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Original Investigation

Smoking Cessation Intervention After Ischemic Stroke or Transient Ischemic Attack. A Randomized Controlled Pilot Trial

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Abstract

Background: Smoking cessation is widely recommended for secondary stroke prevention. However, little is known about the efficacy of smoking cessation intervention after stroke or transient ischemic attack (TIA).

Methods: Ninety-four smokers under age 76, admitted with ischemic stroke or TIA were randomized to minimal smoking cessation intervention or intensive smoking cessation intervention. All patients attended a 30-min individual counseling by the study nurse. Patients randomized to intensive smoking cessation intervention also participated in a 5-session outpatient smoking cessation program by an authorized smoking cessation instructor, a 30-min outpatient visit after 6 weeks, and 5 telephone counseling sessions by the study nurse. Free samples of nicotine replacement therapy were offered as part of the intensive smoking cessation program. Smoking cessation rates at 6 months were determined by self-report and verified by measurement of exhaled carbon monoxide (CO). Fewer patients than expected were recruited, which renders this report a pilot study.

Results: The 6-month self-reported smoking cessation rate was 37.8% in the minimal intervention group and 42.9% in the intensive intervention group. Smoking cessation rates verified by exhaled CO levels in the minimal intervention group and the intensive intervention group were 28.9% and 32.7%, respectively. No difference was found between the two groups ($\chi^2 = 0.16$, $p = .69$).

Conclusions: Overall smoking cessation rates were moderate and comparable to the results from other studies. Intensive smoking cessation intervention was not superior to short smoking cessation intervention. Thus, other factors than intensity of smoking cessation intervention might influence the smoking cessation rates after stroke or TIA.

Introduction

Smoking is a well-recognized risk factor for first-ever stroke and ischemic heart disease. Persistent smoking after stroke is associated with a higher post-stroke mortality rate (Kammersgaard & Olsen 2006; Myint et al., 2006). Based on observational studies, it has been estimated that for every 43 patients who quit smoking after stroke or transient ischemic attack (TIA), one new stroke could be prevented annually (Hankey & Warlow, 1999). Smoking cessation is thus widely recommended for secondary stroke prevention.

Despite these recommendations, only a minority of smokers give up smoking after stroke. In a previous follow-up study, we found that 22% of current smokers gave up smoking within six months after first-ever stroke (Bak et al., 2002). Others have reported smoking cessation rates between 11% and 83% within three months to five years after stroke (Gall, Dewey, & Thrift, 2009; Ives, Heuschmann, Wolfe, & Redfern, 2008; Mouradian, Majumdar, Senthilselvan, Khan, & Shuaib, 2002; Ovbiagele et al., 2004; Redfern, McKevitt, Dundas, Rudd, & Wolfe, 2000; Sappok et al., 2001; Sienkiewicz-Jarosz, Zatorski, Baranowska, Ryglewicz, & Bienkowski, 2009)

Several factors including gender, post-stroke functional status, sociodemographic characteristics, extent of nicotine dependence, and depression have been associated with increased risk of persistent smoking after stroke (Bak et al., 2002; Ives et al., 2008; Redfern et al., 2000; Sienkiewicz-Jarosz et al., 2009). However, little is known about the efficacy of smoking cessation intervention after ischemic stroke or TIA.

We performed a randomized clinical trial to compare the efficacy of a minimal smoking cessation intervention and an intensive smoking cessation intervention among patients with acute ischemic stroke or TIA.

Subjects and Methods

Within the period February 2005 through October 2006, current daily smokers under age 76 admitted to the Department of Neurology, in University Hospital in Odense, with acute ischemic stroke or TIA were invited to participate in the study. Stroke and TIA were defined according to the World Health Organization criteria (Stroke-1989. Recommendations on stroke

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prevention, diagnosis, and therapy. Report of the WHO Task Force on Stroke and other Cerebrovascular Disorders, 1989). The total number of potential participants admitted within the study period was not registered.

