

# A study of cost-effective benefits of cilnidipine versus amlodipine for the treatment of hypertension at tertiary health care centre

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## Abstract

**Background:** Hypertension (HTN), or high blood pressure, now defined as systolic blood pressure of more than 140 mm Hg and diastolic blood pressure of more than 90 mm Hg, is attributed as the leading cause of cardiovascular mortality by the World Health Organization. **Aims and Objectives:** To Study cost effective benefits of Cilnidipine versus Amlodipine for the treatment of Hypertension at tertiary health care centre. **Methodology:** The Present study was undertaken by the department of Pharmacology in collaboration with the department of Medicine on newly diagnosed patients of Hypertension attending Medicine outpatient department of HKE society's Basaveshwara Teaching and General hospital, attached to M.R.Medical College, Kalaburagi a for a period of 12 months from January 2017- December 2017. 100 adult patients aged 18-60 yrs of either sex of newly diagnosed mild and moderate hypertensive patients were included. 50 patients each on Cilnidipine and Amlodipine were randomly chosen and grouped as follows. Data was analyzed using the SPSS version 22.0 for windows (SPSS Inc., Chicago, Illinois®). Quantitative data are presented as means and standard deviation (mean  $\pm$  sd) and qualitative data as frequency and 95% confidence interval (CI). The average cost of the drug per person was calculated. Intergroup analysis was done using paired student's t-test. Significance was defined as  $P < 0.01$ . **Result:** The mean age in the patients received Cilnidipine was  $42.98 \pm 8.35$  and Amlodipine was  $44.48 \pm 9.03$ . Out of total 100 patients, Male: Female ratio of 67:33 was found in the patients enrolled for our study. Both the groups had more patients with moderate elevation of blood pressure. On comparison of ADRs between Cilnidipine and Amlodipine it is clear that Amlodipine has more ADRs than Cilnidipine. The absence of pedal edema in Cilnidipine group when compared to Amlodipine group show a Statistical Significance with  $p= 0.0003$ . We obtain data regarding mean SBP and DBP reduction in two groups and the average monthly cost of the study drug per patient. Our analysis shows no cases of pedal edema and lower number of ADRs in Cilnidipine group when compared with Amlodipine group. **Conclusion:** It can be concluded from our study that significantly less ADRs were in Cilnidipine group with the comparable cost of Amlodipine so Cilnidipine can be cost effectively in comparison with Amlodipine.

**Key Word:** Amlodipine, Cilnidipine, ADRs, Cost effective.

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## INTRODUCTION

Hypertension (HTN) is attributed as the leading cause of cardiovascular mortality by the World Health Organization. In 2000, it was estimated that 972 million adults or 26.4% of the adult population had HTN worldwide<sup>1</sup>. The number of adults with HTN in 2025 is predicted to increase by 60% to 1.56 billion<sup>2</sup>. Among Asian country people with HTN, approximately 19% received pharmacological treatment, but only about 25% of the treated patients had their blood pressure well controlled<sup>3</sup>. The direct medical cost of HTN was \$20.2 billion, according to 2003 National Health Services

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Survey<sup>4</sup>. Uncontrolled HTN may result in various complications (e.g., strokes, heart failure, myocardial infarction [MI], and peripheral vascular disease), which are the major causes of morbidity and mortality. About 54% of stroke, 47% of ischemic heart disease, and 25% of other cardiovascular diseases worldwide were caused by elevated blood pressure. In East Asia and the Pacific, deaths and disability-adjusted life-years of hypertensive patients attributed to stroke were the highest among all cardiovascular end points<sup>5</sup>. The incidence of stroke increases in proportion to both systolic and diastolic blood pressures. Most ischemic strokes occur in individuals with pre-HTN or stage 1 HTN. The incidence of ischemic or hemorrhagic stroke is reduced substantially by adequate treatment of HTN<sup>6</sup>. A slight reduction in blood pressure over a time period of 3 to 4 years among moderately complicated hypertensive patients lowers the incidence of all cardiac events by 35%<sup>7</sup>.

