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Health related quality of life of chronic patients with immune system diseases: a pilot study

Qualidade de vida relacionada com a saúde de doentes crónicos com patologias do sistema imune: estudo piloto

Calidad de vida relacionada con la salud de pacientes crónicos con enfermedades del sistema inmune: estudio piloto

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ABSTRACT

Health related quality of life (HRQL) and survival are two important outcome measures in chronic diseases. This study aimed to compared HRQL in patients with different chronic diseases of immune system and normative data from the general Portuguese Population. It was selected 103 out-patients, by convenience, to complete SF-36v2. The lowest scores were found among measures for general health (41.0), vitality (47.5), bodily pain (51.0), mental health (56.4); women, except for role-physical, and patients with auto-immune diseases have had the worse scores on all assessed dimension of subjective health, when compared with normative data. Highest scores were obtained in the following scales: physical functioning (69.1), social functioning (66.9), role-emotional (64.9). Living with chronic immune disease have impact on HRQL and it can be expected that the Portuguese version of SF-36v2 provide valid and reliable HRQL data.

Key words: SF-36v2; Quality of Life; Health related Quality of Life; Chronic Immune Diseases.

RESUMO

A qualidade de vida relacionada com a saúde (QVRS) e sobrevivência são dois desfechos importantes nas doenças crónicas. Este estudo objetivou comparar a QVRS de pacientes com diferentes patologias crónicas do sistema imune e com os dados normativos da população Portuguesa. Foram seleccionados 103 pacientes para a amostra por conveniência, para completar o SF-32v2. As pontuações mais baixas foram encontradas entre as medidas para a saúde geral (41,0), vitalidade (47,5), dor (51,0) e saúde mental (56,4); as mulheres, exceto na função física, e os doentes com doenças autoimunes obtiveram piores escores em todas as dimensões, quando comparados com os dados normativos. Os escores mais altos foram obtidos nas dimensões: função física (69,1), funcionamento social (66,9) e função emocional (64,9). Viver com doenças crónicas imunológicas apresenta impacto sobre a QVRS e a versão Portuguesa do SF-36v2 fornece dados válidos e confiáveis na mensuração da QdV destes doentes.

Descritores: SF-36v2; Qualidade de Vida; Qualidade de Vida relacionada com a Saúde; Doenças Crónicas Imunes.

RESUMEN

Calidad de vida relacionada con la salud (CVRS) y la supervivencia son dos resultados importantes en las enfermedades crónicas. El objetivo de este estudio fue comparar la calidad de vida relacionada con la salud (CVRS) de los pacientes con diferentes patologías del sistema inmunológico y los datos normativos de la población portuguesa. 103 pacientes fueron seleccionados al acaso para completar el cuestionario SF-32v2. Las más bajas mensuras se encuentran entre las medidas de salud en general (41,0), vitalidad (47,5), dolor (51,0) y salud mental (56,4) que las mujeres en la función física y los pacientes con enfermedades autoinmunes también obtuvieron peores puntuaciones, en todas las dimensiones en comparación con los datos normativos. Las puntuaciones más altas se obtuvieron en las dimensiones: función física (69,1), funcionamiento social (66,9), función emocional (64,9). Vivir con enfermedades crónicas inmunológicas ten un impacto en la CVRS y la versión portuguesa del cuestionario SF 36v2 aporta datos válidos y confiables para medir la CdV de estos pacientes.

Palabras clave: SF-36v2; Calidad de Vida; Calidad de Vida relacionada con la Salud; Enfermedades Inmunológicas Crónicas.

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BACKGROUND

A patient´s well being is determined not only by his or her health status and response treatment, but also by other social and psychological dimensions. The identification of factors that determine quality of life (QoL) is important in order to better tailor health and social care services, and thereby improve the functioning and well being of people living with chronic pathologies of immune diseases.

In addition, the identification of potentially modifiable factors of QoL could help target people in need of additional services in order to improve QoL[1]. Besides physical and mental health-related factors, socio-demographic characteristics, such as age, gender, education, income and employment status, have found to be strongly associated with the QoL of people living with Human Immunodeficiency Virus (PLHIV)[2] and auto-immune diseases (PLAD) like systemic lupus erythematosus[3], scleroderma[4], rheumatoid arthritis[5], Behçet´s disease[6] or Sjögren Syndrome[7].

