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TRANSLATION, VALIDATION AND CULTURAL ADAPTATION OF THE 'ACTIVITIES OF DAILY LIVING' SCALE (ADLS)

PRISCILA ZEITUNE NIGRI¹, MARIA STELLA PECCIN², GUSTAVO JERÔNIMO DE MELO ALMEIDA³, MOISES COHEN⁴

SUMMARY

Objectives: To perform the translation, cultural adaptation and validation of the "Knee Outcome Survey- Activities of Daily Living Scale" (ADLS) into Portuguese, as well as to check its measurement, reproducibility and validity properties in order to make it useful as a specific instrument for evaluating symptoms in Brazilian patients with knee injuries during their daily living activities. Methods: Two interviews were performed; in the first interview, the questionnaire was applied along with Lysholm's, SF-36 and VAS (investigator 1). Approximately 30 minutes after the first interview, the same patients answered only the ADLS (investigator 2). After a break of 7 to 10 days,

a third additional interview with the ADLS was applied (investigator 2). Results: The sample was constituted of 53 subjects, with mean age of 33.0566 years, with the most frequent pathology being ligamentar injury (56.6%). The Spearman's index used for inter-investigator reproducibility was 0.986 (a=0.05, r<0.01), and for intra-investigator reproducibility was 0.980 (a=0.05, r<0.01). Conclusion: The Portuguese language version of ADLS questionnaire is a useful instrument for assessing daily living activities of Brazilian patients with knee injuries.

Keywords: Questionnaires; Evaluation; Activities of daily living; Translation; Validation studies.

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INTRODUCTION

There is a consensus in literature about the need of an evaluation scale for treatment outcomes in individuals with knee injuries in order to provide a standardized method that may be consistently reproduced and report the outcomes of established treatments⁽¹⁾.

The use of questionnaires as evaluation parameters is useful, because it enables to standardize, equalize and reproduce the intended measurements⁽²⁾. However, the selection of an evaluation segment should consider if its components are clear, simple, easy to understand and to apply, and if they have an appropriate application time⁽³⁾. When a questionnaire is prepared, its measurement properties must be first tested and validated in a group of patients, so that it can be subsequently used in population-based studies⁽⁴⁾.

With the development of translation and cultural adaptation methods, it is much likely that an instrument developed for use in a given language and culture could also be used - after translated and adapted - in another language and cultural context⁽⁵⁾.

After performing a literature review, with the analysis of translation and cultural adaptation methodologies designed for questionnaires addressing quality of life, where differences were seen particularly regarding the number and qualification of the involved translators in each phase, Guillemin et al.(6), proposed a standardization for process development, providing guidance regarding the number, sequence and complexity of the phases to be followed.

It is important to highlight that, by describing how compromised an individual's quality of life or health status is, although assessing it from a broader view, we can show how impacting is a condition to the social or health aspects of an individual⁽⁷⁾.

The knee is a load joint, with wide range of motion, located at the central portion of the lower limb. Joint surfaces formed by femoral condyles, by tibial plateau, and by the patella allow for some medial and lateral rolling, sliding and rotational movements. Supported by static (meniscus, ligaments and capsules) and dynamic stabilizers (muscles and tendons), this is a joint subjected to a higher number of mechanical conditions⁽⁸⁾.

Due to the importance of knee joint and to the large number of injuries in it ⁽⁸⁾, the activities of daily living are usually likely to change when some condition is detected in this segment of lower limbs, but that makes difficult to measure to what extension this condition impacts an individual's quality of life.

O'Donoghue⁽⁹⁾ was the first to develop a system for assessing outcomes. Larson⁽¹⁰⁾ developed a scale with 100 score points based on subjective, objective and functional criteria. Irrgang et al.⁽¹¹⁾ developed and validated the ADLS questionnaire, which intends to show a functional measurement for knee conditions during the activities of daily life. This questionnaire is constituted of 14 items, with closed answers alternatives, being divided as follows: items 1-6 measure commonly expressed symptoms during activities of daily living by an individual with knee pathology and injury; items 7-14 address the function during activities of daily life. The score includes only those 14 items, reaching to a maximum score of 70 points, and these are factored out in the measurement, which is graded 0 -100⁽¹⁰⁾.

