POSTER SESSION

POSTER SESSION 44
THERAPEUTIC ASPECTS

PP.44.393 IRBESARTAN/AMLODIPINE FIXED COMBINATION IN PATIENTS UNCONTROLLED ON AMLODIPINE 5 MG (I-COMBINE STUDY)

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Objective: To compare the antihypertensive efficacy of the fixed combination Irbesartan/Amlodipine 150mg/5mg (I150/A5) to Amlodipine 5mg (A5) in lowering Systolic Home Blood Pressure Measurement (SHBPM) after 5 weeks (W5).

Methods: It was a multicenter, prospective, randomized, open-label, with blinded endpoint evaluation (PROBE) phase III study. Uncontrolled patients (SHBPM ≥ 135 mmHg) after at least 1 week of A5 were randomised (1:1) in 2 parallel groups: one received I150/A5 from W0 to W5 followed by forced titration I/A 150/10 from W5 to W10; the other received A5 from W0 to W5 followed by forced titration A10 from W5 to W10. The primary objective was the SHBPM change between the 2 groups at W5. A secondary objective was SHBPM change between the 2 groups at W10. Compliance was monitored by pill count.

Results: 403 patients from 12 countries were enrolled. ITT analysis was performed on 287 patients. Mean age was 57.3 ± 11.2 years, female 51.9%, obesity 41.8% and diabetes 15.3%. History of CV disease: 6.6%. At W0, mean SHBPM was 148.8 ± 10.0 / 85.0 ± 9.2 mmHg similar in the 2 groups. At W5, mean SHBPM were 135.9 ± 11.6 mmHg in group I150/A5 and 142.9 ± 12.2 mmHg in group A5. The adjusted mean difference between groups was -6.2 ± 1.0 mmHg ($p < 0.001$). Percentage of controlled patients (HBPM: < 135 and < 85 mmHg) at W5 was 44.7% in group I150/A5 vs. 21.6% in group A5 ($p < 0.001$). At W10, after Amlodipine forced titration, mean SHBPM were 130.6 ± 11.4 mmHg in group I150/A10 and 135.4 ± 10.3 mmHg in group A10. The adjusted mean difference between groups was -4.5 ± 1.0 mmHg ($p < 0.001$). Percentage of controlled patients (HBPM: < 135 and < 85 mmHg) at W10 was 67.4% in group I150/A10 vs. 44.3% in group A10 ($p < 0.001$). Compliance at W5 was 95.8% in group I150/A5 and 95.1% in group A5. At W5, 37 (12.8%) patients (pts) experienced adverse events (AE): 20 pts in I150/A5 and 17 in A5. Most frequent AE was headache (2 pts and 5 pts in each group respectively) and oedemas (1pt and 5 pts respectively). At W10, 46 (16.4%) patients experienced AE: 22 in I150/A5 and 24 in A5. Most frequent AE was dizziness (1 pt and 2 pts) and oedemas (7 pts and 9 pts respectively). Per protocol analysis (130 patients in group I/A and 132 in group A) shows similar results.

Conclusion: This study shows that combination of I150/A5 achieve clinically higher BP reduction and BP control than monotherapy with A5. Forced titration of amlodipine to 10 mg in both groups induced a further BP decrease but with more AE.

PP.44.394 ADVANCED FORM OF PERINDOPRIL ARGININE IN THE TREATMENT OF HYPERTENSIVE MENOPAUSAL AND NON-MENOPAUSAL WOMEN IN THE NATIONAL PROGRAM PREMIA

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Objective: to estimate antihypertensive efficacy and cardiometabolic effects of the new form of perindopril arginine in menopausal and non-menopausal women with hypertension, 1-2 stages with high risk.

Design and Methods: The study included 1273 women with hypertension, stages 1-2: average age was 57.9 ± 0.22 years, 248 were non menopausal and 1025 were menopausal, average weight was 79.36 ± 0.37 kg, body mass index was 29.77 ± 1.13kg/m^2, waist circumference was 93.28 ± 0.36cm, 5.3% consumed tobacco, 18.5% had family history of cardio-vascular diseases. 27.5% women had increased blood pressure (BP) stage 1,72.5% with stage 2. Women were prescribed 5 mg of perindopril arginine. In women previously treated by another ACE the last was changed to perindopril arginine 5 or 10 mg. If the effect was not enough the therapy included indapamid retard 1.5 mg. All women underwent clinical examination, including the anthropometrical measurement, 24-hour blood pressure monitoring, fasting glucose and glucose during oral glucose tolerance test. Total cholesterol (TC), low density lipoproteins (LDL), high density lipoproteins (HDL), triglycerides (TG) were determined.

