CARE TRANSFORMATION COLLABORATIVE RHODE ISLAND

pcmh kids patient-centered medical home

ADVANCING INTEGRATED HEALTHCARE

Pharmacy QI Learning Collaborative: Pro CGM & ABPM

February 28, 2023

Care Transformation Collaborative of RI

Agenda

Topic	Presenter/Facilitator	Timing
Welcome	Susanne Campbell	7:30-7:35
Practice Sharing	Miriam Hospital Ambulatory Clinic Medical Associates of RI Integra/RIPCPC Providence Community Health Center Coastal Medical Anchor Medical	7:35-8:05
Care Team Survey	Stephen Kogut	8:05-8:15
Diabetes Updated Standards	Kelley Sanzen	8:15-8:55
Next Steps	Kelley Sanzen	8:55-9:00

Standards of Care in Diabetes:
An Update to the American Diabetes Association Pratice Guidelines - 2023

Kelley Sanzen, PharmD, PAHM, CDOE

Special thanks to Danielle D'Achino, URI College of Pharmacy candidate 2023, for assisting with these slides!

Continuous Glucose Monitoring (CGM)

- Recommendation for offering the use of CGM in patients with type 2 diabetes on basal-only insulin therapy (once-daily, long-acting insulin) in addition to people on all other types of insulin regimens
  - Medicare is currently considering coverage of CGM for this population
- Patients should be educated on the interfering substances that can negatively impact sensor accuracy

Table 7.4—Continuous glucose monitoring devices interfering substances

Medication	Systems affected	Effect
Acetaminophen		
>4 g/day	Dexcom G6	Higher sensor readings than actual glucose
Any dose	Medtronic Guardian	Higher sensor readings than actual glucose
Alcohol	Medtronic Guardian	Sensor readings may be higher than actual glucose
Ascorbic acid (vitamin C), >500 mg/day	FreeStyle Libre	Higher sensor readings than actual glucose
Hydroxyurea	Dexcom G6, Medtronic Guardian	Higher sensor readings than actual glucose
Mannitol	Senseonics Eversense	Sensor bias within therapeutic concentration ranges
Tetracycline	Senseonics Eversense	Sensor bias within therapeutic concentration ranges

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CKD and Risk Management

- New levels for initiation of SGLT2 inhibitors
  - Estimated GFR ≥ 20 mL/min/1.73 m2 **and** urinary albumin ≥ 200 mg/g
- SGLT2 inhibitors may also be effective in people with urinary albumin ≥ 200 mg/g
  - B level rated evidence at this time as the study reporting this has not yet been published
- Mineralocorticoid Receptor Antagonists (MRAs) recommended along with other medications for cardiovascular and kidney protection rather than as alternatives when other treatment have not been effective

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Cardiovascular Disease and Risk Management

- Treatment with high intensity statin therapy in individuals with diabetes and **established** atherosclerotic cardiovascular disease to target an LDL cholesterol reduction of ≥50% from baseline and an **LDL cholesterol goal of ≤ 55 mg/dL**
  - If goal is not achieved on max tolerated statin - consider addition of ezetimibe or a PCSK9 inhibitor
- Use of sodium-glucose co-transporter 2 (SGLT2) inhibitors for patients with diabetes and established heart failure with preserved or reduced ejection fraction to improve symptoms, physical limitations, and quality of life
- Addition of finerenone recommended in treatment of patients with type 2 diabetes and CKD with albuminuria treated with maximum tolerated doses of ACEi or ARB

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Renal Outcome Trials

- CREDENCE
  - Canagliflozin vs Placebo
- DAPA-CKD
  - Dapagliflozin vs Placebo
- EMPA-KIDNEY
  - Empagliflozin vs Placebo

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Does canagliflozin slow diabetic kidney disease? You bet your sweet pee it does!

