

Comparison of Two Different Injectable Contraceptive Methods: Depo-medroxy Progesterone Acetate (DMPA) and Cyclofem

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Abstract

Objective: To compare side effects between users of two kinds of injectable contraceptives (Depo-medroxy progesterone acetate and Cyclofem).

Materials and methods: This cross-sectional descriptive study included 250 women, aged 18-40 years, using Depo-medroxy progesterone acetate (DMPA) or Cyclofem. The volunteers were examined six months after using contraceptive, and they were asked about following symptoms: weight changes, irregular bleeding, dyspareunia, vaginal dryness, headache, breast pain, bone pain, and discontinuation reason. The data were analyzed by statistical methods.

Results: The important side effects of DMPA were: irregular bleeding (93.60%), weight gain (48%), bone pain (24%) and vaginal dryness (10.40%), while the side effects in the Cyclofem group were: irregular bleeding (65.60%), headache (14.4%) and breast sensitivity (20%). Bleeding pattern changes were the most important problem leading to discontinuation of both contraceptive methods in our participants.

Conclusion: The results of the study showed that the most important problem in both groups was change in bleeding pattern. Proper consulting by a trained expert reduces the high amount of discontinuation and their failure rates.

Keywords: Injectable Contraceptives, Cyclofem, Depo-Provera, Side Effects

Introduction

Since the rate of population growth increases and food sources are not sufficient, birth control is considered as one of the important solution in order to control the growth rate of population. No ideal contraceptive method has been acknowledged, yet.

For the last four decades, the researchers have strived to produce effective contraceptive methods

with few side effects to provide a better birth control. Acceptability of a contraceptive method depends upon many interacting factors, like: characteristics of the method, demographic and socioeconomic variables pertaining to the population of clients (1). Injectable or implants contraception reduces the need of daily consumption (e.g. combinational pills) or depends upon sexual intercourse (e.g. condoms, etc). Today, nearly 16 million women worldwide use progestin-only or combined injectable contraceptives (2). The growing use of injectable contraceptives can be attributed to its desirable characteristic, inexpensive, not related to coitus, easy to use,

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noninvasive, reversible and long-acting effect.

Depo medroxyprogesterone acetate (DMPA) was presented as a contraceptive method in the USA in 1992. The most side effect of DMPA is irregular bleeding (3,4). However, some problems as amenorrhea, headache and depression were also reported (5). Progesterone injections due to long effect can cause fertility delay after discontinuation. Therefore, other injectable medications including Cyclofem were introduced to have fewer side effects. Cyclofem is consisted of 25 mg medroxy progesterone acetate and 5 mg estradiol cypionate, being used as microcrystalline suspension by deep and intramuscular injection into the gluteal or deltoid muscles. The injection should be done in the first five days of menstrual, or after delivery before the end of sixth week. The purpose of this study was to monitor the side effects of two injectable methods (DMPA, Cyclofem) after using for six months.

Materials and methods

This cross-sectional descriptive study was conducted at Samen-Alaemeh Clinic, Kermanshah, Iran and High Risk Pregnancy Research Center, Imam Reza Hospital, Kermanshah University of Medical Sciences, Kermanshah, Iran from July 2009 to September 2010. The study was reviewed and approved by the Ethics Committee of the Kermanshah University of Medical Sciences. Informed consent was obtained from all participants before admission to the study.

