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Original research article

Postpartum weight loss in overweight and obese women using the etonogestrel subdermal implant: a pilot study☆

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Abstract

Objective: To compare weight loss during the first 6 months postpartum in overweight and obese women using the etonogestrel implant, placed in the immediate postpartum period, with that of controls using nonhormonal contraception, utilizing a pilot design.

Study design: Pilot, prospective cohort study. Analysis groups were divided by body mass index (overweight: 25–29.9 kg/m^2; Class I Obesity: 30–34.5 kg/m^2; Class II Obesity: 35–39.9 kg/m^2) and grouped by use of etonogestrel implant or nonhormonal contraception for all outcomes. Primary outcome was the proportion of women in each group returning to pregravid weight by 6 months postpartum. Secondary outcomes included waist circumference, motivation to lose weight, eating habits, physical activity, feasibility of study procedures and assessment of recruitment potential in the first 6 months postpartum.

Results: A total of 127 women enrolled between June 2014 and August 2015. Fifty-seven chose the etonogestrel implant for immediate postpartum contraception while 70 chose nonhormonal contraceptives. Six months after delivery, about half of women in each group returned to within 1.5 kg of pregravid weight (42% etonogestrel [ENG]-implant vs. 67% nonhormonal methods, p=.19). Retention rates were high with over 75% of total study population providing study data at 6 months. Two nonhormonal contraceptive users conceived in the first 4 months postpartum.

Conclusion: No statistical difference in percentage return to pregravid weight was detected between groups, but data suggest that a somewhat lower proportion of implant users lost weight at 6 months. Rapid recruitment, high retention and marked acceptance of immediate ENG implant use demonstrate feasibility for a larger, adequately powered trial.

Implications: Immediate postpartum insertion of the ENG implant is safe and effective. Study findings suggest modest interference in overweight and obese women's ability to lose gestational weight. If future research demonstrates no statistical difference, increased uptake in immediate implant use should occur in most women, including those who are overweight or obese.

Keywords: Obesity; Postpartum contraception; Weight loss; LARC

1. Introduction

Obesity is a critical public health issue. Two thirds of reproductive aged women in the US are overweight or obese (body mass index≥25 kg/m^2) [1]. Obesity is associated with poor maternal and neonatal health outcomes [2]. Aside from pregnancy-related risks, overweight and obese women face higher risks of chronic disease, including cardiovascular disease, diabetes, orthopedic conditions and cancer [3].

Compared with normal-weight women, overweight and obese women are four times more likely to gain excess weight during pregnancy [4] and retain weight postpartum [5]. Lack of return to prepregnancy weight is an important predictor of long-term obesity [6]. Unintended pregnancy in the postpartum period doubles a woman's risk of weight retention, and safe, reliable contraception is necessary. The etonogestrel (ENG) subdermal implant is a highly effective long-acting reversible contraceptive method, suitable for immediate postpartum initiation [7]. Data suggest that the implant does not impair postpartum weight loss in normal-weight women [8,9], but its metabolic effects on overweight and obese women are unknown.

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The current study sought to obtain pilot data on 6-month postpartum weight loss in overweight and obese women using the ENG implant, placed in the immediate postpartum period, with that of weight-matched controls using nonhormonal contraception.

2. Materials and methods

Participants were enrolled from June 2014 to August 2015. A pilot study design was used to assess feasibility of study procedures, measure participant recruitment and retention rates, quantify the typical rate of postpartum weight loss and preliminarily estimate effect size and determine the acceptability of immediate postpartum implants among overweight and obese postpartum women at our institution. The study protocol was approved by the Institutional Review Board at Northwestern University.

Participants were recruited from two obstetrics and gynecology clinics associated with Northwestern Memorial Hospital in Chicago, IL, USA: the Prentice Ambulatory Care Clinic and the Northwestern Medical Group. Women from both clinics deliver at Northwestern's Prentice Women's Hospital, and their obstetric care is managed by the same group of academic physicians. Study staff recruited women during third trimester prenatal appointments or following delivery on postpartum days (PPD) 1–7.

