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Effect of the timing of insertion of postpartum intrauterine contraceptive device (PPIUCD) copper T380A on expulsion rates

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***Background & objectives*: Postpartum intrauterine contraceptive device (PPIUCD) is well accepted and recommended for contraception. However, anxiety at the time of delivery may restrict the acceptance of a PPIUCD for its immediate insertion. So far there is limited evidence to conclude anything concrete on the association between the expulsion rates and the timing of insertion following a vaginal delivery. Thus, this study was undertaken to compare the expulsion rates in immediate and early insertions and their safety and complications.**

***Methods*: This prospective comparative study was carried out over 17 months on women delivering vaginally in a tertiary care teaching hospital in South India. A copper device (CuT380A) was inserted using Kelly's placental forceps either within 10 min of placental delivery (immediate group, n=160) or between 10 min upto 48 h postpartum (early group, n=160). Ultrasound was done before discharge from the hospital. The expulsion rates and any other complications at six-week and three-month follow up were studied. Chi-square test was used to compare the difference in expulsion rates.**

***Results*: The expulsion rate was five per cent in the immediate compared to 3.7 per cent in the early group (no significant difference). In ten cases, the device was found to be in the lower uterus upon ultrasound before discharge. These were repositioned. There was no case with perforation, irregular bleeding or infection up to the three-month follow up. Higher age, higher parity, lack of satisfaction and motivation to continue were predictors of expulsion.**

***Interpretation & conclusions*: In the present study PPIUCD was found to be safe with overall expulsion in 4.3 per cent. It was marginally, though not significantly, higher in the immediate group.**

Key words Contraception - copper device - copper T 380A - expulsion rates - intrauterine device - postpartum contraception

Postpartum intrauterine contraceptive device (PPIUCD) is a well accepted concept and was recommended and adopted by the Government of India since 2010[1]. It can be inserted within 10 min of a placental delivery (immediate insertion) or after 10 min and upto 48 h of delivery[2,3]. However, higher expulsion rates reported with early versus immediate postpartum insertion are of concern[4]. In a systematic review from 2009[5], the early group was reported to have higher expulsion rates in comparison to the immediate

insertion. However, many of the included studies were heterogeneous including both intra-caesarean and post-vaginal delivery insertion and including various intrauterine devices. Anxiety about the baby condition for the first 24 h may come in the way of whole-hearted acceptance of immediate insertion in spite of antenatal counselling[6]. The 2015 Cochrane analysis reported limited evidence to conclude on the expulsion rates based on the timing of insertion following vaginal delivery[7]. Hence, this study was undertaken with the primary objective of comparing the expulsion rates in the immediate and early PPIUCD insertions and furthermore of study to the safety and complications post PPIUCD insertions after vaginal deliveries.

Material & Methods

This prospective comparative study was carried out in department of Obstetrics and Gynecology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, which is a tertiary care teaching hospital located in the south of India. The study was carried out from July 2017 till December 2018 after obtaining approval from the scientific committee and Institute Ethics Committee. There were about 1500 deliveries every month. Intense counselling was undertaken in the antenatal as well as during labour and in the post-natal wards as a part of the study. Women delivering vaginally and were motivated and willing for intrauterine contraceptive device (IUCD) insertion during the puerperal period were included in this study. Women with a prior caesarean scar, chorioamnionitis, prolonged rupture of membranes, postpartum complications and any known uterine malformations were excluded from the study. Intra-caesarean insertions were not included in the study. Based on the timing of insertion, two groups were studied, (*i*) immediate group: IUCD inserted within 10 min of placental delivery; and (*ii*) early group: devise inserted between 10 min upto 48 h postpartum. The participants were allocated to either group based on their preference. The device used was copper T 380A (CuT380A) (HLL Lifecare Ltd., Kerala, India).

Assuming alpha error of five per cent, power of 80 per cent, expulsion rate with postpartum insertion as 12 per cent[4] and two times higher rates in the delayed postpartum insertion group[5], the sample size come upto 160 per group. The device was inserted under aseptic precautions using Kelly's Placental Forceps. All the insertions were carried out by consultants or post-degree doctors after on-site and on-the-job training. Ultrasound was carried out to confirm the correct placement of the device prior to discharge of every study participant from the hospital. The data were collected in a pro forma, and all the participants were followed up at six weeks and three months.

