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Original Article

Psychiatry/Mental Health Section

Reliability and Validity of Malayalam Version of 5-Item International Index of Erectile Function

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ABSTRACT

Introduction: Erectile Dysfunction (ED) is a common problem affecting men and it also negatively impacts mental health. A self administered questionnaire which is validated in local language will help in better detection of ED.

Aim: To assess the reliability and validity of Malayalam version of 5 item International Index of Erectile Function (IIEF-5) in the Malayali population of India.

Materials and Methods: This prospective observational study was done in Government Medical College, Thiruvananthapuram, India. A total of 136 subjects were recruited into the study after taking written informed consent. Subjects were divided into two groups. Group I included 68 subjects who had complaints of ED and group II included 68 subjects who had no complaints of ED. The subjects were administered Malayalam translated IIEF-5 at baseline and after four weeks.

Results: Internal consistency of the Malayalam IIEF-5 was assessed using Cronbach's alpha and the whole scale had an excellent internal consistency of 0.90. The 5 items had an overall Intraclass Correlation Coefficient (ICC) of 0.91 showing a good test retest reliability. The Malayalam version was also highly sensitive and specific to the change in ED after four weeks.

Conclusion: This study shows that the Malayalam version of IIEF-5 is a reliable and valid tool for assessment of ED, making it useful as an initial screening tool in a clinical setting. The ease of administering and favourable diagnostic properties of Malayalam IIEF-5 can help in the reducing the number of undiagnosed cases of ED.

Keywords: Diagnostic test, Impotence, Male sexual dysfunction, Questionnaire, Sexual function

INTRODUCTION

The Erectile Dysfunction (ED) is defined as the inability to develop or maintain an erection or penile rigidity sufficient for penetration or completion of sexual intercourse, for the past six months [1]. ED was shown to have a prevalence ranging from 1-10% in men below 40 years, 2-9% in men between 40-49 years and 20-40% between 60-69 years [2-4]. The positive correlation of ED and age has been well documented in literature with 52% of men between 40-70 years of age showing some degree of ED [5].

A recent study done in 2016 at a general hospital psychiatry unit from Kolkata, showed that of patients attending sexual dysfunction clinic in the hospital, 20.7% had ED and 16.5% had ED plus premature ejaculation [6]. A study done at family medicine clinics of Liaquat National Hospital Pakistan in sexually active males of 18 years and older, reported a prevalence of ED of 21.11% [7]. The study done by Capogrosso P et al., showed that one in four patients seeking treatment for new onset ED was younger than 40 years [8]. In a study conducted in southern India 47.8% of men had ED [9]. An epidemiological study conducted in South Indian rural population showed that the prevalence of ED was 15.77% [10]. The worldwide prevalence of ED is predicted to reach 322 million by 2025 [11]. Studies have shown that ED is a marker for cardiovascular disease [12-14]. A meta-analysis of 12 prospective cohort studies showed that ED has significant and independent association with high risk of coronary artery disease, stroke and all cause mortality [15,16].

Inadequate history, underreporting of complaints about ED and social barriers may hinder proper assessment of ED [17]. The initial assessment and diagnosis of ED is often by self report questionnaires. The IIEF is a self administered questionnaire consisting of 15 items and five domains, developed in 1997 by Rosen RC et al., [18]. However, the original IIEF was designed primarily for use in clinical trials and there was a need for a simpler patient administered diagnostic tool for ED. Hence, an abridged 5 item version of the IIEF was developed [19]. Both the 15 item and 5 item version of IIEF is very popular and was translated into and validated in multiple languages [20-25].

The ED being a common and treatable condition, the need for an easily administered diagnostic instrument which is validated in the local language is there for use in clinical settings. Malayalam is the official language of Kerala, a southern state in India, and there is no validated translation of IIEF-5 in Malayalam. The present study was conducted with an objective of assessing the reliability and validity of Malayalam version of IIEF-5 in the Malayali population of India.

MATERIALS AND METHODS

This prospective observational study was done in Government Medical College Thiruvananthapuram, a tertiary care centre in southern India from September 2015 to February 2016. Institutional Ethics Committee permission from Government Medical College, Thiruvananthapuram was taken before starting the study (IEC/05/15/2015).

Sample size calculation: As this was a questionnaire validation study, a respondent to item ratio of 10:1 was taken for sample size calculation [26,27]. As IIEF-5 is a 5 item questionnaire, a minimum sample size of 50 was calculated. An attrition rate of 25% was presumed, and to account for that extra recruitment was done and a sample size of 68 in each group was taken.

Inclusion Criteria

1. Male subjects of age above 20 years and having the opportunity to engage in regular sexual intercourse.
2. Subjects who had complaints of ED and were clinically diagnosed by urologist during the study period. (Group I).
3. Subjects who were free from all major acute and chronic diseases and not having ED (Group II).
4. Those who can read and understand Malayalam language.

