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ORIGINAL ARTICLE

Intrauterine Copper Device (CuT380A) as a Contraceptive Method in the Indian Context: Acceptability, Safety and Efficacy Depending on the Timing of Insertion

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Abstract

Background Ideal time of Intrauterine copper device (IUCD) insertion either to space or limit births in Indian women should be known to check fertility effectively and safely. We therefore aimed to compare various IUCD related clinical factors to assess its acceptability, safety and efficacy in immediate postpartum vaginal insertion, intra-caesarean insertion, delayed postpartum insertion and interval insertion at a tertiary-care centre in India.

Methods It was a retrospective analysis of prospectively collected data from July 2013 to July 2014. Data was reviewed about maternal age, socioeconomic status, education, occupation and parity of a total of 1631 eligible mothers and was compared between postpartum group and interval group. Data about spontaneous expulsion rate of IUCD, proportion of patients not able to feel thread, reasons for removal and failure rate of IUCD up to a follow-up period of 6 months was also collected in these women and compared among immediate vaginal insertion, intra-

caesarean insertion, delayed postpartum insertion and interval insertion.

Results Majority of women were between 20 and 35 years of age group, literate, multiparous, unemployed and belonged to middle/lower socio-economic strata in both postpartum and interval groups. Spontaneous expulsion rates were 1.84, 0.84, 2.83 and 1.63%; proportions of patients not able to feel thread were 3.07, 8.73, 4.45 and 1.63%; and removal rates were 7.99, 6.48, 7.69 and 3.47% in immediate vaginal, intra-caesarean, delayed postpartum and interval insertion groups, respectively. Failure was seen in only one case of delayed postpartum insertion.

Conclusion IUCD was more acceptable among young, literate and multiparous women as a contraceptive method. Immediate postpartum period was the safest and most efficacious time for IUCD insertion with least expulsion rate, maximum continuation rate and no failure and, therefore, should be encouraged by adequate counseling of mothers.

Keywords Intrauterine copper device · Postpartum · Interval · Contraception

Introduction

India is the second largest populous country in the world with a total population of 121 crores (Census 2011) [1]. Although there are many reasons behind the rapidly growing population, high unmet need for contraception is an important barrier to check population growth in the country. According to National Family Health Survey-4 (NFHS-4), the current total unmet need for contraception is 12.9% and unmet need for spacing is 5.7% [2]. Population control is not just a target to achieve but also it is a path to better health care in India by decreasing the burden on health-care infrastructure. Needless to say, good contraceptive care of reproductive age women will help in achieving the objective of stable population in future.

Good contraceptive care includes all aspects of contraception including method of contraception to be used and appropriate timing. In contrast to routine care, contraceptive care of a mother is easily overlooked after delivery resulting in unintended pregnancy, thereby increasing the maternal morbidity and mortality. Besides, if a woman does not use any contraception after birth of the baby, she will always be worried about getting pregnant and that may affect rearing up of her child. So clearly, there is need for contraception in the postpartum period. Good contraceptive method is also needed for spacing between childbirths and to check fertility for a woman throughout her reproductive period. Intrauterine copper devices provide a useful method of contraception after birth of a baby as they do not affect breast feeding and once inserted, they remain effective for a long time. In India, the device Copper T 380A (CuT380A) is being supplied free of cost by the government and it is effective for 10 long years. However insertion of copper T in postpartum period also has certain disadvantages like higher expulsion rates and missing threads [3]. However, often mothers are very apprehensive about getting copper T inserted in the postpartum period and insist to come back after 6 weeks (interval) for the same. Therefore, we should have enough evidence to support the most appropriate timing of IUCD insertion especially in Indian scenario where safety and efficacy of the contraceptive method is always a concern due to resource limitation and less awareness about contraceptive needs of a woman among the population. A cost-effective, long acting, reversible contraceptive method with least side effects is the need of the country. We conducted this study to address the above issues at a tertiary referral hospital in India.

