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# Nicotine Chewing Gum Use in the Outpatient Care Setting

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**Background.** The purpose of this study was to assess nicotine gum use when prescribed in a nonresearch, routine outpatient setting. Special attention was given to comparing actual use patterns with established guidelines for use based on clinical research.

**Methods.** A randomly selected group of 612 patients who had received a prescription for nicotine gum during an 18-month period were surveyed regarding their smoking history and use of the gum.

**Results.** Most of the gum prescriptions (75%) were requested by patients rather than recommended by medical care providers. Less than one half of the users were heavy smokers. The reported amount of gum used was small, with more than one half reporting consumption of one box or less, and about one third reporting use of the gum for only 1 week or less. Larger amounts of

gum use, however, were associated with abstinence from tobacco. Only one in 20 users attended a structured behavioral treatment program while using the gum. Over one half of the patients reported using nicotine gum to help them cut down on, rather than quit, smoking.

**Conclusions.** Only a small percentage of the patients used the nicotine gum according to the established guidelines, and most of the patients used the gum in ways that have been shown to be ineffective for smoking cessation. Providers should educate their patients in the techniques that maximize the use and effectiveness of nicotine gum in smoking cessation.

**Key words.** Nicotine; tobacco use disorder; chewing gum; substance dependence. *J Fam Pract* 1992; 34:61-65.

Nicotine chewing gum was approved by the US Food and Drug Administration in 1984 for general distribution as a smoking cessation aid. Since that time a vigorous marketing campaign has made nicotine gum one of the most commonly prescribed pharmaceuticals in the United States, with estimated manufacturer's sales exceeding \$100 million in 1990.<sup>1</sup> Since the average nicotine gum consumption per patient is about two boxes,<sup>2</sup> and each box has an estimated manufacturer's cost of approximately \$21,<sup>3</sup> we estimate that over two million smokers received nicotine gum in 1990.

Despite its large sales volume, relatively little is known about how nicotine gum is actually used by patients outside carefully controlled research environments. Placebo-controlled clinical trials and the distributor's guidelines for use<sup>4</sup> indicate that nicotine gum is an

effective smoking cessation strategy only when patients: (1) completely avoid tobacco while using the gum,<sup>4-6</sup> (2) use the gum as part of a structured, multisession behavioral treatment program for smoking cessation,<sup>6-10</sup> and (3) use from 10 to 12 pieces of the gum per day for 1 to 3 months of treatment.<sup>6,11,12</sup> After 3 months, a gradual withdrawal from gum use is recommended, with completion of treatment within 6 months.<sup>4</sup> Further, the gum has been shown to be most effective for nicotine-dependent smokers (ie, heavy smokers who have trouble abstaining from smoking for more than a short time) and is of little benefit to light or non-nicotine-dependent smokers.<sup>13</sup>

We previously examined pharmacy records to determine nicotine gum prescription patterns among members of a health maintenance organization (HMO)<sup>2</sup> and concluded that three fourths of the patients did not follow the guidelines for dosage and duration of use. Pharmacy records provide a measure of total gum use but do not provide information about the patient's background or the context in which the gum is used. The purpose of the present study was to examine individual

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characteristics and use patterns in a large population of patients who received their prescriptions for nicotine gum during the course of routine outpatient medical care.

## Methods

### Study Population

Subjects for this study were members of the Northwest Region of Kaiser Permanente (KP), a federally certified HMO serving more than 375,000 people in northwest Oregon and southwest Washington. Using computerized pharmacy records, we identified all members who received one or more prescriptions for nicotine gum from KP outpatient pharmacies between July 1, 1987, and January 1, 1989. Nicotine chewing gum is not included in the KP Regional Drug Formulary, and the Formulary Committee actively discourages prescribing the gum unless patients are participating in a group treatment program. Kaiser Permanente providers can, however, prescribe nonformulary drugs, and patients' prescription drug benefits apply.<sup>2</sup>

After excluding members who did not have an address in the KP membership information file, KP employees, and participants in several ongoing smoking cessation research studies,<sup>13</sup> a sample of 1224 nicotine gum users was identified. After excluding the few prescriptions written by dentists, more than 83% of the prescriptions for nicotine chewing gum were from family physicians, internists, and other nonphysician primary care providers.<sup>2</sup>

A random sample of 50% of the 1224 users was surveyed between January and April 1990 regarding their smoking habits, use of nicotine gum, and beliefs and attitudes about the gum. Survey subjects were first sent a postcard informing them that a questionnaire would be sent. One week later the questionnaire was mailed with a cover letter and a postage-paid return envelope. Those who did not return the survey were sent a second mailing 2 weeks later. If they had not responded within 2 weeks after the second mailing, a telephone follow-up was made, and the questionnaire was completed as a telephone interview.

