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Treatment Status and Progression or Regression of Lower Urinary Tract Symptoms among Adults in a General Population Sample

Nancy N. Maserejian, ScD, Shan Chen, MS, Gretchen R. Chiu, MS, Andre B. Araujo, PhD, Varant Kupelian, PhD, Susan A. Hall, PhD, and John B. McKinlay, PhD

New England Research Institutes, 9 Galen St. Watertown, MA 02472, USA

Abstract

Purpose: To report progression and regression of lower urinary tract symptoms (LUTS) in a population-based cohort by race/ethnicity, sex, age and LUTS medication use.

Materials and Methods: The Boston Area Community Health Survey enrolled 5,502 participants aged 30-79 years of black, Hispanic, or white race/ethnicity. Five-year follow-up interviews were completed by 4,144 (1,610 men, 2,534 women; conditional response rate of 80%). Population-weighted estimates of LUTS severity were assessed using American Urological Association Symptom Index (AUASI) and analyzed using multivariable models.

Results: Symptom progression (AUASI increase ≥ 3) was reported by 21-33% of participants, and regression (decrease ≥ 3) by 30-44% of participants, most commonly women and Hispanics. Age and higher body mass index (BMI) were associated with progression ($P < 0.01$), but not regression. LUTS medication use at baseline only was associated with improved symptoms scores five years later (multivariable-adjusted OR=3.10, 95% CI 1.28-7.51, compared to non-users), whereas using medication at both baseline and follow-up was associated with similar rates of progression and regression as observed among participants not using LUTS medication at either time point.

Conclusions: LUTS persisted at follow-up for approximately half of the population experiencing symptoms at baseline, including many men and women using LUTS medications. Overall, however, LUTS medication use and surgical treatment appeared beneficial for symptom control at 5-year follow-up. Age and BMI were associated with symptom worsening, and Hispanic ethnicity was associated with greater symptom fluctuation. Clinicians should consider the higher likelihood of LUTS progression for older or heavier patients, and monitor responsiveness to LUTS medication.

Corresponding Author: Nancy Nairi Maserejian, ScD New England Research Institutes, 9 Galen Street, Watertown, MA 02472, USA Tel.: 617.972.3229 nmaserejian@neriscience.com. Requests for reprints should be sent to: NERI, ATTN: Nancy Maserejian, 9 Galen Street, Watertown, MA 02472..

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Keywords

Lower urinary tract symptoms; Voiding dysfunction; Benign prostatic hyperplasia, Urinary bladder, overactive; Epidemiology; Bladder Outlet Obstruction

Introduction

It has been projected that by 2018, 2.3 billion people worldwide will have one or more of the constellation of voiding and storage problems referred to as lower urinary tract symptoms (LUTS).¹ Research consistently shows that patients with LUTS are more likely to have diminished quality of life, depression symptoms, and various chronic health conditions.²⁻⁴ With numerous pharmaceutical therapies available to treat LUTS, such as anticholinergic medications and 5-alpha reductase inhibitors, direct-to-consumer advertising is common.⁵ Such advertising likely results in an increase in patient requests for medications, and physicians' compliance with such requests.⁵⁻⁷ However, studies of regression of LUTS in the general population have prompted attention towards symptom management or watchful waiting, rather than symptom control using pharmaceutical or surgical treatments.^{8, 9} That is, many men with LUTS report regression of symptoms, which counters the prevailing belief that male LUTS – often due to benign prostatic hyperplasia (BPH) or benign prostatic obstruction – is mostly a progressive condition.^{4, 10} Similarly, evidence among women indicates that fluctuations in symptoms over time are to be expected.^{9, 11, 12}

Currently, support for delaying pharmacotherapy for LUTS is weakened by limited previous studies of the natural history of LUTS. The majority of epidemiological and clinical studies focused on urine leakage among women, or were in European populations.^{9, 12-14} Of two recent studies of LUTS progression among U.S. men, one was restricted to men over aged 65 years,¹⁰ and the other included a largely uniform and Caucasian sample of male health professionals.¹⁵ None of the previously published longitudinal studies of LUTS have included both men and women of diverse ages and racial/ethnic backgrounds. Lastly, the extent to which LUTS medication accounted for fluctuations in symptoms over time in previous studies remains uncertain.

The objectives of this report are to (i) describe progression and regression of LUTS in a diverse U.S. population-based sample of men and women with 5-year follow-up, and (ii) test whether changes in LUTS severity were associated with LUTS treatment or fundamental study design factors of sex, age, and race/ethnicity.

