Nicotine Chewing Gum: Effectiveness and the Influence of Patient Education in a Family Practice

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The effectiveness of nicotine chewing gum in a family practice setting was evaluated. Ninety-nine subjects who were given a prescription for nicotine chewing gum were evaluated after one year to determine smoking status. Forty-nine subjects received only the gum, and 50 received the gum along with extensive personal instruction regarding its use. The two groups were compared with a third control group of 40 smokers who expressed no desire to stop smoking. At the end of one year, 12.2 percent of those receiving only gum and 10 percent receiving gum and instruction had stopped smoking, compared with a 20 percent cessation rate for the control group. The observed difference was not statistically significant ($P > .05$). Results of this study suggest that the use of nicotine gum alone may not be a viable alternative for family physicians whose patients desire to quit smoking.

Nicotine chewing gum has been used as an aid to smoking cessation in Britain and Europe for almost ten years and has been recently approved for use in the United States. Clinical trials[1–7] have yielded generally positive results, with success rates at one year ranging from 12.8[1] to 47 percent.[2] These studies were conducted in smoking withdrawal clinics that used the gum in conjunction with behavioral modification and group support techniques.

The results of these studies, however, should not be generalized to patients seen by primary care physicians. Smokers who are attracted to smoking withdrawal programs may be more motivated than smokers in the general population. Additionally, the intensive contact with specialized staff members who provide counseling in these centers is not always readily available to patients of private physicians. A large multicenter British study failed to show a significant difference between the use of nicotine chewing gum and the advice of general practitioners to stop smoking.[8] A controlled trial involving 260 patients in a general practice setting also failed to show any difference in effectiveness between nicotine gum and placebo after six months.[9]

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Nevertheless, nicotine chewing gum is an attractive choice for patients who desire to stop smoking. This study was conducted in a private family practice office and compared smoking cessation rates in patients receiving nicotine gum with a control group of smoking patients. The effect of extensive patient education on success rates was also evaluated. Smoking cessation rates were hypothesized to be positively related to the use of nicotine gum. Smoking cessation rates were also hypothesized to be greater for nicotine gum with patient education than for nicotine gum alone.

METHODS

The study employed a before–after experimental design with a control group. Subjects for the study were smoking patients of a private family practice office who consented to participate. Patients were excluded if they were currently enrolled in a smoking cessation program or had conditions in which the product was contraindicated (ie, pregnancy, active peptic ulcer disease, life-threatening arrythmias, or severe or worsening angina pectoris).[10] Informed consent was obtained from study participants.

Experimental subjects were alternately assigned to one of two groups. Group A consisted of 49 smokers given a prescription for nicotine gum by their physicians. The patients either requested the gum or were asked by their physicians to try it. These subjects were given the booklet,

TABLE 1. STUDY GROUPS

Variable	Group A Gum Only No. (%)	Group B Gum plus Instruction No. (%)	Group C Control No. (%)
Age (years)			
<20	1 (2.0)	3 (6.0)	3 (7.5)
21 to 30	13 (26.5)	8 (16.0)	12 (30.0)
31 to 40	15 (30.6)	15 (30.0)	15 (37.5)
41 to 50	12 (24.5)	15 (30.0)	4 (10.0)
51 to 60	6 (12.2)	8 (16.0)	3 (7.5)
>60	2 (4.1)	1 (2.0)	3 (7.5)
Sex			
Male	23 (46.9)	18 (36.0)	19 (47.5)
Female	26 (53.1)	32 (64.0)	21 (52.5)
Age started smoking (years)			
<15	14 (28.6)	9 (18.0)	14 (35.0)
15 to 25	35 (71.4)	39 (78.0)	26 (65.0)
>25	0 (0)	2 (4.0)	0 (0)
Prior attempt at smoking cessation*			
Yes	40 (81.6)	46 (92.0)	—
No	8 (16.3)	4 (8.0)	—

** One subject in group A did not answer this question*

Quitting with the Help of Nicorette (provided by Merrell Dow Pharmaceuticals) and were asked to purchase the gum that they would use, with a portion of their cost to be rebated if they completed the study. Group A subjects were not formally instructed on the use of the gum but were told to read the booklet before trying the gum.

