

Guidelines Spell Out Prophylactic Aspirin Use

BY MICHELE G. SULLIVAN

The U.S. Preventive Services Task Force has released the first gender- and age-specific recommendations for aspirin therapy in patients at risk of cardiovascular disease.

Drawing on data from recent studies, the new recommendations conclude that aspirin therapy reduces the risk of heart attack and ischemic stroke in appropriate male candidates, and cuts the risk of ischemic stroke in female candidates. Both groups are at risk of gastrointestinal bleeding.

Daily aspirin therapy therefore should be encouraged in women aged 55-79 years and men aged 45-79 years who have few risks of aspirin-related adverse events and who have potentially large benefits in terms of their respective risk reduction (*Ann. Intern. Med.* 2009; 150:396-410).

The guidelines are the first update to government released recommendations on the topic since 2002.

Seven years ago, "we did not have enough data available to come up with more specific recommendations based on gender," commented Dr. Michael LeFevre, a member of the task force that wrote the document.

"It was really the Women's Health Study that, when added to other studies, resulted in this very clear distinction in the benefits of aspirin in men and women," he said.

That study evaluated the risks and benefits of aspirin in the primary prevention of heart disease in almost 40,000 women. It reported a 23% reduction in the risk of ischemic stroke with aspirin use, but no significant benefit for heart attack.

Dr. LeFevre, of the University of Missouri, Columbia, said that the new recommendation is based on an individual risk assessment rather than being an "overarching policy that makes a blanket recommendation."

The message of individualized risk assessment "is one of the most important pieces of the guidelines," Dr. LeFevre said in an interview.

"Physicians should look at the risks and potential benefits of aspirin therapy for each individual patient, and recommend it only when the benefit of disease prevention clearly exceeds the risk of adverse effects," he added.

For men, recognized 10-year coronary heart disease risk factors include age, total and HDL cholesterol levels, blood pressure, and the presence of diabetes and smoking.

Similarly, 10-year stroke risk in women is estimated on the basis of age and the presence of hypertension, diabetes, smoking, history of cardiovascular disease, atrial fibrillation, or left ventricular hypertrophy.

Men and women older than 80 years should receive careful consideration, according to the guidelines. Although the incidence of heart attack and stroke is high in this population, so is the risk of

gastrointestinal bleeding. "The net benefit of aspirin use in [these patients] is probably best in those without risk factors for gastrointestinal bleeding (those with normal hemoglobin levels, good kidney function, and easy access to emergency care)."

The risk-benefit ratio should be reassessed every 5 years. The document recommends a daily aspirin dosage of 75 mg.

The USPSTF recommendations differ from those offered by academic societies, including the American College of Cardiology and the American Heart Association, Dr. Christine Laine said in an interview.

Such groups recommend daily aspirin therapy in patients with a high risk of cardiovascular disease or a history of heart attack, but offer no age- or gender-specific recommendations.

"It's not a sea change from the previous guidelines, but it does take advantage of these newer studies to make more definite recommendations, and helps move the decision making from less certain to more certain," Dr. Laine commented in the interview. She is the senior deputy editor of the *Annals of Internal Medicine* and a general internist at Jefferson Medical College in Philadelphia. ■



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Important Safety Information

Humalog differs from regular human insulin by its rapid onset of action as well as a shorter duration of action. Therefore, when used as a mealtime insulin, Humalog should be given within 15 minutes before or immediately after a meal. Due to the short duration of action of Humalog, patients with type 1 diabetes also require a longer-acting insulin to maintain glucose control (except when using an insulin pump). Glucose monitoring is recommended for all patients with diabetes.

The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. There are no adequate and well-controlled clinical studies of the use of Humalog in pregnant or nursing women.

Starting or changing insulin therapy should be done cautiously and only under medical supervision.

Humalog is contraindicated during episodes of hypoglycemia and in patients sensitive to Humalog or one of its excipients.

Hypoglycemia

Hypoglycemia is the most common adverse effect associated with insulins, including Humalog. Hypoglycemia can happen suddenly, and symptoms may be different for each person and may change from time to time. Severe hypoglycemia can cause seizures and may be life-threatening.

Other Side Effects

Other potential side effects associated with the use of insulins include: hypokalemia, weight gain, lipodystrophy, and hypersensitivity. Systemic allergy is less common, but may be life-threatening. Because of the difference in action of Humalog, care should be taken in patients in whom hypoglycemia or hypokalemia may be clinically relevant (eg, those who are fasting, have autonomic neuropathy or renal impairment, are using potassium-lowering drugs, or taking drugs sensitive to serum potassium level).

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