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Original Article

Evaluation of Acceptability, Safety, and Efficacy of Intrauterine Device Insertion during the Postpartum Period: A Prospective Analysis

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Abstract

Background: Intrauterine contraceptive devices (IUCD) are a rapidly reversible method of contraception. It is necessary to assess the acceptability and uptake of IUCD in parturients elaborating its safety and success.

Aims and Objectives: The aim of the study was to evaluate the acceptability, safety, and follow-up of postpartum insertion of IUCD both in vaginal and cesarean section deliveries among parturients with the ultimate goal is to avoid unplanned pregnancies and to expand the usage of IUCD.

Materials and Methods: The study was a prospective one conducted during the period of January 2014–January 2015. All the antenatal patients at their visits after 30 weeks of gestation were taken in the study and parturients accepted for postpartum IUCD (PPIUCD) insertion constitute the study population.

Results: A total of 202 patients were included in the study population. Majority of cases accepted for PPIUCD had at least a primary level of education, were primiparous, and had their last childbirth >2 years age consisting of 90.10%, 46.53%, and 44.55%, respectively. About 27.72% of the parturients were aware of the PPIUCD and 58.91% of parturients accepted PPIUCD due to its long-term effect. PPIUCD insertion done for the study was three types such as: Within 10 min, immediate (within 24 h), and trans-cesarean consisting of 23.76%, 15.35%, and 60.89%, respectively. About 96.04%, 79.70%, and 60.90% cases were attaining for follow-up at 6 weeks, 3 months, and 6 months, respectively. At 6 week follow-up, pelvic inflammatory disease, irregular cycles, and pain were the chief concerns consisting of 34.16%, 23.27%, and 16.83%, respectively, whereas bleeding per vagina, lost string, and expulsion were less seen. PPIUCD expulsion was seen in 14.85% of the parturients.

Conclusions: Awareness of the PPIUCD among women was poor despite high acceptance and needs strategies to increase awareness. The PPIUCD was demonstrably safe, having no reported incidence of perforation with low rates of expulsion, pelvic infection, and few lost strings.

Key words: Acceptance, Intrauterine contraceptive devices, Postpartum insertion, Safety

INTRODUCTION

Intrauterine contraceptive devices (IUCD) to prevent pregnancy are among the oldest methods of contraception. Increasing numbers of women in the developing world are having their babies in hospitals. Many of these women welcome the opportunity to delay their next pregnancy. The postpartum insertion of an IUCD offers several advantages in such instances. Having just given birth, the woman is not pregnant, and she may be very motivated to consider long-acting methods. IUCDs work primarily by preventing fertilization and do not act as abortifacients. When the uterus is exposed to an IUCD, a sterile inflammatory reaction occurs, which is toxic to sperms and impairs fertilization.

The modern IUCD is a highly effective, safe, long-acting, coitus independent, and rapidly reversible method of contraception with few side effects of contraception. Many

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women also find IUCD to be very convenient because it requires little action once it is in place. The Cu T 380A has a remarkably low failure rate of <1/100 women in the 1st year of use. IUCD insertion in the immediate postpartum period offers an effective and safe method for spacing and limiting births.[1] Delivery is the best opportunity for the IUCD insertion in developing countries when the healthy women come in contact with the health-care providers and maybe the best scope to curtail the fertility rate.[2] Immediate postplacental insertion should be done only after adequate prenatal counseling and giving her informed consent.

Appropriate times for IUCD insertion in the postpartum periods include the postplacental IUCD insertion, the immediate postpartum IUCD (PPIUCD) insertion, and the trans-cesarean IUCD insertion. The postplacental IUCD insertion is done within 10 min after the expulsion of the placenta, following vaginal delivery. The immediate PPIUCD insertion is done after the postplacental period, but within 48 h of delivery and the trans-cesarean IUCD insertion is done when the insertion takes place following cesarean delivery before the uterus incision is sutured.

Immediate PPIUCD insertion has a higher retention rate if the IUCD is inserted postplacentally, but the IUCD can be inserted safely at any time during the first 48 h after delivery. IUCDs can also be inserted after the 6th week postpartum and after an abortion.

IUCDs inserted postplacentally have a much lower expulsion risk than those inserted later in the postpartum period. The risk of expulsion can be reduced significantly by properly inserting the IUCD. There is no increased risk of pelvic infection, the low risk of uterine perforation, and no effect on breast milk quantity or quality with PPIUCD insertion.