#NephJC

Study Population

Randomized Control Trial (N = 4401)

63 years

HbA1c = 8.3%

Alb/Cr = 927 mg/g

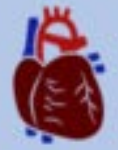
eGFR = 56.2

Primary Outcome

61 per 1000 patient years

Placebo

Composite of ESRD, doubling of serum Cr, renal or CV death



HR = 0.70
(CI, 0.59 to 0.82)

Canagliflozin 43 per 1000 patient years

Renal-Specific Outcome

ESRD, 2 x serum creatinine, death from renal cause

HR = 0.66
CI 0.53 to 0.81

Cardiovascular Outcome

Cardiovascular death, myocardial infarction, or stroke

HR = 0.80
CI 0.67 to 0.95

Fractures

HR = 0.98
CI 0.70 to 1.37

Amputation

HR = 1.11
CI 0.79 to 1.56

Conclusion: In patients with type 2 diabetes and kidney disease, the risk of kidney failure and cardiovascular events was lower in the canagliflozin group than in the placebo group.

Perkovic, Vlado, et al. Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. *NEJM*, 2019, doi:10.1056/nejmoa1811744.

@MarioFunesMD

Could dapagliflozin improve kidney and cardiovascular outcomes in patients with CKD?

#NephJC

Randomized
Double-blind
Placebo-controlled
Multicenter

386 sites in 21 countries

N= 4304

GFR 25-75 ml/min

67.5% diabetes type 2

ACR 200-5000mg/g

Outcomes

Kidney
- Decline in GFR at least 50%
- ESKD
- Death from renal causes

Cardiovascular
- Hospitalization for heart failure
- Death from cardiovascular causes

Placebo

N= 2152

Dapagliflozin 10mg/d

N= 2152

Primary composite outcome	Composite kidney outcome	Composite cardio-vascular outcome	Death from any cause
14.5%	11.3%	6.4%	6.8%
P<0.001	P<0.001	P=0.009	P=0.004
9.2%	6.6%	4.6%	4.7%

Conclusion: Among patients with chronic kidney disease, the risk of any composite kidney or cardiovascular outcomes or death was significantly lower with dapagliflozin than with placebo.

Reference: Heerspink HJL *et al.* Dapagliflozin in Patients with Chronic Kidney Disease. N Engl J Med. 2020 Sep 24. DOI: 10.1056/NEJMoa2024816.

Visual abstract: Denisse Arellano, MD @deniise_am

NEPHROLOGY EST 2015 SOCIAL MEDIA COLLECTIVE

Is Empagliflozin Beneficial in Patients With Variable Chronic Kidney Disease and Diabetes Status?

EMPA-KIDNEY Collaborative Group

#NephJC

6609 patients randomized

2-year follow up

eGFR ≥ 20-45 ml/min/1.73 m^2
or
eGFR ≥ 45-90 ml/min/1.73 m^2
and
Urine Albumin to creatinine ratio of > 200 mg/g

	Progressive CKD* or CV death	Hospitalization for CHF or CV death	Hospitalization any cause (per 100 patient yrs)
Placebo n=3305	16.9%	4.6%	29.2
	HR 0.72 (0.64-0.82) p< 0.001	**HR 0.84 (0.67-1.07) p=0.15**	**HR 0.86 (0.78-0.95) p= 0.003**
Empagliflozin 10mg n=3304	13.1%	4.0%	24.8

*sustained 40% eGFR decline / eGFR <10 ml/min / ESKD

or

Results were consistent in patients with and without diabetes

Empagliflozin in Patients with Chronic Kidney Disease: The EMPA-KIDNEY Collaborative Group. Herrington WG, Staplin N, Wanner C, et al. N Engl J Med. 2022 Nov 4. doi: 10.1056/NEJMoa2204233

Conclusion: Among a wide range of patients with CKD who were at risk for progression, empagliflozin therapy led to a lower risk of progression of CKD or death from cardiovascular causes than placebo.

