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Diabetes:

Pathways to Treatment

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Comprehensive Diabetes Care Metrics

- Three key components:
  - HbA1c control
  - Nephropathy screening
  - Eye exam
- All are critical for proper disease management
- Today's focus is on HbA1c control through pharmaceutical treatment

Learning Objectives

1. Introduce a streamlined approach to diabetes management using CareOregon's diabetes treatment pathway.
2. Provide an overview of GLP-1 agonists: place in therapy, comparative effectiveness, and practical tips.
3. Provide an overview of insulin management: regimens, dosing and adjustment, and behavioral aspects.

Advancing Therapy in Type 2 Diabetes to Reduce A1C and Improve Complications

Andrew Ahmann, MD

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CareOregon

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The "Diabetes Epidemic"
Is Due to Type 2 Diabetes

- In the United States, 30.1 million individuals have diabetes
  - Type 2 diabetes accounts for approximately 90% to 95% of all diagnosed cases of diabetes
  - Annual cost = $245 billion in US in 2012
- Diabetes affects:
  - 12.1 % of adults 18 years of age or older
  - 25.2 % of adults 65 years of age or older
- About 84 million adults have prediabetes
  - Affects 34% of adults 18 years of age or older
- Chance of diabetes for a child born in the United States in 2000:
  - 33% for a male
  - 38.5% for a female

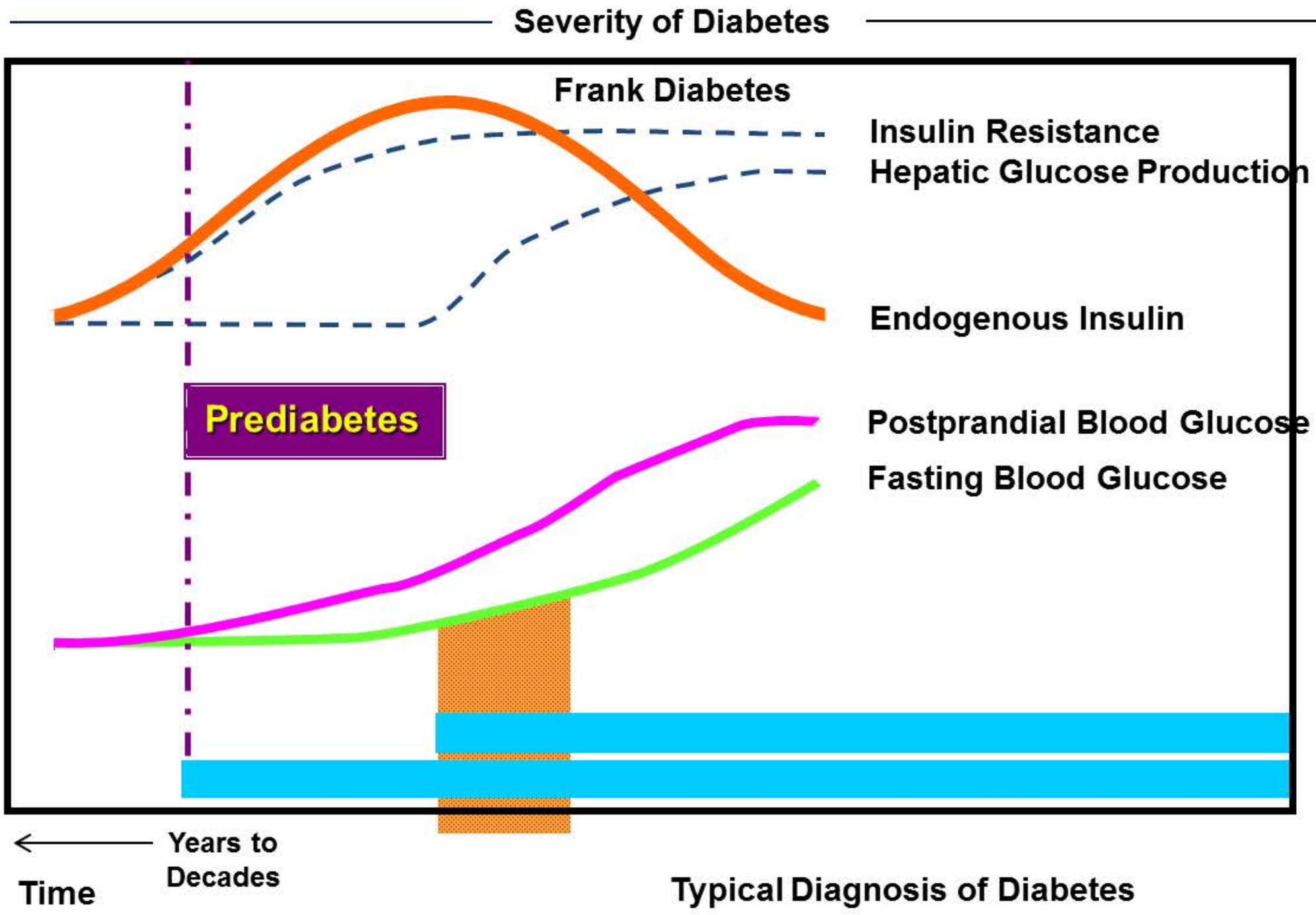
http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2017.pdf

Basic Treatment Principles in Type 2 Diabetes

- Patient education (Diabetes Self-management Education)
  - Initial and intermittent as indicated
- Glucose monitoring individualized for situation
- Exercise
  - At least 150 minutes per week over at least 3 days
    - Resistance exercise 2-3 times weekly as well
- Diet
  - Should work with a RD experienced in diabetes
    - Portion control for weight control
    - Whole grains, vegetables, fruits, legumes, low glycemic load
- Pharmacological therapy

Diabetes Care 2017; 40 7suppl 1): S6-S74

Natural History of Type 2 Diabetes



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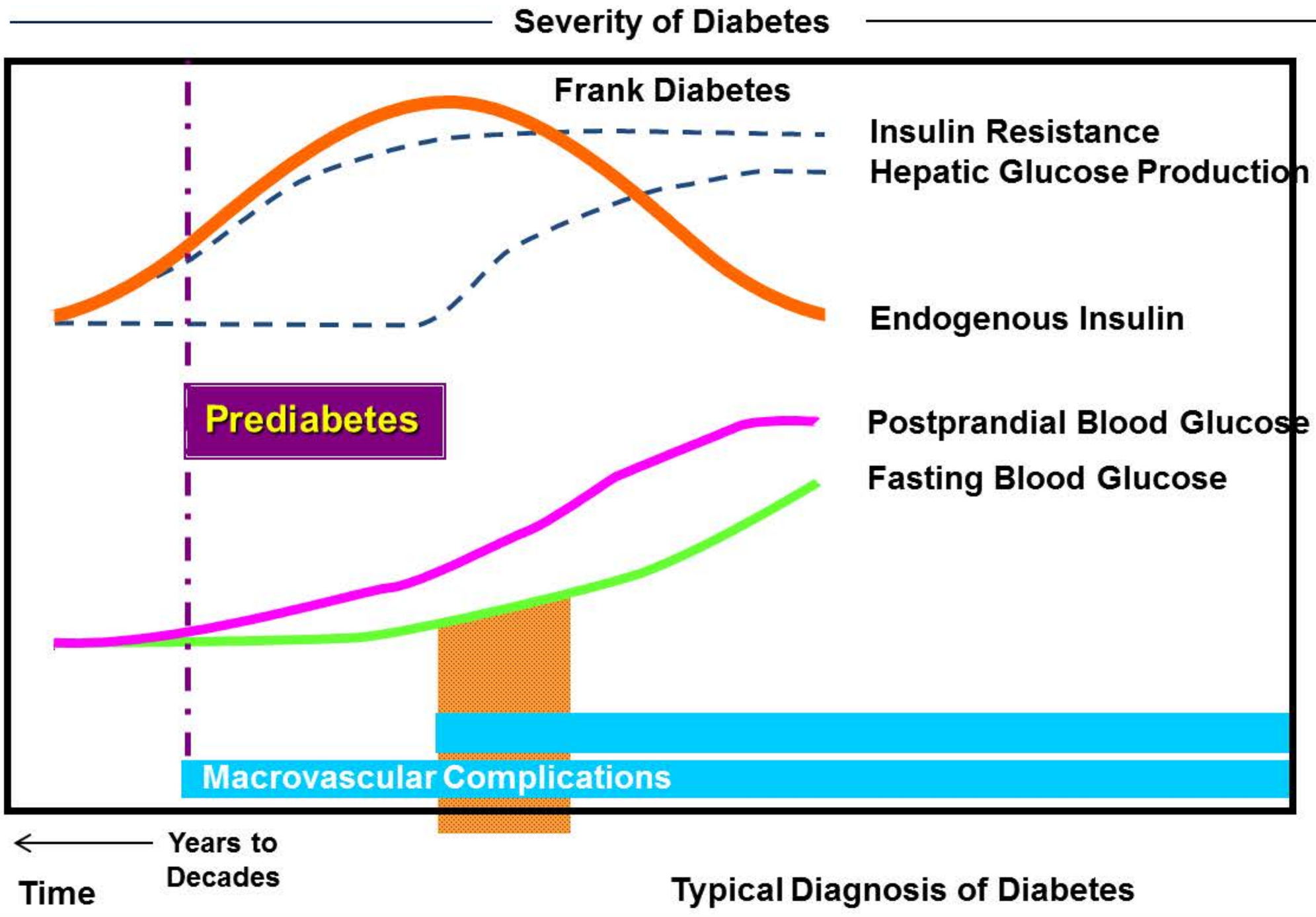

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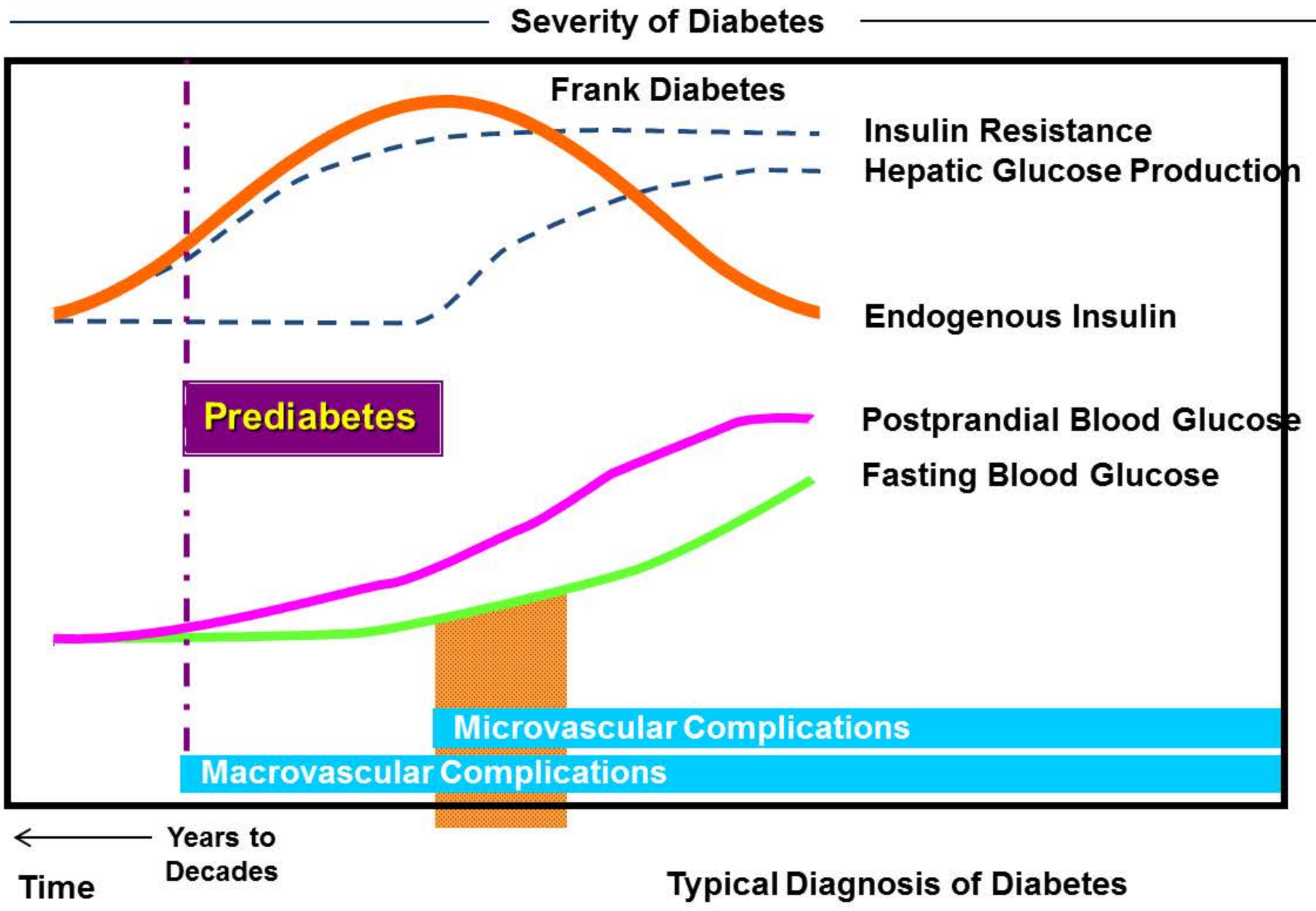

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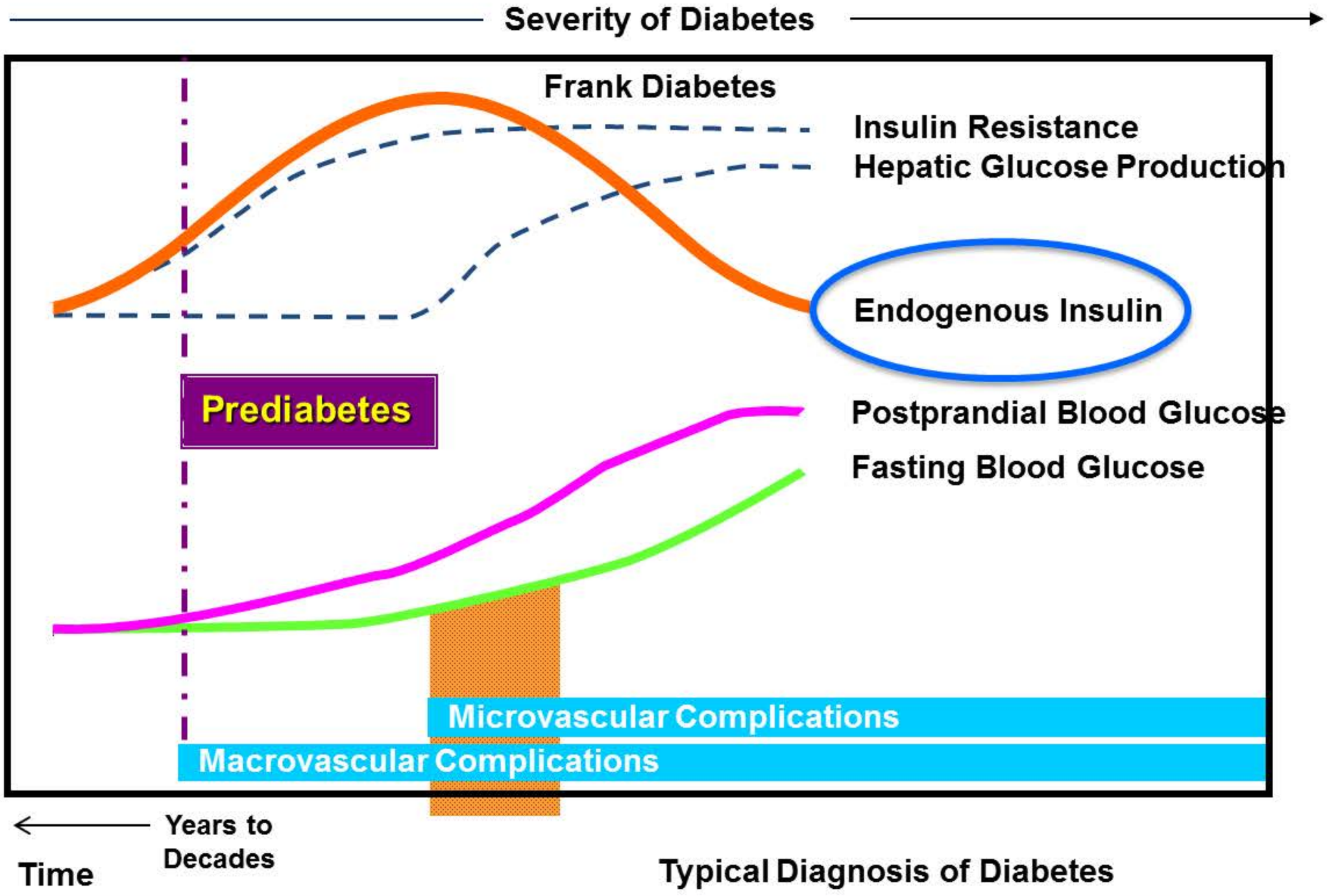
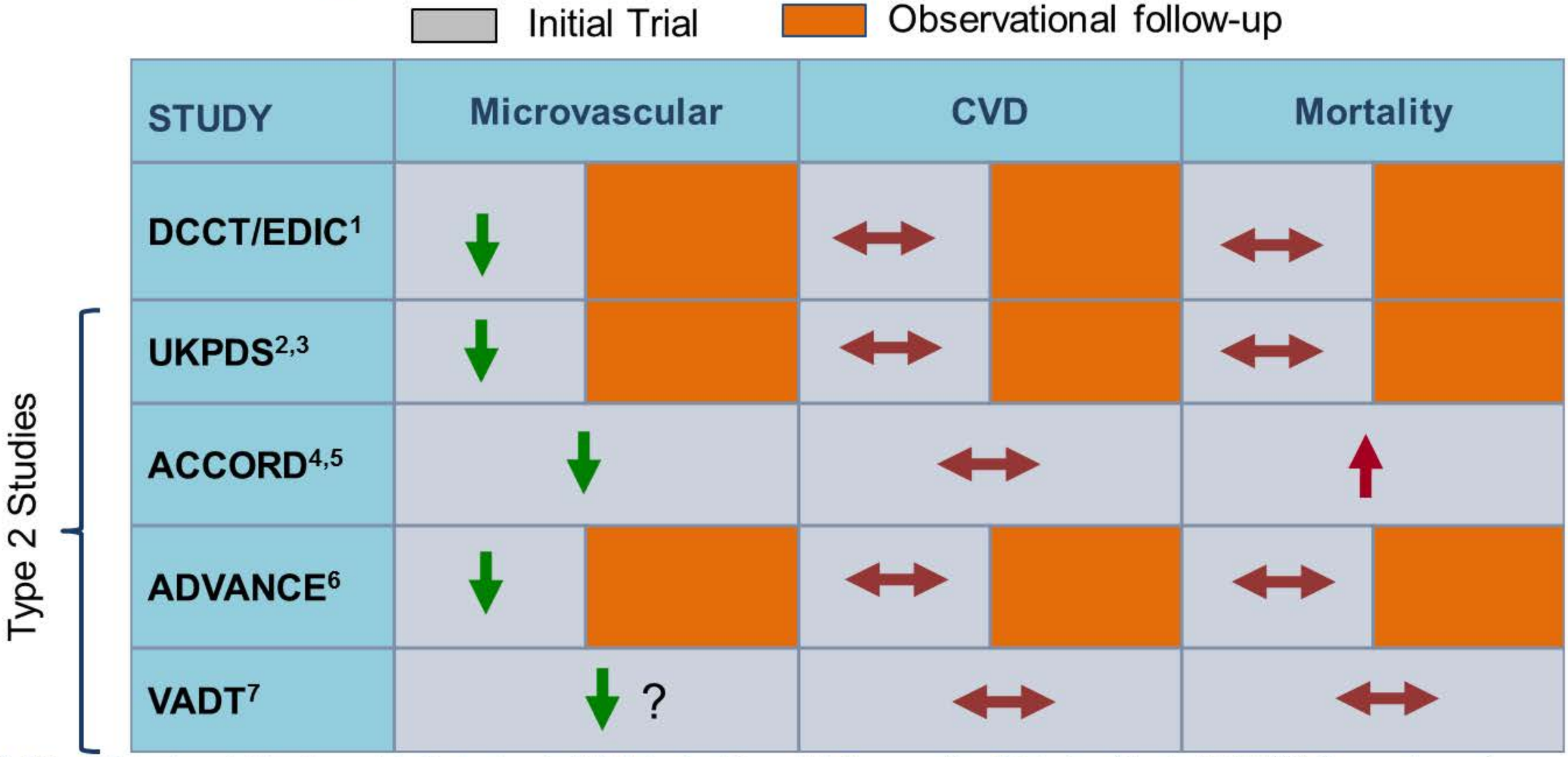


Impact of Intensive Therapy for Diabetes: Summary of Major Clinical Trials



1. http://diabetes.niddk.nih.gov/dm/pubs/control/ 2.Adapted from UK Prospective Diabetes Study (UKPDS) Group. *Lancet*. 1998;352:837-853. 3. Holman RR, et al. *N Engl J Med*. 2008;359:1577-1589. 4. Gerstein, et al. *NEJM*. 2008;358:2545-2559. 5. ACCORD Study Group. *NEJM*. 2010; 363:233-244. 6. Patel, et al. *NEJM*. 2008;358:2560-2572. 7. Duckworth et al, *NEJM* 2009;360:129-139.

