Discontinuation Rates among Copper Intrauterine Device Users in Primary Healthcare Unit and University Clinic. Is There a Difference?

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ABSTRACT

Background: in Egypt, despite the high percentage of women using IUD according to Demographic and Health Surveys (DHS) 2014 (52.9%) of total women using contraceptive methods, the discontinuation rates among Cu-IUD users (within 12 months of use) reaches 14.3% in 2014. **Aim of the Work:** the aim of the study was to compare between primary health care unit and university family planning clinic in discontinuation rate among copper IUD users. **Patients and Method:** study design: prospective analytical observational study. Study setting: This study was conducted at Family planning Outpatient clinic of Ain Shams Maternity Hospital and El-Zahraa primary health care unit for a year. This study included 260 women whom attending family planning clinic for Cu- IUD insertion. Total 100 subjects was enrolled from each clinic. Rest of subjects was lost on follow up either after 6 months or 12 months. Some others refused to participate or gave wrong personal contacts. **Results:** preliminary results of the study revealed that there is no statistically significant difference between discontinuation rate among Copper IUD users in university clinic and primary healthcare clinic (p-value = 0.095). **Conclusion:** in our Study, analysis of data revealed that age, parity and previous usage of IUD may affect discontinuation rate after 12 months of IUD use. The mean cause of IUD discontinuation was bleeding and Anemia was present in 66.6% of patients complaining from bleeding.

Keywords: CU-IUD: Copper containing intrauterine device, DHS: Demographic and Health Surveys, PID: Pelvic inflammatory disease

INTRODUCTION

The intrauterine device (IUD) is one of the most widely used, reversible contraceptive methods in the world[1]. IUD is convenient, safe and highly efficacious. It is recommended as a first-line long-term contraceptive option for women of all reproductive ages, including adolescent and nulliparous women[2]. IUD is globally used by 15% of women aged 15–49 years. In Egypt, the percentage of women using IUD according to Demographic and Health Surveys (DHS) 2014 is 52.9%[3]. These high rates of IUD usage are due to its advantages such as reversible fertility immediately after removal, no need to daily reminder, no effect on breastfeeding, lack of hormonal effects, no interference with sexual activities and medications. But despite all of these advantages; it doesn't always succeed[4]. Analyses of DHS data indicated that 38% of women with an unmet need for modern contraception have used a modern method of contraception in the past but have chosen to discontinue use. This phenomenon, *called contraceptive discontinuation,* is defined as starting contraceptive use and then stopping for any reason while still at risk of an unintended pregnancy[5]. Unintended pregnancy is common worldwide: Eighty-five million pregnancies, representing 40 % of all pregnancies, were unintended in 2012[6]. In 2016, according to DHS there were 952, 000

unintended pregnancies in Egypt[3]. A sizable share (30%) of unintended pregnancies in developing countries is due to contraceptive failure[7]. Unintended pregnancies can have many undesirable physical, emotional and social consequences for individuals. In 2012, 38% of all unintended pregnancies worldwide ended in an unplanned birth, 13% in miscarriage, and 50% in unsafe abortion (which is the third major cause of maternal mortality worldwide)[7]. The majority of cases of contraceptive discontinuation are not due to the desire to get pregnant[9]. Causes include both method-related failures (i.e., failure of a method to work as expected leading to accidental pregnancy) and user-related failures (i.e., failure stemming from incorrect of use or dissatisfaction with the method including side-effects and health concerns or no further need (i.e. menopause) or method-switching[1]. In study held within 14 countries, the median probability of discontinuing an IUD (within 12 months of use) ranged from 9.6 % to 37.3%[1]. In Egypt the discontinuation rate of IUD (within 12 months of use) was 14.3% in 2014[10]. There is evidence suggesting that the quality of services influences contraception discontinuation rates. IUD use was positively associated with the quality of public family planning services in Egypt, which stresses the need to improve service quality, particularly counselling, so that women are

forewarned about side effects and reassured about health concerns[11]. In this study we compared between discontinuation rate among Copper IUD users in university clinic and primary healthcare clinic with detailed rates of each possible cause.

