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Research Article

Comparative Effects of Amlodipine and Cilnidipine on Lipid Profile as an add-on drug to Baseline medication in Hypertensive Chronic Kidney Disease patients

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ABSTRACT

Introduction: Dyslipidemia is highly prevalent in chronic kidney disease (CKD) and is a major contributor to cardiovascular morbidity. Calcium Channel Blockers (CCBs) such as amlodipine and cilnidipine are widely used as antihypertensives in CKD patients, but they differ in the metabolic effects. Cilnidipine is a novel Calcium Channel Blocker (CCB) that blocks both L and N-type calcium channels providing superior efficacy on lipid profile when compared to amlodipine.
Objectives: To compare the effects of amlodipine and cilnidipine on lipid profile parameters in hypertensive patients with CKD.
Methods: This study was a prospective observational one done in the Department of Nephrology at Government T.D. Medical College, Alappuzha for a period of one year (January 2016-December 2016) which was conducted in 90 hypertensive CKD patients aged 18-80 years. Out of this, 45 patients received amlodipine and 45 patients received cilnidipine along with the baseline medications. Fasting lipid parameters were assessed at baseline and after six months.
Results: Cilnidipine significantly reduced total cholesterol, triglycerides, and LDL cholesterol while increasing HDL levels. Amlodipine was associated with an increase in total cholesterol and LDL, with no significant improvement in triglycerides or HDL.
Conclusion: Cilnidipine confers a more favorable lipid profile compared to amlodipine in hypertensive CKD patients.

Keywords: *Hypertension, Chronic Kidney Disease, Cilnidipine, Amlodipine, Lipid profile.*

INTRODUCTION

Patients with CKD frequently exhibit dyslipidemia characterized by elevated triglycerides, increased LDL-C, and reduced HDL-C, which accelerates atherosclerosis and increases cardiovascular risk [3]. Antihypertensive agents with beneficial metabolic effects may therefore provide additional cardiovascular protection.

Calcium Channel Blockers (CCBs) such as amlodipine and cilnidipine are widely used in hypertensive CKD patients, but their metabolic effects differ [1,2]. Amlodipine is a third-generation dihydropyridine CCB that selectively blocks L-type calcium channels, whereas cilnidipine is a fourth-generation agent with dual L- and N-type calcium channel blocking activity [1]. N-type calcium channel blockade suppresses sympathetic nervous system activity, a mechanism implicated in lipid metabolism and insulin resistance [4]. These pharmacological differences may account for divergent effects on lipid profile.

Takashi Masuda, Misao N. Ogura, Tatsumi Moriya, et al (2011) have demonstrated the beneficial effects of L- and N-type CCB on glucose and lipid metabolism and renal function in patients with hypertension and type II diabetes mellitus [5]. Previous reports indicates beneficial effect of Cilnidipine on lipid profile in addition to the antihypertensive activity. [6,7]

The rationale of this study is that if cilnidipine proves to afford significant renoprotective action along with other beneficial effects on lipid profile in comparison to amlodipine, then it will be worthwhile using it along with baseline medication in patients with CKD.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Nephrology at Government T.D. Medical College, Alappuzha over a period of one year (January 2016-December 2016). The study was conducted in 90 hypertensive CKD patients - 45 patients received cilnidipine and 45 patients received amlodipine along with the baseline medications. All CKD patients with age between 18-80 years with GFR 30-60 ml/min and BP more than 140/90mmHg after taking loop diuretic (Tab. Frusemide 80 mg BD), α-blocker (Tab. Prazosin 10 mg BD) and β-blocker (Tab. Metoprolol 50 mg BD) for at least 1 month were included in the study. Patients taking alternative systems of medicine, pregnant ladies and individuals with hypertensive & cardiac emergencies were excluded from the study. Approval was taken from Institutional Ethics Committee (IEC No. B6/79/2015/TDMCA dated 02/12/2015) as well as from Institutional Research Committee (IRC) before commencing the study. Confidentiality was maintained throughout the study. Written informed consent was taken from patients. Sitting systolic and diastolic BP were taken under standard conditions twice at a gap of 20 minutes each and the mean average was taken for study. Weight (kg) of the patients was assessed using a digital platform weighing scale. Patients who were getting either amlodipine 5mg BD or cilnidipine 10 mg BD as add-on therapy were included. All the patients were reviewed at 2 months intervals for a period of 6 months and their BP was recorded at each visit. The dose of amlodipine and cilnidipine was escalated to 10 mg BD and 20 mg BD respectively if the BP did not decrease to 140/90 mmHg. Data entry was done in Excel 2010 and analysis was done using SPSS 18. Fasting serum lipid profile including total cholesterol, triglycerides, HDL-C, and LDL-C was measured at baseline and after six months. Dyslipidemia was defined on the basis of abnormal lipid level (LDL- Cholesterol (LDL-C)≥ 140mg/dl, HDL-Cholesterol(HDL-C)< 40mg/dl,Triglyceride(TG)≥150mg/dl).

