ORIGINAL ARTICLE

Validity and reliability of the dimensional assessment scale after myocardial infarction

Validade e confiabilidade do questionário de avaliação multidimensional após o infarto do miocárdio

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ABSTRACT

The objective of this study was to evaluate the evidence of reliability and validity of the Multidimensional Quality of Life Assessment Scale in patients after acute myocardial infarction. Methodological study. Reliability was verified using internal consistency analysis and test-retest (Cronbach's α). Reproducibility was verified with intra- and inter-examiner assessment. The validity of the instrument was calculated using construct and criterion validity through convergent and concurrent validity. The sample consisted of 83 patients, of which 51 were hospitalized and 32 were receiving outpatient care. All the domains showed a significant correlation with overall score. The Multidimensional Quality of Life Assessment Scale showed evidence of validity and reliability compared to the SF-36 questionnaire, with a correlation of 0.89 ($p<0.01$). Cronbach's alpha for the inpatients and outpatients was 0.85 and 0.83, respectively. The instrument shows evidence of reliability and validity for application in outpatient and hospital settings in Brazil.

Descriptors: Quality of Life; Myocardial Infarction; Validation Studies; Cardiovascular Diseases.

RESUMO

Objetivou-se avaliar as evidências de confiabilidade e a validade do questionário de Avaliação Multidimensional de Qualidade de Vida em pacientes após o infarto do miocárdio. Estudo metodológico. A confiabilidade foi verificada por meio da análise da consistência interna e pelo teste-reteste (α de Cronbach). A reprodutibilidade foi verificada com a avaliação intra e interexaminadores. A validade do instrumento foi calculada por meio da validade de constructo e critério através da validade convergente e concorrente. A amostra foi composta por 83 pacientes, sendo 51 pacientes internados e 32 ambulatoriais. Todos os domínios apresentam correlação significativa com escore geral. O questionário de Avaliação Multidimensional de Qualidade de Vida possui evidências de validade e confiabilidade em comparação ao questionário SF-36 com correlação de 0,89 ($p<0,01$). O Alfa de Cronbach obtido nos pacientes internados ambulatoriais foi de 0,85 e 0,83 respectivamente. O instrumento apresenta evidências de confiabilidade e validade para aplicação no Brasil em ambientes ambulatoriais e hospitalares.

Descritores: Qualidade de Vida; Infarto Agudo do Miocárdio; Estudos de Validação; Doenças Cardiovasculares.

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INTRODUCTION

In infarcted patients, quality of life (QoL) instrumentsare used to assess the effects of diseases on individuals in a range of factors, such as dysfunctions and physical and emotional discomfort, as well as to support decision making, planning and assessment of certain types of treatments[1]. Similarly, the real value of these instruments is to show significant changes that can be represented both statistically and clinically[1-3].

Therefore, QoL instruments necessarily measure and quantify these characteristics to provide a better understanding of the effects of the disease and its treatment in all patient-related dimensions[4,5]. Based on the assessment of mechanisms that negatively affect QoL, it is possible to plan interventions to improve the well-being of patients[3,6].

The Myocardial Infarction Dimensional Assessment Scale (MIDAS) was created as a response to the inability of generic instruments to measure all the specific factors involving acute myocardial infarction (AMI), such as patient confidence level and changes in lifestyle. In this manner, the MIDAS is more sensitive in clinical assessments and to the sequence of changes after the occurrence of an AMI, and it can be applied to promptly measure the outcome of any therapeutic intervention[4,6].

Following specific steps from the initial translation to the pre-test, the process of transcultural adaptation (TA) of the MIDAS was performed satisfactorily in 2016, with the achievement of cultural, conceptual, semantic and idiomatic equivalences in a previous study[6,7]. The TA study revealed that the MIDAS, in its Brazilian Portuguese version, is easy to apply, useful in clinical practice and promptly understood by the target population. It consists of 35 questions divided into seven domains that cover the QoL construct. After the success of the first stage, it was still necessary to evaluate the equivalence of measurement, through psychometric properties, which will be discussed in this article.

The measurement of QoL in patients with myocardial infarction is more related to the benefits than to possible losses during outcome and treatment. The aim is to assess the extent to which infarction worsens or impairs the life of patients, especially over time, since they adopt mechanisms to try to reduce the discomfort caused by treatment that, depending on the intensity, may affect their lifestyle[8].

