The Sensitivity of the Malay Version of Brief Manual of Sexual Function Inventory in Assessing Erectile Dysfunction Secondary to Benign Prostatic Hyperplasia

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Summary

This study aimed to assess the sensitivity of the Malay version of the Brief Manual Sexual Function Inventory (BMSFI) on patients with and without urinary symptoms in Malaysian population. Validity and reliability were studied in patients with lower urinary tract symptoms (LUTS) and patients without LUTS. Reliability and validity was evaluated by using the test-retest method while internal consistency was assessed by Cronbach's alpha. Sensitivity to change was expressed as the effect size in the pre-intervention versus post-intervention score in patients who underwent transurethral resection of the prostate (TURP). Internal consistency was excellent. A high degree of internal consistency was observed for each of the 11 items and 5 domains (Cronbach's alpha value = 0.67 and higher and 0.73 and higher respectively). Test-retest correlation coefficient for the 11 items scores was highly significant. Intraclass correlation coefficient was high (ICC=0.68 and above). The sensitivity and specificity showed a high degree of sensitivity and specificity to the effects of treatment. A high degree of significant level between baseline and post-treatment scores were observed across 3 domains in the treatment corresponds cohort but not in the control group. The Mal-BMSFI is a suitable, reliable, valid and sensitive to clinical change in the Malaysian population.

Key Words: Malay version of Brief Manual Sexual Function Inventory, Cronbach's alpha, Intraclass correlation coefficient, Internal consistency, Test-retest reliability and validity.

Introduction

To conduct studies of the effects of medical treatment, it is important to have a reliable and good measures. Among the aspects of life which was commonly affected by health problem and their treatment is sexuality. For example

transurethral resection of the prostate (TURP) for Benign Prostatic Hyperplasia (BPH) often produces retrograde ejaculation and has been frequently reported to cause erectile dysfunction[1]. Alpha adrenergic blockers can affect sexual function in a small percentage of patients with BPH[2]. The Brief Manual of Sexual Function Inventory (BMSFI) 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 Brief Manual Sexual Function Inventory (BMSFI) been widely used in Western countries and therefore a translation version of the instrument is require for the assessment of the local population study of that country since the study population in each country differed culturally and sociodemographically from one to another. The Brief Manual of Sexual Function Inventory (BMSFI) developed by O'Leary 1995 has been widely used in the studies of ED in many countries both in the community-based study as well in the clinical studies. The 11-item of BMSFI is easy to administer, simple, short and only require 10 minutes to be filled by respondents [3].

The present study was conducted at University Malaya Medical Centre, Kuala Lumpur and was designed to assess the reliability and validity of the Malay version of Brief Manual of Sexual Function Inventory (BMSFI) in the Malaysian population.

Materials and Methods

The BMSFI is a 11 items scale and each item is rated from 0 to 5. The BMSFI has five domains comprises of sexual function; sexual drive, erectile function, orgasmic function, problem assessment and overall sexual satisfaction. The Mal-BMSFI was translated using back-translation technique [4]. 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 treatment for lower urinary

tract symptoms prior to this study. 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 diseases. For the control group of patients, the inclusion criteria includes patients who were free from all major chronic and acute diseases and those with renal stones with minimal severity who did not seek treatment for LUTS while the exclusion criteria were those seeking treatment for urological problems which include BPH and urinary tract infections (UTI). Renal stones patients were chosen as control group in order to have a similar urologic condition for comparison. All patients in the surgical group (TURP) were patients who had TURP from various indications which included acute and chronic retention, recurrent UTI, severe symptoms, failure of medical treatment, renal impairment secondary to bladder outlet obstruction. The study protocol was approved by the University Malaya Medical Centre, Ethics Committee, Kuala Lumpur.

