International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Radhika AG et al. Int J Reprod Contracept Obstet Gynecol. 2024 Nov;13(11):3255-3267
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20243187

Original Research Article

Evaluation of long-term clinical outcomes among PPIUCD users at six medical college hospitals

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Received: 05 September 2024
Revised: 09 October 2024
Accepted: 10 October 2024

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ABSTRACT

Background: Postpartum IUCDs are becoming increasingly popular in low-income countries, but there are few studies addressing long-term outcomes.
Methods: A prospective observational study conducted in six tertiary care hospitals across India to investigate satisfaction rates, expulsions, adverse events and complications of PPIUCD for up to 24 months.
Results: PPIUCD was accepted by 16262 out of 56619 eligible women. Of these, 59.6% had NVDs, and the rest had LSCSs. PPIUCD continuation proportion was 90.3% at 6 weeks and 72.5% at 6 months. It decreased to 50.6% after 24 months. Women reported 73.91% satisfaction at 6 months, but only 48% at 24 months. PPIUCD removal and expulsion rates were 8.39% and 3.76% at 6 months and 13.4% and 2.95% at 24 months. Removal rates were significantly different between NVD and LSCS women (25.37% versus 18.8%; $p<0.001$). Thread discomfort was the most common reason for removal and was more common in LSCS group. Expulsions were higher at six months in the NVD, 9.85% versus 7.10% ($p<0.001$). Reported side effects were abdominal pain, abnormal bleeding and white discharge in both groups.
Conclusions: There was a progressive reduction in continuation and satisfaction with PPIUCD use over 24 months. Thread discomfort, abdominal pain, and abnormal bleeding were major reasons for dissatisfaction. Most of the women chose private practitioners for IUCD. Additionally, the reported side effects highlight the need for further research. Both quality of life and contraceptive efficacy play a major role in the success of contraception.

Keywords: Continuation rate, Lower segment cesarean section, Normal vaginal delivery, Postpartum intrauterine contraceptive device, Satisfaction rate, Short and long-term outcomes

INTRODUCTION

Initiation of family planning at the time of birth is opportunistic since few women in low-resource settings who give birth in a facility return for further care. The offer of postpartum intrauterine contraceptive device (PPIUCD) after antenatal counselling or at birth ensures much-needed contraception. PPIUCD is known to cause less discomfort, bleeding and fewer complications as compared to interval IUCD insertion.[1] Furthermore, it can be used safely by lactating women as well as HIV-positive women.[2] In a study of PPIUCD experience from six low middle-income countries (LMICS), the percentage of acceptors ranged from 2.3% of women counselled in Pakistan to 5.8% in the Philippines. Rates of complications among women returning for follow-up were low. Expulsion rates ranged from 3.7-1.7%. Infection rates did not exceed 1.3%.[3] In another study conducted at a tertiary care hospital in Delhi, out of 1200 women in the immediate postpartum period, only nine percent were aware of PPIUCD, and acceptance was six percent. After awareness building measures in the immediate postpartum period, acceptance increased to 12.67%, highlighting the importance of repeated counselling, including the immediate postpartum period.[4] The reasons for refusal of PPIUCD included lack of awareness (even among well-educated women), fear of malignancy (38%), and menstrual disturbances (36.4%). In the same study, husband and mother-in-law were found to be important decision makers for PPIUCD use (59% refusal).[5] In Ethiopia, 12.4% of women accepted immediate PPIUCD use. Non-acceptors cited concerns and fears of complications (24.8%), religious beliefs (19.8%), and refusal by husband (17.7%). Women who had at least three prenatal visits and were educated were more likely to accept the PPIUCD.[6]

According to NFHS-4 (2015-16) there has been a reduction in contraceptive use by nearly 2% among married women in India from the earlier 56% (2005-06) to 54%. About 1.5% of women use IUD/PPIUCD. Greater involvement of the private sector would be a positive step for increasing the availability and utilization of IUD/PPIUD.[7] Discontinuation rates of 26% for IUD/PPIUCD were noted by Kumar et al though separate figures for interval and postpartum insertion are not stated.[8] Postpartum intrauterine contraceptive devices (PPIUCD) have been included in the national family planning program of India with an emphasis on quantity, but satisfaction of women who have adopted PPIUCD and complication rates needs further characterization to encourage continuation of its use since dissatisfaction expectedly results in high removal rates. Removals ranging from 6% to 13.9% have been reported within one year of use.[9-11] User satisfaction and continuation rates play a vital role in the success of the family welfare programmes.

To further understand the reasons for high rate of removal and low acceptance among users, this study was designed and adopted an in-country multi-site model in 6 medical colleges in India. Funding support was received from ICMR (Indian Council of Medical Research) under ICMR Registry of levo-ormiloxifene (Centchroman) and PPIUCD contraceptive users i.e. the study included two contraceptives- PPIUCD and Centchroman. Results of the PPIUCD arm of the project are being shared in this report.

