#### **ORIGINAL ARTICLE**





# Post-placental Intrauterine Device Insertion Versus Delayed Intrauterine Device Insertion: An Observational Study

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#### Abstract

Immediate post-placental IUD insertion is defined as IUD insertion within 10 min of the expulsion of the placenta. Although the expulsion rate in post-placental insertion is higher than interval insertion, the benefits of highly effective contraception immediately after delivery may outweigh the risks of expulsion.

Aims To compare post-placental IUD (PPIUD) insertion with interval IUD insertion (IIUD) in terms of safety, effect on menstrual cycle, efficacy and satisfaction.

**Materials and Methods** After meeting all eligibility criteria, the patients were asked to choose between post-placental IUD insertion and interval/delayed IUD insertion. In PPIUD group, insertion was done within 10 min of expulsion of placenta by hand technique. Individuals in IIUD group were asked to return after 6 weeks for IUD insertion by withdrawal technique. Both the groups were followed at 6 weeks, 6 months, 12 months by history, physical examination, per speculum examination and ultrasonography.

**Observations** 238 patients were allocated to PPIUD group and 273 to IIUD group. In the PPIUD group, there was no bleeding/spotting demonstrable as it was masked by the lochia. Mild pain at insertion was seen in only 11 patients in the PPIUD group. Slight bleeding/spotting was seen in 7.8% patients in the IIUD group, while mild to moderate pain was seen in 39.9% patients. At 6 weeks, 6 months and 1 year follow up with regard to patients complaining of pelvic pain/dysmenorrhea, the difference between the two groups was not statistically significant. Our study found that irregular bleeding or spotting was more in interval insertion than in the post-placental group. The difference in the two groups was statistically significant at 6 weeks and 6 months, but was not significant at 1 year. There was no case of perforation in either group. Our study found a statistically significant difference in expulsion after post-placental compared to delayed insertion. The difference between the two groups was statistically significant (p = 0.006) for cumulative expulsion. However, for interval expulsion rate, the difference was not statistically significant (p = 0.6). In our study, continuation rates appear to be higher in the PPIUD group, but the difference is not statistically significant.

**Conclusion** PPIUD is a safe, easy and effective alternative to interval IUD insertion and qualifies to be popularized as a first-line contraceptive agent in eligible patients owing to its immediate and sustained contraceptive benefit, patient comfort, convenience and lower incidence of side effects.

**Keywords** Post-placental · Interval IUCD · Contraception · Intrauterine contraceptive device · Delayed IUCD · IUCD expulsion

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## Introduction

An intrauterine device (IUD) is a long acting reversible contraceptive containing either copper or levonorgestrel, which is inserted into the uterus. It is the most effective type of reversible birth control [1]. Post-placental IUD (PPIUD) insertion is the insertion of an IUD in the endometrial cavity shortly after the delivery of placenta. It is termed as immediate when inserted within 10 min of delivery of placenta or



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early postpartum when inserted within < 48 h after delivery. Insertion of an IUD after delivery may avoid the discomfort related to interval insertion (IIUD), and any bleeding from insertion will be disguised by lochia. But the risk of spontaneous expulsion has been reported to be high in PPIUCD insertion in some studies [2]. This disadvantage is outranked by the benefits of highly effective contraception immediately after delivery. Post-placental insertion has an expulsion rate ranging from 6 to 20% for T-shaped IUDs over 1 year, whereas the expulsion rate associated with interval insertion of T-shaped IUDs is approximately 1–4.5% in the first year [2, 3, 4]. The expulsion rate is lower for immediate post-placental compared with early postpartum insertion and is also lower when skilled health care providers insert the IUD [5]. The expulsion rate is not affected by the method of postpartum insertion, whether inserted by ring forceps or by hand [5].

