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Comparing Hemorrhages and Dysmenorrhea with Copper T380A and Multiload 375 Intrauterine Devices: A Randomized Clinical Trial

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ABSTRACT

Introduction: One of the most common complications of IUD users is bleeding and dysmenorrhea. These complications vary in the different types of IUDs. The aim of this study was to compare the bleeding and dysmenorrhea in ML CU 375 IUD and Copper T 380A IUD.

Methods: This randomized double-blind controlled clinical trial was performed on 48 women in a health care centres from January to October 2012, in Tabriz, Iran. Participants allocated into two equal groups of receiving IUD ML CU 375 or receiving IUD Copper T 380A in randomized blocking method. Data were collected by demographic questionnaire and Higham chart and Visual Analog Scale 1 month before IUD insertion and 4 months after IUD insertion. Analysis of covariance, ANOVA with repeated measures, Friedman, Ordinal regression and SPSS Ver. 13 were used to analysis the data.

Results: The results showed that the mean score of bleeding in the first four months after IUD insertion in IUD ML CU 375 users was significantly lower than IUD Copper T 380A group. In the third and fourth months in both groups showed severity of dysmenorrhea in group IUD ML CU 375 was lower than IUD Copper T 380A. The results showed that the duration of dysmenorrhea in the first four months after IUD insertion in IUD ML CU 375 group was significantly lower than IUD Copper T 380A group.

Conclusion: Counseling and educating women by family planning service providers about both Copper T 380A and ML CU 375 IUDs before taking IUD is recommended.

Introduction

Copper intrauterine devices are valuable birth control resources.[1] Copper IUD due to the duration of effect, high impact in contraception, low failure rate, reversibility and low cost[2,3] is used by over 130 million women around the world.[3] In developing countries 14.5% and in developed countries 7.6% of women use this method in reproductive age, which this rate in 2006 have been reported 8.1% in Iran and as 13.8% in Tabriz.[4] There is two types of commonly used IUDs including the Multi Load CU 375 IUD and Copper T 380A IUD. IUD Copper T 380A is a T shaped framework of polyethylene that is made of 380 square millimetres of copper.[3,5] The IUD ML CU 375 is a horseshoe-shaped device that contains 375 square millimetres copper woven around the body. The complications of IUDs are: abnormal uterin bleeding, dysmenorrhea, excretion of the IUD or perforation of the uterus.[3,6] During the One year, 5 to 15 percent of women due to these complications will refuse to use the IUD.[7] The most common

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complication of using IUDs are the increasing amount of menstrual pains and bleeding[8] that are the cause of 15 to 30 percent of the rejection and exclusion of copper IUDs by the users.[9] Except Progesterone IUDs, all IUDs can lead 50-100 percent increase the amount of menstrual blood than before the insertion.[10,11] Immediately after insertion of IUD, uterine cramping may appear and persist for a variable period, usually in the first months after insertion of IUD, pain appears as cramping or dull pains as well as backache.[12] Study in southern Tehran, Zanjan, and Ardabil indicate that bleeding and pain are the most common causes for discontinuation of IUD.[13-15] Another study in Tabriz showed that the most common reasons for withdrawal of IUD Copper T 380A are bleeding and pain.[16] In other studies in Babol and Rasht, the most prevalent reasons for withdrawal of IUDs were bleeding and tendency to be pregnant again.[17,18] Rates of complications in older IUDs are more than new IUDs and researchers in the 1970s with adding copper to IUDs began to develop a new method for producing appropriate IUDs, [19]including the new IUD Copper T 380A and IUD ML CU 375.[7]

The failure rate of IUD ML CU 375 and IUD Copper T 380A is 1 percent.[20] Recently IUD ML CU 375 and IUD Copper T 380As are sold in the market as the most successful IUDs, also they were considered as effective approaches and to be without risk, in which WHO recommended using these two types of IUDs.[21] Today in Germany these two types of IUD are the most used IUDs.[22] IUD ML CU 375 is used around the world except the United States and Canada.[23] Among the Indians IUD ML CU 375 is a popular method to be used.[24]

