

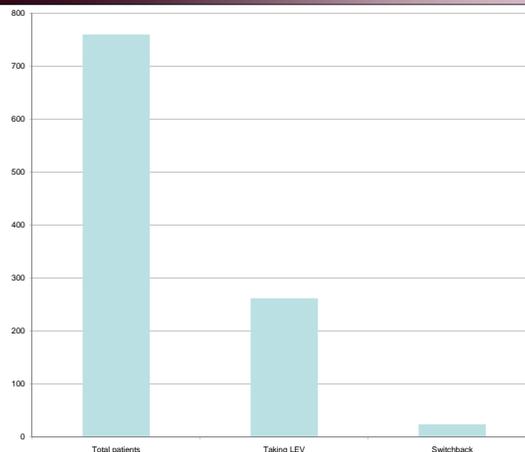
INTRODUCTION

- 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.

SWITCHBACK



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.

Contact Information

Siresha Chaluvadi MD, Baylor College of Medicine, Department of Neurology
NB-302, Houston TX 77030
Tel: 713-798-6151
Fax: 713-798-8530
Email: chaluvad@bcm.tmc.edu

Corey E Goldsmith MD, Department of Neurology NB-302, Baylor College of Medicine,
Houston TX 77030
Tel: 713-873-2961
Email: celam@bcm.tmc.edu

David E Friedman MD, Baylor Comprehensive Epilepsy Center, Dept. of Neurology, NB-302, Houston TX 77030
Tel: 713-798-0980
Email: defriedm@bcm.tmc.edu