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Original Research Article

Comparison of continuation rate, safety and acceptability of intra-caesarean insertion of CuT 380A versus CuT 375: a randomized controlled study

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ABSTRACT

Background: The immediate postpartum period represents an important opportunity to initiate long-acting reversible contraception. Intracesarean insertion of PPIUCD is a convenient and effective method for preventing unintended pregnancies. CuT 380A and CuT 375 are widely used devices; however, comparative evidence regarding continuation and safety following intra-caesarean insertion is limited.
To compare continuation rate, safety profile and acceptability of intra-caesarean insertion of CuT 380A and CuT 375.
Methods: This prospective randomized controlled study was conducted in the Department of Obstetrics and Gynaecology, Kasturba Hospital, Delhi from August 2023 to October 2024. Total of 144 women undergoing caesarean section and consented for IUCD insertion were randomized into two groups: CuT 380A (n=72) and CuT 375 (n=72). Participants were followed at 6 weeks, 3 months, 6 months and 9 months postpartum. Primary outcome was continuation rate. Secondary outcomes included expulsion, removal and complication
Results: Mean age of participants was comparable between CuT 380A and CuT 375 groups (23.83±4.31 vs 23.33±4.00 years; p>0.05). Overall follow-up rate was 97.9%. Expulsion occurred in 5.5% women in CuT 380A group and 4.1% women in CuT 375 group (p>0.05). Removal rates were 6.9% and 2.7% respectively. Continuation rates at 9 months were 84.7% and 91.7% respectively.
Conclusions: Both CuT 380A and CuT 375 are safe and effective for intra-caesarean insertion with comparable continuation and complication rates. CuT 375 demonstrated slightly higher continuation rates though differences were not statistically significant.

Keywords: CuT 380A, CuT 375, Intra-caesarean IUCD, PPIUCD

INTRODUCTION

The postpartum period is a critical time for initiating contraception because many women have limited access to family planning services after delivery.[1] Short interpregnancy intervals are associated with increased maternal and neonatal morbidity. Immediate insertion ensures contraception before discharge from the hospital and eliminates the need for an additional postpartum visit. Insertion during caesarean has several advantages including direct fundal placement under vision, minimal discomfort and high acceptance rates.[3] It is considered a safe and effective method with low failure rate. CuT 380A and CuT 375 are widely used IUCDs under national family planning programs.[4] During the postpartum period, women are often highly motivated to receiving counselling about family planning methods.[5] The immediate post placental insertion of an intrauterine contraceptive device (IUCD) is a highly cost-effective, reversible method of birth control that does not interfere with breastfeeding and has a cumulative pregnancy rate of less than 1 per 100 women within the first year of use.[6] The continuation rate is a crucial indicator for family planning programs focused on IUCD contraception.[7] IUCD services are provided free

of charge at all government facilities. However, low utilization and high rates of discontinuation can be attributed to a lack of knowledge, as well as prevalent myths and misconceptions particularly regarding the copper T.[8] Both devices are highly effective and hormone-free. The present study was conducted to compare continuation rates, safety and acceptability of intra-caesarean insertion of CuT 380A and CuT 375.

METHODS

The study was hospital-based prospective randomized controlled trial, conducted at department of Obstetrics and Gynaecology, Kasturba Hospital, Delhi, from August 2023 to October 2024. Study population was pregnant women undergoing caesarean section who consented for IUCD insertion, were included in the study according to inclusion and exclusion criteria. Study was approved by ethical committee.

Study population

Total of 144 women were enrolled in the study and randomly allocated using computer-generated random numbers into two groups: Group A (CuT 380A, 72 women) and Group B (CuT 375, 72 women).

Inclusion criteria

Pregnant women aged 18–40 years, who were willing for IUCD insertion, undergoing caesarean section and medically eligible for IUCD insertion according to the WHO medical eligibility criteria were included in the study.

Exclusion criteria

Pregnant women with clinical chorioamnionitis, rupture of membranes for more than 18 hours, postpartum haemorrhage, uterine anomalies or active genital infection. Women who were not eligible according to WHO medical eligibility criteria (category 3 or 4) were also excluded from the study.[9]

In the hospital all eligible women received counselling regarding PPIUCD during the antenatal period or in early labour before caesarean section. A total of 144 consenting women were enrolled and randomized to receive either Cu T 380A (Group A) or Cu T 375 (Group B), with IUCD insertion performed immediately after placental delivery before uterine closure. Women received post-insertion counselling and were followed up at 6 weeks, 3 months, 6 months and 9 months postpartum, with telephonic reminders provided before scheduled visits to improve compliance. At each visit, continuation status, spontaneous expulsion, removal, menstrual complaints, abdominal pain, signs of infection, breastfeeding pattern and overall satisfaction were assessed. Speculum examination was performed at the first follow-up to assess IUCD strings, with ultrasonography used when strings were not visible.

