Getting to Goal Can be Difficult:

Advancing T2DM THERAPY with Confidence

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Learning Objectives

1. Explore the rationale for combining GLP-1 receptor agonists with basal insulin as a means of optimizing HbA1C

2. Examine safety and efficacy data on emerging GLP-1 receptor agonist/basal insulin combinations, with an eye towards practical implications for day-to-day practice

3. Consider efficacy, side effects, costs, and tolerability to individualize therapy to meet A1C goals

Pre-Test Question 1

Rolando is a 73-year-old patient with T2DM, an history of severe hypoglycemia, and retinopathy. According to the 2017 ADA Standards of Medical Care, what would be an appropriate A1C goal for a 73 year-old patient with T2DM, a history of severe hypoglycemia, and retinopathy?

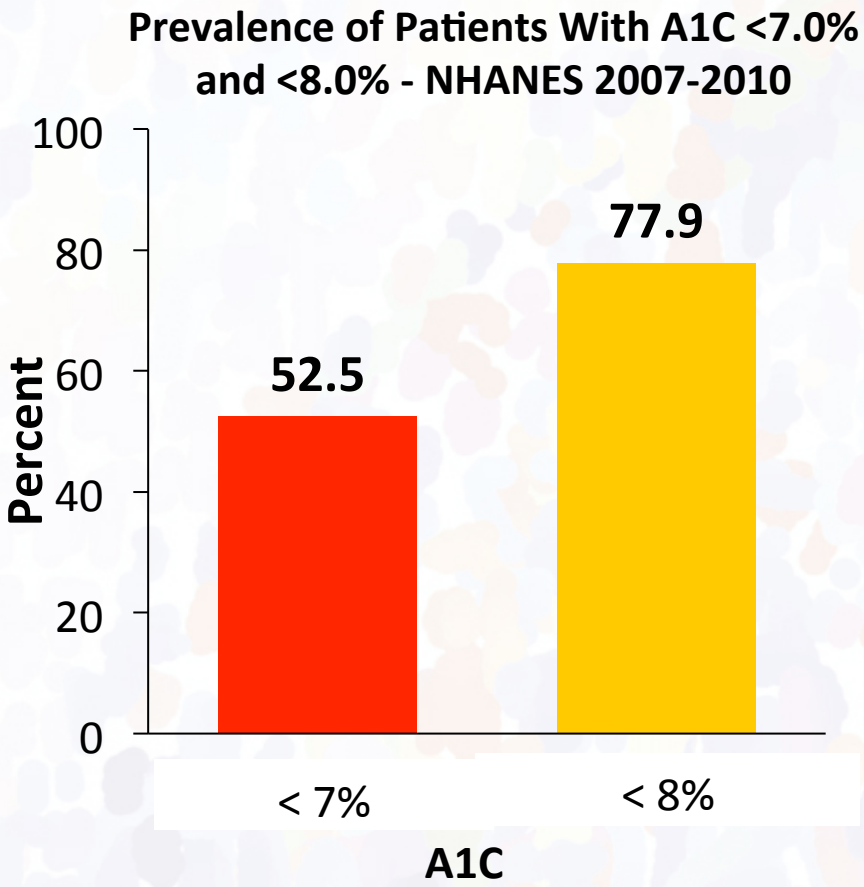
A. < 8%
B. < 7.5%
C. < 7%
D. < 6.5%

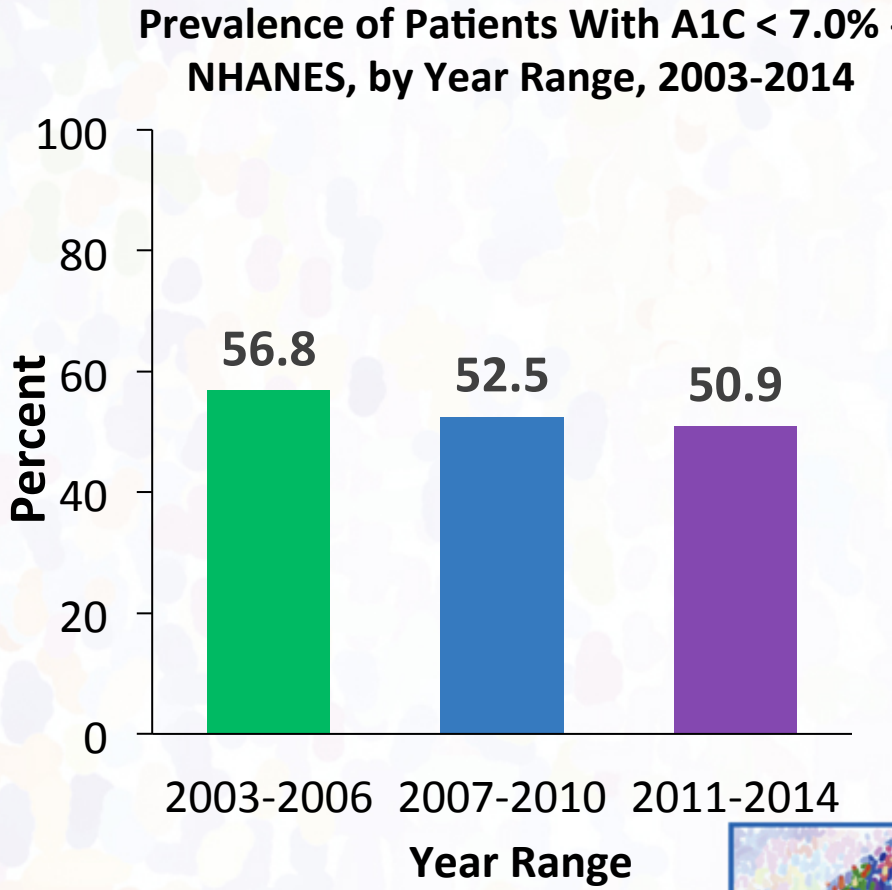
Pre-Test Question 2

Which mechanism **does not** play a role in GLP-1 receptor agonist efficacy in T2DM?

A. Increased glucose-dependent insulin secretion
B. Decreased small intestine motility
C. Decreased insulin dependent glucagon secretion
D. Delayed intestinal glucose absorption

Achieving A1C Goals Continues to Be Challenging Despite Many Advances in Treatment





Stark Casagrande S, et al. *Diabetes Care*. 2013;36:2271-2279.
Ahlers J, 2016. https://www.intarcia.com/media/press-releases/2016-june-12-new-nhanes-analysis.html.

A1C Goals

AACE

A1C ≤6.5
- For patients with low hypoglycemic risk and no concurrent serious illness

A1C >6.5
- For patients with hypoglycemic risk, concurrent illnesses, and significant CVD

