Diabetes Medications for Type 2 Diabetes with Focus on HIV: Part 2

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Disclosures

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Objectives

- Understand how to safely prescribe and use “newer” diabetes medications
- Understand physiology and mechanism of action, efficacy, safety, tolerability, managing side effects, dosing and administration of individual drugs
- Understand how to use these medications in liver disease and CKD
- Assess the cardiac and renal benefits in these newer medications

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Diabetes Medications

- Mechanism of action
- Efficacy (on average how much does it lower blood sugar)
- Does it cause hypoglycemia yes/no
- Common side-effects
- Serious side-effects
- Weight gain/Weight loss/Weight neutral
- Cardiovascular effects
- Use in Liver Disease
- Use in CKD and renal protective effect

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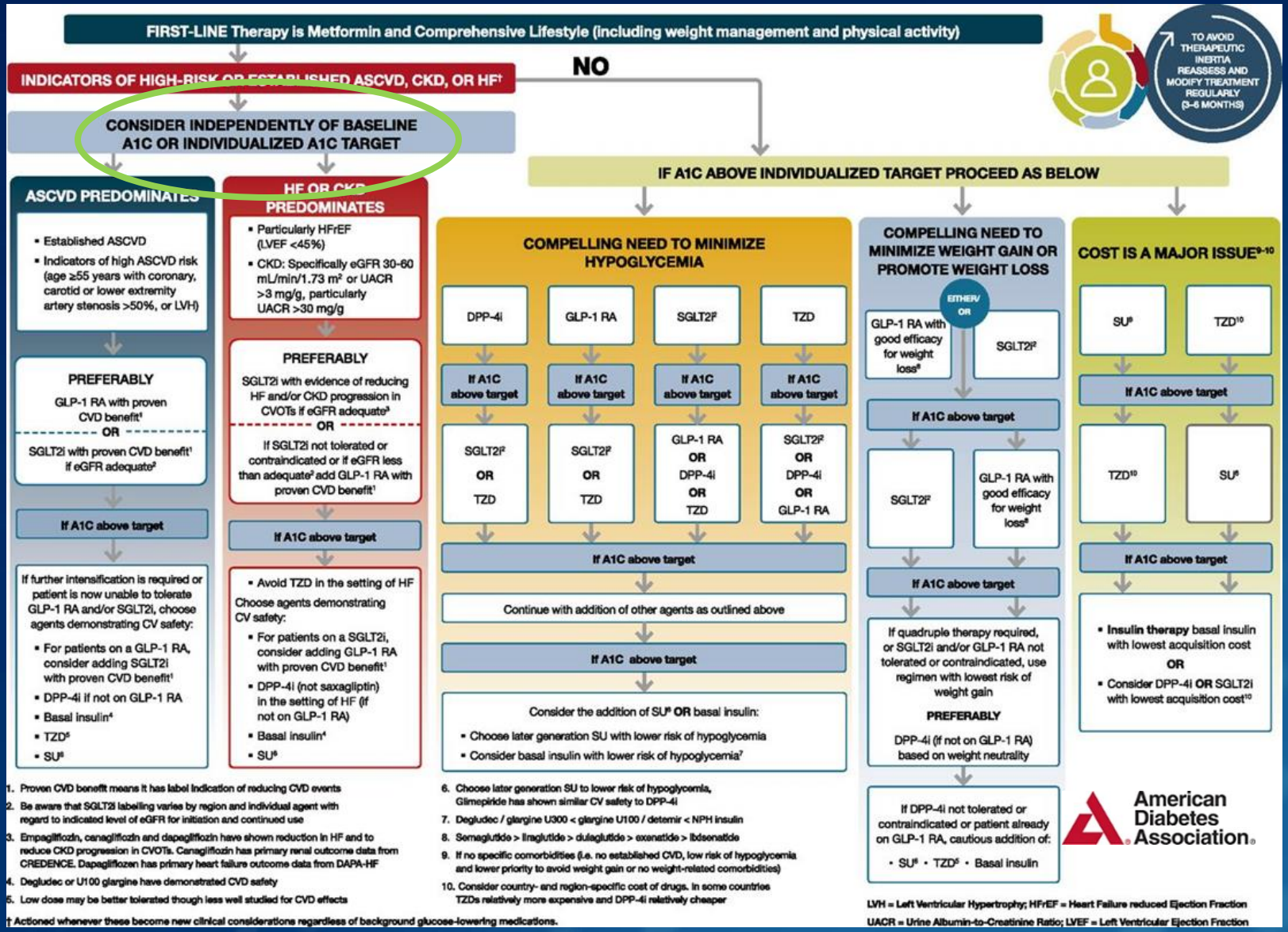
Glucose-lowering medication in type 2 diabetes: overall approach.



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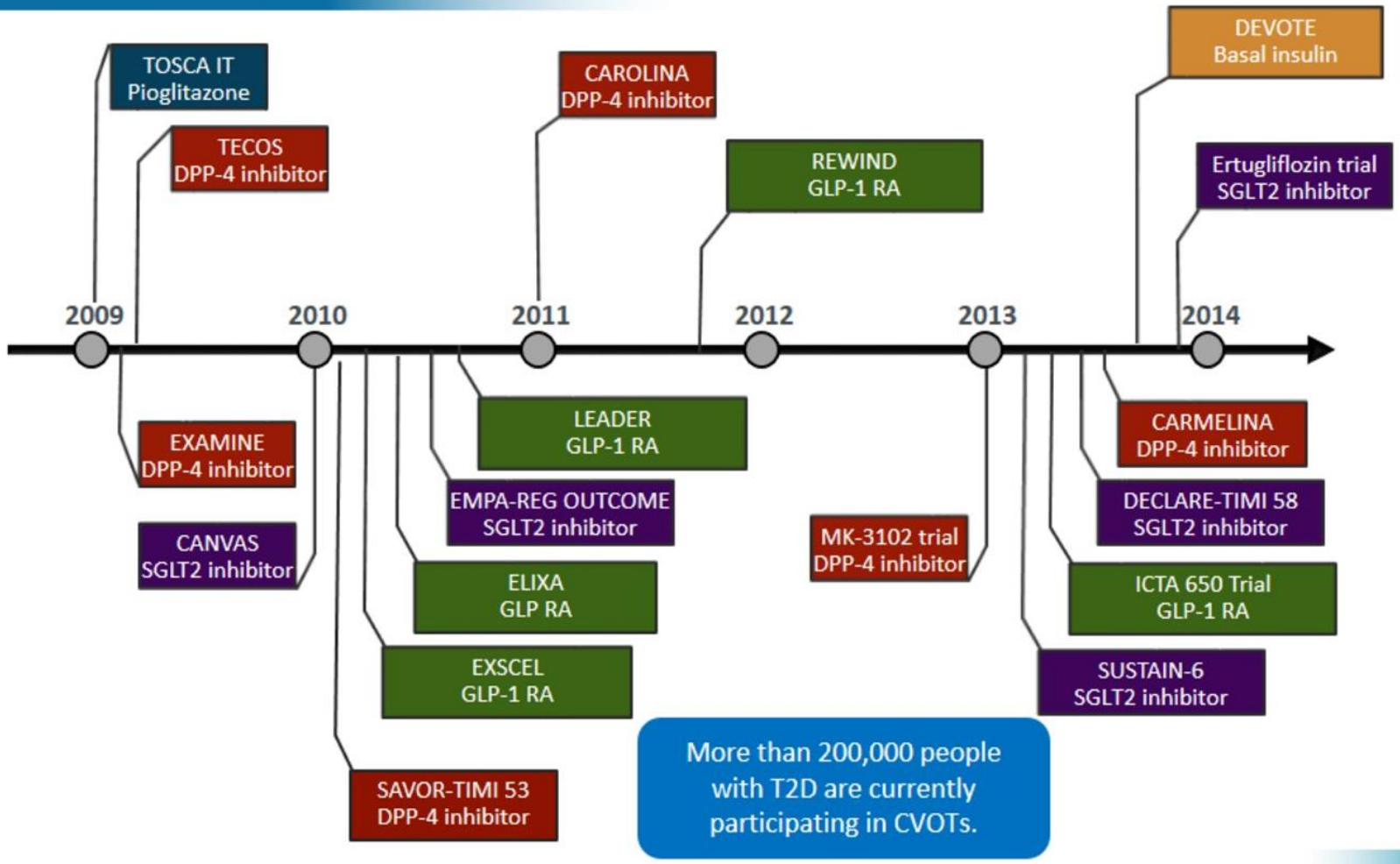
Timing of CV safety trials with Drugs for Type 2 Diabetes



Standl E, et al. *Lancet Diabetes Endrocrinol*. 2017;5:391-402.

