

# The Performance Properties of the International Index of Erectile Function (IIEF-15) in Assessing Erectile Dysfunction in Patients with Lower Urinary Tract Symptoms

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## Summary

To validate the International Index of Erectile Function (IIEF-15) in Malaysian population. Reliability and internal consistency were evaluated using the test-retest method and Cronbach's alpha. Sensitivity to change was expressed as the effect size index. Internal consistency was excellent (Cronbach's alpha value = 0.75 to 0.90). Test-retest correlation coefficient and intraclass correlation coefficient were highly significant (ICG=0.75 and above) and a high degree of sensitivity and specificity was observed. The IIEF-15 is suitable, reliable, valid and sensitive to clinical change in the Malaysian population.

**Key Words:** International Index of Erectile Function, Cronbach's alpha, Intraclass correlation coefficient, Internal consistency, Test-retest reliability and validity.

## Introduction

Erectile dysfunction is defined by the National Institute of Health (NIH) Consensus Development as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance<sup>1</sup>. The problem is strongly age-related with an approximately twofold to threefold increase in the prevalence of moderate to severe ED between the ages of 40 and 70 years<sup>2</sup>. The IIEF-15 has thus become a commonly used instrument in

multicentre, international clinical trials to assess this medical problem.

Existing self-report measures of male sexual function such as IIEF-15 has been widely used in Western countries and therefore needs to be validated for the local population. The International Index of Erectile Function (IIEF-15) developed by Rosen *et al.*, 1997 has been widely used in the studies of ED in many countries both in community based studies as well as clinical

This article was accepted: 16 August 2002

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studies. The 15-item IIEF-15 is easy to administer, simple, short and only requires 10-15 minutes to be filled by respondents<sup>3</sup>.

The present study was conducted at University Malaya Medical Centre, Kuala Lumpur and was designed to assess the reliability and validity of the International Index of Erectile Function (IIEF-15) in the Malaysian population.

## Materials and Methods

The study was carried out by the Health Research Development Unit and the Department of Surgery, University Malaya Medical Centre, Kuala Lumpur. The IIEF-15 is a 15 items rate scale and each item is rated from 0 (or 1) (Severe ED/No sexual activity) to 5 (Mild/No ED). The IIEF-15 has five domains of sexual function which consists of erectile function, sexual drive, orgasmic function, intercourse satisfaction and overall sexual satisfaction. The patients were selected based on the inclusion and exclusion criteria. For patients with LUTS, the inclusion criteria were patients must be stable and literate (understand and able to answer), whereas the exclusion criteria were patients who were not treated with surgical and medical treatment for lower urinary tract symptoms prior to this study were excluded. Patients less than 40 years old who were unable to read, write or understand were excluded in the study as were patients with any chronic and acute disease. For non-LUTS subjects (control), the inclusion criteria includes patients who were free from all major chronic and acute disease while the exclusion criteria, those with urological problems except renal stone with minimal severity. The study protocol was approved by the Ethics Committee, University Malaya Medical Centre, Kuala Lumpur.

### Study Sample

The IIEF-15 was assessed in three different samples. Validity and reliability were studied in a group of patients with LUTS scheduled for

medical treatment (N=108) and control subjects without BPH (N=50) and sensitivity of change was assessed in a group of patients admitted for transurethral resection of the prostate (TURP) (N=79). The management decisions was entirely made by Urologists based on clinical criteria such as medical history, physical and rectal examinations.

### Data Collection

The patients were informed of the nature of the study and all consented to participate in the study. Following this, the patients then completed the IIEF-15. All questionnaires were self administered although guidance were available by one of the authors (K.F.Q) of this study to help the patients if necessary. All patients included in the validity study were scheduled for twelve weeks after the first administration of the IIEF-15. In the sensitivity to change study, patients completed the questionnaires twice, one week before the surgical treatment and were retested three months after TURP.

