SOLIQUA

# Less is More: The Art of Fixed Ratio Combination

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2020-07-12

(SATW.LALI.19.12.0514)

# Outline


01 **Epidemiology of Type 2 Diabetes in Taiwan**

02 FPG and Insulin role in glycemic control

03 When FPG control can not help patient to reach HbA1C goal

04 Benefits of Basal Insulin and GLP-1 RA combination therapy

05 Difference of short-acting GLP-1RA (Lixisentide)

06 New option for optimal glycemic control: SOLIQUA (iGlarLixi)

# 2019年健保10大疾病排行

| 排行 | | 疾病項目 | 醫療費用 | 就醫人數 | 人均就醫費用 |
|---|---|---|---|---|---|
| 1 | 1 | 慢性腎臟疾病 | 約533.16億元 | 39.7萬人 | 13萬4157元 |
| 2 | 2 | 糖尿病 | 約309.6億元 | 153.6萬人 | 2萬150元 |
| 3 | 3 | 齒齦炎及牙周疾病 | 約180億元 | 906.1萬人 | 1987元 |
| 4 | 4 | 齲齒 | 約166.5億元 | 577.9萬人 | 2880元 |
| 5 | 5 | 高血壓 | 約140.2億元 | 179.3萬人 | 7829元 |
| 6 | 6 | 到院抗腫瘤治療 | 約134億元 | 7.7萬人 | 17萬3783元 |
| 7 | 7 | 呼吸衰竭 | 約125.1億元 | 4.1萬人 | 30萬2361元 |
| 8 | 8 | 慢性缺血性心臟病 | 約122.7億元 | 38.2萬人 | 3萬2083元 |
| 9 | 9 | 思覺失調症 | 約115.1億元 | 10.6萬人 | 10萬8473元 |
| 10 | 12 | 支氣管及肺惡性腫瘤 | 約110億元 | 6萬人 | 18萬3000元 |

● 2019排名 ● 2018排名

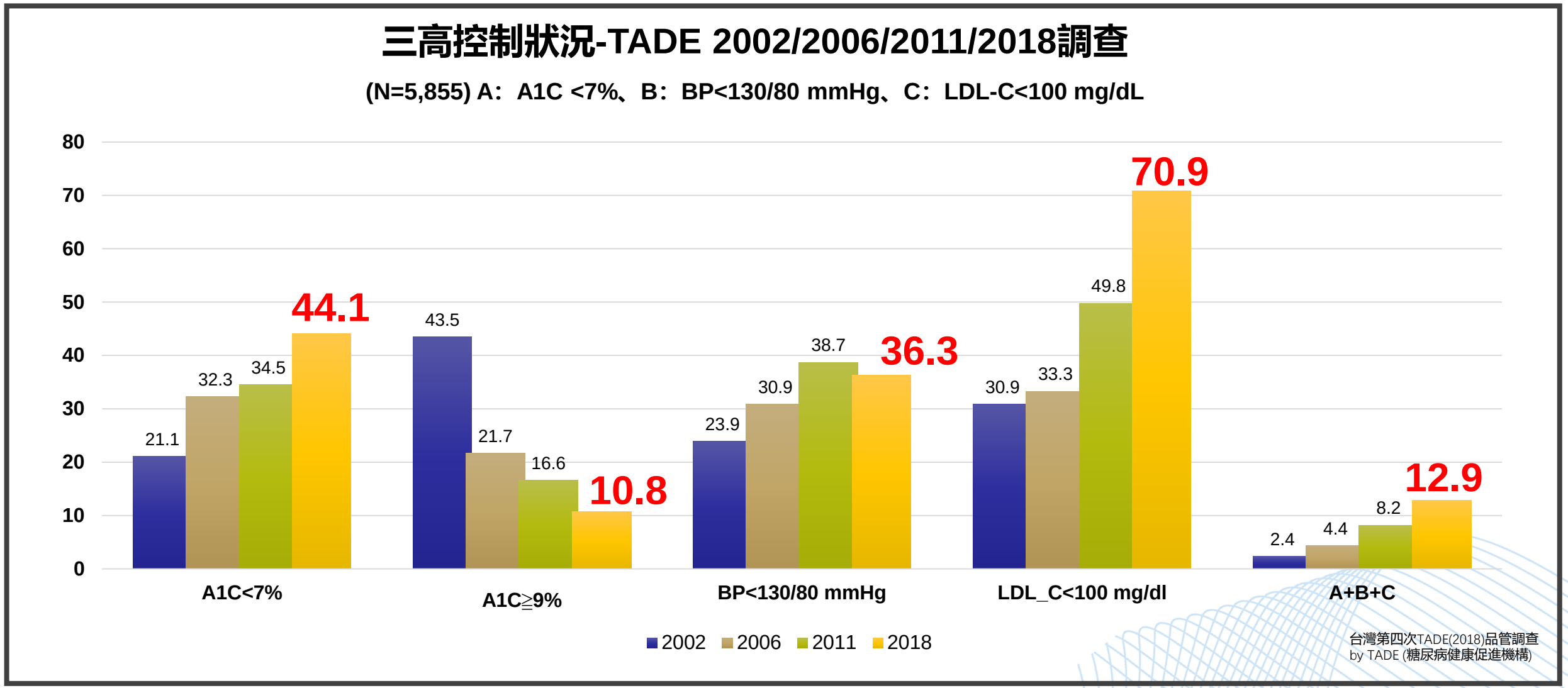
蘋果新聞網 製表

資料來源：中央健保署

# Current Disease Situation of Type 2 Diabetes in Taiwan


2019 台灣糖尿病年鑑報告

# Current Disease Situation of Type 2 Diabetes in Taiwan



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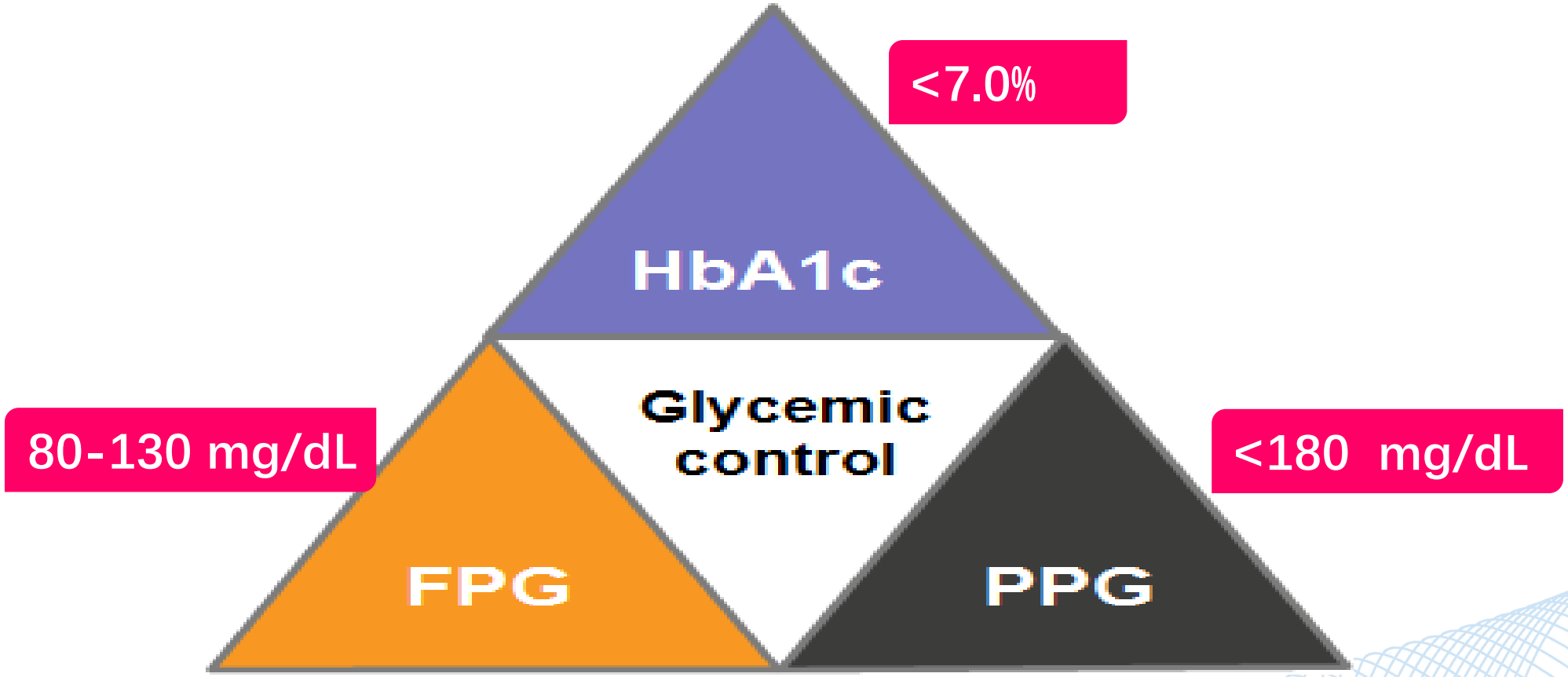
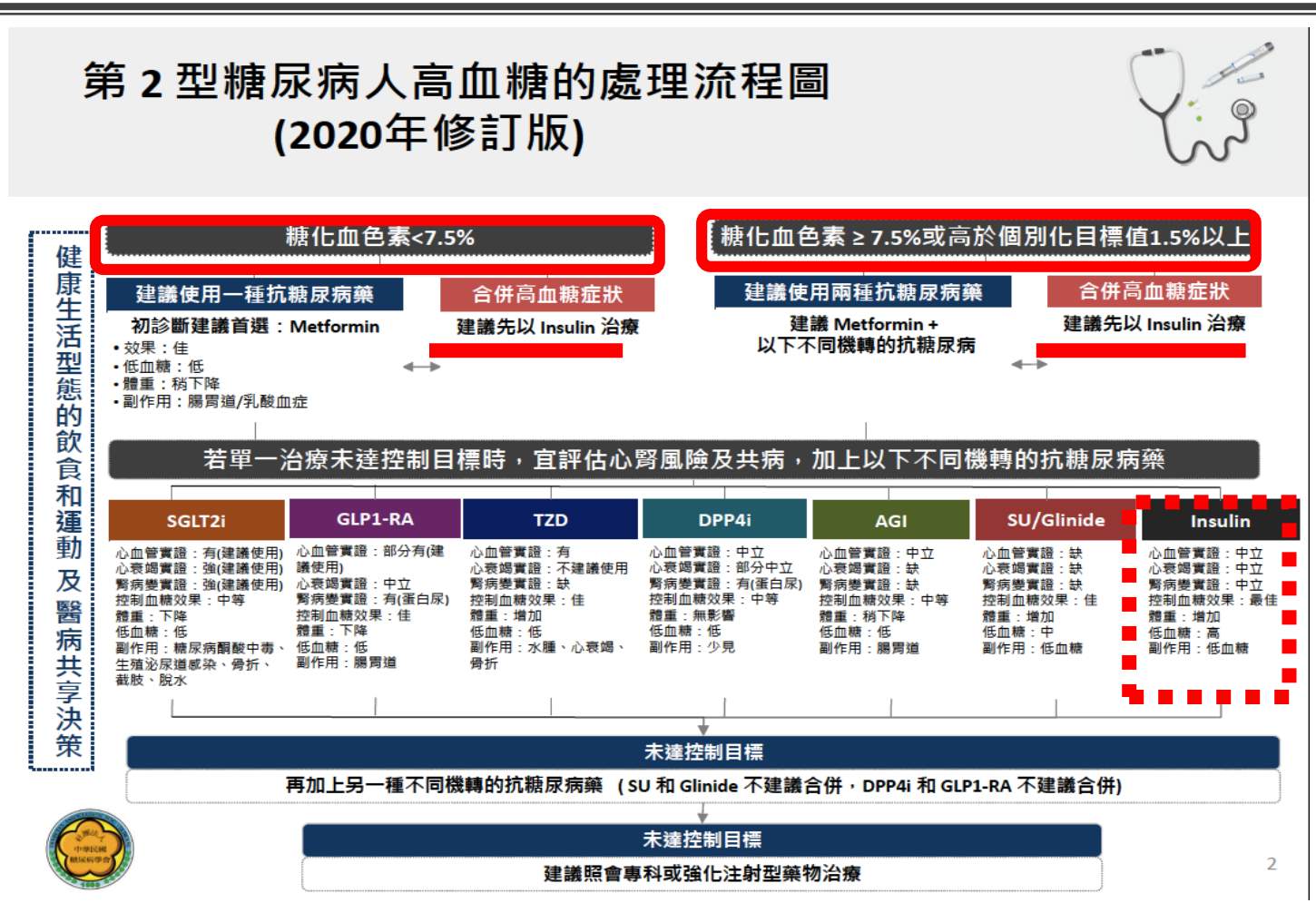
# Achievement of Glycemic Control is The Primary Goal of Treatment for T2DM



# The Role Of Insulin in Glycemic Control- Taiwan Guideline




## Basal insulin

心血管實證：中立
心衰竭實證：中立
腎病變實證：中立
控制血糖效果：最佳
體重：增加
低血糖：高
副作用：低血糖

2019中華民國
糖尿病學會治療指引

# The Role Of Insulin in Glycemic Control



第二型糖尿病患者若在罹病第一年即搭配

**胰島素**治療，和單用口服藥

相較之下，可讓胰島細胞功能增加一倍，
糖化血色素下降的幅度更多，加強胰島素
治療更能有效控制糖尿病併發症風險。

2019糖尿病
品質調查報告

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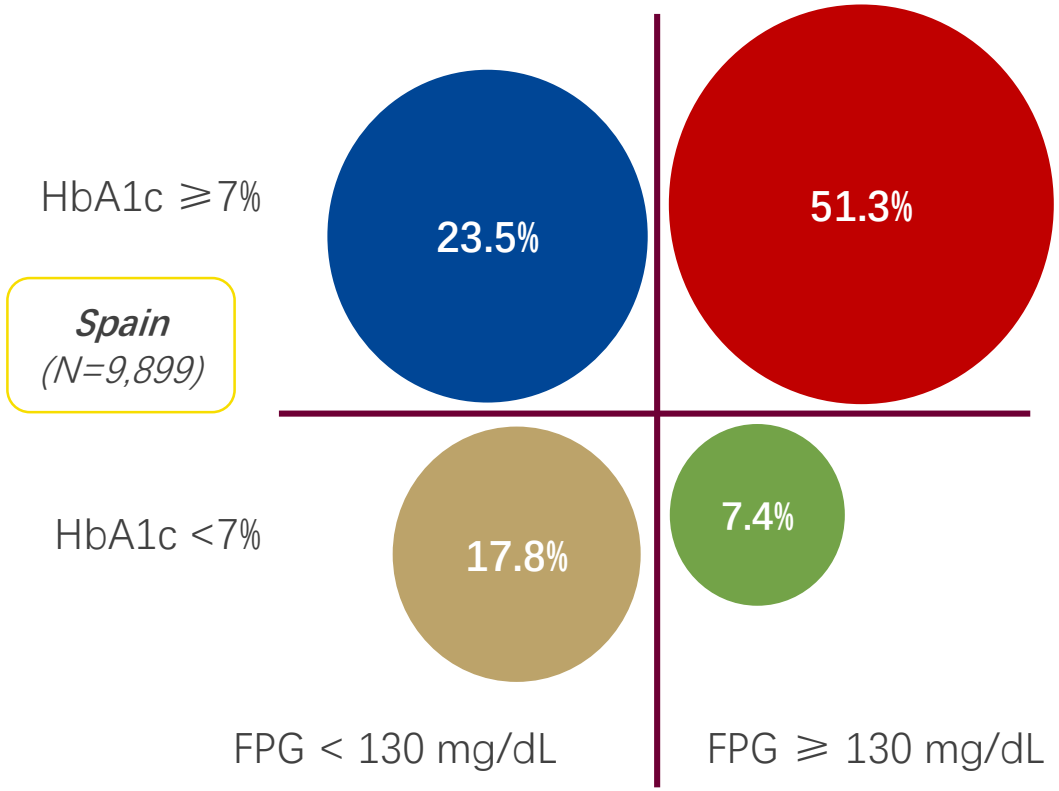
# ~75% T2DM Patients on Basal Insulin Have Uncontrolled FPG and HbA1 or Residual Hyperglycemia

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%);*

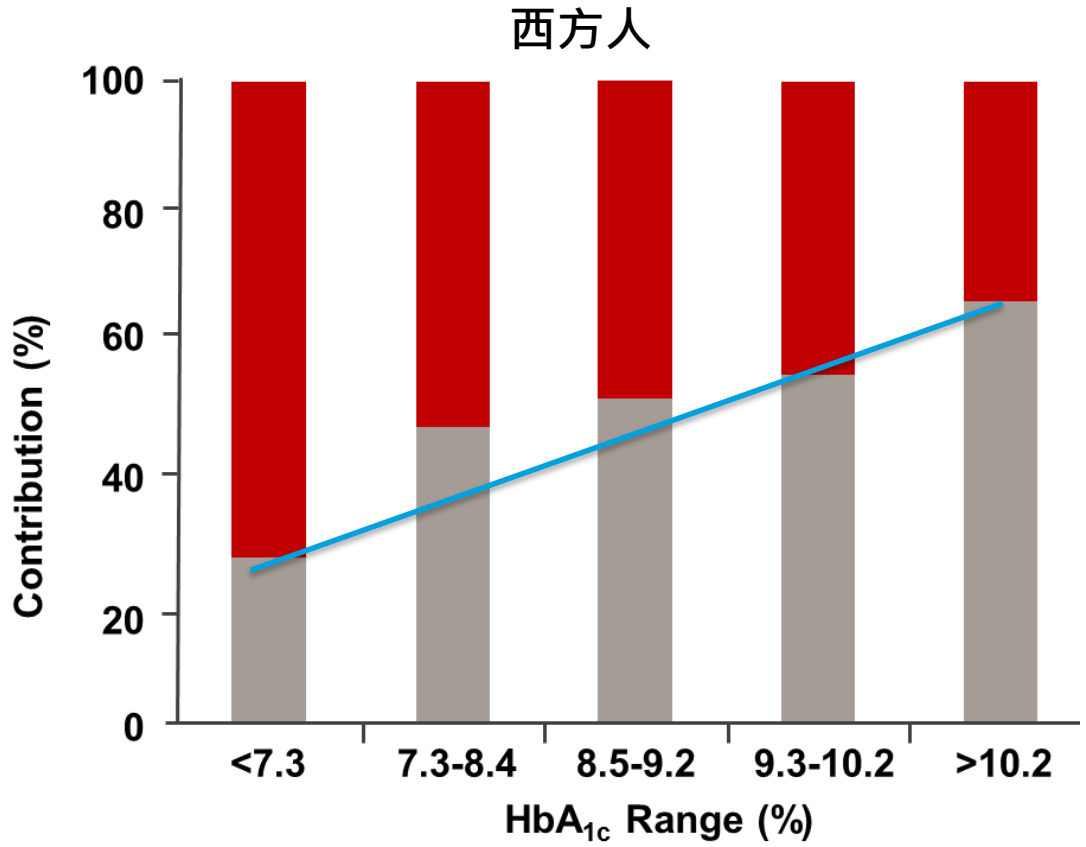
***Residual hyperglycemia*** *defined as HbA1c above target despite FPG at target (FPG <7.2/7.8 mmol/L [<130/140 mg/dL];*

