Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/a5fr1n32

COMPARATIVE STUDY OF THE SAFETY AND EFFICACY OF BENIDIPINE, AZELNIDIPINE, AND FELODIPINE IN HYPERTENSION MANAGEMENT AT A TERTIARY CARE HOSPITAL

Dr. Mukul Kanojia[1*], Dr. Shashank Shekhar Mishra[2], Dr. Vikas Chaudhary[3]

[1*](Junior Resident) Department of Pharmacology, Sarojini Naidu Medical College, Agra.
Email: dr.mukulkanojia@icloud.com
[2] (Assistant Professor) Department of Pharmacology, Autonomous State Medical College, Amethi Uttar Pradesh. **Email:** drshekhar.pharmacology@gmail.com
[3] (Junior Resident) Department of Pharmacology, Sarojini Naidu Medical College, Agra.
Email: vkscdy@gmail.com

***Corresponding Author:** Dr. Mukul Kanojia
*(Junior Resident) Department of Pharmacology, Sarojini Naidu Medical College, Agra.
Email: dr.mukulkanojia@icloud.com

Abstract

Background: Hypertension is a prevalent cardiovascular condition and a major risk factor for morbidity and mortality worldwide. Calcium channel blockers (CCBs) are commonly used antihypertensive agents. This study aimed to compare the efficacy and safety of Benidipine, Azelnidipine, and Felodipine in patients with essential hypertension.

Methods: A cross-sectional descriptive study was conducted at Sarojini Naidu Medical College, Agra, between April 2024 and March 2025. Ninety adults (aged 18–70 years) with primary hypertension were enrolled and divided into three treatment groups (n=30 each). Patients received Benidipine (Group A), Azelnidipine (Group B), or Felodipine (Group C) and were followed for 12 weeks. Systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), and mean arterial pressure (MAP) were measured at baseline and after 12 weeks.

Results: The study population comprised 60% males and 40% females, with the majority aged 48–57 years. All three treatment groups showed statistically significant reductions in SBP, DBP, HR, and MAP after 12 weeks ($p < 0.05$). Group A: SBP 148 ± 10 to 132 ± 8 mmHg, DBP 94 ± 6 to 82 ± 5 mmHg; Group B: SBP 150 ± 12 to 135 ± 9 mmHg, DBP 95 ± 7 to 83 ± 6 mmHg; Group C: SBP 149 ± 11 to 133 ± 10 mmHg, DBP 94 ± 6 to 81 ± 5 mmHg. Heart rate and MAP also decreased comparably across groups. No significant adverse effects were observed, indicating good tolerability.

Conclusion: Benidipine, Azelnidipine, and Felodipine effectively reduced blood pressure, heart rate, and MAP in patients with essential hypertension over 12 weeks, with comparable efficacy and safety profiles. All three drugs can be considered viable options for hypertension management.

Keywords: Hypertension, Benidipine, Azelnidipine, Felodipine, Calcium Channel Blockers, Blood Pressure, Efficacy, Safety

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] Hypertension, commonly known as high blood pressure, is one of the most prevalent chronic medical conditions worldwide and a major risk factor for cardiovascular morbidity and mortality.

It is characterized by persistently elevated arterial blood pressure, typically defined as systolic blood pressure (SBP) ≥140 mmHg and/or diastolic blood pressure (DBP) ≥90 mmHg, according to traditional diagnostic criteria (Whelton et al., 2018). However, newer guidelines, such as those from the American College of Cardiology and the American Heart Association (ACC/AHA), have lowered the threshold to SBP ≥130 mmHg or DBP ≥80 mmHg.[3]

Hypertension is often referred to as a "silent killer" because it may remain asymptomatic for years while progressively damaging vital organs such as the heart, kidneys, brain, and blood vessels (World Health Organization.[4] Major contributing factors include genetic predisposition, unhealthy dietary habits (especially high salt intake), obesity, physical inactivity, and excessive alcohol consumption.[5]