Chronic dysfunction of the immune system, like immunodeficiency and self-immunity, can affect multiple organ systems and lead to increased mortality. However, with more effective treatment[8,], chronic long-term morbidity and relapse are now the most significant aspects of such diseases. Improved survival with continuing morbidity highlights the need for accurate assessment of patients suffering from these diseases and their response to therapy[9]. For chronic illnesses where there is no cure, it is important to establish that therapy really makes people feel better. Thus, survival per se is no longer perceived to be the only end point; the goal is to improve, restore, or preserve QoL.

In this sense, HRQL measurement represents a radical realignment between the objective and subjective elements of clinical medicine[10]. However, each domain of HRQL has many components, and there are an almost infinite number of states of health, all with differing qualities, and all quite independent of longevity[11]. Moreover, since expectations regarding health and the ability to cope with limitation and disability can greatly affect a person's perception of health and satisfaction with life, two persons with the same health status may have different qualities of life. Therefore, the construct can be defined in a number of ways, and a consensus of what the term means has not been reached. Thus a challenge for clinicians and researchers has been to know their patients' QoL[12].

The purpose of this pilot study was to examine QoL among PLHIV, PLAD and norms excepted for Portuguese population and to assess the impact of socio-demographic like gender and age, and disease related variables like diagnosis on QoL in order to facilitate the development of treatment and decisions made.

METHODS

Patient selection

One hundred and three patients in the study were from Unidade de Imunologia Clinica – Hospital Santo António Centro Hospitalar do Porto. This unit is dedicated to treatment of patients with diagnosis of immune system diseases, like systemic autoimmune diseases and primary and secondary (HIV) immunodeficiency´s. As a criterion for inclusion of patients it was considered the diagnosis: infection with HIV or autoimmune disease (arthritis rheumatoid, lupus, scleroderma, Behçet disease or Syndrome Sjögren). Exclusion criteria included patients under age 18 or incomplete medical record data.

Procedure

The survey was conducted from February 2009 to May 2009. The sample under study was selected by convenience. During medical consultation, some patients followed in this service were approached and invited to participate in this research. The patients were informed of our intention to conduct the study. All patients invited, have agreed to participate. Patients answered to the paper questionnaire package, including socio-demographic data and QoL items, after their informed consent and before going to their clinical consultation.The study was approved by Hospital Santo António - Centro Hospitalar do Porto Ethics in Health Committee.

Variables

The variables analyzed in this study were obtained from four thematic sets of questions: HRQL, constituted using the SF-36v2 and sets of socioeconomic, demographic and clinical characteristics.

Independent variables

The independent variables of this study were demographic, socioeconomic and clinical characteristics: gender (male or female), age (<30, 30-50, 57-70 and >71), education (0-4, 5-12 and >12 years), marital status (Married, Single, Widow, Other), employment status (employed, student, retired and unemployed) and immune system diseases.

Dependent variables

The HRQL was measured by the application of the Portuguese version of SF-36v2, adapted to the Portuguese population by Ferreira[13].The SF-36v2 is an updated version of the SF-36 and has been updated to simplify the layout, wording and response formats to minimize cultural bias[14-15].

The dependent variables were the scores of the SF-36v2 scales: Physical Functioning, Role Emotional, Role Physical, Bodily Pain, Social Functioning, Mental Health, Vitality and General Health. These subscales can be summarized into Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. The subscales of PF, RP, and BP contribute to PCS; MH, RE, and SF contribute to MCS; while SF, VT, and GH contribute to both summary scores[15]. All scales are reported as T scores, which correspond to a mean of 50[14]. The scores scales can range from 0 to 100, with higher scores reflecting better functioning or well-being. In addition, physical (PCS) and mental (MCS) component summary scores can be calculated from the SF-36v2 based on a population norm-based scoring function[15].

Internal consistency reliability of scales scores

Different methods were used to assess reliability including internal consistency. The internal consistency was measured

by Cronbach's alpha[16] coefficients wish is a measure of the extent to which items in a questionnaire are homogeneous (correlated) in supporting the same concept. A Cronbach's α value of .70 or higher was generally considered to be sufficient to demonstrate internal consistency[16].

