

ASHP Foundation Pharmacy Resident Health Services Research Grant

Authors:

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Title:

Investigating risk of suicide attempt in veteran patients being treated for bipolar disorder with antiepileptic drugs

Abstract of Proposal:

Purpose:

Stemming from an FDA issued alert, this study seeks to determine whether patients receiving antiepileptic drugs (AEDs) have an increased risk of suicidal behavior or ideation. The primary objective is to determine whether AEDs increase a patient's risk of suicide attempts resulting in hospital admissions. The secondary objectives are to determine whether any of the AEDs studied are more likely to increase a patient's risk of suicide attempts and to determine whether AEDs are associated with an increase in suicidal ideation.

Methods:

A retrospective case-control study will be conducted using national data from the Veterans Health Administration (VHA); a self-controlled case series study may also be conducted. Subsequently, regional (VISN 1) and local data will be collected from the Veterans Affairs Boston Healthcare System (VABHS) to conduct a nested validation study to evaluate the accuracy of exposure and outcome definitions. This study will investigate the three AEDs that are FDA approved to treat bipolar disorder: carbamazepine, lamotrigine, and valproic acid. Data will be collected from October 1, 1999 to September 30, 2007. Subjects will be identified by ICD-9 codes for deliberate self-harm and bipolar disorder. Barring administrative and data limitations, information from state mortality registries will also be obtained. These subjects will then be divided further into two groups defined by the presence or absence of AEDs. Each individual subject who attempted suicide will have five similar controls identified. A number of potential covariates, such as type of military service, comorbidities, age, and marital status will be collected and assessed.

A secondary analysis will be performed on subjects who were followed at VABHS. Suicide attempts resulting in emergency department visits and suicidal ideation will be collected. These outcomes will be identified using ICD-9 codes and progress notes. Sensitivity analyses will evaluate the potential impact that misclassification may have on the observed results within the regional cohort. We will evaluate the sensitivity, specificity, and positive predictive value of suicide attempt data at the VABHS.

Logistic regression models, and their associated adjusted odds ratios, will describe the association between drugs and suicide. All patient identifiers will remain confidential and be destroyed at the conclusion of the study. This pilot study will be submitted to the Institutional Review Board for approval prior to initiation.