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# BENEFITS OF FIXED TRITHERAPY IN SEVERE ARTERIAL HYPERTENSION: REAL-LIFE STUDY AT THE BOUAKE UNIVERSITY HOSPITAL

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## SUMMARY

**Objective:** To evaluate the efficacy and tolerance of short-term fixed triple therapy in the management of severe hypertension in real life.

**Method:** This was a prospective study of grade III hypertensive patients admitted between October 2017 and March 2018 to the cardiology department of Bouaké University Hospital. We included all patients aged 18 years or older without complications. They received fixed triple therapy combining Amlodipine 10 mg, Valsartan 160 mg, hydrochlorothiazide 12.5 mg (n=10) or 25 mg (n=11) for 12 weeks (W) and were reviewed at W2, W6, W10, and W12. The primary endpoint was normalization of blood pressure.

**Results:** Twenty-one patients (age: 58.11±9.3 years, female: 81%) had a blood pressure of 210.7 ± 23.9 mm Hg/113.7 ± 19.9 mm Hg at study entry. During the study, 9.5% experienced adverse effects that required discontinuation of treatment.

At the end of the study, fixed triple therapy resulted in a significant decrease of 70.4 ± 18.7 mmHg in systolic blood pressure (SBP) and 31.2 ± 18.3 mmHg in diastolic blood pressure (DBP). Nine patients (42.9%) had normalized their SBP and 6 (28.6%) their DBP. Seven patients (33.3%) were able to achieve the therapeutic goal. The other unbalanced patients benefited from quadruple therapy.

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**Conclusion:** Fixed triple therapy significantly lowers blood pressure in severe hypertension. However, it often seems insufficient to normalize it in our context.

**Keywords:** Fixed triple therapy, severe hypertension, efficacy, tolerance.

## Introduction

According to the World Health Organization report on cardiovascular risk factors, high blood pressure (HBP) is responsible for 18% of deaths in wealthy countries and 45% of cardiovascular deaths [1**,** 2]. It causes severe disabilities related to stroke, dementia, heart failure, and chronic kidney disease [1.3]. In a 2018 literature review by Houehanou et al., sub-Saharan Africa had high prevalences of HTN among adults aged 18 and over, ranging from 16% to 40%. This prevalence exceeded 60% among people aged 65 and over [4]. Severe essential hypertension poses a problem of compliance and high cost when non-fixed combination therapy is used for its management [5,6]. To resolve these issues, pharmaceutical companies have developed triple therapy, which appears to yield good results [7]. We wanted to evaluate the efficacy and tolerance of fixed triple therapy in the management of severe hypertension in real-life settings. **Methodology:** We conducted a prospective study in the cardiology department of the Bouaké University Hospital Center from October 2017 to March 2018, i.e., over a period of three months. It focused on grade III hypertensive patients (BP ≥180 and/or ≥110 mmHg) who had given their written informed consent before the start of the study. Blood pressure was measured using a well-calibrated Omron electronic sphygmomanometer in a seated position after five to ten minutes of rest. All patients aged 18 years and older were included, regardless of whether they had received ineffective dual antihypertensive therapy. We excluded patients with cardiovascular or renal complications.

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During the study period, our patients received fixed triple therapy combining a calcium channel blocker, amlodipine 10 mg, a renin-angiotensin-aldosterone system blocker, valsartan 160 mg, and a thiazide diuretic, hydrochlorothiazide at a dose of 12.5 mg (n=10) or 25 mg (n=11) for 12 weeks. They were reviewed at 2 weeks (W2), 6 weeks (W6), 10 weeks (W10), and 12 weeks (W12) with the aim of titrating doses. The primary endpoint was normalization of blood pressure readings to strictly below 140/90 mmHg according to WHO guidelines. These quantitative variables were expressed as means ± standard deviations. They were compared using the Student's t-test with a fixed significance value.

**Results:**

During our study period, 21 hypertensive patients were followed. The mean age was 58.11 ± 9.3 years, with a predominance of women (81%).

Upon admission, patients presented with systolic-diastolic hypertension with an average of 210.7 ± 23.9 mmHg/113.7 ± 19.9 mmHg (Table I). During the study, two patients (9.5%) experienced adverse effects such as tinnitus, headaches, nausea, palpitations, and dizziness, requiring discontinuation of treatment.

In terms of compliance, all patients attended their appointments and adhered to the treatment.

