



Original Contribution

Obesity and Oral Contraceptive Failure: Findings from the 2002 National Survey of Family Growth

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Oral contraceptives are the most popular reversible method of contraception in the United States. Although most women using oral contraceptives are reliably protected against pregnancy, nearly half of the 3 million unintended pregnancies in the United States annually occur among the 90% of women who use contraception. Recent findings suggest that obesity may reduce the biologic effectiveness of oral contraceptives. The purpose of this study was to further investigate the potential obesity–oral contraceptive failure association using 2002 National Survey of Family Growth data. In this retrospective cohort of 1,491 women, body mass index (kg/m^2) was derived from self-reported values, and oral contraceptive failure was defined as conceptions that occurred while women used oral contraceptives. Hazard ratios and 95% confidence intervals were obtained from Cox proportional hazards models. Obese women (body mass index ≥ 30 vs. 18.5–24.9) had an increased risk of oral contraceptive failure (hazard ratio = 1.59, 95% confidence interval: 0.94, 2.68). Results were largely attenuated after adjustment for age, race/ethnicity, and parity. This population-based study found no association between obesity and oral contraceptive failure. While it is possible that misclassification or uncontrolled confounding obscured a true relation, it may be that there is no association. Large, prospective studies are needed to assess whether obesity plays a biologically relevant role in oral contraceptive effectiveness.

contraceptives, oral; obesity; women's health

Abbreviations: BMI, body mass index; CI, confidence interval; HR, hazard ratio; NSFG, National Survey of Family Growth; OR, odds ratio.

In 2001, 3.1 million of the 6.4 million pregnancies in the United States were classified as unintended (1). Unintended pregnancies are costly in both an economic sense and a sociobehavioral sense. Direct medical costs associated with unintended pregnancies in the United States reached nearly \$5 billion in 2002 (2). Unintended pregnancies have also been shown to be associated with domestic violence, divorce, inadequate preconceptional and prenatal care, use of alcohol during pregnancy, and low birth weight deliveries (3–6). Consequently, one of the Healthy People 2010 goals is to increase the proportion of intended pregnancies to 70 percent (7).

Nearly half of all unintended pregnancies occur in women who report using some type of contraceptive method during the month they conceive (1). Although some of the unintended pregnancies that occur in women using contraception may be due to noncompliance or ineffective use (8, 9–11), more recent literature suggests that obesity may be affecting the effectiveness of some contraceptive methods. Secondary analyses from efficacy trials of the vaginal ring, Norplant (Wyeth-Ayerst, Madison, New Jersey), and the transdermal patch indicate that obesity is associated with an increased risk of contraceptive failure (12–17). However, studies that examined the association between obesity and

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oral contraceptive failure as their primary hypothesis have been conflicting (18–22). The purpose of this study was to further investigate the potential obesity–oral contraceptive failure association by using data from the 2002 National Survey of Family Growth (NSFG).

MATERIALS AND METHODS

Study population and design

The NSFG provides national estimates of factors affecting pregnancy and birth rates among the noninstitutionalized population of the United States (23). Although prior cycles of the NSFG relied on responses from only women to gather information on these factors, the 2002 NSFG also included men. Between March 2002 and March 2003, a national probability sample of 12,571 men and women 15–44 years of age completed in-person interviews with trained personnel (78 percent response rate for men, 80 percent response rate for women). During these in-person interviews, women completed in-depth contraceptive method histories covering the period from January 1999 until the month of their interview. Life history calendars were used to aid women in recalling their contraceptive method histories as well as other events measured by the NSFG (23). The present retrospective cohort study consisted of the 1,491 women who indicated that they were using oral contraceptives as of January 1999.

Measurement of exposure and covariates

Self-reported height and weight were used to calculate body mass index (BMI; kg/m^2). Categories of BMI were considered in two ways. First, we divided BMI into the following four categories: <20 (underweight), 20–24.9 (normal), 25–29.9 (overweight), and ≥ 30 (obese). These categories were selected because they are widely used in studies of reproductive outcomes, including prior studies of oral contraceptive failure (21, 22, 24–28). We also categorized BMI according to the World Health Organization's International Classification: <18.5 (underweight), 18.5–24.9 (normal), 25–29.9 (overweight), and ≥ 30 (obese) (29, 30). The following self-reported variables were considered as potential confounding factors: age, marital status, education, poverty level, race/ethnicity, future pregnancy intention, parity, and dual-method use (use of oral contraceptives plus another contraceptive method).

Identification of outcome

With the aid of interviewers, women created life history calendars, where they recorded key life events that would help them in remembering dates (23). During interviews, each woman provided a month-to-month history of her contraceptive use from January 1999 through the month of her interview. Dates of conception (i.e., dates of any self-reported pregnancy) that occurred during this same time period were also collected. Women were able to refer to their life history calendars throughout their interviews, including when they answered questions about contraceptive use and

pregnancy histories. All conceptions, regardless of final pregnancy outcome, among women who reported using oral contraceptives during the month of conception were considered oral contraceptive failures.

