

SERBIAN TRANSLATION AND VALIDATION OF THE SF-36 FOR THE ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH DIAGNOSED ARTERIAL HYPERTENSION

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ABSTRACT

Precise estimation of life quality is of special importance in patients with chronic diseases, such as arterial hypertension. There are many questionnaires for that purpose. Short-form 36 (SF-36) with 8 domains has been proved as one of the most appropriate. To date, there was no translated and validated SF 36 in Serbian language for hypertensive patients. The aim of this study was to test validity and reliability of SF-36 in Serbian patients with diagnosed arterial hypertension. Cronbach's alpha coefficient was calculated to assess the internal consistency of the Serbian version of the SF-36. After deducting the overlap between each of the 36 items and its related domain, the collective validity was considered to be good if the correlation coefficient remains > 0.4. Only 2.54% answers on the questions were missing. Values of all the 8 domains were higher in men than in women. Cronbach alpha coefficient was high for SF-36, 0.897, and it suggesting that the SF-36 had good internal reliability. All 8 domains showed high values non-rotating factorial weights (>0.300) (range from 0.742-0.856), and all measure the same thing. It means that all components in this questionnaire measure the things they are assigned to.

Keywords: SF-36, Serbian population, quality of life, hypertension.



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INTRODUCTION

There is increasing demand by doctors and other medical professionals to measure the quality of life in different disease groups. It is very important to assess quality of life especially in patients with chronic diseases, having in mind their longevity and associate problems (1, 2). In Serbian population, there is growing number of hypertensive patients. For that reason, it is important to analyze the quality of life in among these patients. Patients' perception of their life quality may be affected by disease and medication, especially important in patients with arterial hypertension. Namely, patients with moderate and mild hypertension usually do not have any symptoms (3). On the other hand, many antihypertensive drugs may show some side effects that may impact quality of life (4, 5). It was already shown that hypertensive patients had poorer quality of life in comparison to healthy individuals (2).

Many researchers have found wide range of questionnaires to measure patient's quality of life. A short form health survey questionnaire (SF-36) has been proved as one of the most appropriate and has been translated and validated into variety of languages (6-10).

SF-36 consists of 36 questions grouped in 8 domains (11, 12). Scientific evidences showed that SF-36 is reliable questionnaire for the assessment quality of life in different populations (13).

There is an increasing need among health professionals to use validated quality of life questionnaires in hypertensive patients (14). At present, there is no validated form of Serbian version of SF-36. The aim of this study was to test validity and reliability of SF-36 in Serbian patients with diagnosed arterial hypertension.

MATERIAL AND METHOD

The 169 patients with diagnosed arterial hypertension were recruited from September 2019- January 2020 from the Pharmacy department in Kragujevac. Each patient gave informed consent to participate in the study, according to ethical standards and Declaration of Helsinki. The study was anonymous, and the results remain confidential. The completed questionnaires did not contain any identifying information about the individual participant. Enrollment in the study was voluntary-based.

The SF-36 Health Survey is composed of 36 questions and standardized response choices, organized into eight multi-item scales:

- physical functioning (PF);
- role limitations due to physical health problems (RP);
- bodily pain (BP), general health perceptions (GH);
- vitality (VT), social functioning (SF);
- role limitations due to emotional problems (RE);
- general mental health (MH).

In this study, translated Serbian form of SF-36 was used (Appendix 1).

Statistical analysis – Reliability.

Cronbach's alpha coefficient was calculated to assess the internal consistency of the Serbian version of the SF-36. Internal consistency estimates of a magnitude of >0.70 were considered acceptable for group comparisons (15). Test-retest reliability of the SF-36 was assessed using interclass correlations (ICC) between baseline and retest. A correlation of >0.80 was considered 'good' (16).

Statistical analysis – Validity.

The complete statistical analysis was performed using the computer program IBM SPSS Statistics 19.0. All continuous variables are shown in the form of the mean $\pm$ standard deviation with 95% confidence interval or median with interquartile range (25-75th percentiles) (IQR), while the categorical variables are shown with the percentage of certain category frequency. Chi-square test and independent t-test were used for the analysis of socio-demographic characteristics of patients. Kolmogorov-Smirnov test (tests of normality) was used for testing normality of SF 36 domains. Mann-Whitney U test was done to compare SF 36 domains according to gender. The correlation between the two continuous variables was examined by Pearson linear correlation.

