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COMPARISON BETWEEN THE EFFICACIES OF AMLODIPINE AND CILNIDIPINE IN TREATING HYPERTENSIVE PATIENTS

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ABSTRACT ORIGINAL RESEARCH ARTICLE

Background: Controlling systolic blood pressure (SBP) and diastolic blood pressure (DBP) in hypertension (HTN) patients is one of the main challenges. Amlodipine is one of the calcium channel blockers (CCBs) with a remarkable pharmacokinetic and pharmacodynamic profile. But we have not enough research-based information regarding the effectiveness of amlodipine and cilnidipine in treating hypertension patients. **Aim of the study:** The objective of this study was to assess the effectiveness of amlodipine and cilnidipine in treating hypertensive patients.
Methods: This study was conducted at the Upazila Health Complex in Shahrasti, Chandpur, Bangladesh, from January 2021 to December 2021. In the study, 200 patients of either sex between the ages of 18 and 60 years were involved. The total number of participants were divided into two equal groups. There were 100 patients in each of the groups. As the part of the hypertension treatment protocol, patients in the first group, received oral amlodipine 5–10 mg/day whereas in other group, patients received oral cilnidipine 10–20 mg/day. During the checkup, the mean systolic and diastolic blood pressure values were noted and evaluated. SPSS 22.0 was used to analyze the data. **Results:** After 8 weeks of treatment, the cilnidipine group's SBP gradually decreased from 146.2±12.60 to 130.04±5.023 and its DBP gradually decreased from 94.21±6.86 to 84.34±1.79. On the other hand, in the

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amlodipine group, a gradual decline of SBP from 151.46±11.21 to 131.62±3.91 and DBP from 95.5±5.80 to 83±2.55 was observed. The results of the paired t-test statistical analysis were statistically significant, where the P value was found as 0.00001. **Conclusion:** Considering the findings of this current study we can conclude that, both amlodipine and cilnidipine have significant role in controlling blood pressure. But cilnidipine shows some superiority over amlodipine in lowering systolic blood pressure which is equally effective in lowering diastolic blood pressure.

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INTRODUCTION

One of the most prevalent diseases affecting people worldwide is hypertension (HTN), which is also a significant public health issue due to the associated morbidity, mortality, and societal costs [1]. The blood pressure (BP) level at which the initiation of therapy reduces BP-related morbidity and mortality can be used to define HTN [2]. HTN is classified as mild/Stage/Grade 1 (systolic blood pressure between 140 and 159), moderate/Stage/Grade 2 (systolic blood pressure between 160 and 179 and diastolic blood pressure between 100 and 109) and severe/Stage/Grade 3 (systolic blood pressure ≥180, DBP ≥110) [3]. If HTN is not effectively treated, it increases the risk of cardiovascular conditions such as coronary heart disease, congestive heart failure, ischemic and hemorrhagic stroke, renal failure, and peripheral arterial disease [4,5]. Numerous studies are cited in the literature that demonstrate that a strict check and control of blood pressure is necessary to achieve the greatest possible reduction in clinical cardiovascular end points. According to a recent study, a fall in average DBP of about 2-mmHg results in a 14% reduction in the risk of stroke and ischemic attacks. The risk of developing coronary artery disease was simultaneously reduced by 6%, according to the same study. Lowering blood pressure may also be advantageous, according to data from numerous other studies [6–9]. Several classes of antihypertensive medications, such as diuretics, α -blockers, β-blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and organic calcium channel blockers (CCBs) have been used in clinical settings. All of these medications are currently used, singly or in combination, to treat HTN and various heart disease conditions [10]. Amlodipine is one of the CCBs with a remarkable pharmacokinetic and pharmacodynamic profile. The presence of peripheral edema is the only issue with this medication. According to data from several studies, peripheral edema occurs in up to 30% of hypertensive cases taking amlodipine, whereas cilnidipine, a newer generation of CCB, is known to inhibit sympathomimetic activity [11]. Therefore, an effort has been made in this prospective study to contrast the effectiveness of cilnidipine and amlodipine in hypertensive patients.