Therefore, the present study was conducted to assess the acceptability and uptake of post placental, immediate, and trans-cesarean insertion of IUCD (copper T 380 A) in parturients and to elaborate in its safety and success by the end of postpartum.

MATERIALS AND METHODS

The study was a prospective interventional analytical one conducted in the Department of Obstetrics and Gynecology of Calcutta National Medical College and Hospital, a tertiary care teaching hospital during the study period of January 2014–January 2015. Institutional Ethics Committee approval was taken for the study under the Helsinki Declaration of 1975 that was revised in 2000. All the antenatal patients at their visits after 30 weeks of gestation were taken in the study. The patients with 18–40 years old, desire to have Cu-T after counseling, no systemic or pelvic infection, hemoglobin >8 g/dl, and no major systemic illness (diabetes mellitus and heart disease in pregnancy) were included in the study. The patients having stillbirth, sepsis (temp. >38°C during or after labor), rupture of membranes for >24 h before delivery, and postpartum hemorrhage were excluded from the study.

Parameters to be studied were a history of the patient, insertion timings, follow-up, and complications. History of the patient includes age, parity, gravida, education, knowledge, and previous use of any contraceptive, any complicating factor. Insertion timings were during the postpartum period, i.e., within 24 h of placental expulsion. Follow-up was done at 6 weeks, 3 months, and 6 months after IUCD insertion. Pain, bleeding per vagina, perforation, infection, pregnancy, and missing thread were the complications encountered.

Study Tools

Instruments which were used in the study included a structured questionnaire, a checklist, and a PPIUCD follow-up card. A structured open-ended questionnaire was used to extract important information from the parturient and the following variables were collected: Social-demographic characteristics of the women studied, obstetric and gynecological characteristics, previous contraceptive methods used, source of information and awareness of the PPIUCD, reasons for acceptance or decline to PPIUD insertion, and their future pregnancy desires. The checklist was used to counter check the eligibility of the parturient, to ensure that all the instruments required were set before insertion and to check any immediate complications. A PPIUCD follow-up card was given to all the parturients after insertion of the IUCD. This included instructions about recognizing expulsion, for example, through the string length or even vivid expulsion, postpartum warning signs, i.e., bright red bleeding of which the woman needs to change her pad more than 6 times a day, unusual abdominal or pelvic pain (not after-birth pain), and unusual vaginal discharge or pain, or fever. The PPIUCD card also contained information on the date of insertion and follow-up visit, type of IUCD inserted, date of expiry of the IUCD, and the telephone number of the principal investigator (PI).

Data Collection and Sampling Technique

General health education was done for all parturients who had normal vaginal and cesarean section deliveries during their antepartum visits and hospitalization period. During these sessions, postpartum contraception with IUCD was offered together with other options that include Nexplanon, depot medroxyprogesterone acetate, and

minipills suitable for breastfeeding mothers. The merits of each method, their common side effects, and possible complications were explained to all the women. Each eligible woman was then counseled individually, following which PPIUCD was introduced. This approach was used to enable the woman to make a voluntary, informed, and well-considered choice. The ultimate choice was respected. In all cases, reasons for acceptance and refusals were recorded. Counseling for postpartum family planning was offered every morning and afternoon before the parturient was discharged from the hospital. Counseling was done by the research assistant and the PI.

Data were collected conveniently among the eligible parturients. Eligibility was sought by checking their files for the labor events and by asking the woman if she was planning to stay around the area for a month. Those women who were eligible for PPIUCD were identified and approached in the postnatal ward. A written informed consent was given to the parturients on their participation in the study. Questionnaires were filled by the PI and the research assistants. After contraceptive counseling and filling of the questionnaire, those who accepted the PPIUCD insertion had the IUCD inserted immediately. In case of non-acceptance, other methods of postpartum family planning were advised. The IUCD was inserted in a side room adjacent to the postnatal ward.

Women in whom the PPIUCD was inserted were assessed before discharge and followed at 6 weeks after IUCD insertion. On discharge a PPIUCD follow-up card was given which contained information of the date of insertion and follow-up visit, type of IUCD inserted, date of expiry of the IUCD and the telephone number of the PI. These women were advised to phone or come back any time if she had any concern or experiences any warning sign or if the IUCD is expelled. The PI crosschecked the checklist and questionnaire after every shift to ensure proper filling of information.