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THIAZOLIDINEDIONES: “TZDS”

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Thiazolidinediones: “TZDs”

Class/Main Action	Name(s)	Daily Dose Range	Considerations
Thiazolidinediones “TZDs” • Increases insulin sensitivity	pioglitazone (Actos) rosiglitazone (Avandia)	15 – 45 mg daily 4 – 8 mg daily	Black Box Warning: TZDs may cause or worsen CHF. Monitor for edema and weight gain. Increased peripheral fracture risk. Actos may increase risk of bladder cancer. Lowers A1c 0.5% – 1.0%

http://diabetesed.net/pocket-cards-insulin-and-diabetes-meds

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TZD Adverse Effects

- Weight gain
- Increased risk of edema
- Contraindicated in Class III HF or higher and possible increase risk of HF
- Increased risk of long-bone fractures
- possible increased risk macular edema
- Pioglitazone ?? Bladder cancer risk

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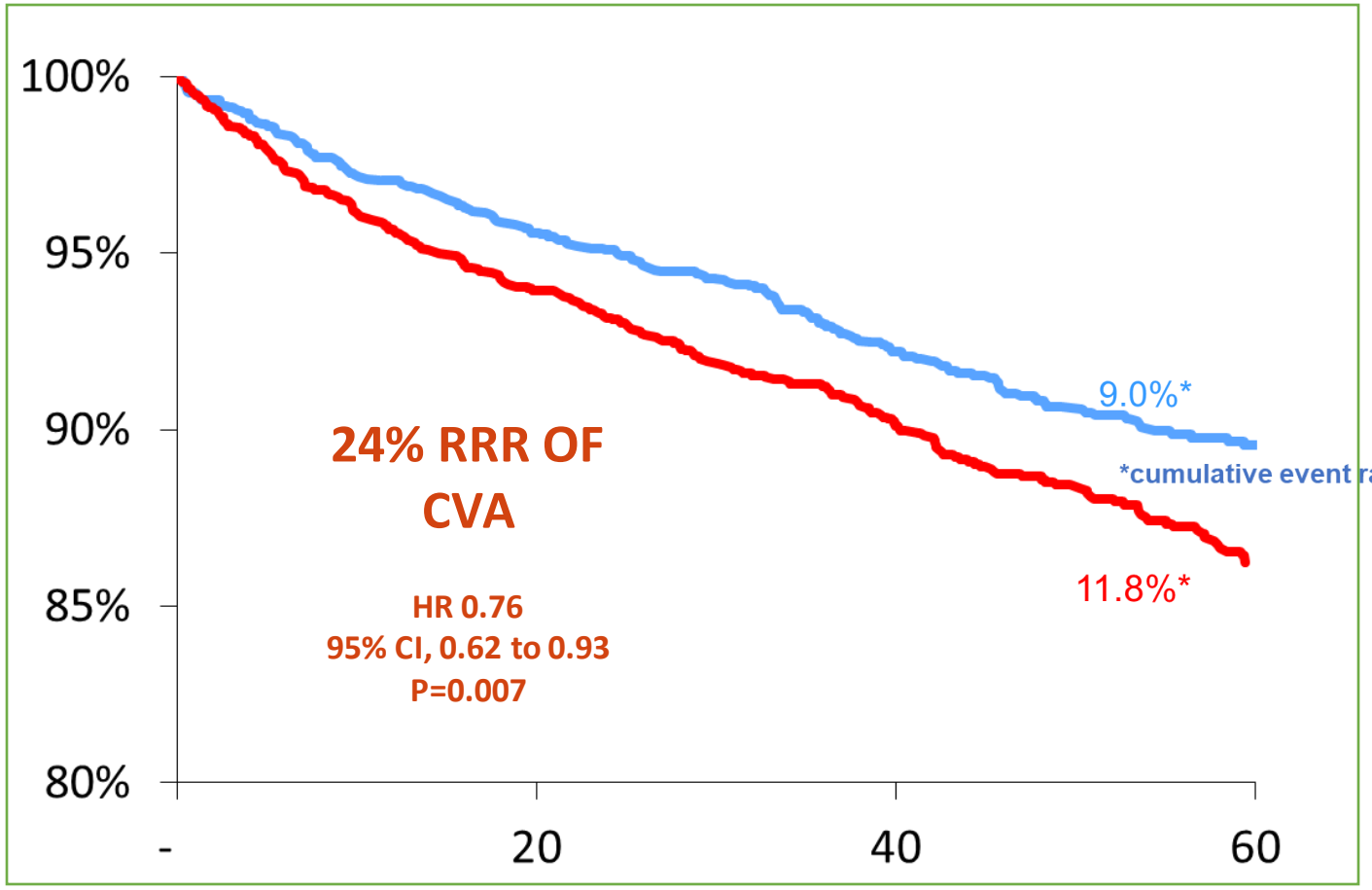
Pioglitazone after CVA or TIA

Insulin Resistance Intervention After **Stroke Trial (IRIS)**:



*Inclusion Criteria: Insulin resistance (did not need a diagnosis of DM)

Kernan et al. N Engl J Med 2016; 374:1321-1331

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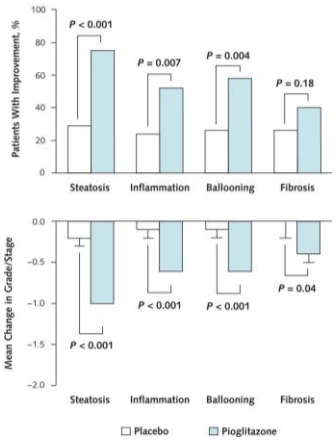
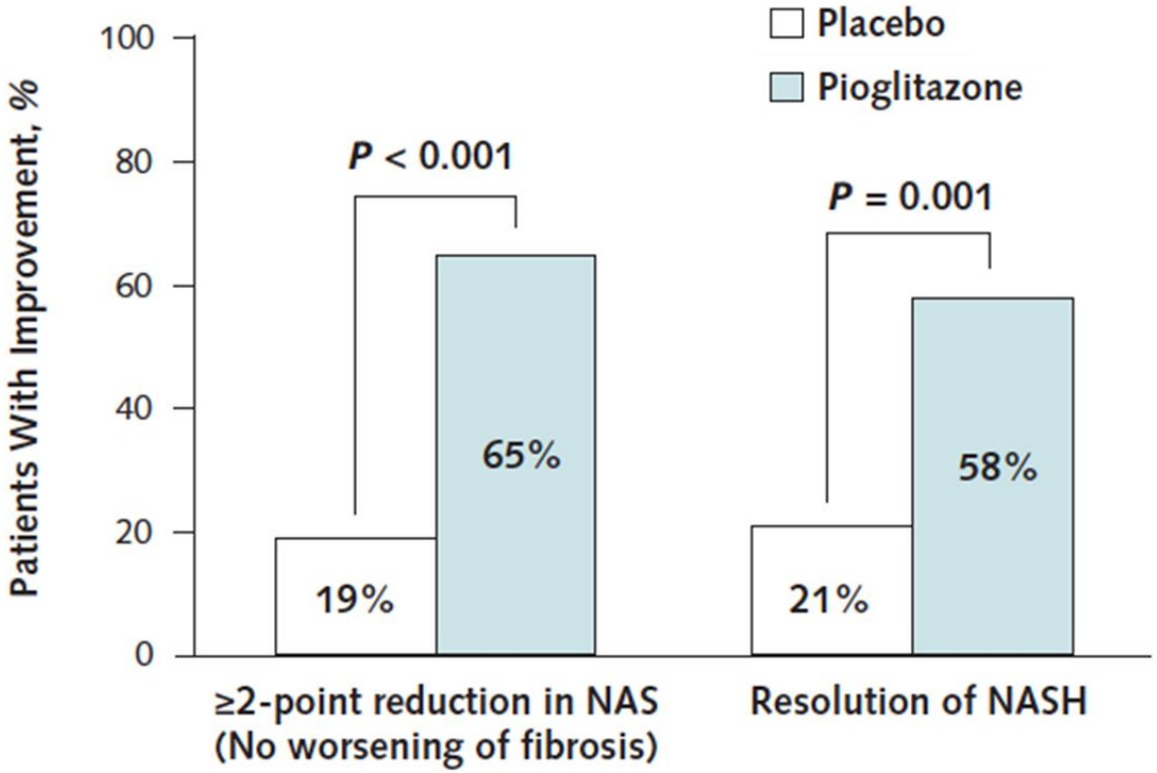
Effect of 18 Months of Pioglitazone Treatment on Primary and Secondary Liver Histologic Outcomes

Fibrosis score: treatment difference, -0.5 [CI, -0.9 to 0.0]; P = 0.039





Resolution of NASH defined as absence of NASH after 18 mo of therapy with definite NASH at baseline

Cusi et al, Ann Intern Med June 21, 2016. [Epub].

