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Original Research Article

Evaluation of safety, efficacy and continuation rates of post-partum intrauterine contraceptive device

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ABSTRACT

Background: Postpartum intrauterine contraceptive device (PPIUCD) is a proven, safe, reversible, and long-acting method of contraception. Despite availability, its acceptance remains low. This study aimed to evaluate the safety, efficacy, and continuation rates of PPIUCD in a tertiary care hospital in Himachal Pradesh.
Methods: A prospective study was conducted from June 2023 to May 2024 among women >34 weeks gestation attending antenatal outpatient department (OPD), admitted in the labor room, and postpartum ward. PPIUCD insertion was performed either post-placental or intra-caesarean after counselling. Women were followed up at 6 weeks, 12 weeks, and 6 months to assess safety, efficacy and continuation rates.
Results: Of 500 women, the acceptance rate was 40%, significantly influenced by antenatal counselling. The main reasons for acceptance were long-term contraception (91.5%), safety (88%), and reduced clinic visits (62.5%). Refusals were attributed to poor knowledge (55.67%), partner/family disapproval (41.33%), preference for another method (35.33%), and fear of complications (33.67%). Most participants were 26–30 years (36.5%), multiparous (66%), graduates (48.5%), from rural areas (62%), and upper middle class (32.7%). Vaginal delivery accounted for 67.5% of insertions. The expulsion rate was 6.84%, with no significant association with type of insertion (p=0.24). At follow-up, 76.31% reported no complaints. Removal rate was 1.58%. Continuation was 91.58% and efficacy 100%, with no failures recorded.
Conclusion: PPIUCD is a safe, effective, and highly acceptable contraceptive option with excellent continuation and satisfaction rates. It is particularly advantageous in rural settings where access to follow-up and contraceptive services is limited.

Keywords: PPIUCD, Counselling, Acceptance, Safety, Continuation

INTRODUCTION

Family planning has been acknowledged worldwide as a crucial health care intervention throughout a women's reproductive life. Postpartum family planning specifically aims to prevent unintended pregnancies.[1] According to an analysis of Demographic and Health Survey data from 27 countries, shows that 95% of women who are 0-12 months postpartum wish to avoid pregnancy in the next 24 months, yet 70% of them are not using any contraception.[2] In sub-Saharan countries, postpartum intrauterine contraceptive device (PPIUCD) continues to constitute a minor fraction of overall contraceptive services provided.[3]

Currently, India is the largest populous country with the current population being 1.45 billion, as of 22nd September 2024, based on interpolation of latest United Nation data. Approximately, 17.78% of world's population is residing in only 2.4% of global land mass.[4] India was pioneer in launching a nationwide family planning programme. The family welfare program aimed to promote family norms to stabilise the population at

about 1.533 billion by 2050 AD.[5] To enhance postpartum family planning, the Government of India introduced PPIUCD services and established a national training centre in Delhi.[6]

Based on recommendations of technical consultants for healthy timing and spacing of pregnancies (HTSP), women should wait at least 24 months, and not more than 5 years after a live birth before attempting next pregnancy. In India, 65% of women in their first year postpartum have an unmet need for family planning, only 26% use any method, while 8% wish to have another child within 2 years.[7] Fertility can return within 4-6 weeks for the women not exclusively breast feeding. Approximately, 40% women resume sexual activity within 3 months postpartum, and about 90% by 10-12 months. Therefore, making them vulnerable to risk of early pregnancy. Thus, initiating family planning within 6 weeks postpartum is crucial. An IUCD can be inserted within 48 hours postpartum, referred to here as PPIUCD. The IUCD recommended by the World Health Organization (WHO) is the CuT380-A, which received United States Food and Drug Administration (USFDA) approval in 1984. CuT380-A and Cu375 are available in government program free of cost and is being utilised for immediate postpartum insertion. The CuT380-A is highly effective (more than 99% effective). There are 0.6 to 0.8 pregnancies per 100 women in the 1st year of use. CuT380-A is effective for 10 years of continuous use.[8] With the introduction of IUCD in India's family welfare program and rising institutional deliveries through JSY and JSSK, access to postpartum long-term reversible contraception for women has significantly increased. Increasing awareness about PPIUCD and integrating PPIUCD counselling services at every delivery point, along with provision of couple counselling, will undoubtedly enhance the success of this program.[9] Postpartum insertion is convenient both for the women and the providers.[10] Training on PPIUCD is important to improve healthcare provider's knowledge and skills. This will encourage greater use of PPIUCD and help lower expulsion rates.[11] Follow up visits can be scheduled along with immunisation visits. Therefore, study of PPIUCD is being done with the aim of knowing the future scope of method.

