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ORIGINAL ARTICLE

Measure of disease impact: instrument construct validity in patients with coronary artery disease*

MEDIDA DO IMPACTO DA DOENÇA: VALIDADE DE CONSTRUCTO DE INSTRUMENTO ENTRE CORONARIOPATAS

MEDICIÓN DEL IMPACTO DE LA ENFERMEDAD: LA VALIDEZ DE CONSTRUCTO DE UN INSTRUMENTO ENTRE PACIENTES CON ENFERMEDAD CORONARIA

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ABSTRACT

This study estimated the known groups construct validity for the Instrument to Measure the Impact of Coronary Disease on Patient's Everyday Life (IDCV) related to signs and symptoms, ventricular systolic function, left ventricular ejection fraction (LVEF) and health-related quality of life (HRQoL) in 153 outpatients with coronary artery disease. Data was obtained through application of IDCV and Brazilian versions of the instruments The *Medical Study 36-item Short Form Health Survey* – SF-36 and the *MacNew Heart Disease Health-related Quality of Life Questionnaire*. Mann-Whitney test was used to verify the ability of IDCV in discriminating impact of signs and symptoms, LVEF and ventricular systolic dysfunction. Also, the Kruskal-Wallis test was used to verify the discrimination power of the IDCV in relation to HRQoL. It was observed that the IDCV discriminated the impact between variables scored in HRQOL quartiles (≤Q1, Q1-Q3, ≥Q3). The study findings contribute for improvement of IDCV in measurement of disease impact in coronary artery disease patients.

RESUMO

Este estudo estimou a validade de construcTo pelo teste de grupos conhecidos do Instrumento para Mensuração do Impacto da Doença no Cotidiano do Valvopata (IDCV) quanto a sinais e sintomas, função ventricular sistólica, fração de ejeção do ventrículo esquerdo (FEVE) e qualidade de vida relacionada à saúde (QVRS) em 153 coronariopatas em seguimento ambulatorial. Os dados foram obtidos pela aplicação do IDCV e das versões brasileiras do *The Medical Study 36-item Short Form Health Survey* – SF-36 e *MacNew Heart Disease Health-related Quality of Life Questionnaire*. Foi utilizado o teste de Mann-Whitney para verificar a capacidade do IDCV em discriminar o impacto quanto a sinais e sintomas, FEVE e disfunção sistólica ventricular, bem como o teste de Kruskal-Wallis para verificar seu poder de discriminação em relação à QVRS. Constatou-se que o IDCV discriminou o impacto entre aqueles que pontuaram nos quartis (≤Q1, Q1-Q3, ≥Q3) de QVRS. Os achados deste estudo contribuem para o refinamento do IDCV na mensuração do impacto da doença entre coronariopatas.

RESUMEN

Este estudio tuvo como objetivo estimar la validez de constructo por medio de pruebas en grupos conocidos del Instrumento para Medición del Impacto de la Enfermedad en la vida diaria del paciente con valvulopatía, relacionado a la búsqueda de signos y síntomas, función ventricular sistólica, fracción de eyección ventricular izquierda (FEVI) y la calidad de vida relacionada con la salud (CVRS). Fue ejecutado en 153 pacientes con enfermedad coronaria que realizaban control regular en los consultorios externos. La recolección de los datos fue a través de la aplicación del instrumento específico y de las versiones brasileñas del *The Medical Study 36-item Short Form Health Survey* – SF-36 y *MacNew Heart Disease Health-related Quality of Life Questionnaire*. Fue utilizado la prueba de Mann-Whitney para verificar la capacidad del Instrumento para Medición del Impacto de la Enfermedad en la vida diaria del paciente con valvulopatía y discriminar el impacto en relación con los signos y síntomas, la fracción de eyección ventricular izquierda (FEVI) y la disfunción sistólica ventricular izquierda; así como la prueba de Kruskal-Wallis para comprobar el poder de discriminación en relación con la CVRS. Fue constatado que el IDCV fue capaz de discriminar el impacto entre los sujetos que puntuaron en los cuartiles (≤Q1, Q1-Q3, ≥Q3) de la CVRS. Los resultados del estudio contribuyen para el perfeccionamiento del IDCV en la medición del impacto de la enfermedad en pacientes con enfermedad coronaria.

DESCRIPTORS
Coronary disease
Quality of life
Sickness impact profile
Validation studies

DESCRITORES
Doença das coronárias
Qualidade de vida
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Estudos de validação

DESCRIPTORES
Enfermedad coronaria
Calidad de vida
Perfil de impacto de enfermedad
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INTRODUCTION

Coronary artery disease (CAD) is the major cause of adult deaths in developed countries[1]. In 2010, DATASUS preliminary data evidenced CAD as responsible for 99,408 deaths, which represents 8.8% of total deaths in Brazil[2].