METHODOLOGY

This study was conducted at the Upazila Health Complex in Shahrasti, Chandpur, Bangladesh, from January 2021 to December 2021. In the study, 200 patients of either sex between the ages of 18–60 were involved. According to how many patients there were, the total number of participants was split into two equal groups. 100 patients in a group and another 100 patients in other group. Patients in the other group received oral cilnidipine 10–20 mg/day as part of the hypertension treatment protocol, while patients in the first group received amlodipine 5–10

mg/day. The current study is an open-label, parallel group, prospective, comparative study. During this time, a complete physical examination and a systemic examination were conducted. With a mercury sphygmomanometer in an upright position, the radial pulse was examined to determine the pulse rate and blood pressure was measured. During the checkup, the mean systolic and diastolic blood pressure values were noted and evaluated. Additionally, the entire cardiovascular and respiratory systems were examined. Patients were enrolled for a total of 8 weeks, after which they were contacted for follow-up visits at weeks 2, 4, and 8. The information gathered was entered into a pro forma (case recording form) created especially for the study. A complete blood count, random blood glucose levels, liver function tests (aspartate aminotransferase and alanine aminotransferase), renal function tests (urea and creatinine), lipid profiles, and urine routines were all performed routinely in the hospital laboratory before and after the institution of therapy in accordance with the predetermined requirements. SPSS 22.0 was used to analyze the data.

RESULT

The present study, patients in the amlodipine group had a mean age of 60.5 years, whereas those in the cilnidipine group had a mean age of 50.5 years. In the amlodipine group and the cilnidipine group, respectively, there were 45 males and 55 females out of the 100 patients. After taking cilnidipine for 8 weeks, SBP gradually decreased from 146.2±12.60 at baseline to 130.04±5.023. P = 0.00001, a statistically significant result, was obtained from the paired t-test. DBP decreased gradually over the course of the treatment period of 8 weeks, dropping from 94.21±6.86 at baseline to 84.34±1.79. P = 0.0001, a statistically significant result, was obtained from the paired t-test. After 8 weeks of amlodipine treatment, the score indicated a gradual decrease in SBP, from 151.46±11.21 at baseline to 131.62±3.91. P = 0.00001 was used as the statistical significance level for the paired t-test analysis. A consistent reduction in DBP over the course of 8 weeks of amlodipine treatment, from 95.5±5.80 at baseline to 83±2.55. A statistically significant result using the paired t-test was obtained (P = 0.0001). The results of the ANOVA test are P = 0.128. Although there is statistically no difference between the two groups, both drugs are equally effective at lowering SBP. At the end of 8 weeks, the ANOVA test results show that there is a statistically significant difference between the two groups (P = 0.0001). Both medications are equally effective at lowering DBP. At the end of 8 weeks, the ANOVA test yields a P value of 0.45, indicating that there was no statistically significant difference between the two groups. Both medications are equally effective at lowering heart rate. At the end of 8 weeks, the ANOVA test yields P = 0.002, indicating that there is a statistically significant difference between the two groups. The distribution of patients is shown in Figure 1 according to the grade of HTN.

Table-1: Demographic details of the patients (N=200)

Parameter		Amlodipine	Cilnidipine
Number of patients		100	100
Mean age (years)		60.5	50.5
Gender	Males	45	45
	Females	55	55

Table-2: Comparison of efficacy in SBP reduction in both the groups (N=200)

Time instance	Amlodipine group	Cilnidipine group	P value
(Weeks)	Mean ±SD SBP	Mean ±SD SBP	
Baseline	151.46±11.21	146.2±12.60	0.303
At 2	144.42±7.34	142.76±11.47	0.341
At 4	139.17±6.07	138.28±7.66	0.00001
At 8	131.62±3.91	130.04±5.023	0.128

Table-3: Comparison of efficacy in DBP reduction in both the groups (N=200)

Time instance	Amlodipine group	Cilnidipine group	P value
(Weeks)	Mean ±SD DBP	Mean ±SD DBP	
Baseline	95.5±5.80	94.21±6.86	0.33
At 2	89.82±4.07	89.46±4.04	0.67
At 4	85.83±2.92	86.27±2.73	0.43
At 8	83±2.55	84.34±1.79	0.0001

Table-4: Assessment of heart rate in both the groups (N=200)

Drugs	At baseline mean	8 weeks mean
Amlodipine	77.34	74.44
Cilnidipine	77.24	74.14

Table-5: Assessment of pulse rate of both the groups (N=200)

Drugs	At baseline mean	8 weeks mean
Amlodipine	73.84	73.29
Cilnidipine	76.02	74.30

