The current status and progression of symptoms and comorbidities among male lower urinary tract symptoms patients in China: a multicenter study from Prostatic Obstruction Investigation Team (POInT)

December 19, 2017
The POInT Study Design

**Title**

The current status and progression of symptoms and comorbidities among male lower urinary tract symptoms patients in China: a multicenter study from Prostatic Obstruction Investigation Team (POInT).

**Aims**

Aim one: To investigate the symptom features and comorbidities among male lower urinary tract symptoms patients in China.

Aim two: To determine the progression of lower urinary tract symptoms and comorbidities after medication or surgical treatment during prospective follow-ups.

**Inclusion Criteria**

1. Male, 45 years or older.
2. The presence of lower urinary tract symptoms, i.e. frequency, urgency, urge incontinence, dysuria, post-micturition dribble, etc.
3. All participants have signed the informed consent form.
4. Clinical data comes from 23 selected hospitals spread across China.

**Exclusion Criteria**

1. Lower urinary tract symptoms as a result of urethral stricture, stone diseases, chronic prostatitis, space-occupying lesions etc.
2. Diagnosis or suspicion of renal, ureteral, bladder, prostate, urethral or pelvic tumor.
3. Known neurogenic or congenital lower urinary tract dysfunction.
4. Known urinary tract, prostate or pelvic surgical history.
5. Existence of anatomical abnormalities of the urinary tract (e.g. diverticulum of the bladder or urethra, ectopic ureteral orifice etc.).
6. The presence of acute conditions, such as, urinary tract infection, fever, heart failure etc.
7. Patients with poor compliance or cognitive competence.
Study design flow diagram

**Overall design**

1. Recruited male LUTS patients
2. History
   - Physical examination
   - Urinalysis
   - Urinary tract ultrasonography
   - Questionnaires
3. Inclusion criteria fulfilled
4. Completion of informed consent form
5. Baseline assessment

Stage I

Stage II

Follow-up assessment

Data collection and analysis
**Stage I**

Patients fulfilled criteria and signed the informed consent

Clinical assessment

- Basic information
- LUTS assessment
- Renal function
- Other comorbidities

Data collection and analysis

**Stage II**

Patients from stage I

- Oral medication
  - 6 months follow-up
  - 12 months follow-up
  - 18 months follow-up
  - 24 months follow-up
  - 36 months follow-up

- Prostate Surgery
  - 1 months follow-up
  - 6 months follow-up
  - 12 months follow-up
  - 18 months follow-up
  - 24 months follow-up
Statistical Analysis

The statistical analysis will be performed using SAS software version 9.4 or higher. Quantitative data will be presented as mean ± standard deviation; Categorical and ranked data will be presented using frequency and proportion. Normal distributed and equal variance quantitative data will be analyzed using independent sample t test, otherwise using a Wilcoxon rank sum test. Categorical data will be assessed by Chi-square test and Fisher's exact test. Ranked data will be analyzed by Wilcoxon rank sum test. Multivariate analysis logistic regression will be used to screen risk factors in the binary variables. The level of significance will be established at <0.05.