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Original Research Article

A study to evaluate and compare the expulsion and continuation rates of post placental insertion of Cu 375 and CuT 380A in Indian women at a premier hospital in New Delhi, India

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ABSTRACT

Background: The Study was planned to evaluate and compare the expulsion and continuation rates of post placental insertion of Cu 375 and CuT380A in Indian women at Safdarjung Hospital New Delhi, after approval was obtained from Institutional Ethical committee.

Methods: Study group consisted of 300 women, divided into two groups: Group A and Group B. The data was analysed by using 'student "t" test/ non-parametric 'Wilcoxon Mann Whitney' for quantitative variables to evaluate the safety, efficacy and acceptability.

Results: Mean age was 24.99 years (range: 19-35years), All women were married (off which 64% literate) and Mean parity in group A was 1.97 and 2.06 in group B. Mean pain score during intrauterine contraceptive device (IUCD) insertion on visual analogue scale was 2.93 in group A and 3 in group B and was not statistically different. 84% women completed 12 months follow up in group A and 83.33% women in group B. Strings were visible in 74% women in group A and in 34% women in group B at 1 month of IUCD insertion. Visibility of strings increased in successive follow up visits and was visible in >80% of women at the end of one year in the both groups. String visibility after intra-Caesarean insertion was delayed. Fifty one percent (n=77) subjects in group A and 54% (n=81) in group B experienced amenorrhea up to six months. Menorrhagia was reported in 7.33% in group A and women 8.66% in group B at the end of 1 year of follow up. Pain was complained by 26 out of 150 (17.3%) women in group A as compared to 36 out of 150 (24%) women in group B after 1 month of insertion. There was no case of PID in group A whereas there were 3 cases of PID in group B. There was no perforation/trauma and pregnancy in either group.

Conclusions: Overall expulsion rate was 13% and removal rate was 5% in our study. Continuation rate was 83.3% in Cu 375 and 80.6% in CuT380A at 12 months. There was no significant difference between the IUCDs regarding the safety, efficacy and complications such as expulsion, bleeding etc.

Keywords: Caesarean, Continuation rate, Expulsion, Intrauterine contraceptive devices, Menorrhagia, Post-placental

INTRODUCTION

Contraceptive prevalence is low in developing countries owing to unmet need for contraception, which in India is around 13% (National Family Health Survey-3).

The reasons for this include lack of awareness, non-availability of accessible family planning services, and women's mobility due to mostly cultural or geographical factors. Recent programs of Government of India are encouraging Institutional deliveries, hence for women

with limited access to medical care, the time of delivery of baby in a hospital setting is an opportunity to address the need of contraception and to provide methods to woman who may not otherwise receive Family Planning services.¹ Many FP methods can be used immediately following childbirth and prevent unwanted pregnancy as fertility can return in 3 weeks following delivery. Postpartum women have limited choice of contraception. Recently W.H.O. has revised guidelines on post-placental family planning services. Immediate postpartum insertion of Intrauterine Contraceptive Device (PPIUCD) is common in number of countries like China, Mexico, and Egypt, where intrauterine contraception is popular.^{2,3} Clinical experiences in these diverse settings confirms the practicality of this approach.

CopperT380 A (CuT380A) IUCD was introduced by Government of India in the National Family Planning Programme in 2002. CuT380A is a highly effective, long term, reversible spacing method of contraception with an effective protection for 10 years. Postpartum insertion of CuT380A is safe, convenient and can be inserted within 48 hours of delivery.⁴ It does not affect the quantity and quality of breast feeding.⁵

PPIUCD insertion has also some limitations. There is slightly higher risk of expulsion (8 to 11%).^{6,7} It also requires special training of providers and follow up of women is must.^{2,7} The benefits of providing highly effective contraception immediately after delivery outweigh its disadvantages.

The continuation rate is an important indicator for family planning programs that are oriented to IUCD contraception. However as with the various available reversible methods; early discontinuation within the first year of IUCD use continues to be a major problem. Major reasons are side effects, complications, failure and/or expulsion.

Government of India started the steps to revive and reposition of both Interval and Postpartum insertion of CuT380A IUCD in India and decided to introduce another type of copper containing IUD-Cu 375 in family welfare program which is a horse shoe shaped device with lateral flexible plastic and serrated fins, developed to minimize the expulsion.

