



INSULIN INERTIA

Who why and How

**Three steps to optimizing
therapy to achieve glucose
targets**

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Learning objectives



- Recognize when to initiate insulin
- Understand how to dose and titrate insulin
- Select the appropriate regimen to intensify treatment beyond basal insulin alone
- Apply the information to your clinical practice

Meet John



- Diagnosed with type 2 diabetes in 2003
- Started on metformin in 2005
- Glyburide in 2006 and Rosiglitazone later that year
- Came off Rosiglitazone in 2008
- Does as well as he can with diet & exercise
- A1c is now 9.5%
- There is a discussion of DPP4, SGLT2,
or.....insulin



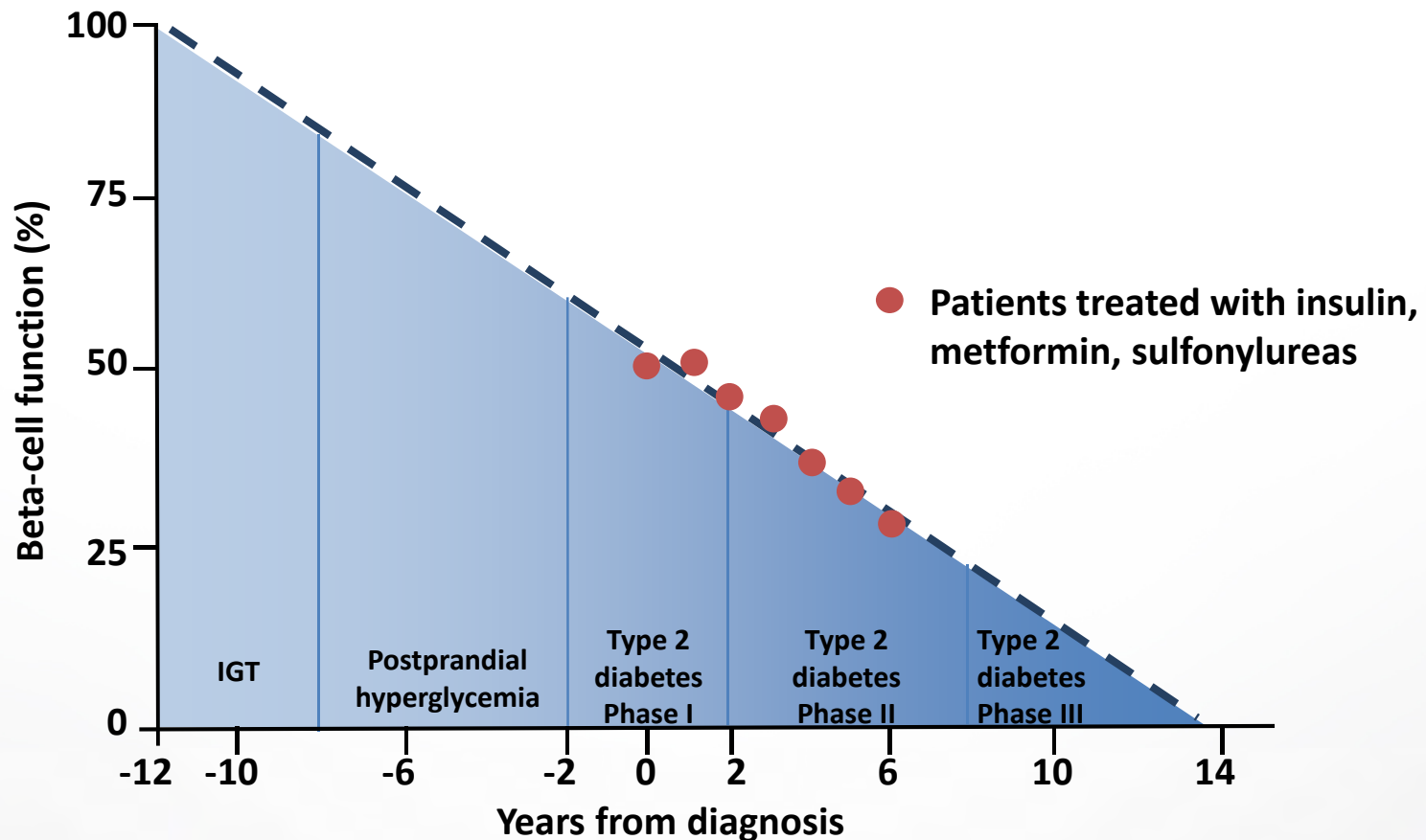


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**How Typical is John's
Story?**

