

Disease Burden, Treatment Landscape, and Health-Related Quality of Life Outcomes in Myasthenia Gravis: Results from the Adelphi Real World Disease Specific Programme in the United States and Europe

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BACKGROUND

- Myasthenia gravis (MG) is an autoimmune disorder characterized by fluctuating fatigability and weakness of the ocular and skeletal muscles.^{1,2}
- Patients with MG experience severe functional impairment along with limited psychological and social well-being.¹

OBJECTIVE

- This study assessed disease burden, treatment landscape, and health-related quality of life (HRQoL) in patients with MG.

METHODS

- Data were drawn from the Adelphi MG Disease Specific Programme™ conducted between March and September 2020 in France, Germany, Italy, Spain and the United Kingdom (EU5) and the United States (US).
- Physician inclusion criteria:**
 - Primary physician specialty identified as a neurologist, geriatrician, or primary care physician (PCP) currently managing at least one patient with a diagnosis of MG.
- Patient inclusion criteria:**
 - Patients with a confirmed diagnosis of MG classified as Myasthenia Gravis Foundation of America (MGFA) Class II–IV were included in this study.
- Physicians completed online patient record forms (PRFs) for their next 1–6 consulting patients, including retrospective chart data and cross-sectional information recorded after the recent consultation.
 - The same patients were offered and voluntarily completed forms with patient-reported outcome (PRO) measures. If the patient was under 18 or unable to complete the form, their caregiver attending the consultation was offered a proxy form.
- The impact of MG on HRQoL was assessed using PRO tools, including the EQ-5D (EuroQol-5 Dimensions 5 Level questionnaire [EQ-5D-5L] and EuroQol-5 Dimensions Visual Analog Scale [EQ-5D-VAS]) and Myasthenia Gravis Quality of Life 15-item Scale – Revised (MG-QoL-15r) questionnaire.
 - The EQ-5D-5L gives a score between 1 (perfect health) and 0 (death) with values less than 1 being possible for states worse than death.
 - The EQ-5D-VAS ranges from 100 (best imaginable) to 0 (worst imaginable) with the patient rating themselves on how they feel on the day of answering.
 - The MG-QoL-15r evaluates an MG patient’s quality of life across 15 questions scored 0 (not at all), 1 (somewhat), and 2 (very much); a higher score is associated with a greater effect on the patient’s quality of life.
- Data were assessed using descriptive statistics.