@brian_rifkin

Renal Outcome Trials

	SGLT2 Inhibitor		
	CREDENCE **N = 4401**	**DAPA-CKD** **N = 4304**	**EMPA-KIDNEY** **N = 6609**
Intervention	**Canagliflozin vs. Placebo** ≥4 weeks stable on ACEi or ARB	**Dapagliflozin vs. Placebo** ≥4 weeks stable on ACEi or ARB	**Empagliflozin vs. Placebo** On ACEi or ARB
Patients	• T2D • eGFR ≥30 to <90 mL/min/1.73m^2 • UACR >300 to ≤5000 mg/g	• T2D and non-diabetes • eGFR ≥25 to ≤75 mL/min/1.73m^2 • UACR ≥200 to ≤5000 mg/g	• T2D and non-diabetes • eGFR ≥20 to <45 mL/min/1.73m^2 ***or*** ≥45 to <90 mL/min/1.73m^2 and UACR ≥200 mg/g

Renal Outcome Trials

	SGLT2 Inhibitor		
	CREDENCE **N = 4401**	**DAPA-CKD** **N = 4304**	**EMPA-KIDNEY** **N = 6609**
Primary Endpoint	**Composite** • Doubling of serum creatinine • ESKD • Renal or CV death	**Composite** • ≥50% sustained eGFR decline • ESKD • Renal or CV death	**Composite** • Kidney failure • ≥40% sustained eGFR decline • Renal death
Secondary Endpoints	• CV death or hospitalized for heart failure (hHF) • CV death, MI, or stroke • hHF • Renal composite • CV death • All-cause death • Composite of CV death, MI, stroke, hHF, or hospitalization for UA	• Renal composite • CV death or hHF • All-cause death	• CV death or hHF • All-cause hospitalizations • All-cause death • Kidney disease progression • CV death • CV death or ESKD

Renal Outcome Trials

	SGLT2 Inhibitor		
	CREDENCE	**DAPA-CKD**	**EMPA-KIDNEY**
Results	**Primary Outcome:** • Placebo: 61 per 1,000 patient years • Canagliflozin: 43 per 1,000 patient years • HR = 0.70 (CI 0.59 to 0.82) **Secondary Outcome:** • Renal-specific: HR = 0.66 (CI 0.53 to 0.81) • CV: HR = 0.80 (CI 0.67 to 0.95)	**Primary Outcome:** • Placebo: 14.5% • Dapagliflozin: 9.2% • p<0.001 **Kidney Outcome:** • Placebo: 11.3% • Dapagliflozin: 6.6% • p<0.001 **CV Outcome:** • Placebo: 6.4% • Dapagliflozin: 4.6% • p=0.009 **Death from any cause:** • Placebo: 6.8% • Dapagliflozin: 4.7% • p=0.004	**Primary Outcome:** • Placebo: 16.9% • Empagliflozin: 13.1% • HR: 0.72 (0.64-0.82) • p<0.001 **Hospitalization for CHF or CV death:** • Placebo:4.6% • Empagliflozin: 4.0% • HR: 0.84 (0.67-1.07) • p=0.15 **Hospitalization any cause (per 100 patient yrs):** • Placebo: 29.2 • Empagliflozin: 24.8 • HR: 0.86 (0.78-0.95) • p=0.003

Renal Outcome Trials

	SGLT2 Inhibitor		
	CREDENCE	**DAPA-CKD**	**EMPA-KIDNEY**
Conclusions	Patients with diabetes and kidney disease: Risk of kidney failure and CV events lower in Canagliflozin group than placebo	Patient with CKD: risk of composite kidney, CV outcomes, or death was significantly lower with dapagliflozin than with placebo	Patients with CKD: risk for progression, empagliflozin therapy led to a lower risk of progression of CKD or death from CV causes than placebo