Our study is unique because it involved collaborative family planning research at multiple tertiary care hospitals with long-term follow-up of PPIUCD users for up to 24 months after insertion.

Specific aims

To assess satisfaction and continuation rates among women using PPIUCD following its use up to a period of 24 months. To determine the side-effects associated with PPIUCD use. To investigate the complication rates in all women and those with previous uterine surgeries and post-caesarean insertion. To understand user perspective i.e. short- and long-term satisfaction among users and reasons for discontinuation.

METHODS

The prospective observational study was conducted at six medical college hospitals across India in the period between June 2019 to May 2023 after obtaining institutional ethics clearance. The sites for the study were Delhi, Meerut, Rohtak, Chandigarh in North, Kolkata in East, and Puducherry in South India. Institutional ethics clearance was obtained at all six centres (it is notable that the COVID pandemic affected the follow up of the PPIUCD acceptors for two years of the study period).

Women attending the antenatal clinic and those presenting in early labor were counselled for PPIUCD after ascertaining the eligibility based on the WHO medical eligibility criteria.[12]

A second assessment was done immediately prior to insertion of the IUCD to rule out any contraindications i.e. i) chorioamnionitis, ii) postpartum endometritis/metritis or puerperal sepsis, iii) more than 18 hours from rupture of membranes to delivery of the baby, iv) unresolved postpartum haemorrhage, v) extensive genital trauma.

Standard steps for insertion of PPIUCD were followed for insertion after obtaining informed consent in local languages.[13] Client details at enrolment and subsequent follow up were recorded in a predesigned standardized proforma which was used in all sites to ensure uniformity of data (Annexure 1). All women underwent abdominal USG before discharge to confirm the intrauterine location of IUCD.

At discharge, the key messages related to PPIUCD were reinforced along with instructions for follow up at 6 weeks or earlier in case of any warning sign (foul smelling discharge, abdominal pain, fever, or excessive bleeding) or

if the IUCD is expelled. The clients were also informed about the subsequent follow-up visits at 3, 6, 12, 18 and 24 months.

Indications for IUCD removal were acute pelvic infection, suspected pregnancy or for personal reasons at any time during follow up visits.

At each visit, the client was asked about discomfort or abnormal symptoms including discomfort due to thread, abdominal pain, abnormal bleeding and vaginal discharge. Satisfaction regarding the use of PPIUCD was recorded. General physical and pelvic examinations were also conducted on each visit.

Timing of PPIUCD insertion

Post placental: insertion within 10 minutes after expulsion of the placenta following a vaginal delivery, on the same delivery table.

Intra-caesarean: insertion during a caesarean delivery, after removal of the placenta and before closure of the uterine incision.

RESULTS

A total of 56619 eligible women were counselled for contraceptives in six study centres of which 16262 women accepted PPIUCD for contraception (Table 1).

Table 1: Recruitment of PPIUCD users across the six centres.

Name of centre (number of women accepted PPIUCD)	Total eligible women counselled (N)	Total women accepted PPIUCD (N)	Acceptance percentage at each center (%)
Rohtak	7896	4332	54.9
Kolkata	6146	2111	34.3
Pondicherry	9972	3387	34
Delhi	20740	5102	24.6
Chandigarh	3271	750	22.9
Meerut	8594	580	6.7
Total	56619	16262	28.7

Table 2: Demography characteristics of PPIUCD acceptors and their spouses.

Education of husband	Percentage
Illiterate	5.5
School	72.9
College	21.62
Occupation of husband	
Unemployed	3.12
Semiskilled	93.43
Skilled	3.44
Urban/rural	
Rural	47.7
Urban	52.3
Education of respondent	
Illiterate	8.7
School	68.3
College	23
Occupation of respondent	
Unemployed	95.6
Semiskilled	3.1
Skilled	1.3
Socioeconomic status	
Lower	0.23
Upper lower- upper middle	98.9
Upper	0.82
Religion	
Hindu	82.1
Muslim	16
Others	1.8

The mean age of women registered for the study was 25.4 years (SD ±4.3 years).

The overall acceptance percentage was 28.7% (95% CI: 28.3 to 29.1%). Demographic details of PPIUCD acceptors and their husbands are presented in Table 2. Nearly equal numbers of women were registered from rural and urban areas. However, this distribution was not similar across the six centres with Delhi having 99.8% of women from urban areas. The majority were Hindus and belonged to upper-lower, lower-middle socioeconomic status of modified Kuppuswamy classification.[14]

The average duration of marriage was less than five years for 61.96% and up to 5 years for 71% of the registered women. Eighty four percent of registered women had one or more living children although 15.7% had three or more children.

Main reason for discontinuation of the earlier contraceptive was the desire for pregnancy (65.1%), followed by the side effects 14.7%. Method failure was reported by 6.0%. Overall, the decision regarding contraception was taken by both the partners in all centres (48.3%) except in Delhi (4.1%), while doctors and paramedical workers were responsible for 16.1% of the decisions.

