Paper III



ORIGINAL ARTICLE

Does smoking cessation improve Quality of Life in patients with coronary heart disease?

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Abstract

Objective. To evaluate whether smoking cessation after a coronary event improves quality of life, and to assess whether quality of life is a predictor of smoking cessation. Design. Health-related quality of life at baseline and at 12 months follow up were measured in a randomised smoking cessation trial of 240 smokers aged under 76 years admitted for myocardial infarction, unstable angina or coronary bypass surgery. At 12 months follow up 101 had managed to give up smoking (quitters), and 117 were smokers (sustained smokers). Results. The quitters and sustained smokers had similar improvements in all quality of life domains from baseline to 12 months follow up. Further, after adjustment for differences in baseline characteristics, the quality of life was not significantly different in the quitters compared to the sustained smokers neither at baseline nor at 12 months follow up. Conclusions. Smoking cessation did not improve quality of life compared to sustained smoking after a coronary event in a 12 month follow up. Quality of life was not a significant predictor of smoking cessation.

Key words: Quality of life, smoking cessation, coronary heart disease, myocardial infarction

Approvals

The study was approved by the regional ethics committee. All patients gave written informed consent.

Quitting smoking after a coronary event reduces the 3-5 years mortality with 35-50% (1), and this reduction increases further with several years of follow up (2). Despite this, only 30 - 40% stop smoking spontaneously (3,4). Randomised trials have shown that smoking cessation rates after myocardial infarction can be significantly increased if applying a smoking cessation program with several months of intervention (3,4). Such programs have also been shown to be very cost-effective in terms of years of life saved (5). However, improvement in quality of life (QoL) may be equally important (6). To our knowledge, there is only one previous investigation on this topic, and this showed that patients who managed to give up smoking after percutaneous coronary intervention improved their health-related QoL to a greater extent than sustained smokers (7). This study included patients without motivation to stop smoking. Therefore, adequate adjustments for confounders may have been difficult to perform. Thus, whether smoking cessation in patients with coronary heart disease has impact on QoL is largely unknown. We addressed this question in patients included in a randomised controlled trial of smoking cessation intervention after admission for coronary heart disease.

Methods

Patients

Patients who were daily smokers, motivated to quit smoking, under 76 years of age and admitted for acute myocardial infarction (n=176), unstable angina (n=36) or recent coronary bypass (n=28), were included in the trial from February 1999 to September 2001. After providing written informed consent and answering baseline questionnaires, the patients were randomly allocated to usual care

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(control group) or intervention. The intervention was a smoking cessation program initiated in the hospital and delivered by cardiac nurses. It was based on a booklet produced for the study, and focused on fear arousal and prevention of relapse. The patients were contacted regularly for several months after discharge. The control group received usual care which included firm and unequivocal advice to stop smoking, but no further instructions on how to stop smoking. Details regarding recruitment methods and the intervention program have been explained elsewhere (4).

Measures

Sociodemographic features, smoking habits and medical history were prospectively recorded. At 12 months follow up patients who stated they were still smoking were classified as sustained smokers and those who claimed they had quit and had a low nicotine metabolite concentration in urine, were classified as quitters. Those who claimed to have quit, but had a nicotine metabolite concentration above a cut off value consistent with smoking, were classified as sustained smokers.

QoL were assessed before randomisation and at 12 months follow up. The questionnaire used in the Cardiac Arrhythmia Suppression Trial (CAST) was employed (8). This questionnaire contains a battery of established scales and items (9-11), to produce a specific health-related QoL instrument for patients with coronary heart disease. Six OoL dimensions were derived from 24 questions addressing topics like Social function, Physical function, Symptoms, Mental health, Life satisfaction and Life expectancy. "Social function" is based on two main questions measuring to what extent, during the last month, the patients' health has limited his or her social activity, and the level of satisfaction the patient feels regarding his or her social life during the last month. "Physical function" comprises one main question and five sub questions, measuring for how long the patient's ability to perform various tasks such as walking, running, carrying bags and climbing stairs has been limited. How often the patient experienced nine physical adverse symptoms (i.e. tiredness, dizziness, chest pain and dyspnoea) during the last month comprises the "Symptoms" item. The "Mental health" domain quantifies the mood, calmness and happiness (five sub questions) the last month. "Life satisfaction" quantifies, with a 10 step "ladder of life", how satisfied the patient is with his or her life at present time. Similarly, "Life expectancy" is the patient's estimated life satisfaction five years in the future compared to the present. For all questions, a low score corresponds to a better QoL.

