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BOTULINUM TOXIN A (BOTOX®) DEMONSTRATES DOSE-DEPENDENT IMPROVEMENTS IN HEALTH-RELATED QUALITY-OF-LIFE MEASURES IN IDIOPATHIC OVERACTIVE BLADDER

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INTRODUCTION AND OBJECTIVE: Symptoms of overactive bladder (OAB), especially urgency urinary incontinence (UUI), can have a substantial negative impact on health-related quality of life (HRQOL). The objective of this dose-ranging study was to assess the effects of BOTOX® treatment for patients with idiopathic OAB (IOAB) and UUI inadequately managed with anticholinergics.

METHODS: In a Phase 2 multicenter, randomized, double-blind study, 313 patients with IOAB and UUI received intradetrusor BOTOX 50U (N=57), 100U (N=54), 150U (N=49), 200U (N=53), 300U (N=56), or placebo (N=44). At baseline, patients were required to have ≥ 8 UUI episodes/week and ≥ 8 micturitions/day. Patients were followed for 36 weeks post-treatment. Assessments included the Incontinence QOL (I-QOL) Instrument, 4 individual Patient Global Assessment (PGA) scales, and a Patient Satisfaction with Treatment Questionnaire (PSTQ).

RESULTS: Mean age was 58.8 years; 92% female. Significantly greater improvements from baseline vs. placebo in I-QOL mean total score and for the 3 domain scores (avoidance and limiting behavior, psychosocial impacts, and social embarrassment) were observed in BOTOX dose groups ≥ 100 U as early as Week 2 and continuing for subsequent post-treatment timepoints to Week 36. A dose-response was apparent. Each individual PGA scale (Symptoms, QOL, Activity Limitations, and Overall Emotions) demonstrated statistically significant improvement for the majority of BOTOX dose groups vs. placebo at visits through Week 12. No BOTOX dose groups demonstrated statistical superiority on the PGA scales beyond 24 weeks. On the PSTQ overall satisfaction question, mean changes from baseline for placebo indicated a negative effect on satisfaction with treatment, while the 100U, 150U, and 300U doses of BOTOX significantly improved satisfaction with treatment at Week 12. On the PSTQ side effects question, 150U, 100U, and 50U BOTOX dose groups were not significantly different from placebo at Week 12. Moreover, none of the BOTOX dose groups were significantly different from placebo beyond Week 12, suggesting that patient ratings of side effects were similar across treatment groups.

CONCLUSIONS: BOTOX treatment resulted in positive, durable, and meaningful benefit relative to placebo in HRQOL, symptom severity, satisfaction with treatment, and patient global ratings for patients with IOAB and UUI refractory to anticholinergics. Dose-response was observed across multiple patient-reported measures.

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