

Evaluation of Safety, Efficacy and Expulsion of Post-Placental and Intra-Cesarean Insertion of Intrauterine Contraceptive Devices (PPIUCD)

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ABSTRACT

Background: This study examines to describe the factors associated with acceptability of immediate PPIUCD insertion in women according to their socio-demographic and obstetrics characteristics, and future pregnancy desires and to determine the rates of uterine perforation, expulsion, pelvic infection, lost strings and displacement following PPIUCD insertion among the acceptors by 6 to 18 months.

Aim: An intrauterine device (IUD) is an effective form of Long Acting Reversible Contraception. Present study is aimed at determining the safety, efficacy, and expulsion of Post-placental and intra-cesarean insertion of Intrauterine contraceptive device (PPIUCD).

Materials & Methods: The study was conducted at Darbhanga Medical College & Hospital, Darbhanga, India. From January 2012 to December 2012. Women admitted and delivered at D.M.C.H, Darbhanga, were counseled. CuT 380A was inserted within 10 minutes of delivery of placenta in accepters who fulfilled the Medical Eligibility Criteria and had no contraindications for PPIUCD. They were followed up till 30th June 2013.

Results: Total women counseled 3209, Accepted 564, Declined 2645, lost to follow up 130, Followed up 434, Complications: 190 (Expulsion 39, Bleeding 102, String problem 49), Removal 43, Continuation 352.

Conclusions: The PPIUCD (Inserting CuT 380 A by 10 minutes after placental delivery) was demonstrably safe,

effective, has high retention rate. The expulsion rate was not very high and it can be reduced with practice. With the high level of acceptance despite low levels of awareness, the government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange training on PPIUCD in order to increase knowledge and skills among healthcare providers. This will also further promote PPIUCD use and aid in reduction of the expulsion rates. Cash incentives to the accepter, motivator and of course provider would bring about a substantial progress in the PPIUCD use in developing countries like India.


Keywords: Intrauterine Device, Postpartum Contraception, Intrauterine Device Insertion, Intra-Cesarean Insertion.

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INTRODUCTION

Intra uterine contraceptive device (IUCD) to prevent pregnancy is among the oldest methods of contraception. The modern IUCD is a highly effective, safe, private, longacting, coitus independent, and rapidly reversible method of contraception with fewer side effects. Intrauterine contraception is the most cost-effective method of contraception today. 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 JSY and JSSK. It allows opportunity for the state to provide PPIUD in a big way. Many of these women welcome the opportunity to delay their next pregnancy when are counseled well. The postpartum insertion of an IUCD is likely to bring about a revolutionary change in

contraceptive use in the country. Opportunity for a success is excellent, because:

- Introduction of JSY has increased institutional deliveries.
- Labor Room is attended by large no's of beneficiaries every day.
- Delivery provides a convenient opportunity for the woman to receive IUCD services.
- This is particularly important for women who have limited access to medical care.
- Having just given birth, the woman is clearly not pregnant, and
- She is likely to be motivated to consider long-acting methods.

IUCD can be inserted safely at any time during the first 48 h after delivery, can also be inserted after 6 weeks postpartum (Extended PP) and after an abortion (PostAbortal).

Despite the many advantages of the IUCD as a method of family planning, it generally suffers from unpopularity in India. In India, less than two percent of women use the IUCD as their modern contraceptive method of choice. National program provides incentives to health care providers to promote sterilization, and very little importance is given to IUD or other temporary contraceptive methods. In this environment, it is not surprising that use of temporary contraceptive methods in the country is limited to 10.2 % and that of IUD only 1.8 % (NFHS 2006). During the last 20 years, use of the IUD has remained low. Recently, however, the MOHFW has been trying to increase the use of temporary methods. Recent studies estimate that prevention of unplanned and unwanted pregnancies could help avert 20–35 % of maternal deaths and as many as 20 % of infant deaths.

OBJECTIVES

1. To determine proportion of women accepting immediate PPIUCD insertion.
2. To describe the factors associated with acceptability of immediate PPIUCD insertion in women according to their socio-demographic and obstetrics characteristics, and future pregnancy desires.
3. To determine the rates of uterine perforation, expulsion, pelvic infection, lost strings and displacement following PPIUCD insertion among the acceptors by 6 to 18 months.

