

Assessing Health Status in Older Men with Lower Urinary Tract Symptoms

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How common are moderate to severe LUTS in men who visit VA primary care clinics, and are these symptoms associated with declining health status? These investigators conducted a prospective, longitudinal study to find some answers.

In 2000, men made 4.4 million visits to physicians' offices for a primary diagnosis of benign prostatic hyperplasia (BPH) or lower urinary tract symptoms (LUTS)—and an additional 3.4 million visits for BPH or LUTS as a secondary diagnosis.¹ The incidence of LUTS associated with BPH increases with age, and most elderly men experience them.² These obstructive and irritative symptoms are bothersome, and cross-sectional studies in many countries consistently show a correlation between increased LUTS and decreased quality of life.³⁻¹⁰ Furthermore, BPH accounts for significant health care expenditures, with direct and indirect costs to the private sector related to BPH treatment estimated at \$3.9 billion in 1999.¹¹ And this estimate is likely low, since it doesn't take into account costs associated with LUTS that go untreated or undertreated because patients mistakenly attribute their symptoms to the normal aging process and do not discuss them with their primary care provider.

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Despite the cross-sectional studies, primarily from overseas, that have shown a correlation between LUTS and health status,³⁻⁸ we could find no published longitudinal studies examining this association. In addition, while most men with LUTS receive their initial diagnosis and treatment from primary care providers, few studies have directly assessed LUTS severity, health status, and treatment utilization in men who attend primary care clinics.

We set out, therefore, to learn more about the prevalence and severity of LUTS in the population of older men who typically visit VHA facilities and to estimate the association of LUTS with both current and future health status in this population. Estimates of disease burden obtained from populations, like this one, that are likely to be seen in primary care clinics can provide medical decision makers with more accurate and relevant information for determining resource priorities. Moreover, a better understanding of the significance of LUTS and health status should give primary care providers the information they need to start a dialogue with their patients about the management of bothersome urinary symptoms.

STUDY DESIGN

We drew our study sample from a cohort of community dwelling male veterans aged 50 and older who were eligible for prostate cancer screening

and had a scheduled primary care appointment between April and June 2001 at one of four participating VHA facilities in the Upper Midwest (the Minneapolis VA Medical Center, Minneapolis, MN; St. Cloud VA Medical Center, St. Cloud, MN; Fargo VA Medical Center, Fargo, ND; and VA Black Hills Health Care System, Fort Meade and Hot Springs, SD). These men were participants in the VA's Prostate Cancer Screening Education (PROCASE) trial, a randomized, controlled study designed to assess the effect of video and pamphlet interventions on patients' knowledge about prostate cancer screening, decision making participation, preferences, and behaviors.

Detailed methods of the PROCASE trial have been published previously.^{12,13} Briefly, using a computer-generated algorithm, researchers randomly assigned a sample of 1,152 eligible veterans to one of three intervention groups: mailed pamphlet, mailed video, or usual care (control group). About one week after the targeted primary care appointment, all study subjects were asked to complete a baseline telephone interview. Included in this interview were questions to determine subjects' American Urological Association symptom index (AUA-SI) score,¹⁴⁻¹⁶ questions related to health status, and demographic characteristics. This survey was repeated one year later. The PROCASE study protocol was reviewed

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Introduction*

Many men over the age of 50 have problems with urination. The next questions are about problems you may or may not have had with urination in the last month or so.

Questions and scoring

For questions 1 through 6, the interviewer read the question and then asked: “*Would you say not at all, less than one time in five, less than half the time, about half the time, more than half the time, or almost always.*” Responses were scored as follows: “not at all” = 0 points, “less than one time in five” = 1 point, “less than half the time” = 2 points, “about half the time” = 3 points, “more than half the time” = 4 points, and “almost always” = 5 points. If the respondent said that the questions did not apply because he uses a catheter, the interviewer coded the responses as “c” and skipped to the end of the interview. Any response of “I don’t know” was coded as “d” and a refusal to answer the question was coded as “r.”

