Telephone Support as an Adjunct to Transdermal Nicotine in Smoking Cessation

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ABSTRACT

Objectives. Transdermal nicotine patches have shown considerable promise in improving smoking cessation outcomes. The present study assessed telephone support as an adjunct to a managed care–based, single-session group orientation smoking cessation program with nicotine patch therapy.

Methods. The unit of randomization was the orientation session (n = 35). Subjects (n = 509) were randomly assigned to a group session without telephone support, the session plus access to a toll-free help line, or the session with telephone help line plus active telephone outreach.

Results. Contrary to hypothesis, there were no differences between treatment conditions. Overall abstinence rates were 22% at 6 months and 21% at 1 year. Fewer than 1% of eligible subjects called the toll-free help line. An average of 3.8 of a possible 4 calls were completed in the telephone outreach condition.

Conclusions. Abstinence results obtained in this program were comparable to those obtained with more extensive counseling. However, there was no evidence of benefit from telephone support beyond the initial physician-led group orientation session. (*Am J Public Health.* 1997;87: 1670–1674)

Introduction

Transdermal nicotine delivery systems produce end-of-treatment results that clearly are superior to placebo, generally doubling the success rate of placebo groups.[1–8] Studies of brief physician counseling, individual counseling, and comprehensive group counseling programs for smoking cessation have consistently demonstrated greater success when nicotine patches are added to the program.[2] Previous research has demonstrated that physician advice alone can significantly increase quitting rates.[9] The impact of physician advice and nicotine patches might be even greater if they were more consistently used in accordance with Food and Drug Administration recommendations as "part of a comprehensive stop smoking program."

Most smokers, however, prefer to quit without attending counseling or group programs.[10,11] Thus, a minimum-intensity smoking cessation program with physician support may be both the most efficient and generally successful approach for a managed care population. This type of program can be delivered in a single face-to-face session. If offered in a group setting, such information also can be delivered efficiently and at relatively low cost.[12,13]

A single session is quite limited, however, in its ability to provide tailored intervention or to address individual patient issues pertaining to nicotine patches and to stopping smoking. An inexpensive follow-up option that has been found to enhance treatment effectiveness is telephone support.[14–20] The purpose of the current study was to assess the effectiveness of telephone support as an adjunct to physician-led orientation to smoking cessation and adjunctive nicotine replacement therapy with nicotine patches. It was hypothesized that proactive telephone outreach would significantly improve abstinence outcomes over the orientation session alone or the orientation session and the toll-free help line.

Methods

Subject Recruitment

A memo describing the study was sent to all physicians in Group Health Inc of Minnesota, a large midwestern health maintenance organization (HMO). In addition, a notice describing the study was published in patient newsletters of several individual HMO clinics.

Subject Eligibility

Eligibility requirements included being between 18 and 65 years of age, having a history of smoking a minimum of 20 cigarettes daily for at least 2 years, and (female subjects only) using an acceptable method of birth control if sexually active. In addition, subjects were required to be motivated to quit smoking, as reflected in a rating of 7 or more on a 0 to 10 scale of desire to quit.[21]

Exclusion criteria included self-reported positive history of heart disease,

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symptomatic peripheral vascular disease, or diabetes; self-reported history of skin irritation or known allergy to adhesives that would preclude use of a transdermal system; current or recent treatment for psychiatric illness or chemical dependency (less than 6 months since completion of treatment); current excessive use of alcohol (consuming seven drinks more than three times per week); self-reported regular use of psychotropic medications, systemic steroids, or antihistamines; pregnancy, lactation, or intention to become pregnant during the study; and current use of any alternative forms of nicotine replacement therapy.

Study staff interviewed 912 patients for study eligibility. Of these 912 patients, 403 were eliminated. The major reasons for exclusion were as follows: 68 (17%) were taking antidepressants, 56 (14%) smoked fewer than 20 cigarettes per day, 52 (13%) failed to attend the orientation session, 40 (10%) were more than 65 years of age, 25 (6%) could not be reached to schedule the orientation, 22 (5%) reported a low motivation to quit (a score of less than 7 on the desire to quit scale), and 19 (5%) were not members of Group Health Inc.

Prior to randomization, subjects had smoked an average of 27.8 cigarettes per day and had smoked for an average of 23.4 years. A substantial percentage of subjects had previous experience with nicotine replacement: 34.8% had used nicotine gum, and 12.0% had used a nicotine patch.

