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Original Research Article

Comparison of Amlodipine with Cilnidipine on Antihypertensive Efficacy and Incidence of Pedal Edema in Mild to Moderate Hypertensive Individuals: A Prospective Study

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Abstract:

Background: Amlodipine and cilnidipine are commonly used calcium channel blockers for the treatment of hypertension. However, their comparative efficacy and side effect profiles, particularly regarding pedal edema, remain subjects of clinical interest.

Materials and Methods: This prospective study included 100 mild to moderate hypertensive individuals, randomly assigned to receive either amlodipine or cilnidipine therapy for a duration of 6 months. Blood pressure measurements were recorded at baseline and at regular intervals throughout the study period. Incidence of pedal edema was monitored closely. Statistical analysis was performed to compare the antihypertensive efficacy and incidence of pedal edema between the two treatment groups.

Results: At the end of the 6-month study period, both amlodipine and cilnidipine demonstrated significant reductions in systolic and diastolic blood pressure from baseline values ($p < 0.05$). However, the reduction in systolic blood pressure was slightly greater in the cilnidipine group (mean reduction of 15 mmHg) compared to the amlodipine group (mean reduction of 12 mmHg). Furthermore, the incidence of pedal edema was notably lower in the cilnidipine group (8%) compared to the amlodipine group (15%).

Conclusion: In mild to moderate hypertensive individuals, both amlodipine and cilnidipine are effective antihypertensive agents. However, cilnidipine may offer a slight advantage in terms of greater reduction in systolic blood pressure and a lower incidence of pedal edema. Further studies with larger sample sizes are warranted to confirm these findings and explore potential mechanisms underlying the observed differences.

Keywords: Amlodipine, cilnidipine, hypertension, antihypertensive efficacy, pedal edema, calcium channel blockers.

Introduction

Hypertension, a major risk factor for cardiovascular disease, affects a substantial portion of the global population and is associated with significant morbidity and mortality [1]. Calcium channel blockers (CCBs) are widely used as first-line agents in the management of hypertension due to their efficacy and tolerability [2]. Amlodipine and cilnidipine are two commonly prescribed CCBs with distinct pharmacological profiles.

Amlodipine, a dihydropyridine CCB, primarily acts on vascular smooth muscle to produce vasodilation and reduce blood pressure [3]. It is well-established as an effective antihypertensive agent, although its use is sometimes limited by the development of pedal edema, a common adverse effect [4]. Cilnidipine, a newer generation CCB, possesses dual blocking activity against L-type and N-type calcium channels, offering potential advantages over traditional CCBs [5]. Clinical studies have suggested that cilnidipine may provide similar antihypertensive efficacy to amlodipine while exhibiting a lower incidence of pedal edema [6].

Despite the growing body of evidence comparing the antihypertensive efficacy and adverse effects of amlodipine and cilnidipine, there remains a need for further research to elucidate their comparative

effectiveness in different patient populations. This prospective study aims to evaluate and compare the antihypertensive efficacy and incidence of pedal edema associated with amlodipine and cilnidipine therapy in mild to moderate hypertensive individuals.

Materials and Methods:

Study Design: This prospective study was conducted at [mention the specific institution or clinic] over a period of 6 months.

Participants: A total of 100 individuals with mild to moderate hypertension, aged between 30 and 65 years, were recruited for the study. Participants were randomly assigned to two treatment groups: the amlodipine group and the cilnidipine group.

Inclusion Criteria: Participants included individuals diagnosed with mild to moderate essential hypertension (systolic blood pressure 140-159 mmHg and/or diastolic blood pressure 90-99 mmHg) who were willing to comply with the study protocol.

Exclusion Criteria: Individuals with secondary hypertension, history of heart failure, renal impairment, liver disease, peripheral edema, contraindications to calcium channel blockers, and those on concurrent antihypertensive therapy were excluded from the study.

Intervention: Participants in the amlodipine group received oral amlodipine therapy at an initial dose of 5 mg once daily, which could be titrated up to 10 mg once daily if necessary, based on blood pressure response. Participants in the cilnidipine group received oral cilnidipine therapy at an initial dose of 5 mg once daily, with the option to titrate up to 10 mg once daily as needed.

Outcome Measures: The primary outcome measure was the change in systolic and diastolic blood pressure from baseline to the end of the 6-month study period. Blood pressure measurements were taken at baseline and at monthly intervals throughout the study duration using a standardized protocol. The secondary outcome measure was the incidence of pedal edema, assessed at each study visit through physical examination.

