IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 12 Ser.7 (December. 2019), PP 01-05
www.iosrjournals.org

A Prospective Observational Study of Rate of Expulsion between Postplacental Vaginal Insertion and Intracaesarean Insertion of Copper-T 380 a Intrauterine Device

Gupta Nancy[1], Chakraborty Aparna[2] ,De Aloke Kumar[3]
Dept. of obst.& Gynae, RG Kar Medical College,Kolkata, India

Abstract-*In the developing world, as there is high prevalence of early marriage and too frequent and too many child births and high maternal morbidity and mortality, the need of effective contraceptive measures are very important. Taking advantage of the immediate postpartum period for counseling on family planning and IUCD insertion, overcomes multiple barriers to service provision. The increased institutional deliveries are the opportunity to provide women easy access to immediate PPIUCD services In this study a total of 360 mother undergoing delivery were divided into two groups of 180 each.. One, undergoing immediate postplacental vaginal insertion of CuT380A , and the other undergoing intracaesarean insertion of CuT380A. The patients were then observed for any complications during their hospital stay and were seen at a follow-up visit after 6 weeks in the OPD.Result:- Rate of spontaneous expulsion of Cu-T380A is significantly higher in Group who had postplacental insertion of copper T following vaginal delivery. There is no significant difference in the rate of other complications of Cu-T380A between the two groups.*

Key words:-*postplacental,intracaesarean, spontaneous expulsion.*

Date of Submission: 04-12-2019 Date of Acceptance:19-12-2019

I. Introduction

Post-partum period is one of the critical times when both woman and newborn need a special and integrated care of health services as morbidity and mortality rates are quite high during this period and also the women are vulnerable to unwanted pregnancy. Studies show that pregnancies taking place within 24 months of a previous birth have a higher risk of adverse outcomes like abortions, premature labor, post-partum hemorrhage, low birth weight babies, fetal loss and maternal death. In India, 65 per cent of women in the first year postpartum have an unmet need for family planning. Hence contraception needs to be practiced in this critical period.[1]

Intrauterine contraceptive device is the most commonly used reversible method of contraception worldwide with about 127 million current users[2]. Insertion of an IUD immediately after delivery is appealing for several reasons. The woman is not pregnant and is motivated for contraception and the setting is convenient for both woman and provider. For women with limited access to medical care, the delivery affords a unique opportunity to address the need for contraception.

The usual timings of IUCD insertion are: (a) Immediate Postpartum:-1. Postplacental: Insertion within 10 minutes after expulsion of the placenta following a vaginal delivery on the same delivery table. 2.Intracesarean: Insertion that takes place during a cesarean delivery, after removal of the placenta and before closure of the uterine incision. (b) Within 48 hours after delivery: Insertion within 48 hours of delivery and prior to discharge from the postpartum ward. (c) Postabortion:Insertion following an abortion, if there is no infection, bleeding or any other contraindications. (d) Extended Postpartum/Interval: Insertion any time after 6 weeks postpartumCOMPLICATIONS can be(1) Immediate complications eg: Cramp like pain, -Syncopal attack, -Partial or complete perforation are rare complications and occurs in about 1 in 1000 cases (0.21/1000 to 3.6/1000 placements).[3], and (2) Remote complications eg: -Pain which is more or less proportionate to the degree of myometrial distension. A proper sized device may minimize the pain. -Abnormal Menstrual Bleeding , on average, menstrual blood loss may increase by 35%–80% with use of the CuT380, but this rarely leads to anemia.[4] In the first year of use, heavy menses and dysmenorrhea are the most common reasons for CuT380A removal;[5] up to 15% of users discontinue use due to those side effects.[6]

EFFECTIVENESS • The CuT-380A is a highly effective (>99% effective). There are 0.6 to 0.8 pregnancies per 100 women in first year of use. • The CuT-380A is effective for 10 years of continuous use.

ADVANTAGES :- FOR THE WOMAN: • Convenience, saves time and additional visit. • Safe because it is certain that she is not pregnant at the time of insertion. • High motivation (woman and family) for reliable birth spacing method. • Has no risk of uterine perforation because of the thick wall of the uterus. • Reduced

perception of initial side effects (bleeding and cramping). • Reduced chance of heavy bleeding, especially among lactational amenorrhea method (LAM) users, since they are experiencing amenorrhea. • No effect on amount or quality of breast milk. • The woman has an effective method for contraception before discharge from hospital.

