Clin. Cardiol. 24, 66–72 (2001)

Combination Treatment with Telmisartan and Hydrochlorothiazide in Black Patients with Mild to Moderate Hypertension

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Summary

Background: Hydrochlorothiazide (HCTZ) is commonly used to treat black patients with hypertension. To avoid the metabolic disturbances associated with high-dose HCTZ, blood pressure control may be achieved by combining low doses with another antihypertensive.

Hypothesis: The study was undertaken to assess the tolerability and antihypertensive dose–response efficacy of telmisartan and HCTZ and their combination in black patients with mild to moderate hypertension (mean supine blood pressure 140/95–200/114 mmHg).

Methods: Following a 4-week, single-blind, placebo run-in period, 222 black patients were randomized to once-daily treatment with one of 20 different double-blind combinations of telmisartan (0, 20, 40, 80, 160 mg) and HCTZ (0, 6.25, 12.5, 25 mg) for 8 weeks. Blood pressure was measured at baseline and after 2, 4, and 8 weeks.

Results: Telmisartan 80 mg/HCTZ 12.5 mg reduced supine trough diastolic blood pressure (DBP)—primary efficacy parameter—by 13.3 mmHg, and supine trough systolic blood pressure (SBP) by 21.5 mmHg. These reductions represented benefits of 13.7/8.7 mmHg over telmisartan 80 mg and 12.3/8.1 mmHg over HCTZ 12.5 mg ($p < 0.01$). Telmisartan 40 mg/HCTZ 12.5 mg reduced supine trough SBP/DBP by 14.3/10.0 mmHg, amounting to 12.3/3.3 mmHg more than telmisartan 40 mg and 5.1/4.8 mmHg more than HCTZ 12.5 mg. This reached significance for the comparisons with telmisartan 40 mg for SBP and HCTZ 12.5 mg for DBP ($p \leq 0.05$). A response surface analysis and therapeutic response rates confirmed the additive antihypertensive effects of telmisartan and HCTZ. All treatments were well tolerated, with side-effect profiles comparable with placebo. Adverse events were mainly transient and of mild to moderate severity.

Conclusions: Telmisartan 80 mg combined with HCTZ 12.5 mg is effective and well tolerated in black patients with mild to moderate hypertension, providing greater antihypertensive activity than the corresponding monotherapies.

Key words: telmisartan, hydrochlorothiazide, hypertension, AT_1 receptor antagonist, combination therapy, blacks

Introduction

The prevalence of hypertension in the black (primarily African-American) population is among the highest in the world. Not only does hypertension tend to develop at a younger age in blacks than in non-blacks, but blacks also present with more severe (stage 3) forms of the disease, leading to a greater burden of target organ damage.[1,2]

Diuretics are currently the cornerstone of antihypertensive therapy in the black population.[1] Nevertheless, concern has been expressed over the adverse metabolic disturbances that are associated with the high doses of diuretics traditionally prescribed to black hypertensive patients.[3]

Hydrochlorothiazide (HCTZ), a benzothiadiazide diuretic, appears to be effective in patients with a low renin profile, such as black individuals,[4,5] and can augment the therapeutic response to other classes of antihypertensives.[6–8] However, as noted above, long-term HCTZ administration has the potential

This work was supported by a restricted grant from Boehringer Ingelheim Pharmaceuticals, Inc.

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Received: September 5, 2000
Accepted with revision: October 27, 2000

to cause dose-dependent metabolic disturbances, including hypokalemia.[9–11] The diuresis induced by HCTZ produces a reactive rise in plasma renin activity (PRA), which promotes urinary potassium excretion leading to serum potassium depletion. These effects are mediated by the renin-angiotensin-aldosterone system (RAAS), specifically angiotensin II. Combination with another antihypertensive agent allows lower doses of HCTZ to be used to achieve blood pressure control, and may blunt or reverse most of the adverse metabolic effects associated with diuretic use.[12]

Adverse metabolic effects notwithstanding, the efficacy of diuretics is limited largely by a reactive rise in angiotensin II; the pressor effects of angiotensin II may mask the full potency of the diuretic. Consequently, it may be postulated that combining an agent that inhibits the RAAS with a diuretic should produce a synergistic antihypertensive response, particularly in patients with low renin hypertension.

