

Quality of Life Assessment after Acute Coronary Syndrome: Systematic Review

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Introduction

The Acute Myocardial Infarction (AMI) has been known worldwide since the beginning of the twentieth century as an almost always fatal disease. The physical and psychoemotional impact caused by the disease and the high prevalence of depression have been described as the major factors that contribute to the impairment of quality of life (QOL) of patients in the medium and long-term¹⁻³.

A systematic review of studies evaluating QOL after acute myocardial infarction demonstrated that the effects of infarction on the QOL dissipate in the long term, but specific evaluation of patients who develop left ventricular function impairment in the acute phase of the event, does not seem to have been investigated⁴. In addition, two studies indicate that the consequences of both chronic ischemic heart disease and heart failure are not temporary, and their effects on QOL assessment worsen soon after diagnosis with no improvement in patient follow-up, differently from what has been observed after an acute event^{4,5}.

Although health systems always focus on morbidity and mortality control, recent concerns have also encouraged the evaluation of the impact of health hazards on patients' daily life. These assessments are usually carried out using questionnaires developed and validated through a specific methodology, which involves replication in other populations rather than the original population for which they were developed.

There are several instruments to assess QOL in patients with ischemic heart disease and specific methodologies have been developed for the translation, cultural adaptation and interpretation of instruments when used in other languages. This systematic review aims at analyzing which instruments translated into Portuguese were used to assess quality of life in patients

Keywords

Acute coronary syndrome, quality of life, sickness impact profile, review.

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E-mail: suzana.silva@cardiol.br, suzanaalvessilva@gmail.com Manuscript received January 11, 2011; revised manuscript received Januart 11, 2011; accepted March 04, 2011. with acute coronary syndrome (ACS) and the interpretation of their results according to their psychometric properties.

Methods

Search strategy

The literature search was performed by a librarian specialized in the medical science field and saved using reference management software (Endnote, release 13.0). The search was not restricted to language or periods. The gateways, their respective databases and syntax used are described in Table 1. We performed a manual search of relevant cross-references.

Criteria for reference selection and data extraction

Reference selection and data collection were performed according to Prisma guideline⁶, by pairs of trained independent researchers.

Reference selection was carried out by reading the abstracts of the available literature (Table 1) and data extraction was performed by reading the full texts of selected references for the variables of interest.

The analysis included all studies that evaluated the quality of life of patients with acute coronary syndrome or myocardial infarction, using instruments translated into Portuguese.

The studies were included in the analysis regardless of the design and follow-up extent. Studies with results that were out of scale variation range were excluded.

Selected variables and outcomes of interest

We analyzed the quality of life (QOL) outcomes defined as the total and summarized scores of each instrument, according to the time elapsed between the diagnosis of acute coronary syndrome and the instrument application, as well as according to the clinical characteristics and socio-demographic profile of the population included in analysis. The validity results, including criterion (sensitivity, specificity, likelihood ratio) and construct validity (Pearson's, Spearman's or Kendall's correlation coeficient), reliability, including internal consistency (Cronbach's alpha test) and reproducibility (Intraclass coefficient of correlation or weighted kappa) and sensitivity, responsiveness, and interpretability were investigated and only the results found were described.

Statistical Analysis

The selected references and data collected were entered into an ACCESS database, release 2007, built specifically for this purpose.

Quantitative variables were summarized by means and standard deviations as measurement of quality of life scores and psychometric properties of the evaluated instruments. Heterogeneity between studies was assessed based on Cochrane's Q² Test with a significance level of 10%7. The l² test was also used to quantify the heterogeneity among studies on a scale from 0 to 100%. Studies with l²> 75% were considered highly heterogeneous. Weighted means and standard deviations of quality of life scores were pooled together according to the methodology standardized by Cochrane⁸.

Data from the longitudinal studies were consolidated by a random-effect model that considered the Inverse of Variance as a weight measure to compare results before and after in relation to the time of questionnaire application. This moment was defined in relation to the ACS diagnosis and stratified as: ≤ 2 months and > 2 months and compared between them. For the cross-sectional studies, the comparison between the two moments was made considering the data imputed from the weighted mean of the other studies in that period (before or after). Statistical tests were performed using the RevMan 5 (Cochrane) program, considering a significance level of 5%. All tests were two-tailed.

Results

Reference selection and characteristics of studies included in the review

The search strategy results and reference selection are depicted in Figure 1 and the characteristics of the selected

studies are shown in Table 1. We found four reviews⁹⁻¹² that were used as basis for cross-reference search.

Of 2,990 reviewed abstracts, eighteen full texts were included in the qualitative synthesis, of which: three cohort studies¹¹³¹⁵, two case-control studies¹⁶¹¹², eleven sectional studies¹¹ð²², one non-randomized clinical trial²⁰ and one randomized clinical trial³⁰. Three abstracts of which full texts were not published³¹¹³³ and two duplicated publications³⁴,³⁵ were excluded. Significant loss to follow up was observed in seven of the eighteen studies that were included. Three studies used different instruments that could not be included in the quantitative synthesis: one used the Seattle questionnaire¹⁵, one used the IPQ (Illness Perception Questionnaire)²⁶ and one the NHP (Nottingham Health Profile)¹⁶. Four studies contributed to the meta-analysis (Figure 1).

Post-ACS quality of life was evaluated in selected populations from the south and southeast regions of Brazil, as well as the districts of Porto and Coimbra in Portugal; the vast majority of the patients were treated at cardiology outpatient clinics and rehabilitation programs of universitarian hospitals (Table 2).

Patient selection in these studies was carried out by searching the medical or hospital records and the sample size was defined by convenience. The time elapsed from ACS diagnosis to the questionnaire application varied among studies and was unclear in two of them. In seven studies the time from diagnosis was less than two months and in nine it ranged from two months to twelve years. The questionnaire application method, whether by interview, telephone contact or self-application was described in only six studies, was unclear in two studies and was not reported in the others (Table 2).

