Is EQ-5D a valid quality of life instrument in patients with acute coronary syndrome?

EQ-5D akut koroner sendromlu hastalarda geçerli bir yaşam kalitesi ölçeği midir?

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ABSTRACT

Objective: To evaluate the construct validity of the Turkish version of the EQ-5D in patients with acute coronary syndrome.
Methods: The study was conducted as a cross-sectional study at the Trakya University Hospital between February and May 2008. All patients completed the Turkish version of the EQ-5D and MacNew heart-related quality of life scale. Construct validity of the EQ-5D was assessed according to relationships with MacNew subscales by using Spearman rank correlation and multiple linear regression analyses.
Results: One hundred and twenty-two patients responded to the instruments. Mean age was 62.9±9.3 years and male gender (88 or 72.1%) was dominant. Mean score of the EQ-5D index was 0.79±0.32, while the global score of MacNew was 5.01±1.16. The correlation coefficients of the EQ-5D index score with the MacNew subscales ranged from 0.557 to 0.721, with EQ-5D VAS score ranging from 0.297 to 0.484 ($p<0.001$ for all of them). According to the stepwise regression model MacNew global score was found to be significantly effective factor on EQ-5D index score (β=0.188; 95% CI: 0.152-0.224; $p<0.001$).
Conclusion: The Turkish version of the EQ-5D-based utility score seems to be a valid instrument in the assessment of quality of life studies in patients with acute coronary syndrome. *(Anadolu Kardiyol Derg 2011; 2: 156-62)*
Key words: Quality of life, acute coronary syndrome, validation, EQ-5D instrument, MacNew score

ÖZET

Amaç: Çalışmanın amacı, akut koroner sendromlu hastalarda yaşam kalitesini ölçmek için EQ-5D genel yaşam kalite ölçeğinin Türkçe versiyonunun kullanılıp kullanılamayacağını belirlemektir.
Yöntemler: Araştırma Şubat-Mayıs 2008 tarihleri arasında Trakya Üniversitesi Tıp Fakültesi Hastanesi Kardiyoloji servisi ve polikliniğinde akut koroner sendrom tanısı konulan 122 hasta üzerinde yürütülen kesitsel çalışmadır. Hastalardan elde edilen veriler EQ-5D genel yaşam kalite ölçeği, MacNew kalp hastalığına özgü yaşam kalite ölçeği ve demografik-klinik verileri kapsayan bir anket formu kullanılarak toplandı. EQ-5D ölçeğinin geçerliliği, MacNew kalp hastalığına özgü yaşam kalitesi ölçeğiyle ilişkisine göre Spearman korelasyon analizi ve çoklu doğrusal regresyon analizi kullanılarak değerlendirildi.
Bulgular: Çalışmada kullanılan ölçekleri 122 hasta cevapladı. Hastaların yaş ortalaması 62.9±9.3 idi ve çoğunluğunu (88 veya %72.1) erkekler oluşturmaktaydı. EQ-5D indeks skor ortalaması 0.79±0.32, MacNew global skor ortalaması 5.01±1.16 olarak bulundu. MacNew kalp hastalığına özgü yaşam kalitesi ölçeğinin alt boyutları ve toplam skoru ile EQ-5D indeks skor arasında 0.557 ile 0.721 arasında değişen, EQ-5D VAS skor arasında 0.297 ile 0.484 arasında değişen pozitif yönde istatistiksel anlamlı ($p<0.001$) korelasyon katsayıları saptandı. Adımsal regresyon modeline göre MacNew global skor EQ-5D indeks skor üzerine etki eden önemli faktör olarak bulundu (β=0.188 ; %95GA: 0.152-0.224; $p<0.001$).
Sonuç: EQ-5D ölçeğinin, Türkçe versiyonu akut koroner sendromlu hastalarda yaşam kalitesinin değerlendirilmesinde geçerli bir ölçektir.
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Anahtar kelimeler: Yaşam kalitesi, akut koroner sendrom, geçerlilik, EQ-5D ölçeği, MacNew ölçeği

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Introduction

Coronary heart disease (CHD) is the leading cause of death in Turkey and worldwide (1). Acute coronary syndromes (ACSs) are very common and life-threatening consequences of CHD. They occur when blood flow in a coronary artery is blocked by a blood clot which reduces oxygen supply to the heart. ACSs include unstable angina, acute myocardial infarction (MI), or sudden cardiac death.

