Original Article

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Acceptability, Safety and Compliance of Copper T 380A as a Postpartum Intrauterine Contraceptive Device Inserted via Vaginal or Intracaesarean Route: A Cohort Study

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Considering the high unmet need for family planning in India, especially in postpartum mothers, there is a necessity for reliable, long-term, highly efficacious, safe and reversible contraception like Intrauterine Device (IUD) in these women. Copper T 380A (CuT 380A) as a Postpartum Intrauterine Contraceptive Device (PPIUCD) can reduce maternal and perinatal mortality by decreasing unintended and closely spaced pregnancies in the postpartum period. Despite many advantages, the acceptability and utilisation of PPIUCD still remain very low due to lack of information about it.

Aim: To determine the acceptance, safety, and efficacy of Copper T 380A; its association with socio-demographic factors and to compare the clinical outcomes between vaginal and intracaesarean insertions of this device.

Materials and Methods: A hospital-based prospective cohort study was conducted in the Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, India, from February 2021 to July 2021 among the cohort of 210 consecutive eligible postpartum mothers delivered either vaginally or by caesarean section. Primarily, acceptance rate was assessed. Postinsertion follow-up was done till six months after delivery to note various clinical outcomes and complications measuring safety of the device in terms of cramping pain abdomen, irregular vaginal bleeding, abnormal vaginal discharge, string problems, and perforation; compliance in terms of pregnancy and expulsion; and continuation of the device. All the follow-up results were compared between two modes of insertions. Comparison between categorical variables was done by Chi-square test.

Results: Out of 210 counselled mothers, Copper T 380A insertions were done in 178 (84.8%) postpartum mothers. The acceptance rate was slightly higher in intracaesarean group (n=87, 85.3%). The mean±Standard Deviation (SD) age of acceptance of IUCD in partcipants was 25.62±4.09 years with the highest rate observed in the age group of 21-25 years (n=98, 46.7%). Acceptance of the device was significantly associated with multipara and the clients completed primary education (p-value <0.05). On follow-up, overall complications are low. No case of perforation was reported. Significantly higher incidences of abnormal vaginal bleeding, foul smelling vaginal discharge, string problems, and expulsions were observed in the vaginal group (p-value <0.05). Pregnancy was recorded in five (5.5%) clients and all of them were in the vaginal group. Out of 178 acceptors, compliance-continuation of the device was shown by 151 (84.8%), with significantly higher in the caesarean group (p-value <0.000051). A significantly higher continuation rate was observed among the clients of low socio-economic status (p-value <0.000207). Abdominal pain (33.33%) was reported to be the most common reason for discontinuation of Copper T 380A.

Conclusion: Regardless of the mode of delivery, Copper T 380A is quite an acceptable, safe, effective, and convenient contraceptive method with a good continuation rate in the immediate postpartum period.

Keywords: Descended strings, Expulsion, Intrauterine device, Perforation, Vaginal insertion

INTRODUCTION

Worldwide, one of the most important public health concerns is to deal with the high unmet need for contraception among the postpartum mothers in low and middle-income countries [1,2]. In India, 65% of women have an unmet need for family planning in their first year of postpartum period, but only 26% of women are adopting any method of family planning during this crucial time [3].

As per the Fifth round of the National Family Health Survey (NFHS-5), an Indian counterpart for the Demographic Health Survey [4], acceptance of PPIUCD is rising and there is a decreasing trend in unmet need across the country, despite having a miserable contribution of intrauterine devices of just 2.1%, among all the available methods of contraception practiced for family planning in India [4]. Moreover, IUCD services are safe, effective and reversible, offered free of cost at all government facilities, and provide effective protection for 10 years with a very low failure rate of (<0.5 hundred woman years) [4]. The under-utilisation of IUCD services is mainly due to the lack of knowledge, myths, and various misconceptions that prevailed both on the part of clients and service providers, which has resulted even in its discontinuation [3].

