Reviewer’s report

Title: Adverse drug reactions associated with six commonly used antiepileptic drugs in southern China from 2003 to 2015

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Reviewer: Balamurugan Tangiisuran

Reviewer's report:

General comment:

This is a prospective observational study involving 4563 epilepsy patients. A secondary data analysis from the WEFURD registry were conducted to identify the common ADR associated with six commonly used AEDs in southern China from 2003 to 2015. Although these information have been published previously especially among paediatrics population, the data presented from the current study are focused on the Southern China region.

In general, the manuscript is moderately written with mainly focus on describing the characteristics of ADR reported due to AEDs. However, we can consider that there is no original conclusion that could be drawn. Comparing to other analysis of of ADR due to AEDS, the current study include patients from all age group and does not confined to paediatrics population.

While the authors is to be commended for their effort, there are a number of questions remaining to be clarified and are outlined below by section.

Title

The title is appropriate and captures the content of the manuscript.

Abstract

* Lack of information on the ADR identification process in the method section.

Introduction

* Lack of information reported in regards to other studies worldwide that have reported the characteristics of ADR due to AEDs.
Methods

* It is not clear how the identification and validation of ADRs were conducted. Was trigger tool method was utilised in the current study?

* How many centres were involved in the ELFURS? What action was undertaken to ensure the reliability of the identification and data being collected in each centre.

* Two epileptologists assessed the causality of the ADRs reported. Was this done prospectively in the ward or each cases were summarised using a case vignette for review.

* Potential information bias - there are several studies have been published showing the existence of variability between healthcare professionals and also in the method utilised for the identification of ADRs. What was done if there was discrepancy between the reviewers during the classification process?

Results

* It was reported that only less than 2 percent of the ADR occurred in children in the current study although they are the major group of patients using multiple antiepileptic agents. It will be interesting to know the breakdown of age based on various categories.

Discussion

* Page 10; Line 7: The systematic process mentioned was not detailed in the method section.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

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