The Effect of Over-the-Counter Sales of the Nicotine Patch and Nicotine Gum on Smoking Cessation in California

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Abstract

The Food and Drug Administration approved over-the-counter (OTC) sale of nicotine gum and nicotine patches in 1996. We used data from the 1996 California Tobacco Survey to compare the rates of nicotine replacement therapy (NRT) use and smoking abstinence in California for each month during a period immediately preceding and immediately following the OTC availability of nicotine gum and patches. For smokers eligible to report a quit attempt, the proportion making a quit attempt using NRT and the proportion remaining abstinent was calculated for each of the 12 months prior to the survey interview. Multiple regression modeling of quit attempts and abstinence included a term for the number of months between the quit attempt and survey interview and dummy variables for the months before and after the OTC availability of NRT. Results showed a significant increase in the fraction of smokers using the patch \( (P < 0.01) \) and gum \( (P < 0.05) \) immediately following their availability OTC. There was also a significantly higher proportion of smokers reporting abstinence with gum use \( (P < 0.01) \) and a significant increase in reported abstinence with patch use \( (P < 0.01) \) during the period of time immediately following the availability of these products without a prescription. The results of this study suggest that removing the prescription status of NRT products resulted in an immediate increase in quit attempts and smoking abstinence with the use of nicotine gum or patches.

Introduction

Nicotine replacement therapy (NRT) for smoking cessation is recommended as proven effective treatment by the USPHS Guidelines for Treating Tobacco Use and Dependence (1). The Food and Drug Administration approved nicotine gum as a prescription drug in 1984 and the nicotine patch in 1991. Nicotine gum became available for use without a prescription in April 1996, and by the end of July of the same year, the nicotine patch was available for purchase over-the-counter (OTC). The switch to OTC status for these products increased the use of NRT in the U.S. by 152\% (2), and this increased use has been maintained for several years (3). Several randomized placebo-controlled trials showed the efficacy of the nicotine patch under simulated OTC conditions with minimal behavioral support and product instruction (4-6), reducing concerns that OTC NRT would not be as effective as prescription NRT (7, 8). Better access to NRT was also expected to improve rates of smoking cessation in the U.S. (9).

However, recent data from population-based surveys in California and Massachusetts have raised questions about the effectiveness of OTC NRT outside of a randomized clinical trial setting (9, 10). Analysis of data from the California Tobacco Surveys showed a significant increase in the use of NRT products, but there was a significant decrease in rates of long-term cessation with NRT use after the availability of these products OTC (10). Using data from several Massachusetts adult tobacco surveys, Thorndike and colleagues (9) found no effect of OTC NRT on quit attempts or smoking abstinence; however, unlike the results from the California Tobacco Surveys, use of NRT products in Massachusetts did not increase following the availability of the NRT without a prescription.

Because of the conflicting results obtained from the California and Massachusetts studies, it is unclear whether the use of gum or the patch increased after their availability OTC. Moreover, these studies (9, 10) did not control for temporal factors (i.e., societal changes, the dramatic increase in the price of cigarettes in 1999, and the influences of differential recall of cessation attempts) occurring during the 3-year interval between 1996 and 1999 that could potentially confound the results observed.

The present study attempts to reconcile the conflicting results obtained from the previous studies and employs a research design that is not dependent on comparisons from different surveys conducted in different years. In this paper, we examine the immediate short-term effects of the availability of OTC NRT on reported quit attempts and on abstinence in California during the months prior to and immediately following OTC availability of NRT.

Materials and Methods

Sample. The population examined was drawn from the 1996 California Tobacco Survey, which is a periodic survey containing questions about tobacco use sponsored by the California Department of Health Services. Details of the 1996 survey are presented elsewhere (11). The California Tobacco Surveys uses a stratified, random digit-dialing technique to sample households in California. The data are weighted to reflect the population of California and to account for the oversampling of smokers. The 1996 California Tobacco Survey was conducted between September 1996 and January 1997. A total of 18,616 adults (18 and over) completed the interview (response rate was 72.9\%).

Current smokers were defined as those who reported smoking at least 100 cigarettes in their lifetime and who responded that they smoke “every day or some days” to the current-smoking status question. We defined former smokers as individuals who smoked at least 100 cigarettes in his or her lifetime and were not currently smoking at the time of the...
survey. The population of smokers examined in these analyses was limited to those current and former smokers age ≥25 who reported being a daily smoker 12 months prior to the survey. These selection criteria were used to minimize inclusion of those who were still experimenting with smoking or who were in the early stages of the smoking uptake continuum (12). These inclusion criteria resulted in a population of 6,211 smokers.

