Comparative study of telmisartan and amlodipine to assess the effect on blood pressure, lipid profile and blood glucose level in Indian hypertensive patients

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Abstract

Introduction: Hypertension is emerging as a major health problem and while treating a patient with hypertension it is not only necessary to control blood pressure but also treat the associated risk factors which lead to metabolic syndrome. Methods: A randomized comparative study was designed to evaluate the effect of telmisartan on blood pressure (BP), lipid profile and blood glucose levels in hypertensive patients. This was compared with amlodipine with 1:1 randomisation. BP>140mm Hg (systolic) and >90mm Hg (diastolic) as well as body mass index (BMI) was taken in consideration. Blood sugar levels, lipid profile and urine samples were collected for protein and sugar. These samples were collected at baseline (first visit) and after 6 months. **Results:** The mean value of systolic BP in telmisartan group decreased from baseline by 17.43% (p<0.001) and 13.79% in diastolic BP (p<0.001). On comparing with amlodipine, telmisartan reduced mean systolic BP significantly more by 8.42% (p<0.001) and 5.59% (p<0.001) in diastolic BP. The mean fasting sugar level in patients with telmisartan group after 6 months was 100.70mg% which decreased by 10.27% (p<0.01) from baseline The effect of post prandial sugar level in telmisartan group was a reduction of 5.57mg% from baseline (p<0.001). There was significant reduction in mean value of urinary protein from 160.22mg% to 92.22 mg% (p<0.001). Conclusion: Besides significant reduction in BP, telmisartan also had beneficial effects on various metabolic parameters, where amlodipine was not effective. The salutary effects of telmisartan on the metabolic profile may be additional attribute beyond its established antihypertensive effect.

Key words: Telmisartan, Amlodipine, Metabolic syndrome, Hypertension, Blood pressure.

Introduction

Increasing prevalence of hypertension is emerging as a major health problem all over the world. At a very conservative estimate of hypertension prevalence in India is of 20% in urban and 10% in rural population, we have 89 million hypertensives in India [1]. Metabolic syndrome is defined by a constellation of interconnected physiological, biochemical, clinical and metabolic factors that directly increases the risk of cardiovascular disease, type 2 diabetes mellitus, and all cause mortality [2].

Manuscript received 14th August 2016 Reviewed: 24th August 2016 Author Corrected: 8th September 2016 Accepted for Publication 20th September 2016 The benefits of treating hypertension have been proved beyond doubt. Antihypertensive therapy is associated with reductions in incidence of stroke by 35% - 40%, myocardial infarction by 20% - 25% and heart failure by more than 50% [3].

Thus, it appears that while treating a patient with hypertension it is not only necessary to control blood pressure (BP) but also simultaneously to treat these associated risk factors as well. The Saga Telmisartan Aggressive Research (STAR) trial as well as many other studies, claimed that telmisartan also possesses lipid as well as glucose lowering properties. The

comparison of telmisartan and amlodipine with regards to effects on these properties, have not been done previously in the literature [4-6].

Material and Methods

The present study is a randomized comparative study, designed to evaluate the effect of telmisartan on blood pressure (BP), lipid profile and blood glucose levels (BGL) in patients with hypertension irrespective of baseline medications being taken.

This effect was compared with amlodipine with 1:1 randomisation. The objective was to assess the BP and metabolic effects of telmisartan in Indian hypertensive population.

The present study was conducted over a period of one academic year in Baba Raghav Das Medical College and associated Nehru Chikitsalaya, Gorakhpur after approval of the ethical committee. Inclusion criteria were age ≥40 years, BP ≥140mm Hg systolic and ≥90mm Hg diastolic. This inclusion criterion was followed irrespective of medications the patient has been taking.

Any patient taking other Angiotensin receptor blockers, having serum creatinine >3 mg% or creatinine clearance <30ml / minute, severe cardiac or cerebrovascular complications, clinically relevant hyperkalemia, bilateral renal artery stenosis or single renal artery stenosis in a solitary kidney was excluded from the study. Pregnant females were also excluded.

The following parameters were observed at the time of entry:

1. BP>140mm Hg (systolic) and >90mm Hg (diastolic) irrespective of symptoms.

2.General and systemic examination were done including measurements of body weight, height and body mass index (BMI).

