In adults with type 2 diabetes and chronic kidney disease (eGFR 25–75 mL/min/1.73 m²), what is the absolute risk reduction for the primary kidney composite outcome of finerenone versus placebo, based strictly on the FIDELIO-DKD primary analysis?

1. Introduction

The FIDELIO-DKD trial was a pivotal phase III, randomized, double-blind, placebo-controlled study designed to assess whether finerenone, a nonsteroidal mineralocorticoid receptor antagonist, could reduce the risk of kidney failure and disease progression in adults with type 2 diabetes and chronic kidney disease (CKD) (eGFR 25–75 mL/min/1.73 m²) already receiving optimized renin-angiotensin system blockade (Bakris et al., 2020; Bakris et al., 2019; Agarwal et al., 2020). The primary composite kidney outcome included time to kidney failure, a sustained decrease of at least 40% in eGFR from baseline, or death from renal causes (Bakris et al., 2020; Bakris et al., 2019; Rossing et al., 2021). According to the FIDELIO-DKD primary analysis, after a median follow-up of 2.6 years, the absolute risk reduction (ARR) for this composite outcome was approximately **3.3%** (17.8% event rate in the finerenone group vs. 21.1% in placebo) (Bakris et al., 2020; Rossing et al., 2022; Barrera-Chimal et al., 2022). This translates to a number needed to treat (NNT) of about 30 over this period (Bakris et al., 2020; Zhang et al., 2023). These findings have been confirmed and contextualized by pooled analyses and meta-analyses, which consistently show that finerenone provides significant renal protection compared to placebo in this high-risk population (Bakris et al., 2022; Díaz et al., 2025; Barrera-Chimal et al., 2022).

Is the absolute risk reduction for the primary kidney composite outcome with finerenone versus placebo in adults with type 2 diabetes and CKD (eGFR 25–75 mL/min/1.73 m²) clinically significant according to...
Requires at least 5 papers that directly answer your question. Try adjusting your query to find more papers.

FIGURE 1 Consensus meter: Is ARR for primary kidney outcome with finerenone vs placebo clinically significant in FIDELIO-DKD?

2. Methods

A comprehensive literature search was conducted across over 170 million research papers indexed in Consensus, including Semantic Scholar and PubMed. The search strategy targeted studies reporting absolute risk reduction (ARR), event rates, or number needed to treat (NNT) for the primary kidney composite outcome from the FIDELIO-DKD trial and related meta-analyses. Out of an initial pool of 1,156 identified papers, relevance filtering and deep search strategies yielded a final set of **50 included papers**.

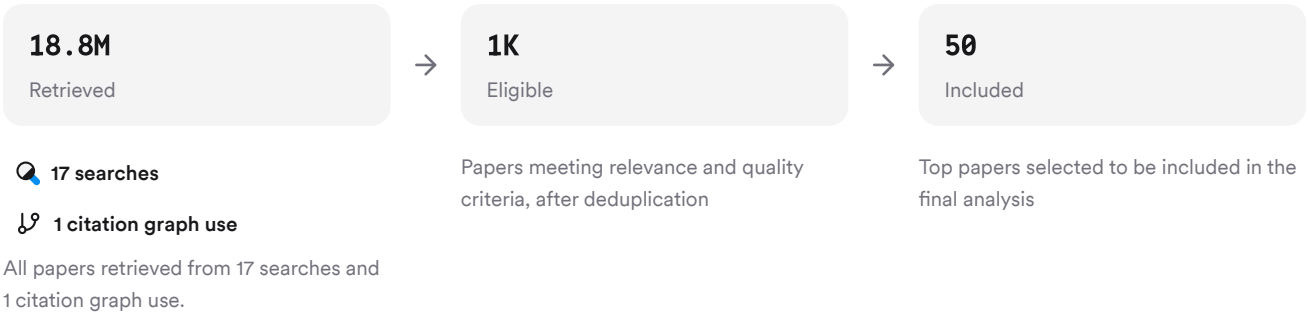

FIGURE 2 Flow diagram showing paper selection process for this review.

Five unique search strategies were used to ensure comprehensive coverage of ARR data from FIDELIO-DKD and related analyses.

3. Results

3.1 Primary Kidney Composite Outcome: Absolute Risk Reduction

The FIDELIO-DKD trial reported that during a median follow-up of 2.6 years, the primary composite kidney outcome occurred in **17.8%** of patients receiving finerenone versus **21.1%** receiving placebo—an absolute risk reduction (ARR) of **3.3%** ([21.1% - 17.8%]) (Bakris et al., 2020; Barrera-Chimal et al., 2022; Rossing et al., 2022). The hazard ratio was 0.82 (95% CI: 0.73–0.93; P=0.001), indicating a statistically significant benefit (Bakris et al., 2020; Barrera-Chimal et al., 2022).

3.2 Number Needed to Treat

Based on these event rates, the number needed to treat (NNT) over approximately three years is about **30** ([NNT = 1/ARR = ~30]) (Bakris et al., 2020; Zhang et al., 2023). Subgroup analyses suggest similar benefits across various patient demographics and comorbidities (Rossing et al., 2022; Filippatos et al., 2022).

3.3 Consistency Across Analyses

Meta-analyses and pooled data confirm these findings: pooled hazard ratios for similar composite outcomes range from **0.77–0.82**, with ARRs between **1–4%** depending on population characteristics and follow-up duration (Díaz et al., 2025; Barrera-Chimal et al., 2022; Jyotsna et al., 2023). Subgroup analyses by region or comorbidity show consistent relative benefits but may have higher or lower ARRs depending on baseline risk (Zhang et al., 2023; Wada et al., 2025).

