RESEARCH PAPER

COMPARISON OF EFFECTIVENESS OF INTRA UTERINE CONTRACEPTIVE DEVICE AFTER INSERTION AMONG POSTPARTUM AND INTERVAL PERIOD: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Intrauterine contraceptive device (IUCD) is a highly effective, long acting reversible contraceptive method. Rate of acceptance, continuation or complications of IUCD following postpartum (PP) insertion compare to standard interval (INT) insertion were not studied in Sri Lanka. Objectives of this to compare the effectiveness of IUCD following insertion in postpartum (PP) and interval (INT) period. Randomized controlled trial was conducted with 182 postpartum mothers from ward 05, Teaching Hospital, Kandy for period from 15th August 2012 to 15th March 2015. Ethical clearance was obtained from institutional Ethical Review Committee. Mothers were randomized to PP or INT group after vaginal delivery and Copper IUCD were inserted. Participants were followed at 6th weeks, 6th months and 2 year. Outcomes of the study were acceptance and continuation of IUCD, expulsion, perforation, pain, abnormal vaginal bleeding and pelvic inflammatory disease. Among participants rate of insertion was 100% (91) in PP group and 78% (71) in the INT group (p-0.001). Continuation of IUCD was 73.6% (67) in PP group and 67% (61) in INT group (p-0.41) on 6thmonths and 61.5% (56) in PP group and 57.1% (52) in INT group (p-0.42) on 2 year. The expulsion of IUCD, on 6th week was 23.1% (21 of 91) in PP and 8.5%(6 of 71) in INT group (p - 0.01), on 6th month, was 4.2%(3 of 70) in PP group and 4.6%(3 of 64) in INT group (p 0.84) and on 2 year, was 3.5%(1 of 58) in PP group and 1.8%(1 of 53) in INT group (p 0.61). The cumulative rate of complications during two year, expulsion was 28.6%(26 of 91) in PP group and 14.1%(10/71) in INT group (p=0.02), abnormal pain was 5.5%(5/91) in PP group and 14.1%(10 of 71) in INT group (p=0.11), abnormal vaginal bleeding was 6.6%(6 of 91) in PP group and 8.5%(6 of 71) in INT group (p=0.88). One perforation of IUCD was observed in INT group. one removal of of IUCD was INT group for bleeding and pain. There was no statistically significant difference in pain or abnormal uterine bleeding related to IUCD in both group. Pregnancy and PID was not observed in both group during study period. The acceptance rate of IUCD was higher in postpartum period but higher expulsion rate limits popularity so further research and training may be necessary to reduce expulsion of IUCD in postpartum insertion.

Introduction

In Sri Lanka, although performing abortions is not legally allowed unless to save mothers life, estimated incidence of induced abortions is 600 to 700 per day within the country[1]. Those induced abortions were recorded mainly among urban and semi-urban married women aged 25 years to 39 years and having two or more children. Higher rate of abortions among married women who have completed their family indicates that unwanted pregnancy is the major cause for unsafe abortions. Therefore, best alternative to reduce unwanted pregnancies would be to offer an acceptable and effective contraceptive method to these eligible couples[1].

According to the report of WHO Technical Consultation on Birth Spacing after a live birth, recommended interval before attempting the next pregnancy is at least 24 months in order to reduce the risk of adverse maternal, perinatal and infant outcomes[1]. Effective contraception is preventing pregnancy-related health risks among women, reducing infant mortality, empowering people, reducing adolescent pregnancies and slowing growth of population[2].

Around 64.6% of women were using contraception and among them only 10.3% were using intra uterine contraceptive devices (IUCD) as the contraceptive method[1]. Among various contraceptive methods, IUCD was preferred as a highly effective, long acting and quickly reversible contraceptive method (LARC). And it appears convenient to use and it does not interfere with intercourse. Although it is a user independent method, potential complications such as abnormal menstrual bleeding, abdominal pain, pelvic inflammatory disease, expulsion of the IUCD and perforation of the uterus may reduce its popularity among users. Another drawback is that the IUCD offers no protection against sexually transmitted infections, including human immune deficiency virus[1]. Failure rate of copper IUCD with typical use is 0.8 percent and with perfect use it is 0.6 percent. Yet IUCD has many advantages.