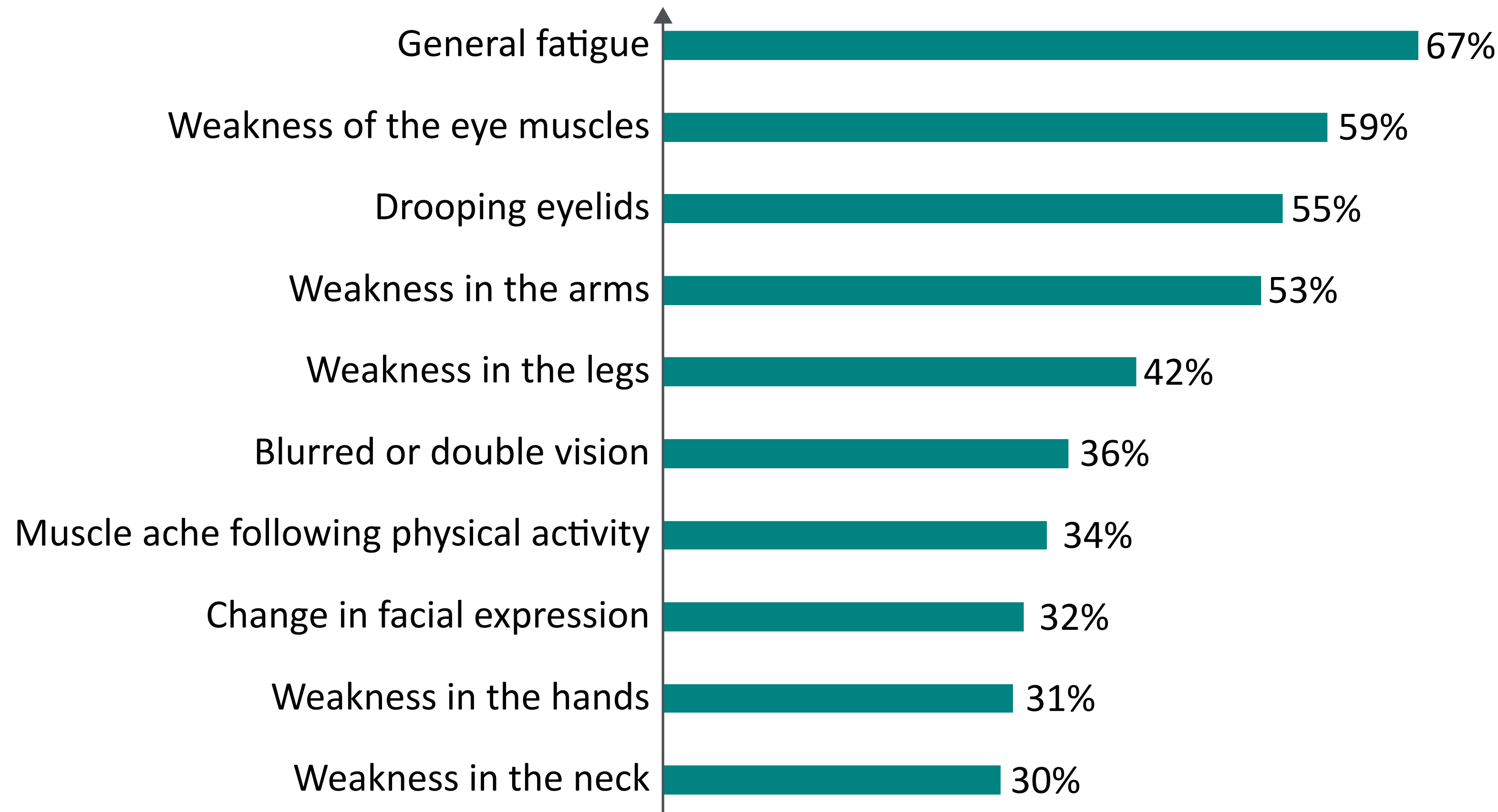
RESULTS

Demographics and clinical characteristics

- A total of 222 physicians (EU5: 144; US: 78) completed PRFs for 865 patients (EU5: $n = 554$; mean age = 53.8 years; 49% male and US: $n = 311$; mean age = 54.5 years; 54% male) with MG; 261 patients and 37 proxy-caregivers provided self-completion forms.
- Most patients were symptomatic at the time of survey (98% in EU5 and 95% in the US). Mean number of symptoms was 6.1 and 6.3 in the US and EU5, respectively.
 - The commonly reported symptoms included general fatigue (67%), weakness of eye muscles (59%), and drooping eyelids (55%; **Figure 1**).

- A total of 69% patients in EU5 and 76% in the US had comorbidities; hypertension (36% in EU5 and 47% in the US) was the most frequently reported comorbidity in patients from both geographies.
- Among patients ($n = 149$) reported by their physician with known antibodies, acetylcholine receptor positivity was found in 81% of patients and 11% of patients were seronegative.

Figure 1: Most frequently experienced symptoms (top 10, $n = 839$)

