0.4%), and dizziness (2% vs 2%). 3 DB placebo patients (1.1%) discontinued due to AEs during OL. There were no SAEs.

Sildenafil was well tolerated among men with ED who were taking multiple anti-HTNs. The incidence of AEs was similar in men taking 2 (n=307) and 3+ (n=222) anti-HTNs and consistent with that previously reported. Less than 2% of patients discontinued because of AEs. Thus, men who are taking multiple anti-HTNs are not at increased risk for more frequent or severe AEs while taking sildenafil for ED.

### MOST FREQUENT AES DURING OL EXTENSION

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Patients From DB Sildenafil (N = 259) n (%)</th>
<th>Patients From DB Placebo (N = 272) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>20 (7.7)</td>
<td>27 (9.9)</td>
</tr>
<tr>
<td>Fecal flushing</td>
<td>15 (5.8)</td>
<td>17 (6.3)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>5 (1.9)</td>
<td>8 (2.9)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>5 (1.9)</td>
<td>5 (2.2)</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>3 (1.2)</td>
<td>6 (2.2)</td>
</tr>
<tr>
<td>Abnormal vision</td>
<td>3 (1.2)</td>
<td>7 (2.6)</td>
</tr>
<tr>
<td>Chromatopsia</td>
<td>4 (1.5)</td>
<td>4 (1.5)</td>
</tr>
</tbody>
</table>

Key Words: Erectile Dysfunction, Controlled Trial, Safety of Sildenafil Citrate

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**P-65**

**PREVALENCE OF ACE-INHIBITOR USE IN DIABETIC HYPERTENSIVES IN HYPERTENSION SPECIALTY CLINIC: A QUALITY ASSURANCE REVIEW**

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Renin Angiotensin Aldosterone (RAA) inhibition has been shown to have beneficial effects in diabetics. We chose to evaluate the usefulness of drugs that block the RAA Axis including ACE inhibitors (ACEIs) and the Angiotensin Receptor Blockers (ARBs) in a Hypertension Specialty Clinic.

Charts of 437 Consecutive patients seen at the Rush University Hypertension Center from September, 1998 to February, 2000 were evaluated for blood pressure control and treatment regimen. The Rush University Hypertension Center is comprised of 4 physicians, 3 of whom are certified Clinical Hypertension Specialists. Physicians based their treatment strategies on current guidelines. No specific clinical pathway was used and no drug regimen was mandated.

Twenty (20%) of the total patients (N=86) were Type II diabetics, 47% were male, there mean age was 61 ± 12 years. The mean blood pressure upon initial presentation to clinic was 156 ± 24/89 ± 12 mm Hg and was reduced to 137 ± 16/78 ± 10 mm Hg after at least one year of enrolment in the clinic.

ACEIs and ARBs were included in the regimen of 76% diabetic patients compared to 43% of non-diabetics. Twenty four (24%) of the diabetics were not treated with ACE inhibitors or Angiotensin Receptor Blockers. In 9/21 (43%) of the patients the failure to use these drugs was due to Side effects like cough (4), angioedema (2), hyperkalemia (1), dizziness (1), and increased creatinine (1). Additionally, physicians elected non-ACEI/ARB regimens in seven patients with already controlled BP. Four patients refused addition of medications to their current regimen, and no reason existed for only one patient.

These results indicate that pharmacologic blockade of the RAA System was used in 76% of diabetics, and that contraindication for such therapy was present in 43% of those who did not receive it. Quality assurance surveys should recognize that not all diabetics will recieve angiotensin antagonists because of existing contraindications and patient preferences.

Key Words: Standard of Care, Quality Assurance, Angiotensin Blockade in Diabetics

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**P-66**

**EFFICACY OF AN OLMESARTAN MEDOXOMIL-BASED TREATMENT ALGORITHM FOR HYPERTENSION CONTROL IN PRACTICE-BASED SETTINGS**

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Introduction: Surveys preferred to assess blood pressure (BP) control have repeatedly demonstrated worldwide BP control rates of approximately 25%. In contrast, recent clinical trials have shown that forced-titration treatment algorithms can help clinicians achieve diastolic BP goals in the vast majority of patients. Systolic BP goals, however, are much more difficult to achieve. In this study we sought to establish a treatment algorithm for a typical clinical setting designed to attain the increasingly accepted stringent BP control of ≤130/85 mm Hg in the majority of patients. The new long-acting angiotensin receptor blocker (ARB) olmesartan medoxomil was the base therapy and additional agents were permitted to achieve target BP.

Methods: This open-label, multicenter, forced-titration study enrolled 201 subjects at 17 clinical practice sites. Subjects were characterized of hypertensive patients commonly seen in U.S. clinical practice. Mean age was 53 years; 65% were male; 74% were Caucasian; 16% were African-American; mean BP was 161.296.6 mm Hg. Following wash-out, all subjects received olmesartan medoxomil 20 mg; if target BP was not achieved at 4 weeks, olmesartan medoxomil was titrated to 40 mg. In step-wise manner, hydrochlorothiazide (HCTZ) 12.5 mg to 25 mg and amlopidine 5 mg to 10 mg were added sequentially beginning at 8 weeks and every 4 weeks thereafter if BP was not at goal.

Results: With this algorithm, olmesartan medoxomil monotherapy controlled DBP to ≤90 mm Hg in 80 % of subjects and SBP to ≤140 mm Hg in 61% of subjects. Using these BP targets, DBP control rates increased to 91%, 96%, 97%, and 97%, respectively, following the addition of HCTZ 12.5 to 25 mg and amlopidine 5 to 10 mg. SBP control rates increased to 78%, 85%, 92% and 94%, respectively, with the stepped algorithm. Overall, 92% of subjects attained the BP goal of ≤140 and ≤90 mm Hg with the olmesartan medoxomil-based regimen, and 82% attained the more stringent goal of ≤130 and ≤85 mm Hg.

Conclusions: We have demonstrated that when forced by a study protocol to follow a logical drug algorithm, doctors in a clinical setting achieved a BP goal of ≤130/85 mm Hg in more than 80% of subjects using an olmesartan medoxomil-based regimen.

Key Words: Olmesartan Medoxomil, Hypertension, Blood Pressure Goals

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**P-67**

**DOSE RESPONSE ANTIHYPERTENSIVE EFFICACY OF ALISKIREN (SPP 100), AN ORALLY ACTIVE RENIN INHIBITOR**

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Aliskiren (SPP 100), an orally active renin inhibitor, has been shown to inhibit the production of angiotensin I and angiotensin II in healthy volunteers. In a pilot study, aliskiren decreased BP in hypertensive patients at daily doses of 75 and 150 mg.

In this multi-centre, double-blind, active comparator trial, the dose-dependent effects of aliskiren were evaluated in 226 patients with mild to moderate hypertension. Parallel groups of randomized patients were assessed at the end of a washout period and again after a 4-week treatment period. Treatment consisted of single oral daily doses of