Minimal Contact Treatment for Smoking Cessation

A Placebo Controlled Trial of Nicotine Polacrilex and Self-directed Relapse Prevention: Initial Results of the Stanford Stop Smoking Project

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To determine the effectiveness of nicotine polacrilex combined with self-administered relapse prevention maintenance in maintaining smoking cessation, we conducted a randomized, double-blind, placebo controlled trial. Volunteers aged 18 to 65 years responding to media announcements were required to quit smoking for 48 hours without assistance. Of 1844 potential participants, 136 were medically excluded, 535 declined to make a quit attempt, and 573 were unable to quit, leaving 600 participants (35%) who were randomized. Eight self-help relapse prevention modules were mailed weekly. Gum was used either ad lib for smoking urges or on a fixed, hourly schedule (12 pieces per day). Only 15% of the subjects in each gum group stopped using the gum altogether because of side effects, but only 20% of the ad lib groups and 40% of the fixed-dosage group used at least eight pieces of gum per day during the first week. The abstinence rates (for at least seven days) at the six-month follow-up were 31% in both active gum groups and 22% in the placebo and no gum groups. Relapse rates in the two active gum groups were about half those in the placebo and no gum groups. Nicotine polacrilex may be a useful adjunct to minimal contact smoking cessation formats, which have broad appeal. Also, minimal contact relapse prevention programs may assist physicians in helping patients to maintain smoking cessation using nicotine polacrilex.

CIGARETTE smoking is the single most important behavior contributing to illness, disability, and death in the United States. Research designed to improve the applicability of cigarette smoking cessation procedures is in its infancy. Such research is important because survey data indicate that relatively few smokers will participate in formal smoking cessation clinics. The large majority of smokers who desire to quit appear interested in self-administered, minimal contact treatment formats. Such formats would be particularly useful to physicians with patients who need to quit smoking.

Although a number of “self-help” smoking cessation programs have appeared in the marketplace, most evaluations of self-help materials have been conducted under therapist-administered conditions. Controlled evaluations of minimal contact cessation programs have appeared infrequently in the literature. The findings from these studies do suggest that self-help programs may provide a reasonably cost-effective means of service delivery. However, more effective self-help programs would greatly enhance the potential impact of this type of treatment.

Nicotine polacrilex is a potentially useful pharmacologic aid for the elimination of cigarette smoking that could be used to enhance the effectiveness of minimal contact interventions. In 11 studies comparing nicotine polacrilex with either placebo gum or no gum, combined with psychological therapy, six reported significantly higher quit rates for active gum at six-month follow-up. Two studies reported only one-year data, and the larger of the two reported a significant effect.

When prescribed in a medical practice context with little additional intervention beyond physician advice, nicotine polacrilex has not proved as useful. Of seven studies examining nicotine polacrilex combined with medical advice, only two reported a significant impact. Both a standard review article and a meta-analysis covering most of these studies concluded that nicotine polacrilex is best used in conjunction with other smoking interventions.

The integration of pharmacologic and innovative psychological strategies within a minimal contact treatment format offers a challenging new area for smoking researchers. To date, only one uncontrolled trial has examined the effects of nicotine polacrilex combined with a minimal contact intervention, which produced a 41% abstinence rate at 12 months. In this article we report two- and six-month smoking abstinence rates from an ongoing investigation of self-help treatment approaches combining nicotine polacrilex or placebo with self-administered smoking relapse prevention materials delivered through the mail. We predicted that abstinence rates for nicotine polacrilex conditions would be significantly greater than rates for placebo conditions at each assessment. If true, this would provide a practical means for intensifying the minimal contact approach, particularly for physicians.

METHODS

Design

The Stanford (Calif) Stop Smoking Project is a randomized clinical trial using a 4 x 3 fully crossed factorial design. The pharmacologic factor contains four levels: nicotine polacrilex (gum) delivered ad lib or on a fixed-dosage schedule, placebo gum, and no gum. The psychological treatment factor contains three levels: self-selected relapse pre-

See also pp 1565, 1570, 1581, 1593, and 1614.
vention modules, randomly adminis-
tered modules, and no modules. The full
study calls for 100 subjects to be ran-
domized into each of the 12 cells to pro-
vide sufficient power to compare pairs of
cells. This design was chosen to allow
early evaluation of the major interven-
tion components by collapsing cells for
analysis. In this article we compare the
four gum conditions, ignoring module con-
ditions, for the first 600 subjects
(about 150 subjects per gum condition).