METHODS

Study setting

This study was conducted between 01 June 2023 to 31 May 2024 in the tertiary care centre at Indra Gandhi Medical College (I.G.M.C) Shimla, Himachal Pradesh, India. This department is largest in the state and receives patients from all sub-district hospitals of the district. On an average 15-20 deliveries are conducted daily.

Study design

A prospective cohort study was done.

Followed up period

The follow up period of the study was till 30 June 2024.

Study population

Women attended antenatal OPD, admitted to labour room and in postpartum ward at Kamla Nehru State Hospital for Mother and Child, I.G.M.C, Shimla.

Inclusion criteria

Women delivering vaginally or by caesarean section who have been counselled for PPIUCD in Antenatal period, in early labour or in immediate postpartum period, Women who gave informed consent to participate in the study and Women willing for follow up.

Exclusion criteria

Women who did not provide consent, had rupture of membranes for more than 18 hours, fever exceeding 38°C, hemoglobin levels below 8 g/dl, unresolved postpartum hemorrhage (PPH), or extensive genital trauma following delivery were excluded. Additionally, women with distorted uterine cavities (such as uterine septum or fibroid uterus), foul-smelling vaginal discharge, bleeding disorders, active sexually transmitted infections (STIs), high-risk sexual behaviour, or copper allergies were also not eligible for inclusion.

IUCD insertion techniques

Post placental

Two types of techniques were used.

Instrumental insertion (using forceps)

All necessary instruments were arranged on the auxiliary table. Insertion was performed by the trained doctor using modified Kelly's placental forceps. Aseptic techniques were enforced throughout the procedure. Sim's speculum was gently inserted into the vagina to visualize cervix. The cervix and vaginal walls were cleaned twice with cotton swabs soaked in povidone iodine solution with speculum in place. The anterior lip of cervix was gently grasped with the help of ring forceps. T

he IUCD was grasped with the modified Kelly's forceps using no touch technique. Once it was inserted into lower uterine segment other hand was moved to the abdomen and placed over the fundus and uterus was pushed gently upward to reduce the angle and curvature between the uterus and vagina. Now IUCD with the forceps was moved upwards until it was felt at the fundus. Then the forceps were opened to release the IUCD and swept to side wall. Uterus was stabilized until forceps removal was complete. The cervical os was then gently inspected for the strings. Sim's speculum was removed.[8,12]

Manual post placental insertion

The IUCD was held in between middle and index finger using long handed gloves reaching midway up to the arm and it was inserted at fundus.

Intra-caesarean insertion

Insertion was done either manually or using a ring forceps. Aseptic precaution was maintained. The doctor was holding the IUCD between the middle and index fingers of the hand or was grasped by ring forceps and was passed through the uterine incision. Once it was placed at the fundus, the hand and forceps were slowly withdrawn, noting whether the IUCD remains properly placed. The strings were pointed towards the cervix, care was taken during closure of the uterine incision.[8,12] All the women after PPIUCD insertion were counselled, to come for the visit at 6 weeks,12 weeks and 6 months postpartum and earlier, in case of, expulsion of IUCD, irregular or heavy vaginal bleeding, abnormal vaginal discharge or fever. Women were advised to feel for the threads every month and report in case of missing of threads. Contact numbers were taken and women were contacted telephonically and reminded of their follow up visits in OPD. Women who were unable to come were asked about missing threads, irregular and heavy bleeding, discharge per vaginum, pain, fever, any lower abdominal discomfort or missed menstrual period.