Data Management and Statistical analysis

Descriptive analyses were performed for socio-demographic variables, clinical status and the health domains of SF-36v2. Descriptive statistics for SF-36v2 are given as mean, standard deviation (SD) and number of participants. SF-36v2 expected scores were calculated based on the normative data from the general Portuguese population aged 18-64 years that were randomly drawn from the Portuguese Population Register (n = 2459)[16]. Internal consistency reliability of multi-item scale was assessed by Cronbach's α coefficient[16]. A value of .70 or greater was considered as adequate for the purposes of group comparisons. All SF-36v2 scale scores were transformed linearly to a scale from 0 to 100, with o and 100 representing the least and most favorable health outcomes respectively. Data were analyzed using SPSS version16.0.

RESULTS

A total of 103 participants were interviewed: 66 women and 37 men, with a mean age of 45.28 years with a standard deviation 15.32. Regarding the marital status, 50.48% of the individuals are married, 20.38% are single, 8.73% are widow and 20.38% have other marital status. About 48 are employed and 72.80% had less than five years of schooling. According to the diagnosis, 70.87% had autoimmune disease and 29.13% was infected by HIV. Table 1 summarizes the main characteristics of the sample studied.

Scores of QoL were lowest in the following dimensions: general health (41.0), vitality (47.5), bodily pain (51.0) and mental health (56.4). Highest scores were obtained in the following scales: physical functioning (69.1), social functioning (66.9), role-emotional (64.9) (Table2).

Women obtained lower scores than men in all domains except for role-physical (Table3). The greatest difference between genders was found in the vitality, with a difference of 12.3 points between mean scores.

According the diagnoses revealed that PLAD obtained lower scores in all dimension than PLHIV (Table4). The greatest difference between PLAD and PLHIV was found in bodily pain with a difference of 21.6 points between mean scores.

Comparisons with the expected scores of the general population

Table 4 shows the SF-36v2 health status scores among patients with chronic immune diseases compared to the Portuguese norms scores. PLHIV and PLAD had worse crude scores for all dimensions of health compared with normative data.

Table 1 - Socio-demographic and clinical variables of the sample (n = 103).

Sample characteristics according to demographic, socioeconomic and clinical variables.		
	N	%
GENDER		
Female	66	64.07
Male	37	35.93
AGE X(SD)	45,28(15,327)	
< 30	19	18.4
30-50	48	46.60
51-70	30	29.12
> 70	6	5.82
EDUCATION YEARS		
0-4	28	27.18
5-12	45	43.68
> 12	30	29.12
MARITAL STATUS		
Married	52	50.48
Single	21	20.38
Widow	9	8.73
Other	21	20.38
EMPLOYMENT STATUS		
Employed	48	46.60
Student	9	8.73
Retired	25	24.27
Unemployed	21	20.38
DIAGNOSIS		
PIHIV	30	29.13
PLAD	73	70.87
LENGTH OF DISEASE X (SD)	7,01 (6,935)	
SYSTEMS/ ORGANS AFFECTED		
Immunological	103	100
Skin	48	40,7%
Osteoarticular	32	27,1
Hematological	10	8,5
Gastrointestinal	9	7,6
Renal	6	5,1
Pulmonary	4	3,4
Cardiac	4	3,4
Others	5	4,2

Table 2 - Mean scores of SF-36v2 scales total sample.

SF-36V2 HEALTH STATUS DOMAINS	n (Total sample)	MEAN	SD	95%CI	Std. ERROR
PHYSICAL FUNCTIONING	103	69.1	23.74	64.5 – 73.6	2.30
ROLE-PHYSICAL	103	62.0	28.95	56.4 – 67.6	2.81
BODILY PAIN	103	51.0	29.62	45.3 – 56.8	2.87
GENERAL HEALTH	103	41.0	21.55	36.9 – 45.2	2.09
VITALITY	103	47.5	24.97	42.7 – 52.3	2.42
ROLE-EMOTIONAL	103	64.9	27.88	59.1 – 70.6	2.89
SOCIAL FUNCTIONING	103	66.9	29.85	61.9 – 72.3	2.70
MENTAL HEALTH	103	56.4	24.42	51.7 – 61.1	2.37

Table 3 - Mean scores SF-36v2 scales according to gender and diagnoses.

