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

Adverse Event (All Causality)	Patients From DB Sildenafil (N = 259) n (%)	Patients From DB Placebo (N = 272) n (%)
Headache	20 (7.7)	27 (9.9)
Facial flushing	15 (5.8)	17 (6.3)
Dyspepsia	5 (1.9)	8 (2.9)
Dizziness	5 (1.9)	5 (2.2)
Rhinitis	3 (1.2)	6 (2.2)
Abnormal vision	3 (1.2)	7 (2.6)
Chromatopsia	4 (1.5)	4 (1.5)

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

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PREVALENCE OF ACE-INHIBITOR USE IN DIABETIC HYPERTENSIVES IN HYPERTENSION SPECIALITY 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 Hypeternsion Speciality 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 recieve 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

P-66

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

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Introduction: Surveys preformed 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 characteristic 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 161.2/96.6 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 amlodipine 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 amlodipine 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

P-67

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

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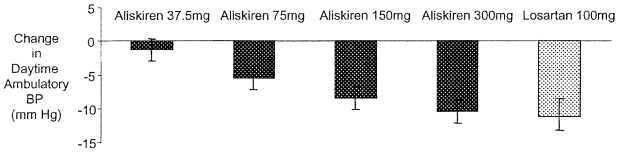
Aliskiren (SPP 100), an orally active renin inhibitor, has been shown to inhibit the production of angiotensin I and angiotensin II in healthy volunteers. In a pilot study, aliskiren decreased BP in hypertensive patients at daily doses of 75 and 150 mg.

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

aliskiren (37.5, 75, 150 or 300 mg) or of losartan 100 mg once daily. Daytime ambulatory systolic BP was defined as the primary variable of the study.

As illustrated in the figure, a clear dose-response curve was observed for the decrease (mean +/- SEM) in daytime ambulatory systolic BP. The mean (SD) change at the end of the 4-week treatment period was -1.3 (9.5) mmHg, -5.5 (10.6) mmHg, -8.5 (10.4) mmHg, -10.5 (10.7) mmHg, and -11.1 (13.4) mmHg for 37.5, 75, 150, and 300 mg aliskiren and 100mg losartan, respectively. Statistically significant lowering occurred with 75, 150 and 300 mg of aliskiren. The daytime ambulatory systolic BP responses to aliskiren doses of 150 and 300 mg were not significantly different from that of 100 mg losartan. Similar results were shown for daytime ambulatory diastolic BP and for night-time ambulatory systolic and diastolic BP. Aliskiren was well tolerated - there was no increase in the number of adverse events with increasing doses of aliskiren, and the safety profile of aliskiren was similar to that of losartan.



The results of this dose-ranging study confirm a dose-dependent reduction in BP with aliskiren in mild to moderate hypertension. Additional exploratory studies testing the efficacy and safety of this new renin inhibitor in patients with renal disease and congestive heart failure are currently underway.

Key Words: Renin Inhibitor, Oral Administration, Hypertension

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THE ANTIHYPERTENSIVE EFFICACY AND SAFETY OF OLMESARTAN MEDOXOMIL COMPARED WITH AMLODIPINE FOR MILD-TO-MODERATE HYPERTENSION

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Introduction: This double-blind, randomized, multicenter study was conducted to compare the efficacy of the newest angiotensin receptor blocker (ARB), olmesartan medoxomil, with one of the most commonly prescribed antihypertensive agents, amlodipine, in subjects with mild-to-moderate hypertension. Olmesartan medoxomil is a new, long-acting, once-daily ARB that has been shown in a previous study to result in statistically superior reductions in blood pressure (BP) as compared with three other ARBs: losartan, valsartan, and irbesartan.

Methods: Following a 4-week placebo run-in period, subjects were randomized to 8 weeks of therapy with placebo (n=66), or the recommended starting doses of amlodipine 5 mg (n=186) or olmesartan medoxomil 20 mg (n=188). The primary efficacy variable was the change from baseline in mean 24-hour diastolic BP as determined by ambulatory BP monitoring at Week 8. Entry criteria included seated cuff diastolic BP 100-115 mm Hg and daytime, ambulatory diastolic BP ≥90 mm Hg. There were no statistically significant differences between groups at baseline. Mean baseline 24-hour ambulatory BP in the placebo, amlodipine and olmesartan medoxomil groups was 154/96, 154/95, and 154/96 mm Hg, respectively.

