Real-world Treatment Patterns Among Patients with Generalized Myasthenia Gravis

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Background

- Generalized myasthenia gravis (gMG) is a rare chronic autoimmune condition causing muscle weakness and muscle function impacts.
- Conventional treatments include acetylcholinesterase inhibitors (AChEI), systemic corticosteroids, and non-steroidal immunosuppressants, while immunoglobulin is commonly used as a rescue treatment for acute exacerbation or crisis
- Targeted immunotherapies, including rituximab, neonatal Fc receptor inhibitors (FcRni), and complement C5 inhibitors (C5i), have recently emerged as potential treatment options for gMG
- Limited real-world data are available on treatment patterns and myasthenia gravis (MG)-related clinical events in the context of this evolving treatment landscape

Objective

To evaluate real-world treatment patterns and MG-related clinical events among an incident cohort of patients with gMG in the US

Methods

Data source

- US insurance claims data from Komodo Research Database (01/2017 09/2023)
- Data were de-identified and complied with requirements of the Health Insurance Portability and Accountability Act

Study design

- Retrospective observational design
- Index date = first MG diagnosis by a neurologist (based on the International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] and revenue codes)
- Baseline period = 12-month period before the index date
- Follow-up period = index date until the end of continuous insurance eligibility or data availability

Patient selection

- ≥1 diagnosis of MG (ICD-10-CM: G70.00, G70.01) during study period (01/01/2017 - 09/30/2023) by a neurologist
- ≥18 years old on the index date
- ≥12 months of continuous insurance eligibility before the first MG diagnosis and ≥12 months after the index date
- No claim for congenital MG (G70.2) during the baseline period

Outcome definitions

- Treatment patterns were assessed based on the first five observed treatment episodes during the follow-up period, each episode included one or multiple gMG-related drug classes
- The first treatment episode comprised of drug classes initiated within the first 30 days. The change in drug class defined the end of the episode
- Subsequent treatment episodes were defined as the period from the end of the first treatment episode until the next drug class change
- The drug classes considered included AChEI, systemic corticosteroids, non-steroidal immunosuppressants, immunoglobulin, rituximab, C5i, and FcRni
- MG exacerbation was defined as separate dates with either a MG with exacerbation diagnosis (G70.01) in any setting, or a MG without exacerbation diagnosis (G70.00) as a primary diagnosis in inpatient or emergency setting
- MG crisis was defined based on procedures for intubation, tracheostomy or mechanical ventilation with an MG diagnosis in inpatient or intensive care unit admission

Statistical analysis

 Means, standard deviations and medians for continuous variables and frequencies and proportions for binary variables were reported for baseline characteristics and outcomes

Results

- The cohort included 6,195 patients (mean follow-up time: 32.7 months)
- 43.8% had MG before confirmation by a neurologist
- There was an average of 27.9 days between the first MG diagnosis to the confirmation by a neurologist

Table 1: Baseline characteristics

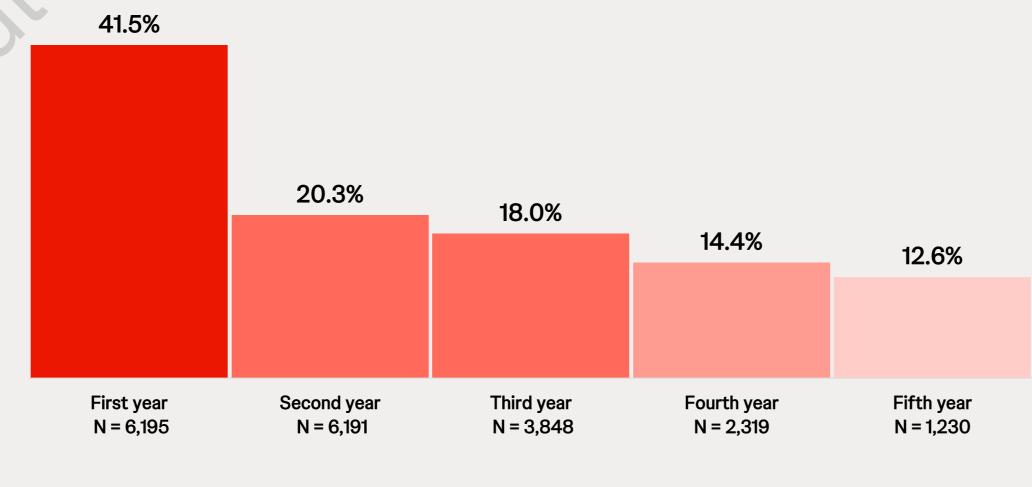
Mean ± SD [median] or n (%)	gMG cohort
	N=6,195
Age at index date (years)	61.1 ± 15.4 [62.6]
Female	3,040 (49.1)
Payer	
Commercial	3,307 (53.4)
Medicare Advantage	2,537 (41.0)
Medicaid	350 (5.6)
Unknown	1 (0.0)
Year of index date	
2018	1,004 (16.2)
2019	1,236 (20.0)
2020	1,249 (20.2)
2021	1,447 (23.4)
2022	1,259 (20.3)
Quan-Charlson comorbidity index ¹	2.0 ± 2.4 [1.0]
Common comorbidities	
Hypertension	3,675 (59.3)
Hyperlipidemia/dyslipidemia	3,505 (56.9)
Obesity	2,155 (34.8)
Diabetes	1,616 (26.1)
gMG characteristics during the baseline period	
Any gMG-related therapy	2,332 (37.6)
Any MG diagnosis by non-neurologist	2,714 (43.8)
Time from first MG diagnosis to index date (days)	27.9 ± 65.1 [0.0]