ADA

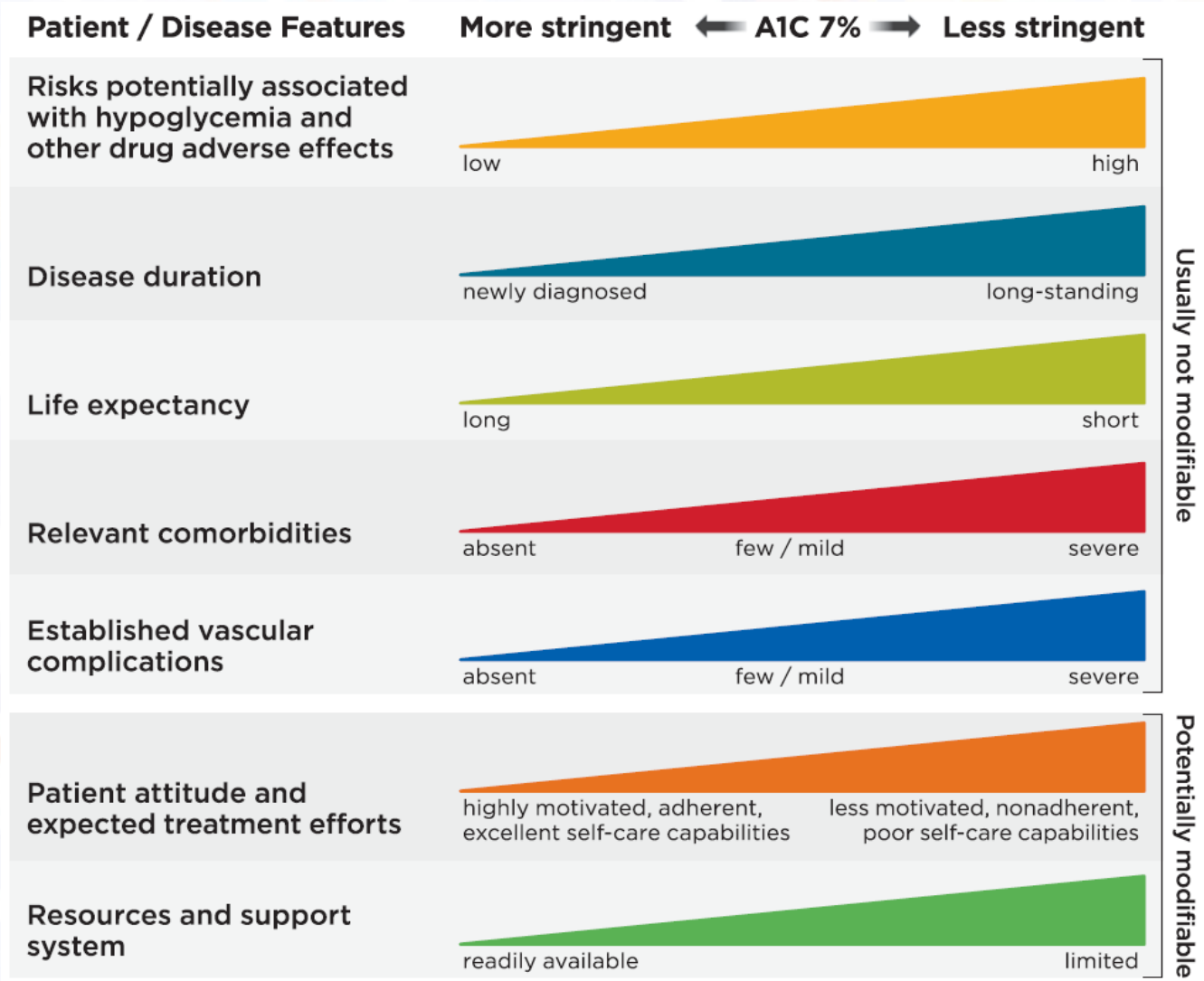
A1C <7.0%
- Most non-pregnant adults

A1C <8.0%
- History of severe hypoglycemia
- Limited life expectancy
- Advanced micro- or macrovascular complications
- Extensive comorbid conditions, or long-standing diabetes where the general goal is difficult to attain despite active management

A1C <6.5%
- Without significant hypoglycemia or other adverse effects
- Short duration of diabetes
- T2DM treated with lifestyle or metformin only
- Long life expectancy
- No significant CVD

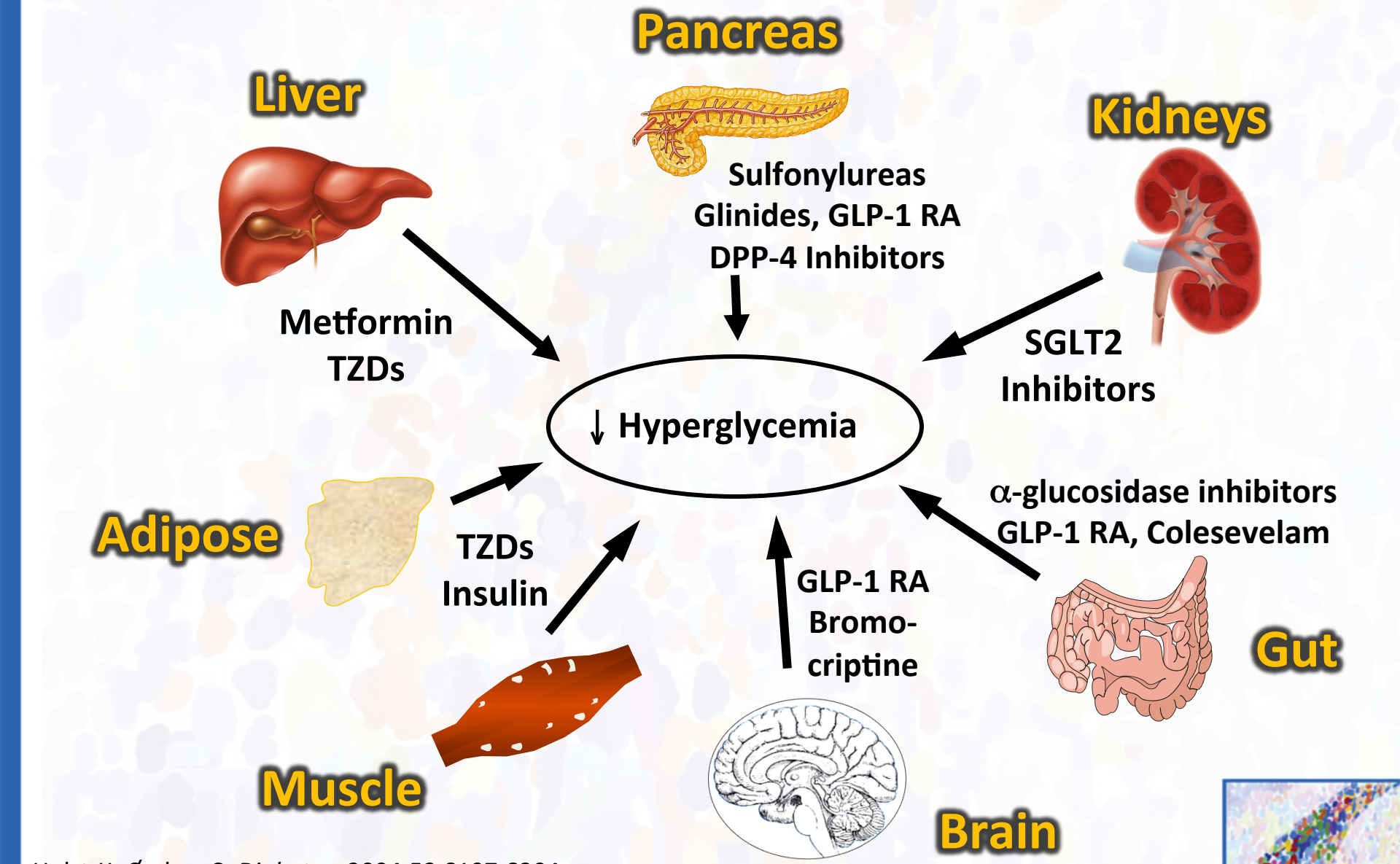
American Diabetes Association. *Diabetes Care.* 2017;40(Suppl. 1):S48–S56.
American Association of Clinical Endocrinologists. 2017. https://www.aace.com/publications/algorithm.

Management of Hyperglycemia



American Diabetes Association. *Diabetes Care.* 2017;40(Suppl. 1):S48–S56.

Organs Involved with Glucose Homeostasis



Holst JJ, Ørskov C. *Diabetes.* 2004;53:S197-S204.
Lebovitz HE. *Diabetes Rev.* 1999;7:139-153.

ADA Algorithm

Start with Monotherapy unless:

A1C is greater than or equal to 9%, **consider Dual Therapy.**

A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dL, or patient is markedly symptomatic, **consider Combination Injectable Therapy** (See Figure 8.2).