Cronbach's alpha, split-half and test-retest methods of reliability were used. For the evaluation of the validity of this scale, the Principal Component Analysis was applied and the criterion for the number of the extracted components was Eigenvalue > 1. The factor loading of 0.4 or greater was considered.

In the present study, factor analysis for the eight domains was used to evaluate the structural validity of the SF-36 questionnaire. The Kaiser-Meyer-Olkin (KMO) statistic and Bartlett's spherical check were carried out to check for sample suitability for the factor analysis. Factor analysis is a statistical method used to test the structural validity of a scale and describes variability among observed variables in terms of fewer unobserved variables – called factors.

RESULTS

Characteristics of patients

The SF-36 was completed by 169 adult patients with diagnosed arterial hypertension. This sample represented 76 males and 93 females with a mean age of 65.04 ± 11.18 years (age range 35-88 years) (Table 1).

Missing data

Out of all patients (169) and all questions (6084), 2.54% or 157 answers on the questions were missing. About 97.5% SF-36 questions were completed.

Descriptive statistics of SF-36

Descriptive statistics of all 8 domains of SF 36 was shown in Table 2. When the check of normality was done, we could see that only in one domain (General health) the condition for normality of data was fulfilled, but with other domains no. Meridian range of all 8 domains was from 50.00 (Role limitations due to physical health) to 66.67 (Role limitations due to emotional problems).

Gender differences

SF-36 domains for the responder sample were further analysed to determine any differences between males and females. Table 3 displays the descriptive characteristics as a function of gender (mean, standard deviation). Analysis revealed many differences between males and females for SF-36 domains (Physical functioning, Role limitations due to physical health, Energy/fatigue, Emotional well-being, Social functioning, and Pain). Values of all the 8 domains were higher in men than in women.

Reliability Analysis

Cronbach alpha coefficient was high for SF-36, 0.897, and it suggesting that the SF-36 had good internal reliability. If we look at the correlation matrix, we will see excellent correlation among all SF 36 domains ($r > 0.300$) (Table 4). The lowest correlation was 0.469 and the highest 0.729. Average inter-item correlation was 0.598.

The summary statistics of all SF 36 domains was displayed in Table 5. If any domain removes from analysis, there is no growing of Cronbach's Alpha. It means that all domains should be analysed and they are valid for our population (Cronbach's Alpha if Item Deleted range from 0.880-0.894). Likewise, in Table 5 we could see good correlation of every domain with overall sum of SF-36 score (Corrected Item-Total Correlation range from 0.688-0.774).

Validity Analysis

Structural validity was evaluated by means of factor analysis. Results showed the KMO measure to be 0.904 and the Bartlett's spherical check to be $\chi^2 = 888.231$ and $p < 0.001$, which taken together, indicated that the samples in this study were suitable for factor analysis.

Factor analysis results indicated that when one component summary score, were included the eight domains whose characteristic roots were > 1 or approaching 1, the accumulative contribution rate was up to 64.93% (Figure 1 and Table 6).

In the end, Component Matrix was gained with factorial analysis, where all 8 domains showed high values non-rotating factorial weights (> 0.300) (range from 0.742-0.856), and all measure the same thing. It means that all components in this questionnaire measure the things they are assigned to (Table 7).

Using a Pearson product moment correlation analysis, the results are presented in Table 8. The outcome of the correlation analysis indicated that the vast majority of items correlated more strongly with their related domain by comparison to an unrelated domain.

The retest of the correlation between the items showed that $r > 0.900$ could be achieved for all eight domains ($p < 0.001$) (Table 9), demonstrating good stability for the SF-36 questionnaire. This analyze was performed in 19 patients two weeks after first test. The difference between the mean values for each domain after two rounds of measurements was not statistically significant ($p > 0.05$ for all domens).