**Survey Measures.** Respondents to the 1996 California Tobacco Survey were asked about their current smoking status, whether they were smokers 12 months ago, and whether they had intentionally made a quit attempt for any reason that lasted for 1 day or longer during the last year. Respondents who reported making a quit attempt during the last year were asked to report the date of their most recent quit attempt and whether they used a cessation aid, such as nicotine gum or the nicotine patch with that attempt. Abstinence was defined by a self-reported smoking status of non-smoking (a response of “not at all” to the smoking status question) at the time of the survey.

**Calculation of the Percentage of Quit Attempts and Abstinence by Calendar Month.** For each month from October 1995 through November 1996, the proportion of eligible smokers reporting a quit attempt was calculated. Quit attempts were divided into those reporting patch use, gum use, or no NRT use with their most recent quit attempt; and the proportion of smokers who were abstinent in each group was calculated with all eligible smokers as the denominator.

The data for each calendar month was further divided by the date of the survey interview into the 5 months in which the survey was conducted (September 1996-January 1997). In order to ensure that the abstinence reported by respondents was for at least 1 month’s duration, we excluded quit attempts reported for the month in which the survey was conducted and for the month prior to the survey. Thus, five rates were calculated based on the month of the survey for each calendar month in which cessation occurred for a 10-month interval spanning 2 to 12 months prior to the month in which the survey data were collected. This generated 50 monthly rates—10 rates for each of the 5 months in which the survey was administered.

The date of the cessation attempt was only available for the respondent’s most recent quit attempt, and therefore information on cessation activity for the period preceding the most recent cessation attempt was not available. In order to minimize the effect of this missing information, all smokers who made a quit attempt (successful or unsuccessful) were excluded (censored) from the denominator of the quit attempt calculation for the months preceding the month of their most recent attempt. This censoring was necessary because it was not possible to determine whether these smokers made a quit attempt in the months before the month in which they reported their most recent cessation attempt.

Respondents with a failed quit attempt were included in the denominator for the month in which their quit attempt took place, as well as for the months following their unsuccessful quit. Respondents reporting abstinence were included in the denominator for the month of their quit but were excluded from the denominators of the months following their quit month because they were no longer available to quit. Smokers who did not report attempting to quit in this sample were included in the denominator for all of the monthly percentage calculations for this study.

These exclusions resulted in a final sample of 5,888 smokers included in our analyses. All percentages were weighted by the sample size to account for sample-size variations.

**Data Analysis and Statistics.** The 95% confidence intervals for the monthly quit attempts and abstinence rates for the 13-month period from November 1995 to November 1996 were estimated using SUDAAN (version 8.0) software for complex survey designs. We did not include data from October 1995 in the analysis because the estimates for reported quit attempts and abstinence were unstable. SAS (version 8.0) was used to separately model reported quit attempts and abstinence before and after the availability of the OTC gum and OTC gum. The regression analyses used the monthly percentages (n = 49) of reported quit attempts with NRT and abstinence with NRT. The percentage of quit attempts and abstinence with NRT for each of the 49 calendar-month by survey-month observations served as the outcome variable for the regression models.

Because smokers’ recall of cessation events in surveys is better for recent attempts than for those more remote in time from the survey interview (13), we controlled for this recall bias by including a term in the regression models for the number of months between the quit attempt and the survey interview. A term for the months before and after nicotine gum and the nicotine patch went OTC was also included in the regression models. We coded quit attempts and abstinence that took place between November 1995 through May 1996 as pre-OTC gum quits and from June 1996 through November 1996 as post-OTC gum quits. Quit attempts and abstinence reported from November 1995 through July 1996 were coded as pre-OTC patch quits and from August 1996 to November 1996 as post-OTC patch quits.

**Results**

In this population of individuals who were ages 25 or older and who were daily smokers 1 year prior to the survey, 35.37 ± 1.31% made a quit attempt and 8.77 ± 0.96% were abstinent at the time of the survey. This translates into 24.8% of those who reported an attempt to quit being abstinence for ≥1 months duration of abstinence at the time of the survey. Of those who attempted to quit, 6.88 ± 1.18% used nicotine gum and 12.13 ± 1.55% used nicotine patches in their most recent quit attempt.