Results: After 16 weeks target levels of systolic BP were achieved in 91% of non-menopausal women and 77% of menopausal women. As a result the systolic BP (SBP) significantly decreased from 155.79 ± 0.85 mmHg to 124.17 ± 0.49 mmHg in non-menopausal women and from 161.15 ± 0.36 mmHg ($p < 0.005$) to 127.87 ± 0.36mmHg in menopausal women ($p < 0.005$), diastolic BP didn't change significantly: from 94.14 ± 0.51 mmHg to 78.14 ± 0.37 mmHg and from 94.91 ± 0.24 mmHg to 79.49 ± 0.20 mmHg respectively. TC level decreased significantly from 5.52 ± 0.07 mmol/L to 5.07 ± 0.05 mmol/L($p < 0.005$) in non- menopausal women and from 5.91 ± 0.03 mmol/L to 5.30 ± 0.03 mmol/L ($p < 0.005$) in menopausal women. Other indicators did not change significantly in non-menopausal and menopausal women: body mass index decreased from 29.63 ± 0.34 kg/m^2 to 28.99 ± 0.34 kg/m^2 and from 29.81 ± 0.14 kg/m^2 to 29.33 ± 0.14 kg/m^2 respectively, waist circumference from 92.03 ± 0.92cm to 89.99 ± 0.89cm and from 93.59 ± 0.39cm to 92.08 ± 0.39cm, LDL from 3.22 ± 0.13mmol/L to 3.05 ± 0.04 mmol/L and from 3.57 ± 0.06mmol/L to 3.11 ± 0.05mmol/L, level of HDL increased from 1.36 ± 0.06mmol/L to 1.36 ± 0.08mmol/L and from 1.33 ± 0.03mmol/L to 1.35 ± 0.03mmol/L, TG from 1.62 ± 0.09mmol/L to 1.64 ± 0.10mmol/L and from 1.80 ± 0.04mmol/L to 1.66 ± 0.05mmol/L respectively. Levels of glucose did not change significantly.

Conclusions: The results of perindopril arginine therapy in women with hypertension showed significant antihypertensive effect. In menopausal women blood pressure was originally higher and both SBP and total cholesterol significantly decreased more in menopausal women than in non-menopausal.

PP.44.395 EFFECTS OF ALISKIREN-BASED THERAPY ON AMBULATORY BLOOD PRESSURE PROFILE AND CENTRAL AORTIC PRESSURE IN UNTREATED PATIENTS WITH MILD-TO-MODERATE ESSENTIAL HYPERTENSION

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Objective: Hypertension is highly prevalent and one of major risk factors of cardiovascular and renal diseases. Accumulated evidence has indicated that activation of the renin-angiotensin system is involved in the pathogenesis of hypertension and the related target organ damage. Among the components of the renin-angiotensin system, renin plays an important role in the regulation of activity of the renin-angiotensin system by catalyzing the rate-limiting step of the system. Aim of this study was to examine the beneficial effects of aliskiren-based therapy on ambulatory blood pressure (BP) profile and in untreated mild-to-moderate essential hypertension.

Design and Method: This study enrolled Japanese patients (N = 12, 6 males and 6 females, mean age 55.8 ± 8.6 years) with untreated mild-to-moderate essential hypertension (140 < 180 mmHg or 90 < 110 mmHg). Diabetic patients were excluded from the study. The aim was to control clinic BP to a level less than 140/90mmHg. All eligible patients were initially given 150mg of aliskiren once daily and the dose of aliskiren was titrated up to 300mg daily 4 weeks after the treatment as needed. In addition, optional addition of concomitant medication (either a thiazide diuretic at low dose or a CCB) was used to achieve the target BP control 8 weeks after the treatment as needed. At baseline and 12 weeks after the treatment, 24-h ambulatory BP monitoring was performed. Measurements of central BP, brachial-ankle pulse wave velocity (baPWV), and biochemical parameters were also performed before and after aliskiren-based therapy.