doi: 10.4274/jus.2015.03.003

Re: A Randomized Double-Blind Placebo-Controlled Phase 2 Dose-Ranging Study of OnabotulinumtoxinA in Men with Benign Prostatic Hyperplasia

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Eur Urol 2013;63:496-503.

EDITORIAL COMMENT

Botulinum toxin is a neurotoxin inhibiting the release of acetylcholine and is used in various fields of medicine. Recently, it has been proposed as an alternative minimally invasive treatment modality for patients unresponsive to oral therapies. The present study is the largest prospective, randomized and placebo-controlled study investigating the efficacy and safety of different onabotulinumtoxinA (BTX-A) doses in men with moderate to severe lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). 100 U, 200 U and 300 U BTX-A doses via transperineal or transrectal route were injected within the transition zone of each lateral lobe. 69.7% of patients (115 of 380) completed the 72-week study. The authors reported significant improvement for all treatment arms including placebo from weeks 2 through 72 including the primary time point of week 12. There were no statistically significant differences between BTX-A groups and placebo in terms of treatment efficacy described as International Prostate Symptom Score (IPSS) reduction, improvement of peak urinary flow rate (Qmax) and post-void residual volume (PVR) and prostate volume reduction at any time point throughout the study. Only in a subgroup of patients, including previous alpha-blocker users, 200 U BTX-A worked better than placebo in terms of IPSS reduction. Adverse event rates were similar between all treatment arms. The unexpected pronounced placebo response in the present study raises question marks in minds regarding the use of BTX-A as an alternative treatment option. These conflicting results suggest that intraprostatic BTX-A injection is still experimental and further trials are required.

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