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Epilepsia®

GRAY MATTERS

Workshop Report

International conference and workshop "Hallmarks of Epileptic Brain Activity" in Tbilisi, Georgia, October 24-27, 2017

More than 50 million people worldwide suffer from epilepsy; 80% of them live in low- and middle-income countries where three-fourths of them have no access to appropriate treatment.[1] Epilepsy surgery is currently not only the most effective,[2] but also a cost-efficient treatment for a drug-resistant form of epilepsy,[3] in particular for low- and middle-income countries.[4,5] Georgia is one of the low- to middle-income countries[6] that still lacks some of the advanced presurgery diagnostic methods as well as an appropriate epilepsy surgery program. To improve this situation and foster the presurgical diagnosis and implementation of epilepsy neurosurgery, a German-Georgian cooperative project (EpilepCure) was initiated with the financial support of the German Federal Ministry of Education and Research. The launching event of this project took place in Tbilisi on October 24-27, 2017 and was structured as a 2-day scientific conference with 2-day case studies in a subsequent workshop (Figure 1). This event brought together 25 invited European and Georgian physicians and researchers to explore and discuss the current situation in Georgia, the potential to optimize diagnostic tools with a special focus on the presurgical evaluation, and the options for surgical interventions. Details of this public meeting can be found on the project homepage https://epilepcure.wordpress.com/.

The broad spectrum of presurgical evaluation and treatment options were introduced in the conference series lectures (Drs. M. Holtkamp, T. Lehmann, and M. Cunningham). In the case studies, German colleagues (Drs. M. Holtkamp and T. Lehmann) emphasized that in patients with discordant indications based on seizure semiology, electroencephalography (EEG) and magnetic resonance imaging (MRI), more sophisticated diagnostic methods, such as intracranial EEG recordings, are required to substantiate the diagnosis and evaluate the potential of surgical intervention. Those methods are still missing in Georgia, but are routinely used in Germany. Therefore, as one aim of the project, the German colleagues offered to assist in their establishment in Georgia. Notable, epilepsy surgery is already feasible in Georgia, with the potential availability of good medical expertise to perform such interventions. In line with this state of the art, the case studies of Georgian colleagues (Drs. S. Kasradze, N. Tatishvili, G. Lomidze, and V. Tsikarishvili) revealed a high potential for surgical intervention with a relatively large proportion of patients with temporal lobe epilepsy and hippocampal sclerosis. Importantly, in contrast to high-income countries,[7] these clear-cut cases are still common in Georgia due to the lack of surgical interventions so far.[8] These patients with concordant indications have a very good outcome prognosis and do not require the implementation of additional diagnostic efforts, thus representing a favorable starting point to launch a coordinated epilepsy surgery program. The essential diagnostic workup for clear-cut cases, including neurological examination, standard video-EEG, and MRI, is readily available. Therefore, drug-resistant mesial temporal lobe epilepsy with hippocampal sclerosis will be a primary focus when starting the implementation of the neurosurgical epilepsy program.

One of the most hotly debated themes of the meeting was the topic of high-frequency oscillations (HFOs) as a potential biomarker to localize the epileptogenic focus and to predict surgical outcome (Drs. T. Gloveli, T. Dugladze, P. Bäuerle, and I. Vida). An important conclusion on this discussion was the aim of linking clinical and experimental research to investigate this neural activity signature in human EEG recordings as well as in local field potential recordings in animal models of epilepsy. Having access to a large number of human patients with hippocampal sclerosis, Georgia provides a unique opportunity within the framework of this project to compare data from chronic human and animal model recordings and evaluate the potential of HFOs as a biomarker. Hence, HFOs will be examined by a close collaboration of clinicians and basic researchers.

All participants admitted that given the generally favorable situation in the development of epilepsy treatment, the Georgian capital Tbilisi is well suited to establish a central epilepsy full-service cooperative health care unit, with the potential for a deep impact not only for the country, but also for the whole of the South Caucasus, where appropriate epilepsy surgery options are largely still lacking. Therefore, the first meeting in Tbilisi will be followed by the exchange of experts, conferences, and workshops in both countries, with the aim of optimizing presurgical epilepsy diagnostics by training Georgian physicians in advanced

FIGURE 1 Participants in the conference and workshop in Tbilisi

diagnostic and neurosurgical strategies and promoting surgical interventions in Georgia in the near future.

FUNDING INFORMATION

The meeting in Georgia was financially supported by the German Federal Ministry of Education and Research.

DISCLOSURE

None of the authors has any conflict of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Letters

Comparing the dosages of lacosamide, eslicarbazepine acetate, and controlled-release carbamazepine in noninferiority epilepsy monotherapy trials: How much "fair" is "fair"?