The instruments must multidimensionally reflect the concept of QoL and must contain essential properties, namely reliability and validity, as a measuring instrument[9]. The term reliability, precision or accuracy is usually used to refer to the reproducibility of a measure, that is, the degree of agreement between multiple measures of the same object. Validity is the ability of an instrument to measure the phenomenon under examination, that is, the adequacy between the items of the instruments and the theoretical concept to be measured, thus referring to the accuracy of the measurement.

The aim of this study is to evaluate the evidence of reliability and validity of the MIDAS in patients after AMI, evidencing its reproducibility in outpatient and hospital settings.

METHODS

This is a methodological study conducted to evaluate psychometric properties and, subsequently, assess the reliability and validity of the MIDAS applied in our health care context. The convenience sample consisted of 83 separately assessed patients, of which 51 were inpatients and 32 were outpatients.

Analysis of internal consistency, test-retest and intra-examiner reliability were used to test reliability. Internal consistency was examined using Cronbach's α. The alpha value must be positive between zero to one and values below 0.6 are considered inadmissible; the higher the value, the greater the consistency of the instrument and the more homogeneous and congruent the scale. An optimal value is considered when the result is >0.7[9,10]. Through an interview, the questionnaire was applied at three moments, both with the inpatients staying at the hospital and with the patients receiving outpatient care. The day in which the patient was recruited for the study was considered as D1.

For outpatients, the collection process occurred as follows: application of the sample categorization instrument and the MIDAS questionnaire on D1, by evaluator 1; application of the MIDASon D1 by researcher 2; reapplication of the MIDASon D7 by researcher 1, for the same patients of D1. For the inpatients, the collection process was the same, however, with a five-day interval between applications.

Intra-and inter-observer reproducibility was assessed using the intraclass correlation coefficient (ICC). This index is used to evaluate the homogeneity between two or more measures, interpreted as the ratio of variability. Another way to evaluate this property is to use Pearson's correlation for the results obtained[9-11].

The validity of the instrument was calculated using construct and criterion validity, through convergent and concurrent validity. Convergent validity was performed by inter-domain correlation, through Pearson's correlation, assuming that most of these correlate or are associated with the overall score. Another strategy was to determine the correlation between the MIDAS domains and the SF-36 domains and their respective overall scores.

Data were collected at the inpatient unit and outpatient clinic of a hospital in Vila Velha. This hospital is a philanthropic institution and model of health care in the state of Espírito Santo, Brazil. It attends patients from all over the state. The sample included infarcted patients with a diagnosis of AMI in their medical records. Readmitted patients with

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complications after AMI were also included. As additional inclusion criteria, the patient must be lucid, able to talk and willing to provide informed consent. The exclusion criteria were patients who were unable to answer the questions or provide consent. All the patients who complied with the inclusion criteria and agreed to participate signed an informed consent form. This study was approved by the Ethics and Research Committee (*Comitê de Ética e Pesquisa* – CEP) filed under CAAE no. 42456915.8.0000.5068.Statistical analysis was performed with the aid of SPSS V17, Minitab 16 and Excel Office 2010.

RESULTS

After performing the initial stages of cross-cultural adaptation and obtaining the semantic, conceptual, idiomatic and cultural equivalences of the MIDAS[6,7], the research was submitted to the specific population to verify the equivalence of measurement. In order to evaluate the psychometric properties, the validity and reliability of the instrument were tested.

There was a predominance of males, totaling 62.7% of the patients, at a proportional ratio of 2:1 in relation to females. Regarding ethnicity, the prevalence was mixed-race. The schooling level of the sample was low. In all, 52.9% of the patients had not completed primary school. Most of the respondents were married or lived with a companion.

The mean age was 63.7 years, with a minimum age of 45 and a maximum age of 91. Chronic diseases may appear as people age which consequently increase the risk of infarction and other cardiovascular diseases. The coefficient of variation (CV) was 15%, indicating a homogeneous sample, which favors the assessment process.

The results presented below refer to the psychometric properties. Validity and reliability in the hospital environment were verified in the first part.

The first measurement property to be evaluated was reproducibility of the instrument, which reveals the stability of the instrument in relation to the phenomenon being measured. Pearson's correlation was used to measure the degree of correlation between the domains of the MIDAS questionnaire on D1, as shown in Table 1.

The correlation between the domains and the relationship of each domain with the general QoL score was applied. It is noted that all domains have a significant correlation with the general score, demonstrating that the domains have the same tendency of assessment in relation to the studied phenomenon.

