Real-World Utilization and Safety of OnabotulinumtoxinA for Chronic Migraine from an Observational Study in the European Union

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INTRODUCTION

- OnabotulinumtoxinA is approved for chronic migraine (CM) prophylaxis with safety and efficacy established in controlled trials
- Recommended treatment paradigm based on the Phase III Research Evaluating Migraine Prophylaxis Therapy (PREEMPT)[1]
  - Total dose: 155 U
  - Minimum of 31 injection sites across 7 specific head/neck muscles
  - Up to an additional 40 U using follow-the-pain (maximum of 195 U to 39 sites at physician's discretion)
  - 30-gauge, 0.5-inch needle
  - Recommended re-treatment every 12 weeks
- However, there are limited data on the real-world utilization and safety of onabotulinumtoxinA for CM headache prophylaxis

OBJECTIVE

- To evaluate real-world treatment utilization patterns and safety of onabotulinumtoxinA for CM in routine clinical practice

METHODS

- Prospective, observational, multinational European post-authorization study (NCT01432379) of utilization and safety among adults treated with onabotulinumtoxinA for CM headache prophylaxis in routine practice
- Physicians who attended Allergan-sponsored injector training were recruited
  - Invited to participate if they had an adequate number of adult CM patients expected to be eligible for onabotulinumtoxinA treatment in the next 3-6 months and ability to host electronic data collection application
- Patients who were selected for treatment with onabotulinumtoxinA in routine practice, per the Summary of Product Characteristics (SmPC), were included
- Study was reviewed/approved by the appropriate ethics committees in each country; patients provided consent prior to study participation
- Decisions to initiate/continue treatment were independent of study participation
- Data were collected at the time of the first study injection and approximately every 3 months for up to 52 weeks (utilization) and up to 64 weeks (safety)

RESULTS

Physician and Patient Characteristics

- 1160 patients treated by 85 physicians at 58 sites across UK, Germany, Spain, and Sweden were included in the study population
- 783 patients completed the study (52-week observation and final interview)
- Most common reason for discontinuation: lack of efficacy (n=164, 14.1%)
- The patient profile was similar between countries **(Table 1)**
  - Patients had a mean age of 46.4 years (range 19 to 79 years)
  - 84.2% of patients were female
  - 97.8% of patients were Caucasian
- 85.8% (n=995) had a CM/transformed migraine diagnosis and 51.6% (n=599) had a migraine diagnosis at baseline
- Patients reported an average 7.7 (SD=6.9) headache-free days per usual month at baseline
- 50.6% (n=587) of patients had used onabotulinumtoxinA for CM in the past

Table 1. Baseline Characteristics and Patient Disposition

Parameter	UK	Germany	Spain	Sweden	Overall
Participating physicians, n	19	39	13	14	85
Participating sites, n	16	19	11	12	58
Patients treated, n	422	287	232	219	1160
Patients completed, n (%)	238 (56.4)	167 (58.2)	204 (87.9)	174 (79.5)	783 (67.5)
Patients discontinued, n (%)	163 (38.6)	111 (38.7)	28 (12.1)	44 (20.1)	346 (29.8)
Patient Age, mean (SD)	46.0 (12.6)	47.2 (11.0)	48.0 (12.1)	45.4 (10.6)	46.6 (11.8)
Patient Gender, Female, n (%)	337 (79.9)	242 (84.3)	201 (86.6)	197 (90.0)	977 (84.2)

Utilization

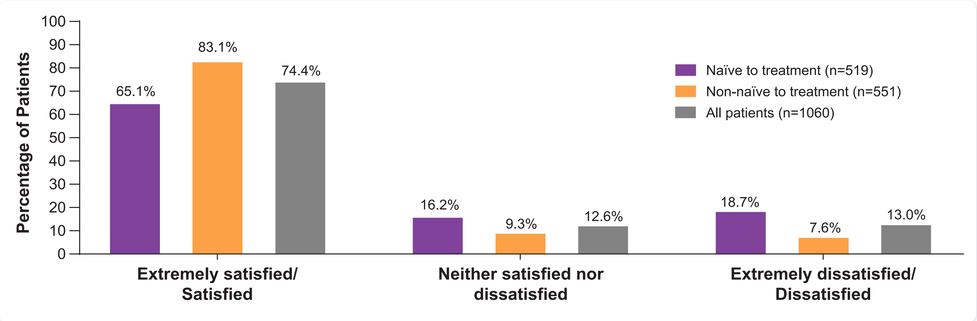
- A total of 4017 onabotulinumtoxinA treatment sessions were observed
- Data were consistent across treatment sessions and countries **(Table 2)**
  - Total dose (median): 155 U
  - Number of injection sites (median): 31
  - Each of the 7 recommended head/neck muscles were injected at each treatment session in >91% of patients
  - Needle length: majority of physicians utilized a 0.5 in/1.25 cm needle
  - Re-treatment (median): 13.7 weeks between sessions

