A prospective interventional study of intra-caesarean copper intrauterine contraceptive devices insertion in a teaching hospital in a rural medical college in Telangana, India

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ABSTRACT

Background: Providing quality contraceptive services to women is essential for achieving maternal and child health. Objective of this study was to evaluate the efficacy of intra-caesarean insertion of copper IUCDs as postpartum contraception. To study the side effects of intra-caesarean copper device. To study the continuation rates of intra-caesarean copper IUCDs. To study the acceptability of intra-caesarean copper IUCD as immediate postpartum contraceptive.

Methods: The prospective study was undertaken at Bhaskar medical college and general hospital, Yenkepally, Moinabad, Telangana, between January 2016 and March 2018 after ethical committee clearance. About 60 pregnant women were enrolled into the study after an informed written consent regarding the procedure, benefits and complications and the need for follow up for at least one year. Copper T 380A/multiload copper 375 was inserted into the uterine cavity after delivery of the placenta and membranes during caesarean section. Patients were followed up at 6 weeks, 6 months and one-year intervals for any complaints, visibility of threads and for ultrasound examination for position of copper IUCDs in the uterus. Data analysis was done using Microsoft excel 2016.

Results: Nearly 48.33% continued intra-caesarean copper IUCDs for more than 1 year. 70% did not have any complaints. 86.67% came for more than one follow-up visit. 47% had copper IUD threads visible by one year. No case of perforation either during insertion or during continuation was noted. None conceived with copper IUCD in situ. Removal of copper IUCD was also easy and none required hysteroscopic removal.

Conclusions: Intra-caesarean copper IUCD insertion is a safe and effective long acting reversible contraceptive method in the postpartum period.

Keywords: Continuation of contraception, Intra-caesarean copper IUCDs, Safety, Visibility of threads

REFERENCES

27% of births occur within 24 months after a previous birth and 34% occur between 24 and 35 months. More than 50% of non-breastfeeding women ovulate and more than 50% are sexually active by 6 weeks postpartum. In India, 65% of women have an unmet need for family planning in the first year postpartum.
Survey shows that 40% of women intend to use contraception in the first year postpartum but only 26% use some method.\textsuperscript{1,4}

A total 86% of postpartum unintended pregnancies resulted from non-use of contraception and 88% ended in induced abortions. Continuation of these pregnancies is also associated with greater maternal and perinatal complications.\textsuperscript{5}

Birth spacing for at least 2 years, especially following caesarean delivery, is required for recovery of mother, healing of uterine incision and adequate lactation.

Postpartum contraception includes intrauterine devices, progesterone only pills and injectable hormonal contraception.

Intrauterine contraceptive devices can be inserted during immediate postpartum period (within 10 minutes of placental delivery to 48 hours after delivery) or as an interval procedure. Copper IUCDs are one of the long acting reversible contraceptives (LARC).

Insertion of copper IUCD during immediate postpartum period can be post-placental, within 48 hours following vaginal delivery or intra-caesarean. World Health Organization (WHO) revised the use of intrauterine contraceptive devices (IUCD) from 6\textsuperscript{th} week postpartum to within 10 minutes of delivery (post placental) and up to 48 hours post-delivery.\textsuperscript{6}

Postpartum IUCD has advantages of safety due to blunt insertion technique and certainty of non-pregnancy of woman. Integrating IUCD insertion with delivery services enables women to obtain an appropriate long term, reversible family planning method before returning home. Women are highly motivated and receptive to accept family planning methods during the postpartum period.\textsuperscript{4} Women who intend to use an intrauterine device for postpartum contraception are often unable to return for a postpartum visit and never receive, due to social and financial constraints, lack of transportation and stable housing and difficulty in communicating with their healthcare providers.\textsuperscript{2}

Hence post-placental IUCD (within 10 minutes of placental delivery) insertion can be an effective and useful contraception. Insertion during caesarean section has a lower expulsion rate than insertion during the postpartum (first 48 hours) period due to the fact that it is easier to reliably reach the uterine fundus during intra-caesarean insertion and insertion is under vision thus obviating the fear of perforation of uterus.\textsuperscript{4,7}

IUCD placement in the immediate postpartum period increases overall IUCD use.\textsuperscript{2} IUCDs have a rapid onset of action after insertion with a rapid return to fertility after discontinuation.\textsuperscript{8}

Recognizing the potential impact of improved family planning programming on maternal and child health, Government of India is committed to expanding access to family planning towards achieving Millennium Development Goals 4 and 5.\textsuperscript{7} Hence postpartum intrauterine contraceptive device (PPIUCD) use is being encouraged.