Finerenone Trials

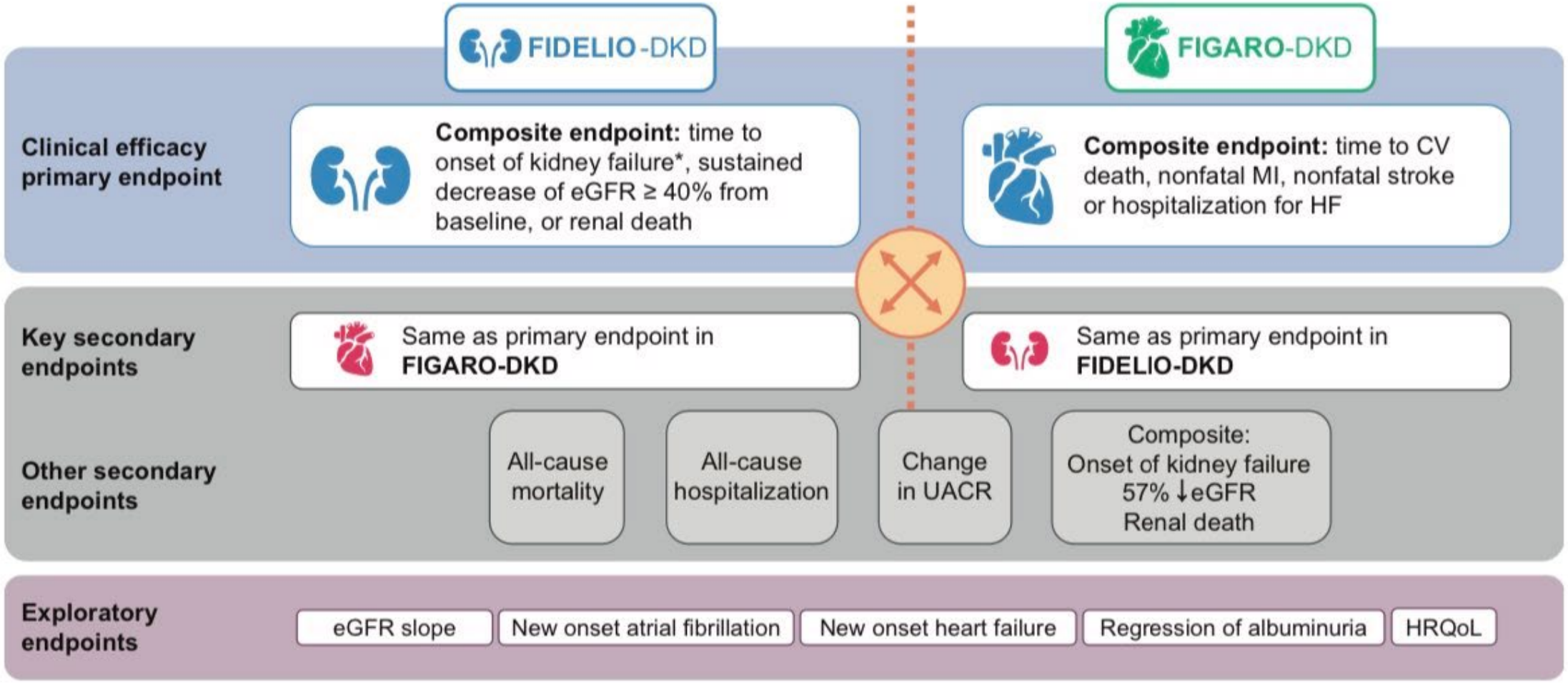


FIGURE 3: FIDELIO-DKD and FIGARO-DKD endpoints. [a]Kidney failure defined as occurrence of ESKD (initiation of chronic dialysis for ≥90 days or renal transplantation) or sustained eGFR <15 mL/min/1.73 m^2. HF: heart failure; HRQoL: health-related quality of life; MI: myocardial infarction.

FIDELIO-DKD

Does finerenone improve outcomes in CKD with type 2 diabetes?

Double-blinded

Type 2 diabetes

2.6 years
Median follow-up

RAAS blockade
Maximum tolerable dose

Stratification

- eGFR 25 to <75 (mL/min/1.73m²)
- uACR 300 to 5000 (mg/g)

- eGFR 25 to <60 (mL/min/1.73m²)
- uACR 30 to <300 (mg/g)
- Diabetic retinopathy

	1 Primary composite outcome Kidney failure Sustained decrease of ≥40% in eGFR Death from renal causes	2 Key secondary composite outcome Cardiovascular death Nonfatal MI and stroke Hospitalization for heart failure	Safety Discontinuation of trial regimen due to hyperkalemia
Placebo n = 2841	**REFERENCE**	**REFERENCE**	**0.9%**
Finerenone n = 2833	**HR 0.82** (0.73 to 0.93)	**HR 0.86** (0.75 to 0.99)	**2.3%**