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Summary: Thiazolidinediones (TZDs)

- Helps to target insulin resistance
- May improve dyslipidemia
- NASH (Non-Alcoholic liver disease)
- Established CVA may have some CV benefit
- Weight gain, edema, and fractures
- Risk for worsening HF - *do not use in CHF*
- Use in select population
- The available evidence does not support the use of thiazolidinediones lipoatrophy

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GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RA)

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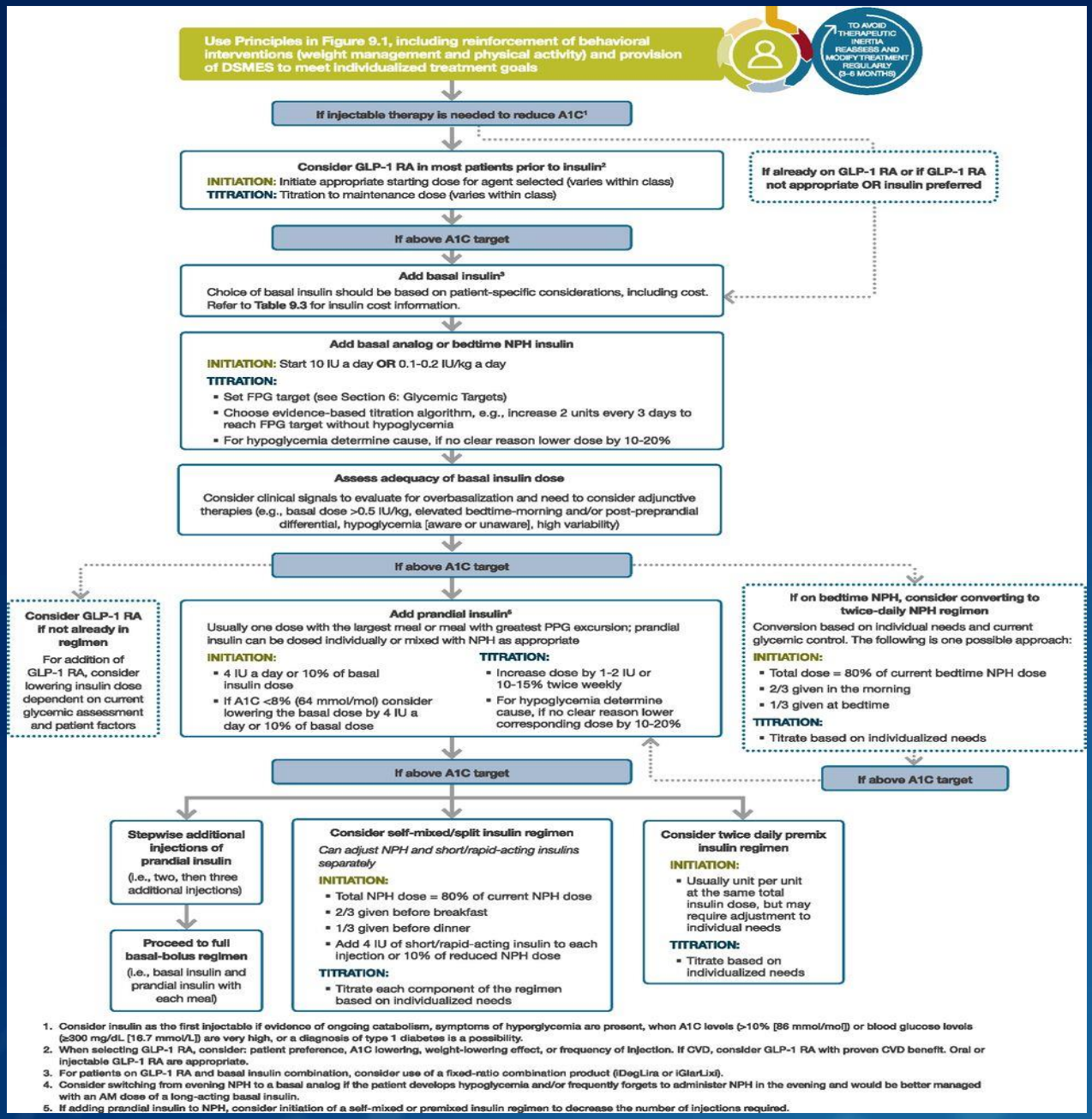
Intensifying to injectable therapies



1. Consider insulin as the first injectable if evidence of ongoing catabolism, symptoms of hyperglycemia are present, when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (≥300 mg/dL [16.7 mmol/L]) are very high, or a diagnosis of type 1 diabetes is a possibility.
2. When selecting GLP-1 RA, consider: patient preference, A1C lowering, weight-lowering effect, or frequency of injection. If CVD, consider GLP-1 RA with proven CVD benefit. Oral or injectable GLP-1 RA are appropriate.
3. For patients on GLP-1 RA and basal insulin combination, consider use of a fixed-ratio combination product (iDegLira or iGlarLixi).
4. Consider switching from evening NPH to a basal analog if the patient develops hypoglycemia and/or frequently forgets to administer NPH in the evening and would be better managed with an AM dose of a long-acting basal insulin.
5. If adding prandial insulin to NPH, consider initiation of a self-mixed or premixed insulin regimen to decrease the number of injections required.

American Diabetes Association Dia Care 2021;44:S111-S124

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Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RA)

Class/Main Action	Name	Dose Range	Considerations
GLP-1 Receptor Agonist (GLP-1 RA) **"Incretin Mimetic"** • Increases insulin release with food • Slows gastric emptying • Promotes satiety • Suppresses glucagon	exenatide (Byetta)	5 and 10 mcg BID	**Side effects for all:** Nausea, vomiting, weight loss, injection site reaction. Report signs of acute pancreatitis (severe abdominal pain, vomiting), stop med. Renally excreted. **Black box warning:** Thyroid C-cell tumor warning for exenatide XR, liraglutide, dulaglutide, and semaglutide (avoid if family history of medullary thyroid tumor). *Significantly reduces risk of CV death, heart attack, and stroke. Lowers A1c 0.5 – 1.6% Weight loss of 1.6 to 6.0kg†
	exenatide XR (Bydureon)	2 mg 1x a week Pen injector - Bydureon BCise	
	liraglutide (Victoza)*	0.6, 1.2 and 1.8 mg daily Approved for pediatrics 10 yrs +	
	dulaglutide (Trulicity)*	0.75, 1.5, 3.0 and 4.5 mg 1x a week pen injector	
	lixisenatide (Adlyxin)	10 mcg 1x a day for 14 days 20 mcg 1x day starting day 15	
	semaglutide (Ozempic)*†	0.5 and 1.0 mg 1x a week pen injector	
	(Rybelsus) Oral tablet	3, 7, and 14 mg daily in a.m. Take on empty stomach w/H2O sip	
Amylin Mimetic • Slows gastric emptying • Supress glucagon	pramlintide (Symlin)	Type 1: 15 - 60 mcg; Type 2: 60 - 120 mcg immediately before major meals	For Type 1 or 2 [illegible] insulin. Severe hypogly[illegible]mic risk, decrease insulin dose wh[illegible] starting. **Side effects:** na[illegible]ea, weight loss. Lowers A1c 0.5 – 1%

