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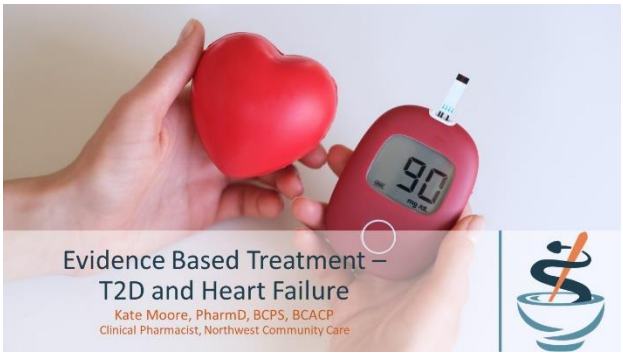
Evidence Based Treatment – T2D and Heart Failure



Faculty
Kate Moore, PharmD, BCPS, BCACP
Clinical Pharmacist,
Northwest Community Care

Co-morbidities are common in patients with heart failure, with evidence showing over half of these patients suffer from an additional chronic disease state. One of those disease states is diabetes. The inter-relationship between heart failure and diabetes has been well documented with estimations of 20-40% of patients with heart failure also having diabetes. Diabetes is also an independent risk factor for developing heart failure and patients are up to two times more likely to develop heart failure than someone without diabetes. We developed this activity to address the potential gaps in pharmacist knowledge of the importance of guideline directed medical therapy and the impact on heart failure related outcomes and the expanded indications of previously approved glucose lowering therapies in patients with type 2 diabetes and established cardiovascular disease.

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Learning Objectives

Pharmacist

1. Outline the guideline directed medical therapy for patients with co-morbid diabetes and cardiovascular disease
2. Compare and contrast evidence-based treatment options that optimize glycemic control and reduce cardiovascular events in patients with co-morbid type 2 diabetes and cardiovascular disease and in those with heart failure alone.
3. Describe a patient with heart failure who would benefit from the addition of a SGLT2 inhibitor to their medication therapy.
4. Identify appropriate strategies to communicate the evidence-based treatment approaches for patients with comorbid diabetes and heart failure to both patients and members of the healthcare team.

Pharmacy Technician

1. Outline the guideline directed medical therapy for patients with co-morbid diabetes and cardiovascular disease
2. Compare and contrast evidence-based treatment options that optimize glycemic control and reduce cardiovascular events in patients with co-morbid type 2 diabetes and cardiovascular disease and in those with heart failure alone.
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Nurse

1. Outline the guideline directed medical therapy for patients with co-morbid diabetes and cardiovascular disease
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Target Audience

Pharmacists, Pharmacy Technicians, Nurses

Universal Activity Number

Pharmacist	Pharmacy Technician	Nurse
0798-0000-20-185-H01-P	0798-0000-20-185-H01-T	0798-0000-20-185-H01-N

Credit Hours

1.5 Hours

Activity Type

Knowledge-Based

CE Broker Tracking Number

20-791524

Activity Release Date

September 9, 2020

Activity Offline Date

September 9, 2021

ACPE Expiration Date

September 2, 2023

Educational Support Provided By

AstraZeneca

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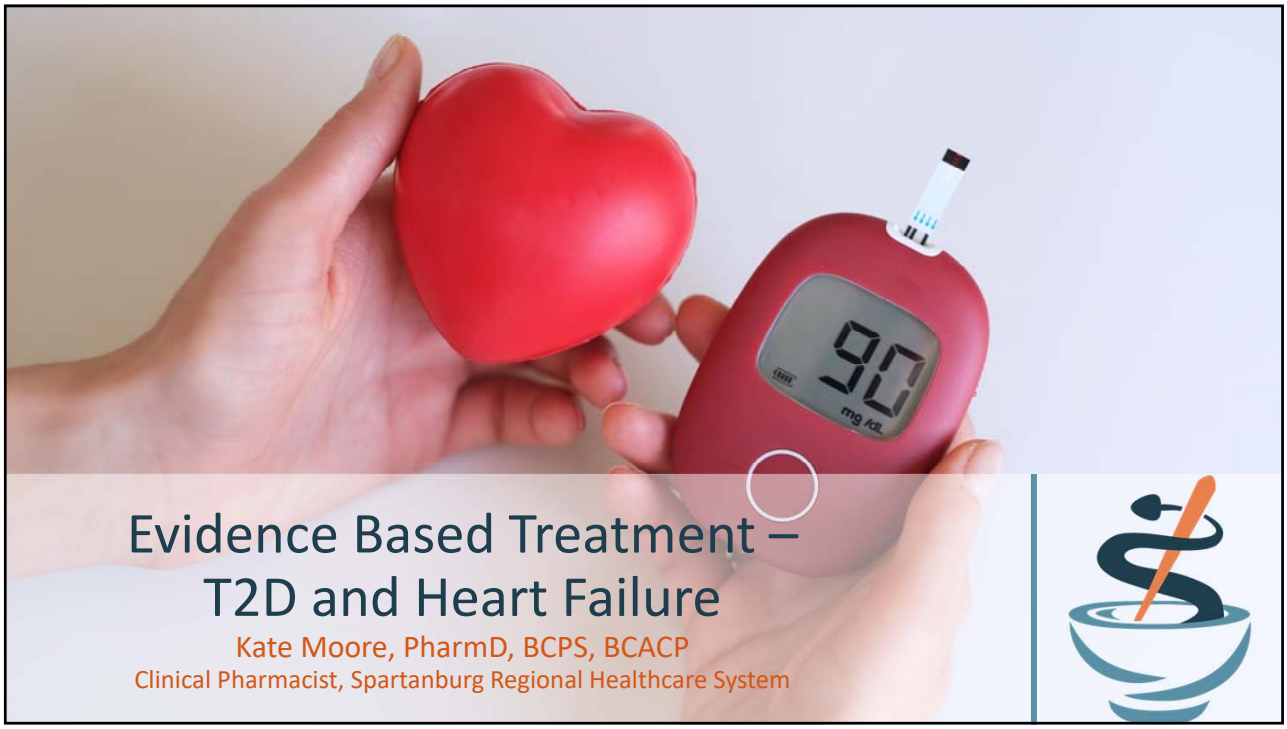

Evidence Based Treatment – T2D and Heart Failure

Kate Moore, PharmD, BCPS, BCACP
Clinical Pharmacist, Spartanburg Regional Healthcare System

1

Faculty Disclosure

- Kate Moore declares no existence of a financial interest in any amount related to the content of this activity.
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2

Learning Objectives

At the conclusion of this activity, participants should be better able to:

- Outline guideline directed medical therapy for patients with co-morbid type 2 diabetes (T2DM) and cardiovascular disease
- Compare and contrast evidence-based treatment options that optimize glycemic control and reduce cardiovascular events in patients with co-morbid T2DM and cardiovascular disease and in those with heart failure alone.
- Describe a patient with heart failure who would benefit from the addition of a SGLT2 inhibitor to their medication therapy.
- Identify appropriate strategies to communicate the evidence-based treatment approaches for patients with co-morbid T2DM and heart failure to both patients and members of the healthcare team.

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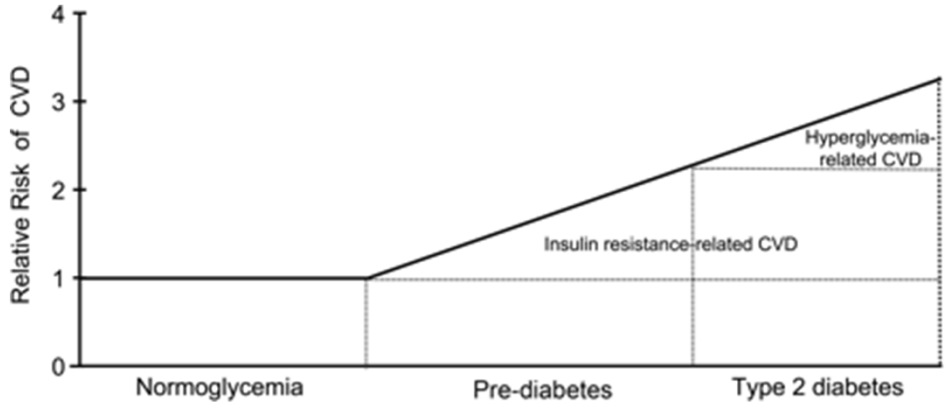
3

Cardiovascular Disease & T2DM



- Diabetes Care 2010;33:442-49

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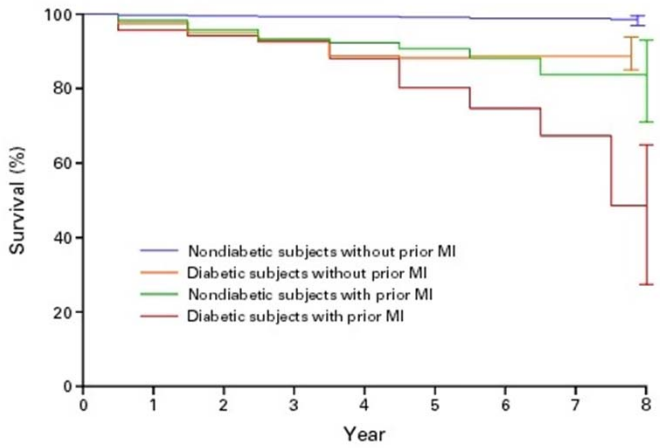
Cardiovascular Disease Mortality & T2DM



- NEJM 1998; 339:229-234

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FDA Requires CV Outcome Trials (CVOT)

- 2008
  - Required for all new therapies for T2DM
  - "demonstrate no unacceptable increase in CV risk"
  - Most designed to show non-inferiority of new drug vs placebo/standard of care
- New 2020 *draft* guidance
  - Include safety data beyond ischemic CV disease
  - Include older patients
  - Include more chronic kidney disease
  - Does not require all new therapies to rule out risk of ischemic CV disease

- www.fda.gov

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6

Case 1

"My best friend just had a heart attack and I'm worried"

