At week 42, 48 % of the patients were still in treatment and blood pressure lowered for all patients (166.8  $\pm$  21.1/97.1  $\pm$  12.8 mm Hg to 133.4  $\pm$  16.2/80.3  $\pm$  8.5 mm Hg) it was also lowered in the nifedipine GITS monotherapy group (165.7  $\pm$  22.2/97.8  $\pm$  13.0 mm Hg to 132.2  $\pm$  12.6/79.0  $\pm$  7.1 mm Hg. The menopause group treated with nifedipine GITS monotherapy lowered 166.2  $\pm$  21.2/96.8  $\pm$  12.5 mm Hg to 132.7  $\pm$  13.2/75.4  $\pm$  10.9 mm Hg. Adverse events were present in 19.8 % of the patients which include ankle edema and headache as the more frequent as described in international reports.

The efficacy and tolerability for Nifedipine GITS monotherapy or combined with any other antihypertensive drugs are well established, the patient compliance found in this report is also within international reports. Nevertheless we found that post-menopause women were 53 % of the total study population and 80 % of the monotherapy group were post-menopause women. Nifedipine GITS as monotherapy shows correlation with postmenopause women as a clinical variant that helps the physician to choose this form of therapy in the management of esential hypertension.

Key Words: Nifedipine, Menopause, Osmotic Release System

#### P-239

## PATIENT COMPLIANCE AND PERSISTENCE WITH COMBINATION VALSARTAN/ HYDROCHLOROTHIAZIDE THERAPY VERSUS HYDROCHLOROTHIAZIDE THERAPY

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The purpose of this study is to compare compliance and persistence of fixeddose combination valsartan/hydrochlorothiazide (valsartan/HCTZ) therapy versus hydrochlorothiazide (HCTZ) in the treatment of hypertension.

We conducted a retrospective cohort study using data from a national all-payer database (Medstat MarketScan®) for the period 2000–2001 to identify hypertensive patients who initiated antihypertensive therapy with valsartan/HCTZ or HCTZ. Compliance was assessed using the medication possession ratio (MPR), or the percentage of time a patient had drug available over a 1-year time period. Persistence was non-discontinuation, where discontinuation was defined as not refilling the index agent at the end of days supply of last fill plus 100% of days supply among patients with more than 1 fill.

A total of 6,023 valsartan/HCTZ patients were compared to 24,310 HCTZ: 12.5 mg (3,308), 25 mg (19,159), and 50 mg (1,843). Age and gender were similar between the groups. Valsartan/HCTZ patients had a mean MPR of 74% compared to 68% for HCTZ patients, with the MPR decreasing as the dosage of HCTZ increased (70% for 12.5 mg; 69% for 25 mg; 67% for 50 mg). Overall, the risk of discontinuation was 1.5 significantly higher (p<0.01) for HCTZ compared to valsartan/HCTZ; RR = 1.7, 1.4, and 1.4 for 12.5 mg, 25 mg, and 50 mg of HCTZ, respectively. Most of the difference between groups with respect to persistence occurred within the first 100 days of therapy.

Patients taking fixed-dose combination valsartan/HCTZ therapy had better compliance and persistence than patients on HCTZ.

Key Words: Compliance, Persistence, Valsartan/Hydrochlorothiazide

### P-240

# PRACTICE PATTERN IMPLICATIONS FOR DIHYDROPYRIDINE CALCIUM-CHANNEL BLOCKER MONOTHERAPY IN THE HYPERTENSION POPULATION

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The purpose of this study is to assess the characteristics of patients and efficacy of blood pressure (BP) control in hypertensive patients receiving dihydropyridine calcium-channel blocker (DHP-CCB) monotherapy.

A cohort study of patients who received a diagnosis of hypertension and were treated continuously over 3 years with a single DHP-CCB agent identified through health plan databases was conducted. Patients with compelling indications for DHP-CCB therapy likely to influence treatment choice were excluded. A medical chart review was performed on randomly selected patients to collect previous antihypertensive therapy prior to initiating DHP-CCB therapy, documented adverse effects from antihypertensive therapy, BP readings, target organ damage, and presence of cardiovascular risk factors.

In a cohort of 181 patients (mean age 63.9 years; 61% female), 68% initiated a DHP-CCB as first-line therapy and 32% tried other antihypertensive therapy agents before switching to DHP-CCB therapy. Side effects were the most common reason for discontinuation of previous antihypertensive therapy with ACE inhibitor associated cough the most frequent complaint. Baseline average BP (DHP-CCB treated) was 135.9/ 77.4 mm Hg with systolic BP control (<140 mm Hg) achieved in 57% of the patients, diastolic BP control (<90 mm Hg) in 91%, and combined control (<140 and <90 mm Hg) in 56%. After 3 years, the average BP was 135.2/76.3 mm Hg. However, the percent of patients who achieved systolic BP control decreased to 45%, diastolic BP control to 81%, and combined control to 38%. Both peripheral artery disease and stroke were present in 7.7% of the cohort. Age (> 55 years for men, > 65 for women) (54%), dyslipidemia (45%), family history of premature cardiovascular disease (21%), cigarette smoking (16%), and diabetes (7%) were the most frequently identified cardiovascular risk factors.

This analysis of actual practice data indicates worsening of BP control over 3 years in patients on DHP-CCB monotherapy. In view of recent guidelines, initial therapy with a DHP-CCB should be reserved for situations where compelling indications exist.

Key Words: Calcium-Channel Blockers, Monotherapy, Antihypertensive Drugs

### P-241

# RISK OF CARDIOVASCULAR EVENTS WITH AMLODIPINE, LISINOPRIL, OR VALSARTAN THERAPY IN HYPERTENSION POPULATION

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The purpose of this study is to examine the relationship of amlodipine, lisinopril, and valsartan use to risk of cardiovascular (CV) events.

Using claims data from a national all-payer database (Medstat MarketScan®), a retrospective case-control study was performed. Patients were included in the study if they met the following criteria: (1) continuous enrollment (1998–2002); (2) hypertension diagnosis (ICD-9-CM 401.1) between July 1998 and June 1999; (3) no hypertensive therapy in first 6 months of 1998; and, (4) no CV event (ICD-9-CM 402–448) between July 1999 and December 2000. Cases were patients who met inclusion criteria and had at least one CV event in 2001–2002, whereas controls did not have a CV event during the same time period. Cases and controls were matched by age and gender. The odds of prior drug exposure (July 1998-Dec 2000) among cases compared to controls were estimated using a conditional logistic regression which included a non-CV comorbidity index (derived from the Charlson Index) as a covariate.

505 cases and 505 controls were included. The average age was 54 and 36% were female The mean comorbidity index was 0.3 for controls and 0.5 for cases. Among controls 10.5% (n=53) had taken amlodipine, 8.7% (n=44) had taken lisinopril, and 4% (n=20) had taken valsartan. Higher percentages of cases had taken amlodipine (14.5%; OR=1.4, P<0.14)