### Data Analysis

Cronbach's alpha coefficient was calculated for each item as a measure of the internal consistency of the IIEF-15<sup>4</sup>. The internal consistency shows the resulting values of Cronbach's alpha for the scale when individual item are excluded from the analysis. Test-retest reliability was assessed using the intraclass correlation coefficient (ICC) which is derived from analysis of variance. Values of ICC varies from 1 (perfectly reliable) to 0 (totally unreliable)<sup>5</sup>. Sensitivity to change was analyzed by calculating the difference between mean IIEF-15 before and after TURP and dividing it by the mean standard deviation of the scores before TURP (effect size index)<sup>6</sup>.

Mean differences in IIEF-15 scores before and after TURP was also calculated for each individual item by means of a paired t test or by dividing it by the standard deviation of stable LUTS patients scores (Guyatt statistic)<sup>7</sup>.

Sensitivity of the IIEF-15 was assessed by comparing between the mean of pre-treatment and post-treatment domain scores of patients who undergone TURP whereas specificity was assessed by comparing the pre-treatment and post-treatment domain scores in subjects rated as control.

## Results

A total of 237 respondents participated in the validity and reliability study. The mean age for the medical group was 63.67 (SD=8.37) years, surgical group 70.01 (SD=8.17) and control group 50.04 (SD=12.29). The Chinese formed the largest ethnic groups in all three groups, medical (66.67%), surgical (75.95%) and control (58.00%) followed by Indian (28.70%, 22.78% and 42.00%) and Others (4.63%, 1.27% and 0%). Patients were older and had higher IIEF-15 indicating higher frequency and severity of ED ( $p<0.001$ ). Of the 237, 108 patients with LUTS had mean scores for erectile function of 17.16, orgasmic function of 6.20, sexual drive of 5.24, intercourse satisfaction of 6.22 and overall satisfaction of 6.64 while 79 patients undergoing TURP has the mean scores erectile function of 9.91, orgasmic function of 3.24, sexual drive of 3.85, intercourse satisfaction of 2.81 and overall satisfaction of 5.48 respectively (Table I & Table II).

Internal consistency for the IIEF-15 was high for all items of IIEF-15 indicating a high level of homogeneity among items in the scale. Test-retest reliability was assessed in 108 patients after 12 weeks and the domains of erectile, orgasmic, sexual drive, intercourse satisfaction and sexual satisfaction had an ICC of 0.89, 0.86, 0.83, 0.92 and 0.78 ( $p<0.001$ ) and a Pearson's product moment correlation of 0.80, 0.78, 0.71, 0.85 and 0.66 ( $p<0.01$ ) respectively (Table I).

Sensitivity to change of the IIEF-15 was assessed in patients undergoing TURP. Table II shows pre and post scores, mean difference, effect size index, and the Guyatt statistic for individual items,

and for global scores. The mean pre intervention score on the domains of erectile function, orgasmic function, sexual drive, intercourse satisfaction and sexual satisfaction were 9.91 (SD=8.17), 3.24 (SD=3.62), 3.85 (SD=1.51), 2.81 (SD=3.40) and 5.48 (SD=1.71) while the mean post intervention scores were 9.97 (SD=8.24), 2.39 (SD=2.55), 3.76 (SD=1.38), 2.29 (SD=2.57) and 4.80 (SD=1.56) ( $p<0.0001$ ), giving an average improvement after TURP on erectile function of 0.06 (SD=4.64) but deterioration in orgasmic function of 0.85 (SD=2.96), sexual drive of 0.09 (SD=0.89), intercourse satisfaction of 0.52 (SD=2.41) and sexual satisfaction of 0.68 (SD=1.52). Overall effect size index and therefore sensitivity to change were found to be high indicating TURP-induced urinary symptoms improvement in these patients.

In treatment responsiveness, sensitivity and specificity of instrument was evaluated by comparing the change between baseline and end point scores following treatment. All items of the IIEF-15 demonstrated a high degree of sensitivity and specificity to the effects of treatment (Table III). Significant changes were observed across some items and domains in the LUTS group. The lowest magnitude of change was noted in desire level. In contrast, none of the comparison in the treatment of the control subjects approached significance ( $p=0.16$  to 1.0). Discriminant validity of the IIEF-15 indicated that it was able to discriminate between the surgical group and control group where significant differences were observed in a majority of the items and domains (Table IV).

