control rate, and fewer adverse effects than component monotherapies. The SELECT (Systolic Evaluation of Lotrel® Efficacy and Comparative Therapies) trial was a randomized, multicenter, prospective, double-blinded, parallel-group study that compared the effects of amlodipine/benazepril combination therapy with those of amlodipine and benazepril monotherapies on SBP in patients ≥55 years of age with systolic hypertension (mean seated SBP 160-200 mm Hg; mean daytime ambulatory SBP 150-200 mm Hg). Eligible patients had newly diagnosed hypertension or had discontinued previous antihypertensive medication. Following a single-blind, 2-4-week, placebo run-in period, patients were randomized to: amlodipine/benazepril 5/20 mg qd, amlodipine 5 mg qd, or benazepril 20 mg qd. Patients were maintained on this treatment for a period of 8 weeks. The primary objective of the study was to compare the effects of combination therapy with those of component monotherapy on mean 24-hour SBP. Secondary objectives were to assess the effects of these therapies on mean 24-hour pulse pressure, 24-hour diastolic BP, incidence of peripheral edema, safety, quality of life, and response and control rates. Primary results will be available for presentation.

Key Words: systolic hypertension, amlodipine, benazepril

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COMPARISON OF THE EFFECTS OF AMLODIPINE/BENAZEPRIL FIXED-DOSE COMBINATION THERAPY VS AMLODIPINE MONOTHERAPY ON SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN STAGE 2 OR STAGE 3 HYPERTENSION: RESULTS OF THE SOLACE TRIAL

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Monotherapy controls arterial blood pressure (BP) in only about half of hypertensive patients, and may result in adverse effects which further diminishes efficacy through non-compliance. Combination drug therapy can offer better BP reduction while minimizing adverse effects by using lower doses of 2 drugs instead of higher doses of 1 drug. The SOLACE (Study Comparing the Efficacy of Lotrel® vs Amlodipine in the Treatment of Moderate to Severe Hypertension) trial was a 12-week, randomized, multicenter, double-blind, parallel-group study. The primary objective of the trial was to compare the percentage of subjects treated with fixed-dose combination amlodipine/benazepril therapy with subjects treated with amlodipine monotherapy who achieved first treatment success in systolic BP (SBP), defined as a reduction in SBP of ≥25 mm Hg (if baseline SBP was <180 mm Hg); or a reduction in SBP of ≥32 mm Hg (if baseline systolic BP was 180 mm Hg). Patients 18 to 80 years of age (inclusive) with a documented diagnosis of stage 2 or stage 3 essential hypertension (SBP of ≥160 mm Hg and ≤210 mm Hg and/or a diastolic BP [DBP] ≥100 mm Hg and ≤120 mm Hg) were eligible for the trial. Subjects taking antihypertensive medication at screening or within 2 weeks prior to screening underwent a minimum 72-h washout from their current medication. At the 72-h safety visit, subjects with an SBP of <200 mm Hg and/or a DBP of <110 mm Hg continued the washout period for 1 week. Following the 3- to 10-day placebo washout period, 317 patients were randomized to either amlodipine/benazepril 5/20 mg qd or amlodipine 5 mg qd (dose level 1). Patients who achieved a target BP of ≤130/85 mm Hg at Week 2 continued treatment at dose level 1; those who did not achieve target BP were titrated to amlodipine/benazepril 10/20 mg qd or amlodipine 10 mg qd (dose level 2). If a patient's SBP was ≥180 mm Hg and ≤210 mm Hg and/or DBP was ≥110 mm Hg and ≤120 mm Hg after 3 weeks on dose level 2, hydrochlorothiazide (HCTZ) 12.5 mg qd was added. Patients with an SBP >210 mm Hg and/or a DBP >120 mm Hg at any time during the trial were discontinued from the study. Primary results of SOLACE will be available for presentation.

Key Words: amlodipine, benazepril, hypertension

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COMPARATIVE EFFECTS OF AMLODIPINE, RAMIPRIL AND TELMISARTAN ON 24-HOUR AMBULATORY BLOOD PRESSURE IN MILD TO MODERATE HYPERTENSIVE PATIENTS

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The objective of the present study was to compare the antihypertensive effects of amlodipine (AML), ramipril (RAM) and telmisartan (TEL) on 24-hour ambulatory blood pressure (BP) in patients with mild to moderate essential hypertension. For this purpose, 57 patients (41 M/16F) with a mean age of 60.1±7.0 years were enrolled in the study and were randomised to either RAM 2.5 mg (n=17), AML 5 mg (n=22) or TEL 80 mg (n=18) for a period of 8 weeks. Patients were respectively titrated to RAM 5 mg and 10 mg after 1 and 4 weeks of treatment and to AML 10 mg at week 4. Patients treated with TEL received 80 mg during the 8 weeks of the study. Ambulatory BP monitoring was performed at baseline and at the end of the 8-week treatment period.

At the end of the study, TEL and AML provided significant ($p<0.05$) and similar reductions in ambulatory BP during the daytime (6h00-23h00) and the nighttime (23h00-06h00) periods with a trend in favour of AML. In contrast, although RAM provided significant reductions in ambulatory systolic and diastolic BP from 2 to 6 hours post dose (peak effect), it failed to induce significant reductions in mean daytime and nighttime ambulatory BP. In addition, comparisons of the area-under-the-curve (AUC) for the mean BP reductions during the 24-hour interval demonstrated significant and similar antihypertensive effects on systolic, diastolic and mean BP for TEL and AML. In contrast, the 24-hour ambulatory AUCs were not significantly modified by RAM.

	Amlodipine	Rcamipril	Telmisartan
Daytime (mean±SD) (systolic/diastolic)			
Baseline	147.5 ± 13.1/93.1 ± 8.7	159.3 ± 15.9/93.4 ± 11.3	148.5 ± 16.4/91.9 ± 11.1
Week 8	132.7 ± 11.4/83.7 ± 9.2	155.0 ± 18.3/91.7 ± 12.5	140.7 ± 18.6/87.4 ± 13.0
Mean decrease	−15/−9	−4/−2	−8/−5
Nighttime (mean±SD) (systolic/diastolic)			
Baseline	139.7 ± 16.2/86.8 ± 12.0	154.3 ± 16.5/88.8 ± 12.4	145.2 ± 18.2/88.9 ± 12.7
Week 8	125.0 ± 13.7/77.4 ± 11.3	154.5 ± 19.9/89.4 ± 13.7	133.0 ± 19.4/82.1 ± 14.5
Mean decrease	−15/−9	−1/0	−12/−7

All data in mm Hg

The results of the present study confirm the efficacy of both TEL and AML in reducing ambulatory BP during each period of the 24-hour interval. Because BP reduction with RAM was restricted to its peak effect, our data do not support the use of this agent as administered once daily.

Key Words: Ambulatory blood pressure monitoring, Angiotensin, Calcium antagonists

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AMLODIPINE VS LOSARTAN IN THE TREATMENT OF TYPE 2 DIABETIC PATIENTS WITH AMBULATORY HYPERTENSION AND NORMOALBUMINURIA OR MICROALBUMINURIA: A 3-YEAR ANALYSIS

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The objectives of the study were to compare the long-term effects of an amlodipine (AML)- based and a losartan (LOS)- based treatment on blood pressure (BP) reduction, urinary albumin excretion (UAE) and renal function in type 2 diabetic patients with ambulatory hypertension and normoalbuminuria (n=47) or microalbuminuria (n=46). Patients