QUALITY OF LIFE IN HYPERTENSION: THE SF-12 COMPARED TO THE SF-36

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ABSTRACT

Background

The SF-36 has frequently been used to measure health related quality of life (HRQOL) in hypertension. Recently, the SF-12, a shorter form of the SF-36, has been proposed. However, the validity of the SF-12 in hypertension has not yet been assessed.

Objectives

To determine the extent to which the SF-12 provides similar measurements of HRQOL to those of the SF-36 in hypertensive individuals.

Methods

A study assessing the impact of a pharmacy-based intervention program on hypertensive individuals served as background for this study. One hundred and twelve individuals participated in this study. We compared the SF-36 with the SF-12 on item scores and summary measures using intraclass correlation coefficients (ICC), Pearson's correlation coefficients and linear regression.

Results

The concordance between the SF-12 and the SF-36 on both physical (ICC=0.88) and mental (ICC=0.92) component summary scores (PCS and MCS respectively) is high and the relationship is linear and positive. Most of the variance in the SF-36 PCS (R2=0.78) and MCS (R2=0.85) can be explained by their SF-12 counterparts. The SF-12 PCS and MCS are the only significant predictor variables for the corresponding measure of the SF-36.

Conclusions

The SF-12 appears to be a valid alternative to the SF-36 for clinical practice or research purposes when studying hypertensive individuals and their treatment.

Key Words: quality of life; SF-36; SF-12; hypertension.

Quality of life is not a new concept. Many sciences such as sociology, psychology and economics have used it.

In health care research and practice, quality of life has become ever more important since the World Health Organization¹ defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being. The terms "quality of life" and more specifically "health related quality of life" (HRQOL) refer to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions.²

Individuals' perceptions of their quality of life may be affected not only by their illness but also by their therapy. This is the case with individuals who have hypertension. Many patients with mild to moderate hypertension have no symptoms.³ Nevertheless, antihypertensive drug therapies are frequently associated with unpleasant side effects that may have an impact on many aspects pertaining to quality of life.^{4,5}

Many components of quality of life cannot be observed directly. They are usually evaluated according to classical principles of itemmeasurement theory. This theory proposes that there is a true quality of life value, which may be measured indirectly by asking a series of questions known as "items."²

Many instruments are currently available to measure HRQOL. These instruments are sometimes too long for use in research or clinical practice, for example, the Health Insurance Experiment health scales includes 108 items and requires around 45 minutes to be completed.⁶ The length of most available instruments has prompted investigators to develop shorter instruments.⁶

The 36-item Short Form Health Survey (SF-36) has been frequently used to measure quality of life.⁷ The SF-36 is a short form instrument. It has been put together by selecting 36 items from a large series of health status instruments including 245 items employed in the Medical Outcomes Study.⁸ The SF-36 consists of 36 items with one item used to measure health transition and the remaining 35 items, which may be grouped into scales, used to assess eight domains. These are:

- 1. physical functioning;
- 2. role-physical;
- 3. bodily pain;
- 4. general health;
- 5. vitality;
- 6. social functioning;
- 7. role-emotional; and
- 8. mental health.

These eight domains may be further aggregated into two summary measures: the physical component summary measure and the mental component summary measure.⁹ The physical component summary measure includes physical functioning, role-physical, bodily pain and general health scales while the mental component summary measure includes vitality, social functioning, role-emotional and mental health scales.

Recently, a 12-item Short Form Health Survey (SF-12) has been constructed using 12 items from the SF-36 to cover the same eight domains. Compared to the SF-36, the SF-12 has the advantage of being able to be completed in less than two minutes. This is about 10 minutes shorter than for the SF-36.¹⁰ However, the validity of the SF-12 in hypertension has not yet been assessed.

The objective of this study was to determine the extent to which the SF-12 provides similar measurements of quality of life to those of the SF-36 when applied to individuals receiving antihypertensive medication.

