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Polish Cross-Cultural Adaptation and Validation of the Knee Outcome Survey Activities of Daily Living Scale (KOS-ADLS) in Patients Undergoing Total Knee Arthroplasty

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEF G 1 **Magdalena Szczepanik**
ADE 1 **Agnieszka Bejer**
AD 1,2 **Sławomir Snela**
DE 1 **Daniel Szymczyk**
AB 2 **Jarosław Jabłoński**
EF 1 **Joanna Majewska**

1 Institute of Physiotherapy, Medical Faculty, University of Rzeszów, Rzeszów, Poland
2 Orthopedics and Traumatology Clinic for Adults, Clinical Hospital No. 2 in Rzeszów, Rzeszów, Poland

Corresponding Author: Magdalena Szczepanik, e-mail: mszczep@univ.rzeszow.pl

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Background: The Knee Outcome Survey Activities of Daily Living Scale (KOS-ADLS) is a self-reported questionnaire used for the evaluation of the overall health of patients with knee dysfunctions. The purpose of this study was to perform a cross-cultural adaptation of the Polish version of KOS-ADLS and to evaluate its psychometric properties in patients at the end-stage of knee osteoarthritis who were qualified for a total knee replacement (TKR).

Material/Methods: Seventy patients consecutively qualified for surgical TKR procedure participated in this study. To adapt the KOS-ADLS, the following scales and reference tests were used: Knee injury and Osteoarthritis Outcome Score (KOOS), Visual Analogue Scale (VAS), Time Up and Go test (TUG), and Five Times Sit to Stand test (5×STS). The studies were conducted 3 times: 2 weeks before surgery (first study), 6 to 13 days later (retest), and 6 months after surgery.

Results: The Polish version of KOS-ADLS showed excellent reliability (ICC=0.89 SEM=2.68, MDC=7.43) and high responsiveness (ES=4.76, SRM=3.18). The internal consistency was poor in the first assessment (Cronbach's alpha=0.68), but acceptable in the post-surgery evaluation (Cronbach's alpha=0.86). There were fair and moderate correlations found between KOS-ADLS and VAS scales in the first examination, TUG, and 5×STS. Stronger correlations were observed between the results obtained in KOS-ADLS and KOOS.

Conclusions: The Polish version of the KOS-ADLS demonstrated good reliability, validity, and responsiveness for use in patients who have undergone TKR surgery.

MeSH Keywords: **Arthroplasty, Replacement, Knee • Osteoarthritis, Knee • Validation Studies**

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Background

In recent years we have observed an increasing trend towards extending standard medical and radiological examinations of patients diagnosed with end-stage knee osteoarthritis (OA) by subjective, self-reported evaluation of overall health. This is related to the fact that results of medical examination and additional functional tests are not always consistent with patients' subjective symptoms, discomfort, and functional limitations in their activities of daily living. The extension of diagnostics with a subjective health evaluation enables monitoring and planning of the treatment of osteoarthritis in a more efficient way [1–3]. This kind of evaluation is also very important before planning total knee replacement (TKR), which is currently one of the most common orthopedic surgical procedure in patients with end-stage knee OA [4,5].

There are numerous patient self-reported questionnaires used in knee osteoarthritis. The majority of them were created in English-speaking countries; therefore, their application in different countries or communities speaking different languages or dialects and representing different cultures has created the need for translation, cross-cultural adaptation, and validation of these instruments. Such an adaptation should be conducted according to the methodology available in the scientific literature [6,7]. One of the scales commonly used in patients with hip and knee osteoarthritis is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [8]. Lysholm's scale, Cincinnati Knee Ligament Rating System (CKLRS), and International Knee Documentation Committee (IKDC) are the most popular scales used for the assessment of patients with knee joint ligaments and articular capsule injuries [9–11]. Additionally, IKDC can be used in patients with knee arthrosis. The Knee Injury and Osteoarthritis Outcome Scale (KOOS) is one of the scales used for the subjective assessment of patients with various knee disorders [12].

One of the subjective scales used to evaluate the overall health of a patients with various dysfunctions of the knee, including osteoarthritis, is the Knee Outcome Survey Activities of Daily Living Scale (KOS-ADLS). The KOS-ADLS was created as a self-reported questionnaire to evaluate symptoms and functional limitations experienced during activities of daily living by subjects with various knee disorders. This questionnaire was created by Irgang et al. in 1998 in Pittsburg (USA) [13]. Since then, the KOS-ADLS has been validated in various countries, including Germany, Portugal, Turkey, Greece, Japan, China, Brazil, Iceland, Canada, and Kuwait. KOS-ADLS has been found to be a reliable, valid, and responsive self-reported tool for patients with various knee disorders [3,14–22]. The purpose of this study was to perform a translation and cross-cultural adaptation of the Polish version of KOS-ADLS and to assess its reliability, validity, and responsiveness in a group of patients

diagnosed with end-stage knee OA and undergoing total knee replacement.

