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## Full Length Research Paper

# Comparison of side effects and marital satisfaction between the women taking cyclofem and depomedroxyprogesterone contraceptive ampoules

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None of the contraceptive methods is fault-free and all come with some complications. In this study we investigated the comparison of complications and marital satisfaction between the women taking cyclofem contraceptive ampoule and depo-medroxyprogesterone acetate (DMPA). This study was performed on 300 married women using cyclofem and depot medroxyprogesterone for family planning, with 150 people in each group. Data collection tools included two types of questionnaires; one for studying the complications and the other for examining the marital satisfaction (Enrich Couple Questionnaire). The results obtained indicated that increased days of menstrual bleeding in depomedroxy consumers were more than those of cyclofem consumers, and there was a significant difference (P = 0.004). Furthermore, both groups are similar in terms of weight changes, mood disorders, libido changes and all other complications and there was no significant difference. It was also found that cyclofem ampoule was used by 62% for one year, while depo-medroxy ampoule was used by 60% for one year; the continuation rate of using depo-medroxyprogesterone was more than cyclofem (P = 0.02). There was no significant relationship between marital satisfaction and age, education, number of children and job. Average marital satisfaction in women using depomedroxyprogesterone contraceptive method was 116.79± 8.62, which was significantly higher than the average marital satisfaction in women using cyclofem contraceptive method as 114.53± 7.16 (P = 0.01). Based on the results achieved in the present and similar studies, it can be concluded that the complications caused by cyclofem and depo-medroxyprogesterone ampoules are similar and they have no significant difference; and these complications are not fatal and irreversible.

Key words: Side effects, family planning, cyclofem, depo-medroxy.

#### INTRODUCTION

Although in recent years, world population (Nowels and Veillette, 2010) as well as Iran's population growth has been declining (Mohammad, 2009; UNFPA, 2008), there is still a need for family planning to reduce poverty and to enjoy more health for mother and child as well as for better training (Cleland et al., 2006). On the other hand,

recent reports indicate that the rate of unwanted pregnancies (Faghihzadeh et al., 2003) and induced abortion is high in Iran (Majlessi et al., 2008; Nojomi et al., 2006). Based on the past studies, one-third of pregnancies in large cities (Tehran) are unwanted, resulting in increased rate of illegal abortions and thus endangering maternal health (Nojomi et al., 2006).

Nowadays, there are a variety of contraceptive methods, including hormonal contraceptives such as cyclofem and depo-medroxyprogesterone. In Some countries, the use of injectable contraceptive is more than

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other family planning methods (Gizaw and Regassa, 2011). In its report in 2000, prepared based on the researches conducted in relation to reproductive issues, the World Health Organization (WHO) wrote that though depo-medroxyprogesterone acetate (DMPA) ampoules are highly effective contraceptives, although the rate of discontinuation is still remarkable due to side effects. For this reason, researchers are seeking a better alternative to this ampoule (Biennale Report, 2000). Considerable efforts have been made to reduce hormonal compounds doses in order to minimize the complications risk. Such efforts made for reducing hormonal content were based on "low as much as possible and high as much as necessary" (Endricat et al., 2001). Injection hormonal method as one of the contraception methods with high efficacy and assumed suitable because it is easy to use and has no interference with sexual intercourse (Rominjo et al., 2005).

Cyclofem ampoule is a very effective method of contraception with 1-month intervals; it contains 25 mg of medroxyprogesterone acetate and 5 mg of estradiol cypionate. DMPA is also an effective hormonal contraception; it is injected intramuscular once every 12 weeks (Stubblefield et al., 2007). They do not need to be repeated every day and their acceptability are more than pills (Adebara and Ijaiya, 2010). However, none of the contraceptive methods is fault-free and all come with some complications. Among these complications of methods menstrual hormonal are: disorders. amenorrhea, irregular uterine bleeding, weight gain, headache, decreased libido, nervousness, fatigue, mood changes, etc. (Polaneczky et al., 1996; Hagh et al., 1996; Fraser and Dennerstein, 1994; Nelson, 1996). Studies have shown that such complications occur with different rates in different communities (Nelson, 1996; Kaunitz, 1998; Davidson et al., 1997) Thus, the complaints of side effects occurrence for the clients could be reduced by careful consideration of side effects, and their satisfaction would be promoted.