Mail or telephone follow-up was obtained for 529 (86.4%) of those surveyed. Nonrespondents included 3.9% who refused to participate, 7.7% who could not be located, and 2.0% who were deceased. Of the respondents, 498 (94.1%) reported that they had been regular smokers of cigarettes during the previous 3 years. The remainder reported either regular use of cigars or pipes or regular use of chewing tobacco during the previous 3

Table 1. Cigarettes per Day at the Time Nicotine Chewing Gum Was First Prescribed

| Number of Cigarettes | % of Smokers<br>(n = 445)* |
|----------------------|----------------------------|
| 0†                   | 2.7                        |
| 1-10                 | 12.6                       |
| 10-20                | 38.4                       |
| 21-40                | 38.4                       |
| >40                  | 7.9                        |

\*Number who responded to this question.

†Those reporting no cigarettes may have already quit smoking and were requesting gum to help maintain abstinence.

years. This paper focuses on the 498 nicotine gum users who reported being regular smokers of cigarettes during the previous 3 years. More than 90% of users had a new prescription (first dispensing) during the observation period, suggesting that for most users nicotine gum use was initiated during that time.<sup>2</sup>

## Results

The median age of those receiving a prescription for gum was 45 years (age range 15 to 78 years) and 54.6% were female. Most respondents (75%) reported that they had initially requested nicotine gum from their physician, dentist, or nurse, as opposed to having their provider encourage them to try the gum. Most patients said they had learned about the gum either from friends, family, and co-workers (43%), or from newspapers, magazines, and television (17%). Only about one third learned about nicotine gum from a health care professional.

Over three fourths of patients said that in the past 3 years their physician, dentist, or nurse had advised them to stop smoking. Eighty percent believed that physicians, dentists, and nurses should actively encourage their patients to stop smoking. The remainder were not sure (12%) or disagreed (8%). Two thirds of the respondents said that active encouragement from their physician, dentist, or nurse to stop smoking was helpful, while the remainder said that it was not helpful or they were not sure whether it was helpful.

At the time they received the gum, only 40% of the patients were smoking 25 or more cigarettes per day and could therefore be considered heavy smokers.<sup>12</sup> Fifty-four percent of the patients reported smoking one pack a day or less at the time they received the gum (Table 1). Twelve users reported that they were not smoking at the time they received their first prescription for the gum.

Eighty-eight percent reported making at least one serious attempt to quit smoking during the previous 3

Table 2. Amount of Nicotine Gum Used During the Past 3 Years

| Amount of Gum       | % of Smokers<br>(n = 487)* |
|---------------------|----------------------------|
| None                | 12.7                       |
| Less than 10 pieces | 18.3                       |
| 10 pieces–1 box†    | 30.0                       |
| Number of boxes     |                            |
| 1–5                 | 30.8                       |
| 6–10                | 3.1                        |
| 11–20               | 2.7                        |
| 21–30               | 0.6                        |
| >30                 | 1.8                        |

\*Number who responded to this question.

†One box contains 96 pieces

years (the period in which they had received a prescription for the gum). About one half indicated that they had made one or two serious attempts to quit smoking, and an additional 35% indicated that they had made three or more serious attempts. When asked to report the longest time they had abstained from smoking cigarettes during the past 3 years, almost 30% reported 1 week or less, 25% reported from 1 week to 2 months, and almost 27% reported abstaining from cigarettes for 6 months or longer. Fifteen percent of respondents reported abstinence from all forms of tobacco both during the 30 days before the survey and for 6 months or longer during the previous 3 years. Only 5% of gum users reported that they had participated in a stop-smoking group or class at the time they received their first prescription.

Table 2 shows that 61% reported that they had used less than one box of the gum in the previous 3 years. One box (96 pieces) provides the minimum recommended dosage of 10 pieces per day for about 10 days. Thirty-one percent of patients used a total of fewer than 10 pieces of gum. Among the 62 (12.7%) who received a prescription but reported not using nicotine gum during the past 3 years, 35 said they had not received a prescription for the gum in the past 3 years. This latter discrepancy could have resulted from failure to recall the receipt of a prescription (as long as 3 years could have transpired) or a reluctance to admit to the use of the gum.

Table 3 shows the reported duration of the use of nicotine chewing gum. More than one half (57%) of respondents said they used the gum for less than 1 month, and approximately one third (31%) said less than 1 week. At the other extreme, 11% reported that they used the gum for longer than 6 months. About one third of respondents reported using the gum for the recommended 1 to 6 months.