The World Health Organisation (WHO) recommends an interval between the last live birth and the next pregnancy of at least 24 months, a birth interval of 33 months to diminish detrimental maternal outcomes [5]. Evidence shows that shorter inter-pregnancy interval (less than 18 months) rises the risk of adverse perinatal outcomes [6]. Because of the high unmet need for family planning, the postpartum period is highly vulnerable of having unplanned pregnancy which causes unfavourable outcomes like abortion, premature labour, low birth weight baby, foetal loss, Postpartum Haemorrhage (PPH), and maternal death [7,8]. This behests effective and reliable long-term contraception in the postpartum period. PPIUCD is the only family planning method that is extremely effective, reliable, inexpensive, immediately reversible, non hormonal, and long-acting contraceptive that can be introduced during the

immediate postpartum period and it has no negative effect on breastfeeding [7-9]. When it is introduced after delivery, the PPIUCD has proved that, it can improve maternal and neonatal health by preventing adverse obstetric outcomes such as maternal and neonatal mortality and other health hazards associated with closely spaced pregnancies [10]. Moreover, women are highly motivated and receptive in the postpartum period, and the need for additional hospital visits is minimal [11]. Thus, postpartum family planning services must have to be emphasised, so that the mother can leave the healthcare facility with an effective contraceptive in place.

In numerous settings, evidence of the safety and feasibility of PPIUCD insertion has been systematically reviewed in the Cochrane database which concluded that the quality of evidence was moderate and future trials are necessary to estimate expulsion rates and side-effects of PPIUCD [12]. However, most of the previous studies reported that the expulsion rate was high [13-15]. Immediate postpartum Copper T 380A insertion is associated with lower expulsion rates than delayed postpartum insertion. Moreover, post-placental placement during caesarean section has lower expulsion rates than that of vaginal insertions [16].

So many advancements have been attempted to raise the acceptance rate and to reduce the expulsion rate. There might have some variations of outcomes at follow-up when PPIUCD was inserted through the vaginal route or intracaesarean. Comparative study results between vaginal and caesarean insertions are sparse. So far in India, limited researches have been conducted about the safety, efficacy, and follow-up data on adverse outcomes among the acceptors of PPIUCD [17-20]. Moreover, there are gaps in available pieces of literature regarding the insertion of PPIUCD between vaginal and intracaesarean routes, which may have different outcomes on follow-up. So, with this background, the present study aimed to evaluate the outcome, complications, and continuation rate of Copper T 380A insertion and to compare outcomes of vaginal and intracaesarean insertions of it in a tertiary care teaching hospital in India.

MATERIALS AND METHODS

It was a hospital-based prospective cohort study conducted in the Department of Obstetrics and Gynaecology, R.G. Kar Medical College and Hospital, Kolkata, India, from February 2021 to July 2021, among the 210 consecutive eligible postpartum mothers, who attended either an antenatal clinic or were admitted to labour ward and delivered in the study Institution. The study was carried out after obtaining the Ethical clearance for the study protocol from the Institutional Ethics Committee (vide memo No. RKC/124 dated 12.02.2020). Just prior to the insertion of the IUD, written informed consent was taken only from those eligible mothers, who accepted the device.

Inclusion criteria: Mothers having age ≤35 years, gestational age 34-40 weeks, anticipate Vaginal Delivery (VD) or caesarean section, no infection, willing to follow-up, meeting all eligibility criteria of postpartum IUCD insertion, willing to have CuT 380A after counselling.

Exclusion criteria: Those having uterine anomalies and distorted uterine cavity (septate uterus, bicornuate uterus, fibroid uterus etc.,), known active case of sexually transmitted disease, multiple partners, known case of bleeding diathesis, unresolved PPH, chorioamnionitis and rupture of membranes more than 18 hours, suffering from an immunosuppressive disease {e.g., Acquired Immunodeficiency Syndrom (AIDS)}, known case to copper allergy, haemoglobin less than 7 gm% and extensive genital trauma.

