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Randomized trial of a smoking cessation intervention in hospitalized patients

Yves Lacasse, Réjean Lamontagne, Sylvie Martin, Serge Simard, Marie Arsenault

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A hospitalization is a time when perceived vulnerability to dangers from smoking and quitting motivation may be at their peak. Aim was to determine whether a smoking cessation intervention of moderate intensity would increase the smoking cessation rate in hospitalized smokers. Design was randomized trial, conducted in a university-affiliated cardio-pulmonary tertiary care center. Participants were hospitalized smokers aged $\leqslant$70 years. Intervention was a smoking cessation intervention consisting of education and psychological support, with or without pharmacological therapy, associated with follow-up phone calls. Patients assigned to the control group received usual care. Measurement was point prevalence cessation rate at 1-year follow-up. A total of 468 patients were screened; 196 were randomized. Although the smoking cessation rates at 12-month follow-up were higher than expected, we found no significant difference between the study groups (intervention: 30.3%; control: 27.8%). Similar results were obtained in patients whose smoking status was validated by urinary cotinine assay. Length of stay and dependence to nicotine were the only significant predictors of smoking cessation. A smoking cessation intervention of moderate intensity delivered in a tertiary cardio-pulmonary center did not increase the smoking cessation rate at 1-year follow-up. The results of this trial should not divert those who deliver care to inpatients from delivering a brief smoking cessation intervention.

Introduction

The rationale for a smoking cessation intervention in inpatients is that hospitalization is a window of opportunity (Emmons & Goldstein, 1992), that is, a time when perceived vulnerability to dangers from smoking, quitting motivation and receptivity to smoking cessation intervention may be at their peak, especially for those smokers hospitalized for a condition that is caused or complicated by smoking (Orleans, Kristeller, & Gritz, 1993). Trials of smoking cessation interventions in hospitalized patients have also resulted in increased cessation rates, especially in specific populations such as those with acute myocardial infarction (Taylor, Houston-Miller, Killen, & DeBusk, 1990; DeBusk et al., 1994) or, to a lesser extent, those undergoing elective surgery (Simon, Solkowitz, Carmody, & Browner, 1997). Whether these results may be generalized to patients hospitalized in a tertiary care center remains uncertain.

We report the results of a randomized trial conducted in a cardiothoracic hospital comparing the effect of a smoking cessation intervention of moderate intensity to usual care. We wished to determine whether an intervention consisting of education and psychological support, with or without pharmacological therapy, associated with follow-up phone calls would increase the cessation rate at 1-year follow-up in hospitalized smokers aged $\leqslant$70. Our hypothesis was that such an intervention would be effective in increasing the 1-year cessation rate by 10% (absolute difference).

Yves Lacasse, M.D., M.Sc., Sylvie Martin, M.Sc., Serge Simard, M.Sc., Centre de recherche, Centre de pneumologie, Hôpital Laval, Institut universitaire de cardiologie et de pneumologie de l'Université Laval, Québec, Canada; Réjean Lamontagne, M.A., Pavillon de prévention des maladies cardiaques, Hôpital Laval, Institut universitaire de cardiologie et de pneumologie de l'Université Laval, Québec, Canada; Marie Arsenault, M.D., Centre de recherche, Institut de cardiologie, Hôpital Laval, Institut universitaire de cardiologie et de pneumologie de l'Université Laval, Québec, Canada. The study was carried out at Laval Hospital.

Correspondence: Yves Lacasse, Centre de Pneumologie, Hôpital Laval, 2725 Chemin Ste-Foy, Ste-Foy, Quebec, G1V 4G5, Canada. Tel: 418-656-4747; Fax: 418-656-4762; E-mail: Yves.Lacasse@med.ulaval.ca

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Methods

Clinical setting and study population

This randomized trial was conducted in Laval Hospital, the Quebec Heart and Lung Institute. This is a referral, 307-bed center that provides tertiary care in cardiology, respiratory medicine, general internal medicine, cardiac surgery, thoracic surgery, and general surgery. The study protocol received approval from the hospital's research ethics committee.