CuT380A has not attained much popularity due to myths and misconceptions associated with it. Cu375 is popular in Indian women. It is observed that Acceptance of Copper375 IUCDs for interval contraception is more as compared to T Shaped Cu IUDs in India.

If the clinical outcome of Cu 375 IUDs for Postpartum insertion is known, it will give wider choice of contraception to postpartum women and should be a valuable addition to National family planning program and will enable women to choose the device with characteristics most suitable to user.

Presently there is very limited data available on the clinical outcome of PPIUCD insertion using the CuT380A and Cu 375 IUD therefore present study was undertaken to evaluate and compare the expulsion and continuation rates of CuT380A and Cu 375 insertion in postpartum period.⁸⁻¹⁰

The aim and objective of the study was to evaluate and compare the continuation and expulsion rates of post placental insertion of CuT380A and Cu375 intrauterine contraceptive devices. To identify the factors affecting the continuation and expulsion rates of intrauterine contraceptive devices.

METHODS

This Prospective Randomized Comparative study was conducted in the department of Obstetrics and Gynecology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi from November 2011 to March 2013. This study included 300 women who delivered in this Hospital and divided into two groups:

Group A

Included 150 women who had post placental insertion of Cu 375 IUD.

Group B

Included 150 women who had post placental insertion of CuT380A IUD.

- The data was analysed by using 'student "t" test/non-parametric 'Wilcoxon Mann Whitney' for quantitative variables to evaluate the safety, efficacy and acceptability
- Chi Square / Fisher's exact test was used for testing the statistical significance of qualitative variables
- Life table analysis was used to determine expulsion and discontinuation rates for different group of IUD insertion.

Women attending ANC clinic, admitted in antenatal ward and in early labour (in labour room) were counseled about all postpartum family planning methods available, their advantages, limitations, effectiveness and side effects using suitable IEC (information, education and communication) materials and models and were screened according to WHO Medical eligibility criteria. They were given option of PPIUCD or interval IUCD insertion and enrolled for the study only when they agreed to come for follow-up visits post insertion and were followed up at 1 month, 3 months, 6 months and at 1 year post IUCD insertion.

Inclusion criteria

Postpartum women desirous of IUCD insertion and willing to come for follow up.

Exclusion criteria

Intrapartum and recent antepartum fever (within 7 days), Puerperal sepsis, Postpartum hemorrhage, Rupture of membranes for greater than 18 hours prior to delivery, Prolong labour more than 12 hours, History of sexually transmitted infection during the index pregnancy or in the last 3 months prior to enrollment.

RESULTS

Age distribution

Maximum women in both groups were within age group 21-25 years. Mean age of the study population was 24.99±4.2 years (Table 1).

Table 1: Age wise distribution.

Type of IUCD		Age group (yrs)					Mean age±SD (yrs)	P value
		≤20	21-25	26-30	31-35	> 35		
Group A, n=150	Number	14	73	33	23	7	25.80±4.95	0.069
	%	9.3	48.6	22	15.3	4.6		
Group B, n=150	Number	8	90	45	7	0	24.19±3.10	
	%	5.3	60	30	4.6	0		

Table 2: Distribution according to literacy status.

Literacy	IUCD acceptance	
	n	%
Literate*	194	63.8
Illiterate**	106	36.2
Total	300	100.0

*Literate: who can read and write at least one language.

**Illiterate: who cannot read and write any language.

Distribution according to literacy status

Acceptance of IUCD insertion was significantly more in literate women (63.8%) as shown in Table 2 This

difference was statistically significant (P >0.05) (Table 2).

Socioeconomic status of IUCD acceptors

According to Modified Kuppuswamy scale based on level of education, occupation, and household income, majority of IUCD acceptors (71.33%) in our study were of low socioeconomic status followed closely by middle class (28.66%).

No statistical difference in socioeconomic status was obtained between group A and group B (p=0.903 by Pearson chi-square test) (Table 3).

Table 3: Socioeconomic status of IUCD acceptors.

Socioeconomic status	Group A, (n=150)		Group B, (n=150)		Total(n=300)	
	Number	%	Number	%	Number	%
Low	104	69.3	110	73.3	214	71.33
Middle	46	30.6	40	26.6	86	28.66
Upper	Nil	Nil	Nil	Nil	Nil	Nil

Insertion related factors

Provider's perception of ease of IUCD insertion

Majority (96.3%) of the insertions were perceived to be easy by provider.

