

# The Art of Fixed Ratio in DM Treatment

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# PLEASE TAKE NOTE

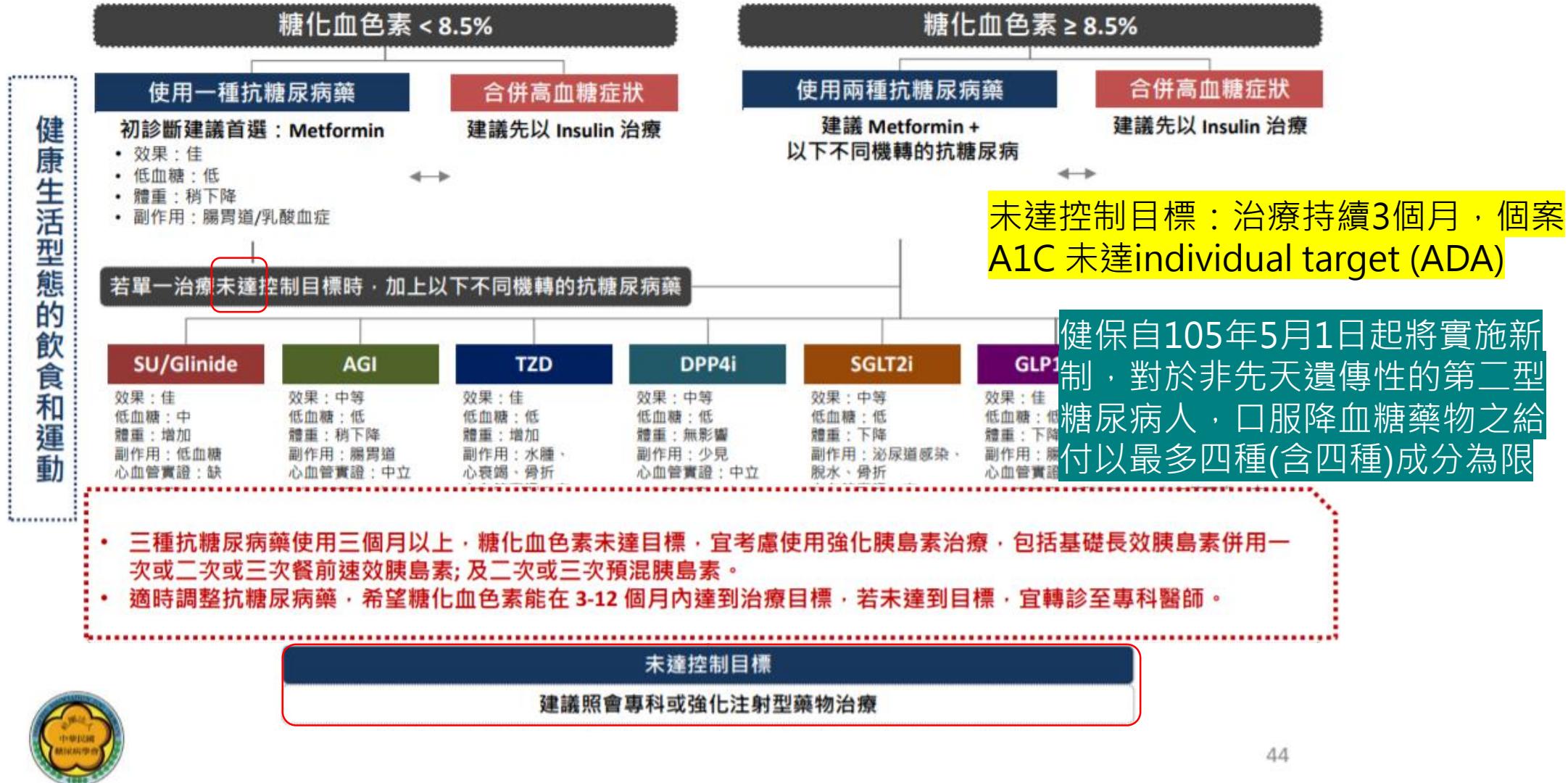
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# Clinical Question 1