Sample size calculation: The sample size was calculated based on a study conducted on the Indian population which showed that as a reversible method of contraception, the acceptance rate of PPIUCD was 67.12% among the acceptors [21]. Considering 95% confidence interval, (Z_1-α/2)=Standard normal deviation had a value of 1.96, the authors used the formula to calculate the sample size as, $N=(Z_1-\alpha/2)^2\times Q\times P/L^2$.

N=Sample size

P=Expected proportion of cases mentioning the reason for accepting PPIUD as 67.12% (reversible method).

Q=(100-P)

L=Precision in absolute term i.e., 6.71

So, $N=(1.96)^2\times(100-67.12)\times67.12/6.71^2$

$=8474.51/45.02$

$=188.23$

Taking lost to follow-up cases into account, 10% more cases were added to estimate sample size. So, the sample size was, N=188.23+18.82=207.05, in round figure it was 210. Considering the short period of observation to be only six months, only a small portion of these patients could be included by convenience sampling.

Study Procedure

A predesigned pretested proforma, bed head tickets, antenatal cards, medical records, investigation reports etc., were used as a study tool. Details regarding the socio-demographic factors like age, education, occupation, Socio-economic Status (SES) [22], religion, residence and obstetric history i.e., parity, the timing of PPIUCD insertion, client perception of pain during and after PPIUCD insertion and duration of last childbirth, as well as, data from the follow-up visits i.e., compliance of PPIUCD, side-effects, the reason for removal and satisfaction were recorded in proforma sheet.

The CuT 380A used in the present study was available free of cost in the study institution as PPIUCD services became a Government of India program in 2010. The device was inserted either post-placental (within 10 minutes of placental delivery); postpartum (within 48 hours of delivery) or intracaesarean. The IUCD was placed in the uterine fundus with the help of Kelly's placental forceps by trained doctors only, during vaginal insertion either post-placental or postpartum period under sterile conditions. For intracaesarean insertion, IUCD was held between the middle finger and index finger of the surgeon's hand after passing it through the lower uterine incision and placed at the uterine fundus followed by the withdrawal of the hand, taking care of the IUCD remains in the proper place and subsequently lower segment incision was closed. Records were maintained regarding PPIUCD insertions and services by the provider. Postinsertion counselling was done and patients were advised to follow-up routinely for examination at the postpartum unit of the present study center as Outpatient Department (OPD) basis after six weeks, three months, and at six months postdelivery to assess complications, expulsion and failure rate of this device.

During the follow-up visit, the women were asked, if they had any complaints, and a physical and pelvic examination was carried out to assess uterine subinvolution and suprapubic tenderness, and ultrasonography was performed, if necessary to assess the IUCD strings have descended into the vagina or in cases of missing string, the authors checked the expulsion and confirm the presence of intrauterine IUCD. Descended strings were trimmed 3 cm beyond the external os. For any medical or personal reason, if the mother requested for removal of IUCD, she was counselled and the device was removed. In case of removals or expulsions, the women were offered reinsertion of IUCD or alternative contraceptive measures. Findings of the follow-up visit within six weeks, after three months, and after six months of delivery were recorded for all clients. Follow-up findings like abdominal or pelvic pain, vaginal bleeding, infection, fever, spontaneous expulsion, abnormal vaginal discharge, perforation, long string, missing string, other side-effects and symptoms of pregnancy, or willingness to continue or not were recorded. In case, women failed to return for follow-up, they were contacted over the telephone.

The primary outcome measure was the acceptability of PPIUCD among various socio-demographic variables in the present study study participants. The secondary outcome measures were the clinical parameters in terms of safety (abnormal foul smelling vaginal discharge, infection, irregular and heavy bleeding, pelvic pain, perforation), IUCD string problems, pregnancy or failure, expulsion and continuation compliance. These outcome measures were compared between intracaesarean and vaginal insertions of PPIUCD.

STATISTICAL ANALYSIS

Statistical analysis was done by Statistical Package for the Social Sciences (SPSS) software version 27.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarised as the mean and, standard deviation for numerical variables and count and percentages for categorical variables. A Chi-square test (χ^2 test) was used for comparison between categorical variables. A p-value of ≤0.05 was considered statistically significant.

