Assessing the generalizability of finerenone trial criteria to a British Columbia population with type 2 diabetes in a community endocrinology setting

Considering the substantial health care burden of end-stage renal disease, integrating therapies like finerenone that reduce renal risk is essential, especially in populations with a higher prevalence of pre-existing cardiovascular disease.

Aria Jazdarehee, MD, David Shu, MD, FRCPC, Akshay Jain, MD, FRCPC

ABSTRACT

Background: Finerenone improves renal and cardiovascular outcomes in chronic kidney disease and type 2 diabetes, as demonstrated in the FIDELIO-DKD and FIGARO-DKD trials. The use of finerenone has recently been incorporated into Canadian guidelines. Previous studies have established the broad applicability of the FIDELIO-DKD and FIGARO-DKD inclusion criteria to international populations. We assessed whether these criteria similarly apply to an outpatient population at an endocrinology clinic in British Columbia.

Methods: We applied the FIDELIO-DKD and FIGARO-DKD enrollment criteria to determine the proportion of patients in a community endocrinology practice who would meet trial-based eligibility criteria.

Results: Of 369 individuals with type 2 diabetes who were receiving standard of care treatment, 99 (27%) met FIDELIO-DKD or FIGARO-DKD enrollment criteria for residual cardiorenal risk. Their population characteristics were comparable to those in the inclusion trials: 65% male, mean age 71 years, A1c 7.9%, glomerular filtration rate 58 mL/min/1.73 m^2, urine albumin:creatinine ratio 32.2 mg/mmol, and systolic blood pressure 135 mm Hg. Our study population had a higher prevalence of prior myocardial infarction than those in the FIDELIO-DKD and FIGARO-DKD trials (26.2% vs 13.3% and 7.4%, respectively; $P < .05$).

Conclusions: In our study, 27% of individuals with type 2 diabetes had residual renal risk despite optimization. The higher proportion of patients in our study population who had pre-existing cardiovascular disease emphasizes the need for effective cardiorenal risk reduction among this population.

Dr Jazdarehee is an endocrinology and metabolism subspecialty resident at the University of Alberta. He completed his medical school training at the University of British Columbia. Dr Shu is an endocrinologist in New Westminster and a clinical assistant professor with the UBC Division of Endocrinology. Dr Jain is an endocrinologist at TLC Diabetes and Endocrinology in Surrey.

Corresponding author: Dr Aria Jazdarehee, jazdareh@ualberta.ca.

This article has been peer reviewed.

Background

Finerenone is a nonsteroidal mineralocorticoid receptor antagonist that has been shown to lower the risk of cardiovascular and renal events in people with type 2 diabetes and chronic kidney disease.[1-3] Despite evidence that finerenone reduced the risk of cardiovascular outcomes by up to 14% and renal outcomes by 23% across two phase 3 clinical trials (FIDELIO-DKD and FIGARO-DKD) and their pooled FIDELITY analysis, clinical uptake of finerenone remains low.[1-3] Given the substantial burden of cardiovascular and renal disease in patients with type 2 diabetes, we conducted a chart review in a community endocrinology practice in British Columbia to determine the proportion of patients who would meet finerenone trial criteria and potentially benefit from therapy.

Chronic kidney disease impacts up to 40% of people with type 2 diabetes, and diabetes mellitus remains the leading cause of end-stage renal disease in Canada and worldwide.[4,5] Further, renal disease is an independent risk factor for cardiovascular disease among those with diabetes, and this population is more likely to experience death from a cardiovascular event before progressing to end-stage renal disease.[6,7]

Management of chronic kidney disease in people with type 2 diabetes has classically been centred on the control of hypertension and hyperglycemia through the use of renin-angiotensin system (RAS) inhibitors and sodium-glucose transport protein 2 (SGLT2) inhibitors.[8] Despite treatment, many people develop worsening renal function, resulting in residual cardiorenal

risk, defined as the risk of progression of cardiovascular and/or renal events despite standard of care treatment.[9]

Development of cardiorenal disease has been associated with mineralocorticoid overactivation, which has resulted in the emergence of mineralocorticoid receptor antagonists in the management of chronic kidney disease associated with diabetes.[10] The steroidal mineralocorticoid receptor antagonists spironolactone and eplerenone have been shown to significantly improve proteinuria in patients with chronic kidney disease; however, long-term data, particularly for people with type 2 diabetes who are receiving standard of care treatment, are lacking.[10] Further, treatment with steroidal mineralocorticoid receptor antagonists is often limited due to side effects, including hyperkalemia and gynecomastia.[11]

