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ORIGINAL ARTICLE

Continuation of Copper T in Immediate Postplacental, Immediate Postabortal and Interval Period of Insertion

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Abstract

Aim Copper containing IUCDs are one of most effective mode of contraception for birth spacing. We conducted this prospective observational study to suggest a possible better period of insertion of IUCDs with cost-saving benefits.

Methods All married women in the reproductive age group desirous of Copper-T 375 IUD insertion in either immediate postplacental (PP), immediate postabortal (PA) or interval (INT) period were recruited. The women were asked to return for scheduled follow-up visits at 6 weeks, 6 months and 12 months. They were advised to visit family planning clinic any time if they experienced pelvic pain, discharge per vaginum, unusual bleeding or missed periods. At each visit, women were interviewed for any side effects they have experienced and were asked to elaborate. Pelvic pain was assessed from visual analogue scale. Continuation rate was measured at the end of one year.

Results Women in INT group (90.14%) had the highest continuation rate followed by PP (83.18%) and PA (80%) groups. Women in PP (AOR = 3.37, 95% CI 1.17–9.72) and PA (AOR = 4.53, 95% CI 1.33–14.04) groups had higher odds of discontinuation compared to INT group after adjusting for age, parity, working and education status. There was a significant difference between the groups when cumulative expulsion was considered ($p = 0.045$), but none when cumulative removal ($p = 0.107$) was taken into account.

Conclusion The continuation rate remained high in women who had insertion in the interval period compared to immediate postplacental and postabortal periods.

Keywords Intrauterine device · Postplacental · Postabortal · Interval · Continuation rate

Introduction

The intrauterine device (IUD) has received global acceptance as one of the best methods of contraception for reasons well attributed to its least adverse systemic effects, prolonged and effective contraceptive action, non-interference with sexual intercourse and cost-effectiveness [1]. India being one of the most populous nations, population control remains the foremost goal for planners of the health policies. Copper T is one such tool to achieve this goal. With the introduction of Lippes Loop in 1965 to Copper-T 375 IUD in 2012 by the National Family Welfare Program of the Government of India [2], Copper T remained the most effective, reversible and long acting mode of contraception. Presently, Copper T is being inserted at either of postplacental (PP), postabortal (PA) and interval (INT) periods depending on feasibility and eligibility.

According to National Family Health Survey, 2015–2016, the contraceptive prevalence rate of currently married women in the age 15–49 in India was 54 percent. Among them, female sterilization remained the most popular modern contraceptive method. IUD/PPIUD (intrauterine device/postpartum intrauterine device) was used by only 1.5% of women. Contraceptive discontinuation rate for IUDs/PPIUDs was 26% [3]. Even in our institution, a significant number of women opted to discontinue copper T after insertion at different intervals with respect to menstruation, delivery

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and abortion. There were, however, no comparison studies to find differences between them. This has motivated us to conduct an analysis of the expulsion, removal and continuation of copper T in patients who had insertion in immediate postplacental, immediate postabortal and interval periods. We conducted this study to explore the best time of insertion to achieve lower complication and discontinuation rates. This will guide us to suggest a possible better period of insertion with cost-saving benefits in terms of lesser clinical visits.

Methodology

Design

The study was conducted in the Department of Obstetrics and Gynaecology at a tertiary center in Northern India, after getting clearance from the ethical committee of the institute. It was a prospective observational study carried out between January 2018 and June 2018 where all married women in reproductive age group (18 to 49 years) desirous of Copper-T 375 IUD insertion and who fulfilled the World Health Organization Medical Eligibility Criteria (WHO MEC) for IUD insertion [4] were recruited. Patients were recruited both from antenatal and Family Planning Clinic.

Patients in the third trimester of pregnancy were counseled for PPIUCD insertion during prenatal visits at antenatal clinic. Repeat counseling was done prior to caesarean section or after vaginal delivery, and a written informed consent was taken.