Besides the economic impact that CAD represents, the occurrence of an ischemic event causes important repercussions in an individual's life. The impact on physical aspects has been associated with the presence of symptoms, particularly precordial pain, dyspnea and fatigue[3-5]. The feelings of insecurity, anxiety and depression associated with fear of a new event reflect compromised emotional aspects. Difficulties in return to work and financial concerns are examples of the social impact caused by CAD in an individual's life[3-4].

Consequences of an ischemic event can lead to different conceptions about the disease and the treatment and, therefore, differences in subjects' ways of adaptation to the new life condition. Understanding the patients' perception of their illness is fundamental to intervening in the way they handle being ill, the proposed treatment, as well as their capacity to appropriately manage the course of their disease. It is thought that beliefs about the disease and its effects mediate construction of an individual's perception about the disease impact and treatment in his life[6].

Besides the economic impact that CAD represents, the occurrence of an ischemic event causes important repercussions in an individual's life.

Assuming that the impact of the disease results from the balance between a subject's perception of consequences of the disease on the different dimensions of his life, and evaluation (good or bad) of those consequences, it is likely that those who experience a very negative impact of the disease have a worse evaluation of their quality of life[7].

In 2007, an instrument for evaluation of the impact of disease in the daily life of patients with valve heart disease was created and validated for Brazilian culture. The instrument was called the Instrument to Measure the Impact of Coronary Disease on Patient's Everyday Life (IDCV) and presented satisfactory measurement properties when applied to patients with valvular heart disease[7]. Although the instrument was developed to measure impact among patients with valvular heart disease, the refinement of its items resulted in selection of pertinent aspects to measuring impact on other cardiac conditions with similar symptoms[8].

A previous study showed evidence of IDCV validity and reliability when used in patients with CAD[8]. However, IDCV construct validity through the approach of known groups has not been estimated. The known groups validity is a subtype of the construct validity, based on the principle that in certain subjects' groups, different scores are expected when compared to others and the instrument must be sensitive to this difference. Therefore, a scale with evidenced validity would be the one capable of discriminating the difference between the groups in the predicted direction[9].

Considering the importance of providing the scientific community with an instrument that enables evaluation of the impact of CAD in the daily activities of these patients, this study had as *main goal* to estimate known groups construct validity of IDCV in outpatients with CAD. The *specific goals* were to estimate the IDCV capacity in discriminating disease impact related to signs and symptoms, left ventricular dysfunction, left ventricular ejection fraction (LVEF) and both general and specific health-related quality of life (HRQoL).

The findings of this study contribute to the psychometric refinement of an instrument constructed in the Brazilian culture aimed at measuring heart disease impact in individuals' lives, especially regarding sensitivity detection of the impact in different situations of CAD severity.

METHOD

Type and location of the study

This was a transversal study of methodological type that investigated methods for obtaining, organizing and analyzing data intended to develop and validate instruments and research techniques[10]. It is emphasized that the data from the present study derived from a larger study[8], whose aim was to evaluate the convergent validity of the IDCV and the generic, general (*Medical Study 36-Item Short Form Health Survey* - SF-36) and specific measures of HRQoL (MacNew Heart Disease Health-related Quality of Life Questionnaire – MacNew), when applied to outpatients with CAD. The study was developed in a Cardiologic Clinic of the University of Campinas Hospital.

Subjects

This study included 153 outpatients with CAD of the referred setting. For this research, patients selected were older than 18 years, with a history of myocardial infarction (MI) or angina that occurred for a period longer than six months, and who agreed to participate in the research by signing the Informed Consent. Patients who presented incapacity for effective verbal communication were excluded.

Sampling Procedure

The sample was composed of patients treated in the referred service that met all inclusion criteria, and none of the exclusion criteria, enrolled for the research from December 2007 up to January 2009. Since this is a section

from a larger study, the sample size was estimated by correlation coefficients among the instruments[11], that is, between IDCV scores and SF-36 and MacNew domains, based on a pilot study sample (n=74). Considering correlation coefficients between 0.30 and 0.40, as well as the values of α=0.05 and β=0.10, the sample size was estimated at 113 subjects. A loss percentage of 35% was adopted, so the final sample size was increased to 153 subjects.