Co- morbidities in PPIUCD acceptors

Six hundred and seven (3.7%) of PPIUCD acceptors were diabetic, the highest being in Kolkata (8.2%); 11.6% of women were non-anaemic, 18.9%, 66.9% and 2.5% of women had mild, moderate, and severe anaemia respectively.

Route of delivery

Of PPIUCD acceptors, 59.6% (n=9688) had normal vaginal delivery (NVD) and the remaining 40.4% (n=6574) had delivered through cesarean. Foetal distress was the most common indication (31.0%) for LSCS. Delhi (83.7%) and Rohtak (60.8%) had the highest rates of NVD while Kolkata has the highest caesarean delivery at 77.9%.

Regional acceptance of PPIUCD

The overall acceptance of PPIUCD was 28.7% (95% CI: 28.3 to 29.1%). The highest acceptance percentage (54.9%) was at Rohtak while the lowest was observed in Meerut 6.7% (Figure 1).

Of the 15741 women who had USG before discharge, IUD was not found in the uterine or abdominal cavity in five women (0.003%) at abdominal USG. There was no history of expulsion. IUDs were not visible even on abdominal x-rays. The possibility of expulsion, which was missed, or erroneous documentation of insertion were considered as possible explanations.

PPIUCD removals and expulsions

PPIUCD removal and expulsion in 6 months was 8.39% and 3.76% respectively while those at 24 months were 2.53% and 10.36% respectively (Table 5). However, the majority of the removals and expulsions took place in 6 to 12 months (Figure 2). Reasons for requests for PPIUCD removal are presented in Figure 3. The important reasons included abnormal bleeding initially though discomfort due to thread remained the constant reason all through the follow up period. Pain was the most important reason at 24 months though numerically less women experienced it over time. Vaginal discharge was also a reason for seeking removal of PPIUCD.

Most of the users preferred removal in private settings. Distance from home and crowded clinics were the reasons for not coming to the public hospital. No counselling was provided at these clinics to encourage continued use of PPIUCD. Reasons for removal were indicated due to discomfort with threads, irregular bleeding, abdominal pain, and vaginal discharge (Figure 3).

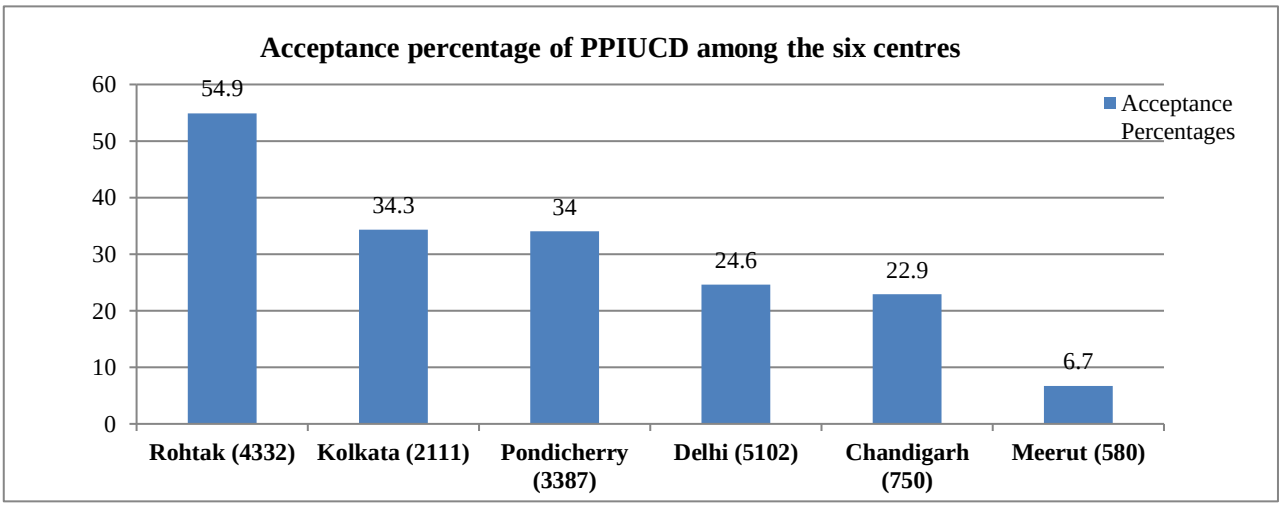

Figure 1: PPIUCD acceptance across the six centres.

