AM/N to AM or BN monotherapy (Frishman et al, J Clin Pharmacol 1995;35:1060-6; Poo et al, J Hum Hypertens 2001;15:495-8; Kuschnit et al, Clin Ther 1996;18:1213-24). Efficacy outcomes were mean reduction in seated systolic BP (SBP) and diastolic BP (DBP) and response rate (proportion of patients achieving a DBP <90 mmHg or ≥10 mmHg decrease from baseline) after 8 weeks of therapy (Table).

<table>
<thead>
<tr>
<th>Combination therapy (mg)</th>
<th>No. of subjects</th>
<th>SBP/DBP reduction, mmHg (response rate %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OLM/HCTZ 20/12.5</td>
<td>502</td>
<td>20.1/16.4 (78.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>26.8/21.9 (92.3)</td>
</tr>
<tr>
<td>AM/N 5/10</td>
<td>332</td>
<td>13/11 (61.5)</td>
</tr>
<tr>
<td>AM/N 5/20</td>
<td>530</td>
<td>11.7/8.6 (66)</td>
</tr>
<tr>
<td>AM/N 10/20*</td>
<td>308</td>
<td>24.7/13.2 (87)</td>
</tr>
</tbody>
</table>


OM/HCT 20/12.5 and 40/25mg reduced SBP/DBP by 20.1/16.4 and 26.8/21.9 mmHg respectively, compared with 13/11, 11.7/8.6, 24.7/13.2 mmHg for AM/N 5/10, 5/20, and 5/20mg. All combinations were well tolerated. Although the highest marketed dose of AM/N (10/20mg) was not tested in these factorial studies, data from a recent non-factorial study are listed in Table for indirect comparison vs the highest marketed OM/HCT dose. In conclusion, data from these studies suggest that the lowest and highest marketed doses of OM/HCT produce greater decreases in BP vs the lowest and highest marketed doses of AM/N.

AM/N head-to-head clinical trials should be done to confirm whether these observations reach statistical significance.

Key Words: Combination Therapy, Factorial Design Studies, Olmesartan

P-186
COSTS OF MORE EFFECTIVE ANTIHYPERTENSIVE TREATMENT
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The advantages of blood pressure (BP) reduction are well known and the controlled clinical trials have clearly demonstrated that with intensive therapy the BP targets set by the scientific guidelines may be reached in most of the patients; on the other end the degree of BP control in the community is still disappointing and the effectiveness and costs of more intensive treatment are largely unknown.

Purpose of our study was to evaluate the outcome of a regular attendance to an hypertension clinic on BP control and the extra costs associated with a more effective drug treatment. All outpatients attending the clinic in a two years period were retrospectively identified. BP values and data on drug treatment and on other cardiovascular risk factors were collected at baseline and at the last available visit; the level of global cardiovascular risk was classified according to the ESH guidelines. The daily cost of drug treatment was calculated assuming the reference price for each drug class, set by the Italian Health Agency for reimbursement.

579 patients with 3 or more visits (average follow-up 20 months) were included; patients excluded (with less than 3 visits) had BP better controlled and an overall lower risk, while for most of the patients included the level of risk was high (52.7% or very high (31.4%); 87% were already on drug treatment at baseline but diastolic BP was controlled in about 20% of them. With judicious changes of initial drug therapy or, more often, the addition of new drugs (average n° of drugs/patient = 1.4 at baseline and 2.15 at follow-up) BP was reduced from 152/97 mmHg to 141/89 mmHg and a satisfactory diastolic BP control was reached in about 50% of the patients; as expected patients at very high risk required more drugs (2.75 vs 1.9). At follow-up all classes of drugs were used more often than at baseline and 25% of the patients were treated with 3 or more drugs. This was associated with an increased cost of treatment; for the entire group the average daily cost of treatment increased from 0.647 Euro to 1.02 Euro, which means that the substantial improvement in BP control that we obtained, costs an extra 136 Euro/year.

Conclusions: More rational drug treatment, more drugs and an improved compliance allow a better BP control in the community and the extra costs involved seem reasonable.

Key Words: Cost of Drug Treatment, Drug Therapy, Hypertension

P-187 MP-15
EVALUATION OF HEALTHCARE RESOURCE UTILIZATION ASSOCIATED WITH AMLODIPINE BESYLATE AND DIURETICS IN A LARGE MANAGED CARE POPULATION
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JNC 7 guidelines prefer the use of diuretics (DIR) based in part on their low acquisition costs. When evaluating the economics of treatment strategies, however, use of healthcare resources, such as office visits, lab testing, and concomitant medications, should be included in the total direct medical cost of treating hypertension. This study examined healthcare resource utilization between patients treated with amlopidine besylate (AML) versus DIR in a large managed care population.

A retrospective cohort study was conducted using a US-based managed care administrative claims dataset. Adults ≥18 years who were hypertensive (by ICD-9 codes) and newly treated with either AML or any DIR (as a single-agent formulation) were identified. Patients were continuously enrolled in the same health plan for at least 1 year during the period of 2000-2002. Patients who were on AML/benazepril HCl combinations were excluded. A propensity scoring statistical methodology was used to adjust for differences in demographics, risk factors, and concomitant diseases to reduce confounding between the cohorts. Study measures included physician visits, lab testing, concomitant medications (cardiovascular [CV] and non-CV) among all hypertensive patients and those with diabetes.

A total of 111,027 patients were included in the study (17,541 on AML; 93,486 on DIR). The propensity scoring analysis was successful with only one variable (CD score) exhibiting lack of balance after adjustment (P < 0.05). Among hypertensive patients overall, per year there were 0.336 lab tests, 0.464 physician visits, 2.88 CV medications, and 3.81 non-CV medications more per DIR patient than per AML patient. Among patients with diabetes, there were 0.371 lab tests, 0.698 physician visits, 2.82 CV medications, and 5.55 non-CV medications more per DIR patient than per AML patient per year.

In this hypertensive population, the use of DIR was associated with higher healthcare resource utilization compared with the use of AML. As multiple medications are frequently needed to achieve treatment goals, it is important to consider total direct medical costs for all drugs and related resources when comparing costs among alternative antihypertensive therapies.

Key Words: Amlodipine, Diuretics, Healthcare Resource Utilization

P-188
LONG-TERM ANTIProTEINURIC EFFECT OF AN L/N TYPE CALCIUM CHANNEL ANTAGONIST, CILNIDINE
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We investigated the long-term antiproteinuric effect of an L/N-type calcium channel (Ca) antagonist, cilnidpine in the patients with essential hypertension (EHT).

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