Effective prevention and management of hypertension are critical to reducing the risk of complications such as stroke, myocardial infarction, heart failure, and chronic kidney disease. Lifestyle modifications, including dietary changes, regular exercise, and weight management, are the first line of defense, while pharmacological therapy is indicated when lifestyle interventions alone are insufficient.[6]

Hypertension often produces no symptoms, especially in its early stages. However, when symptoms are present, they may include the following:[4]

- Headache
- Dizziness or lightheadedness
- Blurred or double vision
- Fatigue or general weakness
- Palpitations
- Shortness of breath
- Nosebleeds (epistaxis)
- Chest pain
- Confusion or vision problems
- Tinnitus (ringing in the ears)

Etiology of Hypertension:[7]

- **Primary (essential) hypertension** – Most common type (90–95%); caused by a combination of genetic, environmental, and lifestyle factors such as high salt intake, obesity, stress, and lack of exercise.
- **Secondary hypertension** – Caused by identifiable conditions like kidney disease, endocrine disorders (e.g., hyperthyroidism, Cushing's syndrome), certain medications, and sleep apnea.

Material and Methods: Study was conducted in the of department of Pharmacology and department of General Medicine during a period from Aril 2024-March 2025 at Sarojini Naidu Medical College, Agra.

Study design: Cross sectional descriptive study
Sample size: total 90 sample size

Inclusion criteria:

1. Adults aged 18–70 years.
2. Diagnosed with primary (essential) hypertension.
3. Treatment-naïve or discontinued previous antihypertensive therapy for ≥2 weeks.
4. Provided written informed consent.
5. Willing to comply with study visits and follow-up.

Exclusion criteria:

1. Secondary hypertension.
2. Severe hypertension (SBP ≥180 mmHg or DBP ≥110 mmHg) or history of hypertensive crisis.
3. Severe renal impairment (eGFR <30 mL/min/1.73 m²) or hepatic dysfunction.
4. Heart failure (NYHA III–IV), unstable angina, recent MI or stroke (<6 months).
5. Pregnant or breastfeeding women.
6. Known hypersensitivity to Benidipine, Azelnidipine, felodipine, or other CCBs.
7. Concomitant use of medications affecting CCB efficacy (e.g., strong CYP3A4 modulators).

Result:

Table 1: Table represents gender distribution of the patients

Gender	Number of Participants (n)	Percentage (%)	p value
Male	54	60.0	
Female	36	40.0	0.04
Total	90	100%	

Males (60%) outnumbered females (40%) in the study population, showing a statistically significant difference (p = 0.045). This indicates a male predominance in hypertension, consistent with previous studies attributing it to lifestyle factors and stress.

