

1-1-2012

Validity and reliability of three commonly used Quality of Life measures in a large European population of coronary heart disease patients.

Delphine De Smedt
University of Ghent

Els Clays
University of Ghent

Frank Doyle
Royal College of Surgeons in Ireland, fdoyl4@rcsi.ie

Kornelia Kotseva
Imperial College London

Christof Prugger
University of Munster

See next page for additional authors

Citation

De Smedt D, Clays E, Doyle F, Kotseva K, Prugger C, Pajak A, Jennings C, Wood D, De Bacquer D. Validity and reliability of three commonly used Quality of Life measures in a large European population of coronary heart disease patients. *International Journal of Cardiology*. 2012 (in press)

This Article is brought to you for free and open access by the Department of Psychology at e-publications@RCSI. It has been accepted for inclusion in Psychology Articles by an authorized administrator of e-publications@RCSI. For more information, please contact epubs@rcsi.ie.

Authors

Delphine De Smedt, Els Clays, Frank Doyle, Kornelia Kotseva, Christof Prugger, Andrzej Pajak, Catriona Jennings, David Wood, and Dirk De Bacquer

Attribution-Non-Commercial-ShareAlike 1.0

You are free:

- to copy, distribute, display, and perform the work.
- to make derivative works.

Under the following conditions:

- Attribution — You must give the original author credit.
- Non-Commercial — You may not use this work for commercial purposes.
- Share Alike — If you alter, transform, or build upon this work, you may distribute the resulting work only under a licence identical to this one.

For any reuse or distribution, you must make clear to others the licence terms of this work. Any of these conditions can be waived if you get permission from the author.

Your fair use and other rights are in no way affected by the above.

This work is licenced under the Creative Commons Attribution-Non-Commercial-ShareAlike License. To view a copy of this licence, visit:

URL (human-readable summary):

- <http://creativecommons.org/licenses/by-nc-sa/1.0/>

URL (legal code):

- <http://creativecommons.org/worldwide/uk/translated-license>
-

Title: Validity and reliability of three commonly used Quality of Life measures in a large European population of coronary heart disease patients.

Authors: Delphine De Smedt, Els Clays, Frank Doyle, Kornelia Kotseva, Christof Prugger, Andrzej Pająk, Catriona Jennings, David Wood, Dirk De Bacquer on behalf of the EUROASPIRE Study Group*

Abstract:

Objective: To investigate the validity and reliability of the EuroQol (EQ-5D), the Short form health survey (SF-12v2), and the Hospital Anxiety and Depression Scale (HADS) in a stable coronary population.

Study Design: Cross-sectional study EUROPASPIRE III

Setting: Quality of Life data (QoL) were available on 8745 patients hospitalized for coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI) or acute myocardial infarction (AMI). They were interviewed and examined at least 6 months after their hospital admission. Reliability and validity of the 3 instruments were tested. Internal consistency, and discriminative, convergent, criterion and construct validity were assessed.

Results: Cronbach's alpha indicated good internal consistency for all measures (0.73 to 0.87).

Discriminative validity analyses confirmed significant QoL differences between known groups: age, gender, educational level. In addition, all hypothesized correlations between QoL constructs (convergent validity) and items (criterion validity) were confirmed with significant correlations. Confirmatory factor analyses indicated good construct validity for HADS and SF-12v2. On country-specific level, results were roughly similar.

Conclusion: The EQ-5D as well as the SF-12v2 and the HADS are reliable and valid instruments for use in a stable coronary population, both on aggregate European level as on country-specific level. However, our results must be generalized with caution, because EUROASPIRE III patients might not be representative for all patients with stable coronary heart disease.

Introduction

Due to improved cardiovascular prevention and management, Coronary Heart Disease (CHD) death rates have decreased in Western, Northern, and Southern European countries during the last decades (1;2).

Despite this reduction, CHD remains the most common cause of disease burden throughout Europe.

Conventional medicine focuses mainly on clinical measures and functional outcomes, however the use of health related Quality of Life (QoL) instruments has become increasingly important to assess the patient's emotional, social and physical well-being (3;4). Patients suffering from CHD are likely to have an impaired QoL, due to pain, anxiety, functional and social limitations (5-8). Although still under debate, several studies have observed a relationship between QoL, depression, anxiety and worse long-term health outcomes (9-13). Many QoL measures are available, and most of them have been comprehensively tested in the general population with regard to their reliability and validity. In addition, different studies have assessed the psychometric properties of QoL instruments in various disease-specific samples, including CHD patients; however in general, cross-European data were limited (14-17).

