

The measurement properties of the five-item International Index of Erectile Function (IIEF-5): a Dutch validation study

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ABSTRACT

Erectile dysfunction, affecting men worldwide, is associated with worse mental health. The severity of erectile dysfunction as well as the effect of its treatment can be assessed using valid self-reported outcome measures. A widely used measure is the International Index of Erectile Function short form (IIEF-5) which is not yet validated in Dutch. The objective of this study was to translate the IIEF-5 into Dutch and to investigate its reliability and validity to provide a useful evaluation tool. The IIEF-5 was translated into Dutch following standardized forward-backward procedures. To conduct this observational study, men with symptoms of erectile dysfunction completed the Dutch IIEF-5 at inclusion, one week later, and six months after inclusion. A population-based sample (reference group) completed the IIEF-5 once. The quality domains reliability and validity were addressed by testing the measurement properties internal consistency, reliability, measurement error, and content validity. Data of 82 patients and 253 reference group participants were analysed. Internal consistency was adequate with Cronbach's alpha of 0.94 in both patient and reference group. In patients, the test-retest reliability was adequate with an Intraclass correlation coefficient for agreement of 0.88. A floor effect was present in the patient group (42%), though not in the reference group (3%). There was no ceiling effect in patients (0%), while this was present in the reference group (17%). Analysis of responsiveness was not possible due to the limited number of patients receiving treatment. The Dutch IIEF-5 is a reliable and valid measure to determine severity of symptoms of erectile dysfunction. This evaluation tool is valuable for clinical use and interpreting results across international clinical studies. The context of a patient's sexual life is however indispensable and should be taken in mind.

INTRODUCTION

The estimated overall prevalence rate of erectile dysfunction (ED) ranges from 10% to 20% worldwide, considering variations in definitions, methodology, and study population.¹ A population-based study in the Netherlands - the Krimpen study - determined a crude incidence of 14.1 cases per 1,000 person years for clinically relevant ED.² We defined ED as a man's consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual activity.³ Erectile dysfunction, as well as satisfaction with sex life, were found to be related with worse mental health in men of all ages.^{4,5} As help seeking behaviour of Dutch men with ED slightly increased in the past 20 years⁶, valid self-reported measures are important to evaluate symptoms associated with ED as well as to evaluate treatment effect. The International Index of Erectile Function (IIEF) is such a measure.^{7,8} The widely used IIEF was "Grade A" recommended in erectile function assessment by the International Consultation of Sexual Medicine in 2010.⁹ The demand for a brief, easily administered measure resulted in an abridged five-item version of the 15-item IIEF: the IIEF-5, also known as the Sexual Health Inventory for Men (SHIM).^{10,11} It was developed for screening and diagnostic severity assessment in clinical practice and in clinical trials. Although the IIEF-5 has been validated in other languages,¹²⁻¹⁵ a Dutch version is still lacking. We therefore translated the IIEF-5 into Dutch. For translated measures to be useful in research or clinical practice, they must adequately address measurement properties, including reliability, validity, responsiveness, and interpretability.^{16,17}

This study was designed to translate the IIEF-5 into Dutch and to investigate its reliability and validity to provide a useful evaluation tool for men reporting symptoms of ED.

METHODS

We conducted this observational study at a tertiary urology centre as part of a larger validation study of health-related quality of life (HRQOL) pelvic floor measures.^{18,19} The study was approved by the Institutional Ethics Committee (MEC-2008-376) and pre-registered at The Netherlands National Trial Register (NTR2355).

Study population and study design

Patient inclusion criteria were men aged 18 years or older with self-reported ED, and fluent and literate in the Dutch language. As described by the original developer, men were also supposed to be in a stable relationship with a female partner and to have the

possibility to engage in sexual activity and intercourse.²⁰ Exclusion criteria were active malignant tumours, dementia, and mental retardation.

