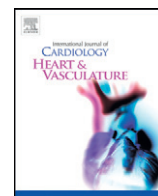


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Predictors of subjective health status 10 years post-PCI

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ABSTRACT

Background: Subjective health status is an increasingly important parameter to assess the effect of percutaneous coronary intervention (PCI) in clinical practice.**Aim** of this study was to determine medical and psychosocial predictors of poor subjective health status over a 10 years' post-PCI period.**Methods:** We included a series of consecutive PCI patients (n = 573) as part of the RESEARCH registry, a Dutch single-center retrospective cohort study.**Results:** These patients completed the 36-item Short-Form Health Survey (SF-36) at baseline and 10 years post-PCI. We found 6 predictors of poor subjective health status 10 years post-PCI: SF-36 at baseline, age, previous PCI, obesity, acute myocardial infarction as indication for PCI, and diabetes mellitus (arranged from most to least numbers of sub domains).**Conclusions:** SF-36 scores at baseline, age, and previous PCI were significant predictors of subjective health status 10 years post-PCI. Specifically, the SF-36 score at baseline was an important predictor. Thus assessment of subjective health status at baseline is useful as an indicator to predict long-term subjective health status. Subjective health status becomes better by optimal medical treatment, cardiac rehabilitation and psychosocial support. This is the first study determining predictors of subjective health status 10 years post-PCI.© 2016 The Authors. Published by Elsevier Ireland Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Percutaneous coronary intervention (PCI) is an effective therapy for atherosclerotic cardiovascular disease [1]. During the last decade, PCI has resulted in a better prognosis; it has decreased restenosis [2]. Furthermore, PCI appeared to have a positive influence on subjective health status [3–7]. Thereafter, subjective health status became an increasingly important parameter to assess the effect of PCI in clinical practice [8–12].

Until now, a clear conceptual framework that describes specific predictors for long-term subjective health status after PCI is lacking. Only a few studies have reported on medical and psychosocial predictors of (subjective) health status post-PCI [13–18]. Some of these studies found baseline subjective health status to be an important predictor of subjective health status post-PCI. [13,14,17,18] Furthermore, age [13],

male gender, previous coronary artery bypass grafting (CABG), renal impairment [17], and smoking [16] were predictors of health status post-PCI. An important limitation of these studies was the short duration of follow-up; all these studies had a follow-up of 12 months only [13–17].

Medical and psychosocial predictors of subjective health status at longer term are still unknown. The overall goal of this study is to bridge this gap in knowledge and gain insight in this domain. Specifically, this study's aim is to determine medical and psychosocial predictors of poor subjective health status over a 10 years period post-PCI. We hypothesized that the medical predictors, as found in the few previous studies (with a maximum follow-up of 1 year) up, will also be significant predictors at 10 years follow-up. Therefore, we selected these predictors as candidate predictors in this study.

2. Methods

2.1. Inclusion/Exclusion

The initial study population of this study was part of the RESEARCH registry. The design of the RESEARCH registry has been published elsewhere [19]. Briefly, the RESEARCH registry is a single-center registry

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evaluating the safety and efficacy of sirolimus-eluting stent (SES) implantation in patients treated in daily clinical practice.

In this study, 1411 consecutive patients treated with PCI with implantation of bare metal stents (BMSs) (October 2001 to April 2002) or SES (April 2002 to October 2002) were included.

2.2. Assessment procedure

For this study, of the 1411 patients, all surviving patients were contacted by mail at 6 months (referred to as baseline in the remainder of the paper) and 10 years post-PCI. They were asked to complete questionnaires about anginal status and medication usage, and the 36-item Short-Form Health Survey (SF-36), assessing subjective health status. At each assessment moment, a reminder was sent to patients who did not return their questionnaire. Only patients (N = 1055) who did not die or were not lost over 10 years follow-up were selected. The assessment at 6 months was chosen to ascertain a stable medical condition. A similar approach has been adopted in other studies of PCI patients [20].

Information about the in-hospital outcomes was obtained from our hospital electronic clinical database maintained at our institution and by reviewing the hospital records for those discharged to referring hospitals. The survival status at each assessment moment was obtained from the Municipal Civil Registries. The referring physicians and institutions were contacted whenever necessary for additional information.

