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Research Article

A comparative study of clinical outcomes of post placental insertion versus interval insertion of Copper T 380A intrauterine device

Suchi Gupta*, Shubha Sagar Trivedi, Ratna Biswas

Department of Obstetrics & Gynecology, Lady Hardinge Medical College & Associated Hospitals, New Delhi, India

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***Correspondence:**

Dr. Suchi Gupta,

E-mail: suchi86mon@gmail.com

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ABSTRACT

Background: The objective of this study was to study the safety and efficacy of PPIUCD insertion and to compare it with interval insertion.

Methods: A prospective study was conducted enrolling 100 women as study group (PPIUCD) and 100 as control group (interval CuT insertion). All women were followed up for 6 months and clinical outcomes were measured in terms of safety, efficacy, effect on menstrual cycles and continuation rates. Chi square test was used to detect differences in the rate of clinical outcomes, and $P < 0.05$ was considered statistically significant.

Results: Spontaneous expulsions were more in study group, but the difference was not significant. Number of women having missing thread was significantly higher in study group. Total number of CuT removals and incidence of pelvic infection were significantly higher in controls. Number of women complaining of menorrhagia were more in control group and continuation rate at 6 months was higher in study group, but this difference was not statistically significant. No case of pregnancy or perforation occurred in either group.

Conclusions: PPIUCD is an effective, safe, convenient, low cost and long term method of post-partum contraception.

Keywords: PPIUCD-post placental IUCD, CuT-Copper T 380A, Expulsion, Missing thread, Menorrhagia, Removal

INTRODUCTION

Post-partum IUD insertion refers to IUD insertion within 48 hours after delivery. IUD insertion within 10 minutes of placental expulsion is known as post placental IUD insertion. The concept of post-partum IUD insertion arose in 1970's¹ but it was not commonly used in general practice before 21st century because the previous studies showed very high rates of expulsion.²

In postpartum period, ovulation is highly unpredictable and, it can occur as early as 45 days after delivery in non-breast feeding and partially breast feeding women and couples often underestimate the likelihood of pregnancy.

Also, post-partum contraceptive options are limited to barrier method, progesterone only pills and lactational amenorrhea method, all of which have higher failure rates. This exposes the woman to the risk of unintended pregnancy and the morbidity associated with subsequent abortion or repeat frequent pregnancy. Postpartum women often want a method that provides long term temporary contraception, but do not want permanent sterilization.

Post placental insertion of intra uterine device has many advantages such that the woman is definitely not pregnant, she has high motivation to use contraception after delivery, lesser discomfort is experienced during IUD insertion in dilated cervix, and any bleeding from

the insertion is disguised by the expected bleeding after delivery. Among women who have limited access to a clinician, institutional delivery provides a unique opportunity to address a woman's need for contraception. But it carries higher risk of expulsion due to involution of uterus, theoretically increased risk of perforation due to softening of the uterine wall and potential concern of infection due to lochia.

In previous studies, there was a debate on, whether differences in the expulsion rates were related to the time of insertion, type of IUD used, technique of insertion² and skill & experience of the service providers. Present study was an attempt to further elaborate on this issue.

The objective of this study was to study the safety and efficacy PPIUCD insertion and to compare it with interval insertion.

METHODS

A prospective study was carried out in the department of Obstetrics and Gynecology, Lady Hardinge Medical College and Smt. Sucheta Kriplani Hospital, New Delhi for a period of one year and 4 months. The women presenting to antenatal OPD and in labor room in early labor were counseled about family planning methods and were encouraged to opt for PPIUCD. Inclusion criteria included delivery of a live baby within 10 minutes and exclusion criteria were chorioamnionitis, unresolved post-partum hemorrhage, past history of ectopic pregnancy, history of any hemorrhagic disorder, history of past or current genital infection or conditions that predispose to recurrent genital infections such as HIV and medical conditions such as diabetes mellitus, known history of heart disease, suspected genital neoplasia, uterine abnormalities, woman or husband having multiple sexual partners, known pelvic tuberculosis. PPIUCD insertion was done in a total of 143 women who met the eligibility criteria after taking informed consent. Out of these, 100 women could be followed for 6 months and were labeled as study group. A total of 100 eligible women, who opted for interval CuT insertion and followed up for the period of 6 months, served as control group.

