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Translation and validation of two Chinese health-related quality of life instruments in patients with coronary heart disease

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Key Messages

1. The Chinese version of the 27-item MacNew health-related quality of life (HRQL) questionnaire is a valid, reliable and responsive core coronary heart disease (CHD)–specific HRQL measure. It can be used to compare the health outcomes, burdens of illness, and treatment effectiveness in pure or mixed populations of patients with myocardial infarction, angina, or heart failure in clinical trials and in routine clinical practice.
2. The Chinese version of the 35-item Myocardial Infarction Dimensional Assessment Scale (MIDAS) did not perform as well. Although four of the seven subscales, which cover the physical and psychosocial aspects of HRQL, are psychometrically sound when used to evaluate HRQL among CHD patients with different cardiac diagnostic categories, the remaining three subscales covering treatment-related aspects are not. The latter had only weak validity and responsiveness, which may be due to cultural differences.
3. To improve the overall performance of the Chinese version of the MIDAS, further effort is required to clarify the treatment-related impact of CHD on well being from the patient's perspective.

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Introduction

The prevalence of coronary heart disease (CHD) is increasing in Asia, including Hong Kong and mainland China, where it is a major cause of death and disability.[1] Patients with CHD are typically diagnosed by physician with one or more of three inter-related (but clinically distinct) conditions: myocardial infarction (MI), angina pectoris, or heart failure. This diagnostic conceptualisation has led to important increases in specific treatments with researchers increasingly focusing their attention on comparing the efficacy of one intervention with another among homogeneous groups of patients meeting explicit diagnostic criteria. Comparing the burden of illness and treatment effectiveness for CHD across the spectrum of patients with frequently co-occurring conditions, such as MI, angina pectoris or heart failure, requires a common outcome measure. Yet, a major limitation of existing condition-specific health-related quality of life (HRQL) instruments is that they are not suitable for making comparisons across different CHD diagnoses.

The purpose of this study was to translate the MacNew health-related quality of life questionnaire[2] (MacNew) and the Myocardial Infarction Dimensional Assessment Scale[3] (MIDAS) into Chinese, and to examine their psychometric properties in Chinese patients with differential diagnoses of CHD, including MI, angina pectoris or heart failure.

Methods

Study design
This was a longitudinal study.

Subjects and settings
A convenience sample of 398 patients with evidence of CHD was recruited from the cardiac unit of a regional hospital between December 2004 and February 2006. Of these, 365 (MI: 117; angina: 154; heart failure: 94) completed all the study instruments; 92 of the latter were randomly selected for 7-day post-test assessment with the tested instruments, and the 3-month repeat data collection was completed in 363. The mean age of the patients was 65 (standard deviation, 12) years, with more heart failure patients being older (P=0.009). The male-to-female ratio was lower among patients with heart failure (2:1) than MI or angina (4:1).

Main study instruments
The 27-item C-MacNew and the 35-item C-MIDAS were translated from their original English versions by using Brislin's model of forward and backward translation. Based on a 7-point and 5-point Likert scale, the C-MacNew and the C-MacNew examine CHD disease–specific quality of life in three (physical, emotional, and social) and seven (physical activity, insecurity, emotional reaction, dependency, diet, concerns over medication, side-effects) dimensions, respectively. Previous studies have demonstrated high validity and reliability for both of these instruments.

Table 1. Reliability of Chinese versions of MacNew health-related quality of life questionnaire (C-MacNew) and the Myocardial Infarction Dimensional Assessment Scale (C-MIDAS)

Instruments	Myocardial infarction	Angina	Heart failure
C-MacNew			
Overall scale	0.91	0.94	0.94
Physical	0.86	0.89	0.88
Emotion	0.90	0.92	0.92
Social	0.88	0.91	0.90
C-MIDAS			
Overall scale	0.94	0.95	0.93
Physical activity	0.90	0.92	0.87
Insecurity	0.95	0.94	0.92
Emotional reaction	0.86	0.90	0.88
Dependency	0.78	0.79	0.65
Diet	0.88	0.85	0.90
Concerns over medication	0.79	0.82	0.70
Side-effects	0.70	0.77	0.67

