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Cross-Cultural Adaptation, Reliability, and Validity of the Polish Version of the Neck Outcome Score

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Abstract: This study aimed to translate and psychometrically validate the Neck Outcome Score (NOOS) in the Polish population according to the recommendations of American Academy of Orthopedic Surgeons (AAOS) for the Cross-Cultural Adaptation of Health Status Measures. Participants completed the NOOS, Neck Disability Index (NDI), and Visual Analogue Scale (VAS) for pain assessment. The questionnaires were completed by 57 women and 32 men with cervical spine ailments. A retest was performed in all patients after 48 hours. The analysis confirmed the high internal consistency (Cronbach's alpha of 0.95) of the Polish NOOS. No floor / ceiling effects were observed. The Polish NOOS showed a significant correlation with NDI (0.87; $p<0.001$) and VAS (0.79; $p<0.001$). The intraclass correlation coefficient (ICC) for the test-retest was found to be high (0.97). The Polish version of NOOS can be used for clinical and research purposes as an equivalent to the original English version. This study contributes to the area of patient-reported outcome measures available in the Polish language.

Keywords: cervical pain; patient-reported outcome measure; Validation Study; Poland

1. Introduction

It is estimated that between 20% and 70% of the population [1] experience neck pain (NP) during life with the highest prevalence in developed countries and urban areas, especially in women [2]. It can be somatic, neuropathic, or a combination of both. A common cause of NP is poor ergonomics at work [3], especially maintaining an unfavorable posture with the cervical spine bent [1]. The NP has also significant economic aspects of pain-related absences from work and the need for medical care [4]. Therefore, it is important to develop tools to help clinicians to assess these conditions. This will allow a proper and reliable evaluation of NP before the start of treatment and adaptation of therapy to the individual needs of the patient. At the end of therapy, questionnaires are used to assess the effectiveness of the treatment and the health progress [1]. PROMs (Patient Reported Outcome Measures) can be very useful tools, being questionnaires that help to assess health status based on patient self-assessment. Their use can contribute to better understanding of the patient's quality of life than traditional OROs (Observer Reported Outcomes) filled by doctor/physiotherapist [6]. Due to the diversity of patients, it is crucial to translate and adapt PROMs into different languages or dialects to ensure appropriate care regardless of the nationality or ethnicity of the patient.

The Neck Outcome Score (NOOS) is used to assess cervical spine dysfunction and pain in scientific research and clinical practice [14]. It is self-administered and can be used in paper or electronic version on computer/tablet/smartphone. The scale contains 34 items and takes 10-15 minutes to complete. It is divided into subdomains: 'Mobility'; 'Stiffness'; 'Symptoms'; 'Sleep disorders'; 'Daily Activities and Pain'; 'Participation in everyday life' and 'Quality of life'. The patient assigns a score from 0 to 5 for each question, with 0 being no problems and 5 being the highest level of difficulty or pain. The total of points is converted into a percentage score that indicates the degree

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of dysfunction [1]. It's already translated into Arabic, Turkish and Danish [8-10]. The availability of NOOS in different languages allow researchers to compare results and conduct multicenter international studies or metanalysis among patients with NP [5].

In this article, we present the translation and validation of the Neck Outcome Score (NOOS) questionnaire into Polish [7]. The Polish version of the questionnaire was validated in accordance with the American Academy of Orthopedic Surgeons (AAOS) Institute for Work & Health Recommendations for the Cross-Cultural Adaptation of Health Status Measures [11]. The original version of NOOS was used with the written permission of the authors from the Institute of Sports Science and Clinical Biomechanics, The University of Southern Denmark, Odense [15].

2. Materials and Methods

2.1. Study Participants

The study received a positive opinion from the Bioethics Committee of the Medical University of Warsaw (AKBE/158/2021). The criteria for selecting patients were as follows: consent to participate in the study, ability to complete the questionnaire electronically in Polish language, age over 18 years old, and current chronic pain in the cervical spine (persisting for a minimum of 3 months). Individuals were excluded from the study on the basis of past surgical procedures of the cervical segment of the spine, confirmed congenital defects of the spine or any malignant neoplasms. The patients from Outpatient Clinic of Department of Orthopedics and Traumatology, Medical University of Warsaw, were sent an emailed online survey (between 23.11.2021 and 09.04.2022) including Polish NOOS, Visual Analogue Scale (VAS) for pain assessment and Polish version of Neck Disability Index (NDI). All participants were informed of the purpose and process of the study and gave their informed consent to participate in it. All respondents' rights, including the right to personal data protection, were respected. A total of 89 patients participated in the study. All personal data collected have been anonymized according to the Medical University of Warsaw regulations.