Fasting (minimum 12 hours) venous blood samples (10ml) were obtained for laboratory evaluation of hematology and clinical chemistry parameters including total cholesterol, Low density lipoprotein cholesterol (LDL-C), High density lipoprotein cholesterol (HDL-C), triglycerides (TG) and glucose.

Other routine blood investigations like blood samples were obtained for laboratory evaluation of postprandial sugar level. Simultaneously urine samples were collected for biochemical analysis of protein and sugar. These samples were collected at baseline (first visit) and after 6 months.

An autoanalyser was used to assay plasma glucose using the hexokinase method, plasma triglycerides using glycerol-3-phopshate-oxidase p-aminophenazone mehod, HDL-C using immunoinhibition. LDL-C was calculated using the Friedewald formula:- LDL-C=TC-[HDL-C+TG/5].

Biochemical analysis was done for urinary protein by sulphosalicylic acid method and for sugar by Benedict's method. BP measurements were taken at baseline (at first visit), at regular follow-up visits and after 6 months treatment using cuff sphygmanometry.

Data were collected at baseline and 6 months after the initiation of therapy. Results were reported as mean \pm SD and percentage were calculated. The difference between two means or the reduction in the mean among two group values were compared by Z test and p value < 0.05 was taken as significant.

Results

The demographic characteristics including the pretreatment values of various study variables of the patients were noted (Table 1). No significant difference was observed in both the groups.

Larger numbers of patients (24 out of 65) dropped out for some reasons compared with Telmisartan group (7 out of 65).

The drop out were not due to drug inefficacy or side effects as inquired by the patients on telephone. In Telmisartan group, the drugs was given as a new isolated prescription in 36 and in rest 22 cases as add on. In Amlodipine group, these figures were 29 and 12 respectively.

Number of patients enrolled in Telmisartan group were 58 with mean age 61.48 years of which, 36 (62.06%) were males and 22 (37.93%) females. The total number of patients included in Amlodipine therapy was 41 with mean of 58.34 years. Among them, 28 (68.29%) were males and 13 females (31.70%).

Table-1: Patients baseline characteristics.

	Values in telmisartan group	Values in amlodipine group	p value
Number of patients	58	41	
Male	36	28	
Female	22	13	
Age (years)	61.48±9.80	58.34±10.49	>0.05
BMI (kg/m²)	25.35±4.43	26.48±5.89	>0.05
Systolic BP (mm Hg)	157.93±16.38	155.12±18.57	>0.05
Diastolic BP (mm Hg)	98.41±16.88	100.09±16.67	>0.05
Total Cholesterol (mg%)	184.91±27.66	177.70±25.87	>0.05
LDL-C (mg%)	121.41±26.91	115.17±29.28	>0.05
Triglycerides (mg%)	160.0±16.67	157.97±26.84	>0.05
Fasting sugar level (mg%)	112.23±20.41	111.07±24.34	>0.05
Post prandial sugar level (mg%)	140.37±18.52	146.60±28.99	>0.05
Diabetes	7	6	
Nephropathy	5	4	
Impaired sugar level	8	8	

The mean body mass index (BMI) in telmisartan group patients was 26.48kg/m². Maximum number of patients were in overweight category (n=27, 46.55%). The number of patients having normal BMI was 17. The numbers of obese patients were 9 male patients. The underweight patients were only 5.

The mean BMI in amlodipine group was 26kg/m2 in males and 26.34kg/m2 in females. Normal BMI and overweight patients were almost same being 17 and 18 respectively. Only 3 male patients in this group included in the obese category.

Out of all 99 patients, 13 were diabetic, comprising 8 males and 5 females. Eight cases were newly diagnosed in the study and the rest were old cases with diabetes. Besides, 4 of the diabetic patient had nephropathy. Impaired glucose levels were seen in 16 patients, of which 9 had impaired fasting sugar level whereas 7 had impaired glucose tolerance (IGT).

Effect of Telmisartan- The mean value of systolic BP in Telmisartan group before therapy was 157mm Hg. In 20 patients systolic BP was \geq 160mm Hg. After 6 months, the value was 130.4mm Hg with more than $2/3^{rd}$ patients achieving their goal below 140mm Hg. The reduction in total mean value was 17.43% with p value < 0.001.

