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A RANDOMIZED, OPEN LABEL, PROSPECTIVE STUDY TO COMPARE EFFICACY AND SAFETY OF LOSARTAN WITH AMLODIPINE VERSUS LOSARTAN WITH HYDRO-CHLOROTHIAZIDE IN THE TREATMENT OF NEWLY DIAGNOSED PATIENTS OF ESSENTIAL HYPERTENSION IN A RURAL TERTIARY HEALTH CARE CENTRE

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Keywords:

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ABSTRACT: Introduction: Hypertension is a leading global health concern, contributing significantly to cardiovascular morbidity and mortality. Despite the availability of various antihypertensive therapies, the optimal treatment regimen, particularly in diverse populations, remains a subject of ongoing research. This study aims to compare the efficacy, safety, and patient satisfaction of two commonly prescribed antihypertensive combinations: Losartan + Amlodipine and Losartan + Hydrochlorothiazide (HCTZ). **Materials & Methods:** This prospective, randomized, open-label study involved 300 newly diagnosed hypertension patients (aged 18-80) at UPUMS, Saifai. Patients were randomly assigned to Group A (Losartan + Amlodipine) or Group B (Losartan + Hydrochlorothiazide). Over a year, blood pressure, heart rate, and adverse effects were monitored at baseline, 4 weeks, and 12 weeks. Data were analyzed using SPSS, with significance set at $p < 0.05$. Ethical approval was obtained. **Results:** The baseline demographic characteristics showed no significant differences between the two groups. In Group A (Losartan + Amlodipine), 54.67% were male, and 45.33% were female. Group B (Losartan + Hydro-Chlorothiazide) had 50.67% males and 49.33% females. Age distribution was also similar between the groups: in Group A, 34% were under 40 years, 37.33% were 40-49 years, 21.33% were 50-59 years, and 7.33% were over 60 years old. In years old. The p-values for gender and age were 0.76 and 0.41, respectively. **Conclusion:** Both Losartan + Amlodipine and Losartan + Hydrochlorothiazide effectively reduced blood pressure and improved lipid profiles in hypertensive patients, with minimal side effects. Treatment choice depends on individual patient needs and tolerability.

INTRODUCTION: Hypertension is a significant global health issue, affecting an estimated one billion people worldwide and representing one of the most common risk factors for cardiovascular morbidity and mortality [1].

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Defined by a sustained elevation of blood pressure, hypertension is a critical contributor to conditions such as stroke, coronary artery disease, heart failure, and renal dysfunction.

Despite its prevalence, hypertension often remains undiagnosed until it manifests as severe complications, underscoring the need for improved detection and management strategies. Globally, the prevalence of hypertension continues to rise, with projections indicating that by 2025, approximately 1.56 billion adults will be living with the condition

[2]. In India, the scenario is similarly concerning, with prevalence rates varying between 25% in urban and 10% in rural populations. The increase in hypertension cases is not only a public health challenge but also a significant economic burden, given the long-term treatment and management required to control the condition and prevent associated complications.

Hypertension is often classified into two major categories: essential (primary) hypertension, which accounts for 90-95% of cases, and secondary hypertension [3, 4, 5] which arises from underlying conditions such as renal disease or endocrine disorders. The management of hypertension involves a multifaceted approach, incorporating lifestyle modifications and pharmacotherapy aimed at reducing blood pressure to target levels and minimizing the risk of cardiovascular events.

Pharmacological management of hypertension has evolved considerably over the past few decades, with several classes of antihypertensive drugs available, including diuretics, calcium channel blockers (CCBs), beta-blockers, angiotensin-converting enzyme inhibitors (ACEIs), and angiotensin II receptor blockers (ARBs) [6]. Among these, ARBs have gained prominence due to their efficacy in lowering blood pressure and their favorable safety profile. Recent clinical trials have demonstrated the efficacy of ARBs, such as losartan, in managing hypertension, particularly in patients who require combination therapy to achieve optimal blood pressure control.

Losartan, an ARB, has been extensively studied for its antihypertensive effects, particularly when used in combination with other agents such as hydrochlorothiazide, a thiazide diuretic [7, 8]. This combination therapy is often employed to enhance the antihypertensive effect while minimizing side effects. Comparative studies have suggested that losartan, either alone or in combination with hydrochlorothiazide, provides effective blood pressure control with a lower incidence of adverse effects, such as peripheral edema, compared to other antihypertensive regimens like amlodipine [8].

