# Trial Nixes ARBs for Atrial Fibrillation

## *Stand-alone angiotensin inhibitor treatment did not curb fibrillations over a 1-year period.*

BY BRUCE JANCIN

FROM THE ANNUAL CONGRESS OF THE EUROPEAN SOCIETY OF CARDIOLOGY

STOCKHOLM – Stand-alone angiotensin II receptor blocker therapy proved of no benefit in preventing recurrences of paroxysmal atrial fibrillation in patients without structural heart disease in a large German randomized double-blind trial.

"ARB therapy may not be recommended as first-line treatment for paroxysmal atrial fibrillation if not indicated for other reasons," Dr. Andreas Goette concluded, in presenting the results of the ANTIPAF trial at the congress.

**Analysis of nearly 88,000 tele-ECGs showed that olmesartan had no impact on total atrial fibrillation burden.**

DR. GOETTE

The ANTIPAF (Angiotensin II Antagonist in Paroxysmal Atrial Fibrillation) trial involved a total of 425 patients at 37 participating German centers.

All participants had documented paroxysmal atrial fibrillation (PAF) and no or minimal structural heart disease. They were randomized in double-blind fashion to receive olmesartan at 40 mg/day or placebo and followed for 12 months, during which they were not permitted to be on concomitant antiarrhythmic agents, other ARBs, or ACE inhibitors. If they were on a beta-blocker before enrollment, they could stay on it, but starting a beta-blocker after randomization was not allowed.

The primary study end point was total atrial fibrillation burden during 1 year of follow-up, as assessed using a novel tele-ECG technology employed on a daily basis.

Based on an analysis of nearly 88,000 tele-ECGs, it was clear that olmesartan had no impact on total atrial fibrillation burden. Patients on olmesartan had a mean 0.151% of days of atrial fibrillation during follow-up, while those on placebo had 0.147%, reported Dr. Goette of St. Vincenz Hospital in Paderborn, Germany.

The two groups did not differ in terms of numerous prespecified secondary end points either, including time to first recurrence of atrial fibrillation, quality of life measures, time to development of persistent atrial fibrillation, and number of hospitalizations.

Atrial fibrillation affects roughly 4% of people in their 60s and up to 20% of those in their 80s. Good-quality animal and cellular data suggest angiotensin II is a major player in atrial fibrillation, figuring prominently in the vicious cycle in which atrial fibrillation begets more frequent and severe atrial fibrillation by promoting atrial remodeling and left ventricular dysfunction, and vice versa.

"From experimental work, it appears very appealing to inhibit the action of angiotensin II to treat atrial fibrillation," the cardiologist observed.

Early clinical trials suggested that PAF could be suppressed by ARB therapy, particularly when combined with an antiarrhythmic agent. These studies, however, had various weaknesses that left open the question of whether stand-alone ARB therapy is effective in PAF. This was the question the ANTIPAF trial was designed to address.

Dr. Goette said that he sees the tele-ECG monitoring as one of the trial's unique strengths. Patients carried the credit card–sized tele-ECG device around with them during the day and were asked to press a button and hold it to their chest to record an ECG at least once daily. They phoned in the data for storage and analysis.

Unlike Dr. Goette, however, discussant Dr. A. John Camm took a dim view of the tele-ECG–based primary end point.

"The intermittent and noncontinuous monitoring of the heart rhythm is important. Although we heard of the tens of thousands of ECGs that were involved, there are on the order of a thousandfold that number of heart beats, and continuous monitoring might have been much better," said Dr. Camm of St. George's University of London.

He also took issue with the duration of follow-up in ANTIPAF: "The length of the follow-up is intermediate. For an effect to reverse fibrosis we might need far longer than 1 year."

Although there are reasonably persuasive clinical trials data indicating ARBs are effective for the primary prevention of atrial fibrillation, ANTIPAF joins several earlier studies in failing to show any benefit for various ARBs in preventing recurrences of PAF, Dr. Camm said.

The ANTIPAF trial was funded by the German Ministry of Research and Education and carried out by the German Competence Network on Atrial Fibrillation.

Dr. Goette said he had no financial conflicts. ■

# *'Stars' of CABG Featured on Consumer Reports Web Site*

BY MITCHEL L. ZOLER

A star-based system for rating the performance of more than 200 U.S. thoracic surgery programs doing isolated coronary artery bypass surgery went live on the Consumer Reports Health Web site on Sept. 7, using data collected and analyzed by the Society of Thoracic Surgeons.

