A Prospective Study of Effectivity, Expulsion, and Acceptability of Post-placental IUD Cu T380A Insertion Using Clamp in a Tertiary Hospital

Eka R Gunardi¹, Ribkhi A Putri², Yogi Pasidri³

ABSTRACT

Aim: Intrauterine device (IUD) has a high effectivity of long-term contraception method. Post-placental IUD increases the number of contraception use and decreases the unmet need for contraception. The purposes of this study were to evaluate the effectivity, expulsion, acceptability, and side effects of post-placental IUD insertion using a clamp at Dr. Cipto Mangunkusumo National General Hospital.

Materials and methods: This prospective longitudinal observational study was conducted at a tertiary teaching hospital (Dr. Cipto Mangunkusumo General Hospital, Jakarta, Indonesia) from April 2018 to March 2019. Post-placental IUD was inserted using a clamp. We interviewed the patients at 3 months and 6 months after insertion to evaluate the outcome. A total of 94 women were included in this study.

Results: The effectivity was 100%. The expulsion rate was 2.13, 3.45, and 0% at 6 weeks, 3 months, and 6 months, respectively. The total acceptability rate at 6 weeks, 3 months, and 6 months was 96.81, 93.3, and 90.8%, respectively. Most of the subjects were satisfied with the IUD contraception at 3 months and 6 months.

Conclusion: Post-placental IUD insertion using a clamp had good safety, effectivity, acceptance, and satisfaction. This data could be used for family planning counseling in daily practice. Post-placental IUD insertion should be routinely offered to all eligible postpartum women undergoing institutional deliveries.

Keywords: Acceptability, Effectivity, Expulsion, Insertion using a clamp, Post-placental IUD.

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INTRODUCTION

Post-placental intrauterine device (IUD) increases women's access to health facilities and decreases the unmet need for contraception. In Indonesia, two kinds of techniques have been used previously: using inserter and manually using hand.¹⁻³ The insertion technique using clamp has been started in India since 2014.^{4,5}

MATERIALS AND METHODS

This prospective longitudinal observational study was conducted in a tertiary teaching hospital (Dr. Cipto Mangunkusumo General Hospital, Indonesia) from April 2018 to March 2019. The inclusion criteria were patients with a history of a normal menstrual period and interviewed at the time of follow-up. We excluded patients with a history of anatomical abnormality of the uterus, abnormal uterine bleeding, blood coagulation dysfunction, fever or other clinical signs of intrauterine and intrapartum infections, premature rupture of the membrane for more than 24 hours, prolonged labor for more than 24 hours, postpartum hemorrhage, and who refused to participate in this study. Informed consent was obtained from all patients before IUD insertion. We did the IUD insertion within 10 minutes after the delivery of placenta using Kelly clamp or placenta forceps. The procedures were done by trained doctors.

We interviewed the patients at 6 weeks, 3 months, and 6 months after delivery. We evaluated the patient's complaints: Abdominal pain, vaginal bleeding, vaginal discharge, and dyspareunia. Patients with these complaints during the interview were advised to visit the health facilities. We calculated the

¹⁻³Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Indonesia, Dr. Cipto Mangunkusumo General Hospital, Jakarta, Indonesia

Corresponding Author: Yogi Pasidri, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Indonesia, Dr. Cipto Mangunkusumo General Hospital, Jakarta, Indonesia, e-mail: yogipasidri@gmail.com

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effectivity, total expulsion, and the IUD acceptance in descriptive analysis. In addition, we calculated the incidence of pregnancy, expulsion, perforation, infection, abdominal pain, vaginal bleeding, and satisfaction.

RESULTS

There were 1,186 deliveries in the period of study: 429 vaginal deliveries (36.17%) and 757 cesarean sections (63.83%). A total of 94 patients were included in this study (7.95% from total deliveries). Other patients were applied trans-cesarean IUD insertion (62%) and manual post-placental IUD insertion using hand (10.3%). A total of 10 and 8 patients were lost to follow-up at 3 months and 6 months, respectively.

Characteristics

The characteristics of the subjects that showed the most number in every group were: 19 to 25 years old (32.98%), high school graduates (36.17%), housewife (51.13%), and first pregnancy (48.94%). Almost all subjects had birth spacing due to contraception motivation (71.34%), and 56.38% use IUD due to long-term contraception method (Table 1).

Almost all the subjects visited the health facilities during the period of evaluation (more than 85% in every period of evaluation): The hospital, public health care, and private midwife service. Table 2 shows the description of the subject's evaluation visit.

PPIUD Acceptance

The IUD acceptance at 6 weeks, 3 months, and 6 months was 96.8, 93.3, and 90.7%, respectively. A subject did reinsertion after expulsion at 6-week period and two subjects did at 3-month period. The reasons for IUD removal request at 6 weeks were family's request (2.1%); at 3 months were dyspareunia, vaginal bleeding, and pain (1.15%); and at 6 months were vaginal discharge (1.43%). The post-placental IUD insertion using clamp acceptance at 6 weeks, 3 months, and 6 months was 95.74, 88.89, and 85.63%, respectively. Figure 1 shows the IUD acceptance chart of this study.

