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To assess the safety & expulsion rate of cut 380a in immediate postpartum period

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Abstract

Aims and Objectives: To assess safety of PPIUCD in terms of perforation, pain, bleeding, foul smelling vaginal discharge and assess expulsion rate at 6 weeks follow up and reasons for removal.

Methods: It was prospective study to assess the safety and efficacy of CuT 380A when inserted within ten minutes of placental expulsion up to 48 hours after delivery in 100 women delivering at tertiary Hospital, irrespective of maternal age, risk factors and mode of delivery (Vaginal /C- section).

Results: 5% patient had abdominal pain, 3% had vaginal discharge, 2% had coital discomfort, 7% had irregular bleeding, 7% had threads coming out of vagina, 2% had thread not felt, 5% had expulsion 2% had displacement, no perforation were found. CuT thread not felt in 2% women. Pelvic ultrasound was done. Suggestive of 1% expelled CuT and 1% normally placed CuT.

Conclusion: PPIUCD as a method of family planning helps to bring down the maternal mortality and to inculcate the good quality of life among the illiterate and economically lower strata women who are utilizing the health services in India.

Keywords: PPIUCD, cut, family planning, safety, expulsion

1. Introduction

Reduction in maternal mortality is an area of concern for governments across the globe. India's population, which crossed one billion in 2000, is projected to reach 1.53 billion by 2050 making it the most populous country in world [1]. Women of reproductive age group (15-49) make up approximately 248 million [1], with 1.24 billion population [2] and 254 women dying in childbirth for every 100000 births [3]. India accounts for more than 20% of global maternal and child deaths—most of them preventable. Indian women have more children than desired and often too close together. Family Planning can have a positive impact on population growth, maternal mortality, and infant and newborn outcomes.

Maternal outcomes when short birth to pregnancy (BTP) intervals <24 months are associated with increased risk of maternal mortality, induced abortion, miscarriage, adverse perinatal/neonatal/infant outcomes [4, 5].

During the postpartum period, delay in initiating contraception is common because of the challenges of caring for a new infant resulting an unintended pregnancy [6, 7].

The recommended interval before attempting the next pregnancy is at least 24 months in order to reduce the risk of adverse maternal, perinatal and infant outcomes by WHO [6]. For women with limited access to medical care, postpartum care before discharge provides an opportunity to discuss contraception, 65% may never return for the insertion [8, 9].

PPIUCD (Postpartum IUCD) are still emerging as a relatively new contraception choice in India. CuT380A is in the government supply. It is effective for 10 years, with failure rate of 0.6 to 0.8%. Risks of pregnancy, infection, perforation and expulsion are low among all IUD users. Immediate postpartum Cu-IUD insertion, particularly when insertion occurs immediately after delivery of the placenta, is associated with lower expulsion rates than delayed postpartum insertion. Additionally, post-placental placement at the time of caesarean section has lower expulsion rates than post-placental vaginal insertions. Insertion complications of perforation and infection are not increased by IUD placement at any time during the postpartum period [10-23].

2. Aims and Objectives

To assess safety of PPIUCD in terms of perforation, pain, bleeding, foul smelling vaginal discharge and assess expulsion rate at 6 weeks follow up and reasons for removal.

3. Materials and Methods

- Study design-prospective observational study
- Study period: SEP 2016 to NOV 2017
- Place of study: Women delivering in tertiary care hospital
- Sample size: 100
- Time of insertion: IUCD inserted up to 48 of delivery.

The present study is prospective study to assess the safety and efficacy of Cut 380A when inserted within ten minutes of placental expulsion up to 48 hours after delivery in women delivering at tertiary Hospital, irrespective of maternal age, risk factors and mode of delivery (vaginal /C- section).

Counselling for PPIUCD is done as a part of study either during their antenatal visit or early labour or post- partum period (within 48hrs.), while preparing for a scheduled cesarean section.

To assess the safety in terms of abdominal pain, vaginal discharge/coital discomfort, abnormal bleeding, missing CUT thread, ex, pulsion, displacement of CuT and perforation, if woman is having one of the mention side effect then woman may be unsatisfied, if not then satisfied.

3.1 Inclusion criteria

- All antenatal women admitted in tertiary care hospital between 28 to 42 weeks of gestation
- Prior consent obtained for PPIUCD after counselling
- Willing to have Cu T inserted and follow up
- Anticipate delivery (vaginal/C-section)

3.2 Exclusion criteria

- Patient's refusal.
- Patients with puerperal sepsis,
- Unresolved postpartum haemorrhage
- Rupture of membranes >18 hrs.
- Temperature >38-degree C, tender uterus
- Tumours distorting uterine cavity like fibroids
- AIDS not on ARV therapy
- Extensive genital trauma.