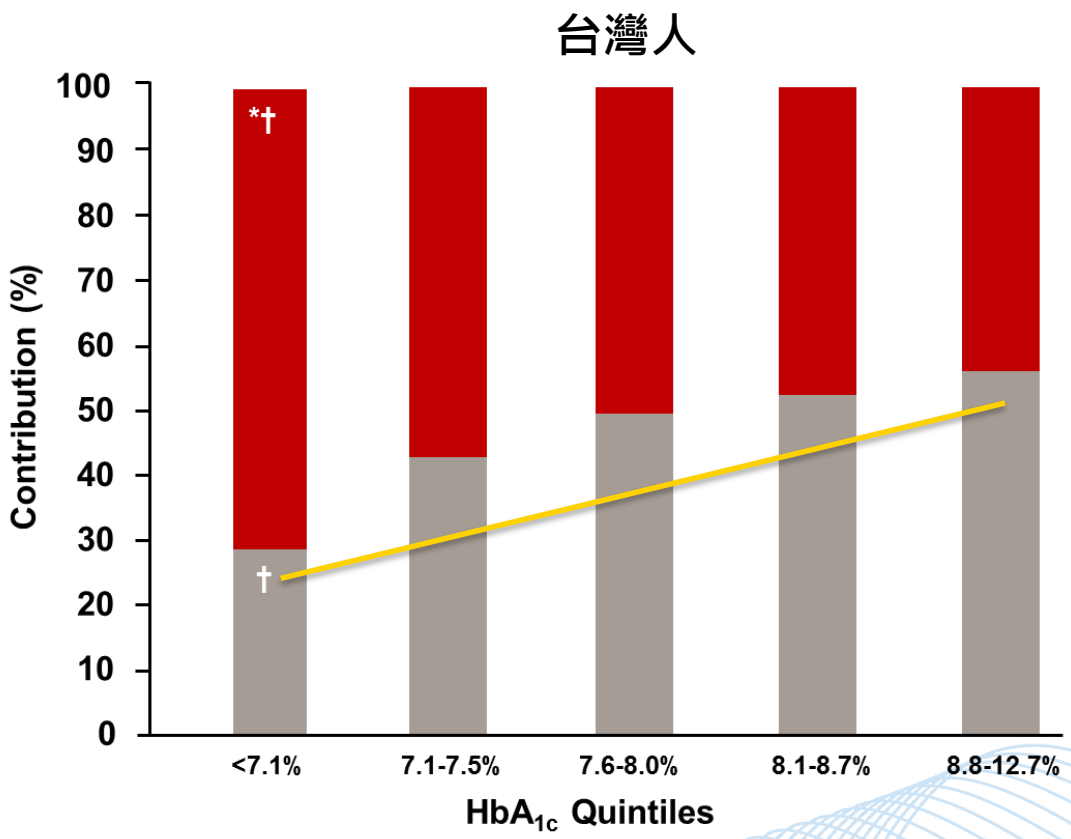
***Uncontrolled*** *defined as neither HbA1c nor FPG at target*

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

Mata-Cases.M. et al, Journal of diabetes. 2016

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

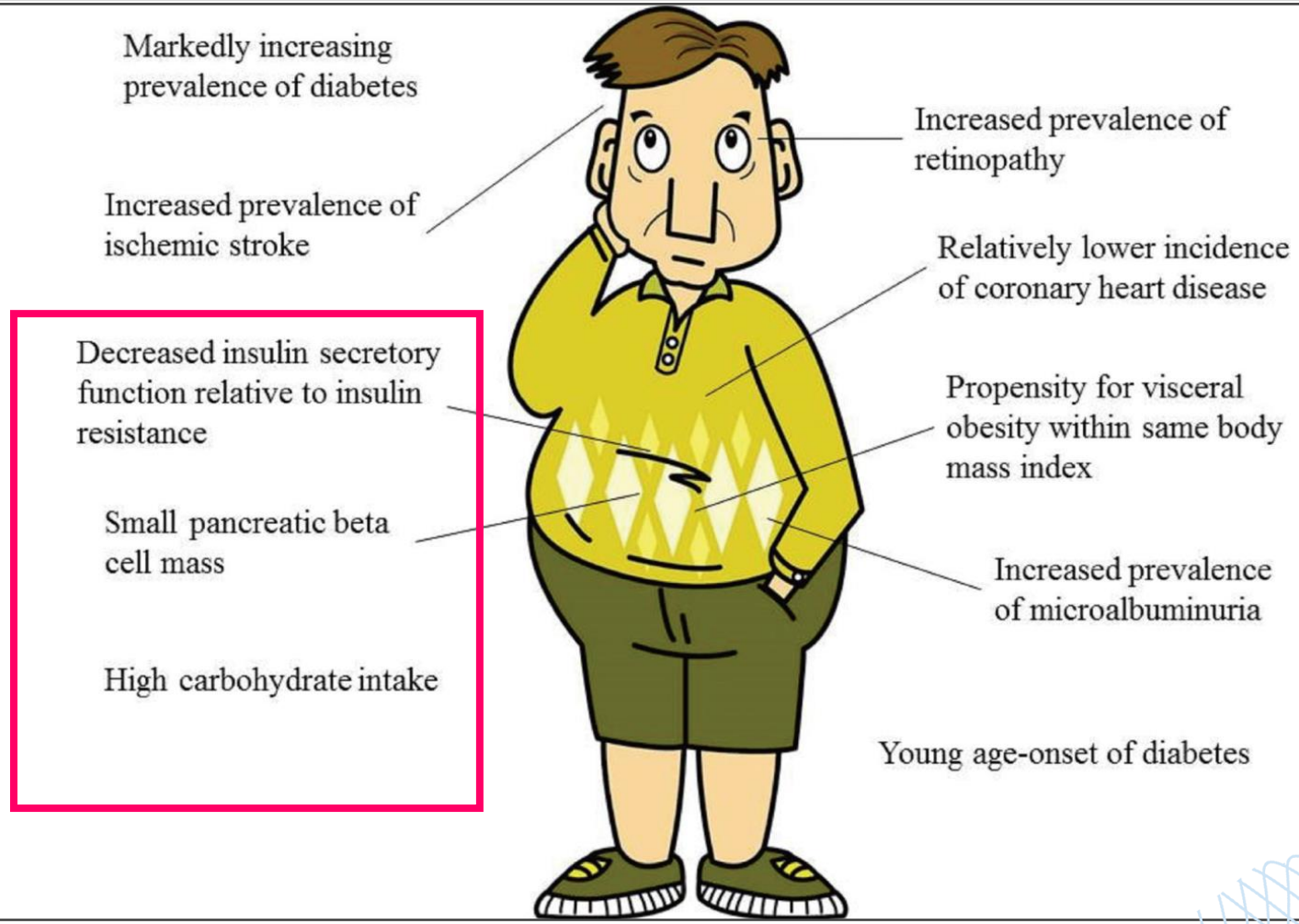



*Significant difference between FBG and PPG; †Significant difference from all other quintiles.

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.

# Characteristics of Asian Patients with Diabetes




Endocrinol Metab. 2015 Sep;30(3):263-269.
http://dx.doi.org/10.3803/EnM.2015.30.3.263

# Basal Glucose Can Be Controlled, but the Prandial Problem Persisted. It's the Next Target!

*Matthew C. Riddle*

Diabetes Care 2017;40:291–300 | DOI: 10.2337/dc16-2380

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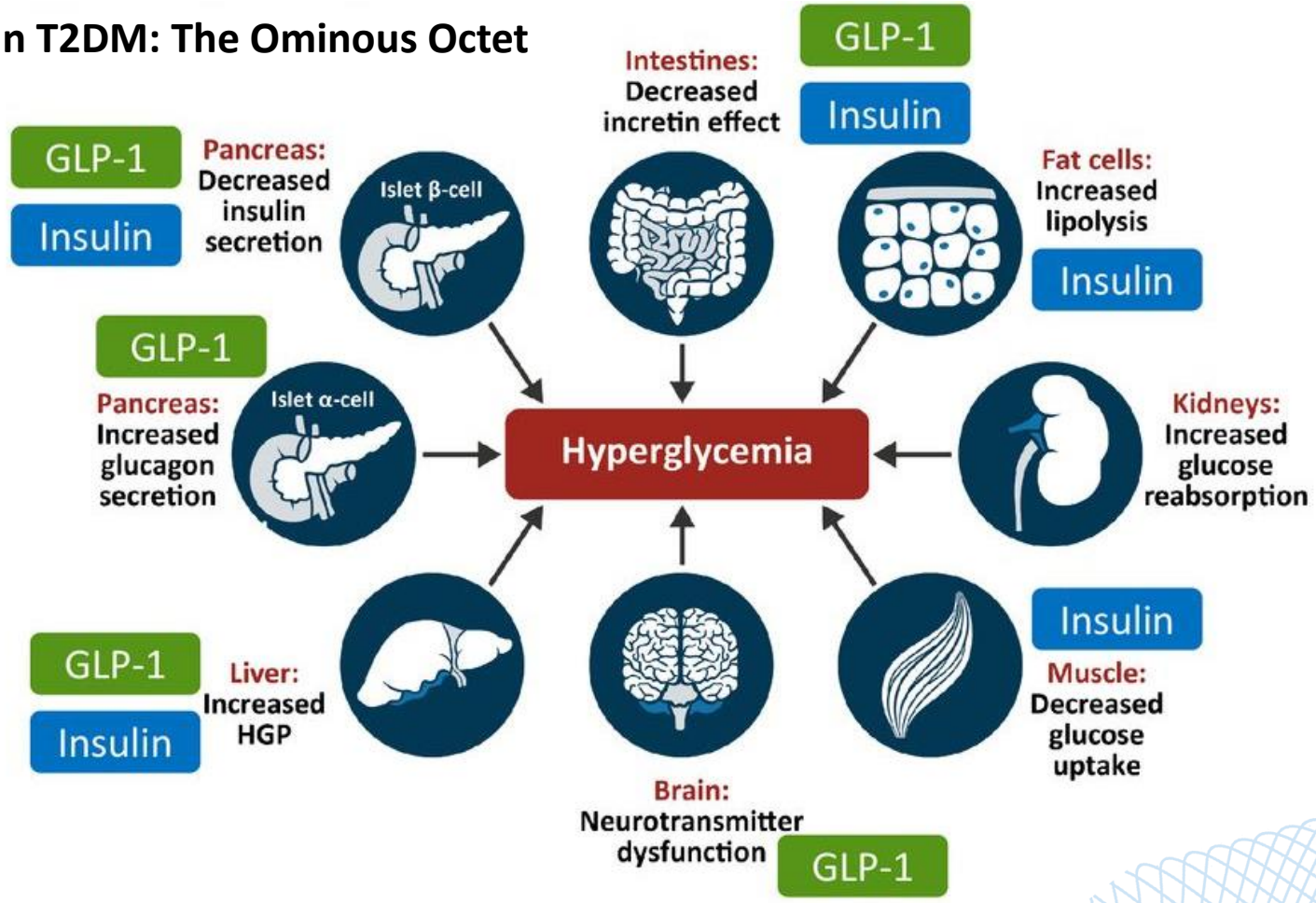
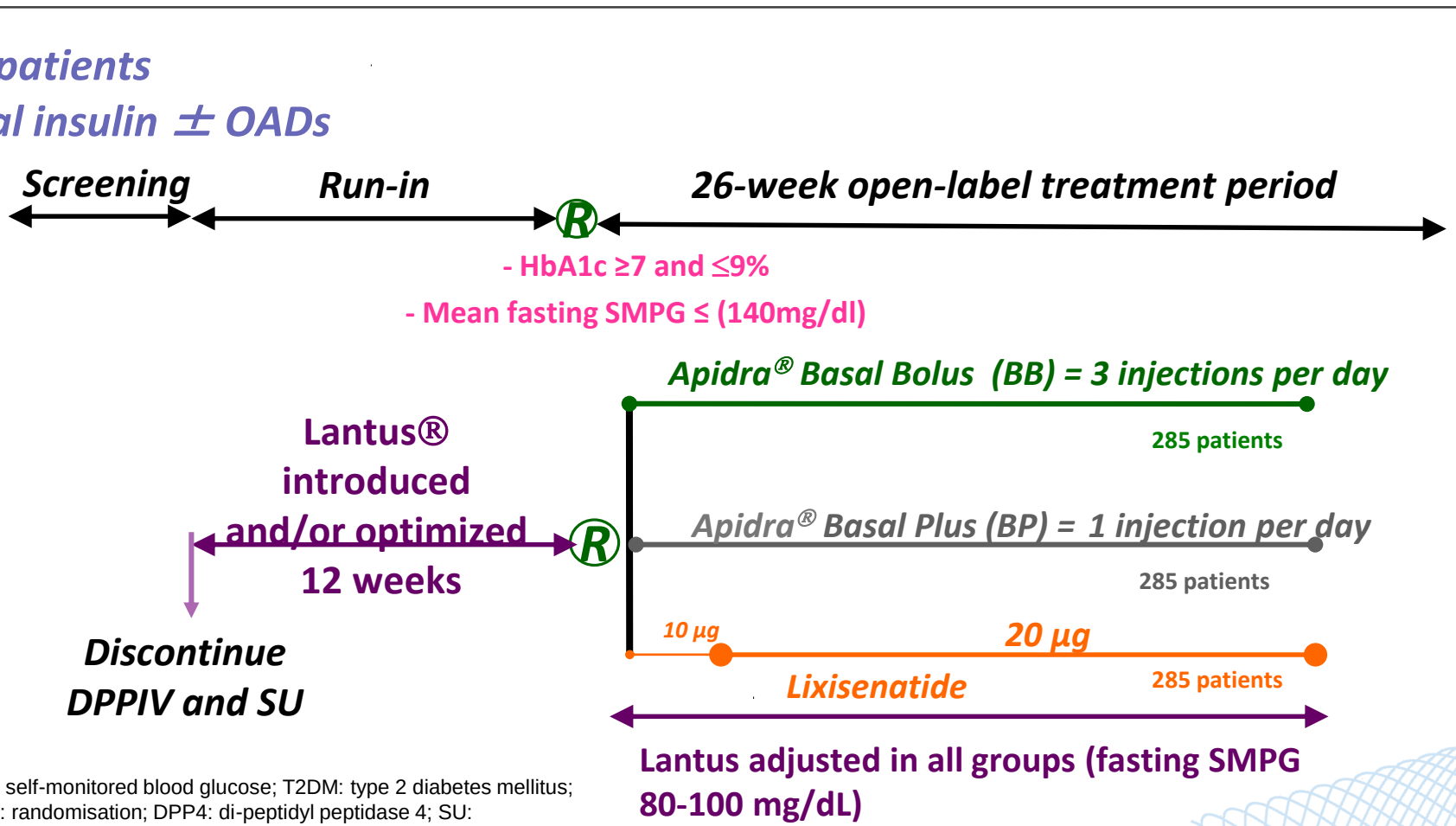
# Benefits of Combination Therapy of Basal Insulin and GLP-1 RA

**Pathophysiologic Defects in T2DM: The Ominous Octet**




DeFronzo RA. Diabetes. 2009;58:773-795

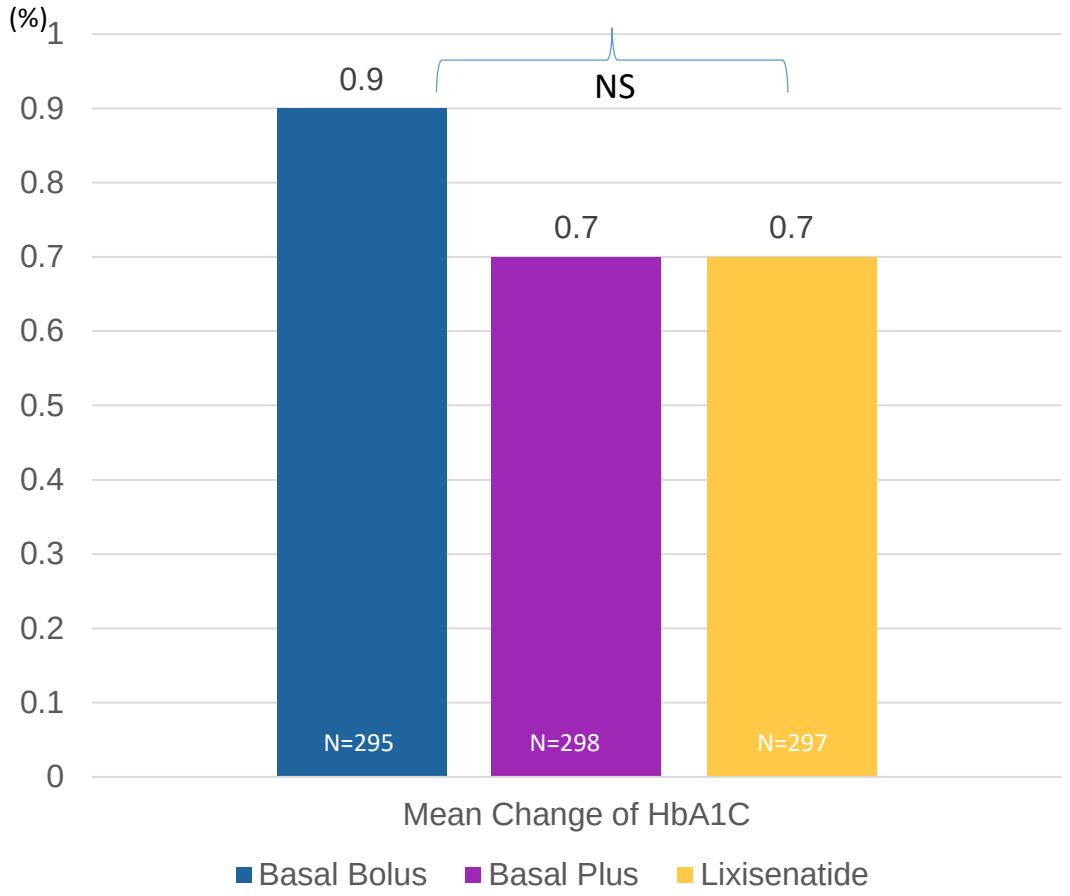
# GetGoal-Duo 2: Basal Insulin/Lixisenatide Free Combination V.S BB/BP