Insertion of IUD Copper T 380A disposed by Family Planning Administering Department in free, but the IUD ML CU 375 is bought in case of consumer demand by her. Some studies showed no differences of effects of the two IUD ML CU 375 and IUD Copper T 380A types.[5,25] In two studies were conducted in Yugoslavia and Nigeria, results have shown that the amount of bleeding in IUD Copper T 380A is further.[26-28] Arowojolu et al., in their study that compared three different IUD ML CU 375 and IUD Copper T 380A and IUD ML CU 250, concluded that the level of dysmenorrhea in consumers of IUD Copper T 380A was higher, and the rate of sever bleeding in IUD Copper T 380A was 5 percent, in IUD ML CU 375 as much as 4%, and in IUD ML CU 250 was 2 percent.[28]
Afkari et al., in a descriptive study showed that bleeding and dysmenorrhea are the most common complications for IUD ML CU 375 and IUD Copper T 380A, so that these two complications in users of IUD ML CU 375 was significantly higher than IUD Copper T 380A group.[29]

As mentioned before, one of the problems of IUDs is bleeding and dysmenorrhea that most of users are involved with it. Since these complications are dissimilar for different types of IUDs and at different users and also information on complications such as bleeding and dysmenorrhea in these two common IUD types are contradictory, so the aim of this study is to compare bleeding and dysmenorrhea in two types of IUDs , so that in addition to overcome the shortcomings of previous studies, researcher could take steps to increase the quality of family planning services.

Materials and methods

This double-blind equivalenced clinical trial aimed to compare bleeding and dysmenorrhea in IUD ML CU 375 and IUD Copper T 380A. The target population was married women in reproductive age (15-48 years old) who referred to Bavafa Health Centre of Tabriz from January 2012 to October 2012. The reason for choosing this health care center was the high rate of IUD insertion that was apporoximately 40 cases for each month. According to a study conducted by Milson et al.,[30] with respect to

the mean bleeding score (M1) = 89.21 with SD1 = 8.3 in Copper T 380A IUD and the mean bleeding score in MLCU 375 IUD (M2) = 81.1 with SD2 = 8.3, α = 0.5, power 90%, 10% of the attrition by using the formula of comparing two means, 24 participants were considered for each group. The target population consisted of all women referring to the health center to apply IUD, inclusion criteria included: married women in 15-48 years old, without contraindications to apply IUD in accordance with national guidelines [including pregnancy, puerperium infection, catching PID or sexual diseases (in current or within 3 past months), endometrial or cervical cancer, AUB, uterus abnormalities and fibroid tumours that cause changes in uterus cavity, allergy to copper and Wilson disease],[2] exclusion criteria included: using hormonal methods of contraception (DMPA over the past year, and OCP, Cyclofem injections within 3 months), women who has passed less than 6 months from their delivery, women whose their score of bleeding during menstruation was 100 or more based on Higham Chart, women whose their severity score of pain during menstruation was more than 7 based on the VAS.

Data collection tool was consisted of three parts, the first part was the socio-demographic and reproductive history questionnaires; that included information such as age, education level, job status, Gravidity, history of abortion, number of normal deliveries and cesarean section, the time of last birth, history of breastfeeding, history of IUD insertion, previous IUD withdrawal reason, previous contraceptive method that was completed by the researcher as an interview before IUD insertion. Content validity of the questionnair was determined by several faculty members in the School of Nursing and Midwifery, Tabriz University of Medical Sciences (Iran). The second part was Higham Chart which was pictorial blood assessment chart (PBAC). This chart is a non-laboratory simple method for diagnosis of menorrhagia. It is a general scoring system which takes observing pads, tampons, and clot appearing as the basis. This method allows the comparison between the perceived bleeding and real blood loss. It is the best tool available for the assessment of menstrual blood loss with 86% sensivity and 89% accuracy.[31] Since Higham chart is valid, there was no need for its retest validity. To determine the reliability, test-retest was used with 10 days intervals on 48 subjects (r=0.85).

