Comparing the satisfaction and efficacy of Cyclofem and contraceptive pills among females in Northern Iran: A randomized controlled trial study

Bita Jamali, Azade Kiapoor, Mozhgan Firoozbakht, Fatemeh Kazeminavaei, Fatemeh Taghlili

Department of Midwifery, Babol Branch, Islamic Azad University, Babol, Iran

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ABSTRACT

Hormonal contraceptives are the most effective method for birth control, though they may have some default or complications. This research aimed to comparison of the efficacy and satisfaction of Cyclofem with oral contraceptives (OCs) among females. A descriptive-comparative method was conducted on 80 women who were selected through cluster sampling during November 2011-December 2012. The selected subjects start using OCs or Cyclofem for the 1st time in their life. They evaluated in 2 times frames, at the beginning of the study and then 3 and 6 months after the contraceptive precautions. The data were collected by questionnaire. The data were analysed using parametric and nonparametric test in SPSS 16 software. The reasons for discontinuation of the methods were varied, in which 50% of the sample group were Cyclofem users who discontinued because of menstrual changes and the desire to use other methods, and 50% were the OC users whose reason was medical problems, and absent-mindedness was the last reason for 35.7% of the cases. The efficacy of the both (OCs and Cyclofem) was high and only one unwanted pregnancy occurred at the end of the 6th month among OC users. There was no significant difference in term of satisfaction of two groups at the end of 3-6 months (PV = 0.433). The results indicated that Cyclofem can be well used by those women who desire for an easy and effective method which is not disturbing the sexual activity and does not also need to be used daily, but the users should be consulted before using the method.

Key words: Combined oral contraceptive pills, Cyclofem, efficacy, satisfaction

INTRODUCTION

Over the last two decades, Iran has achieved significant success in terms of birth control,^[1] though in the meantime, it has faced many failures as such many reports reveal about one-third of unwanted pregnancies in Tehran, the

Address for correspondence:

Dr. Mozhgan Firoozbakht, Department of Midwifery, Babol Branch, Islamic Azad University, Babol, Iran. E-mail: didehdar@gmail.com

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capital of Iran.^[2] The unwanted pregnancy is one of the most important social health problems related to birth control plans which may result in serious mental and physical problem for mother and kid, and for all the family members as well.^[3]

The hormonal contraceptive methods are the most effective ways in birth control, though despite of their efficacy and usefulness they may have some defaults such as headache, depression, anxiety etc., and the users may complain normally.^[4] Using oral contraceptive (OC) pills is the most effective method which is taken by 100 million women in worldwide. Although the number of women who are using this method is great, yet the discontinuation of this method is also significant because of two main reasons, the side effects, that is, weight gain, headache, depression etc., and the need for daily use.^[5] The validity of this method is 99.9% if it will be used correctly,^[6] but many people reported problem regarding daily use of OC, Consequently 5% of the women, for the low acceptability of this method, are about to become

pregnant unwontedly and the lack of high acceptability of this method is due to its daily use. $\ensuremath{^{[7]}}$

Immunity, easy to use and efficacy are the main factors to decide for using hormonal contraceptives, Hence, spreading contraceptive methods which have been accepted by the clients well and which have had useful effects without having any relation to coitus or disturbing the daily users, are the strongest stimuli for decreasing unwanted pregnancy.^[8] Meanwhile Cyclofem is one of the methods designed for this purpose.^[9]

Cyclofem is a combination of 25 mg of medroxyprostrogen acetate and 5 mg of estradiol cypionate which has been widely studied outside of the US by the World Health Organization (WHO)[10] and was confirmed by Food and Drug Administration in October 2000.^[6] This method is safe and tolerated well^[11] with low rate of unwanted pregnancy. The continuation rate is high and has rapid return of fertility after discontinuation which is comparable with other contraceptive methods.^[12] In addition, since Cyclofem is using monthly, it doesn't result in the inconvenience and discomfort of females and its efficacy and side effects is relatively similar with OC, medroxy progesterone acetate and norplant.^[6] The cumulative pregnancy rate in the 1st year of using is, 0.2%.^[6] As well, in worldwide studies Cyclofem has been accepted by females and their satisfaction was as high as OC users.^[7] In a study about Cyclofem acceptance which was done by Yazdanpanah, only 12.6% of the females had choice Cyclofem. The reasons for rejection were the side effects, injection fears, referral problems and their last contraceptive method satisfaction.^[13]

