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A Study to Compare the Efficacy, Safety & Outcome of Immediate Postpartum Intrauterine Contraceptive Device (PPIUCD) With That of Delayed Insertion

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Abstract: ***Background: Worldwide around 115 million women have unmet needs of family planning. Increasing rates of institutional deliveries create opportunities for providing quality postpartum family planning services thus helps to overcome the unmet needs. PPIUCD appears an ideal method for limiting & spacing births. Objective: The present study was undertaken to assess the efficacy, safety & outcome of Postpartum Intrauterine Contraceptive Device (PPIUCD) insertion & to compare it with delayed insertion at Jawaharlal Nehru Medical College & Hospital (J.N.M.C.H.), Aligarh, U.P. Methods: A prospective study done after getting approval from the Ethical Committee of the institution. Results: A total of 168 clients were included in the study (94 in immediate post partum group & 74 in the delayed insertion group). Among these 10.63%, 6.02% & 5.19% in the immediate insertion group (GROUP-I) and 16.22%, 13.11%, 11.54% in the delayed insertion group (GROUP-II) went lost to follow up at 6 weeks, 3 months & 6 months respectively. There were 1.2% expulsions in GROUP-I & 1.6% in GROUP-II. There were no perforations. Overall the side effect profile was better in GROUP-I when compared to GROUP-II. There was no case of failure. Continuation rates after 6 months of follow up were 73.4% in GROUP-I and 59.5% in GROUP-II. Conclusion: Immediate post partum IUCD insertion is an effective, safe and even better means of contraception when compared with that of delayed insertion.***

Keywords: IUCD, PPIUCD, delayed insertion, expulsion, continuation, efficacy, safety

1. Introduction

India's population has crossed one billion in the year 2000. In recent censes of 2011 it has reached 121 crores [1] and it is estimated to reach a figure of1.53 billion by 2050, making it the most populous country in the world [2].Government of India has launched several programmes which emphasizes on promotion of adequate birth spacing. One of the major hurdles in the way to achieve the goal of family planning in India is unmet needs for contraception. According to NFHS-3(2005-06) data, the contraceptive prevalence rate in India is 56.3% and more than 40% of the couples are not using any method of contraception[1]. The countries with the highest percentage of unmet need are in Sub-Saharan Africa in which only 22% of the population use contraceptives [3].

In the developing world like India, the various government plans promoting institutional deliveries all across the country create opportunities for providing quality postpartum family planning services.[4] After child birth, most of the couples need proper counseling to space their next pregnancy or, if they have completed their family size, to terminate the child bearing altogether. IUCDs are among the most commonly used reversible method of contraception in women of reproductive age worldwide. 1 in 5(or 153 million) married contraceptive users are using IUDCs [5]. It is the ideal method for spacing births. IUCDs are the LONG ACTING REVERSIBLE CONTRACEPTIVE which reverts fertility quickly as soon as withdrawn and fertility is not impaired at all [6][7][8]. IUCDs are USE AND FORGET type of method for contraception thereby it is good choice for illiterate population.

IUCD may be inserted in post partum period, post abortal or in interval period. Immediate PPIUCD insertion has distinct advantages of ease of insertion, availability of skilled personnel and appropriate facilities and convenience for the women, as the side effects of Copper-T insertion (menstrual problems, lower abdominal pain & cramps) get masked with the after pains of delivery. IUCD inserted within 10 min of delivery of placenta has much lower expulsion rates as compared to insertion later in the post partum period but the expulsion is still higher than the interval insertion**.** PPIUCD appears an IDEAL METHOD for limiting & spacing births.

2. Material & Methods

This prospective study was conducted in the department of obstetrics & gynaecology, JNMCH, AMU, Aligarh, U.P. between February 2012 & November 2013 after getting approval from the ethical committee.
After informed consent, those clients who met the eligibility criteria for PPIUCD insertion were included in the study.

Inclusion Criteria:

- Women willing for Copper T insertion and its follow up.
- Women meeting all the eligibility criteria for Post Partum IUCD Insertion.

