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Spanish Translation and Pilot Validation of the Scale for the Assessment and Rating of Ataxia (SARA)

Scale for the Assessment and Rating of Ataxia (SARA): Estudio piloto de validación y traducción al idioma español

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Abstract

Introduction: Ataxias are a heterogeneous group of disorders with multiple etiologies. Despite the existence of several rating scales, no validated Spanish version of the SARA scale has been available. Given that more than 480 million people worldwide are Spanish speakers, the absence of such a tool represents a gap in clinical practice and research. **Methods:** The SARA scale was translated and cross-culturally adapted following ITC guidelines. A pilot test was conducted in 13 patients with genetically confirmed (n=11) or immune-mediated (n=2) ataxia. Internal consistency was assessed using Cronbach's alpha, and external validity was evaluated against Barthel index, disease stage, and disease duration. **Results:** The Spanish version of SARA

showed good internal consistency (Cronbach's alpha = 0.87). A significant negative correlation with Barthel index (r=-0.94, p<0.01) and a positive correlation with disease stage (r=0.921, p<0.01) were observed. Correlation with disease duration was weak and not significant (r=0.55, p=0.51). **Discussion:** This pilot study demonstrates the feasibility of a Spanish adaptation of SARA, aligning with results from international validations (Portuguese, Japanese, Chinese, French). Although preliminary, these findings suggest that this tool may provide a reliable measure for clinical and research purposes in Spanish-speaking populations. We generated a Spanish version of the SARA scale with promising preliminary results in terms of reliability and validity. Further multicenter studies with larger cohorts are warranted to confirm its definitive validation.

Keywords: spinocerebellar ataxia, assessment and rating of ataxia, translation, validation, psychometric properties, cross-cultural adaptation

Resumen

Introducción: Las ataxias son un grupo heterogéneo de trastornos de etiología múltiple. A pesar de la existencia de diversas escalas de valoración, hasta el momento no se dispone de una versión validada en español de la escala SARA. Considerando que más de 480 millones de personas en el mundo son hispanohablantes, la ausencia de esta herramienta representa una brecha en la práctica clínica y la investigación. **Métodos:** La escala SARA fue traducida y adaptada transculturalmente siguiendo las guías de la ITC. Se realizó una prueba piloto en 13 pacientes con ataxia genéticamente confirmada (n=11) o inmunomediada (n=2). La consistencia interna se evaluó mediante el alfa de Cronbach y la validez externa se analizó en relación con el índice de Barthel, el estadio de la enfermedad y la duración de la misma. **Resultados:** La versión en español de la SARA mostró una buena consistencia interna (alfa de Cronbach = 0,87). Se observó una correlación negativa significativa con el índice de Barthel (r=-0,94, p<0,01) y una correlación positiva con el estadio de la enfermedad (r=0,921, p<0,01). La correlación con la duración de la enfermedad fue débil y no significativa (r=0,55, p=0,51). **Discusión:** Este estudio piloto demuestra la factibilidad de una adaptación al español de la SARA, en línea con los resultados de validaciones internacionales (portugués, japonés, chino, francés). Aunque preliminares, estos hallazgos sugieren que la escala podría ser una herramienta fiable tanto para la práctica clínica como para la investigación en poblaciones hispanohablantes.

Palabras claves: ataxia espinocerebelosa, evaluación de la ataxia, traducción, validación, propiedades psicométricas, adaptación transcultural.

INTRODUCTION

Ataxias comprise a heterogeneous group of neurodegenerative disorders, whose essential symptom is slowly progressive ataxia, which can be inherited determined as well as secondary to an immune-mediated process, structural damage (e.g. stroke, multiple sclerosis) or metabolic/toxic etiology. These conditions may be associated with other neurological manifestations including dysarthria, oculomotor disturbances or peripheral sensory loss (1).

