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FEASIBILITY OF POST PARTUM INSERTION OF INTRAUTERINE CONTRACEPTIVE DEVICE-EXPANDING THE USE OF INTRAUTERINE CONTRACEPTIVE DEVICE IN POST PARTUM PERIOD - A CROSS SECTIONAL STUDY IN DEVELOPING COUNTRY, INDIA

Sudha T. R. Banapurmath¹, Girija B. S. Dotrad², Nirmala Doreswamy², Shyamala²

¹Hassan Institute of Medical Sciences (HIMS), Hassan, Karnataka, India

²Department of Obstetrics and Gynecology, Hassan Institute of Medical Sciences, Hassan, Karnataka, India

E-mail of Corresponding Author: sudha.tr2009@gmail.com

ABSTRACT

Aim: Post partum contraception is the best evidence based intervention in prevention of pregnancy and abortion related maternal morbidity and mortality in the developing countries. The unmet need for contraception among women in the postpartum period can be effectively fulfilled by post partum insertion of IUCD, in a single visit under the Government scheme of providing free maternity services during institutional delivery. PPIUCD is an effective, safe, reversible method of long term contraception with high reported expulsion and low perforation rate, compared to interval insertion.

Objective: To evaluate the acceptability, safety, efficacy and feasibility of PPIUCD as a method of post partum contraception.

Study design: This is a prospective cross sectional study conducted between October 2011 to December 2013 at Sri Chamarajendra Government Hospital, Hassan, Karnataka, India. 26,123 pregnant women were counseled (clients) for Post partum IUCD insertion as a method of contraception in pregnancy, early in labor and in the immediate post partum period (<48 hours). Among the clients, 1832(7%) accepted and had PPIUCD inserted under asepsis by skilled Obstetricians. The timing of PPIUCD insertion were- 510(27.8 %) post placental, 427(23.3 %) in immediate post partum period<48hrs, and 895(49 %) Intra caesarian insertions. The side effects were minimal, Infection and perforation were 00%, pregnancy reported were 0%, Expulsion rate was 0.32 %(6/1832), and Removal rate was 0.76% (14/1832). IUCD retention rate was 98.90% (1812/1832) at 14weeks post partum.

Conclusion: PPIUCD is a feasible, safe and effective method of immediate postpartum contraception that may be practiced during a single visit for institutional delivery which may be continued as a long term reversible contraception.

Keywords: Post-partum intrauterine contraceptive Device (PPIUCD), Post placental, Client, Caesarian Delivery, Expulsion, Contraception, Counseling.

INTRODUCTION

The maternal health is one of the health indicators of the country. The antenatal, labor and postpartum period is the crucial period of optimal

maternal care that influences the outcome of pregnancy. Poor spacing between pregnancies, the unmet need for post partum contraception may

lead to intervention in an unwanted subsequent pregnancy.

Postpartum insertion of IUCD (PPIUCD) is a method of post partum contraception that may be utilized to overcome the unmet need of contraception, in a single hospital visit during institutional delivery. The postpartum period following three months after delivery, weaning from breast feeding and resuming sexual activity among married couple, is the risk period for unintended pregnancy. This necessitates the use of some postpartum reversible contraception which is met by PPIUCD insertion.

Approximately 27% of women in India practice birth to birth interval of <24 months and 34% between 24-35 months, a total of 61% women practice birth to birth to interval of < 36 months, 40% of women are not using any contraceptives for spacing. IUD-1.6%, natural method (LAM)-5.4%, condom use-5.3%, and female sterilization-34.2%, male sterilization 1.9% are the methods of contraception among the married couple in India¹.². Unmet need in India, in the first year after delivery is 65%⁶. Postpartum LAM method is not reliable after three months following delivery².

The introduction of GOI- JSY scheme for improvising implementation of Institutional delivery (GOI 2009) also provides adequate opportunity to generate clients for introduction of postpartum contraceptive services, thereby providing the women an access to immediate PPIUCD services. Provision of quality contraceptive services during the postpartum period by utilizing the opportunities of increased institutional deliveries is a critical intervention for ensuring maternal and child health besides population stabilization. To achieve this objective, postpartum IUCD has been introduced in the National Family Welfare Programme since March 2010 in several states.