2.2. NOOS translation

The translation process consisted of forward translation, reconciliation, back translation, harmonization, and proofreading. Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN), guidelines, and checklists were used to verify the full translation and validation process [11]. Two independent forward translations from English to Polish (T1 & T2) were received from two native Polish translators. A meeting was then held where both translators had the opportunity to agree on one common version. This process of synthesis of the initial translations resulted in a unified forward translation version (T12). Next, two independent back-translations into English (BT1 & BT2) were performed blindly to the original NOOS from the unified forward translation version (T12). Native English translators fluent in the target language were employed for these translations. Translators have not received the original English source items or item definitions. The two back translated versions (BT1 & BT2) were then compared with the unified forward translation version (UFT). Then an agreement was reached on a few minor differences that considered the cultural context and the specificity of the spoken Polish language to propose a preliminary version of Polish NOOS. Five patients with NP tested this version to ensure the purpose and meaning of each question and to develop the final Polish version of NOOS (Supplementary file 1.).

2.3. Psychometric Validation of the Polish Version of the NOOS

The analysis consisted of evaluating discriminatory power, internal consistency, and potential floor and ceiling effects and then determining the validity of the construct and the reliability of the test-retest. Analysis was carried out using commonly accepted questionnaires, i.e. NDI [12] and VAS [13]. Participants were asked to complete all questionnaires using Google Forms. The retest was carried out after a 48-hour break.

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2.4. Questionnaires used in external validation

The Neck Disability Index (NDI) is a tool for evaluating problems associated with neck pain, limitations in mobility, and difficulties in daily activities. The scale consists of 10 questions about different areas of functioning and the patient assigns points from 0 to 5, assessing the degree of difficulty. The sum of the points gives an overall score that indicates the degree of disability. Higher scores mean greater difficulty and disabilities [1][12].

The Visual Analogue Scale (VAS) can be used to subjectively assess the intensity of pain or other sensations of the patient. It involves presenting the patient with a line where one end means "no pain" or "no discomfort" and the other end means "greatest possible pain" or "greatest pain". The patient places a marker on the line, indicating the place that corresponds to the intensity of the sensations. The distance from the beginning of the line to the marker is measured and represents the subjective assessment of the intensity of pain or other sensations, where a higher value means a higher intensity of sensations [16].

2.5. Statistical Analysis

The analyses were performed using Statistica version 13, developed by TIBCO Inc. based in Palo Alto, CA 94304, USA (2017). The results were considered statistically significant at a significance level of $\alpha = 0.05$. The normality of quantitative variables was checked using the Shapiro -Wilk test. Normally, quantitative variables are presented as mean ± standard deviation. Nonnormally distributed quantitative variables are presented as the median (Me) with the first and third quartiles (P25-P75). Qualitative variables are shown as absolute values and frequency percentages. The Cronbach's alpha coefficient was used to evaluate internal consistency. A high value of the internal consistency coefficient means a value greater than 0.70. An analysis of the effect of the ceiling and floor was also carried out. The effect of the ceiling and floor was considered significant if it exceeded 15% of the population, indicating that the responses were concentrated on the highest or lowest score. To assess the design validity, reliable NOOS items were analyzed using Spearman's correlation coefficient due to anomalous data distribution. The intraclass correlation coefficient (ICC) was used to assess reliability. ICC values are limited to -1 to 1, where ICC ≈ 1 means very high reliability.

3. Results

3.1. Descriptive analysis

A total of 89 patients were included in the study. Patients were asked to complete the online version of NOOS questionnaire, the NDI questionnaire, and the VAS questionnaire. There were 57 (64%) women and 32 (36%) men in the study group. The average age of the subject in the study group was 36.84 years (women - 37.51 years and men - 35.65 years). The normality analysis showed that none of the variables had a normal distribution.

