Validity of the SF-6D index in Brazilian patients with rheumatoid arthritis

A. Gonçalves Campolina¹, A. Bruscato Bortoluzzo², M. Bosi Ferraz¹, R. Mesquita Ciconelli¹

¹Rheumatology Division, School of Medicine, Federal University of São Paulo, Brazil; ²School of Administration and Economics, IBMEC, São Paulo, Brazil.

Abstract Objective

To evaluate the construct validity of the SF-6D among a sample of Brazilian patients with rheumatoid arthritis.

Methods

This was a validation and cross-cultural adaptation study. Preference evaluation instruments were applied: SF-6D, EQ-5D, VAS, TTO and SG. Clinical and sociodemographic parameters were obtained. Descriptive statistics, correlation coefficients and ANOVA were used to analyze the results.

Results

200 patients were evaluated, among whom the non-completion rates were 0.5% for VAS, 1.5% for TTO and 6.5% for SG. The preferences derived from the SF-6D presented the strongest correlations with EQ-5D and HAQ, followed by VAS, TTO and SG, in decreasing order. The correlations with clinical and sociodemographic parameters were, in most cases, small. The preferences obtained with the SF-6D could discriminate patients with different HAQ levels.

Conclusion

The SF-6D is a valid method for measuring preferences in patients with rheumatoid arthritis in a Brazilian context.

Key words

Rheumatoid arthritis, SF-36, SF-6D, utility, preference, quality of life.

Alessandro Gonçalves Campolina, MD, MSc Adriana Bruscato Bortoluzzo, MSc, Professor Marcos Bosi Ferraz, MD, PhD, Professor Rozana Mesquita Ciconelli, MD, PhD, Associated Professor.

Please address correspondence and reprint request to:
Alessandro Gonçalves Campolina,
Disciplina de Reumatologia,
R. Pedro de Toledo 650,
Vila Clementino, São Paulo,
SP Brazil.
E-mail: alecampolina@gmail.com
Received on February 21, 2008; accepted in revised form on September 16, 2008.
© Copyright CLINICAL AND
EXPERIMENTAL RHEUMATOLOGY 2009.

Introduction

Preference measurements are generic quality-of-life assessments that seek to learn the value or usefulness that individuals attribute to a given state of health. These measurements are important for constructing the health indicator known as quality-adjusted life years (QALYs), which has been greatly used as an outcome in economic analyses of cost-utility type (1).

The advantage of using this health indicator is that it makes it possible to simultaneously identify gains due to reductions in morbidity (quality gains) and gains due to reductions in mortality (quantity gains), thus integrating them into a single measurement. At the same time, it makes it possible to sum the benefits obtained through different interventions and under different health conditions (2).

There are basically three well-used techniques for directly measuring preferences: standard gamble (SG); time trade-off (TTO); and visual analogue scale (VAS) (3).

However, direct preference measurements are complex and require lengthy and costly application processes (4). One other practical approach that has often been used consists of questionnaires that make it possible to describe and calculate preferences in relation to different states of health. Among the better-known instruments are the Euro-Qol-5D (EQ-5D), Quality of Well-Being (QWB) and Health Utilities Index (HUI) (5-7).

Over recent years, several authors have described methods for deriving preferences from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) (8) generic quality-of-life instrument, since this questionnaire is widely available, can be applied to more than 200 diseases and has been translated in approximately 40 countries (9). The use of a single instrument for describing and placing a value on states of health would facilitate the analysis of the results, and, by implication, would be less tiring for the individuals evaluated and for the evaluators.

With this aim, Brazier *et al.* restructured the SF-36 into a health index called the Short Form Six-dimension (SF-6D),

from scenarios that were constructed using questions from that questionnaire and measured using the SG and VAS techniques (10). The classification system obtained was thus structured into six domains that were capable of describing 9,000 states of health. Finally, the states of health described by the classification system were mapped out and associated with the direct preference measurements (VAS and SG), by means of two multiple regression methods.

In 2002, Brazier et al. revised the SF-36 into the six-dimensional health state classification. A sample of 249 states defined by the SF-6D was valued by a representative sample of 611 members of the UK general population, using standard gamble technique. An SF-6D health state is defined by selecting one statement from each dimension, starting with physical functioning and ending with vitality. A total of 18,000 states can be defined in this way. All responses to the original SF-36 questionnaire can be assigned to the SF-6D provided the 10 itens used in the six dimensions of the SF-6D have been completed (11).

