

Clinical Outcome of Postplacental Copper T 380A Insertion in Women Delivering by Caesarean Section

SUNITA SINGAL¹, REKHA BHARTI², RUPALI DEWAN³, DIVYA⁴, ANJALI DABRAL⁵,
ACHLA BATRA⁶, MANJULA SHARMA⁷, PRATIMA MITTAL⁸

ABSTRACT

Introduction: Short interconception period after caesarean section and its associated risk of increased morbidity, mortality and surgical interventions could be avoided by postplacental IUCD insertion during the procedure. Despite the safety reports on intra-caesarean IUCD insertion, obstetricians are still hesitant to extend the benefit of this long acting reversible contraception to women undergoing operative delivery.

Objective: To study the clinical outcome (safety, efficacy, expulsion and continuation rates) of postplacental Copper T 380A insertion in primiparous women undergoing caesarean section.

Materials and Methods: This study was a prospective observational study, carried out in the Department of Obstetrics and Gynaecology, Safdarjung hospital, which is a tertiary care hospital of Northern India. Primiparous women who delivered by caesarean section over a period of six months (July 2012 to December 2012), willing for postplacental intra-caesarean IUCD insertion, and willing to comply with the study protocol,

were recruited for the study. All these subjects fulfilled the WHO Standard Medical Criteria for PPIUCD insertion; follow up visits were scheduled at 1, 3, 6 and 12 months.

Results: A total of 300 primiparous women underwent postpartum intra-caesarean insertion of Copper T 380A. The mean age of women included in the study was 23.12 ± 2.42 years. Most common postinsertion complication observed in the immediate postoperative period was febrile morbidity (2%). Majority of women (94.33%) had hospital stay of less than 4 days. The common adverse events observed during follow-up of 12 months were menstrual complaints, excessive vaginal discharge and persistent pelvic pain. At the end of one year, there were 16 expulsions, 21 removals, and 2 pregnancies with gross cumulative expulsion, removal, failure and continuation rates of 5.33%, 7%, 0.67% and 91%, respectively.

Conclusion: Postplacental intra-caesarean Copper T 380A insertion in primiparous women is a safe and effective method of reversible contraception, with low expulsion and high continuation rates.

Keywords: Intrauterine device, Intra-caesarean insertion, Postplacental insertion

INTRODUCTION

Short interconception period after caesarean section puts a woman at increased risk of morbidity, mortality and surgical interventions [1]. Immediate postplacental intra-caesarean intrauterine contraceptive device (IUCD) insertion could fulfil a long standing need for a reversible and effective, long term contraception, which does not interfere with breast feeding [2,3].

In India, Copper T 380A is being supplied free of cost by the government, to all health centres and private practitioners. This device is a proven highly effective and reversible spacing method of interval contraception, with effective protection for 10 years [3]. However, the device has not attained much popularity due to the myths and misconceptions amongst the general public and health care personnel. Besides, due to the fear of perforation and infection, and also, lack of proper training, most health care providers are reluctant in performing interval IUCD insertion in women with previous caesarean delivery [4].

The efficacy of intra-caesarean IUCD insertion without any added risk of infectious morbidity has also been reported by various studies [5-7]. 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. 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 [5]. Initiating IUCD use during caesarean has the added advantage of eliminating a six week postpartum waiting period and an additional hospital visit.

The present study was designed to evaluate the clinical outcomes (safety, efficacy, expulsion and continuation rates) of postplacental Copper T 380A insertion in primiparous women undergoing caesarean section.

MATERIALS AND METHODS

This study was a prospective observational study carried out in the Department of Obstetrics and Gynaecology, Safdarjung Hospital which is a tertiary care hospital of North India. All nulliparous women delivering by caesarean section over a period of six months (July 2012 to December 2012), willing for postplacental intra-caesarean Cu T 380A insertion, who met WHO Standard Medical Criteria for PPIUCD insertion and were willing to comply with the study protocol were recruited for the study [3]. Women received counselling about PPIUCD insertion during prenatal visits, or after admission to the hospital. Repeat counselling was done prior to caesarean section and a written, informed consent was taken. The insertion of IUCD was done after delivering the baby, using ring forceps, 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 during the entire hospital stay.