Despite the availability of multiple antihypertensive agents, the optimal choice of therapy, particularly in diverse populations, remains a subject of ongoing research. Studies have indicated that patient response to antihypertensive therapy can vary based on factors such as age, race, and coexisting medical conditions. For instance, diuretics and CCBs may be more effective in older adults and African American patients, whereas ARBs and ACEIs may be preferred in younger patients and those with comorbid conditions like diabetes and chronic kidney disease [9, 10].

Given the variations in response to antihypertensive therapy, particularly among different populations, this study aims to evaluate and compare the efficacy and safety of two combination therapies: losartan with amlodipine and losartan with hydrochlorothiazide, in newly diagnosed patients with essential hypertension in a rural tertiary care center. By focusing on a rural population, this study seeks to address the gap in research concerning the management of hypertension in underserved areas, where access to healthcare and medication adherence may be limited [10, 11].

The primary objectives of this study are to ascertain the efficacy of these combination therapies in achieving target blood pressure levels and to assess their safety profiles in the study population. Additionally, the study will explore the incidence of adverse effects associated with each regimen, providing insights into the tolerability of these treatments in a real-world rural healthcare setting [12].

MATERIALS & METHODS:

Study Design: This study was designed as prospective, randomized, open-label study. The research was conducted on newly diagnosed patients with essential hypertension, aged between 18 and 80 years, of either gender, attending the outpatient department of Medicine at UPUMS, Saifai, Etawah. Ethical clearance was obtained from the institutional Ethical Committee, with clearance number 84/2022-23. The study was carried out over a period of one year, from January 2023 to January 2024. The study took place in the Department of Pharmacology and the Department of Medicine at UPUMS, Saifai, Etawah, U.P. Using the "Power and Sample Size Calculator," the required sample size was calculated with an 80% power of the study and a 95% confidence level.

The sample size for each group came out to be 148, rounded up to 150. Hence, 150 patients were enrolled in each group. Inclusion Criteria: Patients providing written informed consent were included in the study.

Confirmed cases of hypertension, with a systolic blood pressure (SBP) of 140-180 mmHg and/or a diastolic blood pressure (DBP) of 90-110 mmHg, as diagnosed by a physician. Patients aged between 18 and 80 years of either gender. Exclusion Criteria: 1) Patients unwilling to participate. 2) Hypertensive patients with any comorbidities. 3) Patients below 18 years or above 80 years of age. 4) Perioperative patients. Study Tools: Informed Consent Form & Case Reporting Form

Study Design Details: Participants were randomly assigned to one of two groups: Group A: Losartan with Amlodipine (N=150) & Group B: Losartan with Hydrochlorothiazide (N=150). Random allocation was done in a 1:1 ratio, with 150 patients in each group. The objective was to compare the efficacy and safety of Losartan combined with Amlodipine versus Losartan combined with Hydrochlorothiazide in the treatment of newly diagnosed essential hypertension at a rural tertiary health care center.

Drugs Administered:

Group I: Tablet Losartan 25/50 mg combined with Amlodipine 5/10 mg.

Group II: Tablet Losartan 25/50 mg combined with Hydrochlorothiazide (HCTZ) 12.5/25 mg.

Methodology: The study was conducted in the Department of Pharmacology, in collaboration with the Department of Medicine at UPUMS, Saifai, Etawah. Written informed consent was obtained from all eligible participants. Patients who did not meet the inclusion criteria were excluded from the study.

Participants were randomly allocated to either Group A (Losartan with Amlodipine) or Group B (Losartan with Hydrochlorothiazide). A detailed history and physical examination were conducted and documented using a pre-designed format (Annexure I). Medications were prescribed based on the criteria for each group. Personal history, physical examination details (age, sex, blood pressure), clinical findings, and laboratory measurements (blood sugar, lipid profile, liver function tests, kidney function tests, electrolytes) were recorded at baseline (Day 0), and at 4th and 12th weeks. The interview format was prepared in both English and the local language (Hindi) to ensure ease of communication with participants. The study's endpoint was at the 12-week follow-up or when the baseline blood pressure of 130/80 mmHg was achieved. At each visit, blood pressure and heart rate were recorded, and patients were monitored for adverse events. Any adverse drug reactions were recorded and assessed for severity using Hartwig and Siegel's assessment scale.

