hikma.

edarbi
azilsartan medoxomil
40 mg • 80 mg tablets

edarbyclor
azilsartan medoxomil/chlorthalidone
40/12.5 mg • 40/25 mg tablets

World-Class Hypertension Treatment By Iraqi Experts

Hypertension in Iraq: Prevalence, Management, and Azilsartan's Place in Therapy

Introduction

Hypertension is a significant public health concern worldwide, and Iraq is no exception. Despite the challenges in obtaining precise statistics, estimates suggest that a substantial portion of the Iraqi population suffers from hypertension (1). Effective management of this condition is crucial to reduce cardiovascular morbidity and mortality (2). This article presents insights from five physicians to explore hypertension prevalence in Iraq, common treatments, and the potential role of azilsartan in therapy.

Prevalence of Hypertension in Iraq

The prevalence of hypertension among the adult population in Iraq is a significant public health concern, with varying rates reported across different regions. In Erbil, Kurdistan, the prevalence among older adults is 54.7%, with many undiagnosed cases (1). In Babylon city, despite a highly educated population, hypertension remains high, underscoring the need for increased awareness and education on risk factors (3). A nationwide survey revealed a 35.6% prevalence among adults, with poor blood pressure control, particularly among those with hypertriglyceridemia and unhealthy dietary habits (4).

Dr. Ghazi Farhan Haji, a senior consultant cardiologist, the vice president of the supreme council of academic societies in Iraq, and the president of the Iraqi hypertension society noted that the Iraqi Ministry of Health's 2015 data showed a 35.6% prevalence, slightly more common in males, but comparable between genders around age 55. This highlights the need for public health interventions and policies to address hypertension. Dr. Hilal Al Saffar, a consultant cardiologist, the RCP Global international adviser (IA), and the chair of the RCP Iraq network mentioned that 'in a cross-sectional study that screened 350 adults aged ≥18 years at four primary health care centers in Baghdad for hypertension, the overall prevalence of hypertension was found to be 24%, with a slightly higher prevalence in males (25%) than females (23%); and most hypertensive patients were aged ≥40 years (5)'. Dr. Nagham Karim, a senior consultant interventional cardiologist in Iraq pointed out the lack of a general registry, estimating that 40-50% of the population may be hypertensive based on local data from specific areas like Kurdistan (1). Practically, Dr. Oday Jasim Alsalihi, a professor of internal medicine and clinical cardiology at the Babylon University College of Medicine estimated from his clinical practice that in Babylon, about 40% of people over 40 have hypertension, with equal gender distribution.

These findings underscore the urgent need for comprehensive health education, screening programs, and improved management strategies to address the burden of hypertension in Iraq.

Despite variations in exact figures, there is consensus that hypertension is highly prevalent in Iraq, affecting a significant portion of the population across different age groups and genders.

Common Treatments for Hypertension

Hypertension necessitates a multifaceted approach for effective management. Pharmacological interventions such as thiazide diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), and in selected cases, mineralocorticoid receptor antagonists or beta-blockers, are recommended for better treatment outcomes (6–8). Locally, Dr. Ghazi said that the primary treatments for hypertension in Iraq include combination therapies rather than monotherapies. Medications typically used are ARBs or ACE inhibitors combined with diuretics or CCBs. Dr. Hilal highlighted that the most common antihypertensives used in Iraq are ARBs, which are favored due to their fewer side effects and good reputation among doctors and patients. Dr. Nagham agreed by stating that "the first-line treatment often involves ARBs. Beta-blockers may be used for younger patients due to high sympathetic activity." Dr. Oday specified that "it depends on patient age and comorbidities. For

those below 55, we usually use ACE inhibitors or ARBs. For those above 55 or 60, we may use calcium channel blockers."

The choice of antihypertensive treatment in Iraq varies based on patient age and comorbidities, with ARBs and ACE inhibitors being common first-line options.