Women with expelled IUCDs were counselled and offered alternative contraceptive methods. Any findings suggestive of pelvic inflammatory disease (PID) were managed according to NACO guidelines.[10]

At each follow-up visit, continuation status, expulsion, removal, menstrual complaints, abdominal pain and signs of infection were recorded. The primary outcome was the continuation rate at 9 months, while the secondary outcomes included expulsion rate, removal rate, complications and acceptability of IUCD.

Data collection

Follow up was done at regular intervals (6 week, 3-month, 6-month, 9 month) post-caesarean. continuation status, expulsion, removal, menstrual complaints, abdominal pain and signs of infection were compared between both groups.

Statistical analysis

Statistical analysis was carried out using statistical packages for IBM SPSS vs 22 for Windows. Two-sided p values were considered as statistically significant at $p<0.05$. Chi -square test was used for comparison between groups.

RESULTS

Group A consisted of 72 women who received CuT 380A, while Group B included 72 women who received CuT 375 divided by randomised method.

Demographic profile

The summary of major demographic parameters are shown in Table 2. As is seen, the majority of participants belonged to the 18–25 years age group (69.4%), followed by 26–30 years (23.6%). The mean age was 23.83±4.31 years in the CuT 380 A group and 23.33±4.00 years in the CuT 375 group, with no statistically significant difference ($p=0.713$). Most participants were Muslims (77.8%), while 22.2% were Hindus, with comparable distribution between the two groups ($p=0.423$). Regarding literacy status, 88.2% of women were literate and 11.8% were illiterate, with $p=0.796$. The majority of participants belonged to the lower socioeconomic class (41.0%), followed by lower middle (23.6%) and middle class (19.4%), with $p=0.293$.

Comparison of continuation rate

Follow-up rate

The follow-up rate of PPIUCD is the proportion (percentage) of women who return or are successfully

contacted for follow-up after PPIUCD insertion at a specified time period out of the total number of women who had the device inserted.

Follow-up compliance was high in both groups . In the CuT 380 A group, 97.2% of participants completed follow-up visits, while 98.6% CuT 375, group. Overall, 97.9% of participants adhered to follow-up across both groups. Only 2.8% of participants in Group A and 1.4% in Group B missed follow-up visits, with an overall loss to follow-up of 2.1%. The difference between the groups was not statistically significant (p=0.560).

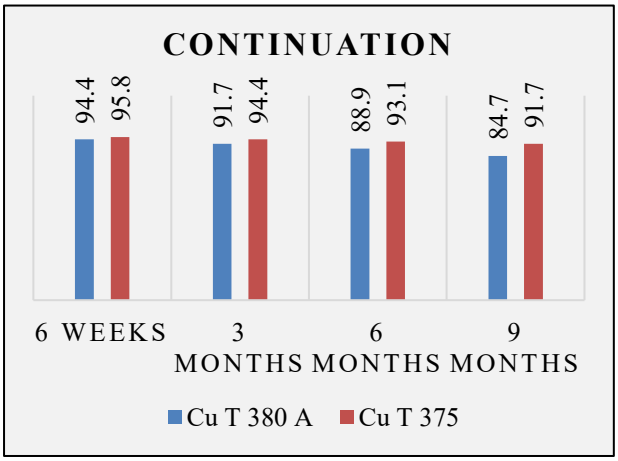

Figure 1: Continuation at 6 weeks, 3 months, 6 months, 9 months.

Expulsion rate

The overall expulsion rate during the 9-month follow-up was 4.9%, with rates of 5.5% in the CuT 380A group and 4.1% in the CuT 375 group (p=0.320). Expulsions occurred at 6 weeks only in the CuT 375 group (2.8%), at 3 months only in the CuT 380A group (2.8%) and at 6 months in both groups (2.8% in CuT 380A and 1.4% in CuT 375), with no expulsions observed at 9 months; most expulsions occurred within the first 6 months postpartum.

Removal rate

During the 9-month follow-up period, the overall IUCD removal rate was 4.9%. Removals occurred at 6 weeks only in the Cu T 380A group (2.8%), at 3 months only in the Cu T 375 group (1.4%) and by 9 months were reported in 4.2% and 1.4% of participants in the Cu T 380A and Cu T 375 groups, respectively. Common reasons for removal included bleeding and pain abdomen.