Data collection

Data collection was performed by one of the researchers, individually, in a private setting after obtaining the consent. A method of registering available data on the medical chart was used to obtain sociodemographic and clinical characteristics: name, hospital registration number, date of birth, age, gender, origin, MI or angina diagnosis date, presence of previous MI, affected wall, type of treatment, data related to risk factors and associated clinical conditions. Data obtained by echocardiography – LVEF by the Teichholz method, systolic ventricular dysfunction (defined as the presence of isolated or associated abnormalities of ventricular wall motion: akinesia, hypokinesia, dyskinesia or LVEF <0.58), up to one year prior to data collection, were also considered. The interview technique was used to gather sociodemographic and clinical data not available in the hospital records (education, marital status, work status before and after MI, family and individual income, signs and symptoms in the last month prior to the interview), and also for evaluation of the disease impact (IDCV) and the general (SF-36) and specific (MacNew) HRQoL.

Data Collection Instruments

Sociodemographic and clinical characterization instrument: an instrument previously constructed and validated for obtaining sociodemographic and clinical data was used[12];

Instrument to Measure the Impact of Coronary Disease on Patient's Everyday Life (IDCV): an instrument constructed in the Brazilian culture to assess the impact of valvulopathy in the daily life of valvular heart disease patients[7]. The concept is that the impact is the product of disease repercussions; the assessment of each consequence led to the development of two parts (A and B), each with 14 items. Part A is designed to measure the degree of impact perceived by the subject in different dimensions of life, while Part B was developed to consider the evaluation (good or bad) of each one of the consequences noted in Part A. In part A, the patient responds to each of the items using a five-point Likert scale which ranges from 1 – totally disagree up to 5 – totally agree. In part B, a Likert-type scale is used for each item, with responses that range from 1 – really bad up to 5 – really good. The items are grouped into four factors or domains: *Physical impact of the disease – symptoms* (items 11, 12 and 13), *Impact of the disease in daily activities* (5, 7, 9, 10 and 14), *Social and emotional impact of the disease* (items 2, 3, 4 and 6) and *Adaptation to the disease* (1 and 8). To determine the final IDCV score, all items in part B are reversed. Items 1, 5 and 8 from Part A that correspond to perceptions related to favorable impact, have their scores reversed. To calculate the score, each item corresponds to the product of the scores obtained in Parts A and B of IDCV, generating a minimum score of 1 and a maximum of 25 for each statement evaluated. The closer the score is to 1, the smaller the perceived impact by the subject; the closer to 25, the greater the perceived impact. The total score is calculated by adding all the products obtained, varying from 14 – 350. High scores mean that the patient perceives the negative consequences of the disease in his life and that these consequences are, in fact, interpreted as negative. Lower scores mean that patient does not recognize the disease and treatment consequences in his life and, if they occur, they are not evaluated as bad. Although this instrument has been developed to evaluate beliefs of patients with valvular heart disease[7], it was observed that the IDCV can also be used to evaluate the impact imposed by cardiac disease chronicity[7]. A previous study demonstrated its reliability and validity for assessment of the disease impact among patients with CAD[8]. The present study showed satisfactory Cronbach's alpha coefficients for total score (0.85) and for the majority of dimensions - *Physical impact of the disease – symptoms* (0.71), *Impact of the disease in daily activities* (0.72) and *Social and emotional impact of the disease* (0.78). No evaluation of internal consistence of the domain *Adaptation to the disease* was conducted because it is composed of two items.

MacNew Heart Disease Health-related Quality of Life Questionnaire – *MacNew:* consists of a modified instrument from the *Quality of Life after Myocardial Infarction (QLMI) Questionnaire*, which was originally developed in English for patients who survived a MI and who had an indication to participate in a cardiac rehabilitation program[12]. It is composed of 27 items distributed in three domains, with some of the same items being part of more than one domain: *Physical Limitation* (13 items – 6, 9, 12, 14, 16, 17, 19, 20, 21, 24, 25, 26 e 27), *Emotional Function* (14 items - 1, 2, 3, 4, 5, 6, 7, 8, 10, 13, 15, 18, 23) and *Social Function* (13 items - 2, 11, 12, 13, 15, 17, 20, 21, 22, 23, 24, 25, 26). The maximum possible score in each domain is 7 (better HRQOL) and the minimum is 1 (worst HRQoL). Missed responses do not contribute to the score and item 27 (sexual intercourse) can be excluded without changing the domain score. The domain scores are calculated by average responses in that domain. It is emphasized that if more than 50% of the items for a domain are missing, the score for that domain must not be calculated. The instrument also has a total score calculated as the mean of all items counted, unless one of the domains is completely missing[13]. This instrument was adapted for Brazilian Portuguese [14] and its psychometric

performance in the Brazilian culture was evaluated in a previous study[10]. The present study found evidence of reliability for the total score (Cronbach's alpha = 0.91) and for the domains: *Physical Function* (0.84), *Emotional Function* (0.90) and *Social Function* (0.84).