Analysis

Women who reported using oral contraceptives although they or their partners were surgically sterile or unable to have a child for another reason were excluded from the analysis ($n = 176$). In addition, women less than 18 years of age ($n = 5$) and women who did not provide a height measurement ($n = 9$) were excluded. Thus, 1,301 women remained for analysis.

A survival analysis was conducted by using a Cox proportional hazards model. Women who reported using oral contraceptives in January 1999 were included in the cohort and were followed up until the month of their interview. Women who reported using oral contraceptives during the month they conceived were considered to experience a failure. Observations for other women in the cohort were censored when they stopped using oral contraceptives during the study period without conceiving or at the end of the study period. Once a woman had an oral contraceptive failure, she did not contribute any additional time to the cohort, thus allowing at most one failure per woman.

Unadjusted hazard ratios and 95 percent confidence intervals were obtained to provide a crude association of BMI with oral contraceptive failure and to identify other risk factors for such failure. Potential confounding factors that altered the BMI–oral contraceptive failure hazard ratio estimates by 10 percent or more were included in the final models (31). Ultimately, age, race/ethnicity, and parity were confirmed as confounders in this data set. Because the NSFG utilizes complex sampling designs, a weighted analysis must be used to accurately represent the data. In particular, sampling weights are used to adjust for the different sampling rates, response rates, and coverage rates seen among subgroups of the population so that unbiased national estimates can be made from the NSFG data (32). SUDAAN Software for the Statistical Analysis of Correlated Data, release 8.0.2 (Research Triangle Institute, Research Triangle Park, North Carolina), was used in all analyses.

RESULTS

The majority of study participants were between 26 and 35 years of age, married, well educated, above the poverty threshold, and non-Hispanic White (table 1). Of the 142 oral contraceptive failures that occurred during the study period, the final pregnancy outcomes were as follows: 44 percent livebirths ($n = 63$), 23.7 percent induced abortions ($n = 37$), 25.3 percent stillbirth or spontaneous abortion ($n = 34$), and 7.0 percent currently pregnant ($n = 8$). Women ≤ 25 years of age were at an increased risk of oral contraceptive failure (hazard ratio (HR) = 3.04, 95 percent confidence interval (CI): 1.54, 5.99), as were women living with a partner and non-Hispanic Black women (HR = 2.07, 95 percent: 1.09,

TABLE 1. Demographic and medical characteristics of women aged 15–44 years who used oral contraceptives as of January 1999 ($n = 1,301$), 2002 National Survey of Family Growth, United States

Characteristic	Sample size	Weighted %*
Demographic		
Age (years)		
≤25	421	30.3
26–35	616	47.9
>35	264	21.9
Marital status		
Married	611	53.7
Living with a partner	144	10.8
Separated, divorced, or widowed	136	8.0
Single	410	27.6
Educational level		
Less than high school	145	8.9
High school	267	18.4
At least some college	655	53.8
More than college	234	18.9
Poverty level		
Above the poverty threshold	816	66.5
Below the poverty threshold	485	33.5
Race/ethnicity		
Hispanic	213	11.1
Non-Hispanic White	847	73.8
Non-Hispanic Black	192	10.7
Other	49	4.4
Future pregnancy intention		
Would like a child in the future	777	59.7
Would not like a child in the future	524	40.3
Medical		
Parity		
0	623	47.1
≥1	678	52.9
Dual-method use of contraception		
Yes	150	10.9
No	1,151	89.1
Body mass index (kg/m ²)		
<20	145	12.8
20–24.9	589	46.3
25–29.9	321	23.3
≥30	246	17.6
<18.5	25	2.8
18.5–24.9	709	56.3
25–29.9	321	23.3
≥30	246	17.6
Oral contraceptive failure		
Yes	142	10.0
No	1,159	90.0

* Percentages may not total 100 because of rounding.

3.95 and HR = 2.62, 95 percent CI: 1.54, 4.45, respectively; table 2). Hispanic and non-Hispanic Black women were more likely to be overweight or obese compared with non-Hispanic White women (odds ratio (OR) = 1.64, 95 percent CI: 1.11, 2.41 and OR = 3.82, 95 percent CI: 2.46, 5.95, respectively), whereas women ≤25 years of age and nulliparous women were less likely to be overweight or obese (OR = 0.53, 95 percent CI: 0.37, 0.76 and OR = 0.58, 95 percent CI: 0.45, 0.70, respectively; data not shown).

