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Contraceptive Failures in Overweight and Obese Combined Hormonal Contraceptive Users

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Abstract

Objective—To estimate weather contraceptive failure rates among combined oral contraceptive pill, patch, and vaginal ring users was associated with increasing body mass index (BMI).

Methods—Females enrolled in a large contraceptive study offering the reversible method of their choice at no cost, were followed for 2 to 3 years. We compared the failure rates (pregnancy) among users of the oral contraceptive pill (OCP), transdermal patch, and contraceptive vaginal ring stratified by BMI.

Results—Among the 7,486 participants available for this analysis, 1,523 chose OCPs, patch, or ring at enrollment. Of the 334 unintended pregnancies, 128 were found to be a result of pill, patch, or ring failure. Three-year failure rates were not different across BMI categories (BMI <25: 8.44% (95% CI 6.1, 11.5), BMI 25–30: 11.03% (95% CI 7.5, 16.0), BMI >30: 8.92% (95% CI 7.6, 11.5). Increasing parity (HR: 3.06, CI 1.31–7.18), and history of a previous unintended pregnancy (HR: 2.82, CI: 1.63–4.87), but not BMI, were significant risk factors for unintended pregnancy.

Conclusion—Overweight and obese females do not appear to be at increased risk for contraceptive failure when using the contraceptive pill, patch, or vaginal ring.

Introduction

The epidemic of obesity worldwide is continuing to grow. Current statistics estimate that 61.3% of adult females in the United States are classified as overweight, with 34.3% classified as obese. (1) The remarkable growth can be best illustrated when we compare these rates to just ten years ago when only 20.8% of the US female population was classified as obese. (1)The increase in obesity has led to the development of sub-classifications within the larger obese group; class I: BMI 30–34.9, class II BMI 35–39.9 and class III BMI ≥ 40. (2) In 2007–2008, 10.5% of reproductive age females age 20–39 were class II obese and 7.5% were class III. (1)

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Equally discouraging is the prevalence of unintended pregnancy which despite widespread use of contraception is still estimated to be 49%. (3) Preventing unplanned pregnancy in obese females is especially important given the associated comorbidities and pregnancy complications. Still understudied is the role that obesity plays in contraceptive effectiveness. Most contraceptive research has been limited to females who are within 130% of ideal body weight. To date, there has been conflicting data regarding contraceptive failure rates among overweight and obese females using combined hormonal contraception (oral contraceptive pill (OCP) and the contraceptive patch and ring). (4–7) Holt and colleges performed a case-control study evaluating pregnancy failures in oral contraceptive users and suggest that being overweight may be associated with an increased risk of pregnancy while using OCPs. (8) The methodology of this study has been challenged however citing recall bias, as well as flaws in the design and data collection. (9) Among the proposed mechanisms for increased failure rates are incomplete ovarian suppression leading to more frequent ovulation and altered bioavailability of the active drugs perhaps because of variable rates of metabolism and clearance or differences in steroid distribution and absorption. (10–12) Thus, accurate contraceptive counseling regarding failure rates in obese females is difficult.

The objective of our study was to estimate whether contraceptive failure rates were associated with increasing body mass index (BMI). Our null hypothesis was that there would be no difference in failure rates with increasing BMI.

Materials and Methods

The methodologic details of the Contraceptive CHOICE Project have been previously published (13) and enrolled participants from August 2007 through September 2011. A brief description of the project and this specific analysis are described below. The CHOICE protocol was approved by the Institutional Review Board at Washington University in St. Louis.

The CHOICE Project is a prospective cohort study of 9256 reproductive-age females in the St Louis area that was designed to promote long-acting reversible contraceptive (LARC) methods by reducing cost, knowledge, and access barriers. Each potential participant received standardized contraceptive counseling on all available reversible methods. This counseling included information regarding effectiveness, common side-effects, as well as risks and benefits for each method. (14) Each participant was then provided with the reversible contraceptive method of her choice at no cost for three years (first 5090 participants) or two years (remainder of the cohort). Participants choosing oral contraceptive pills could choose from various types based on their own preference or provider recommendation. Ethinyl estradiol dose in the combined hormonal methods ranged from 20mcg to 35mcg. Participants were allowed to change methods as many times as desired during the follow-up period.

