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Original Article

A Comparison between the Efficacies of Amlodipine & Cilnidipine among Hypertensive Patients

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ABSTRACT

Introduction: *Calcium channel blockers (CCB) play a vital role in the management and control of hypertension. Amlodipine, a dihydropyridine-type calcium channel blocker is frequently used for its strong antihypertensive and minimal adverse side effects in hypertensive patients. On the other hand, Cilnidipine, another new generation CCB (Calcium channel blocker) is considered for ensuring lesser edema (Pedal) with satisfactory control of hypertension by negligible side effects. But we have very few research-based comparative information regarding the efficacies of Amlodipine and Cilnidipine in treating hypertensive patients.* ***Aim of the study:*** *The study aimed to compare the efficacies of Amlodipine and Cilnidipine in treating hypertensive patients.* ***Methods:*** *This comparative observational study was conducted in the Department of Cardiology, Anwer Khan Modern Medical College Hospital, Dhaka, Bangladesh. June 2021 to November 2021. In this study, in total 60 hypertensive patients were selected as the study people. The standard mercury sphygmomanometer was used to measure the blood pressure of the patients. All the patients were divided into two groups, by 30 patients in each group. The first group comprised of patients, taken amlodipine 5-10 mg/day while the other group included patients, taken cilnidipine 10–20 mg/day orally as the treatment protocol for hypertension. The mean values of SBP (Systolic blood pressure) and DBP (Diastolic blood pressure) during check-up were recorded and assessed. Data were processed, analyzed and disseminated by MS Office and SPSS programs as per need.* ***Results:*** *In this study, at 2-, 4- and 8-week's follow-ups, we did not find any significant difference between both group patient's SBP readings where the p values were found as 0.517, 0.705 and 0.517 respectively. Besides these, at 2-, 4- and 8-week's follow-ups, we did not also find any significant difference between both group patient's SBP readings where the p values were found as 0.673, 0.201 and 0.614 respectively. After 8 week's treatment, the mean pulse rates were found 74.96 in Amlodipine group whereas it was found as 75.47 in Cilnidipine group at the same time. In analyzing the incidences of pedal edema among both group participants we found pedal edema among 43% patients in Amlodipine group whereas it was found in only 7% in Cilnidipine group.* ***Conclusion:*** *As per the findings of this study, it can be concluded that, Amlodipine is more effective in controlling blood pressure than Cilnidipine. But considering the possible pedal edema, Cilnidipine is safer than*

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amlodipine as an antihypertensive CCB.

Keywords: Amlodipine, Cilnidipine, Efficacy, Calcium channel blockers, Systolic blood pressure, Pedal edema.

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INTRODUCTION

Calcium channel blockers (CCB) play a vital role in the management and control of hypertension. Amlodipine, a dihydropyridine-type calcium channel blocker is frequently used for its strong antihypertensive and minimal adverse side effects in hypertensive patients. In a study it was reported that, hypertension (HTN) is one of the most common diseases afflicting humans throughout the world and considering the associated morbidity, mortality and the cost to society, it is an important public health challenge. [1] Hypertension may be defined as that the level of blood pressure at which the institution of therapy reduces BP-related morbidity and mortality. [2] It is graded as mild Stage/Grade 1 (SBP between 140 and 159 and DBP between 90 and 99), moderate Stage/Grade 2 (SBP range: 160-179 and DBP range: 100-109), and severe Stage/Grade 3 (SBP ≥180 and DBP ≥110). [3] lake of proper treatment, HTN usually doubles the risk of cardiovascular diseases including coronary heart disease (CHD), congestive heart failure (CHF), renal failure, ischemic and hemorrhagic stroke as well as peripheral arterial disease. [4] In a study, they reported fourteen percent (approximately) risk reduction of stroke and ischemic attacks by falling approximately 2-mmHg of average diastolic blood pressure. Besides that, they also reported a simultaneous 6% reduction in risk of coronary artery disease. Several classes of antihypertensive agents have been in regular clinical use, including diuretics, angiotensin-converting enzyme inhibitors (ACE inhibitor), α-blockers, β-blockers, angiotensin receptor blockers (ARB), and calcium channel blockers (CCBs). Several studies reported that, lowering of blood pressure might also be beneficial. [5] Amlodipine is a dihydropyridine-type calcium channel blocker is frequently used for its strong antihypertensive and minimal adverse side effects in hypertensive patients. On the other hand, Cilnidipine, another new generation CCB (Calcium channel blocker) is considered for ensuring lesser edema (Pedal) with satisfactory control of hypertension by negligible side effects. Besides those CCBs several drugs are being currently used in the treatment of hypertension and various disease conditions of the heart either alone or in combination. [6] Amlodipine is one of the trusted CCBs with outstanding pharmacokinetic as well as pharmaco-dynamic profile. The only problem encountered with this CCB is the presence of peripheral edema. Some studies showed that, approximately up to 30% of patients with hypertension treated with amlodipine show the presence of peripheral edema while cilnidipine is known to inhibit sympathomimetic activity. [7] Although a single drug treatment may be effective in controlling BP, some cases might require prescription of more than one drug for proper controlling of blood pressure. [8]

