Niacin does not reduce heart attack, stroke risk in stable CV patients

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In patients whose bad cholesterol is very well-controlled by statins for a long time period, the addition of high-dose, extended release niacin did not reduce the risk of cardiovascular events, including heart attack and stroke.

That is the finding being reported today (Nov. 15) at the American Heart Association annual meeting by the study's co-principal investigator, University at Buffalo professor of medicine William E. Boden, MD; the results are also being published as the lead article in today's New England Journal of Medicine.

Boden was co-principal investigator, along with Jeffrey Probstfield, MD, professor of cardiology and medicine at the University of Washington. Both researchers led the Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglycerides: Impact on Global Health (AIM-HIGH) study.

The trial's purpose was to find out if -- in the setting of well-treated LDL ("bad" cholesterol levels) and low HDL ("good" cholesterol levels)/elevated triglycerides -- there was an incremental benefit of adding extended-release niacin. Unexpectedly, Boden explains, most patients enrolled in the trial met existing guideline recommendations for LDL and non-HDL levels, and therefore would not have been considered candidates for further lipid-modifying therapy.

Many patients with stable heart and vascular disease are still at high risk

for cardiac death, heart attack or stroke even after their LDL cholesterol has reached ideal levels -- between 40 and 80 mg/dL on statin therapy. It is believed that this increased residual risk occurs because they have too little HDL cholesterol along with high levels of triglycerides.

In the AIM-HIGH study, 1,718 patients received a high-dose (1,500 to 2,000 mg per day) of extended-release niacin, while 1,696 patients received a placebo.

After two years, HDL and triglyceride levels improved in the niacin group, with a 25 percent increase in good cholesterol, a 29 percent drop in triglycerides and a further decrease in bad cholesterol of approximately 12 percent. By contrast, in the placebo group, there was minimal change, with a 10 percent increase in good cholesterol and an eight percent drop in triglycerides.

The trial found that adding high-dose, extended-release niacin to statin treatment in these well-controlled patients with heart and cardiovascular disease, who had low HDL did not further reduce the risk of cardiovascular events, including heart attacks and stroke.

Because of the lack of benefit, the National Heart, Lung and Blood Institute, upon the recommendation of its Data Safety Monitoring Committee, decided to stop the trial 18 months before its planned completion.

"If you are a patient with stable cardiovascular disease who has achieved and maintained very low levels of LDL cholesterol on a statin for a long time period, these research findings indicate the addition of high-dose niacin does not improve your risk for future events, and is not needed," explains Boden.

He cautions, however, that these results do not apply to the majority of

patients seen in routine clinical settings, where more than 80 percent are unable to lower their cholesterol levels to the degree seen in AIM-HIGH.

"The AIM-HIGH trial was designed to study extended-release niacin or Niaspan, in a specific, narrowly defined patient population," says Boden. "That is why the results of AIM-HIGH cannot be extrapolated to apply to a broader patient population, especially higher-risk patients admitted for heart attack or acute coronary syndrome, for example, or those whose LDL, or non-HDL levels, are not as well-controlled as those in AIM-HIGH, where prior studies have shown benefit.

"The more relevant observation is that, in this modern era of statin therapy, we've made profound progress in controlling LDL," Boden continues. "However, based on these results, physicians should not assume that boosting HDL levels with Niaspan is without merit."

Provided by University at Buffalo