## Clinical Outcome of Ppiucd (Copper-380A)-Intracaesarean Insertion

### Lakshmi Garuda<sup>1,\*</sup>, Suhasini Kambham<sup>2</sup>, Neelohita B<sup>3</sup>

<sup>1,2</sup>Associate Professor, <sup>3</sup>Post graduate, Department of Obstetrics and Gynaecology, Kakatiya Medical College, Warangal.

### \*Corresponding Author:

E-mail: garudalakshmi5@gmail.com

#### ABSTRACT

**Background:** This study examines the factors responsible for acceptability of the post placental intracaesarean insertion of IUCD among the clients in the study and evaluates the safety and efficacy and occurrence of complications like bleeding, missing strings, infection, pregnancy and expulsion and their incidence of occurrence after a follow up of 6 months post insertion.

**Aim:** To assess the acceptability, efficacy, feasibility and safety of IUCD insertion immediately after expulsion of the placenta in a caesarean section.

**Materials and Methods:** We have conducted a study on 220 patients delivering by caesarean section at our hospital, Kakatiya Medical College, Warangal, INDIA. After taking informed consent and explaining the patients about the advantages and limitations, we have succeeded in inserting intrauterine device cu-t380A immediately after expulsion of placenta in patients delivering by caesarean section in 220 patients and followed up the patients at 2-6 weeks and 6weeks-6months period to evaluate the safety, efficacy and complications occurring and their incidence of occurrence.

**Results:** Total women counseled were 480, Accepted in 231, Declined in 249. Intrauterine cesarean insertion was done in 220 patients and deferred in 11 patients due to post partum hemorrhage. Out of 220 patients, 28 patients lost to follow up, Removal rate was 20 and continued in 160. The total complications are 68 (Expulsion 12,Bleeding 20, Strings not visible 32,Infections 4,Pregnancy 0),These results were comparable to other national and international studies. We compared complications between elective and emergency intracesarean insertions and their statistical significance were evaluated.

**Conclusion:** Advantages of immediate post-partum insertion include high motivation, assurance that the woman is not pregnant, and convenience. However, expulsion rates appear to be higher than with interval insertion. The popularity of immediate post-partum IUCD insertion in countries as diverse as China, Mexico, and Egypt support the feasibility of this approach. Early follow-up may be important in identifying spontaneous IUD expulsions.

#### INTRODUCTION

Provision of IUCD in the immediate postpartum period offers effective and safe method for spacing and limiting births. Taking advantage of the immediate postpartum period for counseling on family planning, IUCD is a good option as a contraceptive method. The increased institutional deliveries are the opportunity to provide women easy access to immediate PPIUCD services. The popularity of immediate post-partum IUCD insertion in countries as diverse as China, Mexico, and Egypt support the feasibility of this approach. PPIUCD has a huge potentiality and abundant scope in India and if widely used it will have a strong impact on population control and will prevent unplanned pregnancy and its sequelae. So, the Ministry of Health and Family Welfare, Govt. of India introduced PPIUCD service in 19 states of India in 2010, in collaboration with Jhpiego, India[16].

The National Family Health Survey (2005-2006) reported that 61% of births were spaced less than 3yrs in India. Unmet need is greater in 1<sup>st</sup> year post partum. Uttar Pradesh is known to have high unmet need for PPFP[18]. Only 3-5% of post partum women wants another child within two years(Ross and Winfrey 2001). Post partum contraception helps to reduce un-intended pregnancies and space births to improve maternal and child health. Postpartum contraception reduces 1/3<sup>rd</sup> of maternal mortality, miscarriages PROM, Maternal Anemia, preterm births, low birth weight babies and more than 10% Neonatal mortality[21].

Cut is highly effective in preventing pregnancies. The incidence of occurrence of pregnancies is 0.6-0.8 per hundred women in the first year of its use. The TCu380A is approved to remain in place for 10 years but is effective for at least 12 years. IUCDs work primarily by preventing fertilization, and do not act as abortifacients. When the uterus is exposed to an IUCD, a sterile inflammatory reaction occurs, which is toxic to sperms and impairs fertilization. The production of cytotoxic peptides and activation of enzymes lead to inhibition of sperm motility, reduced sperm capacitation and survival.

#### **OBJECTIVE**

To evaluate the safety and efficacy of post caesarean insertion of IUCD and follow up for any complications and their incidence.

