

MEASURING HEALTH RELATED QUALITY OF LIFE – METHODS AND TOOLS

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Abstract: Assessing the internal consistency of SF-36v2, Romanian version vs. SF-36v1, and the correlations between SF-36v2 and the decimal scale results. *Materials and methods:* Both SF-36v2-RO and a decimal scale were applied in 928 Romanian subjects, selected through the “snowball method”, for measuring perceived HRQoL. Alpha Cronbach coefficient was used for assessing internal consistency of SF-36v2- RO, by eight domains, MCS and PCS and comparison with SF-36v1 results, and Pearson coefficient for testing correlations. *Results:* Cronbach’s α of the eight areas of SF-36v2RO was \geq then SF-36v1; for PCS and MCS, not assessed for SF-36v1, the values were ≥ 0.700 . Pearson correlation revealed positive, medium and significant correlations between simple scale scores and all SF-36v2 areas, except RE (weaker). *Conclusions:* SF-36v2-RO is an appropriate tool for measuring the impact of various intervention on HRQoL in Romanian patients. When appropriate, a simple decimal self-assessment scale can quickly provide the physician results with indicative value.

INTRODUCTION

The quality of life is defined by the World Health Organization as “the perception of individuals about their position in life, in the cultural context and in the value system in which they live, and in relation to their goals, expectations, standards and concerns.”(1) Health Related Quality of Life (HRQoL) refers to the way health status affects the individual’s ability to function and perceived well-being in the three main areas - physical, mental and social. Considering the data generation essential for the evidence based public health, assessing the results of health interventions implies not only measuring the impact on the frequency and severity of the diseases, but also on the well-being of individuals - the health-related quality of life.(2) Therefore, having access to good instruments like the SF-36 Health Survey, which is also the most utilised for patient reported health outcomes in clinical trials, translated and validated for the Romanian population, is very important for Romanian health professionals.(3) The SF-36 Health Survey has been translated in over 60 languages (including Romanian) as part of the International Quality of Life Assessment (IQOLA) Project in 1995 and it has been tested for validity and reliability in Romanian population for the eight explored areas, but not for the synthetic domains MCS and PCS.(4) Currently, the updated Quality Metrics Incorporated - Optum SF-36v2 version, available since 2012, is being used on a large scale.(5) Although considered a valuable tool, the SF-36’s complexity makes it difficult to apply at certain times and at certain levels of healthcare. Developing an additional simple and easy-to-use instrument for measuring QoL could provide healthcare professionals an alternative solution for rapidly obtaining information about patient’s well-being, with an indicative value.

AIM

Our research focused on three objectives:

- to assess the internal consistency of the SF-36v2 Health Survey standard 2012, Romanian version, by the eight domains and two synthetic components;
- to perform a comparative analysis with the results of the SF-36v1 validation study (1995).
- to explore the possibility of using a simple decimal scale to measure health-related wellbeing status, with indicative value, assessing the correlations between the results of SF-36v2, and the simplified decimal scale.

MATERIALS AND METHODS

To achieve the set objectives, we conducted a cross-sectional study in a group of 928 adult subjects, selected by the “snowball” method from three different geographical regions of Romania. The SF-36v2 Health Survey 2012 questionnaire, Romanian version (SF-36v2-RO) has been used as a data collection tool (self-administered, printed). This study was a part of a wider research, in which a general questionnaire (collecting demographic and socio-economic data and perceived stress level), a *self-assessment scale of the perceived health status*, based on a score range from 0 (the worst) to 10 (the best possible health status) was applied simultaneously with the SF-36v2-RO. The SF-36 v2 Health survey is a multi-dimensional questionnaire with 36 questions exploring 8 domains related to functionality and well-being - Physical functioning (PF), role limitation related to physical health (RP) or caused by emotional issues (RE), vitality/tiredness (VT), mental health (MH), social functioning (SF), bodily pain (BP) and general health (GH).(6) The SF-36 questionnaire is considered to be a general tool “opposable to age-specific, or specific to different conditions or therapeutic interventions”(6), very useful when comparing the relative burden of different diseases and measuring the difference in health benefits obtained by applying various interventions, both in studies addressed to the general population, subpopulations and in clinical trials.(2,7)

