Patient Characteristics, Treatment Patterns, and Healthcare Resource Utilization Among Patients With Epilepsy on Brivaracetam Monotherapy: A Cohort Study Using US Claims Data

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Background

- Brivaracetam (BRV) is approved as adjunctive therapy and monotherapy for focal-onset seizures in the United States in patients ≥1 month of age,[1] as adjunctive therapy for focal-onset seizures in patients ≥2 years of age in Europe,[2] and as adjunctive therapy and monotherapy for focal-onset seizures with or without secondary generalization in patients ≥15 years of age in Japan[3,4]; however, BRV monotherapy real-world clinical data are limited.

Objective

- To assess patient characteristics, treatment patterns, and epilepsy/seizure-related healthcare resource utilization (HCRU) in patients with epilepsy who initiated BRV monotherapy in real-world clinical practice.

Methods

- Retrospective analysis of de-identified data from Merative MarketScan (Commercial, Medicare, and Medicaid Supplemental databases) of patients with an epilepsy/seizure diagnosis (identified as ≥2 claims 30 days or more apart with *International Classification of Disease [ICD]-9/-10* codes 345.X/G40.X, or with *ICD-9/-10* codes 780.39/R56.9, during baseline; or ≥1 claim with *ICD-9/-10* codes 345.X/G40.X 30 days or more apart with the occurrence of ≥1 claim with *ICD-9/-10* codes 780.3X/R56.X during baseline) who received BRV monotherapy.
- Patients were included if they:
  - Had a BRV pharmacy claim (date of first BRV claim during the identification period [January 1, 2016 through December 31, 2020] = index date);
  - Were supplied BRV for ≥30 days;
  - Had made no claim for BRV within 365 days before the index date; and
  - Had medical/pharmacy benefits for ≥12 months before and ≥90 days after index (shorter pre-index period for patients <12 months of age).
- BRV monotherapy was defined as patients with a BRV pharmacy claim, with antiseizure medications (ASMs) prescribed before BRV initiation discontinued <90 days after BRV initiation, and no claim for other ASM within 90 days after BRV initiation.
- Outcomes included baseline characteristics, treatment patterns, and HCRU, and were assessed in all patients who initiated BRV monotherapy and subgroups stratified by age (<16 years, 16-64 years, and ≥65 years of age).
  - Seizure/epilepsy-related HCRU (hospitalizations, intensive care unit visits, emergency department visits, and outpatient neurology visits) were captured 12 months before (baseline) and after first BRV prescription (follow-up; ranging from 3 to 12 months).
  - For BRV daily dose at 12 months, a prescription claim within 30 days before the 12-month timepoint was required.
  - Outcomes are reported for all patients who initiated BRV monotherapy at index, regardless of BRV treatment status at follow-up (ie, included patients who remained on BRV monotherapy and those who added ≥1 ASM at least 90 days after initiating BRV monotherapy).

Results

BASELINE CHARACTERISTICS

- Of 594 patients identified, 105 (17.7%), 471 (79.3%), and 18 (3.0%) patients were <16, 16-64, and ≥65 years of age, respectively.

Baseline demographics

	ALL PATIENTS (N=594)	STRATIFIED BY AGE		
		<16 YEARS OF AGE (n=105)	16–64 YEARS OF AGE (n=471)	≥65 YEARS OF AGE (n=18)
Patient demographics				
Age, mean (SD), years	32.9 (18.2)	9.0 (4.0)	36.6 (14.2)	74.7 (10.1)
Female, n (%)	338 (56.9)	55 (52.4)	274 (58.2)	9 (50.0)
Seizure type during baseline, n (%)				
Focal-onset[a]	288 (48.5)	52 (49.5)	225 (47.8)	11 (61.1)
Generalized-onset[b]	141 (23.7)	31 (29.5)	110 (23.4)	0
Undefined seizure type	165 (27.8)	22 (21.0)	136 (28.9)	7 (38.9)
Psychiatric comorbidities in ≥20% of patients in any group during baseline,[c] n (%)				
Other anxiety disorders	189 (31.8)	15 (14.3)	170 (36.1)	4 (22.2)
Mood disorders	170 (28.6)	9 (8.6)	158 (33.5)	3 (16.7)
Cognitive disorders	112 (18.9)	47 (44.8)	62 (13.2)	3 (16.7)
Attention deficit hyperactivity disorder	61 (10.3)	26 (24.8)	35 (7.4)	0
Autism and pervasive developmental disorders	57 (9.6)	26 (24.8)	30 (6.4)	1 (5.6)

[a]Included patients with an *ICD* code for focal seizures, with or without *ICD* codes for generalized seizures; [b]Included patients with an *ICD* code for generalized seizures only; [c]Patients could have had more than one psychiatric comorbidity during baseline. *ICD, International Classification of Disease.*

Overview

QUESTION

What are the patient characteristics, treatment patterns, and healthcare resource utilization (HCRU) among patients with epilepsy on brivaracetam (BRV) monotherapy?