Hereditary ataxias are classified according to their pattern of inheritance as autosomal dominant, autosomal recessive, X-linked, and secondary to mitochondrial DNA disorders. Autosomal dominant ataxias are the most common with a prevalence of approximately 1 to 5 in 100,000 inhabitants. There is a wide regional variation, being the most frequent worldwide is spinocerebellar ataxia type 3 (2-3). On the other hand, autosomal recessive ataxias have a prevalence of approximately 3 in 100,000 population, being Friedreich's ataxia the most frequent disorder in this group (4). The last group of hereditary ataxias are much rarer and include X-linked ataxias and ataxias secondary to mitochondrial DNA disorder (5).

At the present time, the management of hereditary ataxias is symptomatic and focuses on improving the quality of life of patients through speech, swallowing, and occupational therapy and with kinesiological assistance aimed at improving motor coordination and gait(6-7). The increasing tendency to develop a treatment that modifies the course of the disease has generated a growing interest in its diagnosis and management. Additionally, the development of international studies and cultural diversity are constantly increasing. This requires evaluation instruments that are culturally adapted in the different countries in order to be able to compare the results obtained with other national and international studies that have used the same instrument. Therefore, it is necessary to have rating scales that are not only sensitive but also locally validated.

There are several rating scales for the objective assessment of ataxias. One of the most widely used is the International Cooperative Ataxia Rating Scale (ICARS), which is reliable and has acceptable internal validity; however, it presents some problems with feasibility and the structure of the subscales as well as the large number of items it evaluates, makes it impractical, mainly for clinical evaluation (8-9). Other scales currently in use are the Brief Ataxia Rating Scale (BARS) based on a shorter and modified ICARS and some specific scales such as the Friedreich Ataxia Rating Scale (FARS) for Friedreich's ataxia and the United Multiple System Rating Scale (UMSARS) for multiple system atrophy (10-12).

In 2006 Schmitz-Hübsch T et al. developed a practical and easy to perform scale called Scale of the Assessment and Rating of Ataxia (SARA) which has proven to be a reliable and valid measure of ataxia in patients with hereditary spinocerebellar ataxia and other ataxias (13). It has since become, along with the ICARS scale, the most widely used ataxia assessment tool

for both research trials and clinical evaluation. One of the strengths of this scale is its practicality for clinical evaluation, as it consists of only eight easily applied subscales and takes only a few minutes to complete. Comparatively, SARA does not present a subscale for the evaluation of oculomotor skills, which has revealed a relatively low interobserver agreement, so the usefulness of this scale could be preferred over others.

Currently, SARA it is validated in multiple languages except Spanish (14-18) Moreover, it is estimated that more than 480 million people are native Spanish speakers (19). The absence of a validated Spanish version of SARA limits both clinical practice and the inclusion of Spanish-speaking patients in international clinical trials. The prevalence of hereditary ataxias in Spanish-speaking countries is comparable to that reported in other regions, with population-based studies estimating rates between 3 and 5 per 100,000 inhabitants (3). In Latin America, large cohorts have been described in Cuba and Mexico, particularly in relation to spinocerebellar ataxia type 2 (SCA2) (20-21). Despite this epidemiological burden, no validated Spanish version of the SARA scale has been available to date, which limits both clinical practice and the participation of Spanish-speaking patients in multicenter trials.

The validation of a scale is initially performed in the original language and must be repeated when the structure is altered or when the language in which it is applied changes. The validation process in a different language consists of culturally adapting the questionnaire to the environment in which it is to be used and rechecking that it retains the psychometric characteristics such as reliability, validity, sensitivity, and feasibility, which are appropriate for measuring what it was designed to measure.

Therefore, the objective was to translate and cross-culturally adapt this instrument to the Spanish language and to conduct a pilot test for its subsequent validation in this language.

MATERIAL AND METHODS

Study design and setting

This was a cross-sectional observational pilot study conducted between April and July 2022 at two neurology centers in Buenos Aires, Argentina.

