RESEARCH ARTICLE

Translation, Linguistic Validation, and Readability of the Spanish Version of the VISA-H Scale in Elite Athletes

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Abstract

Background: Data regarding the diagnosis of Proximal Hamstring Tendinopathy (PHT) is limited. There is a need for a standardized, valid, and reliable instrument for evaluating PHT among Spanish population. The purpose of this study was to linguistically validate and cross-culturally adapt the Spanish version of the VISA-H for Spanish population and to assess its readability, initial feasibility, appropriateness and acceptability.

Methods: Cross-cultural adaptation was done according to established guidelines. Process included 5 steps: independent translations, synthesis of the translations, back-translations, expert committee, and pre-test. The linguistic validation of the questionnaire followed a standard methodology that included comprehension test interviews to assess the relevance, understanding and acceptability of the VISA-H. Comprehension was analyzed with cognitive interviews of 18 Spanish Professional basketball and soccer players (n = 8 male, n = 10 female end-users, healthy individuals at risk), using think-aloud and probing techniques.

Results: All subjects (18/18) reported that the items were clear and did not cause upset. Additionally, every respondent had no difficulty in completing the form and found it fairly easy. No difficulties with the instructions were reported. Readability score resulted in adequate levels of understanding (Fernandez-Huerta score of 67.5), showing high level of acceptability.

Conclusion: The results of the linguistic and semantic validation conducted with health risky population enable the identification that the Sp-VISA-H was well accepted and easily understood by the participants. Further testing on PHT patients is needed to corroborate these preliminary data.

Level of evidence: III

Keywords: Comprehension, Hamstring, Patient outcome assessment, Surveys and questionnaires, Tendinopathy

Introduction

Tendon degeneration, myotendinous junction inflammatory reaction, and partial or complete proximal hamstring ruptures are less common causes of hamstring pathology at its proximal insertion. Proximal hamstring tendinopathy (PHT) concept was firstly alluded to by Puranen and Orava with a more generic term, "hamstring syndrome" (1). It has emerged as a relatively rare condition that is often overlooked as a cause of chronic buttock and/or thigh pain.

Clinical presentation of PHT includes deep gluteal/subgluteal region pain occurring during regular sport activity or stretching. Symptoms may also be aggravated by running, car-driving, or just sitting on hard surfaces, and can radiate down through posterior thigh till the popliteal region. However, data regarding the diagnosis and treatment of PHT are limited. Histopathological

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investigations have shown dense fibrotic tissue at the proximal hamstring insertion at the ischial tuberosity (2). Clinical examination reveals a deep focal tenderness around ischial tuberosity which may be accompanied by a sensation of pain or tightness when active stretching is reproduced. Knee flexion and hip extension strength are barely affected. No peripheral neurological implication is usually reported (3).

Standardized patient-reported outcome measure (PROMs) instruments represent a convenient resource to compare research results among different studies and patient populations, to assess treatment outcomes, and to provide a guideline for intervention. English-language evaluation tools are not considered fully applicable to most of the English-speaking countries in the world and several English population subgroups, with recognized cultural and semantic differences between American, British and Australian, among other examples (4). A previous review has identified tens of cross-cultural adaptation guidelines, and no consensus exist regarding the best approach (5). Cross-cultural adaptation process generally comprises translation, cultural readjustment, and subsequent validation for each culture (6,7). Spanish-speaking population is speedily growing worldwide, especially in the US where nearly 20% of Americans are projected to prefer Spanish language over other by 2050 (8).

The VISA-H is a self-report 8-item scale developed for patients with PHT that assesses severity of symptoms, function and ability to perform a sport. It can be used to determine the patient's clinical status, and provide a guideline for treatment or monitor its effect. VISA-H can also be employed to facilitate comparisons between different PHT patient populations (9). The development of the Spanish version of the VISA-H (Sp-VISA-H) is then crucial for the assessment of PHT patients since no other instrument exists for evaluating specifically these clinical situations among Spanish population. The objective of this paper is: (i) to describe the translation and cultural adaptation process, (ii) to introduce the preliminary version of the VISA-H for Spanish-speaking patients with PHT, and (iii) to assess its readability, initial feasibility, appropriateness, and acceptability.

Materials and Methods
Instrument
The VISA-H is a simple, self-administered, multi-item PRO instrument that mainly employs an inverted 100-point numeric rating scale (NRS), and is designed for use in routine clinical practice and clinical trials. As similar tools like VISA-A and VISA-P, it can be used both to determine the patient's clinical severity and provide a guideline for therapeutic interventions and to monitor their effect (9-11). This tool contains eight items covering the three domains of pain and function (items 1-6) and sporting activity (items 7 and 8). The first six items (pain and function) employ a 0-10 NRS, while the last two items (sporting activity) use a categorical rating index. The maximum score of items 1 to 7 is 10, while item 8 yields a maximum of 30. Consequently, an asymptomatic person would score 100, whereas the

worst punctuation possible is 0 points (9). The VISA-H questionnaire currently represents the only valid, reliable, region-specific functional score to measure the proximal hamstring tendon condition and to monitor the recovery process. However, as most PROMs, this tool has only been initially developed for an English-speaking population.

