

## Acute Epilepsy Exacerbations In Patients Switched Between A-Rated Anti-Epileptic Drugs

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**Background:** Concerns have been raised over the use of different manufacturer's versions of A-rated antiepileptic drug (AED) formulations in epilepsy patients. Our previous research found no significant relationship between a switch and an exacerbation when controlling for important covariates.

**Objective:** To estimate the association between acute epilepsy exacerbations and switching between different A-rated AEDs and to determine if there is a differential effect based upon if the final product was branded or generic.

**Study Design:** Observational case-control.

**Methods:** We conducted an observational case-control study using pharmacy and medical claims data from January 1, 2005 through December 31, 2007. A patient population aged 18 to 64 who had an epilepsy diagnosis and were on AED therapy during 2005 was identified. Cases of epilepsy exacerbation were defined as individuals with a documented inpatient hospitalization or emergency room claim for epilepsy during 2006 or 2007. Controls from the same population were matched on baseline epilepsy diagnosis and follow-up time since January 1, 2006. The exposure was a switch between A-rated AEDs in the 90 days prior to the matching date. Conditional logistic regression was used to estimate the odds of an epilepsy exacerbation after a switch controlling for important covariates, stratified by brand or generic medication use.

**Results:** A total of 34,216 individuals were eligible for study, and a final sample of 2,949 cases was matched to 8,847 controls. The unadjusted and adjusted odds ratio between a switch and an epilepsy exacerbation were 1.51 (95% CI=1.29-1.76) and 1.08 (95% CI=0.91 – 1.29), respectively. When the patient switched to a branded medication, the adjusted odds ratio was 1.13 (95% CI=0.93-1.38) while switching to a generic medication resulted in an adjusted odds ratio of 1.01 (95% CI=0.70-1.47).

**Conclusions:** After addressing potential confounders, no evidence was found that A-rated switching was associated with increased acute exacerbations of epilepsy. This effect was similar regardless of whether the new agent was a branded or a generic product. Study limitations include potentially incomplete identification of seizures and limited information on duration and severity of disease. This study provides additional insight into the relationship between A-rated AED switching and acute exacerbations of epilepsy.