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Major Depression and PTSD in Pregnant Smokers Enrolled in Nicotine Gum Treatment Trial

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Abstract

Background and Objectives—Pregnant women face considerable barriers to smoking cessation. The purpose of this study was to determine the prevalence of major depressive disorder (MDD) and post-traumatic stress disorder (PTSD) and response to smoking cessation treatment in pregnant smokers participating in a randomized, placebo-controlled trial of nicotine gum.

Methods—Participants were 194 low-income, ethnically diverse pregnant smokers.

Results—Utilizing a structured interview, 45% and 18% of the subjects met criteria for a lifetime diagnosis of MDD and PTSD, respectively. There was no difference in response to treatment, based on the presence of either of these psychiatric disorders.

Conclusions—Cumulatively, these findings provide evidence of the high degree of unmet mental health needs in pregnant smokers.

Scientific Significance—Pregnant women with a history of MDD and PTSD appear to be as likely to benefit from smoking cessation treatment as those without such a history.

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Declaration of Interest: Dr. Oncken has received consulting fees and honoraria from Pfizer (New York, NY) for advisory board meetings. She has received at no cost nicotine and/or placebo products from Glaxo-SmithKline (Philadelphia, PA) for smoking-cessation studies (ie, for pregnant women, postmenopausal women). She has received grant funding from Pfizer and from Nabi Biopharmaceuticals (Boca Raton, FL).

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The authors alone are responsible for the content and writing of this paper.

Introduction

Approximately 12% of women in the United States smoke during pregnancy^{1, 2}. Smoking rates are highest among women who are poor³, have low education⁴ and those who have low social support⁵. Psychological distress and a history of psychological trauma are common in low-income pregnant women⁶ and present a critical barrier to smoking cessation⁷. Among women who smoke cigarettes during pregnancy, 45% meet criteria for at least one mental health disorder⁸.

Depression is a common concomitant of cigarette smoking. Rates of depression in pregnant smokers have been found to be as high as 63%⁹, depending on how depression is defined and the demographic characteristics of the sample under study. The rate of anxiety disorders is also disproportionately high among pregnant women¹⁰. Post-traumatic stress disorder (PTSD) in pregnant women has also been shown to be associated with alcohol and illicit drug use^{11, 12} and there is preliminary evidence that smoking rates are higher in pregnant women with PTSD than those without the diagnosis¹². A history of PTSD is associated with an odds ratio of 4.0 for the 10-year incidence of nicotine dependence in adult men and women. Despite the fact that the highest risk for trauma exposure occurs in late adolescence, little is known about the prevalence of PTSD in pregnant women. There are few published reports⁷ on response to smoking cessation treatment for pregnant women with PTSD.

Similarly, although Hispanic women are the fastest growing ethnic group in the United States¹³, there has been little research conducted on Hispanic pregnant smokers. Although Hispanic women are less likely than non-Hispanic Caucasian women to be offered nicotine replacement therapy¹⁴, there are no reports of ethnic differences in the response to smoking cessation treatment during pregnancy.

The present study was designed to: 1) assess the prevalence of current and lifetime MDD and PTSD in an ethnically diverse sample of pregnant smokers enrolled in a randomized, placebo-controlled trial of nicotine gum for smoking cessation and 2) examine response to smoking cessation treatment in subgroups of interest.

Method

Participants were recruited from three area hospitals, including two in central Connecticut (Hartford Hospital and New Britain General Hospital) and one in western Massachusetts (Baystate Medical Center). All subjects provided written informed consent with a consent form written in English or Spanish, to participate in the study, which was approved by the Institutional Review Board at all participating institutions. At each site, patients were referred by physicians, nurses and clinic staff, as well as from the community.

The study design has been described in detail in a prior publication¹⁵. Eligibility criteria included: a) smoking at least one cigarette per day for the preceding 7 days; b) < 26 weeks gestation; c) > 16 years of age; d) able to speak English or Spanish; e) intent to carry pregnancy to term; f) stable residence. Potential subjects were excluded from the study if they had a) current drug or alcohol abuse or dependence; b) twins or multiple gestation; c) an unstable psychiatric disorder; d) an unstable medical problem (e.g., pre-eclampsia,

threatened abortion, hyperemesis gravidarum); or a condition that would interfere with the use of nicotine gum (e.g., temporo-mandibular joint problems).

