

($P < 0.05$ or $P < 0.01$ respectively). In contrast, in the F + M treated women, scores for the items "sexual desire" and "lubrication" were statistically lower. The concentration of the serum estradiol was less ($P < 0.01$) and testosterone was higher than those of the initiated time ($P < 0.01$).

Conclusion: Felodipine combined with Irbesartan or Metoprolol for 12 months equally reduced BP both in male and female patients with hypertension. Felodipine plus Irbesartan regimen may be more beneficial to the erectile functions for male hypertensive patients and improved sexual function to a certain extent in female hypertensive patients. However, further investigations are needed.

PP.15.423 IRBESARTAN/AMLODIPINE FIXED COMBINATION IN PATIENTS UNCONTROLLED ON IRBESARTAN 150 MG (I-ADD STUDY)

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Objective: To compare the antihypertensive efficacy of the fixed combination Irbesartan/Amlodipine 300/5mg (I300/A5) to Irbesartan 300mg (I300) monotherapy in lowering Systolic Home Blood Pressure Measurements (SHBPM) after 10 weeks (W10).

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 treatment by I150 monotherapy were randomized (1:1) in 2 parallel groups: one received I150/A5 from W0 to W5 followed by forced titration I300/A5 from W5 to W10; the other received I150 from W0 to W5 followed by forced titration I300 from W5 to W10. The primary objective was the change in SHBPM between the 2 groups at W10. A secondary objective was SHBPM change between the 2 groups at W5. Compliance was monitored by pill count.

Results: 436 patients from 10 countries were enrolled. ITT analysis was performed on 320 patients. Mean age was 56.7 ± 11.4 years, female 58.8%, obesity 42.2% and diabetes 20.3%. History of CV disease: 5.9%. At W0, mean HBPM was $151.5 \pm 11.0/86.3 \pm 10.2$ mmHg, similar in the 2 groups. At W10, SHBPM were 133.6 ± 10.9 mmHg in group I300/A5 and 140.7 ± 13.7 mmHg in group I300; the adjusted mean changes from baseline to W10 were -19.2 ± 10.2 mmHg in group I300/A5 and -9.7 ± 10.8 mmHg in group I300. The adjusted mean difference between the 2 groups was -8.8 ± 1.1 mmHg ($p < 0.001$). The percentage of controlled patients (HBPM: systolic < 135 and diastolic < 85 mmHg) at W10 was 54.1% vs. 31.8% respectively ($p < 0.001$). At W5, SHBPM were 136.8 ± 12.1 mmHg in group I150/A5 and 144.8 ± 13.6 mmHg in group I150; the adjusted mean changes from baseline to W5 were -15.4 ± 0.8 mmHg in group I150/A5 and -5.63 ± 0.8 mmHg in group I150. The adjusted mean difference between the 2 groups was -9.8 ± 1.1 mmHg ($p < 0.001$). The percentage of controlled patients (HBPM: systolic < 135 and diastolic < 85 mmHg) at W5 was 41.6 vs. 22.0% respectively ($p < 0.001$). Compliance at W10 was 100% in group I300/A5 and 99.4% in group I300. At W10, 52 (16.0%) patients (pts) experienced adverse events (AE): 29 in I300/A5 and 23 in I300. Most frequent AE was oedemas (6 pts) in group I300/A5 and headache (4 pts) in group A5. Per protocol analysis (137 patients in group I/A and 138 in group I) shows similar results.

Conclusion: This study shows that combination of I300/A5 achieve clinically significant higher BP reduction and BP control than monotherapy with I300.

PP.15.424 SINGLE-PILL COMBINATION OF TELMISARTAN 80 MG/AMLODIPINE 10 MG PROVIDES SUPERIOR BLOOD PRESSURE REDUCTIONS TO AMLODIPINE IN ADDED- RISK HYPERTENSIVE PATIENTS: SUB-ANALYSIS OF THE OBESE PATIENTS IN THE TEAMSTA DIABETES STUDY

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Objective: To compare the efficacy and safety of the single-pill combination (SPC) of telmisartan 80 mg/amlodipine 10 mg (T80/A10) with amlodipine 10 mg (A10) in patients with diabetes and hypertension who were either obese (BMI ≥ 30 kg/m²) or non-obese (BMI < 30 kg/m²).