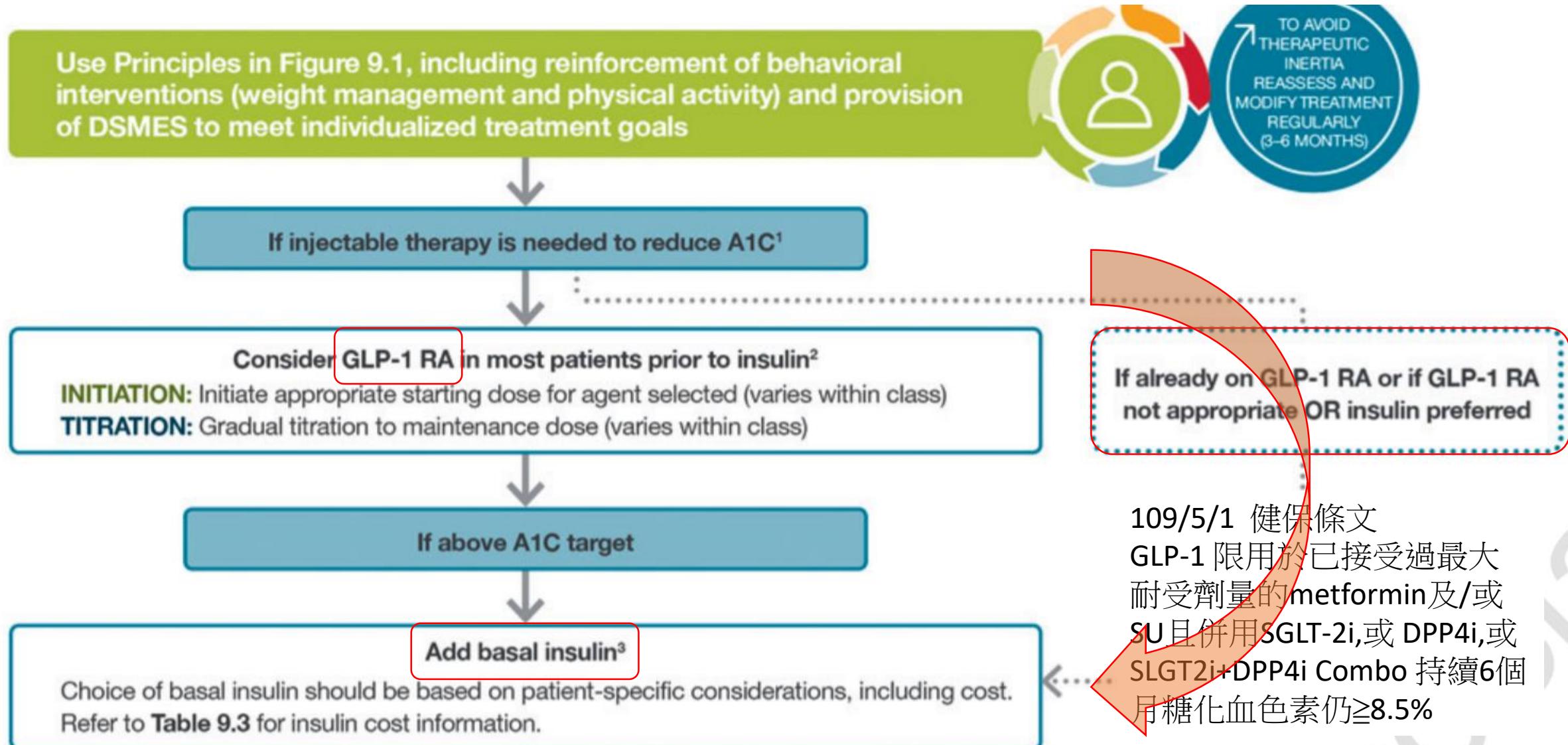
- 以臨床經驗及基層診所可行性考量，您何時開始考慮給病人胰島素治療？



# 第2型糖尿病人高血糖的處理流程圖



# 2020 ADA guideline- Basal + GLP1-RA before Insulin Intensification

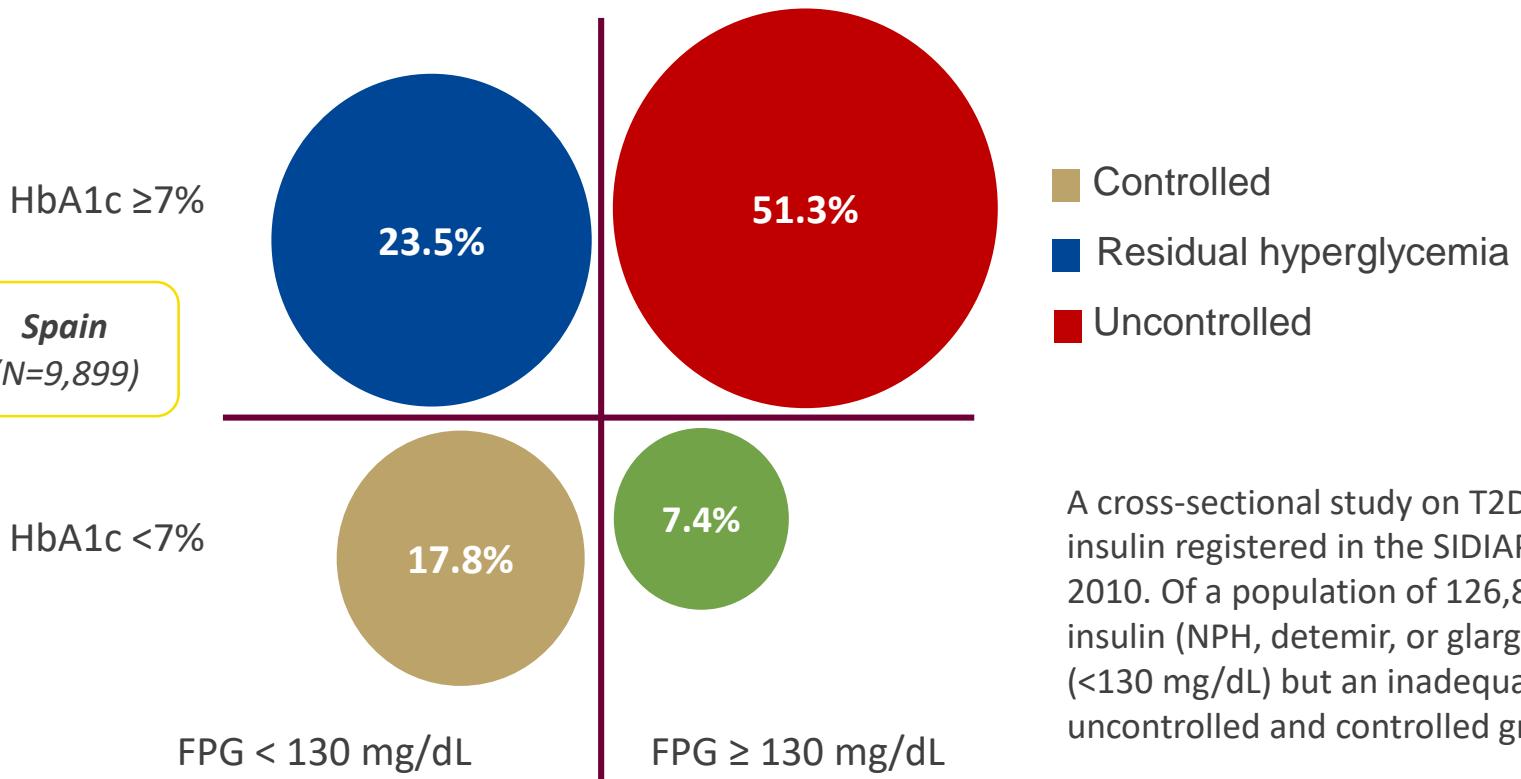


# Clinical Question 2

- 打了基礎胰島素，有多少病人會達標？

# ~75% T2DM Patients Have Uncontrolled FPG and HbA1c or Residual Hyperglycemia

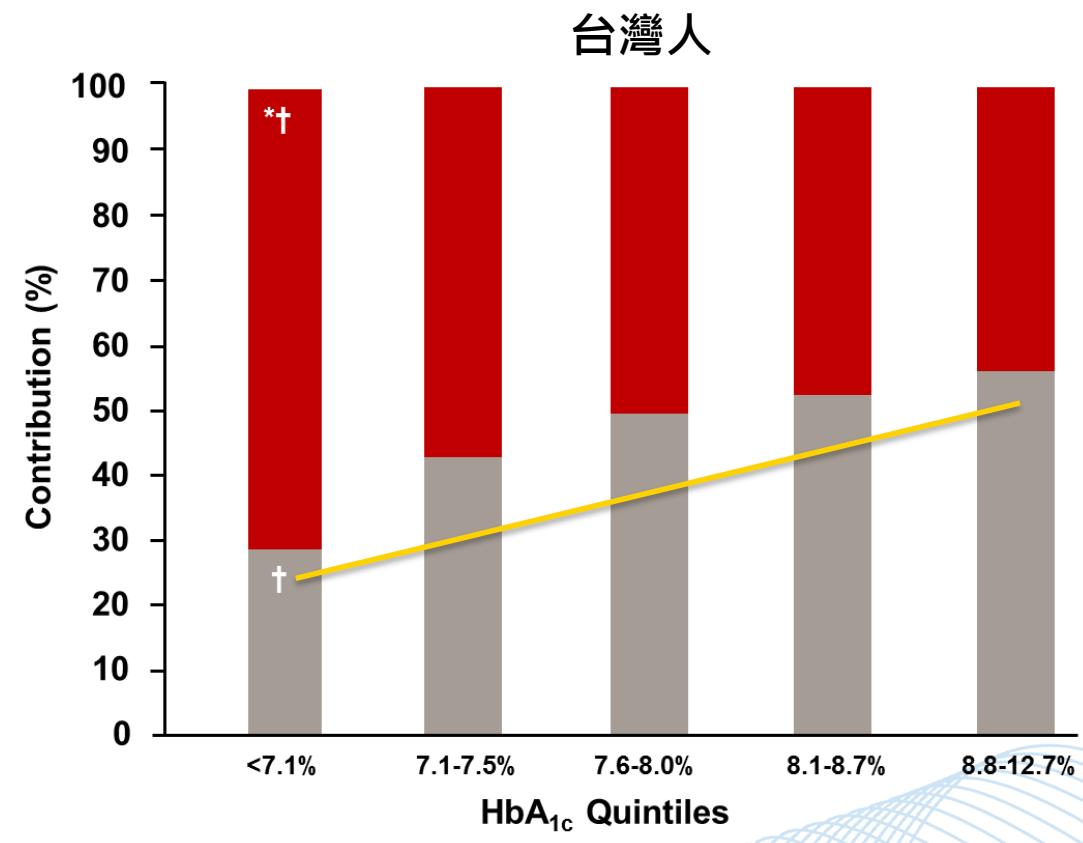
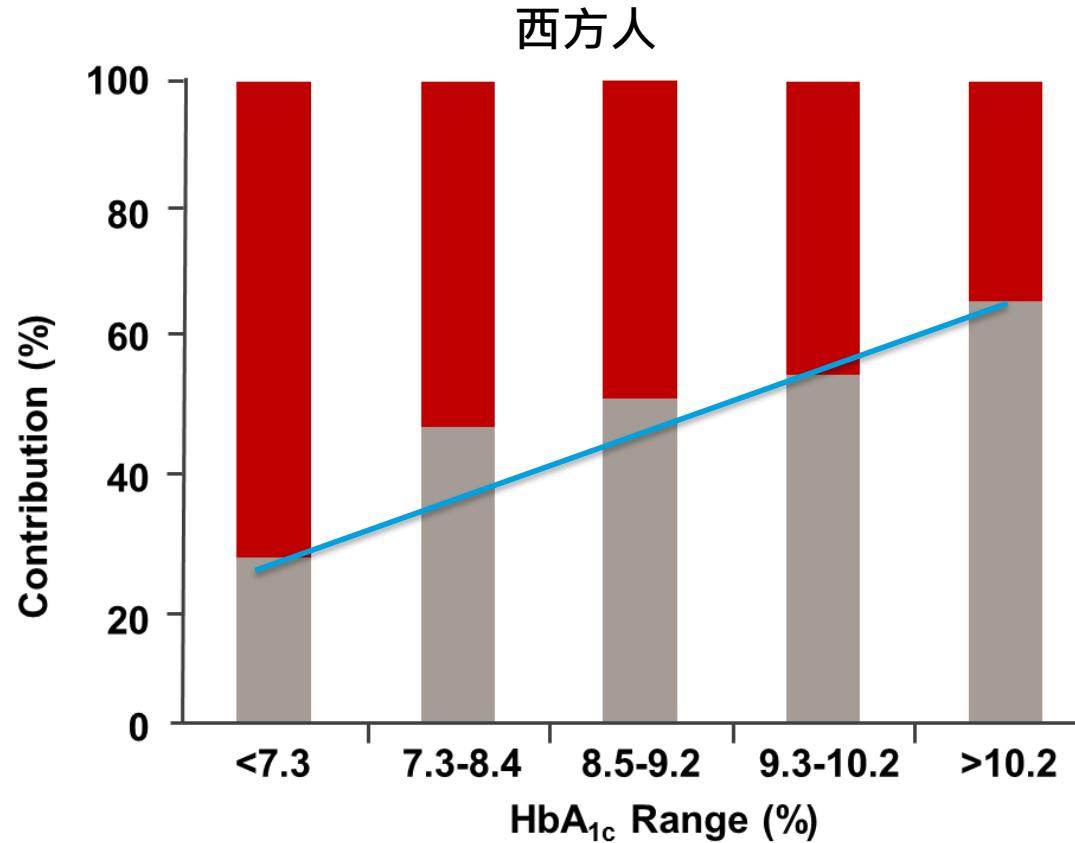
Distribution of the overall population according to HbA1c and FPG levels. Of a population of 126,811 T2DM subjects, **9,899 were treated with basal insulin (NPH, detemir, or glargine)**



**Controlled** defined as HbA1c at target (HbA1c < 7%);  
**Residual hyperglycemia** defined as HbA1c above target despite FPG at target (FPG < 7.2/7.8 mmol/L [ $<130/140$  mg/dL]);  
**Uncontrolled** defined as neither HbA1c nor FPG at target

A cross-sectional study on T2DM patients aged 31–90 years treated with basal insulin registered in the SIDIAPQ primary healthcare electronic database during 2010. Of a population of 126,811 T2DM subjects, 9,899 were treated with basal insulin (NPH, detemir, or glargine). Of these, 23.5% ( $n = 2322$ ) achieved optimal FPG ( $<130$  mg/dL) but an inadequate HbA1c target ( $>7\%$ ). Mean HbA1c values in the uncontrolled and controlled groups were 8.15% and 6.31%, respectively

# FPG/PPG Contribution to HbA1C Differs in Caucasians and Asian Type 2 Diabetes



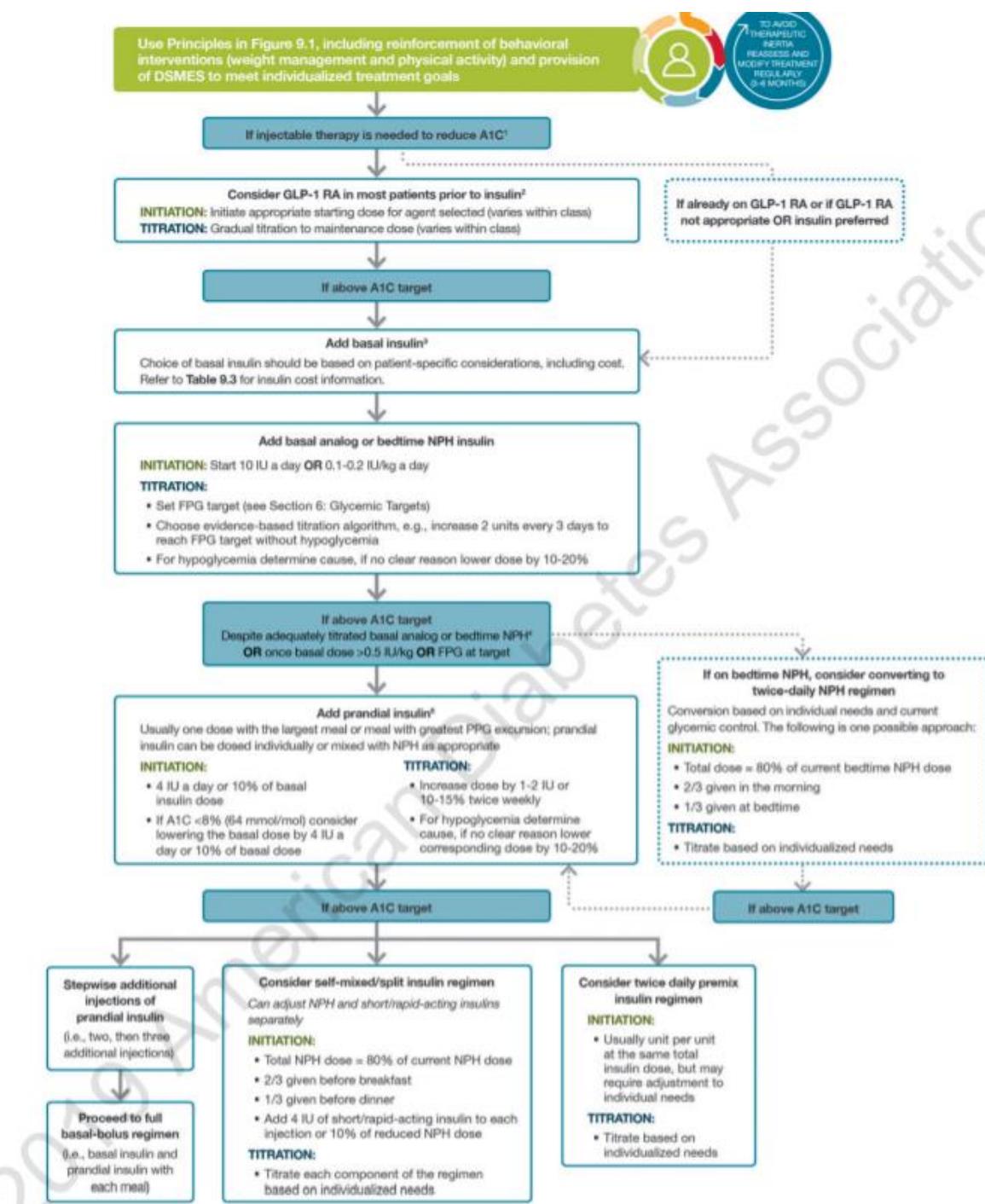
\*Significant difference between FBG and PPG; †Significant difference from all other quintiles.

1. Monnier L, et al. Diabetes Care. 2003;26(3):881-885. 2. Wang JS, et al. Diabetes Metab Res Rev. 2011;27(1):79-84.

# Clinical Question 3

- 使用基礎胰島素不達標怎麼辦?
  - Control Residual Hyperglycemia (treatment intensification)

# Before Intensification



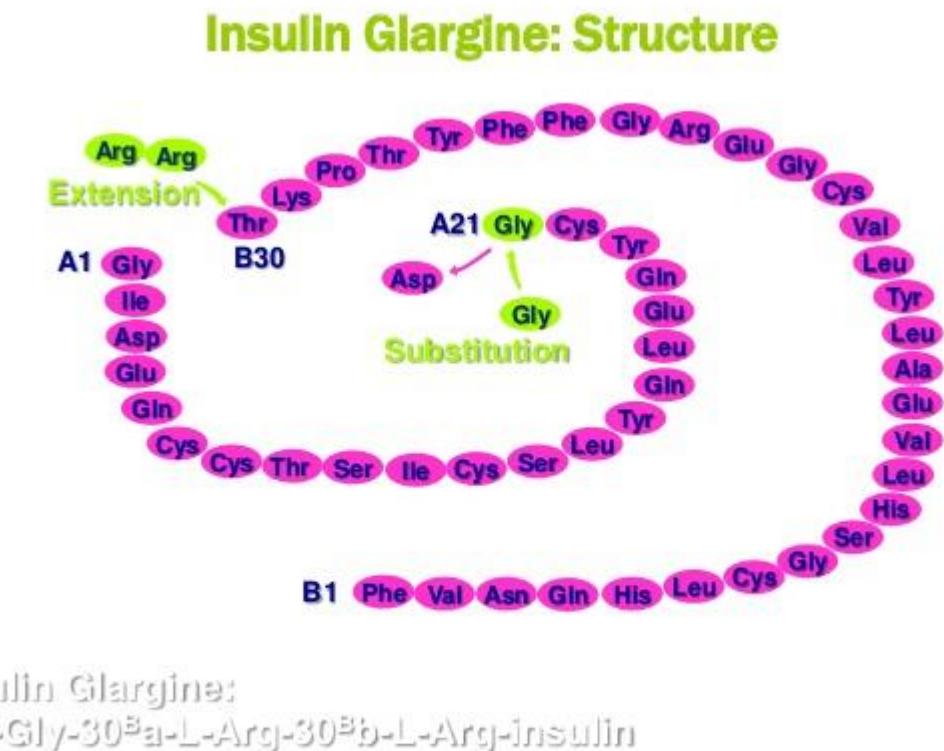
# Introduction of iGlar/Lixi

# 爽胰達 Soliqua®

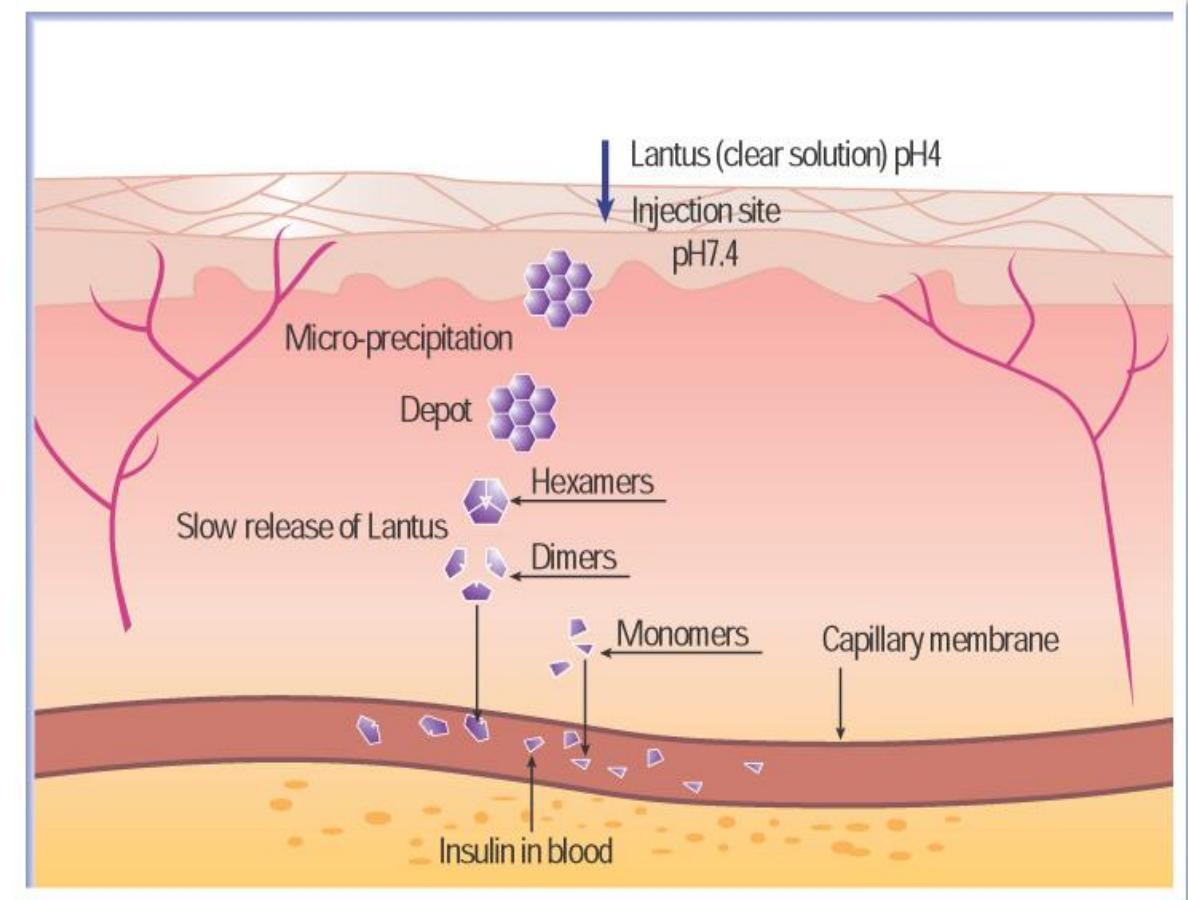


Composition	Soliqua SoloStar® 300 units of insulin glargine and 150 µg lixisenatide in 3 mL solution (100 units/mL + 50 µg/mL)
Lixisenatide concentration	50 µg/mL
Ratio Glargine: lixisenatide	2 IU : 1 µg
Dose range	10 IU to 40 IU insulin glargine <b>10-40 units</b> 合併 lixisenatide <b>5-20 µg</b>
Color	Peach 黃桃色