PPIUD Effectivity, Side Effects, and Satisfaction

There was no pregnancy in the period of evaluation. The side effects at the period of follow-up were shown in Table 3. No pregnancy was found in all subjects. Abdominal pain was the

major complaint at 6 weeks, 3 months, and 6 months of 7.45, 3.45, and 4.35%, respectively. The other dominant complaints were vaginal bleeding and vaginal discharge (3.45%) at 3 months and dyspareunia (3.19%) at 6 weeks. The satisfaction using IUD was 90.4, 91.1, and 88.16% at 6 weeks, 3 months, and 6 months, respectively.

DISCUSSION

Post-placental IUD insertion prevents less unwanted pregnancy and provides more opportunity to achieve long-term contraception.^{6,7} The hypothesis of insertion immediately after placental delivery using Kelly forceps makes the procedure more comfortable and less painful for the patients.⁸⁻¹¹

A total of 100% of IUD effectivity occurred until 6 months of evaluation in this study. The lactation amenorrhea method has 98% of effectivity if only done with appropriate exclusive breastfeeding criteria.^{8,12} Although the lactation status occurred in >80% of subjects, we can conclude that lactation activity in this study did not affect the measurement of contraceptive effect of IUD as more than 50% of lactating subjects already had a menstrual period (not fulfilled the prerequisite of lactation amenorrhea method). Despite that, these data show that IUD method does not affect the lactation process as the previous report.¹³

The overall total expulsion rate for 6 months of follow-up was 5.9%. The IUD expulsion rate reported in China, Turki, Mali, India, and Tanzania, was 13.3; 10.68; 33.4; 7, and 2.3%, respectively.¹⁴⁻¹⁹

Table 1: Characteristics of the subjects

Characteristics	Subjects (n = 94)	
	N	%
Age (years)		
≤18	7	7.45
19–25	31	32.98
26–30	23	24.47
31–35	11	11.7
>35	22	23.4
Level of education		
Elementary school	13	13.83
Junior high school	24	25.53
Senior high school	34	36.1
Diploma or post-graduate	23	24.47
Occupation		
Medic or paramedic	9	9.57
Others	36	38.3
Housewife	49	51.13
Obstetrical status		
Primiparity	46	48.94
Multiparity	42	44.68
Grand multiparity	6	6.38
Contraception motivation		
Birth spacing	68	71.34
No more children	26	27.66
Reason for IUD use		
Effective	39	41.49
Long-term	53	56.38
Others	2	2.13

Table 2: Description of evaluation visit

Evaluation	6 weeks (n = 94)	3 months (n = 87)	6 months (n = 70)
Visit health facility, n (%)	91 (96.81)	75 (86.21)	68 (97.14)
Hospital, n (%)	12 (13.19)	11 (14.67)	8 (11.76)
Public health care, n (%)	38 (41.76)	40 (53.33)	34 (50)
Midwife, n (%)	41 (45.05)	24 (32)	26 (38.24)
Didn't visit health facility, n (%)	3 (3.19)	12 (13.79)	2 (2.86)

Table 3: Incidence of pregnancy, complication, and satisfaction

Parameters	6 weeks (n = 94)	3 months (n = 87)	6 months (n = 70)
Pregnant, n (%)	0 (0)	0 (0)	0 (0)
Lactation, n (%)	89 (94.68)	74 (94.68)	61 (94.68)
Vaginal bleeding, n (%)	2 (2.13)	3 (3.45)	1 (1.45)
Abdominal pain, n (%)	7 (7.45)	3 (3.45)	3 (4.35)
VAS <3, n (%)	5 (5.32)	2 (2.3)	2 (2.9)
VAS ≥3, n (%)	2 (2.13)	1 (1.15)	1 (1.45)
Expulsion, n (%)	2 (2.13)	3 (3.45)	0 (0)
Perforation, n (%)	0 (0)	0 (0)	0 (0)
Vaginal discharge, n (%)	1 (1.06)	3 (3.45)	1 (1.45)
Sign of infection, n (%)	0 (0)	0 (0)	0 (0)
Dyspareunia, n (%)	3 (3.19)	2 (2.3)	1 (1.45)
Thread coming out from vagina, n (%)	22 (33.4)	2 (2.3)	1 (1.45)
>1 complaints, n (%)	3 (3.19)	3 (3.45)	1 (1.45)
No complaint, n (%)	57 (60.64)	71 (81.61)	62 (89.86)
Satisfaction, n (%)	85 (90.4)	82 (91.1)	67 (88.16)