In addition to receiving a prescription for the gum, subjects assigned to group B (n = 50) received extensive patient education from a clinical pharmacist, including a review of the purpose, proper use, and adverse effects of the gum. Participants were told that the gum would relieve the urge to smoke while they worked on removing smoking from their daily routine. The gum was prescribed to be chewed when needed, either to relieve or to prevent the urge to smoke. To prevent side effects resulting from excessive release of nicotine, subjects were instructed to chew the gum briefly, and then hold the gum in the cheek. Each subject was encouraged to use the gum for a period of at least three months, but for no longer than one year. Pharmacist consultations were conducted in a private room and averaged about 10 minutes.

Subjects in group C, the control group (n = 40), were smokers who expressed no desire to stop smoking at the onset of the study. Subjects were solicited during the study period by means of a poster in the waiting room of the family practice. Members of the control group did not receive any type of intervention but were used to assess smoking cessation rates in the general smoking population during the study period.

After one year subjects were contacted by letter for follow-up and reminded of their eligibility for a rebate for the cost of their gum at completion of the study. If the subject failed to return, a reminder letter was mailed. If the patient still did not return for follow-up, the patient's smoking status was obtained by telephone. All but one claim of smoking abstinence was confirmed by expired air carbon monoxide determination. Expired air carbon monoxide levels correlate with serum carboxyhemoglobin and can accurately identify smokers.[11]

The research design permits the assessment of two possible outcomes: the relative success of the treatment (the nicotine gum) and the relative success of the program (the use of nicotine gum in a family practice setting). Nicotine gum may be effective in curbing the smoking urge, but the effectiveness of the gum in an outpatient program may be negated by side effects or adverse reactions to the drug. To evaluate the success of nicotine gum, the proportion of subjects who completed the study and stopped smoking was compared for the three groups. The relative success of the outpatient program was assessed by comparing the proportion of all subjects who had stopped smoking at the end of 12 months. Analysis of variance was used to test for overall differences in smoking cessation rates.

RESULTS

A total of 139 patients participated in the study. Chi-square analysis indicated no significant differences ($P > .05$) between the three groups with regard to age, sex, age started smoking, or smoking history (Table 1). A total of 39 subjects could not be contacted and thus failed to complete

TABLE 2. SMOKING CESSATION RATES BY GROUP

Group	Number Entered	Number Finished	Number Not Smoking	Percent of Subjects Entered	Percent of Subjects Completing Study
A—Gum only	49	33	6	12.2	18.2
B—Gum plus instruction	50	32	5	10.0	15.6
C—Control	40	35	8	20.0	22.9
Total	139	100	19		

the study. The response rate of the original study group was therefore 72 percent. There were no differences between the three groups with respect to dropout rates ($P > .05$). Six subjects in group A (gum only) and four subjects in group B (gum and instruction) never used the gum and were classified as still smoking.

At the end of 12 months, subjects in all three groups had stopped smoking. Subjects who did not complete the study were assumed to still be smoking. Six (12.2 percent) of those receiving a prescription for the gum only (group A) and 5 (10 percent) of those receiving the gum and individual instruction (group B) had stopped smoking, compared with 8 (20.0 percent) in the control group (Table 2). An analysis of variance of the proportion of subjects who had stopped smoking showed no significant differences among the three groups.

To assess the effectiveness of nicotine gum independent of program effects and attrition, the proportion of subjects who completed the study and had stopped smoking were compared for the three groups. As shown in Table 2, 18.2 percent of the subjects receiving gum only and 15.6 percent of the subjects receiving gum and instruction had stopped smoking at the end of 12 months. These results are similar to a 22.9 percent cessation rate in the control group. An analysis of variance indicates no difference in cessation rates for the subjects in the three groups who remained in the study for the entire period ($F = .29$, $P > .05$) or when all subjects entered into the study are considered ($F = .039$, $P > .05$).

Side effects with the gum were reported in both experimental groups and are summarized in Table 3. There was no significant difference in the average number of side effects reported by the two groups (chi-square = 1.41). Twelve subjects receiving gum only (group A) and seven receiving gum and instruction reported one or more side effects were severe enough for them to discontinue using the gum.