Within the EUROASPIRE III programme (EUROpean Action on Secondary and Primary Prevention through Intervention to Reduce Events), a multicentre European survey developed to assess how clinical guidelines on cardiovascular disease prevention are implemented throughout Europe, QoL assessment was performed on the basis of 3 questionnaires: the EuroQol-5D (EQ-5D) (18;19), the 12-item Short-Form Health Survey (SF-12v2) (20), and the Hospital Anxiety and Depression Scales (HADS) (21).

EQ-5D is a widely used simple, generic instrument to measure health in a standardized way. The measure is applicable to a wide range of conditions and treatments and contains a self-classifier and a visual analogue scale. Based on the self-classifier, a single index value can be calculated, representing the overall health status (19;22). Another commonly used health status questionnaire is the SF-12, a downsized version of the SF-36 and therefore useful for large studies. The measure allows to calculate a

Physical Component Summary (PCS-12) score and a Mental Component Summary (MCS-12) score (20). In addition to these general health measures, specific instruments are available for assessing anxiety, depression or depressive symptoms; feelings that are highly common in coronary patients (7;11). In order to adapt treatment accordingly, screening for depressive feelings and anxiety is important. The HADS instrument permits to calculate both an anxiety (HADS-A) and a depression (HADS-D) score.

The present study investigates the psychometric properties of the EQ-5D, SF-12 and HADS instruments in a large multi-country European cross-sectional sample of coronary patients, the EUROASPIRE III survey.

Methods

Study population and data collection

Analyses were based on data gathered during the EUROASPIRE III survey. The details of the study have been reported elsewhere (23). In brief, EUROASPIRE III, performed in 2006-2007 among patients with established CHD, is a cross-sectional study aimed at determining whether the European recommendations of cardiovascular disease prevention are being followed in daily practice. Patients, aged 80 years or less, hospitalized for coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), acute myocardial infarction (AMI) or myocardial ischemia were retrospectively identified from diagnostic registers, hospital discharge lists or other sources at 76 different hospital centres in 22 European countries: Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovenia, Spain, The Netherlands, Turkey, and the United Kingdom (UK). Data collection was conducted by trained research staff using standardized methods and instruments. Of the 13,935 patients identified, 8,966 were interviewed and examined at least 6 months and not later than 3 years after their index hospital admission.

In addition to the collection of disease related clinical measures, patients were asked to fill in 3 self-administered questionnaires related to QoL and perceived overall health status: EQ-5D, HADS and SF-12v2. In each country, questionnaires were administered in the official language. EQ-5D contains a self-classifier (EQ-5D_{index}) and a visual analogue scale (EQ-VAS). The former is made up of five likert-scale items covering the following dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. A single summary index, according to the weighting system derived by Dolan *et al* (1997) is derived from the answers given on the self-classifier; with 1 representing perfect health, 0 representing death, and <0 representing a health state perceived worse than death (22;24). The EQ-VAS is a 20-cm vertical scale, ranging between 0 (worst imaginable health state) and 100 (best imaginable health state) on which the respondent is asked to indicate how good or bad his or her health is today.

The SF-12v2 exists of 12 questions, with 3 to 5 response levels, and is intended to assess both physical and mental functioning, represented by a Physical Component Summary (PCS-12) score and a Mental Component Summary (MCS-12) score respectively. The PCS-12 and MCS-12 scores were calculated based on a US general population scoring algorithm (25). Results are represented by a value ranging between 0 and 100, with 0 representing the lowest level of health and 100 the highest level of health. The SF-12v2 was not administered in Hungary. In Germany, the SF-36 was used instead of the SF-12v2, however an overall physical and mental component score could be calculated using the SF-12 items embedded in the SF-36.

The HADS, intended for use in a hospital setting, contains 14 items, each with a four-point response scale. Seven items are related to anxiety and the other 7 items to depression. The instrument gives information about possible or probable anxiety or depressive feelings, but is not appropriate to screen for clinical depression. Item scores can be added to obtain the summary scores on anxiety (HADS-A) and depression (HADS-D) separately. The total score on each subscale ranges between 0 and 21. A score < 8 can be

considered as being in the normal range, higher scores can indicate a possible or probable disorder (21;26).

Psychometric analyses

Psychometrics aims to evaluate the reliability and validity of measures by assessing the characteristics of scales (27). Stratification by country, gender, age and educational level was performed. Four age groups were considered: <50 year, 50-59 years, 60-69 years and >70 years. And 3 educational levels were used: primary education, defined as primary school or less; secondary education, defined as secondary school completed, high school completed or intermediate between secondary level completed; and high education, defined as a university/college degree or equivalent. Patient records for which no summary score could be calculated were excluded from the analyses.

