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Original Article

A Comparative Study on Effectiveness of Different Fixed Dose Combination Therapies in Hypertensive Patients

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ABSTRACT

Background: Hypertension is a primary contributor to cardiovascular morbidity and mortality. Combination therapy with Fixed-Dose Combinations (FDCs) is often recommended to improve drug adherence and blood pressure control. **Objectives:** This study aimed to evaluate the effectiveness of two commonly prescribed FDC treatments in patients with hypertension: Angiotensin Receptor Blocker with Diuretic (ARB + Diuretic) and Angiotensin Receptor Blocker with Calcium Channel Blocker (ARB + CCB). **Materials and Methods:** A six-month prospective observational study was conducted in the General Medicine Department of MVJ Medical College and Research Hospital in Hoskote, Karnataka. Sixty patients with essential hypertension were enrolled, with 30 receiving ARB + CCB and 30 receiving ARB + Diuretic. Baseline systolic and diastolic blood pressure readings were recorded before initiating therapy, with follow-up measurements taken after four weeks. Paired and independent *t*-tests ($p<0.05$) were used for statistical analysis. **Results:** Both groups experienced significant reductions in SBP and DBP after four weeks ($p<0.0001$). The ARB + CCB group showed decreases of 30.53 mmHg in SBP and 15.27 mmHg in DBP, while the ARB + Diuretic group showed decreases of 34.54 mmHg and 17.20 mmHg, respectively. The ARB + Diuretic group demonstrated statistically greater blood pressure reduction than the ARB + CCB group ($p<0.05$). **Conclusion:** Both regimens effectively lowered blood pressure, with the ARB + Diuretic combination producing slightly greater reductions. Factors such as comorbidities, tolerability, and patient characteristics should be considered when selecting a medication.

Keywords: ARB, CCB, Diuretics, Fixed Dose Combination, Hypertension.

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INTRODUCTION

Hypertension is one of the most common chronic diseases worldwide and a major factor in cardiovascular illness and death. The World Health Organization (WHO) reports that over 1.28 billion adults aged 30-79 worldwide live with hypertension, with two-thirds in low- and middle- income countries.[1] Less than 20% of hypertensive adults in some LMIC settings achieve target Blood Pressure (BP), regardless of the availability of numerous effective pharmaceutical agents.[2]

According to estimates, the prevalence of hypertension in India is roughly 29.8%, with rates in urban areas exceeding 33% and in rural areas around 25%.[3] The country's hypertension rates have increased due to ageing populations, dietary changes, sedentary lifestyles, and rapid urbanisation.[4] A considerable percentage of cardiovascular events, such as ischaemic heart disease, stroke, heart failure, chronic kidney disease, and early death, are caused by these conditions.[5] Effective management of hypertension is a top public health priority due to its high prevalence and correlation with negative outcomes.

Monotherapy is typically insufficient, particularly in moderate to severe hypertension, people with high cardiovascular risk, and populations with excessive salt intake and obesity incidence.[6] Fewer than half of patients respond satisfactorily to monotherapy.[7] Combination therapy treats many causes of high blood pressure by targeting different mechanisms and lowering blood pressure in different ways.[8]

Calcium Channel Blockers (CCBs) relax vascular smooth muscle, thiazide/thiazide- like diuretics decrease extracellular fluid volume and peripheral resistance, and angiotensin II Receptor Blockers (ARBs) lessen vasoconstriction and aldosterone-mediated sodium retention.[9] Combining these classes at lower dosages lessens side effects like hypokalemia and peripheral oedema.[10]

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Two or more antihypertensive medications in a single tablet, known as Fixed-Dose Combinations (FDCs), have the benefit of lower pill burden, streamlining regimens, and enhancing adherence, a crucial factor in treatment success.[11] Adherence is crucial to results because up to 50% of patients stop treatment within a year.[12] According to a meta-analysis by Gupta *et al.* FDC therapy increases adherence by roughly 21-29% when compared to free-drug combinations, and this improvement is correlated with improved blood pressure control.[13] Additionally, the streamlined regimen improves long-term therapy adherence by reducing confusion in older patients and those with polypharmacy.

