

Original Research

Clinical and Biochemical Profile of Hypertensive Patients treated with Amlodipine and Cilnidipine: A Comparative Evaluation conducted at a Tertiary Care Hospital

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ABSTRACT

Background: Hypertension is usually defined by the presence of a chronic elevation of systemic arterial pressure above a certain threshold value. However, increasing evidence indicates that the cardiovascular (CV) risk associated with elevation of blood pressure (BP) above approximately 115/75 mmHg increases in a log-linear fashion.

Materials and Methods: 100 patients classified as having mild to moderate hypertension, 50 were assigned to the amlodipine group (Group-A) and the remaining 50 to the cilnidipine group (Group-B). Participants in Group-A received a daily dosage of 5 mg of Amlodipine, while those in Group-B were administered 10 mg of Cilnidipine daily, with both groups having been on their respective treatments for over six months. The selection of patients was conducted with careful adherence to established eligibility criteria, and various demographic, clinical, and biochemical parameters were recorded and subsequently analyzed for comparison. Using SPSS software.

Results: In this study, the mean age of the subjects of Amlodipine group was 52.28 ± 7.35 years and the mean age of the subjects of Cilnidipine group was 52.07 ± 11.43 years. In Amlodipine group, there were 30 males and 20 females. In Cilnidipine group, there were 33 males and 17 females. The systolic BP of subjects in Amlodipine group and Cilnidipine group was 143.26 ± 3.41 mm Hg and 139.11 ± 2.73 mm Hg, respectively. The diastolic BP of subjects in Amlodipine group and Cilnidipine group was 85.63 ± 8.11 mm Hg and 81.41 ± 5.70 mm Hg, respectively. The pulse rate of subjects in Amlodipine group and Cilnidipine group was 79.50 ± 13.81 breathes/minute and 72.66 ± 9.59 breathes/minute, respectively.

Conclusion: Both Amlodipine and Cilnidipine are recognized as effective antihypertensive agents. However, the group receiving Cilnidipine exhibited a greater decrease in blood pressure compared to the group treated with Amlodipine.

Keywords: Amlodipine, Cilnidipine, Hypertension.

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INTRODUCTION

Hypertension is usually defined by the presence of a chronic elevation of systemic arterial pressure above a certain threshold value. However, increasing evidence indicates that the cardiovascular (CV) risk associated with elevation of blood pressure (BP) above approximately 115/75 mm Hg increases in a log-linear fashion.¹⁻⁴ In the Seventh Report of the Joint National Committee on Prevention, Detection,

Evaluation, and Treatment of High Blood Pressure (JNC 7) a category of “prehypertension” was created using BP criteria of 120/80 mm Hg to 139/89 mm Hg.⁵ This category did not emphasize that some individuals with prehypertension already had the disease, hypertension, while others did not. In 2003, a writing group,⁶ offered a written definition of hypertension that did not depend on threshold values of BP above optimal.⁷ As for the JNC-8, guideline

CCBs are the primary antihypertensive drugs. There are two types of CCBs present; depending on the chemical structure they are classified into dihydropyridine and non-dihydropyridine groups. There are different type of calcium channels present in our body, such as L, N, T, P/Q, and R-type.⁸ Pharmacokinetics and pharmacodynamics property vary between different classes of CCBs.⁹

Amlodipine is third generation CCB with an excellent pharmacological profile. The major drawback of amlodipine is, it induces pedal oedema. Chronic therapy of amlodipine enhances the release of more catecholamines from sympathetic nerve terminals¹⁰, few clinical studies showed that amlodipine enhances the release of more endothelial nitric oxides¹¹, and decreases the Atrial Natriuretic Peptide (ANP).¹² Cilnidipine is a fourth generation L/N type of CCB¹³, which blocks the N-type of calcium channels at the sympathetic nerve endings and decreases the release of catecholamines and by blocking L-type calcium channels relaxes arteriolar smooth muscles, which decreases the peripheral vascular resistance.^{14,15}

MATERIALS AND METHODS

100 patients classified as having mild to moderate hypertension according to the JNC-8 guidelines, 50 were assigned to the amlodipine group (Group-A) and the remaining 50 to the cilnidipine group (Group-B). Participants in Group-A received a daily dosage of 5

mg of Amlodipine, while those in Group-B were administered 10 mg of Cilnidipine daily, with both groups having been on their respective treatments for over six months. The selection of patients was conducted with careful adherence to established eligibility criteria, and various demographic, clinical, and biochemical parameters were recorded and subsequently analyzed for comparison. Using SPSS software (version 15.0). Values are expressed as mean±SD, Inter-Quartile Range (IQR) and percentage.

RESULTS

In this study, the mean age of the subjects of Amlodipine group was 52.28 ±7.35 years and the mean age of the subjects of Cilnidipine group was 52.07 ±11.43 years. In Amlodipine group, there were 30 males and 20 females. In Cilnidipine group, there were 33 males and 17 females.

The systolic BP of subjects in Amlodipine group and Cilnidipine group was 143.26±3.41 mm Hg and 139.11±2.73 mm Hg, respectively. The diastolic BP of subjects in Amlodipine group and Cilnidipine group was 85.63±8.11 mm Hg and 81.41±5.70 mm Hg, respectively. The pulse rate of subjects in Amlodipine group and Cilnidipine group was 79.50±13.81 breathes/minute and 72.66±9.59 breathes/minute, respectively.