Reliability

Internal consistency of the EQ-5D self-classifier, PCS-12, MCS-12, HADS-A and HADS-D was examined using the Cronbach's coefficient alpha (27). A threshold of 0.7 was considered acceptable, a value >0.8 good, >0.9 indicated excellent internal consistency (28).

Validity

Confirmatory factor analysis (CFA) for the SF-12 and HADS measures was conducted in order to test whether the original scale construct was confirmed in this sample. No CFA was performed for EQ-5D since this measure does not include different theoretical constructs. The Weighted Least Squares Means and Variance adjusted (WLSMV) estimation method was used for ordinal data. Multiple goodness of fit tests were used, including the Root mean Square Error of Approximation (RMSEA), the Comparative Fit Index (CFI) and the Tucker-Lewis Index (TLI). Since it is well known that the overall χ^2 fit index is largely influenced by sample size, tending to over-reject models with large sample size, this index was not used in drawing conclusions (29). For CFI and TLI, a threshold value >0.9 was considered as a good fit (30).

Whereas for the RMSEA, a value <0.06 was considered as a good fit, a value <0.08 was considered as an acceptable fit and a value >0.1 led to rejection of the model (29;31). Factor loadings represent the correlation between observed variables and extracted components. Standardized factor loadings >0.5 were perceived as good, loading >0.4 indicated an acceptable correlation and those <0.4 were perceived as not good.

Discriminative validity was examined with the known-group method by assessing the relationship of the QoL constructs with age, gender and education. Non-parametric tests (Kruskall-Wallis) were used due to the skewed nature of data. We hypothesized that QoL would decrease with age and lower education, and would be lower in female patients.

Convergent validity was evaluated with the Spearman correlations for theoretically correlated constructs. Constructs capturing similar functional or emotional characteristics were expected to highly correlate with one another. Correlations <0.3 were considered as negligible, a value between 0.3 and 0.5 as moderate and >0.5 as strong (32). It was hypothesized that MCS-12 would correlate with HADS-A and HADS-D and that the two HADS-scales would correlate with each other. Furthermore, it was expected that the EQ-5D_{index} correlates with PCS-12 and MCS-12.

In addition, the EQ-VAS was considered as criterion for overall health, hence a correlation between EQ-VAS and PCS-12, MCS-12 and EQ-5D_{index} was expected. Likewise, the first question of the SF-12v2 instrument (SF12-1), asking about the general state of an individual's health, was also considered as a criterion of overall health. The SF12-1 was hypothesized to correlate with EQ-5D_{index} and the EQ-VAS. Similarly the EQ-5D anxiety/depression item and question 6c of the SF-12 item "Have you felt downhearted and depressed?" were considered as an overall criterion for anxiety and depression. Therefore these items were expected to correlate with both HADS-A and HADS-D.

All analyses were performed using IBM SPSS 19, except the CFA, which was conducted using M-plus version 6.11.

Results

General characteristics

The patient characteristics are presented in table 1. In total, data on 8,745 patients from 22 European countries are included in the psychometric analyses, ranging from 120 Greek patients to 550 patients from Germany. The majority of patients were male (74.6%) and their mean age was 63.2 +/-9.5 years. Regarding educational level, about a quarter (25.3%) of the patients had a primary education. More than half (56.7%) of the patients had a secondary education and 18.0% had a higher education.

[insert table 1 somewhere here]

Mean values of the different QoL scales and subscales are shown in table 2. Intraclass correlation coefficients (ICC) were calculated for all QoL measures, in order to assess the proportion of variance due to the grouping structure on country-level. ICC's indicated a significant proportion of variance that could be assigned to the countries. Variation in HADS-A and HADS-D scores amounted to 5.70% and 5.37% respectively. For EQ-5D and EQ-VAS, ICC values of 4.92% and 8.26% were observed respectively. Country grouping explained 8.44% and 5.67% in the variation of PCS-12 and MCS-12 scores respectively.

[insert table 2 somewhere here]

Reliability

The overall Cronbach's alpha for the EQ-5D self-classifier equals 0.73, indicating an acceptable internal consistency of the measure (see table 3). The variation between countries ranged between 0.58 and 0.82. Ten countries had a value < 0.70, indicating less acceptable internal reliability. The SF-12 subscales had

higher Cronbach's alpha values with an overall value of 0.87 and 0.84 for PCS-12 and MCS-12 respectively. Country-specific values for PCS-12 ranged between 0.81 and 0.90, indicating good to excellent internal consistency. For MCS-12, Cronbach's alpha values ranged between 0.74 and 0.89, indicating acceptable to good internal consistency. In addition, for both HADS-scales satisfying values were found overall, with a value of 0.82 and 0.74 for HADS-A and HADS-D respectively. For HADS-A Cronbach's alpha ranged between 0.73 and 0.86, for HADS-D, values fluctuated between 0.52 and 0.82, with only 2 countries (Germany and Latvia) having a value <0.7.

