

# Validity and Reliability of Short Form-12 Questionnaire in Iranian Hemodialysis Patients

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**Introduction.** The aim of the study was to assess the validity and reliability of the SF-12 questionnaire in a sample of Iranian patients undergoing hemodialysis.

**Materials and Methods.** One hundred and forty-four hemodialysis patients were included from dialysis centers in Zanjan, Iran, and were asked to complete the SF-12 and SF-36 questionnaires. An initial test-retest reliability evaluation was performed on a sample of 70 patients from the total group, with a retest interval of 14 days. Reliability was estimated by internal consistency and validity was assessed using known-group comparisons and construct validity on the patient group as a whole. A linear regression analysis was used to assess any variation in the physical component summary and mental component summary scores of the SF-36 with the respective component summary scores of the SF-12. In addition, the factor structure of the questionnaire was extracted by performing a confirmatory factor analysis.

**Results.** Cronbach  $\alpha$  for physical and mental component summaries were 0.89 and 0.90, respectively. The SF-12 showed a good discriminatory ability between subgroups of patients based on demographic and clinical variables. The confirmatory factor analysis for the original two-factor structure showed a good fit index ( $\chi^2 = 23.30$ , degrees of freedom = 13), goodness-of-fit index = 0.96, and root mean squared error of approximation = 0.079).

**Conclusions.** In general, the SF-12 has good psychometric properties and can be used as a shorter version of the SF-36 questionnaire in future studies involving Iranian patients undergoing hemodialysis.

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## INTRODUCTION

End-stage renal disease (ESRD) is a chronic disease with increasing prevalence worldwide. According to data collected from 120 countries in which dialysis programs have been adopted, about 1 900 000 people were receiving renal replacement therapy (RRT) at the end of 2005.<sup>1</sup> Of these individuals, 1 297 000 (68%) were on hemodialysis and 158 000 (8%) on peritoneal dialysis as a form of treatment. In terms of annual incidence of ESRD, a

report for 2006 documented 342 cases per million of population in the United States.<sup>2</sup> In Iran, a value from the same year, is somewhat lower, with an estimated 64 patients per million of population developing ESRD.<sup>3,4</sup> Moreover, studies show that ESRD is associated with chronic pain, depression, limited functional abilities, inability to maintain employment, and poor quality of life.<sup>4-7</sup>

Health-related quality of life (HRQOL) is an important aspect in terms of evaluating the

effectiveness of medical treatment. Several studies have revealed that treatments aimed at minimizing morbidity and mortality in ESRD have very often been ineffective.<sup>8,9</sup> Therefore, attention to HRQOL among ESRD patients is crucial. To this end, a number of generic and disease-specific instruments, designed to assess HRQOL in patients with ESRD, exist. One of them, which is generic, and used worldwide, is the Short Form-36 (SF-36) Health Survey.<sup>10</sup> The SF-36 is a self-administered health assessment tool consisting of 36 items, which can be used for patients and the general public alike. Eight health concepts related to the physical and mental status are measured in the SF-36.<sup>10</sup> Encompassing all these attributes, the SF-36 is useful for (1) monitoring patients, (2) comparing the health status of patients with different conditions, and (3) comparisons involving the general population.<sup>10</sup> However, despite the fact that the SF-36 is a popular tool, it is often reported to be “time-consuming” by respondents. It is for this very reason that Ware and Sherbourne suggested that the SF-36 could be shortened to a version comprising only 12 items.<sup>11</sup> Indeed, the physical component summary (PCS-12) of the abridged SF-12 has been found to be highly correlated with the PCS of the SF-36, as 90% of the variation noted using the PCS-36 could be explained by the PCS-12.<sup>11</sup> Furthermore, the mental component summary (MCS) obtained using the MCS-12 has been found to be highly correlated with the MCS from the SF-36, with 93% of the variation noted using the MCS-36 being explained by the MCS-12.<sup>11</sup> It has therefore been determined that the SF-12 is a valid and reliable tool in terms of the assessment of a patient’s health status.<sup>12,13</sup>

Since there are relatively few studies that document the use of the SF-12 in the assessment of HRQOL in patients with ESRD,<sup>14</sup> the aim of this study was to assess the validity and reliability of the SF-12 in a sample of Iranian patients undergoing hemodialysis.

## MATERIALS AND METHODS

### Patients

One hundred and forty-four patients on hemodialysis were included from 2 dialysis centers in Zanjan. The inclusion criteria were being on dialysis for more than 3 months, understanding the Persian language, agreeing to complete the SF-36 and SF-12 questionnaires, and being older than 18

years of age. Patients who were too frail or mentally unfit, and those who were unable to understand the questionnaire or unwilling to provide a written informed consent were excluded. The study was approved by ethics board of Qazvin University of Medical Sciences, and all patients gave their informed consent to participation in the study.