In order to maximise adherence, the 2023 European Society of Hypertension (ESH) guidelines advices starting treatment with an FDC that contains an ACE inhibitor or ARB plus a CCB or a thiazide/thiazide-like diuretic. If necessary, this can be escalated to triple-drug combinations, ideally in single-pill formulations.[14] In a similar fashion, the 2017 American College of Cardiology/American Heart Association (ACC/AHA) recommendations support the early use of FDCs in high-risk or stage 2 hypertension patients.[15] ARB + CCB and ARB + diuretic regimens are commonly given among FDCs. Compared to ARB + diuretic regimens, ARB + CCB combinations have shown strong BP-lowering effects and acceptable metabolic profiles, with a decreased prevalence of hypokalemia and dyslipidaemia.[16]

On the other hand, patients with high extracellular fluid volume and salt intake sensitivity benefit most from ARB + diuretic therapy; however, it may increase the risk of electrolyte imbalances that require monitoring.[17] Results from comparative studies have been inconsistent, with some favouring ARB +CCB and others demonstrating equivalency or a small benefit for ARB + diuretics in people with excessive salt intake.[18–20] Both ARB +CCB and ARB + diuretic FDCs are often recommended in India; instead, the majority of the data is derived from studies conducted in the West and East Asia.[21]

The study was designed to examine the BP-lowering effectiveness of ARB + CCB and ARB + diuretic FDCs in hypertensive patients visiting a Karnataka tertiary care hospital. The main goal is to compare the two groups' systolic and diastolic blood pressure reductions over a four-week timeframe. This study aims to produce useful, context-specific information to direct clinical decision- making and optimise hypertension care in the Indian environment by concentrating on actual patients and frequently used combinations.

Table 1: Age distribution.

Age Group	No of Patients	Percentage (%)
30-39	3	5
40-49	5	8.33
50-59	13	21.67
60-69	23	38.33
70-79	13	21.67
80-89	3	5

MATERIALS AND METHODS

Study Methodology

A prospective observational study was conducted in the General Medicine Department at MVJ Medical College and Research Hospital in Hoskote, Karnataka. The study began after obtaining approval from the Institutional Ethics Committee (IEC). Eligible patients meeting the inclusion and exclusion criteria were enrolled consecutively. Participants were categorised into two groups based on the Fixed-Dose Combination (FDC) therapy prescribed. The study included 60 patients, 30 in each group. Data were collected at two time points: at baseline (before starting FDC therapy) and at a four-week follow-up. Treatment effectiveness was assessed by comparing mean seated Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) from baseline to the four-week mark. The overall study spanned six months, during which patients were enrolled consecutively as they were newly initiated on FDC therapy; however, each patient's outcome was assessed over a four-week follow-up window from their own baseline. All data were systematically compiled at the end of the six-month enrolment period. As this was an observational study, patients were not randomised to treatment groups; allocation to ARB+CCB or ARB+Diuretic reflected the treating physician's clinical judgement based on patient comorbidities, salt sensitivity, tolerability history, and cost considerations, consistent with routine prescribing practice. This non-randomised allocation may introduce selection bias and confounding by indication, since the two groups could differ systematically in ways that also influence blood pressure response. Treatment outcomes were evaluated using descriptive statistics, such as mean and standard deviation. When necessary, statistical tests were used to compare the two groups.

ETHICAL APPROVAL

The study protocol was submitted to the Institutional Ethics Committee of the MVJ Medical College and Research Hospital, Dandupalya, Hoskote, for review and ethical approval. After the committee reviewed and approved the study, an ethical clearance certificate was obtained.

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Table 2: Change in Blood Pressure for ARB + CCB Group.

Group (ARB+CCB)	Blood pressure	Mean before (mmHg)	Mean after (mmHg)	Change in BP (mmHg)	*p* value
Telmisartan +Cilnidipine	Systolic	164.0	130.0	34.0	<0.0001
	Diastolic	96.27	80.27	16.0	<0.0001
Telmisartan+Amlodipine	Systolic	161.07	134.0	27.07	<0.0001
	Diastolic	97.47	82.93	14.54	<0.0001
Olmesartan+Amlodipine	Systolic	162.0	125.0	37.0	0.0051
	Diastolic	93.0	77.0	16.0	0.0083

Table 3: Blood Pressure Reduction for ARB + Diuretic Group.

