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RESEARCH ARTICLE

A randomised study to compare Cu T 380A and Cu 375 as postpartum intrauterine contraceptive method

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ABSTRACT

Objectives: To compare the efficacy of Cu T 380 A and Cu 375 in terms of failure rates. To compare side effects, expulsion rates, acceptability and problems experienced while using the two intrauterine devices. **Method: A** randomized case control study was conducted on 320 postpartum women willing for PPIUCD insertion after normal vaginal delivery.160 women each group A and B were inserted with IUCD Cu T 380A and Cu 375 respectively. Follow up visits were done at 6 weeks, 6 months and 1 year. Observations were recorded and comparative analysis was done. **Results:** Acceptability of PPIUCD was very high in both groups, 71.25 % (n=114) in group A and 79.38 % (n=127) in Group B. Menorrhagia was reported amongst 6.52% women in group A and 11% in group B at the end of 1 year of follow up. In group A, 22 (15.28%) women and 18 (12.85%) women in group B had expulsion of IUCD over one year. IUCD removal was rate was 30 (18.75%) women in group A and 23 (14.38%) in group B. Overall continuation rate at one year was 57.5% in group A and 62.5% in group B (P value=0.59). No failure was reported. **Conclusion**: Cu T 380 A and Cu 375 were found to be similar in terms of efficacy, complications and expulsion rates. Overall satisfaction was higher for Cu 375 than Cu 380A.

Keywords: PPIUCD, intrauterine contraceptive device, copper T, postpartum, long-acting reversible contraceptive.

India is the most populous country in the world and the population in our country is also one of the youngest in the world [1]. Even though fertility rates have declined, the large number of young reproductive population will continue to increase the overall population resulting in a continuous higher need for family planning services. In our country family size limitation relies too heavily on permanent method of contraception in the form of female sterilization and there is a large unmet need for temporary methods.

Another major problem in India is short interpregnancy interval which contributes to higher maternal morbidity and mortality. We expect that the long-acting reversible contraception usage will increase the birth intervals and thereby reduce the incidence of anemia, abortions, premature labor, PPH, low birth weight babies, fetal loss and maternal death.[2]

The current contraceptive prevalence rate in the married women aged 15 to 49 is only about 54%.[3] In Indian community early conception after marriage is very common. Most couples avoid using contraception soon after the marriage. It's also observed that after childbirth couples do not think about contraception immediately believing that the breast feeding will protect the subsequent childbirth for some time. The time passes quicker than the realization and then they either don't have the felt need for contraception or it remains as an unmet need. It has been found that only 26% of women use contraception during the first year postpartum.[4] These factors result in a load of unintended pregnancies. There is thus a compelling need for long-acting reversible contraception for both spacing and family size limitation.

The family planning program in India is now promoting

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the use of postpartum contraception especially postpartum intrauterine devices as long-acting reversible method. The use of copper IUCD in the immediate postpartum period, including after cesarean delivery, has category 1 rating in the WHO medical eligibility for contraceptive use.[5] A wider choice of basket to the women is known to increasethe acceptability. Therefore, this study was done to compare copper T 380A and Cu 375, the two most commonly used IUCD in our family planning units, as postpartum contraceptive methods. Their efficacy, safety and complications were compared.

Objectives: To compare the efficacy of Cu T 380 A and Cu 375 in terms of failure rates. To compare side effects (abnormal bleeding, vaginitis and dysmenorrhea) expulsion rates, acceptability and problems experienced while using the two intrauterine devices.

Materials and methods

We conducted a prospective case control study in postpartum women who delivered vaginally in the labor room of obstetrics department of Dr. Baba Saheb Ambedkar Hospital & Medical College over a period of 12 months (March 2017- 2018).