Material and Methods

The Knee Outcome Survey Activities of Daily Living Scale (KOS-ADLS)

The KOS-ADLS is a 14-item self-reported questionnaire designed to evaluate symptoms and limitation during activities of daily living among patients with various knee disorders, experienced within the last 1 to 2 days. First 6 items assess symptoms such as pain, stiffness, swelling, instability, weakness, and limping (subscale "symptoms"). Next 8 items assess subjects' functional limitation during daily activities such as walking, ascending and descending the stairs, standing, squatting, kneeling, sitting with bent knees, and getting up from a chair (subscale "activities of daily living"). Each item is scored on a 6-point Likert scale (0–5 points). The KOS-ADLS maximum final score is 70 points and it can be transformed to a 0–100% scale (where 100% indicates no symptoms and no limitation in daily activities) [13,14].

Translation and cross-cultural adaptation

The process of translation and adaptation was performed according to Beaton et al. and included 5 steps:

- Step I: Initial translation. Two independent translators whose first language is Polish (the physical therapist, who was informed about purpose of this study and an engineer, who was not informed about purpose of this one), performed translation from the original language into the Polish language.
- Step II: Synthesis of the translations.
- Step III: Back translation. Two independent native English speakers (not familiar with the original version of KOS-ADLS, without a medical background, and not informed about the aim of this translations) performed translations back into English.
- Step IV: Creation of the pre-final version. An expert committee (methodologist, orthopedic surgeon, physical therapists, all translators), after comparing all translations and discussing all discrepancies, created the Polish pre-final version of KOS-ADLS.
- Step V: Test of the Polish pre-final version. The pre-final version was tested on a cohort of 20 subjects undergoing physical therapy due to knee OA. After completing the questionnaire, each patient was interviewed to determine if all questions and instructions in the questionnaire were understandable. All the comments from the patients were discussed and evaluated by an expert committee and after minor modifications, the Polish version of KOS-ADLS (KOS-ADLS-P) was established [6].

Study population

The inclusion criteria in the study group were: qualification for TKR due to end-stage knee OA, ability to independently walk with or without walking aids (walking stick, crutches) and, patient written informed consent. All subjects participating in this study had to be native Polish speakers in order to understand and answer the questionnaire. The exclusion criteria in the study group were: previous injuries and surgeries of the lower limbs (hip joint, knee joint, and ankle joint); congenital defects of the lower limbs; presence of another, serious lower limb condition affecting patients function (e.g., hip osteoarthritis), for both operated and non-operated side; knee joint infections; other serious diseases reducing patients mobility; and taking medications that can reduce psychophysical skills.

We initially invited 102 patients, diagnosed with end-stage knee OA, who were qualified for TKR by experienced orthopedic surgeon (from January 2013 to March 2015), to participate in this study. Seventy-three patients who met the study inclusion criteria took part in the first assessment. Ten out of 29 remaining patients did not meet the study inclusion criteria, and 19 subjects did not agree to participate in this study. Additionally, 2 subjects did not take part in the postoperative assessment and 1 patient died. Seventy patients (59 females and 11 males, with a mean age of 66.5 years) were included for final analysis. The limited number of male subjects in this research can be partly explained due to the fact that the knee OA is far more common in women, and more women with the end-stage knee OA are qualified for the TKR surgery (Table 1).

All patients were operated on in the Orthopedics and Traumatology Clinic for Adults, Clinical Hospital No. 2 in Rzeszow (Poland) and the Department of Orthopedics and Traumatology of the Musculoskeletal System, The Holy Family Specialist Hospital in Rudna Mala/Rzeszow (Poland). The research project was carried out between January 2013 and September 2015. All patients had undergone a standard TKR surgical procedure (Columbus, Aesculap B. Braun, Germany). The knee replacement surgeries were performed by the same orthopedic surgeon team. All the patients had the same medical care, physiotherapy, and recommendations after surgery. To adapt the KOS-ADLS scale, the following scales and reference tests were used: Knee injury and Osteoarthritis Outcome Score (KOOS) and VAS, Time Up and Go test (TUG), and Five time sit to stand test (5×STS). The studies were conducted 3 times. The first examination took place 2 weeks before the surgery and consisted of medical interview, completion of both self-reported scales, VAS, and performance of all tests. The second examination was conducted within 6 to 13 days after the first study and its aim was to complete the KOS-ADLS questionnaire (retest). The test-retest time interval was selected according to the

Table 1. Baseline patient's characteristics.

