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Smoking and oral contraceptive continuation

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Abstract

Background—Smoking may be related to early discontinuation of oral contraceptives (OC).

Study design—This was a planned secondary analysis of a randomized clinical trial. Women aged less than 25 initiating OC at 3 inner-city publicly funded family planning clinics enrolled in the study. Subjects reported smoking status at enrollment; 3- and 6-month interviews assessed OC continuation.

Results—One hundred eighty-nine of 1598 participants (12%) were current smokers. Smokers were more often lost to follow-up than non-smokers ($p < 0.01$). Among participants with a 6-month interview, only 26% of smokers and 46% of nonsmokers were continuing OC ($p < 0.001$). After adjustment for confounding factors, smokers were still somewhat less likely to be continuing OC (adjusted OR 0.6, 95% CI 0.4, 1.0). This association was unrelated to number of cigarettes smoked per day.

Conclusions—These data suggest that young smokers may be more likely to discontinue OC within 6 months than nonsmokers. Smoking may be a marker for risk-taking behavior that extends to the premature discontinuation of OC.

Keywords

oral contraceptives; continuation; smoking

1. Introduction

National survey data show that smoking is associated with engaging in “high risk sexual behavior”; for instance, non-use of condoms [1]. Breakthrough bleeding during oral

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contraceptive (OC) use may be more common among smokers [2], which may in turn lead to premature OC discontinuation by smokers. Finally, women with unintended pregnancies are more likely to smoke cigarettes than women with intended pregnancies [3]. These associations, taken together, are all hints that smokers may have lower OC continuation rates than non-smokers. This paper is a planned secondary analysis from a large trial of OC continuation to evaluate whether smokers differ from nonsmokers in OC continuation rates.

2. Materials and methods

Seventeen hundred sixteen (1716) women aged 12–24 years enrolled in a multicenter randomized trial to evaluate the impact of two OC initiation protocols on continuation and unintended pregnancy. Publicly funded family planning clinics in Atlanta, Dallas, and New York City participated as clinical centers. Columbia University was the coordinating center for the study and all participating institutions obtained IRB approval. The main study results have been previously published [4]; this paper focuses on a planned secondary analysis to explore differences in OC continuation between smokers and nonsmokers. In brief, after the clinical encounter during which the clinician made decisions about who received the and how many packs to dispense (based on local protocol and individual judgment), all subjects underwent a detailed baseline interview to assess reproductive history, motivation to avoid pregnancy, smoking status, and many other characteristics. Subjects reported on how many of the past 30 days they had smoked at least one cigarette, and how many cigarettes they typically smoked per day. We used this information to categorize subjects as smokers or nonsmokers, and to characterize the intensity of their smoking in units of cigarettes per day (c/d). We multiplied reported number of smoking days times reported number of cigarettes per day, and divided this product by 30 to generate a smoking level in cigarettes/day. After baseline interviews, subjects began the either immediately or with the next menses, according to the randomized treatment assignment. Subjects in the two treatment groups were well balanced with regard to baseline characteristics, including smoking status. Follow-up telephone interviews to ascertain OC continuation took place 3 and 6 months after enrollment. Follow-up interviews also included detailed, structured questions about five symptoms often attributed to – weight changes, headache, moodiness, visual changes and changes in sexual satisfaction. We collected no information about bleeding patterns [5].

We included subjects in the present analysis if they provided smoking information at baseline, were not already pregnant at baseline, and if they underwent at least one follow-up interview. All women who underwent a 6-month interview were included in the analysis. We classified women as continuing users of OC if they were current OC users at the 6-month interview who reported no episodes of missing 7 days or more of OC during follow-up. We classified women who were continuing users at 3 months, but missed the 6-month interview as lost to follow-up for this analysis; women who had already discontinued OC at 3-month interview were classified as discontinuers regardless of whether they underwent the 6-month interview. This approach is conservative with regard to continuation rates.

We used univariable and multivariable logistic regression analyses to estimate odds ratios and 95% confidence intervals for OC continuation among smokers versus nonsmokers. The adjusted analyses incorporated those baseline characteristics associated with continuation in the main analysis [4]; these variables were age, site, Quick Start, plan to use pills more than 6 months, certainty about wanting to use OC, partner knows of plan to use OC, and remaining OC supplies at the 3-month interview. The sample size of this study was selected to compare differences in OC continuation based on treatment assignment (Quick Start versus conventional start).