This study was not subject to the Dutch Medical Research Involving Human Subjects Act. Therefore, approval from the local research ethics committee to conduct this retrospective follow-up study was not required at the time of enrollment. Moreover, the study was conducted according to the Helsinki Declaration [21]. All patients consented participation in this study.

2.3. Baseline variables

Demographic variables included gender and age. Information about clinical variables was prospectively collected at the time of the procedure and recorded in the institutional database. Clinical variables included hypertension, smoking, diabetes mellitus, family history of CAD, indication for PCI, type of stent, previous myocardial infarction, previous CABG, previous PCI, multi-vessel disease, and body mass index [BMI]. Multivessel disease was defined as PCI in more than one coronary artery or in the left main. BMI was categorized in three groups: BMI < 25 kg/m², BMI 25–30 kg/m² and BMI ≥ 30 kg/m².

2.4. Subjective health status

The subjective health status was assessed with the SF-36 Health Survey. The SF-36 assesses 8 health status domains: physical functioning, role limitations due to physical problems, bodily pain, general health, social functioning, role limitations due to emotional functioning, mental health, and vitality. The score range is from 0 to 100. A higher score on the SF-36 sub domains represents an improved functioning; a high score on the bodily pain scale indicates the absence of pain [22]. Good reliability and validity have been reported for the Dutch version of the SF-36, with Cronbach α ranging from 0.65 to 0.96 for all subscales [23].

2.5. Outcome

The clinical end point was defined as poor subjective health status at 10-year follow-up. As recommended by others [9,24], to enhance clinical interpretability, we dichotomized the health status sub domains into: poor health status (i.e. the lowest tertile) versus good health status (i.e. the other two tertiles).

2.6. Statistical analysis

Discrete variables were compared with the χ^2 test and continuous variables with Student *t* test. Univariable and multivariable logistic regression analyses were done to examine the predictors of poor subjective health status for all of the eight health status subscales. Predictors were ranked in a forward stepwise logistic regression model.

To determine predictors of poor subjective health status 10 years post-PCI, analyses were done on data of those patients who completed the SF-36 questionnaire at both baseline and 10 years post-PCI (N = 573). In multivariable analyses, we used all baseline characteristics, and baseline SF-36 scores of the corresponding SF-36 sub domain. All tests were 2-tailed, using a probability value of $p < 0.05$. For logistic regression analyses, odds ratios (ORs) and their corresponding 95% confidence intervals (95% CIs) were reported. All data were analyzed using SPSS 20.0 for Windows (SPSS Inc., Chicago, IL).

3. Results

3.1. Participants (flow)

Fig. 1 shows the patient flow throughout the study. At the start of the study, 1411 participants were contacted of whom 356 were lost during 10 years follow-up. Of these 356 patients, 322 died and 34 were lost to follow-up. Of these 1055 eligible patients 573 patients filled in questionnaires at both baseline and 10 years post-PCI.

3.2. Baseline characteristics

Baseline characteristics of the 573 patients who responded at baseline and 10 years vs. the 482 patients who did not respond at both baseline and 10 years are listed in Table 1. Overall, between these two groups, baseline characteristics are comparable, apart from three exceptions: patients who responded at both baseline and 10 years have lower rate of multivessel disease (47% vs. 54%; $p = 0.021$), lower rate of diabetes mellitus (11% vs. 18%; $p = 0.001$), and their BMI is lower (27 ± 3.6 vs. 28 ± 6.7 ; $p = 0.009$).

