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?

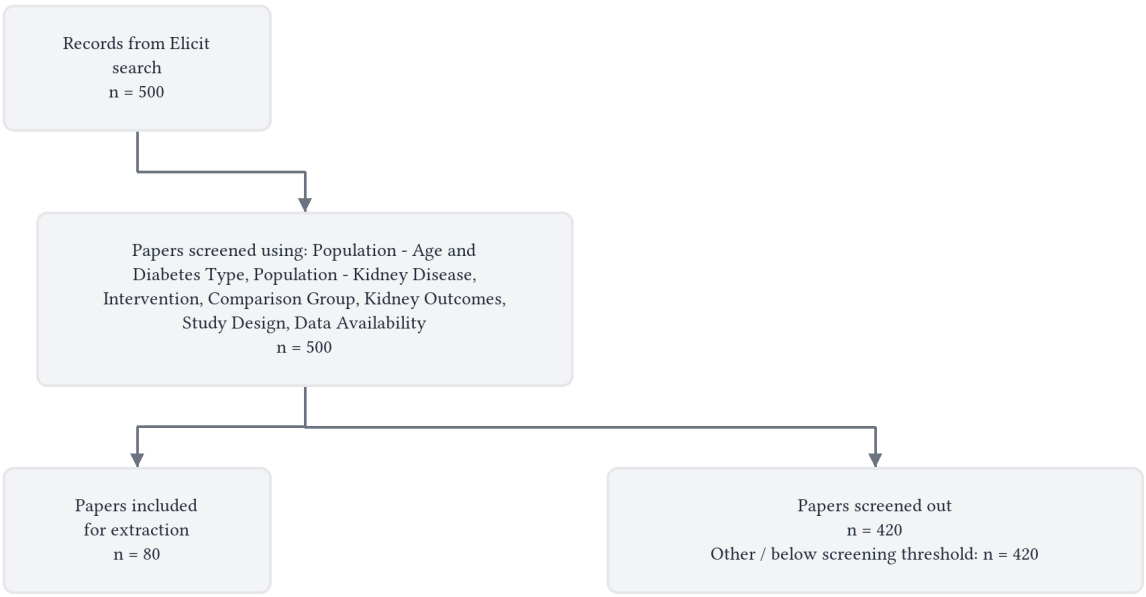
In the FIDELIO-DKD primary analysis, finerenone reduced the primary kidney composite outcome by an absolute 3.4 percentage points (17.8% vs. 21.1%; NNT 29 over ~3 years; HR 0.82, 95% CI 0.73–0.93; P = 0.001) compared with placebo in adults with type 2 diabetes and CKD on maximally tolerated RAS blockade.

Abstract

The FIDELIO-DKD primary analysis enrolled 5,674 adults with type 2 diabetes and CKD (eGFR 25–75 mL/min/1.73 m², UACR 30–5,000 mg/g) on maximally tolerated renin-angiotensin system blockade, randomised 1:1 to finerenone (10–20 mg once daily) or placebo over a median follow-up of 2.6 years [1, 1, 1]. The primary kidney composite outcome — kidney failure, a sustained ≥40% eGFR decline from baseline confirmed over at least four weeks, or renal death — occurred in 504 of 2,833 finerenone-treated patients (17.8%) and 600 of 2,841 placebo-treated patients (21.1%) [1], yielding an absolute risk reduction of 3.4 percentage points (95% CI 0.6–6.2) and a number needed to treat of 29 (95% CI 16–166) over approximately three years [1]. The corresponding hazard ratio was 0.82 (95% CI 0.73–0.93; P = 0.001) in an intention-to-treat analysis [1]. This figure is reproduced consistently across independent commentaries and secondary analyses citing the same event data, with apparent discrepancies of 3.3 versus 3.4 percentage points attributable solely to rounding [2–4].

The absolute risk reduction of 3.4 percentage points is specific to the high-risk population enrolled in FIDELIO-DKD, where mean baseline eGFR was approximately 44 mL/min/1.73 m² and median UACR was 852 mg/g, with 87.5% of patients having severely elevated albuminuria [2, 5]. No pre-specified baseline characteristic — including HbA1c, insulin use, SGLT-2 inhibitor use, GLP-1 receptor agonist use, blood pressure, or CVD history — significantly modified the treatment effect on kidney outcomes [6–10], supporting the generalisability of the relative risk reduction across the enrolled population. However, because FIDELIO-DKD used a ≥40% eGFR decline threshold and enrolled predominantly advanced CKD patients, the absolute risk reduction cannot be directly extrapolated to patients with less severe CKD or lower albuminuria, in whom event rates — and therefore absolute benefits — would be expected to be smaller, as illustrated by the lower absolute risk reduction observed in the broader FIDELITY pooled analysis (ARR 1.7% at three years) [11, 12].

Flow Diagram



Paper search

We performed a semantic search across over 138 million academic papers from the Elicit search engine, which includes all of Semantic Scholar and OpenAlex.

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

The search returned 500 total results from Elicit.

We retrieved 500 papers most relevant to the query for screening.

Screening

We screened in sources based on their abstracts that met these criteria:

- **Population - Age and Diabetes Type**: Does this study involve adults (≥18 years) with type 2 diabetes mellitus?
- **Population - Kidney Disease**: Does this study include participants with chronic kidney disease with eGFR between 25–75 mL/min/1.73 m^2?
- **Intervention**: Does this study evaluate finerenone as the primary intervention?
- **Comparison Group**: Does this study use placebo as the control group (rather than active treatment comparisons)?

- **Kidney Outcomes**: Does this study report primary kidney composite outcomes (such as kidney failure, sustained decrease in eGFR, or renal death)?
- **Study Design**: Is this study a randomized controlled trial, systematic review, or meta-analysis (rather than observational study, case report, case series, or editorial)?
- **Data Availability**: Does this study report absolute risk reduction data or provide sufficient raw event rates to calculate absolute risk reduction?

