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Original Investigation

Adherence to nicotine replacement therapy among pregnant smokers

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Abstract

Introduction: This secondary analysis examined the association between adherence to nicotine replacement therapy (NRT) and smoking cessation among pregnant smokers enrolled in Baby Steps, an open-label randomized controlled trial testing cognitive-behavioral therapy (CBT) versus CBT plus NRT.

Method: The analysis included only women who received NRT for whom we had complete data ($N = 104$). Data came from daily calendars created from recordings of counseling sessions and from telephone surveys at baseline and 38 weeks gestation.

Results: Overall, 29% of the 104 women used NRT for the recommended 6 weeks and 41% used NRT as directed in the first 48 hr after a quit attempt. Ordinal logistic regression modeling indicated that using NRT as directed in the first 48 hr and having made a previous quit attempt were the strongest predictors of longer NRT use. Univariate analyses suggested that primigravid women and women who used NRT longer were more likely to report quitting at 38 weeks gestation.

Discussion: Findings indicated that adherence to NRT is low among pregnant smokers, but adherence was a predictor of cessation. Future trials should emphasize adherence, particularly more days on NRT, to promote cessation during pregnancy.

Introduction

Although nicotine replacement therapies (NRTs) have been shown to be efficacious in nonpregnant populations (Hughes, 1995; Silagy, Lancaster, Stead, Mant, & Fowler, 2008), NRT use during pregnancy has been tempered by concerns for the fetus (Slotkin, 2008). Several short-term trials suggest that NRT, when used as directed, produces lower maternal nicotine levels than *ad libitum* smoking (Ogburn et al., 1999; Oncken et al., 1996, 1997; Wright et al., 1997). Studies of NRT use during pregnancy revealed that many women do not use NRT as directed (Pollak et al., 2007; Wisborg, Henriksen, Jespersen, & Secher, 2000). Adherence with NRT typically is low (Alterman, Gariti, Cook, & Cnaan, 1999; Orleans et al., 1994) but has been associated with cessation among nonpregnant smokers (Bansal, Cummings, Hyland, & Giovino, 2004; Shiffman et al., 2002). Scant data are available on the relationship between adherence to NRT and cessation among pregnant smokers.

This report describes findings from a secondary analysis in which we examined adherence to NRT among pregnant smokers.

Methods

Procedures

Data for this secondary analysis come from a randomized trial of NRT use in pregnancy (Pollak et al., 2007). Descriptions of the trial sample and intervention have been published elsewhere

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(Pollak et al., 2006, 2007). Women assigned to use NRT (choice of patch, gum, or lozenge) received NRT doses based on current smoking level. Women who chose the patch were instructed to wear it only while awake (Dempsey & Benowitz, 2001): 7-mg patch for fewer than 10 cigarettes/day, 14-mg patch for 10–14 cigarettes/day, and 21-mg patch for 15+ cigarettes/day. Gum or lozenge users were instructed to use one 2-mg piece for every cigarette smoked per day. Women were instructed to begin use during the second trimester for 6 weeks and to avoid use during the third trimester. However, if women feared a return to smoking, they were instructed to continue NRT use. Adherence was encouraged at each of six counseling sessions. Women were required to sign a contract to stop smoking while using NRT, with specific instructions to wait at least 12 hr after using NRT if they chose to return to smoking.

Data collection

Data came from two sources, counseling audio recordings and telephone surveys. Women who received NRT and counseling ($N = 108$) comprised the full sample; audio recordings were unavailable for 14 of the 122 original participants. Two independent coders (LJF and RJNB) transcribed segments about smoking and NRT use from each audio recording, supplemented with data collected by interventionists. Coders used transcripts to create a daily calendar for smoking (yes or no) and NRT use (yes or no). Some 20% of the cases were double coded; interrater reliability was excellent (interclass correlation = .83). Cessation data were obtained via telephone surveys at 38 weeks gestation. Cessation was biochemically validated 7-day point-prevalence abstinence at 38 weeks.

Variables

Background. Age, education (less than high school/graduated high school or more), being partnered (yes or no), race (White or non-White), prior pregnancy, and weeks gestation at randomization were measured at baseline.

Smoking history. Number of previous quit attempts, number of cigarettes smoked 30 days prior to pregnancy, and Revised Tolerance Questionnaire (Tate & Schmitz, 1993) scores were measured at baseline.