The third part was Visual Analog Scale for pain (VAS), a 10 cm ruler that there is no pain at one end and the worst pain imaginable written is at the other end.[18] Due to the validity of VAS, there is no need for re-validation of this tool in determining the severity of pain. Phumdoung in his study in Thailand calculated the reliability coefficient of the instrument to measure pain intensity as 0.95.[32] To determine the reliability of this instrument the test-retest method was used (r = 0.80).

After obtaining permission from the Etihcs and Research Committee of Tabriz University of Medical Scineces (code: 9069), the researcher referred to the Bavafa health care center and invited women with IUD to participate in the study by telephone calls.

Women who came to the center were examined by a midwife and if they had the inclusion criteria, the aim of the study was explained to them and written consent was obtained from them. Then information about Higham chart, VAS and its work method was given to them and they were asked to complete the demographic, social and reproductive history questionnaires.

CONSORT guidelines was followed to conduct study (Figure 1). The random allocation of individuals in groups was done by computer random number table with randome blocks four and six with allocation ratio of 1:1. Participants were randomely assigned into two groups: Multiload 375 IUD and Copper T 380A IUD. The researcher and the patients were not aware of the IUD allocation in any groups. It was explained to

the participants that in order to keep the randome assigning of the subjects, the possibility of being assigned to the groups was the same, and even the researcher did not know who would be placed in each group. Each participant was given a sealed envelope (all the envelopes had similar appearance) by the researcher and they were numbered from 1 to 48. The envelopes contained two IUD MLCU 375 and IUD Copper T 380A. So that the samples divided into two groups of IUD ML CU 375 or IUD Copper T 380A. During the measure of bleeding, women should not use hormonal methods and they were asked to report if they take any drugs during the study.

Insertion performed by an experienced midwife. The studied samples have used pads with the same sizes and types. The participants were given the same pads because of the identical assessment of bleeding amount. The Higham Chart was used to measure the amount of bleeding, and the Visual Analog Scale (VAS) was used to measure dysmenorrhea. The samples were trained how to fill the Higham Chart and VAS. The scores assigned be 1 if the amount of blood in pad was a bright spots, 5 if moderately soiled and 20 if it was completely saturated with blood. Small and large clots scored 1 and 5 respectively.[31,33]

It was explained to the participants that the 0 on VAS means no pain and 10 indicates that the pain is very severe. Depending on the severity of pain experienced by the patient, the woman marks on the ruler. The distance between no pain and the point where the patient is marked in millimetres is measured to determine the individual score for pain.[18] The women measured a cycle before IUD insertion using Higham Chart the amount of bleeding and VAS dysmenorrhea, and then after insertion of IUD during a cycle the samples were asked to report their menstrual bleeding and dysmenorrhea for four cycles. Data for qualitative variables were reported as frequency (percentage) and for quantitative variables as mean (SD).

Normality of the quantitative variables for each group was reviewed and upheld through descriptive tests. To compare qualitative variables in two groups the Chi-square ($\chi 2$) test with accurate P-value, and in case of ranking of the variables, the trend chi-square was used. To compare the bleeding variables between two groups, the t-test was used, and to compare the mean scores for bleeding between the groups after IUD insertion, the ANCOVA statistical test, with adjusting the baseline and confounding variable were used. In this analysis the basic measurement of bleeding and confounders (Drug use during the study and the distance from last delivery to IUD insertion) were adjusted. In order to measure the variation in the time of measurements in each group for bleeding, the analysis of variance with repeated measures was used. To compare Dysmenorrhea variable between two groups, Mann-Whitney U test and Analysis of Ordinal Regression was used for basic comparison between two groups after four measurements (and by adjusting the baseline value). In this analysis, the basic measurements of dysmenorrhea and confounders were adjusted. In order to measure the variation in the time of measurements in each group for the variable of dysmenorrhea, the Fridmans rank test was used. Analysis of the data was conducted by the software SPSS Ver. 13 and $P < 0.05$ was considered significant.

