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## To cite this version:

Elisabeth Polard, André Happe, Emmanuel Nowak, Arnaud Biraben, Emmanuel Oger. Oc031–Generic Substitution Of Antiepileptic Drug (Aed) And Loss Of Seizure Control: A Population-Based Case-Crossover Study. 11th Conference of the European Association for Clinical Pharmacology and Therapeutics, Aug 2013, Genève, Switzerland. pp.e13, 10.1016/j.clinthera.2013.07.030 . hal-00874515

**HAL Id: hal-00874515**

**https://univ-rennes.hal.science/hal-00874515**

Submitted on 18 Oct 2013

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# OC031—GENERIC SUBSTITUTION OF ANTIEPILEPTIC DRUG (AED) AND LOSS OF SEIZURE CONTROL: A POPULATION-BASED CASE-CROSSOVER STUDY

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**Introduction:** There are still controversies over pill substitution among AEDs: some studies claimed that switching between brand and generic AED (generic substitution) can lead to breakthrough seizures; other studies have refuted these concerns. France and some US states recommend limiting substitution of generic AED. We aimed at further estimating the association between generic substitution and loss of seizure control.

**Patients (or Materials) and Methods:** We used data from the French National Health Insurance Information System linked with the French Hospital Discharge Database to identify a cohort of patients aged 18 years or more who filled a prescription in 2010 for AED that had at least 1 brand-name and 1 generic form available on the French market (carbamazepine, lamotrigine, levetiracetam, oxcarbazepine, topiramate, or valproic acid). Patients with a medical history of stroke or cancer and women who gave birth (ICD-10 codes, O80–O84) were excluded. We used a case-crossover design to assess the relationship between seizure-related hospitalization and generic substitution. For this preliminary analysis, cases were identified as individuals with a seizure-related hospitalization between July 2010 and December 2010 (ICD-10 codes, G40 or G41). The index date was defined as the date of first occurrence in the inpatient file of the codes of interest pending a preceding hospitalization-free period of at least 6 months with regular dispensations of targeted AED. The case period corresponded to the 3 months preceding the index date; the control period was defined as the 3 months immediately preceding the case period. Generic substitution was defined as a filled prescription for a generic AED that was preceded by a filled prescription for a brand-name counterpart. Matched odds ratio estimates were based on the ratio of discordant pairs of case and control periods in regard to generic substitution; ORs and 95% CIs were estimated using conditional logistic regression model. All analyses were conducted using the SAS statistical package (version 9.2; SAS Institute).

**Results:** The cohort included 566,549 adult patients filling targeted AED. We identified 10,089 patients with eligible seizure-related hospitalization in the second half of 2010, excluding stroke, cancer, and childbirth. Among them, 2980 had regular dispensations. Generic substitution was observed in 461 patients, 273 in the case period and 258 in the control period; matched OR = 1.08 (95% CI, 0.88–1.32).

**Conclusion:** Generic substitution was not associated with an elevated risk of seizure-related hospitalization.

**Disclosure of Interest:** None declared.