

# Reproducibility and Clinical and Concurrent Validity of the MSF-4: A Four-Item Male Sexual Function Questionnaire for Patients with Benign Prostatic Hyperplasia

Patrick Marquis, MD and Alexia Marrel, MA

Mapi Values, 27 rue de la Villette, 69003 Lyon, France

## ABSTRACT

**Introduction:** The MSF-4 (Male Sexual Function 4-item) questionnaire is a condition-specific four-item scale of men's sexuality. We describe two studies that were conducted to assess the reproducibility and validity of the MSF-4 questionnaire.

**Methods:** Study 1 was a Phase III, multicenter study with a double-blind, parallel group design which was conducted in five countries. The objectives were to check the construct validity and factorial structure of the MSF-4, along with internal consistency reliability and clinical validity. Study 2 was a longitudinal, noncomparative, observational multicenter study to assess the reproducibility and the clinical and concurrent validity of the MSF-4.

**Results:** When exploratory factor analysis was performed with a free number of factors, the variability of the global MSF-4 score was based on a single factor across all countries in Study 1 except Spain. There was a high level of internal consistency reliability (Cron-

bach's alphas 0.68–0.90) and the MSF-4 was able to significantly discriminate different health states as assessed by the International Prostate Symptom Score (I-PSS) or Quality of Life (QoL) questionnaire. In study 2, there was a significant correlation between the MSF-4 and the International Index of Erectile Function (IIEF) scores ( $p = .0001$  for all items) especially erectile function (correlation coefficient  $-0.77$ ). The MSF-4 was able to distinguish among patients with differing degrees of benign prostatic hyperplasia (BPH) symptoms as measured by the I-PSS ( $p = .0001$ ) and between those with and without sexual disorders ( $p = .0001$ ).

**Conclusion:** The MSF-4 is a psychometrically validated questionnaire with good reproducibility and clinical validity, which allows easy and appropriate assessment of male sexual function in the clinical setting.

**Keywords:** benign prostatic hyperplasia, 5 $\alpha$ -reductase inhibitor, MSF-4, male sexual function, questionnaire, Permixon, *Serenoa repens* extract.

## Introduction

Benign prostatic hyperplasia (BPH) is a common phenomenon of the aging process in men [1]. Despite the recent increase in awareness of BPH and the various treatment options available, the relationship between BPH and sexuality remains under investigation [2]. However, it is known that both BPH and some of the treatments for this condition can have a negative impact on sexual function and activity [3–6].

In a Swedish study of 435 randomly selected men aged 50 to 80, the Radiumhemmet questionnaire was used to assess sexual desire, erectile capacity, orgasm and ejaculation, and the extent to which declining sexual function caused distress. Overall, 13% of men in this age group stated that sex was “very important” to them, 29% stated

that sex was “important,” and 41% stated that it added “spice to life.” [7] This emphasizes that assessment of sexuality is an important consideration when evaluating treatment outcomes in men of this age group. Although the frequency of sexual activity naturally declines with age, sexuality continues to be important for many elderly men [7,8].

In a further study, 73 French and 44 English patients with an International Prostate Symptom Score (I-PSS) superior to 7 were asked to fill out an 89-item Quality of Life (QoL) questionnaire [8] to determine which aspects of QoL were most affected by prostatic symptoms and which aspects were considered to be the most important by patients. The questionnaire was made of an exhaustive list of QoL concepts measured in specific BPH questionnaires and concepts chosen from the health-related QoL classification [9]. Items were derived from models known as psychometrically sound.

*Address correspondence to:* Mapi Values, 27 rue de la Villette, 69003 Lyon, France.

Such study was conducted in the perspective of developing a sound QoL questionnaire for BPH. The major areas considered to be of importance by these men included sexual activities and satisfaction with sexual relationships. This study confirmed the importance of including an assessment of sexual functioning in evaluating the effect of BPH, and its treatment, on quality of life.

Various quality-of-life instruments assess interest in sex (sexual desire) and/or sexual function and questionnaires that are specific to sexual issues are also available [2,10,11]. These include the Brief Male Sexual Function Inventory (BMSFI) [12] and the International Index of Erectile Function (IIEF) [13], which cover the main domains of male sexual function. However, many questionnaires are too lengthy (most use at least 9 to 20 questions) and have limited reproducibility [10].

The Male Sexual Function-4 item (MSF-4) questionnaire is a concise survey that is easy to complete and is available in several languages including French, English, Spanish, Portuguese, German, Greek, Italian, Czech, Polish, and Dutch. Each version was obtained through a linguistic validation process (forward translations, backward translation). Psychometric properties were thus checked on the languages involved in the two studies described hereafter. The MSF-4 is composed of four items: interest in sex, quality of erection, achievement of ejaculation, and achievement of orgasm.

