Intensive Smoking Cessation Counseling versus Minimal Counseling among Hospitalized Smokers Treated with Transdermal Nicotine Replacement: A Randomized Trial

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PURPOSE: To determine whether an intensive cognitive-behavioral intervention begun during hospitalization when combined with transdermal nicotine replacement therapy is more effective than a minimal counseling intervention combined with transdermal nicotine replacement therapy in helping inpatients to quit smoking.

METHODS: A total of 223 patients who smoked were enrolled in a hospital-based randomized smoking cessation trial at the San Francisco Veterans Affairs Medical Center. One hundred and seven participants (48%) received intensive counseling and outpatient telephone follow-up; 116 participants (52%) received minimal counseling. All study participants received 2 months of transdermal nicotine replacement therapy. We determined 6-month quit rates by self-report and measured saliva cotinine levels or obtained proxy reports to confirm self-reported smoking cessation at 12 months. Analyses adjusted for baseline differences in the distribution of coronary disease.

RESULTS: At 6 months, 35% (36/103) of the intensive intervention group reported quitting, compared with 21% (23/109) of the comparison group (relative risk [RR] = 1.7; 95% confidence interval [CI]: 1.1 to 2.7). At 12 months, the self-reported quit rate was 33% (33/99) in the intensive intervention group versus 20% (21/103) in the comparison group (RR = 1.7; 95% CI: 1.1 to 2.7). Based on biochemical or proxy confirmation, 29% (30/102) in the intensive intervention group versus 20% (21/107) in the comparison group quit smoking at 12 months (RR = 1.6; 95% CI: 0.96 to 2.5).

CONCLUSION: Hospital-initiated smoking cessation interventions that include transdermal nicotine replacement therapy can improve long-term quit rates. **Am J Med. 2003;114: 555–562.** ©2003 by Excerpta Medica Inc.

Cigarette smoking is the largest cause of preventable mortality in the United States (1), resulting in as many as 440,000 deaths each year (2). If the Healthy People 2010 goal of a smoking prevalence of 12% of adults is to be met, new smoking cessation approaches will be needed (3). Millions of persons who smoke are hospitalized each year, often for smoking-related illnesses (4). These hospital admissions provide a window of opportunity to reach those who want to quit smoking. Current practice guidelines recommend that hospitalized patients who smoke be offered smoking cessation treatment (5). Of the hospital-based smoking cessation studies (6–18), however, only three have used transdermal nicotine in some of their participants (15–17).

We undertook this study to determine whether an intensive cognitive-behavioral intervention begun during hospitalization when combined with transdermal nicotine would be more effective in helping persons to quit smoking than would a minimal counseling intervention combined with the same transdermal nicotine. If minimal counseling plus transdermal nicotine was roughly equivalent to intensive intervention plus transdermal nicotine, it would suggest that hospitalized patients who want to quit smoking receive nicotine replacement and the less intensive intervention first, reserving the more intensive intervention for outpatients who require more individualized attention.

METHODS

Patients

Between October 1997 and March 2000, we enrolled 217 men and 6 women who had been hospitalized at the San Francisco Veterans Affairs Medical Center for at least 2 days (Figure). Participants were current smokers (≥20 cigarettes during the prehospitalization week). Patients hospitalized for a psychiatric or terminal illness, or who had a contraindication to nicotine replacement, were excluded. We assessed readiness to quit using the Stages of