Several domains correlated positively and significantly, highlighting the correlation between the domains of the instrument. The domain insecurity was correlated with the domains emotion, concern with medication and physical activity ($p<0.01$). Similarly, the domain physical activity correlated with the domains dependence and side effects. The domain dependence, in turn, correlated with that of diet. These correlations strengthen the relationship between the factors that make up the construct.

Table 1. Correlation between the domains of the MIDAS questionnaire. Espírito Santo, Brazil, 2019.

MIDAS DOMAINS*		Physical activity	Insecurity	Emotion	Dependency	Diet	Concern with medication	Side effects
Insecurity	Corr (r)**	*0.461*						
	p-value	0.001						
Emotion	Corr (r)	*0.258*	*0.391*					
	p-value	0.047	0.005					
Dependency	Corr (r)	*0.251*	-0.005	0.218				
	p-value	0.036	0.974	0.124				
Diet	Corr (r)	0.216	0.244	0.208	*0.313*			
	p-value	0.129	0.084	0.143	0.025			
Concern with medication	Corr (r)	-0.124	*0.298*	0.179	0	0.165		
	p-value	0.385	0.034	0.208	0.999	0.249		
Side effects	Corr (r)	*0.251*	0.204	0.179	-0.061	0.232	-0.012	
	p-value	0.036	0.151	0.208	0.672	0.101	0.933	
Overall score	Corr (r)	*0.52*	*0.66*	*0.62*	*0.44*	*0.63*	*0.44*	*0.51*
	p-value	<0.001	<0.001	<0.001	0.001	<0.001	0.001	<0.001

*Multidimensional assessment questionnaire.
** Pearson correlation.

A comparison of the overall scores of the MIDAS questionnaire with that of the SF-36 questionnaire on D1 of collection was performed to investigate whether the instruments are evaluating the same characteristics and whether they are sensitive to changes. In addition to the correlation, the intraclass correlation coefficient (ICC) was used to measure reliability. Pearson's correlation was -0.89 ($p<0.001$) and ICC was -0.89 ($p<0.001$). The correlation between the MIDAS questionnaire and the SF-36 was negative, as the scores of both instruments are inversely proportional. In the MIDAS questionnaire, the closer to 100 the worse the QoL status, and in the SF-36 questionnaire, the closer to zero the worse the evaluated QoL. The MIDAS questionnaire presented evidence of reliability and validity when compared to the SF-36 questionnaire. This assessment is of paramount importance for the evaluation of the validity of criteria, as it compares two instruments.

To evaluate internal consistency, Cronbach's alpha test was performed in relation to the general instrument and its score. The obtained coefficient was 0.85, with inadmissible values being considered those below 0.60.

Convergent validity was performed using Pearson's correlation in order to measure the correlation between the scores of the MIDAS questionnaire and the scores of the SF-36. Pearson's correlation test was used to validate the correlations. As shown in Table 2, the MIDAS questionnaire presented good correlation with the overall score of the SF-36.

Several statistically significant correlations were obtained, including some that are considered perfect (± 1). Similar domains between the MIDAS and the SF-36 showed strong and significant correlations. The correlation of the domain mental health (SF-36) showed a significant correlation with all domains of the MIDAS questionnaire. The results are consistent with the hypotheses raised since functional capacity was significantly correlated with the domains physical activity and insecurity; physical factors with dependence; pain with side effects; general condition with physical activity, insecurity, emotion and concern with medication; and emotional factors with insecurity and emotion. Therefore, excellent validation between the domains of the instruments is explicit, thus guaranteeing their validity.

The evaluation of intra-and inter-observer reproducibility was performed using Pearson's correlation test and ICC. These correlations used the data obtained with application of the MIDAS questionnaire of D1 with D1.1 (relating the data

Table 2. Correlation between the domains of the MIDAS questionnaire and SF-36. Espírito Santo, Brazil, 2019.

