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Research Article

A randomized study for two techniques of immediate post-partum intrauterine contraceptive device insertion in India

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ABSTRACT

Background: Postpartum women are susceptible for unintended pregnancy in the first postpartum year. They should be counselled by cafeteria approach and those who opt for Postpartum Intrauterine Contraceptive Device (PPIUCD), it should be inserted in the same sitting. Aims of current study were to compare 1) The technical feasibility in terms of client discomfort, immediate expulsion, perforation and time taken in insertion of the two insertion techniques, Manually vs Kelly's placental forceps. 2) The complications of the two techniques of insertion. 3) The expulsion rates at 1, 3 and 6 months.
Methods: This was a randomized study in which 150 women were recruited. Group A had 75 subjects and insertion of PPIUCD was done manually. Group B had 75 subjects and insertion was done with Kelly's placental forceps.
Results: There was no statistically significant difference in the mild discomfort during insertion by either technique. Time taken for insertion was significantly lower in group A. The combined expulsion rate (spontaneous complete expulsion and partial expulsion) at the end of 6 months was 11.9% in group A and 10.5% in group B (not statistically significant). Pain (16% in group A and 12% in group B) was the most common problem encountered by IUD users followed by menstrual problems (10.7% in group A and 8% in group B). There was no significant difference in the complication rate for the two groups (P >0.05).
Conclusions: Manual technique of insertion of PPIUCD is equally good as compared to Kelly's placental forceps and it has no economic implications for purchasing and maintenance.

Keywords: Postpartum intrauterine contraceptive device, CuT 380A, Kelly's placental forceps, Manual insertion

INTRODUCTION

In developing countries, many women in far flung areas where health facilities are minimal & the women have very little knowledge of various types of contraceptives, pregnancy and sometimes delivery of a baby is the only time when they get an opportunity to visit a health set-up.[1]

Methods of contraception available for a breast feeding woman during post-partum period are- condoms/ spermicidal agents, intrauterine contraceptive devices, Lactational Amenorrhea Method (LAM), progestin only methods and female sterilization.[2] They should be counselled by cafeteria approach and for those women who want immediate, one time, reversible & easily available, free of cost available in government facility option of intrauterine contraceptive device insertion should be given.[3-5]

Techniques of insertion may be manual or by an inserter- Kelly's placental forceps or Sponge holding forceps (ring

forceps). Inserter recommended by WHO is Kelly's placental forceps. This study was designed to compare the differences of two insertion techniques in insertion of CuT380-A (Average life 10 years), manually and by Kelly's placental forceps among Indian women.

Aims

1) To compare the technical feasibility in terms of client discomfort, immediate expulsion, perforation and time taken in insertion of the two insertion techniques of Postpartum Intrauterine Contraceptive Device (PPIUCD) insertion, manually (Group A) vs. Kelly's placental forceps (Group B).
2) To compare the complications of the two techniques of insertion.
3) To compare the expulsion rates at 1 month, 3 months and 6 months.

METHODS

A randomized study was conducted in the department of obstetrics & gynaecology, Vardhman Mahavir medical College and Safdarjung Hospital, New Delhi. 150 women of immediate post-placental period (within 10 minutes after delivery of placenta) & early postpartum period (within 48 hours after delivery of baby) were recruited for the study over a period of one year (2010-11). Women having one or more living healthy issues, not having any contraindications of PPIUCD insertion, able to come for follow up visits were included in the study. The exclusion criteria were fever or any other signs of abdominal or pelvic infection, prolonged rupture of membranes (>24 hours), intrapartum or postpartum haemorrhage that continues after completely emptying the uterus, bleeding problems such as DIC caused by eclampsia or pre-eclampsia, STD or risk of STD & having recent or recurrent PID, cancer or strong suspicion of cancer of uterus & uterine anomalies.

The participants were randomized to be in either of the two groups i.e. the manual insertion group (Group A) and the Kelly's forceps insertion group (Group B) by flipping a coin, therefore each study participant who fulfilled the inclusion criteria had an equal and 50% chance of being in each group. Informed written consent was obtained.

Group A had 75 subjects. Insertion of PPIUCD was done manually.

Group B had 75 Subjects. Insertion of PPIUCD was done with Kelly's placental forceps.

Post insertion counselling and advice was given to each woman. During follow up visits at 1, 3 and 6 months, the detailed history was taken and examination was done for any complications, trimming of threads were also done as and when indicated. In non-visible threads ultrasound was done.

In case of expulsion, another contraceptive method was offered or re-insertion after 6 weeks post-partum was done if the woman wished to continue using IUCD.

Data analysis

The data was analysed by applying the standard statistical tests. Chi-square test for categorical variables and the Student's t-test for quantitative variables were applied. P value <0.05 was considered statistically significant. Analysis was done on SPSS version 17.0 (Statistical package for social sciences, Microsoft Inc, Chicago IL, USA).

RESULTS

All the participants in both groups were comparable and were not having any significant difference (P >0.05) in terms of their basics characteristics like age, religion, booking status, socioeconomic status, education level of women, parity, living issue, time of counselling and purpose of insertion (spacing/limiting).

