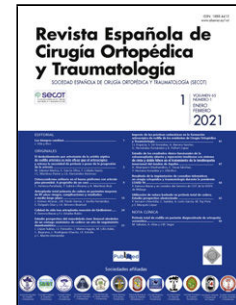# Journal Pre-proof

4 Domain Sports PROM in Spanish: Cross-cultural adaptation in the Chilean population and reliability analysis

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ORIGINAL

4 Domain Sports PROM en español: adaptación transcultural en la población chilena y análisis de confiabilidad<!--<RunningTitle>*4 Domain Sports PROM* en español: adaptación transcultural en población chilena</RunningTitle>-->

[[en]]4 Domain Sports PROM in Spanish: Cross-cultural adaptation in the Chilean population and reliability analysis

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Resumen

Antecedentes y objetivo Las medidas de resultado reportadas por el paciente (PROM) son herramientas de interés creciente en la población deportiva. El propósito de este estudio fue realizar la adaptación transcultural y análisis de confiabilidad del *4-Domain Sports Patient-Reported Outcome Measure* (4DSP) al español.

Métodos Se ejecutó un protocolo de adaptación transcultural en seis etapas para obtener la versión en español del 4DSP (S-4DSP). Posteriormente, se aplicó el cuestionario a una población de 108 deportistas posoperados de reconstrucción de ligamento cruzado anterior (RLCA). Se aplicó nuevamente el cuestionario luego de 30 días. Se evaluó la aceptabilidad, efecto piso y techo, consistencia interna (alfa de Cronbach) y reproducibilidad (correlación intraclase).

Resultados La S-4DSP fue respondida completamente por 108 participantes (edad media 34 ± 10,75, 26% mujeres) alcanzando una aceptabilidad de 100%. No se detectó efecto piso. El análisis estadístico entregó un alfa de Cronbach global para el cuestionario de 0,65, y desagregado por dominios de 0,88, 0,72, 0,27, 0,68 para el primer, segundo, tercer y cuarto dominio, respectivamente. El estudio de correlación intraclase alcanzó un máximo de 0,94 y un mínimo de 0,48 en la primera y quinta preguntas, respectivamente.

Conclusión El S-4DSP es una herramienta confiable y útil para evaluar deportistas de habla hispana posterior a una RLCA.

Abstract

Background Patient-Reported Outcome Measures (PROMs) are tools of increasing interest in the sports population. The purpose of this study was to perform the cross-cultural adaptation and reliability analysis of the 4 Domain Sports Patient-Reported Outcome Measure (4 DSP) into Spanish.

Methods A six-stage cross-cultural adaptation protocol was executed to obtain the Spanish version of the 4 DSP (S-4DSP). Subsequently, the questionnaire was administered to a population of 108 postoperative athletes with ACL (Anterior Cruciate Ligament) injuries. The questionnaire was administered again after 30 days. Acceptability, floor and ceiling effects, internal consistency (Cronbach's alpha), and reproducibility (Intraclass Correlation) were evaluated.

Results The S-4DSP was fully completed by 108 participants (mean age 34 ± 10.75, 26% women), achieving 100% acceptability. No floor effect was detected. The statistical analysis yielded a global Cronbach's alpha for the questionnaire of 0.65, and domain-specific alphas of 0.88, 0.72, 0.27, and 0.68 for the first, second, third, and fourth domains, respectively. The Intraclass Correlation test reached a maximum of 0.94 and a minimum of 0.48 for the first and fifth questions, respectively.

Conclusions The S-4DSP is a reliable and useful tool for evaluating Spanish-speaking athletes after ACL reconstruction.