http://diabetesed.net/pocket-cards-insulin-and-diabetes-meds

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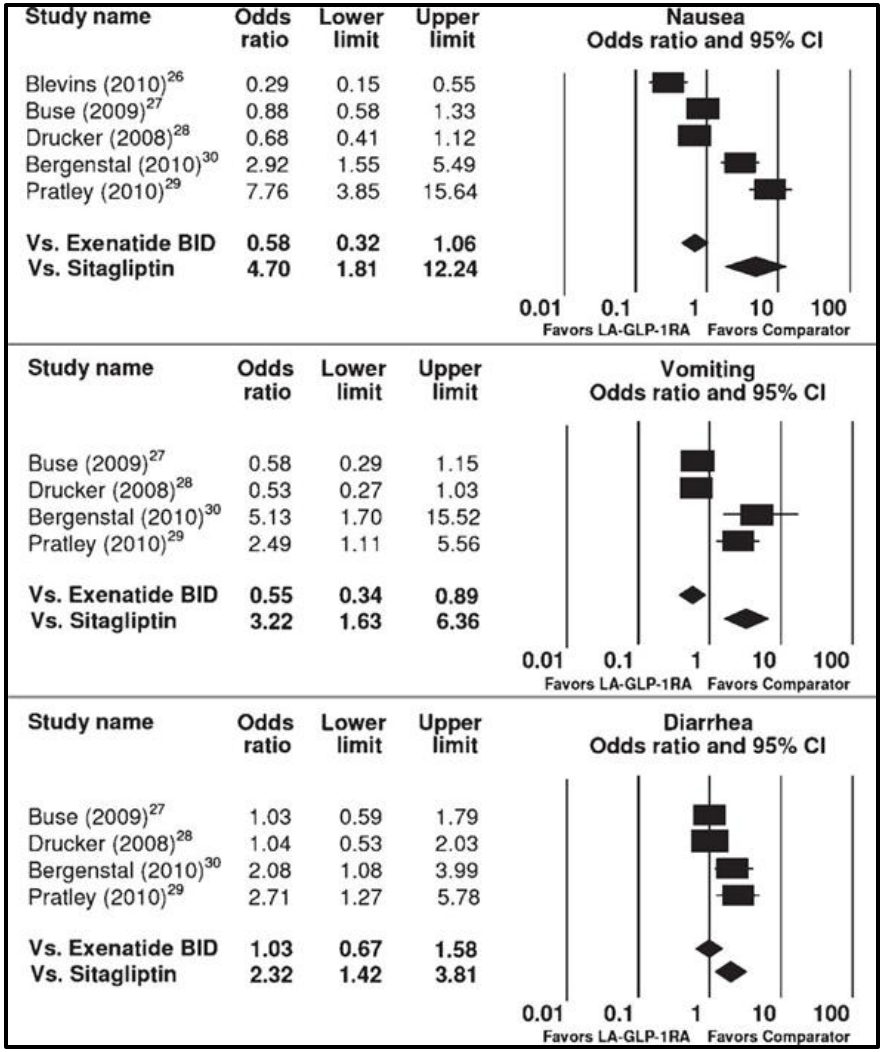
GLP-1 RA: Side-Effects /Potential Patient Perceived Barriers

- Nausea/diarrhea/constipation
- Possible risk for Pancreatitis??
- Theoretical risk for medullary thyroid cancer??
  - Induces rodent thyroid C-cell tumors
- Injection



Study name	Odds ratio	Lower limit	Upper limit
Blevins (2010)[26]	0.29	0.15	0.55
Buse (2009)[27]	0.88	0.58	1.33
Drucker (2008)[28]	0.68	0.41	1.12
Bergenstal (2010)[30]	2.92	1.55	5.49
Pratley (2010)[29]	7.76	3.85	15.64
Vs. Exenatide BID	**0.58**	**0.32**	**1.06**
Vs. Sitagliptin	**4.70**	**1.81**	**12.24**

Study name	Odds ratio	Lower limit	Upper limit
Buse (2009)[27]	0.58	0.29	1.15
Drucker (2008)[28]	0.53	0.27	1.03
Bergenstal (2010)[30]	5.13	1.70	15.52
Pratley (2010)[29]	2.49	1.11	5.56
Vs. Exenatide BID	**0.55**	**0.34**	**0.89**
Vs. Sitagliptin	**3.22**	**1.63**	**6.36**

Study name	Odds ratio	Lower limit	Upper limit
Buse (2009)[27]	1.03	0.59	1.79
Drucker (2008)[28]	1.04	0.53	2.03
Bergenstal (2010)[30]	2.08	1.08	3.99
Pratley (2010)[29]	2.71	1.27	5.78
Vs. Exenatide BID	**1.03**	**0.67**	**1.58**
Vs. Sitagliptin	**2.32**	**1.42**	**3.81**

Ann Pharmacother 2011;45:850-860

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	GLP-1 receptor agonists								GLP-1 receptor agonist/ basal insulin fixed-dose combinations	
Pen devices for injection										
Drug name: Generic Commercial	Exenatide b.i.d. Byetta®	Lixisenatide Lyxumia®	Liraglutide Victoza®	Exenatide once weekly, Bydureon® (original)	Bydureon® BCise (improved)	Dulalgutide Trulicity®	Albiglutide Eperzan®, Tanzeum®	Semaglutide Ozempic®	IdegLira Xultophy®	iGlarLixi Soliqua®
Pen for single or multiple use?	multiple	multiple	multiple	single	single	single	single	multiple	multiple	multiple
Pen for pre-determined single dose/ variable dosing	single	single	variable (0.6, 1.2, or 1.8 mg)	single	single	single	single	single	variable, for titration	variable, for titration
Pen devices available (maximum dose)	5 or 10 µg	10 or 20 µg	1.8 mg	2 mg	2 mg	0.75 or 1.5 mg	30 or 50 mg	0.25, 0.5 or 1.0 mg	Up to 1.8 mg (plus insulin *degludec* up to 50 IU)	Up to 20 µg (plus insulin *glargine* up to 60 IU)
Resuspension before injection necessary?	no	no	no	yes	No, but thorrough mixing	no	yes	no	no	no

Nauck MA et al. Eur J Endocrinol. 2019 Dec;181(6):R211-R234

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0.6, 1.2 and 1.8 daily dosing

0.75 and 1.5mg weekly dosing

Recent approval of 3.0 an 4.5mg dosing

0.25, 0.5mg, and 1mg weekly dosing

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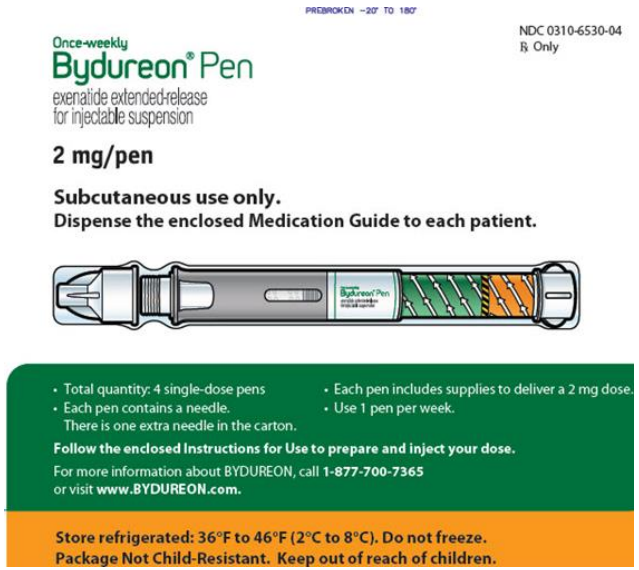
How to use Exenatide (Bydureon)

English: https://www.youtube.com/watch?v=72w756RKawY

Spanish: https://www.youtube.com/watch?v=Wqn1iKBiQkk



https://www.molinahealthcare.com/-/media/Files/formulary.pd

TRADJENTA TAB 5MG	
INCRETIN MIMETIC AGENTS (GLP-1 RECEPTOR AGONISTS)	
BYDUREON PEN INJ 2MG	QL (4 pens / 25 days)
BYETTA INJ 5MCG	QL (1 pen / 25 days)
BYETTA INJ 10MCG	QL (1 pen / 25 days)
VICTOZA INJ 18MG/3ML	QL (9 mL / 30 days)

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Oral Semaglutide

Take on an empty stomach

Take with a small amount of water (no more than 4oz)

Wait 30 minutes after taking it and then eat food

3, 7, and 14 mg dosing

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GLP-1 RA in CKD

- In CKD stages 2 and 3: no dose adjustment is required for liraglutide and dulaglutide, semaglutide, extended release exenatide
    - Exenatide: reduce dose to 5mcg bid if 30–50 mL/min
- In CKD stages 4 and 5: GLP-1 RA limited data
- What about Stage 3 CKD GFR < 45??