AIM OF THE WORK

The Research Hypothesis: (Null hypothesis): In women using copper IUD, discontinuation rate in primary health care unit and university clinic may be similar.

The Research Question: In women using copper IUD, Does discontinuation rate in primary health care unit and university clinic differ?

PATIENTS AND METHODS

Study design: prospective analytical observational study. **Study setting:** This study was conducted at Family planning Outpatient clinic of Ain Shams Maternity Hospital and El-Zahraa primary health care unit for a year. **Study population:** This study included 260 women whom attending family planning clinic for Cu-IUD insertion.Finally only 100 subjects was enrolled from each clinic. Participants *included* in the study had the following criteria: 1. Age from 18-49 years, 2. Women planning for Cu-IUD insertion as a contraceptive method. The following patients were *Excluded* from the study: Any woman with condition included in Category 3 or 4 for Cu-IUD in medical eligibility criteria for contraceptive use (MEC) [18] **Aim of the Study:** The aim of this research was to compare between primary health care unit and university family planning clinic in discontinuation rate among copper IUD users. **Sample size justification:** Sample size was calculated using PASS 11 (Sample size computer program). After review of literature, no previous similar study was done before, so assume a discontinuation rate of 50% among Cu-IUD users in primary healthcare unit and 25% among Cu-IUD users in university clinic. Based on these values; the study will included 170 Cu-IUD users; equally selected as 85 subjects from each clinic. But due to the expected drop outs, recruitment was started by 200 women from each clinic. **The study was approved by the Ethics Board of Ain Shams University and an informed written consent was taken from each participant in the study.**

Intervention: All patients were subjected to: After approval of the ethical committee and authorities in Ain Shams University Maternity Hospital and El-Zahraa primary health care unit, an oral informed consent was taken from all participants in the study after explaining the details and the aim of the study to them, all patients were subjected to history taking (including menstrual, contraceptive, and obstetric history), follow up visits/questionnaire were conducted for each subject at 6months and 12months after Cu-IUD insertion and User satisfaction score was included in the questionnaire. **The following data were recorded for every patient (in case record form *Appendix 1*):** Case number, maternal age, parity, type of previous contraception use, place of IUD insertion, hemoglobin serum level, follow up after 6 months of use, follow up after 12 months of use, reason of discontinuation, satisfaction score (*in satisfaction Questionnaire Appendix 2*)
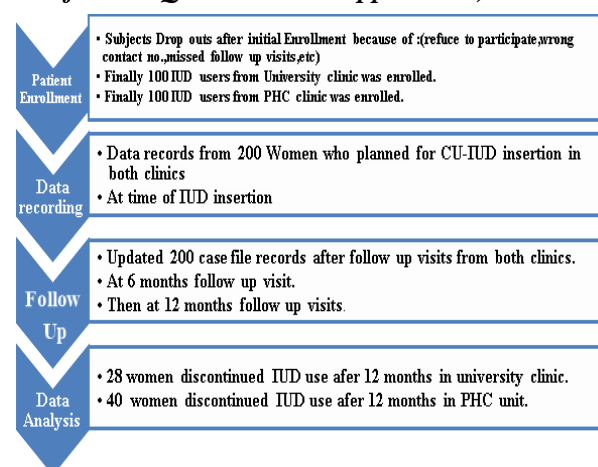

Figure (1): Flow chart of the progress through the phases of the study which are (Enrolment, data recording, follow up and data analysis).

Statistical analysis: Data were analyzed using: 1. IBM© SPSS© Statistics version 23 (IBM© Corp., Armonk, NY), 2. MedCalc© version 18.2.1 (MedCalc© Software bvba, Ostend, Belgium). Numerical variables were presented as mean and SD and inter-group differences were compared using the unpaired t test. Nominal variables were presented as number and percentage and differences were compared using the Pearson chi-squared test or Fisher's exact test. Ordinal data were compared using the chi-squared test for trend. Time to event analysis was done using the Kaplan-Meier method. Two-sided p-values <0.05 were considered statistically significant.