More than one half (56.6%) of the gum users in the

Table 3. Longest Period of Nicotine Gum Use During the Past 3 Years

| Length of Time of Gum Use | % of Smokers<br>(n = 428)* |
|---------------------------|----------------------------|
| <1 d                      | 7.2                        |
| 1–7 d                     | 24.1                       |
| 1–4 wk                    | 25.3                       |
| 1–2 mo                    | 17.3                       |
| 2–6 mo                    | 14.7                       |
| 6–12 mo                   | 4.2                        |
| 1–2 y                     | 4.4                        |
| >2 y                      | 2.8                        |

\*Number who responded to this question.

total sample reported that they had used nicotine gum to help them “cut down on the amount smoked each day.” Respondents who said they had last used the gum within 4 weeks of the follow-up survey were classified as current users. When asked their reasons for using the gum, those reasons most frequently reported were “when I have cravings” and “to help me avoid smoking completely” (Table 4). Other reasons frequently given were “I use the gum in situations where smoking is prohibited,” and “I use the gum in situations where it is not convenient to smoke.”

A stepwise multiple regression analysis found that larger amounts of gum were used by those who smoked more at baseline ( $\beta = .05$ ,  $P = .07$ ) and by those who reported abstinence at the follow-up survey ( $\beta = 3.98$ ,  $P < .001$ ). In the same regression model, the amount of gum used was not related to age, sex, or whether the patient or the provider initially suggested using the gum.

Table 4. Reasons for Current Use of Nicotine Gum

| Reason   | % of Current Users Reporting<br>(n = 63)* |
|--|---|
| I use the gum when I have cravings                         | 60.5                                      |
| It helps me avoid smoking completely                       | 45.4                                      |
| I use the gum in situations where smoking is prohibited    | 37.8                                      |
| I use the gum when I am nervous                            | 26.9                                      |
| I use it in situations where it is not convenient to smoke | 25.2                                      |
| I like the taste of the gum                                | 7.6                                       |
| Other  | 2.5                                       |

\*“Current users” were those who reported using the gum within the past 4 weeks.

## Discussion

Few of these patients used nicotine gum in accordance with recommended guidelines. It appears that most gum use was initiated as a result of patients' requests rather than a medical care provider's recommendation. Perhaps as a result, only 40% of the nicotine gum users were heavy smokers (25 cigarettes per day or more) who would be most likely to benefit from using gum. It did appear, however, that heavier smokers were more likely to use more gum.

Most patients used only small amounts of gum for short periods rather than the recommended dose of 10 to 12 pieces of gum per day for 1 to 3 months, with decreasing dosage for as long as 6 months. Also, those who used more gum were more likely to be abstinent. This finding is consistent with a recent trial<sup>11</sup> showing that higher doses of gum led to improved long-term smoking cessation results.

Another concern was that over one half of all users, including continuing users at the time of the survey, reported that they used gum to help them cut down on the amount of cigarettes that they smoked each day. Concurrent use of tobacco and nicotine gum is not effective as a cessation strategy. It appears that many patients were using nicotine gum when smoking was inconvenient or prohibited. This use may actually help or enable smokers to remain addicted to tobacco.

Only one in 20 patients participated in a structured behavioral treatment program upon receiving the gum despite the knowledge that nicotine gum has been demonstrated to be effective only when used in this context.<sup>6,10,12,15</sup> Randomized clinical trials<sup>5,7-10,16</sup> of gum use in similar outpatient settings not offering this type of structured multisession group support have shown that nicotine gum does not enhance long-term quit rates relative to placebos.

Medical care providers should welcome the idea that most respondents believed that physicians, nurses, and dentists should actively advise their patients to stop smoking. We also noted that a relatively high percentage of these self-selected patients reported that their medical care provider had advised them to stop smoking. This is an encouraging finding, since numerous studies have shown that simple physician advice, with or without nicotine replacement, is a powerful smoking-cessation intervention.<sup>17-19</sup>

## Conclusions

Few patients in this setting appeared to use nicotine gum in ways that were appropriate for smoking cessation.

Patients in other outpatient care settings should be studied to test the generalizability of these results, although we suspect the problem may be widespread. We recommend that providers of nicotine replacement therapy screen their patients to confirm that they are heavy smokers, that they are willing to use nicotine gum instead of (not in addition to) tobacco, and that they will be using gum as an adjunct to a multisession, structured behavioral treatment program. Patients also need instruction in how to chew the gum so as to avoid side effects and receive a dose adequate to facilitate tobacco cessation. When refill prescriptions are requested, providers and pharmacists should first check to see if the gum is being used correctly and should discourage use beyond 6 months. Following these recommendations will increase the likelihood that nicotine gum will help patients stop smoking.

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