- 59 years old, white male
- PMH
  - Hypertension
  - T2DM
  - GERD
- Objective information:
  - BP: 134/82 mmHg
  - Wt: 254 lbs (BMI 35.4 kg/m^2)
  - eGFR: 75 ml/min/m^2
  - HbA1c: 8.9% (3 weeks ago)
  - TC: 198, HDL 48, LDL 125, TG 240
- ASCVD score 19.7% (10 yr risk)
- Medications:
  - Metformin 1000 mg twice daily
  - Glipizide 10mg daily
  - Sitagliptin 100mg daily
  - Pravastatin 40mg daily
  - Omeprazole 40mg daily
  - Lisinopril 20mg daily
  - Amlodipine 10mg daily

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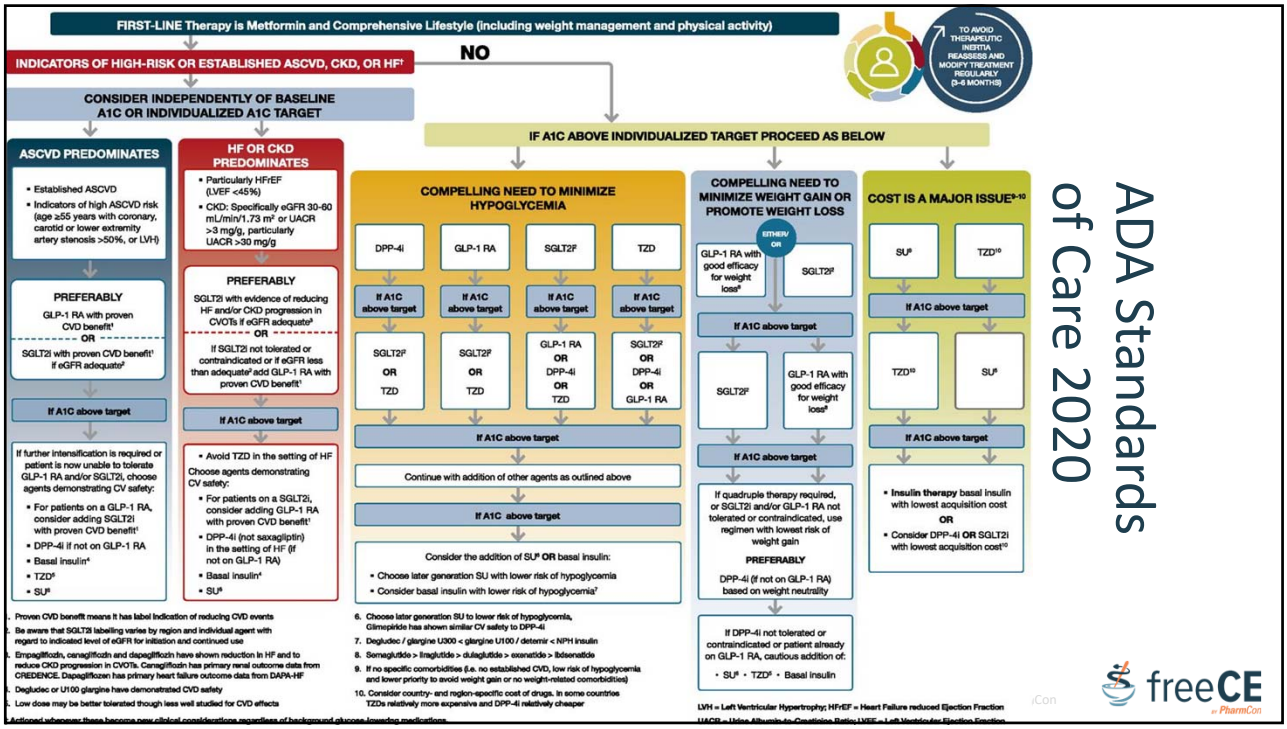

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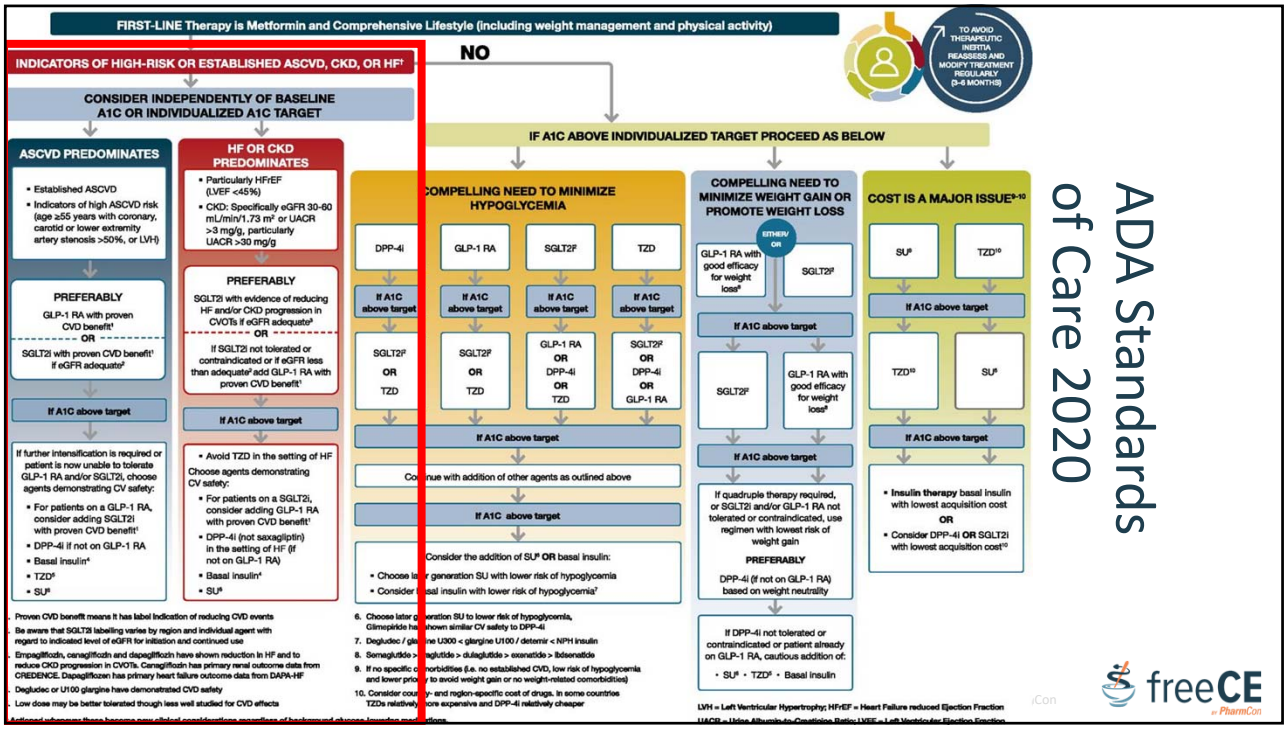

9

DM Medications and CV Outcomes

Metformin	• Decrease mortality and risk of MI when started at diagnosis in overweight patients (UKPDS)
Sulfonylureas	• Possible link to increased CV mortality
TZD (Thiazolidinediones)	• Increase risk of heart failure • Potential link between rosiglitazone and increased risk of MI and death
DPP-4 inhibitors (Dipeptidyl Peptidase-4 Inhibitors)	• Sitagliptin, linagliptin, alogliptin likely neutral effect • Saxagliptin increases risk of hospitalization for heart failure
GLP-1 receptor agonists (Glucagon-like Peptide-1 Agonists)	• liraglutide, semaglutide (inj), dulaglutide decrease in MI, stroke, CV death • Neutral effect: lixisenatide, exenatide, semaglutide (oral)
SGLT-2 Inhibitors (Sodium-Glucose Cotransporter 2)	• empagliflozin, canagliflozin decrease MI, stroke, CV death • Dapagliflozin decrease CV death and worsening HF in patients with HF

Pre-CVOT

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Pre-CVOT

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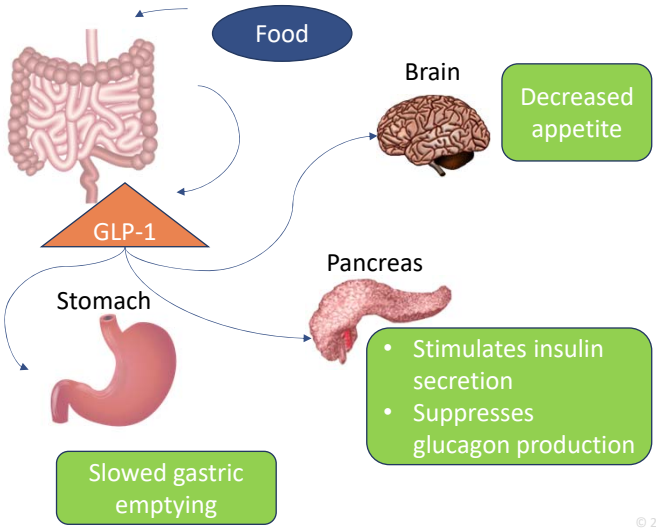
11

GLP-1 Receptor Agonists



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GLP-1 Receptor Agonists

Product	Route of administration	Dosing	FDA Indications
Exenatide	SQ injection	5-10mg twice daily	T2DM
Exenatide ER	SQ injection	2mg once weekly	T2DM
Dulaglutide	SQ injection	0.75-1.5mg once weekly	T2DM, risk reduction of CV events with DM & *CVD or multiple risk factors*
Liraglutide	SQ injection	0.6 x 1 week, 1.2-1.8mg daily	T2DM, risk reduction of CV events with DM & CVD
Lixisenatide	SQ injection	10mg x 2 week, 20mg daily	T2DM
Semaglutide	SQ injection	Weekly	T2DM, risk reduction of CV events with DM & CVD
Semaglutide	Oral	3mg x 1 month, then 7-14mg daily	T2DM

Adverse Effects:
- Nausea, vomiting, diarrhea
- black box warning against use in patients with family history of medullary thyroid cancer or multiple endocrine neoplasia-2

