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International Journal of Current Research
Vol. 9, Issue, 06, pp.52710-52713, June, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

A COMPARATIVE STUDY OF EXPULSION RATE OF PPIUCD CU-T INSERTION AMONG VAGINAL AND CAESAREAN DELIVERY CASES

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ARTICLE INFO

Article History:
Received 10th March, 2017
Received in revised form
18th April, 2017
Accepted 21st May, 2017
Published online 30th June, 2017

Key words:

PPIUCD,
Expulsion,
Continuation.

ABSTRACT

Background: In India, 65% of women in the first year postpartum have an unmet need for family planning. Copper IUCDs are the most commonly used type of IUD and the Cu T 380A has been found to be most effective IUD available in govt. Sector free of charge. The IUCD is a safe and effective contraceptive option for postpartum women who wish to either space or limit subsequent births. Methods: In a hospital based prospective observational, study we compared expulsion rate of post placental IUCD in vaginal and caesarean delivery groups.
Results: We found that over all continuation rate for PPIUCD was good (84.5%) at 3 months follow up. Continuation rate was significantly higher in LSCS group (91%) as compared to vaginal delivery group (78%); P=0.019.We found that expulsion rate is significantly higher in vaginal group (10%) as compared to caesarean delivery (2%) group at 3 months of follow up.
Conclusions: The acceptance of PPIUCD was high in the parturients studied and comparable to other studies done globally. We can conclude that inserting CuT 380A postplacentally is safe, effective and has high retention rate along with immediate return of fertility on discontinuation. The expulsion rate was not high, and further can be reduced with practice.

Citation: Jasmine Lall, Lata Rajoria and Oby Nagar, 2017. "A comparative study of expulsion rate of PPIUCD cu-t insertion among vaginal and caesarean delivery cases", *International Journal of Current Research*, 9, (06), 52710-52713.

INTRODUCTION

Postpartum period is one of the critical times when both woman and newborn need a special and integrated package of health services as morbidity and mortality rates are quite high during this period and also the women are vulnerable to unintended 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, postpartum hemorrhage, low birth weight babies, fetal loss and maternal death. Only 26% of women are using any method of family planning during the first year postpartum. The reasons for non-use of contraception are many, including lack of awareness, non-availability of accessible family planning services and limitations on women's mobility due mostly to cultural or geographical factors. Intrauterine devices (IUDs) have been used by women in India for decades for spacing pregnancy. Copper IUDs are the most commonly used type of IUD and the Cu T 380A has been found to be most effective IUD available in govt. sector free of charge (United Nations Population information network (POPIN), 1996). To achieve this objective, postpartum IUCD has been introduced in the National Family Welfare Programme since March 2010 in several states. To address the unmet need during the post-partum period the Ministry of Health and Family Welfare, Government of India developed a national strategy to expand Post-Partum Intrauterine Device (PPIUD) services among public sector facilities.

Since, not much work has been done in assessing the complications and side effects of PPIUCD in CAESAREAN AND VAGINAL DELIVERIES, we decided to undertake this study.

MATERIALS AND METHODS

Study design: The present study is hospital based prospective study.

Study place: Department of Obstetrics & Gynaecology, S.M.S. Medical College & attached group of Hospitals, Jaipur from March 2015 onwards

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Study population: Study will be conducted on the patients undergoing deliveries at Mahila Chikitsalaya, SMS Medical College, Jaipur

Study duration: One year (March 2015 to Feb 2016)

Sample size

Sample size is calculated at 80%study power and alpha error of .05 assuming 75% continuation rate till 6 months of PPIUCD in normal vaginal delivery cases and 90.24% in caesarean section cases as found in the study of Sharma *et al*. {Int J Res Med Sci. 2015 Jan; 3(1)183-187}. 94 Cases in each group are required with continuity correction which are further enhanced to 100 cases in each group considering 15% dropout rate as per reference article

Statistical analysis

Descriptive statistics will be used to describe demographic variables and clinical characteristics. Continuous variable will be summarized as mean and SD whereas Nominal/Categorical variables as proportion unpaired T test will be used(%) for comparison of continuous variable while Chi square test will be used for Nominal/Categorical variables P<0.05 will be taken as significant Med Calc 14.0.0 software will be used for statistical calculation.

