



A Quarterly Newsletter from The National Association For Continence

BOTOX® Treatment for Overactive Bladder



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Where do we stand with the use of botulinum toxin A, commonly known as BOTOX®, for the treatment of overactive bladder (OAB)? Trials have been conducted by Allergan (Irvine, CA), the makers of BOTOX, for patients with OAB who have failed to improve with medication.

BOTOX has been tested on patients who have no known cause for their OAB symptoms (this is termed idiopathic OAB), as well as patients with neurological diseases that interfere with the signals running from the brain to the bladder. There are two major phase III neurogenic trials, both of which are closed with respect to accepting new patients. The results of these trials are still being evaluated. Some patients with neurogenic bladder problems are being treated “off-label” (use of the drug in a non-FDA approved manner) with BOTOX now and some insurance carriers – including Medicare in certain states – are covering its use. In addition, some patients who were in the phase III trial will be eligible for entry into a long-term extension of the initial study, allowing for the evaluation of long-term efficacy and safety. There are several studies that have shown that repeat injections will provide similar improvements in symptoms without an increase in side effects.

A program evaluating the use of BOTOX for the treatment of patients with idiopathic OAB is also underway. A recently completed phase II trial sponsored by Allergan closed, showing improvement in both voiding diaries and quality of life parameters. Data from this trial were presented this year at the American Urological Association meeting in Chicago. This initial phase II study appears to show that doses of BOTOX at 00-50 units optimally balanced efficacy (e.g., fewer incontinence episodes, less urinary urgency) and safety (e.g., less risk of incomplete bladder emptying requiring intermittent catheterization). A phase III trial will begin later this year.

One other trial of note, performed through the National Institute of Child Health and Human Development without company funding was published in the *Journal of Urology* in 2008 by Brubaker, et al. This trial, which used 200 units of BOTOX to treat patients with idiopathic OAB, also showed improved results compared to placebo. However, this trial was prematurely terminated due to a higher than expected incidence of urinary retention as noted in 2 of 28 patients injected with the active drug. Urinary retention was defined as retaining more than 200 ml of urine after voiding, whether or not the patients complained of any lower urinary tract symptoms, and did not necessarily require catheterization.

Finally, while BOTOX is the only brand of botulinum toxin A currently available in the US, a competitor marketed as Dysport in Europe will be introduced to US physicians later this year. ❖

Dr. Ginsberg has disclosed that he is a consultant for Allergan and Pfizer, as well as a Speakers' Bureau member for Allergan, Pfizer, P&G, and Boston Scientific.