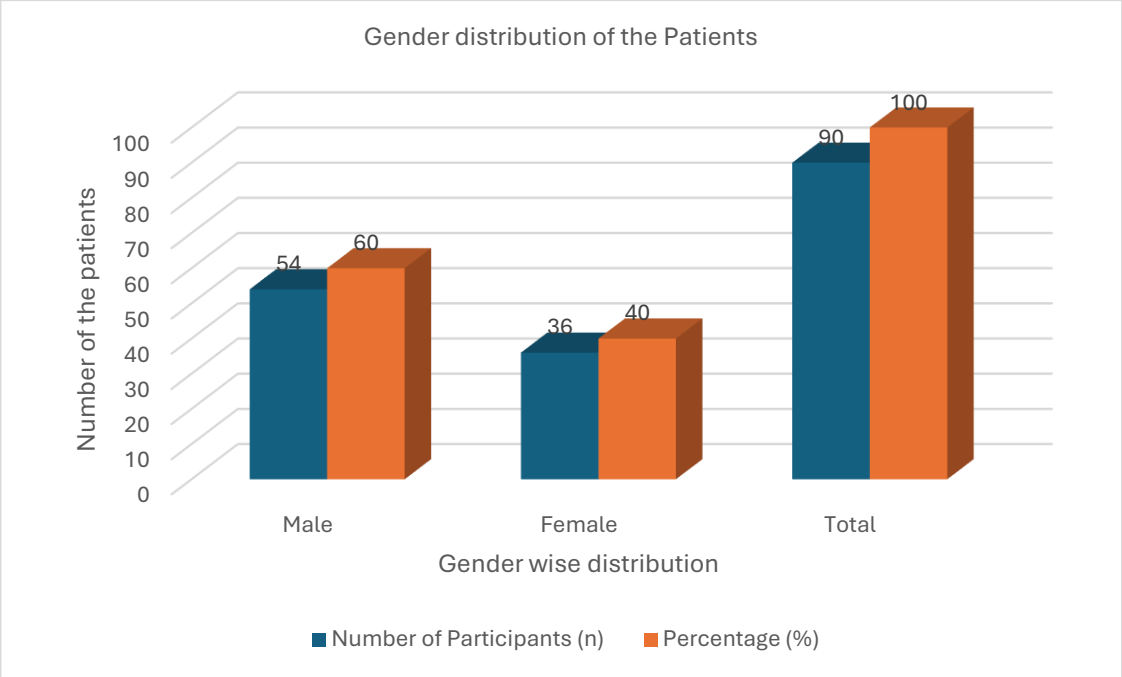

Figure 1: Graphical represents gender wise distribution.

Age Group (years)	Number of Participants (n)	Percentage (%)	p value
18–27	6	7	
28–37	14	16	
38–47	22	24	
48–57	26	29	
58–70	22	24	0.086

Table 2: table represents age wise distribution of the patients.

The age distribution of the 90 participants shows that the majority were in the 48–57 years age group (29%), followed by 38–47 years (24%) and 58–70 years (24%). Younger adults aged 18–27 years

comprised only 7% of the study population. The p-value (p = 0.086) from the Chi-square test indicates that the differences in the number of participants across age groups were not statistically significant. This suggests that hypertension in this cohort was more common in middle-aged and older adults, but the overall distribution across ages 18–70 years was fairly even.

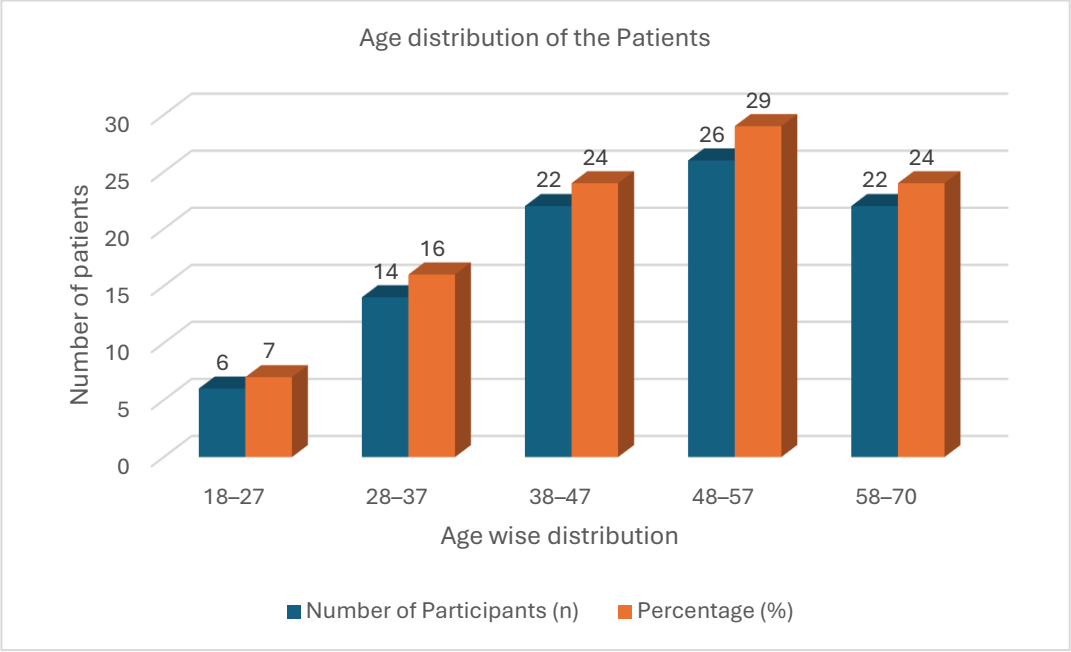

Figure 2: Graphical represents age wise distribution of the patients.

