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Smoking prevalence in early pregnancy: comparison of self-report and anonymous urine cotinine testing

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Abstract

Objective—Societal pressures against smoking during pregnancy may lead to a reduction in disclosure of smoking status. The objective of this study was to compare prevalence of smoking at prenatal intake by self-report with anonymous biochemical validation.

Methods—Women receiving care at the Duke Obstetrics Clinic from February 2005 through January 2006 were eligible for evaluation. Self-reported smoking and urine samples were obtained anonymously at prenatal intake. The NicCheckTM I semi-quantitative dipstick was used to detect urinary nicotine, cotinine, and 3-hydroxycotinine. The difference, with 95% confidence interval, between the proportions of smokers by self-report and urine testing was calculated for (1) high-positive vs. low-positive and negative results combined and (2) any positive vs. negative results.

Results—Among 297 subjects, self-reported smoking was 18.2 vs. 14.8% for low-positive and negative results combined with an absolute difference of 3.4%, [−2.9%, 9.6%]. When comparing self-report with any positive result (43.1%), the absolute difference was 24.9%, [17.4%, 32.1%].

Conclusions—Our findings suggest that most pregnant women disclose their smoking and many nonsmokers may have significant second-hand exposure. Universal urinary cotinine screening of pregnant women could aid in appropriately counseling women about second-hand exposure as well as monitoring women at high risk for adverse pregnancy outcomes.

Keywords

Tobacco; pregnancy; self-report

Introduction

Smoking during pregnancy has been associated with adverse outcomes such as spontaneous abortion, fetal demise, premature rupture of membranes, preterm birth, and low birthweight [1,2] Most women of childbearing age in the United States are clearly aware of the risks of smoking during pregnancy, given that approximately 30% quit smoking when they discover

they are pregnant [3–5]. Women who continue to smoke during pregnancy may be reluctant to disclose their smoking, particularly to their prenatal care providers who will probably attempt to persuade them to quit [6]. Women are even less likely to report significant second-hand or environmental tobacco smoke (ETS) exposure as most prenatal care providers do not inquire about ETS. Without knowing a woman's true tobacco exposure during pregnancy, prenatal care providers cannot assist with smoking cessation or minimization of ETS exposure, nor can they carefully monitor for and potentially prevent adverse outcomes.

Several studies have compared self-reported and actual smoking rates during pregnancy via biochemical validation of cotinine, the predominant metabolite of nicotine [7–12]. Findings of these investigations have been inconclusive, with misclassification rates ranging from 3 to 73%. Several of these studies were performed outside the United States where societal attitudes and acceptance toward smoking both during and outside of pregnancy are quite different [8,9,11]. Within the United States, studies have been restricted to publicly funded clinical sites where health compromising behaviors may be higher therefore limiting the generalizability of the results [7,10,11]. Moreover, pregnant women consented to biochemical validation of smoking in all but one of these studies, which may have biased their response to questions regarding their tobacco use [7–9,11,12]. Ross et al. performed anonymous cotinine validation, but their sample population was limited to 98 women who were actively recruited to participate in a Women, Infants and Children (WIC) study [10].

Our study was conducted in a university-based clinic that included both Medicaid and privately insured pregnant women. The purpose of this investigation was to compare the prevalence of smoking based on self-report to the prevalence based on anonymous biochemical validation of tobacco exposure in a diverse academic medical center obstetric population.

Methods

The protocol was reviewed by the Duke Institutional Review Board chair and declared exempt (IRB# 6317-04EX). Women initiating prenatal care at the Duke University Obstetrics Clinic from February 2005 to January 2006 were eligible for anonymous testing. As part of routine practice, all women attended a prenatal intake appointment conducted by obstetric nurses. A full medical, family, and social history—including smoking behavior—was obtained during this visit, as well as blood and urine specimens for routine prenatal laboratory testing. The portion of the urine sample remaining after routine testing was used for analysis. A log was maintained to ensure that no woman was tested more than once. Self-reported smoking behaviors, maternal race, maternal age, and insurance status were obtained from the intake visit and recorded separately from the sample log as overall counts. Smoking behaviors were recorded as nonsmokers, recent quitters (quit smoking since becoming pregnant), or smokers (currently smoking or quit 1–2 days prior to intake visit). Given that the half-life of cotinine in the nonpregnant state is 16–19 h and approximately 9 h during pregnancy, women reporting quitting smoking just prior to their intake visit would likely have detectable urinary cotinine and were thus classified as smokers for the purposes of this analysis.

Urine samples were stored in sterile sample collection containers at 2–8°C and tested within 48 h of collection. No identifying information or smoking behaviors were linked to the urine samples at the time of analysis, allowing for anonymous biochemical validation. The presence of urinary cotinine, 3-hydroxycotinine and nicotine was determined using NicCheck™ I test strips (Mossman Associates, Blackstone, MA). Using NicCheck I provides cotinine levels that are suggestive of active smoking *versus* environmental tobacco

exposure. Test strips were also stored at 2–8°C to protect against excessive light and moisture exposure.

