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A Prospective Study to Evaluate the Safety and Efficacy of PPIUCD and Interval Insertion of IUCD in a Rural Hospital of West Bengal.

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Abstract:
Background: *Short Interval between births is linked to higher maternal and child mortality, In India 15.60 million abortion are performed with abortion rate of 47.0/1000women aged 15-49 years (Jan2018). In spite of widely available contraceptives in free of cost, unplanned and unwanted pregnancies complicate maternal health especially in rural areas. Preventing unplanned pregnancy and abortion, contraceptives in immediate use of delivery may be a remedy and IUCD CU-T is one of the answers.*
In this context of our study was to evaluate the safety and efficacy of insertion of immediate post placental IUCD (PPIUCD) using CU-T 380A in women delivering vaginally in a rural hospital and to compare it with interval insertion of IUCD CU-T 380A in same setting.
Materials and methods*: This prospective observational study was carried out in rural based community hospital in West Bengal between January 2019 and December2019. After counseling 122 willing parturient mothers in labour room and antenatal ward were consented for postpartum IUCD insertion within10 minutes of delivery of placenta, and 68 willing mothers were selected from family planning clinic any time after 6 weeks of delivery for interval IUCD insertion. After taking written consent both groups of women were inserted CU-T 380 A and they were advised to attend FP clinic after 6 weeks and 6 months of insertion for follow-up study.*
Results*: Among 520 women admitted for delivery 122 (23.46%) consented for PPIUCD insertion and 110 women were available for follow-up study after six month and among 410 women, 68 women (16.58%) were consented for interval IUCD insertion. Of that 62 women were available for follow-up after 6 months. On side effects study abnormal vaginal bleeding (7.27% VS 6.45%) dysmenorrhoea (3.63%Vs 3.22%), PID (2.7% VS 1.61%) and mixed side effects (6.36% VS 6.45%) were comparable of both PPIUCD and interval insertion group. But abnormal vaginal discharge was significantly more in interval insertion group (14.51% VS 4.54%) (P<0.05). Rate of discontinuation was more (20.99% VS 16.52%) in interval insertion group of women and are due to more side effects. PPIUCD inserted women continues more in percentage (85.48% VS 79.01%) than interval IUCD users.*
Conclusion*: IUCD CUT 380 A is a safe, efficacious and long durable (10 years longevity) contraceptive and birth spacing method and PPIUCD is a better option than interval IUCD. Moreover women can take the advantages of family planning services on the same day of delivery through PPIUCD insertion option.*
Keywords: *PPIUCD. CUT 380 A, Dysmeorrhoea, Contraception.*

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I. Introduction

Sperof et al 2008, on average women who do not breastfed ovulate by 45 days after child birth and possible as soon as the 28th day after child birth. Fertility begins prior to return of menses in 2 out of 3 women. In 2015 total fertility rate of India was 2.45 births per women [1]. 15.60 million abortions performed with an abortion rate of 47.0 per 1000 women aged 15-49 years [2].

National population policy of India was formulated in the year 2000 with the long term objectives of achieving a stable population by 2045, at level consistent with requirements of sustainable economic growth. Although the India government offers IUCD services for free of cost, it still remain largely underutilized. According to NFHS-3 IUCD accounts for only 1.2-1.6% of total contraceptive usage in the country [3].

In last decade Government of India has started a program, Janani Suraksha Yojana, a conditional cash transfer scheme for promoting institutional deliveries. Through this program there is an ample scope of motivating a large quantity of eligible poor women and bringing them for IUCD insertion immediately after

vaginal delivery specially in rural areas. According to a 2010 cochrane review PPIUCD is a safe and effective contraceptive method [4].

In umbrella of quality postpartum family planning services, inserting Cu-T 380 A within 10 minutes of lacental delivery leads to safe expanding usage of IUCD in majority of unmet needs.

Hence the aims and objectives of this study were to evaluate the safety and efficacy of insertion of immediate post placental IUCD after vaginal delivery using CU-T 380A in women in a rural hospital and to compare it with interval insertion of IUCD , CU-T 380A in same rural setting.

II. Material and Methods

The present study was a prospective observational study conducted in Domjur Rural Hospital, West Bengal ,during the period of January 2019 to December 2019. Admitted 520 parturient women were counseled for insertion of IUCD CU-T 380A within 10 minutes of placental delivery following vaginal delivery. 122 women were consented and considering exclusion criteria, PPIUCD insertion was done by trained personnel. For interval IUCD insertion, total 410 women were counseled in any time after 6 weeks of vaginal delivery, considering exclusion criteria 68 women consented for insertion of IUCD at FP clinic of this rural hospital. Informed written consent were taken from both groups before IUCD insertion. They were followed up after 6 wks and 6 months at FP clinic for studying any adverse side effects, like abnormal vaginal bleeding, unusual vaginal discharge, any complaint of dysmennorric pain, sign and symptoms of PID and combination of above side effects. Pelvic examination was done at both follow up visits of all the PPIUD users for identification of any displacement of CU-T and Ultrasonography was done if any misplacement of IUCD was suspected. Ultimately 110 women among PPIUCD group and 62 women among interval insertion group were attended at FP clinic after 6 months follow up visit and two groups were compared in different parameters.