After subjects were assessed for eligibility, they returned for a baseline visit, at which eligible subjects were randomized into treatment with either nicotine or placebo gum dispensed by a research study nurse at each study visit. Subjects who completed all data collection forms for each of the six study visits were provided with a \$15.00 incentive at each visit to reimburse for their time, travel or parking costs. Smoking cessation treatment consisted of 6 weeks of treatment with gum followed by a 6-week taper period. The primary dependent variable of interest was smoking status measured at end of pregnancy. "End of pregnancy" was defined as 32-34 weeks gestation, as the latest point in the third trimester at which smoking status could reasonably be collected for the research study, prior to delivery. Participants received individual smoking cessation counseling in two 35 minute counseling sessions, delivered in English or Spanish by a trained research assistant. The research assistants were trained to deliver smoking cessation counseling using a motivational interviewing approach previously shown to be effective in the same patient population¹⁶. Two of the research assistants were native Spanish speakers and all received six hours of didactic training, reviewed videotaped smoking cessation counseling sessions and observed two counseling sessions delivered by the trainer. In addition, the participants were contacted twice monthly by the counselor to monitor progress until delivery.

Two sections of the Structured Clinical Interview for DSM-IV¹⁷ (SCID) were used to diagnose past and current MDD and PTSD. Research assistants who had at least a masters degree in psychology, underwent 10 hours of training and supervision to administer the SCID. SCID interviews were videotaped and reviewed with the assessment team as part of on-going supervision. Past psychiatric treatment (e.g., outpatient and inpatient drug and psychiatric treatment, use of psychotropic medication and suicide attempts) was assessed with a mental health history questionnaire.

The Fagerstrom Test of Nicotine Dependence (FTND)¹⁸ was used to measure the severity of nicotine dependence. Cronbach's alpha for the FTND for this sample was 0.43. The perceived stress subscale of the Rhode Island Stress and Coping Inventory¹⁹ was administered to assess perceived stress. Cronbach's alpha for the subscale was 0.79. The Minnesota Nicotine Withdrawal Scale (MNWS; 7 items)²⁰ was used to measure the 7 DSM-IV items that measure nicotine withdrawal (depression, insomnia, irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, and increased appetite/weight gain). Cronbach's alpha for the MNWS in this sample was 0.75.

The data were analyzed using SPSS 15 (SPSS Inc., Chicago, IL). Group means were compared using one-way analysis of variance and frequencies were compared with chi-square or Fischer exact test.

Results

The demographic, medical and psychosocial characteristics of the study sample are listed in Table 1.

There were 194 subjects randomized from three publicly funded prenatal clinics. The majority (66%) of subjects were recruited from Hartford Hospital (n=128), with 18% recruited from New Britain General Hospital (n=35) and 16% from Baystate Medical Center (n=31). Overall, the sample is ethnically diverse and the overall racial breakdown is Caucasian/non-Hispanic (36%), Hispanic (28%), African American (8%), Multi-racial (25%) and Native American, other or unknown (3%). The racial subgroups in the Hispanic and Non-Hispanic categories are reflected in Table 1. All but two of the Hispanic participants identified themselves as Puerto Rican. Many (42%) participants described themselves as “unemployed” and half of the sample had not completed high school. The majority (83%) of women enrolled in this study were publicly insured (primarily Medicaid recipients) and 17% of the sample had commercial insurance. The mean age of participants was 25 years and 64% had one or more children.

Two sections of the SCID were utilized to measure current and lifetime MDD and PTSD (see Table 1). There were 17 subjects who did not complete the SCID because they were unwilling or unable to undergo the interview. Approximately half the sample (52%) had neither history of MDD nor PTSD and 13% of the sample met criteria for both lifetime MDD and PTSD. Current MDD or PTSD was operationally defined according to SCID diagnostic criteria as having met the threshold level of symptoms within the past month. Lifetime history of MDD was operationally defined as having diagnostic criteria for a period of two weeks or greater during adulthood (18 years or older). Lifetime history of PTSD was operationally defined as having met diagnostic criteria for a period of more than one month during adulthood (18 years or older).