Inclusion criteria for the CHOICE project included 1) age 14–45 years; 2) not currently using contraception or willing to change reversible contraceptive methods; 3) not desiring pregnancy in the next 12 months; 4) sexually active or intending sexual activity with a male partner in the next six months; 5) reside in or seeking health care in the St Louis area; and 6)

able to consent in English or Spanish. Females were excluded if they had a history of a previous sterilization procedure. This analysis includes the first 7,486 participants enrolled in the CHOICE Project, of which 1,523 chose the contraceptive pill, patch, or vaginal ring at enrollment. All participants who used the OCP, patch or vaginal ring at any point during their study enrollment and had their body mass index (BMI) calculated at the time of enrollment using objectively measured weight and height were included.

Participants were followed with telephone interviews at 3 and 6 months, and every 6 months thereafter and received a $10 gift card for each completed follow-up survey. The possibility of contraceptive failure was assessed at each follow-up survey with questions about missed menses and the participant's perception of the possibility of pregnancy. Any participant concerned about pregnancy was offered a clinic appointment for urine pregnancy testing. All pregnancies were documented in a pregnancy log. Each participant with a documented pregnancy was then asked if the pregnancy was planned, and what contraceptive method they were using at the time. A true contraceptive failure was defined as pregnancy that occurred during a period of OCP, patch, or vaginal ring use. Intended or planned pregnancies and pregnancies occurring with other contraceptive method use (or no method) were excluded.

The primary outcome of this analysis was contraceptive failure in females using the contraceptive pill, patch, or vaginal ring by BMI class. Participants were classified in one of 4 weight categories according to their BMI as defined by the World Health Organization. (15) Normal weight woman are defined as those with BMI less than 25, overweight females with BMI 25.0–29.9, obese females with BMI 30.0–39.9, and morbidly obese with BMI ≥ 40.

All statistical analyses were performed using STATA 11(StataCorp). Significance levels were set at 0.05. Demographic characteristics of all participants identified for this analysis are presented as frequencies, percentages, means, and standard deviations. Baseline characteristics of females in each method group (contraceptive pill, patch, and ring) were compared using chi-square and Fisher's exact tests for categorical variables and Student's *t*-test for normally distributed continuous variables. Normality was evaluated by checking on the distribution of the variable via histogram charts. Demographic characteristics of females were also compared across four BMI categories. Contraceptive failures across methods (OCPs, ring, and patch) were combined for the remainder of analyses. Kaplan-Meier failure curves were used to estimate the contraceptive failure rates by BMI group. The Log-rank test was performed to test the equivalence of contraceptive failure rates among BMI groups. Cox proportional hazard models were used to estimate the hazard ratios for unintended pregnancy between different BMI categories. Because we measured distinct segments of contraceptive method use by each participant, there are correlations among different periods of contraceptive use from the same participant. To account for this correlation effect, we used robust variance-covariance estimation methods. (16) Univariable analyses were conducted to evaluate crude associations between each baseline covariate and unintended pregnancy. Confounding was defined as a greater than 10% relative change in the association between unintended pregnancy and BMI category with or without the covariate of interest in the model. Confounders were included in the final multivariable model.

To confirm we had an adequate sample size to detect a two-fold difference in failure rates across BMI groups a post-hoc sample size using nQuery software was calculated. Using the observed failure rate at three years of 8% in the normal weight group as the reference, we determined that 274 distinct periods of pill, patch, or ring use per BMI group would be required to achieve 80% power with an alpha error of 0.05. We combined our obese and morbidly obese groups to maintain 80% power for our analyses.

