Evaluation of effect of pospartum intrauterine contraceptive device

Dinesh Wade¹, Shweta Avinash Khade²*

¹Department of Obstetrics and Gynecology, Dr. SCGMC Vishnupuri, Nanded, Maharashtra, India
²Department of Obstetrics and Gynecology, LTMMC and GH, Sion, Mumbai, Maharashtra, India

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*Correspondence:
Dr. Shweta Avinash Khade,
E-mail: drshwetam2009@gmail.com

Introduction

Reduction in mortality of women is an area of concern for various health systems across globe. Current population of India is 1,21,05,69,573 (2011 census).

India is the second largest country in the world accounting for 17.5% of world’s population. With roughly 25 million births annually, India at present contribute one fifth of total world population growth more than any other country.

Family planning during postpartum period has the potential to reduce a significant proportion of unintended pregnancies because, as research has demonstrated, women experience a large-unmet need for family planning during this time. Loosely defined, unmet need refers to the percentage of women who do not wish to become pregnant but are not currently using a contraceptive.

The postpartum intrauterine contraceptive device (PPIUCD)-a long-acting, reversible contraceptive-offers a safe, effective and convenient alternative. It has also been found to be acceptable among Indian women. Among the various method of family planning available for an women, insertion of post-partum IUCD appears appealing for several reasons: commencement of ovulation is unpredictable after delivery, women wish to avoid pregnancy, but still may not be using any form of contraception, delivery may be only time when a healthy women comes in contact with health care providers,
women is likely to be highly motivated for accepting contraception during postpartum, long term and reversible method, newer understanding about IUCD in terms of acceptability, low expulsion when inserted by proper technique, cost effectiveness, safety and feasibility of inserting immediately after child birth.5

Advantages of immediate postpartum insertion of the IUCD include client motivation, safety, convenience, assurance of no pregnancy, does not interfere with lactation, facilitates adequate birth spacing, immediately reversible and does not require repeated health care visits for contraceptive refills. PPIUCD insertion gives these women an extra edge of leaving the hospital with contraception after institutional delivery.

This study was an attempt to compare and evaluate safety, efficacy and complications of PPIUCD and interval IUCD insertion and to generate evidence on the safety and effectiveness of these two types of IUCD insertions based on this experience.

Aim and Objective of study was to study rate of expulsion. To study incidence of complication with respect to time of insertion. To study compliance of patient with respect to time of insertion. To reduce the rate of unintended pregnancy during lactational amenorrhea.

METHODS

This prospective study was carried out at tertiary care center and Teaching Institute in the Department of obstetrics and gynecology. All enrolled patients in obstetrics and gynecology from 1/2/16 to 31/7/16 were included in this study. Women fulfilling inclusion criteria were included in the study after obtaining informed consent. Study protocol was approved by ethics committee. Patients were divided into three groups on the basis of time of Cu T insertion

- Immediate post placental IUCD insertion in normal vaginal delivery.
- Immediate post placental IUCD during caesarean section.
- Interval IUCD 6 weeks after delivery.

Study subjects were included according to the following criteria:

Inclusion criteria

- A woman delivering vaginally or by caesarean section, counselled for IUD insertion in pre-natal period or in labour and willing to participate in the study,
- Patients willing for cu t insertion n ready for timely follow up,
- Patients aged 18 onwards.

Exclusion criteria

- According to medical eligibility criteria for IUD by WHO
  - Women having anemia (Hb<10 g/dl),
  - PPH,
  - Pre-labour rupture of membranes >18 hours,
  - Obstructed labour was excluded.
- Women having distorted uterine cavity by fibroid,
- Congenital malformation of uterus,
- Age <18 years and those who were not willing for insertion of IUCD,
- Those patients who didn’t come for regular follow up were excluded from this study.

Timely follow up on OPD basis will be taken to collect the information about compliance, expulsion and complication after the insertion at 6weeks, 6 month and 1-year duration

All ethical considerations and necessary approvals were taken findings were recorded in the case record form and the same information was entered in the Microsoft excel 2010 version. This information was represented in the form frequencies, proportions, tables etc. Graphs, Charts figures were drawn wherever necessary.

RESULTS

A total of 44 women fulfilling WHO standard medical criteria for PPIUCD insertion and willing to comply with study protocol had PPIUCD insertion.