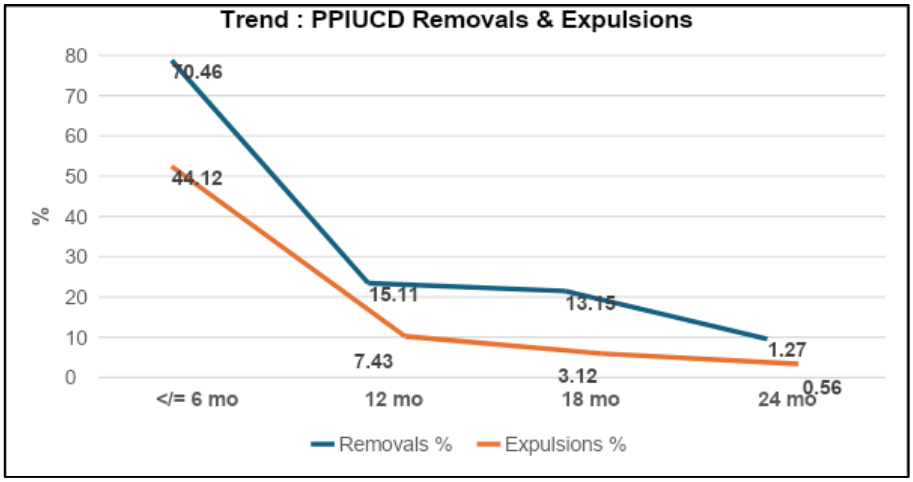

Figure 2: PPIUCD removal and expulsion trend over time.

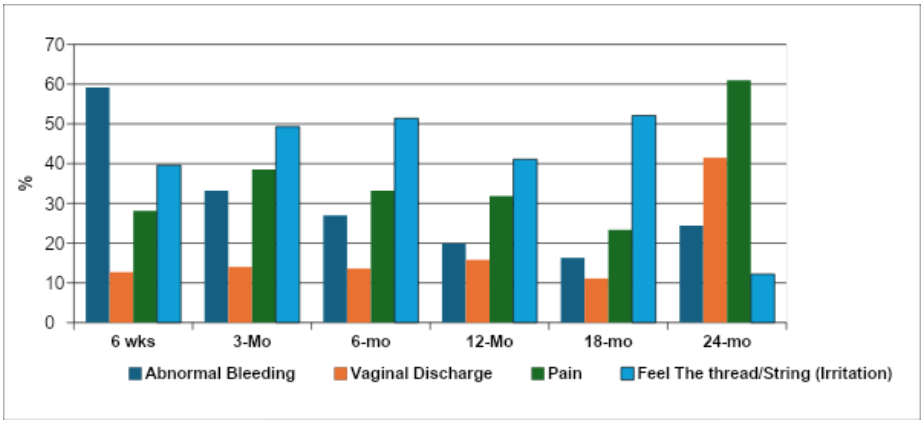

Figure 3: Reasons for seeking removal of PPIUCD.

Side effects experienced with PPIUCD use

Abnormal bleeding, thread discomfort, abdominal and/back pain and vaginal discharge were the prominent discomforts.

Short term (up to 6 months)

Women who delivered vaginally: There were 70.4% of women who reported side effects. There were 1.53 events per woman. The most common side effect was "feeling of the thread", followed by abdominal pain (38.5%), abnormal bleeding (22.9%), and white discharge in 11.4%.

Women with LSCS: In total, 77.7% of women reported side effects at 1.35 events per woman. Among this group, (84.61%) reported "feeling of thread" followed by abdomen pain in (24.81%), abnormal bleeding in (13.66%), and white discharge in (8.96%).

Comparison of NVD and LSCS side effects: There was a significantly higher proportion of complaints due to thread in the LSCS than in NVD. NVD women experienced more Side effects than LSCS women. Abdominal pain, abnormal bleeding, and white discharge were the most significant.

Long-term (24 months)

Women with NVD: A total of 72.4% women reported side effects at 1.23 events per woman. The most common (85.7%) problem reported was "feeling the thread" followed by abdominal pain in 17.2%, abnormal bleeding in 10.2% and white discharge in 9.3% (Table 3).

Table 3: Comparison of NVD and LSCS at 24 months.

	NVD	LSCS	P value
Feeling the thread	85.7%	88.2%	0.042
Abdominal pain	17.2%	18.9%	
Abnormal bleeding	10.2%	9.5%	
White discharge	9.3%	7.7%	
Expulsions	1.15%	1%	0.1117
Removals	12.3%	13.4%	
Side effects	72.4%	77.2%	
Side effects/woman	1.23	1.25	

Women with LSCS: A total of 77.2% women reported Side effects at 1.25 events per woman and 22.8% of women did not report any of the Side effects. The most common problem (88.2%) reported was "feeling the thread" followed by abdominal pain in 18.9%, abnormal bleeding in 9.5% and white discharge in 7.7% (Table 3).