RESULTS

The current prospective analytical observational study was conducted at family planning outpatient clinic of Ain Shams Maternity Hospital and El-Zahraa primary health care unit for one year. Two hundred -sixty women were approached. A total of 100 women were enrolled from each clinic. The rest were lost for follow up either after 6 months or 12 months. Some others refused to participate or gave a wrong personal contact.

Table (1): Demographic characteristics in both study groups

| Variable | Health care facility | | | | |
	University clinic (n=100)	Primary health care unit (n=100)	Difference	95% CI	P-value*
Age (years)	31 ± 7	30 ± 6	-0.86	-2.68 to 0.96	0.352

Data are mean ± SD; 95% CI = 95% confidence interval; *Unpaired t test.

Table (2): Past obstetric and contraception history in both study groups

| Variable | | Health care facility | | | | χ² (df) | p-value |
| | | University clinic (n=100) | | Primary health care unit (n=100) | | | |
		n	%	n	%		
Parity	P1	20	20.0%	22	22.0%	2.583 (1)	0.108*
	P2	41	41.0%	31	31.0%		
	P3	36	36.0%	29	29.0%		
	P4 or more	3	3.0%	18	18.0%		
Previous contraception	Nil	22	22.0%	21	21.0%	-	<0.001#
	IUD	39	39.0%	47	47.0%		
	OCP	6	6.0%	20	20.0%		
	Injection	16	16.0%	12	12.0%		
	Implant	1	1.0%	0	0.0%		
	IUD & OCP	5	5.0%	0	0.0%		
	IUD & Injection	10	10.0%	0	0.0%		
	OCP & Injection	1	1.0%	0	0.0%		

Data are number (n) and percentage (%); χ² = chi-squared statistic, df = degree of freedom; *Chi-squared test for trend; #Fisher's exact test.
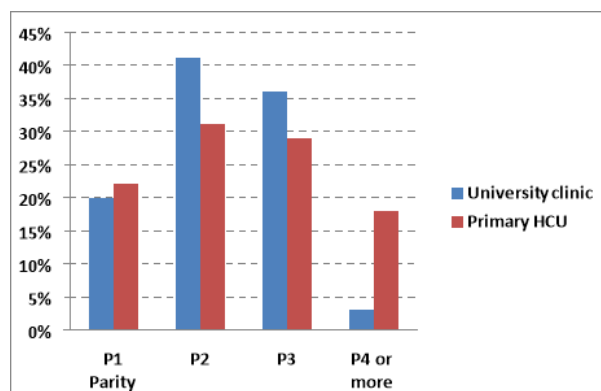

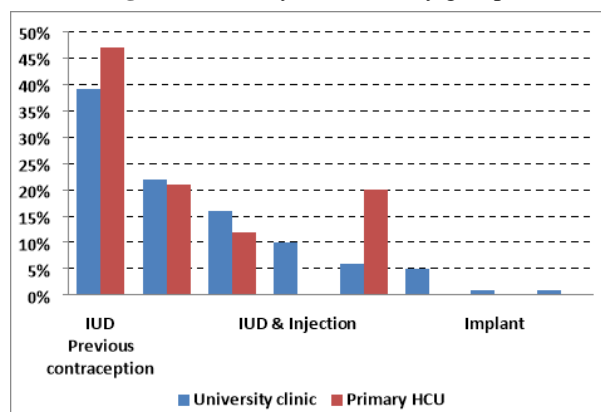**Figure (2):** Parity in both study groups.

Figure (3): History of previous contraceptive usage in both study groups.

There was no significant difference between the two groups as regards age or parity; however there were slight differences in both groups as regards previous contraceptive experiences as shown below.

