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ORIGINAL ARTICLE

A Prospective Study to Evaluate Vaginal Insertion and Intra-Cesarean Insertion of Post-Partum Intrauterine Contraceptive Device

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Abstract

Objectives Evaluation and comparison of safety and efficacy of vaginal and intra-cesarean insertion of Post-Partum Intrauterine Contraceptive device (PPIUCD).

Methods An interventional prospective study conducted in the Department of Obstetrics and Gynaecology at NRS Medical College, Kolkata. PPIUCD were inserted in 263 mothers in 1-year study period. Among them, first 100 mothers who delivered vaginally and the first 100 who underwent cesarean section were regarded as study groups and were followed up for 1 year.

Results Both modes of PPIUCD insertion were found to have very low rates of expulsion, vaginal bleeding, infection, missing strings, and also effective as contraceptive. Expulsion rate was 4 % in the vaginal group and 2 % in intra-cesarean group. Strings of PPIUCD were less visible after cesarean insertion than vaginal insertion ($p = 0.028$).

Conclusion PPIUCD is an appealing approach and may become the best choice as post-partum contraception after vaginal as well as cesarean delivery.

Keywords PPIUCD · Vaginal insertion- post-placental · Immediate post-partum · Intra-cesarean insertion

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Introduction

61 % of births in India occur at intervals that are shorter than the recommended birth to birth interval of 36 months (27 % of births occur within 24 months after a previous birth, and 34 % of births occur between 24 and 35 months). Only 26 % of women are using any method of family planning during the first year post-partum [1]. Hence, the issue of spacing may be addressed during post-partum period by intrauterine contraceptive device.

With a remarkably low failure rate of less than 1 per 100 women in the first year of use, the Cu T 380A is on the top tier of contraceptives in terms of efficacy. Provision of IUCD in the immediate post-partum period offers an effective and safe method for spacing and limiting births [1].

Taking advantage of the immediate post-partum period for counseling on Family planning Post-Partum Intrauterine Contraceptive Device (PPIUCD) is a good option as a contraceptive method. In developing countries, delivery is the only opportunity when the healthy women come in contact to the health care providers, and they may never return seeking contraception advice, so IUCD insertion during delivery may be the best scope to curtail the fertility rate.

There is a common belief that post-partum intrauterine contraceptive device (PPIUCD) insertion immediately after delivery is associated with higher expulsion rate than interval IUCD insertion. The objective of this study was to evaluate the efficacy and safety in terms of primary complications like failure rate i.e., accidental pregnancy and secondary complications like clinical (spontaneous expulsion, infection, missing string, pain abdomen, bleeding per vagina, white discharge, and uterine perforation), psychological (satisfied or not), discontinuation, and removal and to compare them among the two modes of insertion i.e., vaginal insertion with intra-cesarean insertion.

Materials and Methods

This was a hospital-based interventional prospective study conducted from April 2012 to March 2013 in the Department of Obstetrics and Gynaecology at Nilratan Sircar Medical College and Hospital, Kolkata, a tertiary care hospital in eastern India. All eligible women fulfilling the inclusion criteria (post-partum mothers of any age and parity within 48 h of delivery) were enrolled for study. Mothers >48 h post-partum, history of chorioamnionitis or prolonged rupture of membrane >18 h, unresolved PPH, HIV not on antiretroviral therapy, high risk of Chlamydia and gonorrhea infection, known pelvic tuberculosis, diabetes, and heart disease who were excluded for PPIUCD insertion were enrolled in the study. Clients who did not wish PPIUCD were also excluded.

The mothers were explained about the benefits and side effects of IUCD and other available methods of contraception as cafeteria approach during antenatal period. An informed consent was taken, and Cu T was placed high up the fundus immediately following vaginal delivery by long Kelley's forceps (called post-placental) in lithotomy position. Those mothers who agreed IUCD within 48-h post-partum were also inserted in the same method (immediate post-partum). The strings were not cut and not visible vaginally. Mothers were discharged 48 h after delivery.

Those undergoing cesarean section, IUCD, were placed high up at the fundus manually holding the IUCD in between middle and index fingers of the hand and passed it through the uterine incision followed by slow withdrawal of hand. Strings were pointed toward cervical canal but not pushed to the canal to avoid infection by vaginal flora, contamination, and displacement of the IUCD. Care was taken to avoid stings to be included during suture. Uterus was repaired in two layers (Vicryl 1-0).

