Treatment and Dosage Patterns of Oral Corticosteroids among Patients with Myasthenia Gravis: A Tale of Two Countries

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INTRODUCTION

- Myasthenia gravis (MG) is a rare, chronic, autoimmune disorder characterized by muscle weakness and fatigue that leads to hallmark symptoms including ptosis, shortness of breath, and limb weakness.[1]
- Corticosteroids are the mainstay treatment for patients with MG; however, little is known about the treatment and dosage patterns of oral corticosteroids (OCS) in this population.

OBJECTIVES

- To describe the treatment utilization and dosing patterns of OCS among patients with MG in the United states (US) and Sweden.

METHODS

- Adults with ≥2 diagnosis of MG (ICD-10: G70.0), with 1 diagnosis recorded by a neurologist and ≥1 record of OCS were identified from two administrative data sources in the US and Sweden:
  - IBM MarketScan® Commercial and Medicare Supplemental databases.
  - Swedish National Patient Register, and linked with Prescribed Drug Registry, Cause of Death Registry, and Longitudinal integration Database for health insurance and labor market studies.
  - Index date: date of the first OCS fill within 12-month after MG diagnosis.
- Proportion of days covered (PDC): defined as sum of non-overlapped days supplies of the index treatment divided by 365 days.
- Persistence: defined as the number of days from the index date to discontinuation date, which is the fill date plus days' supply of the last prescription filled, given the maximum allowed gap of 90 days; if no discontinuation is observed, patients will be censored at the end date of the study period.
  - Long-term (≥3months)
  - Short-term (<3 months)
- Average daily dose (ADD): calculated by using the days' supply, metric quantity and strength of the claim and a prednisone conversion factor and categorized as low, medium, high-dose; categories defined based on dose distribution.
  - High-dose (≥40 mg/day)
  - Medium-dose (≥7.5 mg/day to <40mg/day)
  - Low-dose (<7.5 mg/day)

RESULTS

Attrition tables

Step	Market Scan US Claims Inclusion and Exclusion Criteria	N	%
1	Patients with ≥2 claims in the inpatient, outpatient, ER or other setting with a diagnosis of MG provided by neurologist from 1/1/2016 to 12/31/2022	9,724	
2	Patients aged ≥18 years	9,208	94.7
3	Patients with ≥24 months continuous healthplan enrollment	4,230	45.9
4	MG Patients with ≥1 OCS within 12-month post-index treatment period	2,356	55.7

Step	Swedish National Registries Inclusion and Exclusion Criteria	N	%
1	Patients with ≥2 primary MG diagnoses filed ≥12 months but ≤24-month apart, with at least one of those diagnoses being a primary MG diagnosis filed by neurologist specialists, in inpatient or outpatient specialist visit from 1/1/2010 to 12/31/2017	1,403	
2	Patients aged ≥18 years	1,380	98.4
3	Patients with ≥24 months follow-up period	1,308	94.8
4	MG Patients with ≥1 OCS within 12-month post-index treatment period	859	65.7

ER, emergency room; MG, myasthenia gravis; OCS, oral corticosteroids.