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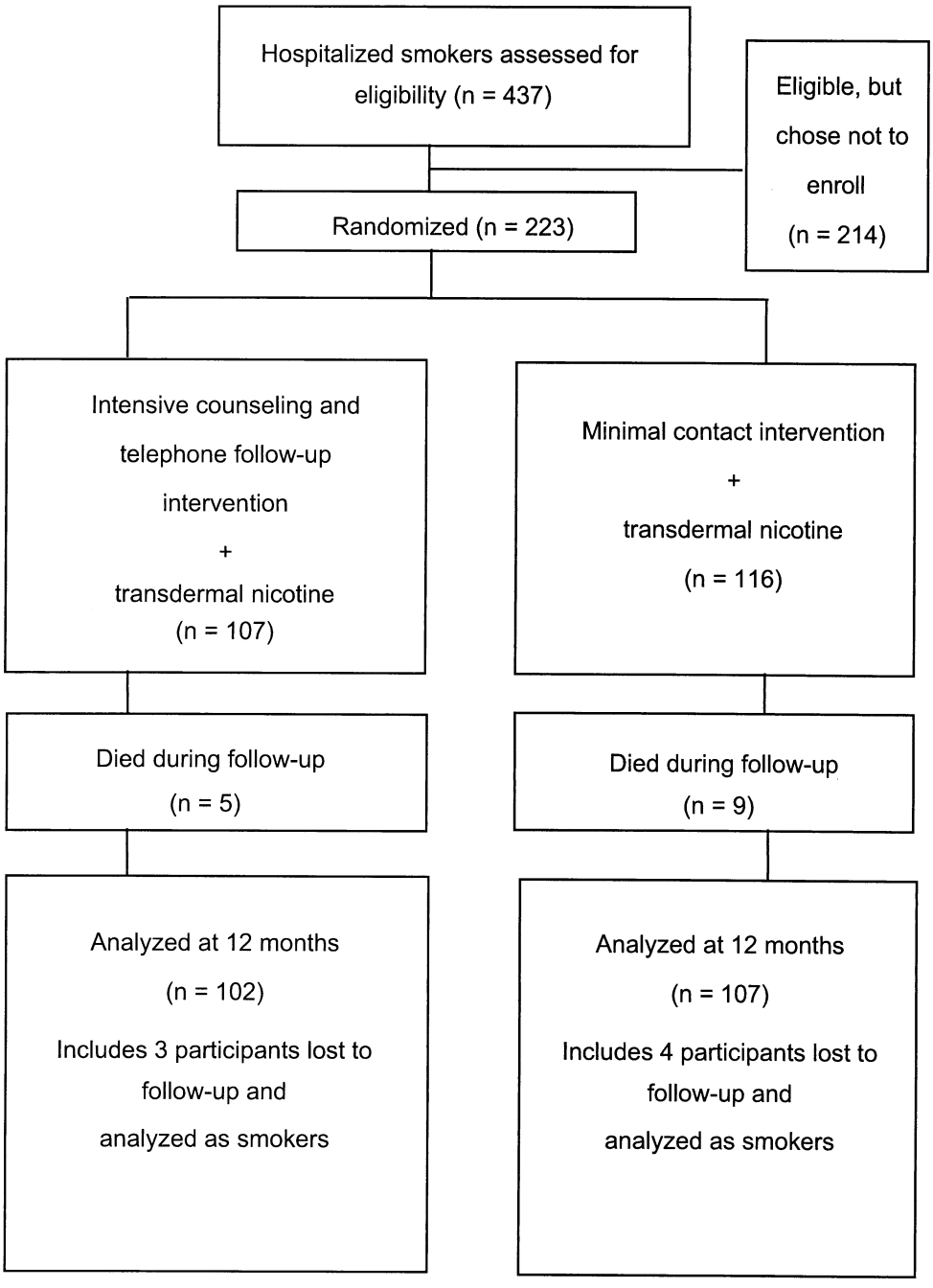

Figure. Flow chart of participant recruitment and follow-up.

Change model (19) and recruited participants at the contemplation or action stage of quitting.

Local institutional review board approval was obtained, and all participants signed an informed consent. Of the 223 participants, 7 (3%) were lost to follow-up and 14 (6%) died. Thus, 209 subjects were available for analyses that considered participants who were lost to follow-up as smokers.

A total of 214 (or 49%) eligible participants declined to enroll. Approximately 95% of those who chose not to participate (n = 203) completed a questionnaire. Compared with participants, these patients had a longer history of smoking, were 3 years older, were less likely to have attempted quitting in the past, were less likely to have a history of drug abuse and depression, and completed fewer years of education (all $P \leq 0.02$). There were no significant differences in race, history of coronary disease, chronic obstructive pulmonary disease (COPD), smoking-related cancers, hypertension, alcohol abuse, or pack-years of smoking (all $P > 0.05$).

