A Randomized Trial of a Family Physician Intervention for Smoking Cessation

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We assessed the impact of three conditions on one-year smoking cessation rates. Physicians in 70 community general practices were randomly allocated by practice to one of three groups: In the usual care group, smoking patients were to receive the care they normally would receive. In the gum only group, physicians were asked to speak to patients about smoking cessation and offer nicotine gum. In the gum plus group, physicians were trained in the experimental intervention. This intervention involved advice to stop smoking, the setting of a quit date, the offer of nicotine gum, and four follow-up visits. Smoking cessation was measured by self-report after one year and validated using saliva cotinine measures. Using a criterion of at least three months of abstinence, 8.8% of the patients of the trained physicians had stopped smoking at the one-year follow-up compared with 4.4% and 6.1% of the patients in the usual care and gum only groups, respectively.

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STUDIES in Europe and Australia have demonstrated that family physicians can have an impact on smoking cessation among their patients.[1-5] British community physicians, recruiting all visiting smokers, increased one-year cessation rates by giving advice to quit and take-home literature. However, the effectiveness of counseling by primary care physicians within the North American health care delivery system has not been adequately tested in a randomized trial. When physicians offer more elaborate interventions, including the offer of follow-up support visits, cessation rates improve as a function of the level of motivation of the patients[3,6] and the intensity of the intervention.[7,8] The evidence supporting the effects of follow-up on cessation rates is equivocal. Three randomized trials have evaluated the effect of offers of follow-up[3,6,7]; all had results that favored follow-up, but the only study that had statistically significant results does not meet the current standards of rigorous follow-up.

See also pp 1565, 1575, 1581, 1593, and 1614.

The availability of nicotine gum has provided physicians with the first nicotine replacement approach to help patients quit smoking. Placebo controlled trials[9-11] have demonstrated the efficacy of the gum in special settings, but its effectiveness in family practice is unproved. Three studies, all European, have examined the effect of nicotine gum in general practice.[2,3,12] Two trials found significant differences in favor of the gum, but one included only motivated patients.[3] The other study with significant results validated cessation in only two thirds of the patients, and it is not clear how patients were selected for validation.[2] The one trial with negative results[12] included only failures from a previous cessation program, possibly leading to spuriously low rates of cessation.

Patient compliance with maneuvers to change behavior is a major problem generally in primary care settings and is a key issue in the study of the effectiveness of nicotine gum in smoking cessation. In adddition, physician noncompliance with the protocol may account for treatment failure. A combination of physician and patient education focused on encouraging specific behaviors as integral parts of experimental interventions has been recommended to reduce noncompliance,[13,14] but this has not been tested for smoking cessation in primary care settings. The present study has great strength in this area; physician training was standardized, and efforts were made to assess implementation. Furthermore, our success in recruiting a large number of physicians and a high proportion of patients approached make it likely that the effect of the educational maneuver is generalizable.

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METHODS

Overview

We provided a four-hour training session to teach physicians in the experimental (gum plus) group a protocol involving the following: simple advice, setting a date for quitting, the offer of nicotine gum with instructions for proper use, a contract for quitting, and the offer of continuing support. The impact of this intervention on one-year smoking cessation rates is compared with the rates produced by untrained physicians who offered their "usual care" to patients and by untrained physicians who offered advice and nicotine gum in the manner they judged appropriate (gum only).

Sample Size

Because the trial involved randomizing physician practices but assessing the outcome on patients, the sample size for both the number of practices and the number of patients per practice was determined through a computer simulation based on predicted one-year smoking cessation rates of 10%, 15%, and 22.5% for the usual care, gum only, and gum plus groups, respectively. The 10% rate for usual care is based on one-year cessation prevalence rates in two large practice-based studies.[1,2] The trial was designed to have a power of 80% using an error of 5% with 25 practices in each group and 30 patients from each practice.

Physician Recruitment

We invited 460 family physicians in the Ontario Medical Association registry who practiced within a 40-mile radius of Hamilton to participate. Of these, 22% responded positively. Twenty physicians were not included for various reasons, leaving 70 practices consisting of 83 physicians.