Studies comparing IUCD insertion immediately after vaginal and caesarean delivery, in delayed postpartum period and after 6 weeks, in a single setting in Indian scenario are sparse. Therefore we conducted this study to evaluate the same in the Indian context at a tertiary care centre which caters to a large area of population. We therefore aimed to compare various IUCD related clinical factors to assess its acceptability, safety and efficacy in immediate postpartum vaginal insertion, intra-caesarean insertion, delayed postpartum insertion and interval insertion at a tertiary-care centre in India.

Materials and Methods

It was a retrospective cohort study of prospectively collected data conducted in the department of Obstetrics and Gynaecology at a tertiary care referral hospital in India. Data related to women who had CuT380A insertion at the study centre from July 2013 to July 2014 for the period of 1 year duration was retrieved from the medical case record sheets. At the study centre, all data related to family planning procedures is routinely noted down in prospective manner in case record sheets. We included all women who underwent IUCD insertion at the study centre during the above period. We divided them into postpartum ($\leq$ 6 weeks after delivery) and interval ($>$ 6 weeks after delivery) groups. Postpartum group included only those women who had vaginal delivery or caesarean section at our centre. We further subdivided the postpartum group into immediate postpartum (within 10 min after expulsion of placenta) and delayed postpartum (between 10 min to 48 h of delivery) groups. Those women who had copper T

Table 1 Demographic and clinical profile of studied women

S. No.	Variables	Postpartum group ($n = 1416$)	Interval group ($n = 183$)
1.	Maternal age		
	< 20 years	127 (8.97%)	13 (7.10%)
	20–35 years	1220 (86.16%)	49 (26.77%)
	> 35 years	69 (4.87%)	121 (66.12%)
2.	Maternal education		
	Literate	989 (69.84%)	105 (57.38%)
	Illiterate	427 (30.16%)	78 (42.62%)
3.	Mother's socioeconomic status		
	Upper	225 (15.89%)	45 (24.60%)
	Middle/Lower	1191 (84.11%)	138 (75.41%)
4.	Mother's occupation		
	Employed	157 (11.09%)	34 (18.58%)
	Unemployed	1259 (88.91%)	149 (81.42%)
5.	Parity		
	Primipara	492 (34.74%)	33 (18.03%)
	Multipara	924 (65.25%)	150 (81.97%)

Table 2 Comparison of spontaneous expulsion rate of IUCD among various groups

S. No.	Groups	Total number of patients	Number of patients with spontaneous expulsion	Percentage of patients with spontaneous expulsion (%)
1.	Post-partum insertion	1416	25	1.76
	Immediate vaginal insertion	814	15	1.84
	Intra-caesarean insertion	355	3	0.84
	Delayed postpartum insertion	247	7	2.83
2.	Interval insertion	183	3	1.63

insertion done outside the study centre or delivered outside our hospital were excluded from the study.

IUCD Insertion and Follow-up

Every patient eligible for IUCD insertion after delivery was counseled to choose between postpartum (immediate or delayed) or interval insertion. Kelley's forceps was used for immediate postpartum insertion of CuT380A after vaginal delivery and 'no touch' technique was used for interval insertion. All doctors who performed IUCD insertion were adequately trained for the procedure and a standardized protocol was followed. The cohort of patients underwent follow up at 6 weeks, 12 weeks and then at 6 months. At every follow up patients were asked about any complaint and whether they were able to feel the thread of IUCD or not. If they were not able to feel the thread, in situ position of copper T was confirmed by clinical examination/X-ray examination/ultrasound wherever needed. If after above examination copper T was found in situ, the case was categorized under inability to feel thread. If no copper T was found inside, it was considered as a case of spontaneous expulsion. The reasons for IUCD removal were also noted. These included irregular bleeding per vaginum (BPV), chronic pelvic pain, pelvic infection or patient's willingness to use either permanent method or another method of contraception. Failure was confirmed with confirmation of pregnancy while copper T was still in situ.

