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

Joseph Jankovic[1], Charles Adler[2], David Charles[3], Cynthia Comella[4], Mark Stacy[5], Matthias Kurth[6], Mitchell Brin[6,7], Lisa Misel[8], Lee Ming Boo[6] for The CD PROBE Study Group

[1]Baylor College of Medicine, TX; [2]Mayo Clinic Arizona, AZ; [3]Vanderbilt University Medical Center, TN; [4]Rush University Medical Center, IL; [5]Duke University Medical Center, NC; [6]Allergan Inc., CA; [7]University of California, Irvine, CA; [8]Suneva Medical Inc., CA

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 interim patient reported outcome after onabotulinumtoxinA injections from the ongoing registry (peak 1 phone interview : 4-6 weeks post-injection 1).

Methods

- Multi-center, prospective, observational study.
- Phone interview completed 4-6 weeks after botulinum toxin injection
- Patient reported Pain Numerical Rating Scale (NRS) , Patient Global Impression of Change, and Cervical Dystonia Impact Profile (CDIP – 58).

Subjects

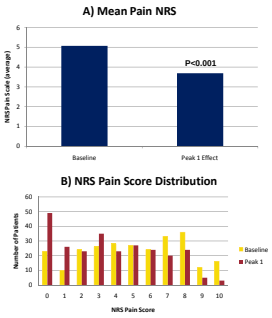
- 330 patients enrolled as of February 27, 2010.
- Inclusion criteria:
  1. Diagnosis of CD and deemed by the physician to be a candidate for BOTOX® therapy.
  2. Patient must be:
     a) New to principle physician's practice
     b) New to botulinum toxin therapy
     c) If previously participated in 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.

Results

- Of the 259 patients with available pain data, 90.3% (n=234) reported experiencing pain from their CD at baseline.
- Pain Numerical Rating Scale (NRS) improved from baseline 5.07±2.89 to 3.69±2.81 (p<0.001) at phone interview 4-6 weeks after injection 1 (Figure 1).
- Number of subjects reporting no pain increased from 23 at baseline to 49 post-injection 1 (Figure 1).
- The median days to pain relieve was 5 days (range 1-14+ days)

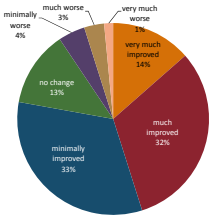
Results

Figure 1. Pain NRS scores at Peak 1



- At peak 1 phone interview, 79% of patients reported "minimal" to "very much" improvement in Patient Reported Global Impression of Change compared to their baseline conditions (Figure 2).

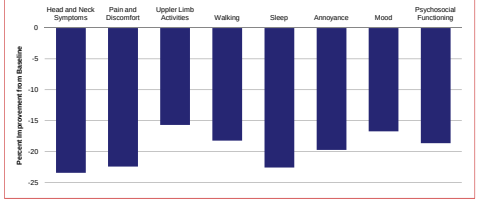
Figure 2. Patient Reported Global Impression of Change at Peak 1.



Results

- All subscales of CDIP-58 improved at Peak 1 (all p<0.001) (Figure 3) including:
  - Head and Neck Symptoms,
  - Pain and Discomfort, and
  - Sleep

Figure 3. Percent decrease from baseline in CDIP-58 subscales.



Conclusion

- Cervical dystonia patients treated with onabotulinumtoxinA report a reduction in pain and improvement in all domains of the CDIP-58.
- Majority of patients reported CD conditions improved as assessed by Patient Global Impression of Change after onabotulinumtoxinA injection.
- Patterns of response will become more apparent as additional patients enter this large study.

References

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2. BOTOX® Prescribing Information. Allergan Inc. 2010.

CD PROBE Study Group

Lefko Aftonomos, CA; Pinky Agarwal, WA; Richard Barbano, NY; Peter Barbour, PA; Jay Bhatt, IN; David Bowers, TN; James Boyd, VT; Allison Brashear, NC; Mary Caire, TX; Mahan Chehrenama, VA; Shilpa Chitnis, TX; Paul Cullis, MI; Lisa Davidson, MN; Thomas Davis, TN; J Antonelle De Marcaida, CT; Christina Drafta, NY; Richard Dubinsky, KS; Jeffrey Esper, PA; Virgilio Evidente, AZ; Grace Forde, NY; Ramon Gil, FL; John Goudreau, MI; David Greeley, WA; Gregory Hanes, FL; Robert Hauser, FL; Venessa Hinson, SC; Patrick Hogan, WA; Tomas Holmlund, NY; Stuart Isaacson, FL; Bahman Jabbari, CT; Paul Jett, TN; Peter LeWitt, MI; Julie Leegwater-Kim, MA; Tsao-Wei Liang, PA; Anthony May, PA; Stephen McGuire, TX; Tamara Miller, CO; Eric Molho, NY; Srinivas Nalamachu, KS; Suneetha Nuthaiapaty, TN; Padraig O'Suilleabhain, TX; William Ondo, TX; Atul Patel, KS; Diana Pollock, FL; Ben Renfroe, FL; Perry Richardson, DC; Jason Rosenberg, SC; David Ross, FL; Michael Rossen, MA; Kyle Ruffing, FL; Ejaz Shamim, DC; Carlos Singer, FL; Natividad Stover, AL; Thyagarajan Subramanian, PA; William Sunter, FL; Michele Tagliati, NY; Martin Taylor, OH; Margaret Tilton, NH; Richard Trosch, MI; Miodrag Velickovic, NY; Maureen Watts, TX; Cindy Zadikoff, IL; Lin Zhang, CA; Chong-Hao Zhao, CA.

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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. Misel received salary from Allergan Inc., and owned Allergan stock. She currently receives salary from Suneva Medical and owns Suneva Medical stock options.