ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 7, Issue – 2, March – 2022 , Page No. : 237 - 244

A comparative study to assess continuation rate of postplacental insertion of CuT-380A and Cu375 IUCD

[1]Dr. Manju Khicher, PG Resident, Department of Obstetrics and Gynaecology, ABVIMS and Dr. Ram Manohar Lohia Hospital, New Delhi.

[2]Dr. Alka Goel, Associate Professor, Department of Obstetrics and Gynaecology, ABVIMS and Dr. Ram Manohar Lohia Hospital, New Delhi.

Corresponding Author: Dr. Manju Khicher, PG Resident, Department of Obstetrics and Gynaecology, ABVIMS and Dr. Ram Manohar Lohia Hospital, New Delhi.

Citation this Article: Dr. Manju Khicher, Dr. Alka Goel, "A comparative study to assess continuation rate of postplacental insertion of CuT-380A and Cu375 IUCD", IJMSIR- March - 2022, Vol – 7, Issue - 2, P. No. 237 – 244.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: The IUD is a highly effective (>99% effective) contraceptive device. There are 0.6 to 0.8 pregnancies per 100 women in first year of use.

Providing quality contraception services to women is one of the cornerstones for achieving Millennium Development Goals of improved maternal and child health.

Aims and Objectives: A comparative study to assess continuation rate of post-placental insertion of CuT380A and Cu375 IUCD.

Materials and Methods: Two hundred subjects were recruited from antenatal clinic for the study and randomly divided into two groups. Group A consisted of 100 women who received CuT-380A and Group B consisted of 100 women who received Cu375 for contraception in post placental period. The data was analyzed by using unpaired t-test/Mann-Whitney Test for quantitative variables and Chi-Square test /Fisher's exact test for qualitative variables to evaluate the safety, efficacy and acceptability.

Results: The mean age of cases was 27.49 years (range:21-30years). On first follow up visit at 6 weeks all patients were asymptomatic. Continuation rate was 92% in Cu375 group and 85% in CuT-380A group at 6 month follow up. Removal rate was higher (15%) in CuT380A Group compared to Cu375 Group (8%). In Group Cu375, 9% cases had subjective change in bleeding pattern and in Group CuT-380A, 21% cases. The difference was statistically significant. Incidence of adverse effect was significantly higher in CuT380A group. 20% had heavy bleeding and 8% pain abdomen in CuT380A group as compared to 9% had heavy bleeding and 2% pain abdomen in Cu375 group.

Conclusion: Efficacy and continuation rate of post placental insertion of Cu 375 and CuT380A are comparable however adverse effects are more in CuT380A insertion.

Keywords: Intrauterine contraceptive devices (IUCD)

Introduction

Family planning entails a couple's decision regarding how many children they choose to have and when they want to have them, that is size of family, timing of

pregnancies and birth spacing. The recommended interval between pregnancies is 18 to 60 months in order to reduce risks to the mother and infant [1]. A woman is particularly vulnerable for pregnancy in the post -partum period. Time taken to resumption of ovulation after delivery is highly unpredictable. [2]

Intrauterine devices are reversible birth control devices placed in the uterine cavity for contraception. Copper intrauterine devices are the most widely used method of long-acting reversible contraception (LARC) with a very low failure rate. The early postpartum insertion of IUDs would be suitable because the cervix is patulous and the lochia will mask any bleeding associated with the IUD insertion.[3]

Along with personal benefits of family planning, there are other equally important global factors pertaining to family limitation, namely, achievement of sustainable development goals for all by 2030 as well as maintenance of ecological balance on our beautiful planet Earth. India has the largest number of women with unmet needs than any other country in the world.