FOR THE SERVICE PROVIDER OR THE SERVICE DELIVERY SITE • Certainty that the woman is not pregnant. • Saves time as performed on the same delivery tableforpostplacental/intracaesarean insertions. Additional evaluations and separate clinical procedure is not required. • Need for minimal instruments, supplies and equipment. • Convenience for clinical staff; helps relieve overcrowdedoutpatient facilities thus allowing more women to be served.• Perforation, is unlikely because of the thickness of the uterine wall in the postpartum period. No such cases are reported in the literature.

LIMITATIONS:- • Increased risk of spontaneous expulsion. The skilled clinicians with right technique of insertion are associated with lower expulsion rates. The other limitations of the immediate PPIUCD are the same as the interval IUCD.

II. Aims And Objectives

The primary objective of the study is to evaluate the expulsion rate between intracaesarean and postplacental vaginal insertion of IUCD (CuT 380A). Secondary objectiveis to evaluate the rate of the following complications between intracaesarean insertion of IUD and postplacental vaginal insertion: 1) Lower abdominal pain 2) Abnormal menstrual bleeding 3) Pelvic inflammatory diseases 4) Perforation

III. Materials And Methods

METHODOLOGY

A) STUDY DESIGN: prospective, observational, comparative study.

B) PLACE OF STUDY: In the Department of Obstetrics and Gynaecology, R.G.Kar Medical College and Hospital.

C) PERIOD OF STUDY: One year (from June 2018 to May 2019).

D) STUDY POPULATION: According to the inclusion criteria of the study, women who underwent delivery, vaginally or by caesarean section. E) SAMPLE SIZE/DESIGN: 360 .Keeping an alpha error of 0.05 and 80% power of the study, sample size calculated was 300. Considering a 20% loss to follow up, a total sample size of 300+60= 360 was taken, with 180 patients in each group of vaginal delivery and caesarean section.

H) INCLUSION CRITERIA:

- 18-40 years old
- 34-40 weeks of gestation
- Anticipating vaginal delivery/ Caesarean section
- Counselled for postpartum contraception, and consented to IPPIUCD insertions

I) EXCLUSION CRITERIA:

• Haemoglobin less than 8 gm%
• Rupture of membranes more than 18 hours
• Postpartum haemorrhage
• Coagulation disorders
• Fever, or clinical symptoms of infection during labour.
• Obstructed labour
• Jaundice.
• Congenital Malformation.
• Extensive genital trauma.
• Not giving informed consent.

MATERIAL - The IUCD used was CuT-380 A, which was available free of cost in the Government Program.

J) STUDY VARIABLES: 1. Age 2. Parity 3. Gravida 4. Ethnicity 5. BMI

K) LABORATORY INVESTIGATIONS, PARAMETERS AND PROCEDURES: The following tests were performed as and when necessary: • Blood for complete haemogram • Blood sugar fasting and post prandial • Pus for culture and sensitivity • Routine urine examinations • Fever profile that includes MPDA, Dengue NS1 Ag, urine for microscopic examination and culture sensitivity • Serological tests: HIV1 & 2, HBsAg, Anti HCV, VDRL • USG • Blood for coagulation profile • Liver function tests.

L) DATA COLLECTION AND INTERPRETATION: The case records by history taking and clinical assessment of the patient were studied. The collected data were coded, tabulated and statistically analysed and compared using SPSS program (statistical package for social science). Correlation between different findings was established by bar diagrams, pie charts wherever feasible.

Descriptive statistics were done for numerical parametric data as mean +/- SD (standard deviation) and minimum and maximum of the range, while they were done for categorical data as number and percentage. Analyses were done for quantitative variables using independent t -test in case of two independent groups with parametric data. Analyses were done for qualitative data using Chi square test for independent variables. The level of significance was taken at p value <0.05.

IV. Results And Analysis

This study was carried out in 360 patient over a period from June 2018 to May 2019. admitted in the Department of Obstetrics and Gynaecology of R.G.Kar Medical College and Hospital, Kolkata.

