Research Paper

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A Study Of Acceptance, Follow Up & Outcome Of Post Partum Intra Uterine Devices

Medical Science

KEYWORDS : PPIUCD, IUCD, POST PARTUM, POST PLACENTAL, CONTRACEPTION.

Dr. Mitesh V. Dhuda	3rd year resident, Dept. of Obs&Gynac
Dr. Saral G. bhatiya	Associate Professor, Dept. of Obs&Gynac
Dr. Pooja Agarwal	2nd year resident, Dept. of Obs&Gynac
Dr. yogita Lad	2nd year resident, Dept. of Obs&Gynac

ABSTRACT

Objective : To study patient's acceptance of PPIUCD. To study post insertion trends of follow up. To study any adverse factor / failure due to PPIUCD.

Material and methods : This prospective study was carried out in the department of Obstetrics and Gynaecology at the Government Medical College and New Civil Hospital, Surat between January 2012 to January 2013.All pregnant and laboring women were counselled about the need for contraception as part of their counselling. The various options of contraception were discussed and the newly introduced postpartum insertion of IUCD was also discussed with them. The options of insertion of IUCD within ten minutes of placental delivery of during CS were explained. The safety and effectiveness of this method was emphasized. The common side effects and their management were also discussed to help these ladies make an informed choice.After insertion patients were counselled for follow up at seven days, six weeks and six months of delivery. They were discharged after 48 hours of normal delivery or on the fifth day of CS.

Results : This study enrolled 961 subjects undergoing PPIUCD (CuT 380A) insertion in the immediate post placental period or during CS. Majority of our subjects was in the 21 to 25 years age group. Overall 65% of the acceptors were the ones who had undergone a CS. 72.42% did not have a single male child. Overall 71.38% subjects turned up for their 4-6 weeks follow-up (74.96% of subjects of CS and 64.67% of subjects of FTND turned up for their 4-6 weeks follow up). The difference in the follow-ups after CS and FTND at 4-6 weeks was statistically significant (p=0.001)t. At six months – almost 53% subjects were available for follow up with almost similar follow up rates after CS and FTND. Overall 28.61% subjects were lost at their 4-6 weeks follow-up (25.04% of subjects of CS and 35.33% of subjects of FTND were lost at their 4-6 weeks follow up). The difference in the lost to follow-ups after CS and FTND at 4-6 weeks was statistically significant (p=0.001). At six months – almost 46% subjects were lost to follow up with almost similar loss rates after CS and FTND. Subjects with FTND had a slightly higher complaints rate at six weeks (probably because tolerance of complaints was better by CS subjects) and those with CS had a slightly higher rate of complaints at six months follow up.

The differences were not statistically significant. Though there was no statistical significance found between CS and FTND subjects regarding pain and bleeding problems at 4-6 weeks and 6 months follow up except for missing strings which was seen more in CS subjects at 4- 6 weeks follow up (p<0.05). But at 6 months follow up complain of missing strings were same in both CS and FTND.

CONCLUSION : The insertion of immediate post-partum IUCD is safe and effective in the means of complications. Though it is a new concept for the population, it is well accepted by community. The expulsion rates were though higher than the conventional interval post-partum IUCD but it is also equally effective in regards of proper counseling, maintaining strict aseptic precautions and with proper insertion technique. Advantages of immediate post-partum insertion include high motivation, assurance that the woman is not pregnant, and convenience. It is very helpful measure to meet the unmet need of contraception in developing countries like India. Our prospective study has concluded that the immediate post-partum IUCD can play a significant role in providing birth spacing as well as reversible effective contraception without having any effect on the health of the baby. As the study results show that the pain and bleeding encounter as most common complaints in majority of the patients in normal delivery as well as LSCS patients, which can be compensated appropriately by proper counseling at the time of insertion. We recommend that this method can be employed for providing birth spacing and reversible contraception.