RESULTS

A total of 210 study participants, with a mean age of 25.62±4.09 years, were counselled for Copper T 380A insertion during their antenatal visits in OPD and following their admission with early labour in labour room, and also in postpartum period. Most of the study population were in the age group of 21-25 years (n=98, 46.7%), multipara (n=141, 67.1%) and belonged to lower socio-economic class (n=176, 83.3%) [Table/Fig-1]. Out of total study population, 102 (48.6%) patients underwent caesarean section and 108 (51.4%) women delivered vaginally.

Parameters	n	Percentage (%)
Age groups (years) Mean±SD=25.62±4.09		
≤20	19	9
21-25	98	46.7
26-30	63	30
31-35	30	14.3
Parity		
Multi	141	67.1
Primi	69	32.9
Socio-economic status		
Lower class	176	83.8
Low middle class	17	8.1
Upper middle class	17	8.1
Residence		
Rural	159	75.7
Urban	51	24.3
Religion		
Hindu	72	34.3
Muslim	129	61.4
Others	9	4.3
Education		
Graduate	13	6.2
Higher secondary	15	7.1
Illiterate	30	14.3
Primary	100	47.6
Secondary	52	24.8

[Table/Fig-1]: Socio-demographic characteristics of the study participants (N=210).

Out of 210 study population, the number of PPIUCD acceptors was 178 (84.8%), whereas 32 (15.2%) clients declined insertion. The observed difference in the proportion of acceptors between intracaesarean and VD group was statistically insignificant (p-value=0.8347) [Table/Fig-2]. Among the mothers who declined to insertion of device, majority were reported due to fear and concern of complications (34.37%), followed by husband or family refusal (21.87%) and religious belief (15.6%) [Table/Fig-3].

Acceptability	Mode of delivery		Total (N=210) n (%)	p-value
	CS (n=102) n (%)	VD (n=108) n (%)		
No	15 (14.7)	17 (15.7)	32 (15.2)	0.8347
Yes	87 (85.3)	91 (84.3)	178 (84.8)	

[Table/Fig-2]: Association of acceptability with mode of delivery.
CS: Caeserean section; Chi-square test was used

Reasons	Frequency (n)	Percentage (%)
Prefers permanent method	3	9.3
Fear of complications	11	34.37
Husband/family refusal	7	21.87
Religious belief	5	15.6
Desirous of more children	2	6.25
Belief in interference in sex	3	9.3
No reason	1	3.1

[Table/Fig-3]: Reasons for non acceptability of Copper T 380A (n=32).

The mean age of acceptance of IUCD was 25.59±4.06 years with highest acceptance being in the age group of 21-25 years (n=82, 46.1%). The observed difference in acceptability of Copper T 380A between multipara (61.2%) and primipara (38.8%) was statistically significant (p-value <0.0001) [Table/Fig-4].

Variables	Acceptability		Total (N=210) n (%)	p-value
	No (n=32) n (%)	Yes (n=178) n (%)		
Age groups (years) Mean±SD age of acceptance=25.9±4.06				
≤20	2 (6.3)	17 (9.6)	19 (9)	0.9144
21-25	16 (50)	82 (46.1)	98 (46.7)	
26-30	10 (31.3)	53 (29.8)	63 (30)	
31-35	4 (12.5)	26 (14.6)	30 (14.3)	
Parity				
Multi	32 (100)	109 (61.2)	141 (67.1)	**<0.0001**
Primi	0	69 (38.8)	69 (32.9)	
Socio-economic status				
Lower class	28 (87.5)	148 (83.1)	176 (83.8)	0.8274
Low middle class	2 (6.3)	15 (8.4)	17 (8.1)	
Upper middle class	2 (6.3)	15 (8.4)	17 (8.1)	
Residence				
Rural	25 (78.1)	134 (75.3)	159 (75.7)	0.7297
Urban	7 (21.9)	44 (24.7)	51 (24.3)	
Religion				
Hindu	7 (21.9)	65 (36.5)	72 (34.3)	0.0810
Muslim	25 (78.1)	104 (58.4)	129 (61.4)	
Others	0	9 (5.1)	9 (4.3)	
Education				
Graduate	0	13 (7.3)	13 (6.2)	<0.0001
Higher secondary	2 (6.3)	13 (7.3)	15 (7.1)	
Illiterate	16 (50)	14 (7.9)	30 (14.3)	
Primary	12 (37.5)	88 (49.4)	100 (47.6)	
Secondary	2 (6.3)	50 (28.1)	52 (24.8)	