Clin Pharmacol. 2016; 8:61-81

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GLP-1 use in CKD: LIRA-RENAL Study

	Liraglutide 1.8 mg (*n* = 140)	Placebo (*n* = 137)
Sex, *n* (%)		
Female	65 (46.4)	72 (52.6)
Male	75 (53.6)	65 (47.4)
Age, mean (SD), years	68.0 (8.3)	66.3 (8.0)

****Can use/initiate in GFR 30-45**

GFR

30 to < 45	61 (43.6)	59 (43.1)
45–59	78 (55.7)	78 (56.9)
> 59	1 (0.7)	0 (0.0)

Diabetes Care 2016 Feb; 39(2): 222-230

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GLP-1 RAs and CV Risk Baseline Characteristics

	ELIXA	LEADER	SUSTAIN 6	REWIND
Drug tested	Lisixenatide	Liraglutide	Semaglutide	Dulaglutide
Dose	20 µg/d	1.8 mg/d	0.5 or 1 mg/wk	1.5 mg/wk
N	6068	9340	3297	9901
Mean age, years	60	64	65	66
Percent women	31	36	39	46
Percent prior CVD	100	81	59	31
Mean BMI, kg/m^2	30	33	31	32
Mean HbA1c, %	7.7	8.7	8.7	7.3
Primary outcome	MACE[a] or unstable angina	MACE[a]	MACE[a]	MACE[a]

Gerstein et al. Diabetes Obes Metab. 2018 Jan;20(1):42-49

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CV and Renal Benefits of GLP-1 RAs

Administration:	subcutaneous						oral	
Compound:	Exenatide	Lixisenatide	Liraglutide	Exenatide	Dulaglutide	Semaglutide	Semaglutide	
Frequency:	b.i.d.	q.w.	q.d.	q.w.	q.w.	q.w.	q.d.	
Effects:								
HbA_{1c} reduction:	+	+	++	+	++	+++	++(+)	
Post-prandial glucose	++[a]	++[a]	+	+	+	+	+	
Body weight reduction:	+(+)	+	++	+	+(+)	+++	++(+)	
Injection device:	+	+	++	(+)	+++	++	n.a.	
Conveniance/adherence:	(+)	+	++	+	+++	+++	+++?[b]	YES
CV benefit („MACE"):	not known	±	++	(+)	++	++	(+)	YES
Mortality benefit:	not known	±	++	(+)	±	±	±	YES
Renal benefit:	±	(+)	+	±	+	+	+	
Nausea/vomiting:	- -	-	- (-)	-	- (-)	- (-)	- (-)	
Immunogenicity[c]:	++	++	(+)	++	(+)	(+)	? (not known)	

Nauck MA et al. Eur J Endocrinol. 2019 Dec;181(6):R211-R234

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GLP-1 RA and Liver Disease

GLP-1 receptor agonists

- Induces weight loss
- Low risk of hypoglycemia
- Restores peripheral and hepatic insulin sensitivity
- Improves amiontransferases, hepatic steatosis/fibrosis in NAFLD/NASH
- May inhibit alcohol consumption in experimental models
- Eliminated by proteolytic degradation

- Limited therapeutic experience in advanced cirrhosis

Initial data on NASH and GLP-1 RA encouraging

Fasting serum GLP-1 levels were decreased in patients with chronic HCV, but not those with HBV

Yan J et al *Hepatology* 2019; 69: 2414-2426
Armstrong MJ, et al. . *Lancet* 2016; 387: 679-690
Chung et al. *World J Hepatol* 2020 September 27; 12(9): 533-692
Oriot P et al. Ann Endocrinol (Paris) 2011;72:244–246
Diabetes Care. 2012 May; 35(5): e34.

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NASH and GLP-1 RA

The NEW ENGLAND JOURNAL of MEDICINE

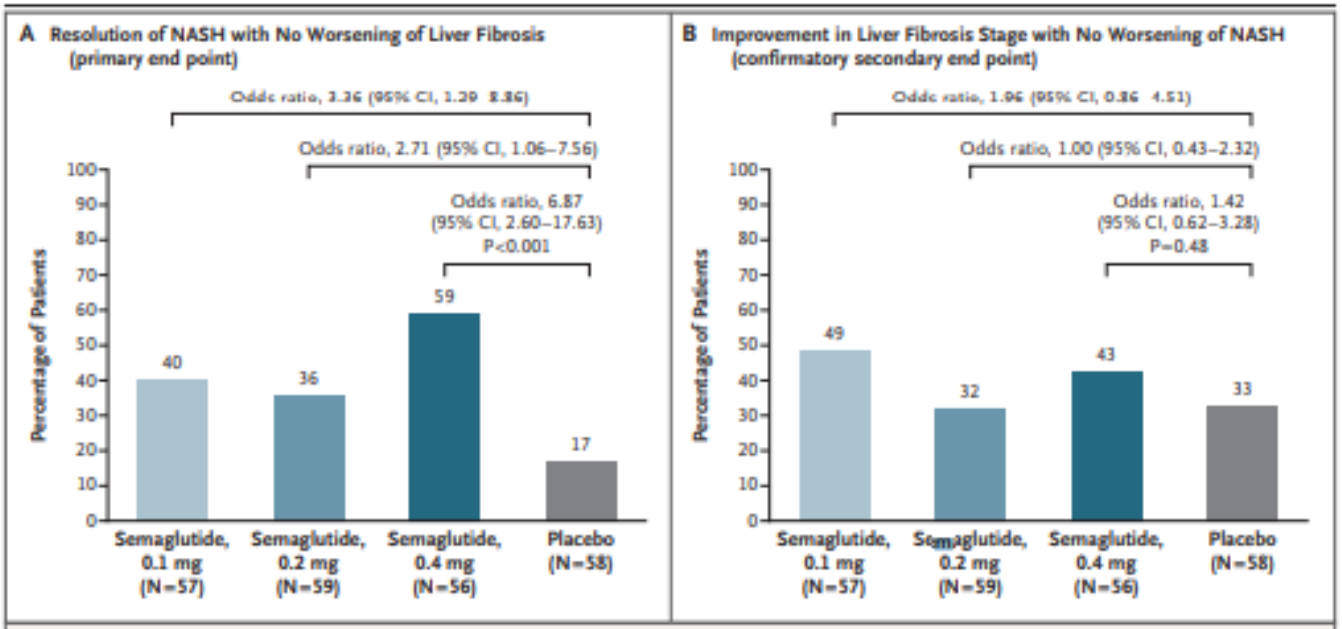

Figure 1. Primary and Secondary Confirmatory End Points.

Panel A shows the observed percentages of patients with stage F2 or F3 fibrosis in whom resolution of nonalcoholic steatohepatitis (NASH) was achieved by week 72 with no worsening of liver fibrosis (with worsening defined as an increase of one stage or more). Resolution was defined by the NASH Clinical Research Network as no more than mild residual inflammatory cells [score of 0 or 1] and no hepatocyte ballooning [score of 0]). Panel B shows the observed percentages of patients with stage F2 or F3 fibrosis who had an improvement of at least one fibrosis stage by week 72 with no worsening of NASH (with worsening defined as an increase of ≥1 point in either the lobular inflammation score or the hepatocyte ballooning score according to the NASH Clinical Research Network criteria). Data were analyzed with the use of a Cochran–Mantel–Haenszel test stratified according to baseline diabetes status and baseline fibrosis stage. Data from the in-trial observation period (from randomization until the last study-related procedure) were included, and missing outcome data were imputed as nonresponse.

NASH resolution/no worsening of fibrosis : 59% vs. 17% (P<0.001)

Improvement in fibrosis stage occurred in 43% and in 33% vs. (P=0.48).

