Research Paper Medical Science

Evaluation of Safety Efficacy and Expulsion of Ppiucd

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ABSTRACT

AIM : This study is aimed at determining the safety , efficacy and expulsion of PPIUCD. This study also aims to determine the rates of complications(bleeding, pelvic infection, lost strings, and displacement) following PPIUCD insertion among the clients by 6 to 12 months.

Materials & Methods : This study was conducted at Civil hospital Ahmedabad, India from May 1St 2012 to April 30th 2014. Women admitted and delivered at Civil hospital, Ahmedabad were counselled and those who fulfilled the medical eligibility criteria and had no contra indication for PPIUCD were provided the PPIUCD services.

Results: Total women 250, lost to follow-up 18, complications 27 (expulsion 9, bleeding 14, string problem 4), removal 8, continuation 230.

Conclusion: The PPIUCD (Cu380A) is demonstrably safe, effective, has high retention rate. The expulsion rate is not very high and it can be reduced with correct techniques, correct selection of clients, and correct time selection for the client.

KEYWORDS PPIUCD- Post partum intra uterine contraceptive device

Introduction:

Postpartum period is a very vulnerable period both for women and infant. Initiation of contraception during this period is important to prevent unintended pregnancy and short birth intervals. It can avert more than 30% of maternal deaths and 10% of child mortality. Pregnancy occurring within six months of the last delivery holds a 7.5-fold increased risk for induced abortion and a 1.6-fold increased risk of stillbirth.

The postpartum period is an important time to initiate contraception because women are accessing the health-care system, generally have multiple encounters with the health care system, and might have increased motivation to avoid early pregnancy. Ovulation can occur as early as 25 days postpartum among non-breastfeeding women, underscoring the importance of initiating contraception in the very early postpartum period. Providing contraception during this time is cost-effective and efficient.

In India postpartum IUCD program is started by Family planning division of Ministry of Health and Family Welfare under Janani Shishu Suraksha Yojana, National Rural Health Mission in association with Bill and Melinda Gates Foundation, Norway India Partnership Initiative, JHPIEGO (India), USAID and Packard. The Government of India supplies CuT380A free of cost in all government institutes.

Women are highly motivated and receptive to accept family planning methods during the postpartum period. Demographic and Health Survey show that 40 percent of women in the first year postpartum intend to use a family planning method but are not doing so.

So this study was planned to initiate contraception before hospital discharge after delivery. It is a potentially practical and cost-effective strategy to increase effective postpartum contraceptive use, given that the women are already within the health care system and motivation for contraception may be high.

AIMS AND OBJECTIVES

- To Motivate the patient for Contraception.
- To study retention rate of postpartum IUCD.
- To find out various complications of postpartum IUCD.
- To study failure rate of Postpartum IUCD.
- To study the expulsion rate of postpartum IUCD

MATERIALS AND METHODS

Study design: Prospective study

Period of study: May 1st 2012 to 30th April 2014

Sample size: study group: 250

Setting: Department of Obstetrics and Gynecology, Civil hospital Ahmedabad.

STUDY GROUP:

A total of 250 women who opted for insertion of Copper T 380A in immediate post delivery period, within 10 minutes of expulsion of placenta i.e.(immediate post placental insertion) and intra caesarean section and insertions within first 48 hours of delivery(Immediate Post Partum) formed the study group.

The women presenting to antenatal OPD were counseled about family planning methods and were encouraged to opt for copper T insertion immediately after delivery. The women presenting to labor room were counseled and invited to participate in the study. The inclusion and exclusion criteria were applied and eligible women were selected. A total of 250 women who met the inclusion criteria were selected and after explaining the purpose and the procedure, the consent form in their own vernacular was signed.

INCLUSION CRITERIA:

1) Age greater than or equal to 18 years
2) Those who have given written informed consent for postpartum IUD insertion.
3) Those who have delivered a live baby within 10 minutes.
4) Those who do not have any contraindications for IUD insertion.

5) Those who do not have premature rupture of membranes 12 hours prior to admission, chorioamnionitis and unresolved postpartum hemorrhage.

After selecting the women who fulfilled the eligibility criteria, detailed medical, obstetrical and gynecological history was taken and complete general physical as well as pelvic examination was done and the findings were recorded in the pre-designed Performa. The procedure was carefully explained to the women to make her as comfortable as possible.

METHOD:

- In study group, Copper-T was inserted within 10 minutes of expulsion of placenta upto 48 hours postpartum in normal vaginal delivery, using Kelly's placental forceps, taking all aseptic precautions by standard technique.

PPIUCD insertion is done on a delivery table, with adequate privacy for the woman and lighting for the service provider, with proper aseptic precautions.

The following instruments and supplies are required for the postpartum insertion of IUCD. All the instruments are either sterilized or high level disinfected before use.