Characteristic (n=70)	
Age at the surgery, mean (SD) years	66.5 (6.6)
Sex (Female/Male)	59/11
Symptoms durations, mean (SD) years	9.9 (7.5)

SD –standard deviation.

scientific literature, which indicates that 1 to 2 weeks is adequate and reasonable in such studies [23,24].

The third examination, conducted 6 months after the surgery, was identical to the first one.

Questionnaires

KOOS is a 42-item self-administered, knee-specific questionnaire, which includes questions about pain, symptoms, activities of daily living, sports and recreation, and knee-related quality of life. Each item is scored on a 5-point Likert scale. A score from 0 (extreme problems) to 100 (no problems at all) is calculated separately for each subscale. The KOOS had already been validated in Polish on a cohort of patients undergoing TKR due to end-stage knee OA [1,12].

VAS is a 0–10 scale in which the patient defines the level of pain, where 0 means no pain and 10 means extreme pain [14].

Functional tests

TUG is designed for the assessment of patients' mobility and fall risk. It consists of measuring the time it takes for a patient to stand up from a chair (height 46 cm), walk 3 meters, turn, walk back, and sit on the chair. The test is performed twice and the score is the average time achieved in the 2 trials [25,26].

5×STS is designed for the functional assessment of the lower-leg muscles strength and balance. It consists of measuring the time it takes a patient to stand up and sit down on a chair (height 46 cm) 5 times with arms crossed at the chest. The test was performed twice and the score is the average time achieved in 2 trials [27,28].

Ethical considerations

The study was approved by the Bioethics Committee of the Faculty of Medicine of the University of Rzeszow. All participants were informed about the procedures of these studies and signed written informed consent.

Statistical analysis

All statistical analyses were conducted using the Statistica 10.0 software. The level of statistical significance was assumed at $\alpha < 0.05$.

Study population

We compared the results obtained both in the preoperative and postoperative evaluation, between female and male subjects (age of the patients, VAS, TUG, 5×STS Test, KOS-ADLS-P, KOOS). Normal distribution of the results was verified using Shapiro-Wilk test. A parametric *t* test and non-parametric Mann-Whitney *U* test were used for the purpose of this statistical analysis.

Clinical validation study

The results of KOS-ADLS-P are presented as a percentage of the maximal score (final result divided by 70 and then multiplied by 100 percent).

Normal distribution of the results of this study was verified using Shapiro-Wilk test. A non-parametric Wilcoxon test was used for the basic statistical analysis.

Reliability

The test-retest reliability

The test-retest reliability reflects the stability of the tested questionnaire (tool) over time. To assess the reliability of the KOS-ADLS-P, 54 patients were asked to complete the questionnaire on 2 nonconsecutive days (range 6–13 days intervals, preoperatively). We used the intraclass correlation coefficient (ICC) with 95% confidence interval (CI). The ICC values were described as follow: poor reliability < 0.20 , fair reliability between 0.21 and 0.40, moderate reliability between 0.41 and 0.60, good reliability between 0.61 and 0.80, and excellent reliability ≥ 0.81 [29]. Additionally, the standard error of measurement (SEM) and the minimal detectable change (MDC) were calculated. SEM is the random error of a patient's score, which estimates how repeated measures of a person on the same tool tend to be distributed around the true score. SEM was calculated as follows: $SEM = SD \sqrt{1-R}$, where SD represents SD of the sample and R the reliability parameter (ICC). MDC is a statistical evaluation of the smallest amount of change that can be detected by a measure that corresponds to a noticeable change in ability. MDC was calculated as follows: $MDC = SEM \times 1.96 \times \sqrt{2}$, where 1.96 derives from the 0.95% CI of no change, and $\sqrt{2}$ shows 2 measurements assessing the change [30].

Internal consistency

Internal consistency indicates the strength of the inter-related items in the instrument. It was calculated by using Cronbach's alpha coefficient, preoperatively and postoperatively. An alpha value ≥ 0.7 is acceptable [24,31].

Validity

Construct validity is defined as the degree to which the instrument measures the characteristics to be measured. To assess the validity of the KOS-ADLS-P, 72 patients were asked to complete KOOS and VAS and to perform functional tests: TUG and 5×STS (preoperative examination). The results obtained from these scales and functional tests were compared using Spearman's rank coefficient. Correlations were classified as: poor ($r \leq 0.20$), fair ($r = 0.21$ to 0.40), moderate ($r = 0.41$ to 0.60), very good ($r = 0.61$ to 0.80), and excellent ($r > 0.81$) [19]. We hypothesized that correlations between the KOS-ADLS-P and KOOS, VAS, TUG, and 5×STS would be moderate.