Four percent (4%) insertions were found to be difficult in group A as compared to 3.3 % in group B and this difference was not statistically significant (Table 4).

Perception of pain during IUCD insertion by acceptors

All women were asked to grade their pain perception during IUCD insertion on a Visual Analogue Scale (VAS) of 0 to10, where score of 0 represents no pain and 10 represents severe pain experienced ever.

Visual analogue scale (0-10)



- Mean pain score during IUCD insertion on visual analogue scale was 2.93 ± 1.76 in group A and 3 ± 1.652 in group B (Table 5).
- On analysis by student t test the difference in the mean pain score between group A and group B was not found to be statistically significant ($p = 0.526$).

Table 4: Provider’s perception of ease of IUCD insertion.

Type of IUCD		Ease of insertion (1-10)	
		Easy (1-5)	Difficult (6-10)
Group A, n=150	Number	144	6
	%	96	4
Group B, n=150	Number	145	5
	%	96.6	3.3
Total, n=300	Number	289	11
	%	96.3	3.6

Table 5: Perception of pain during IUCD insertion.

Type of IUCD		Perception of pain on insertion*		Mean VAS±SD
		VAS (0-5)	VAS (6-10)	
Group A, n=120	Number	106	14	2.93±1.76
	%	97.7%	2.3%	
Group B, n=120	Number	104	16	3±1.65
	%	94.2%	5.8%	
Total	Number	210	30	P=0.526
	%	96.0%	4.0%	

Table 7: Distance of horizontal limb of IUCD from fundus at 1 month of follow up.

Distance (mm)	Group A, n=137*		Group B, n=139*		Total, n=300	
	Number	%	Number	%	Number	%
<8mm	115	81.8	104	69.3	219	75.33
>8mm	22	18.6	35	30.6	57	24.66
P value	P=0.013					

Mean distance of horizontal limb of IUCD from fundus of uterus was 5.2 ± 2.3 mm in group A and 6.7 ± 4.3 mm in group B. There was statistically significant difference in distance of horizontal limb of IUCD from fundus of uterus between group A and B by Pearson chi-square test (p value= 0.013).

Menstrual patterns

Fifty one percent (n=77) subjects in group A and 54% (n=81) in group B experienced amenorrhea up to six months. In group A, amenorrhea persisted till 12 months in 2 cases (1.33%); whereas in group B, all women resumed menstruation at 12 months.

- In group A, 68.3% (n=103) subjects and in group B, 67.3% (n=101) subjects had normal periods at the end of 12 month

Observations during follow up

Duration of breast feeding

All women were breastfeeding their baby at first follow up visit at 1 month. Majority (71.3%) of women continued breast feeding beyond 6 months in group A as compared to 64.6% in group B as shown in Table 6.

Table 6: Duration of breast feeding.

Duration of breast feeding	Group A, n=150		Group B, n=150	
	Number	%	Number	%
>6 months	107	71.3	97	64.6
<6 months	43	28.7	53	35.4

On comparing the duration of breastfeeding by Fisher’s exact test the difference was not found to be statistically significant ($p=0.005$) in both the groups.

Distance of horizontal limb of IUCD from endometrial lining of fundus of uterus

Distance was measured ultrasonographically after 1month of insertion, which was more than 8mm in 18.6% subjects in group A as compared to 24.6% in group B (Table 7).

- In group A 12% (n=18) women and in group B 14% (n=21) subjects complained of post insertion bleeding/spotting per vaginum at 1 month of IUCD insertion
- Menorrhagia was reported by 7.33% (n=11) subjects in group A and 8.66% (n=13) subjects in group B at the end of 1 year of follow up. This difference was not statistically significant ($P>0.05$). Oligomenorrhea was reported by 6.6% (n=10) subjects in group A and 7.3% (n=11) subjects in group B at 12 months of insertion.

Expulsion of IUCD

Overall expulsion rate was 13%. Eighteen women out of 150 (12 %) had expulsion of IUCD over one-year period in group A and 21 women (14%) in group B as shown in Table 8.

Table 8: Timing of insertion and expulsion of IUCD.