[insert table 3 somewhere here]

Validity

CFA of the HADS 2-factor model suggested a good construct validity with the observed data fitting well with the theoretical model. The Bentler's CFI, TLI and RMSEA (0.96, 0.96 and 0.06 respectively), indicated a good fit and factor loadings >0.55 were found, representing a good correlation between observed variables and extracted components. The CFA of the SF-12 allowed for covariations between the error of the items that belong to one overall question (2a and 2b; 3a and 3b; 4a and 4b; 6a, 6b and 6c). Again, Bentler's CFI, TLI and RMSEA indices indicated acceptable to good fit (0.98, 0.98 and 0.09 resp.) and good correlation between observed variables and extracted components was seen with factor loadings ranging between 0.55 and 0.83.

Known-group discriminative validity analyses confirmed that all QoL measures distinguished well between patient groups with a different age, gender or educational level (Table 2). Male patients had significantly lower HADS-A and HADS-D scores, and higher EQ-5D_{index}, EQ-VAS, PCS-12 and MSC-12 scores compared to females. Significant differences for all measures were found between all three educational levels, with lower QoL values in lower educated patients. Higher anxiety, lower depression, higher EQ-

5D_{index}, EQ-VAS, PCS-12 and MCS-12 were found in younger patients compared to the older ones. On country-specific level, the above reported results were roughly similar.

A correlation matrix for the different constructs or items can be found in Table 4. All theoretically hypothesized correlations were confirmed. There was a strong correlation among the mental health scores HADS-A, HADS-D and MCS-12. Also the overall health score EQ-5D_{index} correlated strongly with PCS-12 and moderately with MCS-12. Criterion validity was confirmed for PCS-12, MCS-12 and EQ-5D_{index} given the correlations with EQ-VAS as criterion for overall health perception. Likewise, EQ-5D_{index} and EQ-VAS showed good correlations with the overall health criterion SF12-1. Both HADS-A and HADS-D correlated moderate to strong with the individual mental health items EQ-5D anxiety/depression and SF12-6c.

[insert table 4 somewhere here]

Discussion

Psychometric evaluations of the HADS, EQ-5D and SF12-v2 measures were performed in this study. Our study has the advantage that it comprises data on 8,745 coronary patients, spread over 22 European countries. This is, to our knowledge the largest study assessing the psychometric aspects of 3 different QoL questionnaires in a coronary population. Patients included were stable coronary patients, suffering from an event 6 months to 3 years prior to the interview. Data collection was organized in a standardized way by trained research staff, making the data suitable to compare across patients and countries. Coding of the data and data analyses were performed in a systematic way. Previous studies often included analyses on only 1 single measure and in 1 specific region or country (14;15;33-35).

Overall, favorable results were found, supporting the use of these QoL measures in a European coronary population. Internal consistency was confirmed for all the QoL measures with good to excellent Cronbach's alpha values for the PCS-12 scale, and moderate to good values for the MCS-12 scale and

both HADS-scales, across all 22 countries. EQ-5D Cronbach's alpha values were somewhat lower with about half of the countries having a value slightly below 0.70, this is possibly due to the heterogeneity of the questionnaire. In addition, the Cronbach's alpha is sensitive to the number of items, with a tendency to have a smaller value for scales with a limited number of items (36).

A good construct validity was shown for HADS and SF12v2. For both HADS and SF-12 the TLI and CFI showed good fit. The RMSEA showed good fit for HADS and a borderline acceptable fit for SF12. In addition, high factor loadings were observed, indicating a good correlation between observed variables and extracted components for both measures.

Discriminative validity of all the QoL measures was confirmed. Higher QoL values as well as lower depression and anxiety scores were observed in men compared to women. These results support the findings previously reported in the literature (8;37-41). Likewise, in agreement with published papers, our study confirmed QoL differences between groups with different educational levels, with higher EQ-VAS, PCS-12 and MCS-12 scores among higher educated ones (34). As expected anxiety and depression scores were higher for the lower educated ones. In addition, it was shown that across all groups, age significantly influenced the perceived QoL. In general, younger persons had a higher anxiety score but a lower depression score. This is in line with the results reported by Spinhoven *et al.* (1997) (42). Likewise, Hinz *et al.* (2011) reported similar results, with lower anxiety scores for older patients (39). In contrast, as confirmed in the literature, older patients had lower EQ-5D_{index}, EQ-VAS, PCS-12 and MCS-12 scores (37;40).

