

# Botox Benefits Overactive Bladder Patients

BY SUSAN BIRK

CHICAGO — Patients with idiopathic overactive bladder refractory to anticholinergics reported significant improvements in health-related quality of life, symptom severity, and satisfaction for at least 24 weeks after treatment with botulinum neurotoxin type A (Botox) in a randomized trial of 313 patients.

“Botox doses at or above 100 U con-

sistently [provided] meaningful benefit as measured by improvements on these questionnaires,” Dr. David A. Ginsberg and his colleagues reported in a poster at the annual meeting of the American Urological Association. “The benefit to patients was rapid, as early as 2 weeks, and was sustained for at least 24 weeks” at these doses.

Treatment with 100 U “may be the best dose in terms of balancing efficacy and

safety” and lowering the risk of urinary retention as a possible side effect, Dr. Ginsberg of the University of Southern California in Los Angeles said in an interview.

Several earlier studies showed the drug’s effectiveness in terms of urodynamics, but the present study offers some of the first objective data on changes in quality of life and patient satisfaction, he said. The use of Botox for overactive bladder is currently an off-label indication.

At baseline, participants (mean age 58.8 years, 91% female) were having eight or more episodes of urge urinary incontinence per week with no more than one incontinence-free day, and an average of eight micturitions daily based on a 7-day voiding diary. Patients were randomized to receive Botox 50 U, 100 U, 150 U, 200 U, or 300 U or placebo intradetrusor injections. Patients received a single treatment of 20 injections under local anesthesia, said Dr. Ginsberg, who disclosed that he is a consultant for Allergan, which supported the multicenter, double-blind, phase II study.

Health-related quality of life was assessed at baseline and at weeks 2, 6, 12, 18, 24, and 36 using the Incontinence Quality of Life questionnaire (I-QOL), the incontinence-specific King’s Health Questionnaire (KHQ), and the Overactive Bladder–Urinary Incontinence Patient Satisfaction With Treatment Questionnaire (PSTQ). Global assessments of overall symptoms, activity limitations, and emotions related to overactive bladder since the last clinic visit were performed at the same intervals following treatment.

Significant improvements in incontinence-related QOL and urinary symptoms were found in all of the treatment groups, compared with the placebo group. “A clear dose-response relationship was observed for Botox at week 12, with mean increases from baseline in I-QOL total scores ranging from 29.8 in the Botox 50 U group to 39.7 in the 300 U group versus a mean increase from baseline of 17.9 in the placebo group,” Dr. Ginsberg said. “This dose-response relationship was evident at all subsequent time points.”

Global assessments of symptoms, QOL, activity limitations, and emotions were significantly more positive for up to 24 weeks in patients in all of the Botox treatment groups except those receiving the lowest dose, compared with the placebo group. At week 12, mean changes from baseline in patient satisfaction scores were significantly higher for the 100 U, 150 U, and 300 U groups.

Patient reports of side effects on the PSTQ did not differ between the placebo and Botox groups past week 12 of the study. Patients in the 200-U group had the highest incidence of postvoid residual urine of 200 mL or more. The proportion of patients with postvoid retention over 200 mL were 0%, 12.5%, 14.5%, 20.0%, 28.8%, and 27.3% for the placebo and Botox 50-U, 100-U, 150-U, 200-U, and 300-U dose groups, respectively.

A recent study of Botox in 81 patients with idiopathic overactive bladder (J. Urol. 2009;181:1773-8) reported that more than 2 of 5 patients required clean intermittent self-catheterization following treatment. Dr. Ginsberg noted that patients in this study received Botox 200 U, an amount higher than what appears to be the optimal dose of 100 U.

“I tell my patients there is about a 10%-20% risk that they might need [intermittent catheterization] to empty their bladder,” Dr. Ginsberg said. ■

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