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Treatment Outcomes in Cervical Dystonia Patient Registry for Observation of OnabotulinumtoxinA Efficacy (CD PROBE)

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INTRODUCTION

- Cervical dystonia (CD) is the most common form of focal dystonia and involves involuntary muscular contraction, resulting in abnormal head and shoulder movements and/or postures[1]
- Botulinum toxin (BoNT) is considered the standard of care for treatment of CD[2,3]
  - Its safety and efficacy were established in controlled clinical trials[4,5]
  - However, few long-term studies have assessed the impacts of BoNT treatment on quality of life (QOL) and other outcomes in real-world practice
- Thus, an observational, multicenter, prospective registry (CD PROBE) was designed to assess the safety, effectiveness, and utilization patterns of onabotulinumtoxinA as a treatment for CD in clinical practice

OBJECTIVE

- To present the effectiveness and safety results from CD PROBE of onabotulinumtoxinA as a treatment for CD

METHODS

Study design and subjects

- CD PROBE was a multicenter, prospective, observational registry designed to capture real-world practices and outcomes for onabotulinumtoxinA CD treatment in the US
- Subjects diagnosed with CD and identified by the physician as candidates for onabotulinumtoxinA therapy were: new to principal physician's practice, new to BoNT therapy, or if previously participated in a BoNT clinical trial, must not have received BoNT for ≥16 weeks
- Subjects could receive 3 onabotulinumtoxinA treatment sessions
  - Dilution, dosing, and muscles injected with onabotulinumtoxinA were at the full discretion of the treating physician
  - The time to the next treatment session was determined by the physician, so treatment intervals, and thus assessment intervals, were variable
- Effectiveness assessments reported here are Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Clinician Global Impression of Change (CGIC), Patient Global Impression of Change (PGIC), and Pain Numeric Rating Scale (PNRS)
- Adverse events (AEs) were assessed throughout the study
- Phone interviews were conducted 4-6 weeks post-injection; study assessments were performed during phone interviews and office visits

Statistical analyses

- Descriptive and inferential statistics, including analysis of variance and analysis of covariance analyses when appropriate, were utilized to evaluate the change in outcome measures over study treatment sessions
- Effectiveness data are reported for subjects who had the first treatment session, reported their prior exposure to BoNT at baseline, and had completed all assessments for a given measure

RESULTS

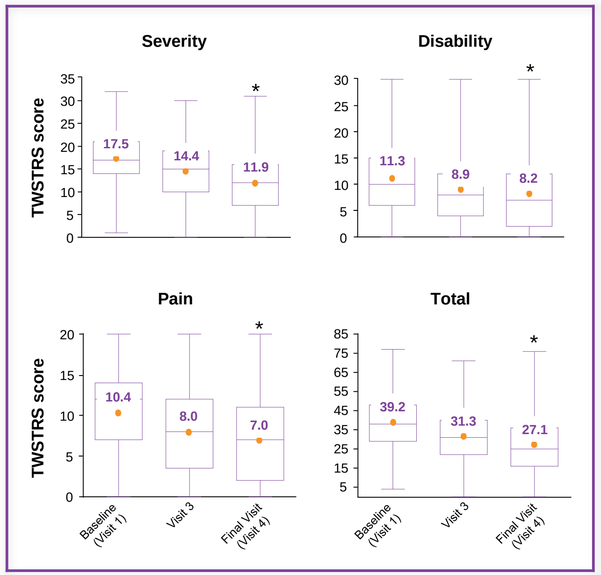
- 1041 subjects (out of 1046 enrolled) comprised the as-treated population
- Baseline characteristics are shown in **Table 1**
- Mean dose was 189.8 ± 87.1U, with an average of 14.6 and 15.1 weeks between treatments
- Highly significant, sustained improvements in all TWSTRS subscale scores and total score were demonstrated with onabotulinumtoxinA over the course of the study (**Figure 1**)

Table 1. Baseline Demographics and Disease Characteristics

Characteristic	N=1041
Age, y	58.0 ± 14.7
Gender, n (%)	
Female	774 (74.4)
Race, n (%)	
White	961 (92.3)
Non-white	80 (7.7)
Body mass index[a], kg/m^2	26.6 ± 5.4
Predominant Subtype[b], n (%)	
Anterocollis	59 (5.7)
Laterocollis	404 (38.9)
Retrocollis	55 (5.3)
Torticollis	494 (47.5)
Other	27 (2.6)
Severity[b], n (%)	
Mild	345 (33.2)
Moderate	548 (52.7)
Severe	146 (14.1)
Age at symptom onset, y	49.0 ± 16.7
Time from CD onset to diagnosis, y	5.0 ± 8.1
Time from diagnosis to treatment, y	1.1 ± 4.5
Prior treatment with botulinum toxin, n (%)	380 (36.5)

Data are presented as mean ± standard deviation unless otherwise indicated. [a]Data were not available for 76 subjects. [b]Data were not available for 2 subjects.

