

Evaluation of Safety and Efficacy of Post Placental and Post-Surgical Abortion Insertion of Intrauterine CU-T 380a Devices: A Prospective Study

Jaydeb Mandal¹, Purnima Mandal²

¹Assistant Professor, Department of Obstetrics and Gynaecology, Malda Medical College, Malda, West Bengal. ²Clinical Instructor, College of Nursing, Kolkata Medical College, West Bengal.

ABSTRACT

BACKGROUND

India is the second most populated country in the world with a high abortion rate. In spite of availability of various contraception methods, numerous unwanted and unplanned pregnancies occur.

METHODS

This prospective study of [post placental (within 10 minutes of placenta delivery) and post-surgical abortion (by dilatation & evacuation)] CU-T 380A intrauterine contraceptive devices (IUCD) insertion was conducted at our institution from January 2016 to December 2016. Follow up study was done one year of last insertion up to December 2017. Total 580 post placental IUCD (PPIUCD) insertion after natural delivery and total 140 post-surgical evacuation insertions were done. Out of 580 PPIUCD insertion women, 394 (68%) and out of 140 post-surgical evacuation insertion women 105 (75%) attended follow up check-up. Their safety (perforation, irregular vaginal bleeding, unusual vaginal discharge, infection) and efficacy (pregnancy, expulsion, discontinuation) status were studied. Statistical analysis was carried out; descriptives were calculated for various clinical outcomes and chi square tests was used in categorical variations. For all the tests performed, results were considered statistically significant for $p < 0.05$ (table value 3.87) where variance is 1.

RESULTS

Out of 394 PPIUCD and out of 105 post-surgical evacuations IUCD followed up women, overall complications were low. No cases of uterine perforation or pregnancy were reported from any woman. Spontaneous expulsion rate was higher 11.16% (44) in PPIUCD insertions, expulsion in post-surgical evacuation women was only 4.76% (03). Unusual vaginal discharge was nearly 12% in both group of insertions. Infection rate was very low (3.80% in PPIUCD and 2.85% in post abortion insertion women). 25 women (6.34%) of PPIUCD insertion and 10 women (9.52%) of post abortion insertion women discontinued contraception by removing IUCD.

CONCLUSIONS

CU-T 380A IUCD is a strong weapon in family planning, as it allows women to obtain safe, long acting (10 years effectiveness), highly effective contraception. PPIUCD and post-surgical abortion IUCD insertion is the opportunity for the eligible candidates of immediate insertion of contraceptive devices and that should not to be missed.

KEYWORDS

PPIUCD, CU-T 380A, Surgical Abortion, D & E

Corresponding Author:

*Dr. Jaydeb Mandal,
Konark Apartment,
Flat 1E, 48 Sreenagar Main Road,
Kolkata-700094, West Bengal.
E-mail: jaydebmandal013@gmail.com*

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BACKGROUND

India has one of the highest number of maternal deaths in the world (122/100000 live birth, 2015-2017). Indian women have more children than desired. Recent studies estimate that prevention of unplanned and unwanted pregnancies could help avert 20-35% of maternal deaths and as many as 20% of infant deaths. Short interval between births are linked to higher maternal and child mortality.¹ Speroff et al 2008, on average women who do not breastfed ovulate by 45 days after child birth and possible as soon as the 28th day after child birth. Fertility begins prior to return of menses in 2 out of 3 women. It is evident, after surgical abortion that ovulation can occur as early as 10 days of evacuation of uterus² and more than 80% of women ovulate within one month of first trimester abortion.³

In 2015, total fertility rate of India was 2.40 births per women⁴ and 15.60 million abortions performed with an abortion rate 47.0 per 1000 women aged 15-49 years.⁵ Overall the abortion occurring in India for one third of pregnancies and out of all pregnancies occurring, almost half were not planned.⁵ In India as in many other countries post-partum and post abortion family planning is usually initiated after 6 weeks. Moreover in developing countries particularly, women who once go back home after delivery or abortions do not return even as routine post-partum and post abortion check-up leave aside contraception. Thus immediate post-delivery and post abortion family planning services need to be emphasized wherein the women leaves the hospital with an effective contraception in place. An IUCD has several advantages for use in post abortion and post delivery period as it is an effective, long term and reversible contraception, is coitus independent and does not interfere with breast feeding.