Comparison between the items of IIEF-15 validated in Malaysia and United States is shown in Table V. The IIEF-15 validated in this study is almost similar and reliable suggesting that IIEF-15 in Malaysia is cross-culturally comparable and that scores obtained using the instrument can be used (Table V).

Table 1  
Validity and Reliability: Mean Test-Retest score, Intraclass correlation coefficient and internal consistency for individual IIEF-15 items (medication group)

	Intraclass Correlation Coefficient (ICC)*	Pearson's moment product correlation coefficient**	Internal Consistency***	Mean Test Score	SD	Mean Retest Score	SD	Mean Difference	SD	95% Confidence Interval Lower	95% Confidence Interval Upper
Erection frequency	0.87	0.77	0.87	3.13	1.61	2.95	1.68	0.18	1.13	-0.04	0.39
Erection firmness	0.86	0.76	0.86	3.08	1.64	2.94	1.71	0.14	1.17	-0.08	0.36
Penetration ability	0.89	0.80	0.89	2.79	1.99	2.79	1.99	0.00	1.25	-0.24	0.24
Maintenance frequency	0.90	0.81	0.89	2.63	1.87	2.64	1.88	0.01	1.16	-0.23	0.21
Maintenance ability	0.90	0.83	0.90	2.78	1.91	2.64	1.89	0.14	1.12	-0.07	0.35
Intercourse frequency	0.89	0.83	0.90	1.42	1.30	1.24	1.05	0.18****	0.72	0.04	0.31
Intercourse satisfaction	0.89	0.81	0.89	2.50	1.81	2.55	1.87	0.05	1.15	-0.26	0.17
Intercourse enjoyment	0.90	0.82	0.90	2.19	1.52	2.14	1.51	0.05	0.91	-0.12	0.23
Ejaculation frequency	0.84	0.72	0.84	3.21	2.01	3.19	1.96	0.02	1.49	-0.26	0.30
Orgasm frequency	0.87	0.77	0.87	2.82	1.82	2.87	1.75	0.05	1.21	-0.28	0.18
Desire frequency	0.82	0.70	0.82	2.46	0.90	2.56	0.94	0.10	0.72	-0.23	0.04
Desire level	0.79	0.69	0.79	2.73	2.73	2.66	0.91	0.07	0.72	-0.08	0.19
Overall satisfaction	0.75	0.66	0.75	3.19	0.99	3.10	1.10	0.09	0.88	-0.08	0.25
Relationship satisfaction	0.75	0.60	0.75	3.38	0.96	3.26	1.01	0.12	0.88	-0.05	0.29
Erection confidence	0.85	0.75	0.86	2.70	0.87	2.64	0.90	0.06	0.63	-0.05	0.18
Overall erectile function	0.89	0.80	0.89	17.16	8.93	17.27	8.99	0.11	5.66	-1.19	0.97
Overall orgasmic function	0.86	0.78	0.87	6.20	3.65	6.27	3.55	0.07	2.41	-0.52	0.39
Overall sexual drive	0.83	0.71	0.83	5.24	1.58	5.25	1.63	0.01	1.22	-0.22	0.24
Overall intercourse satisfaction	0.92	0.85	0.92	6.22	4.18	6.18	4.03	0.04	2.25	-0.38	0.47
Overall sexual satisfaction	0.78	0.66	0.79	6.64	1.72	6.32	2.03	0.32	1.58	0.01	0.62

p<0.001 for all ICC(\*)  
p<0.01 for all Pearson's coefficient (\*\*)  
Cronbach's alpha: note that Cronbach's alpha value given for each item represent the effect of removing that item from the calculation of the alpha value (eg if item 1 is omitted, the resulting value for the scale is 0.87, if item 2 is omitted, it is 0.86, and so forth)(\*\*\*)  
t test for paired comparisons significant (\*\*\*\*)

