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Long-term effect of a low-intensity smoking intervention embedded in an adherence program for patients with hypercholesterolemia: Randomized controlled trial

Rebecca Muckelbauer [a,*], Heike Englert [b], Nina Rieckmann [a], Chih-Mei Chen [c], Karl Wegscheider [d], Heinz Völler [e], Hugo A. Katus [f], Stefan N. Willich [c], Jacqueline Müller-Nordhorn [a]

[a] Berlin School of Public Health, Charité — Universitätsmedizin Berlin, 13347 Berlin, Germany
[b] University of Applied Sciences, Oecotrophology, 48149 Münster, Germany
[c] Institute for Social Medicine, Epidemiology and Health Economics, Charité — Universitätsmedizin Berlin, 10117 Berlin, Germany
[d] Department of Medical Biometry and Epidemiology, University of Hamburg, 20246 Hamburg, Germany
[e] Center of Rehabilitation Research, University of Potsdam, 14469 Potsdam, Germany
[f] Department of Cardiology, Angiology, and Pulmology, University of Heidelberg, 69120 Heidelberg, Germany

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ABSTRACT

Objective. We evaluated the long-term effect of a smoking intervention embedded in an adherence program in patients with an increased risk for cardiovascular disease.

Method. Secondary analysis of a randomized controlled trial: In 2002–2004, 8108 patients with hypercholesterolemia were enrolled from general practices in Germany. Patients received a 12-month adherence program and statin medication (intervention) or statin medication only (control). The program aimed to improve adherence to medication and lifestyle by educational material, mailings, and phone calls. Smoking was self-reported at baseline and every 6 months during the 3-year follow-up.

Results. In total, 7640 patients were analyzed. At baseline, smoking prevalence was 21.7% in the intervention and 21.5% in the control group. Prevalence decreased in both groups to 16.6% vs. 19.5%, 15.3% vs. 16.8%, and 14.2% vs. 15.6% at the 12-, 24-, and 36-month follow-up. The intervention had a beneficial effect on smoking differing over time (group × time: $P = 0.005$). The effect was largest after 6 and 12 months [odds ratios (95% confidence intervals): 0.67 (0.54–0.82) and 0.63 (0.51–0.78)]. The effect decreased until the 18-month follow-up [0.72 (0.58–0.90)] and was not significant after 24 months.

Conclusion. A low-intensity smoking intervention embedded in an adherence program can contribute to smoking cessation although the intervention effect diminished over time.

Trial Registration: ClinicalTrials.gov (www.clinicaltrials.gov): NCT00379249.

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Introduction

Smoking remains a major risk factor for cardiovascular events and preventable cause of premature mortality (Glantz and Gonzalez, 2012; Ezzati and Lopez, 2003; Yusuf et al., 2004). In the year 2000, cardiovascular disease was the leading cause of death from smoking (Ezzati and Lopez, 2003); and worldwide 11% of cardiovascular deaths in adults were attributable to smoking (Ezzati et al., 2005). The reduction of smoking is important in both the primary and secondary preventions of cardiovascular disease (Perk et al., 2012; Pearson et al., 2002; Montalescot et al., 2013). In patients, for example, who already had a coronary heart disease, smoking cessation reduced mortality risk by 36% compared with those who continued smoking (Critchley and Capewell, 2003).

Numerous interventions for smoking cessation have shown to be effective (Lemmens et al., 2008; Hartmann-Boyce et al., 2013). The most effective non-pharmaceutical interventions include group behavioral therapies and physician advice while other interventions such as telephone and individual behavioral counseling were slightly less effective (Lemmens et al., 2008).

Interventions for smoking cessation can be implemented as a standalone intervention or as part of a multiple lifestyle intervention. For the prevention of cardiovascular disease, clinical guidelines recommend the

Abbreviations: CI, confidence interval; GEE, generalized estimating equations; OR, odds ratio; ORBITAL, Open Label Primary Care Study: Rosuvastatin Based Compliance Initiatives to Achievements of LDL Goals; SD, standard deviation.