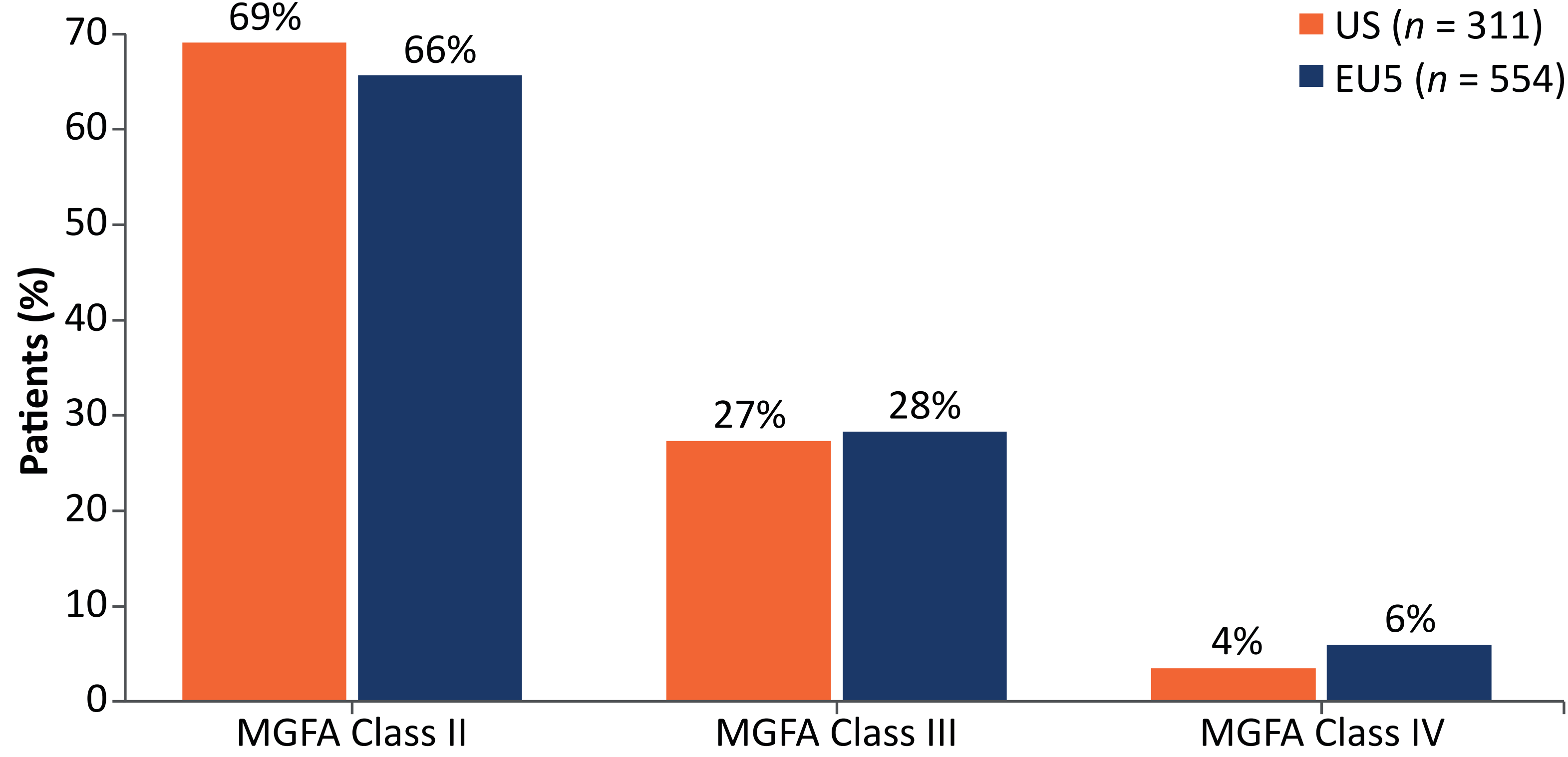


Base: All physician-reported patients MGFA Class II–IV ($n = 865$).
*Base had dropped from 865 to 839 as non-symptomatic patients were excluded.
MGFA, Myasthenia Gravis Foundation of America

Patient journey

- Mean time from symptom onset to MG diagnosis was 11.9 months in EU5 and 8.5 months in the US.
- Over three quarters of patients decided to consult a healthcare professional on their own initiative. They were most likely to initially consult a general practitioner/PCP while a neurologist typically provided their diagnosis.
- Patients in the US and the EU5 countries were distributed similarly across MGFA classifications (**Figure 2**).
- Almost a third of the EU5 patients (30%) were reported to have experienced myasthenic crisis, whereas this was considerably lower in the US (19%).

