Generic drug switch in epilepsy – Pharmacokinetic and Clinical aspects

Background: Generic drug substitution of antiepileptic drugs (AEDs) has been controversial for many years. Earlier retrospective studies have indicated increased seizure frequency, and high switchback rates to brand name drugs, after the generic switch. More recent prospective studies have not found any pharmacokinetic differences between brand and generic AEDs or higher switchback rates compared to generic substitution of non-AEDs.

Methods: A prospective naturalistic study of generic drug switch of levetiracetam (LEV) was conducted with repeated LEV serum concentration measurements and assessment of quality of life before and after the switch. Furthermore, a cross-sectional survey study was conducted to analyze attitudes to generic AEDs among patients on branded AED drug treatment.

Results: Fluctuation of LEV serum concentrations was equal with branded LEV and the generic LEV. Within-subject variability was much larger than the small, non-significant differences between the two LEV products. No switchbacks occurred. Irrespective of brand or generic treatment, subjects were less worried about seizures at the end of the study compared to at inclusion. Preliminary results are that Survey respondents with prior experience of generic AED substitution were more likely to accept a future switch.

Importance: Recent evidence supports psychological reasons rather than pharmacological differences to explain the previously reported high switchback rates following generic drug switch in epilepsy. A structured nurse-led follow-up after generic AED substitution could possibly decrease seizure worries and facilitate successful generic substitution. That would lead to substantial cost savings and more efficient allocation of health-care resources.

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