Study Participants

The study participants comprised of three categories of women:

1. Pregnant women consenting to insertion of Copper T immediately after delivery of placenta.
2. Pregnant women consenting to insertion of Copper T immediately after abortion (< 10 weeks).
3. Women coming with desire for contraception with no h/o pregnancy for the last 3 months.

Women were recruited if they met the following criteria: (a) Age ≥ 18 years, (b) sexually active residing with partner (c) desiring to adopt IUD as method of contraception, (d) willing for follow-up services for at least 12 months at family planning clinic of our institution (e) able to give informed consent.

Immediate post placental (PP) Copper-T 375 IUD was inserted within 10 min of placental delivery, after vaginal or caesarean delivery. Women having anemia (Hb% < 8gm/dl), chorioamnionitis, antenatal leakage of amniotic fluid for more than 18 h, postpartum hemorrhage (PPH), extensive birth trauma, genital tract infection, hemorrhagic disorders and uterine anomaly were excluded from the study.

Immediate post abortal (PA) Copper-T 375 IUD was inserted in women who fulfilled the criteria after induced surgical abortion of an intrauterine pregnancy less than 10 weeks. Sonogram was done immediately after the procedure to confirm complete evacuation before insertion. Women with excessive bleeding during abortion, any pelvic infection and uterine anomaly were excluded from the study.

Interval (INT) Copper-T 375 IUD was inserted in women who were desiring contraception but had no history of pregnancy in the last 3 months nor aspire to conceive for at least 12 months. Women with history of uterine anomaly, unexplained vaginal bleeding and ongoing pelvic infection were excluded from the study. All IUDs are inserted during the menstrual cycle after possible pregnancy is excluded.

Study Procedure

Copper-T 375 IUDs are provided free of cost by the Ministry of Health, India in the hospital. Women were recruited for a period of one year. All the insertions were done by resident doctors who had received training in IUD insertion including PPIUCD. All procedures were undertaken after proper infection prevention procedures. IUDs were loaded by 'no touch' technique inside a sterile pack using Kelly (placental) forceps and insertion was done by a standardized technique [2] after vaginal delivery. ICS (Intra-caesarean) post placental insertion was done by ring forceps within 10 min of caesarean delivery through the uterine incision ensuring fundal placement of the device in both techniques. Fundal placement of the IUD was confirmed by abdominal ultrasonography before discharge from the hospital in all cases in PP group [5]. In insertion during post abortal and interval period, depth and position of the uterus was measured with uterine sound. IUD was slowly and gently inserted into the uterus and the inserter was removed. The string of the IUD was cut, leaving about 3 cm hanging out of the cervix.

All patients were examined prior to planned insertion. If existing infection is diagnosed by visual inspection, samples were taken from the cervix and urethra for culture for a final diagnosis of the type of infection. If a patient with excessive vaginal discharge has positive cultures, the patient was excluded from the study and treatment given accordingly.

Follow-Up

The women were asked to return for scheduled follow-up visits at 6 weeks, 6 months and 12 months. They were advised to visit family planning clinic any time if they experienced

pelvic pain, discharge per vaginum, unusual bleeding or missed periods. At each visit women were interviewed for any side effects they have experienced and were asked to elaborate. Pelvic pain was assessed from visual analogue scale. In case the women failed to follow-up at the scheduled visit, she was communicated by telephone and motivated to do so. Reason for denial despite this was recorded. Number of women opting for removals for various causes was noted. Continuation rate was measured at the end of one year.

A woman was considered 'user' when she reported using the primary Copper-T 375 IUD at the 6 weeks, 6 and 12-month follow up visits without ceasing to use it or 4 weeks or longer. When the women ceased to use the primary Copper-T 375 IUD at any time of the study period of one year for a period of 4 weeks or longer, she was assumed to discontinue. IUD replacement was offered to patients who had an expulsion. If she opts for replacement and continues to use it till 1 year, she was considered to be user. If she opted not to get it replaced, she was considered to discontinue.

