Less is more

*In lifestyle-related risk factor management in secondary prevention of coronary artery disease*

Minneboo, M.

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CHAPTER 1

Introduction and outline of the thesis
INTRODUCTION

Cardiovascular diseases (CVD), including coronary heart disease, cerebrovascular disease, and peripheral artery disease, are a major worldwide health problem. An estimated 17.7 million people died from CVD in 2015, representing 31% of all global deaths. Of these deaths, an estimated 7.4 million were due to coronary heart disease and 6.7 million were due to stroke. The World Health Organization predicts that both mortality and the total burden of CVD will increase in the future, given the global rise in unhealthy lifestyles. CVD is largely preventable. It has been estimated that the burden at the population level may be reduced by as much as 80% if all modifiable risk factors were adequately addressed. Preventive strategies are classified by the World Health Organization into three categories: primary, secondary and tertiary prevention. Primary prevention includes management of risk factors in people who have not yet developed clinically manifest cardiovascular disease. Secondary prevention includes risk factor management in patients with established CVD. This thesis addresses issues related to the secondary prevention of CVD, in particular in patients who have suffered from a complication of coronary artery disease (CAD).

Secondary prevention of CVD

Patients with established CVD have a high risk of recurrent cardiovascular events, including myocardial infarction, stroke, and death. As outlined in the European Society of Cardiology (ESC) and American Heart Association (AHA) secondary prevention guidelines, all patients with established CVD should receive interventions to prevent recurrent CVD events. Table 1 lists the secondary prevention targets in patient with established CVD, as recommended by ESC.

Secondary prevention has proven benefits and it can improve outcomes within months after initiation of treatments. Two main strategies can be defined in secondary prevention: prescribing medication and changing unhealthy lifestyles. Drug interventions reduce mortality in CAD patients, with a potential cumulative relative risk reduction of 75% if all of the following four drug categories are prescribed: aspirin, beta-blockers, statins, and ACE inhibitors.

Changing an unhealthy lifestyle includes increasing physical activity, dietary modification, weight loss, and smoking cessation. The effect of smoking cessation is convincingly shown in a meta-analysis among 12,603 smokers with established CVD, with a follow-up of at least 2 years. The relative risk of mortality for quitters compared with those who continued to smoke was 0.64 (95% CI 0.58-0.71). A systematic review found that in CAD patients the effects of lifestyle interventions on all-cause mortality vary from 35% for smoking cessation, to 25% for increased physical activity, and to 20% for moderation of alcohol consumption. The potential benefits of successfully changing adverse
lifestyles are therefore substantial. In line with this, guidelines emphasize the importance of these preventive strategies and stimulate implementation of both lifestyle and pharmacological interventions.

**Cardiac rehabilitation**

Cardiac rehabilitation programs were developed to support physical and psychosocial recovery after a CAD event, and to improve secondary prevention.(7, 11, 12) These programs are comprehensive, medium-term services involving medical evaluation, supervised exercise, cardiac risk factor modification, education, and counselling. Several studies have found that cardiac rehabilitation improves risk factor control, exercise capacity, and medication adherence, and in the long term improves survival after percutaneous coronary intervention and coronary artery bypass graft surgery.(13, 14) While all components of cardiac rehabilitation programs are important for long-term benefit, the relative strengths of the components are not known.

**Implementation**

Many international surveys and registries have evaluated the implementation of guidelines in daily practice. In the REACH registry (recruitment 2003-2004), risk factor control varied widely in patients admitted for CABG and only 60% of the European patients with stable atherothrombotic disease had a good control of the major cardiovascular risk factors.(15, 16) The EUROASPIRE IV (European Action on Secondary and Primary Preventions by Intervention to Reduce Events) survey (2012-2013) found that the majority of 7998 patients with established CVD (hospital arm) do not achieve the lifestyles, risk factor levels, and therapeutic goals as recommended in the 2012 ESC guideline.(17)

### Table 1. Risk factor goals and target levels for important cardiovascular risk factors

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Goals and target levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>No exposure to tobacco in any form</td>
</tr>
<tr>
<td>Food habits</td>
<td>Low in saturated fat with a focus on wholegrain products, vegetables, fruit and fish.</td>
</tr>
<tr>
<td>Physical activity</td>
<td>At least 150 minutes a week of moderate aerobic PA (30 minutes for 5 days/week) or 75 minutes a week of vigorous aerobic PA (15 minutes for 5 days/week) or a combination thereof.</td>
</tr>
<tr>
<td>Body Weight</td>
<td>BMI 20–25 kg/m².</td>
</tr>
<tr>
<td></td>
<td>Waist circumference &lt;94 cm (men) or &lt;80 cm (women).</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>&lt;140/90 mmHg</td>
</tr>
<tr>
<td>Lipids: LDL-C is the primary target</td>
<td>&lt;1.8 mmol/L (&lt;70 mg/dL), or a reduction of at least 50% if the baseline is between 1.8 and 3.5 mmol/L (70 and 135 mg/dL)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>HbA1c &lt;7% (&lt;53 mmol/mol)</td>
</tr>
</tbody>
</table>

