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## A study to evaluate and compare the expulsion, removal and continuation of post placental insertion of Cu 375 and CuT 380A in Indian women

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### Abstract

**Background:** Post Partum period is the ideal time for family planning counselling. Accessibility to health care facility is more during this period in our country. In view of repeated pregnancies, the present study is planned to evaluate the expulsion, removal and continuation of PPIUCD (Cu 380A and Multiload 375) in women delivering vaginally or by caesarean section in a tertiary care facility.

**Material and Methods:** 220 women had PPIUCD insertion immediately after delivery of the placenta in vaginal and caesarean section (110 each in CuT 380A and Multiload 375) after applying inclusion and exclusion criteria. They were then followed up at 6 weeks and 3 months.

**Results:** There were total of 6 expulsion, 4 in CuT 380A and 2 in Multiload at 6 weeks follow up and 2 expulsion in Copper T 380A and none in Multiload at 3 months. Expulsion was more in case of vaginal delivery. There was 5.5% removal at 3 months (7.8% in Cu T 380A and 3.8% in Multiload 375). Main reasons for removal were pain lower abdomen (23.1%, Bleeding 38.4%, Discharge 15.3% and Family Pressure 23.1%). At the end of 3 months 86.7% continued with Copper T 380 A and 94.6% in the Multiload 375.

**Conclusion:** Immediate postpartum IUCD insertion provides highly effective contraception immediately after delivery with minimal side effects. The expulsion in our study was not very high and can be reduced with skill and practice. Cash incentives to the acceptor, motivator and provider could bring about a substantial progress in the PPIUCD use in developing countries like India.

**Keywords:** Postpartum intrauterine contraceptive device, expulsion, removal, continuation, vaginal delivery, intra caesarean insertion

### Introduction

India is the second most populated country in the world after China with an estimated total population of 1.32 billion. India's maternal mortality stays at an alarming figure of 167/100000 live births which causes many women to die from pregnancy and child birth complications every year. This contributes to 20% of global maternal deaths [1]. In 2005 under the National Rural Health Mission, a conditional cash transfer scheme named "Janani Suraksha Yojana" (JSY) was launched by the Government of India; this brought about a phenomenal rise in the institutional delivery rate. Consequently, "Janani Shishu Suraksha Yojana" (JSSY) was launched by the Government of India on June 1, 2011, to provide completely free and cashless services to women who were pregnant, including delivery, cesarean delivery, drugs and diagnostics, transportation and neonatal health care up to 30 days postpartum [2]. Insertion of an IUCD immediately after delivery is appealing for several reasons: women are strongly motivated to begin contraception in the postpartum period, assurance that a woman is not pregnant, side effects of IUCD like pain and irregular bleeding merges with the after pains and lochia of puerperium, no effect on the breast milk as do many systemic contraceptive methods, reduced risk of uterine perforation because of thick wall, situations where the baby is distressed, especially during caesarean section, Postpartum IUCD offers the best alternative and is coitus independent. [3] Despite advantages, it generally suffers unpopularity in India. Hence the present study is planned to evaluate and compare the expulsion, removal and continuation of post placental insertion of Cu 375 and CuT 380A in Indian women.

### Objectives

To evaluate and compare the expulsion, removal, reasons for removal and continuation of post placental insertion of Cu 375 and CuT 380A in Indian women

## Material and methods

### Study Design

This observational hospital based study was conducted in the Department of Obstetrics & Gynaecology, SMS Medical College, Jaipur (Rajasthan) from February 2016 onwards.

