

CLINICAL STUDY

Translation, intercultural adaptation, and validation of the Slovak version of AOSpine patient reported outcome for spinal trauma

Martin HOLAS^{1,3}, Radomir GAJDOS¹, Juraj SVAC¹, Juliana HOLASOVA^{2,3}, Marta VALIHOROVA⁴, Roman ALBERTY⁵

2nd Department of Trauma Surgery, Slovak Medical University, F. D. Roosevelt University General Hospital of Banská Bystrica, Banská Bystrica, Slovakia. mholas@nspbb.sk

ABSTRACT

OBJECTIVES: The implementation of patient-reported outcome measurements has become a standard component of evaluating the effect of treatment. For spine injuries, an evaluation tool AOSpine Patient Reported Outcome for Spinal Trauma (AOSpine PROST) has been developed. The aim of this study was to translate, intercultural adapt and validate the Slovak version of AOSpine PROST.

METHODS: Based on methodologies we translated and culturally adapted the AOSpine PROST into Slovak. We then validated it on a representative sample of patients treated at a single level-one trauma center in the Slovak Republic. Content validity was assessed by evaluating the number of inapplicable or missing questions. Internal consistency was assessed by calculating Cronbach's alpha and Corrected item-total correlations.

RESULTS: 37 patients were included in the study. The questionnaire was understandable to patients. The mean T-score across questions and participants in the questionnaire was 79.6 with a narrow range of 70.4 to 97.3 for all questions, which is relatively high. The internal consistency of total score was excellent with Cronbach's alpha of 0.92. Total correlation across questions revealed relatively good results ranging from 0.17 to 0.90.

CONCLUSIONS: The results indicate that the Slovak version of AOSpine PROST is reliable and valid and can be used in practice (Tab. 2, Ref. 14). Text in PDF www.elis.sk

KEY WORDS: AOSpine PROST, patient reported outcome, spinal trauma, translation, intercultural adaptation.

Introduction

The need for a single relevant tool for evaluating treatment outcomes is based on the requirement for a more detailed examination of the functional outcomes of spinal injuries treatment. This is since, even nowadays, we do not find a broader consensus in surgical treatment indications for certain types of spinal injuries in the literature. As further research is needed, it is essential to have a high-quality tool for evaluating treatment outcomes. Such a tool should unconditionally include a subjective assessment of the patient's condition. Therefore, it seems essential that a ver-

sion of the questionnaire be available in the mother language of the respondents.

Several tools to evaluate the results of treatment after a spinal injury are used in clinical practice, but these are focused mainly on assessing the impact of spinal cord injury (5). The tool to measure the results of treatment after spinal injury in patients with no neurological symptomatology or only minimal neurological disability (AISA C-E) has so far been lacking. The most commonly used tools (3, 8) to evaluate the results of spinal injuries treatment are VAS (Visual Analogue Scale), ODI (Oswestry Disability Index) (2) and SF-36 (Medical Outcomes Study 36-item Short-Form Health Survey) (10). However, these tools are not specifically designed to evaluate the outcome results after a spinal injury.

For this reason, according to the International Classification of Functioning, Disability and Health (ICF) methodology published by WHO in 2017 (7), the AOSpine Knowledge Forum Trauma developed a tool to evaluate a subjective outcome of spinal injuries treatment called PROST (Patient Reported Outcome for Spinal Trauma) (4, 11).

In 19 questions, the AOSpine PROST questionnaire assesses several aspects of the patient's functioning after a spinal injury and compares the current condition with that preceding the accident. The questionnaire asks respondents about their symptoms

¹2nd Department of Trauma Surgery, Slovak Medical University, F. D. Roosevelt University General Hospital of Banská Bystrica, Slovakia, ²Department of Haematology, F. D. Roosevelt University General Hospital of Banská Bystrica, Slovakia, ³Slovak Medical University, Bratislava, Slovakia, ⁴Faculty of Economics, Matej Bel University, Banská Bystrica, Slovakia, and ⁵Faculty of Natural Sciences, Matej Bel University, Banská Bystrica, Slovakia

Address for correspondence: Martin HOLAS, MD, 2nd Department of Trauma Surgery, Slovak Medical University, F. D. Roosevelt University General Hospital of Banská Bystrica, Nám L. Svobodu 1, SK-975 17 Banská Bystrica, Slovakia.
Phone: +421.48.4412993

and perceived ability to perform specific activities in compare with the condition before the accident. Each answer is scored on a scale from 0 to 100, with 100 representing “no difficulty” and zero representing “unable.”

The final value is the arithmetic average of partial values of the questionnaire in the scale from 0 to 100 points; a higher score indicates a better outcome.

The original Dutch version of PROST showed very promising results for reliability, validity, and responsiveness in a validation study. Internal consistency was evaluated as excellent (Cronbach’s alpha of 0.96) (11).