In order to investigate the performance of this questionnaire, two complementary studies were carried out. The objective of Study 1 was to analyze the psychometric properties and clinical validity of the MSF-4. Study 2 aimed to verify the reproducibility of the MSF-4 and further assess the clinical validity of the questionnaire.

## Patients and Methods

### Design

Study 1 was a 15-week, Phase III, multicenter (71 centers) study with a double-blind, parallel group design which compared two dosing regimens of Permixon (320 mg once daily and 160 mg twice daily). The study was conducted in five countries: Austria, France, Germany, Portugal, and Spain.

Study 2 was a longitudinal, noncomparative, observational, multicenter (17 centers) study conducted in France. The primary objective was to verify the reproducibility (test-retest) of the MSF-4 (Appendix 1) in patients presenting with BPH. The design called for two administrations of the MSF-4 at a 7-day interval.

### Patients

**Inclusion Criteria.** In Study 1, men aged 50 to 75 with symptomatic BPH not requiring surgery were included if they had a diagnosis of BPH for more than 6 months. An I-PSS score superior to 7 and less than or equal to 19, a maximum urinary flow rate ( $Q_{\max}$ ) from 5 to 15 ml/s (for a voided volume  $\geq 150$  and  $\leq 400$  ml), residual volume less than 150 ml, and a prostatic volume superior to 25 cm<sup>3</sup> were also required.

Study 2 included men aged over 50 who had presented with uncomplicated BPH for more than 3 months and engaged in regular sexual activity. Half of the included patients were to have documented sexual disorders.

**Exclusion Criteria.** Study 1 excluded patients diagnosed as having prostate cancer or prostatitis, or with a history of bladder, neck, or prostate surgery. Other criteria for exclusion included those with complicated BPH (e.g., neurogenic bladder dysfunction, recurrent urinary tract infection, abnormal liver function), patients receiving drugs with antiandrogenic properties during the previous 3 months, and patients treated within the previous 14 days using an  $\alpha$ -adrenoreceptor blocker, finasteride, or any plant extracts that could have an effect on BPH.

Study 2 excluded patients suffering from complicated BPH, including those with renal impairment, recurrent macroscopic hematuria, acute urinary retention, and urinary infection. Patients with serious concomitant events taking place in the past 3 months that could have influenced their lives (e.g., bereavement, unemployment, serious concomitant disease) were also excluded.

### Procedures

In Study 1, the MSF-4 was administered at baseline and at endpoint (15 weeks) or withdrawal. Additional assessment variables were the I-PSS and a global question assessing the impact of urinary symptoms on QoL (measured in terms of satisfaction or dissatisfaction).

In Study 2, patients completed the MSF-4 on two occasions: once at day 0 (baseline) and once at day 7. The IIEF [13] was completed at baseline. Medical data collected included the presence or absence of sexual problems (baseline and endpoint) and details of any other events that may have influenced sexual function over the course of the study.

### Statistical Methods

In Study 1, the construct validity of the MSF-4 was assessed by exploratory factor analysis (prin-

principal component analysis with varimax rotation) and multitrait analysis, which were performed for each country and for all five countries together. Internal consistency reliability was assessed with Cronbach's alpha. To establish the clinical validity of the MSF-4, Spearman correlation coefficients between the MSF-4 global score and the quantitative clinical variables were calculated as well as the distribution of the MSF-4 global score according to I-PSS items, including the item related to QoL and the global score. In addition, as the global score cannot be assumed to have even approximately the normal distribution form, nonparametric tests were used [14].

In Study 2, the primary objective was to verify the reproducibility by test-retest of the MSF-4. This reproducibility was used to assess the stability of scores in patients whose state of health was stable between the two administrations of the questionnaire. The Wilcoxon signed rank test was used to compare the evolution of scores between day 0 and day 7. A linear regression equation of the global MSF-4 score on day 7 as a function of the score on day 0 was obtained. The null hypothesis was that the MSF-4 score at day 7 was a simple linear function of the score at day 0. Thus, the nearer the MSF-4 score at day 7 was to the MSF-4 score at day 0, the better was the reproducibility of the questionnaire.

The calculation of intraclass correlation coefficient (ICC) values allowed the stability of the MSF-4 scores to be verified. ICC measurements are derived from the analysis of variance and are considered as the ratio of the intersubject variability compared to the total variability (a high level of ICC indicates that the responses of patient remained invariable from one evaluation the other). The ICC ratio varies from  $-1$  to  $+1$  and is judged to be satisfactory from a threshold of 0.80 [15].