**Use of NRT Products for Smoking Cessation by Calendar Month.** Figure 1 shows the percentage of smokers who reported making a quit attempt using nicotine patches or gum during each month from November 1995 to November 1996. The percentage of smokers using either the nicotine patch or nicotine gum in any given month was relatively low. There are higher rates of gum and patch use in the months following their availability OTC (April for the gum and August for the patch). The use of nicotine gum peaked at 0.67 ± 0.26% in June 1996, whereas the use of nicotine patches peaked later in the year with 1.13 ± 0.54% of smokers using the patch with their quit attempts in October 1996. There is also a suggestion that the availability of nicotine patches may have led to a decline in the number of smokers using gum, as the rate of gum usage declined after the patch became available OTC in July 1996. Figure 1 also shows the results of four separate multiple regression models testing whether cessation attempts and smoking abstinence increased after the OTC availability of the patch and gum although controlling for the biased recall of failed cessation attempts with time since cessation. Results from these models indicate a significant increase in the percentage of smokers reporting a quit attempt with nicotine gum (P < 0.001) and the nicotine patch (P < 0.05) following OTC availability. In both models, the term representing the number of months between the quit month and survey month was significant (Table 1), which suggests a recall bias for unsuccessful quit attempts.

**NRT Use and Smoking Abstinence by Calendar Month.** Figure 2 presents the percentage of eligible smokers who were abstinent at the time of the survey by the month of their quit attempt. The abstinent smokers are separated into those who...
used nicotine gum, nicotine patches, or no NRT in their most recent quit attempt. The values are presented as percentages of all smokers who were available to quit in that month rather than as percentages of those who made a quit attempt or percentages of those who made a quit attempt using NRT. These absolute rates of abstinence with and without NRT use reflect the net contribution of smokers whose quit attempts were made with and without NRT to the abstinent population of recent quitters. The high absolute rates of abstinence among those who did not use NRT reflects the high percentage of smokers who attempt to quit without NRT and the expression of all of the rates as a percentage of all eligible smokers rather than those who try to quit.

As observed in Fig. 2, no smokers reported abstinence with nicotine gum during the months of November and December 1995 or in November 1996. The months following the OTC availability of nicotine gum or the patch generally showed higher rates of abstinence among those using NRT and this observation is supported by the results of separate regression models (Table 1). Results from each model showed a significant increase in the proportion of smokers reporting abstinence with the nicotine patch following the availability of the patch OTC ($P < 0.01$) and a significant increase in the proportion of smokers reporting abstinence with nicotine gum after OTC availability ($P < 0.01$). These results suggest that, following OTC availability, the absolute rate of abstinence associated with NRT use increased in the population of smokers as a whole, defining a net (percentage using NRT multiplied by the percentage using NRT who achieve abstinence) improvement in abstinence associated with OTC availability. The term representing the number of months between the quit month and survey month was not significant in either of the models, suggesting no bias in the recall of successful quits.

There was no increase in abstinence rates across time for smokers not using NRT ($P = 0.87$). The absence of a time trend for abstinence rates among those who did not use NRT suggests that the increases in abstinence observed with the patch and gum after OTC availability is not simply the result of a temporal bias produced by the greater likelihood of relapse by smokers as the time since their last quit attempt increases.

Effectiveness of OTC NRT. The possibility that increased use of OTC NRT was associated with a decreased effectiveness of NRT for achieving abstinence is examined in Fig. 3. It presents the percentage of quit attempts resulting in abstinence at the time of the survey among those who used NRT in the quit attempt and for those who did not. If NRT became less effective following availability OTC, one would expect to see a decline in the percentage of quitters achieving abstinence in the months following OTC availability among those who used NRT. There is no decline in the percentage abstinent for those who used NRT. Indeed, there was a marginally significant increase ($P < 0.08$) in the rates of reported abstinence among individuals who used NRT. In contrast, rates of abstinence for smokers who did not use NRT with their most recent quit

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**Figure 1.** Percentage of smokers available to quit in a given month who used nicotine patches or gum in a quit attempt by the month and year of their most recent attempt to quit.

**Table 1.** Multiple regression modeling of quit attempts and abstinence before and after the availability of NRT products OTC controlling for biased recall of quits

<table>
<thead>
<tr>
<th>Model covariates</th>
<th>Model 1: Quit attempts with patch</th>
<th>Model 2: Abstinence with patch</th>
<th>Model 3: Quit attempts with gum</th>
<th>Model 3: Abstinence with gum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of months between quit and interview</td>
<td>$\beta$</td>
<td>$P$</td>
<td>$\beta$</td>
<td>$P$</td>
</tr>
<tr>
<td>Before/after OTC NRT</td>
<td>$-0.052^*$</td>
<td>0.004</td>
<td>$-0.015^*$</td>
<td>0.082</td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.263</td>
<td>0.028</td>
<td>0.159</td>
<td>0.008</td>
</tr>
</tbody>
</table>

*$Linear term.$

$^1Logarithmic term.$
attempt decreased significantly as time since the quit attempt increased ($P < 0.01$). The difference in slopes of abstinence rates across time between those who used NRT and those who did not provides further evidence that the effect of NRT was not diminished following OTC availability.

