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Lacosamide as a monotherapy for seizures with focal onset

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Abstract
Purpose: To assess oral lacosamide's 1-year safety and effectiveness as conversion monotherapy in adult patients with partial onset seizures, whether or not they are generalized
Method: After a year of seizure-free treatment with lacosamide add-on therapy and stopping the concomitant antiepileptic medication, we prospectively monitored a subsequent group of patients who were switched to lacosamide monotherapy (AED). Every three months for up to a year, the incidence of seizures, adherence to therapy, and drug toxicity were evaluated. The retention rate of lacosamide as a single AED and the independence from seizures under lacosamide monotherapy after a year after stopping the baseline AED were the study's outcomes. The frequency of adverse events (AEs) associated with lacosamide served as the safety variable.
Results: Out of the 116 patients who were part of the study, 74 (63.8%) continued to take lacosamide as their only antiemetic drug after a year, and 64 (55.2%) did not experience any seizures while on lacosamide monotherapy for the duration of the follow-up. It was found that using less than three AEDs in one's lifetime was a significant predictor of not having seizures (adjusted OR = 6.38, 95% CI 1.85-21.98, p = 0.003). The most prevalent adverse events (20.8%) reported by 24 patients were headache, dizziness, and drowsiness.
Conclusion: For a limited group of adult patients with partial onset seizures who had achieved seizure independence while receiving lacosamide add-on medication, switching to lacosamide alone may be both successful and well tolerated.

Keywords: Epilepsy**,** partial seizures**,** lacosamide**,** antiepileptic drugs

1. Introduction
Lacosamide is an approved antiepileptic medication (AED) that has just gained approval. It is the R-enantiomer of 2-acetamido-N-benzyl-3-methoxypropionamide and has a unique pharmacological profile. In contrast to conventional sodium channel blockers, which influence the quick inactivation of the channel, lacosamide specifically increases the slow inactivation. Without impairing physiological function, this method stabilizes hyperexcitable neuronal membranes, inhibits the recurrent firing of neurons that cause epilepsy, and reduces long-term channel availability [1]. It exhibits a good pharmacokinetic profile with a quick rate of absorption, less protein binding and cytochrome P450 interactions, and little chance of drug interactions. Moreover, the fact that it comes in a variety of formulations allows for flexible dosing.
2008 saw the approval of lacosamide as an adjuvant treatment for adults with partial onset seizures, whether or not they were generalized [2, 3, 4, 5]. The long-term safety and effectiveness of this additional medication have been extensively evaluated [5, 6, 7, 8]. Notably, the U.S. Food and Drug Administration has approved lacosamide for use as a monotherapy [8]. Since the single-drug regimen offers various potential advantages over polytherapy, such as a lower likelihood of pharmacological interactions or side effects and an improvement in tolerance and long-term compliance, the clinical implications could be very significant. Therefore, the purpose of this study was to assess the safety and effectiveness of oral lacosamide as conversion monotherapy for a year in adult patients with focal onset seizures.

2. Methods
2.1 Participants and study outcome: Study participants were chosen from a cohort of patients who were consecutively referred to the outpatients and inpatients of Amara city between January

2023 and April 2024, and who were successfully converted to lacosamide monotherapy following a successful response (defined as at least a year without seizures) to lacosamide as add-on therapy and the discontinuation of concurrent AED medication. Age over eighteen and a diagnosis of epilepsy with partial-onset seizures (either simple or complex, with or without secondary generalizations) were the inclusion criteria, as stated in the 1981 International League against Epilepsy (ILAE) Classification of Epileptic Seizures [9]. a minimum of one seizure within a year prior to adding lacosamide to a stable AED monotherapy regimen, assuming the prescribed maintenance dosages; a minimum of one year without experiencing seizures while on lacosamide add-on treat History of primary generalized epilepsy, alcoholism, drug misuse, conversion disorders, or other non-epileptic ictal episodes, as well as having an implanted vagus nerve stimulator, were all considered exclusion criteria. Demographics, clinical history, seizure types, epilepsy as defined by international criteria [9, 10], baseline seizure frequency as the total number of seizures that occurred in the year prior to lacosamide employment, and seizure diaries or patient clinical records were among the data collected for each subject. From the time of conversion to lacosamide monotherapy to the end of the year, all patients had a clinical review that included data collecting on the frequency of seizures, adherence to treatment, and drug toxicity every three months.