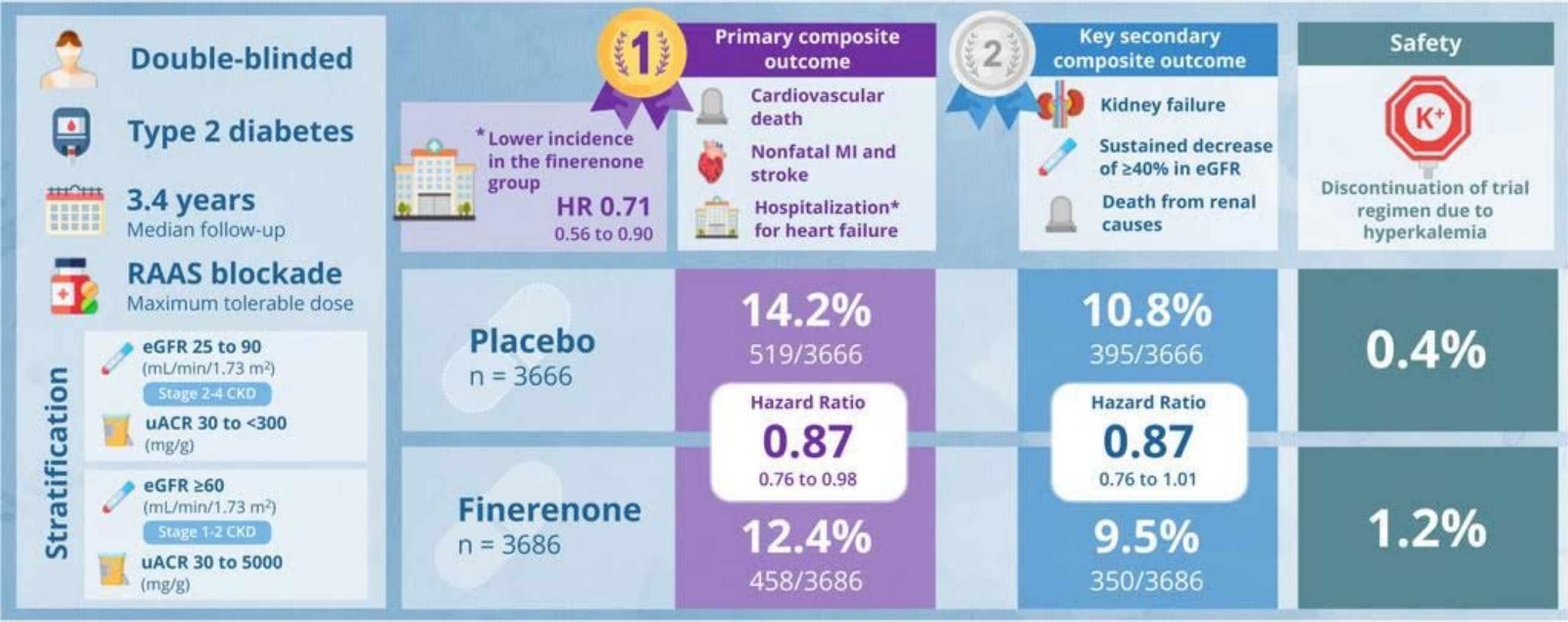
Conclusion In patients with CKD and type 2 diabetes, treatment with finerenone resulted in lower risks of CKD progression and cardiovascular events than placebo

Bakris GL, Agarwal R, Anker SD, et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. *N Engl J Med*. Published online October 23, 2020:NEJMoa2025845.

Visual abstract by Michelle Lim MBChB, MRCP

Figure 2. FIGARO-DKD

Does finerenone improve cardiovascular outcomes in type 2 diabetes and CKD?



Conclusion Among patients with type 2 diabetes and stage 2 to 4 CKD with moderately elevated albuminuria or stage 1 or 2 CKD with severely elevated albuminuria, finerenone therapy improved cardiovascular outcomes as compared with placebo.