INTRODUCTION

According to census 2011, India has 1.21 billion people, more than 1/6th of world's population.

As a national problem, population over growth, as seen in all developing countries including India, is a major culprit hindering the growth of country in all its aspects.

As advances in technology, medical sciences & improvements in healthcare delivery system, we have decrease death rate, Infant mortality rate and thus average life expectancy of an Indian is around 70 years.

As a matter of fact, Govt. of India can't enforce *one* child norm or compulsory sterilization on the population; we need to educate them for BIRTH SPACING.

As, we can't control the number of children, a couple will have, we should and must educate them to have birth spacing.

On the other hand, most common cause of maternal morbidity & mortality in developing countries is haemorrhage either due to anaemia or due to any other obstetrical cause.

These causes are preventable just only by effective birth spacing.

Women who have conceived in lactational amenorrhea are more prone to develop nutritional deficiencies. These nutritional deficiencies will lead to poor pregnancy outcome.

By birth spacing, this can be stop effectively. PPCuT insertion has been established as a long-term effective, reliable and reversible method of contraception as it offers numerous advantages.

Easy insertion, no adverse effect on breast-feeding, cost effective, protective against unwanted pregnancy and consequently abortion and relief from overcrowded outpatient facilities. In addition, insertion complains are masked by lochial blood and cramping.

As PPIUCD is a newer concept of contraception, we must study about it.

The current approach in Family Planning emphasizes on offering high quality contraceptive services among eligible clients on a voluntary basis. An important component of the program is promoting adequate spacing of births. The National Population Policy 2000 has recognized, as its immediate objective, the task

of addressing the unmet need for contraception to achieve the medium term objective of bringing the Total Fertility Rate (TFR) to replacement level by 2010 (i.e. to reduce the Net Reproductive Rate to 1) so as to achieve the long-term goal of population stabilization by 2045.

As per NFHS –3, the contraceptive prevalence rate in India is 56.3 %, which varies widely among different states and the unmet need for family planning is high at 13% (6% for spacing).

Intrauterine Contraceptive Device (IUCD) is one of the most commonly used reversible methods of contraception among married women of reproductive age worldwide. Results of recent studies and literature have confirmed that IUCDs provide very effective, safe and long-term protection against pregnancy and the health risks associated with the method are negligible too.

Altogether, 13.6% of couples around the world have selected the IUCD for birth control. Utilization rates are not homogenous from country to country. IUCD use is high (14.5%) in less developed countries and low (7.6%) in more developed countries. Beyond socioeconomic status, rates of IUCD use also vary on a geographic basis. Central and East Asian countries along with Latin American countries report that more than 70% of women, who use any form of contraception, use IUCD. In contrast, in Western Europe, approximately 11% of women use IUCD, whereas in most parts of Africa, less than 1% of women use IUCD.

MATERIAL AND METHODS

Place of study: Department of Obstetrics & Gynaecology, NCH & Medical Collage, Surat Type of study: Prospective Analytical Study Agent used: Copper T 380 A Sample size: 961 cases

Subjects and method:

This prospective study was carried out in the department of Obstetrics and Gynaecology at the Government Medical College and New Civil Hospital, Surat between January 2012 to January 2013.All pregnant and laboring women were counselled about the need for contraception as part of their counselling. The various options of contraception were discussed and the newly introduced postpartum insertion of IUCD was also discussed with them. The options of insertion of IUCD within ten minutes of placental delivery of during CS were explained. The safety and effectiveness of this method was emphasized. The common side effects and their management were also discussed to help these ladies make an informed choice. The intra-natal and post-natal management the subjects were unchanged except for IUCD insertion as described in the section of review of literature after placental expulsion in normal delivery or in CS. After insertion patients were counselled for follow up at seven days, six weeks and six months of delivery. They were discharged after 48 hours of normal delivery or on the fifth day of CS. The data was recorded in the enclosed proforma and data analysis was done using EPI-Info software.