Results

From August 2007 through May 2011, we identified 334 unintended pregnancies, of which 128 were attributed to pill, patch, or vaginal ring failure. Table 1 describes the demographic characteristics of females choosing the contraceptive pill, patch, or vaginal ring at enrollment by method type. The demographic characteristics of pill and ring users were similar. Pill and ring users were more likely to be white, educated, have private insurance, and nulliparous than were patch users. Patch users were more likely to be black, have less education, report low socioeconomic status, no insurance, higher parity, and a history of unintended pregnancy and abortion. Despite demographic differences, one-year contraceptive failure rates among the three methods were similar (pill: 5.6%, patch: 4.6%, vaginal ring: 3.4% p=0.22). In addition, no statistically significant interactions were found between contraceptive method and BMI; thus, the three methods were combined for analysis across BMI categories.

Table 2 describes demographic and reproductive characteristics of participants by BMI category. Normal weight females (n=1476) contributed 1,473 woman-years of pill, patch, or vaginal ring use. Overweight females, BMI 25–30 (n=817), contributed 694 women-years of pill, patch, or vaginal ring use. Obese females, BMI 30–40 (n=702), contributed 572 women-years of pill, patch, or vaginal ring use. And finally, morbidly obese females, BMI ≥ 40 (n=171), contributed 124 women-years of pill, patch, or vaginal ring use. As BMI category increased, so did the mean age. Overweight, obese, and morbidly obese females were more likely to be black, have less education, lower socioeconomic status, higher parity, and a history of unintended pregnancy and abortion.

The total number of failures and cumulative failure rates per year for 3 years by BMI class are presented in Table 3. As expected, the cumulative failure rates increase with each year, but do not appear to differ across BMI categories (3-year contraceptive failure range: 8.4–11.0% 95% CI 6.1, 16.0%). The probability of contraceptive failure using log-rank testing was not different (p=0.34) when BMI classes are compared (Figure 1).

Table 4 shows the crude and adjusted risk of contraceptive failure associated with BMI and participant characteristics. For the final model, obese and morbidly obese classes were combined. We found no difference in the risk of unintended pregnancy by BMI class. While older age was negatively associated with unintended pregnancy (HR=0.9, CI: 0.85–0.95), increasing parity (HR: 3.06, CI: 1.31–7.18) and history of unintended pregnancy (HR= 2.82, CI: 1.63–4.87) remained significant risk factors for contraceptive failure.

Discussion

We found no difference in contraceptive failure rates among females using the pill, patch, or vaginal ring across BMI categories. Contraceptive failure is influenced by many factors including compliance, frequency of intercourse, ovulatory function, and the inherent efficacy of the contraceptive method. The potential risk of combined hormonal contraceptive failure with increasing BMI is not well understood, but is extremely important as the epidemic of obesity continues to grow, and pregnancy in this population is associated with significant maternal and neonatal morbidity. (17–22) Although there may be sound biologic plausibility for theories of increased failure rates among obese females, (10, 23) we did not find clinically important differences in contraceptive failure rates with increasing BMI.

Our findings support previous studies that have been limited by self-reported BMI and contraceptive use, as well as small numbers of obese subjects. (24–26) One possible explanation for the similar effectiveness of combined hormonal contraceptives is that fertility is reduced with increasing BMI. (22, 27–29) The contraceptive efficacy of the pill, patch, or vaginal ring in overweight and obese females, even if reduced compared to normal weight females, results in similar levels of pregnancy protection to that of a normal weight woman with intact fertility. Although understanding the mechanism by which reversible contraceptives work in obese females may be important, it is more critical to be able to assure females that their risk of pregnancy when using these methods is not increased because of their BMI.

