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Hamid R[1], Lorenzo-Gómez M F[2], Henrichs T[3], Aboushwareb T[4], Farrelly E[5]
1. *University College London Hospitals, London, UK,* ***2.*** *University Hospital of Salamanca, Salamanca, Spain,* ***3.*** *Ecron Acunova, Frankfurt, Germany,* ***4.*** *Allergan plc, Irvine, CA, USA,* ***5.*** *Södersjukhuset, Stockholm South General Hospital, Stockholm, Sweden*

SIGNIFICANT REDUCTION IN INCONTINENCE EPISODES WITH ONABOTULINUMTOXINA AND CLINICALLY MEANINGFUL IMPROVEMENTS IN THE PRACTICAL ASPECTS OF OVERACTIVE BLADDER PATIENTS' DAILY LIVES IN REAL-WORLD CLINICAL PRACTICE

Hypothesis / aims of study
The symptoms of overactive bladder (OAB), particularly urinary incontinence (UI), have a substantial negative effect on patients' quality of life. Management of these symptoms with conservative interventions such as long-term use of incontinence pads presents a considerable cost burden to patients and healthcare systems. OnabotulinumtoxinA has been shown to significantly reduce UI and improve patients' quality of life and their perception of treatment benefit in two large, randomized, placebo-controlled, phase 3 trials. There are few published reports on the real-world use of onabotulinumtoxinA in everyday clinical practice. This prospective real-world study examined the efficacy of onabotulinumtoxinA and the practical impact of urinary symptom improvements on OAB patients' daily lives, including the use of incontinence products and the frequency of the need to urinate.

Study design, materials and methods
This multicentre, prospective, observational, non-interventional, study enrolled idiopathic OAB patients ≥18 years of age in the UK, Germany, Sweden, and Spain. All patients were inadequately managed by ≥1 anticholinergic and had to be willing to initiate clean intermittent catheterisation if necessary. Patients who had ever received botulinum toxin treatment for OAB or had received treatment with any type A botulinum toxin in the preceding 18 months were excluded. Patients were treated with onabotulinumtoxinA, and treatment details, retreatment, or discontinuation of therapy were decided by the physician. Assessments at week 12 post-treatment included mean number of incontinence products used, concomitant use of anticholinergic/other OAB therapies, mean (co-primary endpoint) and percentage change in UI episodes/day, proportions of patients with a positive response ("improvement" or "great improvement" in their urinary condition) on the Treatment Benefit Scale (TBS; co-primary endpoint), mean and percentage change in urgency UI (UUI) episodes/day, and proportions of patients with ≥50% and 100% reduction in UI and UUI episodes/day. An evaluation in which patients ranked each urination during the 3 days prior to a study visit by the need to urinate from 0-3 on a 4-point scale was also included. Adverse events were recorded. The safety population (n=485) was comprised of all patients who received ≥1 onabotulinumtoxinA treatment. Treatment outcomes were assessed for patients with data available at the evaluated timepoint (UI and UUI episodes, n=159; TBS response, n=144).

Results
The patients' mean age was 63.7 years and 85.6% were female. Mean onabotulinumtoxinA dose/patient at treatment 1 was 100.3U. At the time of this analysis, 485 patients had received at least 1 dose and 3 patients had received 2 doses. The mean number of injection sites was 17.6 ± 5.1. Patients reported a 2- to 3-fold decrease in the use of incontinence products at week 12 after onabotulinumtoxinA treatment; patients used an average of 71.9 pads/liners and 12.7 diapers per month at baseline compared with 31.8 and 4.3 after treatment, respectively. Use of concomitant anticholinergic/other OAB medications was low at week 12 (2.1%). Treatment with onabotulinumtoxinA resulted in improvements in OAB symptoms, including significant mean decreases in UI episodes/day (-7.7; P<0.001) and percentage reductions from baseline in UI episodes (-63.7%; P<.001). Similarly, significant decreases were seen in the mean UUI episodes/day (-5.1; P<.001) and percentage change from baseline in UUI episodes/day (-61.1; P<0.001). A high proportion of patients (70.6%) achieved ≥50% reduction in UI episodes/day and 23.9% became "dry" (100% UI reduction). A majority of patients (87.5%) reported an improvement in their urinary symptoms on the TBS. Patients responded "I could delay urination as long as necessary without worrying to wet myself" with greater frequency at week 12 postinjection than at baseline (mean score: 7.6 vs 2.0), and "I could not delay urination, had to rush to the toilet" with lesser frequency at week 12 postinjection than at baseline (mean score: 5.1 vs 18.6). OnabotulinumtoxinA was well tolerated; the rate of adverse drug reactions was 2.9%.

Interpretation of results
In this interim analysis of a real-world study, treatment with onabotulinumtoxinA resulted in significant reductions in UI and UUI episodes in patients who were inadequately managed by ≥1 anticholinergic. High proportions of patients achieved ≥50% reduction in UI episodes and and reported treatment benefit; 23.9% of the patients became 'dry". Improvements were similar to those in prior phase 3, randomised, controlled clinical trials. In addition, onabotulinumtoxinA-treated patients reported decreases in the use of incontinence products and in the frequency of the need to urinate.

Concluding message
OnabotulinumtoxinA significantly improved the urinary symptoms and provided treatment benefit in OAB patients in everyday clinical practice. The reductions in incontinence had clinically meaningful effects on the practical aspects of patients' daily lives including decreases in the use of incontinence products and the frequency of the need to urinate. OnabotulinumtoxinA was well tolerated.

Disclosures
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