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HEART OF THE MATTER

Obsessing on Atrial Fib

SIDNEY

the recent Registry on Cardiac Rhythm Disorders Assessing the Control of Atrial Fibrillation (RECORD AF) provides further data to belie our obsession with obtaining or maintaining normal sinus rhythm in patients with intermittent or paroxysmal AF (J. Am. Coll. Cardiol. 2011;58:493-501).

Registry studies fail to provide the randomized data that we demand in control trials, but can often yield data

about real-world therapy. This registry, which included 5,604 patients from around the world and whose authors were either consultants or employees of Sanofi-Aventis, the makers of dronedarone, confirms much of what has already been said on the issue. There is little or no benefit associated with the rhythm control therapy compared to a heart rate strategy when examined in this communitybased unselected population.

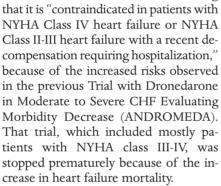
Because patients in this study were not randomized to a particular therapy, participating doctors could use either strategy. Unfortunately, patients in the rate control arm were older and more often had AE heart failure, and valvular heart disease at baseline. Despite this imbalance, the heart rate strategy was as good as rhythm control. Both groups experienced an 18% incidence of adverse clinical events that were determined by the clinical characteristics of the patient and not the therapeutic strategy used or heart rate achieved. Success was measured by the presence of normal sinus rhythm in the rhythm-controlled patients or a heart rate of less than 80 bpm in the rate-controlled patients at 1 year follow-up, which was achieved in 60% and 47%, respectively. If the heart rate target was below 85 bpm, the success was achieved in 60% vs. 52%, respectively. These observations are consistent with previous studies comparing rhythm and rate control strategies.

This obsession with the maintenance of normal sinus rhythm in patients with AF has spawned a whole industry associated with the technology and application of catheter ablation, atrial defibrillation, left atrial occlusive devices, and the continued development of anti-arrhythmic drugs. All of these interventions have achieved some success but have been associated with significant drug and device adverse events.

The most recently approved anti-arrhythmic drug, dronedarone (Multaq), has been extensively studied in AF. Three major clinical trials have examined the drug in paroxysmal, persistent, and permanent AF. The most recent trial, Permanent Atrial Fibrillation Outcome Study Using Dronedarone (PALLAS), compared dronedarone to placebo in 3,000 patients with permanent AF and who also had a number of comorbidities, including symptomatic heart failure and a decrease in ejection fraction, but excluded New York Heart Association class III heart failure. Only an electrophysiologist is able to make the distinction between these two clinical heart failure settings. The study was prematurely stopped because of a significant increase in cardiovascular events, including mortality (CARDIOLOGY NEWS, August 2011, p. 5).

Dronedarone was approved in 2009 for patients with paroxysmal and persis-

> tent AF and atrial flutter by the Food and Drug Administration based on the ATHENA trial, which reported a decrease in recurrent AF in patients treated with the drug. In addition, dronedarone decreased the combined cardiovascular end point of mortality and rehospitalization, achieved mostly by a decrease in rehospitalization. However, its approval included a boxed warning



Dr. Stuart Connolly, the co-primary investigator of PALLAS, emphasized the difference between ATHENA, which randomized patients with nonpermanent AF, and PALLAS, which randomized patients with permanent AF. He thought that it was "reasonable" for patients with nonpermanent AF to continue with dronedarone, because "they will still benefit from it in terms of reduced CV hospitalization."

Although there are surely some patients in whom AF causes significant symptoms that warrant aggressive therapy, the vast majority of patients, as indicated in RECORD AF, tolerate AF quite well. Much of the quest for rhythm control is related to the need to prevent systemic emboli and the requirement for anticoagulation therapy using vitamin K derivatives. The development of new antithrombotic drugs and factor Xa inhibitors now provides a safer and more effective alternative. It is time to relax our obsessive approach to atrial fibrillation therapy and become more realistic about our long-term goals for its therapy.

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