Table II  
Sensitivity to change: mean scores before and after TURP, effect size and Guyatt Statistic

	PreTURP		Post TURP		Mean Differences	SD	Effect size index	Guyatt statistic
	Mean	SD	Mean	SD				
Erection frequency	2.04	1.49	1.98	1.52	0.06	1.03	0.04	0.04
Erection firmness	2.01	1.50	1.96	1.54	0.05	1.01	0.03	0.03
Penetration ability	1.34	1.73	1.57	1.77	0.23	1.21	0.13	0.12
Maintenance frequency	1.25	1.61	1.42	1.59	0.17	1.06	0.11	0.09
Maintenance ability	1.27	1.67	1.44	1.66	0.17	1.13	0.10	0.09
Intercourse frequency	0.52	0.66	0.57	0.59	0.05	0.50	0.08	0.04
Intercourse satisfaction	1.15	1.58	0.99	1.20	0.16	1.11	0.10	0.09
Intercourse enjoyment	1.03	1.29	0.82	0.96	0.21	0.95	0.16	0.14
Ejaculation frequency	1.69	1.98	1.03	1.37	0.66*	1.93	0.33	0.33
Orgasm frequency	1.47	1.69	1.54	1.55	0.07	1.29	0.04	0.04
Desire frequency	1.86	0.67	1.86	0.71	0.00	0.53	0.00	0.00
Desire level	1.92	0.98	1.91	0.84	0.01	0.54	0.01	0.01
Overall satisfaction	2.58	0.98	2.20	0.92	0.38*	0.95	0.39	0.38
Relationship satisfaction	2.97	0.83	2.73	0.79	0.24*	0.64	0.29	0.25
Erection confidence	1.90	0.90	1.85	0.82	0.05	0.62	0.06	0.06
Overall erectile function	9.91	8.17	9.97	8.24	0.06	4.64	0.01	0.01
Overall orgasmic function	3.24	3.62	2.39	2.55	0.85*	2.96	0.24	0.23
Overall sexual drive	3.85	1.51	3.76	1.38	0.09	0.89	0.06	0.06
Overall intercourse satisfaction	2.81	3.40	2.29	2.57	0.52	2.41	0.15	0.12
Overall sexual satisfaction	5.48	1.71	4.80	1.56	0.68*	1.52	0.40	0.39

Effect size index=Mean difference/SD PreTURP

Guyatt statistics=Mean difference/SD of stable patients with LUTS (medication group)

\*p.0.05

**Table III**  
**IIEF-15 items and domains characteristics of patients undergoing TURP and the control group:**  
**Sensitivity and Specificity**

