EPIDEMIOLOGY

The additional value of patient-reported health status in predicting 1-year mortality after invasive coronary procedures: a report from the Euro Heart Survey on Coronary Revascularisation

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Objective: Self-perceived health status may be helpful in identifying patients at high risk for adverse outcomes. The Euro Heart Survey on Coronary Revascularization (EHS-CR) provided an opportunity to explore whether impaired health status was a predictor of 1-year mortality in patients with coronary artery disease (CAD) undergoing angiographic procedures.

Methods: Data from the EHS-CR that included 5619 patients from 31 member countries of the European Society of Cardiology were used. Inclusion criteria for the current study were completion of a self-report measure of health status, the EuroQol Questionnaire (EQ-5D) at discharge and information on 1-year follow-up, resulting in a study population of 3786 patients.

Results: The 1-year mortality was 3.2% (n = 120). Survivors reported fewer problems on the five dimensions of the EQ-5D as compared with non-survivors. A broad range of potential confounders were adjusted for, which reached a $p<0.10$ in the unadjusted analyses. In the adjusted analyses, problems with self-care (OR 3.45; 95% CI 2.14 to 5.59) and a low rating ($\leqslant 60$) on health status (OR 2.41; 95% CI 1.47 to 3.94) were the most powerful independent predictors of mortality, among the 22 clinical variables included in the analysis. Furthermore, patients who reported no problems on all five dimensions had significantly lower 1-year mortality rates (OR 0.47; 95% CI 0.28 to 0.81).

Conclusions: This analysis shows that impaired health status is associated with a 2–3-fold increased risk of all-cause mortality in patients with CAD, independent of other conventional risk factors. These results highlight the importance of including patients' subjective experience of their own health status in the evaluation strategy to optimise risk stratification and management in clinical practice.

Treatment options for patients with coronary artery disease (CAD) have expanded considerably over the past two decades. In addition to pharmacological therapy, mechanical revascularisation by coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) can be offered to relieve ischaemic symptoms and improve prognosis in some subsets.[1–6] In addition, behavioural interventions, which include prevention and treatment of lifestyle risk factors and psychological risk factors (eg, anger or anxiety), are known to be beneficial for patients with cardiovascular diseases.[7] However, choosing the most appropriate treatment for the individual patient remains controversial in many instances.[8]

As the observed differences in outcome between competitive treatment options (eg, CABG and PCI) diminish,[9–11] researchers and clinicians have become increasingly interested in measuring patients' health status. In addition to using health-related quality of life (HRQL) or health status as an end point in clinical trials, health status may prove useful in the clinical decision-making process as to which treatment to favour.[12 13] It is also important to note that health status is an important patient-centred outcome, and subsets of patients are known to prefer health status over prolonged survival.[14] In addition, measuring health status may help identify patients at high risk for adverse outcomes.[12 15–18] Identification of these patients is important as they may benefit from more invasive management and more intensive follow-up.[17] Yet, health status measures are rarely used in clinical practice.[19]

The aim of this study was to explore whether impaired health status was a predictor of 1-year all-cause mortality in a cohort of patients with established CAD enrolled in the Euro Heart Survey on Coronary Revascularization (EHS-CR).

METHODS

Patients

Data for this study were derived from the database of the EHS-CR. Details of this prospective, observational study were published previously.[20] All consecutive patients undergoing invasive diagnostic or therapeutic procedures in the catheterisation laboratory were screened between November 2001 and March 2002 in 130 hospitals from 31 member countries of the European Society of Cardiology (ESC). Consenting patients with a >50% diameter stenosis in at least one coronary artery were included and detailed information was retrieved from their medical records. The EuroSCORE was calculated from the available variables.[21] From the 5619 patients enrolled in the

Abbreviations: CABG, coronary artery bypass grafting; CAD, coronary artery disease; EHS-CR, Euro Heart Survey on Coronary Revascularization; EQ-5D, EuroQol-5D; HRQL, health-related quality of life; PCI, percutaneous coronary intervention; VAS, visual analogue scale

EHS-CR, 4515 (80%) patients had complete data on all five questions (dimensions) of the EuroQol Questionnaire (EQ-5D) at baseline. The study protocol included a 1-year follow-up, which was available in 3786 (84%) patients.