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Exclusion Criteria

Women having-
a. Chorioamnionitis or Puerperal sepsis.
b. Prolonged rupture of membranes of >18hrs
c. Extensive genital trauma.
d. Unresolved PPH
e. Any abnormality of uterus or a large Fibroid distorting its cavity
f. Pelvic Inflammatory Disease
g. Malignant or benign Trophoblastic disease
h. HIV/AIDS

Participants were divided into two major groups Immediate Post Partum& Delayed Post Partum group according to their choices. IUCD was placed within 10 min. of delivery of placenta in clients of Immediate Post partum group using Kelly's forceps in case of vaginal delivery & using ring forceps in case of caesarean section. These clients were followed at 6 weeks, 3 months & 6 months interval for satisfaction, efficacy, safety, effect on menstrual cycle, removal and continuation. These results were compared with that of delayed insertion group, in whom IUCD was inserted after 6 weeks of delivery.

Results

Table 1: Lost to follow up of cases in study

Follow up visits	*Within 10 min GROUP-I n=19 (%)*			*Delayed insertion GROUP-II n=26 (%)*			*Total (n=45) (26.8%)*
	Lost to follow up	*Clients*	*(%)*	*Lost to follow up*	*Clients*	*(%)*	
1st follow up	10	94	10.6%	12	74	16.2%	22
2nd follow up	5	83*	6.02%	8	61*	13.1%	13
3rd follow up	4	77#	5.2%	6	52#	42.9%	10

(*)- 1 client had expulsion of IUCD at 1st follow up visit
(#)- 1 client got IUCD removed at 2nd follow up visit

Table 2: Sociodemographic characteristics of the cases in study (n= 253)

Characteristics	Total IUCD insertions(n=168)			
	Immediate PPIUCD insertion (n=94) [GROUP-I]		Delayedinsertion (n=74) [GROUP-II]	
Age (in yrs.)	Clients	(%)	Clients	(%)
20-25	30	(31.9)	15	(20.3)
25-30	43	(45.7)	43	(58.1)
30-35	18	(19.2)	14	(18.9)
35-40	3	(3.2)	2	(2.7)
Educational Status				
Literate	37	(39.4)	25	(33.8)
Illiterate	57	(60.6)	49	(66.2)
Religion				
Hindu	24	(25.5)	15	(20.3)
Muslim	70	(74.5)	59	(79.7)
Occupation				
Housewife	93	(98.3)	72	(97.3)
Employed	1	(1.7)	2	(2.7)
Residence				
Rural	28	(29.8)	16	(21.6)
Urban	66	(70.2)	58	(78.4)

Table 3: Distribution of clients according to complaint of menorrhagia

Follow up	Immediate insertion GROUP-I (n=94)			Delayed insertion GROUP-II (n=74)			p-value
	Total clients	Menorrhagia	%	Total clients	Menorrhagia	%	
1st Follow up	83	4	4.8	61	15	24.6	<0.01
2nd Follow up	77	4	5.2	52	11	21.2	<0.05
3rd Follow up	69	4	5.8	44	8	18.2	<0.05

Table 4: Clients complaining of irregular bleeding (spotting) after IUCD insertion

Follow up	Immediate insertion GROUP-I (n=94)			Delayed insertion GROUP-II (n=74)			p-value
	Total clients	Irregular bleeding	%	Total clients	Irregular bleeding	%	
1st Follow up	83	2	2.4	61	4	6.6	<0.05
2nd Follow up	77	3	3.9	52	2	3.9	>0.05
3rd Follow up	69	2	2.9	44	1	2.3	>0.05

Table 5: Clients having pelvic infection after insertion of IUCD

Follow up	Immediate insertion GROUP-I (n=94)			Delayed insertion GROUP-II (n=74)		
	Total clients	Pelvic infection	%	Total clients	Pelvic infection	%
1st Follow up	83	0	0	61	0	0
2nd Follow up	77	0	0	52	1	1.9
3rd Follow up	69	0	0	44	2	4.5