SF-36/MIDAS*		Physical activity	Insecurity	Emotion	Dependency	Diet	Concern with medication	Side effects	Overall score
Functional capacity	Corr (r)**	-1	-0.46	-0.261	-0.247	-0.216	0.128	-0.25	-0.513
	p-value	<0.001	0.001	0.064	0.081	0.129	0.373	0.077	<0.001
Physical factors	Corr (r)	-0.264	-0.011	-0.234	-0987	-0.31	0.011	0.032	-0.448
	p-value	0.062	0.937	0.098	<0.001	0.027	0.936	0.823	0.001
Pain	Corr (r)	-0.251	-0.203	-0.179	0.06	-0.232	0.013	-1	-0.514
	p-value	0.076	0.154	0.208	0.673	0.101	0.927	<0.001	<0.001
General condition	Corr (r)	-0.509	-0.9	-0.394	-0.004	-0.198	-0.29	-0.155	-0.612
	p-value	<0.001	<0.001	0.004	0.976	0.164	0.039	0.278	<0.001
Vitality	Corr (r)	-0.244	-0.238	-0.112	-0.108	-0.148	-0.116	0.12	-0.193
	p-value	0.084	0.092	0.435	0.452	0.301	0.418	0.403	0.175
Social factors	Corr (r)	-0.252	0.006	-0.22	-1	-0.312	0.001	0.06	-0.436
	p-value	0.075	0.967	0.121	<0.001	0.026	0.992	0.675	0.001
Emotional factors	Corr (r)	-0.259	-0.393	-1	-0.218	-0.207	-0.182	-0.178	-0.618
	p-value	0.067	0.004	<0.001	0.124	0.145	0.202	0.210	<0.001
Mental health	Corr (r)	-0.516	-0.661	-0.618	-0.436	-0.63	-0.439	-0.512	-1
	p-value	<0.001	<0.001	<0.001	0.001	<0.001	0.001	<0.001	<0.001
General coefficient	Corr (r)	-0.62	-0.524	-0.616	-0.664	-0.465	-0.154	-0.451	-0.896
	p-value	<0.001	<0.001	<0.001	<0.001	0.001	0.280	0.001	<0.001

*Multidimensional assessment questionnaire.
** Pearson correlation.

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between different collectors on the same day) and D5 (on the fifth day after application of the instrument) for each domain, as shown in Table 3.

The data show that all correlations were statistically significant, thus ensuring the intra- and inter-observer reproducibility of the instrument. All ICCs are statistically significant with high values and classified as optimal.

Due to the need to validate the instrument in settings other than that of the hospital environment, the reliability of the instrument in the outpatient care setting was evaluated. Validity is a property that is not affected by the collection site, unlike reproducibility[10,12]. Thus, the MIDAS questionnaire was also applied, in the second part, with patients with AMI in outpatient treatment.

In the outpatient evaluation, all inter-observer correlations presented a statistically significant combination of ICC, always greater than 0.9, which is considered optimal, as its lowest value is 0.912 and its highest value is 0.989, and all with p<0.05. The ICC among the general scores obtained for the two applications on D1 was 0.992, while between D1 and D7, the score was 0.972 and between the second collection of D1 and D7, the score was 0.986. Thus, correlating all applications, an intraclass interval of 0.989 was identified, all with p-value <0.001. Internal consistency was also verified using Cronbach's alpha, obtaining a value

of 0.830. This result is similar to the coefficient obtained for the inpatients.

DISCUSSION

Quality of life can be defined as each individual's personal conception of their living conditions[2,12]. This indicator is becoming increasingly valued to assess technologies and therapies used in health care. To measure QoL, specific instruments have been created and validated for each disease, such as the MIDAS questionnaire in relation to AMI[6,7,13].

When choosing an instrument to assess QoL, it is important to analyze the evidence of psychometric properties of the selected instrument, namely reliability and validity, and, thus, verify the ability of the instrument to measure the desired phenomenon[14-16]. The process of transcultural adaptation is known to be a continuous process[11]. Evidence of reliability and validity was found both in the hospital environment in patients admitted after AMI and in patients undergoing outpatient follow-up. This reinforces the applicability of the MIDAS in these two assessment scenarios.

To evaluate psychometric properties, neither large samples nor sample calculation is required. The key requirement is to determine the stability of the instrument. In general, authors suggest around 30 to 50 participants[10,15-17].

Table 3. Correlation between the domains of the MIDAS questionnaire in the three applications. Espírito Santo, Brazil, 2019.

		D1.1	D5		D1.1	D5
Physical activity	Corr (r)*	0.994	0.99	ICC**	0.997	0.995
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Insecurity	Corr (r)	0.837	0.865	ICC	0.907	0.889
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Emotion	Corr (r)	0.979	0.957	ICC	0.989	0.976
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Dependency	Corr (r)	0.987	0.069	ICC	0.993	0.974
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Diet	Corr (r)	0.993	0.923	ICC	0.996	0.958
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Concern with medication	Corr (r)	1	0.959	ICC	1	0.975
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Side effects	Corr (r)	0.982	0.827	ICC	0.991	0.929
	p-value	<0.001	<0.001	p-value	<0.001	<0.001
Overall score	Corr (r)	0.986	0.948	ICC	0.992	0.067
	p-value	<0.001	<0.001	p-value	<0.001	<0.001

*Pearson correlation.
**Intraclass correlation coefficient.