Health status

In addition to collecting clinical variables, all patients were asked to fill in the self-report EQ-5D questionnaire[22] at the time of hospital discharge. The EQ-5D is a standardised generic instrument for assessing health status, with valid translations available for 29 of the 31 participating countries in the current study. This validated questionnaire comprises five dimensions—namely, mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each of these dimensions has three levels of severity, corresponding to ''no problems'', ''moderate problems'' and ''severe problems''. Patients were asked which statement best described their health status on the day the questionnaire was filled in. Theoretically, 243 different health states can be generated by this classification. The ratings can be analysed on an individual level using health-state utility scores. These scores range from –0.594 to 1, with scores <0 being regarded as worse than death and 1 representing full health, from the perspective of the general population.[22] The second part of the EQ-5D consists of a visual analogue scale (VAS) ranging from 0 (best imaginable health state) to 100 (worst imaginable health state), which is used for rating the overall health.

Statistical analysis

Continuous variables are reported as mean or median scores with corresponding values (SD and inter quartiles ranges, respectively). Dichotomous variables are presented as numbers and percentages. To evaluate differences between the different groups, χ^2 tests, Student's t test, analysis of variance or Mann–Whitney U tests were applied as appropriate. Univariate and multivariate logistic regression analyses were performed to evaluate the relationship between the five dimensions of the EQ-5D at baseline and all-cause mortality at 1 year. To examine the relationship between the dimensions of the EQ-5D, we dichotomised the three levels of severity: ''no problems'' was coded 0, whereas ''moderate problems'' and ''severe problems'' were coded 1. The VAS was dichotomised by using the lowest 25th centile indicating impaired health. These dichotomised variables were then entered separately in the adjusted analyses. Crude and adjusted odds ratios (ORs) with their corresponding 95% confidence intervals (CIs) are reported. We adjusted for a broad range of potential confounders, which reached a p value of <0.10 in the unadjusted analyses. These variables included age, risk factors, co-morbidity, admission diagnosis and treatment. Goodness of fit was determined by the Hosmer–Lemeshow test, and discriminatory power was evaluated using c-statistics. For all tests, a p value <0.05 (two-sided) was considered significant. Statistical analyses were performed using SPSS V.12.0.1 for Windows.

RESULTS

Table 1 summarises the baseline characteristics of the 3786 patients who were included in the current study, comparing survivors at 1-year follow-up with non-survivors. The all-cause mortality at 1 year was 3.2% (120 deaths). Cardiac death was observed in 69% of those with a known cause of death (n = 97). Survivors were younger (62.8 vs 69; p<0.001), had a better risk profile (including age, diabetes, cardiovascular history and EuroSCORE), and were more often offered revascularisation (80% vs 63%; p<0.001) as compared with non-survivors. No significant differences were observed between the admission diagnosis of survivors and non-survivors. By univariate analysis, conventional variables negatively associated with death were: age, diabetes, peripheral vascular disease, previous myocardial infarction, history of heart failure, previous CABG, multivessel disease, ejection fraction <40%, EuroSCORE and only medical treatment. PCI, use of antiplatelet agents and use of statins were associated with improved outcome. Stable angina was the most frequent indication to perform angiography (54%), followed by non-ST myocardial infarction or unstable angina (30%) and ST elevation myocardial infarction (15%). On all five EQ-5D dimensions, survivors reported significantly fewer problems and had a better overall health (ie, VAS) than non-survivors. The univariate analysis showed that problems on these dimensions were negatively associated with death (table 2). Identical results were observed in a subgroup of patients with cardiac mortality, instead of all-cause mortality.