Telmisartan is a long-acting, oral angiotensin II type 1 (AT_1) receptor antagonist that exerts its antihypertensive efficacy through blockade of the RAAS.[13] Previous clinical studies have confirmed the sustained 24-h antihypertensive effects and placebo-like tolerability of once-daily telmisartan in patients with mild to moderate essential hypertension.[13–17] However, some evidence suggests that antihypertensive agents acting on the RAAS—angiotensin-converting enzyme (ACE) inhibitors and AT_1 antagonists—may be less effective in black patients than in Caucasians.[5, 18, 19] The low renin status of black individuals may be responsible for their relatively poor therapeutic response to these classes of antihypertensives.[20]

The current study had a two-fold rationale. First, angiotensin II receptor blockade with telmisartan would be expected to augment the antihypertensive efficacy of HCTZ by inhibiting reactive angiotensin II-mediated vasoconstriction. Second, since angiotensin II appears to mediate the potassium depletion associated with HCTZ treatment, the concomitant administration of telmisartan may be expected to prevent or attenuate this effect.

The benefits of combination therapy with telmisartan and HCTZ in the general population that are included in this study have already been reported.[21] The current paper focuses on the results of a prespecified subgroup analysis evaluating the antihypertensive efficacy, safety, and tolerability of dose combinations of HCTZ (6.25–25 mg) and telmisartan (20–160 mg) in black patients with mild to moderate hypertension.

Patients and Methods

Patient Selection and Study Design

This was a 47-center, randomized, double-blind, double-dummy, placebo-controlled, parallel group, 4 × 5 factorial comparison of telmisartan, HCTZ, or telmisartan/HCTZ combination therapy. Patients aged 18–80 years with mild to moderate hypertension (mean supine diastolic blood pressure [DBP] 95–114 mmHg; mean supine systolic blood pressure [SBP] 140–200 mmHg) who had given written informed consent were eligible for inclusion. Those with secondary hypertension, other significant cardiovascular disease, hepatic or renal impairment, sodium or potassium electrolyte imbalance, diabetes mellitus, retinal hemorrhage/exudate, drug or alcohol dependency, hypersensitivity to any component of the study formulations, previous exposure to telmisartan, or those on drugs prohibited in the protocol were excluded. Women who were pregnant or of childbearing potential were also ineligible.

Following a 4-week, single-blind, placebo run-in period, patients were randomized to 8 weeks of once-daily, double-blind treatment with placebo, telmisartan (20, 40, 80, or 160 mg), HCTZ (6.25, 12.5, or 25 mg), or one of 12 telmisartan/HCTZ combinations of these doses.

Efficacy Measurements

Supine SBP and DBP were measured throughout the placebo run-in period, after 2, 4, and 8 weeks of double-blind treatment, and 24 h after administration of the final dose of study medication. The primary efficacy parameter was the change in supine trough DBP (24 h post dose) between baseline and the last evaluable measurement during double-blind treatment. Secondary parameters included the changes from baseline in supine trough SBP and supine trough heart rate. Percentages of patients achieving a DBP response (supine trough DBP ≤ 90 mmHg and/or a ≥ 10 mmHg reduction from baseline) and an adequate SBP response (≥ 10 mmHg reduction in supine trough SBP) were also computed.

Safety Evaluations

Safety assessments included physical examinations, measurements of serum electrolytes and other laboratory parameters, 12-lead electrocardiograms (ECGs), blood pressure and heart rate monitoring, and evaluation of adverse events.

