The Journal of Obstetrics and Gynecology of India (July-August 2021) 71(4):430–436
https://doi.org/10.1007/s13224-021-01445-6

ORIGINAL ARTICLE

Clinical Outcome of Cu-T 375 PPIUCD by Novel Dedicated Inserter Technique

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Received: 8 October 2020 / Accepted: 12 January 2021 / Published online: 15 March 2021

Abstract

Background Intrauterine contraceptive devices (IUCDs) have been used by women in India for decades for spacing pregnancies. The increased institutional deliveries are an opportunity to provide women easy access to immediate PPIUCD services. Hence, we planned a study to evaluate the role of a novel dedicated inserter technique to improve compliance in postpartum women.

Materials and Methods A prospective case–control study was conducted on postpartum women who underwent vaginal delivery. Cases were selected and divided randomly into two groups: the long inserter (n = 292) and control groups (n = 301 using conventional method of insertion). PPIUD was inserted by trained providers, followed by ultrasound within 48 hours of insertion to assess location and fundal placement of the IUD. Follow-up was done at 2 weeks, 6 weeks and 3 months post-insertion, and ultrasound assessment was done for IUD location at each visit. Final statistical analysis was done by using Chi-square test.

Results There were fewer complications like pain and irregular bleeding in the long inserter group as compared to the control group. None of the cases reported missing thread in the long inserter group. Expulsion was seen in only one case from the long inserter group and five cases in the control group. Client satisfaction was good (98.4%) in the long inserter group, and with each follow-up, satisfaction level also improved in the control group (96.6%, p value− 0.03).

Conclusion The long inserter PPIUD insertion is a safe and convenient method. It has better ease of insertion, high fundal placement and good thread visibility and has reduced risk of infections as compared to the conventional PPIUD insertion technique.

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Keywords Long inserter Cu-T 375 · Conventional PPIUD · Kelly forceps · Long-acting reversible contraceptive (LARC) · Postpartum contraception

Introduction

The postpartum period is considered important as women are available at health facility and receptive for contraception. Short birth–pregnancy intervals are associated with poor maternal and perinatal health outcomes like abortions, preterm labors, postpartum hemorrhage, low birth weight babies, fetal loss and maternal deaths.

Postpartum family planning (PPFP) is the prevention of unintended and closely spaced pregnancies in the first twelve months following childbirth. The postpartum period is potentially an ideal time to begin contraception. Women are more strongly motivated to do so at this time, which also has the advantage of being convenient for both patient and healthcare providers and also the discomfort related to interval insertion can be avoided, and any bleeding from insertion is disguised in lochia.

Under the National Family Welfare Programme, Cu-T-200B was initially being used. In the year 2003–2004, an advanced version of intrauterine device, i.e., Cu-T-380-A with a longer protection period of 10 years, was introduced in the program. From the year 2012-2013, IUD 380A and IUD 375 were procured by the ministry.

Post-placental (performed within 10 min of placental delivery or while the woman is still in the delivery room) and immediately postpartum (within 48 h post-delivery) insertions of the IUD are associated with more participant benefits than interval insertion (performed at 6 weeks or more postpartum). Participants report less discomfort and fewer side effects with postpartum IUD (PPIUD) insertion.

Until now, two methods have been commonly used for PPIUCD insertions.

(1) manual placement, obsolete these days due to the patient's discomfort.

(2) Kelly's forcep insertion, commonly used. In this, the provider removes the IUD from the package, holds it with the forceps and then places the IUD at the uterine fundus.

Both approaches require the IUD to be manipulated by hand providing an opportunity for contamination, possible subsequent infection and damage to the IUD. Though PPIUD insertion has several benefits to clients and providers, it also comes with certain challenges due to the shape and size of the postpartum uterus. Conventional IUD inserters are neither long nor firm enough to reach the postpartum uterine fundus. So they have used Kelly's forceps and the string used is too short to be visible after PPIUD insertion. The visibility of the string reassures the provider that an IUD is properly placed.

