

# Fewer Side Effects With Adenosine Analogue

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CHICAGO — A selective adenosine receptor agonist was as effective as conventional adenosine for cardiac stress imaging and produced fewer adverse events in results from two pivotal, controlled trials with a total of about 800 patients.

Treating patients with binodenoson “provides similar clinical information on the extent and severity of ischemia as adenosine and is associated with a significant reduction in the incidence and intensity of many side effects,” Dr. James E. Udelson said at the annual meeting of the American College of Cardiology. A major



**Binodenoson provides similar clinical information to adenosine, with a significant reduction in many side effects.**

DR. UDELSON

feature of the improved safety profile was that treatment with binodenoson led to no episodes of second- or third-degree atrioventricular block in about 800 treated patients, compared with about a 2% rate of this complication when the same patients were treated with adenosine, reported Dr. Udelson, professor and acting chief of cardiology at Tufts Medical Center in Boston.

Binodenoson is being developed as CorVue by King Pharmaceuticals Inc. Dr. Udelson said that he received research grants and consulting honoraria from the company, as did several of his collaborators.

Results from the two studies reported by Dr. Udelson showed that the diagnostic accuracy of stress perfusion imaging with single-photon emission CT was comparable in binodenoson- and adenosine-treated patients, with binodenoson causing fewer adverse events and having easier, bolus dosing, commented Dr. Jagat Narula, professor and chief of cardiology at the University of California, Irvine. “It will all boil down to dollars. If we can reduce or contain the cost then [binodenoson] will become the preferred agent,” he said.

Dr. Udelson reported data from two separate arms of the Vasodilator Induced Stress in Concordance with Adenosine (VISION) study, conducted at 79 U.S. centers. Both studies enrolled patients aged 30 years or older who were scheduled to undergo pharmacologic stress imaging of their hearts because of typical or atypical angina and suspected ischemia. The study excluded patients with a very low pretest likelihood of disease, a contraindication for adenosine, or severe left-ventricular dysfunction. The two studies enrolled a total of 842 patients, with an average age of 63 years and an average BMI of 31 kg/m<sup>2</sup>. More than 90% of patients underwent imaging because of chest pain.

In both studies, patients were randomized to initial imaging with either binodenoson or adenosine and also received a placebo dose in place of the other agent. Imaging was repeated 2-7 days later with

the same protocol, but the active and placebo agents were reversed. Binodenoson (and its matched placebo) was administered at a dose of 1.5 mcg/kg as a bolus injection that lasted 30 seconds; adenosine (and its matching placebo) was given at a dose of 140 mcg/kg per minute administered as an intravenous infusion for 6 minutes. The imaging aspect of the study was done identically both times each patient was tested.

Efficacy was assessed by comparing

the extent of myocardial ischemia diagnosed by blinded readers using the two stress methods. The study’s prespecified criteria said that the two stress agents would be considered identical in performance if the average summed difference in stress ischemia between the two methods was less than 1.5 U, and if fewer than 10% of all tested patients had highly discordant findings.

The average summed difference in stress scores was 0.09 in one study and 0.68 in

the other, which meant that the results from both trials fulfilled the criterion that the average difference between the summed stress scores was less than 1.5.

The safety analysis showed that binodenoson consistently produced fewer adverse events in both studies. In addition to causing no episodes of atrioventricular block, treatment with binodenoson was associated with significantly fewer and less intense episodes of flushing, chest pain, and dyspnea, Dr. Udelson said. ■

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