Convergent validity was supported by the correlations found between the different constructs for which an association was theoretically expected. Moderate to strong correlations were observed between the SF-12 constructs and the EQ-5D_{index} and EQ-VAS scores. Strengths were similar to the ones reported by

Johnson and Pickard (2000) (40). Likewise a strong correlation was seen among both HADS-scales and MCS-12.

The strong correlation between SF12-1 and both the EQ-5D_{index} and EQ-VAS confirmed good criterion validity for EQ-5D_{index} and EQ-VAS. A similar correlation was seen in 2 previously published papers (33;35). Furthermore the EQ-VAS correlates well with the EQ-5D_{index} and PCS-12 and moderate with MCS-12. Correlations reported by Ellis *et al.* (2005), between EQ-VAS and the physical and mental component of SF-8 (a derivate from SF-36) were slightly higher (0.77 and 0.55 resp.) (33). The EQ-5D_{index} anxiety component and the SF12-6c as criterion for anxiety and depression, correlated well with both HADS-scales.

The main limitation of the EUROASPIRE study is its cross-sectional design, making it impossible to compare QoL outcomes over a given period of time and to test responsiveness and test-retest reliability. In addition patients are not a representative sample of all patients with CHD in each country, since they were identified from selected geographical areas and cardiac centers (Kotseva 2009).

While the EQ-5D gives an overall view on a person's general health, the SF-12v2 clearly distinguishes between mental and physical health. Both measures can be used at any given time, whereas HADS is intended for use in the hospital setting, useful in screening for anxiety and depressive feelings in patients. In order to have an in-depth insight in a patient's QoL, it is advised to use a combination of general (e.g. EQ-5D, SF-12v2), domain specific (e.g. HADS) and disease specific (e.g. McNew, Seattle Angina Questionnaire) QoL measures, and not to restrict to the use of a single instrument. The integrated HeartQoL, a coronary heart disease-specific, health-related QoL questionnaire, might be a good alternative (43).

In conclusion, the results observed in our study confirm the validity and reliability of the EQ-5D, the SF-12v2 and the HADS for use in a stable coronary population, both on aggregate European level as on

country-specific level. However, our results must be generalized with caution, because EUROASPIRE III patients might not be representative for all patients with stable coronary heart disease.

Acknowledgment

The authors thank the administrative staff, physicians, nurses, and other personnel at the hospitals in which the study was carried out, and all the patients who participated in the EUROASPIRE studies.

Unrestricted educational grants to the European Society of Cardiology were obtained from AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, Sanofi-Aventis, Servier, Merck/Schering-Plough, Novartis.

Reference List

- (1) Allender S, Scarborough P, Peto V, Rayner M, Leal L, Lueng-Fernandez R, et al. European Cardiovascular Disease Statistics. 2008.
- (2) Leal J, Luengo-Fernandez R, Gray A, Petersen S, Rayner M. Economic burden of cardiovascular diseases in the enlarged European Union. *Eur Heart J* 2006;27(13):1610-9.
- (3) Celano CM, Huffman JC. Depression and cardiac disease: a review. *Cardiol Rev* 2011;19(3):130-42.
- (4) Cepeda-Valery B, Cheong AP, Lee A, Yan BP. Measuring health related quality of life in coronary heart disease: the importance of feeling well. *Int J Cardiol* 2011;149(1):4-9.
- (5) Dyer MT, Goldsmith KA, Sharples LS, Buxton MJ. A review of health utilities using the EQ-5D in studies of cardiovascular disease. *Health Qual Life Outcomes* 2010;8:13.
- (6) Mols F, Pelle AJ, Kupper N. Normative data of the SF-12 health survey with validation using postmyocardial infarction patients in the Dutch population. *Qual Life Res* 2009;18(4):403-14.
- (7) Thombs BD, Bass EB, Ford DE, Stewart KJ, Tsilidis KK, Patel U, et al. Prevalence of depression in survivors of acute myocardial infarction. *J Gen Intern Med* 2006;21(1):30-8.
- (8) Xie J, Wu EQ, Zheng ZJ, Sullivan PW, Zhan L, Labarthe DR. Patient-reported health status in coronary heart disease in the United States: age, sex, racial, and ethnic differences. *Circulation* 2008;118(5):491-7.
- (9) Nicholson A, Kuper H, Hemingway H. Depression as an aetiologic and prognostic factor in coronary heart disease: a meta-analysis of 6362 events among 146 538 participants in 54 observational studies. *Eur Heart J* 2006;27(23):2763-74.
- (10) Meijer A, Conradi HJ, Bos EH, Thombs BD, van Melle JP, de JP. Prognostic association of depression following myocardial infarction with mortality and cardiovascular events: a meta-analysis of 25 years of research. *Gen Hosp Psychiatry* 2011;33(3):203-16.
- (11) Roest AM, Martens EJ, Denollet J, de JP. Prognostic association of anxiety post myocardial infarction with mortality and new cardiac events: a meta-analysis. *Psychosom Med* 2010;72(6):563-9.
- (12) DeSalvo KB, Bloser N, Reynolds K, He J, Muntner P. Mortality prediction with a single general self-rated health question. A meta-analysis. *J Gen Intern Med* 2006;21(3):267-75.
- (13) Burstrom B, Fredlund P. Self rated health: Is it as good a predictor of subsequent mortality among adults in lower as well as in higher social classes? *J Epidemiol Community Health* 2001;55(11):836-40.
- (14) Cosco TD, Doyle F, Ward M, McGee H. Latent structure of the Hospital Anxiety And Depression Scale: a 10-year systematic review. *J Psychosom Res* 2012;72(3):180-4.