English version of the AOSpine PROST also indicated very good validity and reliability. Internal consistency was reported as excellent (Cronbach’s alpha of 0.97) (12).

The aim of this work is translation, intercultural adaptation, and validation of the Slovak version of AOSpine PROST.

Materials and methods

Several cultural and linguistic adaptation methodologies for PRO (Patient Reported Outcome) questionnaires have been described (4, 5). Based on these methodologies, the translation and cultural adaptation process consisted of four stages, namely (1) translation to Slovak language, (2) synthesis, (3) back translation to English and (4) final review.

In step one, two orthopedic trauma surgeons translated the AOSpine PROST from English into Slovak. They were both native Slovak speakers and both translations were independent from each other. In step two, a synthesis of both versions of the translations was done. In step three, the AOSpine PROST questionnaire was translated back to English by both a professional translator from outside of healthcare and a medical doctor who had never seen the original questionnaire.

This reverse translation was then reviewed by the original translators and compared to original text of the questionnaire. After a subsequent critical appraisal by all translations and incorporation of comments and proposed changes, we completed step four and accepted the working Slovak version of AOSpine PROST (AOSpine PROST SK).

We validated this version of the questionnaire on a representative sample of patients treated at a single level-one trauma center in the Slovak Republic. All patients were native Slovak speakers who were in treatment for at least 13 months following their spinal injuries. Patients were over 18 years old, and capable of understanding and filling out the questionnaire. Patients with ASIA A or B spinal cord injury, and poly-trauma patients (ISS > 15) were excluded. Ethical approval was obtained from the institutional review board and all patients gave informed consent. Due to the need for

a balanced representation of entities from different environments (1, 6), we developed an algorithm for selecting entities by group where each group was represented by at least two entities. Groups were divided by gender, age, and highest educational attainment. The aim was to acquire a representative cohort compared to the general population in the Slovak Republic.

After completing the AOSpine PROST questionnaire, patients were interviewed briefly about their understanding of the questionnaire and whether they perceived any uncertainty or irregularities pertaining to the questions. They were then asked to answer questions about the complexity, completeness, and comprehensibility of the questionnaire.

Statistical analyses

Patient demographic, clinical and psychometric variables are presented with descriptive statistics. All categorical data (age groups, sex, level of education, etc.) are presented as frequencies and percentages (%). Floor and ceiling (F/C) effects were defined as the proportion of respondents scoring the highest (ceiling) or lowest (floor) possible score (scale from 0 to 100 points) for any given question. F/C effects were classified as significant if 15 %, moderate if 10 % to < 15 %, minor if 5 % to < 10 %, and negligible if they were < 5 %. Comparisons between categorical variables were performed using Fisher’s exact test (for small sample size). Continual data (age and T-scores) are presented as mean ± standard deviation (SD). Continual variables were compared using an independent Student *t*-test. Corrected item-total correlations and Cronbach α were calculated as previously described (14, 15). Average inter-item correlations were used to assess internal consistency and reliability. Significance was set at a two tailed $p < 0.05$. SPSS Statistics for Windows (version 20.0, Chicago, IL) was used for all data analyses.

Tab. 1. Sociodemographic and clinical characteristics by age and sex*.

Variable	Age in years		p	Sex		p
	20–49	≥50		Males	Females	
No. of patients	14	23		22	15	
Age	32.4±7.5	65.3±9.3	<0.001	43.8±17.4	66.1±9.5	<0.001
Females (%)	0 (0.0)	15 (65.2)	<0.001	–	–	
Education						
Primary school	1 (7.1)	4 (17.4)	0.630	3 (13.6)	2 (13.3)	1.000
High school	8 (57.1)	16 (69.6)	0.495	12 (54.5)	12 (80.0)	0.165
University	5 (35.7)	3 (13.0)	0.117	7 (31.8)	1 (6.7)	0.108
Fracture						
Cervical spine	2 (14.3)	3 (13.0)	1.000	3 (13.6)	2 (13.3)	1.000
Thoracic spine	7 (50.0)	10 (43.5)	0.745	11 (50.0)	6 (40.0)	0.738
Lumbar spine	5 (35.7)	10 (43.5)	0.738	8 (36.4)	7 (46.7)	0.734
Fracture type						
Type A	10 (71.4)	18 (78.3)	0.705	15 (68.2)	13 (86.7)	0.261
Type B	4 (28.6)	4 (17.4)	0.682	6 (27.3)	2 (13.3)	0.431
Type C	0 (0.0)	1 (4.3)	1.000	1 (4.5)	0 (0.0)	1.000
Treatment						
Conservative	4 (28.6)	10 (43.5)	0.491	6 (27.3)	8 (53.3)	0.169
Surgical	10 (71.4)	13 (56.5)	0.491	16 (72.7)	7 (46.7)	0.169

*The percentage of each characteristic is derived from the available total number of patients for the particular characteristic. Bold indicates a significant value (Student *t*-test or Fisher exact test).

