ADA 2018 conference

Highlights AP

Orlando, 22 ·26 Juny 2018

Francesc Xavier Cos Claramunt
EAP Sant Martí de Provençals. SAP Litoral. Barcelona. ICS
Grup d'Estudi de la Diabetis a l'Atenció Primària de Salut (RedGedapS)
Chairman Primary Care Diabetes Europe

Conflicto Interes

Consultant:

AstraZeneca, Boehringer Ingelheim, Lilly, Novartis, Novo Nordisk and Sanofi Diabetes, Sanofi Pasteur.

Research Support:

AstraZeneca, Novartis, SANOFI, Boehringer Ingelheim

Speaker's Bureau:

AstraZeneca, Boehringer Ingelheim, Lilly, Novartis, Novo Nordisk, Sanofi Diabetes, Sanofi Pasteur.


American
Diabetes
Association.
Diabetes
Is Primary

Agenda

- Prediabetes and type 2 diabetes prevention
- Adherence
- CKD & Diabetes
- Diabetes technology in primary care
- Management of hyperglycemia in type 2 diabetes
- Obesity management in type 2 diabetes
- Cardiovascular risk and treatment options

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Enfermedad Renal Diabética (ERD)

Andrew S. Narva (National Institut of medicina , Bethesda, Maryland)

National Institute of Diabetes and Digestive and Kidney Diseases

“Función y daño”

Función: Conceptos de eGFR (estimación) MDRD /CK-EPI

Daño: Microalbuminuria (?)

Coc Alb/ Creatinina > 30 mg/d

Enfermedad Renal Diabética (ERD)

Andrew S. Narva (National Institut of medicina , Bethesda, Maryland)

National Institute of Diabetes and Digestive and Kidney Diseases

Acciones

- Diagnóstico correcto
- Monitorizar progresión
- Cribar complicaciones EDR
- Educar en EDR en la consulta
- Utilizar fármacos adecuados para evitar la progresion de CKD

  Ex: Evitar daño renal (AINES) https://youtu.be/J2YaULhMx5g

American Diabetes Association. Diabetes Is Primary

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Mobile

Android

iPhone

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

James J. Chamberlain, MD

- Glucómetros
- App calcular dosis de insulina
- Registro continuo de glucosa
- Bombas de insulina
- Hybrid inetragrated insulin sensor
- ¨La red¨ y los estilos de vida.

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

James J. Chamberlain, MD

Glucómetros

- Descarga de resultados
  - Muchos sistemas, cables,….
  - Tiempo para interpretarlos
  - Variabilidad glucemia

- Margen error 5-10%

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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Glucómetros

- Glooko Sistema unificado de manejo de la Diabetes
- Smart meters (verio flex⋯)

American Diabetes Association. | Diabetes Is Primary

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App calcular dosis de insulina

Diabnext clipsulin insulin dosing and BG app

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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App calcular dosis de insulina

Roche accu check connect Insulin doseing app
Companion medical inpen smart insulin delivecalcular dosis/ dexcom sensor

American Diabetes Association. | Diabetes Is Primary

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CGM (RCG)

Glucosa intersticial muy similar a la glucemia
DEXCOM G4/ DEXCOM G5/Medtronic
7 dias sensor
Determinación de glucemia cada 5 ‘
2 calibraciones al dia (AGC)
Resultados se puede observar en apple watch, androids…
No se necesita ACG para tomar decisiones
Dexcom clarity
Dexcom app

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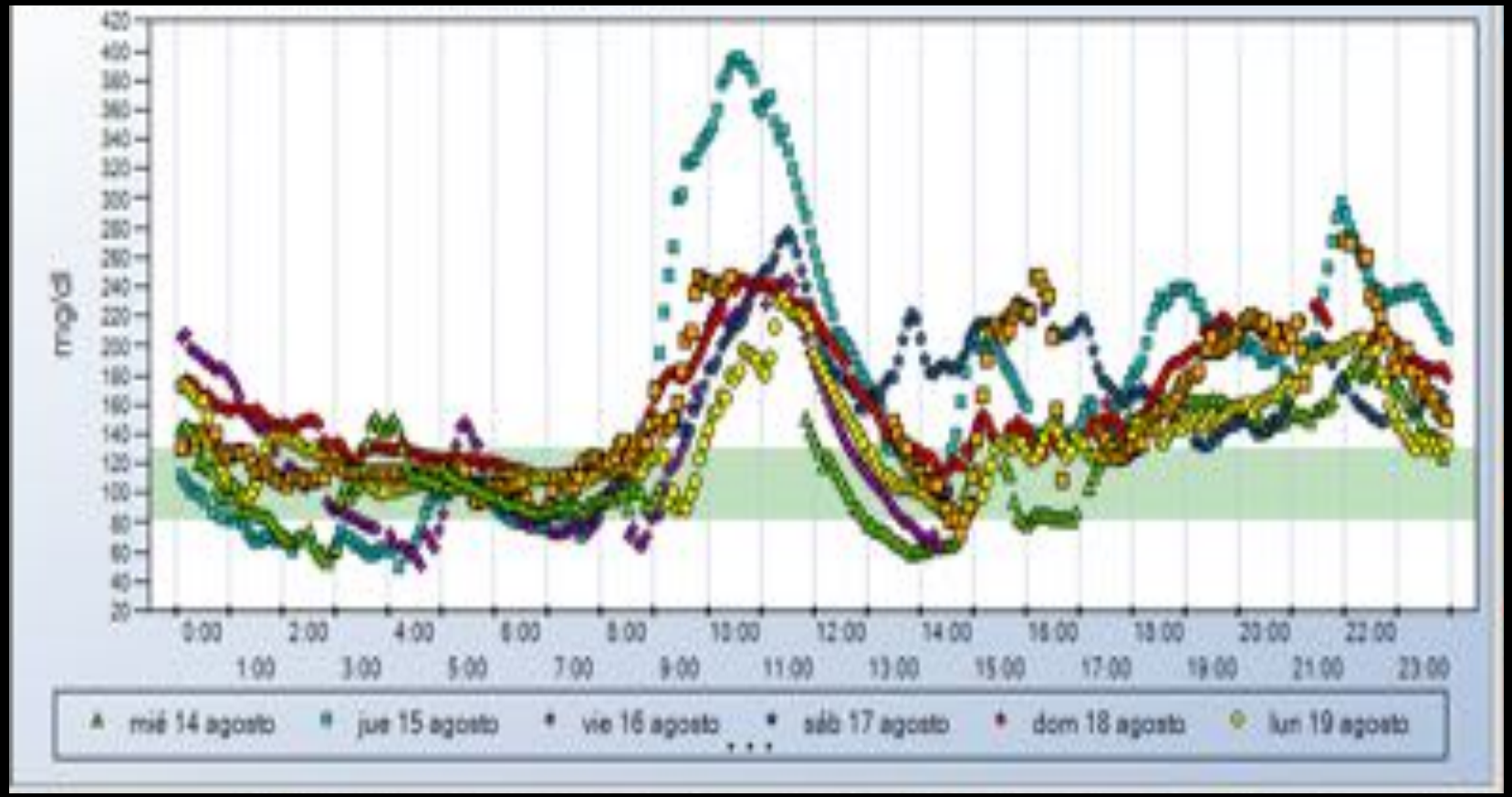
CGM (RCG)



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Dexcom G6 new

- ✓ 10 day sensor duration
- ✓ No calibrations required
- ✓ Patient may choose to calibrate
- ✓ MARD ~ 9% with no calibrations
- ✓ New 'urgent low soon' alert

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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Freestyle libre

10 dias
No calibración
Necesario realizar ACG si valor alterado
No hay alarmas de hipo o hiper

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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CGM studies

- Star 3 study
- Switch study

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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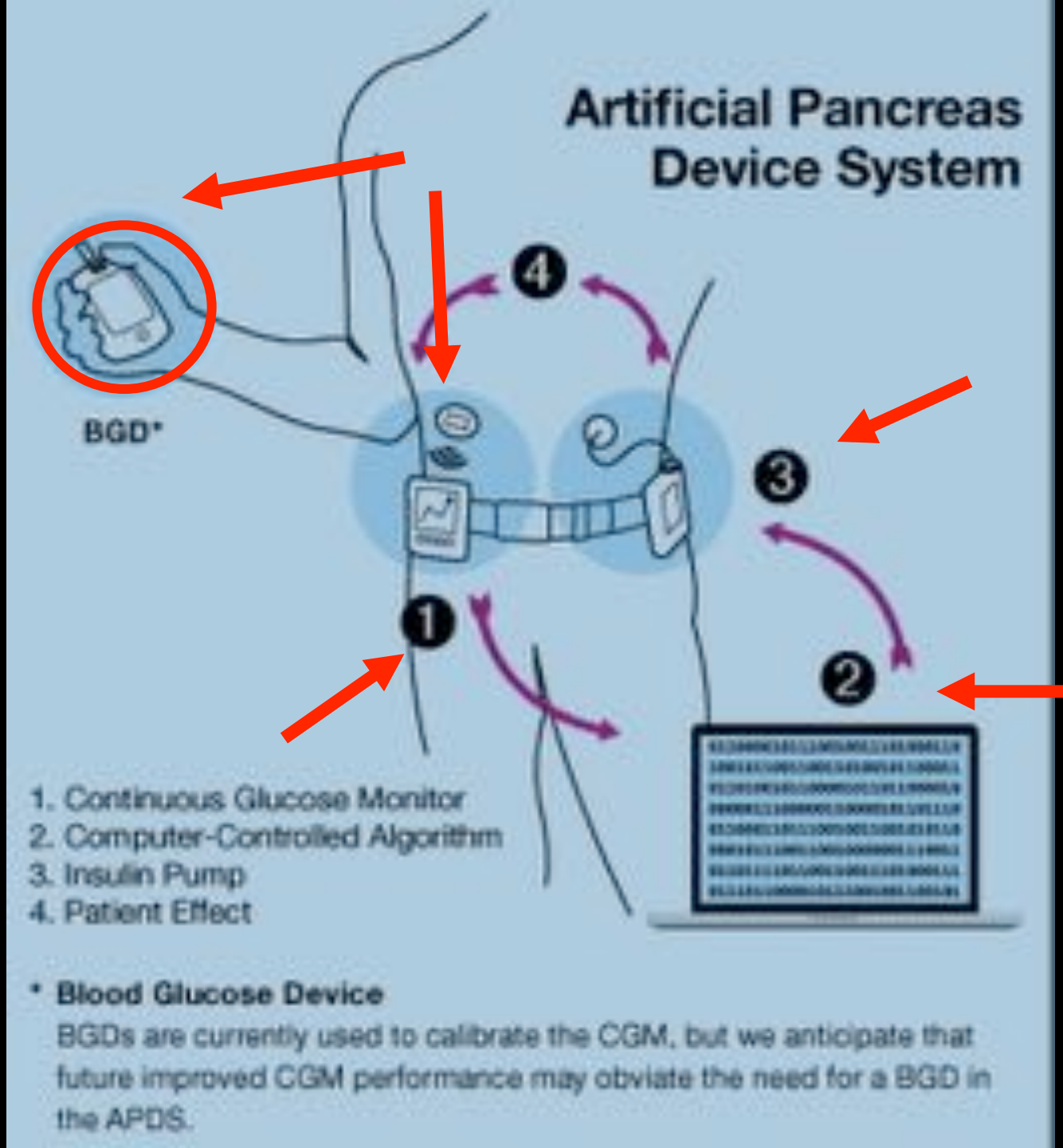
Insulin pump

Pancreas artificial

Como funciona?