Table (3): IUCD discontinuation rate in both study groups

| Variable | | Health care facility | | | | χ² (df) | p-value* |
| | | University clinic (n=100) | | Primary health care unit (n=100) | | | |
		n	%	n	%		
6-month visit	Discontinued	5	5.0%	7	7.0%	0.355 (1)	0.552
	Retained	95	95.0%	93	93.0%		
12-month visit	Discontinued	28	28.0%	40	40.0%	3.209 (1)	0.073
	Retained	72	72.0%	60	60.0%		

Data are number (n) and percentage (%); χ² = chi-squared statistic, df = degree of freedom; *Pearson chi-squared test.
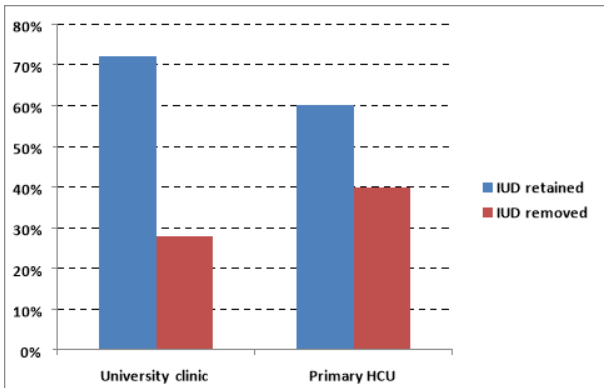
Figure (4): Rate of IUD removal in both study groups.

On follow up at 6months, IUCD discontinuation was 5% in the university clinic & 7% in the primary health care (PHC) unit. While at 12months follow up, discontinuation was 28% in the university clinic & 40% in the PHC unit. Despite the difference, this was not statistically significant difference.

Table (4): Rate and reason of IUD removal in both study groups

Variable		University clinic		Primary health care unit		χ^2 (df)	p-value
		Health care facility					
		n	%	n	%		
Removal of IUD	-	72	72.0%	60	60.0%	3.209 (1)	0.073
	+	28	28.0%	40	40.0%		
Reason for IUD removal	Infection	1	3.6%	12	30.0%	-	**0.024**
	Bleeding	18	64.3%	13	32.5%		
	Seeking pregnancy	3	10.7%	5	12.5%		
	Perforation	1	3.6%	0	0.0%		
	Pain	3	10.7%	5	12.5%		
	Expulsion	2	7.1%	3	7.5%		
	Failed contraception	0	0.0%	2	5.0%		

Data are number (n) and percentage (%); χ^2 = chi-squared statistic, df = degree of freedom; *Chi-squared test for trend; #Fisher's exact test.

As regards reasons for removal of the IUCD, there was no statistically significant difference between the two study groups; with the (bleeding) as the most common cause. But the second common cause was different, being (infections) in the PHC unit and (pain) in the university clinic group.
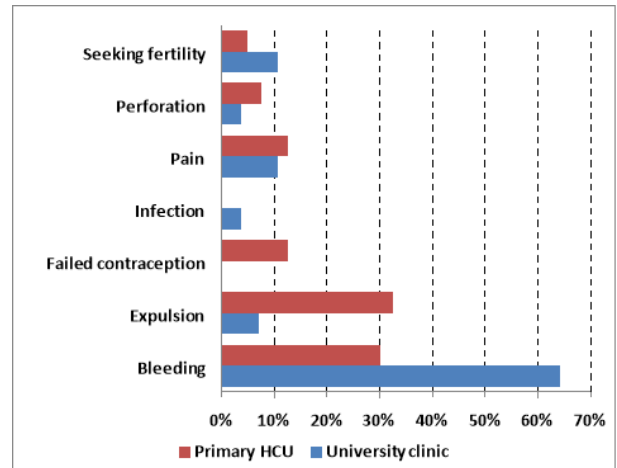

Figure (5): Reason of IUD removal in both study groups.

Table (5): Time to removal of IUD and hemoglobin level in patients with excessive bleeding in both study groups

Variable	University clinic		Primary health care unit		Difference	95% CI	P-value*
	n	Mean ± SD	n	Mean ± SD			
Time to removal of IUD (days)	28	234 ± 91	40	244± 100	10.1	-37.2 to 57.4	0.671
Hemoglobin level (g/dl)	20	8.6 ± 0.7	23	9.3 ± 1.3	0.7	-0.009 to 1.4	0.053