[Table/Fig-4]: Association of acceptability of Copper T 380A with socio-demographic variables.
Chi-square test (χ^2 test) was used; The p-value in bold font indicates statistically significant values

Of the total acceptance (n=178), only 11 (6.2%) mothers had heavy and prolonged vaginal bleeding. Among the acceptors, 4 (2.2%) patients had complete expulsion and 9 (5.1%) patients experienced partial expulsion of Copper T 380A. The compliance-

continuation rate was 84.8% (n=151) and failure rate was 2.8% (n=5) [Table/Fig-5].

Parameters	n (n=178)	Percentage (%)
Changes in menstrual bleeding patterns		
Heavy and prolong	11	6.2
Normal	167	93.8
Cramping and pain		
No	124	69.7
Yes	54	30.3
Infection and foul smelling discharge		
No	153	86
Yes	25	14
IUCD string problem		
No	171	96.1
Yes	7	3.9
Perforation		
No	178	100
Expulsion		
Complete	4	2.2
No	165	92.7
Partial	9	5.1
Pregnancy/contraceptive failure		
No	173	97.2
Yes	5	2.8
Compliance-continuation		
Yes	151	84.8
No	27	15.2

[Table/Fig-5]: Complications and clinical outcome of copper IUD users.

The acceptors were followed-up to evaluate the complication at the 6th week, 3rd month and 6th month of insertion. Abdominal pain was the most common adverse event and noted in 67 (37.64%), 56 (31.4%), 54 (30.3%) mothers at 6th week, 3rd month and 6th month of follow-up, respectively. Highest incidence (n=13, 7.3%) of expulsion was recorded at 6th month of insertion [Table/Fig-6].

Complications	6 weeks	3 months	6 months
	n=178 n (%)		
Bleeding	17 (9.5)	12 (6.7)	11 (6.2)
Abdominal pain	67 (37.64)	56 (31.4)	54 (30.3)
Infection and vaginal discharge	06 (3.3)	21 (11.79)	25 (14)
String problems	03 (1.6)	4 (2.2)	7 (3.9)
Perforation	0	0	0
Expulsions	02 (1.1)	07 (3.4)	13 (7.3)
Pregnancy/contraceptive failure	0	0	5 (2.8)

[Table/Fig-6]: Complications at 6th week, 3rd month and 6th month of insertion of device on follow-up.

In the present study, a significantly higher incidence of excessive vaginal bleeding was reported in VD group than that of intracaesarean group (p-value=0.0064). In the present study, total five (5.5%) clients who had pregnancy or contraceptive failure belonged to VD cohort which was statistically significant (p-value=0.0265) [Table/Fig-7].

Association of mode of delivery with continuation compliance was statistically significant (p-value=0.000051). The current study indicated that highest continuation rate of use of Copper T 380A was observed among the acceptors who belonged to lower socio-economic status (n=133, 86.8%). Association of socio-economic status with compliance-continuation of IUCD use was found to be statistically significant (p-value=0.000207) [Table/Fig-8].