Translation and Cross-Cultural Adaptation of the VISA-H
The Spanish translation, cultural adaptation, and validation of the VISA-H were authorized by the original authors. Translation and cross-cultural adaptation were conducted according to the cross-cultural adaptation guidelines of self-report measures proposed by Beaton et al., which included the following steps: (i) independent translations, (ii) synthesis of these translations, (iii) back-translations, (iv) expert committee evaluation, and (v) pretest of the prefinal version(7) [Figure 1].
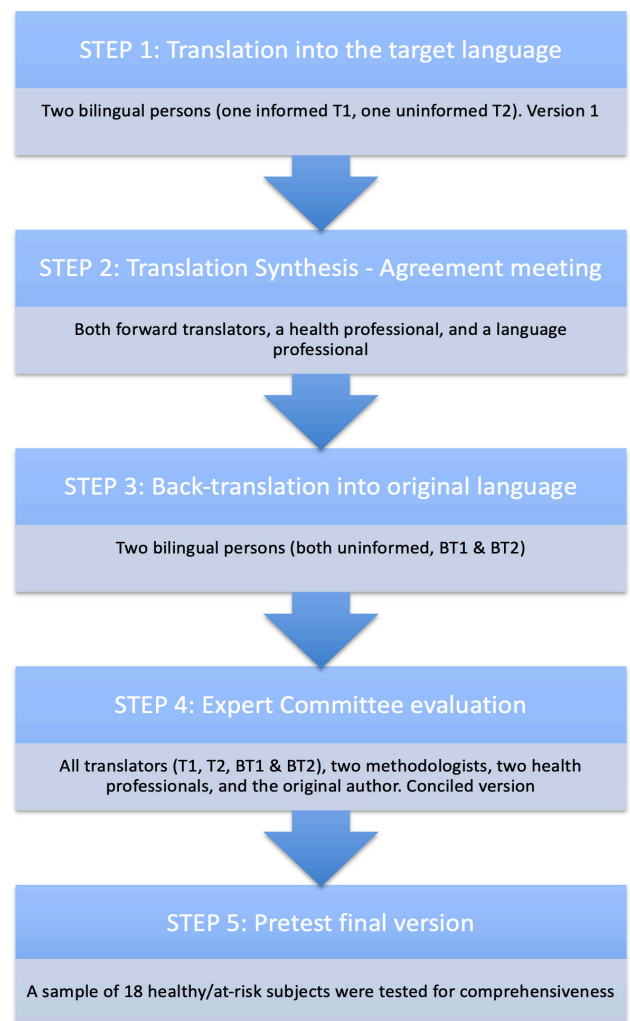

STEP 1: Translation into the target language
Two bilingual persons (one informed T1, one uninformed T2). Version 1

STEP 2: Translation Synthesis - Agreement meeting
Both forward translators, a health professional, and a language professional

STEP 3: Back-translation into original language
Two bilingual persons (both uninformed, BT1 & BT2)

STEP 4: Expert Committee evaluation
All translators (T1, T2, BT1 & BT2), two methodologists, two health professionals, and the original author. Conciled version

STEP 5: Pretest final version
A sample of 18 healthy/at-risk subjects were tested for comprehensiveness

Figure 1. Flowchart of the translation and cultural adaptation process.

Conceptual and item equivalences: evaluation

This evaluation involved a literature review on Proximal Hamstring Tendinopathy (PHT) and discussions with a panel of experts comprising two sports medicine doctors, one orthopedic surgeon, and two physical therapists. The appropriateness of every item included in the original instrument for assessing PHT in the Spanish population was also assessed.

Semantic equivalence: evaluation

The process of semantic evaluation was divided into the following steps:

Step 1: Translation

Two Spanish native bilingual translators initially translated the VISA-H from English into Spanish. All translators had expertise in cross-cultural translation scale study design and were fluent in both English and Spanish. Each translator produced an independent forward translation of the original items and response options, along with specific instructions (7). One of the translators was neither aware of the concepts on the questionnaire nor informed about its conceptual content.

A combined version (version 1) of the two translations was generated through discussion between both translators and the project manager, who agreed on a single version. Therefore, a conceptually equivalent and easy-to-understand translation of the original questionnaire was then obtained. This process involved additional changes to the original version where words or concepts could have a specific meaning in one language but a semantically different meaning in the Spanish language, or where words or terms were simply untranslatable.

Step 2: Translation Synthesis

This stage consisted of the synthesis of both translations. All disagreements were resolved through discussion until consensus was reached.