1. Registro continuo glucosa (Sensor)
2. Ordenador /smart phone (software)
3. Bomba insulina
4. Lector de glucemia



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Medtronic 670G Hybrid closed loop system

- Sensor similar a las caracteristocas de DEXCOM
- Como funciona
- - objetivos de Glucemia entre 120 i 150
- Ajustes automáticos de insulina cada 5 min en relacion aCGM con objetivo de 120 mg/dl
- Bolos automáticos con objetivo de 150 mg/dl
- Existe un a función automática si desconexión···

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

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Otros sistemas

- Basal IQ Tandem / Dexcom Type zero
- Big food artificial pancreas tech
- Openaps.orgs

What Every PCP Needs to Know about Diabetes Technology in 2018 and Beyond

James J. Chamberlain, MD

App en estilos de vida

Itrack bites

Myfitnessapp

Calorie king trusted

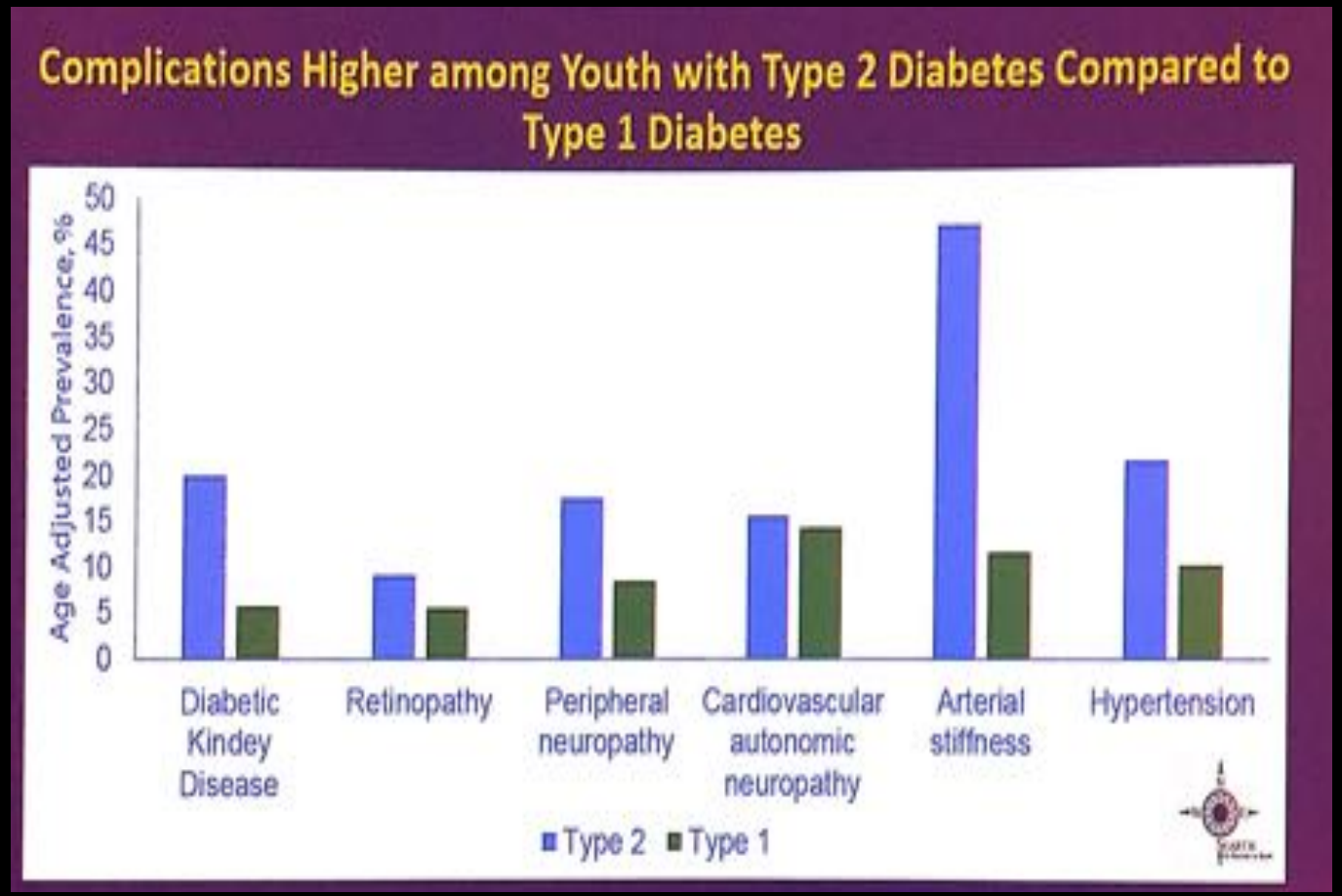
redGDPS HIGHLIGHTS

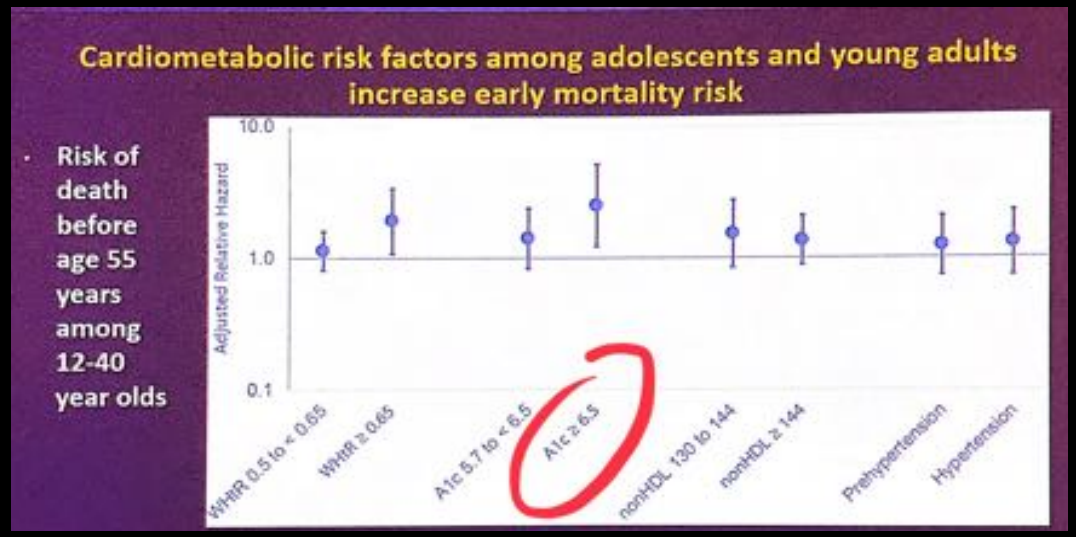
Agenda

- New-Onset Type 2 Diabetes in the Youngest and the Oldest
- Real-World Evidence in Diabetes
- Should Metformin Remain the First-Line Therapy for Type 2 Diabetes?
- Cardiovascular Outcomes Trials (CVOTs) in Diabetes—Shall We Continue or Change Course?
- The New World of Glucose Monitoring
- VADT 15 years later
- Bright study
- New ADA·EASD recommendations

New-Onset Type 2 Diabetes in the Yougest and the oldest

S. Saydah; Type 2 Diabetes in Children, Adolescents, and Young Adults





La cohorte SEARCH estimó 20262 jóvenes en 2009; incremento anual en la incidencia del 2,3%

New-Onset Type 2 Diabetes in the Yougest and the oldest

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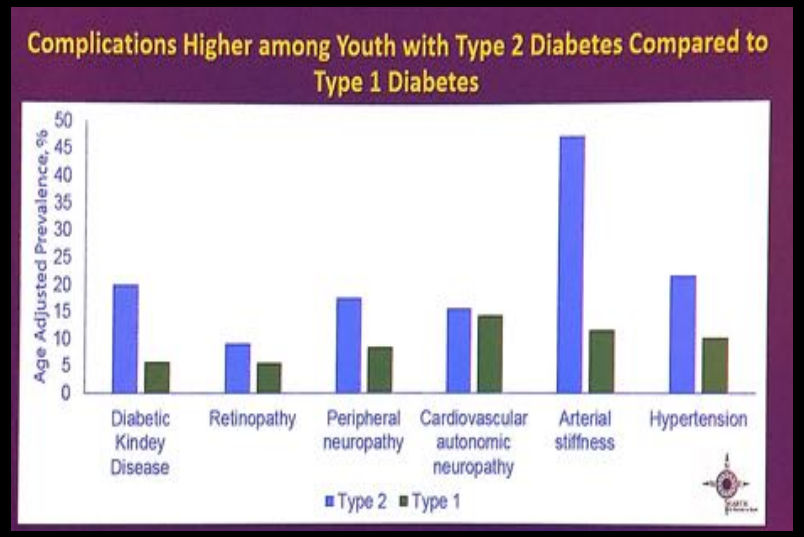

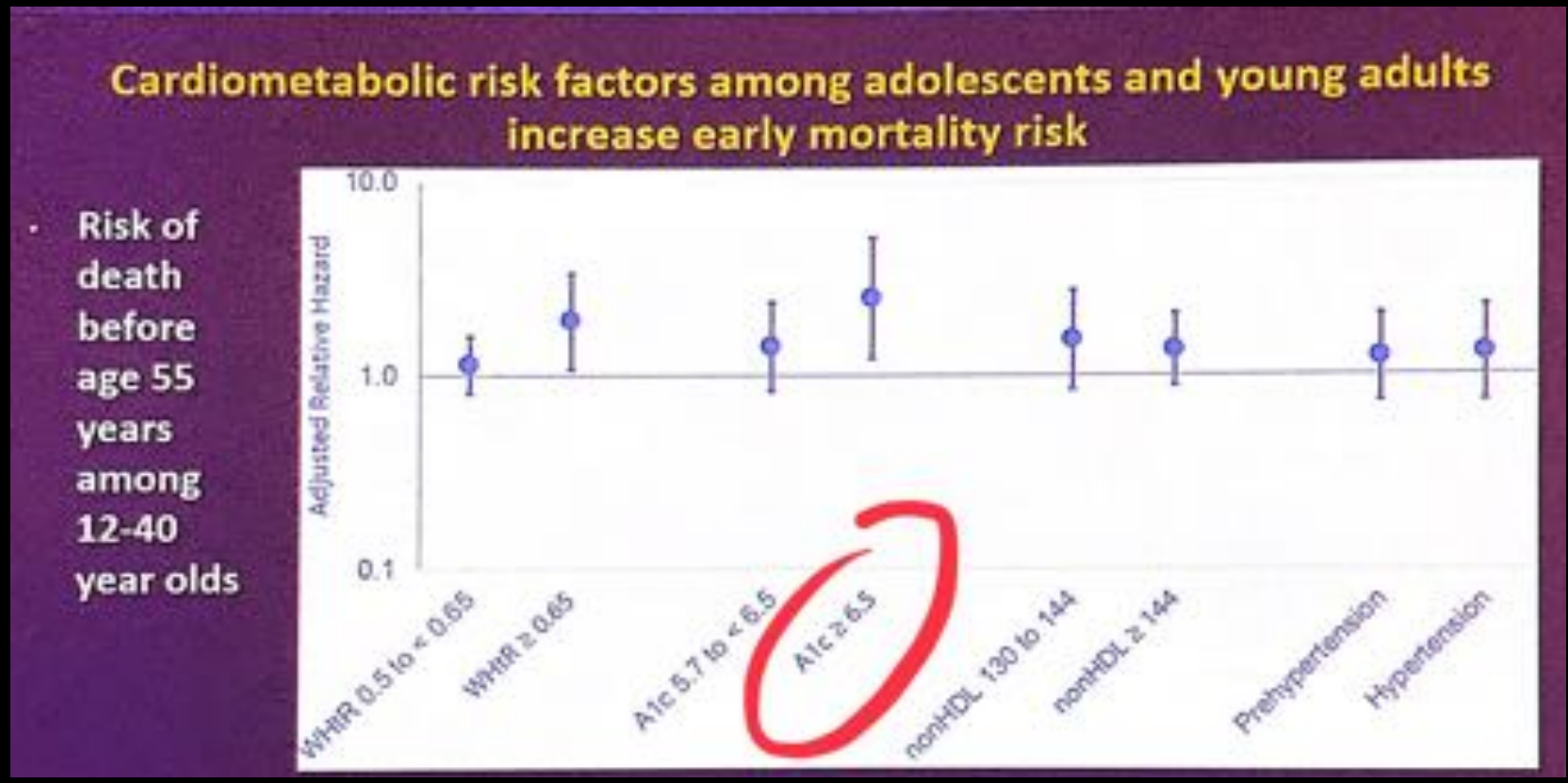

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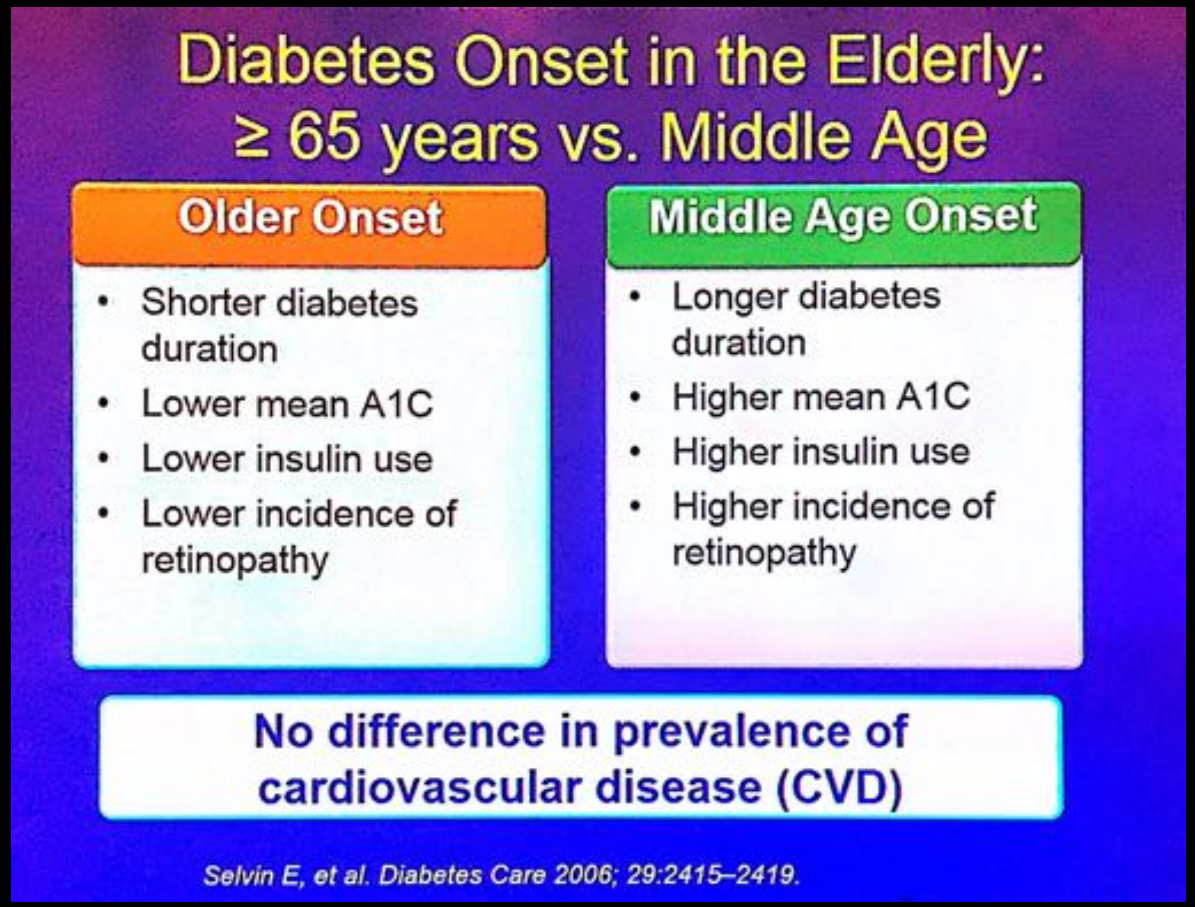
New-Onset Type 2 Diabetes in the Yougest and the oldest