N Engl J Med. 2020 Nov 13. doi:

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Summary: GLP-1 RAs

- Expensive
- May cause weight loss (8-12 pounds)
- CV benefit and renal benefit
- > 1% HbA1c reduction
- Weekly dosing likely improves compliance
- Low risk for hypoglycemia
- Oral version now available
- Nausea main side-effect
- I would consider in compensated cirrhosis especially NASH

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SODIUM-GLUCOSE CO-TRANSPORTER INHIBITORS (SGLT2I)

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Sodium-Glucose Co-Transporter Inhibitors (SGLT2I)

Class/Main Action	Name(s)	Daily Dose Range	Considerations
SGLT2 Inhibitors "Glucoretic" • Decreases glucose reabsorption in kidneys	Canagliflozin* (Invokana) Dapagliflozin* (Farxiga) Empagliflozin* (Jardiance) Ertugliflozin (Steglatro)	100 - 300 mg 1x daily Don't start if GFR <45. 5 - 10 mg 1x daily Don't start if GFR<45. 10 - 25 mg 1x daily Don't start if GFR <45. 5 – 15 mg 1x daily Don't start if GFR <60.	**Side effects:** hypotension, UTIs, increased urination, genital infections, ketoacidosis. **Monitor GFR and other considerations:** See package insert for dosing based on GFR. *Empagliflozin, Dapagliflozin, & Canagliflozin: - Reduce risk of CV death, heart failure and preserve long-term kidney function. **Benefits:** no hypo or weight gain. Lowers A1c 0.6%-1.5%. Lowers wt 1-3 lbs.

http://diabetesed.net/pocket-cards-insulin-and-diabetes-meds

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Sodium-Glucose Co-Transporter Inhibitors (SGLT2I)

TABLE. A1C REDUCTION VERSUS PLACEBO

Medication	Mean A1C Reduction (95% CI)
Canagliflozin 300 mg	−0.86% (−0.96 to −0.76)
Canagliflozin 100 mg	−0.76% (−0.86 to −0.66)
Dapagliflozin 10 mg	−0.66% (−0.74 to −0.58)
Dapagliflozin 5 mg	−0.56% (−0.67 to −0.44)
Empagliflozin 25 mg	−0.66% (−0.76 to −0.56)
Empagliflozin 10 mg	−0.60% (−0.70 to −0.50)

A1C = glycated hemoglobin.

Zaccardi F et al. *Diabetes Obes Metab*. 2016;18(8):783-794

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SGLT2 Inhibitors:

Warnings and Precautions - Canagliflozin/Dapagliflozin/Empagliflozin

- Hypoglycemia: risk with secretagogues, insulin
- Genital mycotic infections
- UTI, urosepsis
- Volume depletion/orthostatic changes
- DKA
- Bladder cancer (Dapagliflozin only)
  - removed recently
- Increased fracture risk
- Increased risk for amputation

Diabetes Care 2015;38:1638-1642
Diabetes Therr.. 2020 Jan; 11(1): 7–1
Fralick M et al. *BMJ* 2020; 370 :m2812

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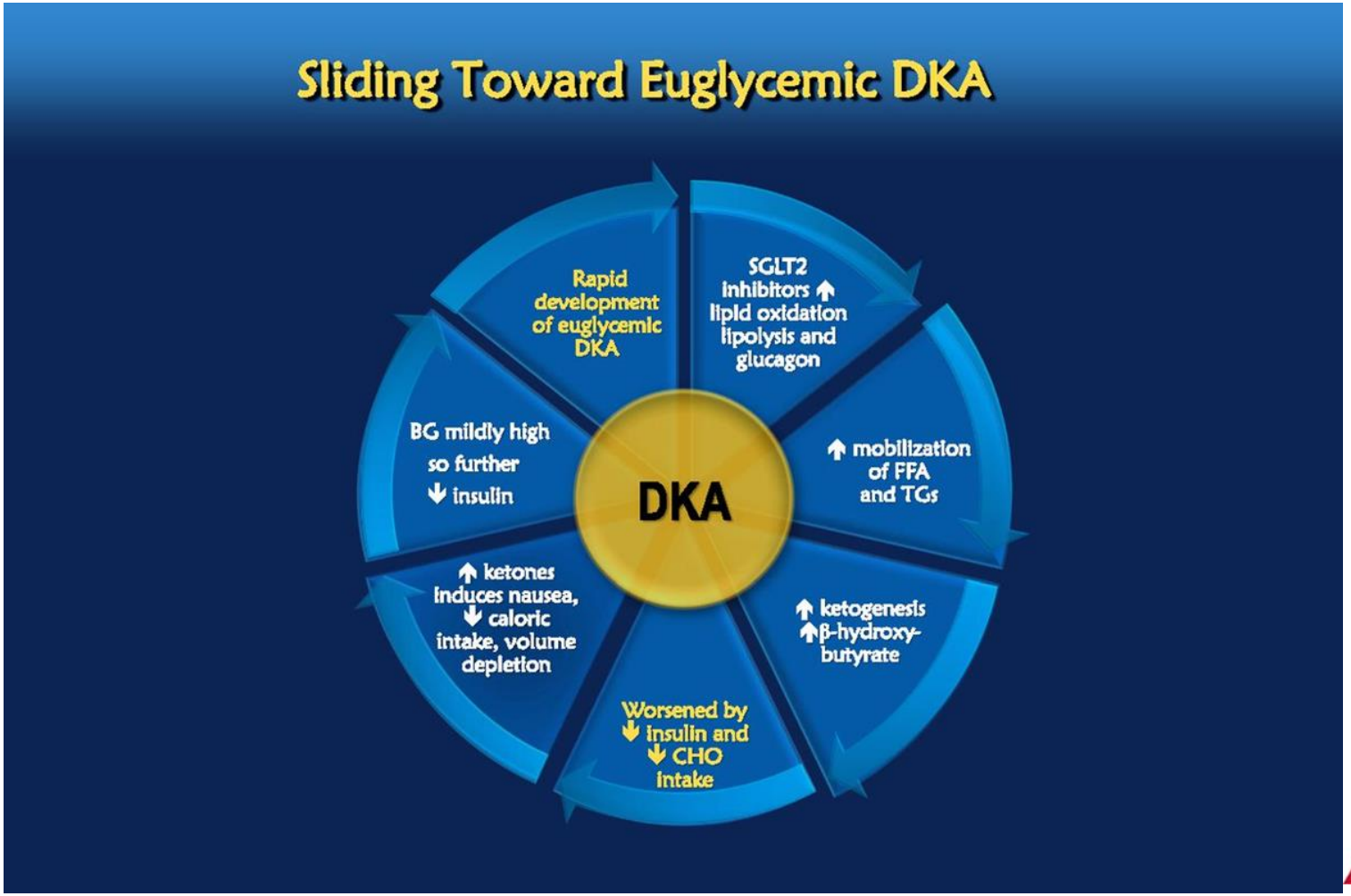
Demonstration of the cascade of clinical events and metabolic changes that contribute sequentially to progressive clinical deterioration and development of full-blown episodes of euDKA.



American Diabetes Association.

Diabetes Care 2015;38:1638-1642

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Risk for DKA , Genital Infections, Amputation and Factures

- DECLARE and EMPA-REG: less than 0.1% risk for DKA
- CANVAS: The estimated DKA incidence rates—0.5, 0.8, and 0.2 per 1,000 patient-years
- EMPA-REG OUTCOME: 22 vs 75 had genital infections
- Rare case reports of ARI and risk for orthostatic hypotension
- Fournier's gangrene
- CANVAS increased fracture risk (4% vs. 2.6%) but neutral in pooled non-CANVAS studies
- CANVAS Amputation (6.3% vs 3.4%) but neutral in recent large retrospective study

EMPA- REG N Engl J Med 2015; 373:2117-2128
Yu O et al.. Diabetes Care. 2020 Oct;43(10):2444-2452
CANVAS. Lancet Diabetes Endocrinol. 2018 Sep;6(9):691-704
DECLARE. N Engl J Med 2019; 380:347-357

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SGLT2 inhibitor use in CKD - For Glycemic Management

- Invokana (canagliflozin) < 45mL/min- Do Not use
- Jardiance (empagliflozin) < 45ml/min Do Not use
- Farxiga (dapagliflozin) < 60ml/min- Do Not Use
- Example: patient on empagliflozin GFR < 60 mL/min decrease to 10 mg daily when < GFR 45 mL/min stop
- At stage 3b CKD or greater, all SGLT-2 inhibitors are contraindicated, mainly because efficacy may be worst at GFR < 60mL/min

