PSYCHOMETRICS

Colombian Clinical Validation of the International Index of Erectile Function (IIEF-5)

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ABSTRACT

Background: Erectile dysfunction represents an important health problem and the instrument most frequently used for the evaluation of its evaluation is the International Index of Erectile Function (IIEF-5).

Aim: Due to lack of adaptation and validation for Spanish-speaking populations, this study aimed to adapt and validate the Colombian version of International Index of Erectile Function (IIEF-5).

Methods: Two independent samples were evaluated. One used to validate the scale and the other to calculate cut-off point of this version, with 2,021 men from the general population and outpatients from a clinic. The age range was 18 to 75 years old (M = 37.80; SD = 14.06). The second sample included 74 men, 64.9% did not meet DSM-5 criteria for erectile dysfunction, and 35.1% meet DSM-5 criteria to ED. Age range was 19 to 73 years old (M = 40.38; SD = 13.22).

Outcomes: All participants answered the Spanish versions of the International Index of Erectile Function-5 (IIEF-5) and the Massachusetts General Health-Sexual Functioning Questionnaire.

Results: The Colombian version of IIEF-5 showed adequate psychometric properties, confirmed the one-dimension factorization of the scale, and showed adequate evidence of reliability and validity. Significant differences were observed in the IIEF-5 total score between the non-clinical and clinical groups who meet DSM-5 criteria for erectile dysfunction, with a large effect size. Also, the cut-off the Colombian version was set to 16, with an area under the curve of 94.9%.

Clinical Implications: The Colombian version of the IIEF-5 is a useful evaluation instrument that provides to determine the presence of erectile dysfunction compatible with DSM-5 criteria.

Strengths & Limitations: The inventory reports adequate psychometric properties, a confirmed one-dimensional structure, evidence of reliability and validity, and the first cut-off point for Hispanic populations. A more in-depth evaluation of the diagnosis of ED and thus replication in other Spanish-speaking countries and sexual minorities is recommended.

Conclusion: The Spanish version of the IIEF-5 is a useful evaluation tool for identifying erectile dysfunction, following DSM-5 criteria. **Vallejo-Medina P, Saffon JP, Álvarez-Muelas A Colombian Clinical Validation of the International Index of Erectile Function (IIEF-5). Sex Med 2022;10:100461.**

Key Words: IIEF-5; Erectile dysfunction; Spanish; DSM-5; Sexual function; Men

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INTRODUCTION

Erectile Dysfunction (ED) is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance.[1] It represents an important health problem, affecting psychological well-being and quality of life, as well as the couple relationship.[2,3] ED is a common disorder, whose prevalence may vary from country to country.[4] Its global prevalence is estimated at 3-76.5%.[5] Many factors are involved in its

etiology, including vascular, hormonal, neurological, psychological, and lifestyle causes.[6] Furthermore, ED is associated with numerous physiological diseases[7] and the presence of psychological disorder symptoms.[8] For instance, erectile dysfunction has been identified as a risk factor and as a comorbid symptom in depression.[7] On the other hand, several anxiety disorders have been associated with ED,[7] such as social phobia[9,10] or generalized anxiety,[11] and positive relationships with age and low quality of life have also been described.[12,13]

The International Index of Erectile Function (IIEF)[14] is widely used for the evaluation of men's sexual issues[15,16] and has been translated into more than 32 languages,[17] which makes it the instrument most frequently reported by male patients as part of the evaluation of their sexual function.[18] The index uses five domains to evaluate erectile function (6 items), orgasmic function (2 items), sexual desire (2 items), intercourse satisfaction (3 items), and overall satisfaction (2 items). A short version composed of five items the IIEF-5, was developed to allow for the evaluation of ED specifically, according to the criteria established by the National Institutes of Health.[1] In a systematic review by Neijenhuijs et al.,[17] the authors conclude that the IIEF-5 presents adequate evidence of criterion validity, moderate evidence of structural and construct validity, and adequate evidence of test-retest reliability. Nevertheless, despite these pieces of evidence, the inventory includes items related to the erectile function domain and one item related to sexual satisfaction; therefore, the unidimensionality of the scale should be assessed to adequately determine its internal consistency.