Parameters	Mode of delivery		Total (n=178) n (%)	p-value
	CS (n=87) n (%)	VD (n=91) n (%)		
Menstrual bleeding patterns				
Heavy and prolong	1 (1.1)	10 (11)	11 (6.2)	**0.0064**
Normal	86 (98.9)	81 (89)	167 (93.8)	
Cramping and pain				
No	66 (75.9)	58 (63.7)	124 (69.7)	0.0785
Yes	21 (24.1)	33 (36.3)	54 (30.3)	
Infection and foul smelling discharge				
No	83 (95.4)	70 (76.9)	153 (86)	**0.0003**
Yes	4 (4.6)	21 (23.1)	25 (14)	
IUCD string problem				
No	87 (100)	84 (92.3)	171 (96.1)	**0.0083**
Yes	0	7 (7.7)	7 (3.9)	
Expulsion				
Complete	2 (2.3)	2 (2.2)	4 (2.2)	**0.0107**
No	85 (97.7)	80 (87.9)	165 (92.7)	
Partial	0	9 (9.9)	9 (5.1)	
Pregnancy/contraceptive failure				
No	87 (100)	86 (94.5)	173 (97.2)	**0.0265**
Yes	0	5 (5.5)	5 (2.8)	

[Table/Fig-7]: Association of various complications of Copper T 380A with mode of delivery.
Chi-square test (χ^2 test) was used; The p-value in bold font indicates statistically significant values

Variables	Continued compliance		Total (n=178)	p-value
	No (n=27)	Yes (n=151)		
Mode of delivery, n (%)				
CS	3 (11.1)	84 (55.6)	87 (48.9)	**0.000051**
VD	24 (88.9)	67 (44.4)	91 (51.1)	
Residence, n (%)				
Rural	19 (66.7)	115 (76.8)	134 (48.9)	0.376485
Urban	8 (33.3)	36 (23.2)	44 (51.1)	
Parity, n (%)				
Primi	11 (40.7)	58 (38.4)	69 (38.8)	0.988466
Multi	16 (59.3)	93 (61.6)	109 (61.2)	
Religion, n (%)				
Hindu	11 (44.4)	54 (35.1)	65 (36.6)	0.638133
Muslim	15 (51.9)	89 (59.6)	104 (58.4)	
Others	1 (3.7)	8 (5.3)	9 (5)	
Socio-economic status, n (%)				
Lower class	15 (55.6)	133 (86.8)	148 (82)	**0.000207**
Upper middle class	5 (18.6)	10 (7.9)	15 (9.6)	
Lower middle class	7 (25.8)	8 (5.3)	15 (8.4)	

[Table/Fig-8]: Association of continued compliance among the acceptors with different variables.
Chi-square test (χ^2 test) was used. The p-value in bold font indicates statistically significant values

[Table/Fig-9] depicted the most common reasons to discontinue the method. These were cramping pain abdomen (n=9, 33.33%); followed by irregular excessive bleeding per vaginal in 6 (22.22%) patients; objection from husband and in-laws was experienced by 3 (11.11%) participants. Of all, 5 (18.57%) participants requested discontinuation of the method following expulsion of the device.

DISCUSSION

The mean age of the present study population is almost comparable to the study participants in the study by Gonie A et al., and Divakar H et al., where the mean age of study participants was 26.26±4.78 years and 24.5±4.295 years, respectively [10,23]. Out

Reasons for discontinuation/removal of PPIUCD	n (n=27)	Percentage (%)
Irregular excessive vaginal bleeding	6	22.22
Cramping pain abdomen	9	33.33
Foul smelling vaginal discharge	1	3.7
Objection from husband and in-laws	3	11.11
String problems/missing threads	1	3.7
Adopting other contraceptive methods	2	7.4
Expulsion	5	18.51

[Table/Fig-9]: Reasons for discontinuation of Copper T 380A.

of 210 participants, largest proportion of women were in the age group of 21-25 years (46.7%), multigravida (67.1%), and belonged to lower socio-economic status (83.8%). This demographic profile is almost similar to a study done by Gonie A et al., [10]. In a recent study conducted in Delhi, revealed majority (78.6%) of participants belonged to the age group of 20-30 years, with 79.2% having education of Class X and above, 70.9% of the women were from urban sector and 73% belonged to upper or upper middle class [24]. A high rate of acceptance (84.8%) of PPIUCD in the present study, was in concordance with the studies by Chattopadhyay S et al., and Kant S et al., but in discordance to other studies [10,25-27].

