presenting a minimal decrease of 20 mmHg in SBP and 10 mmHg in DBP.

Results: Mean follow-up (months) was 9.13 (HP>65 years), 9.36 (HDP) and 9.43 (ISH) respectively. For the group of HP >65 years, a total mean decrease of 30.4(SD=18.0) mmHg in SBP and 14.2(SD=11.2) mmHg in DBP was observed (Wilcoxon: p-value <0.001). 72.3% of P were R and 47.8% were C at the end of study.

For HDP, a total mean decrease of 30.7(SD=17.3) mmHg on SBP and 15.0(SD=9.5) mmHg on DBP was observed (Wilcoxon: p-value <0.001). 59.8% of P were R and 9.8% were C at the end of study.

For ISH, a total mean decrease of 25.8(SD=17.4) mmHg on SBP and 5.7(SD=10.1)mmHg on DBP was observed (Wilcoxon: p-value <0.001). 60.0% of P were R and 53.8% were C at the end of study.

95 P from the HP >65 years (27.2%), 29 from the HDP (21.5%) and 25 from the ISH (25.0%) presented some adverse event, being oedema and flushing the most frequent adverse events for all studied subgroups, with 10.6%, 7.4% and 10.0% of patients referring oedema and 7.4%, 5.2% and 7% referring flushing, respectively.

Conclusions: The results confirmed the long-term effectiveness of a fixed combination of enalapril + nitrendipine in the hypertension therapy after failure of previous treatment in special populations.

Key Words: Enalapril + Nitrendipine, Hypertension, Subgroups

P-131

EFFECTIVENESS AND TOLERABILITY IN HYPERTENSIVE PATIENTS TREATED WITH A FIXED DOSE OF ENALAPRIL PLUS NITRENDIPINE FOLLOWED UP TO ONE YEAR

Alex De la Sierra, Manuel Luque, Caridad Pontes, Josep Combalia. Hypertension Unit, Hospital Clinico de Barcelona, Barcelona, Barcelona, Spain; Hypertension Unit, Hospital Clinico San Carlos, Madrid, Madrid, Spain; Medical Department, Vita P&G, Sant Joan Despi, Barcelona, Spain.

Purpose: To assess the effectiveness and tolerability of a fixed dose of enalapril + nitrendipine (10 + 20 mg, respectively) in hypertensive patients with long-term of follow-up.

Methods: Observational, prospective and multicentre study. The study included a cohort of 546 patients with a non controlled arterial hypertension despite treatment with monotherapy or other pharmacological combination, and were assessed by 64 primary care physicians. Patients were assessed after 1, 3, 6, 9 and 12 months. Patients were defined as responders if they had a minimal BP decrease of 20 mmHg in SBP and 10 mmHg in DBP or they reached their goal BP: SBP < 140 mmHg and DBP < 90 mmHg in non-diabetic patients or SBP < 130 mmHg and DBP < 85 mmHg in diabetic patients.

Results: Mean follow-up was 9.2 months, with 4.978 patient-months of follow-up. Mean age was 66.7 (CI 95% from 65.8 to 67.6) years, 57.0% of the patients were women. Patients were classified as having a cardiovascular risk factor when they were smokers (22.6%), had alcohol consumption habits (16.5%), reported sedentarism (50.3%), had dislipemia (40.5%), had diabetes (24.7%), had cardiovascular disease (15.0%) or presented a BMI > 30 kg/m2 (35.9% of patients).

A mean decrease from baseline of 30.6 (SD = 17.4) mmHg on SBP and 15.6 (SD = 11.0) mmHg on DBP was observed at study completion (Wilcoxon test: p < 0.001). 48.7% of patients presented response to treatment at month 1, and 75.1% after one year with treatment (McNemar test: p-value < 0.001). The proportion of controlled was 24.3% after 1 month and 49.4% at month 12.

