Triple-Drug Pill Shows Promise to Reduce BP

VITALS

Major Finding: After 12 weeks, 66% of blacks and 72% of nonblacks reached a target BP goal of less than 140/90 mm Hg and 23% of blacks and 29% of nonblacks reached a target of less than 120/80 mm Hg by taking a pill combining three different medications, compared with those who took dual-combination therapies for 12 weeks.

Data Source: A phase III, randomized, parallel-group study of 2,492 adults with moderate to severe hypertension.

Disclosures: The study was funded by Daiichi Sankyo Inc. Dr. Oparil has received research grants from, and served as a speaker or consultant for, multiple pharmaceutical companies, including Daiichi Sankyo.

BY HEIDI SPLETE

FROM THE ANNUAL MEETING OF THE INTERNATIONAL SOCIETY ON HYPERTENSION IN BLACKS

WASHINGTON — A triple-combination pill including 40 mg olmesartan, 10 mg amlodipine, and 25 mg hydrochlorothiazide significantly improved diastolic and systolic blood pressure in black and nonblack adults with moderate to severe hypertension, based on an investigational study.

Dr. Suzanne Oparil of the University of Alabama at Birmingham and her colleagues reviewed data from 2,492 patients in TRINITY, a randomized, phase III, parallel-group study conducted at 317 U.S. and Puerto Rico clinical sites.

The primary measure of effectiveness was a significant reduction in seated diastolic BP after 12 weeks of daily treatment; the secondary measure was a significant reduction in systolic BP over the same period, Dr. Oparil said at the meeting.

Patients were randomized to receive one of four treatment protocols: 40 mg olmesartan, 10 mg amlodipine, and 25 mg hydrochlorothiazide (HCTZ); 40 mg olmesartan and 10 mg amlodipine; 40 mg olmesartan and 25 mg HCTZ; and 10 mg amlodipine and 25 mg HCTZ.

All treatment regimens yielded significant improvements in both systolic and diastolic BP compared with baseline measures. But the triple-drug combination reduced seated diastolic BP by an average of 20.8 mm Hg in black patients and 21.8 mm Hg in nonblack patients, which was significantly greater than the reductions in the three dual-therapy combinations.

The triple-drug combination also significantly reduced systolic BP in blacks and nonblacks, with average reductions of 37.1 mm Hg and 38.9 mm Hg, respectively, both of which were significantly greater than the reductions in each of the three dual-therapy combinations.

In addition, 66% of blacks and 72% of nonblacks with a target BP goal of less than 140/90 mm Hg were able to reach their goal on the triple-combination regimen, as were 23% of blacks and 29% of nonblacks with a target BP goal of less than 120/80 mm Hg. The percentages in the triple-combination group were significantly higher than those in any of the dual-therapy groups.

The researchers excluded pregnant or lactating women and individuals with severe renal insufficiency, uncontrolled diabetes, uncontrolled hypertension, and a history of significant cardiac disease. The baseline demographics were similar across all groups, and the mean age of the patients was 54 years. About 15% of the study population had controlled diabetes, and about 63% were obese.

The incidence of adverse events was similar in all four treatment groups. Adverse events that emerged during treatment in at least 3% of any group included dizziness, headache, peripheral edema, fatigue, and nausea. ■

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Editor's note: *At press time, Daiichi Sankyo announced that the drug combination had received Food and Drug Administration approval for the treatment of uncontrolled hypertension, and that it would be marketed as Tribenzor.*