Patient Recruitment

Receptionists were to attempt to recruit the first one or two eligible smokers attending a regular office appointment each day and to keep a log of all smokers approached. To qualify for the study, patients had to smoke at least one cigarette every day or most days, had to be between the ages of 16 and 65 years, and could not be pregnant or breast-feeding. By consenting to participate, patients were agreeing to be followed up over one year but not necessarily agreeing to make an attempt to quit smoking.

Physicians in the usual care group were not alerted as to which of their patients had been recruited, in contrast to physicians in the other two groups. Physicians in the gum only group were instructed to approach patients in their usual manner about quitting smoking and to offer nicotine gum as an aid to quitting. Physicians in the gum plus group attended a four-hour training session on the delivery of a smoking-cessation maneuver. The key components of the intervention consisted of challenging smokers to quit, negotiating a contract for a quit date, prescribing nicotine gum appropriately (2 mg), and offering supportive follow-up visits. The intervention is described in detail in a recent publication.[15]

Briefly, the intervention involved up to six visits. At the initial *challenge* visit, the physician asked the patient for a clear decision about quitting and to set a quit date within the month. The physician also informed the patient about nicotine gum and provided self-help literature ("tip sheets"). A quit date visit, and, if possible, four follow-up visits were arranged. Patients also received a "contract" indicating their decision to try to stop smoking.

At the ten-minute *quit date* visit, physicians determined whether patients were still willing to try to quit. A key focus of this visit was to teach patients who wished to quit with nicotine gum about its proper use. Physicians were to invite patients back for a visit within a week.

The content of the four brief *supportive follow-up* visits, occurring over a two-month period, was to be individualized according to patient needs.

Payment for visits was covered in the usual way by the Ontario Health Insurance Plan. Patients were responsible for the cost of the nicotine gum.

Outcome Measures

All patients were mailed a two-month follow-up questionnaire. Nonrespondents were telephoned. The main follow-up occurred after one year. The initial contact attempt was by mail. Nonrespondents received up to two additional mailings and, if necessary, were called within six weeks of the first mailing. Respondents who reported not smoking in the past week were visited at home to obtain a saliva sample for cotinine validation. These visits were scheduled as soon as possible after telephone contact, and patients were not informed that they would be asked for a saliva sample.

Compliance

Physician compliance was assessed in two ways: (1) Through phone interviews we interviewed a 15% random sample of the patients from all groups within three days of their first visit to the physician. To minimize reactivity among patients, we asked open-ended questions to assess the content of their visit with regard to smoking cessation. (2) An audit of project documents in the medical records of patients in the gum plus group provided specific information about the procedures the physician followed, the questions asked during the visit, and patient responses. These data were not available in the other two experimental groups, because the special medical record provided was part of the maneuver in the gum plus group only.

Patient compliance was assessed by questionnaire. After two months and after one year, patients were asked about attempts to quit smoking, their use of nicotine gum, and follow-up visits to their physician.

Definition of Outcomes

Patients were considered successful quitters if on the one-year questionnaire they reported not having smoked even a puff of a cigarette in the last week, reported not having used other tobacco products, and were confirmed as nonsmokers by biochemical validation. The criterion used for validation was a saliva cotinine value of 0.057 μmol/L or lower, or a saliva thiocyanate level of 1724 μmol/L or lower if the patient was still chewing nicotine gum.

We defined successful cessation in three different ways. Our primary definition of success was self-reported sustained abstinence for three months prior to biochemically validated cessation after one year. Patients who smoked even a puff in the week before the one-year follow-up were considered smokers.

The second definition of outcome was a biochemically validated report of nonsmoking in the week before completion of the one-year follow-up questionnaire. Sustained abstinence for the three previous months was not required. Patients who admitted to smoking even a puff in the week before the one-year follow-up were considered smokers.