134 patients, referred at least one adverse event (20.7%), being the most frequently referred: oedema or peripheral oedema (8.8%), flushing (6.0%), headache (3.8%) and coughing (2.0%).

Conclusions: The results confirmed the long-term effectiveness of a fixed combination of enalapril + nitrendipine in reducing BP after the failure of a previous treatment.

Key Words: Enalapril + Nitrendipine, Hypertension

P-132

VALSARTAN MAY IMPROVE HYPERTENSION IN ELDERLY OBESE PATIENTS

Maria Leonarda De Rosa, Mariangela Esposito, Carmela Chiarolanza, Massimo Chiariello. Cardiology and Internal Medicine, University of Naples Faculty of Medicine Federico II, Naples, Naples, Italy.

Obesity directly and indirectly promotes diabetes mellitus II, hypertension (H) and dyslipidemia.

The present study evaluated the impact of valsartan 160 mg/die (V) on clinical and instrumental parameters in a selected group of obese patients with H.

An overall population of 175 H patients was sub-grouped on the basis of the Body Mass Index (BMI) :8.2% were under weight (BMI <20.7), 63.9% normal weight (BMI: 20.7-27.7), 19.6% overweight (BM I: 27.8-31), and 8.3% obese (BMI >31). Of the 49 overweight and obese H patients 24 (age 64-80 years) accepted a tailored low-caloric dietary program for at least 4 months,in opposite other 25 H(age 61-79 years) taken V without dietetic program.The 49 patients belonged to both obese and overweight groups (BMI > 27.8) and were in WHO classe I. Mean follow-up was 5 months.

Results: The mean loss of body weight was 4 Kg in 81.4% of patients, versus 3 Kg mean increase in whole (175 H patients) population (72.5-75.5 Kg). In both group H patients with and without dietetic program we recorded a significant (p<0.05) improvement of WHO class,better control of arterial blood pressure and statistically significant (p <0.05) lowering of total colesterol and triglyceride levels.

Conclusion: V may improve clinical and instrumental parameters in the elerly obese patients with hypertension, underlining the controversial role of obesity as an independent risk factor or as a positive prognostic factor in the elderly, too.

Key Words: Elderly, Obesity, Valsartan

P-133

VALSARTAN VERSUS LISINOPRIL OR METOPROLOL TO PREVENT CARDIOVASCULAR EVENTS IN PATIENTS WITH HYPERTENSION

Thomas E Delea, Simu K Thomas, Aaron Moynihan, Feride Frech, Gerry Oster. Policy Analysis Inc. (PAI), Brookline, MA; Health Economics & Outcomes Research, Novartis Pharmaceuticals Corp., East Hanover, NJ.

Purpose: Compare cardiovascular and renal events in patients with hypertension receiving valsartan versus lisinopril or metoprolol succinate (metoprolol).

Methods: Retrospective, observational study using data from health insurance claims database spanning 1/97-12/03 and representing ~40 million members enrolled in >70 health plans across US. Study patients included those with ≥2 prescriptions for valsartan, lisinopril, or metoprolol ("study drugs") and ≥1 prior claim with diagnosis of hypertension. Patients were classified into three groups based on first prescription for study drugs ("index prescription"). Those with major cardiovascular or renal events (diagnosis of myocardial infarction or stroke, revascularization procedure, diagnosis of renal failure, or dialysis or kidney transplant procedure), other antihypertensive medications except diuretics, or gap in eligibility during 12 months pre-index were excluded. Risks of major cardiovascular or renal event were compared between groups (valsartan vs lisinopril and valsartan vs metoprolol) using Cox proportional hazards regression to control for differences between groups in baseline characteristics.

Results: We identified 6664 valsartan, 17,422 lisinopril, and 5437 metoprolol patients with mean (max) follow-up of 13.4 (69.0), 16.3 (70.9), 12.7 (70.6) months respectively. Mean age was approximately 55 years in all three groups; 43 percent of valsartan and metoprolol patients were male; 49 percent of lisinopril patients were male (p<.001 vs