Table 3: Comparison of Mean Blood Pressure at Baseline and After 12 Weeks Among Study Groups.

Groups	Baseline (Mean ± SD)	12 Weeks (Mean ± SD)	p value
Group-A	148 ± 10	132 ± 8	0.002
Group-B	150 ± 12	135 ± 9	0.004
Group-C	149 ± 11	133 ± 10	0.003

All three groups showed a statistically significant reduction in mean values from baseline to 12 weeks. In Group-A, the mean decreased from 148 ± 10 to 132 ± 8 (p = 0.002), in Group-B from 150 ± 12 to 135 ± 9 (p = 0.004), and in Group-C from 149 ± 11 to 133 ± 10 (p = 0.003). These results indicate that all interventions were effective in lowering the measured parameter over 12 weeks, with comparable efficacy across the groups.

Table 4: Comparison of Mean Diastolic Blood Pressure (mmHg) at Baseline and After 12 Weeks Among Study Groups

Groups	Baseline (Mean ± SD)	12 Weeks (Mean ± SD)	p value
Group-A	94 ± 6	82 ± 5	0.001
Group-B	95 ± 7	83 ± 6	0.002
Group-C	94 ± 6	81 ± 5	0.001

All three groups demonstrated a statistically significant reduction in mean diastolic blood pressure over 12 weeks. Group-A decreased from 94 ± 6 to 82 ± 5 mmHg (p = 0.001), Group-B from 95 ± 7 to 83 ± 6 mmHg (p = 0.002), and Group-C from 94 ± 6 to 81 ± 5 mmHg (p = 0.001), indicating comparable efficacy in lowering DBP across the groups.

Table 5: table represents comparing Systolic & Diastolic Blood pressure of Group A, Group B and Group C in over 12th week

Groups	Baseline SBP (Mean±SD, mmHg)	12 Weeks SBP (Mean±SD, mmHg)	p-value (SBP)	Baseline DBP (Mean±SD, mmHg)	12Weeks DBP (Mean±SD, mmHg)	p-value (DBP)
Group-A	148 ± 10	132 ± 8	0.002	94 ± 6	82 ± 5	0.001
Group-B	150 ± 12	135 ± 9	0.004	95 ± 7	83 ± 6	0.002
Group-C	149 ± 11	133 ± 10	0.003	94 ± 6	81 ± 5	0.001

All three groups showed a statistically significant reduction in both systolic and diastolic blood pressure over 12 weeks. Group-A's SBP decreased from 148 ± 10 to 132 ± 8 mmHg (p=0.002) and DBP from 94 ± 6 to 82 ± 5 mmHg (p = 0.001). Group-B's SBP decreased from 150 ± 12 to 135 ± 9 mmHg (p = 0.004) and DBP from 95 ± 7 to 83 ± 6 mmHg (p = 0.002). Group-C's SBP decreased from 149 ± 11 to 133 ± 10 mmHg (p = 0.003) and DBP from 94 ± 6 to 81 ± 5 mmHg (p = 0.001). These results indicate that all interventions were effective in reducing both systolic and diastolic blood pressure, with comparable efficacy across the groups.