TABLE 3. MOST FREQUENTLY REPORTED SIDE EFFECTS

Side Effect	Gum Only	Gum and Instruction
Nausea	9	14
Headache	7	3
Oral irritation (taste, aphthae)	7	15
Hiccup	8	3

DISCUSSION

In this trial patients who received a prescription for nicotine chewing gum had no greater chance of smoking cessation than those who tried to quit on their own. Moreover, education of the subject about the product did not improve the rate of smoking cessation. Results of this study are similar to other general practice studies conducted in Britain.[8,9] As the gum has been more effective in smoking cessation clinics, it is likely that the combination of both pharmacologic and psychological interventions is effective in breaking the smoking habit.

The effectiveness of nicotine chewing gum may be also related to the motivation of the patient. This attribute is difficult to determine, but those patients who approach a smoking cessation clinic for help and are willing to commit to several weeks of group meetings may be more motivated to stop smoking than those who visit their primary care physician.

Subjects in this study were obtained from a private, nonuniversity-related family practice office. Admission into the study required only a prescription for the gum, and all subjects were required to pay for the gum at the time of use. This design mimics the real-life primary care setting in which the gum is frequently used, and minimizes the chance for a reactive effect due to the experimental arrangement.[12]

As in other trials,[1,7,8] dropouts were considered to be still smoking. Although none of the dropouts contacted by telephone reported that they had stopped smoking, it is possible that including dropouts in the analysis introduced bias, albeit conservative, in the results. Another limitation of this study is the self-reported nature of the data; however, all but one claim of smoking cessation were confirmed by expired carbon monoxide measurement at the end of 12 months.

CONCLUSIONS

The use of nicotine chewing gum in a private family practice office without the use of concurrent behavioral modification and group support techniques is associated with a poor chance for success. Extensive patient education does not appear to improve cessation rates in this setting. Based on these results, nicotine chewing gum should not be recommended for use in primary care settings without the addition of proper counseling and support programs. Smoking should be viewed as a significant health problem requiring constant and ongoing treatment and follow-up, consultations with experts when primary attempts fail, and the active collaboration of the physician and patient. Patients should not perceive the drug as a cure for their smoking problem.

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References

1. Fee WM, Stewart MJ: A controlled trial of nicotine chewing gum in a smoking withdrawal clinic. Practitioner 1982; 226:148–151
2. Jarvis MJ, Raw M, Russell MAH, Feyerabend C: Randomised controlled trial of nicotine chewing gum. Br Med J 1982; 285: 537–540
3. Puska P, Bjorkqvist S, Koskela K: Nicotine-containing chewing gum in smoking cessation: A double blind trial with half year follow-up. Addict Behav 1979; 4:141–146
4. Russell MAH, Wilson C, Feyerabend C, Cole PV: Effect of nicotine chewing gum on smoking behaviour and as an aid to cigarette withdrawal. Br Med J 1976; 2:391–393
5. Raw M, Jarvis MJ, Feyerabend C, Russell MAH: Comparison of nicotine chewing-gum and psychological treatments for dependent smokers. Br Med J 1980; 281:481–482
6. Jarvik ME, Schneider NG: Degree of addiction and effectiveness of nicotine gum therapy for smoking. Am J Psychiatry 1984; 141: 790–791
7. Hjalmarson AIM: Effect of nicotine chewing gum in smoking cessation. A randomized, placebo-controlled, double-blind study. JAMA 1984; 252:2835–2838
8. Russell MAH, Merriman R, Stapleton J, Taylor W: Effect of nicotine chewing gum as an adjunct to general practitioners' advice against smoking. Br Med J 1983; 287:1782–1785
9. Jamrozik K, Fowler G, Vessey M, Wald N: Placebo controlled trial of nicotine chewing gum in general practice. Br Med J 1984; 289: 794–797
10. Nicorette product information. Cincinnati, Ohio, Merrell Dow Pharmaceuticals, 1984
11. Wald NJ, Idle M, Boreham J, Bailey A: Carbon monoxide in breath in relation to smoking and carboxyhaemoglobin levels. Thorax 1981; 36:366–369
12. Jang R: General purpose of research designs. In Nelson AA (ed): Research in Pharmacy Practice: Principles and Methods. Bethesda, Md, American Society of Hospital Pharmacists, 1981, pp 17–22