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Measured and reported weight change for women using a vaginal contraceptive ring vs. a low-dose oral contraceptive

Katharine J. O'Connell*, Lauren M. Osborne, Carolyn Westhoff

Department of Obstetrics and Gynecology, Columbia University, New York, NY 10032, USA

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Abstract

Background: Women often stop hormonal contraception because of perceived weight change. We conducted a randomized trial comparing the contraceptive vaginal ring to a low-dose oral contraceptive (OC). We examined the difference between women's reported and measured baseline weights and looked at factors affecting perceived weight change.

Methods: We randomized 201 participants to either the vaginal ring or an OC for three cycles. We weighed participants upon enrollment ($n=194$) and at exit ($n=167$), using the same instrument for all measurements. Participants also provided self-reported height and their reactions to perceived weight changes.

Results: Baseline weight and body mass index were similar for both groups (mean weight=145.9 lb). Measured weight was, on average, 4.4 lb more than reported weight; this difference was greater in overweight and obese participants. Participants gained an average of 2.8 lb over 3 months; this gain did not differ between groups or by baseline weight. Subjects who reported a "bad change" in weight at exit ($n=34$) gained an average of 4.4 lb, whereas those who reported "no change" ($n=112$) gained 2.2 lb and those who reported a "good change" ($n=14$) gained 3.3 lb.

Conclusion: Participants underreported their weight, and this difference was greater for heavier women. There was little weight change for the women in our study. Participants' opinions about weight change were not correlated with measured weight changes.

Keywords: Body weight; Vaginal ring; Oral contraceptives; Body image

1. Introduction

Over 80% of women in the United States use oral contraceptives (OCs) for an average of 5 years [1,2]. Many women, however, discontinue the pill when they are still at risk of an undesired pregnancy (while remaining sexually active). Multiple studies show OC discontinuation rates of 29% to 60% within the first 6 to 12 months of use [3–8]. Women often cite side effects as a primary reason for OC discontinuation. In a national prospective study of women initiating OCs, 46% discontinued within 6 months due to side effects [7].

Perceived weight gain is a frequently reported side effect. Multiple surveys show that as many as 75% of subjects cite weight gain as a disadvantage of the pill [9,10]. Among university students who use OCs, 31% cited weight gain as their primary concern about the method [11]. Women who experience weight gain while using OCs are more likely to discontinue early than women who do not report weight gain [12]. A survey of American women indicated that weight gain was the most common physical complaint leading to discontinuation of OCs — more common than nausea, headache or menstrual abnormalities [13].

Do data substantiate these fears? Reports of weight gain are often based on women's perceptions rather than on measurements. Daily self-measurements of weight over 4 months by women using OCs showed no mean weight changes [7]. In two randomized, placebo-controlled trial of OCs with 704 women, there was an equal amount of weight gain in each group over six cycles [14]. A recent Cochrane review of randomized trials that examined the relationship between combined hormonal contraception and weight gain concluded that there was insufficient evidence to determine the effect of OCs on weight, and that no large effect was apparent [15].

Many normal-weight women classify themselves as overweight and obese in population-based surveys [16,17]. We could find no studies that compared subjects' estimates of their weight in pounds to their measured weight, nor did

* Corresponding author. Tel.: +1 212 305 4805; fax: +1 212 305 6438.
E-mail address: ko2032@columbia.edu (K.J. O'Connell).

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we find studies that compared opinions about weight change to measured weight change. Thus, we hypothesize that women may discontinue hormonal contraception due to imagined, rather than real, weight gain. A mismatch between perceived and measured weight may seriously affect contraceptive continuation, and it holds great implications for counseling.

We conducted a randomized trial comparing the contraceptive vaginal ring to a low-dose OC to examine acceptability and satisfaction. We examined the difference between women's reported and measured baseline weights and between measured weight change and opinions about that change over the course of the study.