### Questionnaires

The sociodemographic and clinical data were obtained from a structured questionnaire and from the clinical records of the patient. The SF-36 has 36 questions which are grouped into 8 domains or scales of physical functioning (PF), role limitations due to physical health (RP), bodily pain (BP), general health perception (GH), social functioning (SF), role limitations due to emotional problems (RE), vitality (VT), and mental health (MH). These eight scales can then be reduced into 2 summary components of PCS and MCS. Moreover, the SF-36 has previously been evaluated in its original, as well as its Persian form, and been shown to be both reliable and valid.<sup>10,15</sup>

In addition to the SF-36 questionnaire, this study included the SF-12 questionnaire with its 12 items (questions) and 8 scales including PF, RP, GH, SF, RE, VT, and MH. These eight scales can also be computed into 2 distinct clusters of PCS-12 and MCS-12. The Persian version of the SF-12 was assessed using members of the Iranian general population, and results revealed that the psychometric tests of the Persian version of the SF-12 questionnaire were satisfactory.<sup>15</sup>

Ceiling effects were taken as being the percentage of respondents with scores of 100 and floor effects were the percentage of respondents having a score of zero. Ceiling and floor effects should be less than 20% to ensure that the scale captures the full range of potential responses within a given population, and that changes over time are detectable.

### Statistical Analyses

It is generally recommended that the number of cases needed to generate stable, reliable, and valid estimates be 5 to 10 times the number of variables employed in any given multivariate statistical model.<sup>16</sup> Accordingly, 144 patients were selected for this study.

Reliability was assessed using an internal consistency method and a test-retest analysis. For

assessment of internal consistency, the Cronbach  $\alpha$  coefficient was computed. The Cronbach  $\alpha$  coefficient covers a range from 0 to 1, with values greater than 0.70 being generally considered acceptable for group comparisons, and values greater than 0.90 being considered suitable for person-level comparisons.<sup>17</sup> In order to assess the test-retest reliability, 2 weeks later, the questionnaire was again completed by the same patients, and the intraclass correlation coefficient (ICC) was evaluated for the patients. Convergent validity was assessed using a correlation between each item and its own scale, corrected for overlap. The assessment was performed by means of the Pearson correlation coefficient. This test assumes that correlations of 0.4 or greater are to be considered acceptable.<sup>18,19</sup> In terms of clinical validation, group comparisons were made to disclose the sensitivity of the questionnaire in terms of its ability to discriminate between subgroups of the patients (eg, age, gender, educational level, and clinical aspects, including length of disease, and index of dialysis adequacy [Kt/V]). It was assumed that female patients, older patients, and those with a lower level of education and long disease duration would attain a low HRQOL score. Statistical significance was assessed in this case using the independent *t* test, and *P* values less than .05 were accepted as being significant.

Linear regression analysis was used to assess the variation in the PCS-36 and MCS-36 scores against their respective PCS-12 and MCS-12 scores. The model was adjusted for sex and age.

A confirmatory factor analysis was performed to evaluate the factor structure of the SF-12, originally, the questionnaire comprised a two-factor model. Model fit was assessed in several ways, including the comparative fit index, normed fit index, the root mean square error of approximation, goodness of fit index (GFI), and adjusted GFI. The comparative fit index ranges from 0 to 1, where a comparative fit index close to 1 indicates a very good fit and a value greater than 0.9 indicates an acceptable fit. The normed fit index specifies the practicality of the model to the collated data, with an assessment being deemed acceptable when it equals or is greater than 0.90. The root mean square error of approximation is a measure of the discrepancy of the model to the collated data, expressed per degree of freedom, with a typical cutoff point for

the root mean square error of approximation being 0.05 or less, whilst an adequate fit is acceptable at 0.08. The GFI measures the relative difference between the data and estimated values obtained from a model, with the adjusted GFI compensating for the degrees of freedom. Previous studies have suggested a cutoff point equal to or greater than 0.90 for GFI and adjusted GFI.<sup>19,20</sup>

Since it was assumed that illiterate patients may quite likely be included in this study, and that they would need help to complete the questionnaire, a trained assistant helped such patients by reading the questions and optional answers without any further explanation after which he left the patients to think freely with regard to their most appropriate answer to the posed questions.