Consumers of such hormonal methods also face physical, psychological and mental disorders due to unwanted complications, which sometimes affect marital satisfaction. Marital satisfaction is a condition in which married couples are happy and satisfied with each other (Mirahmadizadeh et al., 2003). Many variables are effective on how couples communicate with each other during their common life, including income, employment, children, illness and sexual satisfaction (The reasons of marital satisfaction, Culture and research.

Available at www.fpm.ir/archive/no-169/farsi:2006) Changes in physical and psychological status of these individuals may lead to unfavorable reactions and behaviors by avoiding their housekeeping obligations as well as routine duties and functions. Although marital satisfaction and factors affecting it has been the focus of attention by Iranian researchers, there are no studies on this particular issue on these people. Therefore,

considering the shortages and the importance of this topic, we decided to study the comparison of complications and marital satisfaction between the women taking cyclofem contraceptive ampoule and DMPA.

#### **MATERIALS AND METHODS**

This study is comparative and was conducted by cluster sampling. The population under study was women using contraceptive methods of cyclofem and DMPA provided from health centers in Babol, Iran. Sampling was done in 15 health centers allocated among 42 urban and rural Health center with cluster. The duration of sampling was 6 month. Precondition for entering the study was at least two 3-month periods; that is 6-month use of depomedroxyprogesterone ampoule and at least 3 one-month periods; that is 3 months use of cyclofem ampoule due to adjustment of side effects of the hormonal methods after first few months of use. Furthermore, the samples should not use any other hormonal method while using this method. The women should have at least 1 child, do not have any illness that interfered with complication and do not have any psycho logic disorder and no recent death of a close relative. With the use of pilot study, sample size was determined as 150 people in each group.

Data collection tools included two types of questionnaires; one for studying the complications and the other for examining the marital satisfaction. Questionnaires related to complications were prepared considering the previous studies and the existing scientific resources. And for validity, 10 expert persons and gynecologist review the questions that consist in two parts: (1) profile consisting of 6 demographic questions involving age, occupation, education, number of children, method of contraception, duration of consumption of the method and (2) a part related to the complications of ampoules including 15 questions about menstrual disorder, mood disorder, weight, libido, hirsutism, vomiting, headache, breast sensitivity, backache, early exhaustion, hair shedding, foot muscle contraction, abdominal bloat, face rash, vertigo and decrease power. These variables are defined as follows:

Demographics variables: Age: The women age between 15-45 years, those use family planning method;

Number of children: The number of childbearing that they have; Occupation: The women divided in 3 groups.1-household 2-work out of house 3-work in the house; Education: The women divided in 5 groups .1-no education 2-guidance school 3-high school 4-Diploma 5- university education.

Menstrual disorder: Amenorrhea: stop menstruation during consumption.

Decreasing days of bleeding: Reduce the days of bleeding lower than 3 days or lower than use previous method, Increase days of bleeding: Increase days of bleeding more than 7 days or more than use previous method,

Increase volume of bleeding: Use 6 or more than 6 pads at 3 first days.

Regular menstruation: menstruation occurs in ordinary duration between 28-30 days.

Irregular menstruation: menstruation occur in untidy duration. Change in libido: Decrease or Increase sexual tendency in comparison previous method.

Change in weight: Decrease or Increase in weight in comparison previous method.