Sample size was calculated based on the basis of study by Shazia A Khan et al using the following formula.[6]

$$n \geq \frac{p_C(1-p_C)+p_E(1-p_E)}{\delta_0^2}(Z_\alpha + Z_\beta)^2$$

$n \geq [0.97\times(1\text{-}0.97) + 0.89\times(1\text{-}0.89)] / (0.97\text{-}0.89)^2 \times (1.96+0.84)^2 = 155.575 = 156$ (approx).

$\delta_0 = P_c - P_E$; Where Z_α is value of Z at two-sided alpha error of 5% and Z_β is value of Z at power of 80%. A sample size of minimum 160 women in each group was calculated.

Study was started after getting ethical clearance from the ethical committee of the hospital for registration number 125 - 20110 – 161 - 209423. Computer generated random numbers were used to divide the women in two groups. Group A were those who received Cu T 380A and group B were inserted with Cu 375. Women were counseled routinely for PPIUCD insertion in ANC clinic, during early labor and in immediate postpartum period. Those who agreed were screened for inclusion and exclusion criteria and were enrolled in the study after informed consent. Inclusion criteria were postpartum women within 48 hours of delivery who came under WHO MEC category 1 and 2 and were willing to follow up. Exclusion criteria were WHO MEC category 3 (between 48 hours and 6 weeks postpartum, chorioamnionitis and prolonged rupture of membranes >18 hours) and category 4 (puerperal sepsis and unresolved PPH) for PPIUCD.[5]

Demographic profile including age, socioeconomic status, and education was noted. Detailed history was recorded including fever, unhealthy vaginal discharge, prolonged rupture of membranes, chorioamnionitis, past history of IUCD usage, history of STD and any past medical or surgical illness etc. Complete general physical and systemic examination was done to rule out any active infection.

Insertion was done as per standard protocol according to guidelines of Government of India using Kelly's forceps.[3] After insertion, initial assessment was done after 72 hours. Women's experience regarding PPIUCD was asked for and complaints if any were recorded. Signs of pelvic inflammation were looked for. Thereafter women were called up for follow up at 6 weeks, 6 months and 1 year. History of pain, dysmenorrhea, menstrual irregularity, PID, feeling the IUCD thread and any other problem was enquired and recorded. Women were explained to report back in case of missing thread or any warning sign of infection or missed period. If a woman requested for removal of IUCD, reasons for removal of IUCD were noted and if deemed right woman was counseled against removal too. The women who didn't visit the hospital were followed telephonically.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables were compared using unpaired t-test/Mann-Whitney test (when the data sets were not normally distributed) between the two groups. A p value of <0.05 was considered statistically significant.

Results

Study was conducted on 320 postpartum women who agreed for IUCD as contraceptive method. Both groups A and B had 160 women each. The demographic profile with respect to age, socioeconomic status and religion was comparable in both groups with no statistically significant difference (table 1). Maximum numbers of women in the study population were in the age group of 21-30 years (81.56%). Mean age in group A was 24.74 ± 3.98 years and in group B was 24.36 ± 3.66 years. Maximum number (72.19%) of the IUCD acceptors in both groups belonged to

low socioeconomic status followed by middle socioeconomic status (27.81%). 87.81% were Hindus.

Table 1: Demography

Age in years	Group A N (%)	Group B N (%)	Total N (%)	P value
< 20 yrs	16(10.00%)	22(13.75%)	38(11.88 %)	0.430
20-30 yrs	135 (84.38 %)	126(78.75 %)	261(81.56 %)	
>30 yrs	9 (5.63 %)	12(7.50%)	21(6.56 %)	
Religion				
Hindu	138(86.25 %)	143(89.38 %)	281(87.81 %)	0.393
Muslim	22 (13.75 %)	17(10.63 %)	39(12.19 %)	
Socioeconomic status				
Lower	116 (72.50%)	115(71.88 %)	231 (72.19 %)	0.901
Middle	44(27.50 %)	45(28.13 %)	89(27.81 %)	

When acceptability of IUCD insertion was studies, 75.31% of the women agreed immediately, 18.75% women needed motivation while 5.94 % needed greater motivational effort before they consented. The difference between the groups was non-significant (p value - 0.283).