Statistical Methods

The possible difference in response of the black patient subgroup was prespecified in the protocol. The primary efficacy analysis was restricted to a 2 × 3 factorial arrangement comprising 118 patients in the following key treatment cells: telmisartan 40 mg, telmisartan 80 mg, HCTZ 12.5 mg, telmisartan 40 mg/HCTZ 12.5 mg, telmisartan 80 mg/HCTZ 12.5 mg, and placebo. The Global Average/MIN test was used to determine whether either or both of the combinations was more effective than its individual components at decreasing supine trough DBP from baseline after 8 weeks of treatment. With this study design and the prestated hypothesis of showing that either or both combinations was more effective, a one-sided, $\alpha = 0.05$ test is appropriate.[22, 23] A response surface analysis was conducted on the changes from baseline in supine blood pressure of patients from all 20 treatment groups.[24] Included in the statistical model for the response surface analysis was the covariate of baseline PRA. The DBP and SBP response rates were compared using the Mantel-Haenszel test.

Results

Patients

In all, 222 black patients were randomized and 198 patients completed the trial. Discontinuation was due mainly to adverse events (n = 8) and lack of efficacy (n = 6). The intent-to-treat (ITT) population included 219 patients (3 patients discontinued with no evaluable measurements of vital signs during the double-blind treatment period). The number of ITT black patients randomized to each treatment group is shown in Table I.

The median age of the black patients was 48 years (range 19–80 years) and 51% were men (Table II). Baseline PRA values were non-normally distributed. As expected, median PRA values were lower in blacks (0.3 ng/ml/h) than in non-blacks (0.7 ng/ml/h), but the range did not differ appreciably by race. Forty-three percent of patients had previously used diuretics, whereas drugs acting on the RAAS (ACE inhibitors and AT_1 receptor antagonists) had been used by only 25% of patients. No clinically relevant differences in baseline supine SBP, DBP, or heart rate were detected among the treatment groupings (Table II). Mean compliance to treatment, based on pill counts at each clinic visit, was > 99%.

Efficacy

The Global Average/MIN test indicated that, in the ITT population, at least one of the two key telmisartan/HCTZ combinations (telmisartan 80 mg/HCTZ 12.5 mg or telmisartan 40 mg/HCTZ 12.5 mg) was significantly superior to the respective monotherapies in terms of the effect on the primary efficacy parameter, supine trough DBP, after 8 weeks of treatment.

The telmisartan 80 mg/HCTZ 12.5 mg combination reduced supine trough DBP from baseline by 13.3 mmHg. This amounted to a benefit of 8.7 mmHg over the reduction in supine trough DBP with telmisartan 80 mg monotherapy and of 8.1 mmHg over the reduction with HCTZ 12.5 mg mono-

TABLE I Number of black patients randomized to each treatment group

	Number of patients, n				
	Telmisartan				
	0 mg	20 mg	40 mg	80 mg	160 mg
HCTZ 0 mg	**18**	7	**20**	**22**	10
HCTZ 6.25 mg	4	8	5	5	8
HCTZ 12.5 mg	**20**	5	**16**	**22**	10
HCTZ 25 mg	8	8	8	9	9

Figures in bold represent the 118 patients randomized to each of the six key treatment groups. Three randomized patients (one each in the HCTZ 12.5 mg, HCTZ 25 mg, and telmisartan 20 mg/HCTZ 12.5 mg groups) had no postrandomization trough blood pressure measurements and were excluded from the intent-to-treat analysis population.

TABLE II Baseline demographic characteristics of black patients randomized to placebo, telmisartan (20–160 mg), HCTZ (6.25–25 mg), or telmisartan/HCTZ combination therapy