## METHODOLOGY

The Present study was undertaken by the department of Pharmacology in collaboration with the department of Medicine on newly diagnosed patients of Hypertension attending Medicine outpatient department of HKE society's Basaveshwara Teaching and General hospital, attached to M.R.Medical College, Kalaburagi a for a period of 12 months from January 2017- December 2017. After approval by the Institutional Ethics Committee (IEC), 100 adult patients aged 18-60 yrs of either sex of newly diagnosed mild and moderate hypertensive patients were included. The present study is a prospective, open-label, parallel group, comparative study. Patients aged <18 years and >60 years, History of severe hepatic, renal disease and severe cardiac disease, Pregnant and lactating mothers, Major Depressive Disorder with psychotic symptoms, Patients on drugs with known drug

interactions with the study drugs were excluded from the study. 100 consenting patients who were prescribed either of Cilnidipine or Amlodipine for mild and moderate hypertensive, patients were randomly selected after applying inclusion-exclusion criteria. Patients were screened by clinical examination by a physician . A detailed history which included information regarding co morbidities, allergies, past hospital admissions, reproductive history and addictions was obtained. 50 patients each on Cilnidipine and Amlodipine were randomly chosen and grouped as follows

**Group A-** 50 patients who were prescribed Tab Cilnidipine (5-10mg/day)

**Group B-** 50 patients who were prescribed Tab Amlodipine (2.5-10mg/day)

Patients were informed in detail about the study procedure and written informed consent was taken from all the subjects before including them in the study. General physical examination and systemic examination was performed during this time. The Radial pulse was examined for the Blood Pressure was recorded with a Mercury Sphygmomanometer in upright position. Complete cardiovascular and respiratory system evaluation was also performed. Patients were recruited for a period of 8 weeks and were called for follow-up visit at 2nd, 4th, and 8th week. The data collected was entered into a specially designed proforma (Case Recording form) for the study. All the data collected was entered into a pre approved, case recording form and tabulated using Microsoft Office Excel software. Data was analyzed using the SPSS version 22.0 for windows (SPSS Inc., Chicago, Illinois®). Quantitative data are presented as means and standard deviation (mean ± sd) and qualitative data as frequency and 95% confidence interval (CI). The average cost of the drug per person was calculated. Intergroup analysis was done using paired student's t-test.

## RESULT

**Table 1:** Age wise distribution of patients among two groups

Group	Mean age (years)	Standard Deviation
Cilnidipine	42.98	8.35
Amlodipine	44.48	9.03

The mean age in the patients received Cilnidipine was 42. 98 ± 8.35 and Amlodipine was 44.48 ± 9.03.

**Table 2:** sex distribution of patient among two group

Gender	Cilnidipine	Amlodipine	Total number of cases
Male	33	34	67
Female	17	16	33

Out of total 100 patients, Male: Female ratio of 67:33 was found in the patients enrolled for our study.

**Table 3:** Distribution of patients according to Grade of Hypertension

Grades	Cilnidipine (N=50)	Amlodipine (N=50)
Mild	19(38%)	23(46%)
Moderate	31(62%)	27(54%)

Both the groups had more patients with moderate elevation of blood pressure

**Table 4:** Comparative assessment of the adverse drug reactions in two groups

ADRs	Cilnidipine(n=50)	Amlodipine(n=50)
Pedal Edema	—	13 (26%)
Headache	7 (14%)	5 (10%)
GI Disturbances	5 (10%)	6 (12%)
Dizziness	3 (6%)	4 (8%)
Hypotension	5 (10%)	6 (12%)
Palpitation/Tachycardia	7 (14%)	9 (18%)
Myalgia	5 (10%)	3 (6%)
Blurring vision	5 (10%)	6 (12%)
Flushing	2 (4%)	2 (4%)
Urinary problem	6 (12%)	6 (12%)
Nausea/Vomiting	9 (18%)	3 (6%)
Others	3 (6%)	2 (4%)
<b>Total</b>	<b>57</b>	<b>65</b>

On comparison of ADRs between Cilnidipine and Amlodipine it is clear that Amlodipine has more ADRs than Cilnidipine. The absence of pedal edema in Cilnidipine group when compared to Amlodipine group show a Statistical Significance with p= 0.0003