There is high susceptibility of unintended pregnancy in the first postpartum year the rate being 10–44% [6]. Anovulatory infertility lasts approximately 5 weeks in nonlactating women and more than 8 weeks in fully lactating women. The lactational pregnancy rate is approximately 1–2% at 1 year postpartum [7]. Postpartum IUD insertion is an opportunity which is not to be missed particularly in developing countries like ours where delivery may be the only time when a healthy woman comes into contact with health care provider. There are several reasons that make PPIUCD insertion an attractive option. The woman has high acceptance for contraception: Her non-pregnant state is confirmed; her motivation for contraception is high; it is free from systemic side effects and does not affect breast-feeding; the pain on insertion when used post-placentally is masked by the after pains; it has not been associated with increased infection, uterine perforation, postpartum bleeding, uterine sub-involution [5, 8]; there is a benefit of immediate action as delay in initiating contraception in the postpartum period may occur, because the women gets busy with the chores of the new infant [9].

The aim of the current study was to compare post-placental IUD insertion with interval IUD insertion in terms of safety, effect on menstrual cycle, expulsion rate, efficacy and patient satisfaction.

#### **Methods**

This randomized controlled trial was conducted from March 2015 to November 2016. The study was approved by the Institute Ethics Committee (GMC, Srinagar).

Patients delivering vaginally and willing for post-placental or interval intrauterine device insertion were enrolled in the study as per inclusion and exclusion criteria in Table 1 and were followed up at 6 weeks, 6 months and 12 months post IUD insertion, and the results of two were compared.

After proper counseling regarding IUD, an informed consent was taken from all patients in writing prior to insertions. Counseling was done during antenatal visits or during early labor. Detailed history regarding pelvic inflammatory disease, uterine anomalies, fibroid, prolonged rupture of membranes (>18 h), chorioamnionitis, extensive genital trauma was elicited followed by a thorough pelvic examination to rule out genital lesions and any uterine abnormality. The cases were investigated to specifically rule out uterine anomalies, fibroids and genital lesions with the help of ultrasound.

After meeting all eligibility criteria, the patients who consented for IUD insertion were randomly allocated to post-placental or interval/delayed IUD group. The IUD used was CuT380A. In PPIUD, IUD insertion was done within 10 min of expulsion of placenta by hand technique. Individuals in IIUD group were asked to return after 6 weeks for IUD insertion. IUD was inserted with the help of withdrawal technique. Women in both the groups were educated on how to check whether IUD is in place and to inform in case of any untoward effects like unusual vaginal discharge, irregular bleeding per vagina, severe lower abdominal pain and any expulsions were noticed.

Both the groups were followed up at 6 weeks, 6 months and 12 months for safety, efficacy, expulsion rate, side effects and removal and continuation rates by means of

Inclusion criteria:

- 1. Women delivering at our institute and subsequently willing for copper T insertion
- 2. Women agreeing to report for follow-up

# Exclusion criteria:

- 1. Chorioamnionitis
- 2. Prolonged rupture of membranes > 18 h
- 3. Unresolved PPH
- 4. Uterine anomaly
- 5. Cervical carcinoma
- 6. Leiomyoma more than one or greater than 3 cm or impinging on uterine cavity
- 7. Those treated for gonorrhea, chlamydia, trichomoniasis during pregnancy
- 8. Desire for pregnancy within 1 year of delivery



history, physical examination, per speculum examination and ultrasonography.

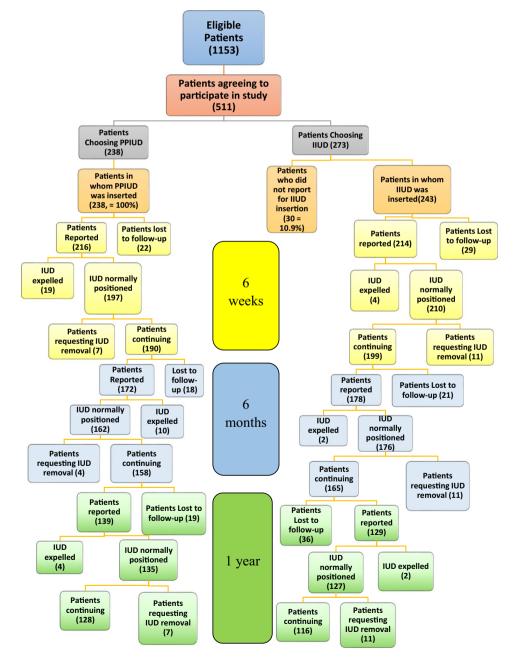
#### Results

During the course of our study, 1153 patients were selected as per inclusion and exclusion criteria and were offered IUD insertion as a means of contraception. Of these 511 (44.3%) patients agreed to participate in the study and were randomly allocated to one the two groups. 238 patients were assigned to the post-placental intrauterine device (PPIUD) insertion group and 273 patients

were assigned to the interval intrauterine device (IIUD) insertion group. 30 patients (10.9%) in the IIUD group did not report after 6 weeks for the IUD insertion and were excluded from the statistical analysis.

