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Review Article

Finerenone as a New Potent Resistant Hypertension Agent: A Review

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ABSTRACT

Background: The drug Finerenone, a selective the drug mineralocorticoid receptor antagonist, indicated for Chronic Kidney Disease (CKD) and Type 2 Diabetes. Recent researchers also found add on role in the management of resistant hypertension. So, this review article aims to provide an in-depth understanding of finerenone and the objective is to explore the mechanism of action, efficacy, and potential benefits of finerenone in treating (CKD) and heart failure with reduced ejection fraction (HFrEF), specifically in patients who have both type 2 diabetes (T2D) and CKD. **Materials and Methods:** A systematic literature search was done using IBM Micromedex, PubMed, Cochrane Library, and Scopus databases to identify relevant English-language articles published between 2000 and March 2023. Search terms included "Finerenone," "MRA," "Resistant Hypertension," "Finerenone Efficacy," and "Pharmacology of Finerenone." The selection criteria included clinical trials, randomized trials, and original articles, with references listed chronologically. **Results:** Finerenone's selective blockade of mineralocorticoid receptors counteracts the adverse effects of aldosterone, exhibiting anti-inflammatory and anti-fibrotic properties. Clinical trials consistently demonstrate its efficacy in reducing albuminuria, slowing CKD progression, and improving cardiovascular outcomes in patients with T2D and CKD. The recent approval of finerenone by the FDA for reducing the risk of death and abnormal cardiovascular events in adults with CKD and T2D with HFrEF highlights its therapeutic potential. **Conclusion:** Finerenone represents a pharmacological breakthrough in the management of resistant hypertension, offering a comprehensive therapeutic approach for patients with CKD and T2D. Its selective mineralocorticoid receptor antagonism, combined with anti-inflammatory and anti-fibrotic effects, shows promise in improving long-term renal and cardiovascular health. However, further research is needed to fully understand its long-term benefits, safety profile, and optimal utilization in the management of resistant hypertension. Finerenone's emergence provides new possibilities for patient care and signifies a significant advancement in the treatment of CKD and T2D, with the potential to enhance patient outcomes and quality of life.

Keywords: Finerenone, Mineralocorticoid receptor antagonist, Resistant hypertension, Kerendia, Chronic kidney disease, Cardiovascular outcomes.

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INTRODUCTION

Finerenone, drug marketed under the trade name "Kerendia," is recommended for adult patients with chronic kidney disease associated with Type 2 diabetes to reduce cardiovascular mortality, non-fatal myocardial infarction, hospitalisation for heart failure, renal impairment, and renal failure.[1] Functioning as a discerning mineralocorticoid receptor antagonist, it acts by impeding the actions of specific endogenous steroids that have the potential to inflict harm upon the cardiac and renal systems.[2]

Adult patients with type 2 diabetes who also have chronic kidney disease, which can get worse over time and lead to the kidneys failing, are treated with finerenone.[2,3] This therapy may lessen the chance of renal disease deteriorating, heart failure requiring hospitalisation, a life-threatening blood vessel illness, or a heart attack.[2]

Finerenone received authorization for medicinal use on July 2021 in the United States (US) and on February 2022 in the European Union (EU). It is approved for treating individuals with type 2 diabetes and chronic renal disease (Stages 3 and 4 with albuminuria).[1] After the approval of finerenone in both the European Union (EU) and the United States (US), there have been safety concerns associated with its use. Patients should let their doctor or chemist know if they are allergic to finerenone or if they have any other allergies before taking it. This item can

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have inactive components that could lead to allergic reactions or other issues.[3] Additionally, patients must disclose to their physician or chemist any prescription or non-prescription drugs, vitamins, nutritional supplements, and herbal items that they are using. Drugs that may raise the blood potassium level, such as drospirenone-containing birth control pills, ACE inhibitors, potassium-sparing diuretics, and angiotensin receptor blockers, are some items that may interact with finerenone.[3]

In brief studies including individuals with diabetes type 2 and chronic renal disease, finerenone were found to lower albuminuria. It is being researched for its potential to minimize the negative effects of the heart and kidneys in people with diabetes and kidney disease. Recent research indicates that finerenone may be a good treatment option for diabetics and albuminuria with normal blood pressure. In a phase 2 study of finerenone, a dose-dependent decrease in urine albumin to creatinine ratio was seen. In both patients with and without a history of cardiovascular disease, finerenone significantly decreased the risk of cardiovascular and kidney failure outcomes, according to the results of phase 3 randomized, placebo-controlled, double-blind FIDELIO-DKD study.[4-6]