To the Editors:

We read with great interest the results of the noninferiority randomized controlled trial (RCT) comparing eslicarbazepine acetate (ESL) with controlled-release carbamazepine (CR-CBZ) as monotherapy treatment for patients (aged ≥18 years) with newly diagnosed focal epilepsy.[1] The trial was conducted according to standards of the European Medicines Agency and recommendations of the International League Against Epilepsy, adopted a robust methodology, and will undoubtedly have great impact in clinical practice. However, one main point is worth noticing.

According to the requirements of the European regulatory agency for the evaluation of medicinal products, noninferiority analysis can be adequate to demonstrate the efficacy of an antiepileptic drug, provided that the molecule under investigation has been compared with an acknowledged standard at optimized dosages. In the ESL monotherapy trial, the authors evaluated ESL up to 1600 mg/d, which is a dosage higher than the highest effective recommended daily dose of 1200 mg for add-on therapy. Interestingly, the same choice of "pushing up" the dose of the tested drug was adopted in the trial assessing lacosamide (LCS) monotherapy.[2] LCS was up-titrated to a 600-mg daily dose, which is higher than the highest recommended dosage (400 mg/d) for adjunctive therapy.

Conversely, CR-CBZ was allowed up to 1200 mg/d, and this choice was in line with 3 previous monotherapy RCTs evaluating LCS,[2] levetiracetam,[3] and zonisamide.[4]

To date, there is no definitive information on the equieffective doses of different antiepileptic drugs.[5] However, the dosages being tested in this ESL monotherapy RCT (ESL up to 1600 mg/d, CR-CBZ up to 1200 mg/d) might have somewhat benefited ESL regarding overall efficacy and influenced the primary endpoint of seizure freedom, particularly considering the good seizure control obtained with ESL at the 1600-mg daily dose in the conversion-to-monotherapy trials.[6] A higher dose of CR-CBZ could have increased the occurrence of adverse events, but could have also improved its efficacy, possibly allowing a less "unfair" (or more "fair") comparison between the two antiepileptic drugs.

DISCLOSURE OF CONFLICT OF INTEREST

F.B. received speakers' honoraria from Eisai and PeerVoice, payment for consultancy from Eisai, and travel support from Eisai, ITALFARMACO, and UCB Pharma. S.L. has no conflict of interest. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Response: Comparing the dosages of lacosamide, eslicarbazepine acetate, and controlled-release carbamazepine in noninferiority epilepsy monotherapy trials: How much "fair" is "fair"

To the Editors:

The issue raised by Brigo and Lattanzi in this issue of *Epilepsia* is an interesting one and deserves the following comment. Carbamazepine-CR (CBZ-CR) was chosen as the active comparator in clinical trial BIA-2093-311[1] because it is considered one of the primary standards of monotherapy treatment for patients with newly diagnosed epilepsy, and the doses chosen (200 mg twice daily [BID], 400 mg BID and 600 mg BID) were based on those used in previous head-to-head trials, as the authors also noted. The lowest dose of eslicarbazepine acetate (ESL; 800 mg) was chosen on the basis of previous clinical studies, where lower doses were not effective as add-on therapy. Previous experience with oxcarbazepine has shown that higher doses of voltage-gated sodium channel blockers may be required when they are used as monotherapy compared to add-on therapy. We, therefore, set the highest target dose of ESL at 1600 mg, despite potentially less tolerability, assuming that tolerability of ESL should be better when it is used as monotherapy compared to adjunctive therapy. It should be underlined that previously ESL 1600 mg demonstrated efficacy and tolerability in 2 conversion-to-monotherapy studies in patients who were refractory to antiepileptic therapy.[2] Additionally, as stated in the European guideline, assay sensitivity may be a problem in monotherapy studies. Although the design, featuring stepwise fixed-dose increments based on response, could minimize the issue, it does not eliminate it, as the majority of subjects remain seizure-free at the first dose level. Our study, with a starting dose, slow titration, and the possibility for subjects to remain on the lowest effective dose, mimics the clinical practice in tailoring dosage to balance efficacy with tolerability. This is completely in line with data collected from clinical practice, where most subjects with newly diagnosed epilepsy respond to their first antiepileptic drug at a low dose.[3] Furthermore, the other controlled pivotal studies of levetiracetam,[4] zonisamide,[5] and lacosamide[6] confirmed this uncontrolled observation. In all of these clinical studies, the majority of subjects who remained seizure-free did so at the first dose level. Due to the uptitration study design and inherently low number of subjects at upper dose levels, any comparison of treatment effect by individual dose levels or attempt to establish a dose relationship is inappropriate due to lack of adequate power. As mentioned, in our study,[1] the number of subjects that needed uptitration to higher dose levels was relatively small, and at the last dose level, the number of CBZ-CR subjects was half that of ESL subjects. Therefore, overall, the conclusion from our study was that ESL at the dose range of 800-1600 mg once daily was noninferior in tailoring dosage to balance efficacy with tolerability to CBZ-CR 200-600 mg BID.

