

Patient satisfaction of Depot Medroxyprogesterone Acetate (dmpa-sc) injection as contraceptive

Rizwana Chaudhri,¹ Farwa Rizvi,² Muhammad Afzal³

Department of Gynecology and Obstetrics, Holy Family Hospital, Rawalpindi,¹ Department of Community Medicine, Islamabad Medical and Dental College, Bara Kaho, Islamabad,² RTMC, CPSP, Islamabad,³ Pakistan.

Abstract

Objective: To determine Patient Satisfaction of DMPA-SC (104 mg/0.65 mL) injected subcutaneously once every 3 months.

Methods: It was a Descriptive case series with the centre in Rawalpindi (Holy Family Hospital, Gynecology and Obstetrics Unit), Pakistan. Twenty five patients were selected by purposive sampling and followed up in Rawalpindi center (Holy Family Hospital, Gynaecology and Obstetric Unit) for one year as a part of the Asian Trial These patients had successfully completed their contraception using DMPA-sc at 3 months interval. Hospital Ethical Committee Permission was obtained prior to commencement of study. Informed written consent was taken from the patients.

Body weight was measured at baseline and every 3 months thereafter. Bleeding analysis was also done at 3 months interval using a 5 point scale based on patient's own records. Participant satisfaction with treatment results was evaluated using a patient satisfaction questionnaire (PSQ). It collected data regarding the respondent's experience with the study, the aspects of treatment that were liked and disliked and the likelihood of selecting that method for future contraceptive purposes.

Results: Out of twenty five, 15 (60%) patients had a high inclination Six (24%) patients and 9 (36%) very highly likely to use this contraceptive method in future. Eleven (44%) women replied that the probability of recommending this contraceptive method to their friends was very highly likely.

Conclusions: DMPA-SC has a very high percentage score of Patient Satisfaction for the contraceptive method as well as its likelihood of selecting it in future (JPMA 60:536; 2010).

Introduction

Depot medroxyprogesterone acetate (DMPA) is a highly effective and convenient contraceptive method that has been used worldwide for many decades.¹ This new formulation provides an improved adverse event profile, to empower the subject to do self-injection, and potentially to increase compliance by eliminating the need for periodic return to the health care system for injections.¹

The 'unmet' need for reproductive health care in Asia requires a wide demand net. Besides the efforts being made to increase the availability of oral contraceptives, condoms and IUDs, an approach for increasing awareness and knowledge is recommended through education about the variety of safe contraceptives and the use of traditional methods as well. Increase in educational status is partly responsible for the recent fertility decline. There are different social and cultural aspects incorporated into the realm of the reproductive health for women and multiple factors play their role in accessing modern contraceptive technologies. While guidelines of the World Health

Organization for quality care in family planning should be implemented in rural and urban sectors, efforts should also be made to translate recent advances in contraceptive technology from laboratory to service sector for improving women's reproductive health.²

Similar to the intramuscular DMPA injection (Depo-Provera intramuscular or contraceptive injection), the subcutaneous injection provides effective contraceptive and pain-management therapy for endometriosis, with a 3-monthly injectable protocol for women who seek long-term and reversible contraception without the need for a daily pill or a more frequent dosing regimen.³ According to the USAID report in June 2007, a community based distribution programme in three subdistricts of Bangladesh more than doubled their region's contraceptive use and increased the percentage of contraceptive users choosing injectable methods from 0.1 percent to 25 percent among the women of reproductive age group. Another community based distribution programme in Guatemala provided DMPA to 750 women in four districts and achieved a contraceptive continuation rate

of 90 percent. Similarly, the success of a pilot project to test the CBD (community based distribution) programme of injectable contraceptives in Afghanistan led to a change in national policy allowing community health workers to administer injectable methods.⁴

Injectable contraceptive methods are safe, highly efficacious, and commonly used worldwide. It is a convenient, discrete, and low-maintenance method, and is ideal for patients with contraindications to estrogen use and certain medical conditions. In addition, there are many noncontraceptive benefits to Depo-Provera use. Side effects with this method including irregular bleeding, breast tenderness, weight gain, and the impact on bone mineral density should be taken into consideration when prescribing the method.⁵ Use of DMPA is recommended for women as a form of effective contraceptive, without the fear of pregnancy or the burden of remembering to take the oral pills on a daily basis, other than remembering the 12 weekly appointments. For many women this is a great advantage.⁶