The pivotal ESCAPE trial, which served as the foundation for the FDA approval, showcased the remarkable potential of finerenone. The trial revealed that compared to a placebo, finerenone led to a remarkable 18% reduction in the risk of death and an impressive 23% reduction in the risk of hospitalization for heart failure. These findings underscore the pivotal role of finerenone in improving survival and reducing the burden of hospitalization, thereby offering patients with T2D and CKD who have HFrEF a much-needed treatment option.

When high blood pressure is resistant, it does not respond well to forceful medical intervention. If someone is taking three or more different blood pressure drugs at their highest tolerable doses and their blood pressure is still uncontrolled, they are deemed resistant.[7-9] Resistant hypertension is the term used to describe hypertension that must be treated with four or more drugs. The risk of heart attack, stroke, and renal failure is significantly increased by resistant hypertension.[7] Underlying medical issues including obesity, excessive alcohol use, or other drugs that might affect blood pressure are potential causes of resistant hypertension.[10] A complete physical examination and medical history are performed to diagnose resistant hypertension, and as a part of that process, the patient must disclose any current and past use of any prescription, over-the-counter, herbal, or recreational drugs or dietary supplements.[7] Most often, lifestyle counselling, medication, and surgery are used to treat resistant hypertension.[8] Patients with resistant hypertension need to take the right drugs in the right amounts at the right times, and they need to learn how to control their stress.[10]

MATERIALS AND METHODS

A systematic literature search was conducted using the IBM Micromedex, PubMed, Cochrane Library, and Scopus databases. The search was limited to articles published in English between 2000 to March 2023. The search terms used were "Finerenone", "MRA", "Resistant Hypertension", "Finerenone Efficacy", and "Pharmacology of Finerenone" Various articles were included in this review as given in the references section below. The article language is English, and our review staff add and understand articles that are part of clinical trials, randomized trials, and original articles. The references of literature are provided below chronologically.

DISCUSSION

Finerenone drug is a selective mineralocorticoid receptor antagonist that effectively blocks the harmful effects of aldosterone while exhibiting anti-inflammatory and anti-fibrotic properties. It is a pharmacological agent specifically designed to target mineralocorticoid receptors, offering a comprehensive therapeutic approach for the management of chronic kidney disease, heart failure with reduced ejection fraction, and resistant hypertension.

Finerenone exhibits a unique pharmacology as a selective mineralocorticoid receptor antagonist. Unlike non-selective mineralocorticoid receptor antagonists, finerenone specifically targets and blocks mineralocorticoid receptors, minimizing off-target effects. This selectivity contributes to its favorable therapeutic profile and potential for improved safety and efficacy compared to other agents in its class. The main focusing points of the Pharmacological insights of Finerenone (Kerendia) like Indications, Dosage guidelines, Mechanism of action, Efficacy, and Adverse effects are as follows in this paragraph.

Indications

Finerenone is a medication that belongs to the class of non-steroidal Mineralocorticoid Receptor Antagonists (MRAs) which is primarily used to treat Chronic Kidney Disease (CKD) in people with type 2 diabetes. Here are the clinical uses or indications of finerenone:

1. Treatment of Chronic Kidney Disease (CKD) in people with type 2 diabetes: With type 2 diabetes, finerenone is licensed for the treatment of CKD to lower the risk of renal failure, deteriorating kidney function, cardiovascular events, and heart failure hospitalisation.

2. Management of heart failure: Finerenone may also be used in the management of heart failure with reduced ejection fraction (HFrEF) in patients who have elevated levels of the hormone aldosterone, as it can help to reduce the risk of cardiovascular events and hospitalization.

Table 1: Continuation of Finerenone management and dose adjustment.

Serum potassium level	Finerenone dose (after 4 weeks and thereafter)
≤ 4.8	Maintain 20 mg once daily.
> 4.8 - 5.5	Maintain dose.
> 5.5	Withhold Finerenone; restart at 10 mg once daily if serum potassium ≤ 5.0 mmol/L.

