

## A cross sectional study on acceptability, safety and evaluation of post-vaginal delivery and intra-caesarean insertion of PPIUCD at tertiary Centre

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### Abstract

**Introduction:** India is world's second most populated country with nearly 20.7% of the Indian population have unmet needs for family planning with 65% in the first year of postpartum period. Postpartum period is the ideal time of family planning studies as spacing less than two years of child birth can lead to obstetric complications and maternal mortality. Hence practice of contraception is mandatory.

In this study we have emphasised Cu375insertion which has the advantage of high motivation, safety and convenience for both patients and the service provider. Here we conducted a pilot clinical study comparing intra-caesarean Cu375 insertion and post-placental insertion following vaginal deliveries.

**Materials and Methods:** A systematic study with 60 patients in each group recruited clients randomly based on acceptance and mode of delivery. Group A intra-caesarean insertion and Group B post- placental insertion following vaginal deliveries. The cases were followed up at 6weeks and 6months post-insertion with a set of parameters. Here we look for Missed strings, Expulsion and Infection rate as the primary outcome measures. Complications as the secondary outcome measures.

**Results:** Infection rate is found to be higher in Group B(5%) than Group B at 6th week. At 6th month, infection is higher in Group B (1.8%) than Group A(0.9%) p=0.617. Missed strings are found to be higher in intra-caesarean than interval method both at 6th week and 6th month follow up. Expulsion rate is found to be higher in Group B(3.3%) than Group B(1.67%) p=0.5 at 6th week. At 6th month there is no IUCD expulsion in Group A (0%) than in Group B where there is (1.9%) expulsion p=0.497. Uterine perforation noted among 3.35% in group A compared to 1.67% in group B. There is no complications or contraceptive failures in both groups during the study period. On statistical analysis, it is found that there is no significant difference in infection and expulsion rate between the groups. For missed strings there is a significant difference between the groups with more missed strings in intra-caesarean method.

**Conclusion:** To conclude that, intra-caesarean method is equally effective as interval method without any added complications for contraception in caesarean deliveries, with added advantage of high motivation, good compliance and safety and easy for provider to deliver the services.

**Keywords:** PPIUCD, Contraception

## Introduction

India is world's second most populated country with 1.3 billion people. It contributes 17.5% of the world's population by adding 25 million births every year. Nearly 20.7% of the Indian population have unmet needs for family planning with 65% of the needs in the first year of postpartum period.

This study helps to determine the socio economic and demographic factors associated with post placental insertion of copper 375. It also helps to determine the complications.

The intra uterine device is highly effective, safe, rapidly reversible, long acting, coital independent method of contraception with relatively few side effects. With the increased number of institutional deliveries due to the provision of Janani suraksha yojana - a cash transfer scheme, there is increased access to the pregnant women for promoting family planning services. Furthermore in the immediate postpartum period, the insertion of intrauterine device is convenient and these women are highly motivated.

The approach to contraception has often been manipulated and constrained by forces from outside the medical community includes social, religious, and political groups have been particularly intrusive and coercive in the area of family planning <sup>[1]</sup>.

National Population Policy 2000 aims to attain a stable population, gender and demographic balance by 2045 by providing affordable and quality health care. Providing quality contraception services to women is one of the cornerstone for MDG goals of improved maternal and child health <sup>[1, 2]</sup>. Unwanted and mistimed pregnancy results in adverse outcomes for both mother and child. A large proportion of women in the postpartum period want to accept a contraception method to regulate their fertility either by spacing or limiting future pregnancies.

Accordingly, the postpartum family planning services need to be strengthened and the providers are to be updated on recent developments in contraceptive services. Postpartum IUCD is an important step towards reducing the unmet need for contraception in the postpartum period and for promoting maternal and child health <sup>[2]</sup>. Access to safe and effective contraceptive services in the postpartum period is of utmost importance for a woman to prevent unwanted / mistimed pregnancy

Immediate postpartum insertion of IUCD is being seen as an effective and safe contraception which can be accepted by the woman immediately after delivery <sup>[1, 2]</sup>. The post placental IUCD insertion is particularly suitable for our country where even para medical personnel can insert the cu T and delivery is the only time these patients come in contact with the hospital.