Translation and validation plan

1. The reliability of the C-MacNew and the C-MIDAS was determined by examining their internal consistency and 7-day test-retest reliability with Cronbach's alpha and intraclass correlation coefficient, respectively.
2. Construct validity of the C-MacNew and the C-MIDAS was established by computing their correlations with the Short-Form 36-item Health Survey (SF-36) and the Hospital Anxiety and Depression Scale (HADS). Confirmatory factor analysis was also used to determine whether the C-MacNew and the C-MIDAS conform to the factor structure of their respective original versions.
3. Discriminatory validity was determined by using the logic of 'known-groups' approach, using age, gender, the presence or absence of anxiety and depression according to the HADS score, and perceived health deterioration (according to the health transition item of the SF-36) as discriminative variables.
4. Longitudinal validity was determined by examining the correlations of the changes in the C-MacNew and the C-MIDAS scores with the changes in the SF-36 scores over a 3-month period.
5. Responsiveness of the C-MacNew and the C-MIDAS was determined by computing the effect size and standardised response mean for the changes of scores over a 3-month period.

RESULTS

Reliability

The results suggest good internal consistency for the C-MacNew and the C-MIDAS in measuring HRQL for patients with different cardiac diagnostic categories, though the Cronbach's alphas for the 'side-effects' and 'dependency' subscales of the C-MIDAS were slightly lower than the criterion level in heart failure patients (Table 1). Both the instruments are reproducible, with intraclass correlation coefficient ranged from 0.88-0.93 and 0.72-0.92, respectively.

Validity

The construct validity of the C-MacNew and the C-MIDAS (except the 'diet', 'concerns over medication' and 'side-effects') was supported by their significant moderate-to-strong correlations with both SF-36 physical and mental component scores and the HADS anxiety and depression scores (Table 2). Results of confirmatory factor analysis also indicated that the C-MacNew (χ^2/df=1.41, RMSEA=0.043, NFI=0.93, NNFI=0.94 and CFI=0.95) and C-MIDAS (χ^2/df=2.32, RMSEA=0.059, NFI=0.94, NNFI=0.95, CFI=0.96) conformed to the original 3-factor and 7-factor structure, respectively. However, the measurement model of the C-MacNew suggested that there was only one item (instead of 12 items in the original version) that loaded significantly onto more than one subscale, whereas that of the C-MIDAS suggested the existence of error covariance between item 2 (had angina symptom) and item 3 (had angina that affected life).

The results of discriminative validity indicated that both the C-MacNew and the C-MIDAS (except for 'diet', 'concerns over medication', 'side-effects' subscales) identified poorer HRQL in MI or angina patients who reported anxiety and perceived deteriorated health. Both instruments also identified a significantly poorer HRQL in female patients with angina. As for heart failure patients, the C-MacNew and two subscales of the C-MIDAS scores (ie 'physical activity' and 'insecurity') indicated significantly poorer HRQL in patients who were female, at old age, with anxiety and with perceived health deterioration.

Longitudinal validity of the C-MacNew and the C-MIDAS was also established as the changes in the majority of the subscales' scores showed a significant and moderate relationship with the changes in the SF-36 physical and mental component scores over a 3-month period. Nevertheless, three C-MIDAS subscales which had low discriminative validity (ie 'diet', 'concerns over medication', 'side-effects') also had poor performance on longitudinal validity testing (Table 3).

Responsiveness

The mean changes in the C-MacNew and C-MIDAS scores were statistically significant (P<0.001) in the three cardiac diagnostic groups. The results indicated a moderate-to-strong responsiveness of C-MacNew in detecting changes in HRQL (effect size: 0.51-0.78; standardised response mean: 0.53-0.78) in all the three cardiac diagnostic groups. This was also true for most of the C-MIDAS subscales (effect size: 0.43-0.94; standardised response mean: 0.46-0.96), with the exception of 'concerns over medication' and 'side-effects' subscales (effect size, 0.20-0.38; standardised response mean, 0.21-0.37).