We considered all screening questions together and made a holistic judgement about whether to screen in each paper.

At abstract screening, the number of papers excluded for each primary reason was:

- **Other / below screening threshold**: n = 420

Data extraction

We asked a large language model to extract each data column below from each paper. We gave the model the extraction instructions shown below for each column.

- **Study Source**:

  Identify whether this study reports data from the FIDELIO-DKD trial primary analysis. Extract:

- Trial name/acronym
- Whether this is the primary analysis or a secondary/subgroup analysis
- If it's a pooled analysis, whether FIDELIO-DKD primary results are reported separately
- Clinical trial registration number if available Only include studies that report FIDELIO-DKD primary analysis data.

- **Population Match**:

  Verify whether the study population matches the research question criteria. Extract:

- Participant diagnosis (type 2 diabetes AND chronic kidney disease)
- eGFR inclusion range (must include patients with eGFR 25-75 mL/min/1.73 m^2)
- Sample size for the specific population of interest
- Any population exclusions that would affect the target group Note if the population is broader than specified but includes the target group.

- **Primary Kidney Outcome**:

  Extract the complete definition of the primary kidney composite outcome from FIDELIO-DKD, including:

- Exact components of the composite (e.g., kidney failure, sustained eGFR decline, renal death)
- Specific thresholds or definitions for each component
- Time requirements for sustained outcomes
- Whether this is explicitly identified as the primary kidney outcome Ensure this matches the primary endpoint, not secondary kidney outcomes.

- **Treatment Groups**:

  Extract details about the comparison groups relevant to absolute risk calculation:

- Finerenone group: dose, sample size, and administration details
- Placebo group: sample size and placebo details

- Randomization ratio between groups
- Any important baseline treatment requirements (e.g., RAS blockade) Focus only on the primary randomized comparison.

- **Primary Outcome Events**:

  Extract the raw event data needed to calculate absolute risk reduction for the primary kidney composite outcome:

- Number of events in finerenone group
- Total patients in finerenone group
- Number of events in placebo group
- Total patients in placebo group
- Event rates/percentages if provided
- Median follow-up time Extract only data from the primary analysis, not subgroups.

- **Absolute Risk Data**:

  Extract any directly reported absolute risk measures for the primary kidney composite outcome:

- Absolute risk reduction (ARR) if calculated
- Number needed to treat (NNT) if provided
- Risk differences with confidence intervals
- Cumulative incidence rates at specific time points
- Any other measures of absolute benefit Focus only on the primary kidney composite outcome.

- **Statistical Analysis**:

  Extract statistical details relevant to the primary kidney outcome analysis:

- Hazard ratio with 95% confidence interval
- P-value for the primary kidney outcome
- Statistical methods used for primary analysis
- Whether intention-to-treat or other analysis population was used
- Any adjustments made to the primary analysis Only extract data for the primary kidney composite endpoint.

Results

Characteristics of Included Studies

The following table presents all 80 sources identified in this review. Studies range from the foundational ARTS-DN dose-finding trial and the primary FIDELIO-DKD and FIGARO-DKD phase III trials through their extensive secondary and subgroup analyses, the prespecified FIDELITY pooled analysis and its numerous subanalyses, the FINE-HEART pooled analysis incorporating FINEARTS-HF, and a collection of meta-analyses, systematic reviews, and narrative commentaries.