Study conducted at the Department of Orthopaedics and Traumatology, Paulista Medical School, Federal University of São Paulo (DOT-EPM/UNIFESP).

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Correspondences to: Rua Caraíbas, 684/73, Perdizes - Cep: 05020-000 , São Paulo - SP - E-mail: prinigri@ig.com.br

¹⁻ Master student in Locomotive Apparatus Applied Sciences - UNIFESP.

²⁻ Associate Professor, Department of Health Sciences, UNIFESP.

³⁻ Researcher - PhD student, Department of Physical Therapy, University of Pittsburgh

⁴⁻ Associate Professor, Full Professor, Department of Orthopaedics and Traumatology, Paulista Medical School, UNIFESP.

The ADLS also includes 3 additional items that were not included in the score. The answers to those items are reported separately in order to provide an overall description of an individual's function level. One item is designed for electing the overall knee function rate during usual activities of daily life within a scale ranging from 0 to 100, with 100 being the level of function previously to injury/ trauma and 0 (zero) being the inability of performing any usual activity of daily life. In the two remaining items, the individual is requested to describe his/ her overall knee function during activities of daily life and their current rate for daily activities as normal, almost normal, abnormal, extremely abnormal⁽¹⁰⁾.

The present study is intended to provide a translation, cultural adaptation and validation of the worldwide accepted questionnaire Activities of daily living scale (ADLS), for demonstrating the functional measurement imposed by knee disorders and injuries during the activities of daily life. For this process, we followed the rules proposed by Guillemin et al.⁽⁶⁾.

METHODS

The survey consists of a cross-sectional study. Fifty-three patients presenting with knee-related complaints were randomly selected, who had been diagnosed by an orthopaedic doctor by means of clinical and imaging tests. This study was approved by the Committee on Ethics in Research (nr. 0884/05) of the Federal University of São Paulo, Paulista Medical School.

The patients selected for this study were those who fit the following inclusion criteria:

• Brazilian patients, at least 15 years old, with ligament injury, meniscal injury, cartilage injury, recurrent patelar dislocation, knee tendonitis either isolated or combined diagnosis, either surgical or non-surgical.

• Diagnosis complemented by imaging studies (X-ray, ultrasound, computed tomography or magnetic resonance).

• Patients not submitted to medication changes or to any other procedure, for the last 15 days, for evaluating questionnaire reproducibility;

• Informed consent form signed by the patient or caregiver.

Patients with acute trauma, cognitive changes and with conditions of other lower limb's joints were excluded from the analyses.

The ADLS was translated by following the translation, cultural adaptation and validation protocol proposed by Guillemin et al.⁽⁶⁾. At the first phase, the questionnaire was translated from English into Portuguese by two different translators and English teachers. Both translations were compared and adapted by the multidisciplinary committee, building version 1. This version was then translated back into the original language by two native translators. After that phase, the committee constituted of a multidisciplinary team with expertise on the researched disease reviewed the

translation. From these two new versions, a single English version was built, which was then compared to the original one in order to check for equivalence. This version was named version 2, Figure 1.

Version 2 was applied to 12 patients randomly selected according to the inclusion criteria, intending to check for equivalence between the original and final versions, assessing errors and deviations made during translation process. As over 10% of the population considered 2 questions as difficult to understand, the review committee consulted the author of the present questionnaire under translation, cultural adaptation and validation for further explanations. Version 2 was then changed, maintaining the original objectives of the ADLS. The new version was applied to a second pilot group constituted of 11 patients with the same characteristics as the previous group, but, this time, the questionnaire was understood by over 95% of the interviewed individuals, resulting in a definitive version.

Adjusting scores weights was not required, because the changes do not alter the system.

Sample measurement was performed by using a 95% confidence interval, 80% power and a maximum sampling error equal to 40% standard deviation, resulting in a sample size (n) of 49 patients.

