

[Beyond The Wrinkles: Botulinum Toxin A and Its Innovative Treatment for Bladder Disorders](#)

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

**New Orleans, LA, May 15, 2015** — While Botulinum toxin A (BTX-A), known to the public as Botox®, is commonly associated with smoothing wrinkles for a more youthful appearance, three studies presented at the 110<sup>th</sup> 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 New Orleans Ernest N. Morial Convention Center in New Orleans, LA, May 15 at 1:30 p.m. CT, researchers will share data highlighting this therapy as an effective treatment option for bladder disorders such as overactive bladder (OAB) and neurogenic bladder dysfunction.

**Study Details**

Publication Number: PI-04

**Durable Reductions in Urinary Incontinence with Long-Term OnabotulinumtoxinA Treatment in Patients with Overactive Bladder Syndrome: Final Results of 3.5-Year Study**

Presenting final results of a multicenter study evaluating the long-term efficiency and safety of repeated BTX-A treatments in patients with OAB, researchers from Canada, Europe and the United States found after just a few weeks—and still after one year—a higher percentage of patients receiving Botox injections reported control of their urinary incontinence symptoms.

Patients were eligible to enter an extended three year study and receive multiple BTX-A treatments after completing a 24-week randomized phase three trial. Botox, a treatment for OAB that's delivered via injection, works by blocking the muscles and nerves that lead to a feeling of urgently needing to urinate. Patients were treated "as needed" based on their request and fulfillment of pre-specified qualification criteria. Researchers assessed the duration between treatments and any side effects associated with the treatment option.

Results showed:

- More than half of the 543 patients completed the study.
- Patients who received fewer treatments had a longer duration of effect than patients who received more treatments.
- Nearly 40 percent of patients reported control of their urinary incontinence symptoms for at least six months, with nearly 30 percent reporting control of their symptoms for more than one year.
- The most common side effect of the treatment was a urinary tract infection.

Through the examination of this data, researchers concluded long-term treatment with BTX-A resulted in consistent reductions of daily urinary incontinence episodes with no increases in the rate of adverse effects due to repeated treatment.

**Study Details**

Publication Number: PD27-08

**Real World Retention Rates After Intravesical OnabotulinumtoxinA for Idiopathic Overactive Bladder**

When no identifiable cause for overactive bladder can be found, it is termed idiopathic OAB. The incidence of idiopathic OAB is 12-19 percent and among the list of therapies, according to researchers in Woodbury, MN, is BTX-A delivered via injection. The primary objective of the study was to determine the incidence of acute urinary retention requiring catheterization after initial BTX-A treatment for idiopathic OAB and to evaluate the factors predicting acute urinary retention after BTX-A injections. Researchers examined medical records of patients undergoing BTX-A treatments since 2010, excluding patients with interstitial cystitis or neurogenic bladder. The factors analyzed to determine association with acute urinary retention or the inability to voluntarily pass urine included age, gender, diagnosis of diabetes, baseline post void residual presence of urodynamic detrusor overactivity, bladder capacity, peak flow rate and BTX-A dose.

Results showed:

- Of the patients analyzed, the overall incidence individuals needing catheterization after initial BTX-A injections was nearly 21 percent.
- Diabetic patients comprised nearly 25 percent of the group with acute urinary retention.
- The overall incidence of a urinary tract infection was 30 percent reported by 62 percent of patients in the acute urinary retention group and 22 percent of patients in the non-acute urinary retention group.

- Forty percent of patients continued with a second BTX-A treatment despite acute urinary retention.

Researchers concluded the overall incidence of acute urinary retention requiring catheterization is 30 percent. They also determined standardization of acute urinary retention definition is needed to provide better counsel to patients considering BTX-A injections as a treatment option, as well as, more research into specific risk factors.

### **Study Details**

Publication Number: PD1-01

### **Long-term Efficacy and Safety of OnabotulinumtoxinA in Patients with Neurogenic Detrusor Overactivity: Analysis among Patients Who Completed 4 Years of Treatment**

Long-term outcomes following repeat BTX-A injections for urinary incontinence due to neurogenic bladder are not well studied, which is why researchers from Canada, France, Germany, Italy and the United States were determined to assess the efficacy and safety outcomes in patients with neurogenic bladder who completed four years of BTX-A treatment. Researchers followed patients who entered a three year extension study to receive multiple BTX-A treatments after completing a 52-week phase three study of BTX-A injections for treatment of urinary incontinence due to neurogenic bladder. A total of 227 patients completed the entire four year study. Outcomes were assessed by year of treatment with each patient's six week outcome measure calculated from all treatments received in a given year. Efficacy and safety assessments included mean change from baseline (at week six) in the number of daily urinary incontinence episodes, Incontinence-Quality of Life total summary score, the median duration of the effect, adverse effects of treatment and the initiation of de novo clean intermittent catheterization.

Results showed:

- The majority of patients (88-90 percent) experienced a 50 percent or more reduction in urinary incontinence episodes a day.
- Forty-four to 52 percent of patients reported a full reduction in urinary incontinence episodes per day each year of treatment.
- Incontinence-Quality of Life scores were consistently 2-3 times greater year over year with treatment.
- The most common adverse effect in patients was a urinary tract infection with no increase in incidence over time.

The study concluded neurogenic detrusor overactivity patients who completed four years of BTX-A treatment experience long-term benefits with consistent improvements year to year in their daily urinary incontinence episodes. There were no new safety signals observed over time.

"As more research is being performed, the results continue to confirm BTX-A is more than just a solution for cosmetic procedures," explains Michael Chancellor, MD, urologist and director, Aikens Neurourology Research Center at Beaumont Health System, Royal Oak, Michigan. "Patients who suffer from overactive bladder or neurogenic bladder now have a minimally-invasive treatment option giving them the successful results they want with minimal side effects.

**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](mailto:cfrey@AUAnet.org).**

***About the American Urological Association:*** The 110<sup>th</sup> Annual Meeting of the American Urological Association takes place May 15 - 20 at the New Orleans Ernest N. Morial Convention Center in New Orleans, LA.

*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 21,000 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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