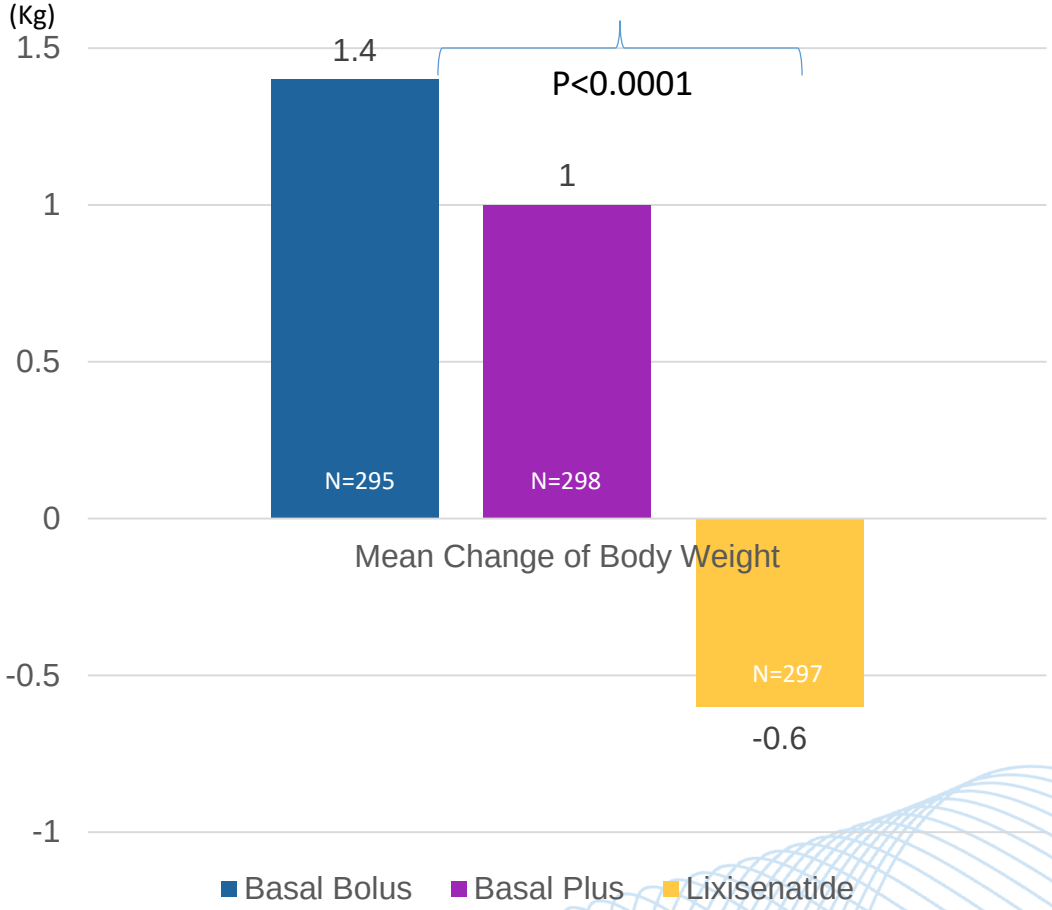



RAI: rapid acting insulin; SMBG: self-monitored blood glucose; T2DM: type 2 diabetes mellitus; OADs: oral antidiabetic drugs; R: randomisation; DPP4: di-peptidyl peptidase 4; SU: sulphonylurea.

Diabetes Care Publish Ahead of Print, published online May 23, 2016

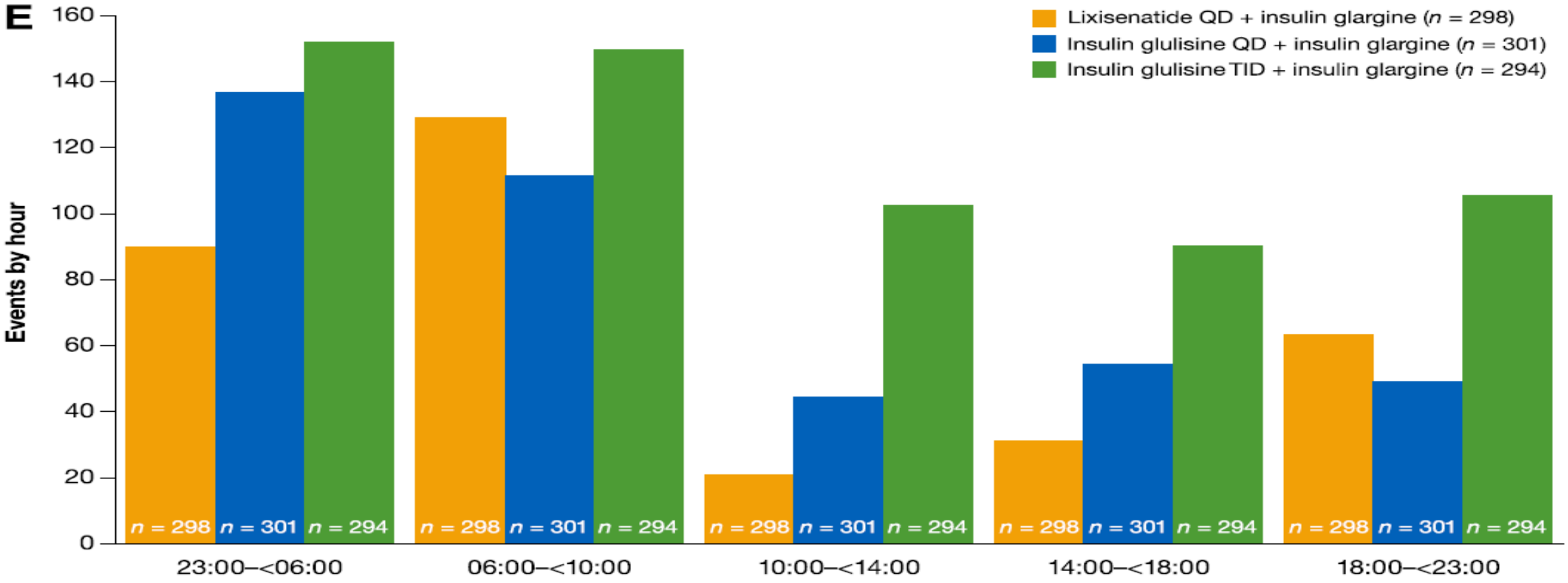
# Combination of Basal Insulin/Lixisenatide provides similar HbA1C control with less weight gain




Diabetes Care Publish Ahead of Print, published online May 23, 2016

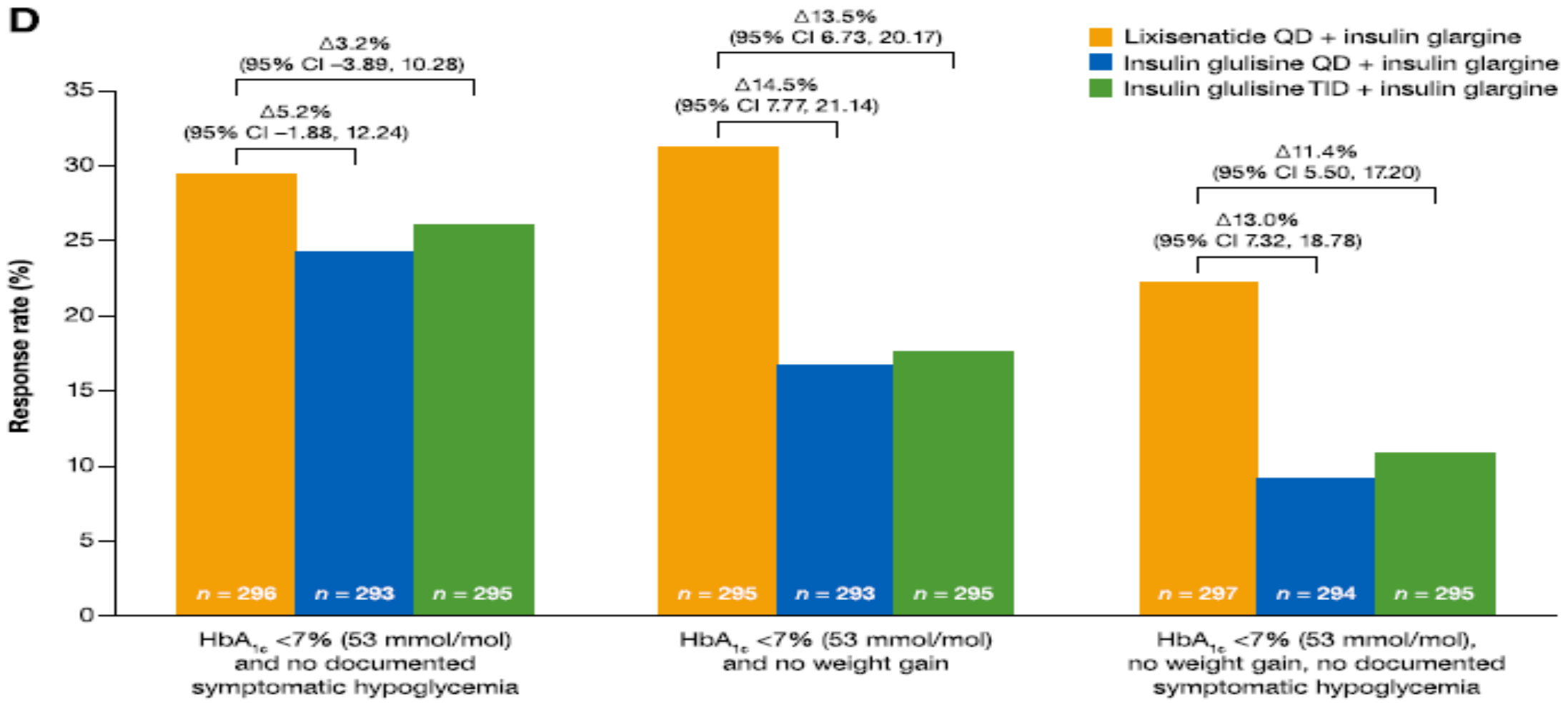
# GetGoal-Duo 2: Hypoglycemia events by hour of the day at week 26




Data for symptomatic hypoglycemia per protocol(glucose <60 mg/dL]/recovery with oral carbohydrate if no glucose measurement available). All treatment arms with or without metformin; 70% of patients receiving lixisenatide or insulin glulisine once daily (QD) administered their dose in the evening. TID, thrice daily.

Diabetes Care Publish Ahead of Print, published online May 23, 2016

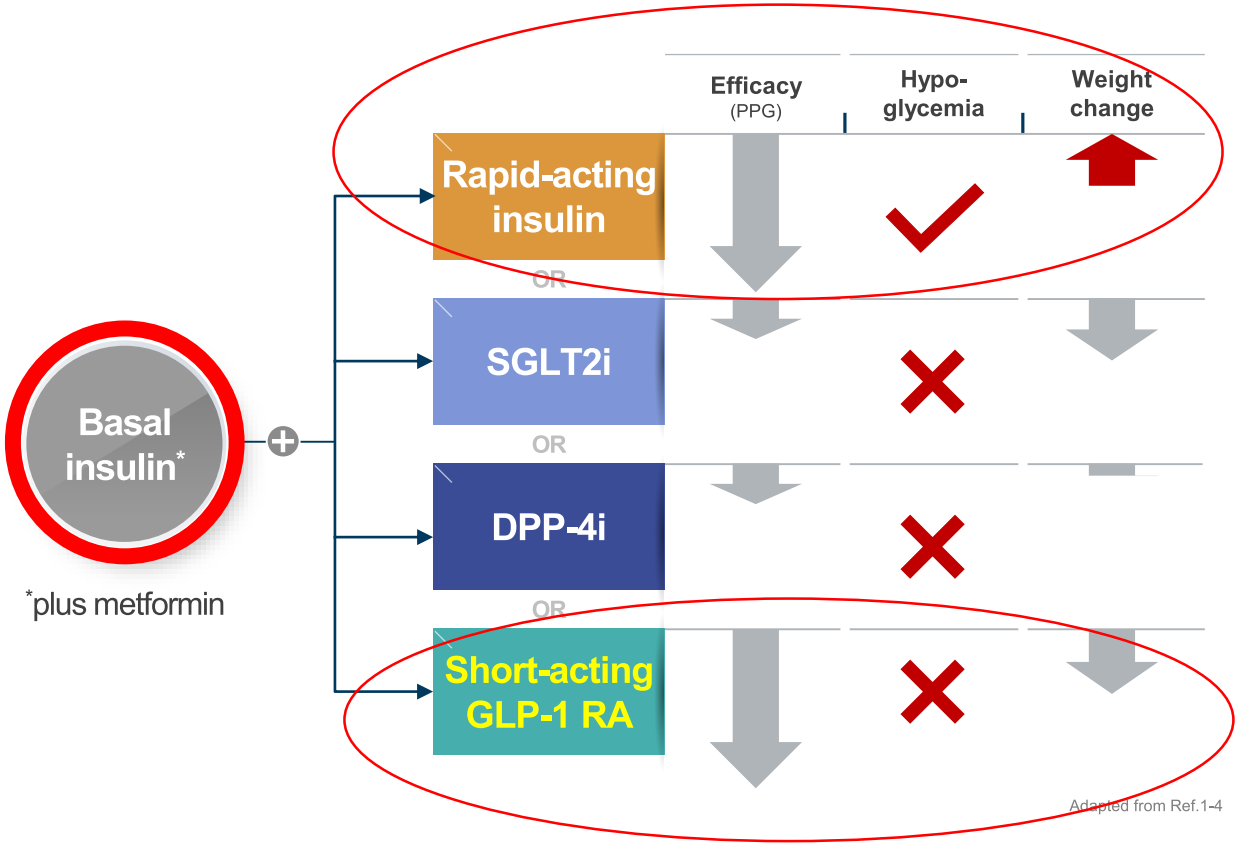
# GetGoal-Duo 2: Glycemic Goal Attainment




Data for symptomatic hypoglycemia per protocol(glucose <60 mg/dL]/recovery with oral carbohydrate if no glucose measurement available). All treatment arms with or without metformin; 70% of patients receiving lixisenatide or insulin glulisine once daily (QD) administered their dose in the evening. TID, thrice daily.