Type 2 Diabetes is a Progressive Disease

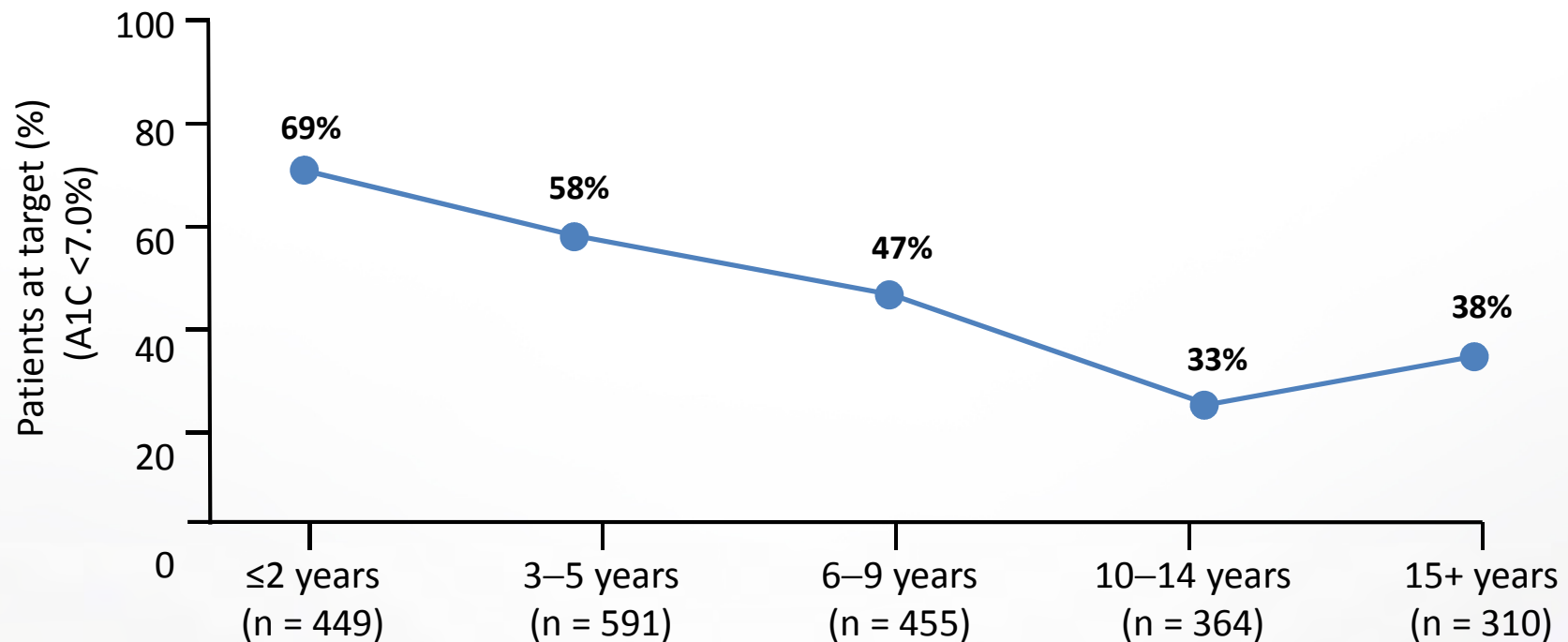


UKPDS = United Kingdom Prospective Diabetes Study

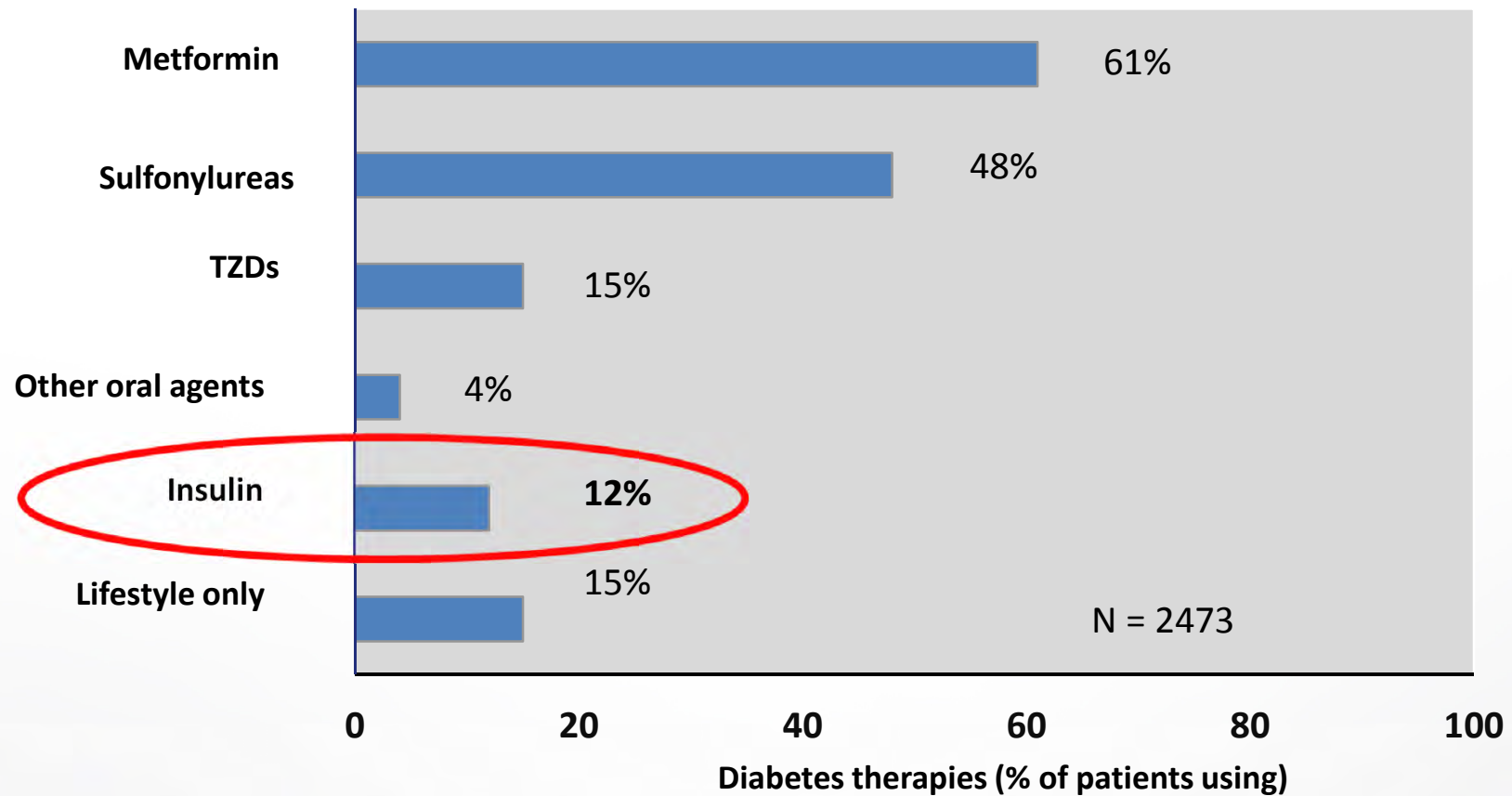
Control Erodes the Longer Patients Have Type 2 Diabetes



Only 38% of patients who have had diabetes for 15+ years are well controlled.



Underutilization of Insulin Therapy: 2005



Underutilization of Insulin Therapy: 2011



In a Canadian cohort of 2335 participants with type 2 diabetes and:

- Mean age of 62.9 years
- Mean duration of diabetes of 10.6 years
- High prevalence of complications/comorbidities
- **20% reported using insulin**

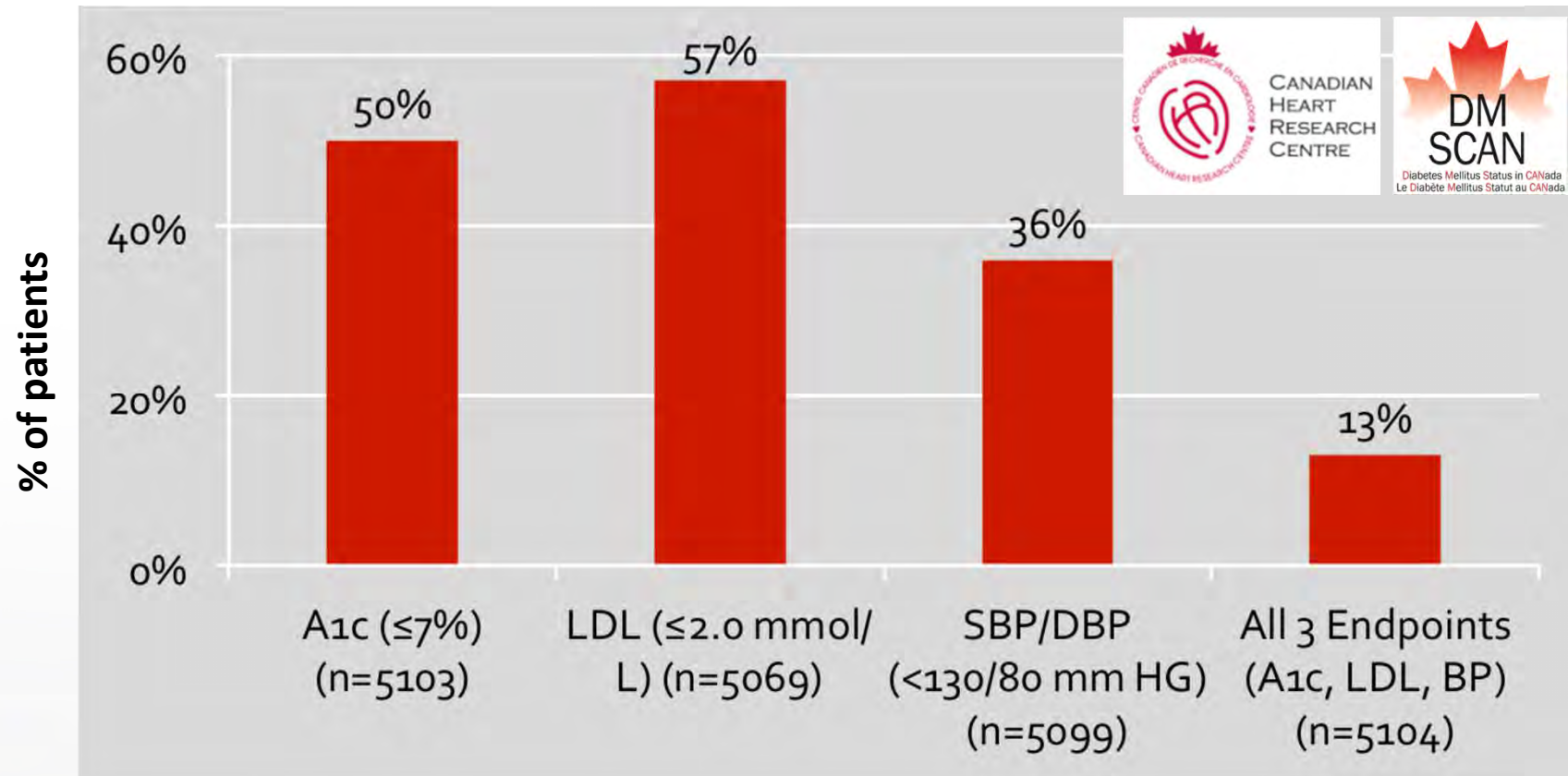
Insulin Therapy – Too Late and Too Little



