European registry evaluating management practices of general practitioners and urologists and pharmacological treatment outcomes in patients with Lower Urinary Tract Symptoms associated with Benign Prostatic Hyperplasia (LUTS/BPH). Protocol ID: EAU-RF 08-02

**Timeline**

- Start date recruitment: February 2010
- End date of recruitment: April 2011
- End date of registry: April 2013
- Status: Completed

**In Brief**

This is a registry conducted within a sample of European Union (EU) general practitioner (GP) outpatient clinics and urologist’s hospital or office based clinics. The registry aims to collect real-life data across the different countries on i) the usual management of Lower Urinary Tract Symptoms associated with Benign Prostatic Hyperplasia (LUTS/BPH), ii) the effect of LUTS/BPH and its pharmacological treatment outcomes on LUTS/BPH-related health status, general quality of life (QoL), and sexual function.

**Primary objective:**

- To evaluate symptom persistence (defined as International Prostate Symptom Score [IPSS] of 8 points or more) in patients with LUTS/BPH under LUTS/BPH pharmacological treatment.

**Secondary objectives:**

- To evaluate the effect of LUTS/BPH and LUTS/BPH pharmacological treatment on symptom improvement and worsening
- To evaluate the effect of LUTS/BPH and LUTS/BPH pharmacological treatment on disease-specific and generic QoL measures;
- To evaluate patients’ and physicians’ satisfaction with treatment;
- To gain a better understanding of the relationship between sexual dysfunction and LUTS/BPH, and its changes under pharmacological treatment (presently/recently untreated patients only);
- To describe real-life proportion and type of disease progression events;
- To describe real-life LUTS/BPH management practices by GP’s and urologists, and assess adherence to BPH Guidelines (presently/recently untreated patients only);
- To assess direct costs of LUTS/BPH management in relation to treatment outcomes and progression.

**Registry design**

Two patient populations were studied in the registry:

1) patients with LUTS-BPH who presently / recently are untreated with pharmacological agents for LUTS-BPH and start BPH pharmacological treatment at or directly after the baseline visit and

2) patients with LUTS-BPH presently / recently treated with BPH pharmacological treatment who will continue their BPH pharmacological treatment.

After baseline, the patient will visit the physician at the same frequency as in routine practice which is at 6-, 12 and 24-months for the presently / recently untreated patients. For presently/recently treated patients visits are scheduled at 12 and 24-months. During the visits patient data (including clinical progression events) and outcomes of the questionnaires are collected in a web-based data management system. The registry also collects data on how physicians follow existing guideline recommendations.

Please find the full description of the trial on the Nederlands Trial Register.
Patient recruitment

2175 patients were registered in 5 European countries (the United Kingdom, France, Germany, Italy and Spain) across 86 urological and general practitioner's centers.

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