At the initial visit, the treating practitioner explained the study to each consecutive patient potentially eligible for inclusion. The practitioner provided an information package including two sets of questionnaires to patients who were interested in participation. As this study was part of a larger validation study of HRQOL pelvic floor measures, the practitioner specified on the cover of the sets of questionnaires for which measure or measures the patient was eligible. The patients were then phoned by the investigator for further explanation, and were asked to complete the informed consent form and the first questionnaire immediately (baseline) and the second questionnaire one week later (T1). Six months after baseline patients received a third questionnaire to be completed at home through postal mail (T2). After each completion patients returned the questionnaires through postal mail using a return envelope. No treatment was initiated or changed during the test-retest period of one week. This one week period was long enough to prevent recall, though short enough to ensure that clinical change had not occurred. Information from the patient's medical record was retrieved about the cause of ED and the applied treatment, if any. Treatment was categorized into "conservative", "pharmaceutical", or "surgical". Date of birth and education were documented through the questionnaire. Educational level was classified as "low" (primary school), "intermediate" (high school), or "high" (college or university degree). The third questionnaire included a question about the change in patient's general health compared to one year ago. This health transition item of the RAND 36-Item Health Survey²¹⁻²³ contained the following response options: "much better", "a little better", "same", "a little worse", and "much worse". Patients who did not return the questionnaire were sent a reminder including a reply form where they could indicate if they required a replacement questionnaire, or if they refrained from further participation with the option to motivate. If questions were skipped or questionnaires were left empty without providing any reasons, a copy of the uncompleted questionnaire was sent immediately to the patient with the request to fully complete the questionnaire. Also, patients were then asked to motivate if they intentionally skipped a question or questions.

Reference data

Data from a representative sample of men aged 18 years or older in the Netherlands were collected through an ISO-certified Dutch online panel (ISO 26362).²⁴ This sample was stratified by age, educational level and residential area, and therefore representative for the Dutch male population above the age of 18. The presence or absence of ED in the participants was unknown beforehand. No inclusion or exclusion criteria were applied.

Questionnaire

The IIEF-5 consists of five items originating from the IIEF. Four of its five items were taken from the six-item erectile function domain of the IIEF which is a validated measure as a diagnostic evaluation tool.²⁵ The fifth item of the IIEF-5 concerns intercourse satisfaction.

Response options are based on rating scales from 0 to 5 or 1 to 5. The responses are summed resulting in a total IIEF-5 score ranging from 1 to 25, with lower values representing poorer sexual function. Erectile dysfunction can be classified into five severity grades: absence of ED (IIEF-5 score 22-25), mild (17-21), mild to moderate (12-16), moderate (8-11), and severe (1-7).^{10,11}

Linguistic validation

The IIEF-5 was translated into Dutch following standardized forward-backward procedures: three independent forward translations and a backward translation by a native speaker.²⁶ The Dutch version of the IIEF-5 was tested in 10 patients with ED, where potential problems were explored and discussed guided by a checklist. Erectile dysfunction was defined according to the International Consultation on Sexual Dysfunctions.⁹ This pilot testing led to the following adjustments: the word “penetration” (question 3) appeared too formal. We therefore used “entered” and put the word “penetration” between brackets. The words “sexual stimulation” (question 2) and “intercourse” (questions 3 to 5) were exemplified with footnotes. Some other minor textual changes were added without changing the content. The Dutch version of the IIEF-5 was then finalized and subsequently used in this validation study (See “Vragenlijsten”).

Measurement properties

To address the quality domains reliability and validity, we tested the measurement properties internal consistency, reliability, measurement error, and content validity of the Dutch IIEF-5.¹⁶

- The **internal consistency** is the degree of interrelatedness among the items in the measure. A reliable measure assesses a single underlying concept by using multiple items. This was calculated with the Cronbach’s alpha. A high Cronbach’s alpha indicates high correlations between the multiple items. Values between 0.70 and 0.95 were considered to reflect adequate internal consistency.^{17,27}
- The **reliability** is the proportion of the total variance because of “true” differences among patients. To assess the degree to which repeated measurements in stable patients provide similar answers we performed a test-retest. An Intraclass correlation coefficient (ICC) for agreement²⁴ of ≥ 0.70 was considered to reflect adequate reliability.^{17,27}
- The **measurement error** is the systematic and random error of a patient’s score not attributed to true changes. This was quantified using the limits of agreement

by Bland and Altman.²⁸ The absolute mean change in scores of repeated measurements during the test-retest period ($\text{mean}_{\text{change}} \pm 1.96 * \text{standard deviation of these changes (SD}_{\text{change}})$) were the limits of agreement.