The retention rate of lacosamide as a single AED and the independence from seizures under lacosamide monotherapy after a year after stopping the baseline AED were the study's outcomes. The frequency of adverse events (AEs) associated with lacosamide served as the safety variable.

2.2 Statistical analysis

For continuous variables, values are reported as mean ± SD or median (interquartile range [IQR]); for categorical variables, values are reported as the number of participants (percent). The Student t-test, Mann-Whitney test, or Chi-squared test were used for comparisons, depending on the situation. In order to find potential predictors of seizure freedom, logistic regression analysis was used; relationships with outcomes that made biological sense were found for statistical analysis. Type of epilepsy, number of AEDs used in lifetime (one or two vs. three or more), and frequency of seizures (as the total number of seizures) in the year before to using lacosamide were the variables that were chosen.

Findings were deemed noteworthy when the p values (two-sided) were less than 0.05. STATA/IC 13

2.3 Standard protocol approvals, registrations, and patient consents

In compliance with the Declaration of Helsinki, all participants gave written informed consent, and the study was approved by the local ethical committee.

3. Results

Table 1: Baseline demographics and epilepsy characteristics.

	Full cohort (*n* = 116)	**Seizure freedom (*n* = 64)**	**Seizure occurrence (*n* = 52)**	***p* value**
Age, median (IQR), (years)	81 (28.0-47.0)	82.0 (27.0-49.5)	80.0 (28.0-45.0)	0.573[a]
Gender, no. (%) Male	52 (44.8)	30 (46.9)	22 (42.3)	0.728[b]
Age at onset of epilepsy, median (IQR), (years)	51 (18.0-34.0)	33 (21.0-34.0)	54.0 (22.0-32.0)	0.213[a]
[c]Type of seizure, no. (%)				
Simple partial	48 (41.4)	28 (43.8)	20 (38.5)	0.684[b]
Complex partial	82 (70.7)	46 (71.9)	36 (69.2)	0.826[b]
Secondary generalized	36 (31.0)	22 (34.4)	14 (26.7)	0.542[b]
[d]Type of epilepsy, no. (%)				
Symptomatic	46 (39.6)	26 (40.6)	20 (38.5)	0.867[b]
Cryptogenic	64 (55.2)	36 (56.3)	28 (53.8)	0.855[b]
Idiopathic	6 (5.2)	2 (3.1)	4 (7.7)	0.435[b]
[e]Pre-lacosamide seizure frequency, median (IQR)				
	19 (4-53)	14 (4-49)	25 (7-55)	0.218[a]
Background AED, no. (%)				
CBZ	36 (31.0)	22 (34.4)	14 (26.9)	0.542[b]
LEV	32 (27.6)	16 (25.0)	16 (30.8)	0.625[b]
OXC	22 (19.0)	10 (15.6)	12 (23.1)	0.472[b]
TPM	6 (5.2)	4 (6.25)	2 (3.85)	0.681[b]
VPA	10 (8.6)	8 (12.5)	2 (3.85)	0.243[b]
[f]Others	10 (8.6)	4 (6.25)	6 (11.5)	0.475[b]
Lifetime AEDs, no. (%)				
1-2	87 (67.2)	54 (84.4)	24 (46.2)	0.002[b]
≥3	38 (32.8)	10 (15.6)	28 (53.8)	

Abbreviations: AED, anti-epileptic drug; CBZ, carbamazepine; IQR, interquartile range; LEV, levetiracetam; OXC, oxcarbazepine; TPM, topiramate; VPA, valproic acid.

a) Mann-Whitney test.
b) Chi-squared test.
c) Commission on Classification and Terminology of the International League against Epilepsy. Proposal for revised clinical and electroencephalographic classification of epileptic seizures. Epilepsia 1981;22:489-501.
d) Commission on Classification and Terminology of the International League Against Epilepsy. Proposal for revised classification of epilepsies and epileptic syndromes. Epilepsia 1989;30:389-99.
e) Total number of seizures occurred during the 12-months preceding the start of lacosamide add-on treatment.
f) Treatments accounting for fewer than 3% of the total subjects were grouped.