Continuation rate

Continuation rates remained high in both groups throughout the 9 months follow-up period. In the CuT 380A and CuT 375 groups, continuation rates were 94.4% and 95.8% at 6 weeks, 91.7% and 94.4% at 3 months, 88.9% and 93.1% at 6 months and 84.7% and 91.7% at 9 months, respectively. Overall continuation rates were 95.1%, 93.1%, 91.0% and 88.2% at the corresponding follow-up visits. Discontinuation due to expulsion, removal and loss to follow-up remained low, with only 2.1% of participants lost to follow-up.

Comparison of acceptability

The acceptability of PPIUCD in both groups depends on number of several factors. Demographic factor as shown in Table 2 including age, religion, literacy, socioeconomic status. Other factors as shown in Table 3 like gravida, timing of counselling, type of LSCS, partner permission and its non-hormonal nature.

Comparison of safety

The safety of PPIUCD refers to the absence or low occurrence of adverse effects, complications or health risks associated with its insertion and use in the postpartum period. As shown in Table 4 it is assessed by monitoring the incidence of complications such as expulsion of the IUCD, excessive bleeding (menorrhagia), lower abdominal pain, infection including pelvic infection, missing threads and rare events like uterine perforation.

In the study, the most common adverse event during follow-up in both groups was bleeding per vagina. At 6 weeks, bleeding was reported in 16.7% of women in Group A (Cu T 380 A) and 11.1% in Group B (Cu T 375), followed by abdominal pain (5.6% vs 4.2%), lost string (5.6% vs 1.4%) and vaginal discharge (4.2% in both groups), which was managed according to NACO guidelines.[9]

By 9 months, the pattern remained similar, with bleeding (8.3% vs 6.9%), abdominal pain (6.9% vs 2.8%), vaginal discharge (5.6% vs 6.9%) and lost string (4.2% vs 1.4%) being the common adverse events. Only one case of intrauterine pregnancy with IUCD in situ was reported in Group A, which was managed with medical termination of pregnancy and IUCD removal, while no cases of uterine perforation or expulsion were observed at 9 months.

A total of 83.3% of women in Group A and 90.3% in Group B recommended IUCD use to their friends and family members, with no statistically significant difference between the groups. Similarly, 87.5% of women in Group A and 93.1% in Group B reported satisfaction with IUCD use, (p=0.261, Chi-square test). Discontinuation in our study included expulsion, loss to follow-up and voluntary removal. Expulsions occurred spontaneously, while removals were mainly due to bleeding per vaginum, partner-related concerns, fear of delayed future pregnancy, abdominal pain and religious beliefs.

Table 1: Continuation at 6 weeks, 3 months, 6 months, 9 month.

Time	Continuation	CuT 380 A		CuT 375		Total		P value
		n=72	%	n=72	%	n=144	%	
6 weeks	Continuation	68	94.4	69	95.8	137	95.1	0.843
	Expulsion	0	0	2	2.8	2	1.3	
	Removal	2	2.8	0	0	2	1.3	
	Loss of follow up	2	2.8	1	1.4	3	2.1	
3 months	Continuation	66	91.7	68	94.4	134	93.1	0.776
	Expulsion	2	2.8	0	0	2	1.3	
	Removal	0	0	1	1.4	1	0.07	
	Loss of follow up	2	2.8	1	1.4	3	2.1	
6 months	Continuation	64	88.9	67	93.1	131	91	0.670
	Expulsion	2	2.8	1	1.4	3	2.1	
	Removal	0	0	0	0	0	0	
	Loss of follow up	2	2.8	1	1.4	3	2.1	
9 months	Continuation	61	84.7	66	91.7	127	88.2	0.433
	Expulsion	0	0	0	0	0	0	
	Removal	3	4.2	1	1.4	4	2.77	
	Loss of follow up	2	2.8	1	1.4	3	2.1	

Chi- square test; p>0.05 not significant.

Table 2: Acceptance of IUCD determine by demographic factor.

Demographic factor	CuT 380 A		CuT 375		Total		P value
	n=72	%	n=72	%	n=144	%	
Age group (in years)							
18-25	48	67	52	72	100	69	0.713
26-30	18	25	16	22	34	24	
31-35	6	8.3	4	5.6	10	6.9	
Mean	23.83±4.31		23.33±4.00				
Religion							
Hindu	18	25	14	19	32	22	0.423
Muslim	54	75	58	81	112	78	
Literacy							
Illiterate	8	11	9	13	17	12	0.796
Literate	64	89	63	88	127	88	
SES							
Lower	24	33	35	49	59	41	0.293
Lower middle	20	28	14	19	34	24	
Middle	16	22	12	17	28	1	
Upper middle	12	17	11	15	23	16	

Table 3: Others factors influencing acceptance of IUCD type among participants.