In our research, we used the SF-36v2 Health Survey

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standard, Romanian version, provided by QualityMetric Incorporated together with the license for utilization and the document issued by Health Research Associates Incorporated attesting the certified translation of the revised version. The SF-36v2 scores were calculated both by the eight components and by the two synthetic dimensions - the Physical Component score (PCS) and the Mental Component score (MCS), using the score calculation instructions presented in the MOS Core Survey Instrument.(8,9) For each analysed domain, we calculated means and standard deviations. The Kolmogorov-Smirnov test was utilised to assess the distribution normality. Non-symmetric variables were reported as medians. Parametrical (T student test) or non-parametrical tests (Mann-Whitney U-test or Kruskal Wallis test) were used to compare means and medians.

A p value < 0.05 was taken into consideration for statistical significance (two tailed test). The categorical variables were presented as proportions with two decimals and were compared using Chi square test (p <0.05). Although the standard questionnaire SF-36 Health Survey in Romanian was validated for the population of Romania in 1995 (4), we also analysed the internal consistency of each area for the SF-36v2 2012 updated version, using Alpha Cronbach coefficient.

For analysing the correlations between the areas of the SF-36 questionnaire and perceived health scores measured with the decimal scale, considering the unsymmetrical distribution of the scores, we used Pearson coefficient, the results being interpreted as follows:

- values between 0 and 0.3 (0 and -0.3) indicate a weak positive (negative) linear relationship;
- values between 0.3 and 0.7 (-0.3 and -0.7) indicate a moderate positive (negative) linear relationship;
- values between 0.7 and 1.0 (-0.7 and -1.0) indicate a strong positive (negative) linear relationship.

The database was created using Microsoft Office Excel 2007 for Windows, and the statistical analysis was performed using licensed SPSS, version 17.0.

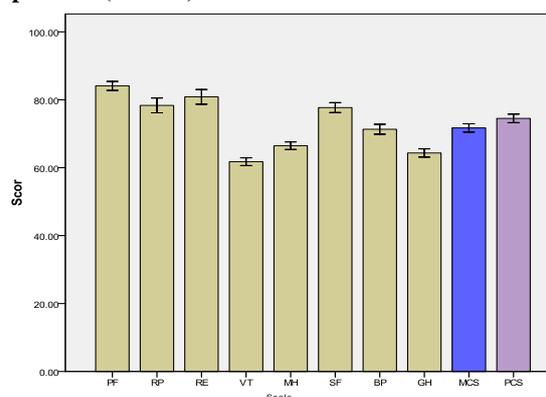
RESULTS

The total study population consisted of a group of 928 subjects from all the geographic regions of Romania., with a mean age of 40.22±13.10 years (min18, max 90 years), out of which 2/3 were women. The structure by other demographic and

socio-economic characteristics and the correlations with the HRQoL scores were described in a previous article.(10)

The SF-36v2-RO scores in overall population are shown in figure no. 1. The lowest value was registered for vitality (61.8±17.69) and the highest for physical functioning (84.1±20.52), but MCS and PCS had closed values (71.7±19.02 and 74.5±19.44 respectively). The highest SF-36 scores were obtained for *Physical functionality* (84.10+/-20.52), while the lowest values were recorded for the *Vitality* domain (61.80+/-17.69) and the *General Health Status* (64.34+/-18.82). The synthetic scores MCS and PCS recorded relatively close values (71.70+/-19.02, 74.50+/-19.44 respectively).

Figure no. 1. Mean SF-36v2-RO scores in overall study population (n = 928)



Details on central trend and dispersion indicators on the eight areas of the questionnaire and for the two synthetic dimensions - PCS (physical component score) and MCS (mental component score) are presented in table no.1.