Medical Record Review

Data was reviewed about age, socioeconomic status, education, occupation and parity of all mothers included in the study. Data about spontaneous expulsion rate, proportion of patients not able to feel thread, removal of copper T due to various reasons and failure of IUCD was also retrieved. Socioeconomic status was calculated by modified Kuppuswamy's scale [4]. A total of 1631 women who fulfilled inclusion criteria underwent IUCD insertion during the study

Table 3 Comparison of proportion of patients not able to feel thread among various groups

S. No.	Groups	Total number of patients	Number of patients who could not feel thread	Percentage of patients who could not feel thread (%)
1.	Post-partum insertion	1416	67	4.73
	Immediate vaginal insertion	814	25	3.07
	Intra-caesarean insertion	355	31	8.73
	Delayed postpartum insertion	247	11	4.45
2.	Interval insertion	183	3	1.63

Table 4 Comparison of removal of IUCD among various groups

S. No.	Groups	Total number of patients	Number of patients who got copper T removed	Patients with irregular BPV	Patients with chronic pelvic pain	Patients with pelvic infection	Patients willing for permanent contraception	Patients willing to use another method
1.	Post-partum insertion	1416	107 (7.56%)	10 (0.71%)	55 (3.88%)	13 (0.92%)	17 (1.20%)	12 (0.85%)
	Immediate vaginal insertion	814	65 (7.99%)	7 (0.86%)	28 (3.44%)	9 (1.10%)	12 (1.47%)	9 (1.10%)
	Intra-caesarean insertion	355	23 (6.48%)	1 (0.28%)	18 (5.07%)	2 (0.56%)	1 (0.28%)	1 (0.28%)
	Delayed postpartum insertion	247	19 (7.69%)	2 (0.81%)	9 (3.64%)	2 (0.81%)	4 (1.62%)	2 (0.81%)
2.	Interval insertion	183	8 (4.37%)	4 (2.18%)	1 (0.55%)	1 (0.55%)	2 (1.09%)	–

period. Total 824 women had immediate insertion after vaginal delivery and 367 had intra-caesarean insertion. The number of patients with delayed postpartum insertion was 254 whereas 186 patients had interval insertion of IUCD. Out of the above patients, 32 patients were lost to follow-up at the end of 6 months including 10 patients (1.21%) in immediate vaginal insertion group, 12 patients (3.27%) in intra-caesarean insertion group, 7 patients (2.75%) in delayed postpartum insertion group and 3 patients (1.61%) in interval insertion group. Data were analyzed and the results were expressed as number of patients and percentage in each category of demographic and clinical factors.

Results

Out of the total 1599 women, 1269 women belonged to the age group 20–35 years. In this age group, 1220 women had post-partum insertion and 49 women had interval insertion. Majority of women in the post-partum group as well as interval group were literate (69.84 vs. 57.38%), belonged to middle/lower class of socioeconomic strata (84.11 vs. 75.41%), were unemployed (88.91 vs. 81.42%) and had parity more than one (65.25 vs. 81.97%) at the time of insertion of copper T (Table 1).

In the postpartum group, a total of 25 patients (1.76%) had spontaneous copper T expulsion which included 15 patients with immediate vaginal insertion, 3 patients with intra-caesarean insertion and 7 patients with delayed postpartum insertion. On the other hand, in the interval group, three patients (1.63%) had spontaneous expulsion. Immediate postpartum insertion group had the lowest expulsion rate of 1.54% (18 out of 1169 patients) while delayed postpartum insertion group had the highest expulsion rate (2.88%, 7 out of 254 patients) (Table 2). At the end of 6 months, a total of 67 patients (4.73%) in the post-partum group could not feel thread while copper T was still in situ, whereas in the interval group there were 3 such patients (1.63%). The complaint of missing thread was most commonly seen in the intra-caesarean insertion group (8.73%) followed by delayed postpartum insertion group (4.45%), immediate vaginal insertion group (3.07%) and interval insertion group (1.63%) (Table 3).