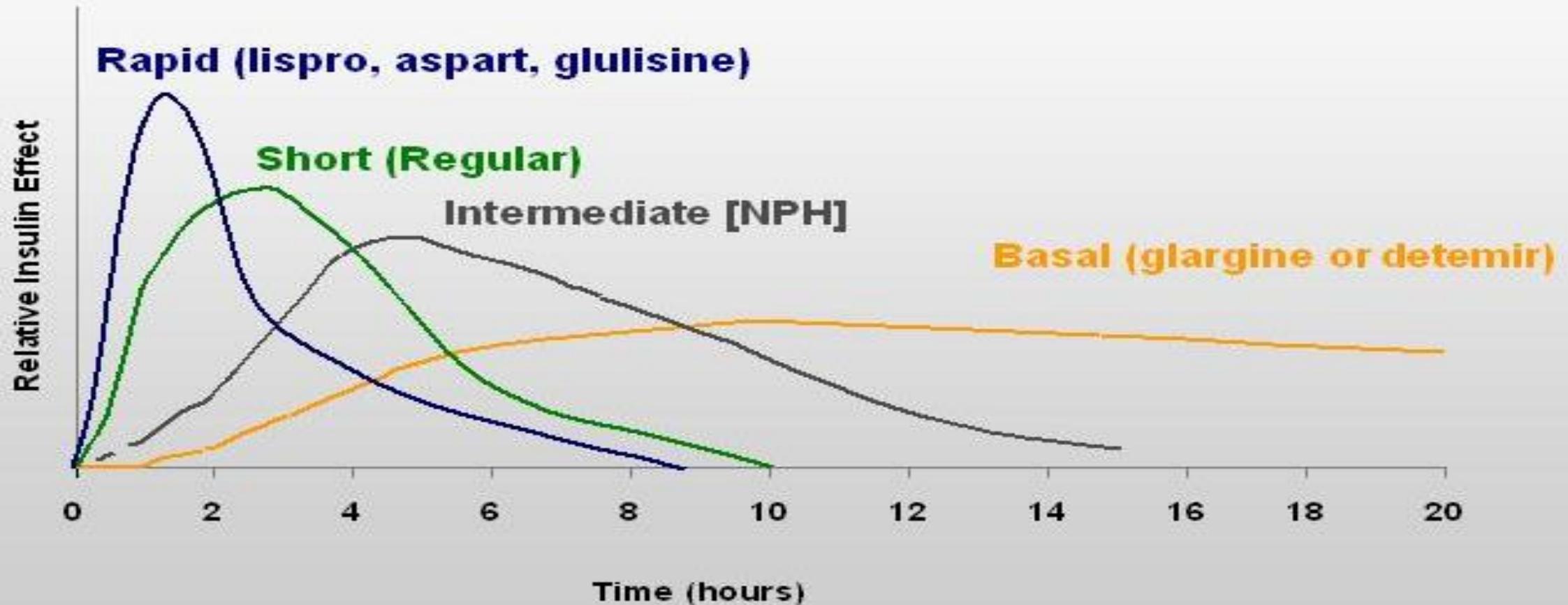
# What is insulin Glargine



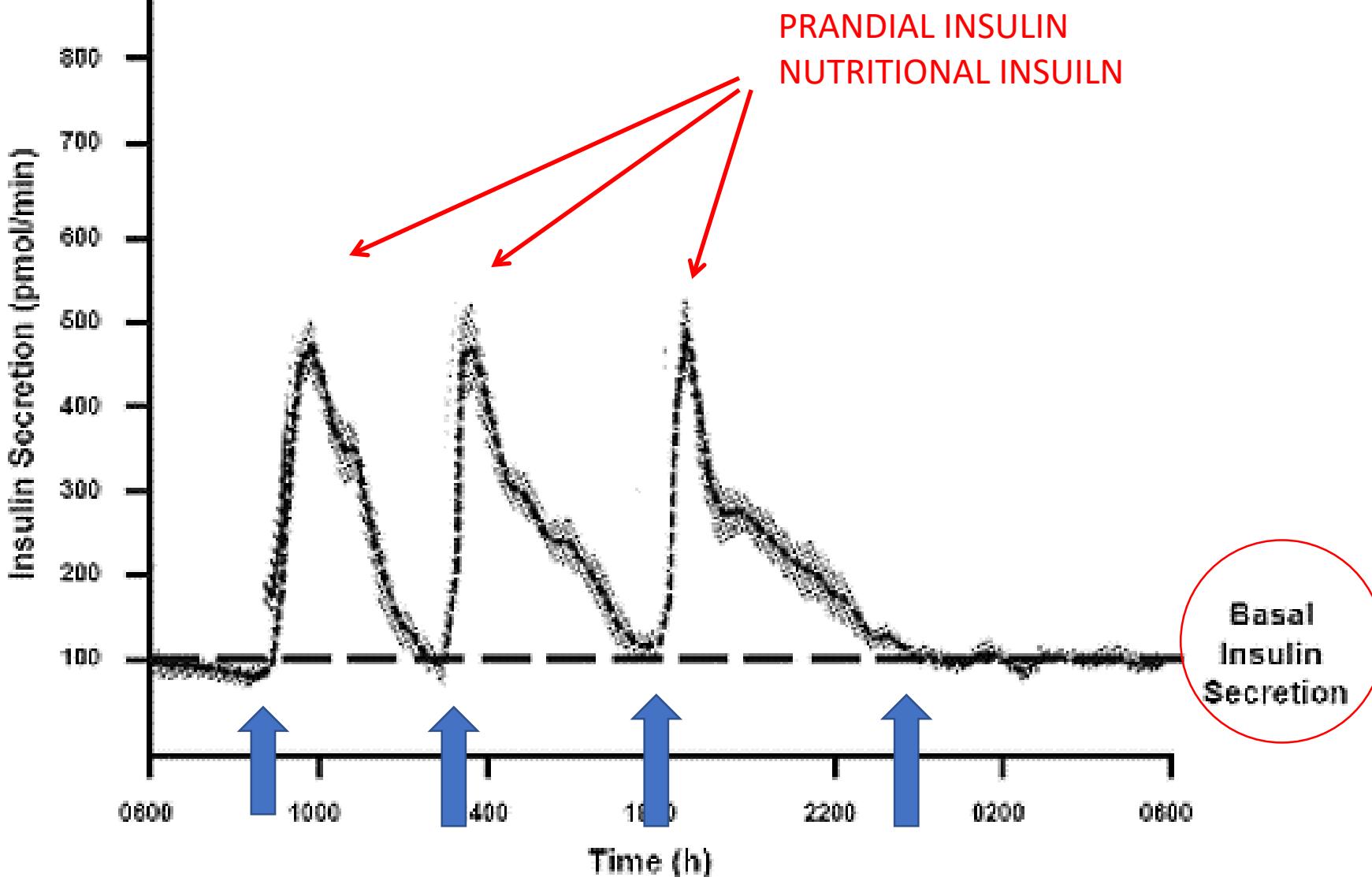
pH = 4; Clear solution; Do not mix



# Insulin Glargine as basal insulin(yellow line)

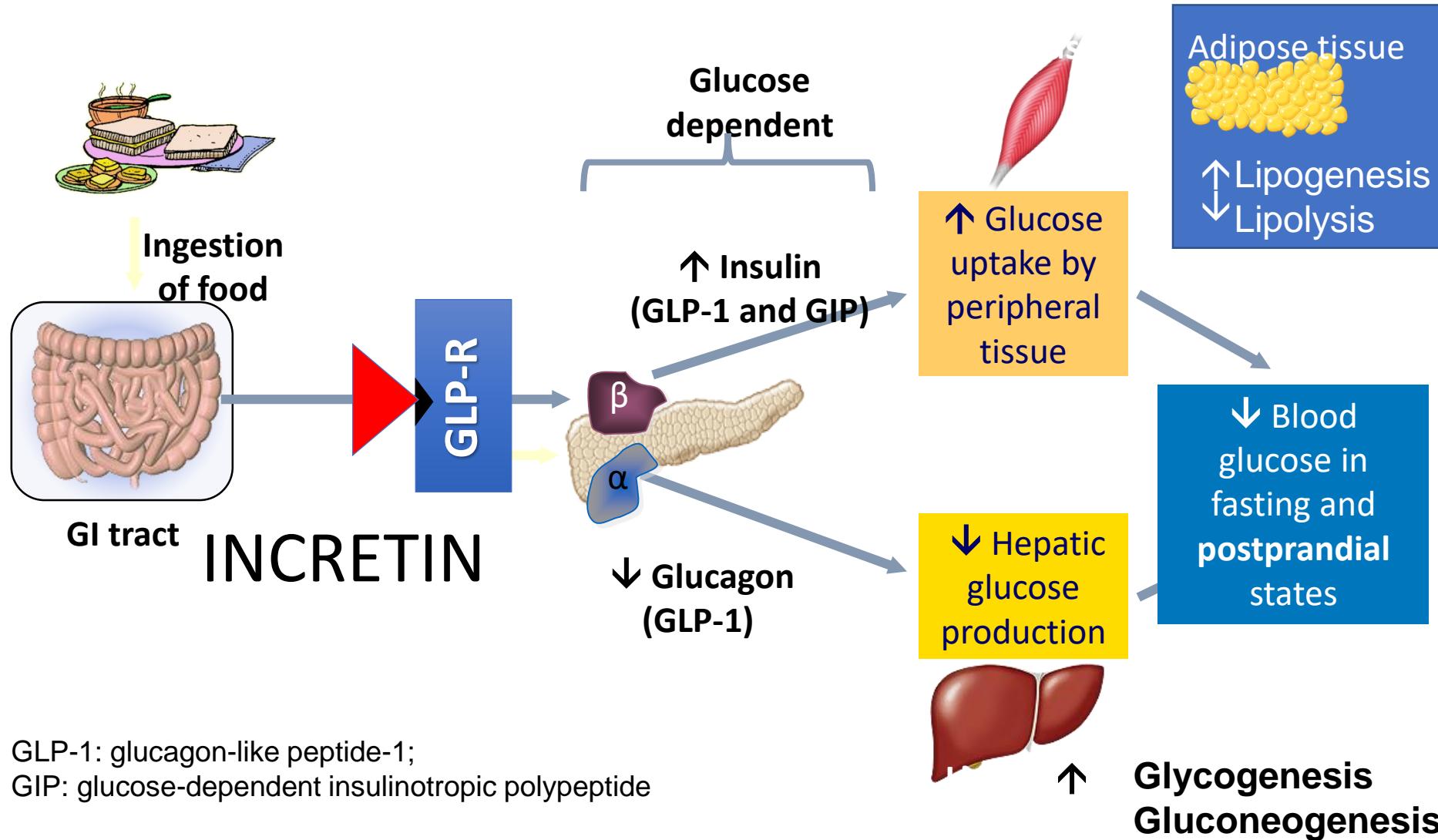


# 生理胰島素分泌



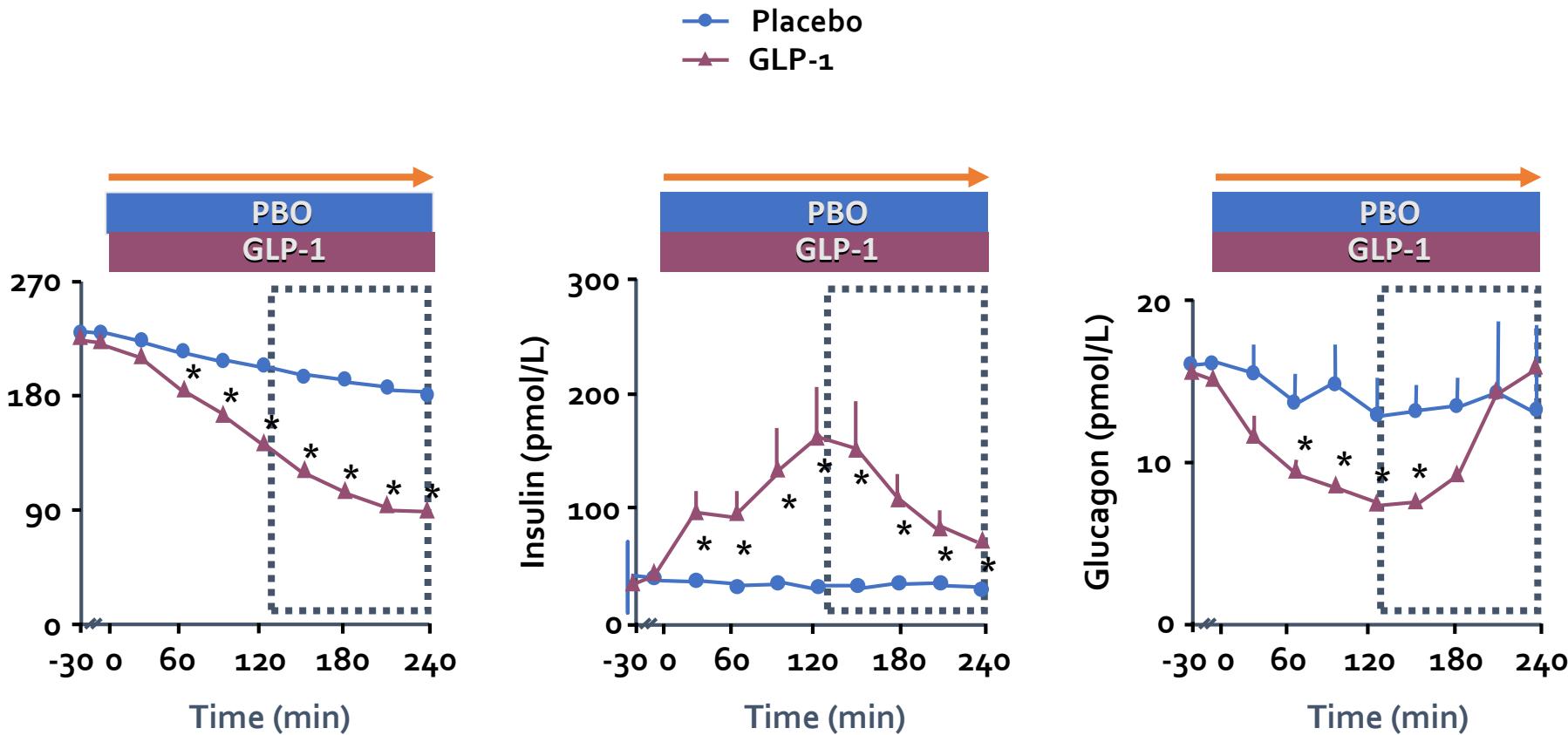
# What is Incretin?