The possibility of deriving preferences from the SF-36 would open a new field of application for this instrument, thus allowing its use in pharmacoeconomic studies and contributing for the continuous increasing of quantitative measurement of patient status in the regular care of rheumatic diseases, experienced in the last years (12).

Our objective was to evaluate the construct validity of the SF-6D among a sample of Brazilian patients with rheumatoid arthritis.

Material and methods

The sample was selected by convenience at the rheumatology outpatient clinic of the Federal University of São Paulo (Unifesp), between April 2005 and April 2006. Patients with a diagnosis of rheumatoid arthritis in conformity with the criteria of the American College of Rheumatology (ACR) were selected (13). The patients selected were more than 18 years old and less than or equal to 65 years old and were being followed up at this service. They agreed to collaborate with the study and signed

Competing interests: none declared.

a free and informed consent statement. Patients with a diagnosis of or undergoing treatment for psychiatric diseases or fibromyalgia were excluded. These conditions would imply a worse prognosis and compromised quality of life for rheumatoid arthritis patients (14). The data were gathered by applying the instruments in interviews that were conducted by this investigator. After including the participants, the direct preference measurements were obtained first, in a random manner (SG, TTO and VAS). Next, the questionnaires were applied (SF-36, HAQ [Health Assessment Questionnaire] and EQ-5D), and finally the clinical and demographic evaluations were performed using a structured questionnaire.

Instruments for evaluating the health status

Visual analogue scale (VAS)

To directly assess preferences in relation to states of health, the VAS measurement was used to create three initial hypothetical scenarios.

Each of the scenarios described a different state of health involving quality-of-life levels: poor, moderate and good. The respondents were asked to indicate how many times worse a given state of health (scenario) was, in relation to another, on a scale from 0 to 1. On this scale, the value 1 corresponded to the best state of health possible and 0 to the worst possible.

After anchoring the hypothetical scenarios on the scale, the respondents were asked to think about their own state of health at that moment, and to mark a point on this same scale that would correspond to the preference value for their own state of health (3).

Time trade-off (TTO)

Using the TTO technique, the respondents were asked to choose between or be indifferent to two alternatives for their state of health, if faced with a hypothetical health intervention.

In one alternative, the respondents were offered maintenance of their state of health for the rest of their lives. In the other alternative, they were offered a better state of health for a shorter period of time (for example, good quality

of life for ten years, followed immediate death). Based on the responses, the shorter period of time was varied until the point of indifference was determined. This would be the shortest time with the maximum quality of life possible that would make the individual abandon his or her intermediate health condition and undergo the possible therapeutic procedure.

This point, or the indifference time, was the TTO for the respondent's current state of health, on a scale from 0 (signifying immediate death) to 1 (signifying the best state of health for the remainder of his or her life (3).

For this study, which was based on 2003 data from DATASUS Brazilian Life Table, we assumed a life expectancy at birth of 73 years for females and 65 years for males. Likewise, we assumed a life expectancy at the age of 60 years of 20 years for females and 16 years for males (15).

The technique was then applied in "ping-pong" format, with visual aids available.

Standard gamble (SG)

In the SG technique, the respondents were asked to choose between two alternatives offered, if faced with a hypothetical health intervention.

In one alternative, the respondents were offered an intermediate state of health, i.e. there would be certainty regarding their state of health. In the other alternative, the respondents were offered two states of health under conditions of uncertainty. One of these would be the best possible, for example perfect health (with a probability p that it might occur if the patient underwent the therapeutic procedure), while the other would be the worst scenario possible, for example the patient's own death (with a probability of 1-p). Based on the responses given, the probability p was varied until the point of indifference was determined (p^*) . This would be a point at which the individual would be indifferent regarding undergoing a procedure capable of bringing uncertain results, or remaining in a situation of certainty (in this case, the individual's current state of health). This point of indifference (p^*) was the respondent's SG for the intermediate state of health presented initially, on a scale from 0 (worst state) to 1 (best health) (3).

The "ping-pong" format was used for applying the technique, with visual aids available.

The short form six-dimension (SF-6D) The indirect preference measurement obtained using the SF-6D was derived in accordance with the algorithm described by Brazier *et al*, from the items of the SF-36 that make up the SF-6D questionnaire.