- 1. During the last month or so, how often have you had a sensation after you finished urinating of not emptying your bladder completely?*
- 2. During the last month or so, how often have you had to urinate again less than two hours after you finished urinating?*
- 3. During the last month or so, how often have you found you stopped and started again several times during urination?*
- 4. During the last month or so, how often have you found it difficult to postpone urination?*
- 5. During the last month or so, how often have you had a weak urinary stream?*
- 6. During the last month or so, how often have you had to push or strain to begin urination?*

For question 7, the interviewer read the question, allowed the participant to respond in an open-ended fashion, and then recorded whether the participant responded, refused to answer, or said that he did not know. If the participant gave any response, the interviewer recorded it verbatim. These open-ended responses were later recoded and scored as follows: none = 0 points, one time = 1 point, two times = 2 points, three times = 3 points, four times = 4 points, five times or more = 5 points, and no response = unable to code (u).

- 7. During the last month or so, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?*

The scores from questions 1 through 7 were summed and classified as follows: 0 points = no symptoms, 1–7 points = mild symptoms, 8–19 points = moderate symptoms, and 20–35 points = severe symptoms.

Figure. Modified American Urological Association symptom index used in the telephone interview developed for the Prostate Cancer Screening Education (PROCASE) trial. *Italicized text was read verbatim to participants during the telephone interview.

and approved by the Institutional Review Boards at each of the four participating VHA facilities and the University of Minnesota.

The PROCASE study researchers slightly modified the self-administered AUA-SI questionnaire for telephone administration (Figure). (Evidence suggests that telephone-administered questionnaires may produce somewhat lower AUA-SI scores than self-administered questionnaires.¹⁷) Based on established

schema, these investigators totaled individual AUA-SI question scores and categorized them as follows: 0 points, no symptoms; 1 to 7 points, mild symptoms; 8 to 19 points, moderate symptoms; and 20 to 35 points, severe symptoms.^{3,14,15} Research shows that, as the LUTS symptom severity score rises, so does the patient’s perception of the degree to which these symptoms are “bothersome.”^{3,7,14}

For the PROCASE trial, participants were stratified by age (two

groups of 50 through 69 years and 70 years or older), whether or not they received a prostate specific antigen (PSA) test in the past year, and which of the four VHA facilities they attended. PSA testing records (at baseline and one year later) were obtained through VHA utilization databases. The researchers also collected data on comorbid conditions and medication use from the nationally centralized VHA outpatient and pharmacy databases. Details regarding these

databases have been published previously.^{18–20} Comorbid conditions included asthma, chronic obstructive pulmonary disease (COPD), congestive heart failure, coronary artery disease, depression, diabetes, and substance abuse. Pharmacy data collected pertained to patients' use of alpha-blockers (the predominate class of drugs prescribed for BPH within the VHA) and diuretics (which could exacerbate LUTS).

The current analysis is based on participants' responses to the baseline telephone survey and to the follow-up survey, when available. We grouped participants into three AUA-SI categories—mild or no LUTS, moderate LUTS, and severe LUTS—according to their baseline scores and tabulated descriptive statistics of cohort characteristics. The categories of no LUTS and mild LUTS were grouped together because so few men reported having no symptoms. When assessing the statistical significance of differences in characteristics between the AUA-SI categories, we used the analysis of variance F test to compare mean age and Pearson's chi-square test to compare percentages of participants with selected attributes (such as the various comorbid conditions).

We determined the association of LUTS with reported health status at baseline (classified as "fair to poor" or "good to excellent") and one year after study enrollment relative to baseline (classified as "much or somewhat better," "about the same," or "much or somewhat worse"), adjusting for confounding covariates according to two models: a basic model and a full model. For both analyses, the basic model took into account the variables used in the PROCASE protocol to select the stratified random sample of participants (age, PSA testing records, and VHA facility) and the educational intervention each

participant received. For the one-year follow-up analysis, the basic model also adjusted for baseline health status. The full model took into account the basic model adjustments plus the variables of education level, race, presence of comorbid conditions, and medication use.