METHODS & MATERIALS

This comparative observational study was conducted in the Department of Cardiology, Anwer Khan Modern Medical College Hospital, Dhaka, Bangladesh. June 2021 to November 2021. In this study, in total 60 hypertensive patients were selected as the study people. The standard mercury sphygmomanometer was used to measure the blood pressure of the patients. All the patients were divided into two groups, by 30 patients in each group. The first group

comprised of patients, taken amlodipine 5-10 mg/day while the other group included patients, taken cilnidipine 10–20 mg/day orally as the treatment protocol for hypertension. The mean values of SBP (Systolic blood pressure) and DBP (Diastolic blood pressure) during check-up were recorded and assessed. Proper written informed consents were taken from all the participants before data collection. As per the inclusion criteria of this study, only new several aged patients, diagnosed as hypertensive with blood pressure of >140/90 mm of mercury, patients without any known drug allergy cases without the history of any other systemic illness and patients with the absence of pre-existing nephritic syndrome, edema and anaemia were selected as the study subjects for this study. Consultant physician measured the blood pressure of the patients in the right arm in the sitting posture. Auscultatory method with standard mercury sphygmomanometer was used for the measurement of the blood pressure. Assessment of pedal edema was performed by the clinical methods over the medial malleolus of both legs. The cases were considered as positive for pedal edema if it was present on either of the legs. All the demographic, personal and medical details of the patients were recorded. Screening of all the patients was done every fortnight for the presence or absence of edema and control of blood pressure over a period of three months. The mean values of SBP and DBP during check-up were recorded and assessed. Data were processed, analyzed and disseminated by MS Office and SPSS programs as per need. P-value of less than 0.05 was considered as significant.

RESULTS

In this study, in total 60 hypertensive patients were selected as the study people. The standard mercury sphygmomanometer was used to measure the blood pressure of the patients. All the patients were divided into two groups, by 30 patients in each group. The first group comprised of patients, taken amlodipine 5-10 mg/day while the other group included patients, taken cilnidipine 10–20 mg/day orally as the treatment protocol for hypertension. In our study, in both the groups, female patients were dominating in number and totally 43% participants were male whereas the rest 57% were female. The mean age of Amlodipine group patients was 47.56 (±14.21) years whereas it was 46.92 (±14.47) years in Cilnidipine group. In comparing the mean (±SD) SBP findings at different stages among participants we observed that, at baseline, in Amlodipine group it was 150.47±11.71 whereas in Cilnidipine group it was found as 149.53±11.48. At 2-, 4- and 8-week's follow-ups, we did not find any significant difference between both group patient's SBP readings where the p values were found as 0.517, 0.705 and 0.517 respectively. In comparing the mean (±SD) DBP findings at different stages among participants we observed that, at baseline, in Amlodipine group it was 94.94±6.45 whereas in Cilnidipine group it was found as 94.18±6.38. At 2-, 4- and 8-week's follow-ups, we did not find any significant difference between both group patient's SBP readings where the p values were found as 0.673, 0.201 and 0.614 respectively. After 8 week's treatment, the mean pulse rates were found 74.96 in Amlodipine group whereas it was found as 75.47 in Cilnidipine group at the same time. In analyzing the incidences of pedal edema among both group participants we found pedal edema among 43% patients in Amlodipine group whereas it was found in only 7% in Cilnidipine group.