Total 735 mothers were counseled. Group A consisted of 680 mothers where counseling was done antenatally. Among this 290 accepted this of which insertion was done in 253. In 131 mothers who delivered vaginally, IUCD was inserted within 10 min of delivery of afterbirths. In 122 mothers, IUCD was placed cesarean section after delivery of placenta.

Group B consisted of 55 mothers where counseling was done after vaginal delivery. Out of 18 who accepted this, IUCD was inserted in cases. Hence, the total member of mothers where vaginal insertion was made was 141.

Depending upon mode of delivery, they were subdivided as vaginal PPIUCD insertion group (post-placental + immediate post-partum) and intra-cesarean insertion PPIUCD group.

They were enlisted serially, and first 100 woman of each group were taken as study population (Fig. 1).

Those going home with IUCD inserted were followed up at 6 weeks, 6 months, 12 months, and 18 months. The information collected, compiled methodically and analyzed according to statistician by Student's t test, Chi-square test, and Fischer Exact tests on SPSS version 15.

Result and Analysis

In this study, it was found that, in both groups (vaginal insertion and intra-cesarean), acceptance of PPIUCD was best in the age group of 21–25 (40 and 44 %) followed by 25–30 years (31 and 23 %). Primipara mothers accepted

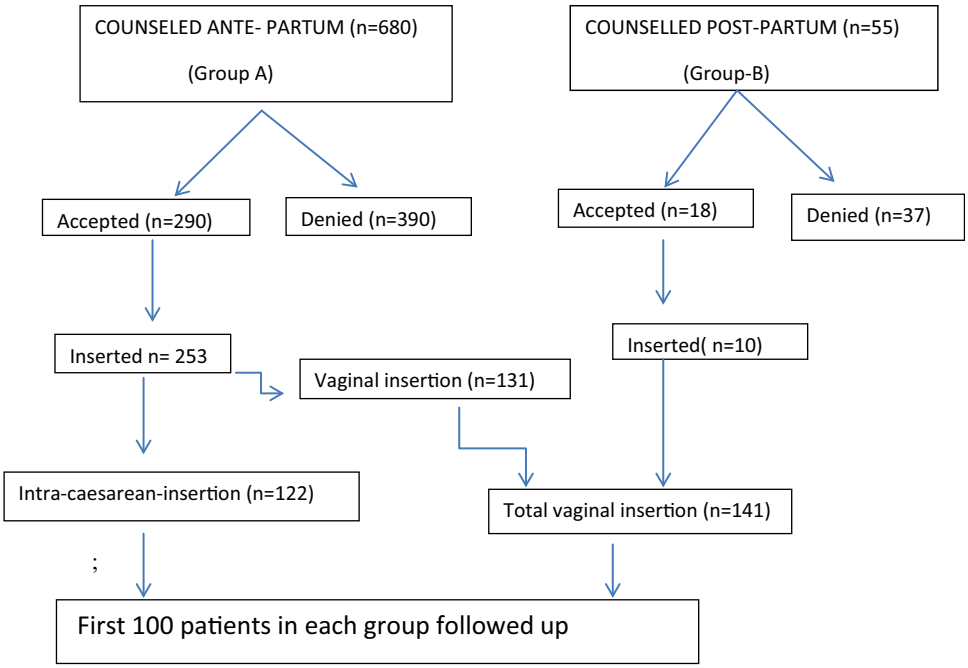

Fig. 1 Showing recruitment of study population

PPIUCD more than the others (44 and 52 % in vaginal &intra-cesarean group, respectively). Mothers from urban background were more motivated toward PPIUCD (62 and 52 % in vaginal group and intra-cesarean group, respectively) in comparison to rural mothers (38 % in vaginal group and 48 % in cesarean group) (Table 1).

Expulsion rate was 4 % in vaginal insertion group and 2 % among intra-cesarean insertion group ($p = 0.651$). Significant statistical difference was found in the study, when expulsion rates were compared between post-placental PPIUCD (3.33) and immediate post-partum PPIUCD (10 %) in vaginal group ($p = 0.0447$) (Table 2).

Vaginal bleeding was complained by 10 % of mothers in each vaginal group and 5 % of mothers in intra-cesarean group. But bleeding was irregular, mild, and on and off in 6.6 % in post-placental insertion, 10 % in immediate post-partum insertion, and 2 % in intra-cesarean insertion; on the other hand, excessive and continuous bleeding was found as 2 and 5 % in vaginal and intra-cesarean insertion, respectively. Pain abdomen was reported by 7 % mothers of vaginal PPIUCD group and 4 % mothers of intra-cesarean PPIUCD group, respectively ($p = 0.602$). IUCD had to be taken out in 2 % of mothers for vaginal bleeding in vaginal insertion group and 1 % in cesarean group. Pain abdomen compelled to remove only in cesarean group (1 %). 2 % couple in vaginal group and 1 % couple among cesarean group desired to remove without any complication. Total removal was 8 % in vaginal group and 4 % in intra-cesarean group (Table 3).