- (15) Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res* 2002;52(2):69-77.
- (16) Coons SJ, Rao S, Keininger DL, Hays RD. A comparative review of generic quality-of-life instruments. *Pharmacoeconomics* 2000;17(1):13-35.
- (17) Haywood KL, Garratt AM, Fitzpatrick R. Quality of life in older people: a structured review of generic self-assessed health instruments. *Qual Life Res* 2005;14(7):1651-68.
- (18) EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy* 1990;16(3):199-208.
- (19) Rabin R, Oemar M, Oppe M. User Guide: Basic information on how to use EQ-5D-3L instrument. 2011.
- (20) Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33.
- (21) Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67(6):361-70.
- (22) Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33(5):337-43.
- (23) Kotseva K, Wood D, De BG, De BD, Pyorala K, Keil U. EUROASPIRE III: a survey on the lifestyle, risk factors and use of cardioprotective drug therapies in coronary patients from 22 European countries. *Eur J Cardiovasc Prev Rehabil* 2009;16(2):121-37.
- (24) Dolan P. Modeling valuations for EuroQol health states. *Med Care* 1997;35(11):1095-108.
- (25) Ware J, Kosinski M, Turner-Bowker D, Gandek B. How to Score Version 2 of the SF-12 Health Survey. Lincoln, RI: QualityMetric Incorporated; 2002.
- (26) Stafford L, Berk M, Jackson HJ. Validity of the Hospital Anxiety and Depression Scale and Patient Health Questionnaire-9 to screen for depression in patients with coronary artery disease. *Gen Hosp Psychiatry* 2007;29(5):417-24.
- (27) Hays RD, Anderson R, Revicki D. Psychometric considerations in evaluating health-related quality of life measures. *Qual Life Res* 1993;2(6):441-9.
- (28) Nunnally JC, Bernstein IH. *Psychometric theory*. 3rd ed ed. New York: McGraw-Hill; 1994.
- (29) Hu L, Bentler P. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modeling* 1999;6(1):1-55.
- (30) Bentler P, Bonett D. Significance tests and goodness of fit in the analysis of covariance structures. *Psychological Bulletin* 1980;88:588-606.
- (31) Brown M, Cudeck R. Alternative ways of assessing model fit. *Sociological Methods and Research* 1992;21:-230.

- (32) Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed ed. Hillsdale, N.J: L. Erlbaum Associates; 1988.
- (33) Ellis JJ, Eagle KA, Kline-Rogers EM, Erickson SR. Validation of the EQ-5D in patients with a history of acute coronary syndrome. *Curr Med Res Opin* 2005;21(8):1209-16.
- (34) Failde I, Medina P, Ramirez C, Arana R. Construct and criterion validity of the SF-12 health questionnaire in patients with acute myocardial infarction and unstable angina. *J Eval Clin Pract* 2010;16(3):569-73.
- (35) Schweikert B, Hahmann H, Leidl R. Validation of the EuroQoL questionnaire in cardiac rehabilitation. *Heart* 2006;92(1):62-7.
- (36) Pallant J. SPSS survival manual: a step by step guide to data analysis using SPSS for Windows. 4th ed ed. Crows Nest, N.S.W: Allen & Unwin; 2011.
- (37) Berg J, Lindgren P, Nieuwlaat R, Bouin O, Crijs H. Factors determining utility measured with the EQ-5D in patients with atrial fibrillation. *Qual Life Res* 2010;19(3):381-90.
- (38) Cherepanov D, Palta M, Fryback DG, Robert SA. Gender differences in health-related quality-of-life are partly explained by sociodemographic and socioeconomic variation between adult men and women in the US: evidence from four US nationally representative data sets. *Qual Life Res* 2010;19(8):1115-24.
- (39) Hinz A, Braehler E. Normative values for the hospital anxiety and depression scale (HADS) in the general German population. *J Psychosom Res* 2011;71(2):74-8.
- (40) Johnson JA, Pickard AS. Comparison of the EQ-5D and SF-12 health surveys in a general population survey in Alberta, Canada. *Med Care* 2000;38(1):115-21.
- (41) Norris CM, Spertus JA, Jensen L, Johnson J, Hegadoren KM, Ghali WA. Sex and gender discrepancies in health-related quality of life outcomes among patients with established coronary artery disease. *Circ Cardiovasc Qual Outcomes* 2008;1(2):123-30.
- (42) Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. *Psychol Med* 1997;27(2):363-70.
- (43) Oldridge N, Saner H, McGee HM. The Euro Cardio-QoL Project. An international study to develop a core heart disease health-related quality of life questionnaire, the HeartQoL. *Eur J Cardiovasc Prev Rehabil* 2005;12(2):87-94.