Figure 2: Distribution of EU5 and US patients based on current Myasthenia Gravis Foundation of America classification



EU5, France, Germany, Italy, Spain, and the United Kingdom; MGFA, Myasthenia Gravis Foundation of America; US, United States

FUNDING

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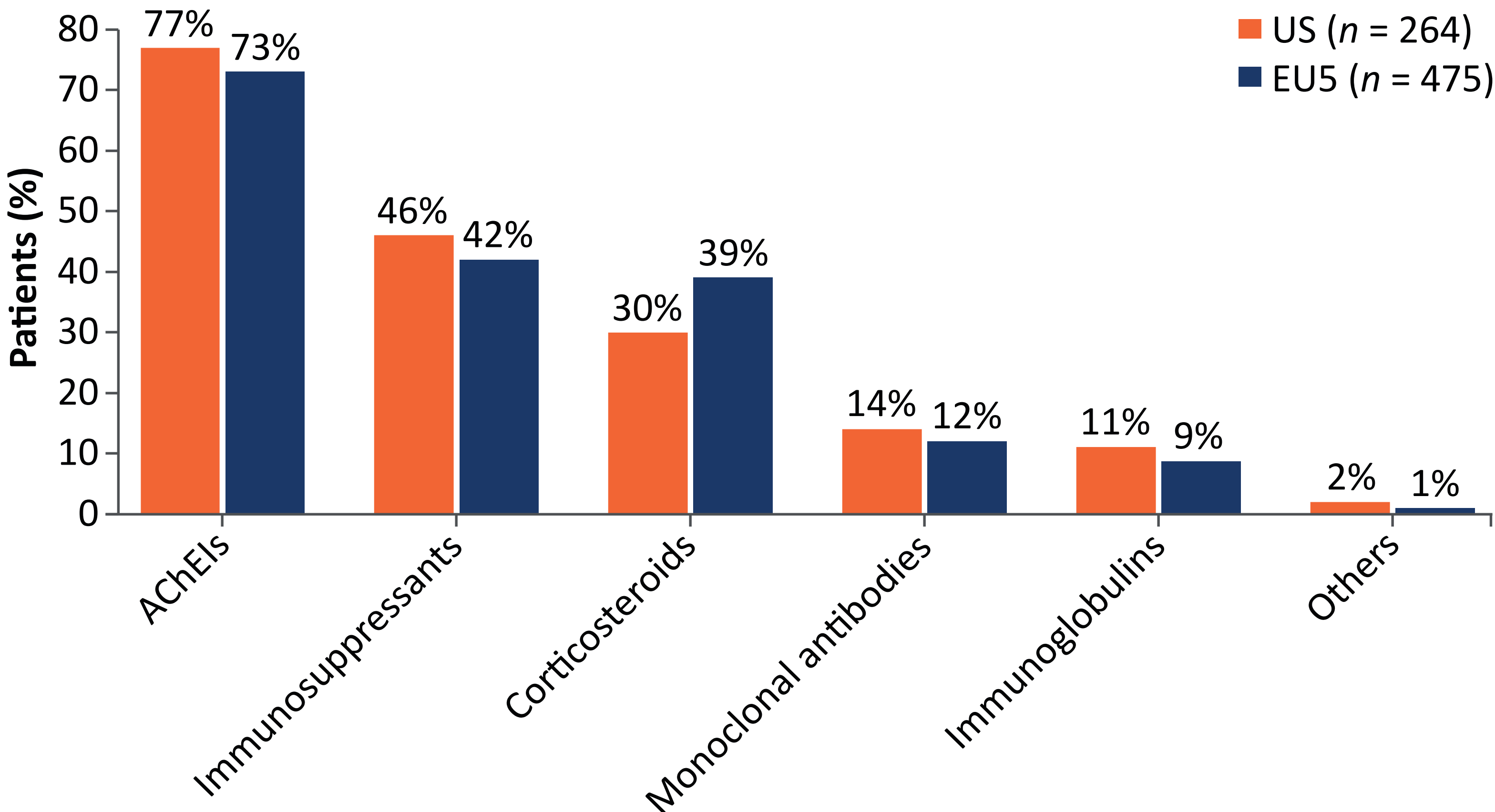
ACKNOWLEDGMENTS

