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Poor clinical guideline adherence and inappropriate testing for incident lower urinary tract symptoms associated with benign prostatic hyperplasia

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Abstract

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Background.—The American Urological Association makes recommendations for evaluation and testing for lower urinary tract symptoms associated with benign prostatic hyperplasia (LUTS/BPH) to help primary care providers and specialists identify LUTS/BPH and harmful related conditions including urinary retention and prostate or bladder cancer. Our understanding of provider adherence to these Guidelines is limited to single-site or non-representative settings.

Methods.—We analyzed two insurance claims databases: the Optum® de-identified Clinformatics® Data Mart database for privately insured males aged 40–64 years (N≈1,650,900 annually) and the Medicare 5% Sample for males aged ≥65 years (N≈546,000 annually). We calculated the annual prevalence of LUTS/BPH and comorbid bladder cancer and bladder stones from 2004–2013. We additionally examined LUTS/BPH incidence and adherence to testing guidelines in a cohort of men newly diagnosed with LUTS/BPH in 2009.

Results.—While LUTS/BPH prevalence and incidence increased with increasing age, evaluation testing became less common. Urinalysis was the most common testing type but was performed in <60% of incident patients. Serum prostate-specific antigen (PSA) was the second most common test across age groups (range: 15–34%). Prevalence of comorbid bladder cancer (range: 0–4%), but not bladder stones (range: 1–2%), increased with increasing age.

Conclusions.—Although older men were at greater risk of LUTS/BPH than younger men, they were less likely to undergo testing at diagnosis. Recommended testing with urinalysis was poor despite higher prevalence of bladder cancer in older men and a standard recommendation for urinalysis since 1994. Providers should be more cognizant of AUA Guidelines when assessing LUTS/BPH patients.

Keywords

benign prostatic hyperplasia; lower urinary tract symptoms; guidelines; screening; epidemiology

INTRODUCTION

Since 1994, the American Urological Association (AUA) Clinical Guidelines have made recommendations regarding the key diagnostic tests and portions of the history and physical examination for the initial evaluation of men with lower urinary tract symptoms associated with benign prostatic hyperplasia (LUTS/BPH). These Guidelines have been developed by panels that include primary care providers (PCPs), urologists, evidence-based medicine experts, and patients, and are intended to be used by all providers who treat men with LUTS/BPH.

The Guidelines traditionally indicate which measures are recommended, optional, or not routinely recommended with the goals of educating providers, avoiding unnecessary testing, and screening for potentially harmful related conditions like urinary retention, bladder stones, upper tract alterations, and prostate or bladder cancer. Guidelines from 1994 onward have recommended routine use of medical history and urinalysis (UA), with serum prostate-specific antigen testing (PSA) becoming recommended in 2003 for age-appropriate men. Unfortunately, our understanding of guideline adherence is limited due to use of single-site or non-representative data sets.^{1,2}

As part of the Urologic Diseases in America project, we addressed these knowledge gaps by assessing adherence to evaluation test guidelines for LUTS/BPH across different age groups among a large, national male population aged 40 years. We further examined whether age-related differences in evaluation testing corresponded to age-related differences in incidence of LUTS/BPH, prevalence of LUTS/BPH, and comorbid bladder cancer and lower urinary tract stones, which function as proxies for fidelity of LUTS/BPH diagnosis and progression/severity of LUTS/BPH, respectively. Our hypothesis was that testing use would largely follow disease incidence and prevalence with older men being more likely to undergo LUTS/BPH specific testing.

MATERIALS/SUBJECTS AND METHODS

Study Population

Descriptions of the study populations and methods have been described previously.³ Briefly, we utilized two data sources in this study: 1) the Optum© de-identified Clinformatics® Data Mart Database (CDM) for men 40–64 years of age (N≈1 650 900 annually) and 2) the Medicare 5% Sample (henceforth “Medicare”) for men 65 years of age (N≈546 000 annually).⁴ Diagnoses and procedures were identified using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology codes. The Copernicus Group Independent Review Board® designated this project exempt from review.