Interventions

We randomly assigned participants to the two study arms using a computerized algorithm. The intensive cognitive-behavioral intervention was administered by a trained nurse or a public health educator and was based on social learning theory (20) and the Stages of Change model (21). Patients assigned to intensive intervention were counseled on the nearest weekday before discharge in a session that lasted 30 to 60 minutes. In these sessions, the dangers of smoking and the benefits of quitting were reviewed; participants' knowledge, beliefs, and potential barriers to smoking cessation were assessed; and counter-arguments to belief barriers were provided. Behavioral self-management techniques to counter relapse triggers were also discussed (22). Hospitalized participants began nicotine replacement therapy and were given a 2-month supply of patches at discharge, the dose of which was based on the number of cigarettes smoked before hospitalization. Self-help literature was also distributed. Intervention participants received five follow-up telephone counseling calls at 1 and 3 weeks after discharge and then monthly for the next 3 months. The telephone sessions, which lasted under 30 minutes, continued the skills training initiated during the initial counseling session. Participants who had relapsed were encouraged to set new quit dates.

Patients in the comparison group received nicotine patches in an identical fashion. During their hospitalization, they were counseled on the dangers of smoking and the benefits of quitting, and were given self-help literature in a session lasting approximately 10 minutes.

Data Collection

We collected baseline questionnaire data on age, race, sex, marital status, presence of persons in the household who smoked, level of education, history of drug or alcohol abuse, history of depression, and type of hospital admission. Body mass index was calculated using self-reported or clinical data. Medical problems were recorded based on interviews and chart reviews. We obtained self-reported data on prehospitalization level of smoking, pack-years of smoking, and number of prior quit attempts. We recorded the length of hospitalization in days. We assessed depressive symptomatology using the Beck Depression Inventory (23). Estimated level of tobacco addiction was based on the Fagerström Tolerance Questionnaire (24). A 20-item self-efficacy questionnaire was administered at baseline to assess whether confidence in quitting and resistance to the temptations of smoking were associated with cessation (25).

At the 6-month telephone follow-up, additional data were obtained regarding quit attempts since discharge, current level of smoking, and date of the last cigarette smoked. At the 12-month telephone follow-up, we collected data on marital status, alcohol consumption, presence of persons in the household who smoked, self-reported smoking status, quit attempts over the previous 6 months, date of last cigarette smoked, longest period of tobacco abstinence, duration of use of nicotine therapy, and use of other tobacco products.

Smoking Cessation and Biochemical Validation

We recorded self-reported tobacco abstinence at the 6-month telephone interview (defined as no smoking for 7 days). For participants who reported they had quit smoking at 12 months, we obtained saliva samples for cotinine testing and used levels $\geq$15 ng/mL as an indicator of current tobacco use (26). For patients who reported quitting and who had cotinine levels $\geq$15 ng/ml, we ascertained by telephone interview whether they were using nicotine replacement at the time the sample was provided. There were 3 such participants who were analyzed as quitters. Participants who had stopped smoking cigarettes, but were using other tobacco products, were considered smokers.

Saliva samples were stored at –21°C until assayed for cotinine. For patients who reported quitting and who provided no saliva specimen, we accepted a statement by spouses about subjects' smoking status. There were 24 such participants: 16 from the intervention group and 8 from the comparison group. Such proxy reports have been reported to be reliable (27).

Hospital Admissions and Mortality

To determine whether the intensive intervention was associated with subsequent hospitalizations and 1-year mortality, we monitored hospital admissions during follow-up. Hospital records were reviewed by a physician investigator in a blinded fashion. Admissions or deaths were judged to be smoking related if they were due to cardiovascular disease, COPD, pneumonia, or cancers of the throat, larynx, esophagus, stomach, lung, or urinary bladder.

Statistical Analysis

To compare baseline variables, we used two-sample *t* tests and Wilcoxon rank-sum tests for continuous variables and chi-squared tests for categorical variables. We calculated the relative risk and 95% confidence interval associated with randomization to the intensive intervention group, and adjusted the relative risks using the Mantel-Haenszel method for baseline differences in the prevalence of coronary heart disease, which was more common in the comparison group.

