TITLE ABSTRACT: =Refractory Idiopathic Urge Urinary Incontinence and Botulinum A Injection

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TEXTE OF ABSTRACT IN FOLLOWING ORDER=

Introduction and Objective: The Refractory Urge Incontinence and Botulinum A Toxin Injection (RUBI) randomized clinical trial was designed to compare the effect of 200 U of intra-detrusor Botulinum A toxin (BoNT-A) versus placebo on improvement in urge incontinence symptoms in neurologically normal women with DOI refractory to at least two first-line treatments. This study also sought to assesses changes in patient quality of life and incidence of urinary incontinence episodes based on standardized bladder diaries. Rates of post-treatment urinary retention and other associated complications are also assessed.

Methods: This IRB approved, multi-center registered trial randomized women with refractory urge incontinence, detrusor overactivity incontinence (DOI) and >6 urge incontinence episodes in 3 days to BoNT-A

or placebo (2:1). Refractory was defined as inadequate symptom control after > 2 attempts at pharmacotherapy and > 1 other first-line therapies for DOI. The primary outcome measurement was time to failure evidenced by a Patient Global Impression of Improvement (PGI-I) score ≥4 at least two months after the injection or changes in treatment (initiation or increase) at any time after the injection. Safety data, including urinary retention (defined as a PVR >200 ml, irrespective of symptoms), was obtained at specified time points.

Results: Approximately 60% of women who received BoNT-A had a clinical response based on the PGI-I; the median duration of their responses was 373 days, significantly longer than placebo (<62 days, p<0.0001). In the BoNT-A group, urinary retention (12/28, 43%) and urinary tract infection in those with retention (9/12, 75%) exceeded expected ranges and further injections were stopped after 43 subjects had been randomized (28 BoNT-A:15 placebo).

Conclusions: Local injection of 200 U BoNT-A was an effective and durable treatment for refractory OAB. However, transient urinary retention was experienced in 43% of patients. BoNT-A for idiopathic OAB is still under investigation.

Key Words: Botulinum toxin, Urinary Incontinence, Urinary Retention, Urge Incontinence, Clinical Trial
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