CONFLICT OF INTEREST

E.T. reports personal fees from Medtronics, Everpharma, Bial, Newbridge, GL Pharma, GlaxoSmithKline, Boehringer, Viropharma, and Actavis; grants and personal fees from Biogen Idec, UCB Pharma, and Eisai; and grants from Red Bull, Merck, the European Union, FWF Österreichischer Fond zur Wissenschaftsförderung, Bundesministerium für Wissenschaft und Forschung, and Jubiläumsfond der Österreichischen Nationalbank outside the submitted work. J.F.R. and P.S.d.S. are employed by BIAL-Portela & C[a]. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Epilepsia – April 2018 – Announcements

EEG in the First Two Years of Life, from Neonate to Toddler

4–7 April 2018
Cambridge, UK
Information: https://www.ilae.org/congresses/eeg-in-the-first-two-years-of-life

2nd International Training Course on Neuropsychology in Epilepsy

15–20 April 2018
Provence, France
Information: http://www.ilae.org/Visitors/Congress/congressinfo/Neuropsych-in-Epilepsy-2018.pdf

2nd Girona EPIPED Course - Treatment Strategies in Pediatric Epilepsies

18–21 April 2018
2nd of a 3 years' cycle, international interactive training course
Girona, Spain
Program: https://www.ilae.org/download.cfm?downloadfile=D70865D0-EFCF-11E7-9477141877632E8F&typename=ilaeEventAsset&fieldname=filename
Website: https://www.epiped-course.com/

31st International Congress of Clinical Neurophysiology (ICCN) of the International Federation of Clinical Neurophysiology (IFCN)

1–6 May 2018
Washington, DC, USA
ICCN 2018 Website: http://iccn2018.acns.org/

4th International Congress on Epilepsy, Brain & Mind

2–5 May 2018
Brno, Czech Republic
Website: http://www.epilepsy-brain-mind2018.eu/

Young Epilepsy Section: YES Kick-Off Workshop

12–13 May 2018
London, UK
Information: https://www.ilae.org/congresses/young-epilepsy-section-yes-kick-off-workshop

EILAT Conference on New Antiepileptic Drugs and Devices (EILAT XIV)

13–16 May 2018
Madrid, Spain
Website: https://www.eilatxiv.com/

8th Congress of the Polish Society of Epileptology

17–19 May 2018
Warsaw, Poland

Infantile epilepsy in light of new ILAE classification – new terminology, etiology and treatment perspectives

28 May 2018
Tbilisi, Georgia
Information: https://www.ilae.org/congresses/infantile-epilepsy-in-light-of-new-ilae-classification-new-terminology-etiology-and-treatment-perspectives

30th Annual Meeting of the European Academy of Childhood Disability (EACD)

28–31 May 2018
Tbilisi, Georgia
Information: https://www.ilae.org/congresses/30th-annual-meeting-of-the-european-academy-of-childhood-disability-eacd

Joint Annual Meeting of the Swiss League Against Epilepsy and the Swiss Society of Clinical Neurophysiology

30–31 May 2018
Aarau, Switzerland
Website: http://www.sgkn-congress.ch/

9th Simposio Internacional de Epilepsias

31 May–1 June 2018
Santiago, Chile
More information: https://www.ilae.org/congresses/9th-simposio-internacional-de-epilepsias

Norwegian League Against Epilepsy 2018 Chapter Congress

1–2 June 2018
Trondheim, Norway

37th Congresso da Liga Brasiliera de Epilepsia

6–9 June 2018
São Paulo, SP, Brazil
Website: http://congresso.epilepsia.org.br/2018/

4th East European Course on Epilepsy

13 June 2018
Shishkinn, Chernihiv Region, Ukraine
Website (Russian): http://ulae.org.ua/index.php/uk/
Website (English): http://ulae.org.ua/eece/2018/

54th Annual Meeting of the German Society of Epileptology (DGfE) e. V.

