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Assessment of acceptability, safety and efficacy of immediate postpartum Cu-T insertion in a tertiary care centre

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ABSTRACT

Background: India is the most populous nation in the world. In India, understanding and awareness of contraceptive methods are insufficient, and the culture is rife with myths. IUCD insertion in the immediate postpartum period is an effective, safe and convenient method of contraception for both cesarean and vaginal births.

Materials and Methods: The present study is a prospective study to assess the acceptability, safety and efficacy of Cu-T when inserted within ten minutes of placental expulsion up to 48 hours after delivery both in vaginal delivery or cesarean section and the patients were followed after 6 weeks and again after 6 months for any complications and reason for removal, if any.

Results: 197 patients opted for IUCD insertion. At 6 weeks the majority of patients had no complaints 129 (70.88%) followed by menstrual complaints 27(14.84%). At 6 months most of the patients had no complaints 108(75%) while 21 patients had menstrual complaints 14.58%. None of the patients had perforation and pregnancy.

Conclusion: Cu-T's is a feasible and acceptable method of contraception. The feasibility of accepting IUCD insertion can increase with antenatal counselling and institutional deliveries. A low expulsion rate was observed in our study. It is better to give this contraceptive option than leave a post-partum woman at risk of another pregnancy within a short interval.

1. Introduction

After female sterilization, the intra-uterine contraceptive device (IUCD) is the second most-used contraceptive method worldwide, accounting for 13.7% of the contemporary contraceptive prevalence rate. Intrauterine contraceptive devices are one of the oldest and most effective contraceptive methods.[1] Women have natural contraception during puerperium due to lactational amenorrhea, however in a study puerperal menstruation was present in 31.8% of subjects.[2] The cumulative probabilities of ovulation during lactational amenorrhoea were found to be 30.9% at 6 months.[3] Ovulation can commence in the absence of menstruation, and pregnancy can occur.[4–6] In a study of Turkey, 34% of the research sample of women with six-month-old infants were said to use lactational amenorrhoea to prevent pregnancy after childbirth. Still, the pregnancy rate of the women using lactational amenorrhoea was 32.8%.[7] Hence, non-lactating mothers should use contraceptive measures after three weeks, and lactating mothers after three months of delivery.[8]

IUCD insertion in the immediate postpartum period is an effective, safe, and convenient method of contraception for both caesarean and vaginal births.[9] The current rate of IUCD use in India is 2%, which is significantly lower than recommended. The current Indian medical literature

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is unclear on the factors for this lower acceptance. To investigate the acceptability, safety, efficacy, and outcome of PPIUCD, the present study was done.

2. Materials and Methods

A prospective study, to assess Cu-T's acceptability, safety & efficacy in the immediate postpartum period was done from March 2021- August 2022 in the Labour Room and operation theatre of a tertiary care centre in north India.

All antenatal women admitted to this tertiary care centre, between 28 to 42 weeks of gestation were included in this study. Women with unresolved postpartum haemorrhage, rupture of membranes >18 hrs or/and chorioamnionitis/ puerperal sepsis were excluded from this study.

2.1. Methodology

2.2. For vaginal delivery

Consent was obtained by explaining the procedure and complications. After delivery and active management of third-stage labour, willingness for Cu-T insertion was reconfirmed. The perineum, labia & vagina was inspected for any trauma. The cervix was visualized by depressing posterior vaginal wall by Sims speculum & the anterior lip of the cervix was held with ring forceps. Cu-T was grasped with Kelly's forceps with no touch technique. With all aseptic precautions, Kelly's forceps with Cu-T was inserted through the cervix to the lower uterine cavity while avoiding any touch to the vagina. The left hand was then moved to the woman's abdomen & the entire uterus was pushed superiorly to straighten the angle between the uterus & vagina. The forceps were opened and the Cu-T was released at the fundus. The uterus was stabilized until forceps were out. The cervix was examined for protruding thread. The woman was allowed to rest for a few minutes.