Table 6: Clients having Expulsion of IUCD

Follow up	Immediate insertion GROUP-I (n=94)			Delayed insertion GROUP-II (n=74)			p-value
	Total clients	Expulsions	%	Total clients	Expulsions	%	
1st Follow up	84	1	1.2	62	1	1.6	>0.05
2nd Follow up	77	0	0	52	0	0	
3rd Follow up	69	0	0	44	0	0	

Table 7: Distribution of clients according to rates of removal of IUCD

Follow up	*Immediate insertion GROUP-I (n=94)*			*Delayed insertion GROUP-II (n=74)*		
	Total clients	*Removal*	*%*	*Total clients*	*Removal*	*%*
1st Follow up	83	0	0	61	0	0
2nd Follow up	78	1	1.3	53	1	1.9
3rd Follow up	73	4	5.5	46	2	4.3

There was no case of perforation in either of the two groups. Continuation rates after 6 months of follow up were 73.4% (69/94) in GROUP-I & 59.5% (44/74) in GROUP-II.

3. Discussion

Unintended pregnancy is still a major concern in India. Despite the availability of safe and effective forms of contraception and increasing contraceptive use, societies of

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developing and developed countries encounter unacceptably high rates of unintended and unwanted pregnancies which contribute to population growth.

Post partum period is highly vulnerable period to unintended pregnancy as there are limited contraceptive options available in the breast feeding women. At the same time ovulation is highly unpredictable in non breast feeding or non exclusive breast feeding women. Thus, 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 women and health-care providers [9].

Though Post partum IUCD insertion immediately after delivery is an upcoming topic, its efficacy and safety is to be determined. Various studies were carried out to determine its efficacy, safety outcome using different techniques of insertion, but data on post partum IUCD insertion using Kelly's forceps is deficient.

Thus, this study was undertaken to evaluate the efficacy, safety, side effects, and failure of immediate post partum IUCD and its comparison to delayed IUCD insertion. In our study 26.8% of the clients had lost to follow up by 6 months and immediate insertion group were found to be more compliant than delayed insertion group. Manju et al (2000), found that 21.38% clients had lost to follow up at 4-6 wkspost partum and only 11.37% clients returned at 6 month follow up [10].

In the present study there was difficulty in insertion with Kelly's forceps in 3 clients (1.1%). Rests of the insertion were performed without any difficulty. The difficulty was encountered during initial cases only. Later on with subsequent expertise in insertion technique, no difficulty was encountered. In delayed insertion group no difficulty was encountered during insertion. The results were nearly same in the study conducted by Kittur et al (2012)in which difficulty was encountered in only 0.5% of the clients and there was no difficulty during caesarean section [11]. Chenet al (2009) found successful levonorgestrol IUD insertion in 50 out of 51 clients in post placental insertion using inserter under ultrasound guidance or using ring forceps. Difficulty was encountered only in 1.9% of the clients. No difficulty was seen in insertion 6-8 wkspost partum insertion group [12].

In our study, no case of perforation was seen in any of the groups, the possible reason could be low perforation in GROUP-I was thick post partum uterine wall immediately after delivery and in GROUP-II because of use of withdrawl technique. Our study was consistent with other studies conducted byShuklaet al, Kittur S et al, Sevki et al [10][11][13]. In the present study, 1 spontaneous expulsion was seen in clients in whom IUCD was inserted in the immediate post partum period and 1 indelayed insertion group. No expulsions occurred after 3 months. These finding were consistent with other studies of El-Shafei et al, Gupta et al [14][15].