Data Collection and Statistical Analysis: The collected data were entered into an Excel spreadsheet under the supervision of a statistician. Means and standard deviations for each group were calculated. Statistical analysis was performed using SPSS version 25.0 for Windows (SPSS Inc., Chicago, USA). A t-test and chi-square test were employed to compare the two groups, with a significance level set at $p < 0.05$.

RESULTS:

TABLE 1: BASELINE DEMOGRAPHIC CHARACTERISTICS

Demographic	Group A: Losartan + Amlodipine (N=150)	Group B: Losartan + Hydro-Chlorothiazide (N=150)	p-value
Gender			
Male	82 (54.67%)	76 (50.67%)	0.76
Female	68 (45.33%)	74 (49.33%)	
Age (years)			
<40	51 (34%)	43 (28.67%)	0.41
40-49	56 (37.33%)	59 (39.33%)	
50-59	32 (21.33%)	36 (24%)	
>60	11 (7.33%)	12 (8%)	

In Group A (Losartan + Amlodipine), 54.67% (82) were male and 45.33% (68) were female, while in Group B (Losartan + Hydro-Chlorothiazide), 50.67% (76) were male and 49.33% (74) were female (p=0.76). In terms of age, 34% (51) of Group A participants were under 40 years, 37.33% (56) were aged 40-49, 21.33% (32) were 50-59, and 7.33% (11) were over 60. In Group B, 28.67% (43) were under 40, 39.33% (59) were aged 40-49, 24% (36) were 50-59, and 8% (12) were over 60 (p=0.41).

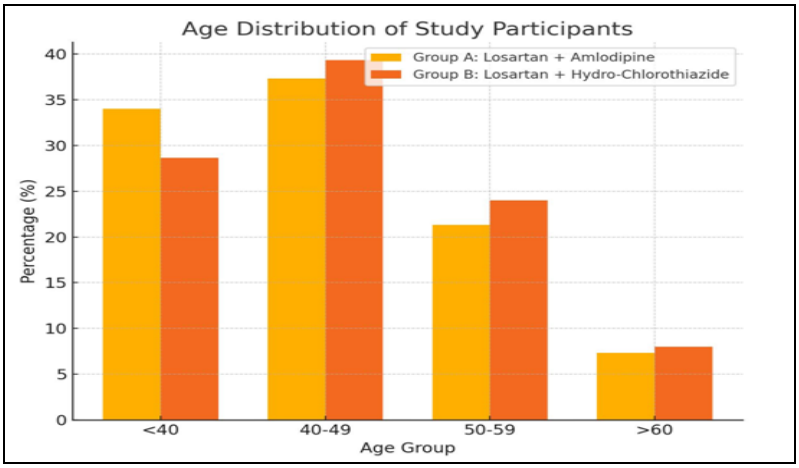

FIG. 1: AGE DISTRIBUTION

TABLE 2: BASELINE CLINICAL CHARACTERISTICS

Variable	Group A: Losartan + Amlodipine (N=150)	Group B: Losartan + Hydro-Chlorothiazide (N=150)	p-value
Triglycerides	148.62 ± 6.83	152.35 ± 7.51	0.45
HDL	38.11 ± 2.92	37.94 ± 2.70	0.80
LDL	106.42 ± 6.17	108.63 ± 5.36	0.66
VLDL	39.16 ± 2.59	39.97 ± 3.30	0.77
Cholesterol	209.2 ± 14.61	212.59 ± 16.13	0.59
Systolic BP	168.3 ± 6.9	169.8 ± 7.4	0.82

Group A (Losartan + Amlodipine) had triglycerides of 148.62 ± 6.83, HDL of 38.11 ± 2.92, LDL of 106.42 ± 6.17, VLDL of 39.16 ± 2.59, cholesterol of 209.2 ± 14.61, and systolic BP of 168.3 ± 6.9. Group B (Losartan + Hydro-Chlorothiazide) had triglycerides of 152.35 ± 7.51, HDL of 37.94 ± 2.70, LDL of 108.63 ± 5.36, VLDL of 39.97 ± 3.30, cholesterol of 212.59 ± 16.13, and systolic BP of 169.8 ± 7.4. No significant differences were observed between the groups (all p-values > 0.4).