Comparison of NVD and LSCS (side effects): There was a significantly higher proportion of the thread complaints in the LSCS than NVD (p=0.042). The remaining proportion of side effects were nearly equal in the NVD women and the LSCS women for long-term. The number of expulsions of IUCDs was equivalent in the NVD at Long-term follow-up, 1.00% (LSCS) versus 1.15% (NVD) not significant because p=0.1117 i.e. >0.05

Comparing removal rates in women with LSCS versus NVD

As compared to LSCS women, the NVD women experienced significantly higher rates of removal (25.37% versus 18.8%; p<0.001).

Short-term follow-up (up to 6 months): Significantly higher percentage of satisfaction in NVD women than in LSCS women (79.7% versus 64.4%, p<0.001). The number of expulsions of IUCDs was higher in the NVD at short-term follow-up, 7.10% (LSCS) versus 9.85% (NVD) (p<0.001); Number of removals of IUCDs was also higher in the NVD at short-term follow-up, 11.68% (LSCS) versus 15.51% (NVD) (p<0.001) (Table 4).

Table 4: NVD versus LSCS at short-term follow-up (up to 6 months).

	NVD	LSCS	P value
Satisfaction	79.9%	64.4%	<0.0001
Removal	15.50%	11.68%	<0.001
Expulsion	9.85%	7.10%	<0.001
Thread discomfort	54.26%	65%	<0.001
Side effects present	70.4%	77.7%	
Side effects/woman	1.53	1.35	

There was no significant difference in the two groups at short term follow up with respect to the major side effects i.e. abdominal pain, abnormal bleeding, and white discharge.

Table 5: Calculation for continuation percentage, removal, or expulsion percentage (n=16262).

Follow-up	Total women visited at follow-up	Expulsion (%)	Removal (%)	The number of women lost to follow at a current follow-up visit or removed due to the closing date of the study	Total no. of women absent at follow-up	Women did not appear in the respective follow-up but came on any of the next follow-up	The total cumulative number of women excluded in the follow-up visit	Total women who expected to continue in the next follow-up visit
6 weeks	11420	658 (5.77)	819 (7.18)	2223	4842	2619	3700	12562
3 months	9893	475 (4.81)	807 (8.16)	1118	6369	1551	6100	10162
6 months	7690	289 (3.76)	645 (8.39)	1688	8572	784	8722	7540
12 months	4705	119 (2.53)	487 (10.36)	2502	11557	333	11830	4432
18 months	2962	50 (1.69)	424 (14.32)	1359	13300	111	13663	2599
24 months	306	9 (2.95)	41 (13.4)	2293	15956	0	16006	256

*Total expulsion (9.84%) and total removal (19.82%) out of total women accepted PPIUCD (16262) under project duration. Assumptions: For calculating the continuation percentage following assumptions were made: 1) women who did not report in the respective follow-up or were not able to contact telephonically but came in the next follow-up visit were considered to be continued with the PPICU contraceptive; 2) the women who reported the expulsion are treated as discontinued from the study. For instance, if any women again used PPIUCD after the expulsion it was not included in the study.

Table 6: Life table analysis to find the continuation proportion and its 95% confidence interval of 16262 women registered for the PPIUCD.

Duration	The number lost to follow-up plus, the number with drawn due to the closing date of the study (Li)	Number of removals + expulsion (Di)	Number entering at the interval (Ni)	Number expected at risk (ENi=Ni-(Di+Li)	Proportion of discontinued (qi=Di/ENi)	Proportion of continued pi=1-qi	Cumulative proportion of continued S(ti)= pi*S(ti); S(0) =1	Standard error of S(ti)	Lower 95% CI of S(ti)	Upper 95% CI of S(ti)
6 weeks	2223	1477	16262	12562	0.118	0.882	0.882	0.003	0.876	0.888
3 months	1118	1282	12562	10162	0.126	0.874	0.771	0.004	0.763	0.780
6 months	1688	934	10162	7540	0.124	0.876	0.676	0.005	0.665	0.686
12 months	2502	606	7540	4432	0.137	0.863	0.583	0.007	0.570	0.597
18 months	1359	474	4432	2599	0.182	0.818	0.477	0.009	0.459	0.494
24 months	2293	50	2599	256	0.195	0.805	0.384	0.021	0.343	0.424