Ministry of Health and Family welfare, Government of India has introduced PPIUCD services in 19 states of India in 2010 in collaboration with Jhpiego (John Hopkins programme for international education in gynaecology and obstetrics) which expanded rapidly by 2012. Presently the method of long-term contraception has shifted from tubal sterilisation and vasectomy to PPIUCD.\textsuperscript{10}

Hence, the present study was undertaken to study efficacy, side effects and acceptability of intra caesarean copper IUCD.

**METHODS**

This is a prospective interventional study conducted at Bhaskar medical college and general hospital between January 2016 and March 2018 after institutional ethical committee clearance.

This study recruited 60 pregnant women undergoing primary or repeat caesarean section. Screening and recruitment took place during prenatal care in elective caesarean sections or at the time of decision making for emergency caesarean section. After obtaining written informed consent of patients regarding technique, advantages, complications and need for follow up visits at 6 weeks, 6 months and one year of study, authors proceeded for intra-caesarean copper IUCD insertion using Copper T 380A or Multiload Copper 375 which were provided free of cost.

Exclusion criteria were uterine anomaly that distorted the uterine cavity, HIV positive women not on treatment, allergy to components of copper IUCD, chorioamnionitis, intrapartum fever or ruptured membranes for greater than 18 hours, intractable postpartum hemorrhage, history of genital tuberculosis.

After delivery of the baby, placenta and membranes, bleeding was minimized by active management of third stage of labour and prophylactic administration of prostaglandin PG F2 alpha.

Copper T 380A/multiload Copper375 was placed in a standardized fashion by the principal investigators. The vertical limb was held between middle and index fingers of right hand and inserted into the uterine cavity through the lower segment uterine incision and placed close to uterine fundus. The entire length of nylon threads were guided into the uterine cavity but not into cervical canal. Care was taken not to include the threads in the uterine incision during suturing.
On discharge, women were advised for follow up visits at 6 weeks, 6 months and one year or if there are any complaints. At follow-up visit unusual vaginal discharge, irregular bleeding per vaginum, pain abdomen, amenorrhoea and any expulsion of IUCD were enquired. Pelvic examination was performed for the visibility of IUCD strings and signs of infection.

Strings that descended up to introitus were trimmed leaving 2 cm length from the external os. Ultrasonogram was performed for uterine size, presence of IUCD, its distance from fundal endometrium and any adnexal pathology. Women were offered reinsertion of IUCD or alternative method of contraception in cases of spontaneous expulsion or displacement. At least 3-4 attempts to contact women by phone were made before labelling any case as lost to follow-up.

The primary outcome was IUCD use up to one year. Secondary outcomes included IUCD expulsion, discontinuation, strings visibility, complications and pregnancy with IUCD in situ.

Statistical analysis

The data was analyzed using Microsoft excel 2016. Descriptive statistics such as frequency and percentage for the categorical variables were used for data representation.

RESULTS

From Table 1, This study shows that majority (81.67%) of study population was in the age group of 21-30 years and 16.67% were less than 20 years old. Nearly 58.33% were second gravidae and 30% were primigravidae. About 11.67% were multi gravidae. Almost 95% were educated. Minimum of school education was seen in 55% and intermediate education in 16.66% whereas 23.33% were graduates. Only 5% were illiterate.