Prevalence

The prevalence of CHD in Turkish adults aged 35 to 64 has been estimated at 5.8% in men and 5% in women and is predicted to rise rapidly (2-4). The estimated prevalence of CHD for those aged 40 to 59 has been estimated at 7.8% in men and 5.5% in women in the United States (5). The estimated prevalence of CHD in England was 6.5% in men and 4.0% in women according to data from the 2006 Health Survey for England (6).

Quality of life

Health related quality of life (HRQoL) assessment is an increasingly important aspect of contemporary medical practice. It can be measured by general and/or disease-specific instruments. One of the general health state instruments is the EQ-5D scale (7, 8). It is a generic, HRQoL instrument for use as a measure of health outcomes. An international team, the European Quality of Life Group, developed it in 1987. The EQ-5D was first published in 1990, and its five dimensions have remained unchanged since 1991 (8). The validity of the EQ-5D has been assessed within a number of different patient groups and within the general population in different countries; however, validation of a Turkish version in patients with ACS has not been examined up to now.

Health-related quality of life measurement in patients with ACS is difficult to define. There are several disease-specific instruments to determine HRQoL for ACS, such as the MacNew heart disease quality of life instrument, the Canadian Cardiovascular Society (CCS) angina severity class, treadmill exercise time (ETT), and scales of the Seattle Angina Questionnaire (SAQ). Among these, Turkish validity and reliability was reported only for the MacNew heart disease scale in patients with angina by Daşkapan et al. (9). Therefore, we used the MacNew heart disease scale in order to determine quality of life in patients with ACS.

The main purpose of this study was to examine the validity of the EQ-5D scale in routine clinical practices in patients with ACS as compared to the MacNew Heart Disease Quality of Life instrument. We hypothesized that as the disease severity worsens, the EQ-5D utility score also worsens.

Methods

Patients

The study was conducted as a cross-sectional study at the Trakya University Hospital between February 2008 and May 2008. One hundred and twenty-two consecutive patients with ACS were included in the study. The patients were divided into two clinical subgroups: (i) myocardial infarction (n=55) and (ii) unstable angina pectoris (n=67) according to the primary clinical problem at the time of the study. The patients responded to the EQ-D5 scale and the MacNew heart related quality of life scales in face-to-face interviews. The consents of the patients were obtained. The local Ethics Committee approved protocol of this study.

Construct validity

The validity of an instrument is the extent to which it measures what it claims to measure. It can be defined and assessed several ways. One of the ways is construct validity. It is an ongoing process whereby hypothetical constructs are tested (10). In other words, it is an assessment of the degree to which an instrument measures the construct that it was designed to measure. It involves first forming a hypothetical model describing the constructs being assessed and postulating their relationships. Data are then collected, and an assessment is made as to the degree to which these relationships are confirmed. If the results confirm prior expectations about the constructs, the implication is that the instrument may be valid and that we may therefore use it to make inferences about patients (11). In our study, construct validity was measured by assessing the ability of the instrument to distinguish between patients with lesser and more severe health-related problems.

