conclude from this study, that immediate PPIUCD is an effective and inexpensive contraceptive for all delivered women, as it can be easily provided by trained midwives due to its ease of insertion, high continuation rate and no major complications. Thus, we can prevent unwanted pregnancies, abortions and its untoward effects.

Keywords: Copper T 380A, Immediate postplacental insertion, Intracesarean insertion, Postpartum intrauterine contraceptive device

INTRODUCTION

Preventing unintended pregnancies in the 18 months following delivery is an important aspect in promoting the health of the newborn, maintaining and restoring maternal health and nutrition thereby lowering the risk of future preterm birth. Approximately 27% of births in India occur in less than 24 months after a previous birth. Another 34% of births occur between 24 and 35 months i.e. 61% of births in India occur at intervals that are shorter than the recommended birth-to-birth interval of approximately 36 months. Studies have found that conception within 24 months of previous birth have higher risk of adverse outcomes like abortion, premature labour, postpartum haemorrhage, low birth weight babies, foetal loss and sometimes maternal deaths. This clearly explains the need for an effective form of contraception during postpartum period.[1]

In India, the unmet need for contraception in the first year postpartum is as high as 65%. The reasons for this are as follows.[2]

- Returning to health facilities for postpartum services after delivery is challenging to mothers who have competing demands.
- Concerns about health risks or side effects.
- Opposition to use, either by the woman or her partner, for personal or religious reasons.
- Perception that they would not get pregnant because they had intercourse infrequently, had postpartum amenorrhea, or were breast feeding.
- Lack of knowledge about methods of contraception or where they could get them.
- Inability to obtain or afford contraceptives.

Postpartum period is the ideal time for providing contraception, as women are highly motivated and receptive to accept family planning methods.

Also, institutional deliveries have increased significantly across the country, thereby creating opportunities for providing quality postpartum family planning services and postpartum intrauterine contraceptive device (PPIUCD) insertion is one such service. PPIUCD is the only family planning method for couples requesting a highly effective and long-acting reversible contraceptive (LARC) that can be initiated during the immediate postpartum period.

Recent research from 2016 shows that when given the option, women in India will choose LARC methods (which includes IUCD) over sterilization. Also, LARC is suitable for many women, regardless of age or purpose.

India is unique as a country that has established a government program to regulate population growth. Postpartum IUCD insertion has also been promoted by the Government of India and is being provided in Government health centres by trained health care providers.

The extension of such services to private health sectors can further help in extending family planning services to all mothers and will further help in meeting the unmet needs of contraception. This study was carried out in KIMS Hospital and Research Centre, a non-government medical institution and aimed to assess the safety and efficacy of immediate postpartum IUCD insertion and to evaluate patient compliance. The study will provide the institution with information, which will help in deciding PPIUCD as an effective form of contraception and as one which can be safely offered to women delivering in our institution.

METHODS

This observational study was conducted in KIMS Hospital and Research Centre, Bangalore, with a sample size of 60 over a period of 18 months. Sample design was purposive sampling. Women were counselled and selection done based on the inclusion and exclusion criteria.

Inclusion criteria

All women delivering vaginally or by cesarean section and willing to participate in the study.

Exclusion criteria

Postpartum haemorrhage, distortion of uterus (fibroids, congential anomalies), PROM >12hrs, chorioamnionitis, puerperal Sepsis, STD/ increased risk of STD or pelvic tuberculosis, placental abnormalities e.g. placenta previa and all conditions stated under Category 3 and 4 of MEC.

Written informed consent was taken. Assessment of patients were carried out in 2 phases. Initial assessment was carried out in the antenatal period or on admission to the labour ward, to rule out conditions stated in the MEC category 3 and 4 for IUCD insertion. Second assessment was done immediately prior to insertion of IUCD after expulsion of placenta.

The instruments needed for insertion of PPIUCD would be arranged on a sterile flat tray. The instruments used for vaginal insertion are Sims speculum, sponge holding forceps, Kelly forceps, cotton swabs and Cu T 380 A in a sterile package, for vaginal insertion, and opened onto a sterile field for intracesarean insertion. Under aseptic precautions perineum, labia and vaginal walls are inspected and cleaned. Cervix visualised and gently cleansed with betadine. Anterior lip of cervix was grasped with ring forceps and IUCD inserted under aseptic precautions using Kelly's forceps. IUCD was placed at the fundus. Kelly's forceps were removed by taking care not to dislodge the IUCD. All the instruments were removed. In intracesarean insertion, the IUCD was inserted manually after removal of placenta and the uterine incision was repaired taking care not to include the IUCD strings. After insertion, patient's details and experience during insertion were recorded in the patients records and PPIUCD register. Prior to discharge women were provided with information regarding complications and warning signs were explained and asked to report immediately if she experienced any of the said signs. The patients were followed up at 6 weeks and 6 months. During follow up, complete history was taken and the woman was examined. Compli- cations like bleeding, pain and infection were treated with NSAIDS and antibiotics accordingly. Women with missing strings were subjected to pelvic ultrasound, to confirm the position of IUCD. The information collected was recorded in the PPIUCD register. If the PPIUCD was in place and the woman had no problems, she was followed up at 6 months. The data collected during follow up was recorded and statistically analysed.