Table 1 - Search method used to locate references related to quality of life assessment after acute myocardial infarction

Source	Search method	Results
BVS (Medline, Lilacs, Scielo)	(Myocardial Infarction OR Acute Coronary Syndrome OR Acute Coronary Disease) AND (Quality of Life or Life Quality) AND (Questionnaire or Questionnaires)	321
PubMed (Medline)	("myocardial infarction"[Title/Abstract] OR "acute coronary syndrome"[Title/Abstract] OR "myocardial infarction"[Mesh] OR "acute coronary syndrome"[Mesh]) AND ("quality of life"[Title/Abstract] OR "quality of life"[Mesh] OR "life quality"[Title/Abstract])	1690
Science Direct	(TITLE-ABS-KEY("myocardial infarction") OR TITLE-ABS-KEY("acute coronary syndrome")) AND (TITLE-ABS-KEY("quality of life" OR "life quality") OR TITLE-ABS-KEY("questionnaire "OR" questionnaires"))	891
Scopus	((((((TITLE-ABS-KEY("myocardial infarction"))OR(TITLE-ABS-KEY("acute coronary syndrome"))))AND(TITLE-ABS-KEY("quality of life"))))AND(TITLE-ABS-KEY("questionnaire" OR" questionnaires")))	497
OVID (Cochrane, PsycInfo, CRD, Medline)	(*Myocardial Infarction/ or myocardial infarction.mp. or *acute coronary syndrome/ or Acute Coronary Syndrome.mp.) and (*"Quality of Life"/ or quality of life.mp. or quality of life.ti,ab. or life qualities.mp. or life quality.mp.)	1768
Web of Science	Topic=(myocardial infarction OR acute coronary syndrome) AND Topic=(quality of life) AND Topic=(questionnaire OR questionnaires)	179
Google Scholar	"questionnaire" + "quality of life" + ("acute coronary syndrome" OR "acute myocardial infarction" OR "acute coronary disease")	1000
EMBASE	(('acute coronary syndrome'/exp) OR ('acute coronary syndrome'.ti,ab) OR ('heart Infarction'/exp) OR ('heart Infarction'. ti,ab)) AND (('quality of life'/exp) OR ('quality of life'.ti,ab)) AND (('questionnaire'/exp) OR ('questionnaire'.ti,ab))	456
<u> </u>	Total	6802

Most studies did not report on the previous history, habits, except for smoking, and socio-demographic characteristics of the studied populations (Table 3). None of the selected studies adjusted their results for any of these characteristics. Family income was less than four minimum wages^{19,25,26,28} and the level of schooling was less than four years in more than 50% of the studied population, except for the study by Dias et al¹³, which excluded patients with low educational level. Only two studies described the percentage of patients that returned to work after the coronary event, ranging from 26%¹⁹ to 52%²⁸.

Quality of Life Questionnaires

The most widely used QOL questionnaires were: SF-36 in nine studies; MacNew in six studies; WHOQOL in three of them and Seattle, IPQ and NPH in one study each. The summarized and overall scores obtained in the periods before and after two months, and the mean of the difference between the two points are shown for the SF-36 and MacNew questionnaires in Figures 2 and 3, respectively, for both cross-sectional and longitudinal studies.

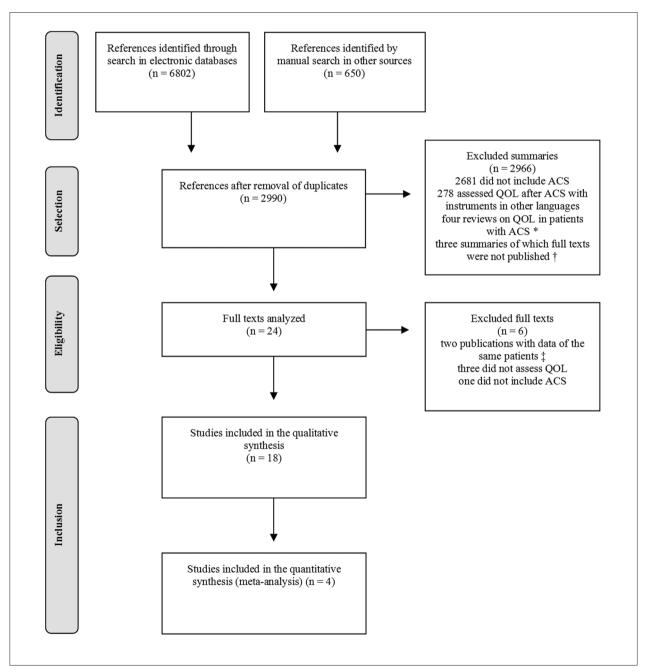


Figure 1 - Flow chart; QOL – Quality of Life; ACS – Acute Coronary Syndrome; (*) Adánez, 1999; Breda, 2005; Dougherty, 1998; Passamani, 19919-12; (†) Almeida, 1997; Benetti, 2001; Coelho, 200031-33; (‡) Bettencourt, 2005; Ancantara, 200734.35.

The two meta-analysis performed for the longitudinal studies suggest QOL improvement in the late follow-up of 0.55 (95%CI: 0.34 to 0.76) for the MacNew questionnaire and 5.87 (95%CI: 3.42 to 8.31) for the SF-36 questionnaire compared with the initial follow-up of up to two months after the ACS diagnosis.

The weighted means of the SF36, MacNew and WHOQOL ³⁶ and the Seattle results observed in the study by Souza et al¹⁵ were similar to those observed in patients with acute coronary syndrome in other countries (Table 4)³⁷⁻⁴⁰, and lower than the scores observed in the general population of the United States and other countries (Table 4)⁴¹, except for the summarized measurements, which had a behavior more similar to that of the general population in other countries than with the ACS population⁴².

Psychometric Properties

The psychometric properties of the MacNew, SF36 and WHOQOL questionnaires were evaluated in four of the eighteen analyzed studies. Convergent validity (a type of construct validity) was analyzed using Pearson's correlation between the MacNew, disease-specific, and SF-36, general, questionnaires (Alcântara²⁵, Leal et al¹⁴ and Nakajima et al¹⁹), and between the WHOQOL-brief and SF-36 questionnaires, both general (Cruz et al²⁶).

