CD-PROBE (Cervical Dystonia Patient Registry for Observation of BOTOX® Efficacy) - A Multicenter, Observational Study of OnabotulinumtoxinA Injections in Cervical Dystonia Patients – Preliminary Baseline Data

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Introduction

- Cervical dystonia (CD), also referred to as spasmodic torticollis, is one of the most common forms of adult-onset focal dystonias.
- Treatment of CD with injections of botulinum toxin has become the standard of care to provide relief from the abnormal head position and pain.[1]
- BOTOX® (onabotulinumtoxinA, Allergan Inc.) was the first botulinum toxin formulation approved in the United States (1989), initially for blepharospasm associated with dystonia, including benign essential belpharospasm or VII nerve disorders, and in 2000 it was approved for the treatment of CD.[2]
- After two decades of experience with BOTOX® use in treating CD, many unanswered questions remain about CD such as how best to treat this chronic, disabling neurological condition.

Objectives

- The CD PROBE observational study will attempt to answer a number of questions including:
  1. Do specific presentations of CD influence treatment choices?
  2. Should there be standard approaches to treating patients presenting with similar symptoms?
  3. What is the effect of CD and its treatment on quality of life?
  4. Does baseline presentation, treatment approach and injector's practice characteristics influence outcomes?
- CD PROBE captures real world clinical practice for neurologists, movement disorders specialists, and other physicians who treat CD patients.
- Analysis of these differing practice types will allow comparison of CD treatment between groups of injectors.
- The objective of this presentation is to report on initial baseline demographic data from this ongoing registry.

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- Dr. Kurth receives personal compensation from Allergan Inc. for consulting services.
- Dr. Brin and Dr. Boo are employee of Allergan Inc. Dr. Brin receives stock and stock options from Allergan Inc.
- Dr. Misell received salary from Allergan Inc., and owned Allergan stock. She currently receives salary from Suneva Medical and owns Suneva Medical stock options.

Subjects

- 330 subjects enrolled as of February 27, 2010
- Inclusion criteria:
  1. Diagnosis of CD and deemed by the physician to be a candidate for BOTOX® therapy.
  2. Patient must be:
     a) New to principle physician's practice
     b) New to botulinum toxin therapy
     c) If previously participated in a botulinum toxin clinical trial, must not have received botulinum toxin for 16 or more weeks and the last injection received by the patient must have been directed by the clinical trial protocol (no interim injections between clinical study end and CD PROBE entry should have occurred).
     - Patients can be included if they meet criteria A only, B only, C only.
  3. Provide informed consent and written authorization for use and release of health and research observational study information (as applicable).
  4. Ability to follow study instructions and complete required study activities.
- Exclusion criteria:
  1. Patients planning elective surgery during the observational study period.
  2. Females who are pregnant, nursing, or planning a pregnancy.
  3. History of poor cooperation or non-compliance with medical treatment.
  4. Any condition or situation which, in the physician's opinion, places the patient at significant risk, could confound the registry data, or may interfere with the patient's participation such as unstable medical conditions.

Methods

- This is a multi-center, prospective, standard-of-care, observational study designed to capture current diagnosis and treatment approaches for CD and their effects on patients quality-of-life.
- Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Cervical Dystonia Impact Profile (CDIP-58), CD severity and symptom.

Results

Table 1. Baseline patient demographics

Total enrolled as of Feb. 27, 2010	330	
Female (%)	259	(78.5)
Male (%)	71	(21.5)
Caucasian (%)	315	(95.5)
Age (range)	57.5 ± 14.3	(20-90)
Height (inch, range)	65.4 ± 3.54	(53-75)
Weight (lbs, range)	159.7 ± 38.8	(64-335)
BMI (range)	26.8 ± 9.1	(16-47)
Age at symptoms onset (yrs, range)	48.3 ± 16.3	(5-88)
Age at CD diagnosis (yrs, range)	53.7 ± 15.0	(9-88)
Time to CD diagnosis (yrs, range)	5.5 ± 9.1	(0-53)
Time to CD treatment after diagnosis (yrs)	0.92 ± 3.22	(0-31)
TWSTRS* Total (range)	37.9 ± 13.2	(10-77)
Severity (range)	16.9 ± 5.4	(2-30)
Disability (range)	10.5 ± 6.4	(0-30)
Pain (range)	10.6 ± 5.2	(0-20)

* Maximum scores: Severity=35, Disability=30, Pain=20, Total=85

- CDIP-58 baseline subscales scores are presented in Table 2.

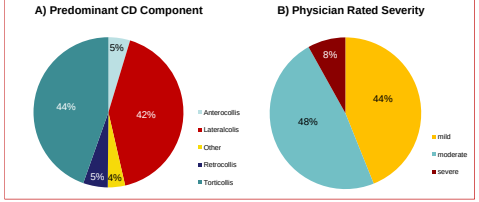
Table 2. Baseline CDIP-58 domain scores scaled to maximum of 100.

CDIP-58 Domain	Mean	Std
Head and Neck Symptoms	68.2	19.0
Pain and Discomfort	70.2	22.6
Upper Limb Activities	50.7	22.3
Walking	43.1	23.9
Sleep	57.6	27.0
Annoyance	57.1	21.2
Mood	48.0	21.8
Psychosocial Functioning	50.1	23.2

- Baseline TWSTRS total scores = 37.89 ± 13.17 (range 10-77).
- The majority of CD symptoms were rated by the physician to be moderate in severity.
- Torticollis and lateralcollis were the predominant postures (Figure 1).

Results

Figure 1. CD Class and Severity as Rated by Physician.



Conclusion

- Cervical dystonia typically presents in mid life and affects women more often than men.
- The majority of people with cervical dystonia experience pain in addition to involuntary movement and abnormal posture of the head and neck.
- Results of this study will provide useful information about the impact of onabotulinumtoxinA on disease status, quality of life and work productivity.

References

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CD PROBE Study Group

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