Validation of the International Index of Erectile Function (IIFE) for Use in Brazil

Ana Inês Gonzáles, Sabrina Weiss Sties, Priscilla Geraldine Wittkopf, Lourenço Sampaio de Mara, Anderson Zampier Ulbrich, Fernando Luiz Cardoso, Tales de Carvalho

Universidade do Estado de Santa Catarina, Florianópolis, SC - Brazil

Abstract

Background: The International Index of Erectile Function has been proposed as a method for assessing sexual function assisting the diagnosis and classification of erectile dysfunction. However, IIEF was not validated for the Portuguese language.

Objective: Validate the International Index of Erectile Function in patients with cardiopulmonary and metabolic diseases.

Methods: The sample consisted of 108 participants of to Cardiopulmonary and Metabolic program Rehabilitation (CPMR) in southern Brazil. The clarity assessment of the instrument was performed using a scale ranging from zero to 10. The construct validity was carried out by confirmatory factor analysis (KMO = 0.85; Barllet p < 0.001), internal consistency by Cronbach's alpha and reproducibility and interrater reliability via the test retest method.

Results: The items were considered very clear with averages superior to 9. The internal consistency resulted in 0.89. The majority of items related correctly with their domains, with exception of three questions from sexual satisfaction domain, and one from erectile function. All items showed excellent stability of measure and substantial to almost perfect agreement.

Conclusion: The present study showed that the IIEF is valid and reliable for use in participants of a cardiopulmonary and metabolic rehabilitation program. (Arq Bras Cardiol. 2013;101(2):176-182)

Keywords: Erectile Dysfunction; Cardiovascular Diseases; Rehabilitation; Sexual Health.

Introduction

Sexual function is critical for a satisfactory experience. However, some subjects have sexual problems, such as disorders of desire, pain, excitement and orgasm, among others[1].

Sexual dysfunction (SD) is a common disorder, with prevalence of 20-30% in the world male population[2]. It is estimated that over 152 million men worldwide have erectile dysfunction (ED) to some extent[3]. In Brazil, this index is of 45% in the population with >18 years[4,5]. ED affects more than 52% of men aged 40-70 years[6]. This is a significant universal health problem that has strong correlation with cardiovascular diseases[7-10], which share physiopathological mechanism and similar risk factors, such as hypertension, diabetes, dyslipidemia, obesity, sedentism and smoking[8,11].

Mailing Address: Sabrina Weiss Sties •
Rua Paschoal Simone, 358, Coqueiros. Postal Code 88080-350, Florianópolis, SC - Brazil
E-mail: sabrinasties@yahoo.com.br, sabrinaweissties@gmail.com
Manuscript received November 01, 2012; revised November 28, 2012; accepted March 16, 2013.

DOI: 10.5935/abc.20130141

The ED diagnosis can be performed through nocturnal penile monitoring[8], penile Doppler, cavernosography, pelvic arteriography, neurological studies, such as research of the bulbocavernosus reflex, endocrinological studies, psychodiagnostic assessment, among others[12]. However, the patient self-report technique has been proposed as a sexual function assessment method, in addition to diagnosing and classifying ED in clinical trials[13].

Multidimensional assessment instruments have been proposed for ED assessment[14]. Among the currently used are the Brief Male Sexual Function Inventory[15], male sexual quotient (MSQ)[16] and the International Index of Erectile Function (IIEF)[14], which is the most widely used, being considered as "gold standard" by global health entities[17].

IIEF was validated in 32 languages[13] and used to evaluate the sexual function of patients with cardiovascular[18,19] and metabolic[19-21] diseases.

In Brazil, Ferraz and Cicconelli[22] carried out the translation and transcultural adaptation of IIFE to Portuguese. However, its validation was not performed. In light of the foregoing, and because it has a strong correlation of ED and cardiovascular diseases, the goal of this study is to validate the International Index of Erectile Function in patients with cardiopulmonary and metabolic diseases, allowing its implementation in clinical practice and diagnostic screening of ED in this population.