Definitions

Annual Cohorts—To examine prevalence of LUTS/BPH and comorbid lower urinary tract stones and bladder cancer, annual cohorts were examined for each study year with available data (2004–2013). To be included in each year’s cohort, participants had to be enrolled for that full calendar year or until death. Prevalent LUTS/BPH patients in each calendar year were defined as those with at least one evaluation and management claim with a qualifying ICD-9-CM diagnostic code (Supplementary Table 1).³ Among identified prevalent LUTS/BPH patients, comorbid bladder cancer patients were defined as those with at least one institutional claim or two non-institutional claims with an ICD-9-CM diagnostic code of 188 in any diagnostic field during the calendar year. Patients with lower urinary tract stones were defined as those with at least one evaluation and management claim with an ICD-9-CM diagnostic code of 594 in any diagnostic field during the calendar year.

Incident Cohort—We also created a cohort of incident LUTS/BPH patients for a single year (2009) to assess evaluation testing among newly identified LUTS/BPH cases. Incident LUTS/BPH patients were defined as cases identified in 2009 who had no evidence of LUTS/BPH between January 2006 and December 2008. Evaluation test categories of interest included: UA, urodynamics (including cystometrogram, uroflowmetry, and electromyography), post-void residual urine (PVR), serum PSA, serum creatinine, cystoscopy, transrectal prostate ultrasound (TRUS), intravenous pyelogram, renal ultrasound, and computed tomography scan of the abdomen/pelvis. Patients in the Incident Cohort were defined as having undergone a LUTS/BPH evaluation test if a claim was

identified with a qualifying procedure code (Supplementary Table 2) and a diagnostic code for LUTS/BPH in any diagnosis field.

Statistical Analysis

Among the 2004–2013 Annual Cohorts, we calculated the annual prevalence of LUTS/BPH and the annual prevalence of comorbid bladder cancer and lower urinary tract stones among LUTS/BPH patients. Annual prevalence was averaged across the available data period to arrive at the 10-year average annual prevalence. Among the 2009 Incident Cohort, we calculated the incidence of LUTS/BPH and the prevalence of evaluation tests in that year.

All analyses were conducted overall and stratified by age. Analyses were conducted in SAS 9.4. (SAS Institute, Inc., Cary, NC).

RESULTS

LUTS/BPH prevalence increased with increasing patient age, ranging from 2.6% among men aged 40–49 years to 33.6% among men aged ≥85 years (Table 1). Among men with prevalent LUTS/BPH, concomitant diagnosis of bladder cancer occurred in 1.1% of CDM enrollees and 2.8% of Medicare beneficiaries (Table 2). Older men were more likely than younger men to be concomitantly diagnosed with LUTS/BPH and bladder cancer (0.4% among those aged 40–44 years vs. 3.7% among those aged ≥85 years). We observed comorbid lower tract stones among 1.6% of CDM LUTS/BPH patients and 1.2% of Medicare LUTS/BPH patients; interestingly, lower tract stones did not appear to have age-related variation.

LUTS/BPH incidence also increased with age; 13.7% of men aged ≥85 years were newly diagnosed with LUTS/BPH in 2009 compared to only 2.1% among men aged 40–49 years (Table 1). With few exceptions, the use of LUTS/BPH-related evaluation testing decreased with increasing patient age which was contrary to our hypothesis (Figure 1). UA was the most common testing type but was performed in fewer than 60% of men, ranging from 38.1% among patients aged ≥85 years to 55.7% among those aged 40–49 years. Serum PSA was the second most commonly performed test, with the lowest use (14.6%) among patients aged ≥85 years and the highest use among those aged 50–59 years (33.9%). Cystoscopy and PVR prevalence modestly increased with increasing patient age, with a slight decrease among the oldest age group. Use of TRUS demonstrated a bell-shaped curve across age groups, peaking at 5.3% among men aged 60–64 years.