Group (ARB+Diuretic)	Blood pressure	Mean before (mmHg)	Mean after (mmHg)	Change in BP (mmHg)	*p* value
Telmisartan +HCTZ	Systolic	162.22	129.44	32.78	<0.0001
	Diastolic	97.78	82.33	15.45	<0.0001
Olmesartan+HCTZ	Systolic	165.80	128.80	37	<0.0001
	Diastolic	100.00	79.60	20.4	<0.0001
Losartan+HCTZ	Systolic	166.00	128.00	38	0.0335
	Diastolic	95.00	78.00	17	0.0374

Table 4: Comparison between ARB + Diuretic and ARB + CCB therapy for Blood Pressure Reduction.

Fixed dose combination	Blood pressure	Mean level before (mmHg)	Mean level after (mmHg)	BP reduction (mmHg)	*p* value	Interpretation
ARB + CCB	Systolic	162.53±6.03	132.00±8.10	30.53	<0.05	Statistically significant: ARB + Diuretic showed greater short-term (4-week) reduction.
	Diastolic	96.87±4.97	81.60±5.52	15.27		
ARB+DIURETIC	Systolic	163.67±6.08	129.13±3.51	34.54	<0.05	
	Diastolic	98.33±4.40	81.13±4.35	17.20		

Inclusion Criteria

Adults 18 years of age and older, identified as having essential hypertension, prescribed ARB+CCB or ARB+ Diuretic FDC and ready to give informed consent and comply with follow-up

Exclusion Criteria

Individuals with secondary high blood pressure, serious co-morbid conditions that affect blood pressure regulation, medication non-compliance in the past and women who are pregnant or nursing.

Data analysis

Through the univariate method, the paired t-test in SAS 9.4 was used for data analysis and MS Excel was used to evaluate the drugs' effectiveness utilising distribution of differences, paired profiles, agreement and Q-Q plot.

Descriptive summary statistics are displayed using either the mean and Standard Deviation (SD) or the median (minimum and maximum). A univariate technique employing a QQ PLOT was used to determine the statistical significance of the comparison of response proportions. Paired t-tests and independent t-tests were used to compare the decrease in blood pressure within and between groups. A *p*-value <0.05 was considered statistically significant.

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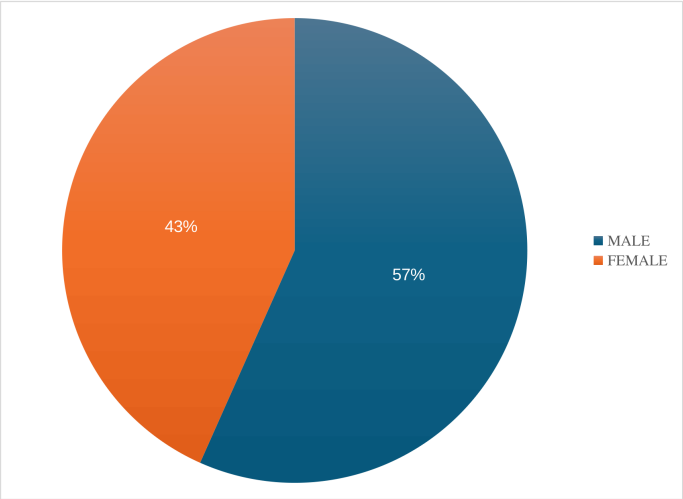


Figure 1: Gender distribution.