The IIEF-5, also known as the Sexual Health Inventory for Men, has shown good discriminant validity between patients with and without ED, and it can identify different ED severity levels.[19,20] Therefore, this index is a primary criterion in clinical trials around the world,[21] and it is the most widely used tool for the diagnosis of erectile dysfunction.[18,20] More research on the IIEF-5 cut-off point is considered necessary because different cut-off points have been reported in different studies. In the original version, Rosen et al.[19] recommended a cut-off point of 21 points; however, the authors also indicated the need to determine this cut-off point in other contexts. Thus, the Chinese version scored 16 points,[22] the Malay,[23] and Korean[24] versions scored 17, and the Portuguese[25] version scored 18. The Dutch version fails to indicate a specific cut-off point, but the authors suggest that a value of 21 would lead to the wrong conclusions.[26] Neijenhuijs et al.[17] indicate that the value of 21 is inaccurate due to the significant imbalance between comparison groups, which would skew the CART algorithm and the use of trained samples. In view of the widespread use of the scale and its discrimination capacity, we would like to highlight the lack of adaptation and validation for Spanish-speaking populations. For this purpose, the present study aimed to adapt and validate the IIEF-5 for the Colombian population. Thus, we evaluated factor structure, different item psychometric properties, criterion validity, and discriminant validity using clinical samples, and criteria were based on the DSM-5.[27] A specific and sensitive cut-off point to be used for this Spanish language version was also determined. Therefore, the research question is, will the IIEF-5 be an instrument with evidence of reliability and validity in the Colombian population?

MATERIALS AND METHODS

Participants

The study evaluated two independent samples. The first sample was used to validate the scale. This sample consisted of 2,021 men from the general population and a group of outpatients from a Colombian sexology clinic (hidden for review). The "non-clinical" group (n = 936) reported no sexual dysfunction problems. Whereas the "clinical" group (n = 1085) reported erectile dysfunction issues. Participant age range was 18 to 75 years old (M = 37.88; SD = 14.06). A total of 86.47% of the participants reported being exclusively heterosexual, 9.35% exclusively homosexual, 2.72% asexual, and 3.46% indicated different levels of bisexuality. All participants were Colombian; 38.30% lived in Bogotá, 9.3% in Medellín, 5.74% in Cali, 3.71% in Barranquilla, and 42.95% lived in other Colombian cities. Inclusion criteria for this sample were being 18 years of age or older, living in Colombia, and being literate, Exclusion criteria were not having signed an informed consent form.

A second sample was used to validate the Spanish language IIEF-5 cut-off point. This sample consisted of 74 men between 19 and 73 years of age (M = 40.38; SD = 13.22). The "non-ED" group included volunteers not meeting DSM-5[25] diagnostic criteria for ED; they represented 64.9% (n = 48) of the second sample. The remaining 35.1% (n = 26) of participants represented the "ED" group, that is, people who met DSM-5[25] diagnostic criteria for ED. ROC curve power calculation suggested a power analysis in our case (ED n = 26; Controls n = 46; auc = 0.949; sig.level = 0.05) of 1. Inclusion/exclusion criteria were the same as those in the first sample. Table 1 presents additional information about first and second samples.

Instruments

International Index of Erectile Function-5 (IIEF-5)[19]. This self-reporting instrument consists of five items that evaluate the presence or absence of ED. Four of its items focus on erectile function and one on sexual intercourse satisfaction. Response options are given on a Likert-type scale with possible scores between 1 and 5. Low values indicate the presence of ED symptoms.