Unmet need for family planning is defined as percentage of women of reproductive age, either married or in a union, who want to stop or delay childbearing but are not using any method of contraception. Unmet need for family planning indicates the gap between women's reproductive intentions and their contraceptive behaviour.[4] According to National Family Health Survey (NFHS-4) 2015-2016, unmet need for spacing is 5.7% and total unmet need for FP is 12.9% for India.[5]

The IUD is a highly effective (>99% effective) contraceptive device. There are 0.6 to 0.8 pregnancies per 100 women in first year of use. The CuT-380A is effective for 10 years of continuous use and Cu375 is effective for 5 years of continuous use.[6]

Government of India has actively revitalized post-partum family planning services in India since the year 2009. CuT380A has since been extensively used and researched.[1] As rate of post-partum care is low in India with limited access to care public health, benefit of PPIUCD is high, despite a higher expulsion rate than interval insertion. The current study was undertaken to assess whether same benefits could be availed with Multiload by women opting for post-partum insertion of IUD in order to expand the basket of choices available in post- partum period.

Materials and methods

This was a Prospective Comparative Randomized study conducted from 1st November 2019 to 31st march 2021 at department of Obstetrics and Gynaecology, ABVIMS & Dr RML Hospital, New Delhi. A total of 200 women included in our study (100 in each group). The study was approved by the institutional ethics and research board.

Group I – Post placental CuT-380A IUCD insertion.

Group II –Post placental Cu375 IUCD insertion.

Statistical analysis

Categorical variables are presented in number and percentage (%) and continuous variables are presented as mean ± SD and median. The data was analyzed by using unpaired t-test/Mann-Whitney Test for quantitative variables and Chi-Square test /Fisher's exact test for qualitative variables to evaluate the safety, efficacy and acceptability.

A p value of <0.05 has been considered statistically significant. The data has been entered in MS EXCEL spreadsheet and analysis has been done using Statistical Package for Social Sciences (SPSS) version 21.0.

Method of randomization

Randomization with Sealed envelope system

Inclusion criteria

1. All postpartum patients either delivered vaginally or by caesarean section, within 10 minutes of placental delivery.

Exclusion criteria

1. Chorioamnionitis.
2. Puerperal sepsis.
3. Leaking per vagina >18 hrs.
4. Unresolved PPH.
5. Uterine cavity anomaly.
6. Current carcinoma of cervix.
7. Sexually transmitted infection.
8. Wilson's disease.
9. HIV positive patients.

Primary outcome

1. Continuation rate

Secondary outcome:

1. Expulsion rate
2. Removal rate
3. Change in menstrual pattern

Observations and results

Table 1: Distribution of cases according to age group

Age group	Cu375		CuT-380A	
	N	%	N	%
≤20 years	2	2	4	4
21-25 years	25	25	29	29
26-30 years	53	53	49	49
31-35 years	16	16	14	14
>35 years	4	4	4	4
Total	100	100	100	100
Mean±SD	27.65±4.13		27.49±3.93	
P-value	0.7793			

The mean age of cases in group Cu375 was 27.65 years with majority of cases in age group 26-30 years (53%) followed by 25% in age group 21-25 years. The mean age of cases in group CuT-380A was 27.49 years with majority of cases in age group 26-30 years (49%) followed by 29% in age group 21-25 years. There was no statistically significant difference in distribution of age between two groups (p-value- 0.7793).

Table 2: Distribution of cases according to parity

Parity	Cu375		CuT-380A	
	N	%	N	%
Parity-1	60	60	50	50
Parity-2	40	40	50	50
Total	100	100	100	100

Chi-square statistic = 2.0202; P-value =0.1552

In group Cu375 60% cases were para1 followed by 40% para 2. Similarly, in group CuT-380A 50% cases were para 1 and 50% were para2. There was no statistically significant difference in parity between two groups (p-value- 0.1552).

Both groups had same number of cases of LSCS and VD each, 13 and 87 respectively.

The first follow-up was done at 6 weeks post-partum

On first follow up visit at 6 weeks all patients were asymptomatic. none of the patients had expulsion, and there was no request for removal for IUCD at 6 weeks postpartum in either group.

Next follow-up was done at 6 months

None of the patient had expulsion in either group. (Chi-square statistic = 0; P-value = 1)

Distribution of cases according to continuation rate

Continuation rate was 92% in Cu375 group and 85% in CuT-380A group. Statistically there was no significant difference in continuation rates in both groups (Chi-square statistic = 2.4073; P-value =0.1207).