The mean value of diastolic BP before therapy was 98.41 ± 16.88 mm Hg with maximum number of patients (n=28) having value>100mm Hg. After 6 months, the mean value was 84.84 ± 11.67 mm Hg with change in reduction being 13.78% (p value<0.001). Most of the patients (n=50, 82%) achieved their goal <90mm Hg. (Table 2).

Before therapy mean fasting blood sugar (FBS) level was 112.23mg% with 5 patients had value between 110-126mg% (impaired FBS level). After 6 months therapy, the mean level came down to 100.70±22.32mg% with reduction being 11.53% (p value<0.05).

At the entry of the study post prandial blood sugar(PPBS) level was 140.37 ± 18.52 mg% with 3 patients having value between 140-200(IGT). After 6 months, total mean value came down to 132.55 ± 16.08 mg% with change in reduction being 7.82% (p value<0.05). (Table 2).

The mean total cholesterol level at entry was 184.91±27.66mg%. Maximum patients (n=36) had level below <199mg% while only 9 patients had value in range of 199-238 (borderline high). Only 3 patients had value in high range (>240mg%).

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Table-2: Effect of telmisartan (on Blood Pressure (BP). Blood	l sugar level and Lipid profile level.

Total number of patients	BP Before therapy	BP After 6 months therapy	Change	p value
(n=58)	Mean±SD	Mean±SD	(%) in mean	
	(mm Hg)	(mm Hg)		
Systolic BP	157.93±16.38	130.40±20.22	-17.43	< 0.001
Diastolic BP	98.41±16.88	84.84±11.67	-13.79	< 0.001
Total number of patients	Blood Sugar level	Blood Sugar level	Change	p value
(n=58)	Before therapy	After 6 months therapy	(%) in mean	
	Mean±SD	Mean±SD		
	(mg%)	(mg%)		
Fasting sugar level	112.23±20.41	100.70±22.32	-10.27	< 0.001
Post prandial sugar level	140.37±18.52	132.55±16.08	-5.57	< 0.001
Lipid profile (n=58)	Before therapy	After 6 months therapy	Change	p value
	Mean±SD	Mean±SD	(%) in mean	
	(mg%)	(mg%)		
Total Cholesterol	184.91±27.66	160.9±12.76	-12.98	< 0.001
HDL-C	45.32±4.80	45.06±4.45	+0.57	>0.05
LDL-C	121.41±26.91	101.25±10.59	-16.60	< 0.001
Triglyceride level	160.0 ±16.67	152.12±18.67	-4.92	< 0.01

After therapy, total mean came down to 160.9±12.76mg% with change in reduction being12.98%. No value was in the high range and only 3 patients were borderline high. Level of HDL-C before therapy was 45.32±4.8mg% while after 6 months, it was 45.06±4.45mg%. The change was 0.57% which was not statistically significant. Total mean value of low density cholesterol before therapy was 121.41±26.91mg%. Only 10 patients had value in high range,159-188mg%. After 6 months of Telmisartan therapy, mean value was 101.25±10.59mg%. Maximum number of patients (n=32) had triglyceride level in borderline high range149-198mg%, while in the rest it was in the desirable level of <150mg% with mean value of 130.9±10.82mg%. After 6 months, total mean value was 152.12±18.67mg% with change in reduction being 4.92%. (Table-2)

Effect of Amlodipine

Systolic BP in this group in the beginning was 155.12mm Hg. At the end of the study more than $2/3^{rd}$ patients (n=30) achieved their goal below 140mm Hg, while the rest had range in between 141-150mm Hg. Total mean value was 138.82 ± 16.51 mm Hg with change in reduction of 10.56% (p<0.001).

Diastolic BP in this group before therapy was 100.09mm Hg. After 6 months, treatment total mean of diastolic BP was 90.43 ± 14.76 mm Hg with more than $2/3^{rd}$ (n=26) achieving their target value of <90mm Hg. The total change in reduction was about 9.65% with p value<0.001. (Table-8)

Before therapy, mean FBS level was 111.07mg% which came down to 109.36mg% with change in reduction being 1.54% after 6 months of therapy (Table 3). Before therapy mean PPBS level was 146.60mg% which came down to 144.29mg% with change in reduction being 1.58% after 6 months of therapy. (Table-3)

Before therapy, mean value for total cholesterol was 177.70mg% while after 6 months, these values came down to 174.7mg% with change in reduction being 1.68%.