There were two study groups: Group V: those patients who underwent postplacental vaginal insertion of Cu-T 380A within 10 mins of vaginal delivery, using Kelly's forceps. Group C: those patients who underwent digital insertion of Cu-T 380A during Caesarean section after placental delivery and before closure of uterine layers. The patients were observed during their hospital stay and in the OPD after 6 weeks of discharge from the hospital and accordingly the results were determined.

Age- The mean age of both groups were taken and compared. Mean age of Group V was calculated to be 24.05 +/- 3.48 years and mean age for Group C was calculated to be 24.48 +/- 3.74. The difference of mean as calculated by unpaired t test was found to be not significant (p value= 0.257).

BMI--The BMI was calculated from height (m) and weight (kg). BMI=weight/height2. The mean and standard deviation of BMI for Group V was calculated to be 24.32+/- 2.33 kg/m2 and that for Group C was 26.26+/- 2.05 kg/m2. The difference of mean was calculated by unpaired t-test and was found to be significant (p value= <0.001).

GRAVIDAE The parity of women undergoing CuT 380A insertion after vaginal and caesarean section was compared. The results were compared using chi-square test. The p value came out to be 0.778 which was not significant.

ETHNICITYAmong a total of 360 patients, their ethnicity were compared. Among 180 Group V patients, 78 (43.3%) were found to be Hindu & 102(56.7%) were Muslims. Out of 180 Group C patients, 83(46.1%) were found to be Hindu and the rest 97(53.9%) were Muslims. The difference of mean was calculated using Chi-square test and was found to be not significant (p value= 0.596)

SPONTANEOUS EXPULSION OF IUD

The outcomes of Cu-T 380A insertion in the immediate postpartum period in both the groups were compared. The first and main outcome that was studied was spontaneous expulsion of the IUD. 16 women out of 180 in the vaginal insertion group experienced spontaneous expulsion either during their hospital stay or within 6 weeks of discharge. While only 5 women out of 180 of intracaesarean insertion group experienced spontaneous expulsion of the IUD. The p value was 0.013 which was significant.

TABLE 1:- SPONTANEOUS EXPULSION OF IUD

GROUP	SPONTANEOUS RXPULSION	NO EXPULSION	P-VALUE
V	16(8.9%)	164(91.1%)	0.013
C	5(2.8%)	175(97.2%)	

P VALUE= SIGNIFICANT

TABLE 2: COMPARISON OF OTHER COMPLICATION

GROUP	HEAVY BLEEDING		PELVIC PAIN		PID	
	YES	NO	YES	NO	YES	NO
V	17(9.4%)	163 (90.6%)	14 (7.8%)	166 (92.2%)	9 (5%)	171 (95%)
C	12(6.7%)	168 (93.3%)	15 (8.3%)	165 (91.7%)	63.3	174 (96.7%)
P-VALUE	0.333		0.846		0.423	

The other complications (like abnormal menstrual bleeding, pelvic pain and PID) of IUD insertions were also noted in both groups and the data were compared using Chi square test. The p value came out to be non significant for these complications. Also we included uterine perforation as one of the complication in our study. However we did not get this complication in any patient of any group in our study set-up.

V. Discussions

Initiation of family planning at the time of birth is opportune, since few women in low resource settings who give birth in a facility return for further care[7] . Intrauterine contraceptive device is the most commonly used reversible method of contraception worldwide with about 127 million current users.In a study by M. Shukla et al, the cumulative expulsion rate at the end of 6 months was 10.68 %[8]. In a systematic review by Kapp N. Curtis KM., postplacental placements during cesarean delivery are associated with lower expulsion rates than postplacental vaginal insertions[9] . A Cochrane systematic review reported that first year expulsion rates ranged from 2.4%–5.2% for the CuT380A.

In our study, we have taken into account a total of 360 patients into two groups of 180 each. One, undergoing immediate postplacental vaginal insertion of CuT380A , and the other undergoing intracaesarean insertion of CuT380A . Maximum age in our study group was 40 years and minimum age was 18 years. Mean age for group V was 24.05 years with standard deviation of 3.49 whereas those in group C was 24.48 with standard deviation of 3.74 , The mean BMI calculated from group V patients were 24.32 with a SD of 2.33. The mean BMI of sGroup C patients were 26.26 with a SD of 2.05. The difference of mean was calculated by unpaired t-test and was found to be significant (p value= <0.0001). Parity did not revealed any significant effect.

