Improvement in poststroke upper limb spasticity patterns after treatment with Botulinum toxin A: A prospective observational study

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Introduction and Objectives

- Botulinum toxin A (BoNT-A) is an effective treatment for poststroke spasticity. However, more data are needed to assess its beneficial effects in real-life clinical settings.
- The aim of this study was to document functional changes in upper limb poststroke spasticity before and after treatment with BoNT-A.

Methods

- Postmarketing, multicenter, prospective, observational, longitudinal, open, single-cohort study was conducted in 37 BoNT-A-naive adults (age ≥18 years), diagnosed with poststroke upper limb spasticity in Catalonia, Spain. The study enrollment period was December 19, 2012 to June 10, 2014.
- All patients received one cycle of BoNT-A injections. Patients were assessed at baseline (pre-BoNT-A treatment) and at 3 to 6 months post-treatment.
- The primary outcome measure, assessed at baseline and post-treatment, was change in spasticity patterns. Additional study variables included the Modified Ashworth Scale (MAS) and Goal Attainment Scale (GAS). The Paired T-test (non-parametric bootstrap) was used to test for differences.

Results

- Thirty-four of the 37 patients (92%) completed the study. Median age was 62 years (range: 33 to 86 years). The majority of subjects (70.6%) were males. At baseline, the most common spasticity patterns were elbow flexion (n=24; 70.6%), shoulder adduction/internal rotation (n=23; 67.6%), and wrist flexion (n=22; 64.7%).

Table 1. Demographic data and baseline characteristics – PAS population (n=34)

Age, years, median (range)	62 (33-86)
Male/Female, n (%)	24 (70.6) / 10 (29.4)
Pattern of spasticity, n (%)	
Elbow in flexion position	24 (70.6)
Shoulder in adduction/internal rotation	23 (67.6)
Wrist in flexion position	22 (64.7)
Claw hand	20 (58.8)
Forearm in prone position	19 (55.9)
Subject autonomy, n (%)	
Lives alone	1 (2.9)
Lives in a residence	5 (14.7)
Lives in his / her own home	11 (32.4)
Lives with a relative as a caregiver	14 (41.2)
Has the assistance of a relative as caregiver	3 (8.8)
Has the assistance of a part-time professional caregiver	3 (8.8)
Other situation	2 (5.9)
Height, cm, mean (SD)	166.0 (10.4)
Weight, Kg, mean (SD)	72.9 (15.3)
BMI, Kg/m², mean (SD)	26.3 (4.6)

PAS = Primary Analysis Set. BMI = Body Mass Index.

- The total number of spasticity patterns decreased from 110 (3.24/patient) at baseline to 102 (3.0/patient) post-treatment. The most frequently injected muscles were the flexor digitorum superficialis (50% of patients) and the flexor carpi radialis (47.1% of patients).
- Overall MAS scores decreased significantly from baseline to final study visit ($P<0.0001$), from a mean (SD) of 2.7 (0.8) at baseline to 2.2 (0.7) post-treatment, with highly significant decreases in claw hand, elbow flexion, forearm prone position, shoulder adduction and wrist flexion (all $P<0.0001$).
- Visual Analog Scale (VAS) pain scores improved significantly ($P<0.0001$) from a mean (SD) of 50.8 (35.7) at baseline to 17.4 (23.7).

Table 2. Secondary efficacy outcomes – PAS population (n=34)

	Baseline	Final Visit	
Derived MAS score[a], mean (SD)	2.7 (0.8)	2.2 (0.7)	$P<0.0001$
Pain score (VAS), mean (SD)	50.8 (35.7)	17.4 (23.7)	$P<0.0001$
Unweighted GAS T-score, mean (SD)	35.5 (5.7)	55.0 (9.8)	$P<0.0001$

[a]MAS scored on a derived scale where a score of 0 = 0, 1 = 1, +1 = 1.5, 2 = 2, 3 = 3, and 4 = 4.
PAS=Primary Analysis Set

- The majority of patients (28/34; 82.4%) achieved their primary GAS objective, with the most common being pain reduction (achieved in 14/17 pts; 82.4%) and improved self-care (7/8 pts; 87.5%). The mean (SD) unweighted GAS T-score also improved significantly, from 35.5 (5.7) at baseline to 55.0 (9.8) post-treatment ($P<0.0001$).
- One death, unrelated to treatment, was reported.

Figure 1. Goals set at baseline.

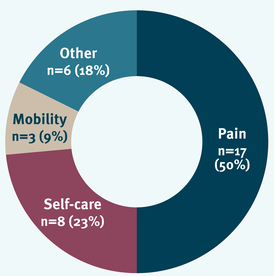
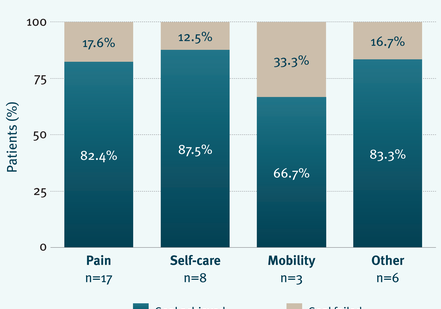


Figure 2. Goal achievement after one cycle of BONT-A injection.



Conclusions

- In this sample of patients with severe spasticity, the majority of patients benefited from treatment with a single cycle of BoNT-A injections, as evidenced by the significant improvements in pain, MAS, and GAS T-scores.
- These data, obtained in a real-life setting, further support the use of BoNT-A for the treatment of poststroke spasticity.

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