

CLINICAL STUDY

Is the Arthritis Impact Measurement Scales 2 a good tool to assess quality of life in Slovak patients with rheumatoid arthritis?

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Abstract: *Objectives:* The aim of this study is to evaluate the measurement properties of the Arthritis Impact Measurement Scales 2 (AIMS2) in Slovak patients with rheumatoid arthritis (RA).

Background: RA impacts all aspects of life quality (QoL). Many instruments for QoL in RA patients frequently assess only biological aspects. The AIMS2 instrument covers physical, emotional and social QoL and it is widely and successfully used as an indicator of the outcomes of care for arthritis patients, but not in Slovak RA patients.

Methods: After translation 178 patients with RA were asked to complete the AIMS2, Visual Analogue Scale for pain – VAS, Health Assessment Questionnaire Disability Index – HAQ-DI, Beck Anxiety Inventory – BAI and Zung Self-Rating Depression Scale – SDS to analyse the validity of the Slovak-AIMS2. Pearson correlations, one-way analysis of variance (ANOVA), t-test, and principal component analysis were used to test validity of AIMS2. The reliability was assessed by internal consistency, as estimated by Cronbach's alpha coefficients, and using the test-retest procedure.

Results: The Cronbach's alpha coefficients for AIMS2 scales ranged from 0.78 to 0.94, the test-retest reliability was significant ($p < 0.05$), ranging from 0.61 to 0.99. The correlations between most of the Slovak-AIMS2 scales and HAQ-DI, VAS, BAI and SDS were statistically significant ($p < 0.05$). The principal component analysis identified three factor models explaining 66.82 % of the variance.

Conclusions: The results showed that Slovak-AIMS2 is culturally appropriate, valid and reliable for measuring the health status in adult RA patients (Tab. 6, Ref. 20). Full Text in PDF www.elis.sk.

Key words: Arthritis Impact Measurement Scales 2, quality of life in Slovak patients, rheumatoid arthritis.

Rheumatoid arthritis (RA) is a complex inflammatory disease which affects 0.5–1 % of the adult population in Slovakia (1). RA impacts all aspects of HRQL; it is a major cause of pain and functional impairment that can result in psychological, social and economic problems (1). The earliest measurements such as revised Steinbrocker criteria for global functional status (2), the Stanford Health Assessment Questionnaire Disability Index (3) are widely accepted and extensively used in RA patients and provide a quick and simple method for classifying functional capacity, but they neither include psychosocial aspects of well-being nor patient own perceptions of disease impact. The second version of the Arthritis Impact Measurement Scales (AIMS2) (4) is the revised and expanded version of the Arthritis Impact Measurement Scales. It is a multidimensional, disease-specific, self-

administered questionnaire designed to measure the health status outcomes in arthritis patients. It contains 78 items, out of which the first 57 are grouped into 12 scales: mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks, social activity, support from family and friends, arthritis pain, work, level of tension, and mood. Further 44 questions cover satisfaction with health, the impact of the patient's arthritis on his or her functions, the patient's priorities for improvement, general perception of current and future health, overall impact of arthritis, type and duration of patient's arthritis, using medication, patient's co-morbidity, and demographic data. The 12 scales can be subdivided into five components: Physical (e.g. mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks), Symptoms (arthritis pain), Role (work), Social Interaction (social activity and social support), and Affect (tension and mood). AIMS2 takes approximately 20–25 minutes to complete. Scores for items in each of the 12 scales are then added and converted to a range of 0 to 10 (0 represented good health status, 10 poor health status), using simple standardization formulae for each of the sections. The AIMS2 instrument has been translated into many languages, and many studies demonstrated that AIMS2 instrument was efficient in assessing patients' mobility, pain level, and social and emotional health (5). In several studies AIMS2 have been evaluated in RA patients (5).

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Acknowledgements: We wish to thank the members of the expert panel for their contribution in the initial stage of the development of the Slovak-AIMS2 and also to rheumatologists, who agreed with implementation of this study in their out-patient clinics.