Floor/ceiling effect

Floor and ceiling effects were evaluated preoperatively and postoperatively and were considered present if the percentage of the lowest or highest scores on the self-reported scale was greater than 15% [24].

Structural validity

Factors analysis was performed using principal component analysis with varimax rotation, and retained factors had eigenvalues > 1 [32].

Responsiveness

The responsiveness of the instrument is defined as the ability to detect changes in health status of patients who have undergone some medical procedure (e.g., TKR) over time. Husted et al. suggest assessing 2 kinds of responsiveness: internal and external responsiveness [33]. To assess external responsiveness of the KOS-ADLS-P, we compared the results obtained preoperatively and postoperatively from KOS-ADLS-P, KOOS, TUG, and 5×STS. We expected that the changes in KOS-ADLS-P would moderately correlate with changes in KOOS and the functional tests. To compare the changes of results obtained in the preoperative and postoperative examinations, Spearman's rank coefficient was calculated. Correlations were described as: poor ($r \leq 0.20$), fair ($r = 0.21$ to 0.40), moderate ($r = 0.41$ to 0.60), very good ($r = 0.61$ to 0.80), and excellent ($r > 0.80$) [19]. To assess the internal responsiveness, we calculated standard effect size (ES) and standardized response mean (SRM). ES is defined as a score change in KOS-ADLS divided by baseline SD, and SRM

Table 2. Test-retest of KOS-ADLS-P (6–13 days interval).

KOS-ADL-P (n=54) (number of items)	ICC (95% CI)	SEM	MDC
Symptoms (6)	0.8916 (0.8202–0.9356)	4.03	11.18
Activities of daily living (8)	0.8853 (0.8102–0.9318)	2.62	7.27
Total score of KOS-ADLS-P	0.8905 (0.8185–0.9350)	2.68	7.43

KOS-ADLS-P – Polish version of the Knee Outcome Survey Activities of Daily Living Scale; ICC – intraclass correlation coefficient; 95% CI – 95% confidence interval; SEM – standard error of measurement; MDC – minimal detectable change.

Table 3. Internal consistency of KOS-ADLS-P, pre and postoperative evaluation.

KOS-ADL-P (n=70) (number of items)	Cronbach's alpha preoperative evaluation	Cronbach's alpha postoperative evaluation
Symptoms (6)	0.59	0.75
Activities of daily living (8)	0.65	0.79
Total score of KOS-ADLS-P	0.68	0.86

KOS-ADLS-P – Polish version of the Knee Outcome Survey Activities of Daily Living Scale.

was calculated by dividing the mean score change by the SD of that score change. Values of 0.20, 0.50, and 0.80 or greater represent small, moderate, and large responsiveness, respectively, for ES and SRM [33].

Results

Translation and cross-cultural adaptation

The translation and adaptation procedure revealed no major content or linguistic problems. The KOS-ADLS-P was well evaluated by patients with knee OA. The patients did not have any problems with understanding the instructions in the pre-final version of KOS-ADLS-P, the questions and answer options except for the question about giving way, buckling, or shifting of the knee. After discussion, the expert committee modified this question and the new version of KOS-ADLS-P was used in further studies.

Study population

There were no statistically significant differences between female and male subjects, excluding 2 parameters (KOS-ADLS-P activities of daily living in the pre-surgery evaluation $p=0.048$ and KOOS sport and recreation in the post-surgery evaluation $p=0,002$); therefore, we decided to evaluate the psychometric properties of KOS-ADLS regardless of the subject's gender (together for male and female).

Clinical validation study

Reliability

The reliability of all KOS-ADLS-P subscales was excellent. The value of ICC ranged from 0.88 to 0.89 ICC (Table 2). SEM ranged from 2.62 to 4.03 and MDC ranged from 7.27 to 11.8 (Table 2).

Internal consistency

In the preoperative study, the internal consistency was poor – Cronbach's alpha ranged from 0.59 to 0.68 (Table 3). We have also evaluated the alpha coefficient from data obtained in the postoperative examinations, which ranged from 0.75 to 0.86.

Construct validity

We observed fair to moderate correlation between KOS-ADLS-P and VAS (r from -0.30 to -0.47), and between KOS-ADLS-P and the functional test (TUG: r from -0.39 to -0.50 , 5×STS: r from -0.26 to -0.43). There were stronger correlations between KOS-ADLS-P and subscales of KOOS (r from 0.15 to 0.63) (Table 4).

