Original Paper

Amlodipine/Atorvastatin Single-Pill Therapy for Blood Pressure and Lipid Goals in African Americans: Influence of the Metabolic Syndrome and Type 2 Diabetes Mellitus

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African Americans with diabetes ± the metabolic syndrome are at high risk for cardiovascular disease. This subanalysis of the Clinical Utility of Caduet in Simultaneously Achieving Blood Pressure and Lipid End Points (CAPABLE) trial studied attainment of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) and the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) blood pressure (BP) and low-density lipoprotein cholesterol (LDL-C) goals by 8 flexibly titrated doses (5/10–10/80 mg) of amlodipine/atorvastatin single pill in 494 African Americans with hypertension and dyslipidemia, according to the presence of diabetes ± the metabolic syndrome. In 169 diabetic patients, the metabolic syndrome was associated with poorer BP goal attainment (38.5% vs 48.5% in diabetic patients without the metabolic syndrome). Among diabetic patients (± the metabolic syndrome) 61% to 62% reached LDL-C goal. More than 60% of patients with diabetes uncontrolled for LDL-C were maintained on suboptimal atorvastatin therapy (mean final dose: 29.9 mg vs maximum of 80 mg). Reluctance to intensify therapy to attain accepted targets in high-risk individuals suggests a degree of clinical inertia not explained by objective evidence of dose-dependent intolerance. J Clin Hypertens (Greenwich). *2009;11:585–593.* ©*2009 Wiley Periodicals, Inc.*

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Manuscript received October 1, 2008; revised February 10, 2009; accepted April 3, 2009

doi: 10.1111/j.1559-4572.2009.00062.x

Cardiovascular disease (CVD) is the most common cause of death in the United States and worldwide.[1] Modifiable cardiovascular (CV) risk factors such as hypertension and dyslipidemia may contribute synergistically to the development of CVD.[2] Approximately one third of US adults have the metabolic syndrome (MS),[3] and various clinical threshold levels for components of MS have been defined in recent years by the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III),[4] the

American Heart Association/National Heart, Lung, and Blood Institute (AHA/NHLBI),[5] and the International Diabetes Federation.[6] These components include abdominal obesity, elevated blood pressure (BP), high fasting plasma glucose, and—to a lesser extent—elevated triglyceride and reduced high-density lipoprotein cholesterol (HDL-C). The relationship between multiple comorbid CV risk factors and enhanced CV risk is clear.[7–10] A recent meta-analysis of 172,573 individuals has reported a significantly higher risk of CV events associated with MS.[10] A post hoc analysis of the West of Scotland Coronary Prevention Study (WOSCOPS) has shown a linear relationship between the number of components of MS and risk of coronary artery disease (CAD).[9] Similarly, a post hoc analysis of the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS) showed that the presence of MS increases 10-year Framingham risk of coronary heart disease (CHD).[8]

African Americans have a higher CV risk than Caucasians[1,11] and have the highest rate of CHD mortality in the United States.[11,12] Among non-Hispanic blacks aged 20 years and older, the prevalence of diabetes is 1.8 times greater than in non-Hispanic whites of similar age.[1] The relationship between MS, particularly with regard to its triglyceride and HDL-C components, and CV events is less clear for blacks than for Caucasians, but an association between MS and age- and sex-adjusted risk for CVD and CHD in African Americans has been reported.[13] African Americans appear to have lower triglyceride levels and higher HDL-C levels than might be anticipated from the prevalence of CV events in this population.[14] Nevertheless, more than 1 in 5 adult African Americans have MS.[11,12] For example, the age-adjusted prevalence of MS has been reported as 21.6% in African Americans vs 23.8% and 31.9% in whites and Mexican Americans, respectively.[1]

Despite their heightened susceptibility to atherosclerotic disease, African Americans remain undertreated for hypertension and dyslipidemia. The efficacy of single-pill atorvastatin/amlodipine therapy in non–African American patients has been established.[15] In the Clinical Utility of Caduet in Simultaneously Achieving Blood Pressure and Lipid End Points (CAPABLE) trial we also reported the clinical benefits of single-pill amlodipine besylate/atorvastatin calcium therapy for the simultaneous treatment of hypertension and dyslipidemia in an African American population.[16] While only 1% of patients were at both BP and low-density lipoprotein cholesterol (LDL-C) goals at entry to the study, almost half reached both goals at the end of the study. In CAPABLE, however, patients at the highest risk of CV events (those with CHD or CHD risk-equivalent conditions, including diabetes) were least likely to meet accepted BP and/or LDL-C goals, in part because they were no more intensively treated than patients at lower risk. It was not clear whether submaximal goal attainment in certain higher-risk patients simply reflected more stringent target BP and LDL-C levels, whether these individuals were resistant to intensive therapy, or whether there was reluctance among physicians to titrate drug doses aggressively.

