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Artikel Penelitian

META-ANALISIS UJI ACAK TERKONTROL FINERENON TERHADAP LUARAN KARDIOVASKULAR PADA DIABETES TIPE 2 DAN PENYAKIT GINJAL KRONIK

META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS ON FINERENONE FOR CARDIOVASCULAR OUTCOMES IN TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE

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A B S T R A K

Pasien dengan penyakit ginjal kronik dan diabetes melitus tipe 2 memiliki risiko tinggi terhadap kejadian kardiovaskular. Finerenone, antagonis reseptor mineralokortikoid non-steroid, menunjukkan potensi sebagai terapi tambahan yang bersifat kardioprotektif. Kami melakukan meta-analisis berdasarkan data uji klinis acak terkontrol melalui penelusuran literatur di database PubMed dan ScienceDirect, menggunakan kerangka PICOS, yaitu: penyakit ginjal kronik dan diabetes melitus tipe 2 (P); finerenone (I); plasebo (C); luaran kardiovaskular (O); dan uji klinis acak terkontrol (S). Artikel yang diikutkan adalah artikel yang diterbitkan dalam 10 tahun terakhir dan tersedia dalam bentuk teks lengkap. Sebanyak 4 studi RCT dimasukkan dalam analisis ini. Analisis statistik dilakukan menggunakan Random Effect Model. Hasil analisis menunjukkan bahwa finerenone menurunkan odds ratio kejadian infark miokard non-fatal sebesar 9% dibandingkan plasebo (OR 0,91; 95% CI: 0,80–1,03) dan menurunkan kejadian rawat inap akibat gagal jantung sebesar 17% (OR 0,73; 95% CI: 0,66–0,82). Seluruh hasil analisis statistik signifikan kecuali untuk kejadian infark miokard non-fatal. Tingkat heterogenitas dinilai rendah hingga sedang (I^2 = 10%, 0%, dan 58%). Penilaian risiko bias menggunakan RoB-2 menunjukkan seluruh studi memiliki risiko bias rendah. Finerenone memberikan hasil lebih baik dibanding plasebo, sehingga dapat bermanfaat dalam memperbaiki luaran kardiovaskular pada populasi ini.

A B S T R A C T

Patients with chronic kidney disease and type 2 diabetes mellitus are at high risk for cardiovascular events. Finerenone, a non-steroidal mineralocorticoid receptor antagonist, shows potential as an additional therapy with cardioprotective effects. We conducted a meta-analysis based on data from randomized controlled trials by systematically searching the PubMed and ScienceDirect databases, using the PICOS framework: chronic kidney disease and type 2 diabetes mellitus (P); finerenone (I); placebo (C); cardiovascular outcomes (O); and randomized controlled trials (S). We included articles published within the last 10 years and available in full-text format. A total of 4 RCTs were included in this analysis. Statistical analysis was performed using the Random Effect Model. The analysis showed that finerenone reduced the odds of non-fatal myocardial infarction by 9% compared to placebo (OR 0.91; 95% CI: 0.80–1.03) and reduced the risk of hospitalization due to heart failure by 17% (OR 0.73; 95% CI: 0.66–0.82). All statistical results were significant, except for non-fatal myocardial infarction. The heterogeneity level was assessed as low to moderate (I^2 = 10%, 0%, and 58%). Risk of bias assessment using the RoB-2 tool indicated that all included studies had a low risk of bias. Finerenone demonstrated better outcomes compared to placebo, suggesting its potential benefit in improving cardiovascular outcomes in this population.

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INTRODUCTION

Chronic Kidney Disease (CKD) and Type 2 Diabetes Mellitus are two cases that are currently increasing due to various factors, especially due to lifestyle.[1,2] Moreover, these two diseases are not independent, but have interrelationships that can be a risk factor and also worsen the patient's outcome.[3] Because of this connection, in addition to these two cases increasing, CKD cases in T2DM patients are also increasing as Fenta et al (2023) found that the prevalence of these cases was 27% of the global population, the highest cases occurred in the USA and the lowest in the United Arab Emirates.[4]

It is estimated that individuals with T2DM have up to a fourfold increased risk of developing CKD compared to the general population, contributing significantly to global morbidity.[5] Furthermore, diabetic kidney disease is recognized as the leading cause of end-stage renal disease (ESRD) worldwide.[6]

Recent evidence indicates that finerenone offers additional cardiovascular and renal protection when used alongside SGLT2 inhibitors and GLP-1 receptor agonists, especially in diabetic kidney disease where residual risk remains high.[7]