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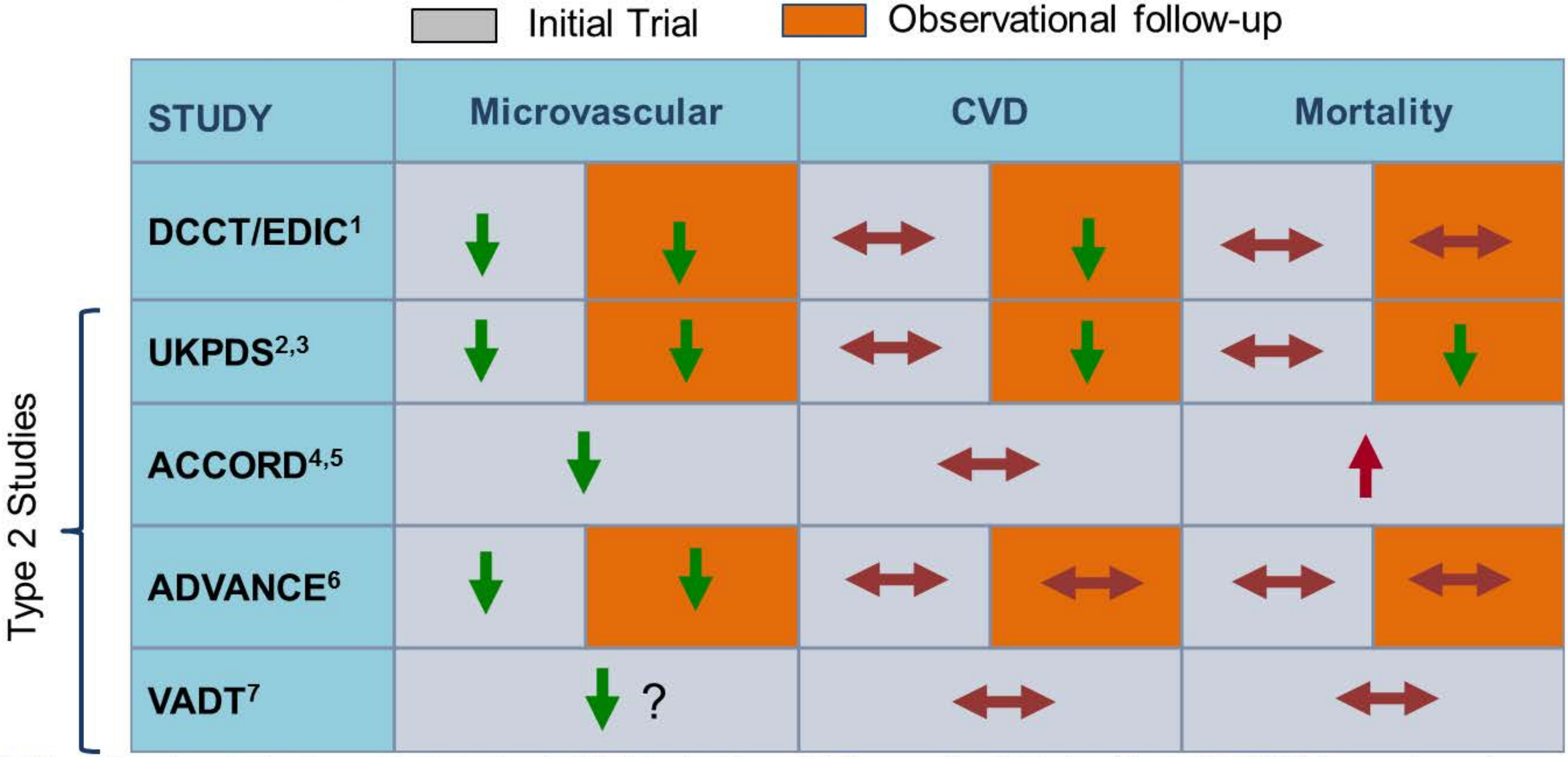

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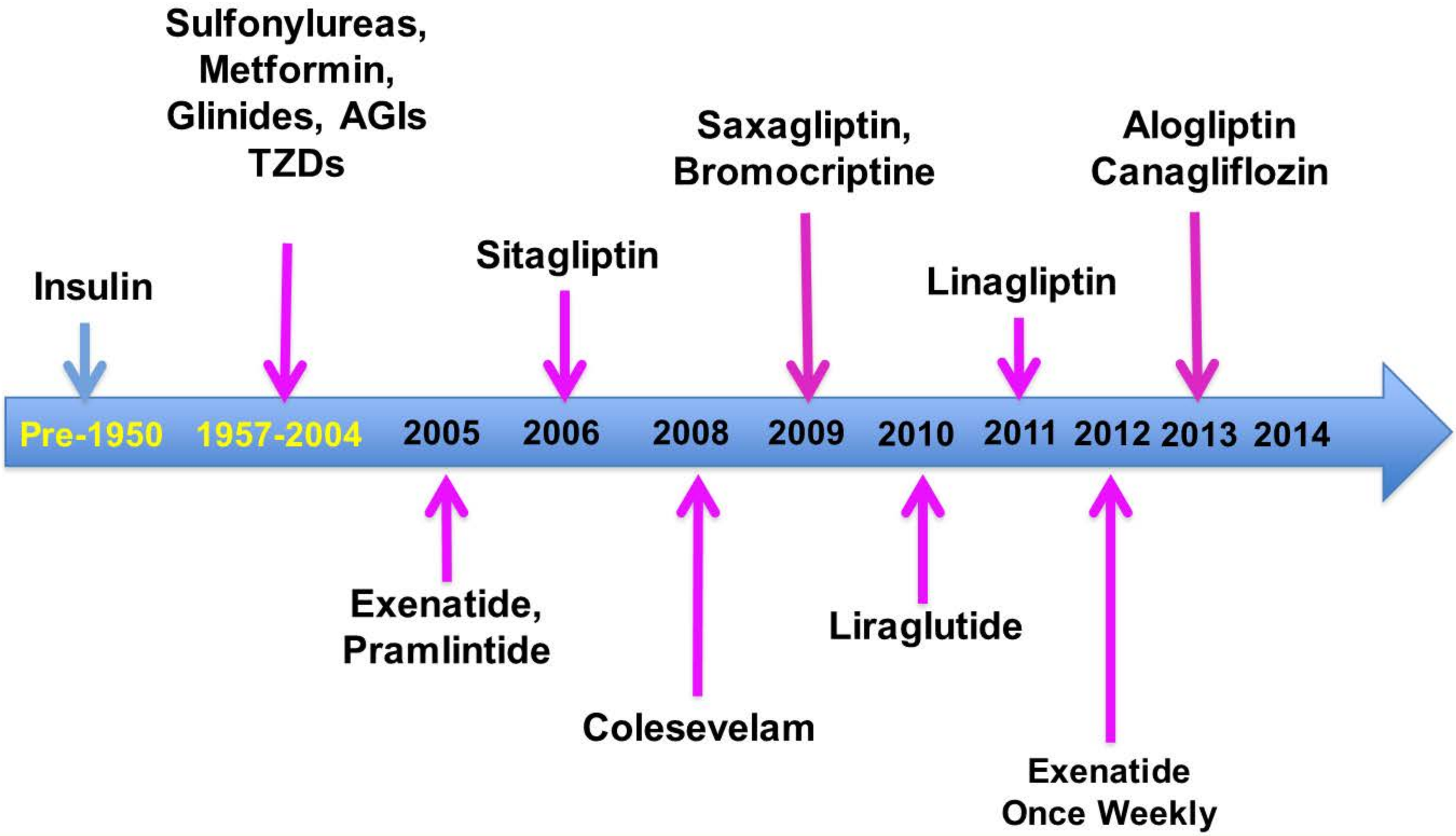
Anti-hyperglycemic Agents In US



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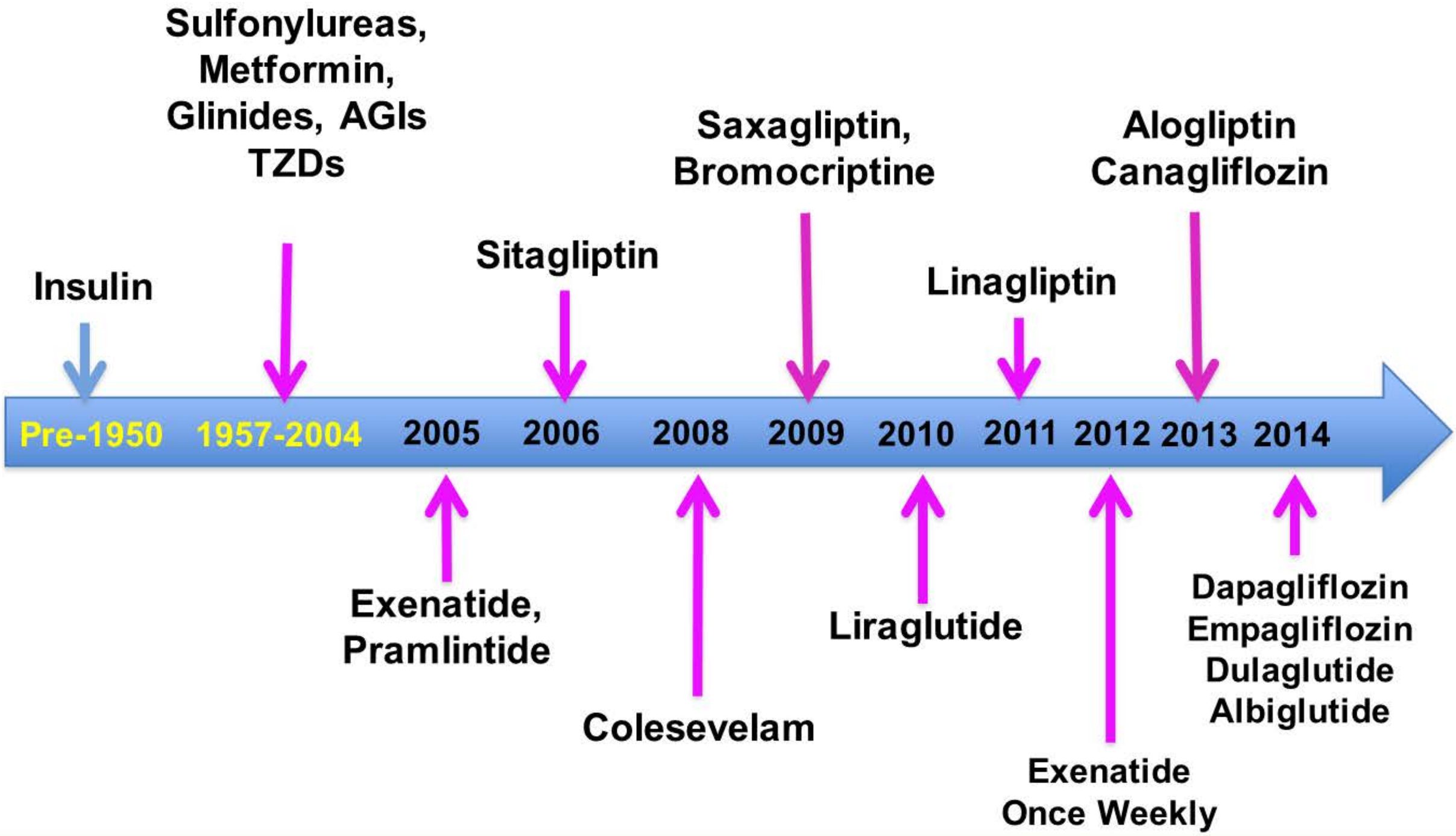
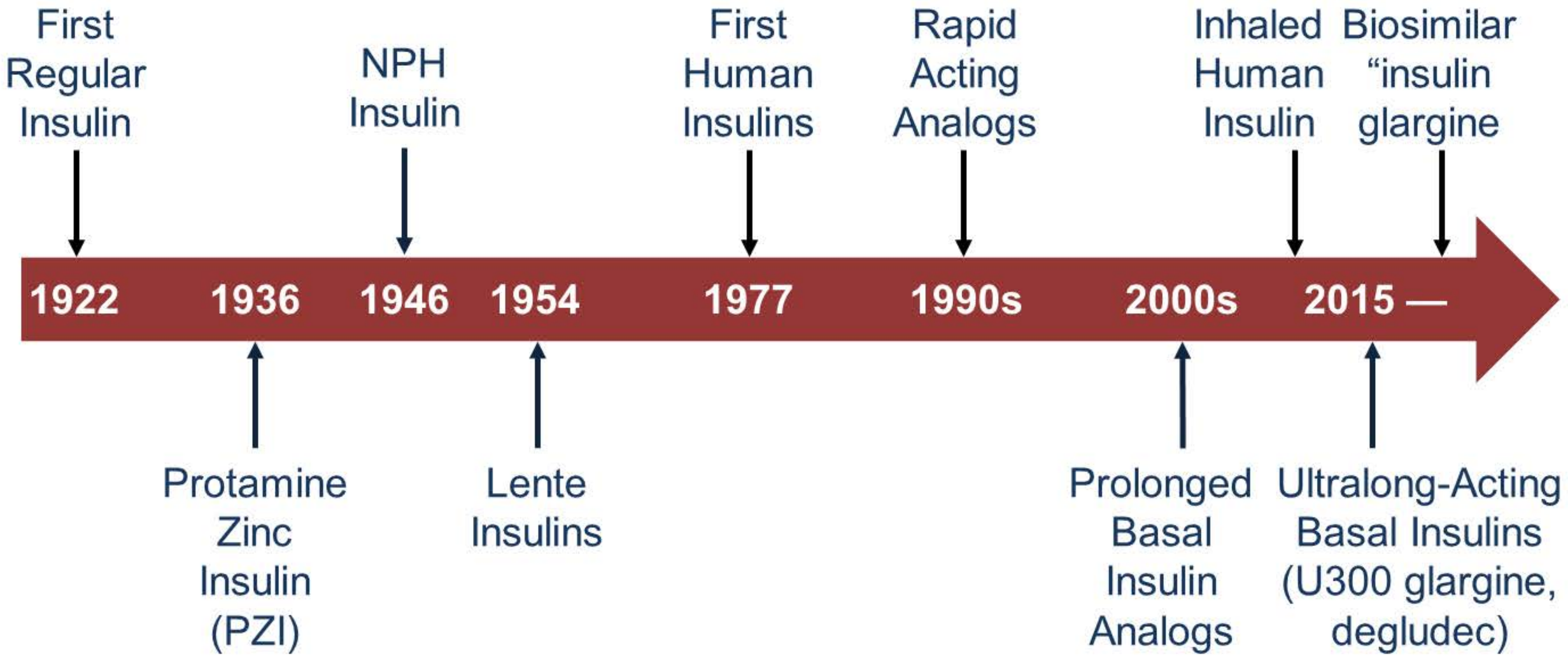
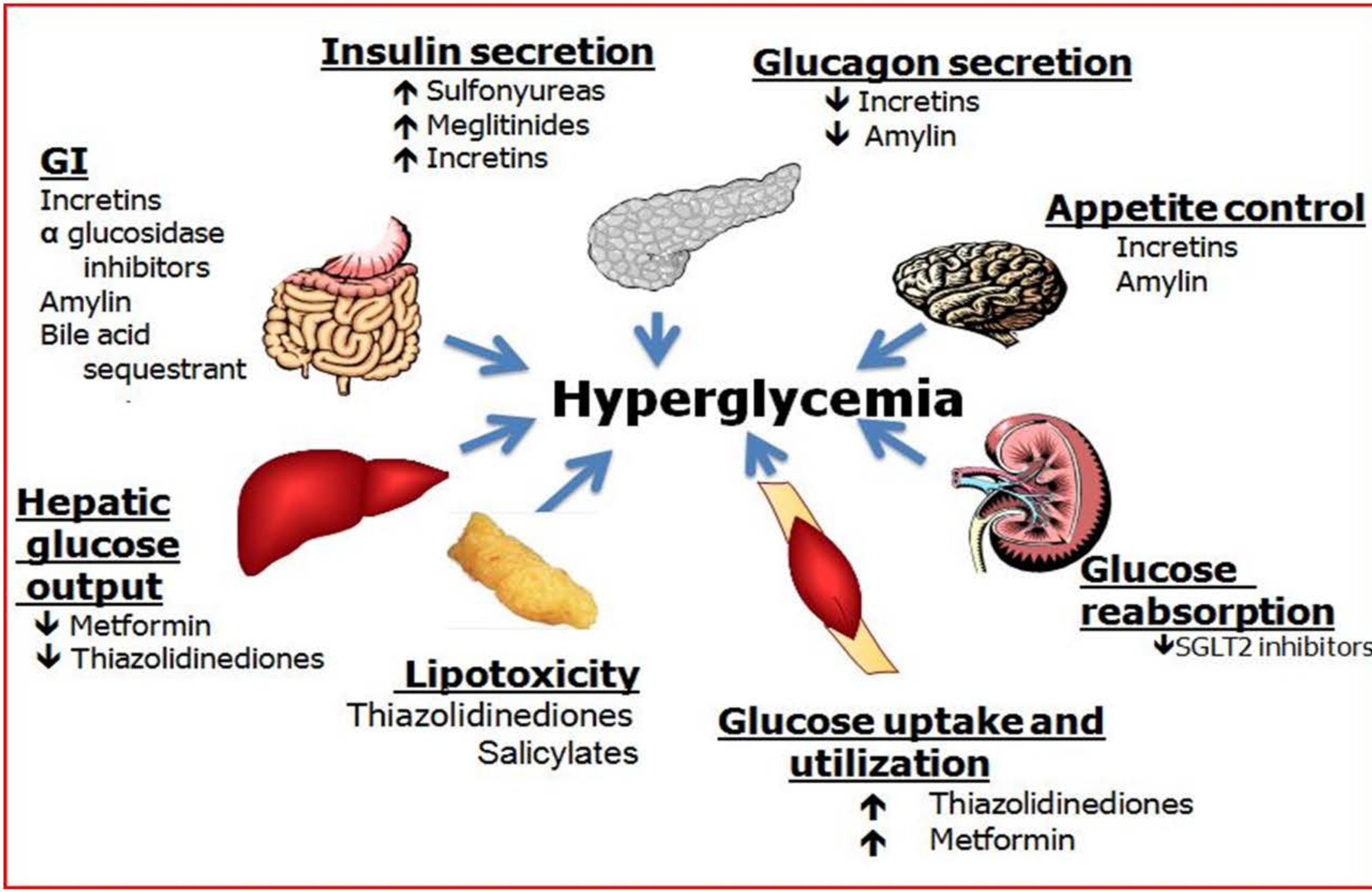


The Evolution of Insulin Products



Tibaldi JM. *Am J Med*. 2014;127:S25-S38. http://www.pdr.net/drug-summary/Toujeo-insulin-glargine-3688. Accessed March 28, 2016. http://www.pdr.net/drug-summary/Tresiba-insulin-degludec-3796. Accessed March 28, 2016.

Drugs for DM Management



ADA Antihyperglycemia Treatment in T2DM

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 (See Figure 8.2)

Antihyperglycemic Agents in Type 2 Diabetes

Class	A1C Reduction	Hypo-glycemia	Weight Change	Dosing (times/day)	Diabetes Comorbidity Contraindications
Metformin	> 1.0	No	Neutral	2	Caution in kidney, liver
Insulin, Long-acting	> 1.0	Yes	Gain	1, Injected	None
Sulfonylureas	> 1.0	Yes	Gain	1	Reduce with kidney
Thiazolidinediones	~ 1,0	No	Gain	1	Avoid in CHF, liver
Repaglinide	> 1.0	Yes	Gain	3	Essentially none
Nateglinide	< 1.0	Rare	Gain	3	Essentially none
Alpha-glucosidase Inhibitors	< 1.0	No	Neutral	3	Essentially none
Amylin-mimetics	< 1.0	No	Loss	3, Injected	Caution in gastroparesis or GERD
Short-acting GLP-1 R Agonists	~ 1.0	No	Loss	2, Injected	Adjust for kidney
Long-Acting GLP-1 R Agonists	> 1.0	No	Loss	1 or < 1	Pancreatitis
DPP-IV Inhibitor	< 1.0	No	Neutral	1	Adjust for kidney in some
Bile acid sequestrant	< 1.0	No	Neutral	1-2	Avoid in severe TG's
Bromocriptine	< 1.0	No	Neutral	1	Essentially none
SGLT-2 Inhibitors	> 1.0	No	Loss	1	Genital mycotic infection

Israili ZH Am J Therap 2011; 18:117. Nathan DM Diabetologia 2009; 52:17. Nathan DM *Diabetes Care*. 2008;31:17. Gross JL Ann Intern Med 2011; 154:672.

Modified Diabetes Treatment Plan

All patients should receive diabetes education + metformin

Metformin

Monotherapy

A1c > 7%

Add a sulfonylurea like glimepiride if not at goal on metformin monotherapy

Sulfonylurea

Dual Therapy

A1c > 7%

Start insulin at 0.15 units/kg

If after 3 months of basal insulin or GLP-1 titration:

A1c not 10% lower or > 7.5%

or FBS remains ≥ 120mg/dl →

Move to next level

Basal Insulin (NPH, Basaglar) **OR** **GLP-1 Agonist**

Consider GLP-1 if BMI ≥ 30 or Wt ≥ 100kg.

Expect some N/V, but it will likely subside; eat smaller meals.

Triple Therapy

A1c ≥ 9%

A1c ≤ 9%

Consider meal time insulin with one dose at largest meal of the day.

Consider GLP-1 if there are barriers to insulin.

Mealtime Insulin (Novolog) **OR** **GLP-1 Agonist**

Basal Insulin

Combination Injectable Therapy

Treatment pearls: Review for treatment barriers, such as adherence, behavioral health and social determinants, before adding therapy. Consider frequent follow-up visits to improve patient engagement and treatment success.