Results

64 women in reproductive age participated in this study, 16 of them were excluded due to not having the inclusion criteria, and the study was done on 48 women in two groups, 24 in IUD ML CU 375 and 24 in IUD Copper T 380A group. The data collection lasted nine months. No sample loss was observed during the study and all participants continued the study to the end (Figure 1).

Both groups were matched in demographic and pregnancy characteristics (except drug

use during the study and the distance from last delivery to IUD insertion) with no statistically significant differences (P>0.05).

The majority of the investigated samples were aged 27-33 years. The level of education in both groups mostly was middle school and high school, and most samples in both groups were worked at home (Table 1,2).

The results with controlling the basic values before IUD insertion and confounding variables showed that the mean score of bleeding in the first four months after IUD insertion in IUD ML CU 375 group was significantly lower than IUD Copper T 380A group (Table 3). The results of repeated measures ANOVA, in intergroup comparison of the mean of bleeding , showed a statistically significant difference between the five time intervals (in both groups p<0.001).

As, in the group IUD ML CU 375 compared to IUD Copper T 380A, the score mean of bleeding changes was decreased (Table 4).

The results of the regression analysis with controlling the effect of the median severity of the dysmenorrhea before IUD insertion and confounding variables showed that the median severity of the dysmenorrhea in the first and second months after IUD between the two groups was not statistically significant (P=0.06, P=0.19). In the third and fourth months, the median severity of the dysmenorrhea in the group using IUD ML CU 375 was significantly lower than IUD Copper T 380A group (P=0.005 , P=0.02).

By controlling the effect of the duration of the dysmenorrhea before IUD insertion and confounder, using regression analysis of the results showed that the duration of the dysmenorrhea in the first, second, third and fourth months after IUD insertion in group IUD ML CU 375 was significantly lower than group IUD Copper T 380A (P<0.001). The results of Friedman test, in intergroup comparison of the severity and duration of dysmenorrhea, showed a statistically significant difference between the five time intervals (in both groups P<0.001). So, in group IUD ML CU 375 compared to IUD Copper T 380A, the median severity and duration of the dysmenorrhea was further decreased (Table 5, 6).