Discussion

This study substantiates previously published psychometric data on the original versions of MacNew and MIDAS

Table 2. Construct validity of Chinese versions of MacNew health-related quality of life questionnaire (C-MacNew) and the Myocardial Infarction Dimensional Assessment Scale (C-MIDAS)

Instruments	Myocardial infarction	Angina	Heart failure
Correlation with Short-Form 36-item Health Survey (SF-36) physical component scores			
C-MacNew: physical	0.60‡	0.62‡	0.64‡
C-MacNew: emotional	0.48‡	0.47‡	0.50‡
C-MacNew: social	0.55‡	0.55‡	0.57‡
C-MIDAS: physical activity	-0.61†	-0.69†	-0.71†
C-MIDAS: insecurity	-0.43†	-0.56†	-0.54†
C-MIDAS: emotional reaction	-0.28†	-0.39†	-0.41†
C-MIDAS: dependency	-0.43†	-0.47†	-0.50†
C-MIDAS: diet	-0.17§	-0.12§	-0.04§
C-MIDAS: concerns over medication	-0.22*	-0.16§	-0.07§
C-MIDAS: side-effects	-0.29†	-0.29†	-0.07§
Correlation with SF-36 mental component scores			
C-MacNew: physical	0.58‡	0.56‡	0.66‡
C-MacNew: emotional	0.59‡	0.59‡	0.70‡
C-MacNew: social	0.56‡	0.57‡	0.66‡
C-MIDAS: physical activity	-0.54†	-0.63†	-0.58†
C-MIDAS: insecurity	-0.44†	-0.62†	-0.58†
C-MIDAS: emotional reaction	-0.46†	-0.53†	-0.58†
C-MIDAS: dependency	-0.48†	-0.46†	-0.46†
C-MIDAS: diet	-0.22*	-0.07§	-0.12§
C-MIDAS: concerns over medication	-0.30†	-0.13§	-0.27†
C-MIDAS: side-effects	-0.29†	-0.16*	-0.26†
Correlation with Hospital Anxiety and Depression Scale (HADS) anxiety score			
C-MacNew: physical	-0.44‡	-0.47‡	-0.37‡
C-MacNew: emotional	-0.67‡	-0.68‡	-0.59‡
C-MacNew: social	-0.47‡	-0.50‡	-0.44‡
C-MIDAS: physical activity	0.39‡	0.38‡	0.32†
C-MIDAS: insecurity	0.59‡	0.56‡	0.51‡
C-MIDAS: emotional reaction	0.58‡	0.49‡	0.46‡
C-MIDAS: dependency	0.49‡	0.46‡	0.45‡
C-MIDAS: diet	-0.06§	-0.01§	-0.20§
C-MIDAS: concerns over medication	0.28†	0.21†	0.16§
C-MIDAS: side-effects	0.17§	0.25†	0.23*
Correlation with HADS depression score			
C-MacNew: physical	-0.53‡	-0.55‡	-0.61‡
C-MacNew: emotional	-0.80‡	-0.75‡	0.70‡
C-MacNew: social	-0.56‡	-0.59‡	-0.67‡
C-MIDAS: physical activity	0.47‡	0.47‡	0.57‡
C-MIDAS: insecurity	0.62‡	0.54‡	0.53‡
C-MIDAS: emotional reaction	0.53‡	0.34‡	0.36‡
C-MIDAS: dependency	0.48‡	0.37‡	0.49‡
C-MIDAS: diet	0.02§	-0.02§	0.02§
C-MIDAS: concerns over medication	0.36‡	0.18*	0.05§
C-MIDAS: side-effects	0.23*	0.25†	-0.01§

* P<0.05
† P<0.01
‡ P<0.001
§ Not significant

Table 3. Longitudinal validity of Chinese versions of MacNew health-related quality of life questionnaire (C-MacNew) and the Myocardial Infarction Dimensional Assessment Scale (C-MIDAS)