Challenges in Hypertension Management

Barriers to hypertension management include limited healthcare access, low health literacy, and socioeconomic factors. Addressing these issues through improved policies and social determinants of health is vital for better outcomes (9). Collaboration between governments, healthcare providers, and communities is essential to combat hypertension effectively.
Dr. Ghazi noted that "There is no national registry, leading to inconsistent diagnosis and follow-up. The lack of patient education about hypertension as a chronic disease further complicates management." This issue is compounded by the healthcare system's complexity, as Dr. Hilal pointed out, with "55-60% of services provided by the private sector,"

Dr. Nagham emphasized the economic barriers, stating, "Some effective medications are very expensive. Many patients mistakenly treat hypertension like a short-term illness and stop their medication once they feel better." This sentiment is echoed by Dr. Oday, who highlighted that "The main challenge is compliance, largely due to the cost of medications as there is no medical insurance in Iraq." Together, these insights illustrate the multifaceted challenges in managing hypertension. effectively in Iraq.

Challenges in managing hypertension in Iraq include economic barriers, lack of a national registry, patient non-compliance, and discrepancies in medication availability.

Management of Resistant Hypertension

The management of resistant hypertension involves lifestyle modifications, identification and treatment of secondary causes, and the use of multidrug regimens. Lifestyle changes such as dietary adjustments, weight loss, and limiting alcohol intake are crucial, along with pharmacological therapies including diuretics, beta blockers, and mineralocorticoid receptor antagonists like spironolactone (10). Additionally, the optimization of antihypertensive drug regimens, close monitoring of treatment compliance, and consideration of factors affecting treatment resistance are essential steps in managing this condition effectively. Furthermore, newer approaches like renal denervation and selective mineralocorticoid receptor antagonists are emerging as potential adjunct treatments for resistant hypertension (10).

Dr. Ghazi emphasized the importance of "escalating the dose of medications like Azilsartan and incorporating diuretics or beta blockers in selected cases for managing resistant hypertension." Dr. Hilal highlighted that "combination therapy plays a crucial role in managing hypertensive patients with metabolic syndrome," noting that "adding a diuretic like chlorthalidone to existing treatments has shown to be more effective than increasing the dose of a single medication." Dr. Nagham agreed, stating, "Combination therapy is often preferred to improve patient compliance and achieve better blood pressure control." Dr. Oday further specified that "the best combination includes thiazide or thiazide-like diuretics such as chlorthalidone or indapamide." Together, these insights underscore the effectiveness of combination therapy in managing hypertension, particularly with the inclusion of diuretics to enhance treatment outcomes.

Combination therapy is essential in managing resistant hypertension, with specific combinations such as azilsartan and diuretics showing superior efficacy.

Efficacy of Azilsartan in Blood Pressure Control

Azilsartan, an ARB, demonstrates superior efficacy in reducing blood pressure and albuminuria compared to Enalapril (11). Azilsartan and amlodipine combination was found to be non-inferior to telmisartan and amlodipine combination in lowering blood pressure (12).

Studies have shown that Azilsartan effectively lowers urine albumin creatinine ratio as shown in Figure (1), highlighting its renoprotective effects in hypertensive patients with chronic kidney disease (11). Additionally, the Azilsartan/ Chlorthalidone combination has been found to be more efficient at lowering blood pressure in elderly hypertensive patients compared to Olmesartan/HCTZ as shown in Figure (2), although it may be associated with a higher risk of adverse events (13). Furthermore, in patients with stable coronary artery disease and overweight or obesity, Azilsartan has demonstrated significant antihypertensive properties, metabolic profile improvement, and tolerability, making it a favorable choice in clinical practice (14).

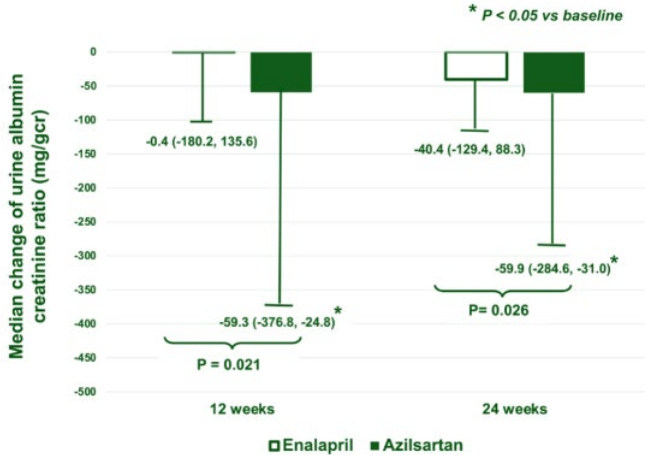

Figure 1. Reduction of urine albumin creatinine ratios in the enalapril group and azilsartan group (11).

