16. Translation validity

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ANDROLOGY
Original Article

Translation validity and reliability of the Indonesian version of the 5-item International Index of Erectile Function (IIEF-5)

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ABSTRACT

Objective: This study aimed to translate the IIEF-5 questionnaire into Indonesian and perform a validity and reliability assessment of the translated instrument.

Material and Methods: A methodological study on 106 male outpatients, recruited consecutively, was carried out in a tertiary hospital in Surabaya, East Java from January to March 2020. This study was conducted in two stages: translation and validation. Two independent sworn translators performed a forward and backward translation of the first draft. The final version was synthesized by a team of experts comprised two urologists and another sworn translator. The validity of the questionnaire is determined through a Pearson correlation analysis. Cronbach's α internal consistency measurement was used to assess its reliability. Inter-rater reliability between the patient and the physician was measured using the Cohen's κ coefficient.

Results: Pearson's "r" value is significantly higher than the critical value table and indicates a high to a very high level of validity based on Guilford's interpretation (r = 0.70-1.00). A good internal consistency is shown by the Cronbach's α coefficient value ($\alpha = 0.828$). An almost perfect agreement between the patient's results and the assessment made by the physicians is shown by the Cohen's κ coefficient value ($\kappa = 0.879$, $P < .001$).

Conclusion: The Indonesian IIEF-5 is a valid and reliable patient-reported outcome measure for evaluating erectile dysfunction in the literate middle-aged and older adult male population in Indonesia.

Keywords: Erectile dysfunction; Indonesian IIEF; International Index of Erectile Function (IIEF); reliability; validity.

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Introduction

Erectile dysfunction (ED) is one of the most prevalent sexual dysfunctions among men, which has progressed from an individual issue to a significant public health problem affecting both developed and developing countries.[1] The global prevalence of ED is predicted to rise each year, with an estimated projection of 322 million men affected by the year 2025. This overwhelming projection is consistent by the upward trend from reports in recent years.[2] A systematic review by Hemelrijck and coworkers[3] in 2019 discovered that the global prevalence of ED ranged from 3 to 76.5% as determined by studies using various questionnaires. The prevalence of ED was reported in Europe (10-76.5%), Asia (8-71.2%), Oceania (40.3-60.69%), Africa (24-58.9%), North America (20.7-57.8%), and South America (14-55.2%).[3] As the data for prevalence were obtained through multiple studies around the world, there are limitations due to the possible variability of reports between studies. Several reports come from a single area, which was generalized to a larger population. In order to maintain accurate generalizability and comparison between results, a standard instrument to correctly define ED in individual patients and asses its prevalence is required.[4] The diagnosis and severity of ED is usually made clinically with the International Index Of Erectile

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Function (IIEF) questionnaire. It is a widely used patient-reported outcomes measurement for both research purposes and daily clinical practice.[5] However, a validated questionnaire in English may not work in another country, in which the majority of the population use English as a secondary language or do not speak English at all. A dedicated, modified questionnaire to adapt with the language and appropriate cultural terms of a particular population is necessary to prevent potential confusions and misinterpretations, which could lead to inaccurate assessments.[6] In a cross-cultural research, the translated version is expected to measure the same construct as the original source of translation.[7] The IIEF has been translated and validated into more than 32 languages. Currently, there are two versions of the IIEF questionnaire, the 15-items (IIEF-15) and five-items (IIEF-5) version, which is an abridged version of the original.[8] The IIEF-5 was developed and published by Rosen et al.[9] in 2002 for a simple and diagnostically valid instrument to be used in a clinical setting. The Indonesian version IIEF-15 has been translated and tested for its validity and reliability by Kloping et al.[10] However, at the time of this study's conduction, the Indonesian version of IIEF-5 has not been published. The fewer number of questions makes it easier for respondents to comprehend and respond to accurately compared to the substantial number of the original questionnaire. A published version of the abridged version would allow physicians to evaluate certain patients more efficiently during their daily practice. This study aimed to translate the IIEF-5 questionnaire into Indonesian and perform a validity and reliability assessment.