A network meta-analysis comparing finerenone, SGLT2i, and GLP-1 RA found that while all classes reduced major adverse cardiovascular and renal events, finerenone uniquely lowered hospitalization for heart failure, highlighting its complementary role to RAS inhibition.[8]

Finerenone, a selective nonsteroidal mineralocorticoid receptor antagonist (MRA), is intended as therapy in Diabetic Kidney Disease (DKD) and Chronic Heart Failure (CHF).[9] Compared to steroidal MRAs, Finerenone demonstrates reduced risk of hyperkalemia and better safety profile in vulnerable populations, such as those with CKD.[10] Finerenone, a third-generation nonsteroidal MRA, has demonstrated beneficial effects in heart failure (HF) and chronic kidney disease (CKD).[11] Finerenone was shown in a recent comprehensive meta-analysis to reduce the risk of heart-failure-related hospitalizations by approximately 20 % (RR 0.82; 95 % CI 0.76–0.87) compared to control in patients with cardiorenal-metabolic conditions.[12]

Several studies have been conducted on the use of Finerenone with mixed outcomes. However, to date, no meta-analysis has specifically evaluated the cardiovascular outcomes of finerenone in a population with both CKD and T2DM, independent from renal endpoints. This gap in the literature forms the rationale for our current study. A growing body of evidence suggests that early intervention targeting mineralocorticoid receptor overactivation can delay both cardiovascular and renal complications in T2DM.[13] It has also been reported that Finerenone slows DKD progression, reduces albuminuria, and lowers cardiovascular risk, regardless of baseline HbA1c levels and concomitant treatments such as SGLT2-i, GLP-1RA, or insulin.[14]

In a post hoc analysis of the FIGARO-DKD trial, finerenone significantly reduced the incidence of new-onset heart failure—by 32% (HR 0.68; 95% CI 0.50–0.93)—regardless of baseline heart failure

status.[15] In the FINE-HEART pooled analysis (FIDELIO-DKD, FIGARO-DKD, and FINEARTS-HF trials), finerenone consistently reduced the risk of kidney composite outcomes by 20% and lowered rates of hospitalization for heart failure as well as all-cause mortality across a range of cardiovascular-kidney-metabolic phenotypes.[16]

The purpose of this study was to analyze the pooled effectiveness in cardiovascular outcomes in the use of Finerenone.

METHODS

We conducted a systematic review and meta-analysis of intervention. The writing of this systematic review and meta-analysis was based on the PRISMA Guideline 2020.[17] We used the PICOS framework as a reference in the literature search which consists of : (P)atient, Diagnosed with T2DM and CKD; (I)ntervention, Finerenone; (C)omparator, placebo; (O)utcome, Cardiovascular Outcome (number of death caused by cardiovascular, Non-fatal Myocardial Infarction, and Hospitalization due to Heart Failure; (S)tudy, Randomized Controlled Trial (RCT). We do not limit the publication time of inclusion articles, but we only use articles that are in Indonesian or English.

Each author was assigned to various available databases such as PubMed, and ScienceDirect. The searches that were found were then subjected to duplication selection using the application if the search data could be collected automatically, and continued with manual duplication selection for databases that could not be collected in their entirety. Articles were then independently selected based on the established PICOS framework. Selected articles were searched for full-article availability. If a full-article was not found, it was excluded. The articles that had been collected were then analyzed for suitability of the flow.

Inclusion criteria were: (1) randomized controlled trials; (2) adult patients with T2DM and CKD; (3) studies reporting at least one cardiovascular outcome of interest (cardiovascular death, non-fatal MI, or heart failure hospitalization); (4) published in English or Indonesian; and (5) available in full-text format.

Exclusion criteria were: (1) studies that involved patients with acute heart failure; (2) studies reporting only renal outcomes without cardiovascular data; (3) observational studies or non-RCTs.

Study selection was conducted independently by two reviewers. In case of disagreement, resolution was made through consensus or consultation with a third independent reviewer.

Appropriate articles were then extracted independently using Google Sheet, followed by joint evaluation. If there was disagreement, it was resolved through mutual consensus. Data that was confirmed for inclusion was extracted for the following data: (1) Author, Year), (2) Number of Sample received Finerenone, (3) Number of sample received Placebo. (4) Age, (5) Gender, (6) Description of Intervention, (7) Number of Death from Cardiovascular, (8) Number of Non-Fatal Myocardial Infarction, and (9) Number of Hospitalization due to Heart Failure.

