sive drug) with weekly observations. During the check-up visits, blood pressure was measured with Dinamap R, and blood samples were obtained to measured serum levels of Hcys and the folate according to the Fluorescence Polarizing Immunoassay (FPIA) technique (first week), and 1 mg of folic acid was administered oral during eight week and at the end, serum levels of Hcys were determined.

Results: There were a statistical difference between Hcys and intake of fortified folic acid in patients with High Blood Pressure. A value of \( p=0.001 \) was obtained (\( t=8.327 \)).

Conclusions: Fortified Folic Acid reduces serum levels of Homocysteine in Hypertensive Patients. Table 1 SBP = Sistolic Blood Pressure, DBP = Diastolic Blood Pressure. SD = Standard Deviation. Hcys = Homocysteine

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-test (week-1)</th>
<th>Post-test (week-8)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>148.85 (8.29)</td>
<td>122 (9.65)</td>
</tr>
<tr>
<td>Hcys (umol/L)</td>
<td>11.17 (5.32)</td>
<td>6.98 (3.02)</td>
</tr>
</tbody>
</table>

Key Words: Folic Acid, Hypertension, Homocysteine

P-235
HYZAA AS A FIRST LINE AGENT IN THE TREATMENT OF SEVERE HYPERTENSIVE PATIENTS
Alan H. Gradman, Christina M. Salerno, Barry J. Gertz, Robin Mukherjee, Laura A. Demopoulos, Western Pennsylvania Hospital, Pittsburgh, PA, United States; Cardiovascular Clinical Research, Merck & Co., Inc., West Point, PA, United States.

Background: Patients with severe hypertension are at high risk for cardiovascular events. Effective control of blood pressure (BP) reduces events, but generally requires multiple medications. We hypothesized that initial treatment with a combination angiotensin II antagonist/diuretic agent would be safe and more effective than initial treatment with a single agent.

Methods: We explored the safety and efficacy of losartan/hydrochlorothiazide (L/H) versus losartan (L) monotherapy regimen in the initial treatment of severe hypertension (confirmed sitting diastolic BP (SDBP) ≥ 110 mmHg) in 585 patients. In this 6-week, double-blind, parallel-arm trial, patients were randomized 2:1 to combination therapy or monotherapy, and titrated as needed at 2-week intervals to reach goal BP (treatment). Patients randomized to combination therapy were titrated from L/H 50/12.5 mg to L/H 100/25 mg, and patients randomized to monotherapy were titrated from L 50 mg to L 100 mg to L 150 mg. However, patients on L/H 50/12.5 were not titrated at the 2-week timepoint unless trough SDBP was ≥ 110 mmHg. The primary objective was to compare the proportion of patients who achieved goal BP at 4 weeks on L/H 50/12.5 mg vs L (L 50 mg titrated as needed to L 100 mg at 2 weeks). Patients on combination therapy who were titrated at 2 weeks were not considered to have achieved goal BP at 4 weeks. P-values are based on the chi-square test.

Results: The preliminary efficacy data for the proportion of patients achieving goal BP and those responding to treatment (SDBP <90 mmHg or decrease in SDBP of at least 10 mmHg from baseline) at 4 and 6 weeks on combination versus monotherapy are described below:

<table>
<thead>
<tr>
<th>Number (%) to Goal</th>
<th>L/H (N = 393)</th>
<th>L (N = 192)</th>
<th>p value</th>
<th>L/H (N = 393)</th>
<th>L (N = 192)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 4</td>
<td>77 (19.6)</td>
<td>19 (9.9)</td>
<td>264 (67.2)</td>
<td>107 (55.7)</td>
<td>0.0002</td>
<td></td>
</tr>
<tr>
<td>Week 6</td>
<td>122 (31.0)</td>
<td>24 (12.5)</td>
<td>&lt;0.0001</td>
<td>318 (80.9)</td>
<td>110 (57.3)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Changes from baseline in SDBP (mmHg) for L/H and L, respectively, are as follows: Week 4: -13.6 vs. -10.5 and Week 6: -17.1 vs. -11.6.

The preliminary number of overall adverse experiences on L/H was significantly less than that on L (170 (43%) vs. 101 (52.6%), respectively). Additionally, there was a lower incidence of dizziness and headache in the L/H group than the L group. Lab chemistry parameters did not differ between the two groups.

Conclusion: Initial treatment with losartan/HCTZ achieves goal BP in approximately twice as many patients with severe hypertension as losartan, with a similar safety profile.

Key Words: Severe Hypertension, Losartan-Hydrochlorothiazide, Combination Therapy

P-236
AMLODIPINE AND LOSARTAN IN THE TREATMENT OF ELDERLY HYPERTENSIVES INCLUDING PERSISTENCE OF EFFECT IN CASE OF MISSED DOSES
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To study the efficacy and offset of action of amlodipine and losartan in elderly hypertensives.

Randomized, double-blind, parallel group study of 12-weeks duration followed by 2 drug free days in 210 patients ≥65 years of age. The initial dose of amlodipine 5mg and losartan 50mg could be doubled at week 6 if DBP was still >90mmHg. ABPM was performed at baseline, after 12-weeks treatment, and after 2 missed doses (48-72 hours after the last dose).

Evaluable ABPMs were available in 207,190 and 197 patients respectively at these three visits. The mean doses at week 12 were 7.3mg amlodipine and 79.6mg losartan. The figure shows the effect on the average 24-hour SBP and DBP. Both SBP and DBP were significantly lower at the end of therapy and after two missed doses. At the end of active therapy BP was lowered 18.7±17.3/11.7±9.4 mmHg on amlodipine and 12.6±15.2/9.0±9.4 mmHg on losartan (p=0.002). After the second missed dose BP was still lowered by 12.7±17.4/8.6±9.2 mmHg on amlodipine and 9.7±15.0/7.0±9.4 mmHg on losartan (n.s.). The increase in BP during the drug holiday was not significantly different in the two groups. The drugs were equally well tolerated. 18 patients on amlodipine and 16 on losartan reported adverse events. 3 versus 2 patients had their dose reduced or discontinued due to adverse events.

In elderly hypertensives monotherapy with amlodipine is more potent than losartan particularly concerning SBP both during therapy and in case of missed doses.

Key Words: Hypertension, Elderly, Therapeutic Coverage