Patients were recruited from January 1, 2004 to December 31, 2005. Those who fulfilled the following criteria were eligible: (a) current smokers aged $\leqslant 70$; (b) anticipated duration of hospitalization $\geqslant 36$ hr; (c) patients in the contemplation, preparation or action stage of change (Prochaska & DiClemente, 1983). Exclusion criteria were: (a) refusal to participate; (b) patients in the precontemplation stage of change; (c) patients hospitalized for alcoholism or drug abuse; (d) critically or terminally ill patients; and (e) any other disorder with a severe short-term prognosis.

Intervention

The smoking cessation intervention was tailored to a model assuming that smoking involves physiologic addiction and psychological dependence to nicotine (The Tobacco Use and Dependence Clinical Practice Guideline Panel, 2000). Its basic components included a strong quit smoking message from the treating physician, self-help motivational quitting or relapse prevention materials, brief cessation counseling, the use of pharmacological adjuncts when indicated, and follow-up support. Such intervention typically involves five steps (the 5 A's).

- *Ask about smoking:* This initial step involved a brief (<5 min) assessment of smoking history and degree of physical addiction. Quitting motivation (i.e., patients' stage of change) was determined using Prochaska's definitions and items (Prochaska & Goldstein, 1991).
- *Advise to quit:* All the physicians practicing at Laval Hospital were instructed that a trial of a smoking cessation intervention was ongoing in the hospital. They were reminded, from a fluorescent reminder sticker placed on the chart of patients who had been assigned to the intervention group, to advise them to stop smoking. This message was reinforced by the counselor during the intervention session(s).
- *Assess willingness to quit*: The patients were interviewed regarding their beliefs and behaviors related to smoking, and their past experience with smoking cessation.
- *Assist smokers to stop smoking*: To conclude the first 10–20-min intervention session or, if necessary, during a second 15-min session, the counselor assisted the patient in his/her smoking cessation process. The intervention was based on Bandura's self-efficacy theory (Bandura, 1982). Self-efficacy refers to the personal conviction people have regarding whether they feel that they can successfully execute particular behaviors in order to produce certain outcomes. The higher the level of induced self-efficacy, the higher the performance accomplishment. Patients were taught to monitor their smoking habit and observe the conditions under which smoking occurs, and to reward their successful efforts. Self-efficacy was achieved by guided practice and corrective feedback in simulated high-risk situations. At hospital discharge, creation of social support for desired personal changes was encouraged.
- Nicotine replacement therapy (NRT) by transdermal nicotine patches was offered to all patients regardless of their level of dependence (The Tobacco Use and Dependence Clinical Practice Guideline Panel, 2000). NRT was given to reduce nicotine withdrawal symptoms to those in their contemplation or preparation stage of change. NRT was continued after discharge for a total of 8 weeks (Jorenby et al., 1999) by those who entered in the action stage during the hospitalization. Although NRT had no adverse effects in patients with active heart disease (Joseph et al., 1996; Working Group for the Study of Transdermal Nicotine in Patients with Coronary Artery Disease, 1994), we considered the risks and benefits among patients in the immediate (within 4 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with severe or worsening angina pectoris (The Tobacco Use and Dependence Clinical Practice Guideline Panel, 2000). The final decision of NRT was left to the treating physician. Initial dosage (Nicoderm®, GlaxosmithKline, 21, 14 or 7 mg ID), was according to the severity of dependence.
- *Arrange for follow-up:* Within 6 weeks after hospital discharge, the patients randomized to the intervention group were contacted by telephone up to four times (Zhu et al., 1996) by the same therapist who delivered the inpatient smoking cessation intervention to provide continued support and further advice regarding relapse prevention. Phone calls were scheduled $\leqslant 7$, 14, 30 and 45 days after discharge or after the quit date. Each time, the phone call lasted about 10 min.

Usual care

Patients in the group receiving usual care were not given any specific instruction on how to stop smoking. Contacts between the patients in the control group and the study personnel were limited

to obtaining measures at baseline, and at 6-month and 1-year follow-up.