3.2. Psychometric Validation

3.2.1. External validity

To verify the external validity of the constructed tool, a series of correlation analyses (the Spearman rho) between the results obtained in Polish NOOS (1st measurement) and the result on the VAS scale was carried out. Positive, and strong relationships were found between the VAS Scale and the subscales of Polish NOOS in test and retest measurements (Table 1). Similarly significant correlations were found between NDI and subscales of Polish NOOS (1st measurement) (Table 2). Table 3 represents correlations for the total score of NOOS in 1st and 2nd measurement with VAS and NDI.

Table 1. Spearman's rho correlation coefficients for Polish NOOS and VAS.

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Individual Domains of NOOS	VAS (Spearman's rho)
Mobility	0.54***
Stiffness	0.75***
Symptoms	0.73***
Sleep disorders	0.70***
Daily Activities and Pain	0.74***
Participation in everyday life	0.44***
Quality of life	0.77***

*NOOS – Neck Outcome Score; NDI - Neck Disability Index; VAS – Visual Analogue Scale; *** - $p < 0.001$; ** - $p < 0.010$; * - $p < 0.050$.*

Table 2. Spearman's rho correlation coefficients for Polish NOOS and NDI

Individual Domains of NOOS	NDI (Spearman's rho)
Mobility	0,48***
Stiffness	0,73***
Symptoms	0,77***
Sleep disorders	0,75***
Daily Activities and Pain	0,81***

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Participation in everyday life	0,55***
Quality of life	0,81***

*NOOS – Neck Outcome Score; NDI - Neck Disability Index; VAS – Visual Analogue Scale; *** - $p < 0.001$; ** - $p < 0.010$; * - $p < 0.050$.*

Table 3. Correlation for total score of Polish NOOS with NDI and VAS

	NOOS 1st	NOOS 2nd	VAS	NDI
NOOS 1st	NA	0,88***	0,79***	0,87***
NOOS 2nd	0,88***	NA	0,84***	0,86***
VAS	0,79***	0,84***	NA	0,78***
NDI	0,87***	0,86***	0,78***	NA

*NOOS – Neck Outcome Score; NDI - Neck Disability Index; VAS – Visual Analogue Scale; NA – not applicable; *** - $p < 0.001$; ** - $p < 0.010$; * - $p < 0.050$.*

3.2.2. Reliability Analysis

In order to verify the reliability of Polish NOOS, an analysis was carried out using Cronbah's alpha coefficient separately for the results from the first and second measurements. Based on the results presented in Table 4, it was found that the coefficients for a 'Mobility' and 'Participation in everyday life' domain in the first and second measurements were below alpha = 0.70. Other domains coefficients where greater than acceptable treshold for Cronbah's alpha (0.70)

Table 4. Reliability coefficients of the in subsequent measurements of Polish NOOS.

Polish NOOS	Domain	Cronbah's alpha
Measurement 1st	Mobility	0.53
	Stiffness	0.86
	Symptoms	0.85
	Sleep disorders	0.92
	Daily Activities and Pain	0.95

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	Participation in everyday life	-0.09
	Quality of life	0.93
	NOOS total score (1st)	0.95
Measurement 2nd	Mobility	-0.17
	Stiffness	0.93
	Symptoms	0.88
	Sleep disorders	0.94
	Daily Activities and Pain	0.97
	Participation in everyday life	-0.14
	Quality of life	0.94
	NOOS total score (2nd)	0.95

NOOS – Neck Outcome Score.

3.3.3. Intra - class correlations ICC

In addition, the coefficients of intraclass coherence for the measured scales (test-retest) were calculated. Based on the results presented in Table 5, the coefficients of intraclass coherence were found to exceed 0.70 in all domains exept 'Mobility' and 'Participation in Everyday life'.

Table 5. Intraclass correlation coefficients for the measured scales (test-retest) after a 48-hour break.

Individual domains	ICC
Mobility	0.43

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Stiffness	0.93
Symptoms	0.93
Sleep disorders	0.96
Daily Activities and Pain	0.97
Participation in everyday life	0.33
Quality of life	0.96
NOOS score	0.97

*NOOS – Neck Outcome Score; *** - $p < 0.001$; ** - $p < 0.010$; * - $p < 0.050$.*

3.3.4. Floor and Ceiling Effects

None of the patients had the lowest score (0 points) or the highest score (100 points) on the questionnaire. Therefore, neither the floor nor the ceiling effect was found in the questionnaire.