Recruitment and Exclusion Criteria

Participants aged 18 to 65 years were
recruited through newspaper adver-
tisements, radio public service an-
nouncements, and local television pro-
grams. The “self-help” nature of the
study was emphasized in these an-
nouncements but no mention of nicotine
gum was included. Interested smokers
were instructed to telephone the pro-
ject office and were then provided a
brief overview of the study and adminis-
tered the telephone survey. The study was
then explained in detail, including the
requirement that, to participate in the
study, each person had to quit smoking
for 48 hours and then come to a project
office for additional interviews and bio-
chemical confirmation of nonsmoking.
Smokers who remained interested in
participating set a quit date and were
scheduled for a center visit 48 hours
erlier. All other individuals were given
even the names of other smoking cessation
resources in their area. Written in-
formed consent was obtained during the
postquit visit.

Potential participants were also
asked a series of medical questions to
assess their eligibility for nicotine pola-
crilix. Individuals who were pregnant,
lactating, or receiving active treatment
for cancer or peptic ulcer disease were
excluded from the study. Individuals
who reported temporomandibular joint
disease or other difficulties with chew-
ing gum were also excluded. Those who
reported a history of heart disease, re-
cent chest pain, diabetes, or thyroid dis-
ease were asked to obtain written per-
mission to participate from their phy-
sicians. We provided a detailed letter to
each physician explaining the nature of
the study and the Food and Drug Ad-
ministration cautions on the use of nicot-
tine polacrilex.

The 48-hour abstinence requirement
was included in the study for two rea-
sons: (1) The intervention materials
focus on relapse prevention, because
this is the most important aspect of sus-
tained smoking cessation (most smok-
ers report previous quit attempts with
abstinence periods as long as several
months). (2) We wanted to exclude quitters
who were likely to fail early so we
could offer the intervention program to
those most likely to benefit.

Evaluation

Questionnaires.—The baseline tele-
phone questionnaire assessed demo-
graphic variables, smoking history,
previous quit attempts, an index of nic-
tine dependence, and pertinent medical
history. The dependence index was the
Fagerstrom Tolerance Questionnaire®
modified for telephone administration.
During the first project center visit, 48
to 96 hours after quitting, additional
information was collected by self-ad-
ministered questionnaire, including the
quit methods used, craving, urges, and
withdrawal symptoms.

Follow-up questionnaires were ad-
ministered by telephone 2, 6, 12, and 24
months after randomization. Self-re-
ported smoking status was obtained for
the past week, the past month, and
since the previous assessment. Only
participants who denied smoking even a
single puff of a cigarette were consid-
ered nonsmokers (for the appropriate
duration); they were asked to come to
the project office for biochemical
testing.

Biochemical Assessment.—Non-
smoking status was assessed by expired
air carbon monoxide measurement and
by saliva thiocyanate (two-month
follow-up) or cotinine (6-, 12-, and 24-
month follow-up) concentrations. Ex-
pired air carbon monoxide measure-
ments were performed with the Ecoly-
zer (Energetics Science Inc, New
York), and thiocyanate concentrations
were measured using the automated
method of Butts et al® slightly modified
for saliva. Saliva samples were collected
by having participants hold a dental roll
in their mouths until it was saturated, as
explained by Luepker et al.® Thiocya-
nate measurements were used at two
months because some subjects were
still using active nicotine polacrilex and
would therefore test positive for cotin-
ine, a direct metabolite of nicotine (thio-
cyanate concentrations are elevated in
the body fluids of smokers because of
trace amounts of hydrogen cyanide in
cigarette smoke). Cotinine is a better
biochemical marker than thiocyanate
because the latter has dietary sources
and is therefore present in all individ-
uals, whereas cotinine is undetectable
in nonsmokers. Cotinine concentrations
were measured for this study according
to the method of Jacob et al.®
Nonsmokers were reclassified as
smokers at the two-month visit if both
the carbon monoxide concentration was
greater than 8 ppm and the saliva thio-
cyanate concentration was greater than
100 mg/L.® At subsequent assess-
ments, cotinine measurements alone
were used, and reclassification occurred
when the cotinine level exceeded 20
µg/L (this allows for some indirect ciga-
rette smoke exposure).