Table 3 shows the adjusted association between the EQ-5D and 1-year mortality. Patients who reported problems on perceived health status and patients who had a relatively low score (⩽60) on the EQ-VAS had a higher mortality rate as compared with patients who reported no problems. Problems with self-care (OR 3.45; 95% CI 2.14 to 5.59) and a health rating ⩽60 (OR 2.41; 95% CI 1.47 to 3.94) were the most powerful predictors of mortality. Furthermore, patients who reported no problems on all five dimensions had significantly lower 1-year mortality (OR 0.47; 95% CI 0.28 to 0.81), whereas patients who reported problems on all dimensions were in the highest risk group (OR 3.85; 95% CI 2.30 to 6.44). The EQ-5D improved the model c-statistics (from 0.78 to 0.81). Calibration was good for the adjusted analyses as Hosmer–Lemeshow tests showed no significant difference between the observed and predicted probabilities.

Figure 1 shows per dimension that patients who reported no problems had a low mortality (<3%), whereas patients who had moderate or severe problems had considerably higher mortality (range 4–21%).

As 33% of all patients enrolled in the EHS-CR were excluded from this analysis, we compared the baseline characteristics of these patients with the study population. With the exception of a higher in-hospital mortality in those who were excluded (5.1% vs 0.3%), no major differences were observed.

DISCUSSION

This study showed that impaired health status, as measured by the EQ-5D before discharge, is associated with a 2–3-fold increased risk of all-cause mortality in patients with established CAD. After adjustment for other prognostic variables, including age, risk factors, comorbidity and admission diagnosis, impaired health status remained an independent predictor of 1-year mortality.

Several studies have reported on the predictive value of HRQL and health status questionnaires in relation to adverse clinical outcomes in patients with cardiovascular diseases.[15 16 18 23] To our knowledge, this study is the first to use the EQ-5D, a brief generic self-perceived health status questionnaire, to predict short-term mortality (ie, after 1 year) independently of established biomedical risk factors in patients with CAD with a relatively low overall risk. We identified reduced self-care as the most powerful predictor of mortality. Of note, this dimension is strongly related to patients' abilities to care for themselves and adequately manage their condition. As a consequence, targeting and improving self-care behaviour in intervention programmes could not only lead to improved HRQL but also enhance survival in this subset of patients.[24 25] In addition, a major advantage of the EQ-5D is that it is a brief and

Table 1 Baseline characteristics of patients

	Vital status at 1-year follow-up		Univariate predictor for mortality (OR, 95% CI)	p Value
	Alive (n = 3666)	Dead (n = 120)		
Male sex (%)	2785 (76)	93 (78)	1.09 (0.70 to 1.68)	0.71
Mean (SD) age (years)	62.8 (10.6)	69 (9.9)	1.06 (1.04 to 1.08)	<0.001
Risk factors (%)				
Smoking ever	2166 (61)	75 (63)	1.05 (0.72 to 1.53)	0.79
Diabetes mellitus	850 (23)	43 (36)	1.85 (1.26 to 2.70)	0.002
Hypertension	2254 (62)	75 (63)	1.04 (0.71 to 1.51)	0.85
Hyperlipidaemia	2417 (67)	78 (66)	0.98 (0.66 to 1.44)	0.9
Cardiovascular history (%)				
Peripheral vascular disease	412 (11)	32 (27)	2.87 (1.89 to 4.35)	<0.001
Cerebral vascular disease	283 (8)	12 (10)	1.33 (0.72 to 2.44)	0.36
Prior myocardial infarction	1440 (39)	72 (60)	2.31 (1.59 to 3.35)	<0.001
Congestive heart failure	673 (18)	50 (42)	3.17 (2.19 to 4.61)	<0.001
Prior percutaneous coronary intervention	764 (21)	19 (16)	0.71 (0.43 to 1.17)	0.18
Prior coronary artery bypass grafting	368 (10)	24 (20)	2.24 (1.41 to 3.55)	<0.001
Diagnosis at admission (%)				
Stable angina	1978 (55)	60 (52)	0.85 (0.59 to 1.23)	0.39
NSTE-ACS	1105 (31)	40 (35)	1.16 (0.79 to 1.71)	0.45
STEMI	537 (15)	16 (14)	0.90 (0.53 to 1.53)	0.90
Angiographic results (%)				
Multivessel disease	2308 (63)	89 (74)	1.68 (1.11 to 2.54)	0.01
Left main lesions	284 (8)	15 (13)	1.70 (0.98 to 2.96)	0.06
Ejection fraction <40%	296 (12)	34 (37)	4.25 (2.74 to 6.60)	<0.001
Mean (SD) EuroSCORE	4.2 (2.8)	6.8 (3.4)	1.28 (1.21 to 1.35)	<0.001
Treatment option (%)				
Percutaneous coronary intervention	2201 (60)	54 (45)	0.55 (0.38 to 0.79)	0.001
Coronary artery bypass grafting	745 (20)	22 (18)	0.88 (0.55 to 1.41)	0.59
Only medical treatment	720 (20)	44 (37)	2.37 (1.62 to 3.46)	<0.001
Medical treatment at discharge (%)				
Antiplatelet agents/oral anticoagulants	3464 (95)	105 (88)	0.41 (0.23 to 0.71)	0.002
β-blockers	2796 (76)	86 (72)	0.79 (0.53 to 1.18)	0.25
Statins	2498 (68)	71 (59)	0.68 (0.47 to 0.98)	0.04
ACE inhibitors	2027 (55)	76 (63)	1.40 (0.96 to 2.04)	0.08