Pitt B, et al.; FIGARO-DKD Investigators. Cardiovascular events with finerenone in kidney disease and type 2 diabetes. *N Engl J Med* [published online ahead of print August 28, 2021]. doi: 10.1056/NEJMoa2110956

Visual abstract by Michelle Lim, MBChB, MRCP

Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

- Pioglitazone may be considered in patients with a history of stroke and evidence of insulin resistance to lower the risk of stroke or myocardial infarction

  Consider risk of weight gain, edema, fracture

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Obesity and Weight Management for Prevention and Treatment of Type 2 Diabetes

- Dual GLP-1 receptor agonists/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (tirzepatide) added as a glucose-lowering option with the potential for weight loss

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Pharmacologic Approaches to Glycemic Treatment

- A GLP-1 receptor agonist is **preferred** to insulin when possible
- Consider combination therapy with a GLP-1 receptor agonist when using insulin for greater efficacy, durability of treatment effect, weight and hypoglycemia benefit

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Medical Evaluation and Assessment of Comorbidities

- Managing patients with type 2 diabetes who have nonalcoholic fatty liver disease (NAFLD)
  - Treatment focus: managing hyperglycemia and obesity especially in cases of significant fibrosis
  - Pioglitazone and glucagon-like peptide 1 (GLP-1) receptor agonists have proven to be effective to treat steatohepatitis and may slow fibrosis progression

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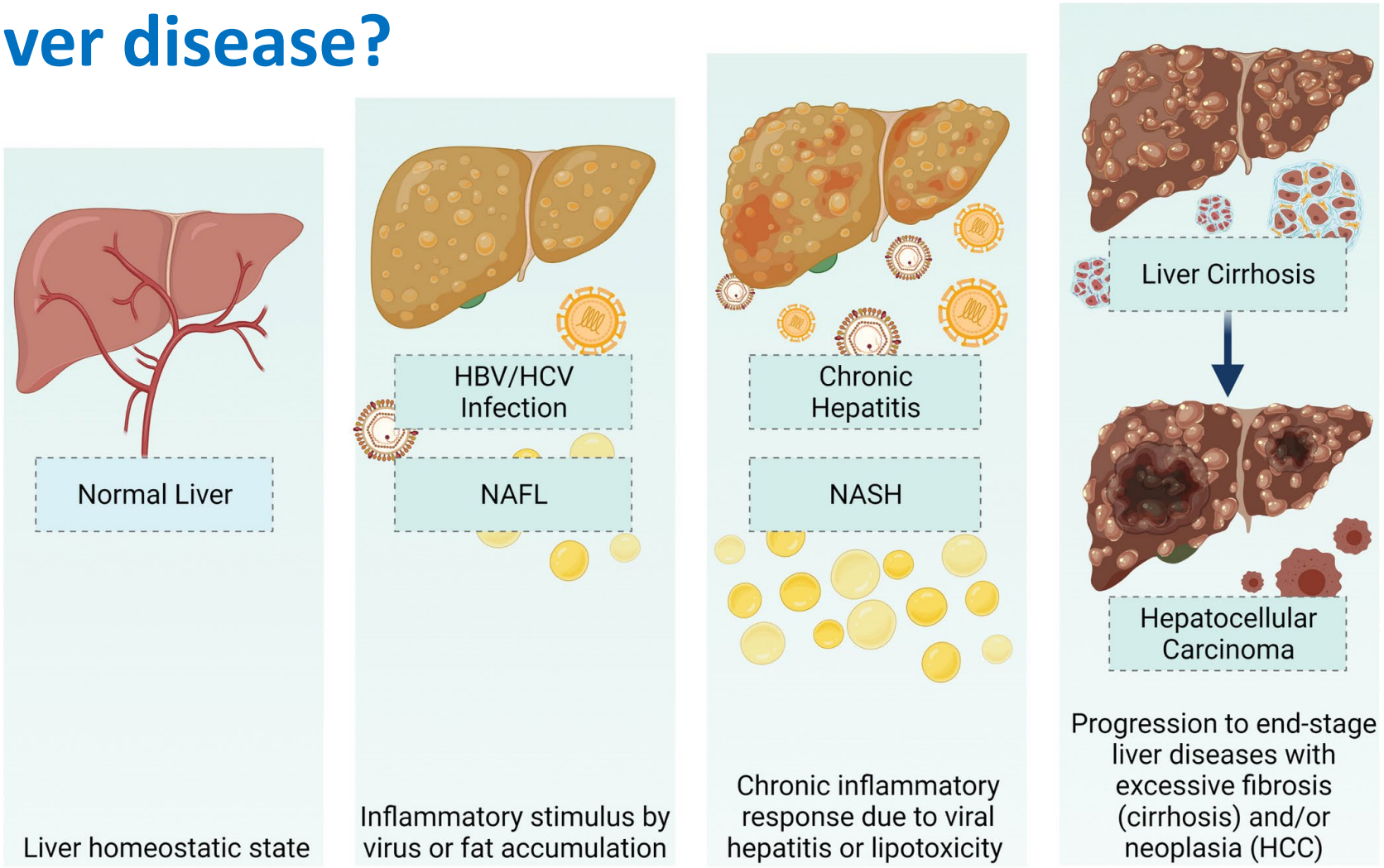
What is chronic liver disease?