Additionally, to analyze the known-group validity in Study 2, the relationship between the MSF-4 scores and the presence or absence of sexual disorders and the distribution of I-PSS scores was investigated.

### Scoring of the MSF-4

Each of the four items is scored on a six-point Likert scale ranging from 0 to 5. The sex life (global) score was calculated by the mean of the non-missing answer given to the four items of the questionnaire (when more than two items out of four had a missing answer, the score could not be calculated). Then, the resulting score was linearly transformed to obtain a score ranging from 0 to 100. The lower

the score, the better preserved the sexual function for both individual items and the index.

## Results

### Study 1

A total of 810 patients aged 44 to 80 (mean age of 64) were recruited. The mean baseline I-PSS score was 13.45 (range 7–25). Thirteen patients had an I-PSS score greater than 19 and six patients had a score greater than 21. At baseline the QoL questionnaire showed that 24% of patients were mostly satisfied to delighted with their condition, 43% had mixed feelings, and 33% were mostly to terribly dissatisfied. The mean age and I-PSS score were similar across the five countries but there were some differences in the QoL responses. Whereas 47.62% of Spanish patients felt mostly satisfied about spending the rest of their lives with their urinary condition, only 9.63% of French and 11.54% of Austrian patients felt the same, with the highest proportion being mostly dissatisfied to do so (31% and 34.6%, respectively). In addition, nearly half of German patients answered “mixed” (equally satisfied and dissatisfied) about spending the rest of their lives with their urinary condition.

Out of the 810 patients recruited, 721 (89.01%) completed the MSF-4 at baseline (i.e., 89 patients did not complete or insufficiently completed the questionnaire to be taken into account in the analyses) and 692 (85.43%) did so at endpoint. For the group as a whole, the mean of the transformed global sex-life scores at baseline and endpoint for the five countries were 40.42 and 40.78, respectively. Significant differences were detected between the countries at baseline and endpoint (Table 1) [ $p = .0001$ ]. For example, patients in Portugal, Spain, and Austria had less impaired sexual function than patients in France and Germany. Thus, at baseline the mean scores ranged from 27.62 for Spanish patients to 45.89 for German patients, whereas at endpoint the respective scores were 26.83 and 45.72. The mean evolution in the MSF-4 score was 0.51, with mean scores ranging from  $-1.22$  (Spanish patients) to 4.57 (Austrian patients). The difference in MSF-4 score evolution between the five countries was significant ( $p = .0011$ ).

**Construct Validity.** When exploratory factor analysis was performed on the MSF-4 with a free number of factors, the variability of the MSF-4 global score was based on a single factor (factor 1) for all five countries as a whole. Similar results were obtained when the countries were analyzed individu-

**Table 1** The mean global MSF-4 score at baseline and endpoint in Study 1 by country\*

Mean global MSF-4 score (standard deviation) and internal consistency reliability in Study 1 at baseline, and mean global MSF-4 score at endpoint					
Country	n	Baseline		Endpoint	
		Mean scores <sup>†</sup> (SD)	Cronbach alpha	n	Mean scores <sup>†</sup> (SD)
France	184	36.98 (26)	0.90	173	38.38 (27)
Germany	371	45.89 (21)	0.88	361	45.72 (22)
Austria	52	33.75 (21)	0.83	46	37.12 (23)
Portugal	69	33.04 (19)	0.83	67	31.42 (21)
Spain	42	27.62 (15)	0.68	41	26.83 (15)
Five countries together	718	40.42 (23)	0.88	688	40.78 (24)

\*Score from 0 (no impairment) to 100 (highest impairment).

<sup>†</sup>p = 0.0001 for between country comparisons (Kruskal Wallis test).

ally, with the exception of Spain, for which the four items of the MSF-4 were spread across two factors: factor 1 was composed of items 2, 3, and 4 whereas factor 2 was composed of item 1 (Appendix 2).

Overall, the multitrait analysis indicated good item convergent validity. For all five countries, the analysis showed that items were correlated to their scale, with item-scale coefficients ranging from 0.59 (item 1) to 0.87 (item 3). When results from individual countries were analyzed, the results from Spain differed from those of the remaining countries. Four countries (France, Germany, Austria, and Portugal) had equivalent results, with the analysis confirming good item-scale correlation ( $\geq 0.65$  for items 2, 3, 4; 0.46–0.69 for item 1 depending on the country). Spain had a high item-scale correlation for items 3 and 4 alone.

The internal consistency reliability of the questionnaire was considered satisfactory for all of the countries combined and separately and Cronbach's alpha ranged from 0.68 to 0.90 depending on the country. The theoretical Cronbach's alpha coefficient for a 10-item scale was also high ( $\geq 0.84$ ) [16].

