



# Health-related quality of life is poor but does not vary with cardiovascular disease burden among patients operated for severe atherosclerotic disease



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## ABSTRACT

**Background:** Patients with cardiovascular disease (CVD) are reported to have a poorer health-related quality of life (HRQoL) compared to healthy age- and gender-matched individuals. Moreover, HRQoL seems to predict survival in CVD populations. We studied HRQoL and the association with outcome during follow-up in a population undergoing surgery for peripheral artery disease or cerebrovascular large artery disease.

**Methods:** In the Athero-Express biobank cohort study patients filled in a questionnaire containing RAND-36. We stratified the cohort to compare HRQoL scores (range 0–100, higher scores representing better HRQoL) and assessed three-year event-free survival for composite cardiovascular endpoints of patients with good (above median) versus poor (equal to and below median) HRQoL at baseline. Additionally we compared the cohort to a healthy age-matched population.

**Results:** 2012 and 865 patients undergoing carotid endarterectomy (CEA) or endarterectomy of femoral/iliac arteries (FEA) were included respectively. The median HRQoL was 75 (IQR 0–100 (both patient groups)) for physical role limitations versus 0 (IQR 0–100 (CEA) and 0–66.7 (FEA)) for emotional role limitations. No differences in HRQoL subscores were found, CVD burden did not associate with HRQoL and three-year composite event rates did not associate with the reported HRQoL in both CEA and FEA. Both groups had poor HRQoL scores compared to an age-matched general population, especially regarding emotional role limitations and social functioning.

**Conclusions:** HRQoL is poor and does not associate with CVD burden within patients suffering from severe atherosclerotic disease. Reported HRQoL was not associated with incident cardiovascular events during follow-up.

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## 1. Background

Cardiovascular diseases (CVDs) are the world's leading cause of death [1]. The majority of CVDs are caused by atherosclerosis, a systemic inflammatory disease that manifests in different organs including the brain, heart, kidneys and legs. Disease burden of CVD is high as symptomatic atherosclerosis in these organs can be physically as well as mentally disabling. Physical functioning is for example affected by paralysis due to cerebrovascular ischemia, while depression is known to co-occur with cardiovascular diseases [2].

Scoring systems of health-related quality of life (HRQoL), such as RAND-36 (a questionnaire equivalent to SF-36) are developed to measure the subjectively perceived influence of disease on physical, social and emotional functioning [3,4]. Investigating HRQoL in various patient groups is clinically relevant as patients with poor HRQoL might benefit from referral to both occupational therapy for simple practical interventions and psychological support to learn to cope with their emotional and physical problems.

Patients with symptomatic atherosclerosis, such as peripheral arterial occlusive disease [5], carotid artery occlusive disease [6], coronary artery disease [7], abdominal aortic aneurysms [8] and stroke [9], as well as the known risk factors for atherosclerosis, e.g. hypertension [10], diabetes [11] and obesity [12], are reported to have a poorer HRQoL as measured by SF/RAND-36 when compared to healthy age and gender matched individuals even when they are free of symptoms [13]. Patients with risk factors but without overt CVD report declined

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physical HRQoL scores with almost no effect on mental subdomains of HRQoL. Individuals with diagnosed CVD report even lower scores on the physical subdomains with notably declined mental HRQoL scores as well, although social functioning remains largely unaffected. Moreover, compromised quality of life seems to be an independent predictor for survival in CVD populations [14–16].

The purpose of this study is to investigate whether HRQoL differs between people with different cardiovascular disease burdens in a cohort of patients suffering from severe atherosclerotic disease undergoing surgery for peripheral artery disease or cerebrovascular large artery disease. Furthermore cardiovascular event rates during follow-up are compared between groups with differentially reported HRQoL. Additionally we compared the cohort to a healthy age matched population.

We hypothesize that among patients with severe atherosclerotic disease, HRQoL varies depending on cardiovascular disease burden. A negative effect of poor HRQoL on cardiovascular event rates during follow-up is expected. We expect a HRQoL in the patients that is significantly worse than the general population.

## 2. Methods

### 2.1. Population

Since 2002 the Athero-Express biobank study is an ongoing cohort study that includes carotid and femoral endarterectomy patients from two large tertiary vascular referral hospitals in The Netherlands without any exclusion criteria. Upon surgery, atherosclerotic plaques are obtained for histological assessment. To date, over 3000 carotid and femoral endarterectomy patients have been included. In the three years of follow-up time, in which patients are asked to fill in a follow-up questionnaire after 1, 2, and 3 years, approximately 30% of patients reach an endpoint of cardiovascular origin. Study outline and protocol have been described in detail before [17]. Upon inclusion in the Athero-Express biobank study patients are asked to fill in a detailed questionnaire that contains 36 questions from RAND-36. All patients that were included up to September 2013 and completed the questionnaire were included in the present analysis.