More specifically, we sought to determine:

1. The extent to which both the physical and the mental component summary score of the SF-12 (PCS-12 and MCS-12 respectively) are concordant with the physical and mental component summary score of the SF-36 (PCS-36 and MCS-36 respectively);

2. The variance between the PCS-12 and the PCS-36, and the variance between the MCS-12 and the MCS-36; and

3. The ability of the PCS-12 and MCS-12 to predict the PCS-36 and MCS-36 respectively.

METHODS

Study population and data collection

A study assessing a pharmacy-based health intervention program targeting individuals treated for hypertension, served as background for the present study. Details of this background study have been published elsewhere.¹¹ In summary, from October 1998 to January 1999, community pharmacists in the Quebec City area recruited individuals taking a pharmacological treatment for hypertension.

To be eligible, patients had to be between 18 and 80 years of age and be taking at least one antihypertensive drug dispensed as a 30-day regimen. No modification to the antihypertensive drug therapy should have been recorded in the patient file for a 3-month period prior to study enrollment. Pharmacists sent the names of those who accepted to participate in the study to the coordinating center. A research assistant later met the participants at their home. During this first inhome interview, the research assistant obtained a written informed consent from the participant and administered a computer-assisted structured questionnaire so as to obtain personal and health information. Throughout these interviews, quality of life was measured using the French Canadian version of the SF-36,¹² embedded in a long questionnaire.

Analysis

Data was checked and recoded according to the guidelines proposed in the SF-36 Health Survey Manual and Interpretation Guide.¹³ We computed a score for each of the eight scales of both the SF-36 and the SF-12, averaging algebraically the responses for all items in each scale. Finally, we transformed each scale score into a 0 to 100 scale using the formula proposed by Ware et al,¹³ the higher the score, the higher the quality of life.

We calculated Pearson's correlation coefficients between each scale and its component items, and between the general health scale and the seven other scales so as to verify whether all correlations were positive in direction and substantial in magnitude (0.30 or higher), as recommended by Ware.¹³ Using a paired t-test, we also compared the mean score of the PCS-12 with that of the PCS-36, and the mean score of the MCS-12 with that of the MCS-36. We used intraclass correlation coefficients to evaluate the concordance between the PCS-12 and PCS-36, and between the MCS-12 and MCS-36. Following this, we carried out a simple linear regression in order to determine the proportion of variance (R2) in PCS-36 and MCS-36 scores that was explained by the corresponding measures in the SF-12.

Simple linear regression was also used to determine the ability of the PCS-12 and MCS-12 to predict the PCS-36 and MCS-36 respectively. The PCS-36 and MCS-36 were the dependent variables, with the corresponding SF-12 measures used as independent variables. All analyses were performed using the SAS software package (SAS Institute Inc., Cary, North Carolina).

TABLE 1. Characteristics of study participants (N=112)

Characteristic	N (%) ^a
Age (years)	
<60	30 (26.8)
60-70	34 (30.4)
>70	48 (42.9)
Sex	
Male	40 (35.7)
Female	72 (64.3)
Highest level of education completed	
Elementary	29 (25.9)
High school	46 (41.1)
Beyond high school	37 (33.0)
Blood pressure ^b	
Controlled	89 (79.5)
Not controlled	23 (20.5)
3 7	

^a Percentages may not total 100 because of rounding off.

^b Blood pressure was considered controlled for individuals aged less than 60 years when systolic/diastolic blood pressure was lower than 140/90 mm Hg; blood pressure was considered controlled for individuals aged 60 years or more when systolic/diastolic was lower than 160/90 mm Hg.