To develop the SF-6D, the SF-36 questionnaire was first reduced by combining two domains (physical limitations and emotional limitations) and eliminating the domain of general state of health. The classification system obtained was thus structured into six domains that were capable of describing 9,000 states of health. The models obtained were capable of predicting 68% of the preference measurement variation according to the VAS (SF-6D VAS algorithm) and 49.5% of the measurements according to the SG (SF-6D SG algorithm) (10). In this study, the SF-36 questionnaire was applied by face-to-face interview, based on the version that has been cross-cultural adapted and validated for Brazil (16). A Portuguese version was developed and evaluated in Brazilian patients with rheumatoid arthritis. Only two questions were modified in the cross-cultural adaptation phase. It took an average of 7 minutes to complete the questionnaire. The evaluation of the SF-36 was clinically satisfactory and statistically significant for the 8 scales with Pearson's correlation coefficient ranging from 0.4426 to 0.8468 for the test-retest reliability and from 0.5542 to 0.8101 for the interobserver reliability. The evaluation of the construct validity was also satisfactory and statistically significant when the components physical functioning, role-physical, pain and general health status were correlated with clinical parameters such as number of painful and swollen joints, pain and global disease assessment by patient and physician. For similar dimension scales, the correlation coefficients between SF-36 and HAQ, Arthritis Impact Measurement Scale (AIM-2) and Nottingham Health Profile (NHP) were clinically important and statistically significant (*p*<0.01) (16).

We used the two algorithms from Brazier *et al.*, to obtain the SF-6D VAS and SF-6D SG, mapping the items from the version of the SF-36 that has been cross-cultural adapted and validated for Brazil. The SF-6D questionnaire adapted for Brazilian context is presented in the Appendix.

Health Assessment Questionnaire (HAQ)

The Health Assessment Questionnaire (HAQ) is a specific quality-of-life instrument that was developed to enable evaluation of state-of-health parameters in clinical trials involving patients with rheumatoid arthritis. This scale has a total of 20 items grouped into eight categories, with two or three questions in each, according to the activities of daily living that the category refers to. The score for each category ranges from 0 (no difficulty) to 3 (incapacity to perform a given activity). The final score for the instrument is obtained from the category scores, and it also ranges from 0 to 3 (17).

Euroqol-5D (EQ-5D)

Euroqol-5D (EQ-5D) is an instrument developed in Europe for indirect preference measurements relating to states of health. This tool is composed of five assessment domains that make it possible to calculate a health index, with a scale ranging from -0.594 to 1.000, and a visual analogue scale of 20 cm that ranges from 0 (worst state of health imaginable) to 100 (best state of health imaginable) (7). The EQ-5D score was obtained through York tariffs for an English population (18).

Clinical and demographic questionnaire

To collect clinical and demographic data, a structured questionnaire was used, which was applied directly to the patients by means of oral interviews. After applying the questionnaires and finishing the interviews, the patients were referred for normal appointments in the rheumatoid arthritis outpatient clinic.

Statistical analysis

The construct validity of the algorithms was tested by comparing the scores obtained through the indirect preference measurement used in this study (the EQ-5D) and through the direct preference measurements (VAS, TTO and SG), and the sociodemographic and clinical parameters for the disease.

As a validation hypothesis, taking into consideration the closeness of the construct, we expected to obtain correlations for SF-6D that were at least good in relation to EQ-5D and HAQ, low to moderate in relation to the direct preference measurements (VAS, TTO and SG) and nonexistent to low

in relation to the sociodemographic parameters.

The analyses were performed using the SPSS® statistical package, version 8.0 for Windows®. Descriptive statistics were used to characterize the sample. Analysis of variance (ANOVA) was used to compare the means.

The correlations between the preferences obtained with SF-6D, those obtained using the SG, TTO, VAS and EQ-5D techniques and those with HAQ, the sociodemographic and clinical parameters of the sample were determined using the Pearson correlation coefficient.

P<0.05 ($\alpha=5\%$) was taken to be sta-

Table I. Sociodemographic characteristics of the patients with rheumatoid arthritis.

	Mean / standard deviation or n %		
Age (years)			
n	200		
Mean / standard deviation	49.22 / 10.0		
Minimum - Maximum	20.00 - 65.00		
Sex (n %)			
Female	156 / 78.0		
Male	44 / 22.0		
Schooling (years)			
n	200		
Mean / standard deviation	6.38 / 4.1		
Minimum - Maximum	0 - 15.00		
Per capita family income (R\$)			
n	200		
Mean / standard deviation	366.88 / 367.60		
Minimum - Maximum	33.00 - 3000.00		
Number of people in the household			
n	200		
Mean / standard deviation	3.80 / 1.8		
Minimum - Maximum	1.00 - 11.00		
Self-reported color (n %)			
White	82 / 41.0		
Brown	79 / 39.5		
Black	33 / 16.5		
Yellow	6 / 3.0		
Marital status (n %)			
Single	43 / 21.5		
Married	113 / 56.5		
Stable partnership	12 / 6.0		
Divorced	24 / 12.0		
Widowed	8 / 4.0		
Situation in the work market (n %)			
Inactive			
Retired	51 / 25.5		
Unemployed	38 / 19.0		
On sickness benefit	35 / 17.5		
Active			
Working in the formal market	59 / 29.5		
Working in the informal market	6 / 3.0		
Self-employed	11 / 5.5		

Table II. Clinical characteristics and measurements of the state of health of the patients with rheumatoid arthritis.