Eligible women are recruited among clients seeking family planning services at the two selected centers. Based on the previous studies, the reported complications about DMPA and Cyclofem were 24.6% and 43.5%, respectively. By assuming the study power 90% and $\alpha = 0.05$, sample size in each group was 125 people.(6)

The inclusion criteria were women aged 18-40 years and no contraindication for using of Cyclofem and DMPA. The participants were informed to use this new method for 6 consecutive months. The exclusion criteria were: history of menstrual problem, breast feeding, pregnancy, previous injectable contraceptive, and history of other diseases, like diabetics, blood pressure, goiter, etc. About 125 women were in one-month Cyclofem injection, while 125 people were in 3-month injection of DMPA. The procedure ensured that the number of individuals allocated to each study group was equal. Participants were visited by a psychologist at the selected center,

and were subjected to Beck Depression Inventory (BDI), so they were excluded from the study if they had suffered from anxiety, depression, etc. The first injection was applied during the first five days of the menstrual cycle. If the participants remained with the study for six months, they would be psychologically re-evaluated, and their mood changes would be recorded. Follow-up visits were performed every 30 days for both group. After first injection, the participants were monitored for the next six months. Information on demographic and personal characteristics were obtained from a self-administered questionnaire, completed by each participant after entering to the study. After six months, they were asked to have any problems, such as weight changes, menstrual problem (increase or decrease bleeding), amenorrhea, dyspareunia, vaginal dryness, painful sexual intercourse, headache, bone pains, as well as other questions, like their reasons for using/not using the methods. Data were analyzed by statistic staff by required methods.

Results

The mean age in DMPA group was 32.1 ± 5.2 , while in Cyclofem group was 29.9 ± 5.6 . The mean parity in DMPA group was slightly greater than Cyclofem group, 2.39 ± 1.24 vs. 1.5 ± 1 , respectively.

In this study, the weight gain, breast tenderness, bone pain, headache, vaginal dryness, mood changes and menstrual pattern change variables were studied as side effects of DMPA and Cyclofem methods. The most important side effects in DMPA group were menstrual cycle problems, like amenorrhea (74.4%), weight gain (48%), bone pains (24%), and vaginal dryness (10.4%). However, in Cyclofem group, the side effects were reported as menstrual problem, like bleeding reduction 47(37.6%), headache (14.4%) and breasts tenderness (20%) (Table 1).

Table 1: The comparison of side effects of two methods

	DMPA (n=125)	Cyclofem (n=125)	p value
Weight gain	60(48%)	25(20%)	<0.001
Breast tenderness	6(4.8%)	25(20%)	<0.001
Bone pain	30(24%)	18(14.4%)	0.054
Headache	2(1.6%)	18(14.4%)	<0.001
Vaginal dryness	13(10.40%)	5(4%)	0.05
Mood reduction	16(12.8%)	32(25.6%)	0.05
Spotting	6(4.8%)	6(4.8%)	0.557
Amenorrhea	93(74.4%)	7(5.60%)	<0.001
Reducing bleeding	14(11.20%)	47(37.60%)	<0.001

In this study, menstrual change was the most common discontinuation reason in DMPA and Cyclofem groups (about 25% in each group). Weight gain (18.6%) and bone pain (23.25%) in DMPA group, whereas headache (10.4%) and mood changes (8%) in Cyclofem group were also reported for discontinuation reasons (Table 2).

Table 2: The discontinuation reasons in two groups

	DMPA (n=87 from 125)	Cyclofem (n=125)	p value
Menstrual change	32(25.6%)	31(24.8%)	0.307
Weight gain	16(18.60%)	5(6.1%)	0.038
Bone pain	20(23.25%)	0	0.003
Mood change	0	10(8%)	<0.001
Headache	1(1.16%)	13(10.4%)	0.003
Breast pain	0	4(3.2%)	-
Want to pregnancy	2(1.6%)	0	-
Vaginal dryness	0	0	-