Difference in the educational level of participants, awareness, misconceptions, and religious faiths about PPIUCD insertion might be the cause for the differences [10]. Availability of trained healthcare workers with improved counselling skills in antenatal clinic in the present study institute, made it possible for higher acceptance of Copper T 380A in current study as compared to the previous published literature [15,28,29]. There was comparable proportion of study participants in both VD and caesarean section group (n=108, 51.4% and n=102, 48.6% respectively) in present study but the acceptance rate among caesarean section cohort (n=87, 85.3%) was slightly higher than that of VD group (n=91, 84.3%) which is similar to other studies [17,19,26,28]. Postcaesarean conception fear might be the reason for higher acceptance of the PPIUCD among the caesarean insertion cohort. Most common perceived reasons of non acceptability of the copper device use reported by the participants were fear and concerns of complications (34.37%), followed by husband or family refusal (21.87%) and religious belief (15.6%). These observations of the present study were supported by other studies conducted in India and abroad [10,21,25].

In the present study, highest acceptance among women of 21-25 years (46.7%) which was comparable to that of other studies [15,29]. Significant proportion of acceptors in the current study, were multipara (61.2%) which is supported by published literatures [30,31]. Some recent studies also reported that most of the acceptors of PPIUCD were delivering for the second time [10,27,32]. In contrast to othe present study, a higher acceptance among primipara was reported in several previous studies [15,19,28].

Level of education plays a vital role in motivating and creating a positive attitude of clients towards the use of PPIUCD which was reflected in the current study where a significant proportion of acceptability (p-value <0.0001) of IUCD device was reported among women who completed the primary and secondary level of education, which was similar to other studies [21,25]. The majority of women were primary school educated (39.2%), while 37.2% were illiterate in a study conducted by Bhadra B et al., [32]. Although socio-economic status and religion did not appear to be significantly related to acceptance of PPIUD insertion in the present study (p-value was 0.8274 and 0.0810, respectively), there was high acceptability among lower socio-economic class (83.1%) and among the Muslim acceptors (58.4%). This was concurrent with a study conducted in North India by Kant S et al., that revealed a higher acceptance rate (48.6%) of IUCD among poorer families as compared to those from richer ones (26.1%) and higher acceptability of the method (70.6%) among women belonging to Muslim religion [26]. Higher acceptance was also reported in the clients of lower SES in a study done by Agarwal N et al., [20]. The reason might be that acceptors of higher economic families had better knowledge and access to other alternative methods such as injectable hormonal contraceptives and thereby, these women could have preferred contraceptive methods apart from PPIUCD. High acceptance of the method among women belonging to the Muslim religion could be explained by the fact that, if confidentiality, privacy, and adequate counselling could be provided to the Muslim clients, acceptability of PPIUCD would be higher as their Hindu fellows.

Sharma N et al., observed that irregular bleeding was the most common complaint (5.64% at 6th week and 3.07% in 6th month) on follow-up visits which was corroborative to current study findings [27]. Menorrhagia was also noted by Hooda R et al., in 10.5% of women at their six weeks of postinsertion follow-up visit [17]. On follow-up, the incidence of abnormal and offensive vaginal discharge (p-value=0.0003), was significant between two modes of insertions (vaginal and intracaesarean) of CuT 380A. Hooda R et al., reported unusual vaginal discharge in 12.3% women at follow-up and this was significantly higher after caesarean IUCD insertions (p-value=0.037) and there was no significant difference in rates of irregular bleeding between the two insertion groups, which was discordant to the present findings [17].

In a recent study, the observed difference was not statistically significant (p-value >0.05) when the complications were compared between the two groups of insertions [33]. Higher incidence of bleeding per vaginal and pelvic pain was reported in vaginal insertions compared to intracaesarean insertions, but this difference was statistically not significant (p-value >0.05) [34]. Shukla M et al., indicated a higher incidence of vaginal bleeding (27.2%) with use of CuT 200 in postpartum mothers [14].