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GLP-1 & CV outcomes

	Dulaglutide REWIND
Comparison	Dulaglutide 1.5mg vs placebo
Population	31% with CVD, baseline A1c ~7.3%, BMI 32, Avg BP 137/78, 66% on statin, 8% with HF
N	9901
Follow-up (years)	5.4
MACE outcome HR (95% CI)	0.88 (0.79-0.99) (NNT 72)
Trial highlights	Long duration, largely primary prevention population, outcome driven by reduction in strokes
reference	Lancet 2019;394 (10193):121-130

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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GLP-1 & CV outcomes

	Dulaglutide REWIND	Liraglutide LEADER
Comparison	Dulaglutide 1.5mg vs placebo	Liraglutide 1.8mg vs placebo
Population	31% with CVD, baseline A1c ~7.3%, BMI 32, Avg BP 137/78, 66% on statin, 8% with HF	82% with CVD, baseline A1c 8.7%, BMI 32.5, avg BP 136/77, 72% on statin, 17.9% with HF
N	9901	9340
Follow-up (years)	5.4	3.8
MACE outcome HR (95% CI)	0.88 (0.79-0.99) (NNT 72)	0.87 (0.78-0.97) (NNT 53)
Trial highlights	Long duration, largely primary prevention population, outcome driven by reduction in strokes	Largely secondary prevention, outcome driven by reduction in death
reference	Lancet 2019;394 (10193):121-130	NEJM 2016;374 (4): 311-322

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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GLP-1 & CV outcomes

	Dulaglutide REWIND	Liraglutide LEADER	Semaglutide SUSTAIN-6
Comparison	Dulaglutide 1.5mg vs placebo	Liraglutide 1.8mg vs placebo	Semaglutide 0.5mg or 1mg vs placebo
Population	31% with CVD, baseline A1c ~7.3%, BMI 32, Avg BP 137/78, 66% on statin, 8% with HF	82% with CVD, baseline A1c 8.7%, BMI 32.5, avg BP 136/77, 72% on statin, 17.9% with HF	83% with CVD, baseline A1c 8.7%, avg BP 135/77, BMI 32.5, 72% on statin, 23% with HF
N	9901	9340	3297
Follow-up (years)	5.4	3.8	2.1
MACE outcome HR (95% CI)	0.88 (0.79-0.99) (NNT 72)	0.87 (0.78-0.97) (NNT 53)	0.74 (0.58-0.95) (NNT 44)
Trial highlights	Long duration, largely primary prevention population, outcome driven by reduction in strokes	Largely secondary prevention, outcome driven by reduction in death	Largely secondary prevention, outcome driven by reduction in non-fatal stroke, reduction seen in revascularization
reference	Lancet 2019;394 (10193):121-130	NEJM 2016;374 (4): 311-322	NEJM 2016;375(19): 1834-44

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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GLP-1 Receptor Agonists
CVOT and Harms

	Dulaglutide vs placebo REWIND	Liraglutide vs placebo LEADER	Semaglutide (0.5-1mg) vs placebo (0.5-1mg) SUSTAIN-6
Any serious adverse event		49.7 vs 50.4 (p=0.12)	33-35.6 vs 39.9-36.1
Acute pancreatitis	0.5 vs 0.3 (p=0.01)	0.4 vs 0.5 (p=0.44)	0.7-0.4 vs 0.4-1.1
Thyroid cancer	0.1 vs 0.1 (p=0.21)	0 vs <0.1 (p=0.32)	--
Serious GI event	2.4 vs 2.4 (p=0.87)	--	50.7-52.3 vs 35.7-35.2
Hypoglycemia	1.3 vs 1.5 (p=0.38)	43.7 vs 45.6 (p=0.06)	23.1-21.7 vs 21.5-21
reference	Lancet 2019;394 (10193):121-130	NEJM 2016;374 (4): 311-322	NEJM 2016;375(19): 1834-44

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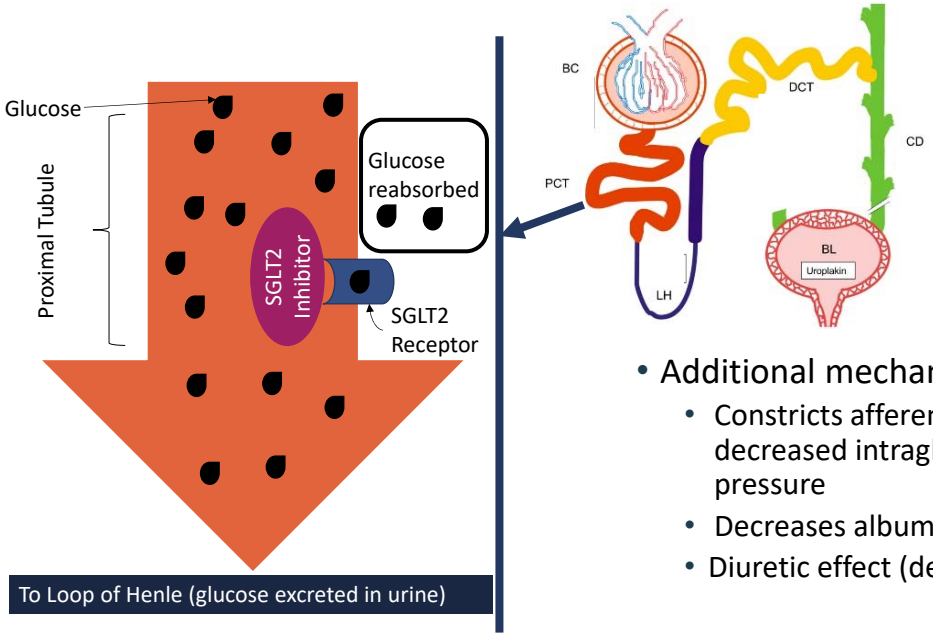
17

SGLT-2 Inhibitors



- Additional mechanisms:
  - Constricts afferent arteriole → decreased intraglomerular pressure
  - Decreases albuminurea
  - Diuretic effect (decreased BP)

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18

SGLT-2 Inhibitors

	Canagliflozin	Dapagliflozin	Empagliflozin	Ertugliflozin
FDA Indications	-Adjunct in T2DM -Risk reduction of major cardiovascular events in T2DM and established CV disease -Risk reduction of ESRD, doubling of SCr, CV death, and hospitalization for HF in T2DM & diabetic nephropathy	-Adjunct in T2DM -Risk reduction of HF hospitalization with T2DM and CV disease or multiple risk factors -Reduce risk of CV death and hospitalization for HF in HFrEF	-Adjunct in T2DM -Risk reduction of CV mortality with DM & established CV disease	-Adjunct in T2DM
Dosing	100mg daily 300mg daily	5mg daily 10mg daily	10mg daily 25mg daily	5mg daily 15mg daily
eGFR dose adjustment	eGFR 45-60 ml/min: 100mg/d eGFR <45 ml/min + >300 mg/d urine albumin: 100mg/d eGFR <45 ml/min + <300 mg/d urine albumin: do not use	Discontinue if eGFR <45 ml/min (unknown in HF)	Discontinue if eGFR <45 ml/min	Discontinue if eGFR <60 ml/min
Adverse Effects	Common: Genital mycotic infections, urinary tract infections, hypotension, volume depletion Rare/medication specific: increased fractures, amputations			

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19

SGLT-2 Inhibitors and CV Outcomes

	Canagliflozin CANVAS, CANVAS-R
Comparison	Canagliflozin 100mg or 300mg vs placebo
Population	66% had CVD, 14% had HF, avg BP 136/77, baseline A1c 8.2%, 75% on statin, BMI 32
N	4330
Follow-up (years)	2.4
MACE outcome HR (95% CI)	0.86 (0.75 - 0.97)
Trial highlights	lower rate of hospitalization for HF, 30% discontinued treatment early, increased risk of amputation of toe, lower rate of progression of albuminurea
reference	NEJM 2017;377:644-57

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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20

SGLT-2 Inhibitors and CV Outcomes

	Canagliflozin CANVAS, CANVAS-R	Dapagliflozin DECLARE TIMI 58
Comparison	Canagliflozin 100mg or 300mg vs placebo	Dapagliflozin 10mg vs placebo
Population	66% had CVD, 14% had HF, avg BP 136/77, baseline A1c 8.2%, 75% on statin, BMI 32	41% had CVD, mostly males, 10% had HF, baseline A1c 8.3%, avg SBP 135, 75% on statin, BMI 32
N	4330	17160
Follow-up (years)	2.4	4.2
MACE outcome HR (95% CI)	0.86 (0.75 - 0.97)	0.93 (0.84-1.03)
Trial highlights	lower rate of hospitalization for HF, 30% discontinued treatment early, increased risk of amputation of toe, lower rate of progression of albuminurea	lower rate of hospitalization for HF, 23% discontinued treatment early (genital infection, adverse event), lower rate of decrease in eGFR and progression to ESRD
reference	NEJM 2017;377:644-57	NEJM 2019;380:347-57

DECLARE TIMI 58 additional Primary outcome:
cardiovascular death or hospitalization from heart failure
HR 0.83 (0.73-0.95)
*Driven by reduction in hospitalization from HF

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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SGLT-2 Inhibitors and CV Outcomes

	Canagliflozin CANVAS, CANVAS-R	Dapagliflozin DECLARE TIMI 58	Empagliflozin EMPA-REG
Comparison	Canagliflozin 100mg or 300mg vs placebo	Dapagliflozin 10mg vs placebo	Empagliflozin 10mg or 25mg vs placebo
Population	66% had CVD, avg BP 136/77, baseline A1c 8.2%, 75% on statin, BMI 32	41% had CVD, mostly males, baseline A1c 8.3%, avg SBP 135, 75% on statin, BMI 32	75% had CVD, mostly male, baseline A1c 8%, avg BP 135/77, BMI 30, 77% on statin
N	4330	17160	7020
Follow-up (years)	2.4	4.2	3.1
MACE outcome HR (95% CI)	0.86 (0.75 - 0.97)	0.93 (0.84-1.03)	0.86 (0.74-0.99)
Trial highlights	lower rate of hospitalization for HF, 30% discontinued treatment early, increased risk of amputation of toe, lower rate of progression of albuminurea	lower rate of hospitalization for HF, 23% discontinued treatment early (genital infection, adverse event), lower rate of decrease in eGFR and progression to ESRD	Outcome driven by death from any cause and CV death, lower rate of hospitalization for HF, 25% discontinuation (similar between groups)
reference	NEJM 2017;377:644-57	NEJM 2019;380:347-57	NEJM 2015;373:2117-28