Methods

Study Design and Population

The Boston Area Community Health (BACH) Survey is an observational cohort study designed to assess the epidemiology of urologic symptoms in a racially/ethnically diverse population-based sample. Using a stratified 2-stage cluster design, BACH recruited a random sample of 5,502 residents (2,301 men, 3,201 women) aged 30-79 years from three racial/ethnic groups in Boston, MA. Participants completed an in-person interview at baseline (occurring between 2002 and 2005) and approximately 5 years later (2006-2010).

Further details on BACH's study design have been published.¹⁶ All participants provided written informed consent. The study was approved by the New England Research Institutes' Institutional Review Board.

Completed follow-up interviews were obtained for 4,144 individuals (1,610 men; 2,534 women) from the 5,154 eligible, resulting in a conditional response rate of 80.4%. Participants were ineligible for follow-up if they were deceased, incarcerated, on active military duty, or medically incompetent. Loss to follow-up was mostly due to non-contact and more common for Hispanics, >70 y old, and males, but there were no significant differences in LUTS at baseline.

Measurement of Lower Urinary Tract Symptoms

During in-person interviews at baseline and follow-up, LUTS was assessed by the validated English or Spanish versions of the American Urological Symptom Index (AUASI), also referred to as the International Prostate Symptom Score for men.¹⁷ The AUASI was originally developed and validated for benign prostatic hyperplasia in men,¹⁷ but has been validated¹⁸ and repeatedly shown to capture LUTS in women.¹⁹⁻²² Symptom severity is classified as: 1-7 points=mild; 8-20 points=moderate; 20-35 points=severe. Progression and regression of LUTS were examined by change from baseline (i) in the AUASI symptom severity classification, and (ii) by 3+ points for slight progression/regression.²³ Secondary analyses examined the outcome of moderate improvement (a decrease of 5+ points)²³ among those with LUTS (AUASI ≥ 8) at baseline.

LUTS treatment was defined as current use of anticholinergic medications, 5-alpha reductase inhibitors, or any of the following overactive bladder or urinary incontinence medications: oxybutynin chloride (Ditropan[®]), transdermal oxybutynin chloride (Ditropan Transdermal[®]), tolterodine tartrate (Detrol[®]), darifenacin hydrobromide (Enablex[®]); solifenacin succinate (Vesicare[®]); trospium chloride (Sanctura[®]); fesoterodine fumarate (Toviaz[®]); propantheline bromide (Pro-Banthine[®]); hyoscyamine (Levsin[®]).

At both study visits, medication use in the last 4 weeks was collected by recording of medication container labels and self-report with prompts for specific indications. Medication labels and/or responses were coded using the Slone Drug Dictionary,²⁴ which classifies medications using a modification of the American Hospital Formulary Service Pharmacologic-Therapeutic Classification System. LUTS medication was categorized into four groups: (i) both baseline and follow-up, (ii) baseline only, (iii) follow-up only, and (iv) neither time point. Surgical treatment for LUTS was self-reported as ever having surgery for urinary incontinence or surgery on the bladder or prostate.

Statistical Analysis

For analyses of LUTS progression or regression defined as change from baseline AUASI by 3+ points, the analysis included 4,139 participants (1,608 men, 2,531 women) eligible for progression (baseline AUASI < 33), or 2,154 participants (774 men, 1,380 women) eligible for regression (baseline AUASI ≥ 2 points). To account for missing data (<1% of urological data), multiple imputation was performed in IVEware, generating 15 complete datasets, based upon multivariate sequential regression. To account for the multistage sampling

design and obtain population-generalizable estimates, data observations were weighted inversely to their probability of selection at baseline, adjusted for non-response bias at follow-up, and then post-stratified to the Boston census population in 2000.

Progression and regression rates were calculated overall and by sex, 10-year age strata, race/ethnicity, and LUTS treatment medication. Separate multivariable logistic regression models were created for progression and regression to obtain adjusted odds ratio and 95% confidence intervals with the following variables: age, race/ethnicity, body mass index (BMI, kg/m²), heart disease, diabetes, and LUTS medication use. Surgical treatment was analyzed as a secondary variable due to possible inaccuracies in recall of surgical dates. Analyses were conducted in SAS v.9.3 (SAS Institute, Cary, NC) and SUDAAN v.11.0 (Research Triangle Park, NC).

Results

Demographic characteristics at baseline for the 4,144 men and women in the BACH-II analytic sample are presented in Table 1. The mean (SD) time between the baseline and follow-up assessments was 4.8 (0.6) years. Moderate-to-severe LUTS was reported by 20.0% of participants at follow-up, which was slightly greater than the prevalence of 18.8% at baseline. Among individuals using LUTS medication at baseline (4.1%), 51.5% still reported moderate-to-severe symptoms at baseline and 48.5% had no or mild symptoms. Surgical treatment was reported by 4.2% of all participants at follow-up, with 2.9% of women reporting surgery for incontinence and 5.7% of men reporting bladder or prostate surgery.