| Age group      | No. of cases | Percentage |
|----------------|--------------|------------|
| < 20 years     | 10           | 16.67%     |
| 21-30 years    | 49           | 81.67%     |
| > 31 years     | 1            | 1.66%      |

| Parity         | No. of cases | Percentage |
|----------------|--------------|------------|
| Primi          | 18           | 30%        |
| Gravida 2      | 35           | 58.33%     |
| Gravida 3 and above | 7   | 11.67%     |

| Literacy status| No. of cases | Percentage |
|----------------|--------------|------------|
| Illiterate     | 3            | 5%         |
| School education | 33          | 55%        |
| Intermediate   | 10           | 16.66%     |
| Graduate       | 14           | 23.33%     |
| professional   | 0            | 0%         |

From table 2, authors observe that elective LSCS was seen in 51.67% and emergency LSCS in 48.33%. Primary LSCS cases were 38.33% whereas repeat LSCS cases were 61.67%.

| Type of LSCS | No. of cases | Percentage |
|--------------|--------------|------------|
| Elective LSCS| 31           | 51.67%     |
| Emergency LSCS | 29          | 48.33%     |
| Primary LSCS | 23           | 38.33%     |
| Repeat LSCS  | 37           | 61.67%     |

From Figure 1, 70% of cases did not have any complaints following intracesarean copper IUCD insertion. Menstrual disturbances were noticed in 25% of cases using intra-caesarean copper device. Leucorrhoea was seen in 11.6% of cases. Abdominal pain was observed in 1.6%, dyspareunia in 1.6% and spontaneous expulsion in 1.6%.

| Incidence of complaints among users (n = 60). |
|---------------------------------------------|
| no complaints                             |
| complaints                                |
| dyspareunia, 1.6%                          |
| abdominal pain, 1.6%                       |
| leucorrhoea, 11.6%                         |
| menstrual disturbances, 25%                |

From Figure 2, Follow up visits and visibility of threads during follow-up (n = 60).

Figure 2 depicts the incidence of follow up to know the position of intracasarean copper IUCD. It also depicts...
the incidence of visibility of copper T threads per vaginally during clinical follow-up.

As shown in Figure 2, about 35% came for two follow up visits, 31.67% came for three follow-up visits while 20% had 1 follow-up visit. About 13.33% did not come even once for follow-up.

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During follow up check-up, 47% of cases with intra-caesarean copper IUCD had threads visible through cervix within 1 year. While 33% did not have threads visibility by 1 year, no information could be obtained regarding threads visibility through cervix in 20% of cases.

Figure 3 shows that 48.33% continued intra-caesarean copper IUCD for more than 1 year. 15% cases continued for 1 year. 11.67% continued for 6 months while 8.33% used between 6 to 12 months.

Figure 4 shows that most common reason for discontinuation of intra-caesarean copper IUCD in 29.03% cases was patient's request. In 19.35% cases, the reason for removal of intra-caesarean IUCD was side effects while in 16.12% cases it was for planning a pregnancy. About 12.9% underwent tubectomy, 9.67% had spontaneous expulsion and 9.7% had displaced intra-caesarean copper IUCD.

**DISCUSSION**

In the present study of 60 cases of intra-caesarean copper IUCD insertion, Table 1 shows that 81.67% were in the age group of 20-30 years similar to 85.51% in a study by Swathi et al. 30% were primigravidae and 58.33% were second gravidae in this study against 42.3% primis and 30.7% second gravidae in a study by Swathi et al.

As shown in Table 1 in this study 95% of women were educated (55% high school education, 16.66% intermediate and 23.33% graduation). Only 5% were illiterate. In a study by Geetha et al, 35% were illiterates. Literacy status does influence acceptability and continuation of intra-caesarean IUCD. Proper counseling about the safety and efficacy in preventing pregnancy is important for acceptability of intra-caesarean IUCD.

As shown in Table 1, 51.67% of this study population underwent elective LSCS, 48.33% underwent emergency LSCS and 61.67% were repeat caesareans. Intra-caesarean copper IUCD can be used as an effective long-term contraception not only in primary LSCS but also repeat LSCS where permanent sterilization could not be combined.

In a study, by Ramya et al, the PPIUCD acceptance was 34.1% and 29.7% in caesarean and vaginal delivery respectively. The need for PPIUCD is also more following a caesarean section.