TABLE 3: CHANGES IN BLOOD PRESSURE AND LIPID PROFILE AT WEEK 4 AND WEEK 12

Variable	Group A (Losartan + Amlodipine)	Group B (Losartan + Hydro-Chlorothiazide)	p-value
Systolic BP (mmHg)			
Baseline	168.3 ± 6.9	169.8 ± 7.4	0.82
4 Weeks	142.7 ± 6.2	145.1 ± 7.1	0.39
12 Weeks	131.5 ± 5.7	135.3 ± 6.7	0.12
Diastolic BP (mmHg)			
Baseline	105.7 ± 5.1	106.2 ± 5.5	0.76
4 Weeks	92.3 ± 4.6	94.9 ± 4.8	0.33
12 Weeks	87.1 ± 3.9	90.5 ± 4.2	0.12
Triglycerides			
Baseline	148.62 ± 6.83	152.35 ± 7.51	0.45
4 Weeks	144.66 ± 6.67	150.53 ± 7.14	0.13
12 Weeks	142.71 ± 6.11	145.73 ± 7.05	0.33

At baseline, systolic BP was 168.3 ± 6.9 mmHg in Group A and 169.8 ± 7.4 mmHg in Group B. By week 12, Group A's systolic BP dropped to 131.5 ± 5.7 mmHg, and Group B's dropped to 135.3 ± 6.7

mmHg (p=0.12). Diastolic BP in Group A went from 105.7 ± 5.1 mmHg to 87.1 ± 3.9 mmHg, and in Group B from 106.2 ± 5.5 mmHg to 90.5 ± 4.2 mmHg (p=0.12). Triglyceride levels also decreased for both groups by week 12 (p=0.33).

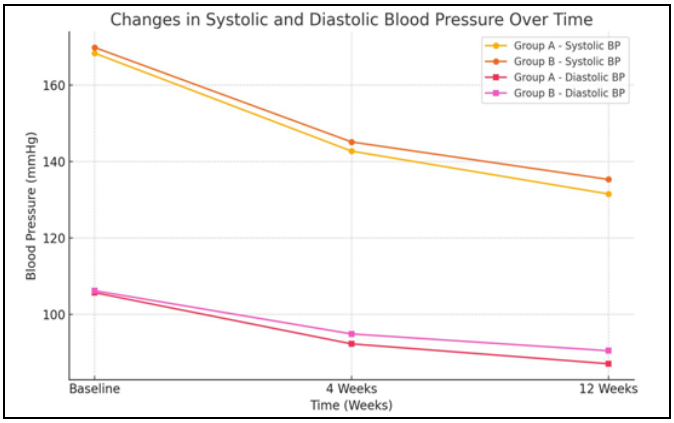

FIG. 2: BLOOD PRESSURE CHANGES

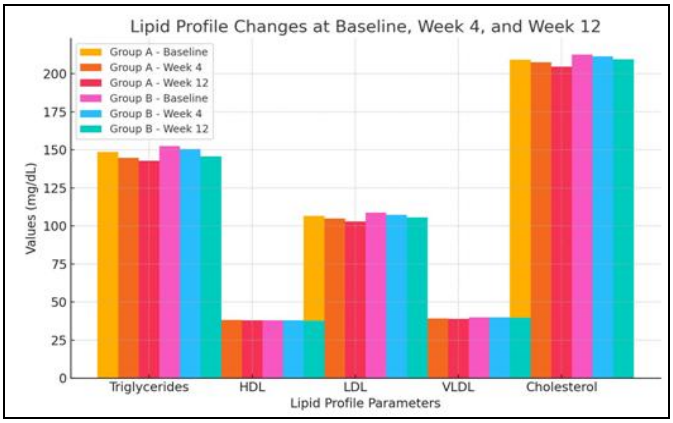

FIG. 3: LIPID PROFILE CHANGES

TABLE 4: ADVERSE EFFECTS

Adverse Effect	Group A: Losartan + Amlodipine (N=150)	Group B: Losartan + Hydro-Chlorothiazide (N=150)	p-value
Dizziness	2 (1.33%)	1 (0.67%)	0.73
Headache	1 (0.67%)	0 (0%)	
GI Upset	2 (1.33%)	0 (0%)	
Skin Rashes	0 (0%)	1 (0.67%)	
Others	3 (2%)	2 (1.33%)	

In Group A (Losartan + Amlodipine), 1.33% (2) experienced dizziness, 0.67% (1) had headaches, 1.33% (2) had GI upset, and 2% (3) reported other effects. In Group B (Losartan + Hydro-Chlorothiazide), 0.67% (1) experienced dizziness, 0.67% (1) had skin rashes, and 1.33% (2) reported other effects. No significant differences were found between the groups.