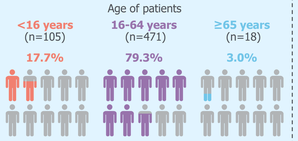
INVESTIGATION

Retrospective analysis of de-identified data from Merative MarketScan of patients with an epilepsy/seizure diagnosis who were restricted to BRV monotherapy (patients with a BRV pharmacy claim [date of first BRV claim during the identification period (01/01/2016 through 12/31/2020) = index date] with antiseizure medications [ASMs] prescribed before BRV initiation discontinued <90 days after BRV initiation, and no claim for other ASM within 90 days after BRV initiation.

RESULTS

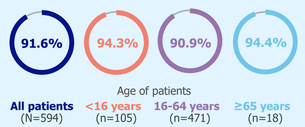
Patient characteristics

594 patients initiated BRV as monotherapy

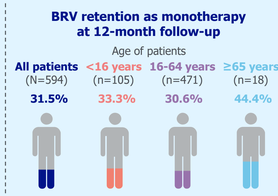


Treatment patterns

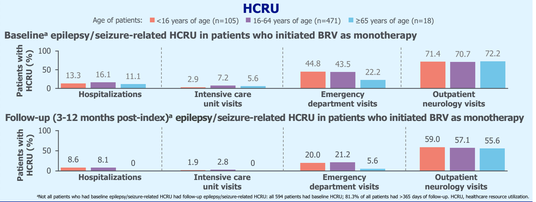
Patients taking >1 ASM in the year before BRV initiation



BRV retention as monotherapy at 12-month follow-up



HCRU



[a]Not all patients who had baseline epilepsy/seizure-related HCRU had follow-up epilepsy/seizure-related HCRU; all 594 patients had baseline HCRU; 81.3% of all patients had >365 days of follow-up. HCRU, healthcare resource utilization.

CONCLUSIONS

Retention of BRV monotherapy was maintained by approximately 1 in every 3 patients for at least 12 months, and epilepsy/seizure-related HCRU decreased from baseline up to 12-month follow-up, regardless of age.

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TREATMENT PATTERNS

- More than 90% of patients irrespective of age were taking >1 ASM in the year before BRV initiation.
  - 91.6%, 94.3%, 90.9%, and 94.4% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively, were taking ≥1 ASM.
- Levetiracetam (LEV) was the most frequently initiated last ASM before BRV initiation in all groups.

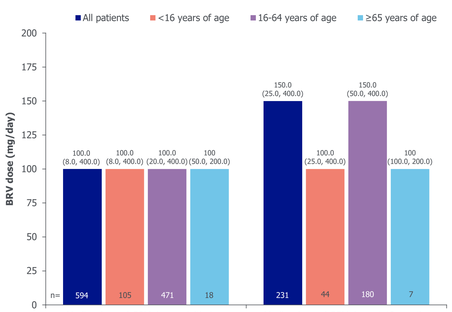
ASMs before BRV initiation and at 12-month timepoint

	ALL PATIENTS (N=594)	STRATIFIED BY AGE		
		<16 YEARS OF AGE (n=105)	16-64 YEARS OF AGE (n=471)	≥65 YEARS OF AGE (n=18)
Last ASM initiated before BRV initiation[a,b] (≥10% in any group)	n=555	n=100	n=438	n=17
Levetiracetam, n (%)	273 (49.2)	49 (49.0)	215 (49.1)	9 (52.9)
Lamotrigine, n (%)	36 (6.5)	1 (1.0)	32 (7.3)	3 (17.6)
Oxcarbazepine, n (%)	28 (5.0)	11 (11.0)	15 (3.4)	2 (11.8)
Clonazepam, n (%)	27 (4.9)	10 (10.0)	16 (3.7)	1 (5.9)
BRV treatment status at 12-month timepoint	N=594	n=105	n=471	n=18
BRV monotherapy, n (%)	187 (31.5)	35 (33.3)	144 (30.6)	8 (44.4)
Adjunctive therapy,[c] n (%)	49 (8.2)	11 (10.5)	38 (8.1)	0
BRV discontinued, n (%)	280 (47.1)	51 (48.6)	223 (47.3)	6 (33.3)
Lost to follow-up, n (%)	78 (13.1)	8 (7.6)	66 (14.0)	4 (22.2)
ASMs at 12-month timepoint[b,d,e] (≥10% in any group)	n=53	n=11	n=42	n=0
Lamotrigine, n (%)	10 (18.9)	1 (9.1)	9 (21.4)	0
Topiramate, n (%)	7 (13.2)	2 (18.2)	5 (11.9)	0
Valproate, n (%)	5 (9.4)	0	5 (11.9)	0
Oxcarbazepine, n (%)	3 (5.7)	2 (18.2)	1 (2.4)	0