Methods

Instruments and procedures

This is a descriptive cross-sectional study with non-probability sampling. The participants were males included for at least three months in two programs of cardiopulmonary and metabolic rehabilitation (CPMR) in southern Brazil.

For the different types of analysis required in a validation process, data collection was performed in two stages. Initially, 78 subjects were interviewed. Subsequently, 30 subjects were interviewed in two occasions, with a seven day-interval for the analysis of reproducibility and reliability. Subjects who were not sexually active within the prior month were not included. Table 1 shows the characteristics of the study participants.

After explaining the study goals, everyone signed the Informed Consent Form approved by Research Ethics Committee (117/2010), according to Resolution 196/96 of the National Board of Health. Researchers scheduled an appointment that would best fit the participants' routine. The collection was performed while ensuring there was no external interference, every study participant was interviewed individually by researchers working in CPMR programs. The time to fill out the questionnaire, including the answer on the clarity of the participants, was of approximately 14 minutes.

Clinical and sociodemographic characterization

Initially, a semistructured questionnaire with topics on aspects related to cardiovascular risk factors (arterial hypertension/diabetes/hypercholesterolemia/obesity/smoking) and to medical diagnosis.

For socioeconomic classification, the criterion standard of economic classification of the Brazilian Association of Research Companies[23] was used, which evaluates the existing items in the participant's residency and education level of the head of household. The questionnaire is strongly related to the family income ($r = 0.785$ and $r^2 = 62\%$).

International Index of Erectile Function

The International Index of Erectile Function was developed and validated by Rosen et al[14], with the purpose to create a short and reproducible questionnaire to measure the erectile function that is culturally, linguistically and psychometrically valid. The instrument could also be used by doctors and researchers in therapeutic clinical trials as another assessment parameter of efficacy/effectiveness for the several interventions currently proposed[22]. It is worth noting that IIFE was developed for exclusive use in relationship between men and their partners[26].

The questionnaire consists of 15 questions, grouped in five domains: erectile function, orgasm, sexual desire, sexual satisfaction and general satisfaction. Each question has a value ranging from 1 to 5, and the sum of the answers results in the final score for each domain, with low values indicating a bad quality sex life.

Table 1 - Sample characteristics

	$\bar{x}$	SD
Age	**59.60**	**9.41**
	N	**%**
Nutritional state*		
Low weight	1	1.3
Eutrophic	24	30.8
Overweight	25	32.1
Obesity	28	35.9
Marital Status		
Single	3	3.8
Married/Common-law marriage	71	91
Divorced/Widower	4	5.1
Socioeconomic status†		
High (A1 and A2)	5	6.4
Median (B1 and B2)	51	65.4
Low (C1, C2)	21	26.9
(D)	1	1.3
Education level		
Unfinished primary school	7	16.7
Primary school	2	4.8
Unfinished high school	7	16.7
High school	12	28.6
Unfinished higher education	4	9.5
Higher education	10	23.8
Ethnics		
Caucasian	69	88.5
Asian	2	2.6
Afro-descendant	7	9
Diagnosis		
Systemic arterial hypertension	46	59
Coronary artery disease	40	51.3
Dyslipidemia	14	17.9
Heart failure	26	33.3
Diabetes mellitus	22	28.2
Peripheral arterial obstructive disease	3	3.8

**WHO: World Health Organization, 2000[24] and PAHO: Pan American Health Organization , 2001[25]. †BARC: Brazilian Association of Research Companies, 2012[23].*

Capelleri et al[26] suggest the ED can be classified in five categories, as of the erectile function domain, ranging from a minimum score of 6 to a maximum of 30, for sexually active patients, according to Table 2.

Table 2 - Classification of Erectile Dysfunction

Category	Scores
Severe	6-10
Moderate	11-16
Mild to moderate	17-21
Mild	22-25
No erectile dysfunction	26-30

Cappelleri et al[26], 1999.

Statistical Analysis

The descriptive analysis was shown in mean, standard deviation and frequency. Analysis of the data was carried out using the program *Statistical Package for the Social Sciences* (SPSS®) version 20.0 for Windows®.

