Aliskiren Dual Therapy Beats Amlodipine for BP

Central systolic BP was reduced by 30 mm Hg in two studies.

BY HEIDI SPLETE

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

CRYSTAL CITY, VA. — Aliskiren in combination with either hydrochlorothiazide or amlodipine reduced central systolic blood pressure significantly more than did amlodipine alone in an African American population, based on data from two studies of several hundred adults.

Findings from previous studies have suggested that cardiovascular morbidity might be more closely associated with central blood pressure than it is with systolic blood pressure, according to Dr. Keith Ferdinand of Emory University in Atlanta, and his colleagues.

Additional studies have shown that central blood pressure tends to be higher in healthy young African American men, compared with that in healthy young white men, the researchers noted in a poster at the meeting.

To compare the effects of a combination aliskiren/hydrochlorothiazide (HCTZ) in African Americans with stage II hypertension, Dr. Ferdinand and his colleagues reviewed a subset of patients from two safety and efficacy studies of aliskiren/HCTZ.

Overall, central systolic blood pressure was reduced by approximately 30 mm Hg from baseline in each study, the researchers said, which suggests that aliskiren combined with either a diuretic or calcium channel blocker might be equally effective in African American patients.

VITALS

Major Finding: In study 2, the mean reduction in the central measure of systolic blood pressure was significantly greater in the aliskiren/amlodipine group, compared with the amlodipine-only group after 8 weeks of treatment (29.8 mm Hg and 24.2 mm Hg, respectively).

Data Source: A subset of patients totaling 775 from two safety and efficacy studies of aliskiren/hydrochlorothiazide.

Disclosures: Novartis Pharmaceuticals supported the study. Dr. Ferdinand had no financial conflicts to disclose, but one of the study coauthors is an employee of Novartis Pharmaceuticals.

In study 1, which included 53 sites throughout the United States, 166 patients were randomized to 300 mg aliskiren/25 mg HCTZ, and 166 received 10 mg amlodipine.

In study 2, a total of 220 adults were randomized to receive 300 mg aliskiren/10 mg amlodipine, and 223 received 10 mg amlodipine.

In study 1, the mean reduction in the central measure of systolic blood pressure was significantly greater in the aliskiren/HCTZ group, compared with the amlodipine-only group (30.1 mm Hg and 21.2 mm Hg, respectively) after 8 weeks of treatment, the researchers noted.

Changes in the peripheral measure of systolic blood pressure were not significant in either of the groups.

In study 2, the mean reduction in the central measure of systolic blood pressure was significantly greater in patients in the aliskiren/amlodipine group, compared with the amlodipine-only group after 8 weeks of treatment (29.8 mm Hg and 24.2 mm Hg, respectively).

But in this study, the mean reduction in the peripheral measure of systolic blood pressure also was significant (34.1 mm Hg and 28.9 mm Hg, respectively).

Aliskiren-based combination therapy also reduced diastolic blood pressure in both studies, but the mean reductions only reached significance in study 2. In that study, the mean reductions in the central measure of diastolic blood pressure in the aliskiren/amlodipine group and the amlodipine-only group were 16.0 mm Hg vs. 9.9 mm Hg, respectively, and the mean reductions in the peripheral measure of diastolic blood pressure for the two groups were 14.3 mm Hg and 10.5 mm Hg, respectively.

The average age of the patients was 53 years, and approximately half were women.

Patients with type 1 diabetes or type 2 diabetes who took insulin were excluded, as were patients with a history of heart failure, myocardial infarction, or other heart problems within a year of the study.

Reports of adverse events were similar between the two groups in each study, and the most common adverse events included headache, diarrhea, nausea, hypokalemia, nasopharyngitis, upper respiratory tract infection, peripheral edema, and pain. ■

Self-Monitoring Appears Superior for Blood Pressure Control

BY JENNIE SMITH

FROM THE LANCET

People with hypertension trained to monitor their own blood pressure and adjust their medication achieve greater control over their disease than do patients whose hypertension is managed through conventional care, according to new research.