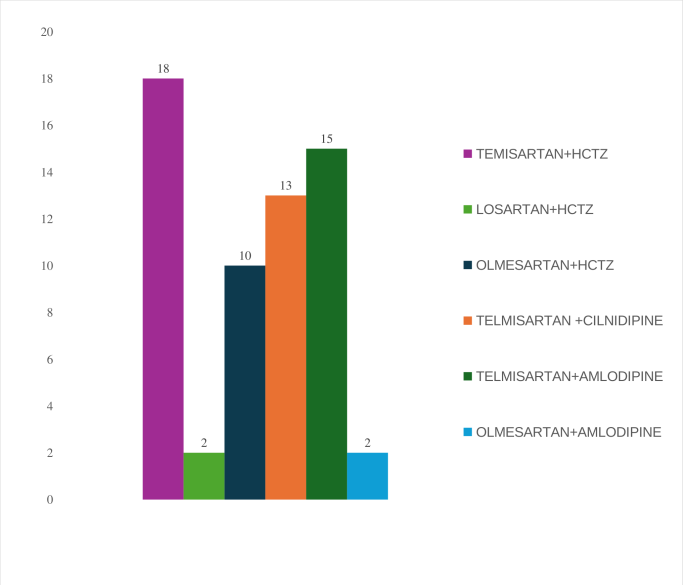


Figure 2: Distribution of Prescribed Fixed-Dose Combination Therapies in Hypertensive Patients.

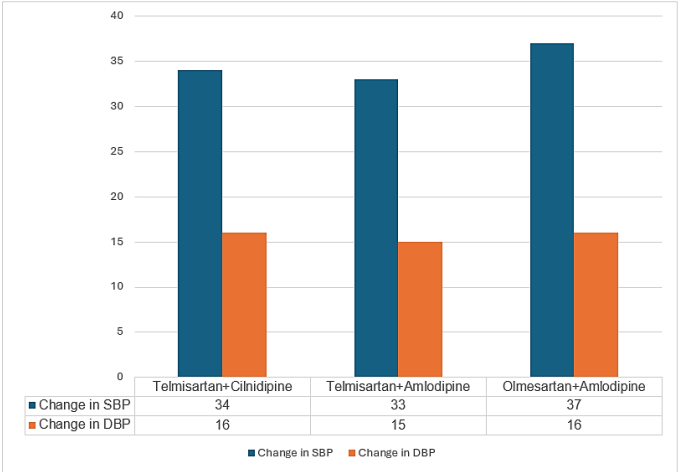


Figure 3: Change in SBP and DBP: Pre- and post-ARB + CCB therapy.

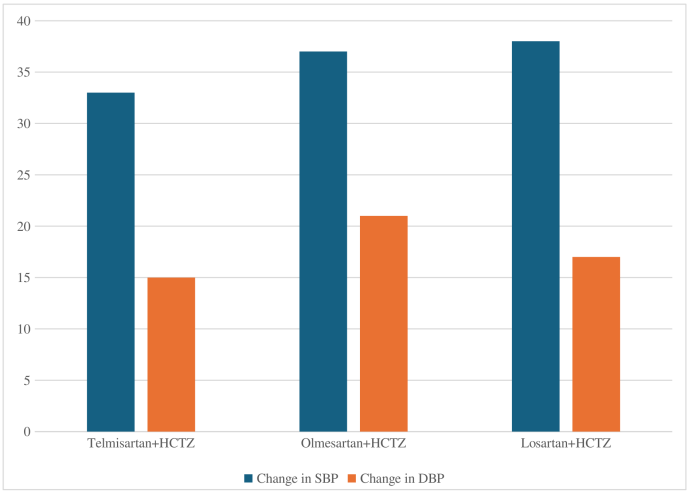


Figure 4: Change in SBP and DBP: pre and post ARB + Diuretics therapy.

RESULTS

Demographic details

Age distribution

The age distribution of the study participants ranged from 30 to 89 years. The majority of patients were aged 60- 69 years old (Table 1).

Gender distribution

The gender distribution of the study participants showed a higher proportion of males than females. Out of the total sample, 34 patients were male, and 26 patients were female (Figure 1).

Distribution of different Fixed Dose Combination therapies

Thirty of the 60 patients in the sample were prescribed the ARB + CCB combination, whereas the remaining 30 were prescribed ARB +Diuretic. The most prevalent combination in the ARB+ CCB group was Telmisartan +Amlodipine. Telmisartan + HCTZ was the most prescribed medication in the ARB + Diuretic category (Figure 2).