	Mean / standard deviation or n $\%$		
Length of time with disease (year)			
n M	200		
Mean / standard deviation Minimum - Maximum	11.16 / 8.4 1.00 – 42.00		
Functional class ¹ (n %)	1.00 42.00		
I	66 / 33.0		
II	77 / 38.5		
III	54 / 27.0		
IV	3 / 1.5		
Number of painful joints	200		
n Mean / standard deviation	200 5.56 / 6.9		
Minimum - Maximum	0 – 42.00		
Number of edematous joints			
n	200		
Mean / standard deviation	7.35 / 6.7		
Minimum - Maximum	0 - 32.00		
HAQ ²			
n Na da la	199		
Mean / standard deviation Minimum - Maximum	1.02 / 0.7 0 – 2.63		
	0 2.03		
VAS for pain ³	200		
Mean / standard deviation	41.42 / 25.1		
Minimum - Maximum	0 – 100.0		
SF-6D SG ⁴			
n M	200		
Mean / standard deviation Minimum - Maximum	0.80 / 0.1 0.47 – 0.99		
	0.47 – 0.99		
SF-6D VAS ⁴	200		
Mean / standard deviation	0.45 / 0.2		
Minimum - Maximum	0.12 - 0.92		
EQ-5D ⁵			
n	200		
Mean / standard deviation Minimum - Maximum	0.65 / 0.3		
	- 0.48 / 1.00		
TTO ⁶	197		
n Mean / standard deviation	0.86		
Minimum – Maximum	0 – 1.00		
SG^7			
n	188		
Mean / standard deviation	0.76 / 0.3		
Minimum – Maximum	0.01 -1.00		

¹Class I-Completely capable of performing activities of daily living (self-care, vocational and non-vocational activities); Class II-Capable of performing usual self-care and vocational activities, but presenting limitations for non-vocational activities); Class III-Capable of carrying out usual self-care activities, but presenting limitations for vocational and non-vocational activities; Class IV-Limited ability to perform usual self-care, vocational and non-vocational activities; ²HAQ: Health Assessment Questionnaire, in which 0=no incapacity and 3=maximum incapacity; ³VAS for pain: visual analogue scale for pain (obtained from HAQ), in which 0=no pain and 100=intense pain; ⁴Brazier J *et al.* J *Clin Epidemiol* 1998; 51(11): 1115-1128; ⁵EQ-5D: The Euroqol index of health-related quality of life. °TTO: Time Trade-off. ⁷SG: Standard Gamble.

tistically significant. The correlations were considered to be small if they were between 0 and ±0.25; moderate if

between ± 0.26 and ± 0.50 ; good if between ± 0.51 and ± 0.75 ; and very good if they were >0.75 or <-0.75 (19).

Results

Two hundred patients who fulfilled the ACR criteria for rheumatoid arthritis and who agreed to take part in the study were evaluated. Among these 200 individuals, all of them completed the SF-36 and EQ-5D, 199 HAQ, 199 VAS, 197 TTO and 188 SG.

Table I presents the study participants' sociodemographic characteristics. The participants' mean age was 49.22 years (SD=10.0), and 78.0% of them were female. Most of the participants said that they had white skin color (41.0%) or brown skin color (56.5%). The majority were married (56.5%) and not active in the work market (62.0%). The mean length of schooling was 6.38 years (SD=4.1); mean family income per month was R\$366.88 (SD=367.60) or \$530.68 US dollars (SD=398.8) and mean number of inhabitants per home was 3.80 (SD=1.8).

Table II presents the clinical characteristics and the health status measures of the 200 patients with rheumatoid arthritis. The mean length of time with the disease was 11.16 years (SD=8.4), and the majority of the participants were in functional classes I, II and III (33.0%, 38.5% and 27.0%, respectively) and presented mean HAQ of 1.02. 74.5% of the individuals did not present any extra-articular manifestations, while 73.0% presented joint deformities. At the time of the evaluation, the mean number of painful joints was 5.56 and the mean number of swelling joints was 7.35. The participants' mean self-assessed pain and general state of health using VAS was 41.42 (SD=25.1) and 67.30 (SD=20.7), considering 0 no pain and 100 best health state, respectively. The means for the preference measurements obtained using the SF-6D VAS was lower than the SF-6D SG (0.45 and 0.80, respectively).

