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Self-administration of subcutaneous depot medroxyprogesterone acetate by adolescent women☆,☆☆

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Abstract

Background: Intramuscular depot medroxyprogesterone acetate (DMPA-IM) is now available in subcutaneous (SC) formulation, potentially allowing for home-based self-administration. We examined adolescents' interest in and proficiency at DMPA-SC self-administration.
Study Design: This is a planned secondary analysis of a randomized controlled trial comparing pain between DMPA-IM and DMPA-SC. In the trial, study participants (N=55) aged 14–21 years were recruited at DMPA initiation and randomized to receive DMPA-IM or DMPA-SC. Participants received the alternate formulation at 3 months, chose formulation at 6 months and could learn self-administration at 9 months. The current analysis is of the women who chose self-administration of DMPA-SC. Proficiency was rated for each step of self-administration: independently [I], with reassurance [R], with verbal instruction [V] or nurse performed [RN]. Data were analyzed using descriptive and comparative statistics.
Results: Thirty-five percent (19/55) of participants learned self-administration. Proficiency ratings were as follows: chose injection site (I=78.9%, R=5.3%, V=5.3%, RN=10.5%), cleaned site (I=89.5%, RN=10.5%), assembled injection device (I=47.4%, R=36.8%, V=15.8%), self-injected (I=31.6%, R=36.8%, V=15.8%, RN=15.8%) and disposed of device (I=21.1%, R=21.1%, RN=57.9%).
Conclusions: Many adolescents are interested in and capable of DMPA-SC self-administration with brief education and minimal assistance.

Keywords: Depot medroxyprogesterone acetate; Adolescent; Contraception; Self-injection

1. Introduction

Intramuscular depot medroxyprogesterone acetate (DMPA-IM) is a popular contraceptive choice among adolescent women and has contributed to the decline in teen pregnancy rates [1]. In 2006–2010, 20.3% of sexually experienced females 15–19 years of age used DMPA-IM, double the rate of DMPA use in 1995 [1,2]. However, administration of DMPA-IM requires quarterly office visits, with associated costs, time and transportation needs which may serve as a barrier to adherence to follow-up injections. Self-administration would make it possible for young women with limited availability of health care providers, transportation and financial resources to use this convenient, safe and reliable contraceptive method.

Subcutaneous DMPA (DMPA-SC) was approved by the US Food and Drug Administration (FDA) in 2005 for use in women of childbearing potential, including adolescents. The FDA approval and medication labeling do not specify who may administer the injection (e.g., provider, pharmacist, patient) or in what setting (e.g., clinic, home) [3]. DMPA-SC was developed with the goals of (a) providing a formulation of DMPA which could be self-administered at home, (b) minimizing side effects through dose reduction (104 mg DMPA-SC versus 150 mg DMPA-IM), (c) hastening the return to cyclic ovulation after DMPA discontinuation and (d) maintaining contraceptive efficacy. While contraceptive efficacy is equivalent between the two formulations, studies among adult women demonstrate equivalent adverse event profiles [4], including time to ovulation after drug cessation [5]. Studies of adult women have demonstrated interest in and feasibility of self-administration of DMPA-SC [6], but this issue has not been addressed among younger women.

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We conducted this study of DMPA use among adolescent women to assess adolescent women's (a) interest in self-administration of DMPA-SC, (b) proficiency in self-administering DMPA-SC and (c) perceived supports needed for home-based self-administration of DMPA-SC.

2. Materials and methods

Data for this descriptive analysis exploring DMPA-SC self-administration were drawn from a study designed to compare DMPA-SC and DMPA-IM with respect to injection pain and likelihood of DMPA continuation among 55 adolescent women (unpublished, data available from first author). The larger study used a two-treatment, randomized cross-over design with a primary outcome of self-reported injection pain.

Eligible study participants were English-speaking adolescent females 14–21 years of age who were initiating or restarting therapy with DMPA as part of a routine health care visit in Midwest, urban, primary care adolescent medicine clinics. Participants were eligible regardless of medical indication for DMPA or prior history of sexual activity, as hormonal contraceptive methods are also used in anticipation of future sexual activity and for other reasons including menstrual irregularities.