We observed the floor/ceiling effects, both in the preoperative and postoperative evaluation. In preoperative evaluation, the floor effects (indicating worst possible status) were found for the questions about performing the squat (76%) and kneeling (84%). The ceiling effects (indicating best possible status) were observed for the questions about the presence of swelling (39%) and giving way of the knee (41%). In the postoperative evaluation, the floor effects concerned the question about

Table 4. Construct validity evaluation, correlation between KOS-ADLS-P and VAS, TUG, 5×STS test and KOOS.

Reference tools (n=70)	KOS-ADLS-P preoperative evaluation (n=70)					
	Symptoms (p value)		Activities of daily living (p value)		Total score of KOS-ADLS (p value)	
VAS	-0.41	(0.0004)	-0.30	(0.0114)	-0.47	(0.0000)
TUG	-0.39	(0.0008)	-0.48	(0.0000)	-0.50	(0.0000)
5×STS test	-0.26	(0.0307)	-0.43	(0.0002)	-0.38	(0.0013)
KOOS						
Symptoms	0.53	(0.0000)	0.15	(0.2074)	0.42	(0.0003)
Pain	0.34	(0.0046)	0.48	(0.0000)	0.48	(0.0000)
Activities of daily living	0.42	(0.0003)	0.58	(0.0000)	0.63	(0.0000)
Sport and recreation	0.15	(0.2250)	0.47	(0.0000)	0.33	(0.0060)
Quality of life	0.37	(0.0015)	0.43	(0.0002)	0.48	(0.0000)

KOS-ADLS-P – Polish version of the Knee Outcome Survey Activities of Daily Living Scale, VAS – visual analogue scale; TUG –Time Up and Go test, 5×STS – five time sit to stand test; KOOS – Knee injury and Osteoarthritis Outcome, p-value of statistical significance.

Table 5. Factor analysis and varimax rotated factor matrix for KOS-ADLS-P, (n=70).

Factor	Eigenvalues	% Variance	Cumulative%	
Factor 1	3.32	23.7	23.7	
Factor 2	1.89	13.5	37.3	
Factor 3	1.64	11.7	49.0	
Factor 4	1.15	8.2	57.2	

The strongest correlations are highlighted				
Item	Factor 1	Factor 2	Factor 3	Factor 4
ADLS 1	0.51	0.10	0.45	-0.01
ADLS 2	0.51	0.15	0.13	0.10
ADLS 3	0.51	0.02	0.09	0.30
ADLS 4	0.27	-0.28	0.33	0.09
ADLS 5	0.82	-0.05	-0.02	-0.09
ADLS 6	0.85	-0.06	0.09	-0.16
ADLS 7	0.32	0.13	0.66	0.05
ADLS 8	0.02	0.08	0.83	0.10
ADLS 9	-0.02	0.02	0.80	-0.17
ADLS 10	0.11	-0.04	0.61	0.38
ADLS 11	-0.04	0.86	0.07	-0.11
ADLS 12	0.16	0.81	0.10	0.16
ADLS 13	-0.04	-0.02	0.08	0.83
ADLS 14	0.06	0.50	-0.03	0.53

Table 6. External responsiveness evaluation, correlation between changes in KOS-ADLS-P and changes in VAS, TUG, 5×STS test and KOOS.

Reference tools (n=70)	KOS-ADLS-P (n=70)		
	Symptoms (p value)	Activities of daily living (p value)	Total score of KOS-ADLS-P (p value)
VAS	-0.68 (0.0000)	-0.54 (0.0000)	-0.68 (0.0000)
TUG	-0.19	-0.12	-0.15
5×STS test	-0.12	-0.18	-0.13
KOOS			
Symptoms	0.51 (0.0000)	0.25 (0.0334)	0.45 (0.0001)
Pain	0.56 (0.0000)	0.55 (0.0000)	0.64 (0.0000)
Activities of daily living	0.45 (0.0001)	0.74 (0.0000)	0.73 (0.0000)
Sport and recreation	0.17 (0.1689)	0.38 (0.0011)	0.29 (0.0145)
Quality of life	0.50 (0.0000)	0.46 (0.0001)	0.52 (0.0000)

KOS-ADLS-P – Polish version of the Knee Outcome Survey Activities of Daily Living Scale; VAS – visual analogue scale; TUG – Time Up and Go test, 5×STS – five time sit to stand test; KOOS – Knee injury and Osteoarthritis Outcome; p-value of statistical significance.

kneeling (83%). We observed ceiling effects for the question about giving way (86%).

