The Efficacy of Nicotine Gum in Group-Centered Smoking Cessation Therapy in a Family Practice

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The efficacy of nicotine gum in conjunction with group support for smoking cessation was examined. Of 388 participants enrolled in the smoking cessation program, lapse-free abstinence rates of 38 percent and 30 percent were obtained at six and 12 months follow-up, respectively. One-year abstinence rates were confirmed by the measurement of expired carbon monoxide levels. One third of claimed abstainers were randomly selected at one-year follow-up for confirmation, with a resultant 3 percent deception rate. When this deception rate was applied to the overall results, six-month and 12-month abstinence rates became 36 percent and 29 percent, respectively. These abstinence rates suggest an efficacious role for nicotine gum in association with group support.

Nicotine chewing gum was introduced by Ferno et al in 1973,[1] and early clinical trials suggested this gum could be useful as an aid to smoking cessation.[2,3] Subsequent randomized, double-blind, placebo-controlled trials performed in the setting of an expert-mediated smoking cessation clinic demonstrated the effectiveness of nicotine gum in association with group support[4,5] or intensive individualized follow-up.[6,7] Additional research has attempted to delineate a role for the use of nicotine gum in primary care practice, as the impact of specialized smoking cessation clinics on the total number of smokers is limited. Russell et al[8] demonstrated in a nonplacebo-controlled trial a 9 percent one-year success rate compared with 4 percent when nicotine gum was added to a general practitioner's advice without group support or individual follow-up. When Jamrozik et al[9] and the British Thoracic Society[10] performed placebo-controlled trials, however, no improvement in long-term success was noted with the addition of nicotine gum to British physicians' advice when compared with placebo. Additionally, Marshall and Raw[11] and Fagerstrom[12] demonstrated no statistically significant improvement in long-term success by adding individual physician follow-up appointments to a physician's advice when utilizing nicotine gum.

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These results would seem to indicate no convincing role for the implementation of nicotine gum in conjunction with a physician's advice and individual follow-up in the setting of primary care practice. Nicotine gum has been demonstrated effective, however, outside the setting of primary care when utilizing group support as noted by Jarvis et al[4] and Hjalmarson[5]; therefore, a possible role for nicotine gum in primary care practice, which has yet to be adequately evaluated, could be in conjunction with group support. This article reviews the results of such a group-centered smoking cessation clinic, directed by family practice residents, utilizing nicotine gum.

METHODS

The smoking cessation program was conducted at David Grant Medical Center, Travis Air Force Base (AFB), California, under the supervision of family practice residents. Data were collected from 388 participants who attended classes from November 1984 through September 1985. During this time, 21 sessions were convened, with one to four new sessions beginning monthly. Public awareness was created through newspaper advertisements and articles, posters, physician referrals, and word of mouth. Enrollment into the program was through telephone registration.

Classes were open to all military active-duty personnel, retirees, and dependents. There was no registration fee for participants attending the class. Each class was at-

TABLE 1. DEMOGRAPHY OF PARTICIPANTS

Groups	No. of Patients	Age (years)		No. of Patients	Years Smoking	
		Average	Range		Average	Range
Active duty						
Men	121	32.2	20–55	103	17.8	4–35
Women	35	26.7	20–40	35	11.0	3–22
Non-active duty						
Men	84	52.8	16–77	75	36.6	2–54
Women	142	46.1	18–72	138	27.0	2–50
Total	382	41.6	16–77	351	24.1	2–54

tended by an average of 18.5 individuals. Of the 380 individuals with known military status, 121 were active-duty men, 35 were active-duty women, 84 were non-active-duty men, and 142 were non-active-duty women (Table 1). Ages ranged from 16 to 77 years, with an average of 41.6 years. The average number of years smoked was 24.1. No enrolled individuals were known to be pregnant or nursing, experiencing significant cardiac arrhythmias or increasing angina pectoris, or recovering from a myocardial infarction in the six months prior to class.