Step 3: Back-translation

The final phase was the back-translation of the Spanish version of the VISA-H (Sp-VISA-H) into English language by a local professional translator, an English native speaker who was fluent in Spanish, and was blinded to the original English version of the VISA-H scale. The back-translated VISA-H was compared to the original by the project manager and the author of the original scale to detect any misconceptions or imprecisions in the translation proceeding (9).

The used translation methodology was explicitly selected to reduce the cultural and social bias that may have resulted when one single translator is responsible for the translation. Beaton et al. proposed this approach to ensure that the final version obtained has conceptual and semantic equivalence to the English VISA-H with regards to the items, response options, and questionnaire-specific instructions (7).

Step 4: Expert committee evaluation

The expert committee was comprised by two methodologists, all translators involved during the process, two health professionals (physiotherapists), and the original author of the questionnaire. Both translation synthesis and back-translation versions of the VISA-H were submitted to the consideration of the expert committee, which reviewed all translations and reached a consensus regarding identified differences in the proceeding. Finally, the translation was proofread for grammar, spelling, and content errors, generating the simplified Sp-VISA-H.

Step 5: Final pretest through Cognitive Interviewing Procedure

The Sp-VISA-H items were additionally examined through cognitive debriefing as the last step of the translation procedure and cultural adaptation of the questionnaire (12). This interview phase was aimed to certify whether the translation (items, responses options, and specific instructions) is acceptable and easy to understand, and whether the patients understood both the instructions and the items included in the Sp-VISA-H questionnaire. Format of the instrument, phrasing, answer options, and ease of response of the employed terminology were also evaluated.

The pre-final Sp-VISA-H questionnaire was then subjected to comprehensibility in 18 asymptomatic, high-level athletes. The choice of this population is justified as potential final users of this instrument may meet this profile. Between January and March 2019, data were collected from members of two sport teams (female and male) belonging to a simple geographic zone in Spain. The participants had to be at least at the age of 18, willing to participate in research, and able to give informed consent. Subjects under 18 years, who were not Spanish native-speakers, had a past history of PHT, or rejected to participate were excluded.

One round of cognitive interviews was conducted in a private area and involved the following: (i) the administration of a Sp-VISA-H survey composed of a set of Sp-VISA-H items; (ii) a semi scripted debriefing interview with cognitive probing of clarity, upsetting, and ease of comprehension through a general impressions form [Table 1]. Subsequently the participants answered the questions of the specific form [Table 2]. Both grade of understanding of each item and clarity along with instructions for using the instrument were assessed by each subject through an adapted verbal-numeric scale attached to the pre-final version of the Sp-VISA-H. The following question accompanied every item: "Did you understand the item?" A 5-point Likert-type scale was adapted, as it has been advocated (13). The response options ranged from: 0 ("I did not understand anything") to 4 ("I understood almost everything"), being 1 ("I understood just a bit"), 2 ("I understood it more or less"), 3 ("I understood almost everything, but I had some doubts"), and 4 ("I understood almost everything") intermediate scores. For the purpose of this study, levels 3 and 4 were considered a sufficient understanding.

Participants were first invited to complete the abovementioned set of Sp-VISA-H questions by paper and pencil. Respondents were asked to indicate those Sp-

Table 1. Demographics of participants (healthy subjects, n = 18)		
Characteristics	**n**	**%**
Age, range (median±SD)	18-35 (26.55±5.00)	
Gender, male (female)	8(10)	
Weight (kg)	73.5 ±10.56	
Height (m)	1.78 ±0.94	
BMI (kg/m^2)	22.89 ±1.44	
Training hours per week	11,66 ±3.28	
Sport discipline		
Soccer	8	44.4
Basketball	10	55.6
Education level	n	%
No elementary	0	-
Elementary	0	-
High School	10	55.6
College/University	8	44.4

VISA-H items where they have difficulties to understand and those for which they experimented difficulties when selecting a response. The interviewers did not provide any advice or assistance, and encouraged participants to complete the survey to the best of their ability on the basis of the instructions provided. After completing the Sp-VISA-H survey, a semi scripted cognitive debriefing interview was developed.

Cognitive interviews were conducted face-to-face in an egalitarian manner by two experienced, native Spanish interviewers with experience conducting cognitive interviews in a high-level sport context. An explanation of the study including its primary goals, participation conditions, and confidentiality was offered before each face-to-face interview. Both interviewers were assisted by principal investigator who prepared field notes. First, several questions regarding the patient's sociodemographic and physical characteristics were asked. Respondents were then asked to indicate those

Sp-VISA-H items that they found difficult to understand and those for which they had difficulty selecting a response. Individuals' interpretations of Sp-VISA-H questions with suggestions for improvements by asking those interviewed subjects to express in their own words the perceived significance of each question were considered. Interviewers registered any spontaneous respondent comments about the clarity or understandability of the items or response options; any verbal hesitation and/or body language or facial expression that might indicate an unexpected reaction to the items was also taken into consideration. Each patient was also encouraged to provide any remarks, comments, or questions regarding the applicability of the questionnaire. The presence of the researchers standardized the procedure and ensured the attention of the participants as they stressed the importance of careful reading of each item.