Structural validity

Principal component analysis extracted 4 factors with eigenvalues >1, which contain 57% of the information derived from 14 baseline questions in the KOS-ADLS-P. Varimax rotation showed that the first factor comprised 5 items related to the symptoms. This factor was not related to the item “giving way”, which was characterized with low factor loading. The second factor comprised 2 items related to kneeling and squatting. The third factor comprised 4 items concerning standing and mobility, and the fourth factor comprised 2 items concerning sitting with bent knees and getting up from a chair (Table 5).

Responsiveness

The results of our study did not reveal significant correlations between the changes in KOS-ADLS-P and the functional tests (data from preoperative and postoperative evaluation), while we observed moderate and very good correlations between KOS-ADLS-P and VAS (r from -0.54 to -0.68). Stronger correlations were shown between the changes in KOS-ADLS-P and the changes in subscales of KOOS (r from 0.17 to 0.74) (Table 6). We calculated ES and SRM for KOS-ADLS-P, KOOS, VAS, TUG, and 5×STS. The value of ES for KOS-ADLS-P, KOOS ranged from 2.96 to 4.83, and value of SRM for KOS-ADLS-P ranged from 2.39 to 3.18 (Table 7).

Discussion

The purpose of this study was to translate the KOS-ADLS into the Polish language and to evaluate its psychometric properties in patients diagnosed with end-stage knee OA undergoing TKR.

Performing the complex validation and adaptation process of KOS-ADLS, according to current standards and guidelines, allows for its widespread and valid use in clinical practice and scientific research. The KOS-ADLS is a self-reported questionnaire widely used for the evaluation of patients with different knee disorders, but it has not been validated in Poland. Moreover, only few questionnaires for patients with knee dysfunctions have been comprehensively adapted and validated in Poland. Sometimes, only translation and adaptation are needed. One such scale, which was translated, adapted, and comprehensively validated in Poland, is KOOS. Its validation and assessment of psychometric properties was performed in patients with ACL injury, as well as in patients undergoing TKR [1,30]. That was the reason for using KOOS as a reference tool in our study. Lysholm’s scale and IKDC were also translated into Polish language, but the authors evaluated only internal consistency using Cronbach’s alpha and reliability using the Wilcoxon test [34]. Lysholm’s scale was also used in patients with ACL, meniscus, and cartilage injuries. There is also a Polish version of the WOMAC scale available [35]. The main advantages of the KOS-ADLS against other similar scales are as follows: KOS-ADLS is easy to understand and quick to complete (in our study, the mean time for completing the questionnaire was 6 minutes), and consisted of only 14 items, which

Table 7. Internal responsiveness evaluation of KOS-ADLS-P and reference tools.

KOS-ADLS-P (n=70)	\bar{x}	SD	ES	SRM
Symptoms	35.5	14.8	2.96	2.39
Activities of daily living	36.7	12.5	4.83	2.94
Total score of KOS-ADLS-P	36.2	11.4	4.76	3.18
Reference tools (n=70)				
VAS	-5.9	2.0	4.36	2.95
TUG	-2,1	3.1	0.62	0.68
5xSTS test	-4,1	5.7	0.63	0.72
KOOS				
Symptoms	36.6	19.5	2.46	1.88
Pain	46.6	15.5	4.75	3.01
Activities of daily living	39.7	16.1	3.86	2.47
Sport and recreation	6.9	9.9	1.03	0.7
Quality of life	33.4	16.0	2.58	2.09

KOS-ADLS-P – Polish version of the Knee Outcome Survey Activities of Daily Living Scale; VAS – visual analogue scale; TUG – Time Up and Go test; 5xSTS – five time sit to stand test; KOOS – Knee injury and Osteoarthritis Outcome; \bar{x} – mean change in KOS-ADLS and reference tools after total knee replacement; SD – standard deviation; ES – effect size; SRM – standardized response mean.

reflects the main symptoms and limitations during activities of daily living in patients with a wide spectrum of knee disorders. KOS-ADLS has also been widely used in many scientific research and clinical settings [36–38]. It is essential to implement standardized scales in scientific research and clinical practice. Moreover, such an instrument should have very solid psychometric properties to justify its clinical use [3]. The original English version of KOS-ADLS showed very good psychometric properties, so we hypothesized that the Polish version of KOS-ADLS would also show good psychometric characteristics, following an appropriate process of its translation and adaptation [13].