DISCUSSION

We demonstrate strong age-related increases in the incidence and prevalence of LUTS/BPH, ultimately finding that one-third of men aged ≥85 years were diagnosed with this condition. We further found concerning and erratic age-related variation in use of LUTS/BPH evaluation testing, which has a single age-related recommendation (PSA), among newly diagnosed LUTS/BPH patients. To our knowledge, these data provide the most comprehensive assessment of LUTS/BPH incidence, prevalence, and diagnostic testing among men in the US to date, providing important information for patient education and

safety, health policy, and health care cost planning. These findings refute our hypothesis as younger men, with a lower prevalence and incidence of LUTS/BPH, are more likely to undergo testing.

LUTS/BPH Clinical Guidelines have been developed by the AUA for more than 25 years. Guidelines development involves collaboration between PCPs, urologists, evidence-based medicine experts, and patients, as many urologic diseases and conditions are frequently treated by both PCPs and urologists. These Guidelines are meant to provide evidence-based rationale for patient evaluation and endorse a reasonable quality of care. While urologic sub-specialty societies may publish guidelines on specific topics (e.g., PSA screening), LUTS/BPH has only one set of guidelines meant to serve as a reference for all providers who treat LUTS/BPH.

In this paper, we examined compliance with the 2003 version of the Guidelines as these would have been in effect in 2009 when our incident cohort was identified. The 2003 Guidelines recommended UA for all patients and PSA testing for men with “at least a 10 years life expectancy and for whom knowledge of the presence of prostate cancer would change management.”⁵ PSA testing was included in the LUTS/BPH Guidelines as this simple test predicts the natural history of urinary symptoms, urinary flow rate, risk of acute urinary retention, risk of BPH-related surgery, and of course has utility in screening for prostate cancer.⁶⁻⁹

In the 2003 Guidelines, PVR and uroflowmetry were considered optional and not required before initiating watchful waiting or medical therapy. Additional adjuvant testing (e.g. cystoscopy, urodynamics, TRUS) was recommended before considering procedural options. We found that less than 60% of newly diagnosed LUTS/BPH patients had the recommended testing of UA, demonstrating poor guideline compliance. Other testing like PVR, a simple and useful test, occurred infrequently with only 14–16% of any age group getting this test. While PVR was considered adjuvant in the 2003 Guidelines, the recently updated guidelines endorsed a PVR for all patients before proceeding to surgery.¹⁰

The deficits observed in basic testing may partially be explained by provider or testing location. For example, patients may be initially diagnosed and treated by PCPs without routine access to an in-office ultrasound to check PVR. However, the provider location/specialty argument does not account for poor compliance with routine laboratory testing like UA and PSA, which would be available uniformly and are frequently ordered by both PCPs and urologists. While the granularity of these data does not allow for investigation of underlying causes of these findings, it provides an opportunity for providers from all medical disciplines to examine and improve their own practice patterns.

The age-related variation in routine testing is concerning for a variety of reasons. In most cases, incidence of the diseases screened for by this testing (including bladder and prostate cancer) increase with age.^{11,12} Accordingly, one would expect that older patients would be *more* likely to have testing like UA and PSA than younger patients who are less at risk for these comorbid conditions. As older patients were more likely to have the combined diagnosis of LUTS/BPH and bladder cancer in this study, the need for more

diligent screening in this older cohort using UA is evident and guidelines adherence should be emphasized. The decrease in recommended testing with age is troubling, however the rationale for these findings cannot be elucidated from these data.