- The **content validity** is the degree to which the content of a measure adequately reflects the target construct. This was subjectively assessed and verified by examining whether the items appeared to be measuring what they are intended to measure ("face validity"). The floor and ceiling effects were also assessed. This may occur when 15% or more of the respondents score at the lower (floor) or upper (ceiling) end of the scale, thus could indicate a limited content validity.^{17,27}

Statistical methods

Statistical significance was defined as p -value $< .05$. For comparison of patient and reference group the unpaired t test was used for numerical variables, and the chi-square test for categorical variables. General linear models were used to compare measure scores, controlling for demographics that differed significantly between patient and reference group in univariate analysis. Statistical analysis was performed using IBM® SPSS software 21.0, SPSS Inc., Chicago, IL, USA.

RESULTS

A total of 108 consecutive patients were initially interested and eligible, of which 82 (76%) consented to participate (Flowchart, Figure 6.1). The measure was sent out to 480 panel participants of which 253 (53%) responded. In the patient group, the mean age (64.4 ± 11.5 years) was higher ($p < .001$) than in the reference group (50.6 ± 15.7 years, Table 6.1). Also, educational levels differed significantly between patient and reference group. Information from the patient's medical record indicated that symptoms of ED were mostly due to an organic cause (81%). The patient group had a significant ($p < .001$) lower score of IIEF-5 (mean 5.5 ± 6.1 , Table 6.2), indicating worse sexual health than the reference group (mean 18.8 ± 7.2). The IIEF-5 score was used to classify the severity of ED: the majority of the patients (71%) versus 13% of the participants of the reference group were classified as "severe" ED. Most participants of the reference group had no ED (53%). These differences remained significant after adjusting for age and educational level.

Before reminders were sent, the missing item rate was highest in the questionnaire after one week follow-up (Table 6.3): 15% of patients left at least one item empty (three questionnaires were left completely empty). The final missing rates and the missing rates at other time-points were 6 to 7%. Missing items were balanced in numbers across the different items of the IIEF-5.