In study group, CuT was inserted within 10 minutes of expulsion of placenta in normal vaginal delivery, using Kelly's placental forceps, taking all aseptic precautions as per the guidelines of USAID, Ministry of health and family welfare, government of India 2010.³ After Active management of third stage of labor, cervix was visualized with Sim's speculum and cleaned twice with betadine solution, anterior lip of cervix was grasped with sponge holder, CuT 380A was grasped inside the sterile package using Kelly's placental forceps so that junction of vertical & horizontal arms was gripped by the instrument (Figure 1), anterior lip of cervix was raised and CuT 380A was introduced into the uterine cavity and advanced towards the fundus. Fundus of the uterus was gently pushed

upwards and backwards to straighten the angle between the vagina and the uterus, and right hand was lowered to negotiate this angle. Forceps was opened to release CuT 380A at the fundus and forceps was slowly removed in slightly open position, sweeping along the lateral uterine wall, so that the CuT remained at its place. Cervix was examined to ensure that CuT strings were not visible. If strings were visible, it meant that CuT was not at the fundus and it was removed and reinserted. Other instruments were removed and woman was allowed to relax and breastfeed the baby. All postpartum women were observed for 6 hours after delivery and re-examined before discharge from the hospital. In control group, CuT was inserted between 4th to 7th days of menstrual cycle by standard 'no touch' withdrawal technique, under all aseptic precautions.



Figure 1: Kelly's placental forceps holding CuT 380A.

Women were explained about follow up at 6 weeks, 3 months and 6 months or earlier if she notices any warning sign such as foul smelling lochia, excessive bleeding, lower abdominal pain, fever and in case of expulsion. Physical and pelvic examinations were carried out to check the thread of CuT, to check for signs of infection and excessive bleeding. Long thread of post placental CuT was trimmed in the first follow up visit. Ultrasound examination was carried out at 6 weeks in all women, to confirm the presence of IUCD in the uterus and to verify it's the correct placement.

The observations were described in terms of percentages/proportions. Both groups were compared with respect to clinical outcomes. Chi square test was used to detect differences in prevalence rate of clinical outcomes, and $P < 0.05$ was considered statistically significant.

RESULTS

Amongst 100 women in study group, 3 had spontaneous complete expulsions at 3 weeks, 4 weeks and 8 weeks respectively. No expulsion occurred after 2 months of insertion. No expulsion occurred in control group. This difference at 6 weeks ($P=0.147$) and 3 months ($P=0.298$) was statistically not significant. At 6 weeks, one woman in PPIUCD group was found to have CuT in the lower

uterine segment i.e. partial expulsion, whereas, none case occurred in interval group. But the difference was statistically not significant ($P=0.316$).

The number of women who menstruated after delivery by 6 weeks, 3 months and 6 months were 28, 51 and 73 respectively. The number of women complaining of menorrhagia at 6 weeks, 3 months and 6 months in study group were 6 (21.4%), 9 (17.6%) and 6 (8.2%) respectively. In control group, 19 (19.2%) women complained of menorrhagia at 6 weeks. At 3 months, 4 of these women got their IUD removed and 2 additional women developed menorrhagia so that a total of 17 women out of 95 (17.8%) had this complaint. At 6 months, 5 out of these women got their IUD removed and no additional women reported menorrhagia, so that a total of 12 out of 82 (14.6%) women had this complaint. All women were evaluated to find out any other cause of menorrhagia and appropriate treatment was instituted. All these women were reassured about temporary nature of such menorrhagia and were counselled to continue with CuT usage. This difference between two groups at 6 weeks ($P=0.749$), 3 months ($P=0.965$) and 6 months ($P=0.136$) was statistically not significant.

At 6 weeks, 3 months and 6 months; 2, 1 and 0 women in PPIUCD group and 6, 5 and 6 women in control group respectively, complained of cramping pain lower abdomen not related to the phase of menstrual cycle. Such women were evaluated to rule out infection, bladder and bowel cause of pain lower abdomen. All women were explained about the temporary nature of such pain and mefenamic acid was advised to provide temporary relief on as and when required basis. The difference in lower abdominal pain between subjects and controls at 6 weeks ($P=0.162$) and 3 months ($P=0.111$) was statistically not significant. At 6 months, the difference was statistically significant ($P=0.014$).

None of the women in PPIUCD group had pelvic inflammatory disease. In control group, 4 women had PID at 6 weeks. All these women were given appropriate treatment. Three more women developed PID at 3 months and two improved with treatment. At 6 months, no additional woman was found to have PID. Four women in the control group demanded CuT removal at 6 months due to pelvic inflammatory disease. The difference in the occurrence of pelvic inflammatory disease between subjects and controls at 6 weeks ($P=0.047$) and 3 months ($P=0.027$) was statistically significant; while at 6 months ($P=0.324$) was not significant.