The study had 58 patients who were Caucasian. Table 1 presents a summary of baseline characteristics. At one year following the

discontinuation of their baseline medication, all patients 37 (63.8%) as monotherapy and 21 (36.2%) as polytherapy retained lacosamide. When the single medication regimen failed to produce the desired results, AEDs were resumed, and in nearly all cases, this occurred within the first nine months (18/21). Of all subjects, 32 (55.2%) were free from seizures during the 12-month follow-up while on lacosamide monotherapy; the five remaining subjects (8.6%) who were taking lacosamide as a single agent experienced a reduction in seizure frequency of ≥75% when compared to the 1-year prior to employment of lacosamide.

400 (IQR 350-400) mg/day was the maintenance dosage of lacosamide used as a monotherapy. Following patient classification based on seizure frequency, 84.4% of participants who remained seizure-free for the duration of the 1-year lacosamide monotherapy had used less than three AEDs throughout their lifetime (Table 1). 69.2% and 26.3% of participants with 1-2 and ≥3 previous treatments, respectively, sustained seizure freedom (Fig. 1). The history of fewer than three AEDs during one's lifetime was found to be a reliable predictor of seizure freedom by logistic regression analysis (adjusted OR = 6.38, 95% CI 1.85-21.98, p = 0.003); unadjusted OR = 6.30, 95% CI 1.85-21.48, p = 0.003.

4. Discussion

The main discovery of this research was that adult patients with partial onset seizures who had responded effectively to lacosamide add-on therapy following the failure of prior antiepileptic treatment could benefit from lacosamide as monotherapy, provided that it was well tolerated. Over 60% of patients were still using lacosamide as a single medication a year after the background AED was discontinued, and over half of the participants experienced no seizure episodes while on lacosamide monotherapy. Furthermore, if lacosamide was added successfully in the early phase, after less than three pharmacological tries, the chance of seizure control rose.

There is little data to support the use of lacosamide as a stand-alone AED, and variations in patient selection and study design make it difficult to compare findings across studies. A post hoc analysis of the historical-controlled conversion to lacosamide monotherapy study [8] found that, of the subjects who completed the monotherapy phase, approximately 15% and 60%, respectively, experienced seizure freedom and a reduction in seizure frequency of more than 50% compared to baseline. Notably, the study by Wechsler *et al.* [8] markedly varied from the current one due to the high percentage of patients with high baseline seizure frequency who were somewhat more medication resistant than would typically be regarded for monotheraphy in clinical practice. History of using three or more AEDs over one's lifetime, concurrent use of several AEDs, and switching to a single medication regimen notwithstanding the maintenance phase's response. Conversely, our results are somewhat in line with a recent open label extension experiment that found that nearly all patients switched to lacosamide monotherapy experienced a 50-100% decrease in monthly seizure frequency [5]. Interestingly, data on monotherapy came from less than 10 people, despite the fact that the experiment included over three hundred patients.

The safety profile of lacosamide generally matched what is currently known, with sleepiness and dizziness being among the most frequent adverse events. Rates and severity of adverse events (AEs) were, as anticipated, lower than in studies with lacosamide adjunctive therapy. Because of pharmacokinetic and pharmacodynamic interactions, using concurrent drugs actually increases the incidence of adverse events (AEs). This is especially true during the titration period, when background AEDs are still presumed, as opposed to the maintenance phase. Additionally, adverse events (AEs) tend to regress over time and are more common during the initial few weeks of treatment, when cessation is therefore most likely to occur.

The open label approach, lack of a reference group, limited sample size, and very narrow age range of the included population limit generalizability to middle-aged epileptic people. These limitations should be considered when interpreting our findings. Furthermore, those who had relatively few seizure events in the year before beginning lacosamide monotherapy may not have any more episodes in the upcoming year due to remission, which could have influenced the assessment of the true effectiveness of the medication. It is noteworthy, therefore, that only a small portion of the group had extremely low pre-lacosamide seizure frequencies.