When problems were identified, alternative linguistic changes were then proposed and implemented so that a version 2 of the scale could be created. As previously proposed, when the percentage is greater than 15% as if more subjects are included, the reconciled version of the instrument is changed and a new pretest is conducted (14).

The patients' characteristics included age, gender, height, weight, body mass index, educational level, training hours per week, duration of sport activity, previous specific- injury (PHT) experience were also recorded. Two researchers screened the patients and asked for consent before proceeding with the questionnaire. All included patients independently completed the Sp-VISA-H questionnaire.

Readability of the questionnaire

The instrument readability was assessed using available online resources. The Flesch-Kincaid Reading Ease score was employed for measuring literacy difficulty level of the questionnaire. This tool ranges from 0 to 100, with 0 as the most difficult and 100 as the least difficult to read. Any score below 30 will be considered very difficult, while a score of 70 will be considered appropriate for adult readers (15). This punctuation is one of the most widely used readability assessment formulas. It is based on number of syllables per 100 words and average

Table 2. General Impression Form Survey. Results of the survey in relation to the specific impression of the Sp-*VISA-H* according to the respondents		
General Impression Form Questions	**Possible answers**	**Responses (%, n)**
How clear were the questions?	Very clear	88.23%, 15/17
	Fairly clear	11,76%, 2/17
	Not clear	0.0%, 0/17
How difficult was it to fill in the questionnaire?	Not difficult	100%, 17/17
	Fairly difficult	0.0%, 0/17
	Very difficult	0.0%, 0/17
How upsetting was it to fill in the questionnaire?	Not upsetting	100%, 17/17
	Fairly upsetting	0.0%, 0/17
	Very upsetting	0.0%, 0/17

number of words per sentence. The lower the score, the more difficult the material is to read and understand. Analogous Spanish-language scales with the same objective have been employed. The Fernandez-Huerta Reading score emerges as a Spanish adaptation of the Flesch Reading Ease score based on sentence length and syllable count in a text sample. The output is an index from 0-100, with lower scores indicating the text is more difficult to read (16). As in its predecessor difficulty levels can then be converted to U.S. reading grade levels. Equivalent readability scores have been introduced for the same purpose. The Flesch-Szigrist legibility index or Clarity Formula measures some text readability with a score of 50-65 is considered average, and as the score approaches 0, where scientific literature is situated, texts become progressively more difficult (17). On the other hand, the INFLESZ Scale establishes 5 sections: (i) Very difficult (<80); (ii) Somewhat difficult (40-55); (iii) Normal (55-65); (iv) Quite easy (65-80); and (v) Very easy (>80). Finally, Legibility μ formula is based on number of words, mean and number-of-letters-in-a-word variance, and it permits to analyze and obtain legibility indexes as well as the ease of texts. This proposal scores (i) Very difficult (<30), (ii) Difficult (31-50), (iii) Somewhat difficult (51-60), (iv) Adequate (61-70), (v) Somewhat easy (71-80), (vi) Easy (81-90), and (vii) Very easy (>90). Again, in all these instruments the lower the score, the more difficult the material is to read and understand (18).

The original VISA-H instrument readability was assessed via online legibility analyzer with an available evaluator (https://goodcalculators.com/flesch-kincaid-calculator/© 2015-2019). The Sp-VISA-H readability was assessed via online legibility analyzer with a free-access evaluator (https://legible.es/© 2016-2018), as well as all available Spanish versions for analogous scales (VISA-A, VISA-P).

Acceptability and feasibility
The time employed by each subject to fill out the questionnaire was registered to assess feasibility. The number of missing answers and wrong or multiple responses, along with possible difficulties or errors in the questionnaire compilation were also recorded by the interviewer.

Ethical and legal considerations
According to the Standards and Operational Guidance for the Ethical Review of Health-related Research with Human Participants, written informed consent was obtained from all pretest participants after receiving a complete explanation about the research procedures and objectives, and before including them in the study (19). The anonymity was assured during the whole process and afterwards. This study was approved by the research ethics committee of University of Malaga, Spain (protocol no. 505/115-2018-H) and complied with the principles of the Declaration of Helsinki. Despite VISA-H is a free-use questionnaire, before accomplishing this project convenient original author´s permission was required and obtained to adapt and to use VISA-H in our setting.