DISCUSSION: At the outset, the baseline demographic characteristics were evenly distributed between the two groups, with no statistically significant differences in gender or age. In Group A, 54.67% of the participants were male, compared to 50.67% in Group B, with a p-value of 0.76. Similarly, the age distribution across both groups was comparable, with the majority of participants falling within the 40-49 years age group. This homogeneity at baseline is essential, as it ensures that any observed differences in clinical outcomes are likely attributable to the interventions rather than demographic confounders.

The similar demographic profiles lend strength to the comparative analysis, as the even distribution of participants across age and gender groups allows for fair comparisons. The lack of significant differences in these baseline characteristics suggests that both treatment groups were comparable in terms of their potential risk factors and comorbidities.

The baseline clinical parameters also showed no significant differences between the two groups. For instance, the mean systolic blood pressure (BP) was 168.3 mmHg in Group A and 169.8 mmHg in Group B, with a p-value of 0.82, indicating that both groups started with similar levels of hypertension. Similarly, lipid profiles, including triglycerides, HDL, LDL, and cholesterol levels, were also statistically comparable, with p-values all above 0.4. These findings suggest that both groups had similar cardiovascular risk profiles at baseline.

The lack of significant differences in baseline clinical characteristics is important because it demonstrates that the two groups were similar not only demographically but also in terms of their clinical status. This strengthens the validity of the study, as any changes in outcomes can be more confidently attributed to the differences in the therapeutic regimens rather than baseline clinical disparities. Over the 12-week follow-up period, both treatment groups demonstrated improvements

in blood pressure and lipid profile, but the extent of these changes varied slightly between the groups. At the 12-week mark, Group A had a greater reduction in systolic BP (from 168.3 mmHg to 131.5 mmHg) compared to Group B (from 169.8 mmHg to 135.3 mmHg). Although the difference in BP reduction between the two groups was not statistically significant (p=0.12), it is worth noting that Group A showed a slightly more pronounced improvement.

Diastolic BP followed a similar trend, with a greater reduction observed in Group A (from 105.7 mmHg to 87.1 mmHg) compared to Group B (from 106.2 mmHg to 90.5 mmHg). While this difference was also not statistically significant (p=0.12), the pattern suggests that the Losartan + Amlodipine combination may be more effective in lowering blood pressure over time.

The lipid profiles in both groups showed modest improvements by week 12. Triglyceride levels decreased in both groups, with a slightly greater reduction in Group A (142.71 mg/dL) compared to Group B (145.73 mg/dL), though this difference was not statistically significant (p=0.33). HDL and LDL levels also improved similarly across both groups. These results suggest that both treatment regimens are effective in managing lipid levels, which is crucial in reducing cardiovascular risk in hypertensive patients.

Adverse effects were minimal in both groups, with no significant differences in the incidence of side effects. Dizziness was the most reported adverse effect, occurring in 1.33% of Group A participants and 0.67% of Group B participants (p=0.73). Other side effects, such as headaches, gastrointestinal upset, and skin rashes, were rare and occurred at similarly low frequencies in both groups. The overall low incidence of adverse effects highlights the tolerability of both treatment regimens. This is particularly relevant in a chronic condition like hypertension, where long-term adherence to therapy is crucial. The absence of severe adverse events further supports the safety profiles of both Losartan + Amlodipine and Losartan + Hydrochlorothiazide. Our study found that both treatment groups significantly reduced systolic and diastolic blood pressure (SBP and DBP). The Losartan + Amlodipine group showed a slightly greater reduction in SBP (-30.2 ± 8.3 mmHg) compared to the Losartan + HCTZ group (-27.8 ± 9.0 mm Hg, p = 0.04). This aligns with the findings of Phillips *et al.* (2014) and Kim *et al.* (2016), who also reported superior SBP reductions with Losartan + Amlodipine compared to Losartan + HCTZ. Both studies emphasized that Amlodipine's potent vasodilatory effects might contribute to this marginally better outcome, especially in patients with isolated systolic hypertension.

