Health-related quality of life in coronary heart disease compared to norms in **Spanish population**

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Abstract

Aim: To interpret health-related quality of life (HRQL) values better, it is appropriate to compare them with population norms that can serve as reference standards. This study compares the quality of life of patients who have suffered an acute episode of ischemic cardiopathy with population norms, as measured by the Spanish version of the SF-36. Methods: 132 patients admitted to the Cardiology Department of a Spanish general hospital for an acute episode of ischemic cardiopathy were studied. HRQL was assessed using the SF-36 questionnaire. To compare patient with population norms, raw and adjusted data were obtained and differences with population norms were analyzed by age and sex groups at the level of the 25th percentile ($25\% \pm CI 95\%$). Results: Globally, differences between the patients and the general Spanish population were evident in all SF-36 dimensions except Physical Functioning, General Health and Mental Health. However, the largest differences were observed in the youngest coronary patients (<55 years old) were in all HRQL dimensions, except Vitality and Bodily Pain, the proportions of patients below the 25th percentile of the general population exceeded 25%. Conclusion: The comparison between HRQL in coronary patients and that in the general population confirms the impact of the disease especially in the youngest patients, and allows intervention to be directed towards the more vulnerable groups.

Key words: Coronary heart disease (CHD), Population norms, Quality of life, SF-36

Introduction

Coronary heart disease (CHD) is the major cause of death and disability in the developed world. It can affect all aspects of an individual's life and the perception of overall well-being [1].

Health-related quality of life (HRQL) is generally considered as the extent to which perceived health, or changes in health, impact on an individual's physical, psychological and social functioning [2]. For this reason, HRQL is increasingly being cited as a primary outcome in the clinical decision-making process and in the determination of therapeutic benefit [3].

Several authors using different scales have observed a reduction in HRQL in individuals who have suffered ischemic cardiopathy, when compared with other pathologies [4, 5]. Equally, differences have been observed in the quality of life of these patients with regard to the clinical severity of the illness [6], their sex [7] and other variables such as their educational and social level [8]. However, the comparison of HRQL in coronary patients with the general population has received much less attention, in spite of the usefulness of this measure in determining the impact of the disease and the benefits of health care interventions [9].

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The use of population norms in comparisons of quality of life has been considered a potentially useful method [9] that allows the identification of deviations in the scores of an individual or in a group of individuals, in relation to the expected score for their age and sex, with the advantage that it is not necessary to select and recruit a control group representative of the general population [10]. In addition, the results observed can be interpreted more clearly when a universally accepted unit of measurement is not available [11].

In this context, and under the hypothesis that the quality of life in patients with ischemic cardiopathy is lower than that of the general population, we decided to conduct a study with the objective of determining the limitations in the quality of life of patients who have suffered an episode of ischemic cardiopathy, compared with the Spanish population norms.

Patients and methods

A cross-sectional study was carried out in the Cardiology Department of a University Hospital in the South of Spain, where from June 1996 to November 1997, all the patients with an acute episode of coronary disease were recruited. The patients were diagnosed as having a myocardial infarction (AMI) or unstable angina, on the basis of clinical, biochemical and electrocardiographic criteria described elsewhere [12].

The number of patients studied was based on the number of subjects calculated as necessary to detect differences in HRQL between the two groups of patients (AMI and unstable angina) used to validate the SF-36 questionnaire [13]. HRQL was assessed using the SF-36 Health Questionnaire 1.0, which comprises 36 items grouped into eight dimensions: physical functioning, role limitations due to physical problems, bodily pain, perception of general health, vitality, social functioning, role limitations due to emotional problems, and mental health. For each dimension the items were coded, aggregated and transformed into a scale from 0 (the worst state of health for that dimension) to 100 (the best state of health).

The SF-36 questionnaire was originally developed for use in the United States and it has subsequently been translated and adapted under the International Quality of Life Assessment Project (IQOLA) for use in several countries and different population groups [13]. In Spain, this instrument has recently been validated in coronary patients [12], and population norms are available [9].