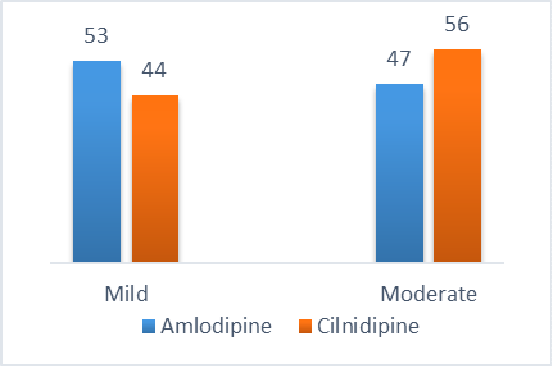

Figure-1: Distribution of patients according to the grade of hypertension

DISCUSSION

The objective of this study is to assess the effectiveness of amlodipine and cilnidipine in treating hypertension patients. According to this study, patients in the amlodipine group had a mean age of 60.5 years, whereas those in the cilnidipine group had a mean age of 50.5 years. In the amlodipine group and the cilnidipine group, respectively, there were 45 males and 55 females out of the 100 patients. After taking cilnidipine for 8 weeks, SBP gradually

decreased from 146.2±12.60 at baseline to 130.04±5.023. P =0.00001, a statistically significant result, was obtained from the paired t-test. DBP decreased gradually over the course of the treatment period of 8 weeks, dropping from 94.21±6.86 at baseline to 84.34±1.79. P = 0.0001, a statistically significant result, was obtained from the paired t-test. After 8 weeks of amlodipine treatment, the score indicated a gradual decrease in SBP, from 151.46±11.21 at baseline to 131.62±3.91. P = 0.00001 was used as the statistical significance level for the paired t-test analysis. A consistent reduction in DBP over the course of 8 weeks of amlodipine treatment, from 95.5±5.80 at baseline to 83±2.55. A statistically significant result using the paired t-test was obtained (P = 0.0001). The results of the ANOVA test are P = 0.128. Although there is statistically no difference between the two groups, both drugs are equally effective at lowering SBP. At the end of 8 weeks, the ANOVA test results show that there is a statistically significant difference between the two groups (P = 0.0001). Both medications are equally effective at lowering DBP. At the end of 8 weeks, the ANOVA test yields a P value of 0.45, indicating that there was no statistically significant difference between the two groups. Both medications are equally effective at lowering heart rate. At the end of 8 weeks, the ANOVA test yields P = 0.002, indicating that there is a statistically significant difference between the two groups. The distribution of patients is shown in Figure 1 according to the grade of HTN. The findings of the earlier study by Adake et al. [12] revealed a significant decrease in systolic and DBP (P < 0.05) in both groups compared to baseline data. The antihypertensive efficacy of the two drugs did not significantly differ from one another, though (P > 0.05). Both cilnidipine and amlodipine equally decreased blood pressure, according to the study by Ando et al. [13] (systolic and diastolic BP, after treatment: 130.40 ± 13.93/73.37 ± 10.20 mmHg) and the changes were not different between the groups (systolic and diastolic BP: P = 0.88 and P = 0.51, respectively). Both drugs had no effect on the PR (after treatment: 74.19 ± 11.96 and 74.19 ± 11.63 bpm), and there was no statistically significant difference between the two groups (P = 0.46). According to a study by Babu [14], the mean SBP in the amlodipine group and the cilnidipine group patients was 139.1 and 144.2 mmHg, respectively, while the mean DBP was 80.2 and 85.3 mmHg, respectively. When comparing the mean SBP and DBP between patients in the two study groups, non-significant results were found (P < 0.05). According to the research by Shanbhag et al. [15], the subjects in the cilnidipine group had a significantly higher baseline mean heart rate than the subjects in the amlodipine group (P < 0.049). The study by Singh et al. [16] revealed that there was no observable difference between the mean pulse rate at the conclusion of the study and the baseline values for amlodipine. The outcomes of this study and ours were comparable.

Limitation of the study:

This was a single center study with a small sized sample. A follow-up of only 8 weeks is insufficient. It was necessary to monitor adverse drug reaction.

CONCLUSION & RECOMMENDATION

Our study showed that, both medicines significantly lowered blood pressure, but cilnidipine was superior to amlodipine in lowering systolic blood pressure and equally effective in lowering diastolic blood pressure.

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