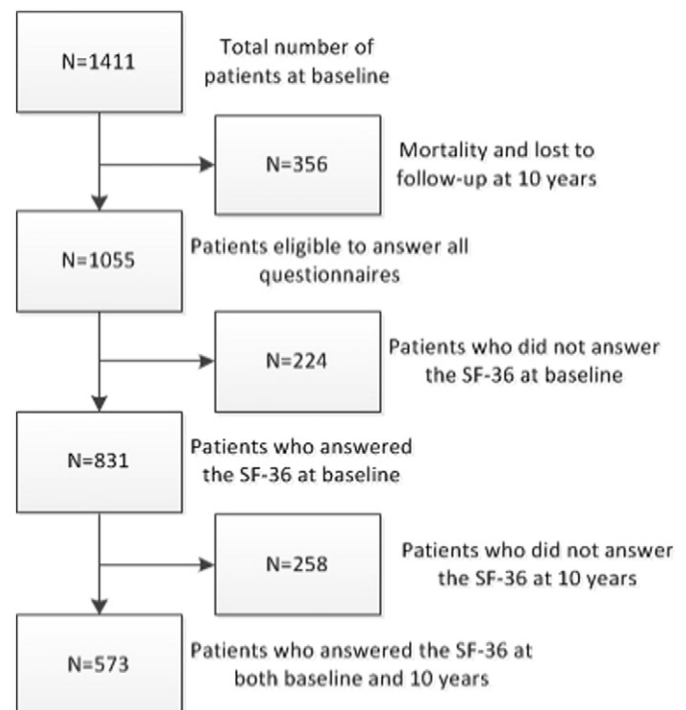


Fig. 1. Flowchart of patient selection.

Table 1
Baseline characteristics.

	Patients who responded at baseline and 10 years	Patients who did not respond at both baseline and 10 years	P
No. of patients	573	482	
Male	427 (75%)	342 (71%)	0.19
Age ± SD	60 ± 9.6	59 ± 11.6	0.33
Cardiovascular history			
Previous MI	215 (38%)	165 (34%)	0.24
Previous CABG	50 (9%)	35 (7%)	0.38
Previous PCI	103 (18%)	105 (22%)	0.12
Multivessel disease	267 (47%)	259 (54%)	0.02
Risk factors			
Hypertension	188 (33%)	167 (35%)	0.53
Family history	186 (33%)	162 (34%)	0.69
Current smoker	214 (37%)	201 (42%)	0.15
Diabetes mellitus	62 (11%)	85 (18%)	0.001
Body mass index	27 ± 3.6	28 ± 6.7	0.01
Indication for PCI			0.92
Stable angina	279 (49%)	229 (48%)	
Unstable angina	198 (35%)	172 (36%)	
Acute myocardial infarction	96 (17%)	81 (17%)	
Type of stent			0.75
Bare metal stent	298 (52%)	246 (51%)	
Sirolimus-eluting stent	275 (48%)	236 (49%)	

Compared with the 1055 eligible patients who were alive 10 years post-PCI, baseline characteristics of the 34 patients who were lost to follow-up did not differ significantly, except for indication of PCI. Furthermore, compared with the 1055 patients who were alive after 10 years follow-up, patients who died differed significantly in all baseline characteristics.

3.3. Predictors of poor subjective health status

Univariable analyses showed that SF-36 score at baseline significantly predicted all 8 sub domains, whereas acute myocardial infarction as indication for PCI significantly predicted 7 sub domains. Other significant predictors were gender, age, and previous PCI (all predicting 6 sub domains), obesity (predicting 5 sub domains), and smoking and diabetes mellitus (predicting 4 sub domains). (Appendix 1).

Multivariable analyses again showed that SF-36 at baseline significantly predicted all 8 sub domains. Age significantly predicted 6 sub domains, previous PCI 5 sub domains, obesity 3 sub domains, acute

myocardial infarction as indication for PCI 2 sub domains, and diabetes mellitus 1 sub domain. (Table 2).

4. Discussion

Besides the SF-36 scores at baseline, age and prior PCI were predictors of a broad range of sub domains of subjective health status 10 years post-PCI. The SF-36 score at baseline significantly predicted all 8 sub domains of the SF-36. Thus SF-36 at baseline can be regarded as a predictor of long-term subjective health status post-PCI.

Our results were partly similar to previous studies, which had a shorter follow-up interval. These studies also found that baseline subjective health status was an important predictor for health status post-PCI [13,14,17,18]. In other studies, age predicted health status post-PCI as well [13,17,18]. This was also found in studies with CABG patients [25–30] or patients with coronary artery disease [31]. Furthermore, obesity and diabetes mellitus were previously found to be predictors of health status [26–28,30,32]. However, this was not found in studies that measured health status post-PCI.

In contrast with other studies [13,17] and with trends in the general population [33], female gender was not a predictor of subjective health status 10 years post-PCI. This result has not been previously found and is hard to explain. In contrast, for CABG patients, gender was still predictive for subjective health status, even after long follow-up duration [25–27].