The covariate questions covering social support, social integration and life events, were not included.

Statistical methods

Continuous baseline characteristics were compared using the independent samples t-test and Mann Whitney U-test for normally and nonnormally distributed data, respectively. Categorical baseline characteristics were compared using χ^2 tests. When analysing QoL improvements within groups, paired samples t-test and Wilcoxon test for two related samples were used for normally and non-normally distributed data, respectively. All tests were twotailed, with significance level of 0.05 and 95% confidence interval. To be able to adjust for differences in baseline characteristics, the OoL scores in non-randomised groups (i.e. quitters versus sustained smokers) were compared using multivariate linear regression analysis. Multivariate logistic regression models were used to test the relations between smoking cessation at 12 months follow up and QoL scores at baseline. In these models, we adjusted for variables being significantly associated with smoking cessation in univariate analysis (12). Only patients available at 12 months follow up, with cotinine-validated smoking status, were included in the analyses. When calculating the Total QoL score, single missing answers among 21 sub questions were replaced by case-means in the same answer category. If more than two missing answers, cases were excluded from the analysis. When assessing the six QoL domains separately, only cases with no missing values were included in the analyses. Since the QoL questionnaire uses various scales (ranging from 1-3to 1 - 10), all main questions were transformed to give scores from 0 - 10 when computing the Total QoL score (13). We used SPSS for Windows (version 12.0) for all analyses.

Results

The flow of patients through trial, patient characteristics, and smoking cessation rates have been published previously (4). Two hundred and forty patients were assigned either the intervention (n=118) or usual care group (n=122); control group). One hundred patients in the intervention group and 118 patients in the control group were available at 12 months follow up, giving a total drop out rate of 9%. Forty six percent (101/218) were abstainers at 12 months follow up (37% (44/118)) in the control group and 57% (57/100) in the intervention group).

Most patients answered all questions in the QoL questionnaire. The Symptoms item had the most missing values, and could be analysed in 89%

(195/218) and 90% (197/218) of patients at baseline and at 12 months follow up, respectively. The Total QoL score were computed in 90% (196/218) and 94% (204/218) of patients at baseline and 12 months follow up, respectively.

Intervention versus control group

Baseline characteristics were similar in the intervention and control group (4). The intervention and control groups also had similar OoL scores in all dimensions, both at baseline (Total QoL score 27.9 (SD 10.8) and 27.6 (SD 10.4), respectively) and at 12 months follow up (Total QoL score 24.6 (SD 10.4) and (24.8 (SD 10.0), respectively).

Sustained smokers versus quitters

The only baseline characteristics that differed significantly between the sustained smokers and the quitters were the number of patients with previous coronary heart disease, the number of patients with myocardial infarction as reason for admission, and the number of patients having employment (Table I). These three parameters were also significantly associated with better OoL scores both at baseline and at 12 months follow up in univariate analysis, and were thereby important confounders in the QoL assessments. Thus, when comparing the various QoL dimensions between sustained smokers and quitters, adjustments for these three variables were performed. The other baseline characteristics shown in Table I were not significantly different in the two groups, and including these variables in the regression analyses did not alter the results.

The percentages with assessable Total QoL scores at baseline and at 12 months follow up were not significantly different in the quitters compared to the sustained smokers (91% v 89% and 93% v 94%, respectively).

No significant differences in QoL scores could be demonstrated between quitters and sustained smokers, neither at baseline nor at 12 months follow up

(Table II). The quitters had statistically significant improvements only in Life satisfaction from baseline to 12 months follow up (Figure 1). Similarly, the sustained smokers improved with statistical significance Social function, Life satisfaction and Total QoL (Figure 1). The improvements in the various QoL dimensions were not significantly different between the quitters and the sustained smokers, neither before nor after adjustments for baseline characteristics (Figure 1).

