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Real-World evidence study of patients with Lennox-Gastaut syndrome taking clobazam oral soluble film: Demographics, medications, and comorbidities

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INTRODUCTION

- Lennox-Gastaut syndrome (LGS) is a rare but severe form of childhood-onset epilepsy characterized by frequent treatment-resistant seizures and cognitive impairment[1,2]
- The estimated prevalence of LGS ranges from 2.9–28 cases per 100,000 individuals across the United States and Europe, and LGS has a higher mortality rate compared with both the epileptic and general population[2]
- Managing LGS is challenging due to its treatment-resistant seizures and the need for individualized approaches to address evolving symptoms over a patient's lifetime[1,2]
- Historically, clobazam was only available in an oral tablet or suspension form, and there is an unmet need for other formulation options for patients with dysphagia[3]
- A novel oral soluble film formulation of clobazam was approved by the FDA in 2018 for adjunctive treatment of seizures associated with LGS in patients ≥ 2 years of age[4]
- To date, there is a lack of awareness and real-world data regarding the safety, efficacy, and/or utilization of clobazam oral film

OBJECTIVE

- To report real-world demographics, concomitant antiseizure medication use, and comorbidities in patients with epilepsy or LGS who have been treated with clobazam oral soluble film

METHODS

- A retrospective, new user cohort study was conducted using electronic health records collected during routine care at Stanford Health Care between 2015 and 2024
- Patients were identified based on the International Classification of Diseases, Tenth Revision code diagnoses for epilepsy (G40) and LGS (G40.81)
- Information from health records of patients taking clobazam oral soluble film, including patient demographics, antiseizure medication use, and comorbidities, were extracted and described using summary statistics

RESULTS

Patient characteristics

- Overall, 181 patients with epilepsy and a subset of 29 patients with LGS were identified (**Table 1**)
- Patients had a mean (SD) age of 21.1 (19.3) years in the epilepsy group and 13.6 (12.1) years in the LGS group
- Sex, race, and ethnicity were similar between groups

Table 1. Demographics and Patient Characteristics

Characteristic	Epilepsy n = 181	LGS[a] n = 29
Age, years		
Mean (SD)	21.1 (19.3)	13.6 (12.1)
Age category, years, n (%)		
< 18	108 (59.7)	22 (75.9)
18–29	32 (17.7)	5 (17.2)
30–39	16 (8.8)	1 (3.4)
40–49	5 (2.8)	0
50–59	8 (4.4)	0
60–69	3 (1.7)	1 (3.4)
70–79	6 (3.3)	0
80–89	3 (1.7)	0
Female, n (%)	89 (49.2)	15 (51.7)
Race, n (%)		
White	100 (55.2)	14 (48.3)
Black	15 (8.3)	4 (13.8)
Asian	1 (0.6)	0
Other[b]	65 (35.9)	11 (37.9)
Hispanic, n (%)	9 (4.9)	1 (3.4)

[a]The LGS group is included in the epilepsy group.
[b]Other includes "Unknown" and "Not otherwise classified."
LGS, Lennox-Gastaut syndrome; SD, standard deviation.

Clobazam oral film use

- A larger proportion of patients with LGS (66%) than those with epilepsy (56%) switched from the tablet or suspension form of clobazam to the oral film formulation (**Table 2**)
- Both groups averaged over 1 year of oral film use