Statistical Analysis: Values are expressed as the mean±SD. The difference of the baseline characteristics and change in parameters between the Amlodipine and Cilnidipine groups were compared using an unpaired t-test. Intragroup comparisons were performed using paired t-tests and $p < 0.05$ was considered statistically significant.

RESULTS

A total of 90 hypertensive CKD patients were included in the study - 45 patients received cilnidipine and 45 patients received amlodipine along with the baseline medications. There were 61 (67.8%) males and 29 (32.2%) females. Out of 61 males, 29 (32.2%) were treated with amlodipine and 32 (35.6%) were treated with cilnidipine. Out of 29 females, 16 (17.8%) were treated with amlodipine and 13 (14.4%) were treated with cilnidipine.

Out of 90 patients, 48 had Diabetes Mellitus(DM), 17 had Coronary Artery Disease(CAD) and 45 had dyslipidemia. In 45 cases of dyslipidemia, 30(33.3%) were males and 15(16.7%) were females. The sex wise distribution of the number and proportion of patients with co-morbidities were given in Figure1.

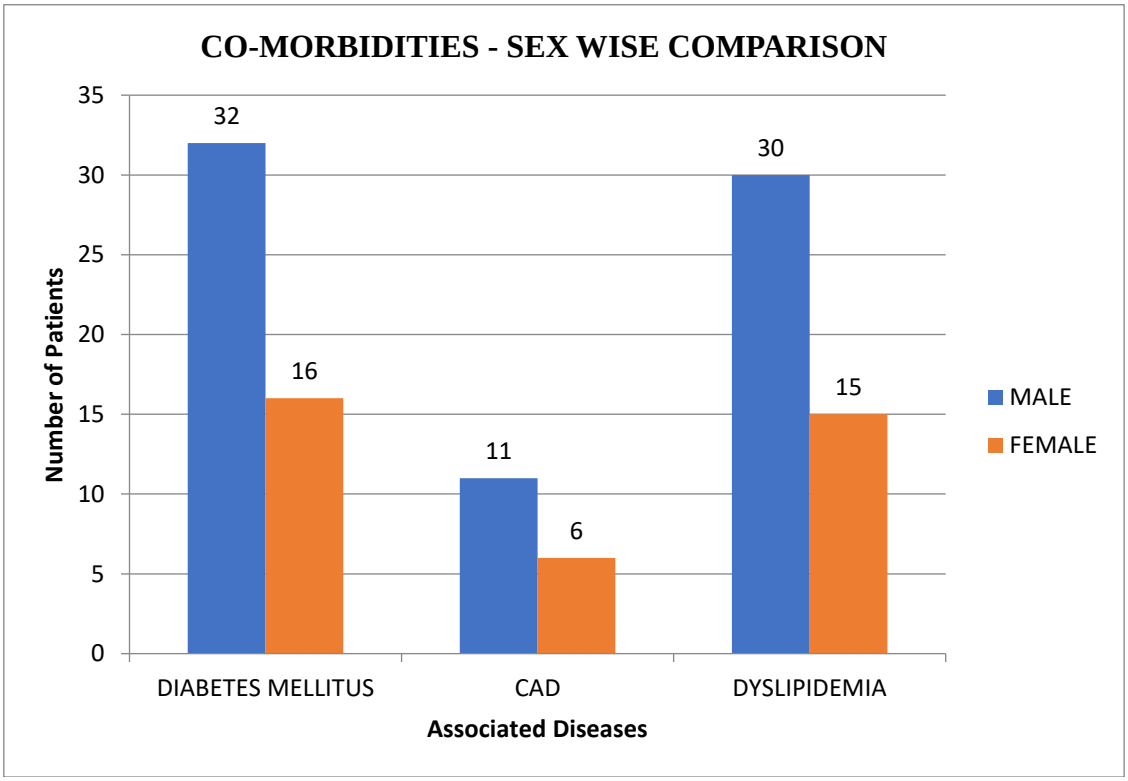

Figure 1: Co-morbidities of cases under study - Sex wise comparison

The mean ± SD of the variables under study before and after treatment at fourth visit in both amlodipine and cilnidipine groups are as given in Table 1.