Table 1: Distribution of patients as per type of IUCD insertion.

| Type of IUCD Insertion | No. of patients | %   |
|------------------------|-----------------|-----|
| Vaginal                | 20              | 33.33|
| Trans-Cesarean         | 24              | 40  |
| Interval               | 16              | 36.67|
| Total                  | 44              | 100 |

Table 1 shows total of 44 PPIUCD insertions were done. Out of these 24 (54.54%) insertions were intra cesarean and 20 (45.45%) IUCD were placed after vaginal delivery. 16 interval IUCDs were inserted.

Table 2 shows the age group wise distribution of the patients. Maximum patient (30 out of 60) were belonging to the 19-23 years age group. Only 7 patients were 29 years and above. Mean age of the patients was 24.15 + 3.8348.

Table 3 shows the parity wise distribution of the patients. The maximum proportion of primipara is for trans cesarean group (70.83%) and maximum proportion of multi was for interval group (50%).
Table 2: Age group-wise distribution of study subjects.

| Age group in years | Vaginal | Trans-cesarean | Interval | Total |
|--------------------|---------|----------------|----------|-------|
| 19-23              | 12 (40%)| 13 (43.33%)    | 5 (16.17%)| 30    |
| 24-28              | 7 (33.33%)| 9 (33.33%)    | 7 (33.33%)| 23    |
| 29 and above       | 1 (14.28%)| 2 (28.56%)    | 4 (57.16%)| 7     |
| Total              | 20 (33.33%)| 24 (40%)      | 16 (26.67%)| 60   |

Table 3: Parity wise distribution of study subjects.

| Type of insertion | Primipara | Multi para | Total |
|-------------------|-----------|------------|-------|
| Vaginal PPL       | 14 (70%)  | 6 (30%)    | 20    |
| T.C. PPL          | 17 (70.83%)| 7 (29.17%)| 24    |
| Interval IUCD     | 8 (50%)   | 8 (50%)    | 16    |
| Total             | 29 (48.33%)| 31 (51.67%)| 60    |

Table 4 Shows IUCD were removed because of social factors in most of women with PPIUCD. Cause of removal was mainly bleeding (2 cases, 50%) in interval IUCD group.

Table 5 shows No case of uterine perforation or unplanned pregnancy were noted.

Spontaneous expulsion noted in vaginal delivery group prior to 6 weeks. It could be due to improper fundal placement or string entanglement in Kelly’s forceps causing downward displacement.

Only 9.16% of women suffered from symptom suggestive of infection after insertion. Symptoms that are considered suggestive of infection include lower abdominal pain, fever, foul smelling or abnormal vaginal discharge, painful intercourse and bleeding after intercourse and responded to antifungal treatment.

Table 4: Reason for removal in PPIUCD.

| Cause of Removal                  | Vaginal (n=20) | Trans-cesarean (n=24) | Interval (n=16) |
|-----------------------------------|----------------|-----------------------|-----------------|
| Social causes without Any medical reason | 2 (66.67%) | 2 (66.67%) | 1 (25%) |
| Bleeding                          | 1 (33.33%) | 1 (33.33%) | 2 (50%) |
| Discharge P/V                     | 0 (0%)     | 0 (0%)                | 0               |
| Pain/PID                          | 0 (0%)     | 0 (0%)                | 1 (25%)         |
| For conception                    | 0 (0%)     | 0 (0%)                | 0               |
| Other Contraceptive method        | 0 (0%)     | 0 (0%)                | 0               |
| Total                             | 3 (100%)   | 3 (100%)              | 4 (100%)        |

Table 5: Complication percentage in PPIUCD.

| Complication  | Vaginal PPL (%) (n=20) | Transcesarean (%) (n=24) | Interval (n=16) |
|---------------|------------------------|--------------------------|-----------------|
| Bleeding      | 2 (10%)                | 1(33.33%)                | 2 (50%)         |
| Discharge P/V | 1 (5%)                 | 1 (33.33%)               | 1 (25%)         |
| Pain abdomen  | 1 (5%)                 | 0 (0%)                   | 0               |
| PID           | 0 (0%)                 | 0 (0%)                   | 1 (25%)         |
| Misplaced IUCD| 1 (5%)                 | 0 (0%)                   | 0               |
| Expulsion     | 4 (20%)                | 1(33.33%)                | 0               |
| Total         | 9 (45%)                | 3 (12.49%)               | 4               |

Missing string at follow up was a matter of concern for patient. This was noted in vaginal group (5%). Other self-reported normal side effect of PPIUCD insertion include cramps and abdominal pain which was 5% of women reported experiencing.