Monotherapy — Metformin — Lifestyle Management

EFFICACY*	high
HYPO RISK	low risk
WEIGHT	neutral/loss
SIDE EFFECTS	GI/lactic acidosis
COSTS*	low

If A1C target not achieved after approximately 3 months of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

Dual Therapy — Metformin + — Lifestyle Management

	Sulfonylurea	Thiazolidinedione	DPP-4 inhibitor	SGLT2 inhibitor	GLP-1 receptor agonist	Insulin (basal)
EFFICACY*	high	high	intermediate	intermediate	high	highest
HYPO RISK	moderate risk	low risk	low risk	low risk	low risk	high risk
WEIGHT	gain	gain	neutral	loss	loss	gain
SIDE EFFECTS	hypoglycemia	edema, HF, fxs	rare	GU, dehydration, fxs	GI	hypoglycemia
COSTS*	low	low	high	high	high	high

If A1C target not achieved after approximately 3 months of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

Triple Therapy — Metformin + — Lifestyle Management

Sulfonylurea +	Thiazolidinedione +	DPP-4 inhibitor +	SGLT2 inhibitor +	GLP-1 receptor agonist +	Insulin (basal) +
TZD	SU	SU	SU	SU	TZD
or DPP-4-i	or DPP-4-i	or TZD	or TZD	or TZD	or DPP-4-i
or SGLT2-i	or SGLT2-i	or SGLT2-i	or DPP-4-i	or SGLT2-i	or SGLT2-i
or GLP-1-RA	or GLP-1-RA	or Insulin[§]	or GLP-1-RA	or Insulin[§]	or GLP-1-RA
or Insulin[§]	or Insulin[§]		or Insulin[§]		

If A1C target not achieved after approximately 3 months of triple therapy and patient (1) on oral combination, move to basal insulin or GLP-1 RA, (2) on GLP-1 RA, add basal insulin, or (3) on optimally titrated basal insulin, add GLP-1 RA or mealtime insulin. Metformin therapy should be maintained, while other oral agents may be discontinued on an individual basis to avoid unnecessarily complex or costly regimens (i.e., adding a fourth antihyperglycemic agent).

Combination Injectable Therapy

GLYCEMIC CONTROL ALGORITHM

LIFESTYLE THERAPY
(Including Medically Assisted Weight Loss)

Entry A1C < 7.5%

MONOTHERAPY*

- ✓ Metformin
- ✓ GLP-1 RA
- ✓ SGLT-2i
- ✓ DPP-4i
- ! TZD
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to Dual Therapy

Entry A1C ≥ 7.5%

DUAL THERAPY*

MET or other 1st-line agent +

- ✓ GLP-1 RA
- ✓ SGLT-2i
- ✓ DPP-4i
- ! TZD
- ! Basal Insulin
- ✓ Colesevelam
- ✓ Bromocriptine QR
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to Triple Therapy

TRIPLE THERAPY*

MET or other 1st-line agent + 2nd-line agent +

- ✓ GLP-1 RA
- ✓ SGLT-2i
- ! TZD
- ! Basal insulin
- ✓ DPP-4i
- ✓ Colesevelam
- ✓ Bromocriptine QR
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to or intensify insulin therapy

Entry A1C > 9.0%

SYMPTOMS

NO	YES
DUAL Therapy OR TRIPLE Therapy	INSULIN ± Other Agents

ADD OR INTENSIFY INSULIN

Refer to Insulin Algorithm

LEGEND

- ✓ Few adverse events and/or possible benefits
- ! Use with caution

* Order of medications represents a suggested hierarchy of usage; length of line reflects strength of recommendation

PROGRESSION OF DISEASE

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ALGORITHM FOR ADDING/INTENSIFYING INSULIN

START BASAL (Long-Acting Insulin)

A1C < 8%

TDD 0.1–0.2 U/kg

A1C > 8%

TDD 0.2–0.3 U/kg

Insulin titration every 2–3 days to reach glycemic goal:

- Fixed regimen: Increase TDD by 2 U
- Adjustable regimen:
  - **FBG** > 180 mg/dL: add 20% of TDD
  - **FBG** 140–180 mg/dL: add 10% of TDD
  - **FBG** 110–139 mg/dL: add 1 unit
- If hypoglycemia, reduce TDD by:
  - **BG** < 70 mg/dL: 10% – 20%
  - **BG** < 40 mg/dL: 20% – 40%

Consider discontinuing or reducing sulfonylurea after starting basal insulin (basal analogs preferred to NPH)

***Glycemic Goal:**

- <7% for most patients with T2D; fasting and premeal BG < 110 mg/dL; absence of hypoglycemia
- A1C and FBG targets may be adjusted based on patient's age, duration of diabetes, presence of comorbidities, diabetic complications, and hypoglycemia risk

Glycemic Control Not at Goal*

INTENSIFY (Prandial Control)

Add GLP-1 RA

Or SGLT-2i
Or DPP-4i

Add Prandial Insulin

Basal Plus 1, Plus 2, Plus 3

- Begin prandial insulin before largest meal
- If not at goal, progress to injections before 2 or 3 meals
- Start: 10% of basal dose or 5 units

Basal Bolus

- Begin prandial insulin before each meal
- 50% Basal / 50% Prandial TDD 0.3–0.5 U/kg
- Start: 50% of TDD in three doses before meals

Insulin titration every 2–3 days to reach glycemic goal:

- Increase prandial dose by 10% or 1-2 units if 2-h postprandial or next premeal glucose consistently > 140 mg/dL
- If hypoglycemia, reduce TDD basal and/or prandial insulin by:
  - BG consistently < 70 mg/dL: 10% - 20%
  - Severe hypoglycemia (requiring assistance from another person) or BG < 40 mg/dL: 20% - 40%

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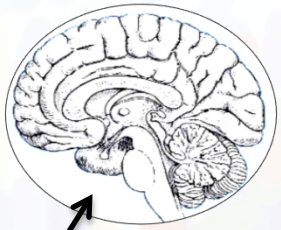
Diabetes Drugs and Associated Risk Factors

Drug	Weight	Blood Pressure	Hypoglycemia Risk
α-glucosidase inhibitors	Neutral	Improved	Low
DPP-4 inhibitors	Loss/Neutral	Neutral	Low
GLP-1 agonists	Loss	Improved	Low
Insulin	Gain	Neutral*	High
Meglitinides	Gain	Neutral	Moderate
Metformin	Loss/Neutral	Neutral	Low
SGLT2 inhibitors	Loss	Improved	Low
Sulfonylureas-	Gain	Neutral	Moderate
TZD	Gain	Improved	Low

*Hyperinsulinemia is associated with hypertension

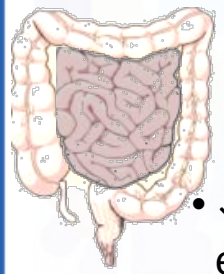
Basile JN. *J Diabetes Complications*. 2013;27(3):280-286.

Role of Incretins in Glucose Homeostasis



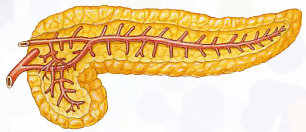
↑ satiety
↓ appetite

↑ glucose uptake by muscles



Release

Active GLP-1 and GIP

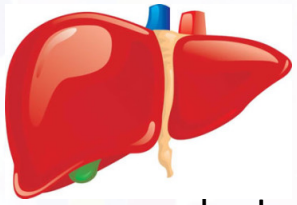


Decreased blood glucose

- ↓ gastric emptying
- Delayed intestinal glucose absorption

DPP-4

- ↓ glucose-dependent glucagon release from α-cells (GLP-1)
- ↑ glucose-dependent insulin release, ↑ β-cell regeneration? (GLP-1 & GIP)

