well-received, as there was a high rate of participation on the part of the health professionals, the peer volunteers, and the community participants. The CHAP study demonstrated that this is an effective approach to CV management and risk reduction at the community level. More information regarding this program can be found at www.CHAPprogram.ca.

All Patients with Uncontrolled Blood Pressure on Valsartan Monotherapy Benefit from Switch to Combination Therapy

Classifying patients with uncontrolled hypertension by degree of response to valsartan monotherapy has a limited value in predicting which patients will benefit from the addition of hydrochlorothiazide (HCTZ), according to findings from a new study. Despite failing to meet blood pressure (BP) targets with valsartan monotherapy, all patients with stage 2 hypertension experienced dose-dependent improvements in BP control with the addition of HCTZ.

In studies of new antihypertensive agents, patients who do not reach predefined BP targets with monotherapy are described as non-responders. Despite not reaching goal, however, some of these patients may have had some degree of BP reduction in response to monotherapy. The magnitude of response to single-agent antihypertensive therapy in these patients can be classified according to change in systolic BP (SBP) as non-response (no change), poor response (0 to <10 mm Hg), or good response (≥10 mm Hg).

The current study was designed to evaluate whether initial response to valsartan monotherapy predicts response to additional treatment with valsartan monotherapy or combination therapy with valsartan plus HCTZ. Domenic A. Sica, MD, Virginia Commonwealth University, Richmond, Virginia, USA, presented results from a pooled analysis of two large hypertension trials.

Together, the two hypertension trials included 6800 patients with a baseline diastolic BP (DBP) ≥95 mm Hg. After 4 weeks of valsartan 160-320 mg monotherapy, 4704 patients were classified as non-responders with uncontrolled DBP (>90 mm Hg). These patients were randomly assigned to additional treatment with valsartan monotherapy or valsartan plus HCTZ 12.5-25 mg.

Initial response to valsartan monotherapy was not a strong predictor of future response to valsartan-based therapy. Patients who were classified as poor responders to monotherapy had the largest reductions in SBP after additional treatment with valsartan monotherapy (-13.7 mm Hg), valsartan plus HCTZ 12.5 mg (-19.3 mm Hg), and valsartan plus HCTZ 25 mg (-22.7 mm Hg). After 8 weeks of additional treatment, poor responders had absolute BP levels that were similar of those to good responders.

Patients who showed a good initial response to valsartan monotherapy had modest additional reductions in SBP levels (-2.3 mm Hg) after 8 additional weeks of single-agent valsartan. Patients in all response groups experienced dose-dependent benefits with add-on HCTZ therapy. These findings suggest that all patients benefit from combination therapy with valsartan and HCTZ, regardless of initial response to valsartan monotherapy.

Olmesartan Reduces Microalbuminuria in Patients with Type 2 Diabetes

Early treatment with the angiotensin receptor blocker (ARB) olmesartan significantly reduced the risk of developing microalbuminuria among patients with type 2 diabetes, according to new interim findings from the ongoing Randomized Olmesartan and Diabetes Microalbuminuria Prevention (ROADMAP) trial. However, olmesartan also appeared to increase the risk of cardiovascular (CV) mortality, raising concerns about the safety of ARBs in this patient population.

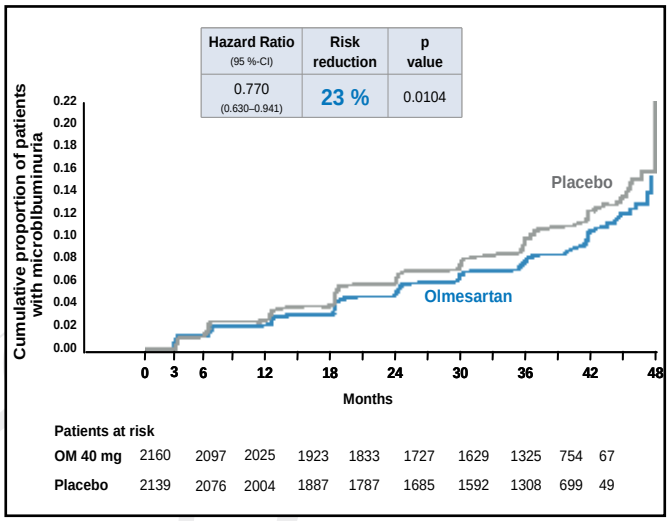
The ROADMAP trial was designed to evaluate whether early intervention with an ARB prevented or delayed the onset of microalbuminuria (MAU), an early marker of renal disease and future CV events, in patients with type 2 diabetes. The multicenter randomized trial included 4449 men and women with type 2 diabetes, normal kidney function, and at least one additional CV risk factor, including hypertension. The mean baseline blood pressure (BP) level was 136/81 mm Hg.