Progression and Regression

Changes in LUTS severity category (none, mild, moderate, severe) are depicted in Table 2. Of those with moderate symptoms at baseline, approximately half (47-48%) continued to report moderate symptoms at follow-up; improvement to mild symptoms was also common (41%). Most men with severe LUTS at baseline continued to have severe LUTS at follow-up (61.5%). In contrast, only 18.3% of women with severe symptoms at baseline did so at follow-up; improvement to the “moderate” category was most common (60.0%) for all ages except women over 70 years old.

As measured by decrease in AUASI score of 3 or more points (indicating slightly improved symptoms), regression was reported by 30-44% of participants, depending on race/ethnicity and sex (Figure). Participants taking LUTS medication at baseline were most likely to experience regression and least likely to experience progression, with no significant differences by sex ($P_{\text{intx}}=0.5$) or race/ethnicity ($P_{\text{intx}}=0.4$). In the multivariable models (Table 3), individuals using LUTS medications at baseline had 60% lower odds of progression (OR=0.39, 95% CI 0.17, 0.91) and three times the odds of regression (OR=3.10, 95% CI 1.28, 7.51), compared to those who did not use LUTS medication at either time point. In contrast, LUTS medication use at follow-up only was positively associated with having had progression. Surgical treatment had no association with LUTS progression ($P=0.8$), but was associated with 77% higher odds of LUTS regression (multivariable-model-OR=1.77, 95% CI: 1.11-2.82, $P=0.02$). Compared to white participants, Hispanics

had 1.6 times the odds of progression or regression in AUASI scores. Age and baseline BMI were statistically significant predictors of progression, but not regression. Sex was not associated with progression or regression in the multivariable model.

Among participants with moderate-to-severe LUTS at baseline, regression by 5 or more points (indicating moderately improved symptoms) was twice as common in women compared to men, except in the youngest age group. For those aged 30-40 years, women more frequently progressed (22.2% vs. 7.6% men), whereas men's symptoms more frequently regressed (24.9% vs. 46.6% men).

To examine the natural history in untreated individuals, additional analyses excluded 487 individuals who ever received treatment for LUTS by surgery or medication. Results (Table 4) showed that among individuals with none-to-mild symptoms at baseline, regression and progression happened at similar rates (23%-25%). As severity of baseline LUTS increased, regression was more common. When stratified by gender and LUTS subdomain, women with storage symptoms had notably higher rates of LUTS progression compared to men, while women with voiding symptoms had the highest rates of LUTS regression compared to all other subgroups.

Discussion

BACH is the first U.S. population-based observational study designed to examine the natural history of LUTS in a racially/ethnically balanced sample of men and women. Results showed that although the prevalence of LUTS increased from 19% at baseline to 20% at follow-up, the population reporting LUTS changed considerably over time. In fact, 43% of those with moderate-to-severe LUTS at baseline had remission to no or mild LUTS at follow-up. Symptom progression was reported by 21-33% of participants, and regression by 30-44% of participants, most commonly among women and Hispanics. Higher baseline BMI was significantly predictive of LUTS progression, a finding consistent with prior studies.^{9, 25} Participants using LUTS medication at baseline generally had better rates of regression and progression compared to non-users. However, for participants who continued using LUTS medication at follow-up, regression and progression rates were similar to those who had not used LUTS medication at either time point. Thus, results indicate that the natural history of LUTS varies by race/ethnicity, age and sex, yet regardless of these factors, frequent assessments of a patient's symptom changes are important both before and after treatment has been initiated to understand his/her symptom course and future treatment needs.

Although prior longitudinal studies on racial/ethnic differences in LUTS non-specific to incontinence among women are lacking, our results are consistent with studies of LUTS among men. In BACH, white men had the lowest rates for progression of LUTS, which confirms results from the Prostate Cancer Prevention Trial.²⁶ Progression rates among BACH's black men corroborated those of the Flint study; both studies found that 23-24% of black men experienced LUTS progression over 4 or 5 years follow-up, with similar rates of regression (BACH 36%, Flint 30%).²⁷ BACH's Hispanics had the highest rates for both progression and regression, even after accounting for medication use. Language issues are

unlikely to explain this finding, because BACH interviewers were fluently bilingual and used a validated Spanish version of the AUASI when appropriate. A genetic component to LUTS development is plausible,²⁸ but there are no prior studies on racial/ethnic differences in LUTS regression. A speculative explanation is that culture-based differences in perceptions of symptoms may have contributed to greater variations in symptom scores among Hispanic participants, but additional research on this question is necessary.

