Original Research Article

Evaluation of Safety and Efficacy of Postpartum Intrauterine Contraceptive Device (PPIUCD) in Vaginal and Caesarean Section Deliveries: A 7 years prospective study

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Received: 18-07-2021 / Revised: 28-09-2021 / Accepted: 25-10-2021

Abstract

Background: Majority of women are in need of an effective contraceptive method in postpartum period. PPIUCD is a reversible and coitus independent method. This study is to evaluate safety and efficacy of PPIUCD in long term follow up period.**Materials & Methods:** A prospective observational study was done over a period of seven years in which acceptors of PPIUCD were followed up for safety and efficacy of PPIUCD. Follow up was done at 6th weeks, 6th months, 3rd years, 5th years & 7th years from insertion.**Results:** Majority of clients had no complaints on follow up. Irregular bleeding and pain abdomen were most common complaints in rest of clients. Expulsion rate was 1.1%. Removal rate was 48.16%. Main reason for removal was wish to have next child. Lost to follow up was 22.24%. No perforation was reported and failure rate was zero in this study. Continuation rate at seven year was found to be 28.49%.**Conclusion:** PPICUD is safe, reversible and cost-effective method of contraception. With regular counselling and management of side effects continuation rate can be improved.

Keywords: CuT380A, Intra-caesarean insertion, Postpartum intrauterine contraceptive device, Postpartum insertion, Safety.

Introduction

According to USAID/ACCESS survey 2009[1], In India 65% of women in first postpartum year have unmet need for family planning. Postpartum contraception can reduce one-third of maternal deaths and 10% of neonatal deaths when pregnancies are spaced two years apart.[2]

IUCD is most frequently used reversible method of family planning in the world. WHO has approve IUCD use even in breast-feeding women since it has no effect on lactation, not even in terms of any increased copper in milk. [3,4]

PPIUCD overcomes the pain and anxiety of procedure as compared to the interval insertion. It is a good method of spacing and also beneficial for females who don't want further child bearing as they can opt for sterilisation once their child grows, keeping in mind the higher rate of child mortality in developing countries. [5]

Cochrane reviews provide evidence of safety and feasibility of postpartum IUCD (PPIUCD) insertions in various settings. [6,7]

However, studies have reported high expulsion rates (10.4–16.4%). [8-11]

PPIUCD insertions via different routes (vaginal or caesarean) may have different outcomes at follow-up. Sharma et al, in their study compared the outcomes of PPIUCD insertion after vaginal delivery and caesarean section in terms of side effects, removal and expulsion. [12]

With this background the aim of present study is to evaluate safety and efficacy of Postpartum-intrauterine contraceptive device inserted in vaginal and caesarean deliveries in tertiary care centre of Southern Rajasthan with seven years follow up.

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Methodology

A prospective open label study was conducted from September 2012 to March 2021. Intrauterine contraceptive device was inserted in post placental, postpartum and intra-caesarean period after counselling and taking proper consent from all females who came for child birth in this institution between September 2012 to March 2014 under PPIUCD initiative of family welfare program, GOI.

These participants were followed up and counselled if required at 6th weeks, 6th months, 3rd years, 5th years & 7th years from insertion for safety and evaluation of efficacy of IUCD. The CuT380A was used as IUCD in the study as it was provided in PPIUCD program from government.

During enrolment following criteria were considered:

Inclusion criteria

- Maternal age: 18-40 years.
- 20 or more EGA.
- Desire to have IUCD after counselling.
- Anticipated vaginal/assisted delivery/C-section.
- Active management of III stage of labour.

Exclusion criteria

- The patient with Hb<8g/dl.
- Any medical/surgical complication during pregnancy.
- Temperature >38^{0}C during or after labour/ chorio-amnionitis.
- Rupture of membrane >24 hours prior to delivery.
- 5.Un resolved Postpartum haemorrhage (PPH)

Safety was assessed on basis of patient's complaints with respect to excess & irregular bleeding, pain abdomen, abnormal discharge if any. Complications such as perforation (if any) was noted.