[a]Last ASM initiated before BRV initiation was calculated from the total number of last ASMs initiated before BRV initiation; [b]Data presented at the drug-level; [c]BRV treatment maintained with the addition of ≥1 other ASM; [d]ASMs at 12-month timepoint included ASMs started before 12 months and not stopped before the timepoint; [e]ASMs at 12-month timepoint were calculated from the total number of ASMs at the 12-month timepoint. ASM, antiseizure medication.

BRV DOSING

BRV dosing at BRV initiation and at 12 months

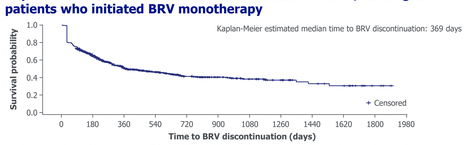


- At initiation, BRV daily dose was ≤200 mg for 99.3%, 99.0%, 99.4%, and 100.0% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.
  - At initiation, BRV daily dose was >200 mg for 0.7%, 1.0%, 0.6%, and 0%.
- At 12 months, BRV daily dose was ≤200 mg for 94.8%, 93.2%, 95.0%, and 100% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.
  - At 12 months, BRV daily dose was >200 mg for 5.2%, 6.8%, 5.0%, and 0%.

BRV RETENTION

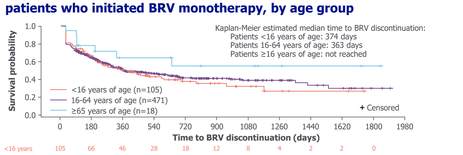
- More than 365 days of follow-up was achieved by 81.3%, 85.7%, 80.9%, and 66.7% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.
- Retention on BRV monotherapy at 12-month follow-up was achieved by 31.5%, 33.3%, 30.6%, and 44.4% of all patients, and patients <16, 16-64, and ≥65 years of age, respectively.

Kaplan-Meier estimated time to discontinuation of BRV,[a] among all patients who initiated BRV monotherapy



[a]Defined as discontinuation of BRV, regardless of BRV treatment status (monotherapy or adjunctive) during follow-up.

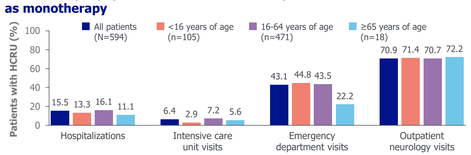
Kaplan-Meier estimated time to discontinuation of BRV,[a] among patients who initiated BRV monotherapy, by age group



[a]Defined as discontinuation of BRV, regardless of BRV treatment status (monotherapy or adjunctive) during follow-up.

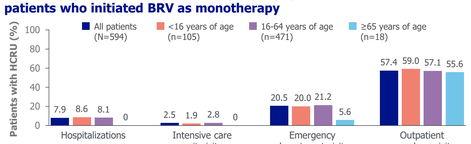
HEALTHCARE RESOURCE UTILIZATION

Baseline[a] epilepsy/seizure-related HCRU in patients who initiated BRV as monotherapy



[a]All 594 patients had baseline HCRU. HCRU, healthcare resource utilization.

Follow-up (3-12 months post-index)[a] epilepsy/seizure-related HCRU in patients who initiated BRV as monotherapy



[a]81.3% of all patients had >365 days of follow-up. HCRU, healthcare resource utilization.

- Not all patients had 12-month follow-up epilepsy/seizure-related HCRU.
- From baseline to follow-up, there was a numerical reduction in epilepsy/seizure-related HCRU in all age groups, with the greatest reductions observed for emergency department visits.

Limitations

- The study population was limited to patients with insurance coverage and, therefore, results may not be representative of the entire epilepsy population.
- There might be missing information, miscoding, or underreporting of information in the claims data.
- There was a small number of patients in the ≥65 years of age subgroup.
- The inclusion criterion of ≥90 days medical and pharmacy benefit coverage after index date may have created a selection bias; however, a sensitivity analysis revealed it had minimal impact on the results.
- Not all patients had 12 months of follow-up.

Conclusions

- This retrospective data claims analysis demonstrated that approximately 1 in every 3 patients maintained BRV treatment as monotherapy for at least 12 months.
- Patients who initiated BRV as monotherapy had a decrease in epilepsy/seizure-related HCRU from baseline up to 12-month follow-up, regardless of age.

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