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

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Abstract

OBJECTIVE—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.

METHODS—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.

RESULTS—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.

CONCLUSION—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

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APPENDIX

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.urology.2013.09.042.

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.

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.[1,2] Treatments for LUTD are costly, with yearly estimated direct expenditures of at least $2 billion that are expected to rise.[3-5]

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.[6] 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.[7] 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.[7] 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).[6] These studies suggest that our real-world LUTD management strategies have considerable variation and might not follow data-driven guidelines.[8-10] 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 ≥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[2] (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 ≤$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.[11] 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 co-morbid conditions of MT and ST with WW, respectively, across our 3 patient cohorts (WW, MT, and ST) using the Pearson c^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 northeast 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 demographic characteristics of patients receiving various MT regimens. Men receiving AC and combined AB + 5ARI had significantly more comorbidities when + compared with men receiving AB alone. PSA values were the highest in those receiving AB + 5ARI treatment. PCPs were significantly less likely to prescribe 5ARI, AC, and combined therapies compared with urologists (all *P* values <.0001). Among men receiving AB, PCPs were significantly more likely to prescribe titrated AB. Regional variations in MT were seen. For example, in the northeast, although less likely to receive MT overall, those receiving MT were more likely to receive 5ARI, AC, and combined AB + 5ARI therapy vs AB alone.

Multivariate Analysis

Factors associated with increased receipt of MT included white (odds ratio [OR] 1.06 95% confidence interval = 1.04-1.08) and black (OR 1.05 [1.05-1.08]; as compared with other) race, residing in the south (OR 1.10 [1.08-1.12]; relative to the midwest), and service connection (OR 1.19 [1.17-1.22]) or low income status (OR 1.34 [1.31-1.36]; relative to higher income; Table 3). Factors associated with reduced receipt of MT included initial diagnosis by a urologist (OR 0.48 [0.46-0.49]) and residence in the northeast (OR 0.70 [0.69-0.72]).

Factors associated with increased receipt of ST included older age (OR 1.03 [1.02-1.04]), white race (OR 1.79 [1.26-2.08]), service connection (OR 1.52 [1.10-2.08]) or low income status (OR 2.11 [1.57-2.84]), initial treatment by a urologist (OR 1.99 [1.51-2.62]), and higher baseline PSA level (OR 1.03 [1.02-1.04]). Factors associated with reduced receipt of ST included residence in the northeast (OR 0.55 [0.37-0.80]) or south (OR 0.66 [0.50-0.87]).

COMMENT

In a study using contemporary real-world data from the VHA for nearly 400,000 men with newly diagnosed cases of LUTD, we identified a number of important findings. First, we found that a majority of patients were initially managed with WW, whereas <1% of patients received surgery within 3 months of diagnosis. Second, we found that the initial treatment (WW, MT, and ST) appeared to be associated with patient demographics, comorbidities, and socioeconomic status. Third, we found evidence of variation in both initial treatment (WW, MT, and ST) and choice of medication across geographic regions.

A number of our findings are important and merit further discussion. We found that 40% of our LUTD population was treated with MT within the first 3 months of diagnosis, which is similar to the 45% rate of MT reported within 1 year from diagnosis in the TRIUMPH study. Although this MT rate might seem low, our findings are consistent with treatment guidelines that increasingly recommend WW as the preferred initial treatment for men with mild LUTD, which was likely the case in many of our patients. Clinical practice guidelines published by the American Urological Association[9] and the European Association of Urology[8] suggest that reassurance and behavioral modifications are acceptable first- line therapies in men with low to moderate symptoms; our finding that 58% of men initially received WW are consistent with these recommendations. It is also important to note that our data would not capture men who chose complementary and alternative medicines such as phytotherapies, including saw palmetto.[12]

Of men receiving MT in our analysis, nearly 80% received AB monotherapy, which was similar to the TRIUMPH population and not surprising given the ease of administration and tolerability of AB monotherapy.[13] A significantly smaller percentage of men received initial 5ARI (7.7%) or AB + 5ARI (7.3%) therapies, with both these regimens more common in older men and in men with higher PSAs. These percentages of 5ARI use were similar to what was noted in BPH Registry and Patient Survey populations (5ARI monotherapy [7.4%]; AB + 5ARI [12.4%]).[6] Although AB monotherapy is considered an acceptable initial treatment in the American Urological Association[9] and European Association of Urology[8] guidelines, well-conducted randomized trials, including the MTOPS[14] and CombAT[15] studies suggest that combined therapy with AB + 5ARI decreases symptoms and disease progression more effectively than monotherapy alone. For example, in the MTOPS study, the need for surgery was not diminished by doxazosin (an AB) monotherapy when compared with the placebo group.[14] Thus, our finding that only 7.3% of men received combination therapy is interesting and suggests that combination therapy might be significantly under-used in the VHA population.