Intervention

Individuals who quit for 48 hours (car-
bon monoxide concentration <8 ppm)
were randomized into one of the 12 in-
tervention cells. Assignment to gum
condition was double-blind; since the
placebo gum was given only ad lib, ne-
ither the project staff nor the partici-
pants were told the details of the design
during the study. Unblinding occurs at
the 24-month follow-up. In the
Active (2 mg) and placebo gum were
supplied to the participants in identical
packaging along with appropriate in-
structions and warnings (both active
and placebo gum were supplied by the
Merrell Dow Research Institute, a divi-
sion of Merrell Dow Pharmaceuticals
Inc, Cincinnati). Participants in the ad
lib and placebo groups were instructed
to chew a piece of gum whenever they
felt a strong need to smoke a cigarette.
Starting in week 4, these participants
were asked to cut back on their gum use
as quickly or as slowly as they chose,
with the goal of chewing no gum by
week 9. An upper limit of 30 pieces of
gum per day was set. Participants in the
fixed-dosage group (all using active
gum) were instructed to chew one piece
of gum per hour at least 12 hours per
day. This could be doubled to two pieces
two per hour if smoking urges continued.
Beginning in week 4, a fixed tapering
schedule was provided to gradually
eliminate gum use by week 9. Gum use
could be extended to three months, but
we provided no additional gum, active
or placebo, beyond that time. All in-
structions were provided by trained re-
search assistants who were not phy-
sicians.

Sixteen written modules were de-
signed by the investigators to provide
self-instruction on how to avoid smok-
ing in specific high-risk situations (eg,
while drinking alcohol, while driving,
after eating). Using the modules, par-
ticipants identified specific triggers in
the context of the situation and made
cognitive and behavioral plans for
avoiding relapse when confronted by
the triggers. The modules emphasized
performance-based experience by en-
couraging participants to place them-
selves in high-risk situations and to use
their plans to overcome urges to smoke.

All participants in the relapse pre-
vention module conditions were given
the first module, “How to Cope With
the Urge to Smoke Without Smoking.” In-
dividuals in the self-selecting condition
then chose another seven modules to
receive weekly by mail based on their

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perceived efficacy at coping with different high-risk situations. The random group received seven modules selected at random from the 15 remaining modules.

The entire study center visit required between 45 and 75 minutes, most of which was spent in data collection. Instruction on gum and module use lasted 10 to 20 minutes. No specific relapse prevention advice was offered by the research assistants, who were not acting as therapists. Contact during the eight-week intervention period was limited to data collection inquiries and responses to problems with the gum, both by telephone, and averaged one to two contacts per participant.

Adherence to the treatment program was monitored through weekly progress reports mailed to participants to the project offices. These reports included the number of cigarettes smoked each day, degree of craving, a 16-item self-efficacy scale, and, where appropriate, the number of pieces of gum used, gum side effects, and questions about use of the modules. Each participant left a $40 deposit, which was returned if all assessment materials were returned and the two-month visit was completed. In addition, subjects returned all unused gum at the two-month visit.

**Analysis**

Analyses were limited to the first 600 participants in the study and compared the results by gum condition, ignoring module condition. This analysis was planned at the beginning of the study because the final sample size is required for individual cell pair comparisons; the effectiveness of nicotine polacrilex can therefore be evaluated at this time. This analysis can be repeated in the second 600 subjects later as a replication study; this will be a more powerful test of the effectiveness of nicotine polacrilex than evaluating the gum once in all 1200 subjects.

The smoking status after two and six months was available for all 600 participants. The principal outcome variable was the proportion of each group that reported not smoking even a puff for the past week (seven-day abstinence rate). We also compared the proportion who reported not smoking for the past month (one-month abstinence rate).

A χ² analysis was done to test the hypothesis that the different gum conditions were statistically the same. Individual gum groups were compared in pairs using the Bonferroni adjustment for multiple comparisons (alpha, 0.05; confidence, 0.95). Standard statistical software packages were used.

In addition to comparing abstinence rates at two specific time points, we also compared relapse rates during the entire follow-up. Relapse was defined as self-reported smoking of at least one puff on seven consecutive days. All subjects were abstinent when randomized, and the time to relapse was obtained at follow-up. The proportion of each experimental group that remained abstinent over time can thus be plotted using standard survival analysis methods.

**RESULTS**

**Recruitment**

During the first year of recruitment, nearly 2500 telephone inquiries were received, evenly distributed among the three program offices (Oakland, Calif, 29%; San Jose, Calif, 26%; and Stanford, 37%). Baseline interviews were completed for 75% of these inquiries; about half of the 25% of the callers who were not interviewed were ineligible (out of the age range or calling for someone else), and the other half of these callers could not be reached or were no longer interested when telephoned. Of the 1844 individuals who completed baseline surveys, 156 were ineligible, mostly on medical grounds. Sixty-nine percent of those eligible to participate (1173) scheduled a postquit visit, and 600 were successfully randomized (51% of those scheduled, or 35% of those eligible). Eligible subjects who did not schedule a postquit visit (633 subjects [81%]) were not interested in participating in the study or after it was fully explained at the end of the baseline interview. The 573 scheduled participants who were not randomized were unable to quit for the required 48 hours.