* Corresponding author at: Berlin School of Public Health, Charité — Universitätsmedizin Berlin, Seestr. 73, 13347 Berlin, Germany. Fax: +49 30 450 570972.
E-mail addresses: rebecca.muckelbauer@charite.de (R. Muckelbauer), englert@fh-muenster.de (H. Englert), nina.rieckmann@charite.de (N. Rieckmann), chih-mei.hettler-chen@charite.de (C.-M. Chen), karl.wegscheider@t-online.de (K. Wegscheider), heinz.Voeller@uni-potsdam.de (H. Völler), hugo.Katus@med.uni-heidelberg.de (H.A. Katus), stefan.willich@charite.de (S.N. Willich), jacqueline.mueller-nordhorn@charite.de (J. Müller-Nordhorn).

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modification of several lifestyle factors including smoking, diet, alcohol consumption, and physical activity (Perk et al., 2012; Montalescot et al., 2013). Thus, smoking cessation is often one factor targeted in programs on reducing overall cardiovascular risk (Lager Kate et al., 2014). These multiple lifestyle or risk factor interventions target at least two factors and are often implemented in high-risk patients with several risk factors. A recent systematic review showed that multiple risk factor interventions could reduce coronary heart disease mortality or events in high-risk patients. The review indicated that the interventions improved smoking behavior (Ebrahim et al., 2011), but only one study evaluated the intervention effect in the long-term beyond the end of the intervention phase (Ellingsen et al., 2005). In this review as well as in other reviews evaluating interventions for smoking cessation, the majority of the included studies assessed smoking during a follow-up period of 12 months or less (Stead et al., 2013; Lancaster and Stead, 2005). Thus, the evidence of the long-term success of interventions was limited.

The ORBITAL (Open Label Primary Care Study: Rosuvastatin Based Compliance Initiatives to Achievements of LDL Goals) study included a low-intensity smoking intervention in an adherence to medication and lifestyle program for patients with a high risk for cardiovascular events. In a secondary analysis, we investigated whether the program reduced smoking prevalence during the 1-year intervention period and whether the effect was maintained in the subsequent 2-year observational period. We also investigated the effect of the program on the number of cigarettes consumed per day in patients who smoked.

Methods

Study design and population

We performed a secondary analysis of the ORBITAL study evaluating the effect of an adherence program on smoking prevalence within 36 months. Methods of the ORBITAL study were previously described in detail (Willich et al., 2004, 2009). The study was a two-arm, open-label randomized controlled trial, registered at www.clinicaltrials.gov (identifier: NCT00379249). The primary study aim was to investigate the cost-effectiveness of the program (Willich et al., 2004). Participants with hypercholesterolemia and an increased risk (10-year coronary heart disease risk ≥20% defined according the European recommendations (1998) (Anon, 1998) and/or diabetes) or with an already existing cardiovascular disease were recruited by general practitioners in 1961 primary care practices in Germany between 2002 and 2004. They were randomized to receive a statin therapy alone (control group) or together with a 12-month adherence program (intervention group). The ethics committee of the Charité — Universitätsmedizin Berlin approved the study protocol.

Study groups

Participants of both the intervention and control groups received a statin medication. At baseline, the treating general practitioner provided information on each patient's risk factors and their overall risk according to the European recommendations for the prevention of coronary heart disease (Anon, 1998).

Intervention group

Participants in the intervention group received an adherence to medication and lifestyle program in addition to statin medication (Willich et al., 2004, 2009). The program aimed at increasing patients' adherence to the statin medication as well as at improving lifestyle factors including diet, physical activity, body weight status, and smoking. The program included educational material and reminders by phone calls and letters. At baseline, participants received a starter pack (brochure, video tape, webpage, and phone helpline) by mail informing about hypercholesterolemia, cardiovascular risk factors, and the targeted lifestyle factors. As follow-up interventions during the 12-month intervention period, participants received nine standardized letters and six phone calls. The phone calls were delivered by trained study staff consisting of health care professionals who received a standardized 7-day training course. The course included information about hypercholesterolemia as well as training in telephone calling and psychologically reinforcing patient adherence. The quality of the phone calls was regularly controlled and if necessary, staff members were retrained (Willich et al., 2004, 2009).

