OnabotulinumtoxinA Improves Idiopathic Overactive Bladder Symptoms in Patients Refractory to Specific Classes of Oral Medications: Subanalysis of the GRACE Study

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OBJECTIVE

To examine real-world treatment benefit and rates of urinary incontinence (UI) after treatment with onabotulinumtoxinA (onabotA) in patients with overactive bladder (OAB) symptoms inadequately managed by one or more classes of OAB medications.

CONCLUSIONS

- Real-world treatment with onabotulinumtoxinA led to sustained reductions in UI episodes in patients with OAB who discontinued anticholinergics and/or b3 adrenergic agonists due to inadequate response
- 88% of OAB patients who discontinued anticholinergics and/or β3 adrenergic agonists due to inadequate response report improvements in symptoms on the Treatment Benefit Scale[9] 12 weeks after onabotA
- Given these real-world findings, patients may benefit from onabotA treatment rather than cycling through more than one oral OAB medications

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References

1. Nitti VW, et al. J Urol. 2013;189:2186–2193
2. Gormley EA, et al. J Urol. 2015; 1572-1580
3. Staskin DR, et al. Am J Med. 2006; Suppl. 1, 9-15
4. Bragg R, et al. Consult Pharm. 2014;29:823-837
5. Chapple C, et al. Eur Urol. 2013;64:249–256
6. Herschorn S, et al. J Urol. 2017;198:167–175
7. McCammon K, et al. Female Pelvic Med Reconstr Surg. 2021;27:450–456
8. Hamid R, et al. Int Urogynecol J, 2021;32(1):65-74
9. Coleman S, et al. Urol. 2008;72(4):803-807

INTRODUCTION

Prevalence: More than 546 million individuals worldwide report symptoms consistent with overactive bladder (OAB)[1]

- Quality of life (QoL) is often reduced for those with urinary incontinence (UI) and symptoms of OAB[1]

Treatment: After first-line treatment of behavior modifications, oral medications (anticholinergics [ACs] and β3 adrenergic agonists [β3s]) are second-line treatments for OAB with UI, followed by onabotulinumtoxinA[2]

- ACs are often associated with side effects of dry mouth, constipation, and blurred vision[3]
- β3s are often associated with side effects of constipation, headaches, and increased risk of hypertension[4]
- OnabotulinumtoxinA (onabotA) 100 U is approved for use in adults with symptoms of urge UI, urgency, and frequency who have inadequate response to oral medications or intolerance to ≥1 anticholinergic
  - Randomized, controlled clinical trials demonstrate onabotA-mediated improvements in UI symptoms and QoL in patients with OAB who have symptoms that are inadequately managed by oral medications[5-8]

METHODS

Study Design: This subanalysis of the GRACE study was a real-world, prospective, multinational, phase 4 observational study (ClinicalTrials.gov: NCT02161159) that included adult patients with OAB inadequately managed by oral OAB medications and naïve to and eligible for botulinum toxin type A treatment for OAB[6]

- Study excluded patients unwilling or unable to initiate clean intermittent catheterization post-onabotA treatment or who received treatment with any botulinum toxin type A in the preceding 18 months

Assessments, Safety, Efficacy*:* Safety analyses were conducted on those that received ≥1 dose of onabotA

- Adverse events (AEs) and adverse drug reactions (ADRs) were recorded for up to 12 months after onabotA
- UI episodes and treatment benefit scores (TBS) were evaluated in patients with OAB symptoms inadequately managed by β3 and/or AC prior to onabotA treatment alone (without oral OAB medications), and with at least one bladder diary entry for the indicated week

Statistics: Frequencies and percentages in each category were evaluated

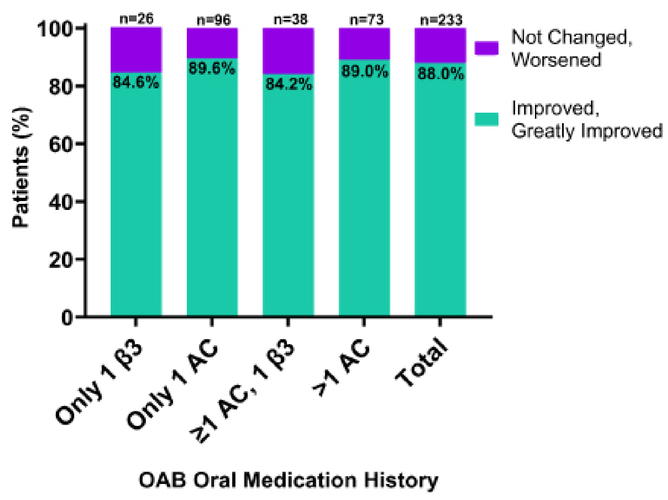
- Reductions in the number of UI episodes were evaluated with a one-sided Wilcoxon signed rank test
- Statistical testing was exploratory and performed at the two-sided 0.05 level of significance

RESULTS

Baseline Demographics and Patient Characteristics	Study Population (N=504)
Age (years)	
n	496
Mean (SD)	63.3 (14.1)
Age group, years, n (%)	
≥18 and <30	15 (3.0)
≥30 and <40	20 (4.0)
≥40 and <50	43 (8.5)
≥50	418 (82.9)
Sex, n (%)	
Female	428 (84.9)
Circumstances of life, n (%)	
At home - independent	476 (94.4)
At home with nursing care	26 (5.2)
Nursing home	2 (0.4)
Time since initial onset of symptoms, months, mean (SD)	84.6 (80.6)