Table 1: Demographic status of participants (N=60)

Variables	Amlodipine (n=30)		Cilnidipine (n=30)		Total	
	n (%)/Mean ±SD		n (%)/Mean ±SD		(n=60)	
Mean age (Years)	47.56 ± 14.21		46.92 ±14.47		47.24±47	
Male	12	40%	14	47%	26	43%
Female	18	60%	16	53%	34	57%

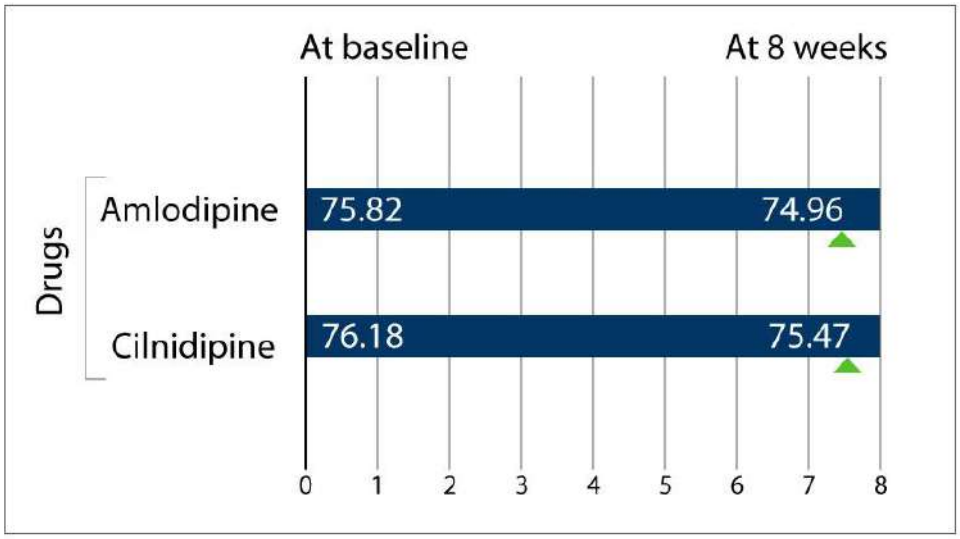
Table 2: Comparative mean (±SD) SBP findings at different stages among participants (N=60)

Time instance (Weeks)	Amlodipine	Cilnidipine	P value
Baseline	150.47±11.71	149.53±11.48	0.755
At 2	144.61±9.55	142.93±10.41	0.517
At 4	138.75±7.86	137.96±8.21	0.705
At 8	133.46±6.52	132.37±6.43	0.517

Table 3: Comparative mean (±SD) DBP findings at different period among participants (N=60)

Time instance (Weeks)	Amlodipine	Cilnidipine	P value
Baseline	94.94±6.45	94.18±6.38	0.648
At 2	89.88±4.14	89.42±4.27	0.673
At 4	86.73±2.54	85.87±2.61	0.201
At 8	83.55±2.37	83.87±2.51	0.614

Table 4: Comparative mean pulse rates at different period among participants (N=60)