Table 1: Sociodemographic and clinical characteristics

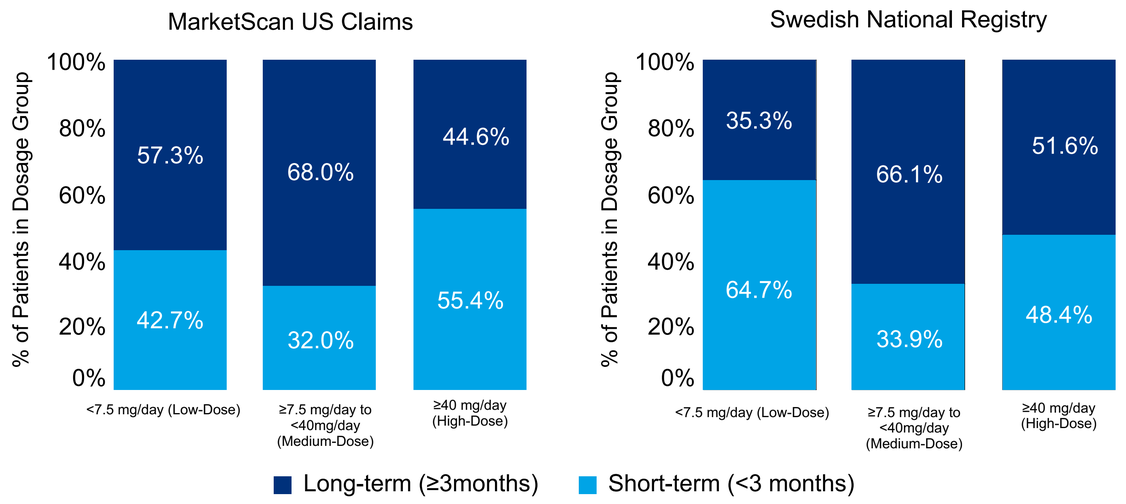
Market Scan US Claims	N=2,356
Age, year, mean (SD)	58 (15.0)
Gender (n, %)	
Male	1,160 (49.2)
Female	1,196 (50.8)
Region (n, %)	
North Central	591 (25.1)
Northeast	430 (18.3)
South	1,091 (46.3)
West	241 (10.2)
Unknown	3 (0.1)
Types of benefit design (n, %)	
CDHP/HDHP	385 (16.3)
PPO	1,240 (52.6)
HMO	248 (10.5)
Others	483 (20.5)
12-month pre-index CCI, mean (SD)	1.688 (1.9)
Duration of OCS	
≥3 months (long-term)	1,456 (61.8)
<3 months (short-term)	900 (38.2)
ADD of OCS	
≥40 mg/day (high-dose)	383 (16.3)
≥7.5 mg/day to <40mg/day (medium-dose)	1,446 (61.4)
<7.5 mg/day (low-dose)	527 (22.4)
Patients with long-term high-dose, n (%)	171 (7.3)

Swedish National Registries	N=859
Age, year, mean (SD)	62.8 (16.7)
Gender (n, %)	
Male	427 (49.7)
Female	432 (50.3)
Education (n, %)	
0-9 yrs	251 (29.2)
10-13 (high school)	323 (37.6)
13+ (post-secondary education)	262 (30.5)
Doctoral education	10 (1.2)
Missing	13 (1.5)
Employment status (n, %)	
In employment	303 (35.3)
Not in employment	147 (17.1)
Not working due to older age	408 (47.5)
Missing	1 (0.1)
12-month pre-index CCI, mean (SD)	3.75 (1.5)
Duration of OCS	
≥3 months (long-term)	504 (58.7)
<3 months (short-term)	355 (41.3)
ADD of OCS	
≥40 mg/day (high-dose)	157 (18.3)
≥7.5 mg/day to <40mg/day (medium-dose)	569 (66.2)
<7.5 mg/day (low-dose)	133 (15.5)
Patients with long-term high-dose, n (%)	81 (9.4)

ADD, average daily dose; CCI, consumer confidence index; CDHP, consumer-driven health plans; HDHP, high deductible health plan; HMO, health maintenance organization; OCS, oral corticosteroids; PPO, preferred provider organization; SD, standard deviation.

- Greater than 75% of patients received medium or high-dose therapy.
  - Average time to OCS discontinuation was similar at 5.4 and 5.8 months in Sweden and the US respectively, and similar percentage of patients with OCS ≥3 months (61.8% in US and 58.7% in Sweden).
  - Over 77% of patients with ADD ≥7.5mg/day were observed in both countries.

Figure 1: MG patients with OCS use by dosage and duration



MG, myasthenia gravis; OCS, oral corticosteroids.

- Among patients with high-dose OCS (ADD ≥40mg/day), a higher percentage of MG patients remained on treatment longer than 3 months in Sweden than in the US (51.6% vs 44.6%).
- Outcomes were similar in terms of average PDC (0.32 in US and 0.37 in Sweden).

REFERENCES

1. Myasthenia Gravis Fact Sheet. NIH Publication No. 20-768. Publication date March 2020.

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KEY TAKEAWAY

Two real-world evidence studies, in alignment with patient identification criteria and key outcomes measures, demonstrated similar results on high-dose, long-term OCS use in US and Sweden.

CONCLUSIONS

Study findings on OCS use using administrative databases from the US and Sweden, showed comparable results on persistence, discontinuation, OCS duration and dose use.

- More than 75% patients on medium (≥7.5 mg/day to <40mg/day) or high (≥40 mg/day) OCS use
- Average time to discontinuation was ~5 months

Further studies are warranted to assess the impact of high-dose and long- term OCS use in this population.

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DISCLOSURES:
Qian Cai, Daniel Labson, Kavita Gandhi, Alberto E. Batista, Kristin Heerlein and Shane Kavanagh are or were employees of Janssen Pharmaceuticals and may own stock or stock options in Johnson & Johnson. Jakob Börsum was employed by SDS Life Science AB, Uppsala, Sweden.

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