Since improving the acceptability of a method requires the users' satisfaction and the efficacy of the method, and satisfaction of users from the contraceptives influence their applicability and the amount of usage.^[14] Conversely, such a comparative study has not been done in our country, a thorough study needed to be conducted to comparison of the efficacy and satisfaction of Cyclofem and contraceptive pills. Surely being aware of these important facts is a valuable finding which can be useful in solving some of the problems related to contraceptive methods and helps to plan some educational programs and appropriate interventions. Clarifying the effective methods with fewer side effects will result the continuation of the usage, efficacy feeling, and also being at ease. Therefore we aimed to evaluate and compare the satisfaction and efficacy of Cyclofem and contraceptive pills among user females of Northern Iran.

MATERIALS AND METHODS

This study is a descriptive and comparative one. The subjects were those women who came to the health center for the 1st time to take OC pills or Cyclofem.

Sampling

To determine the sample size, the Pocock formula^[15] was used. 80 females selected and randomized in two groups (N = 40 each group). The subjects selected through two-stage cluster sampling method so among the Health Care Centers in Babol six Centers were chosen by random. Then among the referrals, after the required explanation about the research, the subjects were chosen through an introductory interview and also based on their own will (by filling out a consent form) to participate in the study. Gathering subjects and follow up steps lasted from November 2011 to January 2012. The exclusion criteria were the subjects with any forms of contraindications to OC, for instance; those women with chronic blood pressure > 160.90, diabetes, chronic headaches, and obesity. The research units accepted to use their contraceptive method in 26 weeks (6 months).

Tool

The data was completed by expert interviewers. The data-gathering tools were included two-part questionnaires in which the first part included demographic data, menstrual changes, side effects, desire to continue, reasons for discontinuation, recording of the weight and blood pressure; and the second part of the questionnaire (the satisfaction part) contained eight questions which were planned to ask the users' ideas and to analyze based on likert scale. Consulting the lecturer staff members of the universities and also the clear-sighted authorities, the validity of the tools was estimated and the reliability came to be seven based on Cronbache's alpha coefficient.

In each month of the study period, the research units had daily note taking cards about menstrual patterns in which they recorded the patterns based on the following definition: Nothing = no spotting or bleeding; spotting = requiring light pads, not sanitary protection; bleeding = requiring sanitary protection.

The efficacy of the method was evaluated based on the number of pregnancies occurred within 6 months of the study (Gathering samples, intervention and follow ups take around one half year). The additional evaluated results were: menstrual bleeding patterns, the willingness to continue to use the method and the immunity (based on side effects such as: Spotting, breast tenderness, headaches, amenorrhea, dysmenorrhea, acne, etc). The subjects were evaluated at the beginning of the study, then at the end of the 3rd month and 6 months after using the OC or injection, or they were evaluated as long as they quitted from the study for any reasons. The subjects' weight and blood pressure were measured at their first visit and then at the end of the third and the 6 months.

Analysis

The data was analyzed by using parametric test like *t*-test and variance analysis by repetitive measurement

and nonparametric tests like Chi-square, Man-Whitney, Friedman and Cochran in SPSS 16 (Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc) software.

