

An Analysis of Prescription Patterns in Cases of Uncomplicated Hypertension In A Tertiary Care Hospital

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Abstracts: Background & objectives- Prescribing pattern in hypertension patients were found to be different from the recommended guidelines in the past. The objectives of the present study were to analyze prescribing trends in uncomplicated hypertension and to compare with those of current international guidelines with the objective to note any deviation. Methods- A prescription based analysis in 1400 hundred uncomplicated hypertensives in the age group 30 to 60 years was carried out. Results- Monotherapy was prescribed to 893 cases (M 407; F 486) and combination therapy to 507 cases (M 342; F 165). Overall, Calcium Channel Blockers (CCBs) were the most common agents used 787 (56.21%) cases, 350 monotherapy and 437 as combination therapy. Angiotensin Converting Enzyme Inhibitors (ACE I) 452 (32.28%) and Angiotensin II Receptor Blockers (ARBs) 231 (16.5%) cases were the next preferred groups. In double drug combination CCB+ Beta Blockers (BB) and for triple drug combination CCB+ARB+ Diuretics (D) were more preferred. A significant effect of age ($p < 0.01$) on prescription of CCBs was noted. Prescription of ARBs and D were significantly ($p < 0.05$ and < 0.01 respectively) influenced by gender. Gender had no significant effect on the prescribing trend of antihypertensive agents in combination therapy, while a significant effect ($p < 0.05$) of age and combined drug classes CCB+ACE I and CCB+BB+D was noted. The overall prescription rate for diuretics was 40.24% and that for monotherapy was meagre 5.15% (M 1.23%±; F 3.92%). Diuretics were always prescribed in triple drug combinations. Interpretation & Conclusions- CCBs were the most commonly prescribed agents. A deviation existed between antihypertensives prescribed and current international guidelines thus calling upon greater awareness. [Shalini et al NJIRM 2012; 3(1) : 13-20]

Key Words: Combination therapy, Diuretics, monotherapy, Uncomplicated hypertension.

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Introduction: Hypertension is a common and eminently treatable risk factor for major cardiovascular events including coronary heart disease and stroke¹. The prevalence of hypertension seems to be increasing in both developed nations where it currently affects approximately 1 in 3 adults and in developing countries^{2,3}. In most countries, 15% to 30% of the adult population and more than 50% of the elderly population suffer from high blood pressure, making it a clear general public health problem. As with smoking, diabetes, and dyslipidemia, hypertension is an important risk factor for cardiovascular diseases, which are responsible for roughly 30% of deaths worldwide⁴.

The main guidelines for the pharmacotherapy of hypertension were established by the Seventh Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)⁵. British Hypertension Society and the World Health

Organization/International Society of Hypertension (WHO/ISH) also made similar therapeutic guidelines^{6,7}. The JNC 7 recommends that antihypertensive drugs documented to reduce cardiovascular morbidity and mortality, like diuretics (D), beta blockers (BB) and angiotensin converting enzyme inhibitor (ACE I) be the agents of choice and should be prescribed in their minimum effective dose; unless they are contraindicated or unacceptable. The JNC 7 further recommends that polypharmacy should be avoided in hypertension therapy as much as possible. The clear central theme of the JNC 7 guidelines is the benefit of lowering blood pressure to optimal goal levels. Although the guidelines call for the use of diuretics in most patients, the key emphasis, based on data from the newer clinical trials, is on the fact that lowering of BP is more important than the choice of antihypertensive agent(s). The prescribing pattern of drug used for treating hypertension changes over time in response to changes in

recommended guidelines and innovations of drug formulations. Knowledge of existing prescription patterns in the treatment of hypertension can not only provide useful informations for improving clinical practice in this field but also help to compare with current guidelines⁸. During the past decade, various clinical trials and Studies have been published and a range of clinical guidelines on antihypertensive treatment have been advocated. The choice of antihypertensive drugs in general should be guided by several considerations.

Currently available antihypertensive drugs are similar in their overall effectiveness in lowering blood pressure. The response to different agents varies from person to person. To effectively control blood pressure, the clinician may increase the drug dose or change to another drug or combination therapy may be started. Rather than combining drugs on an empirical basis, there are rational combinations of drugs with different and complimentary modes of action that should be considered. Examples of recognized combinations include diuretics (D) and β blockers (BB), diuretics and angiotensin converting enzyme inhibitor (ACE I), diuretics and Angiotensin II receptor blockers (ARBs), ACE I and calcium channel blockers (CCBs).