Updated Metformin–CKD Prescribing Guidelines (April 2016)

- Obtain eGFR before starting metformin and annually, more frequently in those at risk for renal impairment (e.g., elderly).
- Metformin contraindicated in patients with an eGFR <30.
- Starting metformin in patients with an eGFR between 30-45 not recommended.
- If eGFR falls <45, assess the benefits and risks of continuing treatment. D/C if eGFR falls <30.
- Hold metformin at the time of / before iodinated contrast procedure if eGFR 30-60; if h/o liver disease, alcoholism, or heart failure; or if intra-arterial contrast. Recheck eGFR 48 hrs after procedure and restart if renal function stable.

http://www.fda.gov/Drugs/DrugSafety/ucm493244.htm *(accessed 4-8-16)*

Sulfonylureas

- Effective and inexpensive
- Impact both fasting and postprandial effect
- Forced insulin secretion:
  - Must eat within 30 minutes of ingestion
  - Hypoglycemia is most significant adverse effect
    - A particular risk in elderly
- Lack of durability of response proposed
  - Answer will come from the GRADE trial
- A small subset of patients will be very sensitive

When to Consider Basal Insulin

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- Basal insulin may be second agent after metformin

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- Able to target high FPG* in type 2 diabetes

*FPG = fasting plasma glucose;

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When to Consider Basal Insulin

- Basal insulin may be second agent after metformin
- When combination noninsulin agents become inadequate A1C >7.0-)
- Able to target high FPG* in type 2 diabetes
- Unacceptable side effects of other agents
- Patient with advanced hepatic or renal disease

*FPG = fasting plasma glucose;

Why consider insulin early?

The benefits of insulin

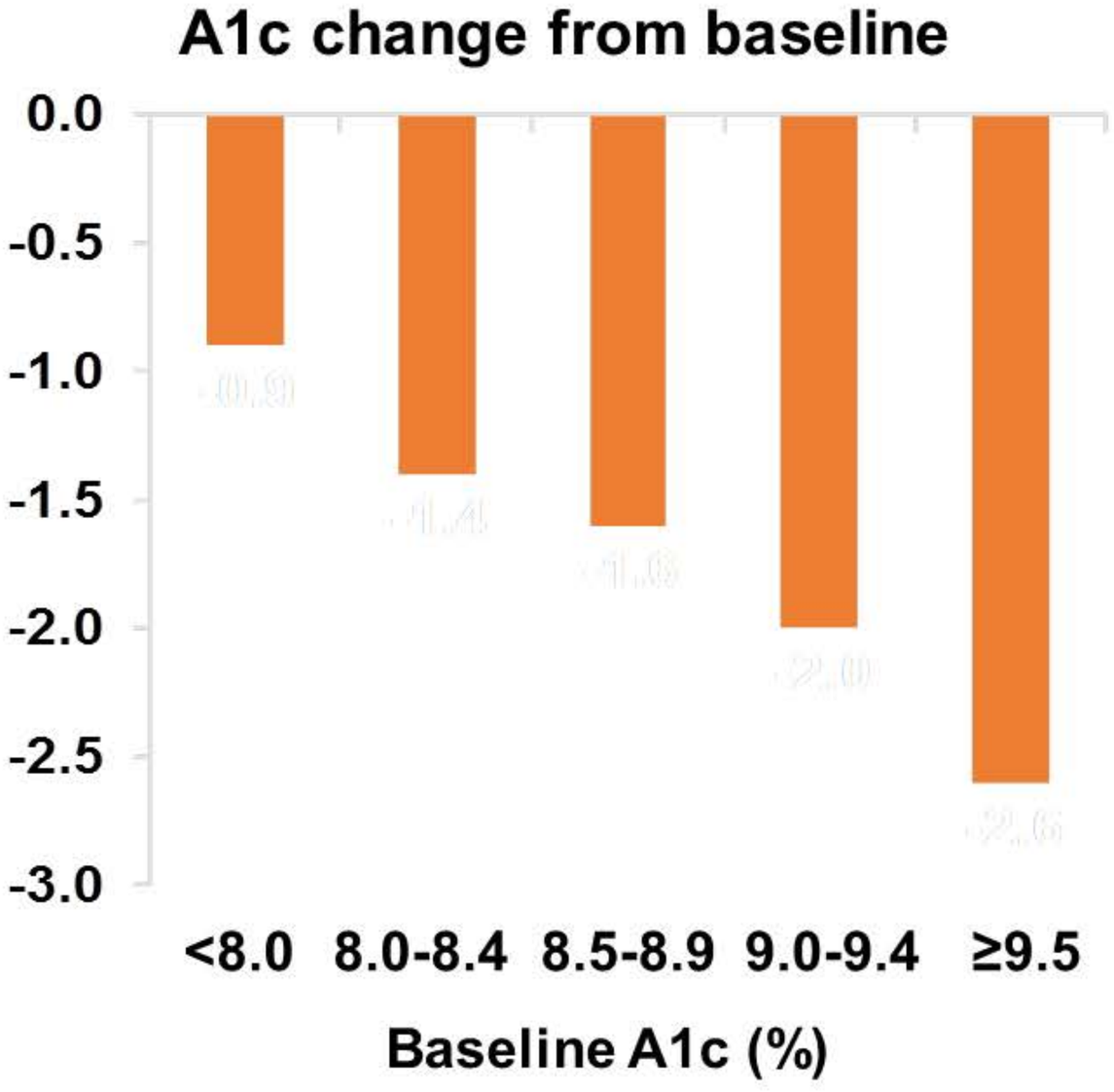
- The most predictable glucose reduction
  - Most effective.
  - Particularly important when A1C is > 9.0% at diagnosis
- Effective targeting of fasting and post-prandial glucose
- Potential for preservation of beta cell function
  - Evidence of diabetes prevention in Origin Trial
  - Evidence of improved insulin secretion when added to oral agents
  - Evidence of beta cell preservation/ prolonged remission when used early in T2DM
- Good safety record other than hypoglycemia
  - No evidence of increased cancer or heart disease

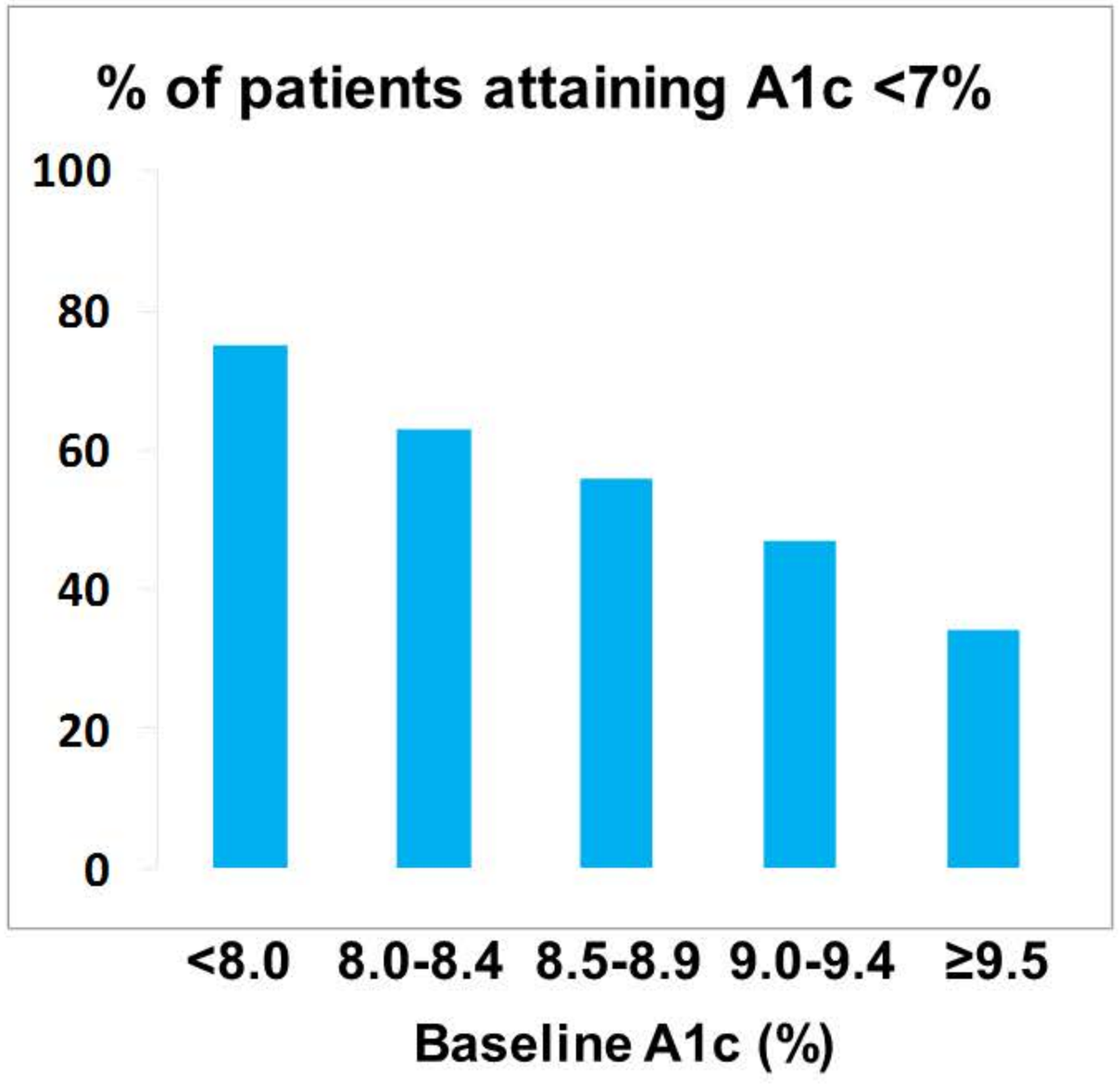
ADA. Diabetes Care. 2015; 38 (suppl 1): S41-S48; Weng J, et al. *Lancet*. 2008;371:1753–60; Pennartz C, et al. Diabetes Care 2011; 34:2048-2053. ORIGIN Trial Investigators, Gerstein HC, et al. N Engl J Med. 2012;367(4):319-28.

Is it likely that basal insulin will result in meeting the target glucose in T2DM?

A1C Reduction vs Baseline with Glargine

Pooled analysis of 2193 patients with 24 weeks titrated glargine added to OAD



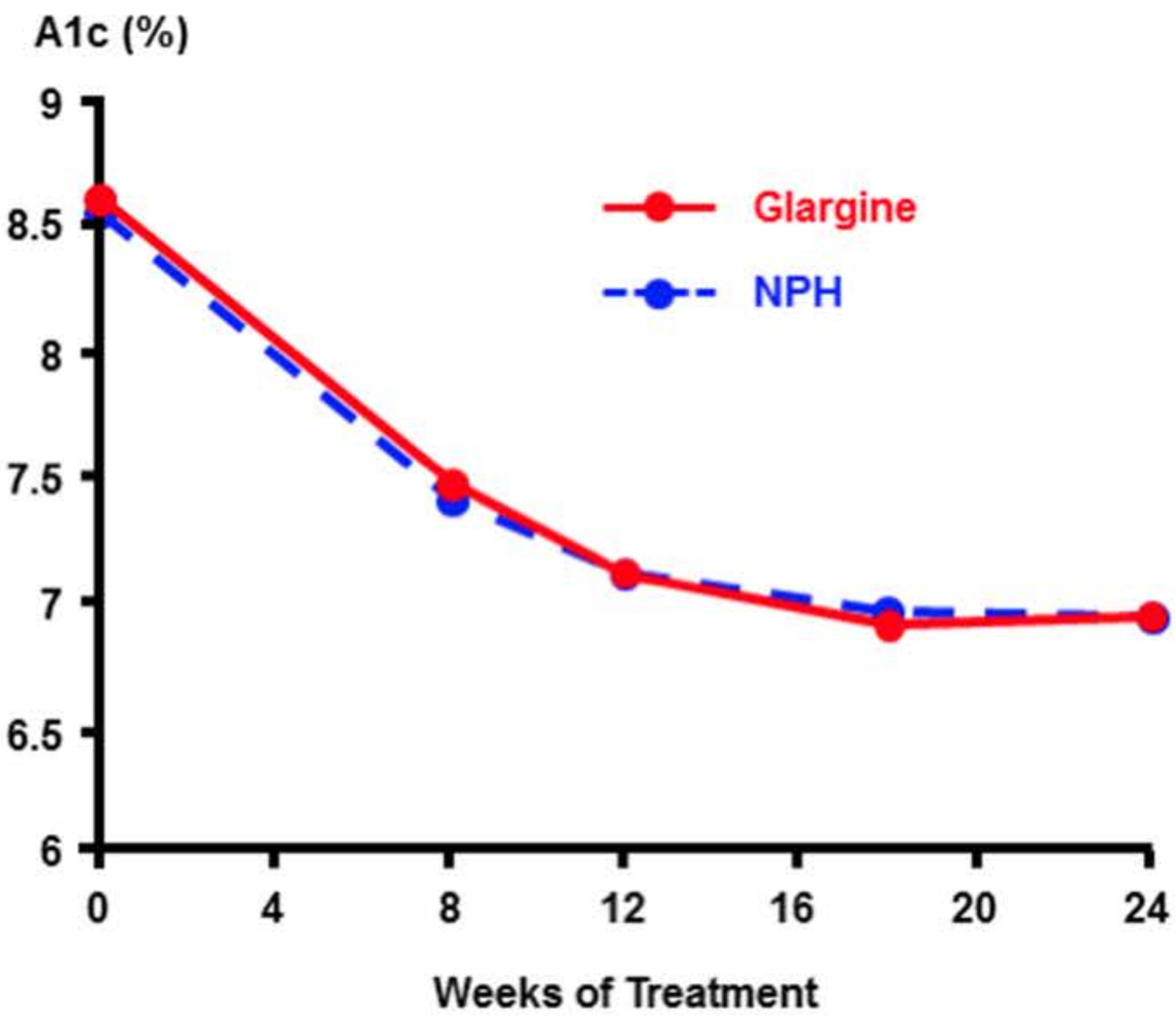


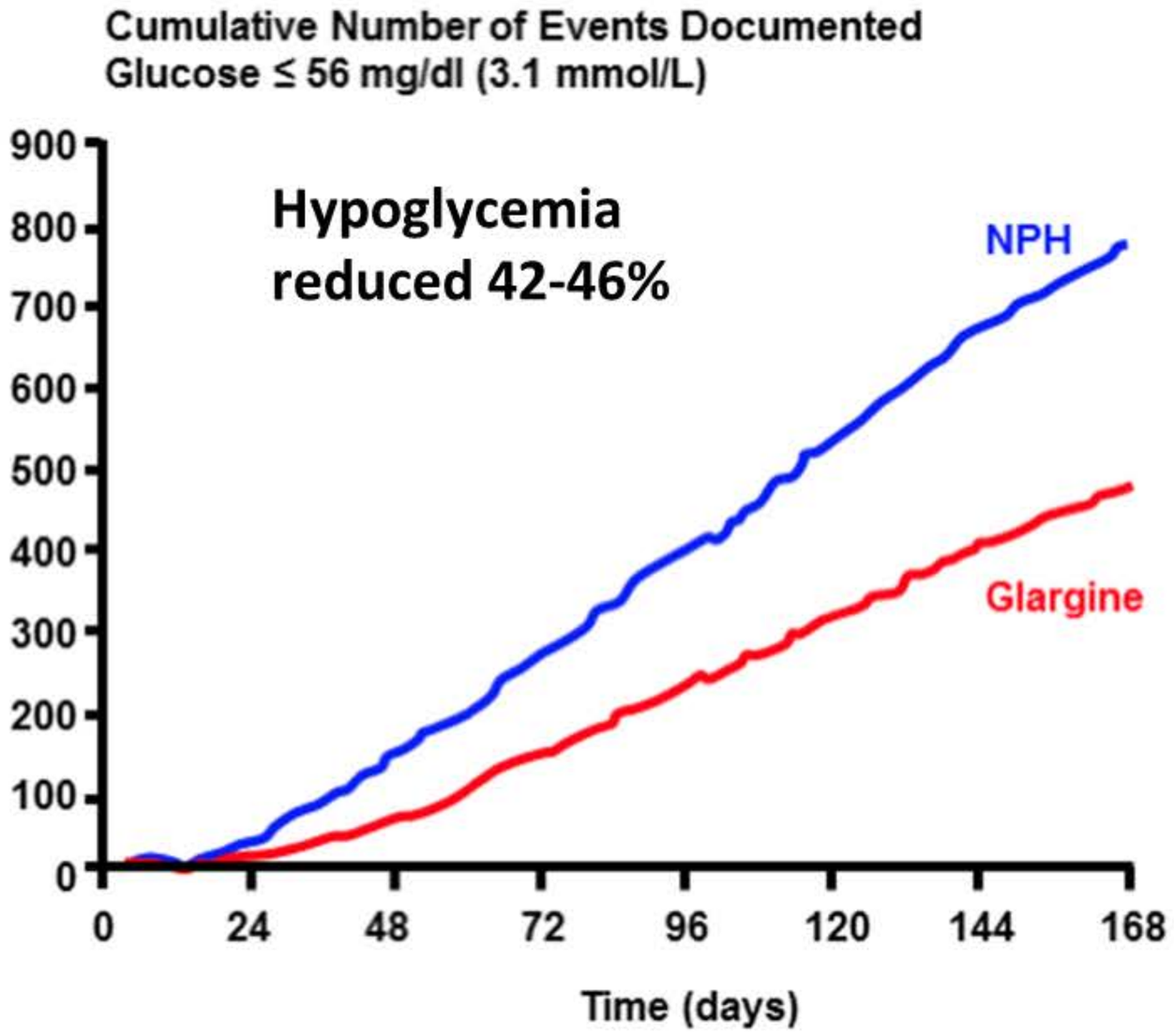
No difference in hypoglycemia rates

Riddle MC, et al. *Diabetes*. 2009;58(Suppl.1):A125.

Glargine vs NPH in Treat-To-Target

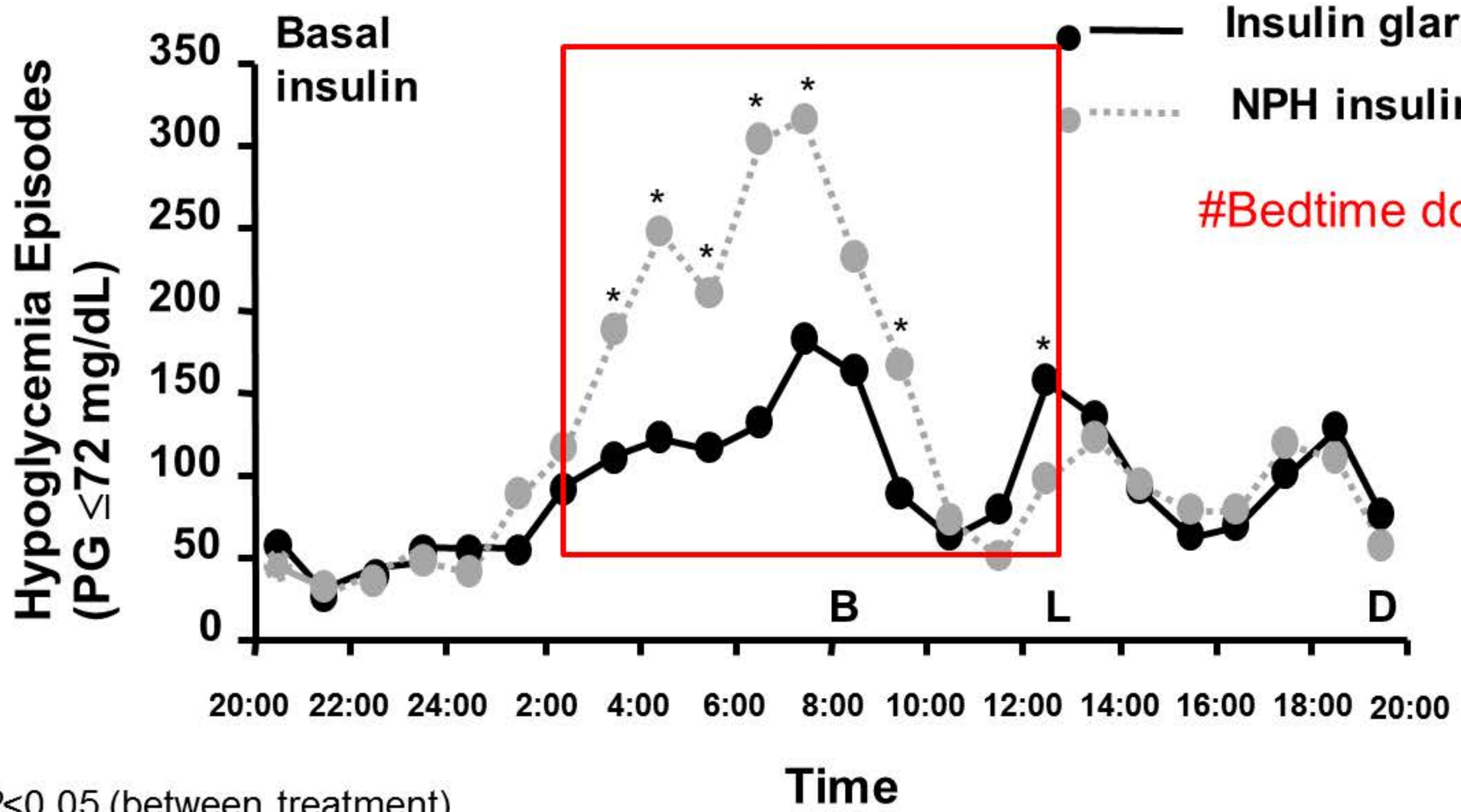
No difference in A1c but reduced hypoglycemia





Riddle M et al. Diabetes Care 2003; 26:3080-3086

Treat-to-Target Trial: Timing and Frequency of Hypoglycemia



*P<0.05 (between treatment).

Adapted from Riddle MC et al. *Diabetes Care*. 2003;26:3080-3086.

When Basal Alone is Not Enough

When A1C is >2% above target

When A1C values are still not at target on basal

AND…

- Fasting BG* levels at or approaching target
- Post-prandial BG values remain above target

OR…

- Total basal insulin dose exceeds 0.5 units per Kg/day

Options:

- **Advance insulin therapy** with additional prandial insulin
  - Basal bolus insulin regimen
  - Premixed insulin
- **Add GLP-1 agonist therapy** if tolerated, not contraindicated and is affordable for the patient

***BG = blood glucose.**

American Diabetes Association. Diabetes Care. 2015;38(suppl 1):S41-S48.