Accordingly we undertook the present post hoc analysis of the CAPABLE trial to examine the influence on BP and LDL-C goal attainment in high-risk patients, of (1) differing BP and LDL-C goals, (2) of diabetes and MS on resistance to goal attainment, and (3) of physician titration of the antihypertensive and lipid-lowering components of amlodipine/atorvastatin single-pill therapy.

METHODS

Study Design

The design of the CAPABLE trial has already been reported in detail.[16] CAPABLE was a 20-week, open-label, noncomparative, multicenter trial conducted between July 19, 2004, and August 9, 2005, among self-identified African American men and women (n=499) between 18 and 80 years of age with uncontrolled hypertension (treated or untreated), and dyslipidemia (treated or untreated).[16] Patients with type 1 diabetes were excluded.

Patients were classified as belonging to 1 of 3 CV risk groups (group 1, hypertension and dyslipidemia only; group 2, hypertension and dyslipidemia and $\geq$1 additional risk factor, excluding CHD or diabetes; and group 3, hypertension and dyslipidemia with CHD or CHD risk equivalent [diabetes or other atherosclerotic disease]) and corresponding treatment goals were based on criteria outlined in the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)[17] and the NCEP ATP III[4] guidelines. BP treatment targets were: group 1, <140/90 mm Hg, group 2, <140/90 mm Hg, and group 3, <130/80 mm Hg; and LDL-C treatment goals were: group 1, <160 mg/dL, group 2, <130 mg/dL, and group 3, <100 mg/dL. The protocol-stipulated BP target for the highest-risk group (group 3, <130/80 mm Hg) was that recommended in JNC 7 for patients with diabetes or chronic kidney disease, rather than for

Table I. Criteria Used to Define the Metabolic Syndrome[5]	
Measure	Categorical Cut Points
Elevated waist circumference	≥102 cm (≥40 inches) in men, ≥88 cm (≥35 inches) in women
Elevated triglycerides	≥150 mg/dL (1.7 mmol/L) or on drug treatment for elevated triglycerides
Reduced high-density lipoprotein cholesterol (HDL-C)	<40 mg/dL (1.03 mmol/L) in men, <50 mg/dL (1.3 mmol/L) in women or on drug treatment for reduced HDL-C
Elevated blood pressure (BP)	≥130 mm Hg systolic BP or ≥85 mm Hg diastolic BP or on antihypertensive drug treatment in a patient with a history of hypertension
Elevated fasting glucose	≥100 mg/dL[a] or on drug treatment for elevated glucose
[a]Includes fasting plasma glucose categories for type 2 diabetes mellitus and prediabetes, according to guidelines by the American Diabetes Association.[28]	

CHD,[17] but this target for hypertension in high-risk patients (with CHD or at high risk for CHD, including patients with MS) was recommended by the International Society for Hypertension in Blacks (ISHIB).[18] More recently the same BP target for CAD or CAD equivalent has been recommended by the AHA.[19] Although the relationships between on-treatment BP or LDL-C and CV outcomes have been less rigorously demonstrated for African Americans in prospective controlled trials, consensus guidelines focused on African Americans currently endorse the same targets for these patients.[18,20]

The protocol did not stipulate specific identification of, or therapy for, patients with MS, the presence of which was determined in this post hoc analysis.

Amlodipine/atorvastatin single-pill therapy was provided as 5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40, and 10/80 mg, and doses were titrated at the investigator's discretion, with the intent of achieving BP and LDL-C levels below the protocol-specified goals.[16] Additional antihypertensive therapy during the treatment phase was prohibited. Antihypertensive medications initiated prior to the trial could be continued, with the exception of single-pill amlodipine and/or other calcium channel blockers.

