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Urogynecology digest

Presented by Tamara Grisales

Efficacy and safety of OnabotulinumtoxinA therapy are sustained over 4 Years of treatment in patients with neurogenic detrusor Overactivity: Final results of a long term extension study

Michael Kennelly, Roger Dmochowski, Heinrich Schulte-Baukloh, Karen Ethans, Giulio del Popolo, Courtney Moore, Brenda Jenkins, Steven guard, Yan Zheng, and Gilles Karsenty. Neurourology and Urodynamics DOI 10.1002/nau

This was a 3-year extension study from a prospective, multicenter trial evaluating the efficacy of onabotulinumtoxin A for the treatment of urinary incontinence (UI) from neurogenic detrusor overactivity (NDO). Patients with NDO due to multiple sclerosis (MS) or spinal cord injury (SCI) who had failed at least one anticholinergic, and completed one of two 52-week phase III trials, were eligible to participate.

Patients received additional treatments of onubotulinumtoxin A by patient request if they reported ≥1 UI episode/3 days AND ≥12 weeks had elapsed since last treatment. Initially, the protocol allowed for patients to receive the same dose (200u or 300u) that had been administered in the original study. However, after 2011, 200 unit dose was used for all extension study treatments.

The primary outcome was a change in UI episodes per day from study baseline at week 6 after each treatment. Baseline was defined as the value prior to the first treatment in the phase III studies. Secondary outcomes included: the proportion of patients with >50% and 100% reductions from baseline in UI episodes/day; changes from baseline in volume/void, and Incontinence-Quality of Life (I-QOL) total summary score. Adverse effects (AE) included urinary retention and initiation of CIC and development of toxin neutralizing antibodies.

Of the 396 patients who entered the extension study, 240 (60.6%) were followed at least 4 years. Only 2% (8/396) discontinued due to lack of efficacy, 3% (12/396) due to AEs, and 5.8% (23/396) were lost to follow up.

The mean participant age was 46.4 years. At baseline, study patients reported mean of 4.5 UI episodes/day, and 150.7 mL/void. At week 6 after each treatment, 200 units reduced the number of mean daily UI episodes from baseline by 3.2–4.1 UI episodes/day and increased voided volumes by 133.2–166.1 mL. Secondary outcomes were as follows: The proportion of patients achieving ≥50% reduction in UI episodes was 83.2–91.1%, and the proportion achieving 100% reduction in UI episodes was 43–56% over 6 treatments. I-QOL scores nearly doubled from baseline of 34.4 after each treatment. Median duration of treatment effect was <6 months in 22%, 6–12 months in 52% and >12 months in 26% of patients. Adverse effects included urinary retention measured by denovo CIC rates. Of those who had not initiated CIC prior to treatment, 29.5% initiated CIC following their first treatment in the extension study. Denovo CIC rates were much lower after subsequent treatments (3.4–6.0%). Development of toxin-neutralizing antibody occurred 2.3% (8/381) of patients enrolled in the extension study. Antibody formation was more common in those receiving higher doses and those receiving treatment more frequently (median time between treatments 4.9 vs 9.1 months).

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