Eligibility

Ages Eligible For Study: 18 years and older

Criteria

INCLUSION CRITERIA

Pregnant at time of enrollment
Desires to use the Copper T 380A for contraception
Willing and able to sign an informed consent
Willing to comply with the study protocol
Age greater than or equal to 18 years

EXCLUSION CRITERIA

- Unwilling for IUCD insertion.
- Age <18 yrs. or > 45 yrs.
- Delivery outside NCH, Surat.
- PROM > 12 hrs.
- Severe Anaemia
- Bleeding tendency/ APH
- Unresolved Traumatic / Atonic PPH
- Patient admitted with fever
- Allergy to Copper or pelvic tuberculosis, severe thrombocytopenia.
- Presence of leiomyoma significantly distorting the uterine cavity and thus not allowing placement of the CuT380A.
- Uterine anomaly, which would not allow placement of the CuT380A.
- Evidence of intra-uterine infection (Chorioamnionitis)
- Pre-term birth
- IUFD
- Ruptured uterus

METHOD OF CASE ALLOCATION

- Randomized post-partum cases taken satisfying inclusion and exclusion criteria were taken in the study from time period of Jan-2012 to Jan-2013 (961 cases)
- Study was the insertion of IUCD (CopperT380A) immediately after delivery of placenta i.e., within 10 minutes of delivery of placenta in either normal delivery or during LSCS.
- It is to ensure that the patient has given valid consent. The CopperT380A is inserted immediately after the delivery of the placenta.
- The Copper T involved in study was supplied by Government in hospital supply of RCH, NCH Surat, which is CuT380A having effectiveness of 10 years.
- Otherwise active management of third stage of labour conducted according to WHO guidelines.

METHOD OF OBSERVATION

- Each patient observed for one hour in labour room for vital & for any post- partum unusual events.
- Patients were shifted to post-partum ward.
- Patient was asked about complaints and managed accordingly.

RISK INVOLVED IN STUDY

- Improper process of decision-making by patient leading to disapproval or dissatisfaction with services
- Possibility of infection of uterine cavity due to high level of activity in labour room with limited manpower.
- Lost to follow up can adversely affect the study.
- Patient has false sense of increased post-partum bleeding especially in case of primipara.
- Having worry about missing strings particularly in intracaesarean cases.

STEPS TAKEN TO REDUCE RISK

- Persons involved in counselling will be properly trained in various issues to be discussed with the patient.
- Reconfirmation of the patient's desire at the time of insertion.
- The investigator shall take aseptic & antiseptic precautions.
- Proper history taking at the time of insertion regarding exclusion criteria by the investigator.
- Preferably the patient should be from Surat city whose address, phone number shall be taken & the investigator shall communicate regarding when & where to come for follow up.
- When patient comes for emergency follow up, mechanism is established in the dept. to inform the investigator to attend & arrange for treatment.

RESULTS

A prospective study was carried out on PPIUCD insertion during

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Jan-2012 to Jan 2013. A total of 961 patients were enrolled during study and observed. Following are the observation of my study:

BASIC PROFILE

PARITY (n=961)		
	NO. OF PATIENTS	%
PRIMIPARA	476	49.53%
MULTIPARA	485	50.47%
MODE OF DELIVERY (n=961)		
FTND	334	34.76%
C A E S A R I A N SECTION	627	65.24%
PREGNANCY OUTCOME (n=961)		
MALE	551	57.34%
FEMALE	410	42.66%
MALE CHILD		
0	696	72.42%
1 OR MORE	265	27.58%

AGE

AGE (yrs.)	Frequency	Percent
A (≤ 20)	258	26.85%
B (21-25)	489	50.88%
C (26-30)	193	20.08%
D (>30)	21	2.19%
Total	961	100.00%

As shown in above table

- 50.88% women who accepted PPIUCD as a contraception method belonged to age group of 21-25 years.
- Of concern value is that about 26.85% women were below or of age 20 years, which shows early marriage before 20 years is still prevalent in India.
- Only 2.19% women belonged to age group >30 years probably because of higher preference of tubal ligation in this group of subjects who completed their child bearing.
- The reproductive age group of 21-30 years comprised of about 71% acceptors of PPIUCD.