At the end of the study period, IUCD was removed in total 115 patients due to various reasons. Cumulative

removal rate was more in postpartum insertion group (7.56%) than interval group (4.37%). Chronic pelvic pain was the most common reason for IUCD removal in post-partum group (3.88%). On subgroup analysis, all three postpartum subgroups had removal rate between 6 and 8% and chronic pelvic pain was the most common reason for IUCD removal in all three subgroups. Irregular BPV seemed the least common problem (0.71%) in post-partum group overall as well as in all the three subgroups. In interval insertion group, total 8 patients got copper T removed at the end of 6 months. Irregular BPV was the commonest cause (4 patients) for IUCD removal in interval insertion group. A total of 19 patients were motivated enough and adopted for permanent sterilization. The prevalence of pelvic infection (0.92 vs. 0.55%) and chronic pelvic pain (3.88 vs. 0.55%) were more in post-partum group compared to interval group (Table 4). Overall, the continuation rate was maximum in interval group (95.27%) followed by intra-caesarean group (93.52%), delayed postpartum group (92.31%) and immediate vaginal insertion group (92.01%). We reported failure in one case of delayed postpartum IUCD insertion. No failure was noticed in the interval insertion group. We did not come across any case of perforation in our study.

Discussion

Quality contraceptive care embraces safe and effective contraception for all women in the reproductive age group. Intrauterine copper devices are an effective method of controlling fertility but perceived efficacy may vary depending on the local settings. For example, if a woman is not motivated enough (common situation in rural India) to check its thread regularly or to come for follow-up regularly, she might expel the IUCD and may get pregnant without even being aware about it. This may reduce the perceived efficacy of IUCD among general population. Safety of these methods especially in Indian context, where women are not much aware about regular check-up, are prone for infection/anemia and are reluctant to seek medical advice in emergency situations, is still a big concern for health-care providers. Therefore we conducted this study to look for efficacy and safety of CuT380A depending on the time of insertion by comparing maternal demographic and clinical profile, expulsion rate, inability to feel thread, side effects profile (or reasons for removal) and failure rates in a tertiary-care setup in India which caters to a large heterogenous population in its catchment area.

Majority of the women in our study belonged to age group 20–35 years in both post-partum and interval groups. Comparable to our results, Singh et al. had maximum number of women between 25 and 30 years of age group in their study [5]. Jairaj et al. reported 23.70 years as the mean age of acceptance for postpartum copper T insertion [6]. Therefore, we conclude that acceptance for IUCD as a contraceptive method was more in the younger age group (< 35 years). Majority of the women who underwent IUCD insertion were literate and therefore were able to understand the pros and cons of postpartum and interval insertion. A higher literacy rate made them understand the importance of follow-up visits. We had literacy rate 57.38% in interval group and 69.84% in postpartum group. Singh et al. reported a literacy rate between 70 and 80% in both the groups [5]. Kant et al. also stated that acceptance of postpartum IUCD was more in literate women [7].

India is a developing country where an effective, safe and durable contraception at low-cost is necessity. Majority of women in our study belonged to lower/middle class of socioeconomic strata. IUCD CuT380A is the best option for such patients as it is available free of cost in India and once inserted, it is effective for 10 years with very low failure rate (< 0.8 per 100-women year) [8]. Multigravida patients were more motivated to use IUCD as contraceptive method than primigravida in our study. This finding may suggest that IUCDs are still not a popular method for spacing. However, Kumar et al. reported a higher acceptance rate for post partum IUCD in primigravida than in multigravida women [9]. Young primiparous patients should be adequately counseled in the antenatal period, intrapartum and postpartum period for accepting IUCD as a spacing method. Detailed information can be provided to mothers in antenatal clinic and labor wards.

Expulsion of IUCD is a cause of concern for both the acceptor and the provider. According to Cochrane Database Systemic Review, expulsion rates appeared to be higher in postpartum group than interval group [3]. We also found higher expulsion rate in postpartum group (1.76%) than interval group (1.63%). On the other hand, a study done by Lucksom et al. reported no case of spontaneous expulsion in postpartum group [10]. In our study, expulsion rate was highest in delayed postpartum insertion group (2.83%) and lowest in immediate insertion group (1.54%). Similarly, Jain et al. found higher expulsion rate (1.6%) in delayed group than immediate postpartum group (1.2%) [11], although the difference was not significant. In our study, a higher number of patients expelled IUCD when it was inserted immediately after vaginal delivery as compared to intra-caesarean insertion. Lall et al. also reported higher expulsion rate in patients who had IUCD insertion immediately after vaginal delivery (10%) than in patients who underwent intra-caesarean insertion (2%) [12]. However, the expulsion rate in their study for both the groups was much higher than the expulsion rate which we noticed in our study. We conclude that immediate postpartum insertion has the lowest expulsion rate and therefore

constitutes a great opportunity to provide reliable and effective contraception to a mother in the postpartum period.