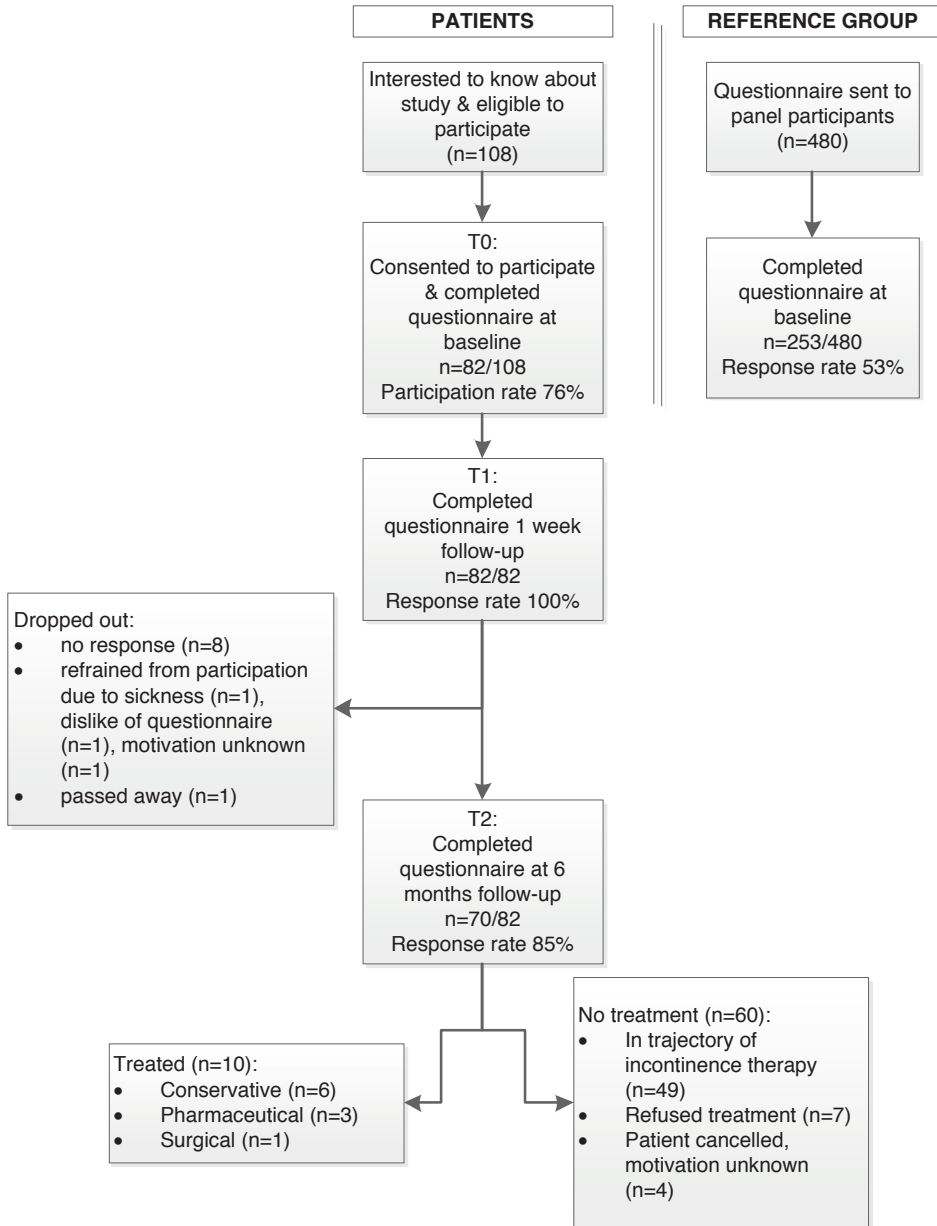


Figure 6.1 Study flowchart

Internal consistency, reliability and measurement error

The IIEF-5 score demonstrated adequate internal consistency with a high Cronbach's alpha of 0.94 in both patient and reference group (Table 6.4). On average, the retest assessments were completed nine days after baseline measurement. The ICC_{agreement}

Table 6.1 Characteristics of respondents

Demographics	Patients (n = 82)	Reference group (n = 253)	p-value ^a
Age (years)	64.4 ± 11.5	50.6 ± 15.7	<.001
Educational level			<.001
Low	23 (29%)	24 (10%)	
Intermediate	36 (45%)	166 (66%)	
High	21 (26%)	63 (25%)	
Primary cause of ED		NA	
Organic	66 (81%)		
Psychogenic	8 (10%)		
Mixed	6 (7%)		
Unknown/missing	2 (2%)		

Data are mean ± standard deviation or number (%).

Abbreviations: *GLM* general linear models; *NA* not available

^ap-value: corrected for age and educational level with general linear modeling

Table 6.2 IIEF-5 scores

	Patients (n = 82)	Reference group (n = 253)	p-value univariate	p-value GLM ^b
Score IIEF-5 ^a at baseline ± SD (range 1 – 25)	5.5 ± 6.1	18.8 ± 7.2	<.001	<.001
Missing	5 (6%)	0 (0%)		
Score IIEF-5 after 1 week ± SD (range 1 – 25)	5.5 ± 5.6	NA		
Missing	6 (7%)	NA		
Score IIEF-5 after 6 months ± SD (range 1 – 25)	4.6 ± 5.4	NA		
Missing	4 (6%)	NA		
Classification of severity of ED at baseline ^c , number (%)			<.001	
Severe (score 1-7)	55 (71%)	32 (13%)		
Moderate (score 8-11)	8 (10%)	15 (6%)		
Mild to moderate (score 12-16)	7 (9%)	20 (8%)		
Mild (score 17-21)	7 (9%)	52 (21%)		
No ED (22-25)	0	134 (53%)		