SF-36v2	Variables	N = 103	Mean	Std. Deviation	95%CI		Std Error
					Min	Máx	
Gender							
Physical Functioning	Female	66	68.516	23.86	62.78	74.24	2.87
	Male	37	70.22	23.74	62.30	78.14	3.90
Physical Problem	Female	66	61.02	28.06	54.27	67.76	3.37
	Male	37	64.02	30.84	53.73	74.30	5.07
Bodily Pain	Female	66	48.30	27.23	41.76	54.84	3.27
	Male	37	56.29	33.40	45.15	67.43	5.49
General Health	Female	66	39.71	22.01	34.42	44.99	2.64
	Male	37	43.67	20.71	36.77	50.58	3.40
Vitality	Female	66	43.29	24.14	37.49	49.09	2.90
	Male	37	55.57	24.86	47.28	63.86	4.08
Social Function	Female	66	64.49	26.82	58.04	70.93	3.22
	Male	37	71.62	29.55	61.76	81.47	4.85
Emotional Problems	Female	66	64.97	31.26	57.46	72.48	3.76
	Male	37	64.86	27.43	55.71	74.01	4.51
Mental health	Female	66	52.89	24.79	46.94	58.85	2.98
	Male	37	63.10	22.55	55.58	70.62	3.70
Diagnoses							
Physical Function	PLHIV	30	76,074	23,214	67.40	84.74	4.23
	PLAD	73	65,257	23,290	59.82	70.69	2.72
Physical Problems	PLHIV	30	69,375	29,285	58.43	80.31	5.34
	PLAD	73	57,934	28,229	51.34	64.52	3.30
Bodily Pain	PLHIV	30	66,433	26,758	56.44	76.42	4.88
	PLAD	73	44,863	28,745	38.15	44.29	3.36
General Health	PLHIV	30	46,667	19,007	39.56	53.76	3.47
	PLAD	73	39,397	22,455	34.15	44.63	2.62
Vitality	PLHIV	30	56,667	23,439	47.91	65.41	4.27
	PLAD	73	43,579	24,956	37.75	49.40	2.92
Social Function	PLHIV	30	70,833	28,868	70.83	60.05	5.27
	PLAD	73	65,411	27,601	58.97	71.85	3.23
Emotional Problems	PLHIV	30	65,833	30,976	65.83	54.26	5.65
	PLAD	73	64,041	29,784	57.09	70.99	3.48
Mental health	PLHIV	30	59,167	22,325	50.83	67.50	4.07
	PLAD	73	55,480	25,224	49.59	61.36	2.95

Table 4 - Health status patients with chronic disease versus Portuguese norms scores

SF-36v2 Health status domains	MEAN		SD		95%CI	
	n (Total sample) 103	n (General population) 2459	n (Total sample)	n (General population)	n (Total sample)	n (General population)
Physical Function	69.1	75.2	23.7	26.7	64.5 – 73.6	60.00 – 85.00
Physical Problems	62.0	71.2	28.9	25.7	56.4 – 67.6	56.3 – 75.0
Bodily Pain	51.0	63.3	29.6	24.9	45.3 – 56.8	42.0 – 62.0
General Health	41.0	55.8	21.5	18.8	36.9 – 45.2	45.0-55.0
Vitality	47.5	58.4	24.9	25.6	42.7 – 52.3	40.0 – 60.0
Social Function	64.9	74.9	27.8	22.8	59.1 – 70.6	62.5 – 75.0
Emotional Problems	66.9	73.5	29.8	24.5	61.9 – 72.3	58.3 – 75.0
Mental Health	56.4	64.0	24.4	22.8	51.7 – 61.1	52.0 – 68.0

*The Portuguese norms SF-36v2 and dimensions´ scores of health status perception from patients with chronic immune diseases: means and standard deviations.

Table 5 - Cronbach's α for the SF-36v2.