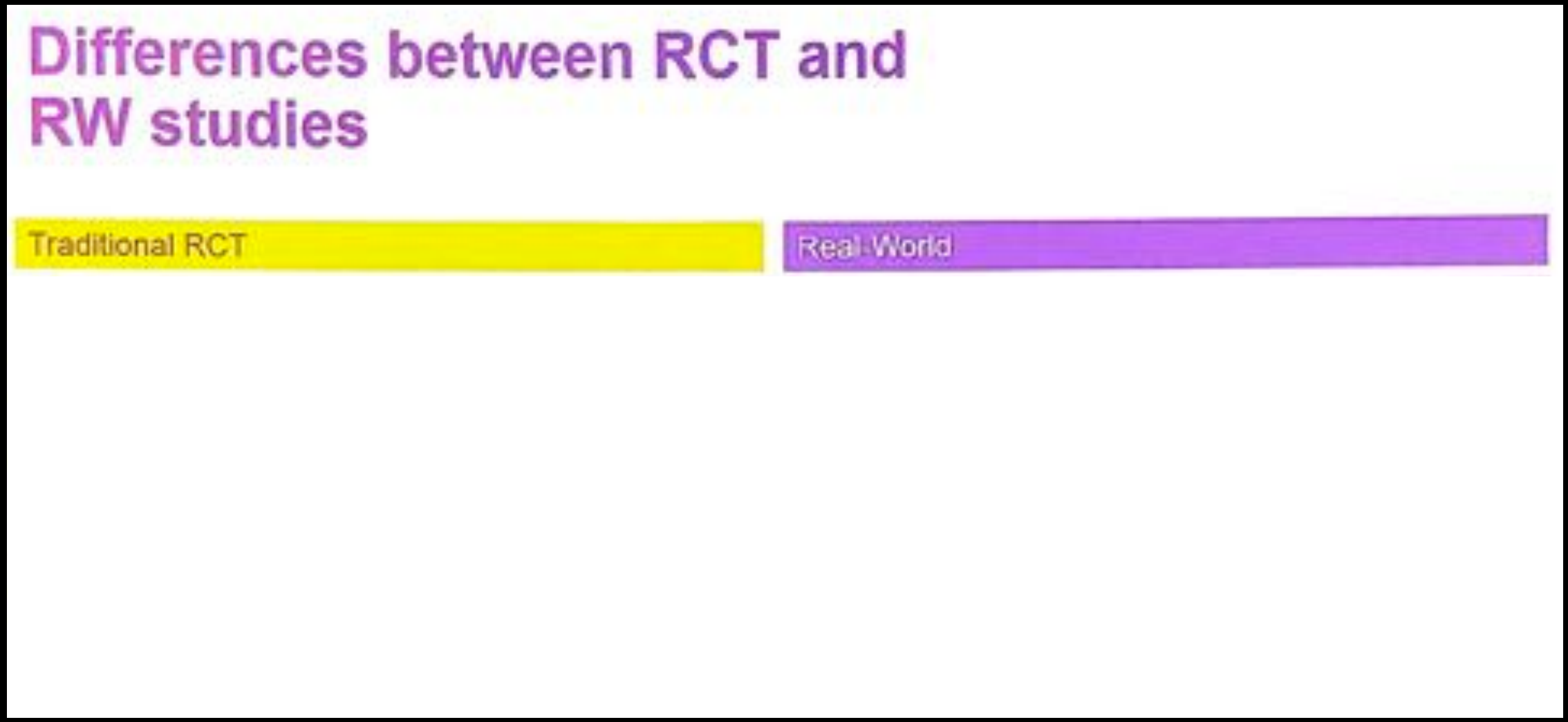
H. Florez; New-Onset Type 2 Diabetes among the Elderly



Mortalidad significativamente superior HbA1c sup a 7,5% VS inf a 6,5%

Real-World Evidence in Diabetes

Kamlesh Khunti, Sean D. Sullivan, Timothy S. Bailey, Lawrence Blond, Stewart Harris



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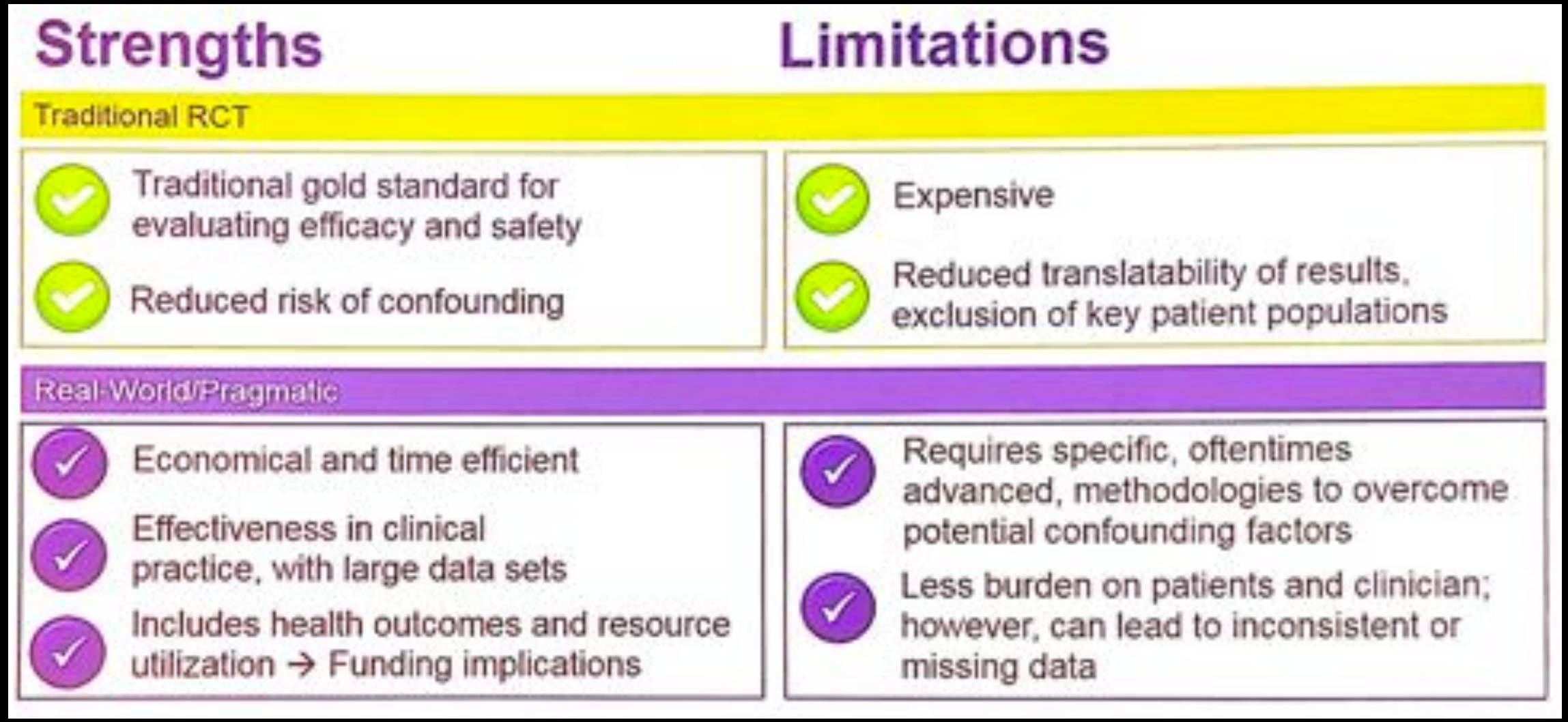

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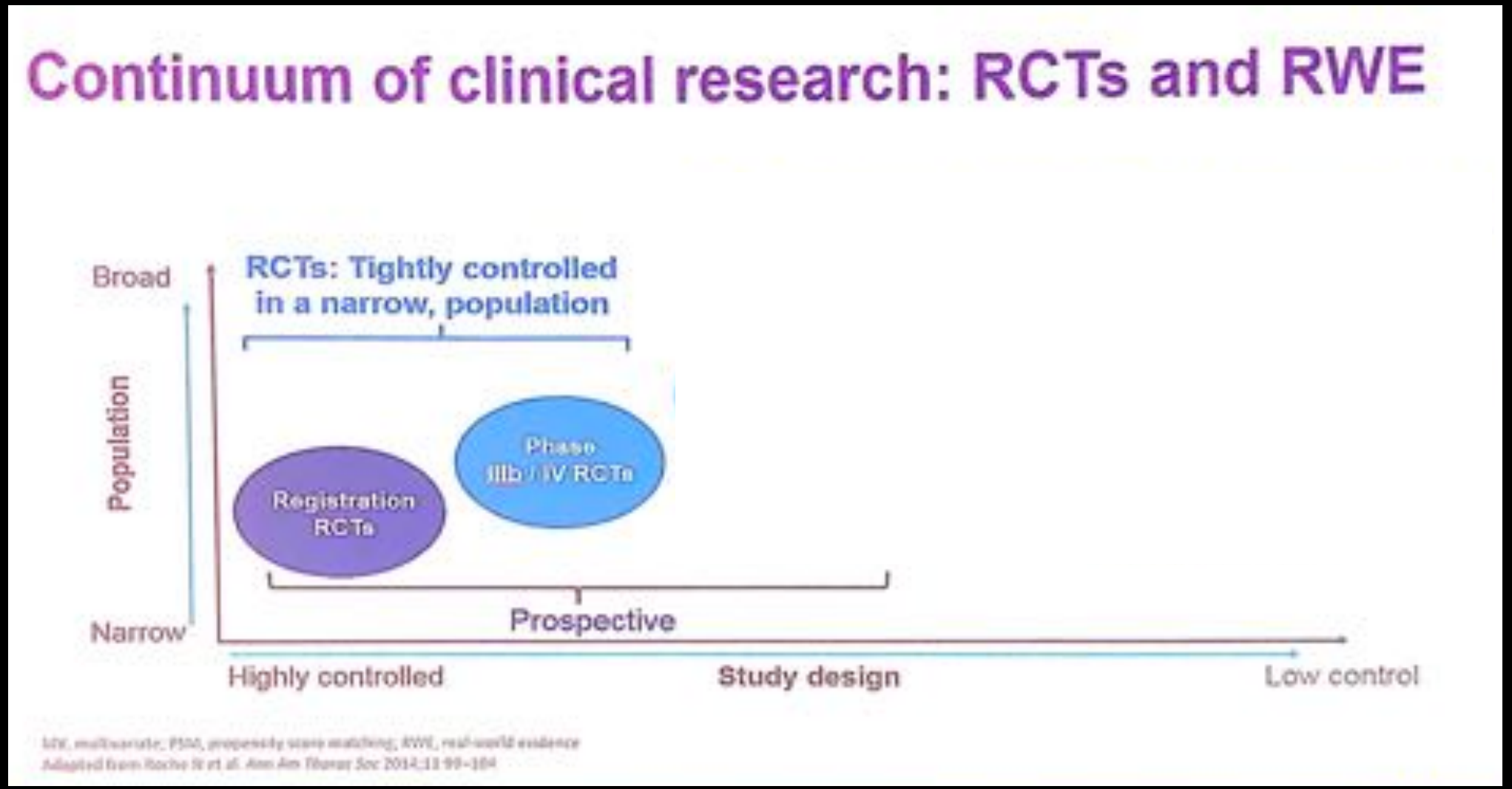
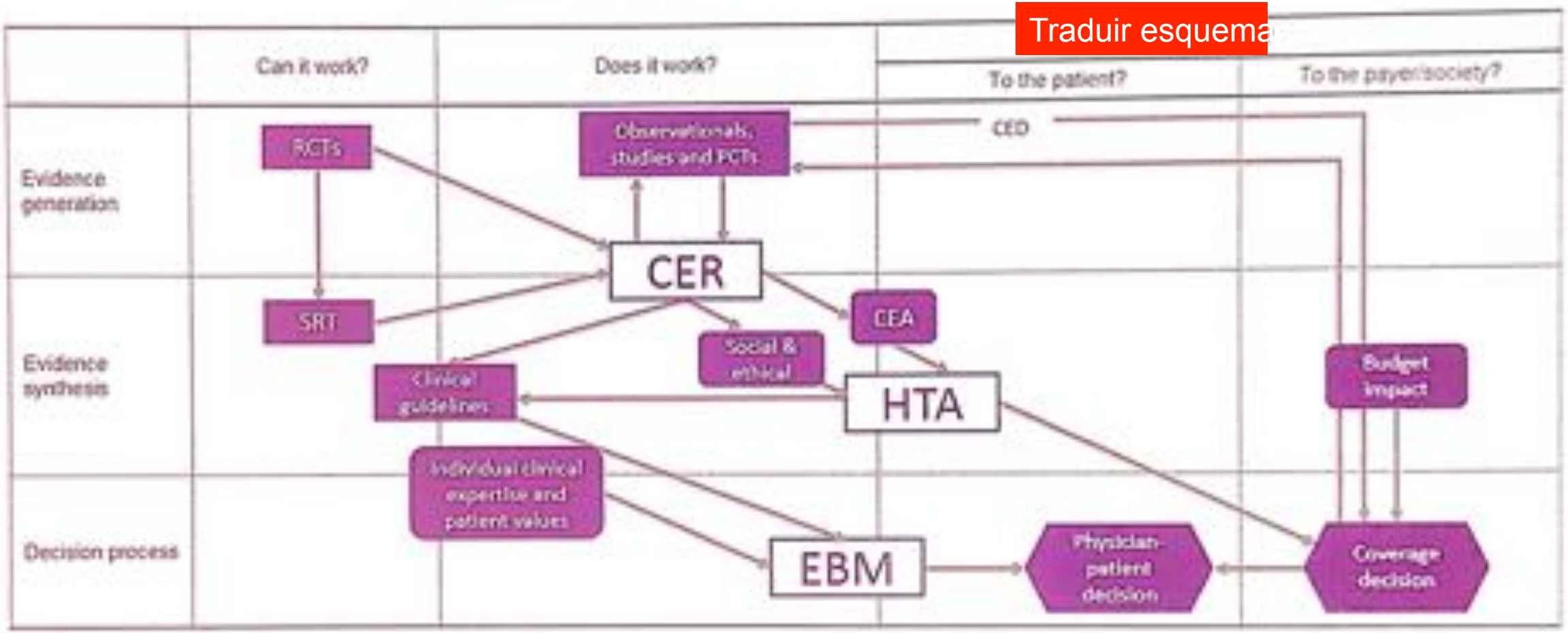