Bleeding was most common complication in interval IUCD 2 (50%) patients. The concerned women were reassured and medical treatment was given.

Table 7 shows beyond 6 week there was no spontaneous expulsion. 4 cases of spontaneous expulsion noted in vaginal delivery group prior to 6 weeks.
It could be due to improper fundal placement or string entanglement in Kelly’s forcep causing downward displacement. Among the 16 cases of interval IUCD insertion where no touch technique was used not a single case of spontaneous expulsion noted.

Table 6: Rate of expulsion of PPIUCD-mode of delivery.

| Type of insertion          | Total expulsions | Percentage |
|---------------------------|------------------|------------|
| Vaginal PPL (n=20)        | 4                | 20         |
| TC PPL (n=24)             | 1                | 4.16       |
| Interval IUCD (n=16)      | 0                | 0          |

Table 7: Removal of IUCD at different follow up visits.

| Mode of delivery /insertion type | Follow up I | Follow up II | Follow up III | Total number of removals |
|---------------------------------|-------------|--------------|---------------|--------------------------|
| Vaginal PPL (n=20)              | 2 (10%)     | 0            | 1 (5%)        | 3 (15%)                  |
| Trans cesarean (n=24)           | 1 (4.17%)   | 1 (4.17%)    | 1 (4.17%)     | 3 (12.5%)                |
| Interval IUCD (n=16)            | 0           | 3 (18.75%)   | 1 (6.25%)     | 4 (25%)                  |

Table 8 shows total no of removal among 44 case of PPIUCD was 6(13.6%). Most of the removal was done at first follow up visit for reason of social cause without any medical condition. Bleeding was most common reason at 12 moths follow up visit.

After removal of Cu T all patient being informed about other available choices of contraception. Among interval IUCD group maximum removal were done at 6 months follow up visit.

Table 9 shows compliance of patient is more with PPIUCD highest in trans cesarean group (87.5%) as compared to Interval Group (75%).

Table 8 shows rate of compliance was high in PPIUCD which is more in vaginal group (20%). Among vaginal PPIUCD expulsion was more with multigravida. A single case of expulsion was noted in trans cesarean IUCD group.

Table 9: Expulsion rate as per the parity.

| Mode of insertion | Primi Para | Mult para | Total | Expulsion rate |
|-------------------|------------|-----------|-------|----------------|
| Vaginal PPL (n=20)| 1          | 3         | 4     | 20%            |
| Trans cesarean (n=24)| 0         | 1         | 1     | 4.16%          |
| Interval IUCD (n=16)| 0         | 0         | 0     | 0%             |

Table 10 shows, in our study 17 women (38 %) received counseling in routine antenatal care visit and 17 (38%) received counseling after delivery only 22.73 % received counseling in early labour.

Most of the patient based their decision to use PPIUCD based on discussing with husband. Though 25 % women made their decision to use PPIUCD after consulting with family.

More than 90 % of women choosing to use PPIUCD as contraceptive method received PPFP counseling by dedicated doctor and many stated that they received some information about PPIUCD from para medical staff (ANM, ASHA, AWW etc.).

Table 11 shows the timing of PPIUCD insertion and perception of pain are shown in this table. In this table more than half of the IUCD were inserted during caesarean section.

About three quarter of women reported no pain at all during or after insertion. Only small portion of women reported no pain at all during or after insertion.
**Table 10: Counseling and decision-making about PPIUCD at baseline.**

| Characteristic                                            | Number (%)                        |
|-----------------------------------------------------------|-----------------------------------|
| Period of counseling (%)                                  |                                   |
| Antenatal clinic                                          | 17 (38.64%)                       |
| Early labor                                               | 10 (22.73%)                       |
| After delivery                                            | 17 (38.64%)                       |
| Satisfied with counseling (%)                             |                                   |
| Yes                                                       | 41 (93.18%)                       |
| No                                                        | 3 (6.82%)                         |
| Decision-making in PPIUCD as the method of family planning (%) |                                   |
| Self, alone                                               | 6 (13.64%)                        |
| Self, after consulting with family                        | 11 (25%)                          |
| Husband                                                   | 20 (45.45)                        |
| Mother                                                    | 1 (2.27%)                         |
| Mother-in-law                                             | 3 (6.82%)                         |
| Sister                                                    | 1 (2.27%)                         |
| Others                                                    | 2 (4.45%)                         |
| Counseling provider (multiple responses allowed)          |                                   |
| ASHA                                                      | 28 (63.64%)                       |
| Doctor                                                    | 41 (93.18%)                       |
| Nurse                                                     | 29 (65.91%)                       |
| ANM                                                       | 36 (81.82%)                       |
| Aaganwadi worker                                          | 16 (36.36%)                       |
| No                                                        | 2 (4.55%)                         |