	Reliability			Correlation	
Dimension	Number of items	Split-half reliability	Cronbach's alfa	Correlations between dimensions and items inside	Correlations between dimensions and items outside
Physical Function	10	.936	.893	.497 – .830	.046 – .575
Physical Problems	4	.938	.907	.827 – .928	.177 – .724
Bodily Pain	2	.917	.917	.950 – .952	.072 – .571
General Health	5	.701	.780	.601 – .777	.195 – .521
Vitality	4	.930	.848	.791 – .826	.149 – .596
Social Function	2	.777	.777	.883 – .907	.153 – .649
Emotional Problems	3	.842	.886	.854 – .926	.126 – .702
Mental Health	5	.855	.893	.805 – .887	.106 – .650

Internal consistency reliability

Cronbach´s Alpha was .944 at baseline and item correlation ranged from .940 to .949 (SF dimension with .777 and the BP dimension .917) (Table5). These data provide evidence of the internal consistency of the scale.

DISCUSSION

Quality of life is a study area that has attracted increasing interests over the past two decades and SF-36v2 has been used as an instrument for assessing QoL worldwide. Normative data have also been obtained in many countries. In Portugal, SF-36v2 has been used in a few surveys to assess the quality of life of general population and the population with special chronic diseases[16]. Summary scores can be used to minimize problems with multiple comparisons.

Poor (low) scores on the PCS indicate limitations in physical/role functions, bodily pain, and general health, while better (higher) scores suggest no physical limitations, disabilities, or decrements in well-being. In like manner, a low score on the MCS suggests frequent limitations in psychosocial health, emotional problems, and reduced vitality (a fatigue construct), while a high score indicates frequent positive affect and vitality, absence of psychological distress, and reduced or no limitations in daily social and role activities[15].

In this present study among the eight dimensions assessed by the SF-36v2, the population studied in the present survey obtained worst scores in the scales general health, vitality, bodily pain and mental health. There were also differences in health status between the subgroups and the expected scores of the general population, and differences between the groups according to clinical diagnosis. PLAD had significantly reduced scores than PLHIV. This can be due to the nature of the diseases, were autoimmune diseases will have more manifestations of physical symptoms that are more prone to affect especially physical health domains, whereas having infected by HIV may cause more worries and distress because there might be more uncertainties around symptoms, management of disease, potentially affecting more psychological measures.

Analyzing HRQL according to gender, this study showed that women were in worse situation than men in all SF-36v2 scales except in role-physical. Similar results were found in other studies[18-19]. The fact that women exhibit a worse self-assessed level of health may be attributed to the greater perception and knowledge that have regarding diseases and symptoms[20]. The role as a family health caregiver makes women dedicate more attention to the signs of diseases. Studies generally demonstrate a greater prevalence of reported illness and use of healthcare services among women in comparison to men[20].

The demographic changes occurring in the country, with a growing number of patients with chronic illnesses, stressed the need to assess and to monitor different health dimensions in order to guide specific interventions[20]. Measures of HRQoL are especially required from the perspective of promoting active ageing that foresees the inclusion of the chronic patients in social contexts, with autonomy and independence in their activities, as well as actively contributing in community.

Croncbach's alpha was used to determine whether the items within the scaled questionnaires had the same degree of association in the mode of administration at the baseline assessment. The internal consistency reliability of the SF-36v2 scales was satisfactory. Our data demonstrate SF-36v2 can be used to assess HRQL in patients with different chronic immune diseases.

In addition, this study had limitations that should be noted. First our sample was relatively small. Second, the questionnaire required self-completion. This could be possibly had a negative effect on the response rate, particularly in illiterate individuals whose literacy rates tend to be lower. For last, compared diseases so different it unusually but the ultimate goal, will be in the future measured HRQL in practice daily routine in Unidade de Imunologia Clinica – Hospital Santo António Centro Hospitalar do Porto, responsible to consult patients with affections of immune system.

CONCLUSION

In conclusion, living with chronic immune diseases is most likely to health status vulnerability. In general, persons with

chronic immune diseases perceive their current health; health outlook and resistance to illness to be lower than general population, and for these patients physical health and mental health can in addition limit and interfere with work or daily activities.

This data contributes to the input needed for planning health care service and intervention that address QoL improvement for PLHIV and PLAD. The availability of HR-QOL score immediately during the consultation could contribute to patient centered care, help to focus the patient-physician consultation, supporting the definition of therapeutic goals as well as the evaluation of their achievement, and provides standardized data, which can be compared intra- and inter- individually.

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