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Generic, Disease-Specific and Individualised Approaches to Measuring Health-Related Quality of Life Among People With Heart Disease – a Comparative Analysis

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Running title: Comparing QoL Instruments Among Cardiac Patients

ABSTRACT

Increasing emphasis is being placed on the evaluation of health-related quality of life. However, there is no consensus on the definition of this concept and as a result there are a plethora of existing measurement instruments. Head-to-head comparisons of the psychometric properties of existing instruments are necessary to facilitate evidence-based decisions about which instrument should be chosen for routine use. Therefore, an individualised instrument (the modified Patient Generated Index), a generic instrument (the Short Form 36) and a disease-specific instrument (the Quality of Life after Myocardial Infarction questionnaire) were administered to patients with ischaemic heart disease (n=117) and the evidence for the validity, reliability and sensitivity of each instrument was examined and compared. The modified Patient Generated Index compared favourably with the other instruments but none of the instruments examined provided sound evidence for sensitivity to change. Therefore, any recommendation for the use of the individualised approach in the routine collection of health-related quality of life data in clinical practice must be conditional upon the submission of further evidence to support the sensitivity of such instruments.

Key words: health-related quality of life, psychometrics, ischaemic heart disease

INTRODUCTION

Evaluations of health and social care interventions for ischaemic heart disease are placing increasing emphasis on quality of life outcomes as well as quantity of life, though a clear agreed definition of quality of life remains elusive. In recent years there has been an implicit agreement among health care researchers that their efforts should concentrate on trying to measure health-related quality of life (HRQoL). A person's quality of life may be affected by many factors, some of which may be unrelated to their health status. Focusing on "health-related quality of life" means that researchers can investigate, with greater thoroughness and rigour, issues which may affect life quality particularly the relationship between HRQoL and health care interventions.

Definitions of HRQoL usually refer to physical, emotional and social well-being - the three main components of health as defined by the World Health Organisation (1958). However, there is limited consensus about the specific composition of HRQoL or how elements or dimensions combine to produce an index of HRQoL. This is evidenced by the plethora of HRQoL measurement instruments and their relative lack of commonality. For example, a recent comprehensive literature review of the instruments used to measure HRQoL among people with ischaemic heart disease identified four generic instruments and nine disease-specific instruments, none of which comprised the same composition of domains and scales (Dempster & Donnelly, 2000a). This review also concluded that, based on available psychometric evidence, the Short Form 36 (Ware, Snow, Kosinski & Gandek, 1993) and the Quality of Life after Myocardial Infarction (Valenti, Lim, Heller & Knapp, 1996) questionnaires were, respectively, the most appropriate generic and disease-

specific instruments with which to measure the HRQoL of people with ischaemic heart disease.

One of the problems with defining HRQoL is that it may have a different meaning for different individuals. In other words, an important aspect of the life quality of one individual may hold less or no value for someone else. This individualised view of HRQoL is not recognised nor assessed by standardised generic and condition-specific instruments. An individualised perspective or approach provides a structure and opportunity for each individual to define the life domains that are important to them and that constitute their HRQoL.

Several individualised measures of quality of life and HRQoL have been designed in recent years. The most common individualised measure of global quality of life is the Schedule for the Evaluation of Individual Quality of Life (O'Boyle, Browne, Hickey, McGee & Joyce, 1993) and the most common individualised measure of HRQoL is the Patient Generated Index (Ruta, Garratt, Leng, Russell & MacDonald, 1994). These two instruments allow respondents the freedom to identify any important areas of life rather than requiring them to choose life areas from a predetermined list, as is the case with other partially individualised measures of quality of life which have been used among cardiac patients, such as the Quality of Life Index (Ferrans & Powers, 1985), the Chronic Heart Failure Questionnaire (Guyatt, Nogradi, Halcrow, Singer, Sullivan & Fallen, 1989), the Quality of Life Systemic Inventory (Duquette, Dupuis & Perrault, 1994) and the Netherlands Organization for Applied Scientific Research Adult Quality of Life Questionnaire (Fekkes, Kamphuis, Ottenkamp, Verrips, Vogels, Kamphuis & Verloove-Vanhorick,

2001). The Patient Generated Index and Schedule for the Evaluation of Individual Quality of Life also facilitate the ascribing of relative importance to the life areas identified by each individual.