Abbreviations: gMG =generalized myasthenia gravis; MG = myasthenia gravis; SD = standard deviation. **Note:** [1] Quan H, Sundararajan V, Halfon P et al. Coding Algorithms for Defining Comorbidities in ICD-10-CM Administrative Data. Medical Care

MG-related clinical events

Post-index, 48.8% and 3.1% of patients had MG exacerbation or crisis, respectively, over the follow-up period of 33 months. Exacerbations and crises were most common 1-year post-index (41.5%), but declined over time (20.3%, 18.0%, and 14.4% in the second, third, and fourth year, respectively; Figure 1)

Figure 1: Prevalence of clinical events over time

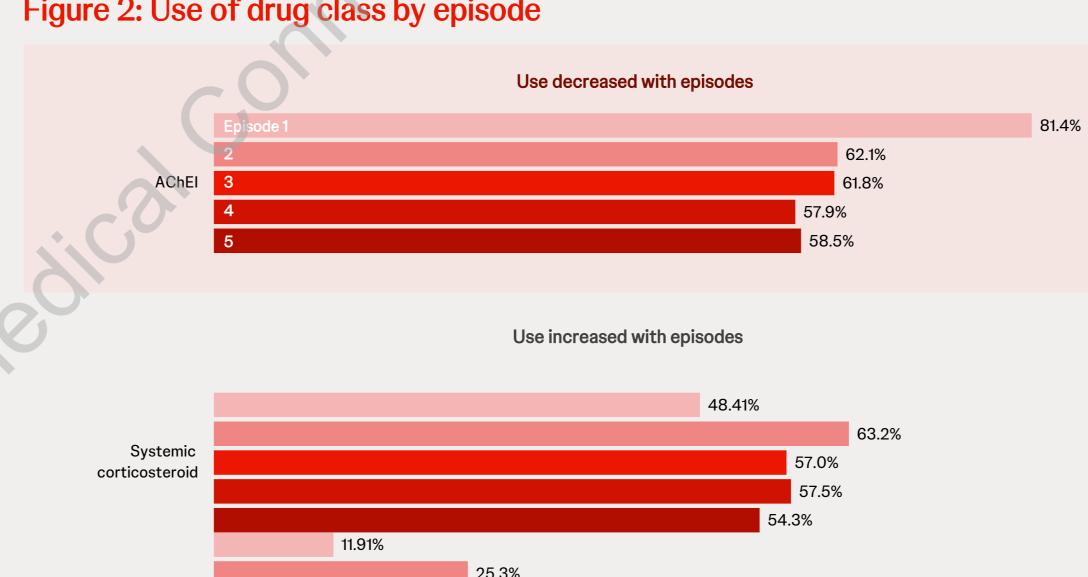


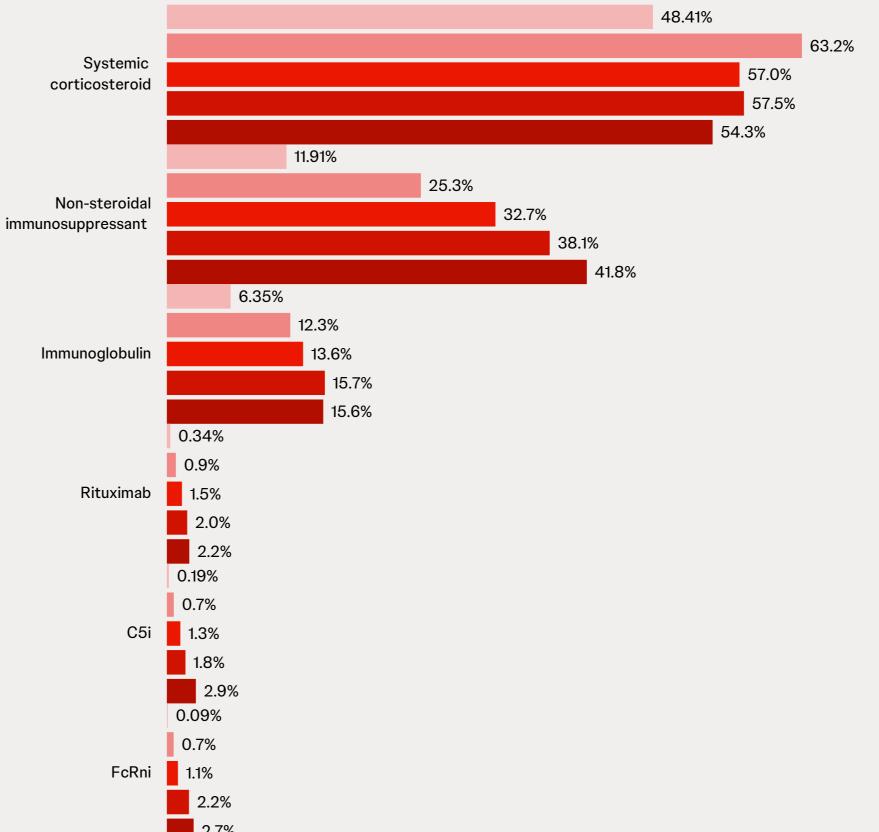
Notes: [1] MG-related clinical event includes MG exacerbation and crisis. [2] Each N represents the total number of patients included in the analysis for each follow-up year.