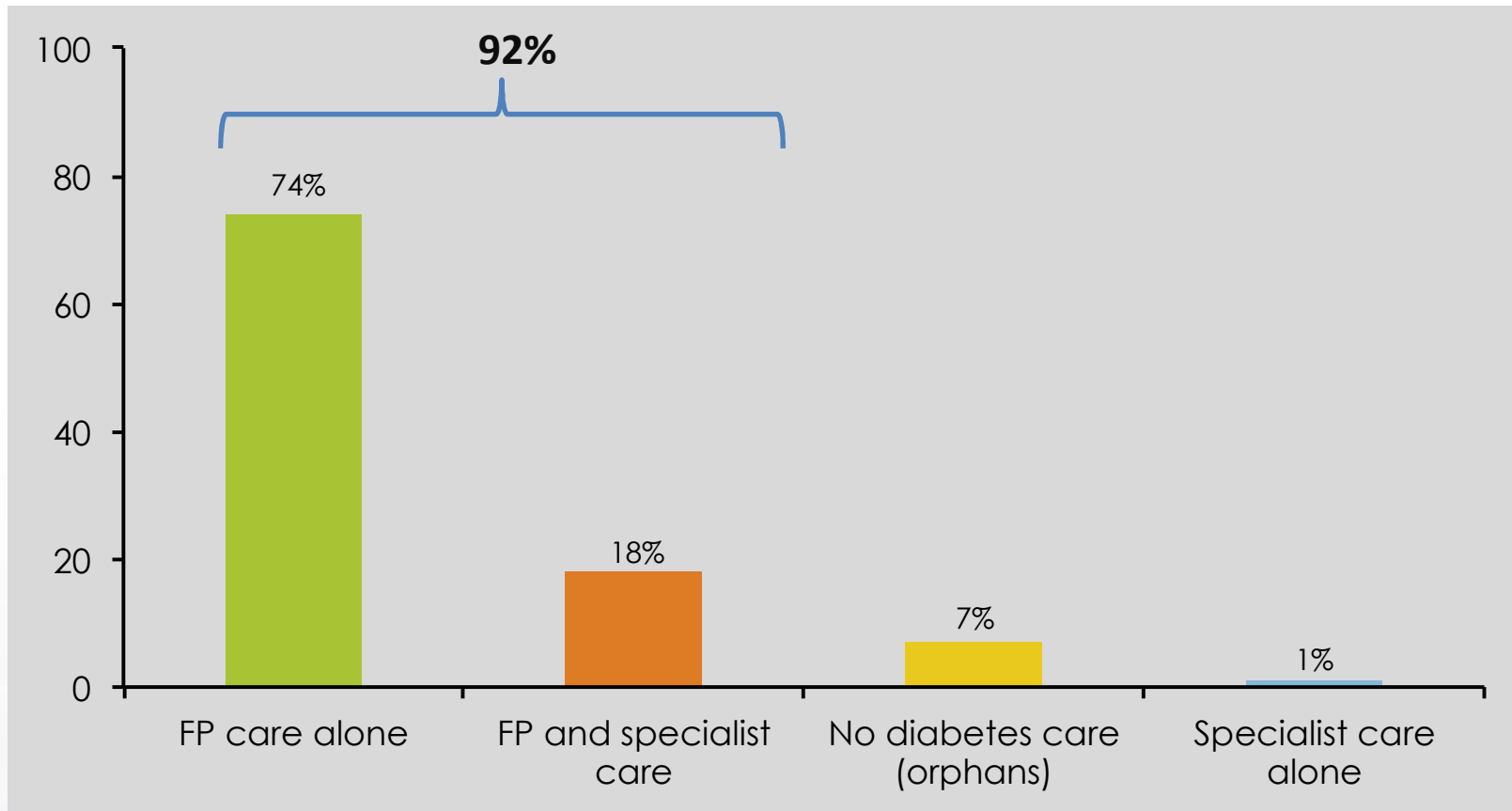
- Mean time to insulin initiation: **9.2 years**
- Mean A1C values were:
 - **9.5%** before insulin initiation
 - **8.1%** at visit 2 (median 1.2 years later), and
 - **7.9%** at visit 3 (median 3.9 years after initiation).
- At visit 3, 20% of patients continued to have very poor glycemic control (A1C >9.0%).
- 35% Endo, 55 % Primary Care, and 8% Diabetes Centres



Guideline Targets Achieved



Family Physicians Provide 92% of Diabetes Care



Insulin Intensification Must Happen in the Primary Care Setting



- **Family physicians** must accept the responsibility of intensifying insulin therapy
- It is **currently poorly done** – insulin initiation happens too late and is not aggressive enough
- There is a **need for simplified approaches** that are effective, safe and feasible.



Insulin Initiation In Type 2



Options:

- Once daily basal at hs
- Twice daily NPH
- Once or twice daily premix
- Premeal rapid or short acting

Most practical:

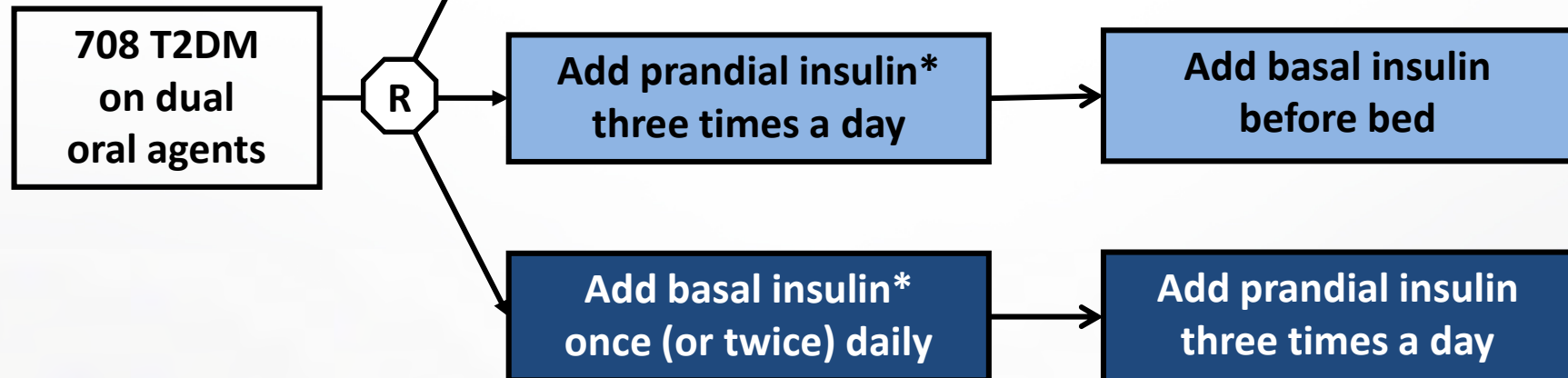
- Addition of basal insulin to daytime oral agents

What is the Better Starting Regimen for Insulin?

Learnings from the 4T Study



From one year onwards, if HbA_{1c} levels were >6.5%, sulfonylurea therapy was stopped and a second type of insulin was added



* Intensify to a complex insulin regimen in year one if unacceptable hyperglycaemia

Summary



- Three quarters of patients added a **second insulin**
- Those commencing therapy with a basal or prandial insulin more often **achieved glycaemic targets** than patients commencing with a biphasic insulin
- Patients commencing therapy with basal insulin had **fewer hypoglycaemic episodes** and less weight gain

These findings provide clear evidence in people with type 2 diabetes to support starting insulin therapy with a once a day basal insulin, and then adding a mealtime insulin if glycaemic targets are not met

Starting Bedtime Insulin The “Canadian Way”



- Start basal insulin 10 U QHS
- The insulin algorithm was simple and patient-managed:
 - ✓ Self-titration of 1 U per day until the fasting plasma glucose was ≤ 5.5 mmol/L.
 - ✓ Do not increase dose if patient has 2 episodes of hypoglycemia in 1 week, or any episode of nocturnal hypoglycemia.
- Oral agents:
 - Continue metformin and sulfonylurea

BMJ

DOI: 10.1136/bmj.3464-549.1.2006.01881.x

A randomized trial of adding insulin glargine vs. avoidance of insulin in people with Type 2 diabetes on either no oral glucose-lowering agents or submaximal doses of metformin and/or sulphonylureas. The Canadian INSIGHT (Implementing New Strategies with Insulin Glargine for Hyperglycaemia Treatment) Study

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Abstract

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Accepted 23 November 2005

Aims Insulin is generally withheld until people with Type 2 diabetes are unresponsive to other therapies. However, its potential advantages suggest that it could be added earlier to achieve glycaemic goals; this possibility was tested in a clinical trial.

Methods Consenting adults aged 18–80 years with Type 2 diabetes for at least 6 months, HbA_{1c} of 7.5–11%, and on 0, 1 or 2 oral agents, were randomized to one of two therapeutic approaches for 24 weeks: evening insulin glargine plus self-titration by 1 unit/day if the fasting plasma glucose (FPG) was > 5.5 mmol/L; or conventional therapy with physician adjustment of oral glucose-lowering agents if capillary FPG levels were > 5.5 mmol/L. The primary outcome was the first achievement of two consecutive HbA_{1c} levels $\leq 6.5\%$.