The aims of the present study are to analyze prescribing trends in uncomplicated hypertension in younger age group (30-60 years), whether there is any gender bias or prescription of particular class of drugs based on age group and to compare pattern of antihypertensive therapy with current international guidelines in particular JNC 7 guidelines.

Material and Methods: A prescription based survey among patients with uncomplicated essential hypertension was conducted in Rohilkhand Medical College and Hospital [RMCH] Bareilly from Jan. 2007 to Dec. 2009 with prior approval from institutional ethical committee.

The patients included in the study were those having uncomplicated essential hypertension for at least past 6 months with no other associated illnesses. Hypertensive patients with complications such as diabetes mellitus, diseases of pulmonary

system (tuberculosis, bronchiectasis, asthma), diseases of gastrointestinal tract, osteoarthritis, Ischemic heart disease and other forms of heart disease (heart failure, arrhythmias), renal diseases, stroke, or any other chronic disease were excluded from the study. Exclusion also included all acutely ill patients requiring admission, patients who were uncooperative, pregnant and those showing poor compliance. A total of fourteen hundred ninety one uncomplicated hypertensive individuals were initially screened. Of these, sixty three patients, who were uncooperative and noncompliant, were excluded. Besides, twenty eight patients who were treated with other classes of antihypertensive agents (α blockers, vasodilators and other classes of antihypertensive) due to their fewer numbers were not included for the purpose of study.

Thus the present study analyzed the prescription pattern of only five classes of antihypertensive agents namely BB, D, CCB, ACE I and ARB in only fourteen hundred uncomplicated hypertensive individuals. The study population included each and every consecutive uncomplicated hypertensive patient of age ranging 30yrs to 60yrs attending to the medical OPD of RMCH during study period.

The data entered and analyzed include the age and gender of the patient, number of drugs, class and type of drugs prescribed. Age and gender are important parameters in pharmacotherapeutic analysis of drug utilization in general. Patient history was recorded by direct interviewing and analyzed along with prescription. Only prescriptions containing antihypertensive medications were included. The prescriptions of study group were screened for drug prescription pattern. Since each prescription might have contained different drug/combinations of drugs, analysis of data was undertaken using prescription rate, calculated as the number of prescriptions containing specific antihypertensive agent divided by total number of prescriptions.

Statistical Analysis: Data analysis was done by using EPI Info software. Chi-Square T test was carried out to determine the statistical significances of the difference between the prescription rates. A $p < 0.05$ was considered statistically significant.

Result: In the present study a total of 1400 uncomplicated hypertensive individuals having mean base line BP of 160/100 mm of Hg were analyzed for the purpose of determining the prescription pattern in a tertiary care hospital. The

study population comprised of 749 (53.5%) males and 651(46.5%) females (Table 1). The mean age of men was 43.69 (SD ± 7.70). The mean age of women was 46.21 (SD ± 7.17).

Table – 1 Age and sex wise distribution of patients

	Age group						Total (%)	
	30-40		41-50		51-60			
	M No (%)	F No (%)	M No (%)	F No (%)	M No (%)	F No (%)	M No (%)	F No (%)
	278 (19.86)	133 (9.5)	291 (20.78)	306 (21.85)	180 (12.85)	212 (15.14)	749 (53.5)	651 (46.5)
Total (%)	411 (29.36)		597 (42.64)		392 (27.99)		1400 (100 %)	

It was observed that more subjects 893 (63.78%) received monotherapy and 507 (36.21%) received combination therapy. 486 (34.71%) women and 407 (29.07%) men were on monotherapy whereas 342 (24.43%) men and 165 (11.78%) women received combination treatment. Chi-Square T test for the differences in the pattern of treatment between men and women gave $p < 0.01$ showing significant difference (Table 2).