The Medical Study 36-item Short Form Health Survey – SF-36: comprises a self-administered, and multidimensional questionnaire, consisting of 36 items divided into eight scales or components: *Physical functioning* (10 items), *Role physical* (4 items), *Bodily Pain* (2 items), *General Health* (5 items), *Vitality* (4 items), *Social Functioning* (2 items), *Mental Health* (5 items) and one more question of comparative evaluation between current health conditions and those from one year ago. The final score ranges from 0 up to 100, where 0 corresponds to the worst general health status and 100 to the best health status[15]. The version adapted to the Brazilian culture was used[16]. This study found evidence of reliability for the majority of SF-36 domains (Cronbach's alpha coefficient ranged between 0.64 and 0.92).

Data Analysis

Data was entered into an electronic spreadsheet in the *Statistical Package for Social Sciences* (SPSS) software, version 17.0 for Windows, and then transferred to the *Statistical Analysis System for Windows* program, version 9.2 (*Statistical Analysis System Institute* Inc., Cary, NC, USA, 2008), to perform the statistical analyses. Descriptive analysis was performed with production of frequency tables, measures of location and dispersion for sociodemographic and clinical data, IDVC and MacNew, and SF-36 domains.

To test the IDCV construct validity through the method of known groups, the starting point was the hypothesis that patients with signs and symptoms (precordial pain, dyspnea, lipothymia, palpitations and edema) or lowered LVEF (≤0.58, value adopted by the service), or with ventricular systolic dysfunction, or with greater impairment of HRQoL (those who scored ≤ first HRQoL quartile) would present significantly higher impact of disease than patients without symptoms, with preserved LVEF, without systolic dysfunction and with lower HRQoL impairment (who scored ≥ third HRQoL quartile), respectively. Thus, scores of the generic and specific HRQoL measures were considered as categorical variables and groups were assembled using as a cut-off point the scores from the first and the third quartile, per the example of a previous study[17]. Therefore, patients with HRQoL scores ≤ Q1, between Q1 and Q3 and ≥ Q3 were compared. The Mann-Whitney test was used to examine differences between two groups (patients with or without signs/symptoms - precordial pain, dyspnea, palpitations and edema; with normal LVEF or ≤0.58 and with or without systolic ventricular dysfunction). The Kruskal-Wallis test followed by Dunn's *pos hoc* test, were used to identify and compare difference between three groups, i.e., the patients with CAD that scored in general and specific HRQoL quartiles (≤ Q1, Q1-Q3, ≥Q3). Two by two differences were lower than 0.05 (p-value <0.05). Nonparametric tests were used in comparison analysis due to lack of normal distribution of the variables of interest. The Shapiro-Wilk test was used to test the normality. The level of significance of ≤ 0.05 was adopted.

Ethical Aspects

This study was approved by the Ethics in Research Committee of the Faculty of Medical Sciences, University of Campinas, and it was approved in the Regular Meeting VIII on August 24, 2010 (Report nº 370/2007). All enrolled patients signed the informed consent.

RESULTS

Sociodemographic and Clinical Characterization

There was an observed predominance of men (69.9%), mean age of 62.2 (10.1) years, mean schooling of 4.9 years (3.9), married (66.7%), retired (70.0%), mean individual income of 2.3 (1.9) minimum wages (MW)/month and average household income of 3.8 (2.8) MW/month.

The majority of patients (91.5%) had experienced a MI (isolated or associated with post-MI angina), mean of 1.2 (0.8) previous MI and 2.9 (1.1) clinical conditions or associated risk factors. All participants reported presence of symptoms in the month prior to the interview, with mean of 1.3 (1.2) associated symptoms. A mean use of 5.8 (1.7) medications per day was found. LVEF was lowered in 43.7% of the 64 patients with available information from hospital records, and 57.8% of the sample had systolic dysfunction.

Construct validity by known groups test

Data for comparison of the IDCV scores among patients with CAD related to clinical variables are presented in Table 1.

The results presented in Table 1 revealed that the dimensions and the total IDCV score do not discriminate in the impact of disease among patients with CAD for the presence of signs and symptoms, as well as in relation to LVEF and LV systolic function. Therefore, patients with lowered LVEF (≤0.58) or with systolic dysfunction had similar scores as asymptomatic patients with CAD with normal LVEF, and no changes in ventricular systolic function were observed.