Table 1: Patient characteristics of the EUROASPIRE population

	Number of patients	Gender (%male)	Age (mean \pm SD)	Education level		
				Primary education (%)	Secondary education (%)	High education (%)
All Countries	8745	74.6	63.2 \pm 9.5	25.3	56.7	18.0
Belgium	281	85.4	62.4 \pm 8.8	16.3	61.6	22.1
Bulgaria	538	69.5	64.8 \pm 10.4	3.6	63.1	33.3
Cyprus	434	87.3	61.1 \pm 9.3	41.3	42.1	16.6
Czech Rep.	475	79.2	62.9 \pm 8.6	3.0	80.3	16.7
Germany	550	79.3	63.7 \pm 9.1	6.4	80.0	13.6
Spain	505	74.7	62.0 \pm 9.7	70.3	23.9	5.8
Finland	237	66.7	66.2 \pm 9.9	17.7	76.4	5.9
France	303	78.3	62.2 \pm 10.4	44.9	45.9	9.2
UK	322	73.6	63.0 \pm 9.8	8.5	66.3	25.2
Greece	120	88.3	62.4 \pm 9.6	33.3	37.5	29.2
Croatia	450	77.1	61.2 \pm 9.3	22.9	60.7	16.4
Hungary	457	58.0	63.8 \pm 8.5	23.9	49.6	26.5
Ireland	385	76.9	62.5 \pm 9.6	59.7	34.8	5.5
Italy	377	79.3	65.2 \pm 9.1	39.9	53.2	6.9
Lithuania	509	77.8	63.0 \pm 8.8	8.5	60.8	30.7
Latvia	519	65.7	66.2 \pm 8.4	17.6	60.2	22.2
Netherlands	223	81.6	64.8 \pm 8.9	26.3	67.2	6.5
Poland	502	69.9	62.6 \pm 8.8	32.3	50.0	17.7
Romania	521	72.6	61.7 \pm 9.8	10.4	74.4	15.2
Russia	409	64.3	64.9 \pm 10.1	7.8	54.1	38.1
Slovenia	293	73.0	64.8 \pm 9.7	32.1	57.7	10.2
Turkey	335	80.6	59.8 \pm 10.1	56.7	31.4	11.9

Table 2: Mean values of the QoL constructs

	HADS-A	HADS-D	EQ-5D _{index}	EQ-VAS	PCS-12	MCS-12
All Countries	5.93	5.08	0.76	65.66	42.14	49.15
Belgium	5.91	4.99	0.82	72.53	45.13	49.25
Bulgaria	6.74	5.92	0.77	63.26	42.16	50.31
Cyprus	4.68	3.68	0.81	69.97	47.49	52.85
Czech Rep.	4.59	4.89	0.76	65.40	41.41	49.58
Germany	5.29	5.64	0.76	67.66	42.47	51.37
Spain	7.09	5.29	0.73	66.75	39.39	46.42
Finland	4.87	4.32	0.78	74.03	38.01	53.62
France	6.59	5.61	0.71	66.66	41.63	44.42
UK	6.16	4.47	0.71	73.34	41.93	49.36
Greece	6.44	4.90	0.80	68.85	46.51	50.82
Croatia	6.64	5.22	0.73	63.74	41.21	48.21
Hungary	6.66	5.45	0.70	66.30	-	-
Ireland	5.64	3.26	0.81	73.60	45.37	51.91
Italy	5.10	4.23	0.86	75.08	47.08	51.43
Lithuania	6.03	4.85	0.74	58.93	38.70	48.69
Latvia	4.30	4.65	0.84	55.52	43.93	50.42
Netherlands	4.28	3.40	0.85	75.74	47.08	52.77
Poland	7.21	5.65	0.73	60.75	38.78	46.37
Romania	5.78	4.86	0.75	69.32	41.13	49.39
Russia	7.18	6.67	0.65	59.51	36.74	45.85
Slovenia	7.01	6.49	0.66	62.93	40.21	46.91
Turkey	5.96	6.01	0.77	69.13	45.73	44.08
Significance	*	*	*	*	*	*
Gender						
Men	5.48	4.75	0.78	67.85	43.20	49.93
Women	7.24	6.01	0.69	62.22	38.82	46.75
Significance	*	*	*	*	*	*
Age						
<50 year	6.35	4.42	0.81	71.43	45.59	48.84
50-59 years	6.12	4.73	0.77	67.48	43.31	48.94
60-69 years	5.71	5.05	0.76	66.72	42.16	49.57
>70 years	5.89	5.70	0.72	63.03	39.56	48.90
Significance	*	*	*	*	*	*
Education level						
Primary education	6.55	5.61	0.72	64.87	40.95	47.98
Secondary education	5.85	5.04	0.76	66.44	41.95	49.27
High education	5.31	4.40	0.80	68.32	44.28	50.44
Significance	*	*	*	*	*	*