- MACE: Non-fatal MI, non-fatal stroke, death from CV cause

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22

SGLT-2 Inhibitors CVOT and Harms

	Canagliflozin vs Placebo (event rate per 1000 pt-yr)	Dapagliflozin vs Placebo (event rate)	Empagliflozin vs Placebo (event rate)
All serious adverse events	104.3 vs 120 (p=0.04)	34.1 vs 36.2 (p<0.001)	23.5 vs 25.4
DKA	0.6 vs 0.3 (p=0.14)	0.3 vs 0.1 (p=0.02)	0.1 vs <0.1
Amputations	6.3 vs 3.4 (p<0.001)	1.4 vs 1.3 (p=0.53)	--
Fracture	15.4 vs 11.9 (p=0.02)	5.3 vs 5.1 (p=0.59)	3.8 vs 3.9
Genital infection Male Female	 34.9 vs 10.8 (p<0.001) 68.8 vs 17.5 (p<0.001)	0.9 vs 0.1 (p<0.001)	 5 vs 1.5 10 vs 2.6
Volume depletion	26 vs 18.5 (p=0.009)	2.5 vs 2.4 (p=0.99)	5.1 vs 4.9
Hypoglycemia	50 vs 46.4 (p=0.2)	0.7 vs 1 (p=0.02)	27.8 vs 27.9
reference	NEJM 2017;377:644-57	NEJM 2019;380:347-57	NEJM 2015;373:2117-28

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23

Case 1
Optimize Medications to Reduce CV Risk

- 59 years old, white male
- PMH
  - Hypertension
  - T2DM (15 years)
  - GERD
- Objective information:
  - BP: 134/82 mmHg
  - Wt: 254 lbs (BMI 35.4 kg/m^2)
  - eGFR: 75 ml/min/m^2
  - HbA1c: 8.9% (3 weeks ago)
  - TC: 198, HDL 48, LDL 125, TG 240
- ASCVD score 19.7% (10 yr risk)
- Medications:
  - Metformin 1000 mg twice daily
  - Glipizide 10mg daily
  - Sitagliptin 100mg daily
  - Pravastatin 40mg daily
  - Omeprazole 40mg daily
  - Lisinopril 20mg daily
  - Amlodipine 10mg daily

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24

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25

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  - Sitagliptin 100mg daily
  - Pravastatin 40mg daily
  - Omeprazole 40mg daily
  - Lisinopril 20mg daily
  - Amlodipine 10mg daily

Dulaglutide 0.75mg weekly (stop sitagliptin & glipizide)
OR
Empagliflozin 10mg daily (consider stopping glipizide)

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26

Type 2 DM and Heart Failure

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27

Heart Failure & T2DM

- Patients with HF have 4-fold higher prevalence of T2DM
- Patients with T2DM have 75% higher risk of CV death or HF hospitalization
  - 2.5-fold increased risk of developing HF

- European Heart Journal 2018;39:4243-54, Diabetes Care 2004;27:699-703, Circulation 2017;135:724-35, Diabetes Care 2004;27:1879-1884

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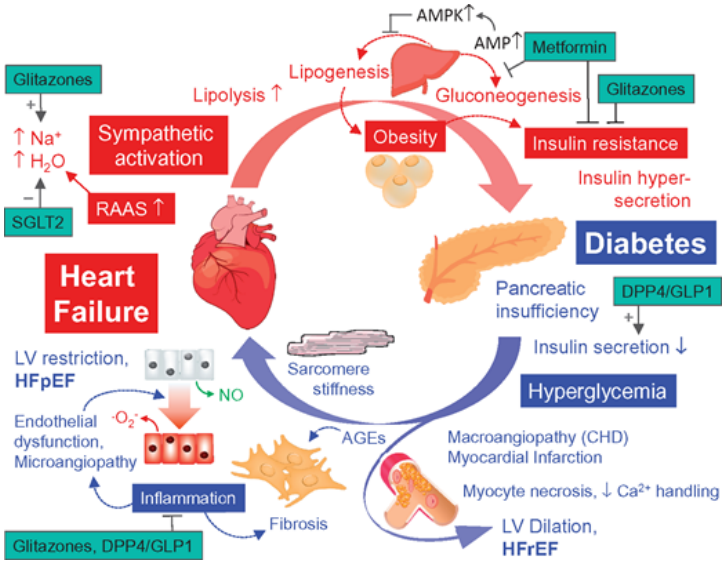
28

Heart Failure & T2DM

- Patients with HF have 4-fold higher prevalence of T2DM
- Patients with T2DM have 75% higher risk of CV death or HF hospitalization
  - 2.5-fold increased risk of developing HF



- European Heart Journal 2018;39:4243-54, Diabetes Care 2004;27:699-703, Circulation 2017;135:724-35, Diabetes Care 2004;27:1879-1884

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29

Heart Failure

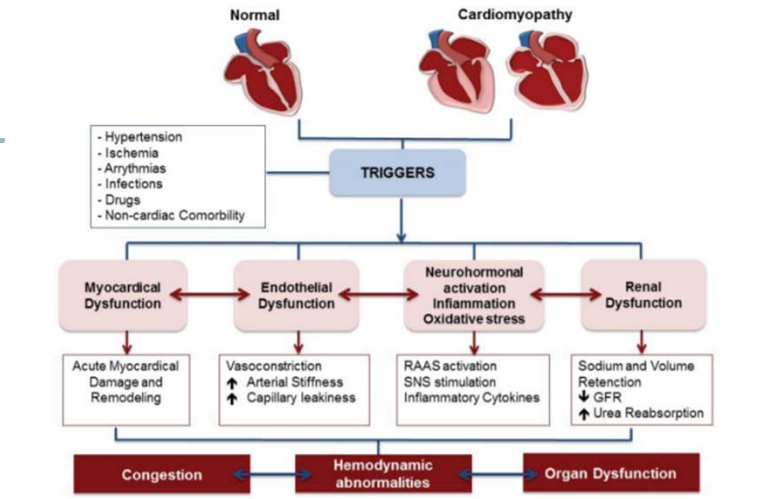

Figure 7: Complex pathophysiological mechanism of AHF: AHF combines a substrate and a triggering factor that may be the myocardial, vascular, neurohormonal, inflammatory and renal, which lead to severe acute hemodynamic abnormalities with congestion and organ dysfunction. RAAS: Renin Angiotensin Aldosterone System; SNS: Sympathetic Nervous System; GFR: Glomerular Filtrate Rate. Modified from ref [1].

- Int J Crit Care Emerg Med 2017;3:6-10

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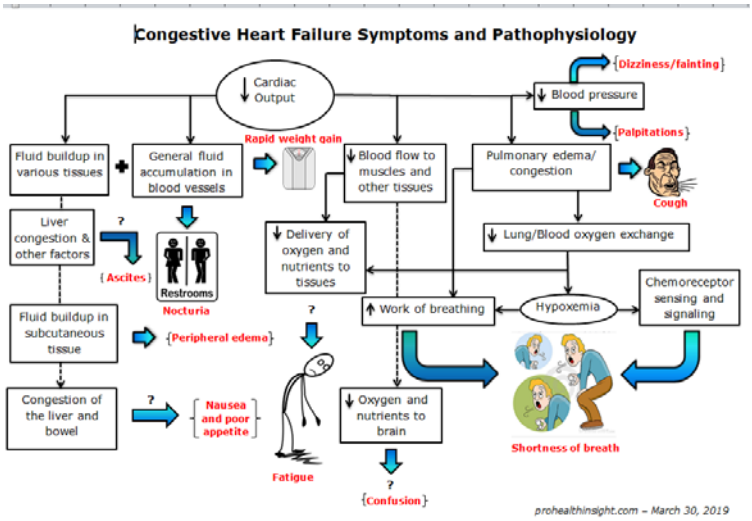
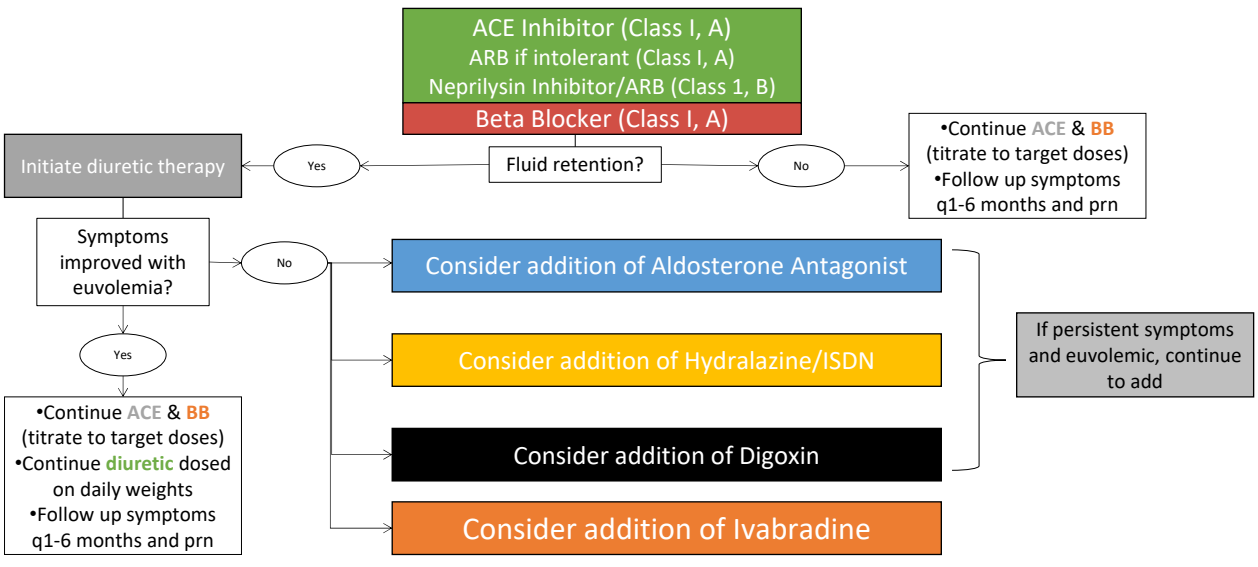
30

