factor and end-organ damage data for the group includes: Cholesterol 200.7 ± 41.1 mg/dL, LDL-C 119.8 ± 33.3 mg/dL, HDL-C 41.7 ± 11.6 mg/dL, % of patients with Estes Score (ECG) >4 = 51.2%, HbA1c 8.4 ± 1.4% and Urinary Albumin Excretion 298.2 ± 705.1 mg/L/24h. These data indicate that the hypertensive cohort of ABCD-2V is at a relatively high risk for cardiovascular events and the progression of nephropathy.

| | Intensive (n = 116) | Moderate (n = 99) |
|---|---|---|
| Age (years) | 64.1 ± 8.2 | 64.3 ± 7.8 |
| DBP (mmHg)* | 79.3 ± 8.1 | 83.4 ± 8.5 |
| SBP (mmHg) | 137.8 ± 17.9 | 141.6 ± 17.7 |
| BMI (kg/m$^2$) | 32.1 ± 5.5 | 31.7 ± 5.3 |
| Duration of Diabetes (years) | 15.6 ± 7.0 | 15.7 ± 7.4 |
| Duration of Htn (years) | 19.1 ± 10.4 | 19.1 ± 11.1 |
| Smoking History (pk-yrs) | 18.8 ± 34.2 | 15.5 ± 21.4 |

*$p = 0.004$.

Key Words: Hypertension; diabetes; valsartan; ABCD-2V

**B010**

## AMLODIPINE VERSUS CILAZAPRIL/LOSARTAN IN RENAL TRANSPLANT RECIPIENTS WITH HYPERTENSION

*K. Almeshari, F. Pieters, J. Powe, E. DeVol, and O. Alfurayh.*
*King Faisal Specialist Hospital and Research Centre, Department of Medicine, Riyadh, Saudi Arabia*

We conducted a prospective, randomized, double-blind, parallel group trial for a period of 20 weeks, to compare the antihypertensive and cardiac protective effects of Amlodipine and Cilazapril in renal transplant recipients (RTR) with mild to moderate hypertension. Immediately thereafter, patients who experienced side effects were crossed over, in an open-label fashion, to either the other drug, or Losartan. At one-year follow-up, those RTR who remained on Amlodipine were compared with those who remained on Cilazapril or had been crossed over to Losartan. Diastolic blood pressure was measured by conventional methods (CDBP) and an average whole-day diastolic BP (WDDBP) was obtained by ambulatory blood pressure monitoring (ABPM) at baseline (1), 8 weeks (2), and 20 weeks (3) of randomization, and by (CDBP) at 52 weeks (4) of follow-up. Left ventricular mass (LVM) was evaluated by echocardiography at baseline (1), 20 weeks (3), and 52 weeks (4) of follow up. Twenty-three RTR were randomized to Amlodipine (G1) and 25 to Cilazapril (G2). The mean age was 37.4 and 39.6 years respectively (P=NS). Seventy percent of subjects in each group were males, and all but one in each group required a washout period because of other antihypertensive drugs. All subjects were on cyclosporine and prednisone. Average serum creatinine at baseline was 122 and 135 $\mu$mol/L in G1 and G2 respectively (P = NS). A repeated measure analysis was conducted on the outcome variables at the four points in time (1, 2, 3, and 4). Data are shown in average values.

| | $CDBP_1$ | $WDDBP_1$ | $LVM_1$ |
|---|---|---|---|
| G1 (n = 23) | 99 mmHg | 90 mmHg | 175 gm |
| G2 (n = 25) | 100 mmHg | 95 mmHg | 164 gm |
| P | NS | NS | NS |

| | $CDBP_2$ | $WDDBP_2$ | *$CDBP_3$ | $WDDBP_3$ | $LVM_3$ |
|---|---|---|---|---|---|
| G1 (n=23) | 89 mmHg | 84 mmHg | 86 mmHg | 83 mmHg | 167 gm |
| G2 (n=25) | 89 mmHg | 84 mmHg | 91 mmHg | 85 mmHg | 160 gm |

*$p = <0.05$.

At 52 weeks of follow up, average CDBP (CDBP4) was 84 and 85mmHg in Amlodipine (n=17) and Cilazapril/Losartan (n=16) groups, respectively (P=NS); and the average LV mass (LVM4) was 156 and 150gm in both groups respectively.

**Conclusion:** Antihypertensive monotherapy with Amlodipine, Cilazapril or Losartan appears to be equally effective in

controlling BP and in reducing LV mass in RTR with mild to moderate hypertension.