Data are mean ± SD; n = number, 95% CI = 95% confidence interval; *Unpaired t test.
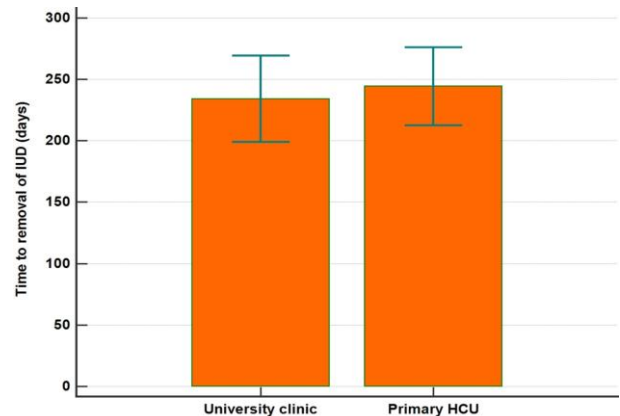

Figure (6): Mean time to removal of IUD in both study groups. Error bars represent the 95% confidence interval (95% CI).
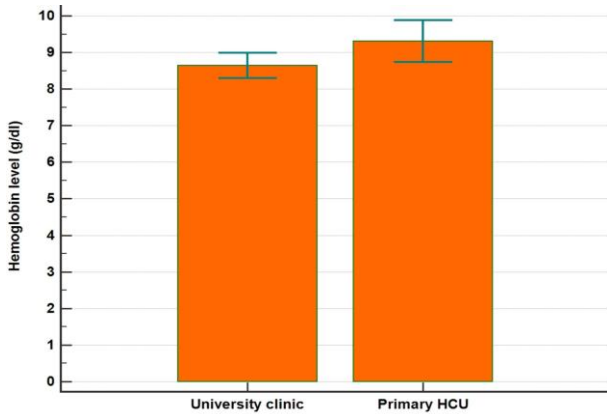
Figure (7): Mean hemoglobin level in both study groups. Error bars represent the 95% confidence interval (95% CI).

As regards satisfaction score, both groups showed similar satisfaction scores (mean: 7 & 8 in university clinic & PHC unit respectively.

Table (6): Patient satisfaction score in both study groups

Variable	University clinic (n=100)	Primary health care unit (n=100)	Difference	95% CI	P-value*
Satisfaction score	7 ± 3	8 ± 3	0.29	-0.6 to 1.1	0.502

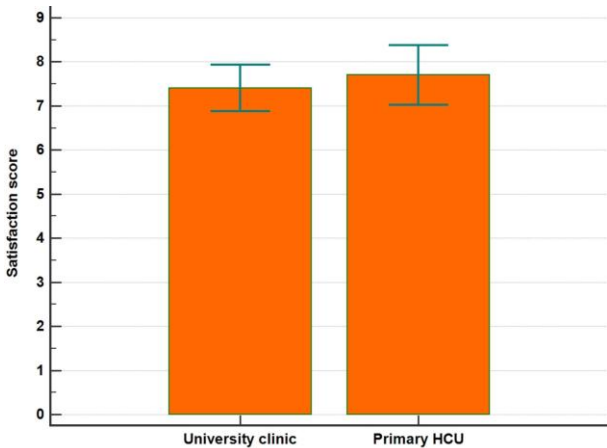Data are mean ± SD; 95% CI = 95% confidence interval; *Unpaired t test.

Figure (8): Mean satisfaction score in both study groups. Error bars represent the 95% confidence interval (95% CI).

Table (7): Incidence of adverse outcomes in both study groups

Variable	Health care facility				χ^2 (df)	p-value
	University clinic		Primary health care unit			
	n	%	n	%		
Bleeding -	82	82.0%	87	87.0%	0.954 (1)	0.329*
+	18	18.0%	13	13.0%		
Infection -	99	99.0%	88	88.0%	9.955 (1)	**0.002***
+	1	1.0%	12	12.0%		
Pain -	97	97.0%	95	95.0%	-	0.721#
+	3	3.0%	5	5.0%		
Failed contraception -	100	100.0%	98	98.0%	-	0.497#
+	0	0.0%	2	2.0%		
Spontaneous expulsion -	98	98.0%	97	97.0%	-	1.000#
+	2	2.0%	3	3.0%		
Perforation -	99	99.0%	100	100.0%	-	1.000#
+	1	1.0%	0	0.0%		