Statistical Analysis

Categorical variables are presented in number and percentage (%) and continuous variables are presented as mean ± SD and median. Normality of data was tested by the Kolmogorov–Smirnov test. If normality was rejected then a non-parametric test was used. Quantitative variables were compared using ANOVA/Kruskal Wallis test (for non-parametric data) between three groups and comparison between the two groups were performed by Unpaired t-test/Mann–Whitney Test (when the data sets were not normally distributed). Qualitative variables were compared using the Chi-Square test /Fisher's exact test. P value of < 0.05 was considered statistically significant. Regression analysis was carried out to adjust for potential confounders. Analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0

Results

The study group consisted of 534 women who were approached for consent for the following insertions: 346 PP, 102 PA and 86 INT. However, 495 patients were actually recruited to the study: 337 in PP group, 86 in PA group and 72 in INT group. 25 patients refused to participate in the study and 14 patients were not eligible. 409 (83.64%) women were still using the primary contraceptive device, 6 (1.22%) patients were lost to follow up while 80 (16.35%) women discontinued the use due to various reasons at 12 months. The number of women who attended follow-up visits were recorded for the three groups (Fig. 1).

In our observational analysis, the women in all groups had a high user acceptability reflected in the continuation rate. With an average continuation rate of 83.64%, women in INT group (90.14%) had the highest rate followed by PP (83.18) and PA (80%) groups. The significance test applied to the three groups regarding the descriptive and obstetrics characteristics of the women showed no statistically significant difference except for age ($p < 0.05$) and parity ($p < 0.05$). Higher proportion of women in PP group were young with a significant difference between PP and INT group ($p = 0.011$). Higher number of women in the PP group (49.85%) were primiparous while the majority of women in PA (67.44%) and INT group (38.9%) were parity 2. There was no difference in mode of delivery between the groups (Table 1).

When demographic characteristics were stratified into dichotomous variables (Table 2), women < 21yrs of age ($p = 0.051$, OR = 1.73, 95% CI 1.01–2.96) and those having education up till primary ($p = 0.006$, OR = 1.94, 95% CI 1.19–3.15) were more likely to discontinue although the continuation rates ($p = 0.216$) and mean duration (months) of continuation (10.68 ± 3.12, P = 0.249) between the groups did not reach statistical significance. Regression analysis revealed women in PP (AOR = 3.37, 95% CI 1.17–9.72) and PA (AOR = 4.53, 95% CI 1.33–14.04) groups had slightly higher odds of discontinuation compared to INT group after adjusting for potential confounders viz age, parity, working and education status. Women opting for removal were found in all the three groups (PP-10.81%, PA-18.82%, INT-9.85%) in different proportions but did not reach statistical significance. Out of a total 59 cases opting for removal, 25 (42.37%) cases had excessive vaginal bleeding, 18 (30.50%) cases had lower abdominal pain, 12 (20.33%) cases had vaginal discharge and 4 (6.78%) cases had subjective issues (Table 3). The reasons for removal among the groups had almost no difference except for abdominal pain ($p = 0.001$) (Table 4). The difference was significant between the groups when cumulative expulsion was considered ($p = 0.045$) but none when cumulative removal ($p = 0.107$) was taken into account. Only 1 case at the end of one year had pregnancy with copper T in situ in the PP group.

Discussion

Copper T continuation rates in the three groups were evaluated by survival analysis curve that revealed no significant difference in the first year follow period (Fig. 2) though the hazard of discontinuation at 12 months was higher in PP and PA group. Consequent to data stratification to dichotomous variables, higher discontinuation rates were observed with certain patient characteristics that included young age (< 21yrs), multiparity and lack of adequate education.