Taxonomy of Evidence

Traduir esquema



RCT = Randomized Controlled Trials; SRT = Systematic Review Trials;
PCT = Pragmatic Clinical Trials; CER = Comparative Effectiveness Research
CEA = Cost-effectiveness Analysis; CED = Coverage with Evidence Development;
EBM = Evidence-based Medicine

UNIVERSITY of WASHINGTON

Recognizing the Limitations of Real-World Evidence

Interesant!!!

- Can be costly to undertake
- Can be complicated to design and execute
  - Medical record abstraction
  - Record linkage
  - What will happen if data analysis becomes simply about pressing a few buttons?
- Can be difficult to interpret and communicate
  - Odds and hazard ratio's instead of NNT or NNH
  - Lots of jargon (e.g. propensity score, et

Recognizing the Limitations of Real-World Evidence

Interesant!!!

- Most significant concern is bias:
  - There is selection bias in treatment decisions and this bias can lead to differences in outcomes unrelated to treatment.
  - Despite sophisticated statistical techniques, bias is never fully taken account – leaving decision makers skeptical of the internal validity of RWE.
  - This is particularly relevant for comparative treatment studies undertaken with observational data.

Advances in RWE methodologies

Interesant!!!

- Strategies can be employed to address the limit
  real-world evidence
- These can include:
  - Appropriate study design
    - Pragmatic RCTs…
  - Matching and statistical adjustment
    - Propensity score matching
  - Machine learning

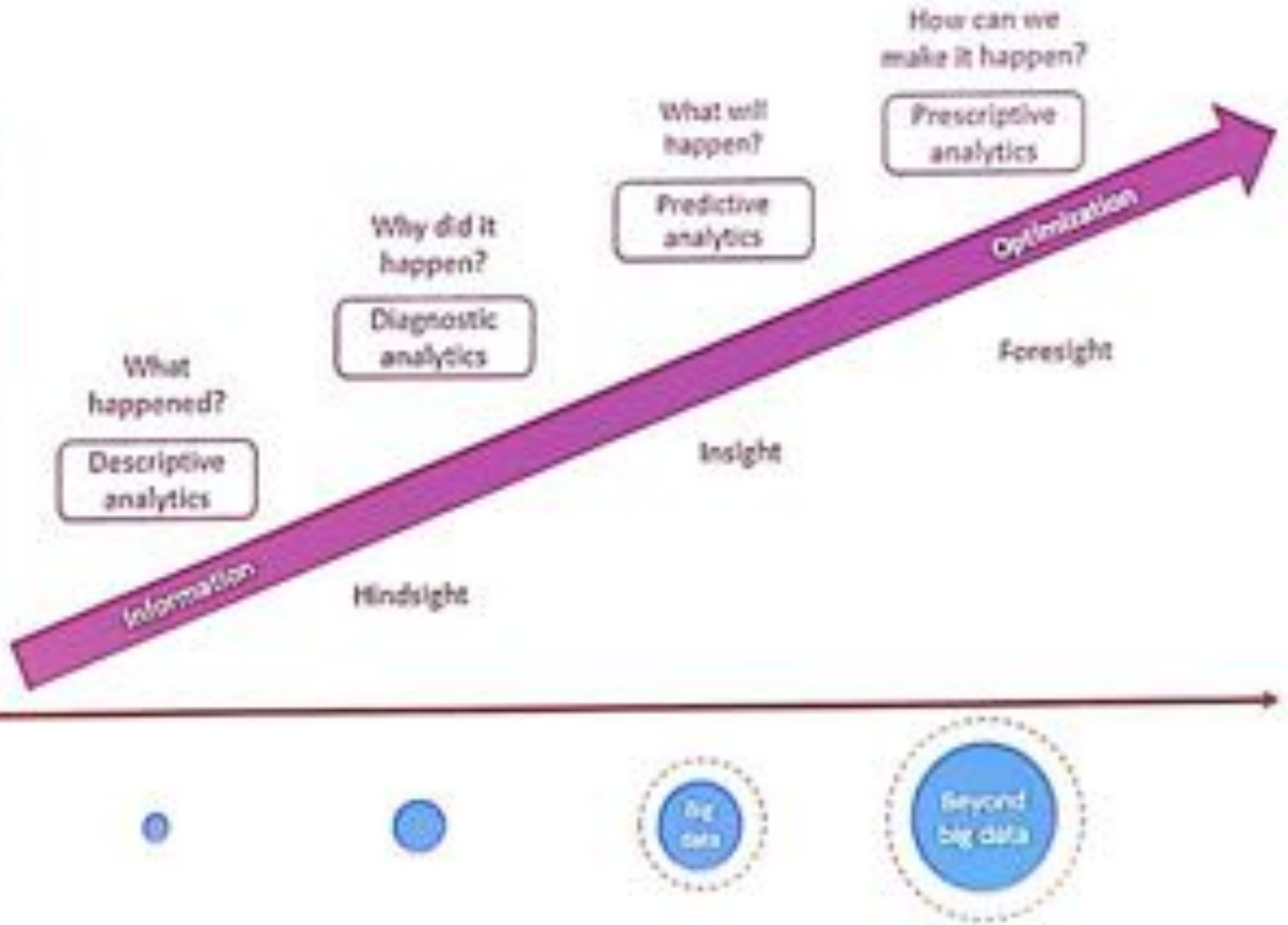
Interesant!!!

Analytics Continuum for Real-World Evidence Approach

Traditional RWE analytics	Machine learning and advanced analytics
Confirm existing hypotheses based on experience or existing data	Generate new hypotheses for clinical or commercial significance
Applies standard statistical methods to compare outcomes between matched patient cohorts	Advanced capability to find for non-obvious patient segments that experience best or worst outcomes
Reduce variability as much as possible by crafting highly controlled patient cohorts	Embraces variability to find a 'signal' across 1000s of variables
Focus on single data source, or network of highly homogeneous data sources, to analyse endpoints that are directly observable in the data	Integrate a range of heterogeneous sources to build complex models for proxy endpoints
Run a linear process executing against a pre-defined research plan	Run an iterative process by refocusing analytical effort to go deeper in areas that are most promising and valuable

Artificial intelligence – big data and analytics

Analytics types



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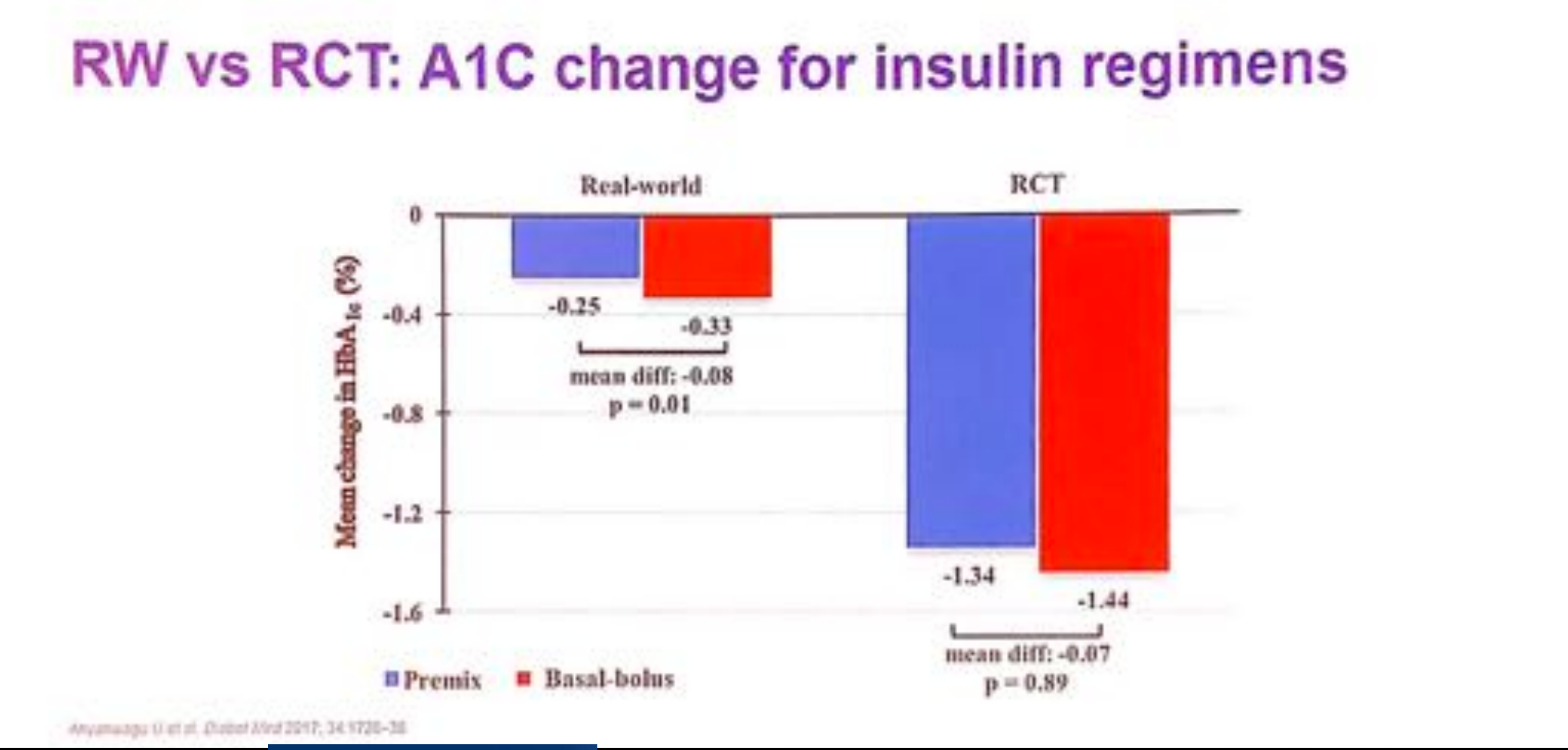

