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Misuse of and dependence on over-the-counter nicotine gum in a volunteer sample

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To estimate the amount of misuse of and dependence on nicotine gum in an over-the-counter (OTC) setting, we conducted two telephone surveys of smokers recruited by newspaper ads. Study 1 surveyed 266 U.S. ever-smokers using OTC gum to determine the percentage who used the gum for noncessation reasons or used gum and cigarettes concurrently. In Study 1, 6% initially purchased nicotine gum to reduce smoking and 1% to avoid smoking restrictions. At the time of interview, 35% chewed gum and smoked cigarettes concurrently with a mean of six cigarettes per day and 15 mg/day of nicotine from gum. Among long-term users ($\geq$90 days), 20% attributed their use to addiction. To determine what proportion of those reporting addiction would meet *DSM-IV* or ICD-10 criteria for dependence, Study 2 surveyed 100 current and ex-smokers who reported addiction to OTC nicotine gum. In these gum users, 66% met *DSM-IV* and 74% met ICD-10 criteria for dependence. Combining the results of Studies 1 and 2 with other data suggests very few gum users develop dependence on the gum. We conclude (a) very few people use nicotine gum for noncessation reasons, (b) concurrent use of gum and cigarettes is common but involves a small number of cigarettes and pieces of gum per day, and (c) the incidence of dependence on OTC nicotine gum is very small.

Introduction

Nicotine gum is approved in more than 50 countries and is a nonprescription product in approximately 70% of these countries (Corrao, Guindon, Sharma, & Shokoohi, 2000). The U.S. Food and Drug Administration (FDA) approved the switch of nicotine gum from prescription to over-the-counter (OTC) status in 1996 (Burton, Kemper, Baxter, Shiffman, Gitchell, & Currence, 1997; Centers for Disease Control and Prevention, 2000; Shiffman et al., 1997). One concern regarding the switch to OTC status has been the potential increase in misuse of, abuse of, or dependence on nicotine gum (Hughes, 1998).

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The terms *misuse, abuse*, and *dependence* have been used in several ways. Neither the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., text rev.) (*DSM-IV-TR*) (American Psychiatric Association, 2000) nor the *International Classification of Diseases* (10th ed.; *ICD-10*) (World Health Organization, 1992) uses the term *misuse*, but this term commonly refers to use of medications for reasons other than their indication. If actual harm from repeated episodes of such off-label use also occurs, this is typically labeled *abuse* and is defined in *DSM-IV-TR* (American Psychiatric Association, 2000) and *ICD-10* (World Health Organization, 1992). Although the definition of *misuse* could be extended to encompass any form of noncompliance (e.g., underdosing), typically the term represents off-label use that might be seen as a precursor to abuse or dependence. The most commonly cited misuse concerns about nicotine replacement therapy (NRT) have been use by never-smokers, use for noncessation reasons, or concurrent use of gum and cigarettes (Hughes, 1998). Use of nicotine gum by never-smokers is extremely rare (Hughes, 1998). Some studies report some smokers used prescription gum to avoid

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smoking in smoke-free areas or used gum concurrently with cigarettes; however, whether these actions were part of a quit attempt was unclear (Hughes, 1998). This distinction is important because although concurrent use or use to avoid smoking restrictions could represent smokers who never intended to use the gum to stop smoking, it also could represent smokers who tried to quit, were not able to do so, and are now gradually reducing smoking as a way to stop smoking; or smokers who quit for a while and are in the process of relapsing.

In both *DSM-IV* and *ICD-10*, *dependence* refers to impaired control of drug use, for example, inability to quit (American Psychiatric Association, 2000). In past studies of OTC gum, long-term use has been used as a proxy measure of dependence (Johnson, Hollis, Stevens, & Woodson, 1991; Johnson, Stevens, Hollis, & Woodson, 1992; Ramstrom, 1994; Sinclair, Bond, Lennox, Taylor, & Winfield, 1995; Thorndike, Biener, & Rigotti, 2001); however, the assumption that all long-term use represents dependence carries with it several problems (Hughes, 1998). We are unaware of studies directly testing for dependence on nicotine gum by using standard *DSM-IV* or *ICD-10* criteria for dependence.