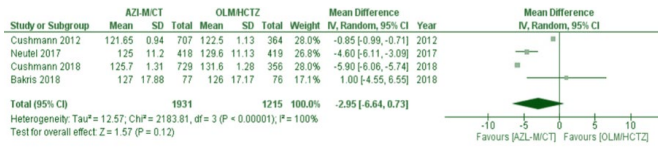

Figure 2. Efficacy forest plot of Azilsartan/ Chlorthalidone versus Olmesartan/HCTZ in lowering blood pressure (13).

Dr. Ghazi highlighted that "Azilsartan has shown a significant increase in affinity to the AT1 receptor compared to other ARBs, potentially enhancing blood pressure control and cardiovascular outcomes". This higher affinity is echoed by Dr. William B. White, a medical and scientific consultant, and a professor emeritus of medicine in the cardiology center at the University of Connecticut Health Center, who noted, "Azilsartan's unique pharmacological profile, characterized by its high binding affinity to and slow dissociation from the AT1 receptor, translates into significant clinical benefits" (15). Figure (3) summarizes the main signaling pathways of the AT1 receptor which azilsartan antagonizes and blocks angiotensin II from exerting its effects (15). Dr. White mentioned that from his extensive clinical experience, he noticed azilsartan's superiority in reducing blood pressure compared to other ARBs like valsartan and olmesartan medoximil. This efficacy, particularly when combined with diuretics such as chlorthalidone, positions azilsartan as a preferred first-line therapy for patients with hypertension, especially those with difficult-to-treat stage 2 hypertension. The synergistic effect with diuretics enhances the antihypertensive potency of azilsartan medoximil, addressing therapeutic challenges in managing severe hypertension effectively.

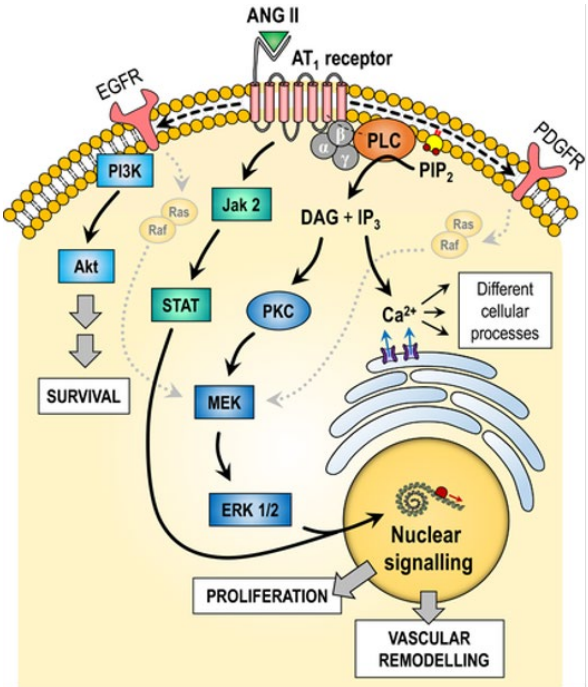

Figure 3. Angiotensin II-stimulated signaling pathways of the AT1 receptor (15).

Dr. Hilal and Dr. Nagham both emphasized Azilsartan's efficacy in providing 24-hour blood pressure control without dips, with Dr. Nagham adding that "This is critical as it helps prevent the 'silent killer' effects of high blood pressure." Dr. Oday further reinforced the medication's effectiveness, particularly in patients with poorly controlled hypertension on other ARBs, stating that "Its high affinity for the AT1 receptor makes it more potent in lowering blood pressure, especially in patients experiencing blood pressure spikes at night." These combined insights underscore Azilsartan's superior capability in managing blood pressure continuously and effectively.

Azilsartan's robust efficacy profile and synergism with diuretics underscore its role as a primary ARB choice, particularly in challenging cases of hypertension requiring intensive blood pressure management.

Dosing and Administration of Azilsartan in Special Populations

Regarding dosing considerations, Dr. White emphasized that azilsartan medoximil, a prodrug hydrolyzed to the active form of azilsartan, does not require adjustment in patients with mild or moderate renal impairment. As for patients with mild to moderate hepatic impairment, there is limited experience with the use of azilsartan, therefore close monitoring for these patients is warranted, and a starting dose of 20 mg should be considered. However, azilsartan has not been studied in those with severe hepatic impairment, so its use is not recommended in this patient group. Standard initial dosing at 40 mg daily, titratable up to 80 mg if necessary, ensures effective blood pressure control in a fairly wide group of patients unless its use is otherwise deemed not recommended. This approach underscores its versatility and reliability in clinical use, particularly in managing hypertensive patients with coexisting renal or hepatic conditions.