2.3. For caesarean delivery

Consent was obtained by explaining the procedure and complications. The Cu-T was held between the middle & index finger It was passed through the incision & placed at the fundus. Hands were withdrawn slowly the string was pointed towards the cervix. It was noted that the string of the Cu-T should not be included in the suture

2.4. Post insertion counselling

The key messages related to Cu-T were reinforced and the woman was informed regarding the importance and schedule of follow-up visits. A Cu-T card providing all relevant instructions was given to the patient. The necessity for follow-up visits was emphasized and the patient should return after 6 weeks or first menstruation, whichever is earlier, for a follow-up examination. It was emphasized that the patient should return at any time if she has any concerns, experiences any warning signs, or if the Cu-T was expelled. Follow up again at 6 months to assess expulsion, infection, abdominal pain, menstrual irregularities, thread-related problems, any other complications and reason for removal, if any, was done.

2.5. Statistical analysis

Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, IL, USA) for the Windows program (26.0 version). The continuous variables were evaluated by mean (standard deviation) or range value when required. The dichotomous variables were presented in number/frequency and were analysed using the Chi-square test. A p-value of < 0.05 or 0.001 was regarded as significant.

3. Results

This Hospital-based prospective observational study was carried out at the Department of Obstetrics and Gynaecology, at a tertiary care centre in North India. After obtaining ethical clearance and informed consent, 197 patients were enrolled as per inclusion-exclusion criteria. From March 2021 to March 2022, the total deliveries conducted were 2114, out of which 1362 patients had a vaginal delivery while 752 patients had a caesarean delivery. A total of 150 patients opted for tubal ligation. After excluding 24 patients by exclusion criteria, 1940 patients were counselled for PPIUCD insertion, in which only 197 patients accepted as contraceptive method and were followed up till August 2022 in the study period of 18 months. Hence the acceptability came out to be 10.15%.

Acceptability: 197/1940*100=10.15%.

Most patients who accepted Cu-T were under the age group of 20-29 years [122(61.93%)], employed [125(63.45%)], Hindu [111(56.35%)], belonged to the middle class [136(69.04%)], while only [13(6.60%)] of patients were from the upper class. Most patients were graduates [81(41.12%)] while patients who were educated up to 5th grade were the minimum [18(9.14%)]. The majority of the patients were primipara [146(74.11%)], followed by multi-para with 2 parities [39(19.80%)]. Among all the patients who accepted IUCD insertion, [141(71.57%)] patients were booked while [56(28.43%)] were unbooked. Maximum no. of patients were counselled during their antenatal period [83(42.13%)], followed by early labour [78(39.59%)] and post-partum [36(18.27%)]. The maximum number of patients had post-placental IUCD insertion [143(72.59%)], followed by intra-caesarean insertion [54(27.41%)]. (Table 1)

Out of 197 patients who had Cu-T insertion, 15 patients were lost to follow-up hence the patients who were followed up till 6 weeks were 182(92.38%). By 6 months, 11 IUCDs were expelled,7 patients got it removed and 20 patients were

Table 1: Demographic features of the participants

Parameters	N	Demography
Age in years		
< 20 years	2	1.02%
20-29 years	122	61.93%
30-39 years	71	36.04%
>40 years	2	1.02%
Religion	111	Hindu - 56.35%
	57	Muslim - 28.9%
	29	Others - 14.72%
Occupation	125	Employed - 63.45%
	72	Housewifes - 36.55%
Socio-economic status	136	Middle class - 69.04%
	48	Low class - 24.37%
	13	Upper class - 6.6%
ANC Care	141	Booked - 71.57%
	56	Unbooked - 28.43%
Education	81	Graduate - 41.11%
	90	Schooled - 45.69%
	26	Illiterate - 13.20%
Parity	146	Primipara - 74.11%
	39	Multipara - 19.79%

lost to follow-up, so the no. of patients followed up till 6 months were 144(73.10%) and no significant difference was observed [P=0.1360].

The expulsion rate was high till 6 weeks and was observed in 11 patients in total (6.04%). Until 6 months, it was seen in 3 patients (2.08%). Statistically, no significant difference was observed [at P=0.0926].