During the postpartum period, women are often strongly motivated to initiate contraceptive practices. IUCD insertion during this time period is an ideal method for

some women, as it does not interfere with breastfeeding, is convenient for both women and their health care providers, is associated with less discomfort and fewer side effects than interval insertions and allows women to obtain safe, long-acting, highly effective contraception before leaving the hospital. However postpartum IUCD insertion increases the risk of adverse events affecting safety (perforation, pain, bleeding) as well as effectiveness (expulsion)[1]. But a number of studies have shown that postpartum insertion of CuT 380 models was effective, useful, safe, convenient and affordable. And acceptance rate was also high during the postpartum period. Postpartum IUCD is especially useful in rural settings to increase the catch up rate of contraceptive usage.

Methods

A randomized control trial was conducted with two parallel arms at Teaching Hospital Kandy from 15th August 2012 to 15th March 2015. Women who were willing to undergo IUCD insertion as a contraceptive method following vaginal delivery were considered as the study population. Age of the study participants ranged from 8 years to 45 years. Participants who underwent vaginal delivery, assisted vaginal delivery or instrumental delivery were included. Evidence of chorioamnionitis at the time of delivery, grand multipara and mothers who had experienced postpartum hemorrhage were excluded. 182 mothers were selected for the study with 76 in each arm.

Women who had undergone insertion of IUCD during the postpartum period (treatment group) and women who had undergone insertion of IUCD during the interval period (Control group) were longitudinally followed up for two years and effectiveness of IUCD insertion during postpartum period and interval period were assessed. Participants were instructed to return for follow up procedures at six weeks, six months and two years after insertion of the IUCD. Participants were given a leaflet with advice to supplement the verbal instructions. An interviewer administered pretested structured data collection sheet was used as the study instrument. Data were entered and analyzed by using statistical package of social sciences 16.0. To compare the basic characteristics, mean, SD and t test were used for continuous data with normal distribution. Comparison of primary and secondary outcome between the postpartum and the interval group was analyzed by using proportion and chi square test. Acceptance

and continuation were analyzed as intention to treat basis. Project was ethically reviewed and cleared by the Ethics Review Committee, Teaching Hospital Kandy. No conflicts of interests to be declared.

Results

Majority of the study participants from each group were included into the 21 years to 30 years age group. Mean age of the postpartum group was 27.1 (95% CI 25.8-28.5) and in the interval group it was 25.7(95% CI 24.4-26.8) (p=0.10). Among the participants, 11% had received higher education and 48% had studied up to advanced level. Among participants, majority (73.1%) was unemployed. As a significant difference in the basic characteristics was not identified between both groups (postpartum and interval), randomization was done correctly (Table 1).

More than 53% of the participants included into both groups were primi mothers. Median value of parity was one in both groups. Majority of the participants included into both groups had delivered at term. Mean gestational age identified in the postpartum group was 275 days (95% CI 273-277) and in the interval group it was 274 (95% CI 272-276) (p= 0.27) (Table 2).

Acceptance rate and continuation were analyzed through intention to treat basis according to allocation into both groups. Therefore, the total number of participants included into each group was 91. Continuation rate of IUCD did not significantly differ between the postpartum or interval groups at 6 weeks, 6 months and 2 years follow up period. Number of expulsion of IUCDs were 26 in the postpartum group and 9 in the interval group. During the study period, 9 IUCDs in the postpartum group and 6 IUCDs in the interval group were removed on request of participants as pregnancy was planned. Two IUCDs were removed following complications in the interval group (Table 3). At 6 weeks, the postpartum group had experienced statistically significant higher proportion of expulsion than that of the interval group (p=0.01). All the other complications did not show any statistically significant difference between both groups (Table 4). At 6 months there were 21(23%) expulsions in the postpartum group and 6 expulsions and one removal due to perforation in the interval group. Therefore, the study population became 70 for the

Table 1: Distribution of sociodemographic characteristics of study participants.