Massachusetts General Hospital-Sexual Functioning Questionnaire (MGH-SFQ)[28,29]. The present study used the Colombia-validated version for men, composed of five items. These items evaluate sexual desire, sexual arousal, orgasm, erection, and general satisfaction. The questionnaire uses a five-point Likert-type scale (0 to 4) where scores under 2 indicate possible sexual

Table 1. Demographic information, first sample and second sample

	First sample			Second sample		
	Clinical (n = 1085)	non-clinical (n = 936)	Contrast	ED (n = 41)	No ED (n = 82)	Contrast
Age	*M* = 33.08 (*SD* = 13.22)	*M* = 42.02 (*SD* = 13.43)	t = -15.03; $P < .01$	*M* = 35.76 (*SD* = 10.40)	*M* = 33.40 (SD = 13.63)	t = 3.35; $P < .01$
Sexual orientation			$\chi^2 = 91.94$; $P < .001$			$\chi^2 = 2.51$; $P = .29$
Asexual	3.70%	1.60%		0%	0%	
Heterosexual	89.5%	78.50%		76.90%	97.90%	
Bisexual	2.00%	5.00%		3.80%	2.10%	
Homosexual	12.70%	5.50%		0%	13.40%	
Couple relationship			$\chi^2 = 83.6$; $P < .001$			$\chi^2 = 0.86$; $P = .35$
Sí	79.10%	60.50%		73.10%	87.50%	
No	20.90%	39.50%		19.20%	12.50%	
Marital Status			$\chi^2 = 248.05$; $P < .001$			$\chi^2 = 5.70$; $P = .22$
Married	40%	17.40%		34.60%	29.20%	
Single	26.70%	60.60%		15.40%	40.40%	
Separated	9.60%	6.30%		11.50%	4.20%	
Widowed	1.20%	0.30%		3.80%	2.10%	
Common-law marriage	21.50%	14.4.%		34.60%	22.90%	
Medications			$\chi^2 = 1.06$; $P = .03$			$\chi^2 = 7.33$; $P < .01$
Does use	8.76%	7.27%		4.90%	72.90%	
Does not use	91.24%	92.73%		95.10%	27.10%	
Disease			$\chi^2 = 606.05$; $P < .001$			$\chi^2 = 0.46$; $P = .50$
Yes	47,9%	97,8%		61.50%	29.20%	
No	52,1%	2,2%		38.50%	70.80%	

ED = erectile dysfunction.
Disease includes: apoplexy, high/low blood pleasure, thyroid issues, heart problems, cerebral infarction, urological problems, psychiatric diagnosis, anxiety, alcohol abuse, drug abuse, diabetes, cancer, neurological issues, blood-related issues, STIs.

problems. A Cronbach's alpha of .91 was observed in the present study.

Procedure

The study procedure began by considering the two Spanish language versions of the IIEF-5 available at https://www.pfizerpcoa.com/, the US Spanish and Spain Spanish versions. None of these two versions was deemed adequate for the Colombian context. Therefore, we decided to translate and adapt a new version specifically for the South American country of Colombia. Two independent and certified translations were carried out by two independent translators. These translations were discussed by a group including experts in psychometrics and sexology and the translators themselves. After the discussion, a new version was created using contributions from both translators. This new version was back-translated into English and analyzed for content differences. The process was conducted per international guidelines.[30–32] The final version will be available at https://www.pfizerpcoa.com/ and is included in the Supplementary Materials section in this paper.

The study used two types of samples that collected between June 2018 and June 2019. Data from the first sample was collected using a web-based survey that was uploaded to SurveyMonkey and disseminated via social media (Facebook and Twitter) and distributed to contacts in an updated patient directory provided by Boston Medical Group clinic, with which an agreement was signed for the purposes of the present study. The second sample was obtained by administering a pencil and paper instrument to people who sought attention in the clinic due to ED issues for the first time. Subjects without ED were administered the instrument in libraries, universities, study halls, and training rooms. Thus, all sampling was incidental and non-probabilistic. Individual evaluations lasted approximately 10 minutes.

Ethical Statement

This paper derives from a research project revised (Number: 2015-009 55270152) and approved by an ethical committee of Fundación Universitaria Konrad Lorenz. All subjects signed an informed consent agreement, and confidentiality was maintained throughout the study. Participation was voluntary and anonymous.