The participants were asked to return for scheduled follow up visits at 1, 3, 6 & 12 months or earlier in case of any adverse event like pelvic pain, foul smelling vaginal discharge or excessive bleeding.

At each visit, a detailed history regarding excessive bleeding, symptoms of infection, abdominal cramps or any other complaint was taken, along with general physical and pelvic examination.

Parameters	Number	Percentage (%)
Age Group (yrs)		
≤20	16	5.33
21-25	196	65.33
26-30	88	29.33
Literacy		
Literate	192	64
Illiterate	108	36
Socioeconomic status		
Low	215	71.67
Middle	85	28.33
Upper	nil	-
Time of counseling		
Antenatal period	92	30.67
Early labour/before LSCS	208	69.33
Type of LSCS		
Emergency	250	83.33
Elective	50	16.67

[Table/Fig-1]: Demographic and clinical profile of IntraCaesarean Cu T 380 A acceptors

Complication	Number	Percentage (%)
Fever	6	2.00
Postpartum haemorrhage	0	-
Lochia with foul odour/Puerperal sepsis	1	0.33
Wound infection	5	1.67
Urinary tract infection	3	1.00

[Table/Fig-2]: Post insertion Complications

Hospital stay	Number	Percentage (%)
<4 days	283	94.33
4-8 days	7	2.33
>8 days	10	3.33

[Table/Fig-3]: Duration of Hospital Stay

If vaginal discharge was present, a wet smear was performed; ultrasonography was done at first visit to ascertain the location of IUCD and at subsequent visits if the IUCD thread was not visible.

Data was validated, entered into a computer and statistical analysis was carried out using SPSS version 12. Descriptive data were summarized as percentages or means. Parameters studied were continuation rate of intraCaesarean Cu T 380A and spectrum of adverse events associated with it, including expulsion, removal and failure rates.

RESULTS

A total of 300 nulliparous women fulfilling WHO Standard Medical Criteria for PPIUCD insertion and willing to comply with the study protocol had post placental intraCaesarean insertion of Copper T 380A. The mean age of women included in the study was 23.12 ± 2.42 years. The demographic and clinical profile of the women is shown in [Table/Fig-1].

The most common post-insertion complication observed in the post operative period was febrile morbidity [Table/Fig-2]; majority of women (94.33%) had a hospital stay of less than 4days [Table/Fig-3].

Follow up	1 month n (%)	3 months n (%)	6 months n (%)	12 months n (%)
Continuation rate	299 (100%)	293 (97.67%)	289 (96.33%)	273 (91%)
Adverse Events				
Discharge P/V	60 (20.07%)	65 (22.18%)	27 (9.34%)	10 (3.66%)
Menstrual complaints	39 (13.04%)	26 (8.87%)	26 (8.99)	28 (10.26%)
Pelvic pain	38 (12.71%)	69 (23.55%)	31 (10.73%)	12 (4.39%)
Pelvic infection	1 (0.33%)	0	3 (1.04%)	0
Other complaints*	46 (15.38%)	37 (12.63%)	35 (12.11%)	27 (9.89%)
Pregnancy	0	0	1 (0.35%)	1 (0.37%)
String Visibility with Cu T in uterine cavity				
String visible	185(61.87%)	209(71.33%)	225(77.85%)	231(84.62%)
String not visible	110(36.79%)	80(27.30%)	58(20.07%)	40(14.65%)
Spontaneous Expulsion				
Complete expulsion	0	0	4	2
Partial expulsion	4	4	2	0
Reasons for Cu T removal				
Pelvic pain	0	0	2	0
Menstrual complaints	0	0	3	2
Pelvic infection	1†	0	0	0
psychosocial cause	2	0	4	5
Failure/pregnancy	0	0	1	1

[Table/Fig-4]: Follow up of Postplacental IntraCaesarean Cu T 380 A

* weakness, weight loss, fatigue, generalized body pains

† removal was done postinsertion before 1 month, due to puerperal sepsis

The common adverse events noted during 12 months follow up were menstrual complaints, excessive vaginal discharge and pelvic pain [Table/Fig-4].