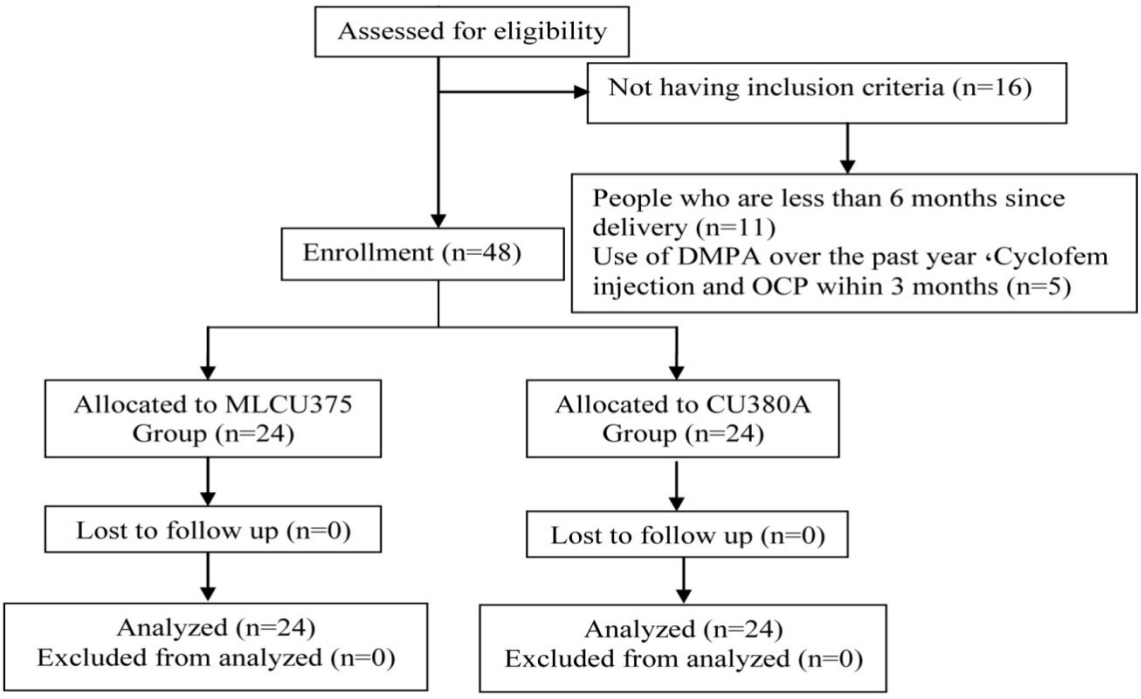

Figure 1. Flowchart of the study Participants

Table 1. Demographic characteristics in MLCU375 IUD group and Copper T380A IUD group

	Group of MLCU 375 IUD (N= 24) N (%)	Group of CUT 380A IUD (N= 24) N (%)	Total (N= 48) N (%)	Statistical indicators
Age (year)				
≤ 27	11 (45.8)	8 (33.3)	19 (39.5)	χ^2= 1.10
28-32	7 (29.2)	7 (29.2)	14 (29.2)	df= 2
≥33	6 (25)	9 (37.5)	15 (31.3)	P= 0.5
Total	24 (100)	24 (100)	48 (100)	
Education				
Elementary	3 (12.4)	6 (25)	9 (18.8)	χ^2= 3.82
Middle school	10 (41.7)	8 (33.3)	18 (37.5)	df= 3
High school & Diplma	10 (41.7)	6 (25)	16 (33.3)	P= 0.25
University	1 (4.2)	4 (16.7)	5 (10.4)	
Total	24 (100)	24 (100)	48 (100)	
Job Status				
Working at home	24 (100)	22 (91.7)	46 (95.8)	χ^2= 1.95
Employed outside	0 (0)	2 (8.3)	2 (4.2)	df= 2
Total	24 (100)	24 (100)	48 (100)	P= 0.35

Table 2. Reproductive characteristics in MLCU375 IUD group and Copper T380A IUD group

	Group of MLCU 375 IUD (N= 24) N (%)	Group of CUT 380A IUD (N= 24) N (%)	Total (N= 48) N (%)	Statistical indicators
Gravidity				
1	7 (29.2)	7 (29.2)	14 (29.2)	χ^2= 0.21
2	11 (45.8)	12 (50)	23 (47.9)	df= 2
≥ 3	6 (25)	5 (20.8)	11 (22.9)	P= 0.13
Total	24 (100)	24 (100)	48 (100)	
History of normal delivery				
Yes	13 (54.2)	17 (70.8)	30 (62.5)	χ^2= 1.42
No	11 (45.8)	7 (29.2)	18 (37.5)	df= 1
Total	24 (100)	24 (100)	48 (100)	P= 0.23
Number of cesarean				
0	11 (45.8)	6 (25)	17 (35.4)	χ^2= 4.41
1	3 (12.5)	9 (37.5)	12 (25)	df= 2
2	10 (41.7)	9 (37.5)	19 (39.6)	P= 0.10
Total	24 (100)	24 (100)	48 (100)	
History of abortion				
Yes	18 (75)	19 (79.2)	37 (77.1)	χ2= 0.11
No	6 (25)	5 (20.8)	11 (22.9)	df= 1
Total	24(100)	24 (100)	48 (100)	P= 0.73

Table 2. (Continued)Reproductive characteristics in MLCU375 IUD group and Copper T380A IUD group

