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Original Article

Obstetrics and Gynaecology Section

Evaluation of Acceptability, Safety, Efficacy and Outcome of Postplacental IUCD Insertion in Women Undergoing both Vaginal Delivery and Caesarean Section- A Cohort Study

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ABSTRACT

Introduction: Prevention of unplanned and unwanted pregnancies could help avert 20-35% of maternal deaths and as many as 20% of infant death. Despite many advantages of, mothers of India are reluctant for IUCD use.

Aim: To determine the acceptability, safety, efficacy and outcome of Postpartum Intrauterine Contraceptive Device (PPIUCD) following both vaginal delivery and caesarean section.

Materials and Methods: A descriptive prospective cohort study conducted in the Department of Obstetrics and Gynaecology in a tertiary care institute in Eastern India from August 2019 to July 2020. Among the women delivered almost all mothers were counseled about postplacental IUCD insertion and the first 100 mother who satisfy inclusion criteria were incorporated in the present study. Out of 100 mothers, six mother refused and 94 mothers accepted PPIUCD. Only three mothers were lost to follow-up. Ninety-one mothers were followed-up in postnatal clinic after 6 weeks, 12 weeks, 24 weeks and 48 weeks. Primary parameter was to assess acceptance rate and reason for acceptance. Secondary variables were refusal rate and reason for refusal, reason for removal, failure rate and complications. Collected data were then analysed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5.

Results: Majority of mothers were in the 21-25 years age group and completed secondary school education. A very high rate of acceptance of about 94% was found. The most common reason for acceptance was its long-term effect of contraception (40.4%) followed by reversible nature (27.7%). This study showed that refusal rate was 6%, majority due to fear of complications. Among 91 mothers followed-up for safety profile of PPIUCD, majority (81.3%) had no complication which was statistically significant ($p<0.0001$). Out of 91 women, 80 mothers (87.9%) continued PPIUCD, three mothers had abdominal discomfort, 10 had abnormal bleeding P/V, and 67 mothers (90.4%) had no complications and failure rate was 2.2%. Only two mothers conceived with PPIUCD in-situ. Expulsion rate was 4.4%. Out of 91 mothers followed-up, only four had expulsion.

Conclusion: PPIUCD is widely accepted, efficacious, safe method of family planning, that can reduce maternal morbidity and mortality.

Keywords: Complications, Failure rate, Intrauterine device, Postpartum

INTRODUCTION

Insertion of IUCD in immediate postpartum period is an effective, safe, and convenient contraceptive intervention in both cesarean and vaginal deliveries [1]. India launched the national family welfare programme in 1951. Over the years India's family planning programme has evolved with the shift in focus from merely population control to more critical issues of saving the lives and improving the health of mothers and newborns [2]. Use of reversible or spacing methods of contraceptives can save women's lives and health due to a reduction in unwanted, closely spaced and mistimed pregnancies and thus avoiding pregnancies with higher risks and chances of abortions, many of which may be unsafe [2].

Approximately, 61% of births in India occur within 36 months of previous births. This means the birth to pregnancy intervals in 61% of births are shorter than the recommended birth to pregnancy interval [2]. Immediate postpartum Cu-IUD insertion, particularly when insertion occurs immediately after delivery of the placenta, is associated with lower expulsion rates than delayed postpartum insertion. Additionally, postplacental placement at the time of caesarean section has lower expulsion rates than postplacental vaginal insertions [3]. In India knowledge of awareness of contraceptive methods is inadequate and many misconceptions are present in the society [4].

Thus, importance of spacing between childbirths with the use of PPIUCD can be considered. Taking advantage of the immediate postplacental period for counseling on family planning, PPIUCD is a good option as a contraceptive method. In low-resource countries, delivery is probably the only time when a healthy woman comes into contact with a healthcare provider and the likelihood of her returning for contraceptive advice is low [5]. The postpartum period is potentially an ideal time to begin contraception as women are more strongly motivated to do so at this time, which also has the advantage of being convenient for both patients and healthcare providers [6]. This is particularly important for women who have limited access to medical care.