At the end of one year, out of 300 intraCaesarean IUCD insertions, there were 16 expulsions, 21 removals, and 2 pregnancies with gross cumulative expulsion, removal, failure and continuation rates of 5.33%, 7%, 0.67% and 91%, respectively.

DISCUSSION

The importance of having healthy spacing of pregnancy in India is emphasized by the fact that approximately 27% of births occur in less than 24month after previous birth [3]. The postpartum period provides opportunity to the health care provider for counseling a woman, regarding the available family planning methods, including IUD insertion, to avoid unintended conceptions. It is observed that women who have been counseled for postpartum IUCD insertion have 10 times higher chance of using IUCD, than those, where insertion was delayed till complete involution of the uterus [8].

The intrauterine device is an effective long lasting and reversible method of birth control [3,9,10]. The insertion of IUCDs is now gaining popularity as a method of postpartum contraception worldwide. The Indian Government is also focusing programmatic attention to postpartum IUCD insertion. Immediate postplacental IUCD insertion (PPIUCD) during caesarean section provides a good opportunity to achieve long term contraception with minimal discomfort to the women [7]. It is being increasingly practiced after reported safety and lower expulsion rates following intraCaesarean IUCD insertion [11-13].

Immediate postpartum insertion of IUCDs has been practiced in China since 1975. In a controlled trial comparing intraCaesarean IUCD insertions at caesarean section with non-intervention controls, only a few complications were reported, and no difference was found in puerperal morbidity or infection [12].

Infectious morbidity in the present study was consistent with previous reports by Celen et al., and Eroglu et al., but lower than that reported by Bhutta et al., [4,11,14]. Fever was observed to be the most common postinsertion complication in 6 out of 300 women (2%). It was due to superficial wound infection in 4, wound infection with puerperal sepsis in 1, and urinary tract infection in 1 subject. Women with superficial wound infection responded to local treatment, but the one with wound infection and puerperal sepsis required removal of IUCD, higher antibiotics, and resuturing of the wound. Urinary tract infection was observed in 3 women, of which only one was symptomatic with fever; all these women responded to antibiotics. No case of excessive bleeding was observed in the study.

Majority of women (94.33%) had a hospital stay of less than 4d. However, in 17 women, hospital stay was more than 4d; this was due to febrile morbidity in 6, and admission of neonates to NICU in 11 cases. Bhutta et al., also reported mean duration of hospital stay in women with intra-caesarean IUCD insertion as 3.48d [3].

Follow-up care after immediate PPIUCD insertions is a vital component for ensuring detection of early expulsions and higher continuation rates. Close clinical follow-up can ensure proper placement and reinsertion of IUCD if expulsion has occurred. Current guidelines recommend that asymptomatic IUD users should return for a follow-up visit after 3–6 weeks of insertion [15]. In most of the studies, first follow up visit was scheduled between 4–6 wk except in study by Dahlke et al., with first visit at two weeks [16]. In the present study, follow up was scheduled at 1, 3, 6, and 12 months of IUCD insertion. None of the women were lost to follow up; this emphasizes the significance of good counselling and constant contact with the clients, to ensure optimal follow up. The observed decrease in the number of women during follow up visits was due to the terminal events like expulsion, removal, and failure. More than 90% women successfully completed 12month follow up.