Statistical analysis
Data were analyzed by SPSS software (version 25.0). Descriptive data were reported in all measured variables. Measures of dispersion (deviation-standard - SD, minimum and maximum values), central tendency (mean and median) were calculated for continuous variables, whereas measures of absolute and relative frequencies were calculated for categorical variables. Alpha (α) was set at .05. Data were tested for normality by use of the Kolmogorov-Smirnov test.

Results
Demographics and Final version pretest
The translated instrument was then piloted on 18 healthy subjects who were at risk of developing PHT. All of the participants approached gave their informed consent to participate. Their median age was 26.55 years; Ten were female and had attained at least an upper secondary level of education. The participants´ interviews were 7-13 min long (media=575s). was 9´45" minutes (585 s; SD 99.41) (range 7 to 13). The subjects´ formal education level varied: secondary school (n = 10), and university/college (n = 8). Further sociodemographic and physical characteristics of the participants are presented in [Table 3]. No participant scored under 100 in Sp-VISA-H which confirmed their asymptomatic profile.

Translation/Back Translation process
The cross-cultural adaptation of the VISA-H required then not only translation but conversion of cultural expressions and locutions. A minor transformation of certain items was accomplished in order to maintain the essence of the original terms. As a result, simple formal Spanish words and idioms that can be easily understood were adapted to increase understandability. The finalized translation was proofread, checked for spelling, content, and grammar issues. A simplified version of Sp-VISA-H was obtained. To sum up, the original scale remained unchanged except for two minor adjustements. The item reading 'lunge' was changed to 'zancada hacia delante' in Spanish in order to faithfully follow proposed recommendations and avoid anglicisms, even when they are well known and extended among sport practitioners. In this sense, the item reading 'sprinting' was changed to 'carrera a máxima intensidad' for the same reason. In general, no major difficulties were detected in reconciling the back-translated version. The complete translation, cross-cultural adaptation, and apparent validation procedure is further illustrated in [Figure 1].

Table 1 and Table 2 summarize the result of cognitive interviews through general and specific impression forms [Tables 1; 2]. Cognitive interviews did not identify items causing gross difficulties. A 55.6% of subjects reported that the items were very clear, while 44.4% found it fairly clear. All respondents manifested no difficulties with completing it and consider the Sp-VISA-H not to be upsetting at all. Through forward/back translation process minor problematically worded items were identified and optimized. Only item 1 was partially understood for 11% of the participants and required clarification by the interviewer. However, no feedback or

Table 3. Specific Impression Form Survey. Results of the survey in relation to the specific impression of the Sp-*VISA-H* according to the respondents				
Item				
No. The answers are repeated:	**Level of clarity / understanding**			
	I did not under-stand anything (%)	I understood just a bit (%)	I understood it more or less (%)	I understood almost everything, but I had some doubts (%)	I understood almost everything and had no doubts (%)
1. ¿Durante cuántos minutos puede sentarse o conducir el coche sin dolor?	0.0	0.0	0.0	0.0	100
2. ¿Cuánto dolor tiene durante o inmediatamente después de estirar la zona posterior del muslo/isquiotibiales (con la rodilla estirada)?	0.0	0.0	0.0	0.0	100
3. ¿Cuánto dolor tiene durante o inmediatamente después de una carrera normal?	0.0	0.0	0.0	0.0	100
4. ¿Cuánto dolor tiene durante o inmediatamente después de hacer un esprint?	0.0	0.0	0.0	0.0	100
5. ¿Cuánto dolor tiene durante o inmediatamente después de una zancada hacia delante a peso completo?	0.0	0.0	0.0	0.0	100
6. ¿Cuánto dolor tiene durante o inmediatamente después de levantar un objeto del suelo (con las rodillas estiradas)?	0.0	0.0	0.0	0.0	100
7. ¿Está realizando actualmente deporte u otra actividad física?	0.0	0.0	0.0	0.0	100
8. Instrucciones	0.0	0.0	0.0	0.0	100
8A. Si no tiene dolor mientras realiza deporte, ¿durante cuánto tiempo puede entrenar/practicar deporte?	0.0	0.0	0.0	0.0	100
8B. Si tiene dolor mientras realiza deporte pero no le impide completar el entrenamiento/la práctica deportiva, ¿durante cuánto tiempo puede entrenar/practicar deporte?	0.0	0.0	0.0	0.0	100
8C. Si tiene dolor que le impide completar el entrenamiento/la práctica deportiva, ¿durante cuánto tiempo puede entrenar/practicar deporte?	0.0	0.0	0.0	0.0	100

alternative translations were suggested. The individuals referred no doubts related to scale items and considered the instrument easy to understand. The overall impression was that the questionnaire was accepted in its current format with regards to employed terminology, phrasing, and response options. The pretest demonstrated high acceptability of the instrument. No changes were therefore made as a result of this pretesting. Overall, participants commented that the Sp-VISA-H was easy to complete and the items were understandable and relevant. Specifically, there were no problems with the instructions.