Many women also find the IUCD to be very convenient, because it requires little attention once it is inserted. Increasing numbers of women in India are having their babies born in hospitals after introduction of Janani Suraksha Yojana (JSY) and Janani Shishu Suraksha Yojna (JSSY). It allows opportunity for the state to provide PPIUCD in a big way. Despite of IUCD being a cost-effective, long acting, safe, reversible, coital independent method for contraception, mothers in India are reluctant for IUCD use. Due to lack of awareness and myths prevailing for IUCD, present rate of IUCD use in India is 2%, which is way lesser than required [5]. It is still relatively unknown why acceptance of IUCD among women

both urban and rural is low. This can be due to various reasons i.e., medical or social. Current Indian medical literature does not reflect clearly on this aspect. Thus, this present study was conducted to determine the acceptability, safety, efficacy and outcome of PPIUCD following both vaginal delivery and caesarean section.

MATERIALS AND METHODS

This was a descriptive prospective cohort study conducted in the Department of Obstetrics and Gynaecology, Nil Ratan Sircar Medical College and Hospital, Kolkata, a tertiary care institution in Eastern India. It was performed between the time period of one year from August 2019 to July 2020. A prior approval for the protocol of the study was obtained from the Institutional Ethics Committee (No/NMC/10084 dated 03/01/2019) and each participant was enrolled after proper informed consent in their vernacular language.

Inclusion criteria: Women with singleton or multiple pregnancy, age between 19 to 35 years, delivering at 36-40 weeks of gestation irrespective of baby outcome, not willing for permanent sterilisation, delivering by vaginal or caesarean section, haemoglobin level more than 9 gm% and mothers willing to participate were included in this study.

Exclusion criteria: Women having history of rupture of membranes >12 hours, fever in the last trimester, heart disease, antepartum haemorrhage, lower genital tract infections, mothers with anaemia, postpartum haemorrhage complicating deliveries, manual removal of placenta with previous allergic reaction to IUCD, anomalous uterus as evidenced in early scans, not willing for IUCD insertion were excluded from our study.

Sample size calculation: A previous study [6] showed that acceptance rate was 37.4%. Sample size was calculated using OpenEpi, Version 3, open source calculator-SSPropor by taking 95% confidence interval. It was found to be 87. After adding 10% drop out, total of 100 women were taken for this study.

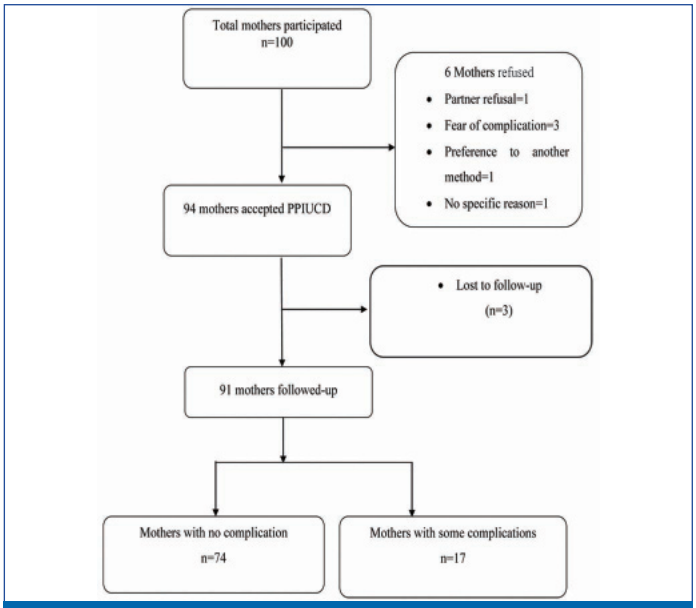
Study Procedure

Among the women delivered at our institution, almost all mothers were counseled about postplacental IUCD insertion in antenatal period and the first 100 mother who satisfy inclusion criteria were incorporated in our study. Out of 100 mothers, six mothers refused and 94 mothers accepted PPIUCD [Table/Fig-1]. All women had postplacental insertion of IUCD under sterile conditions and antibiotic coverage to ensure asepsis in the mother. Primary parameter was to assess acceptance rate and reason for acceptance. Secondary variables were refusal rate and reason for refusal, reason for removal, failure rate and complications. Informed written consent was taken from the mother before insertion after elaborating the possible complaints following insertion and reassurance. After taking consent, a Cu-T 380A was inserted using Kelly's Forceps by doctors only within 10 minutes of placental expulsion in vaginal deliveries. IUCD was held suitably with the instrument and was inserted up to the fundus of the uterus and the IUCD was released. Intraoperative insertion at cesarean delivery was done by holding the IUCD between the middle and index fingers of the hand and passed it through the uterine incision. After placing it at the fundus of the uterus, the hand was withdrawn taking care that the IUCD remains properly placed.

