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# The Role of Body Weight in Oral Contraceptive Failure: Results from the 1995 National Survey of Family Growth

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**PURPOSE:** Many unintended pregnancies occur in women who use contraception. We conducted this study to determine if increasing body weight is associated with oral contraceptive (OC) failure.
**METHODS:** This retrospective cohort study consists of the 1916 women who reported using OCs in January 1993 and provided complete covariate information on the 1993 National Health Interview Survey and 1995 National Survey of Family Growth. Body weight and body mass index (BMI) were self-reported in 1993. The outcome was defined to be any conception occurring in women reporting OC use during the month of conception. Cox proportional hazards models were used to model the body weight/BMI–OC failure association.
**RESULTS:** Women with a BMI $\geq 30$ had a statistically significant increased risk of having an OC failure as compared to women with BMIs of 20 to 24.9 (HR = 1.80, 95% CI, 1.01, 3.20). However, after adjustment for age, marital status, education, poverty, race/ethnicity, parity, and dual method use, this increased risk was attenuated and no longer statistically significant (HR = 1.51, 95% CI, 0.81, 2.82). Increasing body weight was not associated with an increased risk of OC failure in the unadjusted or adjusted models.
**CONCLUSIONS:** We did not find a strong or statistically significant association between increasing body weight/BMI and OC failure among this population of women. Prospective studies specifically designed to examine this association are needed to determine if heavier women should be advised to use a contraceptive method other than OCs to prevent pregnancy.
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KEY WORDS: Contraceptives, Oral, Obesity, Women's Health.

## INTRODUCTION

Each year, 3 million of the 6 million pregnancies in the US are classified as unintended (1). It is estimated that nearly half of these unintended pregnancies occur in the 90% of women who use some type of contraceptive (2). Researchers attribute these contraceptive failures to noncompliance and ineffective use (2–5). Few studies have investigated whether biologic factors, rather than ineffective use, may be responsible for the large number of pregnancies that occur in women using contraceptives. Body weight is one such biologic factor that may affect how contraceptives work, specifically hormonal contraceptives. Excess weight may cause an enhanced metabolic rate and hence more rapid drug metabolism (6). Suggestions of the association between higher body weight and increased contraceptive failure emerge from secondary analyses of efficacy trials of Norplant and the transdermal contraceptive patch (7–10). In 2002 Holt et al. (6) also demonstrated an association between higher body weight and increased risk of oral contraceptive (OC) failure in an analysis whose primary purpose was to examine the association between body weight and risk of OC failure. We used data from the 1995 National Survey of Family Growth (NSFG), a large survey of US women, to further investigate if increasing body weight is associated with OC failure in a retrospective cohort study.

## MATERIALS AND METHODS

### Study Population and Design

The 1995 NSFG sample was drawn from respondents of the 1993 National Health Interview Survey (NHIS), a survey designed to provide information on the health of the civilian, noninstitutionalized, household population of the US. Through personal interviews with a national sample of women 15 to 44 years of age who responded to the 1993 NHIS, the NSFG aimed to collect more detailed data on factors affecting pregnancy and women's health. In 1995 trained personnel conducted interviews with 10,847 women, reflecting a survey response rate of 79%. The interviews covered the time period from January 1993 until the month of the interview in 1995. The present retrospective cohort study consists of the 2064 women who indicated that they were using OCs as of January 1993.

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**Selected Abbreviations and Acronyms**

BMI = body mass index
CI = confidence interval
EE = ethinyl estradiol
EDDA = ethynodiol diacetate
HR = hazard ratio
NHIS = National Health Interview Survey
NSFG = National Survey of Family Growth
NEA = norethindrone
NET = norethisterone
OR = odds ratio
OC = oral contraceptive

### Measurement of Exposure and Covariates

Self-reported body weight and height, collected during the 1993 NHIS, were used to categorize the exposure as body weight and body mass index (BMI). Body weight was *a priori* divided into six 20-pound categories (80–110 pounds, 111–130 pounds, 131–150 pounds, 151–170 pounds, 171–190 pounds, and > 190 pounds) as a way to assess a possible dose–response relationship between body weight and OC failure. BMI was divided into the four World Health Organization categories of underweight (< 20), normal (20–24.9), overweight (25–29.9), and obese (≥ 30). The selected BMI categories are widely used in studies of reproductive outcomes (11–14). The following self-reported variables were considered as potential confounding factors: age, marital status, education, poverty level, race/ethnicity, parity, dual method use (use of OCs plus another contraceptive method), and fecundity.

Information on age, marital status, educational level, poverty level, and parity came from the 1993 NHIS while information on race/ethnicity, dual method use, and fecundity came from the 1995 NSFG. The NSFG created fecundity variable was based on women's responses to the reproductive history portion of the interview. A woman was classified as subfecund if she reported that it would be difficult for her and/or her current husband/partner to conceive or deliver a baby or if a medical doctor advised her never to become pregnant (15). If a woman reported having a space of 3 or more years of marriage or cohabitation during which she used no contraception, had no months of non-intercourse, and never had a pregnancy, the NSFG classified her as having a long interval. Women who were not sterile and did not meet the criteria of subfecund or long interval were classified as fecund by the NSFG. For our purposes, we collapsed the NSFG definitions of subfecund and long interval into one category (subfecund).

### Identification of Outcome

The NSFG collected a month-to-month history of a woman's contraceptive use from January 1993 through the month of her interview in 1995, as well as dates of conception that occurred during this period. We classified OC failures to be all conceptions, regardless of final pregnancy outcome, among women who reported using OCs during the month of conception.

### Analysis

Women were excluded from the analysis if height and weight measurements were missing (n = 118). Additionally, women who used OCs though they or their partners were sterile (n = 24) and women who provided no information on their marital status or education (n = 7) were excluded. Thus, 1916 women remained for analysis.

A survival analysis was conducted using a Cox proportional hazards model. All women who reported using OCs in January 1993 during their 1995 NSFG interviews were included in the cohort and followed until the month of their interview in 1995. Women who reported conceiving while using OCs were considered to have a failure. Once a woman had an OC failure, she did not contribute any additional time to the cohort. Thus, we allowed at most one failure per woman. Observations for other women were censored either when they stopped using OCs during the study period without conceiving or at the end of the study period. A total of 41 women stopped and restarted OCs during the study period. We did not include this subsequent follow-up time since we did not know the circumstances surrounding a woman's decision to stop and restart OCs.

Unadjusted hazard ratios and 95% confidence intervals (CIs) were obtained to provide a crude association of body weight/BMI and OC failure and to determine other risk factors for OC failure. Age, marital status, education, poverty level, race/ethnicity, parity, dual method use, and fecundity were entered in the model as potential confounding factors. Adjusted hazard ratios and 95% CIs were obtained to model the association between body weight/BMI and OC failure while accounting for confounding. We assessed confounding by dropping each variable from the model one at a time. If the percent change in the hazard ratio was less than 10% and resulted in a more precise CI, we considered dropping the variable from the model (16).

The analyses were conducted using three different study populations. First, all 1916 women were analyzed, regardless of their fecundity status. Second, all 1916 women were analyzed while controlling for their fecundity status as determined in 1995. Finally, the analysis was conducted in only those women classified as being fecund (n = 1763).

Since the NSFG does not contain information on a woman's adherence with an OC regimen over the entire study period and adherence is related to OC failure, we conducted a secondary analysis to determine if there was an association between body weight/BMI and adherence. Women using OCs at the time of their NSFG interview in