The third definition of outcome was in terms of two-point prevalence. Patients who were verified nonsmokers after one year and who also self-reported not smoking in the week before the two-month follow-up were considered successes. We report two-point prevalence primarily to permit the comparison of results with those of other studies. We believe this measure to be biased in favor of any trial's experimental condition.[16] Relatively vigorous treatments such as in our gum plus group often have the capability to influence short-term cessation rates more than long-term rates. Thus, in comparing two treatments that produce equally high long-term cessation rates, an outcome criterion that demands quitting at an early time will be biased in favor of a vigorous maneuver that produces high short-term rates.

Nine patients (0.5%) were excluded from the analysis due to death or illness, 60 (3.1%) could not be located, six (0.3%) refused follow-up, 21 (1.1%) self-reported quitters refused verification, and one self-reported quitter was using another tobacco product. Thus, 87 patients (4.5%) who may have been nonsmokers were classified as cigarette smokers for the purpose of the analysis.

Statistical Methods

The unit of randomization in this study was the clinical practice. Therefore, although patient smoking cessation is the primary outcome, a statistically valid analysis requires the use of a single outcome measure associated with each of the 70 practices. The proportion of patients who met our definition of success in each practice (the practice quit rate) was therefore used as the outcome for each practice.

The main analysis used analysis of covariance. Covariates were selected by consensus of the investigators as to those factors likely to affect outcome as well as any baseline variable found to vary significantly between treatment groups. Covariate values associated with each practice were obtained by av-

Table 1.—Baseline Variables by Treatment Group*

Variable	Group			P
	Usual Care	Gum Only	Gum Plus	
No. of practices	23	24	23	...
No. of patients	601	726	606	...
No. of study patients per practice	26.1	30.3	26.3	.16
≥20 cigarettes per day, % of patients	62	65	67	.25
Smoker >15 y, % of patients	52	51	53	.83
Longest time not smoking ≥3 mo, % of patients	32	29	33	.54
First cigarette <15 min after rising, % of patients	44	45	50	.30
First cigarette <15 min after rising and ≥20 cigarettes per day, % of patients	36	38	42	.20
Score of 6-10 on wanting to quit, % of patients†	61	71	76	<.001
Score of 6-10 on confidence in ability to quit, % of patients†	30	39	48	<.001
Score of 6-10 on willingness to try to quit, % of patients†	55	70	77	<.001
Reason for quitting, % of patients				
Expense	58	59	64	.19
Health	66	72	74	.02
Role model	33	40	41	.02
≥1 person in house smokes, % of patients	58	59	62	.27
≥70% of friends smoke, % of patients	44	38	41	.27
≥70% of coworkers smoke, % of patients	30	25	25	.21
Score of 6-10 on smoke in your presence	62	62	60	.68
Age (y), % of patients				
<25	22	19	17	.41
25-44	50	54	56	.48
≥45	27	27	27	.95
Sex, % of patients				
M	39	42	33	.03
F	61	58	67	
Education ≥grade 12, % of patients	55	58	57	.85
Married, % of patients	63	64	62	.92
% of practices with <30 patients per day	50	43	48	.61

*Means and SDs of continuous variables are available upon request from the authors.
†Scale of 1 to 10.

Table 2.—Physician Variables

Variable	Group			χ^2	P
	Usual Care (n=27)	Gum Only (n=29)	Gum Plus (n=27)		
Score of 8-10 on whether it is important to help smokers quit*	73.1	72.4	80.0	0.49	.78
Score of 8-10 on whether it is worthwhile economically to help smokers quit†	52.4	22.2	56.0	7.25	.03
Smoke now, % of physicians	15.4	3.4	8.0	2.47	.29
Smoke pipe/cigar, % of physicians	0	10.3	4.0	3.17	.21
Exsmoker, % of physicians	12.0	28.6	32.0	3.13	.21
Monitor smoking, % of physicians	92.3	75.0	87.5	3.32	.19
Use gum now, % of physicians	92.6	82.8	88.5	1.28	.53
Male, % of physicians	92.6	93.1	81.5	2.44	.29
Solo practice, % of physicians	55.6	41.4	51.9	1.22	.54
Mean age, y	41.64	41.77	40.57	...	.90‡

*One indicates not important and 10 indicates extremely important.
†One indicates not worthwhile and 10 indicates very worthwhile.
‡$F = 0.10$.

eraging patient values within the practice. For example, we determined the proportion of patients within each practice smoking at least 20 cigarettes per day as one of the covariates of interest. Only covariates that were predictive of outcome at a statistically significant level were retained in the final model for evaluating the effect of treatment. Thus, baseline differences between groups (Table 1) were taken into account by the analysis.