Diabetes Care Publish Ahead of Print, published online May 23, 2016

# Comparison of Available Intensification Options in Patients Suboptimally Controlled with Basal Insulin




- Traditional approach of adding **a prandial insulin increases the risk for hypoglycemia**[1,2]
- **GLP-1 RA more effective** than DPP-4i or SGLT-2i at HbA1c lowering in patients with long-standing T2DM not achieving glycemic targets[1]


1. Standard of Medical Care in Diabetes. 2018. Diabetes Care. 2018; 41(Suppl1):S1-S159
2. J Diabetes. 2016 Dec 15. [Epub ahead of print]
3. Clin Diabetes. 2015 Oct;33(4):175-80
4. J Korean Diabetes 2015;16:252-259

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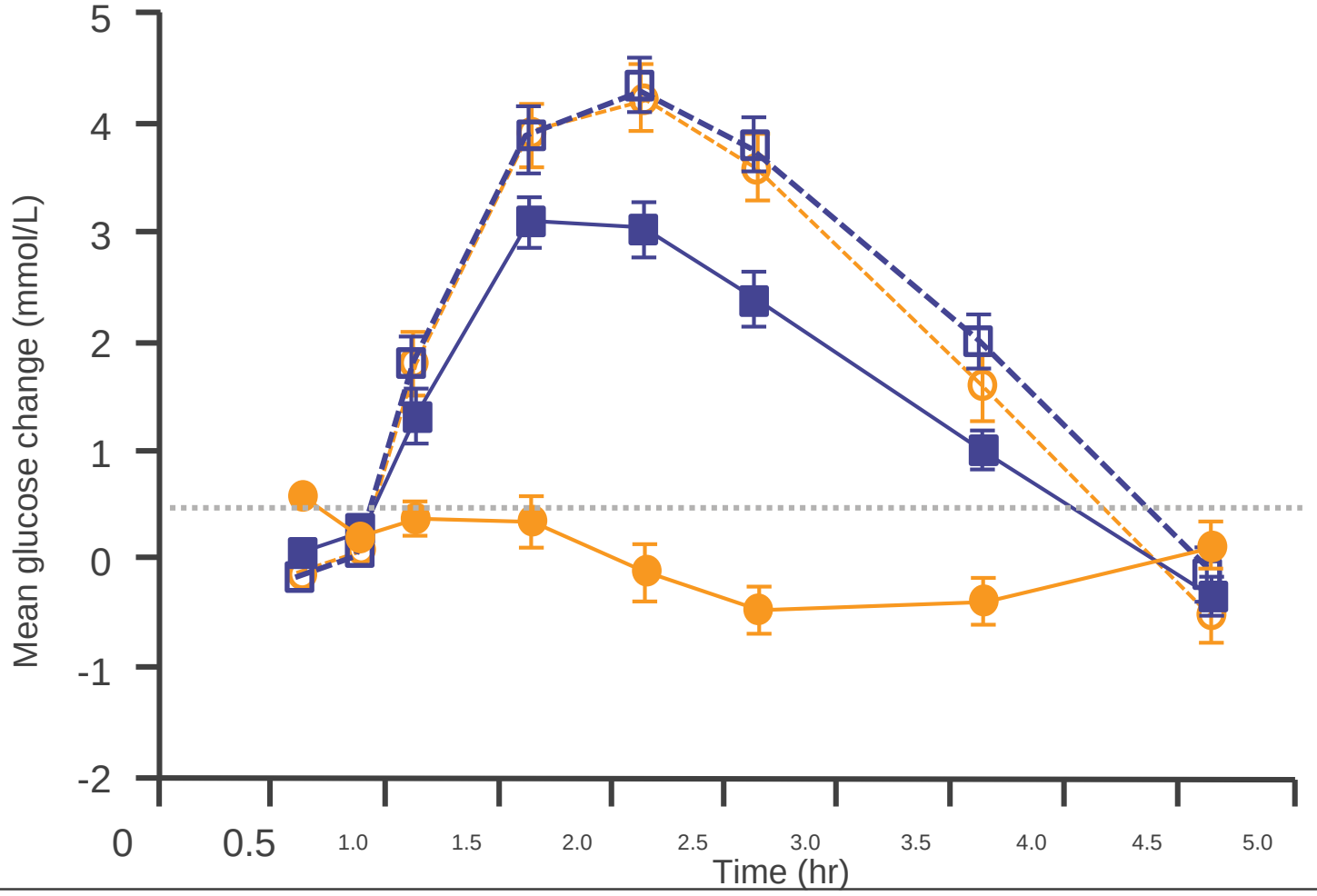
# Difference Mechanisms of GLP-1 RA-Taiwan Guideline

## 類升糖素肽-1 受體促效劑的比較

| | Pharmacokinetics | | Structure | | Size | |
|---|---|---|---|---|---|---|
| | Short-acting | Long-acting | Exendin-4-based | GLP-1-based | Small | Large |
| GLP-1 RA | • Exenatide BID<br>• Lixisenatide | • Exenatide QW<br>• Liraglutide<br>• Albiglutide<br>• Semaglutide<br>• Dulaglutide | • Exenatide BID<br>• Exenatide QW<br>• Lixisenatide | • Liraglutide<br>• Albiglutide<br>• Semaglutide<br>• Dulaglutide | • Exenatide BID<br>• Exenatide QW<br>• Liraglutide<br>• Lixisenatide<br>• Semaglutide | • Albiglutide<br>• Dulaglutide |
| Effect | Gastric emptying<br>PPG | FPG | May produce antibodies | | Better penetration in the brain<br>Better effect on appetite suppression | Smaller effect on body weight |

2019中華民國
糖尿病學會治療指引

# Lixisenatide Demonstrates Better Postprandial Glucose Lowering Effects Than Liraglutide




Lixisenatide (baseline)

Lixisenatide (Day 28)

Liraglutide (baseline)

Liraglutide (Day 28)

148 adults with T2DM insufficiently controlled (A1C 6.5−9.0%) on ≥1.5 g/day of metformin

Kapitza C, et al. *Diabetes Obes Metab* 2013;15:642-649

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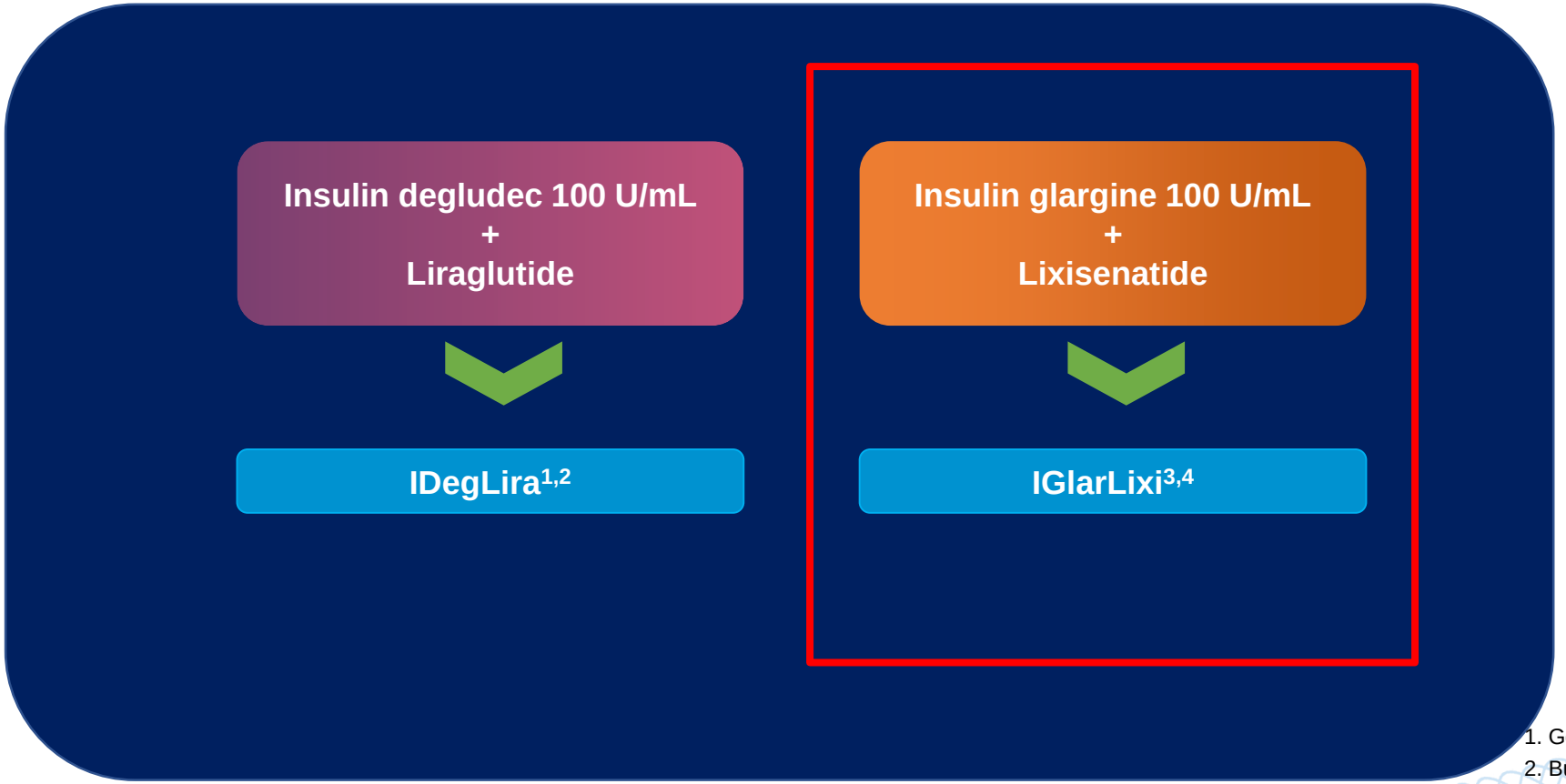
# Two Basal Insulin / GLP-1 RA Fixed Ratio Combination Therapies Developed To Date




1. Gough S, et al. *Lancet Diab Endocrinol* 2014;2:885–9
2. Buse JB, et al. *Diabetes Care* 2014;37:2926–33
3. Rosenstock J, et al. *Diabetes Care* 2016;39:2026–35
4. Aroda VR, et al. *Diabetes Care* 2016;39:1972–80



**Table 1 Studies evaluating the efficacy of IDegLira and IGlarLixi in patients with diabetes mellitus type 2 inadequately controlled with oral medication and insulin naive**

| Study | DUAL-1 | | | LixiLan-O | | |
|---|---|---|---|---|---|---|
| | IDegLira | Degludec | Liraglutide | IGlarLixi | Glargine U100 | Lixisenatide |
| Duration | 26 weeks | | | 30 weeks | | |
| Population | 1663 T2DM adults, A1c 8.3 ± 0.9; BMI 31.2 ± 4.8 kg/m$^2$, metformin ± pioglitazone | | | 1170 T2DM adults, A1c 8.2 ± 0.7; BMI 31.7 ± 4.4 kg/m$^2$; metformin ± pioglitazone | | |
| △ A1c | -1.9 | -1.4 | -1.3 | -1.6 | -1.3 | -0.8 |
| Final A1c (week 30) | 6.4 ± 1.0 | 6.9 ± 1.1 | 7.0 ± 1.2 | 6.5 ± 0.8 | 6.8 ± 0.8 | 7.3 ± 0.9 |
| Δ body weight (kg) | − 0.5 ± 3.5 | + 1.6 ± 4.0 | − 3.0 ± 3.5 | − 0.3 ± 0.2 | + 1.1 ± 0.2 | − 2.3 ± 0.3 |
| % A1c < 7% | 81 | 65 | 60 | 74 | 59 | 33 |
| %A1c < 7% without weight gain | 46 | 21 | 54 | 43 | 25 | 28 |
| %A1c < 7% without hypoglycemia | 60 | 41 | 58 | 53 | 44 | 30 |
| %A1c < 7% without weight gain or hypoglycemia | 36 | 14 | 52 | 32 | 19 | 26 |
| Hypoglycemia (%)[a] | 32 | 39 | 7 | 26 | 24 | 6 |

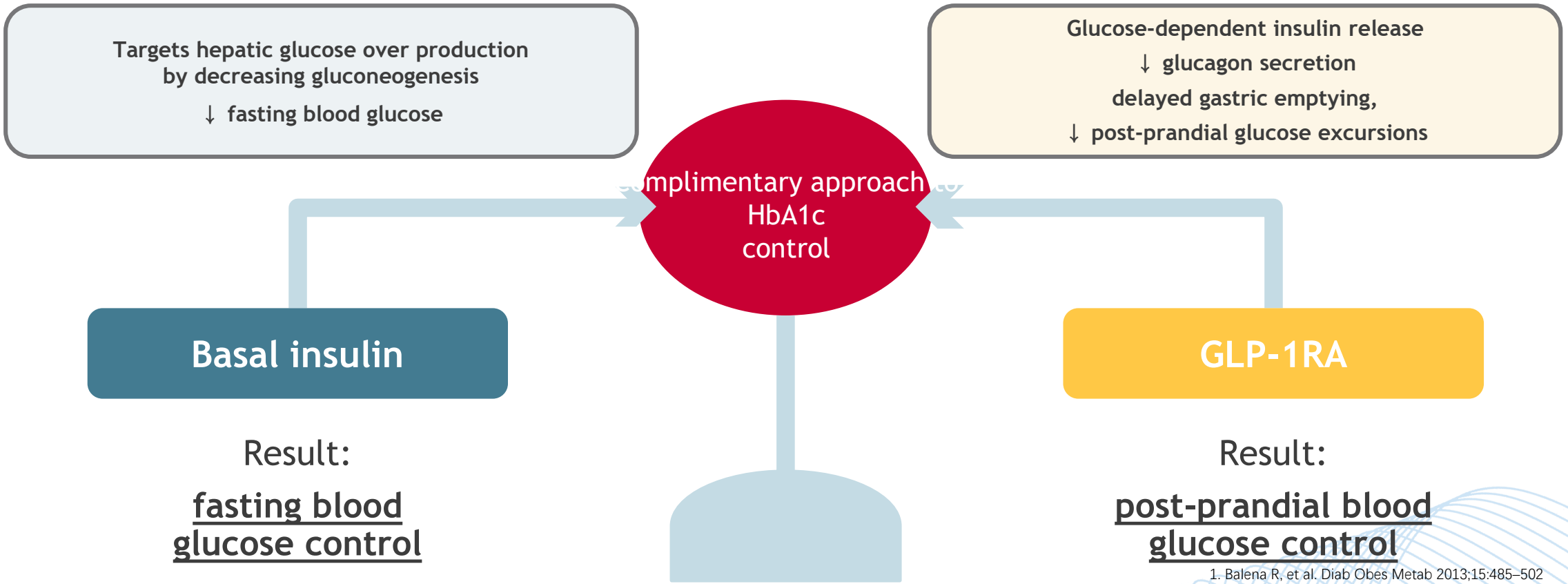
Moreira et al. Diabetol Metab Syndr (2018) 10:26

# 爽胰達 Soliqua®


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

Soliqua 仿單

# The Complementary Modes of Action of Basal Insulins and GLP-1 RAs Provide Control of Both FPG and PPG





1. Balena R, et al. Diab Obes Metab 2013;15:485–502
2 Baggio LL and Drucker DJ. Gastroenterol 2007;132: 2131–57
3. Wang Z, et al. Diab Care 2010;33:1555–60;
4. Holst JJ, et al. Physiol Rev 2007;87:1409–39

# LixiLan-L: T2DM Patients Uncontrolled on Basal Insulin ± OADs

**Two randomized, open-label, active controlled, parallel-group trials have been completed**

**LixiLan-L**

iGlarLixi demonstrated superiority over iGlar on HbA1c reduction in patients previously treated with iGlar, with a safety profile reflecting those of iGlar and lixisenatide[1]

**LixiLan-O**

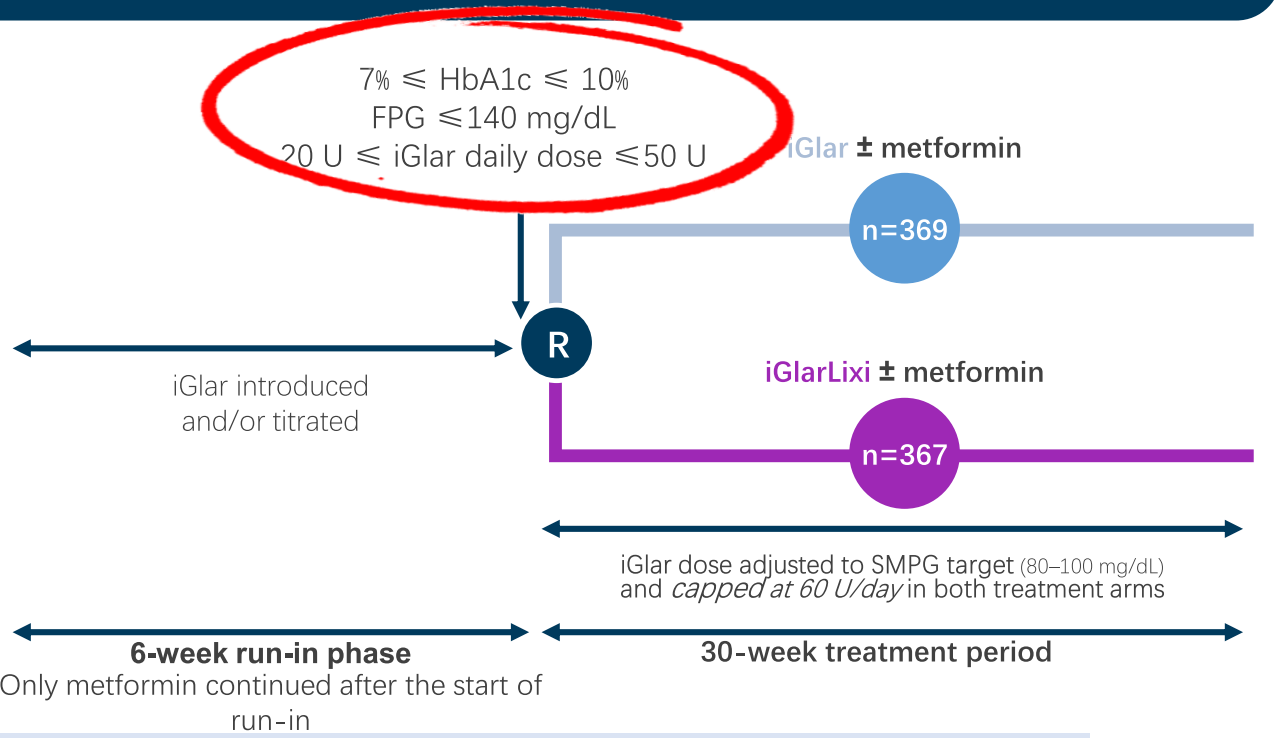
iGlarLixi demonstrated superiority over iGlar or lixisenatide on HbA1c reduction in patients previously treated with metformin ± other OADs, with a safety profile reflecting those of iGlar and lixisenatide[2]

1. Aroda VR et al. Diabetes Care. 2016;39(11):1972-1980
2. Rosenstock J et al. Diabetes Care. 2016;39(11):2026-2035

# LixiLan-L: Patients with T2DM Not Controlled on Basal Insulin ± OADs

**DESIGN: Randomized, open-label, parallel-group, 30-week treatment study**

- T2DM patients with:
- Basal insulin >6 months
- Stable dose 15–40 U/day ± OADs
- HbA1c ⩾7.5%–10%
- FPG ⩽180–200 mg/dL

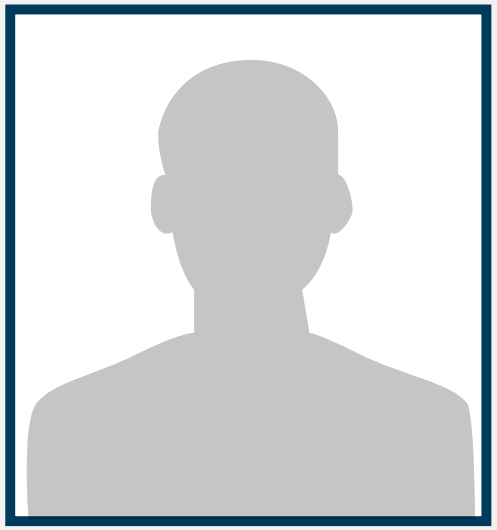



Primary objective:
Superiority of iGlarLixi over iGlar in HbA1c change at Week 30