Age of the patients in PPIUD group ranged from 19 to 35 years (mean—27.9  $\pm$  9.33). Age of the patients in the IIUD group ranged from 19–38 years (mean—28.9  $\pm$  9.58). In the PPIUD group, 46 (19.3%) were Para 1, 89 (37.3%) were Para 2 and 103 (43.2%) were Para 3 or above. In the DIUD group, 41 (16.8%) were Para 1, 82 (33.6%) were Para 2 and 120 (49.3%) were Para 3 or above. The difference between the two groups was not statistically significant.

Fig. 1 Consort flow diagram





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Total number of patients at each stage of the study is shown in the chart in Fig. 1.

# **Expulsion**

Cumulative expulsion rate was 8.7%, 14.5% and 17.3% in the PPIUD group at 6 weeks, 6 months and 1 year, respectively, while it was 1.8%, 2.9% and 4.4% in the IIUD group at 6 weeks, 6 months and 1 year, respectively. The difference between the two groups was statistically significant (p value of 0.001, 0.005 and 0.006 at 6 weeks, 6 months and 1 year, respectively). Patients in whom IUD expulsion had taken place were offered reinsertion but were subsequently excluded from further statistical analysis. Expulsion rate between 6 weeks and 6 months was 5.8% in the PPIUD group and 1.1% in the IIUD. The difference between the two groups was statistically significant (p=0.01) Difference in expulsion rate from 6 months to 1 year between the two groups was not statistically significant (Table 2).

## **Discontinuation Rate**

Discontinuation was defined as removal of the IUD at the patient's request. Cumulative discontinuation rate was 3.55%, 5.95% and 11.13% at 6 weeks, 6 months and 1 year post-insertion, respectively, in the PPIUD group, while it was 5.2%, 10.3% and 18.97% at 6 weeks, 6 months and 1 year post-insertion, respectively, in the PPIUD group. The difference between the two groups was not statistically significant (Table 3).

# **Complications**

#### **Immediate Complications**

Pain upon insertion of the IUD was seen in 11(4.6%) patients in the PPIUD group. In the IIUD group, 97(39.9%) patients reported pain on IUD insertion. The difference between the two groups was statistically significant (p < 0.0001). 19 (7.8%) patients in the IIUD group experienced mild spotting which did not require any treatment. In the PPIUD group, mild bleeding/spotting if any was masked by lochia. Massive bleeding requiring treatment/admission/transfusion did not occur in any patient in either group. The difference between the two groups was statistically significant (p = 0.000017). No patient in either group experienced a syncopal episode upon IUD insertion. No instance of uterine perforation occurred in either group.

## **Late Complications**

The percentage of patients with late complications at various stages of assessment is given in Table 4.

## **Pregnancy Rate**

No pregnancy was recorded in either group at 6 weeks or 6 months post IUD insertion. Contraceptive failure with pregnancy was noted in one patient in the PPIUD group between 6 months and 1 year. This was due to an unnoticed expulsion of the IUD and was confirmed by USG.