Participants

Patients older than 18 years with genetically confirmed hereditary ataxia or immune-mediated ataxia were recruited during routine visits. The diagnosis of genetic ataxia was confirmed by specific molecular testing (gene panel for hereditary ataxias from Igenomix®) performed in certified laboratories in Argentina. The diagnosis of immune-mediated ataxia was established by the detection of Anti Glutamic Acid Decarboxylase-65 (anti-GAD65) antibodies in serum by

immunoblot in an accredited laboratory and RFC1gene examination for Cerebellar Ataxia with Neuropathy and Vestibular Areflexia Syndrome (CANVAS). Exclusion criteria included patients under 18 years of age and patients with alternative diagnosis that explains the ataxic picture such as presence of motor or sensitive polyneuropathy, spasticity, motor neuron disease, parkinsonism, and ataxias of infectious, metabolic or toxic origin. Other conditions that limits the evaluation of gait according to the criteria of the evaluating physician also was an exclusion criterion.

Variables

The primary outcome was the SARA score. Secondary measures included Barthel index, disease stage, disease duration, and MRI cerebellar atrophy.

Data sources and measurement

Data were collected using Google® Forms, complemented with clinical records and patient interviews.

Bias control

Potential sources of bias include selection bias due to recruitment from only two centers and measurement bias given evaluation by a single examiner.

Study size

The sample size (n=13) was justified as appropriate for a pilot feasibility study.

Statistical method

Statistical analysis was performed using IBM® SPSS® Statistics 28.0.1.1. Cronbach's alpha was used to evaluate internal consistency; Pearson and Spearman correlations were used for external validity against Barthel index, disease stage, and duration.

Linguistic and conceptual adaptation was carried out according to the International Test Commission (ITC) (22) for which the following stages were considered:
1) Translation: a professional translator whose native language was Spanish and who was proficient in the original language of the instrument (English) carried out the direct translation from English to Spanish (T1). Then, a second translator, blind to the original questionnaire and a native English speaker and proficient in Spanish, performed the reverse translation or back-translation (T2). Both were professionals with expertise in instrument translation and independent of the research team. Members of the research team collaborated in both processes to advise the translators on the methodology to be applied.

2) Conceptual equivalences: the versions obtained were evaluated by a panel of four judges. Each member of the jury independently compared the suitability of the adaptation (from English to Spanish) of each scale item (T3). Two mainly conceptual discrepancies between T1 and T2 were found during the translation process and were resolved at T3. Discrepancies between direct and reverse translations were discussed in a consensus meeting with the panel of judges, reaching a final version by unanimous agreement. Formal concordance metrics were not used, but all differences were documented and resolved through qualitative discussion.

3) Apparent content validity: to validate the appropriateness of the content of the scale items, five judges with expertise in ataxias were consulted and a pre-final translation or PFT was generated.

4) Pilot test, in which the PFT scale was administered to 13 participants who met the inclusion criteria to examine the clarity of the survey items and instructions. Based on the suggestions of the experts and the comments made by the pilot study participants, the final version (FV) was obtained.

The validation process in a different language consists of culturally adapting the questionnaire to the environment in which it is to be used so that the instrument is equivalent at the semantic, conceptual and technical levels and then rechecking that it retains psychometric characteristics such as reliability, validity, sensitivity and feasibility appropriate for measuring what it was designed to measure (See Figure 1.)