At 6 weeks interval, those women whom the PPIUCD was inserted were reassessed by the PI at the examination room in the antenatal/postnatal clinic. The follow-up checklist was filled by checking their oral temperature, and an abdominal examination for suprapubic tenderness and involution of the uterus was done. A speculum examination was then performed to check if the strings were visible and any discharge noted. The visible IUCD strings were trimmed at approximately 3 cm. A digital vaginal examination was then done to assess for cervical motion tenderness. Those women who had a pelvic infection were treated with antibiotics (Injection Ceftriaxone 250 mg stat followed by oral Erythromycin 500 mg 12 hourly and Metronidazole 400 mg 8 hourly for 2 weeks). Women who reported expulsion of the IUCD or those whom their strings were not visible had a pelvic ultrasound to confirm expulsion.

Insertion Techniques

All necessary instruments (Copper T 380A, 2 ring forceps, Sim's speculum, headlamp, Povidone-iodine, Savlon, kidney dish, and cotton swabs) were arranged on top of an auxiliary table covered with a sterile drape. IUCD insertion was performed by the PI under proper aseptic techniques throughout the procedure. The IUCD was inserted through the dilated cervix to the level of the uterine fundus, as confirmed by palpation with a hand placed on the abdomen overlying the fundus. The ring forceps were oriented, so the arms of the IUCD lies parallel to the anterior and posterior walls of the uterus and then the forceps were opened to release the IUCD. The cervical os was then gently inspected with the Sims Speculum for the strings. If the strings were visible then the IUCD was reinserted. Before discharge, the patient was assessed for comfortability by the research assistants.

Data Analysis

Statistical analysis was performed using SPSS version 17.0. The Chi-square test was used to measure the strength of associations between variables, $P < 0.05$ was considered to be statistically significant.

RESULTS

Among the total 587 parturients counseled for PPIUCD, 385 cases declined for the PPIUCD and the majority of the women declined due to their preferences for other forms of contraception (30.3%) and need to discuss with their partners and other family members (28%). Only 202 cases (34.4%) accepted for PPIUCD insertion and constitute the study population.

Table 1 showed the socio-demographic factors of the parturients studied. The majority were in the age range 20–29 (48.51%). Most of the study population had at least a primary level of education (90.10%). The majority were of Muslim religion (56.93%). Median parity was two (Range: 1–7). Grand multipara made up a small percentage (3.47%) of the study sample whiles the majority (46.53%) were primiparous. Majority of the women accepted for IUCD had their last childbirth <2 years ago consisting of 44.55% of cases.

While the majority never had used any method of contraception (46.04%), natural methods (20.30%) and oral contraceptives pills (16.34%) were commonly used methods of contraception. Nearly a quarter of the parturients (27.72%) were aware of the PPIUCD,

Table 1: Socio-demographic factors

Parameters	Number (*n*=202) with percentage (%)
Age in years	
≤19	61 (30.20)
20–29	98 (48.51)
30–39	38 (18.81)
≥ 40	5 (2.48)
Education status	
No formal education	20 (9.90)
Primary	66 (32.67)
Secondary	93 (46.04)
Higher education	23 (11.39)
Religion	
Hindu	64 (31.68)
Muslim	115 (56.93)
Christian	23 (11.39)
Occupation status	
Housewife	153 (75.74)
Business lady	5 (2.48)
Employed	44 (21.78)
Parity	
1	94 (46.53)
2	66 (32.67)
3	35 (17.33)
4	4 (1.98)
≥5	3 (1.49)
Last childbirth (years)	
0–2	90 (44.55)
February 3	62 (30.69)
March 4	27 (13.37)
≥5	23 (11.39)
Future pregnancy desire: Year	
1–2	19 (9.41)
3–5	138 (68.32)
>5	13 (6.43)
Not sure	17 (8.42)
No intension	15 (7.42)

Table 2: Previous contraceptive method used, source of information and type of PPIUCD insertion

Sources	Number (202) percentage (%)
Previous contraceptive method used	
Never used	93 (46.04)
Natural	41 (20.30)
OCPs	33 (16.34)
Male condom	24 (11.88)
Internal IUCD	2 (0.99)
Depot medroxyprogesterone acetate	8 (3.96)
Spermicidal agents	1 (0.49)
Source of information	
Unaware	146 (72.28)
Aware	56 (27.72)
Type of PPIUCD insertion	
Within 10 min	48 (23.76)
Immediate (within 24 h)	31 (15.35)
Trans cesarean	123 (60.89)

IUCD: Intrauterine contraceptive devices, PPIUCD: Postpartum IUCD

Table 3: Reasons for acceptance

Sources	Number (*n*) percentage (%)
Reasons	
Long-term effect	119 (58.91)
Safe	32 (15.84)
Fewer clinic visit	24 (11.88)
Non-hormonal	21 (10.40)
No remembrance once inserted	15 (7.43)
Reversible	7 (3.47)
No interference with breastfeeding	3 (1.49)

i.e., having source of information. Among these, the majority (48.21%) had the antenatal clinic as their source of information followed by family planning clinic (17.86%), relative/friend (17.86%), and media (16.07%) as other sources of information. Majority of the PPIUCD was inserted after placental expulsion during cesarean deliveries (60.89%) [Table 2]. More than half (58.91%) of those women who accepted PPIUCD were due to the reason of its long-term effect [Table 3].