Out of 500 women counseled, 220 willing for PPIUCD insertion were included in the study 110 in CuT 380A group and 110 in the Multiload 375 group. Then all candidates signed an informed written consent. Inclusion and exclusion criteria was applied and were subjected to detailed history, clinical examination and relevant investigations

### Inclusion criteria

- Women in post placental period (within 10 minutes of placental expulsion) in vaginal and caesarean delivery
- Those willing for PPIUCD insertion
- Those willing for participation in the study

### Exclusion criteria

- Fever during labour and delivery (Temp > 38 degree celsius)
- Hb<8 gm /dl
- Having active STD and other genital tract infection or high risk for STD
- Known to have ruptured membranes for >18 hrs prior to delivery
- Known uterine abnormalities eg. Bicornuate/septate uterus, uterine myomas
- Manual removal of the placenta
- Unresolved postpartum hemorrhage (PPH) requiring use of additional oxytocic agents in addition to Active Management of Third Stage of Labour
- Liver or renal dysfunction
- Diabetes mellitus
- IUFD

### Method of Insertion

#### A) During Vaginal Delivery

All necessary instruments (CuT 380A, Multiload 375, Sim's speculum, over head lamp, Povidone Iodine, kidney tray, and cotton swabs) were arranged on an auxiliary table covered with a sterile drape. Insertion was performed using Kelly's placental forceps<sup>4</sup>. The patient was placed in a lithotomy position with buttocks at the edge of the table. Aseptic techniques were enforced throughout the procedure issued. The uterus was palpated to evaluate the height of the fundus and its tone. This is important to assess the size of the uterus to know whether the strings are likely to protrude through the cervix even when PPIUCD is placed at fundus. After performing the appropriate hand washing, a pair of sterile gloves was worn. The perineum was cleaned with povidone iodine. The perineum, labia, and vaginal walls were inspected for lacerations. Sim's speculum was gently inserted into the vagina to visualize the cervix. The cervix and the vaginal walls were cleaned twice with two separate cotton swabs soaked in povidone iodine solution. The anterior lip of the cervix was then gently grasped with the sponge holding forceps. The IUCD was removed from the insertion sleeve and grasped with the Kelly's forceps using no-touch technique. Once it is inserted into lower uterine segment,

other hand was moved to the abdomen; and placed over the fundus and uterus was pushed gently upward to reduce the angle and curvature between the uterus and vagina. IUCD with forceps was moved upward until it was felt at the fundus which is identified by the resistance felt and also the thrust of the instrument at the fundus with her left hand which is placed on the abdomen. Then the forceps was opened to release the IUCD and swept to side wall. Uterus was stabilized until forceps removal was complete. The cervical os was then gently inspected for the strings. Sims speculum was removed. She was allowed to take rest for some time.

#### B) During Caesarean Section

Uterine cavity was inspected for presence of malformations following placental delivery, which would limit used of IUCD.<sup>4</sup> The IUCD was removed from the insertion sleeve and placed on the sterile field. Uterus was stabilized by grasping it at fundus. IUCD was held between middle and index finger. It was inserted into the uterus through uterine incision and released at the fundus of uterus. Hand will be removed slowly from the uterus. Enough care was taken not to dislodge IUCD as hand was removed. Strings were guided toward the lower uterine segment without disturbing IUCD fundal position. Enough care was taken not to include IUCD strings during uterine closure.

#### Later prior to discharge

- Discharge card showing type of IUCD and date of insertion was given.
- She was advised to come back any time she has
- ❖ Foul smelling vaginal discharge different from the usual lochia
- ❖ Lower abdominal pain, especially if accompanied by not feeling well, fever or chills
- ❖ Suspicion that the IUCD has fallen out.
- ❖ Excessive bleeding

Follow up at 6 weeks and 3 months was done with regards to expulsion, removal, reasons for removal and continuation with the help of per vaginal examination, clinical examination, USG if strings were not visible and a set of questionnaire, followed by statistical analysis done. In case women failed to turn up for follow up, they were contacted through telephone.

### Statistics

Statistical analysis was done using Chisquare test, Fisher's exact test.

### Result

Out of 500 women admitted only 220 agreed for PPIUCD insertion. 49.5% of the study subjects were less than 25 years of age as this represents the most fertile and reproductive age group. 57.3% of the participants belong to rural area and 42.7% in the urban area. In our study, Hindus 75.9% participated and 24.1% were Muslims which could be due to demographic profile of Rajasthan. 35.4% of the population belong to low socioeconomic status as our Hospital been a government institute caters this group. Literacy also plays important role as evidenced by 61.3% of the participants belonging to the literate group.