Of the 499 patients enrolled in the treatment phase of the main CAPABLE trial, 494 were included in this post hoc analysis. In 5 patients, data to determine MS status were not available. Patients included in the analysis were stratified into 4 groups, according to the absence or presence of MS or diabetes mellitus (DM) at baseline: −MS/−DM, +MS/−DM, −MS/+DM, and +MS/+DM. Diabetes was defined as having a diagnosis of type 2 diabetes and/or receiving treatment with antidiabetic medication. MS criteria were based on the AHA/NHLBI guidelines[5] and are shown in Table I. Patients were considered to have MS if they fulfilled 3 or more of the 5 criteria listed in Table I.

The main objective of this post hoc analysis was to determine the percentage of intention-to-treat patients in the 4 subgroups who reached JNC 7 BP and/or NCEP ATP III LDL-C goals at end point (week 20).

Safety and Tolerability

The definition and frequency of treatment-related adverse events in patients who took at least 1 dose of study medication and had at least 1 follow-up safety assessment have already been reported for the entire CAPABLE study cohort.[16] We further analyzed safety and tolerability according to the presence or absence of diabetes and of MS in the 494 patients eligible for inclusion in this subanalysis. The following safety cut-off values were used: creatine phosphokinase values >5× the upper limit of normal (ULN) and >10× ULN occurring (1) on 1 occasion and (2) persistently (≥2 consecutive measurements within a 14-day period); alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, alkaline phosphatase, and total bilirubin >3× ULN occurring (1) on 1 occasion, and (2) persistently (≥2 consecutive measurements within a 14-day period). These thresholds are in accordance with guidelines by the American College of Cardiology, the AHA, and the NHLBI.[21]

Statistical Analysis

CAPABLE was a noncomparative clinical utility study. Descriptive statistics on baseline demographics, percentage of patients reaching BP and/or LDL-C goals, mean dose of study medication, and patient safety data were summarized for the 4 −MS/−DM, +MS/−DM, −MS/+DM, +MS/+DM subgroups. Additionally, the study drug titration

Table II. Baseline Demographics

	−DM		+DM	
	−MS	+MS	−MS	+MS
Patient subgroups, No. (%)	165 (33.4)	160 (32.4)	34 (6.9)	135 (27.3)
Characteristics				
Male, No. (%)	85 (51.5)	61 (38.1)	28 (82.4)	60 (44.4)
Age, y, mean (SD)	53.2±11.0	55.0±11.1	59.1±10.5	57.5±10.0
Weight, kg, mean (SD)	89.7±20.4	100.3±21.7	85.8±19.9	100.7±21.2
Height, cm, mean (SD)	170.0±10.3	168.7±11.9	172.0±8.3	169.3±9.6
BMI, kg/m^2, mean (SD)	31.1±6.1	35.2±6.8	29.0±6.4	35.1±6.9
Waist circumference, cm, mean (SD)	96.5±16.8	109.2±14.9	87.0±21.7	108.6±16.4
No. of prior antihypertensives, mean (SD)	1.1±1.1	1.1±1.0	2.1±1.4	1.7±1.0
No. of concurrent antihypertensives, mean (SD)	1.0±1.0	1.0±1.0	1.8±1.1	1.6±0.9
Baseline measurements				
SBP, mm Hg, mean (SD)	146.8±11.8	150.3±11.7	143.0±12.2	145.6±10.8
DBP, mm Hg, mean (SD)	92.7±7.2	92.6±8.7	87.3±6.7	88.5±7.2
Fasting blood glucose, mg/dL, mean (SD)	90.3±7.8	102.7±26.1	133.3±44.8	140.8±52.7
LDL-C, mg/dL, mean (SD)	153.2±38.8	146.9±40.1	125.6±32.8	126.2±36.6
TC, mg/dL, mean (SD)	230.1±42.2	222.0±44.8	199.4±35.1	202.8±43.2
HDL-C, mg/dL, mean (SD)	58.1±13.0	48.5±10.9	56.9±13.2	49.4±12.4
Triglycerides, mg/dL, mean (SD)	94.1±40.1	133.3±60.4	84.7±37.7	136.8±93.5
VLDL, mg/dL, mean (SD)	18.8±8.0	26.7±12.1	16.9±7.6	25.6±14.6
Medical history				
CHD, No. (%)	13 (7.9)	15 (9.4)	5 (14.7)	19 (14.1)
Stroke, No. (%)	16 (9.7)	4 (2.5)	1 (2.9)	7 (5.2)
PVD, No. (%)	7 (4.2)	4 (2.5)	3 (8.8)	3 (2.2)