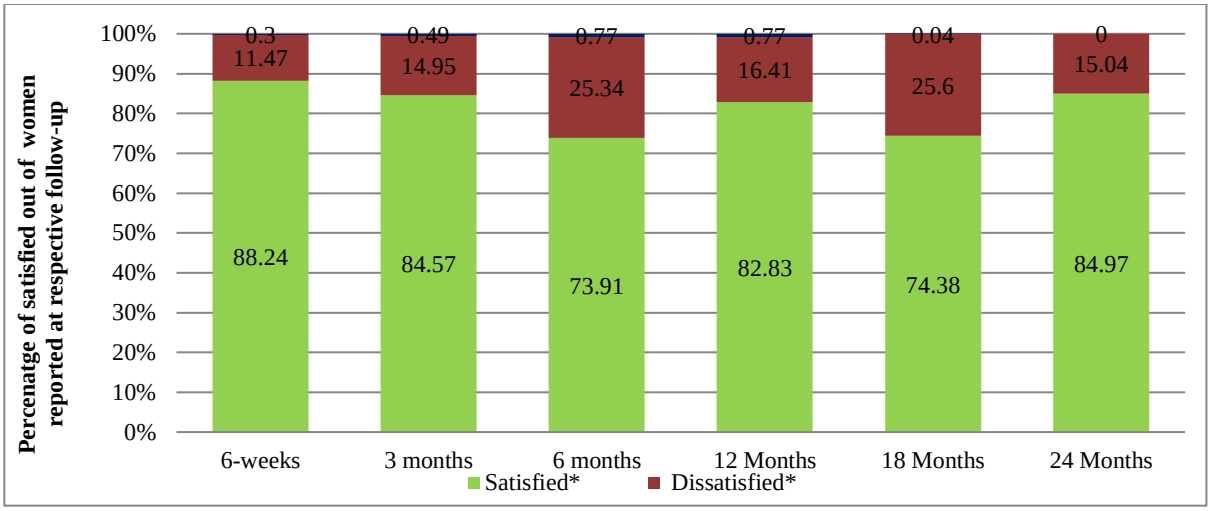

Figure 4: Satisfaction percentage among PPIUCD users at respective follow-up.

*Percentage of satisfaction was calculated taking the base of a total of women present at follow-up. Despite getting the IUCD removed, 44.6% of the clients were satisfied, while 55.2% were dissatisfied.

PPIUCD continuation proportion

Based on the Greenwood formula, the continuation proportion for PPIUCD at respective follow-ups was calculated using the life table survival analysis method.[18] At 6 weeks, the continuation proportion was 90.3% (95% CI: 89.8% to 90.8%) and at 3 months it was 80.6% (95% CI: 79.9 to 81.3%). It was 72.5% (CI 71.6% to 73.4%) in 6 months. At 24 months, the continuation proportion was 50.6% (95% CI: 47.8% to 53.4%) (Table 6).

The satisfaction number/percentage was determined at each contact point for women who came for follow-up or were contacted via telephone.

The life table survival analysis method was applied to calculate the continuation proportion of PPIUCD at respective follow-up with a 95% confidence interval and standard error determined using the Greenwood formula.

Formula

$Total\ women\ who\ continued\ the\ PPIUCD$

For determining of the continuation percentage = $Total\ number\ of\ women\ registered$

(a) For calculating the removal percentage = $Total\ number\ of\ women\ who\ removed\ the\ PPIUCD$

$Total\ number\ of\ women\ who\ reported\ at\ respective\ follow\text{-}up$

(b) For calculating the expulsion = $Total\ number\ of\ women\ who\ reported\ expulsion$

$Total\ number\ of\ women\ who\ reported\ at\ respective\ follow\text{-}up$

The removal percentage increased at each follow-up out of the women who came for the follow-up or contacted telephonically.

Satisfaction expressed at short term (up to 6 months) follow up

Definition: If the client attended any of the three follow-up visits (6 weeks, 3 months, or 6 months), the client was considered for short-term outcomes. Among the 16262 registered women, 2223 were lost to follow-up (not reported).

Women who attended two or three follow-up visits were evaluated based on the response closest to the short-term cut-off point, which is six months. Figure 4 shows short-term satisfaction with PPIUCD use (up to six months). Majority (73.91%) of women expressed satisfaction with PPIUCD at 6 months, at 24 months it decreased to 48%.

Despite the expulsion within six months of insertion, 50.0% of the women expressed satisfaction indicating that expulsion was not viewed negatively. Of all women who had PPIUCD expulsion, 9.3% chose not to respond to the query on satisfaction.

DISCUSSION

As a long-acting reversible contraceptive (LARC), PPIUCD is an important choice for low resource settings since women find it difficult to return to the health facility after discharge. In some cases, it can be used for up to 10 years (depending on the type of IUCD). While it has minimal side effects during the postpartum period, some women seek to remove it due to discomfort caused by it. Total of 56619 eligible women were counselled in six study centres, 16262 women accepted PPIUCD for