Selection of patients

Inclusion criteria

1. Women in immediate post placental period (within 10 minutes of placental expulsion) in vaginal and caesarean delivery
2. All women who give consent to participate in the study

Exclusion criteria

1. PPH
2. PROM > 18 hours
3. Congenital uterine anomaly
4. History of any previous ectopic pregnancy
5. Distorted uterine cavity
6. Patients consenting for sterilization
7. Chorioamnionitis

Plan of action

Informed consent of all the eligible candidates will be taken. Inclusion and exclusion criteria will be taken into consideration.

Recruitment plan

The study participants will be recruited from Inpatients of the Department of Obstetrics and Gynaecology. All patients will be subjected to detailed history, clinical examination and relevant investigations.

Following tests will be done in all the selected participants:

1. Haemoglobin
2. ABO with Rh factor
3. Complete urine analysis
4. HBsAg, VDRL, HIV
5. Fasting blood sugar
6. Blood urea, S. Creatinine
7. USG uterus for any uterine anomaly.

After the work up and based on mode of delivery the study participants will be divided into two groups:

Procedure details

All pregnant women who are attending our antenatal clinic or admitted in the labor ward will be counseled for different postpartum family planning methods. Those women who chose PPIUD will be informed regarding advantages, limitations, effectiveness and side effects related to IUD. Every woman will be screened for clinical situations as per WHO medical eligibility criteria in the antenatal period, as well as immediately prior to insertion after delivery. After obtaining Informed consent in all subjects. The PPIUD (CuT-380A) will be placed within 10 minutes following delivery of the placenta using Kelly's placental forceps. Subjects will be followed up at 6 weeks postpartum and then at 3 months. During the follow up visit they will be subjected to detailed history and Per Speculum examination. In cases in which threads are not visible USG pelvis will be done to confirm the presence of IUCD in the uterus.

RESULTS

Most of the subject in Vaginal delivery group (88%) and LSCS group (89%) belonged to 20–30 years age group. Application of Chi square test revealed that the two group did not differ significantly in their age composition. As far as distribution based on religion is concerned 81% of the study subjects were Hindu (86% of vaginal delivery patients and 76% of LSCS group), rest were Muslims. Application of Chi square test revealed that the two groups were comparable in relation to their religion. When study subjects are compared according to complaints they have, 57.5% of the subjects had no complain at 6 week follow up (52% in vaginal delivery group and 63% in LSCS group). At 3 months follow up 55% subjects in vaginal delivery group and 53% in LSCS group did not have any complain. The two groups did not differ significantly in relation to absence of complaint at 6 weeks and 3 months follow up. (Table 1) Our study reveals that at 6 weeks follow up thread visibility in vaginal delivery group was significantly higher (96%) as compared to LSCS group (60%); P value<0.001, overall the thread visibility was not significantly different at among the two group at 3 month follow up (P=0.075). At 3 months follow up expulsion rate in vaginal delivery group was significantly higher (10%) as compared to LSCS group (2%); P value=0.037.Overall the expulsion rate was 6% at 3 months .the removal rate at 6 week and 3 month follow up was 8% and 12% respectively. (Figure 1) (Table 2) Chi square test shows that the two groups did not differ significantly regarding removal of IUCD. Over all continuation rate for PPIUCD was good (84.5%) at 3 months follow up. Continuation rate was significantly higher in LSCS group (91%) as compared to vaginal delivery group (78%); P=0.019.