An evidence based practice of post partum IUCD insertion as post partum contraception suggests that it is a safe, easy and effective, long term method that can be provided immediately post

placental, during caesarian delivery or in the immediate post partum period within 48 hours after delivery^{3, 5,6,9,10,11,14,18}. The postpartum period of stay at the hospital provides adequate time for motivation, counseling and convenience of easy insertion, implementation of postpartum contraceptive services during a period of high motivation, with few side effects. The woman goes home with a contraceptive method of her choice which also ensures in fulfilling her unmet need of contraception, in a single visit at the hospital⁵. Several studies among women in China, Egypt, Mexico, Turkey, and Peru reveal PPIUCD as a popular, acceptable, and feasible method of contraception but they have reported high expulsion rates.

This study is conducted, to evaluate the feasibility, acceptability, efficacy and safety of PPIUCD as an optional method of post partum contraception among women in India, where the IUCD acceptance is very low, due to non medical reasons. This study also is intended to evaluate PPIUCD as a method of intervention in reducing maternal mortality in developing countries.

MATERIAL AND METHODS

This is a prospective, cross sectional, cohort, study conducted between Oct 2011- Oct 2013 at Sri Chamarajendra Government Hospital, Hassan District, Karnataka, India to evaluate the acceptability, feasibility, safety, expulsion, and retention rate of PPIUCD among 1832 women in the postpartum period.

METHODOLOGY

All the pregnant women attending the antenatal clinic at Sri Chamarajendra government hospital, Hassan, Karnataka, India. (population-1721669) were counseled during their antenatal visit regarding the benefits of birth spacing, advantages of choosing and availing postpartum contraception during their stay at hospital, child care, various methods available for post partum contraception and post partum sterilization, advantages of choosing long term temporary,

reversible contraceptive methods, and PPIUCD. The method chosen for contraception was marked on their Antenatal records, and called as clients. Women in Early labor and in the post natal ward were counseled for PPIUCD. The insertion was done by skilled obstetricians under asepsis after

informed consent (fig-2, 3). The standard infection prevention protocols were followed. The quality of PPIUCD services provided at the hospital were assessed and monitored as per the performance standards for immediate PPIUCD counseling and services, April 2011^{3,4}.

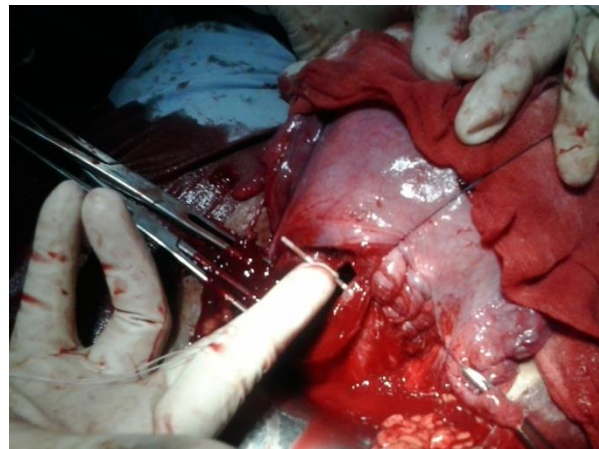


Fig: 2-Intracaesarian insertion -Manual technique



Fig: 3-Insertion of IUCD with Kellys Placental forceps

The women after PPIUCD insertion were advised routine post partum care, and to report for follow up at 6, 10, and 14 weeks or earlier when necessary. A record of follow up was maintained at the post partum clinic. A telephonic follow up was done when a clinic visit was not feasible or to report symptoms, expulsion of IUCD or at the convenience of the client.

The inclusion criteria in this study were as per Medical eligibility criteria (M.E.C)- 1&2 that included all clients accepting for IUCD insertion in post partum period.

Exclusion criteria (MEC criteria 3&4) are- chorioamnionitis, premature rupture of membranes of >18 hours, intractable post partum hemorrhage (atonic or traumatic) and abnormal uterine cavity.

However contraindications are few. This expands the client number for PPIUCD insertion.

Limitations of PPIUCD as a method of post partum contraception are:

High expulsion rate compared to interval insertion. The expulsion rate is 5-10% which means retention rate of 90-95%. Post placental and intra caesarian insertions have low expulsion rate. Expulsion rates may be reduced by appropriate fundal placement of IUCD which is acquired through skill training in PPIUCD insertion^{3,5}.

RESULTS The data of PPIUCD services provided, observations during follow up of clients

were as shown in Observations (charts 1a, b-chart 5).