In unadjusted models, women with a BMI of ≥30 had an increased risk of oral contraceptive failure compared with women of normal BMI, although this result was not statistically significant. Results were similar for both definitions of BMI (HR = 1.61, 95 percent CI: 0.94, 2.76 when 20–24.9 was used as the referent and HR = 1.59, 95 percent CI: 0.94, 2.68 when 18.5–24.9 was used as the referent). When adjusted for age, race/ethnicity, and parity, the results were largely attenuated and did not attain statistical significance (table 3). Specifically, when the World Health Organization BMI classification was used, obese women had 1.30 times the risk of oral contraceptive failure compared with women with a normal BMI (95 percent CI: 0.78, 2.18). Again, results were similar when the other BMI classification was considered.

DISCUSSION

In this population-based study, we found a weak, although not statistically significant, association between obesity and oral contraceptive failure. However, associations were largely attenuated after adjustment for age, race/ethnicity, and parity.

This study has several limitations. Since height and weight were self-reported by study participants, nondifferential misclassification of the exposure is possible. Numerous studies indicate that self-reported height and weight give an accurate representation of true height and weight (33). Since women tend to overreport their height and underreport their weight by a few pounds (1 pound = 0.45 kg), BMI derived from self-reported height and weight will underestimate true BMI. Although any resulting nondifferential misclassification will likely bias the results toward the null, bias away from the null is possible since the exposure category is polytomous. Minimizing this possibility is the fact that there were sufficient numbers of women of normal, overweight, and obese BMI who did not experience an oral contraceptive failure (34).

Nondifferential misclassification of the outcome is also possible since women recalled both their contraceptive use histories and dates of conception for approximately a 2-year time period. Self-reported oral contraceptive histories have been shown to be reproducible and valid, particularly in terms of total duration of use (35–41). However, recall of start and stop dates for oral contraceptive use is less accurate (37, 39). The accuracy of self-reported dates of conception is less certain. Among women who have delivered liveborn infants, self-report of pregnancy-related variables such as time to pregnancy and gestational age is valid, even after

TABLE 2. Hazard ratios and 95% confidence intervals for women aged 15–44 years who used oral contraceptives as of January 1999 by whether they experienced oral contraceptive failure,* according to demographic and medical characteristics, 2002 National Survey of Family Growth, United States

Characteristic	No. of failures	HR†	95% CI†
Demographic			
Age (years)			
<25	68	3.04	1.54, 5.99
26–35	60	1.93	0.87, 4.27
>35	14	1.00	Referent
Marital status			
Married	52	1.00	Referent
Living with a partner	21	2.07	1.09, 3.95
Separated, divorced, or widowed	18	1.52	0.85, 2.72
Single	51	1.59	0.93, 2.72
Educational level			
Less than high school	25	1.44	0.85, 2.42
High school	37	1.22	0.74, 2.03
At least some college	68	1.00	Referent
More than college	12	0.66	0.31, 1.42
Poverty level			
Above the poverty threshold	73	1.00	Referent
Below the poverty threshold	69	1.59	1.03, 2.46
Race/ethnicity			
Hispanic	24	1.26	0.72, 2.23
Non-Hispanic White	75	1.00	Referent
Non-Hispanic Black	37	2.62	1.54, 4.45
Other	6	1.20	0.42, 3.43
Future pregnancy intention			
Would like a child in the future	89	1.00	Referent
Would not like a child in the future	53	1.13	0.74, 1.73
Medical			
Parity			
0	42	0.39	0.25, 0.60
≥1	100	1.00	Referent
Dual-method use of contraception			
Yes	15	0.74	0.42, 1.31
No	127	1.00	Referent
Body mass index (kg/m ²)			
<20	16	1.14	0.48, 2.66
20–24.9	59	1.00	Referent
25–29.9	35	1.15	0.71, 1.87
≥30	32	1.61	0.94, 2.76
<18.5	1	1.26	0.17, 9.47
18.5–24.9	74	1.00	Referent
25–29.9	35	1.14	0.71, 1.82
≥30	32	1.59	0.94, 2.68

* Conception during oral contraceptive use.

† HR, hazard ratio; CI, confidence interval.

TABLE 3. Adjusted hazard ratios* and 95% confidence intervals for the association between body mass index and oral contraceptive failure among women aged 15–44 years who used oral contraceptives as of January 1999, 2002 National Survey of Family Growth, United States

Body mass index (kg/m ²)	No. of failures	Adjusted HR†	95% CI†
<20	16	1.28	0.55, 2.98
20–24.9	59	1.00	Referent
25–29.9	39	0.93	0.56, 1.53
≥30	32	1.35	0.79, 2.30
<18.5	1	1.26	0.14, 11.62
18.5–24.9	74	1.00	Referent
25–29.9	35	0.89	0.55, 1.45
≥30	32	1.30	0.78, 2.18

* Adjusted for age, race/ethnicity, and parity.