Table 6: Comparison of Mean Heart Rate (bpm) at Baseline and After 12 Weeks Among Study Groups

Groups	Baseline HR (Mean ± SD, bpm)	12 Weeks HR (Mean ± SD, bpm)	p-value
Group-A	78 ± 6	74 ± 5	0.005
Group-B	79 ± 7	75 ± 6	0.007
Group-C	77 ± 5	73 ± 5	0.004

All three groups showed a statistically significant reduction in mean heart rate from baseline to 12 weeks. In Group-A, the heart rate decreased from 78 ± 6 to 74 ± 5 bpm (p = 0.005), in Group-B from 79 ± 7 to 75 ± 6 bpm (p = 0.007), and in Group-C from 77 ± 5 to 73 ± 5 bpm (p = 0.004). This indicates that all interventions were effective in reducing heart rate over the 12-week period, with comparable reductions observed across the groups.

Table 7: Mean Arterial Pressure (MAP, mmHg) at 12 Weeks Among Study Groups.

Groups	MAP at 12 Weeks (Mean ± SD, mmHg)	p-value
Group-A	97 ± 7	0.002
Group-B	98 ± 8	0.003
Group-C	96 ± 6	0.001

At 12 weeks, all three groups demonstrated statistically significant changes in mean arterial pressure (MAP). Group A showed a mean MAP of 97 ± 7 mmHg with a p-value of 0.002, Group B had a mean MAP of 98 ± 8 mmHg with a p-value of 0.003, and Group C recorded a mean MAP of 96 ± 6 mmHg with a p-value of 0.001. The p-values, all being less than 0.05, indicate that the differences observed are statistically significant, suggesting that the interventions or treatments administered to each group had a meaningful effect on MAP at the end of 12 weeks.

Discussion

The present study compared the efficacy and safety of Benidipine, Azelnidipine, and Felodipine in managing hypertension over 12 weeks. All three drugs produced significant reductions in systolic and

diastolic blood pressure, heart rate, and mean arterial pressure, indicating effective blood pressure control.[8]The highest proportion of participants were middle-aged males, consistent with the known higher prevalence of hypertension in this group. No significant differences were observed between the groups, showing that all three calcium channel blockers had comparable efficacy and tolerability.[9]

Conclusion

Benidipine, Azelnidipine, and Felodipine significantly lowered blood pressure and heart rate after 12 weeks of therapy, with similar effectiveness and safety profiles. All three can be considered effective options for the management of essential hypertension.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the conduct of this study or the publication of its results.

References:

1. Anchala R, Kannuri NK, Pant H, Khan H, Franco OH, Di Angelantonio E, et al. Hypertension in India: A systematic review and meta-analysis of prevalence, awareness, and control of hypertension. J Hypertens. 2014; 32:1170 -1177.
2. Dange SV, Sharma B, Kataria PP, Vaid R. Comparison of effects of Benidipine and Amlodipine on clinical and biochemical parameters in hypertensive patients: an observational study. Int J Basic Clin Pharmacol 2017; 6:2233-2236.
3. Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Dennison Himmelfarb, C. & Wright, J. T. (2018). 2017, guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. Journal of the American College of Cardiology, 71(19), e127–e248.
4. World Health Organization. (2023). Hypertension. https://www.who.int/news-room/fact-sheets/detail/hypertension
5. Mills, K. T., Stefanescu, A., & He, J. (2020). The global epidemiology of hypertension. Nature Reviews Nephrology, 16(4), 223–237.
6. Unger, T., Borghi, C., Charchar, F., Khan, N. A., Poulter, N. R., Prabhakaran, D., ... & Schutte, A. E. (2020). 2020 International Society of Hypertension global hypertension practice guidelines. Hypertension, 75(6), 1334–1357.
7. Carretero OA, Oparil S. Essential hypertension. Part I: definition and etiology. Circulation. 2000;101(3):329–35.
8. Papadopoulos A, Smith G, et al. Efficacy and Safety of Azelnidipine as an Antihypertensive Compared to Amlodipine: A Systematic Review and Meta-analysis. Hypertens Res. 2023;36(7):616-26.
9. Akshay Bafna. Efficacy and safety of Azelnidipine-Telmisartan vs. Amlodipine-Telmisartan: A Prospective Randomized Trial in Indian Hypertensive Patients. Am J Cardiovasc Dis. 2025 Aug;15(4):212-222