No pregnancy was recorded in any of the group within 1-year follow-up. 1 % of mothers presented with infection like PID in each vaginal and intra-cesarean group. No infection was found in immediate insertion of PPIUCD.

6.6 % of mothers among post-placental insertion were found to have long strings, 10 % of mothers in immediate post-partum insertion found to have long strings on speculum examination, and 3 % among intra-cesarean insertion group had long strings ($p = 0.194$).

Missing strings were complained by 16 % of mothers in vaginal group and 30 % of mothers in intra-cesarean group. In the vaginal group, no strings were missing among immediate post-partum insertion. Statistically significant ($p = 0.028$) difference between vaginal insertion and cesarean insertion was found. Total removal by mothers was 8 % among vaginal group and 4 % among intra-cesarean group which is not statistically significant ($p = 0.234$). 2 % cause for removal was partial spontaneous expulsion in vaginal group, and 1 % of partial expulsion was found in cesarean group. Excessive vaginal bleeding formed 2 % cause for removal in vaginal group and 1 % in intra-cesarean group. In intra-cesarean insertion group, 1 % removal was done for severe pain abdomen. Among 100 mothers in vaginal group, accidentally 1 woman lost her husband within 1 year and discontinued IUCD, and 1 baby died within 6 weeks and the mother wanted removal (Table 2). Continuation rate at 18 months was 94 % in vaginal insertion group and 88 % in cesarean insertion group.

94.2 % of mothers in vaginal insertion group and 83.7 % in intra-cesarean group had visible strings at the end of 18 months follow-up. (Those who had spontaneous expulsion and who removed PPIUCD for their own desire were excluded).

Table 1 Demographic distribution of study population (n = 200)

Age group (years)	Vaginal insertion	Intra-cesarean insertion	Significance
<20	23	19	$p = 0.670$
21–25	40	44	
26–30	31	23	
31–35	5	12	
>35	1	2	
Mean ± SD	24.56 ± 4.48	24.84 ± 4.79	
Parity			
Para 1	44	52	$p = 0.411$
Para 2	38	40	
Parity 3	15	8	
Parity 4	3	0	
Mean ± SD	1.68 ± 0.76	1.34 ± 0.50	
Educational status			
No formal education	14	8	$p = 0.2582$
Primary education	32	41	$p = 0.2399$
Secondary education	42	44	$p = 0.8865$
Higher secondary	7	7	$p = 1.000$
Residence			
Rural	38	62	
Urban	48	52	$p = 0.564$

Table 2 Complications of PPIUCD and comparison between vaginal and intra-cesarean group (n = 100)

Complications	Vaginal insertion group		Total (n = 100)	Intra-Cesarean insertion group (n = 100)	*P* value (S/NS)
	Post-placental (n = 90)	Immediate post-partum (n = 10)			
Expulsion	3 (3.33 %)	1 (10 %)	4 (4 %)	2 (2 %)	0.651 (NS)
Bleeding p/v	8 (8.9 %)	2 (20 %)	10 (10 %)	5 (5 %)	0.818 (NS)
Pain abdomen	7.8 % (5.5 %)	0	7 (7 %)	4 (4 %)	0.602 (NS)
Pregnancy	0	0	0	0	0
Infection	1 (1.1 %)	0	1 (1 %)	1 (1 %)	1.00 (NS)
White discharge	4 (4.4 %)	1 (10 %)	5 (5 %)	6 (6 %)	0.756 (NS)
Perforation	0	0	0	0	
Long strings	6 (6.6 %)	1 (10 %)	7 (7 %)	3 (3 %)	0.194 (NS)
Missing strings	16 (17.7 %)	0	16 (16 %)	30 (30 %)	0.028 (S)

In vaginal insertion group, 81 % of strings were visible at the end of 6 weeks when 4 mothers removed PPIUCD, 2 mothers presented with spontaneous expulsion and 2 with partial expulsion. At 6 months, total threads were visible in 84 among 92 mothers (91.3 %). Among those 92 mothers, 3 mothers removed PPIUCD at 6 months. So at the end of 18 months among 89 mothers, 84 PPIUCD strings were visible i.e., 94.4 %. In intra-cesarean group, among the 100 mothers 65 % had visible threads at the end of 6 weeks. 1 mother removed her Cu T. At the end of 6 months among 99 mothers, 79 had visible threads (81.8 %) and 2 mothers removed Cu T. At the end of 18 months among 97 mothers, 81 had visible strings i.e., 83.6 % (Fig. 2). 74 % of mothers were satisfied with PPIUCD in vaginal group and 72 % in cesarean group.

