Clinical Experience with Generic Levetiracetam in a Tertiary Care Epilepsy Clinic

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INTRODUCTION

• There has been recent controversy regarding the appropriateness of generic anti-epileptic drug (AED) use for PWE.

• Generic AEDs can potentially lead to increase in seizure frequency, adverse effects (AEs), and higher healthcare utilization costs.

• The AAN recently instituted guidelines opposing generic substitution of AEDs without physician approval.

• To our knowledge, there is no study to date that specifically assesses the consequences of substituting generic for branded LEV among PWE.

METHODS

• We conducted a retrospective chart review of 760 unduplicated consecutive adult patients attending a tertiary care epilepsy clinic over 12 months at Ben Taub General Hospital (BTGH).

• BTGH is the largest county hospital in Houston, Texas and provides quality healthcare access to all residents regardless of financial status.

• Once generic medications are available, patients at BTGH are automatically switched to the generic formulation.

• We specifically assessed the rates of switch-back to brand from the generic LEV.

• Demographic and clinical characteristics of the patients were obtained, as well as reason for switch-back.

RESULTS

• Patients were switched from brand to generic LEV on November 1, 2008. 262 of the 760 patients (34%) were taking LEV during the study period.

• Twenty-four (9%) of these patients were switched back to brand name LEV by their treating physicians.

• Reasons for switch-back included AEs (100%) and a combination of AEs and increase in seizure frequency (88%). AEs included headache, fatigue, and aggression.

• Switch-back occurred among patients taking both monotherapy (10%) and polytherapy (8.5%).

CONCLUSION

• A relatively small proportion of patients in our cohort on generic LEV required switch-back to the branded drug. Nevertheless, careful monitoring is imperative because changing to generic LEV may lead to poor outcomes, with risk of AEs and increased seizures.

• This study could improve our understanding of the role of generic AED in the daily care of our PWE.

• While our data and previous medical claims database analysis are consistent in our concern of the current practice of switching to generic AEDs, there is continued need for either a double-blinded placebo-controlled trial or a prospective observational study of sufficient breathe to determine therapeutic equivalence and assess clinical changes in seizure frequency, adverse events, and economic impact.

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