Table 1: The mean ± SD of the variables under study

Parameter	Amlodipine		Paired t-test (t, p)	Cilnidipine		Paired t-test (t, p)
	Before Treatment	Post Treatment		Before Treatment	Post Treatment	
S. Cholestrol	198.2±32.7	210.1±39.9	-3.98, <0.001	206.6±40	182.5±24.6	5.75, <0.001
Triglycerides	130.95±18.2	134.07±21.6	-1.38, 0.175	140.6±31.5	123.5±29.7	6.37, <0.001
HDL	41.04±3.7	41.2±4.5	-0.19, 0.85	41.1±7.7	49.7±11.2	-7.17, <0.001
LDL	135.8±33.3	141.9±31.8	-4.46, <0.001	130±45.4	112.6±33.5	4.3, <0.001

The mean serum total cholestrol of amlodipine and cilnidipine at each visits was given in Figure 2.

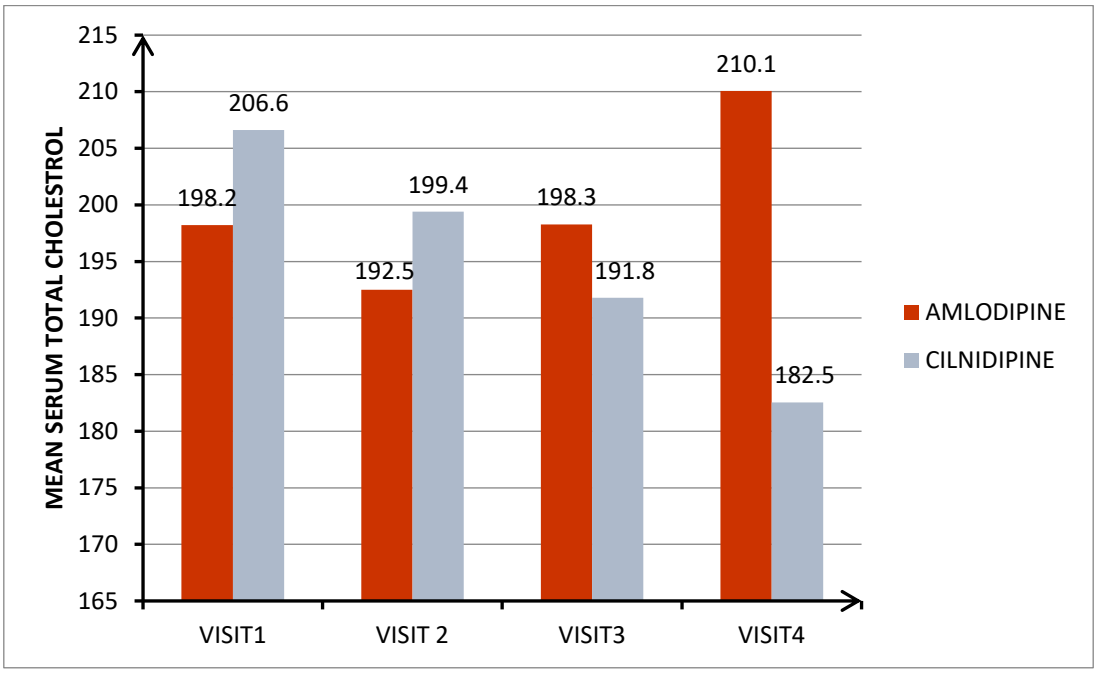

Figure 2: Comparison of mean serum total cholestrol in both groups

The mean serum TG of amlodipine and cilnidipine at each visits was given in Figure 3.