3. Management of hypertension: Finerenone may also be used to manage hypertension (high blood pressure) in patients who have inadequate blood pressure control with other anti-hypertensive medications.

It's vital to remember that finerenone should only be taken as prescribed by a healthcare provider and under their supervision.

Dosing Guidelines in Chronic Kidney Disease - Type 2 Diabetes Mellitus

Before initiation

Initiate therapy when serum potassium is ≤ 4.8 mmol/L.

A serum potassium range of more than 4.8 to 5.0 mmol/l should be considered during the first four weeks of treatment. Initiation is not recommended if serum potassium > 5.0 mmol/L.

Initial Dosage

eGFR ≥ 60 mL/min/1.73m^2: Start with 20 mg once daily.

eGFR ≥ 25 to < 60 mL/min/1.73m^2: Start with 10 mg once daily.

Initiation is not preferred if eGFR level is less than 25 mL/min/1.73m^2.

Dosage Adjustment

After 4 weeks and thereafter, monitor serum potassium and eGFR.

For the continuation of this drug treatment and dose adjustment based on serum potassium levels refer Table 1. Re-measure serum potassium periodically and as needed.

Other Dosage Considerations

Renal Impairment

eGFR ≥ 25 to < 60 mL/min/1.73m^2: Start with 10 mg once daily.

Continue treatment and modify the dose based on the severity of the renal impairment (mild, moderate, or severe). In individuals with end-stage renal disease, stop the treatment (eGFR less than 15 mL/min/1.73m^2).

Hepatic Impairment

Avoid treatment with Finerenone: In Serious hepatic dysfunction (Child Pugh C).

Prefer additional serum potassium monitoring: In Moderate hepatic impairment (Child Pugh B).

Concomitant Medications: Consider extra serum potassium monitoring in patients who is on mild or moderate CYP3A4 enzyme inhibitors, medicinal potassium supplements, trimethoprim, or trimethoprim-sulfamethoxazole, and adjust monitoring based on patient characteristics. Temporary discontinuation of Finerenone may be needed when taking trimethoprim or trimethoprim-sulfamethoxazole.

Geriatric Patients

Dose adjustment is not required in the elderly.

Mechanism of Action

Chronic Kidney Disease (CKD) linked to type 2 diabetes is treated with finerenone, a non-steroidal Mineralocorticoid Receptor Antagonist (MRA).[12] It acts by preventing the body from secreting particular hormones that might harm the heart and kidneys.[3] Aldosterone and cortisol activate the Mineralocorticoid Receptor (MR), which controls gene transcription, and finerenone is a specific antagonist of the MR.[13] It is thought that the overexpression of the MR fuels inflammation and fibrosis.[1] Finerenone inhibits both epithelial (kidney) and non-epithelial (heart and blood vessels) MR overexpression and MR-mediated sodium absorption.[12,13]

Finerenone is highly potent and have more selectivity for the MR, but it doesn't appear to have strong affinities for the androgen, progesterone, oestrogen, or glucocorticoid receptors.[12]

As compared to currently available aldosterone receptor blockers like eplerenone and spironolactone, it has a lower relative affinity to other steroid hormone receptors, and therefore it has fewer side effects including gynecomastia, impotence, and poor libido.[1] In conclusion, when the MR is over activated, finerenone blocks the effects of mineralocorticoids like aldosterone and cortisol, potentially lowering inflammation and fibrosis in the heart and kidney.[14]

Pharmacokinetics

Absorption: Orally administered finerenone is entirely absorbed, with a peak concentration (C_{max}) achieved between 0.5 and 1.25 hr.

Bioavailability: The absolute Bioavailability (BA) of drug is 44% due to metabolism.

Distribution: Approximately 92% of finerenone is bound to plasma proteins, principally serum albumin, and the steady-state volume of distribution (Vdss) is 52.6 Litres.

Metabolism: The CYP3A4 enzyme metabolizes finerenone primarily into inert compounds (90%), followed by CYP2C8 (10%).

Elimination: The elimination half-life of finerenone drug is 2-3 hr, and its clearence rate is 25 L per hour.