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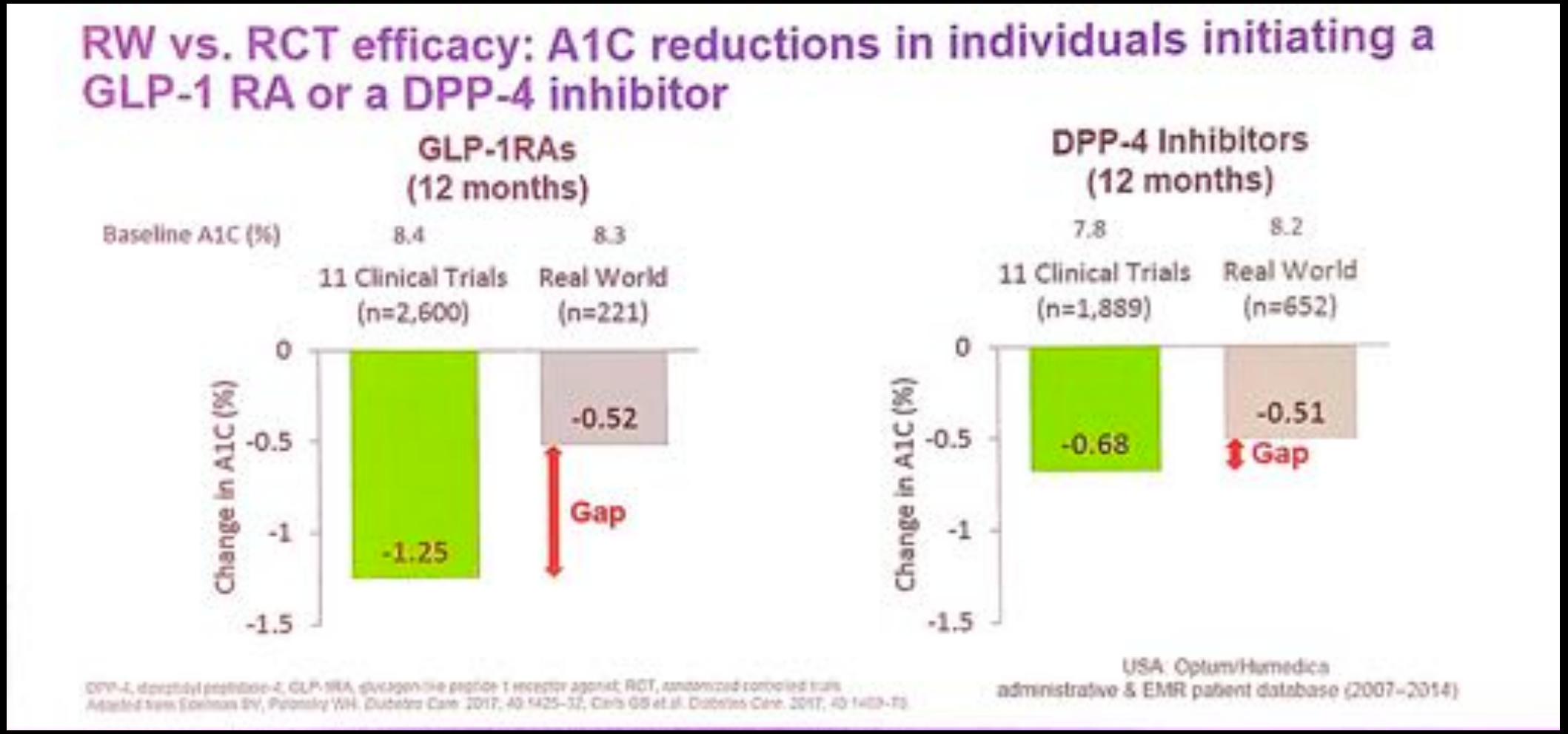

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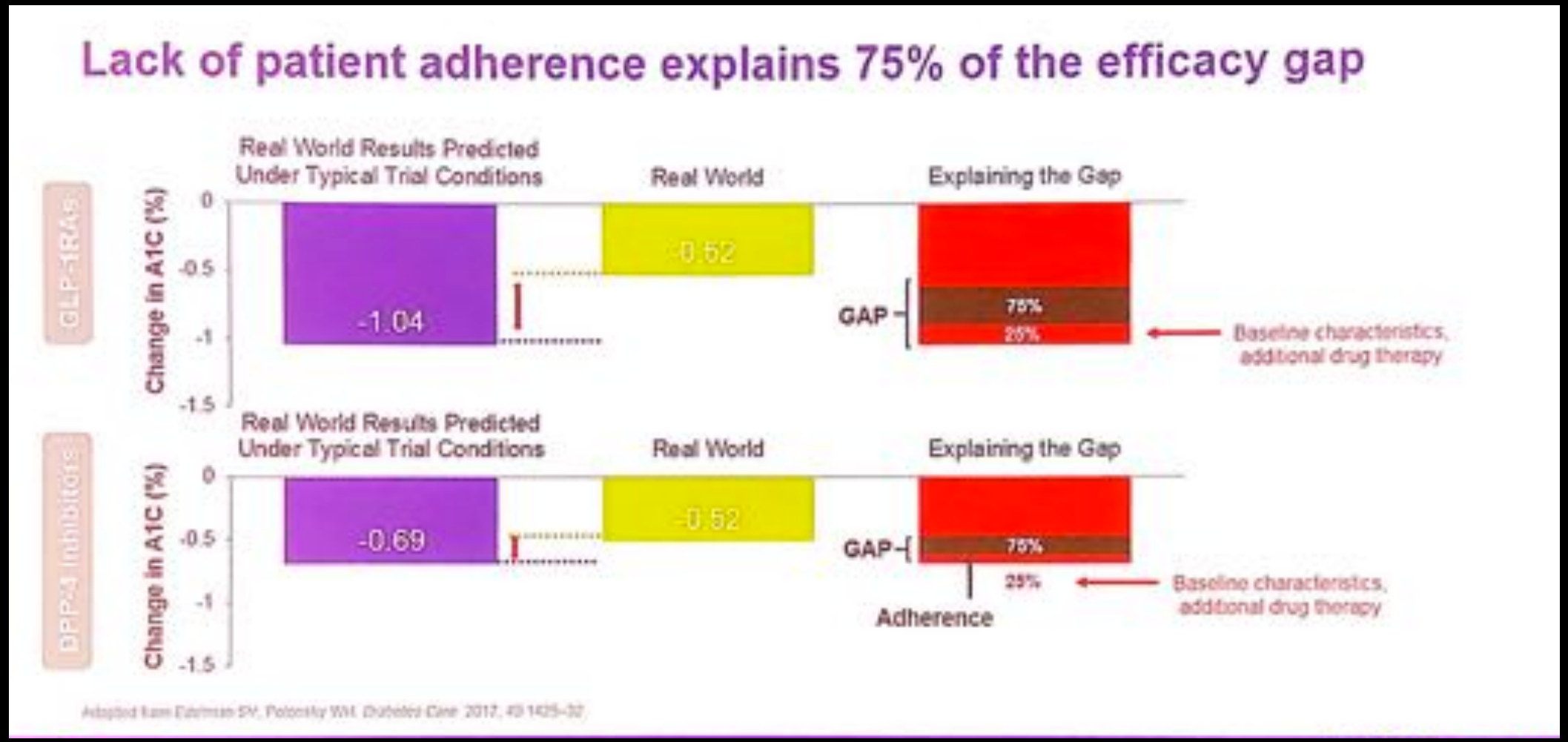


Real-World Evidence in Diabetes

Kamlesh Khunti, Sean D. Sullivan, Timothy S. Bailey, Lawrence Blond, Stewart Harris

Real-World Evidence in Diabetes

Estudio CVD real 2

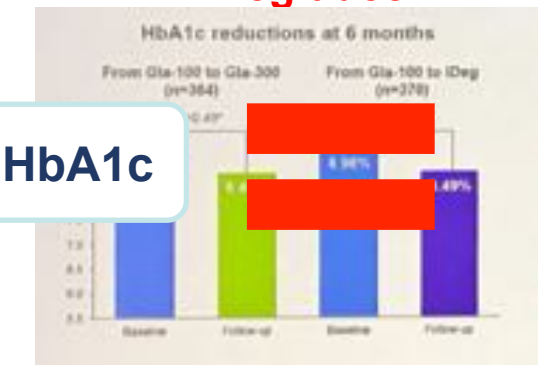
Real world evidence: insulinas de 2ª generación

DELIVER-D: U300 vs Degludec

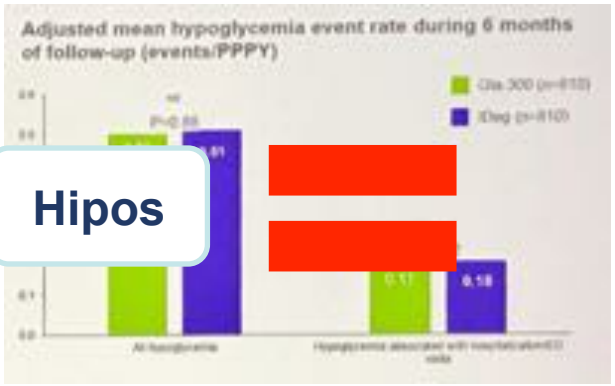
1620 pacientes
Propensity score matching

Glargina U100→ Glar U300 ó Degludec

HbA1c



Hipos

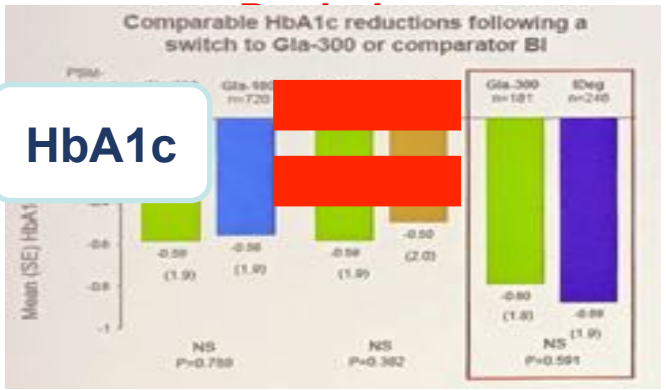


LIGHTNING: U300 vs Degludec

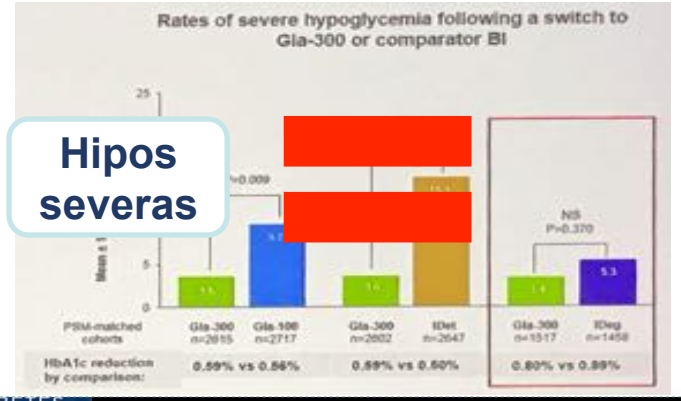
3000 pacientes
Propensity score matching (subestudio)

Glar U100 o Det→ Gla U300 ó

HbA1c



Hipos severas

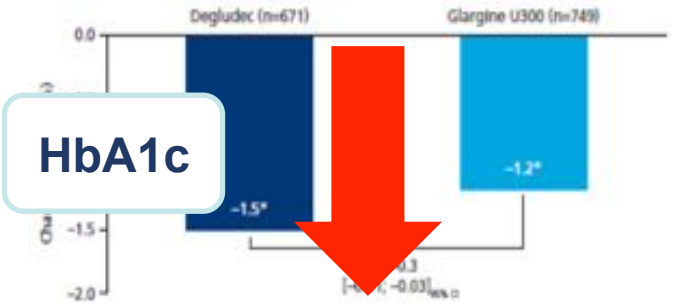


CONFIRM: Degludec vs U300

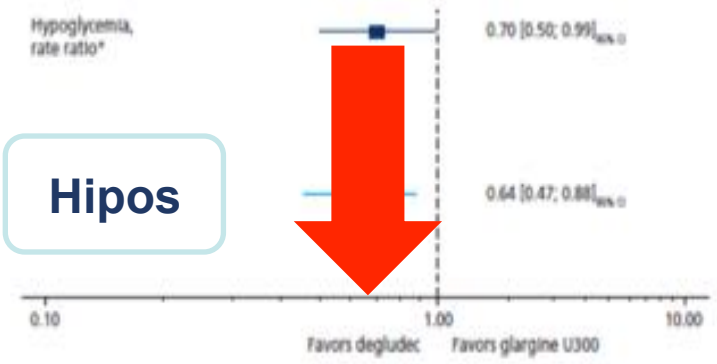
4056 pacientes
Propensity score matching

ADOs → Gla U300 ó Degludec

HbA1c



Hipos



Real-World Evidence in Diabetes

Estudio CVD real 2

El segundo estudio de vida real presentado en formato p.ster fue el CVD- Real 2 que muestra los resultados de eventos CV y muerte tras el inicio de ISGLT2 vs IDPP4.
La poblaci.n objetivo son pacientes adultos con DM2 que iniciaron tratamiento con ISGLT2 o bien con IDPP4.
El estudio cuenta con pacientes de 12 pa.ses, incluido Espa.a con una representaci.n de 11.430 pacientes.
En total 1,7 millones de pacientes cumpl.an los criterios de selecci.n, tras aplicar el propensity score el n.mero de pacientes en cada grupo fue de 181,620.
Durante el seguimiento hubo 4,768 muertes por todas las causas; 1,818 en el grupo de ISGLT-2 (IR 0.83 por 100 personas-a.o) y 2,950 en el grupo IDPP4 (IR 1.33 por 100 personas a.o).
El tratamiento con ISGLT2 comparado con IDPP4 mostr. menor mortalidad por todas las causas as. como por hospitalizaci.n por fallo cardiaco

112-LB Efficacy and Safety of continuing Sitagliptin when Initiating Insulin Therapy in subjects with type 2 Diabetes Mellitus