Abbreviations: BMI, body mass index; CHD, coronary heart disease; DBP, diastolic blood pressure; DM, diabetes mellitus; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; MS, metabolic syndrome; PVD, peripheral vascular disease; SBP, systolic blood pressure; SD, standard deviation; TC, total cholesterol; VLDL, very low-density lipoprotein.

pattern at each visit was summarized for those patients who did not reach corresponding BP/LDL-C goals. All analyses were performed on the intention-to-treat population.

In this analysis, because of differing LDL-C and BP goals between risk groups, particular attention was paid to the highest risk group (group 3), which contained all of the diabetic patients and most of those with MS, and in which all patients were treated to BP <130/80 mm Hg and LDL-C <100 mg/dL.

RESULTS

Baseline Demographics

Baseline demographic characteristics for the 494 patients included in this analysis are shown in Table II. Overall, 59.7% had MS and 34.2% of patients had diabetes. Of those patients with MS, 56.9% were in risk group 3; all patients with diabetes were in risk group 3. Overall, the mean age was 55 years, the mean body mass index was 33.4 kg/m^2, and 47% of patients were men. The following proportions of patients were in each of these 4 subgroups: −MS/−DM, 33.4%; +MS/−DM, 32.4%; −MS/+DM, 6.9%; and +MS/+DM, 27.3%. Mean baseline BP and LDL-C were lower in diabetic patients than in nondiabetic patients. Patients with diabetes were older and a higher proportion had a history of CHD compared with nondiabetic patients. The frequency of CHD was similar between patients with and without MS, therefore it is reasonable to infer that any differences in drug dosing or goal attainment between those with and without MS were not driven by imbalance in the prevalence of coexistent CHD. Patients with diabetes were receiving more prior or concurrent antihypertensive medications compared with nondiabetic patients. Discontinuation rates were higher among diabetic than among nondiabetic patients (Table III).

Goal Attainment

BP, LDL-C, and joint BP/LDL-C goal attainment for patients in CV risk group 3 are represented in Figure 1.

Table III. Discontinuations Among Participants in the Presence (+) and Absence (−) of the Metabolic Syndrome (MS) and Diabetes Mellitus (DM)

	−DM		+DM	
	−MS	+MS	−MS	+MS
Patient subgroups, No. (%)	165 (33.4)	160 (32.4)	34 (6.9)	135 (27.3)
Category				
Discontinuations, No. (%)	29 (17.6)	43 (26.9)	11 (32.4)	37 (27.4)
Related to study drug, No. (%)	5 (3.0)	6 (3.8)	2 (5.9)	12 (8.9)
Adverse event	2 (1.2)	3 (1.9)	2 (5.9)	8 (5.9)
Laboratory test abnormality	2 (1.2)	1 (0.6)	0 (0.0)	4 (3.0)
Lack of efficacy	1 (0.6)	2 (1.3)	0 (0.0)	0 (0.0)
Not related to study drug, No. (%)	24 (14.5)	37 (23.1)	9 (26.5)	25 (18.5)
Adverse event	1 (0.6)	3 (1.9)	1 (2.9)	4 (3.0)
Laboratory test abnormality	0 (0.0)	2 (1.3)	0 (0.0)	1 (0.7)
Patient defaulted	9 (5.5)	6 (3.8)	2 (5.9)	4 (3.0)
Other	14 (8.5)	26 (16.3)	6 (17.6)	16 (11.9)
Patients completing study, No. (%)	136 (82.4)	117 (73.1)	23 (67.6)	98 (72.6)

