



Clinical Research

A COMPARATIVE STUDY TO ASSESS THE EFFICACY OF BENIDIPINE, AMLODIPINE AND CILNIDIPINE ON CLINICAL AND BIOCHEMICAL PARAMETERS ON PATIENTS SUFFERING FROM HYPERTENSION.

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ABSTRACT This comparative group study was done to evaluate the efficacy of Benidipine, Amlodipine and cilnidipine. 120 patients of Hypertension were selected from the medicine department & were divided into three groups, each group consist of 40 patients. The patients in Group A, Group B and Group C were administered Amlodipine 5 mg/day, Cilnidipine 10 mg/day and Benidipine 4 mg/day Newly Diagnosis was confirmed by standard mercury sphygmomanometer. Two recordings of blood pressure were taken at an interval of 15-20 min. The BP was measured at monthly intervals and target BP was defined as 130/85mm Hg. We found in this comparative study that amlodipine (5mg/day), cilnidipine (10mg/day) and benidipine (4mg/day) were equally effective in reducing the Systolic blood pressure and Diastolic Blood pressure in hypertensive patients. However, there was significant decrease in pulse rate and no incidence of pedal edema in benidipine treated patients. Similarly, the serum triglyceride levels decreased and urinary microalbumin excretion also decreased significantly in benidipine group. Pedal edema was seen in 20% patients in amlodipine group and 5% patients in Cilnidipine group while none of the patients from benidipine group had pedal edema. There was significant ($P < 0.05$) reduction in serum triglyceride and urinary microalbumin levels, from baseline in the benidipine group. Benidipine was found to be more safe than Amlodipine and Cilnidipine

KEYWORDS :**INTRODUCTION**

Hypertension is the most common cardiovascular disease. In India, 29.8% population are suffering from hypertension.^[1] Amlodipine, a calcium channel blocker, dilates arterioles by blocking L-type calcium channels.^[2] Benidipine inhibits L, N, and T type calcium channels^[2] and Cilnidipine inhibits L, and N type calcium channels.^[3] Amlodipine has a potent blood pressure lowering effect and few adverse effects like pedal edema and tachycardia.^[2] Cilnidipine has a potent blood pressure lowering effect same as Amlodipine and adverse effects like pedal edema and tachycardia are less than Amlodipine.^[3] Recently, a new calcium-channel blocker-Benidipine has become available in Indian market. It is a triple L, N, T-calcium channel blocker with promising end organ protection effects.^[2]

MATERIALS AND METHODS

Out of 125 patients 5 patients dropped out from the study and thus 120 patients completed the study. Patients with other body site involvement, patients who had received Antihypertensive drug upto 6 week, respectively, prior to initiation of the study were excluded. Participants with known history of hypersensitivity to study drugs. Patients with preexisting renal, hepatic or cardiac disease or pedal edema, hypoproteinemia, anemia, Pregnant women or taking drugs such as non-steroidal antiinflammatory drugs were also not recruited. Participants were randomized with the help of table of random numbers in three groups containing 40 participants each. Group A received Amlodipine 5 mg/day for six weeks, Group B received Cilnidipine 10 mg/day for six weeks; while Group C received Benidipine 4 mg/day. The study medication was dispensed to the subject following randomization technique, provided all inclusion and exclusion criteria were satisfied.

Inclusion criteria: New patients of Hypertension-stage 1 (BP 140-160/90-100mm Hg) Both sexes, Age: 35-75 years.

Exclusion criteria: Patients with preexisting renal, hepatic or cardiac disease or pedal edema, hypoproteinemia, anemia, Pregnant women or Patients taking drugs such as non-steroidal antiinflammatory drugs.

Patients were followed up at monthly intervals for 6 week from the start of the study. At the end of treatment in screened for the presence of pedal edema as compared to baseline.

RESULT

120 patients were taken for study, 40 patients in Group A (given Amlodipine 5 mg/day), 40 patients in Group B (Given Cilnidipine 10 mg/day) and Group C (given Benidipine 4 mg/day) completed the study after 6 week. At end of treatment, Pedal edema was seen in 20% patients in Amlodipine group, 5% patients in Cilnidipine group while

none of the patients from Benidipine group had pedal edema.

Table 1: Baseline clinical features of patients.