Key Words: Hypertension; LV mass; kidney transplantation; ABPM

**B011**

## THE ANGLO-SCANDINAVIAN CARDIAC OUTCOMES TRIAL (ASCOT)—DEMOGRAPHY OF FIRST 15000 PATIENTS RANDOMISED

*P.S. Sever, B. Dahlof (co-chairs), N.R. Poulter (Secretary), H. Wedel, (Statistician); on behalf of the ASCOT Steering Committee*

ASCOT is a prospective, randomised, open blinded endpoint trial designed to test the primary hypothesis that a newer antihypertensive treatment regimen comprising a calcium channel blocker (amlodipine) ± an angiotensin converting enzyme inhibitor (perindopril) is more effective than an older regimen of a β-blocker (atenolol) ± a diuretic (bendroflumethiazide-K) in the prevention of coronary heart disease (CHD) in hypertensive subjects aged 40–79. Incorporated into a 2 × 2 factorial design trial is the test of a second hypothesis that the addition of lipid lowering with a statin (atorvastatin) compared with placebo will further protect against CHD endpoints in those hypertensive subjects with a total cholesterol ≤6.5mmol/l. ASCOT will randomise *at least* 18,000 hypertensive patients with 3 or more additional cardiovascular risk factors to the different treatment regimens, with a follow up period of on average 5 years. By December 1999 15000 patients, mean age 62.6 ± 8.5 years (22% previously untreated), had been randomised, of whom 48% and 52% respectively had 3 and ≥ 4 risk factors. The prevalence of these risk factors among those randomised were:

| Risk factor | % | Risk Factor | % |
|---|---|---|---|
| ≥55 years | 83 | Total: HDL-chol. ratio ≥6 | 24 |
| Male | 74 | LVH | 14 |
| Microalbuminuria/Proteinuria | 64 | Abnormal ECG | 15 |
| Smoker | 32 | Prior vascular events | 17 |
| Family History of CHD | 30 | NIDDM | 22 |

51% of patients have been randomised into the lipid lowering limb of the study. Recruitment will complete in 2000 and the trial will report in 2004 if it runs its full course.

Key Words: Randomized trial; calcium channel blocker; angiotensin converting enzyme inhibitor; β-blocker; statins; CHD prevention

**B012**

## ABPM COMPARISON OF TELMISARTAN AND VALSARTAN IN PATIENTS WITH MILD-TO-MODERATE HYPERTENSION

*T.W. Littlejohn. Piedmont Research Association, Winston-Salem, NC, US*

This prospective, randomized, open-label, parallel-group, multicenter study compared the antihypertensive efficacies of the angiotensin II antagonists, telmisartan and valsartan, in patients with mild-to-moderate hypertension. Efficacy was evaluated by 24-h ambulatory blood pressure monitoring (ABPM) and cuff sphygmomanometry.

After a 4-week, single-blind, placebo run-in phase, 426 patients were randomized to 8 weeks of open-label, once-daily, oral treatment with either telmisartan 80 mg (n=214) or valsartan 80 mg (n=212).

At the end of the 8-week active treatment period, telmisartan produced a significantly greater mean reduction from baseline in DBP over the last 6 h of the 24-h ABPM period than valsartan (−7.5±0.6 mmHg versus −5.2±0.6 mmHg; P<0.01). Telmisartan treatment was also associated with significantly greater reductions from baseline than valsartan in mean SBP and DBP during the daytime (06:00–21:59), morning (06:00–11:59), and entire 24-h ABPM periods, and in trough cuff blood pressure (P≤0.01). In addition, significantly more telmisartan-treated patients than valsartan-treated patients achieved DBP control or a DBP response (P≤0.01). Both telmisartan and valsartan had tolerability profiles comparable to placebo.

In conclusion, telmisartan 80 mg once daily was significantly more effective than valsartan 80 mg once daily at lowering DBP over the last 6 h of the dosing interval in patients with mild-to-moderate hypertension. These findings are in accordance with other studies, demonstrating that telmisartan has a long duration of action and provides consistent and sustained blood pressure control even during the last 6 h of the dosing interval. This time is likely to coincide with the early morning period, when patients are at greatest cardiovascular risk.

Key Words: Telmisartan; valsartan; angiotensin II antagonist; ambulatory blood pressure monitoring

**B013**

## COMPARISON OF TELMISARTAN MONOTHERAPY WITH LOSARTAN + HCTZ IN MILD-TO-MODERATE HYPERTENSION

*J.M. Neutel[1], R.E. Kolloch[2], P.F. Plouin[3]. [1]Orange County Heart Institute & Research Center, Orange, CA, US; [2]Krankenanstalten Gilead, Bielefeld, Germany; [3]Hôpital Broussais, Paris, France*

The primary objective of this prospective, randomized, open-label, blinded-endpoint, parallel-group, multicenter study in ten countries (Europe, South Africa) was to show that telmisartan 80 mg is as effective as the fixed dose combination of losartan 50 mg/HCTZ 12.5 mg in patients with mild-to-moderate hypertension. To meet this criterion it was necessary to rule out a treatment difference of at most 3.0 mmHg in the reduction of 24-h mean DBP, measured by ABPM.

The study comprised a 4-week placebo run-in period and a 6-week active treatment period with either telmisartan 80 mg (n=332) or losartan 50 mg/HCTZ 12.5 mg (n=350) once daily.

In the intent-to-treat population, 24-h ABPM DBP (mean±SD) decreased by 8.3±6.7 mmHg (from 93.2±6.7 mmHg to 84.9±8.1 mmHg) with telmisartan 80 mg and by 10.3±6.3 mmHg (from 93.8±6.6 mmHg to 83.4±8.1 mmHg) with losartan 50 mg/HCTZ 12.5 mg. The mean difference in DBP change between the groups, adjusted for baseline val-