The translation and adaptation procedure revealed no major content or linguistic problems. In this study, we observed an excellent test-retest reliability (ICC ranged from 0.88 to 0.89, with SEM 2.68 and MDC 7.43). The interval between the test and retest assessment ranged from 6 to 13 days. This result was lower when compared with the original version created by Irgang (ICC 0.97) and results obtained in the adaptation of KOS-ADLS performed in other countries (Kuwait – ICC=0.97, Turkey – ICC=0.99, Greece – ICC=0.97, Portugal – ICC=0.97, Germany – ICC=0.97, Canada – ICC=0.92, China – ICC=0.94, Iceland – ICC=0.95) for total score of KOS-ADLS) [3,13–17,19,21,22]. The higher value of ICC observed in other studies can be explained by the shorter interval between the test and retest assessment than in our study; the test-retest assessment performed in the original study conducted by

Irgang took place on the same day, before and after the first session of physiotherapy [13]. To assess internal consistency of the KOS-ADLS-P, we used Cronbach’s alpha coefficient. It is well-accepted that Cronbach’s alpha values between 0.70 and 0.95 indicate good internal consistency [31]. In our study, values in the first examination were lower (0.69 for total score of KOS-ADLS-P). Our study group was very homogeneous, so we expected that the results of the assessment of internal consistency would be similar to those obtained by other researchers. The results of Cronbach’s alpha in the other studies ranged from 0.87 in the Canadian research to 0.99 in the Brazilian research [3,13–17,19–22]. Therefore, we decided to assess internal consistency using data obtained from postoperative evaluation, and Cronbach’s alpha value was 0.86 for the total score of KOS-ADLS-P.

The KOOS, VAS, TUG, and 5xSTS tests were used in our study as reference tools to assess the construct validity of the KOS-ADLS-P. KOOS was chosen because this questionnaire was validated in Poland in patients undergoing TKR due to end-stage knee OA and it is characterized by high reliability, validity, and responsiveness [1]. In previous validation studies of KOS-ADLS, the researchers used different questionnaires, such as Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), International Knee Documentation Committee (IKDC), Short Form 36 (SF-36), Global Rating of Function (GRF), or Lysholm’s Knee Scale, which are also focused on symptoms presenting in knee disorders (including knee OA) and limitation

in activities of daily living. In those studies, the correlations between KOS-ADLS and reference questionnaires, excluding SF-36, were very good and excellent [3,13,15,19,20]. The SF-36 questionnaire was used to validate the Arabic, Portuguese, Brazilian, and Chinese versions of KOS-ADLS [3,15,19,20]. The level of correlation depended on which subscale of SF-36 was correlated with KOS-ADL. In the Chinese version, the authors found the correlations ranged from poor (subscale “mental health”) to very good (subscale “physical function”) [19]. In the original version of KOS-ADLS, Irgang et al. used the GRF and Lysholm’s Knee Scale to assess validity. They reported higher correlations between KOS-ADLS and GRF than between KOS-ADLS and Lysholm’s Knee Scale [13]. In our study, the strongest correlation was observed between the total score of KOS-ADLS-P and subscale “activities in daily living” of KOOS ($r=0.63$). VAS is easy to administer by patients and it was used in further validation processes conducted in other countries. Our result ($r=-0.47$ for total score of KOS-ADLS-P) was similar to validations conducted in Greece ($r=-0.42$), in Portugal ($r=-0.53$), in Brazil ($r=-0.5$), in Canada (r ranged from -0.38 to -0.57), and in Turkey ($r=-0.56$), but was much less than those in Iceland ($r=-0.73$) and in the German version of KOS-ADLS ($r=-0.78$) [14–17,20–22]. The functional tests were included in this study because the main limitations in activities of daily living in patients with end-stage knee OA and after TKR concerned using stairs (especially going down the stairs) and getting up from a chair [39,40]. We expected that these functional tests would correlate moderately with subscale “activities of daily living” of KOS-ADLS-P, and our results (TUG $r=-0.48$, 5×STS test $r=-0.43$) confirmed this hypothesis. Similar results were obtained by Bizinni (TUG $r=-0.46$) and by Briem (TUG $r=-0.49$), but a much smaller correlation was reported by Evcik (TUG $r=-0.22$) [14,16,21]. In the Arabic version of KOS-ADLS, there was a moderate correlation between total score of KOS-ADLS and TUG ($r=-0.60$). In the validation studies of KOS-ADLS conducted in Germany, Kuwait, and Turkey, the ascending/descending stairs test was used and moderate correlations were observed [3,14,16]. Evcik et al. noticed that the lack or low level of correlations between the results of self-reported questionnaires and functional tests in this group of patients could be explained by the fact that some patients exaggerate or minimize their complaints, thus leading to discrepancies between patients’ self-reported assessment and evaluation using functional tests [16]. De Groot et al. assessed the level of actual physical activity in patients with end-stage knee or hip OA compared with healthy controls. They noticed that the patients’ perception of their function concerning activities of daily living does not always correspond with their actual physical activity [41].