Distribution of cases according to removal

Removal rate was higher (15%) in CuT380A Group compared to Cu375 Group (8%). Statistically there was

no significant difference in both groups (Chi-square statistic =2.4073; P-value =0.1207).

Table 3: Distribution of cases according to reason for removal

Reason for Removal	Cu375		CuT-380A		P-value
	N	%	N	%	
Heavy bleeding	6	6	9	9	0.4218
Pain abdomen	2	2	6	6	0.1317
No Removal	92	92	85	85	0.1217

Reasons for removal of IUCD were same in both the groups. Most common reason for removal was heavy bleeding described by patient as increase in number of pads per day or increase number of days of bleeding or both as compared to previous cycles. Heavy bleeding was reason for removal in 6% of women in Cu375 group and 9% of women in CuT380A group.

Second reason given for removal was pain abdomen off and on following IUCD insertion. Pain occurred in 2% of women in Cu375 group and 6% of women in CuT380A group.

There was statistically no significant difference in reason of removing IUCD in both groups (P-value>0.05).

Distribution of cases according to subjective change in bleeding pattern

Subjective change in bleeding pattern described by patient as increased number of days of bleeding or decrease interval of cycle or both as compared with previous cycles. In Group Cu375, 9% cases had subjective change in bleeding pattern and in Group CuT-380A, 21% cases had subjective change in bleeding pattern. The difference was statistically significant with respect to subjective change in bleeding pattern in both group (Chi-square statistic =5.6471; P-value =0.0174).

Distribution of cases according to visibility of strings

On per speculum examination done at 6 months of follow up, strings were visible in all the women of both groups. (Chi-square statistic =0; P-value =1)

Table 4: Distribution of cases according to adverse effects of PPIUCD

Adverse effects	Cu-375		CuT-380A		P-value
	N	%	N	%	
Heavy bleeding	9	9	20	20	0.0276
Pain abdomen	2	2	8	8	0.0522
No Complication	89	89	72	72	0.0025

All women had resumed their menstruation within 6 months of post-partum.

Incidence of adverse effect was significantly higher in CuT380A group (P-value<0.05). 20% had heavy bleeding in CuT380A group as compared to 9% in Cu375 group. This difference was statistically significant (P value- 0.0276).

Complaint of pain abdomen was present in 8% of women in CuT380A group compared to 2% in Cu 375 group. The difference was statistically significant (P value- 0.0522).

Discussion

In our study mean age of cases in group Cu-375 was 27.65 years with majority of cases in age group 26-30 years (53%) followed by 25% in age group 21-25 years. The mean age of cases in group CuT-380A was 27.49 years with majority of cases in age group 26-30 years (49%) followed by 29% in age group 21-25 years. There was no statistically significant difference in age between two groups as p-value is equal to 0.7793.

In group Cu-375 there were 60% cases had parity equal to 1 followed by 40% had parity equal to 2. Similarly, in

group CuT-380A there were 50% cases had parity equal to 1 followed by 50% had parity equal to 2. There was no statistically significant difference in parity between two groups as p-value is equal to 0.1552.

At the first follow up at 6 weeks post- partum, all women in both groups had no complaints, there were neither any expulsion nor any requests for removal.

On second follow up visit at 6 months, in group Cu-375 had 92% continuation rate and in group CuT-380A had 85% continuation rate. Here, also statistically no significant difference in continuation rate in both group (P-value= 0.1207). Somila Xess et al [7] in the year 2018 evaluated and found 86.7% cases continued with post-partum insertion of CuT380A group and 94.6% cases continued with Multiload (Pvalue-0.066). The difference was not statistically significant. Divya and Dewan [8] reported 86% continuation rate in post placental intra caesarean insertion of Cu-375 IUCD user as compared to 89.3% in Cu-380A IUCD. There was no statistically significant difference (P-value-> 0.05). Lara R [9] observed continuation rates of 77.1% and 82.6% for post placental insertion of CuT380A and Cu 375 respectively at one-year. there was no statistically significant difference in the continuation rates (Pvalue-0.76). Kumar et al[10] study observed that continuation rate was 83.3% in Cu 375 and 80.6% in CuT380A at 12 months there was no significant difference seen in continuation rates in two groups (p>0.05). Sulaiman Sastrawinata [11] et al in 1991 conducted a study in Indonesia and found 24 months continuation rates were 85.5%, 85% and 85.4% for TCu380A, LLD and MLCu375 respectively. There were no statistically significant differences in the continuation rates (Pvalue->0.05)