MATERIALS & METHODS

Study Location

The study was conducted at Darbhanga Medical College & Hospital, Darbhanga, Bihar, India. From January 2012 to December 2012. This department is the largest one in the District. The hospital receives patients from all the sub-district hospitals of the District and also from nearby district hospitals. 20 to 30 numbers of Deliveries are conducted daily. Those women who delivered in the afternoon and over the night are discharged on the following day, while those who deliver during the early hours of the day are discharged in the evening to ease up congestion in the ward. Those who encounter complications (e.g., Cesarean Section, PPH, Anemia, or PIH) are kept for longer period.

Study Period

January 2012 to December 2012.

Study Population

The study population included all women who delivered Darbhanga Medical College & Hospital, Darbhanga, Bihar, India, during the study period.

Inclusion Criteria

All antenatal patients admitted for delivery to our hospital were counseled for PPIUCD. Consent was obtained from those, who opted for insertion; among those who fulfilled the following criteria were considered for inclusion:

- 18–45 years old.
- GA 36–40 weeks.
- Desire to have CuT after counseling before insertion.
- No infections.
- Hb \geq 8 g/dl.
- AMTSL universally provided after the delivery of the infant.

Exclusion Criteria

- Fever during labor and delivery.
- Having active STD or other lower genital tract infection or high risk for STD.
- Known to have ruptured membranes for more than 24 h prior to delivery.
- Known uterine abnormalities e.g., Bicornuate/septate Uterus, uterine myomas,
- Manual removal of the placenta.
- Unresolved postpartum hemorrhage or postpartum uterine atony requiring use of additional oxytocic agents in addition to AMTSL.

INSERTION TECHNIQUES

Post-Placental Insertion

All necessary instruments (Copper T 380A, 2 ring forceps, Sim's speculum, over head lamp, Povidone Iodine, kidney tray, and cotton swabs) were arranged on an auxiliary table covered with a sterile drape. Insertion was performed by the consultant using modified Kelley placental forceps. The patient was placed in a lithotomy position with buttocks at the edge of the table. Aseptic techniques were enforced throughout the procedure.

The uterus was palpated to evaluate the height of the fundus and its tone. This is important to assess the size of the uterus to know whether the strings are likely to protrude through the cervix even when CuT is placed at fundus.

After performing the appropriate hand washing, a pair of sterile gloves was worn. The perineum was cleaned with povidone iodine. The perineum, labia, and vaginal walls were inspected for lacerations. HLD Sim's speculum was gently inserted into the vagina to visualize the cervix. The cervix and the vaginal walls were cleaned twice with cotton swabs soaked in povidone iodine solution with speculum in place. The anterior lip of the cervix was then gently grasped with the same ring forceps used earlier.

The IUCD was removed from the insertion sleeve and grasped with the modified Kelley forceps using no-touch technique. Once it is inserted in to lower uterine segment Other hand was moved to abdomen; and placed over the fundus and uterus was pushed gently upward to reduce the angle and curvature between the uterus and vagina.

IUCD with forceps was moved upward until it can be felt at the fundus. Then the forceps were opened to release the IUCD and swept to side wall. Uterus was stabilized until forceps removal was complete. The cervical os was then gently inspected for the strings. Sims speculum was removed. She was allowed to take rest for some time.

Intra-Cesarean Insertion of the IUCD

Uterine cavity was inspected for presence of malformations following placental delivery, which would limit use of IUCD. The IUCD was removed from the insertion sleeve and placed on the sterile field. Uterus is stabilized by grasping it at fundus. IUCD is Hold between middle and index finger. It was inserted into the uterus through uterine incision and released at fundus of uterus. Hand was removed slowly from the uterus. Enough care was taken not to dislodge IUCD as hand is removed. Strings were guided toward the lower uterine segment without disturbing IUCD'S fundal position. Enough Care was taken not to include IUCD strings during uterine closure.

Later Prior to Discharge

- IUCD Client card, showing type of IUCD and date of insertion were prepared.
- She was informed about the IUCD side effects and normal postpartum symptoms.
- Woman was told when to return for IUCD follow-up/ PNC/newborn checkup
- She was advised to come back any time she has
 - Foul smelling vaginal discharge different from the usual lochia
 - Lower abdominal pain, especially if accompanied by not feeling well, fever or chills,
 - Feeling of being pregnant.
 - Suspicion that the IUCD has fallen out.
- Finally, the client's comfort was assessed by the trained assistant (Staff Nurse) and provided with the Client Card.