The AIMS2 instrument covers physical, social and emotional QoL and it is widely and successfully used as an indicator of the outcomes of care for arthritis patients, but not in Slovak RA patients. Evaluation of the Slovak-AIMS2 instrument also enhances its usefulness in international comparisons. The aim of this study was to translate the original version of the AIMS2 questionnaire into Slovak and to evaluate its measurement properties in the Slovak RA patients.

Methods

Design

This descriptive study was used to evaluate measurement properties of the Slovak version of the AIMS2 (Slovak-AIMS2). Cultural and linguistic validation of this instrument was the first stage of this study. Data for validity and reliability analysis were obtained from RA patients from the five out-patients' clinics from Eastern Slovakia. This study was carried out between September 2007 and June 2009. The study was approved by the institutional research ethics committee. It was judged to carry no significant risks to patients who were told that they could withdraw at any time without giving a reason. Each received written information and signed a consent form following discussion with the nurse researcher. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Translation

The first stage of validation of the Slovak-AIMS2 questionnaire is the cultural and linguistic adaptation. Comparable methodology with Salafi et al (6) in Italian version of AIMS2 was used. Two Slovak independent professionals in the English language made its translation into the Slovak language. The cultural, language and content equivalency of the translation was discussed by translators and bilingual experts (one rheumatologist with validation experience, one academic researcher with a nurse background) and monolingual experts (one psychologist, one nurse working in rheumatology, one professional in the Slovak language and three RA patients). No significant differences were found between the translations. The results of the discussion showed that all items were clear to patients. Only item 15 – Could you easily open a new jar of food? – was discussed, because in the Slovak culture people do not usually prepare food from a jar. It was changed as follows: Could you easily open a new bottle of mineral water? The question about racial background was excluded, and two items, concerning the education level and income were culturally adapted in the Slovak-AIMS2.

Sample

Participants for the study were consecutive RA patients. Inclusion criteria were: all participants fulfilled the American Rheumatism Association (ARA) criteria (7) for RA and were of the age ≥ 18 and ≤ 70 . The exclusion criteria included diagnosis of other rheumatic conditions and other severe or disabling chronic illness.

Instrumentation

Patients were asked to complete the Slovak-AIMS2 and the following valid and reliable instruments: HAQ-DI (3) – its Slovak version (8), VAS, the Beck Anxiety Inventory – BAI (9) and the Self-Rating Depression Scale – SDS (10).

The HAQ-DI (3) assesses patient's level of functional ability during the past week. There are 20 questions in eight categories of functioning: dressing, arising, eating, walking, hygiene, reach, grip, and usual activities. Each of the categories contains at least two specific component questions and check-list records related to the aids used or assistance received. An overall HAQ-DI score ranged from 0 to 3. Scores of 0 to 1 are generally considered to represent mild to moderate difficulty, 1 to 2 moderate to severe disability, and 2 to 3 severe to very severe disability.

The VAS (5 according to various authors) provides a simple way to record subjective estimates of pain intensity. The scale is a straight 100 mm long line being marked at each end with labels that indicate the range 0 – no pain (left end) and 100 – extreme pain (right end).

The BAI (9) measures the severity of anxiety. The scale consists of 21 items and the respondent rates how much he or she was bothered by each of the symptoms of anxiety over the past week on the scale ranging from 0 to 3. A total score is the sum of the item scale and it indicates the level of anxiety. The overall score can range from 0 to 63. A score ranging from 0 to 7 indicates the minimal level of anxiety, the scores of 8 to 15 are an indicator of a mild anxiety, the scores of 16 to 25 reflect moderate anxiety, and the scores of 26 to 63 indicate severe anxiety.

The SDS (10) was developed to quantify the severity of current depression in patients of all ages. The SDS comprises 20 items. Item scores are added to form a total ranging from 20 to 80, in which higher scores indicated increasing depression. The raw score is converted to a 25–100 index score. SDS index scores of less than 50 are within the normal range, the scores of 51 to 59 indicated minimal or mild depression, 60 to 69 moderate to marked depression, and the scores above 70 indicate severe depression.