Unfortunately, we also observed inappropriate over-testing in some age groups. PSA testing has been subject to controversy due to the unique clinical course for prostate cancer, the value of PSA to accurately predict clinically relevant prostate cancer, and the harms related to screening/treatment. Although the AUA and United States Preventative Service Task Force (USPSTF) guidelines have differed in their recommendations, the most recent guidelines from both allow for screening in men ages 55 to 69 years.^{13,14} However, given that our incident cohort is from 2009, we interpret our findings in the context of the appropriate recommendations for both PCPs and urologists: the 2003 AUA Guidelines and the 2008 version of the USPSTF recommendations.^{5,15} We will look at these recommendations separately.

The 2003 BPH Guidelines effective during our study period recommended PSA testing for men with at least a 10-year life expectancy and “for whom knowledge of the presence of prostate cancer would change management.”⁵ The second part of this statement is more subjective and difficult to place in the context of patient goals, shared decision making and surgeon comfort with different surgical techniques. If our findings are interpreted in the context of the 2003 Guidelines for PSA purely as a prostate cancer screening test, both over- and under-testing with PSA are evident. For example, almost all men in the younger age groups would have a 10-year life expectancy. Ideally, PSA screening for these men would have been close to 100%; however, in 2009, less than one third of incident LUTS/BPH patients aged 65 years underwent PSA testing, suggesting under-testing among younger patients. Conversely, almost all men over 85 years would not have a 10-year life expectancy, and PSA testing should have been very infrequent. However, in our 2009 incident cohort, nearly 15% of patients aged 85 years had a PSA test, suggesting over-testing among older patients. Although using the modern recommendation of testing for men aged 55 to 69 years would change this interpretation, we cannot expect practitioners in 2009 to adhere to 2010 or 2018 Guidelines.

The 2008 USPSTF recommendations differed from the comparable AUA Guidelines and stated that men over 75 years (or those with a less than 10 year life expectancy) should *not* be screened for prostate cancer with PSA.¹⁵ The USPSTF recommendations further stated that insufficient evidence precluded them from making a recommendation for or against prostate cancer screening for men younger than 75.¹⁵ Interpreting our results considering the USPSTF Guidelines, we again observe significant over-testing, as all men over 75 years who received a PSA test were inappropriately screened. Whether from a primary care or urology perspective, this over-testing with PSA provokes unnecessary financial and emotional costs and is a poor use of healthcare dollars. While not as uniformly recognized at the time, the potential downstream costs of detecting and treating non-clinically significant cancers was likely substantial and certainly wasteful.

The testing usually considered ancillary for LUTS/BPH that was captured also has a variety of interesting findings. We observed a bell-shaped age distribution for TRUS, with a peak of

5.3% of men aged 60–64 years undergoing this test. A portion of the TRUS performed in LUTS/BPH patients aged 60–64 years may have been related to prostate biopsy rather than LUTS/BPH evaluation; however, this distinction could not be made with the available claims data. Testing which had little usefulness for LUTS/BPH (e.g., intravenous pyelogram, serum creatinine, and renal ultrasound) was seen at low levels in this data set and could be related to testing for other diagnoses or clinical problems.

Few other papers have assessed compliance with LUTS/BPH specific guidelines. In 2014, Auffenburg et al. noted that physician adherence to the 2010 AUA Guidelines for LUTS/BPH evaluations was between 53.0–92.8% within a single academic practice, demonstrating room for improvement in guideline adherence.¹ In a multicenter assessment of guideline adherence, 402 urologists and PCPs were examined, finding that urologists were more likely than PCPs to follow guidelines-based testing.² However, the study only included patients from a limited number of sites which were largely academic centers.

A recently published study looking at data from 2008 to 2015 assessed both urologist and PCPs performance of digital rectal exam and use of PSA and UA testing at visits for either new onset or worsening LUTS/BPH.¹⁶ Authors used the National Ambulatory Medical Care Survey and looked at 878 ambulatory visits. Interestingly, about half of the study population was seen by PCPs which highlights the need for inclusion of all providers who may see men for LUTS/BPH in guideline statements. Authors found that PSA was ordered in 24% of visits, 61% of visits included a UA and 18% of patients had a digital rectal exam performed. Curiously, over 70% of visits had no testing performed and like our study, older men were less likely to have relevant testing. Unfortunately, their data set only looked at a singular visit for these patients and would miss relevant testing already performed on patients for the diagnosis of LUTS/BPH.