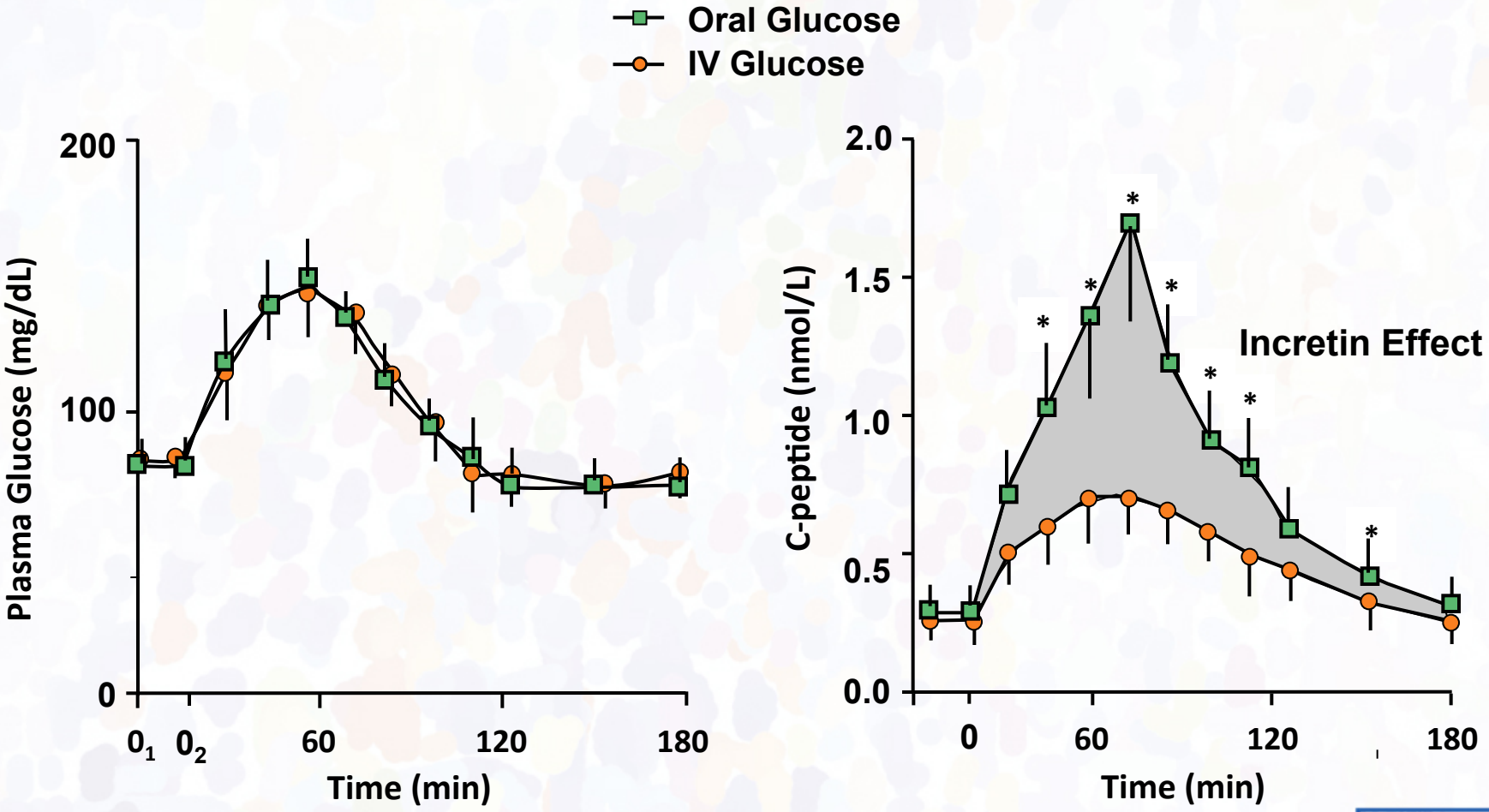


↓ glucose production

Inactive

Adapted from Drucker DJ. *Cell Metab*. 2006;3(3):153-165.
Nauck MA. *Am J Med*. 2011;124(1 Suppl):S3-18.

The Incretin Effect in Healthy Subjects



Mean ± SE; N = 6; *p ≤ .05; 0_1-0_2 = glucose infusion time.

Nauck MA, et al. Incretin effects of increasing glucose loads in man calculated from venous insulin and C-peptide responses. *J Clin Endocrinol Metab.* 1986;63:492-498. Copyright 1986, The Endocrine Society.

GLP-1 Receptor Agonists

	Short-Acting	Long-Acting
FDA-approved drugs	Exenatide (Byetta) Lixisenatide (Adlyxin)	Liraglutide (Victoza) Exenatide-LAR (Bydureon) Albiglutide (Tanzeum) Dulaglutide (Trulicity)
Half-life	2–5 h	12 h–several days
Fasting BG	Modest reduction	Strong reduction
A1C	Modest reduction	Strong reduction
Postprandial hyperglycemia	Strong reduction	Modest reduction
Gastric emptying rate	Pronounced deceleration	Less pronounced deceleration
Blood pressure	Reduction	Reduction
Weight reduction	1–5 kg	2–5 kg
Nausea	20%– 50%; slowly attenuates (weeks/months)	20%–40%; quickly attenuates (≅4 –8 weeks)
Heart rate	No/small increase (0-2 bpm)	Moderate increase (2-5 bpm)

Meier JJ. *Nat Rev Endocrinol*. 2012;8(12):728-742.
Lund A, et al. *Eur J Intern Med*. 2014;25(5):407-414.

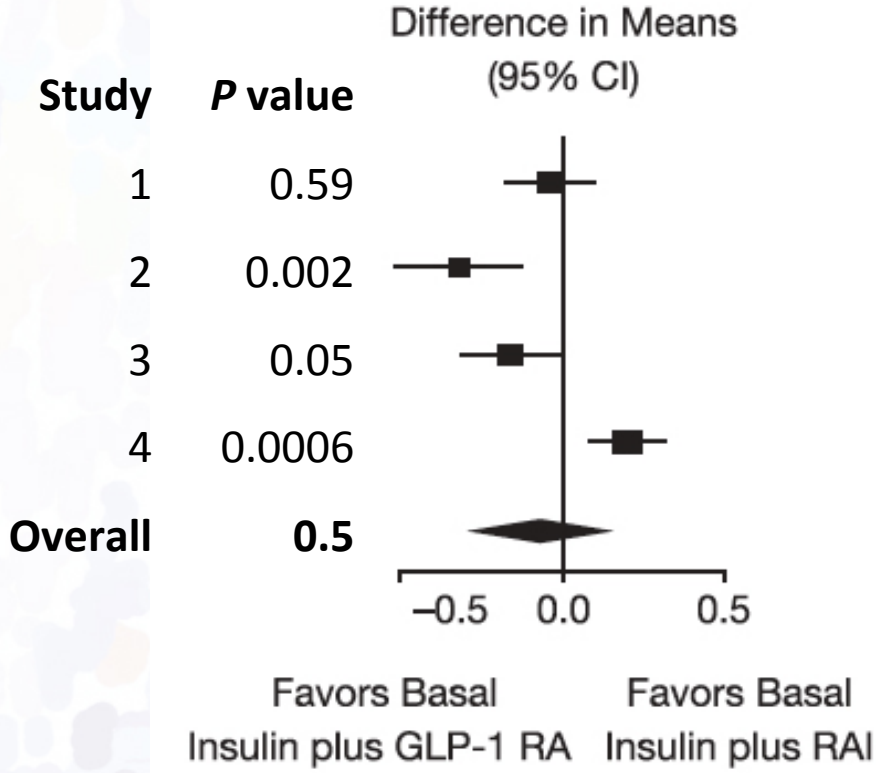
Rationale for Combining GLP-1 RAs and Basal Insulin: Complementary Effects

Characteristic	GLP-1 RA	Basal Insulin
MOA	• ↑ glucose-dependent pancreatic insulin secretion • ↓ glucose-dependent glucagon secretion • ↓ gastric emptying • ↑ satiety/↓appetite	• Mimics basal rate of endogenous insulin • ↑ glucose disposal • ↓ hepatic glucose production
Glucose profile	• Short-acting agents: ↓ PPG excursions • Long-acting agents: ↓ PPG and FPG	• ↓ FPG
Body weight	• ↓ weight	• ↑ weight
Injection frequency	• SubQ 1-2/day or 1/week	• SubQ 1-2/day
Effect on pancreatic beta cells	• May improve beta cell function	• Rests beta cells • Reduces glucose toxicity

