

## Lacosamide in patients with temporal lobe epilepsy: a multicentric observational open label study

G. Borzi<sup>1</sup>, Di Gennaro<sup>3</sup>, D'Aniello<sup>3</sup>, M. Sturniolo<sup>1</sup>, F. Pucci<sup>1</sup>, L. Mumoli<sup>1</sup>, A. Fratto<sup>1</sup>, F.C. Schmitt<sup>4</sup>, A. Gambardella<sup>1,2</sup>, A. Labate<sup>1,2</sup>

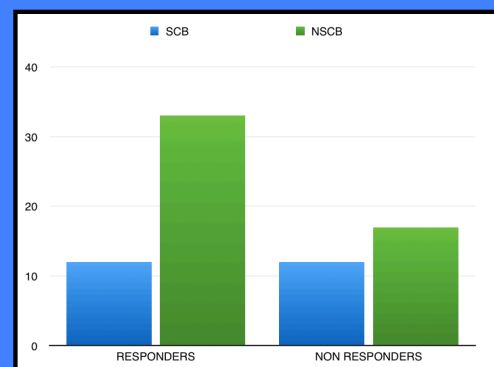
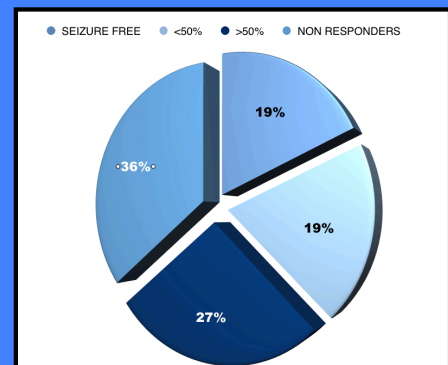
<sup>1</sup>Institute of Neurology, University "Magna Graecia", Catanzaro, Italy. <sup>2</sup>Institute of Molecular Biomedicine and Physiology of the National Research Council (IBFM-CNR), Catanzaro, Italy. <sup>3</sup>IRCSS Neuromedi, Pozzilli, IS, Italy. <sup>4</sup>Department of Neurology, Otto-von-Guericke-University, Magdeburg, Germany.

**Objective:** Lacosamide (LAC) is a novel antiepileptic drug approved in Europe as adjunctive treatment for adults with partial seizures with or without secondary generalization; moreover it was recently approved also for monotherapy in U.S.. In this study, we aimed to evaluate the efficacy and tolerability of LAC both as 'add-on' therapy or monotherapy in patients with temporal lobe epilepsy (TLE).

**Materials and methods:** we reviewed the clinical and instrumental records of 81 patients (mean age  $44,7 \pm 12,37$ ; 45 females) with a diagnosis of TLE according to ILAE Classification (2001). The following clinical characteristics were noted: sex, age, family history of epilepsy and febrile convulsions, onset of seizures, antiepileptic drugs (AEDs) used together with LAC. All patients underwent several interictal awake and sleep electroencephalograms (EEG) and a 3 Tesla MRI scanner with specific protocol for epilepsy patients. Patients received LAC as monotherapy or with other AEDs. Seizure frequency, adverse effects were observed and follow-up was conducted for 6 to 52 months (median 12 months). Efficacy of antiepileptic therapy was assessed by measuring changes in seizure frequency, classifying patients, into four categories: those achieving seizure freedom, those achieving  $\leq 50\%$  reduction in seizures, those who achieve  $\geq 50\%$  reduction in seizures and non responders.

**Results:** 58 out of 81 patients (71%) had hippocampal sclerosis (HS). Seven patients were on monotherapy (after switching), 33 patients received bi-therapy LAC plus another AED whereas 41 patients received a polytherapy. The mean dose of LAC was  $318,06 \pm 101,99$  mg. Fifty-two out of 81 (64%) patients were responders (in detail, 15 were seizure free, 22 achieved a reduction  $\geq 50\%$ , 15 achieved a reduction  $\leq 50\%$ ), 29 out 81 (35%) were non responder. Dividing the whole group in patients taking, in association with LAC, sodium channel blockers, SCBs (24, 29%) or not, n-SCBs (50, 61%), the portion of responder was higher in patients who received LAC with a n-SCB drug (66% vs 50%). All the 7 patients switched to a LAC monotherapy were responders (5 out 7 patients were seizure free, follow-up 6-30 months).

**Discussion and conclusion:** our results may suggest that LAC at doses of 200 to 400 mg/day reduces seizure frequency in adults with TLE with and without HS. Responder rates may be higher when LAC is used with an other nSCB drug. Finally, our data shows that LAC is well tolerated, and it can be effective, in selected cases, also as monotherapy.



### References

- Malmgren K, Thom M. Hippocampal sclerosis-origins and imaging. *Epilepsia*. 2012 Sep; 53 Suppl 4:19-33.
- Villanueva V, López-Gomáriz E, López-Trigo J, Palau J, García M, Villarroya T, Bonet M, Santafé C. Rational polytherapy with lacosamide in clinical practice: Results of a Spanish cohort analysis RELACOVA. *Epilepsy & Behavior* 23 2012 298-304.
- Villanueva V, López FJ, Serratosa JM, González-Giraldez B, Campos D, Molins A, Rodríguez Uranga J, Mauri JA, Salas-Puig J, Toledo M, Sánchez-Alvarez JC, Moreno A, Serrano-Castro PJ, Saiz-Diaz RA, González de la Aleja J, de la Peña P, Asensio M. Control of seizures in different stages of partial epilepsy: LACO-EXP, a Spanish retrospective study of lacosamide. *Epilepsy & Behavior* 29 2013 349-356.