#### METHODS AND MATERIAL

The study was conducted from June 2012 to December 2013 at CKM Hospital/Kakatiya Medical College, Warangal, Telangana. 480 patients who were due for elective/emergency caesarean section were counseled for post placental IUCD insertion, out of which 231 patients accepted. Informed written consent was taken by explaining the advantages and limitations of the method. Intracaesarean insertion was done in 220 patients and deferred in 11 patients due to postpartum hemorrhage.

#### FOLLOW-UP:-

The patients inserted with the IUCD were followed up at 2-6 weeks and 6wks-6months period either on phone or on clinical visit and the safety and efficacy evaluated along with the documentation of occurrence of complications.

#### **INCLUSION CRITERIA:**

- 1.20-35 yrs old
- 2. Delivering by caesarean at term gestation.
- 3. No infections
- 4. No postpartum haemorrhage
- 5. Hb>9g%.
- 6. Patients satisfying the WHO MEC criteria for IUCD insertion.

#### **EXCLUSION CRITERIA**:

- 1. Fever
- 2. STDs
- 3. Ruptured membranes for more than 24 hours before delivery.
- 4. Uterine abnormalities.
- 5. Manual removal of placenta.
- 6. Unresolved postpartum hemorrhage.

# INTRACAESAREAN INSERTION TECHNIQUE:

Insertion can be done either manually or using a ring forceps since the provider can easily see and reach the uterine fundus. Aseptic precautions is critical to prevent infections during post caesarean insertion of IUCD. The provider should hold the IUCD between the middle and index fingers of the hand and pass it through the uterine incision. Once it is placed at the fundus, the hand should be slowly withdrawn, noting whether the IUCD remains properly placed.

1. The strings can be pointed towards the cervix but should NOT be pushed through the cervical canal. This is to prevent uterine infection by contamination of the uterine cavity with vaginal flora, and to prevent displacement of the IUCD from the fundus by drawing the strings downward toward the cervical canal.

2. Care should be taken during closure of the uterine incision that the strings of the IUCD do not get included into the suture.

Later after insertion IUCD client card showing type of IUCD and the date of insertion were prepared .She was informed about the IUCD side effects and normal postpartum symptoms. Women were informed to return for IUCD follow-up at the outpatient department. She was advised to come back if she had noticed any of the following symptoms:-

- 1. Foul smelling vaginal discharge.
- 2. Lower abdominal pain.
- 3. Fever.
- 4. Symptoms of pregnancy.
- 5. Suspicion of expulsion of IUCD.

Client card was provided for assessment for client comfort.

Counseling done regarding possibility of irregular bleeding pattern and cramping pain in the first 6 months.



Table 1: Parity 0f patients in study group

PARITY	Ν	%
Primi parous	148	67.27
Multiparous-2	69	31.36
3	3	1.36
4	0	0
5/>5	0	0

Chart 1:





Chart 3: Future Pregnancy Desire of the Clients in Study Group.



COUNSELLING	Ν	%
ANTENATAL	65	26.81
INTRAPARTUM	166	73.18

### Table 3: Age group of patients included in the study

AGE	Ν	%
<19	48	21.81
20-29	144	65.45
30-39	28	12.72
>/=40	0	0



#### Table 4: Reasons for acceptance among the parturients included in the study

REASON FOR ACCEPTANCE	Ν	%
Long term	28	12.72
safe	40	18.18
Fewer clinical visits	0	0
No influence in breast feeding	62	28.18
Non-hormonal	8	3.6
One time procedure	184	83.63
Belief in doctor	172	78.18
reversible	148	67.27



#### Chart 4: Reasons for Refusal among Counselled

\*The total number is more than clients counselled due to multiple reasons.

#### Total number of Insertions in Emergency and Elective Caesarean section:

TYPE OF LSCS	Ν	%
ELECTIVE LSCS	153	69.54
EMERGENCY LSCS	67	30.45

More acceptance in Elective LSCS in view of counselling done starting from antenatal period, less maternal complications in elective caesarean like pyrexia, PROM, severe maternal anemia &post-partum hemorrhage.