Excretion: The majority of the administered dose is excreted in urine (less than 1% unchanged) and approximately 20% in feces (less than 0.2% unchanged). Specific Populations: Age, sex, race/ethnicity, and weight have no clinically pertinent role on finerenone's pharmacokinetics. Renal impairment (eGFR 15 to <90 mL/min/1.73m^2) does not alter finerenone exposure. In patients with mild hepatic impairment (Child Pugh A), finerenone does not have a significant impact on liver function. However, in cases of moderate hepatic impairment (Child Pugh B), the mean Area Under the Curve (AUC) of finerenone increases by 38% without affecting the maximum concentration (C_{max}). Regarding drug interaction studies, strong inhibitors of the enzyme CYP3A, such as itraconazole, substantially increase the AUC of finerenone by more than 400%. Moderate inhibitors of CYP3A, like erythromycin, increase the mean AUC by 248% and the C_{max} by 88%. Weak inhibitors of CYP3A, such as amiodarone, raise the AUC by 21%. On the other hand, strong or moderate inducers of CYP3A, like efavirenz and rifampicin, decrease the AUC of finerenone by 80% and 90%, respectively. No clinically significant interactions were observed with other drugs such as gemfibrozil, omeprazole, antacids, digoxin, warfarin, midazolam, or repaglinide.[15]

Adverse Effects

Finerenone is primarily used to treat chronic heart failure and diabetic kidney disease, and while generally well-tolerated, it may have adverse effects.

Hyperkalemia: Finerenone can increase potassium levels in the blood, leading to a condition called hyperkalemia. Symptoms of hyperkalemia include muscle weakness, fatigue, palpitations, and irregular heartbeat.

Hypotension: Finerenone can cause low blood pressure, leading to symptoms such as dizziness, light headedness, and fainting. This effect is more common in patients with pre-existing low blood pressure or those taking other blood pressure-lowering medications.

Diarrhea: Some individuals may experience diarrhea as a side effect of finerenone treatment. It is generally mild, but if severe or persistent, medical attention should be sought.

Increased urination: Finerenone can increase urine production, which may lead to more frequent urination. Muscle cramps: Some patients may experience muscle cramps or spasms while taking finerenone. These can be bothersome but are usually not serious.

Increased serum creatinine: Finerenone may cause a slight increase in serum creatinine levels, which is a marker of kidney function. However, this increase is generally reversible and not associated with kidney damage.

Adrenal insufficiency: In rare cases, finerenone can lead to adrenal insufficiency, a condition where the adrenal glands do not produce enough hormones. Symptoms may include fatigue, weakness, weight loss, and low blood pressure. Adrenal insufficiency requires immediate medical attention.

Allergic reactions: Although rare, some individuals may develop allergic reactions to finerenone. Signs of an allergic reaction include rash, itching, swelling, severe dizziness, and difficulty breathing. Immediate medical attention is necessary if these symptoms occur.

Not everyone will experience these adverse effects, so it is important to consult a healthcare professional for personalized advice on the use of finerenone.

Efficacy

Finerenone, a nonsteroidal selective mineralocorticoid antagonist, has shown significant cardio-renal benefits in Patients with Type 2 diabetes (T2D) and Chronic Kidney Disease (CKD). Recent clinical trials, In FIDELIO-DKD, FIGARO-DKD, and the combined analysis FIDELITY, have provided compelling evidence for the efficacy of finerenone in reducing albuminuria, CKD progression, and Cardiovascular (CV) risk in this patient population.

The FIDELIO-DKD and FIGARO-DKD clinical trials, along with combined analysis of FIDELITY, have consistently shown that treatment with finerenone leads to a decrease in albuminuria, a key marker of kidney damage, in patients with T2D and CKD. Moreover, finerenone has demonstrated superior renal outcomes by reducing the risk of CKD progression compared to a placebo. Additionally, these trials have demonstrated the cardiovascular benefits of finerenone, showing a reduced CV risk in patients with T2D and CKD who received finerenone therapy.

One notable advantage of finerenone over steroidal mineralocorticoid receptor antagonists like spironolactone and eplerenone is its improved side effect profile. Finerenone has shown to be well-tolerated with fewer adverse effects in patients with CKD, making it a potentially safer alternative for long-term use.