Expulsion of IUCD is an important factor affecting efficacy of the device. Maximal expulsions in previous studies have been detected during the first follow up visit [11,13,17]. In the present study, 16 IUCDs were expelled (6 complete and 10 partial), making expulsion rate as 5.33%; the majority of expulsions (87.5%) were within 6 months, of which 4 (25%) were detected at one month. Partially expelled IUCDs were promptly removed as its contraceptive efficacy is uncertain. Our observations are similar to those of Chi et al., however, Celen et al., have reported a higher cumulative expulsion rate of 17.6 per 100 women per year [14,17].

Visibility of strings is important as it assures both, the IUCD user and the health care worker about proper placement of the device, and provides ease of removal. In intra-caesarean insertion, though at the time of insertion threads are not outside cervical os, involution of uterus makes them visible in most cases at the first visit; however in a few cases threads may get curled up and not be seen at external os. This may cause apprehension to the health care worker as missing strings may indicate expulsion, malpositioning or perforation.

In the present study, IUCD strings were visible in 61.87% women at first visit and visibility increased to 84.62% at 12 months. Ultrasound was done in all cases to ensure proper placement of IUCD. In 40 (14.65%) women strings were not visible at 12 month, despite ultrasonographic confirmation of the IUCD being in place. Bhutta et al., reported string visibility of 92% and 96% at six months after intra-caesarean and interval insertion, respectively [4]. Ergoglu et al., reported missing strings rate of 3.3% and 7.8% at six months and 12 months after postpartum IUCD insertion, respectively, this was lower than that observed in the present study [11]. The higher cases of missing strings in the present study could be because of the use of Copper T 380 A that has shorter string compared to Multiload 375 inserted in the study by Bhutta et al.

The common adverse events observed during follow up were menstrual complaints, excessive vaginal discharge and persistent

pelvic pain. At the first followup visit, postinsertion bleeding or spotting was reported by 13.04% while 20.07% women had vaginal discharge. Wet smear of vaginal discharge was nonspecific in all except four which showed *Candida Albicans* in three and *Trichomonas Vaginalis* in one woman. Pelvic pain in most of the women was relieved by analgesics, and persisted in only 4.4% at 12 months. According to an ICMR study on urban women, pelvic pain is a common symptom reported in 25% users following interval IUCD insertion [18]. All women diagnosed with pelvic infection in the present study, were treated successfully with antibiotics; however, one woman who developed puerperal sepsis, required Cu T removal.

The cumulative removal rate of IUCD at 1 year, observed in the present study was 7months%; this was less than 10% at 10 weeks as reported by Hayes et al., [19]. The commonest cause of removal was psychosocial (52.48%), followed by menstrual complaints (23.80%) and persistent pelvic pain (9.52%).

There were two cases of unintended pregnancy with Copper T in situ, with a failure rate of 0.67 per 100 women per year; both women opted for medical termination of pregnancy. These observations are similar to the previously reported cumulative pregnancy rate of less than 1/100 women within one year of use [9,10].

LIMITATION

Limitation of study was small sample size and inclusion of only primiparous women in the study; therefore, results may not be applicable to all women undergoing intra-caesarean Copper T 380A insertion.

CONCLUSION

Postplacental intra-caesarean Copper T 380A insertion in primiparous women is safe and effective, with low expulsion and high continuation rates; it can contribute significantly to increase the use of IUCD as a long acting reversible contraception in Indian population.

