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Development and Validation of a New Treatment Outcome Score for Men With LUTS

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Aims: To develop, validate, and test elements of a new outcome score for men with lower urinary tract symptoms (LUTS). **Methods:** Elements of well-established questions from the International Prostate Symptom Score (IPSS) assessment were combined with both established noninvasive objective determinants of voiding function including maximum uroflow (Qmax), postvoid residual urine volume (PVR), total number voids, maximum voided volume (MVV) as well as a subjective patient assessment parameter, to create a new LUTS treatment outcome instrument which we have termed the "LUTS outcome score" (LOS). The LOS is comprised of eight items; each assigned a score of 0, 1, or 2. Thus, the score ranges from 0 (best) to 16 (worst). Patients were divided into surgical/nonsurgical (pharmacologic or behavior modification) treatment groups. Content validity and cutoff values for cure/improve/fail were established by an expert panel. Criterion validity was established by comparison to the IPSS. Internal reliability analysis was performed to obtain information about the relationships between individual items in the scale. Individual LOS items were correlated with the subjective outcome score. We also calculated the correlations between the LOS, IPSS, subjective post-treatment response, and age. Internal consistency, based on the average inter-item correlation was calculated using Cronbach's alpha statistic. Associations between continuous variables were examined by calculating the Pearson correlation coefficient, and between ordinal variables, using Spearman's rho. Test–retest analysis was recorded to determine reproducibility of the patient subjective outcome score. Seventy-seven men who underwent treatment for LUTS for at least 6 months participated in the study. All completed a detailed pretreatment and post-treatment clinical evaluation consisting of history/physical, questionnaire, voiding diary, urinalysis, Q, PVR, and videourodynamic study. Subjective responses of cured/improved/failed status following treatment were assessed by independent investigators. **Results:** A high level of internal consistency was observed among the LOS symptom questions, Cronbach's alpha = 0.81 for the total cohort. The LOS correlated directly and significantly with the patient's subjective post-treatment response ($r = 0.75$, $P < 0.001$), age ($r = 0.27$, $P = 0.02$), and with the total IPSS ($r = 0.62$, $P < 0.001$). The IPSS also correlated directly and significantly with the patient's subjective post-treatment response ($r = 0.48$, $P < 0.001$) but did not correlate with the patient's age ($r = 0.10$, $P = 0.41$). When the subjective parameter for post-treatment response was subtracted from the LOS, the resulting correlation ($r = 0.52$, $P < 0.001$) approximated that obtained using the IPSS. **Conclusions:** The LOS is valid and internally consistent. Unlike the IPSS, it combines subjective, semisubjective, and objective parameters. Because of the objective components, it diminishes the possibility of overestimating cure and underestimating improvement relying only on patient's symptoms. Further, we believe it will prove to be useful for post hoc analysis in patients who have not had pre-treatment assessment. *Neurourol. Urodynam. 23:88–93, 2004.* © 2004 Wiley-Liss, Inc.

Key words: benign prostatic hyperplasia; bladder outlet obstruction; detrusor contractility; patient outcomes; post-void residual

INTRODUCTION

Men who undergo treatment for lower urinary tract symptoms (LUTS) form a heterogeneous group [Neal, 1994]. Few predictors of treatment outcome have been identified, and post-treatment outcomes have not been well quantified.

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TABLE I. The International Prostate Symptom Score (IPSS) [McConnell et al., 1994]

(1) How often have you had a sensation of not emptying your bladder completely after you finished urinating?
(2) How often have you had to urinate again less than 2 hr after you finished urinating?
(3) How often have you found you stopped and started several times when you urinated?
(4) Over the past month, how often have you found it difficult to postpone urination?
(5) How often have you had a weak urinary stream?
(6) How often have you had to push or strain to begin urination?
(7) How many times did you get up to urinate from the time you went to bed until the time you got up?