Type of IUCD	1 month		3 months		6 months		12 months		Total expulsion
	Number	%	Number	%	Number	%	Number	%	Number (%)
Group A, n=150	13	8.6	3	1.2	1	0.6	1	0.6	18(12)
Group B, N=150	11	7.3	3	1.2	4	2.6	3	2	21(14)
Total, n=300	24	8	6	2	5	1.6	4	1.3	39(13)

- There was no statistically significant difference (p=0.028) in expulsion rate between group A and group B by Pearson Chi-square test.

Factors affecting expulsion of IUCD (Cu 375 and CuT380 A)

- Factors taken into consideration were age, socioeconomic status, literacy status, type of IUCD and distance of horizontal limb of IUCD from fundus of uterus (IUD-ED) and Logistic regression analysis was performed
- There was no significant correlation between age and parity on expulsion of IUCD
- Distance of horizontal limb of IUCD from fundus of uterus was measured at 1 month after insertion by USG in both groups. Thirteen subjects in group A and 11 subjects in group B had expulsion at 1 month of insertion hence IUD-ED was not measured. IUD-ED in rest of the 5 expulsions in group A was less

than 8 mm and in group B, IUD-ED was less than 8 mm in 7 expulsions and more than 8 mm in 3 expulsions. There was no correlation between Type of IUD (Cu 375 and Cu 380A) and expulsions.

Continuation of IUCD use at different time periods

In group A, 125 out of 150 (83.3%) women and in group B, 121 out of 150 (80.6%) women continued IUCD use after 12 months.

Twenty five out of 150 (16.6%) women in group A and 29 out of 150 (19.3%) women in group B discontinued IUCD use with overall discontinuation rate of 18% (54 out of 300).

Using Log rank test in Kaplan-Meier survival analysis the difference in the discontinuation rate of group A and group B was not found statistically significant (p= 0.058) (Table 9).

Table 9: Overall continuation of IUDs.

Follow up	Group A			Group B		
	Total n=150	Vaginal Insertions n=120	Intracesarean insertions n=30	Total n=150	Vaginal insertions n=120	Intracesarean insertions n=30
Expulsion	18 (12%)	18 (18%)	0	21 (14%)	20 (16.6%)	1 (3.3%)
Removals	7 (4.6%)	7 (4.6%)	0	8 (5.3%)	7 (4.6%)	1 (3.3%)
Total discontinuation	25 (16.6%)	25 (16.6%)	0	29 (19.3%)	27 (22.5%)	2 (6.6%)
Total continuation	125 (83.3%)	95 (79.1%)	30 (100%)	121 (80.6%)	93 (77.5%)	28 (93.3%)

Table 10: Level of satisfaction at the end of 1 year or time of discontinuation.

Satisfaction	Group A, N=150		Group B, N=150		Total, N=300	
	Number	%	Number	%	Number	%
Satisfied	122	81.3	118	78.6	240	80
Unsatisfied	28	18.7	32	21.4	60	20

There was 100% continuation rate in group A intracesarean IUD insertions, as no expulsion/removals occurred in this group.

Continuation rate was 93.3% due to one expulsion and one removal in group B intra cesarean IUD insertions.

Overall satisfaction with IUCD use

80% of the women were satisfied with the treatment and 60% to an extent that they would like to recommend it to others whereas 20% were not, either due to adverse events or spontaneous expulsion of IUCD. On statistical analysis, the difference in level of satisfaction with IUCD

use was statistically significant ($p= 0.001$) by Fisher's Exact test (Table 10).

DISCUSSION

Post-partum period is one of the critical times when both woman and newborn need a special and integrated package of health services as morbidity and mortality rates are quite high during this period, and the women are vulnerable to unintended pregnancy. Studies show that pregnancies taking place within 24 months of a previous birth have a higher risk of adverse maternal and perinatal outcome.¹¹

IUD expulsion

Partial or complete IUCD expulsion can occur silently or may be associated with other signs/symptoms. Spontaneous expulsion has been shown to be affected by type of IUD, type of IUD insertion, timing of insertion, providers experience and insertion techniques.²

In the present study 18 out of 150 (12 %) women had expulsion of IUCD over one-year period in Cu 375 insertions (group A) and 21 women (14 %) in CuT380A insertions (group B). The expulsions were higher in first 1 month of IUD insertion and decreased successively in next follow up visits (Table 12). There were more expulsions in CuT380A users as compare to Cu 375 users but the difference was not statistically significant. Similar results were seen by Beltagy et al, Eroglu et al, Celen et al (Table 11).