Figure 1. Scree plot

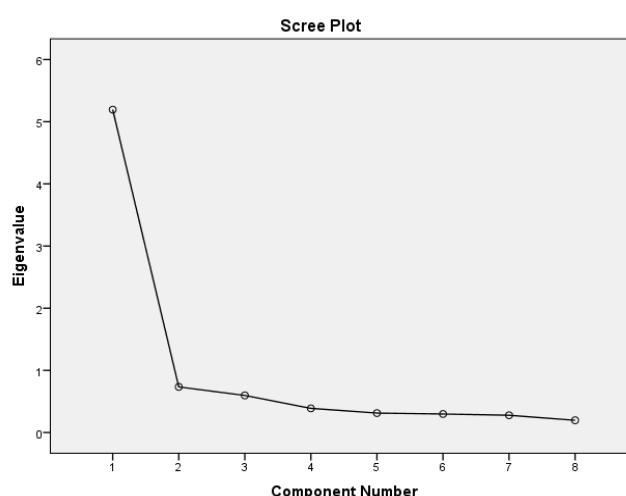


Table 1. Socio-demographic characteristics of patients with diagnosed hypertension

	Male	Female	p value
Gender; n (%)	76 (45%)	93 (55%)	
Age; M $\pm$ SD	65.32 $\pm$ 11.27	64.83 $\pm$ 11.17	0.789*
Level of education; n (%)			
primary school	13 (17%)	22 (25%)	0.050**
secondary school	31 (42%)	48 (54%)	
higher school	10 (13%)	7 (8%)	
University	21 (28%)	12 (13%)	

n (%) - number (%); M $\pm$ SD - mean $\pm$ standard deviation; * - Independent samples t test; ** - Chi-square test

Table 2. Parametric and non-parametric descriptive statistics of SF-36 domains

SF-36 domains	Mean	SD	95% CI	p value*	Median	IQR
Physical functioning	62.02	29.71	57.50-66.53	<0.001	65.00	44.72-89.44
Role limitations due to physical health	46.94	43.83	40.29-54.00	<0.001	50.00	0.00-100.00
Role limitations due to emotional problems	53.55	44.51	46.79-60.31	<0.001	66.67	0.00-100.00
Energy/fatigue	54.21	20.55	51.09-57.33	0.030	52.00	44.00-68.00
Emotional well-being	65.59	19.09	62.69-68.48	<0.001	63.33	52.00-83.33
Social functioning	64.79	23.88	61.17-68.42	<0.001	62.50	50.00-87.50
Pain	62.97	23.84	59.35-66.59	<0.001	57.50	45.00-78.75
General health	51.36	20.98	48.17-54.55	0.200	52.27	38.64-65.91

* - Kolmogorov-Smirnov test (Tests of normality); SD - standard deviation; 95% CI - 95% confidence interval; IQR - interquartile range (25-75th percentiles)

Table 3. Descriptive statistics of SF-36 domains according to gender

SF-36 domains	Male	Female	p value*
Physical functioning	75.00 (51.25-90.00)	60.00 (35.00-86.94)	0.033
Role limitations due to physical health	75.00 (0.00-100.00)	25.00 (0.00-100.00)	0.007
Role limitations due to emotional problems	83.33 (0.00-100.00)	66.67 (0.00-100.00)	0.184
Energy/fatigue	56.00 (49.00-76.00)	52.00 (36.00-64.00)	0.001
Emotional well-being	68.33 (53.33-86.67)	63.33 (50.00-73.33)	0.025
Social functioning	75.00 (53.12-87.50)	50.00 (50.00-75.00)	<0.001
Pain	67.50 (45.00-90.00)	55.00 (45.00-77.50)	0.002
General health	52.27 (38.64-65.91)	47.73 (31.82-68.18)	0.168

* - Mann-Whitney U test; Median (IQR - interquartile range (25-75th percentiles))

Table 4. Inter-item correlation matrix of SF-36 domains*

	Physical functioning	Role limitations due to physical health	Role limitations due to emotional problems	Energy/fatigue	Emotional well-being	Social functioning	Pain	General health
Physical functioning	1.000							
Role limitations due to physical health	0.618	1.000						
Role limitations due to emotional problems	0.502	0.699	1.000					
Energy/fatigue	0.595	0.605	0.545	1.000				