In subgroup analyses, assessing patients with myocardial infarction, unstable angina, and coronary bypass surgery separately, the results were similar to the pooled analyses, with no statistically significant differences in OoL scores between the quitters and the sustained smokers neither at baseline nor at 12 months follow up. Further, in all three subgroups the improvements in the various QoL dimensions, including the Total QoL score, from baseline to 12 months follow up were not significantly different in the quitters compared to the sustained smokers.

Baseline QoL versus smoking cessation

In a multivariate logistic regression analysis, the Total QoL score at baseline was not a significant predictor of smoking cessation at 12 months. In this analysis, adjustment for all significant predictors of smoking cessation were performed (12); being employed, absence versus occurrence of previous coronary heart disease, having myocardial infarction as reason for admission, number of days spent in the intensive care unit, the level of self-efficacy in quitting, and the level of nicotine addiction.

Discussion

In this prospective observational study, we have shown that patients who managed to quit smoking after a coronary event did not improve their healthrelated QoL to a greater extent than the sustained smokers. Further, the QoL at baseline was not a significant predictor of smoking cessation.

Table I. Baseline characteristics of quitters versus sustained smokers at 12 months follow up. Values are numbers (percentages) if not stated otherwise.

Characteristic	Quitters at 12 months (n = 101)	Sustained smokers at 12 months (n = 117)	p value	
Mean age (SD)	56 (9)	57 (9)	0.74	
Men	85 (84)	88 (75)	0.48	
Married or living with partner	77 (76)	92 (79)	0.67	
Employed	63 (62)	50 (43)	0.004	
No education after primary school	28 (28)	40 (34)	0.30	
Previous coronary heart disease	14 (14)	45 (39)	< 0.001	
Myocardial infarction as reason for admission	85 (84)	73 (62)	< 0.001	
Mean years of smoking (SD)	36 (15)	38 (10)	0.28	
Mean number of cigarettes a day (SD)	14 (6)	16 (7)	0.42	

Table II. Mean quality of life scores (SD) at baseline and at 12 months follow up in patients who were quitters at 12 months (n = 101) compared to patients who were sustained smokers at 12 months (n = 117). A low score corresponds to a better quality of life. All p values are adjusted for differences in baseline characteristics between groups.

	Baseline			12 months		
	Quitters	Sustained smokers	p value	Quitters	Sustained smokers	p value
Social function	3.7 (2.2)	4.6 (2.7)	0.6	3.5 (2.1)	3.8 (2.1)	0.6
Physical function	3.4 (1.9)	4.1 (2.0)	0.9	3.6 (2.2)	3.8 (1.9)	0.9
Symptoms	11.9 (10.0)	15.6 (10.7)	0.5	10.8 (9.8)	12.8 (9.1	0.5
Mental health	9.8 (1.9)	10.2 (2.0)	0.5	9.6 (1.9)	10.0 (2.3)	0.5
Life satisfaction	4.9 (2.0)	4.7 (2.2)	0.6	3.7 (1.9)	3.9 (1.9)	0.5
Life expectancy	-2.1(2.3)	-1.7(2.4)	0.9	-0.8(1.7)	-0.7(1.9)	0.9
Total QOL score	25.5 (9.8)	29.7 (10.8)	0.3	23.5 (10.3)	25.8 (10.0)	0.5

We believe lack of statistical power was not the reason for the absence of an effect on QoL from quitting smoking. First, our study was large enough to detect a 10% difference in OoL improvement between the quitters and the sustained smokers (i.e. a 13% v a 3% improvement) with a power of 80% and a significance level of 5%. A lower difference may not be of clinical significance. Second, the CAST QoL questionnaire was designed to be especially sensitive to clinical changes in patients with coronary heart disease (11,14,15). It has been shown to be reliable, with internal consistency \geq 70% (Cronbach's $\alpha \geq$ 0.70) for symptoms, mental health and physical function (11). This was confirmed in our trial, with Cronbach's α being over 0.70 for all items. The questionnaire has also been