Results Two hundred and six participants were allocated to glargine and 199 to oral agents. Compared with control subjects, participants receiving glargine: (i) were 1.68 times more likely to achieve two consecutive HbA_{1c} levels $\leq 6.5\%$ (95% CI 1.00–2.83; $P = 0.049$); (ii) reduced their HbA_{1c} by 1.55 vs. 1.25% ($P = 0.005$), achieving adjusted means of 7.0 vs. 7.2% ($P = 0.0007$); (iii) had lower FPG ($P = 0.0001$), non-high-density lipoprotein (HDL) cholesterol ($P = 0.02$) and triglycerides ($P = 0.02$); (iv) had greater increases in treatment satisfaction ($P = 0.045$); and (v) had a 1.9-kg greater increase in weight ($P < 0.0001$). No differences in hypoglycaemia were noted.

Conclusions Adding insulin glargine is more likely to achieve a lower HbA_{1c} level than conventional therapy with oral agents.

Diabet. Med. 23, 736–742 (2006)

Keywords diabetes, insulin glargine, oral glucose-lowering drugs, randomized controlled trial

Abbreviations BMI, body mass index; DTSQ, Diabetes Treatment Satisfaction Questionnaire; FPG, fasting plasma glucose; HDL, high-density lipoprotein; INSIGHT, Implementing New Strategies with Insulin Glargine for Hyperglycaemia Treatment; LDL, low-density lipoprotein

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736

© 2006 The Authors
Journal compilation © 2006 Diabetes UK. *Diabetic Medicine*, 23, 736–742

Harris SB *et al.* *Can Fam Phys* 2008;54:550–8.
Gerstein HC *et al.* *Diabetic Med* 2006;23(7):736–42.

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John...3 months later



- Has started basal insulin and is currently taking 50 units at bedtime
- On glyburide and metformin maximum doses
- Fasting glucose average is still 9 mmol/L
- A1 c 8.5%
- Stop titrating because that seemed like a lot
- Next steps?



There is no Upper Limit of Insulin Dose



Treat To Target

- average dose 42 – 47 units at hs
- 2 Oral Hypoglycemic Agents at max dose

INSIGHT

- 30 units
- “young” 0-1.5 OHA’ s

4T

- mean dose 1.2 units per kg (106 units)

Riddle M. et al. Diabetes Care 2003;26:3080–6.

Harris S., et al. Can Fam Physician 2008;54:550–8.

Holman RR et al. N Engl J Med 2009;361:1736-1747.

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Contents lists available at ScienceDirect

Diabetes Research
and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres



International
Diabetes
Federation



Review article

Clinical approach to the patient with diabetes mellitus and very high insulin requirements

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Can expect 1 – 2 units per kg even up to 3 U/kg

When Basal Insulin Therapy in Type 2 Diabetes Mellitus is not Enough –What's Next?



What if...

John returns with an average fasting blood glucose of 5.5 mmol/l and A1c 8.3%



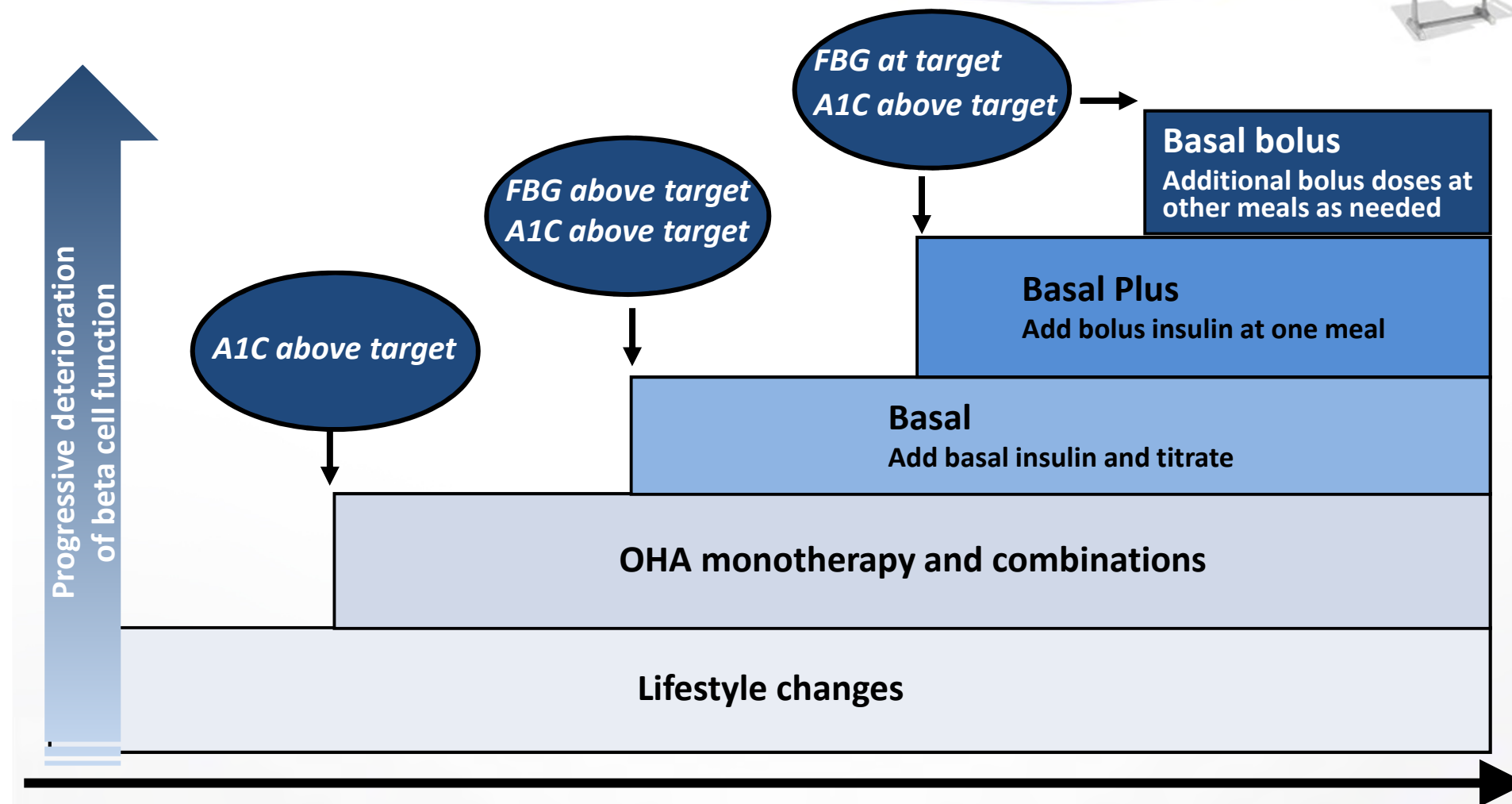
Key Learning – Basal Insulin Therapy

A Progressive Disease Requires Progressive Treatment



- Basal insulin analogs are often added to oral anti-hyperglycemic agents (OADs)
- Over time, basal insulin may not be sufficient to maintain optimal control
- The following indicate the need for addition of prandial (bolus) insulin:
 - A1C levels remain above target, despite acceptable fasting values with basal insulin (indicating increased postprandial values)
 - Inability to further uptitrate basal insulin due to nocturnal hypoglycemia

Keeping It Simple – A Stepwise Approach to Therapy



OHA=oral hypoglycemic agent

Progressive deterioration of β -cell function

Racah D et al. *Diabetes Metab Res Rev* 2007;23(4):257-264.

Nathan DM et al. *Diabetologia* 2006;49:1711–1721.

Woerle H. *Arch Intern Med* 2004;164:1627–1632.

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Who why and How

“Basal Plus”

Why should we try it?

What has been done?

How was it done?

When was it done?

“Canadian Recipe”

Learnings from the OPAL Trial



Study objective:

Does the addition of a single bolus of insulin, administered at either **breakfast or main mealtime**, in combination with basal insulin and oral hypoglycemic agents (OHAs), provides equivalent glycemic control in patients with type 2 diabetes, irrespective of the time of bolus insulin injection?

Methods:

393 patients with type 2 diabetes with suboptimal glycemic control were randomized to receive a single injection of glulisine, either at breakfast or at main mealtime, to their existing therapy (glargine and OHAs).

Results:

- A single bolus of glulisine, added to glargine and OADs, resulted in significantly improved HbA1c levels, **irrespective of whether glulisine was administered at breakfast or at main mealtime.**
- Number of hypoglycemia was low and comparable between the two treatment groups.