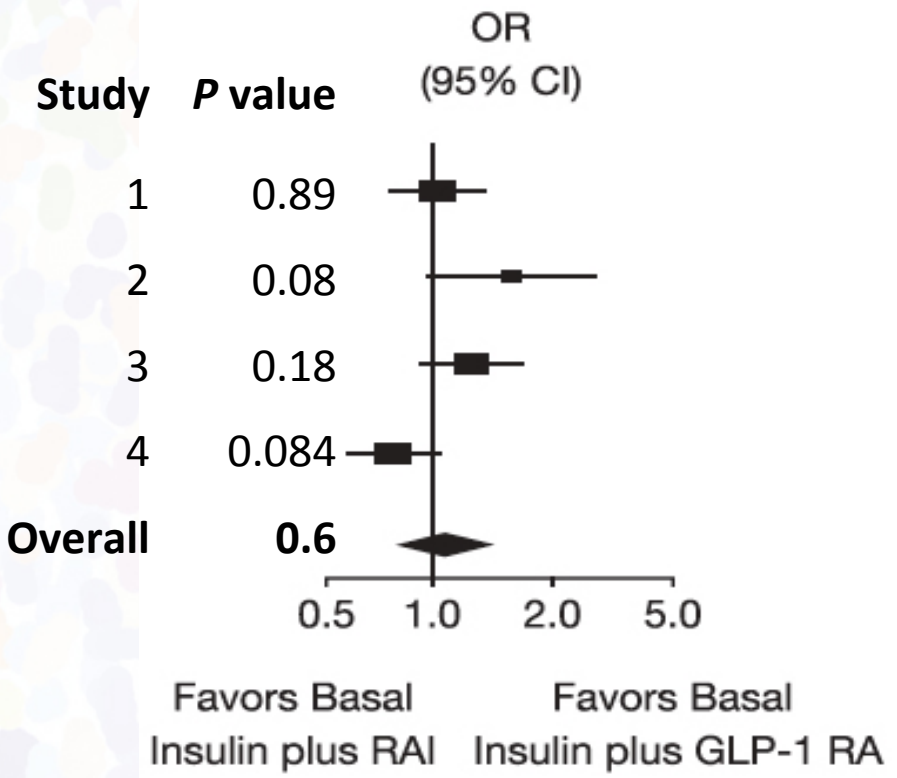
Anderson SL, Trujillo JM. *Diabetes Spectrum.* 2016; 29:152-160.
Vedtofte L, et al. *Exper Rev Clin Pharmacol.* 2015;8:273-282.

Adding to Basal Insulin: GLP-1 RA vs Prandial Insulin*

Reduction in A1C (%)



Percent of Patients with A1C <7%

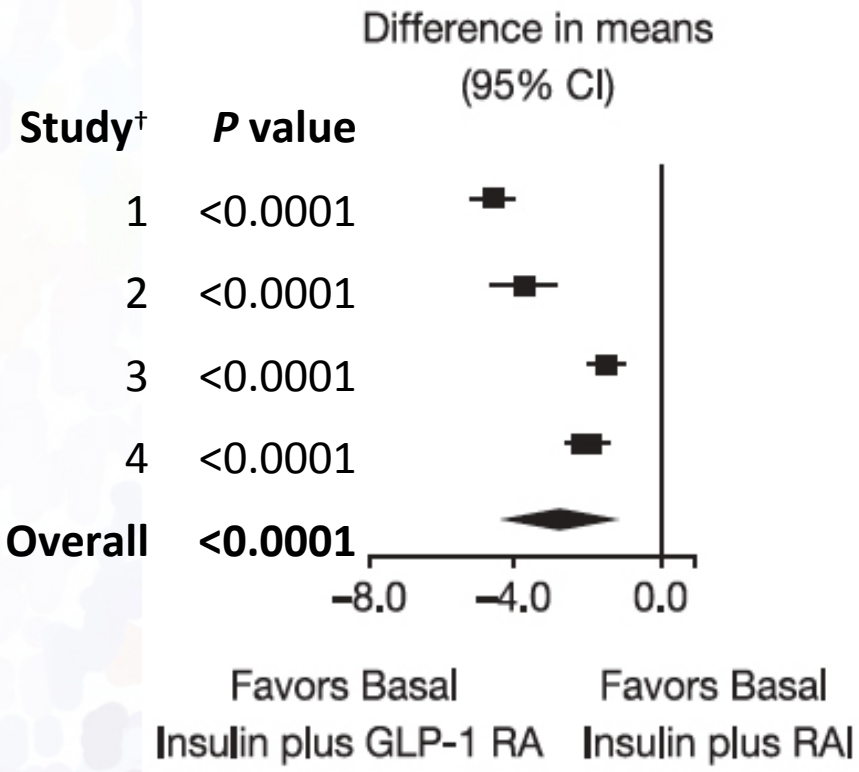


*Met-analysis by Wysham CH, et al. *Postgrad Med.* 2017;129:436-445.

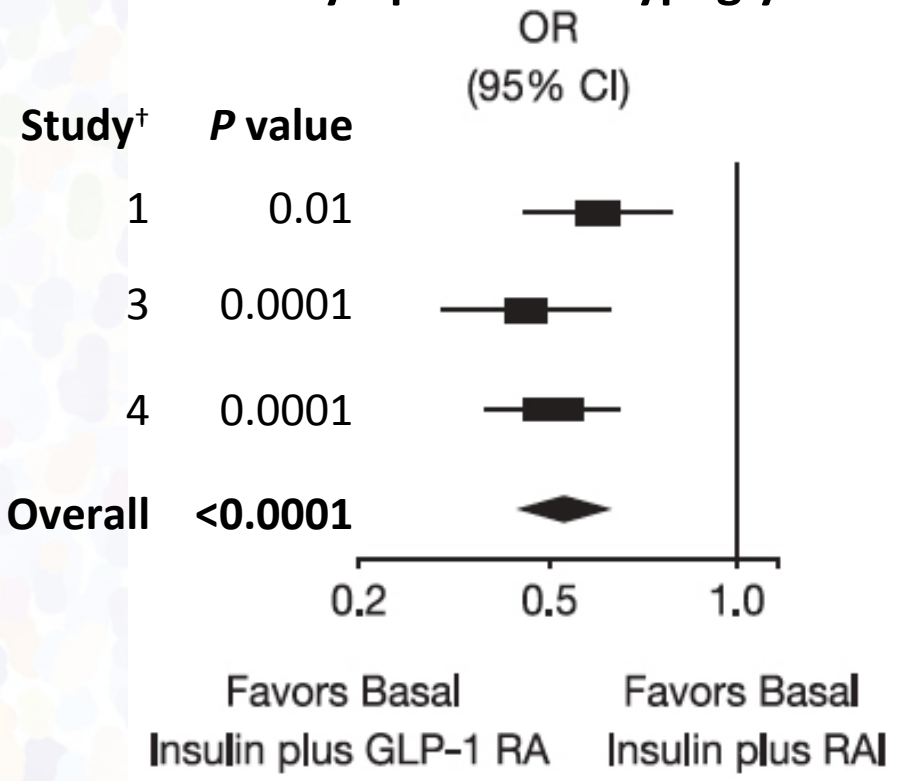
†**Study 1**: Diamant M, et al. *Diabetes Care*. 2014;37:2763-2773; **Study 2**: Mathieu C, et al. *Diabetes Obes Metab*. 2014;16:636-644; **Study 3**: Rosenstock J, et al. *Diabetes Care*. 2014;37:2317-2325; **Study 4:** Rosenstock J et al. *Diabetes Care*. 2016;39:1579-1586.

Adding to Basal Insulin: GLP-1 RA vs Prandial Insulin (cont)*

Weight Reduction



Reduced Risk of Symptomatic Hypoglycemia



*Met-analysis by Wysham CH, et al. *Postgrad Med.* 2017;129:436-445.
†**Study 1**: Diamant M, et al. *Diabetes Care*. 2014;37:2763-2773; **Study 2**: Mathieu C, et al. *Diabetes Obes Metab*. 2014;16:636-644; **Study 3**: Rosenstock J, et al. *Diabetes Care*. 2014;37:2317-2325; **Study 4:** Rosenstock J et al. *Diabetes Care*. 2016;39:1579-1586.