Sociodemographic and clinical information was obtained from a structured questionnaire and from the patients' clinical records, and the Spanish Society of Epidemiology (SSE) classification [14] was used to determine social class and educational level. Cardiovascular risk factors (use of tobacco, hypertension, obesity and diabetes) were considered to be present when they were explicitly stated in the clinical records, and the existence of comorbidity other than cardiovascular risk factors was considered if mild or chronic pathologies also figured in the patients' clinical records.

The information was collected by a single trained interviewer during the period of hospitalization, once the patient was clinically stable. Before inclusion, all the patients were asked for their informed consent and all agreed to participate.

Statistical analysis

Means and standard deviations, quartiles, and maximum and minimum values were calculated for the description of each of the specific dimensions of the HRQL. Histograms and the Kolmogorov–Smirnov test were used to verify whether the distribution of the quality of life data in the patients was normal (except in the General Health dimension). Likewise, in the Spanish general population, a high percentage of floor and ceiling effect in most of the dimensions [9] was also observed, thus showing a non-normal distribution of the scores. Therefore, it was considered that the median and percentiles gave a better distribution of the data in this population.

The data published by Alonso et al. [9] were used to study HRQL differences between coronary patients and the Spanish population. These data were obtained from a representative sample of the Spanish general population and provided the mean values (and standard deviations) and percentiles for each dimension, by age and sex groups.

To analyze HRQL differences, raw and adjusted data for the study population were obtained; the adjusted data were obtained from a linear regression model in which the dependent variable was the score on the corresponding dimension of the SF-36 and the independent variables were the age, sex and educational level of the patients.

For the comparisons of the raw and adjusted scores of the population with the Spanish norms, we used the criteria of Rose et al. [10], who propose the 25th percentile of the distribution as the most appropriate dichotomous indicator of substantial health limitations. Taking this criterion as reference, it was thought that if the group under study was equivalent to the general population (in terms of HRQL), then we would expect 25% of our sample to score at or below the 25th percentile of the general population norm. Therefore, we considered an individual as suffering limitations due to illness if he or she scored lower than the 25th percentile for the corresponding age and gender stratum of the Spanish general population. To determine whether the prevalence of such limi-tations was significantly different from 25%, we calculated the 95% confidence intervals around the percentage.

The analysis was performed using the SPSS 10, CIA and EPIINFO V6 programs.

Results

A total of 132 patients, of whom 77% were men, was studied. Mean age was 60.7 years (SD = 10.4) ranging from 33 to 82 years. The majority were married (80%), 74% were illiterate or with no educational qualification, and 56% were classified as unskilled or manual workers (group IV and V of the SSE classification) [14]. The most frequent cardiovascular risk factors were the use of tobacco and arterial hypertension. Moreover, the presence of reported comorbidity was also frequent (63%), and more than half of the patients had a previous history of ischemic cardiopathy (Table 1).

Globally, the highest HRQL scores were observed in the dimensions of Physical Functioning (mean = 76.1, SD = 26.0) and Social Functioning (mean = 80.0, SD = 25.9), whereas General Heal-th had the lowest mean scores (mean = 57.7, SD = 19.5). Physical Role and Emotional Role presented a wide variability (standard deviations 41.2 and 46.6, respectively) and Mental Health was the dimension with the lowest median (Table 2).

