838 Outcomes Research: Old Treatments, New Insights

Tuesday, March 09, 2004, 10:30 a.m.-Noon
Morial Convention Center, Room 265

10:30 a.m.

838-T National Patterns of Spironolactone Prescription for Older Patients With Heart Failure and Left Ventricular Systolic Dysfunction Before and After RALES

Frederick A. Masoudi, Cary P. Gross, Yongle Wang, Edward P. Havranek, Salf S. Rathore, JoAnne M. Foody, Harlan M. Krumholz, Denver Health Medical Center, Denver, CO, Yale University School of Medicine, New Haven, CT

Background: In the RALES trial, published in September 1999, spironolactone improved survival in selected patients with heart failure and left ventricular systolic dysfunction (LVDSD). Because of the risk of hyperkalemia, however, guidelines advise against use in patients with K+≥5.0 mmol/L or creatinine >2.5 mg/dL.

Methods: Using data from the Centers for Medicare and Medicaid Services’ National Heart Care Project, we studied Medicare patients ≥65 years old with LVDSD discharge after hospitalization for heart failure in two time periods: 4/1998–3/1999 (before RALES) and 7/2000–6/2001 (after RALES, n=9,468). We assessed changes in rates of spironolactone prescription at discharge between periods in all patients and in strata according to potassium and creatinine levels.

Results: Spironolactone prescriptions increased more than seven-fold between the two samples (Table). Although prescription rates were higher in patients with creatinine >2.5 mg/dL, proportions of patients receiving spironolactone increased significantly in both creatinine strata. Rates were similar in patients with normal potassium and those with relative hyperkalemia.

Conclusions: Spironolactone use nationwide increased markedly after the publication of the RALES trial among older patients hospitalized with heart failure and LVDSD. This use, however, has extended to patients who are at high risk for adverse outcomes. Current patterns of practice may pose hazards to the safety of some patients.

<table>
<thead>
<tr>
<th>Rate before RALES (%)</th>
<th>Rate after RALES (%)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>3.0% (9,758)</td>
<td></td>
</tr>
<tr>
<td>Creatinine &lt;2.5 mg/dL</td>
<td>3.1% (8,933)</td>
<td></td>
</tr>
<tr>
<td>Creatinine ≥2.5 mg/dL</td>
<td>1.9% (825)</td>
<td></td>
</tr>
<tr>
<td>K+&lt;5.0 mmol/dL</td>
<td>3.0% (9,267)</td>
<td></td>
</tr>
<tr>
<td>K+≥5.0 mmol/dL</td>
<td>2.7% (491)</td>
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</tbody>
</table>

10:45 a.m.

838-2 Rofecoxib Increases Cardiovascular Events in Arthritis Patients but Celecoxib and Nonspecific Nonsteroidal Anti-Inflammatory Drugs Do Not: Results From A Large New England Health Care Claims Database

Andrew Whelton, William M. Spalding, William B. White, Matthew J. Reeves, Sandy S. Suh, John G. Fort, Universal Clinical Research Center Inc, Hunt, MD

Background: Treatment with cyclooxygenase-2 (COX-2) specific inhibitors may lead to adverse cardiovascular (CV) events.

Objective: Determine relative risk (RR) of acute MI (AMI) or stroke associated with the COX-2 specific inhibitors celecoxib and rofecoxib, and nonspecific NSAIDs in treated hypertensive patients with osteoarthritis (OA) and/or rheumatoid arthritis (RA) in a large New England healthcare claims database.

Methods: Population based retrospective analysis of >3 million patients aged ≥18 years enrolled in a private medical insurance plan in the New England region of the US, from January 1, 1999 - June 30, 2001. Enrollment, medical claims data and pharmacy claim records were computer linked. NSAID and COX-2 specific users were identified using NDC codes. Outcomes of interest were identified by ICD-9-CM codes 410-414 (AMI) or 430-436 (stroke). Sub-group analysis included prostaglandin-mediated antiplatelets (ACEI, ARB, β-blocker).

Results: The incidence of CV events was estimated using Cox proportional hazard time-to-event models adjusted for CV risk factors.

Results: RR for CV events with rofecoxib vs nonsusers of NSAIDs was 2.45. No differences in RR were noted for celecoxib vs NSAIDs (p = 0.40) or nonsusers (p = 0.06) and NSAIDs vs non-users (p = 0.59).

11:15 a.m.

838-4 National Evaluation of Long-Term Adherence to Beta-Blocker Therapy After Acute Myocardial Infarction in Patients With Commercial Health Insurance

Judith M. Kramer, Donald Fetterolf, John P. Charde, Richard Snyder, Daniel Checkman, Elizabeth DeLong, Nancy Allen LaPointe, Barbara Hoffman, Rhonda L. Arrington, Eric Peterson, Duke Clinical Research Institute, Durham, NC

Background: Despite a Class IA guideline recommendation for chronic use of beta-blockers after acute myocardial infarction (MI), few studies have evaluated long-term adherence to beta-blocker therapy after MI in a population with commercial insurance.

Methods: Using pharmacy claims data, nine health plans that are members of the Council for Affordable Quality Healthcare (CAQH) performed a retrospective analysis of one-year survivors of MI to measure cumulative population adherence to beta-blockers for 3, 6, 9, and 12 months after MI. Patients with MI in year 2000 were identified; beta-blocker claims were determined for the subsequent 12 months. Health plans used common tech-