Compared with steroidal mineralocorticoid receptor antagonists, finerenone has been shown to have more potent anti-inflammatory and antifibrotic effects, with a more favorable side effect profile.[2,12] Despite Health Canada's approval of finerenone in October 2022, clinical uptake has remained slow, and Canadian guidelines have incorporated finerenone only within the past year **[Table 1]**.[13] In this study, we assessed the applicability of the FIDELIO-DKD and FIGARO-DKD inclusion criteria to a sample of British Columbia's population within a community endocrinology setting. A similar study done in the United States found that 2.2 million Americans would qualify for finerenone by clinical trial criteria.[14]

Compared with steroidal mineralocorticoid receptor antagonists, finerenone has been shown to have more potent anti-inflammatory and antifibrotic effects, with a more favorable side effect profile.

Methods

We performed a retrospective study in which we applied the FIDELIO-DKD and FIGARO-DKD inclusion criteria to a representative British Columbia population with type 2 diabetes optimized on standard care in a community endocrinology setting with a total census of 811 patients with type 2 diabetes. The study designs and enrollment criteria of the FIDELIO-DKD and FIGARO-DKD trials have been previously documented.[1,2]

We performed a structured electronic medical record query to identify nonpregnant adults aged 18 years or older with type 2 diabetes who were receiving standard care, defined as the use of maximum tolerated doses of RAS and SGLT2 inhibitors for a minimum of 4 weeks and 3 months, respectively. This was followed by manual extraction of selected variables. The enrollment criteria of the FIDELIO-DKD and FIGARO-DKD trials were then applied to this group. Patients were considered eligible if they met the criteria for either trial. In these criteria, chronic kidney disease was defined as a urine albumin:creatinine ratio (UACR) of 30 to 300 mg/g with a glomerular filtration rate (GFR) of 25 to 60 mL/min/1.73 m^2 or a UACR of 300 to 5000 mg/g with a GFR of 25 to 75 mL/min/1.73 m^2 as per the FIDELIO-DKD trial or a UACR of 30 to 300 mg/g with a GFR of 25 to 90 mL/min/1.73 m^2 as per the FIGARO-DKD trial.[1,2]

In accordance with the two trials, we excluded patients with nondiabetic chronic kidney disease; A1c higher than 12%; uncontrolled hypertension with systolic blood pressure (SBP) of 170 mm Hg or higher; uncontrolled hypertension with diastolic blood pressure of 110 mm Hg or higher; hypotension with SBP of 90 mm Hg or lower; serum potassium of 4.8 mmol/L or higher; concomitant therapy with both ACE inhibitors and angiotensin receptor blockers; or concomitant therapy with eplerenone, spironolactone, any renin inhibitor, CYP3A4 inducers, or other potassium-sparing diuretics.

TABLE 1. Guideline recommendations for finerenone use in diabetic kidney disease.

Guideline	Population	Recommendation	Strength
Diabetes Canada	T2D + CKD (GFR 25–90 mL/min/1.73 m^2) with UACR 50–500 mg/mmol, on maximally tolerated RASi with serum potassium < 4.8 mmol/L	Finerenone recommended alongside potassium monitoring to reduce CKD progression and cardiovascular events.	Strong
Canadian Cardiovascular Society	T2D + CKD with high cardiovascular risk	Use of finerenone supported for cardiovascular risk reduction as an adjunct to guideline-directed therapy.	Moderate
Kidney Disease: Improving Global Outcomes (KDIGO)	T2D with GFR ≥ 25 mL/min/1.73 m^2, normal potassium, and albuminuria (UACR ≥ 30 mg/g) despite maximally tolerated RASi	Nonsteroidal MRA recommended if persistent albuminuria (UACR ≥ 30 mg/g) despite standard of care.	Grade 2A
American Diabetes Association	T2D with CKD and albuminuria (GFR ≥ 25 mL/min/1.73 m^2)	Nonsteroidal MRA recommended to reduce CKD progression and cardiovascular events. Monitor potassium 4 weeks after initiation.	Grade A

CKD = chronic kidney disease; GFR = glomerular filtration rate; MRA = mineralocorticoid receptor antagonist; RASi = renin-angiotensin system inhibitor; T2D = type 2 diabetes mellitus; UACR = urine albumin:creatinine ratio.

The demographic and clinical characteristics of our population were compared with those of the inclusion trial populations, and we assessed for statistical significance using the chi-square test.[1,2]

Results

The FIDELIO-DKD and FIGARO-DKD trial criteria were applied to 369 individuals with type 2 diabetes who were receiving standard of care treatment with RAS and SGLT2 inhibitors; 99 (27%) met trial criteria for initiation of finerenone.

