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PRELIMINARY ANALYSIS OF SPANISH PATIENTS WITH OVERACTIVE BLADDER: DATA FROM A NATIONAL REGISTRY

Hypothesis / aims of study

Describe the baseline characteristics and the preliminary results of the intradetrusor injection of onabotulinumtoxinA (onabotA BOTOX®; Allergan, Inc.) in patients with idiopathic (iOAB) and neurogenic (nOAB) overactive bladder in Spain.

Study design, materials and methods

With the aim to capture the data about the population treated with onabotA for symptoms of OAB in Spain, the expert panel of the Spanish Group of Botulinum Toxin A in Urology designed a prospective, multicenter, naturalistic, observational study. 24-hr voiding frequency, incontinence [UI] and urgency, urodynamic parameters have been collected, as well as OAB-q scores and adverse events. Data collection started in February 2011 through an on-line database password encrypted and safeguarding confidential information.

Results

Here we report the results of the analysis of the firsts 88 patients included in the registry, mainly female (77.3%, N=68). Mean age \pm SD was 59.87 ± 17.90 years, 56.8% (N=50) of them suffered from iOAB, 43.2% (N=38) nOAB. According to the clinic guidelines agreed by the expert panel, iOAB patients received intradetrusor injection of onabotA 100 or 200 U and nOAB patients 200 or 300 U. 95.6% of idiopathic and 77.4% of neurogenic patients reported urgency at pre-treatment visit and 9 patients were reported to use pads (mean: $7.5/\text{day} \pm 6.06$). When compared with baseline, urgency, pad use were significantly reduced with onabotA ($p < 0.05$) at the first urodynamic control (aprox 4 months after the injection). At the same time point, is possible to observe improvements in maximum cystometric capacity [MCC] and maximum detrusor pressure [MDP] during 1st involuntary detrusor contraction [IDC] versus baseline in both groups of patients. In particular, in nOAB population, MDP as well as MCC significantly ameliorated after treatment. AEs were infrequent and mainly limited to the urinary tract (UTIs urinary retention).

Concluding message

This registry is the first observational study of patients with OAB treated with onabotA in Spain that will provide a naturalistic, prospective data that can be utilized to assess the efficacy and safety of the treatment. Preliminary results showed that onabotA caused significant improvements in patients with iOAB and nOAB, and the treatment is in general well tolerated. This pool of data could also be useful for optimizing treatment, following up easily the patients and predicting adverse events.

Disclosures

Funding: no disclosures **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** it is not a clinical trial **Helsinki:** No **Helsinki not Req'd:** does not need it **Informed Consent:** Yes