PARITY

PRIMI/ MULTI	Frequency	Percent
Multi	485	50.47%
Primi	476	49.53%
Total	961	100.00%

As shown in above table the acceptance of PPIUCD in our study was similar amongst primiparas and multiparas.

MODE OF DELIVERY

CS/FTND	Frequency	Percent
CS	627	65.24%
FTND	334	34.76%
Total	961	100.00%

Above table shows 627 subjects of CS consented for PPIUCD as compared to 334 subjects of FTND, as subjects are more concerned about an operative procedure rather than normal delivery and can be easily counselled for PPIUCD and need for spacing.

STATUS OF MALE CHILD

Following tables show a different trend of having a male child and its relation to contraception.

Male child	No. of patients	%
0	696	72.42%
1 or more	265	27.58%
0 male child in multi	220	31.61%

Table shows, 72.42% of acceptors of PPIUCD subjects did not have any male child. Of the 696 acceptors of PPIUCD- 220 (31.61%) subjects were multiparous.

	Present pregnancy outcome	
CS/FTND	F	M
CS(n=627)	251(40.04%)	376 (59.96%)
FTND(n=334)	159(38.78%)	175(52.40%)
TOTAL	410	551

	Child	
PRIMI/ MULTI	F	M
Multi(n=485)	213(43.92%)	272(56.08%)
Primi(n=476)	197(41.39%)	279(58.61%)
TOTAL	410	551

Though, in our country, most couples want a male child to propagate their family, this impact also seen in our study.

As those who have born a male child in this pregnancy were more to accept PPIUCD method of contraception compared to those who have born a female child.

In mode of delivery, a total of 376 women who have male child prefer to have PPIUCD compared to 251 women who have female child by caesarian section.

And also in FTND 175 women with a male child preferred a PPIUCD, compared to 159 women who have a female child born. Statistically it is significant and p value is <0.05

Comparing primigravida and multigravida for acceptance of PPIUCD, also shows predominance of women who have born a male child. Though it is statistically not significant, p is >0.05.

These results were comparable to results in National Family Health Survey of India 2011.

But in conclusion, to have 1 or more male child in family didn't affect the decision of parturient to have PPIUCD.

FOLLOW UP

Following is the data about the follow up at 1 month and at 6 months.

Tables show number of subjects who turn up for their routine check at 4-6 weeks and 6 months and those who did not.

FOLLOW UP	CS	FTND	TOTAL
4-6 wks.	470/627 (74.96%)	216/334 (64.67%)	686/961 (71.38%)
6 Months	339/627 (54.06%)	179/334 (53.59%)	518/961 (53.90%)

Overall 71.38% subjects turned up for their 4-6 weeks follow-up- 74.96% of subjects of CS and 64.67% of subjects of FTND turned up for their 4-6 weeks follow up. **The difference in the follow-ups after CS and FTND at 4-6 weeks was statistically significant (p=0.001).**

At six months – almost 53% subjects were available for follow up with almost similar follow up rates after CS and FTND.

LOST TO FOLLOW UP	CS	FTND	TOTAL
4-6 WKS.	157/627 (25.04%)	118/334 (35.33%)	275/961 (28.61%)
6 MONTHS	288/627 (45.94%)	155/334 (46.41%)	443/961 (46.09%)

TYPES OF COMPLAINTS AT FOLLOW UP

On follow up, following are the complaints subjects had.

The common complaints noted were abdominal pain, abnormal bleeding per vaginum and missing strings.