The characteristics of our study and inclusion trial populations are outlined in **Table 2**. The demographic profile of our cohort that was eligible for finerenone closely resembled that of the trial populations, with 65% being male and a mean age of 71 years. Renal function parameters were also comparable, with mean GFR of 58 mL/min/1.73 m^2, median UACR of 32.2 mg/mmol, mean serum potassium of 4.58 mmol/L, and mean SBP of 135 mm Hg. In our population, 43 individuals (43%) had moderately increased albuminuria, 18 (18%) had severely increased albuminuria, and 18 (18%) had potassium levels of 5.0 mmol/L or higher. The median duration of type 2 diabetes in our population was 17 years, with a mean A1c level of 7.9%. In the population that was eligible for finerenone, 44 (44%) were being treated with a glucagon-like peptide-1 (GLP-1) receptor agonist.

In terms of complications, our study population exhibited a higher prevalence of prior myocardial infarction compared with individuals in the FIDELIO-DKD and FIGARO-DKD trials (26.2% vs 13.3% and 7.4%, respectively; $P < .05$). However, the prevalence of stroke in our cohort (12.1%) was comparable.

Despite Health Canada's approval of finerenone, its adoption into clinical practice remains slow.

In our study, the main reasons why individuals with type 2 diabetes who were receiving standard care did not meet the eligibility criteria for initiating finerenone included the absence of a UACR, suboptimal optimization with RAS or SGLT2 inhibitors, or chronic kidney disease attributed to causes other than type 2 diabetes.

Discussion

Finerenone was approved by Health Canada in October 2022, but Canadian guidelines have only recently recommended its use in reducing cardiorenal risk.[13] Despite Health Canada's approval of finerenone, its adoption into clinical practice remains slow. Similarly, the American Diabetes Association guidelines endorse a Grade A recommendation for finerenone for those with chronic kidney disease and type 2 diabetes at elevated risk.[15] A comprehensive overview of guideline recommendations for finerenone use is outlined in **Table 1**. Studies have demonstrated the broad generalizability of the FIDELIO-DKD and FIGARO-DKD trial criteria to the US population.[14] Chiu and colleagues reported that 2.2 million patients in the US who had type 2 diabetes and were on RAS therapy met initiation criteria for finerenone by at least one full trial criterion, which highlights significant potential for its clinical application.[14]

We similarly demonstrated the applicability of these trial criteria to our study population. Renal function in our participants was between that observed in the FIDELIO-DKD and FIGARO-DKD trials, with GFR that was intermediate to the advanced renal impairment in the

TABLE 2. Demographics of patients eligible for finerenone based on the FIDELIO-DKD and FIGARO-DKD inclusion trials compared with US and Canadian studies.

	FIDELIO-DKD	FIGARO-DKD	Chiu and colleagues[14] (US)	Current study (Canada)	*P* value
Age (mean, years)	65.40	64.10	67.00	70.83	—
Sex: male (%)	68.9	68.6	58.5	64.6	.896
Sex: female (%)	31.1	31.4	41.5	35.4	.896
Systolic blood pressure (mean, mm Hg)	138.1	135.8	138.2	135.3	—
Diastolic blood pressure (mean, mm Hg)	75.8	76.8	68.5	75.3	—
A1c (mean, %)	7.7	7.7	7.6	7.9	—
Glomerular filtration rate (mean, mL/min/1.73 m^2)	44.4	67.6	65.7	57.6	—
Urine albumin:creatinine ratio (median, mg/mmol)	83.3	30.2	11.0	32.2	—
Serum potassium (mean, mmol/L)	4.37	4.33	4.10	4.58	—
Myocardial infarction (%)	13.3	7.4	10.9	26.2	< .001
Stroke (%)	11.6	12.0	11.7	12.1	.490

FIDELIO-DKD trial and the milder impairment in the FIGARO-DKD trial. However, our study population differed notably from the inclusion trial populations by having a higher prevalence of background cardiac disease. This may have been due to the advanced age of our cohort compared with that of the inclusion trial cohorts, or to background SGLT2 use, which may reflect more advanced disease and a higher cardiovascular risk profile. Evidence from the FINE-HEART trial, which demonstrated reductions in heart failure hospitalizations, cardiovascular events, and all-cause mortality with finerenone, supports its potential benefit in higher-risk populations that are similar to our study cohort.[16]

Our study population included patients who were already optimized on SGLT2 inhibitors. This criterion was more restrictive compared with the inclusion trials, which required optimization only on RAS inhibitors. Additionally, nearly half of our eligible participants were also receiving GLP-1 therapy, agents that also demonstrate renal benefit, according to recent studies such as the FLOW trial.[17] The CONFIDENCE trial showed that simultaneous initiation of finerenone and empagliflozin led to a 52% reduction in UACR at 180 days, which outperformed finerenone (29%) and empagliflozin (32%) alone.[18] Despite optimization with these additional agents, many patients in our study still met the eligibility criteria for initiating finerenone.