Comparing Women with and Without Depression

Forty-five percent of all participants met DSM-IV criteria for lifetime MDD and 14% met criteria for current MDD. Participants with lifetime MDD were more likely to have a lifetime history of PTSD ($\chi^2 = 7.61$ (1) $p=.006$) and a history of suicide attempt ($\chi^2 = 10.4$ (1) $p=.001$). Neither the number of cigarettes smoked per day at baseline nor FTND total score was different between women with and without a lifetime history of MDD.

As shown in Table 2, compared to women without a lifetime history of MDD, participants with a history of depression had higher scores on the Rhode Island Stress and Coping Survey ($F=13.35$, 1/174, $p=.000$) and on the Minnesota Nicotine Withdrawal Scale ($F=10.19$, 1/174, $p=.002$). However, there was no difference between these groups in their response to smoking cessation treatment, defined as abstinence at end of pregnancy. There was also no difference between the groups in terms of birth weight of their infants. There were also no differences between these groups in terms of gestational age or admissions to the neonatal intensive care unit. As would be expected, women with a lifetime history of MDD were also more likely to have a history of psychiatric hospitalization ($\chi^2=7.03$ (1), $p=.003$) and current treatment with an antidepressant ($\chi^2=9.73$ (1), $p=.002$) than those without such history,

Comparing Women with and Without PTSD

Eighteen percent of subjects met criteria for lifetime PTSD and 8.4% met criteria for current PTSD. Trauma exposure was categorized as sexual trauma (e.g., childhood sexual abuse or rape as an adult), physical trauma (e.g., physical assault) and/or emotional trauma (e.g., witnessing domestic violence). Sexual abuse was the most commonly endorsed type of trauma exposure by 54% of participants with a lifetime history of PTSD and 8% of the total sample.

As shown in Table 3, compared to women without a lifetime history of PTSD, pregnant smokers with a history of PTSD had higher scores on the Rhode Island Stress and Coping Survey ($F=7.94$, $1/168$, $p=.005$) and on the Minnesota Nicotine Withdrawal Scale ($F=10.97$, $1/168$, $p=.001$). However, there was no difference between these groups in their response to smoking cessation treatment or the birth weight of their infants. There were also no differences between these groups in terms of gestational age or admissions to the neonatal intensive care unit. Women with lifetime history of PTSD were more likely than those without such history to report a history of treatment for substance abuse and past psychiatric hospitalization and more than half reported that they had attempted suicide compared to 16% of women without a history of PTSD.

Comparing Hispanic and Non-Hispanic Pregnant Smokers

As Table 4 shows, Hispanic women were younger, ($F=16.38$, $(1/191)$, $p<.0001$) less likely to be employed ($\chi^2=20.7$ (1), $p<.0001$) and less likely to have completed high school ($\chi^2=48.2$ (1), $p<.0001$) than non-Hispanics. More Hispanic women (18.6%) met criteria for current MDD than did non-Hispanic participants (7.7%) ($\chi^2 = 4.3$ (1) $p=.038$). Hispanic participants had rates of smoking prior to pregnancy that were similar to non-Hispanic women. Although smoking cessation rates at end of pregnancy did not differ between Hispanic and non-Hispanic women, birth weights for Hispanic infants were lower than for non-Hispanics ($F=4.72$, $(1/176)$, $p=.031$). However, when maternal body weight was factored in the analysis, this difference was no longer significant ($F=3.33$ $(1/170)$, $p=.070$).

Conclusions

In this sample of ethnically diverse women who continued to smoke during pregnancy and enrolled in a clinical trial evaluating the safety and efficacy of nicotine gum, the lifetime rates of MDD and PTSD were notable, at 45 and 18%, respectively. We believe that this is one of few early reports of the prevalence of PTSD in a sample of urban, pregnant smokers and one of only a few reports of an ethnically diverse sample with a large proportion of Hispanic women. The findings from this study also underscore that nicotine dependence and history of PTSD and depression can often exist as part of a constellation of psychosocial problems. More attention to screening and treatment for depression during the antepartum and postpartum periods is needed for this vulnerable population. Similarly, women in our sample with a history of PTSD were more likely to indicate history of treatment for substance abuse, a finding that is consistent with research that has shown that a substantial proportion of women with substance abuse disorders have PTSD²¹ and that PTSD often precedes substance abuse²².