The findings underscore earlier research (JAMA 2008;299:2857-67) suggesting that with appropriate clinical support and feedback—in this case, through telemonitoring of home blood pressure measurements—self-management can be an effective strategy for reducing hypertension.

Systolic BP fell after 6 months by a mean 12.9 mm Hg in the self-monitoring group and 9.2 mm Hg in controls, and by 17.6 mm Hg and 12.2 mm Hg, respectively, after 12 months.

The current study's lead author, Dr. Richard J. McManus of the Primary Care Clinical Sciences and Health Economics Unit of the University of Birmingham, England, attributed the results to more changes, often including the addition of medications, to the treatment plans of self-monitoring patients.

For their research, funded by government grants, Dr. McManus and colleagues enrolled 527 men and women with blood pressure higher than 140/90 mm Hg (but less than 200/100 mm Hg) despite treatment with up to two antihypertensive drugs, who were able to participate in a self-monitoring program.

A total of 263 patients were then randomly assigned to self-management and 264 to conventional care under their primary care physicians. Of these, 480 patients (234 self-managed and 246 control) were included in the analysis. Neither investigators nor patients could be blinded to treatment assignment; the treatment group underwent initial training sessions in the use of a sphygmomanometer and in transmitting their readings to the research team using a modem. This group could titrate its medications according to a fixed scheme, and also was able to demand prescriptions according to the results of their self-monitoring, bypassing their general practitioners.

After adjustment for factors including diabetes, chronic kidney disease, and sex, mean systolic blood pressure decreased after 6 months by a mean of 12.9 mm Hg from baseline in the self-management group and by 9.2 mm Hg in the control group. From baseline to 12 months, mean systolic blood pressure in the two groups decreased by 17.6 mm Hg and 12.2 mm Hg, respectively.

However, the decrease in mean diastolic blood pressure did not differ as much between the intervention and control groups, with smaller differences from baseline to 6 months (decreases of 5.2 mm Hg and 3.9 mm Hg) and baseline to 12 months (7.6 mm Hg and 5.0 mm Hg). "This finding might be caused by lack of power," the investigators wrote (Lancet 2010 July 8 [doi:10.1016/S0140- 6736(10)60964-6]).

Adverse effects were similar between the groups—except for leg swelling, which was higher in the self-management group, "probably caused by increased use of calcium antagonists" in that group, the researchers wrote.

The self-management group, after 12 months, was using more varied medication than the control group, which the investigators saw as an important factor in the results. Though all study subjects were taking only one or two antihypertensive drugs at baseline, by 12 months more participants had been prescribed at least three drugs in the self-monitoring group than in the control group, and were more likely to have been prescribed thiazides and calcium antagonists.

One related issue, not addressed in the study, was cost, as the self-management group received more prescriptions. Dr. McManus and colleagues wrote that they had investigated the cost-effectiveness of the intervention and would report it separately.

Compliance was good in the self-management group, with approximately three-quarters of patients completing at least 90% of the expected number of readings. When readings were particularly high or low (over 200/100 mm Hg or systolic under 100 mm Hg), as 60% of the self-management group experienced at least once, most contacted the research team, as instructed. Only 3% of the self-monitoring patients had to be contacted by researchers about a high or low reading.

But the study's authors acknowledged that such compliance would be difficult to attain in the hypertension population at large and that a weakness of the study was its paucity of low-income and ethnic minority patients.

"Self-management will not be suitable for all patients," they wrote. "However, even if only 20% of individuals with hypertension self-managed their disorder, this proportion would still represent around 4% of the U.K. population—i.e., more than 2 million individuals."

Dr. McManus acknowledged having received a consultancy fee from the firm Tplus Medical to advise on telemonitoring services. One of his coauthors on the study acknowledged receiving donations of blood pressure devices from Microlife and BpTRU for research purposes.

In an editorial (doi:10.1016/S0140-6736[10]61050-1) accompanying the study, Dr. Gbenga Ogedegbe of New York University cautioned that until these findings "are replicated by other investigators, especially in low-income, low-literate patients who receive care in low-resource, nonacademic settings," it would be premature to advocate self-monitoring strategies for hypertension on a wide scale. Dr. Ogedegbe declared no conflicts of interest. ■