Clinical procedures

Disease activity was evaluated in a subgroup of 43 patients. It included assessment of a number of tender joints – TJ and swollen joints – SJ, the duration of morning stiffness in minutes – MS, physician's overall assessment of the disease activity – VAS-Ph, and the Erythrocyte Sedimentation Rate – ESR (mm h^{-1}).

Data analysis

Descriptive analysis was used for items and scales. We examined frequency (N), percentage (%), mean (M), standard deviation (SD), minimum (MIN) and maximum (MAX) range.

The reliability of the Slovak-AIMS2 was evaluated by calculating Cronbach's alpha (α) internal consistency coefficients and the test-retest procedure of health status scales. Cronbach's alpha ≥ 0.70 was considered acceptable. The test-retest reliability of the 12 scales of the instrument by calculating the intraclass correlation coefficient and analysis of variance (ANOVA) was evaluated in a subgroup of 29 patients 2 weeks after the first examination. We accepted test-re-

test correlation coefficients ≥ 0.61 (11) between repeated measures as appropriate in terms of the same patient's health status scales.

The convergent validity was tested using both internal and external criteria. The external validity of each scale was calculated by Pearson's correlations with the HAQ-DI, VAS, BAI, SDS, and the other clinical measure of the RA activity. Internal validity was also calculated by one way ANOVA using internal item of the questionnaire itself (impact of the patient's arthritis on the area of health and priority for improvement).

The construct validity was estimated by principal components factor analysis and varimax rotation method with Keiser normalization for the 12 Slovak-AIMS2 scales.

Any possible differences among sex and age subgroups (up to 60 years versus ≥ 61 years) were verified by one way ANOVA.

The findings were examined in 95% confidence interval (95% CI); the significance level (P) was assessed by Student's t-test. Statistical analyses available in the Statistical Package for the Social Sciences 15.0 (SPSS, Chicago, IL, USA) were used.

Results

Demographic and clinical characteristics

One hundred and seventy eight RA patients, 79.2% female and 20.8% male, completed the Slovak-AIMS2. Table 1 shows the demographics and clinical characteristics of the patients and Table 2 presents the distributions for the AIMS2 scales. Mean scores ranged from 1.38 for support from family and friends to 6.14 for pain.

Reliability

The main results related to the reliability tests are summarized in Table 3. The internal consistency of the individual subscales was satisfactory, Cronbach's alpha coefficient ranged from 0.78 to 0.94. The test-retest correlation coefficients between the scores of two administrations of the questionnaire were statistically significant ($p \leq 0.05$), equalled or exceeded 0.79 in case of 11 out of 12 scales.

Validity

The principal components factor analysis for construct validity within each scale showed all the Slovak-AIMS2 scales to be loaded on three factors explaining 66.82% of the cumulated variance (Tab. 4). The first factor explained 32.86% of the vari-

Tab. 1. Demographic and clinical characteristics in Slovak patients with RA.

Variables	
Sex:	
Male: N (%)	37 (20.80)
Female: N (%)	141 (79.20)
Age in years: M (SD)	54.57 (10.54)
Education level: N (%)	
Primary school	31 (17.40)
Secondary school	125 (70.20)
College	22 (12.40)
Marital status: N (%)	
Married	120 (67.40)
Separate	2 (1.10)
Divorced	11 (6.20)
Widowed	33 (18.50)
Never married	12 (6.70)
Main form of work: N (%)	
Paid work	44 (24.90)
House work	4 (2.30)
School	0 (0.00)
Unemployed	13 (7.30)
Disabled	60 (33.90)
Retired	56 (31.60)
Duration of disease in years: M (SD)	12.82 (7.85)
HAQ-DI: M (SD)	1.48 (0.78)
VAS: M (SD)	54.02 (25.22)
BAI: M (SD)	18.38 (9.94)
SDS: M (SD)	57.03 (11.24)
Disease activity (subgroup of 43 patients):	
Number of tender joints: M (SD)	6.40 (5.96)
Number of swollen joints: M (SD)	1.33 (3.06)
Morning stiffness (in minutes): M (SD)	45.81 (47.27)
VAS – physician: M (SD)	36.37 (19.62)
ESR after 1 hour: M (SD)	37.63 (19.42)

ance, the second factor explained 21.29% and the third factor 12.67% of the variance.