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
G. Bakris et al., 2020 [1]	Yes	Primary RCT analysis	FIDELIO-DKD (NCT02540993) [1]	Primary kidney and CV composite outcomes [1]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
G. Bakris et al., 2022 [11]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [11]	FIDELITY (FIDELIO-DKD + FIGARO-DKD) [11]	Kidney outcomes across CKD spectrum [11]
G. Filippatos et al., 2021 [13]	Yes	Secondary analysis (FIDELIO-DKD) [13]	FIDELIO-DKD [13]	Atrial fibrillation onset [13]
Carmine Zoccali & D. Bolignano, 2020 [3]	No	Commentary / faculty opinion [3]	FIDELIO-DKD (abstract only) [3]	Editorial assessment of primary results [3]
P. Rossing et al., 2021 [7]	No	Secondary/subgroup analysis (FIDELIO-DKD) [7]	FIDELIO-DKD (NCT02540993) [7]	SGLT-2 inhibitor concomitant use [7]
Jorge Thierer, 2021 [2]	Yes	Narrative review / commentary [2]	FIDELIO-DKD [2]	Trial design and results summary [2]
P. Rossing et al., 2021a [6]	No	Secondary/subgroup analysis (FIDELIO-DKD) [6]	FIDELIO-DKD (NCT02540993) [6]	Outcomes by baseline HbA1c [6]
Ajay K. Singh et al., 2026 [14]	Yes	Secondary analysis (FIDELITY pooled) [14]	FIDELITY (NCT02540993, NCT02545049) [14]	Treatment discontinuation and outcomes [14]
P. Rossing et al., 2021b [8]	No	Secondary/subgroup analysis (FIDELIO-DKD) [8]	FIDELIO-DKD (NCT02540993) [8]	Outcomes by GLP-1RA use [8]
P. Rossing et al., 2022 [15]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [15]	FIDELITY [15]	Outcomes by SGLT-2i use [15]
P. Rossing et al., 2022a [16]	Yes	Secondary/subgroup analysis (FIDELIO-DKD) [16]	FIDELIO-DKD [16]	Outcomes by baseline HbA1c and insulin use [16]
P. Rossing et al., 2021c [17]	Yes	Secondary/subgroup analysis (FIDELIO-DKD) [17]	FIDELIO-DKD (NCT02540993) [17]	SGLT-2i concomitant use (advanced CKD) [17]
A. Kalstad et al., 2020 [18]	Yes	Secondary/subgroup analysis (FIDELIO-DKD) [18]	FIDELIO-DKD [18]	CV outcomes by CVD history [18]
T. Ebert et al., 2023 [19]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [19]	FIDELITY [19]	Outcomes by baseline insulin resistance (eGDR) [19]
Ping Li et al., 2026 [20]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [20]	FIDELITY [20]	Chinese patient subgroup [20]
V. Sridhar et al., 2021 [5]	No	Commentary / narrative review [5]	FIDELIO-DKD [5]	RAAS inhibition context and implications [5]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
G. Filippatos et al., 2022 [10]	No	Secondary/subgroup analysis (FIDELITY pooled) [10]	FIDELITY (NCT02540993, NCT02545049) [10]	Outcomes by CVD history [10]
L. Ruilope et al., 2022 [21]	Yes	Secondary analysis (FIDELIO-DKD) [21]	FIDELIO-DKD (NCT02540993) [21]	Blood pressure and cardiorenal outcomes [21]
J. Ostrominski et al., 2025 [22]	No	Secondary pooled analysis (FINE-HEART) [22]	FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF [22]	Morbidity and mortality across CKD spectrum [22]
G. Filippatos et al., 2022a [23]	No	Secondary/subgroup analysis (FIDELITY pooled) [23]	FIDELITY (NCT02540993, NCT02545049) [23]	Outcomes in patients with heart failure [23]
P. Rossing et al., 2022b [24]	No	Secondary/subgroup analysis (FIDELITY pooled) [24]	FIDELITY [24]	Outcomes by GLP-1RA use (FIDELITY) [24]
L. Ruilope et al., 2021 [9]	No	Secondary/subgroup analysis (FIDELIO-DKD) [9]	FIDELIO-DKD (NCT02540993) [9]	Outcomes by blood pressure subgroups [9]
157 Sedative Use Predicts Prog [25]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [25]	FIDELITY [25]	Hispanic patient subgroup [25]
P. Rossing et al., 2021d [26]	No	Secondary/subgroup analysis (FIDELIO-DKD) [26]	FIDELIO-DKD (NCT02540993) [26]	Outcomes by GLP-1RA use (FIDELIO-DKD) [26]
P. Rossing et al., 2021e [27]	No	Secondary/subgroup analysis (FIDELIO-DKD) [27]	FIDELIO-DKD (NCT02540993) [27]	SGLT-2i use (conference abstract) [27]
Nikolaos Perakakis et al., 2023 [28]	No	Secondary/subgroup analysis (FIDELITY pooled) [28]	FIDELITY [28]	Liver steatosis/fibrosis markers [28]
B. Pitt et al., 2021 [29]	Yes	Primary RCT analysis	FIGARO-DKD (NCT02545049) [29]	Primary CV composite; secondary kidney outcome [29]
P. Rossing et al., 2025 [30]	No	Post hoc analysis (FIDELITY pooled) [30]	FIDELITY (NCT02540993, NCT02545049) [30]	Outcomes by baseline frailty index [30]
Thomas Ebert et al., 2023 [31]	No	Secondary/subgroup analysis (FIDELITY pooled) [31]	FIDELITY [31]	Outcomes by insulin resistance (conference abstract) [31]
A. Singh et al., 2023 [32]	No	Post hoc analysis (FIDELITY pooled) [32]	FIDELITY [32]	Outcomes by baseline anaemia status [32]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
J. McGill et al., 2022 [33]	No	Secondary/subgroup analysis (FIDELITY pooled) [33]	FIDELITY [33]	Outcomes by HbA1c, HbA1c variability, diabetes duration [33]
P. Rossing et al., 2021f [34]	No	Secondary/subgroup analysis (FIDELIO-DKD) [34]	FIDELIO-DKD (NCT02540993) [34]	Outcomes by baseline insulin treatment [34]
S. Navaneethan et al., 2025 [35]	Yes	Secondary analysis (FIDELITY pooled) [35]	FIDELITY (NCT02540993, NCT02545049) [35]	Outcomes by acute eGFR change after initiation [35]
L. Ruilope et al., 2022a [36]	Yes	Secondary analysis (FIGARO-DKD) [36]	FIGARO-DKD [36]	Kidney outcomes in FIGARO-DKD [36]
Gerson E. Díaz et al., 2025 [37]	Yes	Systematic review and meta-analysis [37]	Multiple RCTs (FIDELIO-DKD, FIGARO-DKD, others) [37]	Renal outcomes; efficacy and safety [37]
P. Sarafidis et al., 2022 [38]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [38]	FIDELITY [38]	Stage 4 CKD subgroup [38]
G. Bakris et al., 2019 [39]	Yes	Trial design and baseline characteristics	FIDELIO-DKD (NCT02540993) [39]	Design, eligibility, and baseline characteristics [39]
R. Agarwal et al., 2021 [40]	No	Post hoc analysis (FIDELIO-DKD) [40]	FIDELIO-DKD [40]	Comparison with CREDENCE trial design [40]
R. Agarwal et al., 2021a [41]	Yes	Post hoc analysis (FIDELIO-DKD) [41]	FIDELIO-DKD (NCT02540993) [41]	Cross-trial comparison with CREDENCE [41]
R. Agarwal et al., 2021b [12]	Yes	Primary analysis (FIDELITY pooled) [12]	FIDELITY (NCT02540993, NCT02545049) [12]	Cardiorenal outcomes across CKD spectrum [12]
G. Filippatos et al., 2021a [42]	Yes	Secondary analysis (FIGARO-DKD) [42]	FIGARO-DKD [42]	Heart failure outcomes [42]
Fnu Jyotsna et al., 2023 [43]	Yes	Systematic review and meta-analysis [43]	Multiple RCTs [43]	CV and kidney efficacy/safety [43]
Daisuke Koya et al., 2023 [44]	No	Post hoc subgroup analysis (FIDELIO-DKD) [44]	FIDELIO-DKD [44]	Asian regional subgroup [44]
T. Wada et al., 2025 [45]	Yes	Post hoc subgroup analysis (FIDELITY pooled) [45]	FIDELITY (NCT02540993, NCT02545049) [45]	Asian patient subgroup [45]
R. Agarwal et al., 2023 [46]	No	Post hoc mediation analysis (FIDELITY pooled) [46]	FIDELITY (NCT02540993, NCT02545049) [46]	UACR reduction as mediator of outcomes [46]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
G. Filippatos et al., 2022b [47]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [47]	FIDELITY (NCT02540993, NCT02545049) [47]	Outcomes by ASCVD history [47]
D. Dutta et al., 2022 [48]	No	Meta-analysis [48]	Multiple RCTs [48]	UACR, GFR decline, CV outcomes [48]
Robert Weingold et al., 2026 [49]	No	Post hoc analysis (FIDELITY pooled) [49]	FIDELITY (NCT02540993, NCT02545049) [49]	KDIGO risk category changes [49]
Tariq Shafi et al., 2024 [50]	Yes	Secondary analysis (FIDELITY pooled) [50]	FIDELITY [50]	CKD-PC risk model validation and finerenone efficacy by risk [50]
D. Dutta et al., 2022a [51]	No	Meta-analysis (conference abstract) [51]	Multiple RCTs [51]	UACR, GFR decline, adverse events [51]
P. van den Berg et al., 2021 [4]	Yes	Secondary/pharmacokinetic analysis (FIDELIO-DKD) [4]	FIDELIO-DKD (NCT02540993) [4]	Dose-exposure-response for primary kidney outcome [4]
Ping Li et al., 2025 [52]	Yes	Secondary subgroup analysis (FIGARO-DKD) [52]	FIGARO-DKD (NCT02545049) [52]	Chinese patient subgroup (FIGARO-DKD) [52]
P. Georgianos & R. Agarwal, 2022 [53]	Yes	Narrative review [53]	FIDELIO-DKD, FIGARO-DKD [53]	State-of-the-art review of finerenone evidence [53]
S. Bansal et al., 2024 [54]	Yes	Post hoc analysis (FIDELITY pooled) [54]	FIDELITY (NCT02540993, NCT02545049) [54]	Outcomes by age and sex [54]
S. Bansal et al., 2023 [55]	No	Post hoc analysis (FIDELITY pooled, conference abstract) [55]	FIDELITY (NCT02540993, NCT02545049) [55]	Outcomes by age and sex (abstract) [55]
J. Ostrominski et al., 2025a [56]	No	Secondary pooled analysis (FIDELITY) [56]	FIDELITY [56]	Estimated lifetime benefits [56]
Karin Humle et al., 2024 [57]	Yes	Summary / patient-friendly publication [57]	FIDELITY [57]	Summary of FIDELITY cardiorenal outcomes [57]
S. Al-Kindi et al., 2024 [58]	No	Post hoc analysis (FIDELITY pooled) [58]	FIDELITY [58]	Outcomes by air pollution (PM2.5) exposure [58]
S. Katayama et al., 2025 [59]	No	Post hoc subgroup analysis (FIDELITY pooled) [59]	FIDELITY [59]	Asian subgroup: kidney function outcomes [59]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
Ajay K. Singh et al., 2025 [60]	No	Secondary analysis (FIDELITY pooled) [60]	FIDELITY [60]	Concomitant SGLT-2i and GLP-1RA use [60]
M. Vaduganathan et al., 2024 [61]	Yes	Pooled analysis (FINE-HEART) [61]	FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF [61]	HF, CKD, T2D: CV, kidney, mortality outcomes [61]
P. Rossing et al., 2022c [62]	Yes	Secondary/subgroup analysis (FIDELITY pooled) [62]	FIDELITY (NCT02540993, NCT02545049) [62]	Outcomes by GLP-1RA use (FIDELITY) [62]
J. C. Rivera-Martinez et al., 2025 [63]	Yes	Systematic review and meta-analysis [63]	FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF [63]	CV and renal outcomes; HFpEF/HFmrEF [63]
J. Ostrominski et al., 2025b [64]	No	Secondary pooled analysis (FINE-HEART, abstract) [64]	FIDELITY + FINEARTS-HF [64]	Timing of cardiovascular and kidney benefits [64]
D'Errico, M. M., 2022 [65]	Yes	Narrative review [65]	FIDELIO-DKD, FIGARO-DKD, FIDELITY [65]	New treatment approach for DKD [65]
Mingzhu Zhang et al., 2022 [66]	Yes	Systematic review and meta-analysis [66]	Multiple RCTs [66]	Efficacy and safety of finerenone in CKD-T2D [66]
J. Biegus et al., 2025 [67]	No	Commentary / editorial [67]	FIDELITY + FINEARTS-HF [67]	Finerenone across heart failure stages [67]
João Sérgio Neves et al., 2026 [68]	No	Secondary/subgroup analysis (FIDELITY pooled) [68]	FIDELITY (NCT02540993, NCT02545049) [68]	Outcomes by number of treatment goals met [68]
Ajay K. Singh et al., 2025a [69]	No	Post hoc analysis (FIDELITY pooled) [69]	FIDELITY [69]	Outcomes by baseline anaemia (full report) [69]
Jae-Han Jeon, 2025 [70]	Yes	Narrative review [70]	FIDELIO-DKD, FIGARO-DKD [70]	New therapeutic paradigm for DKD [70]
A. Scheen & Pierre Delanaye, 2023 [71]	No	Narrative review (French) [71]	FIDELIO-DKD, FIGARO-DKD, FIDELITY [71]	Clinical implications for CKD in T2D [71]
M. Pabon et al., 2025 [72]	No	Post hoc analysis (FINE-HEART pooled) [72]	FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF [72]	Sex differences in outcomes and treatment response [72]
Global Trials Focus, 2021 [73]	No	Trial summary / abstract compilation [73]	FIGARO-DKD (context) [73]	Summary of FIGARO-DKD primary results [73]