**Chart 2: Percentage of Occurrence of Complications** 

#### Table 5: Complications at Follow-Up in the Study

FOLLOW-UP (N)	EXPULSION (%)	BLEEDING (%)	STRINGS NOT VISIBLE (%)	INFECTION (%)	PREGNANCY (%)
2-6WKS	11(91.6)	18(90)	29(89.65)	3(75)	0(0)
6WKS-6MNTH	1(8.3)	2(10)	3(10.34)	1(25)	0(0)

Table 6: Incidence of occurrence	of complications	(out of 192)
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COMPLICATION	Ν	%
EXPULSION	12	6.25
BLEEDING	20	10.41
STRINGS NOT VISIBLE	32	20
INFECTION	4	2.08
PREGNANCY	0	0

Table 7: Continuation rate in the study (out of 192
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CONTINUATION RATE	Ν	%
Expulsion	12	6.25
Removal	20	10.41
Continuation	160	83.3

#### Comparison of complications between emergency and elective intracaesarean insertions:

Table 8: Expulsion rate			
No. of cases Elective(N=153) Emergency(N=6			
Expelled	4	8	
Not expelled	149	59	

In our study most of the emergency cases were taken up in active labour, hence expulsion rate is more in them when compared to elective insertions which is statistically significant.( $\chi^2 = 7.86$ ; P=0.005).

Table 9: Post insertion bleeding				
No of cases	Elective(N=153)	Emergency(67)		
Bleeding present	9	11		
Bleeding absent	144	56		

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Post insertion bleeding is more in emergency insertions which is statistically significant in our study.  $(\chi^2=6.26; P=0.01)$ .

Table 10: Visibility of strings			
No of cases	Elective(N=153)	Emergency(N=67)	
Strings not seen	19	13	
Strings visible	134	54	

Our observation of comparison between elective and emergency insertion regarding visibility of strings is not statistically significant( $\chi^2=1.82$ ;P=>0.05).

Table 11: Infection rate				
No of cases	Elective(N=153)	Emergency(N=67)		
Infection present	1	3		
Infection absent	152	64		

In our study more no. of emergency insertions done in cases of premature rupture of membranes, hence infection rates were more in these cases which is statistically significant.( $\chi^2=3.81$ ; P=0.05).

#### 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 [1,2,3]. The insertion of IUCDs is now gaining popularity as a method of postpartum contraception worldwide. Indian Government is also focusing The programmatic attention to postpartum IUCD insertion. Immediate post placental 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 [9,10]

In this study,majority of the women(67.27%) were primipara who had at least primary level of education. Most common reasons for acceptance include:

- One time procedure (patient need not come for IUCD insertion later as in interval insertion)(83.63%).
- Belief in doctor's advice(78.18%).
- Reversibility of the IUCD(67.27%).

The age group of women included in the study mostly falls between 20-29 as comparable to the

study by Singal S et al. in which the mean age of women included in the study was  $23.12 \pm 2.42$  years.

In a study conducted in Egypt, of the 3,541 clients, 1,024 (28.9%) accepted the use of IUCD after delivery. Acceptance was approximately the same during antenatal and postpartum counseling: 26.4 and 31.8%, respectively. Verbal acceptance was higher among women with formal education than among illiterate women.. Planning another pregnancy in the near future, preference for another contraceptive namely lactational-infertility, method. and complications from previous use of IUCD were the most common reasons for refusing the use of IUCD. Of the 1,024 verbal acceptors, only 243 (23.7%) had the actual insertion of IUCD. In this study the most common reasons for refusal were fear of complications, need to talk to husband and fear of not getting pregnancy early after removal.

The most common complications occurring in the patients included in this study was non visibility of strings(20%) which was most commonly seen at follow-up at 2-6wks(92.5%) and is most commonly due to coiling of the string at the cervical canal which was demonstrated to them on outpatient basis. Few patients needed to get an Ultrasound done for the confirmation of IUCD in uterine cavity and they were found to be in situ. The patients were reassured and sent back for a follow up at a later date. At follow-up at 6wks to 6 months the incidence was 7.5%.Bhutta et al., reported string visibility of 92% and 96% at six months after intracaesarean 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. 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.

Other complications the patients presented with included bleeding(10.41%),expulsion(6.25%), pelvic infection(2.08%) and pregnancy(0%). The expulsion rate was highest(91.6%) at follow-up at 2-6wks.According to Multicentric International study done in Belgium, Chile and Phillipines which showed the rate of expulsion at one month ranging from 4.6-16%[19]. One recent Study from Turkey of Postpartum Intracaesarean insertion reported an expulsion rate of nearly 18%[20]. 80% expulsions happen in first 3 months according to Thiery M, et al; Contraception Apr 1985. According to an ICMR study on urban women, pelvic pain is a common symptom reported in 25% users following interval IUCD insertion[1]. All women diagnosed with pelvic infection in the present study, were treated successfully with antibiotics.