Reproducibility assessment was made by applying the definitive version of the ADLS in 53 patients meeting pre-established inclusion criteria. In the first interview, the questionnaire was applied together with the Lysholm's, SF-36 and EAV questionnaires by investigator 1. Approximately 30 minutes after the first interview, the patients answered only to ADLS, now applied by investigator 2 (inter-investigator evaluation). After a time interval of 7-10 days, the third interview was made, which constituted of a re-application of the questionnaire under validation - the ADLS - conducted by one of the investigators (investigator 2 - intra-investigator evaluation).

After that phase, collected data were assessed by means of statistical analysis in order to evaluate inter- and intra-investigator reproducibility, as well as data correlation between ADLS and Lysholm's questionnaires, SF-36 and pain visual analogous scale.



Figure 1- Summary of the methodology employed

RESULTS

The sample was constituted of 53 interviewed individuals, with 33 males (62.3%) and 20 females (37.7%). The mean age was 33.06 years (standard deviation 13.13), ranging from 15 to 70 years. Regarding pathology, the most common one was ligament injury (56.6%) (Chart 1).

When we assess the inter-investigator reproducibility (by comparing investigator 1 to the first interview conducted by investigator 2), we can see that the Sperman's index shows a strong positive correlation of 0.986 (α =0.05, ρ <0.1), Graph 1. When the mean intra-class correlation coefficient between total 1 and total 2 values was analyzed, we also see a strong correlation of 0.997 (CI 95%: lowest lim =0.995 and highest lim = 0.998).

The results obtained from the ADLS questionnaire in the 2nd and 3rd interview (investigator 2) were used as a parameter for intra-investigator reproducibility analysis. When we analyzed the result of total score, we find a strong and positive correlation of Sperman's index of 0.980 (α =0.05, ρ <0.01), according to Graph 2. We could also see a strong correlation on mean total intra-class correlation coefficient 2 and 3: 0.996 (Cl 95%: lowest lim=0.993 and highest lim=0.997).

When we assess the consistency of the first interview ap-

	Frequency	Percentage	
Cartilage injury	11	20,8	
Ligament injury	30	56,6	
Meniscal injury	6	11,3	
Recurrent patelar			
injury	2	3,8	
Tendonitis	4	7,5	

Chart 1- Frequency and percentage of pathologies in the studied sample.



Graph 1 - Inter-investigator correlation of ADLS questionnaire total scores.



Graph 2 - Intra-investigator correlation of ADLS questionnaire total scores.

plying the ADLS questionnaire by one investigator, compared to the subsequent interviews with the same patient, but at two different moments in time, we can see that the median was very similar between those conditions, as well as scoring variability, resulting in an excellent reproducibility. The Chronbach's coefficient shows a good internal consistency, as shown (Chart 2).

	Chronbach's alpha		
Total 1 and total 2	0,997		
Total 2 and total 3	0,996		

Chart 2 – Inter- and Intra-investigator consistency values We found that the correlations between questionnaires ADLS and SF-36 achieved statistical significance (ρ =0.05) when the Sperman's correlation

coefficient (r) was used, the scales: Functional Capacity (r = 0.848; ρ =0.000), Physical Aspect (r= 0.463; ρ =0.000), Pain (r = 0.496; ρ =0.000), Overall Status (r= 0.300; ρ =0.029) and Social Aspects (r= 0.362; ρ =0.008), respectively. Regarding Vitality, Emotional Aspects and Mental Health, the correlations were found to be weak, with a b value not statistically significant (r= 0.227 and ρ =0.102; r = 0.193 and ρ =0.165; r = 0.159 and ρ =0.256, respectively).

The score on ALDS questionnaire shows a strong positive correlation with Lysholm's ordinal scoring, showing a correlation coefficient of 0.783 with a significant statistics (ρ =0.05, ρ <0.01), and with Lysholm's nominal scoring, coefficient of 0.792 with a significant statistics (ρ =0.05, ρ <0.01).

The score on ADLS questionnaire shows a moderate negative correlation with the pain visual analogous scale, showing a correlation coefficient of -0.503 with a significant statistics (a=0.05, ρ <0.01)

DISCUSSION

The use of questionnaires as an evaluation instrument has been enhanced in scientific research lately. This is because health researchers are becoming increasingly interested on subjective methods of clinical assessment. Thus, patient's opinion about his/ her health status is valued. These instruments, usually written in English language, assess the impact of these dysfunctions on patients' quality of life ⁽¹²⁾.