Essentially, the generic, disease-specific and individualised approaches are the three main techniques used to measure HRQoL. As a result of the different approaches available and the lack of consensus on what constitutes HRQoL, health psychologists are often asked to recommend or choose the "best" instrument with which to measure HRQoL among specific patient groups. In order to facilitate this decision, it is necessary to conduct head-to-head comparisons of candidate instruments, so that choices can be made on the basis of evidence (Fitzpatrick, 2000).

Following this line of thought, Smith, Taylor and Mitchell (2000) compared the sensitivity of the Short Form 36, the Quality of Life after Myocardial Infarction questionnaire and the Schedule for the Evaluation of Individual Quality of Life among patients undergoing cardiac rehabilitation. However, this type of comparison needs to be extended to investigate other psychometric properties, especially because none of the individualised instruments have been validated for use among people with heart disease.

Therefore, the main aims of this study were to assess and compare the reliability, validity and sensitivity of an individualised instrument (the modified Patient Generated Index), a heart disease-specific standardised instrument (the Quality of Life after Myocardial Infarction questionnaire) and a standardised generic measure

of HRQoL (the Short Form 36), when all three instruments were administered to a group of people with ischaemic heart disease.

METHOD

Participants And Procedure

Patients who were diagnosed as having ischaemic heart disease and were admitted consecutively to a tertiary referral centre between March and June 1999 comprised the sample (n=119). All patients were asked, at hospital, for their consent to participate in the study. Only two patients (one male, one female) refused to take part in the study. Therefore, 117 patients (mean age 60.61 years; 84 males) were interviewed in hospital (101/117) or at a hospital-based cardiac rehabilitation class (16/117). Ethical approval for the study was sought and obtained from the participating hospital.

Of the initial 117 patients interviewed, 15 were unavailable to complete a follow-up interview. Therefore, 102 patients were asked to complete the second interview and 89 agreed. However, 7/89 patients were too sick to complete the second interview; 7/89 patients did not reply to the follow-up contact; and a further 3/89 patients did not take part for other reasons (death in the family, depression, holidays). The remaining 72 patients (mean age 59.3 years; 56 males) completed the second interview (three weeks later, on average) at hospital (n = 2) or at the patient's own home (n=70). This time interval is similar to that used in previous studies (Brazier et al., 1992; O'Keeffe, Lye, Donnellan & Carmichael, 1998). On both occasions, a modified Patient Generated Index (PGI), the Short Form 36 (SF-36) and the Quality

of Life after Myocardial Infarction questionnaire (QLMI-2) were administered, and biographical information and disease status details were also collected.

Instruments

The SF-36 and the QLMI-2 are commonly used generic and condition-specific measures of HRQoL among ischaemic heart disease patients (Campbell, Thain, Deans, Ritchie, Rawles & Squair, 1998; Dempster, Bradley, Wallace & McCoy, 1997; Hillers et al., 1994; Lim et al., 1993; Marquis, Fayol, Joire & Leplege, 1995; Valenti et al., 1996). The QLMI-2 is divided into three scales – emotional functioning, physical functioning, and social functioning. The SF-36 is divided into eight scales – physical functioning, social functioning, general health, role limitations due to emotional problems, role limitations due to physical problems, vitality, bodily pain, and mental health.

The modified PGI is the individualised HRQoL instrument adapted from the original PGI in the course of this study. A previous study (Dempster & Donnelly, 2000b) found that many people had difficulty comprehending and completing the final stage of the PGI, and suggested that a visual aid may be beneficial to aid comprehension. Therefore, the final stage of the original PGI was modified by the inclusion of a visual aid to assist the participants' decision-making process. Furthermore, the modified PGI includes an extra stage (stage 3), which we added to prime the participants for the final stage and therefore facilitate further the completion of the problematic final stage. In summary, the first two stages of the modified PGI

are identical to the first two stages of the original PGI, stage 3 is an additional stage and stage 4 has been modified by the inclusion of a visual aid.