All mothers were advised to attend postnatal clinic after 6 weeks, 12 weeks, 24 weeks and 48 weeks for follow-up, and presence of Cu-T were verified, patients were treated symptomatically and reassured about the safety of Cu-T. Mothers who did not come for follow-up were telephoned to the number provided during admission for follow-up examination at OPD. Complications (e.g., expulsion, missing thread) were recorded at return visits. Only three mothers were lost to follow-up.

STATISTICAL ANALYSIS

Data was entered into a Microsoft excel spreadsheet and then analysed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarised as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Unpaired proportions were compared by Chi-square test or Fischer's-exact test, as appropriate. Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. Once a t value was determined, a p-value was found using a table of values from Student's t distribution. p-value ≤0.05 was considered for statistically significant.



[Table/Fig-1]: Participation flow chart.

RESULTS

During the study period, among the women delivered at the institution, almost all mothers were counselled about postplacental IUCD insertion in antenatal period and the first 100 women who were willing were incorporated. Out of 100 mothers, six mothers refused and three mothers were lost to follow-up. A total of 91 women were followed-up. [Table/Fig-2] showed that the majority of mothers who made an informed choice for PPIUD insertion were

Characteristics	Numbers	Percentages (%)	p-value
Age (years)*			
≤20	14	14	0.77182
21-25	41	41	
26-30	39	39	
>30	6	6	
Total	100	100	
Parity†			
P0+0	17	17	0.03
P0+1	30	30	
P1+0	14	14	
P1+1	11	11	
P2+0	14	14	
P2+1	14	14	
Total	100	100	
Level of education			
No formal education	8	8	0.001
Primary education	32	32	
Secondary education	60	60	

[Table/Fig-2]: Baseline characteristics of PPIUCD mothers.
*Student's unpaired t-test; †Chi square test

in the 21-25 years age group. About 47% women who accepted PPIUCD, were primipara mother which was statistically significant (p=0.03). The majority of women had secondary school education. The remainders were illiterate or had primary school education. The result was statistically significant (p<0.0001). In our study, 42 (42.0%) mothers delivered by caesarean section whereas 58 (58.0%) mothers delivered by vaginal route.

[Table/Fig-3] showed that the most common reason for acceptance of PPIUCD was its long-term effect of contraception followed by reversible nature. A total of 21 women accepted for non hormonal contraceptive and only nine mothers accepted for safety of PPIUCD. The result was statistically significant (p<0.05). Refusal rate was 6%. Among the women who refused, majority was due to fear of complications, followed by partner's refusal and preference to other methods and only one mother had no specific reason. Among 94 mothers, who accepted PPIUCD, only three mothers were lost to follow-up and out of 91 mothers, PPIUCD was removed in seven mothers, four mothers had spontaneously expelled and 80 mothers continued PPIUCD. Two mothers had complication and two had family pressure for the removal of PPIUCD which was statistically significant (p<0.0001). Only two mothers conceived with PPIUCD in-situ.

Reasons	Numbers (n)	Percentages (%)	p-value
Reason for acceptance			
Long-term contraceptive	38	40.4	0.05
Non hormonal contraceptive	21	22.3	
Reversible	26	27.7	
Safe	9	9.6	
Total number of mothers accepted PPIUCD	94	100	
Reason for refusal			
Partner refusal	1	16.7	<0.0001
Fear of complications	3	50	
Religious	0	0	
Preference to another method	1	16.7	
Fears cancer	0	0	
No specific reason	1	16.7	
Total no of mother refused	6	100	
Removal of PPIUCD	7	100	
Reason for removal			
Complication	2	28.6	0.0455
Family pressure	2	28.6	
Preference to other method	1	14.3	
Conceived with PPIUCD in-situ (Failure)	2	28.6	
Expulsion of PPIUCD	4		
Continuation of PPIUCD	80		

[Table/Fig-3]: Distribution of patients according to reason for acceptance, refusal and removal of PPIUCD.

[Table/Fig-4] showed that out of 91 mothers, majority mothers (87.9%) continued PPIUCD among them only three mothers had abdominal discomfort, 10 had abnormal bleeding P/V, and 67 (90.4%) mothers had no complications. Failure rate was 2.2%. Only two mothers conceived with PPIUCD in-situ. Expulsion rate was 5.4%.