**Table 11: Timing of PPIUCD insertion and perceptions of pain related to insertion.**

| Characteristic                                            | Number (%)                        |
|-----------------------------------------------------------|-----------------------------------|
| Timing of PPIUCD insertion (%)                            |                                   |
| Immediately after delivery                                | 20 (45.45)                        |
| During C-section                                          | 24 (55.55)                        |
| Client perception of pain during insertion (%)            |                                   |
| No pain at all                                            | 34 (77.27)                        |
| Little discomfort                                         | 8 (18.18)                         |
| Somewhat painful                                          | 1 (2.27)                          |
| Painful/very painful                                      | 1 (2.27)                          |
| Client perception of pain after insertion (%)             |                                   |
| No pain at all                                            | 31 (70.45)                        |
| Little discomfort                                         | 10 (22.73)                        |
| Somewhat painful                                          | 2 (4.55)                          |
| Painful/very painful                                      | 1 (2.27)                          |

**DISCUSSION**

This prospective study was done in tertiary care center and teaching hospital in Maharashtra during Feb 2016 to July 2017. Total 60 patients were included in the study after the fulfillment of the eligibility criteria and the written informed consent given by the study subjects. A total of 44 PPIUCD insertion were done, out of these 24 (54.54%) insertions were intra caesarean and 20 (45.45%) IUCD were placed after vaginal delivery.

All these women were asked to come for follow up at 6wk, 6 month and 12 months postpartum. In group 1 and 2 IUCD was introduced with help of Kelly’s forcep. In group 3 interval IUCD was introduced using no touch technique. In every visit pelvic examination was done to look for any abnormality. When all the patient reviewed at the end of all follow up visit, complication, removal, expulsion and compliance were noticed in our study. 16 Interval IUCDs were inserted out of total 60 patients.

**Age of patient**

Maximum patient (30 out of 60) were belonging to the 19-23 years age group. Only 7 patients were 29 years and above. Mean age of the patients was 24.15 ± 3.8348.

**Parity**

The maximum proportion of primiparas for trans cesarean group (70.83%) and maximum proportion of multiparas were for Interval group (50%).

**Complications**

While comparing PPIUCD with interval IUCD the cumulative rate of complications was higher in PPIUCD
group in our study (12 out of 44 i.e. 27.27% and 4 out of 20% in PPIUCD group and interval IUCD group respectively). No case of uterine perforation or unplanned pregnancy was noted.

Expulsion of IUCD

4 cases of spontaneous expulsion noted in transvaginal delivery group prior to 6 weeks. It could be due to improper fundal placement or string entanglement in Kelly’s forceps causing downward displacement. Rate of expulsion was high in PPIUCD which is more in transvaginal group (20%).

Among transvaginal PPIUCD expulsion was more with multigravida. A single case of expulsion was noted in trans cesarean IUCD group. Beyond 6 week there was no spontaneous expulsion.

Among the 16 case of interval IUCD insertion where no touch technique was used not a single case of spontaneous expulsion noted. In 5 cases out of total 44 PPIUCD case spontaneous expulsion occurred i.e.11.36% which was more compared to the expulsion rate of 5.6% reported among 210 women in a clinic in Hubli, Karnataka state in India, 1.6% among 3000 women in a hospital in Paraguay, and 5.6% among women among 305 peri urban Lusaka, Zambia and much similar to another study of 1317 women in north India reported a cumulative expulsion rate of 10.7% by six months.

Infection

Only 9.16 % of women suffered from symptom suggestive of infection after insertion. Symptoms that are considered suggestive of infection include lower abdominal pain, fever, foul smelling or abnormal vaginal discharge painful intercourse and bleeding after intercourse and responded to antifungal treatment.

Missing thread

Missing string at follow up was a matter of concern for patient. This was noted in vaginal group (5 %)

Pain

Other self-reported normal side effect of PPIUCD insertion include cramps and abdominal pain which was 5 % of women reported experiencing.