Patients with severe stroke (e.g., continuously impaired consciousness, aphasia, or symptoms that would make it impossible to smoke), patients with severe concomitant disease that causes decreased life expectancy, and patients who were otherwise unable to participate in a smoking cessation program were excluded. The Scandinavian Stroke Scale (Multicenter trial of hemodilution in ischemic stroke—Background and study protocol. Scandinavian Stroke Study Group, 1985) was used to assess the stroke severity on admission. Information on previous stroke, previous myocardial infarction, alcohol consumption, and stroke severity on admission was retrieved from the medical records. All patients had a computed tomography scan on admission to establish the diagnosis.

Trained study nurses daily checked the records of patients admitted to the Department of Neurology. As soon as written informed consent was given, eligible patients were randomized to either a minimal or an intensive smoking cessation intervention. Patients were randomized using a computer-generated list of odd and even numbers. These numbers, representing minimal and intensive smoking cessation intervention, respectively, were used to create consecutive numbered sealed envelopes. After having obtained informed consent, the study nurse opened the randomization envelope and the patients were informed to which intervention they had been assigned.

The patients completed a short structured interview, including questions on smoking habits and marital status. Daily tobacco consumption was calculated by equating one cigarette to 1 g, one cheroot to 3 g, and one cigar to 5 g of tobacco. Patients were categorized as moderate smokers (1–14 g/day) or heavy smokers (more than 14 g/day). A weekly alcohol consumption of more than 21 drinks for men and 14 drinks for women was classified as high alcohol consumption. Whether participants lived with current smokers was registered at baseline. Information on length of hospital stay, depressive symptoms, and degree of nicotine addiction was not registered.

Intervention

All patients included in the study received a 30-min individual counseling by the study nurse. The study nurse advised the patient to quit smoking and handed out a booklet containing information on smoking cessation. Free nicotine replacement therapy, nicotine patch, was offered during the hospital stay on the patients' request and was ordered by a physician.

Patients in the minimal smoking cessation intervention group did not receive any further smoking cessation advice as part of the study.

Patients randomized to the intensive smoking cessation intervention were offered a five-session outpatient smoking cessation program after discharge. The smoking cessation course was given by an authorized smoking cessation instructor. Free samples of nicotine replacement therapy (gum, patches, tablets, or nasal spray) were offered as part of the program. Furthermore, the patients were invited to a 30-min outpatient visit after six weeks and five telephone counseling sessions by the study nurse at two days, one week, three weeks, three months, and four months, respectively, after discharge. At each session, patients completed a short structured interview on current smoking habits including daily consumption of cigarettes and use of nicotine replacement therapy. Persistent smokers were given repeated advised to stop smoking.

The initial sample size estimated for this study was 300 patients, 150 patients in each group. With an alpha value of .05 (90% power), we would be able to detect a difference of approximately 18%, with a cessation rate of 22% in the minimal intervention group versus 40% in the intensive intervention group. However, fewer patients than expected were recruited within the inclusion period, which renders this report a pilot study.

Follow-up

All patients in both groups were invited to a follow-up visit at six months after discharge. Smoking cessation rates at six months were determined by self-report and verified by measurement of exhaled carbon monoxide (CO). We used the Micro-Smokerlyzer (Bedfont Scientific) to measure the amount of exhaled CO. The equipment was used for this study only and calibrated according to the recommendations from the manufacture.

Patients were instructed to exhale completely, fully inhale, hold their breath, and then exhale slowly and fully into the equipment. The amount of exhaled CO was reported as parts per million (ppm). As in other studies, patients with 8 ppm or more CO were classified as current smokers (Christensen et al., 2004).

Patients lost to follow-up and patients who refused to participate in CO measurement at the final visit were considered persistent smokers. Thus, all randomized patients were included in the final analysis of smoking cessation rates. None of the patients died within the follow-up period.

The chi-square test and the odds ratio were used to compare the smoking cessation rates in the two groups.