Intrauterine contraceptive devices are the safest method of contraception available at present. Due to its safety, efficacy, coitus independent, rapidly reversible, long acting nature intrauterine contraceptive devices are the most widely used method of contraception. The national population as on May 2016 is 1.3 billion. Of this 20.7% have unmet needs of family planning. Intrauterine contraceptive devices are ideal for the purpose of temporary family planning over contraceptive pills because of long term action.

The intrauterine device (IUD) is a small, flexible apparatus that is inserted into a woman's uterus to prevent pregnancy. An intrauterine device (IUD) is the most frequently used reversible family planning method in the world. It offers safe, effective, and long term contraception.

More than 100 million women in the developing countries would prefer to avoid a pregnancy, but they are not on any contraception. India, being the 2ND most populated country, is the pioneer in starting the Family Planning programme. Despite this stellar initiative, the unmet needs can be attributed to a lack of knowledge, resources, awareness, hesitations, superstitions and desire of reversibility.

Intra-uterine contraceptive devices are the most effective, safe, long acting mode of contraception and this study aims at enhancing the contraceptive usage and consumption in India by achieving efficient post-placental intra-uterine contraceptive device insertion and thereby increasing the Indian IUCD uptake. In the process, we also need to shed light on the acceptability and reasons of refusal according to demographic parameters in an attempt to

overcome the inertia faced for intrauterine contraception.

Insertion of PPIUCD is appealing because-

- Recommencement of ovulation is highly unpredictable and Copper-T is an exceedingly useful contraception.
- The woman is likely to have a high motivation and vulnerability for accepting contraception and provides a convenient setting.
- In developing countries, delivery time may often be the only time of contact between the woman and a health-care provider and the chances of return for contraceptive advice is very minimal at best. Short inter conception period after delivery or caesarean section and its associated risk of increased morbidity, mortality and surgical interventions could be avoided by post-placental insertion of IUCD during the said procedure <sup>[2]</sup>.

### Objectives

1. To know the knowledge and prevalent contraceptive practices, acceptability of PPIUCD, reasons for refusal and socio-demographic correlation, Safety, Efficacy and complications of PPIUCD.
2. To compare the efficacy, sensitivity, specificity and expulsion rates between post- vaginal delivery IUCD insertion and Intra-caesarean PPIUCD insertion.
3. To compare the statistics of women accepting other modes of contraception. To obtain comparison between acceptability, feasibility between other modes of contraception.
4. To obtain information post 6weeks and post 6 months follow-up and tabulate the voluntary removal of IUCD, expulsion rates, pregnancy rates following IUCD insertion, complications like uterine/ cervical perforations and discontinuations.
5. To spread contraceptive awareness among target population and increase National Contraceptive rates.

### Materials and Methods

This is a prospective and Cross-sectional study to assess the safety and efficacy of the Copper T 375 when inserted within 10 minutes of placental expulsion after vaginal delivery and placental extraction after caesarean section.

Study participants were recruited through the Hospital antenatal clinics. Post-placental contraception routinely discussed at prenatal visits using visual aids. All participants willing for immediate postpartum insertion of CuT375 were included in study after obtaining informed consent and Questionnaire. 120 women were included in the study. Hence N=120 (60 Post-vaginal delivery and 60 Intra-caesarian)

### Method of insertion

- Informed consent obtained
- Acceptability Questionnaire duly filled.

### Materials

Sterile gloves, Betadine solution, uterine sound, CuT 375, Kellers PPIUCD forceps.

### Method

1. **Post-vaginal delivery:** Bimanual examination performed to assess the cervix and uterus after delivery of placenta and universal administration of oxytocin. Ensure empty cavity with contracted uterus. Measure the utero-cervical length using the uterine sound and adjust the flange on the PPIUCD with the package intact. Remove IUCD from the package and insert into the uterine cavity with Kelley's PPIUCD forceps. Ensure fundal placement, cut the IUCD strings 2cm to the level of cervix.
2. **Trans-caesarean delivery:** The insertion of PPIUCD to be done after the delivery using PPIUCD forceps through the uterine incision, ensure fundal placement. Attempt and bring the IUCD strings through the cervical os.