	Treatment grouping				
	Placebo	Telmisartan	HCTZ	Telmisartan/HCTZ	All groups
No. of patients	18	59	32	113	222
Age, years					
Median (interquartile range)	42.5 (15)	50 (16)	47 (16.5)	49 (15)	48 (15)
Min-max	35–69	20–72	19–68	24–80	19–80
Gender, n (%)					
Men	9 (50)	31 (52.5)	18 (56.3)	56 (49.6)	114 (51.4)
Women	9 (50)	28 (47.5)	14 (43.8)	57 (50.4)	108 (48.6)
BMI, kg/m^2					
Median (interquartile range)	30.4 (10.4)	28.9 (8.9)	30.3 (8.1)	29.9 (6.3)	29.8 (7.6)
Supine vital signs [a], mean ± SD					
No. of patients	18	59	30	112	219
SBP, mmHg	150.4 ± 9.7	155.1 ± 13.3	154.8 ± 13.1	155.0 ± 12.5	154.6 ± 12.6
DBP, mmHg	101.2 ± 3.9	101.0 ± 4.1	101.7 ± 5.1	101.5 ± 4.7	101.4 ± 4.5
Heart rate, beats/min	75.2 ± 10.0	70.0 ± 8.6	71.6 ± 9.3	70.5 ± 8.1	70.9 ± 8.6
PRA [a], ng/ml/h					
No. of patients	15	55	28	101	199
Median (interquartile range)	0.3	0.3	0.3	0.3	0.3
Min-max	0.0–2.2	0.0–8.7	0.0–1.5	0.0–8.6	0.0–8.7

[a] Mean data on vital signs and PRA were calculated from patients in the intent-to-treat population.

Abbreviations: BMI = body mass index, SBP = systolic blood pressure, DBP = diastolic blood pressure, PRA = plasma renin activity, HCTZ = hydrochlorothiazide.

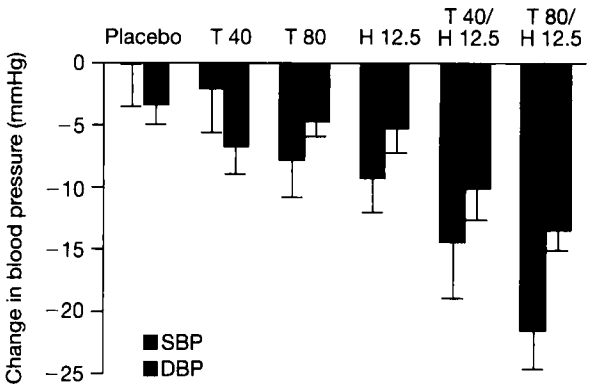

FIG. 1 Observed mean changes (± SE) from baseline in supine trough systolic blood pressure (SBP) and diastolic blood pressure (DBP) in black patients in the six key treatment groups at last observation (intent-to-treat population). T = telmisartan, H = HCTZ.

therapy ($p < 0.01$) (Fig. 1). The reductions in supine trough DBP for telmisartan 80 mg and HCTZ 12.5 mg monotherapies compared with placebo were small—< 2 mmHg—and not statistically superior to placebo. This finding suggests a synergistic or "super-additive" effect of the telmisartan 80 mg/HCTZ 12.5 mg combination on DBP in black patients (Table III).

Similarly, as shown in Figure 1, the reduction in supine trough SBP with the telmisartan 80 mg/HCTZ 12.5 mg combination (21.5 mmHg) was significantly greater than the reductions achieved with either telmisartan 80 mg (7.8 mmHg) or HCTZ 12.5 mg (9.2 mmHg) alone ($p < 0.01$). Both monotherapies produced statistically greater reductions in supine trough SBP than placebo: the placebo-adjusted reduction was 7.7 mmHg for telmisartan 80 mg monotherapy and 9.1 mmHg for HCTZ 12.5 mg monotherapy ($p \leq 0.05$ for both comparisons vs. placebo) (Table III). Therefore, the decrease of 21.5 mmHg in supine SBP achieved with telmisartan 80 mg/HCTZ 12.5 mg treatment compared with the decreases achieved with the respective monotherapies suggests a synergistic or super-additive effect of this combination on SBP in black patients.

The telmisartan 40 mg/HCTZ 12.5 mg combination reduced supine trough blood pressure (SBP/DBP) by 14.3/10.0 mmHg, representing a benefit of 12.3/3.3 mmHg over telmisartan 40 mg and 5.1/4.8 mmHg over HCTZ 12.5 mg. This difference was statistically significant only for comparison of the combination with telmisartan 40 mg monotherapy for SBP ($p \leq 0.01$) and with HCTZ 12.5 mg monotherapy for DBP ($p = 0.05$) (Table III). None of the treatments produced any clinically relevant changes in heart rate.