The scores for all the eight SF-36v2-RO areas and also for MCS and PCS scores had unsymmetrical distributions (p <0.001, Shapiro Wilks Test). The internal consistency of the eight plus two questionnaire areas, measured using the Alpha Cronbach coefficient and compared with the values obtained in the Romanian population during the validation process, is shown in table no. 2.

Table no. 1. Main indicators - SF-36v2 Romanian version

Indicator	PF	RP	RE	VT	MH	SF	BP	GH	MCS	PCS
Mean	84.08	78.34	80.85	61.77	66.48	77.70	71.32	64.34	71.70	74.52
CI - inf lim.	82.76	76.17	78.68	60.63	65.37	76.24	69.86	63.12	70.48	73.27
CI- sup lim.	85.40	80.51	83.03	62.91	67.59	79.16	72.79	65.55	72.93	75.77
Median	95.00	100.00	100.00	65.00	68.00	87.50	77.50	65.00	77.02	80.63
Variance	421.03	1139.0	1134.92	312.84	297.77	513.09	516.64	354.49	361.92	377.91
Std. Dev.	20.519	33.750	33.689	17.687	17.256	22.652	22.730	18.828	19.024	19.440
Min	.00	.00	.00	.00	4.00	.00	.00	.00	9.75	9.38
Max	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Amplitude	100.00	100.00	100.00	100.00	96.00	100.00	100.00	100.00	90.25	90.63

Table no. 2. Internal consistency SF-36v2-RO vs SF-36v1-RO

Tool	PF	RP	RE	VT	MH	SF	BP	GH	MCS	PCS
SF-36v2	0.922	0.905	0.910	0.909	0.888	0.922	0.967	0.846	0.872	0.865
SF-36v1	0.92	0.91	0.86	0.82	0.84	0.73	0.92	0.83	NA	NA

Table no. 3. Correlation coefficients of the perceived health score with SF-36v2 – RO areas

	PF	RP	RE	VT	MH	SF	BP	GH	MCS	PCS
r	.517**	.386**	.277**	.451**	.386**	.426**	.537**	.605**	.459**	.607**
p (2 tails)	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000
N	928	928	928	928	928	928	928	928	928	928

For all the eight domains of the SF-36v2-RO questionnaire, it can be noticed that the Alpha Cronbach coefficient values were at least equal to the ones obtained for SF-36v1-RO in the validation study. Also, for PCS and MCS, for which Alpha Cronbach coefficients were not available in the SF-36v1-RO validation study, values higher than 0.700 (considered the accepted threshold) were obtained, confirming that SF-36v2 Romanian version has an internal consistency which makes it appropriate for use.

Exploring the correlations between the perceived health score, measured with the simple decimal scale and the scores obtained in each of the SF-36v2 areas (Pearson coefficient) revealed that there are positive, medium and significant correlations with all the areas (the strongest for GH and PF), with just one exception - RE area - Emotional functional limitation, where the correlation was weaker (table no. 3)

DISCUSSIONS

Despite the main limitations, caused by the "snowball" selection method, considering the large number and the diversity of demographic and socio-economic characteristics of the subjects, this study provides a number of interesting results on the health-related quality of life in the study population, which may have an indicative value, may generate hypotheses and could be the starting point for other research initiatives.

At the same time, the internal consistency of the SF-36v2 Health Survey Standard questionnaire 2012, Romanian version, demonstrates that it is suitable for use.

The positive, medium and significant correlations (Pearson coefficient) between the decimal scale scores and all the areas with just one exception - RE area, reveal the potential practical implications – when applying a complex and laborious instrument like SF-36v2 - RO is not possible, the simple request to quantify the perceived health status on a scale of 0-10 may give the physician an indicative picture of the patient's well-being, considering the limitations in terms of highlighting issues related to emotional health.

CONCLUSIONS

In our opinion, the results of this study provide additional arguments regarding the value of using the SF-36v2-RO questionnaire as a tool for measuring the impact of various interventions on the health status/well-being of individuals in Romanian patient, and furthermore suggest that when there are no requirements to use complex tools, the application of a simple self-assessment of the health status/well-being using a decimal scale can quickly provide the physician results with indicative value.

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