Results from cognitive interviews suggested that translation process was accurately understood by the participants in a manner that was conceptually equivalent to the English source.

Final version in Spanish
Based on the results of the cognitive interviews and following further review and discussion by the expert committee, a consensus was reached and a final adaptation was created [Figure 2]. This final version of the Sp-VISA-H was then sent to and approved by the original author of the instrument.

Readability of the questionnaire
The original VISA-H readability evaluation revealed that

VISA-H Score

8. Por favor complete una de las opciones A, B o C en esta pregunta.

- Si **no** tiene **dolor** mientras realiza deporte, por favor, complete solo la pregunta **8a**
- Si tiene **dolor mientras realiza deporte pero no le impide completar la actividad**, por favor, complete solo la pregunta **8b**
- Si tiene **dolor que le impide completar la actividad deportiva**, por favor, complete solo la pregunta **8c**.

8a. Si no tiene dolor mientras realiza deporte, ¿durante cuánto tiempo puede entrenar/practicar deporte?

0-20 mins	21-40 mins	41-60 mins	61-90 mins	>90 mins	Puntos
☐	☐	☐	☐	☐	
0	**7**	**14**	**21**	**30**	

8b. Si tiene dolor mientras realiza deporte pero no le impide completar el entrenamiento/la práctica deportiva, ¿durante cuánto tiempo puede entrenar/practicar deporte?

0-15 mins	16-30 mins	31-45 mins	46-60 mins	>60 mins	Puntos
☐	☐	☐	☐	☐	
0	**4**	**10**	**14**	**20**	

8c. Si tiene dolor que le impide completar el entrenamiento/la práctica deportiva, ¿durante cuánto tiempo puede entrenar/practicar deporte?

NADA	1-10 mins	11-20 mins	21-30 mins	>30 mins	Puntos
☐	☐	☐	☐	☐	
0	**2**	**5**	**7**	**10**	

PUNTUACIÓN TOTAL [/100] [ ] %

Figure 2. VISA-H Spanish version reconciled.

CROSS-CULTURAL ADAPTATION OF THE SPANISH VISA-H

Table 4. Readability and Comprehensibility Levels of Spanish-Language VISA questionnaires				
	Sp-VISA-H	Sp-VISA-A (2018)	Sp-Ch-VISA-A (2018)	Sp-VISA-P (2011)
Fernandez-Huerta score	60.9	73.79	73.88	69.09
Szigriszt-Pazos score	55.75	69.5	69.21	64.17
INFLESZ	55.75	69.5	69.21	64.17
Legibility μ	58.1	60.38	61.83	54.4
Required academic level (Crawford, school yrs)	5.4	4.8	4.7	5
Readiness estimated time (min)	1.3	1.9	2.1	1.7

Sp: Spanish; Ch: Chilean; A: Achilles; H: Hamstring; P: Patellar.

the Flesch-Kincaid Grade Level (literacy difficulty level of the questionnaire) was 5.1, showing that respondents would need a seventh-grade reading level to understand the items. All subjects comprising our simple had reached at least secondary school level being academically accepted. The Flesch Reading Ease score for the original questionnaire was 72.1. The Fernandez-Huerta score for the Sp-VISA-H was 67.57 which is considered to be normal, with an associated literacy difficulty level of fifth grade. Table 4 gathers the similar instruments readability scores and word and sentence difficulty results [Table 4]. This table includes data from the related VISA Spanish versions for Achilles (Sp-VISA-A and Sp-Ch-VISA-A) and Patellar (Sp-VISA-P) tendinopathies. In general, equivalent scores were obtained for every employed formula in all cases.

Comprehension, acceptability and feasibility
The median time to complete the Sp-VISA-H questionnaire was 2´42" minutes (162s; SD 37.97) (range 102 to 220). No blank items were recorded. Considering both the instructions of the questionnaire and the phrasing of the 8 items, the mean values obtained in the adapted verbal-numeric scale among the healthy volunteers were mostly >3.0. The registered grade of understanding varied from 3.77 to 4 (maximum 4.0), as shown in [Table 5]. Difficulties were more pronounced

Table 5. Level of clarity and understanding of the Spanish-VISA-H (n=18)				
	Mean	SD	Min Score	Max Score
Item 1	3.78	0.65	2.00	4.00
Item 2	3.78	0.55	2.00	4.00
Item 3	3.83	0.51	2.00	4.00
Item 4	3.94	0.23	3.00	4.00
Item 5	3.83	0.51	2.00	4.00
Item 6	3.94	0.23	3.00	4.00
Item 7	3.94	0.23	3.00	4.00
Item 8	4.00	0.00	4.00	4.00

SD: Standard deviation

for items 1 and 2, whereas item 8 showed higher levels of understanding.