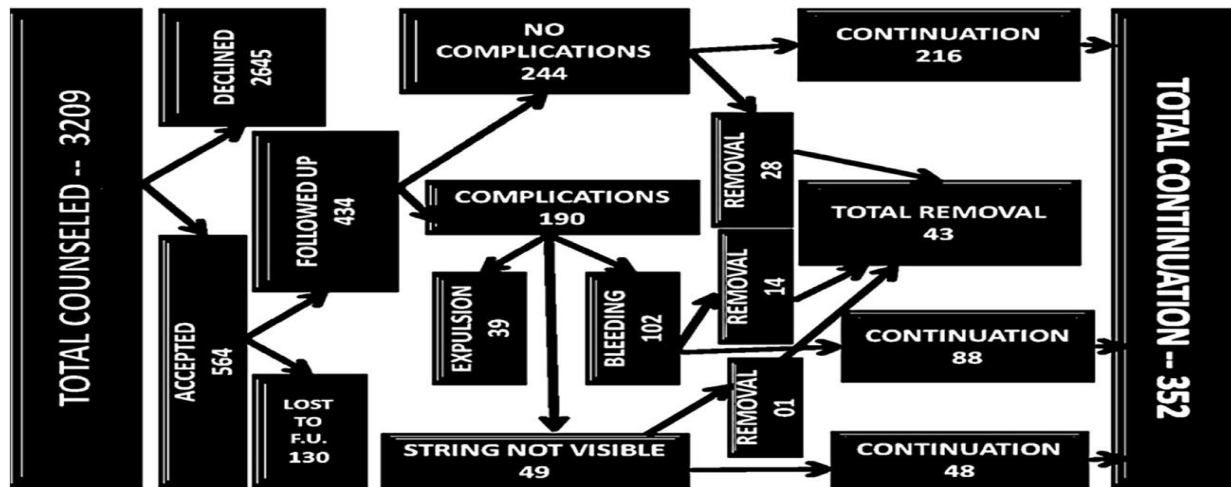


Figure 1: Recruitment of participants and summary of findings

Table 1: Socio-demographic and obstetric characteristics of the parturient included in the study

Characteristics		Total counseled		Accepted		Declined	
		N = 3,209	%	N = 564	%	N = 2,635	%
Age	≤ 19	187	5.83	7	3.74	180	96.26
	20–29	1,787	56.19	384	21.49	1,403	78.51
	30–39	1,224	37.64	181	14.79	1,043	85.21
	≥40	11	0.34	2	18.18	9	81.82
Educational status	No formal education	129	4.02	10	7.75	119	92.25
	Primary	942	29.36	269	28.56	673	71.44
	Secondary	1,931	60.17	268	13.88	1,663	86.12
	Higher education	207	6.45	17	8.21	190	91.79
Religion	Hindu	3,168	98.72	559	17.65	2,609	82.35
	Christian	23	0.72	4	17.39	19	82.61
	Muslim	18	0.56	1	5.56	17	94.44
Occupation	Housewife	2,517	78.44	503	19.98	2,014	80.02
	Employed	692	21.56	61	8.82	631	91.18
Parity	1	1,756	54.72	364	20.73	1,392	79.27
	2	1,103	34.37	171	15.50	932	84.50
	3	227	7.07	17	7.49	210	92.51
	4	123	3.84	12	9.76	111	90.24
	≥5	0	0	0	0	0	
Last child birth	0–2 years	1,953	60.86	417	21.35	1,536	78.65
	2–3 years	607	18.92	121	19.93	486	80.07
	3–4 years	553	17.23	24	4.34	529	95.66
	≥5 years	96	2.99	2	2.08	94	97.92
Future pregnancy desire	1–2 years	913	28.45	35	3.83	878	96.17
	3–5 years	1,678	52.29	308	18.36	1,370	81.64
	5 years	221	6.89	126	57.01	95	42.99
	Not sure	188	5.86	55	29.26	133	70.74
Economic status	Low income group	2,077	64.72	429	20.65	1,648	79.35
	Medium income group	989	30.82	106	10.72	883	89.28
	High income group	143	4.46	29	20.28	114	79.72