Table 2: Expulsion of PPIUCD

Expulsion of IUCD	Group A N (%)	Group B N (%)	Total N (%)	P value
At 6 weeks	17 (11.81 %)	14(10.00 %)	31(10.92 %)	0.945
At 6 months	4 (2.78 %)	3 (2.14 %)	7 (2.46%)	
At 1 year	1 (0.69 %)	1(0.71 %)	2(0.70%)	
Total expulsion	22 (15.28 %)	18 (12. 85 %)	40(13.45 %)	
No expulsion	122 (84 .72 %)	123 (87.84 %)	245 (85.92%)	
Total	144(100.00 %)	141 (100.00 %)	285(100.00%)	

Insertions were successful in first attempt in 92.19% women. Two attempts at insertion were needed in 6.88% women in group A and 8.75% in group B (p value - 0.532).

Table 3: Outcomes of PPIUCD at 1 year

Categories	Group A N (%)	Group B N (%)	Total N (%)	P value
Expulsions	22(13.75%)	18(11.25 %)	40 (12.50 %)	0.590
Removals	30(18.75 %)	23(14 .38 %)	53(16.56%)	
Total continuation	92(57.50 %)	100 (62.50 %)	192 (60.00 %)	

Pain perception was graded on Visual Analogue Scale (VAS) of 0 to 10, where 0 represents no pain and 10 represents severe pain. The mean VAS score was 2.34 ± 1.34 in group A and 23 ± 1.25 in group B. The difference between two groups was not statistically significant (p=0.413).

Table 4: Causes of PPIUCD removal

Causes	Group A N (%)	Group B N (%)	Total N (%)	P value
Social causes	10(33.3 %)	4(17.39 %)	14 (26.42 %)	0.350
Pain abdomen	1(3.33 %)	1 (4.35 %)	2(3.77%)	
Vaginal discharge	4 (13.33 %)	3(13.05 %)	7 (13.2 %)	
Menorrhagia	8 (26.66 %)	10 (43.48 %)	18 (33.96 %)	
For conception	7 (23.33 %)	4 (17.39 %)	11 (20.75 %)	
Wanted to other method of contraception	0 (0.00 %)	1 (4.35 %)	1 (1.89 %)	
Total	30(100 %)	23 (100 %)	53(100 %)	

Post insertions potting was reported by 14(15.22%) women in group A and 19 (19.00%) women in group B (p value - 0.48).

At 6 weeks follow-up, all women were amenorrhoeic, though 19 women in group A and 14 women in group B complained of spotting off and on. Dull aching lower abdominal pain was complained by 2 women in group A and none in group B. IUCD expulsion was noted in 17 and 14 women in group A and B respectively (p value= 0.945). Five women each in group A and B got the IUCD removed.

At 6 months follow-up 54 women in group A and 61 women in group B resumed menstruation. Lower abdominal pain was complained by 3 and 7 women in group A and B respectively. IUCD was expelled 4 and 3 women in group A and B respectively. In group A and B, 15 and 14 women respectively got the IUCD removed.

At the one year follow up 92 women in group A and 100 women in group B resumed menstruation. Abnormal uterine bleeding was reported by 7 women in group A and 12 in group B. Menorrhagia was reported by 6.52% (n=6) women in group A and 11% (n=11) in group B. Oligomenorrhea was reported by 1.09% (n=1) in group A and 1 % (n=1) in group B at end of 1 year follow up.

No women complained of pain abdomen. Total 11 PID cases were reported. 6 (6.52%) in group A and 5 (5.0%) in group B over a follow up of 1 year period. None was within 72 hours and one woman in each group had expelled IUCD whereas 10 in group A and 4 in group B got the IUCD removed.

