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Pain in Patients With Spasticity: Patient Characteristics From the Adult Spasticity International Registry (ASPIRE) Study

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OBJECTIVE

To describe the baseline demographics and clinical characteristics in spasticity patients from any etiology and pain (NPRS > 0) at baseline using data from the ASPIRE study

CONCLUSIONS

Real-world baseline characteristics of spasticity patients of any etiology and pain at baseline (NPRS > 0) provide important information about pain in patients seeking onabotulinumtoxinA treatment for spasticity

The effectiveness and safety of onabotulinumtoxinA in this patient population continues to be evaluated

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INTRODUCTION

- Spasticity is a disorder characterized by muscle stiffness, tightness, and involuntary muscle contractions, which can lead to difficulties in movement and coordination, and patients suffering from spasticity may also suffer from pain[1-2]
- OnabotulinumtoxinA (onabotA) is indicated for treatment of upper limb (UL) and lower limb (LL) spasticity[3]
- Limited data is available assessing pain management in adults with spasticity[4-6]
- A better understanding of the effectiveness of onabotA on pain in patients with spasticity is needed to inform treatment decisions in clinical practice

ASPIRE, Adult Spasticity International Registry; NPRS, numeric pain rating scale. [1]Wissel J et al. J Pain Symptom Manage. 2000;20(1):44-9; [2]Francisco GE et al. J Rehabil Med. 2017;49(8):659-66. [3]Botox Label (package insert). Allergan USA. 2021. [4]Wissel J et al. J Pain and Symptom Manage. 2016;52(1):17-26; [5]Francisco GE et al. PM&R. 2020;12(11):1120-33. [6]Esquenazi A et al. PM&R. 2021;13(10):1079-1093.

METHODS

Study Design

- The Adult Spasticity International Registry (ASPIRE) is an international, multicenter, prospective, observational study (NCT01930786) that examined onabotulinumtoxinA (onabotA) utilization and effectiveness in spasticity patients over a 2-year period
- Data from spasticity patients across etiologies treated with onabotA were analyzed
- This analysis includes spasticity patients who received with ≥ 1 onabotA treatment and who had pain (NPRS > 0) at baseline

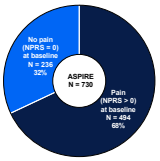
Assessments at Baseline

- Patient demographics and clinical characteristics
- Pain was assessed with:
  - -Numeric Pain Rating Scale (NPRS)
  - -Disability Assessment Scale (DAS)

ASPIRE, Adult SPasticity International REgistry; DAS, disability assessment scale; NPRS, numeric pain rating scale; onabotA, onabotulinumtoxinA.

RESULTS

Out of 730 Patients in ASPIRE Who Received ≥ 1 OnabotA for Spasticity, 68% Reported Pain at Baseline (NPRS > 0) and Were Included in This Analysis - Patient Demographics

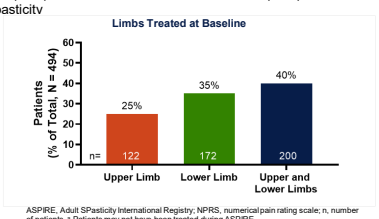


Parameter	Patients with NPRS > 0 N = 494
Age, years, mean (SD)	54.0 (15.4)
Sex, n (%)	
Female	281 (56.9%)
Male	213 (43.1%)
Race, n (%)	
American Indian or Alaska Native	1 (0.2%)
Asian	34 (6.9%)
Black or African American	59 (11.9%)
Latino/Hispanic	13 (2.6%)
Middle Eastern or Arabic	3 (0.6%)
White	375 (75.9%)
Data not available	8 (1.6%)
Other	1 (0.2%)
BMI, kg/m^2, mean (SD)[a]	26.7 (5.8)

ASPIRE, Adult SPasticity International REgistry; BMI, body mass index; n, number of patients; NPRS, numeric pain rating scale; onabotA, onabotulinumtoxinA; SD, standard deviation. [a]BMI data for 401 patients were included in this analysis; percentage was calculated using this number of patients.

Most Patients[a] (40%) Were Treated for Both Upper and Lower Limb Spasticity

- Among the 494 spasticity patients[a] with pain (NPRS > 0) at baseline, 122 (25%) were treated for upper limb, 172 (35%) were treated for lower limb, and 200 (40%) were treated for upper and lower limb spasticity



ASPIRE, Adult SPasticity International Registry; NPRS, numerical pain rating scale; n, number of patients. [a] Patients may not have been treated during ASPIRE.