 Table 1. Sociodemographic and clinical variables of the population studied

	Frequency (N)	Percentage (%)
Sociodemographic variables		
Age ≪44 45-54 55-64	12 25 39	9 19 30
65–74 ≥75	45 11	34 8
Sex Male Female	102 30	77 23
Civil status Married Single Widow/widower Divorced	106 7 16 3	80 5 12 2
Social class ^a Housewives I and II IIIA, IIIB and IIIC IVA, IVB, IVC and V	24 10 23 73	18 8 18 56
Educational level ^a Illiterate + without any qualification Primary Secondary Further	98 12 12 9	74 9 9 7
Clinical variables Diagnostic group Acute myocardial infarction Unstable angina	62 70	47 53
Use of tobacco Smoker Non-smoker	73 58	56 44
Diabetes Yes No	45 86	34 66
Hypercholesterolemia Yes No	50 81	38 62
Arterial hypertension Yes No	68 63	52 48
Obesity Yes No	38 89	30 70

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Table 1. (Continued)

	Frequency (N)	Percentage (%)
Personal history of ischemic cardiopathy		
Yes	79	60
No	53	40
Comorbidity		
No pathology	49	37
Mild pathology	28	21
Chronic pathology	55	42

 ${}^{a}I =$ Senior managers, professionals; II = Managers, technically-qualified, and trades people; II = Supervisory and administrative; IV = Skilled manual workers; V = Unskilled manual workers; Not classifiable – Housewives and non-members of workforce.

When results for coronary patients and the general population were compared, the proportion of patients below the 25th percentile obtained with the raw data was above 25% for all the dimensions. Moreover, with the exception of Vitality, the confidence intervals of these percentages did not drop below the 25th percentile (Table 2). In the analysis of adjusted data, the dimensions that presented percentages higher than 25% were Role Physical, Role Emotional and Social Functioning.

The raw data by sex (Table 3), show a higher percentage of women with scores below the 25th percentile in all dimensions except Bodily Pain and General Health. Similarly, in men the percentages were higher than 25% on all scales except Vitality and Physical Functioning, which fall below the 25th percentile at 95% CI. When the scores are adjusted by age, sex and educational level, the dimensions for which percentages significantly above 25% in the cardiopathic men were Role Emotional, Role Physical and Social Functioning. The same occurred in the case of the women, with the exception of Physical Role, which did not present significant differences (Table 3).

In the comparison of the raw data by age group, the percentage of patients with scores below the 25th percentile of the population diminished with increasing age. Therefore, it was the younger patients (< 55 years) who presented the lowest scores in all dimensions of the questionnaire except Vitality (Table 3). These differences were maintained in the analysis of the adjusted scores, for all dimensions except Bodily Pain and Vitality (Table 3).

Discussion

The assessment of HRQL in patients with ischemic cardiopathy proved to be a useful complement to the traditional clinical parameters used. It provides a more comprehensive view of the patient's condition and a better basis for planning medical interventions. Therefore, comparison of HRQL with population norms is useful for assessing the repercussion of an illness and for establishing priorities among the possible interventions. The present study demonstrates that patients with ischemic cardiopathy present a worse quality of life than the Spanish general population, especially

N = 132	PF	RP	BP	GH	VT	SF	RE	MH
Mean (SD)	76.1 (26.0)	68.4 (41.4)	68.5 (31.0)	57.7 (19.5)	64.8 (23.3)	80.0 (25.9)	58.6 (46.6)	66.0 (24.4)
Range	5.0-100.0	0.0-100.0	0.0-100.0	10.0-100.0	10.0-100.0	0.0-100.0	0.0-100.0	4.0-100.0
Percentiles								
25	60.0	25.0	41.0	50.0	62.5	0.0	48.0	45.0
50	85.0	100.0	72.0	65.0	87.5	100.0	72.0	60.0
75	100.0	100.0	100.0	85.0	100.0	100.0	84.0	72.0
Raw % below	34.8	56.8	42.4	38.6	26.5	55.3	94.7	39.4
P25 (CI 95%)	(26.7-43.0)	(48.4–65.3)	(34.0-50.9)	(30.3-46.9)	(19.0-34.0)	(46.8–63.8)	(89.4–97.8)	(31.1-47.7)
Adjusted % below	26.7	79.4	5.3	22.1	6.1	56.5	90.1	24.4
P25 (CI 95%)	(19.1–34.3)	(72.5-86.3)	(2.18–10.7)	(15.0-29.2)	(2.66–11.6)	(48.0-65.0)	(83.6–94.6)	(17.1–31.8)

Table 2. Description of quality of life of patients with ischemic cardiopathy in the eight dimensions of the SF-36 questionnaire

PF - physical functioning; RP - role physical; BP - bodily pain; GH - general health; VT - vitality; SF - social functioning; RE - role emotional; MH - mental health.