Discussion
Research conducted in multinational and multicultural settings is increasing and including a growing number of languages (20, 21). PROs for clinical studies often include technical concepts or unusual terminology that difficult patient´s understanding. More accurate translations are needed to ensure that clinical differences found in trials really reflect a true difference rather than a systemic error due to literal translation. Every instrument specifically developed for a given population has to be comprehensible at the most basic level so that respondents can properly contribute. Guidelines for accurately translating PRO instruments have been introduced by different research groups worldwide, with minor variations among them (5). However, the optimal procedure for cross-cultural adapting and validating these instruments is still being debated. Researchers tend to combine available resources with translation techniques based on the context and essence of their research. A combination of these resources and the translation techniques specifically adapted to the research question may lead to successful translations and cultural adaptations. Most guidelines recommend that questionnaires be translated (i), back-translated (ii), and then evaluated by an expert committee (iii) to ensure equivalence to the original. The purpose of the translation, therefore, is not only to achieve a literal translation, but to maintain both the essence and the intention in the original questionnaire. This study followed a linguistic validation process that included forward and backward translations, cognitive interviews and readability testing. For this purpose, we have employed rigorous methods for conducting the translation process and ensuring cultural appropriateness. In this study, use of the internationally accepted Beaton et al. guidelines in conjunction with the qualitatively based debriefing interview indicated that the constructs being measured in the Sp-VISA-H were conceptually equivalent with the original version prior to field testing with patients. Although reliability and validity of the instrument have been recommended to be verified after the translation and adaptation process by most international guidelines for cross-cultural process,

several investigations have reported the translation and cross-cultural adaptation phases with no additional analysis of the psychometric properties (22-26). The Sp-VISA-H, as a whole, was well accepted by both respondents and interviewers. No question was experienced as inappropriate or upsetting, and most questions were judged easy to understand. The time to complete Sp-VISA-H and perform the interview were regarded as accepted by interviewed subjects, and the questionnaire was generally experienced as easy to complete.

The Sp-VISA-H questionnaire has proven fair readability, appropriateness, is self-administered and relatively easy and quick to complete. However, since its introduction, to our knowledge it has been scarcely used to date in clinical or research situations to evaluate therapeutic interventions in patients with PHT (9). Only two case reports and a pilot study have been reported in the international literature (27-29). We encourage Spanish researchers dealing with PHT patients to use this instrument as a valid outcome evaluating tool. In general, VISA-H is a questionnaire of easy translation and adaptation since it does not include colloquial expressions or specific cultural aspects and reflects well-defined locutions. For these reasons, its semantic equivalence does not seem to be altered when translated into other languages. Literacy plays also an important role clinical in terms of equity. Despite the zeal and attention paid by PROM developers, high-level language and complex sentences can be usually found building different types of PROMs. In those cases, populations with low literacy skills may encounter difficulties when completing or understanding these instruments (30). This poor understanding may prone people with low literacy skills to be less likely to participate in musculoskeletal trials (31). Ethical and equity issues then arise as all hypothetical users from any health organization have the right to take part in research, being their exclusion a potential cause of selection bias (32). Our study only included high-school and university-level subjects due to the non-probability sampling method employed, which may represent itself a limitation.

Readability is comprised by the semantic and syntactic attributes of the written text. Through readability one can determine the relative utility of text compositions for people with varying degrees of reading skills. Calculations can be made employing any of the available computerized readability formulas. Most of these formulae are based on the word difficulty and sentence length - number of words per sentence and number of syllables per word-, turning into figures the reading skills needed to comprehend a given text. Since interviewed population may not understand items with readability scores exceeding their reading ability, estimating the readability of each questionnaire item involves an important component of their evaluation. In this sense, standards for measuring the readability of questionnaires are needed. The employment of readability formulas to assess the VISA-H tool required us to exclude the related question response scales, leaving only the instructions and the questionnaire questions and preambles themselves. Every question response scales were voluntarily deleted

from the questionnaire text due to the lack of sentence structure, which readability formulas assumed.

The cross-cultural adaptation process represents a concept that can be initially considered equivalent to literal translation. However, beyond translation, when applying questionnaire items in different cultural contexts an adaptation process is required to ensure their equivalence in content. This warrants that a construct is being measured the same direction across cultures, supports fidelity of the culturally adapted tool, and allows for valid comparisons of study outcomes across those cultures. The referred equivalence between the original and adapted versions of a questionnaire indicates how similar the interpretation of the instrument in different cultures is (13). Comprehensibility remains then an important consideration when translating and adapting PROs. This was tested in our study by means of cognitive interviews using "probing and paraphrasing" methodology, which provided patient feedback regarding mistakes or misconceptions originating from the translation process (33). Such cognitive interview techniques are known to minimize translation process-associated measurement error and enable respondent misconceptions to be rectified (34).