A family practice resident met with 11 to 28 participants one hour weekly for eight weeks. Major emphasis during these sessions was placed on the use of nicotine gum and group support. Additionally, informal instruction was given on behavior modification, weight management, stress management, and the prevention of relapse. Specifically, week 1 consisted of a course overview, participant introductions, and the instruction of behavior modification techniques helpful in smoking cessation. At session 2, participants were encouraged and instructed to quit smoking completely and to replace their tobacco cravings with nicotine gum. Boxes of and prescriptions for nicotine gum (2-mg pieces) were dispensed at this session in conjunction with extensive instruction on its use. Total abstinence was greatly encouraged throughout the program. The six remaining classes centered on group support under the direction of the group leader. Participants were given the opportunity to share their experiences and to gain further knowledge of their smoking habit. Positive motivational techniques were utilized to encourage participants to continue in their attempted abstinence.

Seven family practice residents participated as group leaders throughout the year. None had formalized training or experience in the management of smoking cessation prior to the initiation of this program. All expertise was gained through article reviews, textbooks, and fellow resident feedback. No smoker or ex-smoker participated as a group leader.

In the initial eight groups, all participants received free nicotine gum for a total of 12 months. In the remainder of the groups, only active-duty military personnel received free gum. All other participants were required to purchase the gum with a prescription, given by the group leaders, at local pharmacies. This change was made because of cost constraints.

At the last class participants were instructed to chew the gum as needed for three months, followed by gradual tapering to be completed by the six-month follow-up. After completion of the program, participants who attended at least one class received refills of nicotine gum in the Family Practice Clinic for up to six months. Participants received minimal follow-up except for telephone contact at three months. Those who requested the gum past six months were contacted by a group leader, who encouraged them to taper off the gum slowly. Following this advice, patients received nicotine gum for up to one year.

Follow-up and Definition of Success

Any participant who attended at least one class was contacted by telephone at three, six, and 12 months after the last class convened. Telephone calls were made by two ex-smokers who had participated in the program. Attempted telephone contacts were considered unsuccessful after five attempts were made at different periods of the day. Participants were asked whether they had completely refrained from smoking tobacco following the date of the eighth session, and whether they were still using the nicotine gum. For purposes of this study, a participant was considered successful if complete abstinence from smoking was maintained following completion of session 8.

Biochemical Validation

At the one-year follow-up, one third of the claimed abstainers (31/93) were randomly telephoned and asked to come to the Family Practice Clinic within seven days "to discuss feedback on the merits of the quit smoking clinic." At this time claims of abstinence were biochemically val-

TABLE 2. DEMOGRAPHY OF NONRESPONDERS VS RESPONDERS

Demographics	Nonresponders (n = 79)	Responders (n = 309)
Age (years)		
Range	16–64	16–77
Average	35.6	41.6
Years smoked		
Range	2–54	2–45
Average	19.5	24.4
Sex (percent)		
Men	62	54
Women	38	46

idated by measurement of expired air carbon monoxide utilizing a Vitalograph CO Meter. Participants exhaling carbon monoxide levels exceeding 10 ppm were assumed to be smoking.

RESULTS

Overall Success

Of the original 388 participants who attended at least one class, 336 at the six-month and 309 at the 12-month follow-up were successfully contacted. The overall lapse-free abstinence rates of those contacted at six and 12 months were 38 percent and 30 percent, respectively. Of the 93 claimed abstainers at the 12-month follow-up, 31 were tested for biochemical validation. Of these 31 participants, one person had a carbon monoxide level greater than 10 ppm, indicating an overall deception rate of 3 percent. By applying this deception rate to the overall results, the six-month and 12-month success rates become 36 percent and 29 percent, respectively. By applying more stringent criteria in which all participants not contacted are included as smokers and a 3 percent deception rate is assumed, the six-month and 12-month success rates become 31 percent and 23 percent, respectively.