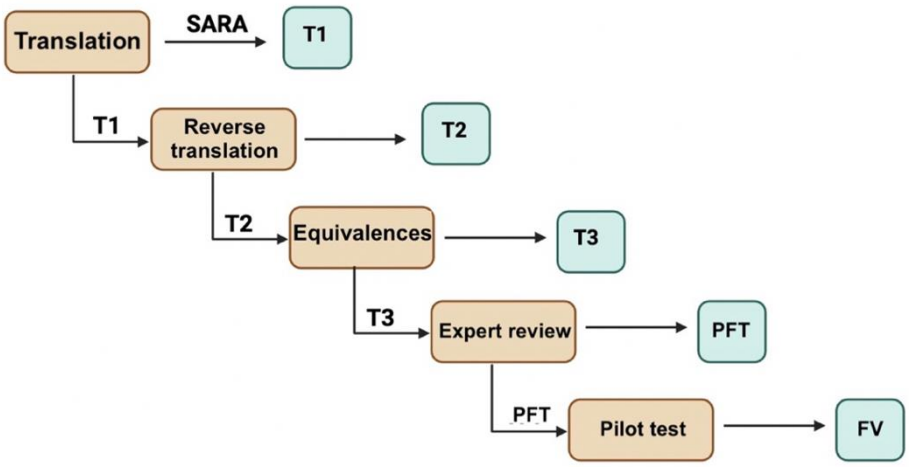

Figure 1. *Stages of the cross-cultural adaptation process*

The pilot test used the PFT of the SARA scale translated into Spanish. This scale evaluates 8 items with a total score ranging from 0 (no ataxia) to 40 (severe ataxia): 1. gait, 2. stance, 3.

sitting, 4. speech disturbance, 5. finger chase, 6. nose-finger test, 7. fast alternating hand movements and 8. heel-shin slide were included. From limbic kinetic functions (items 5 to 8), is scored independently for both sides and the arithmetic mean of both sides is then taken as the final score.

The *Arbizu Barrena et al*. version of the Barthel index was also used (23). This index is a widely used scale to assess the patient's level of independence in carrying out activities of daily living (ADL). The ADLs assessed are: feeding, transferring from chair to bed and back, personal hygiene, sitting and getting up from the toilet, bathing, walking on a flat surface, going up and down stairs, dressing, bowel control and bladder control.

This index assigns 0, 5, 10 or 15 points for each of the ADLs assessed depending on the degree of need or physical assistance needed by the subject to perform them, i.e. they are classified according to whether patients can perform the task independently, with help, or are totally dependent. The total score is calculated by adding the individual scores, and ranges from 0 (total dependence) to 100 (total independence).

The disease stage defined in the original work of Schmitz-Hübsch et al. was also used as: 0 = patient has no gait disturbance; 1 = gait disturbance evident; 2 = loss of gait independence defined as cane/walker use and 3 = permanent wheelchair uses of bed confinement (13).

This study was approved by the teaching and research committee according with the ethical standards of both institutions and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

RESULTS

For the preliminary trial, the PFT in Spanish language of SARA was used in 13 subjects with ataxia, which 11 patients were diagnosed with familial ataxia and 2 with Anti-GAD65 (Anti Glutamic Acid Decarboxylase-65) immune-mediated ataxia. Demographic variables are summarized in Table 1.

Table 1.
Demographics characteristics (n=13)

Parameter	
Age, years	57 ± 14.07
Gender	
Female	9 (69.2)
Male	4 (30.8)
Education, years	12 ± 3.12
Age of onset, years	45.4 ± 13.5

Disease duration, years	10 ± 12.5
Disease stage	
Stage 1	5 (38.5)
Stage 2	6 (46.2)
Stage 3	2 (15.3)
Ataxia type	
SCA2	4 (31)
SCA3	5 (38)
SCA5	1 (8)
Ab-GAD-65	2 (15)
CANVAS	1 (8)
Ataxia symptoms at onset	
Gait disturbance	12 (92.3)
Oculomotor disorder	1 (7.7)
Cerebellar atrophy	11 (84.6)
Time of SARA realization, minutes	10.6 ± 2.02
Total SARA score	17.65 ± 7.8
Total Barthel score	75.77 ± 22.7

Data are presented as mean (SD) for continuous variables and n (%) for categorical variables. SCA = Spinocerebellar Ataxia Ab-GAD = Anti-glutamic acid decarboxylase-65 antibody associated cerebellar ataxia. CANVAS = Cerebellar Ataxia with Neuropathy and Vestibular Areflexia Syndrome. SARA = Scale for the Assessment and Rating of Ataxia. Note: Items with no cases (e.g., absent onset symptoms) were explicitly coded as '0' to avoid confusion with missing data.