Age group	Postpartum		Interval		Total	
	No	%	No	%	No	%
<20	11	12.1	09	12.7	22	12.1
21-30	54	59.3	49	69.0	114	62.6
>30	26	28.6	13	18.3	46	25.3
Educational Status						
Secondary education	36	39.6	31	43.7	74	40.7
Advanced level	44	48.4	35	49.3	88	48.4
Higher education	11	12.1	05	7.0	20	11.0
Occupation						
Unemployed	68	74.7	51	71.8	133	73.1
Employed	23	25.3	20	28.2	49	26.9
Total	91	100.0	71	100.0	162	100.0

postpartum group and 64 for the interval group (Table 4). No statistically significant difference was seen in rate of expulsion, in abnormal pain or in abnormal vaginal bleeding between the interval and postpartum groups at 6 months (Table 4). At the end of 6 months there were 24 expulsions in the postpartum group and 9 expulsions and 2 removals (one for perforation and one for pain) in the interval group. Between 6 months to 2 years period, 9 IUCDs in the postpartum group and 6 IUCDs in the interval group were removed on request of participants as pregnancy was planned. Therefore, at two year the study population was 58 for postpartum group and 53 for the interval group (Table 4).

No significant difference in rate of complications was seen between postpartum or interval group during 6 months to 2 years period (Table 4). Ninety-one participants in the postpartum group and 71 in the interval group received IUCDs and followed up. Total expulsion of IUCDs during the study period was significantly higher in the interval group (28.6% Vs 12.7%, p=0.02). A significant difference was not observed

Table 2: Distribution of parity and gestational age of the participants

Parity	**Postpartum**		**Interval**		**Total**	
	No	%	No	%	No	%
1	49	53.8	38	53.5	87	53.7
2	27	29.7	19	26.8	46	28.4
3	10	11	12	16.9	22	13.5
4	5	5.5	2	2.8	7	4.4
Period of gestation						
34-36+6 days	5	5.5	3	4.2	8	4.9
37-41+6 days	86	94.5	68	95.8	154	95.1
Total	91	100.0	71	100.0	162	100.0

Table 3 : Relationship between the time of insertion and the acceptance and continuation of IUCD.

Primary Outcome	**Postpartum (n-91)**		**Interval (n-91)**		**Significance**
	Yes	No	Yes	No	
Acceptance	91(100%)	00	71(78.0%)	20(22.0%)	P=0.001*
Continuation					
First 6weeks	70(76.9%)	21(23.1%)	64(70.3%)	27(29.7%)	$\chi 2$=1.01 p=0.40*
Six weeks to 6 months	67(73.6%)	24(26.4%)	61(67.0%)	30(33.0%)	$\chi 2$=0.33 p=0.41*
Six months to 2 years	56(61.5%)	35(38.5%)	52(57.1)%	39(42.9%)	$\chi 2$ =0.36 p=0.42*

Table 4 : Relationship between the time of insertion and the complications.

Complication	Postpartum		Interval		Significance	
	Yes (%)	No (%)	Yes (%)	No (%)	$\chi 2$	*p*
At Six weeks of time						
Expulsion	21(23.1)	70(76.9)	06(8.5)	65(91.5)	6.14	0.01
Perforation	-	91(100)	01(1.4)	70(98.6)	-	-
Abnormal pain	03(3.3)	88(96.7)	05(7.0)	66(92.9)	1.19	0.27
Abnormal vaginal bleeding	02(2.2)	89(97.8)	02(2.8)	69(97.2)	0.63	0.80
PID	-	91(100)	-	71(100)	-	-
Unintended pregnancy	-	91(100)	-	71(100)	-	-
6 weeks -6 months						
Expulsion	03(4.2)	67(95.8)	03(4.6)	61(95.4)	0.17	0.89
Perforation	-	70(100)	-	64(100)	-	-
Abnormal pain	02(2.9)	68(97.1)	03(4.6)	61(95.4)	0.33	0.56
Abnormal vaginal bleeding	02(2.9)	68(97.1)	02(3.1)	62(96.9)	0.01	0.91
PID	-	70(100)	00	64(100)	-	-
Unintended pregnancy	-	70(100)	00	64(100)	-	-
6 months – 2 years						
Expulsion	02(3.5)	56(96.5)	01(1.8)	52(98.2)	0.26	0.61
Perforation	-	58(100)	00	53(100)	-	-
Abnormal pain	02(3.4)	56(96.6)	01(1.9)	52(98.1)	0.26	0.61
Abnormal vaginal bleeding	02(3.4)	56(96.6)	01(1.9)	52(98.1)	0.26	0.61
PID	-	58(100)	00	53(100)	-	-
Unintended pregnancy	-	58(100)	00	53(100)	-	-
After 2 years						
Expulsion	26(28.6)	65(71.4)	9(12.7)	62(87.3)	5.04	0.02
Perforation	-	91(100)	01(1.4)	70(98.6)	-	0.46
Abnormal pain	05(5.5)	86(94.5)	10(14.1)	61(85.9)	3.5	0.11
Abnormal vaginal bleeding	06(6.6)	85(93.4)	06(8.5)	65(91.5)	0.02	0.88
PID	-	91(100)	00	71(100)	-	-
Unintended pregnancy	-	91(100)	00	71(100)	-	-

Among other complications such as perforation, abnormal pain or abnormal bleeding between the postpartum and the interval groups (Table 4).