Measures and outcomes

Primary outcome. Point prevalence abstinence at 1-year follow-up was the primary outcome of this trial. Self-reported abstinence was recorded at 6-month and 1-year follow-up through telephone contacts. Self-reported smoking status at 1-year follow-up was validated by urinary cotinine assay (Jarvis, Tunstall-Pedoe, Feyerabend, Vesey, & Saloojee, 1987; Bramer & Kallungal, 2003) (Double Antibody Nicotine Metabolite, Diagnostic Products Corporation, Markham, Ontario).

Other measures. We administered four short questionnaires at study entry. The level of nicotine dependence was measured using the Fagerström Test for Nicotine Dependence, a six-item, internally consistent questionnaire that is closely related to biochemical indices of heaviness of smoking (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). In order to measure the intensity of tobacco withdrawal, we selected the Questionnaire on Smoking Urges (Tiffany & Drobes, 1991), a 32-item questionnaire for which validity and reliability have been provided by independent investigators (Willner, Hardman, & Eaton, 1995). We measured self-efficacy using the Velicer's scale, a valid and reliable instrument specific to the smoking cessation area (Velicer, DiClemente, Rossi, & Prochaska, 1990). Finally, we limited our use of the SCL-90 to its depression domain (Derogatis & Cleary, 1977).

Study protocol

Patients admitted in the hospital within the last 24 hr were located through the hospital's admission service. Those who were eligible and who accepted to participate were immediately assigned to either the intervention or the control group by one of the hospital pharmacists using a table of random numbers. For those randomized to the intervention group, the cessation intervention began immediately after the baseline data collection, with the exception of the surgical patients whose intervention was delivered either pre- or postoperatively, according to the timing of the surgery and the patient's condition. In order to minimize biases, the 6-month and 12-month follow-up outcomes were assessed using a short standardized and closed questionnaire by a research assistant who did not know the patients' group allocation. Urinary spots were collected at 1-year follow-up during a coincidental visit to the treating physician or were sent by mail to the study office using sealed test tubes.

Statistical analysis

Primary analyses. Baseline characteristics were compared using unpaired *t*-tests for continuous variables and Fisher's exact tests for the categorical variables. We used the weighted Kappa statistic to measure the concordance between self-reported smoking status and that validated by urinary cotinine (Kramer & Feinstein, 1981). We reported the cessation rates at 6-months and 1-year follow-up in both groups and the absolute rate difference with 95% confidence intervals (CI). From the absolute rate differences, we computed the number needed to treat (NNT), i.e., the number of patients who must receive an intervention in order to obtain a successful event in one of them (Laupacis, Sackett, & Roberts, 1988). We also provided 95% *CI*s around the NNTs (Altman, 1998). Three separate analyses were conducted. A first analysis involved only patients who were available at follow-up. A second analysis included those lost to follow-up. These patients were counted as if the were continuing smokers at the end of the trial. A third analysis considered only the smoking status validated by urinary cotinine. We set statistical significance at the 0.05 level (two-sided).

Secondary analyses: predictors of smoking cessation at 1-year follow-up. We investigated the influence of each of the demographic and pretreatment smoking characteristics on likelihood of smoking cessation at 1-year follow-up. To do so, we conducted logistic regression analyses in which the dependent variable consisted of the abstinence rate among those available at 1-year follow-up.

Sample size: In order to decide what difference in cessation rates the trial should be able to detect, we introduced the concept of NNT to health care providers from our out-patient smoking cessation clinic. The staff members agreed on an NNT of 10, which corresponds to an absolute difference in smoking cessation rates at 1-year follow-up between the intervention and usual care groups of 10%. We computed that a sample size of 366 patients (183 per group) would be needed to complete this trial (expected smoking cessation rate at 1-year follow-up in the control group: 16% (Glasgow, Stevens, Vogt, Mullooly, & Lichtenstein, 1991); one-sided alpha error: 5%; power: 80%). All analyses were run according to the intention-to-treat principle.