Since all data were collected by telephone, without prior knowledge by the interviewers of who would be available for follow-up, collection of these data was felt to have been performed in a random fashion. Support for this conclusion is demonstrated by noting the similar demographic characteristics between the individuals not contacted (nonresponders) and those contacted (responders) for follow-up (Table 2). The six-month and 12-month lapse-free abstinence rates of 36 percent and 29 percent, respectively, are therefore considered to be a statistically accurate reflection of the success of this program.

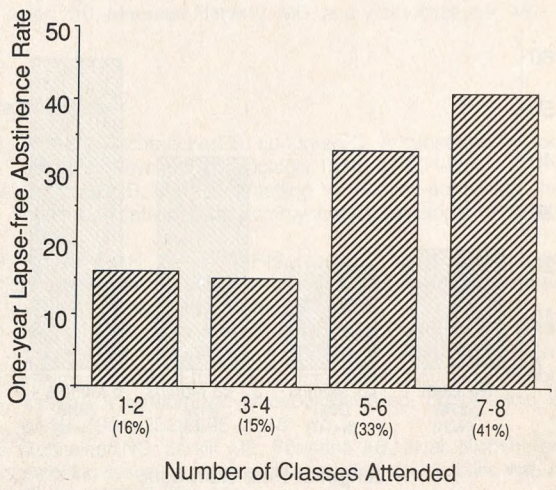

Figure 1. One-year lapse-free abstinence rates relative to number of classes attended. Note: (1) Data on number of classes attended were not available on one person who was not smoking at 12-month follow-up. (2) Those who could not be contacted (79 of 388) for follow-up at 12 months are not included in the data

Free vs Nonfree Gum

A subset of non-active-duty participants (207/388) were required to purchase, at their expense, all nicotine gum used during the study period. The overall lapse-free abstinence rate for these individuals at the 12-month follow-up was 25 percent. The remainder of non-active-duty individuals (23/388) received the nicotine gum free of charge and demonstrated an overall lapse-free abstinence rate of 38.1 percent at one year. Because of the small sample size of this group, no statistically significant difference ($P = .15$) can be inferred between these two groups. The remainder of individuals who received nicotine gum free of charge were on active duty and demonstrated a one-year lapse-free abstinence rate of 38 percent.

Number of Classes Attended

Overall success rates were directly influenced by the number of classes each participant attended (Figure 1). Those attending seven to eight classes had an overall one-year success rate of 42 percent as opposed to 14 percent for those attending one to two classes. Additionally, participants attending three to four and five to six classes had one-year success rates of 15 percent and 32 percent, respectively.

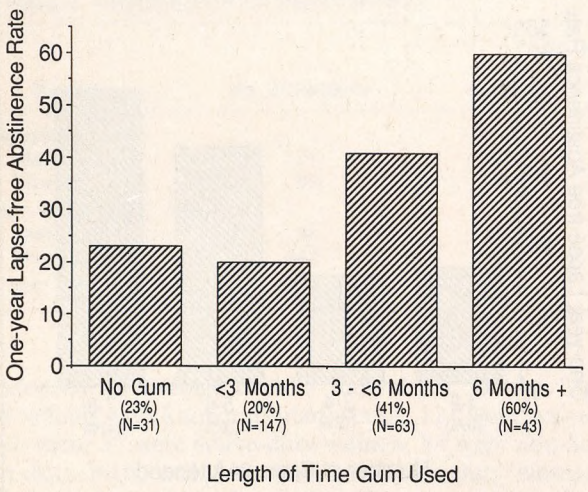

Figure 2. One year lapse-free abstinence rates relative to length of nicotine gum use. Note: (1) Data on nicotine gum use for 25 participants were not available. The quit rate in this group was 16 percent. (2) Those who could not be contacted (79 of 388) for follow-up at 12 months are not included in the data

Success Rate by Length of Gum Use

The length of nicotine gum utilization correlated directly with one-year abstinence rates (Figure 2). Individuals using nicotine gum for less than three months demonstrated a one-year success rate of 20 percent, whereas those utilizing the gum for three to six months and longer than six months demonstrated one-year success rates of 41 percent and 60 percent, respectively. Participants not using nicotine gum obtained a 12-month success rate of 23 percent.