Assessment of the clarity of the instrument was performed using a scale ranging from zero (not clear) to 10 (very clear)[27]. For the analysis of this stage, we used the resource of the mean and median descriptive statistics and interquartile interval.

Confirmatory factorial analysis was used to evaluate the construct validity. Kaiser-Meyer-Olkin (KMO) index, a measure of the factorability of correlation matrices on which the factorial analysis is based, was used to verify the data adequacy. Subsequently, Bartlett sphericity test was performed to verify if the data meet the sphericity pre-requirement.

The instrument factorial analysis was performed by means of the principal components method for extraction of factors, using for extraction a fixed number of factors equal to 5. 0.4 was established as minimum load for the question to be part of the factor. For interpreting the matrix, the principal components extraction method via orthogonal rotation was applied, by means of *varimax* method.

Cronbach's Alpha (minimum value of 0.6) was used to evaluate the instrument internal consistency. For reproducibility assessment, interclass correlation coefficient (R) was used, this was classified as: $R < 0.4$, poor; $0.4 \leq R < 0.75$, satisfactory; $R \geq 0.75$, excellent[28].

Interrater reliability was verified by the agreement coefficient for nominal scales (kappa) with classification of evaluated items proposed by Landis and Koch[29].

Agreement measured by *kappa* followed the guidance of the literature, including: *kappa* <0.00 = almost nonexistent; 0-0.19 = small; 0.20-0.39 = unsatisfactory; 0.40-0.59 = moderate; 0.60-0.79 = substantial; 0.80-1.00, almost perfect[29].

Results

When analyzing the clarity, all questions of the International Index of Erectile Function showed averages superior to 9 and the median of all questions resulted in 10, demonstrating all questions of the instrument were considered very clear (Table 3).

Regarding the construct validity, KMO test had a result of 0.85 and, added to Barllet test ($p < 0.001$), it indicated the data was suitable for factorial analysis.

By observing the matrix, it was verified that most questions were loaded correctly in their respective domains, except for sexual satisfaction domain, which comprises questions 6, 7, and 8, which presented a confounding factor. Question 1 equally loaded in another factor (Table 4).

The extraction of the five factors explained 75.8% of the total variance of the subjects' responses.

When the internal consistency of domains was analyzed, we verified the sexual satisfaction demonstrated a value of 0.55, below the acceptance value (0.6) for this study (Table 5). The low value of the internal consistency of this domain corroborates the factorial analysis in which the questions corresponding to this domain showed a confounding factor.

Table 6 shows the results of the analysis of reproducibility and interrater reliability. Reproducibility values showed significance in all items ($p < 0.001$), with R values greater than 0.75 in all questions of the questionnaire, being classified as excellent (Table 6). Interrater reliability, assessed by means of *kappa* coefficient, showed significant values for all items ($p < 0.005$) and showed moderated agreement only in question 11 ($k = 0.594$), substantial and almost perfect agreement for the remaining IIFE questions.

Discussion

Studies have demonstrated the strong correlation between sexual function scores, cardiovascular diseases and life quality in patients with cardiopulmonary and metabolic disease[30-32]. Elements complexity and subjectivity comprising the sexual function, assessment difficulty and large number of factors that influence it can explain the small number of validated instruments allowed to be used[33], both in basic clinical practice and in programs of cardiopulmonary and metabolic rehabilitation.

In Brazil, IIFE translation and cultural adaptation was performed for patients with sexual dysfunction[22], not specifically in patients with cardiopulmonary and metabolic diseases; up to this moment, no procedures for its validation were performed.

This study contributes to evaluate and diagnose SD of patients with cardiopulmonary and metabolic diseases in order to promote new strategies of treatment and reception of such patients.

When analyzing the clarity of the instrument we observed that, on the average, participants considered all questions very clear. According to Pasquali[34], clarity is a key criterion for creating and validating items of instruments, being that these must be intelligible even for the lowest strata of the population, using short phrases, with simple and unambiguous expressions.

When analyzing the construct validity, it was observed that, although all KMO and Barllet sphericity tests having considered the data as eligible for factorial analysis, this did not behave as expected, since a few questions showed a confounding factor, relating to more than one factor. However, when observing the data shown by Rosen et al[14], in the original validation article, it is possible to notice the same questions behaved similarly in both studies.