Discussion

Mothers having more than two living children had much lower acceptance of IUCD (1 %) among cesarean group in comparison to vaginal group (13 %). This may be due to their preference to permanent sterilization as evidenced during counseling. Acceptance of the PPIUCD was higher among parity 1 and parity 2, contradicted by the study done by Safwat et al. in Egypt, where 16 % of primipara mothers

Table 3 Reasons of discontinuation of PPIUCD in both groups

Reasons of removal	Type of insertion (n = 100 each group)	Removal at 6 weeks	Removal at 6 months	Removal at 12 month	Removal at 18 months	Total number of removal
Couple desires	Vaginal	0	1	1	0	2
	Intra-cesarean	0	0	1	0	1
Partial expulsion	Vaginal	2	0	0	0	2
	Intra-cesarean	1	0	0	0	1
Excessive vaginal bleeding	Vaginal	0	1	1	0	2
	Intra-cesarean	0	1	0	0	1
Severe pain abdomen	Vaginal	0	0	0	0	0
	Intra-cesarean	0	0	1	0	1
Baby died	Vaginal	1	0	0	0	1
	Intra-cesarean	0	0	0	0	0
Husband expired	Vaginal	0	1	0	0	1
	Intra-cesarean	0	0	0	0	0
Total removal	Vaginal	3	3	2	0	8
	Intra-cesarean	1	2	1	0	4

P value = 0.234

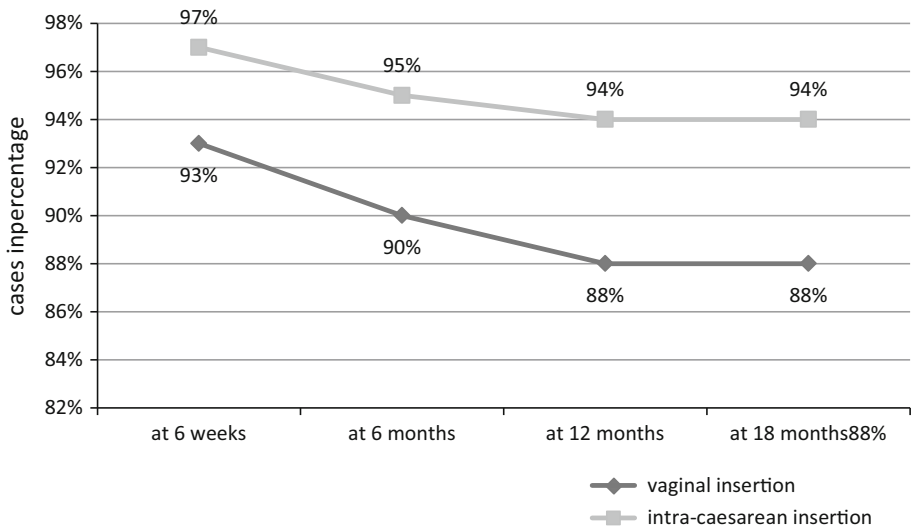

Fig. 2 Showing the continuation pattern of PPIUCD

accepted the use of PPIUCD compared to one-third of grand multiparous [2].

This may be due to higher educational status of the urban population compared to rural in India. A study by Safwat et al. supports this (women with no formal education had an acceptance of 9.4 %, while those with formal education were 19.4 %) [2]. No significant difference in acceptance was found for birth weight, gender, habitat, and education status of the study population.

Expulsion rate in the existing study was 4 % in the vaginal group and 2 % in intra-cesarean group which were much lower than the previous hypothesis and studies. Celen S et al. in 2004 found that the 1-year cumulative expulsion rate with Cu T was 12.3 % in early post-placental insertion of IUCD [3]. Another study in 2011 found 17.6 % expulsion rate in intra-cesarean IUCD [4]. No statistical difference was found among the two groups ($p = 0.651$) in contradiction to a pilot study done by Letti Muller et al. Expulsion rates were statistically different after a vaginal birth, 50 % (ultrasound only) + 27.8 % (clinical examination); post-cesarean section, 0 % ($p < 0.001$; OR 5.75, 95 % CI 2.36–14.01) after a vaginal birth, 50 % (ultrasound only) + 27.8 % (clinical examination); and post-cesarean section, 0 % ($p < 0.001$; OR 5.75, 95 % CI 2.36–14.01) [5]. Lower expulsion were found when Cu T was inserted within 10 minutes of delivery (post placental) than immediate post-partum (10 minutes to 48 hours of delivery). A systemic review by Kapp N et al. also found the same [6].