To overcome the above short comings, this study was conducted to evaluate the feasibility, acceptability and safety of the dedicated postpartum intrauterine device (PPIUD) inserter (Fig. 1) specifically designed for the post-delivery setting, in comparison with the conventional PPIUCD. Primary objectives of fundal placement and ease of insertion along with added advantage of thread visibility post-insertion, were assessed. Secondary objectives were participant satisfaction, expulsion and IUD retention.

Criteria for Inclusion

1. Primiparous or multiparous women delivering vaginally and willing for postpartum IUD insertion.
2. Consenting and willing for cut.

Criteria for Exclusion

The cases which were excluded from the study are cases with-

1. Prolonged rupture of membrane (> 18 h).
2. Unresolved postpartum hemorrhage.
3. Extensive genital trauma.
4. Coagulopathies.
5. Distorted uterine cavity.
6. Cesarean delivery.

Methods

A prospective and case–control study was conducted from October 2018 to March 2019 in the Department of Obstetrics and Gynecology. Women were counseled during their antenatal visits, at the time of early labor and just after delivery and were encouraged to opt for post-placental IUCD insertion. Eligible participants met the World Health Organization (WHO) medical eligibility criteria. It gives detailed guidance regarding whether a woman with a certain condition can safely use a given method of family planning. The MEC (Medical Eligibility Criteria) has four categories:

Category 1: A condition for which there is no restriction for the use of the contraceptive method. Safely use.

Category 2: A condition where the advantages of using the method generally outweigh the theoretical or proven risks. Generally, use.

Category 3: A condition where the theoretical or proven risks usually outweigh the advantages of using the method. Generally, do not use.

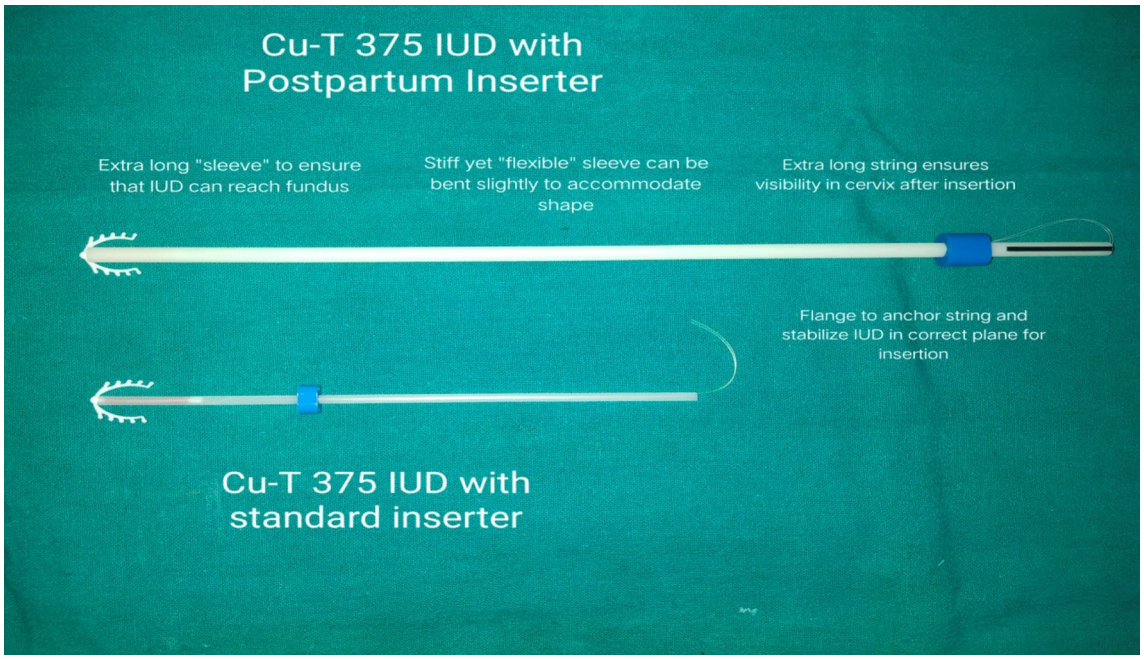

Fig. 1 Cu-T 375 IUD with postpartum inserter and Cu-T 375 IUD with standard inserter

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used. Do not use.