Overall, studies addressing knee are based on objective aspects of surgical ⁽¹³⁾, drug ⁽¹⁴⁾, clinical ⁽¹⁵⁾, treatment, as well as on joint anatomy ⁽¹⁶⁾. Little emphasis has been placed on activities of daily life of patients with knee conditions. That is why it is necessary to conduct studies measuring the degree of difficult in performing day-by-day activities, which are directly related to those patients' quality of life.

The vast majority of evaluation instruments addressing health-related quality of life are based on questionnaires. Those questionnaires should be selected according to the intended objective and, based on that, measurement properties should be quite clear and able to be correlated with the specific objective ⁽¹⁷⁾.

There is a strong concern among scientific community in developing questionnaires assessing health status, as well as in validating instruments available in other languages and cultures. New or in-validation instruments should be assessed and reassessed by different researchers, in different societies and circumstances ⁽¹⁸⁾. ADLS was validated by following this principle, performing its validation process in 397 patients, in 9 different and reliable centers with 52 patients in 1998 in

a study conducted by Irrgang et al.⁽¹¹⁾.

For translations to reach a high quality level, these should be made according to guidelines, once translations made without required criteria and adaptations, they cannot be reproduced or trusted on ⁽¹⁹⁾. For its use to be appropriate to other languages and cultures, it is required to submit them to international translation and cultural adaptation rules of the target language.

This study followed the guidelines recommended by Guillemin et al.⁽⁶⁾ thus minimizing the occurrence of bias and trendy results. This methodology has made the ADLS able to be applied to Brazilian patients, thus being able to measure clinical endpoints and treatments at the same time, or by means of a given follow-up.

In our study, for standardizing how questionnaires should be applied, we chose to apply them as interviews, and a strong reliability rate (Chronbach's alpha) showing high inter- and intra-investigator consistency values.

Because the ADLS in its original language has been frequently used in many studies, and because its original version has been carefully constructed, assessing clarity and criteria for questions selection, we believe it presents an apparent validity of contents. Criteria, constructive and discriminative validity have been tested by comparing the ADLS questionnaire and the EAV to Lysholm's and SF-36 questionnaires.

As expected, we found a strong statistical correlation on functional capacity, physical aspect, pain, overall status, and social aspects scales. However, regarding vitality, and mental and emotional health aspects, correlations were shown to be poor, as similarly found by Shapiro et al.⁽²⁰⁾ and Peccin⁽¹⁷⁾, probably because on ADLS questionnaire there is no specific question intended to assess non physical/ functional status. This demonstrates the importance of assessing a patient not only with specific questionnaires, but also by adding generic questionnaires addressing overall health status.

When we compare the questionnaire being validated - the

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ADLS - to the Lysholm's questionnaire, a strong positive correlation was found in both presentation forms (nominal and ordinal) and may be related to the fact that the creation of the ADLS questionnaire in its original version was based on the Lysholm's questionnaire ⁽⁹⁾, which contains questions related to these patients' daily lives.

The ADLS questionnaire obtained also a statistical significance (r= -0.503) when compared to the Visual Analogous Scale (a parameter also used when ADLS questionnaire was created), thus showing that the ADLS presents an easy understanding of the pain parameter, assessed in both instruments.

All patients in our sample showed a stable clinical picture, a fact that could justify the excellent intra-investigator consistency (r=0.980), once important picture changes were not seen. Also, the strong inter-investigator consistency (r=0.986) may be also explained by the fact that the questionnaire is easy to apply and understand, not depending on the investigator, as similarly found in the validation process by Irrgang et al.⁽¹⁰⁾.

CONCLUSIONS

The Portuguese translation of the ADLS ("Activities of Daily Living Scale") questionnaire, adapted to Brazilian culture, is easy to manage and apply, since measurement, reproducibility and validity properties have been confirmed by translation and validation into Portuguese.

Thus, the ADLS questionnaire in Portuguese is a useful instrument for assessing activities of daily living of Brazilian patients with knee conditions.

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