Table 11: Spontaneous expulsion rates of PPIUCD in various studies.

Study	Type of IUD	Expulsions at one year (%)
Beltagy et al ¹¹	CuT380A	15
	Cu 375	14.9
Celen S et al ⁶	CuT380A	12.3
Eroglu et al ⁷	CuT380A	14.3
Present study	CuT380A	14
	Cu 375	12

Type of IUD insertion

Studies by Siemens et al and Zhou S et al have reported significantly less expulsion with intracervical insertions compare to vaginal deliveries.^{12,13} Our results are in accordance with studies by Siemens et al and Zhou S et al. There were 97.5% (n=38) and 2.5% (n=1) expulsions in vaginal and intra cesarean insertions respectively.

Timing of insertion

Studies have reported lower expulsion rates with post placental insertions as compared to early post-partum insertions. Similar findings have been reported by Grimes

et al in-Cochrane review based on multiple randomized controlled trials.¹ Cole et al and Brenner PF et al reported lower expulsion rates after post placental IUCD insertion as compared to early post-partum insertion and attributed this to easy and high fundal placement of IUD.^{14,16} However, Dahlke et al reported higher expulsions in post placental insertions.¹⁵

Higher expulsions in early post-partum insertions may be due to anatomical considerations. After delivery angle between upper and lower segment of uterus becomes more acute and difficult to negotiate and may hinder proper placement of IUCD. This emphasizes the need to counsel women for post-partum family planning methods (PPFP/PPIUCD) in ANC period as post placental insertion has fewer expulsions and causes less discomfort to women.

In our study, all the insertion was post placental with expulsion rate of 12% in Cu 375 and 14% in CuT380A insertions which are comparable to the expulsion rates reported in other studies on post placental insertion of IUDs.⁷⁻⁹

Technique of insertion

Most studies have not shown significant difference in expulsion rates between insertions done by hand or by instrument.^{2,17} Uniform methodology for insertion using Kelly's forceps was adopted throughout our study. This long-curved instrument without locking feature allowed not only fundal placement but also prevented entanglement of IUD string while withdrawing the instrument. Other studies have used either ring forceps whose length is not sufficient to place IUCD at fundus or manual insertion, where again fundal placement might not have been achieved.

Experience of provider

Insertion immediately after expulsion of placenta requires special training, and expulsion rates are reduced with the insertion experience of the practitioner.¹⁷ A prospective study in Turkey reported an expulsion rate of 70%, whereas Morrison et al noted a trend toward fewer expulsions (5%) over time with post placental IUCD insertion, when the IUDs were placed by experienced clinicians, suggesting that with experience, placement of IUCD post placentally improves.^{2,7} The importance of insertion skills has also been highlighted in studies done by Cheng D and Suzan G et al.^{19,20} Study by Aznar R et al in which high fundal insertion was done immediately after delivery of placenta showed decreased expulsion.²¹

Breast feeding

Xu et al noted higher expulsion rates (22.4%) in non-breastfeeding women as compared to breastfeeding women (11.9%), however no such difference has been observed in our study as well as by Kennedy KL.^{3,18}

IUD-ED and expulsions

There is much evidence that shows Trans Vaginal Sonography to be highly accurate in monitoring the location of any type of IUCDs. Beltagy et al found the association between the IUD-endometrial distance more than 10 mm and expulsions.⁸ However, the maximum IUD-ED to ensure adequate contraception is under debate. In present study, also no correlation was found between ED-IUD distance and expulsion.

Measures for early detection of IUD expulsion

Early follow up, combined with self-examination for the presence of the strings, may be important in detecting early spontaneous expulsions.^{2,10} Women should be thoroughly counseled to detect expulsion and to return immediately for reinsertion or another contraceptive method. Women themselves detect 90-95% of expulsions and reinsertion rate of 73-93% have been reported.^{9,10}

The benefit of providing highly effective contraception immediately after delivery may outweigh the disadvantage of increased risk for expulsion.