OUTCOME MEASURES:

1) Efficacy - In terms of expulsion and failure rates
2) Safety - In terms of

- Perforation rate,
- Pain
- Infection (vaginal discharge)

OBSERVATION

1. Age Distribution

Age	No of patients	%
18-20	21	8.4
21-25	127	50.8
26-30	84	33.6
31-35	16	6.4
36 & above	2	0.8

Out of 250 cases, majority of patients belonged to 21-25 years age group (50.8%).

s Mean age of women accepting the PPIUCD was 25.49±3.75 year.

2. Socioeconomic status of patients

Socioeconomic class	Frequency	Percentage
Low	174	69.6%
Middle	76	30.4%
Total	250	100%

In the study 69.6% i.e. 174 patients belonged to lower socioeconomic class and 30.4% i.e. 76 patients belonged to middle class according to modified Kuppuswamy's scale.

3. Parity of patients

Parity	No. of patients	Percentage
1 (Primi)	48	19.2
2	126	50.4
3	62	24.8
4 or more	14	5.6
Total	250	100

Majority of the patients opting for postpartum IUCD were second gravida patients comprising of 50.4% i.e. 126 patients, followed by third gravida 24.8% i.e. 62 patients.

4. Mode of delivery

Mode of delivery	No. of patients	Percentage
Vaginal delivery	227	90.8
LSCS	23	9.2
Total	250	100

Out of the 250 IUCD inserted, 90.8% (227) were inserted after vaginal delivery and 9.2% (23) were kept intracaesarean.

5.Timing of insertion

Timing of insertion	No. of patients	Percentage
Postplacental	99	39.6
Immediate postpartum	128	51.2
Intracasarean	23	9.2
Total	250	100

Maximum number of IUCD i.e. 128 (51.2%) were inserted in immediate postpartum period, followed by postplacental 99 (39.6%) and 23 (9.2%) were inserted intra caesarean.

6.Follow up and Complications

Follow up	Yes	No	Not applicable*
2 weeks	212(84.8%)		0
6 weeks	229(91.6%)		0
6 months	200(82.6%)	42	8
1 year	90(50.8%)	87	73

*not applicable means not completed that period of study at the end of analysis.

Follow up rates in the present study was 84.8% at 2 weeks, 91.6% at 6 weeks, 82.6% at 6 month, 50.8% at 1 year

Complications	2 week %) n=212	6 week(%) n=229	6 months (%) n= 200	1 year (%) n=90
Pain	20(9.4%)	8(3.5%)	5(2.5%)	7(7.7%)
Bleeding	7(3.3%)	10(4.4%)	4(2%)	3(3.3%)
Fever	2(0.9%)	1(0.4%)	0	0
Discharge per vaginum	13(6.1%)	22(9.6%)	7(3.5%)	4(4.4%)
Perforation	0	0	0	0
Expulsion	2(0.9%)	3(1.2%)	3(1.5%)	2(2.2%)
Missing-strings	0	4(1.7%)	0	0
Total	44(20.6%)	48(20.9%)	19(19.5%)	16(17.7%)

7. Complication (including self-expulsion) in relation to mode of delivery

Complications	Vaginal delivery (n=227)	LSCS (n=23)
Pain	40(17.6%)	3(13.04%)
Bleeding	18(7.9%)	5(21.73%)
Fever	3(1.3%)	0
Discharge per vaginum	40(17.6%)	5(21.7%)
Perforation	0	0
Expulsion	8(3.5%)	1(4.3%)
Missing string	2(0.8%)	2(8.6%)
Total	111(48.9%)	16(69.6%)

Out of 227 patients delivered vaginally 111 (48.9%) patients some complication and of 23 patients of LSCS 16 (69.6%) patient developed some complication.

8. Relationship between timing of insertion of CuT and self-expulsion

Timing of insertion	Total self-expulsed CuT	%
Post placental (n=99)	2	2.02
Immediate postpartum (n=128)	6	4.7

Intracaesarean (n=23)	1	4.3
	9	

Maximum number of self-expulsion was seen in case of immediate postpartum insertion 6 (4.7%) patients followed by intracaesarean insertion 1 (4.3%) and then 2 (2.02%) patients in case of postplacental insertion.