NSTE-ACS, non ST-elevation acute coronary syndrome; STEMI, ST-elevation myocardial infarction

valid measure of health status that can be easily used in clinical practice.

Our findings support the recommendations of Krumholz *et al*[17] to include health status measurements in clinical practice as an additional tool to identify patients who are at high risk for adverse outcomes. These patients may consequently benefit from a more aggressive treatment, including invasive, pharmacological and/or behavioural interventions or a combination hereof. An earlier report on the EHS-CR showed that there is adequate room for improvement in the medical treatment of these patients, especially with respect to adjunctive pharmacology (glycoprotein IIb/IIIa inhibitors, statins and ACE inhibitors).[20] Another important issue for advocating the use of health status assessment in clinical practice relates to the issue of discrepancy between patient-rated and physician-rated health status.[26] As clinicians frequently underestimate patients' health status as reported by their patients,[27] it is paramount that patients' evaluation of ''how they feel'' is taken into account. In addition, health status is an important patient-centred outcome, with patients emphasising health status over prolonged survival.[14] Hence, entering health status into the equation when discussing treatment options with patients may also be considered an ethical obligation.

Although this study clearly showed that the EQ-5D provides prognostic information, little is known about the ''how and why'' impaired health status predicts mortality, independently of biomedical risk factors. It should be noted, however, that health status involves a much broader range of the effect of disease as experienced by the patient (ie, symptoms, functional limitation, and discrepancy between actual and desired function) compared with the focus of clinicians (ie, symptoms, signs and diagnosis).[19] Further research is warranted into the mechanisms that may be responsible for the relationship between health status and mortality, as this could guide treatment with or the development of effective interventions. Emphasis should also be placed on the identification of the determinants of impaired health status, which has been advocated as a means to close the gap between research and clinical practice.[17] Both depression and the distressed (type D) personality have been shown to predict impaired health status adjusting for measures of severity of disease and other risk factors.[28 29] The question is whether these psychosocial risk factors are more important determinants of individual differences in clinical outcome than health status.