The mean age was 57 ± 14.07 years, with 69% of the patients being female. Forty-six percent of the patients presented grade 2 disease stage. Cerebellar atrophy was observed in 84% of the patients in brain MRI with the most frequent onset symptom being gait disturbance (92%). The mean time to complete the SARA scale was 10.6 ± 2.02 minutes and the mean total score on this scale was 17.65 ± 7.8. The scale demonstrated adequate internal consistency, with a Cronbach's alpha of 0.87, indicating its reliability. The most salient item demonstrated total correlations ranging from 0.57 to 0.86, with the gait and heel-knee test items contributing most to internal homogeneity (see Table 2).

Table *2.*

Reliability and internal consistence of SARA

Item	**Item–total correlation**	**p-value**
Gait	0.86	<0.01

Sitting	0.57	<0.01
Speech disturbance	0.64	<0.01
Fast alternating movements	0.78	<0.01
Heel-shin slide	0.86	<0.01

Cronbach's α = 0.87 (good internal consistency).
All correlations showed significance.

We analyzed external validity by evaluating the associations of the SARA scale with various measures such as the Barthel index, stage and duration of illness. A significant negative correlation was observed with Barthel's index (rho = -0.924, p<0.01) and disease stage (rho = 0.921, p<0.01). A weak and non-significant correlation with disease duration (rho = 0.55, p=0.51) (Figure 2).

Panel A shows a significant negative correlation between SARA and Barthel index, meaning higher ataxia scores are associated with greater disability in activities of daily living. Panel B shows positive correlation with disease stage. Panel C shows non-significant correlation with disease duration.

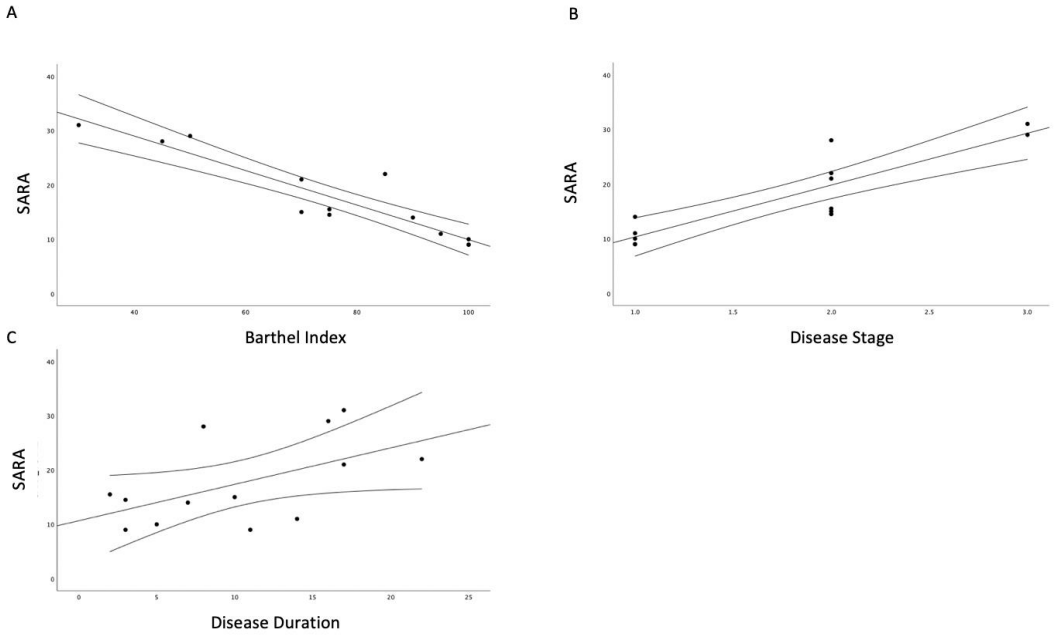

Figure 1. Validation of Scale for the Assessment and Rating of Ataxia (SARA) with external measures. A. Correlation of the SARA score with Barthel Index (r=-0.94, p<0.01). B.