Six hundred sixty-five postpartum women after normal vaginal delivery were selected. After removing participant withdrawals and those lost to follow-up, 593 women were included in analysis. They were divided randomly into two groups:–

Group I–long inserter group.

Group II–control group (where conventional method of insertion was used).

There was statistically no significant difference in demographic profiles of both the groups.

Advantages of the dedicated PPIUD inserter are to eliminates the need of instruments such as forceps and allows an easier technique that is more similar to the interval insertion. It is made from stiff and flexible silastic that allows it to bend and accommodate the shape of the postpartum uterus. It comes preloaded in the insertion sleeve, ready to insert eliminating the need for manipulation and reducing the opportunity for contamination and infection. It does not require the provider to put his/her hand in the woman's vagina to insert the IUD further reducing the risk of infection and discomfort. It has a longer insertion sleeve than the conventional IUD inserter to ensure the better fundal placement, further reducing the risk of expulsion and facilitating insertion. It has a longer thread than the conventional IUD which is visible following the insertion.

All the selected cases were subjected to PPIUCD insertion as per guidelines of the Government of India. Post-insertion, the cases were explained about the follow-up at 2 weeks, 6 weeks and 3 months or as soon as she notices any warning signs such as foul smelling lochia, excessive bleeding per vaginum, any signs and symptoms of infection like fever, myalgia, body ache, discharge per vaginum, pain lower abdomen, expulsion of IUCD.

Participants were asked to report their perceived pain, pre- and post-PPIUCD insertion on a 3-point scale of ''no pain,'' ''bearable'' and ''unbearable.'' An abdominal ultrasound was performed immediately post-insertion to assess fundal placement of the IUD. The distance between the endometrial verge (the fundal termination of the endometrium) and the uppermost (leading) aspect of the IUD was measured.

The healthcare provider inserting the IUD using the dedicated inserter were asked to complete a satisfaction questionnaire. This questionnaire assessed the ease of insertion on a 3-point scale (''easy,'' ''slightly difficult'' and ''difficult'').

At the time of follow-up, detailed history including the satisfaction level and regarding the warning signs was taken. IUCD thread was checked and trimmed. Ultrasound examination was done in order to measure the distance between the endometrial verge and upper most part of the IUCD.

Results

Women ranged from 20 years of age to 40 years. All participants had at least one living child, and parity ranged from one to more than three. The majority of participants in the study received contraceptive counseling for their PPIUD while in early labor (59.58%) from long inserter group and 60.81% from control group; no counseling took place during active labor. There were no significant complaints in the first 48 h of insertion in both the groups. Post-insertion, fundal placement (< 5 mm from the endometrial verge) with the PPIUD inserter was achieved in 53% of cases ($n = 156$) (Table 1) as compared to 37.5% cases of control group. No perforations were reported or observed on ultrasound, and no infections occurred among the participants in both the groups during the subsequent follow-ups.

At the end of 3 month, 10 women from long inserter group had complaints of mild lower abdominal pain as compared to 24 women from control group (Fig. 2).Complaint of irregular bleeding was noted in only 2 women in long inserter group and 16 women in control group (Fig. 3). Vaginal discharge was recorded in 18 women in control group as compared to 4 women in long inserter group (Fig. 4).

The participant satisfaction questionnaire revealed that 8.90% of participants from long inserter group and 14.56% participants from control group experienced pain after PPIUD insertion. Healthcare providers reported 94% of insertions to be easy with long inserter group while in control group easy insertion was experienced only by 67.57%.

Among all participants from both the groups in follow-up visits, the IUD was completely expelled in only one case from long inserter group and five cases from control group. At the time of third follow-up, PPIUCD was removed in single case from long inserter group and five cases from control group for clinical reasons. The mean distance of the IUD from the fundus (on immediate post-insertion ultrasound) among those cases with an expelled IUD at the follow-up visit was between 10 = < 15 mm in long inserter group and between 15 = < 20 mm from control group.