In group A, 22(15.28%) women and 18(12.85%) women in group B had expulsion of IUCD over one year. Over all expulsion rate was 13.45%. Maximum expulsions were seen during first 6 weeks in both the groups, 11.81 % (17) and 10 % (14) in group A and B respectively. On comparing the expulsion rates, the difference was not found to be statistically significant in both groups (p value 0.945).

IUCD removal was requested despite counseling by 30 (18.75%) women in group A and 23 (14.38%) in group B. The causes for getting IUCD removed were analyzed (table - 3). Menstrual disturbances contributed for main cause of removal, next being the social causes.

Overall continuation rate at one year was 57.5% in group A and 62.5% in group B (p value=0.59). There were no failure of contraception and no misplaced IUCDs. Satisfaction levels were determined on a scale of 1-10 at the end of one year. In group A 97.8% and in group B 100% women gave a satisfaction score of more than 6. The difference in the level of satisfaction in two groups was statistically insignificant (p value=0.22).

Discussion

Postpartum contraception is extremely important for prevention of unintended pregnancies and for prolonging the interpregnancy interval. Birth spacing goes a long way not only in preventing many obstetric complications and maternal mortality, but it also reduces infant mortality and morbidity. In India 65% of women in first year postpartum have unmet need for family planning services.[4] The immediate postpartum period is the time period which offers a golden opportunity for introducing a long-acting reversible contraceptive method as there is plenty of interaction with health care professional during antenatal period and after delivery. Easy availability of contraceptive methods at this point of time and a wider choice increases the acceptance rate. PPIUCD is a safe and effective method of postpartum contraception which can be provided during the same visit for institutional delivery and eliminates the need for a return visit to start contraception. Postpartum IUCD (PPIUCD) service was introduced in 2010 in India. In 2012, the Cu 375 was introduced so that women could choose between Cu T 380 A with a lifetime of 10 years and Cu 375 with a lifetime of 5 years.

We compared Cu T 380A and Cu 375 and found that both IUCD are comparable in terms of efficacy, side effects and expulsion rates. Felt need for contraception and thus the acceptability of PPIUCD was high in both groups, 71.25 % (n=114) in group A and 79.38 % (n=127) in group B. Majority of PPIUCD insertions were done in first attempt in both groups, 93.13 % (n =149) in group A and 91.25 % (n=146) in group B. Menorrhagia was reported amongst 6.52% women in group A and 11% in group B at the end of 1 year of follow up. Over all expulsion rate was 13.45%. In group A, 22 (15.28%) women and 18 (12.85%) women in group B had expulsion of IUCD over one year. No failure was reported. 30 (18.75%) women in group A and 23 (14.38%) in group B got the IUCD removed for various reasons.

The mean age in our study in both the group was about 24 years which reflects the reproductive age in our population. Our study population was predominantly low social economic status that is 72.19% but despite that 75.31% of women accepted postpartum contraception immediately. Thus, we can say that contraceptive awareness was good and there definitely was a felt need in the population. Some people needed greater counseling and motivation which was mainly required to eradicate to eradicate their myths, ease out family hindrances and clarify the gravity of side effects perceived by their friends. It was noted that clear and emphatic counseling was a very important motivating factor. Motivating the women further increased the acceptability by another 20-30% which is a good percentage that can be enrolled for family welfare.

Pain perception during introduction of PPIUCD is dependent on the technique of insertion that is whether one uses hand method or the Kelly's forceps method, the experience of introducer and the patient sensitivity. In our study both groups reported a pain score below 5 on VAS scale. We had used Kelly's forceps and all facility providers were trained for the same giving us a lower pain score. The type of IUCD did not seem to contribute to the discomfort at insertion in our study. Another author using Kelly's forceps reported no difference in pain scores with the two types of IUCDs.[7]

Loss of follow ups was also less in our study due to excellent counseling, telephonic follow up and support provided by the researchers. In the first follow up visit at 6 week 15% of group A and 19% in group B women complained of spotting. Counseling and reassurance helped the women to have faith in the method. In both groups about 60% of the women resumed menses by 6 months. This was to do more with the lactation practices and the type of IUCD did not seem to affect the resumption of menses. The amount of bleeding during the menstrual cycle was marginally increased in group B but was not statistically significant.