The difference was not statistically significant. The LDL-C values were 115.17mg% and 118.73mg%, before and after therapy respectively.

The mean value of triglyceride level was 157.97mg% before therapy and 160.0mg% after therapy. There was negligible changes in HDL-C levels. The p value for all of the above changes during studies, were not significant (>0.05). (Table-3)

Table-3: Effect of amlodi	pine on Blood Pressure (B	P). Blood sugar le	vel and lipid profile.
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Total number of patients	BP Before therapy	BP After 6 months therapy	Change	p value
(n=41)	Mean±SD	Mean±SD	(%) in mean	
	(mm Hg)	(mm Hg)		
Systolic BP	155.21±18.57	138.82±16.51	-10.56	< 0.001
Diastolic BP	100.09±16.76	90.43±14.76	-9.65	< 0.001
Total number of patients	Blood Sugar level	Blood Sugar level	Change	p value
(n=41)	Before therapy	After 6 months therapy	(%) in mean	
	Mean±SD	Mean±SD		
	(mg%)	(mg%)		
Fasting sugar level	111.07±24.34	109.36±20.81	-1.54	>0.05
Post prandial sugar level	146.60±28.99	144.29±26.33	-1.58	>0.05
Lipid profile (n=41)	Before therapy	After 6 months therapy	Change	p value
	Mean±SD	Mean±SD	(%) in mean	
	(mg%)	(mg%)		
Total Cholesterol	177.70±25.87	174.7±22.51	-1.69	>0.05
HDL-C	43.43±3.14	43.85±3.77	+0.96	>0.05
LDL-C	118.73±22.98	115.17±29.28	-3.00	>0.05
Triglyceride level	160.0±21.86	157.97 ±26.84	-1.27	>0.05

Comparison between Telmisartan and Amlodipine group- On comparing both the drugs on the basis of various study variables, significant differences were observed not only in systolic and diastolic BP levels but in fasting and post prandial blood glucose levels, total and LDL cholesterol and triglyceride level as well. (Table-4).

Table-4: Comparison between telmisartan and amlodipine group.

	Telmisartan group (n=58)	Amlodipine group	Change in mean	p value
		(n=41)		
	Mean ±SD	Mean ±SD		
	(after 6 months)	(after 6 months)		
Systolic BP (mm Hg)	130.40±20.22	138.82±16.51	6.46	< 0.001
Diastolic BP (mm Hg)	84.84±11.67	90.43±14.76	6.59	< 0.001
Fasting sugar level (mg%)	100.70±22.32	109.36±20.81	8.66	< 0.01
Post prandial sugar level (mg%)	132.55±21.08	144.29±26.33	11.74	< 0.01
Total cholesterol (mg%)	160.90±12.76	174.70±22.51	13.8	< 0.001
LDL-C (mg%)	101.25±10.59	118.73±22.86	17.48	< 0.001
Triglyceride (mg%)	152.12±21.67	160±21.86	7.88	< 0.01

Discussion

From previous studies, telmisartan is approved for the treatment of hypertension, ether as monotherapy or in combination with other antihypertensive drugs. Several studies have reported the additional beneficial effects on the various parameters of the metabolic syndrome, like lowering of blood glucose levels and lipid values. This may be attributed to the fact that it also acts as a partial peroxisome proliferators activated receptor-gamma (PPAR- γ) agonist, a well known target for antidiabetic and antiobesity drugs [7,8].

The present study was planned to see the effects of telmisartan on blood pressure as well as in Indian hypertensive population and compared with the effects of another antihypertensive drug, amlodipine. It was used as a control because its efficacy as an antihypertensive is well established by several studies [9] and mega trials [10] as well as it is widely used as standard treatment in hypertension. The total number of patients followed in our study was 99 with a male to female ratio of 1.82:1. The lesser number of female

patients in the present study was probably due to the fact that the female patients utilize medical facility less often in the Indian set up. The number of drop out was more in Amlodipine group (24 patients) compared with Telmisartan group (7 patients). The cause for this difference was not known but apparently most of the patients were from far off distances and therefore, dropped out of the study due to their inability to come to the outpatient department repeatedly.