**Clinical Validity.** The MSF-4 was able to significantly discriminate ( $p < .05$ ) between patients according to their responses for each of the I-PSS items at baseline (Fig. 1). The higher the I-PSS score, the higher the MSF-4 score tended to be.

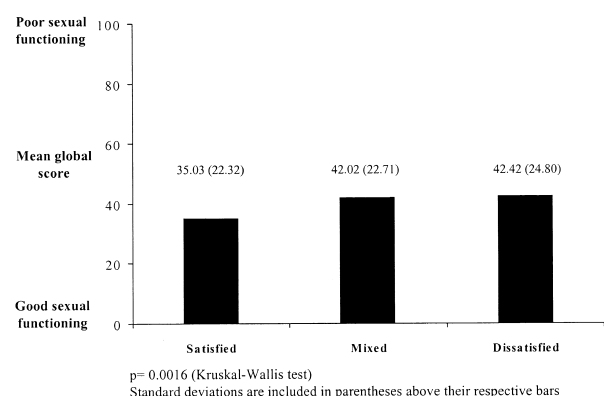
The MSF-4 also significantly discriminated ( $p < .05$ ) between the different QoL responses (Fig. 1). The trend was that the more dissatisfied a patient was about spending the rest of his life with his urinary condition, the higher the MSF-4 score.

There was also a trend for older patients to have a worse (higher) global MSF-4 score than younger patients. When patients were considered as three groups,  $< 60$ , 60 to 70, and  $\geq 70$ , the difference in scores between the groups was significant ( $p < .05$ ).

## Study 2

**Reproducibility.** A total of 124 men aged 48 to 87 (mean age 64) were recruited at 17 investigating centers in France (Table 2). The mean total I-PSS score for these patients was 12.6 and the time since diagnosis with BPH ranged from 3 to 287 months (mean 64.3 months). The mean time between completion of questionnaires was 7.83 days and complete data were available for all but one patient.

Over the 7-day study period, 103 patients were considered to be stable (according to their own judgment and that of the investigator) with respect to general health, sexual disorders, BPH, and other events. The mean global MSF-4 score in these patients on day 0 and day 7 was 41.07 and 43.62, respectively (Table 3). Patients with sexual disorders had significantly higher MSF-4 scores ( $p = .0001$  for the global score), and the correlation between the MSF-4 scores and the number of sexual relations per month was also significant ( $p = .0001$ ).



**Figure 1** The mean item and global MSF-4 scores according to the global QoL item responses of patients in Study 1.

**Table 2** Demographic characteristics of patients in Study 2

Characteristics of patients in Study 2	Value (n = 124)
Mean age (range) [years]	64.3 (48.0 – 87.0)
Family status, number (%) of patients:	
Lived alone	11 (8.9)
Lived in couple	112 (90.3)
Other	1 (0.8)
Mean total I-PSS score (range)	12.6 (0.0 – 25.0)
Mean duration of BPH (range) [months]	64.3 (3.0 – 287.0)
Total number (%) of patients treated for BPH	88 (71.0)
Medical treatments for BPH, number (%) of patients:	
Permixon ( <i>Serenoa repens</i> )	26 (29.6)
Xatral (alfuzosin)	20 (22.7)
Omix (tamsulosin)	14 (15.9)
Chibro-Proscar (finasteride)	12 (13.6)
Total number (%) of patients with sexual disorders	68 (54.8)
Type of sexual disorder, number (%) of patients:	
Decrease or absence of erection	55 (80.9)
Libido disorder	39 (57.4)
Premature ejaculation	14 (20.6)
Retrograde ejaculation	2 (2.9)

BPH, Benign prostatic hyperplasia; I-PSS, International Prostate Symptom Score.

Linear regression of the MSF-4 score at day 0 as a function of the score at day 7 gave similar results ( $r^2 = 0.84$ ), demonstrating that the reproducibility of the global score was acceptable. However, there was a significant evolution of the MSF-4 global score in the intervening period between the two evaluations (i.e., between day 0 and day 7) of patients considered as stable ( $p = .0071$ , Wilcoxon signed rank test). Reproducibility was also evaluated in the stable population by calculation of ICC values and these ranged from 0.84 to 0.89 for individual items (0.92 for the global score): this indicates the good reproducibility of MSF-4, since the ICC values are above the threshold of 0.80.