Study sample

The properties of the Mal-BMSFI were assessed in two different samples. Validity and reliability were studied in a control group of patients (N=20)(Mean age 49.9, SD=12.3 years) and sensitivity of change (responsiveness) was assessed in a group of patients admitted for transurethral resection of the prostate (TURP)(N=20)(Mean age 70.65, SD=12.03 years). Diagnosis of LUTS was made by our Urologist (A.H.R.) in all cases based on clinical criteria such as medical history, physical and rectal examinations.

Data Collection

All patients in the surgical group (TURP) and control group of patients gave their written informed consent to participate in the study after being explained on the purpose and nature of the study. Patients then completed the Mal-BMSFI. All questionnaires were self administered although assisted guidance were available from one of the authors (K.F.Q) of this study to assist the patients if necessary. All patients included in the validity

study were re-tested at 12 weeks after the first administration of the Mal-BMSFI (baseline). In the sensitivity to change study, patients completed the questionnaires 1 week before the surgical treatment and were re-tested at three months after TURP.

Data Analysis

Cronbach's alpha coefficient was used to calculate the internal consistency of the Mal-BMSFI which is an estimation of homogeneity testing[4]. The internal consistency shows the resulting values of Cronbach's alpha for the scale when individual item are excluded from the analysis. On the test-retest reliability of the Mal-BMSFI, the assessment was investigated for all 20 patients at twelve weeks interval. Intraclass correlation coefficient (ICC) corresponding to a one-way random-effects analysis of variance (ANOVA) model was utilised to assess the test-retest reliability. Values of ICC varies from 1 (perfectly reliable) to 0 (totally unreliable)[5]. Sensitivity to change was analyzed by calculating the difference between Mal-BMSFI before and after TURP and dividing it by the standard deviation of the scores before TURP (effect size index)[6].

Mean differences in Mal-BMSFI scores before and after TURP was also calculated for each individual item by means of a paired t test Guyatt statistic was calculated by dividing the mean difference by the standard deviation of Stable patients score (controls).[7]

Sensitivity of the Mal-BMSFI was assessed by comparing between the mean of pre-treatment and post-treatment item scores of patients who undergone TURP whereas specificity was assessed by comparing the pre-treatment and post-treatment item scores in control group of patients.

Results

A total of 40 respondents were involved in this. Older patients had lower Mal-BMSFI scores indicating higher frequency and severity of ED (p<0.001). Patients undergoing TURP has the mean scores of sexual drive (2.95), erection (5.5), ejaculation (4.45), problem assessment (9.20) and overall satisfaction (2.0).

Internal consistency for the Mal-BMSFI was high for all domains of BMSFI indicating a high level of homogeneity among items in the scale. Test-retest reliability was assessed in 20 patients after 12 weeks interval and the domains of sexual drive, erection, ejaculation, problem assessment and satisfaction had an ICC of 0.92, 0.96, 0.74, 0.79 and 0.86 (P<0.001) (Table I).

Sensitivity to change of the Mal-BMSFI 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 sexual drive, erection, ejaculation, problem assessment and overall satisfaction were 2.95 (SD=1.47), 5.5 (SD=3.44), 4.45(SD=3.80), 9.20 (SD=2.50) and 2.00 (SD=1.03) while the mean post intervention score were 2.85 (SD=1.46), 4.60 (SD=2.50), 3.60 (SD=2.91), 7.10 (SD=2.88) and 1.40 (SD=0.88)(p<0.0001), giving an average improvement after TURP on sexual drive 0.10 (SD=0.72) but deterioration in erection 0.90 (SD=1.89), ejaculation 0.85 (SD=2.32), problem assessment 2.1 (SD=3.21) and overall satisfaction 0.60 (SD=0.94). Overall effect size index and sensitivity to change were found to be high indicating TURP-induced sexual dysfunction in these patients.