According to Ethiopian Multicentricstudy[17], 42% of PPIUCD insertions were followed up after 6wks and the results were-97% -Continuation rate. 2.3%-Expulsion rate.

9.16%-Removal rate.

Infection Rate-Negligible.

Experience from India(Jhpiego, New Delhi)[16]-Revitalization of PPIUCD services-At 6wks Post partum-90%-Continuation rate. 3.2%-Expulsion rate.

4.5% -Infection rate.

7%-Removal rate.

The cumulative removal rate was 10.41% and continuation rate with or without complications was 83.3%. There were no cases of unintended pregnancies in this study. These observations are similar to the previously reported cumulative pregnancy rate of less than 1/100 women within one year of use[2, 3]. All the complications and side effects are comparable to all national and international studies.

Global changes in the thinking about IUCD and resurgence of interest in the IUCD are in view of:-

- 1. Accessibility and convenience of using intracaesarean IUCD. Postplacentalintracaesarean Copper T 380A insertion in primiparous women is a safe and effective method of reversible contraception, with low expulsion and high continuation rates.[11].
- 2. Higher satisfaction rate and continuation rates i.e. 99% versus 91% for pill users.[11]
- 3. >99% effectiveness(6-8 pregnancies/1000 in the first year).
- 4. One time procedure and immediately effective.

- 5. Can be used as both short term and long term method.
- 6. Greater coverage of population due to incorporation with institutional deliveries.
- 7. Immediate return of fertility once device is removed.
- 8. No effect on breast feeding.[12]
- 9. Negligible risk of Pelvic inflammatory disease in Intracaesarean IUCD users.
- 10. Intra caesarean IUCD insertion may be an alternative to tubectomy for some couples especially in multiparous women, women near to menopause age and group of women who refuses tubectomy on religious grounds.

#### Post partum insertion versus interval insertion: Challenges and considerations:-

In a study done in Egypt in 2004[14], women were provided with family planning counseling during the antenatal and intrapartum periods. Of those counseled, 28.9% chose IUCD as their method of family planning. Women were more likely to have IUCD inserted intra caesarean (71.2%) than those preferring interval insertion (7.1%). (i.e. they were more certain of their choice than those who chose interval insertion).

- 1. Uterine Perforation:-In a recent systematic review of literature regarding PPIUCD insertion, there were no reported cases of uterine perforation in any of the studies reviewed[7].Perforation of uterine wall during interval IUD insertion is rare but does occur sometimes due to the instrument used to "Sound" the uterus which is not involved in PPIUCD insertion.
- 2. Infection:-Postplacentalintracaesarean insertion appears to have no significant effect on risk of genital tract infections, which is very low in interval IUCD as well. The risk is <1% mostly due to insertion technique or pre-existing infection, rather than IUCD itself[15].
- 3. Expulsion rate was significantly higher in PPIUCD as compared to interval insertions (4.3% v/s 2.0%; p value< 0.05). Number of removal of IUCD was almost similar in both groups(5.6% v/s 6.0%) but bleeding as a cause of removal was significantly more in interval group(23.5% v/s 88.5%).[13]
- 4. Another major advantage of INTRACAESAREAN IUCD is that the discomfort related to interval insertion can be avoided and any bleeding from insertion will be disguised by lochia. These women perceives less of IUCD related irregular bleeding and cramping pain as these two symptoms are common after Caesarean section.

#### Limitations of Intracaesarean PPIUCD: General limitations

1) No protection against HIV or other sexually transmitted infections.

2) Menstrual irregularities.

3) Having an IUD inserted, or removed, always requires a procedure performed by a specially trained provider in a clinical setting.

#### Limitation unique to PPIUCD-

The strings will not be initially visible after post partum insertion because of the length of the string compared to the length of postpartum uterus. Usually the strings will descend into vagina by the time of first follow-up visit at 4-6wks.This occurrence however may be delayed and this may require additional follow-up and investigation to reassure the women that it has not fallen out.(Global PPIUCD Reference Manual).

#### CONCLUSION

Postplacentalintracaesarean Copper T 380A insertion in primiparous and multiparous 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. A 2010 Cochrane Review concluded that PPIUCDs were safe and effective contraceptive method.

With the high level of acceptance despite the low level of awareness, the Indian government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange for training on PPIUCD in order to increase knowledge and skills among health care providers. This will also further promote PPIUCD use and aid in reduction of expulsion rates.

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