

Linguistic and Psychometric Validation of the Erection Hardness Score to Spanish

Eduard García-Cruz, MD,* Javier Romero Otero, MD,[†] Juan Ignacio Martínez Salamanca, MD,[‡] Asier Leibar Tamayo, MD,[§] Alfredo Rodríguez Antolín, MD, PhD,[†] Ander Astobieta Odriozola, MD, PhD,[§] and Antonio Alcaraz, MD, PhD*

*Hospital Clínic, Department of Urology, Barcelona, Spain; [†]Hospital 12 de Octubre, Department of Urology, Madrid, Spain; [‡]Hospital Universitario Puerta de Hierro-Majadahonda, Majadahonda, Spain; [§]Hospital de Galdakao-Usansolo, Galdakao, Spain

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ABSTRACT

Introduction. The Erection Hardness Score (EHS) is a one-item questionnaire that assesses rigidity on a 4-point scale.

Aim. To perform a validation of a Spanish version of the EHS by comparison with the International Index of Erectile Function (IIEF) questionnaire.

Methods. Validation of the EHS included: (i) professional translation of the scale; (ii) scientific evaluation of the translation from four independent urologists; (iii) assessment on five individuals to test correct comprehension and idiomatic adequacy (iv) validation of the EHS by a cross-sectional, multicenter comparison with the IIEF.

Main Outcome Methods. Patients were required to respond to a Spanish version of the EHS and IIEF. Statistic correlation was carried out between the EHS score and IIEF-erectile function domain (EF) score.

Results. A total of 125 patients were recruited. Overall prevalence of erectile dysfunction (ED) by the EHS questionnaire was of 80.2% patients ($n = 97$). Mean EHS was 2.74 ± 0.97 . Mean IIEF-EF score was 17.4 ± 9.5 . The EHS showed good reliability. The rate of missing responses to the EHS questionnaire was 0%. A one-factor analysis of variance was performed between the EHS and EF subdomain of IIEF ($P = 0.000$). Pearson's correlation coefficient between EHS and EF subdomain of IIEF was 0.834, $P < 0.01$.

Conclusions. The EHS is a reliable tool to test ED and its Spanish version was satisfactorily understood by patients and correlated with IIEF-EF. **García-Cruz E, Romero Otero J, Martínez Salamanca JI, Leibar Tamayo A, Rodríguez Antolín A, Astobieta Odriozola A, and Alcaraz A. Linguistic and psychometric validation of erection hardness score to Spanish. J Sex Med 2011;8:470–474.**

Key Words. Erectile Dysfunction; Questionnaire; Methodology; Erection Hardness; Scale

Introduction

Erectile dysfunction (ED) is a highly prevalent disease [1,2]. Moreover, ED is a very reliable marker for diabetes, hypertension (HTA), metabolic syndrome, heart disease, and many other entities affecting males [3]. This sentinel capacity of ED has led the scientific community to develop questionnaires to detect ED in the general population.

As part of the sildenafil trial, an International Index of Erectile Function (IIEF) was developed and validated as a reliable patient-reported questionnaire to diagnose and assess ED [4]. During further discussion of the sildenafil proof-of-efficacy study, it was decided to incorporate a simple method to assess erectile function [5].

In this setting, the Erection Hardness Score (EHS) questionnaire was developed. Psychometric analysis confirms the EHS to be a simple, valid,

reliable, and responsive patient-reported questionnaire [6]. The EHS has been proven useful in detecting ED, grade its severity, and follow the efficacy of treatment [6–8].

It has also been pointed out that there is a close relationship between erection hardness and successful sexual intercourse (SSI) [9]. For example, males with an EHS of 4 were 24 times more likely to have a successful sexual intercourse when compared with those with an EHS of 3 and 42 times more likely than males with a score of 2 [10].

Moreover, EHS correlates with the erectile function subdomain of the IIEF (IIEF-EF) [6], the percentage of successful sexual intercourse (SSI) [5].

However, no validated version of the EHS has been available for use in Spanish-speaking populations. The aim of this study was to perform a validation of the EHS questionnaire in a Spanish-speaking population by comparing it with the IIEF questionnaire.

Material and Methods

We designed a cross-sectional, multicenter, observational study to validate a Spanish version of the EHS questionnaire, by comparing it with the ED domains of the IIEF.

First, a translation was made from the English version of the EHS questionnaire into Spanish. A professional English–Spanish translator carried out this translation.

Second, four urologists with expertise in sexual medicine reviewed the translation to assess its clinical applicability and scientific consistency.

Third, the linguistic adequacy and the lack of ambiguity of the questionnaire was evaluated by five randomly selected patients.

The final version of the questionnaire is displayed in Appendix 1.

