Clinical Effectiveness of Lacosamide and its Impact on Concomitant Antiepileptic Drug Consumption in the Czech Republic

Jíří Klimeš, Milan Vocelka, Tomáš Doležal, Hana Fořtová

Background

- Post-hoc analyses of pooled Phase II/III randomised controlled trials and some registries have shown trends for greater reduction of seizure rate with lacosamide in combination with non-sodium channel blockers (SCBs), whereas other registries and clinical practice data have not shown this difference in efficacy based on use of SCBs or non-SCBs.

Objectives

- The aim of this study was to assess the clinical effectiveness of lacosamide as add-on therapy to standard antiepileptic drugs (AEDs) in Czech Republic clinical practice, to support lacosamide pivotal trial data.
- These clinical effectiveness data were intended as inputs for a cost-effectiveness analysis reflecting clinical practice settings.
- Efficacy of lacosamide was assessed based on mechanisms of action of concomitant AEDs, ie SCBs vs non-SCBs.

Methods

- In this retrospective study conducted at 40 centres in the Czech Republic, data were collected from patients with epilepsy who were treated with adjunctive lacosamide. Patient records were reviewed for a period of 6 months before and 6 months after lacosamide treatment initiation.
- Information on patient demographics, numerical data and type of seizures, and concomitant AEDs (including dosing) before and after lacosamide treatment in clinical practice was recorded.
- Patients were considered to be responders to lacosamide if the number of seizures had decreased by at least 50% during the first 3 months of lacosamide therapy.
- To investigate the potential synergic effect of lacosamide in terms of seizure reduction when combined with SCBs or non-SCBs, a subgroup analysis was performed based on mechanism of action of concomitant AEDs, ie SCBs (carbamazepine, lamotrigine, phenytoin, oxcarbazepine, eslicarbazepine) vs non-SCBs (valproate, levetiracetam, topiramate, zonisamide, pregabalin, gabapentin, tiagabine, etc).
- Adverse events reported after initiating lacosamide treatment were also collected.

Results

- Data were collected from a total of 409 patients, 403 of whom were included in the analysis (6.15% patients had insufficient data for analysis). Patient baseline characteristics are presented in Table 1. Mean (SD) age was 40.4 (14.2) years and mean (SD) time since diagnosis was 18.7 (12.8) years.
- In 91% of patients, lacosamide treatment was initiated because of uncontrolled epilepsy.
- However, this may have been partly a consequence of longer disease duration (by more than 4 years; 20.3 vs 16.2) in the patients treated with SCBs.
- There was also a higher baseline number of seizures (ie before lacosamide treatment) in patients treated with SCBs (median = 15) than in patients not treated with SCBs (median = 10; P<0.002).
- The clinical impact of the potential better effectiveness of lacosamide use in combination with non-SCBs needs further investigation.

Table 1. Patient characteristics at initiation of lacosamide treatment and no. of seizures during baseline

Table 2. Number of seizures before and after lacosamide treatment initiation

- To investigate the potential synergic effect of lacosamide in terms of seizure reduction, when combined with SCBs or non-SCBs, a subgroup analysis was performed.
- For patients treated with concomitant SCBs (246 patients), median seizure reduction was equal to 40.9%; 44.9% of patients were lacosamide ≥50% responders (Table 3).
- The results of the sub-analysis of patients treated with concomitant SCBs (246 patients) vs patients not treated with SCBs (157 patients) are presented in Table 4.

Table 3. Incidence of adverse events

Table 4. Seizure reduction and concomitant AED use after 3 months of lacosamide treatment

Conclusions

- The results of this study support the effectiveness of lacosamide after 3 months' treatment for the reduction of seizure frequency in clinical practice.
- These data are in accordance with efficacy data observed in randomised controlled trials.4 6 However, these data should be viewed in light of the differences in patient populations.
- In addition, the findings suggest that adding lacosamide may lead to a reduced use of other concomitant AEDs after 3 months.
- We reported a higher responder rate (50% seizure reduction) in patients treated with concomitant AEDs other than SCBs. This finding is consistent with published papers reflecting clinical practice with lacosamide, but should be interpreted with caution since patients on non-SCBs may have had less severe epilepsy in terms of time from diagnosis and baseline number of seizures (before lacosamide treatment initiation), which was also the case in the RELACOVA study.7 Hence, further research in this field is needed.

References


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Figure 1. Proportion of patients using standard AEDs before and after initiating lacosamide and mean daily doses in mg of individual AEDs

Table 5. Percentage of patients with ≥50% responders

• The difference for median seizure reduction was equal to 29.8%, 29.4% vs 26.4% in patients treated with concomitant SCBs and non-SCBs.
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