Follow up - 6 weeks after Cut insertion.

3.3 Methodology

A specially designed modified proforma from PPIUCD reference manual will be used to collect the data of women attending hospital between period September 2016 to November 2016, which includes patient's particulars, time of counselling, informed consent will be taken just before insertion, type of PPIUCD insertion, instruments used for insertion, with reporting format including type of follow up (clinic visit/telephonic), time of follow up after 6 weeks of CuT insertion and finding at follow up (expulsion/infection/missing threads/other complaints/no complaints), actions taken for complications.

Procedure

Informed & written consent obtained. After delivery and active management of third stage labour reconfirming willingness for PPIUCD perineum is inspected for lacerations cervix visualized using vaginal speculum and anterior vaginal wall retractor cervix and vagina cleaned twice with sterile swabs grasp anterior lip of cervix with sponge holding forceps IUCD with forceps held in a sterile packet forceps with IUCD inserted through cervix to lower uterine cavity, avoiding touching vagina. Place the left hand on the sterile drape over the fundus of uterus.

IUCD with forceps advanced upward until it can be felt at fundus, following contour of uterine cavity.

Forceps opened and IUD released at fundus keeping the tongs open forceps swept to side walls of uterus and slowly removed uterus stabilized until forceps are out. Proper placement confirmed by non-visibility of strings through cervix. Follow up at 6 weeks to assess expulsion, infection, missing threads, any other.

Intra-Cesarean insertion of the IUCD

Uterine cavity was inspected for presence of malformations following placental delivery, which would limit use of IUCD. The IUCD was removed from the insertion sleeve and placed on the sterile field. Uterus is stabilized by grasping it at fundus. IUCD is held between middle and index finger. It is inserted into the uterus through uterine incision and released at fundus of uterus. Hand is removed slowly from the uterus. Enough care is taken not to dislodge IUCD as hand is removed. Strings were guided towards the lower uterine segment without disturbing IUCD'S fundal position. Enough care was taken not to include IUCD strings during uterine closure.

4. Results and Analysis

Table 1: Distribution as per age group

Age Group	Frequency	Percentage
15-20 Years	10	10%
21-25 Years	50	50%
26-30 Years	28	28%
31-35 Years	9	9%
> 35	3	3%
Total	100	100%

Majority of women were in 21-25 years age group.

Table 2: Distribution as per parity

Parity	Frequency	Percentage
Primiparous	45	45%
Multiparous	55	55%
Total	100	100%

Majority of women were multiparous.

Table 3: Distribution as per the mode of delivery

Mode of delivery	Frequency	Percentage
Vaginal	45	45
Intracessarean	55	55
Total	100	100

Majority of Cut inserted during caesarean section.

Table 4: Distribution as per time of insertion

Time of insertion	Frequency	Percentage
Within 10 min	77	77
10 min to 48 hours	23	23
Total	100	100

Out of 100 women 77 CUT were inserted immediate postpartum and rest of were inserted between 10 minute to 48 hours after delivery.

Table 5: Distribution as per patient's response

Response	Frequency	Percentage
Satisfied	68	68
Unsatisfied	32	32
Total	100	100

Out of 100 women 68 were satisfied with Cut and rest were unsatisfied.

Table 6: Distribution as per complication

Mode of presentation	No of cases	Percentage
Abdominal Pain	5	5
Vaginal Discharge	3	3
Coital Discomfort	2	2
Irregular Bleeding	7	7
Threads Coming Out of Vagina	7	7
Threads Not Felt	2	2
Expulsion	5	5
Perforation	0	0
Displacement	2	2

Out of 100 women 5 were have abdominal pain, 3 were have vaginal discharge, 7 were have irregular bleeding, 2 were have coital discomfort, Cut thread were not felt in 2 women, threads coming out of vagina in 7 women. Cut expelled in 5 women and displaced in 2 women. no perforation was observed. 6 women had their PPIUCD removed within the six weeks of insertion due to side effect (abdominal pain, bleeding, threads coming out of vagina) while 2 women had their PPIUCD removed due to family pressure.

It shows that nearly all women were satisfied with their choice of PPIUCD at the time of insertion and over 67% reported that they were happy with the IUCD at six weeks following insertion.

Table 7: Distribution as per ultrasonographic finding in a missing cut thread per vaginal

Usg Finding	Frequency	Percentage
Normally Placed	1	50%
Displaced	0	0
Perforation	0	0
Expulsion	1	50%
Total	2	100%

Cut thread not felt in 2 women out of 100 in a follow up visit. Pelvic ultrasound suggestive of 1 expulsion and 1 normally placed Cut.