	Physical functioning	Role limitations due to physical health	Role limitations due to emotional problems	Energy/fatigue	Emotional well-being	Social functioning	Pain	General health
Emotional well-being	0.478	0.485	0.531	0.729	1.000			
Social functioning	0.592	0.601	0.527	0.684	0.708	1.000		
Pain	0.673	0.647	0.547	0.619	0.548	0.634	1.000	
General health	0.630	0.522	0.469	0.715	0.601	0.634	0.606	1.000

* - Pearson linear correlation

Table 5. Item-Total Statistics of SF-36 domains

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Physical functioning	399.412	25586.534	0.714	0.572	0.881
Role limitations due to physical health	414.487	21526.545	0.763	0.638	0.883
Role limitations due to emotional problems	407.879	22161.700	0.688	0.540	0.894
Energy/fatigue	407.223	27552.407	0.774	0.692	0.882
Emotional well-being	395.844	28435.334	0.692	0.636	0.888
Social functioning	396.637	26795.792	0.754	0.639	0.880
Pain	398.457	26787.682	0.756	0.597	0.880
General health	410.070	27853.907	0.709	0.600	0.886

Table 6. Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings*
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	5.19	64.93	64.93	5.19	64.93	64.93	4.66
2	0.73	9.18	74.11	0.73	9.18	74.11	4.28
3	0.60	7.46	81.57				
4	0.39	4.86	86.42				
5	0.31	3.91	90.34				
6	0.30	3.72	94.06				
7	0.28	3.48	97.54				
8	0.20	2.46	100.00				

Extraction Method: Principal Component Analysis; *- When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Table 7. Component Matrix

	Component 1
Energy/fatigue	0.856
Social functioning	0.838
Pain	0.819
General health	0.806
Role limitations due to physical health	0.802
Emotional well-being	0.790
Physical functioning	0.789
Role limitations due to emotional problems	0.742

Extraction Method: Principal Component Analysis; One component extracted.

Table 8. Item to domain correlations for the SF-36 data (for all correlations $p < 0.001$)*

	Physical functioning	Role limitations due to physical health	Role limitations due to emotional problems	Energy/fatigue	Emotional well-being	Social functioning	Pain	General health
SF1	-0.507	-0.384	-0.328	-0.490	-0.408	-0.465	-0.495	-0.663
SF2	-0.427	-0.319	-0.271	-0.378	-0.250	-0.333	-0.455	-0.515
SF3	0.755	0.523	0.367	0.509	0.332	0.383	0.624	0.553
SF4	0.822	0.537	0.426	0.536	0.415	0.535	0.557	0.559
SF5	0.863	0.578	0.478	0.567	0.433	0.547	0.538	0.581
SF6	0.837	0.536	0.424	0.490	0.325	0.417	0.552	0.477
SF7	0.822	0.509	0.339	0.514	0.419	0.545	0.544	0.546
SF8	0.823	0.519	0.431	0.422	0.252	0.393	0.583	0.506
SF9	0.852	0.536	0.439	0.572	0.469	0.556	0.604	0.602
SF10	0.856	0.506	0.427	0.498	0.449	0.516	0.562	0.538
SF11	0.786	0.377	0.316	0.407	0.357	0.467	0.438	0.446
SF12	0.711	0.392	0.376	0.393	0.401	0.503	0.418	0.460
SF13	0.570	0.856	0.629	0.535	0.491	0.535	0.558	0.476
SF14	0.471	0.877	0.603	0.465	0.393	0.515	0.543	0.385
SF15	0.510	0.869	0.607	0.532	0.390	0.545	0.559	0.433
SF16	0.600	0.896	0.568	0.607	0.451	0.532	0.623	0.540
SF17	0.511	0.669	0.885	0.549	0.484	0.526	0.551	0.461
SF18	0.424	0.656	0.911	0.484	0.475	0.437	0.487	0.405
SF19	0.385	0.506	0.865	0.448	0.464	0.423	0.440	0.377
SF20	-0.527	-0.553	-0.487	-0.554	-0.598	-0.890	-0.536	-0.513
SF21	-0.604	-0.578	-0.445	-0.510	-0.418	-0.502	-0.934	-0.507
SF22	-0.659	-0.625	-0.550	-0.572	-0.501	-0.620	-0.945	-0.583
SF23	-0.623	-0.556	-0.468	-0.793	-0.526	-0.595	-0.580	-0.676
SF24	0.337	0.322	0.319	0.461	0.665	0.418	0.276	0.359
SF25	0.382	0.363	0.425	0.566	0.834	0.558	0.379	0.452
SF26	-0.352	-0.373	-0.418	-0.556	-0.732	-0.561	-0.392	-0.465
SF27	-0.559	-0.560	-0.520	-0.772	-0.659	-0.617	-0.620	-0.663
SF28	0.347	0.388	0.393	0.542	0.737	0.473	0.350	0.413
SF29	0.384	0.455	0.458	0.777	0.638	0.466	0.368	0.525
SF30	-0.351	-0.367	-0.390	-0.466	-0.712	-0.474	-0.432	-0.471
SF31	0.411	0.426	0.358	0.863	0.516	0.483	0.392	0.482
SF32	0.534	0.523	0.437	0.619	0.612	0.902	0.548	0.575
SF33	0.522	0.539	0.455	0.607	0.554	0.599	0.550	0.788
SF34	-0.472	-0.358	-0.336	-0.427	-0.336	-0.436	-0.398	-0.726
SF35	0.412	0.309	0.255	0.456	0.376	0.404	0.349	0.736
SF36	-0.534	-0.386	-0.373	-0.644	-0.512	-0.474	-0.452	-0.878