Study design study type	Cross-sectional
Allocation	Systematic
Intervention model	Parallel assignment
Masking	No blinding
Primary purpose	Contraception

## Results

**Table 1:** Distribution of patients according to Mode of Delivery

Mode of Delivery	Frequency	Percentage
Cesarean Delivery	60	50
Vaginal Delivery	60	50
Total	120	100

The two arms of study was assigned randomly on basis of mode of delivery and acceptance.

**Table 2:** Tabulation of Ease of Cu T 375 Insertion

Ease of Insertion	Cesarean Delivery	Vaginal Delivery	p-value
No	5(8.47%)	6(10.00%)	0.77
Yes	54(91.53%)	54(90.00%)	
Total	60	60	

This shows the ease of insertion of Cu 375 between the study groups, showing comparable results.

**Table 3:** Tabulation of bleeding at the time of insertion

Bleeding due to insertion	Cesarean Delivery	Vaginal Delivery	p-value
No	59(98.33%)	57(95.00%)	0.31
Yes	1(1.67%)	3(05.00%)	
Total	60	60	

This table demonstrates the presence of excessive bleeding noted more in the post placental IUCD insertion following vaginal delivery.

**Table 4:** Pain abdomen during insertion

Pain during insertion	Cesarean Delivery	Vaginal Delivery	p-value
No	57(95.00%)	56(93.33%)	0.71
Yes	3(05.00%)	4(06.67%)	
Total	60	60	

This table shows comparable results of pain abdomen during insertion.

**Table 5:** Perforation during insertion

Perforation during insertion	Cesarean Delivery	Vaginal Delivery	p-value
No	58(96.66%)	59(98.33%)	0.52
Yes	2(03.34%)	1(01.67%)	
Total	60	60	

This table indicates perforation rates during the modes of delivery with perforation noted more in intra-cesarean insertion.

**Table 6:** Expulsion after PPIUCD insertion

Expulsion after insertion	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.67%)	0(0.0%)	0.5
No	58(96.67%)	58(96.67%)	

Yes	1(1.67%)	2(03.33%)	
Total	60	60	

This table shows the rate if immediate expulsion within 24 hours of insertion.

**Table 7:** Displacement of PPIUCD

Displacement after insertion	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.67%)	2(3.33%)	0.5
No	58(96.67%)	57(95.00%)	
Yes	1(1.67%)	1(1.67%)	
Total	60	60	

This table shows comparable displacement.

**Table 8:** Incidence of Pelvic Inflammatory Disease

Pelvic Inflammatory Disease	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.67%)	1(1.67%)	0.22
No	59(98.33%)	56(93.33%)	
Yes	0(0.00%)	3(5.00%)	
Total	60	60	

This shows presence of PID found more after post vaginal delivery insertion.

**Table 9:** Follow up of PPIUCD

Follow up of PPIUCD	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.72%)	2(3.33%)	0.007
No	33(56.90%)	17(28.33%)	
Yes	24(41.38%)	41(68.33%)	
Total	58	60	

This table shows the turn up for 6 weeks follow up post PPIUCD insertion.

**Table 10:** Position of PPIUCD at 6 weeks follow up

Position of PPIUCD	Cesarean Delivery	Vaginal Delivery	p-value
Displaced	3(5.17%)	2(3.33%)	0.76
Intrauterine	54(93.10%)	56(93.33%)	
NA	1(1.72%)	2(03.33%)	
Total	58	60	

This shows higher displacement rates noted after intra-cesarean insertion during 6 weeks follow up.

**Table 11:** Missing threads at 6 weeks follow up

Missing strings at 6 wk	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.72%)	2(3.33%)	0.004
No	21(36.21%)	39(65.00%)	
Yes	36(62.07%)	19(31.67%)	
Total	58	60	

This shows significant missing string noted after intra-cesarean insertion during 6 weeks follow up

**Table 12:** Continuation of IUCD after 6 weeks follow up

Continuation of IUCD	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.72%)	2(3.33%)	0.01
No	36(62.07%)	21(35.00%)	
Yes	21(36.21%)	37(61.67%)	
Total	58	60	

This table shows willingness for continuation of IUCD more in the post vaginal insertion group.

