# Consistent dosing over time and within treatment interval groups with onabotulinumtoxinA: analysis from the Adult Spasticity International Registry (ASPIRE)

Alberto Esquenazi,[1] Wuwei Feng,[2] George F. Wittenberg,[3] Alessio Baricich,[4] Kristina Fanning,[5] Aleksej Zuzek,[6] Gerard E. Francisco,[7] Daniel S. Bandari[8]

[1]*MossRehab Gait and Motion Analysis Laboratory, Elkins Park, PA, USA;* [2]*Duke University School of Medicine Comprehensive Stroke Center, Durham, NC, USA;* [3]*University of Maryland, Baltimore, MD, USA and University of Pittsburgh, Pittsburgh, PA, USA;* [4]*Università del Piemonte Orientale "A. Avogadro", Novara, Italy;* [5]*Vedanta Research, Wilmington, NC, USA;* [6]*Allergan plc, an AbbVie company, Irvine, CA, USA;* [7]*University of Texas McGovern Medical School and TIRR Memorial Hermann, Houston, Texas, USA;* [8]*Multiple Sclerosis Center of California, Newport Beach, CA, USA*

## CONCLUSIONS

Dosing of onabotulinumtoxinA to treat adult spasticity was generally consistent over treatment sessions regardless of the length of the treatment interval, with the majority of patients receiving onabotulinumtoxinA within the approved dosing ranges

High levels of patient and clinician satisfaction were observed, with no new safety concerns

## RESULTS

### Disposition, Demographics, and Clinical Characteristics

- Of the total population (N=730) that received ≥1 onabotulinumtoxinA treatment for spasticity, 523 patients (71.6%) were categorized as treatment adherent and 207 patients (28.4%) as non-adherent; during the 2-year study, adherent patients had a mean (standard deviation, SD) of 5.3 (1.6) treatment sessions, while non-adherent patients had 1.5 (0.5) sessions and the mean (SD) treatment interval between sessions 1 and 2 was 18.0 (8.2) weeks for adherent patients and 22.9 (15.4) weeks for non-adherent patients.
- The mean (SD) age of patients was 53.6 (15.4) years and sex was evenly distributed; the majority of patients were continuing treatment with onabotulinumtoxinA (ie, non-naive), and stroke was the most frequently reported etiology (**Table 1**)

**Table 1. Patient Demographics and Baseline Characteristics**

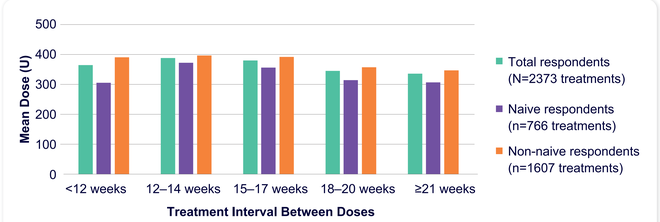
| Parameter | Total (N=730) |
|---|---|
| Age, years | |
| *Mean (SD)* | 53.6 (15.4) |
| *Min-max* | 18.5–93.2 |
| Sex, n (%) | |
| *Female* | 380 (52.1) |
| Race, n (%) | |
| *White* | 562 (77.0) |
| Naive to botulinum toxin for spasticity, n (%) | |
| *Yes* | 269 (36.8) |
| *No* | 461 (63.2) |
| Etiology, n (%) | |
| *Stroke*[a] | 411 (56.3) |
| *Multiple sclerosis* | 119 (16.3) |
| *Cerebral palsy* | 77 (10.5) |
| *Other*[b] | 72 (9.9) |
| *Traumatic brain injury* | 45 (6.2) |
| *Spinal cord injury* | 42 (5.8) |

[a]Ischemic, hemorrhagic, or embolic
[b]Hereditary spastic paraparesis, stroke during aneurysm clipping, chiari malformation, hydrocephalus
SD, standard deviation

### OnabotulinumtoxinA Treatment Utilization

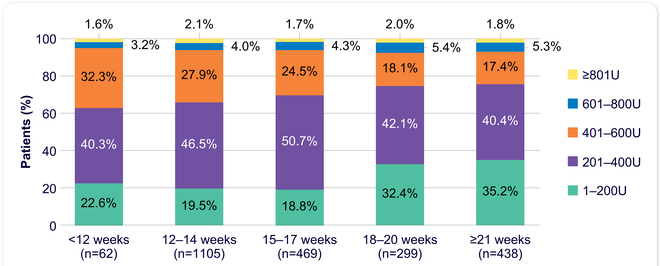
- During the 2-year study period, there were 2373 treatment session intervals for 730 patients (1607 treatment intervals in 461 non-naive patients, and 766 treatment intervals in 269 naive patients)
- OnabotulinumtoxinA doses were generally constant over the treatment interval groups, with the lowest mean dose of 335U reported in the treatment interval group of ≥21 weeks, and the highest dose of 387U reported in the treatment interval group of 12–14 weeks (**Figure 1**)
- Patients naive to toxin at baseline received slightly lower doses in each treatment interval group than non-naive patients, with respective doses ranging from 305–372U and 346–396U (**Figure 1**)