1-2-3 Study: Addition of 1 vs. 2 vs. 3 Bolus of Insulin Glulisine to Basal Insulin and OHAs



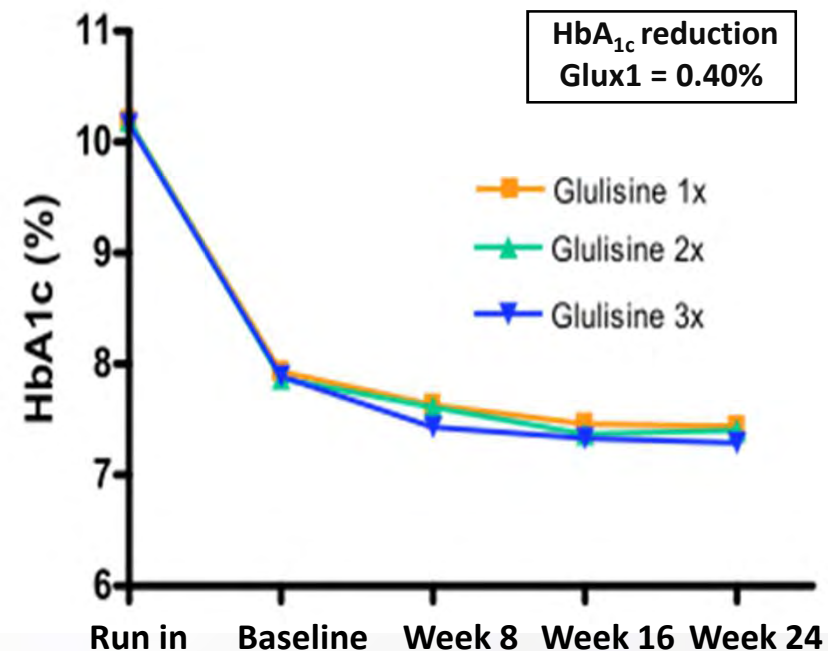
Study objective:

To determine whether 1 or 2 preprandial injections before the meals of greatest glycemic impact can be as effective as 3 preprandial injections in patients with type 2 diabetes mellitus and basal insulin treatment failure.

Results:

- A1C reductions with insulin glulisine once or twice daily were noninferior to insulin glulisine 3 times daily.
- Increased incidence of hypoglycemia in the 3 times daily group.

Randomized patients (HbA_{1c}>7% at baseline) n= 343



STEPwise Trial: Comparing Two Intensification Strategies



Study aim:

Compare efficacy and safety of two insulin aspart intensification strategies in people with T2DM inadequately controlled by basal insulin (insulin detemir) and oral hypoglycemic agents (OHAs)

SimpleSTEP protocole:

- Addition: 4 U with **largest perceived** meal
- Titration: pre-meal FPG 4-6 mmol/L

ExtraSTEP protocole:

- Addition: 4 U with **largest measured PPG** increment
- Titration: 2h PPG 4-8 mmol/L

FPG =fasting plasma glucose; PPG= postprandial plasma glucose

Conclusions:

- **No difference** in mean A1C reduction was seen between the SimpleSTEP and ExtraSTEP intensification groups.
- The frequency of adverse events and hypoglycemia was low and similar between groups.

How About Something...



Diabetes Care Volume 37, March 2014



Does a Patient-Managed Insulin Intensification Strategy With Insulin Glargine and Insulin Glulisine Provide Similar Glycemic Control as a Physician-Managed Strategy? Results of the START (Self-Titration With Apidra to Reach Target) Study

A Randomized Noninferiority Trial

OBJECTIVE

Diabetes self-management is universally regarded as a foundation of diabetes care. We determined whether comparable glycemic control could be achieved by self-titration versus physician titration of a once-daily bolus insulin dose in patients with type 2 diabetes who are unable to achieve optimal glycemia control with a basal insulin.

Stewart B. Harris,¹ Jean-François Yale,²
Lori Berard,³ John Stewart,⁴
Babak Abbaszadeh,⁴ Susan Webster-
Bogaert,¹ and Hertz C. Gerstein⁵



Rationale for the START Study



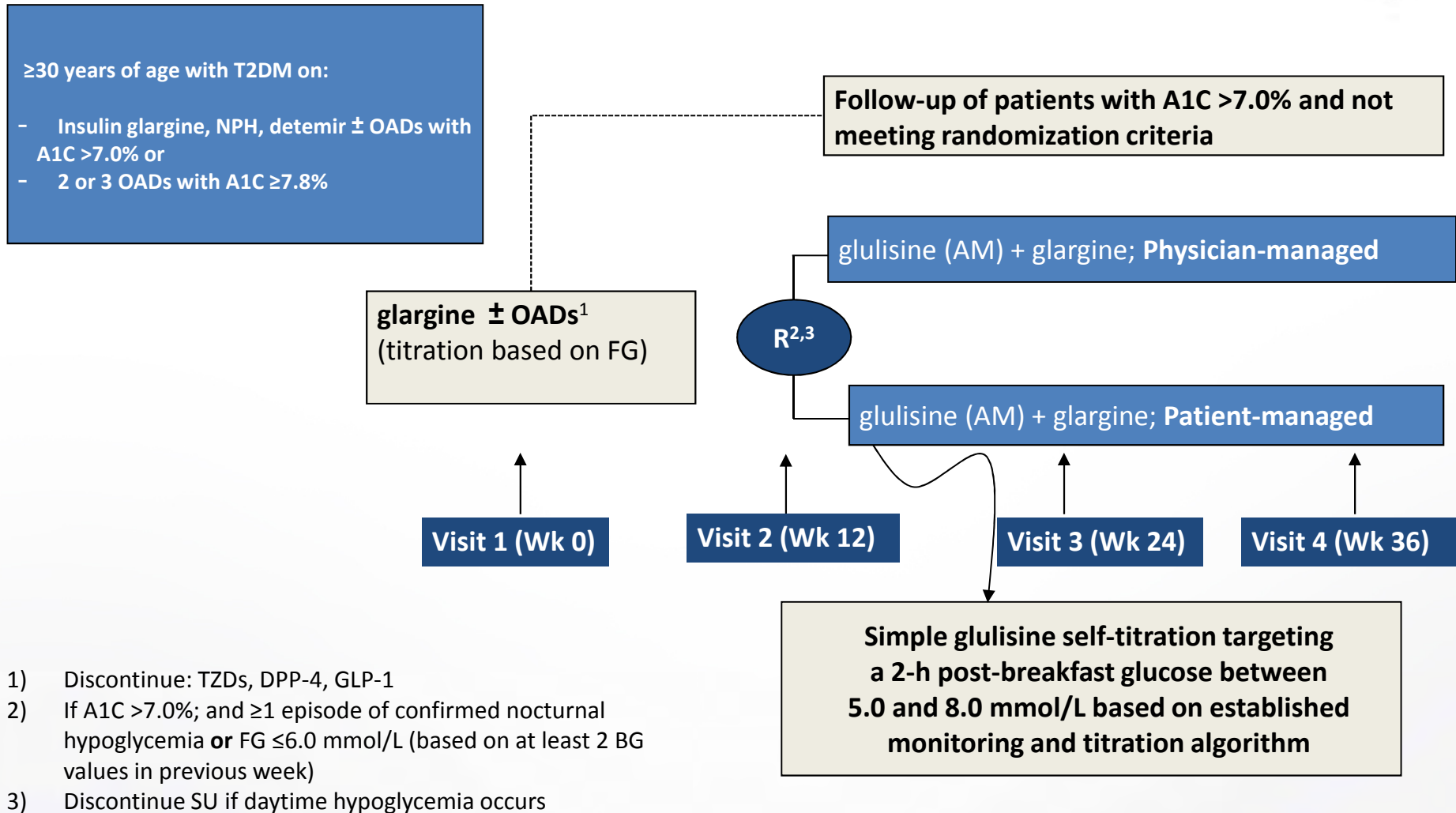
- As family physicians care for the vast majority of patients with type 2 diabetes, they **must** learn how to intensify insulin.
- Family physicians frequently cite their own fear of inducing hypoglycemia and time constraints as barriers to intensifying insulin.
- Increasing acceptance of strategies that progressively add bolus to basal insulin. However... the best way to do this is unclear.
- Could a patient-driven algorithm for bolus insulin work as it has for basal insulin?
- **START:** Could a patient-driven self-titration algorithm achieve glycemic control that was comparable to that achieved by physician-titrated bolus insulin?

Primary Outcome Measure



- Achievement of an **A1C level of $\leq 7\%$ without severe hypoglycemia** 24 weeks after randomization.
 - Severe hypoglycemia defined as:
 - Required assistance and FPG level < 2.0 mmol/L or responded to counteractive treatment
- Test of non-inferiority was performed
 - If the lower end of the CI was **-5.0% or greater**, the patient-managed arm was deemed non-inferior to the physician-managed arm.