This study is the first to use the EQ-5D as a predictor of mortality. Although other generic and disease-specific health status questionnaires have been found to predict mortality, one of the major advantages of the EQ-5D is its brevity. It comprises only six questions, whereas most of the other questionnaires ask many more questions (range 19–36) and are more taxing to patients.[12 15 16 23] In addition, it is important to note that in patients with CAD a simple questionnaire such as EQ-5D is able

Table 2 EuroQol-5D questionnaire and distribution, before hospital discharge

	Vital status at 1-year follow-up		Univariate predictor for mortality (OR, 95% CI)	p Value
	Alive (n = 3666), n (%)	Dead (n = 120), n (%)		
Mobility			3 (2.08 to 4.33)*	<0.001
I have no problems in walking about	2579 (70)	53 (44)		
I have some problems in walking about	1064 (29)	61 (51)		
I am confined to bed	23 (1)	6 (5)		
Self-care			4.64 (3.18 to 6.67)*	<0.001
I have no problems with self-care	3191 (87)	71 (59)		
I have some problems washing or dressing myself	453 (12)	46 (38)		
I am unable to wash or dress myself	22 (1)	3 (3)		
Usual activities (eg, work, housework, family activities)			3.65 (1.93 to 3.85)*	<0.001
I have no problems with performing my usual activities	2311 (63)	47 (39)		
I have some problems with performing my usual activities	1227 (33)	62 (52)		
I am unable to perform my usual activities	128 (4)	11 (9)		
Pain/discomfort			2.12 (1.47 to 3.05)*	<0.001
I have no pain or discomfort	2295 (63)	53 (44)		
I have moderate pain or discomfort	1320 (36)	59 (49)		
I have extreme pain or discomfort	51 (1)	8 (7)		
Anxiety/depression			2.47 (1.71 to 3.55)*	<0.001
I am not anxious or depressed	2505 (68)	56 (47)		
I am moderately anxious or depressed	1061 (29)	54 (45)		
I am extremely anxious or depressed	100 (3)	10 (8)		
EQ-VAS			3.45 (2.29 to 5.19)†	<0.001
Mean (SD)	69 (19)	57 (23)		
Median, interquartile range	70 (60 to 80)	58 (45 to 80)		
EQ-utility score			2.70 (1.87 to 3.9)†	<0.001
Mean (SD)	0.81 (0.23)	0.63 (0.34)		
Median, interquartile range	0.85 (0.69 to 1.0)	0.71 (0.52 to 0.85)		

EQ, EuroQol; EQVAS, EuroQol visual analogue scale; VAS, visual analogue scale.
*Patients indicating problems on the EQ-5D dimension.
†Dichotomised (using the lowest 25th centile indicating impaired health status).

Table 3 Adjusted association between the dimensions of the EuroQol-5D Questionnaire and all-cause mortality*

	Mobility‡		Self-care‡		Usual activities‡		Pain/discomfort‡		Anxiety/depression‡	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
Clinical variables†										
Age (years)	1.03 (1 to 1.06)	0.09	1.03 (1 to 1.06)	0.08	1.03 (1 to 1.06)	0.07	1.03 (1 to 1.06)	0.05	1.03 (1 to 1.07)	0.05
History of HF, n	1.63 (0.99 to 2.67)	0.06	1.52 (0.92 to 2.51)	0.10	1.62 (0.98 to 2.66)	0.06	1.65 (1 to 2.71)	0.05	1.67 (1.01 to 2.75)	0.04
EF <40%	1.87 (1.1 to 3.20)	0.02	1.82 (1.06 to 3.13)	0.03	1.88 (1.1 to 3.21)	0.02	1.83 (1.07 to 3.13)	0.03	1.88 (1.1 to 3.22)	0.02
Prior MI, n	1.96 (1.22 to 3.14)	0.006	1.9 (1.18 to 3.05)	0.008	1.93 (1.2 to 3.1)	0.007	1.96 (1.22 to 3.16)	0.005	1.95 (1.21 to 3.14)	0.006
PVD	1.98 (1.1 to 3.56)	0.02	2.19 (1.21 to 3.99)	0.01	2.01 (1.11 to 3.62)	0.02	1.91 (1.06 to 3.45)	0.03	2.02 (1.12 to 3.64)	0.02
Medical treatment	2.07 (1.05 to 4.07)	0.04	2.26 (1.15 to 4.47)	0.02	2.12 (1.08 to 4.16)	0.03	2.13 (1.09 to 4.18)	0.03	2.06 (1.05 to 4.05)	0.04
EQ-5D dimensions‡	2.2 (1.39 to 3.5)	<0.001	3.45 (2.14 to 5.59)	<0.001	2.13 (1.34 to 3.38)	<0.001	2.12 (1.33 to 3.37)	0.001	2.31 (1.48 to 3.59)	<0.001