Insulin Therapy In Type 2 Diabetes

Initiate Basal Insulin

Usually with metformin +/- other noninsulin agent

Start: 10 U/day or 0.1–0.2 U/kg/day

Adjust: 10–15% or 2–4 units once or twice weekly to reach FBG target

For hypo: Determine & address cause; if no clear reason for hypo, ↓ dose by 4 units or 10–20%

If A1C not controlled, **consider combination injectable therapy**

Add 1 rapid-acting insulin injection before largest meal

Start: 4 units, 0.1 U/kg, or 10% basal dose. If A1C <8%, consider ↓ basal by same amount

Adjust: ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached

For hypo: Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

Add GLP-1 RA

If not tolerated or A1C target not reached, change to 2 injection insulin regimen

If goals not met, **consider changing to alternative insulin regimen**

Change to premixed insulin twice daily (before breakfast and supper)

Start: Divide current basal dose into ⅔ AM, ⅓ PM or ½ AM, ½ PM

Adjust: ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached

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Diabetes Care 2017; 40 (Suppl 1):S64

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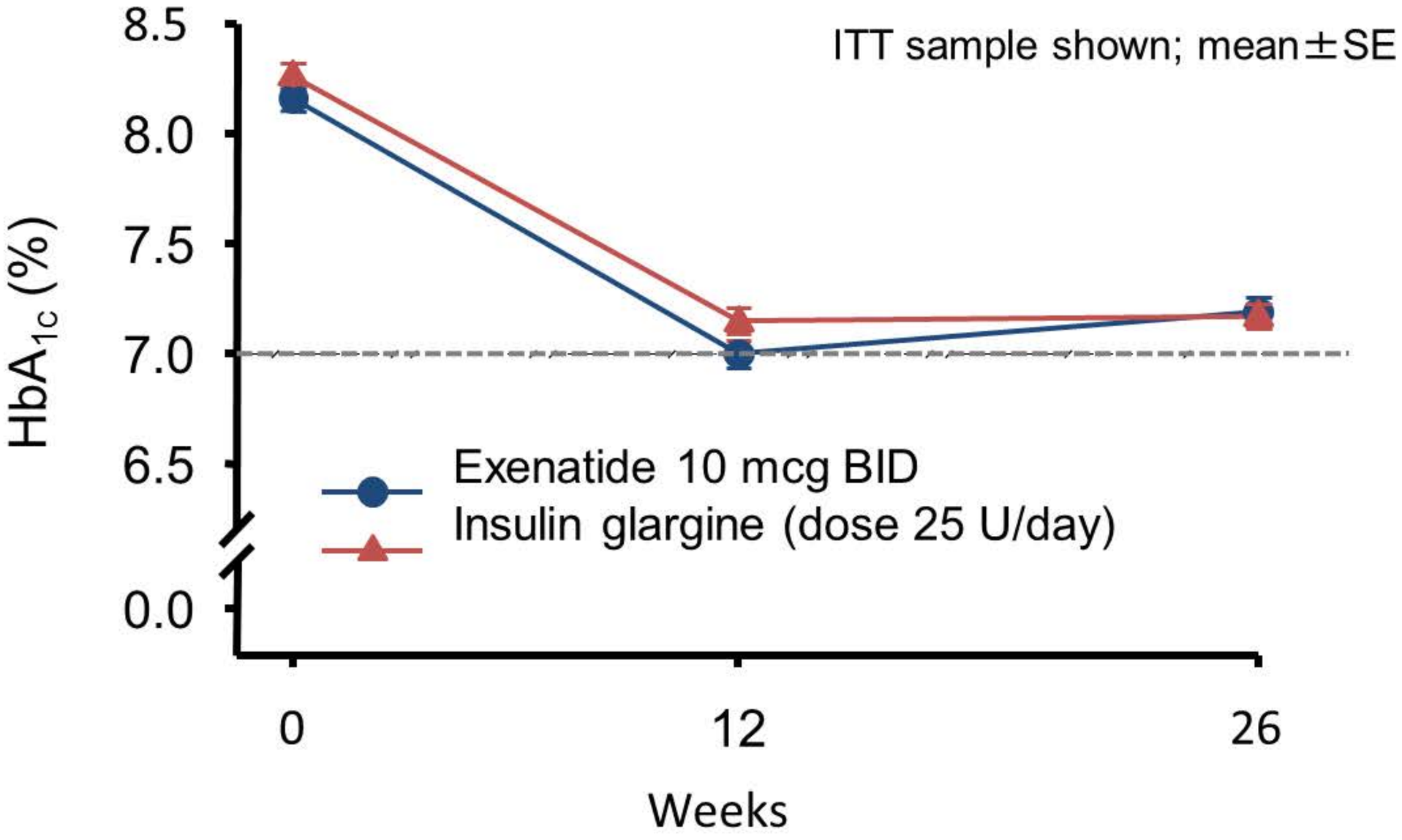
Diabetes Care 2017; 40 (Suppl 1):S64

News in GLP-1 Agonist Use

- Equal or greater A1c reduction compared to basal insulin added to oral agents
- Proven effective when added to basal insulin
  - Raised question of whether prandial insulin should be delayed until after GLP-1 agents are added
    - Evidence for equal efficacy with weight benefit
- Short-acting agents (exenatide) have primary effect on post-prandial glucose.
- Long-acting agents impact fasting and pp glucose
  - Once daily and once weekly have similar effects as long-acting agents
- Risk of pancreatitis is still uncertain but low
- No good evidence for pancreatic cancer.
- Major side effects are GI

How do GLP-1 agonists compare to basal insulin therapy?

Short-acting GLP-1 RA and basal insulin are equally effective in lowering HbA_{1c}

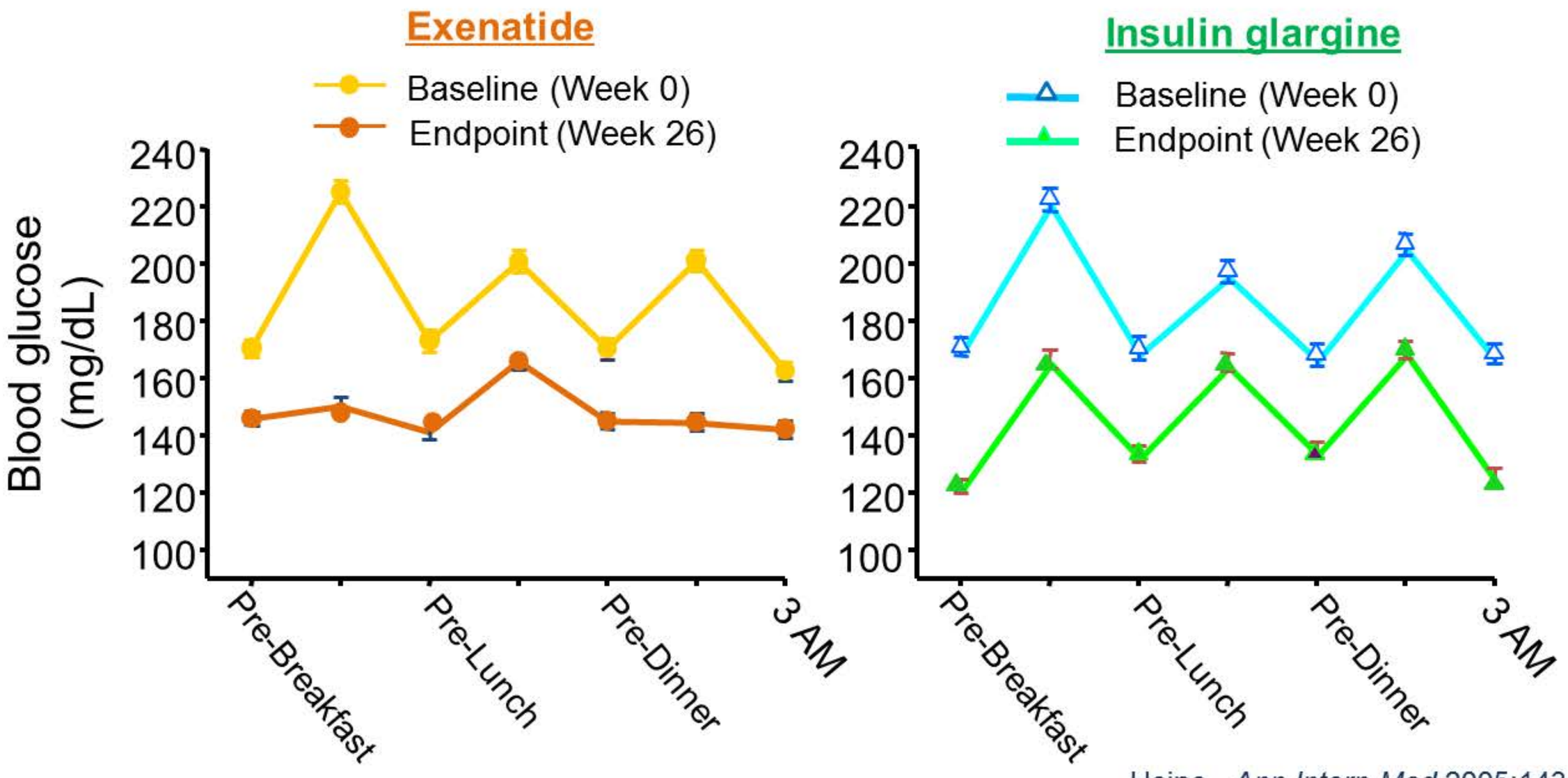


Heine. *Ann Intern Med* 2005;143:559–569.

Exenatide/glargine comparator

Short-acting GLP-1 agonist vs. basal insulin
7-Point Profiles

Basal insulin primarily affects fasting glucose



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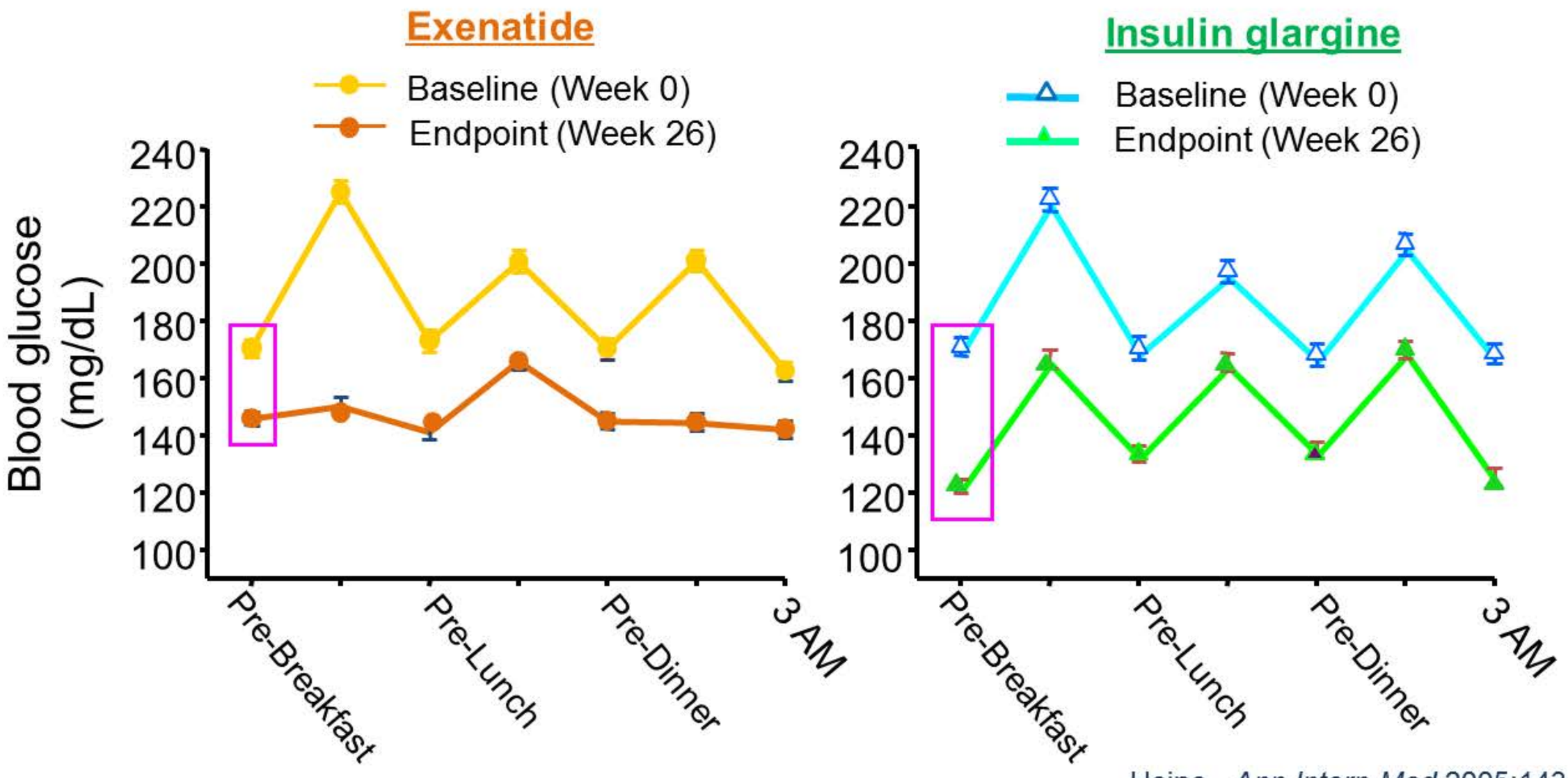

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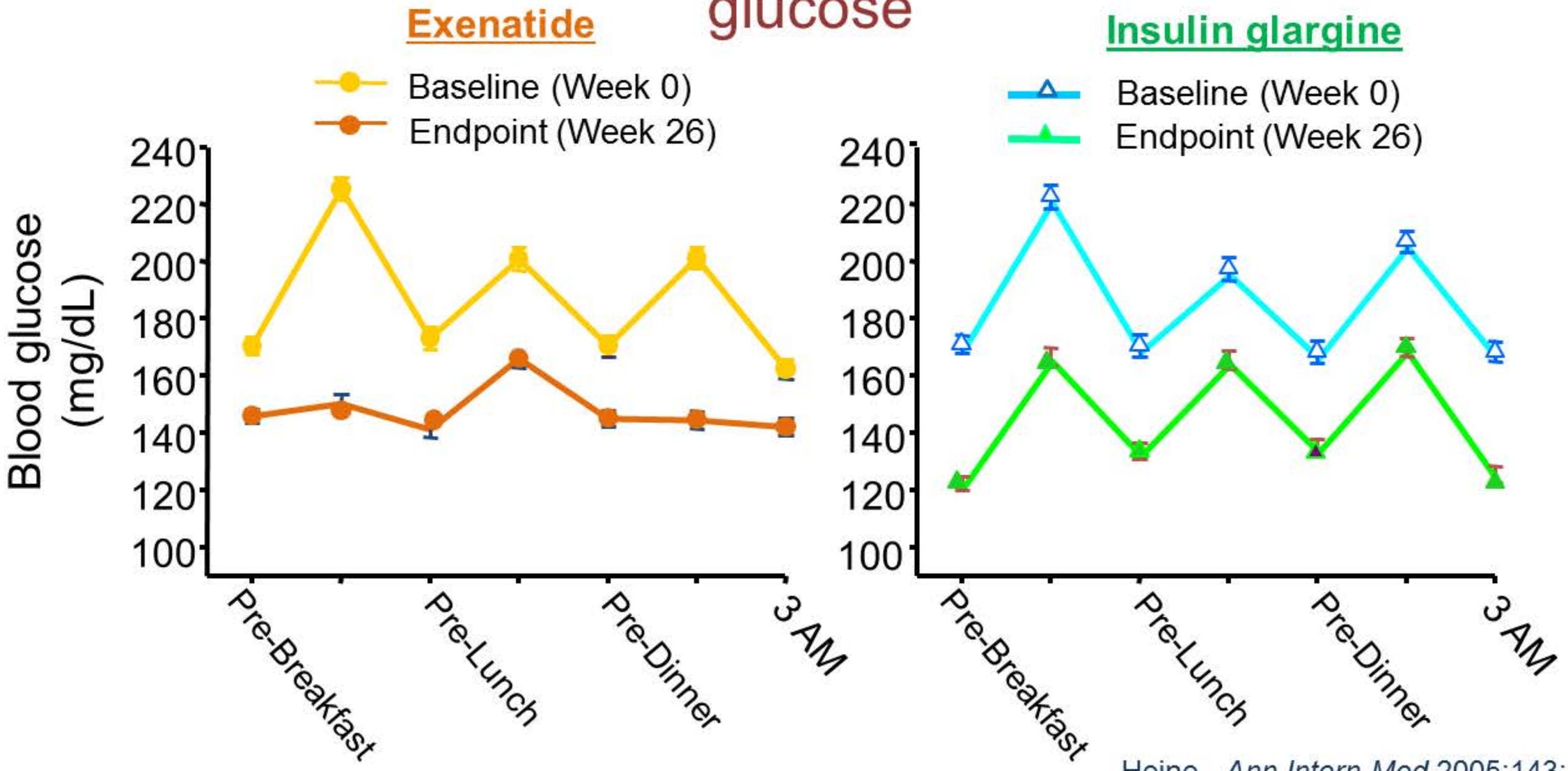

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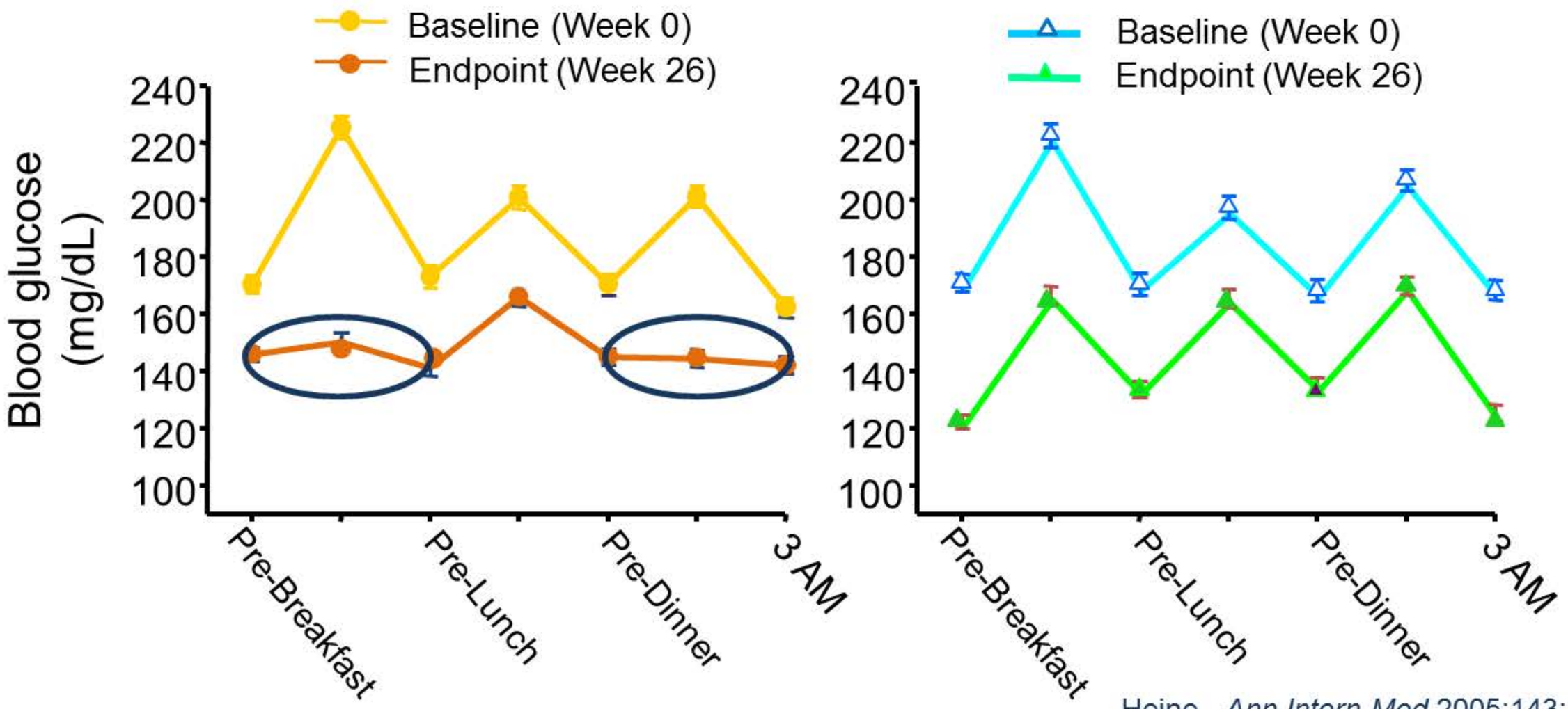

