INTRODUCTION

Cervical dystonia (CD) is a chronic neurologic disorder manifested by involuntary contractions of the muscles that control movement and produce abnormal postures or movements of the head, neck, and shoulders. Upper limb dystonia, a related condition, is characterized by involuntary movements of the arm and hand. Improvement in neck and head posture or movement may adversely impact quality of life.1

OBJECTIVE

To report interim analyses of PROs after repeat injections of onabotulinumtoxinA in subjects enrolled in CD PROBE.

METHODS

Study Design

A multicenter, prospective, observational study of subjects with CD treated with onabotulinumtoxinA [ClinicalTrials.gov, NCT00320617]. Subjects were administered multiple injections separated by 100-day intervals and treatment intervals were based on standard care for the condition. Assessments were made at baseline (injection 1) and 4–6 weeks after each injection (peak effect). The efficacy endpoints assessed were Pain (CDIP-58 subscale scores), Head and Neck, Upper Limb Activities, and Walking. The outcome measure of interest was change in PROs (mean ± standard deviation [SD]) from baseline to injection 2 and 3 peak effect.

Efficacy (CD PROBE Study Group)

Patients

A total of 494 patients were included from October 11, 2010 to December 20, 2010. The mean age was 58.4 years (range, 18–93 years) and 62.4% were female. The mean (± SD) length of time from symptom onset to first treatment was 24.3 ± 12.0 years. The mean (± SD) number of injections received was 1.5 (± 0.9). Exclusion criteria included active or planned surgery that may impact CD, previous participation in a botulinum toxin clinical trial, or if previously enrolled in CD PROBE. The mean ± standard deviation (SD) interval between injection 1 and 2 was 100.4 ± 22.9 days and the mean ± SD dose at injection 1 was 175.6 ± 104.9 Units.

RESULTS

OralabotulinumtoxinA-dosage

The mean interval duration (SD) of effect was 1 week ± 1.5 weeks. The mean ± SD interval between injection 1 and 2 was 10.0 ± 2.3 days and injection 2 and 3 was 10.0 ± 2.3 days. Study peak effect was defined as the date of injection. Subjects enrolled in CD PROBE were excluded from onabotulinumtoxinA treatment for 100 days prior to any study visit.

CD PROBE subscale scores were significantly higher with increasing physician-assessed severity (at baseline) for Head and Neck (P < 0.0001), Upper Limb Activities (P < 0.0001), Walking (P < 0.0001), Annoyance (P < 0.0001), Mood (P < 0.0001), and Disability (P < 0.0001) as compared to baseline. Improvement in symptoms was sustained over the course of 3 injections of onabotulinumtoxinA given at intervals of 100 days.

CONCLUSIONS

The results of CD PROBE support that onabotulinumtoxinA is clinically effective for the treatment of CD at peak effect. These results support the use of onabotulinumtoxinA for the treatment of CD at intervals of 100 days to achieve optimal outcomes.