Acceptability

Acceptability for PPIUCD among women was 7.0%. The observation are as shown in charts 1 and 2

Total number of monthly PPIUCD inserted as shown in chart-1

Observations:

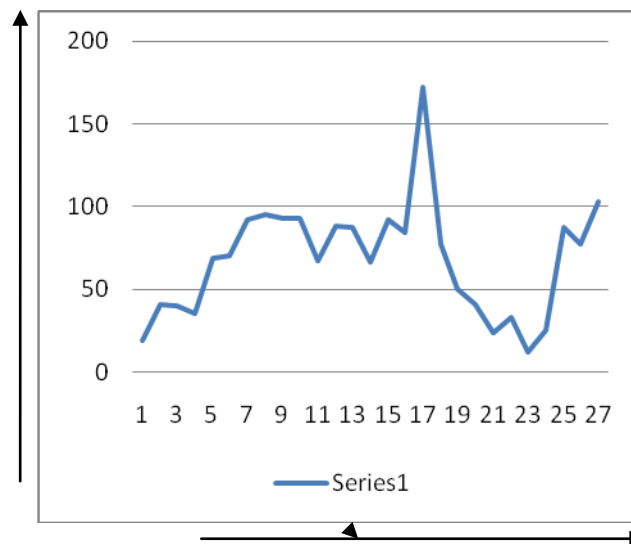
1. Client characteristics

All the clients who accepted for PPIUCD insertion were in the reproductive age group (20-40yrs).

Chart-1a,b show the distribution of clients against monthly statistics

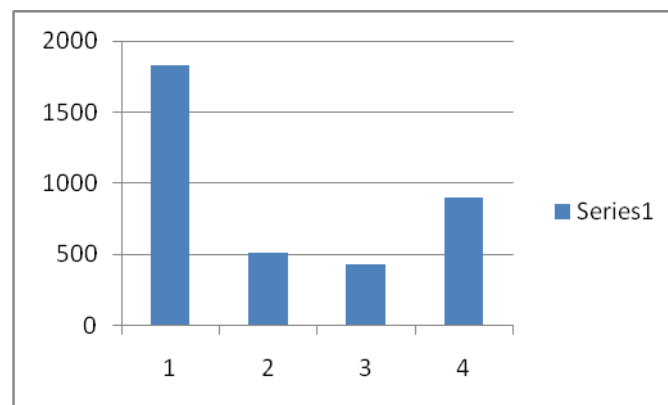
CHART- 1a

Number of PPIUCD



Months

Chart no-1b showing the distribution of subjects



1=total number of PPIUCD Inserted

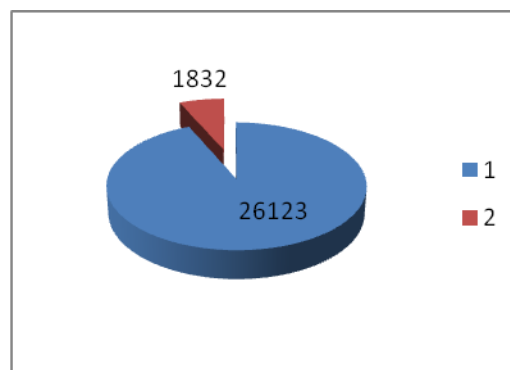
2=total number of post placental PPIUCD

3=total number of post partum PPIUCD<48hrs.

4=total number of intracaesarian PPIUCD

Chart-2 shows acceptance of PPIUCD among counseled women (clients)

Chart no-2, Acceptance of PPIUCD



1-Total number of women counseled for PPIUCD.

2-Total number of women accepting PPIUCD

Chart-3 shows the distribution of clients in number, based on timing of insertion. The clients had PPIUCD insertion in immediate post placental, post partum <48hrs and Intra-caesarian delivery period.

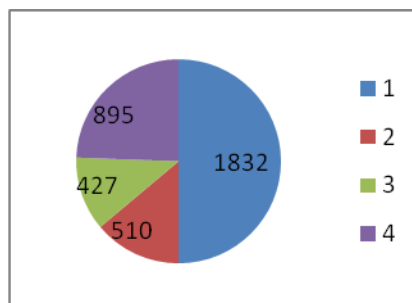


Chart no-3, Distribution of total number of cases based on timing of insertion

Total PPIUCD inserted and different timing of PPIUCD insertion,

1=Total number of PPIUCD inserted

2=total number of post placental PPIUCD

3=total number of post partum PPIUCD<48hrs.

4=total number of intra-caesarian PPIUCD

Follow up of clients: follow up of clients were conducted at 6, 10, and 14 weeks or earlier when necessary. During follow up, the observations were made regarding removal, expulsion and safety of PPIUCD. The Results were as follows-

Efficacy of PPIUCD as a contraceptive

Efficacy of PPIUCD as contraceptive were assessed by pregnancy rate, Expulsion rate, removal and retention rate of IUCD.