Statistical analysis: The data were analyzed using IBM SPSS Statistics for Windows version 22.0 (IBM Corp. Armonk, NY, USA). The two groups were compared for expulsion rates and other complications. All categorical variables such as age parity gravida and IUCD expulsion were expressed as percentages with 95 per cent confidence interval. Expulsion rates in the two groups were analyzed using the Chi-square test. $P<0.05$ was taken as statistically significant. Factors associated with expulsion were also analyzed.

Results

A total of 1550 women were counselled during the antenatal period and/or during labour for considering PIUCD insertion. 320 women (20.6% acceptance rate) accepted the IUCD and completed the study.

More than 85 per cent of the recruited women in either group belonged to Tamil Nadu. They delivered at the study hospital either because their maternal home was in Puducherry or because they sought to deliver there for the quality and free care.

Most of the demographic variables (Table I) were comparable in the two groups. We found that higher income of the husbands was more likely to be associated with early rather than immediate insertion ($\chi^2=9.8015$. $P=0.002$) and women with previous use of contraception were more likely to opt for immediate insertion ($\chi^2=27.28$. $P=0.001$).

In all the 320 cases recruited, the IUCD was inserted with Kelly's placental forceps. There was no technical issues experienced at the time of inserting the IUCD. However, three in the immediate group and seven in the early group were found to have the IUCD inserted in the lower part of the uterus at the time of check scan. The same was repositioned to the fundus of the uterus.

At six week follow up (Table II), many women did not come for check up, but they responded to phone call. Five in the immediate group and six in the early group expelled the IUCD by six weeks. These women responded to phone call only and were not keen on reinsertion. Pain was the only complaint encountered. In nine women (1 in the immediate and 8 in the early group, out of a total 155 who came for the six week

Table I. Frequency distribution of demographic characteristics of the two groups

Baseline demographic variables	Immediate group (n=160), n (%)	Early group (n=160), n (%)	χ^2, *P*
Age (yr)			
18-23	105 (65.6)	111 (69.4)	0.54, 0.763
24-30	51 (31.9)	45 (28.1)	
>30	4 (2.5)	4 (2.5)	
Mean age (yr)	22.77	22.33	
Wife's education			
Graduate	93 (58.1)	109 (68.1)	3.47, 0.176
More than graduate	66 (41.3)	50 (31.3)	
Illiterate	1 (0.6)	1 (0.6)	
Wife's occupation			
Working	11 (6.9)	12 (7.5)	0.046, 0.829
Housewife	149 (93.1)	148 (92.5)	
Husband's education			
<graduate	117 (73.1)	124 (77.5)	1.02, 0.312
>graduate	43 (26.9)	35 (21.9)	
Illiterate	0 (0)	1 (0.6)	
Husband's occupation			
Professional	22 (13.8)	10 (6.2)	5.01, 0.082
Skilled	135 (84.4)	147 (91.9)	
Semiskilled	3 (1.8)	3 (1.9)	
Husband's monthly income			
>Rs. 2000	67 (41.9)	95 (59.4)	9.80, 0.002
<Rs. 2000	93 (58.1)	65 (40.6)	
Religion			
Hindu	150 (93.8)	149 (93.1)	0.44, 0.799
Muslim	5 (3.1)	7 (4.4)	
Christian	5 (3.1)	4 (2.5)	
State of residence			
Tamil Nadu	146 (91.3)	142 (88.8)	0.55, 0.456
Pondicherry	14 (8.8)	18 (11.2)	
Parity			
Primipara	120 (75)	126 (78.8)	0.63, 0.426
>Primipara	40 (25)	34 (21.2)	
Previous delivery (prior to index delivery)			
Government hospital	36 (22.5)	32 (20)	1.05, 0.592
JIPMER	4 (2.5)	2 (1.3)	
Not applicable (primigravida)	120 (75)	126 (78.7)	
Previous abortions			
Yes	21 (13.1)	14 (8.8)	1.57, 0.210
No	139 (86.9)	146 (91.3)	

Contd...

Baseline demographic variables	Immediate group (n=160), n (%)	Early group (n=160), n (%)	χ^2, *P*
Use any contraceptive earlier			
Yes	117 (73.1)	71 (44.4)	27.28, 0.001
No	43 (26.9)	89 (55.6)	

Table II. Findings at six week follow up in the two groups

Study group	Follow up at six weeks n (%)	Speculum findings n (%)	PV findings (n)	USG (n)	Complaints (n)
Immediate group (n=160)	Direct check up=81 (50.6)	Threads at vagina (same cut short)=80 (98.7)	Uterus normal size (81)	Device in the uterus (81)	None (155)
		Threads not seen out of cervix=1 (1.3)			Pain (5)
	Phone call=79 (9.4)			Expelled (5)	
Early (n=160)	Direct check up=74 (46.25)	Threads at vagina (same cut short)=66 (89.2)	Uterus normal size (74)	Device in the uterus (74)	None (155)
		Threads not seen=8 (10.8)			Pain (5)
	Phone call=86 (53.75)			Expelled (6)	

USG, ultrasonography; PV, per vaginal

check up), the threads were not seen. They were reassured as the device was confirmed to be intrauterine by sonography. In the immediate group, there were three more expulsions (Table III). These three women were not willing for a reinsertion.