Sensitivity	N	Mean Changes	SEM	t statistics	p value
Erection frequency	79	0.06	0.12	0.55	0.59
Erection firmness	79	0.05	0.11	0.45	0.66
Penetration ability	79	0.23	0.14	1.66	0.09
Maintenance frequency	79	0.17	0.12	1.39	0.17
Maintenance ability	79	0.17	0.13	1.39	0.17
Intercourse frequency	79	0.05	0.06	0.89	0.37
Intercourse satisfaction	79	0.16	0.13	1.31	0.19
Intercourse enjoyment	79	0.21	0.11	1.89	0.06
Ejaculation frequency	79	0.66	0.22	3.09	0.003
Orgasm frequency	79	0.07	0.15	0.52	0.6
Desire frequency	79	0.00	0.06	0.00	1
Desire level	79	0.01	0.06	0.21	0.84
Overall satisfaction	79	0.38	0.11	3.55	0.001
Relationship satisfaction	79	0.24	0.07	3.32	0.001
Erection confidence	79	0.05	0.07	0.73	0.47
Overall erectile function	79	0.06	0.52	0.12	0.904
Overall orgasmic function	79	0.85	0.33	2.55	0.013
Overall sexual drive	79	0.09	0.10	0.88	0.381
Overall intercourse satisfaction	79	0.52	0.27	1.91	0.06
Overall sexual satisfaction	79	0.68	0.17	3.99	0.001
<b>Specificity</b>	<b>N</b>	<b>Mean Changes</b>	<b>SEM</b>	<b>t statistics</b>	<b>p value</b>
Erection frequency	50	0.08	0.18	0.44	0.66
Erection firmness	50	0.04	0.18	0.22	0.83
Penetration ability	50	0.10	0.21	0.48	0.63
Maintenance frequency	50	0.14	0.19	0.72	0.48
Maintenance ability	50	0.24	0.21	1.13	0.27
Intercourse frequency	50	0.14	0.11	1.13	0.21
Intercourse satisfaction	50	0.22	0.22	1.00	0.32
Intercourse enjoyment	50	0.20	0.17	1.17	0.25
Ejaculation frequency	50	0.32	0.22	1.43	0.16
Orgasm frequency	50	0.26	0.22	1.17	0.25
Desire frequency	50	0.04	0.11	0.35	0.73
Desire level	50	0.04	0.11	0.38	0.71
Overall satisfaction	50	0.04	0.13	0.31	0.76
Relationship satisfaction	50	0.02	0.12	0.17	0.86
Erection confidence	50	0.14	0.10	1.41	0.16
Overall erectile function	50	0.00	0.87	0.00	1
Overall orgasmic function	50	0.08	0.23	0.35	0.725
Overall sexual drive	50	0.06	0.43	0.14	0.89
Overall intercourse satisfaction	50	0.04	0.20	0.19	0.845
Overall sexual satisfaction	50	0.42	0.44	0.96	0.344

Table IV  
 IIEF-15 items and domains characteristics: Discriminant validity

Item	Pre TURP patients		Control		Mean difference	SEM	95% Confidence Interval		p value
	Mean	SEM	Mean	SEM			Lower(-)	Higher	
1	2.04	0.17	3.40	0.26	1.36	0.31	1.98	0.74	0.0001
2	2.01	0.17	3.38	0.26	1.37	0.30	1.95	0.78	0.0001
3	1.34	0.19	2.76	0.31	1.42	0.37	2.15	0.69	0.0001
4	1.25	0.18	2.74	0.31	1.49	0.36	2.20	0.77	0.0001
5	1.27	0.19	2.98	0.33	1.71	0.38	2.46	0.96	0.0001
6	0.52	0.07	1.16	0.17	0.64	0.19	1.02	0.26	0.001
7	1.15	0.18	2.54	0.29	1.39	0.34	2.06	0.71	0.0001
8	1.03	0.14	2.06	0.23	1.03	0.27	1.57	0.50	0.0001
9	1.69	0.22	2.92	0.31	1.23	0.37	1.96	0.49	0.001
10	1.47	0.19	2.82	0.29	1.35	0.34	2.03	0.67	0.0001
11	1.86	0.08	2.44	0.13	0.58	0.15	0.89	0.27	0.0001
12	1.92	0.11	2.68	0.11	0.76	0.16	1.08	0.43	0.0001
13	2.58	0.11	3.58	0.12	1.00	0.17	1.33	0.66	0.0001
14	2.97	0.09	3.64	0.11	0.67	0.15	0.96	0.37	0.0001
15	1.90	0.10	3.18	0.13	1.28	0.16	1.61	0.96	0.0001
Overall erectile function	9.91	0.92	18.84	1.38	8.93	1.66	12.22	5.64	0.0001
Overall orgasmic function	3.24	0.41	5.90	0.59	2.66	0.69	4.03	1.29	0.0001
Overall sexual drive	3.85	0.17	5.14	0.24	1.29	0.29	1.86	0.73	0.0001
Overall intercourse satisfaction	2.81	0.38	6.06	0.63	3.25	0.74	4.72	1.78	0.0001
Overall sexual satisfaction	5.48	0.19	7.16	0.23	1.68	0.30	2.28	1.08	0.0001