At the end of third follow-up, 98.4% of the participants from long inserter group stated that they were satisfied with the overall experience, while from control group 96.6% participants were satisfied.

Discussion

Studies in the past suggest that placement of the IUD at the fundus and the skill of the provider are important factors for effective PPIUD service delivery. In our study, primary objective was comparison between better fundal placement of IUD using a dedicated postpartum inserter and the conventional one along with the side effects in two groups and IUD distance from the endometrial verge. In this study, the dedicated PPIUD inserter functioned well and very much as anticipated with over 53.4% of IUDs being placed high (< 5 mm from the IUD to the endometrial verge) compared to 37.5% of conventional PPIUCD inserter. The majority 276 (94.52%) of insertions using long inserter were found to be easy or very easy among

Table 1 Comparison between IUD-fundal distance in control and long inserter group. The participant satisfaction questionnaire revealed that 8.90% of participants from long inserter group and 14.56% participants from control group experienced pain after PPIUD insertion. Healthcare providers reported 94% of insertions to be easy with long inserter group while in control group easy insertion was experienced only by 67.57%

Follow-up	IUD–fundal distance	PPIUCD			
		Control group $N = 301$		Long inserter $N = 292$	
		No. of participants	Percentage	No. of participants	Percentage
48 h	< 5 mm	113	37.5	156	53.4
	5–10 mm	168	55.8	135	46.2
	10–< 15 mm	18	5.9	01	0.34
	15–< 20 mm	02	0.66	00	00
2 weeks	< 5 mm	150	49.8	173	61.9
	5–10 mm	146	48.5	117	39.1
	10–< 15 mm	01	0.33	00	00
6 weeks	< 5 mm	168	56.5	188	64.3
	5–10 mm	128	43.5	102	35.7
	10–< 15 mm	00	00	00	00
3 months	< 5 mm	269	90	271	93.5
	5–10 mm	27	9.12	19	6.5
	10–< 15 mm	00	00	00	00

