Conclusions: Valsartan 160 mg+HCTZ 25 mg is an effective and well-tolerated therapy in this patient population with possible beneficial effects on vascular markers.

Key Words: Combination Therapy, High-Risk Patients, Vascular Markers

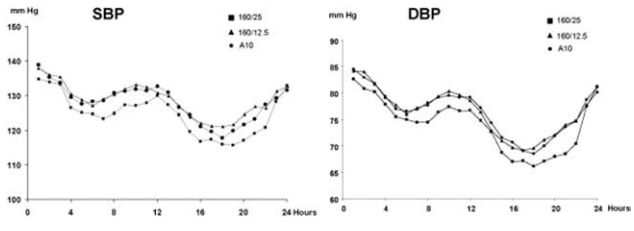
P-182

24-HOUR AMBULATORY BLOOD-PRESSURE EFFECTS OF VALSARTAN + HYDROCHLOROTHIAZIDE COMBINATIONS COMPARED WITH AMLODIPINE IN HYPERTENSIVE PATIENTS AT INCREASED CARDIOVASCULAR RISK

Luis M Ruilope, Daniela Heintz, Andrea A Brandao, Pelle Stolt, Albert Kandra, Massimo Santonastaso, Yasser Khder. Chief Hypertension Unit, Hospital 12 de Octubre, Madrid, Spain; Novartis, Basel, Switzerland; Hospital Universitario Pedro Ernesto, Rio de Janeiro, Brazil; Ospedale Civile, Vittorio Veneto, Italy.

In a randomised, double-blind trial, the effects on 24-hr ABP of the combination valsartan 160 mg od and hydrochlorothiazide (HCTZ) 25 or 12.5 mg during 24 weeks of therapy were compared with the effects of amlodipine 10 mg monotherapy (group A10) in 474 stage-II hypertensive patients with additional cardiovascular risk factors. After a two-week single-blind placebo run-in period, patients were randomised to receive valsartan 160 mg od or amlodipine 5 mg od. At Week 4, HCTZ 12.5 mg (group V160/HCTZ12.5) and 25 mg (group V160/HCTZ25) were added to the valsartan groups and in the A10 patients the amlodipine dose was force-titrated to 10 mg od.

All treatments reduced BP as well as night-time and daytime BP levels from baseline. 24-hr SBP was reduced by 15.9 ±1.0 mmHg (least-squares mean change ±SE), 19.3 ±1.0 mmHg and 16.1 ±1.1 mmHg in the V160/HCTZ12.5, V160/HCTZ25 and A10 groups, respectively and 24-hr DBP was reduced by 9.3 ±0.6 mmHg, 11.4 ±0.6 mmHg and 9.6 ±0.7 mmHg in the three groups. The differences between the V160/HCTZ25 group and the A10 group were significant ($p<0.05$) for the changes in 24-hr systolic BP as well as for changes in daytime systolic BP and night-time diastolic BP. Control rates defined as ABPM ≤130/80 mmHg were: 48.4%, 60.8% and 50.9% in the V160/HCTZ12.5, V160/25 and A10 groups, respectively; the differences between the V160/HCTZ25 group and the other two treatment groups were significant at $p<0.05$.



In conclusion, the fixed-dose combination of valsartan 160 mg + HCTZ 25 mg od is an attractive therapeutic option measured on the effects on 24-hr ABPM, night-time and daytime BP reduction and control rates in hypertensive patients at additional cardiovascular risk.

Key Words: Blood-Pressure Load, Circadian Blood Pressure, Control Rates

P-183

HOME VERSUS CLINIC BLOOD PRESSURE MONITORING IN THE ASSESSMENT OF THE ANTIHYPERTENSIVE EFFICACY OF COMBINATION PHARMACOTHERAPY

Athanasios Simeonidis, Antonios Karotsis, Stelios Mastorantonakis, George S Stergiou, Study Group for the Home-Di-Plus. Hellenic Association of General Practitioners, ELEGEIA, Greece; Hypertension Center, 3rd Department of Medicine, Sotiria Hospital, University of Athens, Athens, Greece.

Self-blood pressure monitoring at home (HBP) is regarded as an important adjunct to clinic measurements (CBP) in hypertensive patients. This study compared HBP with CBP measurements in the assessment of the additional antihypertensive effect of several drugs administered in patients uncontrolled on antihypertensive drug monotherapy.

Hypertensive patients uncontrolled on diltiazem monotherapy (240 mg o.d.) were randomized to receive add-on therapy with the thiazide diuretic (TZD) chlorthalidone (12.5 mg), the dihydropyridine calcium antagonist (DCA) felodipine (5 mg), the ACE inhibitor (ACEI) lisinopril (10 mg), or the angiotensin receptor blocker (ARB) valsartan (80 mg) for 8 weeks. Add-on treatment was doubled if CBP remained uncontrolled after 4 weeks of randomized combination pharmacotherapy. CBP (triplicate measurements) and HBP (3 days, duplicate morning and evening self-measurements) were measured before randomisation and after 4 and 8 weeks using validated automated oscillometric devices A&D 767.

A total of 185 completed the study (mean age 63.9±10.6 years, 43% men). Before randomization average CBP (158.6±13.1/86.1±9.4 mmHg, systolic/diastolic) was higher than average HBP (150.3±13.3/83.0± 8.6 mmHg) ($p<0.001$). After 8 weeks of combination pharmacotherapy a significant decline in both CBP and HBP was observed with all drugs ($p<0.001$, table).

Blood pressure decline achieved by each drug combination (SBP systolic; DBP diastolic; mmHg)

Added drug	N	Clinic SBP	Home SBP	Clinic DBP	Home DBP
TZD	51	22.8 ± 13.1	16.0 ± 10.8	8.5 ± 9.2	5.5 ± 7.6
DCA	36	26.6 ± 17.0	20.5 ± 14.0	9.2 ± 8.5	6.3 ± 6.2
ACEI	50	18.8 ± 15.7	16.6 ± 12.0	6.5 ± 10.6	6.5 ± 6.7
ARB	48	20.9 ± 13.8	15.2 ± 10.8	6.7 ± 9.2	4.5 ± 6.3

There was no statistically significant difference in the additive antihypertensive effects of the four drug classes assessed using either CBP or HBP measurements.

HBP monitoring is a useful alternative to CBP for the assessment of the additional antihypertensive effect of drugs administered in hypertensive patients uncontrolled on monotherapy.

Key Words: Combination Treatment, Diltiazem, Self-Home Blood Pressure Monitoring

P-185

AN EFFICACY EVALUATION OF OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE (OM/HCT) AND AMLODIPINE BESYLATE/BENAZEPRIL HYDROCHLORIDE (AM/BN)

Albert A. Stone. Medical Affairs, Sankyo Pharma Inc, Fuquay-Varina, NC.

Most hypertensive patients require more than one agent in order to achieve adequate blood pressure (BP) control. Fixed-dose combination antihypertensive treatments such as OM/HCT and AM/BN have advantages over monotherapy including increased efficacy, reduced side effects and lower costs. The aim of this review is to compare the efficacy of OM/HCT with AM/BN in similarly designed placebo-controlled factorial studies. MEDLINE, EMBASE and BIOSIS searches identified 4 randomized, double-blind, placebo-controlled, factorial-design efficacy studies. One study compared OM/HCT to OM or HCT monotherapy (Chrysant et al, *Am J Hypertens* 2004;17:252-9) and 3 studies compared