Correlations between MacNew and SF-36 scores were > 0.6 for mental health, vitality and functional capacity scores ¹⁹. The emotional score of MacNew questionnaire showed correlation values > 0.6 with only two domains of SF-36: mental health (r = 0.78) and vitality (r = 0.69) ^{19,25}. The correlations between the physical component of the SF-36 and MacNew overall and physical scores were 0.70 and 0.72, respectively, and between the mental component of SF-36 and the emotional score of MacNew was 0.78 (Leal et al¹⁴).

The correlation between the emotional score of the two questionnaires ranged from -0.15 (Alcantara et al²⁵) to 0.45 (Nakajima et al¹⁹) and between the social scores, it ranged from 0.49 to 0.58 between the studies 14,19,25. Leal et al¹⁴ observed significant correlations (r > 0.70) between the overall and summarized scores of both questionnaires in the same dimensions (physical component of SF-36 vs. overall score and physical score of MacNew and mental component of SF -36 vs. MacNew emotional score). Cruz et al²⁶ found significant Pearson's correlation (r > 0.55) between the physical score of the WHOQOL and all scores of SF-36 (except for the physical impairment and emotional state scores) and between the WHOQOL psychological score and the mental health and vitality scores of SF-36. The vitality (r = 0.58) and mental health scores of SF-36 (r = 0.68) and all WHOQOL scores (r> 0.55) moderately correlated with Beck's depression questionnaire²⁶.

Discriminant validity (another type of construct validity) was investigated in the studies by Nakajima et al¹⁹ and Leal et al¹⁴. Patients with severe ventricular dysfunction had significantly lower QOL scores compared to those with

mild or moderate ventricular dysfunction¹⁹. The MacNew questionnaire was able to significantly discriminate patients with severe LV dysfunction from the others, as well as patients with progressive worsening in SF-36 scores from those with improvement or no change in these scores. The MacNew questionnaire was also able to differentiate patients with and without depression or anxiety using the hospital scale for anxiety and depressão¹⁴.

Internal consistency (Cronbach- α) of SF-36 and WHOQOL, evaluated by Cruz et al 26 was > 0.7 for all dimensions except for the social score. In the studies by Nakajima et al 19 and Leal et al 14 , which evaluated the MacNew questionnaire, internal consistency was > 0.8 for all dimensions. These results are similar to what was observed in other countries (Table 5) $^{43-46}$.

Reproducibility was assessed exclusively by Leal et al¹⁴ using the test-retest intraclass correlation for the MacNew questionnaire, with results ranging from 0.77 to 0.93, also showing results that were similar to those observed in other countries (Table 5)⁴⁴.

The <u>floor-ceiling effect</u>, present when $> 10\%^{47}$, was observed in the "emotional state" and "physical impairment" scores of SF-36 evaluated in the study by Cruz et al²⁶. This effect was not present in the MacNew questionnaire evaluated in the study by Leal et al¹⁴.

Heterogeneity

The longitudinal studies included in the meta-analysis showed moderate heterogeneity. Meta-regression analysis to evaluate the causes of heterogeneity was not performed due to the absence or inconsistency of information in most studies. Possible causes of heterogeneity may be related to different study designs included in the analysis and methods used for the selection of research subjects and questionnaire application. Another possible source of heterogeneity was the time elapsed between the ACS and questionnaire application, mainly in the group classified as evaluation "> two months," which ranged from three months to six years from the diagnosis. In addition, for the cross-sectional studies, other studies included in the analysis within the same category imputed based on the weighted mean of other studies included in the analysis within the same category, so that the comparison of means before and after could be performed for the studies that were found. The clinical and socio-demographic characteristics, when reported, also varied widely between studies and seem to be homogeneous only for age range and sex (Table 3).

Discussion

This systematic review is a survey of what was produced in Brazil and Portugal in relation to the subject "quality of life" in acute coronary disease, taking into account the results of quality of life scores measured by different instruments, according to time of disease and their psychometric properties.

The psychometric properties of the instruments were assessed in only four of eighteen studies analyzed, three of which evaluated the association of a general questionnaire (SF-36) to a specific questionnaire (MacNew) and are discussed below.

Table 2 - Characteristics of selected studies

Author, year, place	QOLQ (method used	Design	PP	Groups (number of patients)	Time elapsed since ACS	Losses	Population and observations
Alcântara, 2005 ²⁵ MG, Brazil	MacNew* SF36 (not reported)	Sectional	Yes	AMI (96)	3 to 18 months	0	Patients with a previous history of AMI treated at the outpatient clinic of Hospital das Clínicas de Uberlândia. Those with EF < 55% were excluded.
Benetti, 2001 ²⁴ SC, Brazil	MacNew (not reported)	Sectional	No	AMI – rehabilitation (15) AMI – spontaneous physical activity (15) AMI – control (15)	>2 months	0	Male patients from the rehabilitation program of Uni. Federal de Santa Catarina in comparison with patients treated by conventional therapy, selected by age, smoking and family history pairing, from Instituto de Cardiologia do Hospital Regional
Benetti, 2010 ²⁹ SC, Brazil	MacNew (not reported)	NRCT (QLQ initially and after 3 months)	No	AMI – control (32); AMI – intense exercise (32); AMI – moderate exercise (33)	8±4 months	11 (11%)	Male patients with a history of AMI for at least 2 and a maximum of 12 months and sedentary for at least 12 months, treated at the outpatient clinic of Univ. do Estado de Santa Catarina. Patients with history of CHF, SAH, COPD or smoking were excluded.
Coelho, 1999 ¹⁶ Porto, Portugal	NHP (not reported)	Case-Control	No	AMI (267) Healthy Control (257)	< 1 month	114 (43%) 101 (39%)	Men > 39 years, admitted at the Cardiology Department of Hospital Universitário after the first episode of AMI, with minimum capacity to answer the questionnaires.
Cruz, 2009 ²⁶ RS, Brazil	SF36 WHOQOL (self-applied)	Sectional	Yes	CAD (105)	6±6 years	2	Patients with history of AMI (74%) or MR >3 months and minimum intellectual capacity to answer the questionnaires. Patients with kidney failure, IDDM, COPD, AIDS, cancer, stroke sequelae, epilepsy or any other debilitating chronic disease were excluded. Two illiterate patients answered the questionnaire through interview.
Dias, 2005 ¹³ Porto, Portugal	SF36 (not reported)	Cohort (QLQ initially and after 12-18 months)	No	ACS (278)	< 1 month	97 (35%)	Patients admitted at the Cardiology Service with a diagnosis of confirmed ACS discharge and schooling level > 4 years.
Gallani, 2003 ²⁷ SP, Brazil	SF36 (not reported)	Sectional	No	AMI (49) Angina (27)	> 2 months?	0	Patients with history of AMI (time?) or angina treated at the outpatient clinic of cardiology of Hospital de Clínicas de Campinas with capacity to understand the questionnaire.
Gouvêa, 2004 ²⁸ Coimbra, Portugal	IPQ (self-applied locally)	Sectional	No	AMI – Men (46) AMI – Women (32)	< 1 month	2 (2,5%)	Patients > 40 years, admitted at the Coronar Unity of two hospitals in the north region of Portugal with AMI, Killip I or II, oriented and capable of reading or understanding Portuguese.
Leal, 2005 ¹⁴ Porto, Portugal	MacNew SF36 (not reported)	Cohort (QLQ initially and after 2 months)	Yes	ACS (150)	< 2 months	100 (67%)	Patients with history of ACS (71% AMI) for a maximum of 2 months treated at outpatient clinic of Hospital Geral de Santt Antonio. Only the 50 patients referred to the rehabilitation program were submitted to the QLQ at 2 months, of which 17% with unknown level of schooling.
Lemos, 2003 ¹⁸ MG, Brazil	MacNew (self-applied locally)	Sectional	No	AMI (58)	> 1 month	207 (80%)	Patients selected by reviewing medical records of treated patients with diagnosis of AMI > 1 month (83% < 15 months), from Hospital Universitário de Uberlândia. Patients > 65 years, with chronic disease or history of rehabilitation were excluded.