Material and Methods

This study was divided into two stages; translation and validation. The ethical approval of this study was obtained from the Ethical Committee of Dr. Soetomo General-Academic Hospital (1723/KEPK/XII/2019).

Main Points

- A translated questionnaire, adapting the appropriate cultural terms of a particular population, is necessary to prevent potential confusions and misinterpretations, which could lead to inaccurate assessments.
- The Indonesian version of IIEF-5 has not been published previously.
- The lack of a standard Indonesian version may contribute to the small number of publications regarding the disease as the original IIEF-15 was only published recently.
- The Indonesian version of IIEF-5 in this study may be used for both research and clinical purposes.

Study Design and Population

This was a methodological study evaluating the validity and reliability of the Indonesian version of IIEF-5 on male outpatients through a consecutive sampling in a tertiary hospital in Surabaya, East Java from January to March 2020. The criteria for the samples included literate married male patients aged 20-70 years old who were sexually active in the past 6 months. The samples had to be able to communicate well in terms of reading, writing, and verbal communication in the Indonesian language.

IIEF-5 Score Interpretation

The IIEF-5 consists of five question items, focusing on the erectile function domain adapted from the original 15 questions version. Each question item is scaled based on a five-point-Likert scale with 1 being the lowest and 5 being the highest. The ordinal scale reflects the frequency and quality of a particular answer to a question item.[9] The original questionnaire is available as a supplementary file. The score results are interpreted as follows: severe ED (5-7), moderate ED (8-11), mild-moderate ED (12-16), mild-ED (17-21), and no ED (22-25).[11]

Translation and Cultural Adaption of the Instrument

The English IIEF-5 questionnaire was translated into Indonesian by an independent sworn translator. The next stage of the Indonesian IIEF-5 manuscript was translated back into English by a different sworn translator. To ensure the objectivity of the back translation process, we made sure that the second translator never read the original IIEF-5. These multiple steps were made to ensure the linguistic validity of the questionnaire. Both end results in Indonesian and English were then analyzed by a team of experts, consisting of two urologists and another sworn translator to assess their eligibility and synthesize a version to be tested in validity and reliability.

Validity Analysis

The prefinalized questionnaire was then given to 20 male patients. Feedbacks regarding difficulties in understanding or answering the question items were noted and used as input. The results were tested for their validity. After finalization based on the early validity results and samples' feedback, the final version was distributed to patients based on the inclusion criteria. Eligible patients signed an informed consent agreement before filling out the questionnaire. Every patient was instructed on how to answer each question item properly based on the five-point-Likert scale. Both the physicians and patients were asked to fill out the form separately. The patients were comprehensively examined regarding the perceived complaints afterward. During the study, neither the physician nor the patient knew the final results. At the end of the examination, both results were collected by the research team. The samples'

Table 1. Interpretation of a Correlation Coefficient Size

Correlation r Value	Interpretation
0.90 to 1.00 or −0.90 to −1.00	Very high positive or negative correlation
0.70 to 0.90 or −0.70 to −0.90	High positive or negative correlation
0.50 to 0.70 or −0.50 to −0.70	Moderate positive or negative correlation
0.30 to 0.50 or −0.30 to −0.50	Low positive or negative correlation
0.00 to 0.30 or 0.00 to −0.30	Negligible correlation

sociodemographic characteristics were presented descriptively. A minimal sample size of 100 patients was required for a validity study.[12] Pearson correlation analysis was used to evaluate the construct validity of each question by correlating the results with the total value and comparing the results with the critical value table. Each question was considered valid if the r value was more than 0.254. This cutoff point was determined based on the Pearson correlation analysis table, in which the value corresponds with 100 samples with a 1% chance of error ($P = .01$).[13] Guilford proposed a rule of thumb for interpreting the size of a correlation efficient, as shown in Table 1.[14]