Table 2: Reasons for acceptance among the parturient included in the study

Reason for acceptance	N	%
Long term	51	9.04
Safe	104	18.44
Fewer clinic visits	0	0
Non-hormonal	15	2.66
No remembrance once inserted	208	36.88
My doctor's advice must be a good one	278	49.29
Reversible	101	17.91
No interference with breast feeding	13	2.3

Table 3: Reasons for refusal among the parturient included in the study

Reason for refusal (decline)	N	%
Prefer to use another method	367	13.93
Satisfied with previous method	158	6.00
Need to discuss with partner	1,132	42.96
Fear of pain and heavy bleeding	679	25.77
Partner and family refusal	1,325	50.28
Don't get pregnant early	1,009	38.29
No reason	1,203	45.65
Not enough knowledge about PPIUCD	1,764	66.94
Fears cancer	214	8.12
Interferes with sexual intercourse	9	0.34
Religious beliefs	1	0.04

Table 4: Follow-up status of the clients in the study

Follow up	N	%
No. of accepters followed-up	434	76.95
Followed-up (At clinic)	327	75.35
Followed-up (Over phone)	107	24.65

Table 5: Complications among the clients in the study

Complications	N	%
Bleeding	102	23.50
Expulsion	39	8.99
Strings not visible	49	11.29
Pelvic infection	0	0
Pregnancy	0	0

Table 6: Timing and rate of expulsion in the study

Time	N	%
Within 7 days	3	0.69
Between 7 days to 4 weeks	33	7.60
After 4 weeks	3	0.69
Total	39	8.99

Table 7: Reasons of removal of IUD in the study

Reasons for removal	N	%
Bleeding	14	32.56
Changes in menstrual cycle	3	6.98
Pressure from family	11	25.58
Getting pain in abdomen/perineum	7	16.28
Don't want to continue	3	6.98
Others(including 1 of string problem)	5	11.63

Table 8: Pregnancy within 6 months of removal/expulsion of IUD in the study (82 cases)

Total	N	%
Post-placental	4	4.88
Intra-cesarean	8	9.76

Table 9: Continuation rate in the study (post-placental + intra-cesarean)

Total insertions	564	
Total followed-up	434	
Expulsions	39	8.99
Removal	43	9.91
Continuation	352	81.11

Table 10: Continuation rate in both groups of clients having and not having complication in the study

Status	No.	Removal		Continuation	
		No	%	No	%
Having complications					
Expulsion	39				
Bleeding	102	15	14.71	87	85.29
String problems	49	1	2.04	48	97.96
Bleeding and string PRLM	151	16	10.60	135	89.40
No complications	244	28	11.48	216	88.52

RESULTS AND DISCUSSION

In this study, majority of the women (95.98 %) in the study population had at least a primary level of education. Acceptance of PPIUCD was higher among women with Primary and secondary education (28.56 % and 13.88), than those with no formal or higher education (7.75 and 8.21 %). This finding confirms importance of education in deciding future pregnancy. This was similar to a study done in Egypt by Safwat et al.¹ where women with no formal education had an acceptance of 9.4 %, while those with formal education were 19.4 %.

Education has a positive effect on contraceptive use as shown in a study done in Zimbabwe. It was only apparent among women who completed secondary education (12 years or more). Women who completed secondary school were about twice as likely to use modern contraceptive methods as women who did complete primary education. In this study, it is as high as four-fold.² Acceptance of intrauterine contraceptive device was the most common among primigravida clients (20.73 %). In case of multiparous, it was 13.76 %; thus, this finding is contrary to that of the study by Grimes et al.³ where they found higher acceptance in multiparous clients (65.1 %).

The duration since last child birth was significantly associated with acceptance of PPIUCD. About 74 % of the PPIUCD accepters had their last childbirth less than 2 years. Women on first delivery and with short pregnancy interval felt the necessity of a long acting and reliable method of contraception. In a report released by WHO in 2006, better family planning and birth-spacing services resulted in better maternal and neonatal outcome. When promoted in countries with high birth rates, 32 % of all maternal deaths and over 1 million deaths of children under 5 could be prevented. Healthy timing and spacing of pregnancies have a positive effect on maternal health and newborn outcomes.⁴ This finding in the study indicates toward a positive maternal health in future. Future pregnancy desire remains almost same in both groups of accepters and non-accepters. This finding suggests that the program managers must give priority toward effective ante natal counseling on PPIUCD, as minimal afford would bring about a huge change. Findings on reason for acceptance are surprising. A majority of the accepters rely on their physician. They value the

advice of the doctor. Many are attracted for its long acting and reversibility properties. A significant number of women declined PPIUCD because of partner's noninvolvement. This reveals the importance of partner involvement during counseling and decision making.