The threads were cut short if these were lower down in the vagina. However, if seen only at level of the cervical os, these were not cut. The threads were seen in all the women at three-month follow up. In one woman, the thread was not seen at six weeks. This was seen at the level of cervix at three month follow up. It was observed that in the immediate group out of 160, there were eight expulsions; 104 women required cutting of thread (80 at 6 wk and another 24 at 3 months) and in 48 women, the thread was seen only at the level of cervix and was never cut.

In the early group out of 160, there were six expulsions. Eighty three women (66 at 6 wk and another 17 at 3 months) required cutting of the threads. The rest of the 71 women did not require cutting of threads as the threads were seen at the cervix only. The threads were not seen in eight women at six weeks in the early group. Five of these eight were at the level of cervix and three low in vagina at three month follow up.

The outcome variable in the two groups is shown in Table IV. There was a total of eight expulsions in the immediate (5%) and six (3.7%) in the early group. There was no case of perforation or excessive bleeding upto the three month follow up period. Ten women in the early and six in the immediate group had pain as the only complaint. None of the women were found to have clinical symptoms or signs of infection. Women in the immediate group were significantly more satisfied (n=155; 96.9%) as compared to those in the early group (n=143, 89.4%). The satisfaction was regarding the subjective feeling of use of IUCD as the method of contraception without any problems and regret (χ^2=7.029, *P*=0.008, 95% CI - 0.87-0.98).

At the end of the three months, all the patients who did not expel the IUCD were motivated to continue the IUCD. None of them requested a removal.

On univariate analysis (Table V), we found that women with lower age, lower parity, lower husband income, motivation to continue and higher satisfaction were less likely to expel the IUCD.

Discussion

In this study, the acceptance rate for PPIUCD was 21.3 per cent as compared to nine to 17 per cent

Table III. Follow up characteristics of the two groups at three months

Total	Speculum findings			Vaginal exam (n)	USG (n)	New complaints after six weeks (n)
	Thread seen at introitus. Same cut short to cervix level, n (%)	Threads seen at cervix level, n (%)	Threads shortened to cervix level at six weeks itself now also seen at cervix, n (%)			
Immediate (n=160−5 expelled before six weeks=155−3 new expulsion=152)	24 (15.8)	48 (31.6)	80 (52.6)	Uterus normal size (152)	Device in uterus (152)	Pain (1)
Early (n=160−6 expelled before six weeks=154) no new expulsions	17 (11)	71 (46)	66 (43)	Uterus normal size (154)	Device in uterus (154)	Pain (5)

USG, ultrasonography

Table IV. Comparison of primary and secondary outcome in the two groups

Complaints	Immediate group, n (%)	Early group, n (%)	Statistical significance
Pain			
Yes	6 (3.75)	10 (6.25)	RR=1.64
No	154 (96.25)	150 (93.75)	χ^2=1.008, df=2
			P=0.317
			95% CI=0.613-4.4
Bleeding infection			
Yes	0 (0)	0 (0)	-
No	160 (50)	160 (50)	
Expulsion			
Yes	8 (5)	6 (3.75)	RR=0.75
No	152 (95)	154 (96.25)	χ^2=0.299, df=1
			P=0.585
			95% CI=0.266-2.11
Satisfaction			
Very	5 (3.1)	17 (10.6)	χ^2=7.02, df=1
Not very	155 (96.9)	147 (89.4)	*P*=0.008
			95% CI=0.87-0.98

RR, relative risk; χ^2, Chi-square value; df, degree of freedom; CI, confidence interval

rate of acceptance as observed in other studies[8-10]. In a six-centre study[11], the acceptance rate was found to be only five per cent. In this study intense one-to-one and small group counselling sessions with videos and pamphlets were carried out. Counselling was carried out in the antenatal clinics as also during early labour and in the post-natal period. The reasons for non-acceptance in this study were not explored. In an earlier study from our group, we found that lack of family support, negative attitude and preferring to use natural methods were the causes for lower acceptance[12].

