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Original Research Article

Evaluation of clinical outcome of post placental insertion of Cu T 380 A in women undergoing caesarean delivery

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ABSTRACT

Background: The objective of the study was to evaluate clinical outcome of insertion of post placental Cu T 380 A in women undergoing caesarean delivery.
Methods: A prospective observational study was carried out in the department of obstetrics and gynecology, Dr RPGMC Kangra at Tanda (Rural Medical College) to evaluate the clinical outcome of post placental Cu T 380 A insertion in women undergoing caesarean section after taking approval of protocol review and institutional ethics committee of the institution. A total of 104 women delivering by caesarean section and wanting post-placental intra-caesarean Cu T 380 A insertion and who were meeting WHO standard medical criteria for PPIUCD insertion and were willing to comply with the study protocol was recruited for the study.
Results: The present study showed that there were no major complications and only minor side effects were like pain, fever, discharge and irregular bleeding which were observed in only 5-15% of women during hospital stay and during follow up visit up to 6 months. String became visible in 72.12% of women at the 6 weeks follow up visit. The string visibility increased with time and at 6 months follow up stings became visible in 90.81% of the cases. Continuation rate was 100% at 6 weeks post-partum follow up. After that spontaneous expulsion occurred in 4 cases (3.84%) and another 4 women (3.84%) requested removal for various reasons leading to continuation rate of 92.3% at six months post-partum follow up. There was no case of pregnancy with Cu T in situ with no failure at the end of study at six months post-partum.
Conclusions: Intra caesarean insertion of PPIUCD is practical, convenient, safe, effective and acceptable contraceptive method for spacing of the birth in this rural setting.

Keywords: Clinical outcomes, Continuation, Cu-T 380 A, Family planning, Intrauterine contraceptive device, Postpartum contraception

INTRODUCTION

Family planning is important not only for population stabilization, but it has been increasingly realized that family planning is central to improve maternal and new-born survival and health. Postpartum period is one of the vulnerable periods both for women and infant where health needs of these women as well as the risk of a future unwanted pregnancy should be taken care of pregnancy occurring within six months of the last delivery holds a 7.5-fold increased risk for induced abortion and a 1.6-fold increased risk of stillbirth.[1] Initiation of contraception during this period is important to prevent unintended pregnancy and short birth intervals. It can avert more than 30% of maternal deaths and 10% of child mortality. IUCD's are among the most commonly used reversible method of contraception in women of reproductive age worldwide.[2] It is a very

inexpensive contraception method for long term pregnancy prevention and is virtually undetectable by both the woman and her partner. This approach is more applicable in our country where delivery may be only time when a healthy-women comes in contact with health care personal. Provision of IUCD in the immediate postpartum period offers effective and safe method for spacing and limiting births. Taking advantage of the antenatal care and in labour room counselling on family planning, immediately post-partum IUCD insertion is a good option as a contraceptive method. The increased institutional deliveries are the opportunity to provide women easy access to immediate PPIUCD services.[3]

Immediate post placental IUCD insertion (PPIUCD) during caesarean section provides a good opportunity to achieve long term contraception with minimal discomfort to the women.[4] The efficacy of intra-caesarean IUCD insertion without any added risk of infectious morbidity has also been reported by various studies. It is being increasingly practiced after reported safety and lower expulsion rates following intra-caesarean IUCD insertion. This technique offers the obstetrician an opportunity to insert the IUCD into the uterus under vision, thus obviating the fear of perforating the uterus during the procedure. Initiating IUCD use during caesarean has the added advantage of eliminating a six-week postpartum waiting period and an additional hospital visit. However, despite the reported safety and efficacy, obstetricians are still hesitant to implement the advantages of Copper T 380A IUCD to women undergoing operative delivery.

PPIUCDs are still emerging as a relatively new contraception choice in India and it has a huge potentiality and abundant scope in India. Intra caesarean IUCD insertion may be an alternative to tubectomy for some couples especially in multiparous women and the group of women who refuse tubectomy on religious grounds. While follow-up data on intra-caesarean PPIUCD insertions are available from international sources, given the scale at which PPIUCD services are being introduced in India, it is important to generate country-based evidence on the post-insertion outcomes. However, safety and acceptance of post placental IUD during caesarean section has not been studied widely in rural health settings. With the above background, this study is being done with the aim of finding the safety and efficacy of post-placental Cu T 380 A insertion during caesarean section as a method of contraception.