# Normal Incretin Physiology



Adapted from: 1. Drucker DJ. *Cell Metab.* 2006; 3: 153–65. 2. Ludwig DS. *JAMA.* 2002; 287: 2414–23

# Glucose-dependent insulin secretion

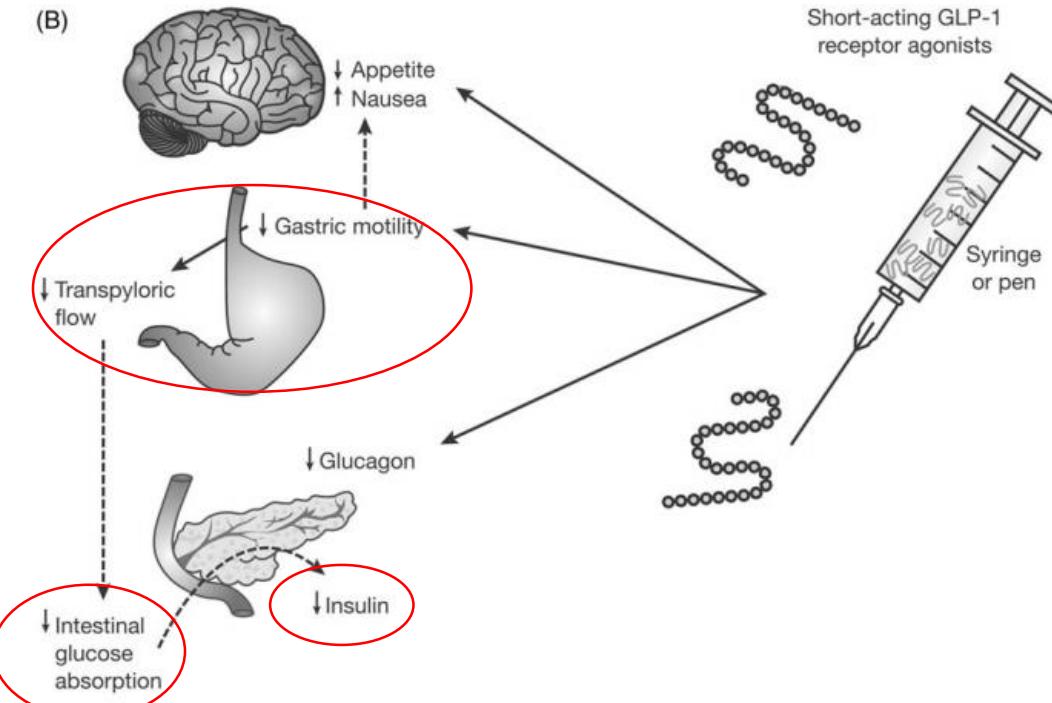


N = 10; Mean (SE); \* $P < 0.05$

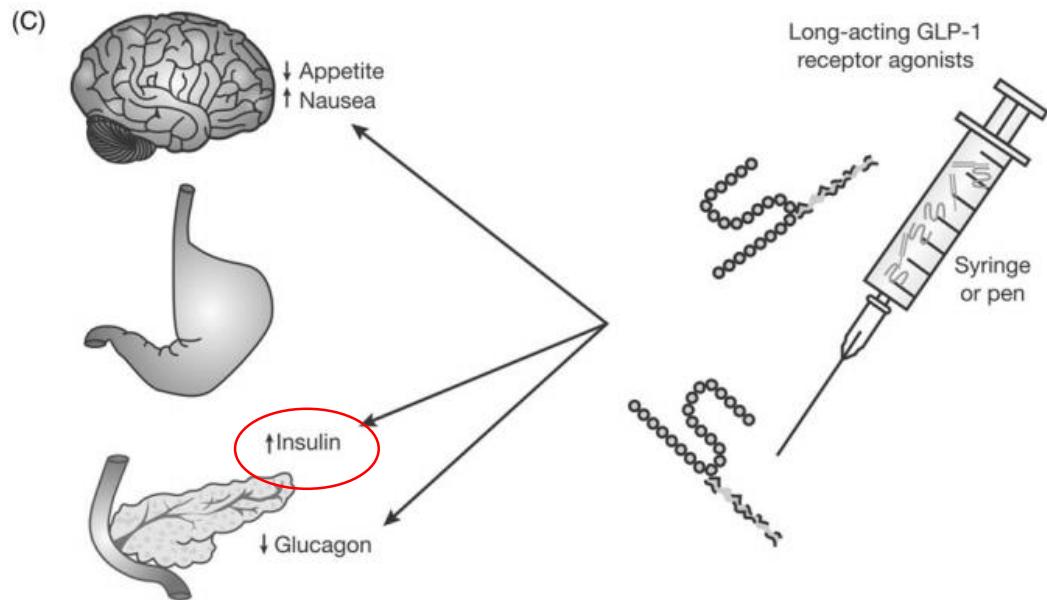
Data from Nauck MA, et al. Diabetologia 1993;36:741-744.

# Difference Mechanisms of GLP-1 RA

## Short-acting GLP-1RA



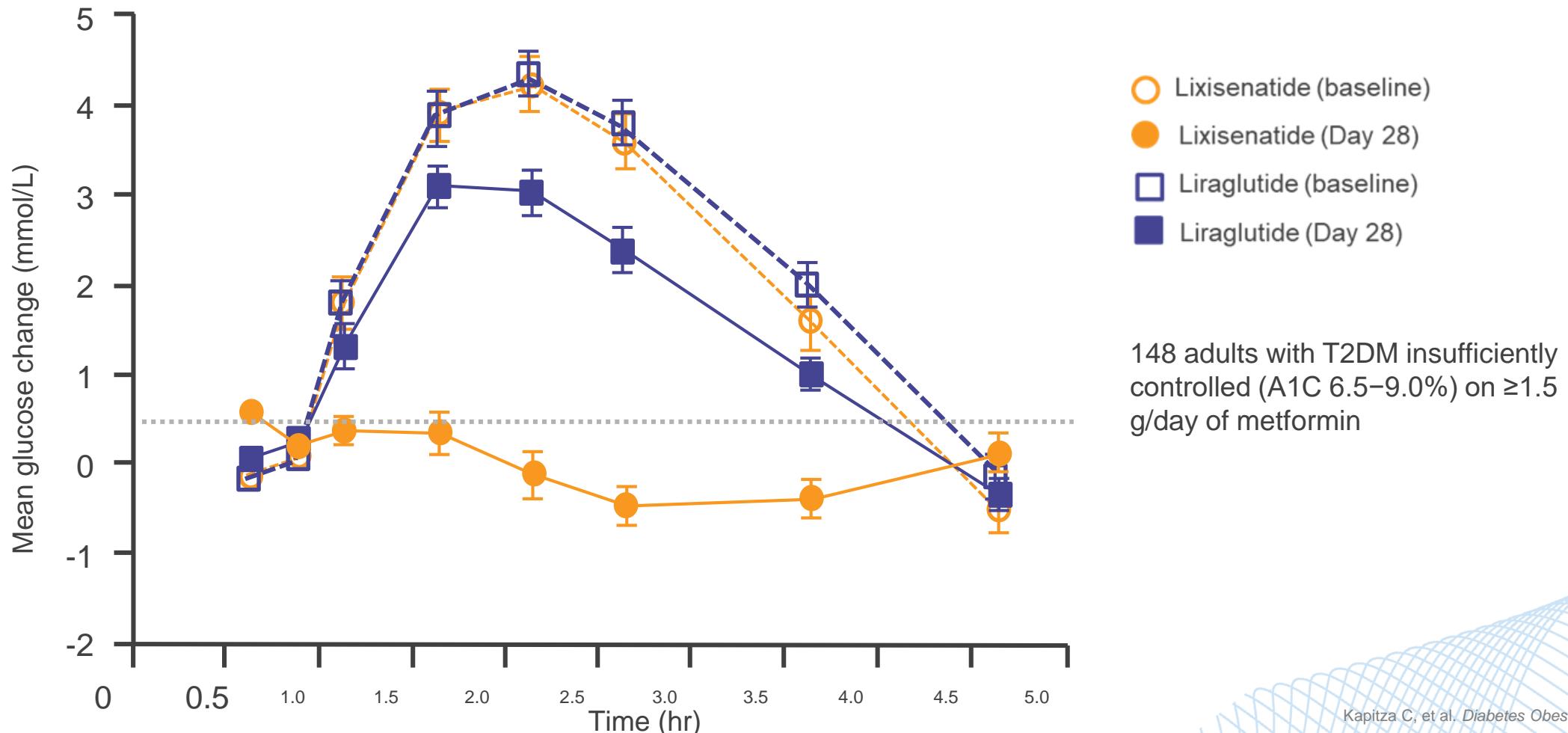
## Long-acting GLP-1RA



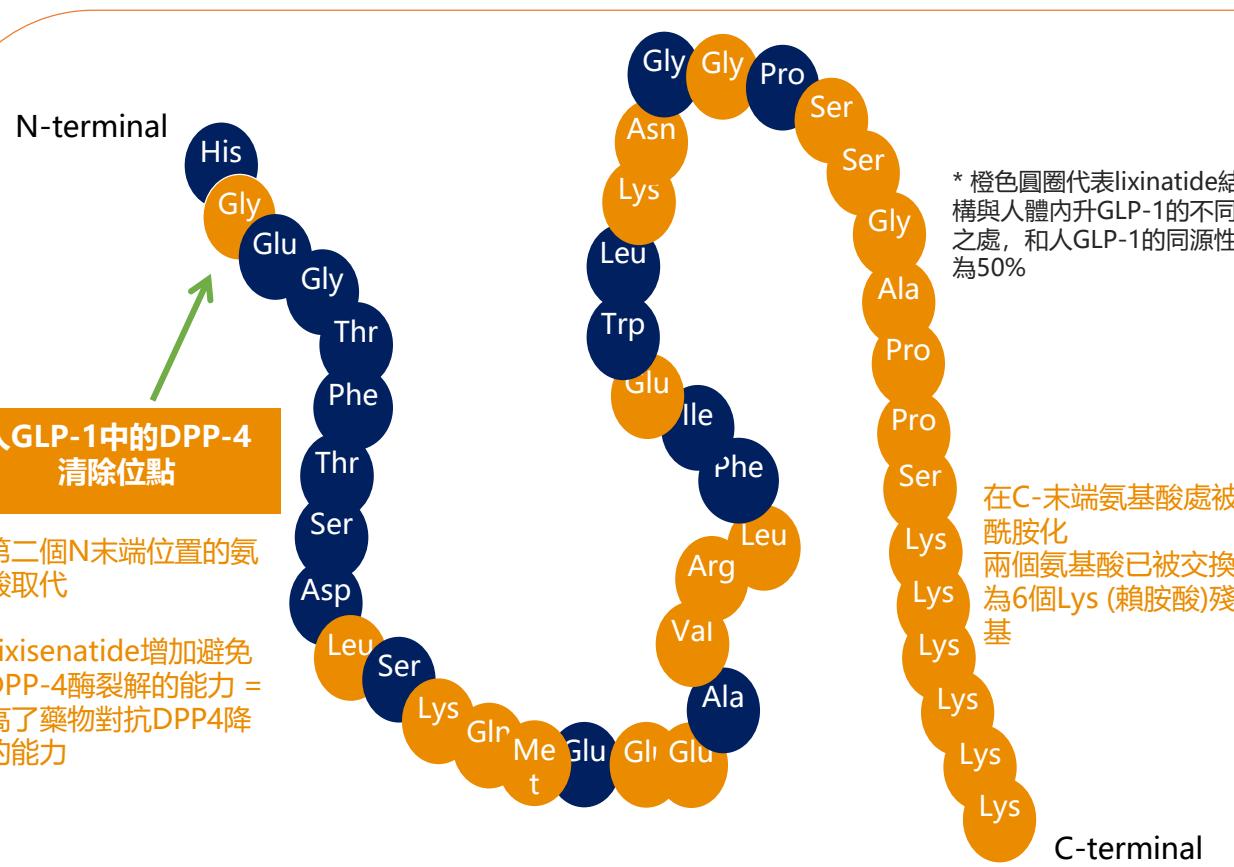
# Overview of Short and Long Acting GLP-1 RA