Table 2. Clobazam Oral Film Use Characteristics

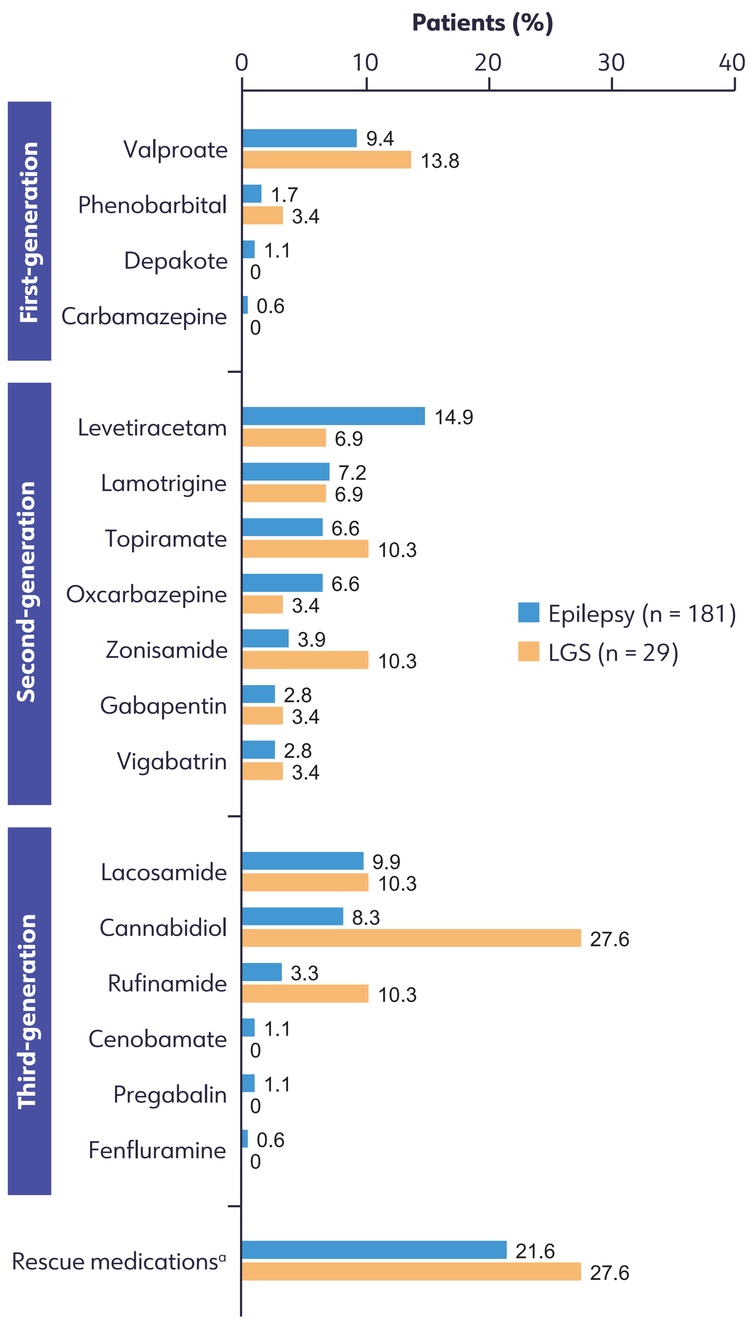
Characteristic	Epilepsy n = 181	LGS n = 29
Index year, n (%)		
2018–2019	34 (18.8)	6 (20.7)
2020–2024	147 (81.2)	23 (79.3)
Switched from clobazam tablet or suspension, n (%)	101 (55.8)	19 (65.5)
Mean (SD) duration of clobazam oral film use, days	394.6 (503.3)	441.9 (505.3)

LGS, Lennox-Gastaut syndrome; SD, standard deviation.

Antiseizure medications

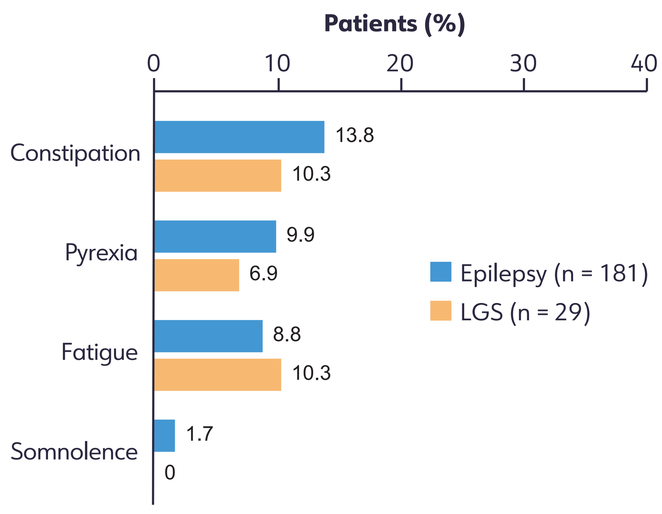
- First-, second-, and third-generation antiseizure medication use is shown in **Figure 1**
- The most commonly (≥ 10%) used antiseizure medications included:
  - Levetiracetam and lacosamide in the epilepsy group
  - Cannabidiol, valproate, topiramate, zonisamide, lacosamide, and rufinamide in the LGS group
  - Cannabidiol use was notably higher in the LGS group (27.6%) than in the epilepsy group (8.3%)
- Over 20% of patients in both groups used rescue medication
- Treatment-emergent adverse events experienced by ≥ 5% of patients in both groups included constipation, pyrexia, and fatigue (**Figure 2**)

Figure 1. Concomitant Antiseizure Medication Use



[a]Rescue medications included diazepam (rectal gel or intranasal) and midazolam (intranasal).
LGS, Lennox-Gastaut syndrome.

