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Original Research Article

Cost-effective analysis of enalapril, amlodipine, and enalapril plus amlodipine combination in newly diagnosed patients of hypertension: A pharmacoeconomic comparison of the antihypertensive efficacy of drugs

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ABSTRACT

Background: Hypertension (HTN) is a chronic condition with severe complications, so early detection and effective management are essential to prevent cardiovascular events and reduce the associated economic burden. This study aims to compare the cost-effectiveness of enalapril, amlodipine, and their combination in terms of blood pressure reduction, considering overall efficacy and economic implications.

Materials and Methods: A prospective, observational cost-effectiveness analysis was conducted in 150 newly diagnosed hypertensive patients who were prescribed either enalapril (5 mg), amlodipine (5 mg), or enalapril plus amlodipine (2.5 mg each). The primary outcome was the difference in systolic and diastolic blood pressure between baseline and follow-up, as well as the evaluation of overall efficacy and cost. Based on the data, statistical analysis was carried out using ANOVA and post hoc Tukey tests for drug efficacy, and cost-effectiveness was compared using MS Excel.

Results: After 30 days, all treatments significantly reduced systolic and diastolic blood pressure ($p = 0.0001$). The combination therapy with a lower dose showed superior efficacy in blood pressure reduction and was most cost-effective, requiring less expense for a 1 mmHg reduction in blood pressure compared to individual drugs with a higher dose. Quality of life assessment favored low-dose combination therapy, with fewer reported adverse effects.

Conclusions: The combination of amlodipine and enalapril at a lower dose demonstrated superior cost-effectiveness, efficacy in blood pressure reduction, and a favorable impact on patients' quality of life compared to individual drugs at a higher dose. This suggests that combination therapy may be a preferred option in the management of hypertension, emphasizing the importance of considering both clinical and economic factors in treatment decisions.

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1. Introduction

Globally, one of the most common chronic illnesses is hypertension (HTN). If untreated, it causes major side effects such as retinal, neuropathy, nephropathy, stroke, and myocardial infarction.^{1,2} This is concerning because, unless they experience one of the micro- or macrovascular problems listed above, many patients would not be aware

that they have hypertension.³ According to the WHO Hypertension Guidelines, cardiovascular disease (CVD) accounted for 30% of the estimated 58 million deaths worldwide from all causes. Hypertension is the third-leading cause of disability-adjusted life years (DALY).⁴ Approximately 2 million fatalities per year were attributed to CVD, according to the Registrar General of India and the Million Death Study investigators. It was also the leading cause of death for both genders (20.3% and 16.9%). Hypertension affects 22.60% of women and 23.10% of

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males in India over the age of 25.⁵ Reduced risks of cardiovascular disease (CVD) are linked to achieving systolic and diastolic blood pressure (SBP) goals of less than 140/90 mmHg.⁶ Reduced stroke and coronary heart disease (CHD) occurrences by 33–48% and 17–27%, respectively, are linked to blood pressure (BP) reductions of 10 mmHg systolic or 5 mmHg diastolic.⁷

The chronic nature of hypertension, coupled with its high prevalence rates and co-morbidities, places a significant financial burden on the healthcare system and the patient.⁸ Systematic blood pressure management has been demonstrated to save a significant amount of money in earlier studies.^{9,10} Therefore, to prevent its major complications, HTN must be properly managed and detected as soon as possible. The multifaceted therapy of high blood pressure (HTN) includes prescription medicine in addition to lifestyle changes such as increased fiber intake, decreased salt intake, weight loss, and exercise.³

The Eighth Joint National Committee (JNC 8) recommends thiazide diuretics (TDs), calcium channel blockers (CCBs), angiotensin-converting enzyme inhibitors (ACEIs), or angiotensin receptor blockers (ARBs) as monotherapy as the first-line treatment for hypertension in the general population. Within a month of starting therapy, if the desired blood pressure is not achieved, the drug dosage should be raised or a second medication should be added.¹¹ Treatment for hypertension is both time-consuming and expensive. Treatment costs are further influenced by the wide variety of antihypertensive drugs available and their varying levels of effectiveness.¹²

Hence, in order to determine which medication is better overall for a tertiary care teaching hospital, this study compared the cost-effectiveness of enalapril, amlodipine, and the enalapril plus amlodipine combination in terms of daily reduction in mmHg of blood pressure per day with the overall efficacy of the drugs.