Because the outcomes of fair to poor health status and one-year decline in health status do not satisfy the rare disease criterion for which odds ratios approximate relative risk ratios, we calculated estimated relative risk ratios directly, using published modified Poisson regression estimate methods available in SAS PROC GENMOD (SAS Institute, Inc., Cary, NC).²¹ Estimated relative risk ratios are appropriate for this study's design and preferable to odds ratios.²² All analyses were performed using SAS version 9.1 (SAS Institute, Inc., Cary, NC).

LUTS SEVERITY LINKED TO HEALTH STATUS

Of the original PROCASE sample of 1,152 participants, 259 were excluded for the following reasons: eight were found to be deceased, five were female, 29 were diagnosed with prostate cancer, and 217 were lost to follow-up before the baseline telephone survey could be administered. A total of 893 men, therefore, completed the baseline survey, for an 80.5% response rate (among eligible men only). Of these respondents, 792 (89%) provided sufficient information to determine health status and calculate the AUA-SI score. Among this sample, 604 patients (76%) also completed the one-year follow-up interview and AUA-SI survey.

The men in our study sample were predominantly elderly and white and had at least a high school education (Table 1). Current health status was fair to poor in 37%, which probably

reflects the known presence of serious chronic comorbid conditions, including coronary artery disease (31%), diabetes (25%), COPD (21%), and depression (15%). About 18% of the men used alpha-blockers.

Of the 792 men who completed the baseline survey, nearly half (387, or 49%) indicated directly or indirectly that they experienced moderate or severe LUTS. In addition to the 342 men (43%) whose baseline AUA-SI scores reflected moderate or severe LUTS, this group includes another 45 men (6%) who, despite reporting mild or no symptoms during the interview, said that they had been using alpha-blockers, which may have mitigated the symptoms they would otherwise have experienced.

Compared with men who reported that their LUTS had improved or remained the same over the year prior to the baseline survey, men who said their LUTS had worsened were older, had generally poorer overall health, had experienced greater declines in overall health during the year prior to the baseline survey, were more likely to have several comorbid conditions, and used more alpha-blockers. Not surprisingly, the percentage of men who used alpha-blockers within the year prior to baseline was substantially higher among men with moderate or severe LUTS (27% and 32%, respectively) than among men with mild or no LUTS (10%). Among the men who reported moderate or severe LUTS at baseline, the use of alpha-blockers increased with age: 24% of these men under the age of 70 reported alpha-blocker use compared with 32% of those aged 70 or older. Diuretic use, a possible confounder of LUTS, did not differ significantly between LUTS severity groups.

Severity of LUTS correlated with self-reported health status at baseline for the 775 men for whom complete

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Table 1. Characteristics of respondents to the baseline telephone survey, by lower urinary tract symptom (LUTS) category

Characteristic	Total sample (n = 792)	LUTS category (n,%)			P value*
		Mild/no (n = 450, 57%)	Moderate (n = 271, 34%)	Severe (n = 71, 9%)	
Demographic characteristics					
Mean age ± SD (years)	68 ± 9	67 ± 9	69 ± 9	70 ± 10	.003
Married	70%	71%	71%	65%	.588
Education of high school or higher	78%	79%	78%	75%	.713
Nonwhite race/ethnicity	5%	5%	4%	4%	.717
Comorbid conditions†					
Asthma	4%	4%	4%	6%	.683
Chronic obstructive pulmonary disease	21%	21%	19%	32%	.056
Congestive heart failure	10%	7%	10%	23%	< .001
Coronary artery disease	31%	29%	33%	38%	.183
Depression	15%	12%	17%	26%	.009
Diabetes	25%	23%	26%	32%	.245
Substance abuse	6%	6%	7%	6%	.959
Two or more comorbid conditions	29%	26%	30%	45%	.013
Reported health status					
Current status					< .001
Excellent/very good	26%	29%	24%	17%	
Good	37%	41%	32%	24%	
Fair	26%	20%	32%	37%	
Poor	11%	9%	12%	23%	
Current status compared to one year prior to baseline					.049
Much/somewhat better	19%	20%	20%	11%	
About the same	65%	65%	61%	60%	
Much/somewhat worse	18%	15%	20%	29%	
Medication use					
Alpha-blocker use in the past year	18%	10%	27%	32%	< .001
Diuretic use in the past year	29%	28%	28%	37%	.322