The mean age of the patient in the present study was 62.57 years while it was higher in the STAR trial (69 years) [4]. The majority of the patients (n=57) were in 40-60 year age group. The mean age of the total males was 59.76 years while 60.73 years in females.

The mean BMI in the present study was 25.09kg/m2. The maximum number of patients (n=45) were in overweight category while 34 patients had normal BMI. In overweight patients, more than half (n=26) were between 40-50 years.

In the present study, both the drugs were started in low dose and up titrated gradually to maximum of 80mg and 10mg in Telmisartan and Amlodipine respectively. This was also done in STAR trial [4], however, in another study by Vitale et al [11], Telmisartan was started with fixed maximum dose of 80 mg.

Similar to STAR trial [4] we have excluded patients with serious complications and critical illnesses like Coronary artery disease, Congestive heart failure, cerebrovascular accidents, etc. Out of the 99 patients, 13 (13.13%) were diabetic comprising 8 males and 5 females. Eight cases were newly diagnosed at the time of entry and the rest were known cases of diabetes. Rest of the patients with nephropathy were related to hypertension. Impaired glucose levels were seen in 16 patients, out of which 9 had impaired fasting glucose level whereas 7 had impaired glucose tolerance.

During study period, no patient was advised life style modifications and diet habit changes. Known diabetics were on oral hypoglycaemic agents including metformin, glimipride and pioglitazone, either singly or in combinations, but no patient was on insulin. Blood sugar levels were well controlled in known diabetics (n=5).

The mean of systolic BP was 155.44mm Hg and diastolic BP was 98.33mm Hg. In STAR trial [4], these

values were 159mm Hg and 87 mm Hg respectively. The mean value of systolic BP in overweight and obese patients (n=55) was 162mm Hg and diastolic BP was 100mm Hg. In patients with normal BMI, mean systolic and diastolic BP was 150mm Hg and 88mm Hg respectively. This difference in blood pressure was significant (<0.001) suggesting that overweight and obese patients have higher blood pressure levels than non obese persons.

In the present study, combined hyperlipidemia was less common than isolated single lipid abnormality, 10 patients had combined lipid elevated patterns (triglycerides > 200mg%, LDL-C≥130mg%) the remaining (n=18) had other predominant lipid patterns. The mean value of LDL-C was 118.40mg% and 158.43mg% for triglycerides. In STAR trial, LDL-C was 122mg% and TG was 141mg%. In diabetic patients (n=13), mean values of LDL-C and TG were 146.76mg% and 172mg respectively [4].

In patients with BP≥160mmHg (n=34), mean value of LDL-C was 130.22mg% in comparison to patients with systolic BP<160mm Hg, which was 116.22mg% (p value<0.001). In overweight persons (n=40), it was 136.77 mmHg and 120.88mm Hg in normal BMI patients (p<0.001). Hence, dyslipidemia was found to be more common in higher BMI persons.

In the present study, total mean value of fasting blood sugar level was 112.24mg%. The reported value in STAR trial [4] was 108mg%. Impaired glucose patterns were seen in 16 patients of which, 9 had impaired fasting glucose tolerance. In diabetic patients (n=13), mean fasting sugar level was 110.24mg% and mean post prandial sugar level was 146.22mg%. In known diabetic patients on OHA, drugs were not changed and in the newly diagnosed diabetic patients, OHA were not prescribed as well as patients in both groups were not given statins. This was intentionally done to observe additional effect of the study drugs.

Comparison of telmisartan & amlodipine- The mean value of systolic BP in telmisartan group decreased from baseline by 17.43% (p<0.001) and 13.79% in diastolic BP (p<0.001). This finding is similar to a previous study (STAR trial) [4], while it was significant p<0.05 in another study by Vitale et al [11]. This change was uniformly distributed among all age groups and in both sexes. The changes in BP in amlodipine were also highly significant (p<0.001), which reduced systolic BP

from baseline by 10.56% and 9.65% in diastolic pressure. It was also not affected by age and sex distribution. On comparing both the drugs, telmisartan reduced mean systolic BP significantly more by 8.42% (p<0.001) and 5.59% (p<0.001) in diastolic BP.

Previous studies [12] support that telmisartan exerts sustained and more effective BP control over 24 hours including the critical last 6 hours of the morning.