Aroda VR et al. Diabetes Care. 2016;39(11):1972-1980

# LixiLan-L: Enrolled Patients Uncontrolled on Basal Insulin[1,2]

## Average Patient at Baseline*



**Age**
59.6 years

**BMI**
31.3 kg/m$^2$
(**57.5%** of patients had a BMI of ≥30 kg/m2)

**Diabetes duration**
12 years

**Duration of basal insulin**
3.1 years

**A1c at baseline**
8.1%

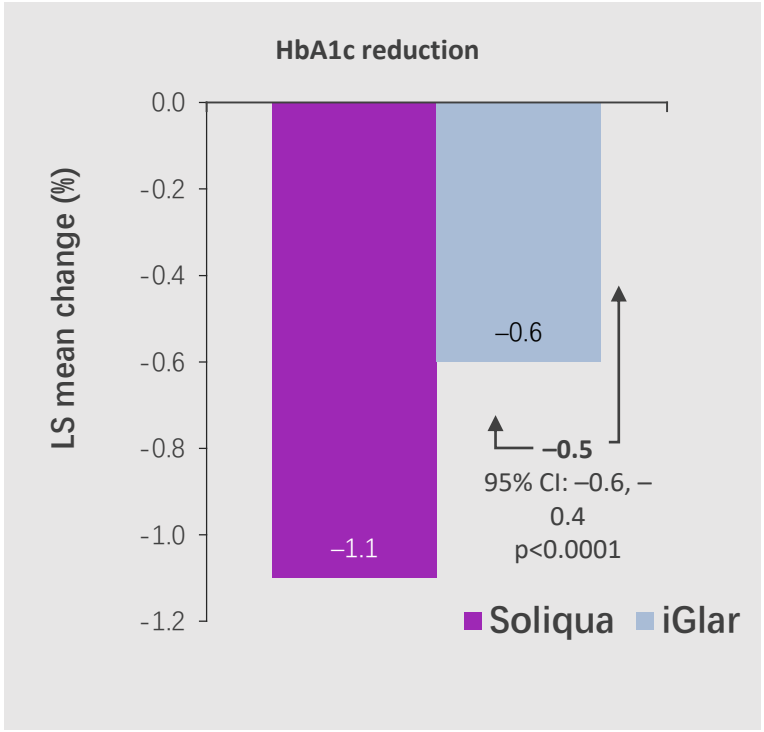
**FPG at baseline**
132 mg/dL

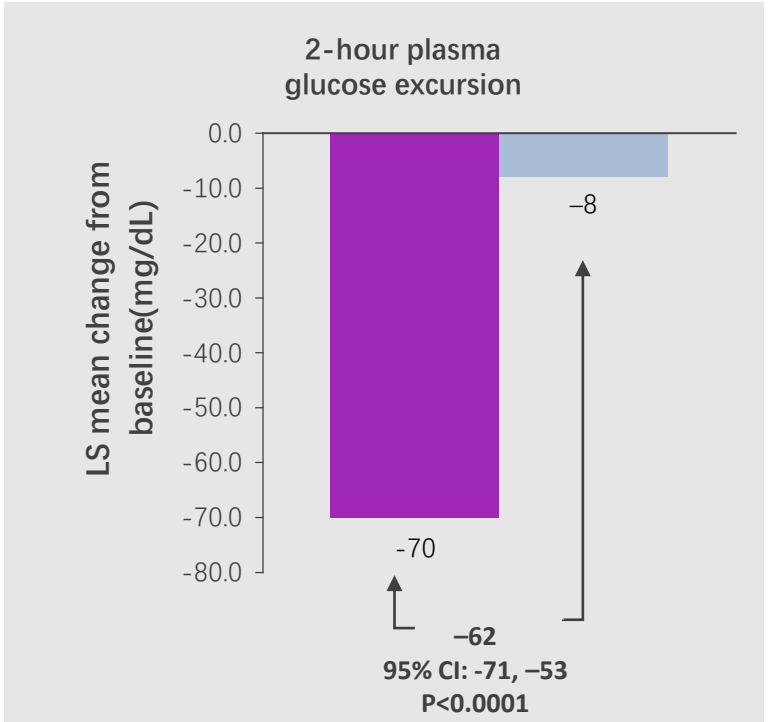
**iGlarLixi was studied in patients with T2DM uncontrolled despite several years on basal insulin and up to 2 OADs**

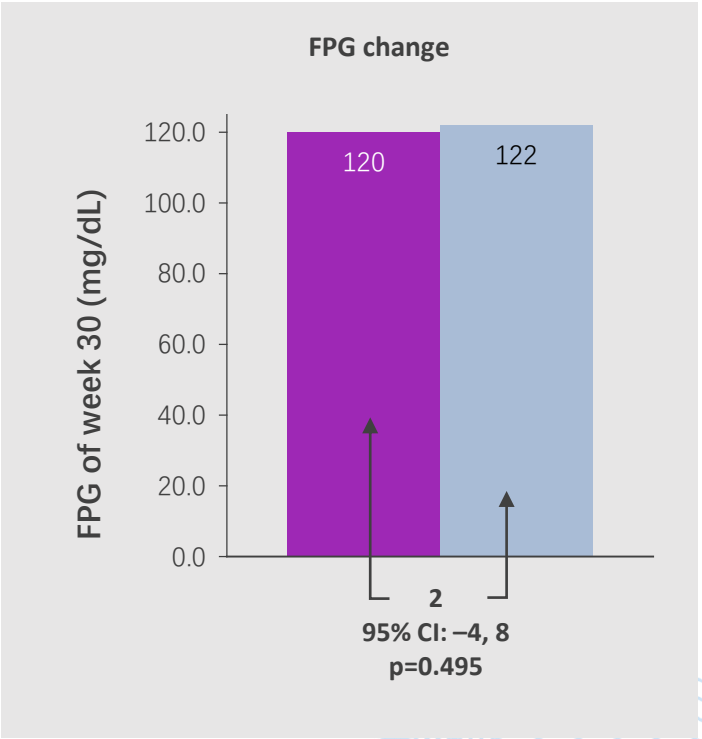
*Data are presented as the mean ± SD, or as indicated. A1c: glycated hemoglobin; BMI: body mass index; FPG: fasting plasma glucose; OAD: oral antidiabetic; T2DM: type 2 diabetes mellitus.

1. Aroda VR et al. *Diabetes Care*. 2016;39:1972-1980
2. Sanofi. Data on file. 2015.

# LixiLan-L: Key Results
# Soliqua Provides Better Glycemic Control Than iGlar

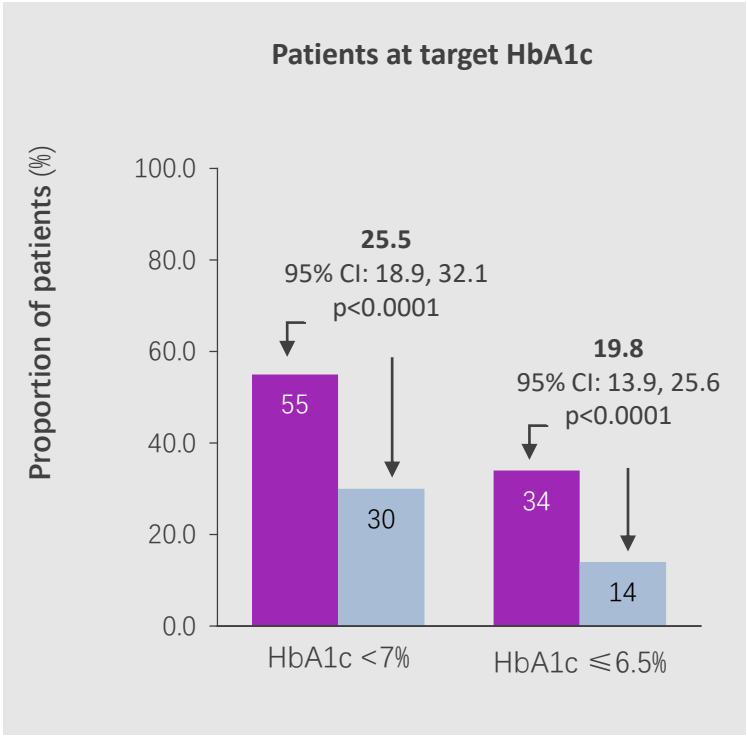


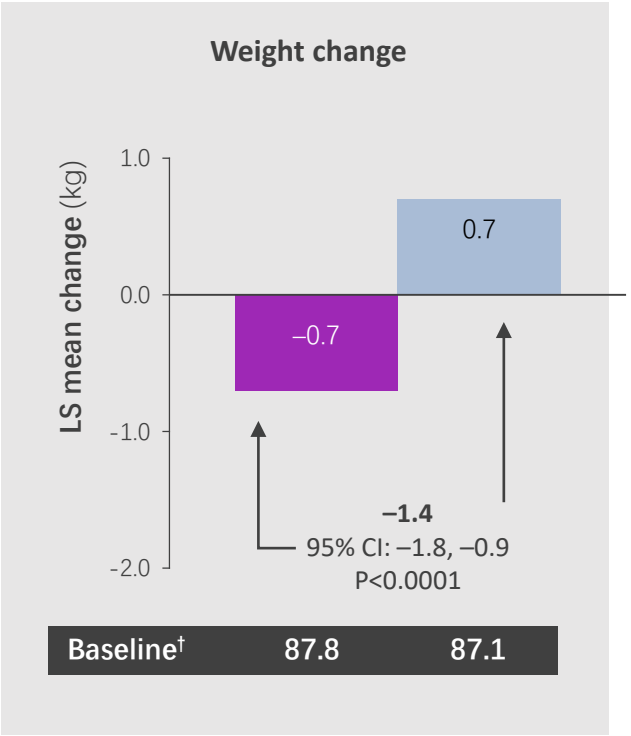



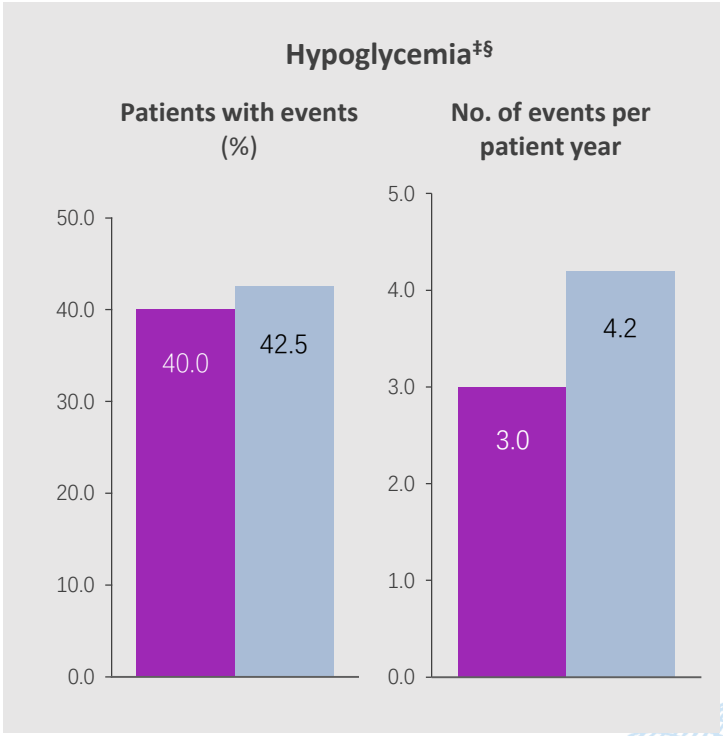




Aroda V, *et al*. Diabetes Care. 2016;39:1972-1980.

# LixiLan-L: Key Results
# Soliqua Provides Better HbA1C Achievement Rate and Body Weight Reduction



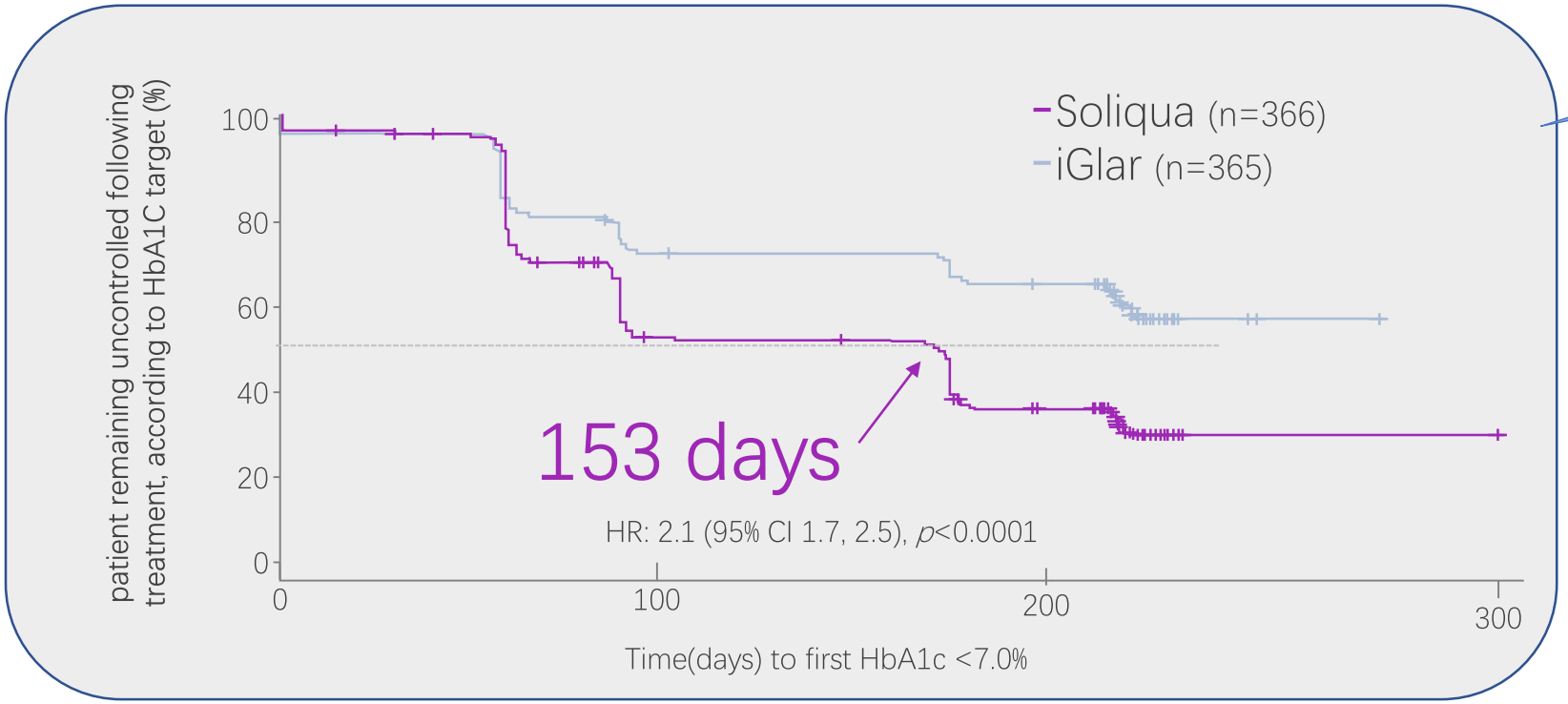




† Mean body weight (kg) at baseline; ‡Documented symptomatic hypoglycemia, defined as plasma glucose ≤70 mg/dL
§ Severe hypoglycemia was reported in 4 (1.1%) patients in the iGlarLixi group and 1 (0.3%) patient in the iGlar group

Aroda V, *et al*. Diabetes Care. 2016;39:1972-1980.

# Shorter Time to Glycemic Control with Soliqua vs. iGlar Alone

**LixiLan-L: Time to First HbA1c <7%**

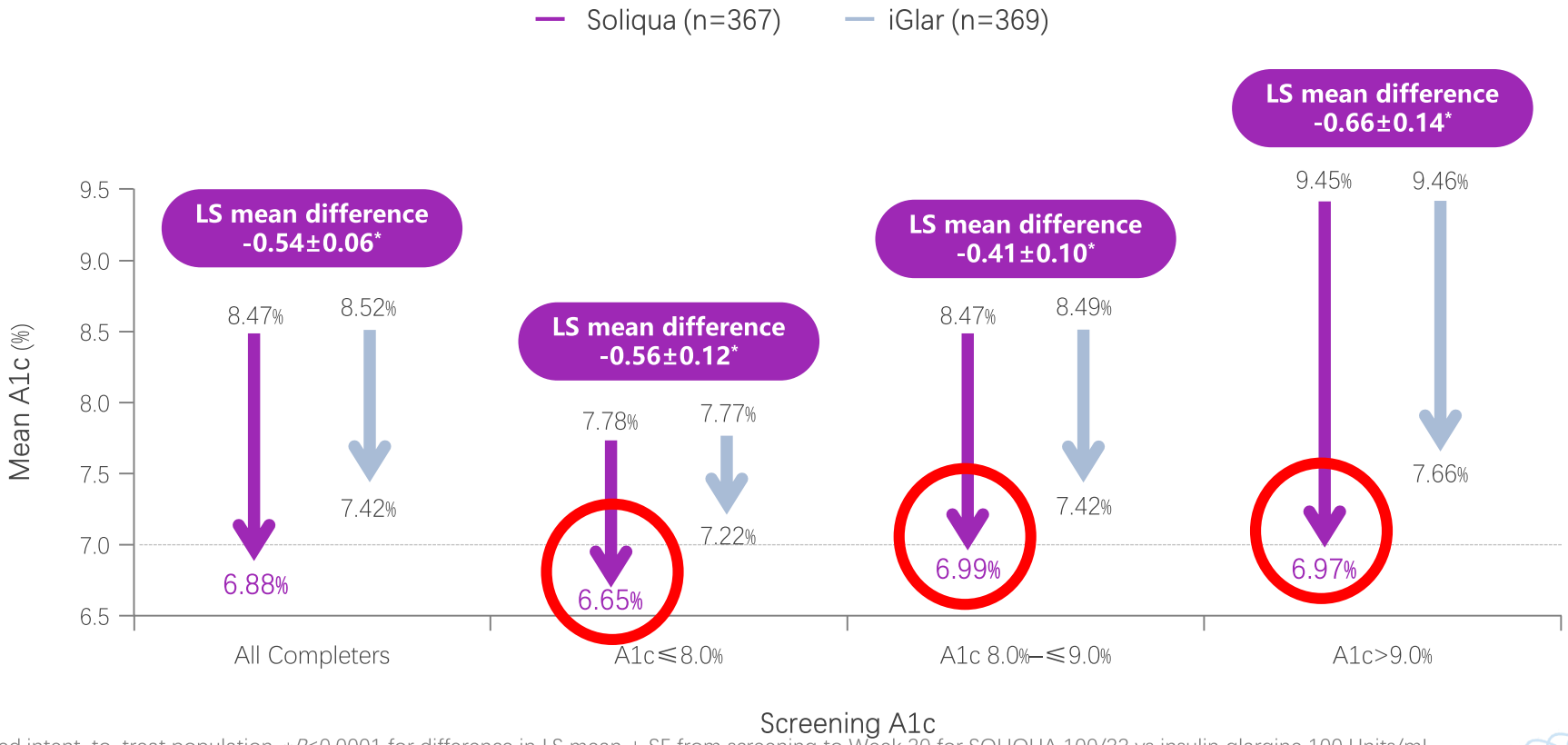



Mean **Baseline HbA1c 8.1±0.7%** in **both** groups.