METHODS

A prospective observational study was carried out in the department of obstetrics and gynecology, DR RPGMC Kangra at Tanda (Rural Medical College) to evaluate the clinical outcome of post placental Cu T 380 A insertion in women undergoing caesarean section after taking approval of protocol review and institutional ethics committee of the institution.

A total of 104 women delivering by caesarean section and wanting post-placental intra-caesarean Cu T 380 A insertion and who were meeting WHO standard medical criteria for PPIUCD insertion and were willing to comply with the study protocol was recruited for the study.

Inclusion criteria

- 18-45 years old
- Gestational age 37-42 weeks
- Desire to have CuT after counselling before insertion
- No infections
- No intra partum haemorrhage
- Hb ≥10 gl/dl.

Exclusion criteria

- Women not meeting WHO standard medical eligibility criteria for PP IUCD insertion
- Known allergy to copper
- History of pelvic inflammatory disease
- Women known to have ruptured membrane for more than 18 hours prior to delivery
- Women with abnormalities of the uterus
- Unresolved PPH
- HIV/AIDS stage 4 diseases.

Women were counselled about PPIUCD insertion during antenatal visits and/or after admission to the hospital. Women were explained about study in detail including advantage and limitations of methods and repeated counselling was done prior to caesarean section. A written, informed consent was taken from the women who were willing to participate in the study and comply with study protocol. The insertion of IUCD was done after delivering the placenta, using the Kelly's/sponge holding forceps/ manually through the uterine incision and fundal placement of the device was ensured. No attempt was made to direct the IUCD strings towards the internal os. Antibiotics were administered as per the hospital protocol for caesarean delivery. Women were observed daily for evidence of postpartum haemorrhage or sepsis and any other complaint during the entire hospital stay. Patient was examined before discharge.

Prior to discharge

The type of Cu T, date of insertion and date of validity was mentioned on the discharge card. The participants were asked to return for scheduled follow-up visits at 6 weeks and 3 months and 6 months. The date of first follow up visit was mentioned on discharge card and will be reminded telephonically for review on due date or earlier in case of

- Foul smelling vaginal discharge different from the usual lochia
- Lower abdominal pain
- Fever with chills

- Suspicion that the IUCD has fallen out
- Excessive bleeding P/V and feeling of being pregnant.

RESULTS

Socio demographic profile of Cu T 380 A acceptors

Majority of the women were aged between 21-30 years (77.89%). Five women (4.81%) were more than 36 years of age and only one woman was <20 years of age (Table 1).

Table 1: Socio demographic profile of Cu T 380 A acceptors (n=104).

Parameters	Number	Percentage
Age group (years)		
≤ 20	1	0.96%
21-25	37	35.58%
26-30	44	42.31%
31-35	17	16.35%
36-40	5	4.81%
Literacy		
Illiterate	7	6.73%
Matric	20	19.23%
Sen secondary	32	30.77%
Graduate and above	45	43.27%
Booking status		
Emergency	Booked	101%
Elective	Unbooked	3%

Out of 104 women in the study, 97 (93.2%) were educated and only 7 women were illiterate. Acceptability of Cu T 380 A increased with education level. Majority of women (97.12%) were booked cases and 90.38 per cent belonged to rural areas from Kangra and adjoining districts of Himachal Pradesh (Table 1).

Obstetric profile of Cu T 380 A acceptors

Forty seven out of 104 women (45.19%) in the study were primipara who had PPIUCD insertion during their first delivery (present) by LSCS and 49 (47.12%) were para 2 (Table 2). Only 8 women (7.69%) were para 3 and above.

In 57 multiparous women who had PPIUCD insertion during caesarean section for the present delivery, 39 women (68.42%) had vaginal delivery in past, 11 women (19.30%) had previous one caesarean section (previous 1 LSCS) and 7 had two or more previous caesarean sections (previous 2 LSCS or more).

Among the 57 multiparous women nearly 80.70% (46 cases) had previous one live issue, 15.7% (9 cases) had 2 or more live issues and only 2 women had no previous live issue.