Table 2. OnabotulinumtoxinA Treatment Characteristics

	Tx 1 (N=1160)	Tx 2 (N=1034)	Tx 3 (N=885)	Tx 4 (N=712)	Tx 5 (N=210)	Tx 6 (N=15)
Total Dose Units Across Muscle Areas[a] (Median [Min, Max])						
Right/Left Sides[b]	75 (30, 160)*	75 (6, 175)*	75 (6, 180)*	75 (20, 180)*	75 (20, 180)*	75 (30, 131)*
Midline[c]	5 (3, 30)	5 (3, 30)	5 (3, 120)	5 (3, 150)	3 (3, 25)	5 (5, 25)
Total Number of Sites Injected[a] (Median [Min, Max])						
Right/Left Sides[b]	15 (5, 30)	15 (3, 29)*	15 (3, 34)*	15 (4, 32)*	15 (4, 32)*	15 (12, 22)*
Midline[b,c]	1 (1, 6)	1 (1, 6)	1 (1, 5)	1 (1, 4)	1 (1, 4)	1 (1, 3)
Needle Length[d] (%)						
0.5 in / 1.25 cm	73.3	77.2	76.0	76.7	77.6	66.7
1 in / 2.5 cm	9.6	7.4	9.2	9.4	21.4	0.0
Other	23.8	21.4	21.0	20.6	17.6	33.3
Prespecified Muscle Areas Injected[e] (%)						
Frontalis	99.5	99.3	99.0	98.9*	99.0	100.0
Corrugator	97.4*	97.2*	98.5	98.5	98.1	100.0
Occipitalis	97.2	96.1*	97.1*	98.7	97.1	100.0
Temporalis	99.5*	98.1*	98.1*	99.2*	98.6	100.0
Trapezius	97.3	96.0*	96.5*	97.9	97.6	100.0
Cervical paraspinal	94.1	91.3*	91.5*	92.0	93.3	100.0
Procerus	94.4	94.5	94.2	95.5	94.3	100.0

Abbreviation: Max, maximum; Min, minimum; Tx, treatment
[a]Data across treatment sessions combined; median was consistent across treatment session; min/max across treatment sessions for the combined data is presented, with any differences between right and left counts indicated with * and the lower min and higher max data reported
[b]Data for one patient not reported at Tx 3 and Tx 4
[c]Data for the following number of patients reported: Tx 1 (N=1095), Tx 2 (N=977), Tx 3 (N=835), Tx 4 (N=681), Tx 5 (N=198), Tx 6 (N=15)
[d]More than one response was allowed; categories are not mutually exclusive
[e]Right and left muscles, where applicable, were counted separately; however, combined data is presented with any differences between right and left counts indicated with * and the lower count reported

Figure 1. Patient Satisfaction Stratified by Treatment History



Patient Satisfaction

- Of the 1090 patients who responded, 74.4% of patients indicated they were satisfied/extremely satisfied with onabotulinumtoxinA treatment for CM **(Figure 1)**
  - Satisfaction with treatment was higher in non-naïve patients

Safety

- 291 patients (25.1%) reported ≥1 treatment-related adverse event (TRAE)
  - Most frequently reported: neck pain (4.4%) and eyelid ptosis (4.1%)
- One (0.1%) serious TRAE was reported (worsening of migraine)
  - There were no treatment-related deaths
  - The nature and incidence of TRAEs were generally consistent between countries

CONCLUSIONS

- Patient demographics/characteristics are consistent with published data on the CM population
- OnabotulinumtoxinA treatment utilization appears to be consistent with the SmPC and published PREEMPT injection paradigm
- No new safety signals were identified
- Data continue to support the favorable safety profile of onabotulinumtoxinA

REFERENCE

1. Blumenfeld A, et al. *Headache.* 2010;50:1406-1418.

DISCLOSURES

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