Interim analysis: We planned an interim analysis after half of the needed sample size had completed the study. Stopping rules were stated *a priori*. The trial could be stopped if the treatment effect reached significance at the 0.001 level (two-sided) (Haybittle, 1971) or if the 95% *CI* around the observed NNT excluded the target NNT of 10.

Results

Patients

The trial profile is depicted in Figure 1—468 patients were screened, 335 were deemed eligible, and 196 were randomized. We found little difference in the baseline characteristics between the subjects of both groups, with the exceptions of more previous quit attempts in the intervention group and higher smoking indices in the control group (Table 1). These differences were small and clinically irrelevant.

Intervention

The 99 patients allocated to the intervention group all received a quit smoking message from the treating physician, self-help motivational quitting or relapse prevention materials and at least one brief cessation counseling. Eighteen received nicotine replacement therapy. On average, the patients were given 1.4 follow-up phone calls after discharge. The last follow-up call was given about 1 month after discharge (median: 37 days).

Primary analysis: smoking cessation rates

The concordance between self-reported smoking status and that validated by urinary cotinine was good (Kappa: 0.74; 95% *CI* 0.60–0.88; Table 2). At 12-month follow-up, 30 of the 99 patients allocated in the intervention group reported having stopped smoking, including 11 of the 18 patients who had received NRT during hospitalization. At the same time, 27 of the 97 control patients had quit. The intervention resulted in no significant increases in smoking cessation rates at 6-month and 1-year follow-up (Table 3). From the differences in cessation rates, we computed NNTs that all exceeded the acceptable threshold of 10 that we had decided *a priori*. Based on this finding, we made the decision to stop the trial after the interim analysis and to declare the intervention ineffective.

Predictors of smoking cessation

We identified two significant predictors of smoking cessation at 1-year follow-up. The longer the stay in hospital, the higher the likelihood of abstinence at 1 year (odds ratio, *OR*, per day in hospital: 1.06; 95% *CI* 1.01–1.12). The more dependent to nicotine, the less likely to be nonsmoker at 12-month follow-up (*OR*, per unit of Fagerström's score: 0.82; 95% *CI* 0.71–0.96). Both predictors remained significant in the multivariable analysis.

Discussion

In this randomized trial, a smoking cessation intervention of moderate intensity delivered in a

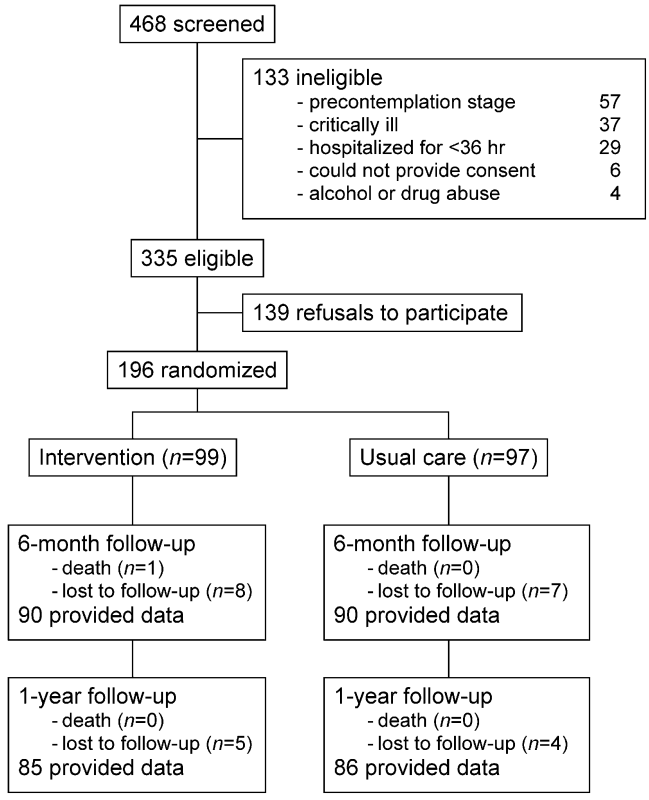

Figure 1. Trial profile.