Continuation.							
Lemos, 2008 ¹⁷ RS, Brazil	WHOQOL (not reported)	Case-Control	No	Outpatient Control (59); CVD outpatient (49); AMI Admission Unit (60)	< 1 month	0	Patients with history of CVD treated at the outpatient clinic or admitted with AMI at Instituto de Cardiologia do Rio Grande do Sul. Patients using anti-depressives, undergoing psychotherapy, or those with psychiatric disorders were excluded.
Nakajima, 2009 ¹⁹ SP, Brazil	MacNew SF36 (interview)	Sectional	Yes	AMI (159)	> 3 months?	0	Patients with history of AMI (time?) treated at the outpatient clinic of Faculdade de Ciências Medicas of Universidade de Campinas. Patients with a history of cardiovascular event in the last 3 months were excluded.
Salvetti, 2008 ³⁰ SP, Brazil	SF36 (not reported)	RCT (QLQ initially and after 3 months)	No	ACS control (20); ACS home exercises (19)	Not reported	0	Patients with history of one acute coronary event admitted at the service of clinical cardiology of Hospital da Escola Paulista de Medicina. Patients with functional capacity < 6 METs or EF<50% or history of CHF, CVA, NYHA III or IV, recurrent angina, ventricular arrhythmia, > 2 AMI, CRP or MVD were excluded
Siviero, 2003 ²⁰ SP, Brazil	WHOQOL (interview)	Sectional	No	AMI (33)	< 1 week	0	Patients admitted with AMI in the intensive care unit of 3 general philanthropic hospitals, in 3 cities of the countryside of São Paulo. Exclusion criteria were not reported. This study describes only the frequency of responses to the questionnaire and does not summarize the results of QOL in measurements of central tendency.
Souza, 2008 ¹⁵ RS, Brazil	Seattle (not reported)	Cohort (QLQ initially and after 6 months)	No	ACS without ST elevation (305)	< 1 month	16 (5.3%)	Patients admitted with ACS without ST elevation (21% AMI), at Instituto de Cardiologia do Rio Grande do Sul. Patients with dilated cardiomyopathy of non-ischemic etiology or valvular disease were excluded.
Stocco, 2009 ²¹ SC, Brazil	SF36 (telephone interview)	Sectional	No	SCA (52)	< 1 month	9 (17%)	Patients with ACS (42% AMI) admitted at Hospital Nossa Senhora da Conceição. Exclusion criteria were not reported.
Thomas, 2007 ²² RS, Brazil	SF36 (interview?)	Sectional nested in NRCT (153)	No	AMI control (28) AMI prevention secondary (15)	< 1 month	77 (50%)	Study nested in RCT of patients admitted with first AMI (time from AMI to inclusion was not defined) at Instituto de Cardiologia do Rio Grande do Sul. Patients admitted at the moment of enrollment or those with incapacitating disease were excluded.
Vasconcelos, 2007 ²³ MG, Brazil	MacNew* (interview?)	Sectional	No	AMI (59)	5-21 months	12 (20%)	AMI between 5 and 21 months with admission record at Hospital da Universidade Federal de Uberlândia. Patients with EF < 50%; NYHA III or IV; > 1 previous AMI or undergoing cardiac rehabilitation were excluded. 27% of the patients were submitted to thrombolysis and the others to angioplasty.

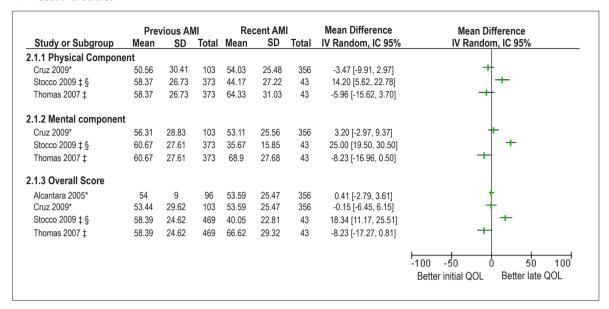
MR- Myocardial Revascularization; CVD- Cardiovascular Disease; DM- Diabetes Mellitus; MVD- Multivessel Disease; RCT- Randomized Clinical Trial; NRCT Non-Randomized Clinical Trial; EF- Ejection Fraction; SAH- Systemic Arterial Hypertension; FH- Family History of Coronary Disease; AMI- Acute Myocardial Infarction; IPQ-Illness Perception Questionnaire; LVF- Left Ventricular Failure; NHP- Nottingham Health Profile; QLQ- Quality of Life Questionnaire; ACS- Acute Coronary Syndrome; PP-Psychometric Properties. (*) Results of scores inconsistent with the instrument scale; ? - indefinite.