RESULTS

As seen in our study, the mean age of the patients who choose PPIUCD as a method of contraception was 24.22 years (Table 1). While majority of patients who had PPIUCD inserted were from the urban areas i.e. 40 (66.7%) patients, only 20 patients were from rural areas.

Table 1: Age distribution of patients studied in relation to two groups of patients (based on mode of delivery) studied.

Age (years)	Vaginal	LSCS	Total
19-24	20 (66.7%)	17 (56.7%)	37 (61.7%)
25-29	9 (30%)	8 (26.7%)	17 (28.3%)
30-34	1 (3.3%)	4 (13.3%)	5 (8.3%)
35-39	0 (0%)	1 (3.3%)	1 (1.7%)
Total	30 (100%)	30 (100%)	60 (100%)

36 (60%) patients were counselled in early labour and 24 (40%) patients had antenatal counselling for PPIUCD insertion.

As shown in Table 2, 59 (98.3%) patients who had PPIUCD inserted were booked and only one patient was unbooked.

Table 2: Distribution of patients studied, based on antenatal booking.

Booked/unbooked	Number of patients	%
Unbooked	1	1.7
Booked in KIMS	27	45
Booked outside	32	53.3
Total	60	100

22 (36.7%) patients who had PPIUCD inserted were primigravida. Among them 12 had vaginal insertion and 10 had intracesarean insertion. Majority were multigravida i.e. 63.3%.

Table 3 demonstrates the ease of insertion of PPIUCD wherein difficulty was encountered in only 2 patients which is 3.3% cases. P value was calculated to be 0.492, which is not statistically significant.

Table 3: Ease of insertion (EOI) of PPIUCD, studied in relation to two groups of patients.

EOI	Vaginal	LSCS	Total
Easy	28 (93.3%)	30 (100%)	58 (96.7%)
Difficult	2 (6.7%)	0 (0%)	2 (3.3%)
Total	30 (100%)	30 (100%)	60 (100%)

Table 4 denotes pain score of all patients. Patients who had intracesarean insertion were under the influence of anaesthesia, therefore are not included in this group. The mean pain experienced by patients was 2.20 which is mild pain.

At 6 weeks, all the 60 (100%) patients were followed up in OPD. At 6 months, 33 (55%) patients were followed up over the phone and remaining patients i.e. 26 (43.3%) were followed up in OPD.

Table 4: Pain Score distribution in patients who had vaginal insertion of IUCD.

Pain score	Vaginal
0	0 (0%)
1-3 (mild)	26 (86.7%)
4-6 (moderate)	2 (6.7%)
7-10 (severe)	2 (6.7%)
Total	30 (100%)
Mean±SD	2.20±1.83

Table 5: Complications of PPIUCD studied in relation to two groups of patients studied at 6 weeks.

Complications	Vaginal (n=30)	LSCS (n=30)	Total (n=60)
None	26(86.7%)	22(73.3%)	48(80%)
Yes	4(13.3%)	8(26.7%)	12(20%)
bleeding	2(6.7%)	2(6.7%)	4(6.7%)
expulsion	0(0%)	1(3.3%)	1(1.7%)
infection	0(0%)	1(3.3%)	1(1.7%)
pain	2(6.7%)	3(10%)	5(8.3%)
spotting	0(0%)	1(3.3%)	1(1.7%)

Majority of patients i.e. 48 accounting for 80% of cases were comfortable with PPIUCD at 6 weeks follow up and did not report any concerns or complications. As shown in Table 5, 20% of cases i.e. 12 cases reported complications among which 8 patients had intracesarean insertion and 4 patients had vaginal insertion. One patient reported IUCD expulsion before 6 weeks follow up. One patient presented with discharge per vagina

Table 6: Missing strings of patients studied in relation to two groups of patients studied at 6 weeks.

Missing strings	Vaginal	LSCS	Total
No	28(93.3%)	18(60%)	46(76.7%)
Yes	2(6.7%)	12(40%)	14(23.3%)
Total	30(100%)	30(100%)	60(100%)

Table 7: Complications at 6 months follow up.

Complications	Vaginal	LSCS	Total
None	29(96.7%)	29(96.7%)	58(96.7%)
Expulsion	1(3.3%)	1(3.3%)	2(3.3%)
Total	30(100%)	30(100%)	60(100%)

As shown in Table 6, at 6 weeks follow up, 14 patients (23.3%) had missing strings on speculum examination, hence underwent a pelvic ultrasound scan. IUCD was found in-situ in all the patients.

At 6 months' follow-up, as shown in Table 7, expulsion was reported by 2 (3.3%) patients. Remaining 58 (96.7%) of the patients were comfortable with IUCD and did not have any complications. IUCD strings were missing in 4 cases and all of them had intracesarean insertion. USG was done to confirm and IUCD was found intact in all 4 cases.