Scale	Range of Pearson's correlation coefficients with the component items	Pearson's correlation coefficients with the general health scale (95% confidence intervals)
Physical functioning		
SF-12	0.83 - 0.83	0.46(0.30 - 0.59)
SF-36	0.38 - 0.72	0.49 (0.33 – 0.62)
Role-physical		
SF-12	0.88 - 0.88	0.43(0.27 - 0.57)
SF-36	0.67 – 0.83	0.37 (0.20 – 0.52)
Bodily pain		
SF-12	*	0.37(0.20 - 0.52)
SF-36	0.85 - 0.91	0.41 (0.24 – 0.55)
General health		
SF-12	*	1.00
SF-36	0.61 - 0.80	1.00
Vitality		
SF-12	*	0.45(0.29 - 0.59)
SF-36	0.77 - 0.84	0.54 (0.39 - 0.66)
Social functioning		
SF-12	*	0.44(0.28 - 0.58)
SF-36	0.86 - 0.92	0.49 (0.33 - 0.62)
Role-emotional		
SF-12	0.92 - 0.94	0.40(0.23 - 0.55)
SF-36	0.88 - 0.89	0.42 (0.25 – 0.56)
Mental health		
SF-12	0.78 - 0.85	0.27(0.09 - 0.43)
SF-36	0.68 - 0.80	0.45 (0.29 – 0.59)

TABLE 2. Pearson's correlation coefficients between each scale of the SF-12 and of the SF-36 and its component items and between the general health scale and other scales (N=112)

* Pearson's correlation coefficient was not available since this scale is measured by only one item in the SF-12.

RESULTS

All 112 respondents completed the SF-36 questionnaire. Mean age of the study population was 65.6 years (SD \pm 10.2; range 34-80 years) with the majority of respondents (64.3%) being female (Table 1).

Three classes of antihypertensive drugs were used most often: calcium channel blockers (30%), angiotensive converting enzyme inhibitors (22%) and diuretics (20%). There were neither missing nor out-of-range values for any item. In both SF-36 and SF-12 versions, Pearson's coefficients between each scale and its component items, and between the general health scale and the seven remaining scales were all positive in direction and substantial in magnitude (0.30 or higher) (Table 2).

Mean physical and mental component summary scores are different between the SF-12 and the SF-36. On the PCS-12, the 112 participants obtained a mean score lower than that obtained on the PCS-36 (65.9 vs. 69.6, p = 0.01). On the other hand, the mean score obtained on the MCS-12 was higher than that obtained on the MCS-36 (74.2 vs. 72.8, p = 0.03). The concordance between the SF-12 and the SF-36 on both physical (intraclass correlation coefficient = 0.88; 95% confidence intervals (CI): 0.83-0.92) and mental (intraclass correlation coefficient =0.92; 95% CI: 0.89-0.94) components is high.

Can J Clin Pharmacol Vol 11(2) Fall: e232-e238; Nov. 9, 2004 ©2004 Canadian Society for Clinical Pharmacology. All rights reserved. Most of the variance related to the PCS-36 and MCS-36 can be explained by the PCS-12 (R2 = 0.78) and the MCS-12 (R2 = 0.85) respectively (Figures 1-2). Linear regression analysis showed

that the PCS-12 is a good predictor of the PCS-36 (Beta=0.77, p<0.01) as is the MCS-12 for the MCS-36 (Beta=0.86, p<0.01).





LEGEND FIGURE 1 PCS-12 = Physical component summary score of the 12-item Short Form Health Survey PCS-36 = Physical component summary score of the 36-item Short Form Health Survey

FIGURE 2 Scatterplot (\blacklozenge) of and Pearson correlation (—) between the MCS-12 and the MCS-36 among 112 individuals taking pharmacological treatment for hypertension (adjusted R² = 0.85)



LEGEND FIGURE 2

MCS-12 = Mental component summary score of the 12-item Short Form Health Survey MCS-36 = Mental component summary score of the 36-item Short Form Health Survey

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DISCUSSION

Our results suggest that the SF-12 could be a valid alternative to the SF-36. In the first place, difference in mean scores for the PCS and for MCS components was 3.7 and 0.4, respectively.

These differences are rather small and unlikely to be of clinical relevance given it has been suggested that a minimal difference threshold for the SF-36 scales is around five points.¹⁴ Secondly, concordance between PCS-12 and PCS-36, and between MCS-12 and MCS-36 is high. Next, the majority of the variance in the PCS-36 and in the MCS-36 may be explained by the PCS-12 and MCS-12 respectively. Lastly, the MCS-12 is a significant predictor for the MCS-36. Likewise the PCS-12 is significant for the PCS-36.