Orientation Session

All eligible participants were invited to a group orientation session. Subjects were randomly assigned to condition by orientation session attended. Orientation sessions were formed on the basis of sign-ups for specific dates and times. Subjects did not know their study condition in advance. A randomized block design was used in which each sequential set of three orientation sessions included the three study conditions. Study conditions were as follows: group orientation session alone, orientation session plus reactive telephone support (subjects were strongly encouraged to call a telephone hot line operated by the patch manufacturer), and orientation session plus both reactive telephone support and active telephone outreach. Orientation sessions were approximately 90 minutes in duration. The sessions were led by a Group Health Inc physician (D.K.) and the study coordinator (L.C.).

At the orientation session, subjects were given an overview of the study, an explanation of data collection forms, instructions for proper use of the patch, and information on the side effects related to smoking cessation and the patch. Information was provided pertaining to behavioral and psychological issues in quitting smoking, and subjects were encouraged to ask questions. Thirty-five orientation sessions were conducted. The overall study goal was to recruit 500 subjects. Once that goal was reached, no further orientation sessions were scheduled. Only 5% of those who signed up for orientation sessions failed to attend. Subjects set their own quit dates but were strongly encouraged to set dates within a maximum of 2 to 3 weeks of the orientation session.

Study Design

All subjects received prescriptions for PROSTEP 22-mg nicotine patches (Wyeth-Ayerst Laboratories, Radnor, Pa), which were provided free to study participants. Subjects were required to fill the prescriptions at an assigned HMO pharmacy. Initial prescriptions were for 2 weeks. Subjects could renew the prescriptions for an additional 4 weeks and then had the option of requesting an additional 2-week prescription for an 11-mg patch.

The standard written materials describing patches and providing recommendations for appropriate use were provided when subjects filled their prescriptions.[22] Subjects were encouraged to use patches for the full 6 weeks unless they experienced significant side effects or engaged in smoking or other tobacco use. Group orientation subjects received this treatment and no additional support. The package insert with the nicotine patch contained information on Lederle Support Services, including a description of a toll-free telephone help line. These services also were described in the informed consent signed by subjects.

In addition to prescriptions for the nicotine patch, subjects assigned to the help-line condition received a registration card for Lederle Support Services, which they could complete and turn in at the group orientation session. The toll-free support services number was discussed at the orientation session and subjects were strongly encouraged to call.

In addition to the previously described intervention components, counselors placed four telephone calls to subjects assigned to the help-line-plus-outreach condition. Both counselors had gained experience in placing supportive telephone calls to subjects in other smoking cessation studies.[17,23] For the current study, they received additional instruction and materials specifically pertaining to nicotine patches.[2,22,24]

The initial call was to occur within 1 week of the quit date; the second, within 4 weeks; the third, within 7 to 9 weeks; and the fourth, within 12 weeks. Telephoners ascertained that subjects had filled their prescriptions for PROSTEP. Reactions to and problems with the patch were discussed. Subjects were advised to consult the study physician in the event of systemic or skin reactions. Adverse events and concomitant medications were to be recorded on study forms. Telephone counselors attempted to reinforce success in those who were abstinent. In all calls, an attempt was made to negotiate a new quit date with subjects who were smoking. The telephone counselor aided the subjects in identifying personally relevant coping strategies for immediate abstinence and continued maintenance. Subjects who were experiencing continuing difficulties in remaining abstinent were alerted to other local smoking cessation resources.

Follow-Up

Brief questionnaires were mailed to subjects, together with postage-paid return envelopes, 2, 5, 8, and 12 weeks after their quit dates. For purposes of follow-up, the quit date was the initial date established by the subject; this was true even for those subjects who negotiated a new quit date. Additional, more extensive questionnaires were mailed 6 and 12 months following subjects' quit dates. Subjects reported on their use of nicotine patches, quitting behaviors, and smoking status. In addition, the rate of filling prescriptions was monitored through computerized pharmacy records. Subjects who were assigned to the two groups with support services were asked about their use of the services.

