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Original Research Article

Clinical and ultrasonographic evaluation of PPIUCD

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ABSTRACT

Background: India is the second most populated country in the world. Effective contraception with low complication rates and high continuation rate in post-partum period can check population growth.
Methods: This is a prospective study carried out at Mahatma Gandhi Hospital after ethical committee approval. 100 patients giving the informed consent were taken in the study. PPIUCD inserted in patients and they were followed up at 48 hrs, 6 weeks and 12 weeks by clinical examination and USG.
Results: In this study, with PPIUCD insertion during LSCS, the expulsion and removal was observed in 4% and 14% whereas in cases with FTVD 8.33% expulsion and 12.5% removal were observed. 82% and 79.2% continued the use of PPIUCD in LSCS and FTVD respectively. The most common complain of the patients with PPIUCD were irritation because of thread. No case of pelvic infection or perforation was observed. There was no expulsion of PPIUCD when the distance of PPIUCD from fundus on USG was <10 mm.
Conclusion: PPIUCD have high continuation rates with low complication rate. Distance of PPIUCD from fundus on USG is not a good indicator for predicting expulsion of PPIUCD.

Keywords: FTVD, LSCS, PPIUCD, Post-partum

INTRODUCTION

India is the second most populated country in the world after China. According to the census 2011 the population of India on 1st March 2011 was 1,210,193,422. In spite of the availability of wide range of contraception the unmet needs of contraception for family planning is estimated to be 12.8%, the reason for the unmet needs are mainly lack of information, fear about the side effects of contraceptive methods and unsatisfactory services.

The recommended birth to birth interval in India is 36 months approximately 27% of birth in India occurs in less than 24 months after the previous birth and another 34% of birth occurs between 24 to 35 months.[1] The main reason for the decreased interval of birth is lack of knowledge of contraception in post-partum period. The contraception used during this period should be safe and effective and focus on extended post-partum period.

Importance of post-partum family planning is as follows:

- Maternal health: Women becoming pregnant at short intervals faces problems like anemia, abortion, premature rupture of membranes and high maternal mortality
- Child health: short birth interval leads to increased risk of pre-term babies, Intra uterine growth retardation (IUGR), and increased death in neonatal period
- To fulfill the Unmet needs: 65% of the women in first year of delivery have unmet needs for family planning. Only 26% of the of the women in India are using any contraception in first year after delivery.[2]

Post-partum period, for the purpose of contraception can be divided as follows:

- Immediate post-partum period: Period starts from the delivery of placental tissue to the 48 hours. after delivery. In this period, the counselling about the exclusive breast feeding and the patient should be provided with provisions of appropriate family planning methods like PPIUCD, sterilization
- Early post-partum period: up to 7 days after the delivery
- Extended post-partum period: from the 6 weeks to 1 year after delivery. Birth spacing methods like IUCD and others can be provided as per medical eligibility criteria (MEC).

Intra uterine contraceptive device (IUCD) has been used since decades for spacing the pregnancy. The patients are highly motivated and receptive to family planning method during the post-partum period. As the IUCD can be inserted in immediate post-partum period this leads to the effective contraception from Day 1 of the delivery. This also reduces the multiple visits to the health care centre.

The objectives of the study are to access continuation rate, expulsion rate and removal rate in patient with PPIUCD, access the complication rates with PPIUCD and to evaluate whether USG is an appropriate investigation for the follow up of the PPIUCD.

METHODS

It is a prospective observational study, carried out at department of obstetrics and gynecology, Mahatma Gandhi medical college and hospital, Jaipur after taking the clearance from Institutional Ethical Committee. The patients delivered, either vaginally or by LSCS, in the department of obstetrics and gynecology, giving informed consent for the insertion of PPIUCD were studied. 190 patients were counseled, 100 cases who gave the informed consent for insertion of PPIUCD were studied. Among those 50 were after normal vaginal delivery and other 50 with lower segment cesarean section. There were 2 cases post FTVD who lost to follow up. The study is carried out from March 2016 to September 2016.

Inclusion criteria

- Patient giving informed consent.
- The cu-T 380 A will be inserted just after delivery of placenta, intra cesarean, and within 48 hours of normal vaginal delivery.

Exclusion criteria

- History of AUB.
- History of sexually transmitted disease (STD) and pelvic inflammatory disease (PID).
- Postpartum hemorrhage, extensive genital trauma during vaginal delivery and LSCS.
- Benign and malignant trophoblastic disease.
- Distorted uterine cavity

Cu-T 380A is approved for the post-partum intra uterine contraceptive device. The cu-T 380 A is very effective. There are only .6 to.8 pregnancies per 100 women in first year of use.[3] It can be used for the 10 years continuously or for whatever time period the women wants up to 10 years. PPIUCD inhibits the sperm migration, sperm survival, ovum transport and causes inflammatory reactions in the endometrium due to sterile foreign body and copper.