Table 2. Subjects' Characteristics

Characteristics	n (%)
Age (years) 21-30	2 (1.9)
31-40	17 (16)
41-50	31 (29.2)
51-60	37 (34.9)
> 60	19 (18)
ED severity No ED	42 (39.6)
Mild ED	9 (8.54)
Mild to moderate ED	14 (13.3)
Moderate ED	21 (19.8)
Severe ED	20 (18.8)
Comorbidities	9 (8.4)
Hypertension and DM	
Hypertension	33 (31.1)
DM	33 (31.1)
Malignancies	9 (8.4)
Others	22 (21)
Education	7 (6.6)
Elementary school	
Junior highschool	19 (17.9)
Senior highschool	59 (55.6)
College	21 (19.9)

Reliability Analysis

Internal consistency of the questionnaire was measured using the Cronbach's α value ($\alpha < 0.5$, unacceptable; $0.5 \leq \alpha < 0.6$, poor; $0.6 \leq \alpha < 0.7$, questionable; $0.7 \leq \alpha < 0.8$, acceptable; $0.8 \leq \alpha < 0.9$, good; $\alpha \geq 0.9$, excellent).[15] Cohen κ was used to assess the inter-rater reliability between the self-diagnostic results from the patient compared with the assessment made by the physicians (≤0 indicates no agreement, 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as an almost perfect agreement).[16] All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) version 24.0 (IBM SPSS Corp.; Armonk, NY, USA).[17] Satisfactory results of both the construct validity, internal consistency, and interrater reliability ensure the content validity of this questionnaire.

Results

There were 106 recruited patients based on the inclusion criteria. Table 2 shows the demographic data of this study, where the majority of samples were 51-60 years of age (34.9%). ED distribution of severity is represented well from the patients, in which the most common grade was moderate. Comorbidities among the patients were dominated by hypertension (33.3%) and diabetes mellitus (23.8%). Table 3 shows that the Pearson's "r" value of every question item is significantly higher compared to the Pearson correlation's critical value table. The results indicate an excellent validity based on the Guilford's interpretation of significant correlations' magnitude, in which

Table 3. Pearson Correlation Analysis Results Between Each Item and Total Score

Questions	r Value	*P*-Value
Q1	0.878	.01
Q2	0.920	.01
Q3	0.929	.01
Q4	0.870	.01
Q5	0.876	.01

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the r value of the question items range from high (r = 0.70–0.90) to very high (r = 0.90-1.00).[14] The Cronbach's α coefficient value indicated a good internal consistency (α = 0.828).[15] The Cohen's κ coefficient value displayed an almost perfect agreement between the patient's results and the assessment made by the physicians (κ = 0.879, $P < .001$).[16] The Indonesian IIEF-5 is available below as a supplementary file.