Sensitivity and specificity of instrument was evaluated by comparing the changes between baseline and 3 months scores following treatment. Majority of the items of the Mal-BMSFI demonstrated a high degree of sensitivity and specificity to the effects of treatment (Table III). Significant changes were observed across some items (4, 10,11) and domains (problem assessment and overall satisfaction) in the surgical group. The lowest magnitude of change was noted in item 1 and 2. In contrast, none of the items and domains in the control group approached significance (p=0.06 to 1.0).

Table I
Validity and Reliability: Mean Test-Retest score, intraclass correlation coefficient and internal consistency for individual BMSFI items (control)

BMSFI Items	Intraclass Correlation Coefficient * (ICC)	Internal Consistency**	Mean Test Score	SD	Mean Retest Score	SD	Mean Difference	SD	95% Confidence Interval Lower	Upper
1	0.91	0.92	2.20	1.10	2.05	1.00	0.15	0.59	-0.12	0.42
2	0.88	0.89	2.50	1.05	2.25	1.02	0.25	0.64	-0.05	0.55
3	0.93	0.94	2.95	1.15	2.70	1.17	0.25	0.55	-0.01	0.51
4	0.92	0.92	2.90	1.21	2.75	1.21	0.15	0.67	-0.16	0.46
5	0.95	0.96	3.55	0.89	3.40	0.88	0.15	0.67	-0.02	0.32
6	0.81	0.80	3.30	1.30	3.30	1.45	0.00	1.12	-0.53	0.53
7	0.68	0.67	3.20	1.32	3.30	1.34	0.10	1.33	-0.72	0.52
8	0.79	0.79	3.50	0.95	3.60	0.75	0.10	0.72	-0.44	0.24
9	0.76	0.78	3.35	0.99	3.05	1.05	0.30	0.86	-0.10	0.70
10	0.74	0.73	3.35	1.27	3.40	1.09	0.05	1.10	-0.56	0.46
11	0.86	0.85	2.95	0.89	2.90	0.79	0.05	0.61	-0.23	0.33
Overall sexual drive	0.92	0.92	4.70	1.98	4.30	1.92	0.40	1.05	-0.09	0.89
Overall erection	0.96	0.97	9.40	3.05	8.85	3.06	0.55***	1.05	0.06	1.04
Overall ejaculation	0.74	0.73	6.50	2.54	6.60	2.74	0.10	2.45	-1.24	1.04
Overall problem assessment	0.79	0.78	10.20	2.33	10.05	2.31	0.15	1.98	-0.78	1.08
Overall satisfaction	0.86	0.85	2.95	0.89	2.90	0.79	0.05	0.61	-0.23	0.33

$p<0.001$ for all ICCs(*)
Cronbach's alpha:note that Cronbach's alpha value given for each item represent the effect of removing that item from from the calculation of the apha value (eg if item 1 is omitted, the resulting value for the scale is 0.92, if item 2 is omitted, it is 0.89, and so forth)(**)
t test for paired comparisons significant (***)

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

BMSFI Item	PreTURP Mean	PreTURP SD	Post TURP Mean	Post TURP SD	Mean Differences	SD	Effect size index	Guyatt statistic
1	1.30	0.66	1.25	0.64	0.05	0.22	0.08	0.05
2	1.65	0.87	1.60	0.88	0.05	0.61	0.06	0.05
3	1.60	1.05	1.40	0.75	0.20	0.62	0.19	0.17
4	1.60	1.19	1.25	0.91	0.35*	0.74	0.29	0.29
5	2.30	1.42	1.95	1.15	0.35	0.87	0.25	0.39
6	2.30	1.95	2.15	1.56	0.15	1.09	0.08	0.11
7	2.00	1.83	1.45	1.47	0.55	1.28	0.30	0.42
8	3.70	0.98	3.40	1.14	0.30	0.98	0.31	0.32
9	2.10	1.52	1.85	1.46	0.25	1.29	0.16	0.25
10	3.40	1.23	1.85	1.93	1.55*	1.90	1.26	1.22
11	2.00	1.03	1.40	0.88	0.60*	0.94	0.58	0.67
Overall sexual drive	2.95	1.47	2.85	1.46	0.10	0.72	0.07	0.05
Overall erection	5.50	3.44	4.60	2.50	0.90*	1.89	0.26	0.29
Overall ejaculation	4.45	3.80	3.60	2.91	0.85	2.32	0.22	0.33
Overall problem assessment	9.20	2.50	7.10	2.88	2.10*	3.21	0.84	0.90
Overall satisfaction	2.00	1.03	1.40	0.88	0.60*	0.94	0.58	0.67