The means for the preference measurements obtained directly using the VAS, TTO and SG techniques were respectively 0.63 (SD=0.2), 0.86 (SD=0.2) and 0.76 (SD=0.3).

Table III presents the correlation coefficients between the SF-6D and the other measurements used in this study (HAQ, VAS, TTO, SG and EQ-5D). We noted that the strongest correlations

Table III. Pearson correlation coefficients between direct and indirect preference measurements among the patients with rheumatoid arthritis.

	SF-6D VAS	SF-6D SG	EQ-5D	VAS	TTO	SG
SF-6D VAS ¹	1.00					
SF-6D SG1	0.83**	1.00				
$EQ-5D^2$	0.59**	0.62**	1.00			
VAS^3	0.47**	0.42**	0.49**	1.00		
TTO^4	0.19**	0.20**	0.19**	0.22**	1.00	
SG ⁵	0.12	0.20**	0.11	0.06	0.34**	1.00
HAQ ⁶	- 0.68**	- 0.54**	- 0.51**	- 0.45**	- 0.19**	-0.08

^{**}p<0.01

Table IV. Pearson correlation coefficients between SF-6D and the sociodemographic and clinical parameters of the patients with rheumatoid arthritis.

	SF-6D VAS ¹	SF-6D SG ¹
Age	0.027	0.003
Schooling	0.176*	0.170*
Per capita income	0.215**	0.194**
Length of time with disease	-0.015	-0.029
Number of comorbidities	-0.117	-0.100
Functional class	-0.492**	-0.394**
Number of edematous joints	-0.282**	-0.125
Number of painful joints	-0.382**	-0.251**

¹ Brazier J et al. J Clin Epidemiol 1998; 51(11): 1115-1128.

Table V. Preference measurements derived using the SF-6D, according to the HAQ level of the patients with rheumatoid arthritis.

	HAQ^2 (0 – 1)	HAQ^2 (1.01 – 2)	HAQ^2 (2.01 – 3)	p^*
Brazier EVA ¹	0.56	0.34	0.28	< 0.01
Brazier SG ¹	0.85	0.75	0.72	< 0.01

^{*}ANOVA

were obtained in relation to EQ-5D and HAQ, followed by VAS, TTO and SG, in decreasing order.

Table IV presents the preference correlations obtained between SF-6D and the sociodemographic and clinical parameters for the disease. In a general manner, the preference measurements correlated with the sociodemographic and clinical parameters of the sample, with the exception of age and length of time with the disease. The correlations obtained were mostly small. The correlations with the functional class of the rheumatoid arthritis were moderate.

Table V shows that preference measurements derived using the SF-6D presents discriminative validity, according to the HAQ level of the patients with rheumatoid arthritis.

Discussion

The focus of the analyses in this study was a comparison between the SF-6D and other preference measurement methods.

The results have revealed variation between the means obtained from direct preference measurements, such that the means for the VAS were lower than

those for the TTO and SG. In the same way, SF-6D derived VAS presented lower scores than SF-6D derived SG. This could be explained by personal attitudes toward risk and sacrifice. TTO and SG introduce an additional dimension to rating scales by offering a choice between 2 alternatives (sacrifice). In addition, SG also incorporates tolerance to risk since one of the alternatives is always uncertain with respect to possible outcomes (20). As people tend to avoid risk, valuations with techniques based on scenarios of certainty (VAS) would state lower values than the ones valuated with SG techniques, which are uncertainty-based.

The results also showed variation between preference measurements (with VAS, TTO, SG and EQ-5D) and the SF-6D, according to other studies (20, 21, 22).

The present study showed a notable strength of correlation between the preferences obtained using the SF-6D and the HAQ, a specific index for this disease that has been widely validated (17, 23). This could be explained by the fact that both instruments are questionnaire based, but it also suggest a clinical validity of the SF-6D (there were also correlations with the functional class and the number of inflamed and edematous joints; SF-6D presents discriminative validity, according to the HAQ level, as presented in Table 5). In this respect, Revicki and Kaplan suggested that the high concordance between generic measurements of quality of life, such as SF-36, and specific measurements of quality of life for certain diseases, is partially due to overlapping of the questions present in these instruments (1).