In our study, we observed a very high level of floor/ceiling effects in preoperative assessment. The floor effect concerned question about squatting and kneeling, but this was not

surprising because our study group consisted of patients with end-stage knee OA, who usually avoid this activity due to the high level of pain and muscle weakness. The ceiling effect concerned the question about swelling and giving way, which are the symptoms that occur more often in patients with ligamentous or meniscal injuries. After surgery, we observed a floor effect for the question about kneeling and a ceiling effect for the question about giving way. The presence of a floor effect for the question about kneeling in postoperative evaluation could be explained by the fact that patients after TKR have a high level of fear related to kneeling. Palmer et al. asked 75 patients after TKR (at less 6 months) about their ability to kneel and asked them to demonstrate this movement. They found that 80% of patients avoided kneeling because of the fear of damage of the prosthesis or because they were told to avoid this type of activity by medical staff or friends, although 64 patients were actually kneeling without discomfort [42].

The assessment of structural validity of KOS-ADLS-P extracted 4 factors with eigenvalues >1 , which is comparable to the results obtained by Roy [22]. In the original version of KOS-ADLS, items from 1 to 6 create the first subscale “symptoms” [13]. In our study, principal component analysis of KOS-ADLS-P revealed the proper location of the 5 items, which describes symptoms, in factor 1. This factor was not related with the item “giving way”; our study group consisted of patients with end-stage knee OA, and this symptom is more characteristic for patient with ligamentous injury. In the original study, items from 7 to 14 describes limitations in daily activities. Due to the fact that in structural analysis of KOS-ADL-P, the second factor (knelling, squatting), the third factor (standing, mobility), and the fourth factor (sitting with bent knees, getting up from chair) comprised items concerning limitation in daily activities, they were left in one subscale, “activities in daily living”.

The results of the responsiveness evaluation confirmed the ability of the KOS-ADLS-P to detect clinical changes in patients undergoing TKR (total ES 4.76, total SRM 3.18). Our results were much higher than those obtained by Irgang in the original study (ES 0.44, 0.94, 1.94 respectively after 1, 4, and 8 weeks of physical therapy) as well as in validations of KOS-ADLS conducted in other countries [3,13,15,17,19,22]. This can be partly explained by the fact that in those studies, the responsiveness of KOS-ADLS were assessed in patients undergoing physical therapy due to various knee disorders such as patellofemoral pain, ligamentous or meniscal injury, tendinopathy, or knee OA. The clinical changes in the patients’ health status were not as significant as in patients undergoing TKR. A high value of SRM (1.1) was also observed in a study conducted by Marx et al., who assessed patients with primary knee disorders a minimum of 3 months after operative or non-operative treatments [36]. Williams et al. assessed reliability and responsiveness of 3 self-reported questionnaires,

including WOMAC, KOS-ADLS, and Lower Extremity Functional Scale (LEFS), on patients with knee OA undergoing physical therapy. The assessment took place 3 times: after 2, 6, and 12 months of physical therapy. They reported similar high reliability and responsiveness to detect the changes in this group of patients for all questionnaires [37].

There are some limitations of our study. The first limitation concerns our study group, which consisted only of patients with end-stage knee OA who were qualified for TKR. Because the KOS-ADLS was created as a self-reported questionnaire to assess patients with an entire spectrum of knee disorders, we see the need for checking its psychometric properties in patients with patellofemoral pain, ligamentous or meniscal injury, or tendinopathy, undergoing physical therapy or some surgical treatment. Besides, in our study, women constituted 84.3% of the study population. This is because the incidence of symptomatic knee OA is 2 to 3 times higher in women than in men. Additionally, women are more often qualified for TKR because they develop more severe symptoms of knee OA than men [43,44].

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Conclusions

The result of our study was creation of a Polish version of KOS-ADLS, which has undergone complex procedure of translation, adaptation, validation, and assessment of its psychometric properties in patients diagnosed with end-stage knee OA and undergoing total knee replacement, according to current standards and guidelines. The translation and adaptation procedure of the Polish version of KOS-ADLS revealed no major content or linguistic problems, as reported by the subjects participating in this study.

The Polish version of KOS-ADLS is a reliable, valid, and responsive tool to assess symptoms and functional limitations due to end-stage knee OA in patients undergoing TKR. The good psychometric properties of KOS-ADLS-P indicate that it can be used as a standardized, patient self-reported, and disease-specific scale in clinical practice and in national and international health care projects concerning patients with end-stage knee OA.

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