Cochrane reviews provide evidence of safety and feasibility of post-partum IUCD insertion in various settings.^{6,7} Remembering all those facts the present study was conducted at our institution to see the safety and efficacy of long acting CU-T 380A, IUCD in immediate post placental (PPIUCD) and immediate post-surgical abortion insertion women.

METHODS

This prospective study of post placental and immediate post-surgical abortion IUCD, insertion was conducted at Malda Medical College from January 2016 to December 2016 after approval of college Ethical committee and proper counseling and informed written consent from studies women. 580 women for PPIUCD and 140 women for post-surgical abortion insertion were enrolled in this study. In the enrolled women government supply IUCD, CU-T 380A were inserted within 10 minutes of placental delivery in 580 women and in 140 women IUCD insertion were done immediately after D & E operation of pregnancy not more than 14 weeks. All IUCD insertions were done by doctors, post insertion

counseling were done before discharge from hospital. They were advised for follow up examination at our Centre after 6 weeks, 6 months and one year of insertion. In all follow up visits, the women were asked for any symptoms of unusual vaginal discharge, irregular vaginal bleeding and any expulsion of CU-T devices noticed. Pelvic examination was performed to examine the descend of IUCD strings into the vagina and to check signs of infection and bleeding.

Exclusion Criteria

1. Haemoglobin less than 8 gm%.
2. Early rupture of membranes (rupture more than 18 hours before delivery).
3. Post-partum haemorrhage and post abortion excessive bleeding.
4. Coagulation disorders.
5. Signs of infection before labour and abortion.
6. Surgical abortion (D & E) more than 14 weeks gestation.

The primary outcome measures in terms of safety (perforation, unusual vaginal discharge, and irregular bleeding), efficacy (pregnancy, expulsion and discontinuations) and incidence of undescended IUCD strings were studied.

RESULTS

After exclusive counseling and maintaining exclusion criteria, 580 women for PPIUCD and 140 women for post-surgical IUCD insertions were recruited in our study. After taking written consent IUCD insertions were done by doctors. Table 1, shows 68% (n=394) women from PPIUCD and 75% (n=105) women of post abortion insertions were attended in our clinic at one year followed up study, all of them attended after 6 weeks follow up. All the parameters were studied among the women who attended both 6 weeks and one year follow up visits. The presence of irregular bleeding (table no 2) did not differ between both groups with 72 out of 394 (18.27%) in PPIUCD and 15 out of 105 (14.28%) in post abortion insertion (p= 2.61).

Symptoms of unusual vaginal discharge in Table no 3, were reported by 11-13% of both insertions, slightly more 48 (12.18%) as percentage in PPIUCD insertions than post abortion insertion (11.42%), p =.796. No woman was detected as serious infection. Women who complained of moderate pain in lower abdomen and foul smelling vaginal discharge (From Incidence of infection study, Table no 4) they were thoroughly examined, 15 women of PPIUCD insertion (3.80%) and 3 women of post-surgical evacuation insertion (2.85%) were detected as pelvic inflammatory disease and bacterial vaginosis, they were given treatment and two of them (one from each group of insertion) required removal of IUCD.

On expulsion study (Table no 5), spontaneous expulsion of IUCD occurred in 44 (11.16%) women in PPIUCD insertion and 5 (4.76%) of post abortion insertion women at follow up. Women who had IUCD after vaginal delivery had

significantly higher expulsion rates (p value 3.84, where table value is 3.84) than post abortion insertion. Among 44 women of post-delivery insertion- expulsions 26 expulsions were within 6 weeks of insertion. On per vaginal examination IUCD strings were not felt in 48 (12.1%) women of PPIUCD insertion and only 2 (1.9%) in post abortion insertion during follow up study (the cases of spontaneous expulsions were excluded). From Table no 6, it is clear that incidence of undescended or misplaced IUCD strings were more common in post-delivery insertion group than post abortion insertion group. All women with undescended strings underwent ultrasonography confirmation of intrauterine placement of the device.