Discussion

Even though ED has no immediate effect to a person's mortality, the male's sexual organ is considered as a symbol of masculinity and sexual prowess. Thus, it is necessary to properly assess a person's erectile function and sexual problems. Currently, studies focusing on ED in Indonesia are limited.[18] The lack of a standard Indonesian version may contribute to the small number of publications regarding the disease as the original IIEF-15 translated version was only published recently in 2020.[10] The abridged version is considered sufficient for daily clinical practice and has been used extensively. There are a few major differences between IIEF-5 and IIEF-15. The original version comprised of 15 questions reflecting five domains of sexual function: (1) erectile function, (2) orgasmic function, (3) sexual desire, (4) intercourse satisfaction, and (5) overall satisfaction.[19] The shortened version selected the items that best discriminated men with ED, comprising four items from the erectile function domain and one item from intercourse satisfaction.[8] A few methodological difference can also be seen between the two versions. The IIEF-5 includes a sexual intercourse satisfaction question that is absent from the erectile function domain of the original version. The erectile function domain of the original version consisted of six items. However, the reduction of this particular question item was considered unlikely to reduce a complete response from patients in clinical settings. The items in the abridged version are phrased to reference conditions felt in a 6-month period, whereas the original version has a reference period of 4 weeks. The 6-month reference period in IIEF-5 conforms with the National Institutes of Health reference period for establishing an ED diagnosis. Based on the level of literacy and education level of Indonesian citizens, previous studies reported that one of the minor difficulties in filling the IIEF questionnaire is due to the large number of questions in the original IIEF. As the abridged version only contains five questions, it is expected to be more effective and easily understood by ED patients, especially by the elderly population. In non-native English-speaking countries, a translated and culturally adapted version of a standardized international questionnaire is necessary.[20] At the time of this study's conduction, IIEF-5 has been validated and translated into many languages, such as Urdu, Dutch, Brazilian, Iranian, and Malaysian.[21–25] Indonesia has more than 718 regional languages. Nevertheless, more than 90% of the population are able to fluently speak Indonesian. Therefore, an Indonesian version of IIEF would mostly work in the Indonesian population as long as the patient is able to communicate in Indonesian.[26] The preliminary phase in this study involved 20 patients, of which one patient did not understand the meaning of the word "*penetrasi*" or penetration, and another asked about the word "*ereksi*" (erection). Upon reviewing and evaluating the issue further, the team decided that no other words were more concise and effective to replace the two words. As the number was insignificantly small, it was concluded that both terms were understood by most respondents. Apart from the misunderstanding of certain words, possible cultural sensitivity issues were anticipated by the physicians, especially in adapting a questionnaire intended for evaluating a sensitive matter.[27] Feedbacks regarding certain terms or words that the samples might not be comfortable with were also taken into consideration during the finalization of the questionnaire.

The finalized questionnaire used in 106 samples showed excellent level of validity based on the Pearson's correlation analysis (r = 0.70-1.00, $P = .01$).[13] It is also reliable based on the Cronbach's α value (α = 0.828).[15] The validity and reliability of the question items in the Indonesian version are in line with previous validation studies of IIEF-5.[5,21,22,28–30] The Cohen's κ coefficient result showed that out of 1,000 patients diagnosed with ED by a physician, 879 patients were correctly classified as ED by the patient's self-assessment (κ = 0.879, $P = .0001$).[16] Therefore, it has a high level of agreement between the physician and the patient, ensuring that each patient's answer is representative of his condition. Overall, these findings suggested that the Indonesian version of IIEF-5 may be used for both research and clinical purposes.

This study was limited by its sampling method, which utilized a consecutive approach in one center as opposed to a large study. Future validation studies should include larger samples from multiple centers and include other population from different cultural and regional backgrounds. The results were, nevertheless, significant as Surabaya, East Java is the second largest province in Indonesia consisting of dominant ethnic groups representing the nation's population.[31] However, illiterate patients would require an assistance from the physician to answer the questions. This tends to not yield valid results. As long as the patient is literate and able to comprehend the Indonesian language, the accuracy of the assessment provided by the Indonesian IIEF-5 should not be questioned. An assistance for specific group of people would require a different adaptation and validity analysis of the questionnaire. The Indonesian

version of IIEF-5 is a valid and reliable patient-reported outcome measure for evaluating ED in the literate middle-aged and older adult male population in Indonesia.

Ethics Committee Approval: Ethical committee approval was received from the Dr. Soetomo General-Academic Hospital (1723/KEPK/XII/2019).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - T.B.L., F.R.; Design - T.B.L., Y.P.K., F.R.; Supervision - L.H., F.R.; Resources - L.H., F.R., F.R.; Materials - L.H., F.R.; Data Collection and/or Processing - T.B.L., Y.P.K.; Analysis and/or Interpretation - T.B.L., Y.P.K., F.R.; Literature Search - T.B.L., Y.P.K.; Writing Manuscript - T.B.L., Y.P.K., L.H., F.R.; Critical Review - T.B.L., Y.P.K., L.H., F.R.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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