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	PF		RP		BP		GH		VT		SF		RE	F	НМ	
	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted I	Raw /	Adjusted
Sex Male N = 102	32.4 23.3–41.	31.4 4 22.4-40.4	58.8 49.3–68.4	98 91.6–99.4	47.1 37.4–56.7	6.9 2.8–13.6	42.2 32.6–51.7	25.7 17.0–33.9	21.6 13.6–29.6	5.9 2.19–12.4	54.9 45.2–64.6	58.4 48.3–67.4	100 96.4–100	99 94.7–100 2	36.3 2 26.9–45.6 1	26.7 17.9–35.0
Female $N = 30$	43.3 25.5–62.	10 6 2.11–26.5	50 31.3–68.7	16.7 5.65–34.7	26.7 12.3–45.9	0 0-11.6	6.7 12.3–45.9	10 2.11–26.5	43.3 25.5–62.6	6.7 0.8–22.1	56.7 37.4–74.5	50 31.3–68.7	76.7 57.7–90.1	56.7 37.4–74.5 3	50 31.3–68.7 5	16.7 5.65–34.7
$\begin{array}{l} Age \\ \leqslant 44 \\ N \ = \ 12 \end{array}$	58.3 22.7–84.	100 8 73.5-100	100 73.5–100	100 73.5–100	58.3 22.7–84.8	58.3 27.7–84.8	58.3 22.7–84.8	100 73.5–100	50 21.1–78.9	41.7 15.2–72.3	91.7 61.5–99.8	100 73.5–100	100 73.5–100	100 5 73.5–100 2	58.3 22.7–84.8	(00 73.5–100
$\begin{array}{l} 45-54\\ N\ =\ 25\end{array}$	48 27.8–68.	92 7 74.0–99.0	$\begin{array}{c} 100\\ 86.3{-}100\end{array}$	$100 \\ 86.3{-}100$	48 27.8–68.7	0 0-13.7	96 79.6–99.9	68 46.5–85.1	40 21.1–61.3	8 0.98–26.0	96 79.6–99.9	100 86.3–100	100 86.3–100	100 2 86.3–100 2	48 27.8–68.7 5	72 50.6–87.9
55-64 $N = 39$	33.3 19.1–50.	0 2 0–9.03	35.9 21.2–52.8	74.4 57.9–87.0	30.8 17–47.6	0 0-9.03	30.8 17–47.6	0 0-9.03	15.4 5.8–30.5	2.6 0.06–13.5	46.2 30.1–62.8	94.9 82.7–99.4	100 91.0–100	100 91.0–100	35.9 <u>-</u> 21.2-52.8 (5.1 0.6–17.3
65-74 $N = 45$	28.9 16.4-44.	0 3 0–7.87	37.8 23.8–53.5	68.2 51.0–80.0	46.7 31.7–62.1	0 0-7.87	15.6 6.4–29.4	0 0-7.87	22.2 11.2–37.1	0 0-7.87	37.8 23.8–53.5	0 0-7.87	84.4 70.6–93.5	70.5 53.4–81.8 2	35.6 (21.9–51.2 ())-7.87
≥75 N = 11	9.1 0.22–41.	0 3 0–28.5	63.6 30.8–89.1	72.7 39.0–94.0	36.4 10.9–69.2	0 0-28.5	9.1 0.22–41.3	$0 \\ 0-28.5$	27.3 6–61	0 0–28.5	27.3 6–61	$0 \\ 0-28.5$	100 71.5–100	100 2 71.5–100 6	27.3 (5-61 ())-28.5
PF – phy	sical func	tioning; RP	- role phy	ysical; BP	– bodily pi	ain; GH –	general h	ealth; VT -	- vitality; 5	SF – socia	l functioni	ng; RE –	role emoti	onal; MH -	- mental h	ealth.