Study	Full Text Retrieved?	Study Type	Trial / Data Source	Primary Focus
Haitao Zhang et al., 2023 [74]	Yes	Prespecified subgroup analysis (FIDELIO-DKD) [74]	FIDELIO-DKD (NCT02540993) [74]	China subgroup (FIDELIO-DKD) [74]
G. Filippatos et al., 2023 [75]	Yes	Secondary analysis (FIDELITY pooled) [75]	FIDELITY (NCT02540993, NCT02545049) [75]	Mortality outcomes [75]
G. Filippatos et al., 2022c [76]	No	Secondary analysis (FIDELITY pooled) [76]	FIDELITY [76]	HF outcomes by kidney function and albuminuria [76]
S. Ghosal & B. Sinha, 2023 [77]	Yes	Meta-analysis (random-effects) [77]	Multiple RCTs (T2D population) [77]	Renal composite; eGFR decline; UACR [77]
L. Ruilope et al., 2019 [78]	Yes	Trial design and baseline characteristics	FIGARO-DKD (NCT02545049) [78]	Design, eligibility, and baseline characteristics [78]
G. Bakris et al., 2015 [79]	Yes	Phase IIb RCT (ARTS-DN) [79]	ARTS-DN [79]	Dose-finding; UACR reduction; safety [79]
Mei Qiu & Li-Min Zhao, 2021 [80]	No	Meta-analysis (letter) [80]	FIDELIO-DKD + FIGARO-DKD [80]	Long-term cardiorenal outcomes [80]