Parameters	Short-acting GLP-1 RAs	Long-acting GLP-1 RAs
<b>Compounds</b>	Exenatide, Lixisenatide	Albiglutide, Dulaglutide, Exenatide-LAR, Liraglutide
<b>Half-life</b>	2-5 h	12 h - several days
<b>FPG levels</b>	Modest reduction	<b>Strong reduction</b>
<b>PPG levels</b>	<b>Strong reduction</b>	Modest reduction
<b>Glucagon secretion</b>	Reduction	Reduction
<b>Blood pressure</b>	Reduction	Reduction
<b>Heart rate</b>	<b>No effect or small increase (0-2 bpm)</b>	<b>Moderate increase (2-5 bpm)</b>
<b>Body weight reduction</b>	1-5 Kg	2-5 Kg
<b>Induction of nausea</b>	20-50%, attenuates slowly (weeks to many months)	20-40%, attenuates quickly (~4-8 weeks)

# Lixisenatide Demonstrates Better Postprandial Glucose Lowering Effects Than Liraglutide



# Lixisenatide, a Selective Short-acting GLP-1 RA



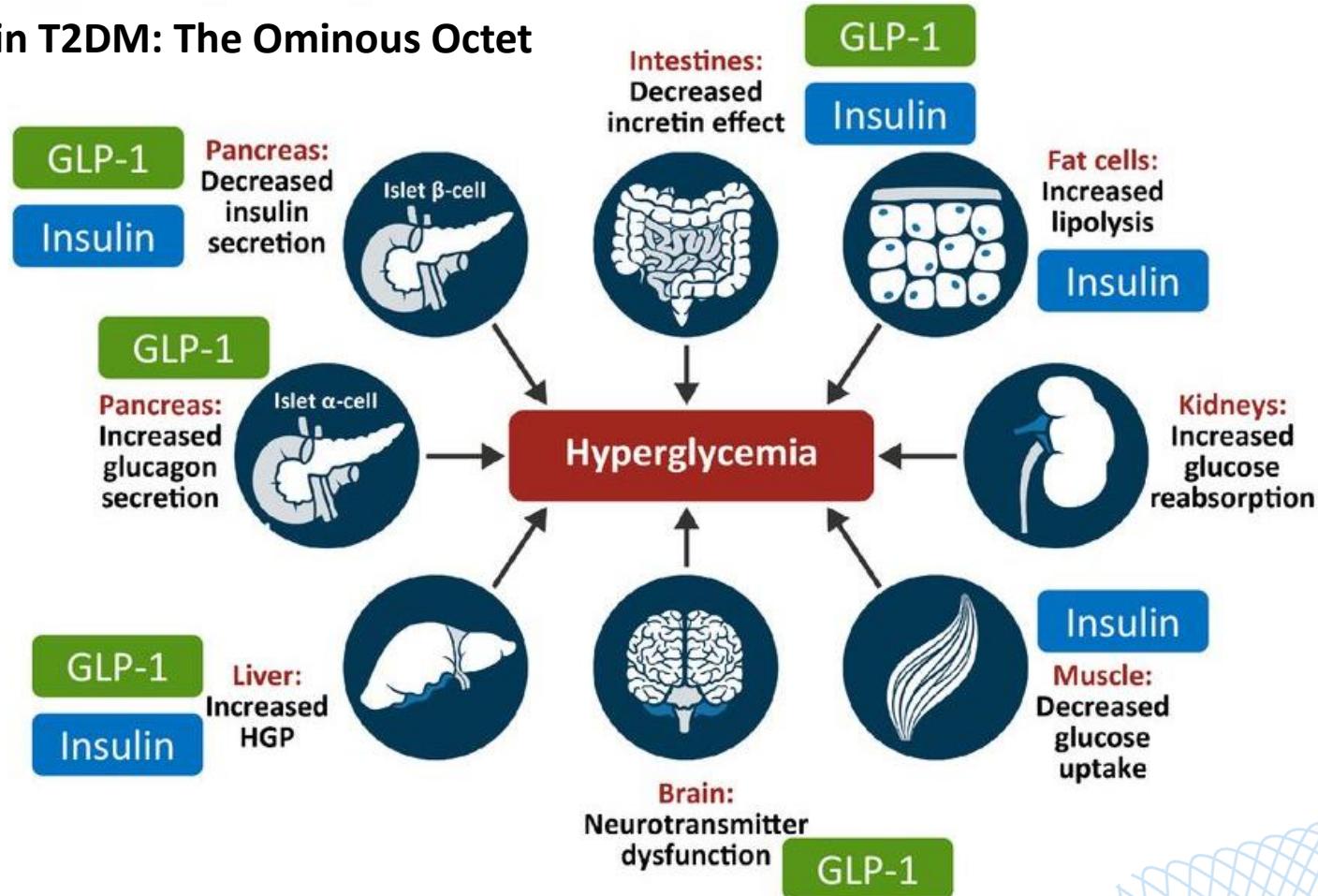
- Lixisenatide可抵抗DPP-4快速降解以長久維持體內活性
  - 血漿半衰期約1.5-4.5h
  - 親和力相對於人體GLP-1的倍數：

親和力相對於人體GLP-1的倍數	
Lixisenatide	4x
Exenatide	0.64x
Liraglutide	3x

相較於內生性GLP-1，Lixisenatide對於GLP-1 receptor具有4倍的高親和性，進而減緩半衰期，因此只需要一天一次給藥

# Benefits of Combination Therapy of Basal Insulin and GLP-1 RA

## Pathophysiologic Defects in T2DM: The Ominous Octet



Intensification With FRC iGlarLixi



# **iGlarLixi FRC, outcomes in T2DM patients uncontrolled on basal insulin**

# The “LixiLan-L” Study

## Fixed-Ratio Combination of Basal Insulin and GLP-1 RA in Patients Inadequately Controlled on Basal Insulin ± Oral Agent(s)

Diabetes Care

1



### Efficacy and Safety of LixiLan, a Titratable Fixed-Ratio Combination of Insulin Glargine Plus Lixisenatide in Type 2 Diabetes Inadequately Controlled on Basal Insulin and Metformin: The LixiLan-L Randomized Trial

DOI: 10.2337/dc16-1495

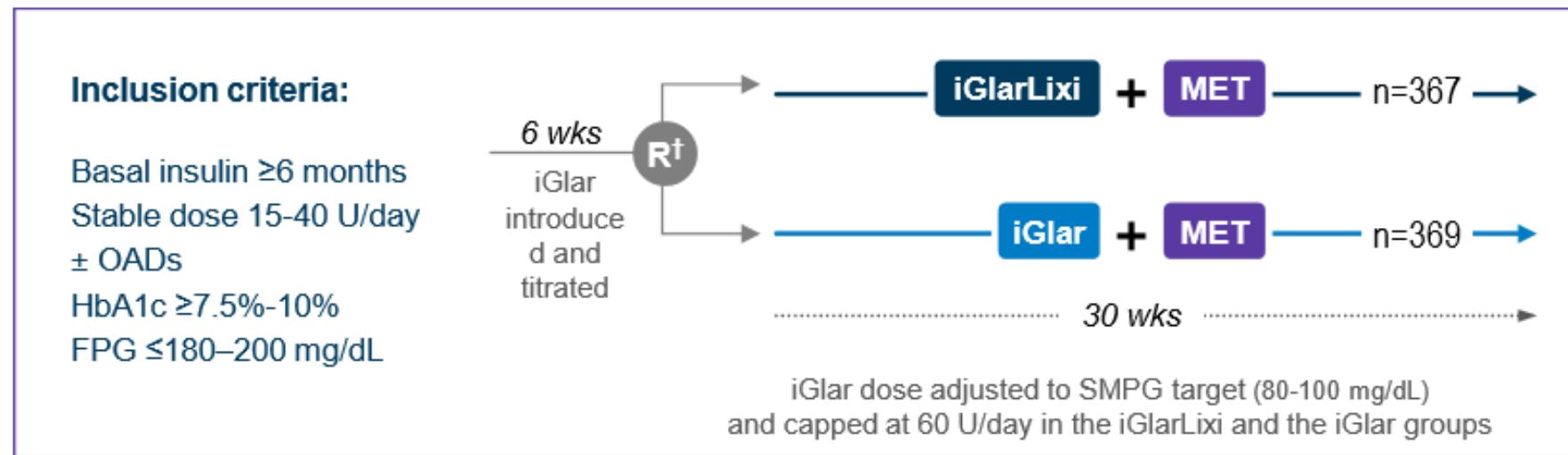


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the LixiLan-L Trial Investigators\*

# Demonstration of safety and efficacy of LixiLan compared with iGlar\*

LixiLan-L



## Primary Endpoint

- HbA<sub>1c</sub> change at Week 30

## Secondary Endpoints

- % patients reaching target HbA<sub>1c</sub>  $<$ 7.0%
- Change in 2-h PPG and 2-h PPG excursion
- Bodyweight change at Week 30
- Change in 7-point SMPG profile
- Composite endpoints

## Safety Endpoints

- Symptomatic hypoglycemia
- Gastrointestinal AEs (plus CV events, allergic reactions, pancreatic events, labs, vital signs, anti-Lixi-/anti-insulin Abs)

\*Open-label.

† Randomization criteria: HbA1c 7–10%, FPG  $\leq$ 140 mg/dL, iGlar QD 20–50 U.

# Patient characteristics at baseline

LixiLan-L

Variables†	iGlarLixi (n=367)	iGlar (n=369)
<b>Mean age, years</b>	<b>60</b>	<b>60</b>
Female (%)	55	52
Caucasian (%)	92	92
<b>BMI (kg/m<sup>2</sup>)</b>	<b>31</b>	<b>31</b>
HbA1c (%) at screening (Week -8)	8.5	8.5
<b>HbA1c (%) at baseline (Week -1)</b>	<b>8.1</b>	<b>8.1</b>
FPG (mmol/L) at baseline (Week -1)	7.3	7.4
Mean daily BI dose (U/d)	35	35
<b>Diabetes duration (years)</b>	<b>12.0</b>	<b>12.1</b>
<b>Duration of insulin therapy (years)</b>	<b>3.1</b>	<b>3.3</b>

Demographics and baseline characteristics were well matched across treatment groups

\*HbA1c at randomization.

Adapted from: Aroda V, et al. Diabetes Care 2016;39:1972–80.

# Insulin titration scale

Initial Dose:

- iGlar group: same dose as before randomization
- iGar-lixi:
  - if dose of iGlar < 30 Units before randomization → starting from 20 U
  - If dose of iGlar > 30 Units before randomization → starting from 30 U