Table -2. Prevalence of monotherapy Vs. Combination therapy and sex wise distribution

Sex	Monotherapy (n=893)	Combination therapy (n= 507)
Male	407 (29.07 %)	342 (24.43 %)
Female	486 (34.71 %)	165 (11.78 %)

In monotherapy (893 cases) , the prescribed agents were CCB, ACE I , BB , ARB, D and their percentages were 20.6%, 17.58%, 6.27%, 6.05%, 3.92% in women and 18.59%, 17.13%, 5.37%, 3.24%, 1.23% in men respectively. Cross tabulation of gender versus CCB, ACE I, BB, ARB and D prescribed and using a Chi-Square T test gave a $p > 0.05$, > 0.05 , > 0.05 , < 0.05 and < 0.01 respectively suggesting that prescribing of ARB and D were significantly influenced by gender and that gender differences did not affect the prescribing of CCB, ACE I and BB (Table 3). Cross tabulation between age and each drug class showed a Chi-Square T test of $p > 0.05$ for each drug class except for CCB in which $p < 0.01$ suggesting significant effect of age on prescription of CCB only and insignificant effect of age on prescribing of other drug classes (Table 3).

Amongst combination drug treatment (507 cases) the two drugs combination therapy namely CCB+BB; CCB+ACE I; ARB+D; CCB+ARB and BB+D were prescribed in 25.24%, 14.79%, 5.72%, 3.35%, 3.55% of males and 13.02%, 6.31%, 3.55%, 2.17%, 0.98% of females respectively. The three drugs combination therapy that of CCB+ARB+D, CCB+ACE I+D and CCB+BB+D were prescribed in 8.28%, 4.14%, 2.37% of males and 4.14%, 0.98% 1.38% of females respectively. Cross tabulation of gender versus each of combined drugs prescribed showed a $p > 0.05$. This meant that gender had no significant affect on the prescribing trend of antihypertensive drugs used either in two drugs or three drugs combinations (Table 4). Cross tabulation of age and each combined drug class gave a $p > 0.05$ except for CCB+ACE I and CCB+BB+D in which $p < 0.05$ suggested significant influence of age (Table 4).

It was observed that more women received monotherapy and more men were on combined drug treatment. Amongst monotherapy, CCBs were more commonly preferred agent in uncomplicated hypertensive patients. This is closely followed by ACE I. The least number of cases were prescribed D. Regarding combination treatment, CCB+BB were more frequently used followed by CCB+ACE I. The combination of BB+D was least deployed. Regarding triple drug combination, CCB+ARB+D got preference over CCB+ACE I+D.

It was further observed that amongst total fourteen hundred subjects, CCBs were the major drugs 787 (56.21%) cases, which were most frequently prescribed in either formats of monotherapy,

double drug or triple drug combinations. ACE I 452 (32.28%) cases and related ARBs 231 (16.5%) cases,

Table -3. Age & Sex wise prescription of drugs in monotherapy

Agents Used					
Sex : No (%)	CCBs:No (%)	ACEI: No (%)	BB:No (%)	ARBs:No (%)	D : No (%)
Male 407 (45.58)	166 (18.59)	153 (17.13)	48 (5.37)	29 (3.24)	11(1.23)
Female 486 (54.42)	184 (20.6)	157 (17.58)	56 (6.27)	54 (6.05)	35(3.92)
Total (893=100%)	350 (39.19)	310 (34.71)	104(11.64)	83 (9.29)	46(5.15)
Chi-Square	0.80	2.73	0.02	4.17	9.18
P.Value	0.3723	0.0983	0.8999	0.0410	0.0024
Age Group : No (%)					
30-40 : 262 (29.33)	129 (14.44)	81 (9.07)	26 (2.91)	17 (1.9)	9 (1.01)
41-50 : 381 (42.66)	136 (15.23)	140 (15.67)	47 (5.26)	40 (4.48)	18 (2.01)
51-60: 250 (28.01)	85 (9.52)	89 (9.97)	31 (3.47)	26 (2.91)	19 (2.13)
Tortal: (893 = 100 %)	350 (39.19)	310 (34.71)	104 (11.64)	83 (9.29)	46 (5.15)
P.Value	0.003	0.294	0.585	0.176	0.105

(CCBs= Calcium Channel Blockers; ACE1= Angiotensin Converting Enzyme Inhibitors; BB=BetaBlockers; ARBs=Angiotensin II receptor blockers; D=Diuretics)