TABLE II. The LUTS Outcome Score (LOS)

Subjective response			
	Cured	Improved	Same/worse
Score	0	1	2
Number of voids per day			
	≤ 8	$>8 \leq 11$	>11
Score	0	1	2
Maximum voided volume (MVV) (cc)			
	≥ 250	$\geq 150 < 250$	<150
Score	0	1	2
Measured peak flow rate (cc/sec)			
	≥ 15	$\geq 10 < 15$	<10
Score	0	1	2
Post-void residual (cc)			
	≤ 50	$>50 \leq 200$	>200
Score	0	1	2
Urgency (no. 4 on AUA-SS)			
	0–1	2–3	4–5
Score	0	1	2
Nocturia (no. 7 on AUA-SS)			
	0–1	2–3	4–5
Score	0	1	2
Voiding difficulty (no. 1, 3, 5, 6 on IPSS)			
	0–1	2–3	4–5
Score no. 1	0	1	2
Score no. 3	0	1	2
Score no. 5	0	1	2
Score no. 6	0	1	2

Sum of above four scores is divided by 4.
Total possible score: 16.
If patient is currently requiring catheterization, then a LOS of 16 is given automatically.

The International Prostate Symptom Score (IPSS) has been recommended as an integral part of the initial evaluation of symptomatic patients by the BPH Guideline Panel of the Agency for Health Care Policy and Research [Licht and Barrett, 1996] (Table I).

Although the IPSS is internally consistent and reliable [Barry et al., 1992; O'Leary, 1995], studies have shown minimal to no correlation between the IPSS and the severity of obstruction, as assessed by pressure-flow urodynamic studies [Yalla et al., 1995; McConnell, 1998]. The IPSS tests the degree to which symptoms are present and bothersome, however, it does not reveal whether a patient is obstructed or will benefit from prostatectomy [Webster and Kreder, 1998]. Further, the IPSS has no objective parameters.

Herein we present a new LUTS outcome score (LOS) for men that combines both objective and subjective parameters, validate it, and present the initial outcome data in a series of men undergoing surgical and non-surgical treatment for LUTS.

MATERIALS AND METHODS

Elements of well-established questions from the IPSS assessment (Table I) were combined with established noninvasive objective determinants of voiding function as well as a subjective patient assessment parameter, to create the LOS. The LOS (Table II) consists of eight parameters; each assigned a score of 0, 1 or 2. Parameters include: subjective cured/improved/failed response, number of voids per 24 hr, functional bladder capacity (FBC), maximum uroflow (Qmax), postvoid residual urine volume (PVR), urgency, nocturia, and voiding difficulty. Measurements of urgency and nocturia were recorded from patient's responses to IPSS questions no. 4 and 7, respectively. The voiding difficulty score was calculated by using the average of IPSS items no. 1, 3, 5, and 6. Patients requiring catheterization were automatically assigned a voiding difficulty score of 2 and total LOS of 16. Thus, the LOS ranges from 0 (best) to 16 (worst).

Content validity and the cutoffs for cure/improve/fail were established by an expert panel. To achieve 'cured' status, a patient must claim to be cured by the treatment (0 points), had a MVV >250 cc (0 point), PVR <50 cc (0 point), urgency limited to once in five-times or less (0 points), nocturia three or less times per night (0–1 points), a voiding difficulty score of 0–1, <12 daily voids (0–1 point), and Qmax >15 (0 points). Therefore, the maximal score allowed for inclusion in the cured group was set at three points. To achieve 'failed' status, the patient required a 'failed' subjective response and a score of 2 for at least one of the remaining LOS parameters, indicating objective failure for a particular symptom parameter (minimum of 4 points). 'Improved' patients consisted of patients with an 'improved' subjective outcome or those not meeting requirements for achieving 'failed' status.

For criterion validity, the LOS was compared to the IPSS. The rationale for this comparison is that the LOS combines most of the (semisubjective) questions from the IPSS in a reweighted fashion while adding subjective and objective parameters; the IPSS is an accepted yardstick for monitoring men's LUTS and can be considered a prevalidated standard of comparison for our newer outcome measuring instrument.