Heart Failure Symptoms & Pathophysiology



31

HFrEF Treatment Algorithm



- J Am Coll Cardiol. 2013;62(16):e147-e239
- J Am Coll Cardiol. 2017:70(6):776-803

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Case 2

- 56 years old, white male
- PMH
  - T2DM (2010)
  - Hypertension (2008)
  - MI (2015)
  - Heart Failure (2016)
- Objective information:
  - BP: 137/78 mmHg
  - Wt: 337 lbs (BMI 43 kg/m^2)
  - eGFR: 82 ml/min/m^2
  - HbA1c: 8.1% (1 week ago)
  - TC: 106, HDL 32, LDL 63, TG 54
  - EF 30%

- Medications:
  - Metformin 1000 mg twice daily
  - Lantus 26 units at bedtime
  - Glimepiride 4mg daily
  - Atorvastatin 40mg daily
  - Sacubitril-valsartan 97/103mg twice daily
  - Carvedilol 25mg twice daily
  - Spironolactone 25mg daily
  - Furosemide 40mg daily
  - Aspirin 81mg daily

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33

DM Medications and HF outcomes

Trial	Comparison	HF at baseline	Hospitalization for HF (HHF)	Summary
ACE	Acarbose vs placebo	--	0.89 (0.63-1.24)	No impact
Bari 2D	Insulin + SU vs metformin + TZD	7%	16.6 % vs 19.4% (p=0.09)	No evidence of insulin having positive or negative impact on HF
Origin	Insulin glargine vs placebo	--	0.9 (0.77-1.05)	
DREAM	Rosiglitazone vs placebo	0%	7.04 (1.6-31)	TZDs have strong evidence to support increase in HHF in those with HF and without
PROactive	Pioglitazone vs placebo	0%	1.49 (1.23-1.8)	
GSK211	Rosiglitazone vs placebo	100%	7.09 (1.6-30.96)	
UKPDS	Sulphonylurea + insulin vs diet	--	0.91 (0.54-1.52)	Limited data to draw conclusion

- Am J Cardiol 2019;124:S12-19

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DPP-4 Inhibitors and HF outcomes

Trial	Comparison	HF at baseline	Hospitalization for HF (HHF)	Summary
SAVOR-TIMI 53	Saxagliptin vs placebo	13%	1.27 (1.07-1.51)	Saxagliptin shows increased risk of HHF, however others show neutral effect
EXAMINE	Alogliptin vs placebo	28%	1.19 (0.89 -1.58)	
TECOS	Sitagliptin vs placebo	18%	1.00 (0.83 -1.20)	
CARMELINA	Linagliptin vs placebo	27%	0.90 (0.74 - 1.08)	
CAROLINA	Linagliptin vs glimepiride	4%	1.1 (0.92 - 1.59)	

- Am J Cardiol 2019;124:S12-19

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GLP-1 Receptor Agonists and HF outcomes

Trial	Comparison	HF at baseline	Hospitalization for HF (HHF)	Summary
EXSCEL	Exenatide vs placebo	16.2%	0.94 (0.78-1.13)	Generally appear to have neutral effect on HHF. Trend in smaller trials of HF specific population is concerning for increased hospitalizations and cardiovascular events
REWIND	Dulaglutide vs placebo	8.6%	0.93 (0.77-1.12)	
ELIXA	Lixisenatide vs placebo	22%	0.96 (0.75-1.23)	
LEADER	Liraglutide vs placebo	17.8%	0.87 (0.73-1.05)	
FIGHT	Liraglutide vs placebo	100% (recent decompensation)	1.3 (0.89-1.88)	
LIVE	Liraglutide vs placebo	100%	10% vs 3% p=0.04 (death or hospitalization)	
SUSTAIN-6	Semaglutide vs placebo	23.6%	1.11 (0.77-1.61)	

- Am J Cardiol 2019;124:S12-19

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SGLT-2 Inhibitors and HF outcomes

Trial	Comparison	HF at baseline	Hospitalization for HF (HHF)	Summary
CANVAS	Canagliflozin vs placebo	14%	0.67 (0.52-0.87)	All in the class have a positive effect on reducing hospitalizations for heart failure
DECLARE-TIMI 58	Dapagliflozin vs placebo	10%	0.73 (0.61-0.88)	
EMPA-REG	Empagliflozin vs placebo	10%	0.65 (0.5-0.85)	
VERTIS-CV	Ertugliflozin vs placebo	--	2.5% vs 3.6% (p=0.006)	

- NEJM 2017;377:644-57, NEJM 2019;380:347-57, NEJM 2015;373:2117-28
- https://www.acc.org/latest-in-cardiology/clinical-trials/2020/06/16/11/24/vertis, accessed 7/30/2020

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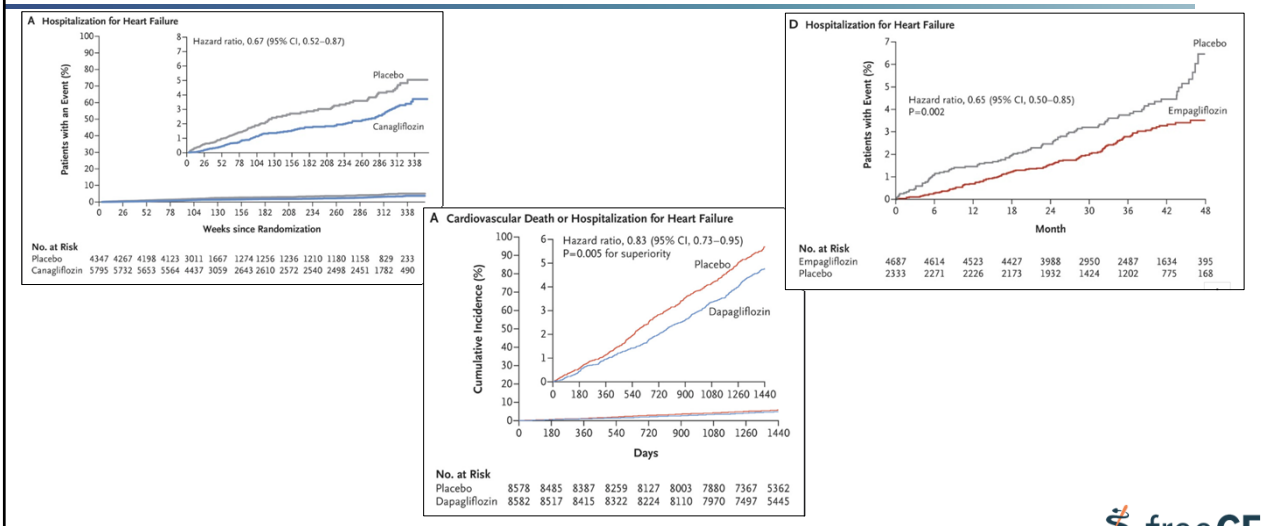
37

Kaplan-Meier Estimates for HHF



- NEJM 2017;377:644-57, NEJM 2019;380:347-57, NEJM 2015;373:2117-28

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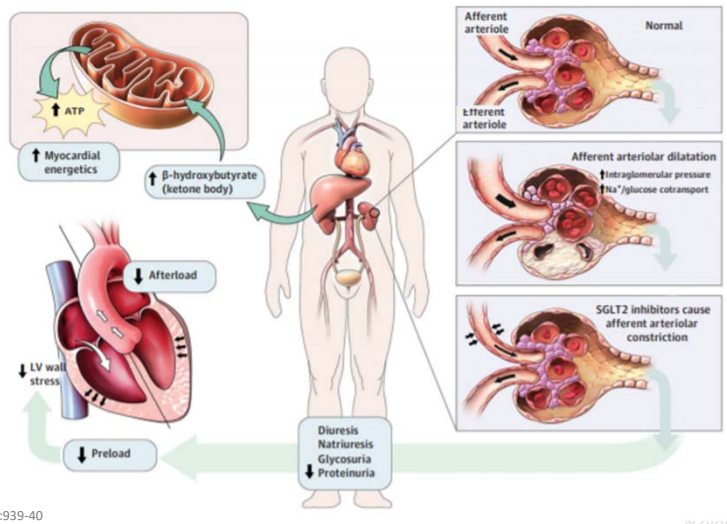
Mechanism Behind SGLT-2 & HF



- JAMA Cardiology 2017;2:939-40

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DM Medications & HF Summary

Likely Beneficial	Likely Harmful	Likely Neutral
• SGLT-2 Inhibitors	• TZDs • Saxagliptin	• Insulin • Acarbose • GLP-1 RA • DPP-4 (except saxagliptin)