GLP-1 RAs Used in Fixed-dose Combinations: Liraglutide and Lixisenatide

Property	Liraglutide	Lixisenatide
Half-life, hours	12.6	2 – 3
A1C change, %	–0.6 to –0.9*	–0.7 to –0.9‡
Body weight change, kg	–1.8 to –3.0†	–1.6 to –3.8‡
Nausea, % of patients	11.3 to 31.0	26.0 to 43.5
Hypoglycemia, % of patients	4.1 to 12.0**	3.7 to 7.2††

*Degree of change depended on study design and dose (1.2 or 1.8 mg).
†Weight gain observed when combined with glimepiride (data not shown).
‡More robust changes in A1C, but with weight gain, seen when combined with pioglitazone plus metformin (data not shown).
**Minor hypoglycemia
††Symptomatic hypoglycemia

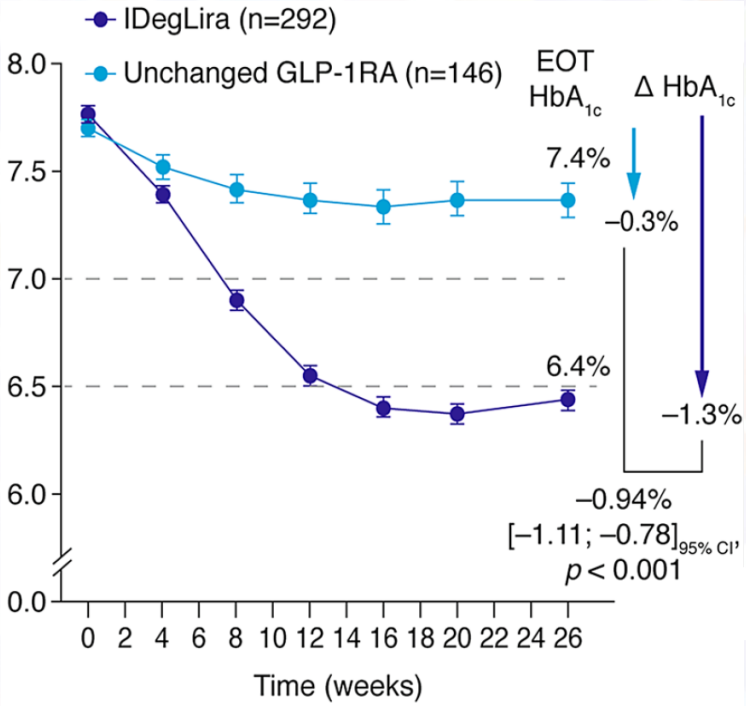
Courtney H, et al. *Diab Metabolic Synd Obes: Targets Ther.* 2017;10:79-87

Newly FDA-Approved GLP-1 RA + Basal Insulin Fixed-dose Combination Agents

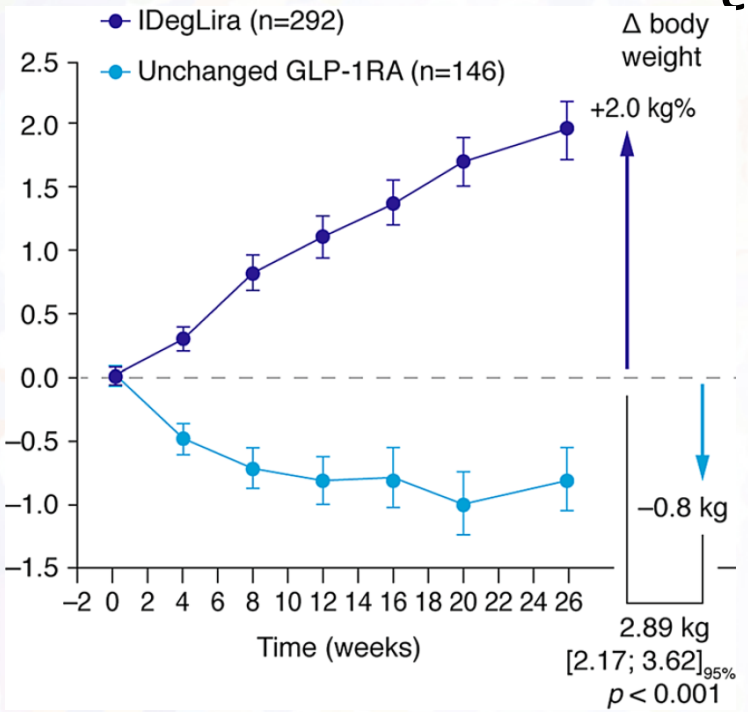
- IDegLira (Xultophy)
  - Insulin degludec (100 U/mL)
  - Liraglutide (3.6 mg/L)
- LixiLan (Soliqua)
  - Insulin glargine (100 U/mL)
  - Lixisenatide (33 mcg/mL)

Combined Insulin and GLP-1 RA: IDegLira vs Max Liraglutide or Exenatide

Change in A1C (%)



Change in BW (kg)



Hypoglycemic events (PPY)

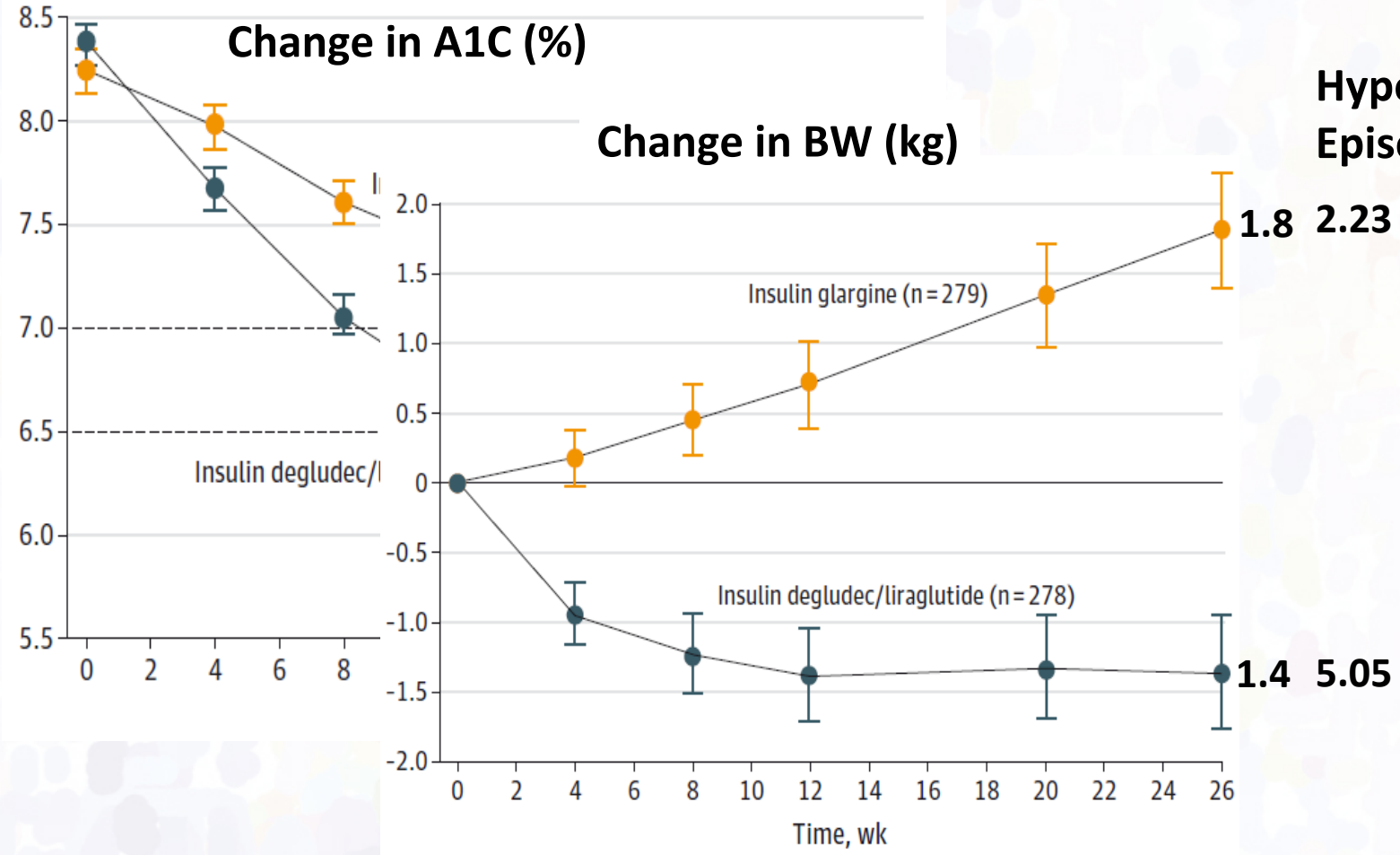
2.82

0.12

*≤ 56 mg/dL

Linjawi S, et al. *Diabetes Ther*. 2017; 8(1): 101–114.