3. Results

Fifteen hundred ninety-eight (1598) study participants provided information regarding their smoking status, were not pregnant at the start of follow-up, and thus contributed information to this analysis (Fig. 1). Only 12% of participants (n=189) in this study reported smoking. Smoking levels tended to be light: 37% of smokers smoked less than 1 c/d, 41% smoked 1–5 c/d, and only 22% smoked more than 5 c/d. Most study participants completed the follow-up interviews; however, smokers were substantially more likely to miss the 3-month interview and the 6-month interview than the nonsmokers (18% versus 9%; 24% versus 18%, respectively, $p < 0.01$ for both comparisons). The 189 smokers were older, less likely to be Latina, and less likely to be married or cohabiting than the nonsmokers. Clinicians directly dispensed contraceptive supplies to the subjects in this study based on local clinic protocols; however, it appears that clinicians gave fewer OC packs to smokers than to nonsmokers (Table 1)

At 6 months, 26% of smokers and 46% of nonsmokers were continuing OC users ($p < 0.0001$). The unadjusted odds of OC continuation in smokers was 0.4 (95% confidence interval 0.3, 0.6). After adjustment for age, site, randomization group, and confounding variables [4] the odds of OC continuation in smokers was 0.6 (95% confidence interval 0.4, 1.0). The strength of this association did not vary according to level of smoking; that is, the odds ratios were essentially the same among women who smoked less than 1 c/d and heavier smokers (data not shown). Reporting of symptoms that may be OC side effects was similar among smokers and nonsmokers; 54% and 51%, respectively, reported at least one side effect during follow-up. Smokers and nonsmokers were similar with regard to continuing sexual activity during follow-up.

4. Discussion

In this study of young inner-city, mainly minority women initiating OC at a publicly funded family planning clinic, smoking was a powerful predictor of discontinuing OC within 6 months. Only 26% of smokers, versus 46% of nonsmokers, were still OC users at the 6-month interview. This difference persisted after adjusting for confounding factors, although the 95% confidence interval of the adjusted odds ratio included 1.0.

In the U.S. about 18% of women are smokers; however, only 12% of the women in the present study reported smoking. While under-reporting of smoking is possible, these women were likely to have lower levels of smoking than the general population due to being young and mainly Hispanic [1]. In addition, their high levels of poverty may have contributed to the low daily number of cigarettes smoked. We do not know if the association seen here between smoking and discontinuation is generalizable to more affluent young white women who have higher rates of smoking.

Smokers, who by definition are willing to risk the direct adverse effects of smoking, may be more willing to risk unintended pregnancy than nonsmokers. This explanation is supported by these results, and also by prenatal clinic data in which smokers were more likely to report unintended pregnancy than nonsmokers [3]. In addition, discontinuation among smokers could possibly cur due to a smoking-mediated influence on the frequency of OC related side effects. Our results, however, do not support any difference in non-bleeding related side effects between smokers and nonsmokers. Rosenberg [2] in a combined analysis of data from three Phase 3 clinical trials of new OC, found that smoking OC users reported more breakthrough bleeding than nonsmokers, and speculated that such breakthrough bleeding may contribute to discontinuation. While we did not assess breakthrough bleeding in the present study, our previous two studies of bleeding patterns among OC users found no difference between

smokers and nonsmokers in bleeding patterns identified using diaries [6,7]) In addition, if smoking changed bleeding patterns, one might expect a dose-response effect on discontinuation, which was entirely absent in these data. Thus, we find little to support the belief that breakthrough bleeding or other differential side effects explain the OC discontinuation rates observed here among smokers.

In the present study the subjects were mainly poor and uninsured, and they thus obtained their OC packs directly from the clinic. Overall, most subjects received only 3 packs of OC at the initiation visit; this limited supply may have contributed to the overall abysmal 6-month continuation rates. Smokers, however, received even fewer OC packs than nonsmokers. This extreme limitation of pack supply may contribute to the greater OC discontinuation among the smokers, and suggests that clinicians may perceive that smokers need closer follow-up while using the OC.

Smoking is bad for health at any age; however, in the women aged less than 25 in this study, smoking is NOT a contraindication for OC use. The public health message that smoking and OC use is a dangerous combination applies to women aged 35 or older [8,9]. An unintended consequence of an oversimplified health message against combining smoking and OC use may be that young women quit the OC rather than quit smoking.

Whether public health messages or clinician messages about the risk of smoking and OC use are driving the excessive discontinuation rates seen in this study deserves further study. In the meanwhile, these data indicate that young smokers may be a high risk group for premature discontinuation of OC. Clinicians need to clarify the appropriate health messages and find ways to support young smokers in avoiding pregnancy.

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Figure 1.
Progress of Subjects Through Study

Table 1

Baseline characteristics of participants

Characteristic *	Smoker		Non-smoker		p-value
	n	%	n	%	
Total	189	12	1409	88	-
Age					
< 18 years	87	46	423	30	< 0.001
18-24 years	102	54	986	70	
Race/Ethnicity					
Black	81	43	474	34	< 0.001
Latina	84	44	875	62	
Other **	24	12	60	4	
Education					
less than HS	115	61	904	64	0.37
completed HS	74	39	505	36	
Study Site					
Atlanta	47	25	239	17	< 0.001
New York	113	60	469	33	
Dallas	29	15	701	50	
Relationship					
Married/cohabiting	29	15	581	41	< 0.001
Single	140	74	741	53	
Previous OC use					
No	99	52	853	61	0.03
Yes	90	48	556	39	
Mean OC packs dispensed at baseline (range)		2 (1-6)		3 (1-14)	< 0.001
Assigned to Quickstart	100	53	704	50	-

* Columns may not add to 100% due to missing data and rounding.

** White or Asian