Subjects who reported abstinence at the 6-month follow-up were scheduled for carbon monoxide measurement to verify self-reports.[25–27] Participants who failed to return 2-, 5-, and 8-week questionnaires were contacted by telephone and asked to do so. No further effort was made to contact individuals who did not respond to these questionnaires. Information from those who did not respond to the 12-week questionnaire was collected by telephone. The total number of calls to nonrespondents prior to the 6-month follow-up was

TABLE 1—Comparison of Treatment Group Characteristics at Baseline: A Managed Care–Based Smoking Cessation Program

	Orientation Session Only		Orientation + Help Line		Orientation + Help Line + Telephone Outreach	
	Mean	n	Mean	n	Mean	n
Female, %*	46.6	174	61.3	173	60.5	162
Caucasian, %	97.1	172	98.2	169	96.9	161
Some college education, %	46.6	174	45.7	173	43.8	162
Employed full time, %	79.9	174	78.0	173	76.5	162
No. cigarettes on typical day, past month	27.6	172	28.5	171	27.4	160
Total no. years smoking	23.4	174	23.7	173	23.2	162
No. quit attempts in previous 12 months	1.1	172	1.4	172	1.1	159
No. lifetime quit attempts	6.1	168	5.1	172	5.2	157
Longest time period off cigarettes, d	193.7	171	174.2	170	182.4	161
Physician advice to quit, %	81.6	174	76.7	172	82.7	162
Participation in formal cessation treatment, %	26.0	173	22.0	173	20.4	162
Previous use of nicotine gum, %	38.5	174	31.8	173	34.0	162
Previous use of nicotine patch, %	12.1	174	12.9	171	11.1	162
Confidence in ability to quit for 24 hours	8.7	153	8.3	154	8.5	145
Confidence in ability to quit permanently	6.6	168	6.5	164	6.4	154
Pounds over (or under) desired weight	15.5	170	17.0	168	14.9	159
Fagerstrom Test for Nicotine Dependence	5.2	174	5.1	173	5.0	162
Age, y	41.3	168	42.9	170	41.6	156

Note. The statistical significance of mean differences in baseline subject characteristics was determined with chi-squared tests (for dichotomous variables) and one-way analyses of variance (for continuous variables).
*Unadjusted $P < .01$ (no longer significant when corrected for number of tests performed; none of the other differences between conditions in baseline characteristics approached statistical significance prior to adjustment).

limited in order to reduce potential confounding between telephone support and telephone assessment.

Statistical Analysis

Chi-squared tests (for dichotomous variables) and one-way analyses of variance (for continuous variables) were used in determining the statistical significance of mean differences in baseline subject characteristics. Treatment differences in point prevalence and continuous cigarette smoking abstinence levels at various follow-up time points were assessed via a mixed-model logistic regression method that accounted for the correlated outcomes within the 35 groups randomly assigned to treatment conditions.[28] Bonferroni adjustment was made for multiple pairwise comparisons. The sample sizes chosen for the three treatment arms were based on 80% statistical power to detect a true 15% difference in 6-month cigarette smoking abstinence level between two treatment groups. Response rates were determined on the basis of responses to surveys. Pharmacy records were consulted in determining use of patches but were not taken into account in determining response rates or outcome status.

Results

Baseline subject characteristics are shown in Table 1. There were fewer women in the orientation-session-only condition than in the other two conditions. However, when corrected for number of tests performed, this difference was no longer significant. None of the other differences between conditions in terms of baseline characteristics approached statistical significance.

The key outcome in the current study was considered to be abstinence at the 6-month follow-up. Extensive efforts were made to contact subjects by mail and by telephone at this point. The overall response rate at 6 months was 99%. Response rates at earlier follow-ups were as follows: 81% at week 2, 71% at week 5, 60% at week 8, and 67% at week 12. The response rate at 12 months was 82%. There were no differences in response rates between conditions. Nonrespondents were counted as smokers for purposes of data analysis.

Lederle records indicated that fewer than 1% of eligible subjects called Lederle Support Services for counseling, despite strong encouragement to do so. Pharmacy dispensing records indicated that, on average, study subjects filled 5 weeks of 22-mg patch prescriptions and 1 week of 11-mg patch prescriptions. No differences were found between groups in number of patches dispensed. There were no reports of discontinuation of patch use because of adverse events.

An average of 3.76 of a possible 4 calls were completed. Refusals to accept calls were rare and totaled only three for all subjects combined. Only 0.6% of subjects could not be reached by telephone at all, 2.5% of subjects were reached no more than once, 8.1% were reached for 2 or fewer calls, and 13% were reached for 3 calls or fewer. Calls averaged between 10 and 15 minutes in duration.