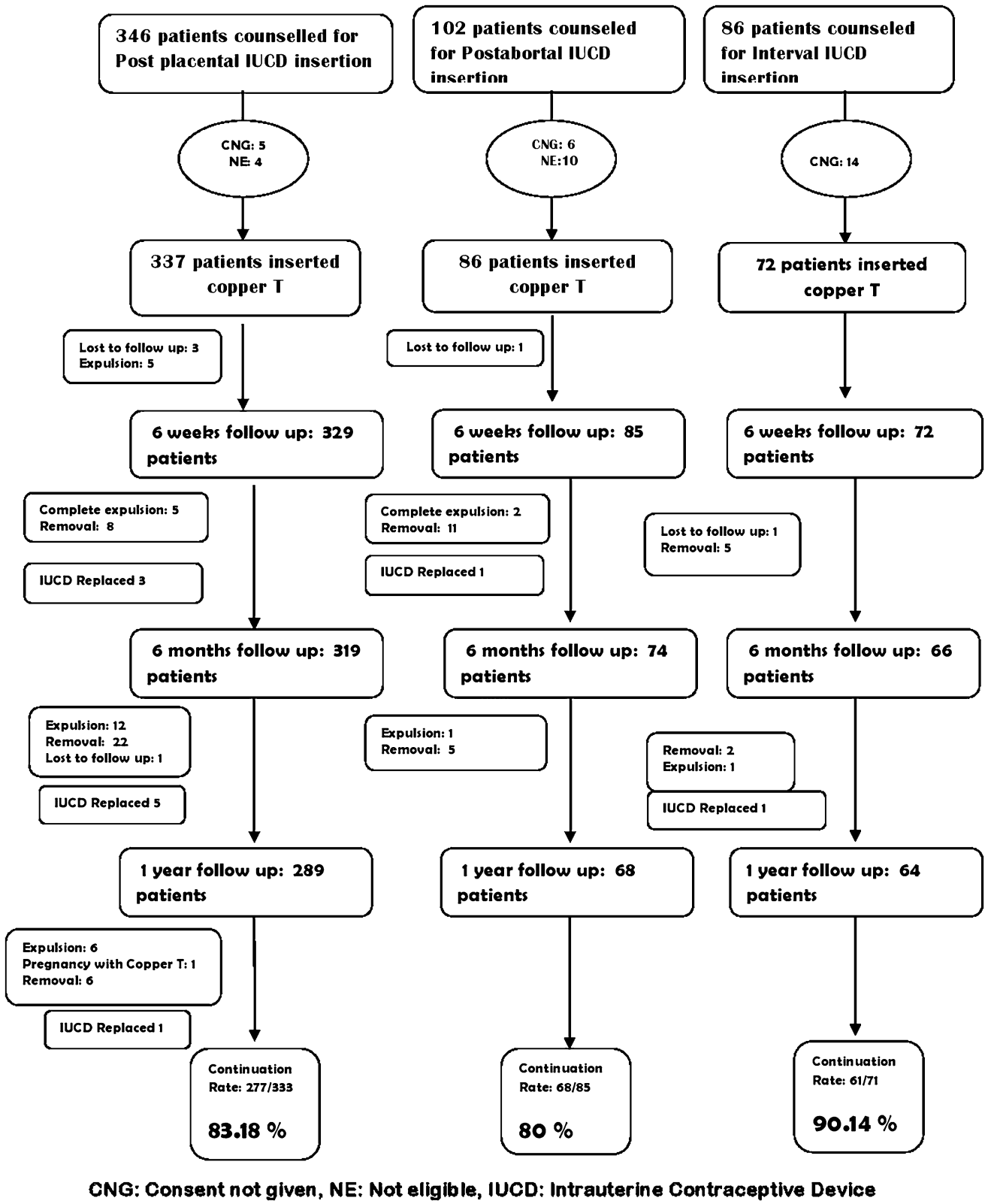

Fig. 1 Flowchart showing follow up of patients at 6 weeks, 6 months and 1 year

Table 1 Sociodemographic and obstetric characteristics of the study groups (including lost to follow up patients)