Table 2: Obstetric profile of Cu T 380 A acceptors.

Parameters	Number	Percentage
Parity		
Primipara	47	45.19%
Multipara 2	49	47.12%
Multipara 3	8	7.69%
Mode of previous delivery		
NVD	39	68.42%
Previous 1 LSCS	11	19.30%
Previous 2 LSCS or more	7	12.28%
Previous live issue among multiparous women		
0	2	3.51%
1	46	80.70%
2 & above	9	15.79%
Period of gestation at time of caesarean section		
37-38	16	15.38%
38-39	23	22.12%
39-40	38	36.54%
40-41	26	25.00%
41-42	1	0.96%
Time of counselling		
Antenatal, early labour and before caesarean section	40	38.46%
Early labour and before caesarean section	64	61.54%
Emergency/elective LSCS		
Emergency	72	69.23%
Elective	32	30.77%

Majority of women (77 cases) had caesarean section at term between 37-40 weeks of period of gestation (74.04%) followed by post-dated gestation between 40-42 weeks in 27 cases (25.96%). None of the patient having period of gestation <37 weeks was included in the study (Table 2).

Table 3: Duration of hospital stay.

Hospital stay	Number	Percentage
4 days	90	86.54%
5 days	9	8.65%
6 days	3	2.88%
7 days	2	1.92%

Counselling for PPIUCD insertion during caesarean section was done during antenatal period in 40 women (38.46%). In these women counselling was done again in early labour and before caesarean section. Whereas, in remaining 64 women (61.54%) the counselling was done for the first time during early labour and again before caesarean section (Table 2).

More than 2/3rd (72/104) of women had emergency caesarean section (69.23%) and in 32 women (30.77%) elective caesarean section was done.

Women were discharged on 4th post-operative day in majority of cases (86.54%) with no major complication and in rest of the women (13.46%) hospital stay was between 5 to 7 days. None of the women required to stay for more than 7 days (Table 3).

Post insertion complication and outcomes

During hospital stay pain was the most common post insertion complication observed in 11 out of 104 women (10.58%) followed by fever in 7 women (6.73%). There was no case of PPH, foul smelling lochia, sepsis, wound infection and urinary complications (Table 4).

Most common complaint during first follow up visit at 6 weeks post-partum was pelvic pain (13.46%) followed by discharge per vaginal (6.73%) and irregular bleeding (5.77%). None of women reported with fever and wound infection (Table 5). Most common complications during first follow up at 6 weeks was pelvic pain (13.46%) followed by discharge per vaginal (6.73%) and bleeding (5.77%).

Table 4: Post insertion complication during hospital stay.

Complication	Hospital stay	
	Number	Percentage
PPH	0	0.00%
Fever	7	6.73%
Pain	11	10.58%
Foul smelling lochia	0	0.00%
Sepsis/post-partum	0	0.00%
Wound infection	0	0.00%

Table 5: Follow up of post placental intra-caesarean Cu T 380 A.

Adverse events	6 weeks		3 months		6 months	
	Number	Percentage	Number	Percentage	Number	Percentage
Discharge	7	6.73%	5	4.81%	4	4.08%
Bleeding	6	5.77%	7	6.73%	5	5.10%
Pelvic pain	14	13.46%	14	13.46%	7	7.14%
Other	0	0.00%	0	0.00%	-	-

Table 6: String visibility with Cu T in situ and spontaneous expulsion.

Follow up	6 weeks No. (%)	3 months No. (%)	6 months No. (%)
String visibility with Cu T in uterine cavity			
String visible	75 (72.12%)	86 (82.69%)	89 (90.81%)
String not visible	29 (27.88%)	18 (17.31%)	9 (9.18%)
Spontaneous expulsion			
Complete expulsion	0	2	1
Partial expulsion	0	1	0

Table 7: Continuation rate of Cu T 380 A at follow-up.

Particulars	1st visit		2nd visit		3rd visit	
	Number	Percentage	Number	Percentage	Number	Percentage
Continuous	104	100.00%	98	94.23%	96	92.30%
Expulsion/removal	0	0.00%	6	5.77%	2	1.92%

At second follow up visit at 3rd month post-partum also pelvic pain (13.46%) was the main complaint of the women. Bleeding (6.73%) and discharge per vaginal (4.81%) were the other symptoms reported by the women. No case of fever and wound infection was reported (Table 5).