## RESULTS

Characteristics of the patients are shown in Table 1. Most of the patients were married (87.5%). Forty-six patients (31.9%) were illiterate and

**Table 1.** Characteristics of Hemodialysis Patients\*

Characteristic	Value
Age, y	54.61 ± 11.38
Years of education	6.75 ± 5.27
Gender	
Male	83 (57.6)
Female	61 (42.4)
Marital status	
Married	126 (87.5)
Single	8 (5.5)
Divorced/widowed	10 (7.0)
Accommodation	
Urban	111 (77.1)
Rural	33 (22.9)
Employment status	
Employed	41 (28.5)
Unemployed	103 (71.5)
Monthly income	
High (> \$ 750)	59 (41.0)
Moderate (\$ 500 to \$ 750)	69 (47.9)
Low (< \$ 500)	16 (11.1)
Primary cause of ESRD	
Hypertension	66 (48.5)
Diabetes mellitus	54 (37.5)
Glomerulonephritis	20 (13.9)
Other	4 (2.8)
Dialysis duration, mo	30.95 ± 22.16
Hemoglobin, g/dL	10.72 ± 1.57
Serum albumin, g/dL	4.52 ± 0.56
Kt/V	1.17 ± 0.25

\*Values in parentheses are percents. ESRD indicates end-stage renal disease.

therefore unable to complete the questionnaire independently. The average time taken to complete the questionnaire was 3.1 minutes. All of the patients understood the questions in the questionnaire and perceived them to be easy to answer.

The responses to the SF-12 items and summary descriptive statistics are presented in Table 2. In all cases, the responses to the SF-12 items were

found to be normally distributed, a finding that highlights the sensitivity of this instrument.

The results from the Cronbach  $\alpha$  coefficient test for internal consistency for each component showed that the components in the questionnaire had a satisfactory internal consistency, as Cronbach  $\alpha$  for PCS and MCS in the SF-12 questionnaire were 0.89 and 0.90, respectively. Furthermore, Cronbach  $\alpha$

**Table 2.** Item Descriptions and Descriptive Statistics for Short Form-12 Questionnaire\*

Short Form-12 Items	Mean Score	Response Frequencies (%)					
		1	2	3	4	5	6
Limitations in moderate physical activities (PF)	1.94 ± 0.76	31.9	41.7	26.4	...	...	...
Limitations in climbing several flights of stairs (PF)	1.88 ± 0.79	37.5	36.1	26.4	...	...	...
Accomplished less due to physical health (RP)	1.40 ± 0.49	59.0	41.0	...	...	...	...
Limited in kind of work or activities due to physical health (RP)	1.36 ± 0.48	63.9	36.1	...	...	...	...
Pain interference with work inside or outside home (BP)	2.05 ± 1.42	21.5	22.2	13.2	26.4	16.7	...
Health rating in general (GH)	1.53 ± 1.31	6.9	19.4	25.7	15.3	23.6	...
Interference of physical health or emotional problems with social activities (SF)	3.04 ± 1.24	6.9	39.6	10.4	28.5	14.6	...
Accomplished less due to emotional problems (RE)	1.38 ± 0.48	61.8	38.2	...	...	...	...
Not careful in work or activities due to emotional problems (RE)	1.41 ± 0.49	58.3	41.7	...	...	...	...
Having a lot of energy (VT)	2.42 ± 1.40	4.2	25.7	17.4	21.5	22.9	8.3
Feel calm and peaceful (MH)	2.81 ± 1.62	16.7	29.9	2.8	29.9	9.7	11.1
Feel downhearted and blue (MH)	2.63 ± 1.66	17.4	21.5	14.6	9.7	29.2	7.6

\*PF indicates physical functioning; RP, role limitations due to physical health; BP, bodily pain; GH, general health perception; SF, social functioning; RE, role limitations due to emotional problems; VT, vitality; and MH, mental health.