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Treatment landscape

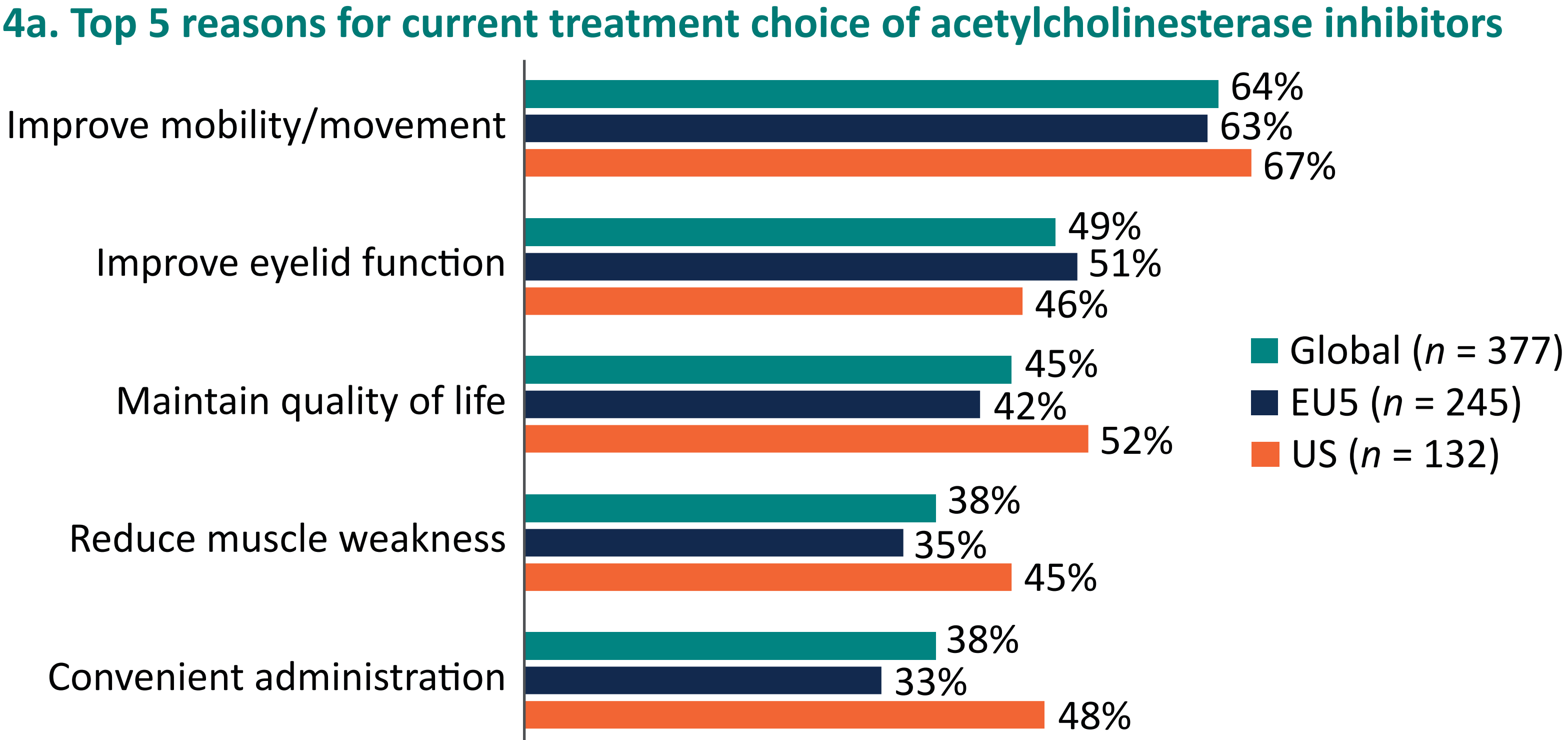
- Acetylcholinesterase inhibitors (AChEIs) were the most commonly used medication class (EU5: 73%; US: 77%; **Figure 3**), and pyridostigmine was the most frequently prescribed medication (EU5: 56%; US: 66%).
- On average, patients in MGFA Class IV had received more treatment lines than those in Class III and Class II.
- In EU5, almost 6 in 10 patients had ever received only one treatment line, whereas around half of the US patients had received more than one line of treatment.
- The most frequently reported reason for choosing an AChEI in those currently receiving AChEIs was to improve mobility (US: 67%; EU5: 63%; **Figure 4a**). Most frequent mention for swapping or stopping an AChEI was due to efficacy diminishing over time in the US (65%), or patient request in Europe (34%; **Figure 4b**).
- Thymectomies were more common among EU5 patients with a larger proportion having either undergone surgery or been on a waiting list compared with patients in the US (24% vs 18%).