This article reports the results of two telephone surveys using volunteer samples. Study 1 was conducted to determine the prevalence of the two forms of nicotine gum misuse most commonly cited as a concern with OTC use, that is, use for noncessation reasons and concurrent use with cigarettes. After Study 1 was completed, we noted some users attributed their gum use to addiction; thus, Study 2 was conducted to determine the proportion of self-reported addiction to nicotine gum that is concordant with standard criteria for drug dependence. Finally, we used the results from a prior population-based sample of the incidence of long-term use of OTC gum (Shiffman, Hughes, Pillitteri, & Burton, 2003a) plus the data from our two studies to estimate the amount of dependence on nicotine gum among all who start gum use.

Methods of Study 1

Participants

Participants were recruited mostly via ads placed in Albany, New York; Boston, Massachusetts; Burlington, Vermont; Hartford, Connecticut; and Providence, Rhode Island newspapers in 1997. Some participants (4%) were recruited via signs in pharmacies in Burlington. Both newspaper and pharmacy ads were very brief and indicated that current nicotine gum users were sought for a telephone survey conducted by the University of Vermont and specified reimbursement of $25 for their time. Neither mentioned the purpose of the survey. The study was approved by the University of Vermont ethics committee.

Initially, 351 potential participants were contacted. A total of four declined to participate following a description of the study requirements, and 81 did not meet the following eligibility criteria: (a) Age 18 years or older, (b) smoked daily in the past, or (c) used at least one piece of nicotine gum on at least two of the past four days. Among the 266 participants, 62% were women, the mean age was 46 years ($SD = 13$), mean cigarettes per day when last smoked was 21 ($SD = 14$), and mean Fagerström Test for Nicotine Dependence (FTND) score (Heatherton, Kozlowski, Frecker, & Fagerström, 1991) when last smoked was 5 ($SD = 2$).

Procedures

All interviews were done over the telephone and focused on reasons for initial use and current use of nicotine gum. Response options for initial use were as follows: "You were smoking and you wanted to stop smoking," "You had stopped smoking and you wanted to prevent going back to smoking," "You were not trying to stop smoking but you were trying to reduce smoking," "You were not trying to stop or reduce smoking but you wanted to avoid smoking in certain places or at certain times," and "Some other reason." For current use reasons, the same options phrased in the present tense were used.

Results of Study 1

Gum use

About half (46%; 95% $CI = 40\%–52\%$) of the sample had used the gum longer than the recommended 3 months. This finding differs substantially from national samples in which only 5%–10% use the gum for 3 months or longer (Shiffman et al., 2003a; Shiffman, Hughes, DiMarino, & Sweeney, 2003b). Results were examined separately for long-term gum users (≥ 90 days of use) and short-term users, and results are reported separately for these two groups when the results were different. Among long-term users, the median number of days of use was 242 days (25th–75th percentile = 158–409), and mean number of milligrams of nicotine per day from gum was 16 mg/day ($SD = 11$); among short-term users, the median number of days of use was 23 days (25th–75th percentile = 14–44), and the mean amount of nicotine from gum was 15 mg/day ($SD = 11$).

Reasons for nicotine gum use

At the time of initial purchase, the large majority of gum use was to stop smoking (83%, $CI = 78\%–87\%$) or

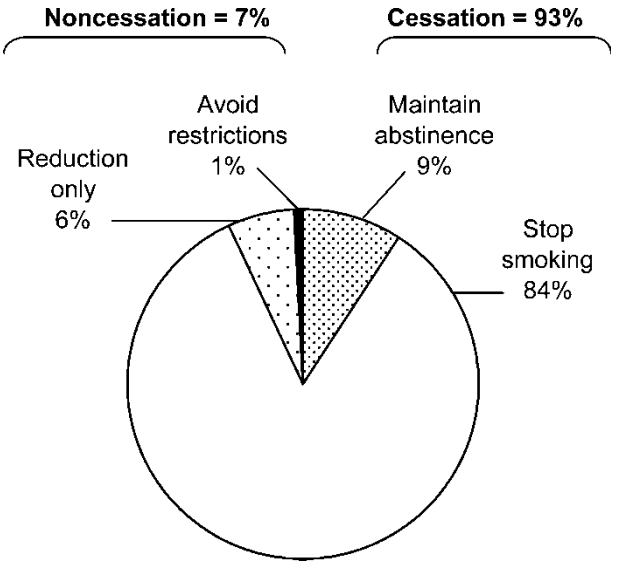

Figure 1. Reasons for initial purchase of over-the-counter nicotine gum.

