Hypothesis / aims of study:

- Symptom overlap between overactive bladder (OAB) and benign prostatic hyperplasia (BPH) presents challenges in the diagnosis and treatment of these conditions in men.
- Research has largely reported on these conditions separately, despite the majority of men presenting with mixed symptoms.
- This study sought to characterize the epidemiology and treatment patterns of adult men (≥40 years) diagnosed with or treated for OAB and/or BPH (collectively referred to as lower urinary tract symptoms [LUTS]).
- Specific objectives included estimating the prevalence of male LUTS in the United States, characterizing treatment and diagnostic patterns, and summarizing clinical and demographic characteristics.

Study design, materials and methods:

- Real-world retrospective cohort study using data from the MarketScan databases from 2012 – 2017; study period starting on January 1, 2013. Data from 2012 were used for baseline characteristics and to establish pre-index treatment and diagnostic patterns. The date of the first observed OAB or BPH-related ICD-9 code and/or fill for an OAB- or BPH-specific medication was defined as the index date.
- Patients were men ≥40 years at the beginning of the study period, with any relevant ICD diagnosis, and/or one medication claim specific to OAB or BPH. (Overall LUTS cohort)
- The denominator for the prevalence estimate was informed by the count of the total number of men ≥40 years on January 1, 2013, and who were observed in the MarketScan database (irrespective of LUTS diagnosis) during the identification period (the first 24 months of the study).

Results:

Patient characteristics (Table 1)

- The prevalence of LUTS was estimated to be 12.2% (LUTS cohort n=17,123).
- The mean age at index was: LUTS cohort: 61.3 years. Treatment Patterns cohort (n=128,951): 58.0 years. New LUTS cohort (n=190,576): 58.5 years.

Table 2  Treatments by lines of therapy for the Treatment Patterns & New LUTS cohorts

- Propensity score matching: One-to-one matching with a 0.05 caliper.
- Treatment sequencing:

Treatment Patterns cohort

- 17,123 (13.3%) individuals received two lines of therapy with alpha-blockers: the most frequently prescribed across all lines of therapy (39 months mean follow-up) (Table 2).
- The most common first-line treatments were BPH treatments, including alpha-blockers (76.7%) and tadalafil (16.1%) (Table 2).
- Following first-line: 3.9% switched from BPH to OAB medication; 1.1% switched from OAB to BPH medication; 0.3% received OAB and BPH in combination (Table 1).
- For patients receiving OAB-specific medication in the first-line:

- Where further lines of therapy were observed, the majority moved to a BPH medication, and a small proportion continued on OAB + BPH combination therapy. 
- Propensity discontinuation treatment or moving to BPH procedures was less for mirabegron than antimuscarinics.
- Only 3.7% who received alpha blockers as first-line moved on to specific medication; 0.7% moved to a combination therapy; 62.4% discontinued treatment.

Results: 

- A Treatment Patterns ("newly treated") cohort was defined as the subset of the overall LUTS cohort who:
  - Had at least 12 months of post-index follow-up data; and
  - Received incident pharmacotherapy during the follow-up period (i.e., those who had no record of therapy during the 12-month pre-index period).
- A New LUTS ("newly diagnosed") cohort was defined to allow for the characterisation of treatment patterns following initial diagnosis.
- Patients were from the overall LUTS cohort with no OAB- or BPH-related diagnosis or treatment codes during the 12-month pre-index period, with at least 12 months of post-index follow-up available.
- Descriptive characteristics of interest included age and Exahuskhar comorbidity index.
- Sequencing of diagnosis and/or treatment for OAB and BPH was characterized for all cohorts.

Interpretation of results:

- LUTS was a prevalent condition among males ≥40 years; 
- Diagnoses and treatments were more common for BPH than for OAB; 
- A large proportion of men who receive alpha blockers as first-line therapy for LUTS continued treatment altogether, while only a small proportion were treated for OAB; 
- Treatment patterns indicated under-treatment of OAB: OAB diagnosis rates were notably lower than BPH diagnosis rates in contrast to BPH, so for which treatment rates were higher than diagnosis rates.

Conclusions:

- Correct diagnosis and management of OAB among males is challenging given the inherent symptom overlap with BPH.
- Our data suggest potential under-treatment of men with LUTS.
- The differences between diagnosis and treatment patterns for BPH and OAB highlight the potential undertreatment of OAB in particular.

Table 1 Diagnostic and treatment sequencing observed during the 12 months post-index

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Age (mean, SD)a</th>
<th>OAB Dx only</th>
<th>BPH Dx only</th>
<th>Never treated for OAB or BPH</th>
<th>BPH Rx and OAB Rx</th>
<th>OAB Rx only</th>
<th>OAB Rx then BPH Rx</th>
<th>BPH Rx then OAB Rx</th>
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<td>50-59</td>
<td>60+</td>
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<td>50-59</td>
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<tr>
<td>50-59</td>
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<td>18.1%</td>
<td>15.1%</td>
<td>17.0%</td>
<td>13.0%</td>
<td>20.2%</td>
<td>14.9%</td>
<td>18.9%</td>
</tr>
<tr>
<td>60+</td>
<td></td>
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<td>9.2%</td>
<td>8.9%</td>
<td>9.2%</td>
<td>8.8%</td>
<td>9.4%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>

Table 2 Treatments by line of therapy for the Treatment Patterns & New LUTS cohorts

- A higher proportion of men who received alpha-blockers as their first-line discontinued treatment altogether (62.4%), compared to those receiving antimuscarinics (55.5%) or mirabegron (47.2%).

New LUTS cohort

- Among newly diagnosed patients who initiated post-index treatment (n=118,591), 60.3% of all newly-diagnosed patients, the median time to initiating treatment was 128 days (interquartile range 21-466 days).
- Similar to the Treatment Patterns cohort, the most common first-line treatments were alpha-blockers (76.9%) and tadalafil (16.4%) (Table 2).
- Among patients initiating a first-line of therapy, 12.8% went on to receive a second-line of therapy, and 6.6% a third-line (Table 2).