We found clinically modest but statistically significant differences in initial treatment according to patient race; most notably, we found that white men were significantly more likely to receive both MT and ST. There are some data to suggest that differences in care-seeking behavior vary among groups by race/ethnicity, and this might be an important explanatory factor in these disparities.[16-19] For example, a study using data from the Olmsted County Study of Urinary symptoms and the Flint Men's Health Study, showed that black men had greater symptom severity than white men but were less likely to be bothered

by the symptoms.[20] As we presume that access to care was relatively similar in all men using the VHA, these patient preferences and care-seeking behavior that vary among races might be the most plausible explanation for the differences we found in our study, although further investigation is warranted.

It is also important to comment on the differences in treatment according to geographic region and initial provider. We found that men treated in the northeast were significantly less likely to receive both MT and ST as compared with men in the midwest; conversely, men in the northeast were more likely to receive initial WW. We also noted that men in the south were more likely to receive MT than men in the midwest, but much less likely to receive ST. Regional variations in treatment for LUTD have not been well described, although geographic variation has been studied extensively in other specialties, in which variations in provider type (specialist vs primary care) and the dissemination of new medical information have been implicated as reasons for the disparities.[21-23]

There are limitations to this study that deserve mention. First, we do not have information about the care these veterans received in the private sector. However, we limited our analysis to Veterans who were regular users of the VHA, making this less likely and the rates of WW that we found were consistent with previous published studies. Second, we relied on administrative data that were analyzed retrospectively and did not have access to the detailed clinical information and likewise do not know the precise reasons why certain treatment protocols were chosen. In addition, the use of ICD-9 and CPT codes for analyzing LUTD populations has never been validated in the VHA (although in other diseases within the VA, validation studies have been performed (eg post-traumatic stress disorder, inflammatory bowel disease),[24-26] indicating some reliability by proxy). Third, although the VHA is the largest integrated health care system in the US, the findings from this study might not necessarily reflect patterns of care in the private sector.

CONCLUSION

We found that a majority of men with newly diagnosed LUTD received an initial trial of WW and that ST was initially chosen in <1% of cases. We also observed significant variation in treatment across geographic regions that was not easily explained by patient demographics, comorbidity, PSA, or initial treating physician. Our study provides practicing urologists with a basic overview of current LUTD treatment patterns and sets the stage for additional efforts to improve care for men with LUTD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Characteristics of patients stratified by initial treatment