The EQ-5D health-related quality of life instrument

The EQ-5D is a generic instrument used for measuring HRQoL. It comprises the EQ-5D index scale and the EQ-5D visual analogue scale (VAS). The EQ-5D index scale currently comprises a questionnaire with five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension of the EQ-5D is divided into three degrees of severity as “no problem,” “some problems,” or “major problems” (8). A single index score can be produced using information from these five dimensions. The EQ-5D index score range from -0.59 to 1 and includes a worse than death measure (negative score), outside the range of 0 (dead) to 1 (perfect health). The EQ-5D index score can be used to calculate so-called Quality Adjusted Life Years (QALY) where 1 QALY (EQ-5D utility score =1) is the equivalent of one year spent in perfect health. The EQ-5D VAS scale is a 20-cm visual analogue scale where the respondent is asked to mark his or her own current state of health on a thermometer-like line calibrated from 0 to 100 (8). Currently there are 60 official language versions of EQ-5D (12). One of them is the Turkish version of EQ-5D, which was obtained from EuroQol (www.euroqol.org) and used in our study.

The MacNew heart disease quality of life instrument

The MacNew Heart Disease Quality of Life Questionnaire is designed to evaluate quality of life in heart diseases. It is simple to administer and well-accepted by patients. Normative data are

available for patients with myocardial infarction, angina pectoris, and heart failure (9). It has been shown to be valid, reliable, and responsive. The MacNew scale has been translated into more than 20 languages (13) including Turkish by Daşkapan et al. (9).

The MacNew scale is designed to assess patients' feelings about how heart disease affects daily physical activities and emotional and social functioning in a 2-week timeframe. It consists of 27 items which fall into three domains (physical limitations, emotional, and social function) with a global HRQoL score (9, 14, 15). Domain scores are calculated by taking the average of the responses to the items in each domain. Possible scores range from 1 to 7, with a higher score indicating a better HRQoL.

Statistical analysis

The Statistica 7.0 (StatSoft Inc., Tulsa, OK, USA) statistical package was used for statistical analysis. Based on the previous report (16), the correlation coefficient between the EQ-5D and MacNew scale was reported as 0.52. We based on this coefficient with an alternative minimum correlation coefficient of 0.35 with an alpha error of 5% and power of 95%. Sample size was calculated as 100 patients however, we included 122 patients in the study that considered probable missing data.

Results are expressed as mean±SD or number (percentage). Normality distribution of the variables was tested by the One Sample Kolmogorov-Smirnov test. The Spearman rank correlation coefficients of the EQ-5D index and VAS score with MacNew subscale scores were calculated. The effect of the MacNew subscale scores on the EQ-5D index score was assessed by linear regression analysis. Internal consistency reliability of the scales was assessed by calculating Cronbach's alpha coefficient. A p-value of <0.05 was considered statistically significant.

Results

Of 138 consecutive patients 16 (11 male/5 female) did not agree to respond to the scales. We studied 122 patients (88 male/34 female). Socio-demographic and clinical characteristics of all patients are shown in Table 1. The mean age was found to be 62.9±9.3 years.

Frequency distribution of the EQ-5D scale is shown in Table 2. As shown in Table 2, most of the patients had reported "no problem" for all domains. However, 5-10% of the patients reported "extreme problems."

Scores of the EQ-5D index, VAS, and MacNew subscales are shown in Table 3. Mean EQ-5D index and VAS scores were 0.79 and 66.9%, respectively. Mean scores of MacNew subscales ranged from 4.96 to 5.16, in which the physical subscale had the highest score, while the emotional subscale had the lowest score.

Cronbach-α coefficients of EQ-5D and MacNew scales are shown in Table 4. Cronbach's coefficient α coefficients were found as 0.860 for the EQ-5D scale and ranged from 0.867 to 0.936 for the MacNew subscale, showing good reliability.

The correlation coefficients of the EQ-5D index and VAS scores with the MacNew subscales are shown in Table 5. The correlation coefficients of the MacNew subscales with EQ-5D index score ranged from 0.557 to 0.721, with EQ-5D VAS scores ranging from 0.297 to 0.484 ($p<0.001$ for all of them). The graphical representations of the rank correlations are shown in Figures 1-2. The EQ-5D index and VAS scores increased while the MacNew subscale scores increased.