In a crossover trial with 111 patients, participants were treated with 20 mg of azilsartan daily for 2 months before being randomized to either continue with azilsartan or switch to 8 mg of candesartan daily for 3 months. The primary outcome, the percent change in urinary protein-to-creatinine ratio (UPCR), showed a mean percent change of −3.8% in the azilsartan group and 30.8% in the candesartan group at the first endpoint (p = 0.0004) as show in Figure (4), and 6.1% in the azilsartan group and 25.8% in the candesartan group at the second endpoint (p = 0.029) as shown in Figure (5). At the primary endpoint, both systolic and diastolic blood pressures were significantly lower in the azilsartan group compared to the candesartan group, with percent reductions of −0.6% versus 3.5% for systolic (p = 0.0006) and 1.5% versus 5.1% for diastolic (p = 0.01) as shown in Figure (4). At the second endpoint, systolic blood pressure and its percent reduction were significantly lower in the azilsartan group compared to the candesartan group, with values of 128.8 mm Hg versus 132.4 mm Hg (p = 0.01) and −1.4% versus 1.2% (p = 0.02) as shown in Figure (5), while diastolic blood pressure and its percent reduction were not significantly different between the groups (16).

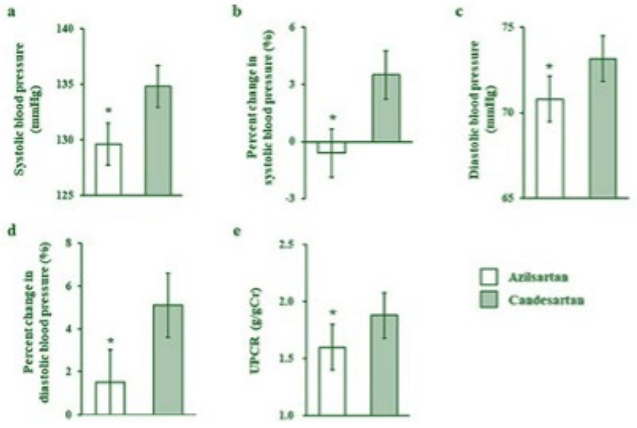

Figure 4. Values at the first endpoint for systolic blood pressure (a), percent change in systolic blood pressure (b), diastolic blood pressure (c), percent change in diastolic blood pressure (d), and urinary protein-to-creatinine ratio (UPCR) (e) in the azilsartan and candesartan groups (16).

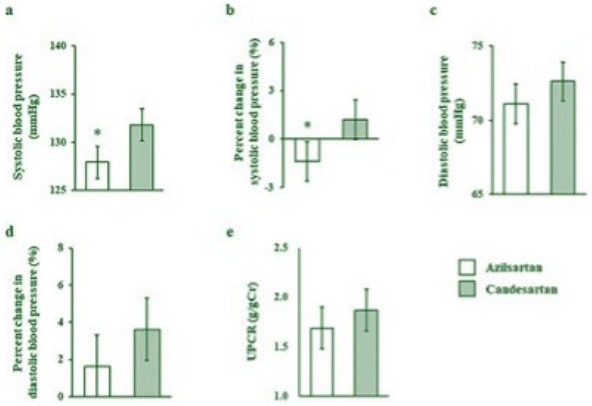

Figure 5. Values at the second endpoint for systolic blood pressure (a), percent change in systolic blood pressure (b), diastolic blood pressure (c), percent change in diastolic blood pressure (d), and urinary protein-to-creatinine ratio (UPCR) (e) in the azilsartan and candesartan groups (16).