Blood Pressure Reduction in ARB + CCB group

According to the results, all three FDCs in the ARB+ CCB class significantly lowered both systolic and diastolic blood pressure, with $p<0.0001$ in the majority of cases. Olmesartan + Amlodipine had the greatest impact on both the systolic and diastolic phases (Table 2) (Figure 3).

Blood Pressure Reduction in ARB + Diuretic group

The results showed that all ARB + Diuretic combinations demonstrated statistically significant reductions in both systolic blood pressure and diastolic blood pressure (Table 3) (Figure 4).

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Changes in Blood Pressure: Class Comparison

The primary objective of this study was a class-level comparison of ARB+CCB versus ARB+Diuretic therapy (Table 4); the molecule-level breakdown presented in Tables 2 and 3 is descriptive and exploratory, characterising the range of FDCs prescribed within each class in real-world practice, and was not powered for pairwise comparisons between individual drug pairs. Significant reductions in systolic blood pressure and diastolic blood pressure were observed in both treatment groups ($p<0.0001$) during the follow-up period (Table 4).

However, ARB + Diuretic therapy demonstrated a slightly greater reduction in both systolic and diastolic blood pressure compared to ARB + CCB therapy. The differences were statistically calculated using an independent t-test ($p<0.05$) (Table 4).

DISCUSSION

This study examined how well two frequently recommended FDC regimens, ARB + CCB and ARB + Diuretic, achieved blood pressure control in a practical setting. Over the course of four weeks, both regimens significantly reduced systolic and diastolic blood pressure ($p<0.0001$), demonstrating the strong antihypertensive efficacy of combination therapy.

Our results are in line with earlier research demonstrating that combination medication is necessary for the majority of hypertensive patients to meet blood pressure goals.[6] The ARB +CCB group's means SBP decrease of 30.5 mmHg and the ARB + diuretic group's means SBP reduction of 34.5 mmHg are consistent with findings from extensive RCTs and meta-analyses.[8,18]

In reducing cardiovascular events, the ALLHAT trial showed that thiazide diuretics were at least as effective as ACE inhibitors and CCBs, and in some cases, more effective.[22] Both Valsartan and Amlodipine - based regimens were found to be beneficial in the VALUE trial; however, amlodipine delivered faster blood pressure control, supporting ARB + CCB regimen.[23]

Current guidelines have been influenced by the ASCOT-BPLA trial, which further demonstrated the superiority of CCB-based regimens over beta-blocker-diuretic combos in lowering cardiovascular events.[24] Research comparing ARB +CCB and ARB + diuretic regimens has yielded conflicting findings. Olmesartan-Amlodipine and Olmesartan-diuretic combinations did not significantly alter blood pressure decrease, according to Setyoko and Ricardo.[25] Valsartan + Cilnidipine and Valsartan + HCTZ were both reported by Fujiwara er al. to be beneficial in lowering blood pressure spikes.[26] However, some research indicates that ARB + CCB therapy may have benefits over ARB + diuretics, such as the preservation of arterial elasticity and a decreased risk of hypokalemia, hyperuricemia, and dyslipidaemia.[16,27]

Diuretic-containing regimens are still beneficial, particularly for groups that are sensitive to salt. In patients with moderate-to-severe hypertension, Sica *et al.* showed that Azilsartan - Chlothalidone reduced blood pressure more than Olmesartan-HCTZ.[28] These data are supported by a somewhat larger SBP reduction in our cohort receiving ARB + diuretic medication; however, due to the short follow-up, long-term metabolic effects could not be assessed.