We examined other predictors of quitting using logistic regression. In these analyses, models were adjusted for treatment assignment and history of coronary heart disease. Multivariate models were also adjusted for length of hospitalization (centered at its mean) and length of hospitalization $\times$ treatment assignment because an interaction was detected. Multivariate models included variables

Table 1. Baseline Characteristics of the Study Participants (n = 223)*

Characteristic	Intervention Group (n = 107)	Comparison Group (n = 116)	*P* Value
	Number (%) or Mean ± SD		
Age (years)	55 ± 11	54 ± 11	0.20
White race	74 (69)	80 (69)	0.98
Black race	21 (20)	23 (20)	0.97
Male sex	105 (98)	112 (97)	0.47
Married	41 (38)	39 (34)	0.47
Level of education (years)	13 ± 2	13 ± 2	0.53
Body mass index (kg/m^2)	26 ± 5	26 ± 5	0.62
Age began smoking (years)	16 ± 4	17 ± 5	0.19
Tobacco use (cigarettes per day)	23 ± 12	24 ± 14	0.66
Smoking (pack-years)	46 ± 30	45 ± 33	0.75
Beck Depression Inventory Score	14 ± 8	14 ± 9	0.84
Fagerström Score	4 ± 2	4 ± 2	0.80
Coronary heart disease	12 (11)	24 (21)	0.06
Vascular disease	18 (17)	27 (23)	0.25
Chronic obstructive pulmonary disease	27 (23)	22 (21)	0.65
History of tobacco-related cancer	4 (4)	4 (3)	0.91
Diabetes mellitus	19 (18)	22 (19)	0.82
Hypertension	46 (43)	44 (38)	0.44
Alcohol abuse	50 (47)	55 (47)	0.97
Drug abuse	23 (22)	32 (28)	0.29
History of depression	41 (38)	49 (42)	0.55
Hospital stay (days)	6 ± 5	7 ± 5	0.86

* n = 221 for level of education achieved; n = 214 for Beck Depression Inventory; n = 222 for Fagerström Score.

associated with smoking cessation at a $P \leq 0.20$ in simple models. Because several variables were highly correlated, we selected those variables most associated with quitting. Specifically, we included the Prochaska Confidence Score and excluded the Prochaska Temptation Score, and included the mean number of cigarettes smoked daily at enrollment and excluded pack-years of smoking and the number of cigarettes smoked daily. Analyses were performed using STATA software (College Station, Texas).

RESULTS

There were no significant differences in baseline characteristics between the two treatment groups (all $P > 0.05$), although slightly more participants with coronary heart disease were assigned to the comparison group (Table 1). Participants were predominantly unmarried, white, and middle-aged. Alcohol and drug abuse and a history of depression were common. Smoking histories were also similar in the two groups. Participants were moderate-to-heavy smokers with a mean of 45 pack-years of smoking, and had been smoking just over one pack of cigarettes daily at the time of hospitalization.

At 6 months and 12 months after hospitalization, the self-reported quit rates were higher among the intensive intervention participants than among the comparison participants (Table 2). At 12 months, quit rates, confirmed either by salivary cotinine level or, when not available, by spousal proxy, were 29% among intensive intervention participants and 20% among comparison participants ($P = 0.07$). Results were similar if participants who were lost to follow-up were excluded from the analyses (Table 2). Rates of self-reported quitting were higher than those confirmed biochemically. However, the magnitude of the benefit at 1 year associated with the intervention was similar in all the models, about an absolute increase of 7% to 10% in quit rates.

Several other variables were associated with quitting, including coronary heart disease, average number of cigarettes smoked per week, body mass index, confidence in quitting score, history of depression, and level of education (Table 3). In multivariate models, baseline confidence in the ability to quit and a history of depression were associated with an increased likelihood of quitting at 1 year (Table 3). Assignment to intensive intervention was also associated with an increased likelihood of quitting in the multivariate model (odds ratio = 2.4; 95% confidence interval: 1.2 to 5.0).

In simple models, only length of hospital stay appeared to modify the effect of treatment assignment ($P = 0.02$).