**Baseline Comparisons**

Table 1 compares the four gum groups at baseline on selected personal and smoking characteristics. Approximately equal numbers of men and women were randomized to each group; most were employed, and most were white. The average smoking level was 25 ± 12 cigarettes per day (mean ± SD). None of the groups differed significantly on these or other variables.

**Adherence**

Table 2 compares the various experimental groups for adherence to differ-
ent elements of the treatment program. Over 80% of the subjects returned at least five of the eight weekly reports, while lower proportions of each group recorded a personal relapse trigger or that they had used a strategy to deal with the trigger without smoking. The groups receiving active gum were the most compliant, and the placebo group was the least compliant; the no gum group fell between the active and placebo groups. A minority of the patients met the adherence criteria, but twice as many met these criteria in the fixed-dosage group. The amount and duration of gum use also varied significantly among the three groups receiving gum. Pairwise comparisons of these three groups using a Bonferroni correction for multiple comparisons showed that the fixed-dosage group used significantly more gum than either the ad lib or placebo groups during both the first and second weeks; the ad lib and placebo groups did not differ from one another. However, all three pairwise comparisons of the duration of gum use (mean number of weeks) were significant. In summary, treatment program adherence was generally better in the groups that received active gum; the fixed-dosage group showed the best adherence and had significantly greater exposure to the gum.

**Side Effects**

Overall, about 75% of the subjects who received gum reported at least one side effect during the first four weeks; this fell to 35% in the last four weeks. Table 3 shows the proportion of each gum group that reported the ten most common side effects ascribed to nicotine gum. Only hiccups and nausea were clearly more prevalent in the active gum groups, although there were trends for anorexia, oral soreness, gastrointestinal distress, and jaw soreness. Not surprisingly, considering the adherence data presented above, the fixed-dosage group tended to have a higher prevalence of side effects than the ad lib group. However, the three groups did not differ in the proportion of participants who actually stopped using the gum because of side effects.

**Follow-up**

At the two-month follow-up, we were unable to locate five subjects (0.8%), who were counted as smokers. Biochemical test results were obtained for 555 subjects (89.2%), while 11 had moved out of the area, and 49 refused to visit the survey center (only eight of these 49 denied smoking). Of the 555 who returned to the survey center, 212 denied smoking in the past seven days; nine of these nonsmokers (4%) were reclassified as smokers based on their carbon monoxide and thiocyanate results. Eight more nonsmokers were reclassified because they were missing both biochemical measures, leaving 195 nonsmokers at the two-month follow-up for analysis.

At the six-month follow-up, we were unable to obtain telephone histories from 20 subjects, and 419 reported that they had had at least a puff of a cigarette in the past seven days. The remaining 161 subjects were self-reported nonsmokers, but 49 (30%) failed to come to the survey center for testing (we have since instituted home visits to reduce this proportion). Of the other 112 subjects, only five (4%) had elevated saliva cotinine levels (12 others were using nicotine gum or had inadequate saliva samples but had low expired air carbon monoxide levels and were classified as nonsmokers). Since visiting a study center requires a significant effort, we did not reclassify the 49 unconfirmed nonsmokers. In fact, nine of these 49 nonsmokers had moved out of the area, and 26 continued to report abstinence at one year (15 had low cotinine levels, often at a home visit), leaving only 14 who could well have been smoking at the six-month follow-up. Considering the very low rate of reclassification in those who did provide saliva, however, some were probably truly abstinent. The outcome results reported below count 198 participants as seven-day nonsmokers at six months. The 49 unconfirmed nonsmokers were equally distributed among the four gum groups ($\chi^2 = 1.17, P = .76$).