Table 1. Comparison of study groups on basis of No. of subjects with No Complain

Follow up time	Vaginal Delivery		LSCS		Total no. of Subjects with no complain		P value (significance)
	N	%	N	%	N	%	
6 week	52	52	63	63	115	57.5	0.153(NS)
3 months	55	55	53	53	108	54	0.887(NS)

This table shows that 57.5% of the subjects had no complain at 6 week follow up (52% in vaginal delivery group and 63% in LSCS group). At 3 months follow up 55% subjects in Vaginal delivery group and 53% in LSCS group did not have any complain. The two groups did not differ significantly in relation to absence of complaint at 6 weeks and 3 months follow up.

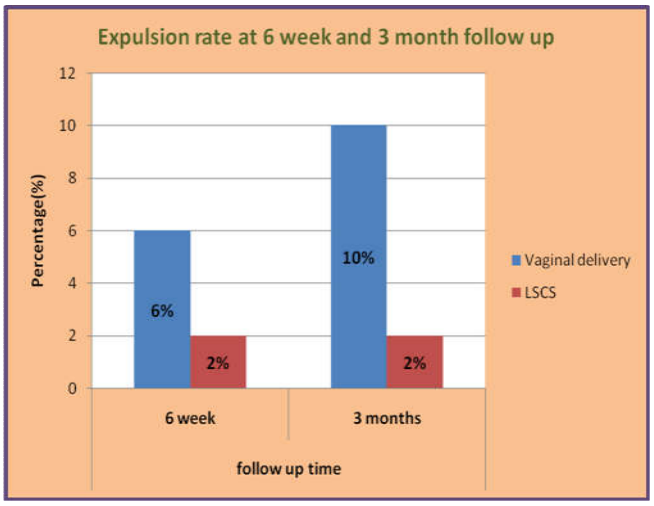
Table 2. Comparison of study groups on basis of Expulsion of IUCD

Follow up time	Vaginal Delivery		LSCS		Total no. of Subjects with Expulsion		P value* (significance)
	N	%	N	%	N	%	
6 week	6	6	2	2	8	4	0.279 (NS)
3 months	10	10	2	2	12	6	0.037 (S)

* P value calculated using Chi square test

This table reveals that at 3 months follow up expulsion rate in vaginal delivery group was significantly higher (10%) as compared to LSCS group (2%); P value=0.037.

Overall the expulsion rate was 6% at 3 months.



DISCUSSION

Post Partum IUCD insertion is a well-accepted method for many years in several countries including India. Cochrane database of systematic reviews 2002 after analyzing several trials concluded that immediate insertion of an IUCD after abortion is both safe and practical. (Grimes *et al*., 2002) Use of Cu T 380A in immediate postpartum period is still not very popular in India. Few concerns like higher expulsion rate, perforation, non-visibility of strings have limited its use. Cochrane database 2010 concluded that PPIUCD appeared safe and effective, early follow-up may be important in identifying expulsion. (Grimes *et al*., 2010) Unintended pregnancy is still a major concern in India. Despite the availability of safe and effective forms of contraception and increasing contraceptive use, societies of developing and developed countries encounter unacceptably high rates of unintended and unwanted pregnancies which contribute to population growth. Post partum period is highly vulnerable period to unintended pregnancy as there are limited contraceptive options available in the breast feeding women. At the same time ovulation is highly unpredictable in non breast feeding or non exclusive breast feeding women. Thus, postpartum period is potentially an ideal time to begin contraception as women are more strongly motivated to do so at this time, which also has the advantage of being convenient for both women and health-care providers (Xu *et al*., 1994). Though Post partum IUCD insertion immediately after delivery is an upcoming topic, its efficacy and safety is to be determined. Various studies were carried out to determine its efficacy, safety outcome using different techniques of insertion, but data on post partum IUCD insertion using Kelly's forceps is deficient. In our study we found that 57.5% of the subjects had no complain at 6 week follow up (52% in vaginal delivery group and 63% in LSCS group). At 3 months follow up 55% subjects in Vaginal delivery group and 53% in LSCS group did not have any complain. The two groups did not differ significantly in relation to absence of complaint at 6week and 3 months follow up period. In an another study by Sharma *et al*. (2015) in 59 (61.45%) women there was no complaint regarding PPIUD results being similar to ours. In an another study by Shukla *et al*. (2012) using Cu T 200 B in immediate post-partum period, they found it was only 11.3% of participants were symptom less at 6 months. Kittur *et al*. (2012) has shown that 86.2% of subjects in their study were satisfied with the PPIUCD insertion. Better acceptance, following standard procedure and close follow up in our study may explain the reason for the same.