At the end of the study, fixed triple therapy resulted in a significant decrease of 70.4 ± 18.7 mmHg in systolic blood pressure (SBP) and 31.2 ± 18.3 mmHg in diastolic blood pressure (DBP) (P=0.004). Nine patients (42.9%) had normalized their SBP and 6 (28.6%) their DBP. Seven patients (33.3%) were able to achieve the therapeutic goal. There was no significant difference between the 12.5 mg hydrochlorothiazide group and the 25 mg group. The other unbalanced patients received quadruple therapy.

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**Discussion**

The objective of this study was to evaluate the efficacy and tolerability of fixed triple therapy in the management of severe hypertension in Bouaké. The results show a significant decrease of 70.4 mmHg in systolic blood pressure (SBP) and 31.2 ± 18.3 mmHg in diastolic blood pressure (DBP) ( ). Normalization of systolic and diastolic blood pressure was achieved in 42.9% and 28.6% of cases, respectively. With regard to the tolerability of this triple therapy, 9.5% of cases experienced adverse effects from the treatment. These results allow us to discuss the efficacy, tolerability, and effect of formulating recommendations on the place of triple therapy in the management of hypertension in black subjects.

Regarding the efficacy of triple therapy, our results are consistent with several data in the literature showing that triple therapy controls blood pressure in 25% of patients [7, 8, 9]**.** These same observations were demonstrated in the ALLHAT study and many others, where after five years, 23% of patients were taking three or more antihypertensive drugs to control their blood pressure [10]. The same finding was observed in the INVEST study [11] and the ACCOMPLISH study [12].

The molecules involved in our study were a calcium channel blocker (amlodipine 10 mg), an angiotensin II receptor antagonist (valsartan 160 mg), and a thiazide diuretic (hydrochlorothiazide 12.5 mg and 25 mg). These molecules, which were the subject of the study, are recommended by learned societies. The 2018 ESH guidelines recommend, in cases of triple therapy, an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) combined with a calcium channel blocker and a thiazide or thiazide-like diuretic in a fixed combination due to their synergistic action [13]. The molecules received by patients were indeed fixed combinations in line with the recommendations. The choice of fixed triple therapy instead of fixed dual therapy is justified by the fact that the subjects admitted to this

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study had severe hypertension on the one hand, and on the other hand because thethe effect of triple therapy has been demonstrated in the management of moderate to severe hypertension in the prevention of cardiovascular events, particularly Amlodipine combined with Valsartan and Hydrochlorothiazide [9,13]. In short, the choice of molecules and the time taken to achieve a reduction in blood pressure figures, which was 12 weeks, were in line with published recommendations [9,13]. The results of this study show that molecules that have proven effective elsewhere do indeed have a place in the management of hypertension in black subjects.

What about their tolerance? Only 9.5% of cases of adverse effects to treatment were found. The majority of patients tolerated triple therapy. This tolerance to treatment is justified in part by the fact that the adverse effects of one of the molecules is compensated for or corrected by the action of another. Long-term use of renin-angiotensin-aldosterone system (RAAS) blockers as monotherapy is associated with reactivation of angiotensin II on renal cells, leading to significant release of renin with its plasma action characterized by an increase in aldosterone levels. This limits the antihypertensive effect of these molecules. The use of calcium channel blockers as monotherapy, characterized by peripheral vasodilation, can trigger compensatory mechanisms, namely the activation of the RAAS, responsible for reflex tachycardia and vasoconstriction, which limits the antihypertensive effect of calcium channel blockers. As for thiazide diuretics, they cause sodium depletion, which can lead to compensatory activation of the RAAS and the sympathetic nervous system, responsible for reducing the antihypertensive effects of diuretics [9].

**Conclusion:** fixed triple therapy significantly lowers blood pressure in severe hypertension. However, it often seems insufficient to normalize it in our context.

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TABLE I Change in blood pressure from S0 to S12

| WEEKS AVERAGE BP | S0 | W2 | S6 | S10 | S12 |
|---|---|---|---|---|---|
| TAS | 210.72 ± 23.93 | 154.57 ± 22.16 | 152.73 ± 19.19 | 148.97 ± 19.51 | 143.76 ± 15.28 |
| TAD | 113.70 ± 19.89 | 85.61 ± 12.36 | 88.18 ± 21.59 | 86.11 ± 10.63 | 84.50 ± 9.10 |
| FC | 88.70 ± 17.86 | 91.32 ± 16.16 | 87.73 ± 13.69 | 87.05 ± 9.60 | 84.50 ± 9.38 |