In 95 women of PPIUCD group, thread of CuT was visualised on per speculum examination at first follow up visit while in five women, thread was not seen. On ultrasound examination, CuT was found to be correctly localized at the fundus of uterus. By 3 months, in one of the above mentioned women, thread came out of the external os. The possible reason for missing threads

might be coiling of long threads inside the uterine cavity. The numbers of women with missing thread on per speculum examination at 3rd and 6th month were four. One of these women gave clear history of expelling threads of CuT out of introitus. All of these women preferred to continue with their pre-existing CuT. They were advised to keep a check on expulsion especially during menstruation and regular follow up in case of any doubt.

In control group, none of the women had missing thread at 6 weeks and 3 months. At 6 months, three women had missing thread. All three of these women gave clear history of expelling threads during menstruation. On ultrasound CuT was visualized to be correctly placed in all of these women. The difference in the occurrence of missing threads between cases and controls at 6 weeks ($P=0.020$) and 3 months ($P=0.037$) was statistically significant; while at 6 months ($P=0.636$) was not statistically significant.

By 6 weeks, 5 women in PPIUCD group had their CuT removed. One had removal 3 hours after delivery due to post-partum hemorrhage. Second removal was on 7th day, due to severe crampy pain abdomen which subsided after CuT removal. Two removals were due to socio-personal reasons after 10 and 15 days. One removal was due to thread irritation at 1 month. By 3 months, 2 more women had removal due to menorrhagia and 1 woman had removal due to continuous spasmodic pain lower abdomen which subsided after removal. No removal was done after 3 months.

In control group 1 woman had removal at 1 week due to severe pain abdomen. By 3 months, 4 more removals were due to polymenorrhagia. By 6 months, 13 more women got their CuT removed. The reason for removal in four women was pelvic inflammatory disease, five removals were due to menorrhagia, two removals were due to missing threads who wanted new CuT insertion, 2 women wanted permanent method of contraception so they got their CuT removed and got laparoscopic ligation done. Hence, a total of 8 women in PPIUCD group and 18 women in interval group got their CuT removed at the end of 6 months. This difference was statistically significant at 6 months ($P=0.003$).

No case of perforation or pregnancy occurred either in study or control group.

The numbers of women who continued with the use of CuT at the end of 6 months were 88 out of 100 women in study group in contrast to 82 out of 100 women in control group. Thus 6 months continuation rate was higher in PPIUCD group than interval group, but this difference was not statistically significant ($P=0.160$). The graphical summarizations of clinical outcomes in study and control groups are depicted in Figure 2 and 3.

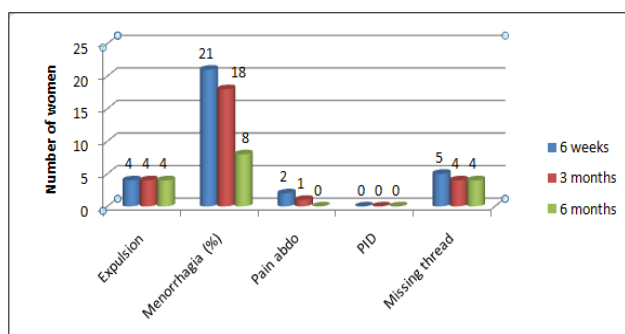


Figure 2: Graphical summarization of clinical outcomes of PPIUCD insertion.

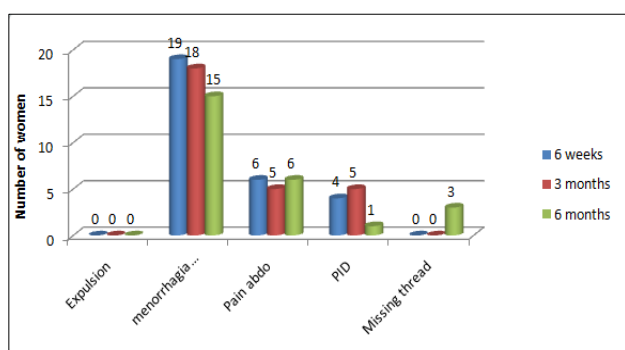


Figure 3: Graphical summarization of clinical outcomes of interval CuT insertion.