In this study 70% had no complaints after intra-caesarean copper IUCD insertion as seen in Figure 1. Out of the 30% cases with complaints, the most common complaints were menstrual disturbances like menorrhagia and metrorrhagia (25%) and leucorrhoea (11.6%) whereas in Somesh et al study, 15.79% had bleeding problems. These menstrual disturbances are similar to intrauterine device inserted during postpartum or interval period.

In a study by Hooda et al where women reported unusual vaginal discharge, actual infection was present in only 1.75% cases on clinical examination. It is known that increased vaginal discharge with the IUCD is usually normal leucorrhoea and not a sign of infection.

Pelvic infection was diagnosed if women had cervical, adnexal, or uterine tenderness or purulent discharge with or without fever. None of this study cases had upper genital tract infection showing that PPIUCD does not cause active genital tract infection even after insertion in emergency cesarean sections. Contrary to the belief, pelvic infection was least common in intra-caesarean insertion group (0.56%) among all three types of
postpartum IUCD insertions in a study by Poornima et al.\textsuperscript{13}

Pain abdomen was noted in only one case which could be treated with simple analgesics. This shows that significant abdominal pain is not seen in intra-caesarean IUCD insertion.

In this study none had perforation similar to study by Hooda.\textsuperscript{5} Nobody conceived with IUCD in situ in this study population confirming the efficacy of intra-caesarean IUCD contraception.

In this study, 86.67% of cases came for follow up as shown in Figure 2. Out of them, 35% came for two follow-up visits while 31.67% for three follow up visits. Only 13.33% did not come for any follow up visits. This shows good compliance and acceptance of intra-caesarean copper IUCD. In a study by Hooda, 83.4% cases returned for follow-up while 16.12% of cases were lost to follow up.\textsuperscript{5} Proper counseling prior to procedure is essential for timely and regular follow-up.

In this study Figure 2 shows that 47% of cases had threads visible by 1 year and 33.33% cases did not have threads visibility even beyond 1 year. In a study by Mishra et al., IUCD strings were not visible in 61.87% women at 1 month and visibility increased to 84.62% at 12 months.\textsuperscript{3} Usually 75% of threads are visible by the end of 3 months.\textsuperscript{3}

One of the main observations at follow-up was that of undescended IUCD strings. The practice of leaving the full length of IUCD strings in uterine cavity during caesarean section and not passing it through the cervix may be responsible for undescended strings in intra-caesarean insertions. Involution of the uterus makes IUCD strings to descend and are visible vaginally.\textsuperscript{8}

The IUCD string is used to locate the device in uterus and to remove the device. Lost strings occurs due to expulsion, curling and in-drawing into the uterine cavity, embedding, breaking of the strings, uterine perforation and translocation into abdominal cavity.\textsuperscript{3} Non-visibility of strings is uncommon in interval IUCD but common with PPIUCD.\textsuperscript{5} Therefore non-visibility of IUCD strings during follow up is not a worrisome finding as long as the ultrasound shows normal intrauterine position.

Contrarily visualization of PPIUCD strings during follow up rules out expulsion and reassures in utero presence to both service provider and women leading to increased acceptance and continuation rate. Also, the removal of IUCD with visible strings is easy.\textsuperscript{7}

In this study, authors observed that patients were more apprehensive of the strings visible at introitus but not about non-visibility.

Non descent of the threads was more common with copper T 380A due to its short strings. Early visibility by 6 weeks postpartum was common with Multiload copper 375 due to longer and stiff threads. Visibility of strings at 6-weeks follow up visit was 62% for CuT380A and 92% for Multiload Cu375 in a study by Kavita et al.\textsuperscript{7}

Lower expulsion rate of 3.33% at 6 weeks follow up was observed in this study as shown in chart 3 due to our technique of insertion, similar to 4.49 % in a study by Swathi et al and 4% in CuT380A and 2% in multiload Cu375 in a study by Kavita et al.\textsuperscript{5,11} Previous studies indicate that expulsion rates after intra-caesarean IUCD insertion are much lower probably due to correct placement at the fundus.\textsuperscript{7} Spontaneous expulsion rate is 0.84% in intra-caesarean insertion compared to vaginal insertion (1.84%) in a study by Gupta P et al.\textsuperscript{13}

Counseling of the women and confirmation of IUCD in uterine cavity by ultrasound are important to reassure and encourage women to continue PPIUCD.\textsuperscript{5}

In all cases irrespective of strings visibility, ultrasound was required to confirm intrauterine position and relation to the fundus because contraceptive efficacy is better when it is in normal position and less than 1cm away from the fundal endometrium.