Consent of the patient is taken in written on pre-designed consent form in both English and Hindi including potential risks.

Timing of insertion of PPIUCD

- Post placental: the PPIUCD is inserted within 10 minutes after the delivery of the placenta. Can be inserted manually or by instruments.
- Intra cesarean: inserted after delivery of placenta, inserted through the uterine incision manually and the incision is closed. Cu-T thread should not come in stichline.
- Within 48 hours of delivery

Method of insertion of PPIUCD

After taking informed consent, the patient and her records were examined to ensure that the patient is fit with respect to inclusion and exclusion criteria. Inspection of perineum, vaginal wall to exclude any tear or lacerations. If present and not bleeding heavily, insert IUCD and then repair. If there is excess bleeding from tear then repair first.

Visualization of cervix with Sim's speculum and grasp anterior lip of cervix with sponge holding forcep after cleaning the cervix with povidine iodine. The IUCD is taken in sponge holding forcep or Kelly's forcep byno touch technique. Gentle traction is given to the anterior lip of the cervix and the PPIUCD is inserted.

Abdominally uterus is pushed superiorly (upwards) thus straightening the angle between the vagina and the uterus. So, that the instrument can easily move and reach uterine fundus. The Kelly's forceps are advanced to the fundus and the resistance felt, this is confirmed by feeling thrust on the hand (per abdomen) on fundus. The PPIUCD is released and the instrument is swept to the right and withdrawn slowly keeping instrument open. The PPIUCD can be inserted manually at the fundus in post-placental and in LSCS cases.

Provide information of PPIUCD on discharge card, inform about the warning sign and side effects and to visit hospital in case of any sign, inform about the follow up.

Follow up: The patient is first evaluated after 48 hrs. of insertion. Patient was asked for satisfaction with this method. Pelvic examination was done to rule out STD, PID, and expulsion of IUCD. The warning signs and expulsion of PPIUCD were explained again. If PPIUCD is expelled then offer other contraceptive methods. USG was done to measure the distance of the horizontal arm of cu-T380A with the fundus, to know that the IUCD is properly placed or not. The same follow up steps were done at 6 weeks and 12 weeks of delivery.

RESULTS

In this study, the 50 cases of LSCS the expulsion and removal was observed in 4% and 14% of cases respectively, whereas in cases with FTVD 8.33% expulsion and 12.5% removal were observed. 82% and 79.2% continued the use of PPIUCD in LSCS and FTVD respectively (Table 1).

Table 1: Comparison of expulsion rate of PPIUCD after FTVD and LSCS.

Mode of delivery	Total Cases followed	Expulsion	Removed	Continued
LSCS	50	2 (4%)	7 (14%)	41 (82%)
FTVD	48	4 (8.33%)	6 (12.5%)	38 (79.2%)
Total	**98**	**6 (6.1%)**	**13 (13.3%)**	**79 (80.6%)**

Table 2: Continuation and Removal rates for the complications at 6 weeks.

Complications at 6 weeks	No. of patients	Continuation at 6 weeks	Removal at 6 weeks	Percentage Removed	Contribution to complications at 6 weeks
Thread Felt	52	52	0	0	53%
Pain abdomen	12	9	3	25	12%
Bleeding	5	5	0	0	5%
Pelvic infection	0	0	0	0	0
Perforation	0	0	0	0	0
No Complain	29	25 (+4expulsion)	0	0	30%

The major complains of the patients with PPIUCD at 6 weeks were irritation because of thread 53%. Pain abdomen is the second major complain (12%). Bleeding PV is observed in 5 cases. No complain was observed in 30% of the patients.

No case of pelvic infection or perforation was observed. Removal rate at 6 weeks is maximum with pain abdomen that is 25% of the patients who complained pain abdomen. Rest in all complains and complications the cases wished to continue the PPIUCD (Table 2).

The patient with no complains increases from 30% at 6 weeks to 74% at 12 wks. The major complain is again thread felt in 12% of the cases. Pain abdomen was there in 9% and bleeding PV was in 5% of the cases. 100% of the patient with bleeding PV gets the PPIUCD removed and 62% of the patient with pain abdomen got the PPIUCD removed (Table 3).

Table 3: Continuation and removal rates for the complications at 12 weeks.