PA = Physical activity; BMI = body mass index; LDL-C = low-density lipoprotein cholesterol; HbA1c = glycated haemoglobin
Results from the EUROASPIRE II, III and IV surveys, (1999 -2013) even show that lifestyle risk factors have deteriorated over time, with increasing prevalences of obesity and central obesity. More patients have diabetes, and the number of persistent smokers does not further decrease. For risk factors influenced by medication, time trends are more encouraging. The prevalence of high blood pressure decreased and lipid management improved, although there is still room for improvement(18)

Changing unhealthy lifestyle habits to a healthier lifestyle is often difficult, even if patients are highly motivated. Successful implementation of a healthy lifestyle involves changes on a population level made by for example by the government, but also requires adequate knowledge and skills of several behaviour change models of care givers, for example nurses and cardiologists. These models for behaviour change highlight the complexity of making and preserving a healthy lifestyle in individual patients. The intentions of patients vary by a range of beliefs and influences for example; their past behaviour, their perceptions of what others think, beliefs about ability to change, self-control and timing.

Secondary prevention interventions to improve lifestyle

Several studies have been performed to improve secondary prevention on a national as well on an international level.(19-22) The EUROACTION trial, which randomly assigned 12 hospitals to deliver either a comprehensive risk factor intervention program or usual care (no cardiac rehabilitation) to over 1800 patients with established CHD, found that patients in the intervention group had significantly higher rates of smoking cessation and better blood pressure control after one-year follow up.(23) Significant improvements in multiple recommended dietary components were also seen in patients in the intervention groups, but there was no significant difference in other end points such as achievement of lipid or body mass index goals(23)(16). In the RESPONSE (Randomised Evaluation of Secondary Prevention Outpatient Nurse SpEcialists) trial, nurse coordinated care improved drug dependent risk factors including blood pressure and lipid profiles. However, with regard to lifestyle-related risk factors there was no significant difference between the intervention and control groups.(24) We hypothesized that hospital based secondary prevention may not be appropriate to change a patient’s daily routines. We therefore designed the RESPONSE 2 trial to evaluate the impact of a comprehensive community-based intervention on lifestyle-related risk factors in-patient with established CVD. The results are described in chapter 6 and 7.

Aim of this thesis

- To evaluate the current status of implementation of secondary prevention, measured as attainment of the goals set by the ESC and AHA guidelines, in a large Dutch con-
temporary cohort including different ethnic minorities and in a large Dutch cardiac rehabilitation population.

- To investigate a new approach to interventions for secondary prevention, predominantly lifestyle-related risk factors, in particular a comprehensive community-based lifestyle intervention, with focus on weight reduction.

OUTLINE OF THIS THESIS

In chapter 2 we evaluate the achieved targets for secondary prevention in the The HEalthy LIfe in an Urban Setting (HELIUS) cohort. HELIUS is a large, multi-ethnic, population-based cohort study in Amsterdam, the Netherlands. The HELIUS study aims to investigate ethnic inequalities in health, focusing on three major causes of disease: cardiovascular disease, mental health, and infectious diseases. In chapter 3, we repeat the concept of chapter 2 and evaluate the achieved targets for secondary prevention in the CArdiac Rehabilitation Decision Support System (CARDSS-II) trial. This was a multicentre, cluster randomised controlled trial conducted in 18 cardiac rehabilitation outpatient clinics in the Netherlands. In this secondary analysis, we focussed on lifestyle-related risk factors (smoking, overweight and physical inactivity) instead of all targets for secondary prevention.

With the knowledge from the initial chapters and with the aim to set up a new trial to improve secondary prevention outcomes, in chapter 4 we studied the effects of a nurse-coordinated prevention programme on health-related quality of life and depression in patients with an acute coronary syndrome included in the Randomized Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists (RESPONSE1 trial). In chapter 5 we describe the results of a pilot study in obese patients with CAD who were referred to a community-based weight reduction programme. In chapter 6 we describe the objectives, design and expected results of the RESPONSE 2 trial. This Dutch multicentre trial aimed to investigate the effect of nurse-coordinated referral to a comprehensive community-based intervention, on top of usual care, in patients with CAD and an unhealthy lifestyle. In chapter 7 we present the main findings of the RESPONSE 2 trial. In chapter 8 we investigate more specifically the influence of the weight reduction programme as part of the comprehensive lifestyle program, on weight change and define predictors of successful weight loss.
REFERENCES


