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Contraception 85 (2012) 458 – 464

Contraception

Original research article

Pilot study of home self-administration of subcutaneous depo-medroxyprogesterone acetate for contraception☆,☆☆

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Received 11 June 2011; revised 15 September 2011; accepted 5 October 2011

Abstract

Background: Subcutaneous depo-medroxyprogesterone acetate (DMPA-SC) offers the possibility of self-administration.

Study Design: This is a pilot study of self-administration of DMPA-SC. Existing users of the intramuscular preparation (DMPA-IM) who wished to self-inject (n=64) were taught self-administration using DMPA-SC. The main outcome was the continuation rate of the method at 12 months compared to a control group of existing users of DMPA-IM (n=64) who continued to attend a clinic to receive the method. Women's satisfaction with the method and the proportion of self-injections given at correct time were also determined.

Results: The 12-month discontinuation rate of the DMPA-SC group (12%) did not differ significantly from that of the DMPA-IM group (22%) (95% confidence intervals of 13%–33% and 6%–23% for DMPA-SC and DMPA-IM, respectively; p=.23). All self-injections were given within the appropriate interval. There was no significant difference in the proportion of women in either group who were satisfied with the method.

Conclusion: Self-administration of DMPA-SC for contraception is feasible and is associated with similar continuation rates and satisfaction to clinician-administered DMPA-IM.

Keywords: Depo-medroxyprogesterone acetate; Contraception; Self-injection; Subcutaneous injection; Acceptability

1. Introduction

Expert clinical opinion is that the more effective methods of contraception could have a wider role in contraception and their increased uptake could help to reduce unintended pregnancy [1]. DMPA (150 mg medroxyprogesterone acetate, Pfizer, UK) is a highly effective contraceptive given by intramuscular injection (IM) at 3-month intervals. However, use of DMPA in Great Britain is low, with only 3% of women of reproductive age reported to have used the method in 2008–2009 [2]. A further problem with the injectable method is that discontinuation rates are high. Data from the United States suggest that only 56% of women continue with this method at 1 year [3]. Clearly, therefore, health providers should not only promote uptake of intermediate- and long-term-acting reversible contraception methods but also focus efforts on improving continuation rates with these methods. Unfortunately, most strategies aimed at improving adherence with hormonal method of contraception have proven ineffective [4].

In recent years, DMPA has been reformulated as a micronized formulation (104 mg medroxyprogesterone acetate, Sayana, USA) that is administered subcutaneously (DMPA-SC) once every 3 months. Although the total dose of medroxyprogesterone acetate is lower with DMPA-SC than intramuscular preparation of DMPA (DMPA-IM) (104 mg versus 150 mg), the efficacy and effect on the return of fertility are no different from those associated with DMPA-IM [5,6]. Since it is administered subcutaneously, this preparation offers the possibility of self-administration. The option of self-administration is potentially attractive since the need to attend a clinic every 12 weeks to receive the injection is a disadvantage for women, a cost to the health service and a possible reason for women stopping the

☆ Funding: This project was funded by an independent research grant from Sayana, Pfizer Inc., USA.

☆☆ Competing interests: There are no competing interests.

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0010-7824/$ – see front matter © 2012 Elsevier Inc. All rights reserved.
doi:10.1016/j.contraception.2011.10.002

method or getting the injection late. A survey of Scottish women who used DMPA-IM demonstrated that the majority would prefer to attend a clinic less often and, if given the choice, would prefer to self-inject at home [7]. In the same survey, a significant proportion of women who have never used the injectable method or who have used it in the past would consider using it or restarting it if they were able to self-inject. Improved continuation rates with the method could translate into fewer unintended pregnancies with their associated emotional distress for women and costs to the health care system.