Depomedroxyprogesterone Acetate (DMPA) should be available as a first line method to all those who wish to make an informed choice about reversible methods of contraception. Pre-use counselling is essential to minimise the effect of menstrual change which occurs in most patients.⁶ Subcutaneous injections may be less painful than intramuscular injections, and the potential for self-administration may aid in compliance. As long-acting progestin-only products, the DMPA injections offer estrogen free contraception without the need for frequent dosing. Prolonged use of DMPA may lead to a decrease in bone mineral density, which may not be completely reversible; the potential impact on bone mineral density should be considered when assessing DMPA as a contraceptive option.⁷ This article presents the results of 25 patients, who were a part of two large, pivotal Phase, Contraceptive trials of DMPA-SC. One of these multinational trials was conducted in North and South America; the other in Europe and Asia. Pakistan was part of the Asian countries Trial in which we have presented the data of 25 patients who underwent the 1 year trial of DMPA-SC and completed it successfully in Holy Family Hospital (Gynecology and Obstetrics unit). This study has been the first of its kind as till now, no work regarding DMPA-SC injectable contraceptives has been done in Pakistan. The objective of this study was to determine patient satisfaction of the DMPA-SC (104 mg/0.65 mL) injected subcutaneously for contraception, once every 3 months. The study design was considered suitable and ethical for these trials because Depo-Provera IM is used

as a contraceptive in many countries including Asian countries and has proven efficacy.

Subjects and Methods

It was a Descriptive Case Series, part of Patient Satisfaction/contraceptive trials of DMPA-SC, conducted in 5 centers of Pakistan as part of Asian Trials (Europe/Asia N=1065). The original sample size was 1065 patients from all over Asia and European countries out of which twenty five patients were from the Rawalpindi center (Holy Family Hospital, Gynaecology and Obstetrics Unit). These twenty-five women represented the Pakistani set of patients who were followed up in Rawalpindi center (Holy Family Hospital, Gynaecology and Obstetrics Unit) for one year period as part of the Asian Trial, as they successfully completed their contraception for one year. Formal permission from Hospital Ethical committee was taken before the commencement of the study. Informed written consent was taken from the patients and every aspect of the study was explained to them before they were enrolled.

The subjects were selected by purposive sampling and included currently married women in the child bearing age i.e. 18-45 years. The women selected were residents of Rawalpindi and had access to the hospital for the visits. These women belonged to different socioeconomic groups. All of these women were house wives and were educated with some of the women's educational status up to grade eight and above. These women had normal 28-35 day menstrual cycles with no history of menorrhagia. Their husbands were using a barrier method of contraception, and women had not used any hormonal contraceptive pills at least for the last 3 months neither did receive any DMPA-SC injection nor an IUD (Intrauterine contraceptive device) in the last one year. It was ensured that these women had normal cervical cytology and Mammograms (if >35 years). Also had no history of uncontrolled Hypertension, Diabetes, thrombotic event, Dysfunctional Uterine Bleeding and abnormal Liver Function Tests. Informed written consent was taken. Depomedroxyprogesterone Acetate-subcutaneous DMPA-SC (104 mg/0.65 mL) was administered every 3 months for 1 year by SC injection into the anterior thigh or abdominal wall. Depomedroxyprogesterone Acetate-subcutaneous (DMPA-SC) was initially injected at first visit within 5 days of the onset of a subject's spontaneous menstrual flow, and subsequently every 91-7 days.

Statistical Analysis

All analysis was done in SPSS version 13. Mean,

SD were calculated for quantitative data and frequency % were calculated for all qualitative data. Demographic and baseline variables, including age, weight, body mass index (BMI) and height were summarized. Abnormalities if any, in the subject's medical history, menstrual history, physical examination or pelvic examination were listed. Body weight was measured at baseline and every 3 months thereafter (at each injection visit).