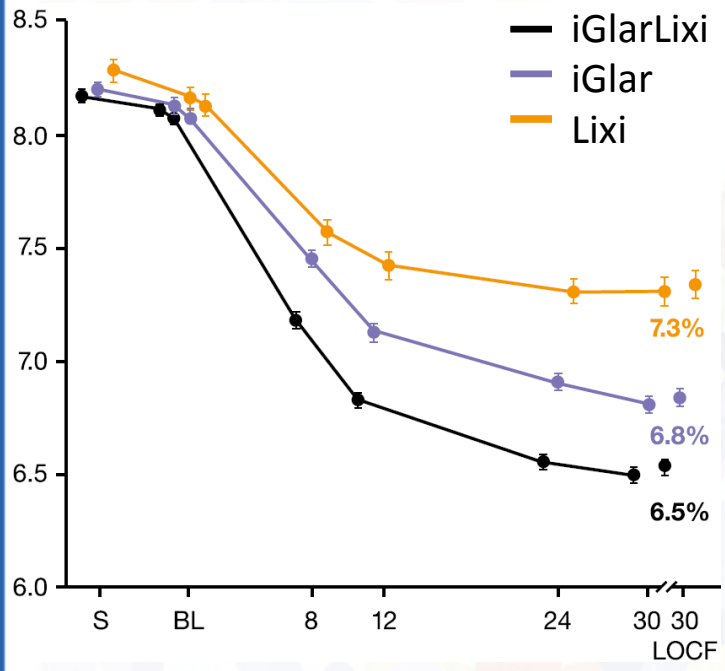
Combined Insulin and GLP-1 RA: IDegLira vs Insulin Glargine up-Titration



Lingvay I, et al; DUAL V Investigators. *JAMA*. 2016;315(9):898-907.

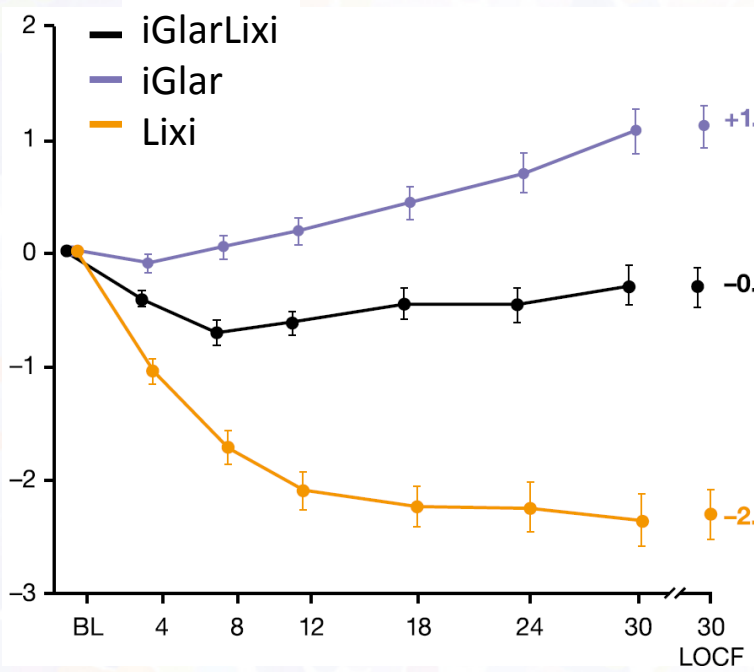
Combined Insulin and GLP-1 RA: LixiLan O

Change in A1C (%)



Time (weeks)

Change in BW (kg)



Time (weeks)

Hypoglycemic Events (PPY)*

	0.3
	0.5
	0.1

*≤ 56 mg/dL

Rosenstock J, et al; LixiLan-O Trial Investigators. *Diabetes Care*. 2016;3:2026-2035.

Combined Insulin/GLP-1 RA

Pros

- Convenient: QD injection
- Less costly than individual agents
- More A1C reduction vs components
- More patients at goal (75% have A1C <7.0%)

Cons

- More BW↑ than GLP-1 RA
- Mild hypoglycemia risk (but not severe hypoglycemia)
- GI-related side effects (wane with time)
- Cost/coverage issues

Key Messages

- **We need to get more patients with T2DM to A1C goal**
  - Goals can be set to fit individual patient needs/characteristics
  - Continuing to augment therapy until the patient is at goal is essential
  - Using different medication combinations is flexible and is a patient/physician decision
- **Combination basal insulin + GLP-1 RA**
  - Can be used safely in primary care
  - Simplicity of medications → adherence, correct dosing, fewer errors
  - Appropriate for a wide range of A1C targets regardless of T2DM duration
  - Have complementary mechanisms of action
  - Have potential advantages over basal + prandial insulin when basal insulin + oral agents control FPG or are maximized and patient is still not at goal

Tools and Resources

- **Management of Hyperglycemia in Type 2 Diabetes, 2015: A Patient-Centered Approach**
  - Inzucchi SE, et al. *Diabetes Care.* 2015;38:140–149.
- **American Diabetes Association**
  - www.diabetes.org
- **Strategies for Improving Care**
  - Diabetes Care. 2015;38(Suppl. 1):S5–S7.
- **Patient assistance programs**
  - http://www.rxassist.org/
- **National Certification Board for Diabetes Educators**
  - http://www.ncbde.org/
- **American Association of Diabetes Educators**
  - http://www.diabeteseducator.org/ProfessionalResources/Certification/
- **Insulin self-injection**
  - https://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/AADE_MedEd.pdf

Please visit
www.T2diabetesCME.org

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Learning Objectives

1. Explore the rationale for combining GLP-1 receptor agonists with basal insulin as a means of optimizing HbA1c

2. Examine safety and efficacy data on emerging GLP-1 receptor agonist/basal insulin combinations, with
   an eye towards practical implications for day-to-day practice

3. Consider efficacy, side effects, costs, and tolerability to individualize therapy to meet A1C goals

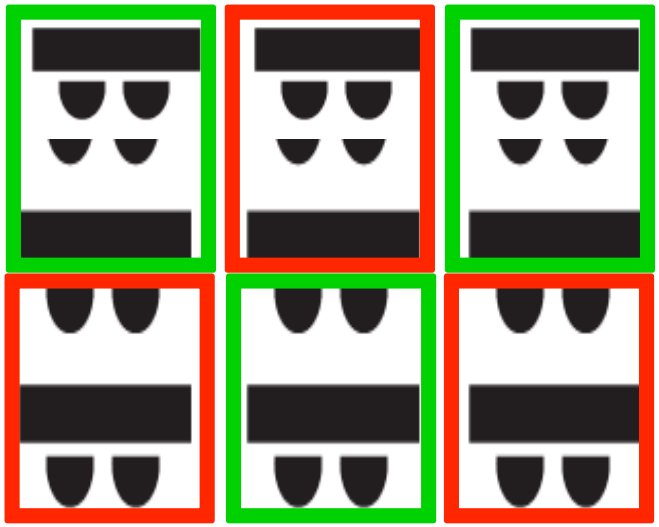
Small Group Discussion

Please Break Into Work Groups

With your neighbor, turn around and form a team

If you are not matched up with a group, join a group that is closest to you

Goal is groups of 8-10



Case Review

GOAL: Work together in multidisciplinary teams to diagnose and manage patients, using clinical cases and problem-based learning

- Each group will have a case to analyze and develop for presentation to the larger group.
- Some patient data will not be supplied and can be generated by the group based on clinical experience. The group should work in this framework to create a case presentation describing their patient.
- A representative of the team will present their case in the second half of the PBL session.
- Case presentations will be 5 minutes each including questions. (Due to time constraints, some cases may not be presented.)

