Patterns of Care for Newly Diagnosed Benign Prostatic Hyperplasia in the United States

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Purpose: We examined diagnostic tests and treatment patterns in men with new onset benign prostatic hyperplasia using consolidated national electronic health record data.

Materials and Methods: The Humedica® electronic health record database consists of de-identified patient records from approximately 25 million patients in the United States. Using this database, men with a new benign prostatic hyperplasia diagnosis (benign prostatic hyperplasia, bladder neck obstruction, urinary retention and incomplete bladder emptying) between July 1, 2009 and June 30, 2012 were included in study. Exclusion criteria included conditions such as genitourinary cancers, radiation cystitis, neurogenic bladder and urological pain diagnoses. Diagnostic tests and treatments were summarized and stratified by age (less than 65 vs 65 years or greater) and serum prostate specific antigen level.

Results: A total of 38,252 men met inclusion criteria. Mean followup was 1,020 days. Serum creatinine in 92% of patients, serum prostate specific antigen in 76% and urinalysis in 52% were the most common tests. Invasive testing was obtained in less than 20% of patients. Treatments included watchful waiting in 40% of patients, pharmacological therapy in 59.4% and surgery in 2.2%. α-Blockers were prescribed in 50.7% of men. Men older than 65 years and with higher prostate specific antigen levels were less likely to be treated with watchful waiting. Therapy with a 5-ARI (5-α reductase inhibitor) was prescribed in 23% to 29% of men across all prostate specific antigen categories.

Conclusions: The majority of clinical care for new onset benign prostatic hyperplasia was in concordance with guideline recommendations. Based on prostate specific antigen values, 5-ARI therapy was underutilized in men with large prostates and was over utilized in men with small prostates.

Key Words: prostatic hyperplasia; diagnostic tests, routine; 5-alpha reductase inhibitors; standards; prostate-specific antigen

Abbreviations and Acronyms

AUA = American Urological Association

BPH = benign prostatic hyperplasia

EHR = electronic health record

LUTS = lower urinary tract symptoms

OAB = overactive bladder

PSA = prostate specific antigen

LOWER urinary tract symptoms refer to a constellation of urinary complaints, including storage symptoms (urgency, frequent urination and nocturia), voiding symptoms (weak urinary stream, hesitancy and incomplete bladder emptying) and post-micturition symptoms. These symptoms are common and can lead to decreased quality of life.[1,2] In men,

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LUTS are frequently attributed to bladder outlet obstruction caused by BPH.

For clinicians who treat male LUTS due to BPH, there have been several relevant clinical practice guidelines available to help guide management decisions.[3] However, there is a limited understanding of the patterns of care (diagnostic testing, medical and surgical therapies) that exist in the approach to this common condition. It is important to understand community practices for common conditions like LUTS as it may provide insight into areas for improvement or further research.

We examined national practice patterns for incident BPH in men using Humedica, an EHR database system with an estimated 25 million lives with 80%+ having more than 4 years of patient history. Nearly 8 million patients have integrated outpatient and hospital information. This database provides a unique opportunity to examine care patterns across all ages and insurance types.

The AUA and Pfizer Inc. were mutually interested in better understanding patterns of care for lower urinary tract dysfunction which commonly cause patients to seek health care. Both organizations strive to characterize the approaches to diagnosing and managing these disorders and to identify whether providers follow recommended guidelines set forth by experts in the field of urology.

METHODS

Humedica electronic health records were used to conduct a retrospective, noninterventional, real-world observational study of patients with newly diagnosed BPH, examining national patterns of care. Data collection and record retention were managed by Humedica. Pfizer has a license agreement to access the Humedica data.

Humedica aggregates electronic health record data directly from providers, integrating multiple electronic health records from both inpatient and ambulatory settings across the United States. The database includes electronic health care records from approximately 25 million patients of all ages across multiple insurers, including private payers and Medicare (but not Medicaid). These data capture a comprehensive clinical picture that includes medications, laboratory results, vital signs, physician notes, diagnoses, procedures, demographics, hospitalizations and outpatient visits. Once aggregated, Humedica normalizes, validates and deidentifies these data.

A BPH diagnosis was defined based on the presence of any of the following ICD-9 codes in the electronic medical record: 600.x, hyperplasia of prostate; 596.0, bladder neck obstruction; 788.20, urinary retention; or 788.21, incomplete bladder emptying. Additional inclusion criteria were male only, age 18+ years, no BPH diagnosis 12 months before the index date, in the IDN (integrated delivery network) throughout the entire study period, 2 BPH diagnoses occurring at least 30 days apart (ie 30+ days between 2 BPH occurrences), and continuous enrollment at least 12 months before and 6 months on or after the index date.

Exclusion criteria applied were females or unknown gender; diagnosis of prostate cancer (ICD-9 185), bladder cancer (188.x), urethral cancer (189.3), urethral stricture (598.X), interstitial cystitis (595.1), prostatitis (601.x), radiation cystitis (595.82), neurogenic bladder (596.54, 596.55, 344.61), multiple sclerosis (340, 341.0, 341.1, 341.8, 341.9), Parkinson's disease (332.0, 332.1, 333.0, 094.82) and cerebrovascular disease (436, 435.9, 997.02); and personal history of other diseases of the circulatory system (V12.59), spina bifida (741, 741.0, 741.9, 756.17), spinal cord injury (952.x), paraplegia (344.1), paralysis (344.9), cerebral palsy (343.x) and quadriplegia (344.x).

The Humedica database encompassing the time period from July 1, 2008 to September 30, 2013 was utilized for the analysis. Specifically, the following study periods were included in this observational study.

The pre-index period was a fixed period of exactly 12 months with continuous enrollment before the index date. This period occurred between July 1, 2008 and the first BPH diagnosis.

The index date was the date of first BPH diagnosis in the medical record, which occurred between July 1, 2009 and June 30, 2012 to assure at least 12 months before and 15 months after the index date. To meet study criteria, a second BPH diagnosis was required at least 30 (ie 30+) days apart from the initial (index) diagnosis, in order to establish and confirm the diagnosis with time.

The post-index period was the followup period from the first diagnosis to the most recent Humedica data available (September 30, 2013).

Patients with BPH were stratified by age (18 to 64 years vs 65+), and the rates of diagnostic tests and treatments were compared across these age groups. Demographics (age and race/ethnicity) were obtained from the pre-index period or the index date. Diagnostic tests, medications and surgeries/procedures were limited to the post-index period. Men with no evidence of treatment with a medication or procedure were considered to be treated with watchful waiting. In men for whom PSA values were available, treatments were stratified by these values (0 to 1.5, greater than 1.5 to 4, greater than 4 to 8 and greater than 8 ng/ml) as a surrogate for prostate volume and BPH treatments were compared across these PSA subgroups. In men with multiple PSA values in the post-index period, the median PSA value was utilized for the analysis.

Diagnostic tests that were examined included measurement of post-void residual urine, cystoscopy, urodynamic testing, renal ultrasonography, prostate ultrasonography, urinalysis, urine culture, urine cytology, serum creatinine and serum PSA. Supplementary Appendix 1 (http://jurology.com/) provides the specific CPT codes that were used to identify these procedures.

Medications analyzed included the α-adrenergic antagonists (prazosin, terazosin, doxazosin, tamsulosin, silodosin and alfuzosin), 5-ARIs (finasteride and dutasteride) and OAB medications, including oxybutynin (oral, patch or gel), tolterodine, solifenacin, darifenacin, fesoterodine, trospium and mirabegron.