Palabras clave: Adaptación transcultural; Validación; *4-Domain Sports Patient-Reported Outcome Measure*; Medidas de resultado reportadas por el paciente; Deporte; Ligamento cruzado anterior

Keywords: Cross-cultural adaptation; Validation; 4-Domain Sports Patient-Reported Outcome Measure; Patient-Reported Outcome Measures; Sport; Anterior cruciate ligament

Introduction

Patient-reported outcome measures (PROMs) are indispensable tools in daily practice in orthopaedics and trauma, as they enable the impact of interventions to be assessed from the perspective of the patient, aiding in clinical decision-making and the continuous improvement of care.[1,2] PROMs have also proven useful in the development of medical research, providing empirical data on the effects of interventions from the patient's point of view.[3]

Despite the growing importance of PROMs in trauma and orthopaedics, there is a considerable lacuna in the literature on how they are specifically deployed in the sports population.[4] This group, who frequently face injuries and rehabilitation procedures, have unique needs and expectations that are not adequately addressed by general or even orthopaedic-specific PROMs, this is particularly evident for high-performance athletes.[4–6]

In this context, the 4-Domain Sports Patient-Reported Outcome Measure (4DSP) has emerged as a valuable tool for assessing sports-specific quality of life. This questionnaire covers four key dimensions of sport assessment: baseline status, sports level, patient expectations, and postoperative outcomes; and provides insight into the pre-injury sports level, self-perception of compromise due to the injury, and the patient's subjective perception of their postoperative outcomes.[7]

Although this tool was developed for use in a variety of anatomical sites and mechanisms of injury, it can be used in knee surgery subjects, particularly those with anterior cruciate ligament (ACL) rupture, which is common in the sports population and in whom the assessment of aspects such as rehabilitation, patient perception of functionality, and expectations of sports performance is crucial to therapeutic success.[8,9]

Given the need for the most appropriate resources for both the surgical procedure and postoperative assessment and management of patients undergoing anterior cruciate ligament

reconstruction (ACLR), it is essential that PROM assessment tools are appropriately translated and adapted to the population for whom they are intended.[10–12]

The aim of this research study is to cross-culturally adapt and validate the 4DSP into Spanish, with a focus on patients who have undergone ACLR surgery.

Materials and methods

Participants

Postoperative ACLR patients, at least one month since the procedure, all over 18 years of age and reporting some degree of sports participation prior to their injury, were included. Those under 18 years of age, with revision ACL surgery or inability to independently answer the questionnaire, were excluded. All participants signed an informed consent form prior to inclusion in the study, which was approved by the institutional ethics committee.

Cross-cultural adaptation

The six-stage protocol of Beaton et al.[10] was followed for the cross-cultural adaptation. Two bilingual translators, native Spanish speakers, independently undertook the initial translation of the questionnaire. Both versions were then synthesised into a single agreed version. This was followed by a back-translation into English by two independent, native English translators with no knowledge of the original questionnaire. On completion of this process, a committee of experts formed by the authors and translators reviewed all the versions and produced the pre-final version of the questionnaire, which was discussed with groups of postoperative knee patients independently, and their comments on the comprehensibility and relevance of the items were collected. The collected feedback was used to develop the final version of the questionnaire in Spanish (S-4DSP).

Application of the questionnaire

The questionnaire was administered digitally via Google Forms (Google LLC, California, USA) to 108 participants one month after surgery. It was answered independently without direct supervision by the treating clinician or researcher. It was repeated 30 days after the first application to assess reproducibility. The data were collected and processed anonymously.

Statistical analysis

A descriptive statistics analysis was performed on the sample for demographic characterisation with mean, standard deviation, minimum, and maximum.

The results of the questionnaire were analysed with the raw score of each item. Those with discrete quantitative variable responses (items 1, 3, 5, 6, 8, 9, 10, 11) were described with mean and

standard deviation for central tendency and dispersion, respectively; these allow responses from 0 to 10.

Cronbach's alpha coefficient was used to evaluate the internal consistency of the questionnaire. This ranges on a scale from 0 to 1, with 1 being a perfect correlation between the answers in the questionnaire.[13] This test was run for the quantitative questions of the questionnaire as a whole, and grouped for each of the assessment domains.