The effect of the MacNew subscale on the EQ-5D index score using multiple regression analysis with enter and backward stepwise methods are shown in Table 6. Adjusted R^2 of the models were found to be 46.4% and 45.6%, respectively. According to the stepwise regression model, MacNew global score was found to be significantly effective factor on EQ-5D index score (β=0.188; 95% CI: 0.152 – 0.224; $p<0.001$).

Table 1. Demographic-clinical characteristics of patients with acute coronary syndrome

Variables	Total (n=122)
Age, years	62.9±9.3
Body mass index, kg/m^2	27.0±3.6
Sex, male, n(%)	88 (72.1)
Marital Status, married, n(%)	106 (86.9)
Working status, n(%)	
Employed	14 (11.5)
Retired	81 (66.4)
Unemployed	27 (22.1)
Education, n(%)	
None	21 (17.2)
Primary school	86 (70.5)
High school	8 (6.6)
University	7 (5.7)
Number of hospitalizations	4.5±3.5
Diagnosis, n(%)	
Angina pectoris	55 (45.1)
Myocardial infarction	67 (54.9)
Co-morbidity, yes, n (%)	60 (49.2)
Family history, yes, n (%)	52 (42.6)

Data are presented as Mean±SD and number (percentage)

Table 2. Frequency distribution of the EQ-5D scale

Variables	No problem	Some problem	Extreme problem
Mobility, n (%)	68 (55.7)	48 (39.3)	6 (4.9)
Self-Care, n (%)	84 (68.9)	31 (25.4)	7 (5.7)
Usual Activities, n (%)	74 (60.7)	40 (32.8)	8 (6.6)
Pain/Discomfort, n (%)	72 (59.0)	40 (32.8)	10 (8.2)
Anxiety/Depression, n (%)	80 (65.6)	34 (27.9)	8 (6.6)

Data are presented as number (percentage)

Discussion

In this study, we sought the validity of the Turkish version of the EQ-5D instrument in patients with ACS. The main findings of this study are: The EQ-5D index score has significant positive correlations with the MacNew subscale scores according to the correlation analysis;Cronbach's α coefficients of EQ-5D and MacNew scales show good reliability.

These findings show that the Turkish version of EQ-5D is a positively valid and reliable generic HRQoL scale in patients with ACS.

The construct validity of an instrument refers to the extent to which it correlates with criteria from an established measure, such as valid disease-specific instruments (7). In the present study we tested the hypothesis that, as quality of life increased using measures of a disease-specific scale (MacNew), health status as measured by the EQ-5D would be increased. The significant correlation coefficients (ranging from 0.557 to 0.721) of EQ-5D index scores with MacNew subscales show the validity of the Turkish version of the EQ-5D scale in patients with ACS. In the work of Schweikert et al. (16), correlation coefficients of EQ-5D with MacNew subscales ranging from 0.527 to 0.798 in patients with ACS were reported. Positive correlations show that the EQ-5D index score increases while the MacNew subscale scores increase. There are many studies in different medical fields regarding comparison of the EQ-5D with generic scales; however, there are few studies regarding comparison of the EQ-5D with disease-specific instruments. In some of these, the correlation coefficients were reported to range from -0.40 to -0.68 in patients with Parkinson's disease (10) and from -0.468 to -0.491 in a heroin-dependent population (17).

Karapolat et al. (18) evaluated quality of life in stable congestive heart failure patients and reported that quality of life decreased while functional status decreased. Vural et al. (19) concluded that ACS patients should be carefully followed and treated for depression and anxiety disorder after ACS treatment to prevent adverse outcomes. Goldsmith et al. (20) reported that the EQ-5D index score decreases as cardiac disease severity increases. We can infer from these reported studies that HRQoL in heart diseases