RESULTS

The individual characteristics of the users of the OC and Cyclofem presented in presented Table 1. There was no significant difference in the two groups in case of age (PV = 0.216), number of pregnancies (PV = 0.192), abortions (PV = 0.536), alive birth (PV = 0.275) and their previous contraceptive method (PV = 0.170), but they were different in education (PV = 0.038), partner's education (PV = 0.001), and occupation (PV = 0.039). The Cyclofem users' education and their partners' were higher. The rate of questionnaire completion in the third and sixth visits in OC and Cyclofem users were 98.8% and 94.4% respectively which shows the total desire to continue the methods in both groups. The Chi-square test results indicated that at the end of the 3rd month the subjects who were interested in continuing the use of OC (n = 32; 82.1%) were more than the subjects who used Cyclofem (n = 27; %60); that is significantly difference (P = 0.001). At the end of the 6th month the desire to continue the OC and Cyclofem in the two groups were 79.45% (*n* = 27) and 82.5% (*n* = 33) respectively in which there was no significant difference (P = 0.138).

The main reasons for discontinuation stated by the users were related to the methods (such as menstrual changes, absent-mindedness, or medical problems), in which 50% (n = 6) of the Cyclofem users discontinued the method because of menstrual changes and the desire to use another method, but the OC users' reasons for discontinuation were more medical problems such as headaches, nervousness (n = 4, 50%) and absent-mindedness (n = 3; 35.7%). There was no significant difference between the two groups in unwanted pregnancies (PV = 0.218) and only one case of the unwanted pregnancy occurred at the end of the 6th month among OC users.

The side effects in OC and Cyclofem users at the end of the 3rd month were 69.2% (n = 27) and 82.5% (n = 33) respectively (PV = 0.168), and at the end of the 6th month 52.9% of the OC users (n = 18) and 52.5% of the Cyclofem users (n = 21) happened to have the side effects which the difference was not significant (PV = 0.97). The most usual side effects in OC and Cyclofem users at end of the 3rd months were respectively: 23.2% nervousness (n = 13); and 22.8% breast tenderness (n = 18); and at the end of the 6th months were 25% nervousness (n = 10), and 29.7% over weight (n = 11) [Table 2].

Also, there wasn't any relationship between the side effects and the discontinuation of the methods based on Chi-square test (PV = 0.289).

The data related to menstrual bleeding patterns, abdominal and pelvic pain in experimental group is shown in Table 3.

Based on Mann-Whitney test, the amount of menstrual bleeding in both groups was the same after 6 months and was informed average for both groups at the end of the 6^{th} month, and no difference was observed (PV = 0.105).

Also, the menstrual duration was the same in both groups so as most subjects - 82.5% (n = 33) in Cyclofem group and 77.5% (n = 31) in OC group - had a >5 days menstrual

Table 1: Characteristics of OC and Cyclofem users

Variables	OC	Cyclofem	P
	n (%)	n (%)	•
Age	$25.47 {\pm} 5.6$	26.9±4.5	0.216
Occupation			
House keeper	36 (90)	22 (62.1)	0.003
Employee/office worker	4 (10)	10 (28.6)	
Education			
University	6 (15)	16 (40)	0.038
High school	23 (57.5)	18 (45)	
Junior high school	8 (20)	6 (15)	
Husbands' education			
University	7 (17.5)	19 (47.5)	0.001
High school	15 (37.5)	17 (42.5)	
Junior high school	13 (32.5)	4 (10)	
Elementary school	5 (12.5)	0	
Number of pregnancies			
1-2	30 (78.9)	35 (89.7)	0.192
3-4	8 (21.1)	4 (10.3)	
Previous contraceptive method			
OC	4 (10)	5 (12.5)	0.170
Condom	8 (20)	12 (30)	
IUD	1 (2.5)	4 (10)	
DMPA	3 (7.5)	5 (12.5)	
Natural	14 (35)	11 (27.5)	
Nothing	5 (12.5)	3 (7.5)	

OC: Oral contraceptive, IUD: Intrauterine device, DMPA: Depot medroxyprogesterone acetate

Side effects	Third month (%)		Sixth month (%)		
	OC (n=18)	Cyclofem (n=32)	OC (n=12)	Cyclofem (n=20)	
Spotting	5 (8.9)	12 (15.2)	0	4 (10.8)	
Breast tenderness	6 (10.7)	18 (22.8)	2 (5)	4 (10.8)	
Acne	0	5 (6.3)	0	2 (5.4)	
Headache	11 (19.6)	14 (17.7)	9 (22.5)	6 (16.2)	
Nausea	6 (10.7)	0	2 (5)	0	
Weight gain	5 (8.9)	10 (12.7)	6 (15)	11 (29.7)	
Decrease libido	5 (8.9)	0	6 (15)	0	
Anxiety	13 (23.2)	11 (13.9)	10 (25)	5 (13.5)	
P _v	0.168		0.97		