2. Materials and Methods

2.1. Study design and setting

At a tertiary care teaching hospital, a prospective, observational, longitudinal cost-effectiveness study was conducted to assess the costs of enalapril, amlodipine, and the combination of enalapril and amlodipine in newly diagnosed hypertensive patients. The Institutional Ethics Committee approved the study. The selection of patients was based on the prescription of enalapril (5 mg), amlodipine (5 mg), or enalapril plus amlodipine (2.5 mg each). Written informed consent was obtained from each of the 150 patients who were to be included in the comparison.

This study included patients of either sex who had hypertension (defined as supine SBP and/or DBP greater than 140 mmHg and 90 mmHg, respectively) and who were between the ages of 18 and 65. Excluded from the study

were patients who were pregnant or nursing, unwilling to participate, illiterate, or hypertensive patients admitted to the intensive care unit.

Data on socioeconomic status, healthcare, drug use, morbidity, and demographics were gathered using a standardized "Case Report Form." Two visits in total were made to conduct the study: on Day 1 and Day 30. On the first day of the trial, blood pressure readings and interviews with study participants were conducted. During each appointment, a digital sphygmomanometer was used to take three blood pressure readings; the mean of these values was taken into account for that visit. Three groups of 150 individuals were assigned to receive either enalapril (5 mg), amlodipine (5 mg), or enalapril plus amlodipine (2.5 mg each) medication.

After 30 days, the patients were called for follow-up appointments. During those instances, a digital sphygmomanometer was used to take the patients' blood pressure, and they were questioned about any side effects or adjustments to their regular activities. Data from both of the visits, including patient demographics and blood pressure readings, was gathered and then subjected to additional analysis as specified in the Case Report Form. The duration of the study was 6 months. Information about all the patients was kept confidential throughout the study period.

3. Data analysis

In order to calculate the statistical parameters, the collected data was imported into Microsoft Excel and analyzed using SPSS version 23. The difference in mmHg between the baseline and follow-up SBP and DBP was used to define the outcome. The final data comparison that led to the study's conclusions was made possible by the analysis's outcome. With one-way ANOVA and the post hoc Tukey test, parameters such as the level of significance were computed based on the drug efficacy data. On the other hand, costs of prescribed drugs were retrieved from the Current Index of Medical Specialties (CIMS) (the easily available in the market among the listed brands). Also, the comparison of the cost as per the efficacy was carried out in an MS Excel spreadsheet. The *p* value (< 0.05) was considered statistically significant.

4. Results

A total of 150 patients who were seen in the hospital's outpatient department were included in the study; 66 (44%) of them were men and 84 (56%) were women. Table 1 presents the demographic and baseline characteristics of hypertensive patients who were divided into three groups: those treated with amlodipine, those treated with enalapril, and those receiving a combination of amlodipine and enalapril. The following parameters were included: gender distribution, age, and baseline blood pressure readings

(systolic and diastolic). Along with hypertension, diabetes mellitus type II accounted for a significant portion of the related conditions (43%).

resents the results of two separate analysis of variance (ANOVA) tests conducted to examine the impact of treatment on systolic blood pressure (SBP) and diastolic blood pressure (DBP) after a 30-day intervention.

For SBP, the between-groups comparison revealed a significant difference ($F(2, 147) = 34.908, p < 0.0001$) in SBP among the treatment groups. For DBP, the between-groups comparison also showed a significant difference ($F(2, 147) = 45.560, p < 0.0001$) in DBP among the treatment groups. These results indicate that the treatments had a significant impact on both SBP and DBP levels after 30 days, with $p < 0.0001$, highlighting the effectiveness of the interventions in altering blood pressure.