Situmorang et al. reported the partial, total, and cumulative expulsion rates of manual post-placental IUD insertion using hand were 0.6; 6.9, and 12.6%, respectively.^{1,2} Benish et al. reported 5.5% of expulsion rate of post-vaginal delivery compared to 3.4% of cesarean section.²⁰ The expulsion rate of post-placental IUD insertion using Kelly forceps had been reported in two studies from India. Gupta et al. reported the expulsion rate was 14.3% at 6 weeks, 2.9% at 3 months, and 0% at 6 months, respectively.⁵ Sharma reported the expulsion rate was 5.2% at 6 months.²¹ Chhari et al. reported a 12% of expulsion rate in the post-placental group compared to 0% in the cesarean group.²² There is no difference in expulsion rate between manual and Kelly forceps techniques. The provider skills and IUD material are factors influencing the expulsion rate.²³ Goldthwaite et al. compared the 12-week post-placental expulsion rate of 38% of levonorgestrel IUD to 20% of copper IUD ($p = 0.05$).²⁴

No perforation was reported in this study, corresponding to the previous study.^{5,22} The previous study of manual post-placental IUD insertion at RSCM before showed no perforation and evidence of translocation.^{1,2}

The incidence of vaginal bleeding in this study was 3.13, 3.45, and 1.45% at 6 weeks, 3 months, and 6 months, respectively. These results were higher than the results of the previous study at RSCM using a manual technique (1 and 1.7% at 6 weeks and 6 months, respectively).² Gupta et al. reported vaginal bleeding of 11.4; 14.5, and 7.4% of patients at 6 weeks, 3 months, and 6 months, respectively.⁵ Sharma, reported that menstrual disturbance occurred in 19.23% of patients. A total of 1.92% of patients ask to remove the IUD due to vaginal bleeding.²¹ The use of Copper T increases fibrinolytic activity and local effect of prostacyclin or thromboxane balance at endometrium that causes prolonged menstrual duration in almost 50% of cases.²⁵ There is no difference in bleeding between post-placental IUD after vaginal delivery and cesarean section.²³

The incidence of abdominal pain in this study was 3.45 and 4.35% at 3-month and 6-month follow-up, respectively. This result was higher than the result of the study of Gupta et al. (4.3 and 1.5% at 3-month and 6-month follow-up, respectively).⁵ Chhari et al. reported 6% of abdominal pain at 3 months and 2% at 6 months.²² Sharma reported a higher rate (13.46%) of pelvic pain at 12 weeks, and 7.69% of patients asked for the removal due to this pain.²¹ This abdominal pain might be correlated to uterine involution and menstrual period.²⁶

The incidence of vaginal discharge in this study was 3.45% at 3 months, lower than that in the study of Gupta (14.5%). In 6-month follow up, the incidence was higher (1.45% compared to 0%).⁵ There were no symptoms of infection in the subjects with vaginal discharge. A previous study reported that bacterial pathogen was only found in 1.6% of women with vaginal discharge after PPIUD, but no other infections in 8-week period.²⁵ Divakar et al. reported 16% of vaginal discharge with 1% in need of antibiotic therapy.²⁷

The IUD acceptance was 96.8, 93.3, and 90.8% at 6 weeks, 3 months, and 6 months of follow-up, respectively. This result was higher than the result of Gupta's study of 86.9% at 6 months of follow-up of IUD acceptance.¹ Sharma reported a lower discontinuation rate of 75% at 6 months of follow-up.²¹ The satisfaction rate was 91.1 and 88.16% at 3 months and 6 months of follow-up, respectively. These results were lower than the results of Gupta's study (92.3 and 95.6% at 3 months and 6 months, respectively) and Ifthikar's study (94.5 and 93% at 6 months and

a year, respectively).^{5,28} Heavy menstrual bleeding was the most common reason for removal.²⁷ In this study, the reasons for IUD discontinuation were dyspareunia, vaginal bleeding, abdominal pain, and vaginal discharge (one patient in each complaint). Two patients had other reasons.

The weakness of this study was the ovum clamps were not in the set of labor equipment and the provider should be get trained well. This study did not compare the safety and clinical outcomes between post-placental IUD insertion manually with hand and using a clamp. The strength of this study was these data could be used for family planning counseling in daily practice.

CONCLUSION

Post-placental IUD insertion using clamp had good safety, effectivity, acceptance, and satisfaction. Post-placental IUD insertion should be routinely offered to all eligible postpartum women undergoing institutional deliveries.

DECLARATIONS

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Health Research Medical Faculty University of Indonesia. The number of ethical approval: 0410/UN2.F1/ETIK/2018. Informed consent was obtained by a written form that was approved by the local research committee of the Health Research Medical Faculty University of Indonesia and Dr. Cipto Mangunkusumo General Hospital.

Consent of Publication

Not Applicable.

Availability of Data and Material

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

ERG supervised the research closely and become the first author. R.A.P collected, analyzed, interpreted the patient data, and wrote the manuscript. Y.P build and revised the manuscript and become correspondence author. All authors read and approved the final manuscript.

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ORCID

Yogi Pasidri <https://orcid.org/0000-0002-2890-1818>

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