The removal rate was low till 6 weeks in 7 patients only (3.84%), while till 6 months, 11 more patients (7.63%) consulted for removal. Statistically, no significant difference was observed [P=0.1597].

Out of a total of 197 patients, 15 were lost to follow-up and 11 IUCDs were expelled till 6 weeks; hence 164 patients continued [164(83.25%)]. And by 6 months, 20 more patients were lost to follow-up, a total of 11 more patients got IUCD removed for various complications and 3 more Cu-T were expelled giving a continuation rate of [130(65.98%)].(Table 2)

Till 6 weeks, 15 patients were lost to follow-up 11 IUCDs were expelled. The complaints were noted in patients at 6 weeks, and it was observed that the majority of the patients had no complaints [129(70.88%)]. 27 patients had menstrual complaints, 7 patients complained of lost strings, 6 patients had vaginal discharge while 5 had pelvic pain and 2 had dyspareunia. 5 patients had more than 1 complaint and

Table 2: Follow-up of enrolled patients

	Till 6 weeks	Till 6 months
Patients followed	197-15=182 (92.38%)	182-20-11-7=144 (73.10%)
Rate of expulsion	11/182 (6.04%)	3/144 (2.08%)
Rate of removal	7/182 (3.84%)	11/144 (7.63%)
Continuation rate	164 (83.24%)	130 (65.98%)

no patient presented with PID or perforation. However, a significant difference was observed [P<0.0001*]. (Table 3)

Table 3: Complaints among enrolled patients at 6 weeks

Complaints	No.	Percentage	P-Value
No complaints	129	70.88%	
Menstrual complaints	27	14.84%	
Pelvic pain	5	2.75%	
Lost string	7	3.85%	X=280.2
Vaginal discharge	6	3.30%	p<0.0001*
Dyspareunia	2	1.10%	
PID	0	0%	
Perforation	0	0%	
Pregnancy	0	0%	

At 6 months, 20 patients were lost to follow-up, and 3 IUCDs were expelled. The complaints were noted in patients at 6 months and it was observed that the majority of the patients had no complaints [108(75%)]. 21 patients had menstrual complaints (14.58%), where the maximum had heavy menstrual bleeding [n=15], and few had intermenstrual bleeding [n=6]. Apart from that, 7 patients had vaginal discharge while 4 had pelvic pain and 2 had PID while only 1 patient had dyspareunia. None of the patients had perforation and pregnancy and 2 patients had more than 1 complaint.

Overall, a significant difference [P<0.0001*] was observed in complaints of the enrolled patients at 6 months. Moreover, 0% of pregnancies occurred after using IUCD for 6 months, showing 100% efficacy of IUCD. (Table 4)

Table 4: Complaints among enrolled patients at 6 months

Complaints	No.	Percentage	P-Value
No complaints	108	75%	
Menstrual complaints	21	14.58%	
Pelvic pain	4	2.78%	
Lost string	0	0%	X=151.8
Vaginal discharge	7	4.86%	p<0.0001*
Dyspareunia	1	0.69%	
PID	2	1.39%	
Perforation	0	0%	
Pregnancy	0	0%	

At 6 weeks, the reasons for removal were Pelvic pain [n=5] and menstrual complaints [n=2], While at 6 months,

the reasons for removal were psychological [n=5] for most of the patients, followed by pelvic pain [n=4]. At 6 weeks, a total of 42 patients had complaints and 7 out of them asked for removal; the rest were managed medically. At 6 months, 33 patients had complaints and 11 out of them asked for removal; the rest were managed conservatively. Maximum patients (50%) asked for removal of IUCD due to pelvic pain, 22.22% of patients due to menstrual complaints and 27.77% of patients due to psychological reasons. However, a non-significant difference was observed [p=0.1085]. (Table 5)

The majority of the patients accepted IUCD because they find it safe [51(25.89%)], beneficial for the long term [42(21.32%)], reversible [29(14.72%)] and so on. Statistically, a significant difference [P<0.0001*] was observed among patients.(Table 6)

4. Discussion

The intra-uterine contraceptive device (IUCD) is the second most-used contraceptive method in the world, but due to a lack of information and widespread misconceptions regarding IUCD, the current rate of IUCD use in India is considerably low. It remains unclear why acceptance of IUCD is low among urban and rural women.