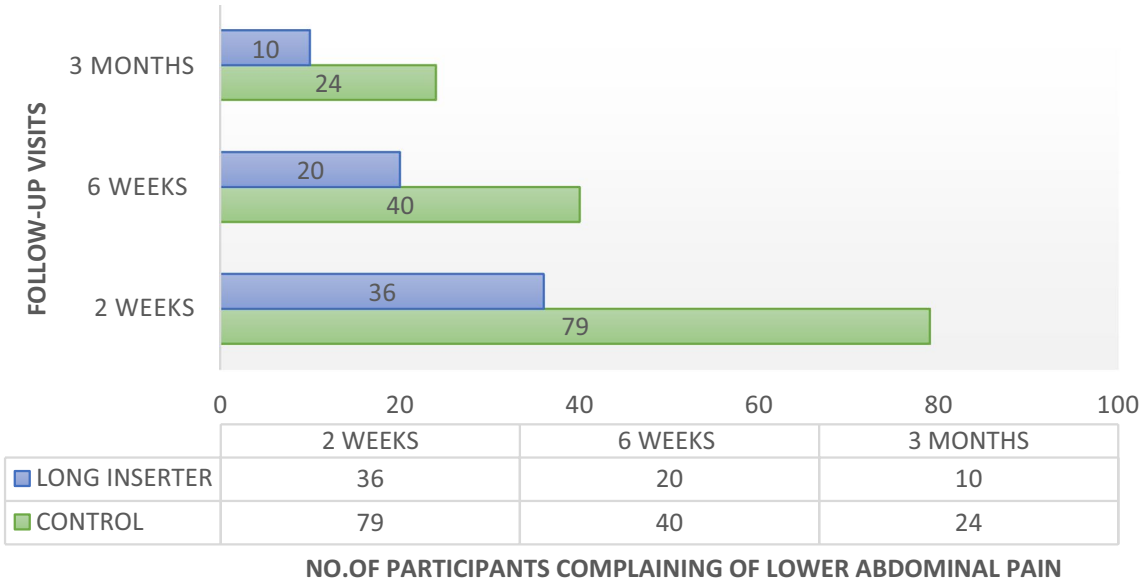

Fig. 2 Complaint of lower abdominal pain during follow-up

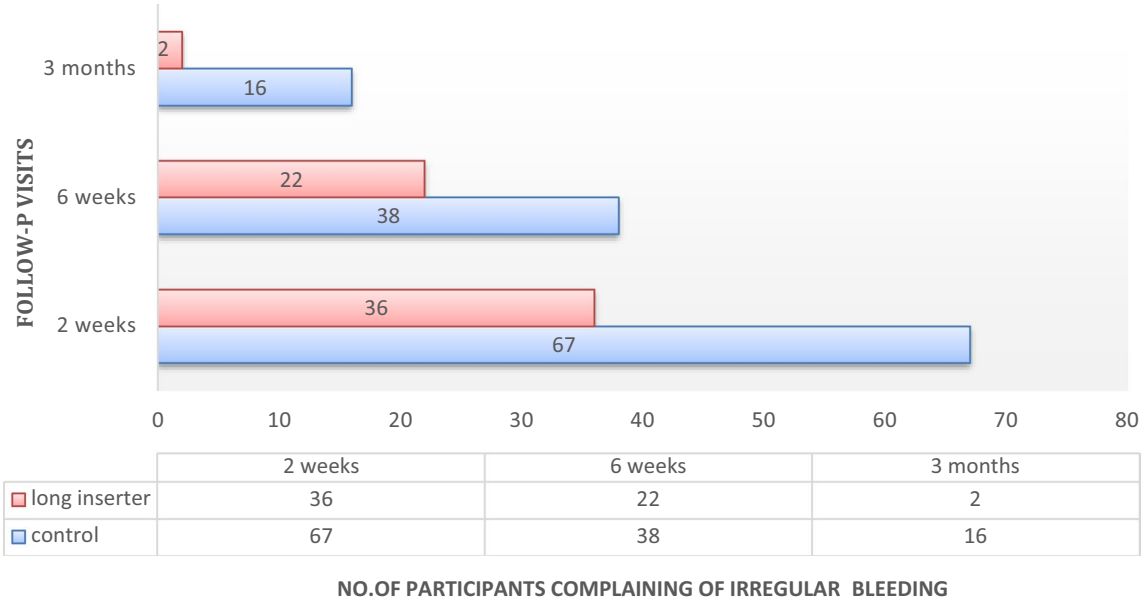

Fig. 3 Complaint of irregular bleeding during follow-up

providers. Among control group 84 (32.43%) insertions were found to be difficult or very difficult by providers. The study conducted by Singh S et al [1] had found that the majority of insertions (93% cases) were easy in the long inserter group. Symptoms of pain, irregular bleeding and vaginal discharge were more common in participants in which fundal placement was not achieved, i.e., more in control group compared to long inserter group.

In the study done by Singh P [2]. it was observed that when the distance from fundus increased, there were more complaints of pain and bleeding per vaginum. Braaten et al [3] studied 211 women using Cu T-380A of whom 155 presented with bleeding and pain related to IUCD use. The top-fundal distance was measured (distance between the device top and the highest point in the uterine cavity). About 50% of complainers had a top-fundal distance of more than 40 mm compared to 28% of non-complainers