Week	Group A (treated With Amlodipine) Mean±sd	Group B (treated With Cilendipine) Mean±sd	Group B (treated With Benidipine) Mean±sd
Mean Age±SD	55 ± 5.02	59 ± 7.16	60 ± 8.18
Sex (Male/Female)	30/10	29/11	32/8
BMI (Kg/m ²)	23 ± 3.11	27 ± 5.12	28 ± 5.25
T2 DM (n)	6	4	5
Systolic BP (mm Hg)	144 ± 2.8	147 ± 3.14	148 ± 2.18
Diastolic BP (mm Hg)	96 ± 3	99 ± 2	97 ± 5
Pulse Rate (bpm)	65 ± 9	70 ± 7	71 ± 8
Pedal edema	Nil	Nil	Nil

Table 2: shows the results of biochemical parameters at base-line.

Week	Group A (treated With Amlodipine) Mean±sd	Group B (treated With Cilendipine) Mean±sd	Group B (treated With Benidipine) Mean±sd
TC (mg/dl)	210 ± 44	208 ± 35	202 ± 40
TG (mg/dl)	123 ± 15	126 ± 25	129 ± 22
HDL-c (mg/dl)	41 ± 10	44 ± 9	47 ± 8
LDL-c (mg/dl)	125 ± 18	128 ± 15	130 ± 14
HbA1c (%)*	7.5 ± 5	7.8 ± 3	7.9 ± 2
Serum creatinine (mg/dl)	0.9 ± 0.3	0.7 ± 0.4	0.6 ± 0.6
Urinary microalbumin (mg/L)	88 ± 24	85 ± 23	82 ± 21

Above result shows that no significant difference between three group profile.

* For Diabetic patient

Table3: Shows The Results After The Treatment With Either Amlodipine, Cilendipine Or Benidipine.

Week	Group A (treated With Amlodipine) Mean±sd	Group B (treated With Cilendipine) Mean±sd	Group C (treated With Benidipine) Mean±sd
Systolic BP* (mm Hg)	137 ± 13	135 ± 12	128 ± 10
Diastolic BP* (mm Hg)	80 ± 7	78 ± 5	77 ± 8
Serum TG* (mg/dl)	121 ± 23	115 ± 19	108 ± 10
Urinary* microalbumin (mg/L)	80 ± 18	65 ± 19	54 ± 12

Pulse Rate*# (bpm)	72 ± 8	64 ± 12	55 ± 10
Pedal edema	20 %	5%	Nil

* P<0.05 Comparison with base-line

#P<0.05 Comparison between the groups

All drugs effectively and significantly (P <0.05) reduced Systolic blood Pressure and Diastolic blood pressure from base-line levels. However, there was significant decrease in pulse rate with benidipine treatment as compared to that with amlodipine and cilnidipine.

Pedal edema was seen in 20%patients in amlodipine group and 5% patients in Cilnidipine group while none of the patients from benidipine group had pedal edema. There was significant (P <0.05) reduction in serum triglyceride and urinary microalbumin levels, from base-line in the benidipine group.

DISCUSSION

This randomized, open-label, comparative study was done to evaluate the efficacy of Amlodipine, Cilnidipine and Benidipine on clinical and biochemical parameters on patients suffering from hypertension during a period of 6 weeks. 120 patients of Hypertension stage I were selected from the Department of medicine, NIMS Hospital and were divided in three groups, each consisting of 40 patients.

In the present study, We found in this comparative study that amlodipine (5mg/day), cilnidipine (10mg/day) and benidipine (4mg/day) were equally effective in reducing the Systolic blood pressure and Diastolic Blood pressure in hypertensive patients. However, there was significant decrease in pulse rate and no incidence of pedal edema in benidipine treated patients. Similarly, the serum triglyceride levels decreased and urinary microalbumin excretion also decreased significantly in benidipine group.

Pedal edema was seen in 20%patients in amlodipine group and 5% patients in Cilnidipine group while none of the patients from benidipine group had pedal edema. There was significant (P <0.05) reduction in serum triglyceride and urinary microalbumin levels, from base-line in the benidipine group. Benidipine was found to be more safe than Amlodipine and Cilnidipine.

CONCLUSION

A comparative study was conducted to compare the effects of amlodipine, cilnidipine and benidipine on BP, serum lipids and proteinuria in hypertensive patients. All drugs effectively lowered the SBP and DBP. However, benidipine treated group had significantly less tachycardia and less pedal edema. In addition there was significant reduction in serum triglycerides and in microalbuminuria with benidipine treatment.

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