The type of follow-up of the parturients was clinic and telephone contact. About 96.04%, 79.70%, and 60.90% of the parturients attended follow-up at the schedule of 6th week, 3rd month, and 6th month, respectively. After 6 weeks, the majority of the parturients came to the clinic for follow-up (70.79%) while 25.24% parturients followed up over the telephone. Infection, irregular cycles, and pain were the common complaints among the parturients during the three follow-up schedules. About 35.57%, 24.23%, and 17.33% of the parturients attaining first follow-up at 6th week had complaints of infection, irregular cycles, and pain, respectively, whereas the percentage for the same complaints will be 34.16%, 23.27%, and 16.83%, respectively, when compared to the total study population. About 12.42%, 31.68%, and 22.36% of the parturients attaining second follow-up at 3rd month had complaints of infection, irregular cycles, and pain, respectively. About 21.14%, 37.40%, and 12.20% of the parturients attaining third follow-up at 6th month had complaints of infection, irregular cycles, and pain, respectively. Missing thread was seen in 8.76% of the parturients and expulsion, and refusal to continue IUCD insertion was seen in 7.22% of the parturients attaining 6th week of follow-up [Table 4]. In overall, PPIUCD expulsion was seen in 10.89% of the parturients and refusal to continue IUCD was seen in 7.43% of the parturients attaining study population.

DISCUSSION

This study was carried out to determine the acceptability, safety, and complications at 6 weeks follow-up in PPIUCD placement together with assessing the success that is the continuation rate at the end of puerperium in a cohort of

Table 4: Follow-up schedules

Complaint	Number (*n*) with percentage (%)		
	6 weeks	3 months	6 months
No complaint	48 (24.74)	31 (19.25)	15 (12.20)
Pain	34 (17.53)	36 (22.36)	15 (12.20)
Bleeding per vagina	12 (6.19)	15 (9.32)	9 (7.32)
Infection	69 (35.57)	20 (12.42)	26 (21.14)
Irregular cycles	47 (24.23)	51 (31.68)	46 (37.40)
Missing thread	17 (8.76)	12 (7.45)	10 (8.13)
Expulsion and refusal to continue	14 (7.22)	11 (6.83)	12 (9.76)

mothers who underwent vaginal delivery or cesarean delivery and required a long term, reversible method of contraception.

Data from India show that 61% of births occur at intervals shorter than the recommended interval of 36 months, i.e., 27% of births occur within 24 months after a previous birth, and 34% of births occur between 24 and 35 months. Lack of awareness is one of the common reasons for non-use of contraception. Less number of women is using any method of family planning during the 1st year postpartum consisting of only 26%.[1,3]

Majority of the women (90.10%) in our study population had at least a primary level of education. Acceptance of PPIUCD was higher among women with primary and secondary education (32.67% and 46.04%) than those with no formal education (9.90%). This finding confirms the importance of education in deciding future pregnancy. This was similar to a study done in Egypt by Safwat *et al.*, where women with no formal education had an acceptance of 9.4%, while those with formal education were 19.4%.[4]

Education has a positive effect on contraceptive use, as shown in a study done in Zimbabwe. It was only apparent among women who completed secondary education (12 years or more). Women who completed secondary school were about twice as likely to use modern contraceptive methods as women who did complete primary education. In this study, it is as high as four-fold.[5]

A study by Halder *et al.* showed that mothers with >2 living children have lower acceptance of IUCD (1%) among cesarean group in comparison to vaginal group (13%) possibly due to their preference to permanent sterilization and acceptance of the PPIUCD was higher among parity 1 and parity 2,[1] whereas study done by Safwat *et al.* in Egypt showed 16% of primipara mothers accepted the use of PPIUCD compared to one-third of grand multiparous possibly due to the higher educational status of the urban population compared to rural in India.[4]

Acceptance of IUCD was the most common among primigravida clients (46.53%). In case of multiparous, it was 3.47%; thus, this finding is contrary to that of the study by Grimes *et al.* where they found higher acceptance in multiparous clients (65.1%).[6] Furthermore, the majority (72.28%) of the study population was not aware of the PPIUCD. Among women who had the PPIUCD inserted, 48.21% have ever heard about the PPIUCD from the antenatal clinic. This could be because PPIUCD is a relatively new method of contraception in this community.