Table -4. Age & Sex wise prescription of drugs in combination therapy

AGENTS USED								
Sex No (%)	CCBs+BB No (%)	CCBs+ACE1 No (%)	ARB+D No (%)	CCBs+ARB No (%)	BB+D No (%)	CCBs+ARB+D No (%)	CCBs+ACE1=D No (%)	CCBs+BB+D No (%)
Male 342 (67.45)	128 (25.24)	75 (14.79)	29 (5.72)	17 (3.35)	18 (3.55)	42 (8.28)	21 (4.14)	12 (2.37)
Female 165 (32.54)	66 (13.02)	32 (6.31)	18 (3.55)	11 (2.17)	5 (0.98)	21 (4.14)	5 (0.98)	7 (1.38)
Total (507=100)	194 (38.26)	107 (21.10)	47 (9.27)	28 (5.52)	23 (4.53)	63 (12.42)	26 (5.12)	19 (3.75)
Chi-Square	0.31	0.43	0.78	0.61	1.28	0.02	2.21	0.17
P.Value	0.576	0.512	0.376	0.433	0.257	0.886	0.136	0.683
Age Group No (%)								
30-40 149 (29.39)	58 (11.44)	21 (4.14)	12 (2.37)	11 (2.17)	55 (0.98)	17 (3.35)	12 (2.36)	13 (2.56)
41-50 216 (42.6)	87 (17.16)	51 (10.06)	22 (4.34)	12 (2.37)	11 (2.17)	21 (4.14)	8 (1.58)	4 (0.79)
51-60 142 (28.01)	49 (9.66)	35 (6.9)	13 (2.56)	5 (0.98)	7 (1.38)	25 (4.95)	6 (1.18)	2 (0.39)
Total 507 = (100)	194 (38.26)	107 (21.10)	47 (9.27)	28 (5.52)	23 (4.53)	63 (12.42)	26 (5.12)	19 (3.75)
Chi-Square	1.25	6.28	0.48	2.08	0.68	5.09	3.76	14.54
P.Value	0.536	0.043	0.786	0.353	0.710	0.078	0.152	0.0006

Where the next preferred group of agents in monotherapy, double drug or triple drug combinations. Diuretics, though under-utilized in monotherapy (5.15%), was an essential component of triple drug combination therapy (Table 3, 4). Regarding specific agent used, it was observed that

the most common agent amongst CCBs, ACE I, ARBs, BB and D were amlodipine, ramipril, valsartan, atenolol, hydrochlorothiazide respectively.

Discussion: Considerable variations in antihypertensive prescribing pattern exist internationally. However in general, choice of antihypertensive agent should be guided by current international guidelines. In the present study, drug

prescriptions of 1400 uncomplicated cases of hypertension in the age group 30-60 years were analyzed. Based on current guidelines of JNC 7 and 1999 WHO-International Society of Hypertension Guidelines for the Management of Hypertension (WHO-ISH 1999), six major categories of antihypertensive drugs are available, including ACE I, ARBs, BB, CCBs, diuretic and others-alpha blockers, vasodilators and other antihypertensive classes. Since the number of patients who were prescribed other classes of drugs was fairly low, hence this study was restricted to the analysis of only five classes of antihypertensive agents used. Of 1400 patients, a total of 749 (53.5%) males and 651 (46.5%) females received antihypertensive therapy, suggesting a M/F ratio of 1.15:1. A predominance of males was also reported by Sweileh⁹. In contrast, others reported a predominance of females¹⁰.

In the present study over half of the prescriptions involved single antihypertensive drug (monotherapy) (n=893; 63.78%), comprising of 486 (34.71%) females and 407(20.07%) males. CCBs were the most common agents used 39.19% as monotherapy, followed by ACE I. In one study which supported our observation reported that CCBs represented 38% of the prescriptions for antihypertensive agents whereas BB and D accounted for only 11% and 8% respectively¹¹. The growing use of CCBs against the recorded facts based on the analysis of nine clinical trials which showed a higher risk of myocardial infarction (MI), congestive heart failure (CHF) and major cardiovascular events with long-acting dihydropyridine CCBs compared with D and BB¹² is quite surprising. Further, ACE I provide greater cardiovascular risk reduction compared to CCBs. ACE I and CCBs are consistently the most frequently prescribed antihypertensive in both younger and older patients in hypertension¹³. This is despite of the fact that definitive isolated effects of ACE I and CCBs on morbidity and mortality in the treatment of uncomplicated hypertension are unknown because there are no placebo- controlled trials evaluating long term benefits.