At 3rd follow up visit at 6-month pain (7.14%) was the most common complaint followed by excessive menstrual bleeding (6.12%) and discharge (4.08%). None of the women had fever and wound infection (Table 5).

In most of studies including the present study pelvic pain and excessive menstrual bleeding were the two most common complaints at 3rd follow up visit at 6 months.

In the present study there were no major complications and only few patients reported minor side effects like pain, discharge and irregular bleeding. Though these minor side effects occurred slightly more in emergency caesarean as compared to elective caesarean during hospital stay and follow up visits at 6 weeks, 3 months and 6 months, however, there was no statically significant

difference between the two. On first follow up visit at 6 weeks the strings were visible on P/S examination in 72.12% (75/104). However, IUCD string was not visible in 29 (27.88%) women on first follow up visit (Table 6).

String visibility increased further in 11 more cases during second follow up visit at 3rd month and strings became visible in total 86 out of 104 cases (82.69%) as compared to 75 cases (72.12%) during first follow up visit.

Strings visibility further increased during third follow up visit at 6 months and strings became visible in 3 more cases increasing string visibility to 89 out of 98 cases. In remaining 9 cases strings were not visible on third visit (Table 6).

During the first follow up visit at 6 weeks there was no case of expulsion or removal of Copper T. During the second follow up visit at 3rd month spontaneous expulsion of IUCD occurred in 2 (1.92%) cases completely and in 1 case IUCD was partially expelled into cervical canal which was removed. Further 3 more women requested for removal for various reasons.

During third follow up visit at 6 months there was one case of complete expulsion of Cu T and in 1 case Cu T was removed on the request of woman.

Therefore, at the end of the study after 6th month post-partum there were 4 cases (3.84%) of spontaneous expulsion and 4 cases (3.84%) of removal out of total 104 women who had PPIUCD insertion (Table 7).

The continuation rates was 100% up to first follow up visit at 6 weeks while during second follow up visit at third months and third follow up visit at sixth months the continuation rate was 94.23 and 92.30%, respectively.

DISCUSSION

From this study, it was found that 77.89 per cent of the patients who accepted PPIUCD were in age group 21-30 years. Upmanyu and Kanhere also found that average age of PPIUCD acceptor was 28.3 years.[5] This was probably because most of the patients who came to the hospital for delivery also belong to the age group 20-30 years.

It was observed that acceptability of PPIUCD increased with the increase in education level. This could be reasoned out that educated women are more aware about the modern contraceptive methods to increase spacing than the less educated women. This was similar to a study done by Singh et al, in which they found that acceptance of PPIUCD was higher among women with primary and secondary education (65.16%) as compared to illiterate.[6] This finding confirms importance of education in declining future pregnancy. Similar findings are in conformity with Safwat et al, which showed that education has a positive effect on modern contraceptive use.[7] In this study most of women were either para 1 or para 2 (92.31%). This may be because of the reason that women with high parity undergoing caesarean section preferred permanent methods of sterilization. Similar observation was made by Garuda et al.[8] However, lesser number of women who accepted PPIUCD were Primipara in the study by Bedi et al, (24%) and Shanavas et al, (26.7%).[9,10] In present study only 7.69 per cent of women Para 3 and above which is similar to Garuda et al, (1.36%).[8] This may be because women having para 3 or above preferred for permanent method of sterilization (Tubectomy) during LSCS.