Table 3 - Clinical and socio-demographic characteristics of the studied population

		,						1												_
(%) so	Depression	19	\$	\$	\$	₹	~ 50	¥	₹	¥	69	40	NA	ΑN	30	≨	≨	Ą	43	
Socio-demographic characteristics (%)	Family income	85% < R\$ 1,000.00	NA	NA	NA	65% < 4 min. wages	NA A	60% < 4 min. wages	49% < €\$ 500.00	N A	NA	NA	50% < US\$ 410.00	NA	NA	NA	NA	NA	Ą	
-demograph	Schooling % sons 4 ≥	92	NA	NA	36	40	0	50	24	53	NA	NA	20	NA	64	+	Ą	NA	NA.	
Socio	Married	9/	¥	\$	≨	65	28	92	11	96	NA	69	62	10	29	¥	¥	N	¥	
	Sedentary	54	NA	NA	20	NA	NA	NA	NA	NA A	16	NA	NA	NA	64	NA	6/	NA	71	
Habits (%)	mailohoolA	NA AN	NA	NA	Ā	NA	A	NA	NA	NA A	NA	13	NA	NA	AN	NA	NA	NA	NA	
	Smoking	9/	NA	0	78	10	35	N A	NA	47	71	48	NA	NA	46	23	NA	NA	78	
	CKE	AN	NA	NA	N	0	NA A	Ą	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
(%) k	ΓΛE	0	NA	0	N	¥.	~50	N A	NA	51	NA	NA	20	~16	NA	NA	NA	NA	0	
Previous history (%)	ATO	38	NA	31	N	NA A	N.	N A	NA	NA	NA	NA	A	23	N	NA	19	NA	34	
Prev	MR	40	NA	56	N	¥.	NA A	N A	NA	NA	NA	NA	NA	NA	NA	38	19	NA	39	
	IMA	AN	Ą	Ą	0	74	39	¥.	02	71	NA	NA	16	77	Ą	42	39	NA	NA	
	НЫ	NA	NA	NA	Ą	N A	A	ΑN	NA	NA NA	NA	63	NA	NA	42	2	11	NA	36	
	Viesity	~50	NA	NA	14	ΑN	N	ΑΑ	NA NA	12	55	23	99	~16	19	NA	37	NA	7	
Cardiovascular Risk Factors de (%)	Dyslipidemia	41	\$	20	44	₹	53	¥	49	¥	62	59	88	72	21	52	75	Ą	44	
ar Risk Fac	H∀S	55	NA	0	30	ΑN	53	ΑΑ	47	NA.	81	40	84	29	22	6/	29	NA	71	
ardiovascu	M eətədsiQ	21	\$	\$	17	30	21	¥	50	¥	71	6	33	18	27	24	31	Ą	50	
3	M xə8	74	100	100	100	58	84	70	29	82	69	73	74	75	64	28	65	65	NA NA	
	egA qb ± sibèm sons±	54±6	53±8*	28±6	> 39	61±10	59±12	6∓09	59±17	59±12	53±9*	51±8	59±10	54±9	46±9	.6∓3 _*	59±11	58±10	50±9*	
Author, year		Alcântara, 2005. ²⁵	Benetti, 2001.24	Benetti, 2010.29	Coelho, 1999.16	Cruz, 2009. ²⁶	Dias, 2005. ¹³	Gallani, 2003.27	Gouvêa, 2004. ²⁸	Leal, 2005. ¹⁴	Lemos, 2003.18	Lemos, 2008.17	Nakajima, 2009.¹³	Salvetti, 2008. [™]	Siviero, 2003™	Souza, 2008.15	Stocco, 2009.21	Thomas, 2007.22	Vasconcelos, 2007. ²³	

CTA – coronary transluminal angioplasty; MR – Myocardial Revascularization; SAH – systemic arterial hypertension; FH – family history of coronary disease; AMI – acute myocardial infarction; CKF –chronic kidney failure; LVF – left ventricular failure; NA – not available; (*) Data estimated from published value; (†) 52% < 8 years.

2.1 - Sectional studies



2.1 - Longitudinal studies

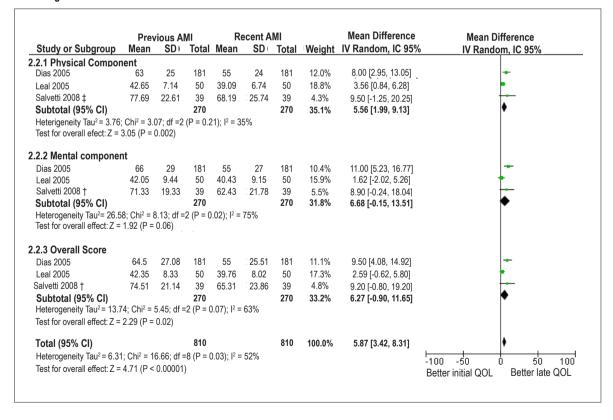
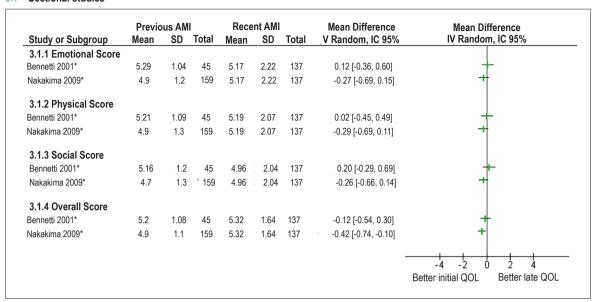


Figure 2 – Difference between the summarized and mean overall scores of QOL in SF-36 according to the time elapsed since the Acute Coronary Syndrome (≤ 2 and > 2 months); (*) Data from the initial follow-up (≤ 2 months) were imputed; (†) Single longitudinal study that evaluated SF36 domains; (‡) Data from late follow-up (> 2 months) were imputed; (§) The SD results of scores were obtained directly from the author based on unpublished data.