Most Patients (62%) Received Prior OnabotA Treatment for Spasticity

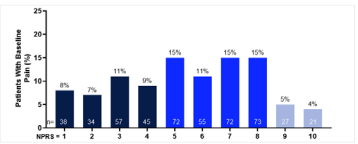
- Mean time from prior onabotA treatment for spasticity was 7.7 months

Clinical Characteristics

Parameter	Patients with NPRS > 0 N = 494
Prior onabotA treatment for spasticity, (%)	
Yes	305 (61.7%)
No	189 (38.3%)
Time from prior onabotA treatment for spasticity, months[a]	
Mean (SD)	7.7 (14.9)
Min, Max	0.1, 186.4
OnabotA treatment within the past 12 weeks, n (%)	
No	488 (98.8%)
Yes	6 (1.2%)

NPRS, numeric pain rating scale; OnabotA, onabotulinumtoxinA; SD, standard deviation. [a]Patients with NPRS > 0 at baseline; [b]Data from 294 patients (with NPRS > 0 at baseline)were included in this analysis; percentage was calculated using this number of patients

Mean Baseline Pain Score Assessed With NPRS Was 5.4

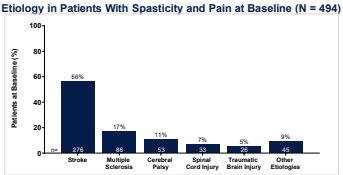


	Upper Limb (n = 122)	Lower Limbs (n = 172)	Upper and Lower Limbs (n = 200)	Total (N = 494)
NPRS				
Mean (SD)	5.3 (2.5)	5.4 (2.4)	5.6 (2.5)	5.4 (2.5)
Min, Max	1.0, 10.0	1.0, 10.0	1.0, 10.0	1.0, 10.0
Median [IQR]	5.0 [3.0, 7.0]	6.0 [3.0, 7.0]	6. 0 [4.0, 8.0]	6.0 [3.0, 7.0]

IQR, inter-quartile range; n, number of patients; NPRS, numeric pain rating scale; SD, standard deviation; [a] Patients may not have been treated during ASPIRE; [b]NPRS is a numeric scale in which a respondent selects a whole number from0 (no pain) to 10 (worst pain imaginable); that best reflects the intensity of their pain; spasticity patients included in this subanalysis had NPRS >0.

Stroke Was the Most Frequently Reported Etiology[a] at Baseline in 56% of Spasticity Patients With Pain (NPRS[b] > 0) at Baseline

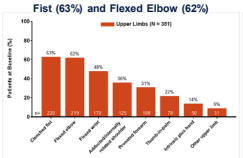
Etiology in Patients With Spasticity and Pain at Baseline (N = 494)



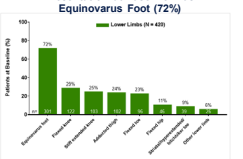
NPRS, numeric pain rating scale; n, number of patients. [a]Patients may have more than one etiology; [b] NPRS scale: 0 (no pain) to 10 (worst pain imaginable).

Baseline Clinical Presentation in Spasticity Patients With Pain at Baseline - Upper and Lower Limb Spasticity[a,b]

Most Common Upper Limb Spasticity Presentations at Baseline Were Clenched Fist (63%) and Flexed Elbow (62%)



Most Common Lower Limb Spasticity Presentation at Baseline Was Equinovarus Foot (72%)



ASPIRE, Adult SPasticity International Registry; n, number of patients. [a]Patients may not have been treated during ASPIRE; [b] Percentages may add to >100% as patients may have more than one presentation.

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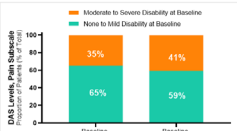
DAS[a] Pain Subscale Levels at Baseline Were Reported as None or Mild by 65% (UL, n = 319) and 59% (LL, n = 292) of Patients

DAS Upper and Lower Limb Pain Subscale Levels at Baseline



DAS Upper and Lower Limb Pain Levels and Scores[b] at Baseline

	Upper Limb Patients	Lower Limb Patients
DAS baseline pain scores		
Mean (SD)	**1.1** (1.1)	**1.2** (1.1)
Min, Max	0.0, 3.0	0.0, 3.0
Median [IQR]	1.0 [0.0, 2.0]	1.0 [0.0, 2.0]
DAS baseline pain subscale levels, n (%)	**n = 491[c]**	**n = 493[c]**
None disability	201 (40.9)	160 (32.5)
Mild disability	118 (24.0)	132 (26.8)
Moderate disability	108 (22.0)	128 (6.0)
Severe disability	64 (13.0)	73 (14.8)

DAS, disability assessment score; n, number of patients; onabotA, onabotulinumtoxinA; UL, upper limb; LL, lower limb; SD, standard deviation. [a]Baseline DAS measurement was taken by the physician prior to injection with onabotA at the first treatment visit (Tx1); [b]Scoring for the questions regarding patient upper and lower limb disability are as follows: 0 = none disability, 1 = mild disability, 2 = moderate disability, 3 = severe disability; [c]Number of patients assessed at baseline.

Limitations:

- Given the observational nature of the study, the generality of this analysis is limited
- Low sample sizes for some outcomes and treatment sessions (due to missing or ambiguous responses resulting in variation in the number of n's for each treatment session)
- DAS has been validated for UL spasticity only; however, it has also been used to evaluate LL spasticity

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