Women were eligible if they met the following criteria: age 18 years or older, pregravid body mass index (BMI) between 25 to 39.9 kg/m^2, total pregnancy weight gain of 10 to 40 lb, delivery at 34 weeks or beyond, English speaking, willing to follow up for 6 months postpartum and desire for either the ENG implant, with placement in the immediate postpartum period (PPD 1–7) or nonhormonal contraception (condoms, postpartum sterilization or copper intrauterine device).

Exclusion criteria included hyperemesis gravidarum during the current pregnancy, pregestational diabetes, insulin-dependent gestational diabetes and prior bariatric surgery. An additional exclusion criterion for ENG implant users was the presence of a contraindication to implant use, based on the Centers for Disease Control Medical Eligibility Criteria (Category 3 or 4 rating) [10].

Written informed consent and baseline demographic data were collected upon enrollment. Women were allocated to either ENG implant arm or comparison arm based on contraceptive choice. *Pregravid BMI* was defined as BMI at the first prenatal appointment. In general, weight gain prior to the initial prenatal appointment in the first trimester is minimal and represents pregravid BMI. If a participant presented for her initial prenatal appointment in the second trimester, her self-reported pregravid weight was used. Previous reports support the accuracy of self-reported weight during clinical research [6].

For comparative analysis, the study sought to enroll a minimum of 60 women in both the ENG implant arm and nonhormonal arm (total study, n=120). Participants were further subdivided into three BMI-based blocks: overweight, BMI: 25–29.9 kg/m^2; Class I Obesity, BMI: 30–34.5 kg/m^2; Class II Obesity, BMI: 35–39.9 kg/m^2. Twenty participants were enrolled into each BMI block within the ENG implant arm. To control for potential losses to follow up, BMI blocks within the nonhormonal arm were overenrolled up to 10 participants each. Overenrollment was not possible in the ENG implant arm, as only 60 implants were available for insertion during the study period.

Participants in the ENG implant arm received implants prior to discharge from the hospital and up to 7 days after delivery. One experienced physician inserted all ENG implants. Study visits occurred 6 weeks and 6 months postpartum. The 6-week study visit coincided with the routine 6-week postpartum appointment at the participant's primary clinic. Data collected included height and weight, lactation status and contraception plan for nonhormonal contraceptive participants. Women choosing to use the copper intrauterine device underwent placement at the 6-week study visit.

Participants completed three validated questionnaires: the International Physical Activity Questionnaire, the Three Factor Eating Questionnaire (r18) and the Motivational Factors Associated with Weight Loss. These questionnaires measure the effect of physical activity, diet and motivation on postpartum weight loss. Each participant received a US$25 gift card at completion of 6-week follow-up. The final study visit occurred 6 months postpartum. Data collected were the same as at the 6-week visit, with the addition of waist circumference. Participants received a US$50 gift card at this last encounter.

If a nonhormonal user chose to initiate hormonal contraception during the study period, the method was documented. If she chose combined hormonal contraceptives (i.e., pills, patch, ring) [11], progestin-only pills or hormone-containing intrauterine device, the participant was retained within the comparison group, as these methods do not affect weight [12]. Women choosing depot-medroxyprogesterone acetate were excluded from further analysis, given potential effects on weight [13].

The primary outcome was percentage return to within 1.5 kg of prepregnancy weight by 6 months postpartum. This magnitude of weight loss was chosen based on data documenting lower risks of obesity related comorbidities in women who achieved this level of weight reduction [14]. Secondary outcomes included waist circumference, descriptive analyses of motivation to lose weight, eating habits and physical activity ascertained by interview and validated instruments and recruitment and retention rates.

All statistical analyses were performed using SAS 9.4. Demographic characteristic comparisons were conducted utilizing Student t test for numerical data and chi-squared or Fisher's Exact Test for categorical data. Relevant variables were analyzed for the total study population and each BMI block. The results are presented as means, standard deviations and percentages. Primary outcome comparison