**Median time to target HbA1c was 153 days with iGlarLixi, while target HbA1c was never reached by 50% of patients with iGlar.**

Frias J et al. Diabetes Obes Metab. 2018 May 21

# Soliqua Helps T2DM Patients Reach HbA1C Goal Even Patients Are Under Poor Control (HbA1C>9%)



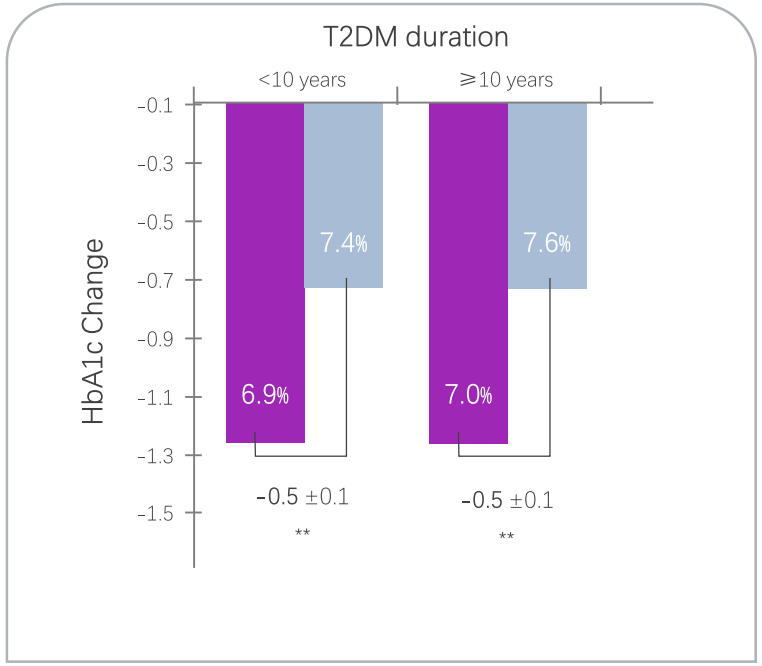

**Consistent superiority of Soliqua vs. iGlar in HbA1c change irrespective of initial HbA1c level**

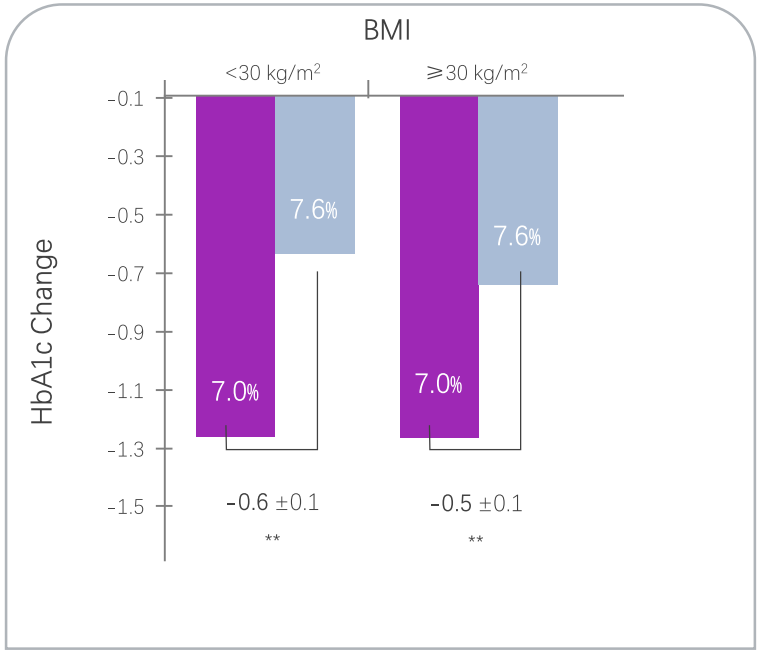
Modified intent-to-treat population. *$P$<0.0001 for difference in LS mean ± SE from screening to Week 30 for SOLIQUA 100/33 vs insulin glargine 100 Units/mL.
A1c: glycated hemoglobin; LS: least squares; SE: standard error; iGlar: Insulin Glargine 100 Units/mL

Niemoeller E et al. Diabetes Ther. 2018 Feb;9(1):373-382

# Soliqua Provides Similar Treatment Response Irrespective of T2DM Duration and BMI

**Similar treatment response irrespective of T2DM duration and BMI**




Soliqua significantly reduced HbA1c vs. iGlar regardless of T2DM duration or BMI

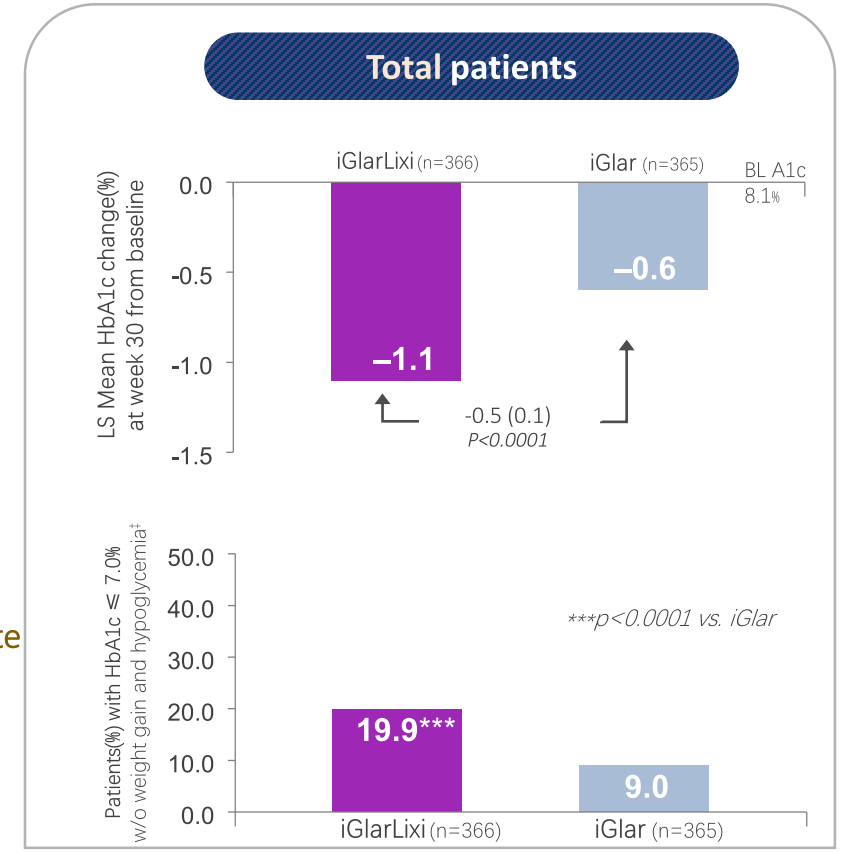
Data are mean ± SE. Treatment comparison *p*-values based on two-factor ANOVA (with last observation carried forward) compared with iGlarLixi
*$p$=0.001, **$p$<0.0001 for iGlarLixi vs iGlar (indicated by arrows and asterisks)
†Between-subpopulation comparison $p$<0.0001; heterogeneity was assessed and all $p$-values for heterogeneity were not significant ANOVA, analysis of variance; BMI, body mass index; HbA1c, glycated hemoglobin;
SE, standard error; T2DM, type 2 diabetes mellitus; iGlar: Insulin Glargine 100 Units/mL

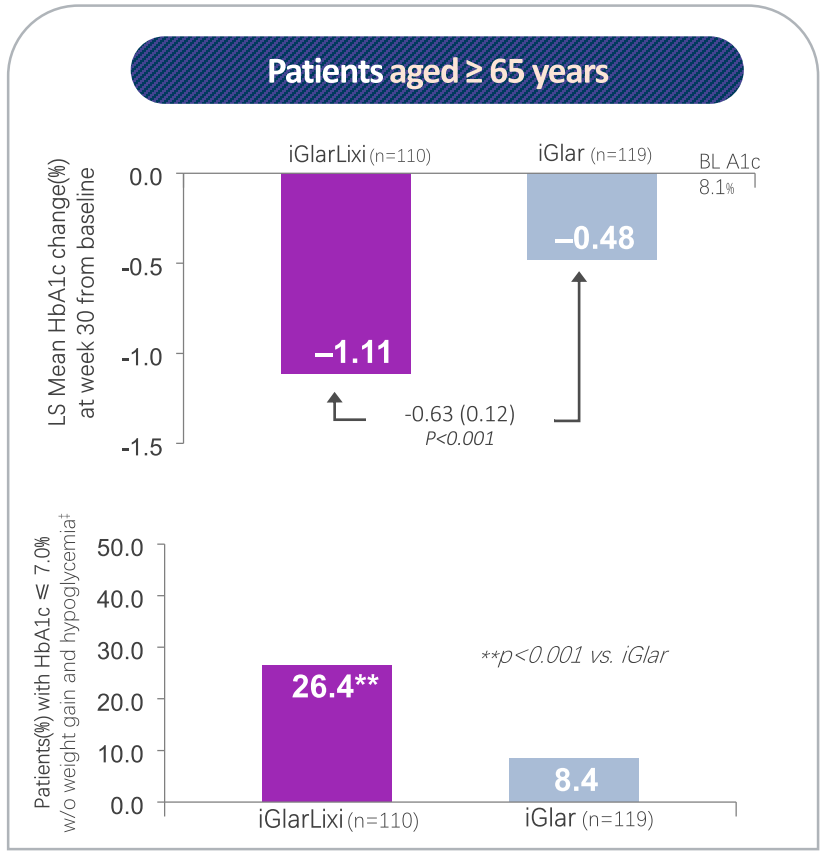
Wysham C *et al.* Diabetes Obes Metab. 2017;19:1408-1415

# Soliqua Provides Similar Treatment Response for Elderly Patients

HbA1c reduction

Composite achieved rate*




**Consistent superiority of Soliqua** vs. iGlar **in patients(%) reached target A1c w/o weight gain and hypoglycemia in elderly**

*Composite of A1c <7.0% + no weight gain + no documented symptomatic hypoglycemia.)

Handelsman Y et al. ADA 2016, Poster 954. Availablte at https://ada.scientificposters.com/epsAbstractADA.cfm?id=1 (as of 2018-07-20)

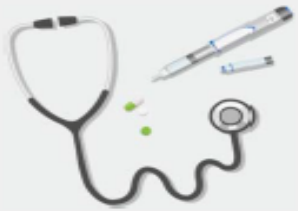
# LixiLan-L: Adverse Events

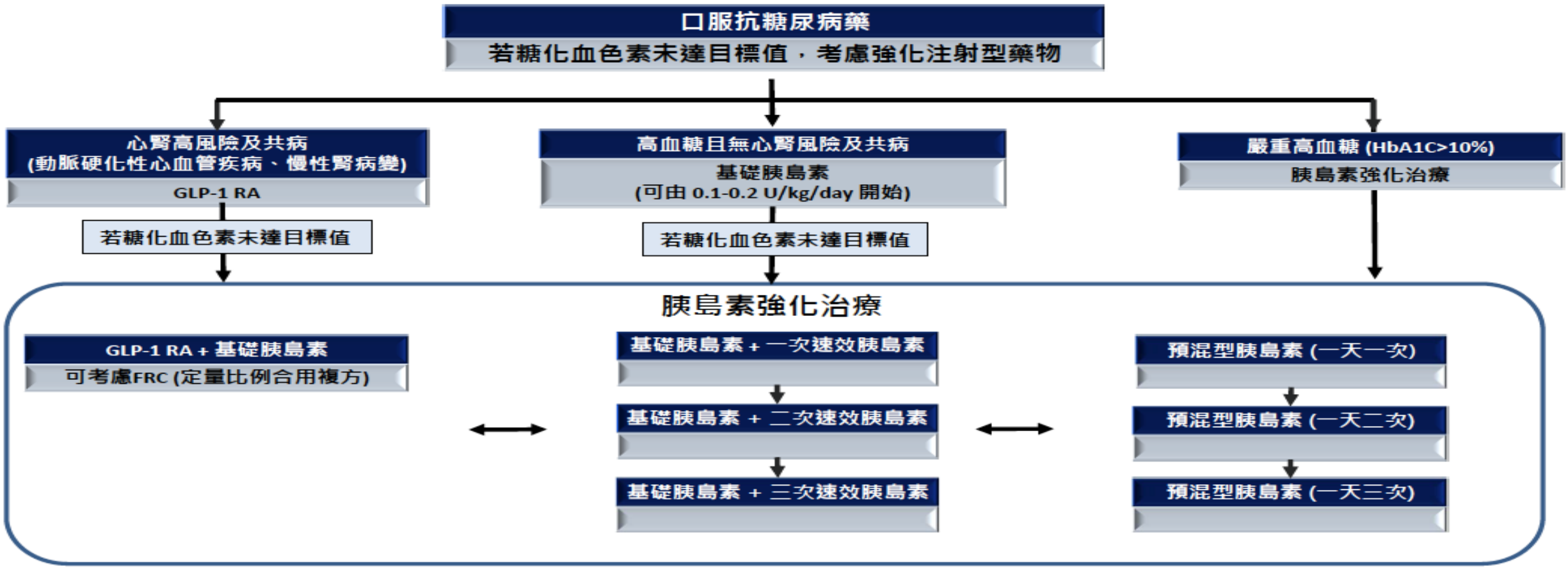
| *Patients with:* | iGlarLixi (n=365) | iGlar (n=365) |
|---|---|---|
| **Nausea** | 10.7% | 0.5% |
| **Vomiting** | 3.6% | 0.5% |
| **Diarrhea** | 4.4% | 2.7% |

- 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%)

Aroda VR, et al. *Diabetes Care* 2016;39:1972–80

# 第 2 型糖尿病人注射型藥物的治療流程圖 (2020)





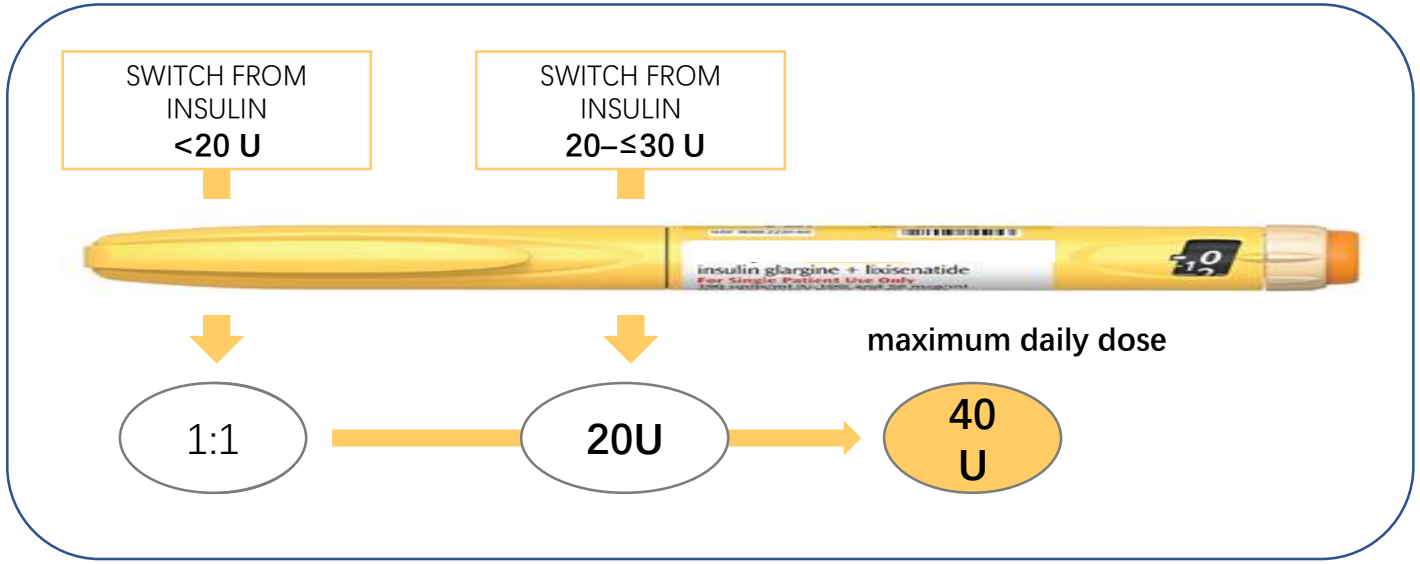

修改自2020年美國糖尿病醫學會糖尿病照護建議

# 劑量及用法

**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**：




****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。

# Example for Patients Switching from Insulin Glargine 300 U/mL Dose Less Than 20 Units

Switching from previous dose of 20 U/day **insulin glargine U300**

Reduce the dose by 20% to get starting dose of iGlarLixi

Starting dose **16**

| Insulin glargine | Lixisenatide |
|---|---|
| 10 U | 5 ug |
| 11 | 5.5 |
| 12 | 6 |
| 13 | 6.5 |
| 14 | 7 |
| 15 | 7.5 |
| 16 | 8 |
| 17 | 8.5 |
| 18 | 9 |
| 19 | 9.5 |
| 20 | 10 |
| 21 | 10.5 |
| 22 | 11 |
| 23 | 11.5 |
| 24 | 12 |
| 25 | 12.5 |
| 26 | 13 |
| 27 | 13.5 |
| 28 | 14 |
| 29 | 14.5 |
| 30 | 15 |
| 31 | 15.5 |
| 32 | 16 |
| 33 | 16.5 |
| 34 | 17 |
| 35 | 17.5 |
| 36 | 18 |
| 37 | 18.5 |
| 38 | 19 |
| 39 | 19.5 |
| 40 | 20 |