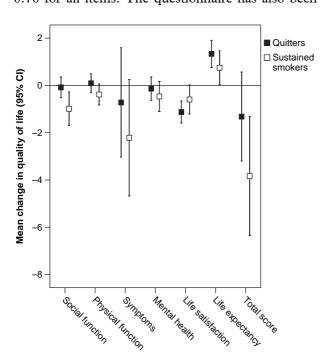


Figure 1. Mean changes (95% CI) in quality of life from baseline to 12 months follow up in quitters (n=101) compared to sustained smokers (n=117) at 12 months. A negative value denotes improvement in quality of life.

reported to be both clinically valid, with acceptable discriminative validity for symptoms, mental health, and physical and social functioning (11), and sensitive to changes over time (responsive) in all QoL domains (14). In an editorial comment the questionnaire was advocated for assessment of healthrelated QoL in patients with coronary heart disease (15). In our trial, the subgroup with coronary bypass surgery had significantly worse quality of life at baseline than the subgroup with myocardial infarction or unstable angina (p < 0.001). Further, among the group with bypass surgery the Total QoL improved significantly from baseline to 12 months follow up (p < 0.001). These findings probably reflect that patients with coronary bypass surgery had angina symptoms impairing QoL during the last month before admission, and indicates that the QoL questionnaire is sensitive to clinically important changes in patients with coronary heart disease. Therefore, we believe our trial should be able to uncover clinically important differences in OoL between quitters and sustained smokers.

Using an established generic QoL questionnaire would have increased the possibility to compare our findings with others, but these instruments are designed for a wide variety of conditions, and are often less responsive to changes in health-related QoL (16).

Several investigations have shown that patients with coronary heart disease who smoke have inferior QoL compared to non-smokers (17,18), but only a few studies have analysed whether smoking cessation has impact on QoL. Two studies in the general population have obtained mixed results regarding this issue (19,20). In patients with coronary heart disease, our results contradict the findings by Taira et al. (7), who found that smoking cessation was associated with greater improvement in QoL compared to sustained smoking in patients after percutaneous coronary revascularisation. In this investigation QoL were not assessed within a randomised smoking cessation trial, and patients without

motivation to stop smoking were included in the analyses. The sustained smokers may therefore have been a negatively selected group of patients with low potential for QoL improvements. It is both unethical and impossible to randomise patients to either smoking cessation or continued smoking. Many factors, such as personality, depression, anxiety and emotional feelings, may influence on whether patients stop smoking or not. It may not be possible to adjust for all these factors in an observational study, and whether the measured change in QoL after smoking cessation is due to smoking cessation itself or unmeasured confounders is difficult to evaluate. Our study was also an observational study, but it was performed within a randomised smoking cessation trial, and included only patients motivated to quit smoking. Maybe our trial design and selection of covariates were successful in adjusting for most of the confounders, and thereby was negative regarding QoL improvements among the quitters compared to the sustained smokers. However, it is also possible that including more covariates in the analysis, such as cardiovascular risk factors like diabetes and hypertension, would have altered the results.

There could be several reasons why there were no differences in QoL improvements among quitters and sustained smokers. Smokers with an acute coronary event tend to be younger and have fewer concomitant cardiac risk factors than non-smokers (21). Therefore, they may have more favourable initial prognosis than non-smokers ("smokers' paradox") (21). Hence, significant improvements in medical symptoms among quitters may take several years to develop. Thus, increased health-related QoL improvements among the abstainers may become evident after a longer follow up period. Another explanation could be that the expected improvement in physical health among quitters is outweighed by an increase in well being among the sustained smokers due to the neuronal effects of nicotine. Further, smoking could be regarded as a social positive behaviour. Indeed, in our investigation the improvement in Social function among the sustained smokers was greater than in the other QoL domains.

To our knowledge, we are the first to investigate whether QoL at the time of an acute coronary event is a predictor of smoking cessation. Our smoking cessation program focused on fear arousal message. In order to live longer one could expect that patients who were the most satisfied with his or her life also were the most likely to quit. Surprisingly, this was not the case in our trial, possibly because other factors such as the level of nicotine addiction and the level of self-efficacy in quitting, is more important (12).

Smoking cessation after a coronary event is the most effective single action to improve prognosis. Often, an agent that improves prognosis also has positive impact on QoL (22,23). Our results indicate that this is not the case regarding smoking cessation in patients motivated to stop smoking. Further studies are needed before we can conclude whether smoking cessation has impact on QoL in patients with coronary heart disease.

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