In this study, 48.33% continued intra-caesarean IUCD for more than one year as observed in Figure 3. 21.67% of cases got the copper IUCD removed by 6 months and 23.33% cases by 1 year. In a study by Urmila et al., continuation of PPIUCD was observed in 76.5% cases.\textsuperscript{14}

The removal rate of CuT380A was higher in the postpartum group (7.56%) than in interval group (4.37%) in a study by Poornima et al.\textsuperscript{13}

Continuation of intra-caesarean PPIUCD for at least 6 months effectively postpones pregnancy by 1 year while use for at least one year reduces pregnancy rate by one third.

Partial expulsion was seen only in 3 cases. They were offered reinsertion of copper IUCD but only one woman accepted reinsertion.

In this study, copper IUCD was removed by holding threads in 62% cases. 38% cases required gentle exploration of the uterine cavity and endo-cervical canal without anesthesia. None required hysteroscopic or laparoscopic removal or laparotomy. This again confirms the safety of intra-caesarean copper IUCD. Need for invasive methods to remove IUCD with nonvisible strings is troublesome for the client and the provider.\textsuperscript{3}

In the present study, common reasons for discontinuation of intra-caesarean IUCD were patient’s request (29.03%), and family pressures or misconceptions as seen in Figure 4. Other reasons were plans for next pregnancy (16.12%)
or for permanent sterilization (12.9%). In a study by Swathi et al, reasons for removal of PPIUCD were irregular bleeding (32.56%), pressure from family (25.58%), abdominal pain (16.28%) and patient’s unwillingness to continue (6.98%). The discontinuation in the first 12 months of use was mostly due to side effects like irregular bleeding, menorrhagia, infection and pain. 15.36% had copper IUCD removed because of family opposition in a study by Sharma M et al. The main reason for acceptance was awareness about its reversibility (73.62%) and safety and effectiveness of PPIUCD (69.96%) as in a study by Urmila et al. Reasons for non-acceptance was refusal by partner/family members (72.75%) and fear of complications (70.05%) as in a study by Ashutosh et al. Absence of uterine perforation and low incidence of infection are strong indicators of safety of PPIUCD.

With effectiveness greater than 99% and being one of LARC methods, copper IUCD is the most effective reversible contraceptive with highest continuation rates. Its use does not require additional adherence to a medication and is independent of coital activity.

The contraceptive CHOICE study offered counseling to more than 9,000 women on contraceptive methods and 75% chose LARC. At 12-month follow-up, 86% of LARC users were continuing the method compared to 55% of users of oral contraceptives or depot medroxyprogesterone acetate.

Since the time of introduction of PPIUCD in national family welfare program many women are opting for long term spacing method with IUCD rather than permanent sterilization.

In this study of 60 cases of intra-caesarean copper intrauterine device insertion, study observed the method to be very effective because none conceived with IUCD in situ in one year of follow up and there were no major complications.

CONCLUSION

Postpartum intrauterine contraceptive device (PPIUCD) insertion is an effective and safe acting reversible contraceptive method. The acceptance for intra-caesarean IUCD insertion is very high with proper counselling. Due to lower expulsion and complication rates and the necessity for birth spacing of at least two years following caesarean section, intra-caesarean copper IUCD insertion is an ideal contraceptive option to be offered to all women undergoing caesarean section.

ACKNOWLEDGMENTS

Authors would like to thank all the faculty and postgraduates of department of obstetrics and gynecology and department of radiology for the help in the follow-up of all cases.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Vijayalakshmi G, Kothapally K, Bhashyakarla U, Kavati V. A prospective interventional study of intra-caesarean copper intrauterine contraceptive devices insertion in a teaching hospital in a rural medical college in Telangana. Int J Reprod Contracept Obstet Gynecol 2020;9:1470-6.