A database of men who underwent treatment for LUTS for at least 6 months was prospectively evaluated. All men over the age of 21 years who elected to undergo treatment

for LUTS were included in the study. Men with overt neurogenic voiding dysfunction or those patients whose evaluations were incomplete were excluded. The study was approved by the Western IRB. Patients completed a detailed pretreatment (and post-treatment) evaluation consisting of a structured history/physical examination, urinary questionnaire (including IPSS), 24-hr voiding diary, urinalysis and culture, noninvasive free-flow uroflowmetry (Q), PVR determination, and videourodynamic study (VUDS). Seventy-seven men with complete records were retrospectively analyzed. Free-flow measurements were conducted in a private setting using a standard toilet. PVR was measured by ultrasound immediately after bladder emptying. Uroflow and PVR were repeated at least twice to ensure consistency. The highest Qmax and lowest PVR were used for analysis. Multichannel VUDS were performed according to the recommendations of the International Continence Society except for cystometry [Abrams et al., 1998]. Contrary to these recommendations patients were not instructed to try to inhibit voiding during the filling phase, but were asked to report sensations to the examiner. Cystometrography utilized a 7Fr double-lumen transurethral catheter through which room temperature radiographic contrast material was infused at a medium fill rate of 75–100 ml/min with rectal pressure monitoring [Groutz et al., 2000b]. Bladder filling was discontinued at FBC, defined as the maximum voided (or catheterized) volume (MVV) in the 24-hr voiding diary. Filling above the FBC was avoided since bladder overfilling may cause a significant decrease in the flow rate [Ryall and Marshall, 1982]. Patients were asked to void and pressure-flow studies were performed with simultaneous fluoroscopy of the bladder outlet; if the patient was unable to void with the urethral catheter in place, it was removed and free-flow measurements were recorded.

Patients were divided into surgical (n = 30) and non-surgical (n = 47) treatment groups. Indications for surgery included either bladder outlet obstruction (Schafer obstruction grade >2) or urinary retention. Surgical treatments included transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), and suprapubic prostatectomy (SPP). Non-surgical treatments included medications (alpha blockers, 5-alpha reductase inhibitors) and/or behavioral modification. The choice of treatment was usually patient-driven, initial preference given to non-surgical therapy where warranted clinically. Post-treatment, patients completed a detailed clinical assessment consisting of 24 hr voiding diary, uroflow, PVR, and IPSS. Additionally, all patients were assessed by independent third-party investigators to evaluate whether the treatment they underwent rendered them cured, improved, or the same/worse (failed) compared to their pre-treatment LUTS status.

Statistical Analysis

Reliability analysis was performed in order to obtain information re: the inter-item correlations and on the internal consistency of the LOS. Individual LOS items were correlated with the subjective outcome score as well as with the IPSS. Internal consistency, based on the average inter-item correlation was calculated using Cronbach's alpha statistic [Cronbach, 1951]. Associations between continuous variables were examined by calculating the Pearson correlation coefficient and between ordinal variables were examined using Spearman's rho. All statistical procedures were performed using SPSS 11.5 (Chicago, IL). A $P < 0.05$ was considered a priori to be statistically significant. Overall comparisons between the LOS and IPSS utilized 95% confidence intervals.

RESULTS

Thirty (39%) patients received surgical treatment while 47 (61%) underwent non-surgical treatment. Mean age at presentation (Table III) was 70.2 years (46–86) in the surgical and 72.7 years (50–93) in the non-surgical group ($P = 0.336$). Of the surgical patients, 25 (83%) underwent TURP, 3 (10.0%) underwent TUIP, and 2 (7%) SPP. Of the non-surgical patients, 42 (89%) received medication while 5 (11%) received behavior modification as the primary therapy.