**Clinical Validity.** The MSF-4 discriminated between patients with mild, moderate, and severe BPH symptoms, as assessed by the I-PSS (Fig. 2). The results obtained for the global MSF-4 score were similar to those obtained in Study 1 and the

differences observed for the three severity groups were significant ( $p = .0001$ , Kruskal-Wallis test).

The MSF-4 was also able to discriminate between patients with sexual disorders and those without. Patients with sexual disorders had a significantly higher MSF-4 global score ( $p = .0001$ , Mann-Whitney-Wilcoxon test) and higher scores for all individual items, indicating a poor sexual function (Fig. 3).

The MSF-4 was moderately correlated to patients' age and duration of BPH. More interestingly, the level of correlation with the average monthly frequency of sexual intercourse was high, indicating the clinical relevance of the questionnaire (Table 4).

**Concurrent Validity.** The correlation between the MSF-4 and the IIEF scales was above 0.60 ( $p = .0001$ ). The highest correlation of the MSF-4 global score was with the erectile function item of the IIEF ( $-0.77$ ) (Table 4).

The MSF-4 global score was significantly related to age (correlation coefficient of 0.34). This was also the case for the duration of BPH symptoms, frequency of sexual intercourse, and handicap caused by sexual disorders (as determined by the investigator).

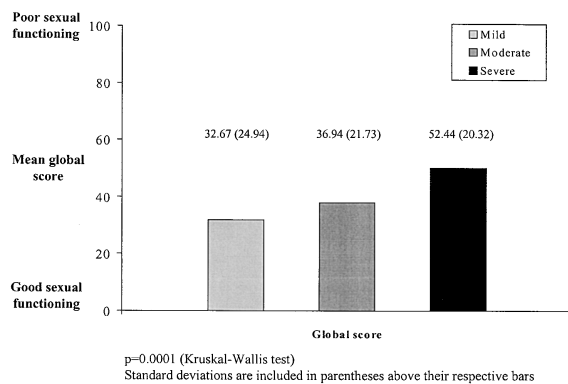
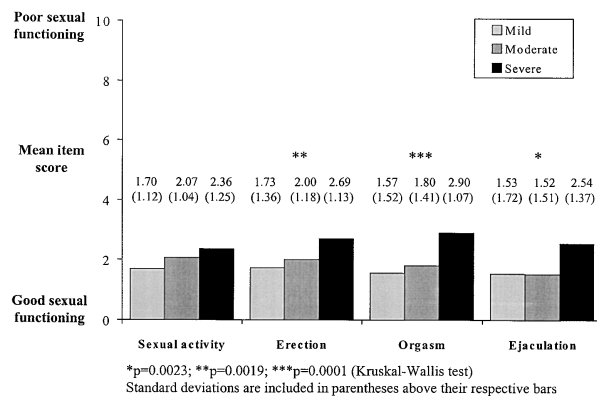
## Discussion

The MSF-4 was designed as a simple, brief, self-administered questionnaire on male sexual function. We reviewed 13 questionnaires used in studies to evaluate consequences of BPH and/or its treatment on quality of life and which included a measure of sexual function. The content of the selected questionnaires was compared with that of the MSF-4. This comparison showed that one possible weakness of the MSF-4 was the lack of detailed assessment of some of the domains appraised by other instruments (satisfaction with sexual life, sexual relations, problems with sexual life, sexual desire). However, the MSF-4 was designed to be a measure of sexual function and, as such, the MSF-4 is useful in detecting sexual difficulties such as ejaculation or erection problems, which are the domains most commonly

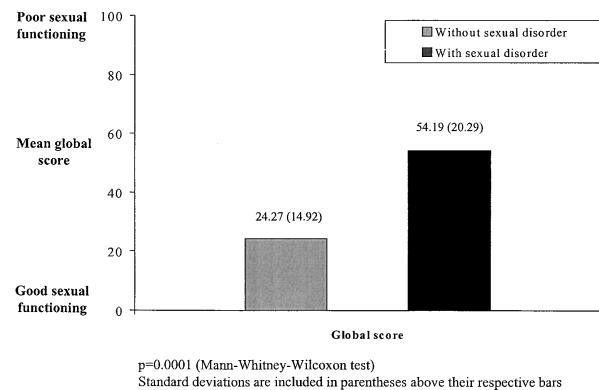
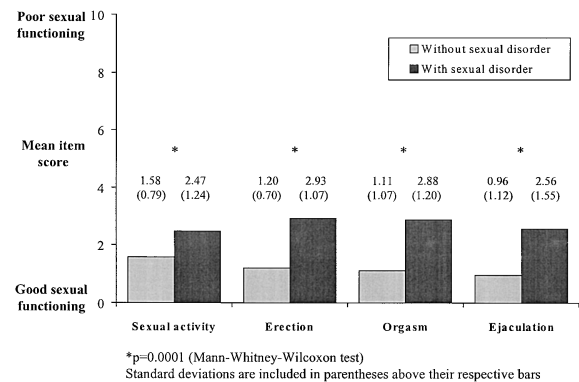
**Table 3** The mean global and item sexual function scores on day 0 and day 7 in Study 2