Table 2 Expulsion rate

	6 weeks	6 months	1 year	
Cumulative expulsion	rate			
PPIUD	19 (8.7%)	29 (14.5%) 33 (17.3%)		
IIUD	4 (1.8%)	6 (2.9%)	6 (2.9%) 8 (4.4%)	
p value	0.001	0.005	0.006	
	Insertion-6 weeks	6 weeks–6 months	6 months-1 year	
Interval expulsion rate	?			
PPIUD	19 (8.7%)	10 (5.8%)	4 (2.8%)	
IIUD	4 (1.8%)	2 (1.1%)	2 (1.5%)	
p value	0.001	0.01	> 0.05	

**Table 3** Cumulative discontinuation rate

	Insertion-6 weeks	6 months	1 year
PPIUD	3.55%	5.95% (3.55+2.4%)	11.13% (3.55 + 2.4 + 5.18%)
IIUD	5.2%	10.31% (5.2 + 5.11%)	18.97% (5.2 + 5.11 + 8.66%)
p	0.6	0.3	0.16



Table 4 Late complications

Complication	Time	PPIUD	DIUD	p
Pain/dysmenorrhea	6 weeks	8.7%	16.3%	0.02
	6 months	14.5%	17.9%	> 0.05
	1 year	15.8%	17.8%	> 0.05
Menorrhagia	6 weeksa	_	_	_
	6 months	16.2%	16.8%	> 0.05
	1 year	16.5%	17.05%	> 0.05
Irregular bleeding/spotting	6 weeks	5.09%	15.4%	0.007
	6 months	6.9%	15.1%	0.02
	1 year	8.6%	14.7%	> 0.05
Abnormal vaginal discharge/	6 weeks <sup>b</sup>	_	_	_
PID	6 months	2.3%	6.7%	> 0.05
	1 year	4.3%	6.9%	> 0.05

<sup>&</sup>lt;sup>a</sup>Almost all of the patients were in lactional amenorrhea at 6 weeks; therefore this parameter was not assessed at 6 weeks

## Discussion

The current study between post-placental IUD insertion and delayed IUD insertion was done with the aim of comparing safety, effect on menstrual cycle, efficacy and satisfaction in terms of desire for removal or continuation of IUD use.

In the present study, age of the patients was 19–38 years. The difference in ages between the two groups was not statistically significant. Majority of patients in both groups were multipara; difference in parity between the two groups was not statistically significant.

In our study, 22 (9.8%) patients were lost to follow-up at 6 weeks. The difference in follow-up between the two groups was not statistically significant (p=0.8). Loss of patients to follow-up is a major problem with health care in third world countries such as India. Patients with poor educational, socioeconomic status and with poor access to health care facilities tend to not give adequate importance to healthrelated issues. This problem also arose when patients were allocated the IIUD group. Out of the 273 patients that opted for IIUD insertion, 30 patients (10.9%) did not show up after 6 weeks for the procedure. These patients therefore consisted of eligible females who understood their need for contraception, but for various reasons such as involvement in child care, no availability of transport, residence in far-off areas, ignorance or forgetfulness did not take any contraceptive measures and were therefore at risk of unwanted pregnancy and all of its associated adversities. At the conclusion of the study, we attempted to telephonically contact these patients and managed to successfully do so in 23 patients. Of these 5 (21.7%) patients had conceived in the intervening period. This reflects the biggest advantage of the PPIUD insertion by which all interested patients are provided with contraceptive effect immediately after delivery. PPIUD method does not allow unforeseen circumstances to interfere with patients ability to report to the health center for IUCD placement.

Immediate complications during IUD insertion included pain and slight spotting. In the PPIUD group, there was no bleeding/spotting demonstrable as it was masked by the lochia. Similarly mild pain was seen in only 11 patients in the PPIUD group. Slight bleeding/spotting was seen in 7.8% patients in the IIUD group, while mild to moderate pain was seen in 39.9% patients. The difference between the two groups was statistically significant for both of the immediate complications. This implies that the IUD insertion is both more comfortable and essentially asymptomatic in patients when inserted immediately following placental expulsion, because the pain if any is masked by the after pains of labor, and the spotting is masked by lochia. Further dilatation was not required in any of the patients in the PPIUD group making the procedure quick and easier to perform while being more comfortable for the patient.

At 6 weeks pelvic pain/dysmenorrhea was more common in the IIUD group. The difference between the two groups was statistically significant. At 6 months and 1 year, the difference between the two groups was not statistically significant. Other studies observed that pain in lower abdomen is almost similar in PPIUCD and interval insertions [10, 11]. Our study shows a comparatively higher incidence of pelvic pain in both the groups, possibly due to the fact that we also included patients having only mild pelvic pain.