**Discussion**

Approval of OTC NRT was expected to increase the use of gum and the patch by removing the requirement for a physician’s prescription (2, 9, 14). Studies of NRT sales data show increases in NRT use following the OTC availability of nicotine gum and the nicotine patch (2, 3). Our results confirm the increased use of NRT by California smokers after it was available for use OTC. The proportion of smokers who used these products in conjunction with a quit attempt increased significantly in the months following OTC availability. These findings complement and extend the results from the sales data studies and suggest that the regulatory status of these products served as a barrier to their use. When NRT products became available without having to see a physician for a prescription, their use by smokers increased almost immediately.

Our results are presented as the percentage of all smokers available to quit in a given month, so that the net effect on abstinence (the combination of use and effectiveness) of increased NRT use after OTC availability could be examined. We also show that the increased NRT use following OTC availability was not accompanied by a decrease in effectiveness of NRT. The results of this study show an increase in net abstinence associated with NRT use immediately following its

Figure 2. Percentage of smokers available to quit in a given month who remain abstinent and whose quit attempt used nicotine gum, nicotine patches, or no NRT by the month and the year of their most recent attempt to quit.

Figure 3. Percentage of smokers remaining abstinent reporting that their quit attempt used NRT or did not use NRT by month of the quit attempt.
availability OTC. A similar increase in abstinence rates was not observed among those whose quit attempt did not include NRT (Fig. 2), suggesting that the improved abstinence occurred preferentially among those who used NRT. This is consistent with a causal relationship between OTC availability and the increased abstinence. Regression modeling of these data also suggests that the increased abstinence was associated with the timing of OTC availability and was not explained by temporal trends in maintaining abstinence following a cessation attempt.

Unlike nicotine gum, two OTC patch products became available during the later half of 1996. The first OTC patch was available for purchase at the end of July 1996, and in early August 1996, the Food and Drug Administration approved a second patch product for sale OTC which was available for purchase not long after the Food and Drug Administration’s approval. For our analyses, we only examined the temporal effects of the first OTC patch availability on smoking cessation and we did not account for the timing of the availability of the second OTC patch in our analyses. Given the close proximity in which both patch products were made available for purchase OTC, it is likely that the availability of both OTC patches increased quit attempts to a greater extent than only having a single OTC patch available.

The conclusions from our analyses differ somewhat from those of population-based surveys in Massachusetts and analyses of sequential surveys from multiple years of the California Tobacco Survey. Thordike and colleagues (9) found no increase in use of NRT or cessation activity between 1993 to 1994 (pre-OTC) and 1997 to 1999 (post-OTC) in a comparison of data from the 1993 to 1994 Massachusetts Tobacco Survey and the 1997 to 1999 Massachusetts Adult Tobacco Survey. Pierce and Gilpin (10) showed that smokers who used NRT in their cessation attempt had higher rates of abstinence when compared with those who used no pharmacological aid in the 1992 and 1996 California Tobacco Surveys. However, analyses of the 1999 California Tobacco Survey showed an improved rate of abstinence among NRT users only for the first 3 months following cessation, with no difference in rates of cessation success at longer intervals following cessation. The sequential California Tobacco Survey did show an increased rate of NRT use between 1996 and 1999, although the rate of NRT use in the 1999 California Tobacco Survey was lower (14.0%) than in the 1997 to 1999 Massachusetts survey (21.4%).

The analyses of California and Massachusetts surveys described above examine data collected several years apart and are able to describe long-term trends across multiple years. However, they are also subject to biases that may be introduced by temporal events other than OTC availability of NRT that may also influence cessation events. For example, the 1999 California Tobacco Survey was conducted following a substantial increase in the cost of cigarettes due to the Master Settlement Agreement of the Attorney General’s Lawsuits in November 1998 and a 50¢ per pack tax increase in California in January 1999. This price increase may have altered the magnitude and timing of cessation events in California, potentially biasing the results for the 1999 California Tobacco Survey.