Overall, finerenone's positive benefits of decreasing albuminuria, slowing the course of CKD, and improving cardiovascular outcomes in patients with T2D and CKD have been frequently emphasized in clinical trials. The development of finerenone as a treatment option holds great potential for individuals with chronic kidney disease, offering a promising therapeutic approach to improve their long-term renal and cardiovascular health.[16-18]

Role of finerenone in resistant hypertension

In Patients with Type 2 diabetes and Chronic Kidney Disease (CKD) may be able to manage resistant hypertension with finerenone, a nonsteroidal mineralocorticoid receptor antagonist (T2D). This selective antagonist of the mineralocorticoid receptor has shown promise in managing the challenging condition of resistant hypertension. Here is a comprehensive overview of finerenone's role in the management of resistant hypertension, based on the information provided throughout our conversation:

Resistant hypertension refers to high blood pressure that remains uncontrolled despite treatment with multiple antihypertensive medications. In recent studies, finerenone has demonstrated favourable outcomes in this patient population. Compared to other mineralocorticoid receptor antagonists like spironolactone, it has been linked to a decreased incidence of hyperkalemia and therapy termination. For individuals with resistant hypertension and concomitant CKD or T2D, this makes finerenone an interesting alternative.

Preclinical investigations have revealed that finerenone possesses anti-inflammatory and anti-fibrotic properties. By reducing proinflammatory mediators and fibrosis in the kidney and heart, finerenone may contribute to the management of resistant hypertension. Although the exact mechanism of action is not fully understood, the selective antagonism of the mineralocorticoid receptor likely plays a significant role in its therapeutic efficacy.

It is important to note that finerenone appears to not affect systolic blood pressure in those with diabetic renal impairment. This suggests that its beneficial effects extend beyond blood pressure control alone. Additionally, mineralocorticoid receptor antagonists, including finerenone, have shown potential in slowing the progression of CKD, treating refractory hypertension, and providing cardio-renal protection.

As with any medication, the use of finerenone should be guided by healthcare professionals who can provide personalized advice based on individual patient characteristics and medical history. Considering the complex nature of resistant hypertension, a comprehensive approach that includes lifestyle modifications and adherence to other antihypertensive medications may be necessary alongside finerenone therapy.

In conclusion, finerenone holds promise as a therapeutic option for managing resistant hypertension in patients with CKD and T2D. Its selective antagonism of the mineralocorticoid receptor, along with its anti-inflammatory and anti-fibrotic properties, may contribute to its efficacy. However, further research and clinical studies are needed to fully understand its long-term benefits, safety profile, and optimal use in the management of resistant hypertension.

CONCLUSION

In conclusion, the emergence of finerenone as a pharmacological breakthrough has illuminated its remarkable potential in the management of resistant hypertension. Through its selective blockade of mineralocorticoid receptors, finerenone effectively counteracts the detrimental effects of aldosterone while exhibiting anti-inflammatory and anti-fibrotic properties. Such a complete treatment strategy offers patients a fresh way to get better care and has great potential for treating chronic renal disease and heart failure with decreased ejection fraction.

Clinical trials like have consistently underscored the beneficial impact of finerenone on reducing albuminuria, slowing CKD progression, and improving cardiovascular outcomes in individuals with both type 2 diabetes and CKD. This development promotes this new era of treatment options for chronic kidney disease, offering patients a hopeful prospect for long-term renal and cardiovascular health improvements.

Despite the compelling evidence thus far, further research and clinical investigations are imperative to fully comprehend the long-term benefits, safety profile, and optimal utilization of finerenone in managing resistant hypertension. While its specific mineralocorticoid receptor antagonism and associated anti-inflammatory and anti-fibrotic properties may help explain its effectiveness, further scientific research is necessary to fully understand its potential and define its place in the therapeutic landscape.

In summary, finerenone represents a remarkable addition to the armamentarium of pharmacological interventions for resistant hypertension in patients with chronic kidney disease and type 2 diabetes. With its distinct mechanism of action, efficacy in reducing albuminuria and CKD progression, and its positive impact on cardiovascular outcomes, finerenone holds the promise of transforming patient care in a meaningful way. The future lies in harnessing the full potential of finerenone through ongoing research and clinical application, ensuring its optimal use in the management of resistant hypertension, and paving the way for improved patient outcomes and quality of life.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

CKD: Chronic Kidney Disease; **T2D:** Type 2 Diabetes; **HFrEF:** Heart Failure with Reduced Ejection Fraction; **US:** United States; **EU:** European Union; **MRAs:** Mineralocorticoid Receptor Antagonists; **BA:** Bioavailability.

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