DISCUSSION

In our study, conducted in a tertiary care hospital, we aimed to determine the acceptability, safety, efficacy and outcome of PPIUCD following both vaginal delivery and caesarean section. Very high rate of acceptance of about 94% was found in this study. The most common reason for acceptance was its long-term effect followed by reversible nature. Our findings were similar to some studies [7,8]. According to other studies, reversible nature of IUCD seems to be the most common cause for acceptance followed by long-term contraceptive property, safety and non hormonal property [9]. Whereas some studies showed safety was the primary reason for acceptance [8,10]. This study showed low refusal rate. Among the women who refused, majority was due to fear of complications followed by partner's refusal and preference to other methods and there was no specific reason in some cases.

Problems	Total	Removal of PPIUCD	Expulsion of PPIUCD	Continuation with PPIUCD	p-value
Abdominal discomfort	5 (5.5%)	2 (40%)	-	3 (60%)	0.5287
Abnormal bleeding P/V	10 (11%)	0	-	10 (100%)	<0.0001
Conceived with PPIUCD in-situ (Failure rate)	2 (2.2%)	2 (2.2%)	-	-	0.0455
No complication	74 (81.3%)	3 (4.05%)	4 (5.4%)	67 (90.5%)	<0.0001
Total	91 (100%)	7 (7.7%)	4 (5.4%)	80 (87.9%)	

[Table/Fig-4]: Continuation with or without PPIUCD complication (n=91).

Acceptance of PPIUD did appear to be related to the quality of PPIUD counselling received and educational status of mothers. All mothers were counselled by doctors. Majority of mothers had completed secondary education, followed by primary schooling and few mothers had no formal education. Education status plays an important role in motivating and preparing patient for PPIUCD use as there are many myths prevailing in country about IUCD. Fear of serious complications, infection, cancer and religious beliefs, hinders its use among mothers but educated mothers understand the advantage and have positive attitude towards its use once counseled. These findings were similar to other studies [9,11]. Majority of women who accepted PPIUCD were primipara mother. Most of the mother receiving PPIUCD were between 20 to 30 years age group. A study conducted in Tamil Nadu by the Directorate of Health, which showed 59% acceptors in 20-24 group, 31% in 25-29 group, 6.5% in 34-44 group and 4% in the 15-19 group [12].

It was found that nonacceptance of PPIUCD was corroborated to its side-effects. Abnormal bleeding P/V and abdominal discomfort being the foremost cause. Among 91 women followed-up for safety profile of PPIUCD, majority had no complication which was statistically significant. Only five mothers suffered from lower abdominal pain and ten mothers reported abnormal bleeding P/V. Failure rate was 2.2%. Only two mothers conceived with IUCD in situ. Kumar S et al., assessed satisfaction and complications following PPIUCD insertion using standardised questionnaire [13]. Of 62.8% women continuing with the method beyond one year, 19.3% reported removal of PPIUCD for associated bleeding P/V and pain abdomen. Another study [14] reported from Sri Lanka showed that at the end of 3 months, 6.7% of women complained abdominal pain in caesarean section group and 0.8% in vaginal delivery group. Abnormal vaginal bleeding with 6% and 2.2% in caesarean section and vaginal delivery group respectively.

The current study also focused upon the outcome of PPIUCD in one-year course under the heading of expulsion, removal and continuation of PPIUCD. We found that expulsion rate was 4.4% within 6 weeks and out of four, only one mother reported expulsion within 1 week. During follow-up visits at 12 weeks and 24 weeks, seven women requested and underwent removal of PPIUCD for varied reasons. Our finding of low expulsion rate was comparable with one study [13]. They found the rate of expulsion was 3.6% and 7.5% by 6 weeks and one year of follow-up respectively. Other studies found low expulsion rate [15,16], One study showed high expulsion rate (18%) and removal rate (13%) at 6 weeks postpartum [17].

Limitation(s)

In spite of every sincere effort, our study had certain limitations. Firstly, our study has been done in a single centre and carried out in a tertiary care hospital. Secondly, the sample size was small and period of follow-up was short. Further, large multicentric trials with a greater number of subjects and long-term follow-up should be carried out.

CONCLUSION(S)

PPIUCD is widely accepted, efficacious, safe method of contraception. This method of family planning can further improve women's health and can reduce maternal morbidity and mortality.

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