A prospective observational study conducted in tertiary teaching hospital of Uttar Pradesh to compare safety and efficacy of PPIUCD and interval IUCD (380A)

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ABSTRACT

Background: The objective of this study was to compare the efficacy and safety of PPIUCD and interval IUCD.

Methods: This was a prospective observational study conducted on women attending the OPD and indoor services of S.N. Medical college, Agra. 800 women willing for PPIUCD insertion were included in the study after informed consent excluding chorioamnionitis, PROM >18 hours, unresolved PPH and puerperal sepsis. Another 200 willing women were inserted interval IUCD according to MEC criteria of WHO. All were followed up for 1 year.

Results: It was found that rate of expulsion was more in PPIUCD group compared to interval IUCD group (6% vs 1.5% p value <.05), rate of removal was almost similar in both groups (11.5% in PPIUCD and 14% in interval IUCD group), cause of removal was mainly social in PPIUCD group while bleeding was more in interval IUCD group compared to PPIUCD (85.7% vs 26%).

Conclusions: Postpartum insertion of IUCD is a safe effective, feasible and reversible method of contraception.

Keywords: Acceptance, Interval IUCD, PPIUCD, Safety

INTRODUCTION

Using family planning to space births at least 36 months apart can avert 30% of maternal deaths and 10% of child deaths. In India, however only 26% of postpartum women are using contraception and more than 60% of birth follow an interval of less than 36 months. Sterilization has remained the leading method of contraception in India accounting for 40% of family planning users and it does not address women’s needs for healthy birth spacing. PPIUCD is a long acting, reversible contraceptive offering a safe, effective and convenient alternative to sterilization. It has also been found acceptable among Indian women as rate of motivation is more in post-partum period. In the last decade more and more women chose to give birth in health institutions because of Janani Suraksha Yojana. This gives a unique opportunity to offer a long acting yet reversible method of contraception to women immediately after child birth. Delaying until later is not effective as most of clients do not return for family planning services. It is advantageous as it is free of cost. Insertion of an IUD after delivery may avoid the discomfort related to interval insertion, and any bleeding from insertion will be disguised by lochia. The benefit of PPIUCD is that woman is known to be non-pregnant, and her motivation for contraception is high. For women with limited access to medical care, delivery offers an unique opportunity to address need for contraception, considering this fact; the mentioned study was conducted to evaluate the safety and efficacy of PPIUCD versus interval IUCD (380A).
And to evaluate the safety and efficacy of PPIUCD compared to interval IUCD in terms of safety, acceptance and complication like bleeding, infection and expulsion.

**METHODS**

This study was a prospective observational study conducted on women attending the OPD and indoor services in the department of obstetrics and Gynecology of S.N. Medical college, Agra, from April 2017 to April 2018. A total of 1000 women were included in the study and divided into two groups. Study group consisted of total 800 women of immediate postpartum, 400 were of normal delivery and 400 were trans caesarian. Control group included 200 women who were willing for interval insertion of Cu T380A after informed choice according to MEC criteria laid down by WHO.

**Inclusion criteria**

- Patients who had institutional deliveries and desire to use CuT380A for contraception and willing to sign an informed consent with age >18 years and are ready to be in regular follow up were included in the study.

**Exclusion criteria**

- Patients who had unresolved PPH, PROM>18hrs, signs of chorioamnionitis, puerperal sepsis or age<18 or >45 were not included in study.

Informed and written consent was taken after which IUCD (Copper T 380A) was inserted immediately after delivery of placenta by using Kelly’s forceps in vaginal delivery and by using sponge holding forceps in caesarian delivery before closure of uterine incision. These cases were followed at 15 days, 6 weeks, 6 months and 1 year. Results were compared with interval IUCDs.

**RESULTS**

Total deliveries conducted in duration of present study was 2500.Total acceptance rate of PPIUCD in present study was 32% and majority of cases who accepted PPIUCD belonged to age group of 20-25 years (Table 1).

| Age group | Total no deliveries | No. of accepted | % |
|-----------|---------------------|-----------------|---|
| < 20      | 42                  | 2               | 4.7|
| 20-25     | 1390                | 520             | 37.4|
| 26-30     | 897                 | 256             | 28.5|
| 30-35     | 106                 | 20              | 18.8|
| >35       | 65                  | 2               | 3|
| Total     | 2500                | 800             | 32|

Expulsion occurred in 48 cases (6%) after immediate PPIUCD of which 38 (9.5%) occurred after normal vaginal delivery which was significantly higher than in trans cesarean group 10 (2.5%). Total 3 (1.5%) expulsion occurred in the interval IUCD group (Table 2).

| Expulsion rate | %  | P value |
|----------------|----|---------|
| Vaginal delivery (200) | 38 | 9.5 | <0.04 |
| LSCS (200) | 10 | 2.5 | >0.04 |
| Interval (100) | 3 | 1.5 | >0.04 |

IUCD were removed in total 92 cases (11.5%) after postpartum insertion, of which 44 were cases with normal delivery and 48 were with Tran’s caesarean, almost equal in both groups. In interval group IUCD was removed in only 28 (14%) cases. More than 85% women continued the IUCD in both the groups (Table 3).