Overall, 23 (30%) patients met criteria for being cured, 36 (47%) improved, and 18 (23%) failed (Table IV). Mean LOS results for each group were 2.38 (95% CI; 1.73–3.03), 5.92 (95% CI; 5.14–6.69), and 10.42 (95% CI; 9.03–11.8), respectively. Mean IPSS was 3.70 (95% CI; 2.28–5.12), 9.86 (95% CI; 7.6–12.1), and 14.94 (95% CI; 10.3–19.5) for the cured, improved, and failed groups, respectively. Thus, the LOS demonstrated differences between all outcome groups (independent of treatment type) with significance. In regards to results of test-retest validation for subjective patient treatment outcome reports,

TABLE III. Demographic Parameters for Surgical and Non-Surgical Groups

	Surgical	Non-surgical	*P*-value
Age	70.2	72.7	0.336
Pre treatment			
No. daily voids	10.87	12.06	0.156
MVV (ml)	361.3	293.2	0.145
Qmax (cc/sec)	8.44	7.05	0.232
PVR (ml)	457.4	97.8	0.007
IPSS (0–35)	14.32	16.09	0.360
Voiding difficulty score (0–2)	1.58	0.87	0.009
Schafer grade (0–6)	4.29	2.05	<0.001
Watts factor (Watts/m^2)	11.21	8.28	0.016
Post treatment			
No. daily voids	8.24	10.73	<0.001
MVV (ml)	368.5	308.4	0.009
Qmax (cc/sec)	16.93	9.15	0.001
PVR (ml)	80.6	86.5	0.899
IPSS (0–35)	5.83	11.09	0.002
Subjective assessment (0–2)	0.70	1.09	0.035
Voiding difficulty score (0–2)	0.75	0.53	0.385
LOS (0–16)	4.32	7.04	0.002

TABLE IV. Overall Comparisons Between LOS and IPSS by Outcome Groups (Surgical + Nonsurgical)

Outcome Group (no.)	LOS (95% CI)	IPSS (95% CI)
Cured (23)	2.38 (1.73–3.03)	3.70 (2.28–5.12)
Improved (36)	5.92 (5.14–6.69)	9.86 (7.6–12.1)
Failed (18)	10.42 (9.03–11.8)	14.94 (10.3–19.5)

all patients in all groups returned the same subjective self-assessment both initially and post treatment.

Table V presents a correlation matrix listing the correlation coefficients between each item of the LOS. In this matrix the individual IPSS voiding symptom questions (1, 3, 5, 6) were entered as separate data points. A high level of internal consistency was observed among the LOS items, Cronbach's alpha = 0.81 to the total cohort. There was a tendency toward low (negative) correlation of PVR with the remaining cohort, indicating the direction of PVR scores was opposite, albeit slightly, to several of the other items. Table VI presents the correlation coefficients of each of the LOS parameters using the re-weighted VDS as opposed to the individual IPSS questions 1, 3, 5, and 6. The resulting Cronbach's alpha for the total cohort using the VDS was 0.73 indicating a strong association of the weighted voiding dysfunction quotient with its associated LOS elements. We additionally calculated the correlations between the LOS, IPSS, subjective post-treatment response and age. The LOS correlated directly and significantly with the patient's subjective post-treatment response ($r = 0.75$, $P < 0.001$), age ($r = 0.27$, $P = 0.02$), and with the total IPSS ($r = 0.65$, $P < 0.001$). The IPSS also correlated directly and significantly with the patient's subjective post-treatment response ($r = 0.48$, $P < 0.001$) but it did not correlate with the patient's age ($r = 0.10$, $P = 0.41$). When the subjective post-treatment response was subtracted from the LOS, the resulting correlation with subjective post-treatment response ($r = 0.52$, $P < 0.001$) approximated the correlation of subjective treatment response with the IPSS ($r = 0.48$, $P < 0.001$). Table VII presents the latter results.

We compared LOS in patients who were subjectively cured by either surgical or nonsurgical treatments. Thirteen patients were subjectively cured by surgery (mean LOS = 1.87) as compared with 10 patients cured by nonsurgical means (mean LOS = 3.05), $P = 0.06$. Further, the LOS returned significant differences between cohorts of surgically cured patients as compared with those17 patients not cured (i.e., improved + failed) by surgery, $P < 0.001$. Similarly, nonsurgical cured patients (mean LOS = 3.05, n = 10) fared significantly better than nonsurgical improved + failed patients (mean LOS = 8.12), $P < 0.001$ (Table VIII).