	PP group (N = 337). n, %	PA group (N = 86)). n, %	Int group (N = 72)). n, %	*p* value
Age				
≥ 18–24	115 (34.12)	22 (25.5)	19 (26.38)	0.00 (Turkey Post Hoc test: sig diff between PP and INT group = 0.011)
25–30	168 (49.85)	45 (52.3)	30 (41.66)	
31–35	46 (13.64)	16 (18.6)	16 (22.3)	
≥ 35	8 (2.37)	3 (3.5)	7 (9.72)	
Mean age ± SD	26.29 ± 4.46	27.35 ± 4.56	28.04 ± 5.29	
*Education**				
Up till Primary Education	132 (39.16)	35 (40.69)	29 (40.27)	0.96
Upper Primary and Secondary	147 (43.62)	35 (40.69)	30 (41.7)	
Senior Secondary and above	58 (17.21)	16 (18.6)	13 (18.05)	
Occupation				
Homemaker	268 (80.1)	71 (83.4)	57 (80)	0.86
Employed outside	69 (19.8)	15 (16.7)	15 (20)	
Parity				
1	168 (49.85)	15 (17.44)	26 (36.1)	0.00
2	130 (38.57)	58 (67.44)	28 (38.9)	
≥ 3	39 (11.57)	13 (15.11)	18 (25)	
History of vaginal delivery				
Yes	203 (60.23)	62 (70)	46 (63.9)	0.31
History of caesarean section				
Yes	168 (49.8)	36 (41.9)	35 (48.6)	0.44

*According to Indian Standard Classification of Education [26]

Table 2 Regression analysis of demographic characteristics in relation to discontinuation of IUCD usage

Demographic characteristics	Copper T continuation		Odds Ratio	P value	Adjusted Odds Ratio	P Value
	Continuer (409) n (%),	Discontinuer (80) n (%)				
Age						
< 21 years	81 (19.8)	24 (30)	1.73 (1.01–2.96)	0.051	2.63 (1.41–4.81)	0.002
> 21 years	328 (80.2)	56 (70)	Ref		Ref	
Parity						
Multiparous	239(58.4)	55 (68.7)	1.56 (0.94–2.61)	0.085	1.96 (1.09–3.51)	0.023
Primiparous	170 (41.6)	25 (31.3)	Ref		Ref	
Working status						
Homemaker	327 (80)	66 (82.5)	1.18 (0.63–2.20)	0.60	1.07 (0.55–2.08)	0.837
Employed Outside	82 (20.0)	14 (17.5)	Ref		Ref	
Education						
Up till Primary Education	153 (37.4)	43 (53.8)	1.94 (1.19–3.15)	0.006	1.71 (1.03–2.84)	0.037
Above Primary Education	256 (62.6)	37 (46.2)				
Three groups of copper T insertion						
PP GROUP (N = 333). n, (%)	277 (67.7)	56 (70)	–	0.216	3.37 (1.17–9.72)	0.024
PA GROUP (N = 85). n, %	68 (16.7)	17 (21.3)			4.33 (1.33–14.04)	0.014
INT GROUP (N = 71). n, %	64 (15.6)	7 (8.7)			Ref	–

Table 3 Cumulative outcome events in the three groups

	PP GROUP ($N=333$). n, (%)	PA GROUP ($N=85$). n, %	INT GROUP ($N=71$). n, %	*p* value
Removal	36 (10.81)	16 (18.82)	7 (9.85)	0.107
Expulsion	28 (8.40)	3 (3.52)	1 (1.40)	0.045
Contraceptive failure	1 (0.30)	0	0	0.791
Mean duration (months) of continuation	10.67 ± 3.07	10.68 ± 3.35	10.63 ± 3.12	0.249
Continuation Rate	277 (83.18)	68 (80%)	64 (90.14%)	0.216

