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Performance of the American Urological Association Symptom Index With and Without an Additional Urge Incontinence Item

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Abstract

Purpose—To examine the value of adding an urge incontinence question to the AUA Symptom Index (AUASI) among men in the Complementary and Alternative Medicine for Urological Symptoms (CAMUS) trial.

Materials and Methods—CAMUS is a randomized trial of Saw palmetto fruit extract versus placebo among men ≥ 45 years old with an AUASI score ≥ 8 and ≤ 24 . Baseline measurements included the AUASI, a question about urge incontinence (UI), the International Prostate Symptom Score Quality of Life (IPSS QOL) question, and the BPH Impact Index (BII). We correlated the items and scales, and examined whether adding the UI question resulted in better prediction of disease-specific health status.

Results—Mean age of the 369 men in CAMUS was 61 and mean baseline AUASI score was 14.6. UI was reported infrequently; about 82% of respondents answered the question “not at all” or “less than 1 time in 5.” UI was significantly correlated with all other AUASI items except for weak stream; the strongest correlation was to urgency ($R=0.51$, $P<.0001$). The correlation between AUASI and the AUASI+UI was 0.98 ($P<0.0001$). In a logistic regression predicting IPSS QOL, adding UI to the AUASI slightly increased discriminating ability (c statistic increased from 0.77 to 0.78, $P<0.0001$). Similarly, in a linear regression predicting BII scores, adding UI to the AUASI slightly increased predictive ability (R^2 statistic increased from 0.22 to 0.26, $P<0.0001$).

Conclusion—Based on our analysis in the CAMUS population, the value of adding a UI question to the AUASI in terms of predicting bother seemed small at best.

Keywords

Prostatic hyperplasia; urinary incontinence, urge; psychometrics; IPSS

Introduction

The American Urological Association Symptom Index (AUASI) for quantifying lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) was first published in 1992.¹ Subsequently, the seven item scale and a one-item bother question, scored separately, became known as the International Prostate Symptom Score (IPSS).^{2,3}

Since its introduction almost twenty years ago, the AUASI/IPSS has been widely used in both clinical practice and clinical research. Use of the index in clinical practice is recommended by both American and international clinical practice guidelines.^{4,5} The index has been translated and linguistically validated in 56 different languages, and is commonly used for LUTS/BPH research. An ISI Web of Knowledge (Thomson Reuters, NY, NY) search performed on March 24, 2010 identified 1192 citations to the original 1992 AUASI validation paper in the subsequent published scientific literature from authors in 49 countries.

Despite its widespread acceptance the performance of the index has been criticized. Chief among concerns has been that the index is not specific for LUTS attributable to BPH.⁶ Thus, the index cannot be used by itself for diagnosis, but that was never an intended use as emphasized by the original validation paper.

Another longstanding criticism has been that the AUASI does not include an urge incontinence item, which would also balance the number of filling and voiding items in the index.⁷⁻¹¹ While the original developers considered incontinence a separate domain of LUTS urge incontinence due to secondary detrusor instability can certainly occur among men with bladder outlet obstruction due to BPH.

The purpose of this study was to examine the value, especially in terms of predicting symptom-related bother, of adding an urge incontinence question to the AUASI among men enrolled in the Complementary and Alternative Medicine for Urological Symptoms (CAMUS) trial.

Materials and Methods

CAMUS (ClinicalTrials.gov Identifier No. NCT00603304) is an NIH-funded, prospective randomized trial of escalating doses of a botanical product, Saw palmetto fruit extract (*Serenoa repens* (W.Bartram) Small), versus placebo; with change in the AUASI from baseline to 72 weeks as the primary outcome measure. Men were eligible for CAMUS if they were at least 45 years of age, had a peak urinary flow rate at least 4 ml/sec with a voided volume of at least 125 ml, had an AUA symptom score ≥ 8 and ≤ 24 at two screening visits, and voluntarily signed informed consent. Subjects were recruited at 11 clinical centers around the United States and Canada (see Appendix); the study was approved by the institutional review boards at these centers as well as the Data Coordinating Center. Enrollment began on June 5, 2008 and was completed on April 17, 2009.

CAMUS baseline measurements were performed on subjects during two screening visits (for enrolled subjects, the second screening visit was considered the baseline visit), and included the AUASI and a question about urge incontinence (UI) in the same format as the other AUASI items:

“Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?”

Possible responses in six ordered categories were also in the AUASI format, from “Not at all” to “Almost always.”

The baseline visit questionnaires also included the IPSS “bother” item (IPSS QOL)³ and the BPH Impact Index (BII), a validated four-item scale also addressing bother due to LUTS.¹² The IPSS QOL item has a response frame with seven ordered categories from “delighted” to “terrible.” The four items in the BPH Impact Index are scored by addition, yielding a scale range of 0-13, with higher scores indicating greater bother.