Participants were excluded from the study if they had received DMPA within 6 months prior to enrollment, if they were unable to complete self-administered written English surveys due to linguistic or intellectual barriers, if they did not have telephone access for scheduled follow-up interviews or if they had contraindications to DMPA use. Participants were also excluded if they received regular intramuscular or subcutaneous administration of other medications (e.g., insulin) or if they were receiving an injected medication at the time of DMPA administration (e.g., ceftriaxone). All participants provided informed consent, and parental permission was obtained for participants less than 18 years of age.

Prior to initiating study recruitment, computer-generated four-person blocked randomization determined injection sequence for 55 study participants. Injection sequence was either DMPA-SC for Visit 1 and DMPA-IM for Visit 2, or DMPA-IM for Visit 1 and DMPA-SC for Visit 2. Opaque sealed envelopes, one per participant, were sequentially numbered and contained a page indicating the randomized injection sequence. After informed consent was obtained at Visit 1 (time 0), the participant was assigned the next sequential numbered envelope and was given the injection formulation indicated for Visit 1. At Visit 2 (time 12 weeks), participants received the alternate DMPA injection. At Visit 3 (time 24 weeks), participants chose which DMPA formulation to receive as an outcome measure of formulation preference. All Visit 1, 2 and 3 injections were administered by study personnel who were trained in standard injection techniques for both DMPA formulations. DMPA-IM 150 mg was administered in the gluteal muscle (participant chose right or left side) using a 23-gauge×1-in. needle. DMPA-SC 104 mg was administered in the anterior abdominal wall (participant again chose right or left side). The injection is available in a 0.65-mL, single-dose, prefilled syringe. It is preassembled with an UltraSafe Passive™ Needle Guard device and packaged with a 26-gauge×3/8-in. needle to be used for injection [3].

Prior to each injection, participants completed written English surveys. The survey measure used in the current analysis was an 11-point Likert item rating desire to receive DMPA outside of the clinic setting ("I would like the Depo shot better if I didn't have to come to clinic to get it"; 0=*not true*, 10=*very true*) and was completed by all participants presenting for the visit, even if discontinuing DMPA.

At the completion of Visit 3, semistructured interviews exploring use of DMPA in general, experiences with each formulation and reasons for choosing DMPA-IM or DMPA-SC were conducted by research personnel. All participants presenting for the visit were interviewed, regardless of DMPA formulation or discontinuation. Interest in self-administration of DMPA-SC at home was further explored with the question "Would you like DMPA-SC better if you could give your shot at home when you could not make it to your clinic appointment?" Participants were then asked if they were interested in learning self-administration of DMPA-SC. Interested participants returned for Visit 4 (time 36 weeks).

At Visit 4, participants again completed a preinjection survey. Self-administration of DMPA-SC was then taught and observed. Using enlargements of the written and illustrated injection instructions from the DMPA-SC package insert and using a sample of the injection device to demonstrate, a research assistant individually educated each participant on the following five steps of self-administration: (a) choosing correct injection site, (b) cleaning injection site, (c) assembling injection device, (d) self-injecting DMPA-SC and (e) disposing of the injection device. For each of these five steps of self-administration, trained observers rated participant *Proficiency* as independent (I), independent with reassurance before proceeding (R), with continuous verbal instruction (V) or nurse performed this step (RN). Trained observers also rated participants' overall proficiency self-administering DMPA-SC as independent, after repeat education, with assistance or not competent to self-administer.

Visit 4 concluded after participants completed a semi-structured interview focusing on the experience of DMPA-SC self-administration and exploring self-administration at home with the question "If the shot were available at your pharmacy, would you want to give it to yourself at home?" Responses (no/yes) were elaborated upon with follow-up questions about benefits and barriers to home DMPA-SC use. The Visit 4 interview also assessed supports needed for home self-administration via the open-ended question "What things would make it easier for you to give the shot to