

Finazzi Agrò E<sup>1</sup>, Palleschi G<sup>1</sup>, Giannantoni A<sup>2</sup>, Del Popolo G<sup>3</sup>, Soligo M<sup>1</sup>, Li Marzi V<sup>1</sup>, Serati M<sup>1</sup>, Pistolesi D<sup>1</sup>, Pastorello M<sup>1</sup>, Giammò A<sup>1</sup>, De Rienzo G<sup>1</sup>, Tubaro A<sup>4</sup>

1. Board Italian Society of Urodynamics, 2. University of Perugia, Italy, 3. Board Italian Society of Urodynamics, 4. Fondazione SIU Urologia - Italian Society of Urology

## THE ITALIAN OAB REGISTRY: DESCRIPTION OF CHARACTERISTICS OF AN ITALIAN PROJECT TO ASSESS MANAGEMENT AND CLINICAL OUTCOMES OF PATIENTS SUFFERING FROM OVERACTIVE BLADDER.

### Hypothesis / aims of study

Overactive bladder (OAB) prevalence in Europe is around 16% of the whole population. The prevalence increases with age and therefore, considering the progressive aging of the European population, it is likely to have a significant increase of OAB patients looking for treatment in the future years, also taking into account the negative impact on quality of life of OAB. Although the literature provides useful informations about epidemiology, diagnosis and treatment of OAB patients, there is a lack of evidence about the most convenient, practical, cost-effective mode of evaluation and treatment of OAB patients, considering also patients' preferences and costs. For this reason, a panel of experts has developed a specific national registry to investigate the management of patients suffering from OAB in a European country (Italy) in the "real life" and outside specific study trials. We present the design of a 4 year OAB registry.

### Study design, materials and methods

The Italian registry has been designed as a case report form (CRF) sub-divided in different parts. A preliminary section is dedicated to patient's feasibility, including age (>18 due to legal aspects), sex, race, BMI, and other general features (smoke, alcohol intake); in this section an informed consent is also obtained; data will be collected anonymously. Finally, in the same section the OAB onset and inclusion/exclusion criteria are reported. In the second part, bladder symptoms are assessed by OAB-questionnaire, the ICI-Q questionnaire, and other standardized methods (severity scales) that allow to assess symptoms severity. Bladder management is also included in this evaluation (voiding by straining, use of clean intermittent catheterisation, use of pads, use of indwelling urethral catheterisation). In this part of the registry concomitant treatments are also recorded, together with the clinical history of the patients (comorbidities); special attention will be dedicated to previous therapies and, in case, reason for failure or discontinuation. The proposed therapy(ies) will be recorded at the first visit. Patients will then be followed for 4 years: during this long-time interval, every subsequent medical visit will be recorded and any change of symptoms and treatment will be reported until the final assessment.

### Results

The registry has been tested by a panel of experts simulating the data filling that will be proposed to the urologic and gynaecologic centres that will like to participate. Participation will be free and the access to the registry will be available through the websites of two scientific Italian societies after a registration procedure. After this step, a user name and passwords will be provided to the medical doctors who will declare to be responsible for inserting data of their own centres. All patients data will be anonymous. Clinical data will be first available next year (estimated first report on July 2018) and it will be updated in the following 3 years to complete the scheduled length of the registry. The epidemiological importance of OAB requires precise management under both the clinical and socio-economic points of view. In fact, an incorrect assessment of the patient from diagnosis to treatment is responsible for worsening patient's quality of life and for increasing costs for the public healthcare system. For these reasons it is important to exactly establish what's the current status of the management of patients with OAB in a European country such as Italy and to understand what is the real percentage of subjects responding to the different available treatments and their adherence to the treatment. The main goal of this registry is to provide data able to guide our clinical behavior, helping us to select treatments on the basis of the clinical picture of the patients and not just as list of increasingly invasive therapies. If this goal will be achieved, we will be able also to reduce consistently the costs of OAB management, avoiding treatments with lower rates of success.

### Concluding message

An Italian OAB Registry has been developed and will collect data from patients in the future 4 years. Significant socio-economic information regarding this condition and data regarding clinical management of OAB patients in Italy are expected. We believe that this register will help us to improve OAB patients management and success rate of treatments, and to understand if there may be strategies to reduce direct and indirect costs for patients and the public healthcare system.

### Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** The projects has been already submitted for approval to Ethical Committee **Helsinki:** Yes **Informed Consent:** Yes