Treatment episodes

- Among those receiving treatments, from episode 1 (n=5,652) to episode 5 (n=2,107, **Figure 2**):
- AChEI use declined (81.4% → 58.5%)
- Systemic corticosteroid use increased (48.4% → 54.3%)
- Non-steroidal immunosuppressants use increased (11.9% → 41.8%)
- Immunoglobulin use increased (6.4% → 15.6%)
- Rituximab use increased (0.3% → 2.2%)
- C5i use increased (0.2% → 2.9%)
- FcRni use increased $(0.1\% \rightarrow 2.7\%)$
- Mean time from index date to C5i and FcRni initiation exceeded one year (Figure 3)

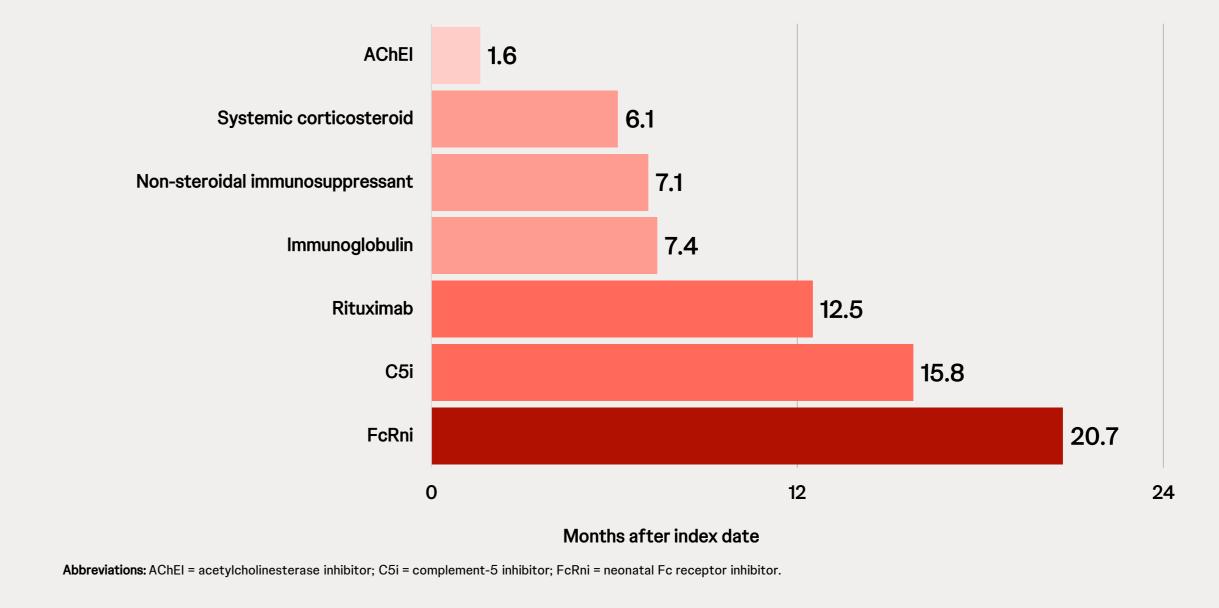
Figure 2: Use of drug class by episode





Abbreviations: AChEI = acetylcholinesterase inhibitor; C5i = complement-5 inhibitor; FcRni = neonatal Fc receptor inhibitor.

Figure 3: Mean number of months to drug class initiation



Strengths and limitations

Strengths

- Use of recent data allowed to capture newly approved treatments in the gMG management landscape
- This is one of the first studies that described MG clinical events and changes of gMG treatments through disease progression

Limitations

- Claims data are subject to data availability and completeness and accuracy of claim records
- Results may not be generalizable to patients without health insurance

Conclusions and key takeaways



Conventional treatments were the primary strategy for most patients, whereas immunoglobulin and targeted immunotherapies became increasingly prevalent as patients progressed through multiple treatment options



Almost half of the patients experienced MG-related clinical events in the first year after gMG diagnosis, and this proportion decreased in the following years



Treatment patterns and high prevalence of MG-related clinical events during the first year of gMG suggest a need for more effective early intervention strategies to achieve better disease control in patients with gMG

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