Discussion

Rapid access to contraceptives is of great importance for women (7). Depo medroxy progesterone acetate (DMPA) is used by most of women in Iran for a long time; however, Cyclofem is newly applied for contraception. In our study, the mean age and parity in women using DMPA were more than women using Cyclofem ($p=0.0008$, $p=0.0001$, respectively). Although DMPA is considered as a long acting birth control, it has not been identified as a successful contraception because of delay in the return of fertility and limited acceptability, especially among young and low-parity women. Ruminjo et al. in their study in 2005 have showed that the mean age and parity was similar in both groups (combined and progestin-only injectable) (6). The weight gain has always been a major concern among the DMPA consumers. In current study, 48% of DMPA users gained weight after six months, but this was less in Cyclofem group. Guazzelli, Bahamondes, Bonny and Seymor have demonstrated that Cyclofem has a few effects on weight gain, but they have agreed on weight gain among DMPA users, especially among young women (8-12). Our study showed that Cyclofem could considerably lead to breast tenderness, but it was not too serious for the participants to discontinue the method. Some studies have also reported the increase of breast tenderness in Cyclofem users (13). Although, one study has reported the reduction of breast pain using Cyclofem (8). It seems that the estrogen in Cyclofem causes

breast tenderness in users. According to the published studies, DMPA, as a pure progesterone, avoids the production of estrogen by suppressing ovaries and reducing blood estradiol level, leading to osteopenia (14-17). In recent study, bone density was not measured, but bone pains as pelvis, waist and legs were investigated. About 24% of the women of our study who used DMPA seriously suffered from bone pains, so stopped using it. Fortunately, osteopenia returns to young women after discontinuation of DMPA (18-19). Some studies emphasized measuring bone density for the women over 40 years old using DMPA for two years, (20). However, in our study, bone pain was less in Cyclofem users (14.4%). In similar studies, Cyclofem users experience less bone pains, so this method has no influence on bone density (8, 21). Headache was observed among the women using Cyclofem in our study, even leading to discontinuation (10.4%). Study by Guazzeli in 2007 has showed that headache is one of the discontinuation reasons of Cyclofem (8). Vaginal dryness was less investigated, but in current study, DMPA in comparison to Cyclofem significantly increased vaginal dryness in users (0.05). Vaginal dryness is not a considerable reason for discontinuation of method, and it can be explained by time restriction (six months). Mood reduction was observed more among Cyclofem users with a rate of 8% for discontinuation. It seems that Cyclofem is not tolerated by some people as oral combined pills. But in other studies, they did not observed any mood change, depression, or affective problems among young women using DMPA for 12 months (22-24). In our study, menstrual pattern change was the most important side effect in both groups.

Amenorrhea in DMPA group and bleeding reduction in Cyclofem were the most common menstrual problems. DMPA, used by millions women in all over the world, causes menstrual problems, namely amenorrhea, even through subcutaneous injection (24-26). Cyclofem, consisting of estrogen and progesterone, is used as combined pills. Although it seems to be a good method to regulate menstrual cycle, in our study, there were many complaints about menstrual problems, causing to discontinuation. According to Hall in 1998, the discontinuation of Cyclofem was high because of menstrual problems (27). Bahamondes and et al. observed that despite having estrogen, the Cyclofem doesn't cause endometrial hyperplasia (28). Simbar and et al. provided endometrial biopsy for the DMPA and

Cyclofem users, and they observed not only reduced endometrial vasculature in both groups, but also endometrial atrophy. So, she concluded that there was no difference between Cyclofem and DMPA (29). In our study, continuation rates for DMPA and Cyclofem were 31% and 34.5%, respectively. Hajikazemi et al showed the continuance rate after six months for DMPA was about 39% (5). In Kenia, the continuance rate after 12 months for DMPA and Cyclofem were 75% and 56.5%, respectively. Also, in Mexico and China, the continuance rate after 12 months for Cyclofem were 26% and 81%, respectively (30-31). This indicates that these two methods are more applicable for other races than Iranian women (8).

Conclusion

Cyclofem and DMPA may be used as highly effective, safe and convenient methods for long term reversible contraception. The main disadvantage of both methods is menstrual irregularity. Weight gain and bone pain in DMPA users, while headache and breast tenderness in Cyclofem users were also observed as the most important side effects. We recommend using more fiber in diet to prevent weight gain. We also suggest women with migraine not to use Cyclofem. Proper consultation by a trained expert reduces the high frequency of discontinuation.

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