3.1 - Sectional studies



3.2 - Longitudinal studies

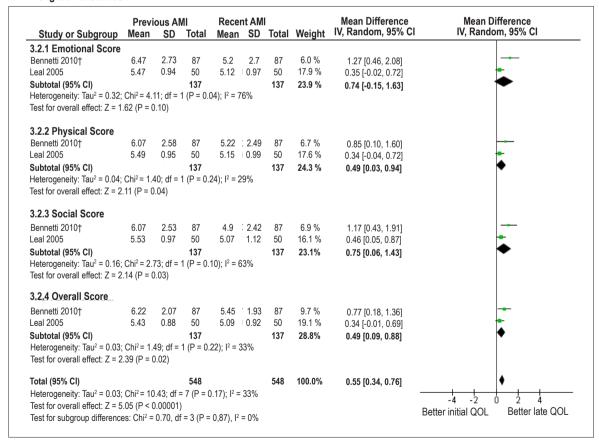


Figure 3 – Difference between the summarized scores and mean overall scores of QOL of the MacNew questionnaire according to the time elapsed since the Acute Coronary Syndrome ≤ 2 and > 2 months); (*) Data from the initial period (≤ 2 months) were imputed; (†) Standard-deviations were estimated based on SD of other studies in this analysis, according with the methodology proposed by Higgies et al⁸.

Table 4 - Quality of life assessment through general (SF-36 and WHOQOL) and specific instruments (MacNew and Seattle), at the early and late follow-up after the acute coronary event, compared to the general population of the United States and of other countries

Saaraa	ACS E	Brazil*	ACS in other	r countries*†	Normal	Normal*		
Scores	Follow-up21	,22,26,27,30	Follov	v-up37	115444	Other		
SF36	< 2m	≥ 2m	1m	12m	USA41	countries45‡		
N	287	125	1,351	1,298	2,474	33,927		
Body pain	54.82±25.92	65.44±21.98	78.83±23.09	82.96±22.51	75.2±23.7	62.20±8.51		
Emotional state	62.72±36.64 25	40.01±42.88	51.70±41.12	68.51±39.55	81.3±33.0	86.07±2.62		
Physical impairment	49.27±42.7	76.75±26.05	34.38±41.64	57.99±43.12	80.9±34.0	83.22±2.34		
Functional Capacity	62.36±24.68 25	65.36±14.51	70.35±25.36	76.17±23.79	84.2±23.3	87.56±2.02		
Social Function	66.42±25.6425	68.16±24.72	82.90±24.27	86.32±22.06	83.3±22.7	77.09±4.80		
General health status	55.63±21.78	65.2±21.04	66.63±20.14	66.45±22.28	71.9±20.3	71.50±2.98		
Mental Health	60.51±21.35	54.60±23.57	76.15±20.36	79.91±18.70	74.7±18.1	76.33±3.27		
Vitality	52.34±22.55	56.56±21.25	55.33±26.19	62.98±25.63	60,9±20,9	66,38±2,86		
Physical Component	58.37±26.7313.14	54.04±25.4814	44.00±9.52	46.81±9.73	50,7±9,5	50,98±9,3142		
Mental Component	60.67±27.6113.14	53.11±25.5614	48.92±10.77	51.73±10.39	50,0±9,9	51,75±9,6342		
WHOQOL-BRIEF	< 2m17	≥ 2m26	1m	> 3m38§	Brazil46(≈)	Other countries46(≈)¶		
N	60	103	NF	145	306	11,830		
Physical Domain	65.60±18.00	53.40±19.30	NF	56.7±18.7	15.2±2.5 (≈69)	16.2±2.9 (≈75)		
Psychological Domain	70.80±14.60	62.9±20.6	NF	66.5±17.6	15.1±2.7 (≈69)	15±2.8 (≈69)		
Social relations	76.30±15.40	63.00±22.7	NF	71.1±19.1	14.8±3.1 (≈69)	14.3±3.2 (≈63)		
Environment	63.20±15.60	58.40±15.00	NF	64±15.3	12.9±2.7 (≈56)	13.5±2.6 (≈63)		
MACNEW	< 2m14.29	≥ 2m14.19.29	< 1m39//	4m55#	-			
N	137	341	232	346	-			
Emotional Score	5.17±2.22	5.30±1.54	4.92±1.12	5.2±1.17				
Physical Score	5.19±2.07	5.33±1.73	4.83±1.24	5.04±1.22				
Social Score	4.96±2.04	5.23±1.75	5.01±1.15	5.38±1.28				
Total Score	5.32±1.64	5.35±1.48	5.04±1.22	5.17±1.11				
SEATTLE	< 2m15	≥ 2m15	< 1m40**	6m40**				
N	281	281	254	254				
Physical Impairment	NF	NF	80.3±23.91	85±23.91				
Stable angina	NF	NF	83.1±31.84	82.6±31.84				
Symptom frequency	NF	NF	89.3±15.94	93.1±15.94				
Satisfaction with treatment	NF	NF	85.5±7.97	86±7.97				
Disease perception	NF	NF	73±15.94	78.1±15.94				
Total score	35.04± 13.51	50.00±15.67	82.24±21.45	84.96±21.31				

NF – Not Found; (*)weighted means and deviations of the groups included in the indicated references; (†) weighted mean of results of the DANAMI-2 study, carried out in 24 reference-hospitals of Cardiology in Denmark comparing women and men, treated with thrombolytic agents or angioplasty³⁷; (‡) weighted mean of the scores observed in general populations of eleven countries: Denmark, France, Germany, Italy, Holland, Norway, Spain, Sweden, United Kingdom and United States⁴⁵; (§) population of female patients selected from a cohort in Norway³⁸; (≈) approximate value in the scale of 0-100 according to the manual³⁸; (¶) population of 23 countries representing all regions covered by the World Health Organization (WHO); (//) patients after acute myocardial infarction referred to one of six cardiac rehabilitation centers in Austria; (#) study of QOL applied to a population of 340,000 inhabitants of Southern Australia. Patients were selected consecutively from fifteen public and three private hospitals⁵⁵; (**) sub-study of QOL in the patients enrolled in the STENT-PAMI study, selected from 32 institutions in the U.S. and one in Canada⁴⁰; (↓) score found to be significantly below the value observed in the general population, based on the minimum significant difference according to Norman's criteria⁵⁴.