Patient Variable	Medical Therapy	Surgery	Watchful Waiting
No. of patients (%)	164,615 (41.8)	735 (0.2)	228,551 (58.0)
Mean (±SD) age	66.9 (10.6)‡	71.1 (9.6)‡	67.1 (10.6)
Race* (n, row %)			
White (n = 274,240)	115,154 (42.0)	491 (0.2)	158,595 (57.8)
Black (n = 48,152)	20,711 (43.0)	65 (0.1)	27,376 (56.9)
Other (n = 71,509)	28,750 (40.2)	179 (0.3)	42,580 (59.5)
P value (column)§	<.0001	<.0001	<.0001
Comorbidities (column %)			
Hypertension	22,874 (13.9)*	89 (14.6)	31,164 (13.6)
Diabetes	50,542 (30.7)‡	208 (34.1)†	66,577 (29.2)
Obesity	5891 (3.6)	14 (2.3)	8225 (3.6)
Depression	1204 (0.7)	7 (1.2)	1678 (0.7)
Dementia	3023 (1.8)	12 (2.0)	4300 (1.9)
Renal disease	47,147 (28.7)‡	126 (20.7)*	54,999 (24.1)
§Comorbidities	3.1 (2.1)‡	3.4 (2.4)‡	3.0 (2.2)
Laboratory values (±SD)			
PSA, mean ± (SD)	2.3 (4.1)‡	5.2 (8.8)‡	2.8 (4.5)
Cr, mean ± (SD)	1.2 (0.5)	1.4 (0.9)‡	1.2 (0.5)
Socioeconomic status (n, row %)			
Low income (n = 147,076)	64,893 (44.1)	369 (0.3)	81,814 (55.6)
Service connected (n = 140,994)	59,286 (42.0)	241 (0.2)	81,467 (57.8)
High Income (n = 105,831)	40,436 (38.2)	125 (0.1)	65,270 (61.7)
P value (column)§	<.0001	<.0001	<.0001
Initial provider (n, row%)			
Primary care (n = 367,439)	157,422 (42.8)	625 (0.2)	209,392 (57.0)
Urologist (n = 26,462)	7193 (27.2)	110 (0.4)	19,159 (72.4)
P value (column)	<.0001	<.0001	<.0001
Region (n, row%)			
Northeast (n = 58,188)	20,174 (34.7)	64 (0.1)	37,950 (65.2)
South (n = 150,896)	67,834 (45.0)	146 (0.01)	82,916 (54.9)
West (n = 73,644)	31,480 (42.7)	137 (0.2)	42,027 (57.1)
Midwest (n = 81,735)	35,126 (43.0)	150 (0.2)	46,459 (56.8)
P value (column)§	<.0001	<.0001	<.0001

Cr, creatinine; PSA, prostate-specific antigen; SD, standard deviation.

P values compare medical therapy with watchful waiting and surgery with watchful waiting using Chi-squared analysis (for categorical variables) and *t* testing (for continuous variables).

[*] Indicates $P < .05$.

[†] Indicates $P < .01$.

[‡] Indicates $P < .0001$.

[§] Compares percentages within column (by initial treatment) using Chi-squared analysis.

Table 2

Characteristics of men stratified by initial pharmaceutical treatment regimen

Patient Variable	AB	5ARI	AC	AB + 5ARI	Other
No. of patients (n = 164,615)	131,353 (79.8%)	12,703 (7.7%)	5487 (3.3%)	12,083 (7.3%)	2989 (1.8%)
Mean ± SD age	66.4 ± 10.5	69.8 ± 10.3‡	66.8 ± 12.0‡	69.4 ± 10.4*	67.2 ± 11.5‡
Race (row%)					
White (n = 115,154)	91,601 (79.5)	8947 (7.8)	3918 (3.4)	8602 (7.5)	2086 (1.8)
Black (n = 20,711)	16,792 (81.1)	1242 (6.0)	691 (3.3)	1536 (7.4)	450 (2.2)
Other (n = 28,750)	22,960 (79.9)	2514 (8.7)	878 (3.1)	1945 (6.8)	453 (1.6)
P value (column)§	<.0001	<.0001	.013	.0002	<.0001
Comorbidities					
Hypertension (n = 22,874)	17,003 (13.0)	2129 (16.8)‡	882 (16.1)‡	2268 (18.8)‡	592 (19.8)‡
Diabetes (n = 50,542)	39,925 (30.4)	3889 (30.6)	1673 (30.6)	4053 (33.6)‡	1002 (33.5)†
Obesity (n = 5891)	4859 (3.7)	310 (2.4)‡	217 (4.0)	377 (3.1)†	128 (4.3)†
Depression (n = 1204)	856 (0.7)	86 (0.7)	97 (1.8)‡	108 (0.9)†	57 (1.9)‡
Dementia (n = 3023)	2395 (1.8)	229 (1.8)	98 (1.8)	233 (1.9)	68 (2.3)*
Renal disease (n = 47,147)	38,030 (29.0)	3076 (24.2)‡	1814 (33.1)‡	3206 (26.6)‡	1021 (34.2)‡
§Comorbid conditions	3.0 ± 2.1	3.0 ± 2.1	3.5 ± 2.3‡	3.4 ± 2.4‡	3.5 ± 2.4‡
Laboratory values					
PSA, mean ± SD	2.1 ± 3.8	3.1 ± 4.6‡	2.0 ± 4.0*	3.4 ± 5.9‡	2.4 ± 4.8*
Cr, mean ± SD	1.2 ± 0.4	1.2 ± 0.5‡	1.2 ± 0.5	1.3 ± 0.7‡	1.2 ± 0.6*
Socioeconomic status					
Low income (n = 64,893)	51,642 (79.6)	4807 (7.4)	2045 (3.2)	5215 (8.0)	1184 (1.8)
Service connected (n = 59,286)	47,224 (79.7)	4353 (7.3)	2226 (3.8)	4293 (7.2)	1190 (2.0)
Higher income (n = 40,436)	32,487 (80.3)	3543 (8.8)	1216 (3.0)	2575 (6.4)	615 (1.5)
P value (column)§	.0065	<.0001	<.0001	<.0001	<.0001
Initial provider					
Primary care/other (n = 157,422)	126,671 (80.4)	11,826 (7.5)	4842 (3.1)	11,284 (7.2)	2799 (1.8)
Urologist (n = 7193)	4682 (65.1)	877 (12.2)	645 (9.0)	799 (11.1)	190 (2.6)
P value (column)§	<.0001	<.0001	<.0001	<.0001	<.0001
Region					
Northeast (n = 20,174)	15,484 (76.8)	1852 (9.2)	763 (3.8)	1695 (8.4)	380 (1.9)
South (n = 67,834)	53,303 (78.6)	6299 (9.3)	1790 (2.6)	5298 (7.8)	1144 (1.7)
West (n = 31,480)	26,788 (85.1)	1379 (4.4)	1219 (3.9)	1571 (5.0)	523 (1.7)
Midwest (n = 35,126)	28,800 (82.0)	2182 (6.2)	1377 (3.9)	2116 (6.0)	651 (1.9)
P value (column)§	<.0001	<.0001	<.0001	<.0001	.06