Table 8: Reason for IUCD removal.

Reason	Vaginal (n=30)	LSCS (n=30)	Total (n=60)
Family pressure	0	1(3.3%)	1(1.7%)
Pain abdomen	1(3.3%)	0	1(1.7%)
Tubectomy	0	1(3.3%)	1(1.7%)
Unhappy with IUCD	0	1(3.3%)	1(1.7%)

As demonstrated in Table 8, total of 4 (6.7%) patients had IUCD removed for various reasons. Table 9 shows the expulsion rate among both the groups. 3 patients reported expulsion during the study period. Expulsion rate of PPIUCD in this study is 5%. Out of 60 cases followed up after 6 months, 53 patients were happy with PPIUCD as a method of contraception and continuation rate is 88.3%, which is comparable to that of interval insertion.

Table 9: Expulsion rate.

Expulsion	Vaginal (n=30)	LSCS (n=30)	Total (n=60)
At 6 weeks	0	1(1.7%)	1(1.7%)
At 6 months	1(1.7%)	1(1.7%)	2(3.3%)
Total			3(5%)

DISCUSSION

Ours was a prospective study aimed at studying the safety and the efficacy of PPIUCD and patient compliance with the same. Most of patients accepting PPIUCD in the present study were in the age group 19-24 years. The mean age being 24.22+3.79 yrs. A study by Manju Shukla et al the women were between 22-30 year of age.[3]

We compared acceptance based on geographic distribution and found that acceptance was high among women from the urban area at 66.7% compared to women from rural areas.

In the present study acceptance rate was comparable between primigravidae (36.7%) and multigravidae (38.3%) women. Gunjan Goswamy et al., found that women with second gravida were high acceptors (48%) likewise Shukla et al found that multiparous women had high acceptance i.e. 68.33% compared to primiparous at 31.66%.[4] All other studies found that primigravida women were high acceptors.

The number of live births affected acceptance of PPIUCD. In this study women who had at least one delivery has high acceptance to IUCD (temporary method) at 51.7%. Women who had 2 or more living issues were more keen on permanent method of contraception hence acceptance dropped to 3.3%. Mishra S et al., found women who had one delivery preferred temporary methods.[5] Satyavathi et al., and Sangeetha Jairaj et al., also found similar results.[6] Insertion of the IUCD was found easy in 96.7% of the cases and 75% patients were happy with their decision of having PPIUCD inserted. 8.3% of the patients were anxious and most of them were later convinced after their fears and doubts were address prior to discharge.

86.7% of the patients who had vaginal insertion experienced only mild pain at the time of insertion. The mean pain score was 2.20 which falls in the category of mild pain on the pain scale. There was no case of perforation at the time of insertion in present study like in all other studies on PPIUCD.

In the present study 20% of patients experienced complications like bleeding, infection, spotting, pain abdomen and expulsion at 6 weeks follow up. Bleeding and pain were the most significant complications experienced by patients. Bleeding was reported by 6.7% cases which settled after treatment with NSAIDS. This correlates with study by Kittur S et al., who reported 6.19% bleeding.

Pain abdomen was reported in 8.3% patients. There is a vast difference in the percentage of patients reporting pain in various studies ranging from 43.8% to 9%. However present study correlates with study by Satyavathi et al who reported 9%. Irregular spotting was reported by one pateinet and and vaginal discharge was also found in one patient, who was subsequently treated for vaginitis. There was no case of PID similar to study by Shukla et al.

There were 23.3% of cases with missing strings. It correlates with studies by Kittur S. et al - 24.76%, Gunjan Goswami et al-20% missing strings.[8]

USG was done for all the cases of missing IUCD strings and IUCD was found to be in situ in all of them. At 6 months follow up, in most these patients with missing strings, strings were visible. In 4 patients in whom strings were not visible, scan showed PPIUCD in-situ. Strings were found to be coiled up in the cervix and was gently brought down using artery forceps.

In the present study 6.7% patients had IUCD removed for reasons such as pain, family pressure to undergo permanent sterilization and anxiousness due to missing strings. This is almost similar to removal rate reported by Kittur S et al., at 7.61% and Mishra S at 7.62%. Expulsion rate in present study was found to be 5% which correlates with study by Kittur S who have reported it to be 5.23%. Continuation Rate in the present study is 88.3% similar to study by Celen S 87.6% and Kittur S et al.[9]

CONCLUSION

PPIUCD is a safe and effective long acting reversible contraception method despite its low awareness and applicability and is particularly beneficial in a setting where women do not return for contraceptive advice. With such low expulsion rates, almost comparable to interval insertion (1-7%) and high continuation rate, we can conclude that, immediate PPIUCD can be the solution in addition to a country like India currently facing population crisis and high maternal and neonatal morbidity and mortality due to great number of births occuring at short intervals. As it can be propagated by well-trained health workers in rural sectors who also provide antenatal services, the government needs to develop strategies to increase public awareness of the PPIUCD through different media sources.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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