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 our study we assessed the visibility of thread at follow up in both the groups, we found that at 6 weeks follow up thread visibility in vaginal delivery group was significantly higher (96%) as compared to LSCS group (60%); P value<0.001, overall the thread visibility was not significantly different at among the two group at 3 month follow up (P=0.075). In intracaesarean 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. Ultrasound was done in all cases to ensure proper placement of IUCD. Similar results were also found in study done by Single *et al*. (2014). In their study, IUCD strings were visible in 61.87% women at first visit and visibility increased to 84.62% at 12 months. In 40 (14.65%) women strings were not visible at 12 month, despite ultrasonographic confirmation of the IUCD being in place. Expulsion of IUCD is very important parameter which has been studied in our present study and we found that at 3 months follow up expulsion rate in vaginal delivery group was significantly higher (10%) as compared to LSCS group (2%) (P value=0.037). Overall the expulsion rate was 6% at 3 months. In a study by Neha Jain *et al*. (2015) expulsion rates of the immediate PPIUCD at 4-6 wks interval were 3.5%. Lower expulsion rate in there study is explained by fact that follow up duration was just 6 weeks. But similar to our study, multicountry study done in Belgium, Chile and Phillippines (Blanchard *et al*., 2006) has showed the rate of expulsion at 1 month ranging from 4.6 to 16 %.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*. (Kittur and Kabadi, 2012), 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. Similar to our study expulsion rate was higher among vaginal group subjects as compared to caesarean group in study conducted by Jisha bai *et al*. (2015). In a study by Kumar *et al*. (Kittur and Kabadi, 2012), the expulsion rate was about 3.6%, in various other studies the expulsion rate of 5.6% reported among 210 women in a clinic in Hubli, Karnataka state in India. In a study done by Aruao *et al*. (2012) it was 1.6% among 3000 women in a hospital in Paraguay, Another study reported expulsion rate of 5.6%, among 305 women belonging to periurban Lusaka, Zambia (Blumenthal *et al*., 2011).

Another study of 1317 women in north India reported a cumulative expulsion rate of 10.7% by six months (Shukla *et al*., 2012). Higher expulsion rates of around 9-16% have been reported in earlier studies (Celen *et al*., 2004). One recent study from Turkey of PPIUCD among women after C-section reported an expulsion rate of nearly 18% (Bonilla Rosales *et al*., 2005). In a study by Sharma *et al*. (2015) expulsion rate was 5.2 percent. In a study be Fernandes *et al*. (2004) the authors used Multiload Cu 375 immediately after vaginal delivery and caesarean section. This study showed a significant difference in expulsion/removal rate in post placental IUD insertion after vaginal deliveries and caesarean sections. The expulsion/removal rate was 32% among the subjects in vaginal delivery group, but there were no expulsions or removals in those submitted to caesarean section. In our study also expulsion rate was more in IUD insertion after vaginal delivery (10%) as compared to caesarean section (2%) at the end of 6 months. Jose, Lopez *et al*. (2012) compared levonorgestrel intrauterine system (LNG-IUS) with Cu T 380A insertion during caesarean section. The IUD expulsion rate was 4.5% in each group. In all the studies including this present study whether this very high retention rate following caesarean relates to the direct visual fundal placement by the surgeon or to the undilated cervix at the time of elective caesarean is unclear.

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