Results: Both active treatments reduced BP at all measures to a significantly greater degree than did placebo; there were no statistically significant differences in BP efficacy between amlodipine and olmesartan medoxomil on any measure. Ambulatory systolic/diastolic BP was reduced by 2.3/1.4 on placebo, 12.3/7.0 on amlodipine, and 12.2/7.7 on olmesartan medoxomil (P<0.001 amlodipine and olmesartan medoxomil vs placebo). Similar findings were reported for cuff BP measurements. Both agents were equally well-tolerated. The only notable differences in adverse events were a significantly higher incidence of nausea (2.7%) with amlodipine as compared with olmesartan medoxomil (0%) or placebo (0%) (P=0.039), and a higher, but not statistically significant, incidence of edema with amlodipine (9.1%) compared with olmesartan medoxomil and placebo (4.3%, and 4.5%, respectively.

Conclusions: Olmesartan medoxomil is safe and similarly effective to amlodipine in subjects with mild-to-moderate hypertension, resulting in equivalent reductions in both cuff and ambulatory systolic and diastolic BP.

Key Words: Hypertension, Olmesartan Medoxomil, Amlodipine

P-69

ATORVASTATIN ASSOCIATED TO VALSARTAN DOES NOT IMPROVE BLOOD PRESSURE CONTROL OR PROTEINURIA EXCRETION IN PATIENTS WITH DIABETIC NEPHROPATHY

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In recent years several papers have been published (1) showing that the use of statins with some antihypertensive drugs could improve the blood pressure control and could have some synergetic effect(2).

Our proposal had a double Objective: To analyse if atorvastatin is able to reduce blood pressure and if it is able to decrease proteinuria in a group of patients with diabetic nephropathy, hypercholesterolemia and hypertension treated with one angiotensin receptor blocker. We included 6 patients (3M,3F), aged (58-71)in treatment with valsartan 160 mg/day as only antihypertensive drug.

The study was an open, secuential design with each period lasting 3 months. Period A: valsartan 160 mg/day. Period B: valsartan 160mg/day and atorvastatin 10 mg/day. Period C: valsatan 160 mg/day. We can detect significant differences in total cholesterol and LDL-cholesterol between periods with and without atorvastatin (p<0,001). There were no significant differences in blood pressure control, serum creatinine or proteinuria in 24 hours.

In conclusion, we can not confirm that atorvastatin treatment modifies systolic or diastolic pressure or has some influence in the progression of diabetic nephropathy in patients previously treated with valsartan.

(1). Borghi. J. Cardiovasc-Pharmacol 2000;35(4):549-55
(2). Sposito. Am-J-Cardiol 1999;83(10):1497-9

	Period A	Period B	Period C
Systolic	142,27 ± 11,96	141,33 ± 8,75	146 ± 10,53
Diastolic	83,55 ± 5,59	85,72 ± 5,83	88,27 ± 9,50
Total Cholesterol	271,76 ± 28,43	224,16 ± 25,4	267,33 ± 11,21
LDL-Cholesterol	137 ± 12,44	113,16 ± 7,44	135 ± 10
Serum Creatinine	1,3 ± 0,08	1,3 ± 0,1	1,4 ± 0,09
Proteinuria/24 hours	1,50 ± 0,5	1,71 ± 0,47	1,75 ± 0,65

Key Words: Atorvastatin, Valsartan, Diabetic Nephropathy

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THE SELECTIVE ALDOSTERONE BLOCKER EPLERENONE IS SAFE AND EFFICACIOUS FOR THE LONG-TERM TREATMENT OF MILD-TO-MODERATE HYPERTENSION

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Eplerenone (EPL), the first selective aldosterone blocker (SAB), binds preferentially to aldosterone receptors, with little affinity for progesterone or androgen receptors. EPL is to be used for the treatment of hypertension and heart failure. This 6- to 16-month, open-label, single-group,