Data Analysis

The items failed to present multivariate normal distribution (Mardia Skewness = 781 and Mardia Kurtosis = 31). Therefore, a robust statistic was used for the Structural Equation Model

(SEM), as well as a robust estimation method (MLM) and, when possible, robust indicators of fit (such as robust comparative fit index (RCFI) and robust Tucker-Lewis index (RTLI). As usual, values above .95 for the RCFI and RTLI and below .080 for RMSEA were considered as good model fit indicators.[33] Our recommendation is to use RMSEA with caution due to the low df associated to our model that may biased this fit index.[34] A polychoric matrix was used for obtaining results depending on a correlation matrix. Therefore, all reported alphas were ordinal. Confidence intervals for the ROC curves were obtained using 1000 bootstrapping samples.

Results were calculated using R software (Version 3.6.0)[35] and the RStudio interface (Version 1.1.463).[36] The psychometrics packages used were: psych (R package, Version 1.7.8),[37] psychometric (R package, Version 2.2),[38] wash, psycho (R package, Version 0.5.0),[39] semPlot (R package, Version 1.1.2),[40] MVN (R package, Version 5.8),[41] and pROC (R package, Version 1.15.3).[42] The ggplot2 tool was also used (R package, Version 3.1.1).[43] The syntax of the analyses and data can be consulted in the Github repository https://github.com/pableres/IIEFbrief.

RESULTS

The IIEF-5 is usually presented as a one-factor scale. However, evidence for this structure is scarce, and only one study[44] has tested it. In the present study, we conducted a different analysis to determine the number of IIEF-5 factors, and the highest consensus was associated with the one-dimensional structure, as suggested by the methods of optimal coordinates, acceleration factor, parallel analysis, kaiser, Vellicer MAP, and VSS complexity 1. Among these, we would like to highlight parallel analysis and MAP -probably the most reliable methods-. On the other hand, Bayesian information criterion (BIC), sample size-adjusted BIC, and VSS complexity 2 suggested a two-factor structure. Consequently, we used confirmatory factor analysis to determine the dimensional structure. Figure 1 shows the fit index and standardized loadings of the proposed model.

Once the scale dimensionality was settled, we evaluated several item psychometric properties. As shown in Table 2, the assessed psychometric properties were adequate.

Once the one-dimensionality of the scale was reliably confirmed, we tested for discriminant validity. A densitogram was created to compare the group of volunteers who answered the survey on the internet and were not attending a medical center due to sexual dysfunction problems (non-clinical) with the group including other volunteers and outpatients attending a medical center who were at different stages (initial assessment to follow-up) of ED treatment (Figure 2 A). Statistically significant differences with considerable effect size differences were observed. Furthermore, the correlation between IIEF-5 and MGHSFQ was r = .55 **.

Finally, we compared an independent clinical sample of individuals meeting DSM-5[27] criteria for ED who were visiting a sexual dysfunction clinic for the first time with a sample of volunteers not meeting DSM-5[27] criteria for ED. Both groups were