The post hoc (Tukey) test findings for the three groups (amlodipine, enalapril, and amlodipine plus enalapril) after 30 days of treatment are shown in Table 3. The test was used to determine differences in systolic blood pressure (SBP) and diastolic blood pressure (DBP). The results indicate that there are significant differences in both systolic and diastolic blood pressure among the treatment groups. The table reports the mean difference (A-B), standard error, statistical significance (Sig.), and 95% confidence intervals (95% CI) for each pairwise comparison.

Difference in SBP after 30 days

With a 95% confidence interval, the mean difference is -5.120 ($p < 0.05$) between amlodipine and enalapril, -10.920 ($p < 0.05$) between amlodipine and amlodipine plus enalapril, and -5.800 ($p < 0.05$) between enalapril and amlodipine plus enalapril. This implies that the combination of the two had a significantly higher effect on SBP than either enalapril or amlodipine alone.

Difference in DBP after 30 days

With a 95% confidence interval, the mean difference is -4.880 ($p < 0.05$) between enalapril and amlodipine plus enalapril, -9.360 ($p < 0.05$) between amlodipine and enalapril, and -4.480 ($p < 0.05$) between enalapril and amlodipine, respectively. This indicates that the combination of the two had a significantly higher effect on DBP than each medication alone (enalapril and amlodipine).

In Table 4, the analysis and comparison of costs revealed that the amounts needed for amlodipine, enalapril, and amlodipine plus enalapril were 0.19, 0.08, and 0.07 INR, respectively, for a 1 mmHg drop in systolic blood pressure. Amlodipine, enalapril, and amlodipine plus enalapril have different costs associated with a 1 mmHg drop in diastolic blood pressure: 0.23 INR, 0.14 INR, and 0.12 INR, respectively. Because of this, the Amlodipine plus Enalapril group's daily cost for a comparable drop in blood pressure was lower at low equivalent dosages than it was for either medication alone.

The quality of life for each patient in either of the three groups was measured using the questionnaire that was completed during the follow-up visits or after 30 days. Among patients using amlodipine, 52% ($n = 26$) reported no change in their normal activity, 38% ($n = 19$) reported little to no change, and 10% ($n = 5$) reported a moderate drop in their routine activities. In total, 58% ($n = 29$) of the patients taking enalapril reported no change in their routine, 34% ($n = 17$) noted a slight change in their daily routines, and 8% ($n = 4$) reported a generally moderate decrease in their routine schedule as a result of their hypertensive treatment. Patients taking the combination of amlodipine and enalapril reported varying degrees of routine change: 60% ($n = 30$) reported no change, 28% ($n = 14$) reported a slight change, and 12% ($n = 6$) reported a moderate overall drop. This study showed that patients receiving a lower dose of both amlodipine and enalapril had a somewhat better quality of life than patients receiving either medication alone. Also, the most common adverse events were dizziness, fatigue, headaches, and nausea. Such side effects were experienced by 10% ($n = 5$) of Amlodipine and 8% ($n = 4$) of Enalapril users, whereas 12% ($n = 6$) of combination users had them [Figure 1]. Overall, the combination of amlodipine and enalapril was found to cause fewer side effects than either medication alone. However, because of the smaller sample size, the frequency of adverse drug reactions with the use of either medication was not statistically significant.

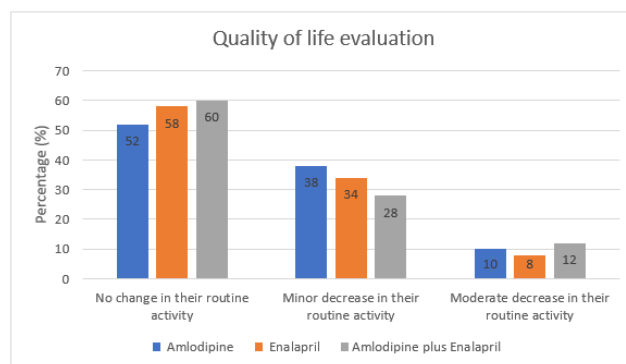


Figure 1: Quality of life evaluation according to adverse effect of treatment group on patient's routine activity.¹³