EF, ejection fraction; EQ, EuroQol; HF, heart failure; MI, myocardial infarction; PVD, peripheral vascular disease; VAS, visual analogue scale.
*Adjusted for age, diabetes, peripheral vascular disease, previous myocardial infarction, history of heart failure, previous coronary artery bypass grafting, multivessel disease, left main, ejection fraction <40%, EuroSCORE, percutaneous coronary intervention, medical treatment, anti-platelet agents, statins and ACE-inhibitors, which reach a p value of 0.10 in the unadjusted analyses (table 1).
†Only clinical variables that remained statistically significant in the adjusted analyses are described.
‡The five dimensions were entered separately in the adjusted analyses.

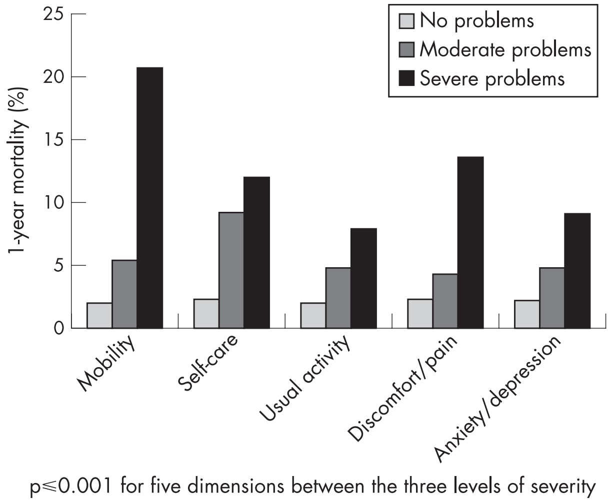

Figure 1 One-year mortality stratified by the EuroQol-5D dimensions.

to discriminate between patients who have a higher mortality risk and those who do not. By contrast, we acknowledge that a lack of familiarity with the concept of health status, the perception of many clinicians that health status is a soft end point in evaluating a treatment[19] and the high workload of physicians in clinical practice may be identified as barriers for implementing self-perceived health status in every day clinical practice. However, it should be noted that it takes less than 5 min to complete the questionnaire, and health care professionals other than physicians can become involved in the assessment.

The current study has several potential limitations. Firstly, patients who did not complete the EQ-5D questionnaire or who had missing follow-up data had to be excluded from analyses. However, a comparison between responders and non-responders did not show major differences. Secondly, it cannot be excluded that ill health conditions, other than cardiovascular diseases, could have had an effect on the results, as only "classical" risk factors and comorbidities were included in the database. Thirdly, health status was assessed only once, and at that time not all patients had undergone a revascularisation procedure. Finally, we used a generic rather than a disease-specific instrument to evaluate health status; it is well known that generic measures may be less sensitive than disease-specific measures to tap dimensions pertinent to clinical populations. Future research is needed to consider issues such as the predictive value of a single measurement as compared with serial measurements, the effect of changes in health status over time on outcomes, and comparing the results of the EQ-5D with disease-specific instruments. Despite these limitations, strengths of this study were the relatively large number of patients included from multiple hospitals across Europe. We were also able to adjust for a number of classical demographic and cardiovascular risk factors, showing that impaired health status is an independent predictor for mortality. Lastly, the enrolled patients are representative of "real life" practice, across a wide spectrum of European hospitals.

In conclusion, this study showed the strong incremental value of the EQ-5D for the prediction of mortality in patients admitted with CAD, independently of other demographic, clinical and angiographic risk factors. Our results highlight the importance of including patients' subjective experience of their own health status to optimise risk stratification in clinical practice.

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