Convergent validity was tested using both internal and external criteria. The results on the validity of the Slovak-AIMS2 instrument tested using an internal standard based on the subject's attribution of the health status problem area and of the three priority areas for improvement, are presented in Table 5. The subjects who designated an AIMS2 scales as a problem related to their arthritis had worse health status scale scores in that area. Validity analyses showed that patient's designation of the three priority areas for

Tab. 2. Slovak AIMS2 health status score.

Scale	N	M	SD	MIN	MAX	95% CI of the Difference	
						Lower	Upper
Mobility	178	4.05	2.52	0.00	9.00	3.68	4.43
Walking and bending	178	5.44	2.96	0.00	10.00	5.00	5.88
Hand and finger function	178	4.34	2.82	0.00	10.00	3.92	4.75
Arm function	178	3.83	2.80	0.00	10.00	3.42	4.25
Self-care	177	3.67	3.16	0.00	10.00	3.20	4.13
Household tasks	177	3.70	2.86	0.00	10.00	3.27	4.12
Social activity	178	5.46	1.93	0.00	10.00	5.18	5.75
Support from family and friends	178	1.38	1.62	0.00	7.50	1.14	1.62
Arthritis pain	178	6.14	2.42	0.00	10.00	5.78	6.50
Work	49	2.82	2.84	0.00	10.00	1.94	3.58
Level of tension	178	5.15	1.61	1.00	10.00	4.92	5.39
Mood	178	3.78	1.72	0.00	10.00	3.52	4.03

Tab. 3. Scaling assumptions and reliability estimates for AIMS2 scales.

Scale	N	Internal consistency (α)	N	test-retest correlation
Mobility	178	0.84	29	0.97***
Walking and bending	178	0.89	29	0.89***
Hand and finger function	178	0.91	29	0.84***
Arm function	178	0.93	29	0.86***
Self-care	177	0.94	29	0.99***
Household tasks	177	0.94	29	0.85***
Social activity	178	0.79	29	0.90***
Support from family and friends	178	0.88	29	0.61***
Arthritis pain	178	0.88	29	0.81***
Work	49	0.89	9	0.79*
Level of tension	178	0.82	29	0.86***
Mood	178	0.78	29	0.94***

* $P \leq 0.05$, ** $P \leq 0.01$, *** $P \leq 0.001$ **Tab. 4. Principal components factor analysis of the Slovak-AIMS2 scales.**

	Factor 1	Factor 2	Factor 3
Mobility	0.525	0.549	
Walking and bending	0.511	0.609	
Hand and finger function	0.756		
Arm function	0.689		
Self-care	0.792		
Household tasks	0.656		
Social activity			0.807
Support from family and friends			0.738
Arthritis pain	0.591		
Work	0.856		
Level of tension		0.851	
Mood		0.686	

Coefficients with value < 0.50 not shown

improvement was significantly associated with a poorer AIMS2 scale score in that area.

The correlations between the Slovak-AIMS2 scales and HAQ-DI, VAS, BAI, SDS, and other clinical measures (validity based on external criteria) are summarized in Table 6. There were very close correlations between VAS, SDS and all Slovak AIMS2 scales. HAQ-DI correlated with most of the scales of the Slovak-AIMS2, except for Social support from family and friends. With exception

of social activity, strong correlations were also between the scales of the Slovak-AIMS2 and BAI. The number of tender joints, morning stiffness, and physician's overall assessment statistically significantly correlated only with some of the Slovak-AIMS2 scales. There were no statistically significant correlations between Slovak AIMS2 scales and the number of swollen joints and ESR. The duration of disease statistically significantly ($p \leq 0.05$) correlated with physically related Slovak AIMS2 scales.

No significant differences were observed between female and male patients, excluding scale of mood, with worse score for men ($p = 0.006$). The differences in mean AIMS2 scores for age subgroups were significantly worse ($p \leq 0.05$) in all scales of physical functions and arthritis pain in ≥ 61 year old patients.