maintain abstinence (9%, *CI* = 6%–14%), and little was to reduce only (6%, *CI* = 4%–10%) or to avoid smoking restrictions (1%, *CI* = 0%–4%) (Figure 1). At the time of the survey, most gum use among short-term users was to stop smoking or maintain abstinence (87%, *CI* = 81%–92%), and again little was for noncessation reasons (12%, *CI* = 7%–18%). Although most long-term users were using the gum to stop smoking or prevent relapse (72%, *CI* = 63%–79%) and few for noncessation reasons (8%, *CI* = 4%–14%), one-fifth (20%, *CI* = 14%–29%) spontaneously volunteered "addiction" as the reason for their continued use.

Concurrent gum and cigarette use

At the time of the survey, 35% (*CI* = 29%–41%) of gum users stated they were smoking and using gum concurrently, that is, on the same day. Many had tried to quit smoking and relapsed but had reduced the number of cigarettes smoked per day (21%, *CI* = 17%–27%), some never quit smoking but reduced smoking (11%, *CI* = 7%–15%), and a few were smoking at their normal rate (3%, *CI* = 1%–6%). Concurrent users at the time of the survey averaged concurrent use on 5 of the past 7 days and on the days of concurrent use averaged 15 mg/day of nicotine from gum (*SD* = 11) and six cigarettes per day (*SD* = 7).

The small sample of participants who reported initially purchasing the gum solely to reduce their smoking ($n = 16$; 6%) smoked a mean of 28 cigarettes per day (*SD* = 23) prior to gum use and decreased this to a mean of 11 cigarettes per day (*SD* = 11) at the time of the survey.

We used logistic regression to determine whether age, sex, FTND score, cigarettes per day, or number of years smoking predicted initial purchase of the gum to reduce smoking vs. to stop smoking, long- vs. short-term use of gum, and volunteering addiction as a reason for continuing use of gum. Heavier smokers tended to be more likely to purchase for reduction ($p = .06$). Those who had smoked longer or were older (these variables were highly correlated) were more likely to be long-term users ($p < .0001$). No variables predicted volunteering addiction as a reason for gum use.

Methods of Study 2

The rate of self-volunteered addiction in Study 1 was not discovered until about 2 months after the interview was completed. An attempt to contact the 27 participants who volunteered addiction produced a very low response rate; thus, we conducted a new study to determine what proportion of those who report addiction to nicotine gum would meet standard criteria for nicotine dependence.

Participants

Participants were recruited via a new set of ads placed in Albany, Burlington, Boston, and Hartford newspapers in 2000. These ads stated, "Are you addicted to nicotine gum? If so we would like to interview you as part of a University of Vermont study. Reimbursement of $25 for one telephone interview."

We contacted 139 potential participants. Three declined to participate following a description of the study requirements, and 36 did not meet the following eligibility criteria: (a) Believed they were addicted to nicotine gum, (b) currently used nicotine gum at least once per week, (c) used gum for at least 1 month and used at least two pieces of gum in past 4 days, (d) age 18 years or older, and (e) smoked in the past. Among the 100 participants, 59% were women; the mean age was 50 years (*SD* = 10), mean cigarettes per day when last smoked was 30 (*SD* = 15), and the mean FTND score was 6.7 (*SD* = 1.8).

Protocol and survey questions

The telephone interviews consisted of the same questions asked in Study 1 plus an interview for dependence on nicotine gum using the diagnostic criteria for dependence from *DSM-IV-TR* and *ICD-10*. The interview was adopted from an interview about nicotine dependence from cigarettes that we have shown to be reliable and to have high concordance with clinician diagnoses (Hughes, Oliveto, Liguori, Carpenter, & Howard, 1998; Hughes, Oliveto, & MacLaughlin, 2000). In Study 2, users were asked

about dependence phenomena that occurred at any point during their gum use. The interview did not use the *DSM-IV* dependence items about a great deal of time obtaining, using, and recovering from drug use or important social, occupational, or recreational activities given up because of drug use, nor did it use *ICD-10* items about progressive neglect of alternative interests. These criteria appear not to apply to gum use. The remaining items were based almost verbatim on *DSM-IV* or *ICD-10*. Thus, the total number of dependence criteria used was five rather than seven for the *DSM-IV* diagnosis and five rather than six for the *ICD-10* diagnosis of dependence.