^aTotal score of IIEF-5 was only calculated if there were no missings, higher scores indicates better sexual health

^bp-value: corrected for age and educational level with general linear model (GLM)

^cClassification according to total score IIEF-5^{20,11}

of the IIEF-5 score was 0.88 (Table 6.4) and indicates adequate reliability. Table 6.4 also presents the absolute mean_{change} of repeated measurements during the test-retest period, the corresponding SD_{change}, and the limits of agreement. Relating the range of the limits of agreement (10.1) to the range of the possible test-retest scores on the IIEF-5, that is -25 to +25 (50), the magnitude of the measurement error is 20%.

Table 6.3 Number of times missing per item

Item of IIEF-5	Baseline ^a	1 week follow-up ^b	6 months follow-up ^c
	(n)	(n)	(n)
1	3	6	4
2	3	7	1
3	2	3	2
4	2	4	2
5	1	6	2
% (number) of patient who skipped an item after reminder	6% (5/82)	7% (6/82) ^d	6% (4/70) ^e

^aOne questionnaire was left completely empty: unknown reason

^bThree questionnaires were left completely empty: unknown reason, all were completed after sending reminder

^cOne questionnaire was left completely empty: not sexually active because ED after radical prostatectomy

^dAt one week follow-up, six patients initially skipped an item before reminder was sent

^eAt six months follow-up, one patient initially skipped an item before reminder was sent

Table 6.4 Internal consistency and reliability

	Internal consistency (Cronbach's alpha)		Test-retest reliability Patients (n = 73)		
	Patients	Reference group	Intraclass Correlation Coefficient	mean _{change} ± SD _{change} ^a	Limits of agreement ^b
	n = 77	n = 253	n = 73		
IIEF-total score (1-25)	0.94	0.94	0.88	1.4 ± 2.6	-3.7 – 6.4

^aHigher scores indicate better sexual health

^bLimits of agreement described by Bland and Altman²⁸ = mean_{change} ± 1.96*SD_{change}

Content validity

In patients, no ceiling effect (0%) was observed in the IIEF-5 score, while floor effect was present in 42%, exhibiting a non-normal score distribution towards the less favourable low score of one (Table 6.5). In the reference group, the contrary was seen: the floor effects were acceptably low (3%) while a ceiling effect (17%) was present.

Follow-up

A total of 70 patients completed the IIEF-5 on average 5.9 months after baseline assessment (T2, Figure 6.1 Flowchart). Of these patients, 10 received treatment during follow-up and 60 men were untreated because they received urinary incontinence therapy (n=49), refused surgical treatment (n=7), or they cancelled surgery due to unknown reasons (n=4). The change in IIEF-5 score in treated patients after six months was 2.2 ± 3.9 compared to -0.6 ± 2.8 in untreated patients ($p=.007$). The change seen is in accordance with the hypothesis that IIEF-5 scores of treated patients will increase,

and therefore suggestive of sensitivity. Analysis of responsiveness and interpretability was not possible because of the limited number of treated patients.

Table 6.5 Floor and ceiling effects at baseline

Questionnaire	Patients (n=77)				Reference group (n=253)			
	Floor		Ceiling		Floor		Ceiling	
	n	%	n	%	n	%	n	%
IIEF-5 total score (1-25)	32	42	0	0	7	3	42	17