**Table 1:** Sociodemographic features of Study population

Age Group	Total		CuT 380A		Multiload 375		P value
	N	%	N	%	N	%	
<25 years	109	49.5	56	50.9	53	48.2	0.656(NS)
25 – 29 years	27	12.3	15	13.6	12	10.9	
≥30 years	84	38.2	39	35.5	45	40.9	
Residence	Total		CuT 380A		Multiload 375		P value
	N	%	N	%	N	%	
Rural	126	57.3	60	54.5	66	60	0.496 (NS)
Urban	94	42.7	50	45.5	44	40	
Religion	Total		CuT 380A		Multiload 375		P value
	N	%	N	%	N	%	
Hindu	167	75.9	80	72.7	87	79.1	0.344 (NS)
Muslim	53	24.1	30	27.3	23	20.9	
Socioeconomic Status	Total		CuT 380A		Multiload 375		P value
	N	%	N	%	N	%	
Upper	4	1.8	2	1.8	2	1.8	0.553 (NS)
Upper middle	18	8.1	10	9.09	8	7.2	
Middle	58	26.3	28	25.4	30	27.2	
Lower Middle	62	28.1	30	27.2	32	29.09	
Lower	78	35.4	40	36.3	38	34.5	
Literacy Status	Total		Cu T 380A		Multi-load 375		P value
	N	%	N	%	N	%	
Illiterate	85	38.6	40	36.3	45	40.9	0.5797
Literate	135	61.3	70	63.6	65	59.09	

**Table 2:** Distribution of Study subjects according to their Parity.

Parity	Total		Cu T 380A		Multi-load 375	
	N	%	N	%	N	%
1	90	40.9	48	43.6	42	38.1
2	52	23.6	24	21.8	28	25.4
3	40	18.1	20	18.1	20	18.1
4 or more	38	17.2	18	16.3	20	18.1
Total	220	100	110	100	110	100

In this study, 40.9% of the study subjects are primipara. The distribution is equal among both the groups with minimum participation of those with parity 4 and more (17.2%)

**Table 3:** Expulsion of PPIUCD at different follow up time.

Time	Expulsion	Total		Cu T 380A		Multi-load 375		Chi square	P value
		N	%	N	%	N	%		
6 week	Yes	6	2.7	4	3.7	2	1.8	0.72	0.28 (NS)
	No	212	97.2	104	96.2	108	98.2		
3 month	Yes	2	1	2	2.1	0	0	0.601	0.43 (NS)
	No	197	98.9	93	97.8	104	100		

As per the study, there were total of 6 expulsions at 6 weeks follow up. 4 out of 6 detected for expulsion by themselves before follow up visit. While rest two of them had an USG done at 6 weeks which confirmed expulsion. The results calculated after excluding removal.

**Table 4:** Removal at different follow up time

Follow up time	Removal	Total		CuT 380A		Multiload 375	
		N	%	N	%	N	%
6 weeks	Yes	2	0.93	2	1.8	0	0
	No	212	99.06	104	98.1	108	100
3 months	Yes	11	5.5	7	7.3	4	3.8
	No	188	94.4	88	92.6	100	96.1

At 6 weeks, there were 2 removal in the Copper T 380 A group and none in the Multiload group. Whereas, at 3 months there were 7 removal in the Copper T 380A group and 4 in the Multiload group.

**Table 5:** Comparison of reason for Removal of PPIUCD among the two groups.

Reason for Removal	Total		Cu T 380A		Multi-load 375	
	N	%	N	%	N	%
Pain lower abdomen	3	23.1	2	22.2	1	25
Bleeding	5	38.4	3	33.4	2	50
Discharge	2	15.3	2	22.2	0	0
Family issue	3	23.1	2	22.2	1	25

In our study, Maximum cause of removal was due to Bleeding 38.4% (33.4% in the Copper T 380A group and 50% in the Multiload group) followed by Pain abdomen 23.1% (22.2% in the Copper T 380A group and 25% in the Multiload group). Family pressure accounted for 23.1% of removal.