NicCheck I test strips and specimens were removed from refrigeration and returned to room temperature at the time of analysis. Using a pipette, approximately 1 mL of urine was transferred to a test tube without contaminating the sides of the tube. Prior to use, test strips were inspected for bright yellow or dark brown discoloration indicating reagent instability. The test strip was removed from the canister using forceps and placed directly into the urine within the test tube. The NicCheck I test strip contains four different chemicals at defined intervals along the length of the strips [13]. Urine diffuses up the test strip, potassium thiocyanate mixes with chloramine-T on the strip, releasing cyanogen chloride. The cyanogen chloride then reacts with nicotine and its metabolites in the urine. Diethylthio-barbituric acid reacts with the resulting glutaconal-dehyde to produce a pale pink to dark pink color along the length of the test strip and in the liquid remaining at the bottom of the tube. After 15 min, results were read and recorded as negative (no color change), low positive (pale pink color change), or high positive (dark pink color change) as compared to quality control supplied by the manufacturer.

The lower limit of cotinine detection for the NicCheck I test is 200 ng/mL, which only slightly exceeds the range of urinary cotinine among individuals with ETS exposure (0–180 ng/mL) [14]. However, this discriminatory level falls within the lower end of the range of urinary cotinine for active smokers (20–4784 ng/mL) [14–16]. Therefore, the test cannot distinguish between individuals with significant ETS exposure and those who are very light smokers, e.g. less than five cigarettes a day. Furthermore, the test cannot be used to determine the number of cigarettes smoked daily, due to the inter-individual variation in smoking behaviors such as type of cigarette, smoking intensity, rate of nicotine metabolism, and increase in nicotine and cotinine metabolism during pregnancy [17–19]. Although consumption of high levels of niacin (daily dose of 500 mg or greater) as therapy for hypercholesterolemia may result in a false-positive reaction by the NicCheck I test, standard prenatal vitamins contain approximately 40 mg of niacin, and should not affect test results.

The misclassification rate, or difference between proportions of smoking behavior by self-report and urinary testing, was calculated with 95% confidence interval for significance determination. The misclassification rate was determined for (1) high-positive results vs. low-positive and negative results combined and (2) any positive result vs. negative results.

While conducting the Baby Steps study—a randomized trial of nicotine replacement therapy for smoking cessation during pregnancy—the self-reported smoking rate for new obstetric patients seen at the Duke Obstetrics Clinic was 9% [20]. However, based on the reported rates of smoking among women in North Carolina and rates of cessation among pregnant women, we anticipated a true smoking rate for new obstetric patients of approximately 15%. Based on this observed difference, we required a minimal sample size of 240 patients to detect a 6% difference between self-report and biochemically validated smoking rates with 90% power and $\alpha = 0.05$.

Results

Two hundred ninety-seven urine samples obtained from an ethnically diverse population were available for analysis (Table I). African-American and Caucasian women each comprised 42% of the population. The remaining women consisted of Hispanics, Asians, and other ethnic groups. The mean maternal age was 29 years, and the population was equally divided between Medicaid and third-party private insurance.

Based on self-report, 18.2% (54/297) of the population was classified as smokers and 81.8% (243/297) as nonsmokers, which included recent quitters (Table II). Using NicCheck I biochemical validation, there were 44 high-positive results, 84 low-positive results, and 169 negative results. Assuming that the majority of women in the low-positive group were likely nonsmokers with ETS exposure, low-positive and negative results were combined (253) for comparison with the high-positive results. Using this strategy, the prevalence of smoking based on self-report was 18.2 *versus* 14.1% for biochemical validation. The absolute difference in proportions is 3.4% with 95% CI [−2.9%, 9.6%], demonstrating no significant difference between self-report and biochemical validation.

NicCheck I results were then grouped as all positive results *versus* negative results for comparison. (Table II) The prevalence of smoking based on self-report *versus* biochemical validation was 18.2% *vs.* 43.1%, with a significant absolute difference of 24.9% and 95% CI [17.4%, 32.1%].

Discussion

Our investigation suggests that, at least for heavy smokers, pregnant women are generally truthful about their smoking behaviors during early pregnancy. Prior studies regarding disclosure of smoking behavior during pregnancy have either been conducted outside the United States, were performed in publicly funded clinical sites, or were usually not anonymous. Our study is unique as it was conducted anonymously and in a large, sociodemographically diverse clinical academic setting in the United States.