For Efficacy analysis Expulsion rate and continuation rate at follow ups was measured.
Data was collected in semi-structured pre-formed questionnaire for each participant on follow up.
Data was statistically analysed in MS excel.
Ethical approval was obtained from institutional ethical committee.

Results

During Sep 2012 to March 2014, total number of deliveries was 18550 of which 12253 were NVD and 6297 were LSCS. Out of these total deliveries, 545 females gave consent for PPUICD insertion after counselling. 321 PPIUCD were inserted after NVD and 224 were inserted during LSCS.

A multiparous client had atonic PPH four hours after delivery and IUCD was removed on client's wish. This client was excluded from study.
Majority of participants were in age group of 21-30 years. (83.12%) followed by less than 20 years of age (10.28%). The mean age of clients was 24.81±3.71 years.
75.60% of participants have their education below 12th standard.
In our study 69.54% clients were multiparous and 30.46% were primiparous.
Among all, maximum (70.29%) insertion were done when patients delivered at term followed by 25.50% in preterm deliveries at 33 to 36 weeks.
During study most of PPIUCDs were inserted in post-placental period (50.09%) followed by intra-caesarean (41.10%) **[Table 1]**

Table 1: Demographic & Obstetrics Profile of Clients

Age Group	**n**	**%**
<20 years	56	10.28
21-30 years	453	83.12
31-40 years	36	6.6
Education		
Illiterate	85	15.60
<12 class	412	75.60
>12 class	48	8.80
Parity	N	%
Primiparous	166	30.46
Multiparous	379	69.54
Gestational Age		
24 to 32 weeks	21	3.85
33-36 weeks	139	25.50
37 to 40 weeks	383	70.29
>40 weeks	2	0.36
Type of Insertion		
Intra-caesarean	224	41.1
Postpartum within 48 hours	48	8.82
Post Placental	273	50.18

Study found lost to follow up was maximum (12.76%) at 7th years of follow up followed by at 5th years of follow up. (12.12%).
In present study majority of patients had no complaints at all follow ups.

In remaining of clients bleeding was most common complaint followed by pain abdomen during all follow ups.
At 6th weeks follow up Six patients informed that they had expelled IUCD spontaneously. All of these insertions were after NVD. So, expulsion rate is 1.10% during the study. **[Table 2]**

Table 2: Lost to follow up & Complaints on follow up

	6 weeks		**6 months**		**3 years**		**5 years**		**7 years**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Lost to Follow up	8	1.47	12	2.23	22	4.40	49	12.12	30	12.76
Complaints	n	%	n	%	n	%	n	%	n	%
No complaints	495	90.99	420	78.35	368	73.74	217	53.17	163	71.91
Irregular Bleeding	16	2.94	34	6.34	14	2.85	3	0.74	0	0
Pain Abdomen	10	1.83	26	4.85	12	2.40	4	0.99	0	0
Pricking	2	0.36	5	0.93	4	0.80	2	0.49	0	0
White discharge	0	0.0	2	0.37	2	0.40	6	1.46	0	0
Multiple	7	1.28	12	2.23	4	0.80	3	0.74	0	0
Expelled	6	1.1	0	0	0	0	0	0	0	0

Majority (29.7%) of removal were done at three years follow up point and main reason for removal was desire of next child (42.74%) followed by irregular bleeding (24.42%).

