Drug Monitor

Anticoagulation Safe for Some Elders, Not Others

Guidelines issued by the American College of Chest Physicians recommend anticoagulation therapy with warfarin in patients aged 75 or older who have atrial fibrillation (AF). But as many as half of those who are older and could benefit from warfarin therapy might not be getting the anticoagulation they need to prevent stroke. Researchers from Montefiore Medical Center, Bronx, NY; New York Institute of Technology, New York; and ReGenesis Community Health Center, Spartanburg, SC say this low rate could be due to clinicians' perceptions about bleeding risk, falls, and the need for frequent monitoring and dosage adjustment.

The researchers conducted a retrospective study to determine how warfarin and acetylsalicylic acid (ASA) are being prescribed for patients at risk for stroke and hemorrhage, including those who have a history of falls or dementia. They identified 106 patients from an urban geriatrics practice who were aged 65 or older, had been diagnosed with AF at least three months prior to the study's start, and were taking warfarin or ASA. They then analyzed a year's worth of data to determine the stroke, hemorrhage, and death rates in this population and to assess the impact of risk factors—such as a history of falls or dementia—on these outcomes.

At 12 months, two of the 90 patients taking warfarin had experienced a stroke; five had experienced a major hemorrhage, and 18 had died. Five (45%) of 11 patients with a history of falls and eight (47%) of 17 patients who had dementia had died, compared with eight (12%) of 65 patients who had no history of falls or dementia. The researchers say it was unclear whether the higher mortality among warfarin-treated patients with falls was due to risk factors underlying a propensity to fall, to AF, or to warfarin use. Because only 16 patients were taking ASA, the power was not great enough to detect treatment differences. The data, the researchers say, support careful screening for falls in older adults as part of decision making about anticoagulant treatment.

They note that, because this was a single-site study, the enhanced coordination of care and monitoring of patients might have limited the variability in international normalized ratio that can result from polypharmacy, drug interactions, and confusion regarding dose alterations. Ultimately, the researchers say, the debate comes down to quality of life versus reducing stroke and hemorrhage risks.

Source: *Am J Geriatr Pharmacother.* 2009;7(3):159–166. doi:10.1016/j.amjopharm.2009.06.002.

New Atypical Antipsychotic for Schizophrenia and Bipolar Disorder

The FDA has approved the atypical antipsychotic asenapine (Saphris, Schering-Plough, Kenilworth, NJ), in sublingual tablet form, to treat schizophrenia and bipolar I disorder. In three short-term clinical trials, asenapine was more effective than placebo in reducing the symptoms of schizophrenia. Two short-term studies compared asenapine with placebo in treating bipolar disorder, and again asenapine was superior to placebo.

Additionally, results of a long-term, Phase III, double-blind, randomized withdrawal design trial comparing asenapine 5 or 10 mg twice per day with placebo for schizophrenia relapse prevention indicated that 12% of patients taking asenapine, versus 47% of patients taking placebo, experienced a relapse of their disease within one year. These results, which were presented in September at the annual congress of the European College of Neuropsychopharmacology in Istanbul, Turkey, also indicated that the drug was well tolerated. The time to treatment discontinuation was significantly longer in patients taking asenapine than in those taking placebo. The most common adverse reactions reported were increased weight, anxiety, and insomnia—the latter two of which were experienced more often by patients taking placebo.

The most commonly reported adverse reactions in the short-term schizophrenia trials were akathisia, oral hypoesthesia, and drowsiness. In the bipolar trials, the most commonly reported adverse reactions were drowsiness, dizziness, movement disorders (other than akathisia), and weight gain.

Like other atypical antipsychotics, asenapine is not approved for use in older patients with dementia-related psychosis.

Sources: FDA press release. August 14, 2009.

Medical News Today news release. September 18, 2009.

Schering-Plough news release. September 14, 2009.