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Original Article

Health-related quality of life in dialysis patients. A report from an Italian study using the SF-36 Health Survey

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Abstract

Background. Interest in measuring health-related quality of life (HRQoL) has increased together with an awareness that such humanistic outcomes require valid and reliable measures. In the last decade short, simple and multidimensional generic and disease-specific questionnaires have been developed. Among the several generic questionnaires available, the Short Form 36 Items Health Survey (SF-36) was translated and validated in several languages, and applied to different settings and diseases.

Methods. Within the framework of a larger, prospective, multicentre study (DIA-QOL project) the SF-36 was administered to 304 patients to test its characteristics in terms of patient acceptability, and psychometric and clinical validity. Standard psychometric techniques were used to evaluate its validity in terms of convergence, divergence and internal consistency reliability (Cronbach's alpha). Correlations between clinical variables and HRQoL scores were performed to test the questionnaire's capability to capture differences across patients groups.

Results. Overall, the findings show that, in this sample, the SF-36's performance was very good. Acceptability was satisfactory, with a response rate higher than 80%. All the questionnaire scales met the psychometric standards suggested in terms of grouping and scaling assumptions. The internal reliability coefficients actually replicate the satisfactory findings reported previously for the original SF-36. In terms of the ability of the questionnaire scales to discriminate between groups expected to differ in a given health concept in relation to clinical variables, the results were also good. On average, females reported lower scores, the impact of ageing was more evident for physical scales. Diabetic patients score significantly worse on the physical function scale and patients with mental health problems score significantly lower on the mental health scale. No significant association was found with the index KtV, haemoglobin levels, body mass index, parathyroid hormone and type of dialysis. A strong association was indeed found between SF-36 scales measuring physical health concepts and the serum albumin level. This association held after adjusting for the confounding effect of age. Comparison of the health profile of the present sample with others from the US and UK and from a representative sample of the Italian general population highlights the potential of such questionnaire in dialysis setting.

Conclusions. The SF-36 questionnaire is easy to use in Italian dialysis patients and SF-36 scores are related to important clinical aspects. This approach can help in caring for dialysis patients and can be useful in outcome assessment programmes.

Key words: dialysis; health outcome assessment; health-related quality of life; SF-36 health survey

Introduction

In patients who have a chronic disease such as end-stage renal disease (ESRD) for which cure is not a realistic goal, maximizing functioning and well-being should be a primary objective of care. Both chronic dialysis and kidney transplantation are very effective medical technologies, and the ability of such technologies to sustain lives is of unquestioned significance. However, mortality data alone are an incomplete measure of outcome and a patient's self-perception of health is becoming increasingly important [1–6].

Over the past few years the therapeutic possibilities in the area of dialysis have changed greatly. The correction of anaemia with erythropoietin, the generalized use of bicarbonate dialysis with controlled ultrafiltration and treatment with high doses of calcitriol to correct the severe hyperparathyroidism secondary to ESRD, have probably had a positive influence on the quality of life of dialysis patients [7–9]. Interest in measuring health-related quality of life (HRQoL) has therefore increased together with the awareness that

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such subjective aspects require appropriate methods [10–12] and valid and reliable measures [13–17].

In the last decade short, simple and multidimensional questionnaires have been developed, frequently containing both negative and positive aspects of health, and having the patient as the primary source of information. Psychometric and clinical tests are recommended to assess whether the instrument is valid (it measures what it claims to measure), reliable (it produces similar estimates under stable conditions), responsive and sensitive (it is able to reflect true changes or differences) before its use in research or clinical settings [1,2,10,17]. As most of the instruments are in English and are intended for use in English-speaking nations, they must be translated and validated before their use in other languages. Among the so-called generic questionnaires that are available in different languages, the Short Form 36 Items Health Survey (SF-36) because of its comprehensiveness, brevity and high standards of reliability and validity [15,16] has been translated by independent Italian teams since 1990. The launch of the International Quality of Life Project (IQOLA) in 1991 made possible the use of data from several comparable applications across the world [18], and a standardized and accredited IQOLA SF-36 version has been tested in more than 10 000 Italian cases [19].

This is the first comprehensive English language report on the performance of the SF-36 in Italian ESRD patients. The paper presents and discusses evidence about the SF-36's validity in terms of applicability and patient acceptance, psychometric performance and cross-sectional relationship with a selected list of clinical variables.