The intervention measures addressing smoking were embedded in the adherence program through the brochure, the video tape, two standardized letters and one phone call. The measures are described in Box 1. They informed about smoking as a risk factor, promoted smoking cessation, and provided advice for successful smoking cessation, for example, by searching for courses or books as well as by seeking advice from successful quitters.

Control group

Participants of the control group received a statin medication without the adherence program. Encouragement of smoking cessation in the control group was part of the usual care provided by the general practitioners but was not standardized in the study protocol (Anon, 1998).

Outcome measures

At baseline, participants completed a standardized self-administered questionnaire including socio-demographic variables, medical history, and smoking. The follow-up data were collected from the participants via mailed questionnaires every 6 months up to 36 months.

Participants were asked in the questionnaires: Do you currently smoke (yes or no)? From this answer the binary outcome variable smoking (yes vs. no) was built. Smokers were asked: How many cigarettes do you smoke on average per day? They were classified into four categories of cigarette consumption (≤10, 11 to 20, 21 to 30, and >30 cigarettes per day) (Heatherton et al., 1991). Non-smokers were asked: If you smoked in the past, when did you quit (month and year)? Participants were classified at baseline into current smokers, former smokers, and never smokers. The educational level was categorized according to the number of school years representing different levels of graduation (≤9, 10, and >10 years). Participants were categorized by their employment status according to whether they were currently employed or not. We categorized participants into quartiles by their reported usual alcohol consumption (no or rare consumption, 1 to 3, 4 to 8, and >8 servings per week). Body weight and height were assessed by the general practitioners at a baseline examination. We calculated the body mass index [BMI: body weight/height^2 (kg/m^2)] and categorized it according to the World Health Organization classification (World Health Organization, 2000). A patient was defined as having a history of cardiovascular disease with any of these four events: myocardial infarction, stroke, coronary artery bypass graft, or percutaneous coronary intervention.

Statistical analysis

For the present analysis, we included all participants of the ORBITAL study with available patients' questionnaires at baseline, irrespective of the implementation of the intervention. We analyzed participants in the group in which they were randomized. All statistical analyses were performed with SAS 9.4. A P value < 0.05 was considered statistically significant.

Descriptive analyses of baseline characteristics were performed for the total study population and separately for the two study groups. We compared the baseline characteristics between the two groups by chi-square test for categorical variables and by t-test for continuous variables. The percentage of smokers during the study period was based on available smoking data at each time point. The Cochran–Armitage test analyzed the trend over time of smoking in the total population and each study group. The intervention effect on smoking (yes vs. no) over the 36-month follow-up period was estimated by using a generalized estimating equations (GEE) model with a logit link and an exchangeable correlation structure to consider within-subject correlation due to repeated measurement (PROC GENMOD in SAS). The GEE model was chosen because it retains also participants with incomplete follow-up data in the analysis provided that data at baseline and at one or more follow-up time points was available. The independent variables were time as a categorical variable (with follow-up time points 1 to 6), study group (intervention vs. control), and baseline smoking category. The interaction term group × time was introduced into the model and kept if the term was significant. We investigated if baseline characteristics listed in Table 1 qualified as potential confounders by testing for an association with study group or with smoking at any time point (by chi-square test or t-test). Because sex was the only variable identified as a potential confounder, all models were adjusted for sex. To test if the intervention effect on smoking was modified by sex, history of cardiovascular disease, or educational level, we added interaction terms into the model.

In a sensitivity analysis, we investigated if the intervention effect could be biased through participants' drop out or missing data during follow-up. Thus,

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