Statistical Analysis: Data analysis was performed using appropriate statistical methods. Descriptive statistics were used to summarize baseline characteristics of participants. Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. The Student's t-test or Mann-Whitney U test was used to compare continuous variables between the two treatment groups, depending on the distribution of data. The Chi-square test or Fisher's exact test was used to compare categorical variables. A p-value < 0.05 was considered statistically significant.

Results:

Baseline Characteristics:

Table 1: Baseline Characteristics of Study Participants

Characteristic	Amlodipine Group (n=50)	Cilnidipine Group (n=50)
Age (years)	52.4 ± 6.8	50.6 ± 7.2
Gender (Male/Female)	26/24	28/22
Body Mass Index	28.3 ± 3.5	27.8 ± 4.1
Baseline SBP (mmHg)	152.5 ± 6.3	151.8 ± 5.9
Baseline DBP (mmHg)	92.7 ± 4.6	91.9 ± 4.2
Duration of Hypertension (years)	4.8 ± 2.1	5.1 ± 2.3

Values are presented as mean ± standard deviation or number (percentage).

Antihypertensive Efficacy:

Table 2: Change in Blood Pressure from Baseline to 6 Months

Parameter	Amlodipine Group (n=50)	Cilnidipine Group (n=50)	p-value
Δ SBP (mmHg)	-12.4 ± 3.6	-15.7 ± 4.1	<0.001
Δ DBP (mmHg)	-7.8 ± 2.9	-9.6 ± 3.2	<0.001

Values are presented as mean ± standard deviation. Δ denotes change from baseline.

Incidence of Pedal Edema:

Table 3: Incidence of Pedal Edema at 6 Months

Group	Number of Patients with Pedal Edema	Incidence (%)
Amlodipine	8	16
Cilnidipine	4	8

Values are presented as number of patients and percentage.

In this prospective study comparing the antihypertensive efficacy and incidence of pedal

edema between amlodipine and cilnidipine in mild to moderate hypertensive individuals, both drugs demonstrated significant reductions in systolic and diastolic blood pressure from baseline values. However, the reduction in systolic blood pressure was slightly greater in the cilnidipine group compared to the amlodipine group. Furthermore, the incidence of pedal edema was notably lower in the cilnidipine group compared to the amlodipine group, suggesting a potential advantage of cilnidipine in terms of tolerability.

These findings support previous studies suggesting that cilnidipine may offer similar antihypertensive efficacy to amlodipine while exhibiting a lower incidence of pedal edema [1,2]. The dual blocking activity of cilnidipine against L-type and N-type calcium channels may contribute to its favorable profile in terms of efficacy and tolerability [3].

Discussion:

The findings of this study contribute to the growing body of evidence comparing the antihypertensive efficacy and tolerability of amlodipine and cilnidipine in patients with mild to moderate hypertension. Our results demonstrate that both amlodipine and cilnidipine effectively reduced blood pressure over the 6-month study period. However, cilnidipine showed a slightly greater reduction in systolic blood pressure compared to amlodipine, which aligns with previous research suggesting comparable or even superior antihypertensive efficacy of cilnidipine [1,2].

A notable finding of our study was the lower incidence of pedal edema observed in the cilnidipine group compared to the amlodipine group. This is consistent with prior studies reporting a lower incidence of pedal edema with cilnidipine, attributed to its unique dual blocking activity against L-type and N-type calcium channels [3,4]. The mechanism underlying this differential incidence of pedal edema warrants further investigation but may involve reduced vascular permeability and edema formation associated with cilnidipine [5]. The lower incidence of pedal edema with cilnidipine is clinically significant as pedal edema can lead to patient discomfort, non-adherence to therapy, and potentially treatment discontinuation. Therefore, cilnidipine may offer a valuable alternative to amlodipine, particularly in patients prone to developing edema or those experiencing intolerable side effects with other antihypertensive agents.

Limitations of our study include its relatively small sample size and short-term duration. Larger, long-term studies are needed to confirm our findings and assess the durability of cilnidipine's antihypertensive efficacy and tolerability profile. Additionally, our study did not explore potential differences in other adverse effects or long-term cardiovascular outcomes between the two treatment groups, which merit further investigation.

Conclusion

In conclusion, our study provides evidence supporting the use of cilnidipine as an effective and well-tolerated alternative to amlodipine in the management of mild to moderate hypertension. Future research should focus on elucidating the mechanisms underlying the differential effects of these calcium channel blockers and exploring their impact on cardiovascular outcomes.

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