Correlation of the SARA score with disease stage (r=0.921, p<0.01). C. Correlation of the SARA score with disease duration (r=0.55, p=0.51).

DISCUSSION

Given that the objective of this study was to generate a pilot test rather than a definitive validation, a small sample size was considered sufficient to assess feasibility, item clarity, and obtain a preliminary estimate of internal consistency.

We acknowledge that the findings of this study do not constitute a definitive validation of the SARA scale in Spanish.

We translated the SARA scale into Spanish language, which showed good internal consistency and a positive correlation in terms of external validity. These results are similar to those obtained by Schmitz-Hübsch et al. in the original work (13) Moreover, our results show high internal consistency (α=0.87), comparable to that reported in the Portuguese (α=0.88), Japanese (α=0.85–0.90), Chinese (α=0.91), and French (α=0.89) validations of the SARA scale. Likewise, the significant correlation with functional measures such as the Barthel index is consistent with the convergent validity described in these international versions, which reinforces the robustness of the instrument in different cultural contexts. which also demonstrated strong internal consistency and external validity (14-16).

The average application time (10.6 minutes) and good acceptance by patients are consistent with what has been described in other studies, highlighting the practicality of SARA as a clinical and research tool in the Spanish-speaking population. Finally, it should be noted that our study is the first cross-cultural adaptation of the scale into Spanish, which represents a unique contribution to the Spanish population.

However, there are also important differences between our study and international validations. Unlike the Portuguese, Japanese, Chinese, and French versions, our work was carried out on a small sample (n=13) and in two neurologic centers, which limits the generalizability of the findings. Furthermore, inter-rater reliability and test-retest stability were not evaluated, aspects that have been addressed in other validations and should be included in future studies. On the other hand, while most studies compared the SARA with specific ataxia scales such as ICARS or FARS, we used the Barthel index and clinical stage due to the lack of previously validated scales in Spanish.

Conversely, availability of a validated Spanish version will facilitate inclusion of Spanish-speaking patients in multicenter clinical trials and provide clinicians with a practical and reliable tool for routine assessment. It is essential to emphasize that when applying the adapted Spanish version, the evaluators found it to be a quick and easy way to evaluate patients with ataxia and, there was also no evidence of difficulty in its interpretation by patients.

Besides the small sample size, the absence of inter-rater reliability testing and test–retest evaluation represents another important methodological limitation. We believe that these results should be interpreted as a first step toward multicenter studies with larger sample sizes that will confirm the validity and reliability of this version.

In a recent review conducted by a working group of the Movement Disorders Society in which they analyzed and made recommendations on current ataxia rating scales, they concluded that the SARA scale presents adequate feasibility, acceptability, reliability, validity and widely demonstrated responsiveness for use in both daily clinical practice and clinical trials (24).

CONCLUSIONS

In this work, we generated a Spanish cross-cultural adaptation of the SARA scale. Our pilot study suggests good internal consistency and external validity. These preliminary findings represent an initial step toward multicenter studies with larger samples to confirm definitive validation.

Conflict of Interest

The authors declare no conflicts of interest.

Ethical Statement

Not applicable.

Data, Materials, and Code Availability

No data analysis was performed for this manuscript.

Authors Contribution

All authors contributed to the study conception and design, performed the research. All authors read and approved the final manuscript. Julian M. Fernandez-Boccazzi and Emilia M. Gatto supervised the data collection.

Statement on the Use of Artificial Intelligence

No artificial intelligence was used for information processing or for the writing of this manuscript.

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