Construct validity

Construct validity was assessed according to previously established methods^{48,49} and showed: 1) high convergence between the items of the MacNew and SF-36 questionnaires, considering the same construct, except for the emotional scores, probably because they measure different quality of life aspects. While the MacNew questionnaire deals with the patient's perception, SF-36 is concerned with the impact of the emotional state on their daily activities, 2) high convergence was observed among all dimensions of the WHOQOL-brief and only the mental health score of SF -36, but not between the other scores of this instrument, probably as a consequence of the fact that the two questionnaires have very different scopes. While the SF-36 was designed to assess health status, the WHOQOL was designed to assess the patient's perception regarding the different aspects of his/her life, in an overall manner, 3) low discriminating capacity of the general questionnaires in opposition to the good discriminating capacity of the MacNew specific questionnaire for changes in quality of life related to heart failure or depression symptoms, and 4) moderate discriminating capacity of the WHOQOL questionnaire for the presence of depression.

The analyses of construct validity of the discriminant type were restricted to the MacNew questionnaire, which showed good discriminating capacity between patients with and without severe ventricular dysfunction, depression and anxiety compared to longitudinal observations with the SF-36. Functional classes of angina or heart failure were not evaluated, but previous studies have suggested that these questionnaires have low discriminant power for these items³.

Criterion validity was not assessed in any of the studies included in this review and its importance would relate primarily to determine performance, mainly of specific instruments to define the presence or absence of clinical conditions of interest, such as re-obstruction of coronary vessels or heart failure during the clinical follow-up of these patients.

Table 5 - Psychometric properties of the version translated into Portuguese of the SF-36, WHOQOL and MacNew QOL questionnaires when applied to patients with heart disease, compared to the general population of other countries

Score	Floor e	ffect (%)	Ceiling	effect (%)	a-Cronbach	Coefficient	Intraclass Correlation		
SF36	Port.* Min-Max	Other† Min-Max	Port. * Min-Max	Other† Min-Max	Port.* Min-Max	Other†‡ Min-Max	Port. Min-Max	Other Min-Max	
Functional Capacity	1-3	0.2-1.1	3-4	26.0-58.7	0.89-0.90	0.87-0.94	0.73	NF	
Body pain	1-2.5	0.4-1.4	12.9-18	30.1-59.1	0.83-0.87	0.76-0.88	0.74	NF	
Emotional State	30-40	5.2-11.2	32-44	69.0-87.2	0.79-0.84	0.76-0.93	0.76	NF	
Social Function	0-2.5	0.1-1.0	25.5-38	34.4-76.0	0.57-0.70	0.68-0.86	0.68	NF	
Physical Impairment	32-39	6.1-13.2	15-31	63.3-82.9	0.79-0.85	0.83-0.96	0.90	NF	
General health	0-1	0.0-0.4	1-2	1.8-13.6	0.72-0.75	0.71-0.84	0.70	NF	
Mental health	0-1	0.0-0.2	5-7.1	1.6-16.1	0.87-0.87	0.78-0.87	0.69	NF	
Vitality	2-2.5	0.1-0.8	1-7.5	1.2-7.9	0.83-0.85	0.72-0.87	0.79	NF	
WHOQOL	Port.*	Other¶ Min-Max	Port.*	Other¶ Min-Max	Port.*	Other¶ Min-Max	Port.	Other	
Physical Score	1	3.6-5.9	1	14.8-35.2	0.83	0.55-0.88	NF	NF	
Psychological Score	1	1.7-4.9	1	11.7-22.1	0.85	0.65-0.89	NF	NF	
Social Score	1	2.4-8.8	8.7	13.9-18.4	0.65	0.51-0.77	NF	NF	
Environment	0	2.9-8.1	0	10.9-22.9	0.74	0.65-0.87	NF	NF	
MACNEW	Port. § 95% CI	Other 95%CI	Port.§ 95%CI	Other 95%CI	Port.§ 95%CI	Other// 95%CI	Port. 95% CI	Other// 95% CI	
Physical	0-1.19	NF	4.00-9.82	NF	0.83-0.91	0.85-0.97	0.82-0.93	0.73-0.93	
Emotional	0-1.19	NF	3.74-9.44	NF	0.85-0.92	0.86-0.93	0.77-0.90	0.77-0.83	
Social	0-1.19	NF	3.49-9.05	NF	0.83-0.91	0.78-0.95	0.77-0.90	0.75-0.91	
Total	0-1.19	NF	3.24-8.66	NF	0.88-0.95	0.92-0.97	0.82-0.93	0.76-0.95	

NF – not found; Port - Refers to the Portuguese version applied to patients with coronary artery disease; Other - Refers to studies carried out with the general population of other countries; (*) Cruz, 2009²⁶ and Franzen, 2005⁶²; (†) Gandek, 1998 (41.642 individuals from eleven countries: Denmark, France, Germany, Italy, Holland, Norway, Spain, Sweden, United Kingdom and United States)⁴⁵. (‡) Data from the physical and mental components were obtained from Kristofferzon, 2005 (148 individuals, Sweden)⁴³; (§) Nakajima, 2009¹⁹ and Leal, 2005¹⁴; (//) Hofer, 2004 (352 North-American, 339 Dutch, 51 Persian, 357 German and 143 Spanish individuals). The intraclass coefficient of correlation was assessed only for the German, Spanish and Persian translations in this study⁴⁴; (¶) general population of 23 countries representing all regions covered by the World Health Organization (WHO)⁴⁶.

Reliability

The internal consistency assessed by Cronbach's α was low for the social score of the general questionnaires, both SF-36 and WHOQOL, whereas the specific questionnaires Seattle and MacNew behaved differently from the general questionnaires and had high internal consistency in all their dimensions.