For the analysis of differences between groups, we decided a priori that if there was no difference between the usual care and gum only groups, we would combine these two groups and compare them with the gum plus group to test the difference between trained and untrained physicians.

It is of clinical interest to determine whether the effect of treatment is greater in some specific subgroups than others. For instance, it might be that the gum plus treatment is particularly effective compared with the other treatments for highly motivated patients but has little or no incremental effect on patients who are less motivated to stop smoking. To evaluate whether there were any statistically significant treatment covariate interactions, a regression analysis was performed on the 70 practice units, adjusting for the effects of predictor variables and treatment and then evaluating whether interaction terms contributed significantly to the model over and above the main effects.

RESULTS

Physician Characteristics

The participants tended to be recent graduates of medical school; 45 (54.2%) of 83 had graduated in the past 15 years. Of those physicians surveyed, 66 (80.5%) of 82 reported that they often or almost always tried to help smokers quit, and 72 (87.8%) 82 reported that they currently prescribed nicotine gum, but only 55 (67.9%) of 81 rated the gum as at least moderately effective. Furthermore, seven (8.8%) of the 80 physicians presently smoked, and 19 (24.4%) of 78 reported being exsmokers. Physician demographic characteristics and attitudes toward smoking cessation are displayed in Table 2.

We were able to compare the demographic characteristics of our study sample with those for all family physicians in the central-west region of Ontario where the study was done. Study participants were likely to be men (74 [89%] of 83 compared with 83%) and were likely to be younger (46 [55%] of 83 compared with 45% under age 40 years) than the general population of family physicians. Virtually all participants were nonacademic physicians practicing in an urban environment, and 41 (49%) of 83 had solo practices.

Patient Characteristics

Patient screening began in February 1985 and concluded in July 1985. Based on the receptionists' logs, the participation consent rates were 91%, 83%, and 76%, respectively, in the usual care, gum only, and gum plus groups ($P<.001$). These rates differed significantly between practices; however, office priorities sometimes interfered with logging, and we believe these acceptance rates may be inaccurately high. In total, 1933 patients participated; 601 in 23 usual care practices, 726 in 24 gum only practices, and 606 in 23 gum plus practices.

Table 3.—Initial Visit Exit Interview

Interview Item	% of Patients by Group: Usual Care (n=90)	Gum Only (n=94)	Gum Plus (n=96)	χ^2*	P
Physician said anything	31.1	70.2	85.4	61.96	<.001
Suggested quitting	24.4	64.0	84.4	59.72	<.001
Offered help	12.2	61.7	84.5	106.93	<.001
Suggested gum method	8.9	58.5	62.5	38.15	<.001
Asked for quit date	2.2	11.7	54.2	80.84	<.001
Wants to see patient again	4.4	22.3	83.3	137.22	<.001
Gave reading materials	2.0	17.0	80.2	144.07	<.001

*χ^2 values are based on differences among the three groups.

Table 4.—Gum Use*

Gum Use	Group: Usual Care (n=550)	Gum Only (n=699)	Gum Plus (n=578)
Not used	76.4	46.1	37.5
A few pieces	14.5	25.0	27.3
≤2 wk	4.0	11.3	12.1
>2 wk	5.1	17.6	23.0

*Patients unavailable for follow-up are not included.

Table 1 demonstrates the comparability of the three groups on the baseline demographic and smoking-related characteristics of the patients. The most noticeable difference between the groups was in terms of "motivation" (ie, confidence, wanting to quit, and willingness to quit in the next month). Patients in the gum only and gum plus groups scored higher on these measures than patients in the usual care group ($P<.05$).