It should be noted that the correlations with the direct measurements were, at best, moderate, for the VAS technique, with which the highest correlations were presented. The TTO and SG techniques showed low correlations with the SF-6D scores. However, good correlations were obtained in comparisons with the EQ-5D. This pattern draws attention to the fact emphasized by Prieto and Sacristán: that preference measurements obtained via questionnaires present characteristics that

¹ Brazier J *et al. J Clin Epidemiol* 1998; 51(11): 1115-1128; ² EQ-5D: The Euroqol index of health-related quality of life; ³ VAS: Visual analogue scale; ⁴ TTO: Time trade-off; ⁵ SG: Standard gamble; ⁶HAQ: Health Assessment Questionnaire, in which 0 = no incapacity and 3 = maximum incapacity.

^{*}p<0.05; **p<0.01.

¹Brazier J *et al. J Clin Epidemiol* 1998; 51(11): 1115-1128; ²HAQ: Health Assessment Questionnaire, in which 0=no incapacity and 3=maximum incapacity; level 1: scores ranging from 0 to 1, level 2: scores ranging from 1.01 to 2, level 3: scores ranging from 2.01 to 3.

are closer to health profile summary indices than to measurements that reflect the social preference for states of health (24). Another explanation is that good correlation with EQ-5D would be expected because both instruments are based on societal valuations, while SG, TTO and VAS are patient estimated valuations.

From the analysis performed, the sample's schooling and per capita income influenced the measurements made using the SF-6D. This is a significant point with regard to using this tool among populations of low social and educational level, although the correlations with these sociodemographic parameters, in the present study, were low. Similarly, Marra *et al.* have also shown educational level to be associated with lower SF-6D utility scores (25).

It is important to consider that in 2002, Brazier reported a method that improves upon the 2 we evaluated (11). In this new approach, a representative sample of the UK general population was evaluated. Unlike the previous study, the respondents were recruited from a range of backgrounds including health professionals, health service managers and administrators, professional and technical staff of the University of Sheffield Medical School in the UK, and students from health economics and medical undergraduate courses. Some other differences must be stated. In the 1998 study, Brazier et al. valuations were made using VAS and SG questionnaires techniques, while in the 2002 study, SG valuations were applied by face-to-face interview. The number of health states described are quite different: 9,000 in the previous study and 18,000 in the later study. Differences in the scoring range are also evident: the unadjusted VAS mean health state values range from 0.163 to 0.859, the SG values are less dispersed along the 0 to 1 scale, with a range of 0.433 to 0.962. The boundaries of the updated SF-6D utility scores are from 0.30 to 1.00, with a score of 1.00 being indicative of "full health". In the 2002 study, ability to predict mean health state values was demonstrated by 10 different models and the best mean model achieved an adjusted R² of 0.58.

We choose the original methods in this preliminary work because they were reported in the open literature and the reader can use publicly available information to replicate these calculations. Although the updated method is available free of charge only for noncommercial applications, it has been widely used. Therefore, a new study has been prepared using this method in the same population and also evaluating other SF-36 preference derivation algorithms, according to Nichol's, Fryback's, Shmueli's and Lundberg's methods (26-29).

Some other limitations of this study need to be highlighted. Firstly, a sample selected from a referral center may not be a good representation of the whole number of patients with rheumatoid arthritis. Secondly, in this study we did not evaluate the responsiveness of the SF-6D to changes in the clinical condition of the disease over the course of time. Nevertheless, the study by Kaplan *et al.* revealed that this instrument showed good responsiveness (30). Lastly, the only indirect preference measurement used in our study was the EQ-5D.

Conclusions

The SF-6D was found to be a valid method for measuring preferences among patients with rheumatoid arthritis, in our environment.

References

- REVICKI D, KAPLAN R: Relationship between psychometric and utility-based approaches to the measurement of health-related quality of life. *Qual Life Res* 1993; 2: 477-87.
- TORRANCE GW: Designing and Conducting Cost-Utility Analyses. In: SPILKER B (Ed.) Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia (USA): Lippincott-Raven Publishers: 1996: 1105-11.
- BENNETT KJ, TORRANCE GW: Measuring Health State Preferences and Utilities: Rating Scale, Time Trade-Off, and Standard Gamble Techniques. In: SPILKER B (Ed.) Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia (USA): Lippincott-Raven Publishers, 1996: 253-65.
- TORRANCE GW, FURLONG W, FEENY D: Health utility estimation. Expert Rev Pharmacoeconomics Outcomes Res 2002; 2: 99-108.
- 5. FEENY DH, TORRANCE GW, FURLONG WJ: Health Utilities Index. *In*: SPILKER B (Ed.) *Quality of Life and Paharmacoeconom-*