REFERENCES

- [1] Mishra N, Dalal N, Joshi V. Intrauterine Device Insertion during Caesarean Section- A Boon for Rural Women. *IOSR-JDMS*. 2013;8(3):21-3.
- [2] Barrett G, Peacock J, Victor CR, Manyonda I. Caesarean section and postnatal sexual health. *Birth*. 2003;32:306-11.
- [3] Postpartum IUCD Reference Manual, New Delhi: Family Planning Division, Ministry of Health and Family Welfare, Government of India. 2010.
- [4] Bhutta SZ, Butt IJ, Bano K. Insertion of intrauterine contraceptive device at caesarean section. *J Coll Physicians Surg Pak*. 2011;21(9):527-30.
- [5] Levi E, Cantillo E, Ades V, Banks E, Murthy A. Immediate postplacental IUCD insertion at caesarean delivery: a prospective cohort study. *Contraception*. 2012; 86:102-05.
- [6] Shukla M, Qureshi S, Chandrawati. Post-placental intrauterine device insertion-a five year experience at a tertiary care centre in north India. *Indian J Med Res*. 2012;136(3):432-35.
- [7] Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review. *Contraception*. 2009;80(4):327-36.
- [8] Cwiak C, Gellasch T, Ziemann M. Peripartum contraceptive attitudes and practices. *Contraception*. 2004;70(5):383-86.
- [9] Thonneau PF, Almont T. Contraceptive efficacy of intrauterine devices. *Am J Obstet Gynecol*. 2008;198(3):248-53.
- [10] Kulier R, O'Brien PA, Helmerhorst FM, Usher-Patel M, D'Arcangues C. Copper containing, framed intra-uterine devices for contraception. *Cochrane Database Syst Rev*. 2007;(4):CD005347.
- [11] Eroglu K, Akkuzu G, Vural G, Dilbaz B, Akin A, Takin L, et al. Comparison of efficacy and complications of IUD insertion in immediate postplacental/early postpartum period with interval period: 1 year follow-up. *Contraception*. 2006;74(5):376-81.
- [12] Xu JX, Reusché C, Burdan A. Immediate postplacental insertion of the intrauterine device: a review of Chinese and the world's experiences. *Adv Contracept*. 1994;10(1):71-82.
- [13] Celen S, Möröy P, Sucak A, Aktulay A, Daniman N. Clinical outcomes of early postplacental insertion of intrauterine contraceptive devices. *Contraception*. 2004;69(4):279-82.
- [14] Çelen, Sucak A, Yıldız Y, Daniman N. Immediate postplacental insertion of an intrauterine contraceptive device during cesarean section. *Contraception*. 2011;84(3):240-43.
- [15] Long-acting reversible contraception the effective and appropriate use of long-acting reversible contraception. Regents Park, London: National Collaborating Centre for Women's and Children's Health Commissioned by the National Institute for Health and Clinical Excellence; 2005. October 2005.

- [16] Dahlke JD, Terpstra ER, Ramseyer AM, Busch JM, Rieg T, Magann EF. Postpartum insertion of levonorgestrel--intrauterine system at three time periods: a prospective randomized pilot study. *Contraception*. 2011;84(3):244-48.
- [17] Chi IC, Zhou SW, Balogh S, NG K. Post-cesarean section insertion of intrauterine devices. *Am J Public Health*, 1984;74(11):1281-82.
- [18] Indian council of Medical Research. Task force study on psycho-social factors affecting continuation and discontinuation of intrauterine device and oral pill in urban India. New Delhi: *Indian Council of medical Research*, 1986.
- [19] Hayes JL, Cwiak C, Goedken P, Ziemann M. A pilot clinical trial of ultrasound-guided postplacental insertion of a levonorgestrel intrauterine device. *Contraception*. 2007;76(4):292-96.

PARTICULARS OF CONTRIBUTORS:

1. Ex Chief Medical Officer (SAG), Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital, New Delhi, India.
2. Assistant Professor, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
3. Consultant & Professor, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
4. Postgraduate student, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
5. Chief Medical Officer (SAG), Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
6. Consultant & Associate Professor, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
7. Consultant & Professor, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.
8. Head of Department, Consultant & Professor, Department of Obstetrics and Gynecology, VMMC and Safdarjung Hospital New Delhi, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Rekha Bharti,
534, Sector 3, R K Puram, New Delhi-110022, India.
Phone : +919871394999, E-mail : rekhabharti@gmail.com

Date of Submission: **Jun 10, 2014**Date of Peer Review: **Jul 17, 2014**Date of Acceptance: **Jul 17, 2014**Date of Publishing: **Sep 20, 2014****FINANCIAL OR OTHER COMPETING INTERESTS:** None.