Table 3. Scores of the EQ-5D and MacNew subscales

Variables	Mean	Standart deviation	Median	Minimum	Maximum
EQ-5D index score	0.79	0.31	0.93	-0.57	1.00
EQ-5D VAS score	66.9	13.9	70.0	20	100
MacNew scale scores					
Emotional	4.96	1.19	5.29	1.50	6.79
Physical	5.16	1.28	5.42	1.62	7.00
Social	5.10	1.27	5.46	1.21	6.71
Global	5.02	1.16	5.31	1.59	6.67

VAS - visual analogue scale

Table 4. Cronbach-α coefficients of EQ-5D and MacNew subscales

Variables	Cronbach alpha (α) coefficient *
EQ-5D scale	0.860
MacNew scale	
Emotional	0.887
Physical	0.878
Social	0.867
Global	0.936

* Reliability analysis

Table 5. Spearman rank correlation coefficients of EQ-5D index and VAS scores with subscales of MacNew

Variables	$EQ\text{-}5D_{index}$ Score (n=122)	EQ-5DVAS Score (n=122)
MacNew Scale		
Emotional	0.644†	0.484†
Physical	0.721†	0.398†
Social	0.557†	0.297†
Global	0.688†	0.438†

Spearman rank correlation analysis; †p<0.001

Table 6. The effect of MacNew subscale on EQ-5D index score using multiple regression analysis

	Enter method			Stepwise method		
Variables	Beta (β)	(95% CI for β)	p	Beta (β)	(95% CI for β)	p
MacNew Scale						
Emotional	0.064	(-0.183-0.310)	0.610	-	-	-
Physical	0.124	(-0.078-0.326)	0.227	-	-	-
Social	-0.037	(-0.168-0.094)	0.578	-	-	-
Global	0.031	(-0.493-0.554)	0.908	0.188	(0.152-0.224)	<0.001
Constant	-0.150	(-0.321-0.066)	0.112	-0.150	(-0.336-0.036)	0.112
Adjusted R^2	46.4%			45.6%		