Physician and Patient Compliance

The results of the exit interviews are shown in Table 3. A comparison of the sample of patients who provided the exit interview data with the total patient sample revealed no indications of sample biases. All the differences recorded in Table 3 are in the expected direction; physicians in the gum plus group were more likely than the untrained physicians to use the procedures they were trained to follow, such as offering advice, inviting patients back for follow-up, and providing take-home materials. Physicians in the gum only group suggested gum to their patients nearly as often as physicians in the gum plus group. A second exit interview was conducted with a sample of 86 patients in the gum plus group who returned for a quit date visit and could be reached by telephone within three days of the visit. The data reveal a fairly high level of adherence to the maneuver by the physicians; 92% of the patients said that the physician had referred to the "tip sheets," 93% indicated that the physician had asked about their readiness to quit, and 99% thought the physician had given them support. The only area of concern was reflected by the patients' memories of what the physician had mentioned about nicotine gum; although 84% indicated the physician had advised to chew the gum slowly, fewer than 70% indicated that they had been told to throw out their cigarettes and not smoke and chew the gum.

Physicians in the gum only and gum plus groups were to record the patient's intention at the conclusion of the initial visit. An intention was recorded for 97.7% of the patients in the gum only group and 89.6% of the patients in the gum plus group. Of those who stated an intention, approximately 85% in each group intended to try to quit, with a significantly higher proportion of patients in the gum plus group (71%) than in the gum only group (61%) intending to quit using gum ($\chi^2=13.5$, $P<.001$). The proportions of patients who reported an attempt to quit within two months of recruitment were 36.4%, 60.7%, and 71.9%, respectively, in the usual care, gum only, and gum plus groups. Each group differed significantly from the others.

Table 4 indicates the pattern of gum use based on patient reports on the one-year follow-up questionnaire. Clearly, a greater proportion of patients in the two gum groups tried the gum ($\chi^2=179.8$, $P<.001$), but the level of gum use for longer than two weeks was only 17.6% in the gum only group and 23% in the gum plus group ($\chi^2=5.79$, $P<.05$).

An important part of the protocol in the gum plus group involved the offer of patient follow-up support visits (Table 5). Approximately 65% of the patients in the gum plus group returned for at least one follow-up visit. The one-year success rate increased with the number of follow-up visits ($\chi^2=3.22$ [linear trend], $P<.001$).

Outcomes

Table 6 lists both unadjusted and adjusted mean cessation rates for the treatment groups. The latter are of greater interest since they adjust for initial differences between groups on baseline covariates. The null hypothesis of equivalent treatment outcomes was rejected ($P<.05$) for three-month sustained abstinence and two-point prevalence but fell short of statistical significance for one-year prevalence. When three-month sustained abstinence was used as the primary outcome, adjusted cessation rates were 4.4%, 6.1%, and 8.8%, respectively, in the usual care, gum only, and gum plus groups. In terms of the individual comparisons, there was clearly no difference between the usual care and gum only groups. Therefore, it was deemed appropriate to collapse these two groups and compare them together with the gum plus group. Again, for three-month sustained abstinence ($t[68]=2.60$, one-tailed $P<.01$) and two-point prevalence ($t[68]=4.72$, one-tailed $P<.001$), the gum plus group was superior to the other two groups (Table 6). For one-year prevalence, this comparison fell short of statistical significance ($t[68]=1.48$, one-tailed $P=.07$).

Table 7 shows the frequency with which different ranges of cessation rates were achieved in practices in the different treatment groups. The proportion of practices that achieved at least a 10% three-month sustained abstinence rate after one year was significantly higher ($P=.016$ by two-tailed Fisher's exact test) in the gum plus group (43%) compared with the usual care and gum only groups (15%). The tests carried out to determine whether there was any evidence of treatment-covariate interaction revealed no evidence of interactions. In addition, cessation rates did not vary significantly among practices within treatment groups.