NRT and quitting. Measures of NRT use included type and dose of NRT initially selected, total days of NRT use, use in the 48 hr after quit attempt, and switching NRT type. Data on use of the patch in the first 48 hr included putting the patch on upon waking (yes or no), taking off at bedtime (yes or no), and using one patch daily (yes or no). Data on gum use in the first 48 hr included chewing one piece for each cigarette smoked (yes or no) and chewing until peppery and then parking (yes or no). Data on lozenge use in the first 48 hr included sucking one lozenge per cigarette smoked (yes or no) and sucking until dissolved (yes or no). Data on quitting included attempted to quit on quit date (yes or no), quit for first 48 hr (yes or no), length of initial quit, and longest quit attempt. A variable was created to describe patterns of NRT use (1 = did not take NRT at all; 2 = used NRT, but not continuously; and 3 = used NRT continuously).

NRT adherence. Adherence was measured as total days per weeks of NRT use.

Cessation. Cessation was measured by self-reported 7-day point-prevalence abstinence at 38 weeks gestation, validated by salivary cotinine.

Data analyses

One objective of the present analysis was to examine predictors of length of NRT use. Potential predictors were age, education, race, previous pregnancy, partner status, prior quit attempt, nicotine dependence, and use of NRT as directed in the first 48 hr. Because number of days of NRT use was severely skewed to the right, we trichotomized this variable at its approximate tertiles and used it as three-level ordinal outcome variable in an ordinal logistic regression model (0 = less than 7 days; 1 = 7–27 days; and 2 = at least 28 days). We put all candidate variables into the model and used stepwise backward elimination to remove variables with p values greater than .50. Harrell (2001) advocates this method of model building to avoid the "severe biases" that come with using smaller p values, such as .05, and with univariate screening of predictors. In addition to fitting the multivariate model, we also examined univariate associations for each predictor with no other variables in the model. Finally, as a secondary objective, we used the logistic regression model to examine univariate predictors of cessation at 38-week follow-up.

Results

Among the108 women, 4 chose not to use NRT and were excluded from further analysis. Characteristics of the women in the sample are shown in Table 1.

Of the 90 women who reported NRT use, nearly two thirds (63%) selected the patch and 37% selected the gum or lozenge. A total of 24 women (23%) eventually switched from one NRT type to another. Overall, the 104 women used NRT for a mean of 26 days ($SD = 29$). Women who initially selected the gum or lozenge used it for a mean of 20 days ($SD = 26$) and those who initially selected the patch used it for a mean of 30 days ($SD = 30$).

Of the 104 women, 34 (33%) started using NRT on their quit date and used it daily for a mean of 31 consecutive days; 56 (54%) started using NRT on the quit date but did not use it every day. Women who used the patch in this manner used it for a mean of 30 nonconsecutive days. Reasons cited for stopping NRT were wanting to smoke (30%), experiencing a side effect (20%), not finding NRT useful (10%), and testing their ability to stay quit without the help of NRT (7%; data not shown).

Overall, 29% of the 104 women used NRT for the recommended 6 weeks and 41% used NRT as directed in the first 48 hr after a quit attempt. Among the 90 women who used NRT, 33% used NRT for the recommended 6 weeks (42 days). Among the 34 women who started using NRT on their quit day and who used it continuously, 32% used it for the recommended 6 weeks or more. Similarly, among the 56 women who used NRT, but not continuously from their quit date, 34% used it for the recommended 6 weeks or more.

Median number of days on NRT was related to type of NRT and use in the first 48 hr (data not shown). Among patch users, the median length of NRT use was 20 days compared with 10 days among gum or lozenge users ($p = .06$). Adherence in the first 48 hr was predictive of length of NRT use. Among women who used

Table 1. Sample characteristics and NRT usage ($N = 104$)

Characteristics	Results
Demographics	
Median age (range)	26 years (18–45)
High school education or more	72%
Race	
White	64%
Other	36%
Partnered	67%
Pregnancy	
First pregnancy	16%
Weeks of pregnancy at randomization	
13–22	92%
≥23	8%
Smoking	
Had a previous quit attempt	77%
Nicotine dependence (scale = 1–5)	
<3.2	47%
≥3.2	53%
NRT usage	
NRT selected at Session 1	
Gum	29%
Lozenge	8%
Patch	63%
Pattern of NRT use	
Did not use	13%
Used, not continuously	54%
Used continuously	33%
Switched NRT type during trial	23%
Used NRT as directed in first 48 hr	41%
Average total days using NRT (range = 0–119)	26 days

Note. NTR, nicotine replacement therapy.