DISCUSSION

The IPSS is widely accepted as the gold standard for assessing LUTS in men, but it is limited as an outcome tool for two basic reasons. First, there are no objective measures in the IPSS. Thus, it is possible for a patient to deny any symptoms at all (and have a low score), yet have severe underlying abnormalities or, conversely, a patient may complain bitterly of symptoms, yet have no underlying abnormality of the lower urinary tract. An example of the former is "silent prostatism" that results in urinary retention. An example of the latter is patients who complain of treatment failure because of urinary frequency, urgency and nocturia (a possible 15 points of the IPSS) due to polyuria (which has little to do with the lower urinary tract). Secondly, the IPSS has no domains relating to treatment outcome; the only way that the IPSS can be used to evaluate outcome is to compare it pre and post treatment and develop another instrument to assess subjective outcome.

The lack of objective assessment in the IPSS has one other serious shortcoming. If outcomes are evaluated only subjectively, neither the clinician nor the researcher develops the tools to gain insight into the effects of treatment on underlying physiology. This stifles both the development of clinical acumen and limits the rationale for developing new avenues of treatment. The LOS on a whole correlates well with the subjective patient outcome evaluation, demonstrating that objective parameters intrinsic to the LOS provide a "built-in"

TABLE V. Correlations Matrix Liosting Correlation Coefficients Between Each Element of the LOS

	No. voids	MVV	Qmax	PVR	IPSS no. 4	IPSS no. 7	IPSS no. 1	IPSS no. 3	IPSS no. 5	IPSS no. 6	Subj
No. voids	1.0										
MVV	0.374	1.0									
Qmax	0.337	0.287	1.0								
PVR	−0.170	−0.088	0.105	1.0							
IPSS no. 4	0.432	0.275	0.359	0.110	1.0						
IPSS no. 7	0.460	0.265	0.341	−0.160	0.352	1.0					
IPSS no. 1	0.228	0.164	0.153	−0.076	0.256	0.323	1.0				
IPSS no. 3	0.308	0.124	0.162	0.051	0.392	0.358	0.670	1.0			
IPSS no. 5	0.309	0.030	0.120	−0.107	0.352	0.263	0.552	0.712	1.0		
IPSS no. 6	0.295	0.159	0.127	0.172	0.321	0.456	0.598	0.784	0.500	1.0	
Subj	0.425	0.292	0.404	0.128	0.454	0.275	0.321	0.373	0.503	0.261	1.0

TABLE VI. Correlation Coefficients of the LOS Elements With the Voiding Dysfunction Score (VDS)

	No. voids	MVV	Qmax	PVR	IPSS no. 4	IPSS no. 7	Subj	VDS
No. voids	1.0							
MVV	0.383	1.0						
Qmax	0.312	0.274	1.0					
PVR	−0.155	−0.081	0.098	1.0				
IPSS no. 4	0.438	0.280	0.348	0.115	1.0			
IPSS no. 7	0.471	0.273	0.324	−0.150	0.359	1.0		
Subj	0.419	0.291	0.401	0.128	0.423	0.274	1.0	
VDS	0.325	0.128	0.151	−0.007	0.386	0.394	0.432	1.0

MVV, functional bladder capacity; Qmax, maximum urinary flow rate; PVR, post-void urinary volume; IPSS, international prostate symptom score; Subj, subjective patient treatment assessment response; VDS, voiding difficulty score (see text).

explanation for cure or lack thereof within the same measuring instrument.

The LOS depicted herein was developed to in response to these shortcomings of the IPSS. We have shown it to be both valid and internally consistent. Unlike the IPSS, it combines subjective and objective outcomes including the patient's own perception about cure/improve/fail. Thus, it is possible to administer the LOS to patients who have not undergone pretreatment assessment.