Abstinence outcomes are presented in Tables 2 and 3. At no point did outcome differences between the three conditions approach statistical significance. The carbon monoxide assessments administered at the 6-month follow-up tended to corroborate subjects' self-reports. Of the 111 subjects who reported 6-month abstinence, 105 (96%) evidenced carbon monoxide levels below the cutoff for disconfirmation (8 parts per million[29]). The 6 subjects who exceeded this criterion were counted as smokers.

Discussion

Active telephone outreach was expected to significantly enhance the effectiveness of nicotine replacement in the context of minimal intervention. However, although promising results for telephone outreach had previously been obtained both in our laboratory[17] and elsewhere,[30] there were no differences in abstinence outcomes between treatment conditions. The very limited use of the telephone help line, despite rather inten-

sive promotion of this service, was not unexpected. The proportion of eligible smokers using reactive help lines has been shown, on occasion, to be quite small (on the order of 1% to 2%)[31]; in some studies, however, the proportion using help lines has been far greater.[14,16]

Both short-term and longer term abstinence rates are encouraging, despite the lack of differences between conditions.[1,2,4,5,32,33] Adherence to use of nicotine patches generally was quite good. Nonetheless, and despite extensive training provided to telephone counselors, telephone calls failed to enhance abstinence outcomes. Perhaps the distribution of free patches was a factor. Subjects may have enrolled in the study in anticipation of receiving the patch at no cost and may not have been interested in other treatment components; thus, they may have been poor candidates for the telephone support.[34] Yet subjects were receptive to telephone calls and tended to rate them as helpful to their efforts to quit smoking. The failure of subjects to use the support services suggests that offering this type of reactive help line may be of only very limited value.

The requirements for participation in the current study were more stringent than those for participation in most previous telephone intervention studies. Of a potential pool of 912 subjects, 403 (44%) were eliminated from the study, 68 (17%) because they were currently taking antidepressants. Furthermore, unlike the case in most prior telephone interventions, subjects were required to attend a face-to-face orientation session and to rate themselves as motivated to quit (although only 5% of those eliminated were excluded on the basis of low motivation). Perhaps the proactive telephone outreach would have been more effective with a broader spectrum of potential quitters.

The majority of subjects in all conditions received telephone calls as part of follow-up data collection. Calls placed in the patch only and patch plus reactive telephone support groups primarily involved requests for return of questionnaires from nonrespondents. However, the receiving of calls may have had a reactive effect.[35] In some of our other studies, subjects have not discriminated between assessment calls and intervention calls. On the other hand, calls requesting return of questionnaires or collecting data were deliberately limited prior to the 6-month follow-up to minimize contamination between assessment and intervention.

TABLE 2—Short-Term Abstinence from Smoking among Treatment Group, by Treatment Condition

	Orientation Session Only (n = 174), %	Orientation + Help Line (n = 173), %	Orientation + Help Line + Telephone Outreach (n = 162), %
24 hours[a]	89	91	94
2 weeks	66	65	65
5 weeks	60	50	52
8 weeks	45	38	37
12 weeks	38	34	26

Note. All figures (other than for 24 hours) represent no smoking in the previous 7 days.
[a]Subjects reported their 24-hour abstinence status on the 2-week follow-up survey.

TABLE 3—Long-Term Abstinence from Smoking among Treatment Group, by Treatment Condition

	Orientation Session Only (n = 174), %	Orientation + Help Line (n = 173), %	Orientation + Help Line + Telephone Outreach (n = 162), %
6 months, point prevalence[a]	23	19	25
12 months, point prevalence[a]	22	20	21
6 months, continuous[b]	15	15	17
12 months, continuous[b]	14	13	13

[a]No smoking in the previous 7 days.
[b]No smoking since the quit date.

The conditions selected for evaluation in the current study were limited. All included a rather intensive face-to-face orientation session. Neither placebo patch nor telephone-only conditions (without face-to-face contact) were included. The lack of outcome differences between the conditions tested does not necessarily indicate that telephone outreach is ineffective; rather, its effectiveness was not demonstrated in the present context. Thus, the current study should not be considered definitive in terms of addressing the question of whether telephone support is an important adjunct to transdermal nicotine delivery systems.

Further work is needed to determine whether the type of group format used in the current study is superior to individual physician or other medical practitioner advice. Additional studies also may shed light on issues of optimal pricing of nicotine replacement, as well as the appropriate format and content of behavioral interventions, so as to produce optimal compliance and abstinence outcomes. □

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