**Table 5:** Assessment of cost benefit of two drugs by comparison of fall in Blood Pressure with expenditure incurred

Group	Mean BP/week at Baseline	Mean BP/week after 8 weeks	Fall in Mean BP/week	Monthly average cost of study drug per person(INR) (mean ± SD)
Cilnidipine	149.2/94.22	131.04/84.36	2.27/1.23	45
Amlodipine	151.56/95.4	132.72/82	2.55/1.67	36

We obtain data regarding mean SBP and DBP reduction in two groups and the average monthly cost of the study drug per patient. Our analysis shows no cases of pedal edema and lower number of ADRs in Cilnidipine group when compared with Amlodipine group

## DISCUSSION

Across the world, stroke is considered the second leading cause of death, responsible for 4.4 million (9%) of the total 50.5 million deaths each year<sup>8</sup>. In Some recent epidemiologic studies confirmed that stroke was the leading cause of adult disability, and the second commonest cause of death, with an incidence more than fivefold that of MI<sup>9</sup>. The direct medical cost of stroke was £24.3 billion, according to 2003 National Health Services Survey<sup>4</sup>. HTN is the single most important risk factor for all types of strokes including both ischemic and hemorrhagic<sup>10</sup>. The association between high blood pressure and stroke has been evident for many years. Meta-analysis of randomized controlled trials showed that lowering of blood pressure was associated with a 30% to 40% reduction in stroke risk<sup>11</sup>. To prevent the future occurrence of stroke among hypertensive patients, it is critical to keep blood pressure under good control with effective pharmacological treatments. There are many classes of antihypertensive drugs in the market with

different mechanisms of action. Among the most important and most widely used are the thiazide diuretics, the angiotensin-converting enzyme inhibitors, the calcium channel blockers (CCBs), the beta blockers, and the angiotensin II receptor blockers (ARBs). ARBs, such as losartan and valsartan, are a newer and safer class of antihypertensive agents. They are primarily used for the treatment of HTN when the patient is intolerant of angiotensin-converting enzyme inhibitor therapy, because of their affirmative efficacy and better tolerance. Clinical trial data showed that ARBs did not adversely affect kidney function, even in the presence of chronic renal insufficiency. Because of their short half-lives, however, many of the ARBs may require twice-daily dosing in some patients to keep the blood pressure under control, which would substantially increase the cost<sup>12</sup>. CCBs is another widely used type of antihypertensive. They account for approximately 60%, with an upward trend of all antihypertensive drugs prescribed by clinicians<sup>13-15</sup>. In our study we have found that the mean age in the patients

received Cilnidipine was  $42.98 \pm 8.35$  and Amlodipine was  $44.48 \pm 9.03$ . Out of total 100 patients, Male: Female ratio of 67:33 was found in the patients enrolled for our study. On comparison of ADRs between Cilnidipine and Amlodipine it is clear that Amlodipine has more ADRs than Cilnidipine. The absence of pedal edema in Cilnidipine group when compared to Amlodipine group show a Statistical Significance with  $p= 0.0003$ . Both the groups had more patients with moderate elevation of blood pressure. We obtain data regarding mean SBP and DBP reduction in two groups and the average monthly cost of the study drug per patient. Our analysis shows no cases of pedal edema and lower number of ADRs in Cilnidipine group when compared with Amlodipine group. A study by Tripathy PK<sup>16</sup> showed lower incidence of pedal edema in Cilnidipine group and likewise our study also depicted 13 (26%) patients had pedal edema in Amlodipine group, pedal edema was the major ADR. 9 (18%) cases of palpitation and tachycardia was noted in Amlodipine group in comparison to 7 (14%) in Cilnidipine group. 7 (14%) cases of headache was noted in Cilnidipine group in comparison to 5 (10%) patients in Amlodipine group.

## CONCLUSION

It can be concluded from our study that significantly less ADRs were in Cilnidipine group with the comparable cost of Amlodipine so Cilnidipine can be used cost effectively in comparisons with Amlodipine.

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