Strengths of our study include the large sample size of overweight and obese females, prospective design, objective assessment of weight and BMI, and prospective assessment of contraceptive failures. There are few reports assessing clinical outcomes in females greater that 130% of ideal body weight and this study begins to fill that knowledge gap. The prospective design of the Contraceptive CHOICE Project incorporates assessment of contraceptive use through different sources (frequent subjective follow-up surveys, and objective pharmacy data). Coupling this with low rates of loss to follow-up (18% at 3 years) allowed for accurate classification of typical (real world) method-failure pregnancies.

Our study is not without limitations. As an observational study, the possibility of residual confounding still exists. The number of patch users in our cohort is limited, and these females have different demographic characteristics than pill or vaginal ring users. In addition, the demographic characteristics of CHOICE participants may differ from other populations, in turn limiting the generalizability of our findings. However, our adjusted analysis demonstrated no effect of BMI on contraceptive effectiveness even after controlling for baseline differences. The sample size of our BMI groups exceeded the calculated sample size required to detect a clinically significant two-fold difference, with the exception of the morbidly obese group (BMI ≥ 40). This group contributed 124 female years of pill, patch, or ring use, translating into a power of 68% to detect a twofold difference in contraceptive failures in this group. It is important to note that there were only four contraceptive failures in the morbidly obese group using combined hormonal contraception over the three years. As is true with many contraceptive studies, we have relied on self-reported correct use of the

method. Females experiencing pregnancy in the CHOICE Project were asked if the pregnancy was planned and if unplanned, what method of contraception they were using at the time. Those reporting no method use were excluded from the analysis. Additionally, we do not have information of specific oral contraceptive dosing. It is reasonable to think that pills with lower ethinyl estradiol could be less effective in females as BMI increases. Lastly, pregnancy risk is affected by many things including frequency of sexual activity. We did not present data on the frequency of intercourse among all females in the CHOICE Project by BMI; however, previous research has shown no differences in sexual behaviors between BMI categories. (30)

In conclusion, our findings are encouraging in that we found there is no difference in failure rates among overweight, obese, and morbidly obese contraceptive pill, patch, or vaginal ring users. Based on this data, there is no evidence to support a change in contraceptive counseling for females based on BMI alone. However, we have previously shown that failure rates for these methods are far greater than long-acting reversible contraceptive (LARC) methods such as the implant and intrauterine device; (31) thus, LARC methods should be first-line contraceptive options for all females. The contraceptive pill, patch, and ring remain excellent second-tier methods. Overweight and obese females do not appear to be at increased risk of contraceptive failure when using combined oral contraceptive pills, patch, or vaginal ring.