Subjects and methods

Patients and study design

The present study is part of a large, prospective, multicentre trial (DIA-QOL study) aimed at describing the natural course of HRQoL in a large dialysis sample and also at developing and validating an Italian dialysis-specific questionnaire. Details on study design, methods and population characteristics are reported elsewhere [20]. Briefly, all consecutive patients treated in four dialysis units were included in the study and then followed-up for 2 years. In addition, all new patients entering dialysis treatment during the study period were also included (see Table 2 for demographic and clinical characteristics of the 571 patients enrolled).

According to the study protocol, the SF-36 questionnaire was administered at baseline to all dialysis patients treated in two of the four participating units (304 patients) to test the performance of the Italian version of SF-36, and to have a concurrent external validation of the new specific kidney questionnaire currently under development.

Data collection

The SF-36 questionnaire was offered to patients by the attending physician who was available for questions and explanations. Patients completed the questionnaires at home (or sometimes in hospital during dialysis treatment) and returned them during the next dialysis session (or scheduled visit for home patients). The SF-36 questionnaire is a 36-item health survey that measures eight different dimensions of health: physical function and role limitations related to physical problems, bodily pain, vitality, general health perception, social function, role limitations due to emotional problems and mental health. An additional one-item measure of self-evaluated change in health status is also available (Table 1). Scores are assembled using the Likert method for summated ratings and the raw scores are linearly transformed into 0–100 scales, with 0 and 100 assigned to lowest and highest possible value, respectively. Higher transformed scores indicate better health [15,16,18,19].

Sociodemographic data, time on dialysis, renal and comorbid conditions, type of dialytic treatment, use of drugs, haemoglobin, parathyroid hormone, serum albumin and body mass index were collected for all patients using standardized forms. In haemodialysis patients the index of haemodialysis adequacy KtV was also collected. These data were chosen for their clinical importance and to test the direction and strength of associations between clinical variables and health status scores.

Statistical analysis

Clinical and demographic variables of the sample were described using descriptive statistics such as mean, standard deviation (SD) and proportion. Grouping and scaling assumption were assessed using standard psychometric analyses as described in the papers presenting the original questionnaire [15,16,18,19]. Briefly, as the questionnaire is based on a multidimensional conceptualization of health, the multitrait analysis approach was adopted to test whether the conceptualization in domains fits the actual data: convergence, divergence and internal consistency reliability (Cronbach's alpha) were evaluated. After recoding the clinical variables in appropriate categories and assembling the scales, associations between clinical and HRQoL variables were estimated using parametric and non-parametric one-way-analyses of variance (ANOVA and Kruskal–Wallis) and correlation coefficients (Pearson and Spearman). Least squares multiple linear regression was utilized to estimate the relationship between HRQoL scores and potential independent covariates [21].

Results

Two-hundred-forty-six patients (80.9%) of 304 dialysis patients completed the questionnaire. Sample's descriptive statistics for clinical variables are reported in Table 2, where they are compared with the whole dialysis population actually included in the study and with the cases cared for in Lombardia, the region where the present sample was assembled. The characteristics of our dialysis patients are quite representative of the regional population, only differing for a somewhat larger presence of hospital dialysis.

The percentage of missing data at the item and scale levels was generally acceptable, at less than 10% for most of the items even if higher than in other surveys carried out in healthier cases [19]. The items associated with the highest percentage of missing data refer to the physical and emotional role scales.

Table 1. Information about the SF-36 health status scales

Concepts	No. of items	No. of levels	Summary of contents
Physical Functioning (PF)	10	21	Extent to which health limits physical activities such as self-care, walking, climbing stairs, bending, lifting, and moderate and vigorous exercises
Role Functioning–physical (RP)	4	5	Extent to which physical health interferes with work of other daily activities, including accomplishing less than wanted, limitations in the kind of activities, or difficulty in performing activities
Bodily Pain (BP)	2	11	Intensity or pain and effect of pain on normal work, both inside and outside the home
General Health (GH)	5	21	Personal evaluation of health, including current health, health outlook, and resistance to illness
Vitality (VT)	4	21	Feeling energetic and full of pep versus feeling tired and worn out
Social Functioning (SF)	2	9	Extent to which physical health or emotional problems interfere with normal social activities
Role Functioning–Emotional (RE)	3	4	Extent to which emotional problems interfere with work or other daily activities, including decreased time spent on activities, accomplishing less, and not working as carefully as usual
Mental Health (MH)	5	26	General mental health, including depression, anxiety, behavioral–emotional control, general positive affect
Reported Health Perception (HP)	1	5	Evaluation of current health compared to one year ago

From Ref. [19].

