Epilepsy & Behavior 75 (2017) 86–89

Contents lists available at ScienceDirect

Epilepsy & Behavior

journal homepage: www.elsevier.com/locate/yebeh

Brief Communication

Clinical management of elderly patients with epilepsy; the use of lacosamide in a single center setting

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ARTICLE INFO

Article history:
Received 20 April 2017
Revised 19 July 2017
Accepted 26 July 2017
Available online 20 August 2017

Keywords:
Lacosamide
Elderly
Tolerability
Treatment

ABSTRACT

Introduction: Lacosamide (LCM) is a third-generation antiepileptic drug (AED) for which there is limited experience in the treatment of elderly patients with epilepsy. This study was performed to evaluate the use of LCM in this particular patient group, focusing on its tolerability and effectiveness. This is a retrospective, single-center study, in patients over 60 years old treated with LCM between 1/2010 and 5/2015. Altogether, 233 elderly patients receiving LCM were identified; of these, 67 fulfilled the inclusion criteria, i.e., LCM administered for at least 2 weeks.

Results: Lacosamide was initiated for acute seizure disorders (prolonged complex partial seizures, recurrent seizures, or status epilepticus) in 54 patients (81%) and for chronic epilepsy in 13 patients in an outpatient setting. The mean follow-up period for LCM treatment was 14 months. The mean daily dose of LCM at the end of follow-up was 368 mg (range: 100–600) for those 57 patients that continued treatment. Ten patients (15%) stopped LCM treatment but none because of lack of efficacy and only three patients (4%) because of side effects. The most frequent side effects were dizziness, fatigue, and tremor.

Conclusions: Lacosamide was well tolerated even at relatively high doses and in combination therapy.

1. Introduction

Epileptic seizures are the third most common neurological disorder in the elderly after cerebrovascular disorders and dementias [1]. The commonest etiologies of new-onset epilepsy in older aged subjects include stroke, dementia, brain tumor, and traumatic head injury [2,3], but there is also a population of elderly patients with chronic epilepsy who have been receiving AED treatment for many decades. The incidence of epilepsy is highest among the elderly in comparison with other age groups [2,4]. As the population of elderly citizens increase, we can expect to encounter more elderly patients with epilepsy.

When treating elderly patients, special attention should be made to selecting an AED that undergoes no interactions with other medications, especially with other AEDs [4]. Furthermore, tolerability issues are of major importance in this patient group.

Lacosamide (LCM) is a third-generation AED that acts by slow inactivation of voltage gated sodium channels. It has been available in Europe since 2008 and in Finland since 2009 as either an intravenous (i.v.) or an oral formulation. The oral formulation is approved in Europe as an adjunctive treatment for partial-onset seizures with or without secondary generalization [5]. The intravenous formulation is approved for as replacement therapy for oral LCM, but it has been used also in emergency situations [6,7]. Lacosamide has a favorable pharmacokinetic profile with minimal drug–drug interactions and neither inducing nor inhibiting the CYP450 enzyme system. These are important features when treating elderly patients. At present, there are limited data on the use of LCM in elderly patients with epilepsy. This study was performed to evaluate the use of LCM in this particular patient group, especially focusing on its tolerability and effectiveness.

2. Materials and methods

This was a retrospective study to analyze the outcome for patients aged sixty years or more treated with LCM in the Neurological Unit of Tampere University Hospital between January 2010 and May 2015. The hospital patient registry was used to identify the patients.

Altogether, 233 patients who had been treated with LCM were found, and their clinical data were reviewed. Sixty-six patients had started LCM in acute settings as treatment for an acute seizure disorder and received LCM for less than 2 weeks; therefore, they were excluded from this evaluation. In another 100 patients, there was a lack of sufficient follow-up data after the initiation of LCM in an acute situation. The majority, i.e., 67/100 of these patients had died soon after the acute situation, mostly because of serious comorbidities, but only 1 of them

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http://dx.doi.org/10.1016/j.yebeh.2017.07.045
1525-5050/

because of status epilepticus. Our hospital serves as a tertiary center for difficult to manage neurological patients and also as the only neurosurgical center for a larger population. Therefore, additional 33 patients in whom there were insufficient follow-up data had originated outside our core hospital district and were treated in our hospital only for the acute emergency situation, which had involved the initiation of LCM treatment.

Thus, in a total of 54 patients who had initiated LCM in the acute setting, there were reliable follow-up data, and these were included in the study as well as 13 patients being treated in the outpatient clinic Fig. 1. After the acute treatment period, patients from our own hospital district were transferred for follow-up of epilepsy to our outpatient neurology clinic, but the overall monitoring of their general health was conducted in health centers by general practitioners.

This study was a noninterventional, retrospective study, which does not require ethical committee approval according to the Finnish Law on Research. Access to patient records was based on the statement provided by the Head of Science Center, Tampere University Hospital Research and Innovation Services, Science Center.