Complications at 12 weeks	No. of patients	Continuation at 12 weeks	Removal at 12 weeks	Percentage Removed	Contribution to Complications at 12 weeks
Thread Felt	11	11	0	0	12
Pain abdomen	8	3	5	62	9
Bleeding	5	0	5	100	5
Pelvic infection	0	0	0	0	0
Perforation	0	0	0	0	0
No Complain	67	65(+2 expulsion)	0	0	74

There was no expulsion of PPIUCD at 12 wks when the distance of PPIUCD was < 10 mm at 6 wks of insertion. There is no relation between the expulsion and the distance of PPIUCD from fundus when the distance is 10-20 mm and more than 20 mm at 6 wks. In both categories the expulsion was in 3% of the cases Table 5.

Table 4: Relation of USG guided measurement of distance between fundus and PPIUCD at 48 hrs. with expulsion at 6 weeks.

Distance	No. of Patients	Expulsion	Percent
< 10 mm.	38	0	0
10-20 mm.	31	2	6.5
> 20 mm.	31	2	6.5

Table 5: Relation of USG guided measurement of distance between fundus and PPIUCD at 6 wks with expulsion at 12 weeks.

Distance	No. of Patients	Expulsion	Percent
< 10 mm.	30	0	0
10-20mm.	33	1	3
> 20 mm.	31	1	3

DISCUSSION

In the present study, the major complains of the patients with PPIUCD at 6 weeks were irritation because of thread 53%. Another study also concluded that the string problem (363 cases) is most common complication.[4] in present study, Pain abdomen is the second major complain (12%). Bleeding PV is observed in 5% cases. Removal rate at 6 weeks is maximum with pain abdomen that is 25% of the patients who complained pain abdomen. Rest in all complains and complications the cases wished to continue the PPIUCD. At 12 weeks, the patient with no complains increases from 30% at 6 weeks to 74% at 12 wks. The major complain is again thread felt in 12% of the cases. Pain abdomen was there in 9% and bleeding PV was in 5% of the cases. Other study also reported pain abdomen in 8.9% and menstrual complains in 5.5% cases.[5]The incidence of bleeding in different studies were 4.3%[6], 27.2%[7] and 23.5%, the removal due to pain and bleeding range from 6 to 8%.[8-10]

No case of pelvic infection or perforation was observed at both 6 weeks and 12 wks. The result is consistent with P. Malathi et al, there also author had no case of perforation and pelvic infection.[4] There is no case of uterine perforation in the study done at Rohtak.[11]Another trial did not find any instance of infection due to PPIUCD.[12] A study in Paraguay reported infection rate of 0.1%.[13] Our study is inconsistent with a study done in Jhansi which had higher pelvic infection rates of 4.3% and with Kumar et al. where the pelvic infections were 5%. A multicentric study in India reported overall infection of 4.5% amongst PPIUCD insertion.[5,14,15] Some studies like our study had not found any case of pelvic infections after PPIUCD insertion.[7,10,12]

There was no expulsion of PPIUCD at 6 weeks and 12 weeks, when the distance of PPIUCD was <10 mm from fundus at 48 hours and 6 wks. of insertion respectively. This study is consistent with Neha Goyal et al in which there is no expulsion in cases of distance <10mm.[16] In this study there was no relation between the expulsion and the distance of PPIUCD from fundus when the distance is 10-20 mm and more than 20 mm. At 6 wks, in both categories the expulsion was in 6.5% of the cases and at 12 weeks in both groups it was 3%. So, this conclude that there is no expulsion when distance is <10 mm but when the distance increases, we cannot predict the expulsion of PPIUCD on the basis of distance from the fundus and the USG is not appropriate diagnosis in predicting the expulsion of PPIUCD. This is contrary Neha G et al as they compared the cases on the basis of <10mm and more than 10 mm and concluded that the USG can predict the expulsion.[16]

The expulsion is more in the post vaginal delivery patients, the finding is consistent with Reetu Hooda et al.[11] In the present study, the Expulsion with the LSCS was 4% which is similar to Celen et al 5.3%.[10] in the present study, the total Expulsion rate is 6.1%, removal rate is 13.3% and the continuation rate is 80.6%. In other studies, where similar procedures and trained providers were there the similar rate of Expulsion were observed like 5.23% in Kittur and Kabadi et al, 5.3% in Reetu Hooda et.[11] The removal rates are higher than other recent studies which range from 3 to 8%.[7,9,10,15,16] Still in this study continuation rates are approx 81% and thus we are providing contraceptive method to the big population thus decreasing the unmet needs of contraception.

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