Physicians were not involved in patient recruitment, smoking cessation intervention, or follow-up visits. The study was approved by the Ethics Committee of Southern Denmark and by the Danish Registry Board.

Results

A total of the 94 patients with stroke or TIA accepted to participate in the study. Of these patients, 45 (47.9%) were randomized to minimal smoking cessation intervention and 49 (52.1%) were randomized to intensive smoking cessation intervention. Baseline characteristics are presented in the Table 1.

Of the patients randomized to minimal smoking cessation intervention, 41 (91.1%) participated in the six-month follow-up visit. The four patients who left the study were considered current smokers. Seventeen patients of the initial 45 patients (37.8%) reported smoking cessation. Of the patients with self-reported smoking cessation, 13 patients accepted measurement of exhaled CO. All of these patients had a CO level of less than

Table 1 Baseline Characteristics

Characteristics	Minimal smoking cessation intervention (*n*=45)	Intensive smoking cessation intervention (*n*=49)
Age, years		
25–49	10 (22.2)	10 (20.4)
50–65	21 (46.7)	29 (59.2)
65 +	14 (31.1)	10 (20.4)
Female	22 (48.9)	17 (34.7)
SSS[a] on admission (mean)	51.6	54.4
High alcohol consumption[b]	2 (4.4)	5 (10.2)
Previous stroke	4 (8.9)	8 (16.3)
Previous myocardial infarction	3 (6.7)	1 (2.0)
Smoking on admission		
moderate (1–14 g/day)	14 (31.1)	9 (18.4)
heavy (> 14 g/day)	31 (68.9)	40 (81.6)
Years of smoking		
0–9	3 (6.7)	1 (2)
10–19	2 (4.4)	2 (4.1)
20 +	40 (88.9)	46 (93.9)
Partner who smokes daily	20 (44.4)	13 (26.5)
Living alone	14 (31.1)	10 (20.4)

Note. All values are *n*(%). [a]Scandinavian Stroke Scale.
[b](female >14 units per week, men > 21 units per week)

8 ppm. Four patients refused to participate in the CO measurement and were thus classified as persistent smokers. Eight patients (17.8%) used nicotine replacement therapy at some time during the six months and one reported smoking cessation.

Forty-three (87.8%) of the patients randomized to the intensive smoking cessation intervention program completed the study. One patient left the study within the first two days, one left after three months, one after four months, and three patients left before the six-month consultation. These patients are considered as current smokers. Among the patients who completed the study, the participation rate was 98.9% for the personal counseling sessions with the study nurse and 95.9% for the telephone consultations. Twenty-nine (67.4%) of the patients who completed the study used gum or nicotine patch at some time during the six months and 12 reported smoking cessation.

At the last visit, 21 of the initial 49 (42.8%) reported smoking cessation. Of these patients, 16 had a CO level of less than 8 ppm. Ten of those (62.5%) had used nicotine replacement therapy at some time during the six months. Eight of the 16 patients (50%), who had CO levels less than 8 ppm at the end of the follow-up period, reported smoking cessation two days after discharge from the hospital.

The smoking cessation rates verified by exhaled CO levels in the minimal intervention group and the intensive intervention group were thus 28.9% and 32.7%, respectively.

No difference was found between the two groups (χ^2 = 0.16, p = .69). The odds ratio of smoking cessation due to intensive smoking cessation intervention was 1.19 (95% *CI*, 0.45–3.17)

Discussion

In the present study, we randomized patients with stroke or TIA to either a minimal or an intensive smoking cessation intervention and found no difference in smoking cessation rates between the two groups at six-month follow-up. The major advantages of the present study were the randomized design, the standardized advice on smoking cessation, and the use of exhaled CO levels for validation of smoking status.

Previously, smoking cessation rates after stroke has been assessed in several non-interventional studies. In a study of 112 patients referred to a stroke prevention clinic after stroke or TIA, Mouradian et al. (2002) identified 38 smokers at baseline. During the clinical visit, all patients were informed about the importance of risk factor modification. The self-reported smoking cessation rate at one-year follow-up was 11%.