Instruments	Changes in Short-Form 36-item Health Survey					
	Physical component score			Mental component score		
	Myocardial infarction	Angina	Heart failure	Myocardial infarction	Angina	Heart failure
Changes in C-MacNew						
Physical	0.63‡	0.66‡	0.65‡	0.53‡	0.59‡	0.58‡
Emotion	0.58‡	0.48‡	0.51‡	0.58‡	0.58‡	0.61†
Social	0.58‡	0.62‡	0.54‡	0.55‡	0.56‡	0.62‡
Changes in C-MIDAS						
Physical activity	-0.61‡	-0.57‡	-0.57‡	-0.47‡	0.60‡	0.50‡
Insecurity	-0.31‡	-0.45‡	-0.45‡	-0.30†	0.58‡	0.47‡
Emotional reaction	-0.26†	-0.33‡	-0.40‡	-0.34‡	0.48‡	0.41‡
Dependency	-0.24*	-0.41‡	-0.52‡	-0.39‡	0.30‡	0.35†
Diet	-0.93§	0.05§	-0.01§	-0.12§	0.13§	0.25*
Concerns over medication	-0.22*	-0.02§	-0.24*	-0.22*	0.10§	0.31†
Side-effects	-0.16§	-0.06§	-0.12§	-0.26†	0.12§	0.20§

* P<0.05
† P<0.01
‡ P<0.001
§ Not significant

in CHD patients. Both of these instruments are internally consistent and reproducible in Chinese patients in each of the three CHD diagnostic groups (MI, angina, and heart failure). Their factor structures are similar to those of their respective original versions for measuring the various aspects of HRQL among CHD patients. C-MacNew and four of the seven subscales of C-MIDAS (physical activity, insecurity, emotional reactions, dependency) demonstrated good construct and longitudinal validity. They are also responsive to detecting changes in HRQL in the three cardiac diagnostic groups. All these findings provide strong evidence to suggest that the C-MacNew may have value as a core questionnaire in patients with a differential diagnosis of CHD.

As for C-MIDAS, the poor performance of the three subscales (diet, concerns over medication and side-effects) may be related to concerns about risk factors for CHD and worries about medical treatment that patients regard as less important in interpreting disease impact and life situations.[4] Some studies also found that CHD patients did not consider adjusting their lifestyle in order to reduce CHD risk factors as important. Such an attitude might be more prominent in the current sample, as older people in Chinese culture tend to adopt a 'do nothing approach' and allow fate to take its course.[5] As for the 'side-effects' subscale, the items such as 'felt the cold more' and 'unwanted side-effect' might not be specific enough to assess patients' problems associated with medical treatment. Although the study provides evidence of adequate psychometric properties of only four of the Chinese MIDAS subscales, these four subscales provide a wide coverage of the physical and psychosocial health and functioning of CHD patients. As the original MIDAS suggests the use of subscale scores, these subscales can be used as an independent, reliable, valid and responsive core CHD-specific HRQL measure among patients in different diagnostic categories. Improving the performance of the Chinese MIDAS requires further effort to clarify patients' perspectives of treatment-related impact of CHD on well being.

This study has limitations. First, recruiting a consecutive sample of CHD patients managed in a single acute care setting may limit the generalisability of the findings for patients in community-dwelling or rehabilitative settings. Second, the over-representation of male patients in the sample further threatens the external validity of the findings. Finally, as we only collected 7-day post-test data from 25% of the patients, the reproducibility of the C-MacNew and the C-MIDAS could not be examined for each cardiac diagnostic group individually.

Conclusions

In conclusion, there is sufficient evidence that the psychometric properties of the C-MacNew and some of the subscales of the C-MIDAS are adequate to warrant recommending these HRQL instruments for Chinese patients with MI, angina or heart failure as an outcome measure to enhance treatment evaluation for patients with CHD. They can be used to compare health outcomes, burden of illness, and treatment effectiveness on pure or mixed populations with the three previously mentioned cardiac diagnoses.

Acknowledgement

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