5ARI, 5-alpha reductase inhibitor; AB, alpha-blocker; AC, anticholinergic; other abbreviations as in Table 1.

P values reflect comparison with alpha-blockers using Chi-squared analysis (for categorical variables) and *t* testing (for continuous variables).

[*] Indicates $P < .05$.

[†] Indicates $P < .01$.

[‡] Indicates $P < .0001$.

[§] Compares percentages within column (by initial treatment) using Chi-squared analysis.

Table 3

Patient and provider factors associated with initial medical and surgical treatments of lower urinary tract dysfunction

	Medical Therapy (Model 1)		Surgery (Model 2)	
Patient Model Variable	**OR (95% CI)**	***P* Value**	**OR (95% CI)**	***P* Value**
Age	1.00 (1.00-1.00)	.0018	1.03 (1.02-1.04)	<.0001
Race				
White	1.06 (1.04-1.08)	<.0001	1.79 (1.26-2.08)	<.0013
Black	1.05 (1.02-1.08)	.0031	1.20 (0.73-1.97)	.4664
Other	1.0		1.0	
Region				
Northeast	0.70 (0.69-0.72)	<.0001	0.55 (0.37-0.80)	.0018
South	1.10 (1.08-1.12)	<.0001	0.66 (0.50-0.87)	.0028
West	1.01 (0.98-1.03)	.6441	1.18 (0.89-1.57)	.2631
Midwest	1.0		1.0	
Socioeconomic status				
Service connected	1.19 (1.17-1.22)	<.0001	1.52 (1.10-2.08)	.0104
Low income	1.34 (1.31-1.36)	<.0001	2.11 (1.57-2.84)	<.0001
Other	1.0		1.0	
Comorbidities	1.02 (1.01-1.02)	<.0001	1.04 (0.99-1.10)	.0840
Initial provider				
Urologist	0.48 (0.46-0.49)	<.0001	1.99 (1.51-2.62)	<.0001
Primary care	1.0		1.0	
PSA	0.97 (0.97-0.97)	<.0001	1.03 (1.02-1.04)	<.0001

CI, confidence interval; OR, odds ratio; other abbreviation as in Table 1.

Logistic regression tests compare odds of medical therapy (vs watchful waiting) in model 1 and odds of surgical therapy (vs watchful waiting) in model 2. All variables listed previously were included in the model (age, race, region of care, socioeconomic status, comorbidity number, initial provider and prostate-specific antigen).