LUTS medication use at baseline and surgical treatment were associated with improved symptom scores at follow-up. Meanwhile, participants who used LUTS medication at follow-up had higher rates of progression, and lower rates of regression, compared to all other groups. This finding is consistent with BACH's previous report that, at baseline, participants who used LUTS medications concomitantly reported worse symptom scores than did non-users of medication.²⁹ Interestingly, the rates of progression and regression among those who used LUTS medication at both baseline and follow-up were similar to those who were not using LUTS medication at either time point. Although it is uncertain that participants used the medications continually throughout the 5-year follow-up, this finding suggests that for some patients, LUTS medication may not be effective. Thus, repeated assessments of symptom severity and treatment outcomes are important to assess whether treatment is beneficial for a patient.

A limitation of this report is that the 5-year duration between assessments may have missed interim phases of symptom regression, progression, or medication use. Also, the analysis did not account for physician-led watchful waiting or interventions for LUTS treatment other than surgery or medication. Lastly, despite the widespread acceptance of its performance to identify clinically significant LUTS, the AUASI has been criticized for certain limitations. For example, it omits assessment of urinary incontinence, and the item on nocturia generally has weak correlations with other items.^{17, 30} However, it was shown that adding an item on urge incontinence only negligibly altered the performance of the AUASI to predict bother and disease-specific health status.³⁰ Overall, criticisms of the AUASI are outweighed by the benefits of using such a widely used instrument, the interpretation of which is well recognized and understood in its current form.³⁰

Although sex was not a statistically significant predictor in the model for AUASI score 3-point changes, few women with severe symptoms at baseline continued to report them at follow-up, unlike men. However, worsening of existing LUTS was approximately three times as likely for women aged <40 years compared to men, and more common for storage symptom subtypes. This gender difference was not apparent in older ages, as women experienced more regression, while men experienced more progression. Symptom fluctuation among women from mid to late adulthood may indicate that LUTS episodes are affected by recent reproductive experiences (e.g., childbirth) or related changes in the hormonal milieu.

Regarding the natural history of LUTS in untreated individuals, approximately one in five participants with untreated moderate-to-severe LUTS had symptoms worsen at 5-year follow-up, while slightly over half reported at least mild improvement (decrease by 3 points). Among untreated individuals, LUTS progression was most common for women

with storage symptoms, and men or women with nocturia. In contrast, untreated voiding symptoms often improved, at least slightly.

In summary, this study showed considerable fluctuation in the presence of LUTS and symptom severity that differed by race/ethnicity, age, and, depending on age, sex. This fluctuation represents a challenge for health care delivery as it introduces a steady flow of new patients to manage. Overall, LUTS medication use appeared to be beneficial for symptom control at 5-year follow-up. However, for many people with LUTS, it actually may be reasonable to delay seeking medical treatment, given the odds that symptoms will improve over time without medication. A key question and challenge is how to efficiently identify which patients are in need of medication for symptom control. In addition to the age, sex and racial/ethnic differences reported here, continued research on the relative contributions of socioeconomic factors, other medication use, diet, and reproductive factors is warranted for better insight on the epidemiology and clinical management of LUTS over time.

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Abbreviations

AUASI	American Urological Association Symptom Index
BACH	Boston Area Community Health
BPH	Benign prostatic hyperplasia
LUTS	Lower urinary tract symptoms

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Figure.

Percentage of BACH-II Participants with Progression or Regression of LUTS (3+ point change in AUASI), by Population Subgroup and LUTS Medication Use.

B=black, H=Hispanic, W=white. BL=baseline, FU=follow-up.

Table 1Characteristics of BACH-II Participants, Overall and by Sex and Presence of LUTS at Baseline^{*}

	Total N=4,144	Sex		LUTS Present at Baseline [†]	
		Male (N=1,610)	Female (N=2,534)	No (N=3,302)	Yes (N=842)
Age (years) mean (SE)	50.3 (0.3)	49.7 (0.4)	50.7 (0.3)	49.4 (0.3)	53.7 (0.4)
Age category, %					
<40 y	24.4	25.0	24.0	27.5	12.3
40-49 y	27.5	29.8	26.0	27.6	27.2
50-59 y	24.7	23.7	25.4	23.4	29.8
60-69 y	16.4	15.2	17.1	15.2	21.0
70+ y	7.0	6.3	7.4	6.3	9.7
Race/ethnicity, %					
Black	32.0	30.2	33.2	31.5	33.9
Hispanic	32.4	30.5	33.5	33.3	28.8
White	35.6	39.3	33.3	35.2	37.2
BMI, mean (SE) kg/m ²	29.9 (0.1)	28.9 (0.2)	30.6 (0.2)	29.5 (0.1)	31.6 (0.3)
LUTS Medication, %					
Both baseline and follow-up	2.5	3.7	1.7	1.5	6.5
Baseline only	1.6	2.0	1.3	1.0	3.8
Follow-up only	4.2	5.5	3.4	2.9	9.3
None	91.7	88.7	93.6	94.6	80.4

* Results are unweighted to represent the true distribution in study participants.