**10–40 Pen**

(2 U:1 µg ratio)

*Soliqua 仿單*

# Example for Patients Switching from Insulin Glargine 300 U/mL Dose Higher Than 20 Units

Switching from previous dose of 30 U/day **insulin glargine U300**

Reduce the total dose by 20% to get starting dose of iGlarLixi (=24 Units)

Check label to determine starting Soliqua dose based on this reduced total daily dose (e.g. ≥20–<30 U/day starts at 20 U/day of iGlarLixi)

Starting dose **20**

**lixisenatide的起始建議劑量不得超過10μg**

| Insulin glargine | Lixisenatide |
|---|---|
| 10 U | 5 ug |
| 11 | 5.5 |
| 12 | 6 |
| 13 | 6.5 |
| 14 | 7 |
| 15 | 7.5 |
| 16 | 8 |
| 17 | 8.5 |
| 18 | 9 |
| 19 | 9.5 |
| 20 | 10 |
| 21 | 10.5 |
| 22 | 11 |
| 23 | 11.5 |
| 24 | 12 |
| 25 | 12.5 |
| 26 | 13 |
| 27 | 13.5 |
| 28 | 14 |
| 29 | 14.5 |
| 30 | 15 |
| 31 | 15.5 |
| 32 | 16 |
| 33 | 16.5 |
| 34 | 17 |
| 35 | 17.5 |
| 36 | 18 |
| 37 | 18.5 |
| 38 | 19 |
| 39 | 19.5 |
| 40 | 20 |

**10–40 Pen**

(2 U:1 μg ratio)


*Soliqua 仿單*

# 特殊族群

**老年人(≥65歲)**
Soliqua可使用於老年病人。劑量的調整因人而異，必須視血糖監測情況而定。老年人的腎臟功能逐漸變差，因此有可能導致胰島素的需求穩定下降。Lixisenatide的劑量不需隨年齡調整。Soliqua使用於75 歲病人的治療經驗有限。

**兒童**
Soliqua無使用於兒童之相關資料。

**肝功能不全**
肝功能不全病人不需調整lixisenatide之劑量。肝功能不全病人，胰島素需求量有可能因糖質新生(gluconeogenesis)的能力下降及胰島素代謝降低而減少。肝功能不全病人使用Soliqua時，可能需頻繁監測血糖並調整劑量。

**腎功能不全**
嚴重腎功能不全及末期腎病病人不建議使用Soliqua，因為lixisenatide在這些病人身上的治療經驗不足。
輕度或中度腎功能不全病人不需調整lixisenatide之劑量。
腎功能不全病人，胰島素需求量有可能因胰島素代謝下降而減少。
輕度至中度腎功能不全的病人使用Soliqua時，可能需頻繁監測血糖並調整劑量。

**懷孕**
Soliqua不應在懷孕期間使用。若病人想要懷孕或已經懷孕，應停用Soliqua。

# 儲存條件

**架儲期**

- 24 個月
- 首次使用後的注射筆:

| | 儲存溫度 | 儲存天數 |
|---|---|---|
| 第一次使用後的注射筆，請選擇一項儲存溫度，並依照相對應之天數儲存： | 放在低於25℃之室溫，不可冷藏，不可冷凍。 | 至多保存28天，如未使用完應丟棄。 |
| | 放在低於30℃之室溫，不可冷藏，不可冷凍。 | 至多保存14天，如未使用完應丟棄。 |

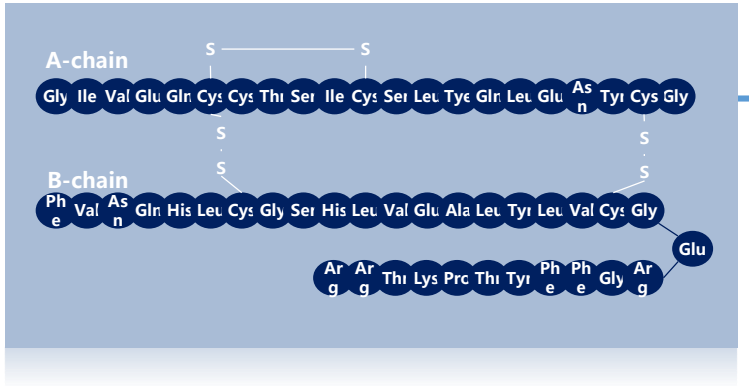
- 儲存時應拔下針頭。
- 注射筆之儲存應遠離直射熱源或光源。每次注射完畢應套回筆蓋以避免光照。

**儲存之特別注意事項**

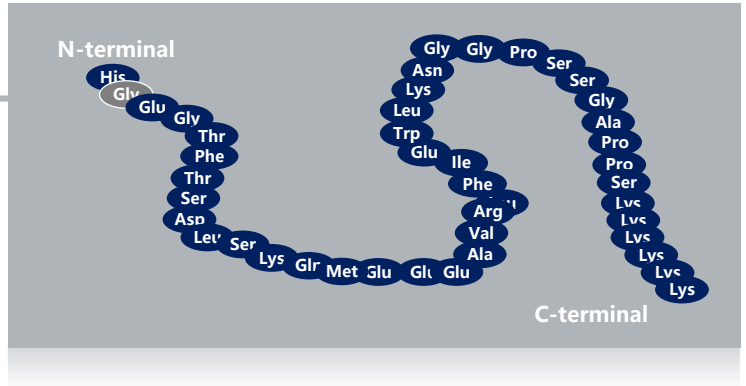
- 未使用過的注射筆
- 應儲存於冰箱(2℃ - 8℃)。
- 不可冷凍或放在冷凍室旁或冰袋旁。
- 預填注射筆應存放在原有的外盒內以避免光照。

# 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 |

*Soliqua 仿單*

# 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**

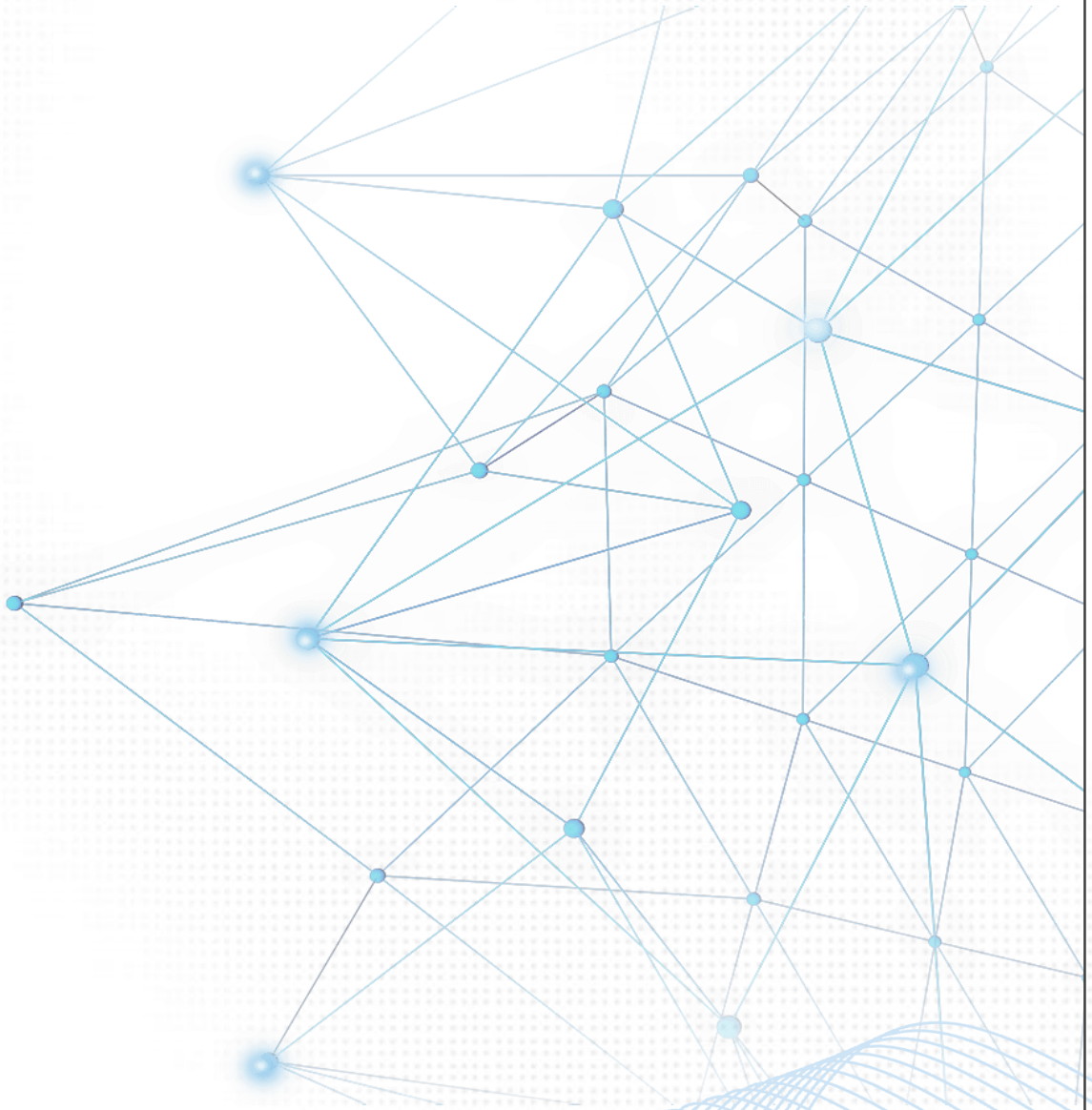
**全民健康保險藥物共同擬訂會議藥品部分第37次(108年4月)會議紀錄*

# Q & A

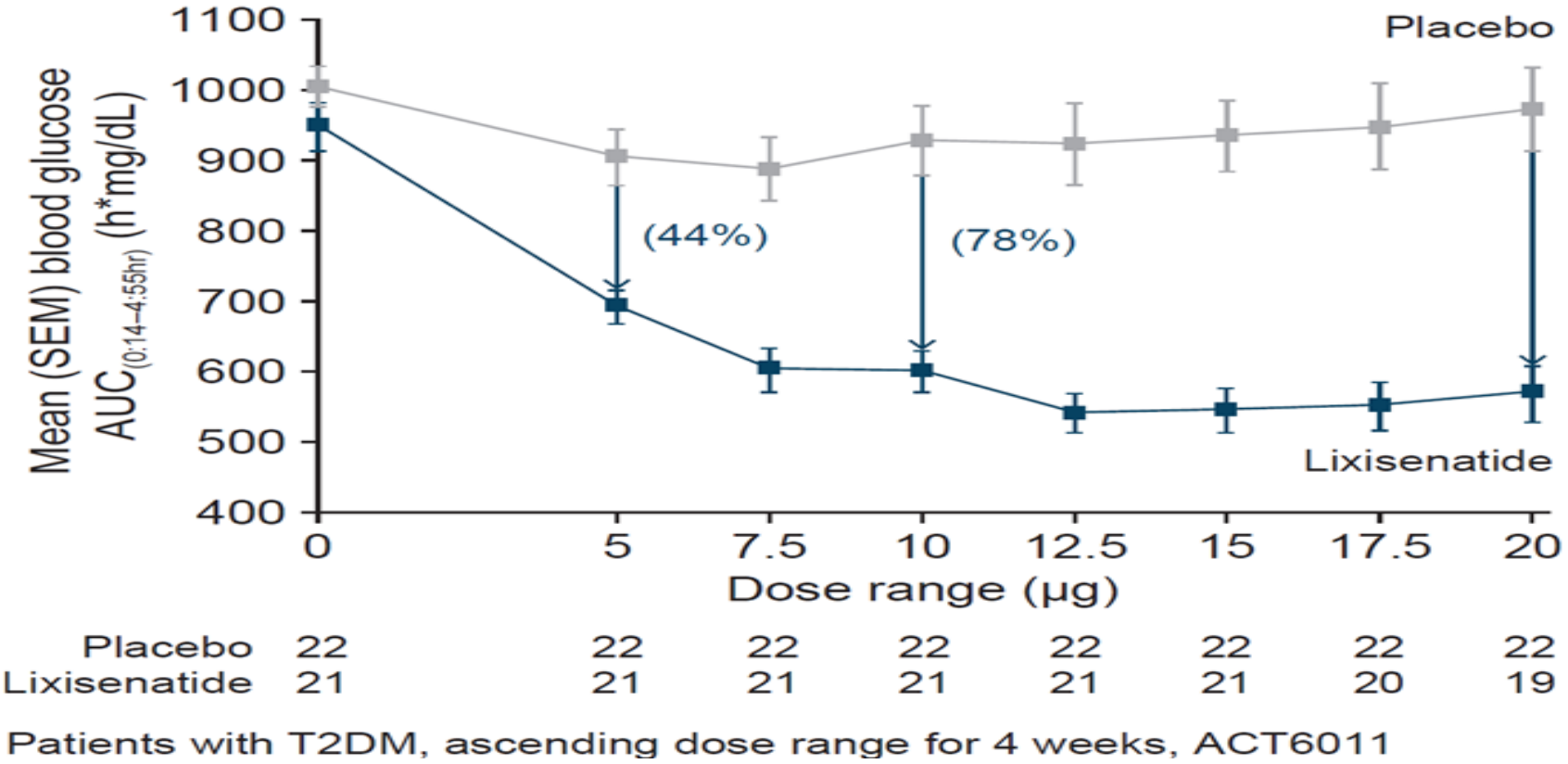

*全民健康保險藥物共同擬訂會議藥品部分第37次(108年4月)會議紀錄

# Lixisenatide

PPG data



# 10 µg Lixisenatide Provides ~80% PPG Lowering Effect in Patients with T2DM

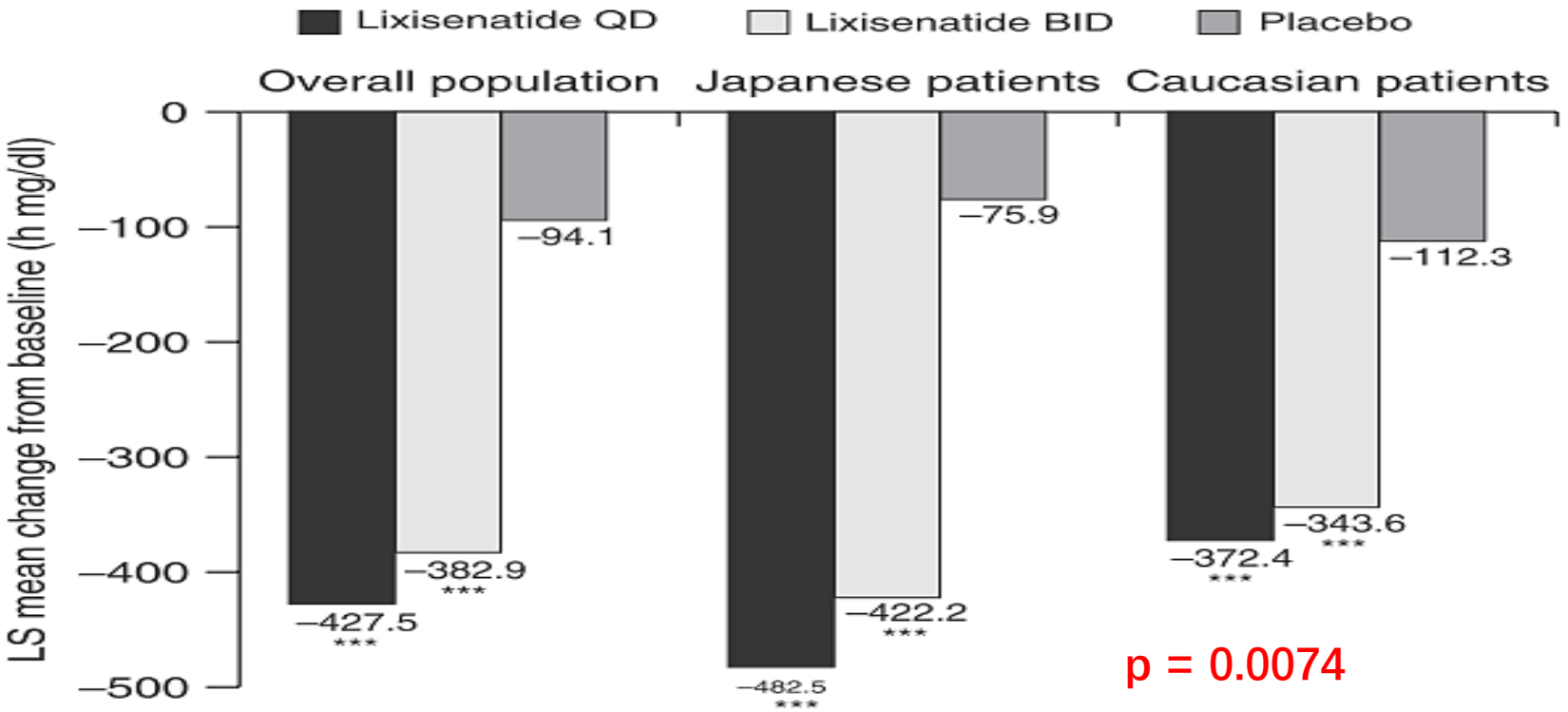



Patients with T2DM, ascending dose range for 4 weeks, ACT6011

*Sanofi data on file*

# Change from Baseline in PPG Area Under The Curve* After a Standardized Breakfast

(AUC)[0:29–4:30 h] (h · mg/dl)