In group Cu-375 in 8% cases IUCD was removed and in group Cu-380A in 15% cases IUCD was removed. But statistically there was no significant difference in in both group (P-value= 0.1207). Divya and Dewan [8] reported 7.3% removal rate in Cu-375 IUCD user as compared to 6.7% in CuT-380A IUCD user which was not statistically significant (Pvalue-0.7788). Kumar et al[10] reported 4.6% IUCD removal in Cu-375 IUCD user and 5.3% in cuT-380A IUCD user which was not statistically significant (Pvalue->0.05%). Somila Xess [7] found that 13.3% in CuT380A group and 5.4% in Multiload group had PPIUCD removal at 3 months which was not statistically significant.

In current study, in group Cu-375 and group CuT-380 none of the patient had expulsion in either group. Agarwal et al [12] found low expulsion rate of IUDs with 4% in CuT380A and 2% in Cu375 IUD. Which was statistically significant (P value-0.001)? AO Arowojolu et al [13] reported expulsion rate 2% case in CuT380A group, 2% case in ML250 group and 0% case in ML 375 group which was statistically significant (P value-<0.05%).

Divya and Dewan [8] reported 6.7%% expulsion rate in Cu-375 IUCD user as compared to 4% in Cu-380 IUCD user. Which was not statistically significant (P value->0.05%).

In contrast, rate of expulsion was comparatively high in study by Kumar et al [10]. They reported an expulsion rate of 12% in Cu375 group and 14% in Cu380A group (Pvalue->0.05%). Lack of any case of expulsion in either group at our institute may be due to through training given by family planning department to the residents of Obs & Gynae department at regular intervals. A proper placement of PPIUCD is the most important factor in reducing expulsion of PPIUCD. Since high risk of expulsion of IUCD is the main drawback of placing it in postpartum period as compared to interval insertion,

training of resident doctors at regular intervals by the department is of umpteen importance.

In Cu-375 group reason for removal of IUCD in 6% cases was heavy bleeding and 2% cases had pain abdomen. In CuT-380A group reason for removal of IUCD was heavy bleeding in 9% and pain abdomen in 6%. There was statistically no significant difference in reason of removing IUCD in both groups (P-value=0.4719). Kumar et al [16] reported that Discomfort due to bleeding, pain in the abdomen or discharge as main reasons for removal. Somila Xess et al [7] found that 33.4% cases had complaint of bleeding and 22.2%% had complaint of pain abdomen in group of CuT380A and in Multiload group 25% cases had complaint of bleeding and 50% case had complaint of pain abdomen which was statistically significant (P value->0.05). M Kumar et al [10] found that 7.33% cases of Cu375 group and 8.66% of CuT380A group had menorrhagia which was not statistically significant (P value->0.05%) and Complaint of pain abdomen was present in 24% in CuT380A group and 17.3% in Cu375 group (Pvalue-0.52).

In current study 100% cases had visibility of string in both the group. Agarwal et al[12] showed string visibility in 100% women in Cu-375 IUCD user group and 47.9% women in CuT380A group. Which was statistically significant (Pvalue-0.001). Divya and Dewan [8] found 97.1% women in Cu375 group and 72.3% women in CuT380A group showed string visibility which was statistically significant (Pvalue-<0.05). M Kumar et al[10] found strings were visible in 74% women in Cu375 group and 34% in CuT380 group at 1 month follow up visits which was statistically significant (Pvalue-<0.05). Thus, most studies have reported a significantly higher rate of visibility of string in woman who had post-partum Cu375 insertion as compared to Cu380A. This might be explained by the presence of longer thread of Cu375 as compared to Cu380A. Visibility of string increase up to more than >80% of women at the end of one year in both the groups.