Response Surface Analysis

A response surface analysis using a full quadratic model and including the covariates of baseline blood pressure and baseline PRA was performed to characterize further the changes in supine trough blood pressure in all 20 treatment groups. The model was a reasonable fit to the data both for supine trough DBP and SBP.

The response surface analysis indicated a potential additive effect of telmisartan/HCTZ combination therapy on both SBP and DBP in black patients, such that the combinations provided greater blood pressure reductions than either agent alone (Fig. 2). The telmisartan 160 mg/HCTZ 25 mg combination produced the most pronounced antihypertensive effect, decreasing supine trough SBP/DBP by 26.4/16.7 mmHg.

Telmisartan as monotherapy exhibited a shallow dose–response relationship in black patients, with some blunting at higher doses. This amounted to differentials between the 20 and 160 mg doses of 6.0 and 2.4 mmHg for the reduction in adjusted supine trough SBP and DBP, respectively. In contrast, HCTZ showed a clear dose–response relationship over the dose range 6.25–25 mg, amounting to differentials of 18.8 mmHg for the reduction in adjusted supine trough SBP and 10.7 mmHg for the reduction in adjusted supine trough DBP.

Therapeutic Response Rates

The proportions of patients achieving a DBP response (supine trough DBP ≤ 90 mmHg and/or a ≥ 10 mmHg reduc-

TABLE III Treatment differences in mean changes from baseline in supine trough SBP and DBP in intent-to-treat patients in the six key treatment groups

Treatment difference	Difference in SBP reduction (mmHg)	Difference in DBP reduction (mmHg)
Telmisartan 40 mg minus placebo	−1.9	−3.3
Telmisartan 80 mg minus placebo	−7.7[a]	−1.2
HCTZ 12.5 mg minus placebo	−9.1[a]	−1.8
Telmisartan 40 mg/HCTZ 12.5 mg minus telmisartan 40 mg	−12.3[b]	−3.3
Telmisartan 40 mg/HCTZ 12.5 mg minus HCTZ 12.5 mg	−5.1	−4.8[a]
Telmisartan 80 mg/HCTZ 12.5 mg minus telmisartan 80 mg	−13.7[b]	−8.7[b]
Telmisartan 80 mg/HCTZ 12.5 mg minus HCTZ 12.5 mg	−12.3[b]	−8.1[b]

[a] $p \leq 0.05$.

[b] $p \leq 0.01$ (one-sided test). Actual reductions are shown in Figure 1.

Abbreviations as in Table I.

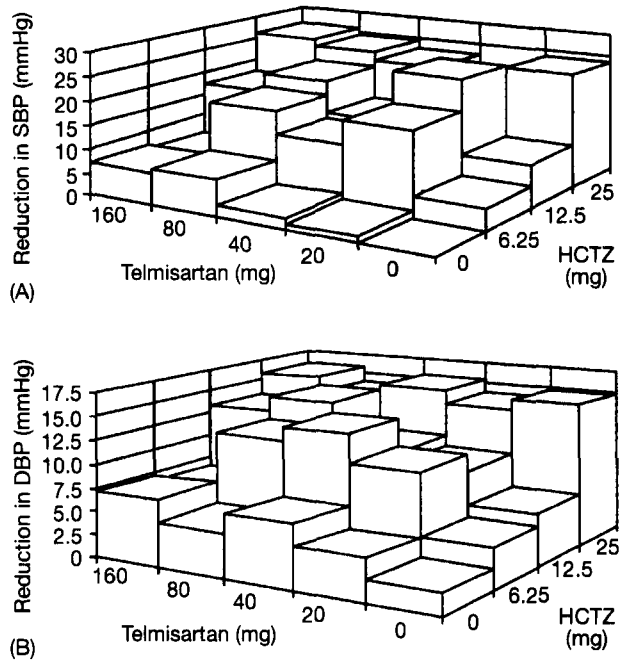

FIG. 2 Response surface analysis of mean reductions in (a) supine trough systolic blood pressure (SBP) and (b) supine trough diastolic blood pressure (DBP) in black patients for each of the 20 treatment groups, adjusted for baseline blood pressure and plasma resin activity (intent-to-treat population).