Mean scores (standard deviation) in Study 2 at baseline, changes over time and test-retest reliability (n = 103)*					
Domain	Day 0	Mean change day 7-day 0 (SD)	Median change day 7-day 0	p (Sign rank test)	ICC
Sexual activity	2.13 (1.2)	0.06 (0.7)	0.00	0.4195	0.84
Erection	2.17 (1.3)	0.00 (0.6)	0.00	0.9925	0.89
Orgasm	2.12 (1.5)	0.19 (0.8)	0.00	0.0092	0.86
Ejaculation	1.80 (1.6)	0.27 (0.8)	0.00	0.0003	0.87
Global (MSF-4) score	41.07 (24.5)	2.56 (10)	0.00	0.0071	0.92

\*Item scores from 0 to 5 and global score from 0 to 100 ICC; Intra-class correlation coefficient.



**Figure 2** The mean item and global MSF-4 scores of patients in Study 2 with mild, moderate, and severe BPH symptoms as assessed by the I-PSS.



**Figure 3** The mean item and global MSF-4 scores for patients with and without sexual disorders in Study 2.

found in other questionnaires. One of the distinguishing features of the MSF-4 is that it measures the quality of erection, in contrast with most other questionnaires, which assess erections in terms of frequency, erection problems, or difficulty obtaining and/or maintaining erections. The MSF-4 is also differentiated from the other questionnaires reviewed by the assessment of interest in sex and orgasm which are evaluated by few questionnaires (Table 5).

The results of the two current studies show that the MSF-4 is psychometrically and clinically valid across different cultures, in addition to being highly reproducible.

In Study 1, the global MSF-4 was supported by a single factor (factor 1) and showed good item convergent validity in all countries (France, Germany, Austria, and Portugal) except Spain. The statistical discrepant results obtained in Spain (two identified factors) confirmed what was highlighted during the linguistic validation process. From a linguistic point of view, items 2, 3, and 4 (factor 1) refer to sexual functioning rather than to the perception of sexuality as expressed in other languages. It is difficult to assess sexuality in Spain in

terms of quality without referring to physical considerations; sexuality seems to be assessed in terms of physical performance by Spanish males.

The internal consistency reliability of the MSF-4 was satisfactory for all countries (considered together and separately) and it was able to significantly differentiate patients based on their I-PSS and QoL scores. The MSF-4 score was demonstrated to be I-PSS and age dependent; however, because the relationship between sexual function

**Table 4** Concurrent and clinical validity of the MSF-4 with the IIEF

	n	MSF-4 index
<b>IIEF scales</b>		
Erectile function	119	-0.77 (.0001)*
Orgasmic function	122	-0.76 (.0001)
Sexual desire	122	-0.74 (.0001)
Intercourse satisfaction	121	-0.73 (.0001)
Overall satisfaction	120	-0.64 (.0001)
Age		0.34 (.0001)
Duration of BPH		0.22 (.01)
Number of intercourses per month		-0.63 (.0001)

Spearman correlation coefficients.

\*P values.

**Table 5** Review of 13 questionnaires and comparison with the MSF-4

	Satisfaction with sexual life	Sexual activity/ sexual relations	Erection	Problems with sexual life	Sexual desire/ arousal	Interest in sex/ importance of sex	Ejaculation	Pleasure/ orgasm
QoL of patients with BPH [19]	✓							
Veterans Affairs [20]		✓	✓					
BPH patient questionnaire [21]			✓	✓				
MOS Sexual Module [22]			✓		✓			✓
Urolife [23]	✓				✓			
QOL-BPHY [24]	✓		✓		✓			
SFI [12]	✓		✓	✓	✓		✓	
QOL-BPH [25]	✓	✓	✓		✓			
DAN-PSSI [26]			✓				✓	
SFQ [27]	✓		✓		✓			
SFQ [28]		✓						
Specific questions on sexual function [8]	✓	✓		✓	✓	✓		✓
IIEF [13]	✓		✓		✓			✓
MSF-4			✓			✓	✓	✓

and BPH symptoms has not been clearly established, our findings could be the results of other factors (poor state of health, for example). However, in Study 2, the MSF-4 again showed good reproducibility, and not only was it able to differentiate patients with BPH symptoms of differing severities (assessed by I-PSS), but it was also able to differentiate patients based on the presence/absence of sexual disorders. The presence of a sexual disorder was associated with a higher global MSF-4 score, which in turn was significantly correlated with a lower frequency of sexual intercourse.