Discussion

The translation and adaptation of the Slovak-AIMS2 was similar to the Italian version of the AIMS2 (6) and was made in accordance with the literature review about cross-cultural adaptation of health-related quality of life measurement too (12, 13). The emphasis was put on finding the best idiomatic translation rather than pure equivalence of vocabulary. A few items were discussed, but the presented differences in translation were not significant. One question was omitted and item 15 and 2 demographic questions were modified.

The demographic features of this study tallied with those in evaluation studies reported previously in RA patients (4, 14, 15). There were middle-aged rheumatic patients and a small number of men in the present study, in agreement with the female: male ratio among patients with RA in general. The majority of RA patients was married. More than a half of the patients completed secondary school education. The RA patients suffered mostly from moderate functional disability and felt pain of moderate intensity. We also observed signs of moderate anxiety and mild depression.

The internal consistency of all health status scales showed good values and the test-retest correlation coefficients between scores of two measures were statistically significant, and for eleven scales in the test-retest correlation coefficients equalled or exceeded 0.79.

Tab. 5. Validity of the AIMS2 health status scales based on internal criteria.

Scale	Health status problem area		Priority area for health status improvement	
	(N)	(M)	(N)	(M)
	"yes/no"	AIMS2 scales "yes/no"	"yes/ no"	AIMS2 scales "yes/no"
Mobility	159/19	4.31/1.87*	90/88	4.46/3.64*
Walking and bending	161/17	5.71/2.82*	86/92	6.30/4.63*
Hand and finger function	158/20	4.65/1.85*	72/106	4.18/4.44
Arm function	147/30	4.41/0.90*	24/154	4.77/3.69
Self-care	137/41	4.41/1.19*	30/147	6.35/3.12*
Household tasks	152/26	4.19/0.82*	37/140	4.14/3.58
Social activity	121/57	5.79/4.75*	7/171	4.36/5.51
Support from family and friends	85/92	1.86/0.96*	10/168	1.63/1.37
Arthritis pain	170/8	6.19/4.86	132/46	6.41/5.36*
Work	21/27	3.10/2.32	4/44	1.88/2.84
Level of tension	124/54	5.46/4.46*	11/167	6.27/5.08*
Mood	117/61	4.31/2.75*	18/159	5.23/3.61*

* $P \leq 0.05$

Tab. 6. Pearson correlations (r) between the Slovak AIMS2 scales and HAQ-DI, VAS, BAI, SDS, and clinical characteristics of disease activity.

Scale	HAQ-DI	VAS	BAI	SDS	TJ	SJ	MS	VAS- Ph	ESR
Mobility	0.78**	0.55**	0.53**	0.58**	-0.11	-0.14	0.11	0.32*	0.09
Walking and bending	0.67**	0.54**	0.37**	0.48**	0.19	0.08	0.37*	0.53**	0.16
Hand and finger function	0.66**	0.47**	0.36**	0.40**	0.11	0.08	0.21	0.09	0.10
Arm function	0.76**	0.55**	0.42**	0.48**	0.13	0.13	0.06	0.14	0.09
Self-care	0.75**	0.52**	0.47**	0.55**	0.01	-0.01	0.26	0.42**	0.00
Household tasks	0.77**	0.48**	0.42**	0.54**	0.02	0.06	0.01	0.12	0.12
Social activity	0.30**	0.26**	0.11	0.20*	0.04	-0.14	0.17	0.18	-0.10
Support from family and friends	0.08	0.18*	0.19*	0.17*	0.11	0.13	0.04	0.06	-0.11
Arthritis pain	0.61**	0.68**	0.43**	0.46**	0.45*	0.23	0.56**	0.69**	0.16
Work	0.72**	0.49**	0.61**	0.50**	0.34	0.29	0.55	0.17	0.22
Level of tension	0.44**	0.42**	0.39**	0.50**	0.33*	0.05	0.40**	0.39**	0.04
Mood	0.51**	0.40**	0.52**	0.59**	0.26	0.11	0.26	0.50**	0.18

* $P \leq 0.05$, ** $P \leq 0.01$, HAQ-DI – the Health Assessment Questionnaire Disability Index, VAS – the Visual Analogue Scale for pain, BAI – the Beck Anxiety Inventory, SDS – the Self-Rating Depression Scale, TJ – number of tender joints, SJ – number of swollen joints, MS – morning stiffness, VAS-Ph – the physician's overall assessment of disease activity, ESR – the Erythrocyte Sedimentation Rate

These findings are in accordance with those reported for the original version of AIMS2 by Meenan et al (4) and other studies (15, 16, 17).