It is also interesting to note that the efficacy of newer antihypertensive medications (ACE I, CCBs) compared with conventional agents D, BB was assessed in the STOP-2 study¹⁴. The primary end

point was a combined end point of fatal MI, fatal stroke and other fatal cardiovascular disease. There was no difference in the combined primary end point between the conventional drugs and newer drugs. While these classes of drugs (CCB, ACE I) definitely reduce BP and left ventricular hypertrophy, yet there is a limited evidence of their prevention of major cardiovascular events including mortality¹⁵. Moreover, ACE I are associated with dry cough and adverse effects on foetus in child bearing age group of women.

Our observations in respect to a greater prevalence of monotherapy, with predominance of females and a larger prescription rate for CCBs were in conformity with those of Liu et al⁸. These authors also observed that the most frequently prescribed antihypertensive agents were CCBs (35.5%) followed by BB (27.3%) as monotherapy agents. And that prescription rates for BB were higher among women and younger patients. These observations were not in conformity with those of our observations. In variance, Crucitti et al¹⁵ reported that the most frequently prescribed antihypertensive drugs were CCBs, diuretics and ACE I. These authors also observed that CCB, ACE I and BB were usually prescribed to younger patients below 65 years.

Liu et al⁸ observed a surprisingly low prescription rate for diuretics (8.3%) supporting our observations. This is definitely a drifting observation from JNC 7 guidelines which calls for the use of diuretics in most patients and upheld that diuretics have been virtually unsurpassed in preventing the cardiovascular complications of hypertension. Despite this, diuretics are not being favored as monotherapy and are underutilized. It is pertinent to mention, that amongst all of the monotherapies, the least average daily medication costs are for diuretics (we have not calculated the cost-effective analysis among different classes of drugs).

Neutal et al¹⁶ reported that the most commonly used antihypertensive medication for men was ACE I, followed by BB but the most common medication for women was diuretics. This fact was corroborated by Sweileh et al¹⁷. These authors also observed significant differences between men and women in use of the four major classes of

antihypertensive agents and that among those who were receiving monotherapy women were less likely to receive CCB or ACE I than D or BB, while men were less likely to use D or CCBs than BB or ACE I. In contrast, we observed that least number 46 (5.15%) cases were treated with diuretics (monotherapy), of these maximum 35 (3.92%) were women as compared to men 11 (1.23%) cases. We observed 184 (20.6%) females and 166(18.59%) males received CCBs as monotherapy followed by ACE I and diuretics lagged far behind. There were no significant sex related differences in use of CCB or ACE I amongst males and females for monotherapy. However more females were prescribed ARBs and diuretics as compared to men. Use of ARBs in females was probably due to the fact that ACE I induced cough is more likely to occur in women¹⁸.

The overall prescription rate for diuretics was 40.24% and that for monotherapy was a meager 5.15%. It was observed further that diuretics were chief ingredients where triple drug therapy was prescribed (108 cases) and these constituted only 70/399 in double drug therapy. The lesser use of diuretics in this part of the country was against the prevailing use of diuretics as main antihypertensive agents in U.K, Denmark and US¹⁹⁻²¹. Moreover, prescribing expensive drug classes of antihypertensive agents could be gauged as a major drift to JNC 7 recommendations in uncomplicated hypertension. Further this trend not only needs a curb but a greater adherence to the existent clinical guidelines based on evidence as well as cost effectiveness be advocated^{22,23}. Workers in the field also observed that primary care clinics more frequently prescribed diuretics than larger medical centers. It may probably be due to cost consciousness and a less reliance towards a new compound (ARB). Adoption of a new classes of medication (ARB, ACE I) reflects the possibility that physicians in large medical facility (medical college) are more frequently exposed to new drugs and tend to readily accept the latest. However, this trend in prescribing patterns may also be due to aggressive promotional activities of pharmaceutical industries²⁴. Furthermore, while prescribing antihypertensive agents in monotherapy, whether physicians are taking into account the indications and contraindications of each class of drug or whether

the prescription was based on clinical experience could not be ascertained.