Table 2. Demographic and clinical characteristics of the samples considered

		DIA-QOL (571)		SF-36 (246)		Lombardia (5141)	
		No.	%	No.	%	No.	%
Age (years)	mean (SD)	61.7	(13.1)	60.8	(13.1)	60	(15)
Gender	Male	324	56.7	127	51.8	2925	56.9
	Female	247	43.3	119	48.2	2216	43.1
School (years)	mean (SD)	6.4	(3.3)	6.6	(3.7)	—	—
Employed	Yes	200	35.0	79	32.1	—	—
	No	317	55.5	167	67.9	—	—
Renal pathology	Glomerular	129	22.6	62	25.3	1337	26.0
	Interstitial	86	15.1	43	17.6	776	15.1
	Hereditary	69	12.3	30	12.2	658	12.8
	Vascular	65	11.4	26	10.6	715	13.9
	Diabetes	42	7.4	20	8.2	375	7.3
	Systemic	22	3.9	11	4.5	195	3.8
	Unknown	136	23.9	39	15.9	79	15.5
Type of treatment	At home HD	29	5.1	15	6.1	200	3.9
	In hospital HD	316	55.5	195	79.3	2689	52.3
	Limited care HD	132	23.2	20	8.1	1213	23.6
	CAPD	92	16.2	16	6.5	1028	20.0
KtV	mean (SD)	1.33	(0.24)	1.36	(0.25)	—	—
Haemoglobin (g/dl)	mean (SD)	10.08	(1.57)	10.15	(1.72)	—	—
Albumin (g/dl)	mean (SD)	3.94	(0.49)	3.97	(0.43)	—	—

HD, haemodialysis.

Table 3 refers to the psychometric characteristics of the questionnaire. Results confirmed that the multidimensional conceptualizations in domains and scales fit the present data. The within-scale correlation coefficients were quite homogeneous and, in most cases, higher than 0.40 (convergent validity). Higher item–scale correlations were also found within scale than between scales (discriminant validity). The internal-consistency reliability indexes (Cronbach's alpha) were always greater than 0.70, the standard recommended for group comparison, and higher than 0.90 in the physical functioning scale [18].

On average, strong and clinically sound associations were found between SF-36 scores and patient variables. Selected mean group differences are reported in Table 4. On average, scores measuring physical domains were significantly associated with age, gender, education, marital status, working status, diabetes and

Table 3. Synthesis of the psychometric results for the SF-36 questionnaire (246)

Scales	No. items	Item internal consistency[1]	Item discriminant validity[2]	Item internal consistency test[3]	Item discriminant validity test[4]	Reliability[5]
Physical functioning (PF)	10	0.53–0.81	0.14–0.59	100	100	0.94
Role physical (RP)	4	0.72–0.77	0.27–0.58	100	100	0.88
Bodily pain (BP)	2	0.82	0.25–0.65	100	100	0.89
General health (GH)	5	0.32–0.61	0.09–0.71	80	87.5	0.70
Vitality (VT)	4	0.66–0.75	0.26–0.68	100	100	0.86
Social functioning (SF)	2	0.72	0.42–0.71	100	100	0.84
Role emotional (RE)	3	0.68–0.77	0.23–0.58	100	100	0.85
Mental health (MH)	5	0.64–0.80	0.29–0.70	100	100	0.88

[1]Range of correlations between items and hypothesized scale corrected for overlap.
[2]Range of correlations between items and other scales.
[3]Item convergent validity scaling success: % of item-scale correlations greater than 0.40.
[4]Item discriminant validity scaling success: % of item-own scales correlations significantly higher than correlations with other scales.
[5]Internal-consistency reliability (Cronbach's alpha).