### 2.2. Measurement of HRQoL

HRQoL was measured according to the validated Dutch version of RAND-36. Scores on all nine subdomains (physical functioning (PF), social functioning (SF), role limitations due to physical functioning (RP), role limitations due to emotional functioning (RE), mental health (MH), vitality (VT), bodily pain (BP), general health perception (GH) and health change (HC)) were computed to a scale from 0 to 100 with higher scores representing better HRQoL.

HRQoL measures in healthy controls were obtained from the Dutch RAND-36 manual [3]. The manual describes a validation study in a random sample of 1063 citizens of the Dutch municipality of Emmen in 1992. Among others they were stratified by age.

### 2.3. Measurement of cardiovascular disease burden

Cardiovascular disease burden was determined in several ways. Firstly, the symptomatology of the operated artery, e.g. indication for surgery, was determined. Symptomatology of the treated femoral/iliac endarterectomy patients was assessed using the Fontaine classification. For carotid endarterectomy patients were stratified according to inclusion diagnosis (stroke, transient ischemic attack patients, patients with ocular symptoms and asymptomatic patients). Secondly, the presence of different risk factors (age, male sex, obesity, smoking, hypertension, diabetes, hypercholesterolemia) was assessed. Thirdly, the history of a second atherosclerotic organ concomitant to the operated artery (defined by having a history of myocardial infarction, stroke,

narrowing carotid artery or peripheral arterial disease) was evaluated. All data were collected from patient files. The presence of risk factors and history of atherosclerotic disease were binned into binary scores (present/absent) as much as possible.

### 2.4. Definition of endpoints

A cardiovascular composite endpoint was defined as having at least one of the following events during follow-up: (fatal) myocardial infarction, (fatal) cerebral infarction or bleeding, coronary angioplasty or coronary artery bypass grafting, peripheral arterial intervention, fatal heart failure, fatal aneurysm rupture, other cardiovascular death, leg amputation or sudden death. Endpoints were collected from validated follow-up of the Athero-Express biobank cohort. For cardiovascular endpoint analyses, HRQoL scores were binned into 'poor' (equal to and below median) and 'good' (above median).

### 2.5. Ethics

All patients provided written informed consent. The study protocol of the Athero-Express biobank study has been approved by the local medical ethics committees.

### 2.6. Statistical analysis

Descriptive statistics were used to analyze the demographics of the population. To explore response bias as a potential confounder, univariate analysis was carried out for associations between baseline characteristics and response rates (chi-square tests for categorical variables and t-tests for continuous variables). p-Values <0.05 were considered statistically significant. Because of non-normal distribution of HRQoL scores, nonparametric tests were used to compare HRQoL scores between groups with the absence and presence of risk factors, history of previous (symptomatic) atherosclerotic disease and symptomatology. Dichotomous variables were compared using the Mann-Whitney *U* test, categorical variables were compared using the Kruskal-Wallis test. After correcting for multiple testing (18 tests in each of the 9 HRQoL subdomains) using the Bonferroni correction, p-values <0.003 were considered statistically significant. Potential confounders in the relation between symptomatology and any of the nine HRQoL subdomains were identified by ANOVA for continuous variables and linear-by-linear association chi-square tests for categorical variables. Variables with  $p < 0.20$  were added to a multivariate regression model. After correcting for multiple testing (nine subdomains in two separate populations) using Bonferroni correction, p-values <0.003 were considered statistically significant. Reference sets for the general population were obtained from the RAND-36 manual. To compare survival of good and poor HRQoL, we plotted Kaplan-Meier curves for the composite cardiovascular endpoint stratified to poor and good HRQoLs. Differences between the strata were tested with log rank tests. SPSS version 20 was used for all analyses. The reporting of this study conforms to the STROBE statement [18].

## 3. Results

The current study included 2012 carotid endarterectomy (CEA) patients and 865 patients with endarterectomy of iliac or femoral arteries (FEAs). Of CEA and FEA patients 68% and 72% were male respectively. Age was 69 (range 35–93) (CEA) and 68 (range 30–100) (FEA). Baseline characteristics are shown in Table 1. Loss to follow-up rates were 10.3% in FEA and 9.3% in CEA with median follow-up times of 2.9 years and 3.0 years respectively. In total, 834 patients reached an endpoint of cardiovascular origin, 469 (23%) after CEA and 379 (44%) after FEA.

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