**Outcome**

Table 4 displays the two- and six-month abstinence rates for each experimental condition. These rates are based on self-reports corrected for biochemical measures as described above (195 nonsmokers at two months and 156 at six months). The seven-day abstinence rates are comparable with those of other studies and clearly show a significant treatment effect, with both active gum groups outperforming the other two groups. A similar pattern is seen for the one-month abstinence rate. Both abstinence rates show a similar pattern at six months, although the $\chi^2$ test no longer shows a statistically significant difference in rates (at the .05 level). Because the outcomes in the active gum groups resemble one another and the outcomes in the placebo and no gum groups also appear similar, we combined these pairs and compared the outcome using active gum with the outcome using no active gum (Table 5). This analysis demonstrates a significant effect of

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**Table 3.—Subjects Reporting Gum Side Effects by Experimental Condition**

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Experimental Condition, % of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ad Lib</td>
</tr>
<tr>
<td>Oral soreness or burning</td>
<td>42.9</td>
</tr>
<tr>
<td>Excessive salivation</td>
<td>24.8</td>
</tr>
<tr>
<td>Hiccups</td>
<td>20.7</td>
</tr>
<tr>
<td>Nausea</td>
<td>24.1</td>
</tr>
<tr>
<td>Light-headedness</td>
<td>19.3</td>
</tr>
<tr>
<td>Oral sore or ulcer</td>
<td>27.0</td>
</tr>
<tr>
<td>Gastrointestinal distress</td>
<td>24.8</td>
</tr>
<tr>
<td>Jaw soreness</td>
<td>19.3</td>
</tr>
<tr>
<td>Anorexia</td>
<td>12.8</td>
</tr>
<tr>
<td>Headache</td>
<td>22.1</td>
</tr>
<tr>
<td>Discontinued gum use due to</td>
<td>13.7</td>
</tr>
<tr>
<td>side effects</td>
<td></td>
</tr>
</tbody>
</table>

*By $\chi^2$ analysis.

**Table 4.—Abstinence Rates Corrected for Biochemical Measures by Experimental Condition**

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Abstinence Rates by Experimental Condition, % of Subjects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ad Lib</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Rate</td>
</tr>
<tr>
<td>2 mo</td>
<td></td>
</tr>
<tr>
<td>7-d</td>
<td>38</td>
</tr>
<tr>
<td>1 mo</td>
<td>36</td>
</tr>
<tr>
<td>6 mo</td>
<td></td>
</tr>
<tr>
<td>7-d</td>
<td>30</td>
</tr>
<tr>
<td>1-mo</td>
<td>24</td>
</tr>
</tbody>
</table>

*By $\chi^2$ analysis.
nicotine polacrilex at both the two- and six-month follow-up. Both the seven-
day and one-month abstinence rates are about 1.5 times higher in the nicotine
polacrilex groups.

As noted above, biochemical test re-
sults are unavailable for 49 of the 156
nonsmokers at the six-month follow-up.
Although most of these subjects were
probably truly abstenent, we repeated the
analysis in Table 5 with these 49
subjects reclassified as smokers. The
abstinence rates were lower, of course
(21% in the active gum users and 14% in
nonusers), but the comparison remains
significantly higher (χ² = 5.30, P = .02).

The "survival" (nonsmoking) analysis is
shown in the Figure. The proportion of
each group that did not have a relapse
decayed rapidly in the first month and
then leveled off, although relapses con-
tinue to occur steadily. The active gum
groups relapsed at about 40% of the rate
of the other two groups over the entire
period, and the benefit is present from
an early point. The average curve for
the two active gum groups is signifi-
cantly different than the one for the placebo
and no gum groups (log-rank χ² = 18.8,
P = .0002).

Table 5.—Abstinence Rates for Active Gum Conditions Combined (n = 299) and No Active Gum Conditions
Combined (n = 301)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Rate</th>
<th>95% Confidence Interval</th>
<th>Rate</th>
<th>95% Confidence Interval</th>
<th>Difference Between Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mo</td>
<td>39</td>
<td>34-45</td>
<td>26</td>
<td>21-31</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6-20 .001</td>
</tr>
<tr>
<td>1 mo</td>
<td>35</td>
<td>30-41</td>
<td>20</td>
<td>16-25</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6-22 &lt;.001</td>
</tr>
<tr>
<td>6 mo</td>
<td>30</td>
<td>25-36</td>
<td>22</td>
<td>18-27</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1-15 .022</td>
</tr>
<tr>
<td>1 mo</td>
<td>26</td>
<td>22-32</td>
<td>18</td>
<td>14-23</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2-15 .016</td>
</tr>
</tbody>
</table>

*By χ² analysis.