We used binary questions and nominal variable for all complication variables. Enrich Couple Questionnaire (Fowers and Olson, 1989)

**Table 1.** Statistical results of the variables analysed in this study.

Side effect	Depo-medroxy	Cyclofem	P value	Side effect	Cyclofem	Depo-medroxy	
	N (%)	N (%)			N (%)	N (%)	P value
Amenorrhea	5/3(74)	48 (72)	P = 0.77	Painful coit	5/3(8)	6(9)	P=0.80
Decreasing days of bleeding	1/3(2)	1/3(2)	P=0.99	Leukorrhea	8/7(13)	4(6)	P=0.09
Breakthrough bleeding	19/3(29)	20/7(31)	P=0.77	Decrease libido	11/3(17)	14(21)	P=0.48
Increase days of bleeding	5/3(8)	0	P=0.004	Increase libido	8(12)	5/3(8)	P=0.35
Increase bleeding	1/3(2)	0	P=0.15	Weight Without change	49/3(74)	51/3(77)	P=0.72
Regular menstruation	0.3(1)	0	P=0.31	Increase weight	34(51)	33/3(50)	P=0.90
Irregular menstruation	6/7(10)	6(9)	P=0.81	Decrease weight	14(21)	13/3(20)	P=0.86
Mood Without change	47/3(71)	49/3(74)	P=0.72	Hirsutism	13/3(20)	11/3(17)	P=0.59
Sensitivity	15/3(23)	16/7(25)	P=0.75	Vomiting	7/3(11)	7/3(11)	P=1
Easy for crying	1/3(2)	2(3)	P=0.65	Headache	19/3(29)	20/7(31)	P=0.77
Nervousness level	16/7(25)	18/7(28)	P=0.65	Breast tendency	14(21)	13/3(20)	P=0.86
Early exhaustion	16(24)	10/7(16)	P=0.17	Backache	23/3(35)	28/7(43)	P=0.29
Decrease power	3/3(5)	2/7(4)	P=0.73	Vertigo	10/7(16)	12(18)	P=0.71
Foot muscle contraction	36/7(55)	34(51)	P=0.62	Face rush	8(12)	9/3(14)	P=0.68
Hair shedding	14/7(22)	19/3(29)	P=0.28	Abdominal bloat	24(36)	23/3(35)	P=0.89

with 92% validity and consisting of 35 questions translated by Asoodeh et al. (1389), including 4 subscales and 35 questions about satisfaction, communication and conflict resolution, was used to examine the marital satisfaction. This questionnaire as a valid research instrument has been used in many researches and clinical works. And Likert scale was used for Evaluation; the score lower than 30 presented intensive dissatisfaction, scores between 30-40 presented dissatisfaction, while scores between 60-70 presented very satisfaction, while scores more than 70 presented intensive marital satisfaction between couple. Finally, the data so collected were analyzed by statistical software SPSS/v19 applying descriptive statistics, Chi-square test, t-test and Pearson's Correlation.

#### **RESULTS**

All respondents were in the age range of 17-50 years old. Average total age of the respondents was  $31.57 \pm 8.03$  and there was no significant

difference between two groups using cyclofem and depo-medroxyprogesterone in respect of age. number of children, occupation and education. According to Table 1, two groups using depomedroxyprogesterone and cyclofem contraceptive methods were similar for menstrual disorders, including amenorrhea, decreased days of bleeding, breakthrough bleeding, increased bleeding, more regular menstrual cycles and irregular menstrual cycles, and they have no significant statistical differences. However, increased days of menstrual bleeding in depo-medroxy consumers were more than those of cyclofem consumers, and there is a significant difference (P = 0.004). Furthermore, both groups are similar in terms of weight changes, mood disorders, libido changes and all other complications and there was no significant difference.

Cyclofem ampoule has been used by 62% for

one year, 22.7% for two years and 15.3% for three years and more. On the other hand, depomedroxy ampoule has been used by 60% for one year, 16.7% for two years and 23.3% for three vears and more. A comparison between the consumption periods of two depomedroxyprogesterone and cyclofem ampoules showed that there is a significant difference between consumption period and type of contraceptive method (P = 0.02); it means that continuation rate of using depo-medroxyprogesterone ampoule for consumers was more than cyclofem ampoule. Pearson's correlation showed no significant relationship between the continuation in the use of the related method and the age of the consumers in two groups of women using cyclofem injection and depo-medroxyprogesterone ampoule and continuous use of contraceptive method in women who have used Cyclofem ampoule and their age (P = 0.07, Rho = 0.14). However, a significant relationship has been observed between continuous use of contraceptive method in women who have used depomedroxyprogesterone ampoule and their age. (P = 0.01, Rho = 0.20).