*P values were determined using the following: the analysis of variance F-test for age and Pearson's chi-square test for the remaining variables. †Participants were determined to have a comorbid condition if the VA outpatient database indicated a diagnosis of the condition within the past two years.

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Table 2. Participants self-reported baseline health status, by lower urinary tract symptom (LUTS) category

Parameter	LUTS category			Total (n = 775)
	Mild/no (n = 438)	Moderate (n = 268)	Severe (n = 69)	
No. of participants reporting health status categories				
Fair to poor	128	117	41	286
Good to excellent	310	151	28	489
Risk ratio for fair to poor health status (95% CI)*				
Basic model [†]	–	1.52 (1.24, 1.85)	2.02 (1.58, 2.57)	–
Full model [‡]	–	1.46 (1.20, 1.77)	1.64 (1.26, 2.14)	–

*Compared to mild/no LUTS group. [†]Adjusted for Prostate Cancer Screening Education (PROCASE) trial intervention group and PROCASE study design stratification variables (prostate-specific antigen testing, age group, and VHA facility). [‡]Adjusted for basic model variables plus education level; race; presence of comorbid asthma, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, depression, substance abuse, or diabetes; and use of alpha-blockers or diuretics.

data were obtained for all the covariates in the full multivariable regression model (Table 2). In the basic model analysis, men with moderate LUTS and severe LUTS were 1.52 and 2.02 times more likely, respectively, than men with mild or no LUTS to report fair or poor health. After the full model adjustments, the relative risk ratios remained high: at 1.46 and 1.64, respectively.

Of the 604 participants who completed the follow-up survey one year after baseline, 589 had complete data for each of the variables in the full multivariable regression model. One quarter of the men who reported moderate or severe LUTS at baseline reported that their health had gotten much worse or somewhat worse one year later. The relative risk ratios for a worsening of health status since baseline were 1.42 and 1.86 in the basic model and 1.57 and 1.93 in the full model analyses for men with moderate and severe LUTS, respectively (Table 3). Despite the evidence of declining health status during the year of follow-up, the distribution of

LUTS between the baseline and one-year follow-up surveys changed little, both in terms of the mean AUA-SI scores and the percentage of individuals classified with mild, moderate, or severe LUTS.

A POPULATION IN NEED

This study contributes to earlier research on LUTS by providing prospective data on the relationship between LUTS and declining health status. Although the investigation was not designed to estimate the prevalence of LUTS within the VHA system, it provides a basis for making reasonable estimates of the association between LUTS and current or future health status.

Our results demonstrate that LUTS, self-reported as moderate to severe, are common and burdensome in older men who visit VA clinics and are associated with worsening health over a one-year period. While the prevalence of LUTS may vary somewhat between patient populations, health systems, and countries, earlier research supports an association

between increased LUTS and poorer health status that persists despite cross-cultural differences.⁶ Compared with men who reported mild or no symptoms, the men in our sample who reported moderate or severe LUTS at baseline experienced both poorer baseline health status and a greater risk of worsening health status over the following year, even after adjusting for multiple possible confounding covariates.