RESULTS

This study was conducted in the department of Obstetrics and Gynecology, I.G.M.C., Shimla. Total 500 women have been counselled for PPIUCD in Antenatal period, in early labour and in immediate postpartum period. Out of them, 200 women who accepted PPIUCD following vaginal or caesarean delivery were included in the study and were followed up for a period of 6 months. Safety, efficacy and continuation rates of PPIUCD were assessed, and results were as follows.

The majority of women (36.5%) were between 26–30 years of age, followed by 21–25 years (27%) and 31–35 years (21%) group, while smaller proportions were observed among those aged 36–40 years (9%), ≤20 years (5%), and >40 years (1.5%). Most participants (64%) had two to four children (P2–P4), 34% had one child (P1), and only 2% had more than four children (P > 4). Nearly half (48.5%) of the women were graduates, followed by those educated up to senior secondary level (27.5%) and secondary school level (10.5%), whereas 8% had middle school, 3% had primary school education, 2% were postgraduates, and 0.5% were illiterate. A majority (62%) of the study participants resided in rural areas, while 38% belonged to urban areas. Regarding socioeconomic status, most women (49.5%) were from the upper middle class, followed by the lower middle (27%) and upper (11%) classes, while smaller proportions were from the upper lower (7%) and lower (5.5%) socioeconomic groups (Table 1).

Participants reported multiple reasons for both acceptance and refusal of PPIUCD. The most common reason for acceptance was its long-term effectiveness (91.5%), followed by safety (88%), fewer clinical visits (62.5%), reversibility (49%), and its non-hormonal nature (33%). Conversely, the main reasons for refusal included inadequate knowledge about the method (55.67%) and partner or family disapproval (41.33%). Other cited factors were preference for alternative contraceptive methods (35.33%), fear of pain (33.67%), concerns about heavy bleeding or uterine perforation (33.33%), and fear of cancer (13%). A small proportion (5%) gave no specific reason. These findings highlight that improving awareness and addressing misconceptions through effective counselling could enhance PPIUCD acceptance rates (Table 2).

Table 1: Co-relation of socio-demographic characteristics with PPIUCD acceptance in the study group.

Variables	Number	Percentage
Age in years		
≤20	10	5.00
21–25	54	27.00
26–30	73	36.50
31–35	42	21.00
36–40	18	9.00
>40	3	1.50
Parity		
P1	68	34.00
P2–P4	128	64.00
>P4	4	2.00
Education		
Illiterate	1	0.50
Primary school	6	3.00
Middle school	16	8.00
Secondary school	21	10.50
Senior secondary school	55	27.50
Graduate	97	48.50
Post graduate	4	2.00
Place of residence		
Rural	124	62.00
Urban	76	38.00
Socioeconomic status		
Lower	11	5.50
Lower middle	54	27.00
Upper lower	14	7.00
Upper middle	99	49.50
Upper	22	11.00

Distribution according to type of insertion and expulsion characteristics of PPIUCD showed that most PPIUCDs (67.5%) were inserted following normal vaginal delivery, while 32.5% were inserted during caesarean section.

Table 2: Distribution according to reasons for acceptance and refusal of PPIUCD among participants (multiple reasons).

Reasons	Number	Percentage
Reasons for acceptance (multiple reasons)		
Long term	183	91.50
Reversible	98	49.00
Safe	176	88.00
Fewer clinical visits	125	62.50
Non hormonal	66	33.00
Reasons for refusal (multiple reasons)		
Partner or family refusal	124	41.33
Preference of another method over PPIUCD	106	35.33
Fear of insertion related pain	101	33.67
Heavy bleeding/uterine perforation	100	33.33
Fear of cancers	39	13.00
Not enough knowledge	167	55.67
No reason	15	5.00