In current study, Cu-375 user group 9% women had subjective change in bleeding pattern and in group Cu-380A 21% women had subjective change in bleeding pattern. The difference was statistically significant with respect to changes in menstrual cycle in both group (P-value= 0.0174). ElSherbieny et al[14] reported that 70 women out of 110 women had subjective changes in bleeding pattern in Cu-375 IUCD user group and in Cu-380 IUCD user group 79 women out of 110 women had subjective changes in bleeding pattern. The study showed insignificant difference between the two groups as regards duration of menses (p-value-<0.001) and significant difference between the two groups as regard number of pads changed per day. Mahnaz Shahnazi et al[15] concluded that ML Cu 375 users had significantly lower mean score of bleeding in the first four months, after post placental IUD insertion than CuT380A group (P-value-<0.001). M Kumar et al [10] found that 7.33% cases of post placental insertion of Cu375 group and 8.66% of CuT380A group had menorrhagia which was not statistically significant (P-value->0.05%) and Complaint of pain abdomen was present 24% in CuT380A group and 17.3% in Cu375 group (P-value-0.52).

Overall, according to current study and previous studies Cu375 IUCD had less complications like pain abdomen, heavy menstrual bleeding etc, so Cu375 more use full for prolonged action.

Here, in our Cu-375 IUCD user group total 11% had developed adverse effects out of them 9% had heavy bleeding and 2% had pain abdomen. Similarly, in group

Cu-380 IUCD user group total 28% had developed adverse effects out of them 20% had heavy bleeding and 8% pain in abdomen. Although there was difference with respect to adverse effects but statistically the difference was significant (P-value< 0.05). In concordance with our results Agarwal et al [12] found that 26% Cu-375 IUCD user had complication, among them 10% had bleeding and 14% had pelvic pain. and, in Cu-380 IUCD user group 28% had complication out of them 12% each had bleeding and pelvic pain. Shahnazi et al [15] showed that the use of post placental insertion of IUD Cu-375 had significantly less mean bleeding in the study participants in the first four months as compared IUD Cu-380A group. Divya and Dewan [8] reported 13% cases of Cu375 group and 15% of CuT380A group had heavy bleeding. which was not statistically significant (P-value->0.05%).

In short, adverse effects like heavy bleeding and pain abdomen; and changes in bleeding pattern as perceived by the women were all significantly higher in women with post- partum CuT380A insertion as compared to Cu375. However, higher continuation rate of PPIUCD in Cu375 group was not statistically significant. This may be due to the fact that sample size was small. A larger study with follow up of clients for a larger duration is required to further clarify the issue. Longer thread of Multiload is an added advantage when inserting IUCD in an enlarged post-partum uterus.

Conclusion

Counselling for post-partum family planning methods is essential not only for initiation of family planning but also for continuation of contraceptive methods. Efficacy and continuation rate of post placental insertion of Cu 375 and CuT380A are comparable however adverse effects are more in CuT380A insertion. Continuation rates are significantly higher in Cu 375 group. Overall satisfaction is higher for Cu375 than CuT380A. This indicates the acceptability of Cu375 as post placental contraceptive method. One of the most common adverse effects of IUCD users is heavy bleeding during menses and these complications vary in the different types of IUCDs. The results of current study showed that the use of the Cu 375 caused a significant change in bleeding pattern compared to other IUCD. Visibility of string is higher in Cu375 group compare to CuT380A group this might be explained by the presence of longer thread of Cu375 IUCD.

Post placental insertion of Cu375 or CuT380A is safe, reversible, long term, convenient and cost-effective method of contraception and can be initiated after immediate vaginal delivery or intra caesarean especially in women of less developed countries with limited knowledge of contraception and less likelihood of return for contraception. It can be safely and effectively integrated into existing PPFP services.