The cost of finerenone is estimated to be $1200 to $1300 per year without private drug coverage.[19] In BC, finerenone is covered for individuals with type 2 diabetes and chronic kidney disease who remain at elevated risk of disease progression despite optimized standard therapy.[20] The full PharmaCare Special Authority eligibility criteria are outlined in the **Box**.

In conclusion, our study highlights the applicability of FIDELIO-DKD and FIGARO-DKD trial criteria to a British Columbia context and emphasizes the ongoing need for proactive management strategies in patients facing residual renal risk despite optimized therapy. Considering the substantial health care burden of end-stage renal disease, integrating therapies like finerenone that reduce renal risk is essential, especially in populations with a higher prevalence of pre-existing cardiovascular disease. ■

BOX. British Columbia PharmaCare finerenone eligibility criteria.

Finerenone may be used as an adjunct to standard of care therapy to reduce the risk of end-stage renal disease and sustained decrease in glomerular filtration rate (GFR), as well as cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in an adult patient who meets all the following criteria:

- The patient has both type 2 diabetes and chronic kidney disease with a GFR of at least 25 mL/min/1.73 m^2.
- The patient has albuminuria of at least 3 mg/mmol or 30 mg/g.
- The patient is receiving maximally tolerated doses of both ACE inhibitors or angiotensin receptor blockers *and* sodium-glucose cotransporter 2 inhibitors.
- The patient does *not* have New York Heart Association class II–IV heart failure.
- The patient is *not* on concurrent treatment with a different mineralocorticoid receptor antagonist.
- Treatment has been prescribed by a health care professional who has experience in the diagnosis and management of patients with type 2 diabetes and chronic kidney disease or in consultation with a nephrologist.

Adapted from the BC Ministry of Health website.[20]

Competing interests

Dr Jazdarehee has no competing interests to declare. Dr Shu has received speaking fees and advisory consulting fees from Boehringer Ingelheim, Bayer, Eli Lilly and Company, and Novo Nordisk. Dr Jain has received grants/research support from Abbott, Amgen, AstraZeneca, Eli Lilly and Company, Novo Nordisk, Roche, and Sanofi; speakers bureau/honoraria from Abbott, AbbVie, AstraZeneca, Amgen, Antibody Healthcare Communications (now part of Dentsu Health), Bausch Health, Bayer, Boehringer Ingelheim, Care to Know, Collaborative CME and Research Network, CPD Network, Dexcom, Diabetes Canada, Eli Lilly and Company, Embecta, eoci Health, GSK (formerly GlaxoSmithKline), HLS Therapeutics, Janssen, Liv Labs, Master Clinician Alliance, MDBriefCase, Merck, Medtronic, Moderna, NP Circle, Novartis, Novo Nordisk, Partners in Progressive Medical Education, Pfizer, Roche, Six Degrees Medical, TimedRight, Unik, and WebMD; and consulting fees from Abbott, AstraZeneca, Amgen, Bausch Health, Bayer, Boehringer Ingelheim, Celltrion Healthcare, Dexcom, Eli Lilly and Company, Embecta, Gilead Sciences, GSK, HLS Therapeutics, Industrii, Insulet, Janssen, Medtronic, NP Circle, Novartis, Novo Nordisk, Partners in Progressive Medical Education, Pendopharm, Pocketpills, Roche, Sandoz, Takeda, and Ypsomed.

Funding

There were no external funding sources.

References

1. Bakris GL, Agarwal R, Anker SD, et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl J Med 2020;383:2219-2229. http://doi.org/10.1056/NEJMoa2025845.
2. Pitt B, Filippatos G, Agarwal R, et al. Cardiovascular events with finerenone in kidney disease and type 2 diabetes. N Engl J Med 2021;385:2252-2263. http://doi.org/10.1056/NEJMoa2110956.
3. Agarwal R, Filippatos G, Pitt B, et al. Cardiovascular and kidney outcomes with finerenone in patients with type 2 diabetes and chronic kidney disease: The FIDELITY pooled analysis. Eur Heart J 2022;43:474-484. http://doi.org/10.1093/eurheartj/ehab777.
4. Wu B, Bell K, Stanford A, et al. Understanding CKD among patients with T2DM: Prevalence, temporal trends, and treatment patterns—NHANES 2007–2012. BMJ Open Diabetes Res Care 2016;4:e000154. http://doi.org/10.1136/bmjdrc-2015-000154.