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Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy (CREDENCE)

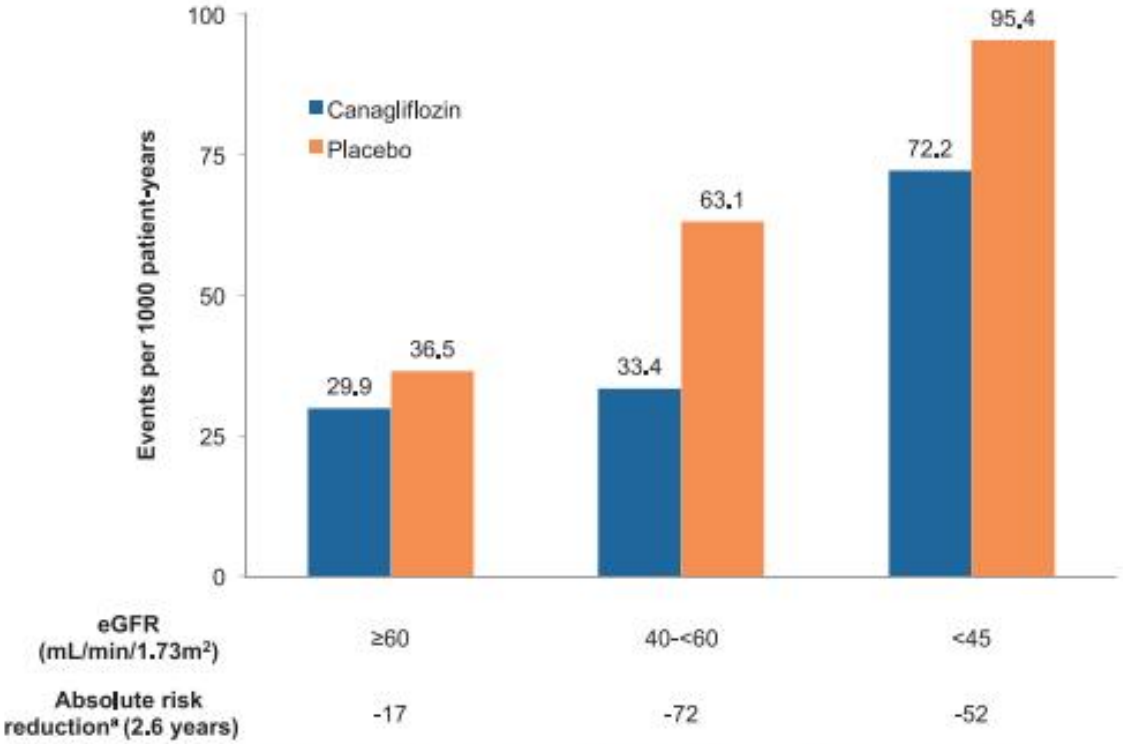

FIGURE 1: Estimated number of primary events (doubling of serum creatinine, ESKD or cardiovascular or kidney-related death) prevented per 1000 patients treated over 2.6 years in the CREDENCE trial by baseline eGFR. *Absolute risk reductions estimated as the number of events prevented per 1000 patients treated over 2.6 years.

ADA guidelines: SGLT2 inhibitors for the prevention of kidney failure, cardiovascular events or both in patients with an eGFR >30 mL/min/1.73 m2

**Especially with severely increased albuminuria

Neuen BL et al. *Nephrol Dial Transplant*. 2020;35(Suppl 1) i48–i55.

Perkovic V, et al. N Engl J Med. 2019 Jun 13;380(24):2295-2306

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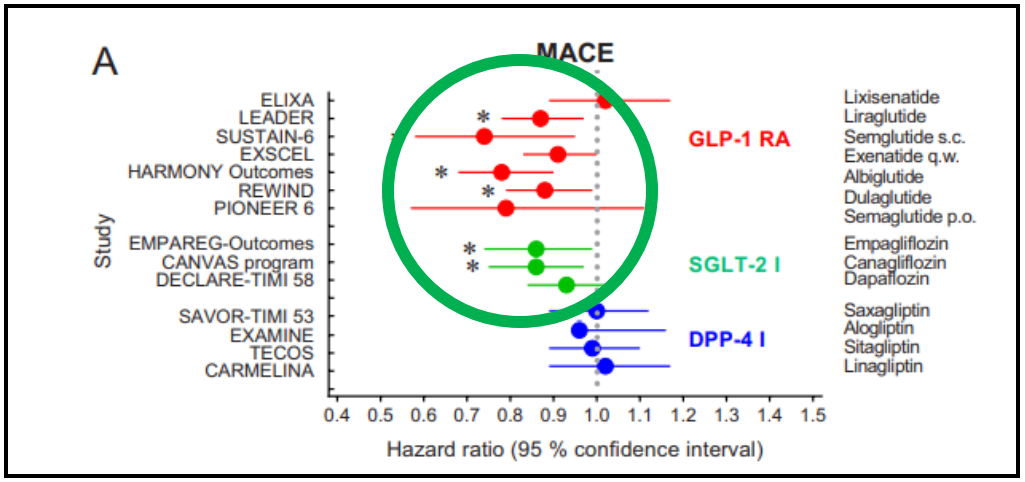
Canagliflozin: SGLT2I : For Renal and CV Benefit

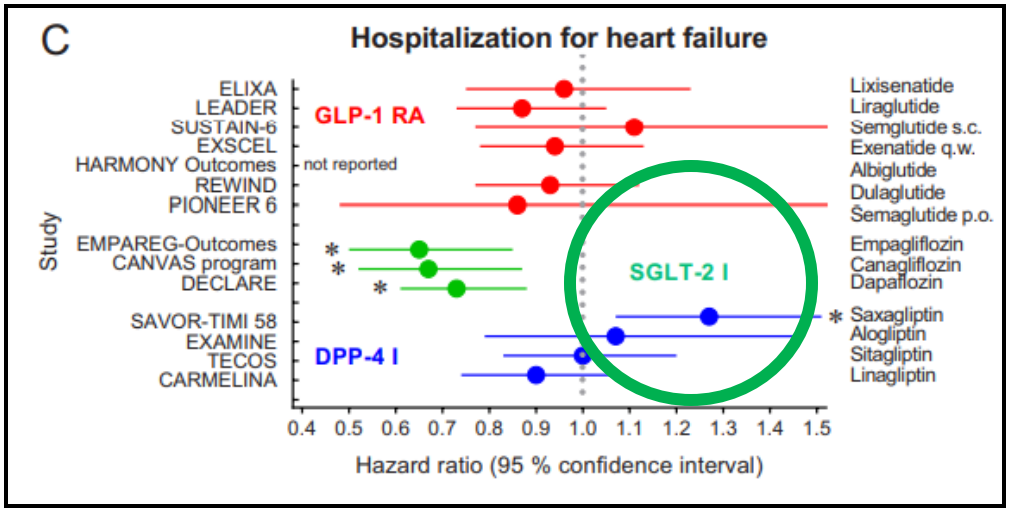
- GFR ≥60 mL/min/1.73 m^2: No dosage adjustment necessary.
- eGFR 30 to <60 mL/min/1.73 m^2: 100 mg qDay.
- eGFR <30 mL/min/1.73 m^2 with albuminuria >300 mg/day: 100 mg qDay to reduce risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for heart failure.