† HR, hazard ratio; CI, confidence interval.

a long duration of recall (42–44). However, the accuracy of pregnancy-related variables, including dates of conception, among women who have had a spontaneous or induced abortion is unclear. Because the definition of oral contraceptive failure is derived from both the contraceptive and pregnancy history responses, it is possible that nondifferential misclassification of the outcome occurred and biased the results toward the null.

Prior research has found that only 50–60 percent of all induced abortions are reported on the NSFG (45). Although the NSFG has changed the data collection process, including using audio computer-assisted self-interviewing for sensitive topics such as induced abortion, this information remains underreported. Of women seeking induced abortions, more than half report using contraception during the month they became pregnant (46). Thus, it is possible that women who participated in the NSFG and also obtained an induced abortion may have not reported their pregnancies at all or reported them as another event, such as a spontaneous abortion. The extent to which BMI is related to these possibilities is largely unknown. To further explore these possibilities, we conducted a sensitivity analysis using data on the percentages of contraceptive failures and unintended pregnancies that end in livebirths. The conclusions remained unchanged over a broad range of reasonable assumptions regarding selection probabilities. However, when more conservative assumptions for these selection probabilities were considered, the associations tended to increase in magnitude. Thus, the possibility of potential bias related to underreporting of induced abortion cannot be completely discounted.

Although we controlled for a number of variables associated with both BMI and oral contraceptive failure, we were not able to control for all potential confounding factors since we were limited by the questions asked during the NSFG interviews. Specifically, we lacked information on frequency of sexual intercourse and adherence to an optimal oral contraceptive regimen. Even though these two factors are major determinants of unintended pregnancy among oral contraceptive users (47), their associations with BMI are

unclear. A small longitudinal study of oral contraceptive users found no association between BMI and frequency of sexual intercourse or adherence (48). However, it is possible that failure to control for these two variables could result in over- or underestimation of the obesity–oral contraceptive failure association.

Prior literature on obesity and risk of oral contraceptive failure is sparse, and results have been conflicting. A study of women who took part in the Oxford Family Planning Association contraceptive study (initial recruitment from 1968 to 1974) found no association between body weight and oral contraceptive failure rates after adjustment for age and parity (18). However, 75 percent of the exposure to oral contraceptives in this study was to preparations containing ≥ 50 μg of estrogen (49), which have rarely been prescribed in the last two decades. Thus, it may be inappropriate to extrapolate the results of this study to current oral contraceptive users.

Holt et al. (19, 20) investigated the obesity–oral contraceptive failure association in two separate studies of women residing in Washington State. In the first study, a retrospective cohort of 755 oral contraceptive users, they found that women who weighed ≥ 70.5 kg (≥ 155 pounds) had a statistically significant increased risk of oral contraceptive failure compared with women who weighed less than 70.5 kg (relative risk = 1.6, 95 percent CI: 1.1, 2.4) after adjustment for parity. The second study, a case-control study of 248 cases and 533 controls, also found an association between obesity and oral contraceptive failure. Specifically, women whose BMI was >27.3 had 1.58 times the risk of having an oral contraceptive failure compared with women whose BMI was <27.3 (95 percent CI: 1.11, 2.24), after adjustment for age, parity, and reference year. Cases and controls were interviewed approximately 7 months after their reference month (defined as a positive pregnancy test for cases). Information on factors including height, weight, adherence to an oral contraceptive regimen, and frequency of sexual intercourse during the reference month was self-reported during these interviews. Thus, inaccuracies may be associated with the classification of these variables.

Brunner and Hogue (21) used 1995 NSFG data to investigate the obesity–oral contraceptive failure association among 1,916 women. In this study, obese women (BMI ≥ 30) had nearly twice the risk of oral contraceptive failure compared with women in the 20–24.9 BMI category (HR = 1.80, 95 percent 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 was no longer statistically significant (HR = 1.51, 95 percent CI: 0.81, 2.82). This study suffered from the same limitations as the current study, although its sample size was larger.

Another population-based case-cohort study ($n = 358$) that used data from the Pregnancy Risk Assessment Monitoring System and the Behavioral Risk Factor Surveillance System found that obese women had nearly a threefold risk (OR = 2.82, 95 percent CI: 1.05, 7.58) of oral contraceptive failure compared with women with a normal BMI (22). However, when the authors adjusted for education, income, and race/ethnicity, the risks for overweight and obese

women were attenuated and were no longer statistically significant (OR = 1.58, 95 percent CI: 0.49, 5.10).

In this population-based study, we found no association between obesity and oral contraceptive failure after adjustment for confounders. Although it is possible that misclassification or uncontrolled confounding obscured a true relation, it may be that there is no association between obesity and oral contraceptive failure. Large, prospective studies are needed to assess whether obesity plays a biologically relevant role in oral contraceptive effectiveness.

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