Results

Patient characteristics

Thirty-seven suitable patients (age ≥20 years) with spinal injury were enrolled in the study. The majority of the examined patients were males (59.5 %) and the mean age of the study population was 52.8 years (range 20–86 years). In general, females were substantially older than males (p < 0.001), and patients who underwent surgery were more numerous and younger than those who opted for a conservative approach. Table 1 shows the basic patient sociodemographic and clinical characteristics.

Content validity

The questionnaire was understandable to patients and no respondent had any serious problems completing it. However, for one patient (62-year-old male with primary education) the questionnaire was difficult to complete and for another patient (22-year-old male university student) some questions were vaguely worded. Patients managed to fill out the questionnaire within a reasonable time frame ranging from 10 to 15 minutes.

Internal consistency

Basic statistics for each question, including item-total correlation, Cronbach alpha score and Pearson correlation analysis are shown in Table 2. The mean T-score across items was relatively high, i.e. 79.6 in narrow range of 70.4 to 97.3. Thus, the floor effects were negligible for all items and did not differ by age, sex and surgical status. In contrast, a strong significant ceiling effect

was present in each item with the exception of “lifting and carrying”, and “recreation and leisure”, which can be considered moderate. The internal consistency of AO Spine PROST total score (Cronbach alpha) was excellent, namely 0.92). Total item correlation revealed relatively good results across items in range of 0.17 to 0.90. The items of “sexual function” and “bowel movement” had the lowest values (0.17 and 0.38, respectively), while those of “work-study” and “social life” were 0.90. Admittedly, as compared to total Cronbach alpha score, the corrected Cronbach alpha scores were lower if item was deleted.

Discussion

In this study, we translated and culturally adapted AOSpine PROST to suit the Slovak environment. We have verified and confirmed its validity and internal consistency on a group of patients treated for vertebral body fracture.

Self-translation into the Slovak language required adaptation of certain terms, as several words and phrases have different meanings in Slovak and English, and literal translation was not possible. The problem was in the semantic difference between the words “help” and “aid” since the author of the original questionnaire cared about using the word “aid”. Another problematic term was the word “disability”, which has no clear meaning in the Slovak language.

Testing the validity and internal consistency of the questionnaire was carried out on a set of 37 patients. In some aspects, the analysis of the cohort shows compliance with the current statistics published on the portal by the Statistical Office of the Slovak

Republic, mainly in the breakdown of the population according to educational attainment. From the perspective of age and sex distribution of the cohort, a bipolar distribution was seen with a peak of about 30 and 50 years, while males were significantly younger than women and at the same time more frequently treated surgically. This corresponds to the distribution of a high-energy injury at a younger age and low-energy injury at an older age. The distribution of the cohort by injury localization corresponds to literary data, where there is the greatest incidence of spinal fractures in the C-TH and Th-L transitions. Also, the distribution according to the AOSpine classifications corresponds to the data from the literature, where A-type injuries prevail. Fractures of A0 type (i.e., vertebral processes fractures) were not included in this study.

The test file is a representative sample with an adequate representation of each group, which is one of the prerequisites to validate the protocol (1).

The internal consistency of the Slovak version of AOSpine PROST shows a high Cronbach’s alpha value (0.92), which is

Tab. 2. Item statistics, floor and ceiling effects, item-total correlation, Cronbach alpha if item deleted and inter-item correlation analysis.

AO spine prost items	Mean±SD	F/C effects (%)	Item-total correlation	Cronbach α if item deleted	High inter-correlation*
1. Household activities	75.1±19.2	0.0/18.9	0.812	0.914	2, 3, 6, 8,
2. Work-study	74.2±24.9	0.0/25.0	0.899	0.910	3, 6, 7, 8, 9, 15
3. Recreation and leisure	73.3±19.6	0.0/13.5	0.725	0.916	6
4. Social life	89.2±18.0	0.0/48.6	0.893	0.919	5, 6
5. Walking	92.8±10.3	0.0/48.6	0.416	0.922	
6. Travel	80.7±24.8	0.0/38.8	0.820	0.912	8
7. Changing posture	78.4±19.6	0.0/25.0	0.795	0.914	15
8. Maintaining posture	70.5±24.6	0.0/16.2	0.774	0.914	
9. Lifting and carrying	71.3±26.4	0.0/10.8	0.701	0.916	16
10. Personal care	89.1±15.5	0.0/45.9	0.524	0.920	
11. Urinating	95.5±7.8	0.0/69.4	0.415	0.923	
12. Bowel movement	97.3±6.6	0.0/78.3	0.377	0.923	
13. Sexual function	86.4±23.2	0.0/45.2	0.166	0.929	
14. Emotional function	86.8±15.0	0.0/36.1	0.738	0.917	15, 16
15. Energy level	81.2±14.3	0.0/21.6	0.840	0.915	16
16. Sleep	82.4±21.9	0.0/35.1	0.580	0.919	
17. Stiffness of your neck and/or back	70.4±25.2	0.0/16.2	0.549	0.920	18, 19
18. Loss of strength in your arms and/or legs	75.8±29.3	0.0/30.6	0.437	0.925	
19. Back and/or neck pain	63.7±26.9	0.0/10.8	0.570	0.920	