Success Rates by Sex

Success rates for women and men at one-year follow-up were 28 percent and 33 percent, respectively.

DISCUSSION

Previous studies attempting to determine the efficacy of nicotine gum in primary care practice have focused on the addition of nicotine gum to a physician's advice with and without individual follow-up.[8-12] Despite low one-year abstinence rates and unconvincing evidence supporting the efficacy of nicotine gum over placebo, the potential widespread accessibility of such an intervention

TABLE 3. DEMOGRAPHY OF COMPARISON PROGRAMS

Demographics	Jarvis et al[4]	Hjalmarson[5]	Travis AFB
Average age (years)	40	42	41.6
Sex (percent)			
Men	45	56	54
Women	55	44	46
Smoking history			
Cigarettes per day (average)	28	24	—
Years (average)	—	—	24.1

modality utilized by primary care providers made further investigations essential. Subsequently, Jarvis et al[4] and Hjalmarson[5] demonstrated an efficacious role for the use of nicotine gum in behaviorally oriented programs utilizing group support. The overall 12-month lapse-free abstinence rate of 29 percent obtained in the current study (Travis AFB program) when utilizing family physicians in conjunction with nicotine gum and group support compares favorably with the 31 percent obtained by Jarvis et al[4] and 29 percent obtained by Hjalmarson.[5] Despite the similar results obtained by the Travis AFB program, no definitive conclusion can be made on the role nicotine gum played in the success of this program, since no control group utilizing placebo was included.

To hypothesize that a positive role for nicotine gum exists in the Travis AFB program, a comparison with the placebo-controlled trials of Jarvis et al[4] and Hjalmarson[5] must demonstrate similar intervention groups and intervention modalities to justify the exclusion of a control group in the present study. All three programs demonstrate similar participant mean age and sex distribution (Table 3), and placed similarly significant emphasis on the proper utilization of nicotine gum and behavior modification. Unfortunately, no common denominator was available to compare smoking histories (Table 3). Unlike the British[4] and Swedish[5] trials, the Travis AFB program utilized family practice residents as the group support mediators, involved a greater number of participants per session (18.5 vs 10), scheduled more sessions per program (eight vs six), and discussed topics (ie, weight management, stress management, and prevention of relapse) not included in the interventions as described by Jarvis et al and Hjalmarson. Despite these differences these programs demonstrate sufficient similarities to support the hypothesis that nicotine gum can be efficacious in this type of program utilizing family physicians. At the very least the results obtained in the Travis AFB program demonstrate that family physicians in the setting of outpatient primary care practice can obtain long-term abstinence rates similar

to those achieved by experienced smoking cessation therapists when utilizing nicotine gum and behavior modification in conjunction with group support. Randomized, double-blind, placebo-controlled trials are essential to substantiate the hypothesized efficacious role of nicotine gum in this type of intervention.

The success of the group-centered intervention model described in this article promises the potential of expanding the accessibility of smoking cessation therapy to the general smoking population. Since 10 to 25 individuals can participate in each group every eight weeks, family physicians can offer all smokers in their practice the opportunity to participate in such an intervention. Assuming abstinence rates similar to those obtained in this program, 15 to 45 new ex-smokers per provider per year could result with the addition of six programs per year to an individual practice. Although these results seem small when compared with the total number of smokers involved, such numbers become impressive when applied to all primary care practices in the United States. Since this intervention necessitates only one hour per week of provider time after the initial training in the proper utilization of nicotine gum and facilitation of group support, a cost-effective model for smoking cessation therapy exists for the primary care provider.

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