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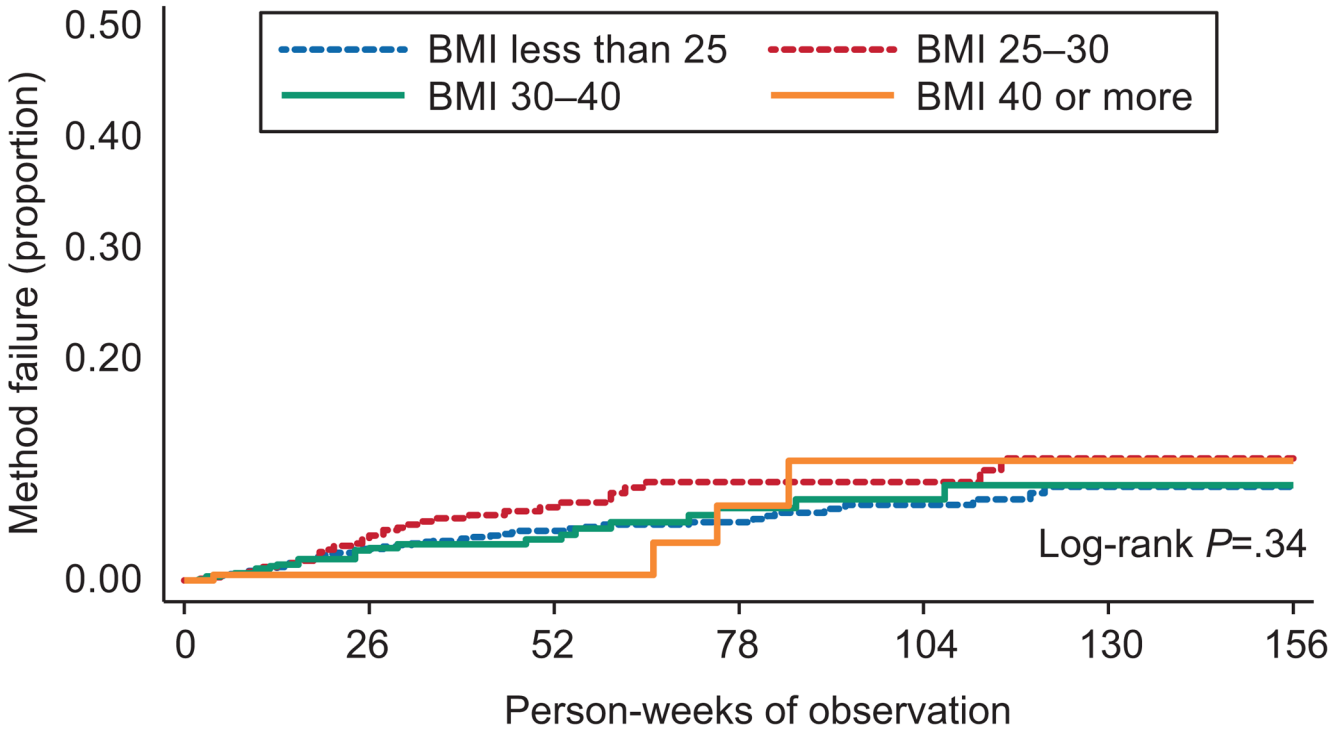

Figure 1.

Kaplan-Meier failure curve. Contraceptive failure rate of pill, patch, and vaginal ring users. Log rank *P*=.34 represents comparison of failure rates across body mass index (BMI) classes over time.

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Table 1

Demographic Characteristics of Pill, Patch, and Ring Users

	Pills (n=779)		Patch (n=143)		Ring (n=601)		*P*
	n	%	n	%	n	%	
Age*	23.7 (5.0)		24.1 (4.4)		24.3 (4.5)	4.5	0.042
Race							<0.001
Black or African American	327	42.1	85	59.4	227	38.2	
White	385	49.5	47	32.9	317	53.3	
Other or multiracial	65	8.4	11	7.7	51	8.6	
Education							<0.001
High school or less	201	25.8	46	32.2	116	19.3	
Some college	350	44.9	66	46.2	266	44.3	
College or graduate school	228	29.3	31	21.7	219	36.4	
Low socio-economic status							0.024
No	427	54.8	64	44.8	345	57.4	
Yes	352	45.2	79	55.2	256	42.6	
Monthly income (US dollars)							0.002
None	135	18.1	23	16.2	74	12.8	
1–800	267	35.9	60	42.3	191	33.1	
801–1600	216	29.0	33	23.2	167	28.9	
1601 or higher	126	16.9	26	18.3	145	25.1	
Insurance							<0.001
None	332	43.1	76	53.5	222	37.6	
Private/student/parent/military	396	51.4	51	35.9	346	58.5	
Medicare/Medicaid/disability	42	5.5	15	10.6	23	3.9	
Parity							0.002
0	584	75.0	81	56.6	420	69.9	
1	124	15.9	38	26.6	116	19.3	
2	53	6.8	17	11.9	45	7.5	
3 or more	18	2.3	7	4.9	20	3.3	
History of unintended pregnancy							<0.001