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In order to enable use of the instrument with inpatients and outpatients, the reproducibility of the instrument was tested in both settings.

A correlation analysis was performed with the obtained QoL scores between the MIDAS and the SF-36, in which several significant correlations were observed. Pearson's correlation and ICC were both strongly significant, which contributes to the validity of the MIDAS and demonstrates that it measures the desired phenomenon satisfactorily[9,15,16]. The MIDAS has evidence of validity and reliability when compared with the SF-36. This analysis is of paramount importance for the evaluation of criterion validity as it compares two instruments. The SF-36, despite being a generic QoL instrument, is widely employed in Brazil and it is considered an appropriate evaluation parameter. We found a high degree of convergent validity for the measurements of the same construct. Divergent validity can be assessed by the mean difference between the risk factors and the domains of the MIDAS, and by observing this significant difference between the means, in which the presence of risk factors for cardiovascular diseases is associated with worse QoL scores between the domains and the overall score[10,16].

When correlating the domains of the MIDAS and the SF-36, correlations ranged significantly from 0.154 to 1.0. In addition, the data were similar to those of the original study[11], indicating that the concepts of the MIDAS have been co-validated. Thus, it is concluded that the MIDAS is a valid instrument capable of corresponding to the true state of the measured phenomenon, in this case, QoL in patients after AMI.

As with validity, reliability, also called reproducibility, precision or accuracy, must be evaluated. This property not only reveals whether the instrument measures that which has been planned, but also whether the instrument can verify that which has been planned at different times, in different realities and with different researchers[3,9,18-20].

Reproducibility was assessed by correlating the intra-and inter-observer QoL scores at different times. For this analysis, internal consistency was initially used by means of Cronbach's alpha. The obtained coefficient was 0.85. The resulting value is particularly good since the maximum for this statistic is 1.0, thus highlighting that the MIDAS presents excellent internal consistency. Moreover, this value was similar to that of the MIDAS creation study, which ranged between 0.74–0.95 for the domains. In the validation of Turkey, the obtained value was 0.89, while in China, it was 0.82. Interestingly, even in such different cultures, the value of internal consistency remains at an optimal value[6,10]. According to the qualification proposed by Gifford and Cummings[21], alpha values greater than 0.80 are considered optimal. Based on this qualification, the MIDAS questionnaire presents values considered excellent in both application settings.

The inter-and intra-observer correlation and association were evaluated, resulting in excellent correlations in the total score comparison between two MIDAS applications at different times, by the same researcher, for all domains and the overall score. When using both Pearson's correlation and ICC, the same behavior was observed with different researchers, which strengthens the evidence of reliability.

The reliability ofan instrument may be affected by the variability of responses to its items. Another factor that could result in a measurement error is the number of items that evaluate the same domain. The greater the number of questions, the lower the chance of errors. This is justified by the fact that the result depends on the average value of the variance of the items. When several items are measuring the object and when these items vary little among themselves (homogeneous measurements), the lower the standard deviation and, therefore, the lower the probability that the instrument is making incorrect measurements and the higher its reliability. The MIDAS has domains with twelve questions (physical activities) and domains with two questions (side effects); regardless, the reliability values were satisfactory[22,23].

Despite these situations, the results provide excellent evidence of the reliability of the MIDAS questionnaire and demonstrate that the instrument is highly reproducible. In general, we can affirm that the translated and applied version of the MIDAS presents good homogeneity in the measurement scale, with values higher than those suggested in the literature[12,18,19,21] and similar to those obtained in other validation studies[1,17], showing adequate levels of internal consistency and stability.

It should be noted that the psychometric properties of the instruments are not static attributes since they are not influenced by the characteristics of the studied population and the situation under which the measurement is conducted. Some authors state that reliability and validity are characteristics that rely on greater or lesser degrees of evidence, and validation is considered a continuous process that adds information every time the instrument is used[15,16,21-24].

The results of the tests presented here show the excellent reliability of the instrument[23,24].

CONCLUSIONS

The MIDAS, for patients after AMI, presents evidence of reliability and validity and has been adapted and validated for application in Brazil.

The MIDAS presents satisfactory values in the assessment of psychometric properties and its applicability has been tested in hospitalized patients, patients in the general population and in follow-up outpatients.

Further studies are needed to verify the responsivity and comprehensibility of the MIDAS and other psychometric

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properties that are adjuvant to the process of equivalence of measurement and to perform factor analysis between questions and domains.

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