Reproducibility, considered satisfactory when > 0.50 for comparison between groups and > 0.90 when comparing the individual with him or herself^{44,47}, was evaluated only for the MacNew questionnaire in 1 study, demonstrating that this questionnaire showed high reliability in the studied population¹⁴.

Sensitivity

The SF-36 dimensions that address the emotional state and social function showed a high floor-ceiling effect, which was also moderately present in the dimensions of body pain and physical impairment, consistent with what was seen in previous studies^{45,46}. The propensity to the floor-ceiling effect was low for both specific questionnaires, MacNew and Seattle. Although the floor-ceiling effect has been described as a good parameter to infer the sensitivity of QOL instruments, as it demonstrates whether the instrument is able to detect variations between individuals rather than the extremes of the measurement, it is a method considered by many authors as insufficient to assess whether the instrument is capable of detecting small differences⁵⁰. The method that has been proposed for the assessment of this property is that of the magnitude of the effect between groups through specific statistical tests, such as Cohen's size effect, Guyatt responsiveness index and the standardized mean difference, which was not was performed in any of the analyzed studies^{50,51}.

Responsiveness

The interpretation of changes in QOL scores over time is another question of great importance when following patients with ischemic heart disease⁵². The floor-ceiling effect has also been used as a useful indicator of instrument responsiveness⁵⁰, but the most widely used concept in the literature is the "minimal important difference" (MID), which represents the smallest difference in score of the domain of interest that is perceived by the patient and would determine, in the absence of clinical or financial limitations, the change in therapeutic conduct^{53,54}. Norman et al⁵⁴, based on a systematic review of QOL studies, showed that the MID can be estimated based on half of the standard deviation of the mean scores resulting from the initial instrument application in that population⁵⁴. It has been shown that a change of at least 0.5 and 3.5 are useful indicators for MID in the scores of the MacNew and Seattle questionnaires, respectively^{55,56}.

For the SF-36 questionnaire, a variation of around 10 points for the individual scores represented a marked change in the perception of the patients' health, whereas a change of about 5 points represented a moderate change⁵⁷. In this review, only four of eighteen studies allowed this analysis, with values of 0.55 found for MacNew and 5.78 points for the SF-36, consistent with what has been established as the

MID for these instruments. A change of approximately fifteen points was observed in the only study that evaluated the Seattle questionnaire¹⁵. This large variation may be related to the time of the first application of the instrument carried out at hospital admission, when the patient presented acute symptoms¹⁵. With the exception of the Seattle questionnaire, these findings corroborate the results of the systematic review by Simpson, which suggests a modest QOL recovery after an acute coronary event⁵⁸.

The results of a previous systematic review, performed by Dempster et al⁵⁹ suggest that the general questionnaires such as SF-36 and Nottingham Health Profile have low responsiveness and therefore their results should be interpreted with caution, as these instruments are little sensitive to the observation of small evolution variations in QOL of patients with ischemic heart disease. In addition to Dempster, other authors have suggested that a specific questionnaire should always be associated with a general questionnaire to assess the quality of life in patients with ischemic heart disease^{3,59}.

Transcultural validation

Although the general instruments such as WHOQOL and SF-36, which were the most widely used in the assessed studies, in the vast majority as isolated instruments, have been validated in Portuguese in patients with clinical features that are completely different from those presented by patients with coronary disease^{60,61}, preliminary assessments suggest that at least SF-36 has high reliability in different cultures and in different clinical conditions, and in Brazil, it showed adequate reproducibility in a population of patients with stable angina⁶². The other instruments (Seattle, MacNew and NHP), which are disease-specific, have been validated in the population of interest. Although there are records of translation and validation of the Seattle questionnaire for Brazilian patients with stable angina, details of the transcultural translation process have not been described⁶².

It is noteworthy the fact that no specific instrument for heart failure has been used in the evaluated studies. It is known that a significant proportion of patients develops heart failure after an acute coronary event and that quality of life information in patients who develop severe ventricular dysfunction in the initial period after the acute coronary event are scarce and when available, restricted to the general questionnaires.

Limitations

The studies included in the meta-analysis showed moderate heterogeneity. The scarcity of available information prevented the inclusion of only prospective cohort studies, which would clearly demonstrate the evolution of quality of life in the early and late periods after an acute coronary event, also preventing a meta-regression to identify other causes of heterogeneity.

The quality of life assessments were not adjusted for any of the clinical or socio-demographic variables studied, which are known to influence the outcome of scores. Patients enrolled in the studies were not homogeneous regarding disease time and severity, as well as the cultural variations between Brazil and Portugal. Moreover, the cross-sectional studies included in the analysis were categorized into early or late evaluation, and the

missing information was imputed based on the weighted mean of the other studies within the same category. Therefore, the before and after comparison was based on study comparison and not on paired groups shown in the figures, except for the summarized scores of SF-36. Variations in mean scores may also be related to the proposed interventions for the treatment of patients, which have not been evaluated in this analysis.

These factors together prevent an accurate interpretation of the quality of life behavior in Brazilian and Portuguese patients suffering from acute coronary events and the differences between early and late assessment must be viewed with caution.

Such information, however, may be useful in formulating hypotheses and selecting the most appropriate instrument for the assessment of these populations.

Conclusion

In spite of the limitations, this review summarizes the studies carried out with instruments to evaluate quality of life, which have been translated into Portuguese, demonstrating flaws in the methods of validation and showing that information on the evolution of the QOL in Brazilian or Portuguese patients that have suffered an acute coronary event are still necessary. There has been a significant increase in the quality of life scores of 0.55 points for the MacNew questionnaire and of 5.8 points for SF-36 questionnaire. This review can be useful to create, design and carry out further studies in this area.

Acknowledgements

We thank Prof. Thomas M. Sakae for the prompt response to our contact and collaboration in providing non-published data that were important for this analysis and to librarian Maria Eduarda Puga for her invaluable help in creating the search strategy.

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Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

This article is part of the thesis of doctoral submitted by Suzana Alves da Silva, from Escola Nacional de Saúde Pública Sérgio Arouca / Fiocruz.

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