Table 1. Baseline characteristics of study participants.

Characteristics	Intervention group (n=99)	Control group (n=97)	*p* value
Age (years)	52 (9)	52 (10)	0.4
Gender, % male	64%	68%	0.3
Education (years)	10 (3)	10 (3)	0.5
Living alone	31%	36%	0.2
At work	59%	58%	1.0
Smoking history			
Cigarettes per day	20.4 (12.6)	22.8 (9.4)	0.04
Pack-years	35 (24)	41 (22)	0.02
Number of previous attempts to quit smoking	2.4 (2.2)	2.0 (2.2)	0.04
Stage of change			
Contemplation	7%	6%	
Preparation	90%	94%	
Action	2%	0%	0.6
Hospitalization			
Cardiology	63%	65%	
Acute myocardial infarction	35% (22/62)	44% (28/63)	
Unstable angina	47% (29/62)	33% (21/63)	
Heart failure	5% (3/62)	5% (3/63)	
Other heart disease	13% (8/62)	18% (11/63)	
Respiratory medicine	27%	18%	
Obstructive lung disease	56% (15/27)	47% (8/17)	
Pneumonia	22% (6/27)	18% (3/17)	
Other lung diseases	22% (6/27)	35% (6/17)	
Other	10%	18%	0.07
Length of stay (days)	8 (6)	8 (7)	0.9
Surgical procedure during hospitalization	11%	18%	0.1
FTND (0–10)	5.1 (2.2)	5.5 (2.2)	0.1
Self-efficacy (1–5)	3.0 (0.8)	3.0 (0.7)	0.5
Questionnaire of Smoking Urges (1–7)	2.1 (1.4)	1.8 (1.1)	0.1
SCL-90 - depression (0–4)	0.7 (0.6)	0.7 (0.7)	0.8

Note. FTND, Fagerström Test of Nicotine Dependence.

Table 2. Concordance between self-reported and validated smoking cessation rates.

		Validated smoking cessation rates*		
		Smoker	Non-smoker	Total
Self-reported smoking cessation rate	Smoker	57	3	60
	Non-smoker	8	27	35
	Total	65	30	95

Note. *A cutoff point of 200 ng/ml was used to discriminate between smokers and non-smokers (Bramer et al., 2003).

tertiary cardiopulmonary center did not increase the smoking cessation rate at 1-year follow-up. We stopped the trial after the first planned interim analysis revealed NNTs that exceeded the acceptable threshold of 10 that we had decided *a priori*. The width of the observed confidence intervals around the differences in cessation rates and their relation to the threshold NNT are clear indications that the sample size of our trial does not explain its negative results (Goodman & Berlin, 1994).

Although NRT was offered to all patients allocated to the intervention group, an important

Table 3. Comparison of smoking cessation rates between the intervention and usual care groups.

	Smoking cessation rates					
Time of follow-up	Intervention group	Usual care group	Absolute difference	95% *CI*	Number needed to treat	Limit of the 95% *CI*
6-month follow-up						
Self-reported smoking cessation rate*	29/90 (32.2%)	27/90 (30.0%)	2.2%	−4.0% to 8.5%	45	12
Self-reported smoking cessation rate†	29/99 (29.3%)	27/97 (27.8%)	1.5%	−4.3% to 7.2%	69	14
1-year follow-up						
Self-reported smoking cessation rate*	30/85 (35.3%)	27/86 (31.4%)	3.9%	−2.9 to 10.6%	27	10
Self-reported smoking cessation rate†	30/99 (30.3%)	27/97 (27.8%)	2.5%	−3.3% to 8.2%	41	13
Smoking cessation rate validated by urinary cotinine measurement	15/46 (32.6%)	17/49 (34.7%)	−2.1%	−11.1% to 6.9%	—	15

Note. *Analysis involving only the patients who were available at follow-up; †analysis involving the patients who were lost to follow-up; those patients were counted as continuing smokers.