In our study, a total of 1362 patients had a vaginal delivery and 752 patients had a caesarean delivery, 197 patients got IUCD inserted, and 150 patients underwent tubal ligation. A significant inter-group difference was observed. Most patients who showed acceptance of IUCD were under the age group of 20-29 years (61.93%), followed by 30-39 years (36.04%). Statistically, a significant difference was observed [P<0.0001*]. Similar to our study, Kanhere AV et al.[10] identified the highest proportion of women between the age group of 20 and 29 years (35%). Similarly, Mishra S[11] observed that the majority of patients (21.49%) were between the ages of 20 and 29 years. Similarly, Jakhar and Singhal[12] also found that 48.5% of patients were between the ages of 20 and 24 years. These findings are comparable to the findings of Afshan and Asim[13] in which the majority of women had caesarean deliveries, the mean age was 26 years, and the majority of the women were between the age group of 20 and 40 years. In our analysis, the majority of patients who accepted IUCD insertion were Hindu (56.35%), followed by Muslims (28.93%) and others (14.72%), with a statistically significant difference between the three groups.

The majority of patients in our study were employed (63.45%). In contrast, Mishra S[11] found that the majority of patients [n=503(19.98%)] were housewives and 61(8.82%) patients were employed. The majority of patients in our study belonged to the middle class (69.04%). At the same time, just 6.60% of the patients were upper class. This might be because the study area is a private institute, where the majority of patients are employed and from the upper or middle class. In contrast, Mishra S[11] observed that the majority of patients were from the lower class 429, with only 29 from the upper class. Among all patients who accepted IUCD insertion, 71.57% were booked. Moreover, Kanhere AV et al.[10] reported that 56% of patients were booked for antenatal care, of which 44% of booked patients accepted PPIUCD, and only 25% of unbooked patients accepted PPIUCD. Frequent ANC visits at the same institute made patients trust their doctor and find IUCD insertion a reliable mode of contraception. The majority of patients (41.12%) who accepted IUCD insertion were graduates. Patients who had completed the fifth grade were the least educated (9.14%). Education has a positive effect on the acceptance of PPIUCD insertion. It's easier to counsel and explain the benefits of PPIUCD to an educated woman. In contrast, Kanhere AV et al.[10] found that 87% were literate; 7% were graduate-level educated, and 38% were just 12th-graders. In addition, Mishra S.[11] observed the highest number of patients with primary qualification [n= 269(28.56%)], followed by those with secondary qualification [n= 268(13.88%)]. Other research, including one by Jakhar and Singhal[12] found that the majority of IUCD-accepting patients were illiterate (59%), 87.5% were Hindu, and 12% were Muslim. The difference may be due to differences in patients at government and private setups.

In our study, among all the patients, only 10.15% accepted IUCD insertion, while most of the patients rejected IUCD insertion (89.85%). The acceptance rate in our study is low, it could be because of a lack of awareness, low education, family pressure and various misconceptions about IUCD insertion. Similarly, Kanhere AV et al.[10] observed that out of 200 eligible patients, 72 gave informed consent to IUCD insertion. The approval rate was 36%. Priya Jha[14] investigated the causes of the low acceptance of PPIUCD. They found that the most prevalent reason for limited acceptance of PPIUCD is the lack of spouse involvement.

In our study, the most common reason for acceptance was its safety (25.89%), beneficial for the long term (21.32%), reversible (14.72%) and so on. Higher literacy levels also might be the reason for acceptance of the PPIUCD rate amongst higher- and middle-class women. To add, in our institute, CuT-375A and CuT-380A are available free of cost with support from the Government of India.