Table 4 Reasons declared by patients opting for removal

	PP GROUP ($N=333$). n, (%)	PA GROUP ($N=85$). n, %	INT GROUP ($N=71$). n, %	*p* value
Excessive Vaginal Bleeding	20 (6)	2 (2.35)	3 (4.22)	0.368
Abdominal Pain	6 (1.80)	9 (10.58)	3 (4.22)	0.001
Excessive Vaginal Discharge	8 (2.40)	3 (3.52)	1 (1.40)	0.691
*Subjective	2 (0.6)	2 (2.35)	0	0.197

*Subjective causes included: Fear of IUD perforating into abdominal cavity, morbidity due to menstrual disorders, discomfort for husband during sexual intercourse, concern for surgical intervention

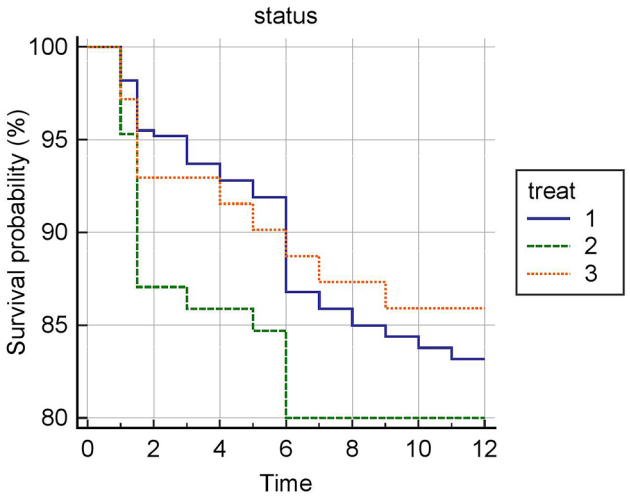

Fig. 2 Kaplan Meier Curve estimating continuation rates of insertion of Copper T in the three different periods. 1: Immediate post placental, 2: Immediate post abortal, 3: Interval

Celen et al. [6] found continuation rate of 76.3% at 12 months after post placental insertion of Copper T 380 IUD. Continuation rates for immediate post-abortion insertion of copper IUD after 6 months of use show the data at 77.9% [7] and 64.2% [8]. While a multicentre randomized clinical trial showed one-year continuation rate for Copper IUD was 76.3% [9] for interval insertion. Our study that was undertaken with systematic method specific counselling and follow up, observed better continuation rates for all insertions. Besides, continuation rates for copper IUD devices have improved over the years due to improvement in its technology when considering its effectiveness and safety [10]. However, whether the present study depicts the precise picture of acceptability and continuation rate in true medical practice beyond the well-organized framed setting of counselling and follow up schedule needs speculation.

This study revealed the cumulative 12-month rates of expulsion was highest among PP group (8.40%) and lowest in the interval group (1.4%) which is in tune with other studies [11–14]. Our overall one-year expulsion rates for 489 patients of 5.93% was similar to Madden et al. [15] for copper IUD included in the the Contraceptive CHOICE Project (CHOICE) which reported it at 5.7%. However, Celen et al. [6] reported a high cumulative expulsion rate of 12.3% at one year of use when IUDs were inserted within 10 min after placental delivery in contrast to 8.40% in our study in PP group. They had high proportion of vaginal delivery (74%) in the study cohort that probably reflect their higher tendency to expel than caesarean delivery (26%) [16–18]. Even when compared with postabortal insertion group (3.52%) in the present study, the expulsion rate remained low in interval group (1.4%). An international trial reported 3.6% expulsion rate in interval group at one year for the same type of device used in our study [19]. Hence the overall lower rate of expulsion in all the groups in our study can be attributed to uniformity in insertion technique done by all trained residents in our study. Postpartum insertion of IUD being a part of routine institutional procedure to accelerate the interventions to curb population growth envisaged by National Family Planning Program, the expertise of placing the Copper IUD in the appropriate fundal area of uterus seemed adequate and gratifying in our institution.