Objectives

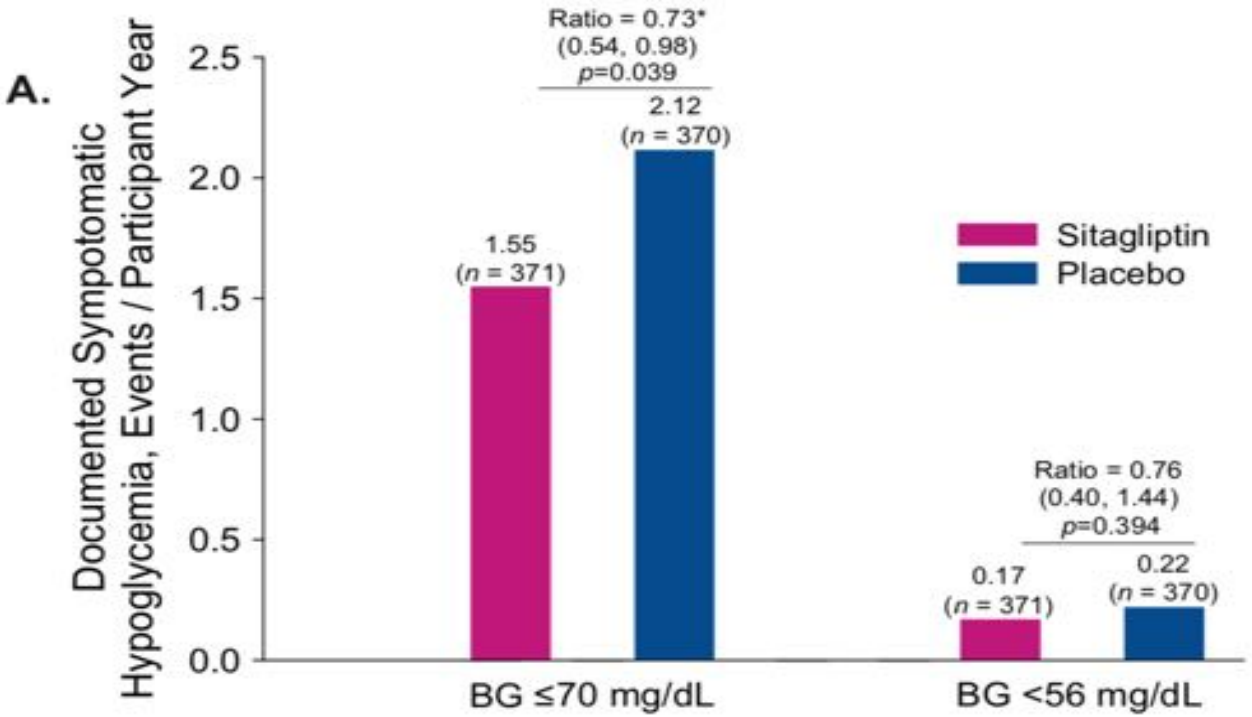
This study was designed to evaluate the impact of continuing the DPP-4i sitagliptin when initiating and intensively titrating insulin glargine on glycemic efficacy and hypoglycemia

Table 1. Baseline Demographic, Anthropometric, and Disease Characteristics

	Sitagliptin *N* = 373	Placebo *N* = 370
Age, years	58.6 ± 9.5	58.1 ± 9.7
Female, *n* (%)	203 (54.4)	180 (48.6)
Body Weight, kg	84.8 ± 19.8	85.6 ± 19.4
BMI, kg/m^2	31.2 ± 5.8	31.1 ± 5.7
A1C, %	8.8 ± 0.9	8.8 ± 1.0
FPG, mg/dL	199.0 ± 50.8	201.2 ± 51.8
eGFR,* ml/min/1.73 m^2	103.7 ± 30.3	106.4 ± 28.1
Duration of type 2 diabetes, years	10.4 ± 6.8	11.1 ± 6.9

Values are mean ± standard deviation unless otherwise noted. BMI=body mass index; FPG=fasting plasma glucose; eGFR=estimated glomerular filtration rate.
*Participants with eGFR <60 mL/min/1.73 m^2 were excluded from the study.

Figure 6. Documented Symptomatic Hypoglycemia Endpoints, Event Rates (A) and Incidences (B)



*Two participants (both in the sitagliptin group) were not included in the analysis value of a model covariate (race); in a post hoc analysis that removed race from the model (thereby allowing the 2 participants to be included), the event rate ratio was 0.76; p=0.073.

MSD

Should Metformin Remain the First-Line Therapy for Type 2 Diabetes?

V. Aroda / A. Cheng

El debate lo inició la Dra. Vanita Aroda a favor de la metformina, en su alegato a favor repasó la evidencia disponible desde los estudios en prediabetes como el DPP hasta los últimos estudios de seguridad cardiovascular como el LEDER, EMPAREG o CVD-REAL donde la metformina estaba presente en aproximadamente el 70-80% de los pacientes. También recordó beneficios adicionales de la meformina.
Recordó que su uso está apoyado desde el 2006 momento de la aparición del primer algoritmo del manejo de la DM2 de la ADA/EASD. La metformina sigue siendo la primera opción basándose en su eficacia, seguridad, coste y beneficio cardiovascular.
Posteriormente llego la réplica para la Dra. Alice Cheng, quien antes de iniciar su ponencia expresó que ella también está a favor de la metformina pero no como primer escalón. Para ello expuso las cinco razones por las que la metformina no debería de ser el primer escalón.
Destacó que a diferencia de otros hipoglucemiantes la metformina solo tiene dos sitios de acción, no mejora los parámetros metabólicos como el peso, la presión arterial o el perfil lipídico, no tiene beneficio a nivel renal, ni cardiovascular y que tampoco disminuye la mortalidad.
En tiempo de preguntas ambas estuvieron de acuerdo que probablemente lo que se necesite sea ser más agresivo inicialmente y emplear conjuntamente con la metformina fármacos que tengan beneficios adicionales.

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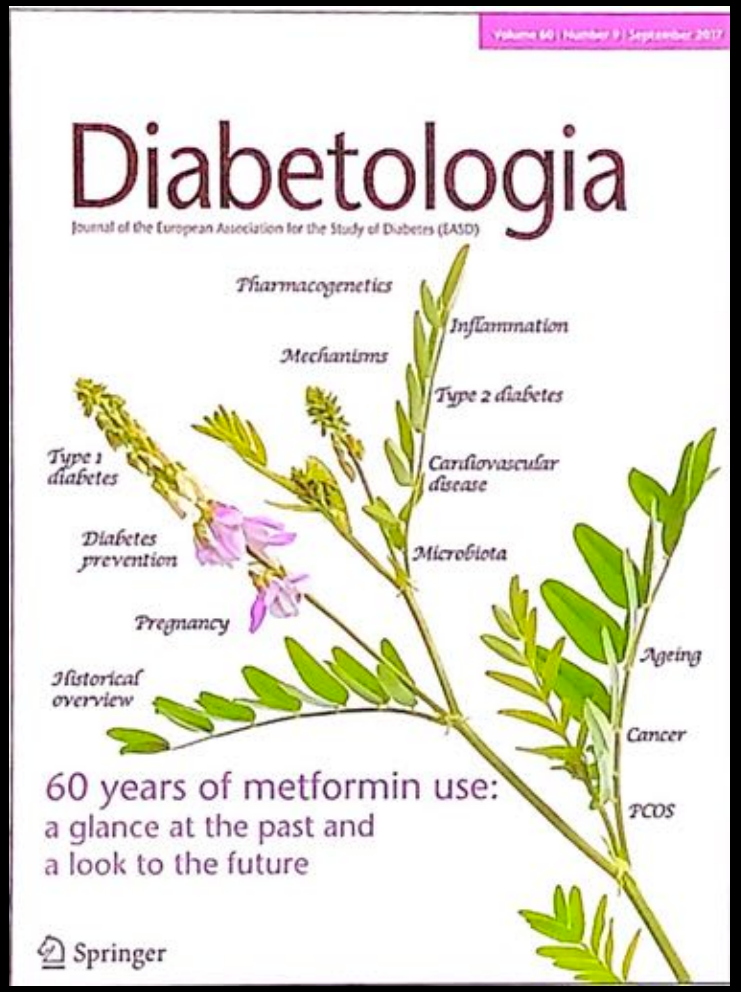


Should Metformin Remain the First-Line Therapy for Type 2 Diabetes?

V. Aroda / A. Cheng

Razones para continuar con metformina

1. Eficacia en **control glucémico**
2. Efecto sobre el **peso**: neutro/↓
3. Ausencia de **hipoglucemias**
4. Buen perfil de **seguridad**
5. Bajo **coste**

- Beneficio cardiovascular (UKPDS)
- 73-80% pacientes en estudios con beneficio CV tenían tto con metformina de base
- Plausibilidad biológica

5 razones para "romper" con la metformina

Otros fármacos pueden:

1. Mecanismo **fisiopatológico**: actuar a más niveles
2. Más allá de HbA1c: beneficio en **otros parámetros metabólicos** (peso, TA, perfil lipídico…)
3. Beneficios **microvasculares** (nefropatía)
4. Beneficios **macrovasculares**
5. **Mortalidad**

Cardiovascular Outcomes Trials (CVOTs) in Diabetes—Shall We Continue or Change Course?

Steven P. Marso, Darren K. McGuire

- MARSO, reforzo lo que hemos aprendido gracias a los ESCV.
- McGUIRE, La necesidad de redefinir el diseño de estos estudios (son muy costosos sobre todo si solo aportan seguridad (no beneficio), falta la generalizacion y limitados a 5 años.

PROPUESTAS

- Poblacion: prevencion 1º,IC, Obesidad, No diabetes
- Objetivo principal: MACE 3 puntos, otros ECV (IC, angina inestable, revascularizacion) progresion de ERC, perdida de peso.
- Comparacion: Farmaco qu ehaya demostrado beneficio CV: Lira, sema, empa , cana, no PBO

Prioritizing Injectable Therapies in Type 2 Diabetes

xxxxxxx

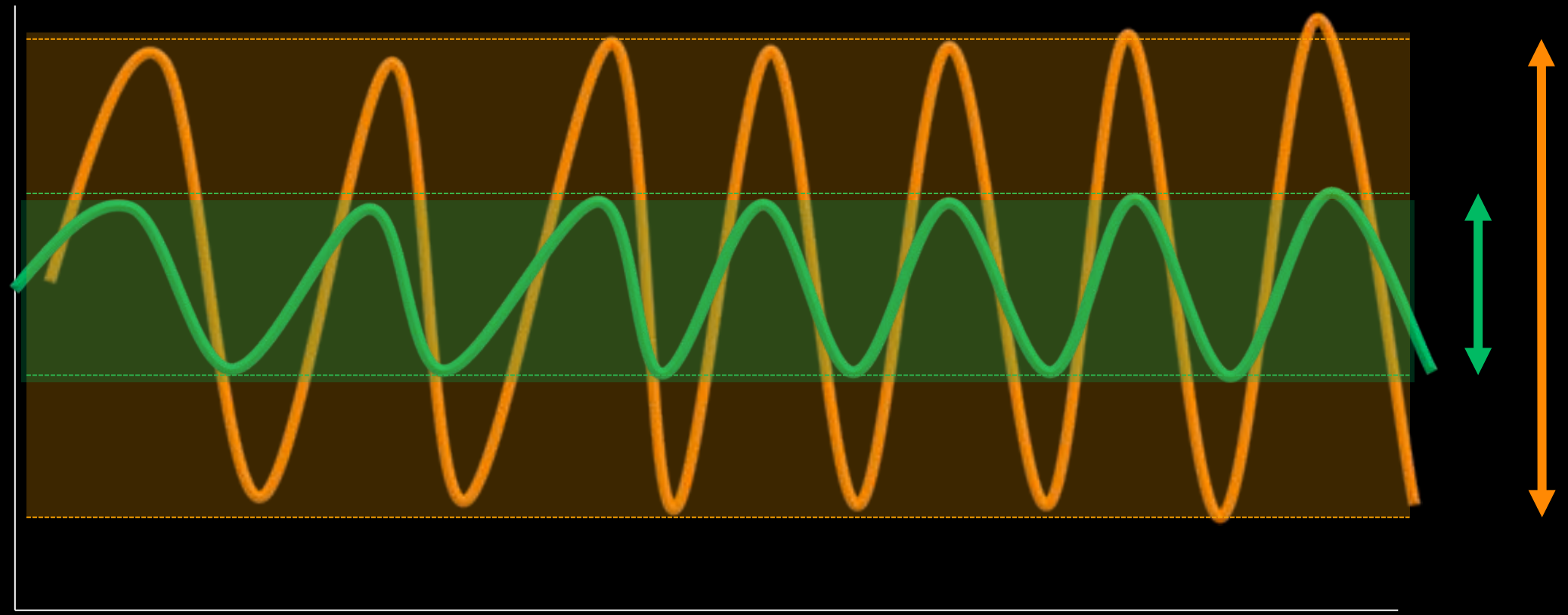
- La utilización del CGM en DM2 con insulina mostró A1c ↓ 0,8%
- Permitía una monitorización mas estrecha de las hipoglucemias, hasta un 21% DM2 con insulina con hipoglucemias severas
- DM2 FFOO A1c ↓ 0,3% (Malanda 2012) , mejora de adherencia al tto y observar el impacto delcambio de plan terapéutico.
- Posible beneficio en algunos personas del autocontrol y ajuste de los estilos de vida (alimentación)
- Coste elevado que limita su uso dados los beneficios terapeuticos discretos en DM2 con FFOO
- Necesidad de programas de educación que permitan a pacientes y sanitarios la comprensión y potencial actitud frente a los resultados del lector