This study's prospective design, real-world setting, and uniform blood pressure measurement are among its strong points. The short follow-up (4 weeks), single-centre design, small sample size and lack of biochemical monitoring for metabolic alterations associated with diuretics are among the limitations. The sample size of 60 patients reflects the constraints of a single-centre study with a defined six-month recruitment window and an inclusion criterion restricted to patients newly initiated on FDC therapy; no a priori power calculation was performed, and the between-group comparison should be interpreted with this limited precision in mind. Laboratory parameters such as serum electrolytes, creatinine, blood glucose, and uric acid were ordered at the treating physician's discretion as part of routine care rather than being protocol-mandated, resulting in inconsistent availability across patients; the analysis was therefore restricted to blood pressure outcomes, and no conclusions regarding comparative metabolic safety can be drawn from this data. Similarly, as patients were not randomised, the observed group differences may partly reflect selection bias or confounding by indication rather than treatment effect alone. Finally, the molecule-level findings in Tables 2 and 3 should be regarded as exploratory rather than confirmatory, given the limited number of patients receiving each individual drug pairing within the two classes.

In conclusion, in Indian hypertensive patients, ARB + CCB and ARB + diuretic FDCs both significantly lowered blood pressure. ARB + CCB regimens produced a slightly smaller reduction at four weeks than ARB + diuretics; any difference in metabolic tolerability between the two classes could not be assessed in this study, as biochemical parameters were not measured. Given the short follow-up window, these findings reflect short-term blood pressure control only and should not be read as establishing overall superiority of either regimen in terms of long-term control, cardiovascular outcomes, or adherence. Comorbidities, tolerability, and cost should all be taken into account when choosing a treatment.[29,30] These results underline the need for larger, longer-term Indian research to enhance hypertension therapy and complement international guidelines.[14,15]

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CONCLUSION

This prospective observational study was carried out over six months in the Department of General Medicine at MVJ Medical College and Research Hospital, Hoskote, Karnataka. The primary objective was to compare the effectiveness of different Fixed-Dose Combination (FDC) antihypertensive therapies.

The study includes 60 adult patients diagnosed with essential hypertension, evenly divided into two groups of 30 each. Baseline blood pressure measurements were recorded before the start of treatment, with follow-up readings taken after four weeks of therapy.

SAS 9.4 was used for statistical analysis, utilising descriptive statistics and paired t-tests to compare the blood pressure within the same group and an independent t-test for class comparison, with significance set at $p<0.05$. The majority of baseline blood pressure measurements were found to be normally distributed by normal testing, with only slight deviations following therapy, most likely as a result of clustering around better readings. This implies that in most individuals, both treatment plans produced a narrow range of control.

The study's findings showed that from baseline to four weeks, both ARB+CCB and ARB+ diuretic combinations significantly lowered systolic and diastolic blood pressure, with all improvements being statistically significant ($p<0.0001$). ARB +diuretic treatment produced slightly larger mean decreases in SBP and DBP than ARB+CCB, even though regimens were successful. Furthermore, both groups' post-treatment standard deviations were decreased, suggesting that the study population's antihypertensive effects were consistent.

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We sincerely thank everyone who supported, guided us and inspired us during our study.

ABBREVIATIONS

FDC: Fixed Dose Combination; **ARB:** Angiotensin Receptor Blocker; **CCB:** Calcium Channel Blocker; **ACE:** Angiotensin Converting Enzyme; **SBP:** Systolic Blood Pressure, **DBP:** Diastolic Blood Pressure; **WHO:** World Health Organisation; **BP:** Blood Pressure, **ESH:** European Society of Hypertension, **ACC:** American College of Cardiology, **AHA:** American Heart Association; **IEC:** Institutional Ethics Committee; **SD:** Standard Deviation; **HCTZ:** Hydrochlorothiazide.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTION

Chaitra Chandran, Preethi Lakshmanan, and Murali Govindappa: Conducted the investigation, data curation, and original draft preparation. **Dr Raman Dang:** Provided supervision and conceptualisation and reviewed the manuscript**.**

SUMMARY

This six-month prospective observational study compared the antihypertensive efficacy of two fixed-dose combinations: ARB + CCB and ARB + Diuretic. Evaluating sixty patients the study found that both regimens significantly lowered blood pressure over four weeks ($p<0.0001$). However, the ARB+ Diuretic combinations demonstrated a statistically greater reduction in both systolic and diastolic blood pressure compared to the ARB+ CCB regimen.

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