Looking at the comparison of technical feasibility of the two insertion methods, there was no statistically significant difference in the mild discomfort felt by the woman during insertion by either technique (P >0.05). It was felt in the 28% in manual inserted group and 21.3% in forceps inserted group. No case of immediate expulsion and uterine perforation was reported in either of the two groups. The mean time taken in insertion of PPIUCD was 6.77 ± 0.967 min in group A which was less than that of group B i.e. 7.31 ± 1.139 min. On applying Independent Student's t-test, t value obtained was 3.092 with 148 degrees of freedom. Thus the difference in both the techniques in terms of time taken in insertion is significant statistically (P = 0.002). Therefore, the manual insertion method is as feasible as the insertion with Kelly's forceps.

All participants were followed up for a period of 6 months. They were asked at all the three visits whether they were satisfied with their IUCD or had any of the following complaints like lower genital pain, bleeding, excessive discharge per vaginum or infection.

The participants reported satisfaction in 65 (86.7%) women in group A and 64 (85.3%) in group B (P >0.05). All the satisfied women would like to recommend this method of contraception to their female relative or friend. Only 10 women in group A (manual insertion group) reported being dissatisfied while 11 women of group B (Kelly's forceps group) reported dissatisfaction. Reasons for dissatisfaction are shown in Table 1.

During 1st visit, on local examination, in 29 (38.6%) women of group A and in 18 (24%) women of group B threads were not visible. On subsequent visits, the visibility of threads on local examination improved. In group A during 2nd and 3rd visit, in 4% women the threads

were not visible in both these visits whereas in group B, they were not visible in 6.7% women in 2nd and in 4% women in the 3rd visit. This difference observed was not significant (P >0.05).

Table 1: Reasons of dissatisfaction.

Reasons of dissatisfaction		Management					
		No. of cases		Relieved with therapy		Removal of IUD	
		Group A[1] (%)	Group B[2] (%)	Group A[1] (%)	Group B[2] (%)	Group A[1] (%)	Group B[2] (%)
Pain in lower abdomen		8 (10.6)	5 (6.6)	6 (8.0)	2 (2.6)	2 (2.6)	3 (4.0)
Menstrual problem	Menorrhagia with dysmenorrhea	3 (4.0)	2 (2.6)	2(2.6)	1 (1.3)	1 (1.3)	1 (1.3)
	Menorrhagia	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Lower genital tract infection		1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Partial expulsion		1 (1.3)	2 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.6)
Psychosocial		3 (1.3)	4 (5.3)	0 (0.0)	0 (0.0)	3 (4.0)	4 (5.3)

*multiple answers, 1 is n = 75, 2 is n = 75

The threads were not visible at any of the three visits in '2' women each, in both groups. In another 2 women each of both groups the threads were not visible at the 1st and 3rd visit but they were visible at the 2nd visit.

In postpartum period, uterus involutes and returns to its pre-pregnant state. The threads were not visible at the time of insertion due to large uterus. During follow up visits, when the thread of IUD was visible and was long enough to cause problems to either partner, it was trimmed at the level slightly below the cervix. Trimming was also necessary as women might pull them by mistake. In other cases, threads were curled up behind the cervix or they were not hanging outside the vagina to cause problems. Threads were trimmed in 54.7% women on 1st visit, 18.7% on 2nd visit in group A (Manual insertion group). No trimming was done in 3rd visit. In group B (Kelly's placental forceps insertion group), trimming was done in 72% women on 1st visit, 13.3% on 2nd visit and 4% on 3rd visit.

The woman in whom IUD thread was not visible, transabdominal ultrasound (USG) was done using 5-8 MHz transducer to diagnose expulsion. Spontaneous expulsion was confirmed on USG. No case was reported in which women had pulled the thread by mistake. On follow up visits, in some cases IUD thread was abnormally long to see the vertical limb of IUD through the cervix or CuT was lying displaced in the vagina. These IUDs were removed and were included in the partial expulsion event. There was no statistically significant difference in the occurrence of these events among the two insertion groups (P >0.05).

The combined expulsion rates (spontaneous expulsion and partial expulsion) at the end of 6th months were 11.9% in manual insertion group (Group A) and 10.5% in forceps insertion group (Group B). This difference had no statistical significance (P >0.5).

The six month total medical removal (bleeding / pain) and non- medical removal (personal reasons, social pressure, wanting pregnancy, husband's request etc.) rates were 3 (4%) and 6 (8%), respectively, in group A; and 4 (5.3%) and 7 (9.3%), respectively, in group B. There is no significant difference (P >0.05).

All the reasons of discontinuation of PPIUCD are summarised in Table 2.

Table 2: Reasons for discontinuation of PPIUCD.