In our study, all the insertions were carried out by consultants or qualified trained doctors. All the insertions were based on standard procedure using Kelly's placental forceps. An overall expulsion rate of 4.4 per cent was found among the study participants. Higher expulsion rates have been described in other studies[7,8,13]. Expulsion rate varying from 3-7 per cent has been reported over the last few years[14-16]. In a study published in 2019 on 372 women with mixed population of vaginal and caesarean delivery, the expulsion rate was found to be 4.2 per cent[17]. The expulsion rate has declined with the standardized

Table V. Factors associated with expulsion of post-partum intrauterine contraceptive device in the study population (n=320)

Factor	Expulsion			χ^2, P	RR (95% CI)
	No	Yes	Total (n=320)		
Age (yr)					
18-23	209	7	216	21.6565	1.2 (0.38-4.2)
24-30	92	4	96	<0.001	
>30	5	3	8		11.57 (3.6-36.6)
Parity					
Primipara	240	6	246	9.5302	4.4 (1.59-12.3)
Multipara	66	8	74	0.002	
Religion					
Hindu	288	11	299	12.9597	6.7 (2.1-21.1)
Muslim	9	3	12	0.002	
Christian	9	0	9		
Husband monthly income (₹)					
>2000	159	3	162	4.9928	3.75 (1.06-13.22)
<2000	147	11	158	0.025	
Motivation to continue					
Yes	306	0	306	320	
No	0	14	14	0.001	
Satisfaction					
Yes very	295	3	298	117.547	
Only fair	11	11	22	0.001	
Timing of insertion					
Immediate	152	8	160	0.299	0.75 (0.266-2.11)
Early	154	6	160	0.585	

RR, relative risk; CI, confidence interval

method of insertion with the Kelly's placental forceps and improved training over the years.

In our study, the expulsion rate was marginally higher at five per cent in the immediate (post-placental) group and 3.7 per cent in the early group (beyond 10 min up to 48 h of placental delivery). A higher expulsion rate in the immediate group compared to the early group was also reported in other published observational studies[11,18]. Only two randomized trials[19,20] have compared the expulsion rates of the device CuT380A based on the timing of insertion. In the trial by Ahuja and Rahtore[19], 108 women were recruited into the two groups. Similar to our study in this study also, all insertions were with instrument. The authors found that that the expulsion rates were significantly higher at 24.11 per cent in the early (10 min to 48 h group) and 9.11 per cent in the immediate post-placental group. In the trial by Singh *et al*[20], immediate post-placental IUCD insertion (n=100) demonstrated lower expulsion rate of 8.3 per cent compared to 10.5 per cent with early post-partum insertion though it was not found to be significant. In the latter study, caesarean cases were also included. It is not specified in these two trials whether ultrasonography was done after insertion[20].

The present study ultrasonography was carried out for all women before discharge from the hospital. Three in the immediate and five in the early group were found to have a low placement of the device. The same were repositioned to the fundus of the uterus. Dias *et al*[21] observed that the distance of lower end of the device from the internal os predicted expulsion with reasonable accuracy. Thus, routine ultrasound in our study helped us pick up eight cases which could have expelled the IUCD if not repositioned.

No case of infection in the present study was found to be similar to other reports[8,22]. As a policy,

no antibiotics were prescribed following PPIUCD insertion. Strict aseptic measures were followed for delivery and no touch technique was followed for loading the device to the Kelly's forceps.

Univariate analysis showed that lower age, lower parity, higher spousal income, motivation to continue and higher satisfaction were associated with lower risk of expulsion. In a study by Kant *et al*[23] also, higher age and parity was associated with higher expulsion rates.

All these women were found to be normal on pelvic exam and sonography. Abdominal pain was the only complaint but all of them responded to pain killers.

The continuation rate among the women who did not expel was found to be 100 per cent in our study. This may possibly be due to the intense antenatal and post-delivery counselling by a committed team. The limitation of this study is that we designed the groups based on women's preference. However, randomized would have been the best approach to bring out the differences in expulsion rate based on timing of insertion.

Overall, this study found PPIUCD to be safe with no observed complications of perforation, infection or bleeding. Higher age, higher parity, lower spousal income, lack of satisfaction and motivation to continue were found to be the predictors of expulsion. The findings of this study may only be extrapolated with inclusion of intense counselling in the antenatal clinic and follow up counselling in labour and post-delivery.

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