Table no. 7 depicts, after 6 weeks follow up visit one women of PPIUCD insertion requested IUCD removal. On subsequent one year follow up visits total 25 (one woman had infection) of 394 women (6.34%) of PPIUCD insertion and 10 (one had infection) of 105 post abortion insertion women (9.52%), requested IUCD removal due to interest in menstrual irregularities, sexual discomfort and family pressure. From figure 1, after one year followed up of IUCD insertion, among 394 PPIUCD insertion women 325 (82.50%) and among 105 post abortion insertion women 90 (85.74%) continued CU-T 380A as contraception. There was no case of uterine perforation and pregnancy detected in either IUCD insertion women during their one year follow up visits.

Mode of Insertion	Total No. of Insertions	Follow Up at 6 Weeks	Follow Up One Year
After natural delivery	580	440	394 (68%)
After surgical abortion	140	119	105 (75%)

Table 1. Follow Up of IUCD Insertion at 6 Weeks and One Year

Type of Insertion	Total No. of Insertions	Irregular Bleeding Yes	Irregular Bleeding No	p
PPIUCD	394	72 (18.27%)	322 (81.72%)	2.611
Post abortion	105	15 (14.28%)	90 (85.71%)	

Table 2. Irregular Vaginal Bleeding

Mode of Insertion	No. of Insertions	Unusual Discharge Yes	Unusual Discharge No	p
After natural delivery	394	48 (12.18%)	346 (87.81%)	.796
After abortion	105	09 (8.57%)	96 (91.43%)	

Table 3. Unusual Vaginal Discharge

Mode of Insertion	Total No. of Insertions	Infection Yes	Infection No	p
PPIUCD	394	15 (3.80%)	379 (96.19%)	0.213
Post abortion	105	03 (2.85%)	102 (97.15%)	Table value is also 3.84

Table 4. Incidence of Infection One Year after IUCD Insertion

Mode of Insertion	Total No. of Insertions	Expulsion of IUCD in One Year Yes	Expulsion of IUCD in One Year No	p
Post natural delivery	394	44 (11.16%)	350 (88.83%)	3.84
After abortion	105	05 (4.76%)	100 (95.23%)	Table value is also 3.84

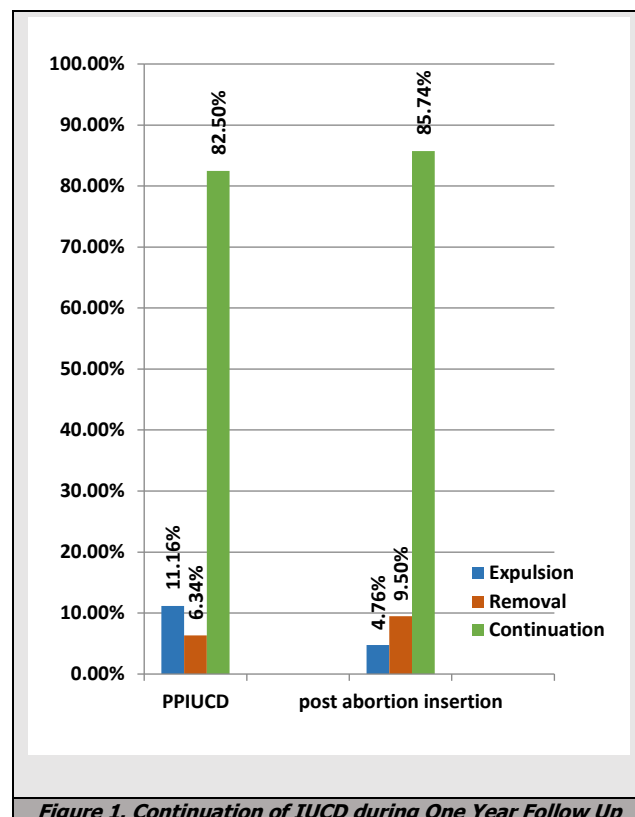
Table 5. Spontaneous Expulsions of PPIUCD

Mode of Insertion	No. of Women	Undescended or Misplaced Strings Yes	Undescended or Misplaced Strings No	p
After natural delivery	394	48 (12.18%)	346 (87.81%)	8.317
After abortion	105	02 (1.90%)	103 (98.09%)	