5. Canadian Institute for Health Information. Canadian Organ Replacement Register annual report: Treatment of end-stage organ failure in Canada, 2003 to 2012. 2014. Accessed 4 May 2026. https://publications.gc.ca/collections/collection_2014/icis-cihi/H115-75-2014-eng.pdf.
6. Eriksen BO, Ingebretsen OC. The progression of chronic kidney disease: A 10-year population-based study of the effects of gender and age. Kidney Int 2006;69:375-382. http://doi.org/10.1038/sj.ki.5000058.
7. Alicic RZ, Rooney MT, Tuttle KR. Diabetic kidney disease: Challenges, progress, and possibilities. Clin J Am Soc Nephrol 2017;12:2032-2045. http://doi.org/10.2215/CJN.11491116.
8. McFarlane P, Cherney D, Gilbert RE, Senior P. Chronic kidney disease in diabetes. Can J Diabetes 2018;42:S201-S209. http://doi.org/10.1016/j.jcjd.2017.11.004.
9. Giugliano D, Maiorino MI, Bellastella G, Esposito K. The residual cardiorenal risk in type 2 diabetes. Cardiovasc Diabetol 2021;20:36. http://doi.org/10.1186/s12933-021-01229-2.
10. Currie G, Taylor AHM, Fujita T, et al. Effect of mineralocorticoid receptor antagonists on proteinuria and progression of chronic kidney disease: A systematic review and meta-analysis. BMC Nephrol 2016;17:127. http://doi.org/10.1186/s12882-016-0337-0.
11. Lerma E, White WB, Bakris G. Effectiveness of non-steroidal mineralocorticoid receptor antagonists in patients with diabetic kidney disease. Postgrad Med 2023;135:224-233. http://doi.org/10.1080/00325481.2022.2060598.
12. Kolkhof P, Jaisser F, Kim S-Y, et al. Steroidal and novel non-steroidal mineralocorticoid receptor antagonists in heart failure and cardiorenal diseases: Comparison at bench and bedside. In: Heart failure. Bauersachs J, Butler J, Sandner P, editors. Cham: Springer International Publishing; 2016. pp. 271-305. http://doi.org/10.1007/164_2016_76.
13. Tobe SW, Bajaj HS, Tangri N, et al. Chronic kidney disease in diabetes: A clinical practice guideline. Can J Diabetes 2025;49:73-86.e14. http://doi.org/10.1016/j.jcjd.2025.01.004.
14. Chiu N, Aggarwal R, Bakris GL, et al. Generalizability of FIGARO-DKD and FIDELIO-DKD trial criteria to the US population eligible for finerenone. J Am Heart Assoc 2022;11:e025079. http://doi.org/10.1161/JAHA.121.025079.
15. American Diabetes Association Professional Practice Committee. Chronic kidney disease and risk management: Standards of medical care in diabetes—2022. Diabetes Care 2021;45(Suppl 1):S175-S184. http://doi.org/10.2337/dc22-S011.
16. Vaduganathan M, Filippatos G, Claggett BL, et al. Finerenone in heart failure and chronic kidney disease with type 2 diabetes: FINE-HEART pooled analysis of cardiovascular, kidney and mortality outcomes. Nat Med 2024;30:3758-3764. http://doi.org/10.1038/s41591-024-03264-4.
17. Mann JFE, Rossing P, Bakris G, et al. Effects of semaglutide with and without concomitant SGLT2 inhibitor use in participants with type 2 diabetes and chronic kidney disease in the FLOW trial. Nat Med 2024;30:2849-2856. http://doi.org/10.1038/s41591-024-03133-0.
18. Agarwal R, Green JB, Heerspink HJL, et al. Finerenone with empagliflozin in chronic kidney disease and type 2 diabetes. N Engl J Med 2025;393:533-543. http://doi.org/10.1056/NEJMoa2410659.
19. Canadian Agency for Drugs and Technologies in Health. Finerenone (Kerendia): CADTH reimbursement recommendation. March 2023. Accessed 27 March 2026. www.ncbi.nlm.nih.gov/books/NBK596313/.
20. British Columbia Ministry of Health. Special Authority drug list. Updated 10 March 2026. Accessed 31 March 2026. www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/programs/special-authority/sa-drug-list.