Pregnancy rate :-

There were no pregnancies observed among clients in the study period. Hence the failure rate was 00% that shows that PPIUCD is efficient in prevention of pregnancy among the clients who continued to retain it.

Expulsion of IUCD :

06/1832(0.32%) of clients reported spontaneous, expulsion within 10 weeks of insertion which was confirmed by clinical and Ultrasound examination. These clients were offered re-

insertion but all of them refused. They were counseled for alternate methods of contraception.

Missing strings

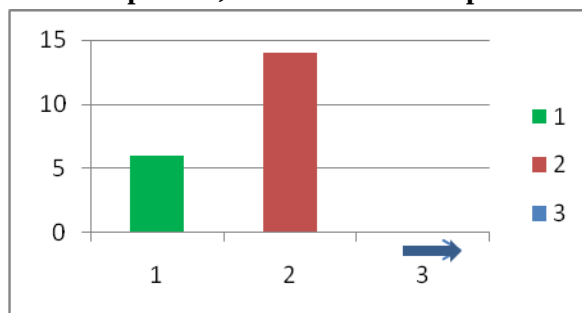
Missing string was termed when the string was not seen at 6 weeks, at the external os of cervix, during per speculum vaginal examination of clients in the post partum clinic. Among the 289 clients followed for 14 wks post partum, missing strings during the follow up in the clinic was observed in 39 clients (13.5%). An ultrasound examination confirmed the presence of IUCD in the uterine cavity. Many clients who were examined clinically had the string curled in vagina or cervical canal. They were reassured and re-examined at 10 and 14 weeks. They continued with IUCD as a long term contraceptive.

Safety of PPIUCD

Safety of IUCD was assessed by the clients. Reported Side effects and complications of IUCD such as infection, menstrual abnormality, perforation, and expulsion. The complications

were few and were managed symptomatically. They are shown in chart-5.

Chart number 5 - Expulsion, Removal and Complications of PPIUCD



1=Expulsion of PPIUCD

2=Removal of PPIUCD

3=complications of PPIUCD

Rate of infection

None of the clients reported nor had infection (00%) in the present study.

Menstrual abnormality

There were no reports of menorrhagia nor any abnormal vaginal bleeding among the clients followed in the study period.

Perforation of uterus

No perforation of uterus by IUCD has been observed in the present study.

Client reported symptoms

Many clients reported to post partum clinic with lower abdominal pain and pricking sensation. They had urinary infection, constipation or non specific symptoms, and were reassured and treated accordingly. All these women continued to retain IUCD.

Removal of PPIUCD

14/ 1832 clients requested for removal of IUCD due to personal and social reasons, but none got it removed for side effects such as infection, Menorrhagia and abdominal pain. Increase in awareness of advantages of PPIUCD, and reassurance by the attending health care worker later reduced the removal rate.

Retention of IUCD

1812(98.90%) clients were willing to continue IUCD by 14 wks, 14 (0.76%) were not willing to get reinsertion of IUCD and preferred an alternate

method of contraception. The Retention rate was 98.9%, which showed that PPIUCD was effective in meeting the unmet need of contraception in the post partum period.

DISCUSSION

Many studies have been published regarding the efficacy, safety of PPIUCD. This was a cross sectional study, at Sri Chamarajendra Government Hospital, Hassan District, Karnataka, India to evaluate the acceptability, feasibility, safety and efficacy of PPIUCD. Lara Ricalde R *et. al.* has reported an acceptance rate of 28.9% (1,024 /3,541) ⁶. In this study the acceptance rate was lower, probably due to low IUCD insertion rates in low resource settings in India. Mohammed *et. al.* observed that Acceptance rate was the same during antenatal and postpartum counseling, 26.4 and 31.8%, respectively¹⁰. Indian experience Of 2 years, PPIUCD services have been established in over 50 facilities across 19 states of India, with the Government of India undertaking more than 22,000 PPIUCD insertions in the target facilities, with 5% of women delivering in these institutions accepting PPIUCD as their choice of contraception¹⁷. In the present study the acceptance rate was higher (7%). The acceptability of intra caesarian placement of IUCD was highest followed by post placental IUCD insertion.

Among clients who accepted for PPIUCD, many refused for PPIUCD insertion due to demotivation by relatives and friends. This was observed as a major barrier for implementation of PPIUCD in this study.