Responses to the sexual function instrument differed for certain countries. The Spanish sample had scores lower (higher sexual functioning) than in the other countries. Again, as previously mentioned, linguistic issues should be taken into account when interpreting such results. Given that in Spain physical performance seems to be important, response choices might not be as relevant as in other countries. Checking the relevance of more specific quantifier response choices for items 2, 3, and 4 could be the subject of further research. However, previous cross-cultural studies [8] showed cultural differences in the report of sexual problems or sexual activities [17]. Moreover, the fact that the Spanish sample had the lowest number of patients in study 1 (42 vs. 371 in Germany and 184 in France) should also be taken into account when interpreting the results. We recommend checking the structure of the MSF-4 again in a larger Spanish sample.

Nevertheless, the MSF-4 was extremely well accepted with very few missing data: 85 percent (study 1) and 99 percent (study 2) of the questionnaires were fully completed. The MSF-4 showed good test-

retest reproducibility, although there was a significant evolution in the global score between day 0 and day 7 in study 2 ( $p = .0071$ ). The study protocol did not call for a visit on day 7, and because the clinical stability of patients was assessed through a telephone interview—both by the investigator and the patient—no medical examination could be made at that time. However, several questions were asked and answers crossed in order to ensure stability over 7 days. Moreover, the inclusion criteria called for stability in treatment over 7 days and such a criterion was met. The change in the median scores between day 0 and day 7 was null for all items (Table 3). This kind of variation has been previously reported with other questionnaires in other settings [18].

Concurrent validity analysis showed a significant correlation between the MSF-4 and the IIEF, which could call into question the use of the MSF-4 versus the IIEF. Such is the interest of the MSF-4, which is highly correlated with a psychometrically sound instrument and is shorter. Hence, in daily practice the instrument can be useful for clinicians; it will require just a few minutes to complete and will therefore not burden patients. Also, having only four items makes the score calculation quick and easy and enables clinicians to make a quick estimate of a patient's sexual status. Being short, the MSF-4 could also be included in a battery of questionnaires—with a generic instrument, for example—without increasing the time for completion.

In conclusion, the MSF-4 is a psychometrically validated questionnaire with good reproducibility and clinical validity, allowing easy and appropriate assessment of male sexual function in BPH clinical settings.

Source of funding: Pierre Fabre Médicaments.