Multiple linear regression analysis; CI - confidence interval

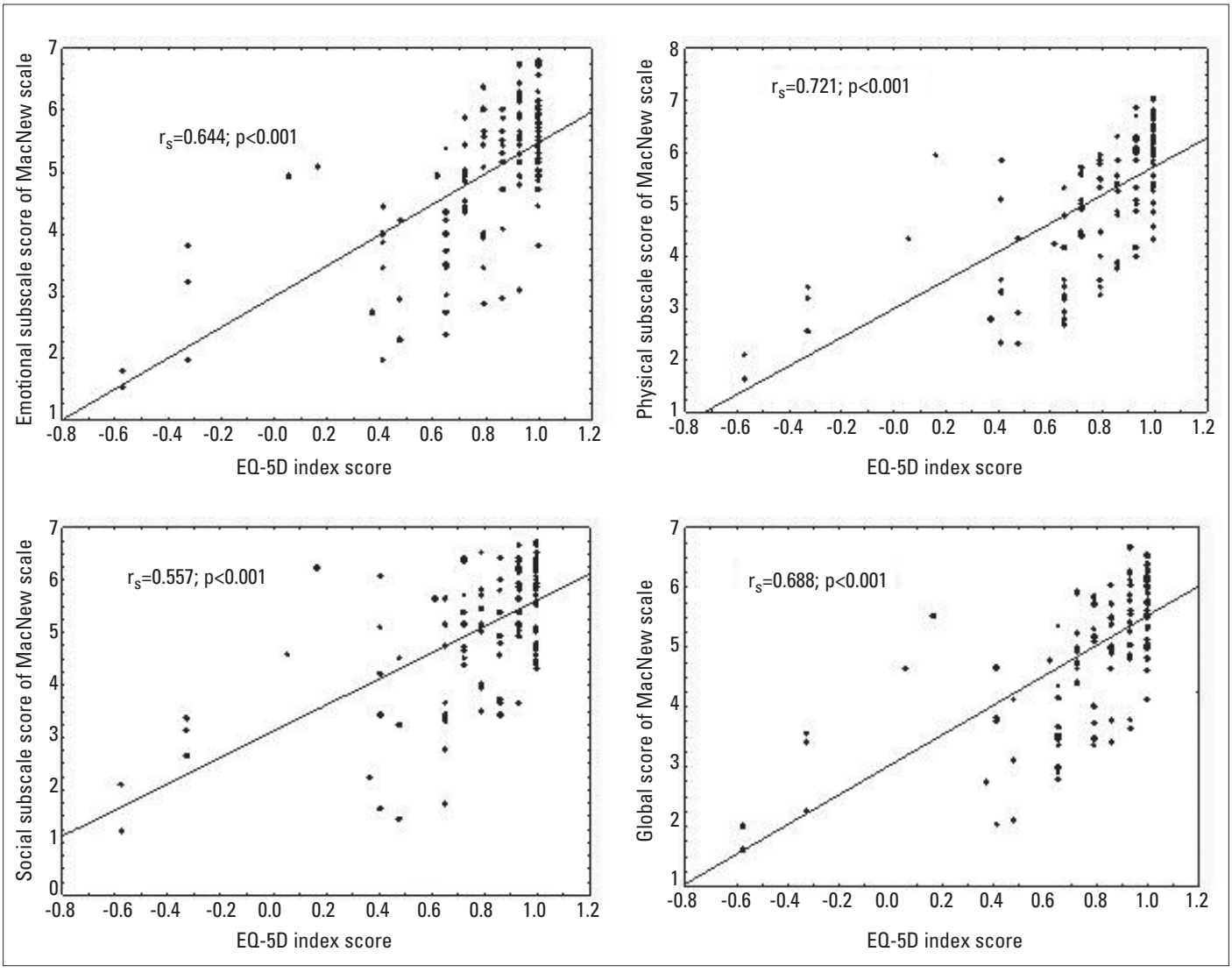

Figure 1. Spearman rank correlation coefficients of EQ-5D index score with subscales of MacNew

decreases while disease severity increases. Our results are similar with the major conclusions of these studies' results.

In the work of Kiessling et al. (21), CHD patients were followed during two years and they were evaluated for quality of life using the EQ-5D scale. The mean EQ-5D index score was reported as 0.76 and the EQ-VAS score was reported as 68%. In our study the mean EQ-5D index and VAS scores were found as 0.79 and 66.9%, respectively. When we compared our quality of life scores (EQ-5D index and VAS) with the work of Kiessling et al. (21), we saw that the scores were quite close to each other.

One of the advantages of EQ-5D is that the questionnaire is short compared to MacNew, and previous studies have shown a higher completion rate (10, 22). In the present study, the MacNew response averaged 12-13 minutes while the EQ-5D response averaged 2-3 minutes. We observed significant correlations between the EQ-5D scale and MacNew subscales; therefore, using EQ-5D instead of MacNew can save time for both patients and researchers, in addition to being easily obtainable. If a study is conducted as a cost-utility analysis, quality-adjusted life year (QALY) is a necessary measurement. The EQ-5D scale, unlike the MacNew disease-specific instrument, produces a utility score. This property of the scale supplies an important advantage, particularly in quantitative quality of life research. Moreover, the utilities can be used as quality weights in order to compute QALY measurement in cost-utility research.

Study limitations

The limitation of the study is that it was conducted as a cross-sectional design, so we cannot provide the test-retest reliability and sensitivity to change (responsiveness) of the EQ-5D. Therefore, additional work must be conducted to determine its usefulness in longitudinal studies.

