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NOVEL AGENT MAKES STRESS TESTING EASIER FOR PATIENTS AND THEIR DOCTORS

New Pharmacologic Stress Drug, Binodenoson, Easier to Use with Fewer Side Effects

CHICAGO, IL –Almost half of the people who need to undergo an exercise stress test to evaluate heart disease are unable to do so because of age or orthopedic issues. But according to a new study being presented today at the American College of Cardiology’s 57th Annual Scientific Session, a new generation of medication can now simulate exercise without the unpleasant side effects caused by similar drugs.

This new kind of agent – the selective adenosine A_{2A} receptor agonist binodenoson – produces the same effect as its predecessors, adenosine or dipyridamole, without causing unpleasant and occasionally dangerous side effects, such as flushing, chest pain, shortness of breath, nausea and atrio-ventricular block, a condition in which the heart slows down alarmingly. Up to 80 percent of people suffer these side effects from adenosine.

Additionally, adenosine is very cumbersome to use, requiring infusion for four to six minutes with an infusion pump to ensure its disbursement at a precise rate. The new agent, binodenoson, offers patients the same stress test effects or “pharmacologic stress” as adenosine, but with fewer side effects.

In two trials done at 90 centers in the United States, a total of 900 patients, referred by their doctors for standard pharmacologic stress testing, underwent two stress tests one week apart -- one with adenosine and one with the new agent, binodenoson.

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The studies were double-blinded -- the patients did not know which drug they were being given, and neither did their doctors. The studies had two aims: first, to determine how effective binodenoson was in detecting patient information about heart disease in comparison with adenosine; and second, to compare the frequency and severity of side effects between the two agents.

Binodenoson was just as effective in revealing the extent and severity of blood flow abnormalities during stress – a measure of the extent of heart disease – as was adenosine. However, it had significantly fewer side effects. Flushing occurred in 50 to 60 percent of patients with adenosine, compared with 30 percent of patients with binodenoson. Chest pain occurred in 60 percent with adenosine versus 38 percent with binodenoson; shortness of breath in 55 percent with adenosine versus 45 percent with binodenoson. There were no reports of atrio-ventricular block with binodenoson, which occurs about 4 percent of the time with adenosine.

When side effects did occur with binodenoson, patients reported that they were much less severe than with adenosine. When patients, still blinded as to study drug, were asked which stress test they preferred, 70 percent said they preferred binodenoson, 20 percent said they preferred adenosine, and 10 percent said they had no preference.

“This was a huge statistical difference, and because the patients did not know which drug they had been given when they responded, it was a very robust result,” said James E. Udelson, M.D., Acting Chief of the Division of Cardiology, Tufts Medical Center, Boston, and lead author of the study. “If and when this drug is approved, it should make a big difference in clinical practice. It can provide the same clinical information about the extent of blockages to the heart with fewer side effects, and is easier to use, since you just inject it over 30 seconds without having to use an infusion pump. This is a significant practice-changing result.”

The American College of Cardiology’s 57th Annual Scientific Session, ACC.08, is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

Dr. Udelson will present this study, “Efficacy and Safety of the Selective Adenosine A2A Receptor Agonist Binodenoson for Pharmacologic Stress: Results of a Phase 3, Randomized, Double-Blind, Risk-Stratified, Active-Controlled, Crossover Trial,” on Monday, March 31 at 1:30p.m in Vista Room S406.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.08 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular

specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.