Table 8: Distribution as per cut removal

Removal due to	Frequency	Percentage
Complication	6	75
Family pressure	2	25
Total	8	100

Out of 100 women 6 cut removed due to complication while 2 due to family pressure. So the removal rate is 8% it shows that Cut is a safe and effective method of reversible contraception, with low expulsion and high continuation rates.

Table 9: Distribution as Per Ultrasonographic Findings in cut Thread Coming out of Vagina

Usg finding	Frequency	Percentage
Normally placed	5	71%
Displaced	2	28%
Perforation	0	0
Expulsion	0	0
Total	7	100

Out of 100 women 7 were complaining of CUT thread coming out of vagina. Pelvic ultrasound suggestive of 2 displaced CuT and 5 normally placed cut.

Table 10: Association between parity and expulsion rate.

Parity	Expulsion Rate	Percentage
Primiparous	1	20
Multiparous	4	80
Total	5	100

Out of 100 women 5 Cut were expelled out. Table shows that expulsion common in multiparous women.

Table 11: Association between expulsion rate and mode of delivery

Mode of delivery	Expulsion Rate	Percent
Vaginal	4	80
Lscs	1	20

It shows that majority of CuT 80% expelled out if they were inserted after vaginal delivery

Table 12: Association between parity and abdominal pain

Parity	Frequency	Percentage
Primiparous	3	60
Multiparous	2	40
Total	5	100

Out of 100 women 5 were have abdominal pain. Out of 5 women 3 were primiparous and 2 were multiparous.

Table 13: Association between parity and irregular bleeding

Parity	Frequency	Percentage
Primiparous	5	71.4
Multiparous	2	28.5
Total	7	100

Out of 100 women 7 were have irregular bleeding. Out of 7 women 5 were primiparous and 2 were multiparous.

Table 14: Association between parity and vaginal discharge

Parity	Frequency	Percentage
Primiparous	2	66.6
Multiparous	1	33.3
Total	3	100

Out of 100 women 3 were have irregular bleeding. Out of 3 women 2 were primiparous and 1 was multiparous.

5. Discussion

In study by Ahuja *et al.* 2014, expulsion, assessed at six weeks, was lower for the immediate group compared with the early group (9% versus 24%, reported $P = 0.0037$). In our study also only 1% CuT expelled.

No perforation or pelvic inflammatory disease occurred, which is same in our study. In Ahuja 2014, complications leading to removals were 2.2%, while in our study 6% were removed due to complications & 2% were removed due to family pressure.

In a study by Halder A. *et al.* (2016), expulsion rate was 4% in the vaginal group and 2% in intra-caesarean group, while in our study 80% of expelled CuT were associated with vaginal delivery and 20% of expelled CuT were associated with caesarean section. 20% of expelled CuT associated with primiparous women, 80% of expelled CuT associated with multiparous women.

In a study by Somesh Kumar *et al.* (2012) nearly all women were satisfied with their choice of PPIUCD at the time of insertion and over 90% reported that they were happy with the IUCD at six weeks following insertion, in our study 68% of women had no complaints and they were satisfied with PPIUCD.

6. Summary

1. Population group with highest number was 21-25 years. Mean age group was 45% patient were primiparous and 55% were multiparous.
2. 45% CuT inserted after vaginal delivery while 55% CuT inserted during caesarean section.
3. 77% CuT were inserted immediate postpartum while delayed CuT insertion seen in 23% patient.
4. Out of 100 patient 68 women had no complaint with CuT. It means they were satisfied, rest of the patient were

unsatisfied.

5. 5% patient had abdominal pain, 3% had vaginal discharge, 2% had coital discomfort, 7% had irregular bleeding, 7% had threads coming out of vagina, 2% had thread not felt, 5% had expulsion 2% had displacement, no perforation were found.
6. CuT thread not felt in 2% women. Pelvic ultrasound was done. Suggestive of 1% expelled CuT and 1% normally placed CuT.
7. 8% women wanted to remove her CuT. 6% were due to complication, 2% were due to family pressure.
8. Out of 100 women 7 had complaint of CuT thread coming out of vagina. Pelvic ultrasound was done. It was suggestive of 5 were normally placed CuT and 2 were displaced CuT.
9. 20% of expelled CuT associated with primiparous women. 80% of expelled CuT associated with multiparous women.
10. 80% of expelled CuT were associated with vaginal delivery and 20% of expelled CuT were associated with caesarean section.

7. Conclusion

PPIUCD as a method of family planning helps to bring down the maternal mortality and to inculcate the good quality of life among the illiterate and economically lower strata women who are utilizing the health services in India.

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