Dr. Oday noted, "For patients with mild renal impairment, azilsartan provides better blood pressure stability. However, in those with severe renal impairment (eGFR <30), I avoid using azilsartan due to the risk of worsening renal function." Dr. Nagham added that "Azilsartan, being metabolized in the intestine, does not heavily impact the liver or kidneys. Therefore, it is considered relatively safe with minimal toxicity concerns for these organs. Regular monitoring for any contraindications is still necessary." Dr. Ghazi highlighted that azilsartan, hydrolyzed in the intestine to its active component, has a half-life of approximately 11 hours, making once-daily dosing preferred for better patient compliance. He also emphasized the importance of its availability through governmental healthcare pathways for broader use. These insights collectively underscore azilsartan's efficacy and safety across different patient populations, particularly those with renal or hepatic considerations.

Azilsartan's straightforward dosing regimen supports its usefulness across diverse patient populations, including those with mild or moderate renal or hepatic impairments, without compromising efficacy.

Monitoring and Management of Side Effects

In addressing potential side effects, Dr. White noted that azilsartan medoxomil was generally well tolerated in a phase 3, open-label study conducted in subjects with essential hypertension. The most commonly reported adverse effects included dizziness, fatigue, and increased blood creatinine levels, which were typically mild to moderate in severity. Although there were some reports of serious adverse events (SAEs), these were few in number and were not attributed to the study drug. The SAEs observed were consistent with the underlying condition of hypertension rather than being caused by azilsartan. Additionally, the study noted slight increases in blood creatinine and potassium levels, but these changes were not clinically significant and did not necessitate discontinuation of the medication. (17). This nuanced approach ensures that patients benefit from effective blood pressure control while mitigating manageable adverse effects. Dr. Oday added, "I monitor renal function and serum electrolytes two weeks after starting azilsartan and again after one month. Patients who show no deterioration in renal function or potassium can continue the medication, while those with deteriorating renal function are switched to labetalol, alpha-methyldopa, or a combination of hydralazine and isosorbide dinitrate, depending on the patient's specific case."

In Dr. Nagham's experience, azilsartan does not significantly elevate serum creatinine levels and has fewer side effects, such as cough, compared to ACE inhibitors. Dr. Ghazi concurred, stating that azilsartan has been reported to have a favorable safety profile, with fewer incidents of cough and dizziness compared to other ARBs and ACE inhibitors, making it a suitable option for patients with renal or hepatic impairment.

For patients on azilsartan medoxomil, it is recommended to regularly monitor blood pressure, renal function, liver enzymes, and serum potassium levels to ensure safety and efficacy (17).

Cardiovascular Outcomes and Long-term Treatment Considerations

While acknowledging the absence of direct effects on cardiovascular mortality, Dr. White discussed azilsartan's potential cardiovascular benefits inferred from its superior blood pressure-lowering efficacy and safety profiles in clinical studies. A systematic review and meta-analysis of 11 randomized controlled trials involving 6,024 patients found that azilsartan reduced clinical systolic blood pressure by an average of 2.85 mm Hg ($p < 0.001$) as shown in Figure (6) and diastolic blood pressure by 2.095 mm Hg ($p < 0.001$) more effectively than other ARBs as shown in Figure (7), with the 80 mg dose showing the greatest reduction (18).

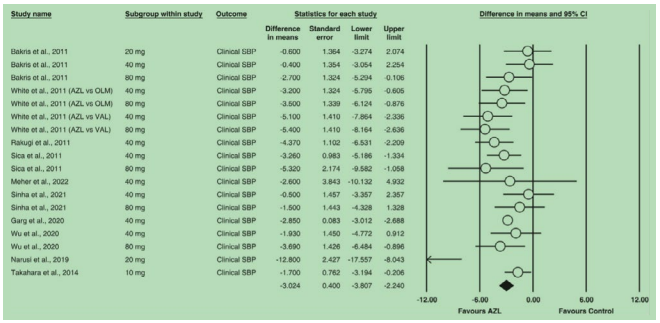

Figure 6. Forest plot for clinical systolic blood pressure of azilsartan versus other ARBs.

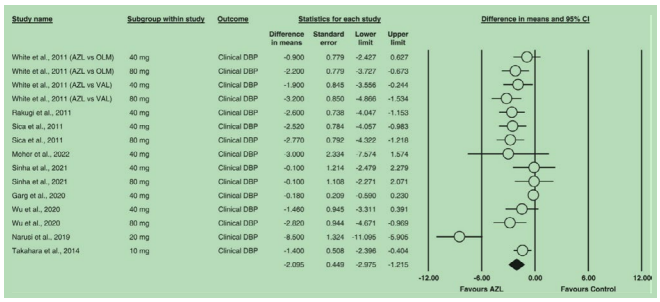

Figure 7. Forest plot for clinical diastolic blood pressure of azilsartan versus other ARBs.