Of late, the use of ARB is showing a rising trend (in comparison of ACE I) since the efficacy of these two types of antihypertensive medication is similar, a trend probably related to lesser adverse effects. Liu et al⁸ observed that this trend was unrelated to the different severity of hypertension. A growing trend in prescribing of ARBs as the initial choice of therapy for uncomplicated hypertension, particularly in medical centre, seems to be inconsistent with the current international guidelines and is also an expensive alternative. Combination therapy is needed in many (most) hypertensive patients to achieve optimal BP levels. In many of new trials 2 or 3 drugs were necessary to achieve goal BP in most patients⁵. Additionally fixed dose combinations provide patients with more convenient options than separate monotherapies, which may help simplify the treatment regimen and overall pill burden.

In present study a total of 507 patients (male 342; females 165) were prescribed combination therapy. This was in variance to JNC 7 guidelines, advocating a preference towards monotherapy and polypharmacy be avoided. Probably medical centers are more prone to combination therapy prescriptions, a fact corroborated by Liu et al⁸ as well. It was noted that more women received monotherapy and more men received combination therapy, and that none of the uncomplicated hypertensive patient received more than three drugs simultaneously. The recommendation to consider initiating combination therapy in some patients with stage 2 hypertension ($\geq 160/100$ mm Hg) should help dispel the mistaken notion that most patients can be controlled with one agent²⁵. Amongst two drug combinations CCB+BB were most commonly prescribed (38.26%) followed by CCB+ACE I (21.10%). Our observations were in conformity with those of Liu et al⁸. In double drug combinations, the combinations of CCB with either of BB, ACE I or ARB found greater preference (329/399 cases). This trend is quite interesting in view of the fact that there is no correct evidence that these classes of drugs (except BB) reduce the risk of morbidity and mortality in hypertensive patients vide JNC 6²⁶. The versatile double drug

combination of BB+D (4.53%) was not preferred and was relegated to last preference despite being quite efficacious and cost effective. Moreover, diuretics enhance the efficacy of BB and in low doses cause less adverse effects was also being an overlooked fact.

JNC 6 observed that combinations of low dose of agents from different classes have been shown to provide additional antihypertensive efficacy, thereby minimizing the likelihood of dose-dependent adverse effects and that low dose combination therapy is found to be appropriate for initial treatment of hypertension. In this context JNC 7 observed that the low dose combinations particularly with very low doses of diuretics will enhance the efficacy of other drugs without inducing electrolyte or hormonal perturbations. Further, it is noted that combinations of drugs will likely improve adherence to therapy²⁷.

Among triple drug combinations presence of diuretic (thiazide) was a must feature. A total of 108/507 patient received triple drug combination therapies (21.29%). This percentage was quite high for uncomplicated hypertension and such therapy was probably resorted to with the aim of rapid, smooth control with minimum adverse effect profile. It appears that triple drug combination found favour in medical college prescribing patterns. Though not much cost effective, it definitely affords better compliance by hypertensive patients. It was further observed that triple drug combination of CCB+ARB+D was prescribed more 63 (12.42%) cases. Of 63 cases of triple drug combinations of CCB+ARB+D, 25 (4.95%) cases belonged to 51-60 years age group and lesser number 17 (3.35%) cases were in the age group of 30-40.

It was also observed that gender had no significant effect on the prescribing trend of antihypertensive drugs used either in double drug or triple drug combinations. Regarding age distribution the combination of CCB+ACE I and CCB+BB+D exhibited a p value <0.05 suggesting significant influence of age (Table 4).

Conclusion: Knowledge of the existing prescription patterns in the treatment of uncomplicated

hypertension not only provides useful information for improving clinical practice in this field but also provide information pertaining to any shift in prescription patterns in respect to JNC 7 guidelines. In addition, whether a gap existed between current clinical practice and current clinical guidelines particularly in respect to mono, double or triple drug combinations can also be assessed. The prescription patterns for antihypertensive therapies for uncomplicated hypertension seemed to be inconsistent with current clinical guidelines. Thus, greater awareness in reference to current international guidelines amongst physicians even of tertiary care hospital is required. Diuretics despite being least expensive are being prescribed at a notably low prescription rate. There has been a growing trend in prescribing ACE I and related ARBs as an initial choice of therapy for uncomplicated hypertension.

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