tion from baseline) or an adequate SBP response (≥ 10 mmHg reduction from baseline in trough SBP) after 8 weeks of double-blind treatment was greater in the telmisartan 80 mg/HCTZ 12.5 mg and telmisartan 40 mg/HCTZ 12.5 mg treatment groups compared with each of the individual components (Table IV). These benefits over monotherapy were statistically significant only for the telmisartan 80 mg/HCTZ 12.5 mg combination ($p \leq 0.05$). Response rates for DBP and SBP with each of the monotherapies in the key treatment groups were higher than for placebo (Table IV).

TABLE IV Proportions of intent-to-treat patients in the six key treatment groups achieving a diastolic or systolic blood pressure response

	DBP response (%)	SBP response (%)
Placebo	28	28
HCTZ 12.5 mg	32	42
Telmisartan 40 mg	45	35
Telmisartan 80 mg	36	36
Telmisartan 40 mg/HCTZ 12.5 mg	56	69
Telmisartan 80 mg/HCTZ 12.5 mg	73[a]	77[a]

Diastolic blood pressure (DBP) response: supine trough DBP ≤ 90 mmHg and/or a ≥ 10 mmHg reduction from baseline; adequate systolic blood pressure (SBP) response: ≥ 10 mmHg reduction from baseline in supine trough SBP.

[a] $p \leq 0.05$ for the combination vs. both monotherapies (Mantel-Haenszel test).

Serum Potassium

Changes in serum potassium levels in black patients varied widely across the treatment groups, with no consistent pattern, ranging from -0.344 ± 0.347 mEq/l with telmisartan 80 mg/HCTZ 25 mg to 0.163 ± 0.505 mEq/l with telmisartan 80 mg.

Safety Parameters

In general, all active treatments were well tolerated, with adverse events being mainly of mild to moderate severity and transient in duration. Similar proportions of patients in each of the key treatment groups reported adverse events: 44.4% (8/18) with placebo, 45.0% (9/20) with HCTZ 12.5 mg, 30.0% (6/20) with telmisartan 40 mg, 40.9% (9/22) with telmisartan 80 mg, 37.5% (6/16) with telmisartan 40 mg/HCTZ 12.5 mg, and 63.6% (14/22) with telmisartan 80 mg/HCTZ 12.5 mg. The adverse events experienced most frequently are listed in Table V, and were consistent with the low incidence of adverse events previously observed with telmisartan. In addition, the adverse events reported in this prespecified population of black patients were similar to those seen in the overall study population. Only one patient in the six key treatment groups experienced hypokalemia; this patient had been treated with telmisartan 80 mg/HCTZ 12.5 mg.

Eight of the 222 randomized patients (3.6%) discontinued the study prematurely because of adverse events. These patients were dispersed among different treatment groups and the adverse events were of various types. No angioedema or deaths occurred during the study.

Discussion

The findings reported in the current study indicate that telmisartan in combination with HCTZ produces clinically and statistically significant reductions in blood pressure in black patients with mild to moderate hypertension. After 8 weeks of treatment, the telmisartan 80 mg/HCTZ 12.5 mg combination reduced supine trough SBP/DBP by 21.5/13.3 mmHg compared with a placebo reduction of 0.1/3.4 mmHg. The magnitude of this reduction in black patients was similar to that seen in the total population with the telmisartan 80 mg/HCTZ 12.5 mg combination (23.9/14.9 mmHg).[21] Furthermore, 73% of black patients receiving the telmisartan 80 mg/HCTZ 12.5 mg combination had a DBP response compared with 28% on placebo. Thus, the combination of telmisartan 80 mg and HCTZ 12.5 mg was efficacious in this prespecified subgroup of black patients.