Fourth, to perform the validation exercise, a total of 125 patients referred from general practitioners to general urological practice were recruited in two centers from January 2009 to March 2009. A comparison was made between responses to the IIEF and EHS questionnaires.

Patients were informed about the study and verbal consent was obtained. Patients were asked to answer the Spanish version of the IIEF questionnaire and the Spanish version of the EHS questionnaire. Patients were not routinely treated for their ED and were only referred for evaluation by a sexual medicine specialist if required on clinical grounds.

The EHS validation was performed prospectively and followed FDA draft guidance [11] and publications on validation on PRO [12–16].

Statistical analysis was carried out to assess the validity of the Spanish version of the EHS questionnaire.

1. Quality and distribution responses: To assess quality of distribution responses, data was used from the inclusion visit of the study. The quality of response was calculated as number of questionnaires with missing EHS scores/number of total questionnaires. For the distribution of responses, data from the inclusion visit was considered.
2. Validity: Convergent validity of the EHS with the erectile function domain of the IIEF questionnaire was calculated using Pearson correlation coefficients, where a strong convergent relationship ($r > 0.6$) was expected. Known-groups differences were evaluated by determining the EHS ability to differentiate between ED severity groups as defined by scores of the erectile function domain.

Results

Among our study population, mean age was 59 ± 12.8 years. Mean BMI was 26 ± 2.83 kg/m². A total of 39.5% of patients were non-smokers, 26% of patients were active smokers and 34.5% were former smokers. Mean alcohol daily intake was 13 ± 29 g of pure alcohol per day. A total of 44.8% of patients had HTA, 22.1% of patients had diabetes mellitus and 34.6% of patients had hypercholesterolemia or hypertriglyceridemia.

Quality and Distribution

The rate of missing responses to the EHS was 0% (0/125). The per-patient mean responses at the inclusion visit were more frequently EHS 3 and EHS 4. There was no evidence of a floor or ceiling effect (Table 1).

Table 1 Erection Hardness Score (EHS) responses distribution (number of cases, percentages, and cumulative percentages)

	%	Cumulative %
EHS 0 ($n = 2$)	1.7	1.7
EHS 1 ($n = 15$)	12.4	14
EHS 2 ($n = 20$)	16.5	30.6
EHS 3 ($n = 60$)	49.6	80.2
EHS 4 ($n = 24$)	19.8	100

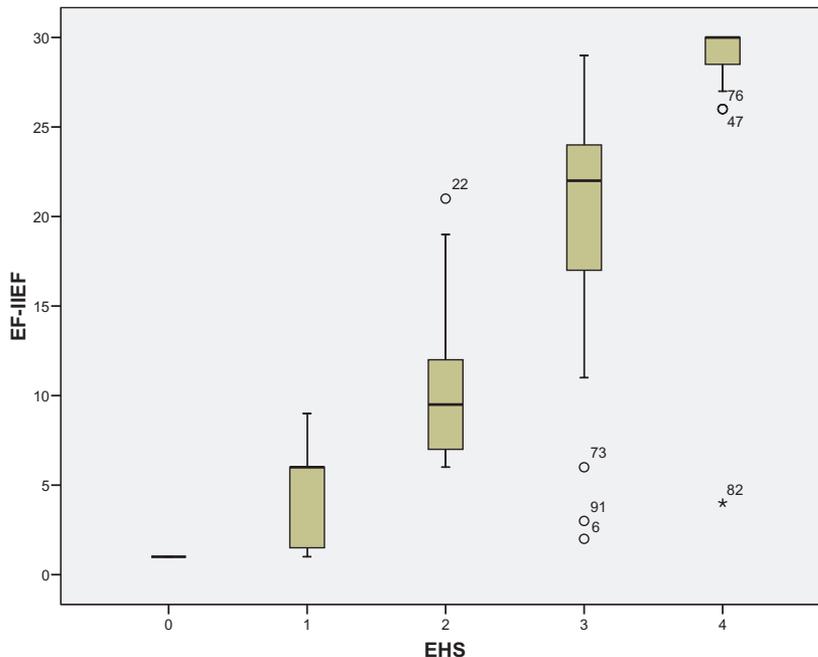


Figure 1 Box plot diagram representing Erection Hardness Score (EHS) and erectile function subdomain. One-factor analysis of variance between EHS and International Index of Erectile Function-erectile function domain (IEF-EF) of the IIEF questionnaire, $P = 0.000$.

Validity

A strong correlation between IIEF-EF and EHS was found (Pearson's correlation coefficient = 0.834, $P < 0.01$). As expected, there was a strong correlation between EHS and erectile function domain of the IIEF (Figure 1). The least squares mean EHS followed the expected direction, being lowest in the men classified in the severe ED group, and increasing with subsequent categories. A one-factor analysis of variance (ANOVA) analysis was made between the EHS and the score of the EF subdomain of the IIEF questionnaire as shown in Figure 1 (one-factor ANOVA, $P = 0.000$).