In this study among the 57 multiparous women nearly 80.70 per cent (46 cases) had previous one live issue. These results are similar to the findings of Sharma et al, who reported more acceptances in women who have 1 or 2 previous live issue as compared to women having more than two previous living children.[11]

Out of 104 women who had PPIUCD insertion during LSCS 64 women (61.54%) were counseled during early labour and before LSCS and in 40 cases (38.46%) counseling for PPIUCD was done during antenatal period also. These results are in conformity with the findings of Shanavas et al, also who concluded that acceptance was higher when women were given information during early labour (56%).[10]

More than 2/3rd (72 cases) of patients in whom PPIUCD was inserted, LSCS were done in emergency and only in 32 cases (30.67%) it was done during elective LSCS. This is because of fact that in study institution nearly 3/4th of LSCS are emergency LSCS. These results are in contrary to that of study by Garuda et al, where they found higher acceptability/insertion during elective LSCS (69.54%).[8]

Majority of women (90) had a hospital stay of 4 days. However, in remaining 14 women hospital stay was between 5-7 days. None of patient required to stay for more than 7 days. These results in conformity with the finding of Singal et al, who reported that 94.33% of women had a hospital stay more than four days.[12]

Most common complications during first follow up at 6 weeks was pelvic pain (13.46%) followed by discharge per vaginal (6.73%) and bleeding (5.77%). Arshad et al, also reported similar findings.[13] They observed back ache/pain abdomen (14.2%), discharge per vaginal (12.5%) and bleeding (11.6%) to be the common complications during first follow up visit at 6 weeks.

The percentage of women with various complications during second follow-up visit at 3 months followed almost similar trend as it was observed during the first follow up visit at 6 weeks. The common complications at second follow up in this study were pelvic pain (13.46%), excessive menstrual bleeding (6.73%) and discharge per vaginum (4.81%). No case of fever with chills, wound infection and pregnancy with IUCD in situ was reported.

These results are in conformity with the findings of Singal et al, and Arshad et al.[12,13]

At 3rd follow-up visit at 6 months pain (7.14%) was the most common complaint followed by excessive menstrual bleeding (6.12%) and discharge (4.08%). None of the women had fever and wound infection. In most of studies including the present study pelvic pain and excessive menstrual bleeding were the two most common complaints at 3rd follow up visit at 6 months. Similarly, the pain was the most common complaint at 6 months follow up visit in the study by Arshad et al, (15%) and Mishra et al (35.60%).[13,14] Whereas excessive bleeding was the most common complaint in the studies by Garuda et al (10.41%), Sharma et al (14.63%), Singh et al. (15.70%) and Rahman and Banerjee (6%).[6,8,11,15] In none of the study pregnancy with Cu T in situ was observed.

In the present study it was observed that visibility of strings of PPIUCD increased with time. In first follow up visit at 6 weeks strings were visible in 72.12% (75/104 cases) which increased with time and during second follow up visit at 3 months in 82.69% (86/104 cases) and at the end of 6 months strings were visible in 90.82% (89/98 cases). These results are in accordance with the findings of Zulficar et al, who reported missing thread in 8% of cases.[16] In another study by Garuda et al, missing thread was observed in 14.54% of cases.[8] Comparatively higher percentage of missing thread about 30% and 35.45% was found in studies by Rahman and Banerjee and Shanavas et al, respectively.[10,15] However, Nayak and Jain observed missing thread in only 4.83% of cases.[17]

The success rate of intra caesarean IUCD placement can be measured by the continuation rate. In the present study continuation rate was 100, 94.23 and 92.30 per cent at the end of 6 weeks, 3 months and 6 months follow visits, respectively. This corresponds with the satisfaction rate of this study i.e. 92.30 % at the end of 6 months. This has emphasis on the correct fundal placement of device during caesarean section avoiding downward displacement. Results similar to present study at first follow up at 6 weeks, continuation rate of 100% was also observed by Singal et al and Shahnavas et al.[10,12] In this study 92.30% cases continued IUCD at the end of 6 months. In various studies by Gupta et al, Arshad et al, Singal et al, Halder et al, Shahnavas et al, also had continuation rate more than 90 per cent at the end of 6 months.[10,12,13,18,19] Whereas, Ndegwa et al, Zulficar et al and Garuda et al had a lower continuation rate of 80, 82 and 83%, respectively.[8,16,20]

CONCLUSION

Intra-caesarean section PPIUCD is easy, safe, effective, long acting and reversible contraception with low expulsion and failure rate and high continuation rate with only minimal minor side effects. Although the number of women in present study was small, authors conclude that intra caesarean insertion of PPIUCD is practical, convenient, safe, effective and acceptable contraceptive method for spacing of the birth in our rural setting where women have limited access to medical care and chance of women returning for postnatal counselling and contraception is low.

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