All questionnaires were self-administered, and were available in English and Spanish depending on subject preference. Only data from the first screening and baseline visits were used in the analyses in this paper.

Analytic methods to address the psychometric properties of the items and scales included descriptive statistics, simple Spearman correlations, calculation of test-retest reliabilities (comparing the screening and baseline values), and calculation of internal consistency reliabilities of scales. We used logistic regression with the dichotomized IPSS QOL (≤ 2 , mostly satisfied or better; or > 2 , mixed-about equally satisfied and dissatisfied or worse) as the dependent variable (given its skewed distribution) and various symptom items and scales as independent variables. Bootstrapping was used test for differences in c statistics for these models. We repeated these analyses using linear regression with the BPH Impact Index score (as scores were closer to a normal distribution) as the dependent variable. Finally, we conducted an exploratory common factor analysis of the AUASI+UI scale with eight items including the UI question, using the Varimax rotation method.¹³ This statistical method is a data reduction and summarization technique that seeks to define underlying constructs (or “factors”) among a set of measured variables; for example, the AUASI has been examined by factor analysis to define underlying “filling” and “voiding” constructs.¹⁴ All analyses were conducted in the SAS system (SAS Institute, Cary, NC).

Results

The mean age of the 369 men enrolled and randomized in CAMUS was 61 years (range 45-89). At the baseline visit, the mean AUASI score was 14.6 (range 8-24), the mean IPSS QOL score was 3.2 (range 0-6), the mean BII score was 3.6 (range 0-12), the mean peak uroflow rate was 14.9 mL/sec (range 4-51), the mean prostate size estimated by digital rectal examination was 34.4 gm (range 10-95), and the mean prostate specific antigen level was 2.0 ng/dL (range 0.1-9.8).

The distribution of responses to the UI item at baseline appears in Table 1. The distribution of responses for this item was skewed toward lower frequencies than the other seven items in the AUASI. For example, while about 46% of respondents answered “not at all” on the UI item, the percentage of “not at all” respondents for the other AUASI items varied from 2% (frequency item) to 30% (hesitancy item).

Test-retest correlations between the first screening and baseline visits (mean time interval 13.0 days, range 2-49 days) for the seven AUASI items ranged from 0.58 (incomplete emptying item) to 0.72 (Nocturia). The UI item had a test-retest correlation of 0.80, at least as good as the other items.

The correlation of the UI item to the seven-item AUASI was 0.31 ($P < 0.0001$). Table 2 provides a correlation matrix of the seven items in the AUASI and the UI item. The UI item was significantly correlated with all other AUASI items except for the weak stream item and incomplete emptying. The strongest correlation, not surprisingly, was to the urgency item ($R = 0.51$). Table 3 provides a cross tabulation of responses for the urgency and urge incontinence items. Among 143 men with no (“none”) or little (“less than 1 time in 5”) urgency, 6 (4.2%) had more than a little urge incontinence; among 156 men with moderate urgency (“less than half the time” or “about half the time”), 26 (16.7%) had more than a

little urge incontinence; and among 70 men with severe urgency (“more than half the time” or “almost always”), 34 (48.6%) had more than a little urge incontinence. Moreover, only 14/369 (3.8%) men responded that their frequency of urge incontinence was higher than their frequency of urgency (Table 3).

At baseline, the internal consistency reliability of the seven-item AUASI as measured by the Cronbach's alpha statistic was 0.56. Adding the UI item to the AUASI to form an eight-item scale resulted in a Cronbach's alpha of 0.61. Table 4 provides a correlation matrix including the seven-item AUASI scale, the eight-item scale with the AUASI items and the UI item, the single item QOL from the IPSS (IPSS QOL), and the BPH Impact Index (BII). The correlation coefficient between the seven-item AUASI and the AUASI+UI is 0.98 ($P<0.0001$), suggesting these two scales provide essentially the same information.

The UI item was significantly correlated with both the IPSS QOL item (Spearman correlation coefficient 0.25, $P<0.0001$) and the BII scale (Spearman correlation coefficient 0.35, $P<0.0001$). In the logistic regression model with dichotomized IPSS QOL as the dependent variable, adding UI to the AUASI alone slightly increased the discriminating ability of the model as evidenced by an increase in the model's c statistic from 0.77 to 0.78. Bootstrapping 1000 samples indicated that this difference, while small, was statistically significant ($P<0.0001$). Similarly, in the linear regression model with continuous BII scores as the dependent variable, adding UI to the AUASI alone increased the model's predictive ability as evidenced by an increase in the model's R^2 statistic from 0.22 to 0.26 ($P<0.0001$).

Finally, in the factor analysis of the eight-item AUASI+UI, a three factor solution emerged, with Factor 1 including incomplete emptying, intermittency, weak stream, and hesitancy (Cronbach's alpha = 0.62), Factor 2 including urgency and urge incontinence (Cronbach's alpha = 0.67), and Factor 3 including incomplete emptying (which loaded on Factor 1 as well) and frequency (Cronbach's alpha = 0.53). Nocturia did not load on any of the three factors.