Data are number (n) and percentage (%); χ^2 = chi-squared statistic, df = degree of freedom; *Pearson chi-squared test; #Fisher's exact test.
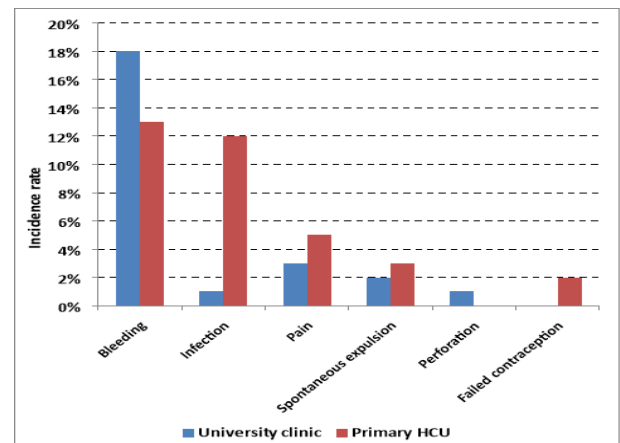

Figure (9): Incidence of adverse outcomes in both study groups.
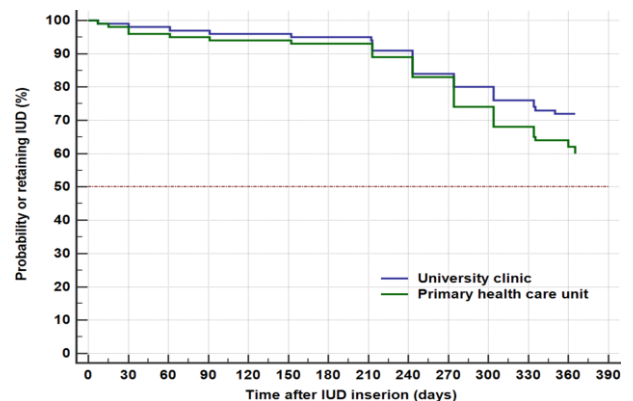

Figure (10): Kaplan-Meier curves for time to IUD removal in both study groups.

There is no statistically significant difference between both groups (log-rank test χ^2 (df) = 2.792 (1), p-value = 0.095, hazard ratio = 1.49, 95% CI = 0.93 to 2.40.

DISCUSSION

Intrauterine device IUCD is one of the most widely used contraceptive method. Globally it's used by 15% of women aged 15–49 years [7]. In Egypt, the percentage of women using IUD according to Demographic and Health Surveys (DHS) 2014 is 52.9 % [3]. Although being one of the safest and the most effective long-acting reversible contraceptive methods, its complications such as bleeding and pain may lead to early removal of IUD by some users [12]. Evidence about contraception - including IUDs- indicates that success in avoiding unwanted pregnancy depends less on initial contraceptive uptake and more on effective and persistent use [13]. There is evidence suggesting that the quality of services influences contraception discontinuation rates. IUD use was positively associated with the quality of public family planning services in Egypt, which stresses the need to improve service quality, particularly counselling, so that women are forewarned about side effects and reassured about health concerns [11]. In our study we hypothesized that among women using copper IUD, discontinuation rate in primary health care unit and university clinic may be similar. As regards our primary outcome (discontinuation rate in both study groups); there was a slight difference in discontinuation rates among the two study groups. However; this difference was found to be statistically insignificant (28% in university clinic and 40% in PHC unit; p value 0.073). Also, there was no statistically significant difference between satisfaction scores in both groups (7 ± 3 out of 12 in university clinic and 8 ± 3 out of 12 in PHC unit; p value 0.502). Data processing showed that the most common cause of IUD discontinuation was bleeding which represented 64.3% in university clinic and 32.5% in PHC unit. While the second important cause of IUD removal was different between both groups. In the PHC unit it was infection (30.0%) but in university clinic pain was the second common cause (10.7%). Anemia was present in 66.6% of patients complaining from bleeding. Although previous studies didn't specify exactly a clear comparison between IUCD discontinuation in university clinic and PHC units; our data are still