Table 2. Smoking Cessation Rates by Group Assignment

	Intervention Group		Comparison Group		Relative Risk of Quitting (95% Confidence Interval)*	*P* Value*
	Number	No. (%) Who Quit	Number	No. (%) Who Quit		
Self-report at 6 months	103	36 (35)	109	23 (21)	1.7 (1.1 to 2.7)	0.02
Self-report at 12 months	99	33 (33)	103	21 (20)	1.7 (1.1 to 2.7)	0.03
Validated at 12 months†	99	30 (30)	103	21 (20)	1.5 (0.95 to 2.5)	0.08
Validated at 12 months‡	102	30 (29)	107	21 (20)	1.6 (0.96 to 2.5)	0.07
Validated at 12 months§	102	16 (16)	107	10 (9)	1.6 (0.76 to 3.3)	0.21

* Adjusted for differences in baseline prevalence of coronary heart disease.
† Participants lost to follow-up were excluded; validated by salivary cotinine level or spousal proxy.
‡ Participants lost to follow-up were considered smokers; validated by salivary cotinine level or spousal proxy.
§ Participants lost to follow-up and participants with nonsmoking status ascertained by spousal proxies were considered smokers; thus, nonsmoking status was based on biochemical validation by salivary cotinine levels only.

In multivariate models, however, this effect-modification was no longer significant ($P = 0.08$).

We examined whether the intensive intervention was associated with other health-related outcomes. During follow-up, hospital admissions for a smoking-related illness (median, 0 in both groups, $P = 0.86$), total hospitalizations (median, 1 in both groups, $P = 0.27$), doctor visits (median, 10 in the comparison group vs. 12 in the intervention group, $P = 0.28$), and emergency room visits (median, 0 in the comparison group vs. 1 in the intervention group, $P = 0.26$) were similar in both groups. There was a median of one quit attempt during follow-up in both groups (range, 0 to 24 in the comparison group vs. 0 to 30 in the intervention group, $P = 0.19$). By the end of the study, 14 participants had died: 5 in the intervention group versus 9 in the comparison group ($P = 0.34$).

DISCUSSION

We found that a hospital-initiated smoking cessation intervention that included 3 months of follow-up telephone counseling and 2 months of transdermal nicotine therapy increased long-term smoking cessation rates compared with a hospital-initiated minimal counseling intervention that included 2 months of transdermal nicotine therapy. We employed several definitions of smoking cessation. Our findings, which were based on self-reported cessation, were statistically significant, and the findings based on the more conservative measures to ascertain cessation were consistent with a trend toward benefit. In models that adjusted for other predictors of cessation, randomization to the intensive intervention group was associated with a statistically significant increase in cessation. The approximately 10% absolute difference in quit rates between treatment arms implies that for every 10 persons who smoked and who received the intensive intervention and follow-up, there was one additional quitter.

Except for the Prochaska Confidence in Quitting score (a measure of self-efficacy) and a history of depression, no other variables were significantly associated with quitting. As expected, participants with greater confidence in

Table 3. Predictors of Smoking Cessation among 209 Participants Alive at 12 Months of Follow-up

Variable	Odds Ratio (95% Confidence Interval)	
	Simple Model*	Multivariate Model†
Level of education (years)	1.15 (1.00 to 1.31)‡	1.10 (0.95 to 1.27)
Prochaska Confidence Score	1.02 (1.01 to 1.04)‡	1.03 (1.01 to 1.05)§
Mean number of cigarettes smoked per day (units of 10 cigarettes)	0.79 (0.60 to 1.04)	0.79 (0.58 to 1.08)
Body mass index (per 5 units)	1.29 (0.95 to 1.75)	1.38 (0.98 to 1.94)
History of depression (yes/no)	1.80 (0.94 to 3.47)	2.11 (1.01 to 4.41)‡
History of coronary disease (yes/no)†	1.80 (0.79 to 4.07)	1.96 (0.77 to 5.02)

* Adjusted for treatment assignment and baseline history of coronary heart disease. The simple model that examined the effect of history of coronary heart disease was adjusted only for treatment assignment. Smoking cessation was based on validation by salivary cotinine level or spousal proxy.
† Adjusted for the variables in the Table, length of hospitalization, and length of hospitalization × treatment assignment. Because of missing data, n = 199.
‡ $P < 0.05$.
§ $P < 0.01$.