	Pills (n=779)		Patch (n=143)		Ring (n=601)		*P*
	n	**%**	**n**	**%**	**n**	**%**	
0	445	57.5	52	36.4	330	54.9	
1	191	24.7	48	33.6	152	25.3	
2	82	10.6	17	11.9	60	10.0	
3 more	56	7.2	26	18.2	59	9.8	
History of abortion							<0.001
0	559	71.8	79	55.2	430	71.5	
1	164	21.1	46	32.2	121	20.1	
2	41	5.3	9	6.3	37	6.2	
3 or more	15	1.9	9	6.3	13	2.2	
History of sexually transmitted infection							<0.001
No	551	70.7	82	57.3	373	62.1	
Yes	228	29.3	61	42.7	228	37.9	
Parity							<0.001
0	584	75.0	81	56.6	420	69.9	
1–2	177	22.7	55	38.5	161	26.8	
3 or more	18	2.3	7	4.9	20	3.3	
History of unintended pregnancy							<0.001
No	445	57.1	52	36.4	330	54.9	
Yes	334	42.9	91	63.6	271	45.1	
History of abortion							<0.001
No	559	71.8	79	55.2	430	71.5	
Yes	220	28.2	64	44.8	171	28.5	

*Data are mean (standard deviation).

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Table 2

Demographic Characteristics by Body Mass Index Class

	BMI Lower Than 25 (n=1476)		BMI 25–30 (n=817)		BMI 30–40 (n=702)		BMI 40 or Higher (n=171)		
	n	%	n	%	n	%	n	%	*P*
Age*	23.4 (4.6)		24.7 (5.2)		25.5 (5.8)		27.0 (5.5)		<0.001
Race									<0.001
Black or African American	458	31.2	437	53.7	455	65.0	131	76.6	
White	864	58.9	314	38.6	211	30.1	34	19.9	
Other or multiracial	146	9.9	63	7.7	34	4.9	6	3.5	
Education									<0.001
High school or less	386	26.2	224	27.4	233	33.2	50	29.2	
Some college	611	41.4	388	47.5	324	46.2	90	52.6	
College or graduate school	479	32.5	205	25.1	144	20.5	31	18.1	
Low socio-economic status									<0.001
No	861	58.4	369	45.2	233	33.2	55	32.2	
Yes	614	41.6	448	54.8	469	66.8	116	67.8	
Monthly income (US dollar)									
None	273	19.2	122	15.2	125	18.2	26	15.3	
1–800	514	36.1	274	34.1	181	26.3	52	30.6	
801–1600	365	25.7	246	30.6	236	34.3	59	34.7	
1601 or higher	271	19.0	162	20.1	146	21.2	33	19.4	
Insurance									<0.001
None	529	36.2	359	44.4	320	45.8	96	56.1	
Private/student/parent/military	814	55.8	364	45.0	279	39.9	59	34.5	
Medicare/Medicaid/disability	117	8.0	86	10.6	100	14.3	16	9.4	
Parity									<0.001
0	1070	72.5	435	53.2	297	42.3	78	45.6	
1	248	16.8	212	25.9	200	28.5	50	29.2	
2	116	7.9	110	13.5	132	18.8	28	16.4	
3 or more	42	2.8	60	7.3	73	10.4	15	8.8	
History of unintended pregnancy									<0.001

	BMI Lower Than 25 (n=1476)		BMI 25–30 (n=817)		BMI 30–40 (n=702)		BMI 40 or Higher (n=171)		
	n	%	n	%	n	%	n	%	*P*
0	812	55.1	323	39.7	232	33.1	61	35.7	
1	347	23.6	219	26.9	200	28.6	50	29.2	
2	171	11.6	131	16.1	119	17.0	29	17.0	
3 or more	143	9.7	141	17.3	149	21.3	31	18.1	
History of abortion									<0.001
0	1038	70.3	501	61.3	429	61.1	120	70.2	
1	298	20.2	204	25.0	170	24.2	27	15.8	
2	106	7.2	71	8.7	66	9.4	16	9.4	
3 or more	34	2.3	41	5.0	37	5.3	8	4.7	
History of sexually transmitted infections									<0.001
No	991	67.1	473	57.9	364	51.9	85	49.7	
Yes	485	32.9	344	42.1	338	48.1	86	50.3	
Parity									<0.001
0	1070	72.5	435	53.2	297	42.3	78	45.6	
1–2	364	24.7	322	39.4	332	47.3	78	45.6	
3 or more	42	2.8	60	7.3	73	10.4	15	8.8	
History of unintended pregnancy									<0.001
No	812	55.0	323	39.5	232	33.0	61	35.7	
Yes	664	45.0	494	60.5	470	67.0	110	64.3	
History of abortion									<0.001
No	1038	70.3	501	61.3	429	61.1	120	70.2	
Yes	438	29.7	316	38.7	273	38.9	51	29.8	