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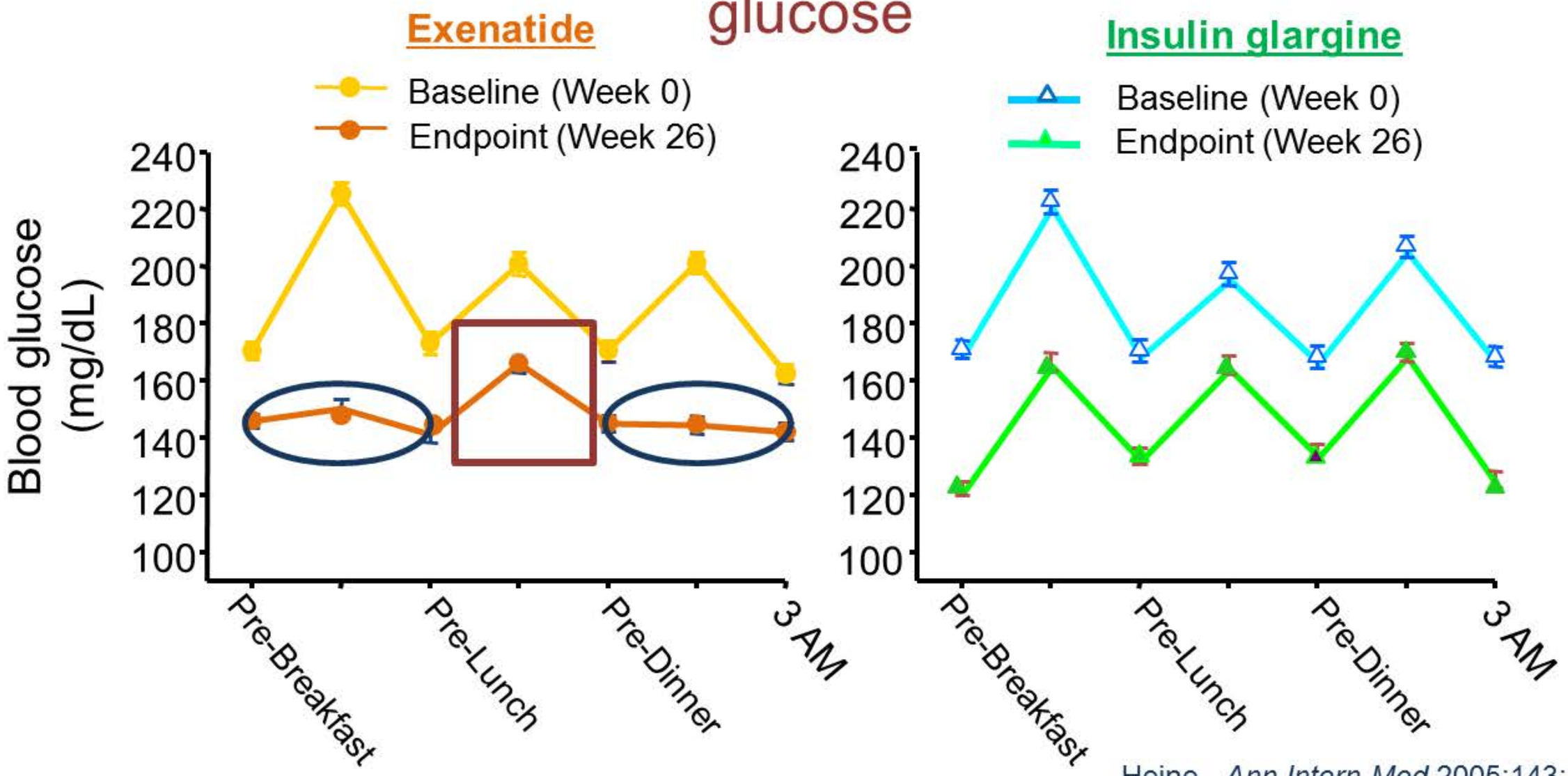
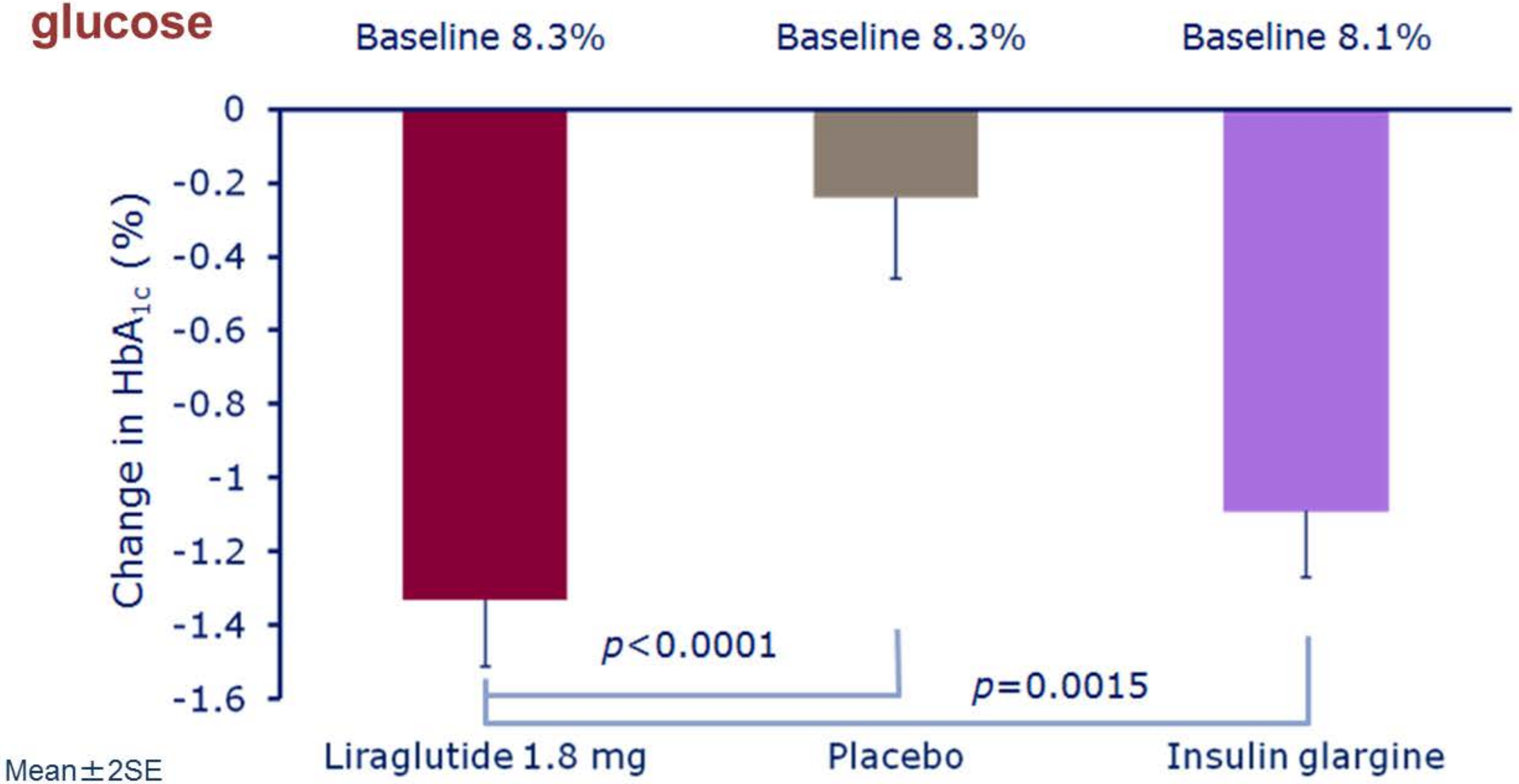


Heine. *Ann Intern Med* 2005;143:559–569.

Long-acting GLP-1 Agonist vs Basal Insulin HbA_{1c} change from baseline

Long-acting GLP-1 agonists affect both fasting and post-prandial glucose



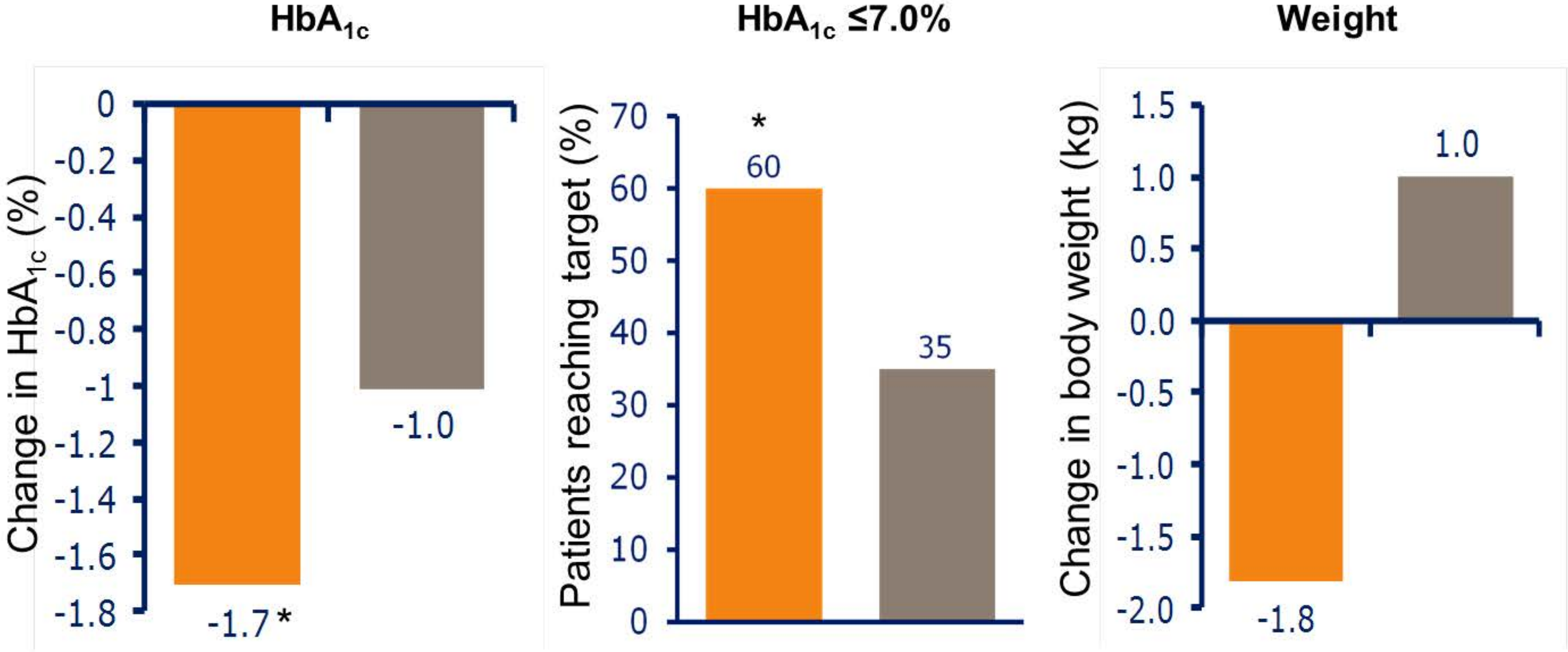
Mean±2SE

Greater reduction in A1C with liraglutide although this may depend on the aggressiveness of glargine titration.

Russell-Jones *et al. Diabetologia* 2009;52:2046–2055 (LEAD-5).

What happens when you add a GLP-1 agonist to basal insulin therapy?

Addition of exenatide to insulin glargine: efficacy



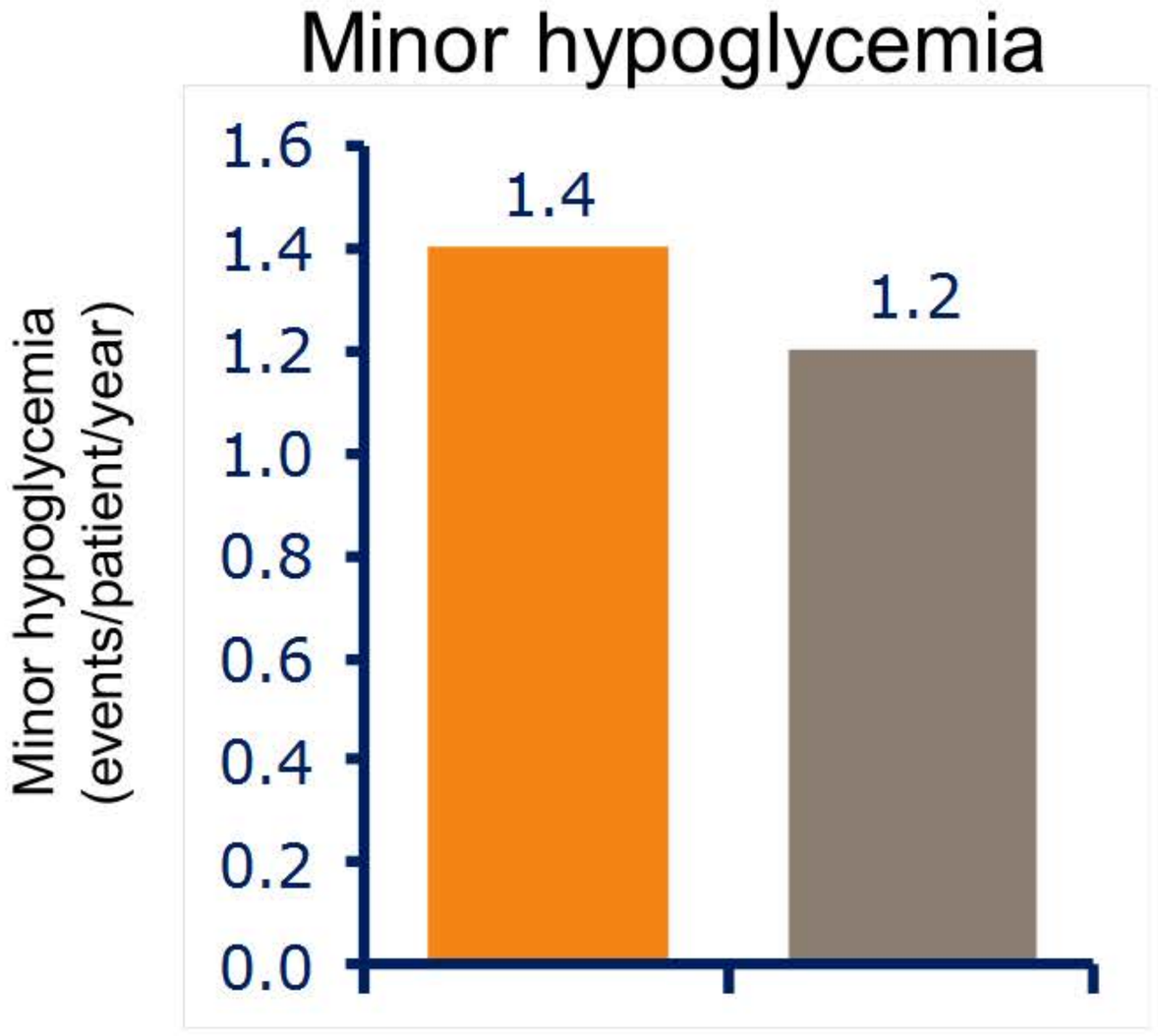
Insulin glargine + exenatide ± OADs (*n*=137) Insulin glargine + placebo ± OADs (*n*=122)

Basal insulin was decreased 20% initially if A1C was < 8.0%

Data are mean. *Significant vs. placebo

Buse *et al. Ann Intern Med* 2011;154:103–112.

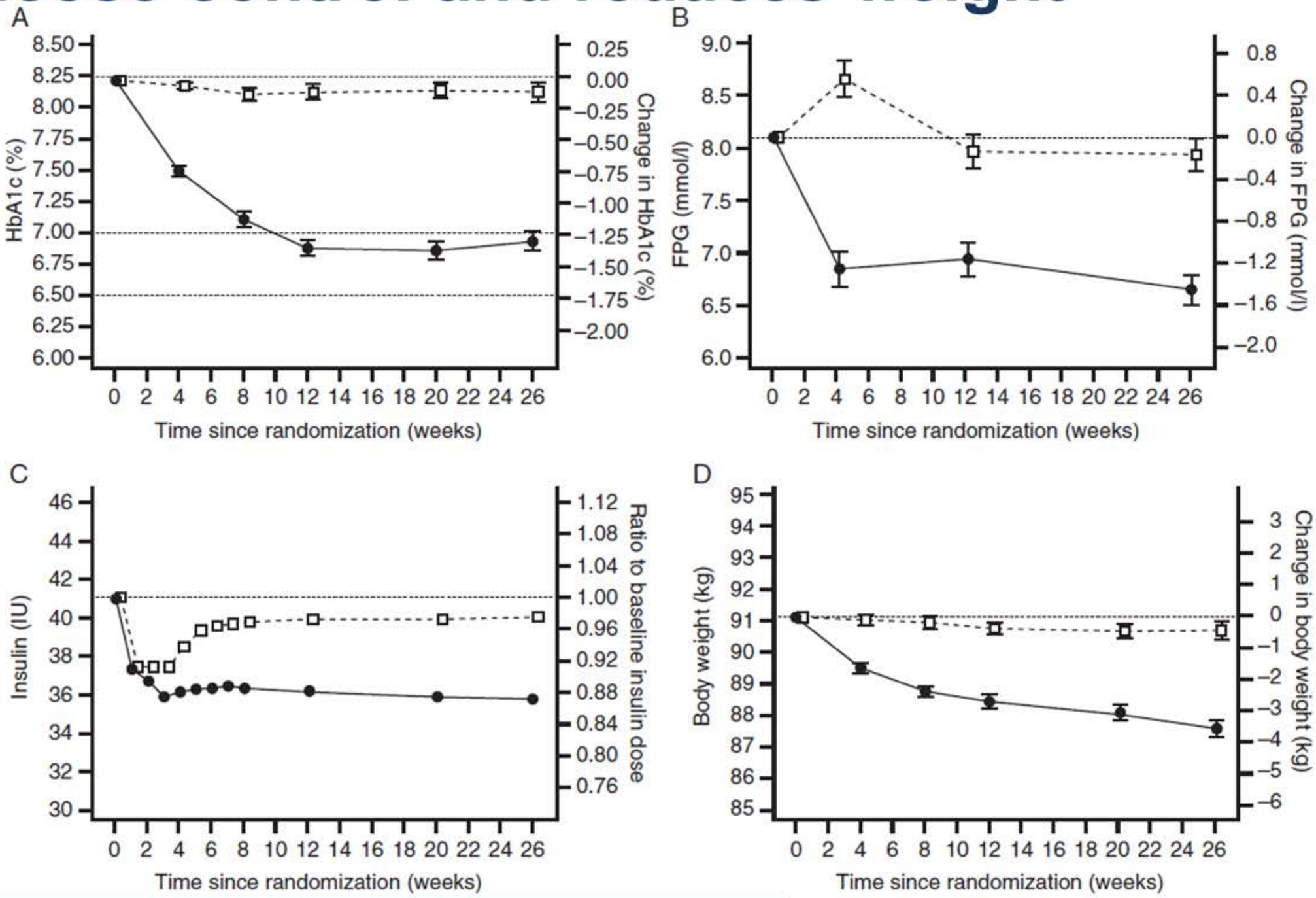
Addition of exenatide to insulin glargine: safety



Two major hypoglycemic episodes were reported in the placebo group

Buse *et al. Ann Intern Med* 2011;154:103–112.