Conclusion

In conclusion, our study shows that the Turkish version of the EQ-5D is a positively valid and reliable generic HRQoL instrument in a subgroup of patients with ACS. The EQ-5D scale is a short and

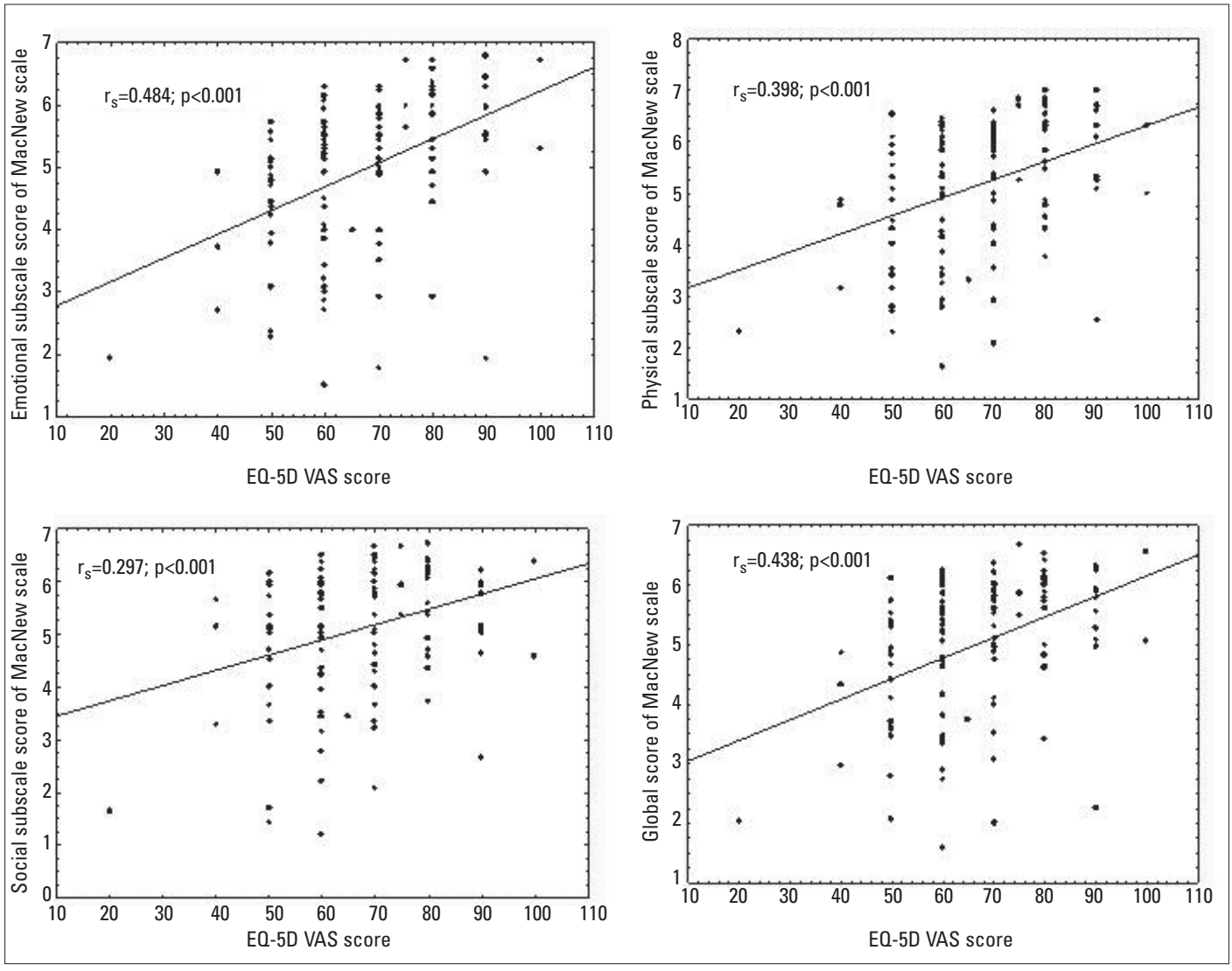

Figure 2. Spearman rank correlation coefficients of EQ-5D VAS (visual analogue scale) score with subscales of MacNew

easy HRQoL instrument compared with the MacNew disease-specific instrument, and many patients can complete it without any assistance. We can suggest the use of the EQ-5D to clinic researchers who are interested HRQoL in patients with ACS.

Conflict of interest: None declared.

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