4-Box Approach

1 Presentation
- History
- Physical exam
- Laboratory values
- Review and interpretation of available information

2 Treatment Recommendations
- Initial treatment
- Team Communication
- Follow-up

Team Communication

3 Results
- Presentation and interpretation of results

4 Care Plan
- Initial treatment
- Monitoring
- Adjustment of therapies
- Appropriate referrals

Checklist

- ❑ Analyze case using 4-box approach
- ❑ Create a case presentation describing your patient
- ❑ Pick a representative of the team to present your case in the second half of session

Case 1: Louise

- 47-year-old African American woman
- T2DM x 1 year
  - Diet + exercise x 6 months not effective (A1C = 8.6)
  - Added metformin (1 g 2x/day)
    - After 3 months A1C = 7.7
    - After 6 months A1C = 8.1
- Weight/Height: 190 lbs, 5’6”
- BMI: Stable at 31
- HTN and lipids: Well controlled
- A1C goal: 6.5%

Case 1

What would you do next to help Louise meet her A1C goal? Why?

Case 2: Brian

- 62-year-old white man
- T2DM x 7 years
  - On maximum metformin (1g 2x/day) and basal insulin (degludec) 26 U/day for 2.5 years
  - A1C = 8.2%
  - FPG = 100-120 mg/dL
- Weight/Height: 230 lbs, 5'10"
- BMI: Increased from 31 to 33 after basal insulin was added
- HTN: 145/85 mm Hg on ACEI
- Goal: A1C < 7.0%

Case 2

What is the best next step to get Brian to A1C goal while avoiding further weight gain or helping him to lose some weight?

Case 3: Stella

- 50-year-old Hispanic woman
- In the office for follow up after a previous visit revealing fatigue and frequent urination
- Weight/height = 188 lbs/5’5”; BMI=31.3
- BP: 132/85 mm Hg
- A1C = 11%
- No prior history of diabetes or hyperglycemia

Case 3

What A1C target would you select for Stella and why?

What initial step(s) will you take to bring her to goal, and why?

Case 4: Reggie

- 62-year-old white man
- Weight/Height: 225 lbs/6'1"; BMI = 29.7
- T2DM X 12 years
  - Well controlled on metformin + basal insulin (A1C = 6.8) until 6 months ago, increase in A1C (8.3%) found on routine checkup
  - Treated by uptitrating insulin
  - Current basal insulin dose = 62 units/d at bedtime
  - Current A1C: 6.7
  - Two hypoglycemic incidents in the past 2 months

Case 4

What should Reggie's target A1C be and why?

What should you do next?

Case 5: Howard

- 49-year-old African American man
- Weight/Height: 250 lbs/6’2”; BMI = 31.6
- T2DM x 2 years
- Current treatment:
  - metformin (1 g in 2 doses/d)
  - basal insulin (degludec) (40 U/d)
- A1C = 8.3
- FPG range: 100 – 130 mg/dL

Case 5

What would you do next for Howard?

Case 6: Felicia

- 47-year-old African American woman
- T2DM X 5 years
- Weight/Height: 185 lbs/5’6”; BMI: 29.9
- A1c = 7.4%
- BP: 125/75 mm Hg
- Blood Lipids: within normal ranges
- Current treatment: metformin (1 g 2x daily)
- Selected target A1C: < 7.0%
- She has concerns about weight gain and does not want to self-inject

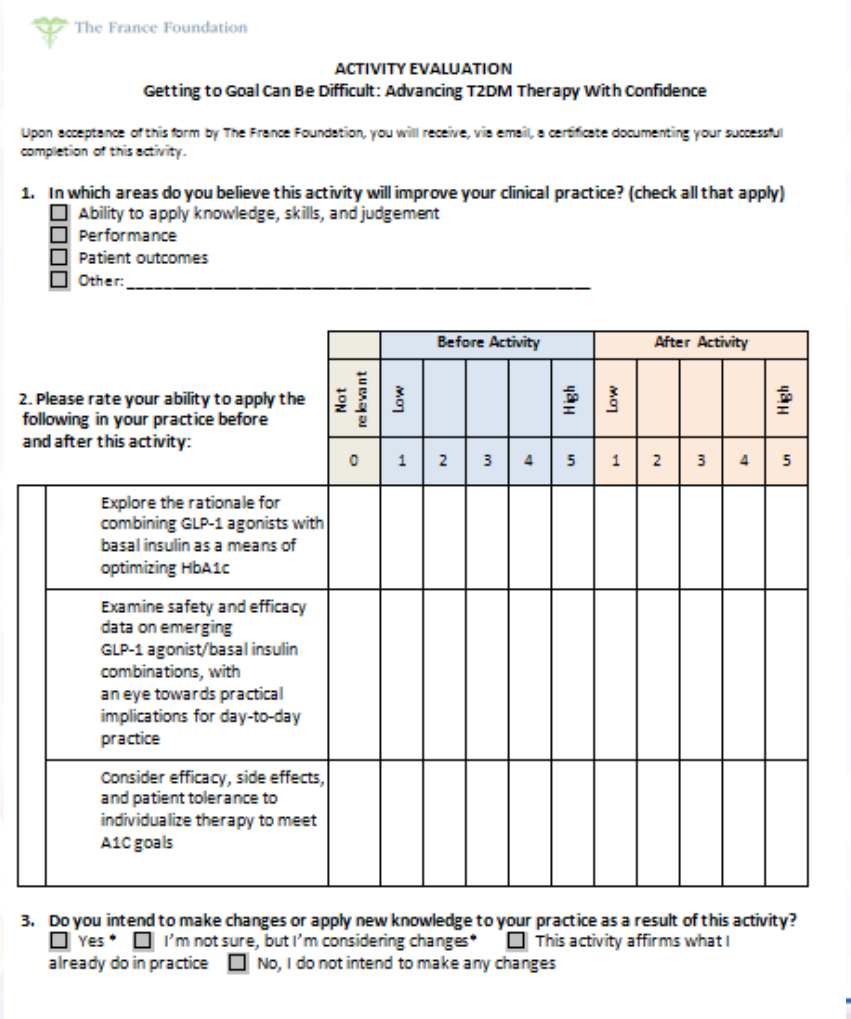
Case 6

What one (1) agent would you add for Felicia and why?

Thank you for your participation!

Please fill out your evaluations!

Your feedback helps us measure educational outcomes and provide continued education.



The France Foundation

ACTIVITY EVALUATION
Getting to Goal Can Be Difficult: Advancing T2DM Therapy With Confidence

Upon acceptance of this form by The France Foundation, you will receive, via email, a certificate documenting your successful completion of this activity.

1. **In which areas do you believe this activity will improve your clinical practice? (check all that apply)**
   - ☐ Ability to apply knowledge, skills, and judgement
   - ☐ Performance
   - ☐ Patient outcomes
   - ☐ Other: _____

2. Please rate your ability to apply the following in your practice before and after this activity:	Before Activity						After Activity				
	Not relevant	Low				High	Low				High
	0	1	2	3	4	5	1	2	3	4	5
Explore the rationale for combining GLP-1 agonists with basal insulin as a means of optimizing HbA1c											
Examine safety and efficacy data on emerging GLP-1 agonist/basal insulin combinations, with an eye towards practical implications for day-to-day practice											
Consider efficacy, side effects, and patient tolerance to individualize therapy to meet A1C goals											

3. **Do you intend to make changes or apply new knowledge to your practice as a result of this activity?**
   ☐ Yes * ☐ I'm not sure, but I'm considering changes* ☐ This activity affirms what I already do in practice ☐ No, I do not intend to make any changes