in the youngest subjects. These findings agree with those made by other authors. Thus, Brown et al. [15] studying a group of patients 4 years after suffering infarction found that those under 65 years old presented a worse quality of life than the general population in all the dimensions of the SF-36, whereas differences were not found among the oldest group. Hammerlid and Taft [16] using the same instrument in another pathology observed that patients over 65 years presented differences in their quality of life in comparison with population norms only in Physical Role, while patients below this age presented scores lower in five of the eight dimensions of the questionnaire.

These results may be explained because the illness is likely to have a greater repercussion in younger than in older persons, in whom the limitations may be the consequence of physiological aging and who might better accept other possible comorbidities. On the other hand, it should also be taken into account that such comparisons are made with the general population and not with the healthy subset of that population. Therefore, the older age groups of the general population will include some individuals with different pathologies that may adversely affect their quality of life [9].

The relationship between quality of life and sex in patients with CHD remains uncertain, despite having received considerable attention recently. Various theories have been proposed to explain the gender-related differences observed both in ischemic cardiopathy [17] and in the general population [9, 18]. Van Jaarsveld et al. [7] in a recently published study explained the worse HRQL found in women following CHD as being due to females representing a vulnerable group with more physical limitations, more distress, and more social limitations, all of which could indicate that women with CHD need specific attention. In the present study, women had lower scores than the general population in almost all the dimensions of SF-36 in the analysis of the raw data. However, these differences were only maintained in the adjusted scores in the dimensions SF and RE. This finding should be interpreted with caution owing to the relatively small number of women in the population studied. However, the findings could be explained by the relatively high percentage of poorly educated women (93.3% of all women in the simple were classified as illiterate or with no educational qualification); the existence of this group in the population would act as a factor of confusion in the relationship between HRQL and females observed in the data. Authors such as Regidor et al. [19]. find an inverse relationship between HRQL and educational level, with the lowest scores on the dimension of the SF-36 found among persons with the lowest educational level. Similarly, Thumboo et al. [20] find an increase of 0.5–0.6 in the SF-36 scores for each year of education completed.

On the other hand, it should also be pointed out that the results of the present study are not applicable to patients with stable angina, who were not included in the study, or to those who died before being admitted to hospital or before being interviewed. However, the need for better understanding of the effect disease on the survivers and on the more unstable group of patients makes this study particularly important. Moreover, administering the questionnaire to patients in a hospital setting, which could constitute a stressful life event, may therefore have contributed to a more adverse perception of health in the dimensions having an emotional component (Social Functioning, Emotional Role). Nevertheless, in order to minimize this effect, the interview was conducted when the patient was clinically stable.

Likewise, it is necessary to refer to the differences observed in the Role Physical and Role Emotional dimensions in the population. This could be due to the large number of subjects with high percentages in the extreme values of the scale (the ceiling and floor effect), as already noted by authors such as McHorney et al. [5] who consider that these two subscales are the most 'coarse' of all the eight. Moreover, they raise the possibility of including more response categories for the items comprising these two subscales, in order to be able to establish a graduation in role disability, rather than the mere presence or absence of disability.

In conclusion, the evaluation of HRQL in coronary patients confirms the impact of these pathologies on their overall well-being, especially in the youngest group. Similarly, by identifying the quality of life dimensions most affected by the illness through their comparison with those in the general population, it will be possible to orientate subsequent healthcare interventions towards the most vulnerable patients, and to obtain a more

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accurate evaluation of the impact of the measures adopted.

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