Figure 3: Current treatment landscape – MGFA Class II–IV



Base: All physician-reported patients MGFA Class II–IV (EU5 [$n = 554$] and US [$n = 311$]) unless otherwise stated.
AChEIs, acetylcholinesterase inhibitors; EU5, France, Germany, Italy, Spain, and the United Kingdom; MGFA, Myasthenia Gravis Foundation of America

Figure 4: Reasons for treatment choice and stop/swap – Acetylcholinesterase inhibitors
4a. Top 5 reasons for current treatment choice of acetylcholinesterase inhibitors

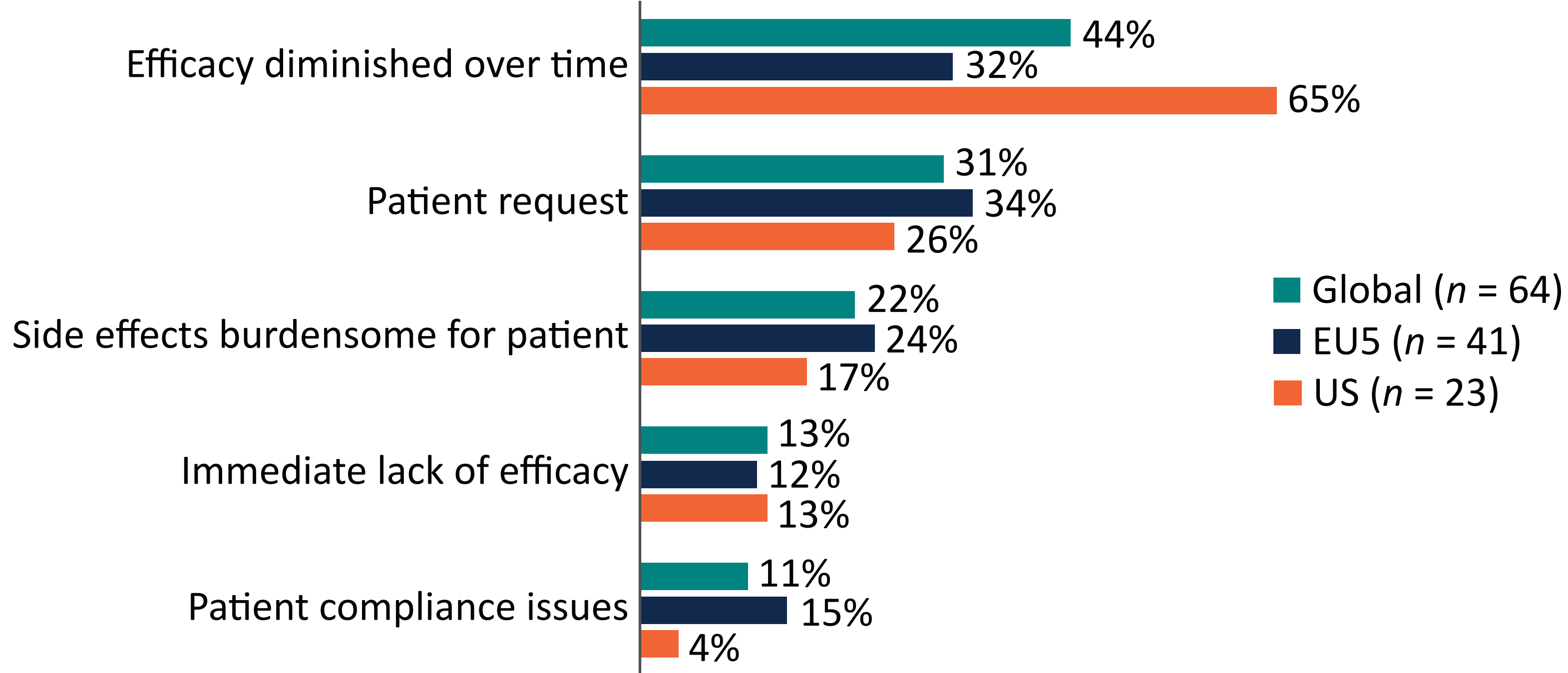


Base: All physician-reported patients MGFA class II–IV (Global [$n = 865$], EU5 [$n = 554$], and US [$n = 311$]) unless otherwise stated.
EU5, France, Germany, Italy, Spain, and the United Kingdom; MGFA, Myasthenia Gravis Foundation of America; US, United States

CONFLICTS OF INTEREST

- CG, NG, SS, and LA are employees of Sanofi and may hold stock/stock-options in Sanofi.
- GG and JdC are employees of Adelphi Real World. The Disease Specific Programme is an Adelphi Real World product. Sanofi was a subscriber to the Disease Specific Programme and did not influence the original survey through either contribution to the design of questionnaires or data collection.

4b. Top 5 reasons for most recent treatment stop/swap of acetylcholinesterase inhibitors



Base: All physician-reported patients MGFA class II–IV (Global [$n = 865$], EU5 [$n = 554$], and US [$n = 311$]) unless otherwise stated.
EU5, France, Germany, Italy, Spain, and the United Kingdom; MGFA, Myasthenia Gravis Foundation of America; US, United States

Disease impact and burden