The duration since last childbirth was significantly associated with acceptance of PPIUCD. About 44.55% of the PPIUCD acceptors had their last childbirth <2 years. Women on the first delivery and with short pregnancy interval felt the necessity of a long acting and reliable method of contraception. In a report released by WHO in 2006, better family planning and birth-spacing services resulted in improved maternal and neonatal outcome. About 32% of all maternal deaths and over 1 million deaths of children under 5 could be prevented in countries with high birth rates. This finding in the study indicates toward positive maternal health in the future.[7] Future pregnancy desire remains almost the same in both groups of accepters and non-accepters. This finding suggests that the program managers must give priority toward effective antenatal counseling on PPIUCD, as the minimal effort would bring about a huge change.

Total acceptance rates remain low consisting of 34.41%. This was similar to the study done by Safwat *et al.* in Egypt (28%).[4] Findings on the reason for acceptance are surprising. A majority of the acceptors rely on their physician. They value the advice of the doctor. Many are attracted for its long acting and reversibility properties.

A significant number of women declined PPIUCD because of partner's noninvolvement during counseling and decision making. When the partner is involved in contraceptive counseling and decision-making, the acceptance and continuation rates were higher. Unfortunately, in our setup, women who visit the antenatal clinic are usually not accompanied by their partners, and the care providers do not allow them during the process even if they are present. Thus, couple counseling is lost during this period. Therefore, it is most important to include proper counseling of the couple together to choose a contraceptive method which will, in turn, increase the compliance.

During follow-up, the present study showed that pelvic inflammatory disease (PID) and irregular cycles were the chief complaints and supported by the data which showed infections are common in developing countries increasing the risk of pelvic infection.[8,9] However, Shukla *et al.* found no case with PID.[10] Prophylactic antibiotics may be required in our setting where the incidence of

post-delivery sepsis is high as compared to developed countries. Fifteen women (7.43%) among those inserted with PPIUCD had lost strings during the first follow-up at 6 weeks. It should be noted that there were no serious complications in this study.

Expulsion rates vary according to clinician's skill in PPIUCD insertion.[2] Therefore, it requires additional training to the clinicians and the provision of a special kit for PPIUCD insertion to the health centers where deliveries are conducted.[11] In a systematic review by Kapp and Curtis, expulsion rates were lower in post-placental insertions during cesarean section in comparison to postplacental vaginal insertions without any added complications.[12] Expulsion rate in a prospective study by Haldar *et al.* was 4% in the vaginal group and 2% in intra-cesarean group which were much lower in comparison to few studies such as Celen *et al.* found the 1-year cumulative expulsion rate of 12.3% in early postplacental insertion of IUCD and another study found 17.6% expulsion rate in intra-cesarean IUCD.[1,13,14] Expulsion rate of immediate PPIUCD in a study done in China by Chi *et al.*. 1994, was 25–37%, while postplacental was 9.5–12.5%. Expulsion of PPIUCD usually occurs in the first few months after insertion.[15]

A study by Shukla *et al.* showed that only 11.3% came for follow-up at 6 months whereas 78% came for follow-up at 6 weeks affecting the true data on the rate of expulsion at 6-month checkup.[10] In our study, 60.90% came for follow-up at 6 months, whereas 96.04% came for follow-up at 6 weeks. These findings indicate a poor integration of vertical programs at all levels.

Limitations

The sample size of this study is small which may not reflect the true picture. Lost to follow-up observed in the study made it difficult to draw a clear conclusion as what happened to those who did not complete their follow-up schedule. The study is a single institution one and it will better for a multicentric study for more representative and powerful.

CONCLUSIONS

In the present study, awareness among women for the PPIUCD was very poor despite high acceptance. The PPIUCD was demonstrably safe, having no reported incidence of perforation with low rates of expulsion, pelvic infection, and few lost strings. We can conclude that Inserting CuT 380 A in the postpartum period is safe and effective, has a high retention rate.

The government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange for training on PPIUCD to increase knowledge and skills among health-care providers. This will also further promote PPIUCD use and aid in the reduction of the expulsion rates. Data on the safety of PPIUCD insertion is less from our country. There is a need for more studies in different settings before declaring the PPIUCD insertion as completely safe.

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