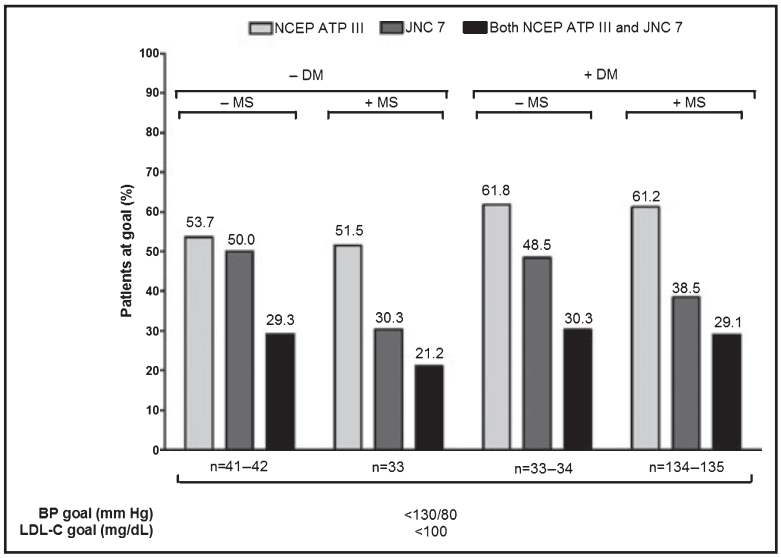

Figure 1. Blood pressure (BP) and low-density lipoprotein cholesterol (LDL-C) goal attainment by diabetes mellitus (DM) and/or the metabolic syndrome (MS) status in patients in risk group 3. JNC 7 indicates the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; NCEP ATP III, the National Cholesterol Education Program Adult Treatment Panel III.

Non–HDL-C goal attainment is recommended as a secondary therapeutic target of lipid-lowering therapy in patients with triglyceride levels ≥200 mg/dL.[16] However, in this post hoc analysis, only 44 of 494 patients (8.9%) had triglyceride levels ≥200 mg/dL at entry; accordingly, a detailed analysis of non–HDL-C goal attainment in each of the 4 subgroups was not conducted.

Influence of diabetes. In CV risk group 3, LDL-C goal (100 mg/dL) was attained 8% to 10% more often in diabetic vs nondiabetic patients, irrespective of the presence or absence of MS (Figure 1). This may simply reflect the fact that at baseline, nondiabetic patients were further from LDL-C goal than diabetic patients (Table II). In patients with MS, 8% more patients with diabetes attained their BP goals compared with nondiabetic patients. In those without MS, diabetes status was not associated with differences in BP control (Figure 1).

Influence of the MS. LDL-C control rates were not influenced by MS, irrespective of the presence or absence of diabetes (Figure 1). In contrast, attainment of BP goal was consistently impaired in patients with MS compared with those without. In

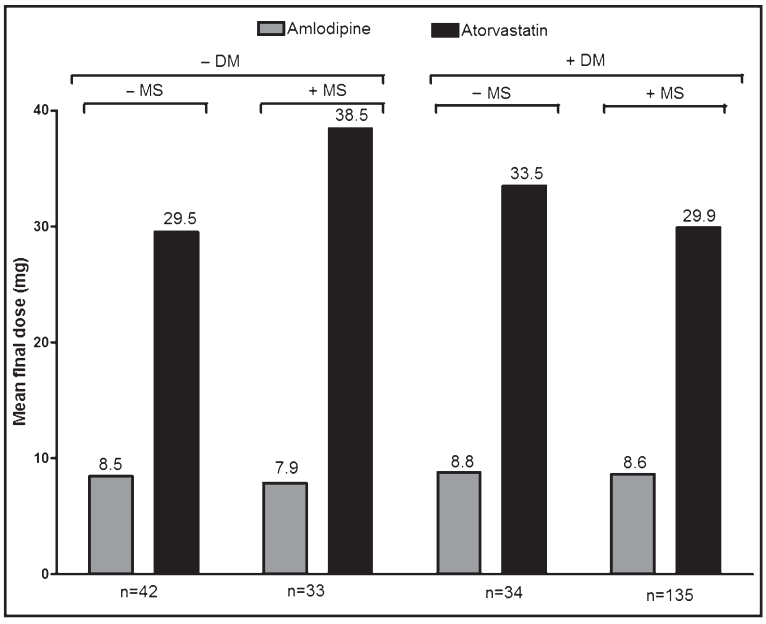

Figure 2. Mean final dose of amlodipine/atorvastatin single-pill therapy in patients in risk group 3 according to the metabolic syndrome (MS) and diabetes mellitus (DM) status.

those with MS compared with those without, BP goal was attained by 20% fewer nondiabetic and 10% fewer diabetic patients (Figure 1).