[†] Moderate-to-severe LUTS at baseline, defined as AUASI ≥ 8 points.

Table 2

Change in LUTS Severity Classification between Baseline and Follow-up: Age-adjusted Percentage of Men and Women with LUTS Severity at Follow-up, by LUTS Severity at Baseline*

Males (N=1,610)					Females (N=2,534)				
Follow-up category					Follow-up category				
None	Mild	Moderate	Severe		None	Mild	Moderate	Severe	
Baseline (Prevalence)					Baseline (Prevalence)				
None (18.1)	26.8	69.9	2.8	0.5	None (13.7)	38.9	58.8	1.8	0.5
Mild (62.7)	12.2	77.0	10.3	0.5	Mild (67.4)	11.8	71.9	15.9	0.4
Mod. (18.4)	7.0	41.3	47.5	4.2	Mod. (17.0)	4.4	40.9	46.6	8.1
Severe (0.8)	0.8	1.0	36.7	61.5	Severe (1.9)	0	21.7	60.0	18.3

* Non-shaded cells of the table, along the diagonal, indicate the percentage of participants with no change in symptom severity category over time. Table cells to the upper-right of the diagonal (lightly shaded) indicate progression of symptoms over follow-up. Table cells to the lower left of the diagonal (darkly shaded) indicate regression (remission or improvement) of symptoms. Percentages are row percentages. Abbreviations: LUTS=Lower urinary tract symptoms; Mod. = moderate.

Table 3

Multivariable-Adjusted Odds Ratios (OR) for Progression or Regression of LUTS*

	<u>Progression</u>		<u>Regression</u>	
	OR (95% CI)	P	OR (95% CI)	P
Baseline age, yr	1.02 (1.00, 1.03)	0.008	0.99 (0.98, 1.01)	0.4
Race/ethnicity		0.02		0.03
Black	1.12 (0.85, 1.46)		1.11 (0.81, 1.52)	
Hispanic	1.55 (1.13, 2.11)		1.65 (1.14, 2.39)	
White	Ref		Ref	
Male sex (vs. female)	0.92 (0.72, 1.18)	0.5	0.85 (0.62, 1.17)	0.3
Body mass index, kg/m ²	1.03 (1.01, 1.05)	0.003	0.98 (0.96, 1.01)	0.14
LUTS medication		0.009		0.02
Both baseline and follow-up	1.04 (0.58, 1.85)		1.35 (0.75, 2.41)	
Baseline only	0.39 (0.17, 0.91)		3.10 (1.28, 7.51)	
Follow-up only	2.19 (1.18, 4.07)		0.62 (0.35, 1.11)	
Never	Ref		Ref	

* Adjusted for age, race/ethnicity, sex, body mass index, LUTS medication, and history of heart disease, hypertension, or diabetes.

Table 4

Age-adjusted Rates of Progression and Regression* of LUTS among Untreated Men and Women (N=3,657), Overall and by Presence of LUTS at Baseline

Baseline LUTS	Progression, %	Regression, %
Total AUASI score		
None or Mild	23.3	25.4
Moderate	16.3	49.5
Severe	2.1	93.6
Subdomains		
Men		
Voiding symptoms [†]	15.0	48.5
Storage symptoms [‡]	9.7	39.6
Nocturia [¶]	19.7	36.9
Women		
Voiding symptoms [†]	13.9	67.2
Storage symptoms [‡]	21.7	42.1
Nocturia [¶]	26.9	35.5

* Defined as 3+ point change in total AUASI between baseline and follow-up study visits. The analysis of progression included 3,654 individuals eligible for progression, and the analysis of regression included 1,791 individuals eligible for regression based on their baseline AUASI score.

[†] Moderate-to-severe voiding symptoms present at baseline, as assessed by AUASI voiding subdomain score ≥ 5 points.

[‡] Moderate-to-severe storage symptoms present at baseline, as assessed by AUASI storage subdomain score ≥ 4 points.

[¶] Defined as getting up to urinate more than once nightly in the past month fairly often, usually, or almost always, assessed at baseline.