**Figure 1. Mean OnabotulinumtoxinA Dose by Treatment Interval in Total Respondents, Naive and Non-naive Respondents**



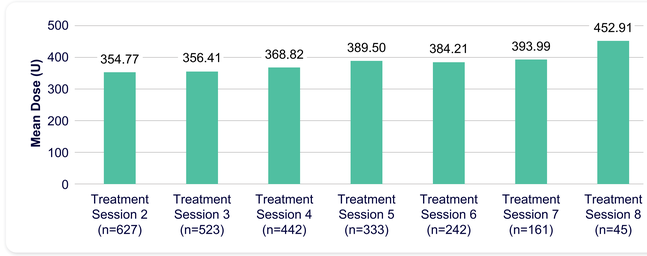

- Most patients received doses ≤400U across all treatment interval groups: <12 (63%), 12–14 (66%), 15–17 (70%), 18–20 (75%), and ≥21 (76%) week groups (**Figure 2**)

**Figure 2. Percentage of Patients Receiving Each Real-world Dosing Category (1–200U, 201–400U, 401–600U, 601–800U, ≥801U) by Treatment Interval**




- Dosing increased over treatment sessions, from 355U at session 2 to 453U at session 8 (**Figure 3**)

**Figure 3. Mean OnabotulinumtoxinA Dose by Treatment Session**

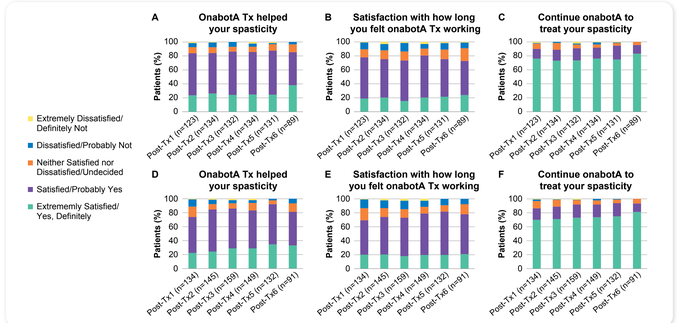



Note: mean dose data for session 8 likely represent a small number of patients (n=45) that required more frequent treatments and/or higher dosing per treatment

### Patient and Clinician Satisfaction

- Treatment-adherent patients reported high rates of satisfaction over treatment sessions: 81–92% stated their most recent onabotulinumtoxinA treatment helped their spasticity, 73–82% were satisfied/extremely satisfied with how long they felt onabotulinumtoxinA working, and 91–96% planned to continue using onabotulinumtoxinA to treat their spasticity (**Figure 4**)

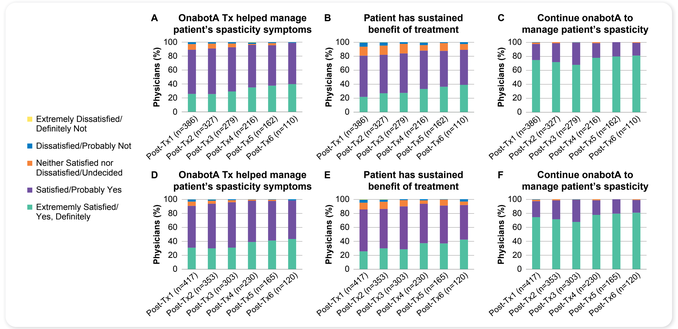
**Figure 4. Patient Satisfaction by Overall Treatment Session Intervals Stratified by Upper Limb (A, B, C) and Lower Limb (D, E, F) Spasticity**




NOTE: In the upper and lower limb populations, post-treatment session 7 (N=71 and N=74 patients, respectively) and post-treatment session 8 (N=21 and N=24 patients, respectively) data are not shown due to small patient numbers
OnabotA, onabotulinumtoxinA; Tx, treatment

- Similar rates of satisfaction were reported by clinicians: 93–99% stated that onabotulinumtoxin A helped manage their patients' spasticity symptoms, 84–94% felt their patients had sustained benefit of treatment, and 99–100% would continue onabotulinumtoxinA therapy to manage their patients' spasticity (**Figure 5**)

**Figure 5. Clinician Satisfaction by Overall Treatment Session Intervals Stratified by Upper Limb (A, B, C) and Lower Limb (D, E, F) Spasticity**