Results of Study 2

Gum use

The median duration of gum use was 32 months (*CI* = 15–50). A total of 98% (*CI* = 96%–100%) of participants had used gum at least 3 months. The mean daily dose of nicotine at the time of the interview was 30 mg/day (*SD* = 20). A total of 92% (*CI* = 87%–97%) purchased gum initially to stop smoking or prevent relapse, 2% (*CI* = 0%–5%) to reduce smoking, and 4% (*CI* = 0%–8%) to avoid restrictions. At the time of the survey, 88% (*CI* = 82%–99%) were not smoking; that is, 12% (*CI* = 6%–23%) were concurrent gum and cigarette users.

Dependence

The *DSM-IV-TR* items about tolerance (65%, *CI* = 56%–75%), withdrawal (72%, *CI* = 63%–81%), inability to control use (65%, *CI* = 55%–74%), and difficulty stopping (75%, *CI* = 66%–84%) and the *ICD-10* item about uncontrollable urges (67%, *CI* = 58%–76%) were each endorsed in two-thirds of participants who reported addiction. Use despite harm was endorsed in only about one-quarter (26%, *CI* = 17%–35%). About two-thirds of those claiming addiction (66%, *CI* = 57%–75%) would meet at least three criteria in the *DSM-IV* system (required for a diagnosis of dependence), and about three-fourths (74%, *CI* = 65%–83%) would meet at least three criteria in the *ICD-10* system (the requirement for diagnosis in that system). The mean self-ratings for severity of current addiction to gum was rated less than that for past addiction to cigarettes (8.3 vs. 9.4 on a 10-point scale, $p = .001$). Among the 80% who had tried to reduce gum use, the most common withdrawal symptoms were craving for gum (90%, *CI* = 83%–97%), restlessness (86%, *CI* = 79%–94%), anxiety (84%, *CI* = 76%–92%), irritability (80%, *CI* = 71%–89%), difficulty concentrating (64%, *CI* = 53%–75%), and craving for cigarettes (58%, *CI* = 46%–69%). A total of 61% (*CI* = 46%–76%) reported that stopping gum was extremely difficult, and 59% (44%–74%) reported that stopping cigarettes was extremely difficult.

Estimate of the incidence of dependence among all users

To provide an estimate of the amount of dependence on nicotine gum among all who begin gum use, we linked our results from Studies 1 and 2 with those of a prior study that determined the rate of long-term use (at least 3 months) of nicotine gum. The prior study examined the purchase pattern of nicotine gum among 824 households in the A.C. Nielsen population-based household panel (Shiffman et al., 2003a), in which households scan all purchases each week. The study examined households that purchased nicotine gum between January 1997 and March 2000. In this sample, 5.2%–9.5% of households purchased gum continuously for at least 3 months, depending on how strict the criteria were for declaring use continuous.

To provide a gross estimate of the incidence of dependence among all who purchased OTC gum, we multiplied the incidence of long-term gum use from the prior study (5.2%–9.5%) by the prevalence of self-reported addiction among long-term users in Study 1 (20%) by the prevalence of dependence among long-term users reporting addiction in Study 2 (66%–74%). This calculation produced an estimate suggesting that very few (.7%–1.4%) of all gum users will develop dependence.

Discussion

Methodological issues

First, both studies recruited volunteer samples; thus our results may not be generalizable to national samples. However, we are unaware of any population-based sample that has or is currently asking about OTC NRT misuse, abuse, or dependence. Second, our studies were single cross-sectional surveys. By definition, such surveys oversample those with more chronic conditions; this explains in part the very high rates of long-term users. In addition, although ads for Study 1 did not mention that we were interested in misuse or dependence, ads for surveys of current users of a product may especially recruit those who have had problems with the product. In contrast, Study 2 explicitly stated that we wished to survey those who were addicted. Another bias is that volunteer samples often have a higher prevalence of and more severe forms of a disorder than population-based samples (Klingemann et al., 2001). However, *addiction* is often

perceived as a pejorative term; therefore, some gum users in Study 1 may have been reluctant to volunteer addiction.

Misuse

The two forms of misuse investigated in this study were use of the gum for reasons other than that intended by the manufacturer and the FDA (i.e., use for noncessation reasons) and concurrent use of gum and cigarettes. Few OTC gum users (< 10%) reported initially purchasing the gum for noncessation reasons. This finding is consistent with the one other survey of OTC misuse (from a non-peer-reviewed source), which found that 17% of Europeans used the gum for noncessation reasons (Ramstrom, 1994). This low rate could be related to the advertising and labeling instructions on the gum or the high initial cost of the gum.