Visibility/feeling of copper T thread are important to ensure that the copper T is in place though sometimes a woman can not feel the thread even when copper T is inside the uterine cavity. Thread feeling/visibility was lower in post-partum group as compared to interval group in our study. Similar finding has been reported in many other studies previously [5, 10, 13]. We found the thread visibility to be lowest in the intra-caesarean insertion group. The cause of lower rate of thread visibility/feeling in postpartum group may be that in postpartum period uterine cavity is enlarged and thread is placed at higher level than interval insertion. Therefore, patients who are undergoing postpartum IUCD insertion should be adequately counseled about this problem. Certainly, mere problem of missing thread should not discourage the patients to accept it in postpartum period as well as the health professionals to encourage more postpartum IUCD insertions.

The removal rate of CuT380A was higher in postpartum group (7.56%) than interval group (4.37%). In their study, Mohan et al. found almost similar cumulative rate of removal in both the groups (6.5 vs. 7%, respectively) [14]. However, higher continuation rate in postpartum group has also been described in literature [5, 10]. The two most common reasons for IUCD removal were chronic pelvic pain and irregular BPV in our study. Mohan et al. also found bleeding and pain as the most common reasons for postpartum IUCD removal [14]. Srivastava et al. reported a higher frequency of irregular bleeding in interval group (17.5%) as compared to post-partum group (4.3%) [15]. We also found that complaint of irregular BPV was more frequent in interval group than in postpartum group. The possible explanation for such finding is that whatever abnormal bleeding occurs after insertion of copper T in puerperium gets masked by lochia. Pelvic infection was least common in intra-caesarean insertion group (0.56%) among all three postpartum subgroups in our study. Singal et al. reported 1.04% pelvic infection rate in patients who underwent intra-caesarean CuT380A insertion [16]. We found the continuation rate to be maximal in the interval group. We feel that postpartum patients are motivated and satisfied with the IUCD insertion till they are at healthcare facility. Therefore good counseling may lessen the number of patients who get IUCD removed during their follow-up visits. One patient in the delayed postpartum group got pregnant with copper T in situ in our study while no failure was seen in interval group. Contrary to our results, Gupta et al. did not have any case of failure at the end of 6 month follow-up [17]. This discrepancy may be due to a larger sample size in our study.

Our study had a number of strengths, including a relatively large sample size and lesser number of lost-to-follow up patients. This study is among one of those few studies which have compared IUCD insertion outcomes simultaneously in all the four groups in India. However, it had some limitations that should be considered while interpreting the results. Firstly, as it was a retrospective study, selection bias cannot be ruled out. However, as we selected the consecutive patients, an attempt was made to mitigate the bias. Secondly, it was a single-institution-based study. Thus, the applicability of the results of our study to the population of the country at large needs consideration. However, being a large-volume tertiary care referral institution, with patients coming from all parts of the country, we boast of a sufficiently heterogeneous patient population, similar to the national population.

Conclusion

Acceptability of IUCD as a contraceptive method was higher among young, literate and multiparous women. Overall, CuT380A was an effective contraceptive method with very low failure rate (1 in 1599). At six months, the continuation rate was found higher than 90% in all the groups. Though the expulsion rate was found to be higher with postpartum insertion than interval insertion, immediate postpartum period was the best time for IUCD insertion in the Indian scenario with least expulsion rate, maximum continuation rate and no failure. As the use of IUCD was found to be safe in both postpartum period and interval period with great efficacy, and keeping in mind that postpartum period is a great opportunity for clinicians to counsel a woman, to allay her anxiety and to provide her a good contraception, immediate postpartum IUCD may play the best role in such scenario. Multi-centric studies with a larger sample size and long term follow-up are needed in the country to know the actual acceptability and continuity of IUCD.

Compliance with Ethical Standards

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

Ethical Approval For this type of study formal consent is not required.

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