Among 190 women followed up, 6.84% experienced spontaneous expulsion, and 1.58% requested removal. Expulsion occurred most frequently within 7 days (38.46%), followed by 8–15 days (23.08%), and after 30 days (23.08%). The mean expulsion time was 35.13±5.58 days, with a median of 10 days (IQR: 3–28) and age range 19-43 (Table 3). When compared by type of insertion, most post-vaginal expulsions occurred within 7–15 days, while intra-caesarean expulsions were more delayed (after 16–30 days or beyond 30 days). However, the difference was not statistically significant (p=0.24) (Table 4). Out of 200 women, 187 (93.5%) returned for routine follow-up, 3 (1.5%) returned specifically for IUCD removal, and 10 (5%) were lost to follow-up. Following up of 190 women at 6 weeks, 12 weeks and 6 months, 145 (76.31%) reported no complaints. The most common adverse effects were mild abdomino-pelvic pain (10.53%), unusual vaginal discharge (8.42%), irregular bleeding (5.26%), and heavy menstrual bleeding (4.74%). No cases of perforation or infection were reported. There were no pregnancies reported, reflecting 100% contraceptive effectiveness of PPIUCD during the 6-month study period. Expulsion occurred in 13 women (6.58%), and total discontinuation was noted in 16 women (8.42%). Out of 190 women, 174 (91.58%) continued using PPIUCD (Table 5).

Table 3: Distribution according to type of insertion and expulsion characteristics of PPIUCD.

Parameters	Number	Percentage (%)	Remarks / notes
Type of insertion			
Following vaginal delivery	135	67.50	Majority of insertions were post-vaginal delivery
Following caesarean delivery	65	32.50	Remaining were intra-caesarean insertions
Total	200	100.00	—
Expulsion/removal			
Spontaneous expulsion	13	6.84	—
Removal	3	1.58	—
Time of spontaneous expulsion (days)			
<7	5	38.46	—
8–15	3	23.08	—
16–30	2	15.38	—
>30	3	23.08	—
Mean±SD	—	—	35.13±5.58 days
Median (IQR)	—	—	10 (3–28)
Range	—	—	0.75–150 days

Table 4: Association of time of expulsion with type of insertion.

Time of expulsion (days)	Post vaginal (n=8)	Intra-caesarean (n=5)	Total (n=13)	P value
<7	4 (50)	1 (20)	5 (38.46)	0.147*
8–15	3 (37.5)	0 (0)	3 (23.08)	
16–30	0 (0)	2 (40)	2 (15.38)	
>30	1 (12.5)	2 (40)	3 (23.08)	
Mean±SD	24.25±50.96	52.55±50.13	35.13±50.58	0.24†
Median (IQR)	7.5 (2.75–10.5)	28 (24–90)	10 (3–28)	
Range	2–150	0.75–120	0.75–150	

*Mann–Whitney test; †Fisher's exact test applied

Table 5: Follow-up, safety, efficacy, and continuation of PPIUCD among participants.

Parameters	Number	Percentage (%)	Remarks/notes
Follow-up status			
Returned for follow-up	187	93.50	Majority attended follow-up visits
Returned for IUCD removal	3	1.50	Removal-specific follow-up
Lost to follow-up	10	5.00	—
Safety outcomes (n=190)			
No complaints	145	76.31	Majority had no complications
Mild abdomino-pelvic pain	20	10.53	Managed with reassurance/medication
Unusual vaginal discharge	16	8.42	—
Irregular bleeding	10	5.26	—
Heavy menstrual bleeding	9	4.74	—
Perforation/infection	0	0.00	No cases reported
Efficacy outcomes (n=190)			
Pregnancy	0	0.00	100% effective during study period
Expulsion	13	6.58	Included in discontinuation
Discontinuation	16	8.42	Total discontinued PPIUCD
Continuation rate (n=190)			
Continued PPIUCD	174	91.58	High continuation indicates good acceptance
Expulsion	13	6.84	Matches efficacy outcomes
Removal	3	1.58	—

DISCUSSION

The present study was conducted in the Department of Obstetrics and Gynaecology, I.G.M.C., Shimla (01 June 2023 to 31 May 2024). The study was conducted to evaluate safety, efficacy and continuation rates of PPIUCD, for a period of 6 months. In the present study, a total of 500 eligible couples were counselled for PPIUCD. Among them, 200 women consented to PPIUCD insertion, accounting for 40% of those counselled.