Discussion

Among men with LUTS attributed to BPH enrolled in a clinical trial of phytotherapy, urge incontinence was less common than the other items in the AUASI, with about 46% of men reporting the symptom not at all, and about 36% less than one time in five. The correlation coefficient between the standard seven-item AUASI and an eight-item version adding the UI item was 0.98, suggesting the two scales are measuring almost the same construct. This high correlation is not only the result of the overlap of seven of the items, but also to a fairly strong correlation between responses on the UI item and the urgency item. This finding is not surprisingly, given that urge incontinence occurs more frequently among men with more severe urgency, and the degree of urgency is captured in the standard seven-item AUASI.

On the other hand, the fact that a symptom doesn't happen very often doesn't mean it isn't bothersome when it does. The addition of the UI item to the AUASI resulted in small increments in the ability to predict men's global assessments of the bother of their lower urinary tract symptoms, whether assessed using the IPSS QOL item or the BPH Impact Index. However, the improvements in prediction are so small that while statistically significant, they are of dubious clinical significance.

An incidental finding in this study was that the internal consistency reliability of the standard seven-item AUASI was lower than in previous studies, with a Cronbach's alpha statistic of 0.56.^{1,14-16} Moreover, in contrast to other analyses, the nocturia item correlated significantly, albeit weakly, only with the frequency item, and not with any of the other items. For example, in the original prospective revalidation of the AUASI, the Cronbach's

alpha for the scale was 0.92.¹ In that study, correlation coefficients between the nocturia item and the other six items ranged from 0.24-0.49. One reason for these discrepancies is the restricted range of baseline AUASI scores from 8-24 imposed by the entry criteria for CAMUS.

Our examination of the value of adding a UI item to the IPSS has a limitation. The UI question was derived from previous questions addressing urge incontinence, including the urge incontinence question from the ICSmaleIS,¹⁶ but it was not subjected to cognitive interviews or other processes to ensure men clearly understood what the question was asking. Nevertheless, the high test-retest reliability and fairly strong correlation with the well-validated urgency item in the AUASI indicate that the item was well understood and provide considerable evidence of its reliability and validity. In addition,, the CAMUS population may be unique in some way so that the findings in this study are not be generalizable; as a result, the value of adding the UI item should be examined in other populations of men with LUTS attributed to BPH.

Conclusions

Based on our analysis in the CAMUS population, the value of adding an eighth item on UI to the AUASI seems small at best, too small to consider changing a scale that is so widely used and interpreted in its current form.

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Table 1

Distribution of responses to the Urinary Incontinence item among CAMUS subjects at baseline.

Response	N	%
Not at all	169	45.8%
Less than 1 time in 5	134	36.3%
Less than half the time	36	9.8%
About half the time	19	5.2%
More than half the time	9	2.4%
Almost always	2	0.5%
Total	369	100%

Table 2
Spearman correlation coefficients of AUASI items and urge incontinence (UI) item (N=368)

	Emptying	Frequency	Intermittency	Urgency	Weak Stream	Hesitancy	Nocturia	UI
Emptying	1.0							
Frequency	0.37*	1.0						
Intermittency	0.39*	0.22*	1.0					
Urgency	0.12*	0.38*	0.14*	1.0				
Weak Stream	0.19*	-0.01	0.35*	0.03	1.0			
Hesitancy	0.23*	0.04	0.28*	0.08	0.34*	1.0		
Nocturia	0.08	0.16*	-0.01	0.06	-0.10	0.04	1.0	
UI	0.10	0.21*	0.11*	0.51*	-0.01	0.16*	0.12*	1.0

* items are significant at $P<0.05$.

Table 3

Cross tabulation of individual participants' responses for the urgency item and the urge incontinence item.

	Urge Incontinence					
	None	<1/5	<1/2	Half	>1/2	Always
Urgency						Total
None	39	5	0	0	0	44
<1/5	65	28	4	1	1	99
<1/2	33	45	10	0	2	90
Half	22	30	7	6	1	66
>1/2	9	19	12	11	4	55
Always	1	7	3	1	1	15
Total	169	134	36	19	9	369

Table 4

Spearman correlation coefficients of the AUASI, the AUASI with the UI item added (AUASI+UI), the single item QOL from the IPSS, and the BPH Impact Index (BII). (Ns vary from 367 to 369 due to item nonresponse). All correlations are significant at $P < 0.0001$. ADD UI.

	AUASI	AUASI+UI	IPSS QOL	BII
AUASI	1.0			
AUASI+UI	0.98	1.0		
IPSS QOL	0.46	0.48	1.0	
BII	0.46	0.48	0.52	1.0