Many studies have shown that when the partner is involved in contraceptive counseling and Decision making, the acceptance and continuation rates were higher. Unfortunately in our setup, women who visit the antenatal clinic are usually not accompanied by their partners, and the care providers do not allow them during the process even if they are present.

Thus, couple counseling is lost during this period. Furthermore, during the short postpartum period, which is not appropriate for counseling, afford to get consent from a partner having no knowledge about PPIUCD is difficult. Therefore, it is most important to include proper counseling of the couple together to choose a contraceptive method which will in turn increase the compliance. Husband and other family member's pressure for IUCD removal was a significant reason (23.26 %) for removal next to bleeding (33.88 %), these findings emphasize the importance of involving the husband in prenatal counseling.

Like other studies⁵ bleeding (23.5 %) out numbers others complications. It is really worrying. But only 14 out of 102 (14.71 %) insisted on removal, rest retained IUCD with reassurance only, which speaks of the importance of positive attitude.

Forty-nine women (8.69 %) among those inserted with PPIUCD had lost strings during first follow-up at 4–6 weeks. In forty-five cases, strings were found at cervical canal. Rest four cases needed ultrasound and confirmed that the IUCD were in situ. One of them insisted on removal. On removal, curling and retraction of strings into the uterine cavity were confirmed. It should be noted that there were no serious complications in this study.

Expulsion rates of the immediate PPIUCD at 4-weeks interval were 6.4 %. This was similar to a multi country study done in Belgium, Chile, and Philippines which showed the rate of expulsion at 1 month ranging from 4.6 to 16.0 %.⁶

Expulsion rate of immediate PPIUCD in a study done in China by Chi et al. 1994, was 25–37 %, while post-placental was 9.5–12.5 %. Expulsion of PPIUCD usually occurs in the first few months after insertion. In a multicenter study done by Tatum et al., the expulsion rates of PPIUCD were similar at 1 and 12 months in Belgium (4 %) and Chile (7 %), while in the Philippines, expulsion increased from 19 % at 1 month to 28 % at 12-months follow-up.⁷

Follow-up

Only 59.98 % visited clinic, another 18.97 % were followed up over phone. And as many as 23.05% were lost to follow up. These findings indicate a poor integration of vertical programs at all levels. "Insert and report and then forget" needs to be replaced by "Counsel and report, insert and report, and follow up and report" and of course provide service every time. Pregnancy within 6 months of expulsion and removal of IUCD is worth watching. About 14.63 % conceived within 6 months of expulsion or removal of IUCD. This is probably due to poor contraceptive practice, counseling, and acceptance of alternative methods after IUCD is out of uterus. Removal rates are similar in clients having or not having complications (89.40 and 88.52 % respectively). It speaks of the importance of knowledge and motivation prior to insertion in continuing PPIUCD.

CONCLUSIONS

The acceptance of PPIUCD was high in the present study, and it is comparable to other studies done globally. Awareness of the PPIUCD among these women was very poor despite high acceptance. Majority of the women never heard about the PPIUCD before admission to labor room. Parturient who had a short duration from their last child birth (less than 2 years) and primigravida had greater acceptance of the PPIUCD. Acceptance was higher among women who had primary education.

The PPIUCD was demonstrably safe, having no reported incidence of perforation with low rates of expulsion, pelvic infection, and few lost strings. We can conclude that Inserting CuT 380 A by 10 min after placental delivery is safe and effective, has high retention rate. The expulsion rate was not high, and further can be reduced with practice. With the high level of acceptance despite low levels of awareness, the government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange for training on PPIUCD in order to increase knowledge and skills among healthcare providers. This will also further promote PPIUCD use and aid in reduction of the expulsion rates. In a nation which moves with discounts, subsidies, and incentives, cash incentives to the acceptor, motivator and of course provider would bring about a substantial progress in the PPIUCD use in developing countries like India.

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