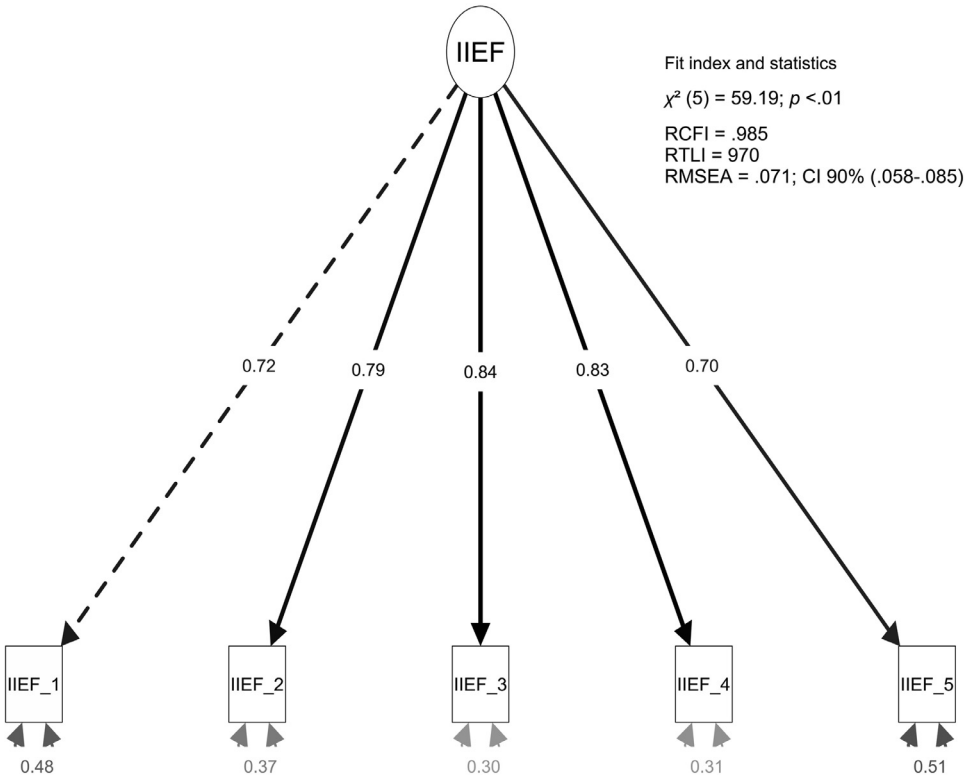

Figure 1. Path diagram for the observed dimensionality of IIEF-5. All loadings are standardized.

Table 2. Selected psychometric properties of IIEF-5

	M(*SD*)	min-max	skewness	kurtosis	r.drop	ord α-item	ordinal α
IIEF_1	3.06(1.21)	1-5	-0.15	-0.85	.72	.90	.91
IIEF_2	3.76(1.23)	1-5	-0.67	-0.66	.79	.88	
IIEF_3	3.56(1.29)	1-5	-0.47	-0.94	.81	.88	
IIEF_4	3.74(1.28)	1-5	-0.59	-0.87	.83	.87	
IIEF_5	3.42(1.19)	1-5	-0.31	-0.88	.69	.90	

M(*SD*) = Mean (Standard Deviation); r.drop = item-total corrected correlation.
Pertinent analyses were performed with the polychoric matrix; therefore, all reported alphas are ordinal.

combined in order to explore a cut-off point for the Colombian Spanish version of the IIEF-5. As shown in Figure 2 B, the results showed that the cut-off point with the highest balance between sensitivity and specificity was 15.5. The area under the curve (AUC) for this value was 94.9%. Subjects with scores of 16 or higher should not be considered as dysfunctional.

DISCUSSION

Evidence of scale validity and reliability is essential for their successful use in research and clinical practice. In this regard, an adequate cultural interpretation of the IIEF-5 requires the validation of both cultural content and cut-off parameters.[18] The present validation of the IIEF-5 validation for Spanish language reports on its adequate psychometric properties, a confirmed one-dimensional structure, evidence of reliability and validity, and a specific cut-off point for Colombia: the first for Hispanic populations.

Given the limited number of studies exploring IIEF-5 factors,[17] we evaluated the content validity of the instrument. The index was originally presented as a one-dimensional scale,[19] and subsequently, Lin et al.[44] successfully replicated it under that consideration. In the present study, standardized weight scores ranged from .70 to .84. Analyses showed adequate the psychometric properties of the inventory, and corrected item-total correlation values were adequate. Previous studies have also reported adequate psychometric properties.[17] In the present study, the value of ordinal alpha was .91. This value is very similar to those found in other studies, in which Cronbach's alpha scores of .64.[22], .89[25], .90[23], .91[13], and .94[26] have been reported. Specifically, the value in this study was the second highest in comparison with previous studies, which provides evidence for the results found.

Secondly, it was exanimated the discriminant validity to evidence differences between the clinical and non-clinical groups to enable to perform the ROC curves. Significant differences were observed in the IIEF-5 total score between the non-clinical and clinical groups, with a large effect size. Thus, as indicated in the original version by Rosen et al.[19], the index obtained good evidence of discriminant validity, differentiating the presence of ED. Additionally, the IIEF-5 correlated positively and significantly with the MGHSFQ. Lower scores on the MGHSFQ would indicate possible problems in sexual functioning which is associated with lower scores on the IIEF-5. In turn, lower scores on the index may indicate the possible presence of erection difficulties. This association would indicate optimal attributes concerning its validity with respect to a criterion. Finally, we established that a score lower than 16 indicates the possible presence of ED. This score differs from the originally presented value of 21reported by Rosen et al.[19], although the authors indicated