Albuquerque-Souza, E, Sahingur, SE. Periodontitis, chronic liver diseases, and the emerging oral-gut-liver axis. *Periodontol 2000*. 2022; 98: 125– 141.

Nonalcoholic Fatty Liver Disease (NAFLD)

- Is considered a “silent disease” with few or no symptoms
- Obesity, metabolic syndrome and diabetes increase likelihood of developing NAFLD
- Includes both nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH)
- NASH: presence of hepatic injury with inflammation with or without fibrosis
- NASH is classified into two types
  - Primary: Obesity and diabetes in absence of excessive alcohol intake
  - Secondary: Toxin or drug-induced
- Treatment
  - Weight loss to reduce fat, inflammation, and fibrosis of the liver
  - **Medication considerations**: use of Pioglitazone or GLP-1 agonist

Dharmalingam M, Yamasandhi PG. Nonalcoholic Fatty Liver Disease and Type 2 Diabetes Mellitus. Indian J Endocrinol Metab. 2018 May-Jun;22(3):421-428. doi: 10.4103/ijem.IJEM_585_17. PMID: 30090738; PMCID: PMC6063173.

Diabetes and NAFLD

- Often coexist together
- Prevalence of NAFLD is ~60% among patients with type 2 diabetes
- Overweight/obesity and insulin resistance (IR) are strongly linked to NAFLD
- NAFLD increases microvascular complications of diabetes
  - Chronic Kidney Disease
  - Retinopathy
- Interventions for the management of NAFLD (lifestyle modifications, GLP-1s, SGLT2 inhibitors, thiazolidinediones (pioglitazone) etc.) indirectly improve IR and glycemia which explains why they are also used to treat T2DM

Dharmalingam M, Yamasandhi PG. Nonalcoholic Fatty Liver Disease and Type 2 Diabetes Mellitus. Indian J Endocrinol Metab. 2018 May-Jun;22(3):421-428. doi: 10.4103/ijem.IJEM_585_17. PMID: 30090738; PMCID: PMC6063173.

What are you currently doing in the space of Chronic Liver Disease?

How are you identifying this population?

What challenges are you encountering?

How often are you using pioglitazone?

Next Steps

- Next Meeting: May 23rd, 2023, 7:30-9:00AM
- PDSA including patient engagement and care team engagement data, key findings and adjustments necessary - due May 9th, 2023


Thank You!

Additional Resources

Resources can be found at

https://www.ctc-ri.org/other-programs/pharmacy-qi-initiative

- Digital Remote Patient Monitoring Guide for Practices FSL2 and FSL14d
- ADCES ProCGM Playbook
- https://www.freestyleprovider.abbott/us-en/freestyle-libre-14-day-system.html
- Libre Billing Resources
- https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system?utm_source=bing&utm_campaign=CGM+-+BRAND+-+Core+-+Exact&utm_medium=cpc&ds_rl=1298299&msclkid=f9c6cae08cdf1a606c13a9e32c6e7db6

Dexcom resources

- Getting Started G6 Pro PowerPoint
- GEMCO Account Setup Instructions
- G6 Pro Work Flow
- Dexcom G6 Pro User Guide
- Dexcom G6 Pro UnBlinded CGM Patient Handout
- Dexcom G6 Pro Patient Tracking Form
- Dexcom G6 Pro Daily Log Sheet
- Dexcom G6 Pro Blinded CGM Patient Handout
- 2022 CPT Billing CGM Reference