Table V  
Comparison of the IIEF-15 validated in Malaysia versus IIEF-15 validated in US

	IIEF-15 validated in Malaysia		IIEF-15 validated in US	
	Test-Retest Reliability (ICC)	Internal Consistency (Cronbach's alpha)	Test-Retest Reliability (ICC)	Internal Consistency (Cronbach's alpha)
Erectile function	0.89	0.89	0.93	0.84
Orgasmic function	0.86	0.87	0.93	0.64
Sexual drive	0.83	0.83	0.91	0.71
Intercourse satisfaction	0.92	0.92	0.88	0.81
Overall sexual satisfaction	0.78	0.79	0.86	0.77

## Discussion

The IIEF-15 has proved to be a valid and reliable in a Malaysian population of patients with LUTS. The IIEF-15 has a higher validity to diagnose ED and the total mean score of IIEF-15 is used for evaluation of ED symptoms. Therefore it is suggested that the IIEF-15 is useful to examine the prevalence and incidence as well as, to evaluate the effects of treatment. In this study we examined the reliability of IIEF-15 in Malaysian population. Its ability to discriminate between patients with LUTS and those without showed high levels of sensitivity and specificity. The large effect size index obtained when the questionnaire was administered before and after an intervention of known efficacy (TURP) indicated a high degree of sensitivity to change. The test-retest correlation of each item was almost confirmed in all 15 items of IIEF-15. However some items did not have significant correlation. This could have been because at twelve weeks there were changes (improving or deteriorating) in sexual function that causes the insignificant findings.

On the investigation of the internal consistency, we confirmed that Cronbach's alpha coefficient was significant for all items. In this study of the reliability and validity of the International Index of Erectile function (IIEF-15) validated in the Malaysian population, the score were consistent with the findings of the International Index of Erectile Function (IIEF-15) by Rosen et al.<sup>3</sup>

The performance properties of the IIEF-15 validated in the Malaysian population and the

IIEF-15 validated in United States<sup>2</sup> are compared in Table V which shows that they are virtually identical with respect to their measurement properties. Although test-retest exhibited statistical significant at  $p < 0.05$  at some items of IIEF-15, this is not surprising because the test-retest was done at 12 weeks, allowing the symptoms to had improved or worsened. In contrast, the minimal changes of symptoms would occurred if test-retest were done at one week, two weeks or at the latest one month after the initial assessment. The test-retest was carried out at twelve weeks because it was easier to make a comparison between the patients with LUTS and patients undergoing TURP and controls at that interval.

## Conclusion

The reliability and validity of the IIEF-15 for 237 patients with LUTS were tested. The study has demonstrated that the IIEF-15 validated in Malaysia showed excellent intraclass reliability, good internal consistency and these findings indicate that the IIEF-15 is a useful and accurate tool for assessing the severity of ED in Malaysian population.

## Acknowledgement

The authors would like to express his gratitude to the University Malaya's Research and Development Management Unit for providing the research grant for this study.



References

1. NIH Consensus Development Panel on Impotence. JAMA 1993; 270: 83-90.
2. Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates results of the Massachusetts Male Aging Study. J Urol 1994; 151: 54-63.
3. Rosen RC, Riley A, Wagner G, Osterloh IA, Kirkpatrick J, Mishra A. The International Index of Erectile Function (IIEF). A multidimensional scale for assessment of erectile dysfunction. Urology 1997; 49: 822-30
4. Cronbach LJ. Coefficient alpha and the internal structure of test. Psychometrika 1951; 16: 297.
5. Deyo RA, Dichr P, Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and Strategies for evaluation. Control Clin Trials 1991; 12 (supp 1): 142S-158S.
6. Cohen J. Statistical Power Analysis for the Behavioral Sciences. New York, Academic Press, 1977; 75-105.
7. Guyatt G, Walter S, Norman G. Measuring changes overtime: assessing the usefulness of evaluative instruments. J. Chronic Dis 1987; 40: 171-78.