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.

Botulinum toxin (BoNT) is considered the standard of care for treatment of CD:
- Its safety and efficacy were established in controlled clinical trials.
- 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, this 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 who had the first treatment from baseline to final assessment:
- 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 ± 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).

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).

Table 2. 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