Incidence of missing threads reported to be more common after caesarean insertion in comparison to vaginal group (4.3% vs. 2.7%), in a study conducted in Kalyani [32]. This was in discordance to the present study, which reported significantly high rate of string problems in vaginal insertion group. In the present study, rate of expulsion of CuT 380A among vaginally delivered patients was appeared to be statistically higher (p-value=0.0107) in comparison to Caesarean group and this finding was similar to recent published literatures [17,35], though overall incidence of expulsion (7.3%) in present study was lesser than other studies [35,36]. Expulsion rate of PPIUCD may differ due to variation in provider's skill, and follow-up services of the device are essential to ensure its continuation as well as client's satisfaction of this method [15]. Lesser expulsion might be due to skilled insertion of all IUCDs by doctors only in our set-up and decreased expulsion rate after trans caesarean insertion as compared to vaginal insertion might be due to direct placement of device at the fundus during caesarean delivery.

No incidence of perforation of the uterus recorded during the procedure of insertion in both groups in the present study. Moreover on follow-up, failure of the procedure in terms of pregnancy was only 2.8% (n=5) and all the cases were in the VD group which was in accordance with a recent literature [25]. However, further follow-up with longer duration is necessary. No cases of perforation also recorded in the study conducted by Bhadra B et al., [32]. The study conducted by other researchers also reported no cases of perforation and pregnancy in their study [17,33]. Out of 52 followed-up acceptors, one case of intrauterine pregnancy was reported by Kanhere AV et al., [37].

In the present study, the rate of continuation of IUCD (84.8%) was much higher than a study conducted by Sarkar S et al., [38]. Moreover, our finding was comparable to reports revealed in literatures which recorded continuation rate more than 80%

[17,39,40]. Low continuation rate (42.6%) was also reported in another study conducted at Agartala [41]. The difference of continuation rate might be explained by the fact that there are variations in the educational levels of acceptors, misconceptions, beliefs and adverse effects experienced by the users. Continuation of CuT 380A was significantly higher in caesarean section group (p-value=0.000051) in the present study which was similar to other recent studies [35,42]. Dedicated counselling in postinsertion period in addition to routine antenatal, intranatal and postnatal counselling among the acceptors might play a pivotal role for very high rate of continuation of copper device used by the lower socio-economic group in the present study. A recent Indian study revealed that there was decreased continuation of CuT 380A among women of higher parity and increased chances of continued use of IUCD with the higher educational levels among the acceptors (AOR: 1.63, CI: 1.10-2.41, p-value <0.01) [43]. This was in contrast to othe present study finding. Discontinuation rate of IUCD was observed to be higher (15.16%) in present study in comparison to that of other studies, where discontinuation rate was 4.1% and 8.08% [17,39].

Agrahari K et al., observed that the IUCD discontinuation rate was lower among the poorest and richest but higher in middle class and this finding was discordant to present study [44]. The study conducted by Sharma M et al., revealed that discontinuation of IUCD inversely varied with the educational level of the women, with the highest discontinuation rate found in illiterate women (95%) and the lowest among graduates (53.6%) [45]. The significant association between SES and continuation of IUCD might be explained by the fact that an improvement in educational status of women will certainly improve the awareness, knowledge and motivation for PPIUCD insertion.

Limitation(s)

As the present study was a facility-based single-centre study and had a short period of follow-up, the findings might not reflect the population as a whole. So, a study with larger sample size and long-term follow-up could sufficiently address the issues like incidence of rare complications like perforation and pregnancy rate in both groups of insertions.

CONCLUSION(S)

Irrespective of the mode of insertion, Copper T 380A is a safe, convenient, and highly efficacious contraceptive intervention in the postpartum period with high acceptability and a good compliance-continuation rate. The device should be incentivised in both vaginal and caesarean deliveries as facility-based births have increased due to governmental boosts in overpopulated countries like India, where there is a high rate of unintended pregnancy in the postpartum period. Expulsion rate was minimal and no incidence of perforation was recorded. The benefits of the device outweigh the insignificant adverse effects of the IUCD. Moreover, these minor risks can be minimised by increasing technical expertisation of healthcare personnel, adequate counselling at every delivery set-up and early follow-up examination.

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