Menorrhagia is another adverse effect of IUCD insertion and was the second most common cause for requests for IUCD removal in our study. The difference in rates of menorrhagia between the two groups was not statistically significant. Our study found that irregular bleeding or spotting was more in interval insertion than in the post-placental group. The difference in the two groups was statistically significant at 6 weeks and 6 months, but was not significant at 1 year. El-Shafei et al. [12] found spotting to be present in 6% patients in post-placental group after 1 year of follow-up but the studies comparing immediate and interval insertion are lacking [13].

No cases of pelvic infection were diagnosed at 6 weeks. In our study, pelvic infection was less in PPIUD group than in IIUD group at 6 months and 1 year but the difference between the two groups was not statistically significant. Our study was similar to others in which the infections were less in PPIUCD group as compared to IIUCD group (0% v/s 1.2%) and (0% v/s 4.5%), respectively [10, 11].

Overall, the side-effect profile was favorable in the PPIUD group as compared to the IIUD group especially in the initial period, i.e., 6 weeks and 6 months. At 1 year, side effects are less common in the PPIUD group; however, the difference is not statistically significant.



<sup>&</sup>lt;sup>b</sup>At 6 weeks no case of clinically apparent PID was diagnosed in either group

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In our study, there was no case of perforation in either group. Our study was consistent with reports from other authors where no case of perforation in PPIUCD insertion was reported [11, 12, 14].

Our study found a statistically significant difference in expulsion after post-placental insertion compared to delayed insertion. The difference between the two groups was statistically significant (p = 0.006) for cumulative expulsion. However, for interval expulsion rate the difference was not statistically significant (p=0.6) Our study was similar to studies by Bonilla Rosales et al. [15], Bednarek et al. [16] and Gupta et al. [13] where expulsion rate was more in PPIUCD [10, 17, 18]. Their results are consistent with our findings. Lucksom et al. [19] observed a higher expulsion rate in interval insertions [20]. In contrast, Levi and colleagues followed 90 women and reported no expulsions [4]. However, that study reported a 47% follow-up rate, limiting accurate estimation of IUD expulsion. Increased expulsion rate in PPIUD group as compared to the interval insertion group is possibly the only disadvantage of PPIUD insertion; cumulative expulsion rates showed a statistically significant difference between the groups, and the difference persisted throughout the study duration. Between 6 months and 1 year, however, the interval expulsion rates were comparable. This implies that interval expulsions are high in the PPIUD groups up to 6 months, and after 1 year the risk of expulsion is same in both the groups.

Majority of the patients showed willingness for continuation of IUD and only a small number requested removal, rest of the patients were satisfied with IUD as a contraceptive. In our study, reason for removal in PPIUD group was due to menorrhagia in 72.2% patients, due to pain in 16.6% patients and due to desire of resumption of fertility in 11.1% patients. Reason for removal of IUCD in interval group was due to menorrhagia in 77.4% patients, pain in 16.1% patients and desire for resumption of fertility in 6.4% patients. Additionally, some other patients in both groups had requested removal of IUCD due to pelvic pain but responded favorably to counseling about benefits of IUCD from the treating physician and agreed to continue with IUCD. In our study, continuation rates appear to be higher in the PPIUD group, but the difference is not statistically significant. Other studies have also reported social reasons, change of method of contraception and psychological factors as additional causes of IUCD removal [13, 21–23].

In conclusion, PPIUD is a safe, easy and effective alternative to interval IUD insertion and qualifies to be popularized as a first-line contraceptive agent in eligible patients owing to its immediate and sustained contraceptive benefit, patient comfort, convenience and lower incidence of side effects.

Author Contributions NK, ST, AQ: Conception, NK, ST, IJK: Design, NK, ST, AQ: Supervision, NK, ST: Fundings, NK, ST, AQ: Materials Processing, NK, ST, AQ, IJK: Analysis and/or Interpretation, NK, ST, IJK: Literature Review, NK, ST, IJK: Writer, NK, ST, AQ: Critical Review.

# **Compliance with Ethical Standards**

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

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Research involving human participants and/or animals** Yes (Interventional study).

**Informed consent** Informed consent for procedures was taken from all patients.

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