Using RevMan 5.4, an intervention dichotomous meta-analysis were performed to examine outcome of cardiovascular. Heterogeneity tests showed I^2 and tau^2 values, and a forest plot with proportion values and 95% CI was used to depict the results. The Random Effect Model method was used to examine the data in order to draw broad generalizations.

We use Risk of Bias for RCT Tools, named RoB-2 Tools, to analyze the risk of bias in the articles we will include. This tool was chosen because it widely used and recommended to assess RCT design. The result will be presented in Summary Plot and Traffic Plot to determine whether the article is considered as Low Risk, Some Concern of Bias, and High Risk of Bias. We also conducted a subgroup analysis to assess the effect of Finerenone based on dosage (10 mg vs. 20 mg) and CKD stage severity. We will proceed to analyze potential publication bias using funnel plot.

RESULT

Study Selection

We identified 155 articles and processed them according to PRISMA Flowchart that was visualized in figure 1. After the removal of duplicates and screening based on title and abstract, 12 articles remained for full-text review. Of these, 4 randomized controlled trials (RCTs) met the inclusion criteria and were included in the final analysis.

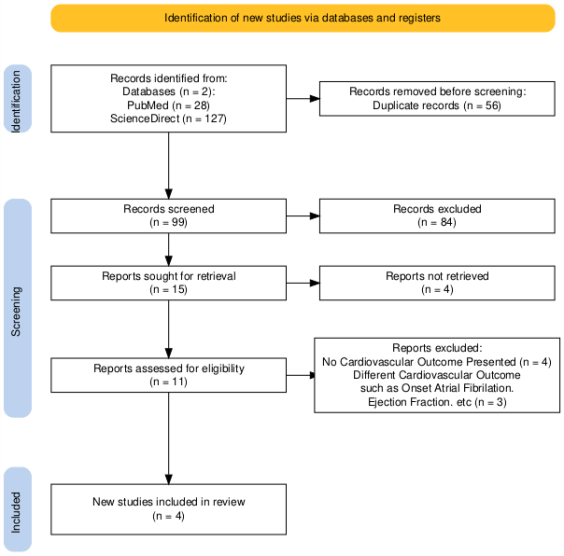

Figure 1. PRISMA Flowchart Process

Characteristics of Included Studies

We include in total 26.942 patients with 13.478 received finerenone and 13.464 received placebo.[18,5,17,19] Looking at the inter-study age and gender comparisons, qualitatively, no significant differences were seen and all intervention patients received finerenone orally at a dose of 10 mg or 20mg. We summarize the characteristics in *Table 1*.

Table 1. Characteristics of Included Studies

Author,Year	Number of Sample		Age		Gender (M/F)		Finerenone Dose	Duration of Intervention
	Finerenone	Placebo	Finerenone	Placebo	Finerenone	Placebo		
Agarwal[20],2024	6519	6507	64.7 +/- 9.4	64.8 +/- 9.7	4481 / 2038	4607 / 1900	Oral, 10 mg or 20mg	3.4 years
Bakris[21],2020	2833	2841	65.4 +/- 8.9	65.7 +/- 9.2	1953 / 880	2030 / 881		2.6 years
Pitt[9],2021	3686	3666	64.1 +/- 9.7	64.1 +/- 10	2525 / 1161	2577 / 1089		3.0 years
Sarafidis[10],2023	440	450	67 +/- 9	67 +/- 9	272 / 168	298 / 152		0.25 years

Risk of Bias Assessment

We proceeded to analyze the Risk of Bias using RoB-2 Tools and visualized it in Figure 2. All included studies were declared as low risk of bias, indicating all included studies used good methodology (minimal bias) and also presented results well.