Our study included a convenience sample of 18 participants (10 female) being at risk of PHT have tested the pre-final version using a cognitive interview process. This method of "cognitive interviewing" or "cognitive testing," is considered a qualitative, evidence-based method explicitly designed to investigate whether a survey item fulfills its original, intended purpose (35). Survey items are presented to participants in much the same way as eligible patients will be administered the scale final version. Therefore, this step was done to test whether respondents understood every question, how they determined their responses, and whether these items were accepted given the given characteristics of the target population. Each subject was asked to answer every item and then discuss their response with the interviewer. Interviews were developed face-to-face by two trained interviewers who were familiar with the method and the assigned population. The cognitive interviewing process is conducted before data collection (pretesting), during data collection, or even after the survey has been administered, as a quality assurance procedure. In our study cognitive interviewing was employed as a validity check to identify problems and restore potential errors. Respondents with previous experience in completing similar surveys stated that it was important to have the possibility to talk with someone about any issue regarding completion during this action.

Each subject, while completing the Sp-VISA-H, was asked to critically review the instrument and answer both generic and specific lists of questions. Those questions meant to probe whether the Sp-VISA-H is easily understood and relevant, and whether the respondents have any changes or comments. Through this process one can ensure that the adapted version still retains its equivalence in any given situation (4, 33). In addition, differential diagnoses should be ruled out before administering these instruments. As it has

been emphasized in the past for similar instruments, the original VISA-H questionnaire should not be considered a diagnostic tool nor does it play a role in decision making for hamstring tendon invasive procedures (10, 11).

In addition, differential diagnosis is recommended to be established before administering any VISA-H version. This statement and recommendation can be extrapolated for the respective translations.

Several limitations to this study should be acknowledged. First, the psychometric properties of the Sp-VISA-H questionnaire were not evaluated since only healthy individuals comprised our sample size. According this, a linguistic validation action was implemented in line with previous research (36, 37). Second, the utilization of convenience sampling which may have led to a disproportionate representation of population from diverse sport disciplines, since our study included only high-level soccer and basketball players. Further studies involving other athletes are needed in the future as PHT is also prevalent in many other sports, such as dancing, rugby, or athletics. Third, the fair educational level of the sample may have played a role and may hinder the understanding of the scale, limiting its self-application. Finally, a relatively small participant sample was employed. However, previous research have stated that modifications of an existing PRO may only require qualitative assessment of that tool rather than an additional repeated validation (13). Our Sp-VISA-H validation process provides the desired content validity any instrument may demonstrated.

The strengths of this study were the several stages of the questionnaire translation process, working in collaboration with the original developer of the scale, and the field testing which was carried out in an applicable population, along with accepted results showed by statistical analyses. In addition, the time needed to fill out previous versions of VISA-H regarding its feasibility has not been recorded in the past. To our knowledge, time for completing equivalent tools like VISA-A and VISA-P have not been evaluated either. Questionnaires assessing different dimensions or designed for different purposes but having analogous structure or same number of items have shown to need similar periods of time to be completed (38).

The adaptation process presented in this paper indicated satisfactory equivalence between the original VISA-H and the Sp-VISA-H. In general, no important semantic problems in the translation of the VISA-H questionnaire into Spanish were found, being not necessary to change the order within the scale of any item. None of the items substantially changed its original meaning during the translation/back translation process. Most of the implemented modifications consisted in changing some expressions with controversial literal translation, maintaining the equivalence between both versions.

No differences in terms of experiences or cultural concepts were identified, since specific cultural aspects are not addressed in any dimension of the questionnaire. All the items were easily understandable in this pilot study and patients did not report major problems for its completion.

The results of this linguistic validation suggest that Sp-VISA-H can be applied to measure functional impairment in PHT patients. However, since sociodemographic, economic, and geopolitical features make each culture unique, linguistic and conceptual equivalence does not automatically imply generalizability of outcomes across different cultural settings. In other words, no universal version has been obtained yet. Thus, Spanish speaking countries should develop their own VISA-H version to warranty all the native Spanish speakers around the world may access this tool. To the best of our knowledge, only a single Spanish version of this tool is being provided.

Moreover, formal validation and reliability testing of the Sp-VISA-H is being conducted in a multicenter study involving PHT patients.

This study created a Spanish version of a PHT evaluation instrument through a well-defined linguistic validation process including forward-backward translation (i), cognitive interviews (ii), and readability testing (iii). This preliminary work to ascertain the cultural equivalence of the VISA-H has indicated that the Sp-VISA-H has proven to have a good readability score in a risk population of elite sportmen and sportwomen. The Sp-VISA-H can be employed in Spanish-speaking population minimizing cultural and linguistic barriers in the context of PHT. Our scheme can also serve as a template for investigators trying to achieve this aim with other instruments and/or other patient populations.

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