

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 Number: EAU-RF 08-02

Timeline

Start date recruitment:	February 2010	End date of registry:	April 2013
End date recruitment:	April 2011	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.

National Coordinators / Steering Committee

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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 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

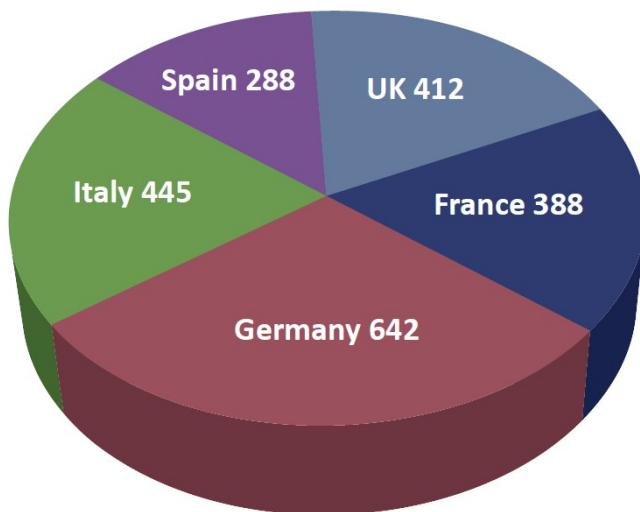
Two patient populations were studied in the registry:

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

and

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

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



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.

Publications

- Tubaro A, Berges R, Speakman M, de la Taille A, Martínez-Piñero L, Patel A, Caris C, Witjes W: 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. The Evolution project. Poster SIU, Glasgow, 2014. Urology 84-4 Supplement 1 Oct. 2014 S222-223. UP.173 2014.
- Tubaro A, Berges R, Speakman M, de la Taille A, Martínez-Piñero L, Patel A, Caris C, Witjes W: 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. The Evolution project. Poster ICS, Rio de Janeiro, 2014. Neurourology and Urodynamics. 33 (6) pp 695-696. 2014.
- Tubaro, R. Berges, M. Speakman, A. de La Taille, L. Martínez-Piñero, A. Patel, C. Caris, W. Witjes, EAU Research Foundation, Arnhem, The Netherlands: Evolution: A European registry evaluating management practices of pharmacologically treated patients with LUTS associated with BPH. Symptomatic improvement, progression and treatment discontinuation results. A comparison between European countries. Podium Presentation, AUA 2015. J. of Urol. 193 Issue 4, Supplement, pages e332-e333. [https://www.jurology.com/article/S0022-5347\(15\)01603-1/pdf](https://www.jurology.com/article/S0022-5347(15)01603-1/pdf)
- A. Tubaro, R. Berges, C. Caris, A. de La Taille, F. Esperto, L. Martínez-Piñero, M. Speakman, W. Witjes: The prevalence of urgency in patients with lower urinary tract symptoms due to benign prostatic enlargement. Analysis of the evolution registry. Presented at AUA 2016. Journal of Urology 195 (4S, supplement) MP35-06, 2016. <https://doi.org/10.1016/j.juro.2016.02.1598>
- Davis NF, Jack GS, Witjes WP, Bjartell A, Caris C, Patel A, de la Taille A, Bolton DM, Tubaro A: Medical therapy versus transurethral resection of the prostate (TURP) for the treatment of symptomatic benign prostatic enlargement (BPE): A cost minimisation analysis". Accepted World Journal of Urology August 2018. <https://doi.org/10.1007/s00345-018-2454-9>
- Malde S, Patel A, Martínez-Piñero L, de la Taille A, Bjartell A, Tubaro A, Witjes W. Caris C. Incidence of Nocturia in Men with Lower Urinary Tract Symptoms Associated with Benign Prostatic Enlargement and Outcomes After Medical Treatment: Results from the Evolution European Association of Urology Research Foundation Prospective Multinational Registry. Eur Urol Focus (2019). <https://doi.org/10.1016/j.euf.2019.07.003>

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