Research Article

CuT 380A IUD Inserted by R-Inserter versus Ring Forceps during Postpartum Period: A Randomized Controlled Trial

IUD CuT 380A yang Dipasang dengan R-inserter Dibandingkan dengan Klem Cincin pada Masa Pascasalin: Sebuah Uji Klinis Acak

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Abstract

Objective: To compare the safety and effectiveness of CuT 380A IUD use inserted by *R-inserter* compared with those inserted by ring forceps during the postpartum period.

Methods: The study was conducted in three puskesmas (community health centre) as affiliated of Sardjito Hospital. Subjects meeting the inclusion and exclusion criteria were recruited to get a 10% proportion expulsion rate difference, type one error 0.05 and type two error 0.20. Insertion using R-inserter was treated while using ring forceps belonged to the control groups. Follow up was carried out one week after the insertion, one month and then monthly for 12months. Rate of the following events i.e.infection, expulsion, pain, bleeding, removal and continuation of use were primary outcomes of interest.

Results: A total of 208 eligible subjects were recruited, consisting of 104 subjects using R-inserter and 104 subjects using ring forceps. Cumulative event rates during 12 months follow up were 1%, 4.3%, 3.4%, 10.1% and 4.8% each for infection, expulsion, bleeding, pain, and removal respectively. There was no difference in the rate of infection between the two groups, i.e. 1,0% for each group. There was one pregnancy over 208 subjects giving the overall failure rate of 0.5%. The overall results showed that there were no differences among those events rates (pain, bleeding, removal and continuation) between *R-inserter* and ring forceps groups. Continuations rate were 93.7%, 93.2%, 90.8%, and 90.8% each for three, six, nine and 12 months follow up respectively.

Conclusions: There were no differences in terms of event rates between the use of CuT 380A IUD inserted by *R-inserter* and ring forceps.

Keywords: continuation rate, expulsion, infection, postpartum IUD, *R-inserter*

Abstrak

Tujuan: *Membandingkan keamanan dan keefektifan pemakaian IUD CuT 380A pascasalin yang dipasang dengan R-inserter vs klem cincin.*

Metode: *Penelitian dilakukan di 3 puskesmas di provinsi DIY. Pasien yang memenuhi kriteria kelayakan dimasukkan dalam penelitian ini untuk memenuhi beda proporsi ekspulsi 10%, kesalahan tipe satu 0,05 dan kesalahan tipe dua 0,20. Kelompok uji adalah mereka yang dipasang IUD dengan R-inserter dan kelompok control adalah mereka yang dipasang dengan klem cincin.Follow up dikerjakan setelah satu minggu, satu bulan dan setiap bulan sampai 12 bulan. Infeksi, ekspulsi, nyeri, perdarahan, pelepasan dan kelangsungan pemakaian adalah hasil utama yang diteliti.*

Hasil: *Sebanyak 208 subyek penelitian memenuhi kriteria kelayakan, terdiri atas 104 subyek dipasang dengan R-inserter dan 104 subyek dengan klem cincin. Kejadian kumulatif pada seluruh kasus selama 12 bulan follow up adalah 1%, 4,3%,3,4%, 10,1%, 4,8% masing-masing untuk infeksi, ekspulsi, perdarahan, nyeri, dan pelepasan. Angka infeksi masing-masing sebesar 1% pada kedua kelompok. Terdapat satu kehamilan (0,5%) dari seluruh kasus. Angka kejadian yang lain (nyeri, perdarahan, pelepasan dan kelangsungan pemakaian) tidak menunjukkan perbedaan yang bermakna. Angka kelangsungan pemakaian kumulatif adalah 93,7%, 93,2% 90,8%, dan 90,8% masing-masing pada follow up tiga, enam, Sembilan dan 12 bulan pascapasang.*

Kesimpulan: *Tidak ada perbedaan dalam hal kejadian efek samping antara pemakaian IUD CuT 380A yang dipasang pada masa pascasalin denganR-inserter dan klem cincin.*

Kata kunci: *Angka kelangsungan, ekspulsi, infeksi, IUD pascasalin, pelepasan, R-inserter.*

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INTRODUCTION

Indonesia, with 248.24 million people (2013) is now occupying the fourth most populated countries after China (1.357 million), India (1.277 million), and the United States (316 million).[1] In 2007 the number of poor people reached 15.58% of the total population of 37.168 million. In 2010 it dropped to 31.02 million, a decrease which was considered to be slow.[2]In 2012 the proportion of the poor decreased to 11.66% or 28.54 million, a large number that must be reduced.[3]

The use of the Intrauterine Device (IUD) as a contraceptive in Indonesia is still relatively low at 7.75% of all contraceptive use,[4] smaller than the use of injectables (50.36%), and pills (17.84%).[5] Meanwhile, IUDs meet several requirements such as cheap, effective, minimal side effects, practical, and easy to deliver provided that the service providers have been given adequate training[6,7] Based on the 2010 Demographic and Health Survey, the number of births in Indonesia reached 4.72 million per year, and 70% of them were conducted at health facilities.[4] Suppose that 10% of postpartum mothers are given IUD's for her contraceptives then the contribution of IUD for all use of contraceptives will increase significantly.