The modified PGI consists of four stages.

- At stage one patients are asked to identify up to five areas of life that are important to them and have been affected by their heart condition.
- Stage two is concerned with the current self-rating of the five identified areas of life. The rating scale ranges from 0 to 10. Patients attributed a score of 0 to any area of life which was rated as "the worst you could imagine" and a score of 10 to any life area which was rated as "exactly as you would like to be".
- Stage three asks patients to rate the five identified areas of life in order of importance.
- At Stage four, each respondent is asked to indicate the relative importance of the five identified areas of life. In order to facilitate this decision, each respondent is given a visual aid, which is a page divided into five boxes. Within each box is written an area of life which the respondent identified at stage one. Each respondent is also given 20 tokens and asked to allocate or place the tokens on top of each box – the more tokens placed on a box, the more they would like to improve that area of life, but they can only allocate a total of 20 tokens across all five identified areas of life. The relative importance of an area of life to each person is indicated by the number of tokens placed on its box. This allows the calculation of a total HRQoL score using the formula:

  Σ(Rating of domain * (Number of tokens placed in that domain/20)). The result is a possible total score range from 0 to 10. Stage three can be used to prompt the distribution of tokens at stage four.

The modified PGI takes approximately 10 minutes to complete.

Statistical Analysis

Scores from the questionnaires can be treated as interval level variables for the purpose of statistical analysis (Labovitz, 1971; Fife-Schaw, 2000). In addition, the central limit theorem enables us to assume an underlying normal sampling distribution, due to the large sample size (Aron & Aron, 1999) and the Kolmogorov-Smirnov test ensured that subgroups with small numbers had approximately normal distributions. Therefore, parametric tests (Pearson's product moment correlation coefficient to assess relationships and test-retest reliability and one-way analysis of variance, to assess between-group differences) were used throughout.

RESULTS

Patients

The patients who participated in the study were similar to participants in previous studies in terms of their age (Cupples, McKnight, O'Neill & Normand, 1996; Lukkarinen & Hentinen, 1997; Smith et al., 2000) and sex (Billing, Hjemdahl & Rehnqvist, 1997; Kee, McDonald & Gaffney, 1997).

There was no statistically significant association between sex of the patient and whether or not they took part in the second interviews ($\chi^2 = 2.59$, $p = 0.11$). There were also no significant differences between the patients who completed and those who did not complete the second interview in terms of age ($t = 1.65$, $p = 0.10$) or in terms of their classification of angina (Mann-Whitney $Z = 1.03$, $p = 0.30$).

All patients had been diagnosed with ischaemic heart disease for a median time of 6 months (range = 2 days to 42 years). Almost 32% (37/117) of patients had been admitted to hospital after a myocardial infarction; 54% (63/117) of patients had angina and 14% (17/117) of patients had no angina at time of admission. The majority of patients (53%) underwent an angiogram during their hospital stay, about 17% underwent percutaneous transluminal coronary angioplasty (PTCA) and a further 6% had a coronary artery bypass graft (CABG). The distribution of patients between the different classes of the Canadian Cardiovascular Society Classification of Angina (CCSCA) was as follows: no chest pain – 43/117 (36.8%), class I – 12/117 (10.3%), class II – 21/117 (17.9%), class III – 16/117 (13.7%), class IV – 25/117 (21.4%). The mean (sd) body mass index for the 117 patients was 27.2 (4.4). The distribution of patients between the different classes of the CCSCA suggested that our group of patients had less severe angina than a group of patients undergoing PTCA (Kee et al., 1997; Papadantonaki, Stotts & Paul, 1994) or CABG (Papadantonaki et al., 1994; Staples & Jeffrey, 1997).