Although 43% of respondents reported moderate or severe LUTS at baseline, only 28% of them had used alpha-blockers in the preceding year. Among men younger than 70 who reported moderate or severe LUTS, this percentage was even lower (24%). These findings suggest the existence of a significant population of generally healthy men in whom LUTS go undetected or undertreated in the primary care setting. Since men with moderate or severe LUTS typically have clinically significant BPH with bothersome symptoms, these individuals are likely to benefit from such intervention.²³ Furthermore, the

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Table 3. Participants self-reported change in health status between baseline and one-year follow-up, by lower urinary tract symptom (LUTS) category

Parameter	LUTS category			Total (n = 589)
	Mild/no (n = 335)	Moderate (n = 204)	Severe (n = 50)	
No. of participants reporting change in health status categories				
Worse	48	46	16	110
Same or better	287	158	34	479
Risk ratio for worse health status (95% CI)*				
Basic model [†]	–	1.42 (0.99, 2.04)	1.86 (1.17, 2.95)	–
Full model [‡]	–	1.57 (1.09, 2.25)	1.93 (1.20, 3.10)	–

*Compared to mild/no LUTS group. [†]Adjusted for dichotomous self-reported health status at the baseline survey, Prostate Cancer Screening Education (PROCASE) trial intervention group, and PROCASE study design stratification variables (prostate-specific antigen testing, age group, and VHA facility). [‡]Adjusted for basic model variables plus education level; race; presence of comorbid asthma, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, depression, substance abuse, or diabetes; and use of alpha-blockers or diuretics.

fact that a number of patients taking alpha-blockers still reported moderate or severe LUTS suggests that the treatment of LUTS with alpha-blockers alone may be inadequate for some patients.

STUDY LIMITATIONS

Although we collected data about LUTS and health status using validated self-report tools, we did not obtain detailed measurements of LUTS-related medical and surgical treatments nor did we perform intensive measurements of LUTS and health-related quality of life. These limitations in measurement precision likely contributed to some misclassification, but any misclassification most likely would have caused our estimates to be overly conservative.

Another limitation, common to most prospective studies, was that some study subjects were lost to follow-up and therefore could not be included in the prospective analyses. If baseline LUTS are associated with declining health, and men who are lost to follow-up are experiencing

greater declines in health than those for whom follow-up data are available, our estimates regarding worsening health also would err on the conservative side.

Participants in this study were part of a randomized, controlled trial, but it is unlikely that the minimal educational intervention they received resulted in a biased sample or affected responses related to the association between LUTS and health status. The intervention was not designed to have an impact on either LUTS or health status, and all analytical models controlled for the allocation of the educational material. Furthermore, tests of effect modification by intervention group revealed no differences.

Finally, both alpha-blockers and 5-alpha-reductase inhibitors are considered first-line pharmacologic treatments for BPH, but we did not assess the use of 5-alpha-reductase inhibitors in our study. It's possible that these medications may improve symptoms or reduce BPH progression in certain groups of men. In practice, however, clinicians pre-

scribe alpha-blockers for BPH much more frequently than they prescribe 5-alpha-reductase inhibitors,^{23,24} and AUA Gallup poll surveys show that the vast majority of urologists recommend alpha-blockers for men with moderate urinary symptoms.²⁵ Furthermore, because of national formulary policies that restrict the use of 5-alpha-reductase inhibitors, alpha-blockers are the primary pharmacologic treatment option for BPH at VA medical centers. For these reasons, it is unlikely that we substantially underestimated the medical treatment of BPH in our participants by not assessing the use of 5-alpha-reductase inhibitors. Data on additional interventions, such as surgeries or minimally invasive procedures, were not available, and we were not able to determine if participants had been offered but declined specific LUTS therapies.

A CALL TO ACTION

Our findings that moderate to severe LUTS are common in older men attending primary care clinics and are

associated with both poorer baseline health status and greater declines in health status, compared with men with mild or no LUTS, support the idea that LUTS contribute to a lower quality of life. Fewer than 60% of men in our sample who reported moderate or severe LUTS were receiving pharmacologic treatment. Increased efforts by primary care providers to identify and effectively treat LUTS in older men could improve both bothersome symptoms and overall quality of life. ●

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