Others factor	CUT380		CUT 375			
Time of counselling						
ANC	55	76.4	60	83.3	115	79.9
Early labour	17	23.6	12	16.7	29	20.1
C section						
EL-LSCS	51	70.8	52	72.2	103	71.5
Em-LSCS	21	29.2	20	27.8	41	28.5
Gravida						
Multigravida	58	80.6	54	75.0	112	77.8
Primigravida	14	19.4	18	25.0	32	22.2
Allowed by partner						

Continued.

Others factor	CUT380		CUT 375			
No	13	18.1	9	12.5	22	15.3
Yes	59	81.9	63	87.5	122	84.7
Prefer due to Non hormonal device						
No	7	9.7	4	5.6	11	7.6
Yes	65	90.3	68	94.4	133	92.4

Most participants received counselling during ANC (79.9%), underwent elective LSCS (71.5%), were multigravida (77.8%), had partner permission for IUCD insertion (84.7%) and chose IUCD because of its non-hormonal nature (92.4%). These characteristics were comparable between the Cu T 380A and Cu T 375 groups, with no statistically significant differences (p>0.05).

Table 4: Comparison of safety outcomes of Cu T 380A and Cu T 375 at 6 weeks, 3, 6 and 9 months.

	Outcomes at 6 weeks				Outcomes at 3 month				Outcomes at 6 month				Outcomes at 9 month			
	CuT 380 A	CuT 375	Total	P value	CuT 380 A	CuT 375	Total	P value	CuT 380 A	CuT 375	Total	P value	CuT 380 A	CuT 375	Total	P value
	N (%)	N (%)	N (%)		N (%)	N (%)	N (%)		N (%)	N (%)	N (%)		N (%)	N (%)	N (%)	
Lost string	4 (5.6)	1 (1.4)	5 (3.5)	0.324	5 (6.9)	2 (2.8)	7 (4.9)	0.628	4 (5.6)	1 (1.4)	7 (4.9)	0.481	3 (4.2)	1 (1.4)	4	0.587
Pain in abdomen	4 (5.6)	3 (4.2)	7 (4.9)	0.776	6 (8.3)	3 (4.2)	9 (6.3)	0.692	5 (6.9)	2 (2.8)	7 (4.9)	0.550	5 (6.9)	2 (2.8)	7	0.511
Bleeding	12 (16.7)	8 (11.1)	20 (13.9)	0.512	8 (11.1)	6 (8.3)	14 (9.7)	0.875	7 (9.7)	5 (6.9)	12 (8.3)	0.816	6 (8.3)	5 (6.9)	11	0.812
Vaginal discharge	3 (4.2)	3 (4.2)	6 (4.2)	0.843	3 (4.2)	4 (5.6)	7 (4.9)	0.494	5 (6.9)	6 (8.3)	11 (7.6)	0.902	4 (5.6)	5 (6.9)	9	0.831
PID	0	0	0	-	1 (1.4)	0	1 (0.7)	0.714	1 (1.4)	1 (1.4)	2 (1.4)	0.917	0	0	0	-
Expulsion	0	2 (2.8)	2 (1.4)	0.494	2 (2.8)	0	2 (1.4)	0.494	0	1 (1.4)	3 ((2.1)	0.831	0	0	0	-
Uterine perforation	0	0	0	-	0	0	0	-	0	0	0	0	0	0	0	-
Pregnancy	0	0	0	-	0	0	0	-	0	0	0	-	1 (1.4)	0	1 (0.7)	0.603

Table 5: Reasons of IUCD removals in both groups.

Reason of removal	CuT 380 A		CuT 375		Total		
	N	%	N	%	N	%	
Bleeding per vaginum	2	2.8	0	0	2	1.4	**P value**
Due to partner	0	0	1	1.4	1	0.7	
Fear to delay pregnancy	1	1.4	0	0	1	0.7	**0.216**
Pain in Abdomen	0	0	1	1.4	1	0.7	
Religious basis	2	2.8	0	0	2	1.4	

Chi-square test; p>0.05 not significant.