Discussion

Family planning (FP) is recognized as a key life-saving intervention for mothers and their children (WHO 2012) and birth spacing for more than 2 years reduces maternal and child mortality by 30% and 10% respectively[2]. The objective of postpartum FP is to ensure that all the mothers receive contraception and reduce the unmet need of contraception. Postpartum IUCD (PPIUCD) was recently introduced in our practice compared to the existing method of interval insertion at 6 weeks and not well established in our country. This is unique as it is a long acting, reversible, user independent and cost-effective FP method that is free of systemic side effects and does not affect breast-feeding[2].

Acceptance rate of contraception was high in the postpartum period. According to this study, the acceptance rate of IUCD in the postpartum group (100%) was higher when compared with the interval group (75%). This reflects that effective antenatal family planning counseling motivates women to accept and use contraceptive methods following delivery. In this study higher acceptance among postpartum women could be due to high profile counseling and temporary unavailability of injectable contraceptive methods in the country due to banning following an adverse event during the study period. However, a similar acceptance rate was observed in the interval period in comparison with the previous study could be due to the influence of external factors on their choice. A study in Peru revealed that acceptance of contraception (any method) among postpartum women was higher (90%) in the interval group and also the continuation rate at 6 month was 82% in the postpartum group and 69% in the interval group[9].

The continuation rate of IUCD was 73.6% and 67% at 6 month and 61.5% and 57.1% at 2 years in the postpartum and interval groups respectively. Higher expulsion rate in the postpartum group was significantly reducing continuation.

Expulsion of IUCD was a main limiting factor that affected the popularity of PP IUCD. In this study, the cumulative rate of expulsion of IUCD was significantly higher in the postpartum group than that of the interval group (26.8% Vs. 12.7% p=0.02).

The results of this study differ from the results of the study done in Mexico (2005)[12], which showed that the rate of expulsion in the postpartum and the interval groups were 16% and 2.7% respectively at three months follow up period (p = 0.0004). Another study done in Belgium and Netherland (1982)[15] revealed that expulsion rates in the postpartum and the interval groups were 9.3%and 2.7% respectively (p= 0.05) at one year follow up period. But in both studies, IUCD was inserted to the postpartum group within 10 minutes of delivery, however in this study, it was done after ten minutes. Subgroup analysis revealed that the expulsion rate of IUCD was not significantly different after 6 weeks (6 weeks to and 2 years) and similar when compared to the above two studies. PPIUCD was recently introduced in Sri Lanka and the learning curve could be a reason for the high expulsion rate. These findings imply the urgent need of an improvement in the insertion techniques of PPIUCD by providing appropriate training and equipment.

Pain and bleeding were the identified reasons for removal of IUCD. A study done in Belgium and Netherlands (1982)15 showed that cumulative rate of removal of CuT200 due to pain or bleeding was 3.6% (95% CI, 2.1–10 min) in the postpartum group compared to 1.9% (95% CI, 0.8–3.1) in the interval group. But in this study, it was 5.5% in the postpartum group and 14.1% in the interval group.

Incidence of PID following IUCD insertion was 9.6 out of 1000 insertions[17] and incidence of unintended pregnancy among IUCD users was 6 per 1000 insertions. In this study there were no cases of PID or unintended pregnancy. The sample size was calculated only to assess the expulsion rate, so none having PID could be due to inadequacy of the sample to assess PID or may be due to low incidence of STD in the study population.

Only one perforation (related to insertion) was seen in the interval group at six weeks in this study. It appeared similar to the study done in Turkey (2006)[11], which showed that rate of perforation was only observed in the interval group. The lower incidence of perforation in this study could be due to inadequate sample size as it was calculated to assess the expulsion rate. This could be an alternative explanation for the statistical insignificance of perforation between both groups observed in this study.