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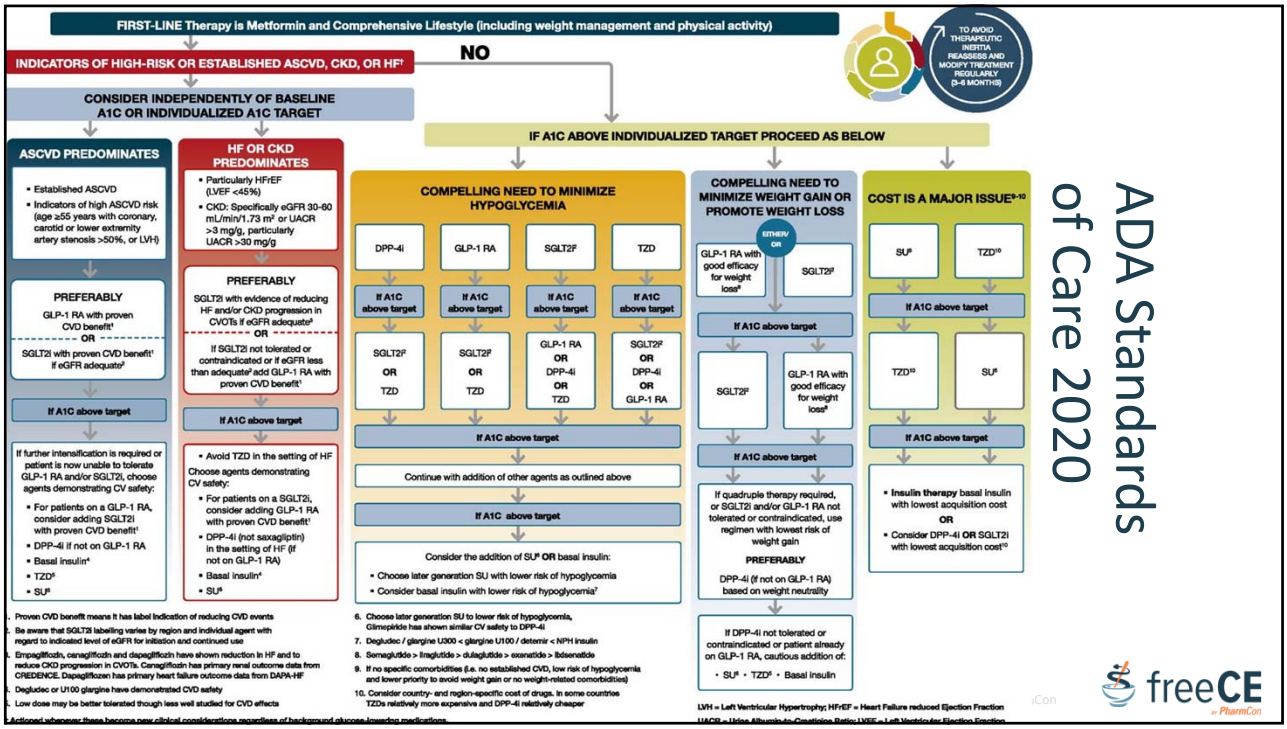
FIRST-LINE Therapy is Metformin and Comprehensive Lifestyle (including weight management and physical activity)
INDICATORS OF HIGH-RISK OR ESTABLISHED ASCVD, CKD, OR HF[1]
NO
TO AVOID THERAPEUTIC INERTIA REASSESS AND MODIFY TREATMENT REGULARLY (3–6 MONTHS)
CONSIDER INDEPENDENTLY OF BASELINE A1C OR INDIVIDUALIZED A1C TARGET
IF A1C ABOVE INDIVIDUALIZED TARGET PROCEED AS BELOW
ASCVD PREDOMINATES
HF OR CKD PREDOMINATES
COMPELLING NEED TO MINIMIZE HYPOGLYCEMIA
COMPELLING NEED TO MINIMIZE WEIGHT GAIN OR PROMOTE WEIGHT LOSS
COST IS A MAJOR ISSUE[9,10]
ADA Standards of Care 2020
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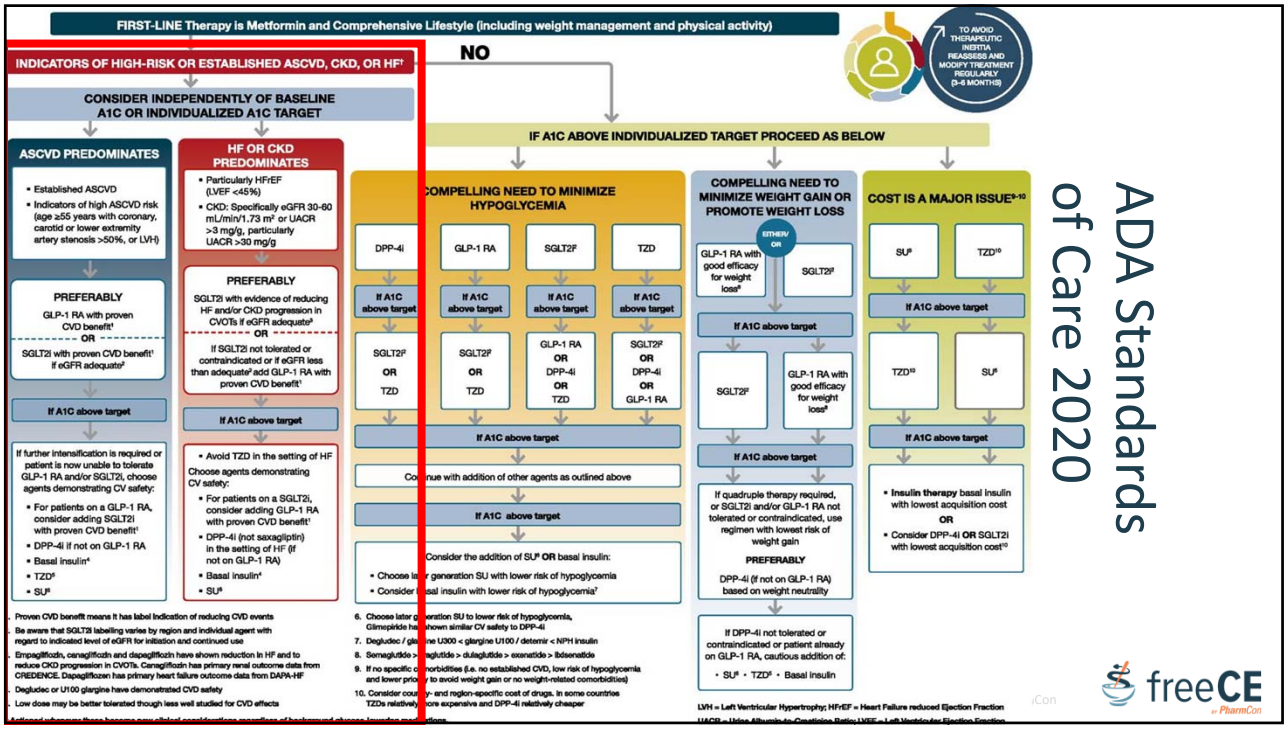
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ADA Standards of Care 2020
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42

Case 2
Optimize Medications for HF and DM

- 56 years old, white male
- PMH
  - T2DM (2010)
  - Hypertension (2008)
  - MI (2015)
  - Heart Failure (2016, last hospitalization 3 months ago)
- Objective information:
  - BP: 137/78 mmHg
  - Wt: 337 lbs (BMI 43 kg/m^2)
  - eGFR: 82 ml/min/m^2
  - HbA1c: 8.1% (1 week ago)
  - TC: 106, HDL 32, LDL 63, TG 54
  - EF 30%

- Medications:
  - Metformin 1000 mg twice daily
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  - Glimepiride 4mg daily
  - Atorvastatin 40mg daily
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43

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  - Spironolactone 25mg daily
  - Furosemide 40mg twice daily
  - Aspirin 81mg daily

Dapagliflozin 5mg daily

OR

Empagliflozin 10mg daily

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SGLT-2 Inhibitors and HF Without DM

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45

Case 3

- 52 years old male
  - SOB with moderate exertion and some fluid in his feet despite medication changes, following salt & fluid restrictions.
- PMH
  - Hypertension
  - MI
  - Heart Failure
  - BPH
  - GERD
- Objective information:
  - BP: 137/78 mmHg, HR 62 bpm
  - eGFR: 76 ml/min/m^2
  - EF 30%
  - Labs: Na: 135, K: 3.8 , BUN: 14, SCr: 0.9, Glucose: 89
- Medications:
  - Sacubitril/valsartan 97/103mg twice daily
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46

Classification of Heart Failure

ACC/AHA Heart Failure Stage	NYHA Functional Class
A. At risk for heart failure but without structural heart disease or symptoms	
B. Structural heart disease but without heart failure	I. Asymptomatic HF: no symptoms
C. Structural heart disease with prior or current heart failure symptoms	II. Mild HF: symptomatic with moderate exertion III. Moderate HF: symptomatic with minimal exertion
D. Refractory heart failure requiring specialized interventions	IV. Severe HF: symptomatic at rest

- J Am Coll Cardiol. 2013;62(16):e147-e239

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Classification of Heart Failure

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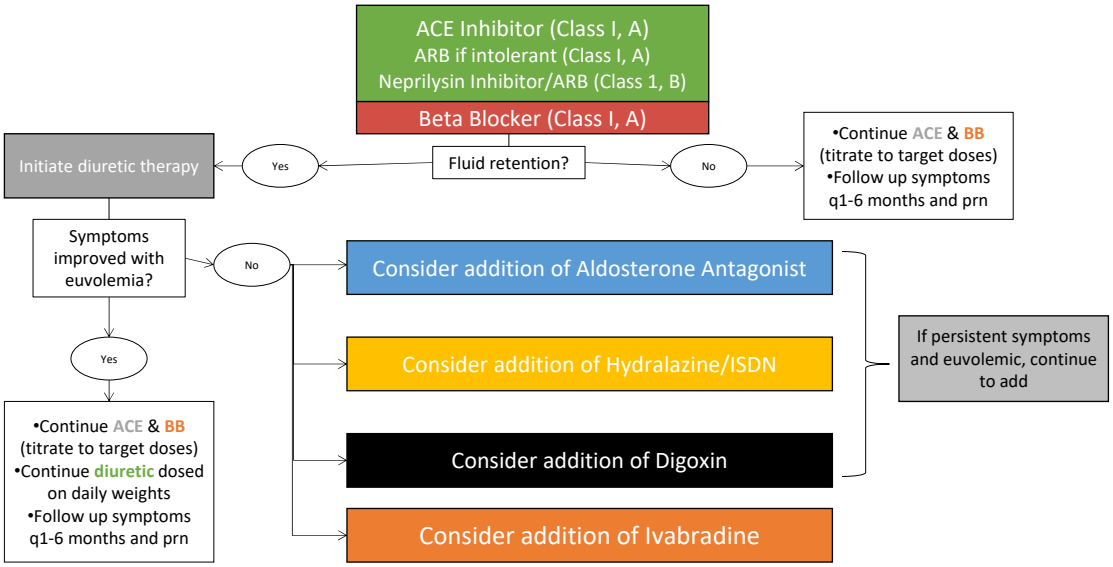
48

HFrEF Treatment Algorithm



- J Am Coll Cardiol. 2013;62(16):e147-e239
- J Am Coll Cardiol. 2017:70(6):776-803

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DAPA-HF Trial

- Objective: To evaluate the efficacy and safety of dapagliflozin in patients with HFrEF, regardless of the presence or absence of DM.