Effect size index=Mean difference/SD PreTURP
Guyatt statistics=Mean difference/SD of stable patients (control group)
* t test for paired comparisons significant

Table III
BMSFI items and domains characteristics of patients undergoing TURP and the control group:
Sensitivity and Specificity

Sensitivity	n	Mean Changes	SEM	t statistics	p value
Items					
1	20	0.05	0.05	1.00	0.33
2	20	0.05	0.13	0.37	0.72
3	20	0.20	0.14	1.45	0.16
4	20	0.35	0.17	2.10	0.05
5	20	0.35	0.19	1.79	0.10
6	20	0.15	0.24	0.62	0.54
7	20	0.55	0.28	1.93	0.07
8	20	0.30	0.22	1.37	0.19
9	20	0.25	0.29	0.86	0.40
10	20	1.55	0.43	3.64	0.01
11	20	0.60	0.21	2.85	0.01
Overall sexual drive	20	0.10	0.16	0.62	0.54
Overall erection	20	0.90	0.42	2.13	0.05
Overall ejaculation	20	0.85	0.52	1.64	0.12
Overall problem assessment	20	2.10	0.72	2.93	0.01
Overall satisfaction	20	0.60	0.21	2.85	0.01
Sensitivity	**n**	**Mean Changes**	**SEM**	**t statistics**	**p value**
Items					
1	20	0.15	0.13	1.14	0.27
2	20	0.25	0.14	1.75	0.10
3	20	0.25	0.12	2.03	0.06
4	20	0.15	0.15	1.00	0.33
5	20	0.15	0.08	1.83	0.08
6	20	0.00	0.25	0.00	1.00
7	20	0.10	0.30	0.33	0.74
8	20	0.10	0.16	0.62	0.54
9	20	0.30	0.19	1.55	0.14
10	20	0.05	0.25	0.20	0.84
11	20	0.05	0.13	0.37	0.72
Overall sexual drive	20	0.40	0.23	1.71	0.10
Overall erection	20	0.55	0.23	2.34	0.06
Overall ejaculation	20	0.10	0.54	0.18	0.86
Overall problem assessment	20	0.15	0.44	0.34	0.74
Overall satisfaction	20	0.05	0.13	0.37	0.72

Table IV

BMSFI items and domain characteristics: Discriminant validity

Item	Pre TURP patients		Control		Mean difference	SEM	95% Confidence Interval		p value
	Mean	SEM	Mean	SEM			Lower	Higher	
1	1.30	0.15	2.20	0.25	0.90	0.29	1.49	0.31	0.005
2	1.65	0.20	2.50	0.23	0.85	0.31	1.47	0.23	0.01
3	1.60	0.23	2.95	0.26	1.35	0.35	2.05	0.65	0.0001
4	1.60	0.27	2.90	0.27	1.30	0.38	2.07	0.53	0.001
5	2.30	0.32	3.55	0.20	1.25	0.37	2.01	0.49	0.005
6	2.30	0.44	3.30	0.29	1.00	0.52	2.07	0.07	0.06
7	2.00	0.41	3.20	0.30	1.20	0.51	2.23	0.17	0.05
8	3.70	0.22	3.50	0.21	0.20	0.30	0.42	0.82	0.51
9	2.10	0.34	3.35	0.22	1.25	0.40	2.07	0.42	0.005
10	3.40	0.27	3.35	0.28	0.05	0.39	0.75	0.85	0.9
11	2.00	0.23	2.95	0.20	0.95	0.30	1.56	0.34	0.005
Overall sexual drive	2.95	0.33	4.70	0.44	1.75	0.55	2.86	0.63	0.005
Overall erection	5.50	0.77	9.40	0.68	3.90	1.03	5.98	1.82	0.001
Overall ejaculation	4.45	0.85	6.50	0.57	2.05	1.02	4.13	0.03	0.05
Overall problem assessment	9.20	0.56	10.20	0.52	1.00	0.76	2.55	0.55	0.2
Overall satisfaction	2.00	0.23	2.95	0.20	0.95	0.30	1.56	0.34	0.005