Table 1: Demographic parameters of amlodipine and cilnidipine groups

Variables	Groups	
	Amlodipine	Cilnidipine
Age	52.28 ±7.35	52.07 ±11.43
Gender		
Males	30	33
Females	20	17

Table 2: Comparison of clinical and echocardiography parameters between amlodipine and cilnidipine groups.

Variables	Amlodipine	Cilnidipine
Systolic BP (mm Hg)	143.26±3.41	139.11±2.73
Diastolic BP (mm Hg)	85.63±8.11	81.41±5.70
Pulse rate (breathe/minute)	79.50±13.81	72.66±9.59

DISCUSSION

Hypertension is the most common cardiovascular disease. In India, 29.8% population are suffering from hypertension. Amlodipine, a calcium channel blocker, dilates arterioles by blocking L-type calcium channels.^{16,17} Benidipine inhibits L, N, and T type calcium channels¹⁸ and Cilnidipine inhibits L, and N type calcium channels. Amlodipine has a potent blood pressure lowering effect and few adverse effects like pedal edema and tachycardia. Cilnidipine has a potent blood pressure lowering effect same as Amlodipine and adverse effects like pedal edema and tachycardia are less than Amlodipine. Recently, a new calcium-channel blocker-Benidipine-has become available in

Indian market. It is a triple L, N, T-calcium channel blocker with promising end organ protection effects.¹⁸ In this study, the mean age of the subjects of Amlodipine group was 52.28 ±7.35 years and the mean age of the subjects of Cilnidipine group was 52.07 ±11.43 years. In Amlodipine group, there were 30 males and 20 females. In Cilnidipine group, there were 33 males and 17 females. The systolic BP of subjects in Amlodipine group and Cilnidipine group was 143.26±3.41 mm Hg and 139.11±2.73 mm Hg, respectively. The diastolic BP of subjects in Amlodipine group and Cilnidipine group was 85.63±8.11 mm Hg and 81.41±5.70 mm Hg, respectively. The pulse rate of subjects in Amlodipine group and Cilnidipine group was 79.50±13.81

breathes/minute and 72.66 ± 9.59 breathes/minute, respectively. Adake P et al¹⁹ compared amlodipine with cilnidipine on antihypertensive efficacy and incidence of pedal edema in hypertensive individuals. This was a three months prospective, observational study done at the tertiary care center of Karnataka, India. A total number of 60 ($n = 60$) newly diagnosed hypertensives ($\geq 140/90$) of either gender, attending outpatient department of medicine, were included in the study. Out of 60 patients, 30 patients who have been prescribed tablet amlodipine 5-10 mg/day and the other 30 who have been prescribed tablet cilnidipine 10-20 mg/day orally by the consulting physician, depending upon the severity of hypertension were followed every fortnight, screened for the presence of pedal edema and blood pressure control over a period of 3 months. Antihypertensive efficacy between two groups was compared by unpaired t-test and incidence of pedal edema was compared by Fisher's exact test. Of 30 patients in the amlodipine group, 19 patients presented with pedal edema (63.3%) and 2 patients (6.66%) in cilnidipine group presented with pedal edema during the study period. There was a significant difference in the incidence of pedal edema between amlodipine and cilnidipine group ($P < 0.05$), but no significant difference was found in the antihypertensive efficacy of amlodipine and cilnidipine ($P > 0.05$). Both amlodipine and cilnidipine have shown equal efficacy in reducing blood pressure in hypertensive individuals. But cilnidipine being N-type and L-type calcium channel blocker, associated with lower incidence of pedal edema compared to only L-type channel blocked by amlodipine. Shetty K et al²⁰ studied the clinical and biochemical profile in Amlodipine and Cilnidipine treated mild to moderate hypertensive patients. The present study was a cross-sectional study. A total of 140 mild to moderate hypertensive patients (HTN classified according to Joint National Committee-8 (JNC-8) HTN guideline), 70 were in Amlodipine group (Group-A), and other 70 patients were in Cilnidipine group (Group-B). Group-A receiving Tab Amlodac 5 mg/day and Group-B receiving Tab Cilacar 10 mg/day, and both the group receiving respective medications since more than six months. Patients enrolled into the study with due consideration of eligibility criteria. Demographic, clinical and biochemical parameters were noted and compared. Demographic parameters are matched, there was no significant difference seen between two study groups. Systolic and Diastolic Blood Pressure (SBP and DBP) showed a significant difference ($p < 0.001$). There was no significant difference in pulse rate between the two groups, both QT/QTc showed statistically significant difference ($p < 0.001$). The biochemical parameters like serum creatinine, albumin, globulin, total protein, serum Na^+ , fractional excretion of Na^+ , serum osmolality, vanillyl mandelic acid, were compared between two study groups, there was no significant difference seen between the two

groups. The Amlodipine and Cilnidipine both are equally effective antihypertensive drugs. Cilnidipine treated group showed more reduction in blood pressure than the Amlodipine treated group and there was no significant change in heart rate between the two groups. Cilnidipine group showed comparatively shortened QT/QTc interval than the Amlodipine group.

CONCLUSION

Both Amlodipine and Cilnidipine are recognized as effective antihypertensive agents. However, the group receiving Cilnidipine exhibited a greater decrease in blood pressure compared to the group treated with Amlodipine, while no significant differences in heart rate were observed between the two groups.

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