3. Results

3.1. Patients

We had reliable follow-up data for at least 2 weeks for a total of 67 patients and these individuals were included in this analysis. The demographics of the patients are presented in Table 1. About every third patient (23/67) had started LCM treatment within 2 weeks of the initial diagnosis of epilepsy, but overall LCM had been initiated for acute seizure disorders (prolonged complex partial seizures, acute repetitive seizures or status epilepticus) in 54 patients (81%). Most of these patients started LCM therapy with an i.v. loading dose of 200–400 mg. Forty-one patients had received a previous epilepsy diagnosis and also previous AED treatment before the initiation of LCM therapy. The mean duration of epilepsy before LCM treatment was 8.8 years (range: 0.9–60).

Table 1
Demographics of the patients.

Number of patients	67
Sex (M/F)	37/30
Mean age when epilepsy was diagnosed (years)	60 (3–83)
Diagnosed >60 years old	49
Diagnosed <60 years old	18
Mean age at onset of LCM treatment (years)	68 (61–84)
Number of previous AEDs	
0	7
1	18
2	18
3 or more	24
Etiology of epilepsy, number (%)	
Poststroke	24 (36)
Brain tumor	12 (18)
CNS infection	5 (7)
Other	13 (19)
Unknown	13 (19)

3.2. Tolerability and efficacy

During the follow-up period, 10 patients discontinued LCM; three were preplanned to terminate the LCM treatment after the acute situation but had actually continued medication for longer than 1 month, four had stopped treatment on their own volition, and only three had discontinued LCM use because of side effects. Of those who had discontinued LCM themselves, two patients had also used previously several other AEDs and also discontinued these drugs by their own volition; one patient who had taken LCM for 17 months then decided to stop using not only that drug but also any other AEDs, and one patients had discontinued LCM, probably because of some misunderstanding in primary health care but continued to take oxcarbazepine (OXC). None of the patients, who stopped LCM after a consultation with a neurologist, stated that a lack of efficacy was the reason for discontinuation. Side effects leading to discontinuation were fatigue, dizziness, and tremor, which were also the most common side effects reported at the follow-up visits. Even in patients with dizziness as a side effect, there were no reported falls. None of the patient records reported falls, but if a fall was mild and not clinically significant, it is possible that they were not presented on hospital records but were evaluated in primary health care or were assumed to be a result of something else than LCM. About every third patient (34%) described some side effect, but no serious treatment-related adverse effects were reported, and in many cases, adverse effects were present only at the beginning of treatment. It should also be noted that many patients were using polytherapy and therefore the side effect profile was not

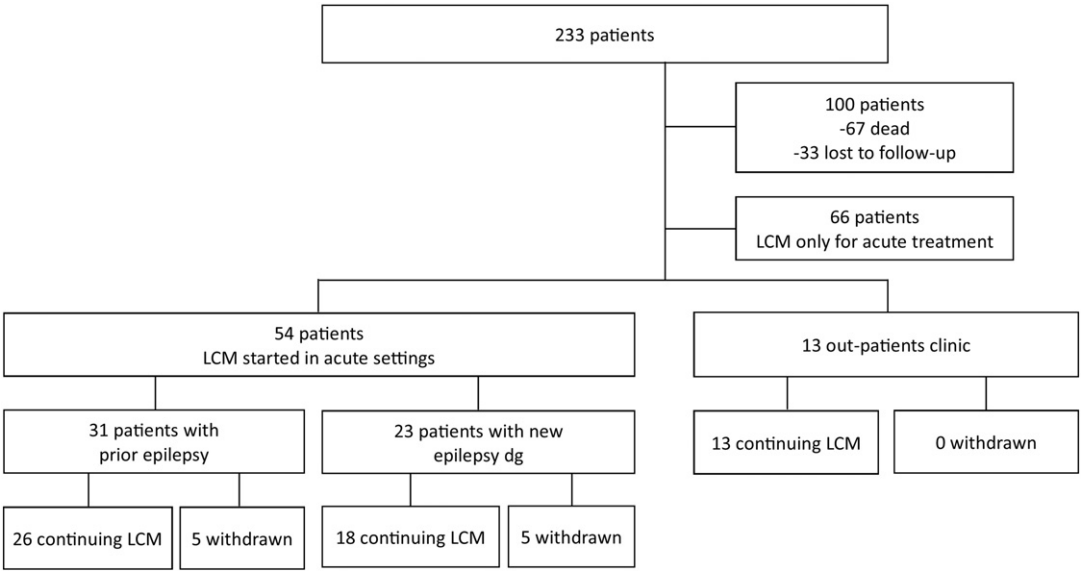

Fig. 1. Participant timeline and study entry. The number of patients that entered or discontinued at each phase is indicated in the figure. Reasons for discontinuation are: death due to severe comorbidity (67), lost to follow-up (33) and LCM only for acute treatment (66). For the patients with proper follow-up LCM was started in acute settings (54) or in out-patient clinic (13); altogether 57 patients continued and 10 patients discontinued LCM treatment.