Our analyses are not in conflict with those of Thordike and colleagues (9) or Pierce and Gilpin (10) because we examine different questions, along with a different time frame. Pierce and Gilpin found an effect of NRT use on abstinence for the survey wave, which was conducted during the year that NRT became available OTC. Our analyses examine the rates of NRT use and rates of abstinence in the months immediately before and immediately after OTC availability in order to examine the questions of whether OTC availability increased use of NRT and whether increased use of NRT resulted in an increase in the percentage of smokers who were abstinent in the months immediately following OTC availability. We offer evidence that there was an immediate benefit of NRT use for abstinence following the OTC availability of NRT, but we offer no data on longer-term changes in efficacy of NRT use over time, on effects beyond the first 6 months of OTC availability, or on the effects of OTC availability on rates of long-term abstinence.

Some of the respondents reporting abstinence with OTC NRT in this study are likely to have subsequently relapsed (15), leading the abstinence rates presented in this paper to overestimate longer-term success. However, because of data censoring, most of the smokers reporting abstinence in this study had been abstinent for a minimum of 1 month or more, eliminating the period of greatest recidivism.

**Study Limitations.** There are a number of important limitations to the analyses that we present, most notably that the cessation and abstinence observations are based on self-reported recall of cessation events from a cross-sectional survey rather than longitudinal follow-up of individuals who quit. Because there is a substantial decline in the frequency of self-reported cessation attempts as the interval between the cessation attempt and the time of the survey interview increases (13), we attempted to deal with this bias by including the duration of the interval between cessation and the survey interview as a term in the model that examines the effect of OTC availability. However, since the survey was conducted over only 5 months, the variability of the data available to control for this bias was limited.

In addition, the recall bias is assumed to be similar for those who used NRT in their cessation attempt compared with those who did not. It is possible, or even likely, that use of NRT might increase the likelihood that a failed quit attempt would be recalled.

Another limitation of this study relates to the use of a 24-hour period of smoking abstinence to define a “legitimate” quit attempt. Because aided quit attempts likely help quitters abstain for >24 hours and the California Tobacco Survey only asks participants about quit attempts that last for at least 24 hours in duration, the monthly percentages of unpaid quit attempts and smokers remaining abstinent may have a bias introduced by NRT use.

There are also differences between smokers who use different methods of cessation assistance (16, 17), and it is possible that our results could be explained by differences among smokers who used prescribed NRT, smokers who used OTC NRT, and smokers do not use NRT products. There were no differences in demographics measures of age, gender, race/ethnicity, or education when comparing smokers who used prescription NRT to those who used OTC NRT. However, a significantly greater proportion of less addicted smokers (i.e., smokers who have their first cigarette in the morning <30 minutes after waking) used the OTC patch compared with the prescribed patch (P < 0.01).

It is also possible that differences between smokers who use NRT and those who do not may explain the results obtained in the study. Smokers who used NRT in their most recent quit attempt (regardless of NRT OTC status) were more likely to be white, female, 45 years and older, more educated, and have higher household income (all P values < 0.05) than smokers who did not use these products. Furthermore, smokers who used NRT were more likely to smoke a cigarette within 30 minutes of waking (P < 0.0001) and smoke 15 or more cigarettes per day (P < 0.0001) than smokers who did not use NRT. The fact that more addicted smokers used NRT and were more likely to successfully quit after these products were available OTC makes the findings of this study even more compelling.

Smoking relapses continue to occur at substantial, albeit declining, rates as the duration of abstinence progresses (18-21). The absence of a decline in abstinence with increasing
time since survey for those who quit without use of NRT (Fig. 3), coupled with the steep increase in abstinence among those using NRT once NRT became available OTC, are consistent with an increase in net abstinence that resulted from OTC availability. However, these results are also consistent with an increased use of NRT by those who were going to be successful in their cessation attempts even if they had not used NRT; therefore, with no net increase in abstinence. The limited precision with which the decline in abstinence with increasing time since the cessation attempt can be determined in our data and the likely differences between the populations of smokers who choose to use or not use NRT confound causal attribution from these analyses, but the modeling suggests that the effect is more closely associated with the timing of OTC availability than with the duration of the interval between cessation attempt and survey date.

Rates of abstinence are also presented using those who reported a quit attempt with NRT or without NRT as the denominator in order to assess trends in successful abstinence per cessation attempt (Fig. 3). Rates of successful abstinence among those who used NRT did not decline after the OTC availability of these NRT products. Our observations do not support a decline in the effectiveness of NRT following OTC availability.

Conclusions. The results of this study show that improving the availability of NRT products in California is likely to have resulted in an increase of quit attempts and successful abstinence during the interval immediately following OTC availability.

References
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