Beyond The Wrinkles: Botulinum Toxin A and Its Innovative Treatments for Bladder Disorders

Panel discusses management, safety and efficacy of botulinum toxin to treat overactive and neurogenic bladder

Orlando, FL, May 17, 2014 — While Botulinum toxin A (BTX-A) has become a household name for addressing wrinkles, two studies presented at the 109th Annual Scientific Meeting of the American Urological Association (AUA) are proving BTX-A to be more than just a cosmetic solution. During a joint press conference at the Orlando County Convention Center in Orlando, FL, May 17 at 11:30 a.m. ET, researchers will share data highlighting this therapy as an effective treatment option for bladder disorders such as neurogenic bladder dysfunction and overactive bladder (OAB).

Study Details

Botulinum Toxin A: The Shift to a Minimally Invasive Management of Neurogenic Bladder (#MP80-14): BTX-A has not only become an effective minimally invasive alternative to treating neurogenic detrusor overactivity (NDO), but it has also changed modern treatment of NDO, according to researchers from the University of Kansas in Kansas City, KS. Researchers performed a retrospective chart review of patients seen in their urology practice from 2003-2013 with anticholinergic refractory NDO who underwent augmentation cystoplasty or cystectomy with urinary diversion. They analyzed their charts and testing data to determine how many patients would have met the indication for treatment with BTX-A - fifty-nine patients met inclusion criteria for the study. They also then compared their practice from when BTX-A was approved in 2011 for the treatment of NDO to see how their treatment of NDO has changed.

Results showed:

- Out of the 59 patients, 34 underwent reconstructive surgery for NDO and 25 were treated with BTX-A detrusor injections (available since August 2011).
- Review of the 34 patients who underwent open surgery revealed 62 percent would have met indication for BTX-A injections.
- Thirty of the 34 patients who underwent reconstructive surgery had surgery in the first eight years of the study, resulting in nearly four open surgeries per year for NDO. After BTX-A was approved by the FDA in 2011; the number of open reconstructive surgeries at the University of Kansas was reduced to less than two per year. During that same time period, an average of 12 patients per year were managed with BTX-A.

Through the examination of this data, researchers concluded BTX-A has become an effective minimally invasive alternative to urinary reconstruction and is evolving the care of patients with NDO.

Prospective Multicenter Double-Blind Placebo-Controlled Trial of the Efficacy and Safety of Liposomal Botulinum Toxin-A Instillation vs. Placebo in Treatment of Patients with Refractory Overactive Bladder (#MP33-02): A two-center, double-blind, prospective, randomized, placebo-controlled, study conducted by researchers in Taiwan and the United States sought to understand the safety and efficacy of a single injection of BTX-A for the treatment of refractory overactive bladder (OAB) in contrast to the cystoscopic procedure with 20-30 needle injections. The study enrolled male and female patients with OAB who were inadequately managed by antimuscarinics, a common medication treatment option. Subjects were randomized to either BTX-A or placebo with the goal of understanding the average number micturitions at four weeks post-treatment. The study also examined the average sense of urgency to use the restroom and
number of incontinence episodes, OAB symptom score, and urgency severity score. Safety assessments included adverse events and urine volume after attempting to empty the bladder.

Results showed:

- BTX-A reduced urinary frequency compared to placebo with no associated increase in urine volume remaining in the bladder.
- Frequency of urgency events also decreased with treatment; however these improvements did not reach statistical significance with respect to the placebo group.
- The urgency severity score decreased for the treatment group as compared to the placebo group at four weeks.
- The results were inconclusive on the effect of treatment on urge incontinence episodes citing the sample population as having a relatively low baseline incidence.

Researchers concluded a single injection of BTX-A decreased several OAB symptoms four weeks post-treatment and was tolerated with a safety profile similar to placebo. They also uncovered no treatment-associated increase in urine volume remaining in the bladder after attempting to empty it. Single injections of BTX-A may be a promising approach for treatment of refractory OAB without the need for multiple needle injections and its associated risk of urinary retention.

“It seems counterintuitive that injecting one of the most poisonous chemicals known to man into the body could have positive results,” explains Roger Dmochowski, MD, director, Pelvic Medicine and Reconstruction at Vanderbilt University. “BTX-A, however, is proving to be an effective solution for bladder disorders with patients experiencing little to no side effects, improved bladder function and potentially avoiding more invasive surgery options.”

NOTE TO REPORTERS: Experts are available to discuss this study outside normal briefing times. To arrange an interview with an expert, please contact the AUA Communications Office at 410-689-3932 or e-mail cfrey@AUAnet.org.

About the American Urological Association: The 109th Annual Meeting of the American Urological Association takes place May 16 – 21 at the Orange County Convention Center in Orlando, FL.

Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology, and has more than 20,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

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