Descriptive Statistics

The summary statistics for each scale are given in Table 1. All scales were transformed so that they had a possible range of 0 to 100, with a higher score indicating a better level of functioning or quality of life. The transformation of scores was completed using the formula suggested for transforming the SF-36 scores (((actual raw score-lowest possible raw score)/possible raw score range)*100). The other scores were transformed using this formula to facilitate comparisons between questionnaires. Patients scored fairly high on all scales except the SF-36 scales of

vitality and role physical. This pattern of SF-36 scores has been found with other groups of cardiac patients (Jette & Downing, 1994).

Validity

All 117 patients who took part in the study were able to complete the modified PGI, though 17/117 (14.5%) patients stated that nothing in their life had been affected by their heart condition and therefore were attributed the maximum possible score. Most of these patients had known about their heart disease for a very short period of time and reported experiencing no deleterious effects. Commensurately, the median scores on most of the other scales were very high for these patients who claimed that nothing important in their life had been affected by their heart condition. Almost half (48%) of the remaining 100 patients identified only one area of life which was important to them and had been affected by their heart condition. A further 34% identified only two life areas and another 16% identified only three life areas. Only two of the patients required the visual aid to assist in their completion of the modified PGI.

The most frequently mentioned life area to be affected by ischaemic heart disease was “work”, which was mentioned by 31 patients and was ranked as the most important life area by 19 of these patients. For some people this meant that they had to leave their jobs, for others it meant that they had to take on a more sedentary position. However, “family life” was identified most frequently as the most important area of life that had been affected by the participants’ heart disease. Life areas that could be grouped under the general heading of physical functioning predominated. Apart from the area of "work", respondents also mentioned "walking" (n = 21),

"physical pastimes/sport" (n = 18), "daily housework" (n = 11) and "DIY" (n = 10) as important areas of their life that had been affected by their heart disease. Other important areas included "social activities" (n = 23), "driving" (n = 7) and "self-confidence" (n = 6).

The correlation coefficients at time one between the three questionnaires are given in Table 2. All correlations were significant ($p < 0.05$) and display a pattern of weak to moderate relationships between the three instruments, with the exception of the correlation between the QLMI-2 emotional functioning scale and the SF-36 mental health scale.

Table 3 shows that the mean scores on each scale of the three questionnaires displayed an overall decrease as disease severity increased. This linear trend was statistically significant for all scales except the modified PGI and the SF-36 role emotional scale.

Test-Retest Reliability And Sensitivity To Change

A medically stable sample is required in order for test-retest reliability to be examined. Therefore, only patients who did not undergo interventional procedures (PTCA or CABG) were included in the analysis of test-retest reliability. A total of 47/72 (65.3%) patients met this criterion. The test-retest reliability coefficients for each scale are given in Table 4. The modified PGI and the SF-36 vitality scale had the strongest reliability coefficients ($r = 0.86$), with the SF-36 role emotional and the QLMI-2 physical functioning scales displaying particularly weak reliability coefficients.

The standardised response mean was used to index sensitivity to change. It is calculated by dividing the mean change in scores by the standard deviation of the score change (Garratt, Ruta, Abdalla & Russell, 1994). The larger the standardised response mean, the more sensitive to change the instrument. The standardised response means for 25 patients who underwent interventional procedures (PTCA or CABG) are given in Table 4. Only the SF-36 general health scale had moderate responsiveness. The responsiveness indices for all other scales are considered weak (Garratt et al., 1994).

DISCUSSION

The main aim of this study was to compare the psychometric properties of a generic, a disease-specific and an individualised measure of HRQoL when used among people with ischaemic heart disease.

The use of the modified PGI with this patient group is feasible as every patient found it easy to understand and complete. Previous work (Dempster & Donnelly, 2000b) showed that some older people (mainly those over 75 years old) had difficulty completing the Patient Generated Index and, consequently, a visual aid was developed to aid completion. Only two patients in the present study required the visual aid and less than 5% of the sample in the study reported here was over the age of 75. Given that the visual aid of the modified PGI was not required, findings reported here are applicable to the original Patient Generated Index as well as to our modified version of the Patient Generated Index. In fact, the main areas of life identified by patients on