Exclusion Criteria

1. Those with mental retardation and severe cognitive impairment.
2. Those who refused to give written informed consent.

Group I consisted of 68 subjects who were diagnosed of ED during the study period. The diagnosis of ED was made by an urologist based on medical history, physical examination and objective testing when required. Group II consisted of 68 subjects who attended the surgical outpatient department for follow-up treatment with their primary condition (like pancreatitis, hernia) relatively well maintained. Subjects were recruited into the study after taking written informed consent. The subjects in group I who had complaints of ED were advised to take treatment from urologist and were requested to follow-up after four weeks for reassessment. Subjects in both groups were instructed to maintain a sexual intercourse activity rate of average three per week during the study period, the reason being that the diagnostic evaluation of IIEF-5 was based on men who actively engaged in sexual activity [19].

Subjects of both groups were administered Malayalam version of IIEF-5 at baseline and after four weeks. Socio-demographic details and medical history was collected using a specially designed proforma. Subjects were given reminders over telephone at the time of review.

5 Item International Index of Erectile Function (IIEF-5)

The IIEF-5 is a 5 item questionnaire in which there are four questions taken from the six item erectile function domain of IIEF and one question measuring the satisfaction in sexual intercourse. Of the five questions, the first question is scored on a scale from 1-5 and the other four are scored on a scale from 0-5. A patient with score below 21 is considered to have ED, with a score of 17-21 being mild ED, 12-16 being mild to moderate ED, 8-11 being moderate ED, and 1-7 being severe ED [19].

Translation Process

The initial translation to Malayalam was done by two independent translators whose mother tongue was Malayalam. One translator was given sufficient information to understand the purpose of IIEF-5, while the other was blinded. The two translations were then contrasted with each other. The translations were then back translated to English by another translator whose mother tongue was Malayalam, but had previous experience in translation and was fluent in both spoken and written English. This was done as the service of a translator whose mother tongue was English couldn't be obtained. The back translator was also blinded to the concept of IIEF-5. A panel constituting principal investigator, the translators, and expert with vast experience in the area of ED decided on the final version.

STATISTICAL ANALYSIS

Statistical analysis was done using GNU PSPP which is a freely available software for statistical analysis. Internal consistency of Malayalam IIEF-5 was assessed using Cronbach's alpha [28]. A high Cronbach's alpha shows good correlation between the items. A Cronbach alpha of 0.70-0.95 indicates good internal consistency [29]. Test retest reliability was assessed by Intraclass Correlation Coefficient (ICC). The ICC values range from 1 (totally reliable) to 0 (totally unreliable) [30]. Discriminant validity was assessed using and independent t-test. Sensitivity of Malayalam version of IIEF-5 was assessed by comparison of mean pretreatment and post-treatment scores of group I. Specificity was assessed by comparison of scores at baseline and after four weeks score of group II. Corrected part whole correlations, where the item of interest was correlated with total score excluding the item was also done.

RESULTS

A total of 136 subjects were recruited into the study. All 68 subjects in each groups were assessed at baseline and after four weeks. There were no dropouts in the study subjects on follow-up. Mean age of the subjects were 52 (standard deviation: 5.7). Socio-demographic and clinical characteristics of the subjects are shown in [Table/Fig-1].

Variables	Characteristics	Group I n=68 (%)	Group II n=68 (%)
Age (Years)	20-29	2 (2.9)	4 (5.9)
	30-39	7 (10.2)	4 (5.9)
	40-49	9 (13.2)	10 (14.7)
	50-59	30 (44.1)	28 (41.1)
	>60	20 (29.4)	22 (32.35)
Education	10^{th} std. and below	35 (51.5)	28 (41.2)
	Above 10^{th} std.	33 (48.5)	40 (58.8)
Occupation	Unemployed	10 (14.7)	8 (11.8)
	Unskilled	13 (19.1)	14 (20.6)
	Skilled	17 (25)	16 (23.5)
	Professional	28 (41.2)	30 (44.1)
Diabetes mellitus	Present	18 (26.4)	19 (27.9)
	Absent	50 (73.5)	49 (72)
Hypertension	Present	24 (35.3)	22 (32.3)
	Absent	44 (64.7)	46 (67.6)
Erectile dysfunction	Mild	4 (5.8)	
	Mild to moderate	9 (13.2)	
	Moderate	26 (38.2)	
	Severe	29 (42.6)	

[Table/Fig-1]: Socio-demographic and clinical characteristics of the participants.

All items showed high internal consistency. The whole scale had a high internal consistency of 0.90. Reliability of test was assessed with readministration after four weeks. The items of confidence to get and keep erection, erection hardness, erection maintenance frequency, erection maintenance ability and satisfaction of intercourse showed an overall ICC of 0.91. Mean differences of all five items on IIEF-5 within two groups is shown in [Table/Fig-2].