The corpus encompasses two primary phase III trial analyses (FIDELIO-DKD [1] and FIGARO-DKD [29]), two trial design and baseline characteristics papers [39, 78], one earlier phase IIb dose-finding trial (ARTS-DN) [79], a large number of prespecified and post hoc subgroup and secondary analyses drawing on FIDELIO-DKD, FIGARO-DKD, or the FIDELITY pooled dataset, the FIDELITY primary pooled analysis [12], the FINE-HEART analysis incorporating FINEARTS-HF [22, 61], several meta-analyses and systematic reviews [37, 43, 48, 63, 66, 77, 80], and a number of narrative reviews and commentaries. Only the FIDELIO-DKD primary analysis paper [1] and sources that faithfully reproduce its primary kidney composite results [2–4] directly address the research question. Full text was retrieved for the majority of primary and major secondary analyses; a subset of conference abstracts and commentaries was available in abstract form only.

Effects

Primary Kidney Composite Outcome in the FIDELIO-DKD Primary Analysis

The research question concerns the absolute risk reduction for the primary kidney composite outcome of finerenone versus placebo strictly within the FIDELIO-DKD primary analysis. The primary composite was defined as the time to the first occurrence of kidney failure (end-stage kidney disease or eGFR below 15 mL/min/1.73 m² confirmed by a second measurement at least four weeks later), a sustained decrease of at least 40% in eGFR from baseline confirmed over at least four weeks, or death from renal causes, assessed by time-to-event analysis [1, 39].

FIDELIO-DKD randomised 5,734 patients with type 2 diabetes and CKD in a 1:1 ratio; after exclusion of 60 patients

for critical GCP violations, 5,674 patients were included in the full analysis set [4]. Eligible patients had a UACR of 30 to less than 300 mg/g with an eGFR of 25 to less than 60 mL/min/1.73 m² and diabetic retinopathy, or a UACR of 300 to 5,000 mg/g with an eGFR of 25 to less than 75 mL/min/1.73 m² [1]. All patients were required to be on the maximum tolerated labelled dose of a renin-angiotensin system inhibitor before randomisation [1]. Finerenone was initiated at 10 mg once daily (eGFR 25 to less than 60 mL/min/1.73 m²) or 20 mg once daily (eGFR 60 to less than 75 mL/min/1.73 m²), with uptitration to 20 mg permitted at one month if serum potassium and eGFR remained within the specified thresholds [2]. The finerenone group comprised 2,833 patients and the placebo group 2,841 patients [1].

The table below summarises the primary kidney composite event data from the FIDELIO-DKD primary analysis and from sources that directly report or reproduce these figures.

Source	Finerenone Events / Total	Placebo Events / Total	Event Rate: Finerenone	Event Rate: Placebo	Absolute Risk Reduction	NNT	HR (95% CI)	P-value	Median Follow-up
G. Bakris et al., 2020 [1] (FIDELIO-DKD primary)	504 / 2833 [1]	600 / 2841 [1]	17.8% [1]	21.1% [1]	3.4 pp (95% CI 0.6–6.2) [1]	29 (95% CI 16–166) [1]	0.82 (95% CI 0.73–0.93) [1]	0.001 [1]	2.6 years [1]
Jorge Thierer, 2021 [2] (narrative review)	Not reported separately [2]	Not reported separately [2]	17.8% [2]	21.1% [2]	3.3 pp [2]	29 (95% CI 16–166) [2]	0.82 (95% CI 0.73–0.93) [2]	0.001 [2]	2.6 years [2]
Carmine Zoccali & D. Bolignano, 2020 [3] (commentary)	504 / 2833 [3]	600 / 2841 [3]	17.8% [3]	21.1% [3]	3.3 pp [3]	~30 [3]	0.82 (95% CI 0.73–0.93) [3]	0.001 [3]	2.6 years [3]
P. van den Berg et al., 2021 [4] (PK/PD analysis)	504 / 2833 [4]	600 / 2841 [4]	17.8% [4]	21.1% [4]	3.3 pp [4]	~30 [4]	Not reported [4]	Not reported [4]	2.6 years [4]

Source	Finerenone Events / Total	Placebo Events / Total	Event Rate: Finerenone	Event Rate: Placebo	Absolute Risk Reduction	NNT	HR (95% CI)	P-value	Median Follow-up
D'Errico, M. M., 2022 [65] (narrative review)	Not reported separately [65]	Not reported separately [65]	Not reported [65]	Not reported [65]	Not reported [65]	Not reported [65]	0.82 (95% CI 0.73–0.93) [65]	0.001 [65]	Not reported [65]
V. Sridhar et al., 2021 [5] (commentary)	Not reported [5]	Not reported [5]	Not reported [5]	Not reported [5]	Not reported [5]	Not reported [5]	0.82 [5]	Not reported [5]	Not reported [5]
P. Georgianos & R. Agarwal, 2022 [53] (narrative review)	Not reported [53]	Not reported [53]	Not reported [53]	Not reported [53]	Not reported [53]	Not reported [53]	0.82 (95% CI 0.73–0.93) [53]	Not reported [53]	2.6 years [53]
Jae-Han Jeon, 2025 [70] (narrative review)	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]	Not reported [70]