- NEJM 2019;381:1995-2008

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DAPA-HF Trial

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- NEJM 2019;381:1995-2008

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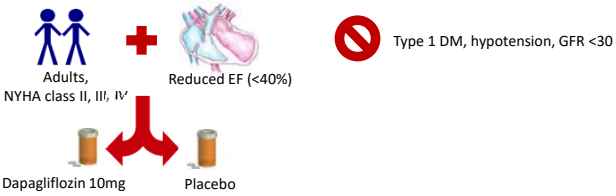

- NEJM 2019;381:1995-2008

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DAPA-HF Trial

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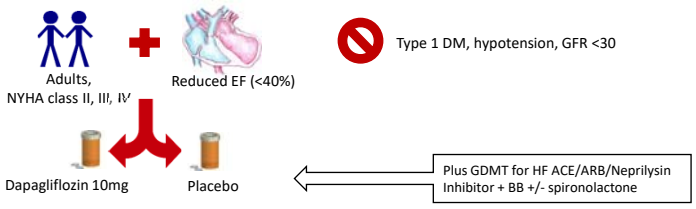

- NEJM 2019;381:1995-2008

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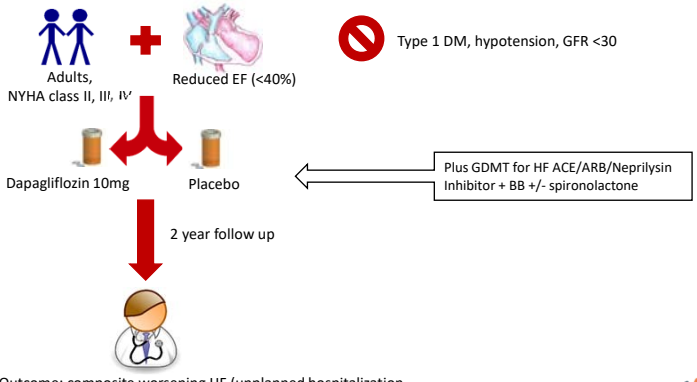

Primary Outcome: composite worsening HF (unplanned hospitalization, urgent visit with IV therapy) or death from CV cause

- NEJM 2019;381:1995-2008

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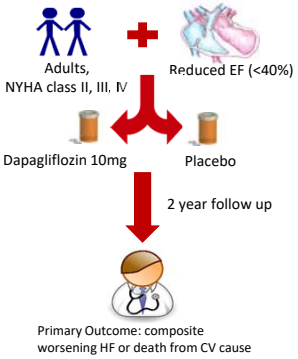
DAPA-HF Trial Baseline Characteristics

Objective: To evaluate the efficacy and safety of dapagliflozin in patients with HFrEF, regardless of the presence or absence of DM.



- NEJM 2019;381:1995-2008

	Dapagliflozin N=2373	Placebo N=2371
Age (yr)	66.2 yr	66.5
BMI	28.2	28.1
White (%)	70	70.5
NYHA Class II	67.7	67.4
NYHA Class III	31.5	31.7
EF	31.2	30.9
Systolic BP	122	121
eGFR	66	65.5
History of DM	41.8	41.8
ACE/ARB/NI	95	93.7
Beta Blocker	96	96.2

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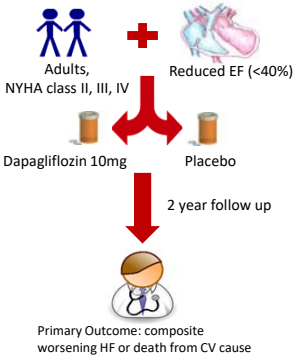
DAPA-HF Trial Results

Objective: To evaluate the efficacy and safety of dapagliflozin in patients with HFrEF, regardless of the presence or absence of DM.



- NEJM 2019;381:1995-2008

	Dapagliflozin N=2373	Placebo N=2371	HR (95% CI)	P value
Primary Composite (%)	386 (16.3)	502 (21.2)	0.74 (0.65-0.85)	<0.001
HHF	231 (9.7)	318 (13.4)	0.7 (0.59-0.83)	--
CV Death	227 (9.6)	273 (11.5)	0.82 (0.69-0.98)	--
Urgent HF visit	10 (0.4)	23 (1)	0.43 (0.2-0.9)	--
Worsening Renal function	28 (1.2)	39 (1.6)	0.71 (0.44-1.16)	--
Change in weight (kg)	-0.88	0.1	-0.87 (-1.11 to -0.62)	<0.001
Change in SBP	-1.92	-0.38	-1.27 (-2.09 to -0.45)	0.002
Change in NT-proBNP	-196	101	-303 (-457 to -150)	<0.001

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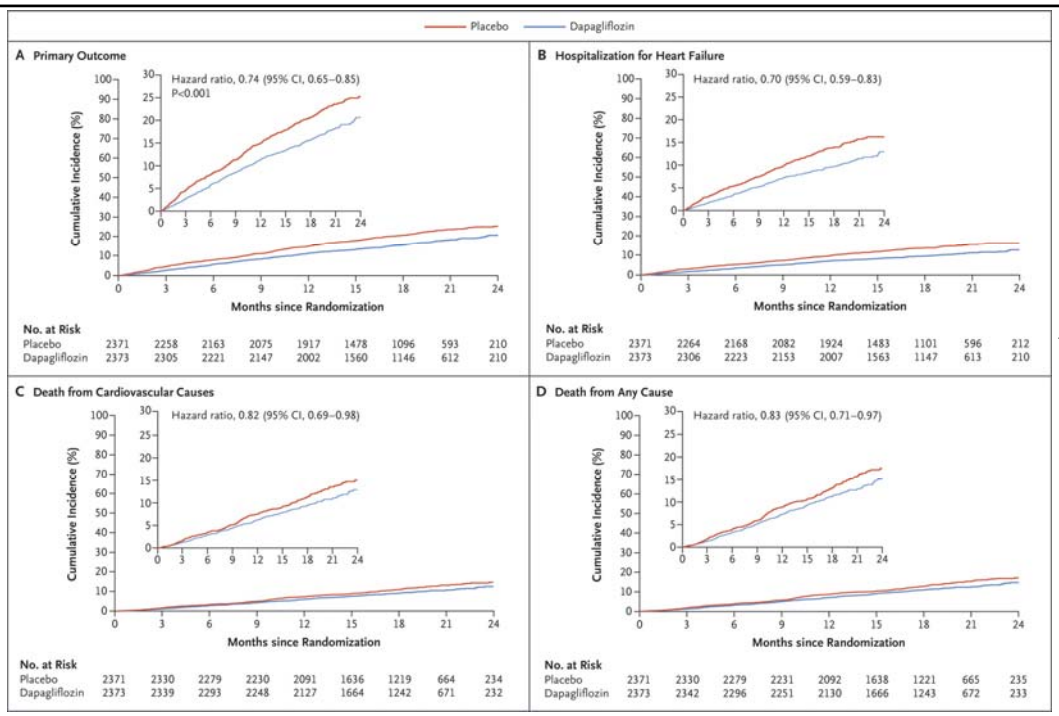

NEJM 2019;381:1995-2008

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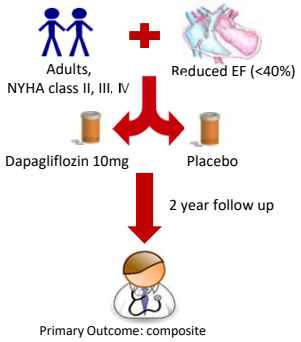
DAPA-HF Trial Adverse Events

Objective: To evaluate the efficacy and safety of dapagliflozin in patients with HFrEF, regardless of the presence or absence of DM.



	Dapagliflozin N=2373	Placebo N=2371	P Value
Discontinuation due to adverse event (%)	4.7	4.9	0.79
Volume depletion	7.5	6.8	0.4
Renal adverse event	6.5	7.2	0.36
Fracture	2.1	2.1	1
Amputation	0.5	0.5	1

- NEJM 2019;381:1995-2008

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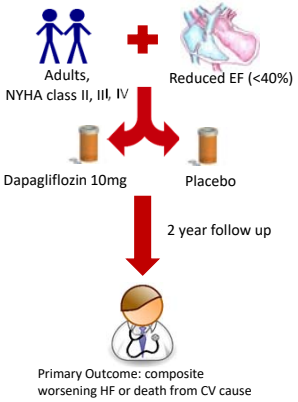
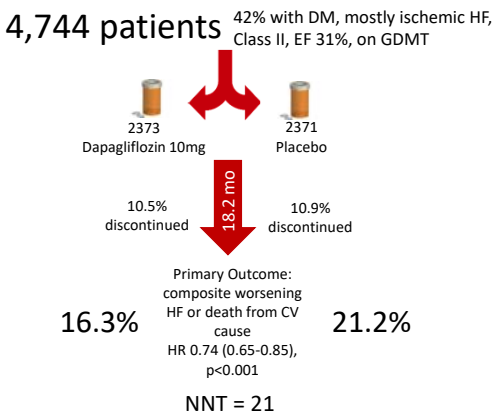
DAPA-HF trial

Objective: To evaluate the efficacy and safety of dapagliflozin in patients with HFrEF, regardless of the presence or absence of DM.