START Study Design



Run-In Phase Protocol



- Patients were switched from their previous basal insulin therapy to once-daily insulin glargine in the evening,
 - Initiation dose at switch:
 - Same dose for NPH once daily and 20% reduction of total dose of NPH twice daily
 - 30% reduction of insulin detemir
 - Dose titration
 - Increased by 1 IU/day, to obtain FPG levels of ≤ 5.5 mmol/L
- OADs remained the same (TZD and DPP-IV discontinued)
- Starting dose of insulin glargine for insulin- naïve patients: 10 U

Intervention – All Patients



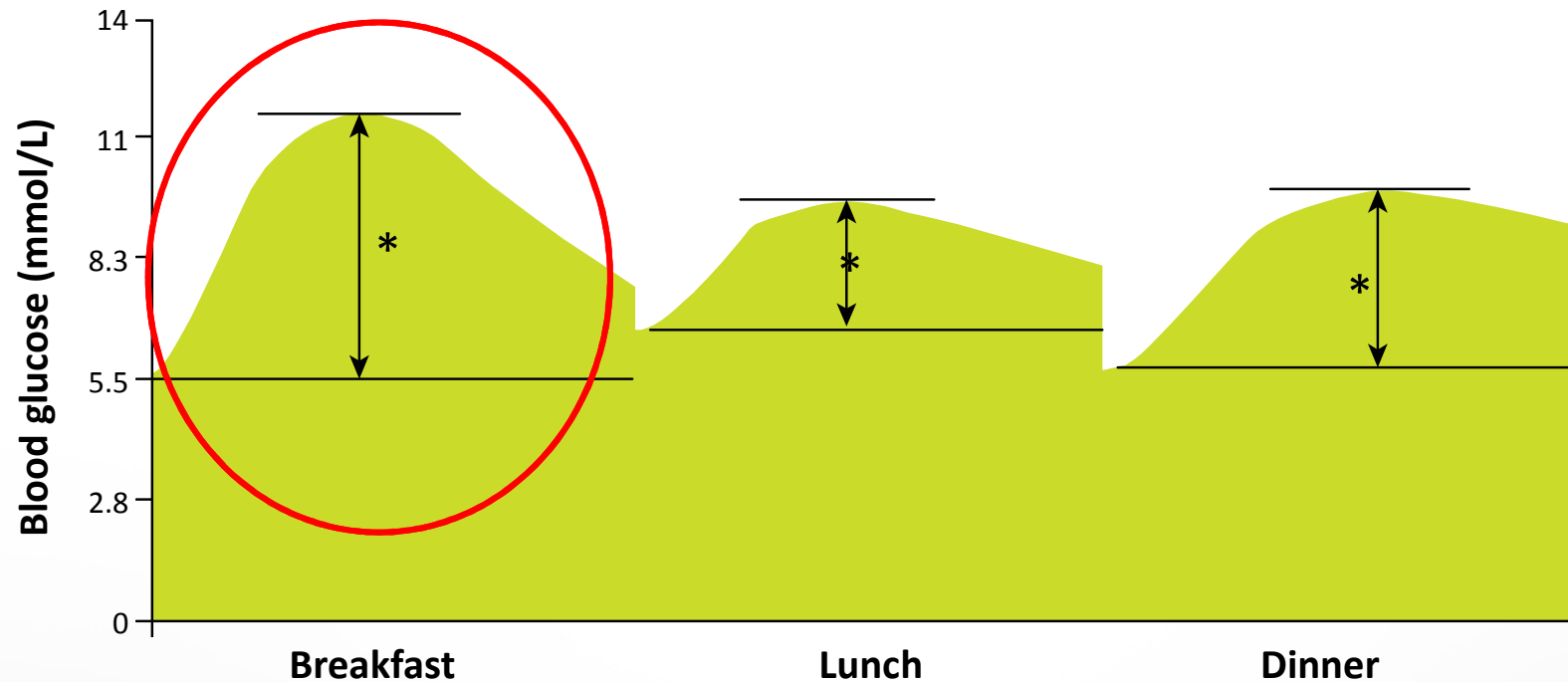
- After randomization, all patients:
 - Continued receiving their fixed glargine dose, and
 - Added insulin glulisine before breakfast.
 - Were instructed to eat their usual breakfast
 - Were not required to log their diet.

Rationale For Adding Glulisine at Breakfast



- To **maximize patient safety** by reducing the risk of nocturnal hypoglycemia
- To expand on **common practice**. Many patients receiving a basal insulin routinely test their blood glucose in the morning. The addition of a breakfast prandial insulin self-titration algorithm requires **only one extra self-monitoring** test later in the same morning.
- Patient **convenience** of injecting at home
- Optimization of blood glucose levels earlier in the day may help to maintain good glycemic control for the **remainder of the day**; and
- It may be easier for patients to pursue self-titration for injection at subsequent meals in their future care.

Breakfast is the Largest Glycemic Excursion of the Day



- For the same carbohydrate intake, the peak blood glucose excursion was two times greater at breakfast and was two-thirds greater at dinner than lunch.¹
- When patients with type 2 diabetes evenly consume carbohydrate throughout the day (70 g per meal), they display a higher blood glucose excursion at breakfast than at lunch or dinner.²
- This may be due to the “dawn phenomenon.”

*peak blood glucose excursion

1. Figure adapted from: Franc S, et al. *Diabetes Care*. 2010;33:1913–18.

2. Pearce KL, et al. *Am J Clin Nutr*. 2008;87:638–44.



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Who why and How

START Study - Results

Patient Characteristics



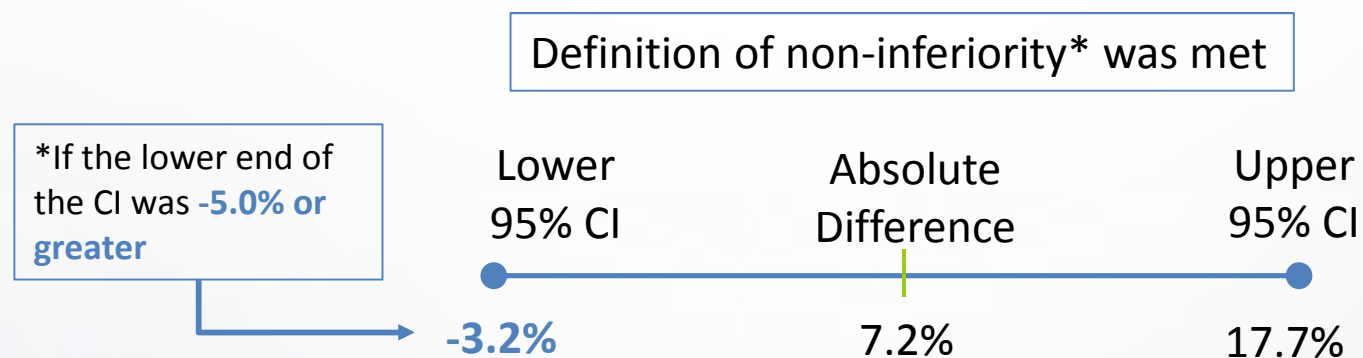
Patient Characteristics*	Patient-managed Group (N = 154)	Physician-managed Group (N = 162)	P value
Age, years, mean (SD)	60.4 (10.0)	60.2 (9.8)	0.72
Duration of diabetes, years, mean (SD)	12.1 (8.0)	12.2 (8.6)	0.86
A1C, %, mean (SD)	8.2 (0.8)	8.3 (1.3)	0.86
BMI, kg/m ² , mean (SD)	34.1 (7.2)	34.3 (7.9)	0.74
Patients with diabetes-related complications at screening, n (%)	47 (30.5)	57 (35.2)	0.38