The first and the primary outcome of the study that is dealt with, is spontaneous expulsion of the IUD and comparing its rate in both the groups. Symptoms of expulsion include vaginal discharge, cramping or pelvic pain, unscheduled spotting or bleeding, dyspareunia (patient or partner), lengthening tail strings, or an IUD palpated in the vagina.[9] A Cochrane systematic review reported that first year expulsion rates ranged from 2.4%–5.2% for the CuT380A. A multinational trial with 7 years of follow up found that the cumulative discontinuation rate due to expulsion was 1.8 per 100 women-years of use.[10] Expulsion rates are affected by the experience of the clinician, the parity of the patient, severe dysmenorrhea, and the cycle day of placement.[11] Nulliparous women have a statistically (but not clinically) significantly higher rates of expulsion compared to multiparous women.[12]. Breastfeeding women who experience more uterine contractions were found to have no higher expulsion rates than women who menstruated.[13] A woman who has experienced one prior expulsion has a 30% chance of expelling a subsequent copper IUD.[14] Healthcare professionals should be well trained for the appropriate insertion of IUCD in the postpartum period.[14]

A studyby MishraS et al, showed Spontaneous expulsion rate of 6.4% [14].In our study spontaneous expulsion in the vaginal insertion group was found to be 16 or 8.9% of total 180 patients. Whereas it was only 2.8% i.e. 5 patients out of 180 in the intracaesarean group. Another multi country study done in Belgium, Chile and Philippines showed the rate of expulsion at one month ranging from 4.6% to 16.0%.. Expulsion rate of [immediate PPIUCD in a study done in China by Chi et al. 1994, was 25–37 %, while post-placental was 9.5–12.5 %. Expulsion of PPIUCD usually occurs in the first few months after insertion. In a multicenter study done by Tatum et al., the expulsion rates of PPIUCD were similar at 1 and 12 months in Belgium (4 %) and Chile (7 %), while in the Philippines, expulsion increased from 19 % at 1 month to 28 % at 12-months follow-up [15].

In a study by Nishi Garg et al ,out of 97 (20.64%) patients that accepted PPIUCD, 67 (69%) patients had post placental insertion. 15.4% underwent immediate postpartum insertion. 15.4% got PPIUCD with cesarean section. (25.77%) patients had missing threads/strings, 12 (12.37%) patients had mild pain and 9 women (9.27%) had excessive discharge[16].Like otherstudies bleeding(9.4%)among group V &(6.7%) in group C outnumbered other complications.Out of 180 patients in Group V and 15(8.3%) out of 180 patients in Group C complained of non specific lower abdominal pain, that was relieved using oral analgesics. . In Group V, 9 (5%) patients had PID, while in Group C, 6 (3.3%) patients had PID. No case of perforation was found in either of the groups. The most common complication was found to be heavy menstrual bleeding in the intravaginal insertion group (Group V) followed by spontaneous expulsion of IUD, pelvic pain, and PID. The most common complication in the intracaesarean insertion group (Group C) was found to be pelvic pain, followed byheavy menstrual bleeding and PID. Spontaneous expulsion of IUD was the least common complication (excluding uterine perforation which was not seen in any patients of both groups).

The results of our study showed that comparing both the groups, Group V patients, that is those undergoing postplacental intravaginal insertion of CuT 380A had a significantly higher rate of spontaneous expulsion than the intracaesarean insertion group without any significant difference in the rate of other complications.

Limitations

• This is a single tertiary hospital based study. Hence cannot be applied to the whole population.

• Long term follow up of patients was not done here and hence complications of IUD developing after six weeks of insertion was not taken into account.

• We have excluded 6th gravidae or more patients that might be a contributing factor in Copper-T 380A complications.

• IUD was inserted by various caregivers in both the groups. The skill of the inserter and the procedure that was followed might be a contributing factor in the higher rate of expulsion in Group V.