References

1. Ministry of healthcare and nutrition. Annual health statistics Sri Lanka. Colombo:
2. Ministry of healthcare and nutrition; 2012.p 43-49.
3. WHO.Fact sheets of Family planning. Geneva: World health organization;2011.2-4.
4. United Nations Population Fund Sri Lanka. ICPD@15.Colombo: United Nations
5. Population Fund Sri Lanka;2009.p25-27.
6. USAID. The postpartum IUD. New York: Engender Health;1997.p 4-45.
7. Trussell, James. Contraceptive Efficacy. Contraceptive Technology. New York:
8. Nathalie K, Kathryn M, Curtis B. Intrauterine device insertion during the postpartum period. Contraception 2009; 80(4):327–336.
9. WHO.Medical eligibility criteria for contraceptive use. 4th edition. Geneva: World Health Organization; 2010: 65-79.
10. Karen G F, James R F, Gloria L ,Alfredo G. Effectiveness and cost-effectiveness of postpartum IUD insertion in Lima Peru. International Family Planning Perspectives .1993;19(1) :19-24
11. Sevki Celen, Perran Moroy, Ayhan Sucak, Ayla Aktulay, Nuri Danısman. Clinical outcomes of early post placental insertion of intrauterine contraceptive devices, Contraception. 2004; 69(4): 279–282.
12. Eroglu K, Akkuzu G, Vural G, Dilbaz B, Akin A, Taskin L, et al. Comparison of efficacy and complications of IUD insertion in immediate postplacental/early postpartum period with interval period:1 year follow-up. Contraception. 2006;74:376–81.
13. Bonilla Rosales F, Aguilar Zamudio M E, Cázares Montero M L, Hernández Ortiz M E, Luna Ruiz M A .Factors for expulsion of intrauterine device Tcu380A applied immediately postpartum and after a delayed period :Rev Med Inst Mex Seguro Soc. 2005.Jan-Feb;43(1):p5-10.
14. Ricalde R L, Tobias G M, Perez C R, Ramirez N V. Random comparative studyBetween intrauterine device multiload Cu375 and TCu 380A

inserted in the postpartum period. Ginecol ObstetMex2006;74: 306–11.

15. Welkovic S, Costa L O, Faundes A, De Alencar X, Costa C F. Postpartum bleeding And infection after post-placental IUD insertion. Contraception.2001;63: 155–8.
16. Thiery M, Van der Pas H, Delbeke L, Van Kets H. Comparative performance of Two copper-wired IUDs (Ml-Cu-250 and T-Cu-200)-immediate postpartum and Interval insertion. Contraceptive Delivery System.1980;1: 27–35
17. David H,Pailein C, Sola P.Side effect from the copper IUD: Do they decrease over the time?.Contraception.2009;79: 356-362.
18. Kelly E K, Rudinsky S W. Intrauterine contraception. Current evidence based recommendation. Journal of Midwifery Womens Health . Sep-Oct 2007;52(5): 505-507.
19. Alan T N, William W. Diagnosis and Management of Clinical Chorioamnionitis. Clinical Perinatology. 2010 June; 37(2): 339–354.
20. Mousa H A, Alfirevic Z. Treatment for primary postpartum haemorrhage. Cochrane Database Syst Rev 2007;(1):CD003249.DOI: 10.1002/14651858.CD003249.pub2.[cited 8th August 2012]
21. WHO. Recommendations for the prevention and treatment of postpartum haemorrhage .Geneva: World Health Organization;2012: 21.
22. Marlies N ,Giovanni T, Friedo W D, Carmine Z, Michael W T, Kitty J J .Sample size calculations: basic principles and common pitfalls .Nephrology Dialysis Transplant. 2010:732.
23. Paula H. Bednarek C, Mitchell D, Matthew FR, Carrie C, Eve E, Jeffrey TJ . For the Post-Aspiration IUD Randomization (PAIR) Study Trial Group .N Engl J Med 2011; 364:2208-2217.
24. APGO. Educational series on women's health issues. Clinical management of abnormal uterine bleeding. Association of Professors of Gynecology and Obstetrics ;2002. RCOG. Management of acute pelvic inflammatory disease. Green top guideline. London: Royal College of

Obstetrician and Gynaecologist.2008;32.

25. Trupin, Suzanne R. "Abortion." eMedicine. Eds. Steven David Spandorfer, et al. 18 Oct. 2004. Medscape. 10 Jan. 2005 <http://emedicine.com/med/topic5.htm> [cited 8th August 2012)