Data obtained from our study was analized by using modern software, Chi –Square and Fischer exact Tests were perform to test for differences in study population of categorical variables in two groups, The level $P < 0.05$ was considered as the cut off value or significance.

Exclusion criteria:

1. Prolonged rupture of membranes >18 hrs
2. Chorioamnionitis.
3. Unresolved PPH
4. Excessive genital tract injury
5. Acute genital tract infection.
6. Hb % <8 gm/dl
7. Insertion of IUCD 48 hours to 6 wks postpartum.

III. Result

After proper counseling and maintaining exclusion criteria 122 women (23.46%) for PPIUCD and 68women (16.58%) for interval insertion was recruited for my study. Twelve women of PPIUCD group and six women of interval IUCD insertion group did not turn up for follow up after 6 months. Finally 110 women (90.16%) of PPIUCD group and 62 women (91.11%) of interval insertion group were available for detailed study, and they were compared . Majority of the cases in both groups who accepted IUCD were up to 24 years of age (among PPIUCD 74.54%, among interval insertion 77.41%) (Table 1).

Table no 1: Age group distribution of IUCD users

Age	PPIUCD users		Interval IUCD users		P value
	No =110	%	No=62	%	
<20 yrs	52	47.27	32	51.61	P =.9446
20-24 yrs	30	27.27	16	25.80	
25-30yr	21	19.09	10	16.12	
>30yrs	07	6.03	04	6.45	

In parity distribution among IUCD users (Table 2),43.63% PPIUCD users were primipara. But among interval IUCD users 67.74% women were primipara. Parity difference of both user groups were statistically significant (p=.00926).

Table no 2: Distribution of IUCD users according to their parity.

parity	PPIUCD Users		Interval IUCD users		P =.00926 significant
	N= 110	%	N=62	%	
One	48	43.63	42	67.74	
Two	52	47.27	16	25.80	
>Two	10	9.09	04	6.45	

In Table 3 depicts majority of both type of IUCD users were Hindu.

Table no 3: Distribution of IUCD users according to their religion.

Religion	PPIUCD Users		Interval IUCD users	
	N= 110	%	N=62	%
Hindu	88	80	50	80.64
Muslim	22	20	12	19.35

In my study majority of IUCD users in both types belong to low socioeconomic group (BPL) and is depicted in table 4.

Table no 4: Distribution of IUCD users according to their socioeconomic status

Religion	PPIUCD Users		Interval IUCD users	
	N= 110	%	N=62	%
* BPL	73	66.36	45	72.58
£APL	37	33.63	17	27.41

* BPL = below poverty line , £APL = Above poverty line.

Side effects study (table 5) showed that overall complications were more in interval IUCD insertion group (33.85% VS 24.52%). Out of 62 interval IUCD users nine women (14.51%) of unusual vaginal discharge at different times and the difference of unusual vaginal discharge of both groups(14.51% VS 4.54% interval insertion VS PPIUCD group respectively) were statistically significant (P =0.01967).Other complications under my study like unusual vaginal bleeding, dysmenorrhoea, PID and mixed sign and symptoms were similar in both groups. Neither pregnancy nor uterine perforation was noted in both study groups.

Table no 5: Frequency and percentage distribution of side effects for both type of IUCD users.

Side effects	PPIUCD users		Interval IUCD users		P value
	N =110	%	N =62	%	
Unusual vaginal discharge	5	4.54	9	14.51	0.1967(significant)
Abnormal vaginal bleeding	8	7.27	4	6.45	1.00
Dysmenorrhoea	4	3.63	2	3.22	.887
PID	3	2.72	1	1.612	.6415
Mixed side effects	7	6.36	4	6.45	.9819
total	27	24.52	20	33.85	

Regarding discontinuation of IUCD (table 6) showed that number of discontinuation of IUCD among interval IUCD users is slightly higher than PPIUCD users (20.99% VS 14.52%). A good percentage of interval IUCD user group discontinued the method due to side effects mostly unusual vaginal bleeding. Table 6 showed that discontinuation of IUCD of both groups due to side effects and their difference (12.93% and 4.54%,interval IUCD and PPIUCD respectively) was statistically significant (P= .04647). Discontinuation due to social ground was more or less equal (5.45% & 6.45%, PPIUCD and interval IUCD respectively).

Table no 6: Frequency and percentage distribution of discontinuation of IUCD along with causes in both groups.