the modified PGI in the present study are very similar to those areas of life reported most commonly by patients on the Patient Generated Index in other studies (Herd, Tidman, Ruta & Hunter, 1997; Macduff & Russell, 1998; Ruta et al., 1994). The exception is that in the present study, patients with heart disease flagged "family life" as the area of life most important to them which had been affected by their heart condition. This was also found to be the case in a study among people undergoing cardiac rehabilitation (Smith et al., 2000). However, "family life" is not an area which appears high on the list of other patient groups. This may be because the other studies using the Patient Generated Index have been administered to samples of patients who were younger than the participants in the present study and family relationships appear to be more important for older people in an assessment of quality of life (Pearlman & Uhlmann, 1988). It may also demonstrate that patients with ischaemic heart disease are affected by their disease course in a different way than patients with other chronic diseases, thereby suggesting that generic measures of HRQoL are limited in their usefulness.

The correlations between the scales on the three questionnaires were weak to moderate. This pattern of correlations has been found between the PGI and the SF-36 in other patient groups (Jenkinson, Stradling & Petersen, 1998; Ruta et al., 1994). This suggests that the modified PGI, the SF-36 and the QLMI-2 each contribute something unique and therefore they are not measuring the same aspects of HRQoL.

Most of the scales' average scores increased as angina severity decreased, thereby providing some evidence for the validity of the scales.

In terms of consistency, the modified PGI total score achieved a high estimate of test-retest reliability which was similar to estimates reported for the Schedule for the Evaluation of Individual Quality of Life (O'Boyle, McGee, Hickey, O'Malley & Joyce, 1992) and slightly higher than the test-retest coefficients reported for the Patient Generated Index (Macduff & Russell, 1998; Ruta et al., 1994) when used among other patient groups such as those with a limiting long term illness and people with back pain. However, several of the SF-36 and QLMI-2 scales had low test-retest reliability coefficients. Previous studies have shown much variation in the reports of test-retest reliability for these two questionnaires (see Dempster & Donnelly, 2000a). It may be that it is almost impossible to obtain a sample of patients with heart disease who will not have received some level of intervention, in the form of medication or advice about the management of their condition, during the test-retest interval.

The sensitivity to change of all the scales was low, apart from the SF-36 general health scale. Nevertheless, like Smith et al. (2000), we found little difference between the instruments in terms of their sensitivity to change. This is surprising, as the main argument for the use of disease-specific measures is that they are likely to be more sensitive (Tullis & Guyatt, 1995).

Overall, the modified PGI appears to be reliable; 2 out of 3 of the QLMI-2 scales lack evidence of reliability or sensitivity; and most of the SF-36 scales have evidence for validity, but some lack reliability and sensitivity.

In conclusion, there is little evidence to support the use of the QLMI-2. The SF-36 can be used across different patient groups, because of its generic nature and

this is its advantage, but several of the SF-36 scales should be used with caution, particularly the role emotional and physical functioning scales. It appears that the modified PGI has equally good psychometric characteristics as the SF-36, but it does have an additional benefit for patients in that it enables clinicians to assess what is important to each individual. The individualised approach can be considered as a means of obtaining a HRQoL score and also as a diagnostic tool providing person-specific useful information for planning multi-disciplinary care. Patients are likely to benefit if this information is accessible to clinicians as this will ensure that the specific factors which contribute to a person's HRQoL can be monitored and considered when treatment protocols are drafted, thereby enabling comprehensive and holistic treatments. However, further research, focussing on the responsiveness of these instruments is required before firm recommendations can be made for their use in clinical practice.