Table 4. Association between selected patient characteristics and selected SF-36 scales

		PF	BP	GH	VT	MH
Age	$\leqslant$70 years vs >70 years	+27.81	+14.65	+4.86	+12.85	+9.64
Gender	male vs female	+19.93	+11.28	+2.40	+9.64	+6.23
School years	>5 years vs $\leqslant$5 years	+26.84	+18.50	+8.19	+15.75	+9.22
Marital status	married vs unmarried	+8.71	+10.28	+6.38	+9.05	+6.71
Living alone	no vs yes	+14.91	+11.57	+9.03	+13.93	+11.02
Employed	yes vs no	+26.89	+13.81	+9.90	+14.83	+9.41
Waiting for transplantation	yes vs no	+22.56	+18.10	+6.40	+14.18	+10.01
Diabetes	no vs yes	+26.22	+3.44	+3.98	+11.53	+10.91
Comorbidity[1]	no vs yes	+17.15	+6.85	+7.92	+10.52	+6.22
Mental comorbidity	no vs yes	+4.41	+14.85	+6.26	+16.65	+21.72

$P<0.01$.
[1]No, no co-existent pathology; yes, cerebrovascular or chronic hepatobiliary or cardiovascular with treatment.
Italic indicates the group with high (better) HRQoL scores.

waiting for a renal transplant. The scale measuring mental health was significantly correlated with the presence of mental comorbid conditions.

No significant association was found with the KtV index, haemoglobin levels, body mass index, parathyroid hormone and type of dialysis (data not shown). A strong association was indeed found with serum albumin level. Such an association was particularly evident in the case of Physical Functioning (PF: $r=0.32$, $P=0.0001$), Role Physical (RP: $r=0.18$, $P=0.0069$) and General Health perception (GH: $r=0.21$, $P=0.0018$) scales. According to these results, in order to better understand the relationship between albumin level and SF-36 scores, patients were classified into four mutually exclusive groups, from low to high albumin level, and an analysis of variance was carried out (see Table 5). With increasing albumin levels a better self-reported HRQoL is registered, with large (30 points of difference between the lowest and highest albumin classes) and statistically significant ($P=0.001$) differences in the case of the PF scale, measuring the extent to which health limits physical activities such a self-care, walking, climbing stairs, and moderate and vigorous activities.

Because age and albumin were correlated and both have been shown to be associated with PF scale at univariate analysis, additional analyses were carried out using the multivariate analysis to factor out their reciprocal confounding effect. When entered alone, age and albumin explained 27% and 8% of PF score variability, respectively. When entered together, they were independently associated with PF scale and explained 29% of variability.

Figures 1 and 2 compare the health profiles of the present sample with those from the survey carried out on a representative sample of the Italian population [19]. This comparison makes it possible to describe the impact of the disease and disease-related treatments on patients' perception of health. Figure 1 presents the results obtained in our sample compared with the entire Italian general population after stratification by age. As expected, dialysis patients scored lower than the general population in both age groups, particularly in physical domains. Nevertheless, it is interesting to highlight that the differences between the elderly were somewhat less evident, mainly in mental (SF, RE, MH) scales.

Figure 2 compares the present sample with cases suffering from two severe medical conditions: congestive heart failure and chronic obstructive pulmonary diseases. This comparison makes it possible to describe the impact of a given disease using as a reference to

Table 5. Association between SF-36 scales and albumin values

Scales	Albumin (g/dl)				*P*-values (*F*-test/Kruskal–Wallis)
	⩽3.48	3.49–3.98	3.99–4.40	>4.40	
Physical functioning (PF)	38.98	41.13	58.60	70.21	0.0001/0.0001
Role physical (RP)	45.67	48.30	55.28	64.80	0.0225/0.0325
Bodily pain (BP)	31.17	36.59	35.21	41.91	0.0608/0.0496
General health (GH)	37.17	40.41	46.98	55.80	0.4075/0.5613
Vitality (VT)	54.00	58.96	62.10	71.68	0.0175/0.0183
Social functioning (SF)	69.02	59.77	62.15	72.00	0.1968/0.1341
Role emotional (RE)	53.70	41.03	58.99	68.25	0.0311/0.0284
Mental health (MH)	54.00	58.96	62.10	71.68	0.0550/0.0579