observation is that only 18 patients (out of 99) received it. Most patients who refused NRT argued that they were able to cope with withdrawal symptoms without adjunct therapy. Another barrier to the prescription of NRT was the reluctance of many physicians to provide their patients (especially those with active heart conditions) with it because of the risks of side-effects. However, this was not substantiated in any of the trials specifically addressing this issue (Joseph et al., 1996; Working Group for the Study of Transdermal Nicotine in Patients with Coronary Artery Disease, 1994). The methods to fill the gap between evidence and practice belong to knowledge transfer (Davis et al., 2003). Several interventions to transfer evidence into practice have been studied (Grol & Grimshaw, 2003). Most strategies (including educational interventions, use of reminders, multi-professional collaborations, and combination of interventions) have only demonstrated limited effectiveness in modifying physicians' behaviors. Knowledge transfer in smoking cessation interventions represents an important area for further research.

Our results are in agreement with those of a recent meta-analysis of smoking cessation interventions in hospitalized patients (Rigotti, Munafo, Murphy, & Stead, 2002). In this meta-analysis, the interventions were categorized according to their level of intensity and to whether they included follow-up after discharge (category 1: minimal intervention, no follow-up support; to category 4: any hospital contact with follow-up $\geqslant$1 month). In this classification, our intervention would fall in category 3 (any hospital contact with follow-up $\leqslant$1 month). The meta-analysis of six controlled trials of category 3 intensity found no increase in smoking cessation rate (relative risk: 1.09; 95% *CI* 0.91–1.31).

Among the randomized trials included in Rigotti's meta-analysis, the pooled abstinence rates at 12-month follow-up in the control groups were 13% (Rigotti et al., 2002). In our trial, the abstinence rate in the control group at 12-month follow-up was 30%. A potential explanation is that patients with cardiovascular diseases (who represented more than 60% of our study population) usually have higher cessation rates during the year that follows a hospitalization (Ockene et al., 1992; Ortigosa et al., 2000). An alternative explanation is that the observed cessation rate in our control group is an indication of some form of intervention even in those allocated to the usual care group. Health care providers (physicians and nonphysicians) who work in a cardiorespiratory center like ours may have integrated advice for smoking cessation as a part of their usual care. Such a brief intervention has, in itself, a significant effect on smoking cessation (Lancaster & Stead, 2004; Mojica et al., 2004).

We noted that, in Rigotti's meta-analysis, only category 4 interventions were associated with a significant increase in quit rates (Rigotti et al., 2002). This emphasized the point that sustained follow-up support after hospital discharge is a key element of a successful smoking cessation intervention that is initiated while the patient is hospitalized. At least another randomized trial published after Rigotti's meta-analysis reinforced this statement (Quist-Paulsen & Gallefoss, 2003).

We identified two significant predictors of smoking cessation at 12-month follow-up (nicotine dependence and length of stay). Previous studies of the predictors of smoking cessation after hospitalization were mainly conducted in patients admitted for cardiovascular events (Bolman, de Vries, & van Breukelen, 2002; Dornelas, Sampson, Gray, Waters, & Thompson, 2000; Hajek, Taylor, & Mills, 2002; Ong, Cheong, Prabhakaran, & Earnest, 2005; Rigotti, McKool, & Shiffman, 1994; Taylor et al., 1990). Results have often been conflicting. The finding that smoking cessation is predicted by nicotine addiction is constant, however, and emphasizes the importance of NRT. Others have identified self-efficacy (Dornelas et al., 2000; Taylor et al., 1990), intention to quit (Bolman et al., 2002; Hajek et al., 2002; Rigotti et al., 1994) and initial hospitalization (Ong et al., 2005) as significant predictors. Such variables may be useful in designing individualized interventions.

We concluded that a smoking cessation intervention of moderate intensity, as we used to deliver in our institution, is ineffective in increasing the cessation rate at 12-month follow-up in hospitalized patients. The results of this trial should not divert those who deliver care to inpatients from delivering a brief smoking cessation intervention. Further studies of smoking cessation interventions of higher intensity in high-risk patients (such as those with high levels of nicotine dependence or those with short stay in hospital) are needed. NRT should be an integral part of such interventions.

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