Reproducibility analysis used the intraclass correlation study in a two-way mixed effects model, comparing the quantitative order responses for each participant between the first and second application of the questionnaire. This score ranges from 0 and 1, with 1 being a perfect correlation between the first and second assessment (no variation in responses).[14]

The tests were performed with 95% confidence, a p-value <.05 was considered clinically significant. STATA® 2023 statistical software (StataCorp LLC, Texas, USA) was used for the analysis.

Results

Two bilingual native translators undertook and agreed the first Spanish translation (Appendix A Annex 1). This was followed by a back-translation into English agreed by two independent translators (Appendix A Annex 2). The final translated questionnaire was produced (Appendix A Annex 3) after review by the authors' group, and in addition to independent patient evaluations.

A total of 108 (100%) participants fully answered the questionnaire. No participant was unable to respond. No entries with missing values were recorded, and no subjects were excluded at this stage. The age and gender distribution of each subject is presented in Table 1. Of these, 26% were female and 74% male. The mean age of the female participants was 35 years, and the mean age of the male participants was 33 years.

Assessment of the internal consistency of the questionnaire gave an overall Cronbach's alpha of .65, and in the disaggregation by domains, alpha values of .88, .72, .27, and .68 were found for the first, second, third, and fourth domains, respectively. In the reproducibility assessment, the responses of 79 participants (73% of the original sample) were recorded. All questionnaires were fully completed and there was no missing information. There was a range of intraclass correlations from a minimum of .48 for question five to a maximum of .94 for question one. These values together with the scores of the quantitative items are summarised in Table 2.

Discussion

The 4DSP was translated, adapted, and validated into Spanish following a structured process widely used in the literature.[10] The target population was selected to offer a practical application of this tool in a clinical situation frequently encountered in sports trauma, such as ACL injuries in athletes.[15]

A Cronbach's alpha score of .65 was obtained in this study (considering all questions). This value is statistically significant, is considered acceptable, and is similar to that reported by the authors in the article on the development of the original questionnaire.[7,16]

When analysing the results by specific domain, a considerable variation in the alpha values was observed, ranging from .27 to .88. This is congruent with the structure of the questionnaire, where each of the four domains assesses different aspects of sport-related quality of life, therefore each domain provides a different level of internal congruence depending on the degree of relationship of the questions it contains.

The first and second assessment domains contain closely related questions. Questions one and three of the first domain assess the influence of sport on the individual's life and the degree of motivation it generates. Five and six of the second domain ask about the impact of the injury on quality of life and sport performance, respectively. It is to be expected that an individual with a life strongly influenced by sport will be highly motivated to do sport (first domain), and in turn the injury will have a greater impact on quality of life, and therefore it is logical that at the same time there will be greater impact on sport performance (second domain). With this reasoning, the intradomain responses are conceptually highly related and should therefore show a higher internal correlation, which is indeed the case as evidenced by higher Cronbach's alpha scores (.88 and .72).[17] The third and fourth domains contain conceptually less associated questions.

In the third domain, question eight asks whether the patient understood the information provided by the treating clinician, and question nine assesses the patient's expectations of returning to the pre-injury level of sports activity. In the fourth domain, question 10 assesses how the subject feels about the treatment received, and question 11 assesses the psychological state of the subject at the end of the treatment. The same individual can score 0 on question 8 (did not understand anything explained by their treatment provider), and at the same time score 10 on question 9 (maximum confidence in returning to pre-injury level of sport). Because the questions are assessing independent aspects of the therapeutic process, a low correlation (translated into a lower alpha coefficient) between the questions for those specific domains is the intuitive and expected result.[18]

In summarising the Cronbach's alpha findings, a difference is observed between the overall questionnaire score and the disaggregated scores per domain, due to differences in the orientation and focus of the questions within each domain. Those with more different approaches show lower alpha values, while those that are similar within a domain show a higher internal correlation.