3.3.5. Reliability of the Test-Retest

To verify the constancy of the measured scales over time, an analysis was performed using the Student's t-test for repeated measures. The average results obtained by the subjects in the first and second surveys were compared. Based on the results presented in Table 6, a statistically significant difference was found on the following subscales: 'Mobility', 'Stiffness', 'Symptoms', 'Sleep disorders', 'Daily activities and pain', 'Participation in daily life', and 'Quality of life'. This means that the results obtained by the subjects after 48 hours have changed. This may indicate the instability of the scales mentioned above over time.

Table 6. Comparison of successive measurements of measured quantitative variables.

NOOS domains	1st		2nd				95% *CI*		
	M	*SD*	*M*	*SD*	*t*	*p*	*LL*	*UL*	*d* Cohen

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Mobility	2.93	0.41	3.33	0.34	-8.56	<0.001	-0.49	-0.31	0.91
Stiffness	1.85	0.83	1.74	0.82	2.13	0.018	0.01	0.22	0.23
Symptoms	2.33	0.86	2.15	0.84	3.76	<0.001	0.08	0.27	0.40
Sleep disorders	1.83	0.86	1.73	0.87	1.94	0.027	0.00	0.20	0.21
Daily Activities and Pain	1.79	0.85	1.74	0.87	0.80	0.213	-0.06	0.14	0.09
Participation in everyday life	2.50	0.34	2.50	0.33	-0.06	0.477	-0.07	0.06	0.01
Quality of life	1.49	0.75	1.48	0.80	0.13	0.447	-0.08	0.09	0.01

m – mean value; SD - standard deviation; t - Student's t-test result; p - significance; 95% CI - confidence interval for the difference between means; LL and UL - lower and upper limits of the confidence interval.

4. Discussion

In recent years, PROMs that have been developed in English-speaking countries for use in international clinical trials are gradually translated into Polish [17]. Our study was carried out to translate the original English NOOS questionnaire according to international guidelines into an understandable and equivalent Polish version [11]. Since the original version of NOOS was first developed and validated in 2015, multiple language versions of the questionnaire have been available [8-10], allowing researchers to compare study results and perform metanalysis.

Psychometric properties for clinical and research applications, comparable to other studies, the proof of the equivalence of the Polish and English versions of the questionnaire was the high consistency with the original, internal consistency (Cronbach's alpha at the level of 0.95), which

turned out to be comparable to the original version. The corresponding internal consistency is comparable to other versions of the NOOS language: Arabic [8], Turkish [9], Danish [10]. The total score and the NOOS individual domains had a very high ICC of 0.7, reflecting excellent reliability. The Polish translation of NOOS showed excellent psychometric properties.

So far, the only PROM available in Polish to assess the impact of NP and other ailments related to the cervical spine on daily living is the NDI [12]. However, the use of NDI is questioned due to the validation process, i.e., a broad selection of patients, achievement of data saturation, and lack of patient input [15]. The Polish version of the NOOS scale is a useful version for assessing pain-related symptoms of the cervical spine, which are important to the patient. This study contributes to the area of patient-reported outcome measures to assess the cervical spine problems available in the Polish language.

4.1. Strengths of the study

The strengths of this study include the use of standardized methods in all procedures and the large sample of patients with cervical spine complaints. The NOOS questionnaire has been specially developed for patients with cervical pain, which is of particular benefit to this group of patients. Furthermore, an additional advantage of the study is the rigorous translation of the questionnaire and the initial translation assessment by an independent group of four translators.

4.2. Limitations

Participants do not necessarily represent the entire spectrum of NP patients with respect to age or cause of symptoms, as the study was carried out online. The study by Rowen et al. indicates that the results of PROMs can be different when validation is carried out over the internet than the traditional method [18].

5. Conclusions

The NOOS questionnaire showed high test-retest consistency and high internal consistency. Translation of this questionnaire into Polish is important and credible in the context of evaluating the results of patients with cervical spine pain. The presented Polish version of the NOOS questionnaire can be used effectively for both clinical and research purposes, being the equivalent of the original English version.

Supplementary Materials: The following supporting information can be downloaded at: Preprints.org., Supplementary file 1.

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