*Inter-correlation Pearson coefficient r > 0.7

similar to the original Dutch and English versions of AOSpine PROST (0.97) (11, 12). Alpha values have not changed significantly (0.91–0.93) when a question was deleted, so there may be some redundancy similar to the original Dutch and English versions of AOSpine PROST (11, 12).

The analysis shows that the “work-study” variable was positively correlated with “traveling”, “changing posture”, “maintaining posture” and “energy level”. “recreation and leisure” and “social life” also had a positive relationship with “travel”. Both “emotional function” and “energy level” were related to “sleep”. These inter-item correlations show the natural interplay between questions and can lead to the simplifying of AOSpine PROST in the future.

Overall, the comprehensibility of the questionnaire was very high, with CVI of 0.973. Even though some of the patients complained about the question formulation, ultimately, all subjects found the questions understandable. In terms of complexity, the questionnaire was rated as time-consuming, with some patients reporting high complexity of the questionnaire (CVI 0.946). On the other hand, according to respondents, some questions lacked completeness (CVI 0.811). After being asked “what question are you missing” patients called for more personalized sub-questions such as “for how long have you had your back pain”, “what do you do to stop your back pain”, etc.

Conclusion

The results obtained in this study indicate that the Slovak version of AOSpine PROST is reliable and valid and can be used in practice. We hope that this translation will be a valuable tool for evaluating the results of treatment of spinal injuries in our region as well as allow for comparison with the data collected internationally.

References

1. **Beaton, DE, Bombardier C, Guillemin F et al.** Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)* 2000; 25 (24): 3186–3191.
2. **Fairbank JC, Couper J, Davies JB et al.** The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980; 66 (8): 271–273.
3. **Pishnamaz M, Oikonomidis S, Knobe M et al.** Open versus percutaneous stabilization of thoracolumbar spine fractures: a short-term functional and radiological follow-up. *Acta Chir Orthop Traumatol Czech* 2015; 82 (4): 274–281.
4. **Sadiqi S, Mechteld Lehr A, Post MW et al.** Development of the AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST): a universal disease-specific outcome instrument for individuals with traumatic spinal column injury. *Eur Spine J* 2017; 26 (5): 1550–1557.
5. **Stadhouder A, Buckens CFM, Holtslag HR et al.** Are existing outcome instruments suitable for assessment of spinal trauma patients? *J Neurosurg Spine* 2010; 13 (5): 638–647.
6. **Wild D, Grove A, Martin M et al.** Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health*, 2005; 8 (2): 94–104.
7. **World Health Organization.** International classification of functioning, disability and health: ICF. Geneva: World Health Organization, 2001.
8. **Zitka R, Gakhar R, Clamp J et al.** Kyphoplasty augmentation in thoracolumbar spine-clinical outcomes after 2 Years. *Acta Chir Orthop Traumatol Cech* 2019; 86 (3): 188–192.
9. **Statistický úrad SR.** DATAcube. Accessed January 14, 2022. <http://datacube.statistics.sk>
10. **Ware JE Jr, Sherbourne CD.** The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection *Med Care* 1992; 30 (6): 473–483.
11. **Sadiqi S, Post MW, Hosman AJ et al.** Reliability, validity and responsiveness of the Dutch version of the AOSpine PROST (Patient Reported Outcome Spine Trauma). *Eur Spine J* 2021; 30 (9): 2631–2644.
12. **Sadiqi S, Dvorak MF, Vaccaro AR et al.** Reliability and Validity of the English Version of the AOSpine PROST (Patient Reported Outcome Spine Trauma). *Spine (Phila Pa 1976)* 2020; 45 (17): E1111–1118.
13. **MacLennan RN.** Interrater reliability with SPSS for Windows 5.0. *Am Stat* 1993; 47 (4): 292–296.
14. **Cronbach LJ, Shavelson RJ.** My current thoughts on coefficient alpha and successor procedures. *Educ Psychol Meas* 2004; 64 (3): 391–418.

Received October 18, 2022.

Accepted November 14, 2022.