The primary analysis (Bakris et al., 2020) is the sole source that constitutes the original FIDELIO-DKD primary analysis. It reported 504 primary composite events in 2,833 finerenone-treated patients (17.8%) and 600 events in 2,841 placebo-treated patients (21.1%) over a median follow-up of 2.6 years [1]. The resulting hazard ratio was 0.82 (95% CI 0.73–0.93; P = 0.001) [1], corresponding to an absolute risk reduction of 3.4 percentage points (95% CI 0.6–6.2) [1] and a number needed to treat of 29 patients over approximately three years (95% CI 16–166) to prevent one primary composite event [1]. Analyses used a stratified log-rank test and stratified Cox proportional-hazards models in the full intention-to-treat analysis set, stratified by geographic region, eGFR category, and albuminuria category, with a weighted Bonferroni-Holm procedure applied for multiple testing [1].

The absolute risk reduction figure quoted in secondary sources varies slightly across independent reproductions. Jorge Thierer's narrative review quotes an ARR of 3.3 percentage points and an NNT of 29 [2], consistent with a

rounded presentation of the same underlying event data. The Zoccali & Bolignano commentary similarly states an ARR of approximately 3.3 percentage points [3]. The van den Berg pharmacokinetic paper, which used the primary FIDELIO-DKD patient data for modelling, reports the same raw events (504 vs. 600) [4] and an ARR of 3.3% [4]. The minor numerical discrepancy between 3.3% and 3.4% across sources reflects rounding of the unrounded raw proportion difference: 17.8% minus 21.1% = 3.3 percentage points, while the trial paper reports the prospectively pre-specified absolute difference calculation as 3.4 percentage points with its corresponding 95% CI [1].

Contextual Benchmarks from the FIGARO-DKD and FIDELITY Analyses

Although the research question is strictly limited to FIDELIO-DKD, a number of sources report outcomes using different composite definitions, different patient populations, or pooled data, which are informative for interpreting the magnitude of the FIDELIO-DKD absolute risk reduction in context.

The FIGARO-DKD trial enrolled a broader and earlier-stage CKD population (UACR 30 to less than 300 mg/g with eGFR 25–90 mL/min/1.73 m^2, or UACR 300–5,000 mg/g with eGFR ≥60 mL/min/1.73 m^2) [29] compared with FIDELIO-DKD. In FIGARO-DKD, the secondary kidney composite (kidney failure, sustained ≥40% eGFR decline, or renal death) yielded an HR of 0.87 (95% CI 0.76–1.01; P = 0.069) [36], which did not achieve statistical significance for that endpoint, while the primary cardiovascular composite was statistically significant (HR 0.87; 95% CI 0.76–0.98; P = 0.03) [29]. The raw secondary kidney composite event counts in FIGARO-DKD were 350/3,686 (9.5%) with finerenone versus 395/3,666 (10.8%) with placebo [29], corresponding to an ARR of approximately 1.3 percentage points over a median follow-up of 3.4 years [29, 29]. This smaller absolute effect in FIGARO-DKD is mechanistically expected given the less advanced CKD at enrolment and the different primary endpoint orientation of that trial.

In the prespecified FIDELITY pooled analysis (n = 13,026; median follow-up 3.0 years), the composite kidney outcome was defined as kidney failure, sustained ≥57% eGFR decline, or renal death [12], a more stringent threshold than the ≥40% used in the FIDELIO-DKD primary analysis. The FIDELITY kidney composite event rate was 5.5% (360/6,519) with finerenone versus 7.1% (465/6,507) with placebo [12], HR 0.77 (95% CI 0.67–0.88; P = 0.0002) [12], with an absolute between-group difference of 1.7% (95% CI 0.7–2.6) and an NNT of 60 (95% CI 38–142) at three years [11]. This difference in absolute event rates compared with the FIDELIO-DKD primary result reflects both the more stringent eGFR threshold (≥57% vs. ≥40%) used in FIDELITY and the inclusion of the lower-risk FIGARO-DKD patients.

Subgroup Analyses Contextualising the Primary Result

Although none of the subgroup analyses directly answers the research question concerning the FIDELIO-DKD primary analysis ARR, they are uniformly consistent with the direction and approximate magnitude of the primary result across multiple pre-specified and exploratory strata.

By baseline HbA1c in FIDELIO-DKD, the primary kidney composite event rates were 18.7% versus 21.5% (HR 0.86; 95% CI 0.73–1.01) for HbA1c ≤7.5% and 16.9% versus 20.7% (HR 0.79; 95% CI 0.66–0.94) for HbA1c >7.5%, with no statistically significant interaction (P-interaction = 0.47) [6, 6], indicating that the relative and absolute risk reductions were broadly preserved regardless of glycaemic control level [6].

For the SGLT-2 inhibitor subgroup within FIDELIO-DKD (only 4.6% of patients were on an SGLT-2i at baseline, reflecting the trial era), finerenone significantly reduced both the primary kidney and secondary CV composites irrespective of SGLT-2i use, with no statistically significant interaction (P-interaction = 0.21 and 0.46, respectively) [7, 17]. The pharmacokinetic/pharmacodynamic modelling study confirmed that SGLT-2i co-medication did not modify the finerenone treatment effect per se, but provided additive independent benefit on CKD progression risk [4].