Furthermore, descriptive analysis showed that there was no significant relationship between marital satisfaction and job. Pearson's correlation test showed that there was no significant relationship between marital satisfaction and age, education and number of children. Score of marital satisfaction in women using cyclofem ampoule was minimum 100 and maximum 136. Score of marital satisfaction in women using depomedroxy-progesterone ampoule was minimum 102 and maximum 142. T-test analysis showed that the average marital satisfaction in women using depo-medroxyprogesterone contraceptive method was 116.79  $\pm$  8.62, which was significantly higher than the average marital satisfaction in women using cyclofem contraceptive method (14.53  $\pm$  7.16; P = 0.01).

#### DISCUSSION

In this study, there was no significant relationship between amenorrhea, reduced days of bleeding, breakthrough bleeding, increased bleeding, regular and irregular menstrual cycles with cyclofem and depomedroxyprogesterone contraceptive methods. However, the increased incidence of bleeding days in depomedroxyprogesterone method (5.3%) was significantly more than that in cyclofem method (0%). Moreover, the most common menstrual disorder in the consumers of depo-medroxyprogesterone and amenorrhea at 48 and 50.3%, respectively. In a study conducted by Afkari et al. (2003) in Kermanshah province, the most common menstrual disorder in consumers of depo-medroxyprogesterone amenorrhea as 53.2%, which is consistent with present study. However, according to Yazdanpanah et al. (2010), the most common disorder in the consumers of cyclofem was the lasted bleeding and then amenorrhea, which was not inconsistent with this study; incidence of amenorrhea in depo-medroxyprogesterone consumers is 50/3% in this study. Similar studies report this amount higher and others have reported it less. Moradan et al. (2009) stated the incidence of amenorrhea as 39.2% in Semnan province, and Kamalifard et al. (2011) reported it as 50% in East Azerbaijan province. In the present study, incidence of amenorrhea was 48% in Cyclofem consumers, while Kamalifard et al. (2011) reported it as 22% in East Azerbaijan province and Yazdanpanah et al. (2010) announced it as 14.7% in Kerman in his studies.

In his study on Iranian women conducting an immunechemistry survey, Symber showed that there is no difference for endometrial and endometrial atrophic vessels density in depo-medroxyprogesterone and cyclofem consumers after 3 - 6 months consumption (Simbar et al., 2007). In this study, increased nervousness level was the most common type of mood changes in cyclofem and depo-medroxyprogesterone consumers as 16.7 and 18.7%, respectively. In his study in Kermanshah, Afkari et al. (2003) reported this level as 25.4% in depo-medroxyprogesterone consumers that was higher than that in the present study; perhaps due to difference in culture context of the races under study. However, no study was found on mood changes in cyclofem consumers. In the present investigation, oneyear continuation rates of Cyclofem and Depomedroxyprogesterone in consumers were 62% and 60% respectively, while in his study Kamalifard et al. (2011) reported that one-year continuation rate of cyclofem and depo-medroxyprogesterone in consumers of these methods are 27 and 42%, respectively. Yazdanpanah et al. (2010) also stated that one-year continuation rate of Cyclofem is 21.2%. In some studies conducted in Kenva (Rominjo et al., 2005), the one-year continuation of cyclofem and depo-medroxyprogesterone consumption were reported as 56 and 75%, respectively. In a similar study conducted on Muslim countries like Indonesia and Tunisia (Garza-Flores, 1998), one-year continuation rate of cyclofem were reported as 66.5 and 28.2%, respectively. Difference in continuation rates in different studies may be due to cultural, economic and social differences of the population under study as well as the quality of advices before starting to use injection methods.

Generally, based on the results achieved in the present and similar studies, the complications caused by cyclofem and depo-medroxyprogesterone ampoules are similar and they have no significant difference. Moreover, these complications are not fatal and irreversible. Health staff may help the women using such methods through their advices and adequate training especially about the possible side effects in higher application and continuity of these methods.

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