Despite the lack of large-scale outcome studies, its effectiveness as an antihypertensive therapy correlates with a reduction in cardiovascular risks, supporting its long-term use and consideration as a cornerstone in hypertension management strategies. Dr. Nagham added that azilsartan's 24-hour efficacy offers consistent blood pressure control, which is essential for reducing cardiovascular risks. Its use can be especially beneficial for patients struggling with compliance due to its once-daily dosing. Dr. Ghazi highlighted that azilsartan has shown a significant increase in affinity to the AT1 receptor compared to other ARBs, potentially enhancing blood pressure control and cardiovascular outcomes. However, he noted that there is limited post-market independent data to fully confirm these benefits.

Azilsartan's favorable efficacy and safety profiles translates into potential long-term cardiovascular benefits, warranting consideration in comprehensive hypertension treatment plans despite limited direct mortality data (19).

Impact on Target Organs in Hypertensive Patients

Dr. White explored azilsartan's therapeutic impact on target organs in hypertensive patients with metabolic syndrome, emphasizing its efficacy in achieving a blood pressure goal of 130/80 mmHg, particularly in high-risk groups. Combining comprehensive assessments such as echocardiography and arterial stiffness measurements provides insights into its broader cardiovascular benefits beyond blood pressure reduction, supporting its role in mitigating long-term cardiovascular risks associated with hypertension and metabolic syndrome. In a 6-month therapy with azilsartan medoxomil (40 or 80 mg) for 32 patients with stage 1-2 hypertension and metabolic syndrome, systolic blood pressure decreased from 151.56 ± 7.16 mm Hg to 131 ± 8.6 mm Hg ($p < 0.0001$), diastolic blood pressure decreased from 86.52 ± 5.9 mm Hg to 80.4 ± 6.1 mm Hg ($p < 0.0001$), and central aortic pulse wave velocity decreased from 11.8 ± 3.1 m/sec to 8.4 ± 1.9 m/sec ($p < 0.05$), with 82% of patients achieving target blood pressure by the end of the study as shown in Figure (8) (19).

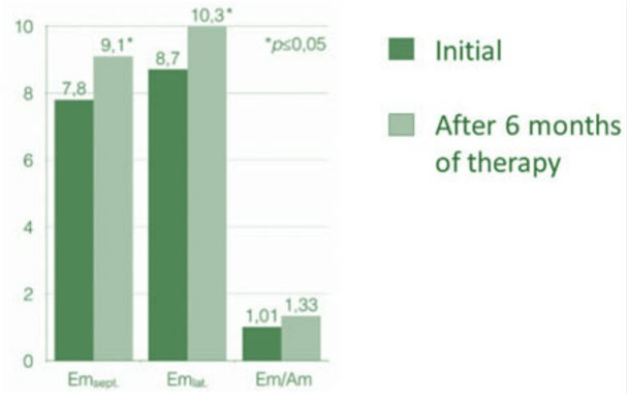

Figure 8. Parameters of left ventricular diastolic dysfunction prior to and after 6 months of azilsartan medoxomil therapy (19).

Dr. Hilal supported this view, noting that in a small study involving 30 patients with stage 1-2 hypertension and type 2 diabetes on dual antihypertensive therapy, replacing their RAAS inhibitor with azilsartan medoxomil significantly decreased blood pressure and had favorable effects on diastolic function and arterial stiffness, with 83% of patients achieving target blood pressure by the end of the study (20).

Azilsartan's efficacy in achieving target blood pressure goals and improving target organ outcomes highlights its utility in managing hypertensive patients, especially those with metabolic syndrome, to reduce cardiovascular risks effectively.