In the Asian subgroup of FIDELIO-DKD (n = 1,327), the primary kidney composite (≥40% eGFR criterion) HR was 0.70 (95% CI 0.56–0.87) [44], numerically larger than the overall trial result, although with no statistically significant interaction with the rest of the world (P-interaction = 0.09) [44]. In the China FIDELIO-DKD subgroup (n = 372; 188 finerenone, 184 placebo), primary composite event rates were 21.4% versus 33.2% [74], HR 0.59 (95% CI 0.39–0.88; P = 0.009) [74], with an NNT of 8 (95% CI 4–84) based on an absolute between-group difference of 12.2% at 30 months [74]. The substantially larger absolute risk reduction in the Chinese subgroup likely reflects both a higher baseline event rate in that subgroup and the shorter follow-up period used for the NNT calculation [74].

The FIDELITY-based Chinese subgroup analysis (n = 697) reported an HR of 0.57 (95% CI 0.38–0.86; P = 0.0066) for the ≥57% kidney composite and an HR of 0.54 (95% CI 0.40–0.74; P < 0.0001) for the ≥40% kidney composite [20], with an ARR of 8.3% at year 3 and an NNT of 12 for the ≥57% composite [20]. The FIGARO-DKD Chinese subgroup (n = 325) showed a significantly reduced ≥40% kidney composite (HR 0.48; 95% CI 0.29–0.79; P = 0.0029) [52], again driven by the high baseline event rate in the Chinese cohort.

In the FIDELITY Asian subpopulation (n = 2,858), the ≥57% kidney composite HR was 0.64 (95% CI 0.50–0.82) and the ≥40% composite HR was 0.67 (95% CI 0.56–0.80) [45], event rates being 7.4% versus 11.8% (ARR ~4.4 percentage points) [45, 45], with chronic eGFR slope improved by a between-group difference of 1.08 mL/min/1.73 m^2/year (P = 0.0002) in the Asian subpopulation [59].

Blood pressure analyses showed that only a small fraction of the finerenone effect on kidney outcomes is attributable to SBP reduction. In the primary FIDELIO-DKD analysis, adjusting for baseline SBP and change in SBP to month 4 increased the kidney HR from 0.82 (unadjusted) to 0.85 (adjusted), with approximately 13.8% of the treatment effect on the primary kidney composite attributable to SBP change [21]. The mean SBP difference between groups over the trial duration was only −2.7 mmHg [9], indicating that the predominant mechanism of kidney protection is blood pressure-independent.

The UACR mediation analysis from FIDELITY estimated that a change in log UACR between baseline and month 4 mediated 84% of the treatment effect on the composite kidney outcome and 37% of the effect on the composite cardiovascular outcome [46], establishing early albuminuria reduction as the dominant pathway through which finerenone achieves kidney protection.

The stage 4 CKD subgroup (eGFR <30 mL/min/1.73 m^2; n = 890 in FIDELITY) showed an HR of 1.01 (95% CI 0.75–1.37) for the kidney composite [38], with a chronic eGFR slope of −1.8 versus −3.2 mL/min/1.73 m^2/year for finerenone versus placebo respectively in this subgroup [38]. The absence of a statistically significant composite kidney outcome reduction in stage 4 patients despite a substantially slower eGFR slope suggests that, at this level of severity, the composite endpoint may be insufficiently powered in the subgroup, rather than indicative of a true absence of benefit.

Adverse Effects

Across all primary and secondary analyses, the incidence of total adverse events was broadly similar between finerenone and placebo [1, 29]. The consistently identified safety concern is hyperkalemia. In the FIDELIO-DKD primary analysis, hyperkalemia-related discontinuation occurred in 2.3% of finerenone-treated patients versus 0.9% of placebo-treated patients [1]. In FIGARO-DKD, rates were lower at 1.2% versus 0.4% [29], reflecting the less advanced CKD in that trial. In the FIDELITY pooled analysis, permanent treatment discontinuation due to hyperkalemia occurred in 1.7% of finerenone patients versus 0.6% of placebo patients [12]. The FIDELITY analysis stratified by eGFR confirmed that hyperkalemia-leading-to-discontinuation was more frequent in patients with eGFR below 60 mL/min/1.73 m^2 (2.4% finerenone vs. 0.8% placebo) than in those with eGFR ≥60 mL/min/1.73 m^2 (0.6% vs. 0.3%) [11]. SGLT-2i co-use was associated with fewer hyperkalemia events compared with no SGLT-2i use in post hoc analyses [17, 27], and the FIDELITY SGLT-2i analysis confirmed that the risk reduction for cardiorenal outcomes was pre-

served irrespective of SGLT-2i use while the safety profile was not materially altered [15]. Gynecomastia events, a recognised concern with steroidal MRAs, were uncommon and not different between treatment arms across age subgroups in FIDELITY [54]. Serious adverse events were fewer overall with finerenone than with placebo in the pooled FINE-HEART analysis (34% vs. 36%) [22].