The Kruskal-Wallis test was used to verify the IDCV total score capacity and capacity of its dimensions in discriminating the impact of CAD among general and specific HRQoL quartiles. Data related to the comparison of total scores and IDCV dimensions according to quartiles (≤ Q1, Q1-Q3, ≥Q3) of the HRQoL generic measure, assessed by the SF-36, are presented in Table 2.

Table 1 – IDCV scores according to clinical variables of outpatients with CAD - Campinas, 2010.

Symptoms		Domains and Total IDCV scores				
		Physical Impact Mean (SD)	Impact in Daily Activities Mean (SD)	Social and Emotional Impact Mean (SD)	Adaptation to the disease Mean (SD)	Total IDCV Mean (SD)
Precordial Pain (n=145)	Yes (n = 58)	36.2 (20.3)	58.6 (28.9)	53.0 (27.6)	10.1 (7.5)	158.0 (68.3)
	No (n = 87)	33.0 (19.8)	56.7 (27.9)	47.9 (26.1)	10.6 (7.4)	148.2 (64.7)
	p-value*	0.372	0.759	0.247	0.768	0.385
Dyspnea (n=146)	Yes (n = 54)	35.6 (19.5)	56.8 (28.0)	51.2 (28.1)	11.0 (7.6)	154.7 (67.3)
	No (n = 92)	33.6 (20.3)	58.1 (28.4)	49.3 (25.9)	10.1(7.3)	151.1 (65.5)
	p-value	0.595	0.852	0.744	0.375	0.753
Palpitation (n=146)	Yes (n = 33)	34.4 (20.7)	60.0 (27.0)	50.4 (28.1)	9.8 (8.4)	154.7 (68.3)
	No (n=113)	34.4 (19.8)	56.9 (28.5)	49.9 (26.3)	10.6 (7.2)	151.8 (65.6)
	p-value	0.897	0.600	0.966	0.371	0.775
Edema (n=83)	Yes (n = 36)	32.4 (19.6)	50.3 (24.9)	43.3 (25.6)	12.1 (8.3)	138.2 (63.4)
	No (n = 47)	30.5 (19.5)	49.6 (26.3)	45.3 (24.9)	12.9 (7.6)	138.3 (63.5)
	p-value	0.636	0.930	0.571	0.515	0.974
Systolic Disfunction (n=112)	Yes (n = 68)	38.4 (18.7)	54.8 (28.1)	50.5 (25.4)	11.3 (6.7)	155.1 (65.4)
	No (n = 44)	33.6 (18.4)	53.6 (27.8)	44.0 (25.0)	12.9 (7.9)	144.1 (63.0)
	p-value	0.263	0.940	0.291	0.696	0.536
LVEF† (n=106)	Decreased‡ (n = 41)	38.3 (18.8)	53.2 (27.0)	47.3 (25.4)	11.1 (6.8)	149.9 (62.8)
	Normal (n = 65)	34.9 (18.5)	55.2 (28.7)	48.1 (25.4)	12.6 (7.6)	150.9 (66.1)
	p-value	0.392	0.849	0.989	0.526	0.967

*Mann-Whitney test; †Left Ventricular ejection fraction, ‡Left Ventricular ejection fraction ≤0.58. Note: (n=153).

Except for the domain *Adaptation to the disease*, lower scores were observed in the remaining domains and the total IDCV score in Q≥3 in all dimensions from SF-36, which demonstrates that the smaller the impact of the disease perceived by the patient with CAD, the better their HRQoL.

The Kruskal-Wallis test showed that all of the domains and the total IDCV score discriminated differences in the impact of the disease among quartiles of the generic measure of HRQoL, except for the domain *Adaptation to the disease.*

It is noted that all the domains and the IDCV total score discriminated the impact of the disease in the SF-36 domains *Bodily pain* and *General Health,* with statistically significant differences in all quartiles from those domains (≤Q1 ≠ ≥Q3 e Q1-Q3 ≠ ≥Q3 e Q1-Q3 ≠ ≤Q1; p-value<0,0001).

However, the domain *Impact of the disease in daily activities* and the total IDCV score only discriminated differences in the impact on the domain *Role emotional* among the patients with CAD who scored in the extreme HRQoL quartiles (≤Q1≠ ≥Q3).

Data related to the comparison of the total IDCV scores and its dimensions, according to the specific measure of HRQoL quartiles, assessed by the application of *MacNew,* are presented in Table 3.