Among all removal (262) maximum occur which were inserted during caesarean deliveries (74.80%). **[Table 3]**

Table 3: Time & cause of PPIUCD removal

Time of Removal	**n**	**%**
6 weeks	26	4.66
6 months	73	14.62
3 years	120	29.70
5 years	36	15.31
7 years	8	4.73

Reason for Removal		
Want next child	112	42.74
Irregular Bleeding	64	24.42
Pain abdomen	56	2.13
Pricking	22	8.39
Others	8	3.05
Type of Delivery		
Vaginal	66	25.19
LSCS	196	74.81

At six weeks 92.83% of acceptors continued their IUCD. Study found declining trend in PPIUCD continuation as 51.11% continued IUCD at 3 years follow up and Only 28.49% acceptors continued PPIUCD after 7 years. **[Table 4]**

Table 4: Continuation rate

Time of follow up	Continuation Rate	%
6 weeks	505	92.83
6 months	420	77.20
3 years	278	51.10
5 years	193	35.47
7 years	155	28.49

Discussion

Similar to majority of previous studies [5,13,14,15] majority of clients were in age group of 21-30 years.

In this study 75.60% clients were educated up to 12th standard. Studies conducted by Pandher D K et al[5], Dhruba Prasad Paul et al.[13] and Vilvapriya S. et al.[14] found 79.4%, 71% and 82.6% clients educated up to senior secondary standard respectively.

In present study primiparous clients were 30.46% & multiparous were 69.54%. Similarly, study done by Pandher D K et al[5] primiparous and multiparous clients were 21.5% & 78.5% respectively. While in study conducted by Dhruba Prasad Paul et al.[13] & Vilvapriya s. et al. [14] primiparous and multiparous clients were 70.4% & 39.6% and 66.4% and 33.6%. respectively.

In present study 70.29% insertions were done when patients delivered at term followed by in preterm deliveries at 33 to 36 weeks (25.50%).During study 50.09% insertions were post placental followed by 41. 10% and 8.80% intra-caesarean and postpartum respectively which is similar to another study conducted by Ranjana et al.[15] which had 52.94% postplacental 42.64% intra caesarean and 4.41% postpartum insertion. While in study by Vilavapriya S. et al. [14] 78.3% insertions were intra Caesarean 14% postplacental and 7.7% were postpartum.Study lost its clients on each follow up point which was maximum (12.76%) at 7th year follow up. 12.12%, 4.40% 2.23% and 1.47% was lost to follow up at 5th year, 3rd year 6th months and 6th weeks follow up respectively. Dhruba Prasad Paul et al[13] had 43.6%, 30.9% and 14.5% lost to follow up at 18th month 12th month and 6th month of follow up respectively. These lost to follow up patients were excluded from further part of study from where they had been lost.

Study found that majority of clients had no complaints at each follow up but major complaints were irregular bleeding and pain abdomen on each follow up which is similar to findings of studies done by Agrawal R. et al.[16], Pandher D K et al.[5], Dhruba Prasad Paul et al.[13] and Vilvapriya s. et al. [14] and Ranjana et al.[15]. Complains of Irregular bleeding & pain abdomen were maximum at 6 month follow up followed by 3rd year follow up.

At 6th weeks follow up Six patients informed that they had expelled IUCD spontaneously. All of these insertions were after NVD. Expulsion rate is 1.10% during the study.

During follow up period total of 262 clients requested to remove IUCD out of which maximum (29.70%) at 3rd year followed by 15.31% on 5th year follow up. Least (4.66%) removals were done at 6th weeks follow up which was in comparable with findings of Agrawal R. et al. [16] and Ranjana et al.[15] while Pandher D K et al. [5] & Dhruba Prasad Paul et al. [13] found least removal at 18th months and 12th month respectively.

Most common reason for removal was wish to have next child (42.74%) followed by irregular bleeding (24.42%).

Study revealed that removal of IUCD was requested more from clients who had LSCS (74.18%).

Present study has continuation rate of 92.83% (maximum) at 6th week follow up which is comparable with study done by Vilavapriya s. et al. [14] Pandher D K et al. [5], Ranjana et al. [15]. Study further found that after 7 years of follow up continuation rate is 28.49%. This may be because of lost to follow up clients (n=121) and IUCD removal for different reasons. (n=262).

Failure rate was zero in this study and none of the client had reported perforation till seven years of follow up which is similar to other studies. [16,17]

Conclusion

PPIUCD is safe & effective method of contraception. With regular counselling and management of side effects continuation rate can be improved. In developing countries where postnatal services including contraception are not frequently utilised by mothers it can be an effective tool to slow down population growth.