Reason of discontinuation	Group A (n=75)			Group B (n=75)		
	1st visit	2nd visit	3rd visit	1st visit	2nd visit	3rd visit
Expulsion (complete)	3 (4%)	1 (1.3%)	0 (0%)	2 (2.6%)	0 (0%)	1 (1.3%)
Expulsion (partial)	3 (4%)	1 (1.3%)	1 (1.3%)	3 (4%)	2 (2.6%)	0 (0%)
Total removal including partial expulsion	3 (4%)	4 (5.3%)	7 (9.3%)	4 (5.3%)	6 (8%)	6 (8%)

Reinsertion was done in 4 (44.4%, n=9) of the women who had gone through expulsion, making the reinsertion rate 5.33% (n=75) in group A. In group B, 5 (62.5%, n=8) women had reinserted IUD, thus the reinsertion rate was 6.67%.

The continuation rate of PPIUCD at the end of 6 months was 76% in group A and it was 74.7% in group B. The difference was not significant (P >0.05). The reasons of discontinuation were spontaneous expulsion, partial expulsion which was removed and removal due to other reasons like excessive bleeding, pain in lower abdomen, social pressure etc. Also in the present study, the women in whom IUD was reinserted were not included in the calculation of continuation rate of both groups.

The complication rates observed due to IUCD insertion in both groups were similar. The most common complication in group A as well as group B was Pain in lower abdomen observed in 16% and 12 % women respectively (Table 3). The difference in the rate of occurrence of any complication in both groups was not statistically significant (P >0.05).

Table 3: Complications observed in both groups due to IUCD insertion.

Complications		No of cases (n=75)		Relieved with therapy		Removal of IUD	
		Group A	Group B	Group A	Group B	Group A	Group B
Perforation		0 (0%)	0 (0%)	0	0	0	0
Lower genital tract infection		2 (2.7%)	1 (1.3%)	2	1	0	0
Persistent lochia		2 (2.7%)	0 (0%)	2	0	0	0
Menstrual problem	Menorrhagia with dysmenorrhea	6 (8%)	6 (8%)	5	5	1	1
	Menorrhagia	2 (2.7%)	1 (1.3%)	2	1	0	0
Pain in lower abdomen	Pain in lower abdomen	12 (16%)	9 (12%)	10	6	2	3

DISCUSSION

On scanning the literature, only one Egyptian study was found in which Kelly's placental forceps was used as a method of IUD insertion but they have not given their data which is comparable to present study. Other available studies on PPIUCD have used ring forceps for insertion. Therefore comparison of the present study is being done with these studies.

No differences were observed in respect to various event rates like continuation rates, removal, and expulsion in comparison of the two insertion techniques in the present study. In a study by Xu et al.,[6] this was also designed to compare the differences of two insertion techniques (manual insertion and insertion using a ring forceps) in vaginal post placental insertion centred on 910 Chinese women, found the similar results of no significant difference. In this present study, continuation of PPIUCD was reasonably high in both the insertion techniques group (76% in group A and 74.7% in group B). After reinsertion total of 61 women were continuing IUD both in group A and group B making the continuation rate for this method of contraception 81.3.

In the present study, total expulsion including both spontaneous and partial expulsion in group A was 12% and group B was 10.7%. Xu et al. showed that the gross cumulative expulsion rates at three and six months were 10.8 and 13.3 in hand insertion group, respectively; and 11.3 and 12.7 in the forceps insertion group.[6]

The six month total medical removal (bleeding / pain) and non-medical removal (personal reasons, social pressure, wanting pregnancy, husband's request etc.) rates were 4% and 8%, respectively, in group A; and 5.3% and 9.3%, respectively, in group B. In a study by Xu et al., the six month gross medical removal (bleeding /pain) and non-medical removal rates were 2.1 and 0.9, respectively, in the hand -insertion group; and 1.0 and 0.8, respectively, in the ring forceps insertion group.[6]

In the present study, 2 women suffered from persistent lochia with an average duration of lochia rubra (15 days) and lochia alba (15 days). No treatment was needed. Lower genital tract infection occurred in '2' cases in group A and in '1' woman in group B, for which treatment were given. No case of persistent lochia was reported in group B. In a study of Xu et al., no woman suffered from infection but 2 cases reported persistent lochia, the duration of lochia was 44 days in this women.[6]

CONCLUSION

Postpartum IUD is the only long acting, reversible method, that does not interfere with breastfeeding that can be provided before the women leaves the birthing facility and requires no transition (from LAM to

hormones). For these reasons, postpartum IUD insertion should be successfully integrated into existing family planning programmes so that this wonderful method of contraception can be made available to the women in low resource settings and developing countries.

It can be concluded from the present study that, the technical feasibility which included the discomfort felt by women during insertion, immediate expulsion, uterine perforation and the mean time taken in insertion, was similar. Very few women reported dissatisfaction with the IUCD in both groups. The continuation rates in both groups were statistically similar as also the rates of complications following IUCD insertion in both groups. Finally the time taken for manual insertion was significantly lower than insertion using Kelly's forceps. Therefore either of the methods may be used effectively for post-partum insertion of IUCD.

As Kelly's placental forceps is not available at all the centers and manual insertion has no economic implications for purchasing and maintenance of equipment, availability is not a problem with it and lower time of insertion will make it a good option at busy centers with high patient load in India.

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