9. Analysis of reason for removal (including self-expulsion)

Reason for removal	2 weeks	6 weeks	6 months	1 year	Total
Pain	0	1	6	6	13
Infection	0	0	0	4	4
Bleeding	0	0	5	9	14
Self-expulsion	2	2	3	2	9
For conceiving	0	0	0	4	4
For Tubal ligation	0	0	2	2	4
Total	2	3	16	27	48

In the study it was observed that out of 48 (n = 48) CuT removed, maximum number of CuT removed was due to complaints of bleeding per vaginum i.e. 14 (29.2%) followed by lower abdominal pain in 13 (27.1 %). 4 (8.3%) patients removed CuT for complains of infection and 9 (16.6%) patients had self-expulsion of CuT, among these 9 patients 2 patients came with intra uterine pregnancy of 12 weeks and 18 weeks gestation each, in both these patients thorough search was made for CuT location and self-expulsion was concluded.8 (16.7%) CuT were removed for nonmedical reasons i.e. for future conceiving and for tubal ligation.

10. Continuation rate

Follow up	CuT removed	CuT self-expulsed	Total patient followed up	CuT present	Continuation Rate
2 weeks	2	2	212	210	99.06%
6 weeks	1	2	229	226	98.68%
6 months	11	3	200	186	93%
1 year	13	2	90	75	83.3%

The continuation rate i.e. number of women continuing the IUCD inserted in their postpartum year was 99.06% at end of 2 weeks, 98.68% at 6weeks interval, 93% at the end of 6 months, 83.3% for 1 year. The mean continuation rate of the study was 87.81±11

DISCUSSION

In the present study of 250 patients, patients were followed up at 2 weeks, 6 weeks, 6 months, 1 year.. There were 18 patients who were lost to follow up.

In present study the mean age of IUCD seekers was 25.49 ±3.75 years.

In the present study majority of the patients opting for postpartum IUCD were second gravida patients comprising of 50.4% patients, followed by third gravida 24.8%, primi gravida comprised of 19.2% and multi gravida were 5.6%.

Follow up rates in the present study was 84.8% at 2 weeks, 91.6% at 6 weeks, 82.6% at 6 months, 50.8% at 1 year interval.

Follow up	Present study	Morrison et al
6 month	82.6%	69%;66%

Expulsion rates of the immediate PPIUCD at 2 weeks was 0.9%, at 6 weeks interval was 3.5%, at 6 months was 1.5% and at the end of at 1 year was 2.2%. This is lower to a multi country study done in Belgium, Chile and Philippines which showed the rate of expulsion at 1 month ranging from 4.6 – 16.0%.[5] Expulsion rate of immediate PPIUCD in a study done in China by Chi et al, 1994, was 9.5 – 12.5%.[3] 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 was similar at one and 12 months in Belgium (4%) and Chile (7%), while in the Philippines expulsion increased from 19% at one month to 28% at 12 months follow up. [5] The study by Morrison et al expulsion rates at 6 months was 0.05% in Kenya and 0.27% in Mali. [2]

Expulsion rate	6 months	1 year
Present study	1.5%	2.2%
Morrison et al	0.05%;0.27%	–
Tatum et al	–	4%; 7%;28%
Chi et al	–	9.5 – 12.5%

In the present study 3.5% (6 months) of patients complained of discharge per vaginum. The study by Morrison et al had lower rates of pelvic infection in Kenya (1%) and in Mali (2%).[2]

In the present study the incidence of abnormal bleeding was 3.3% at 2 weeks, 4.4% at 6 week interval, 2% at end of 6 months, 3.3% at 1 year.

In the present study it was observed that maximum number of CuT removal was due to complaints of bleeding per vaginum i.e. 14 patients, followed by lower abdominal pain in 13 , 4 patients removed CuT for complains of infection and 9 patients had self-expulsion of CuT. Non-medical reason for CuT removal (for conceiving and tubal ligation) accounted for it.

In the present study 2.5% (at 6 months);7.78%(at 1 year) of women removed CuT due to abnormal bleeding which is even observed by Apelo et al 1985 and Zhou et al 1991.[4] They observed that removal of CuT due to abnormal bleeding was 5.5% per 100 women per year and 4.2% at 6 months respectively.

There was no uterine perforation noted in the present study. The findings are consistent with the observations of Safwat et al, Thiery et al 1983, Shafei 2000, Morrison et al and Celen et al 2011.[1],[2]

There was no case of pregnancy with IUCD in utero noted which is in agreement with Morrison et al 1986, Xu 1996, Chen 2009

In the present study continuation rate i.e. number of women continuing the IUCD inserted in their postpartum year was 99.06% at end of 2 weeks, 99.12% at 6weeks interval, 93% at the end of 6 months, 83.3% for 1 year,.The mean continuation rate of the study was 87.81±11.17% . The results were comparable to the study by Tatum et al continuation rates were >80 per 100.

CONCLUSION

The insertion of immediate postpartum IUCD is safe and effective in the means of complications. Though it was a new concept for the population it was well accepted by community. The expulsion rates were though higher than the conventional interval method postpartum IUCD but it is also equally effective in regards of proper counseling, maintaining strict aseptic precautions and with proper insertion technique.

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