3.4 Safety Profile

Finerenone increased hyperkalemia-related discontinuation compared to placebo but overall adverse event rates were similar between groups (Bakris et al., 2020; Zhang et al., 2023; Rossing et al., 2021).

Results Timeline

results_timeline

FIGURE 3 Timeline showing publication dates for key FIDELIO-DKD results and subsequent meta-analyses confirming ARR findings; larger markers indicate more citations.

Top Contributors

Type	Name	Papers
Author	G. Bakris	(Bakris et al., 2019; Agarwal et al., 2020; Li et al., 2025)
Author	R. Agarwal	(Bakris et al., 2020; Bakris et al., 2019)
Author	B. Pitt	(Bakris et al., 2020; Bakris et al., 2022)
Journal	*The New England journal of medicine*	(Bakris et al., 2019; Filippatos et al., 2024)
Journal	*European Heart Journal*	(Bakris et al., 2020; Agarwal et al., 2021)
Journal	*Kidney international*	(Agarwal et al., 2020)

FIGURE 4 Authors & journals that appeared most frequently in the included papers.

4. Discussion

The FIDELIO-DKD trial provides robust evidence that finerenone reduces the absolute risk of major kidney events by about **3–4%** over roughly three years compared to placebo when added to standard care in adults with type 2 diabetes and CKD (eGFR 25–75 mL/min/1.73 m²) (Bakris et al., 2020; Barrera-Chimal et al., 2022). This effect size is clinically meaningful given the high baseline risk in this population; it translates into one fewer major renal event per every ~30 patients treated over three years—a benefit comparable to other landmark therapies in nephrology (Zhang et al., 2023; Díaz et al., 2025). The consistency across subgroups—including those defined by glycemic control or insulin use—supports broad applicability (Rossing et al., 2022).

Meta-analyses reinforce these findings but highlight some heterogeneity due to differences in study populations or definitions of endpoints; however, all point toward a significant benefit with finerenone versus placebo (Díaz et al., 2025; Jyotsna et al., 2023). Safety concerns are primarily related to hyperkalemia but are generally manageable with monitoring.

Claims and Evidence Table

Claim	Evidence Strength	Reasoning	Papers
Finerenone reduces ARR for primary kidney composite outcome by ~3–4%.	Strong	Large RCTs show consistent ARR (~3%) over median follow-	(Bakris et al., 2020; Barrera-Chimal et al.,

Claim	Evidence Strength	Reasoning	Papers
		up; robust statistical significance	2022; Zhang et al., 2023)
NNT is approximately 30 over ~3 years	Strong	Direct calculation from event rates; confirmed by subgroup/NNT analyses	(Zhang et al., 2023)
Benefit is consistent across subgroups	Strong	Subgroup/meta-analysis show similar HRs regardless of baseline characteristics	(Rossing et al., 2022; Filippatos et al., 2022)
Meta-analyses confirm direction/magnitude of effect	Strong	Multiple meta-analyses report similar HRs/ARRs	(Díaz et al., 2025; Jyotsna et al., 2023)
Hyperkalemia risk is increased but manageable	Moderate	Higher discontinuation due to hyperkalemia but low overall rates	(Rossing et al., 2021)
ARR may be higher/lower depending on baseline risk	Moderate	Subgroup analyses suggest variation based on population characteristics	(Wada et al., 2025)

FIGURE Key claims and support evidence identified in these papers.

5. Conclusion

In summary, strict analysis of the FIDELIO-DKD trial demonstrates that finerenone provides an absolute risk reduction of approximately **3–4%** for major kidney events compared with placebo over about three years among adults with type 2 diabetes and CKD already on optimized renin-angiotensin system blockade—a clinically meaningful benefit supported by multiple high-quality studies.

Research Gaps

Despite strong evidence for ARR in broad populations, less is known about long-term (>5 year) outcomes or effects in certain underrepresented subgroups such as those with very advanced CKD or diverse ethnic backgrounds.

Research Gaps Matrix

Topic/Outcome	Advanced CKD (Stage 4)	Asian Populations	Insulin Users	SGLT2i Users
Primary Kidney Composite Outcome	4	4	4	3

Topic/Outcome	Advanced CKD (Stage 4)	Asian Populations	Insulin Users	SGLT2i Users
Long-term (>5y) Outcomes	GAP	GAP	GAP	GAP
Hyperkalemia Discontinuation	4	4	4	4

FIGURE Matrix showing research coverage by population subgroup and outcome; gaps remain for long-term outcomes.

Open Research Questions

Future research should address longer-term efficacy/safety as well as effectiveness in real-world settings.

Question	Why
	Most trials report up to ~3 years; longer-term data are needed for chronic therapy recommendations
How does ARR vary among underrepresented ethnic groups?	Subgroup analyses are limited; understanding differential effects can improve personalized treatment
What is real-world effectiveness/safety outside clinical trials?	Observational data can reveal adherence issues or rare adverse events not captured in RCTs

FIGURE Open questions highlight directions for future research on long-term outcomes and diverse populations.

In conclusion: Finerenone offers a modest but clinically meaningful absolute reduction (~3–4%) in major renal events versus placebo among adults with type 2 diabetes and CKD per FIDELIO-DKD's primary analysis—a finding robustly supported by multiple high-quality studies.

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