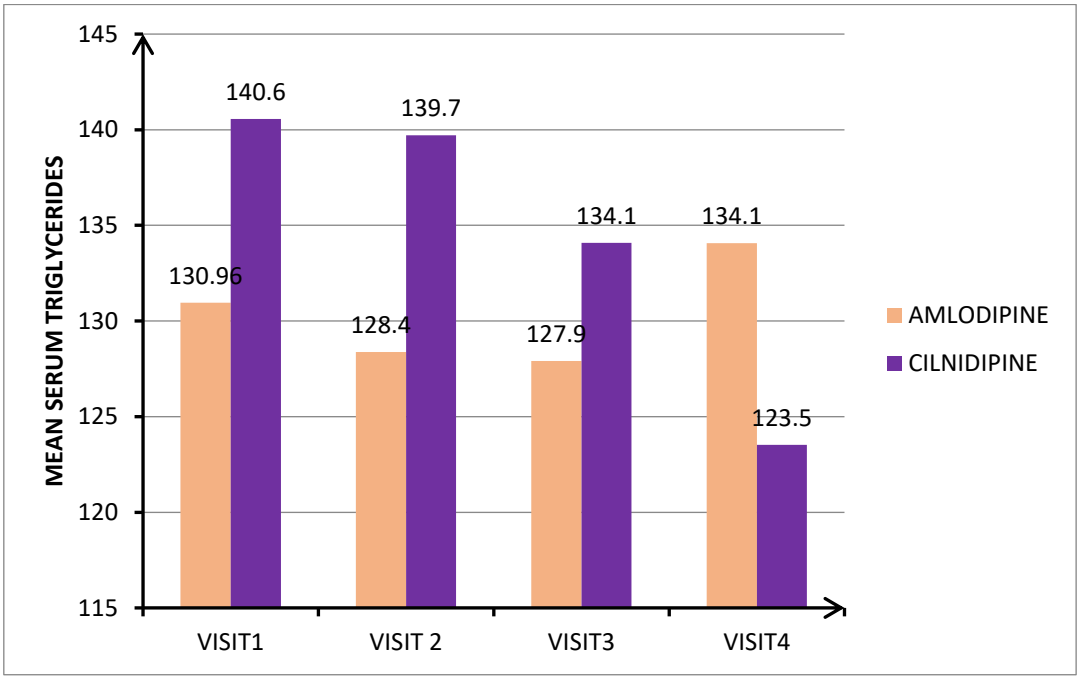

Figure 3: Comparison of mean serum TG in both groups at each visits

The mean serum HDL of amlodipine and cilnidipine at each visits was given in Figure 4.

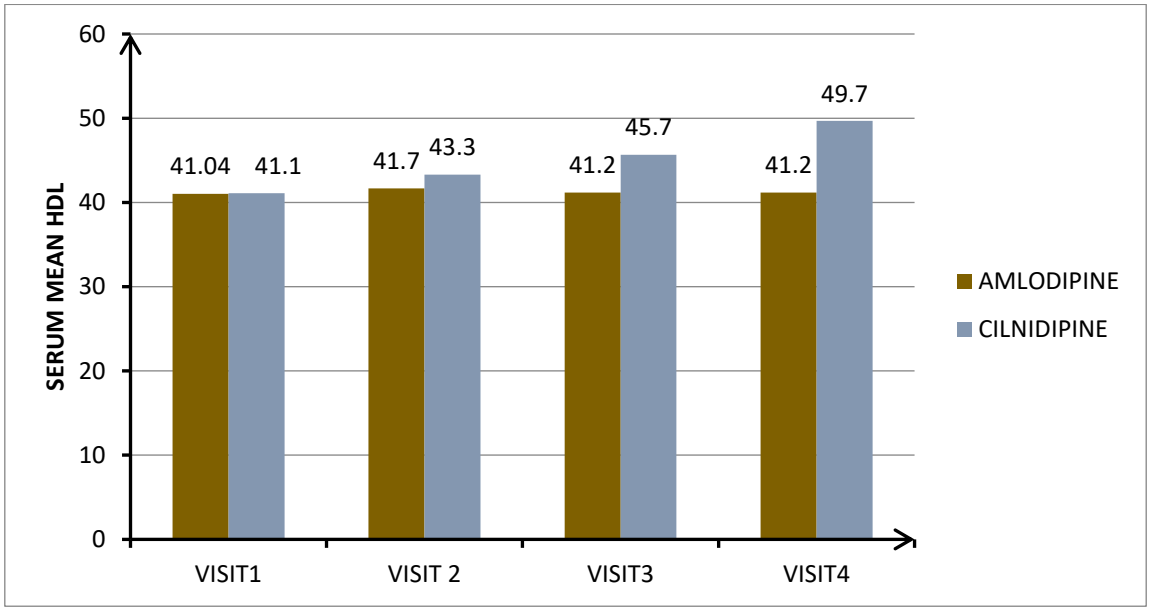

Figure 4: Comparison of mean serum HDL in both groups at each visits

The mean serum LDL of amlodipine and cilnidipine at each visits was given in Figure 5.