Both the drugs were effective in reducing BP significantly. However, on comparison, telmisartan proved more effective. In another study (ASCOT) [9], it was shown that amlodipine/perindopril (ACE inhibitor) based regimen lowered systolic BP by 2.7mm Hg more than atenolol/bendroflumethazide based regimen.

There are very few studies available regarding the effect of Angiotensin receptor blockers (telmisartan) on the metabolic parameters. In the present study, the mean fasting sugar level in patients with telmisartan group after 6 months was 100.70mg% which decreased by 10.27% (p<0.01) from baseline. In study by Vitale et al [11], this reduction was 8.3% (p<0.05). The change was more striking in diabetics and in patients with impaired glucose levels. Their combined mean was 116.28mg% compared with non diabetic patients, with mean value 100.20mg%. The above combined mean value decreased by 10.30% from baseline (p<0.001) which is highly significant. This fact was also supported in STAR trial [4] where FBG, significantly decreased in patients with FBG≥110mg% (20%,p<0.05).

The effect of post prandial sugar level in telmisartan group was also significant. Reduction was being 5.57mg% from baseline (p<0.001). In study by Vitale et al [11], reduction was about 13.2% (p<0.01).

In the STAR trial [4], effect on post prandial sugar level was not observed. In combined patients (diabetic and IGT), value was reduced by 16% from baseline (p<0.001), which was more than non-diabetic patients. This observation leads to the conclusion that the effect of telmisartan is more marked on higher sugar levels.

In the ASCOT-BPLA trial [9] it was shown that amlodipine based regimen induced less diabetes (metabolic syndrome) than the atenolol based regimen. In the present study, the effect of amlodipine on sugar level was not significant (p>0.05). In telmisartan group, the mean value of LDL-C after 6 months was

101.25mg% which reduced from baseline by 16.60% (p<0.001). In previous study (STAR trial) [4] the reduction was 11% (p<0.01). In diabetic patients (n=7), the mean value was 136.30mg%, which came down to 110.30mg% (p<0.001) in comparison with non diabetics, where reduction was 11.3% (p<0.05). The mean value of triglyceride was decreased to 152.2mg%, with reduction of 7.88% (p<0.01).

The reduction was more in diabetic patients, where reduction was 12.66% (p<0.001). In the STAR trial, there was significant decrease in TG in patients with ≥150mg% (270 to 175mg%, p<0.005). This difference in reduction in the present study was apparent due to larger numbers of the patients having TG≥150mg%. In another study by Derosa et al [13] also showed similar results in a 12 month study that compared telmisartan with nifedipine gastrointestinal therapeutic system.

The mechanism of TC and LDL-C lowering in response to telmisartan is not well understood. Dormondy JA et al [14], have shown that, since a direct PPAR-γ agonist, pioglitazone, does not affect TC and LDL-C levels, it may be independent of PPAR-γ activation [14].

In contrast more recently, it has been shown that a high dose telmisartan has a PPAR- γ action that leads to lowering of TC and LDL-C levels through influx of remnant lipoprotein into the liver [5]. The effect of amlodipine on lipid profile was not significant (p<0.05).

In the present study, total patients with nephropathy were 9 of which 4 were diabetic. The mean value of serum creatinine was 1.78. Five cases were in telmisartan group. During study, it was observed that there was significant reduction in mean value of urinary protein from 160.22mg% to 92.22mg% (p<0.001). The mean value of serum creatinine after 6 months 1.60. In a previous study (AMADEO) [15], mean change in urinary protein-creatinine ratio after one year of treatment was better with telmisartan (p=0.0283). The RENAAL study [16] observed that angiotensin receptor blockers reduce proteinuria, the time of creatinine doubling and slow the progression of renal disease independent of the changes in BP. This renoprotective effect was not shown in amlodipine group.

Conclusion

Telmisartan and Amlodipine both reduced BP significantly in most of the patients studied. Telmisartan also had beneficial effects on various metabolic

parameters, where amlodipine was not effective. It reduced blood sugar levels and lipid variables significantly especially in hyperglycaemic and hyperlipidemic patients. It significantly reduced proteinuria in patients with nephropathy. The present study suggests that salutary effects of telmisartan on the metabolic profile may be additional attribute beyond its established antihypertensive effect, which can be useful particularly in the treatment of metabolic syndrome.

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