Questions regarding the sexual satisfaction domain were the ones that showed more confounding factors. When analyzing the internal consistency of these items, it was observed a value below the acceptance value. According to Kay et al[35], sexual satisfaction consists of a general conclusion about how pleasant

Table 3 - Descriptive result on the analysis of the clarity of each item of the International Index of Erectile Function

Item	Min.	Max.	Mean	Md	IQ
1	1	10	9.59	10	0
2	3	10	9.70	10	0
3	4	10	9.83	10	0
4	1	10	9.66	10	0
5	1	10	9.62	10	0
6	8	10	9.88	10	0
7	5	10	9.83	10	0
8	8	10	9.94	10	0
9	3	10	9.72	10	0
10	1	10	9.66	10	0
11	8	10	9.94	10	0
12	8	10	9.85	10	0
13	7	10	9.85	10	0
14	6	10	9.81	10	0
15	8	10	9.85	10	0

Md: median; IQR: interquartile range.

Table 4 - Matrix of the factorial analysis with five factors

	Components				
Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
1			0.718		
2	0.785				
3	0.826				
4	0.855				
5	0.618				
6				0.838	
7	0.490	0.497	0.401		
8			0.855		
9					0.728
10					0.820
11				0.773	
12				0.633	
13		0.709			
14		0.867			
15	0.503				

is the sex life, being a subjective determination of the pleasure generated by the sexual behavior. For being a subjective and self-assessment construct, its analysis is complicated, and this may be seen in validation processes.

Regarding internal consistency, Cronbach's Alpha value showed there is homogeneity between questions, with a value of 0.890, close to that found by Rosen et al[14].

Reproducibility (R) values, which correlate both occasions of the application of questionnaire (test-retest) were excellent in every question, i.e. $R > 0.75$, demonstrating good agreement between both occasions and stability of measures.

The agreement coefficient for nominal scales, in general, presented from substantial to almost perfect results, indicating stability in the application of interrater questionnaire.

Table 5 - Internal consistency of the domains and total of International Index of Erectile Function (IIEF)

Domains	Items	Cronbach's Alpha
Erectile function	1, 2, 3, 4, 5, 15	0.86
Sexual satisfaction	6, 7 ,8	0.50
Orgasm	9, 10	0.63
Sexual desire	11, 12	0.77
General satisfaction	13, 14	0.73
Total	1-15	0.89

Table 6 - Values of the analysis of interclass correlation and *kappa* coefficient

Item	R	*k*	Classification (*k*)
1	0.919	0.846	Almost perfect
2	0.904	0.864	Almost perfect
3	0.975	0.846	Almost perfect
4	0.948	0.663	Substantial
5	0.957	0.789	Substantial
6	0.876	0.656	Substantial
7	0.968	0.825	Almost perfect
8	0.816	0.710	Substantial
9	0.975	0.845	Almost perfect
10	0.907	0.676	Substantial
11	0.923	0.594	Moderate
12	0.796	0.664	Substantial
13	0.893	0.638	Substantial
14	0.979	0.903	Almost perfect
15	0.909	0.626	Substantial

Although the questions related to the sexual desire domain have shown lower reproducibility (R) values and agreement coefficient (*k*), its exclusion must not be considered, because the internal consistency of this domain obtained an acceptable value.

The International Index of Erectile Function has been highly utilized in clinical practice, and its high sensitivity and specificity[14] makes it an effective and suitable instrument to evaluate the erectile function.

Conclusion

This showed that the IIEF is valid and reliable for use in participants of a cardiopulmonary and metabolic rehabilitation program.

Author contributions

Conception and design of the research: Sties SW, Cardoso FL, Gonzáles AI, Wittkopf PG, Carvalho T; Acquisition of data: Sties SW, Gonzáles AI, Wittkopf PG; Analysis and interpretation of the data: Sties SW, Cardoso FL, Gonzáles AI, Ulbrich AZ, Wittkopf PG; Statistical analysis: Sties SW, Cardoso FL, Gonzáles AI, Ulbrich AZ, Wittkopf PG; Writing of the manuscript: Sties SW, Gonzáles AI, Mara LS, Wittkopf PG; Critical revision of the manuscript for intellectual content: Sties SW, Cardoso FL, Gonzáles AI, Ulbrich AZ, Mara LS, Wittkopf PG, Carvalho T.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

This study was funded by FAPESC.