Mean Final Doses of Study Drug

At end point, the mean final dose of amlodipine in patients controlled for BP was 7.9 mg compared with uncontrolled patients who had a mean final dose of 8.7 mg. For atorvastatin, the mean final dose in patients controlled for LDL-C was 22.8 mg compared with 36.9 mg in patients who were uncontrolled. This trend for higher mean final doses in uncontrolled patients compared with those who were controlled was consistent across all 4 subgroups.

The mean final doses for patients in CV risk group 3 are shown in Figure 2. In patients without MS, the mean final dose of the atorvastatin component was higher in the diabetic vs the nondiabetic subgroups (33.5 vs 29.5 mg, respectively). In patients with MS, the mean final dose of atorvastatin was 29.9 mg in the diabetic subgroup vs 38.5 mg in the nondiabetic subgroup. The mean final dose of the amlodipine component ranged from 8 to 9 mg between subgroups and was unaffected by MS or diabetes (Figure 2).

Titration Analysis of Patients Not at Goal for BP and LDL-C by Diabetes and/or MS Status

Figure 3 examines physician titration behavior in patients with diabetes, with or without MS, who were not at goal for BP (Figure 3a) or LDL-C (Figure 3b) at each of a series of prespecified titration visits. Current BP levels were known at each visit; LDL-C for each index visit had been drawn at a titration visit 2 to 4 weeks beforehand.

For the amlodipine component, most patients were quickly titrated to the protocol-specified (and US Food and Drug Administration–approved) maximal dose of 10 mg (Figure 3a). By the final titration visit, at week 14, only 10% to 11% of diabetic patients remained on a submaximal dose (Figure 3a). In contrast, for the atorvastatin component, 61% to 75% of diabetic patients uncontrolled for LDL-C remained on a submaximal dose of atorvastatin at week 14 (Figure 3b).

Thirty-two of 169 diabetics (19%) remained uncontrolled for LDL-C at the final titration visit at week 14 (Figure 3b). Twenty-eight of these patients (88%) had both diabetes and MS; of these, 60.7% continued to receive suboptimal doses of atorvastatin through the end of the study.

Safety and Tolerability

The safety profile of amlodipine/atorvastatin single-pill therapy, including its effect on laboratory variables, was described in detail for the main trial.[16] In the present analysis, no differences in safety profile were observed between the 4 subgroups (−MS/−DM, +MS/−DM, −MS/+DM, and +MS/+DM).

