

Hawthorn Safe but Not Effective in Heart Failure

BY BETSY BATES

Los Angeles Bureau

NEW ORLEANS — Hawthorn extract, a widely used over-the-counter remedy, was found to be safe in heart failure patients in the first large, randomized, placebo-controlled mortality trial involving an herbal compound.

At several time points in the 2-year study, the extract made from the *Crataegus* tree appeared to improve cardiac mortality; however, this was a secondary end point and was not a potent enough indicator to broadly suggest the extract was beneficial over and above standard medications for heart failure, said Dr. Christian J.F. Holubarsch at the annual meeting of the American College of Cardiology.

"Hawthorn extract has been used for centuries in traditional European medicine

death was significantly reduced in patients with LVEF of at least 25%.

Dr. Holubarsch and associates concluded that the herbal extract was "safe and postpones death due to cardiac cause, especially in the subgroup of patients with LVEF greater than or equal to 25%."

This conclusion drew skepticism from the panelists presiding over the late-breaking clinical trials session, who applauded the trial's design but questioned whether any conclusion could be drawn about

mortality in a trial that failed to achieve significance on its primary end point.

"The subgroup analysis should be taken with a large sack of salt," said Dr. Salim Yusuf of Hamilton, Ont. "The safest and the wisest thing is to say that you did a good trial, you have an empiric result. It's safe, but it's not effective," he said.

Such trials are very important in light of how many patients take herbal preparations along with prescribed medications, but their conclusions cannot be extrapolated to other herbal preparations using different concentrations, cautioned Dr. Marc A. Pfeffer of Duke Clinical Research Institute in Durham, N.C.

Dr. Holubarsch agreed, noting that the compound used in the trial uses flowers and leaves of the *Crataegus* tree and is produced at a fixed concentration. Extract potencies can vary depending on where the herb is harvested, which part of the plant is used, and the season in which it is collected. ■



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DR. HOLUBARSCH

for the treatment of heart diseases," said Dr. Holubarsch of Median Kliniken in Bad Krozingen, Germany, at a press conference following his oral presentation.

Today, heart patients in Europe, Asia, and North America buy various concentrations of extracts made from the leaves, flowers, and berries of the tree in the belief that the herb relieves mild cardiac symptoms, yet neither its safety nor its efficacy has been well studied prior to this trial.

A total of 2,681 patients in 156 centers in 13 European countries were enrolled to receive either a placebo or twice-daily pills containing 450 mg of *Crataegus* extract WS 1442, a "moderately high" dose of a 20% concentration marketed in Europe by Schwabe Pharmaceuticals, which sponsored the trial.

Patients were included if they met criteria for New York Heart Association Class II-III heart failure with a reduced (35% or less) left ventricular ejection fraction (LVEF). They were already receiving pharmacologic therapy, which at baseline included diuretics (85%), ACE inhibitors (83%), β -blockers (64%), glycosides (57%), spiro lactone (39%), and nitrates (55%).

The primary end point was a composite of cardiac mortality, nonfatal myocardial infarction, or hospitalization due to progression of heart failure. On this composite measure, "we always saw superiority of *Crataegus* when compared to placebo, but this superiority was not significant through the whole course of the 2-year observational period," Dr. Holubarsch reported.

Over 24 months, 441 of 1,338 patients taking the herbal extract died, compared with 542 of 1,343 patients receiving placebo. However, the differences in deaths at the time points studied—6, 12, 18, and 24 months—were statistically significant only at months 6 and 12.

A subanalysis found that sudden cardiac



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