Data in Table 3 indicate, as has been shown in relation to the generic HRQoL measure, lower total IDCV and dimensions scores in Q≥3 in all the domains and the total *MacNew* score, except for the domain *Adaptation to the disease*, which means that the better the HRQoL, the lower the impact of the disease perceived by the individual.

In addition, it was observed that most of the domains and total IDCV scores discriminated the impact of the disease among all quartiles from all the *MacNew* domains assessed, except for *Adaptation to the disease* (p<0.0001; Kruskal-Wallis; ≤Q1 ≠ ≥Q3 e Q1-Q3≠ ≥Q3 and Q1-Q3≠ ≤Q1).

Table 2 – IDCV scores according to quartiles of HRQOL generic measure (SF-36) from outpatient coronary heart disease - Campinas, 2010

Domains SF-36	Quartiles HRQOL	Domains and Total IDCV score				
		Physical Impact Mean (SD)	Daily Activities Impact Mean (SD)	Social and Emotional Impact Mean (SD)	Adaptation to disease Mean (SD)	Total IDCV Mean (SD)
Physical functioning	≤Q1	50.3 (18.9)	73.5 (24.5)	62.2 (23.6)	10.2 (7.7)	196.1 (58.9)
	Q1-Q3	36.2 (16.1)	61.6 (26.7)	57.2 (26.0)	10.2 (7.2)	165.3 (56.0)
	≥Q3	20.2 (12.8)	40.4 (22.5)	32.1 (18.0)	10.7 (7.4)	103.4 (44.6)
	p-value*	0.0001[c]	0.0001[c]	0.0001[a]	*0.9334*	0.0001[c]
Role physical	≤Q1	44.2 (19.5)	69.0 (24.6)	63.6 (23.2)	10.1 (7.6)	186.9 (59.5)
	Q1-Q3	29.6 (18.3)	53.4 (29.5)	46.6 (23.7)	10.8 (6.7)	140.4 (61.2)
	≥Q3	29.4 (18.2)	49.3 (25.7)	38.0 (25.8)	10.2 (8.0)	126.9 (59.8)
	p-value	0.0002[b]	0.0010[b]	0.0001[b]	*0.4870*	0.0001[b]
Bodily pain	≤Q1	50.9 (16.2)	75.7 (22.6)	67.5 (17.8)	9.6 (7.9)	203.8 (45.4)
	Q1-Q3	34.7 (18.5)	59.1 (28.4)	52.4 (26.2)	10.3 (6.9)	156.6 (63.0)
	≥Q3	19.9 (12.6)	39.2 (19.6)	29.8 (18.2)	10.9 (7.3)	99.8 (39.5)
	p-value	0.0001[c]	0.0001[c]	0.0001[c]	*0.5801*	0.0001[c]
General health	≤Q1	46.6 (18.5)	72.5 (24.3)	66.7 (21.7)	8.9 (7.1)	194.6 (54.5)
	Q1-Q3	33.3 (18.1)	60.5 (27.0)	49.6 (25.2)	11.5 (8.0)	155.0 (60.2)
	≥Q3	22.9 (16.5)	35.5 (18.9)	31.3 (19.3)	10.0 (6.2)	99.7 (44.9)
	p-value	0.0001[c]	0.0001[c]	0.0001[c]	*0.2571*	0.0001[c]
Vitality	≤Q1	43.8 (19.7)	72.2 (27.0)	66.0 (24.3)	12.0 (8.4)	194.0 (63.0)
	Q1-Q3	36.2 (18.5)	58.7 (23.0)	49.1 (23.8)	9.3 (6.6)	153.5 (54.5)
	≥Q3	23.1 (15.4)	41.2 (25.2)	34.1 (20.5)	9.8 (6.8)	108.2 (47.1)
	p-value	0.0001[a]	0.0001[c]	0.0001[c]	*0.2401*	0.0001[c]
Social functioning	≤Q1	46.0 (19.4)	73.3 (24.7)	62.4 (25.3)	9.1 (7.4)	190.9 (61.9)
	Q1-Q3	35.7 (18.6)	60.2 (24.8)	54.8 (25.7)	10.3 (7.3)	161.0 (58.8)
	≥Q3	24.2 (15.8)	42.5 (25.6)	35.4 (20.5)	11.3 (7.4)	113.5 (51.2)
	p-value	0.0001[c]	0.0001[c]	0.0001[a]	*0.2294*	0.0001[c]
Role emotional	≤Q1	45.0 (17.8)	74.5 (24.5)	65.9 (23.5)	10.3 (7.8)	195.6 (56.1)
	Q1-Q3	38.2 (21.2)	61.9 (27.7)	52.5 (23.7)	10.7 (7.3)	163.3 (67.5)
	≥Q3	28.1 (18.0)	47.5 (25.3)	40.7 (24.1)	10.3 (7.2)	126.6 (55.9)
	p-value	0.0001[d]	0.0001[a]	0.0001[d]	*0.9503*	0.0001[a]
Mental health	≤Q1	47.6 (18.1)	77.1 (22.2)	64.7 (22.8)	11.0 (8.4)	200.4 (55.4)
	Q1-Q3	31.2 (18.1)	57.1 (26.9)	52.6 (26.5)	9.5 (6.9)	150.4 (61.3)
	≥Q3	26.8 (18.1)	39.5 (21.7)	31.6 (17.1)	11.1 (7.0)	109.0 (45.5)
	p-value	0.0001[b]	0.0001[c]	0.0001[c]	*0.3416*	0.0001[c]