- ics in Clinical Trials. Philadelphia (USA): Lippincott-Raven Publishers; 1996: 239-50.
- KAPLAN RM, ANDERSON JP: The General Health Policy Model: an integrated approach. In: SPILKER B (Ed.) Quality of Life and Paharmacoeconomics in Clinical Trials.
 Philadelphia(USA): Lippincott-Raven Publishers; 1996: 309-22.
- KIND P: The EuroQol instrument: an index of health-related quality of life. In: SPILKER B, (Ed.) Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia (USA): Lippincott-Raven Publishers; 1996: 191-201
- WARE JE, SHERBOURNE CD: The MOS 36item short health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992; 30: 473-83.
- GARRAT AM, SCHMIDT L, MACKINTOSH A et al.: Quality of life measurement: bibliographic study of patient assessed health outcome measures. BMJ 2002; 324: 1417-21.
- BRAZIER J, USHERWOOD T, HARPER R et al.: Deriving a preference-based single index from the UK SF-36 Health Survey. J Clin Epidemiol 1998; 51: 1115-28.
- BRAZIER J, ROBERTS J, DEVERILL M: The estimation of a preference-based measure of health from the SF-36. *J Health Econ* 2002; 21: 271-92.
- 12. PINCUS T, MACLEAN R, YASICI Y et al.: Quantitative measurement of patient status in the regular care of patients with rheumatic diseases over 25 years as a continuous quality improvement activity rather than traditional research. Clin Exp Rheumatol 2007; 25 (Suppl. 47): 69-81.
- ARNETT FC, EDWORTHY SM, BLOCH DA et al.: The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988; 31: 315-24.
- 14. WOLFE F, MICHAUD K: Severe rheumatoid arthritis (RA), worse outcomes, comorbid illness, and sociodemographic disadvantage characterize RA patients with fibromyalgia. *J Rheumatol* 2004; 31: 695-700.
- DATASUS: Banco de dados sobre informações em saúde [database on the Internet]. Brasil: Ministério da Saúde; 2005 [cited 2005 Mar 3]. Available from: http://tabnet.datasus.gov.br/cgi/idb2004/a11.htm.
- 16. CICONELLI RM, FERRAZ MB, SANTOS W et al.: Tradução para a língua portuguesa e validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). Rev Bras Reumatol 1999; 39: 143-50.
- WOLFE F, KLEINHEKSEL SM, CATHEY MA et al.: The clinical value of the Stanford Health Assessment Questionnaire functional disability index in patients with rheumatoid arthritis. J Rheumatol 1988: 15: 1480-8.
- 18. DOLAN P: Modeling valuations for Euroqol Health States. *Med Care* 1997; 35: 1095-108.
- DAWSON B, TRAPP RG: Temas de pesquisa sobre relações entre variáveis. *In: Bioestatística básica e clínica* (Terceira *Ed.*). DAWSON B, TRAPP RG (Eds.) Rio de Janeiro (Brasil): McGraw-Hill Interamericana do Brasil Ltda; 2003: 163-86.
- 20. SUAREZ-ALMAZOR ME, CONNER-SPADY B: Rating of arthritis health states by patients,

Validity of Brazilian SF-6D / A. Gonçalves Campolina et al.

- physicians, and the general public. Implications for cost-utility analyses. *J Rhematol* 2001; 28: 648-56.
- KOPEC JA, WILLISON KD: A comparative review of four preference-weighted measures of health-related quality of life. *J Clin Epidemiol* 2003; 56: 317-25.
- 22. MARRA CA, WOOLCOTT JC, KOPEC JA *et al.*: A comparison of generic, indirect utility measures (the HUI2, HUI3, SF-6D, and the EQ-5D) and disease-specific instruments (the RAQol and the HAQ) in rheumatoid arthritis. *Soc Sci Med* 2005; 60: 1571-82.
- 23. SAHIN F, KOTEVOGLU N, TASPINAR S et al.: Comparison of functional disability scales and their relevance to radiological progression in patients with rheumatoid arthritis in