Table V

Comparison of the BMSFI validated in Malaysia versus BMSFI validated in US

	BMSFI validated in Malaysia		BMSFI validated in US	
	Test-Retest Reliability (ICC)	Internal Consistency (Cronbach's alpha)	Test-Retest Reliability (ICC)	Internal Consistency (Cronbach's alpha)
Sexual drive	0.92	0.92	0.89	0.88
Erection	0.96	0.97	0.88	0.96
Ejaculation	0.74	0.73	0.83	0.78
Problem assessment	0.79	0.78	0.87	0.81
Overall satisfaction	0.86	0.85	0.78	0.87

Discriminant validity was noted to discriminate reliably between the surgical treated group and control group. A highly significant differences were observed between the surgical group and the control group for most items and domains of Mal-BMSFI. Mean differences between domains scores between these two groups were greatest in the total Mal-BMSFI score (p<0.0001) (Table IV).

The comparison of items of Mal-BMSFI validated in Malaysia and BMSFI validated in US were shown in Table V. The Mal-BMSFI validated here and US is almost similar suggested that the Mal-BMSFI used here in Malaysia can be cross-culturally comparable and the scores obtained by the instruments can be used (Table V).

Discussion

The Mal-BMSFI has proven valid and reliable in a Malaysian population with patients suffered from ED Secondary to LUTS. Its ability to discriminate between patients with LUTS and those without showed high levels of sensitivity and specificity. The effect size index obtained when the questionnaire was administered before and after an intervention of TURP indicated a degree of sensitivity to change which were also noted in other studies as well.

Internal consistency (Cronbach's alpha coefficients) that was obtained in this study were almost similar to those reported by O'Leary, 1995. This finding indicated that majority of items in the Mal-BMSFI exhibited excellent reliability and good homogeneity.

In this study of the reliability and validity of the Malay version of the Brief Manual Sexual Function Inventory (Mal-BMSFI) validated in the Malaysian population, the score was consistent with mild to moderate scores of Brief Manual Sexual Function

Inventory (BMSFI) according to the criteria of the W.H.O [3].

The properties of the Mal-BMSFI validated in the Malaysian population and the BMSFI validated in United States [3] are compared in Table 4.0 which shows that they are almost similar with respect to their measurement properties. None of the test-retest exhibited statistical significant. The reasons for the test-retest to be carried out at 12 weeks interval because most of the patients in the surgical group (TURP) would only achieved maximum benefits or total symptoms improvement and commenced their sexual activity from 8 weeks to 12 weeks and will be easier to make comparison between patients with LUTS on medical treatment, control group and patients who undergoing TURP at this interval.

Conclusion

The reliability and validity of the Mal-BMSFI for 40 patients were tested. The intraclass correlation coefficient for total scores of the domains and individual items of the Mal-BMSFI indicating excellent intraclass reliability. Cronbach's alpha coefficient indicated that Mal-BMSFI exhibited good internal consistency and thus the Mal-BMSFI is a useful and accurate tool for assessing the severity of erectile function secondary to LUTS in the Malaysian populations.

Acknowledgements

ORIGINAL ARTICLE

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