2. Materials and methods

This was a randomized controlled trial conducted at the Department of Obstetrics and Gynecology, Columbia University Medical Center, in New York City, between May 2003 and March 2004. The intervention was random assignment to immediate start of either a low-dose triphasic OC (Ortho Tricyclen Lo®) or the monthly vaginal contraceptive ring (NuvaRing®). Ortho Tricyclen Lo® has 25 μg of ethinyl estradiol in all 21 active tablets, with a triphasic formulation of norgestimate (18, 21.5 and 25 μg of norgestimate). NuvaRing® releases 15 μg of ethinyl estradiol and 120 μg of etonogestrel per day over 3 weeks. The study was reviewed and approved by the Institutional Review Board of Columbia University Medical Center.

The detailed methods of this study have been described previously [18].

Briefly, eligibility criteria included English speaking, aged between 18 and 40 years, regular menstrual cycles of 21–35 days in the past 12 months, no contraindications to use of hormonal contraception, more than two menses since last pregnancy or last use of hormonal contraception (more than six menses for injectable contraception). After informed consent and prior to randomization, subjects underwent a baseline interview that included self-reported height and weight. We then weighed each subject using a single Sterling spring-balance scale. Participants wore light indoor clothing and removed shoes. We then randomized participants to either the pill ($n=100$) or the ring ($n=101$). We instructed participants on correct method use and distributed three cycles of the randomized method to each.

A researcher not otherwise involved in the study generated the treatment assignments in a 1:1 allocation ratio using a random numbers table and simple randomization. Treatment assignments were concealed in sequentially numbered, sealed, opaque envelopes. Study coordinators and interviewers were blinded to the assignment prior to allocation. The sample size of 200 was selected to compare bleeding differences between treatment groups [18]. Post hoc power analysis showed that we had 42% power to detect a difference of five pounds or more between groups (two-sided alpha level, .05).

After completing three cycles of either method, participants completed an exit interview regarding method satisfaction and continuation, side effects and perceptions of bleeding changes. We then weighed the participants upon exit with the same scale used for baseline measurements; participants again wore light indoor clothing and removed shoes.

We analyzed the data using SPSS 10.0 (SPSS, Chicago, IL). We examined baseline and follow-up variables to describe the randomized groups. We calculated body mass index (BMI) using self-reported height and measured weight at baseline, and classified women into three weight categories: normal weight (BMI less than 25 kg/m^2), overweight (BMI between 25 and 29.9) and obese (BMI greater than 30). The normal-weight category included 15 women who were underweight (BMI less than 19). We analyzed the data by treatment assignment (intent-to-treat analysis: pill vs. ring), by baseline weight, by baseline BMI and by follow-up date (on time vs. late).

The main outcome variable was the mean difference between measured and perceived weight at entrance, which we compared with paired Student's t test, one-way analysis of variance (ANOVA) and linear regression. Secondary outcome variables were the measured weight change during the study (compared with paired Student's t test) and the relationship between measured change and participants' opinions about that change (compared with one-way ANOVA).

3. Results

Fig. 1 shows the flow of participants through the trial. Of the 311 who underwent telephone screening, 279 were eligible for the study and made enrollment appointments. Seventy-six women did not attend their enrollment visit. We excluded one potential participant because of elevated blood pressure and another because of pregnancy at the time of the enrollment visit; 201 women were enrolled and randomized. One hundred seventy-four participants (87%) completed an exit interview regarding method satisfaction, continuation and side effects (ring users, 88%; pill users, 85%). One hundred ninety-four (97%) of the women were weighed at baseline, and 161 (80% of total) were also weighed at exit. Twenty-three subjects completed follow-up but discontinued the method before completing three cycles; one (in the pill group) discontinued because of perceived weight gain. Four subjects (one ring user and three pill users) discontinued the method and withdrew from the study before completing three cycles not because of weight changes. Twenty-three subjects did not return for an exit interview; we do not know whether they continued their methods. There were no changes in blood pressure, no pregnancies and no other serious adverse events during the 84-day reference period.

Table 1 shows the demographic characteristics of the study population ($n=201$). Baseline characteristics were balanced overall between ring and pill groups; however, of the pill users, 21% were Hispanic, and of the ring users, only