| No. in each group | No. who continued | Who continued |
|-------------------|-------------------|---------------|
| After ND          | 400               | 356           | 89%           |
| Transcesarean     | 400               | 352           | 88%           |
| Interval          | 200               | 172           | 86%           |

Complication occurred in 20.25% (162) cases after PPIUCD (74 in normal vaginal group and 88 trans caesarean group), while after interval insertion complication occurred in 25% (50) cases.

| Vaginal delivery | Trans cesarean | Interval |
|------------------|----------------|----------|
| No. | %  | No. | %  | No. | %  |
| Bleeding | 14 | 3.5 | 18 | 4.5 | 16 | 8 |
| Discharge | 10 | 2.5 | 20 | 5 | 10 | 5 |
| Pain | 10 | 2.5 | 10 | 2.5 | 4 | 2 |
| PID | 0 | 0 | 0 | 0 | 2 | 1 |
| Missing thread | 2 | 0.5 | 30 | 7.5 | 0 | 0 |
| Expulsion | 38 | 9.5 | 10 | 2.5 | 3 | 1.5 |
| Total | 74 | 18.5 | 88 | 22 | 50 | 25 |
Most common complication after PPIUCD insertion was expulsion while after interval insertion bleeding was most common complication (Table 4).

Cause of removal was mainly bleeding 85.7% (12) cases in interval IUCD group which was more than in PPIUD group (26%) (24). In PPIUCD group the IUCD was mostly removed because of social reasons 65.2% (60) cases (Table 5).

### DISCUSSION

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.5

Total acceptance rate of PPIUCD in present study was 32%. Majority of the cases who accepted PPIUCD belonged to the age group 20-25 years (37.4%) this was probably because most of the patients who come to the hospital for delivery also belong to age group 20-25 years. This is in accordance to study of Katheit G et al 2013.6

The results of present study showed that expulsion rates after vaginal PPIUCD were 9.5% which is in accordance with study of Haynes JL et al 2007.2 In the present study expulsion after transcæsarean insertion occurred in 2.5% cases, which is comparable with the results of study of Muller ALL et al, Lopez-Farfan JA et al.7,8 According to present study rate of expulsion of PPIUCD was significantly higher in the normal vaginal delivery group (9.5%) than in transcæsarean group (3%). The lower expulsion rate after transcæsarean insertion as compared to vaginal insertion may be due to direct placement of IUD at the fundus during caesarean section.

The rate of expulsion in interval IUCD group in present study was 1.5% which was significantly lower (p<0.05) as compared to PPIUCD group (6%). Expulsion rates were comparable between transcæsarean and interval IUCD group; i.e. 3.5% and 1.5% respectively. Bonilla Rosales F et al in their study found expulsion rate of 16% and 2% for PPIUCD and interval IUCD respectively.9 The cumulative rate of removal over 1 year follow up after PPIUCD insertion was 11.5%, almost equal in both vaginal delivery and transcæsarean group (11% and 12% respectively). In present study, rate of removal in interval insertion group was 14% (28 cases), whereas it was 11.5% (92 cases) in PPIUCD group. In present study various complications were seen in 162 cases (20.25%) in those who chose immediate postpartum insertion. Expulsion was the most common complication in the vaginal group (9.5%) while in the transcæsarean group missing thread 7.5% (30 cases) was the most frequent complication. Bleeding occurred in 32 (4%) cases, 14 cases (3.5%) of bleeding were reported from vaginal delivery group and in the transcæsarean group bleeding occurred in 18 cases (4.5%). Celen S et al reported cumulative rates of bleeding equal to 11.4% and 8.2% respectively. No case of PID/endometritis reported in present study.10 EL Beltagy et al also reported no increase in the incidence of PID after immediate postpartum IUCD insertion.11 No case of perforation was reported from both the groups. This decreased risk of uterine perforation may be because of thick wall of the uterus. This is in accordance with the study of El Shafei MM et al and Ricalde et al where no perforations were observed in PPIUCD. No failure reported from both the groups.12,13

While comparing PPIUCD with interval IUCD the cumulative rate of complications in present study were 20.5% and 25% in PPIUCD group and interval IUCD group respectively. This was in accordance with the study Eroglu et al where the rates of complications did not differ significantly between the two groups.14

Present study showed continuation rates of about 88.5% for PPIUCD users over a follow up period of 1 year. Celen et al also showed continuation rates of 87.6% for PPIUCD at 6 months interval.10 On comparing the interval IUCD with PPIUCD, slightly lower continuation rates were obtained for Interval IUCD group (86%) than PPIUCD group (88.5%) in present study. Although slight difference exists between the two groups, but the difference was not statistically significant (p=.49).

### CONCLUSION

From the above study we came to the conclusion that postpartum insertion of PPIUCD is safe effective,
feasible and reversible method of contraception. Compared with interval insertions, postpartum insertions do not increase the risk of infection, endometritis, bleeding, uterine perforation. Nor do they affect the return of uterus to normal size. Particularly noteworthy is the very low rates of perforation in the postpartum period because of the thickened uterine walls. IUCDs if safely inserted in immediate postpartum period and included as a part of obstetrical management of the patient, contraceptive protection can be provided for the high-risk group of obstetrical patients which need but wouldn’t take advantage of available contraceptive services at any other time.

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