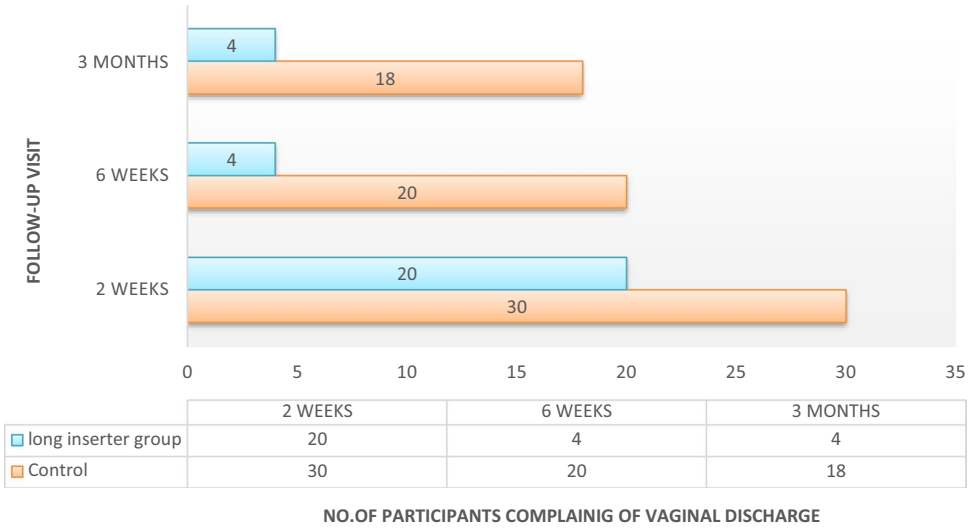

Fig. 4 Complaint of vaginal discharge during follow-up

Table 2 Level of satisfaction among control and long inserter group, *p* value– 0.03

Follow-up	Level of satisfaction	PPIUCD			
		Control group		Long inserter group	
		No. of participants	Percentage	No. of participants	Percentage
2 weeks	Not satisfied	00	00	00	00
	Partially satisfied	54	18	30	10
	Satisfied	246	82	262	90
6 weeks	Not satisfied	00	00	00	00
	Partially satisfied	23	08	09	3.4
	Satisfied	274	92	281	96.6
3 months	Not satisfied	00	00	00	00
	Partially satisfied	11	04	03	1.6
	Satisfied	285	96	287	98.4

and in agreement with our result. With time as the uterus involuted the IUD-fundal distance improved along with the improvement in the complaints of both the groups. Non-visibility of thread creates uncertainty about IUD location in the participants of control group. Missing thread which was a common complaint in the control group was not seen in a single case of long inserter group. Malik J et al [4] in India reported that percentage of cases presenting with missing thread at 6 weeks was 25.5% which reduced to 7.2% at 3 months and 6 months it was only 4.4%.

Complete IUD expulsion at up to 3 months post-insertion was observed in a single case of long inserter group, while 05 cases from control group. It was observed that all these expulsions were the IUDs which were placed at a distance of 10-15 mm in long inserter group and between 15 and < 20 mm from control group. A study done by Singh Set al[1]on dedicated PPIUCD inserter concluded that among all 80 participants, by the follow-up visit, the IUD was completely expelled in only 6 cases (7.5%), partially expelled in 8 cases (10.0%). The mean distance of the IUD from the fundus (on immediate post-insertion ultrasound) among those cases with an expelled IUD at the follow-up visit was 12.2 mm compared with 5.3 mm among women whose IUD was retained at the follow-up visit. A study conducted in June 2015 at Jaipur by N Goyal [5] also states that the expulsion rate was higher where USG showed > 10 mm distance between fundus and Cu-T. Client satisfaction was good in long inserter group, i.e., 98.4%. With each follow-up as there was improvement in the complaints. The satisfaction level improved in control group also 96.6% with *p* value 0.03 (Table 2). Single participant from long inserter and 05 cases from control group got their PPIUCD removed due to various reasons despite counselling.

Conclusion

In our study, we concluded that insertion of postpartum IUCD using a dedicated long inserter is an effective, safe, convenient and comfortable method of PPIUCD insertion. Long inserter has precise fundal placement and better thread visibility as compared to the conventional forceps insertion. We recommend that PPIUCD long inserter can be routinely offered to all eligible postpartum women undergoing institutional deliveries. We also recommend that studies of larger size and longer period of follow-up maybe undertaken to further evaluate its safety and clinical outcome.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Standards. Ethical clearance for doing the study was obtained from the institutional ethics committee.

Informed Consent Informed consent was obtained from all the eligible women for participating in the study.

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