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Table 1: Summary statistics for all scales at time 1

Scale	Mean	Standard deviation
QLMI-2 Social	70.00	22.01
QLMI-2 Physical	70.49	18.22
QLMI-2 Emotional	66.89	19.40
SF-36 General health	66.86	19.70
SF-36 Physical functioning	66.41	27.00
SF-36 Role physical	37.61	46.50
SF-36 Role emotional	84.33	35.44
SF-36 Social functioning	63.78	32.22
SF-36 Bodily pain	70.23	31.94
SF-36 Vitality	42.65	24.04
SF-36 Mental health	70.56	22.51
Modified PGI total	50.51	38.33

Table 2: Correlations between instruments (n=117)

	Modified PGI	QLMI-2 Physical functioning	QLMI-2 Emotional functioning	QLMI-2 Social functioning
Modified PGI	1.00	0.30	0.31	0.20
SF-36 General health	0.23	0.38	0.57	0.11
SF-36 Physical functioning	0.34	0.58	0.59	0.16
SF-36 Role physical	0.48	0.55	0.46	0.31
SF-36 Role emotional	0.27	0.30	0.57	0.24
SF-36 Social functioning	0.37	0.58	0.59	0.38
SF-36 Bodily pain	0.23	0.52	0.36	0.26
SF-36 Vitality	0.31	0.54	0.62	0.16
SF-36 Mental health	0.23	0.41	0.83	0.37

Table 3: Mean (SD) scores on the 3 questionnaires within categories of angina classification

Canadian Cardiovascular Society classification of angina	No angina	Class I	Class II	Class III	Class IV	Linear trend
Modified PGI	57.12	50.79	49.10	52.72	38.78	p = 0.09
	(38.14)	(40.80)	(38.23)	(37.60)	(38.27)	
QLMI-2 Social	67.44	75.00	66.67	68.75	51.33	p = 0.03
Functioning	(26.71)	(26.35)	(28.14)	(27.81)	(27.91)	
QLMI-2 Physical	79.29	74.80	69.95	61.31	59.62	p < 0.01
Functioning	(14.38)	(15.18)	(21.40)	(16.37)	(16.11)	
QLMI-2 Emotional	75.03	74.60	72.00	62.13	54.52	p < 0.01
Functioning	(16.36)	(12.36)	(15.08)	(17.20)	(21.93)	
SF-36 General Health	72.44	80.00	66.86	57.75	56.80	p < 0.01
	(15.38)	(17.24)	(17.65)	(20.31)	(22.46)	
SF-36 Physical	75.81	83.33	59.29	60.00	52.20	p < 0.01
Functioning	(22.47)	(15.13)	(25.31)	(28.23)	(30.31)	
SF-36 Role Physical	63.95	37.50	25.00	29.69	8.00	p < 0.01
	(47.03)	(47.07)	(41.08)	(41.05)	(27.69)	
SF-36 Role Emotional	90.70	100.00	69.84	83.33	78.67	p = 0.07
	(29.39)	(0.00)	(45.83)	(34.43)	(40.69)	
SF-36 Social	76.16	72.92	63.69	56.25	43.00	p < 0.01
Functioning	(27.52)	(28.62)	(32.09)	(30.96)	(32.49)	
SF-36 Bodily Pain	95.35	69.92	50.48	58.56	51.24	p < 0.01

	(13.16)	(22.31)	(32.05)	(32.96)	(30.45)	
SF-36 Vitality	55.58	42.08	41.67	36.88	25.20	$p < 0.01$
	(23.02)	(19.48)	(20.82)	(21.59)	(19.97)	
SF-36 Mental Health	77.30	75.67	71.62	63.25	60.32	$p < 0.01$
	(20.63)	(12.70)	(16.82)	(21.87)	(28.23)	

Table 4: Test-retest reliability coefficients for patients who did not undergo interventional procedures (n = 47) and standardised response means for patients who underwent PTCA or CABG (n = 25)

	Test-retest reliability coefficient (n = 47)	Standardised response mean (n = 25)
Modified PGI	0.86	0.16
QLMI-2 Social functioning	0.57	0.19
QLMI-2 Physical functioning	0.45	0.28
QLMI-2 Emotional functioning	0.81	0.24
SF-36 General health	0.85	0.63
SF-36 Physical functioning	0.57	0.35
SF-36 Role physical	0.80	0.35
SF-36 Role emotional	0.44	0.10
SF-36 Social functioning	0.68	0.28
SF-36 Bodily pain	0.56	0.13
SF-36 Vitality	0.86	0.01
SF-36 Mental health	0.54	0.14