The construct validity was assessed by principal components factor analysis on individual scales. Three factors were identified. All physical scales, arthritis pain and work scale loaded the first factor. The arthritis pain scale was markedly loaded in the physical factor in the Swedish (14) and Dutch (18) report. It can be influenced by the fact that physical impairment and pain are dominant problems in RA (1, 19, 20). The second factor included psychological scales and physical scales for the mobility level and walking and bending. The third factor was determined by social dimensions, as also identified in Swedish (14), Polish (17), and Dutch (18) AIMS2 scales factor analysis.

This study also provides some evidence of convergent validity based on the internal and external criteria. The internal validity analysis showed that patient designation of a health status area as a problem related to his or her arthritis or as a priority for improvement was significantly associated with a poorer AIMS2 scale score in that area of health, as also described by Meenan et al (4), Salaffi et al. (6) in the Italian report, and Riemsma et al (18) in the Dutch version of the AIMS2. The external validity was tested by assessing the correlations with the HAQ-DI, VAS, BAI, SDS, and other clinical measures. The correlations between most of the Slovak AIMS2 scales and HAQ-DI, VAS, BAI, and SDS were statistically significant indicating a good convergent validity. However, we observed no correlation between the social support from family and friends scale and HAQ-DI and the social activity scale and BAI, which was expected from the viewpoint of no social interaction character of the HAQ-DI and BAI questionnaire. Significant correlations were also observed between HAQ, VAS and physical scales and arthritis pain scale of the AIMS2 in the Finnish (15) and Dutch (18) reports. A number of tender joints strongly correlated with the arthritis pain scale and the level of tension. The morning stiffness significantly correlated with the scales of walking and bending, arthritis pain scale, and level of tension. Physician's overall assessment statistically significantly correlated with physical scales, arthritis pain, and psychological scales. There were no statistically significant correlations between Slovak-AIMS2 scales and the number of swollen joints and ESR. The duration of the disease statistically significantly correlated with physically related Slovak-

AIMS2 scales. However, no strong correlations between Slovak-AIMS2 score and disease measures were found in this study. This is in accordance with the previous studies which demonstrated weak to moderate correlation between AIMS score and disease activity measure (4, 15, 16). The poorer correlations between AIMS2 scales and disease activity measures can be explained by the fact that the RA patients receive antirheumatic treatment with good suppression of inflammatory and functional impairment.

Consistent scores of the AIMS2 scales were observed between female and male. Worse physical functions and pain were recognised in 61 year old and older patients. No gender differences in physical functions and arthritis pain, but worse level of tension in female patients were observed by Baczyk (20). According to the same study (20), older patients had worse scores in scales of walking and bending, self-care tasks, household tasks and arthritis pain.

Conclusions

Our results support the thesis that the Slovak-AIMS2 questionnaire is culturally appropriate, valid and reliable for health status assessment in Slovak patients with RA. Our findings agreed with previous studies supporting its usefulness in the context of health status measure. The evaluation of the Slovak-AIMS2 also enhances its utility in international comparisons. AIMS2 is a multidimensional instrument for use in research into rheumatic disease. A further prospective study will be necessary to prove the usefulness of the Slovak-AIMS2 in clinical trials. However, we have found out that it was difficult to administer the questionnaire to elderly patients and patients with a lower education level. The use of AIMS2 in clinical practice is limited by the length of the questionnaire, but this instrument helps to identify patient's problems, allows better understanding of patient's treatment preferences and, consequently, more effective prioritising, targeting of appropriate interventions, and monitors longitudinal course of the disease.

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Received September 26, 2011.

Accepted January 23, 2013.