DISCUSSION

The objective of this study was to validate the Dutch version of the IIEF-5 and thereby to provide a useful measure for use in men with symptoms of ED. Generally, our findings regarding the internal consistency, reliability, and measurement error were very positive. Cronbach’s alphas of 0.94 in both patient and reference group are considered high. We found an ICC_{agreement} of 0.88 (test–retest) for the five items of the Dutch translation of the IIEF-5, which demonstrates adequate reliability. Furthermore, the mean_{change} after one week was ± 1.4 IIEF-5 score points, demonstrating adequate agreement. Finally, comparing patient and reference group mean scores, the IIEF-5 had adequate discriminative ability ($p<.001$). Results obtained in our study were similar to previously reported findings in other studies. *Shamloul et al.* reported adequate internal consistency with high Cronbach’s alpha of 0.91 and adequate test-retest reliability with a high ICC_{agreement} of 0.92.¹⁴

Ceiling effects were high in the reference group and floor effects were low, while in patients ceiling effects were absent but substantial floor effects were observed. This means that 42% of patients, who were all in a stable relationship, actually did not attempted sexual intercourse. *Cappelleri et al.* stated that the IIEF-5 score range of 1 to 7 - representing severe ED - indicates sexual functioning that is so poor that men do not bother to attempt sexual activity and intercourse.²⁰ We agree with *Cappelleri et al.* that the IIEF-5 should not be used blindly and should be placed in context. More important, it is intended to complement clinical judgment and diagnostic assessment, and the practitioner should explore patient’s desire and opportunity for sexual activity to ensure that low IIEF-5 scores are truly indicative of severe ED.²⁹ In other words, the sexual response cycle of the patient consisting of sexual desire and erection (excitement phase); sensation of orgasm and contentment of ejaculation (orgasmic phase); and detumescence including satisfaction (resolution phase); should be examined.³⁰

Furthermore, sexual activity consists of more than intercourse alone and therefore assessment should also include solo sexual activity like masturbation. Regarding the importance of clinical judgment, we were not able to propose any inclusion criteria for the reference group. This group could have been comprised of respondents who are able to have and maintain an erection, but do not have a partner; do not have sexual contact with their partner; or do have sexual contact but no sexual intercourse. Such men will have a score of 21 or lower, indicating ED according to the IIEF-5 classification, while they actually do not have an erection problem. Such an IIEF-5 classification will thus give the wrong impression.

Concerning our evaluation of the measurement properties; unfortunately we were not able to assess convergent and discriminant validity. To assess convergent validity we need to assess its positive correlation with measures of similar constructs. To our knowledge there are no other Dutch validated measures available with similar construct as the IIEF-5, and therefore we were not able to assess convergent validity. For discriminative validity we needed to be able to assess the ability of the measure to differentiate between expected differences between subgroups of patients. We actually found a significant difference in IIEF-5 score between our patient and reference group. However, as discussed earlier, the IIEF-5 classification in the reference group may be not correctly classified as the context of the presence or absence of sexual activity is unknown. Another limitation of our study was that analysing responsiveness and interpretability appeared to be impossible since only 10 patients received treatment during follow-up. During six months of follow-up, the number of men who actually started treatment for ED was limited. Using the IIEF-5 as a measure of responsiveness of ED treatment is debatable. Treatment of ED, with, for example a phosphodiesterase type 5 inhibitor, entails that patients are encouraged to at least attempt sexual activity and/or intercourse. If a patient who presents with ED did not engage in sexual activity and/or intercourse before ED treatment, his IIEF-5 score will improve with at least four points after the initiation of treatment since the attempt in itself will result in better IIEF-5 scores. This may suggest that treatment worked while the treatment did not necessarily result in better erectile function. Finally, the absence of a comorbidity index to assess and score any potential comorbid condition, as outcomes of a chronic condition represents another limitation; indeed, ED may be affected by coexisting comorbid chronic conditions.

In conclusion, our findings support positive evidence for the appropriateness of the Dutch IIEF-5 to evaluate severity of ED symptoms allowing to be used in clinical decision making as a diagnostic aid. This cultural and linguistic adjustment provides opportunity to compare self-reported ED status in international research and analysis of treatment. It seems however necessary to use this measure complementary to the

context of a patient's sexual life. The suitability of the IIEF-5 as a measure of responsiveness remains open to discussion.

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