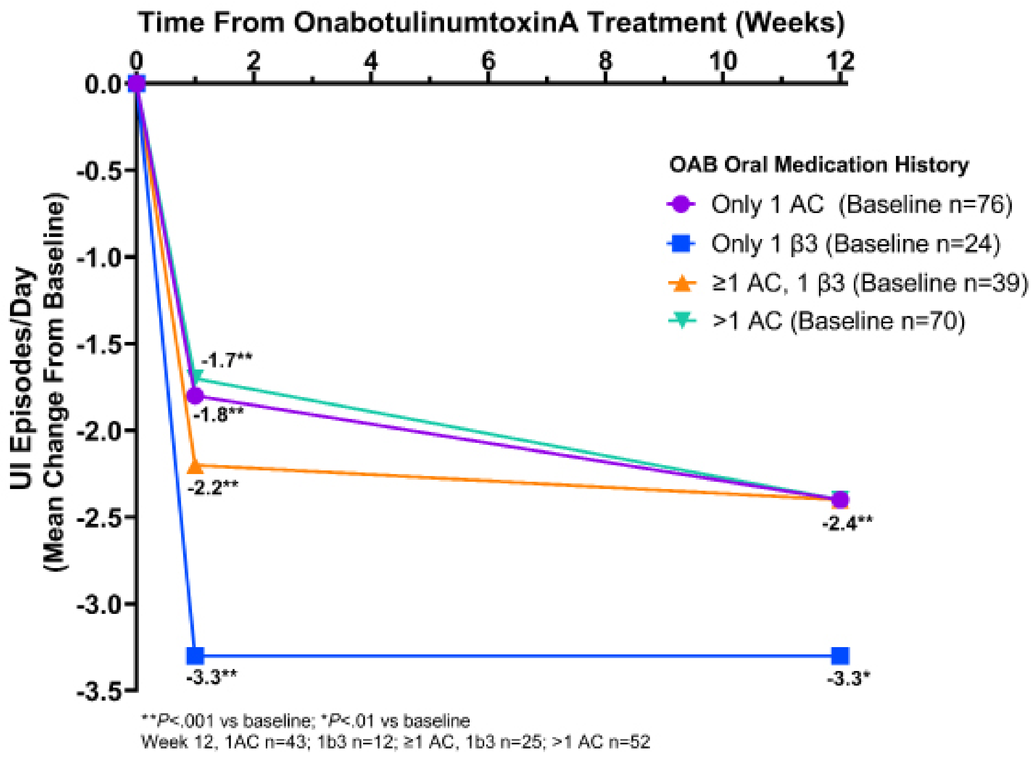
Percentages based on the overall study population
SD, standard deviation

Most Patients Report Improved or Greatly Improved Symptoms After Treatment With OnabotulinumtoxinA Across All OAB Treatment History Groups[a]



[a]Analysis includes patients who discontinued oral OAB medications after treatment with onabotA.

Reductions in UI Episodes 1 Week After OnabotulinumtoxinA Are Sustained at 12 Weeks Across All OAB Treatment History Groups[b]



[b]Analysis at baseline includes patients with inadequate response to oral OAB medications. Analysis at the indicated timepoints includes patients who discontinued oral OAB medications after treatment with onabotA.

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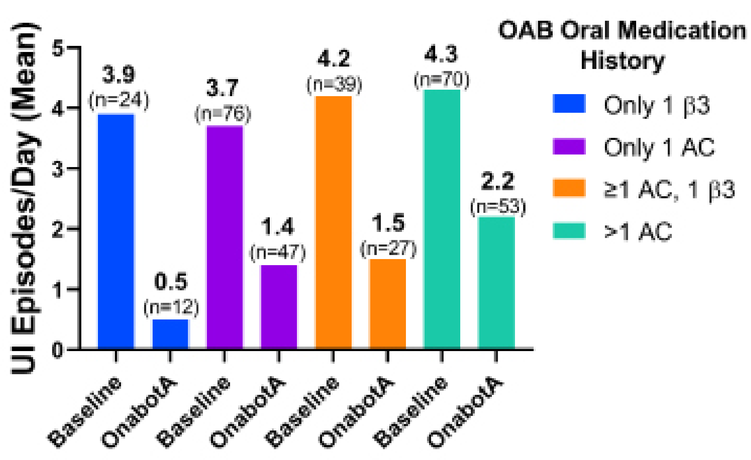
A Single Treatment With OnabotulinumtoxinA Alone Reduces UI Episodes 12 Weeks After Treatment



[a]Analysis includes patients who discontinued oral OAB medications after treatment with onabotA.

Safety

In the safety population (N=504)

- 57 AEs were reported in 38 patients (7.5%)
  - 17 AEs in 9 patients were serious (1.8%)
- Urinary retention (determined by physician) was reported in 5 patients (1.0%)
  - 1 was severe (0.2%)
- Symptomatic urinary tract infection was reported in 2 patients (0.4%)

Percentages based on the overall study population; SD, standard deviation