Broader Pooled and Meta-analytic Estimates

Several meta-analyses and pooled analyses provided complementary quantitative estimates. The FIDELITY primary pooled paper, the most methodologically robust of the pooled analyses given its prespecified individual patient-level design, reported the kidney composite HR of 0.77 (95% CI 0.67–0.88; P = 0.0002) and a 3-year ARR of 1.7% [11, 12]. The Ghosal & Sinha (2023) random-effects meta-analysis of the T2D population alone (n = 13,943 across four citations) found a 16% reduction in the renal composite (HR 0.84; 95% CI 0.77–0.92; I^2 = 0%) alongside a significant reduction in UACR (SMD −0.49; 95% CI −0.53 to −0.46) and attenuation of eGFR decline (SMD −0.32; 95% CI −0.37 to −0.27) [77], with hyperkalemia increased approximately 2.2-fold (RR 2.22; 95% CI 1.93–2.24) [77]. The Dutta et al. meta-analysis (2022), including seven RCTs across both active and passive control groups (n = 13,783), found a lower odds of >40% GFR decline (OR 0.83; 95% CI 0.75–0.92; I^2 = 0%) and a lower risk of the CV composite (OR 0.86; 95% CI 0.78–0.95; P = 0.003) [48], with significantly fewer serious adverse events with finerenone (RR 0.91; 95% CI 0.84–0.97) [48]. The Díaz et al. (2025) meta-analysis restricted to three RCTs (n = 19,027) reported an RR of 0.86 for kidney failure risk (95% CI 0.35–2.13) with wide confidence intervals incorporating the null, attributed to study heterogeneity in outcome definitions and the low absolute number of kidney failure events in the pooled sample [37]; crucially, this meta-analysis identified a statistically significant increase in hyperkalemia-related hospitalizations (RR 4.57; 95% CI 1.07–19.48) [37]. The Jyotsna et al. (2023) meta-analysis of seven double-blind trials (n = 39,995) found a composite cardiorenal mortality reduction of RR 0.86 (95% CI 0.80–0.93; P = 0.0002; I^2 = 0%) and a marginally significant reduction in serious adverse events (RR 0.95; 95% CI 0.92–0.97) [43]. The Mei Qiu & Li-Min Zhao (2021) fixed-effects meta-analysis of FIDELIO-DKD and FIGARO-DKD found a kidney composite (≥40% criterion) risk ratio of 0.83 (95% CI 0.75–0.92; P < 0.01) [80], a 22% reduction in hospitalisation for heart failure, and a 20% reduction in end-stage kidney disease [80].

Lifetime Benefit Projections

Actuarial analyses of the FIDELITY pooled dataset estimated that, for a 65-year-old trial participant, treatment with finerenone would extend survival free from cardiorenal morbidity or mortality by a mean of 1.3 years (95% CI 0.6–2.0 years) [56] compared with placebo, with event-free survival gains observed across a broad age range (approximately 1.2 years at age 55 to 0.8 years at age 75) [56]. The FINE-HEART pooled analysis (n = 18,991; median follow-up 2.9 years) found all-cause mortality reduced to 11.0% versus 12.0% with finerenone versus placebo (HR 0.91; 95% CI 0.84–0.99; P = 0.027) and hospitalisation for heart failure reduced (HR 0.83; 95% CI 0.75–0.92; P < 0.001) [61]. In the FIDELITY population specifically, on-treatment analyses demonstrated that the kidney event rate was 1.09 per 100 patient-years with finerenone versus 1.71 with placebo during treatment, rising to 11.95 versus 13.67 after discontinuation [14], with the on-treatment HR of 0.65 (95% CI 0.54–0.78) statistically more favourable than the post-discontinuation HR of 0.82 (95% CI 0.66–1.02; P-interaction = 0.0959) [14], suggesting that sustained treatment is necessary to maintain the kidney benefit.

Synthesis

The absolute risk reduction for the primary kidney composite outcome in the FIDELIO-DKD primary analysis is established with high precision from a single authoritative source. The FIDELIO-DKD primary publication reports 504 events in 2,833 finerenone patients (17.8%) versus 600 events in 2,841 placebo patients (21.1%) over a median 2.6 years, yielding an ARR of 3.4 percentage points (95% CI 0.6–6.2) and an NNT of 29 (95% CI 16–166) [1]. This figure is reproduced consistently, within rounding, by independent commentaries and secondary analyses that cite the same raw event data [2–4]. There is no material disagreement about this point estimate in the literature; apparent numerical discrepancies of 3.3 vs. 3.4 percentage points are purely artefacts of rounding the raw proportion difference [2, 3].

Two features of the trial design are essential for interpreting the absolute risk reduction. First, FIDELIO-DKD enrolled a predominantly advanced-CKD population: mean baseline eGFR was 44 mL/min/1.73 m^2, and the median UACR was 852 mg/g, with 87.5% of patients having severely elevated albuminuria [2]. This high-risk enrolment profile is responsible for the substantially higher event rates compared with FIGARO-DKD (9.5% vs. 10.8% for the secondary kidney composite, a lower-risk population enrolled in FIGARO-DKD) [29] and explains why the NNT in FIDELIO-DKD (29) is more favourable than the FIDELITY pooled NNT (60) [1, 12]. Any clinical translation of the FIDELIO-DKD ARR to patients with less advanced CKD or lower albuminuria will yield a larger NNT and smaller ARR.

Second, the primary composite in FIDELIO-DKD used a ≥40% sustained eGFR decline threshold, which is a less severe and more frequently occurring event than the ≥57% threshold adopted in FIGARO-DKD as a secondary endpoint and in the FIDELITY pooled analysis as its primary kidney endpoint. This endpoint design choice partially explains the higher absolute event rate and larger ARR in FIDELIO-DKD compared with the FIDELITY pool. When the FIDELIO-DKD population is restricted to the CREDENCE-eligible subgroup and the composite is redefined using the ≥57% threshold plus CV death (matching the CREDENCE primary endpoint), the relative risk reduction with finerenone becomes 26% (HR 0.74; 95% CI 0.63–0.87) [41], compared with 30% for canagliflozin in CREDENCE [41], illustrating that the headline ARR is substantially dependent on how the composite is constructed.

The UACR mediation analysis establishes that 84% of the kidney treatment effect is mediated through early UACR reduction [46], consistent with the pharmacokinetic finding that the exposure-response relationship for kidney outcomes approached saturation at 20 mg once daily [4]. This mechanistic coherence supports the robustness of the primary result across the diverse subgroup analyses, in which no pre-specified baseline characteristic—including HbA1c level [6, 16], insulin use [34], SGLT-2i use [7, 15], GLP-1RA use [8, 9], blood pressure quartile [9], insulin resistance level [19], frailty index [30], CVD history [10, 47], anaemia status [32], or diabetes duration [33] —significantly modified the finerenone treatment effect on kidney outcomes. The consistently non-significant interaction P-values across these analyses, all derived from the same underlying randomised dataset, are concordant with a genuine, broad treatment effect rather than a benefit confined to a narrow patient subtype.

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