	4-6 WEEKS FOLLOW UP		6 MONTH FOLLOW UP		TOTAL
COMPLAINS	FTND	CS	FTND	CS	
PAIN	4/216 (1.85%)	7/470 (1.48%)	5/179 (2.79%)	8/339 (2.35%)	24
MENORRAGHIA/ BLEEDING PROBLEMS	8/216 (3.70%)	15/470 (3.19%)	9/179 (5.03%)	20/339 (5.89%)	52
MISSING STRINGS	2/216 (0.92%)	16/470 (3.40%)	2/179 (1.11%)	9/339 (2.65%)	29

Though there was no statistical significance found between CS and FTND subjects regarding pain and bleeding problems at 4-6 weeks and 6 months follow up except for missing strings which was seen more in CS subjects at 4-6 weeks follow up ($p<0.05$). But at 6 months follow up complain of missing strings were same in both CS and FTND.

REMOVAL OF IUCD

Following table deals with data of IUCD removal and reasons for the same.

	4-6 WEEKS FOLLOW UP		6 MONTH FOLLOW UP		TOTAL
	FTND	CS	FTND	CS	
REMOVAL	37/216 (17.12%)	48/470 (10.21%)	17/179 (9.49%)	33/339 (9.73%)	135
REASON FOR REMOVAL					
WITH COMPLAINTS (n=52)					
PAIN	4/4	7/7	3/5	6/8	20
MENORRAGHIA	8/8	15/15	1/9	8/20	32
WITHOUT COMPLAINTS (n=83)					
TL	17/204	18/448	6/165	9/311	50
FOR FERTILITY	8/204	8/448	7/165	10/311	33

A higher rate of removal of IUCD in FTND group as compared to CS group, which is significant ($p<0.05$).

No statistical significance found in between two (CS and FTND) with regard to pain and bleeding complains.

The other group, those who had no complains but had removed their IUCD, were the subjects who wanted either tubal ligation (higher in FTND group as compared to CS)or to plan a pregnancy in near future (same in CS and FTND group).

Overall: 20 of the 24 subjects with abdominal pain and 32 out of 52 with menorrhagia /abnormal bleeding had their IUCDs removed, while by proper counselling and drug therapy 4 subjects of pain and 20 subjects of bleeding problems had continued their use of IUCD.

EXPULSION OF IUCD

As we all know most common side effect of PPIUCD is its high expulsion rate. This was also observed in our study too.

	FTND	CS	TOTAL
4-6 weeks	8/216 (3.70%)	16/470 (3.40%)	24/686 (3.49%)
6 months	12/179 (6.70%)	21/339 (6.19%)	33/518 (6.37%)

As seen, there was no significant difference found between FTND and CS group in terms of expulsion at follow-up whether at 4 weeks or six months.

24 out of 686 IUCD were expelled at 4-6 weeks of follow up, while 33 out of 518 IUCD were expelled at 6 months follow-up.

CONCLUSSION

- The current approach in Family Planning emphasizes on offering high quality contraceptive services among eligible clients on a voluntary basis. An important component of the program is promoting adequate spacing of births.
- The insertion of immediate post-partum IUCD is safe and effective in the means of complications. Though it is a new concept for the population, it is well accepted by community. The expulsion rates were though higher than the conventional interval post-partum IUCD but it is also equally effective in regards of proper counseling, maintaining strict aseptic precautions and with proper insertion technique.
- Advantages of immediate post-partum insertion include high motivation, assurance that the woman is not pregnant, and convenience. It is very helpful measure to meet the unmet need of contraception in developing countries like India.
- Our prospective study has concluded that the immediate post-partum IUCD can play a significant role in providing birth spacing as well as reversible effective contraception without having any effect on the health of the baby.
- As the study results show that the pain and bleeding encounter as most common complaints in majority of the patients in normal delivery as well as LSCS patients, which can be compensated appropriately by proper counseling at the time of insertion.
- We recommend that this method can be employed for providing birth spacing and reversible contraception.