* At randomization

Primary Outcome



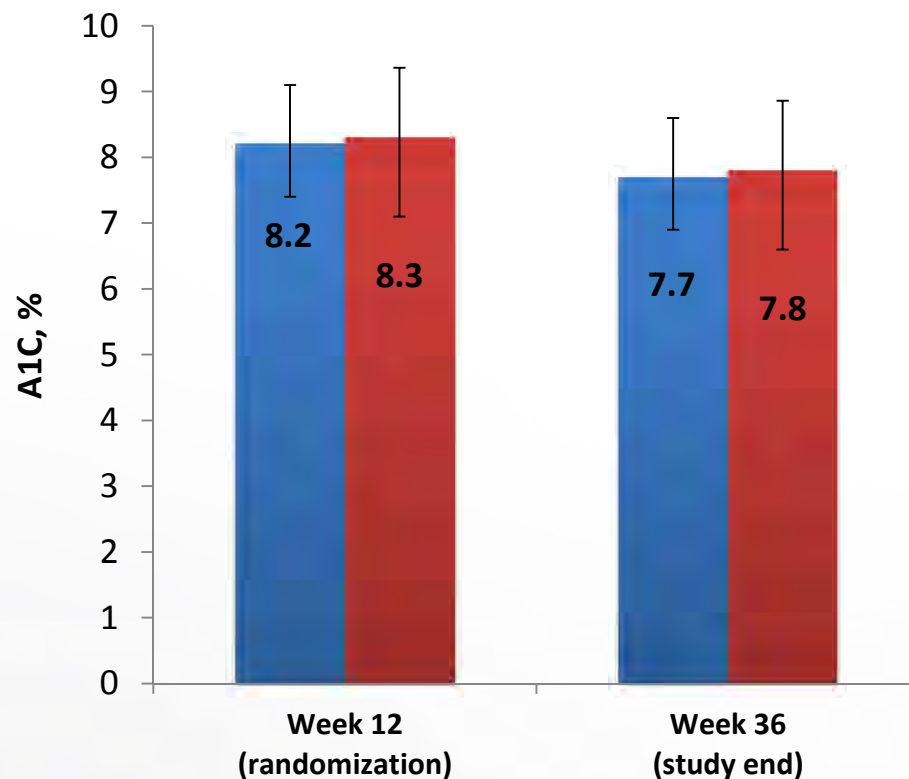
- Double primary outcome: Achievement of an **A1C level of $\leq 7\%$ without severe hypoglycemia**
- After a mean follow-up time of 159.4 days (SD 36.2), the primary outcome was achieved by:
 - **28.4% of subjects in the patient-managed arm**
 - **21.2% in the physician-managed arm**



Secondary Outcome – A1C



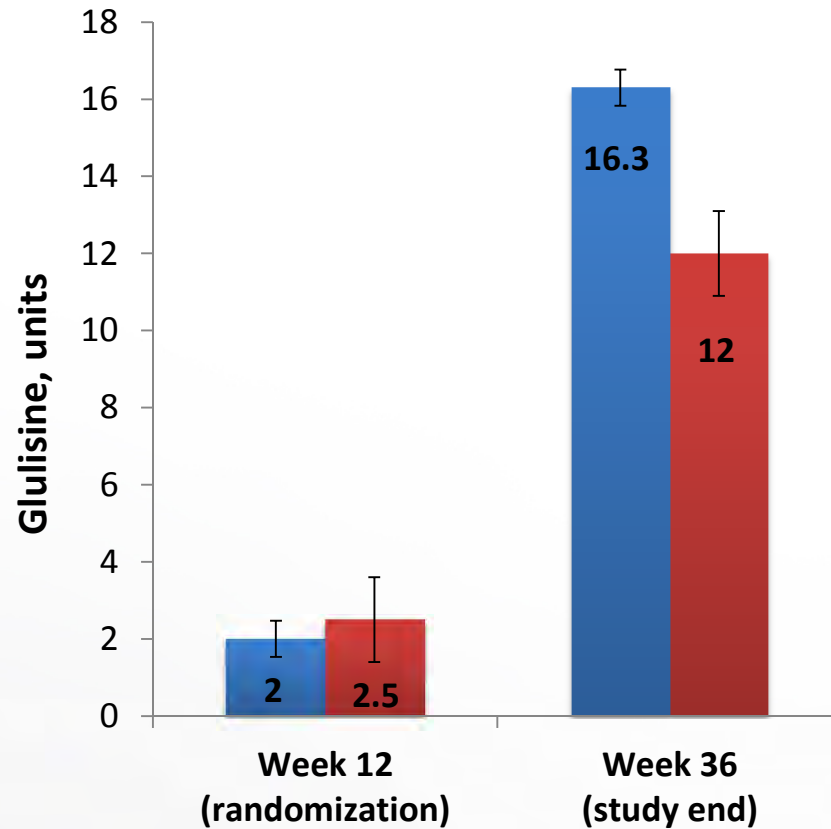
- **A1C decreased** significantly for **both** groups.
- No statistically significant differences **between** groups.



- Within-group p values 0.0001 (for both)
- Between-group p value 0.49

■ Patient-managed
■ Physician-managed

Secondary Outcome – Glulisine Dose



- This increase was significantly **higher** by the end of treatment for **patient-managed** group
- Adjusted mean difference of 5.6 units (SE 1.77) (95% CI 2.1–9.1, P = 0.0018)

■ Patient-managed
■ Physician-managed

Secondary Outcome – Hypoglycemia



Patients with at least one symptomatic hypoglycemic episode

	Patient-managed group (N = 154)	Physician-managed group (N = 162)	95% CI	P value
Any hypoglycemic episode	67.5%	61.1%	-17.0 to 4.1	0.23
- Annualized episode rate*	13.2	13.0	0.76 to 1.28	0.93
Any confirmed episode	63.6%	58.6%	-15.7 to 5.7	0.36
- Annualized episode rate*	11.1	10.4	0.71 to 1.28	0.65
Any episode <3.1 mmol/L	33.8%	30.9%	-13.2 to 7.4	0.58
- Annualized episode rate*	2.9	2.3	0.52 to 1.26	0.34
Any nocturnal episode	26.0%	28.4%	-7.4 to 12.2	0.63
- Annualized episode rate*	3.5	2.9	0.58 to 1.15	0.25
Any severe episode	1.9%	1.9%	-3.1 to 2.9	0.95
- Annualized episode rate*	1.3	1.7	0.32 to 5.62	0.69

Majority of hypoglycemic events occurred between 6:00 AM and noon, patient-managed 58.3%, physician-managed 62.7%.

* N per person per year

Secondary Outcome – Hypoglycemia



Annualized episode rates*, entire patient population

	Patient-managed group (N = 154)	Physician-managed group (N = 162)	95% CI	P value
Hypoglycemic episodes	8.9	8.1	0.62 to 1.32	0.61
Confirmed episodes	7.1	6.2	0.60 to 1.29	0.51
Episodes <3.1 mmol/L	1.4	3.6	0.45 to 1.25	0.27
Nocturnal episodes	0.9	0.8	0.53 to 1.58	0.75
Severe episodes	0.02	0.03	0.24 to 9.32	0.68

* N per person per year

Secondary Outcomes – Hypoglycemia, Weight, Rx Satisfaction



Hypoglycemia

- No difference between the groups for the proportion of patients who experienced a minimum of one hypoglycemic event.
- The majority of hypoglycemic events occurred between 6:00 AM and noon.

Weight

- Mean body weight **significantly increased for both** groups
- Between-group analysis showed a significantly higher increase for the patient-managed group. Adjusted mean difference of 0.87 kg

Satisfaction

- Patients ranked their mean **satisfaction as “high”** by the end of their treatment
- By the end of the trial, the majority of physicians reported a very **high level of confidence** initiating and intensifying insulin therapy.

START Study Conclusions – What Did We Learn in This Real-World Trial?



- A **patient-driven algorithm for bolus insulin works** in the primary care setting (non-inferior to physician-managed)
 - Using a preprandial titration approach at **breakfast** works
 - The **patients** who were responsible for managing their insulin titration **were more aggressive at titrating glulisine** when compared with the physician-managed group

Insulin Intensification is a Dynamic Process



- Only **21% and 28%** of patients in this trial achieved optimal control **with** no severe hypoglycemia
- Highlights the **need for ongoing intensification**
 - i.e. additional bolus therapy at other meals may be required



Summary and Conclusions



- The START study demonstrated that a simple basal plus **patient-driven treatment algorithm was as safe and effective as a physician-driven algorithm.**
- This builds on the **feasibility** of using patient-driven algorithms **in the primary care setting.**
- A **simple safe** way to intensify insulin therapy when basal insulin alone fails.
- A useful strategy for family physicians who treat the vast majority of patients with type 2 diabetes.
- The START study offers a potential strategy to mitigate clinical inertia involving insulin intensification in the primary care setting



INSULIN INERTIA

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**Putting the START Study
Findings Into Practice
“Clinical Pearls”**

Intervention



Patient-managed arm

- Patients received a pamphlet explaining the self-titration method.
- Starting dose of glulisine was **2 units**
- Patients instructed to **self-titrate 1 unit/day** to reach a target 2-h PPG level between 5.0 and 8.0 mmol/L. The PPG was measured 2 h after the start of breakfast.
- Once the target was attained, the maintenance dose was based on the monitoring of two or three 2h postprandial measurements per week.