COMMENT

This study is among the first con-
trolled investigations of nicotine pola-

1crilex combined with a minimal contact
psychological intervention. The com-
bined treatment produced higher absti-
nence rates after six months than either
placebo gum or no gum. While those
receiving a fixed dosage of gum received
a higher dose overall and tended to do
better at two months, by six months
they were indistinguishable from the ad
lib dosage group. Quit rates in the active
gum conditions were about 1.5 times
higher than in the other two groups,
which is clinically significant and consis-
tent with the findings of previous stud-
ies on nicotine polacrilex. The ade-
quate sample size and experimental
design of this trial plus the absence of a
placebo effect (compared with no gum) all
support the inference that the treat-
ment differences were due to the active
agent, nicotine polacrilex.

Side effects from the gum were com-
mon but generally manageable. About
15% of the subjects stopped using the
gum because of the side effects regard-
less of whether it was active or placebo.
Several of the side effects are probably
related to chewing and not to nicotine.
Indeed, despite the efforts of the re-
search team, overall use of the gum (pla-
acebo or active) was rather low (20% of
participants in the ad lib groups and 40% of
those on the fixed-dosage schedule).
These results indicate that some other
route of administration of nicotine (eg,
transnasal) may be preferable.

Bias is an unlikely explanation of the
results presented here. Baseline covar-
iables were equally distributed among
the groups, and the double-blind design
minimized the potential for coinven-
tion. However, the gum groups did re-
ceive, on average, one additional tele-
phone contact to discuss side effects.
It is unlikely that these contacts account
for the treatment effect, since they also
occurred in the placebo group. The ac-
tive gum groups did show better adher-
ence to the written materials, especially
compared with the placebo group. How-
ever, since the materials were self-
administered, this is best viewed as a
desirable coinvenion, perhaps due
to the perceived usefulness of the gum
or to decreased withdrawal symptoms.
Indeed, since the placebo group had the
lowest adherance, it may be that a lack
of perceived gum effect led to "resentful
demoralization" in this group. Biased
self-reporting of smoking status could
not explain the results, because bio-
chemical testing was done for most par-
ticipants, because those who were not
tested were equally distributed among
the four experimental groups, and be-

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cause the results were not changed by restricting the analysis to only those with available biochemical markers.

Some features of the study design may have limited the impact of nicotine polacrilex. Smokers volunteered for a self-help program, not for nicotine gum, and individuals who specifically requested nicotine replacement might benefit more than those who do not. The 48-hour quit requirement may have eliminated some highly dependent smokers who would have benefited more from nicotine polacrilex. We discouraged gum use beyond three months, and a longer intervention period might have resulted in more differences at six months.

This trial may be more generalizable than many smoking cessation studies. Subjects were recruited from a wide geographic area and included equal numbers of men and women. Randomized subjects constituted 35% of people who were eligible for the trial, and most of those eligible who were not randomized were unable to quit initially. The results should be generalizable to the large number of smokers who are sufficiently motivated to make a quit attempt. The intervention involves minimal contact, which has wide appeal to both smokers and health care providers. The results are particularly relevant to practicing physicians, who are asked to prescribe nicotine polacrilex but are rarely able to provide additional behavioral counseling. For patients who are not interested in group programs, physicians can prescribe self-help programs along with nicotine polacrilex.

Some caution is appropriate in comparing the results of this study with those of other smoking cessation studies. The abstinence rates in Tables 4 and 5 are based on the 600 randomized participants who were able to quit smoking for 48 hours without assistance from the investigators. An appropriately equal number of individuals tried to quit for 48 hours but were unsuccessful. The abstinence rates can be halved to assess the impact of the program on all the smokers who were at least interested in trying to quit. It is probable, however, that some proportion of these unsuccessful “attempters” would also have dropped out of a structured group program at an early stage and would not have been included in the final analyses. It is therefore difficult to compare directly the results of this study with those of other smoking cessation studies.

In summary, this study supports the use of nicotine polacrilex to enhance the effectiveness of a self-directed behavior change program in assisting motivated individuals to maintain abstinence from cigarette smoking. Prescribing the gum in a fixed dosage does not appear to improve its efficacy but does significantly increase the amount and duration of gum use. Such a fixed-dosage schedule may be useful, therefore, in selecting individuals with high physical dependency or persistent withdrawal symptoms with ad lib use. Physicians interested in assisting those smoking patients who are uninterested in groups programs could incorporate self-help materials, such as those available from the American Lung Association, New York, and the American Academy of Family Physicians, Kansas City, MO, into a comprehensive approach that includes nicotine polacrilex. Requiring a 48-hour quit time before continuing treatment may also help focus a physician’s efforts on those most likely to benefit.

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