In the present study, there was no removal in the 1st follow up at 6 weeks in any of the groups (GROUP-I and II). At 3 month follow up visit there was 1 removal (1.3%) in GROUP-I (insertion within 10 min of delivery) because of pain lower abdomen which was not relieved by mefenemic acid and analgesics and 1 (1.9%) removal in GROUP-II (delayed insertion group) due to menorrhagia, not relieved by tranexemic acid. At 6 months follow up visit 4 clients (5.5%) in GROUP-Ihad their IUCD removed, 1 because she opted for permanent sterlization, 1 because of irregular bleeding and 2 due to pain lower abdomen while there were 2 (4.3%) removals in GROUP-II, 1 due to menorrhagia and 1 client underwent permanent sterilization. In the immediate insertion group most of the clients got IUCD removed due to pain lower abdomen and in delayed insertion group most of the clients got IUCD removed because of menorrhagia. Our study was consistent with other studies conducted by Shukla et al, Kittur et al, Sevki et al, Gupta et al [10][11][13][15].

In our study clients complaining of menorrhagia was high in delayed insertion group than in the immediate insertion group. The difference of menorrhagia in these two groups were statistically significant $p<0.01$, $p<0.05$ and $p<0.05$ at 1st, 2nd and 3rd follow up visit respectively. Women who resumed menstruation by 1st, 2nd and 3rd follow up visit were 22, 34 and 52 women respectively. Menorrhagia was responsible for 2 removals in delayed insertion group at 6 months follow up. None of the removals in the immediate insertion group were due to it.

The incidence of menorrhagia was less in immediate insertion group because there was varying duration of lactationalamenorrhoea in the post partum period. So, longer period is needed to overcome the bias of lactationalamenorrhoea. Our study was comparable with other studies done by Shukla et al, El-Shafei et al, Celen et al, Eroglu at al [10][14][16][17]. Ei-Shafei et al(2000) found incidence of menorrhagia in 91/1016 clients (9%) in which CuT380A was inserted within 10 min at 1 year follow up [14]. Shukla et al (2000) found 283/1037 (27.3%) clients complaining of menorrhagia in post placental IUCD insertion [10]. Eroglu et al (2006) reported menorrhagia in 2/84 clients in post placental group, and 8/130 in interval/ delayed insertion group at 1 year follow up [17]. Celen et al found negligible incidence of menorrhagia at 1 year follow up [16].

Our study foundthat irregular bleeding (spotting) was more in extended insertion than in the immediate group at 1st follow up visit ($p <0.05$) but was statistically insignificant at 2nd and 3rd follow up visit.El-Shafei et al(2000) found spotting to be 6% in post placental group after 1 year of follow up but the studies comparing immediate and extended insertion is lacking [14]. In the present study, there was no case of pelvic infection in the immediate insertion group whereas in delayed insertion group, 1/52 (1.9%) clients at 3 months follow up and 2/44 (4.5%) clients at 6 months follow up visit had pelvic infection. All 3 clients responded to antibiotics and not a cause for IUCD removal. The result of pelvic infection in our study in immediate insertion group was similar to the studies conducted by Shukla et al, Gupta et al, Tatum et al [10][15][18] and in delayed insertion our study was more comparable with Eroglu et al [17].

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In the present study, there was no case of failure in the form of pregnancy in any of the groups. Gupta et al (2013) found no failure at 6mths of follow up in both immediate insertion and delayed insertion group [15].Ricaldeet al (2006) also reported no pregnancy after 1 year of insertion of CuT380A or ML Cu375 in post placentally and in early post partum period [19]. Eroglu et al(2006) found 2/84 pregnancies in post placental CopperT 380A, 2/43 in early post partum (10 min -72 hrs) and 4/130 in interval insertion group at 1 year of follow up [17]. Tatum et al found intrauterine pregnancy of 1/300 after 1 year of insertion of GYNE-T380 post placentally [18]. Celen et al (2004) reported that the pregnancy rate of 0.7% in 1 year of insertion of post placental CopperT 380A insertion [16]**.** O'Henley et al (1992) found rate of unplanned pregnancy for post placental insertion of IUCD using ring forceps to be 2-2.8/100 users at 24 months follow up [20]. It may be concluded from the present study that post partum IUCD is an effective, safe, reliable, long term and convenient method of contraception.

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