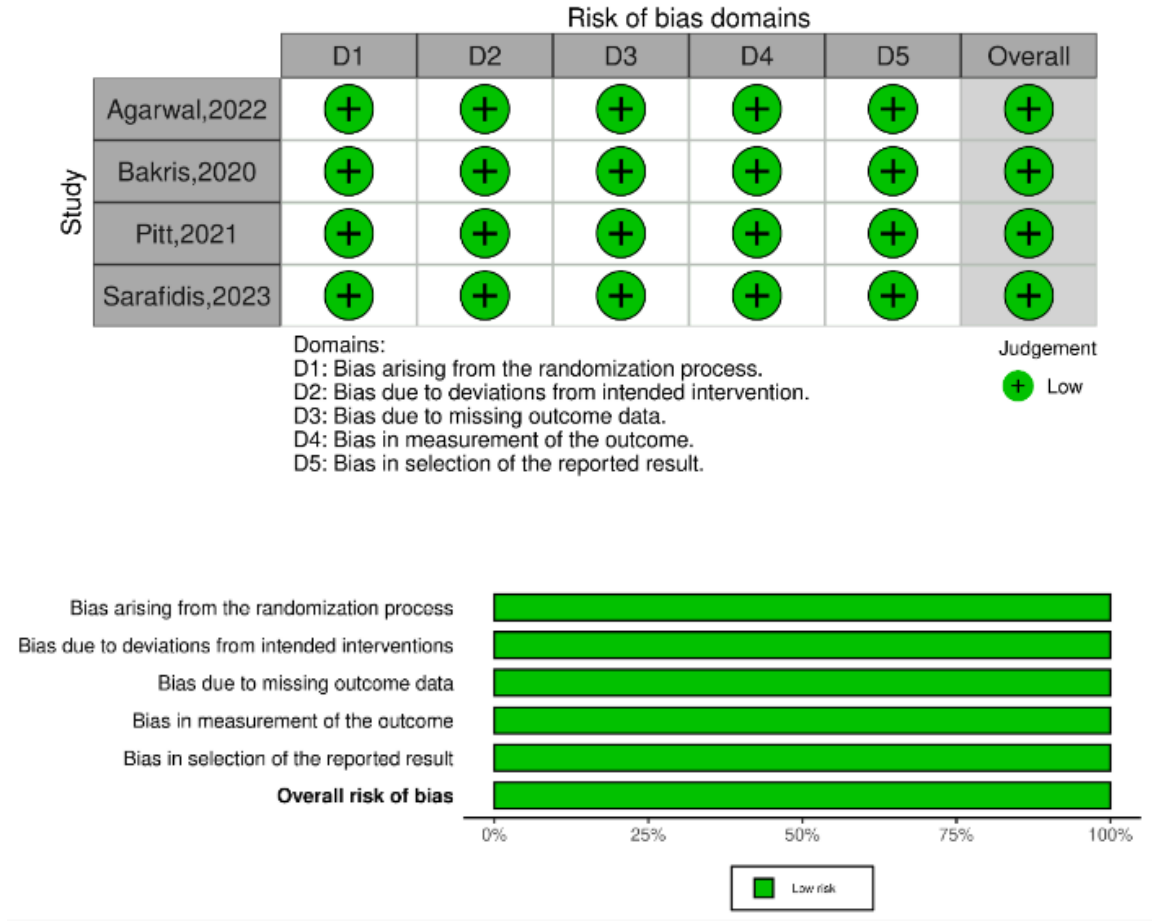

Figure 2. Visualization of Traffic Plot (upper) and Summary Plot (Lower) showed low risk of bias among all included studies.

Cardiovascular Outcome of Finerenone Among CKD and T2DM Patients

Finerenone showed good efficacy in terms of Cardiovascular Outcome. Finerenone showed superior outcome by lower death OR caused by Cardiovascular by 15% (95%CI: 0.76 - 0.94) compared to placebo. The result is statistically significant and has a low heterogeneity (I2 10%). Finerenone also showed lowered OR of Non-Fatal Myocardial Infarction compared to placebo by 9% (95%CI : 0.80 - 1.03), however it showed non-significant statistically. Finerenone still showed a good efficacy by lower OR of Hospitalization by 27% compared to placebo (95%CI: 0.66 - 0.82) and was statistically significant. Heterogeneity considered some concerns as I2 scored more than 50%, there are potential variables that could impact the OR. All of the result were visuzlied in Figure 3.

