

## Initial Treatment of Men With Newly Diagnosed Lower Urinary Tract Dysfunction in the Veterans Health Administration

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<b>OBJECTIVE</b>	To examine initial treatments given to men with newly diagnosed lower urinary tract dysfunction (LUTD) within a large integrated health care system in the United States.
<b>METHODS</b>	We used data from 2003 to 2009 from the Veteran's Health Administration to identify newly diagnosed cases of LUTD using established ICD-9CM codes. Our primary outcome was initial LUTD treatment (3 months), categorized as watchful waiting (WW), medical therapy (MT), or surgical therapy (ST); our secondary outcome was pharmacotherapy class received. We used logistic regression models to examine patient, provider, and health system factors associated with receiving MT or ST when compared with WW.
<b>RESULTS</b>	There were 393,901 incident cases of LUTD, of which 58.0% initially received WW, 41.8% MT, and 0.2% ST. Of the MT men, 79.8% received an alpha-blocker, 7.7% a 5-alpha reductase inhibitor, 3.3% an anticholinergic, and 7.3% combined therapy (alpha-blocker and 5-alpha reductase inhibitor). In our regression models, we found that age (higher), race (white/black), income (low), region (northeast/south), comorbidities (greater), prostate-specific antigen (lower), and provider (nonurologist) were associated with an increased odds of receiving MT. We found that age (higher), race (white), income (low), region (northeast/south), initial provider (urologist), and prostate-specific antigen (higher) increased the odds of receiving ST.
<b>CONCLUSION</b>	Most men with newly diagnosed LUTD in the Veteran's Health Administration receive WW, and initial surgical treatment is rare. A large number of men receiving MT were treated with monotherapy, despite evidence that combination therapy is potentially more effective in the long-term, suggesting opportunities for improvement in initial LUTD management within this population. UROLOGY 83: 304–311, 2014. © 2014 Elsevier Inc.

Clinically significant lower urinary tract dysfunction (LUTD), most commonly presenting with symptoms from benign prostatic hyperplasia (BPH), becomes more common in men as they age with an estimated prevalence of 10.5% in men aged 30–39 years and 25.5% in men aged 70–79 years.<sup>1,2</sup>

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Treatments for LUTD are costly, with yearly estimated direct expenditures of at least \$2 billion that are expected to rise.<sup>3–5</sup>

There are very few studies that rigorously analyze the contemporary management of patients with LUTD in a real-world (ie community, unselected) setting. An observational BPH registry from the United States that includes 6924 men showed that 40%–60% of men received medical therapy (MT) to manage their LUTD in 2004.<sup>6</sup> Similarly, in the Trans European Research into the use of Management Policies for BPH in Primary Healthcare (TRIUMPH) study, nearly 70% of men with LUTD were managed with MT.<sup>7</sup> However, the overall percentages of MT alone fail to capture the extreme variations in treatments that were seen between providers, provider types, and countries. For example, the rate of MT for LUTD in the TRIUMPH study varied from 30% in the United Kingdom vs 80% in Italy.<sup>7</sup> Similarly, in the US BPH registry, men managed by a urologist were significantly more likely to receive MT

than those managed by a primary care physician (PCP; 69%-83% vs 50%-62%;  $P < .0001$ ).<sup>6</sup> These studies suggest that our real-world LUTD management strategies have considerable variation and might not follow data-driven guidelines.<sup>8-10</sup> Moreover, a major limitation of these registries (and all registries in general) is that the patients and providers that they include might not mirror that of the broader population, creating concerns about generalizability of findings. Analysis of large, unselected databases can provide a better estimate of our real-world management of LUTD to detect variations in care and potentially identify areas needing improvement.

Our objective was to examine the initial treatments for LUTD in men using data from a large integrated health care delivery system – the Veteran's Health Administration (VHA). Specifically, we examined the percentage of men with newly diagnosed LUTD who initially received watchful waiting (WW), MT, and surgical therapy (ST). For men who received MT, we examined the class of pharmacotherapy that they received. We hypothesize that patient, provider, and health system level factors will be associated with differences in the initial treatment offered.