	Group of MLCU 375 IUD (N= 24) N (%)	Group of CUT 380A IUD (N= 24) N (%)	Total (N= 48) N (%)	Statistical indicators
The distance from last delivery to IUD insertion				
≤ 11Month	7 (29.2)	10 (41.7)	17 (35.4)	χ^2= 12.79
12-28 Month	13 (54.2)	2 (8.3)	15 (31.3)	df= 2
≥ 29Month	4 (16.7)	12 (50)	16 (33.3)	P= 0.002
Total	24 (100)	24 (100)	48 (100)	
Breastfeeding				
Yes	13 (54.2)	10 (41.7)	23 (47.9)	χ^2= 0.75
No	11 (45.8)	14 (58.3)	25 (52.1)	df= 1
Total	24 (100)	24 (100)	48 (100)	P= 0.38
History of IUD insertion				
Yes	12 (50)	13 (54.2)	25 (52.1)	χ^2= 0.08
No	12 (50)	11 (45.8)	23 (47.9)	df= 1
Total	24 (100)	24 (100)	48 (100)	P= 0.77
Previous IUD withdrawal cause				
Itself	4 (33.3)	1 (7.7)	5 (20)	χ^2= 4.82
Due to Pregnancy	3 (25)	2 (15.4)	5 (20)	df= 3
Due to Complications	5 (41.7)	7 (53.8)	12 (48)	P= 0.51
Other Causes	0 (0)	3 (23.1)	3 (12)	
Total	12 (100)	13 (100)	25 (100)	
Previous contraceptive method				
Withdrawal	11 (45.8)	8 (33.3)	19 (39.6)	χ^2= 1.83
Condom	11 (45.8)	11 (45.8)	22 (45.8)	df= 3
IUD	1 (4.2)	2 (8.3)	3 (6.3)	P= 0.61
Other	1 (4.2)	3 (12.5)	4 (8.3)	
Total	24 (100)	24 (100)	48 (45.8)	
Drug use during the study				
Yes	3 (12.5)	11 (45.8)	14 (29.2)	χ^2= 6.45
No	21 (87.5)	13 (54.2)	34 (70.8)	df= 1
Total	24 (100)	24 (100)	48 (100)	P= 0.01
Types of used drug				
Not use of drugs	21 (87.5)	13 (54.1)	34 (70.8)	χ^2= 6.63
Mefenamic Acid	3 (12.5)	9 (37.5)	12 (25)	df= 3
Ibuprofen	0 (0)	1 (4.2)	1 (2.1)	P= 0.07
Acetaminophen	0 (0)	1 (4.2)	1 (2.1)	
Total	24 (100)	24 (100)	48 (100)	

Table 3. Mean scores for bleeding before and four months after the insertion of IUD in MLCU375 IUD group and Copper T380A IUD group

Variable	Group of MLCU 375 IUD (N= 24) N (%)	Group of CUT 380A IUD (N= 24) N (%)	MD† (CI 95%)	Statistical indicators
Before the IUD insertion	63.33 (14.32)	36.58 (23.37)	26.75 (15.48,38.01)	t‡= 4.78, df= 46, P<0.001
First month	50.29 (15.69)	59.45 (23.98)	-9.16 (-41.25,-10.90)	F•= 12.02, df= 1.42, P<0.001
Second month	44.12 (16.38)	67.33(26.73)	-23.21 (-55.86,-21.51)	F= 20.66, df= 1.42, P<0.001
Third month	42 (13.09)	63.41 (25.79)	-21.41 (-56.44,-26.46)	F= 31.14, df= 1.42, P<0.001
Fourth month	38.58 (14.07)	67.91 (22.39)	-29.33 (-59.27,-30.66)	F= 40.31, df= 1.41, P<0.001

† Mean Difference (Confidence Interval 95%), ‡ Independent sample t-test,• ANCOVA

Table 4. Comparison of mean difference of total scores of bleeding in 5 intervals in MLCU375 IUD group and Copper T380A IUD group