10-40 P

30-60 Pen

30

Starting dose\*

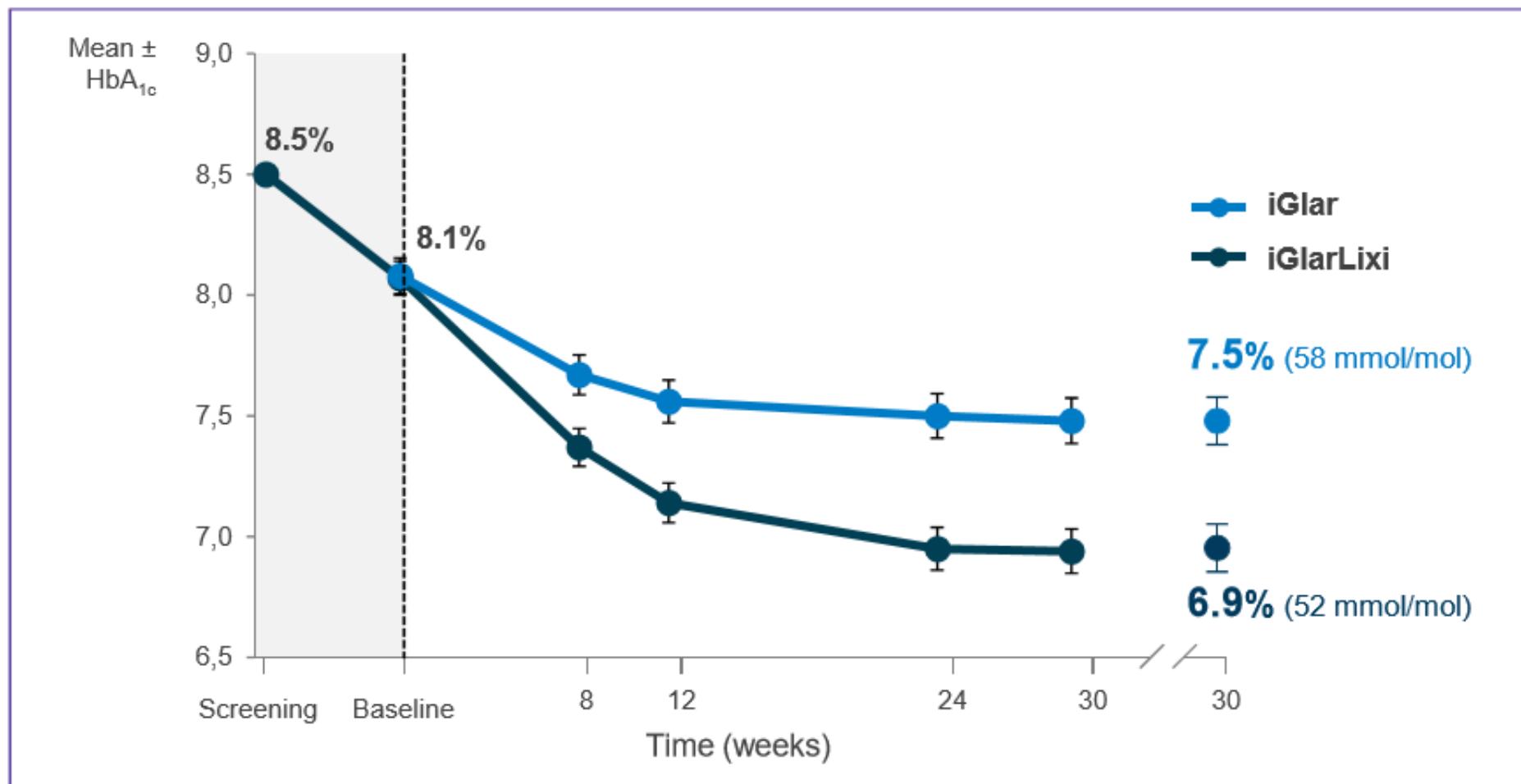


FPG	Dose titration (weekly)
101-140 mg/dl	+2
> 140 mg/dl	+4

# Changes in HbA<sub>1c</sub> over time

## Patients uncontrolled on basal insulin

LixiLan-L

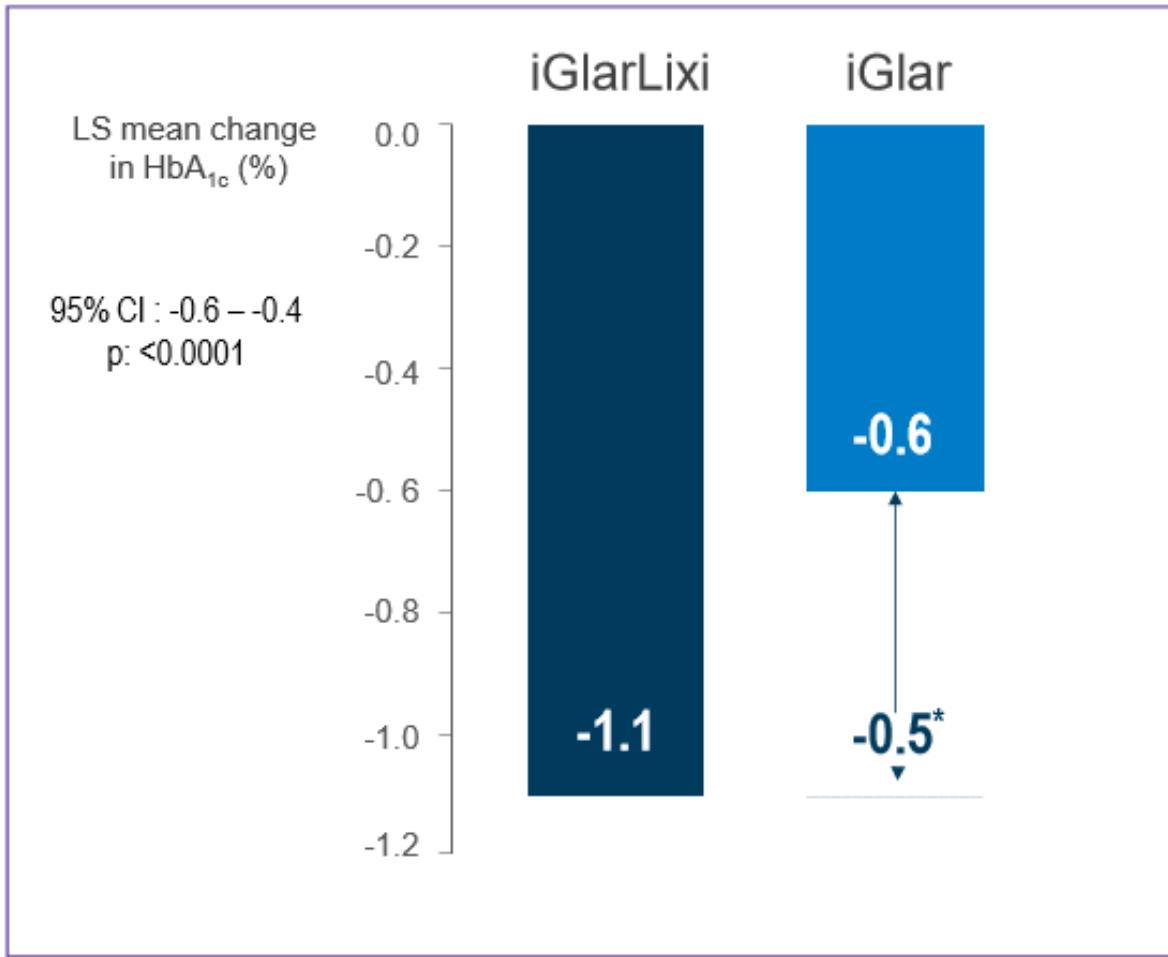


Greater reduction in HbA<sub>1c</sub> with iGlarLixi vs iGlar

# Changes in HbA<sub>1c</sub> from BL at Week 30

## Patients uncontrolled on basal insulin

LixiLan-L

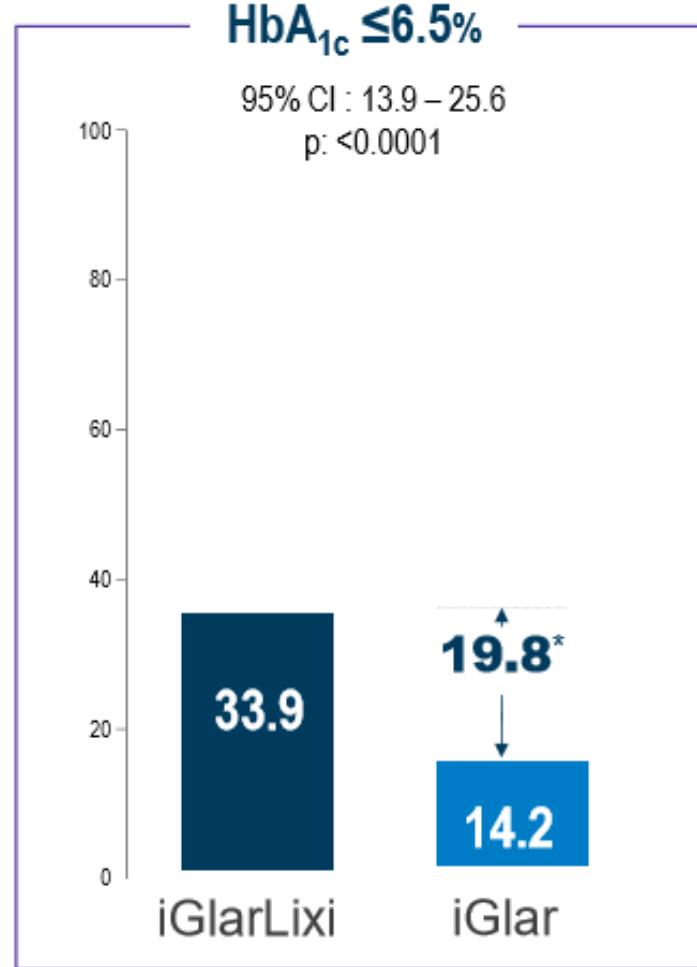
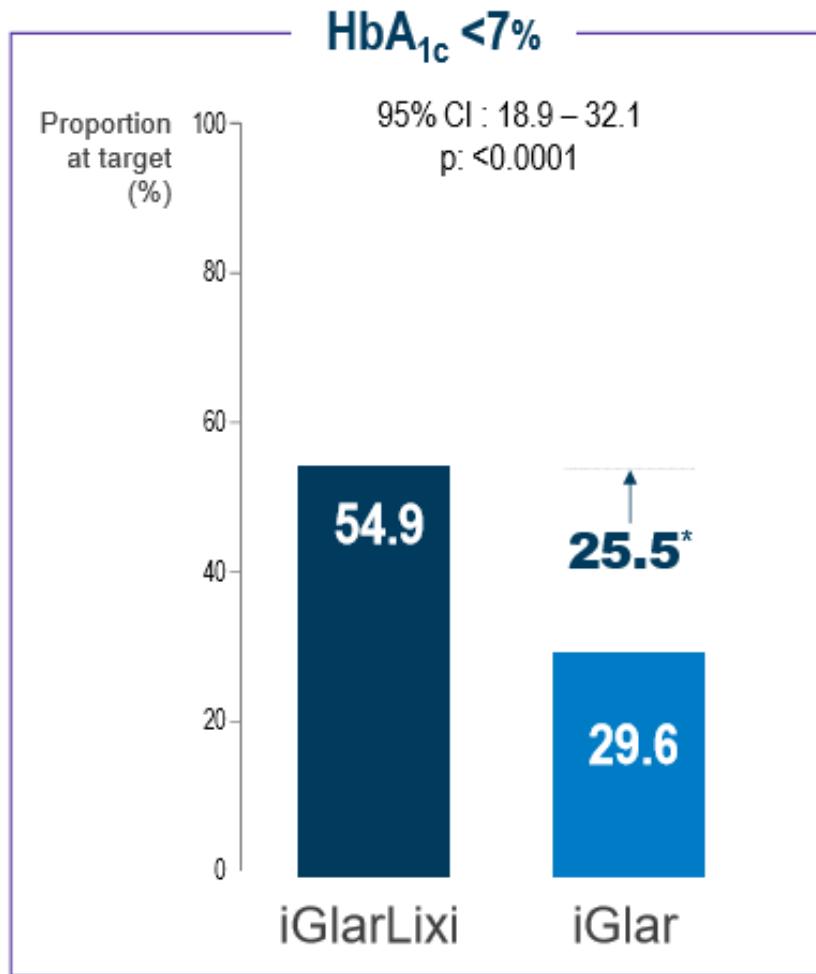


**Significantly greater reduction in HbA<sub>1c</sub> with iGlarLixi vs iGlar**

Statistical superiority of iGlarLixi over iGlar was demonstrated for the change in HbA<sub>1c</sub> from baseline to week 30 (least-squares mean difference vs. iGlar -0.5%; 95% CI -0.6, -0.4; P , 0.0001). Mean HbA<sub>1c</sub> levels were reduced more with iGlarLixi than with iGlar (-1.1% vs. -0.6%, respectively), achieving after 30 weeks of treatment final HbA<sub>1c</sub> levels of 6.9% (52 mmol/mol) for iGlarLixi and 7.5% (58 mmol/mol) for iGlar.

# Patients achieving HbA<sub>1c</sub> target at Week 30

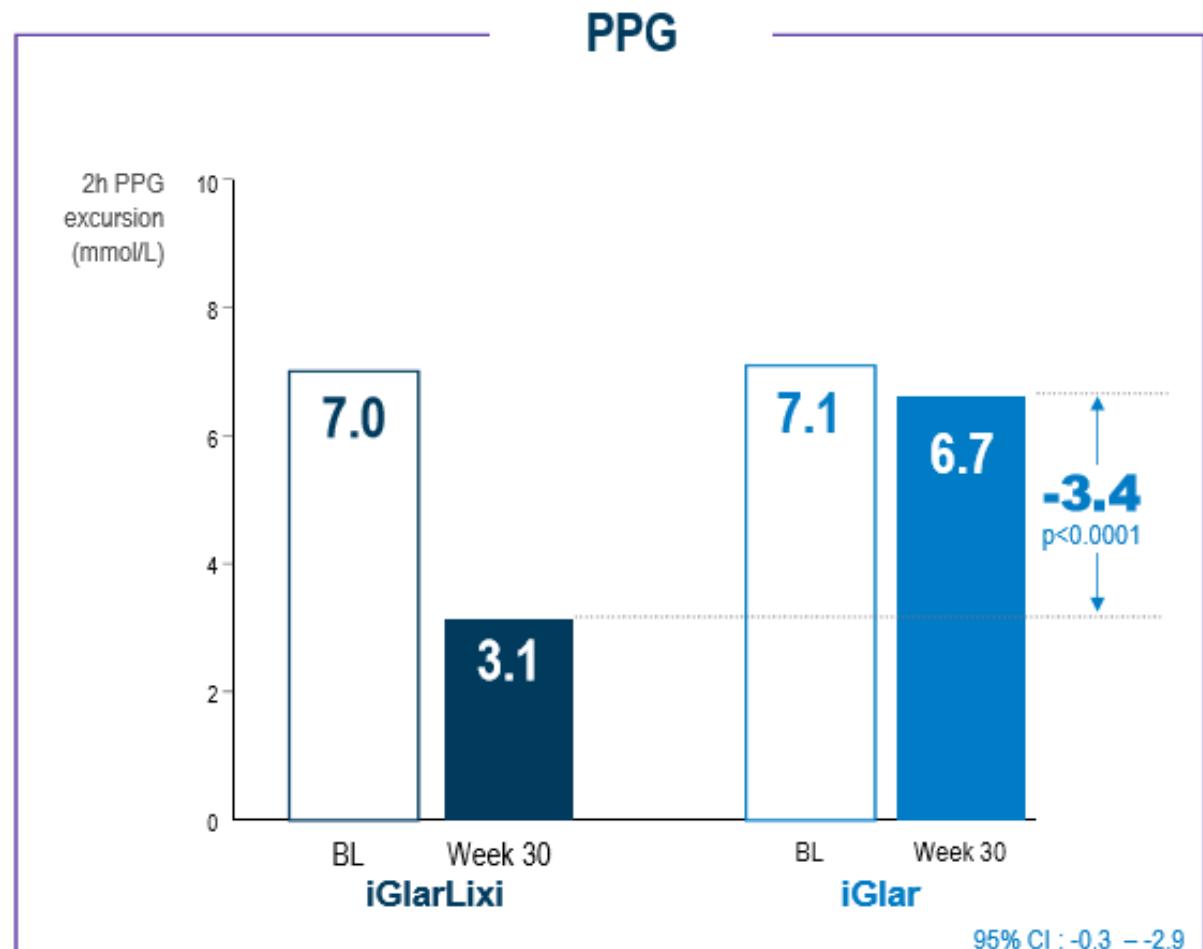
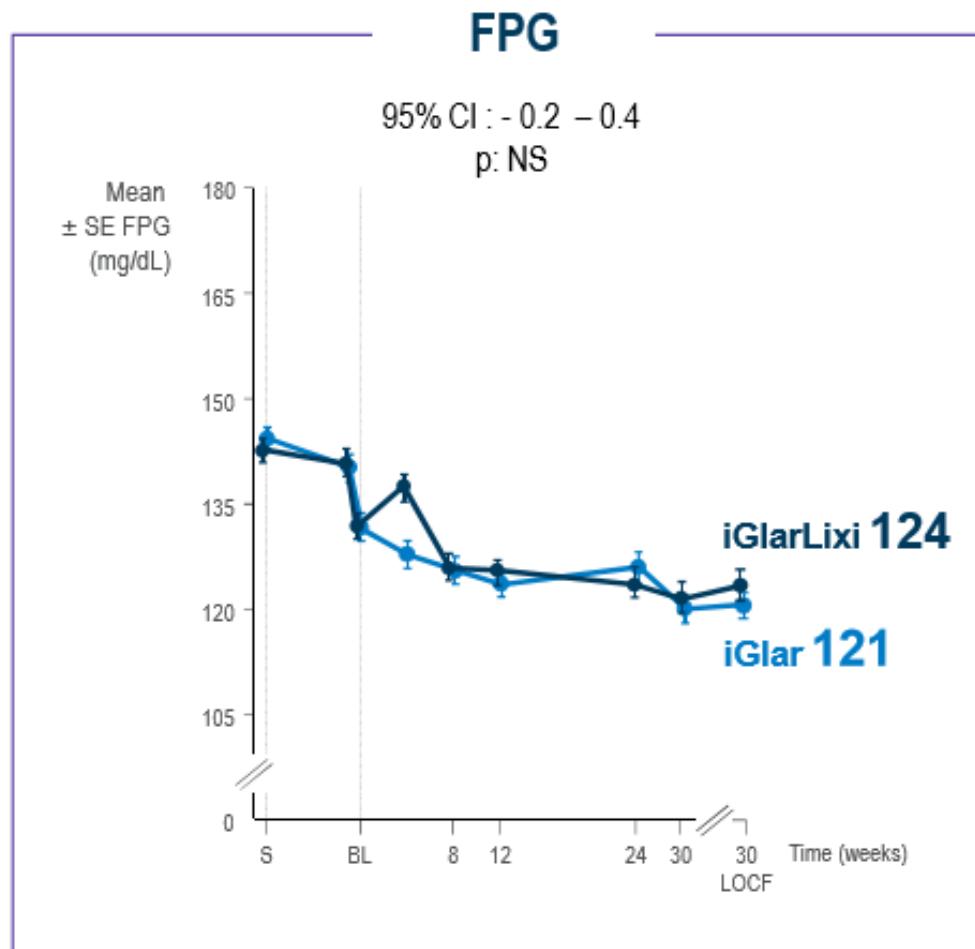
LixiLan-L