The aim of this pilot study was therefore to determine the feasibility of self-administration of the subcutaneous form of DMPA (DMPA-SC) for contraception by women who were established users of DMPA-IM and who chose to self-inject and participate in the study. This pilot study was conducted at a large family planning clinic in Edinburgh and compared women who chose to self-inject DMPA-SC with a control group of existing users who continued to attend a clinic to receive DMPA-IM from a clinician. The main outcome was the continuation rate of the method at 12 months. Women's satisfaction with the method and the proportion of injections given at correct time were also determined.

In addition, we wished to determine the attitudes of a group of key health professionals regarding self-administration of DMPA-SC by women as a regular method of contraception. We thus surveyed the attitudes of a group of practice nurses regarding feasibility of home self-administration of DMPA-SC by women.

2. Methods

The survey of attitudes of practice nurses towards home self-administration of DMPA-SC was conducted among a group of practice nurses (nurses working within a family doctor service) attending a contraceptive update meeting in Edinburgh in December 2008. The questionnaires were self-completed anonymously. They consisted of a brief introduction about the subcutaneous preparation of DMPA-SC followed by 'tick box' response to questions regarding their beliefs about what proportion of existing users of DMPA they thought would be willing and able to self-administer this method correctly.

Between November 2008 and January 2010, all women attending a family planning clinic in central Edinburgh, Scotland, aged 18–40 years, who were existing users of DMPA-IM were invited to participate in the study to self-administer DMPA-SC. In order to be eligible to participate, women had to have been using DMPA-IM for at least 9 months, to be not known to have a contraindication (UK Medical Eligibility Criteria 3 or 4) to the method [8], to be without a significant preexisting medical condition, to be wishing to continue using the method for at least 1 more year and to be planning to remain a resident in the region for at least 1 year. Eligible women who did not wish to self-administer were invited to participate as a control group who would continue to return as usual to the clinic every 12 weeks for the DMPA-IM.

Women who chose to self-administer switched to DMPA-SC when their next injection was due. The injection device used in the study consisted of a preloaded syringe with a separate sterile subcutaneous needle that was required to be attached to the syringe. This preparation was unavailable in the UK, and so the study medication was provided, packaged and shipped by Sayana, Pfizer Inc., USA. Women were taught how to give a subcutaneous injection by the study research nurse using an injection teaching model of artificial skin on a belt that could be worn on different parts of the body. When the women were deemed competent in the technique, they gave themselves the initial self-injection of DMPA-SC into their abdomen under supervision of this nurse at the clinic. The research nurse then provided the participants in the DMPA-SC group with three prefilled syringes of DMPA-SC, together with needles for subcutaneous injection, to take home and a list of dates when the three injections would be due. Women were also given a pack containing written information on the method of self-injection, advice on safe storage of the medicine and safe disposal of the needles (including a small 'sharps' disposal box) and 24-h contact telephone numbers for advice. All subjects were asked to return the sharps box and any unused supplies to the study site at the end of the study. In total, therefore, women were given DMPA-SC providing 12 months of contraception.

All women in the DMPA-SC group were sent a text message 1 week prior to the scheduled date of injection to remind them when the next injection was due. Women in this group were then contacted by telephone by the study nurse 2 weeks after the date that they were supposed to have self-administered DMPA-SC. They were asked if they had given themselves the DMPA-SC, the date of self-injection and if they experienced any difficulties with the injection. Women in the control group (DMPA-IM) simply returned to the clinic every 12 weeks as usual to receive their intramuscular injection from one of the clinic doctors or nurses. No reminders were sent. Women in the both the DMPA-SC and control groups were asked to complete a questionnaire at the end of the study (12 months) or at exit from the study (if premature discontinuation occurred) regarding their satisfaction with the method and future plans for contraception. In addition, all women were asked to keep a diary of all bleeding episodes during the study and to subjectively report these as 'spotting,' 'moderate' or 'severe.'

The study was approved by the local Lothian Research ethics committee (07/S1102/2). All women gave written informed consent.

2.1. Sample size and statistical analysis

Sample size calculation was based upon predicted discontinuation rates in each arm of the study at 1 year.