OC: Oral contraceptive

	Base	(%)	3 rd month (%)		6 th month (%)		P
	Cyclofem (n=40)	OC (n=40)	Cyclofem (n=39)	OC (n=40)	Cyclofem (n=38)	OC (n=33)	·
Duration of menstruation							
1-4 days	7 (17.5)	9 (22.5)	9 (23)	9 (22.5)	8 (21.1)	9 (27.3)	0697
>5 days	33 (82.5)	31 (77.5)	30 (77)	31 (77.5)	30 (78.9)	24 (72.7)	
Amount of bleeding							
Low	3 (7.5)	3 (7.5)	5 (12.8)	4 (10)	3 (8)	2 (6.1)	0.105
Medium	34 (85.5)	34 (85.5)	31 (76.9)	31 (77.5)	35 (92)	27 (81.8)	
Severe	3 (7.5)	3 (7.5)	3 (10.3)	5 (12.5)	0	4 (12.1)	
Menstrual bleeding (spotting)							
Yes	1 (2.5)	0	12 (31.5)	5 (14.5)	4 (11.7)	0	0.55
No	39 (97.5)	40 (100)	27 (69.5)	35 (85.5)	34 (88.3)	34 (100)	
Abdominal or pelvic pain							
Yes	13 (33.3)	15 (37.5)	8 (20.5)	10 (32.3)	7 (17.9)	10 (32.3)	0.031
No	27 (66.7)	25 (63.5)	31 (79.5)	21 (68.7)	32 (82.1)	21	

Table 3: Menstrual bleeding patterns,	abdominal a	and pelvic	pain
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OC: Oral contraceptive

duration at the beginning of the study, and there was no change in the duration after 6 months and was still >5 (72.7%; n = 24 in OC group and 78.9%; n = 30 in Cyclofem group).

The amount of spotting in both groups were 14.7% (n = 5) and 31.5% (n = 12) at the end of the 3rd month respectively and at end of the 6th month decreased to 0% and 11.7% (n = 4). It means spotting in Cyclofem users was more than OC users (PV = 0.37) at the end of the 3rd month and in the continuation of using, the amount of spotting turned to be equal in both groups (PV = 0.55).

In OC users, the observed amenorrhea after 6 months did not appear to be significant; that is, amenorrhea occurred in 6% of the subjects during the whole run of the study. Also, only one woman complained about amenorrhea at the end of the 6th month in Cyclofem users and there was not any significant difference between the two groups (P = 0.462).

At the beginning of the study, 37.3% (n = 15) OC users and 33.3% (n = 13) Cyclofem users had dysmenorrhea and in the continuation of using, at the end of the 3rd month, dysmenorrhea was reported 32.2% (n = 10) and 20.5% (n = 8) in the two groups respectively, and at the end of the 6th month it turned to be 32.2% (n = 10) and 17.9% (n = 7) in OC and Cyclofem users. It means occurring dysmenorrhea within each group was different in 3 months (PV = 0.012, PV = 0.007), but this difference was not significant between the two groups in the similar period (PV = 0. 18, PV = 0.354, PV = 0.225).

The rate of the subjects' satisfaction in both groups at the end of the 3^{rd} month (PV = 0.983) and the sixth (PV = 0.743) was the same and there was no significant difference.