*- Pearson linear correlation

Table 9. Test-retest reliability

SF-36 domains	Mean test	Mean retest	Test-retest reliability *	p value**
Physical functioning	65.22	64.96	0.990	0.749
Role limitations due to physical health	53.51	54.03	0.987	0.742
Role limitations due to emotional problems	52.63	52.81	0.995	0.875
Energy/fatigue	52.74	53.58	0.970	0.130
Emotional well-being	63.75	65.86	0.945	0.131
Social functioning	63.82	63.82	0.987	1.000
Pain	60.92	61.45	0.978	0.630
General health	49.40	49.04	0.972	0.723

*- Pearson Correlation test; **- Paired samples t test

DISCUSSION

The SF 36 is widely used as a reliable, concise and valid questionnaire to measure quality of life in patients with various diseases (17, 18). This study evaluated validity and reliability of SF 36 in Serbian hypertensive patients. To the best of our knowledge, this is the first study to validate SF 36 in Serbian patients with hypertension.

Arterial hypertension is great risk factor for many cardiovascular diseases (19). Hypertensive patients have poorer quality of life and may develop anxiety and depression (20, 21). It was interesting to find out quality of life in Serbian hypertensive patients. Before that, in order to assess quality of life in Serbian hypertensive patients, SF 36 have to be validated. In general, the findings of our study showed that the Serbian version of SF 36 had good agreement with English version of the questionnaire. This is in accordance with previous similar studies (22, 23).

The number of missing items in our study was low (2.54%). This fact indicated good acceptance of SF 36 in Serbian hypertensive patients. Low missing items obtained in our study was similar to other studies in healthy individuals and patients with other diseases (24, 25).

It was an interesting finding that SF-36 domains in our study (Physical functioning, Role limitations due to physical health, Energy/fatigue, Emotional well-being, Social functioning, and Pain) were higher in men than in women. This is similar to the study of de Carvahloet al (2) who assessed the quality of life in hypertensive and normotensive patients and found higher values of all areas of SF in males compared to females.

The Cronbach α was >0.8 for all eight domains of SF 36, indicating very good reliability. In addition, it indicates good internal uniformity. This is in accordance with the study of Zhang et al. ²⁶, where the overall Cronbach α was 0.794.

In our study the SF 36 demonstrated good stability due to the result of retest of correlation between the items ($r > 0.900$) achieved for all eight domains ($p < 0.001$).

The limitation of this study was relatively small number of patients. For that reason, the results of this study should be interpreted with caution to whole population.

CONCLUSION

The findings of our study confirmed cross-cultural validity of SF 36 for hypertensive patients, with good reliability and validity. According to that, we believe the Serbian version of SF 36 is suitable for measurement the quality of life in hypertensive patients.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted in accordance with the Declaration of Helsinki. The protocol of the study was approved by the Ethical committee from the Faculty of Medical Science in Kragujevac (No 01/18-4834). Each patient gave informed consent to participate in the study.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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