Participant satisfaction with treatment results was evaluated using a patient satisfaction questionnaire (PSQ) and end-of-treatment questionnaire (EOTQ). The PSQ was administered at third visit (the second injection visit), fourth (6 months) and sixth visit (1 year). PSQ contained 5-7 items that were rated on a scale from 1 to 10.¹⁴ It collected data regarding the respondent's experience with the study, the aspects of treatment that were liked and disliked and the likelihood of selecting that method for future contraceptive purposes, including their preference for previous methods of birth control versus the method used in this study and satisfaction with the convenience of the treatment method.

Results

A total of 25 women were included in the study. The mean age in years at the time of visit 1 was 34.24 ±

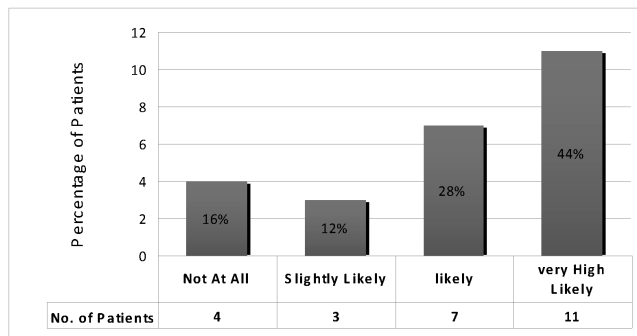


Figure-1: Probability of advising this contraceptive method to friends.

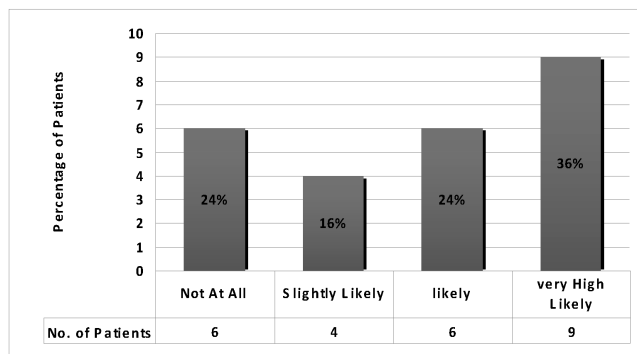


Figure-2: Probability of using DMPA-SC as contraceptive method in future.

Table: Over all Patients Satisfaction Score regarding injection DMPA (SC).

Satisfaction Score confidence	Mean scores (%) (SD)	9 5 % Interval
Visit 3 (2nd Dose Inj. DMPA at 3 months)	75 (4.5)	(71-78)
Visit 4 (3rd Dose Inj. DMPA at 6 months)	72 (5.2)	(67-76)
Visit 6 (5th Dose Inj. DMPA at 12 months)	71 (3.5)	(67-76)

(Reference for analysis from Bre'dart et al, EJC, 41(2005), 2120-2131).

3.57 years with a range of 26-40 years. Mean weight in Kilograms was 63.44 ± 13.81 Kg with a range of 40-98 Kg (at visit 1). Mean Height at Baseline was 156 ± 6.21 cm with a range of 137.16 - 167.64 cm.

There was a high score of Patients satisfaction as 11 (44%) women replied that the probability of recommending this contraceptive method to their friends was very highly likely. Whereas four (16%) women replied in negative (Figure-1).

Fifteen (60%) subjects had a high inclination, out of which 6 (24%) had likely and 9 (36%) very highly likely to use this contraceptive method in future as well, while six (24%) women were reluctant due to fear of injection, weight gain, and relative amenorrhea (Figure-2).

The overall satisfaction score was quite high (71-75), calculated as mean score at every visit (Table).