Impact of Azilsartan on Different Racial Groups

Dr. White addressed the disparity in azilsartan's effectiveness between black and white patients, a phenomenon observed broadly with ACE inhibitors and other ARBs. Azilsartan was found to be less effective in lowering blood pressure in black patients (21)and this is probably due to the differences in sodium and potassium homeostasis that have been noted among black individuals, who show lower plasma renin levels, greater sensitivity to salt, and a reduced capacity to excrete sodium compared to white individuals (9).. Despite this fact, azilsartan is still more effective than other ARBs such as olmesartan in reducing blood pressure in black patients. Two post hoc analyses compared the efficacy of azilsartan medoxomil (AZL-M) and its combination with chlorthalidone (AZL-M/CLD) versus olmesartan (OLM) and its combination with hydrochlorothiazide (OLM/HCTZ) in black and white hypertensive patients. AZL-M 80 mg significantly lowered clinic systolic blood pressure (SBP) by 12.5 mm Hg compared to OLM ($p < 0.01$) as shown in Figure (9), and AZL-M/CLD combinations significantly reduced ambulatory and clinic SBP by up to 34.4 mm Hg and 39.3 mm Hg, respectively, compared to OLM/HCTZ ($p < 0.05$). Both AZL-M and AZL-M/CLD achieved BP targets more frequently than OLM and OLM/HCTZ, with AZL-M/CLD 40 mg/25 mg showing statistically significant reductions in BP for both black and white patients (22).

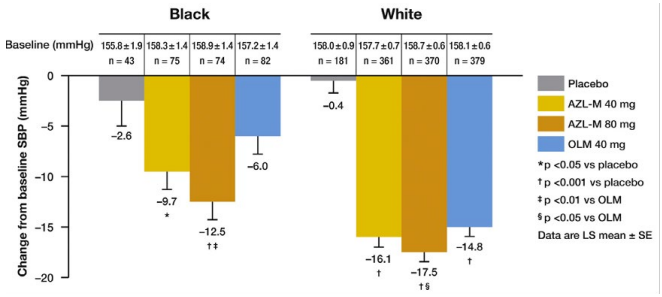

Figure 9. Changes in clinic systolic blood pressure from baseline to week 6, azilsartan medoxomil versus olmesartan versus placebo (22).

Dr. Oday noted that in Iraq, which has a predominantly Caucasian-like population, patients respond well to azilsartan. Dr. Nagham emphasized the importance of personalizing treatment based on clinical status and suggested considering combination therapies like azilsartan with diuretics for black patients. Dr. Hilal explained that lower renin levels in black patients make them less responsive to ACE inhibitors or ARBs, recommending calcium channel blockers or diuretics as first-line treatments to manage hypertension effectively. Dr. Ghazi acknowledged the lack of diversity in his population but several studies indicated azilsartan's greater efficacy in white patients. He emphasized the need to adjust doses and optimize treatment based on individual needs. Dr. White further highlighted the clinical significance of combining azilsartan with chlorthalidone, which effectively reduces plasma volume and enhances renin-angiotensin blockade making it

an effective treatment option for black patients who tend to have lower blood pressure control response compared to white patients treated with ACE inhibitors or ARBs monotherapy (23). This combination also mitigates hypokalemia observed with chlorthalidone alone, making it a valuable option for achieving optimal blood pressure control and cardiovascular outcomes across different racial groups.

Combining azilsartan with diuretics like chlorthalidone mitigates racial disparities in efficacy by addressing sodium sensitivity, thereby optimizing blood pressure control in black patients.

Conclusion

The management of hypertension in Iraq faces several challenges, including high prevalence rates, economic barriers, and patient compliance issues. However, advancements in antihypertensive therapies, particularly with medications like azilsartan, offer promising solutions for better blood pressure control and improved patient outcomes. By understanding and addressing these challenges through a combination of effective treatments and patient education, healthcare providers can enhance hypertension management and reduce cardiovascular risks in the Iraqi population.

CME Activity
"World-Class Hypertension Treatment By Iraqi Experts" Newsletter
Release Date: September 20, 2024
Expiration Date: September 20, 2025

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Learning Objectives: Upon completion of the educational activity, participants should be able to:
- Discuss the pharmacological properties, comparative efficacy, and safety profile of azilsartan medoxomil (AZL) compared to other ARBs
- Evaluate patient cases to determine appropriate dosing strategies and treatment selection for hypertension management using AZL
- Analyze the applicability of azilsartan medoxomil (AZL) within the Iraqi healthcare context, considering factors such as medication availability, patient demographics, and healthcare infrastructure.

Criteria for Success: To obtain a certificate of completion, a score of 80% or better on the post-test is required. After reading this newsletter, please scan the QR code on the back cover to answer all the post-test questions and complete the evaluation. You must participate in the entire activity to receive credit. There is no fee to participate in this activity.

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