- The HRQoL trends were similar among patients in EU5 and the US. Physicians reported that almost 90% of patients were “on long-term sick leave” due to their MG. Over a fifth of those still working had changed to a more sedentary job to accommodate their MG.
- There was decline in patients’ HRQoL with increasing disease severity. Patients with severe MG (MGFA Class IV) reported poorer (MGFA Class II vs MGFA Class IV) HRQoL scores (**Table 1**).
- MG had an impact on patients’ employment/ability to work (13% patients on long-term sick leave due to MG) as well as caregivers’ work productivity (25%) in EU5 and the US.

Table 1: Impact of myasthenia gravis on health-related quality of life

PRO		MGFA Class II	MGFA Class III	MGFA Class IV
EQ-5D-5L score	US	$n = 56$ 0.75	$n = 27$ 0.65	$n = 2$ 0.40
	EU5	$n = 114$ 0.72	$n = 62$ 0.62	$n = 17$ 0.39
EQ-5D-VAS score	US	$n = 57$ 73.9	$n = 27$ 60.1	$n = 2$ 32.5
	EU5	$n = 112$ 68.5	$n = 62$ 54.7	$n = 16$ 38.9
MG-QoL-15r score	US	$n = 51$ 10.8	$n = 28$ 17.0	$n = 2$ 28.5
	EU5	$n = 109$ 11.1	$n = 50$ 15.6	$n = 14$ 21.1

EQ-5D-5L, EuroQol-5 Dimensions 5 Level questionnaire; EQ-5D-VAS, EuroQol-5 Dimensions Visual Analog Scale; EU5, France, Germany, Italy, Spain, and the United Kingdom; MGFA, Myasthenia Gravis Foundation of America; MG-QoL-15r, Myasthenia Gravis Quality of Life 15-item Scale – Revised; PRO, patient reported outcome

CONCLUSIONS

- MG is associated with high disease burden in EU5 and the US with over two-thirds of patients experiencing general fatigue.
- In the real-world, MG negatively impacted patients’ lives. There was a decline in patients’ HRQoL with increasing disease severity.

REFERENCES

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