Healthcare Resource Utilisation with OnabotulinumtoxinA for Symptom Relief in Patients with Chronic Migraine: REPOSE Study 12-Month Interim Analysis

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INTRODUCTION

- The International Burden of Migraine Study (IBMS) found migraine, particularly chronic migraine (CM), to be associated with considerable disability, healthcare resource use, and cost in Europe[1]
  - IBMS also found average healthcare costs for treatment of CM to be low in Germany and not significantly different from the cost of managing episodic migraine, possibly due to cost-control measures resulting from their public healthcare system[1]
- Cost modeling using patient data and dosing protocols from the PREEMPT clinical trials, resource utilisation estimates from UK participants in IBMS, and National Health Service unit costs demonstrated that onabotulinumtoxinA (BOTOX®, Allergan plc, Dublin, Ireland) is likely to represent a cost-effective use of resources in the UK[2]
- The REPOSE Study describes 2-year, real-life use of onabotulinumtoxinA for CM in Europe and examines the impact of treatment on healthcare resource utilisation (HRU)
  - This 12-month interim analysis examines REPOSE Study data with a focus on Germany, where physicians are less incentivised to treat with onabotulinumtoxinA because of the reimbursement structure

OBJECTIVE

- The aim of this interim analysis is to investigate the real-world impact of onabotulinumtoxinA on HRU among patients with CM across Europe, with a focus on Germany

METHODS

Study Design

- REPOSE is a multicentre, prospective, non-interventional, observational, open-label study in adult patients with CM
- The study consists of a 24-month treatment period, during which patients receive onabotulinumtoxinA injections approximately every 12 weeks according to their physician's usual practice, guided by the Summary of Product Characteristics[3]

Patients

- Patients ≥18 years of age enter the study if onabotulinumtoxinA is prescribed and if they have not received any botulinum toxin 26 weeks prior to enrolment
- All participants provide written informed consent

Assessment

- This 12-month interim analysis compares HRU at baseline and at each follow-up visit for re-treatment with onabotulinumtoxinA
- Results are collected and reported for the overall European population and for the subset of patients enrolled at German study centres

RESULTS

- Data were available for 405 patients from 61 centres throughout Europe, including 171 patients enrolled at German study centres
  - Baseline demographic and clinical data are presented in **Table 1**

Table 1. Baseline Patient Demographics and Clinical Characteristics

	European Population (N=405)	German Subpopulation (N=171)
Age, years		
Mean (SD)	44.8 (11.3)	46.8 (11.4)
Range	18–76	19–76
Women, n (%)	342 (84.4)	136 (79.5)
Mean (SD) body mass index, kg/m^2	24.7 (5.0)	24.6 (4.6)
Employed full-/part-time, n (%)	260 (64.2)	107 (62.6)
Mean (SD) age at headache onset, years	18.0 (9.4)	19.8 (9.8)
Mean (SD) time since first CM diagnosis, years	5.1 (7.6)	4.8 (8.1)
Medication use in the 26 weeks before baseline, n (%)*		
Acute treatment for headache	322 (79.5)	138 (80.7)
Headache preventative	215 (53.1)	94 (55.0)

CM=chronic migraine.

*Multiple answers were possible.

- In the 3 months prior to baseline, 47.7% of all patients visited a healthcare professional (HCP; **Table 2**)
  - HCP visits at baseline were most commonly outpatient consultations (n=146, 36.0% of patients) and primary care consultations (n=135, 33.3% of patients)
  - After treatment with onabotulinumtoxinA, 16.0%–19.7% of patients visited an HCP in the 3 months prior to each re-treatment visit **(Figure 1A)**
- In the 3 months before baseline, 5.2% of all patients were admitted to a hospital for a headache-related cause **(Table 2)**
  - After treatment with onabotulinumtoxinA, 1.1%–1.8% of patients were admitted to a hospital in the 3 months prior to each re-treatment visit

Table 2. Headache-Related HRU

European Population, n (%)*	Baseline (n=405)	FU1 (n=370)	FU2 (n=377)	FU3 (n=351)	FU4 (n=331)
Any HCP visit	193 (47.7)	73 (19.7)	61 (16.2)	57 (16.2)	53 (16.0)
Hospital admission	21 (5.2)	5 (1.4)	5 (1.3)	4 (1.1)	6 (1.8)

FU=follow-up re-treatment visit; HCP=healthcare professional; HRU=healthcare resource utilisation.

*Percentages are based on the number of patients (n) with the respective visit; data are not available for all patients. Baseline and follow-up visits analysed HRU in the last 3 months and normalised to 90 days for all FU visits.

- In the German subpopulation, the most frequently used health services for the 6 months before baseline were visits to medical specialists (58.5% of patients) and family doctors (38.6% of patients)
  - After treatment with onabotulinumtoxinA, the frequency of use for all health services was reduced in the 3 months prior to each re-treatment visit **(Table 3)**
  - No notable differences were observed among re-treatment visits **(Table 3, Figure 1B-C)**