**Table 3.** Comparison of Short Form-12 Scores in Terms of Demographic and Clinical Characteristics of Patients\*

Groups	PCS-12		MSC-12	
	Mean	P	Mean	P
Age				
≤ 55 (n = 68)	53.79 ± 30.31		55.75 ± 28.71	
> 55 (n = 76)	24.46 ± 32.45	< .001	32.95 ± 28.17	.006
Gender				
Male (n = 83)	50.18 ± 27.02		55.94 ± 24.86	
Female (n = 61)	27.63 ± 20.38	< .001	30.10 ± 27.83	< .001
Education				
0 to 5 years (n = 59)	28.55 ± 23.19		25.71 ± 18.21	
6 to 8 years (n = 51)	39.88 ± 26.20		50.68 ± 25.64	
> 8 years (n = 34)	46.76 ± 27.70	< .001	61.03 ± 27.38	< .001
Disease duration, mo				
≤ 24 (n = 100)	45.44 ± 32.50		52.30 ± 32.05	
> 24 (n = 112)	32.92 ± 32.08	.01	36.30 ± 26.12	.03
Hemoglobin				
≤ 11 (n = 76)	30.61 ± 24.53		34.79 ± 29.10	
> 11 (n = 68)	49.76 ± 28.41	.002	50.28 ± 25.42	.007
Kt/V				
≤ 1.3 (n = 73)	32.43 ± 33.83		32.77 ± 29.54	
> 1.3 (n = 71)	45.02 ± 29.63	.005	53.29 ± 24.59	.007
Population				
General population <sup>14</sup>	50.10 ± 8.50		46.30 ± 10.40	
The present study	39.12 ± 32.67	.004	43.90 ± 29.04	.005

\*PCS indicates physical summary scale and MSC, mental summary scale.

for PCS and MCS in the SF-36 questionnaire were 0.90 and 0.91, respectively. Finally, it is important to note that the PCS and MCS scores for the SF-12 and SF-36 questionnaires did not suffer adversely from floor or ceiling effects (5.6% for PCS and 3.5% for MCS in SF-12; zero for PCS and 2.8% for MCS in SF-36).

Results from known-group comparisons showed that the SF-12 had the ability to discriminate between subgroups of patients differing in age, gender, level of education, disease duration, Kt/V, and albumin level. Thus, being female, increasing age, lower level of education, longer dialysis duration, and lower levels of albumin and Kt/V were found to have a poor quality of life compared to other patient subgroups (Table 3). Moreover, for each of the summary measurements, the mean scores for the patients were found to be significantly lower compared to scores obtained from the general population in Tehran (Table 3). Regarding convergent validity, the scales were assessed using a correlation between each item and its own scale, corrected for overlap. All of the items showed the highest correlation when compared with their own scale in comparison with other scales.

The intraclass correlation coefficient for the SF-12 showed that the questionnaire had a dependable consistency between the two assessments. The SF-12 scales' intra-class correlation coefficient ranged from 0.67 for BP to 0.90 for PF (Table 4).

Results from the linear regression analysis showed that about 88% of the variation in the PCS-36 scores was explainable by the model. Moreover, 90% of the variation in the MCS-36 scores was explainable by the model (Table 5).

A confirmatory factor analysis was performed

**Table 4.** Test-Retest Reliability of the Persian Version of Short Form-12 Questionnaire in 70 Hemodialysis Patients\*

Scale	ICC
PF	0.90
RP	0.82
BP	0.67
GH	0.71
VT	0.73
SF	0.79
RE	0.70
MH	0.72
PCS	0.76
MCS	0.74

\*ICC indicates intraclass correlation coefficient; PF, physical functioning; RP, role limitations due to physical health; BP, bodily pain; GH, general health perception; VT, vitality; SF, social functioning; RE, role limitations due to emotional problems; MH, mental health; PCS, physical component summary; and MCS, mental component summary.

on the primary 8 scales and these results are shown in the Figure. As originally postulated, the 8 scales must be loaded with the two latent factors (ie, PCS and MCS). The results show that the model provided a good fit for the data, with a fit index of  $\chi^2 = 23.30$ , degree of freedom = 13,  $P = .04$ , GFI = 0.96, adjusted GFI = 0.90, normed fit index = 0.99, comparative fit index = 0.99, standardized root mean square residual = 0.036, and root mean square error of approximation = 0.079 (95% confidence interval, 0.018 to 0.130; Figure).

## DISCUSSION

An assessment of the HRQOL of a given group of patients is considered an outcome of health service research, providing unique information about potential problems as well as identifying important issues pertaining to clinical care. Moreover, just such an assessment of the quality of

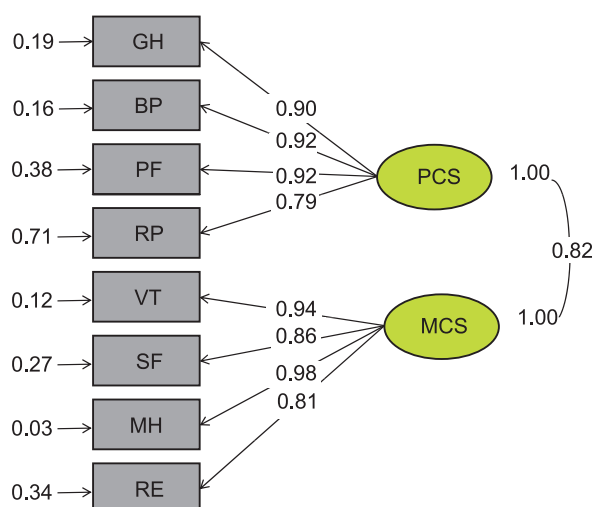
**Table 5.** Variation in Short Form-36 Summary Scale Scores\*