Design and Method: An 8-week, double-blind, parallel-group study, in 706 patients aged ≥ 18 years with type 2 diabetes and stage 1 or 2 hypertension (SBP > 150 mmHg) randomized to T80/A10 (n = 352) or A10 (n = 354); patients received T80/A5 or A5 for the first 2 weeks. The primary endpoint was change from baseline in mean seated trough cuff SBP.

Results: The primary results showed a significant higher reduction of the combination vs monotherapy (-29.0 vs -22.9 mmHg; $p < 0.0001$) as reported elsewhere. 406 (57.5%) of patients were obese. Mean (SD) SBP at baseline was 160.9 (7.8) and 160.5 (7.8) mmHg in obese and non-obese patients, respectively. Reductions in SBP were greater and goal attainment was higher with T80/A10 versus A10 alone (Table), and this relative benefit was consistent across the obese and non-obese groups (interaction $p = 0.6058$). Overall, the most frequent adverse events were peripheral oedema (18.8%) and headache (2.3%), and were less frequent with T80/A10 SPC than with A10 monotherapy.

Conclusions: SBP was reduced in both obese and non-obese patients to a greater extent by T80/A10 SPC compared with A10 monotherapy. Hypertensive patients at added risk, such as those with diabetes and obesity or metabolic syndrome, can benefit from greater SBP reductions and higher goal-rate attainment when treated with T80/A10 SPC compared with A10 monotherapy. Both treatments were well tolerated and the safety profile was comparable to what has been seen in previous trials.

	A10	T80/A10	Descriptive p-value
Primary Endpoint: SBP reduction (mmHg) mean (SD)			
Obese	-22.0 (11.7) (n = 183)	-28.4 (12.8) (n = 198)	< 0.0001
None-obese	-24.3 (12.3) (n = 146)	-29.6 (11.8) (n = 134)	0.0002
Secondary Endpoints: BP goal*SBP goal**/SBP response***(%)			
Obese	48.1/51.4/86.9	68.2/71.2/92.9	n/a
Non-obese	61.0/63.7/88.4	76.1/76.1/93.3	n/a

*SBP < 140 mmHg & DBP < 90 mmHg; **SBP < 140 mmHg; ***SBP < 140 mmHg or reduction of ≥ 10 mmHg.

PP.15.425 PHARMACOLOGICALLY MEDIATED HYPOTENSION DURING THE SUMMER

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Objective: Patients on diuretic treatment frequently report lower blood pressure and hypotensive symptoms during the summer, when there is sustained increase in the ambient temperature for long periods of time. We aimed to investigate patients reporting such symptoms.

Design: The ambulatory blood pressure measurements of 70 patients on fixed dose ARB + HCTZ combination, who had reported symptoms suggestive of hypotension were analyzed. The ABPMs were performed during the summer period, until mid August 2010. Eligibility criteria were report of hypotensive symptoms, patient had to be receiving fixed dose combination of ARB + HCTZ for at least 6 months and he/she should have a valid ABPM at least 6 months before (including previous Autumn period).

Method: We compared the summer visit ABPMs with the previous ABPMs 6 months before. We analyzed the mean BP measurements using the unpaired t-test.

Results: Winter Systolic BP Summer Systolic BP p value Mean 134.79 SD 6.37 132.36 SD 8.70 $p = 0.0336$ Winter Diastolic BP Summer Diastolic BP Mean 80.91 SD 5.44 80.51 SD 7.01 $p = 0.8646$

Conclusion: We observed a statistically significant decrease in mean systolic blood pressure during the warm summer period, but not for the mean diastolic. When therapy with HCTZ is added to a patient, the possible need of decreasing the dose during the warm summer period should be taken into consideration.

PP.15.426 FEATURES OF TREATMENT AND PROGNOSIS OF NON-ST ELEVATION ACUTE CORONARY SYNDROME IN PATIENTS WITH IRON DEFICIENCY ANEMIA

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The aim of the study was to determine features of clinical course and prognosis of non-ST elevation acute coronary syndrome in patients with iron deficiency anemia and high risk of bleeding. The authors analyzed the medical histories of 2473 patients admitted to the coronary care department from October 2006 to October 2009 year with diagnosis of non-ST elevation acute coronary syndrome, and 339 conclusions of post-mortem examination. Based on analysis of archival