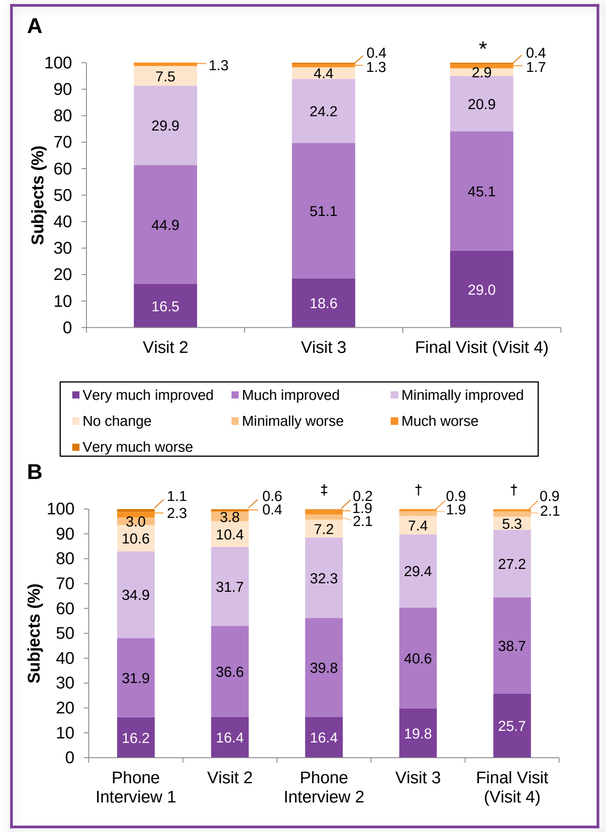
Figure 1. Toronto Western Spasmodic Torticollis Rating Scale



*P<0.0001 vs baseline; n = 479 for all visits. Scales range as follows: Severity, 0-35; Disability, 0-30; Pain, 0-20; and Total, 0-85, with higher scores being worse. Dot = mean; line in box = median; top & bottom of box = interquartile range; TWSTRS = Toronto Western Spasmodic Torticollis Rating Scale; whiskers = minimum & maximum.

- The percentage of physicians who rated patients' CD as minimally, much, or very much improved on the CGIC significantly increased from visit 2 to final visit (91.2% vs 95.0%; P<0.0001) (**Figure 2A**)
- Similarly, the percentage of subjects who reported their CD as minimally, much, or very much improved on the PGIC significantly increased from phone interview 1 to final visit (83.0% vs 91.7%; P<0.0001) (**Figure 2B**)

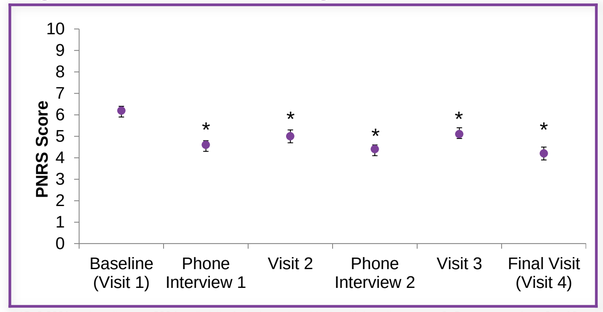
Figure 2. Clinician Global Impression of Change (A) and Patient Global Impression of Change (B)



*P<0.0001 vs Visit 2; †P<0.0001 vs Phone interview 1; ‡P<0.05 vs Phone interview 1; n = 479 for all visits for CGIC; n = 470 for all visits for PGIC. CGIC = Clinician Global Impression of Change; PGIC = Patient Global Impression of Change.

- PNRS scores significantly decreased following onabotulinumtoxinA treatment from baseline to final assessment (6.2 ± 2.2 to 4.2 ± 2.5; P<0.0001).

Figure 3. Pain Numeric Rating Scale



*P<0.0001 vs. baseline; n = 286 for all visits. Includes only subjects with baseline score >0. Scores range from 0 to 10, with 10 the worst. Data are shown as mean ± 95% confidence interval. PNRS = Pain Numeric Rating Scale.

- The most common AEs (≥1%) were muscular weakness, dysphagia, neck pain, headache, injection site pain, and musculoskeletal pain

Table 2. Adverse Events

Event	Subjects, n (%)
Overall AEs	273 (26.2)
Muscular weakness	73 (7.0)
Dysphagia	67 (6.4)
Neck pain	28 (2.7)
Headache	16 (1.5)
Injection site pain	13 (1.2)
Musculoskeletal pain	10 (1.0)
Treatment-related AEs	185 (17.8)
SAEs	33 (3.2)
Treatment-related SAEs	4 (0.4)

Overall AEs ≥1% are shown. AEs = adverse events; SAEs = serious adverse events.

CONCLUSIONS

- OnabotulinumtoxinA treatment significantly improved CD symptoms, as indicated by physician- and patient-assessed measures. Benefits of treatment were sustained over time
- OnabotulinumtoxinA appears to be well tolerated with few treatment-related AEs, and no new safety signals were identified

REFERENCES

1. Albanese A, et al. Mov Disord. 2013;28:863-873. 2. Simpson DM, et al. Neurology. 2008;70:1699-1706. 3. Ramirez-Castaneda J and Jankovic J. Toxins (Basel). 2013;5:249-266. 4. Charles D, et al. Clin Neuropharmacol. 2012;35:208-214. 5. Brin MF, et al. Mov Disord. 2008;23:1353–1360.

DISCLOSURES

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The potency units of onabotulinumtoxinA are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products, and therefore, units of biological activity of onabotulinumtoxinA cannot be compared with or converted into units of any other botulinum toxin products assessed with any other specific assay method.

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