Participants were randomly assigned to treatment with olmesartan 40 mg daily (n=2232) or placebo (n=2215). Patients were permitted to receive other antihypertensive medications during the study, but not other angiotensin-converting enzyme (ACE) inhibitors or ARBs. The primary endpoint was time to onset of MAU, and secondary endpoints included renal and CV events. Hermann Haller, MD, Hannover Medical School, Hanover, Germany, presented 48-month findings from the ongoing ROADMAP trial.

Treatment with olmesartan was associated with effective BP control. After 48 months, 78.2% and 71.3% of patients in the olmesartan and placebo groups, respectively, reached target BP levels of <130/81 mm Hg.

Patients in the olmesartan group were 23% less likely than those in the placebo group to develop microalbuminuria at 48 months (HR, 0.770; p=0.0104). The renoprotective benefit of olmesartan was independent of its effect on BP. MAU was less common in the olmesartan group after correcting for differences in diastolic BP (HR, 0.810; p=0.0398) and systolic BP (HR, 0.814; p=0.0451: Figure 1) between the ARB and placebo groups.

Figure 1. Time to First Occurrence of MAU.



According to a safety analysis, olmesartan showed no detrimental effects on renal outcomes at 48 months. The composite risk of CV morbidity and mortality was 4.3% in the olmesartan group and 4.2% in the placebo group (HR, 1.00; p=0.99). Fatal CV events were rare, but occurred more frequently in the olmesartan group (n=15) than in the placebo group (n=3; HR, 4.94; p=0.01). The risk of CV mortality with olmesartan relative to placebo was significantly increased only among patients with pre-existing CVD (p=0.02). CV deaths in the olmesartan group were also associated with hypotension, occurring more frequently in patients with the lowest systolic BP levels and in those who experienced the greatest reduction in systolic BP.

On June 11, 2010, the U.S. Food & Drug Association (FDA) announced that it is reviewing interim safety data from ROADMAP and the Olmesartan Reducing Incidence of End Stage Renal Disease in Diabetic Nephropathy Trial (ORIENT), which also showed excess CV mortality with olmesartan compared with placebo. According to Prof. Haller, an observational follow-up study of ROADMAP is underway to further understand the long-term benefits of preventing the onset of MAU in patients with type 2 diabetes.

Further Reading: FDA MedWatch. Benicar (olmesartan) Ongoing Safety Review. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm215249.htm.

Self-Management Better Than Usual Care in Reducing Blood Pressure Levels in Patients with Uncontrolled Hypertension

Self-management of hypertension with self-monitoring of blood pressure (BP) levels and self-titration of antihypertensive medications results in significantly lower systolic blood pressure (SBP) compared with usual care, according to findings from the Telemonitoring And Self-Management In The Control Of Hypertension (TASMINH2) trial.

Recent improvements in automated BP meters have lead to the widespread use of self-monitoring by patients with hypertension. However, the effectiveness of a self-management intervention that combines self-monitoring with self-titration of antihypertensive medication in the primary care setting is unknown. Richard J. McManus, University of Birmingham, Birmingham, UK, reported findings from the TASMINH2 trial (ISRCTN17585681), which was designed to evaluate the role of dual-intervention self-management in reducing BP levels in patients with poorly controlled hypertension.

The TASMINH2 trial included 480 patients with elevated BP levels (>140/90 mm Hg) who had previously been treated with up to 2 antihypertensive medications. Patients were randomly assigned to self-management (n=246) or usual care (n=234). Patients in the self-management group agreed to perform monthly self-monitoring of BP levels. Based on BP findings, patients in the self-management group also followed medication titration schedules that were individually tailored to each patient's guideline-recommended BP goals. The primary endpoint was SBP at 6 and 12 months.

Self-management was associated with greater reductions in mean SBP compared with usual care at 6 months (-12.9 mm Hg vs -9.2 mm Hg; p=0.013) and at 12 months (-17.6 mm Hg vs -12.2 mm Hg; p=0.0004). At 6 months, patients in the self-management and usual-care groups showed similar decreases in diastolic BP (DBP; -5.4 mm Hg vs -4.2 mm Hg; p=0.108). However, by 12 months, self-management showed a significant advantage in DBP reduction compared with usual care (-7.6 mm Hg vs -5.0 mm Hg; p=0.001).

Greater BP control within the self-management group may be due to increased use of antihypertensive medication. Overall, 212 patients (80%) in the self-management group adhered to the self-monitoring and self-management regimen for the full 12 months of the study. Of these, 148 patients (70%) made at least one change to their antihypertensive treatment regimen during the course of