

CHARACTERISTICS OF PEOPLE WITH NEW-ONSET FOCAL EPILEPSY STARTED ON LAMOTRIGINE IN THE HUMAN EPILEPSY PROJECT

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Purpose of Study:

Lamotrigine is a common first-line antiseizure medication FDA approved for the treatment of focal epilepsy. Despite its use for the past 30 years, there is ongoing investigation into the characteristics that impact the variability in an individual's plasma concentration once they get to an initial target dose of 100 mg twice daily. By this dose, most people will either have failed the medication due to experiencing side effects or begin to see benefits. This study describes the patient characteristics of people with focal epilepsy on lamotrigine and offers additional insights into the importance of therapeutic monitoring and the relationships between patient baseline demographics and the variability of their initial plasma levels.

Methods Used:

This was a secondary analysis of enrollment data from the Human Epilepsy Project (HEP). Participants with complete enrollment records, as well as information on antiseizure medications, including doses, and initial plasma concentration were analyzed. All information on pre-treatment seizure histories were collected in the form of seizure diaries and medical records from the time of initial diagnosis and treatment and initial study encounters. As part of HEP, plasma concentrations of antiseizure medications (ASMs) were collected at an initial target dose of 200 mg total daily dose (or 100 mg twice daily) for participants started on lamotrigine. Out of 448 participants fully enrolled in HEP, 24 had lamotrigine trough levels and complete records. Drug level variation is described by age, sex, and weight for this group using descriptive statistics.

Summary of Results:

The average age of our cohort was 33.4 (SD = 13.2) and most (n=13, 54.2%) were female. The average weight was 161.2 lbs (SD = 42.3). The cohort included 22 white participants, 1 Asian

participant, and 1 African American participant. Most participants (n=16, 66.7%) obtained some form of higher education, 2 (8.3%) participants had a high school diploma or equivalent, and 6 (25.0%) participants had less than a high school diploma. A documented formal learning disability was recorded for 5 (20.8%) participants. Employment data was as follows: 8 (33.3%) students, 3 (12.5%) unemployed, 4 (16.7%) part-time employed, 9 (37.5%) full-time employed. When people were on a stable dose of 100 mg twice daily, there was variability in initial serum concentrations by age (Figure 1A), weight (Figure 1B), and sex (Figure 1C). Following baseline levels, participants had expected dose dependent increases in plasma levels with increasing doses (Figure 1D).

Conclusions:

This study highlights the variability in initial plasma levels despite patients taking the same dose across demographic variables. This emphasizes the challenge in predicting initial levels of plasma concentration and the need for clinicians to check blood levels early in order to help optimize treatment with lamotrigine.