Telmisartan 40 mg/HCTZ 12.5 mg also produced substantial reductions in blood pressure, amounting to 14.3 mmHg in SBP and 10.0 mmHg in DBP. These were greater than the reductions achieved with either of the constituent agents administered as monotherapy. However, the differences in blood pressure reductions only reached statistical significance for

TABLE V Adverse events occurring at an incidence ≤ 2% in all patients treated in the six key treatment groups

Adverse events, n	Placebo (n = 18)	HCTZ 12.5 mg (n = 20)	Telmisartan 40 mg (n = 20)	Telmisartan 80 mg (n = 22)	Telmisartan 40 mg/HCTZ 12.5 mg (n = 16)	Telmisartan 80 mg/HCTZ 12.5 mg (n = 22)	Total (n = 118) (%)
Headache	5	4	2	2	0	3	16 (13.6)
URTI symptoms	1	3	1	3	2	5	15 (12.7)
Aches/pains	1	1	0	2	0	3	7 (5.9)
Dizziness/hypotension	0	2	2	0	1	2	7 (5.9)
Urinary tract infection	1	0	1	3	1	0	6 (5.1)
Dyspepsia/GI symptoms	0	1	1	2	0	0	4 (3.4)
Edema	0	1	2	0	1	0	4 (3.4)
Fatigue, etc.	0	1	0	0	1	1	3 (2.5)
Leg cramps/pains	2	0	0	1	0	0	3 (2.5)
Miscellaneous	1	5	3	4	1	6	20 (6.9)
Total events [a]	11	18	12	17	7	20	85

[a] Patients may have had more than one adverse event.

Abbreviations: URTI = upper respiratory tract infection, HCTZ = hydrochlorothiazide, GI = gastrointestinal.

comparison of this combination with telmisartan 40 mg for SBP and HCTZ 12.5 mg for DBP.

As expected, telmisartan monotherapy produced minimal blood pressure-lowering responses in black patients. This racial difference in antihypertensive efficacy with telmisartan is consistent with previous observations involving other AT_1 antagonists, such as losartan[25,26] and may be attributable to the lower baseline PRA levels among black individuals. Indeed, it is well recognized that baseline PRA is a good predictor of the response to drugs acting on the RAAS, and that black individuals tend to have a lower degree of RAAS activation than non-black individuals.[5,20,27] Patients with low and medium renin profiles are more likely to respond to diuretics, while patients with medium and high renin profiles are more likely to respond to drugs acting on the RAAS.[5] This is reflected in the current study by the finding that a higher proportion of black patients (43%) had received diuretics in the month preceding the study compared with the overall population (28%).

As confirmed by the response surface analysis, the co-administration of HCTZ and telmisartan produced additive—and potentially synergistic—SBP and DBP reductions in black hypertensive patients. By inhibiting the pressor effects of angiotensin II, telmisartan conceptually offset the HCTZ-induced upregulation of the RAAS, thereby allowing the full antihypertensive potency of the diuretic to be realized at a dose (12.5 mg) that was not associated with adverse metabolic disturbances. Similar benefits of HCTZ add-on therapy have been observed with eprosartan in black hypertensive patients.[28]

Telmisartan alone and in combination with HCTZ was, in general, safe and well tolerated. No dose-related side effects were observed, and the incidence of adverse events and rates of discontinuation were comparable among treatment groups. Such placebo-like tolerability is liable to promote patient compliance to antihypertensive therapy, thereby improving blood pressure control and clinical outcome.

Available evidence indicates that antihypertensive therapy can produce similar blood pressure reductions in blacks as in Caucasians and reduce the incidence of associated cardiovascular disease.[29,30] Given the increased prevalence of stage 3 hypertension and the elevated risk of hypertensive complications in black patients,[1] one could even speculate that the absolute clinical benefits of antihypertensive therapy would be higher in this racial subgroup than in the general population.

Conclusion

The current study has shown that once-daily treatment with a combination of telmisartan 80 mg and HCTZ 12.5 mg represents a safe and effective antihypertensive therapy for black patients with mild to moderate hypertension, providing similar reductions in SBP and DBP to the overall study population. Consequently, telmisartan/HCTZ may be regarded as an appropriate therapeutic option for first-line treatment of black patients with hypertension.

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