5. Discussion

Hypertension is defined as a SBP of 140 mmHg or more or a DBP of 90 mmHg or more. Hypertension is classified as either essential hypertension (EH) or secondary hypertension, and EH accounts for about 90–95% of the cases characterized by high blood pressure with no obvious underlying medical causes.¹⁴ Due to the high incidence of undiagnosed and untreated EH, developing nations face serious medical challenges.¹⁵ Antihypertensive medication has been linked in clinical studies to a lower incidence of (i)

Table 1: Demographic and baseline characteristics of hypertensive patients

Parameters	Amlodipine	Enalapril	Amlodipine plus Enalapril
Gender	Male	26	21
	Female	24	29
Age, Mean ± SD (Years)		49.66±6.5	55.30±11.3
Blood Pressure Mean ± SD	SBP (mmHg)	150.4±4.91	150.8±7.77
	DBP (mmHg)	97.2±4.22	99.2±5.43
			55.4±7.61
			159±5.88
			102±4.26

SD= Standard deviation, SBP= Systolic blood pressure, DBP=Diastolic blood pressure

Table 2: ANOVA test result

ANOVA		Sum of Squares	df	Mean Square	F	Sig.
Difference in SBP after 30 days of treatment	Between Groups	2985.013	2	1492.507	34.908	0.0001
	Within Groups	6284.960	147	42.755		
	Total	9269.973	149			
Difference in DBP after 30 days of treatment	Between Groups	2191.573	2	1095.787	45.560	0.0001
	Within Groups	3535.600	147	24.052		
	Total	5727.173	149			

df= Degree of freedom, F= Ratio of two varianc

Table 3: Post hoc (Tukey) test result

Dependent Variable	Group (A)	Comparison group (B)	Mean Difference (A-B)	Std. Error	Sig.	95% Confidence Interval		
						Lower Bound	Upper Bound	
Difference in SBP after 30 days	Amlodipine	Enalapril	-5.120*	1.308	.0001	-8.22	-2.02	
		Amlodipine plus Enalapril	-10.920*	1.308	.0001	-14.02	-7.82	
	Enalapril	Amlodipine	5.120*	1.308	.0001	2.02	8.22	
		Amlodipine plus Enalapril	-5.800*	1.308	.0001	-8.90	-2.70	
	difference in DBP after 30 days	Amlodipine plus Enalapril	Amlodipine	10.920*	1.308	.0001	7.82	14.02
			Enalapril	5.800*	1.308	.0001	2.70	8.90
Amlodipine		Enalapril	-4.480*	0.981	.0001	-6.80	-2.16	
		Amlodipine plus Enalapril	-9.360*	0.981	.0001	-11.68	-7.04	
	Enalapril	Amlodipine	4.480*	0.981	.0001	2.16	6.80	
		Amlodipine plus Enalapril	-4.880*	0.981	.0001	-7.20	-2.56	
	Amlodipine plus Enalapril	Amlodipine	9.360*	0.981	.0001	7.04	11.68	
		Enalapril	4.880*	0.981	.0001	2.56	7.20	

* The mean difference is significant at the 0.05 level.

Table 4: Cost evaluation in hypertensive patients

Treatment	Cost for reducing 1 mmHg		Per day cost per mmHg	
	SBP(INR)	DBP(INR)	SBP(INR)	DBP(INR)
Amlodipine	3.57	7.07	0.19	0.23
Enalapril	2.58	4.46	0.08	0.14
Amlodipine plus Enalapril	2.25	3.61	0.07	0.12

SBP= Systolic blood pressure, DBP=Diastolic blood pressure, INR= Indian rupee

stroke, which is often 35–40%; (ii) myocardial infarction (MI), which is typically 20–25%; and (iii) heart failure (HF), which is typically >50%.¹⁶ A sustained 12 mmHg reduction in SBP over 10 years is expected to prevent 1 fatality for every 11 individuals treated for stage 1 hypertension (SBP 140–159 mmHg and/or DBP 90–99 mmHg) with additional cardiovascular risk factors. Only nine patients would need such a BP drop with the additional presence of CVD or injury to one of the target organs in order to avoid one fatality.¹⁷ Patients with mild-to-moderate essential hypertension who are not complicated can be treated with a variety of antihypertensive drug classes as a first line of treatment.¹⁸