The New World of Glucose Monitoring

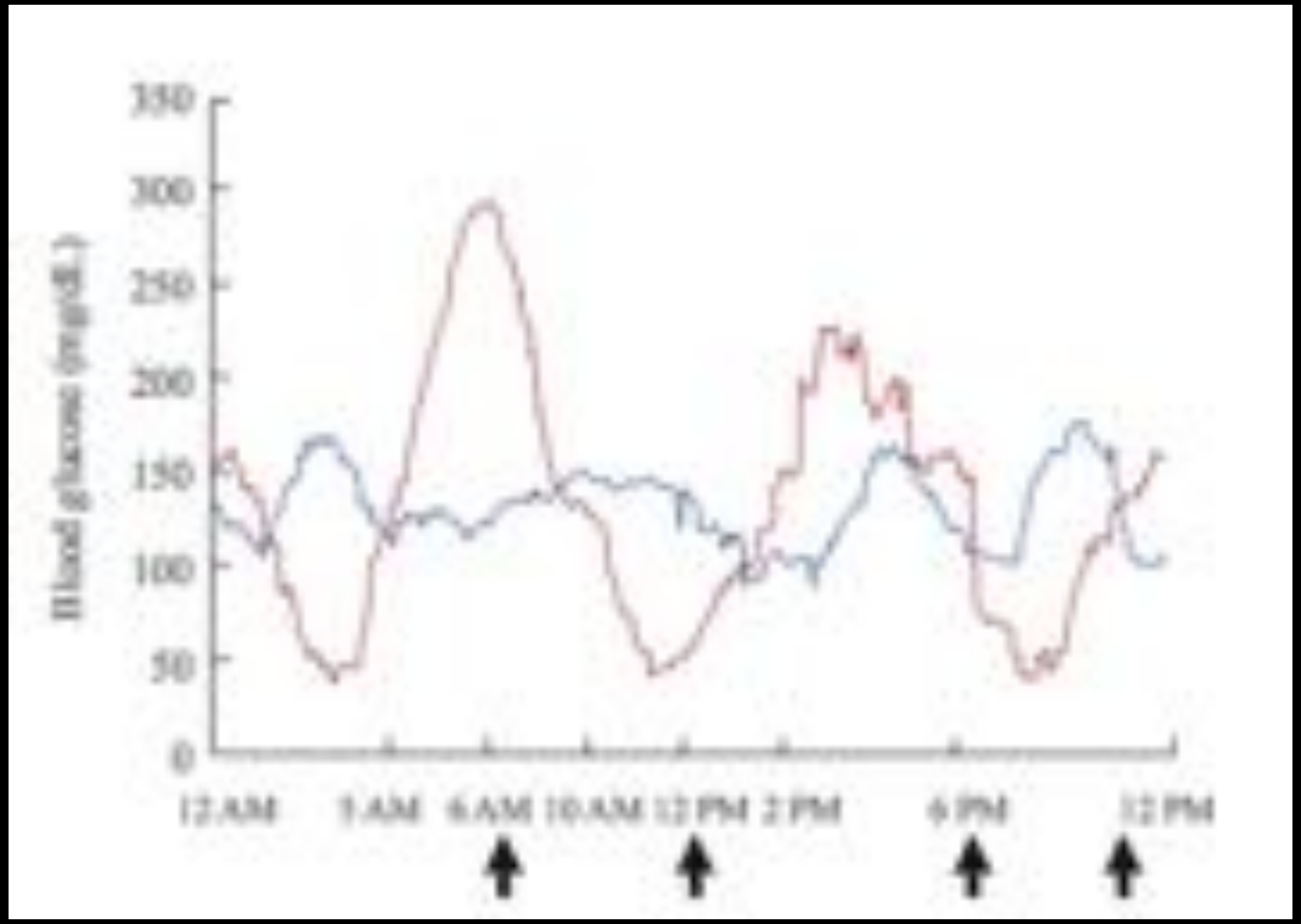
Alison Evert, MS, Mary Johnson, RN, Patricia Knutsen RN, Margaret Pellizzari MS

- El valor de A1c és el “gold standard”
- Importancia de dispossar d’altres parametres que permetin determinar el comportament glucemic (correlació alimentació i act. Física)
- CGM intermitent /CGM profesional
- Standardització dels resultats

Variabilidad glucémica



Variabilidad glucémica



Paciente A

Paciente B

HbA1c similar
Variabilidad diferente

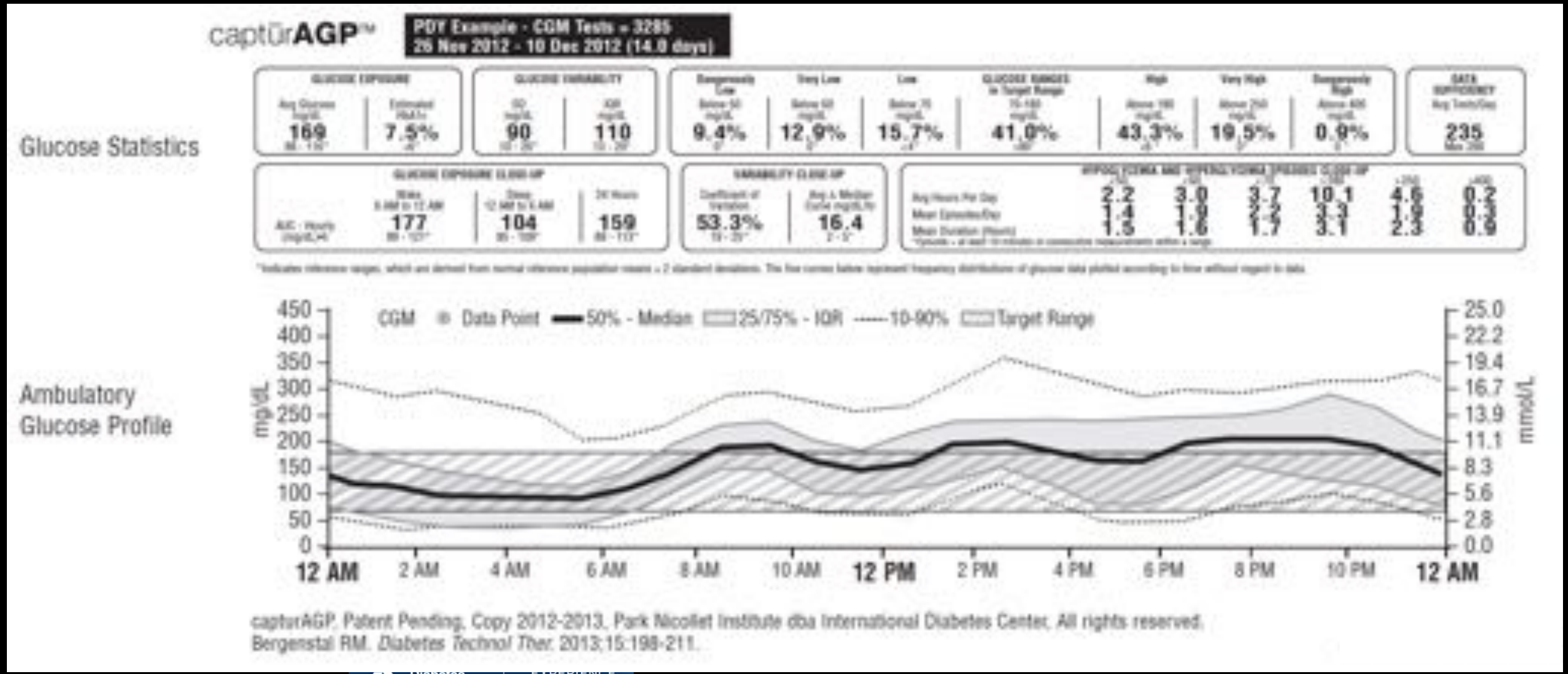
Jung HS. Clinical Implications of Glucose Variability: Chronic Complications of Diabetes. Endocrinol Metab (Seoul) . 2015 Jun;30(2):167-74

The New World of Glucose Monitoring

Alison Evert, MS, Mary Johnson, RN, Patricia Knutsen RN, Margaret Pellizzari MS

Glucose Statistics

Ambulatory Glucose Profile



Bergenstal RM. *Diabetes Technol Ther.* 2013;15:198-211.

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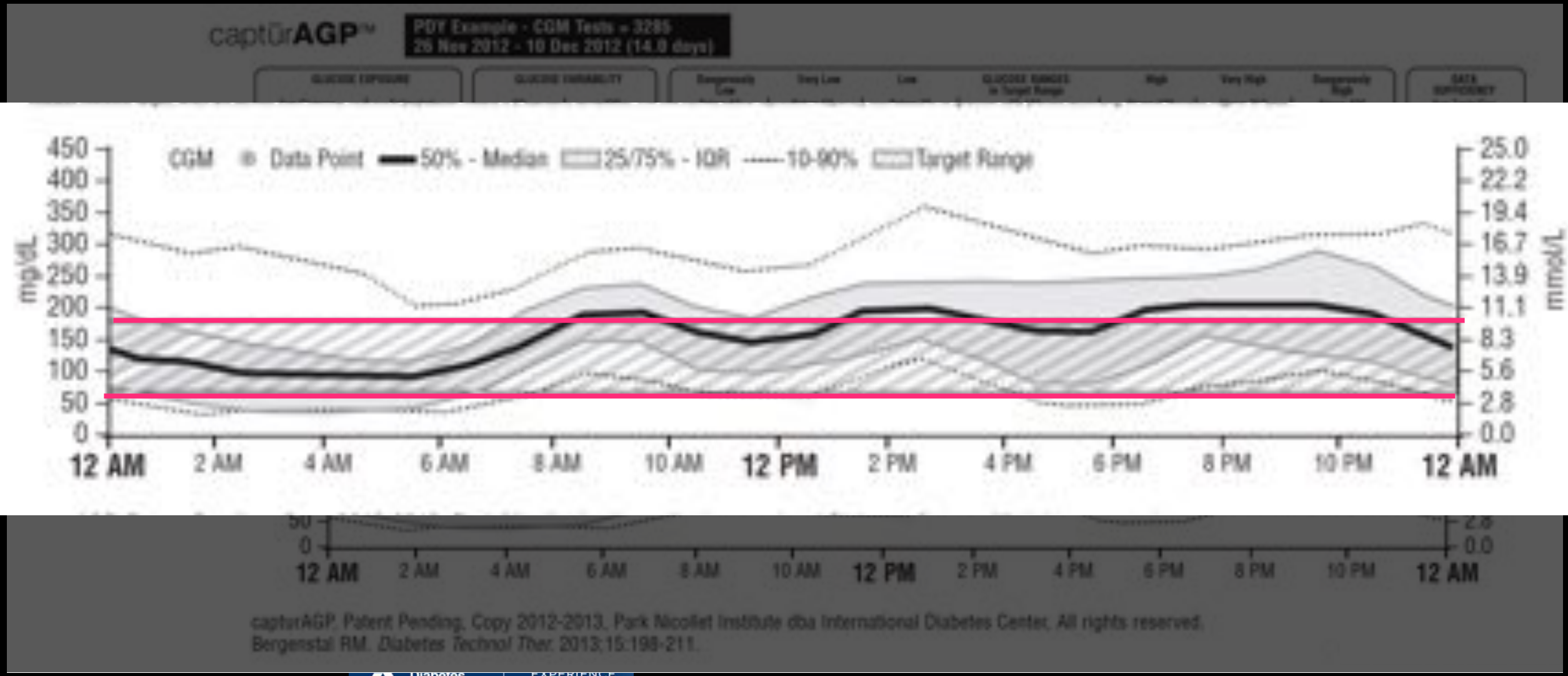