Liraglutide added to basal insulin improved glucose control and reduces weight



Basal insulin was decreased 20% if A1C was < 8.0%

Ahmann A et al. Diab Obes Metab 2015; 17:1056-64

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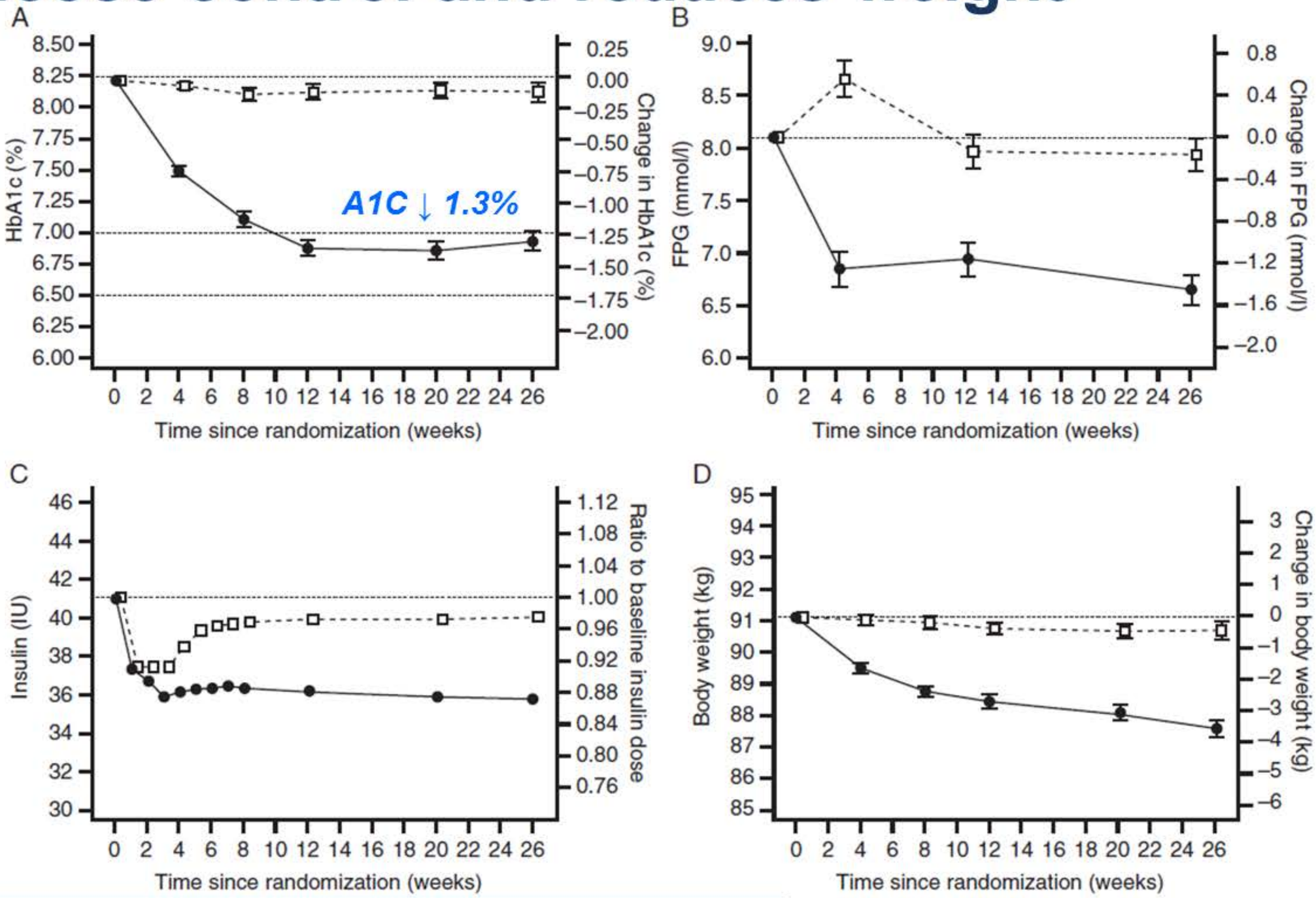

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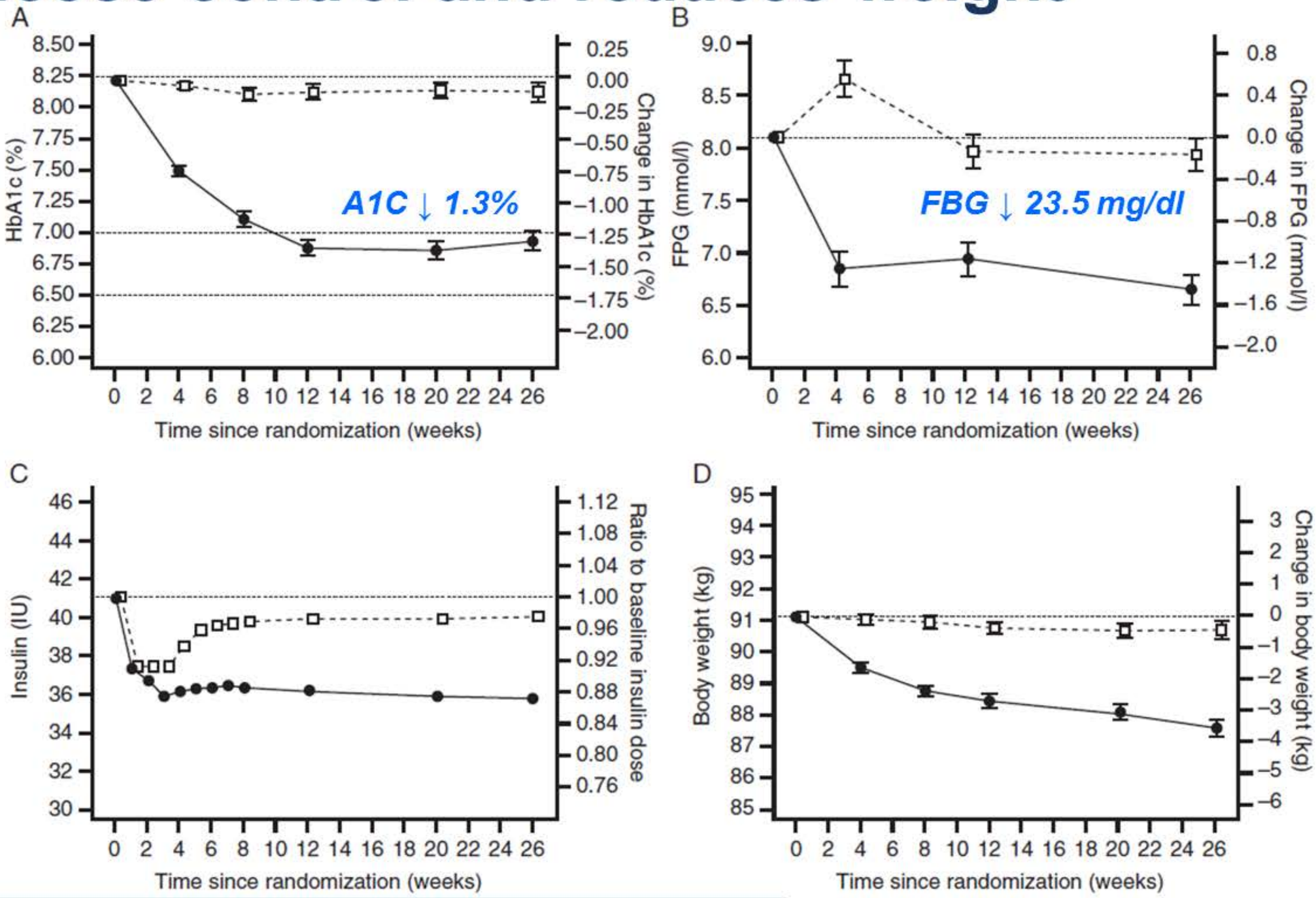

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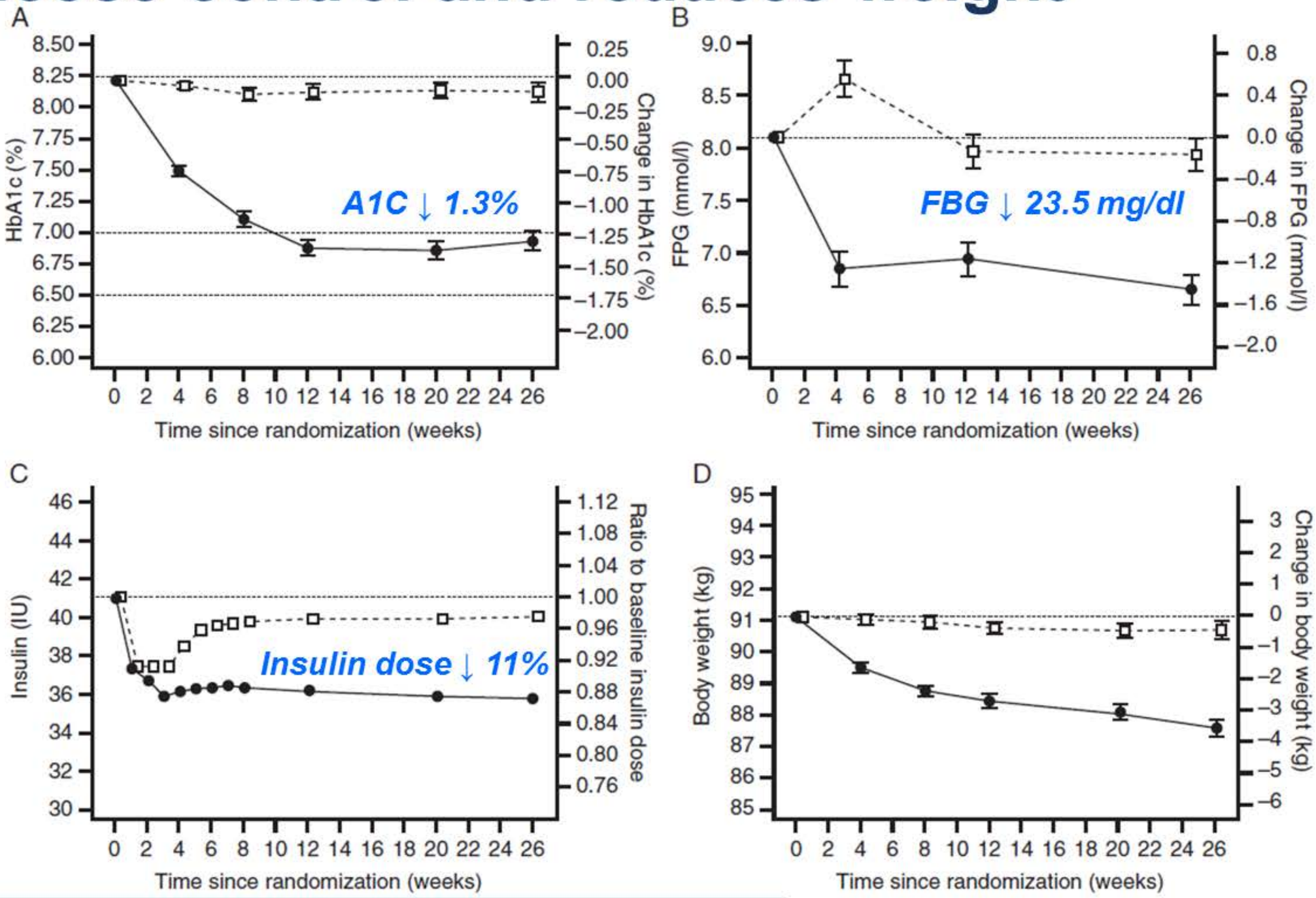

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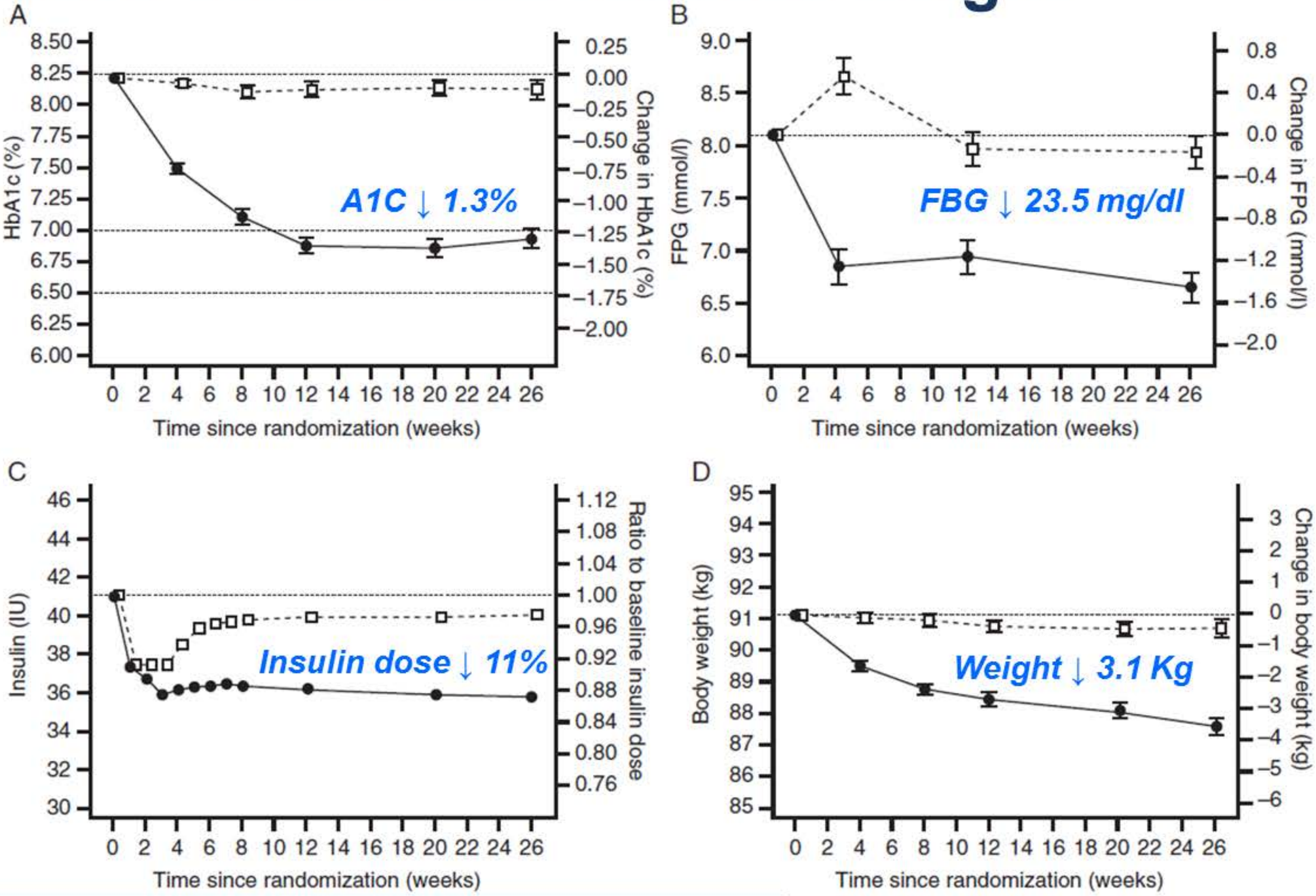

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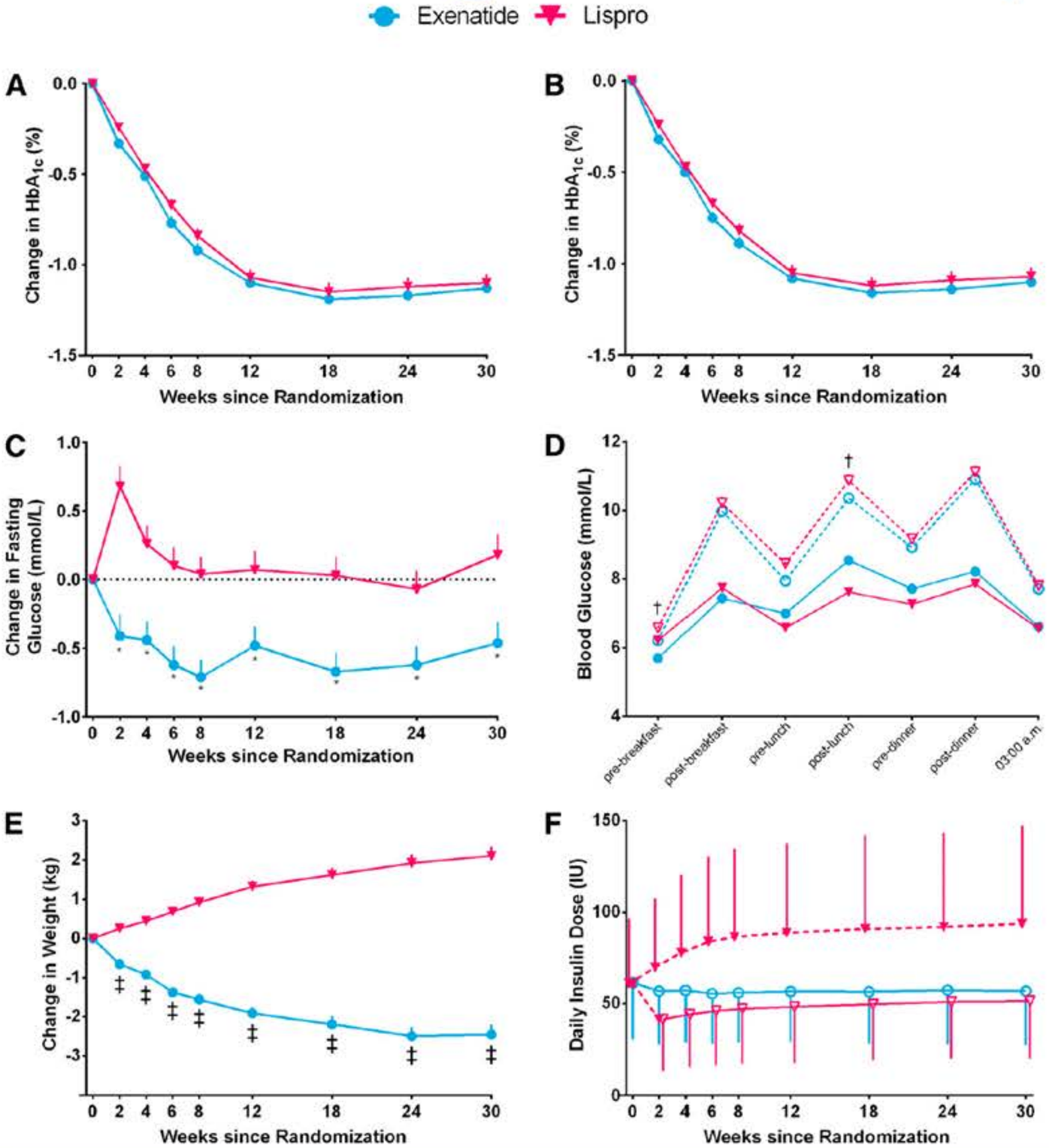
How does the addition of a GLP-1 agonist to basal insulin compare to adding prandial rapid-acting insulin?

Short-Acting GLP-1 vs Rapid Insulin After Basal



30 Week RCT with N = 627

Added Lispro before meals or added exenatide 10 mcg bid

Basal insulin was initially decreased by 10% if A1C < 8%

Adding the GLP-1 agent resulted in:

Diamont M et al. Diabetes Care 2014; 37:2763-2773

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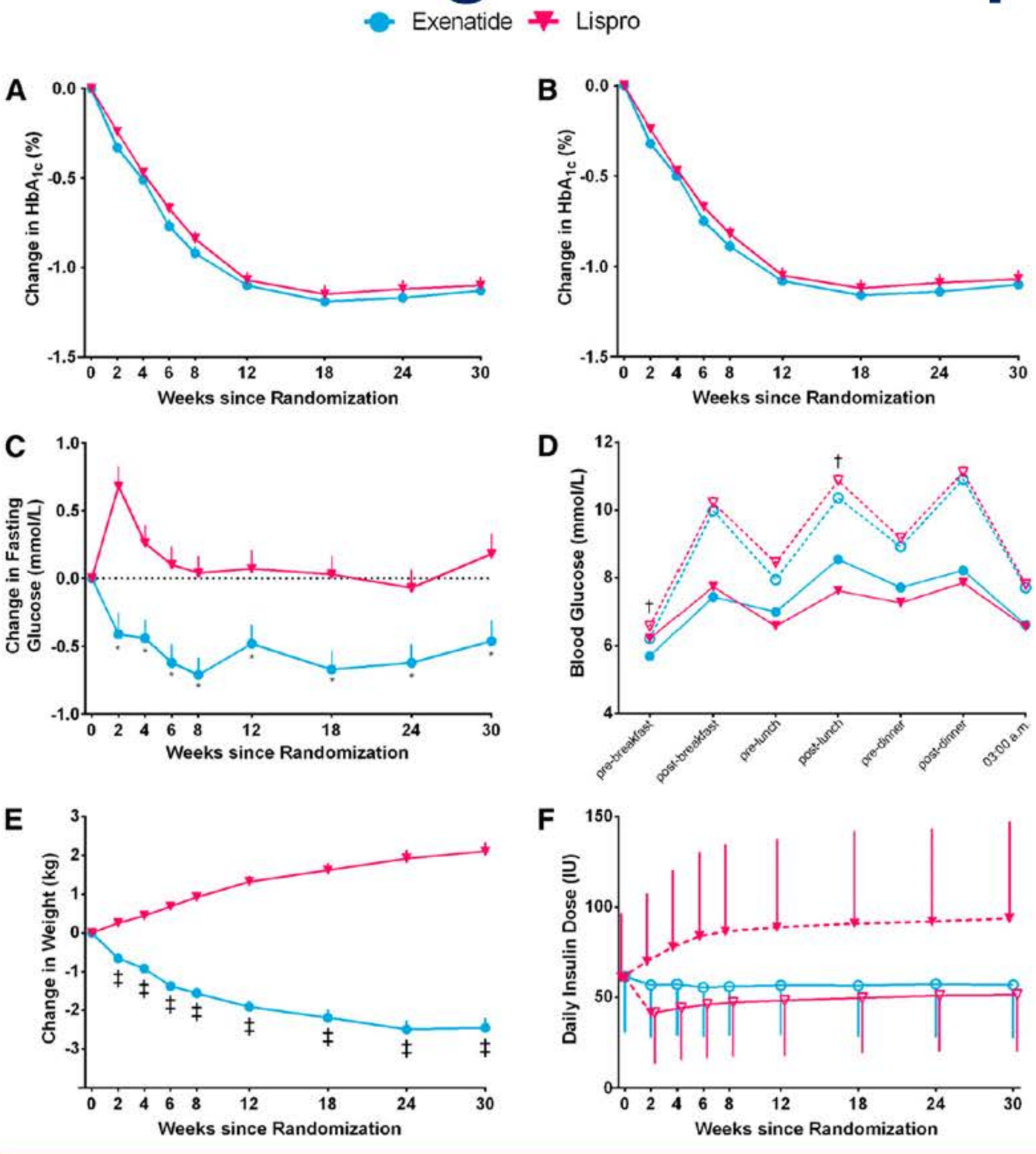
Short-Acting GLP-1 vs Rapid Insulin After Basal