In this study, statistically no significant differences regarding bleeding and infection were found among the vaginal group and intra-cesarean group ($p = 0.818$ and 1.00, respectively) as also noticed by Welkovic S et al. [7].

In this study, pelvic infection (3.2 %) was slightly high compared to a study done in Kenya and Mali which indicated a rate of less than 2 %.

White discharge complained 4.4 and 10 % of mothers with post-vaginal delivery IUCD group and intra-cesarean IUCD group, respectively. No statistically significant difference was recorded for white discharge among both types of insertion ($p = 0.756$). Pain abdomen was found in 7 and 4 % of mothers in vaginal insertion and intra-cesarean insertion, respectively ($p = 0.602$). Significant difference between the two groups was found regarding missing strings ($p = 0.028$). But no strings were missed in immediate post-partum group.

Those mothers complaining missing strings and those not complaining were examined for visibility of threads at each follow-up. Among vaginal insertion group, at 6 weeks, 6 months, 12 months, and 18 months, threads of IUCD were visible in 81, 91.3, 94.4, and 94.4 %, respectively. In the intra-cesarean insertion group, visibility rates were 65, 79.8, and 83.5 % at 6 weeks, 6 months, 12 months, and 18 months, respectively. At each follow-up, visibility of thread was significantly different statistically among the both groups of study ($p < 0.05$ at each follow-up). Although nelson A et al. found the strings in all the 7 intra-cesarean inserted IUCD cases, the present study gives a different picture that a significant portion of intra-cesarean PPIUCD-inserted mothers presented with no clinically visible threads even at 18 months follow-up [8].

In this study, long strings formed one of the major complaints. 6.6 % of mothers in vaginal PPIUCD and 10 % in intra-cesarean PPIUCD had long strings on vaginal examination leading to feeling of uneasiness and discomfort. But statistically significant difference was recorded among the two types of vaginal insertion i.e., among post-placental insertion and immediate post-partum insertion ($p = 0.0105$). It was found that 10 % of immediate post-partum IUCD had long threads visible on speculum examination in comparison with only 4.4 % mothers with post-placental IUCD.

IUCD inserted vaginally or intra-cesarean, contraceptive efficacy were same i.e., 0 per 100 woman year. No perforation was recorded in both groups.

In the present study, discontinuation due to removal and expulsion were 7, 3, 2, and 3, 2, and 2 % at the end of 6 weeks, 6 months, and 12 months in vaginal and cesarean group, respectively ($p = 0.215$), which was lower than reported incidence shown by Celen S et al. (cumulative rates of expulsion, removal for bleeding/pain and other medical reasons were 17.6, 8.2 and 2.4 per 100 women per year, respectively) [4].

74 % of mothers were satisfied with PPIUCD in vaginal group and 72 % in cesarean group ($p = 0.750$) which was comparable to the study by Levi. E. et al. on 90 patients undergoing cesarean delivery. 47 % of women were reached for phone follow-up at 6 months post-partum, and 80 % reported being "happy" or "very happy" with their IUD [9].

In this study, PPIUCD was found to be very safe and effective method of contraception among both the groups simulating the inference drawn by Cochrane Database review by Grimes et al. in 2010 [10].

Conclusion

From the study results, it can be concluded that PPIUCD in the field of PPFP is a promising approach. Whatever may be the mode of delivery, PPIUCD is safe and efficacious in terms of safety and efficacy.

Inserting Cu T 380A post-partum is safe leading to the expanding of the usage of IUCD meeting the unmet needs. The expulsion rate is minimal as the study shows, in contrast to previous studies. Both vaginal insertion and intra-cesarean insertion are safe in terms of complications and efficacious from contraception point of view. Only strings of IUCD after cesarean section are less to be visible at follow-up in comparison to vaginal insertion. The PPIUCD was demonstrably safe, having no reported incidence of perforation, pregnancy with low rates of expulsion, pain abdomen, pelvic infection, and lost strings. Continuation rate in intra-cesarean insertion was higher compared to vaginal insertion.

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Compliance with ethical requirements and Conflict of interest No conflict of interest is declared. Informed consent was taken from all the patients involved in this study. Animal studies not applicable.

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