contraception. The overall acceptance percentage was 28.7% (95% CI: 28.3 to 29.1%). Studies have documented acceptance for PPIUCD ranging from 26% to 60%.[11,15] The life table survival analysis method was applied to calculate the continuation proportion of PPIUCD at respective follow-up with a 95% confidence interval and standard error determined. It varied from 90.3% (95% CI: 89.8% to 90.8%) at 6 weeks to 50.6% (95% CI: 47.8% to 53.4%) at 24 months. Reported continuation rates at one year in other studies vary between 62.8% to 78.5-92% at 6 months.[9,16] In our study, the highest numbers of expulsions were observed at 6 weeks (5.77%). High removals were observed at 12 and 18 months at 10.36% and 14.32% respectively. An expulsion rate of approximately 4% and a removal rate of 5% was reported by Shobha et al over 6 months follow up.[15] In the report by Hooda et al, PPIUCD expulsion at 5.3% was similar in women who delivered vaginally and following caesarean delivery.[17] In our study, PPIUCD removals increased from 7.18% at 6 weeks to 14.32% at 18 months. Major reasons for removal of the Cu-T were irritation due to the IUCD thread discomfort either in self or in partner (45.9%), followed by abnormal bleeding (34.2%), pain (32.1%) and vaginal discharge (13.8%). In the report by Kumar et al, at one year follow-up, 19.3% PPIUCD acceptors reported having removals for associated side effects (bleeding, pain and discharge), and 10.4% reported having removals for other reasons. After removal or expulsion, almost half of the women (46.5%) did not switch to any other modern contraceptive method.[8] The side-effects per woman ranged from 1.2-1.4 over the 24-month study period in our study. A significant linear decreasing trend was observed in the abnormal bleeding in our study which indicates as time progresses the abnormal bleeding likelihood would also decrease. This is an important counselling point to focus on at initiation of PPIUCD. There was a significant rising linear trend in the vague symptoms e.g. body aches, general feeling of being unwell. The pain and vaginal discharge did not demonstrate any trend over the period. On comparing expulsion and removal of PPIUCD in women following caesarean and vaginal delivery was 7.1% versus 11.7% and 9.9 % versus 15.5% respectively ($p<0.001$). After 6 months (short term) of PPIUCD use, nearly 80% of those who delivered normally were satisfied with IUCD use compared to 64% in the LSCS group ($p<0.001$). The total number of events (side-effects) at 6 months in women with PPIUCD after NVD was 1.53 events/woman compared to 1.35 events/woman in the LSCS group. In another report, the incidence of undescended strings was high (38%), with a highly significant difference between both groups ($p=0.000$).[17] In our study, the side-effects were similar for caesarean and vaginal delivery including irritation due to thread, abdominal pain, abnormal uterine bleeding, and vaginal discharge. Complaints due to the thread were higher following post LSCS PPIUCD. Similar trends were seen in long-term follow-up also. Long term satisfaction among LSCS versus NVD was 69.3% versus 75.5% respectively.

A qualitative study was conducted by the authors (under publication) to understand the reasons for PPIUCD removal and user perspective of the operative procedures (hysteroscopic IUCD removal). The findings revealed that IUCD removals in nearly 95% women were done by private practitioners or untrained birth attendants known to the client. There were no questions asked regarding the reason for removal or treatment for any discomfort or problem. Nor were these women advised any other form of contraceptive. Regarding operative interventions for misplaced IUCD removal, the women expressed satisfaction for the focused care. They did not view surgical intervention or admission to hospital as anything serious or important. During the follow-up period, none of the women in our study had to undergo operative removal of IUCD. Also, there were no contraceptive failures.

Research implications

There is an urgent need to address the long-term acceptance of PPIUCD. It is important to identify strategies to reduce the problems associated with thread, abnormal bleeding, and vague abdominal pain caused by long-acting reversible contraceptives. Private practitioners should be encouraged to participate in the family welfare program to support and care for PPIUCD recipients One potential strategy to improve long-term acceptance of PPIUCD is to provide comprehensive education and counselling to both healthcare providers and potential recipients. This can help address misconceptions and concerns about side effects, ensuring that individuals are well informed before deciding. Additionally, incorporating community outreach programs and peer support groups can create a supportive environment that encourages acceptance and provides ongoing assistance to PPIUCD recipients.

Multisite participation represents a wide population, which is the strength of this prospective observational study. In addition, the sample size was large enough for meaningful conclusions to be drawn. However, the limitations include high lost to follow ups mainly due to the COVID pandemic which impacted collection of data. In addition to involving medical colleges, community members would have made the study more representative.

CONCLUSION

A long-acting reversible contraceptive like PPIUCD is particularly useful in resource-limited countries. While it is well accepted for short-term use, newer strategies are needed to improve its long-term use. Private practitioners need to be involved in strategies to support PPIUCD continuation. Some important points have been raised in our study that can be corrected. Health workers and policy makers can use these to identify auditable practice points.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Radhika AG, Gupta R, Suneja A, Dorairajan G, Aggarwal P, Ashok V, et al. Evaluation of long-term clinical outcomes among PPIUCD users at six medical college hospitals. Int J Reprod Contracept Obstet Gynecol 2024;13:3255-67.

ANNEXURE 1

Case Record Form for PPIUCD

Centre code	(See centre codes)
Serial No	

Section-1

A. Respondents No

B.