Variable	Group of MLCU 375 IUD (N= 24) N (%)	Group of CUT 380A IUD (N= 24) N (%)	MD‡ (CI 95%)	Statistical indicators
1 month after and before the IUD insertion	-13.04 (14.21)	22.87 (23.58)	-35.91 (-47.29,-24.53)	t‡= 4.78, df= 46, P<0.001
2 month after and before the IUD insertion	-19.20 (16.32)	30.75 (25.36)	-49.95 (-62.41,-37.50)	F•= 12.02, df= 1.42, P<0.001
3 month after and before the IUD insertion	-21.33 (13.85)	26.83 (22.93)	-48.16 (-59.23,-37.09)	F= 20.66, df= 1.42, P<0.001
4 month after and before the IUD insertion	-24.75 (15.89)	31.33 (22.53)	-55.27 (-66.81,-43.72)	F= 31.14, df= 1.42, P<0.001
ANOVA with repeated measures	F= 26.11 df= 2.97 P< 0.001	F= 21.63 df= 2.75 P< 0.001		F= 40.31, df= 1.41, P<0.001

‡ Mean Difference (Confidence Interval 95%), †Independent sample t-test,• ANCOVA

Table 5. Severity of dysmenorrhea before and four months after the insertion of IUD in MLCU375 IUD group and Copper T380A IUD group (n=24)

Variable	Groups	Median (IQR)‡	P	
Before the IUD insertion	MLCU 375 IUD CU380A IUD	3(2.33, 3.50) 2.50(1.12, 3.37)	†0.159	
First month	MLCU 375 IUD CU380A IUD	1.83(0, 2.37) 2.33(1.63,3)	0.194*	
Second month	MLCU 375 IUD CU380A IUD	1(0,2) 2(1.62, 2.50)	0.060*	
Third month	MLCU 375 IUD CU380A IUD	1.25(0,2) 2(1.61, 2.57)	0.005*	
Fourth month	MLCU 375 IUD CU380A IUD	1(0,1.62) 1.50(1.33, 2)	0.022*	
Statistical indicators		Group of MLCU 375 IUD Group of CU380A IUD		•X^2=56.32, df=4, P<0.001 •X^2=23.06, df=4, P<0.001

‡IQR: Inter quartile range (25,75),†Mann-Whitney U test, * Ordinal Regression test, •Fridman's rank

Table 6. Duration of dysmenorrhea before and four months after the insertion of IUD in MLCU375 IUD group and Copper T380A IUD group (n=24)

Variable	Groups	Median (IQR)‡	P	
Before the IUD insertion	MLCU 375 IUD	2.50(2, 3)	†0.009	
	CU380A IUD	1(1, 2.75)		
First month	MLCU 375 IUD	1.50 (0, 2)	<0.001*	
	CU380A IUD	3.50 (3, 4.75)		
Second month	MLCU 375 IUD	1 (0, 2)	<0.001*	
	CU380A IUD	4 (2, 5)		
Third month	MLCU 375 IUD	1(0,1.75)	<0.001*	
	CU380A IUD	3.50(2.25, 5)		
Fourth month	MLCU 375 IUD	1(0, 1)	<0.001*	
	CU380A IUD	3(1.12, 3.37)		
Statistical indicators		Group of MLCU 375 IUD		•X^2=55.90, df=4, P<0.001
		Group of CU380A IUD		•X^2=20.40, df=4, P<0.001

‡IQR: Inter quartile range (25,75), †Mann-Whitney U test, *Ordinal Regression test, •Fridman's rank test

Discussion

The results of this study showed that the use of IUD ML CU 375 significantly decreases the mean bleeding, as well as severity and duration of dysmenorrhea in the studied participants and IUD Copper T 380A significantly increases. In the fourth month, in the IUD ML CU 375 users, the scores of bleeding severity decreased by as much as 39 percent, but in IUD Copper T 380A users it increased to 86%. The median of severity and duration of dysmenorrhea in the IUD ML CU 375 users was decreased but in IUD Copper T 380A users was increased. Studies showed that the amount of bleeding and dysmenorrhea in IUD Copper T 380A is more than IUD MLCU 375.[26-28] The findings of these three studies are consistent with results of this study. The Causes of bleeding in the women of IUD users are numerous.