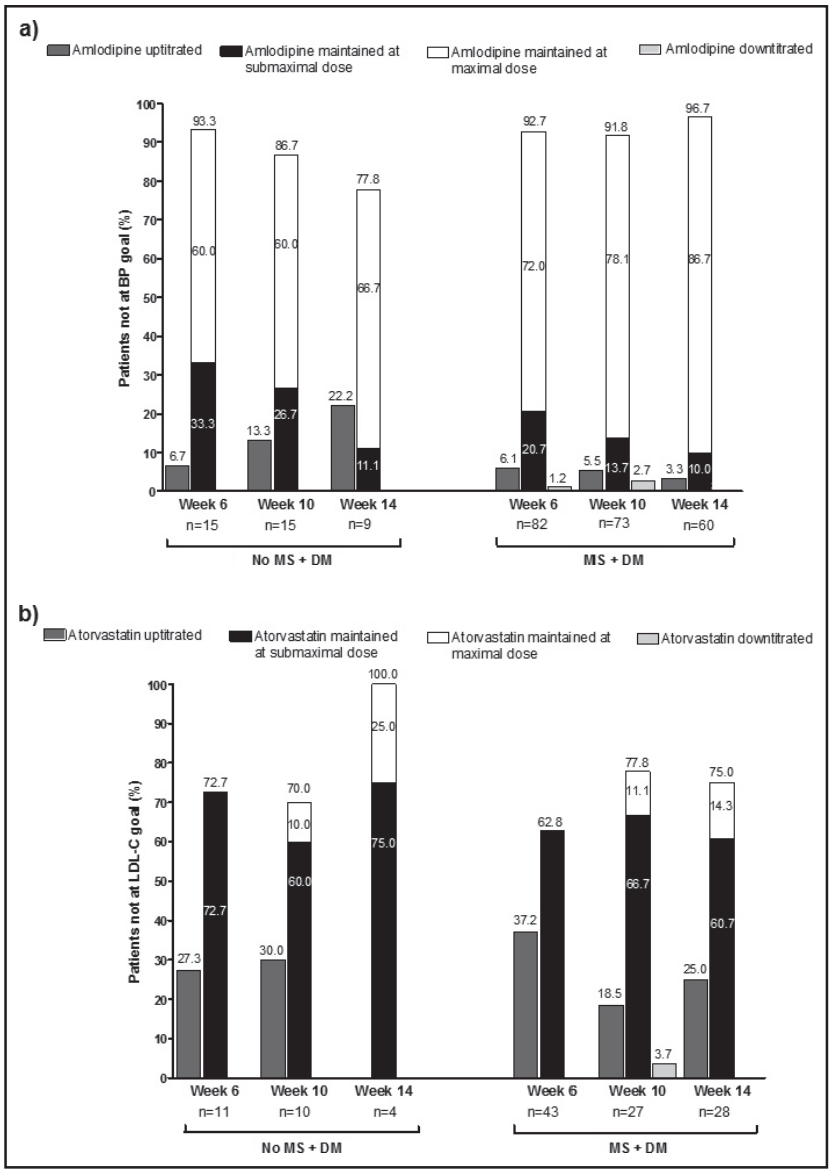

Figure 3. Titration patterns for patients with diabetes mellitus (DM) in the presence and absence of the metabolic syndrome (MS) and (A) not at goal for blood pressure (BP), and (B) not at goal for low-density lipoprotein cholesterol (LDL-C). (a) Patients were included in this analysis if they were not at goal for BP as assessed by BP readings taken by the physician at each titration visit and if information on study drug dose and titration pattern were available for that visit. (b) Patients were included in this analysis if they were not at goal for LDL-C based on the last available measurement of LDL-C, and if information on study drug dose and titration pattern was available for that titration visit.

DISCUSSION

We have previously shown, in a trial designed to approximate a "real-world" clinical setting, that amlodipine/atorvastatin single-pill therapy improves BP and LDL-C goal attainment and is well tolerated in African Americans.[16]

In the present analysis we have shown that fewer than two thirds of African American patients at high risk for CHD events reached the accepted LDL-C goal of <100 mg/dL. BP goal attainment (<130/80 mm Hg) was lower than LDL-C goal attainment, reflecting a protocol-stipulated restriction on additional antihypertensive therapy: only the amlodipine component of the study medication could be uptitrated (up to a maximum of 10 mg) in addition to baseline antihypertensive medication. Less than a third of patients in the present analysis reached their joint BP/LDL-C goals.

BP values were known to the physician at each visit; LDL-C values were available from the

previous visit, 2 to 4 weeks earlier. In clinical practice, shorter or longer delays between ordering LDL-C and any adjustment to statin therapy may occur. The results should be interpreted with this in mind.

Of those arguably at highest risk (those with diabetes and MS), only 61.2% reached LDL-C goal; of those in this subgroup who were uncontrolled, 60.7% were maintained on submaximal atorvastatin therapy (mean final dose: 29.9 mg vs maximum allowed 80 mg). In contrast, almost 90% of these patients received the maximal allowed dose of amlodipine (10 mg). The lack of uptitration of the statin component almost assuredly lowered the observed LDL-C control rates in this analysis. The reasons for the submaximal titration of the atorvastatin component are unclear. It does not seem to reflect intolerance to therapy, but perception of dose-dependent adverse events may be a critical factor. Atorvastatin was dosed more intensively in patients who were uncontrolled for LDL-C than in those who were, suggesting that factors such as inherent resistance to therapy and occult noncompliance may have operated. Nevertheless, two thirds of these patients remained on suboptimal doses of atorvastatin, suggesting a degree of clinical inertia.