13–16 June 2018
Stadthalle Fürth
Fürth, Germany
Website: http://www.epilepsie-tagung.de/

4th Congress of the European Academy of Neurology EAN – Lisbon 2018

16–19 June 2018
Lisbon, Portugal
Website: https://www.ean.org/lisbon2018/

12th Baltic Sea Summer School on Epilepsy (BSSSE 12)

24–29 June 2018
Vilnius, Lithuania
Website: www.epilepsiestiftung-wolf.de

Epileptic channelopathies – clinical spectrum and treatment perspectives

28–29 June 2018
3rd Dianalund International Conference on Epilepsies
Sørup Herregård, Ringsted, Denmark
Program and registration: https://www.ilae.org/congresses/epileptic-channelopathies-3rd-dinalund-international-conference-on-epilepsies

12th Asian and Oceanian Epilepsy Congress

28 June–1 July 2018
Bali, Indonesia
Website: www.epilepsybali2018.org

4th Dianalund Summer School on EEG and Epilepsy

15–21 July 2018
Dianalund, Denmark
Application and Announcement: https://www.ilae.org/congresses/4th-dianalund-summer-school-on-eeg-and-epilepsy

16th Advanced San Servolo Epilepsy Course

16–27 July 2018
San Servolo (Venice), Italy
Application and Announcement: https://www.ilae.org/congresses/16th-advanced-san-servolo-epilepsy-course

8th International Summer School for Neuropathology and Epilepsy Surgery (INES 2018)

26–29 July 2018
Erlangen, Germany
Information: https://www.ilae.org/congresses/8th-international-summer-school-for-neuropathology-and-epilepsy-surgery-ines-2018

4th Summer School on Imaging in Epilepsy: SuSIE 2018

12–15 August 2018
Marburg, Germany
Website: http://www.imaging-in-epilepsy.org/

13th European Congress on Epileptology

26–30 August 2018
Vienna, Austria
Website: www.epilepsyvienna2018.org

ESTM 2018 Vienna: Epilepsy Surgery Techniques

31 August–1 September 2018
Vienna, Austria
Satellite symposium for the European Congress on Epilepsy
Website: http://www.estm2018.at/

Congreso de Epilepsia: 2018. Liga Agentina – LACE

13–14 September 2018
Chapter website: http://www.lace.org.ar/

9th International Summer School for Neuropathology and Epilepsy Surgery (INES 2018)

17–20 September 2018
Beijing, China
Information: https://www.ilae.org/congresses/9th-international-summer-school-for-neuropathology-and-epilepsy-surgery-ines-2018

International Symposium on Severe Infantile Epilepsies: Old and New Treatments (ISSET 2018)

20–22 September 2018
Vatican City, Rome, Italy
Website: http://www.ptsroma.it/isset2018/

CLAE / LCCE 2018 Scientific Meeting

21–23 September 2018
St. John's, Newfoundland
Website: https://canadianleagueagainstepilepsy.wildapricot.org/page-1816302

Cleveland Clinic Epilepsy Update & Review Course.

22–24 September 2018
Cleveland, Ohio, USA
CME Credits available
Website: http://www.clevelandclinicmeded.com/live/courses/epilepsy-update/

ILAE British Chapter Annual Scientific Meeting

26–28 September 2018
Birmingham, UK
Website: http://www.ilaebritishconference.org.uk/

10th Latin American Congress on Epilepsy

29 September–2 October 2018
San José, Costa Rica
Website: http://epilepsysanjose2018.org/

6th Global Symposium on Ketogenic Therapies for Neurological Disorders: Embracing Diversity, Global Implementation and Individualized Care

5–9 October 2018
Jeju, Korea
Website: www.ketoconnect.org

46th Annual Meeting of the International Society for Pediatric Neurosurgery (ISPN 2018)

7–11 October 2018
Tel Aviv, Israel
Website: http://www.ispnmeeting.org/2018

Hungarian Chapter of the ILAE

12 October 2018
Chapter website: http://www.epilepszia.hu/

Journées Françaises de l'Epilepsie

16–19 October 2018
Lyon, France
Website: https://www.jfe-congres.fr/

32nd Epilepsy Society of Australia Annual Scientific Meeting

31 October–2 November 2018
Brisbane, Australia
Website: https://www.epilepsy-society.org.au/conferences/esa-asm.asp

Swedish Chapter National Meeting

15 November 2018
Lund, Sweden

Annual Meeting of the Austrian and German Societies for Epileptology and the Swiss Epilepsy League ("Dreilaendertagung")

8–11 May 2019
Basel, Switzerland
Website: www.epi.ch/fach

33rd International Epilepsy Congress

22–26 June 2019
Bangkok, Thailand
Website: http://internationalepilepsycongress.org/

The Michael Prize 2019

This prize, presented biannually, is an international award for the best scientific and clinical research promoting the further development in epileptology
Nominations now open.
For more information - https://www.stiftung-michael.de/michaelpreis/michaelpreis.php?l=2