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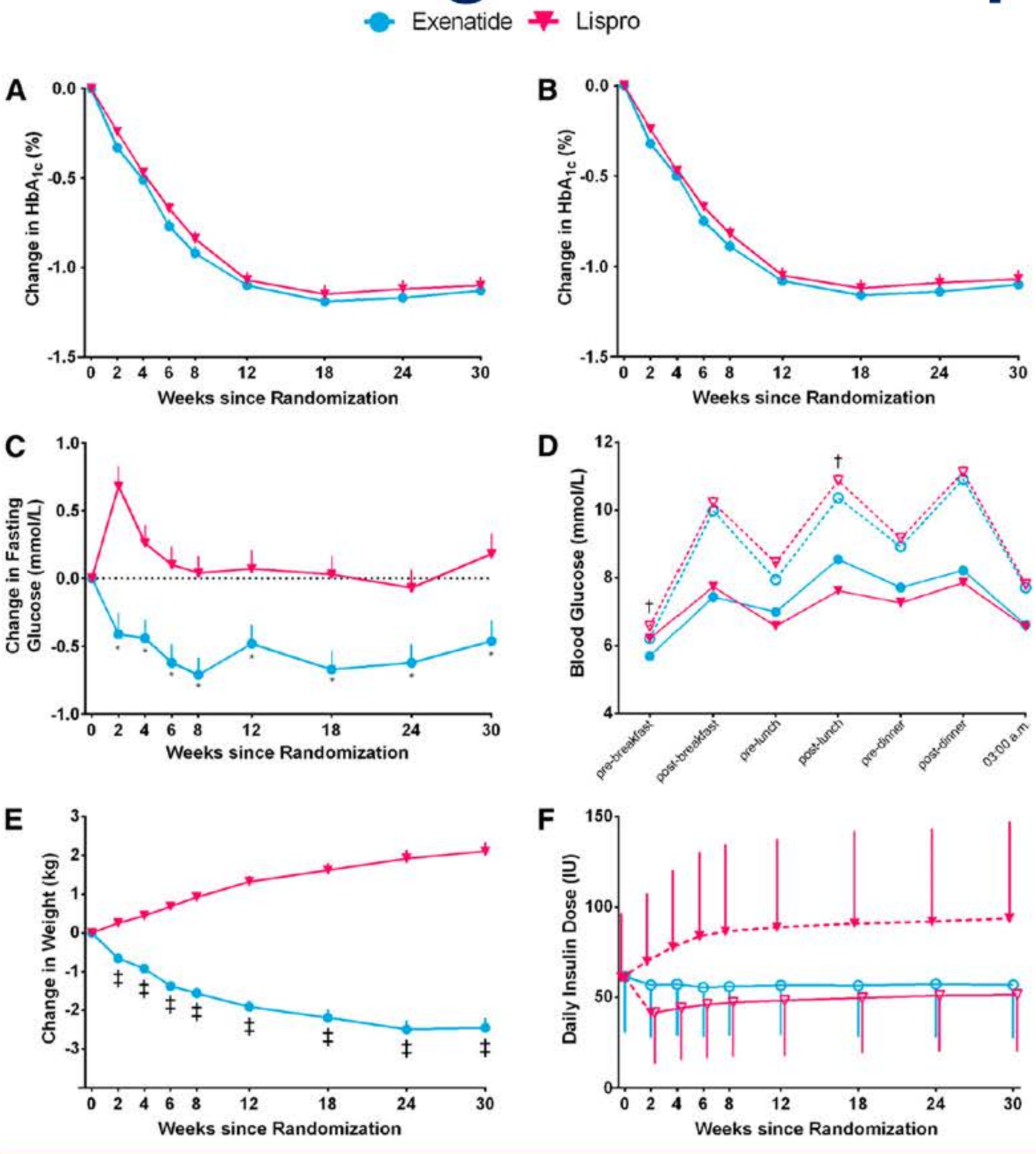

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Adding the GLP-1 agent resulted in:

- Equal A1C reduction
- Lower fasting glucose

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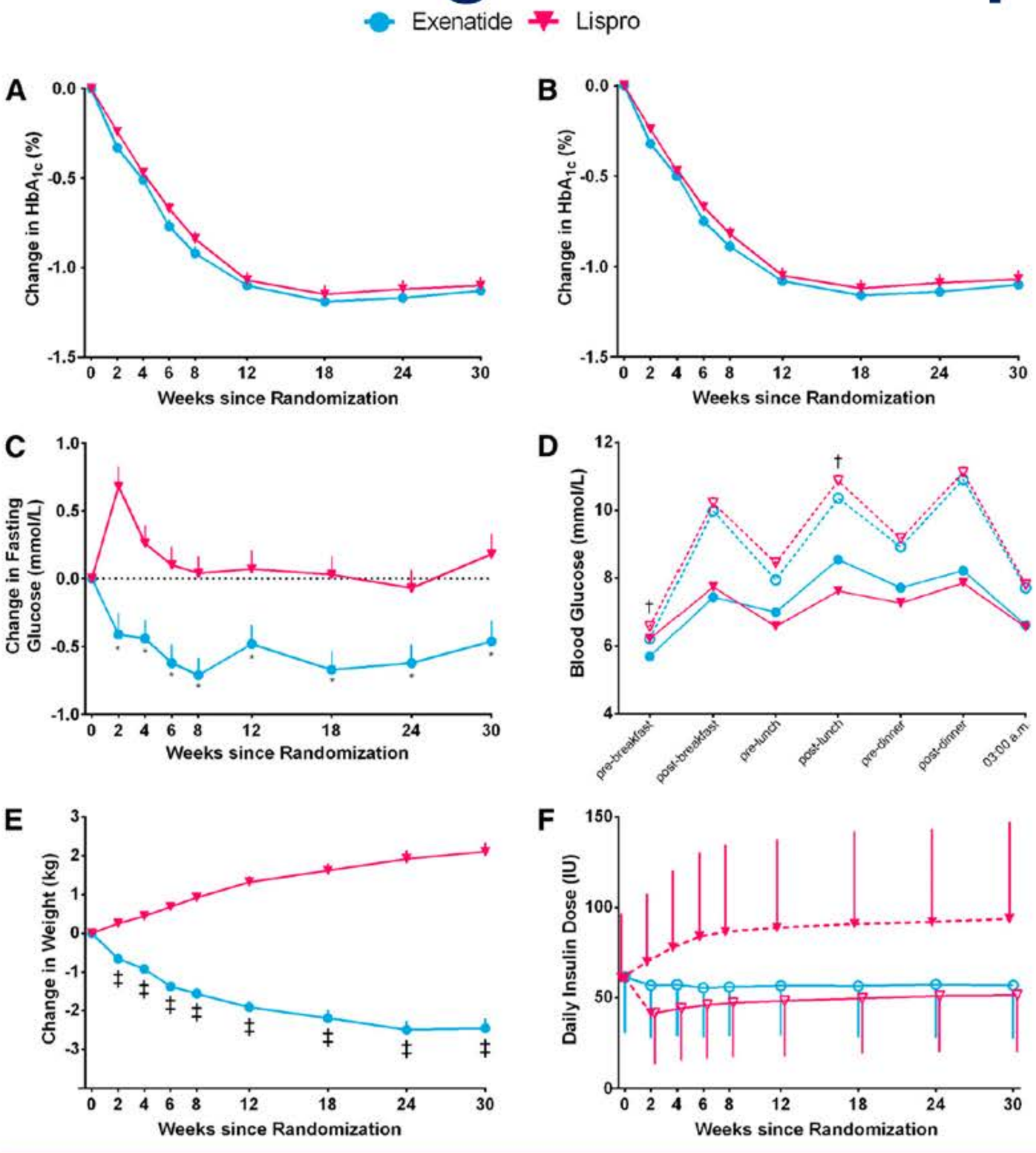

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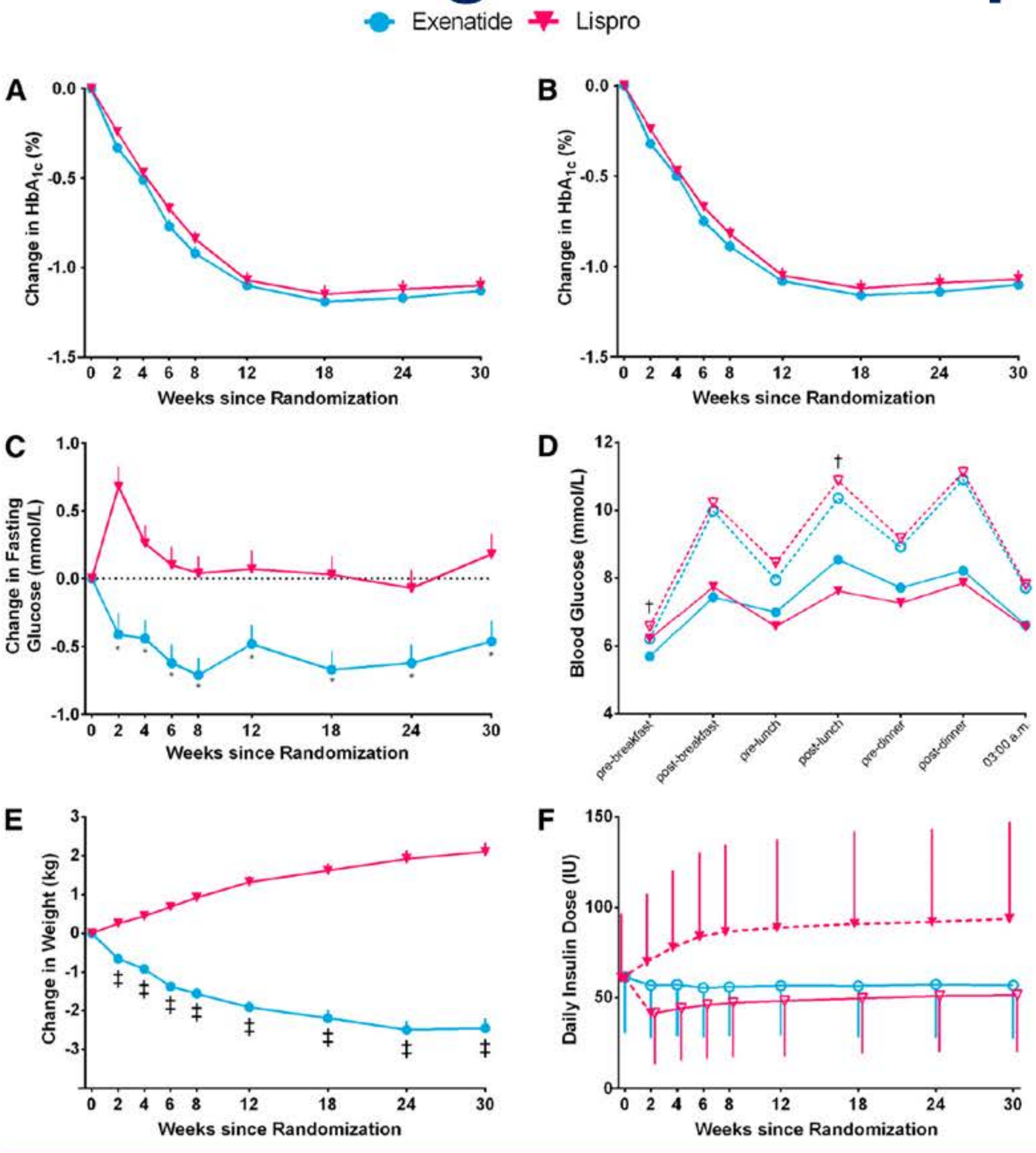

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- Lower fasting glucose
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- Weight benefit

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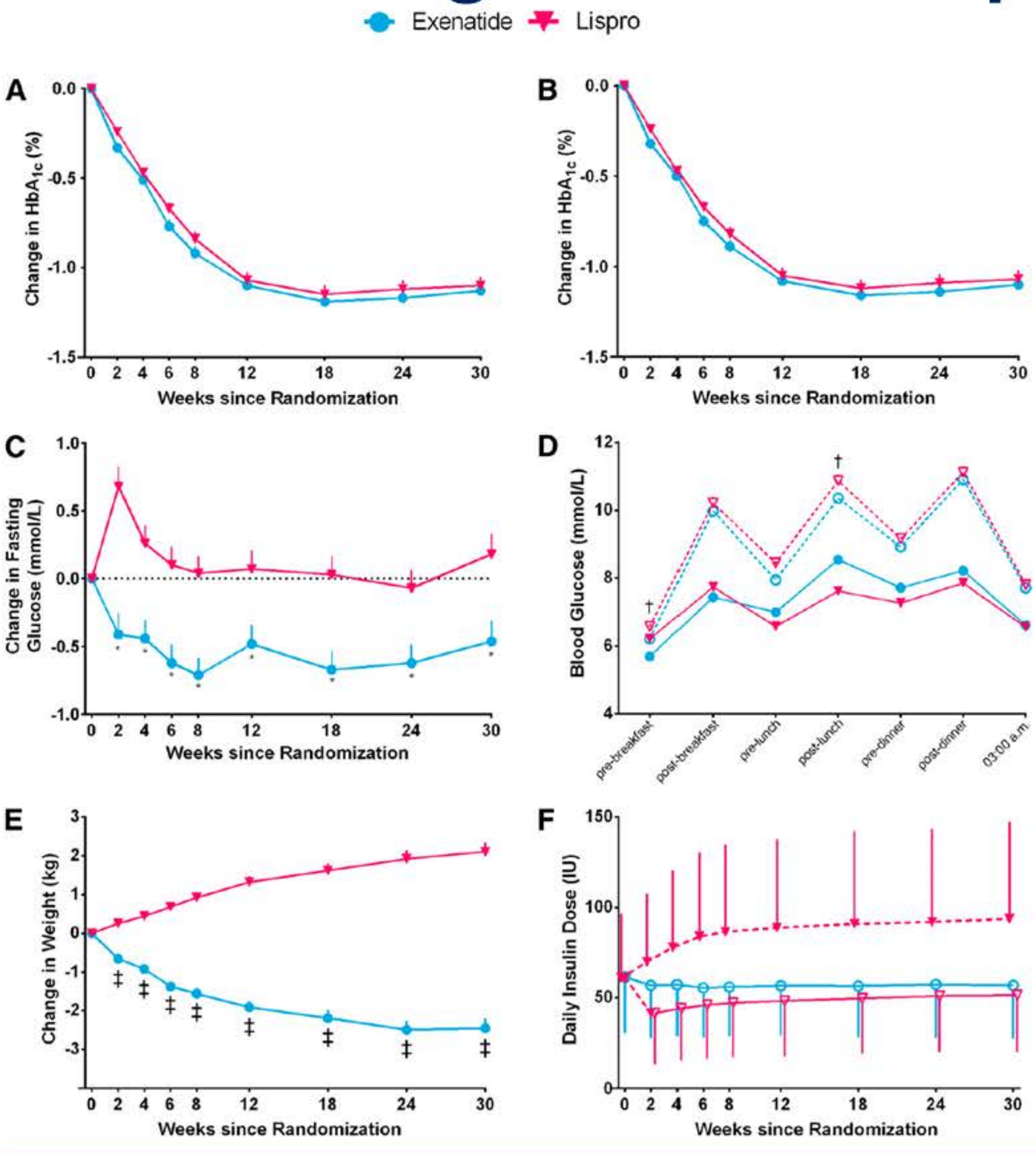

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- Reduced systolic BP

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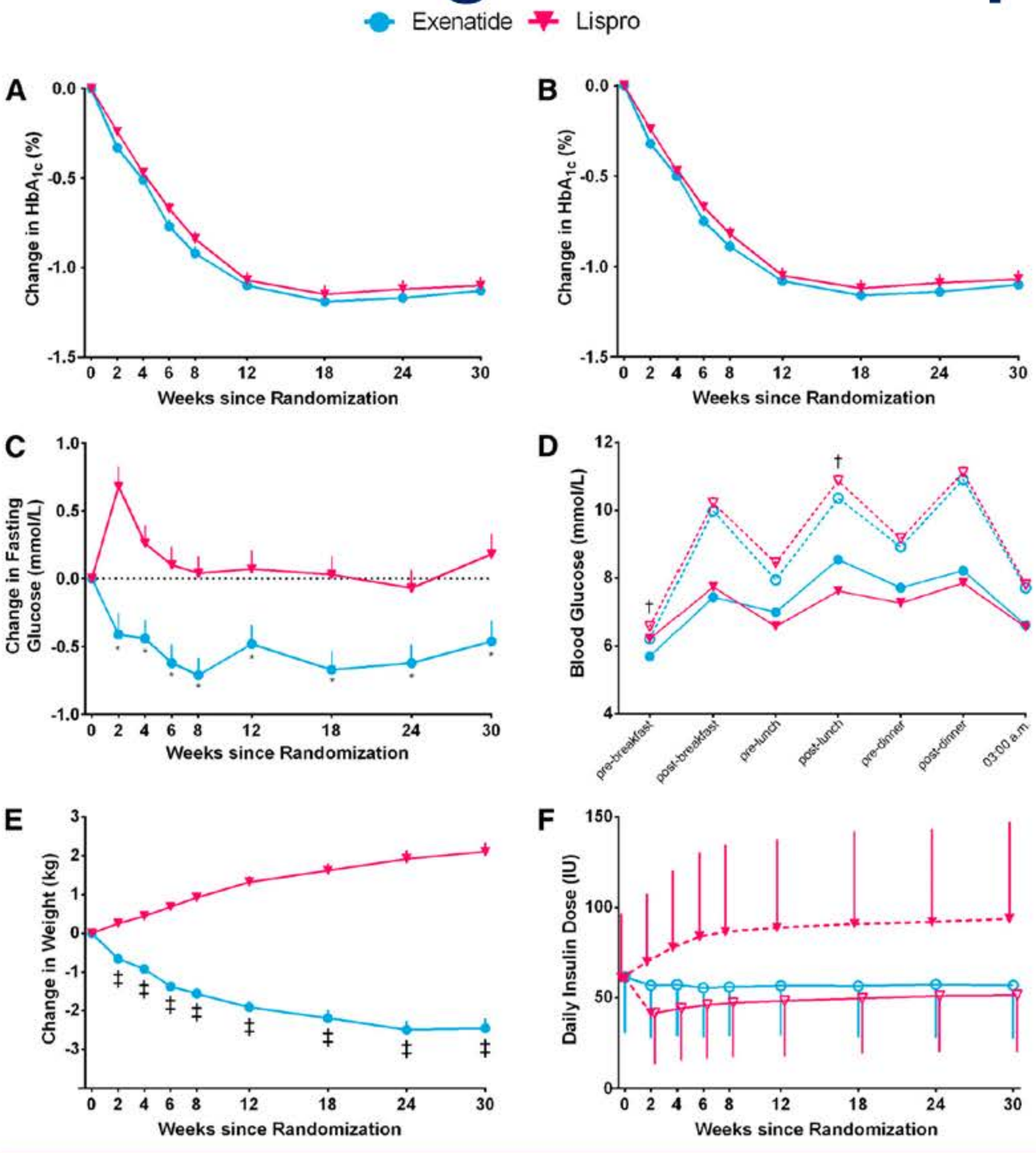

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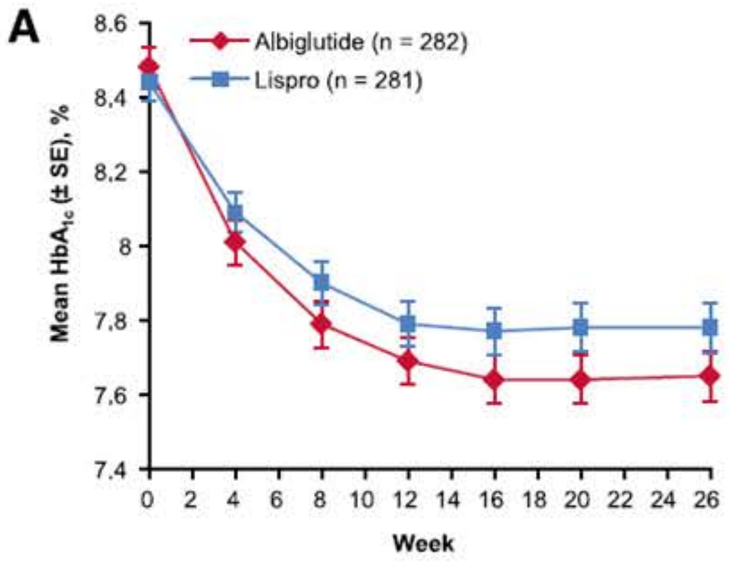
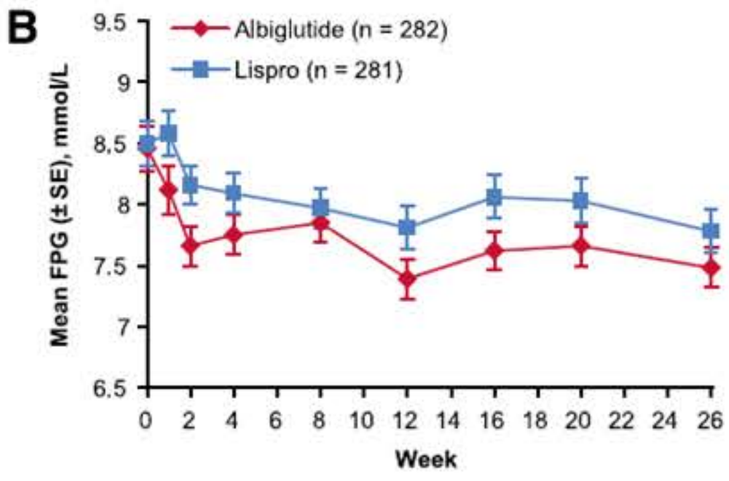
Adding the GLP-1 agent resulted in:

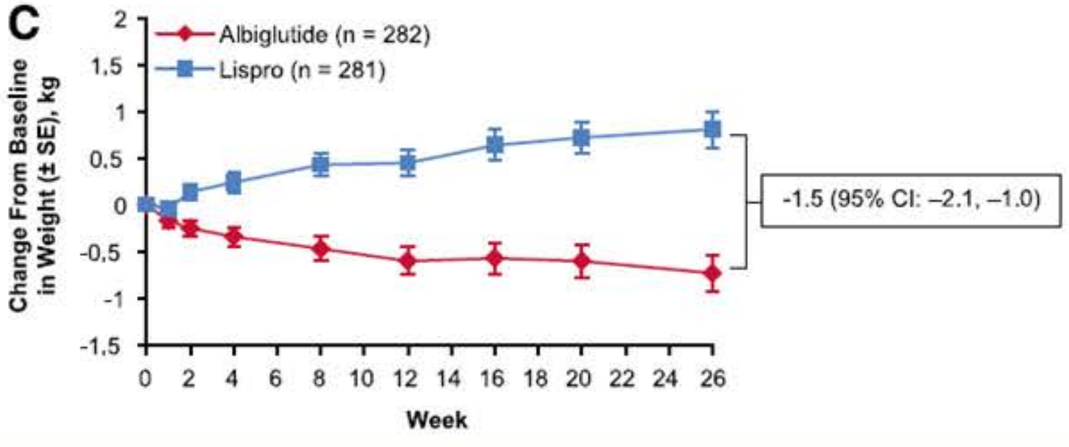
- Equal A1C reduction
- Lower fasting glucose
- Less non-nocturnal hypoglycemia
- Weight benefit
- Reduced systolic BP
- Improved QOL reports

Diamont M et al. Diabetes Care 2014; 37:2763-2773

Abiglutide vs Lispro Added To Glargine in Type 2 Diabetes







563 patients on basal insulin and oral agents were randomized to albiglutide once weekly or lispro before each meal

- Greater A1C reduction with GLP-1 agent
- Weight benefit with GLP-1 agent
- Less hypoglycemia with GLP-1 agent
- More GI symptoms with GLP-1 agent

Rosenstock J et al Diabetes Care 2014; 37:2327-2325

Adding a GLP-1 agonist to basal insulin is equally effective compared to adding prandial analog insulin for most patients

But…

- Less glucose monitoring required
- Significant weight benefit
- Fewer doses
  - Expect improved adherence
- Less hypoglycemia
- Lower insulin dose
- More (GI) side effects

Diamont M et al. Diabetes Care 2014; 37:2763-2773. Balena R et al. Diab Obes Metab 2013; 15:485-502

GLP-1 Agonists: Dosing and Adverse Effects

Brand	Generic	Dosing
Byetta (PA)	exenatide	5mcg SQ BID x 1 mo. ↑ 10mcg SQ BID
Bydureon (PA)	exenatide	2mg SQ once weekly
Victoza (PA)	liraglutide	0.6mg SQ QD x 1 week. ↑ 1.2mg SQ QD

- Side effects: nausea, vomiting, satiety, injection site rxns
- PA criteria for OHP:
  - A1c > 7.5% and ≤ 9.0%- failing oral therapy and basal insulin
    - Or basal is inappropriate d/t obesity (BMI ≥ 30 or Wt ≥ 100kg)
  - A1c ≥ 9.0%- rationale why meal time insulin cannot be used

GLP-1 Agonists: Administration

- Byetta given within 60 min of 2 main meals ≥ 6h apart
  - Must prime the pen with first use
- Victoza is once/day without regards to meals
- Bydureon is once/week without regard to meals or time of day
  - Do not mix in same syringe with insulin

- Note: Tanzeum (albiglutide) being discontinued by manufacturer by July 2018

Case 1

- A 68 y.o. man with type 2 DM of 13 years duration has been on metformin and an SU
- Now has an HbA1c of 9.6%
- PMH:
  - HTN, Hyperlipidemia, Obesity, CAD
  - CABG 18 months ago
- Meds:
  - Metformin 1000 mg bid; Glimepiride 4 mg bid
  - Atorvastatin 40 mg qd; Lisinopril 20 mg qd; HCTZ 12.5 mg qd

Case 1 (cont.)