References

1. USAID/ACCESS, India, 2009
2. Somesh Kumar, Reena Sethi, Sudharsanam Balasubramaniam, Elaine Charurat, Kamlesh Lalchandani, Richard Semba, Bulbul Sood. Women's experience with postpartum intrauterine contraceptive device use in India, Reprod Health. 2014; 11:32.
3. Medical eligibility criteria for contraceptive use – Intrauterine devices. 5th ed 2015. Available at http://apps.who.int/iris/bitstream/10665/181468/1/9789241549158_eng.pdf. Accessed on 23 Dec 2017.
4. Rodrigues da Cunha AC, Doren JG, Cantuaria AA. Intrauterine device and maternal copper metabolism during lactation. Contraception. 2001; 63(1):37-9.
5. Pandher DK, Rani S, Goel P. Two years follow up study of post placental insertion of IUCD during caesarean sections: safety, efficacy and complications. Int J Reprod Contracept Obstet Gynecol. 2018; 7:981-6.
6. Grimes DA, Lopez LM, Schulz KF, Van Vliet HA, Stanwood NL. Immediate post-partum insertion of intrauterine devices. Cochrane Database Syst Rev. 2010; 5:CD003036.
7. Grimes D, Schulz K, Van Vliet HH, Stanwood N, Lopez LM. Immediate post-partum insertion of intrauterine devices. Cochrane Database Syst Rev. 2003; 1:CD003036.

8. Shukla M, Sabuhi Qureshi C. Post-placental intrauterine device insertion- A five-year experience at a tertiary care centre in north India. Indian J Med Res. 2012; 136(3):432.
9. Çelen Ş, Möröy P, Sucak A, Aktulay A, Danışman N. Clinical outcomes of early postplacental insertion of intrauterine contraceptive devices. Contraception. 2004; 69(4):279-82.
10. Tatum HJ, Van Kets H, Sivin I, Schmidt FH, Ortho-McNeil I. Immediate postplacental insertion of GYNE-T 380 and GYNE-T 380 postpartum intrauterine contraceptive devices: randomized study. Am J Obstet Gynecol. 1996; 175(5):1231-5.
11. Xu JX, Rivera R, Dunson TR, Zhuang LQ, Yang XL, Ma GT et al. A comparative study of two techniques used in immediate postplacental insertion (IPPI) of the Copper T-380A IUD in Shanghai, People's Republic of China. Contraception. 1996; 54(1):33-8.
12. Sharma A, Gupta V, Bansal N, Sharma U, Tandon A. A prospective study of immediate postpartum intra uterine device insertion in a tertiary level hospital. Int J Res Med Sci. 2015; 3:183-7.
13. Dhruba Prasad Paul et al. Study of outcome of Intrauterine Contraceptive device (CuT-380A) insertion immediately after vaginal delivery:AIMS Medical Science.2020;7(4):328–336.
14. Vilvapriya et al. Long term clinical outcome of postpartum intra uterine contraceptive device (PPIUCD) insertion Int J Cur Res Rev. 2016; 8(11):1.
15. Ranjana, Verma A, Chawla I. A follow up study of postpartum intrauterine device insertion in a tertiary health care centre. Int J Reprod Contracept Obstet Gynecol. 2017; 6:2800-5.
16. Agarwal R, Singh S. Evaluation of Safety and Efficacy of Postpartum Intrauterine Contraceptive Devices (PPIUCD) in Vaginal and Caesarean Section Deliveries: A Hospital Based Study. MAMC J Med Sci. 2020; 6:199-203.
17. Gupta A, Verma A, Chauhan J. Evaluation of PPIUCD versus interval IUCD (380A) insertion in a teaching hospital of Western UP. Int J Reprod Contracept Obstet Gynecol. 2016; 2:204-8.

Conflict of Interest: Nil
Source of support:Nil