Causes of discontinuation	PPIUCD users		Interval IUCD users		P value
	N =110	%	N =62	%	
Side effects	5	4.54	8	12.93	.04647
Displacement	2	1.81	1	1.61	.9213
Spontaneous Expulsion	3	2.72	0	---	--------
Social ground	6	5.45	4	6.45	.7884
Total	16	14.52%	13	20.99%	

Composite Bar diagram (Figure 1) depicts that continuation rate of PPIUCD after six months was more than Interval IUCD (85.48% VS 79.01%)

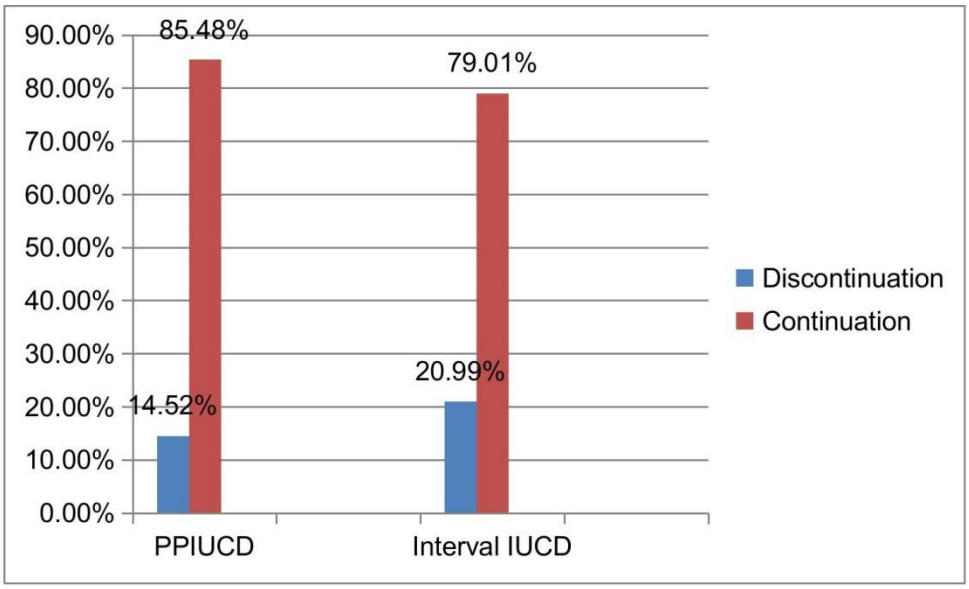

Figure-1

IV. Discussion:

The prevention of unplanned and unwanted pregnancy via the provisions of family planning counseling and methods; could help prevent 20% - 35% of maternal deaths and around 20% of child deaths·[5].

In my study a good number of women attended (90.16% for PPIUCD insertion and 91.11% for interval IUCD insertion) at clinic after six months follow up due to regular contact with field level health staff. More than 80% women of both groups of IUCD insertion were of Hindu religion because the study area was predominantly Hindu based. In my study near about 73% of both group users belong to BPL family. APL group users have different contraceptive options .

The symptoms of abnormal vaginal bleeding was not influenced by type of insertion in my study 7.27% of PPIUCD VS 6.45% interval IUCD Insertion group whereas other researchers reported 10.50% cases had abnormal bleeding in PPIUCD group[7]. 14.51% of interval insertion group and 4.54% of women of PPIUCD insertion group were identified as unusual vaginal discharge though all cases were not due to infections but two cases of PPIUCD and 4 cases of interval insertion warented for removal of IUCD, rest of them responded to adequate treatment.

A multi centric follow up study in India reported an overall infection rate of 4.5% among PPIUCD insertion[8].

Spontaneous expulsion rate of my study was very low only 3 cases (2.72%) of PPIUCD group and no woman of interval insertion group experience spontaneous expulsion of IUCD. One study [9] of Bonila Rosales F et al (2005) in their study they found expulsion rate of 16% and 2 % of PPIUCD and interval IUCD

respectively.

Total discontinuation rate (combined spontaneous expulsion and removal etc) of my study was higher than other recent studies (discontinuation rate ranging 3-8 %) [10] .

In my study total discontinuation rate of interval insertion was 20.99% which is higher than PPIUCD group (14.52%).

My current study found that PPIUCD was more effective (in respect to continuation rate) i.e 79% . Other previous study reported the effectiveness of PPIUCD was 83.37%, 84.76% and 81.6% ref[7,11-12].

Hence I can say that my findings are in comparison with other studies and the PPIUCD is very effective method of contraception. In my study voluntary withdrawal for social ground by the women in PPIUCD group was only 5.45% while among interval IUCD group was 6.45% at the end of 6 months follow up.

At the end from Katheit G, Agarwal J study overall PPIUCD is safe and effective method of contraception when compared with interval IUCD insertion.[7]

V. Conclusion

Though IUCD is an effective, safe and without any effects on neonates , rapidly reversible and convenient methods of contraception, acceptance of IUCD either PPIUCD or interval IUCD is very low. In spite of some percentage spontaneous expulsion of PPIUCD it has more overall continuation rate than interval IUCD. PPIUCD should be encouraged specially in rural India considering the advantage that come along. There should be proper training of the staffs given this will further promote PPIUCD use and aid in relation to expulsion rate. Government needs to develop strategies to increase public awareness and exclusive increment of family counseling which will increase PPIUCD acceptance and continuation rate.

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