NOTE: In the upper and lower limb populations, the post-treatment session 7 (N=32 patients and N=38 patients, respectively) and post-treatment session 8 (both N=0 patients) data were not shown due to small patient numbers
OnabotA, onabotulinumtoxinA; Tx, treatment

### Safety

- A total of 831 AEs were reported in 261 patients (35.7%)
- The most commonly reported AEs were fall (5.5%), urinary tract infection (2.6%), and muscular weakness (2.6%) (**Table 2**)

**Table 2. All AEs Reported by ≥1.5% of Population (N=730)**

| Adverse event | Patients, n (%) | Number of events |
|---|---|---|
| Fall | 40 (5.5) | 54 |
| Urinary tract infection | 19 (2.6) | 26 |
| Muscular weakness | 19 (2.6) | 19 |
| Back pain | 15 (2.1) | 18 |
| Upper respiratory tract infection | 14 (1.9) | 17 |
| Depression | 13 (1.8) | 13 |
| Musculoskeletal pain | 12 (1.6) | 14 |
| Pneumonia | 12 (1.6) | 12 |
| Arthralgia | 11 (1.5) | 13 |

AE, adverse event

## INTRODUCTION

- The frequency of onabotulinumtoxinA treatments in real-world clinical practice varies according to many factors, including severity of spasticity, patient goals, the clinician's approach, administrative/logistical constraints, and others
- There are limited data describing the use of onabotulinumtoxinA in real-world clinical practice to treat spasticity across a range of etiologies
- Real-world, observational data can help guide clinical strategies to optimize patient care including improving our understanding of the relationship between dose and treatment intervals with onabotulinumtoxinA to manage limb spasticity

### Objectives

- To examine the relationship between real-world dosing and treatment intervals of onabotulinumtoxinA for adult limb spasticity, and to quantify the effectiveness of onabotulinumtoxinA according to the level of satisfaction reported by clinicians and patients

## METHODS

- The Adult SPasticity International Registry (ASPIRE) study was designed to describe the clinical characteristics of adult patients being treated with onabotulinumtoxinA for spasticity in the real world across several etiologies and geographical regions and its care burden
- ASPIRE is a prospective, observational registry conducted at 54 sites in North America, Europe, and Asia (NCT01930786)
- Data were collected for multiple neurological etiologies over 2 years in 730 patients who had received >1 treatment of onabotulinumtoxinA during the study period
  - OnabotulinumtoxinA dosing and treatment intervals were at the physician's discretion
  - Treatment intervals for patients with >1 treatment visit (N=2373 intervals) were categorized by the length between treatments: <12, 12–14, 15–17, 18–20, and ≥21 weeks
  - Treatment adherence was defined as those patients receiving ≥3 treatment sessions with onabotulinumtoxinA over the 2-year period
  - Utilization was assessed at each treatment visit, clinician satisfaction was assessed at each subsequent treatment session and patient satisfaction at 5 ± 1 week post-treatment via a questionnaire, and adverse events (AEs) were captured throughout the study

## ADDL INFO

**AUTHOR DISCLOSURES**

This study was sponsored by Allergan plc, Dublin, Ireland. Writing and editorial assistance was provided to the authors by Stuart Murray, MSc, CMPP of Evidence Scientific Solutions, Inc. and funded by Allergan, an AbbVie company. All authors met the ICMJE authorship criteria. Neither honoraria nor payments were made for authorship. Financial arrangements of the authors with companies whose products may be related to the present report are listed below, as declared by the authors.

AE has consulted for Allergan, an AbbVie company, Ipsen, and Merz, and received research grants from Allergan, an AbbVie company, and Ipsen. WF has received research grants from the National Institutes of Health (NIH). GFW has no disclosures. AB has consulted for, and received research grants from, Allergan, an AbbVie company, and Ipsen. KF is an employee of Vedanta Research, which has received support funded by Allergan, an AbbVie company, Dr. Reddy's Laboratories/Promius Pharma, Amgen, and Mallinckrodt. AZ is a full-time employee of AbbVie. GEF has consulted for, and received research grants from, Allergan, an AbbVie company, Merz, and Ipsen. DSB has consulted and/or been a speaker for Biogen, Genentech, Genzyme, and EMD-Serono, and received research support from Biogen, Genentech, and Med-day.

The authors would like to acknowledge Philippe Gallien of Pôle MPR Saint Hélier Rennes MS Clinic, Rennes, France for his contributions to the study.

*Presented at the Association of Academic Physiatrists (AAP), February 9–13, 2021 (fully virtual)*

**To obtain a PDF of this poster,**
- Scan the QR code
- OR
- Visit: www.allergancongressposters.com/116700

Charges may apply. No personal information is stored.

abbvie