**Table 6:** Comparison of Continuation of PPIUCD among the two groups.

Continuation	Total		Cu T 380A		Multi-load 375	
	N	%	N	%	N	%
Yes	199	90.4	95	86.7	104	94.6
No	21	9.5	15	13.3	6	5.4
Total	220	100	110	100	110	100

chi-square = 3.369 with 1 degree of freedom; P = 0.066 (NS)

According to the study, 86.7% of the subjects in the Cu-T 380A group and 94.6% of the subjects in the Multiload group willingly continued IUCD at the end of 3 months follow up.

### Discussion

49.5% of the study subjects belong to < 25 years of age as this represents the most fertile and reproductive age group and that the Indian population get married at an early age and there is short interval between marriage and child birth.

Similar findings were seen in another study, done by Shivani Barala *et al* (2016) [5], in a tertiary care centre in Rajasthan, majority of the women were in the age group 20-29 years (77.8%). Their mean age was 24.16years (SD+2.16. Mwinyi Ali RA [6] found that mean age of PPIUCD acceptors was 27.6 years (SD+5.68).

In our study, 57.3% belonged to the rural area whereas 42.7% belonged to the urban area, P value = 0.496 for both groups which is not significant. Most of the clients were from the urban society as per the study done by Neha Jain *et al* [7] contrary to our finding. This shows the implementation of JSSY in our state and as our hospital is a tertiary centre attracts beneficiaries from rural background. This could also be because women of urban area rely on other methods of contraception like OC pills, condom, sterilisation. Proper information and motivation leads to high acceptance of PPIUCD in the rural women.

In my study, there were 72.7% of the Hindu Population and 27.3% of the muslim in 380A group and 79.1% Hindus and 20.9% muslims agreed for multiload insertion in the immediate post partum period. There were total of 75.9% of PPIUCD insertion in the Hindus as compared to 24.1% in the muslims .P value= 0.344 which is not significant which shows the demographic profile of Rajasthan which is a Hindu dominant state. The study findings suggest that given privacy, anonymity, and proper counselling, Muslim women too are as likely to accept PPIUCD as their Hindu counterparts.

Major population belonged to lower socio economic status (35.4%) followed by Lower Middle (28.1%), Middle class(26.3%), Upper Middle(8.1%), Upper class (1.8%). P value=0.553 which is not significant for both the groups. Our hospital been a Government institute attracts more of lower class than upper and middle class. One of the other reasons could be that women belonging to richer families had better knowledge and access to wider choice of alternative methods such as injectable hormonal contraceptives. Hence, these women might have preferred contraceptive methods other than PPIUCD.

In the current study 36.3% of the population in the Copper T 380A group and 40.9% in the Multiload group are illiterate, overall 38.6% population are illiterate. Whereas, 61.3% of the population are literate of which 63.6% belong to Copper T 380A group and 59.09% are illiterate in the Multiload group. This is similar to the study done By Satyavathi Maluchuru (2015) [4], in which majority of the women (95.98%) in the study population had at least a primary level of education. Acceptance of PPIUCD was higher among women with Primary and secondary education (28.56% and 13.88), than those with no formal or higher education (7.75 and 8.21%). This finding confirms importance of education in deciding future pregnancy. This was similar to a study done in Egypt by Safwat *et al* (2003) where women with no formal education had an acceptance of 9.4%, while those with formal education were 19.4%. IUCDs are USE AND FORGET type of method for contraception thereby it is good choice for illiterate population, however in other type of barrier contraceptives continuous motivation is required thereby increasing the failure rate in inconsistent users.

In this study, 40.9% of the study subjects are primipara. The distribution is equal among both the groups with minimum participation of those with parity 4 or more (17.2%). Healthy timing and spacing of pregnancies have a positive effect on maternal health and new born outcomes.

The importance of having healthy spacing of pregnancy in India is emphasized by the fact that approximately 27% of births occur in less than 24 month after previous birth. Celen S(2011) [8], Gautam *et al*(2014) [9], and Vidyarama *et al*(2012) [10] found an acceptance rate of,13.76%,71.91%, and 15.47%, respectively, in primipara. Whereas, study done by Grimes *et al*(2002) [11], where they found most of the PPIUCD acceptors were multiparous clients (65.1%)which is contrary to our finding.