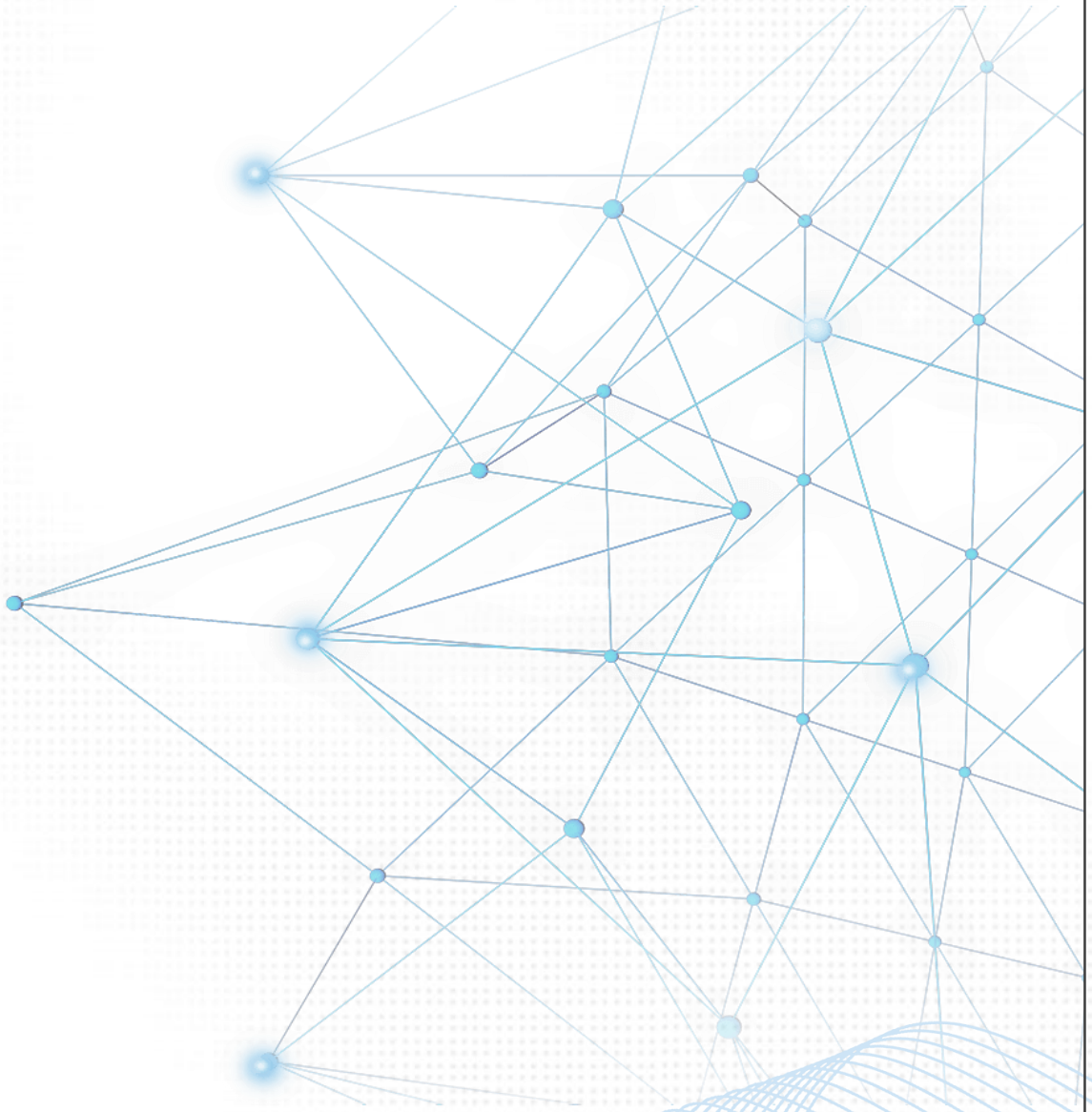



p = 0.0074

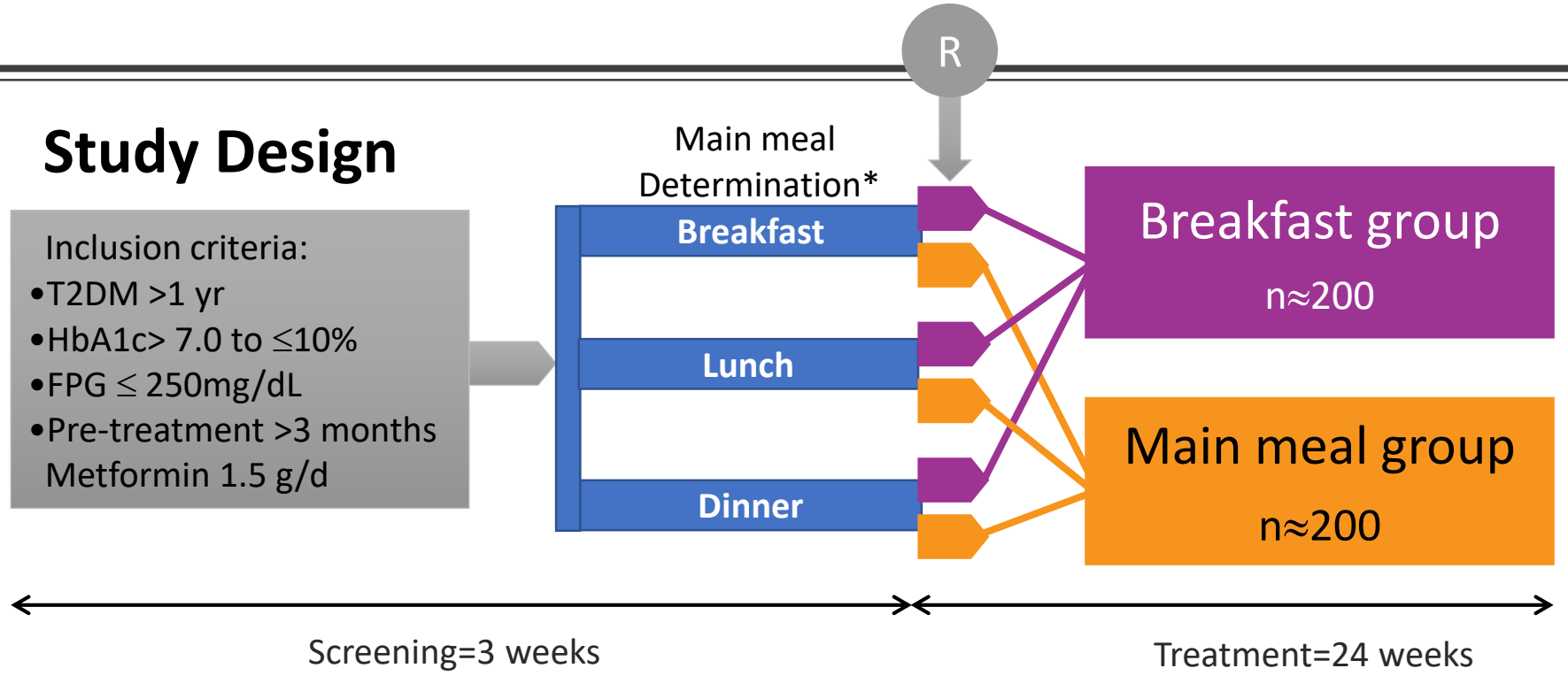
Diabetes, Obesity and Metabolism 16: 739–747, 2014.

# Lixisenatide

Main meal data



# Lixisenatide Main Meal Study




T2DM: type 2 diabetes mellitus; HbA1c: glycated haemoglobin; FPG: fasting plasma glucose.

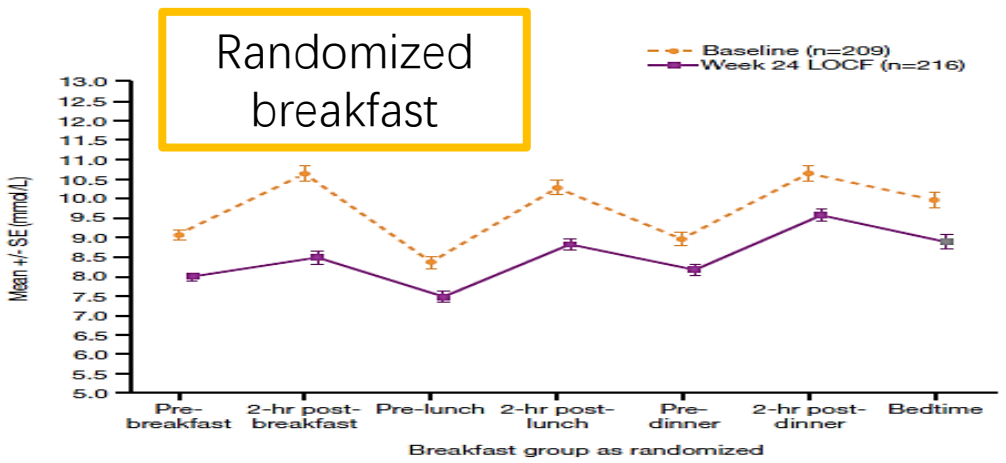
- **Main mealtime determined by asking patients the following question:**

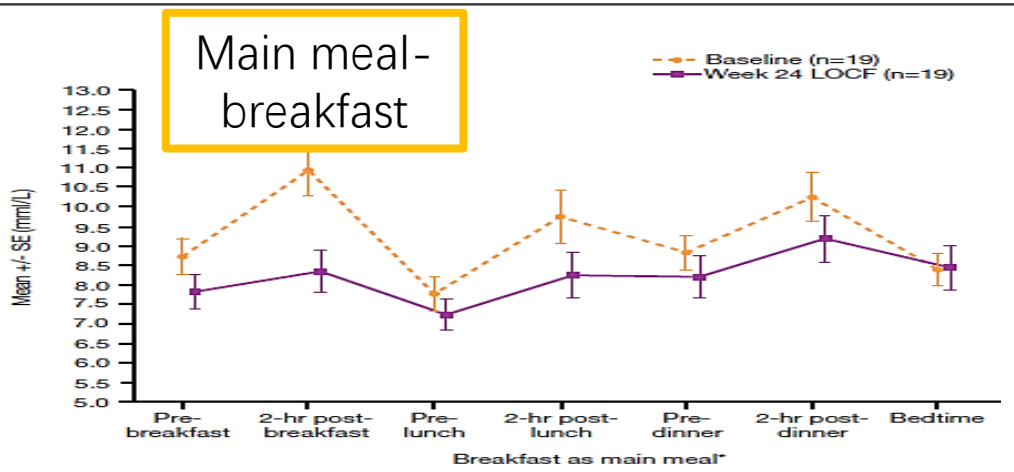
**"On most days, at which meal do you eat the largest amount of food?"**

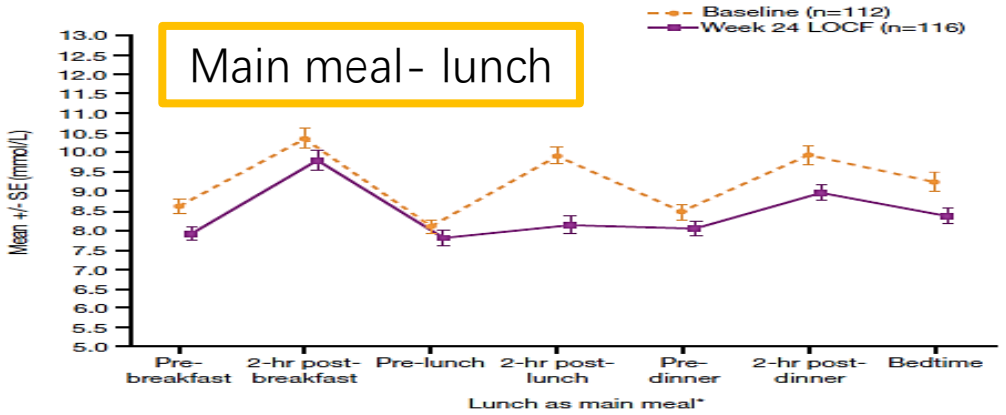
- ***The main meal of the day was also independently determined by a dietician. And it is consistent with patients' awareness.**

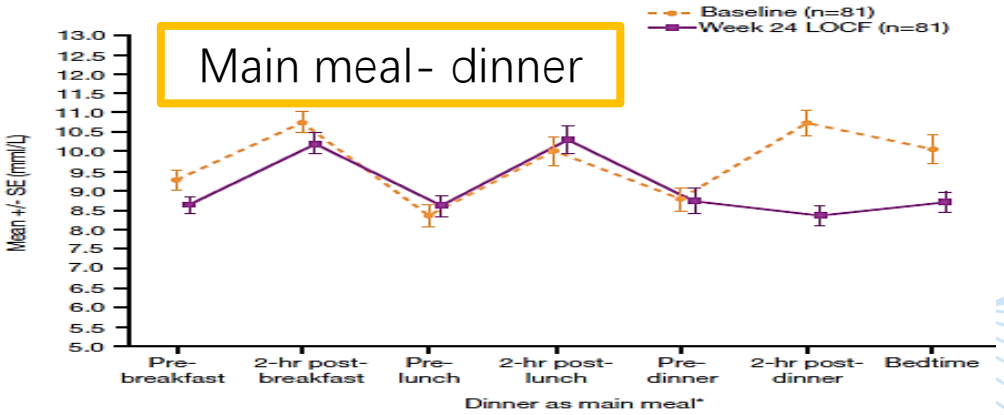
Ahrén B, et al. J Diabetes Complications. 2014 Jun 5

# 7-Point SMPG Profiles at Baseline and Week 24 (mITT population)



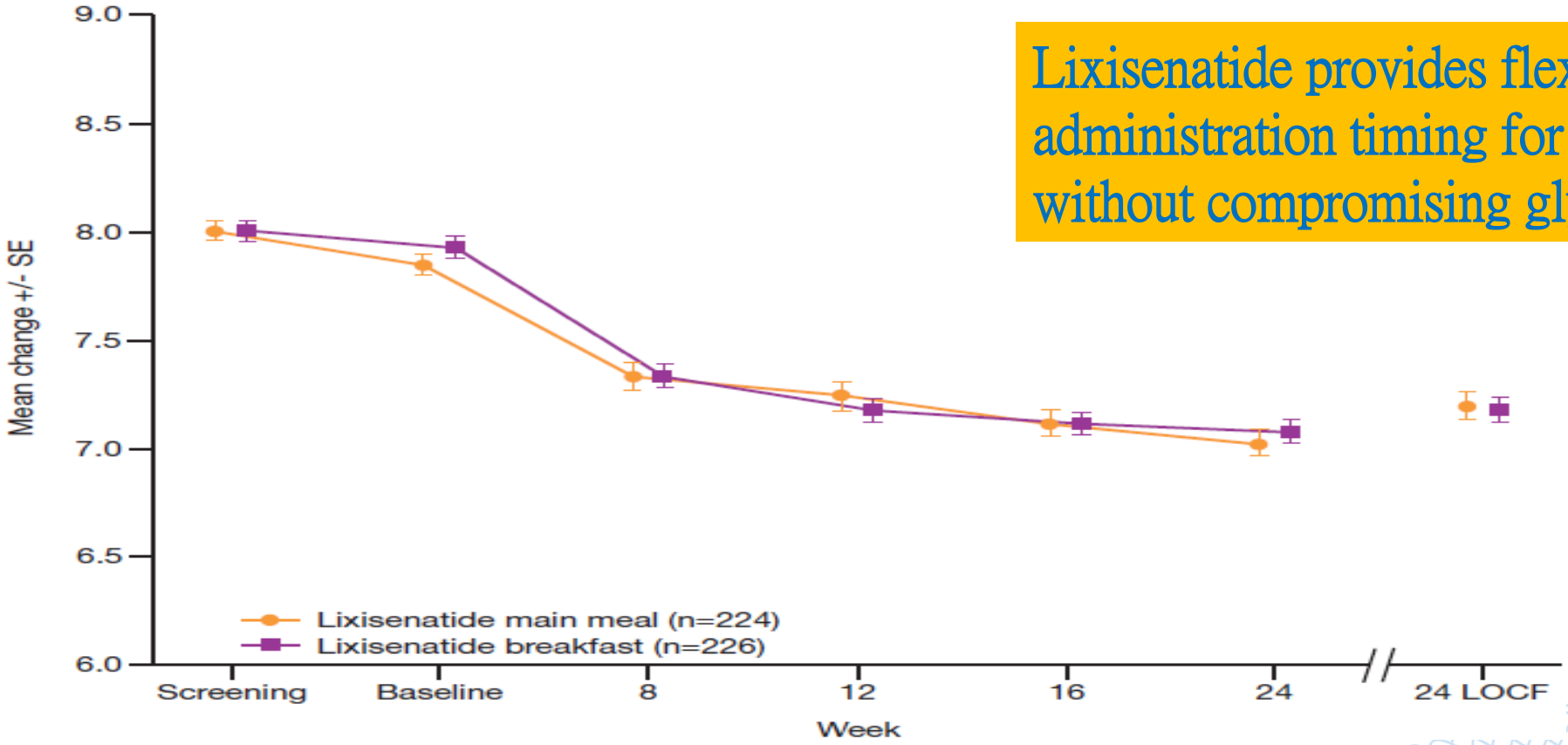




Ahrén B, et al. J Diabetes Complications. 2014 Jun 5

# Comparable HbA1c Reduction in Breakfast Arm and Main Meal Arm




Lixisenatide provides flexibility of administration timing for patients without compromising glycemic control

HbA1c Change Over Time

Ahrén B, et al. J Diabetes Complications. 2014 Jun 5