Eslicarbazepine acetate monotherapy in post-stroke epilepsy: A post hoc analysis from randomized double-blind multicenter clinical trial (BIA-2093-311)

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Objective: To determine efficacy and tolerability of eslicarbazepine acetate (ESL) monotherapy compared to controlled-release carbamazepine (CBZ-CR) in post-stroke epilepsy (PSE) patients. Methods: BIA-2093-311 was a phase III double-blind, randomized, parallel-group study, which demonstrated non-inferiority of ESL vs CBZ-CR for seizure freedom (SF) rates (Epilepsia. 2018, 59(2):479-491). A *post hoc* analysis was conducted for PSE *vs*. non-PSE patients to compare efficacy and tolerability of ESL and CBZ-CR. Results: 52/813 (6.4%) were PSE and 761/813 (93.6%) were non-PSE patients. PSE patients were older and had higher mean age of epilepsy onset. In the PSE and non-PSE groups, no difference in demographics and epilepsy characteristics was observed between ESL and CBZ-CR treatment arms. There was no difference in SF between ESL and CBZ-CR in PSE patients (risk difference= 0.60%) and non-PSE patients (risk difference=-3.5%). In PSE patients, no significant difference in incidence of at least one related treatment emerging adverse events (TEAEs) was observed (ESL 34.8% *vs.* CBZ-CR 55.2%, p=0.17); however, ESL group had significantly lower discontinuation due to at least one related TEAE (ESL 4.3% *vs.* CBZ-CR 31.0%, p=0.03). In non-PSE patients, ESL group had lower incidence of at least one related TEAE (ESL 42.6% *vs*. CBZ-CR 51.2%, p=0.02); but discontinuation due to at least one related TEAE was similar in both groups (ESL 12.4% *vs.* CBZ-CR 12.8%, p=0.96). Conclusion: No difference was observed in seizure freedom between ESL and CBZ-CR in both PSE and non-PSE patients. In PSE patients, ESL was associated with fewer discontinuations due to TEAEs.

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