As per the study, there were total of 6 expulsions at 6 weeks follow up. Out of which 4 (3.7%) were in the Copper T 380A group and 2 (1.8%) in the Multiload group. At 3 months there were 2 expulsions in the Copper T 380A group and none in Multiload. The difference could be due to the shape of Multiload, horse shoe shaped device with lateral flexible plastic and serrated fins, developed to minimize the expulsion .4 out of 6 detected for expulsion by themselves before follow up visit. While rest two of them had an USG done at 6 weeks which confirmed expulsion.

Analysis done by N.S El Beltagy *et al* (2011) [12] revealed that the expulsion rate was fairly high in Cu T380 and Multiload 375 IUD users at 6 weeks (8.1% and 5.4%, respectively) and even

higher at 6 months (15% and 14.9%, respectively) when compared to interval IUD insertion which is similar to our finding. Our results were also comparable to the research done by Mansi Kumar *et al* (2017) <sup>[13]</sup> to evaluate and compare the expulsion and continuation rates of post placental insertion of Cu 375 and Cu-T 380A in New Delhi in 300 women. 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).

Another study by Prager (2007) <sup>[14]</sup> revealed a higher rate of IUD expulsion, either for partial or complete expulsion with 5.2% and 3.9%, respectively, for Multiload 375 IUD versus Cu T380 IUD, at general hospitals in Boston, in an early postpartum IUD insertion study of different types of IUDs during a 5-year period. In the present study, Higher expulsion was noted in vaginal delivery which could be due to faulty techniques of insertion, improper placement. In the Caesarean there is direct fundal placement of PPIUCD hence less expulsion.

Table 4 shows removal at different follow up time. At 6 weeks, there were 2 removal in the Copper T 380 A group and none in the Multiload group. Whereas, at 3 months there were 7 removal in the Copper T 380A group and 4 in the Multiload group. Reasons for removal were pain abdomen, excessive bleeding, Vaginal discharge not relieved by medications and family pressure. Maximum cause of removal was due to Bleeding 38.4% (33.4% in the Copper T 380A group and 50% in the Multiload group) followed by Pain abdomen 23.1% (22.2% in the Copper T 380A group and 25% in the Multiload group). Family pressure accounted for 23.1% of removal (22.2% in the Copper T 380A and 25% in Multoload). Whereas removal due to foul smelling discharge per vaginum was 15.3%. 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.

Ajit Nayak *et al* (2017) <sup>[15]</sup> in his conducted over 4 years at Cuttack Orissa reported common reason for removal of Cu-T was bleeding problem (39.33%) which is similar to reporting done by Runjun and Bornali (2016) <sup>[16]</sup> (42.11%), Mishra (2014) <sup>[17]</sup> (32.56%). Ajit Nayak (2017) <sup>[15]</sup> had reported that 35.14% of removal of PPIUCD was due to family pressure. Mishra <sup>17</sup> has reported that 23.26% of removal of PPIUCD was due to family pressure, whereas Runjun and Bornali <sup>[16]</sup> reported 17.54%.

According to the study, 86.7% of the subjects in the Cu-T 380A group and 94.6% of the subjects in the Multiload group willingly continued IUCD at the end of 3 months follow up. Six subjects in the Cu-T 380A and 2 in Multiload had expelled and 9 in the Copper T 380A group and 4 in the Multiload group removed it.

Lara R *et al* (2006) <sup>[18]</sup> observed continuation rates of 77.1% and 82.6% for postplacental insertion of CuT380A and Cu 375 respectively at one year. In the study conducted by Gupta *et al* (2013) <sup>[19]</sup> the continuation rate of post placental IUCD was 87.3% and that of interval insertion was 92%. Early and repeated counseling during each antenatal visit and at the time of admission to labour room is highly required along with some incentive to both client and service provider and public awareness through different media sources to increase not only acceptance but also continuation rate in a situation of limited access to postpartum care.

## Conclusion

We conclude that both Multiload 375 and CuT 380A are safe, effective and reversible methods of contraception with minimal

side effects. The expulsion rate was not very high and it can be minimized with proper practice and removal can be reduced with counselling, assurance and treating the cause.

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