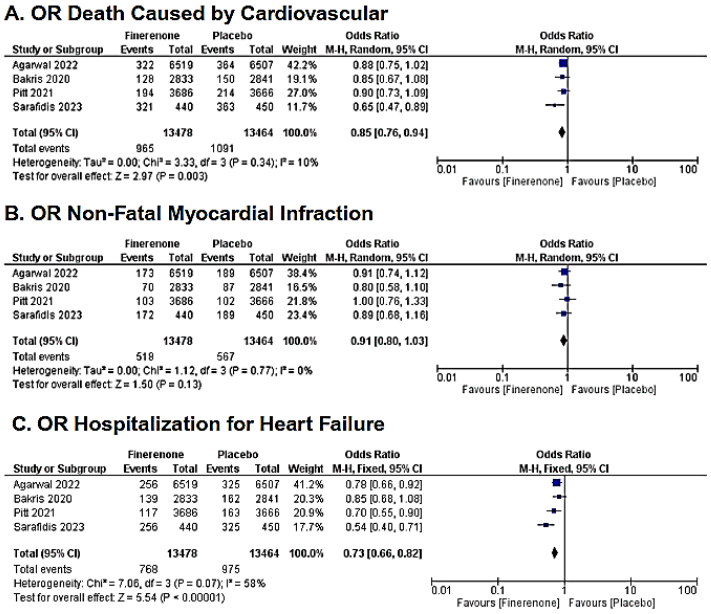

Figure 3. Summary of Forest Plot of Meta-analysis towards: (A) Death caused by Cardiovascular, (B) Non-Fatal Myocardial Infraction, and (C) Hospitalization for Heart Failure.

Publication Bias

We assessed the possibility of publication bias using both a funnel plot (Figure 4) and Egger's regression test. The funnel plots for each cardiovascular outcome showed a relatively symmetric distribution, suggesting a low risk of publication bias. This was supported by Egger's test, which revealed no statistically significant small-study effects for any of the outcomes. A p-value greater than 0.05 indicates no significant publication bias.

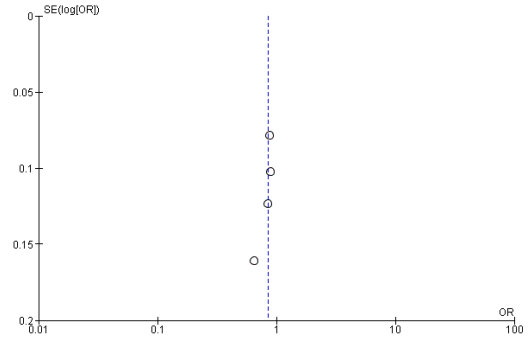

Figure 4. Funnel Plot

Table 2. Egger's Test Result

Outcome	Intercept (Bias Coefficient)	p-value
Cardiovascular Death	−0.017	0.989
Non-Fatal Myocardial Infarction	−0.186	0.943
Heart Failure Hospitalization	+0.028	0.995

DISCUSSION

Clinical Implication: Can We Use Finerenone?

Nowadays, finerenone is a potentially extremely important discovery, particularly in situations of kidney disease. Inhibiting fibrosis, lowering pulmonary artery pressure, improving diabetic retinopathy, improving endothelial function, optimizing metabolism, and lowering oxidative stress are just a few of the ways that finerenone helps to improve renal and cardiovascular conditions. These pleiotropic effects are increasingly supported by preclinical

and translational studies exploring finerenone's anti-inflammatory and anti-fibrotic mechanisms.[22]

This study also showed that Finerenone had a good effect (lower OR) than placebo on cardiovascular mortality (OR 0.85, 95%CI: 0.76 - 0.94), non-fatal myocardial infraction (OR 0.91, 95%CI: 0.80 - 1.03), and hospitalization due to heart failure (OR 0.73, 95%CI: 0.66 - 0.82). Two parameters were statistically significant, cardiovascular death and heart failure hospitalization, indicating that Finerenone has good efficacy in potentially saving patients with CKD and T2DM during their treatment.

One parameter, non-fatal myocardial infarction, did not show a statistically significant reduction with Finerenone use. This may be attributed to several factors, such as heterogeneity in patient populations (e.g., baseline cardiovascular risk, CKD stages), differences in follow-up duration, or variations in how non-fatal MI was defined across trials. Some studies might have used stricter adjudication criteria or relied on different biomarkers or imaging protocols, which can dilute pooled significance**.**

Based on these results, we can administer Finerenone to patients with CKD and T2DM with the target of achieving better cardiovascular outcomes. Cardiovascular outcomes need to be a concern in the case of patients with T2DM and CKD because these conditions greatly impact the occurrence of cardiovascular disease, both macrovascular and microvascular complications.[23,14] Current therapies that have good cardiovascular outcomes can be SGLT2-i or GLP1RA.[14]

When compared to SGLT2 inhibitors and GLP-1 receptor agonists, Finerenone appears to offer comparable or even superior benefits in reducing heart failure hospitalization, but may be less effective in preventing atherosclerotic events such as myocardial infarction. For example, SGLT2-i have shown consistent reductions in both HF hospitalization and major adverse cardiovascular events, while GLP-1RA have been particularly strong in reducing MI and stroke risk. Therefore, Finerenone may be best positioned as a complementary agent rather than a substitute.