The identification of testing by claims data is both a strength and weakness of this study. A limitation inherent to claims data is that the use of ICD-9-CM coding to identify men with LUTS/BPH depends on correct diagnosis and coding by providers. Further, the accuracy of the procedural data relies upon providers correctly matching diagnostic codes with the evaluation test being conducted. For example, if testing is not specific to the diagnostic code, then a test for an unrelated issue (e.g., computed tomography scan for abdominal pain) may be captured as part of our study. Finally, while the study includes a wide range of ages that includes the men most susceptible to LUTS/BPH, the inability to link patients as they cross from private insurance to Medicare at age 65 makes trend identification around this age group challenging to properly interpret. Finally, the data for men aged <65 years is limited to those enrolled in private insurance, and future studies including those enrolled in Medicaid and other government healthcare programs would provide a more comprehensive picture of testing in this younger population.

Despite these limitations, our study also has several strengths. The data used in this analysis include men from a broad age range and geographic area, and represent care at both academic and non-academic centers, improving on the generalizability of prior studies. Additionally, our large national sample size and ability to accurately link patient diagnosis

and testing (independent of provider) allows us to examine the national standard of care along with large scale trends.

Evaluating and reporting on guideline adherence is critical to assure quality care is being provided and healthcare resources are being allocated appropriately. Although older men were at greater risk of LUTS/BPH than younger men, they were less likely to undergo testing at diagnosis. Recommended testing with UA was poor despite a higher prevalence of bladder cancer in older men and a standard recommendation for urinalysis since 1994.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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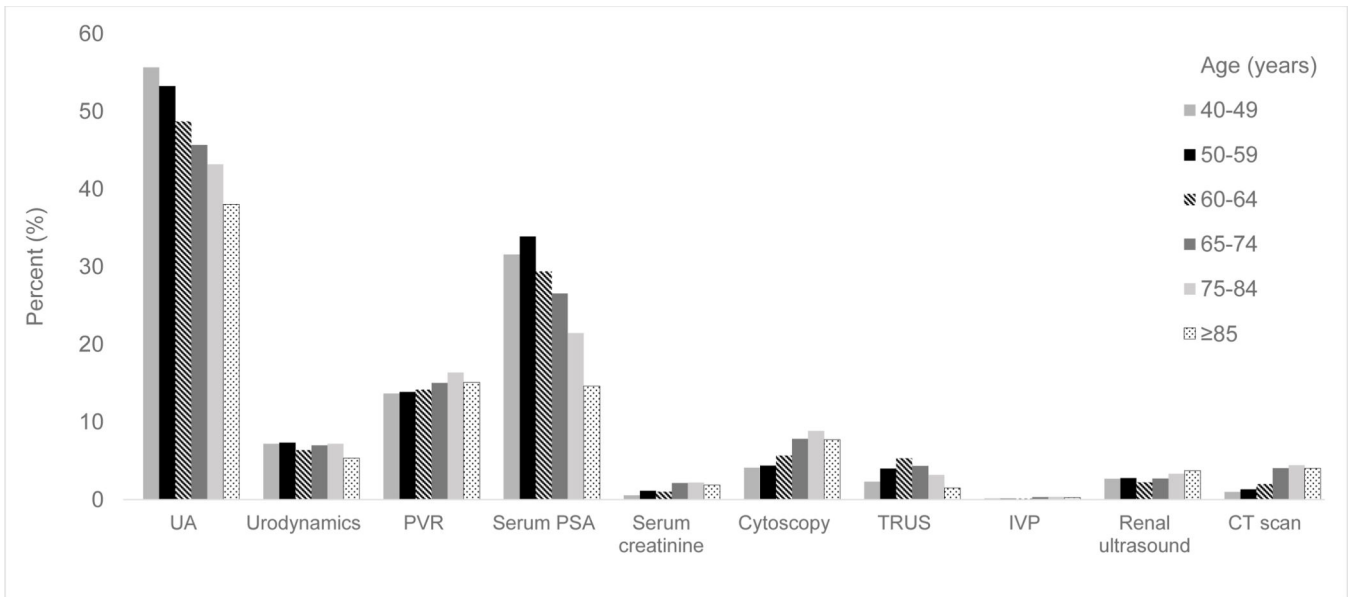