This concordance between the PCS-12 and PCS-36 and between the MCS-12 and MCS-36 has also been assessed in populations of individuals not having hypertension. Pickard et al.¹⁰ determined the degree to which the physical and mental component summary scores of the SF-12 replicate those of the SF-36 in 161 Canadians who had had a stroke. They observed intraclass correlation coefficients between the PCS-12 and PCS-36, and between the MCS-12 and MCS-36 of 0.96 and 0.95 respectively. These results are similar to those we have reported here.

Variance in PCS-36 explained by the PCS-12 has been studied in United States, Europe and Australia. In the study undertaken by Ware et al⁹ in the US, participants had varying diagnosis and disease severity and more than half of them were less than 65 years of age. The majority were females. Another study conducted by Gandek et al¹⁵ in Europe had as its objective the examination of how well the physical and mental component summary measures of the SF-12 reproduced those of the SF-36. Participants were selected from general populations in Denmark, France. Germany, Italy, the Netherlands, Norway, Spain, Sweden and the United Kingdom. Depending on the country, sample sizes varied from 985 to 6124, proportion of women from 44% to 55% and the mean age of the participants from 41.1 to 47.6 vears. In a further study carried out in Australia by Lim and Fisher¹⁶ the objective was to validate the SF-12 in 1,831 patients hospitalized for heart and stroke conditions. Seventy-four percent of the participants were greater than 65 years of age and

61% were male. In the US study, the PCS-12 explained 91% of the variance of the PCS-36, in European countries, 89% to 92% while in Australia, the PCS-12 explained 82% of the variance in the PCS-36.

For our study population, the variance in the PCS-36 explained by the PCS-12 is slightly lower (78%) than that of the above studies. This difference may be related to the configuration of our study population where the majority of respondents (57%) were more than 65 years old and pharmacologically treated for hypertension. While in the elderly population, physical functioning is an important dimension to measure. in the SF-12, only two items measure it compared to 10 items in the SF-36. Therefore, the SF-12 might not be as good a substitute for the SF-36 in an older population than in a younger adult population. However, although the variance explained in our study is lower than what has been reported elsewhere, it is nevertheless substantial.

Variance in MCS-36 explained by the MCS-12 has also been studied in the above studies. In the US study, the MCS-12 explained 92% of the variance of the MCS-36, while the proportion of MCS-36 variance explained by MCS-12 varied from 89% to 92% in the European study and was 56% in the Australian study.

With regard to the variance in the MCS-36 explained by the MCS-12, our result (85%) is similar to those in both the European and the US studies but higher than that in Australia. The discrepancy between the results reported in the Australian study and those reported in the other studies including ours remains unexplained.

We assumed the responses to SF-12 items abstracted from the SF-36 to be the same as those responses obtained from the SF-12 when administered alone. There is increasing evidence that this assumption may be valid. Lim and Fisher¹⁶ reported no significant differences between physical component and mental component summary mean scores obtained from the SF-12 embedded in the SF-36 and those obtained from the SF-12 when administered alone to an equivalent and independent sample. Similar results have also been reported by Ware et al.⁹

Our study did not aim at assessing the psychometric properties of the SF-12 as a measure of HRQOL in hypertension but was limited to the comparison of the SF-12 measurements to those of the SF-36 when applied to individuals receiving hypertension. As these are generic instruments, they may not be as responsive to a change in treatment as other more specific instruments.¹⁷

In conclusion, in a sample of French Canadians taking antihypertensive medications, we compared summary measures of the SF-36 to those of the shorter SF-12. The concordance between the SF-12 and the SF-36 for both the physical and mental components is high. The greater part of the variance in the SF-36 summary scores can be explained by the variance in the corresponding SF-12 scores. The PCS-12 is a good predictor for the PCS-36 as is the MCS-12 for the MCS-36. Given that the SF-12 is an alternative to the SF-36 and because it can be administered quickly, the SF-12 is an attractive generic instrument to use in clinical practice or research purpose when studying HRQOL among hypertensive individuals taking antihypertensive medications.

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