Name	…….. (First) …… (Middle) …….. (Last)
Subject unique Identification No (Voter ID)	
Father/Husband Name	
Area	Rural Urban
Residential Address	H. No. ---------- Mohalla/Street---------- Village/Ward ---------- Tehsil/Town---------- District----------
Contact: (At least one phone of her close relative)	1. 3. 2. 4. Email: ……

C. Education (Tick the Appropriate)

	Respondents	Husband
Illiterate	1	1
Primary School Certificate	2	2
Middle School Certificate	3	3
High School Certificate	4	4
Intermediate or post high school diploma	5	5
Graduate or Post - Graduate	6	6
Profession or honors	7	7

D. Occupation

	Respondents	Husband
Unemployed	1	1
Unskilled Worker	2	2
Semiskilled Worker	3	3
Skilled Worker	4	4
Arithmetic skill jobs	5	5
Semi-professional	6	6
Profession	10	10

E. Monthly Family Income (in Indian Rupees) to be rounded off

<2091	1
2092-6213	2
6214-10356	3
10357-15535	4
15536-20715	6
20716-41429	10
>41430	12

F. Socio-economic Class (Total C+D+E) [Modified Kuppuswamy]

Lower	<5
Upper-Lower	5-10
Lower-Middle	11-15
Upper-Middle	16-25
Upper	26-29

G. Religion

	Respondents	Husband
Hindu	1	1
Muslim	2	2
Sikh	3	3
Christian	4	4
Other (Specify)	9	9

Duration of Marriage in completed years Years

H. No. of living children Male Female

I. Number of Miscarriages /MTPs

Last Delivery Day Month Year

J. Menstrual History

13. Are your menstrual cycles regular?
14. If regular, what is the length of your cycle ----------Days
15. If irregular, how many cycles do you have in a year? ---------- Cycles
16. If irregular, what is the length of your longest cycle and shortest cycle (Days Between two consecutive cycle from day 1)

a. …….days (Longest)

b. ……...days(Shortest)

Last Menstrual period (LMP) ……/……/……..(dd/mm/yy)

I. Decision Maker about Use of Contraception

Mutual (Husband &Wife)	1
Husband	2
Wife	3
In-Laws	4
Any Other	

Section-2

Please tick the suitable option.

Have you ever used any contraceptives? Yes ☐ No ☐

If yes then, please specify

Sr No.	Contraceptives Tick the appropriate	Duration of use	Reason For Non-Usage/ Discontinuing (insert appropriate code given below)
1	Oral Contraceptive Pills		
2	Condoms		
3	Cu – T		
4	Spacing method		
5	~~Male sterilization~~		~~Not Applicable~~
6	Female sterilization		Not Applicable
7	Other(Injectables, Natural method &Emergency Contraceptives)		

Sr. No	Reason For Non-Usage/ Discontinuing The Contraceptive Method
1	Method failure
2	Desire to become pregnant
3	Side effects / Health concerns
4	Costly
5	Infrequent sex/ Partner away
6	Inconvenient to use
7	Religion prohibition
8	Lack of knowledge regarding method and source
9	Any other reason, specify

C. Past History		
Are you known case of PCOS?	Yes…….	No……..
If yes, Are you on any medication?	Yes…….	No……..
Liver disease	Yes…….	No……..
Kidney disease	Yes…….	No……..

D. General Examination
Weight
Blood pressure (mm Hg)
Pulse rate
Thyroid Enlarged yes/no
Breasts normal/ abnormal (specify)
Lymph nodes Yes/no
Pedal edema Yes/no

Systemic examination
Chest b/l lung fields clear y/n
CVS Heart sounds normal y/n
Abdominal Any visceromegaly/ascies/tenderness

Speculum Examination Vagina/Cervix – Healthy/	
Vaginal Examination **Cervix- consistency, movement pain** **Uterus –Size, position** **Adnexa- normal/tender/thickened**	
Investigations	
Hb (gm/dl) </= 8; 8.1-10.9; 11	
Urine –Routine &Microscopy	
Liver function test	Within normal range/outside normal range
Renal function test	Within normal range/outside normal range
Lipid profile	Within normal range/outside normal range
Blood sugar – Fasting & Postparandial/ random	Within normal range/outside normal range
Papsmear (at recruitment and 1 year) NIEL/ASC/LSIL/HSIL	

USG

Abdomen USG **(LO-Left ovary)** **(RO-Right ovary)**	a. LO 2. RO b. Endo thickness:…..mm c. Liver fat grade: (I/II/III), GB, Kidneys, Pancreas
Vaginal USG	a. LO RO b. Endo thickness:…...mm

Any Other
Doctor's Remarks

Follow-up details for PPIUCD

Visit	Clinical Findings	Biochemical tests	USG	Abnormal Bleeding	Amenorrhea	Abdominal Pain	Failure	Any other side effects	Satisfaction Very satisfied/ Somewhat Satisfied/ Neither satisfied/ Dissatisfied/ Somewhat Dissatisfied/ Very dissatisfied	Reason for Satisfaction/ Dissatisfaction
At recruitment										
6 wks										
3 months										
6 months										
1 year										