Physician-managed arm

- Starting dose of insulin glulisine of 2 units recommended to the physicians
- However... the following were left to the **physicians' discretion**:
 - Starting glulisine dose
 - Titration
 - Self-monitoring of blood glucose schedules
- Patients in this arm were required to contact their physician prior to any dose adjustment.

Adding Breakfast Insulin Works



- This approach maximizes **patient convenience**.
- The self-titration intervention capitalized on the **common practice** that most patients receiving a basal insulin routinely test **their blood glucose in the morning**.
- The addition of a breakfast prandial insulin self-titration algorithm requires **only one extra self-monitoring test** later in the same morning
- Also, by targeting the meal with the highest glycemic excursion (breakfast), **all blood glucose values over the day improved**.

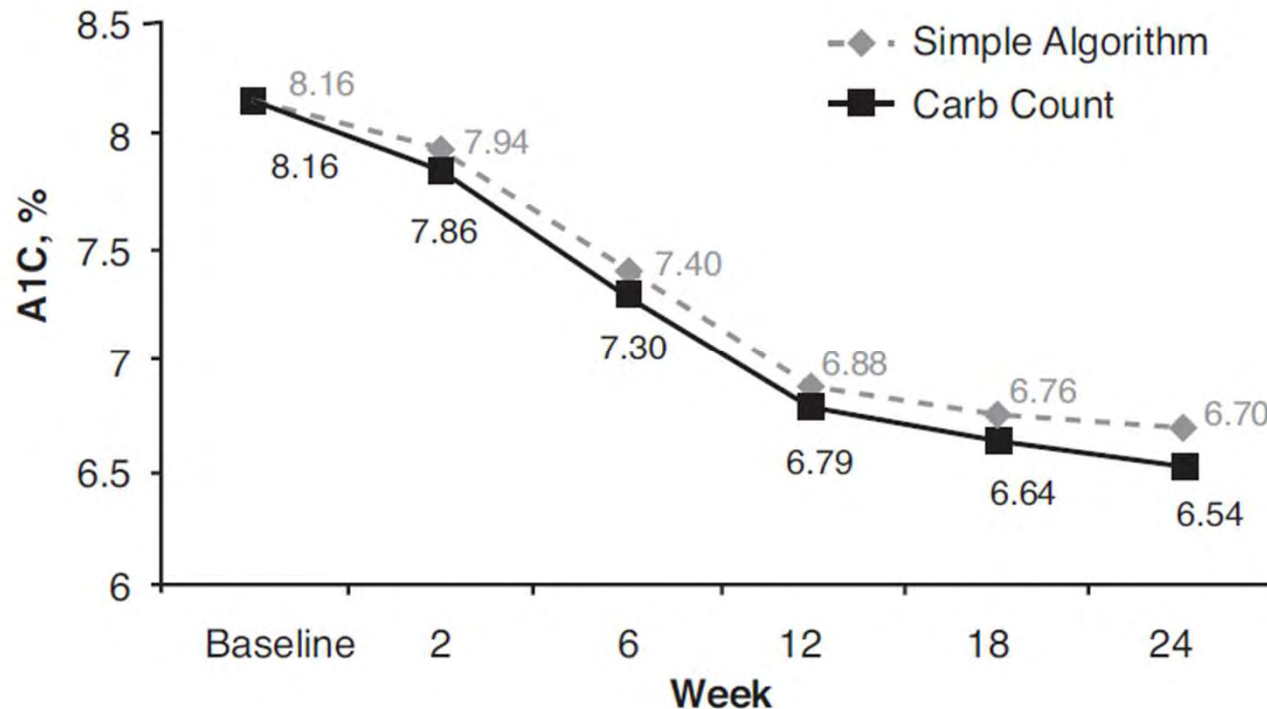


Things to Think About



- All patient need self management education
as well as ongoing self management support
- Hypoglycemia teaching
- Appropriate recommendations and use of SMBG
- How about Carbohydrate Counting and Correction doses? (a.k.a. sliding scale)

Improvement in HbA1c with Basal-bolus Insulin Regimen in Type 2 Diabetes



The majority of patients achieved HbA1c <7.0%

- Simple algorithm: 73.0%
 - CHO counting: 69.2%
- } p=NS

What about the insulin resistant patient?



- Insulin myths and misconceptions
- Provider attitudes and fear
- Positioning of insulin in the diabetes lifecycle
- True “needle phobia”
- Think about technique and device as well as site
- Initial support – ongoing assessment

The Future of Insulin...



U300 – glargine

U-200 degludec

Peglispro

U-200 lispro

FIAsp

Biosimilars

Rapid-Acting Inhaled Insulin



Three steps to achieving glycemic targets

1. Initiate
2. Optimize
3. Intensify

Keeping Insulin
Simple
Success!!!





Back-up Slides

AUTONOMY: Comparison of Two Patient-driven Approaches to Initiate and Titrate Prandial Insulin



Objective:

Compare two self-titration algorithms for initiating and escalating prandial insulin lispro in diabetes patients inadequately controlled on basal insulin.

Method:

Once optimized on insulin glargine, patients were randomized to one of two self-titration algorithm groups adjusting lispro either **every day (Q1D)** or **every 3 days (Q3D)** for 24 weeks.

Results:

- Both algorithms had significant and equivalent reductions in HbA1c from baseline.
- The incidence and rate of hypoglycemia were similar in both groups.

Prandial insulin lispro can effectively and safely be initiated, by either of two self-titrated algorithms, in a variety of practice settings.

Breakfast Habits of Canadians



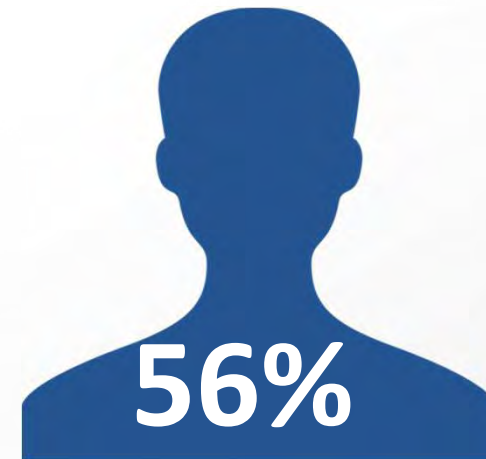
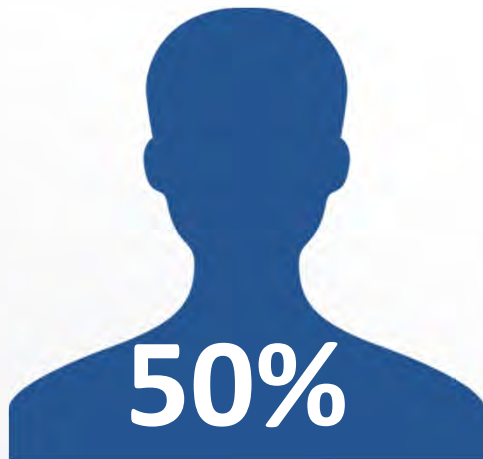
- On average, Canadians ate breakfast on 313 of 365 days in 2009. This has remained relatively constant over the past decade.
- The older we get the **less** likely we are to skip breakfast.
 - Canadians 65+ years old only skipped breakfast on average 7 times per year.
 - Canadians 18-34 years old skipped breakfast on average 59 times per year.
 - Just because this age group skipped breakfast does not mean they don't eat. This age group is more prone to be snackers.

Ready-to-eat cereals were the most popular in-home breakfast food (2008).

Many Patients in Primary Care Require Prandial (Bolus) Insulin



- **INSIGHT trial: 50% of patients** were not on target, even after optimization of basal insulin.¹
- **START study: 56% of patients** to whom basal insulin was prescribed **required prandial insulin** intensification after the 12-week run-in phase.²



1. Gerstein HC, et al. *Diabet Med.* 2006;23:736–42.

2. Harris SB, et al. *Diabetes Care.* 2014;37:604–10.

Certification Statement for CNA



- While this educational activity is not officially endorsed by the Canadian Nurses Association (CNA), nurses may claim it as a continuous learning (CL) activity toward renewal of the CNA certification credential if it is related to their nursing specialty. Pre-authorization from the CNA Certification Program is not required. Participants are encouraged to retain a confirmation of attendance.