According to the Behavioral Risk Factor Surveillance System, a validated, population-based epidemiological survey performed in the United States annually, only 20% of women in North Carolina are active smokers, defined as smoking some days or every day [3]. Given that about 30% of women who actively smoke will quit with pregnancy [4,5], the observed rates of smoking by self-report (18.2%) and high-positive NicCheck I results (14.1%) are consistent with expected rates. Our results are slightly higher than North Carolina birth certificate data from 2003, with a self-reported smoking rate during pregnancy of 12.7% [21]. The higher rate of smoking in our population may be within the margin of measurement error or may be due to selection bias. We studied women in a university obstetric clinic, where we would expect the rate of smoking to be higher than among the obstetric population at large. The higher rate could also be related to the minimization of response bias or lack of disclosure due to the anonymous testing design. Due to clinic scheduling of new prenatal patients, required testing of stored specimens within 48 hours of sample collection, and study resources, we could only perform NicCheck I testing approximately 1–2 days per week. Therefore, we only tested 297 of the approximately 700 pregnant women seen during the study period. While this could be a source of bias, it is unlikely given that there is no systematic bias to scheduling of prenatal intake appointments. Furthermore, the demographic characteristics of our sample population (maternal age, race, and insurance status) were comparable to those for the entire obstetric population seen during the study period.

The high proportion of low-positive results (28.3%, 84/297) in our sample was unexpected. With a lower limit of detection for the NicCheck I test of 200 ng/mL, a low-positive result represents either a very light smoker, e.g. less than five cigarettes a day, or an individual with significant ETS exposure [14,15]. Approximately 37.9% of North Carolina adults permit smoking in the home and 19.5% of women work in places where smoking is permitted in public areas [22]. Therefore, it is most likely that the majority of low-positive results in our study indicate significant ETS exposure during pregnancy. Although the prevalence of ETS and its association with adverse pregnancy outcomes (low birthweight,

birth defects, sudden infant death syndrome, and asthma) [23–28] has been documented, providers do not routinely inquire about or advise women about the risks of ETS exposure during pregnancy. Prenatal care providers should consider evaluating pregnant women for significant ETS exposure with subsequent counseling regarding minimization or elimination of such exposure. ETS exposure can be reduced by avoiding public and workplace areas where smoking is allowed. For those who encounter ETS at home, women should be encouraged to make the home a smoke-free environment and ask close friends/family to smoke outside and even consider wearing a ‘smoking coat’, (i.e. a shirt or jacket) that can be removed and left outside after smoking.

Interpretation of biochemical validation results was limited by the semi-quantitative nature of the NicCheck I test, with regards to the low- and high-positive results. However, there is very good correlation between NicCheck I and gas chromatography urinary cotinine, with a positive and negative predictive value of 98.4% and 96.1%, respectively [13]. Similar results are seen when NicCheck I was compared to exhaled carbon monoxide testing for identification of smokers and nonsmokers, with a positive and negative predictive value of 98.4 and 94.8%, respectively [13]. While gas chromatography is restricted to cotinine measurement only, Nic-Check I provides a complete assessment of nicotine exposure by measuring not only cotinine but also 3-hydroxycotinine and nicotine. Therefore, the majority of low-positive results most likely represent significant ETS exposure during pregnancy as opposed to active smokers. Additional studies are needed to validate this hypothesis.

Owing to the anonymous testing protocol, we could not distinguish the direction of misclassification, i.e. false-negative or false-positive reports of smoking behavior during pregnancy. Given the potential stigma associated with smoking during pregnancy, it seems highly unlikely that nonsmoking women would falsely report smoking during pregnancy. Finally, we could not make any inference about socio-demographic associations with the accuracy of self-report, again due to the anonymous testing protocol. However, we were willing to accept the restrictions posed by anonymous testing to obtain reliable, un-biased self-reported smoking status from our sample population.

Smoking during pregnancy is clearly associated with poor pregnancy outcomes. It is important for healthcare providers to be able to accurately assess smoking status during pregnancy and readily assist women with smoking cessation. Self-report appears to be a fairly reliable method for determining active smoking in early pregnancy. However, a significant proportion of pregnant women are also exposed to considerable levels of ETS, which has also been associated with poor pregnancy outcomes but is often overlooked during routine prenatal care. Prenatal care providers should consider incorporating questions regarding ETS into the medical history evaluation of pregnant women. Universal urinary cotinine screening of pregnant women could aid in appropriately counseling women about their individual level of ETS exposure as well as monitoring women at high risk for adverse pregnancy outcomes. Prior to implementing such a policy, appropriate evaluations of its effectiveness and cost-effectiveness would be necessary.

Acknowledgments

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Table IDemographic characteristics ($n=297$).

Race	%
African-American	42.0
Caucasian	42.0
Hispanic	6.7
Asian	6.3
Other	3.0
Medicaid	49.8
Maternal age, years (mean, range)	29 (16–44)

Table II

Self-reported smoking status compared to anonymous urinary cotinine validation ($n=297$).

	Smoker % (<i>n</i>)	Nonsmoker % (<i>n</i>)
Self-report	18.2 (54)	81.8 (243)
High-positive vs. low-positive + negative results	14.8 (44)	85.2 (253)
Any positive result vs. negative results	43.1 (128)	56.9 (169)