These findings are in line with previous large clinical trials, particularly the FIDELIO-DKD and FIGARO-DKD studies, which demonstrated that Finerenone significantly reduced cardiovascular events and slowed the progression of kidney disease in patients with T2DM and CKD.[24,25] The pooled analysis of both trials (FIDELITY) also confirmed a consistent benefit of Finerenone across different stages of CKD, including in patients with more advanced renal impairment.[4]

Mechanistically, the benefit of Finerenone goes beyond simple blood pressure control. Anti-inflammatory, anti-fibrotic, and anti-oxidative pathways play a central role in its ability to provide both renal and cardiovascular protection.[26] Unlike traditional steroidal MRAs, Finerenone offers these benefits with a lower risk of hyperkalemia, making it more favorable in the management of patients with compromised renal function.[27]

Furthermore, emerging evidence suggests that combining Finerenone with other guideline-recommended therapies, such as SGLT2 inhibitors or GLP-1 receptor agonists, may provide additional cardiovascular and renal protection, although long-term data on combination strategies are still limited and warrant further research.[28,29]

One parameter in this study, non-fatal myocardial infarction, did not show a statistically significant reduction with Finerenone use. This finding is consistent with certain subgroup analyses from previous trials, suggesting that while Finerenone effectively lowers the risk of heart failure hospitalization and cardiovascular death, its impact on ischemic coronary events may be more limited.[30]

Although a subgroup analysis based on CKD severity was available and demonstrated consistent cardiovascular benefits across stages, the included studies did not consistently report outcomes separately for 10 mg and 20 mg doses of finerenone. As a result, subgroup analysis by dosage could not be formally conducted without access to individual patient data.

Nonetheless, considering the high burden of cardiovascular morbidity and mortality in CKD and T2DM, the use of Finerenone represents an important advancement in the effort to reduce adverse outcomes in this vulnerable population.

Strength and Limitation

This power meta-analysis has shown a favorable effect on cardiovascular outcomes with the use of Finerenone in patients with CKD and T2DM. It is hoped that this study can be the basis for the implementation of the use of Finerenone to reduce cardiovascular complications in patients.

Despite involving 13,464 patients using finerenone, we have not further analyzed the possible side effects and other parameters in T2DM and CKD patients more broadly, such as glycemic control, eGFR changes, and other parameters. To be able to carry out further implementation, it is not only limited to cardiovascular outcomes, but needs to look at the patient as a whole. However, this study has been able to support one of the outcomes that is quite important because in CKD and T2DM patients the dominant attention is aimed at cardiovascular outcomes because it affects mortality in patients. The limitation of our study also lies in the absence of studies looking at the interaction of Finerenone with various other medications. This is important because T2DM and CKD patients often receive polypharmacy (consumption of more than 5 kinds of drugs), be it antidiabetic drugs, anti-hypertensive drugs, and others. It is possible that there may be interaction effects that may affect the drug but as far as we have searched, there are no studies that address this.

Moreover, there is potential methodological heterogeneity among included studies, particularly in the definition and reporting of cardiovascular outcomes such as non-fatal myocardial infarction. Some studies did not clearly define adjudication processes or relied on different diagnostic thresholds, which could influence the pooled analysis.

Future Research Direction

Future research can consider other parameters such as glycemic outcomes or renal outcomes and pay attention to the side effects of treatment that may occur, both common adverse effects and rare adverse effects that may occur. There is also a need for studies that look at the interaction of Finerenone with various other treatments. This is proposed because patients with T2DM and CKD often receive polypharmacy, consumption of more than 5 kinds of drugs.

CONCLUSION

This meta-analysis concludes that finerenone significantly reduces cardiovascular death and heart failure hospitalization in patients with chronic kidney disease and type 2 diabetes mellitus, suggesting its beneficial role in this high-risk population. While it also showed a trend for lower non-fatal myocardial infarction, this was not statistically significant. The study, involving a large sample size and low risk of bias, provides strong evidence for clinicians to consider finerenone for improving cardiovascular outcomes in these patients.

RECOMMENDATIONS

Based on the findings of this meta-analysis, Finerenone at a dose of 20 mg/day may be considered for patients with chronic kidney disease stage 3–4 and type 2 diabetes mellitus to reduce the risk of hospitalization due to heart failure. Clinicians should weigh the benefits of Finerenone alongside established therapies such as SGLT2 inhibitors or GLP-1 receptor agonists, especially in patients with high cardiovascular risk. Further studies are encouraged to evaluate long-term outcomes, safety in combination therapies, and its effect on atherosclerotic cardiovascular events such as myocardial infarction and stroke.

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