*Kruskal-Wallis test, followed by Dunn's pos-hoc test [a](≤Q1 ≠ ≥Q3 and Q1-Q3 ≠ ≥Q3); [b](Q1 ≠ ≥Q3 and Q1-Q3 ≠ ≤ Q1); [c](≤ Q1 ≠ ≥Q3 and Q1-Q3 ≠ ≥Q3 and Q1-Q3 ≠ ≤Q1); [d](≤Q1≠ ≥Q3). Note: (n=153).

Table 3 – IDCV scores according to quartiles of the specific HRQoL measure among outpatients with CAD − Campinas, 2010.

Domains MacNew	Quartiles HRQOL	Domains and total IDCV score				
		Physical Impact Mean (SD)	Daily Activities Impact Mean (SD)	Social and Emotional Impact Mean (SD)	Adaptation to the disease Mean (SD)	Total IDCV Mean (SD)
Physical Limitation	≤ Q1	50.3 (17.9)	78.6 (18.5)	67.2 (21.4)	11.1 (7.8)	207.3 (49.4)
	Q1-Q3	35.3 (17.4)	59.4 (27.6)	51.9 (25.7)	8.7 (6.6)	155.2 (58.6)
	≥Q3	17.7 (10.6)	33.5 (15.3)	29.2 (16.1)	12.9 (7.7)	93.2 (32.9)
	p-value*	0.0001[(a)]	0.0001[(a)]	0.0001[(a)]	0.0127	0.0001[(a)]
Social Function	≤ Q1	49.1 (18.2)	76.8 (22.1)	67.5 (21.4)	10.6 (7.9)	203.9 (54.0)
	Q1-Q3	32.9 (18.0)	55.6 (26.9)	51.0 (25.1)	9.1 (6.8)	148.7 (59.7)
	≥Q3	21.9 (14.8)	40.5 (23.3)	28.6 (16.6)	12.6 (7.5)	103.7 (42.6)
	p-value	0.0001[(a)]	0.0001[(a)]	0.0001[(a)]	0.0802	0.0001[(a)]
Emotional Function	≤ Q1	49.6 (17.6)	77.2 (21.9)	67.2 (20.3)	11.0 (8.2)	205.0 (51.5)
	Q1-Q3	36.4 (18.1)	59.7 (27.1)	52.4 (25.2)	9.7 (6.8)	158.3 (57.9)
	≥Q3	19.0 (12.0)	37.8 (20.3)	31.4 (20.6)	11.0 (7.6)	99.0 (43.9)
	p-value	0.0001	0.0001[(a)]	0.0001[(a)]	0.5311	0.0001[(a)]

*Kruskal-Wallis test, followed by Dunn's pos-hoc test [(a)](≤Q1 ≠ ≥Q3 and Q1-Q3 ≠ ≥Q3 and Q1-Q3 ≠ ≤Q1). Note:(n=153)

DISCUSSION

This study aimed to estimate the known groups construct validity of the IDCV in outpatients with coronary artery disease. The IDCV capacity in discriminating the impact of the disease related to signs and symptoms, left ventricular dysfunction, LVEF and HRQOL (general and specific) was estimated. The previous hypothesis was that the IDCV would discriminate a larger impact of the disease among symptomatic patients, with decreased LVEF and systolic ventricular dysfunction (evaluated by presence of akinesia, hypokinesia, and dyskinesia and/or decreased LVEF) and between those who scored in Q≥1 of the generic and specific measures of HRQoL, when compared to asymptomatic patients, with LVEF and ventricular function preserved and that scored in Q≤1 of generic and specific HRQOL. However, this hypothesis was only partially supported, since the IDCV was not capable of discriminating the impact of the disease related to symptoms, LVEF and systolic ventricular dysfunction.