comparable to other studies looking at IUCD discontinuation rates in general. These results agree with **Peipert**[14] who carried a prospective cohort study at the Division of Clinical Research, Department of Obstetrics and Gynecology, Washington University in St. Louis School of Medicine, St. Louis, Missouri. From women of the St. Louis region, 5, 087 participants were enrolled to be offered contraception at no cost for 3 years. They analyzed 12-month data from each participant. The primary purpose was to promote the use of long-acting reversible contraception (IUDs and implants) and to reduce unintended pregnancies. This analysis included those participants who received their baseline contraceptive method within 3 months of enrollment and who reached the 12-month follow-up telephone survey time point (n=4, 167). Sixty-eight percent of the participants chose a long-acting reversible contraception method. Long-acting reversible contraception users had high 12-month continuation rates (86%).The copper IUD had one of the highest 12-month continuation rates (84%). Satisfaction mirrored continuation: more than 80% of users were satisfied with the IUD. IUDs have the highest rates of satisfaction and 12-month continuation. Given that long-acting reversible contraception methods have the highest contraceptive efficacy, these methods should be the first-line contraceptive methods offered to patients. These Results agree with those of **Robabi**[15] who carried out a cross-sectional descriptive-analytical study was conducted on 260 married women in the age range of 15-49 years who referred to discontinue their use of IUD or DMPA in Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, Iran. The data were collected through interviews and using the subjects' medical records: to determine the start date of using IUD or Injectable DMPA, the subjects' medical records were examined; then, using a form containing demographic information (i.e. age, educational level, occupation, marriage age, number of pregnancies and the number of children) and questions about the duration of contraceptive use and reasons for its discontinuation, the required data were collected. The study aimed at analyzing the continuation rates of IUD and three-month injectable DMPA use and reasons for their discontinuation in women referred to health centers. The continuation rate of IUD use in the first six months was %83 and it was %76.2 at the end of the year. The results also indicated that

the most common reasons for IUD discontinuation were side effects (%51.7).The most common complication of IUD use in this study was bleeding (%36.76). The second important complication of IUD use was infection (%26.47). Our Results also agree with those of **Rezaie**[16] who carried out a descriptive analytical study where 5 centers were selected among the health centers of Sanandaj using cluster sapling method. A researcher-made questionnaire was used to collect the data related to the women who discontinued using intrauterine contraceptives device during one year. Data were analyzed by chi-square test using SPSS-PC. The findings revealed that 166 women had removed their IUDs during the study. The most common reason for discontinuation of IUD was the complications (59.04%) of the device and other reasons were desire for pregnancy, concern about its complications, spontaneous expulsion, invisibility of the thread, expired date of use, pregnancy, menopause, husband death, divorce and vasectomy. The most common complications were bleeding (38.77%), infection (28.57%). This results disagree with **Charles;s** [8] who carried out a study through a 3 year retrospective descriptive study of all clients requesting for the removal of intrauterine devices (IUCDs) at the Family Planning clinic Jos University Teaching Hospital, Jos Nigeria. The study aimed to determine the discontinuation rate and factors responsible among IUCD users in the hospital. A total of 849 clients were seen during the study period; 393 (46.3%) clients discontinued within 3 years with the highest rate at 1 year 24.2%. The most common reasons for discontinuation were the desire for pregnancy (50.9%), excessive menstrual bleeding (10.4%), vaginal discharge PID (9.0%). According to our study results, the rate of discontinuation in the first year was higher as compared with that found by **Tadele**[17] where the rate of discontinuation in the first year was only 20 %. It is a review which was conducted through a systematic literature search of articles published between 1997 and 2017, Then 22 studies were retained for final analysis enrolled a total of 19, 805 Married or in union women.

CONCLUSION

In our Study, analysis of data revealed that there were no statistically significant difference between discontinuation rate among Copper IUD users in university clinic and primary healthcare clinic. Age, parity and previous usage of IUD may affect discontinuation rate after 12 months of IUD use. The mean cause of IUD discontinuation was bleeding and Anemia is present in 66.6% of patients complaining from bleeding.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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