With alarming rise in population growth in India, early removal assuredly can impede the strategies devised to curb population hike. Our study design depicted the removal rate was low in interval group compared to PP and PA group which is consistent with other studies [11, 12]. The request for removal was 12.06% in our study which was much higher than reported by iklaki et al. (5.80%). Being a retrospective chart review for a long period of 4 years, Iklaki et al. speculated the low rate was due to loss to follow up or relocation to different locality or removal at other health centre [20]. In another retrospective cohort study by Ravi A et al. [21], request for removal was projected at 17%. This varied removal rates presumably depend on the conceptual and behavioral rearing of the sample population in regard to choosing contraceptive method consequential to health education endorsing knowledge and ability to informed decision making. Such influence on the prospect of continuation have been proven by studies [22].

However, number of women opting for removal in our study was comparable in the three groups ($p = 0.107$) that was not altered with subgroup analysis by age (< 21yrs, > 21yrs) ($p = 0.144$); parity ($p = 0.501$); and education ($p = 0.778$) (data not shown). The reasons ascribed to get copper IUD removed early were excessive vaginal bleeding (42.37%), lower abdominal pain (30.50%) and vaginal discharge (20.33%) and these were present in INT group in lowest numbers. Similar side effects of copper IUD were reported by many other studies [23, 24]. Metallic copper increases bleeding by augmenting local fibrinolytic activity and stimulating the release of prostaglandins which induces inflammatory reaction and contraction of uterine smooth muscles [25]. However, K. Erogˇlu et al. [14] observed higher incidence of excessive bleeding and pelvic infection in the INT group at 6 months which increased at 1 year when Cu T 380A was inserted in 268 women: 84 IPP (Immediate Post placental, less than 10 min), 46 EP (Early Post placental, 10 min to 72 h) and 138 INT (Interval, more than 6 weeks). They however had done Interval insertions to all women after 6 and 8 weeks following vaginal delivery and caesarean section respectively during lactational period with Cu T 380A. They did not mention whether patients were bleeding when insertion was done in the interval period. We had no patients in the lactational period in the INT group and there was no history of pregnancy in the last 3 months prior to insertion.

The strength of our study was loss of low number of patients to follow up. This could possibly be due to our effectual counseling procedure, strict supervision and motivation by regular consultations. The drawbacks include grab sampling of patients attending our institution and willing to adopt a contraceptive device. The possibility of potential bias of sampling approach with subgroups not being representative of the target population due to non-participation bias cannot be ruled out. Women already motivated to adopt a contraceptive method is more likely to continue it than someone who is persuaded to do so. This positive confounding explicitly associated with participants in PP group cannot rule out over-estimation of our primary outcome i.e. continuation rate. Another limitation we presumed was a short duration of follow up i.e. one year only.

The study henceforth concludes interval insertions offer the best period of insertion with lowest hazard for expulsion, removal and discontinuation when compared to immediate post placental and immediate postabortal insertions. If possible, women may be motivated to return after 6 weeks of delivery or abortion with fallback protection in the latter; to achieve the best results. However, women residing in remote areas not adequately motivated for contraception are best counselled for immediate post placental Copper T insertion which has almost similar safety and effectiveness. This also assures that women depart from hospital, feeling protected against unintended pregnancy.

Declarations

Conflict of interest All authors declare they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human or Animal Rights This article does not contain any studies with animals performed by any of the authors.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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About the Author

Banashree Nath completed her senior residency from the Department of Obstetrics and Gynaecology, VMMC and Safdarjung Hospital, New Delhi, during which she undertook the study. She is an efficient and brilliant academician as well as astute clinician. She is an avid mentor to her juniors and is presently working as Assistant Professor in All India Institute of Medical Sciences, Raebareli.

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