OBJECTIVES: To compare divalproex sodium and valproic acid for therapeutic patterns, persistence rates, and predictors of hospitalization among bipolar patients on monotherapy in the Veterans Affairs Health care system. METHODS: Using VA administrative data bases, we conducted a retrospective inception cohort study of VA patients’* Y 18 years of age who had at least one outpatient diagnoses of bipolar disorder and two continuous prescription records for the study drugs in the VA PBPM pharmacy database during the study period of April 1, 2001 to September 30 2003. Persistence for the comparative drugs was reported as continuous variable and compared using t-tests. Logistic regression models were used to examine the risk of hospitalization whereas Cox proportional hazard regression models were used to evaluate the time to hospitalization and time to interruption of therapy for the two drug groups. RESULTS: We identified 4, 624 bipolar patients on monotherapy with valproic acid (n = 4036) and divalproex sodium (n = 588) during the study period. The descriptive statistics included sociodemographics, disability and comorbidity status and were similar for the two groups. For the crude persistence rates there were no statistically significant differences between divalproex sodium (120 days) and valproic acid (110 days). The logistic regression model for risk of hospitalization showed no statistically significant difference between the two comparators (OR = 1.06, 95% CI = 0.787–1.444). The Cox model for time to interruption of therapy showed an insignificant hazard ratio for divalproex sodium versus valproic acid (HR = 0.928, 95% CI = 0.844–1.020) and for time to hospitalization also no statistically significant difference in the hazard ratio for the two drugs (HR = 0.984, 95% CI = 0.784–1.295). CONCLUSION: The study showed a comparable profile of generic valproic acid with divalproex sodium for persistence and predictors of hospitalization for bipolar patients on monotherapy in the VA. Results have important health care implications for treatment and costs.

PMH3

Antidepressant prophylaxis for post-stroke depression: A meta-analysis

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OBJECTIVES: Given the high incidence of post-stroke depression (PSD), its serious sequelae, and inherent problems with diagnosis, prophylactic use of antidepressants may be a viable management strategy in patients experiencing stroke. The purpose of this study was to assess the prophylactic effects of antidepressants in non-depressed patients with stroke.

METHODS: A meta-analysis of randomized placebo-controlled trials (RCTs) evaluating the prophylactic effects of antidepressants in non-depressed patients with stroke was conducted. Literature searches in MEDLINE, PubMed, CINAHL, PsychINFO, EMBASE, Cochrane library, and CNKI from 1950 to August 2006 were used to identify the relevant studies. Outcome measures included the occurrence rate of newly developed PSD cases and severity of depressive symptoms as indicated by mean depression rating scales scores. The effect size was presented as rate difference (RD) or weighted mean difference (WMD).

RESULTS: From 10 RCTs, a total of 703 non-depressed patients after stroke were identified. The pooled occurrence rate of newly developed PSD cases in the intervention and control groups were 12.54% (41/327) and 29.17% (91/312), respectively (pooled RD = −0.17, 95% CI: −0.26 to −0.08). Prophylactic effects of antidepressants were not related to duration of use (coefficient of Pearson’ correlation [a] = 0.57, p = 0.11). CONCLUSION: Antidepressant prophylaxis is associated with a significant reduction in the occurrence rate of newly developed PSD, suggesting antidepressants may be considered along with other vascular preventive strategies in management of stroke patients.

PMH4

Adverse event profile associated with off-label use of antipsychotic medications

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OBJECTIVES: With 50–70% of antipsychotic prescriptions written for off-label purposes, the objective of this study is to explore the pattern and the outcomes of adverse events (ADEs) associated with antipsychotic off-label use. METHODS: A retrospective pharmaco-vigilance analysis was conducted using the FDA Adverse Event Reporting System (AERS) data between April 2004 and March 2006. ADE cases associated with antipsychotic medications were first identified based on the role of the medication in precipitating the ADEs (primary and secondary suspects) and then categorized according to their intended indications as off-label/on-label uses. Thereafter, the most frequently reported off-label antipsychotic uses associated with ADEs were explored, and their clinical outcomes were examined and compared with on-label antipsychotic ADE cases. RESULTS: Out of 27,700 ADEs involving antipsychotic medications, antipsychotics were the primary suspect in 7519 cases and secondary suspect in 2409 cases (Total: 9928). Atypical antipsychotics accounted for majority of the cases (9122, 91.8%) with clozapine (2983, 30.1%) being the most frequently reported antipsychotic medication followed by quetiapine (2186, 22.0%) and risperidone (2153, 21.7%). Off-label use afflicted half of the reported ADEs cases (4767, 48%). The top three reported off-label indications associated with ADEs include psychotic and schizoaffective disorders (1372, 28.8%), mood disorders (1105, 23.2%) and cognitive disorders (406, 8.5%). These ADEs could result into severe clinical outcomes. Of total 4767 ADEs associated with off-label use, (1942, 40.7%) involved hospitalizations and (1043, 21.9%) deaths. Similar pattern of clinical outcomes were found in ADE cases associated with on-label antipsychotic use. CONCLUSION: Most of the off-label antipsychotic-related ADEs reported to FDA is associated with using atypical antipsychotic medications for treating schizoaffective disorders, bipolar disorder, depression and dementia. More than half of these ADEs resulted in severe clinical outcomes such as hospitalizations and death. Therefore, the risk benefit ratio should be seriously considered when physicians prescribe antipsychotics for off-label purposes.

PMH5

A comparison of treatment-emergent diabetes among atypical and typical antipsychotic users: Using a bivariate probit model

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OBJECTIVES: To compare the risk of treatment-emergent diabetes (TED) in schizophrenic patients treated with atypical (AAP) versus typical antipsychotic (TAP) medications.

METHODS: We conducted a retrospective database analysis on episodes of care initiated after 1/1/2000 using data from Medical. Our analysis included episodes for patients 18 years of age or older, diagnosed with schizophrenia, who switched medications after a minimum “wash out” period of 15 days and had no evidence of diabetes in the previous 6 months. We used a simultaneous bivariate probit model to estimate the risk of TED in patients treated with AAP in comparison to TAP. If the error