The finding that MDD and PTSD were associated with greater baseline symptoms of nicotine withdrawal, and greater perceived stress/difficulty in coping, provides evidence that women with such psychiatric histories who smoke during pregnancy may have a more difficult time quitting. However, despite these barriers to quitting smoking, it is encouraging that in our sample women with a history of depression and PTSD were as likely to stop smoking by end of pregnancy with nicotine gum, as those with no such history.

This study also adds to the literature on smoking cessation during pregnancy among Latinas. Our data show that Hispanic women in our study faced difficulties in quitting smoking, as evidenced by their younger age, high unemployment rate, low educational levels and higher rates of current depression. However, there was no difference between Hispanic and non-Hispanic participants with respect to smoking outcomes, suggesting that Hispanic women are as likely to stop smoking using nicotine gum as non-Hispanic women.

This study is limited by the fact that all of the subjects were enrolled in a smoking cessation treatment study and thus may not be representative of all women who continue to smoke during pregnancy. Further, the sample size was comparatively small and thus the statistical power limited, so that the lack of differences on some of the comparisons may reflect Type II error. There is a need for additional research examining the prevalence of PTSD in large samples of pregnant women, including both smokers and non-smokers. Future research with large, diverse samples of pregnant women is also needed to confirm these findings and extend them to other population groups.

In summary, many women who smoke during pregnancy have a history of MDD and PTSD but it is encouraging that none of these factors appeared to impact on the overall response to treatment with nicotine gum, suggesting that such treatment may be equally beneficial to different subgroups of pregnant smokers. Overall, our data support the potential value of comprehensive smoking cessation treatments for pregnant women that are aimed at both abstinence from cigarettes and improvements in their overall quality of life. Such treatments¹⁶ include integrated interventions that target both cigarette smoking and co-occurring mental health problems.

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Table 1

Demographic and Other Characteristics of the Sample (N=194).

<u>Demographic Variables</u>	
Age M (SD)	25.2 (5.81)
Ethnic/Racial Subgroups	
Hispanic	54%
White	38%
Black	1%
Multi-racial	44%
Unknown	17%
Total	100%
Non-Hispanic	46%
White	78%
Black	17%
Multi-racial	5%
Unknown	0%
Total	100%
Employed	
Full-time	16%
Part-time	17%
Unemployed	42%
Homemaker	20%
Other	4%
Education	
Did not complete high school	50%
GED	10%
High School	23%
Junior College	7%
College graduation	4%
Post graduate	6%
Insurance	
Publicly funded insurance	83%
Commercial insurance	17%
Number of children n (%)	
None	36%
One	31%
Two or more	33%
a Psychiatric Diagnosis n (%)	
Neither Depression or PTSD Dx	52%
Current major depression	14%
Current PTSD	8%
Lifetime major depression	45%

<u>Demographic Variables</u>	
Lifetime PTSD	18%
Both Lifetime MDD and Lifetime PTSD	13%
<u>Smoking Variables: M (SD)</u>	
Age began daily smoking	15.52 (3.39)
Current daily smoking	9.42 (6.10)
Daily smoking prior to pregnancy	17.48 (9.33)
Fagerstrom Test for Nicotine Dependence Score	3.7 (1.9)

Table 2

Characteristics of pregnant smokers with and without a history of depression

	Lifetime MDD (n=80)	No Hx of MDD (n=97)	Significance ^a
<u>Smoking Variables</u> M (SD)			
Daily smoking prior to pregnancy	17.68 (8.27)	17.20 (9.80)	<i>p</i> =.730
Fagerstrom Test for Nicotine Dependence Score	3.63 (2.07)	3.84 (1.83)	<i>p</i> =.458
<u>Smoking Outcomes</u>			
Abstinence at end of pregnancy	17.5%	16.49%	<i>p</i> =.649
Infant birthweight in g M (SD)	3039 (566)	3130. (714)	<i>p</i> =.374
<u>Psychological Characteristics</u>			
Rhode Island Stress and Coping score M (SD)	14.33 (4.70)	11.81 (4.40)	<i>p</i> =.000
Minnesota Nicotine Withdrawal Scale score M (SD)	12.78 (6.99)	9.67 (5.93)	<i>p</i> =.002
<u>Psychiatric Diagnosis</u>			
Current PTSD ^b	13.2%	4.7%	<i>p</i> =.066
Lifetime PTSD	27.9%	10.6%	<i>p</i> =.006
Suicide attempt (lifetime)	38.0%	16.5%	<i>p</i> =.001
<u>Mental Health Treatment</u>			
Antidepressant use during study	19.2%	4.2%	<i>p</i> =.002
History of substance abuse treatment	20.3%	14.4%	<i>p</i> =.232
Past inpatient psychiatric hospitalization	26.6%	9.4%	<i>p</i> =.003

^a Note. *P*-value comparing the two groups was based on χ^2 for categorical variables, ANOVA for continuous variables.