Increased local fibrinolytic activity is the main cause for the increase in menstrual blood. Another reason for the increased bleeding is increased prostaglandins, which may be increased by IUD.[6] Every copper IUDs can increase the number of neutrophils, plasma cells and multicore leukocytes cells as well as inflammatory cells. Copper added to a copper IUD has been shown that can significantly alter the metabolism of endometrial cells causing an inflammatory reaction that can lead to increased cell metalloproteinases, which causes damage to cell walls.[3,7] The type of device used, the contact, duration of use of IUD, cultural and social differences, and the number of births may have effects on the blood, adoption, symptoms and motivation to remove the IUD due to the bleeding.[34] Possible cause of differences in bleeding rates in both IUDs could be related to the amount of copper and increase in contact between the two IUDs that by increased amount of copper the contact area and therefore the amount of bleeding will be increased.

All copper IUDs stimulate intrauterine prostaglandins, and the meteria causes contraction and inflammation of uterine smooth muscles. Possible reasons for differences in dysmenorrhea of the two types of IUDs can be related to the copper and the types of two IUDs. ML CU 375 can cause a decrease in the amount of dysmenorrhea because plastic flexible rack and thereby reducing the contact area of arms, as well as the amount of copper in it which is lower than the IUD Copper T 380A.[2,35] Because increasing the amount of copper in the IUD increases the release of prostaglandins, and the increased release of prostaglandins in the uterus increases dysmenorrhea associated with IUD.[22] The study conducted in Indonesia indicates that in the groups

receiving the IUD Copper T 380A and MLCU 375, there is no difference in terms of bleeding and dysmenorrhea; this finding is not consistent with the findings of this study.

A possible explanation for the difference between the results of the study with current study can be because of not measuring the amount of bleeding and dysmenorrheal before the IUD insertion by Sastrawinata and thus, the comparison of bleeding and dysmenorrhea before and after the IUD insertion was not possible for each particioant.

The other reason for the difference could be related to the follow-up duration, which was 12 months in the mentioned study, and 4 months in the present study. Also the possible cause for lack of consistency could be this fact that the assessment of pain as a sign is difficult, since pain is a mental feeling and a combination of sensory, emotional and cognitive components. Pain tolerance is profoundly influenced by culture. Ethnic cultural differences among the study population influences perception and pain tolerance.[36,37] Afkari et al., in their descriptive - analytical study concluded that there was more significant bleeding and dysmenorrhea in the IUD MLCU 375 users compared with IUD Copper T 380A.[30] The study results were not consistent with the above study due to its limitations that caused the study to be repeated because the mentiond study was not a randomized clinical trial, without considering randomization, blinding and concealment of allocation. Secondly, comparing the amount of menstrual bleeding was measured using the questionarie; but based on the results of this study, the best tool available for assessing menstrual blood loss is Higham Chart. In this study, researchers could not have access to the results of a study comparing dysmenorrhea duration term in two types of IUD.

The strengths of this study are the randomized selection of samples and being double-blinded. The limitation of this study was the short-time follow-up period due to time constraints that was not possible.

Conclusion

The results of this study showed that the use of the IUD ML CU 375 causes a significant decrease in the rate of bleeding, as well as severity and duration of dysmenorrhea in the studied cases.

Since complications of IUD are always one of the problems of IUD users, perhaps the problem can be solved with IUD ML CU 375, and they can be saved from the pain which causes economic, social, and psychological damages, and improve their quality of life.

But more qualitative and quantitative research is needed to be done in order to compare these two types of IUDs and the best option be given to people to choose for best results followed by the financial costs and skilled human recources are working in the centers, as well as be more successful in reaching the goals of family planning programs. Thus, considering the importance of family planning and its impact on family relationships, counseling and educating women by family planning service providers about both types of IUD Copper T 380A and IUD ML CU 375 before taking IUD is recommended.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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