The rate of return for follow-up visit were 221 (94%), 210 (89%) and 183 (78%) at 6 weeks, 6 months and 12 months, respectively. Timing of IUCD insertion after vaginal and cesarean delivery were 74% and 26%. Continuation rates of IUCD were relatively high, 87.6% and 76.3%, at 6 and 12 months, respectively. The 1-year cumulative expulsion rate with CuT 380A device was 12.3%¹¹. In the present study the follow up was very low.

Modifications of existing devices, such as adding absorbable sutures or additional appendages did not appear beneficial. Efficacy of interval insertion of IUCD was comparable with PPIUCD¹³. Most studies showed no differences between insertions done by hand or by instruments^{8, 16}. The RHL review 2010, shows a total of nine trials with 7660 subjects, One trial (102 women) had compared immediate postpartum versus delayed insertion (6–8 weeks postpartum) of the levonorgestrel-releasing intrauterine system. A trial directly compared immediate versus delayed insertion reported that at 6 months the two groups were similar in terms of pregnancy prevention²¹.

FHI data show a significantly higher ($p < 0.05$) expulsion rate associated with insertions performed within the period of >10 minutes to 36 hours as compared to the immediate post placental period (within 10 minutes)⁸—we found no such relation regarding timing of insertion and expulsion rate.

Complications observed were more in delayed post partum insertion than immediate post placental insertion⁶. Other trials did not have uniform interventions; hence we were unable to aggregate them in this analysis. Advantages of immediate post-partum insertion include high motivation, assurance that the woman is not pregnant, and provider and client convenience⁶,

^{18,21,22,23}. Lara Ricalde R *et. al.*, observed no infection among clients. The expulsion rates were 10.4, removal rates for bleeding and pain were 4.9 and 4.8, for non medical reasons were 3.7 and 4.9 respectively for the Multiload Cu 375 and 7.7 for the CuT 380A by 10 weeks. There were no pregnancies, nor uterine perforation that is similar in this study.

Xu J. *et. al.* observed a gross cumulative expulsion rate for the manual insertion group after 6, 12, 24, and 36 months were 8.61, 13.55, 15.78, and 16.90 %, respectively with gross expulsion rates for the ring forceps insertion group were 12.99, 17.23, 17.77, and 18.34 %, respectively. The differences between the two groups were not statistically significant¹². In studies by Family Health International (FHI), expulsion rates varied widely between centers using similar devices. Expulsion rates ranged from 6–37/100 women at 6 months after insertion¹³. Sahajakittur and Kabade reported expulsion of 5.23%. No major complications and perforation were observed in this series²². The expulsion rate in present study was very low (0.32%) in comparison with other studies, probably due to skilled training in fundal placement of IUCD.

Thiersh *et. al.* reported that there were no pregnancies and use continuation was 77%.¹⁸ Indian experience showed that at 6 weeks postpartum, 90% of women have continued with the same IUCD. Infection rate was of 4.5% and 7% got the IUCD removed within the first 6 weeks of insertion due to bleeding and abdominal pain¹⁷. In the present study 0.76% were removed for non medical reasons, and 98.90% IUCD were retained at 14 weeks follow up.

CONCLUSION

PPIUCD is a feasible, safe and effective method of postpartum contraception among women in low resource settings, during a single visit for institutional delivery, to empower women to meet

their unmet need of contraception that may be continued as a long term reversible contraception

Limitation of the study

In the present study

- 1) Sample size is small and further study with larger sample size is recommended.
- 2) Follow up rate is inadequate - hence there is a need to increase the follow up of clients for an analysis of data regarding safety and efficacy of PPIUCD.
- 3) Duration of follow up is short. Hence retention rate, safety and efficacy of IUCD as a long term reversible method of contraception could not be assessed.

IMPLICATIONS FOR RESEARCH

There is a need for long term follow up, retention rates and short- and long-term risk of pelvic infections associated with the high incidence of reproductive tract infections in low resource settings.

Recommendations

PPIUCD is a feasible method of contraception in post partum period that can be retained as a long term reversible contraception. Adequate training and supervision of delivery room health providers/ staff in insertion of IUDs is Feasible. Midwives / staff nurses can be trained to insert the IUD after delivery through realistic demonstrations on Zo-E models (fig-1). Repeated PPIUCD sensitization and awareness programmes, client monitoring at Primary care centres, improvised accessibility of PPIUCD services by integrating post partum contraceptive services with Institutional maternity services, are recommended to upscale the PPIUCD services in low resource settings to prevent unintended pregnancy. This may be considered as an important evidence based intervention in averting maternal mortality in low resource settings.



Fig: 1-training for PPIUCD insertion on a ZO-E model

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