- PE:
  - BP = 143 /87 BMI = 31.4
  - Sternotomy scar, 1+ leg edema, abnormal sensory exam in feet
  - NPDR on recent dilated eye exam
- Labs:
  - Creatinine = 1.1
    HDL = 33
  - Potassium = 4.5 mcg/mg (1st time abn)

TG = 198 mg/dl
LDL = 77
Microalb:Creat = 38

Case 1 (cont.)

What is the HbA1c goal for this patient?

Individualizing A1c goals

General goal

<7.0% to reduce microvascular risk

Lower goal - for selected individuals

Short duration of diabetes
Long life expectancy
No significant cardiovascular disease
Pregnancy

Less stringent goals - for high-risk persons

Long-standing diabetes
Limited life expectancy
History of severe hypoglycemia
Advanced micro- or macro-vascular complications
Extensive co-morbid conditions

Case 1 (cont.)

- **What medication would you add now and why?**

Case 1 (cont.)

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    - Patient has a BMI over 30

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- **What differences would you expect if you chose basal insulin vs a GLP-1 agonist?**

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Case 1 (cont.)

- **What medication would you add now and why?**
  - Basal insulin or a GLP-1 agonist are good options
    - Patient has a BMI over 30
- **What differences would you expect if you chose basal insulin vs a GLP-1 agonist?**
  - Basal insulin better targets the fasting glucose and is highly effective
  - The GLP-1 agonist will have more side effects but equal A1C reduction and lower weight.

Case 1 (cont.)

- You chose basal insulin. How do you dose?

Case 1 (cont.)

- You chose basal insulin. How do you dose?
  - Start with 0.15 units per Kg
  - Monitor glucose each AM
  - Increase the dose every 3-7 days by 2 units
  - Target a morning glucose of 120 mg/dl

Case 1 (cont.)

- You chose basal insulin. How do you dose?
  - Start with 0.15 units per Kg
  - Monitor glucose each AM
  - Increase the dose every 3-7 days by 2 units
  - Target a morning glucose of 120 mg/dl

- The basal insulin dose was increased to 48 units
  - A1C decreased to 7.6%

Case 1 (cont.)

- Six months later the A1C is up to 8.3%

Case 1 (cont.)

- Six months later the A1C is up to 8.3%
- What do you do now?

Case 1 (cont.)

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Case 1 (cont.)

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Case 1 (cont.)

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- What do you do now?
- May want to reduce the basal insulin by 20%
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Case 1 (cont.)

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- May want to reduce the basal insulin by 20%
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- Start the dose low and build up slowly to reduce nausea

Case 1 (cont.)

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  - Often the evening basal insulin is dosed to a point where it will cause a larger reduction from a high bedtime glucose
  - In that case the addition of the GLP-1 agonist may cause nocturnal hypoglycemia
- Start the dose low and build up slowly to reduce nausea
  - e.g. liraglutide 0.6 mg the first week and 1.2 the next week

Case 2

- A 59 y.o. woman with type 2 DM of 14 yrs duration
- Medications:
  - Metformin 1000 mg bid
  - Sitagliptin 100 mg qd
  - Glargine 38 units at bedtime.
- PE:
  - BP = 138/80 BMI = 34.3
  - BDR, decreased vibration sensation in feet but normal monofilament sensation
- Labs:
  - Creatinine = 0.96 mg/dl A1c = 9.1%,
  - CBGs indicate fasting glucose mean of 138 mg/dl

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

B. Increase glargine

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

B. Increase glargine

C. Add a TZD

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

B. Increase glargine

C. Add a TZD

D. Add meal insulin three times daily

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

B. Increase glargine

C. Add a TZD

D. Add meal insulin three times daily

E. Add meal insulin at dinner

Case 2 (cont.)

What are the options now?

A. Add a sulfonylurea

B. Increase glargine

C. Add a TZD

D. Add meal insulin three times daily

E. Add meal insulin at dinner

F. Change sitagliptin to liraglutide or exenatide LAR

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Add a sulfonylurea

Case 2 (cont.)

What are the options now?

Add a sulfonylurea

- Could work but not likely this late in the process

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Increase glargine

Case 2 (cont.)

What are the options now?

Increase glargine

- Fasting glucose is higher than goal

Case 2 (cont.)

What are the options now?

Increase glargine

- Fasting glucose is higher than goal
- Average glargine dose in treat to target study was about 48 units to reach goal

Case 2 (cont.)

What are the options now?

Increase glargine

- Fasting glucose is higher than goal
- Average glargine dose in treat to target study was about 48 units to reach goal
- However, reducing to mean fasting <120 mg/dl would not likely have an adequate effect and would not have an enduring effect

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Add a TZD

Case 2 (cont.)

What are the options now?

Add a TZD

- Can increase insulin sensitivity and could drop A1c significantly

Case 2 (cont.)

What are the options now?

Add a TZD

- Can increase insulin sensitivity and could drop A1c significantly
- Would likely be associated with weight gain

Case 2 (cont.)

What are the options now?

Add a TZD

- Can increase insulin sensitivity and could drop A1c significantly
- Would likely be associated with weight gain
- Associated with bone loss in women

Case 2 (cont.)

What are the options now?

Add a TZD

- Can increase insulin sensitivity and could drop A1c significantly
- Would likely be associated with weight gain
- Associated with bone loss in women
- Associated with more edema when used with insulin

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Add meal insulin three times daily

Case 2 (cont.)

What are the options now?

Add meal insulin three times daily

- Reasonable choice

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Add meal insulin at dinner

Case 2 (cont.)

What are the options now?

Add meal insulin at dinner

- Good choice

Case 2 (cont.)

What are the options now?

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

- Might work

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

- Might work
- GLP-1 agonists appear to be a little more effective in A1c reduction than DPP-4 agents

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

- Might work
- GLP-1 agonists appear to be a little more effective in A1c reduction than DPP-4 agents
- Weight benefits

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

- Might work
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- Weight benefits
- Address post-prandial needs

Case 2 (cont.)

What are the options now?

Change sitagliptin to liraglutide or exenatide LAR

- Might work
- GLP-1 agonists appear to be a little more effective in A1c reduction than DPP-4 agents
- Weight benefits
- Address post-prandial needs
- Growing experience using with insulin

35

Break

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Managing Complicated Patients

Leonard Bertheau, DO
Diabetes and Endocrine Center
Adventist Health

CareOregon

MEDS Ed

Diabetes Treatment Pathway

All patients should receive diabetes education + metformin

Metformin

Monotherapy

A1c > 7%

Add a sulfonylurea like glimepiride if not at goal on metformin monotherapy

Sulfonylurea

Dual Therapy

A1c > 7%

Start insulin at 0.15 units/kg

If after 3 months of basal insulin or GLP-1 titration:

A1c not 10% lower or > 7.5%

or FBS remains ≥ 120mg/dl →

Move to next level

Basal Insulin (NPH, Basaglar) **OR** **GLP-1 Agonist**

Consider GLP-1 if BMI ≥ 30 or Wt ≥ 100kg.

Expect some N/V, but it will likely subside; eat smaller meals.

Triple Therapy

A1c ≥ 9% | **A1c ≤ 9%**

Consider meal time insulin with one dose at largest meal of the day.

Consider GLP-1 if there are barriers to insulin.

Mealtime Insulin (Novolog) **OR** **GLP-1 Agonist**

Basal Insulin

Combination Injectable Therapy

Treatment pearls: Review for treatment barriers, such as adherence, behavioral health and social determinants, before adding therapy. Consider frequent follow-up visits to improve patient engagement and treatment success.

When to Start Insulin

- A1c > 9%, not controlled by orals
  - 3 to 6 months

- Newly diagnosed, A1c >10%
  - What insulin do you recommend?

Choosing Insulin

- Basal insulin
  - What dose?
  - What time of day?
  - When to test?

- Bolus insulin
  - When to add?
  - When to test?

- Basal:Bolus ratio = 50:50

What are the barriers to insulin use and what are some thoughts on ways to overcome such barriers?

Barriers to the Potential Benefit of Insulin Therapy in Type 2 Diabetes

Adapted from Funnell MM. *Clinical Diabetes*. 2007;25(1):36-38.
Derr RL, et al. *Diabetes Spectrum*. 2007; 20(3):177-185.
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Barriers to the Potential Benefit of Insulin Therapy in Type 2 Diabetes

- **Provider inertia**
  - Delay in progression of therapy to reach target
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  - Patients – fear of injections, hypoglycemia, insulin causing complications, etc.
  - Providers – fear of hypoglycemia, weight gain

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- **Behavioral barriers to initiating insulin**
  - Patients – fear of injections, hypoglycemia, insulin causing complications, etc.
  - Providers – fear of hypoglycemia, weight gain
- **Objective limitations once initiated**
  - Non-adherence
  - Hypoglycemia
  - Weight gain

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Derr RL, et al. *Diabetes Spectrum*. 2007; 20(3):177-185.
Karter AJ, et al. *Diabetes Care*. 2010;33(4):733-735.

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- Meet with a diabetes educator before initiation of insulin

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Mr. S

- Mr. S has just started on Lantus 10 units at bedtime. When you ask him how his doctor told him to titrate his insulin, he responds “I don’t remember”
  - When should Mr. S test his blood sugar?
  - What are Mr. S’s blood sugar and A1c goals?
  - What is a reasonable titration plan?

One Month Later

- In a follow-up call, Mr. S mentions that he had 2 low blood sugar episodes that he treated with drinking 2 cans of regular soda and 3 slices of leftover pizza.
  - What questions do you ask Mr. S?
  - What key points on management of hypoglycemia do you review with Mr. S?

Hypoglycemia

How low is too low?

- For most patients: **70**
- Gestational diabetes: **60-95**

Why worry?

Can lead to

- Loss of brain cells
- Coma
- Death

Symptoms of low blood sugar

- CNS
  - Headache
  - Confusion
  - Personality changes
  - Blurry vision
- GI
  - Hunger
  - Nausea
  - Gas/upset stomach
- Adrenergic
  - Sweating
  - Anxiety
  - Dizzy/Shaky
  - Fast Heartbeat

A lot of these overlap with symptoms of high blood sugar: patients need to check sugar

Treatment – Rule of 15

- If the patient is awake and able to take oral intake: 15 grams of simple carbs
  - 4 ounces of juice (OJ)
  - 4 glucose tabs
  - 5 lifesavers
  - ½ can regular soda
  - Nothing with fat or protein, as this will slow the absorption of glucose

- If the patient is not awake
  - Glucagon kit

Treatment – Rule of 15

- Recheck sugar in 15 minutes to make sure it is coming up
  - If not, give another 15 grams simple carbs

- If the sugar is normal (above 70) and they can eat, give them something with protein (like peanut butter) or feed them a meal to keep the sugars up

Hypoglycemia

- Normal blood sugars may cause symptoms
  - Treat even if not a true low??
  - May be awhile before 150 feels normal
  - Pay attention: rapid drops can cause symptoms

Mr. S's Next Follow-up

- Mr. S brings in his meter. His sugars are at goal first thing in the morning, but in the 200-300s at lunch and dinner time.
  - What changes to Mr. S's insulin regimen do you recommend?
  - When do you recommend he tests his blood sugar?

One Week Later

- At his last visit, Mr. S was started on Aspart insulin 4 units with breakfast, 6 units with lunch, 6 units with dinner. He brings in his blood sugar log:

Day	Morning	Lunch	Dinner	Bedtime
Sunday	100		101	275
Monday	101	183	175	289
Tuesday	99	193		301
Wednesday	105		310	190
Thursday	99	179	86	264
Friday	103		189	283
Saturday	102	165		299

Next Follow-up

- Mr. S has a follow up phone call. You collect his recent blood sugar values. Over the past week, his sugars have been high first thing in the morning and low at dinner time. Mr. S tells you he loves watching the Olympics, but all of his favorite events are on in the middle of the night.
  - What follow-up questions do you ask Mr. S?
  - What dosing changes do you recommend?
  - What additional education do you provide for Mr. S?

Dawn Phenomenon

- Hormone surge between 2:00 – 8:00am
  - Cortisol, glucagon, epinephrine → hepatic gluconeogenesis → endogenous insulin release
- Patient with diabetes have less endogenous insulin release resulting in high fasting BG
- How to treat/prevent:
  - Find the source: nighttime snacking, medications wearing off
  - Rule out Somogyi Effect

Somogyi Effect

- Blood sugars decrease in middle of night
- Rebound hyperglycemia
- Bad if this is happening because often nighttime insulin gets increased, compounding effect
- If suspect:
  - Can **decrease** Lantus and see if morning sugars go down
  - Refer for continuous glucose monitoring

Pros and Cons of 70/30

Pros	Cons
Basal and prandial coverage	70:30 ratio vs. 50:50
Less injections per day	Less flexible with dose adjustments
Less confusion on units to inject	Requires patient to eat consistently (time and carbs)
One insulin vial – may be more realistic option for patients with unstable housing or no place to store	

Mr. T

- Mr. T said he was too busy to remember to take his insulin. He works in a warehouse loading trucks with locally made bike bags. His job requires that he take lunch and breaks at regular times to coordinate with his coworkers' breaks. Mr. T's doctor started him on 70/30 insulin 20 units 30 minutes before breakfast and dinner.
  - Why is it important for Mr. T to take his insulin 30 minutes before breakfast and dinner?
  - How can you double check that the dose seems reasonable?

Two Weeks Later

- You call Mr. T for a follow up. Last week, he had 2 low blood sugars in the afternoon. He said his job has been stressful since one of his co-workers has been calling in sick. He's had to skip lunch twice to cover his shift.
  - What could be causing Mr. T's low blood sugars?
  - What education will you provide Mr. T?

When to Refer

- New onset DM2 with A1c > 12%
- Uncontrolled DM2 on basal/bolus insulin
- Gestational diabetes
- DM1
- Insulin pumps
  - Note that pump manufacturers can address pump malfunctions

More Than DM1 and DM2

- Other diagnostic considerations when uncontrolled
  - LADA, DM1.5
    - Latent Autoimmune Diabetes in Adults
  - Double diabetes
  - Other types from secondary causes

Case Study #1

- 44 yo male, routine random serum glucose was 271
- Symptoms for the past year and a half:
  - frequent infections
  - polyuria
  - polydipsia
  - weight loss

Case Study #1

- Diagnostic of DM, but what type???

Case Study #1

- Weight loss
- He is 5’9”, 197 pounds (BMI of 29)
- His Maternal grandmother was a DM-2 later in life and she was very obese
- No signs of insulin resistance (AN)
- A1c was 12.5% (blood sugars range from 178 – 508)

Case Study #1

- DM-2
- DM-1
- LADA (DM-1.5)
- Double Diabetes
- Other types from secondary causes

Case Study #1

- I did not know
  - LADA or DM-2
- Autoantibodies
  - Anti insulin
  - Anti GAD
  - Anti islet cell
- Fasting C-peptide with a fasting serum glucose

Case Study #1

- Auto-antibodies were all negative
- C-peptide was low
- So I still did not know

Case Study #1

- He checked his sugars at home:
  - Fasting - 178 - 298
  - 2 hours after breakfast - 395 - 508
  - One HS reading - 295
- Treatment?

Case Study #1

- Basal/bolus insulin therapy
- Ensure control if he is a LADA
- Reverse the glucose toxicity if this is a DM-2.
  - After about 6 – 8 weeks on insulin, will need to DC.

Case Study #1

- He continues to use basal/bolus insulin
- He is a LADA
- Last A1c was 6.6% (with no low blood sugars)

Case #2

- 43 yo male
- 6’2”, 114 pounds (was down to 90)
- 2 - 3 years prior he had his BS checked by his partner's dad's meter and it was over 500
- At the time he did not know what that meant

Case #2

- He was formally diagnosed with diabetes 6 months prior
- He had lost 60 pounds in 1.5 years
- He was eating a lot
- Felt like he was going to die
- A1c 10.2%

Case #2

- Referred by wound care/foot ulcer
- No other symptoms
- He has chronic diarrhea, eight times a day
- Oily stools
- History of heavy alcohol consumption

Case #2

- What type of DM?

Case #2

- DM2
- DM1
- LADA (DM1.5)
- Double Diabetes
- Other types from secondary causes

Case #2

- Other type secondary to:
  - Chronic pancreatitis from Alcoholism
  - Abdominal CT can confirm diagnosis
    - And rule out Pancreatic CA

Case #2

- He was not checking his sugars prior to his initial visit
- Treatment?

Case #2

- Basal/bolus insulin therapy
- Pancreatic enzymes

Case #2

- Update
- No more diarrhea
- His weight is up to 136 pounds
- A1c is 6.8% (some low blood sugars)
- He has cut back on Etoh, but continues to drink

Take Home Points

- Evaluating blood glucose readings helps identify potential issues with diet and/or medications

- Educating patients on the timing of their insulin dosing is key

- Insulin regimens should be individualized to a patient's schedule, lifestyle, and social determinants

Support Staff Roles

- Scrubbing charts
  - DOT phrase:

Last HGA1C: HGA1C 8.8 5/15/2017
Microalbumin due: no
Fasting blood work due: yes
Eye Exam due: no
Foot Exam due: yes
Flu vaccine due: not yet
Pneumovax due: no
Prevnar 13 due: no
>65 but one year after pneumovax.
Testing blood sugar: 3 x day
CGM due: yes
(annual CGM for Insulin taking patient with a HGA1C greater than 8.0)
Order a referral to diabetes education I-Pro2 clinic.

Support Staff: Coordinating Supplies

- Meter
- Strips
- Lancets
- Syringes
- Pen needles
- Control solution
- Batteries
- Alcohol swabs

Diabetic Supplies

Sierra Fung, PharmD

Pharmacy Managed Care Resident

CareOregon

CareOregon

MEDS Ed

Supplies for Medicaid – CareOregon

- DME vendor only – no retail pharmacy
  - Urgent requests can be filled at a pharmacy
  - Must call CareOregon for an override: 503-416-4100
- DME vendors
  - Faxed prescription with patient contact information
  - Or faxed referral form with patient contact information
  - Or call in verbal order
  - Rx must include exact testing directions and ICD-10 codes
- Testing up to 5x per day allowed without authorization
- DME no auth list: http://www.careoregon.org/Res/Documents/Providers/DME_HCPCS_Code_List.pdf

Supplies for CareOregon Medicare

- DME vendor or retail pharmacy
- DME vendor:
  - Rx must include exact testing directions and ICD-10 codes
  - Testing up to 5x per day allowed without authorization
  - For testing more frequently
    - Certificate of medical necessity needed
    - Such as: abnormal A1c, medication adjustment, urine ketones, irregular blood glucose, pregnancy, HTN, hypoglycemia, etc.
    - Include chart notes and blood sugar logs
- Retail pharmacy:
  - 200 strips and lancets per 30 days
  - 1 monitor every 2 years
  - Insulin syringes 500 per 3 months (cannot obtain through DME)

Basaglar

- Basaglar is the preferred basal insulin and is only available as a pen
- Pen needles!!! – pen needles will also be needed
  - These are considered a DME supply and will need to be ordered

Other

- Continuous glucose sensors
- Insulin pump supplies
- Must be ordered by patient directly to DME vendor

- Insulin
  - Vials are preferred (other than Basaglar)
  - PA needed for pens
    - Document dexterity, vision and/or compliance issues

Opportunities

- Diabetes dashboards
  - Clinic level patient registries
  - Pair A1c with pharmacy claims
    - Targeted medication optimization recommendations
    - Adherence data
- Targeted training to your clinic
  - Treatment pathway
  - Dashboard
  - Case review

Questions?

Next Session:

Fundamentals of Severe and Persistent Mental Illness

September 21st

CareOregon

MEDS Ed

Thank you!