On a subscription-only site, Consumer Reports Health lists the names, locations, and a one- to three-star rating for 221 U.S. cardiothoracic surgery practices that perform coronary artery bypass grafting (CABG), participate in the Society of Thoracic Surgeons (STS) database, and agreed to have their rating released to the public. About 90% of the more than 1,000 U.S. thoracic surgery practices that perform CABG participate in the STS database.

The 221 listed practices included 50 with a three-star rating (defined as above-average performance on several process and outcomes measures); 166 with a two-star (average) rating; and 5 with a one-star (a below-average performance) rating. The October issue of Consumer Reports also published the names and locations of the 50 three-star practices.

The launch of this ranking of CABG programs culminates an effort begun by STS officials in early 2009, when they approached the Consumers Union, publisher of Consumer Reports Health, to map out a strategy to create the listing. The STS promoted the program during its annual meeting in January, aiming to list more than 300 practices. The 221 initial participants – fewer than a quarter of the U.S. programs offering CABG – falls short of that number and notably runs short on one-star (below average) programs.

The STS members who developed the data assessment methodology used an approach that produced roughly equal numbers of high and low outliers, the above- and below-average subgroups. The current analysis designated about 10%-15% of the CABG programs as above average, and a similar percentage as below average, with roughly three-quarters tagged as two stars (average), said Dr. David M. Shahian, professor of surgery at Harvard Medical School, Boston, and chairman of the society's national database workforce. Now that the inaugural report is out, several practices not yet involved will feel "pressure to participate" from both patients and payers, and will sign on to be part of next year's list, Dr. Shahian said in an interview.

"I think it's pretty remarkable" that 22% were willing to participate in the initial listing, he said. "I have done several conference calls to answer questions [about the listing], and I did not hear a single comment that this is philosophically wrong." Many programs opted to wait to see how the initial list rolled out, he added.

The methods he and his associates developed to distinguish the three tiers of programs will result in smaller percentages of above- and below-average designations if several low-scoring programs improve. The analysis method has a high level of sensitivity to detect high and low outliers, and high specificity so outlier groups truly deserved their designations. The method has a 99% probability that the three- and one-star programs truly differ from the programs that got two stars.

The list included an overall practice assessment based on four domains of CABG care, and each individual domain received a one- to three-star rating (Ann. Thorac. Surg. 2007;83[suppl. 4]:S3-12).

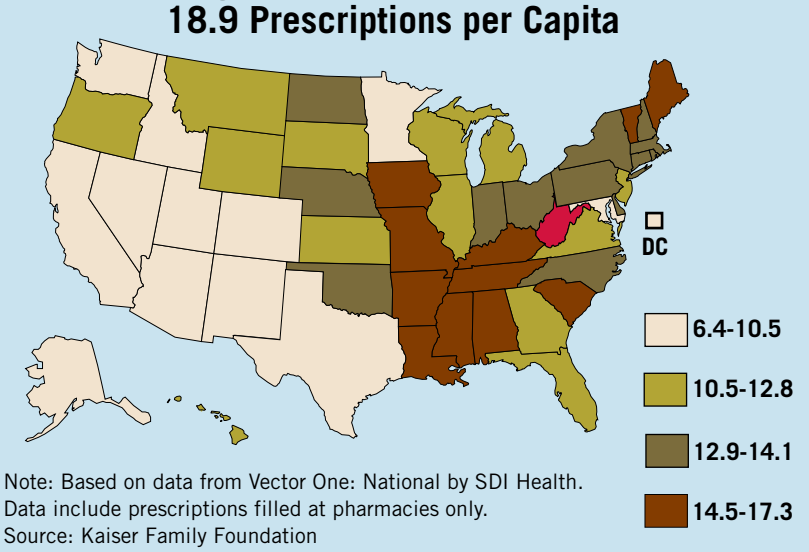
The four domains of care are:

- Operative care focused on whether patients received at least one internal mammary-artery graft.
- Risk-adjusted operative mortality.
- Perioperative medical care focused on preoperative beta-blocker use and on discharge prescribing of aspirin, a beta-blocker, and a lipid-lowering regimen.
- Postoperative morbidity, including renal insufficiency, deep sternal wound infection, and reexploration for any cause, as well as stroke or prolonged ventilation.

Dr. Shahian said he had no conflicts of interest to disclose. ■

DATA WATCH

**West Virginia Led the U.S. in 2009 With 18.9 Prescriptions per Capita**




Note: Based on data from Vector One: National by SDI Health.
Data include prescriptions filled at pharmacies only.
Source: Kaiser Family Foundation

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