## References

- Medina JJ, Parra RO, Moore RG. Benign prostatic hyperplasia (the aging prostate). *Med Clin North Am* 1999;83:1213–29.
- Burger B, Weidner W, Altwein JE. Prostate and sexuality: an overview. *Eur Urol* 1999;35:177–84.
- Uygur MC, Arik AI, Altug U, Erol D. Effects of the 5-alpha-reductase inhibitor finasteride on serum levels of gonadal, adrenal, and hypophyseal hormones and its clinical significance: a prospective clinical study. *Steroids* 1998;63:208–13.
- Debruyne FM, Jardin A, Colloi D, et al. Sustained-release alfuzosin, finasteride and the combination of both in the treatment of benign prostatic hyperplasia. European ALFIN Study Group. *Eur Urol* 1998;34:169–75.
- Bruskewitz R, Girman CJ, Fowler J, et al. Effect of finasteride on bother and other health-related quality of life aspects associated with benign prostatic hyperplasia. PLESS Study Group. Proscar Long-Term Efficacy Safety Study. *Urology* 1999;54(4):670–8.
- Hofner K, Claes H, De Reijke TM, Folkestad B, Speakman MJ, Tamsulosin 0.4 mg once daily: effect on sexual function in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. *Eur Urol* 1999;36(4):335–41.
- Helgason AR, Adolffson J, Dickman P, et al. Sexual desire, erection, orgasm and ejaculatory functions and their importance to elderly Swedish men: a population-based study. *Age Ageing* 1996;25:285–91.
- Calais da Silva F, Marquis P, Deschaseaux P, et al. Relative importance of sexuality and quality of life in patients with prostatic symptoms. *Eur Urol* 1997;31:272–80.
- Patrick DL. In: *Health Status and Health Policy Allocating Resources to Health Care: Concepts of Health-Related Quality of Life* (4th ed.). New York: Oxford University Press, 1993;4:76–112.
- Zlotta AR, Schulman CCBPH. and sexuality. *Eur Urol* 1999;36(Suppl. 1):107–12.
- Mathias SD, O'Leary MP, Henning JM, Pasta DJ, Fromm S, Rosen RC. A comparison of patient and partner responses to a brief sexual function questionnaire. *J Urol* 1999;162:1999–2002.
- O'Leary MP, Fowler FJ, Lenderking WR, Barber B, Sagnier PP, Guess HA, Barry MJ. A brief male sexual function inventory for urology. *Urology* 1995;46(5):697–706.
- Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function (IIEF): a multidimensional scale for assessment of erectile dysfunction. *Urology* 1997;49(6):822–30.
- Fayers MP, Machin D. Cross-sectional analysis. In: *Quality of Life: Assessment, Analysis and Interpretation* (8th ed.). Chichester, West Sussex: John Wiley and Sons, Ltd., 2000.
- Hays RD, Anderson R, Revicki DA. Assessing reliability and validity of measurement in clinical trials. In: Staquet MJ, Hays RD, Fayers MP, eds. *Quality of Life Assessment in Clinical Trials*. New York: Oxford University Press, 1998.
- Nunnally JC. *Psychometric theory* (2nd ed.). New York: McGraw-Hill, 1978.
- Altwein JE, Keuler FU. Benign prostatic hyperplasia and erectile dysfunction: a review. *Urol Int* 1992;48:53–7.
- Deyo R, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Control Clin Trials* 1991;12:142–58.
- Eri LM, Tveter KJ. Measuring the quality of life of patients with benign prostatic hyperplasia. *Eur Urol* 1992;21:257–62.
- The Department of Veterans Affairs Cooperative Study of Transurethral Resection for Benign Prostatic Hyperplasia. A comparison of quality of life with patient reported symptoms and objective findings in men with Benign Prostatic Hyperplasia. *The Journal of Urology* 1993;150:1696–700.
- Fowler FJ, Wennberg JE, Timothy RP, et al. Symptom Status and Quality of Life Following Prostatectomy. *JAMA* 1988;259(20):3016–22.
- Sherbourne CD. Social functioning: sexual problems measures. In: Stewart AL, Ware JE, eds. *Measuring Functioning and Well-Being. The Medical Outcomes Study Approach*. Durham and London: Duke University Press, 1992.
- Lukaca B, McCarthy C, Grange JC, et al. Construction et validation d'une échelle de qualité de vie liée à l'état de santé, spécifique de l'hypertrophie bénigne de la prostate et comportant une échelle d'évaluation de la sexualité. *Progrès en Urologie* 1994;4:688–99.
- Lukaca B, et al. Long-term quality of life in patients with benign prostatic hypertrophy: preliminary results of a cohort survey of 7,093 patients treated with an alpha-1-adrenergic blocker. *Alfuzosin Eur Urol* 1993;24(Suppl.1):34–40.
- Epstein RS, Deverka PA, Chute CG, et al. Validation of a new quality of life questionnaire for Benign Prostatic Hyperplasia. *J Clin Epidemiology* 1992;45(12):1431–45.
- Hansen BJ, Flyger H, Brasso K, et al. Validation of the self-administered Danish Prostatic Symptom Score (DAN-PSSI) system for use in Benign prostatic hyperplasia. *Br J Urology* 1995;76:451–8.
- Girman CJ, Kolman C, Liss CL, et al. Effects of Finasteride on health-related quality of life in men with symptomatic benign prostatic hyperplasia. *The Prostate* 1996;29:83–90.
- te Slaa E, Francisca EA, Hendricks JC, et al. Quality-of-life assessment in patients after laser prostatectomy. *Br J Urology* 1997;80:211–6.



# Appendix 1 MSF-4 (Male Sexual Function-4 item) questionnaire

How would you rate the following aspects of your life?						
Circle one answer for each question :						
	Very strong	Strong	Moderate	Weak	Very weak	None
1. Your interest in sex	0	1	2	3	4	5
2. The quality of your erection	0	1	2	3	4	5
3. Achieving orgasm	0	1	2	3	4	5
4. Achieving ejaculation	0	1	2	3	4	5

# Appendix 2 Exploratory factor analysis of the MSF-4 across countries\*

MSF-4 items	All countries	France	Germany	Austria	Portugal	Spain	
	Factor 1	Factor 1	Factor 1	Factor 1	Factor 1	Factor 1	Factor 2
1. Interest in sex	0.75	0.82	0.73	0.66	0.67	0.17	0.91
2. Quality of erection	0.84	0.85	0.85	0.87	0.81	0.72	-0.49
3. Orgasm	0.93	0.94	0.93	0.90	0.89	0.87	0.18
4. Ejaculation	0.91	0.92	0.92	0.82	0.88	0.88	0.22

\*Item-factor correlations.