Table 4. Characteristics of Published Hospital-Based Smoking Cessation Clinical Trials

	Type of Inpatients				Type of Intervention					
Study (Reference)	Number	Medical	Cardiac	Surgical	Behavioral	Nicotine Gum	Nicotine Patch	Bupropion	Biochemical Validation of Outcome	Results
Simon (current study)	223	+		+	+		+		Yes	Quit rate increase of 9%
Dornelas (18)	100		+		+				No	Quit rate increase of 21%
Rigotti (14)	650	+		+	+				Yes	NS
Simon (15)*	324			+	+	+	+		Yes	Quit rate increase of 9%
Strecher (6)	125	NA	NA	NA	+				No	NS
Taylor (7)	173		+		+	+			Yes	Quit rate increase of 26%
Taylor (16)	660	+	?	+	+	+	+		Yes	Quit rate increase of 10%
Campbell (8)	212	NA	NA	NA	+	+			Yes	NS
Ockene (9)	267		+		+				Yes	Quit rate increase of 11%
Stevens (10)	1119	+	+	NA	+				No	Quit rate increase of 4%
Rigotti (12)	87		+		+				Yes	NS
Stanislaw (11)	26			+	+				Yes	Quit rate increase of 32%
Wewers (13)	80			+	+				Yes	Quit rate increase of 12%
Houston-Miller (17)	990	+	+	+	+	+	+		Yes	Quit rate increase of 7%

* Nicotine replacement therapy begun after hospital discharge.

? = Not known if cardiac patients were enrolled, as authors only state that "smokers hospitalized for various medical and surgical conditions" were enrolled; NA = not available; NS = not significant.

their ability to quit were more likely to quit. The observation that a history of depression increased the likelihood of quitting was unexpected and may be a chance finding. However, it is possible that such participants had previously acquired skills that were helpful in quitting as a result of therapy for depression. Because we did not collect information on use of antidepressant medications, we cannot exclude the possibility that treatment with drugs, such as bupropion, may have affected the finding.

We achieved validated quit rates as high as 30% at 1 year among patients who smoked. Among patients who received minimal counseling and 2 months of transdermal nicotine, we observed an approximately 20% quit rate. In our prior study involving a similar group of patients hospitalized for noncardiac surgery who received minimal counseling but no nicotine replacement, we achieved an 8% 1-year quit rate (15). Hence, the addition of nicotine replacement initiated during hospitalization likely accounts for the increase in long-term quit rates. We believe the use of nicotine replacement begun during hospitalization is reasonable and likely to be cost-effective. Although the feasibility of inpatient treatment of severe nicotine dependence has been examined (28), few hospital-based smoking cessation studies have employed nicotine replacement therapy (7,8,15–17) (Table 4). None of the three hospital-based studies that used transdermal nicotine provided it to all participants, and the percentage of participants in these studies who used nicotine replacement in any form ranged from 44% to 65% (15–17).

We studied mostly male veterans and thus our results may not be generalizable to other hospitalized patients who smoke. We believe, however, that an intervention that is effective among low-income veterans with a long history of heavy smoking and multiple medical problems will also be effective in other groups who smoke. We used transdermal nicotine and cannot comment on the effectiveness of other forms of nicotine replacement begun in the hospital setting.

We expected that an increase in smoking cessation among the intervention participants would be accompanied by better overall health status, fewer clinic visits, and fewer smoking-related hospitalizations. However, we observed no significant difference in any of these outcomes. It is possible that differences in health care utilization might have become apparent if we had been able to follow participants for a longer time.

Millions of adults who smoke are hospitalized yearly (4), providing a window of opportunity for smoking cessation interventions. Practice guidelines recommend that these hospitalized patients be offered smoking cessation treatment (5). The results of our study support this recommendation. Although we did not perform a cost-effectiveness analysis, we believe the expense associated with such efforts represents a reasonable allocation of health care resources.

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