The use of postpartum IUD has several advantages such as easy insertion, the acceptors are clearly not being pregnant, it does not require a specific time again, and patients are protected immediately after leaving the hospital.[6,7] However, IUD should not be given without adequate counselling and informed consent of the patient. For that purpose, counselling of postpartum IUD insertion should have been given since a pregnant woman is taking her antenatal care. Counselling done while the patient is in labour or delivery often leads to regret the decision is taken in an atmosphere that is not conducive. For clients who do not receive initial counselling, it should be done after they are free from the stress and anxiety resulting from birth process.[8]

IUD insertion techniques had been standardized using the no-touch and withdrawal technique. For CuT 380A, both arms should be inserted into the tube inside the wrapper and should not be touched by hands although hands were using sterile gloves.[8] The IUD used for postpartum women was so far using a regular IUD, which was inserted in two ways. The first way was by using two fingers (index and middle fingers) where the IUD is clamped between them and inserted into the uterine cavity through the dilated cervix until it was attached to the fundus. The second way was using ring forceps in which the IUD was held at the junction between the two vertical arms and horizontal bar, and it was inserted through the dilated cervical os and pushed deep into the uterine fundus.[9]

Either way, it violated the principle of no-touch and withdrawal technique that could potentially increase the risk of infection. Such procedures were taken because the conventional package of CuT380A IUDs available in the market was not specifically designed for postpartum IUD insertion.

The problem is that the principle of no-touch and withdrawal technique became impossible to apply since the length of inserter did not fit the depth of postpartum uterus. The length ofCuT 380A IUD's inserter currently available in the market is only 20.5 cm so that the entire inserter will enters the vaginal cavity and there was no part of the inserter could be held.

Our previous study showed that the mean depth of uterine cavity soon after delivery of the placenta (within 10 minutes) was 20 cm with the maximum of 28 cm.[10]Based on that finding the new inserter *(R-inserter)* was designed with the length of inserter become 28 cm.[10]Previous study on the use of R-inserter for delivering postpartum IUD has been conducted in Sardjito and its affiliated hospitals. The results were satisfying except for unfavorable high expulsion rate (11% for one year). It was higher compared with expulsion rate reported during interval insertion, but it was not different compared with another study of postpartum IUD insertion.[11]

The primary objective of the present study was to compare the safety of CuT 380A IUD inserted by *R-inserter* and ring forceps during postpartum period, or during the first two hours after delivery of placenta. The secondary objective was to find out the effectiveness (pregnancy rate), and its continuation of use.

METHOD

This was a randomized controlled trial, comparing the use of CuT 380A IUD inserted by *R-inserter* vs. ring forceps during the postpartum period. Those who were inserted using *R-inserter* belonged to the treated group, while those who were inserted using ring forceps belonged to the control one.

All women who had given birth vaginally and needed IUD as their contraceptive with strong uterine contraction and no bleeding after delivery of the placenta could participate in the study. Those with potentially infected such as prolonged labour, perineal laceration grade three to four were excluded. Using expulsion rate for primary objective with the difference between the two method is not more than 10%, type one error (α) 0.05 and type two error (β) 0.20, and the estimated loss to follow up subjects not more than 10%, then 110 participants were needed for one arm or 220 for both arms. As the recruitment period was limited, then only 208 subjects could participate in this study.

Computer generated random number was used to assigned subjects into treated and control groups, and it was kept by investigator in Sardjito Hospital. Three Puskesmas with high IUD acceptors located around Sardjito hospital was used. The study was started from March to August 2013 for subjects recruitment, and the follow up was conducted a year, from September 2013 to September 2014. Insertions of the IUDs were done by residents of obstetrics and gynecology or midwives in the Puskesmas after a standardized training. The postpartum period was defined as a period of forth stage of labour, namely since the delivery of placenta until two hours thereafter. Insertion was done in this period of time, where subjects were still in the delivery room. Follow up was done after one week, one month and monthly until 12 months. Neither subject nor observer knew the type of intervention.

RESULTS

From March to August 2013, a total of 208 subjects were recruited, consisting of 104 subjects inserted by *R-inserter* and 104 by ring forceps. They came from three *Puskesmas,* i.e. Mergangsan (54.3%), Jetis (26.0%) and Tegalrejo (19.7%). They were comparable in terms of age, parity and time of insertion.