Significantly greater proportion reached target with iGlarLixi vs iGlar

# Effect of iGlarLixi on FPG and PPG

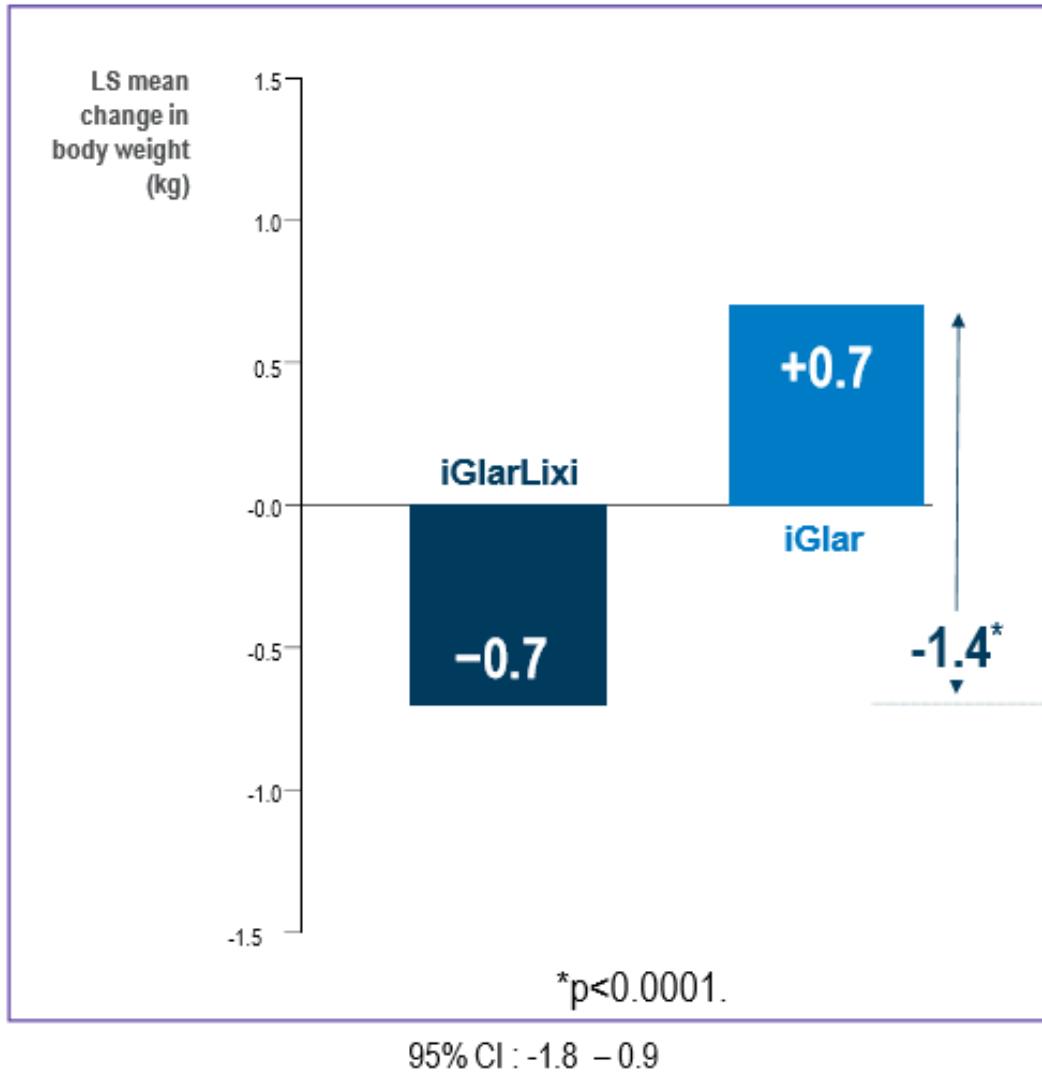
LixiLan-L



iGlarLixi combines the FPG effect of iGlar and the PPG effect of Lixi

# LixiLan-L: Changes in body weight

LixiLan-L



**iGlarLixi was  
not associated with  
the weight gain often  
seen with insulin  
therapy**

# Hypoglycemia

LixiLan-L

Patients with:		iGlarLixi (n=469)	iGlar (n=467)
<b>Documented symptomatic hypoglycemia (≤70 mg/dL; ≤3.9 mmol)</b>	% pts.	40.0%	42.5%
	Events per patient-year	3.0	4.2
<b>Severe hypoglycemia</b>	% pts.	1.1%	0.3%
	Events per patient-year	0.02	<0.01

**Similar hypoglycemia with iGlarLixi vs iGlar despite significantly better A1C with iGlarLixi**

# Adverse Events

## LixiLan-L

- Both treatments were well tolerated
- Safety profile of iGlarLixi generally reflected the established safety profiles of its components
- GI disorders were more common with iGlarLixi, were generally mild to moderate, and led to very few discontinuations (1.1%)

Patients with:	iGlarLixi (n=365)	iGlar (n=365)
<b>Nausea</b>	10.7%	0.5%
<b>Vomiting</b>	3.6%	0.5%
<b>Diarrhea</b>	4.4%	2.7%

Review: Dosing information

# iGlarLixi dosing in patients with previous basal insulin dose <30 U

Initiation

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Starting dose\*

10-40 Pen



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is required, move to

30-60 Pen



When >40 U

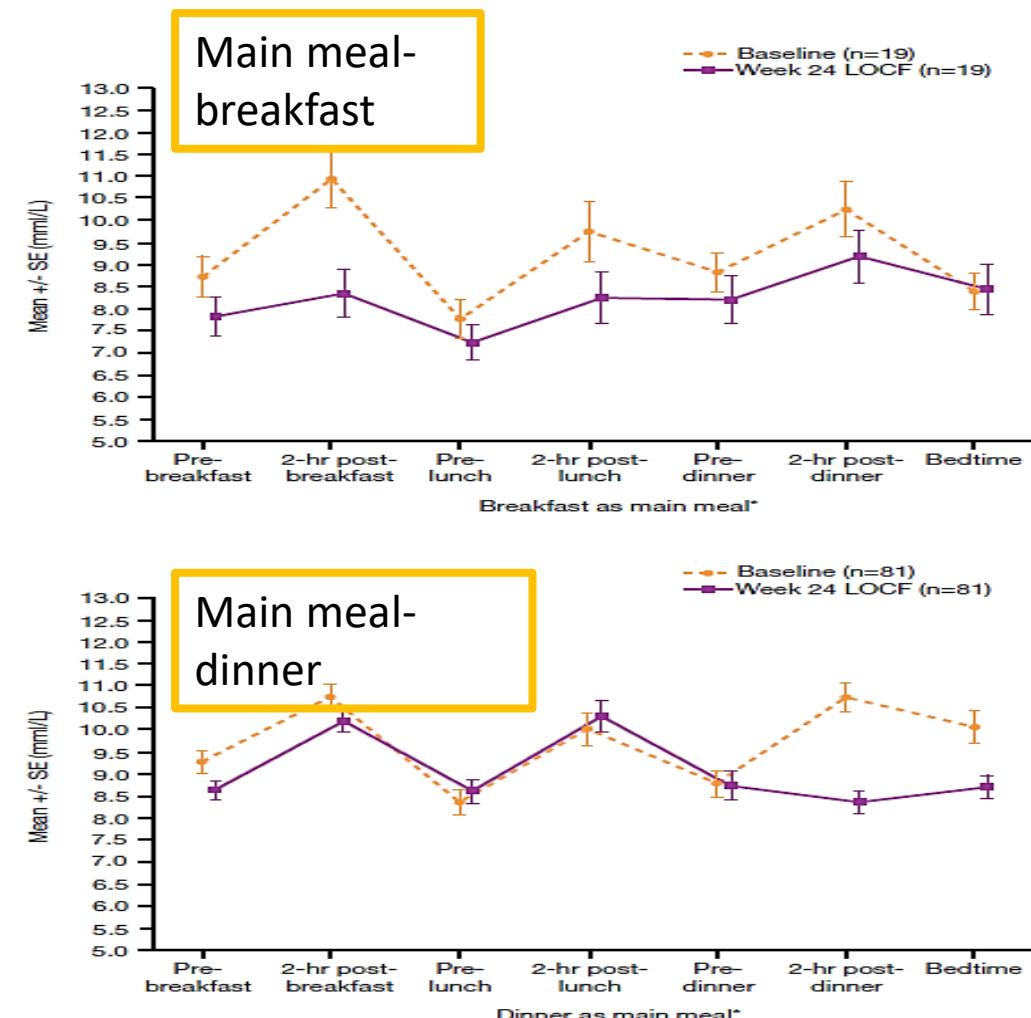
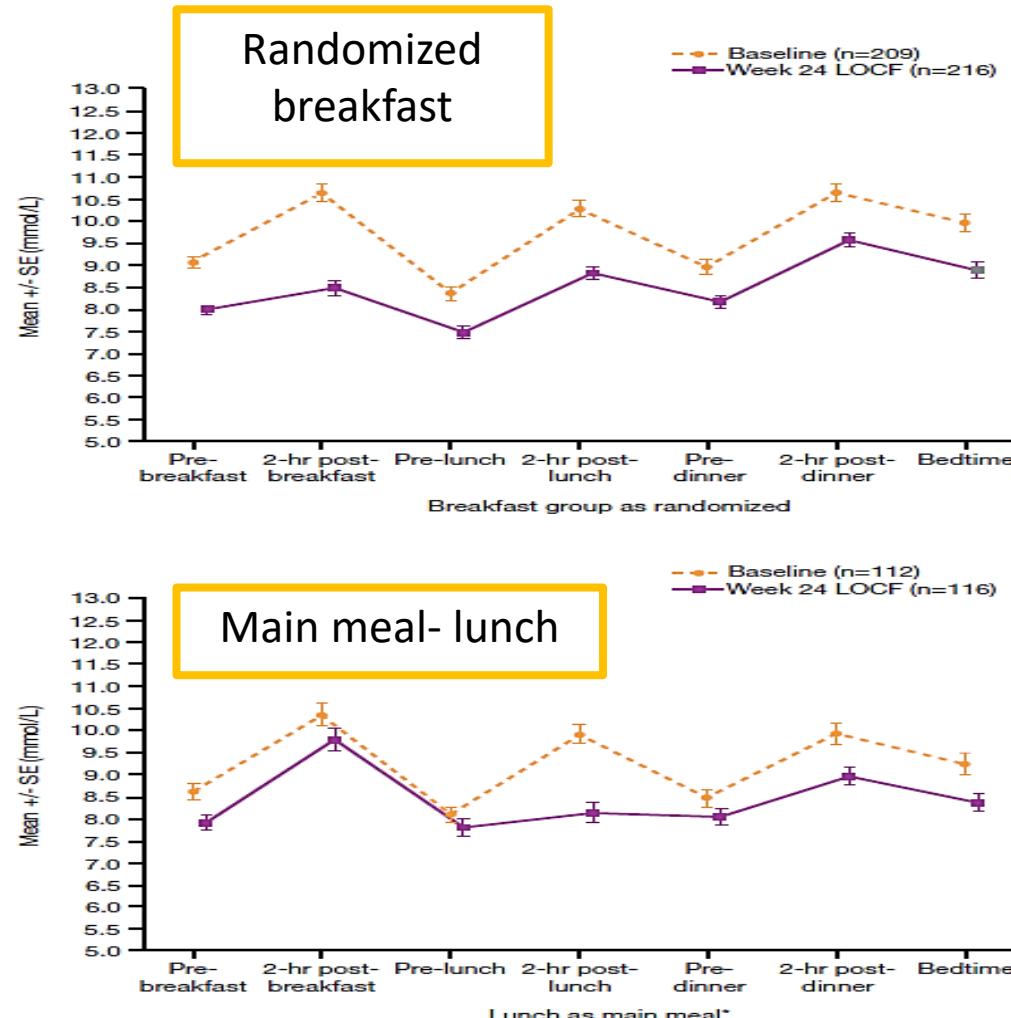
30 U
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\*iGlar Weekly Titration Algorithm

Median FPG (mg/dL)	Dose Adjustment (U/day)
>140	+4
> 100 and ≤140	+2
80-100 (Glycemic target)	No Change
<80	-2 to -4

# Clinical Question-4

- Should iGlar-Lixi be injected at main meal?



