NSAIDs Ineffective for Postop Pericardial Effusion

BY BRUCE JANCIN

ORLANDO — Diclofenac, widely prescribed to reduce pericardial effusion volume and prevent tamponade following cardiac surgery, proved ineffective in a double-blind randomized trial.

"NSAID administration seems to be useless in this setting," said Dr. Philippe Meurin, who presented the findings of the Nonsteroidal Anti-Inflammatory Treatment for Postoperative Pericardial Effusion (POPE) study at the annual scientific sessions of the American Heart Association.

The use of NSAIDs to treat postoperative persistent pericardial effusions is "an old habit" never previously examined in a clinical trial, he said. It's a popular practice: Studies indicate NSAIDs

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are prescribed in one-half to three-quarters of patients with persistent moderate to large pericardial effusions, according to Dr. Meurin of the Cardiac Rehabilitation Center, Villeneuve Saint Denis, France.

Yet there are safety concerns. NSAID therapy is associated with up to a twofold increased risk of MI, a threefold increase in renal failure, and a fourfold greater risk of GI bleeding. The risk of renal failure climbs to sixfold with concomitant ACE inhibitor therapy, and the GI bleeding risk jumps to eightfold with concomitant low-dose aspirin, he added.

POPE was a multicenter study involving 196 patients with grade 2 or greater pericardial effusion on day 15 after cardiac surgery who were randomized in a double-blind fashion to 2 weeks of diclofenac at 50 mg b.i.d. or placebo. Grade 2 is a loculated pericardial effusion of at least 10-14 mm or a circumferential one of up to 9 mm on echocardiography.

Patients with at least a grade 2 pericardial effusion constituted 3.6% of the more than 5,000 cardiac surgery patients who underwent postoperative screening echocardiography, underscoring that this potentially serious complication is uncommon.

The primary study end point was change in mean effusion grade based on fluid volume assessed echocardiographically after 2 weeks of therapy. The diclofenac group had a mean 1.36-grade decrease, not significantly different from the 1.08-grade drop in controls.

Late tamponade requiring pericardial drainage occurred in 11.2% of the placebo group, similar to the 9.2% rate in the NSAID group.

Discussant Dr. Elliott M. Antman expressed "a mixture of disappointment and relief" at the POPE results.

He felt disappointment because persistent pericardial effusion is a potentially serious problem for which it appears there is as yet no good therapy, he said. By the time it converts into tamponade—as occurred at a 10% rate in POPE—the patient has typically been discharged from the hospital, making prompt detection of this life-threatening condition problematic.

Dr. Antman said he felt relief because if POPE had shown efficacy for diclofenac it would have created a problem in light of the American Heart Association's March 2007 scientific statement advising physicians that NSAIDs are not recommended in patients who have ischemic heart disease or are at risk for it.

Diclofenac is a cyclooxygenase-2–selective NSAID and therefore poses a greater cardiovascular risk than do non-COX-2-selective NSAIDs. "It would be on the list of drugs that I'd be a little bit more worried about in a patient who had coronary artery disease," noted Dr. Antman, professor of medicine at Harvard Medical School, Boston.

The POPE study was funded primarily by the French Society of Cardiology. Dr. Meurin reported having no relevant financial relationships. ■