The results of this study have implication in clinical practice. Low SF-36 score, older age, and prior PCI were predictors of long-term poor subjective health. Both age and prior PCI could not be modified. However, clinicians could be alert to the health status in these patients. In contrast, the SF-36 score could be modified. First, patients have to get optimal medical therapy. Optimal medical therapy gives patients a better health status [6,7,10]. Second, physical health status gets better by cardiac rehabilitation [2]. So cardiologists have to refer their patients to cardiac rehabilitation. Last, mental health status could be influenced by psychosocial support of e.g. social workers.

The strength of this study is the long duration of follow-up and the focus on post-PCI patients. This is the first study that determined predictors of subjective health status 10 years post-PCI. Previous studies that determined predictors of health status post-PCI had a maximum follow-up duration of 1 year [13–17]. Furthermore, previous studies reported on predictors of health status after acute coronary syndrome or reported patients with coronary artery disease and not on post-PCI patients [7,11,31,34–37]. None of these studies had a follow-up duration of

Table 2
Multivariable analyses

Predictor	Physical component score				Mental component score			
	Physical functioning	Role physical functioning	Bodily pain	General health	Social functioning	Role emotional functioning	Mental health	Vitality
SF-36 at baseline	8,98	5,12	6,38	5,87	6,93	3,83	5,90	7,49
	5.35–15.07	3.16–8.30	4.11–9.92	3.68–9.36	4.39–10.94	2.35–6.26	3.73–9.33	4.66–12.06
Age	1,09	1,07	1,03		1,04	1,05		1,03
	1.06–1.11	1.04–1.10	1.01–1.05		1.02–1.06	1.03–1.08		1.01–1.05
Previous PCI	1,90	1,97	1,90		1,82	1,74		
	1.05–3.42	1.13–3.45	1.12–3.23		1.06–3.13	1.01–3.00		
BMI >30 ^a				2,16		2,19		2,16
				1.15–4.04		1.19–4.04		1.15–4.06
Indication PCI ^b : AMI	0,32	0,37						
	0.14–0.74	0.17–0.80						
Diabetes Mellitus							1,98	
							1.03–3.81	

Abbreviations: PCI, percutaneous coronary intervention; BMI, body mass index. AMI, acute myocardial infarction.

Outcome measure: odds ratios and 95% CI. Dark cells indicate significant results.

Predictors tested in model: male gender, age, hypertension, current smoker, diabetes mellitus, family history, old MI, previous CABG, previous PCI, multivessel disease, BMI, indication PCI, type of stent, SF-36 at baseline.

^aReference: BMI <25. ^bReference: Indication PCI: stable angina pectoris.

10 years. The study with the longest follow-up had a follow-up of 28 months [36].

Regarding CABG patients, several studies determined predictors of health status [25–30,32,38–42]. Some studies had a follow-up duration of several years [25–28,41]. Especially Herlitz et al. have studies with long follow-up duration, with a maximum of 15 years [27]. This study is therefore unique due to the 10 years' follow-up in PCI patients.

This study had several potential limitations. First, in this study two types of stents were used: SES and BMS. Patients were not randomized in regard of their type of stent. However, the strength of this study is that no exclusion criterion was applied. This means that the study population was representative for the population in the daily practice of interventional cardiology. To close the gap between research and clinical practice, it has been advocated to conduct research in daily practice settings [8]. Second, only 54% of the 1055 eligible patients responded on the SF-36 at both baseline and 10 years post-PCI. It is a well-known problem that there are many non-responders in a long registry. Other studies have this problem as well [25,26]. Third, baseline characteristics of patients who responded at both baseline and 10 years post-PCI and patients who did not respond at both baseline and 10 years post-PCI were not completely similar. Responders had lower rate of multivessel disease and diabetes mellitus, and they had a lower BMI. Fourth, there may also be predictors that are not included in our analyses but that have a predictive value.

Further studies with a comparable long-term follow-up interval are needed to replicate our findings in order to develop a framework of predictors of long-term subjective health status after PCI.

In conclusion, we found that SF-36 scores at baseline, age, and previous PCI are significant predictors of subjective health status 10 years post-PCI. Assessment of health status at baseline is a useful indicator to predict long-term subjective health status.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.ijcha.2016.03.011>.

Conflict of interest

The authors have no competing interests to report.

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