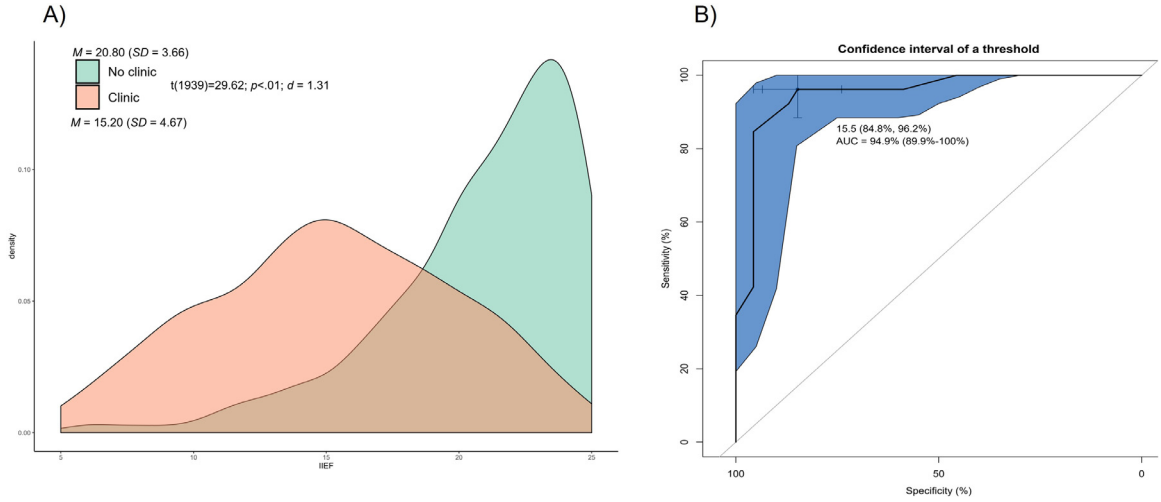

Figure 2. (A) Densitogram for both groups using IIEF raw scores. (B) ROC curve for the IIEF-5.

the need to determine cut-off points for other samples. In this way, it could be considered this value of the cut-off point specific for Colombian population. Moreover, none of the studies that have tested this cut-off point have used the same value for other countries, for instance, in China (16),[22] in Malaysia (17),[23] Portugal (18),[25] Korea (17),[24] or the Netherlands.[26] In Colombia, we also used a lower category and considered the traditional mild erectile dysfunction (scores between 17 and 21) as a non-clinical category. Scores equal or higher to 16 seem to be adequate to exclude ED problems in general. On the other hand, the 21 cut-off point has been considered as inaccurate due to very unequal group sizes, which biases the results of the CART algorithm, and due to the use of a training sample for cross-validation.[17] Nevertheless, methodologies other than COR curves are likely to help close this debate.

Despite the inventory showed compatible with criteria DSM-5,[27] it is required a more in-depth evaluation of the diagnosis of ED. The inventory allows the detection of the possible presence of ED. Moreover, it should be noted that for the analysis of the cut-off point in this study, the "non-ED" group included a larger sample that "ED" group. It is recommended greater research on the cut-off points to determine scores equal or higher to 16 seem are adequate to exclude ED problems. Another limitation of this study was that the sample was Colombian and mostly heterosexual. For this reason, we are unsure if the instrument can be used with other Spanish-speaking populations and sexual minorities with guaranties, further research is needed on this issue.

CONCLUSION

In conclusion, our findings support that the Spanish version of the IIEF-5 is reliable and valid, with evidence for the appropriateness of this version as an instrument for evaluating erectile dysfunction in the Colombian population. In addition, this version provides the first Hispanic cut-off point which can enable clinicians and psychotherapists to determine the presence of erectile dysfunction, compatible with DSM-5 criteria. Therefore, the Colombian version is a tool that can be used as a resource evaluation and guide the treatment of erectile dysfunction. Finally, this validation provides an opportunity to research and compare the evaluation and treatment of erectile in different cultures.

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