The IPSS includes four of its seven core questions that address incomplete emptying, intermittency of stream, weak stream, and straining to void, thus placing heavy weight on voiding difficulty, a symptom of outlet obstruction which is quite variable in terms of patient bother. In contrast, the LOS gives equal weight to the symptoms of voiding difficulty (the composite "voiding difficulty score = VDS"), frequency, urgency, and nocturia, in addition to other subjective and objective parameters. Further, the LOS includes uroflow, the single most reliable noninvasive urodynamic test to detect lower urinary tract obstruction and impaired detrusor contractility [McConnell et al., 1994; Groutz et al., 2000c]. All of the other objective parameters in the LOS have previously been validated as part of the IPSS [Barry et al., 1992; Mebust, 1993], PVR [Mebust, 1993; Blaivas and Chancellor, 1996; McConnell, 1998], FBC [Blaivas and Chancellor, 1996], flow rate [McConnell et al., 1994], and total number of voids per day [Groutz et al., 2000a]. Post-void urine volume determination has had the poorest test-retest validity of all objective measures included in the LOS, an observation confirmed in the present internal reliability study [Hsieh et al., 2002].

While the IPSS has been used extensively as an outcomes instrument, it is often used in conjunction with additional subjective (e.g., quality of life) and objective (e.g., uroflow and PVR) parameters when comparing differing LUTS therapies [Gujral et al., 2000]. We have taken the additional step of adding and re-weighting these multiple parameters into one comprehensive outcome score.

An initial motivation for creation of the LOS was to address whether we are "lowering the bar" of expectation of success of newer surgical alternatives in treating men with LUTS. To this end patients claiming subjective cure having undergone surgical procedures fared better (mean LOS = 1.87) than "cured" patients receiving nonsurgical therapy (mean LOS = 3.05), although small numbers in each group resulted in failure to reach statistical distinction ($P = 0.06$, Table VIII). We expect that with larger patient groups, the LOS presented in this pilot study should confirm that surgical treatment of prostatic obstruction will remain as the "gold standard" treatment for men so afflicted.

TABLE VII. Correlations of LOS, IPSS, Subjective Post-Treatment Response and Age With LOS Minus Subjective Treatment Response

	LOS	LOS-Subj	IPSS	Subj	Age
LOS	1.0				
LOS-Subj	0.71**	1.0			
IPSS	0.65**	0.84**	1.0		
Subj	0.75**	0.52**	0.48**	1.0	
Age	0.27*	0.24*	0.10	0.26*	1.0

LOS, LUTS outcome score; LOS-Subj, LUTS outcome score minus subjective patient treatment assessment response; IPSS, international prostate symptom score; Subj, subjective patient treatment assessment response; Age, no. years.
*Correlation is significant at the 0.05 level.
**Correlation is significant at the 0.01 level.

TABLE VIII. Comparisons of LOS Among Surgical and Nonsurgical Cured Patients vs. Combined Surgical/ Nonsurgical Improved + Failed Groups

	N	Mean LOS, std deviation	*P*-value
Surgical cured	13	1.87 ± 0.99	0.06
Non-surgical cured	10	3.05 ± 1.81	
Surgical cured	13	1.87 ± 0.99	<0.001
Surgical improved + failed	17	6.06 ± 3.49	
Non-surgical cured	10	3.05 ± 1.81	<0.001
Non-surgical improved + failed	37	8.12 ± 3.61	

Despite its appeal, there are several shortcomings inherent to the LOS. It is much more difficult to administer than the IPSS since it demands much more patient cooperation—voiding diaries, uroflow and PVR's. Further, although the cutoffs for cure improve/fail were agreed upon by an expert panel, they are, nevertheless somewhat arbitrary. For example, a patient who feels that he is cured would be considered only improved if his MVV was 249 ml and his uroflow 14 ml/sec. Does a patient need to be normal to be cured?

CONCLUSIONS

The LOS depicted herein was developed to in response to the known shortcomings of the IPSS. We have demonstrated the validity and internal reliability of the subjective patient self-assessment in comparison with other conventional objective and semisubjective parameters of voiding dysfunction. Future studies are projected to bring refinements to the type and weighting of individual LOS components (perhaps adding urodynamic measures of detrusor over- or under-activity as well as obstruction) in order to enhance its usefulness as an outcomes tool.

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