Table 1. Comparability between groups

	R-Inserter		Ring forceps		P - value
	n	%	n	%	
Parity					
Primipara	53	51	49	47	0.67
Multipara	51	49	55	53	
Time of Insertion					
≤ 10 minutes	100	96.2	97	93.8	0.54
> 10 minutes	4	3.8	7	6.7	
Age (years)					
n	104		104		0.07
Mean ± SD	27.38 ± 5.34		28.59 ± 5.99		

Comparison of rates of events based on groups of study

Based on the mode of insertion, it was shown that there was no significant difference in the rate of events until 12 months follow up, as shown on the following table 2.

Table 2. Twelve Months Cumulative Events Rate Based on Mode of Insertion

Variabels	Event Rate yes	% no	RR (95% CI)	P - value	
Infection					
R-inserter	1	102	1	1.01 (0.06 – 15.93)	0.99
Ring forceps	1	103	1	1	
Expulsion					
R-inserter	5	98	4.9	1.26 (0.35 – 4.57	0.72
Ring forceps	4	100	3.8	1	
Pain					
R-inserter	8	95	7.8	0,62 (0,27 – 1,44)	0.26
Ring forceps	13	91	12.5	1	
Bleeding					
R-inserter	5	98	4.9	2.52 (0.50 – 12.72)	0.24
Ring forceps	2	102	1.9	1	
Removal					
R-Inserter	4	99	3.9	0.67 (0.20 – 2.32)	0.53
Ring forceps	6	98	5.8	1	

DISCUSSION

Cumulative event rates during 12 months follow up were 1%, 4.3%, 3.4%, and 10.1% each for infection, expulsion, bleeding, and pain respectively. There was no difference between treated vs controlled groups. The low rate of infection was most likely due to the use of prophylactic antibiotics after delivery. The cumulative rate of expulsion was highest at three months follow up, i.e. 4,3%, and there was no additional expulsion thereafter. Those who suffered from pain and bleeding were treated with mefenamic acid and tranexamic acid, respectively. Three subjects from the *R-inserter* group had their IUDs removed because of bleeding. Two cases from each group had their IUDs removed because of infection unresponsive to a standard antibiotic treatment. Continuation rates were 93.7%, 93.2% 90.8% and 90.8% each for three, six, nine and 12 months respectively.

Compared to our previous study where the cumulative infection rate were 1.4% at three months to 2.1% at six months, it seemed that cumulative infection rate of the present study was lower. The same for the expulsion rate, the present study was 4.3%, much lower than our previous study which was 9.9% until three months follow up and then increased to 10.6% at six months.[11] Other study reported that PID rate was 1.6 per 1000 women per year[8], while expulsion rate was 4%.[12,13]

A multicenter study using CuT 380A IUD inserted by forceps ring during postpartum period reported expulsion rate 13.8%, 16.6% and20.5% each for the first, third and sixth months follow up, respectively.[14,15] Others showed cumulative expulsion rate 2.67% at three months follow up7% at six months and 12.3% at 12 months there after.[16,17]

To find out the safety and effectiveness of our present study, we compared expulsion, continuation and pregnancy rate with those

reported in the Cochrane Review. The twelve-month pregnancy ratewhich was reported by WHO ranged from 0.0% to 12.1%. The expulsion rates at 6–36 months ranged from 6.2 to 44.1 per 100 women and the 6 to 36 months continuation rates varied between 93.3 and 57.3% per 100 women. Cumulative removal rate in our present study was 4.8%, most of them were due to bleeding, infection and pregnancy. Other study showed that most of the cause of removal were bleeding and pain which ranged from 1 to 5.5 per 100 women.[7]

Table 2 showed that the rate of infection, expulsion and removal were practically the same, but pain was smaller in R-inserter group while bleeding was higher. Only one subject (0.5%) got pregnant after seven months of use originating from the ring forceps group. The IUD was removed, but it was unsuccessful because the string was broken. The baby was delivered normally at term, and the IUD was found on the placenta. Other study showed the pregnancy rate was 0.2% at six months follow up and 0.3% at 12 months follow up.[17]

Expulsion happened only during the first 12 weeks after insertion and no difference between both groups, as shown in table 2 and figure 2.

CONCLUSION

The primary and attracting event in the postpartum IUD insertion was high expulsion rate. There was no difference between the R-inserter and ring forceps group, neither in the rate of expulsion nor infection. Postpartum IUD was safe as demonstrated by other rates such as pain, bleeding removal and continuation, which were still in the range reported by other investigators. There was one pregnancy reported from the ring forceps group.

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