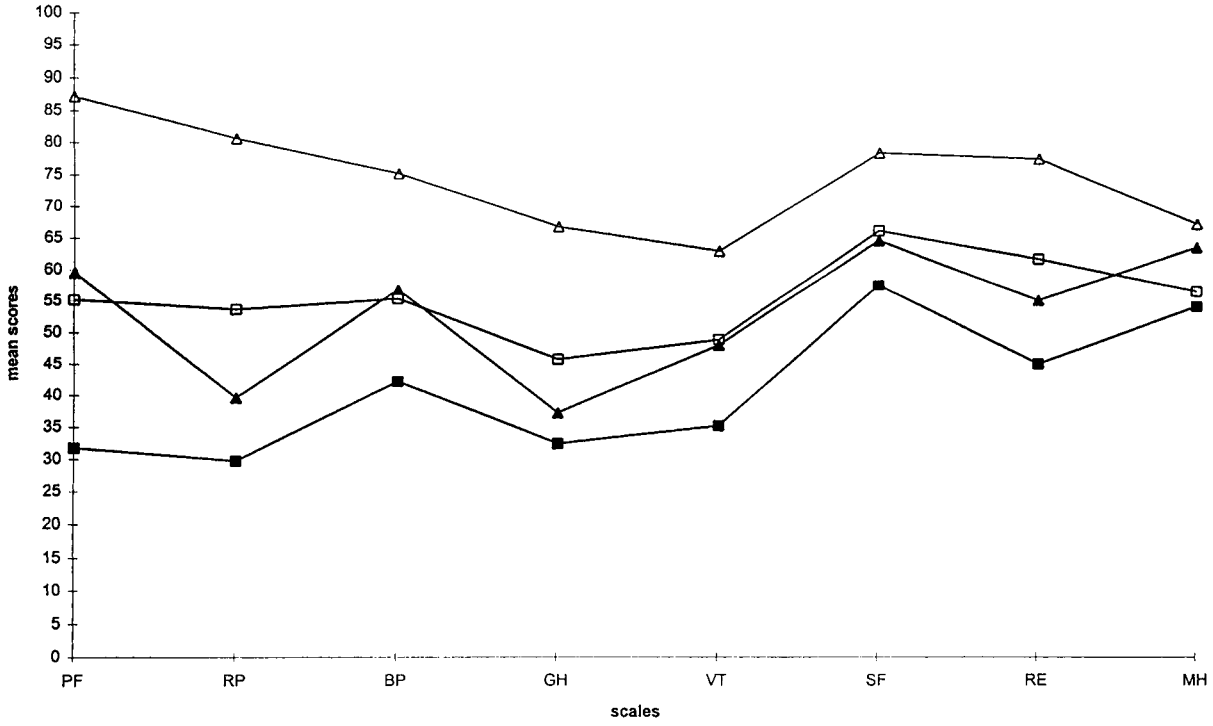

Fig. 1. Comparison between healthy individuals and dialysis patients by age. –▲– <70 years dialysis; –■– >70 years dialysis; –△– <70 years general population; –□– >70 years general population.

other diseases known to have an important impact on health status. At least in our sample, ESRD seems to be have a quite large impact on health status perception, the three health profiles being quite similar.

In Figure 3 results obtained in other ESRD samples using the same questionnaire are compared [22–23]. With the exception of the role limitation scales in the UK sample, a quite homogeneous picture emerges, the differences between samples being very small.

Discussion

In the medical community quality of life (QoL) or HRQoL are adopted interchangeably to describe the effects that diseases, treatments or more complex interventions may have on a person's functioning and well-being. But the concept of quality of life is indeed distinct from health, although related to it. Patients actually perceive and react to many health and non-health-related aspects of their lives, such as family life, finances, housing, work and other aspects of human experience, that are not related to the domain of health and medicine. Hence, only the subset of the overall concept of QoL that relates specifically to a person's health status that is more sensitive to changes in health refers to the measure of the patients' HRQoL. That is an evaluation of his/her functioning, well-being and general health perception in each of three relevant domains: physical, psychological and social.

Our capability to transform patients subjective opinions, ratings and reports into standardized pieces of information is based mainly on the results of the efforts of the past decade and, although the debate is still ongoing [1–3,24–26], several generic (assessing health concepts that represent basic human values and are