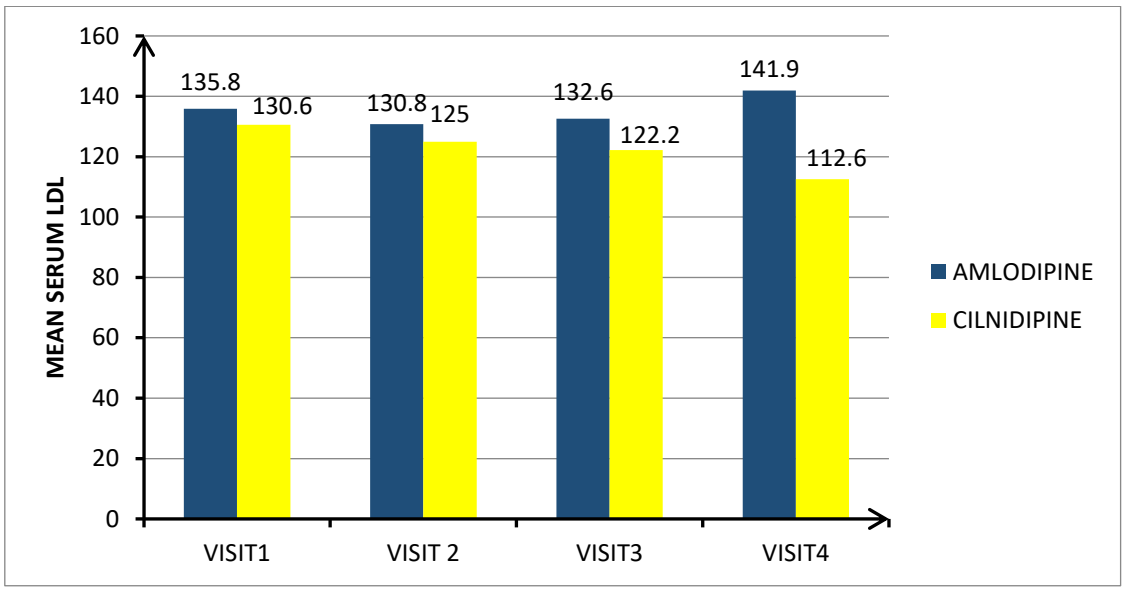

Figure 5: Comparison of mean serum LDL in both groups at each visits

Paired t -test showed that in the amlodipine group, the mean serum total cholesterol and LDL-C increased significantly after six months of therapy, while serum triglycerides and HDL-C showed no statistically significant change. In contrast, patients receiving cilnidipine demonstrated a significant reduction in serum total cholesterol, serum triglycerides, and LDL-C, along with a significant increase in HDL-C.

DISCUSSION

The present study highlights a clear differential effect of calcium channel blockers on lipid profile in hypertensive CKD patients. While amlodipine effectively controls blood pressure, its neutral or adverse effects on lipid parameters may limit its cardiometabolic benefit.

Cilnidipine's dual L- and N-type calcium channel blockade suppresses sympathetic activity and may reduce catecholamine-mediated lipolysis, thereby improving lipid handling [1,4]. In this study, the mean serum total cholesterol and LDL-C increased significantly after six months of therapy with amlodipine, while serum triglycerides and HDL-C showed no statistically significant change. In contrast, patients receiving cilnidipine demonstrated a significant reduction in serum total cholesterol, serum triglycerides, and LDL-C, along with a significant increase in HDL-C. These findings suggest a favorable modulatory effect of cilnidipine on lipid metabolism, consistent with previous clinical studies

[8,9].Clinical studies by Zaman et al. and Masuda et al. reported significant reductions in triglycerides and improvements in lipid profile with cilnidipine compared to amlodipine [8,10].

In the study by Zaman et al, there were no significant differences between the amlodipine and the cilnidipine treatment in terms of total cholesterol, HDL and LDL. Analysis on diabetic cases showed that triglycerides were significantly higher in the amlodipine group whereas the parameter did not differ in the cilnidipine group. [11].

Given the high cardiovascular risk burden in CKD patients, the favorable lipid-modifying effects of cilnidipine may translate into meaningful long-term clinical benefits.

Limitation of this study is the relatively small sample size and the short period of study. Moreover, the study was a prospective observational study. For better assessment of efficacy, a randomised controlled trial is preferable. In addition, medicines were taken by the patients in their own homes and not under direct supervision. Therefore, the complete compliance of the patients on regular intake of medication cannot be ascertained and the study relies on the assumption that the patients in the study are on regular medication.

CONCLUSION

Cilnidipine demonstrates superior lipid-modifying effects compared to amlodipine in hypertensive patients with chronic kidney disease. Its use may provide additional cardiovascular protection and should be considered preferentially in patients with coexisting dyslipidemia.

CONFLICT OF INTEREST- None

Author contribution- All authors have contributed in the manuscript.

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