Study Association

This article is part of the thesis of master submitted by Ana Inês Gonzáles and Sabrina Weiss Sties, from Universidade do Estado de Santa Catarina-UDESC.

References

1. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 4th ed. Washington DC: American Psychiatric Association; 1994.
2. Lewis RW, Fugl-Meyer KS, Bosch R, Fugl-Meyer AR, Laumann EO, Lizza E, et al. Epidemiology/risk factors of sexual dysfunction. J Sex Med. 2004;1(1):35-9.
3. Ayta IA, McKinlay JB, Krane RJ. The likely worldwide increase in erectile dysfunction between 1995 and 2025 and some possible policy consequences. *BJU Int*. 1999;**84(1)**:50-6.
4. Moreira ED Jr, Abdo CH, Torres EB, Lôbo CF, Fittipaldi JA. Prevalence and correlates of erectile dysfunction: results of the Brazilian study of sexual behavior. Urology. 2001;58(4):583-8.
5. Abdo CH, Oliveira WM Jr, Scanavino MT, Martins FG. Disfunção erétil: resultados do estudo da vida sexual do brasileiro. Rev Assoc Med Bras. 2006;52(6):424-9.
6. O'Donnell AB, Araujo AB, McKinlay JB. The health of normally aging men: The Massachusetts Male Aging Study (1987-2004). Exp Gerontol. 2004;39(7):975-84.
7. Böhm M, Baumhäkel M, Teo K, Sleight P, Probstfield J, Gao P, et al; ONTARGET/TRANSCEND Erectile Dysfunction Substudy Investigators. Erectile dysfunction predicts cardiovascular events in high-risk patients receiving telmisartam, ramipril, or both: the ONgoing Telmisartam Alone and in combination with Ramipril Global Endpoint Trial/Telmisartam Randomized AssessmeNt Study in ACE iNtolerant subjects with cardiovascular Disease (ONTARGET/TRANSCEND) trials. Circulation. 2010;121(12):1439-46.
8. Yao F, Huang Y, Zhang Y, Dong Y, Ma H, Deng C, et al. Subclinical endothelial dysfunction and low-grade inflammation play roles in the development of erectile dysfunction in young men with low risk of coronary heart disease. Int J Androl. 2012;35(5):653-9.
9. Nozaki T, Sugiyama S, Koga H, Sugamura K, Ohba K, Matsuzawa Y, et al. Significance of a multiple biomarkers strategy including endothelial dysfunction to improve risk stratification for cardiovascular events in patients at high risk for coronary heart disease. J Am Coll Cardiol. 2009;54(7):601-8.
10. Maroto-Montero JM, Portuondo-Maseda MT, Lozano-Suárez M, Allona A, Pablo-Zarzosa C, Morales-Durán MD, et al. Erectile dysfunction in patients in a cardiac rehabilitation program. Rev Esp Cardiol. 2008;61(9):917-22.
11. Hatzimouratidis K, Amar E, Eardley I, Giuliano F, Hatzichristou D, Montorsi F, et al. Guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation. Eur Urol. 2010;57(5):804-14.
12. Lue TF. Erectile dysfunction. N Engl J Med. 2000;342(24):1802-13.
13. Rosen RC, Cappelleri JC, Gendrano N 3rd. The International Index of Erectile Function (IIEF): a state-of-the-science review. Int J Impot Res. 2002;14(4):226-44.
14. Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology. 1997;49(6):822-30.
15. O'Leary MP, Fowler FJ, Lenderking WR, Barber B, Sagnier PP, Guess HA, et al. A brief male sexual function inventory for urology. Urology. 1995;46(5):697-706.
16. Abdo CHN. Elaboração e validação do quociente sexual - versão masculina, uma escala para avaliar a função sexual do homem. Rev Bras Med. 2006;63(1-2):42-6.