Furthermore, considering the average duration of epilepsy and the fact that longer-lasting seizures are more difficult to control, it is unlikely that a complete spontaneous remission could account for all of the observed improvement, even though fluctuations in seizure frequency are a normal part of the condition. From these angles, it could be beneficial to conduct more research in the future to more accurately calculate the various impact sizes of lacosamide therapy across patient cohorts.

The prospective design, the one-year follow-up, the inclusion of patients at various phases of treatment, and the value of safety and efficacy data from a context that closely resembles standard clinical practice are some of the study's strongest points.

Finally, our research indicates that in certain individuals with partial seizures who had responded to a lacosamide add-on regimen, switching to lacosamide monotherapy may offer long-term, successful seizure control with a tolerable side effect. Since single agent treatment reduces the possibility of side effects, eliminates the possibility of pharmacological interactions, and is anticipated to increase adherence, retention rates, and health care costs, it may have implications for clinical practice.

The prospective design, the one-year follow-up, the inclusion of patients at various phases of treatment, and the value of safety and efficacy data from a context that closely resembles standard clinical practice are some of the study's strongest points.

5. Conclusion

According to our research, some individuals with partial seizures who had responded to a lacosamide add-on regimen may be able to achieve long-term successful seizure control with a good tolerability by switching to lacosamide monotherapy. Since single agent treatment reduces the possibility of side effects, eliminates the possibility of pharmacological interactions, and is anticipated to increase adherence, retention rates, and health care costs, it may have implications for clinical practice.

References

1. Doty P, Hebert D, Mathy FX, Byrnes W, Zackheim J, Simontacchi K. Development of lacosamide for the treatment of partial-onset seizures. Ann N Y Acad Sci. 2013;1291:56-68.
2. Ben-Menachem E, Biton V, Jatuzis D, Abou-Khalil B, Doty P, Rudd GD. Efficacy and safety of oral lacosamide as adjunctive therapy in adults with partial-onset seizures. Epilepsia. 2007;48:1308-1317.
3. Chung S, Sperling MR, Biton V, Krauss G, Hebert D, Rudd

GD, *et al.*; SP754 Study Group. Lacosamide as adjunctive therapy for partial-onset seizures: a randomized controlled trial. Epilepsia. 2010;51:958-967.
4. Halász P, Kälviäinen R, Mazurkiewicz-Beldzinska M, Rosenow F, Doty P, Hebert D, *et al.*; SP755 Study Group. Adjunctive lacosamide for partial-onset seizures: efficacy and safety results from a randomized controlled trial. Epilepsia. 2009;50:443-453.
5. Husain A, Chung S, Faught E, Isojärvi J, McShea C, Doty P. Long-term safety and efficacy in patients with uncontrolled partial-onset seizures treated with adjunctive lacosamide: results from a phase III open-label extension trial. Epilepsia. 2012;53:521-528.
6. Rosenow F, Kelemen A, Ben-Menachem E, McShea C, Isojärvi J, Doty P. Long-term adjunctive lacosamide in patients with uncontrolled partial-onset seizures: results from the SP774 phase III open-label extension trial. Epilepsia. 2011;52(Suppl):505.
7. Rosenfeld W, Fountain N, Kaubrys G, Ben-Menachem E, McShea C, Isojärvi J, *et al.* Lacosamide: long-term safety and efficacy in partial-onset seizures. Epilepsia. 2011;52(Suppl):506.
8. Wechsler RT, Li G, French J, O'Brien TJ, D'Cruz O, Williams P, *et al.*; ALEX-MT Study Group. Conversion to lacosamide monotherapy in the treatment of focal epilepsy: results from a historical-controlled, multicenter, double-blind study. Epilepsia. 2014;55:1088-1098.
9. Commission on Classification and Terminology of the International League Against Epilepsy. Proposal for revised clinical and electroencephalographic classification of epileptic seizures. Epilepsia. 1981;22:489-501.
10. Commission on Classification and Terminology of the International League Against Epilepsy. Proposal for revised classification of epilepsies and epileptic syndromes. Epilepsia. 1989;30:389-399.

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