

HEART OF THE MATTER

Electrical Ablation and Atrial Fib

In 1949, Sir Henry Cohen, Lord of Birkenhead, delivered an address to the Royal College of Surgeons in London on the surgical approaches to hypoglycemia and hyperinsulinism. In that address, while discussing the advisability of total pancreatectomy for the treatment of these disorders, the chair of medicine at the University of Liverpool stated, "the feasibility of an operation is not the best indication for its performance."

While advice like that could be applied to many clinical initiatives that have been carried out in the last half century, a recent American College

of Cardiology meeting presentation on the ablation of electrical pathways in the left atrium to prevent atrial fibrillation brought this quote to mind. Although ablation therapy is a long way from becoming a certainty, the attempts to prevent atrial fibrillation with this technique are currently quite the rage among electrophysiologists.

The trench warfare being carried out in the left atrium as we attempt to prevent atrial fibrillation has captured the imagination of the electrophysiology community. It is proposed

that the scarred and "debulked" left atrium will be more likely to maintain normal sinus rhythm and will be a less fertile ground for thrombi formation. Whether either of these proposals can be proved remains to be seen.

Atrial fibrillation has become a clinical problem of increasing importance as our population ages. The risks associated with atrial fibrillation lie primarily as a source of systemic emboli, particularly to the brain. Although some patients may experience cardiac symptoms as a result of chronic atrial fibrillation, most patients tolerate it very well.

The Atrial Fibrillation Follow-Up Investigation of Rhythm Management (AFFIRM) study clearly showed that there was little to be gained in regard to morbidity and mortality with the establishment of normal sinus rhythm using antiarrhythmic drugs. The major test of efficacy of therapy in atrial fibrillation is the prevention of stroke.

Many patients are driven to ablation therapy to escape the requirement of long-term anticoagulant therapy with warfarin. Although this is a burden, and is associated to some degree with

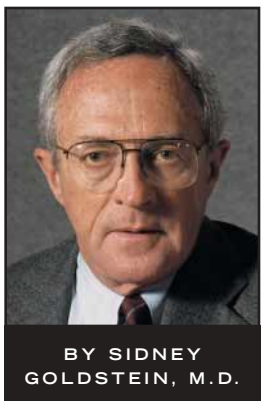
adverse bleeding, help is on the way.

It is likely that in the next few years that advances in pharmacogenetics of warfarin therapy will provide better insight into which patients will benefit from this treatment. In addition, there is likelihood that oral direct thrombin and factor Xa inhibitors will become available and should make anticoagulant therapy more manageable and safer. It also is important to emphasize that ablation therapy may not exclude the left atrium as a source of cerebral embolism.

It is reasonable to continue research in the ablation in patients who are truly symptomatic as a result of chronic atrial fibrillation. However, we should be cautious in offering ablation therapy as an alternative to warfarin anticoagulation at this time.

We are long way from presuming that this form of therapy will give long-term prevention of atrial fibrillation, and even if it does, the risks of stroke may well persist as a result of the of the scarring of the left atrium that occurs with the therapy. ■

DR. GOLDSTEIN, *medical editor of CARDIOLOGY NEWS, is professor of medicine at Wayne State University and division head, emeritus, of cardiovascular medicine at Henry Ford Hospital, Detroit.*



BY SIDNEY GOLDSTEIN, M.D.

Pravachol Generic Approved by FDA

The first generic version of pravastatin was approved by the Food and Drug Administration in April.

Pravastatin is indicated for treatment of individuals with hyperlipidemia or for patients who are at elevated risk for atherosclerosis-related cardiovascular adverse events in which high cholesterol levels are a factor.

Pravastatin was the third highest-selling statin in the United States in 2005, with sales totalling \$1.7 billion, according to IMS Health, a pharmaceutical consulting firm.

Bristol-Myers Squibb's patent for the drug, marketed as Pravachol, expired on April 20, and 180-day exclusivity was granted to Teva Pharmaceutical Industries Ltd., one of the world's largest generic pharmaceutical companies, for the marketing of generic pravastatin tablets in 10-, 20-, and 40-mg quantities.

Shipment of these products will begin immediately, according to the company. In fact, the tablets were found available in May at a Rockville, Md., pharmacy, priced 20% below Pravachol.

"This approval is another example of our agency's endeavor to counter rising health care costs by approving safe and effective generic alternatives as soon as the law permits," Dr. Scott Gottlieb, FDA deputy commissioner for medical and scientific affairs, said in a statement.

"Pravastatin is a widely used cholesterol-lowering agent, and its generic version can bring significant savings to millions of Americans," Dr. Gottlieb added.

—Mark S. Lesney

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