By contrast, concurrent use of gum and cigarettes was common in this study (35%), as in prior studies (33%–49%; Ramstrom, 1994; Sinclair et al., 1995; Thorndike et al., 2001). However, the prior studies were unclear how the concurrent use came about. In our study, the large majority of concurrent use was related not to a priori planned use of the gum for reduction only but rather to relapsed smokers now smoking fewer cigarettes per day. Unfortunately, we did not ask how long such concurrent use had been ongoing. Thus, we do not know whether this concurrent use represents use during a brief transition period from smoking to abstinence or from abstinence to smoking, or if it represents stable long-term concurrent use.

The amount of gum use on a given day of concurrent use was modest yet was associated with a large reduction in cigarettes per day (to only six per day). Whether such gum-assisted reduction in cigarettes per day that continues over a long period confers health benefits or leads to increased quitting is unclear (Godtfredsen, Hoist, Prescott, Vestbo, & Osler, 2002; Nordstrom, Kinnunen, & Garvey, 2000; Stratton, Shetty, Wallace, & Bondurant, 2001).

This study was not designed to examine other forms of misuse. Perhaps the form of misuse of most concern that we did not survey was use by never-smokers; however, other studies suggest this type of misuse is very rare (Hughes, 1998). Also, the study did not examine abuse (i.e., harm from repeated use). Again, other studies suggest clinically significant harm from gum use is very rare (Hughes, 1998).

Dependence

In Study 1, 20% of long-term users spontaneously volunteered addiction as a reason for their continued gum use. Although this figure is substantial, the fact that 80% of long-term users did not report dependence suggests most long-term use is not related to dependence.

Our 20% rate of self-reported dependence may be an underestimate or an overestimate. It may be an underestimate because our calculation of the prevalence of dependence is based solely on those who volunteered addiction in Study 1. Any cases of dependence among those who did not volunteer addiction because of embarrassment were missed. It may be an overestimate because half of participants in Study 1 were long-term users, compared with the 5%–10% in generalizable surveys (Hughes, 1998). In addition, participants in Study 1 who responded to the ad seeking gum users may have been gum users who wanted to tell someone about their dependence, which would have resulted in an overestimate.

In Study 2, among those who claimed addiction to nicotine gum, two-thirds to three-fourths met *DSM-IV* or *ICD-10* criteria for dependence. This estimate also may be an underestimate or overestimate. It may be an underestimate because our estimate does not include cases of dependence that occurred prior to 3 months but then resolved by 3 months. It may be an overestimate because the interviews were conducted by nonclinicians during a brief phone interview. Such interviews did not probe for whether the severity and clinical significance of the criteria endorsed were sufficient.

Our estimate that few of those who initiate nicotine gum use become dependent on the gum is based on combining data from three different studies; thus, study differences in samples (population-based vs. volunteer samples) or mode of ascertainment (purchases vs. self-report) could have introduced error. As a result, we believe our calculated rate of less than 2% should not be cited as a point estimate; however, our results do suggest dependence is uncommon. In addition, as far as we know, none of those dependent on the gum will experience harmful effects from the gum, other than financial loss (Hughes, 1998). Also, nicotine dependence among gum users does not develop de novo but rather represents a transfer of pre-existing nicotine dependence from cigarettes. Finally, because nicotine gum delivers nicotine much more slowly than cigarettes (onset = 15 min vs. 10 s) and because nicotine gum use is less frequent than cigarette use (6 per day vs. 20 per day), dependence on nicotine via gum is likely to be much less severe than dependence on nicotine via cigarettes (Hughes, 2001).

Summary

In summary, our results indicate purchase of OTC gum for reasons other than smoking cessation is probably rare; however, postrelapse continued use of gum to reduce smoking is a common occurrence. Further work into the duration and consequences of

such concurrent use in terms of adverse effects, health benefits, and, perhaps most important, effects on later cessation are needed (Stratton et al., 2001).

Our results also suggest most long-term use is not true dependence and that true dependence is uncommon. Thus, fear of addiction should not be a reason for physicians, tobacco control advocates, administrators, or smokers to avoid recommending nicotine gum as an OTC smoking cessation aid.

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Disclosure of competing interests

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