In present study, complete and partial expulsions were 10 and 29 respectively. Complete expulsions were detected by women herself while partial expulsions were detected during examination. Reinsertion of IUD was done in 31 women. Rests of the women were counselled for other family planning methods.

IUCD removal

IUCD removal rate in our study was 5%. Removal rate was 4.66% in Cu375 users and 5.33% in CuT380A users. Although bleeding related problems were reported by 8.6% subjects in Cu 375 and 10% subjects in Cu T380A and pelvic pain was reported by 4% subjects in both the groups at the end of 1 year, this responded to analgesics, haemostatic agents and proper counselling, Psychosocial (nonmedical/ personal) causes accounted for 33.3% removals in our study.

Woman during labour or immediately after delivery accepts IUCD as her motivational levels are high, but later on regrets her decision. Family pressure was also an important reason. Husband and family members may also be included in counselling session if required. Bahamondes L et al, Batár I et al and Jenabi E et al also reported the similar findings.²²⁻²⁴

In multiple studies bleeding and dysmenorrhea led to CuT380A removal in 4% and 15% women respectively over 1 year of its use.²⁵ Pain and bleeding were cause for removal in 5% women in a multinational study conducted in Yugoslavia and Panama²⁶ Bhatnagar and colleagues, and Grimes et al reported removal rates ranging from 3.1% to 10.6% on account of pelvic pain.^{1,27}

Continuation of IUCD

Continuation rates in present study in both the group are in accordance with that of Lara R et al and Beltalgy et al.^{8,9} Lara R observed continuation rates of 77.1% and 82.6% for postplacental insertion of CuT380A and Cu 375 respectively at one year.⁸ Overall Continuation rate in our study was 83.3% in Cu 375 and 80.6% in CuT380A at 12 months and there was no significant difference seen in continuation rates in two groups ($p>0.05$).

In intracesearean IUD insertions, 100% continuation rate observed in group A, as no expulsion/removals was occurred in this group and in group B, continuation rate was 93.3% due to one expulsion and one removal. Continuation rates were significantly more ($P<0.05$) following intra cesarean PPIUCD insertions as compared to vaginal insertions.

Overall satisfaction

The degree of satisfaction with IUCD at the end of 12 months of use was assessed. It was observed that 80% of the women were satisfied with the treatment and 60% to an extent that they would like to recommend it to others whereas 20% were not satisfied at all either due to adverse events or spontaneous expulsion of IUCD.

Adverse effects were more in CuT380A than Cu 375 in first 6 month of insertion but at 1 year overall adverse effects were low and comparable in both the groups. However, the degree of satisfaction was high in Cu 375 as the side effects were less in this group in first 6 month of insertion. Overall satisfaction was higher in intracesearean insertions than vaginal insertions.

CONCLUSION

Counselling for post-partum family planning methods is essential not only for initiation of family planning but also for continuation of contraceptive methods. Efficacy and continuation rate of post placental insertion of Cu 375 and CuT380A are comparable however adverse effects are more in CuT380A in first 6 month of IUD insertion. Continuation rates are significantly higher in Intra-cesarean insertions in both the groups. Overall satisfaction is higher for Cu375 than CuT380A due to fewer side effects in Cu375 in first 6 months of IUD insertion. This indicates the acceptability of Cu375 as post placental contraceptive method.

Post placental insertion of Cu375 or CuT380A is safe, reversible, long term, convenient and cost-effective method of contraception and can be initiated after immediate vaginal delivery or intra caesarean especially in women of less developed countries with limited knowledge of contraception and less likelihood of return for contraception. It can be safely and effectively integrated into existing PFP services.

Recommendations

Further study is necessary to determine the cause of higher expulsions following post placental Cu375/CuT380A IUD insertions and to find way to reduce it. Studies should also concern to find out the cause of bleeding related problems associated with copper bearing IUDs as this is the most common complaint encountered after Cu IUDs insertions. Implementation research for IUD service utilization can pave the way for population level impact. The immediate post-partum period (within 10 min of delivery) is highly under tapped for CuT insertion in India. It can be major intervention point for increasing utilization of IUCD service. Counseling for post-partum family planning should be an integral part of all ANC services. Obstetrician should acquire counseling, client assessment and insertion skills of PPIUD so as to reposition PPIUCD in National Family Planning Program. Follow up after PPIUCD insertion is vital to detect expulsions and should be integrated with MCH services.

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