Figure 1.

Evaluation test (%) use among Optum© De-identified Clinformatics® Data Mart enrollees and Medicare beneficiaries* with incident LUTS/BPH, stratified by age, 2009†.

CT, computed tomography; IVP, intravenous pyelogram; LUTS/BPH, lower urinary tract symptoms/benign prostatic hyperplasia; PSA, prostate specific antigen; PVR, post-void residual urine; TRUS, transrectal prostate ultrasound; UA, urinalysis.

* Data source: Optum© De-identified Clinformatics® Data Mart Database (ages 40–64) and Centers for Medicare and Medicaid Services, Medicare 5% Sample (ages 65+), 2006–2013.

† Among participants with full enrollment from January 2006 through December 2013 or the death month in death year.

Table 1.

LUTS/BPH prevalence, incidence, and evaluation test use among Optum® De-identified Clinformatics® Data Mart enrollees and Medicare beneficiaries *, stratified by age, 2004–2013.

| Age (years) | Average annual prevalence, 2004–2013 (%) | Incidence, 2009 (per 100 person-years) [†] | Percent of incident LUTS/BPH patients with any evaluation test, 2009 (%) [‡] |
|-------------|--|---|---|
| 40–49 | 2.6 | 2.1 | 71.8 |
| 50–59 | 7.0 | 4.1 | 71.6 |
| 60–64 | 13.4 | 6.5 | 66.2 |
| 65–74 | 22.7 | 9.7 | 62.4 |
| 75–84 | 31.0 | 11.5 | 58.8 |
| 85 | 33.6 | 13.7 | 50.9 |

LUTS/BPH, lower urinary tract symptoms/benign prostatic hyperplasia.

* Data source: Optum® De-identified Clinformatics® Data Mart Database (ages 40–64) and Centers for Medicare and Medicaid Services, Medicare 5% Sample (ages 65+), 2006–2013.

[†] Among participants with full enrollment from January 2006 through December 2013 or the death month in death year.

Table 2.

Prevalence of lower urinary tract stones and bladder cancer among male Optum© De-identified Clinformatics® Data Mart enrollees and Medicare beneficiaries* with LUTS/BPH, stratified by age, 2004–2013.

| Age (years) | Lower urinary tract stones (%) | Bladder cancer (%) |
|----------------|--------------------------------|--------------------|
| 40–64 overall | 1.6 | 1.1 |
| 40 – 44 | 1.5 | 0.4 |
| 45 – 49 | 1.4 | 0.6 |
| 50 – 54 | 1.4 | 0.8 |
| 55 – 59 | 1.5 | 1.0 |
| 60 – 64 | 1.7 | 1.5 |
| 65–85+ overall | 1.2 | 2.8 |
| 65 – 69 | 1.1 | 1.8 |
| 70 – 74 | 1.2 | 2.3 |
| 75 – 79 | 1.2 | 2.9 |
| 80 – 84 | 1.3 | 3.5 |
| 85+ | 1.3 | 3.7 |

LUTS/BPH, lower urinary tract symptoms/benign prostatic hyperplasia.

* Data source: Optum© De-identified Clinformatics® Data Mart Database (ages 40–64) and Centers for Medicare and Medicaid Services, Medicare 5% Sample (ages 65+), 2006–2013.

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