Reflecting the impact of antenal counselling this acceptance rate was more than double the national average of 16.40%. Acceptance rate was comparable to Gudi et al (36%) and higher than Deshpande et al (25%) and Suresh et al (28%).[13,14,16] The study found that most women undergoing IUCD insertion were aged 26–30 years (36.5%), and only 1.5% were above 40 years. Similar findings were reported by Gupta et al, Agarwal et al and Tomar et al, with majority in the 21–25 age group.[3,4,15] Acceptance among primipara and multipara were 34% and 66% respectively, similar to Sharma et al, indicating a preference for an immediate, long-acting, safe, and reversible method with fewer clinical visits. Educational status positively influenced contraceptive use, with the highest acceptance among graduates (48.5%), followed by senior secondary school graduates (27.5%). Among acceptors, no woman lacked formal education. Similarly, Sharma A et al, reported the highest acceptance, (56.95%) among women with secondary education. PPIUCD acceptance was higher among rural women (62%) outnumbering the urban women (38%).[8] In the socioeconomic status, PPIUCD acceptance was highest in the upper middle class (49.5%), and lowest in the lower socioeconomic group (5.5%). Gudi et al and Gupta et al reported similar findings with 66.05% and 32.7% respectively in the upper middle class.[13,3] Most women had multiple reasons for PPIUCD acceptance, with long-term contraception being the most common (91.5%), followed by safety (88%), fewer clinical visits (62.5%), reversibility (49%), and non-hormonal nature (33%). Similar results were published by Gupta et al and Deshpande et al.[3,14] The primary reason for PPIUCD refusal was lack of knowledge (55.67%), followed by partner and family refusal (41.33%), preference for another method (35.33%) and no specific reason (15%). In contrast, studies by Gupta et al, Nigam et al found partner and family resistance as the most common reason, while Gonie et al, reported fear of complications (24.8%) as the primary concern. PPIUCD insertion rates were 67.5% post-vaginal delivery and 32.5% intra-caesarean, similar to Chauhan R et al (67.3% and 31.8%).[1,3,17,18] This was attributed to the higher number of vaginal deliveries. Spontaneous expulsion occurred in 6.84% of women, with 76.92% expulsions within 6 weeks. Mode of delivery had no significant association (p=0.24). Expulsion rate was comparable to Gudi et al (6.45%), Asari et al (6.4%), but lower than Chauhan R et al (9.75%) and was higher than Samntha et al (2.02%) highlights the importance of training of PPIUCD providers.[13,18-20] The most common issues were abdominal pain (10.53%), vaginal discharge (8.42%), irregular bleeding (5.26%).

Similar findings were seen in studies by Chauhan et al and Deshpande et al.[14,18] However, no cases of perforation or infection were reported, indicating the safety of the method. The 6-month PPIUCD continuation rate was 91.58%, comparable to Chauhan et al (91.3%), and Mehta et al (88%), thereby highlighting the efficacy of method.[18,21]

Limitations

It was a single center study; the findings may not be generalized to other settings. The acceptance rate remains low despite antenatal counselling, indicating the need for more effective counselling strategies. The follow-up period was limited to six months, restricting the assessment of long-term outcomes. Expulsion rates were higher than expected despite the doctor's expertise, possibly due to variations in insertion technique, timing, or postpartum uterine changes.

CONCLUSION

PPIUCD is a scientifically validated tool with high retention and satisfaction rates. It is safe, reversible and long-acting contraceptive method, particularly beneficial in the settings, where women live in remote areas and may not return for follow up contraceptive advice. Acceptance and continuation of PPIUCD can be increased through effective counselling, education and increasing availability of trained birth attendants at birthing facilities. Regular follow-up checkups are crucial as they aid in the early detection of complications and side effects associated with the device, facilitating prompt and effective management.

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