References

1. Post-partum IU. reference manual; Family Planning Division. Ministry of health and family welfare. Gov India. 2010;1:2-37.

2. Shukla M, Qureshi S; Chandrawati. Post-placental intrauterine device insertion--a five year experience at a tertiary care centre in north India. Indian J Med Res. 2012 Sep;136(3):432-5.

3. El Beltagy NS, Darwish EA, Kasem MS, he fila NM. Comparison between Cupper T380 IUD and Multiload 375 IUD in early post-partum insertion. Middle East Fertile. Soc. J. 2011;16(2):143-48.

4. World Health Organization (WHO). and Johns Hopkins Bloomberg School of Public Health. Canter for Communication Programs. Information and Knowledge for Optimal Health (INFO). Decision-making tool for

family planning clients and providers. Baltimore, Maryland, INFO and Geneva, WHO, 2005. (WHO Family Planning Cornerstone)

5. Bhattathiry MM, Ethirajan N. Unmet need for family planning among married women of reproductive age group in urban Tamil Nadu. J Family Community Med. 2014 Jan;21(1):53-7.

6. Lanzola E and Ketvertis K. Intrauterine Device. https://www.ncbi.nlm.nih.gov/books/NBK557403/. Updated on 31 July 2021.

7. Xess S, Sharma M, Raj Oria L, Mehta S. A study to evaluate and compare the expulsion, removal and continuation of post placental insertion of Cu 375 and Cut 380A in Indian women.2018;2(1):33-38.

8. Divya, Dewan R, Clinical outcome of post placental copper T380A and copper 375 IUCD insertion in women delivering by caesarean section. Int J Reprod Contracept Obstet Gynecol 2018;7:3731-37.

9. Lara R, Menocal Tobias G. Random comparative study between intrauterine device, Multiload Cu375 and TCu 380a inserted in the postpartum period. Ginecol Obstet Mex. 2006;74:306-11.

10. Kumar M, Kumar M, Aggarwal P, Ganga Nia A, Dewan R. A study to evaluate and compare the expulsion and continuation rates of post placental insertion of Cu 375 and Cut 380A in Indian women at a premier hospital in New Delhi, India. Int J Reprod Contracept Obstet Gynecol. 2017;6(9):3992-4000.

11. Sastrawinata S, Farr G, Prihadi SM, Hutapea H, Anwar M, Wahyudi I, Kemara KP, Champion CB, Robbins M. A comparative clinical trial of the TCu 380A, Lippes Loop D and Multiload Cu 375 IUDs in Indonesia. Contraception. 1991;44(2):141-54.

12. Agarwal K, Dewan R, Mittal P, Aggarwal A. Visibility of Strings After Postplacental Intra caesarean Insertion of CuT380A and Cu375 Intrauterine Contraceptive Device: A Randomized Comparative Study. J Obstet Gynecol India. 2017 Oct;67(5):324–9.

13. Arowojolu AO, Otolorin EO, Ladipo OA. Performances of copper T 380A and multiload copper 375/250 intrauterine contraceptive devices in a comparative clinical trial. Afr J Med Med Sci. 1995;24(1):59-65.

14. ElSherbieny MM, Hussein AM, Rafat RG. Comparison between two types of copper bearing intrauterine device Cu375 and Cu380Ag regarding bleeding pattern: Randomized controlled trial. J. Eviden Based Wom Health.2019;9(1): 372-380.

15. Shahnazi M, Sarrafi S, Jafarabadi MA, Azari S, Esmaili F. Comparing haemorrhages and dysmenorrhea with copper T380A and Multiload 375 intrauterine devices: A randomized clinical trial. Journal of caring sciences. 2014;3(3):193-204.

16. Kumar S, Srivastava A, Sharma S, Yadav V, Mittal A, Kim Y, et al. One-year continuation of postpartum intrauterine contraceptive device: findings from a retrospective cohort study in India. Contraception. 2019 Apr;99(4):212–6.