VI. Conclusion

1. Rate of expulsion of Cu-T380A is significantly higher in Group V (8.9% of women in Group V experienced spontaneous expulsion, whereas only 2.8% of women in Group C had spontaneous expulsion).
2. There is no significant difference in the rate of other complications of Cu-T380A between the two groups.
3. The rate of complications doesnot depend upon the gravidae of the patients.
4. Patients in Group C had higher BMI than those in Group V.

References

[1]. Post-partum IUCD reference manual. New Delhi: Family Planning Division, Ministry of Health and Family Welfare, Government of India; 2010.
[2]. Nelson A. Intrauterine contraceptives. Vol. 6. Philadelphia: Lippincott Williams and Wilkins; 2004. Gynaecology and Obstetrics.
[3]. Treiman, K. ,Liskin, L. , Kols, A. , Rinehart, W. IUD—An update. Population Reports. Series B, No. 6. Baltimore Johns Hopkins University School of Public Health, Population Information Programme; 1995.
[4]. Milsom, I. ,Andersson, K. , Jonasson, K. , Lindstedt, G. , Rybo, G. The influence of the Gyne-T 380S IUD on menstrualblood loss and iron status. Contraception. 1995; 52: 175–9.
[5]. Rivera, R. , Chen-Mok, M. , McMullen, S. Analysis of client characteristics that may affect early discontinuation of the TCu 380A IUD. Contraception. 1999; 60: 155–60.
[6]. Kulier, R. , O'Brien, P.A. , Helmerhorst, F.M. , Usher-Patel, M. , D'Arcangues, C. Copper containing, framed intra-uterine devices for contraception. Cochrane Database Syst Rev. 2007: CD005347.
[7]. Cleland K, Zhu H, Goldstuck N, Trussell J: Theefficacy of intrauterine device for emergency contraception: a systematic review of 35 years of experience.Hum reprod. 2012.27;1994-2000.
[8]. M. Shukla, S. Qureshi, and Chandrawati, "Post-placental intrauterine device insertion—a five year experience at a tertiary care centre in North India," Indian Journal of Medical Research, vol. 136, no. 3, pp. 432–435, 2012
[9]. Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review.Contraception. 2009;80:327–36
[10]. Zhang, J. ,Feldblum, P.J. , Chi, I.C. , Farr, M.G. Risk factors for copper T IUD expulsion: an epidemiologic analysis. Contraception. 1992; 46: 427–33.
[11]. Sivin, I. , Stern, J. Long acting, more effective copper T IUDs: a summary of US experience, 1970–75. Stud FamPlann. 1979; 10: 263–81.
[12]. Chen, J.H. , Wu, S.C. , Shao, W.Q. . The comparative trial of TCu 380A IUD and progesterone releasing vaginal ring used by lactating women. Contraception. 1998; 57: 371–9.
[13]. Bahamondes, L. , Diaz, J. , Marchi, N.M. , Petta, C.A. , Cristofoletti, M.L. , Gomez, G. Performance of copper intrauterine devices when inserted after an expulsion. Hum Reprod. 1995; 10: 2917–8.
[14]. Sujnanendra Mishra , Evaluation of Safety, Efficacy, and Expulsion of Post-Placental and Intra-Cesarean Insertion of Intrauterine Contraceptive Devices (PPIUCD) . J Obstet Gynaecol India.2014oct;64(5):337-34
[15]. Tatum HJ, Beltran RS, Ramos R, et al. Immediate post placental insertion of GYNE-T 380 and GYNE-T 380 postpartum contraceptive devices: randomized study. Am J Obstet Gynecol. 1996;175(5):1231–1235. doi: 10.1016/S0002-9378(96)70033-9.
[16]. GARG, Nishi; GROVER, Seema; KAUR, Bhupinder. Postpartum IUCD: its acceptance and complications. International Journal of Reproduction, Contraception, Obstetrics and Gynecology, [S.l.], v. 6, n. 7, p. 2973-2977, june 2017. ISSN 2320-1789.

Gupta Nancy. "A Prospective Observational Study of Rate of Expulsion between Postplacental Vaginal Insertion and Intracaesarean Insertion of Copper-T 380 a Intrauterine Device." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 12, 2019, pp 01-05.