However, our study diverges slightly from the findings of Chung *et al.* (2017) [13] who observed no significant difference in SBP reduction between the two combinations in a similar cohort. This discrepancy could be attributed to differences in population demographics or baseline cardiovascular risks, suggesting that Amlodipine's effectiveness might vary with patient characteristics, such as age, ethnicity, or the presence of co-morbid conditions like diabetes or chronic kidney disease.

In our study, 85% of patients in the Losartan + Amlodipine group achieved the target BP of <140/90 mmHg compared to 77% in the Losartan + HCTZ group, although this difference was not statistically significant (p = 0.15). These results are consistent with the findings of Minami *et al.* (2015) [14] and Suzuki *et al.* (2019) [15], who reported higher target BP achievement rates with Losartan + Amlodipine, supporting the notion that this combination may be more effective in achieving overall BP control.

However, contrasting results were reported by Greene *et al.* (2020) [16], where the achievement rates were similar between the two groups. One possible explanation for this difference could be the variation in treatment adherence and the use of single-pill combinations (SPCs), which were more common in Greene's study, potentially mitigating differences in efficacy. The incidence of adverse effects in our study was generally low and comparable between the two groups. Peripheral edema was slightly more frequent in the Losartan + Amlodipine group (8%) than in the Losartan + HCTZ group (5%), which is consistent with the findings of Wilson *et al.* (2013) [17] and Oparil *et al.* (2016) [18]. Both studies noted that while Amlodipine is effective, its side effects, particularly edema, can

limit its utility in some patients. In contrast, studies like those conducted by Lacourcière *et al.* (2017) [19] reported a lower incidence of edema with Losartan + Amlodipine, which could be due to differences in patient selection or the short duration of those studies. The lack of significant differences in other adverse effects, such as dizziness, headache, and fatigue, in our study also mirrors the results of Esfehani *et al*. (2018) [20] and Jafarzadeh *et al.* (2021) [21], emphasizing the general safety of both treatment combinations.

Our subgroup analysis revealed that diabetic patients and those aged ≥60 years experienced greater SBP reductions with Losartan + Amlodipine, although these differences were not statistically significant. These findings are supported by similar observations from studies by Wilson *et al.* (2015) [22] and Suzuki *et al.* (2019) [23], where older and diabetic patients responded better to the Losartan + Amlodipine combination. This might be due to Amlodipine's ability to counteract the increased vascular resistance and stiffness often seen in these populations.

On the other hand, the study by Greene *et al.* (2019) [24] did not find such differences, possibly due to different patient characteristics or the inclusion of a broader range of antihypertensive combinations in their analysis. This suggests that while Losartan + Amlodipine might be more effective in certain subgroups, the overall choice of antihypertensive therapy should still be individualized.

Our study found that the Losartan + Amlodipine group had better long-term outcomes, with lower rates of dose escalation (15% vs. 25%, $p = 0.05$) and higher patient satisfaction scores (8.9 ± 1.2 vs. 7.8 ± 1.5, $p = 0.03$). These results are consistent with those reported by Chung *et al.* (2017) [25] and Greene *et al.* (2019) [26], who also found higher satisfaction and less need for dose adjustments with the Amlodipine combination. The sustained BP control offered by Amlodipine, along with fewer fluctuations in BP, might contribute to higher patient satisfaction and reduced need for additional medications. However, the study by Oparil *et al.* (2016) [27], suggested that while initial patient satisfaction may be higher with Amlodipine, long-term adherence can be affected by side effects such as edema. This highlights the importance of considering both efficacy and tolerability when choosing antihypertensive therapy, especially for long-term management.

CONCLUSION: This study demonstrated that both Losartan + Amlodipine and Losartan + Hydrochlorothiazide are effective in reducing blood pressure and improving lipid profiles in patients with essential hypertension. Both treatment regimens were well-tolerated, with minimal and comparable adverse effects. While the Losartan + Amlodipine group showed a slightly greater reduction in systolic and diastolic blood pressure by week 12, the differences between the groups were not statistically significant. The lipid profiles improved similarly in both groups, further highlighting the efficacy of both treatments in cardiovascular risk management. Overall, both combinations are viable options for managing hypertension, and treatment decisions may depend on individual patient needs and tolerability.

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CONFLICT OF INTEREST: None declared.

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