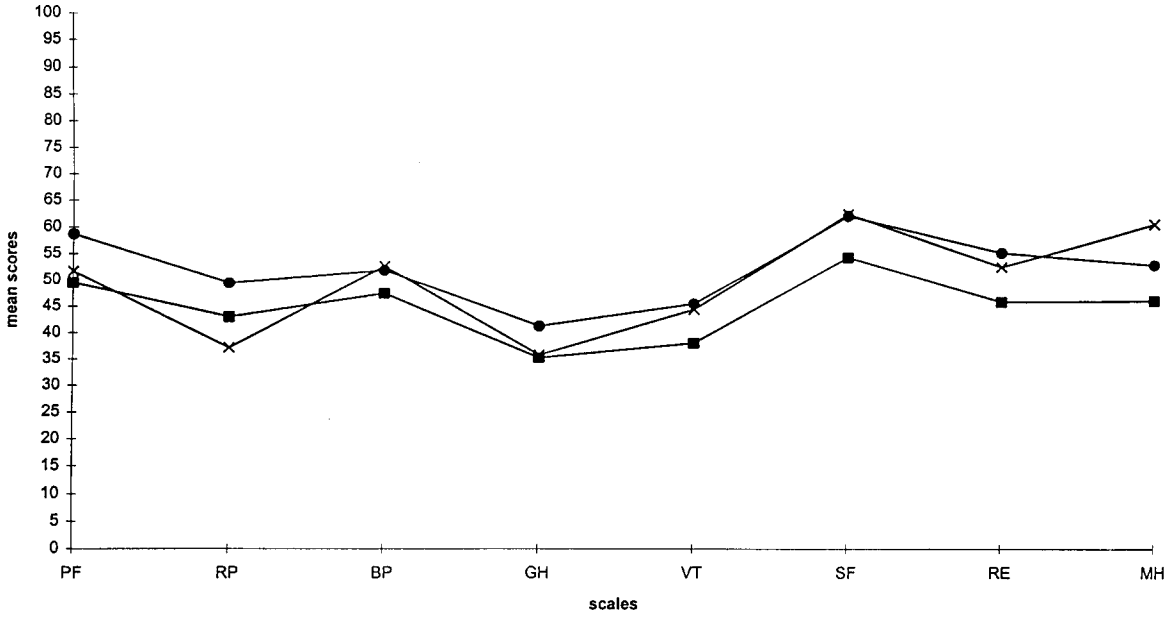

Fig. 2. Comparison of patients with different diseases. —×— Dialysis in Italy (No. = 246); —■— Congestive heart failure (No. = 129); —●— COPD (No. = 188).

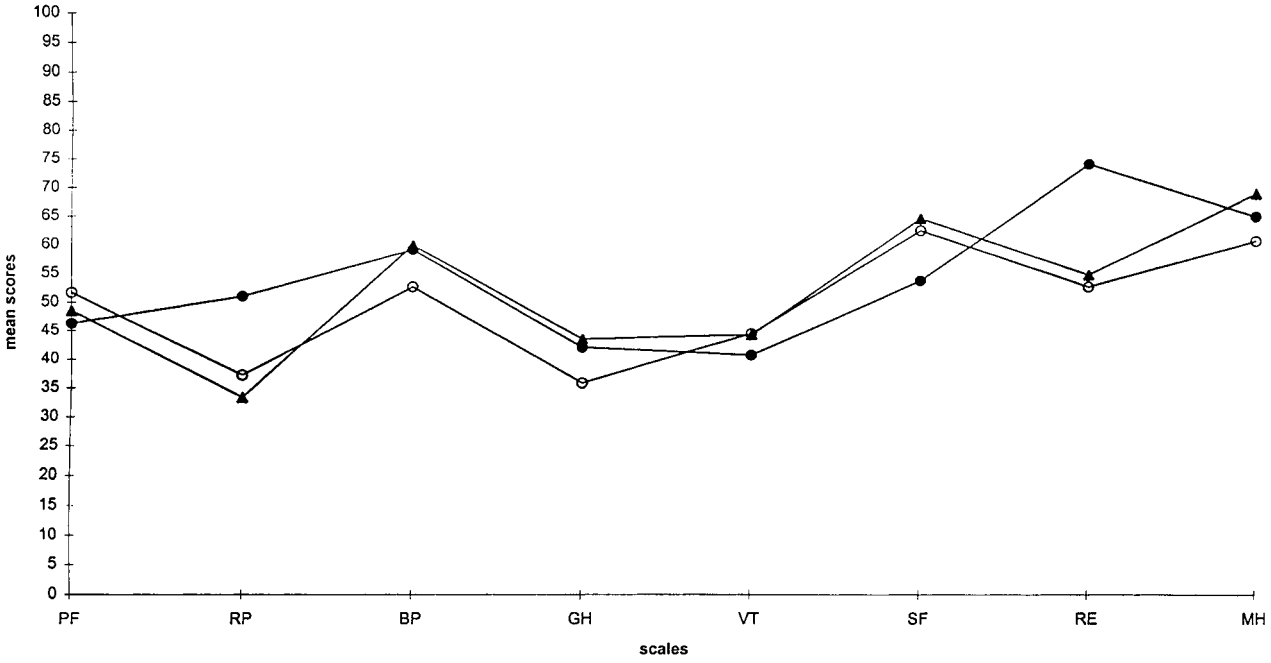

Fig. 3. Comparison of patients undergoing dialysis in different countries. —○— Italy; —●— UK; —▲— USA.

relevant to everyone's health status and well-being) or disease or treatment-specific measures (assessing health concepts that are tailored to a given disease or intervention) have been demonstrated to be valid, reliable and robust across languages, cultures and clinical settings [13–18].