^b PTSD-Post Traumatic Stress Disorder

Table 3

Characteristics of pregnant smokers with and without a history of post traumatic stress disorder

	Lifetime PTSD (n=27)	No Hx of PTSD Significance ^a (n=123)	
<u>Smoking Variables</u> M (SD)			
Daily smoking prior to pregnancy	18.59 (9.42)	17.23 (9.40)	<i>p</i> =.495
Fagerstrom Test for Nicotine Dependence score	3.30 (1.86)	3.65 (1.87)	<i>p</i> =.373
<u>Smoking Outcomes</u>			
Abstinence at end of pregnancy	25.9%	15.4%	<i>p</i> =.193
Infant birthweight in g M (SD)	3190.6 (354.0)	3045.6. (728.6)	<i>p</i> =.344
<u>Psychological Characteristics</u>			
Rhode Island Stress and Coping score M (SD)	15.07 (4.26)	12.07 (4.53)	<i>p</i> =.005
Minnesota Nicotine Withdrawal Scale score M (SD)	14.48 (5.67)	10.13 (6.36)	<i>p</i> =.001
<u>Psychiatric Diagnosis</u>			
Current MDD ^b	25.9%	9.1%	<i>p</i> =.016
Lifetime MDD	70.4%	37.2%	<i>p</i> =.002
Suicide attempt (lifetime)	55.6%	16.3%	<i>p</i> =.000
<u>Mental Health Treatment</u>			
Antidepressant use during the study	18.5%	10.2%	<i>p</i> =.224
History of substance abuse treatment	44.4%	13.1%	<i>p</i> =.000
Past inpatient psychiatric hospitalization	42.3%	12.2%	<i>p</i> =.000

^aNote. *P*-value comparing the two groups was based on χ^2 for categorical variables, ANOVA for continuous variables.

^bPTSD-Post Traumatic Stress Disorder

Table 4

Comparing Hispanic and Non-Hispanic Smokers

Variables	Hispanic (n=105)	Non-Hispanic (n=89)	Significance ^a
<u>Demographics</u>			
Age	23.7 (4.8)	26.8 (6.3)	p<.0001
Employed	20.4%	52.4%	p<.0001
Education < high school	73.3 %	23.0%	p<.0001
<u>Smoking Variables M (SD)</u>			
Daily smoking prior to pregnancy	16.8 (9.4)	18.7 (9.5)	p=.158
Fagerstrom Test for Nicotine Dependence score	3.61 (2.0)	3.80 (1.9)	p=.493
<u>Smoking Outcomes</u>			
Abstinence at end of pregnancy	17.1%	15.7%	p=.792
Infant birthweight in g M (SD)	3021 (665)	3231 (626)	p=.031
<u>Psychological Characteristics</u>			
Rhode Island Stress and Coping	12.7 (5.1)	13.2 (4.4)	p=.557
Minnesota Nicotine Withdrawal Scale score	12.2 (6.9)	10.1 (5.9)	p=.023
<u>Psychiatric Diagnosis</u>			
Current MDD	18.6%	7.7%	p=.038
Lifetime MDD	49.0%	41.0%	p=.292
Lifetime PTSD	11.8%	4.3%	p=.100
Current PTSD	22.4%	13.0%	p=.447
Lifetime PTSD	29.0%	21.5%	p=.255
Suicide attempt (lifetime)			
<u>Mental Health Treatment</u>			
Antidepressant Use During the Study	9.0%	16.0%	p=.119
History of substance abuse treatment	13.3%	24.7%	p=.042
Past inpatient psychiatric hospitalization	19.0%	13.9%	p=.367

^aNote. P-value comparing the two groups was based on χ^2 for categorical variables, ANOVA for continuous variables.