- remission. Clin Exp Rheumatol 2006; 24: 540-5.
- PRIETO L, SACRISTÁN JA: Problems and solutions in calculating quality-adjusted life years (QALY's). Health Qual Life Outcomes 2003; 1: 80.
- 25. MARRA C, LYND LD, ESDAILE JM et al.: The impact of low income on self-reported health outcomes in patients with rheumatoid arthritis within a publicly funded health-care environment. Rheumatology (Oxford) 2004; 43: 1390-7.
- 26. NICHOL MB, SENGUPTA N, GLOBE DR: Evaluating quality-adjusted life years: estimation of the health utility index (HUI2) from the SF-36. *Med Decis Making* 2001; 21: 105-12
- 27. FRYBACK DG, LAWRENCE WF, MARTIN PA et al.: Predicting quality of well-being scores from the SF-36: results from the Beaver Dam Health Outcomes Study. Med Decis Making 1997; 17:1-9.
- 28. SHMUELI A: Subjective health status and health values in the general population. *Med Decis Making* 2001; 21: 105-12.
- LUNDBERG L, JOHANNESSON M, ISACSON DG et al.: The relationship between healthstate utilities and the SF-12 in a general population. Med Decis Making 1999; 19: 128-40.
- 30. KAPLAN RM, GROESSL EJ, SENGUPTA N *et al.*: Comparison of measured utility scores and imputed scores from the SF-36 in patients with rheumatoid arthritis. *Med Care* 2005; 43: 79-87.

Appendix

SF-6D adaptado para língua portuguesa - Brasil

Instruções: Estas informações nos manterão informados de como você se sente e quanto você é capaz de fazer suas atividades de vida diária. Por favor, marque para cada questão o item que mais se aproxima da maneira como vocês se sente. Se estiver em dúvida de como responder, por favor tente responder o melhor que puder.

Capacidade Funcional

- 1. Devido a sua saúde você<u>não</u> teria dificuldades em fazer <u>atividades vigorosas</u> que exigem muito esforço tais como correr, levantar objetos pesados, participar em esportes árduos
- 2. Devido a sua saúde você teria dificuldades em fazer <u>atividades vigorosas</u> que exigem muito esforço tais como correr, levantar objetos pesados, participar em esportes árduos
- 3. Devido a sua saúde você teria dificuldades para subir <u>vários</u> lances de escada ou andar <u>mais de 1 quilômetro</u>
- 4. Devido a sua saúde você teria dificuldades para subir <u>um lance de escada</u> ou andar <u>vários quarteirões</u>
- 5. Devido a sua saúde você teria dificuldades para andar <u>um</u> quarteirão
- 6. Devido a sua saúde você teria dificuldades para tomar banho ou vestir-se

Limitação Global

- 1. Você <u>não</u> teve problemas com seu trabalho ou alguma atividade diária regular como conseqüência de sua saúde física ou problemas emocionais
- Você teve problemas com seu trabalho ou alguma atividade diária regular como conseqüência de sua saúde física ou problemas emocionais

Aspectos Sociais

- 1. Sua saúde física ou problemas emocionais $\underline{n}\underline{\tilde{a}o}$ interferiram nas suas atividades sociais normais
- 2. Sua saúde física ou problemas emocionais interferiram <u>ligeiramente</u> nas suas atividades sociais normais
- 3. Sua saúde física ou problemas emocionais interferiram <u>moderadamente</u> nas suas atividades sociais normais
- 4. Sua saúde física ou problemas emocionais interferiram <u>bastante</u> nas suas atividades sociais normais
- 5. Sua saúde física ou problemas emocionais interferiram <u>extre-mamente</u> nas suas atividades sociais normais

Dor

- 1. Você não tem dor no corpo
- 2. Você tem dor no corpo muito leve
- 3. Você tem dor no corpo leve
- 4. Você tem dor no corpo moderada
- 5. Você tem dor no corpo grave
- 6. Você tem dor no corpo muito grave

Saúde Mental

- 1. Você tem se sentido uma pessoa muito nervosa ou desanimada e abatida uma <u>pequena parte</u> ou <u>nenhuma</u> parte do tempo
- 2. Você tem se sentido uma pessoa muito nervosa ou desanimada e abatida <u>alguma parte</u> do tempo
- 3. Você tem se sentido uma pessoa muito nervosa ou desanimada e abatida <u>uma boa parte</u> do tempo
- Você tem se sentido um pessoa muito nervosa ou desanimada e abatida <u>a maior parte</u> do tempo
- 5. Você tem se sentido uma pessoa muito nervosa ou desanimada e abatida todo tempo

Vitalidade

- 1. Você tem se sentido esgotado ou cansado uma <u>pequena parte</u> ou <u>nenhuma parte</u> do tempo
- 2. Você tem se sentido esgotado ou cansado <u>alguma parte</u> do tempo
- 3. Você tem se sentido esgotado ou cansado <u>uma boa parte</u> do tempo
- 4. Você tem se sentido esgotado ou cansado <u>a maior parte</u> do tempo
- 5. Você tem se sentido esgotado ou cansado todo tempo