CV Outcomes Comparison



CV Benefits and All Cause Mortality Benefit for GLP-1 RA & SGLT-2 I

**Heart Failure Benefit only in SGLT-2I



Nauck MA et al. Eur J Endocrinol. 2019 Dec;181(6):R211-R234

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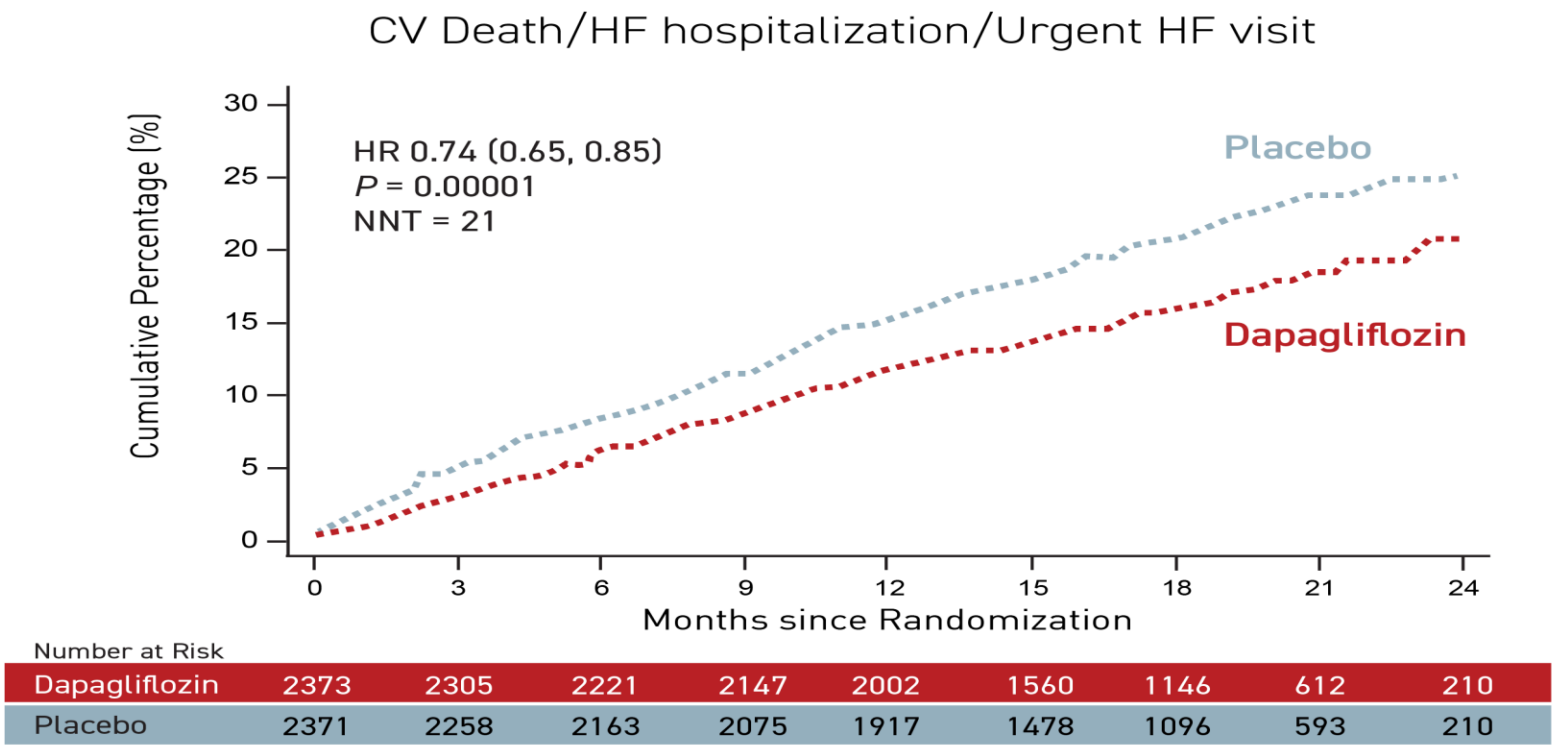
Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction With and Without DM

Primary Composite Outcome



Adapted from McMurray JJV et al. As presented during ESC Congress 2019, Hot Line Session 1.

The Medical Xchange

N Engl J Med 2019; 381:1995-2008

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SGLT-2 Inhibitors and Liver Disease

SGLT-2 inhibitors

- Induces weight loss
- Low risk of hypoglycemia
- Improves hepatic steatosis on imaging and hepatic fibrosis markers in NAFLD/NASH

- Increased risk of urinary and genital tract infections
- Limited therapeutic experience in advanced cirrhosis

? Attenuate HCC development

Benefit in NASH

World J Hepatol 2020 September 27; 12(9): 533-692

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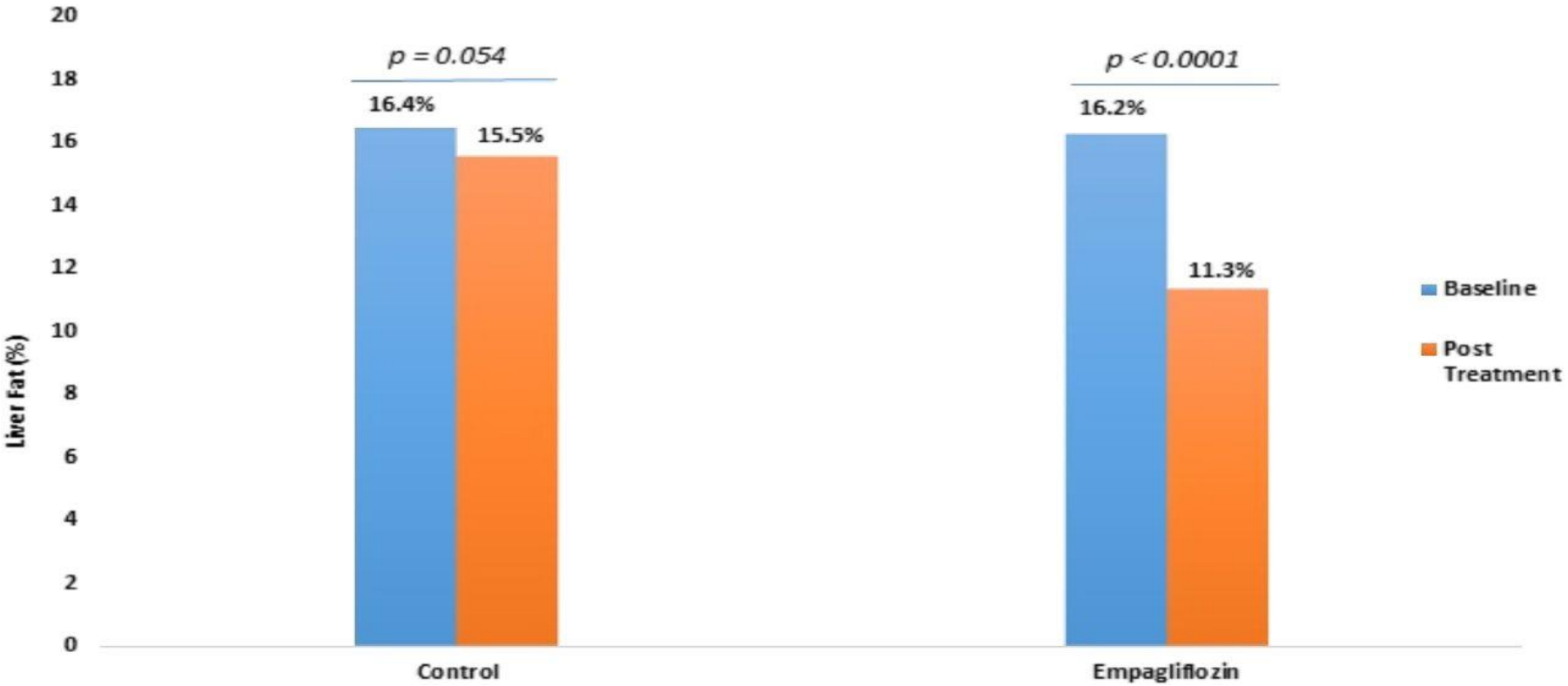
Baseline and posttreatment changes in liver fat in the empagliflozin and control groups as assessed by MRI-PDFF.



American Diabetes Association.

Mohammad Shafi Kuchay et al. Dia Care 2018;41:1801-1808

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Summary: SGLT2 inhibitors

- CV and renal benefit for patients with DM
- HF benefit for patients with and without DM
- Risk for DKA, UTI, genital infections, amputation, bone loss
- Some weight loss
- Overall can be well tolerated
- NASH benefit and promising potential in liver disease but not well studied
- HbA1c drop is usually < 1.0%
- More expensive: Consider using 150 canagliflozin or 12.5mg empagliflozin (cut tablet in ½)

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Conclusions

- Some medications for the treatment of T2D have cardiovascular and reno-protective effects in the those with CVD or are high-risk for CVD
- As well certain medications help initiate weight loss and are less likely to cause hypoglycemia than other agents
- Cost must be a factor in use of these medications
- Evolving data on diabetes medications for NASH and in Hep C and other chronic liver disease and limited data in HIV




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AETC AIDS Education & Training Center Program Mountain West