* Kruskal Wallis p value <0.0001

Table 3: Internal consistency

	Cronbach's alpha				
	<i>EQ-5D index</i>	<i>SF-12 PCS</i>	<i>SF-12 MCS</i>	<i>HADS-A</i>	<i>HADS-D</i>
All Countries	0.73	0.87	0.84	0.82	0.74
Belgium	0.68	0.88	0.87	0.77	0.80
Bulgaria	0.76	0.90	0.88	0.84	0.78
Cyprus	0.67	0.85	0.84	0.83	0.77
Czech Rep.	0.68	0.85	0.79	0.84	0.78
Germany	0.67	-	-	0.80	0.52
Spain	0.72	0.84	0.87	0.81	0.82
Finland	0.67	0.88	0.82	0.77	0.72
France	0.67	0.86	0.87	0.83	0.77
UK	0.80	0.89	0.87	0.86	0.82
Greece	0.75	0.86	0.89	0.79	0.76
Croatia	0.75	0.87	0.84	0.82	0.77
Hungary	0.71	-	-	0.84	0.80
Ireland	0.67	0.86	0.80	0.81	0.72
Italy	0.76	0.89	0.89	0.77	0.75
Lithuania	0.66	0.87	0.80	0.77	0.70
Latvia	0.58	0.84	0.74	0.73	0.62
Netherlands	0.68	0.87	0.85	0.80	0.77
Poland	0.73	0.84	0.82	0.82	0.72
Romania	0.73	0.81	0.81	0.85	0.76
Russia	0.74	0.88	0.85	0.79	0.70
Slovenia	0.80	0.84	0.89	0.80	0.74
Turkey	0.82	0.87	0.81	0.84	0.81

Table 4: Correlation between domains

	HADS-D	EQ-5D _{index}	EQ-5D anx/depr	EQVAS	PCS-12	MCS-12	SF12-1	SF12-6c
HADS-A	0.60(0.36 to 0.73)	-0.51(-0.31 to -0.61)	0.57(0.24 to 0.67)	-0.36(-0.13 to -0.53)	-0.34(-0.16 to -0.47)	-0.59(-0.31 to -0.71)	0.36(0.11 to 0.52)	-0.58 (-0.32 to -0.70)
HADS-D		-0.51(-0.22 to -0.63)	0.45(0.24 to 0.56)	-0.45(-0.14 to -0.57)	-0.41(-0.13 to -0.56)	-0.57(-0.22 to -0.69)	0.44(0.26 to 0.56)	-0.51(-0.13 to -0.63)
EQ-5D _{index}			-0.62(-0.44 to -0.81)	0.53(0.34 to 0.97)	0.64(0.48 to 0.72)	0.47(0.20 to 0.61)	-0.51(-0.33 to -0.63)	0.50(0.32 to 0.56)
EQ-5D anx/depr				-0.34(-0.25 to -0.42)	-0.26(-0.10 to -0.39)	-0.54(-0.42 to -0.63)	0.31(0.16 to 0.46)	-0.55(-0.47 to -0.66)
EQVS					0.55(0.35 to 0.67)	0.41(0.23 to 0.57)	-0.60(-0.48 to -0.73)	0.38(0.24 to 0.47)
PCS-12						0.19(-0.14 to 0.44)	-0.68(-0.51 to -0.75)	0.29(0.07 to 0.35)
MCS-12							-0.38(-0.15 to -0.57)	0.76(0.63 to 0.86)
SF12-1								-0.38(-0.24 to -0.47)

EQ-5D anx/depr: EQ-5D Anxiety/Depression

All correlations are significant (p< 0.05)