**Table 13:** Incidence of pregnancy after PPIUCD

Pregnancy after PPIUCD	Cesarean Delivery	Vaginal Delivery	p-value
NA	1(1.79%)	2(3.45%)	0.22
No	55(98.21%)	56(96.55%)	
Total	56	58	

No pregnancies were noted during follow up.

## Discussion

The need for contraception is highly warranted in our country since approximately 27% of births in India occur in less than 24 months after a previous birth. Another 34% of births occur between 24 and 35 months.

So the term birth-to-pregnancy interval is important which is the time period a live birth and the start of the next pregnancy. After a live birth, a woman should wait at least 24 months (but not more than five years) before attempting the next pregnancy. After a spontaneous or induced abortion, a woman should wait at least 6 months before attempting the next pregnancy <sup>[1]</sup>.

During this period, women needs to be protected from pregnancy. She is in need of contraception. Copper containing IUCD Cu-375 will be the best option in view of easy& one-time insertion effective for 5 years and also cost-effectiveness. Among various types of contraception our study deals with Post placental post-vaginal delivery insertion and Intra-caesarean Method.

Expulsion rate is found to be higher in Group A (2.5%) than Group B (1.7%) p=1.000 at 6th week. At 6th month there is no IUCD expulsion in Group A (0%) than in Group B where there is (1.9%) expulsion p=0.497. Kappa states that immediate insertion following caesarean delivery shows lower expulsion rate than immediate insertion following vaginal delivery <sup>[3]</sup>. Similar results were in studies conducted by Gary *et al.* <sup>[4]</sup> and Ricalde *et al.* <sup>[5]</sup>.

In the study conducted by Lauren *et al.*, some increase in expulsion rates occurred with delayed postpartum insertion when compared to immediate insertion and with immediate insertion when compared to interval insertion, intracaesarean cases are associated with lower expulsion rates than postplacental vaginal insertions, without increasing rates of postoperative complications <sup>[6]</sup>.

A five year experience at a tertiary care centre in north India by Manju Shukla, Sabuhi Qureshi. Compared postplacental insertion with interval insertion. A total of 1317 women were included in the study. Of these, 1037 (78.7%) came for first follow up. The cumulative expulsion rate at the end of 6 months was 10.68 per cent. There was no case of misplaced IUCD. They conclude that although the expulsion rate for immediate postpartum insertion was higher than for interval insertion, the benefits of providing highly effective contraception immediately after delivery outweigh this disadvantage, particularly in country where women have limited access to medical care <sup>[7]</sup>.

Safwat *et al.* compared immediate post-partum insertion with delayed interval insertion. Finally they conclude that immediate post-partum insertion of IUCDs appeared effective, though comparisons with other insertion times were limited. Expulsion rates appear to be higher than with interval insertion. Advantages of immediate postpartum insertion include high motivation, assurance that the woman is not pregnant, and convenience <sup>[8]</sup>.

## Conclusion

Based on above discussion and studies it is found that postpartum IUCD insertion is an excellent method of contraception. In our study we have shown the comparison between intra-caesarean insertion and interval insertion. Results shown difference in Lower abdominal cramp, Menstrual irregularities, Excessive vaginal discharge, Infection, Missed string and

Expulsion rates between groups. But on statistical analysis, it is found that there is no significant difference in Lower abdominal cramp, Menstrual irregularities, Excessive vaginal discharge, infection and expulsion rate between the groups. For missed strings there is a significant difference between the groups with more Missed strings on intra-caesarean method. The other disadvantage of intra-caesarean method is removal of IUCD may require anaesthesia or hysteroscopic guidance because of high rates of missed strings.

To conclude, intra-caesarean Cu375 is equally effective as interval IUCD insertion without any added complications (except for high Missed string rates) for contraception in caesarean deliveries and vaginal deliveries within the period of 6 months follow up, with added advantage of high motivation, good compliance, safety and easy for provider to deliver the services.

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