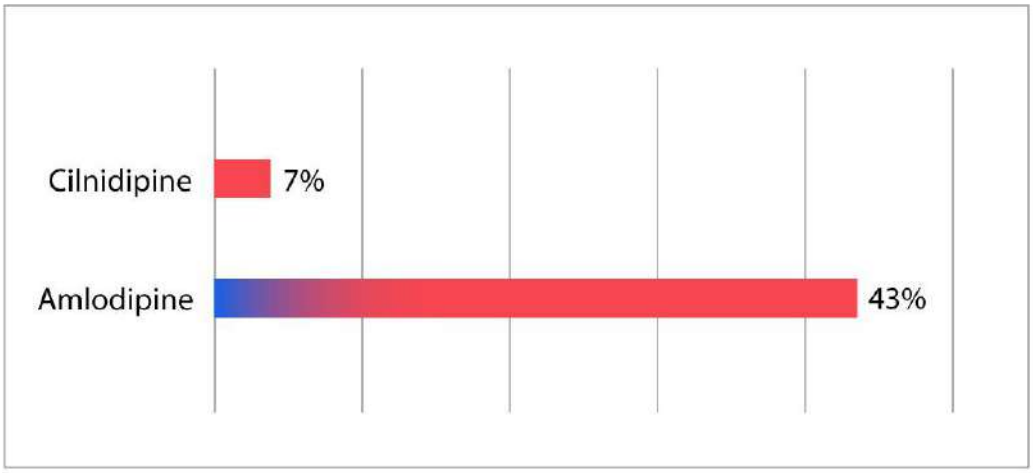


Table 5: Incidences of pedal edema among both group participants (N=60)

DISCUSSION

The aim of this current study was to compare the efficacies of Amlodipine and Cilnidipine in treating hypertensive patients. In this study, in both the groups, female patients were dominating in number and totally 43% participants were male whereas the rest 57% were female. The mean age of Amlodipine group patients was 47.56 (±14.21) years whereas it was 46.92 (±14.47) years in Cilnidipine group. Cessation of the amlodipine therapy is the usual protocol followed in controlling the peripheral edema observed in hypertensive patients with amlodipine-induced edema. [9] In our study, in analyzing the incidences of pedal edema among both group participants we found pedal edema among 43% patients in Amlodipine group whereas it was found in only 7% in Cilnidipine group. A study reported significant difference in the incidence of pedal edema in between the patients of the two study groups. However, they observed equal efficacy of both amlodipine and cilnidipine in reducing blood pressure in hypertensive individuals. [10] Shetty R et al assessed whether edema caused by amlodipine therapy was resolved by cilnidipine while maintaining adequate control of hypertension. They conducted a prospective study on 27 patients who were diagnosed with essential hypertension with presence of amlodipine-induced edema. Cilnidipine is one of the CCBs that are approved for the therapy of essential hypertension. [11] In this study, at 2-, 4- and 8-week's follow-ups, we did not find any significant difference between both group patient's SBP readings where the p values were found as 0.517, 0.705 and 0.517 respectively. Besides these, at 2-, 4- and 8-week's follow-ups, we did not also find any significant difference between both group patient's SBP readings where the p values were found as 0.673, 0.201 and 0.614 respectively. So, in our study, we observed that both amlodipine and cilnidipine exhibited about equal efficacy in controlling the BP of the patients on hypertension. Besides these, in another study, researchers didn't observe any significant difference in the mean arterial blood pressure and pulse rate and from their results, they concluded that, in treating antihypertensive for patients with amlodipine-induced edema, Cilnidipine is an acceptable alternative. [12] In another study, researchers observed non-significant difference in the efficacy of the two drugs is controlling the blood pressure. However, in terms of reno-protective effect, they found that, Cilnidipine exerted a higher

effect by the virtue of its antioxidative properties. [13] A study showed that, the subjects in cilnidipine group had a significantly higher mean heart rate at baseline compared to the subjects in amlodipine group($P < 0.049$). [14] whereas another study [15] showed that in amlodipine, there was no significant reduction in the mean pulse rate at theend of the study in comparison to the baseline values. In our study we found about the same efficacy of Amlodipine and Cilnidipine in treatment of hypertension. But Cilnidipine showed some superiority over Amlodipine because of less side effect of pedal edema.

LIMITATION OF THE STUDY

This was a single centered study with a small sized sample. So, findings of this study may not reflect the exact scenario of the whole country.

CONCLUSION AND RECOMMENDATIONS

In this study we found hypertensive patients got equal efficacy by both Amlodipine and Cilnidipine in reduction of blood pressure although incidence peripheral edema is higher in patients on amlodipine. So, we would like to recommend for using Cilnidipine with more confidence in the treatment of hypertension. For getting more specific findings we would like to recommend for conducting similar more studies with larger sized samples in several places.

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Conflict of interest: *None declared*

Ethical approval: *The study was approved by the Institutional Ethical Committee.*

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