DISCUSSION

Intra-caesarean insertion ensures reliable contraception before hospital discharge. Several studies demonstrated that this procedure does not increase the risk of infection or other complications associated with intra caesarean IUCD insertion.[11] The WHO recommends that PPIUCD insertion can be initiated during the immediate postpartum period without interfering with breastfeeding.[9] Both groups were comparable with respect to baseline demographic characteristics including age, religion, literacy and socioeconomic status, with no statistically significant differences. In 2017, Xess et al reported that the maximum number of women were in the age group below 25 years (50.9% in CuT 380 A and 48.2% in CuT 375) and with higher acceptance in the lower socioeconomic class (35%), followed by the lower middle class (28.1%) which was almost similar to the study.[2] The present study demonstrated high continuation rates for both CuT 380A and CuT 375. Overall continuation rate of 88.2% observed in this study is consistent with previously reported rates in postpartum IUCD studies. In 2017 Kumar et al reported continuation rates of 80.6% for Cu T 380A and 83.3% for Cu T 375 over a 12 months period.[12] Similarly Sneha et al observed continuation rates of 83.3% at 6 weeks and

65.6% at 6months.[13] Gudi et al reported continuation rates of 90% and 83.33% at 6 months in two study groups.[14]

Expulsion and removal rates were low in both groups, with an overall expulsion rate of 4.9% and removal rate of 4.9%. In Sneha et al reported an expulsion rate of 5.6%, while Gudi et al reported expulsion rates of approximately 4% at 6 weeks and 1.31% at 6 months and removal rates reported by these studies were also comparable.[13] Gudi et al found a removal rate of 3.58% at 6 weeks and 0.84% at 6 months.[14]

A high proportion of women (79.9%) received counselling during antenatal care, which likely contributed to the high acceptance of postpartum IUCD insertion observed in this study. In comparison, Sneha et al also reported a 73.1% acceptance rate during antenatal counselling, which decreased to 34.8% during early labour.[13] Most women chose IUCD because of its non-hormonal nature (92.4%) and a large proportion had partner support for the method (84.7%). While in studies of Gudi et al reported that 26.54% of women accepted the PPIUCD because it was allowed by their partner and only 1.53% accepted the device due to its non-hormonal nature.[14] Satisfaction rates were also high, with 87.5% of women in the CuT 380 A group and 93.1% in the CuT 375 group reporting satisfaction, although this difference was not statistically significant (p=0.261). Similarly, a majority of women recommended IUCD use to others.

Both IUCD types were well tolerated, with bleeding per vaginum being the most common adverse event followed by abdominal pain, vaginal discharge and lost strings, while PID was rare and no cases of uterine perforation or sepsis were reported, with no statistically significant differences between the groups. Kumar et al reported no cases of PID in the CuT 375 group, while there were three cases of PID in the Cu T 380A group.[12] One case of intrauterine pregnancy with IUCD in situ occurred in the Cu T 380 A group and was managed with medical termination and IUCD removal and there was no case of intrauterine pregnancy with CuT 375 groups. The incidence of bleeding in the CuT380A group was 16.7%, 11.1%, 9.7% and 8.3% women at six weeks, three months, six months and nine months of follow-up, respectively as compared to in the Cu T 375 group where incidence of bleeding was 11.1%, 8.3%, 6.9% and 6.9% women at the same follow-up intervals. In Gudi et al also reported bleeding in 4.16% of cases at six weeks and 1.58% at six months.[14] In 2023 Sneha et al observed bleeding in 10.7% of cases at six weeks and 10.2% at three months.[13] All the women responded to medical management except where removal was done.

Removal was mainly due to bleeding, abdominal pain, partner-related concerns, fear of delayed future pregnancy and religious beliefs. Both Cu T 380A and Cu T 375 proved to be safe, effective and acceptable, with low and comparable expulsion and removal rates and no major complications, supporting the safety of intra-caesarean IUCD insertion. The expulsion rate in this study was low compared with interval IUCD insertion studies done by Tyagi et al and removal rates were low and comparable between both groups.[8] The most common reasons for removal were abnormal bleeding and abdominal pain

Although CuT 375 showed slightly higher continuation rates, the difference was not statistically significant. Therefore, both devices appear equally suitable for intra-caesarean insertion.

CONCLUSION

The study concludes that Intra-caesarean insertion of CuT 380A and CuT 375 is a safe, effective and acceptable postpartum contraceptive method with comparable continuation, expulsion and removal rates and minimal complications. Effective counselling is essential to improve acceptability and continuation, supporting integration of PPIUCD services into routine postpartum family planning.

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