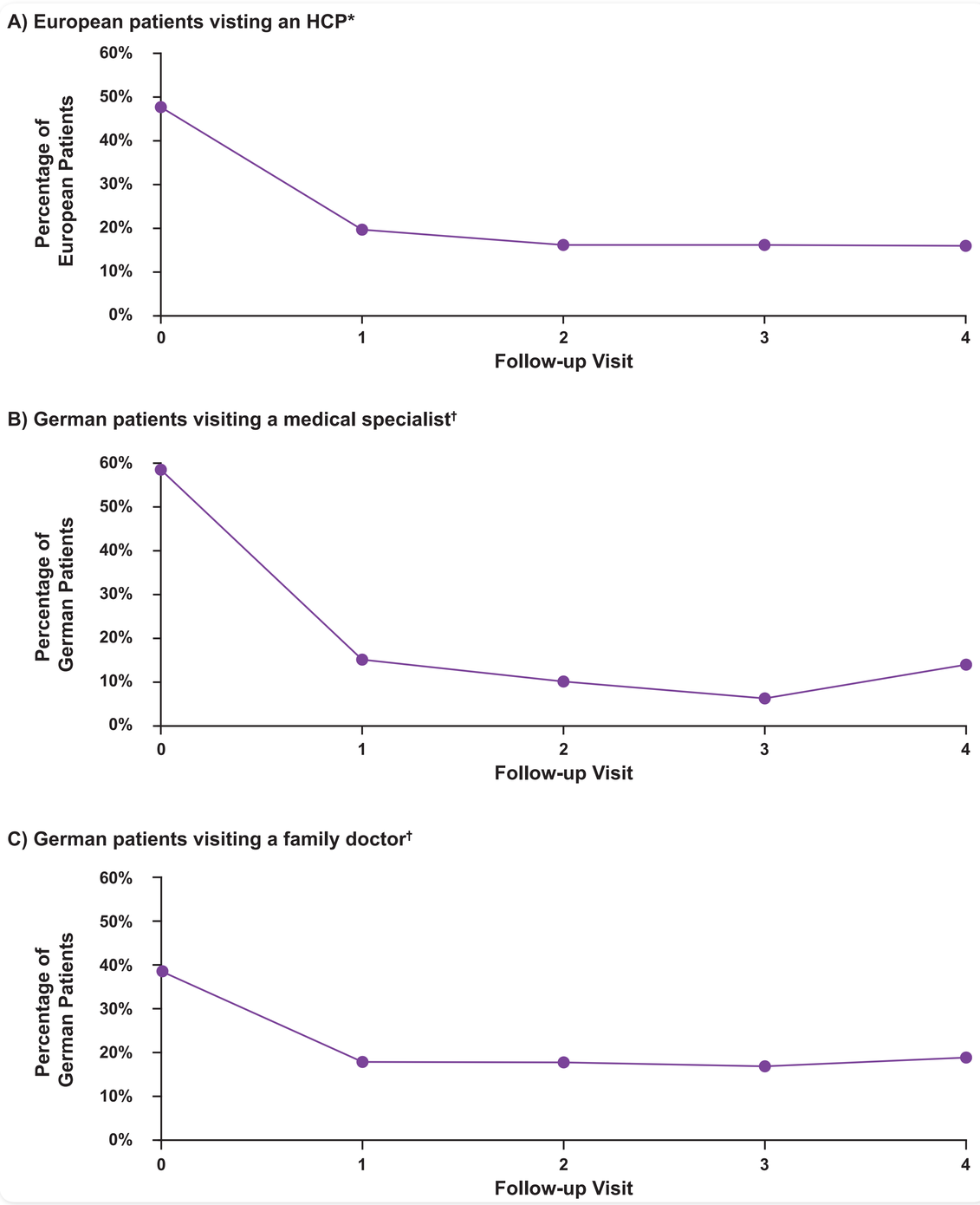
Table 3. Headache-Related HRU for the German Subpopulation

Patients, n (%)*	Baseline (n=171)	FU1 (n=151)	FU2 (n=157)	FU3 (n=142)	FU4 (n=143)
Medical specialist visit	100 (58.5)	23 (15.2)	16 (10.2)	9 (6.3)	20 (14.0)
Family doctor visit	66 (38.6)	27 (17.9)	28 (17.8)	24 (16.9)	27 (18.9)
Technical investigation (e.g., MRI, CT)	32 (18.7)	6 (4.0)	3 (1.9)	2 (1.4)	5 (3.5)
Treatment with acupuncture	27 (15.8)	2 (1.3)	3 (1.9)	2 (1.4)	2 (1.4)
Inpatient treatment in acute care clinic	12 (7.0)	5 (3.3)	2 (1.3)	1 (0.7)	3 (2.1)

CT=computed tomography; FU=follow-up re-treatment visit; HRU=healthcare resource utilisation; MRI=magnetic resonance imaging.

*Percentages are based on the number of patients (n) with the respective visit; data are not available for all patients. Baseline: HRU in the last 6 months; follow-up visits: HRU since the last visit (3 months).

Figure 1. Reduction in HCP Visits



HCP=healthcare professional; HRU=healthcare resource utilisation.

*Baseline and follow-up visits analysed HRU in the last 3 months.

†Baseline: HRU in the last 6 months; follow-up visits: HRU since the last visit (3 months).

- In the German subpopulation, 16 patients (9.4%) reported adverse drug reactions (ADRs), which were typically mild or moderate (n=14, 8.2%) in severity
  - No patient discontinued treatment permanently because of an ADR and no new safety concerns were noted

CONCLUSIONS

- In this 12-month interim analysis, preventative treatment of CM with onabotulinumtoxinA in a real-world setting reduces headache-related HRU in the broader European population as well as the German subpopulation
- Reduced HRU supports the use of onabotulinumtoxinA in clinical practice throughout Europe, although further analysis is required to determine the real-world cost-effectiveness of onabotulinumtoxinA for CM in Europe, and Germany in particular

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