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 blepharospasm or VI nerve disorders, and in 2003 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).

Subjects

• 310 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).
     d) 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.
  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

• 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).

Results

• Of the 250 patients with available pain data, 90.25% (n=229) reported experiencing pain from their CD at baseline.
• Pain Numerical Rating Scale (NRS) improved from baseline 5.07±2.90 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 48 post-injection 1 (Figure 2).
• The median days to pain relief was 5 days (range 1-14 days)

Conclusions

• All sub-scales of CDIP-58 improved at Peak 1 (p<0.001) (Figure 3) including:
  1. Head and Neck Symptoms
  2. Pain and Discomfort
  3. Sleep

References

2. ADVANCE® Prescribing Information. Allergan Inc. 2010
CD PROBE Study Group

Catherine Addis, MD; Philip Gutterman, MD; Richard Haskard, MD; Peter Behrens, MD; Tim Black; Jy Padmanabhan, MD; James Bresnahan, MT; Allison Brinere, MD; Mary Cross, MD; Michael Daroff, MD; Julia Dobos, DC; Paul Emery, MD; Susan Eng, MD; Timothy Finucane, MD; James Flodin, MD; Michael Gilewski, MD; Richard Gold, MD; Brian Good, MD; Joseph Haddad, MD; Charles Hanes, MD; Gary Hardin, MD; Elizabeth Hasturk, MD; James Houghton, MD; Richard Hume, MD; Todd James, MD; Robert Johnson, MD; Gary Johnson, MD; Andrew Jones, MD; Aimee Kehoe, MD; Steven Kassell, MD; Lisa Kassell, MD; Laura Keim, MD; Robert Keen, MD; Scott Keohane, MD; Dan Khuri, MD; Alyson Koh, MD; Robert Köke, MD; Jonathan Kramer, MD; John Lai, MD; John Larkin, MD; Jack Lawrence, MD; Jeffrey Lee, MD; Glenn Lipton, MD; Michael Locke, MD; John Lombardi, MD; John Long, MD; Glen Lord, MD; Jennifer Louis, MD; Marie Lucey, MD; Richard Lumerman, MD; David Lyon, MD; Lisa Mariano, MD; Charles Matha, MD; John McDonald, MD; George McCrory, MD; David Michael, MD; Robert Miller, MD; Stephen Mims, MD; Richard Modder, MD; Robert Morgan, MD; Daniel Moshier, MD; Philip Moseley, MD; David Mount, MD; Charles Murphy, MD; Elizabeth Newhart, MD; Brian Noren, MD; Robert O’Connor, MD; Stephen O’Donnell, MD; Joseph Paine, MD; Arthur Park, MD; Edward Park, MD; Michael Pappas, MD; Rupa Patel, MD; S.S. Patwardhan, MD; Sarah Pearl, MD; Roger Pear, MD; Robert Peet, MD; John Péters, MD; Scott Piesszky, MD; Janet Pirker, MD; tennis; Steve Quinlan, MD; Gary Raney, MD; David Ratner, MD; Gregory Ritter, MD; William Roberts, MD; Thomas Romiti, MD; Jane Rosing, MD; Brian Rusk, MD; John Schilling, MD; Patrick Schmitt, MD; Lewy Smith, MD; Charles Smith, MD; John Smith, MD; Joel Spunt, MD; Laurence Stanislaw, MD; Luan Tran, MD; John Trumo, MD; Joanne Uno, MD; Susan Upp, MD; James Wang, MD; Paul Weir, MD; Thomas Welsh, MD; Gary Winer, MD; preco; Ching Wong, MD; Robert Yablon, MD; James Yagon, MD; Herbert Yahr, MD; Sheryl Yusen, MD; Anna Zdziarski, MD; Peter Zabinski, MD; Jennifer Zalewski, MD; Charles Ziv, MD; Richard Zivin, MD; Vivian Zorich, MD; and John Zuccarello, MD.