Among the so-called generic questionnaires, the Short Form 36 Items Health Survey because of its comprehensiveness, brevity and high standards of reliability and validity [15,16] was translated and validated in several countries [18,19]. Nevertheless, few studies have used the SF-36 questionnaire in patients with ESRD [17,22,23,27], and all were from English-speaking countries. Overall, the present data show that the questionnaire's performance is also very good in a sample of Italian dialysis patients representative of the whole dialysis population of the region in which this study was carried out. The patients' acceptability was satisfactory, with a response rate higher than 80%. The psychometric assumptions usually recommended for group comparison were satisfied: all the grouping and scaling assumptions, as well as the internal reliability

coefficients met the standards suggested and actually replicated the findings reported for the original SF-36 [15,16,18], even if some values were lower than those obtained in general populations [19].

In terms of known-group-validity (the capability of the questionnaire scales to discriminate between groups expected to differ in that concept because of the presence of a particular aspect), the results were also good. On average, females reported lower scores and the impact of ageing was more evident for physical scales. Educational level, familiar situation, employment status and transplant suitability correlated with most scores (Table 4). Diabetic patients were significantly worse on the physical function scale and patients with mental problems scored significantly lower on the mental health scale.

Albumin is known to be a very important indicator in dialysis patients both for morbidity and mortality [28,29]. In at least one other study an association between albumin and HRQoL scores has been reported [30]. A significant and independent association between albumin levels and HRQoL was found in our sample also. These results, once again and from another point of view, underline the importance of albumin level in the clinical evaluation of dialysis patients. The reasons for and clinical value of this association are not yet clear [30].

No correlation was found with the index of dialysis adequacy KtV, usually considered to be a very reliable indicator of mortality [28,31], probably due to the optimal values found in the vast majority of our patients. Also no correlation was found with haemoglobin level, in contrast with other studies, using either prospective or cross design [32–34]. In these studies other measures were used instead of SF-36 questionnaire. In addition, the relatively small size of our sample and the narrow range of haemoglobin levels actually observed, due to the routine use of erythropoietin in Italy, could have masked the potential favourable effects. It was, however, demonstrated in these studies that raising low haemoglobin level is one of the most effective ways of increasing HRQoL in uraemic patients [32–34].

In 1985 Evans *et al.* published a paper that focused the attention of the medical community on HRQoL in ESRD patients [35]. Physicians' judgement of the patients' health, physical performances, and very simple quality of life questionnaires were used, and patients were compared with the general population. Age, education, race, transplantation and home dialysis were the variables most correlated with the subjective quality of life, and patients were reported to have only a slightly lower quality of life than the general population. Despite the fact that they had a poor objective quality of life, they were enjoying life. This lack of congruence between subjective and objective quality of life in ESRD patients was also observed in papers by Khan *et al.* and Meyer *et al.* [22,23]. In Fig. 1 it is evident that patients scored lower than the general population in physical domains and general health, but not in the mental health scale, assessing emotions and attitude toward life. In the group above 70 years of age dialysis patients scores were, however, quite close to those of the general population. Our old uraemic patients have, of course, many problems but their HRQoL seems acceptable in comparison with that of their healthier counterparts. These data underline the difference between patient's subjective judgments and feelings and medical objective parameters. Probably we must be more careful and cautious when judging the value of life of our patients, particularly when we recommend therapeutic interventions.

In conclusion, our study shows that the SF-36 maintains its psychometric properties in the present sample of Italian ESRD patients. This evidence should be considered important because it is the first independent application of the questionnaire in Italy and because it adds new evidence about the utility of a generic HRQoL measures in the ESRD patients. Although further validation studies in which generic and disease-specific instruments are administered are mandatory before conclusions can be drawn about its actual value, these data contribute evidence about the value SF-36 when adopted in a specific clinical setting.

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