In a population-based stroke register, 363 current smokers before first-ever stroke were still alive at three-year follow-up. Forty-seven percent reported smoking cessation within the first three months and 48% reported smoking cessation at three years, but the pattern of smoking cessation and relapses was complex (Ives et al., 2008).

Johnson, Rosewell, and James (2007) studied 98 patients undergoing carotid endarterectomy and 198 patients referred to at rapid access stroke clinic for TIA or nondisabling stroke. Advice on risk factor modification was a part of the usual treatment. The self-reported smoking cessation rate at six months was 22%.

In a follow-up study using a population-based stroke incidence study, Gall et al. (2009) traced 51 stroke survivors who were current smokers at stroke onset. In all, 19 patients (37%) had stopped smoking at five years after stroke. Among the persistent smokers, 40% could not recall receiving any advice about smoking cessation.

Recently, Sienkiewicz-Jarosz et al. (2009) reported the results of a prospective three-month follow-up study of 98 current smokers with first-ever stroke. Self-reported smoking cessation in 37 patients (38%) was confirmed by measuring levels of exhaled CO.

In a prospective study specifically aimed at improving secondary prevention after stroke and TIA, Ovbiagele et al. (2004) found a self-reported smoking cessation rate of 83% among 24 patients followed up for three months. During the admission, the patients received advice on secondary prevention, including smoking cessation, diet, exercise, and personal stroke risk factors. Two telephone interviews after discharge was a part of the prevention program. Compared with the smoking cessation rates in the non-interventional follow-up studies, this study indicates that a focused smoking cessation intervention might be of major importance in lifestyle modification after stroke.

Our study has several potential limitations. The primary limitation was the relatively small sample size, which made it impossible to demonstrate small or moderate differences between the two groups. The necessary sample size was prior to this study calculated to be 150 patients in each group.

Patients admitted to Department of Neurology with stroke or TIA were asked to participate in this study. They received information about their role in the study and the motivation of the study. Only 94 patients agreed to participate, which was significantly fewer than expected. Lack of motivation to stop smoking and the disadvantage in having to participate in outpatient meetings were common causes of nonparticipation.

In spite of the limited sample size, the study had sufficient power to demonstrate a large effect of a smoking cessation intervention as might be indicated by the study by Ovbiagele et al. (2004), However, the possibility of a type 2 error cannot be excluded.

The patients included in the present study were mainly young and suffered a TIA or minor stroke. Therefore, the results cannot be generalized to the entire stroke population. However, the patients studied represent the main target group for lifestyle modification as part of secondary stroke prevention.

Information on patients who refused to participate in the study was not recorded. Therefore, a potential selection bias either toward inclusion of patients with a higher motivation for smoking cessation or patients resistant to smoking cessation might have been introduced. Furthermore, the intervention in the minimal smoking cessation intervention group might have been effective and thus reduced the apparent effect of the intervention in the intensive intervention group. However, the moderate smoking cessation rates at six months were comparable to the results of previous follow-up studies including a follow-up study from the same catchment area (Bak et al., 2002)

Six months is a relative short period of follow-up, and we cannot rule out that major differences between the two groups might appear in the long term. However, the results of previous studies indicate that most quitters seem to stop smoking within the first few months after stroke (Gall et al., 2009; Redfern et al., 2000).

Persistent smoking after stroke might be due to ignorance of the hazards of smoking. However, in the present prospective study, all patients received oral as well as written information on the hazards of smoking. Furthermore, patients randomized to intensive smoking cessation intervention were repeatedly reminded on this information. Thus, ignorance is unlikely to explain the moderate smoking cessation rates in the present study.

In conclusion, the results of this randomized pilot study suggest that the intensity of a smoking cessation program is of minor importance in obtaining smoking abstinence after stroke or TIA. Thus, other factors than intensity of the smoking cessation intervention might influence the smoking cessation rates after stroke or TIA.

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Declaration of Interest

None declared.

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