Update in Pharmacotherapy:

A Patient-Centered Approach to Pharmacotherapy

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Disclosures:

- Dr. Anderson has nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation

Learning Objectives

- Review and analyze recent topics and literature updates regarding pharmacotherapy relevant to diabetes mellitus, heart disease, and stroke prevention

- Discuss the benefits of patient-centered, patient-specific pharmacotherapy and how to integrate this principle into clinical practice

Session Outline

I. Recent FDA Actions
II. What are REMS?
III. Recent Topics and Literature Updates
IV. Selected Previous Studies
V. Conclusions
VI. Clinical Application and Integration

Recent FDA Actions

New Drug Approvals

- Bydureon® (exenatide)
- Tradjenta® (linagliptin)
- Juvisync® (sitagliptin/simvastatin)
- Jentadueto® (linagliptin/metformin)

DRUG DENIALS:

- Dapaglifozin

Indication/Labeling Changes

- Byetta® (exenatide)
- Cycloset® (bromocriptine)
- STATINs
- Thiazolidinediones (TZDs)
  - Actos® (Pioglitazone)
  - Avandia® (Rosiglitazone)

Simvastatin Restrictions

- Simvastatin 80 mg restricted to only those patients that have been on therapy for greater than 12 months
- Dose should not exceed 10 mg/day:
  - Diltiazem
  - Verapamil
- Dose should not exceed 20 mg/day:
  - Amiodarone
  - Amlodipine
  - Ftanolazine

What are REMS?

Risk Evaluation and Mitigation Strategies (REMS)

REMS: Overview

- Strategies ordered by the FDA to ensure that the benefits of particular drugs continue to outweigh their risks
- Three components of REMS:
  1. Medication guide or package insert
  2. Communication plan for healthcare providers
  3. Elements to assure safe use (ETASU)
     - Obtain/Dispense drugs through specific distribution channels
     - Enroll patients in registry programs
  - A particular drug's REMS program might not require all three components

Implications of REMS

- Providers may be required to possess specific training, education, experience, or certification(s) in order to prescribe these drugs
- Patients may be required to enroll in registry programs, maintain tight follow-up, and order their medications through the manufacturer or specialty pharmacies

Drugs That Require REMS

- Thiazolidinediones (TZDs)
  - Avandia® – Medication guide, communication plan, ETASU
  - Actos® – Medication guide
- Bisphosphonates (e.g., Fosamax® and Actonel®)
  - Medication guide
- Chantix®
  - Medication guide
- Narcotics (e.g., OxyContin® and Fentanyl®)
  - Medication guide
- Antidepressants (e.g., Lexapro® and Effexor®)
  - Medication guide

Recent Topics and Literature Updates

CDC Recommendations

- U.S. adults with diabetes roughly have a twofold increased risk for hepatitis B infection
- Hepatitis B vaccination should be routinely given to previously unvaccinated adults with diabetes who are younger than 60 years of age

Abbreviation(s):
CDC = Centers for Disease Control and Prevention

Diabetes and Heart Disease

- Frequent counseling helps diabetic patients reach goals faster
  - A study featuring close to 31,000 primary care patients followed for a minimum of 2 years
  - Patients who received monthly lifestyle counseling and sought a goal A1C < 7.0% expended a median 3.5 months of effort vs. 22.7 months for patients whose counseling occurred less than every 6 months
    - Blood pressure <130/86 mmHg: 3.7 weeks vs. 5.6 months
    - LDL cholesterol < 100 mg/dL: 3.5 months vs. 24.7 months

Diabetes and Heart Disease

- ALTITUDE Study
  - Aliskiren (Tekturna®) plus ACE-inhibitor vs. ACE-inhibitor monotherapy in patients with type 2 diabetes and renal impairment
  - The data safety and monitoring board (DSMB) noted an increased incidence of:
    - Nonfatal stroke
    - Renal complications
    - Hyperkalemia
    - Hypotension
  - Due to this increase in adverse events and no apparent benefits, the DSMB recommended terminating the study early

Stroke Prevention

- AIM-HIGH Study
  - High-dose extended-release Niacin (Niaspan®) plus statin therapy vs. statin monotherapy in patients with a history of cardiovascular (CV) disease, elevated triglycerides, low HDL cholesterol, and at goal LDL cholesterol
  - Study was halted 18 months early
  - Niacin offered no additional benefit
  - There was also a small, unexplained increase in ischemic stroke in the niacin group

Selected Previous Studies

Diabetes and Heart Disease

- ACCOMPLISH Study
  - ACE-inhibitor (benazepril) plus calcium-channel blocker (amlodipine) vs. benazepril plus thiazide diuretic (hydrochlorothiazide)
  - Study was halted early
  - Both treatment arms provided similar blood pressure reduction
  - Benazepril plus amlodipine reduced CV morbidity and mortality by 20% compared to those treated with benazepril plus hydrochlorothiazide
    - CV death, fatal/nonfatal MI, fatal/nonfatal stroke, hospitalization for unstable angina, and coronary revascularization

Diabetes and Heart Disease

- Intensive vs. standard glycemic control
  - Intensive: 6.4% (both ACCORD and ADVANCE)
  - Standard: 7.5% (ACCORD) and 7.0% (ADVANCE)
  - Intensive glycemic control is associated with decreased risk for microvascular complications
  - Intensive glycemic control is associated with increased risk of mortality in patients with significant history of CV disease

Summary of Conclusions

Conclusions

- Individual studies should not undermine the importance of meeting the current guidelines for disease management and care

- However, meeting the current guidelines for disease management and care should not undermine and outweigh the importance of delivering evidence-based, individualized patient-centered healthcare

QUESTIONS?

Clinical Application and Integration

References