Figure 2. Treatment-Emergent Adverse Events[a]

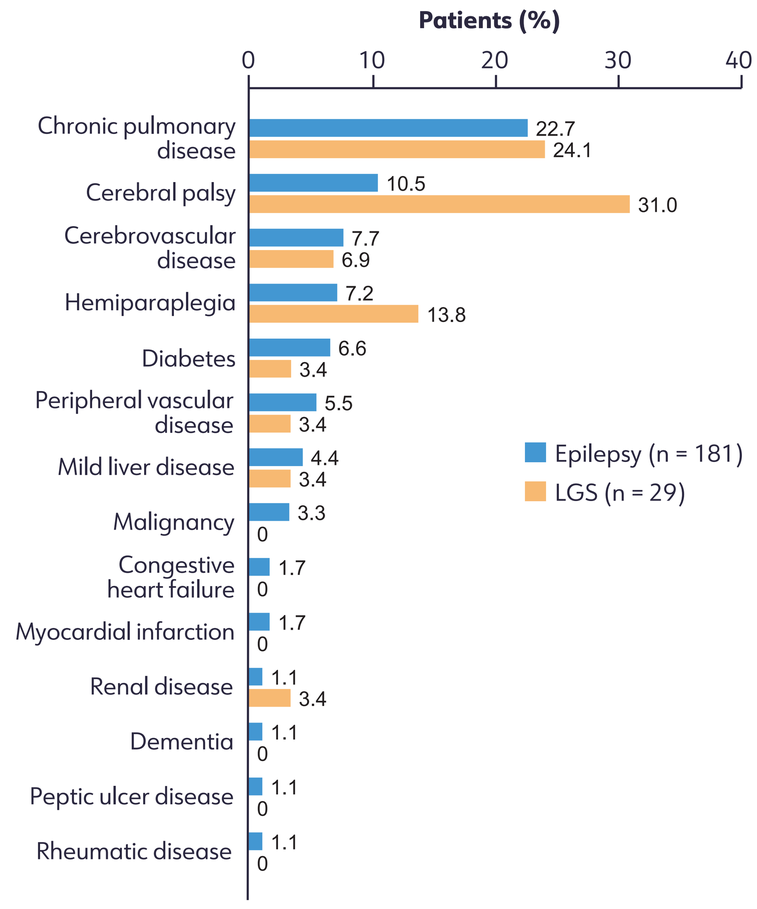


[a]Adverse events were defined by ICD-10 codes: constipation (K59.0, constipation); pyrexia (R50, fever of other and unknown origin); fatigue (R53, malaise and fatigue); somnolence (R40, somnolence, stupor, and coma).
ICD-10, International Classification of Diseases, Tenth Revision; LGS, Lennox-Gastaut syndrome.

Comorbidities

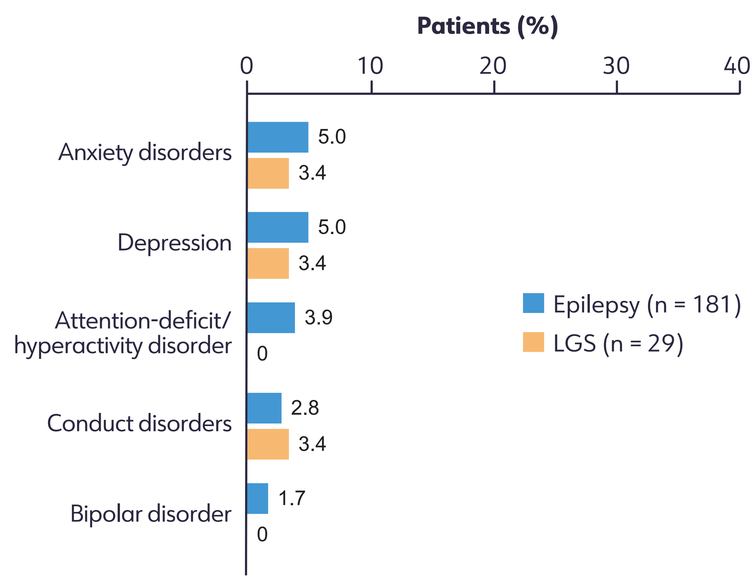
- The most common (≥ 10%) comorbidities included (**Figure 3**):
  - Chronic pulmonary disease and cerebral palsy in the epilepsy group
  - Cerebral palsy, chronic pulmonary disease, and hemiparaplegia in the LGS group
- Mood and conduct disorders were not markedly elevated in either group (**Figure 4**)

Figure 3. Comorbidities in Patients With Epilepsy or LGS



LGS, Lennox-Gastaut syndrome.

Figure 4. Mood and Behavioral Conditions[a]



[a]Conditions were defined by ICD-10 codes: anxiety disorders (F41, other anxiety disorder); depression (F32, depressive episode; F33, major depressive disorder, recurrent); attention-deficit/hyperactivity disorder (F90, hyperkinetic disorders); conduct disorders (F91, conduct disorders); bipolar disorder (F31, bipolar disorder).
ICD-10, International Classification of Diseases, Tenth Revision; LGS, Lennox-Gastaut syndrome.

CONCLUSION

- **In this real-world study of patients with epilepsy or LGS receiving clobazam oral soluble film, patients displayed varying demographics, additional medication use, and comorbidities**
- **Patients in the LGS subset tended to be younger in age, more often switched from clobazam tablets or suspension, and had higher cannabidiol use than those in the epilepsy group**
- **These data provide valuable insights describing patients with epilepsy or LGS and their use of clobazam oral film**

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