Bleeding

Bleeding occurred in 2(10%) case in transvaginal PPL and 1(4.17%) case in trans cesarean PPL while 2(11.25%) cases in interval IUCD. Bleeding was most common complication in interval IUCD patients. The concerned women were reassured and symptomatic medical treatment was given. Celen S et al (2004) reported cumulative rates of bleeding equal to 11.4% and 8.2% respectively. In Gupta et al study Bleeding occurred in 13 (4.33%) cases, 5 cases (3.3%) of bleeding were reported from vaginal delivery group and in the trans cesarean group bleeding occurred in 8 cases (5.3%).

PID

No case of PID in PPIUCD but 1(11.25%) case in interval IUCD. Similarly, there was no case of PID from EL Beltagy et al (2010).

Removal of IUCD

IUCD were removed because of social factors in most of women with PPIUCD while most common reason for PPIUCD removals in study of Gupta et al were bleeding and pain which account for removal in 6 cases (2%).

Among 44 case of PPIUCD 6 women removed Cu T Removal percentage was more transvaginal PPIUCD insertion group (15%) as compared to Trans cesarean group (12.5%) Out of 16 women of interval IUCD group 4 (25%) cases in interval IUCD group and opted for some other method of contraception.

In our study, Cause of removal was mainly bleeding (2 case) in interval IUCD group. Rate of removal in interval insertion group was 25% (4 cases), whereas it was 14% (6 cases out of 44) in PPIUCD group i.e. more in the interval group which was significantly higher than Gupta et al. study in which it was 6% for interval and 5.6% for PPIUCD group. Most of the removal was done at first follow up visit for reason of social cause without any medical condition. Bleeding was most common reason at 12 moths follow up visit.

After removal of Cu T, all patient being informed about other available choices of contraception. Among interval IUCD group maximum removal were done at 6 months follow up visit. Thus, there was removal of total 10 IUCDs out of total 60 patients (16.67%) in the present study, compared with 7.6% reported in Hubali, India, 3.4% among women in Paraguay, and 3% among women in Zambia.

Compliance

Compliance of patient is more with PPIUCD highest in trans cesarean group (87.5%) as compared to Interval Group (75%).

Counseling

Compliance of patient is more with PPIUCD highest in trans cesarean group (87.5%) as compared to Interval Group (75%).
PPIUCD based on discussing with husband. Though, 25% women made their decision to use PPIUCD after consulting with family.

A significant number of women declined the PPIUCD because of non-partner involvement. This reveals the importance of partner involvement during counseling and decision making. In our setup women who visit the antenatal clinic are usually not accompanied by their partner and therefore couple counseling is lost during this period. In Asia postpartum study, husband's desire for IUCD removal was a significant reason for removal, emphasizing the importance of involving the husband in prenatal counseling.\(^1\)

More than 90% of women choosing to use PPIUCD as contraceptive method received Postpartum family planning counseling by dedicated doctor and many stated that they received some information about PPIUCD from para medical staff (ANC, ASHA etc).

**Satisfaction**

More than 90% were satisfied with their decision to use IUCD. Nearly all women were satisfied with their choice of IUCD at the time of insertion and over 90% reported that they were happy with the IUCD at six weeks following insertion. A previous study from Orissa among interval IUD users found that about three-quarters of women were satisfied with this mode of contraception after one year.\(^13\) The present study is somewhat suggestive that satisfaction rates are higher with PPIUCD than with interval IUD use, but the follow-up time in the two studies is not directly comparable.

**The timing of PPIUCD insertion and perception of pain**

More than half of the IUCD were inserted during caesarean section. About three quarter of women reported no pain at all during or after insertion. Only small portion of women reported pain during or after insertion. Similar findings were observed in Kumar et al study (2014).\(^14\)

**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 or 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.

Though rate of complication such as expulsion is there but it outweighs the potential inconvenience of needing to return for care for that subset of women. The acceptability of intra operative placement of IUCD in mother undergoing caesarean section was high.

Misconception and negative attitudes related to IUCD should be addressed through effective counseling by health care provider. Decision making among women who accepted PPIUCD, their perception and satisfaction with PPIUCDs and complication that occurred after insertion of PPIUCDs are the cornerstone in success of PPIUCD program to achieve a goal of family planning campaigns.

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