Discussion

The most detailed questionnaire to assess erectile function in ED patients is the IIEF [4]. Nevertheless, the IIEF is an extensive questionnaire, which includes 15 questions. However only six of these questions were able to adequately discriminate between males with and without ED. The other nine questions did not correlate with erectile function in males. Apart from the inability to adequately identify ED, the IIEF questionnaire takes more than 10 minutes to patients to complete. The Sexual Health Inventory for Men (SHIM) questionnaire was developed to provide the same advantages as IIEF but in a shorter questionnaire.

The SHIM consists of five questions from the IIEF questionnaire that showed good discriminatory ability [17]. However, the SHIM may still be a difficult and long questionnaire to use in daily urological practice [2].

Other questionnaires have also been developed as diagnostic tools, but are focused on primary care, such as the Short Questionnaire for Erectile Dysfunction (SQUED) questionnaire [18].

Our results show the EHS to be a useful questionnaire. The low rate of missing items indicates the EHS questionnaire is easy to use (Table 2). In our experience, patient acceptance was excellent, with 100% of questionnaires completed. Similar results were found in the original EHS validation [6].

The validity of the EHS was compared with the IIEF, a robust, well-known, and established standard of ED evaluation, and the EHS was able to differentiate between severity of ED defined by the IIEF erectile function domain. Importantly, the EHS distinguishes between men without ED and men with compromised erectile function.

Table 2 Erection hardness score

"How would you rate the hardness of your erection?"

- 0: Penis does not enlarge.
- 1: Penis is larger but not hard.
- 2: Penis is hard but not hard enough for penetration.
- 3: Penis is hard enough for penetration but not completely hard.

Mulhall [6] emphasized the ability of the EHS not only to detect ED, but to successfully classify its severity. The EHS Arabic version has been recently published showing its reliability in a Saudi Arabic-speaking population [19].

It is remarkable that the EHS is a single question score that has demonstrated to correlate with the erectile function subdomain (EF) of the IIEF questionnaire. Moreover, the EHS is a rapid and easy questionnaire, easily used by both primary care physicians and urologists. Given its good correlation with the IIEF-EF, the EHS might also allow not only diagnosis and staging of ED severity, but help identify subsequent response to treatment.

There are some limitations to our study. This was a cross-sectional, single-visit study. Thus, conclusions on test–retest reliability, clinically important differences, and responsiveness cannot be extracted. Although the English original EHS validation showed excellent results in these areas, it should be mentioned that acceptable test–retest reliability needed at least three EHS responses. This is caused by the variability in erection hardness at different sexual encounters. Although it was not the aim of the study, parallel results might be expected using the EHS in Spanish-speaking population regarding test–retest variability.

In conclusion, validation of the EHS questionnaire in Spanish shows it can be used for screening in primary care, and staging of ED severity because of a good correlation with the IIEF-EF. Its simplicity also makes it an excellent tool for assessing treatment response.

Conclusion

The EHS is a reliable tool to test ED and its Spanish version was satisfactorily understood by patients and correlated with the EF domain of IIEF.

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Corresponding Author: Eduard García-Cruz, MD, Hospital Clínic, Department of Urology, Barcelona 08026, Spain. Tel: +34619267020; Fax: +34932275545; E-mail: edu_garcia_cruz@yahoo.com

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Statement of Authorship

Category 1

(a) Conception and Design

Eduard García-Cruz; Javier Romero Otero; Juan Ignacio Martínez Salamanca; Asier Leibar Tamayo

(b) Acquisition of Data

Eduard García-Cruz; Javier Romero Otero

(c) Analysis and Interpretation of Data

Eduard García-Cruz; Javier Romero Otero; Antonio Alcaraz

Category 2

(a) Drafting the Article

Eduard García-Cruz

(b) Revising It for Intellectual Content

All authors

Category 3

(a) Final Approval of the Completed Article

All authors

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Appendix 1—The Spanish Version of the EHS Questionnaire

Cómo puntuaría la dureza de su erección?

Por favor escoja la respuesta que mejor describa el estado más frecuente de su pene durante la actividad sexual durante las últimas cuatro semanas.

- 0: El pene no aumenta de tamaño.
- 1: El pene aumenta de tamaño pero no llega a estar duro.
- 2: El pene está duro pero no lo suficiente como para poder penetrar.
- 3: El pene está suficientemente duro como para la penetración pero no completamente duro.
- 4: El pene está completamente duro y plenamente rígido.