

CALCIUM ANTAGONISTS IN BLACKS (CAB) FACT SHEET

Significance:	<ul style="list-style-type: none"> • First-of-its-kind study to provide a direct comparison of three calcium channel blockers in a large number of African Americans – a population at great risk of hypertension and death from heart disease
Design:	<ul style="list-style-type: none"> • Double-blind, randomized, parallel group Phase IV clinical trial of 192 Stage 1 or 2 hypertensive African-American patients across 10 U.S. study centers comparing the blood pressure lowering efficacy of three dihydropyridine calcium channel antagonists after eight weeks of monotherapy • 163 patients were evaluated for efficacy at end of study • Patient groups were demographically similar
Medications:	<ul style="list-style-type: none"> • Adalat CC (nifedipine CC) (30 mg titrated to 60mg once daily to maintain diastolic blood pressure <90mm Hg) • Procardia XL (nifedipine GITS) (30 mg titrated to 60mg once daily to maintain diastolic blood pressure <90mm Hg) • Norvasc (amlodipine) (5 mg titrated to 10mg once daily to maintain diastolic blood pressure <90mm Hg)
Primary Endpoints:	<ul style="list-style-type: none"> • Mean reduction in 24-hour ambulatory diastolic blood pressure
Secondary Endpoints:	<ul style="list-style-type: none"> • Mean reduction in 24-hour ambulatory systolic blood pressure • Mean reduction in office visit diastolic and systolic blood pressure • Responder rates (DBP [diastolic blood pressure] <90 mm Hg or reduced by ≥ 10 mm Hg) • Safety and tolerability
Inclusion Criteria:	<ul style="list-style-type: none"> • Male and female African Americans with Stage 1 or 2 hypertension • 18-75 years of age • Average sitting DBP between 95 and 110 mm Hg • SBP (systolic blood pressure) between 140 and 179 mm Hg at randomization visit following three-week placebo lead-in period • Written consent • No anti-hypertensive medication for at least three weeks during which compliance to placebo was $\geq 80\%$ by pill counts
Major Exclusion Criteria:	<ul style="list-style-type: none"> • Liver disease, renal disease or uncontrolled diabetes mellitus • One-plus or greater pre-tibial edema • Co-morbid cardiovascular conditions (prior stroke, coronary artery disease, arrhythmias, heart failure) • Pregnancy or planned pregnancy during study • Average alcohol intake of ≥ 3 drinks per day • Night shift workers and those with upper-arm circumference more than 37.5 cm (because of ambulatory blood pressure monitoring requirements)

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Study Coordinator:	<ul style="list-style-type: none"> • International Society on Hypertension in Blacks (ISHIB) • Study funded by educational grant from Bayer Corporation, Pharmaceutical Division
Study Sites:	<ul style="list-style-type: none"> • Morehouse School of Medicine, Atlanta, GA • Veterans Administration Medical Center, Jackson, MS • Jackson Cardiology Associates, Jackson, MS • Medical University of South Carolina, Charleston, SC • Roxbury Heart Center, Roxbury, MA • Heartbeats Life Center, New Orleans, LA • Harlem Hospital Center, New York, NY • St. Mary's Family Health Center, Waterbury, CT • King Drew Medical Center, Los Angeles, CA • University of Maryland, Baltimore, MD
Topline Results:	<ul style="list-style-type: none"> • Adalat CC (nifedipine CC) is equivalent to Procardia XL (nifedipine XL) and Norvasc (amlodipine) in maintaining blood pressure control • There was no significant difference in the average 24-hour ambulatory diastolic (-9.0, -8.5 and -6.1 mm Hg, respectively) or systolic (-15.7, -14.3 and -11.8 mm Hg, respectively) blood pressure reduction ($P =$ non significant) • Average office SBP and DBP were reduced to comparable degree (19-22 mm Hg [$P = .50$] and 12-14 mm Hg [$P = 0.51$], respectively) • Response rates to treatment were similar ($P = 0.38$) • Discontinuation rates and adverse event frequency were distributed similarly across all three treatment groups • Results may have cost implications to patients because nifedipine CC is less expensive at equivalent doses than amlodipine or nifedipine GITS • Adverse events reported included dizziness, cough, edema, flushing and headache

Reference: Hall W D, Reed J W, Flack J M *et al.* Comparison of the Efficacy of Dihydropyridine Calcium Channel Blockers in African American Patients with Hypertension. *Archives of Internal Medicine*, October 1998; v158, p. 2029-2034.