Table 6. Undescended or Misplaced IUCD Strings

Mode of IUCD insertion	No. of Women Studied	No. of Removal	%
After natural delivery	394	25	6.34%
After surgical abortion	105	10	9.5%

Table 7. IUCD Removal during One Year Study Period



DISCUSSION

A good number of women attended (68% of PPIUCD and 75% of post abortion insertion) at our follow up clinic due to regular contact with local grass root level health staffs. In a recent prospective study follow up of PPIUCD from peripheral health centre of India, scheduled follow up was observed in 62.5% cases.⁸ Sukla et al reported a follow up of 78.7% in a prospective longitudinal study.⁹ The symptoms of irregular bleeding per vagina was not influenced by type of insertion 18.27% PPIUCD vs. 14.25% post abortion insertion (p value 2.611) and incidence of irregular bleeding per vagina is comparable to other studies. In our studies the symptoms of irregular vaginal bleeding were not warrant removal of any IUCD and that was treated successfully. Sukla et al indicated a higher incidence of menorrhagia (27.2%) with CU-T 380A in post-partum women.⁹ Women reported of unusual vaginal discharge, actual infection was very low in our study, 3.80% in post placental and 2.85% in post abortion insertion. A multi centric follow up study in India reported an overall infection rate of 4.5% among PPIUCD insertion.¹⁰

In this study expulsions of IUCD after abortion was only 5 cases (4.76%) among that 4 cases in second trimester abortion and one case in first trimester abortion but expulsions were significantly higher in post placental IUCD insertion probably due to improper placement of IUCD. In

one retrospective study analysis, the risk of IUCD expulsion associated with second trimester abortion was significantly higher than first trimester abortion (7% vs. 1.6% $p=.02$).¹¹ Myometrial softening during pregnancy may contribute to perforation resulting from IUD placement after delivery.¹² Studies of immediate and delayed IUD insertion after abortion have not yet. Reported perforations in either group and the absolute risk of perforations after post abortion IUD placement is very low.^{13,14,15} Ultrasound guidance during post abortion IUD insertion may further minimize the risks of perforations. However in our study no case of uterine perforation was detected in either groups of PPIUCD and post abortion insertion during follow up.

It is known that some women reported that increased vaginal discharge with the IUCD, which is usually normal leucorrhoea and not a sign of infection.¹⁶ In our study 12.8% women presented with unusual vaginal discharge after PPIUCD insertion and 8.57% women complained of unusual vaginal discharge of post-surgical abortion IUD insertion women. No one case warranted for removal of IUCD, all were treated by a short course of medication and assurance. Total discontinuation rate (combination of removal of IUCD for different medical and personal reasons) of our study was higher than other recent studies (discontinuation rate ranging 3-8%).¹⁷ In our study spontaneous expulsion of IUCD in post-delivery group were more (11.16%) in comparison to post abortion group (4.76%). Probably for personal ground, post abortion insertion women demand more removal than PPIUCD insertion (9.5% vs. 6.34%).

Overall continuation rate in our study was more than 82% (continuation rate in PPIUCD insertion was 82.5% and in post abortion insertion was 85.74%). Regarding undescended IUCD strings in our study, it was not a problem in post abortion cases, only 1.2% strings were not descended in vagina but in post placental insertion IUCD strings were not felt in vagina in 12.18% cases on per vaginal examination. Counseling the women and confirmation of IUCD in uterine cavity by ultrasound were done and that was effective to reassure the women and encourage them to continue with the device.

CONCLUSIONS

Insertion of IUCD, CU-T 380A in post-placental and immediate post-surgical abortion is an effective, safe and convenient contraceptive method of birth spacing and limiting pregnancy. It is available free of cost in government sector hospitals and has long effectiveness. Although there is a relatively higher incidence of expulsions after post placental insertion they should be encouraged considering the advantages that come along. Women can take the advantages of family planning services on the same day by immediate post-delivery and post abortion IUCD insertion. Qualified, trained and experienced service provider plays a key role in reducing undescended strings rate and expulsion rate. Instead of only client counseling, couple counseling and head of the family member counseling will definitely

increase the acceptance rate and reduce removal rate. Promotion of health education highlighting the advantages of contraceptive methods and eliminating apprehension about the use of these methods is the need of hour.

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