Similarly, Kanhere AV et al.[10] found that 28% of patients accepted IUCD because of its long-acting action, followed by 20% of patients due to less follow-up and 17% of patients due to its reversibility. In addition, Mishra S[11] showed that the majority of acceptors rely on their physicians. They value the doctor's advice. A statistically significant difference was detected between IUCD insertion acceptance and rejection. In a study by Kanhere AV et al.[10] interviewed 128 women who denied post-partum IUCD

Table 5: Reason for removal of IUCD in enrolled patients

Reason for removal	At 6 weeks	At 6 months	Total	Percentage	P - Value
Menstrual complaint	2	2	4	22.22%	
Pelvic pain	5	4	9	50%	
PID	0	0	0	0%	X=4.442
Wants pregnancy	0	0	0	0%	P=0.1085
Psychological	0	5	5	27.77%	
Wants sterilization	0	0	0	0%	
Total	7	11	18	100%	

Table 6: Reason for acceptance among enrolled patients

Reason for Acceptance	No.	Percentage	P - Value
Long Term	42	21.32%	
Safe	51	25.89%	
Fewer Clinical visits	12	6.09%	X=36.37
Free of cost	18	9.14%	P<0.0001*
No influence on breast feeding	25	12.69%	
Reversible	29	14.72%	
One time procedure	16	8.12%	
Belief in doctor	4	2.03%	

insertion to determine the reason for their refusal and their choice of alternative contraception; 32% were interested in utilising alternative contraceptive methods, 20% were interested in permanent contraception in the future, 14% refused all forms of contraception, 13% feared menstruation issues such as irregularity and discomfort, 5% feared future infertility, 9% of patients denied due to family pressure from husband and mother-in-law, whereas 10% could not name the reason. Moreover, according to Mishra S[11] 66.94% did not know IUCD; 50.28% of applicants refused due to partner and family reluctance.

In our study, the majority of patients were primipara (74.11%), followed by multi-para with 2 parties (19.8%). Similarly, Mishra S[11] and Kanhere AV et al.[10] observed majority of patients were para 1 (20.73% and 48%) respectively followed by multi-para with 2 parties (15.50% and 22%). The reason can be its reversibility and long-term action making IUCD a good option for spacing.

In our study, the time of counselling for most patients was during antenatal visits (42.13%), followed by early labour (39.59%) and post-partum (18.27%), and a significant difference was observed [P=0.0029*]. This highlights the effect of adequate counselling on each antenatal visit by the concerned doctor. Similar to our study, Kanhere AV et al.[10] showed that all 200 post-partum patients were counselled during their prenatal visits, and 72 of them consented to IUCD insertion.

In our study, at 6 weeks, 7.614% of women were noted as lost to follow-up. At 6 months, 12.19% of women were lost to follow-up, and no significant difference was observed. Patients residing in hilly areas find it difficult to visit hospitals for follow-up timely. Similarly, Mishra S[11] noted that 23.05% of patients were lost to follow-up during 4-6 weeks. These outcomes demonstrate a lack of vertical programme integration at every level. Replace "Insert and report and then forget" with "Counselling and report, insert and report, and follow-up and report" and provide service at all times. According to Kanhere AV et al.,[10] 28% were reported as lost to follow-up. Similarly, Katheit G[15] noted lost to follow up of 16.12%. In addition, Jakhar and Singhal[12] found that 95.5% attended the first follow-up and 94.5% attended the second follow-up, while 4.5% and 5.5%, respectively, were lost to the first and second follow-ups.

In our study, the complaints were first noted in patients at 6 weeks; and it was observed that the majority of the patients had no complaints (70.88%) while 14.84% of patients had menstrual complaints in which most of the patients had reported irregular bleeding/spotting [n=22], and few had heavy bleeding [n=5]. These may be attributed to puerperium and not due to the Cu-T insertion per se. Only 3.85% of patients complained of lost string. The complaints were then noted in patients at 6 months and it was observed that most of the patients had no complaints (75%), while 21 patients had menstrual complaints (14.58%), in which maximum patients had heavy menstrual bleeding [n=15], and few had intermenstrual bleeding [n=6]. The next common complaints were vaginal discharge experienced by 7 patients (4.86%) and pelvic pain by 4 patients (2.78%). Moreover, no patient conceived with IUCD in situ till 6 months, showing 100% efficacy of IUCD. In contrast to our study, Kanhere AV et al.[10] observed 43% of patients with no complaints, 8% of patients experiencing post-insertion pain and 6% of patients with abnormal bleeding. In their study, no cases of perforation, PID, or endometritis were reported. Similarly, Katheit G[15] observed that 76.5%