The circumstance that the IDCV did not distinguish the impact of the disease related to signs and symptoms can be explained by the fact that the sample was composed of patients with chronic disease, with absence of acute manifestation of the illness, whose interaction with the disease over time could have contributed to a better adaptation to the clinical repercussions imposed by it and, consequently, to the lower perception of the impact of the symptoms on daily life. The absence of differences in the extent of the impact between the symptomatic and asymptomatic groups can also be explained by the fact that measures of the impact and evaluation of the symptoms had occurred at different moments in time. While the evaluation of impact occurred at the time of data collection, the survey of the signs and symptoms by self-report considered report of symptoms up to one month prior to the application of IDCV. It is also noted the possibility that these results arose from differences in sample size between the groups, which were characterized by a higher number of asymptomatic patients.

Considering previously reported associations between LVEF and HRQoL in patients with CAD[18], the hypothesis was that patients with decreased LVEF would present a more severe impact of the disease. Thus, it was expected that the IDCV would discriminate this impact between groups of patients with decreased LVEF and patients with preserved LVEF. However, the IDCV did not discriminate the impact related to changes in LVEF and systolic ventricular function. These findings corroborate the results of a preceding study of validation of the specific HRQoL instrument for patients with coronary heart disease[8], in which the instrument being validated did not discriminate HRQoL between subjects with normal or decreased LVEF, although it was able to discriminate HRQoL between subjects with and without left ventricular systolic dysfunction. This finding may also be attributed to the different time of obtaining data of impact (collected during interview) and left ventricular performance, obtained within one year prior to data collection. Also, a lack of consensus in the literature[19] to establish the cut-off point of LVEF should be considered. In this study the value of 0.58 was used, which does not exclude the possibility of bias in the selection of groups.

Furthermore, recent studies investigating the association between HRQOL in heart failure and ventricular

performance indices point to an absence of consensus regarding the association between lower HRQoL and decreased LVEF; the results showed worsened HRQoL in both situations, i.e., in patients with normal LVEF and those with decreased LVEF[19-20]. However, the data suggested that the IDCV was sensitive enough to detect differences in the impact of the disease in patients who scored in different quartiles of general and specific measures of the HRQoL.

These findings partly reflect the multidimensionality of the Quality of Life construct and, consequently, the concept of HRQoL, particularly as regards effects, consequences and impact of the disease on the everyday lives of people[21]. The relationship between HRQoL and the impact of the disease has been demonstrated in studies that seek to measure how much heart disease prevents or hinders the patient to live as he would like, showing a strong relationship between these constructs[22].

Except for the domain, *Adaption to the disease*, the remaining IDCV domains and the total scores discriminated the impact of the disease among those who scored in quartiles of HRQoL generic measures, i.e., IDCV discriminated lower perception of the impact of disease in patients with CAD with better HRQoL, and increased perceived impact on those with poorer HRQoL. The fact that the domain, *Adaptation to the disease*, did not identify differences between groups was attributed to its composition, with only two non correlated items, as evidenced in other studies[7-8].

This study had as limitations the relatively long period between obtaining the impact measures and data related to signs and symptoms and left ventricular performance, the use of moderately elevated cut-off values for LVEF, in addition to considering only two variables of Echocardiography (LVEF and abnormal contractility) to define systolic ventricular dysfunction. However, IDCV sensitivity in detecting impact differences among distinct groups with HRQoL, evidenced in the present study, suggests that the instrument can be responsive or capable of measuring changes in the impact of the disease over time.

Further studies are recommended with inclusion of scales of self-reported fatigue and dyspnea for a better evaluation of symptoms, as well as the use of other indices in the assessment of ventricular performance, in order to investigate the ability of the IDCV in discriminating the impact in different levels of coronary artery disease severity. Longitudinal design studies are recommended in order to evaluate IDCV responsiveness.

CONCLUSION

The findings of this study concluded that total IDCV and most of its domains discriminated the impact of the disease among groups of patients who scored in different quartiles of general and specific HRQoL measures. Yet the IDCV did not discriminate the impact of the disease related to signs and symptoms (edema, dyspnea, angina and arrhythmias), LVEF and left ventricular systolic function. Further research with the inclusion of more accurate measures of clinical variables are recommended in order to contribute to the refinement of the measure provided by the IDCV.

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