COMMENT

The results indicate that the physician training procedure, which taught a prescribed maneuver to be offered to smoking patients who attended a family practice, produced higher cessation rates than either usual care or usual care and nicotine gum. Compared with usual care, the gum plus intervention produced a 100% increase in biochemically validated smoking cessation. However, in absolute terms, the 4.4% increase in the smoking cessation rate in the gum plus group could be viewed as having limited clinical significance. Viewed on a populationwide or communitywide basis, however, the difference between the cessation rates obtained with the gum plus maneuver and those

Table 5.—Follow-up for Gum Plus Group

Patients	No. of Follow-up Visits Attended						Total
	0	1	2	3	4	5	
No. of patients	216	93	89	79	62	67	606
No. (%) of quitters	11 (5.1)	7 (7.5)	6 (6.7)	8 (10.1)	14 (22.6)	19 (28.4)	65 (10.7)

Table 6.—Smoking Cessation Rates by Treatment Group

Group	Smoking Cessation Rate, % of Patients		
	Mean	Adjusted Mean*	SE
Primary Analysis†			
Usual care	4.8	4.4	1.1
Gum only	5.3	6.1	0.9
Gum plus	9.2	8.8	1.1
One-Year Prevalence‡			
Usual care	7.1	7.2	1.1
Gum only	7.6	8.4	0.9
Gum plus	10.9	9.9	1.1
Two-Point Prevalence§			
Usual care	1.3	1.4	0.8
Gum only	2.8	3.3	0.7
Gum plus	7.6	7.0	0.8

*Analysis of covariance adjustment for differences at baseline (see Table 1).
†$P = .036$.
‡$P = .309$.
§$P = .001$.

Table 7.—Smoking Cessation Rates by Practice

Practice	Smoking Cessation Rate,* % of Practices			
	≤4.9	5-9.9	10-14.9	≥15
Usual care	15	4	3	1
Gum only	10	11	3	0
Gum plus	6	7	6	4

*Three-month sustained abstinence.

of the other two groups is potentially important. Cost-effectiveness analysis has demonstrated that this type of maneuver is more economically justifiable in terms of its effects and consequences than other commonly applied medical treatments, such as the treatment of moderate hypertension.[17] Ultimately, individual practitioners will decide whether this smoking cessation rate is worth the time and effort required to integrate the intervention into their practices. Further follow-up is required to assess the long-term impact of this intervention.

We are not aware of any large, published North American trials of smoking interventions delivered by community physicians. Comparison of our findings with those of British and Australian studies is difficult due to differences in the following: (1) patient selection, eg, motivation level; (2) actual interventions, eg, what is meant by advice to quit; (3) definitions of outcome, eg, one- or two-point prevalence; and (4) methods of analysis, eg, use of practice quit rates and adjustment for differences in baseline characteristics. The most similar study found that an intervention including advice, a leaflet, nicotine gum, and the offer of follow-up produced a 4.9% increase in two-point cessation (four months and one year) compared with controls who had no intervention.[2] We observed similar effects using three-month abstinence or two-point prevalence as end points.

The lack of difference between gum only and usual care is striking. Approximately 73% of the physicians in each group believed it was important to help patients quit, and their past smoking cessation practices were similar. As noted in the exit interview data (Table 3), the experimental groups (gum only and gum plus) did provide treatments different from usual care. We know that roughly 33% of patients in the usual care group received advice to quit, whereas at least 70% of patients in the gum only group received advice and the offer of nicotine gum. The lack of difference in cessation rates between these groups brings into question previous evidence that offering advice alone to all smokers attending a general practice is an efficacious maneuver.[1]

The relationship observed between follow-up attendance and the success rate is clear. The most likely explanation is that the most highly motivated patients attend follow-up visits. It is questionable whether attempting to enhance follow-up attendance through experimental manipulation can actually increase smoking cessation rates. These data lend caution to the interpretation of cessation rates among "attenders" participating in smoking cessation programs. Patients who attended all follow-up visits had a quit rate of almost 30%.

Although our trained physicians did produce better cessation rates than the untrained physicians, the study was not designed to identify the specific elements of the gum plus maneuver most critical to producing success. A key question arising out of our data is whether smoking cessation rates would be higher if more patients attended follow-up visits. To maximize feasibility, the physician training included no special procedures to enhance patient compliance with follow-up. In addition, we gave physicians only a checklist of issues to raise at follow-up visits with no special training for counseling style. It is important that future studies take a closer look at the importance of follow-up visits, since they represent a major cost of the intervention.

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