of patients had no complications,12.9% of patients had minor abdominal pain and 10.5% had bleeding issues. According to Kapp N and Curtis KM,[16] IUCD insertion did not raise the likelihood of problems. Similarly, a recent study by Mishra S[11] showed abnormal uterine bleeding in 102(23.5%) women, which was more prevalent than other complications. However, only 14(32.56%) women pursued removal due to bleeding, while the others retained IUCD with just reassurance, underscoring the need for a positive outlook.

In our study, the expulsion rate was high till 6 weeks and was observed in 11 patients (6.04%). While at 6 months, only 3 patients (2.08%) had an expulsion. Mishra S[11] found the rate of expulsion within 7 days to be 0.69%, between 7 days and 4 weeks it was 7.60%, and after 4 weeks, it was (0.69%). The immediate PPIUCD expulsion rate ranged from 25 to 37%, whereas the post-placental rate was between 9.5 and 12.5%. In a study conducted by Tatum et al.[17] the expulsion rates of PPIUCD were comparable at 1 and 12 months in Belgium (4%) and Chile (7%) but increased from 19% at 1 month to 28% during 12 months of follow-up in the Philippines.

In our study, removal rate at 6 weeks was 3.84% (n=7). At 6 months, the rate of removal noted was 7.63% (n=11). At 6 weeks, the reasons for removal were pelvic pain for 5 patients and menstrual complaints for 2 patients. While at 6 months reasons were psychological for most of the patients [n=5] like dislodgement of the IUCD into the abdominal cavity, future fertility, disturbance in day-to-day activities and pelvic pain for 4 patients. Mishra S.[11] found that the leading cause of IUCD removal was bleeding (32.56%), followed by family pressure (25.58%). Patients with and without difficulties have equal removal rates (89.40% and 88.50%). It highlights the importance of knowledge and motivation before implementing PPIUCD.

In our study, the continuation rate was high till 6 weeks (83.25%), but eventually decreased by 6 months (65.98%), and a non-significant difference was observed. According to Mishra S,[11] the acceptance and continuation rates were higher when the spouse participated in contraceptive counselling and decision-making. A continuation rate of (81.11%) was observed.

In our study, women who were followed up till 6 weeks were 92.38% while 73.10% of patients were followed up at 6 months. Similarly, Mishra S[11] observed that the majority 78.95% of women were followed up, and 23.05% were lost to the first follow-up at 6 weeks. Likewise, Jakhar and Singhal[12] found that 95.5% of patients were followed up at 6 weeks. At the same time, 94.5% of women were present at the second follow-up. These findings are comparable to other studies, such as the study by Shukla et al.,[18] in which 21.38% of women were lost to follow-up after 4–6 weeks, and 11.37% returned for a second follow-up after 6 months.

In contrast to our study, Afshan and Asim[13] found only 35% of women at the first follow-up. In the study by Singal et al.[19] all participants were present at the follow-ups. This high retention rate is the outcome of effective counselling.

5. Conclusion

1. Cu-T's is a feasible and acceptable method of contraception.
2. The feasibility of accepting IUCD insertion can increase with antenatal counselling and institutional deliveries. Acceptance was high in primiparous patients. A low expulsion rate was observed in our study.
3. It is better to give this contraceptive option than leave a post-partum woman at risk of another pregnancy within a short interval.

6. Limitations

1. As seen in the study, loss to follow-up was a limitation of the investigation. This made it difficult to determine what happened to those who did not complete their follow-up schedule.
2. Results were limited to a single tertiary care centre that may not be generalized for all settings. Hence, it cannot be incorporated into the larger population.

7. Source of Funding

No funding sources.

8. Conflict of Interest

None declared

9. Ethical approval

The study was approved by the Institutional Ethics Committee.

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