17. Graça B. Índice internacional da função eréctil, protagonista na disfunção eréctil. Acta Urológica. 2008;25(3):45-7.
18. Ortiz J, Ortiz ST, Monaco CG, Yamashita CH, Moreira MC, Monaco CA. Disfunção erétil: um marcador para alterações da perfusão miocárdica? Arq Bras Cardiol. 2005;85(4):241-6.
19. Ponholzer A, Temml C, Mock K, Marszalek M, Obermayr R, Madersbacher S. Prevalence and risk factors for erectile dysfunction in 2869 men using a validated questionnaire. Eur Urol. 2005;47(1):80-6.
20. Riedner CE. Avaliação do efeito da obesidade na associação entre doença cardíaca isquêmica e disfunção erétil [tese]. Porto Alegre; 2010. [Acesso em 2012 set 10]. Disponível em: http://www.lume.ufrgs.br/bitstream/handle/10183/25115/000751947.pdf?sequence=1.
21. Riedner CE. Estudo das medidas antropométricas de obesidade e sua correlação com a disfunção erétil [dissertação]. Porto Alegre; 2005. [Acesso em 2012 set 10]. Disponível em: http://www.lume.ufrgs.br/bitstream/handle/10183/6172/000526281.pdf?sequence=1.
22. Ferraz MB, Ciconelli M. Tradução e adaptação cultural do índice internacional de função erétil para a língua portuguesa. Rev Bras Med. 1998;55(1):35-40.
23. Associação Brasileira de Empresas de Pesquisa (ABEP) – 2012. [Acesso em 2012 jul 2]. Disponível em: http://www.abep.org/novo/Content.aspx?ContentID=301.
24. World Health Organization (WHO). The problem of overweight and obesity. In: Obesity: preventing and managing the global epidemic. Geneva; 2000. (Technical Report Series).
25. Organização Pan-americana de Saúde (OPAS). XXXVI Reunión Del Comitê Asesor de Investigaciones em Salud – Encuestra Multicêntrica – Salud Beinestar y Envejecimento (SABE) em América Latina e el Caribe – Informe preliminar. 2001. [Acesso em 2012 jun 06]. Disponível em: http://www.paho.org/Spanish/HDP/HDR/CAIS-01-05.PDF
26. Cappelleri JC, Rosen RC, Smith MD, Mishra A, Osterloh IH. Diagnostic evaluation of the erectile function domain of the International Index of Erectile Function. Urology. 1999;54(2):346-51.
27. Pasquali L. Psicometria: teoria dos testes na psicologia e na educação. Petrópolis: Vozes; 2009.
28. Thomas JR, Nelson JK. Métodos de pesquisa em atividade física e saúde. 3ª ed. São Paulo: Artmed; 2002.
29. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33(1):159-74.
30. Manolis A, Doumas M. Sexual dysfunction: the 'prima ballerina' of hypertension related quality-of-life complications. J Hypertens. 2008;26(11):2074-84.
31. Belardinelli R, Lacalaprice F, Faccenda E, Purcaro A, Perna G. Effects of short-term moderate exercise training on sexual function in male patients with chronic stable heart failure. Int J Cardiol. 2005;101(1):83-90.
32. Latini DM, Penson DF, Lubeck DP, Wallace KL, Henning JM, Lue TF. Longitudinal differences in disease specific quality of life in men with erectile dysfunction: results from the Exploratory Comprehensive Evaluation of Erectile Dysfunction study. J Urol. 2003;169(4):1437-42.
33. Ambler N, Williams AC, Hill P, Gunary R, Crarchley G. Sexual difficulties of chronic pain patients. Clin J Pain. 2001;17(2):138-45.
34. Pasquali L. Princípios de elaboração de escalas psicológicas. Rev Psiq Clín. 1998;25(5):206-13.
35. Kay J, Tasman A, Lieberman JA. Psiquiatria: ciência comportamental e fundamentos clínicos. São Paulo: Manole; 2002.

Original Article