In our study, the average age of the patients, who included both sexes, was 55. Similarly, research by Machado et al. found that both genders were evenly dispersed at a mean age of 55.¹⁹ The current investigation shows that patients over 50 have a higher risk of hypertension. Similarly, growing older is one of the independent risk factors, according to a study by Singh S et al.^{20,21} Of the patients in this study, the majority (43 females and 22 males) had both hypertension and diabetes mellitus. Similar findings were made by Gress TW et al., who discovered that those with co-morbidities have a higher risk of high blood pressure than those who do not.²²

The ANOVA tests evaluate the differences between treatment groups and within-group variations in SBP and DBP. In this study, the treatments had a significant impact on both SBP and DBP levels after 30 days, with $p = 0.0001$, highlighting the effectiveness of the interventions in altering blood pressure. According to the post hoc (Tukey) test, the combination of amlodipine and enalapril with a lower dose had a statistically significant impact on reducing both SBP and DBP after 30 days compared to either medication used individually with a high dose. Likewise, FDC formulations may be linked to improved clinical outcomes and drug adherence, according to a study by Verma AA et al. Instead of using several tablet therapies, fixed-dose combinations offer a straightforward and possibly inexpensive strategy that lowers the worldwide burden of hypertension-related death and morbidity.²³

The purpose of this pharmacoeconomic study was to compare the cost-effectiveness of medications for people with hypertension. The effectiveness of the medications differed in a way that was clinically meaningful. This comparative investigation revealed that the combination of low-dose amlodipine and enalapril is more effective than either medication alone at lowering both systolic and diastolic blood pressure. Our research clearly shows that the combination of amlodipine and enalapril results in fewer side effects and improves quality of life when compared to either medication alone.¹³ According to Yazed AlRuthia et al., ACEIs and ARBs have been demonstrated to be more effective than amlodipine for managing critical

hypertension at a tolerable incremental cost.²⁴ According to one study by Chen N et al., CCBs are used as first-line therapy in patients who cannot tolerate beta blockers since they are less effective than ACEIs or ARBs with fewer adverse effects but still reduce cardiovascular events, including stroke and myocardial infarction.²⁵ The majority of patients with heart failure and diabetic nephropathy are advised to take ACEIs, according to the British Hypertension Society Guidelines, and diabetes mellitus was a co-occurring illness in our study's treatment recipients.¹⁹

5.1. Clinical implication

The results of this analysis demonstrate that the low-dose combination of amlodipine and enalapril is more cost-effective than either medication alone for the treatment of hypertension. Moreover, it offers a better quality of life and a lower side effect profile than individual medications. It's crucial to provide people with medications that are affordable and have few side effects because neither the signs of hypertension nor the advantages of decreasing blood pressure are immediately obvious to them. This is especially crucial in developing nations like India, as the rising costs of long-term treatment frequently act as a major barrier to patient compliance. The findings of this study aid in the decision-making process for clinicians managing formularies and hypertensive patients.

5.2. Limitations

The treatment duration of 30 days may not capture the long-term effects and adherence patterns of the prescribed medications. The sample size of 150 patients may be considered relatively small, and the study may benefit from a larger and more diverse population. Quality of life assessment and adverse event reporting are subjective measures and may vary among individuals. The cost analysis relies on the assumption that the effectiveness of each drug is comparable, which may not hold true in all cases.

6. Conclusion

In conclusion, the combination of amlodipine and enalapril demonstrated significant blood pressure reduction and appeared to be more cost-effective than individual drugs with high doses in this study. Despite a somewhat lower reported quality of life, the combination therapy showed fewer adverse events. This study provides valuable insights into the comparative effectiveness and cost implications of different antihypertensive treatments, but further research with a larger and more diverse population and a longer duration is warranted to validate these findings.

7. Source of Funding

None.


8. Conflict of Interest

None.

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