The subjects' weight and blood pressure were measured both at the beginning of the study and then, at the end of the third and the 6th months. The average weight and blood pressure of the women in each group was evaluated separately by using ANOVA and repetitive measurement. The Keroit theory evaluated by Mokhli test was confirmed (PV = 0.23). There weren't any differences between the blood pressure and the weight of the subjects in both group comparing the beginning and the end of the third and the 6^{th} month (PV = 0.1 and PV = 0.478). The blood pressure of the Cyclofem users did not change at the end of the 6^{th} month (PV = 0.844), but there was a significant difference between the weight of the Cyclofem users in three runs (PV = 0.037); that is, the average weight of the Cyclofem users at the end of the 6th month was more than the beginning of the study. Based on the independent t-test, there was no significant difference between the weight and the blood pressure in both groups of OC and Cyclofem users during the study.

CONCLUSION

In this study confirmed that both contraceptive methods were very effective ones which indicated a high efficacy so that after 6 months of using the methods, only one unwanted pregnancy occurred in the subjects who used OC pills. While, other studies have shown that unwanted pregnancy didn't occur during the research.^[9,12,13,16]

Therefore, the failure rate of Cyclofem users in this research is ideally comparable with other reports related to researches done in various countries for the women who participated in clinical trial held by WHO^[16] and the efficacy of Cyclofem based on WHO's international studies and other wide-spread research was 99.9%.^[11] It is note worthy to mention that Cyclofem users and their husbands were

more educated than the OC users because the continuation or discontinuation of a method is affected by different factors such as knowledge, necessities, expectations, and mutual understandings of the participants.^[17] Women's satisfaction in both groups was similar at the end of the 6th month. Often, the efficacy is influenced by the effects of the methods on subjects' health. Relevant studies have also shown that Cyclofem and OC users' satisfaction was also the same which shows that the subjects who want to use daily OC pills, are interested in injecting monthly contraceptive Ampulla, too; and the similar level of satisfaction in both groups may be due to the safety and the low side effects of the two methods.[11] The hormonal methods satisfaction is influenced by different factors such as knowledge, life styles, religion, side effects, mutual understanding, anxiety, and apprehension; therefore, it affects the person's idea on the method and its continuation or discontinuation.^[17]

In this study, at the beginning of using contraceptives, spotting was more in Cyclofem users than in other group and finally at the end of the 6th month it declined and was the same in both groups. In a study conducted in Kenya, spotting in Cyclofem users was more, but taking all things into account, it was little (the maximum rate was 6.8% after 6 months injecting), and none of the depot medroxyprogesterone acetate (DMPA) or Cyclofem users reported spotting after 12 months.^[18]

In another study conducted on Cyclofem in Iran, also reveals that the abnormal menstrual cycle of most women (90%) turns to become normal after 6 months.^[13] The main reasons for discontinuation of both options were method related (such as; menstrual cycle changes, absent-mindedness, medical problems, etc). Also, studies in other countries have shown that, menstrual cycle changes were one of the main reasons for discontinuation.^[13,16,18-20] The immune histochemical studies on Iranian women have been shown that those who used Cyclofem or DMPA for 3-6 months, the density of endometrial vessel decreases and become atrophic which by itself causes the menstrual disorders (Simbar et al., 2007). These findings about menstrual changes indicate the importance of appropriate consulting before monthly injection or before taking contraceptive pills and also pursuing the process after beginning the methods,^[16] which in fact, the organized consulting decrease the discontinuation of the methods significantly (Ruminjo et al., 2005). In another study in US, also, most subjects discontinued their contraceptive methods because of nonmedical reasons of which the most common one was unwilling to go to the health center for next visits.^[16] It has been proved some women may find the monthly injection in health center annoying for some reasons such as transportation costs, confusion in going to school or work-place, and baby keeping. It is possible to enhance the subjects' satisfaction to their contraceptive methods by suitable choosing of the women and teaching them the correct self-injection and promoting the success of the methods.^[21] Consequently, it may be useful to do a comparative study between self-injection and injection by personals of health care centers in Iran.

The results of this study show the high efficacy, satisfaction and immunity of Cyclofem. Finally, this primarily done study suggests strong evidences that Cyclofem can be used by those women who desire for an easy, effective and a comfortable, but non coital and nondaily contraceptive method. Furthermore, if consulting appropriately about birth control, it can be probably a suitable choice among other choices for women.

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