Parameters	Corrected part-whole correlations	Mean test score	Mean retest score	Mean difference
Confidence to get and keep erection	0.70	5	4.94	0.06
Erection hardness	0.81	5	4.90	0.1
Erection maintenance frequency	0.82	4.99	4.91	0.08
Erection maintenance ability	0.75	5	4.89	0.11
Satisfaction of Intercourse	0.88	5	4.94	0.06

[Table/Fig-2]: Reliability of Malayalam IIEF-5 (Group II).
*Internal consistency: 0.90; **ICC: 0.91

In group I, significant changes were seen in all items, however no significant changes were observed in group II. The items of IIEF-5 were highly sensitive and specific to the change in ED. Discriminant validity or the ability to discriminate between the group with ED and without ED is shown in [Table/Fig-3].

All 5 items showed significant difference and shows that IIEF-5 is able to discriminate between subjects with ED and without ED [Table/Fig-4].

Sensitivity	Mean score baseline	Mean score after 4 weeks	Mean difference	Standard error of the mean	p-value
Group I					
Confidence to get and keep erection	1.81	4.41	2.6	0.6	0.003
Erection hardness	1.57	4.75	3.18	0.9	<0.001
Erection maintenance frequency	1.51	4.69	3.18	0.9	<0.001
Erection maintenance ability	2.03	4.96	2.93	0.7	0.002
Satisfaction of intercourse	1.5	5	3.5	1.1	<0.001
Group II					
Confidence to get and keep erection	5	4.94	0.06	0.34	0.88
Erection hardness	5	4.90	0.1	0.28	0.86
Erection maintenance frequency	4.99	4.91	0.08	0.31	0.87
Erection maintenance ability	5	4.89	0.11	0.38	0.79
Satisfaction of intercourse	5	4.94	0.06	0.29	0.61

[Table/Fig-3]: Sensitivity and specificity of change: Mean scores at baseline and after four weeks in group I and II.
Statistical test- Paired t-test

Items	Mean test score (Group I)	Mean test score (Group II)	Mean difference	95% Confidence interval		p-value
				Lower	Upper	
Confidence to get and keep erection	1.81	5	3.19	3.32	3.05	<0.001
Erection hardness	1.57	5	3.43	3.54	3.30	<0.001
Erection maintenance frequency	1.51	4.99	3.48	3.62	3.35	<0.001
Erection maintenance ability	2.03	5	2.97	3.13	2.80	0.002
Satisfaction of intercourse	1.5	5	3.5	3.65	3.34	<0.001
Total	8.42	24.99	16.57	15.28	14.04	<0.001

[Table/Fig-4]: Discriminant validity of Malayalam IIEF-5.
Statistical test- Independent t-test

DISCUSSION

Psychological, neurological and vascular pathways combines to manifest a physiologic response in the penile vasculature to achieve erection. Considering the complexity with which the various pathways intersect, there are multitude ways in which they can become disrupted and result in ED [31]. The ED though a common and treatable condition, the patient may often show reluctance to come forward with the problem. Hence, there is a need for an easily administered diagnostic instrument in local language. Malayalam being a language with many dialects, an acceptable ED questionnaire needs to have high validity reliability and it should be in simple Malayalam.

The objective of this study was to validate the Malayalam version of IIEF-5 and thereby, add a valuable instrument in local language for detection of ED. The findings of validity, reliability and internal consistency of Malayalam version were positive. The whole scale had a high internal consistency (Cronbach's alpha of 0.90). A Cronbach's alpha of minimum 0.70 indicates a satisfactory internal consistency [29]. The ICC was found to be 0.91 which indicated a good test retest reliability. The Malayalam version of IIEF-5 also had a good discriminative ability to differentiate between subjects with and without ED (p<0.001).

Results of this study are consistent with previous studies which validated IIEF-5 in other regional languages. Mahmood MA et al., reported a high internal consistency of 0.88 in the Urdu translation of IIEF-5 [32]. The Dutch translation of IIEF-5 by Utomo E et.al., showed high internal consistency with a Cronbach's alpha of 0.94 and the ICC was 0.88 [33]. The arabic version by Shamloul R et al., had an internal consistency of 0.91 and an ICC of 0.92 [34]. An interval of four weeks was chosen to allow for the urological intervention to have an effect. This aided in assessing if Malayalam IIEF-5 was sensitive to the change in ED. All the study subjects had regular opportunities to engage in sexual intercourse and this adds to the validity of the scores. The results showed that Malayalam IIEF-5 was sensitive in detecting the improvement after 4 weeks in group I.

Limitation(s)

Regarding the evaluation of measurement properties, convergent validity of the Malayalam version could not be assessed. For assessing convergent validity its positive correlation with measures of similar constructs need to be assessed. No other Malayalam validated measures with similar constructs as IIEF-5 could be found. Hence, convergent validity of Malayalam version couldn't be assessed.

CONCLUSION(S)

This study shows that the Malayalam version of IIEF-5 is a reliable and valid tool for assessment of ED. The Malayalam version of IIEF-5 has high internal consistency (Cronbach's alpha of 0.90) and good test retest reliability (ICC of 0.91). However, IIEF-5 is intended to complement and not to substitute clinical judgement and diagnostic assessments. It can be useful as an initial screening tool in a general practice and research setting. The ease of use and favourable diagnostic properties can help in improving the detection rate of ED.

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