## MATERIALS AND METHODS

### Cohort Creation

We used VHA Patient Treatment Files and Outpatient Care Files to identify all men aged  $\geq 40$  years with newly diagnosed LUTD between January 1, 2003 (year pharmaceutical data become available) and December 31, 2009. ICD-9CM and CPT codes were then used to identify patients with newly diagnosed LUTD using methods developed by Wei et al<sup>2</sup> (Appendix 1). Newly diagnosed cases of LUTD were defined as patients with a visit that included an LUTD code and no previous codes for LUTD during the 12 months before the index visit. Exclusion criteria included evidence of previous prostate cancer diagnosis (ICD-9CM 185), ICD-9CM coding of only 788.42 (polyuria) or 788.61 (splitting of urinary stream), evidence of previous or incident urinary retention,  $< 2$  primary care visits 1 year before diagnosis, evidence of previous prostate surgery (CPT codes), previous BPH medication use, all-cause mortality within 3 months of diagnosis, and patients receiving care from Pacific Islands/Guam. From 1,767,253 men receiving a BPH diagnosis as an inpatient or outpatient during the study period, the final cohort included 393,901 men (Appendix 1).

### Cohort Characteristics

We collected the following patient-level information for each veteran with newly diagnosed LUTD: age, race (categorized as white, black, and other), provider type (urologist or primary care/other), region of US in which they received their care (northeast, midwest, south, and west), and socioeconomic status (low income  $\leq \$15,000$ ; service connected = care compensated by VHA; other =  $> \$15,000$ ). Comorbid conditions were identified for each patient using ICD-9-CM–based definitions developed by Elixhauser et al and refined by Quan.<sup>11</sup> Key laboratory values included prostate-specific antigen (PSA) and creatinine obtained at up to 12-month before the diagnosis, with the most recent laboratories taking precedent.

### Initial Treatment Identification and Categorization

We identified the initial treatment that each patient received within the 3 months after LUTD diagnosis. A patient was categorized as WW if they did not receive LUTD-specific MT (described in the following sections) or ST in the 3 months after diagnosis. A patient was categorized as MT if the VHA Decisions Support System Pharmacy Files revealed that the patient received a LUTD-specific medication (Appendix 2) within 3 months of diagnosis. A patient was categorized as ST if VHA data identified a CPT code specific for BPH surgery associated with the patient (Appendix 2). If a patient had evidence of both MT and ST within the first 3 months, they were categorized as ST.

For men who received MT, we further evaluated VHA Pharmacy Data to examine the specific pharmacologic regimens that were used. In particular, recipients of MT were stratified into those who received alpha-blocker (AB), 5-alpha reductase inhibitor (5-ARI), anticholinergic (AC), and combinations thereof (Appendix 3). AB used was further subcategorized by the need for titration.

### Statistical Analysis

First, we compared demographics and prevalence of key comorbid conditions of MT and ST with WW, respectively, across our 3 patient cohorts (WW, MT, and ST) using the Pearson  $\chi^2$  test of independence for categorical variables and  $t$  test for continuous variables. Second, among the subset of men who were initially treated with MT, we used similar bivariate methods to compare the demographics and comorbidities of MT men according to the initial medication(s) prescribed (AB, 5ARI, AC, AB + 5ARI, and combinations). Third, we used 2 logistic regression models to examine patient, provider, and system level factors associated with receipt of MT and ST (with WW serving as the reference category). Model 1 compared MT patients with WW patients; model 2 compared ST patients with WW patients. All analyses were conducted using SAS statistical software version 9.3 (SAS Institute, Cary, NC). This study was approved by the Iowa City VHA (IRB #200905772).

## RESULTS

### Patient Characteristics by Initial Treatment

Our study included 393,901 new cases of LUTD, of whom 58.0% received WW, 41.8% received MT, and 0.2% received ST within the first 3 months after diagnosis (Table 1). Men who received MT were younger, had more comorbidities, lower PSA, lower income, and were more likely to be diagnosed by a PCP as compared with those receiving WW. Men who received ST were older and had higher PSAs and higher creatinines when compared with the WW group. Men who received ST were also more likely to have their initial visit with a urologist and were less likely to be located in the north-east and south.

### Patient Characteristics of MT Patients

The most common initial MT strategy was AB alone, which was given to 79.8% of MT men (94.6% titrated AB), followed by 5ARI alone (7.7%), and combined AB + 5ARI (7.3%; Table 2). There were multiple clinically small, but statistically significant, differences in the

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