Data from the 2001 to 2002 National Health and Nutrition Examination Survey (NHANES) indicated poorer joint control rates for hypertension and dyslipidemia than those observed in this analysis: a joint control rate of 6.5% in African American participants overall, and 16.3% in participants of any ethnicity with CVD plus DM or MS.[22] This compares with joint control rates ranging from 21% to 30% (depending on MS and/or DM status) in the African American patients at high risk of CHD reported here. In true real-world clinical practice, access and adherence issues limit goal attainment rates to an extent not seen in a clinical trial setting, and the lower NHANES control rates are likely a reflection of this.

Combination pill therapy may, in theory, influence patient compliance with that therapy in either direction. However, a recent large observational study has reported greater compliance in patients receiving amlodipine/atorvastatin single pill than in those receiving its individual components.[23] Similar findings have been reported for fixed-drug combinations used for hypertension.[24] It is reasonable to infer, therefore, that the use of a single-pill combination of amlodipine/atorvastatin in this study may have had a positive impact on the attainment of therapeutic BP and/or LDL-C goals.

Given the established benefits of atorvastatin therapy in the primary[25] and secondary prevention of CHD,[26] and in diabetes,[27] growing evidence in favor of lower-is-better therapy for both LDL-C and BP, together with the most recent recommendation of the American Diabetes Association[28] for an optimal LDL-C target of <70 mg/dL in patients with diabetes and overt CVD, these are clinically important findings that deserve further study and explanation.

A third of the African American patients included in this analysis had diabetes at baseline. Current diabetes guidelines recommend the use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers as initial antihypertensive therapy in diabetic patients.[28] However, most patients with hypertension—particularly those with diabetes (in whom BP targets are more stringent)—require additional antihypertensive drugs to attain treatment goals.[17,20] Dihydropyridine calcium channel blockers are recommended[20] and routinely used in these patients.

The presence of MS had no influence on LDL-C goal attainment, but was associated with poorer BP goal attainment in nondiabetics. ISHIB recommends more intensive therapy based on the presence of MS.[18] However, the emerging weight of epidemiologic evidence in favor of additional CV risk associated with MS suggests that this deserves further study in prospective outcomes trials.

CONCLUSIONS

African Americans, particularly those with diabetes mellitus combined with MS, have higher mortality from CHD than other ethnic/racial groups in the United States, and require intensive therapy to attain BP and LDL-C goals. Single-pill amlodipine/atorvastatin therapy has been shown to safely and appropriately target hypertension and dyslipidemia in African American patients. This subanalysis of the CAPABLE trial suggests that physicians may be reluctant to intensify lipid-lowering therapy—despite established efficacy and safety—in uncontrolled patients with diabetes and MS, to implement current evidence-based guidelines.

Disclosures: The authors would like to acknowledge the assistance of ***Dr Fiona Nitsche*** *of UBC Scientific Solutions (a medical writer funded by Pfizer Inc), for her contribution to the development of this paper. This study was supported by Pfizer Inc.* ***Dr Ferdinand*** *is a consultant or a member of the Speakers' Bureau for AstraZeneca, Merck, Pfizer Inc, NitroMed, Sanofi-Aventis, Bristol-Myers Squibb, and Novartis.* ***Dr Flack*** *receives grants/research support from Novartis, Pfizer Inc, Smith-Kline, Pharmacia, Astra Merck, AstraZeneca, CDC, and NIH; he acts as a consultant for Merck, Smith-Kline, Novartis, CVRX, Myogen, CDC, and*

NIH; and is on the Speakers' Bureau for Astra Merck. ***Dr Saunders*** *receives grants/research support from Pfizer Inc, Novartis, and Mylon; he acts as a consultant and is on the Speakers' Bureau for Pfizer, Novartis, Wyeth, King, and AstraZeneca.* ***Dr Victor*** *receives grants/research support from Pfizer Inc, Biovail, and the Aetna Foundation, and is also a consultant for Pfizer Inc, Novartis, and CVRx; he serves on the Speakers' Bureau for Pfizer Inc, and Merck.* ***Dr Watson*** *receives grants/research support from Pfizer Inc; she acts as a consultant and is on the Speakers' Bureau for AstraZeneca, Merck, Schering Plough, and Kos Pharmaceuticals.* ***Dr Kursun, Dr Jamieson,*** *and* ***Mr Shi*** *are employees of Pfizer Inc.*

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