Parameter	Regression Coefficient	Standardized Regression Coefficient	95% Confidence Interval		P
			Lower	Upper	
PCS-36†					
PCS-12	0.969	0.903	0.866	1.072	< .001
Age	-0.078	-0.024	-0.326	0.171	.54
Sex	-4.662	-0.063	-11.279	1.956	.17
MCS-36‡					
MCS-12	0.894	0.913	0.786	0.922	< .001
Age	-0.096	-0.040	-0.252	0.060	.22
Sex	-3.053	-0.055	-6.995	0.888	.13

\*PCS indicates physical summary scale and MSC, mental summary scale.

† $R^2 = 0.88$

‡ $R^2 = 0.90$



A two-factor model for the Short Form-12 questionnaire obtained using confirmatory factor analysis. GH indicates general health perception; BP, bodily pain; PF, physical functioning; RP, role limitations due to physical health; VT, vitality; SF, social functioning; MH, mental health; RE, role limitations due to emotional problems; PCS, physical component summary; and MCS, mental component summary.

a patient's life facilitates communication between healthcare workers and patients, facilitating the monitoring of a response to treatment.<sup>7,21-23</sup> The present study constitutes a cross-sectional study for the psychometric evaluation of the SF-12 in Iranian patients undergoing hemodialysis. The study revealed that subscales of the Persian version of the SF-12 had acceptable internal consistency. Moreover, the study showed that the Persian version of the SF-12 was highly reproducible between a month gap. Furthermore, SF-12 subscales predicted at least 88% of the variance in both the physical and mental summary scales of the SF-36. At final, two-factor structure of the SF-12 was confirmed in the study.

This study showed that the mean PCS-12 and MCS-12 scores in the patients were 43.9 and 39.1, respectively. Indeed, these results are consistent with those from a previous study involving Iranian patients undergoing hemodialysis.<sup>4</sup> Furthermore, no floor or ceiling effects for either of the SF-12 summary scores (ie, PCS-12 and MCS-12) were observed, confirming the theory that the summary scales are acceptable as individual tools.

The reliability test for internal consistency showed that the two summary scores yielded acceptable results ( $\alpha > 0.7$ ). However, in comparison with the SF-36 summary scores, the SF-12 questionnaire

was found to have a lower Cronbach  $\alpha$  coefficient.

A test of convergent validity was found to be acceptable for the four scales of the SF-12, mainly since the correlations of items with their own scales were found to be highest in comparison with other items. The findings therefore showed that the items were highly related to their own scales, results that are supported by another study.<sup>15</sup>

All of the SF-12 scales met the minimal recommended correlation coefficient requirements (0.7) in terms of the test-retest reliability evaluation, with the exception of BP (0.67). A possible reason for this particular finding could be that pain and pain control are internal signals that are highly subjective experiences for each individual. This being the case, one could easily imagine that differences between the two assessments, taken after all with a 14-day interval, may arise. In support of which, the data analysis shows that PF with 0.90 and BP with 0.67 had the highest and lowest stabilities, respectively, over the 14-day retest interval. Indeed, the PCS-12 summary scores were also found to have higher stabilities than those for the MCS-12. Finally, these results are very similar to those from a previous study with the SF-12 questionnaire.<sup>11</sup>

Results from known-group comparisons showed that the SF-12 scores could be discriminated by patient subgroups based on age, gender, level of education, and also such clinical variables as Kt/V and hemoglobin. In the present study, patients undergoing hemodialysis, who were compared with the general population of Tehran, obtained a very low score for the SF-12 questionnaire.<sup>14</sup> Moreover, our results support the findings of other studies in which older patients, women, less educated individuals, and patients with a low Kt/V rate and hemoglobin suffered to a greater degree from a poor HRQOL.<sup>4,24-26</sup>

One of the limitations of the current study is that it was a clinical sample from a province (Zanjan). This problem may reduce generalizability of findings to other parts of Iran. Further studies on validation SF-12 from other parts of Iran are needed. Furthermore, we suggest to perform similar studies on other kind of dialysis, ie, peritoneal dialysis.

## CONCLUSIONS

This study shows that the Iranian version of the SF-12 has a high reliability and validity among

hemodialysis patients. Moreover, this questionnaire can be administered by healthcare workers to assess a patients' HRQOL with regard to the effects of kidney disease.

### CONFLICT OF INTEREST

None declared.

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