In the evaluation of the questionnaire results there was no floor effect, however, considering a limit of 15% of maximum responses per item, a ceiling effect was observed for all questions. This finding suggests that the S-4DSP may not be sensitive enough to detect improvement in quality of life in patients already highly functioning in the sports area.[19]

With regard to reproducibility, the reported values vary between .48 and .94, with four of these above .8, and seven of them (out of a possible total of eight) above .6. These values correspond to a two-way mixed effects model (consistent with an intra-observer reproducibility assessment), and are within the range considered good to excellent in a reproducibility assessment.[18] The question with the lowest reproducibility is question five, "To what extent has this injury affected your quality of life?", which may be influenced by the subjective feeling at the time of making the assessment, and therefore vary between applications (a significant degree of improvement is expected during postoperative physiotherapy rehabilitation). It is important to consider that, in the reproducibility assessment, there is always a bias associated with the time of application, where more disparate scores are expected at longer times, which is a plausible explanation for the reported results.[18]

A cross-cultural adaptation inherently assumes that there are not only language but also cultural distances for the application of an instrument, and therefore it is important to recognise as a limitation the fact that this questionnaire was answered by a small group of patients with a surgical condition and clinical centre in common. Therefore, to strengthen the validity and generalisability of the results of the adapted version, additional studies are needed in different groups of athletes, in subjects undergoing different procedures, and in different cultural contexts in our country.

Furthermore, there is an important characteristic in developing this questionnaire that engenders some methodological limitations, namely the incorporation of multiple response categorical variables (several sports actions can be considered in question four, and different symptoms in question seven), although aimed at better typifying the patient in a sport and in a specific constellation of symptoms, it makes it impossible to incorporate these questions within the intradomain reliability analysis with Cronbach's alpha, and one of reproducibility with tools such as the Kappa study.[20]

Finally, we must acknowledge as a limitation that this research study did not conduct comparative validity tests with other instruments, and in the future, comparison of this questionnaire with tools already validated in the area should be considered.

In summary, although Cronbach's alpha coefficient provides useful information on the internal consistency of the 4DSP questionnaire, and the intraclass correlation found indicates that it is reproducible, it is advisable to complement the analysis with other statistical tests and to apply it to a larger and more diverse population of patients. These additional measures will strengthen the evidence of the validity of the questionnaire and improve its usefulness in the assessment of sport-related quality of life in our patients.

Conclusions

These results establish a firm basis for further development, evaluation, and future construct validity of this tool. It is possible to use this questionnaire in the context of postoperative ACLR patients.

Level of evidence

Level of evidence IV.

Conflict of interests

The authors have no conflict of interest to declare.

Appendix A   [{(Annex)}] Additional material

Additional material to this article can be found in its electronic version available at doi:10.1016/j.recot.2024.02.001.

Appendix B   [{(Annex A)}]   Additional material

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Table 1 Age of the participants and proportion according to sex

	N	Relative frequency (%)	Mean	SD	Minimum	Maximum
[0,1-7]*Sex*						
Female	28	26	35	10.73	18	57
Male	80	74	33	10.75	18	63
Total	108	100	34	10.72	18	63

SD: standard deviation.

Table 2 Mean responses, Cronbach's Alpha and intraclass correlations

	Mean (SD)	Floor (%)	Ceiling(%)	Minimum	Maximum	Cronbach's α	ICC[*]
1st domain						0,88	
I1	8.7 (1.6)	0	40.1	3	10		.94
I3	9 (1.4)	0	56.5	3	10		.91
2nd domain						.72	
I5	7.7 (2.2)	0	31.5	1	10		.48
I6	8.3 (2.0)	0	47.2	1	10		.61
3rd domain						.27	
I8	9.4 (1.1)	0	74	3	10		.91
I9	8.4 (1.9)	.93	44.4	0	10		.81
4th domain						.68	
I10	8.8 (1.9)	0	54.6	1	10		.74
I11	7.7 (1.9)	.93	20.4	3	10		.77
Global						.65	

Ceiling: maximum item response rate; ICC: intra-class correlation coefficient; Floor: minimum item response rate; SD: standard deviation.

[*]Each value is the correlation study between the first and second assessment score for each question.