- NEJM 2019;381:1995-2008

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Case 3
Optimize Meds for HF

- 52 years old male
  - SOB with moderate exertion and some fluid in his feet despite medication changes, following salt & fluid restrictions.
- PMH
  - Hypertension
  - MI
  - Heart Failure
  - BPH
  - GERD
- Objective information:
  - BP: 137/78 mmHg, HR 62 bpm
  - eGFR: 76 ml/min/m^2
  - EF 30%
  - Labs: Na: 135, K: 3.8 , BUN: 14, SCr: 0.9, Glucose: 89
- Medications:
  - Sacubitril/valsartan 97/103mg twice daily
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Hydralazine/ISDN

Digoxin

Ivabradine

Dapagliflozin

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Hydralazine/ISDN — High pill burden, adverse effects

Digoxin

Ivabradine

Dapagliflozin

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Hydralazine/ISDN — High pill burden, adverse effects

Digoxin — Narrow therapeutic index, no mortality benefit

Ivabradine

Dapagliflozin

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Hydralazine/ISDN — High pill burden, adverse effects

Digoxin — Narrow therapeutic index, no mortality benefit

Ivabradine — Decreases hospitalizations, HR > 70 at baseline

Dapagliflozin

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64

Case 3
Optimize Meds for HF

- 52 years old male
  - SOB with moderate exertion and some fluid in his feet despite medication changes, following salt & fluid restrictions.
- PMH
  - Hypertension
  - MI
  - Heart Failure
  - BPH
  - GERD
- Objective information:
  - BP: 137/78 mmHg, HR 62 bpm
  - eGFR: 76 ml/min/m^2
  - EF 30%
  - Labs: Na: 135, K: 3.8 , BUN: 14, SCr: 0.9, Glucose: 89

- Medications:
  - Sacubitril/valsartan 97/103mg twice daily
  - Metoprolol succinate 200mg daily
  - Spironolactone 25mg daily
  - Furosemide 40mg daily
  - Aspirin 81mg daily
  - Atorvastatin 40mg

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Ongoing SGLT-2 Heart Failure trials

	SGLT-2	Population	EF	Setting	DM	Anticipated Completion
DELIVER	Dapagliflozin	HFpEF	>40%	Outpatient & Inpatient	+/- T2DM	June 2021
DICTATE-AHF	Dapagliflozin	--	--	Inpatient	+/- T2DM	August 2021
SOLOIST-WHF	Sotagliflozin	Worsening HF	--	Inpatient	+ T2DM	January 2021
EMPEROR-Reduced	Empagliflozin	HFrEF	≤40%	Outpatient	+/- T2DM	completed
EMPEROR-preserved	Empagliflozin	HFpEF	>40%	Outpatient	+/- T2DM	November 2020

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67

How Can We Help?

- Provide patient education
  - Explain how medications work
  - Anticipated adverse effects and plan for management
  - Self-management strategies
    - Nutrition
      - Diabetes: Carbohydrate moderation (plate method)
      - Heart Failure: Sodium restriction (<2-3 grams per day)
    - Disease/symptom assessment
      - Diabetes: checking BG
      - Heart Failure: daily weights

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68

How Can We Help?

- Screen for medication-related problems
  - Ineffective therapies
    - Sulfonylureas in long standing diabetes
  - Potentially harmful therapies
    - TZDs, saxagliptin in heart failure
  - Adverse effects
  - Non-adherence
    - Visual aids/calendars
    - Pill box
    - Recurring timers
    - Optimize administration time

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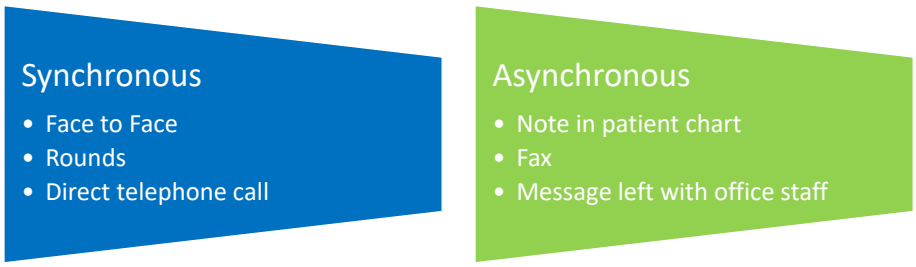
69

Pharmacist-Provider Communication

- Fundamental to high quality care
- Joint Commission
  - Poor communication responsible for 70% of errors resulting in death or permanent loss of function between 2004-2014



- Office of Quality and Safety, The Joint Commission. Sentinel event data: root causes by event type 2004–2014. 2015.

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70

Pharmacist-Provider Communication Perceptions and strategies

Qualitative and Quantitative study of hospital pharmacists & physicians

Personal, Synchronous (face to face, phone call)

Written, asynchronous (written notes, emails)

Interview Themes:

- Good rapport essential
  - -Inter-professional relationship
  - -trustworthiness
- Accuracy and accessibility important to physicians
- Reliability and dependability
- confirmation of receipt important to all

- International Journal of Clinical Pharmacy (2018) 40:464–473

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71

Summary

- GLP-1 receptor agonists and SGLT-2 Inhibitors have unique roles in reducing risk of cardiovascular outcomes in patients with diabetes
- SGLT-2 inhibitors standout as a unique class of medications which additionally improve heart failure outcomes
- Dapagliflozin is now indicated for use in patients with HFrEF without diabetes
- Best communicating recommendations requires rapport and effort to make synchronous communication when possible

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72

Thank You

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73

Activity Test

Evidence Based Treatment - T2D and Heart Failure

Activity tests must be completed online at www.freeCE.com.
A passing grade of 70 or higher and completion of an online activity evaluation are required to earn credit.

1. Which class of medications reduces the risk of hospitalizations for heart failure in patients with type 2 diabetes?
    a. thiazolidindiones
    b. insulin
    c. SGLT-2 inhibitors
    d. GLP-1 receptor agonists

2. You dispense a new prescription today for an SGLT2 inhibitor. Which of the following is the most appropriate adverse effects to counsel your patient?
    a. increased risk of nausea and vomiting
    b. increased risk of hypoglycemia
    c. decreased appetite
    d. increased risk of genital mycotic infections and UTI

3. You have a 54-year-old patient with a history of heart failure after myocardial infarction. Despite optimal therapy, he continues to have shortness of breath with exertion and edema. His current medications include enalapril 10mg twice daily, carvedilol 12.5mg twice daily, furosemide 40mg daily, spironolactone 25mg daily, atorvastatin 80mg daily, and aspirin 81mg daily. What additional medication may be beneficial at reducing the risk of hospitalizations for heart failure with minimal adverse effects?
    a. semaglutide
    b. saxagliptin
    c. dapagliflozin
    d. digoxin

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4. Your patient needs additional therapy for diabetes and will be initiated on an SGLT2 inhibitor. What should you communicate to the patient about SGLT2 inhibitors and the management of type 2 diabetes?
    a. They can reduce risk of heart failure hospitalization and CKD progression
    b. They improve glycemic control with increased risk of hypoglycemia
    c. They all increase risk of amputation and osteoporosis
    d. They improve blood pressure, but not glycemic control

5. Your patient has type 2 diabetes and established cardiovascular disease. The patient's diabetes is managed on metformin and semaglutide. Despite this, the patient's A1c remains above goal and the patient requires additional therapy. Which of the following represents the best choice of medication for this patient?
    a. SGLT-2 inhibitor with proven CVD benefit
    b. Basal insulin
    c. Pioglitazone
    d. DPP-4 inhibitor

6. Select the medication that has proven benefit to reduce the incidence of cardiovascular disease in patients with type 2 diabetes and a history of cardiovascular disease.
    a. sitagliptin
    b. pioglitazone
    c. empagliflozin
    d. lixisenatide

7. Select the medication that has proven benefit to reduce the incidence of cardiovascular disease in patients with type 2 diabetes and no history of cardiovascular disease.
    a. dulaglutide
    b. dapagliflozin
    c. saxagliptin
    d. glipizide

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8. Select the best description for the mechanism of action for SGLT-2 inhibitors.
    a. blocks production of gluconeogenesis
    b. stimulates insulin release from pancreas
    c. blocks reabsorption of glucose in kidneys
    d. increases glucose reuptake by tissues

Use this case to answer questions 9 and 10:
Your patient is a 64 year female with a history of type 2 diabetes, hypertension, chronic kidney disease (eGFR 50), and hypothyroidism. She tells you that she is often worried about doing more to keep herself healthy and prevent further chronic diseases or hospitalizations. Her ASCVD risk score is 22.5%, last BP 125/72, and BMI 29.6%. She exercises 3 days a week by walking on the treadmill for 45 min. Her last A1c was 7.9%
Medications:
Lisinopril 20mg daily
atorvastatin 20mg daily
metformin 1000mg twice daily
insulin glargine 20 units at bedtime
levothyroxine 137mcg daily

9. What additional medication would further reduce the patient's cardiovascular risk and additionally optimize her diabetes?
    a. saxagliptin
    b. dulaglutide
    c. dapagliflozin
    d. exenatide

10. To communicate this recommendation to the patient's physician, which method would be most ideal?
    a. faxed medication recommendation to provider office
    b. phone call directly to provider office
    c. note to provider via patient
    d. note in prescription filling software

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11. Which of the following is a best practice for communicating with patients regarding optimizing the control of their chronic disease state?
    a. Educating patients on self-management of their disease state
    b. Keep recommendations between pharmacist and provider
    c. Encourage patients to learn about their medications via package insert provided
    d. Refer patient to specialists for their care

12. Select the best description for the mechanism of action for GLP-1 receptor agonists.
    a. food dependent increase in insulin secretion and delayed gastric emptying
    b. blocks reabsorption of glucose in kidneys
    c. increases glucose reuptake by tissues
    d. increase tissue sensitization to glucose

13. A patient inquires about the benefit of adding semaglutide to their medication regimen. Which of the following is a statement that best summarizes the role semaglutide plays in type 2 diabetes management?
    a. Its primary role is aiding in weight loss
    b. It reduces risk of developing heart failure
    c. It reduces risk of major cardiovascular events
    d. It improves glycemic control only

14. Which of the following is an example of synchronous pharmacist-provider communication?
    a. Written note in the chart
    b. Email to the provider
    c. Discussion during rounds
    d. Message left with office staff

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15. Which of the following medications is potentially harmful to patients with heart failure?
    a. saxagliptin
    b. dapagliflozin
    c. insulin glargine
    d. glimepiride

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