# Soliqua 健保給付 2019/07/01生效

## 適應症

- Soliqua適用於基礎胰島素(每日劑量少於60單位)或lixisenatide治療時血糖控制不佳的第二型糖尿病成人病人，在飲食與運動外，做為改善血糖之輔助治療

## 健保核價

- 本案藥品為健保已收載長效型胰島素insulin glargine成分，合併GLP-1促效劑lixisenatide成分之複方製劑，可增加臨床醫師及病患用藥選擇，**同意納入健保給付**，屬第2B類新藥，**支付價均核為每支1,215元\***

## 給付條件

- 含 lixisenatide 及 insulin glargine 之複方製劑(如 Soliqua)
  1. 限用於第二型糖尿病成人病人，當患者已接受 lixisenatide 或**基礎胰島素治療仍未達理想血糖控制時，與口服降血糖藥物併用**
  2. 本藥品**不得與DPP-4 抑制劑、SGLT-2 抑制劑併用**

# Posology and method of administration - I 劑量及用法 - I

台灣上市10-40注射筆 · 每日最高劑量為glargine 40 IU/20 µg  
lixisenatide

## 劑量

- 劑量應依照個人的臨床反應及病人對胰島素的需求作調整。
- Lixisenatide的劑量會隨著insulin glargine的劑量而有所增加或減少且視所使用的注射筆而定。

## 起始劑量

- Soliqua開始給藥前應先停用基礎胰島素或lixisenatide。
- Soliqua的起始劑量乃依先前的抗糖尿病治療而定，且 **lixisenatide的起始建議劑量不得超過10µg**：

先前治療		
	Insulin glargine U100 ≥10 ~ <20 units	Insulin glargine U100 ≥20~<30 units
Soliqua (10-40) 1:2 pen	10個劑量單位 (10 u/5mcg)	20個劑量單位(20 u/10mcg)

## \*\*若使用不同的基礎胰島素：

- 若基礎胰島素為**每日給藥2次或使用insulin glargine (300 units/mL)**，則先前給藥的**每日總劑量應下調20%**以作為Soliqua起始劑量的選擇依據。
- 任何其他基礎胰島素的計算方式與insulin glargine (100 units/mL)相同。
- 每日最高劑量**為insulin glargine **40 units**加上**lixisenatide 20 µg**，這相當於60 個劑量步驟。
- Soliqua應於餐**前1小時內注射**，每日一次。當選定最方便注射的那一餐後，最好每日都固定在同一餐的餐前進行注射。

# Clinical Case 1

- 林先生
- 59 Y/O
- 164 cm, 64.8 kg
- DM > 20 years, **r/o polyneuropathy**, HTN, Hyperlipidemia, CKD stage 3a, Gouty arthritis, Tongue cancer.
- s/p Caduet 5/10 0.5# qd colchicine 1# qd concor 5 mg qd , feburic 80 mg qd, tresiba 42 U qn trajenta 1# qd, novonorm 1# tidcc
- AC 119 mg/dl. A1C 10.0% > **Residual hyperglycemia**

# Clinical Case 1

- 2020/2 Start Soliqua from 20 U qdac

Median FPG (mg/dL)	Dose Adjustment (U/day)
>140	+4
> 100 and ≤140	+2
80-100 (Glycemic target)	<b>No Change</b>
<80	-2 to -4

# Clinical Case 1

- 2020/3 Nausea, ever vomiting 2-3 times (intake < 50% usual amount) (Soliqua 22U)
- 2020/4 Soliqua 28 U. AC 170 mg/dl, PC 160 mg/dl (Glucophage 500 mg bid)

DATE	GLU	HbA1C	CREAT	T.C	HDL	TG	ALB/CR	GPT	LDL-C
1060419			1.54						
1090318	119	10.0	1.71	143	48	137		12	72
1090318							3543.3		
1090610	149	7.3	1.71	153		158		12	94

你ㄉ了沒!

血糖記錄表

血糖值

日期	早餐		午餐		晚餐		睡前	血壓	備註
	前	後(二小時)	前	後(二小時)	前	後(二小時)			
3/10/9									
3/8	118	6:50						113/96 71	>0
3/9	159	7:10						119/99 99	>0
3/1	184	7:00						115/118 69	>2
3/2	168	7:00						125/105 82	>4
3/3	107	7:10						118/99 99	>4
3/4	79	早上7:00						112/99 69	>4
3/5	85	早上7:00						119/101 26	>0
3/6	103	7:10						113/105 76	>0
3/7	149	7:00						120/109 78	>0
3/8	132	7:00						118/110 58	>2
3/9	153	7:00						105/90 66	>2
3/10	140	7:00						108/79 63	>2
3/11	118	7:00						115/81 75	>2

胰島素劑量記錄表

日期	早餐	午餐	晚餐	睡前	胰島素種類

18 糖尿病臨床照護指引：糖化血色素小於 7% 空腹血糖值 80-130mg/dl 餐後 2 小時血糖 80 ~ 160

你丫了沒！

血糖記錄表

血糖值

日期	早餐		午餐		晚餐		睡前	血壓	備註
	前	後(二小時)	前	後(二小時)	前	後(二小時)			
3/12	123	7:00						103/86 63	>2
3/13	132	7:05						110/84 70	>2
3/14	119	6:25						111/83 68	>2
3/15	111	7:00						107/83 63	>2
3/16	130	7:00						118/75 71	>2
3/17	116	6:40						113/79 70	>2
3/18	117	5:30						121/77 79	>2
3/19	123	7:10						113/90 79	>2
3/20	0	0						0	-
3/21	135	6:00						103/85 63	>2
3/23	160	6:30						103/82 64	>2
3/24	164	6:30						129/90 80	>2
3/25	0	0						0	0

胰島素劑量記錄表

日期	早餐	午餐	晚餐	睡前	胰島素種類

糖尿病臨床照護指引：糖化血色素小於 7% 空腹血糖值 80-130mg/dl 餐後 2 小時血糖 80 ~ 160 mg/dl

血糖值

日期	早餐		午餐		晚餐		睡前	血壓	備註
	前	後(二小時)	前	午	後(二小時)	前			
3/9	186	7:00			199				4天測次
4/2	189	6:30			146				>400
4/6	175	6:30			199				>4
4/10	153	7:00			103				>4
4/14	156	6:30			165				>4
4/18	170	6:30			172				>4
4/21	172	6:30			160				2K
4/28	177	7:00	午		160				>8
5/5	132	7:00	14:00午		116				>8
5/13	174	7:00	14:00午		124				28
5/20	174	7:00	14:00午		172				28
5/21	149	7:00	14:00午		124				28
6/3	170	7:00	14:00午		110				28

胰島素劑量記錄表

(單位)

日期	早餐	午餐	晚餐	睡前	胰島素種類

18 糖尿病臨床照護指引：糖化血色素小於 7% 空腹血糖值 80-130mg/dl 餐後 2 小時血糖 80 ~ 160 mg/dl

一般建議早餐飲食  
勿任一時間飲食過量

日期	早餐		午餐		晚餐		備註
	前	後(二小時)	前	後(二小時)	前	後(二小時)	
	時間	時間	時間	時間	時間	時間	
6/10	135	7:00	142	午	133		>8
6/17	132	7:00	午	130			>8

記錄表

睡前

胰島素種類

## Case 2

- 廖先生
- 41 Y/O
- 179.8 cm/100.7 kg
- History: DM for 2 years, HTN, Hyperlipidemia, **Schezizophrenia, stressful life event**
- Problem: eat too much
- Medicine: C.T.L 1000 mg qpm, HbA1C 6.4-7.1%

## Case 2

- 2019/10 PC 482 mg/dl, HbA1C 12.8
- 2019/12 Start Tresiba 16 U → 38 U, AC still 253 mg/dl (2020/1) → CTL shift to Kombiglyze
- 2020/2 AC 96, HbA1C 8.2% → shift to Soliqua for Residual hyperglycemia. Kombiglyze shift to Actosmet
- 2020/5 Soliqua 40 U. AC 106 mg/dl. HbA1C 5.7%, no N/V, no hypoglycemia.

# Case 2

DATE	GLU	HbA1C	CREAT	T.C	HDL	TG	ALB/CR	GPT	LDL-C
1041023	108	5.7	1.00	196		252		50	134
1050413			0.89						
1060406	98	5.4	1.04	189	37	191		35	124
1060823	107	5.9	1.08	170	41	139		37	106
1061108	113	5.8	0.97	180	37	210		45	
1070305	113	6.0	1.00	193	35	192		34	
1070517	120	6.0	0.99	169	35	227	5.7	32	
1070806	125	6.4	1.03	189	37	200		39	
1071029	165	7.2	1.00	197	33	245		46	
1080110	105	7.1					159		140
1080422	99	6.4						40	
1080422								10.8	
1081003	336	12.8				191		40	89
1090115	253							8.8	
1090226	96	8.2	0.90	114		187		19	58
1090506	106	5.7							

C.T.L 1000 mg qpm

Tresiba 38 U qd

Soliqua 40 U qdac

Soliqua: Start from 20 U qdac, Titrate 2 U up every 3 days. Targeting FPG 90-110 mg/dl

## Case 3

- 賴先生
- 72 Y/O
- 168 cm, 107.2kg
- History: DM > 20 years, Hypertension, Hyperlipidemia, CAD-I, s/p PCI, CKD stage 4, Asthma, **Dementia**.
- Medication: Humalog (50) 60 U tidac + Amaryl 2# qdac + Trajenta 1# qd
- 2020/7 FPG 200 mg/dl, A1C 10.8 % → FPG 240 mg/dl A1C 11.0 %  
(one touch PC 300-400 mg/dl)

- (忘記自己吃過飯, 女兒想讓他開白內障, 治療牙周病, 割包皮) → 2020/7/8 Self-paid Soliqua 10 U qdac
- Now AC+ PC 160-180 mg/dl
- BW: 107.2 kg → 108.5 kg

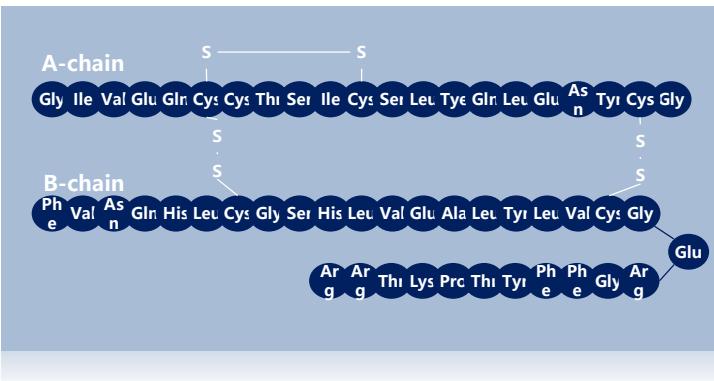
e-就診記錄首頁 - Internet Explorer

日期	時間	身高	體重
109/07/13	10:15		108.5
109/07/12	22:00		其他
	19:15	168.0	
109/06/28	06:59		107.2
109/06/27	07:34		107.8
109/06/26	07:32		108.2
109/06/25	07:19		108.5
109/06/24	07:26		109.6
109/06/23	07:47		110.1
109/06/22	07:26		111.0
109/06/21	07:50		112.0
109/06/20	08:00		111.5
109/06/18	14:20	168.0	111.7

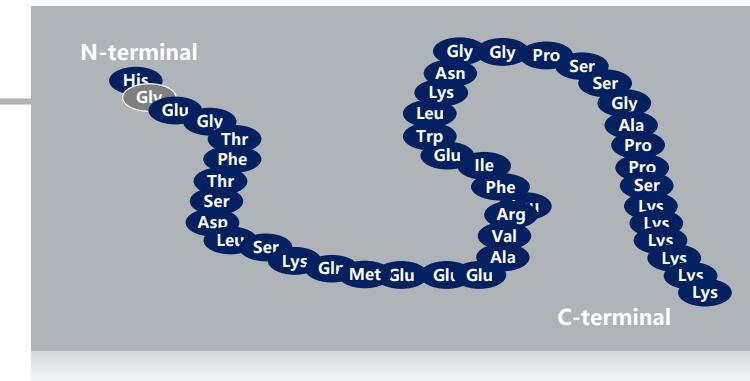
109/07/ 16	Time	BT	HR	RR	BP	BG	SpO2
	19:03					2分	
	17:26	36.7	96	18	147/92		96
	15:36	36.8	95	20	173/97		98
	15:31					166	
	13:00	36.1	104	20	175/95		92
	11:23					185	
	09:00					2分	
	08:45	36.7	101	20	152/91		97
	05:53					187	
	05:21	36.4	74	22			94
	03:52					2分	
	01:14	36.6	76	22			97
	01:02	36.8	88	19	140/79		95
109/07/ 15	22:33	36.6	90	20	140/72		95
	21:02					206	
	19:38	36.1	72	19	139/81		95
	18:31					2分	
	16:52		100		140/79		
	15:18	36.2	95	20	162/95		97
	15:09					151	
	14:42	36.1	92	20	146/70		97
	12:56	36.0	102	16	153/95		97
	11:35					1分	
	10:59					198	
	10:44	36.0	97	21	159/86		95
	09:41					3分	
	09:02	36.1	91	24	168/85		93
	08:30					4分	
	05:47					無法評估： 入睡中	
	05:45					186	
	04:43	36.4	88	18			98
	01:11	36.5	92	17			97

# Summary: Less is More

**Basal insulin**  
(Glargine 100 U/mL [Lantus])



**Short-acting GLP-1RA**  
(lixisenatide)



- ✓ 同時控制飯前及飯後血糖
  - ✓ 有效降低HbA1c
- ✓ 幫助更多病人達到血糖控制目標
- ✓ 減少因為basal insulin增的體重
- ✓ 不增加低血糖發生 vs. basal insulin
- ✓ 減少腸胃道副作用發生 vs. GLP-1RAs

Less	More
Needle Burden	HbA1C Reduction
Weight Gain	PPG Reduction
GI Side Effect	Compliance

# Q & A



\*全民健康保險藥物共同擬訂會議藥品部分第37次  
(108年4月)會議紀錄