Table 2. Univariate factors related to cessation at 38 weeks ($N = 67$)

Factor	Percentage of quitters	*p* value
Age (years)[a]		
<26	43	.67
≥26	38	
Education		
Less than high school	47	.51
High school or more	36	
Race		
White	43	.49
Other	32	
Partnered		
Yes	25	.17
No	45	
First pregnancy		
Yes	75	.002
No	32	
Previous quit attempt		
Yes	42	.33
No	29	
Nicotine dependence score		
<3.2	44	.23
≥3.2	34	
NRT selected at baseline		
Gum and lozenge	39	.99
Patch	41	
Used as directed in first 48 hr		
Yes	50	.19
No	31	
Weeks on NRT[a]		
<3	29	.01
≥3	52	

Note. NTR, nicotine replacement therapy.
[a]These predictors were used as continuous variables in all analyses; they are categorized in this table for purposes of presentation only.

NRT as recommended in the first 48 hr, the median number of days of NRT use was 22 compared with 10 days among those who did not use it as recommended ($p = .002$). Ordinal logistic regression modeling indicated that using NRT as directed in the first 48 hr (odds ratio [OR] = 5.4, 95% CI = 2.2–12.9, $p = .0002$) and having made a previous quit attempt ($OR = 2.9$, 95% CI = 1.1–7.6, $p = .04$) were the strongest predictors of longer NRT use. Finally, we compared the results from the ordinal logistic regression model to results from a general linear model that used number of days on NRT as a continuous variable, and the results were remarkably similar (data not shown).

For 67 of the 104 women, we had data on whether they had quit smoking at 38 weeks gestation; 27 (40%) of these women were abstinent. Univariate analyses suggest that primigravid women ($p = .008$) and women who used NRT longer ($p = .01$) were more likely to have reported quitting at 38 weeks (Table 2).

Discussion

The present study is one of the first to provide a detailed description of how pregnant smokers use NRT offered through a cessation trial. In this secondary analysis, we found that most women tried NRT; however, many women did not use it for the recommended 6 weeks. Using NRT as directed in the first 48 hr of a quit attempt was related to using NRT for longer periods of time, which, in turn, was significantly related to cessation.

Our findings support the work of others suggesting that using NRT for longer periods of time leads to cessation. Thus, recommending continuous use of NRT could help pregnant smokers quit. As in other studies with both pregnant and nonpregnant smokers, our findings showed that women did not use NRT for the length of time recommended. Additional research is needed to determine the optimal length of time for pregnant women to balance benefits of NRT while limiting nicotine exposure to the fetus.

The present study is in agreement with another study showing that intermittent patch use is common and that most women do not use the patch as directed (Hotham, Gilbert, & Atkinson, 2006). Interestingly, we found that most women discontinued NRT because they wanted to smoke, suggesting that cravings were not relieved effectively. Additionally, women were clearly concerned about limiting nicotine exposure to the fetus. Data from focus groups in Australia suggest that pregnant smokers consider using the nicotine patch as "high risk" (Hotham,

Atkinson, & Gilbert, 2002). Belief that NRT may harm the fetus appears to prompt pregnant smokers to limit NRT use as much as possible. Future studies that provide NRT to pregnant smokers should focus on educating women about the comparative effects of NRT and smoking on the fetus.

Using NRT as directed in the first 48 hr was predictive of using it for a longer period of time. These findings imply that women who are able to use NRT as directed early in a quit attempt are likely to continue to use it as directed. This finding is consistent with findings that indicate initial abstinence is an important predictor of continued abstinence (Killen, Fortmann, Davis, & Varady, 1997). Thus, supportive counseling should focus on correct NRT use in the early days of a quit attempt by providing thorough NRT use instructions and by helping women make a detailed NRT use plan. The present study is the first to examine the relationship between NRT use early in a quit attempt (short-term adherence) and long-term use among pregnant smokers. More research is needed to establish the degree to which short-term adherence affects long-term use and cessation.

The present study has several limitations. First, it was a secondary analysis based on a small sample. These preliminary findings are interesting, but further research is needed. Second, NRT use was based on self-report but was abstracted from two sources (recorded counseling sessions and telephone surveys). We asked participants for empty NRT packaging but did not receive much. In addition, recordings of the counseling sessions were unavailable for 11% of the 122 women in the original sample. Future studies would benefit from the use of daily diaries or from implementation of the timeline follow-back technique to collect data on NRT use and smoking.

NRT use clearly helped women quit smoking during pregnancy. The longer women used NRT, the more likely they were to quit. Adherence in the critical first 2 days set the stage for longer use. Future trials with pregnant women should emphasize the importance of adherence to NRT, particularly within the first 48 hr. Understanding how pregnant women use NRT is an important first step in developing more efficacious interventions for this challenging population. More research is needed to understand how pregnant women make decisions about NRT use so that clinical providers can make informed recommendations about the optimum use of NRT to promote cessation while minimizing potential harm.

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Declaration of Interests

GlaxoSmithKline donated the nicotine replacement products for this trial.

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