Discussion

All progestogen-only methods, whether low or high dose, lead to menstrual disturbances. Although troublesome, the menstrual disturbances which occur in DMPA users very rarely require operative or medical intervention, and can often be improved simply by short courses of estrogen or shorter injection intervals. Again, women need to know what can be done so that they are aware that they should seek early medical advice, rather than anxiously waiting for their 12 week appointment. DMPA has no appreciable effects on blood pressure or thrombosis risk. In this it has an advantage over the combined oral contraceptive pill, and provides a simple, effective alternative for women who cannot use the pill for these reasons.⁸

There was a high score of Patients satisfaction. This can be attributed to the fact that subcutaneous injections may be less painful than intramuscular injections, and the potential for self-administration may aid in compliance. As long-acting progestin-only products, the Depomedroxyprogesterone Acetate-subcutaneous (DMPA) injections offer estrogen free contraception without the need for frequent dosing.⁸ As

a progestin-only method, Depot medroxyprogesterone acetate (DMPA-SC) is also a particularly useful and appropriate alternative method for women in whom estrogen use is contraindicated.⁹ Depot medroxyprogesterone acetate (DMPA) and the combination contraceptive vaginal ring (NuvaRing) are most effective for obese women because they don't appear to be affected by body weight.¹⁰ In this study, the mean weight gain was insignificant over a period of one year. Contraceptive failure rate was zero, thus indicating its high efficacy (100%) and leading ultimately to a high patient satisfaction. In a study to estimate the probability of pregnancy for oral contraceptive pill (OCP), injectable contraceptive, and condom users in Uganda, Thailand, and Zimbabwe,¹¹ the overall risk of pregnancy for injectable contraceptive users was substantially lower than for oral contraceptive pill users. However, Thai participants had similarly low cumulative pregnancy probabilities for both methods. Women receiving contraceptive counseling should be informed that their experience with a given method may differ from the average or typical-use pregnancy rates often discussed during contraceptive counseling. It is necessary so that the women can make informed choices.¹¹ Depomedroxyprogesterone acetate (DMPA) (Depo Provera) is a long-acting contraceptive popular in the United Kingdom, particularly among young women. In the United States, use of DMPA has been instrumental in reducing teenage pregnancy rates.¹²

DMPA should be available as a first line method to all who wish to make an informed choice about reversible methods of contraception. Pre-use counselling is essential to minimise the effect of menstrual change which occurs in most patients. However there is great patient variability. Use of DMPA is independent of intercourse and also independent of the user's memory (and thus of continuing motivation), other than remembering the 12 weekly appointments. For many women this is a great advantage. Oral contraceptive methods involve remembering to take a pill each day, in the case of the progestogen only pill within the same three hours each day. This places considerable strain on women who lead irregular lifestyles, who are very busy or travel frequently. Such women often describe a constant 'fear of forgetting', especially with the Progesterone Only Pills.⁶

One-year continuation rates in clinical trials were high, 68% on average at sites in North and South America and 80% in Europe and Asia. In these trials of DMPA-SC, some women gave themselves injections and many said they would prefer self injection. For

example, among 1,787 women participating in trials of DMPA-SC with standard syringes, 16% gave themselves injections. Among the approximately 1,600 participants who answered a questionnaire, 13 (50%) preferred to give themselves the injection at home 5 (21%) in a doctor's office, while 7 (29%) women preferred injections by a provider.¹³

Injections of DMPA-SC are given in the upper thigh or abdomen. DMPA-SC should not be injected intramuscularly, and similarly the intramuscular formulation should not be injected subcutaneously. DMPA-SC is just as effective as the formulation injected into the muscle, and as seen in various studies, the patterns of bleeding changes and amount of weight gain are similar and no significant weight changes have been reported,^{14,15} while other studies reported substantial mean weight gains, ranging from approximately 1.35 to 4.50 kg over one year.¹⁶ Based on a qualitative semi-structured interview, another study was done in India and Yemen and the authors concluded that health education was very important and that clinical teachers were the nodal group having the strongest incentive to obtain and use new knowledge in reproductive health care and that clinical practitioners should have access to such knowledge.¹⁷ Longitudinal data analysis of 10 year community-based access to contraception in Bangladesh has provided a statistical model to determine the changes in reproductive behaviour and motives of respondents exposed to outreach activities.¹⁸

Conclusion

DMPA-SC has a high percentage score of Patient Satisfaction (71-75% mean score on all the visits) for the contraceptive method as well as its likelihood of selecting it in future. It is an effective and reversible contraceptive method and should be available to women who desire Family Planning. Counseling before use should be done so that women can deal with the effects of menstrual changes which are commonly encountered.

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