DISCUSSION

Postpartum period is one of the sensitive times of woman's life when she is in contact with health care facility. As the number of institutional deliveries are increasing, post-partum CuT insertion can provide a unique opportunity to women to opt for this effective and safe contraceptive method immediately after delivery.

Previous studies did not support PPIUCD insertion due to high risk of expulsion. In our PPIUCD group, expulsion rate was 4%. All of these women were multiparous. No expulsion occurred after 2 months of insertion. Expulsion rate of PPIUCD in various studies varied from 2.4%² to 20.5%,⁴ when insertion was done using ring forceps, inserter and manual method. Expulsion rate reported with Kelly's forceps was 6.95%.⁵ Our Expulsion rate was much lower as compared to other studies. This was probably due to use of long Kelly's placental forceps for insertion, which ensures high fundal placement of CuT. This is supported by the fact that PPIUCD insertion in caesarean also ensures correct fundal placement and correct timing of insertion within 10 minutes of expulsion of placenta and hence is associated with lower expulsion rate than after vaginal delivery.⁶ Expulsion rate of interval CuT reported in literature was 2 to 6%.⁷ No expulsion of interval CuT occurred in our study. Although expulsion is higher in PPIUCD group, but 80% to 97% women, in whom it is retained, are protected from unintended pregnancy.

In our study, no case of perforation occurred in study or control group. The possible reason for low perforation rate in post placental insertion is due to thick uterine wall. No perforations were reported in PPIUCD insertion in the studies carried out by Xu et al.,⁸ Villanueva et al.⁹ and Kapp et al.² O'Henley et al.¹⁰ reported 1 perforation out of 1150 PPIUCD insertion, when insertion was done using ring forceps. Eroglu et al.¹¹ reported 3 cases of perforation in interval CuT insertion, 2 perforations were detected at 8 weeks and 1 perforation at 6 months.

In our study, the number of women complaining of menorrhagia were more in interval CuT insertion group than in post placental insertion group. Menorrhagia was responsible for 2 and 9 removals in study and control group respectively at 6 months follow up. The lower incidence of menorrhagia in post placental insertion may be due to varying length of lactational amenorrhea in post-partum women. So, longer period of follow up is required to eliminate this biasing factor of lactational amenorrhea in post-partum women. Missing threads was significantly higher in PPIUCD group than interval group. This was probably due to coiling of long threads inside the uterine cavity or cervical canal.

In our study, pelvic infection was significantly higher in interval group than PPIUCD group. This was probably due to routine antibiotic administration in post-delivery period and extra careful patient selection in PPIUCD group as infection is anticipated to be more often in post-partum women due to lochia. Decrease in sexual frequency during pregnancy and puerperium might also be a contributing factor for the same. Mohllajee AP et al.¹² had found that PID occurs either due to infection introduced during insertion procedure or due to ascent of pre-existing cervical infection. In women who had negative cervical cultures, the risk of pelvic inflammatory disease with IUD placement was 0%-2%, whereas in the presence of infection, it was 0%-5%. He also showed that, areas where rates of unintended pregnancy were high, rates of sexually transmitted infection were also high and these areas also lack laboratory facilities to test for infection. Thus, a reasonable assessment of the risks and benefits should be weighed prior to CuT insertion in women with asymptomatic lower genital tract infection because routine cervical culture before CuT insertion in asymptomatic women, may defer many women from using CuT, who may never return back to hospital.

In our study, no case of pregnancy occurred in study or control group. Failure rate reported in literature varies from 0.003%¹³ to 0.7%.¹⁴ Thus our study demonstrated zero failure rate. This may be due to shorter period of follow up.

The number of women who continued with the use of CuT at the end of 6 months in our study was 88 out of 100 in study group and 82 out of 100 in control group. The probable reason for almost equal continuation rate in both groups was higher rate of expulsion in PPIUCD group which results in discontinuation and higher

incidence of medical problems in interval CuT group which results in its removal.

The continuation rates of PPIUCD and interval CuT group of our study were comparable to the result of the study carried out by Chen et al.¹⁵ and Jaffrey F et al.¹⁶ respectively.

CONCLUSIONS

PPIUCD insertion is an effective, safe, convenient, low cost and long term method of post-partum contraception. We recommend that, it should be routinely offered to all eligible post-partum women undergoing institutional deliveries.

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Ethical approval: The study was approved by the ethics committee for human research, Lady Hardinge Medical College & associated hospitals, New Delhi. (LHMC/ECHR/2015/569)

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