The incidence of PID was slightly higher in group A but was detected at 6 months follow up so it was not related to IUCD insertion but probably due to poor nutrition and hygienic conditions. Other authors had found much lower incidence of PID with IUCD in situ.[8-11] Pain abdomen was a relatively common complaint in our study in both the groups with no significant difference between groups. It was mild and easily managed by analgesics. Other researchers did not compare the incidence between two IUCDs.[10-13]

Spontaneous expulsion has been shown to be affected by type of IUD, timing of insertion, providers experience and insertion technique. In our study there were more expulsions in Cu T 380A (15.28 %) users as compared to Cu 375 (12.85 %) users but it was not statistically significant. Most researchers reported 12-15% expulsion rates in with IUCDs with no difference between type of IUCD.[7,11,14] Literature suggests no significant difference in expulsion rates between insertions done by hand or by Kelly's forceps but lesser expulsion rates are reported with the experience[15,16]. Up to

95% of expulsions can be detected by the women themselves feeling for the thread.[14,17]

In group A and B, 18.75% and 14.38% women respectively got the IUCD removed. Menstrual disturbances were the most common the cause for 33.96% of IUCD removals followed by social causes. Other researchers also found menstrual abnormalities as the most common cause for getting IUCD removed.[18-20] Counseling, reassurance and supportive treatment can reduce the removal rates due to menstrual problems to some extent. Social causes can be minimized by education, family involvement, continuous support and targeting myths by social media. Publicizing PPIUCD as cheapest and easiest method for birth spacing and spacing in turn reducing financial crunch can be a strong motivating factor for adopting and continuing PPIUCD. Many removals in our study were essentially due to psychological and motivational reasons. The society is yet to adapt to the idea of PPIUCD as an effective and simple long-acting reversible contraceptive.

No pregnancy was reported in both Cu T 380A and Cu 375 groups in the present study over 1 year follow up. Failure rate reported in the literature varies from 0.003% to 0.7%.[21]Perforation of uterus by an IUCD is very rare. Most authors including us did not have any perforations.[22,23]

Continuation rate for PPIUCD at one year was 57.5% and 62.5% in group A and B respectively (p value=0.59). The continuation rates are not promising despite the initial good acceptance by the women. The reasons for removal have been discussed. It's not enough to improve the utilization rates unless we make efforts towards achieving at least 90% continuation rates. In this regard we would need to address the society as a whole. Family should be provided knowledge and support to eliminate all the preexistent notions. A good follow up support or a central helpline number for correct information and problem solving may avoid unwanted early removals. Appropriate early management of bleeding related problems with Cu IUCDs needs to be ensured and may decrease removals.

There were certain limitations of the study which includes smaller sample size and short duration of follow up. Also detailed one to one interview by a community person could be better in eliciting the real cause behind IUCD removals and thus help the efforts to be channelized for elimination of those. The reduction in removal rates is one major step towards increasing the continuation rates of PPIUCD. Counseling regarding hygiene, self-care and proper nutrition of the mother should be done to avoid pelvic inflammatory disease. Women should have facility for continuous support as and when needed.

Conclusion

Cu T 380 A and Cu375 were found to be similar in terms of efficacy, complications and expulsion rates. Overall satisfaction was also comparable with both PPIUCDs. Structured training program, counseling for post-partum family planning should be an integral part of all ANC services and information regarding both types of PPIUCDs should be offered. Specific reasons for removal need to be addressed in detail in order to improve the continuation rates of both the PPIUCDs.

Conflict of interest: None. **Disclaimer:** Nil.

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