*Data are mean (standard deviation).

BMI, body mass index.

Table 3

Failure Rates by Body Mass Index Class

	Year 1			Year 2			Year 3		
BMI	**n**	**Rate %**	**95% CI**	**n**	**Rate %**	**95% CI**	**n**	**Rate %**	**95% CI**
Lower than 25	48	4.51	(3.4–6.0)	9	6.85	(5.1–9.2)	3	8.44	(6.1, 11.5)
25–30	33	6.63	(4.7–9.4)	5	8.87	(6.3,12.4)	2	11.03	(7.5, 16.0)
30 or higher	18	4.80	(4.0,5.9)	9	7.90	(6.4,9.4)	1	8.92	(7.6, 11.5)
30–40	17	3.69	(2.3, 6.0)	6	7.36	(4.6, 11.6)	1	8.61	(5.3, 13.9)
40 or higher	1	0.53	(0.08, 3.7)	3	10.84	(3.8, 29.1)	0	10.84	(3.8, 29.1)

BMI, body mass index; n, number of failures per BMI class per year; CI, confidence interval.

Table 4

Risk of Unintended Pregnancy

	Crude Model		Adjusted Model	
	Hazard Ratio	**[95% CI]**	**Hazard Ratio**	**[95% CI]**
Normal weight	Ref		Ref	
Overweight	1.38	(0.91, 2.10)	1.16	(0.76, 1.78)
Obese	0.97	(0.61, 1.53)	0.71	(0.45, 1.12)
Age	0.95	(0.91, 0.99)	0.91	(0.87, 0.96)
Race				
1 Black or African American	1.84	(1.27, 2.67)	1.15	(0.75, 1.75)
White	Ref		Ref	
Other or multiracial	1.26	(0.64, 2.48)	1.18	(0.61, 2.27)
Education				
High school or less	Ref		Ref	
Some college	0.57	(0.39, 0.83)	0.77	(0.53, 1.13)
College or Graduate school	0.22	(0.12, 0.39)	0.61	(0.32, 1.15)
Low socio-economic status				
No	Ref		Ref	
Yes	1.75	(1.22, 2.51)	0.77	(0.48, 1.26)
Monthly income (US dollars)				
None	Ref		Ref	
1–800	0.87	(0.53, 1.42)	-	-
801–1600	0.69	(0.40, 1.16)	-	-
1601 or higher	0.64	(0.36, 1.16)	-	-
Insurance				
None	Ref		Ref	
Private/student/parent/military	0.47	(0.32, 0.69)	0.63	(0.40, 1.00)
Medicare/Medicaid/disability	1.51	(0.86, 2.66)	0.96	(0.54, 1.70)
Parity				
0	Ref		Ref	
1–2	2.68	(1.86, 3.87)	2.00	(1.2, 3.25)
3 or more	3.13	(1.53, 6.42)	3.06	(1.3, 7.18)
History of unintended pregnancy				
No	Ref		Ref	
Yes	4.07	(2.64, 6.28)	2.82	(1.6, 4.87)
History of abortion				
No	Ref		Ref	
Yes	1.76	(1.24, 2.50)	-	-
History of sexually transmitted infections				
No	Ref		Ref	
Yes	1.44	(1.02, 2.05)	1.02	(0.68, 1.51)

CI, confidence interval.