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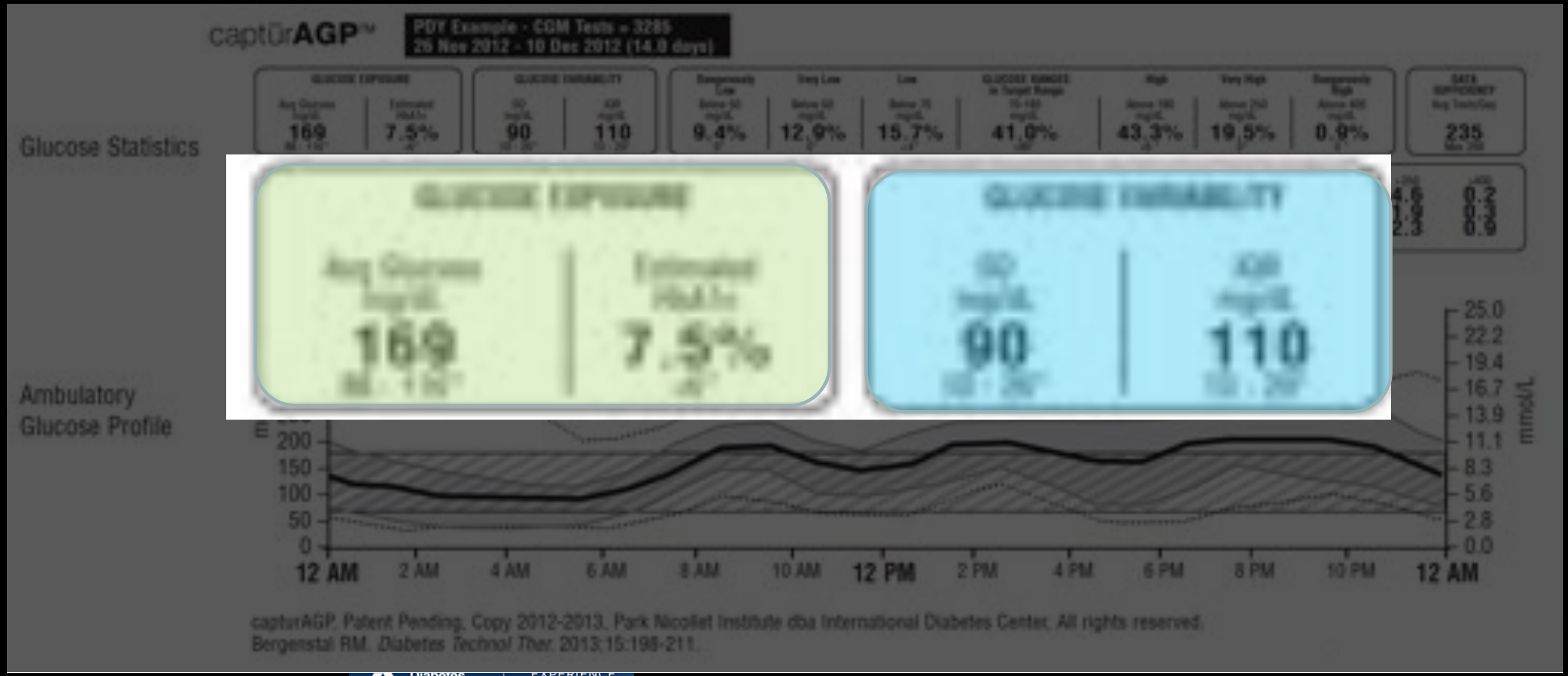

The New World of Glucose Monitoring

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- CGM intermitent /CGM profesional
- Standardització dels resultats
- “ 9 pases per interpretar Registres glucèmics ambulatoris”

The New World of Glucose Monitoring

Alison Evert, MS, Mary Johnson, RN, Patricia Knutsen RN, Margaret Pellizzari MS

“ **9 pases** per interpretar registres glucèmics ambulatoris”

1. Use adequate data (at least **10 days** of measures)
2. “**mark it up**”—meaning edit with meal notations, vacation, snacks, exercise, etc.;
3. Ask the patient “what do you see?” and most importantly, **LISTEN**
4. Identify patterns of **hypoglycemia**
5. Identify patterns of **hyperglycemia**
6. Identify areas of wide glycemic **variability**
7. Compare to past AGPs**, reinforcing** successful **behaviors**
8. Agree on an **action plan** together
9. **Provide** the patient **a copy** and include it in the electronic health record.

Poster Sesion. Real-World Evidence in Diabetes

Diabetes Treatment In T2DM Patients With Renal Disease: How Many Are Receiving Contraindicated Drugs?

Josep Franch Nadal[1,2,3], Manel Mata-Cases[1,2,4], Jordi Real[1,5], Marta Cedenilla[6], Karine Ferreira de Campos[6], Antón Gómez[6], Dídac Mauricio[1,2,7].

SIDIAP

Table 1. Clinical and demographic caracteristics of patients with T2DM and CKD

T2DM patients with CKD (N=122,996)	
Mean age, years (SD)	76.1 (10.9)
Gender (female) %	48.5%
Mean duration of T2DM years [95%CI]	10.9 [6.1;14.0]
Smoking status	
Non smoker, %	58.2%
Smoker, %	10.8%
Former smoker, %	31.0%
Mean blood pressure (SBP/DBP), mmHg (SD)	134 (14.7) /73.0 (10.1)
Mean BMI, kg/m^2 (SD)	30.0 (5.3)
Mean HbA1c, % (SD)	7.2 (1.4)
Lipid profile	
Mean total cholesterol, mg/dL (SD)	177 (40.9)
Mean LDL-c, mg/dL (SD)	97.8 (32.5)
Mean HDL-c, mg/dL (SD)	47.6 (13.0)
Mean total cholesterol, mg/dL (SD)	177 (40.9)
Treatment class	
Metformin	60.4%
DPP4-i	19.7%
SUs	18.6%
SGLT2i	2.1%
Insulin	30.2%

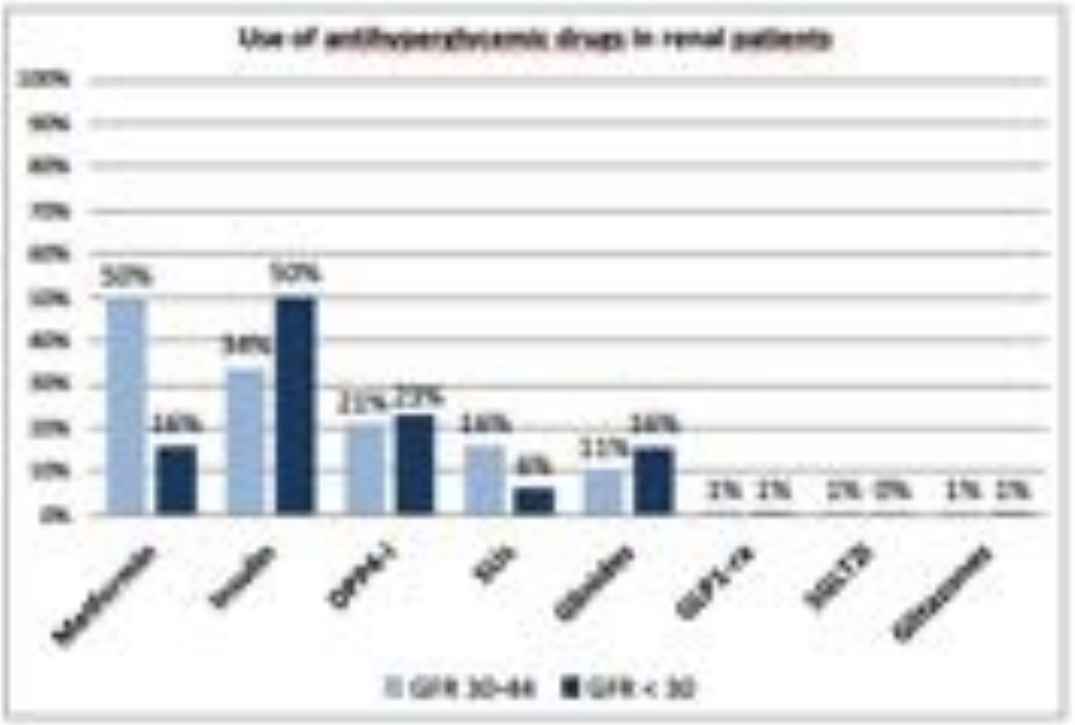


Figure 1. Use of antihyperglycemic agents among T2DM patients with eGFR 30-44 and eGFR <30 mL/min/1.73m^2

Póster nº 1647

MSD

Symposium. ADA/ASN, Management of DKD

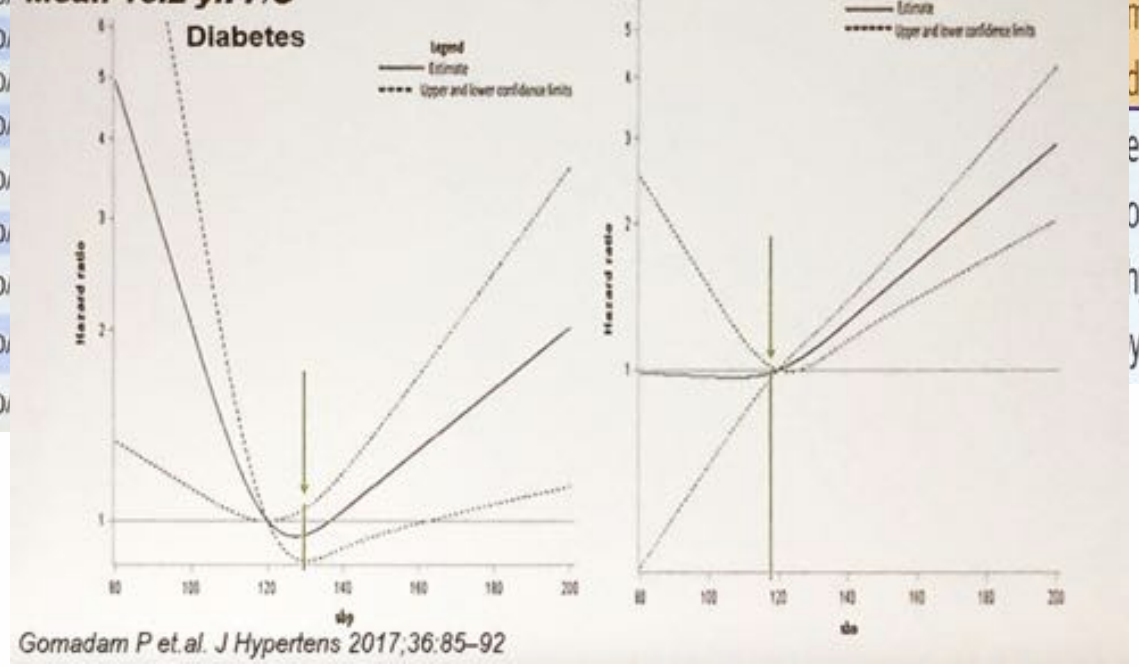
Ponente G Bakris

What is the Goal BP and Initial Therapy in Kidney Disease or Diabetes to Reduce CV Risk?

Group	Goal BP (mmHg)	Initial Therapy
ADA (2018)	<140/90 risk <13	
ACC/AHA BP (2017)	<130	
KDIGO/KDOQI (NKF) (2013)	<140	
2014 Expert Panel Report (2013)	<130	
KDOQI (NKF) (2004)	<130	
JNC 7 (2003)	<130	
Am. Diabetes Assoc (2003)	<130	
Canadian HTN Soc. (2002)	<130	
Am. Diabetes Assoc (2002)	<130	
Natl. Kidney Foundation (2000)	<140	
British HTN Soc. (1999)	<140	
JNC VI (1997)	<130	

Adjusted cubic spline model of the association between hazard ratio and SBP of persons with and without diabetes mellitus

N=17,650 NHANES III +
1439 DM Heart Study TOTAL-19,089
Mean 16.2 yr. F/U



Gomadam P et.al. J Hypertens 2017;36:85–92

The ADA recommendations distinguish BP thresholds used to diagnose hypertension from those used as treatment targets,[1,2] as ...sh hemoglobin A_{1c} thresholds used to diagnose dia- ...se used as treatment targets.[9] With this view, there ...nale to change the BP thresholds used to define hy- ...m 140/90 mm Hg or higher (as recommended in ADA ...d others) to 130/80 mm Hg or higher (as recom- ...e ACC/AHA guidelines).[3] Among people with diabe- ...other conditions with high cardiovascular risk, the ...hypertension is already high and would not increase ...y applying lower BP thresholds. Rather, most adults

MSD

VADT at 15 years_ acute and chronic complications

VADT at 15 years_ acute and chronic complications

- **Surveys:**

Anualmente: QOL, MACE, otros (visión, cirugía ocular, diálisis, tx renal)

- **Chart reviews:**

IAM, ictus, amputaciones

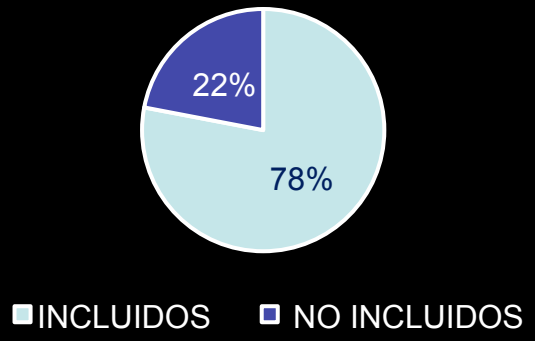
SECONDARY OUTCOMES:
Major outcome (primary + enf renal + amputación no traumática)
- Muerte CV
- Cualquier causa de muerte

OTROS OUTCOMES:
- **QOL, hospitalización, enf renal, eventos oculares**

N Engl J Med 2015;372:2197-206.

VADT at 15 years_ acute and chronic complications

OTHERS OUTCOMES



Análisis por intención de tratar

Media de seguimiento para mortalidad total = 15 años
Media de seguimiento para primary outcome = 13,6 años

Análisis de confusores: riesgo CV basal, historia de ECV, duración de la DM.

PRIMARY OUTCOME: objetivo compuesto	HR 0,91 (0,78, 1.06), p = 0,23	
SECONDARY OUTCOMES	No ES	
OTROS OUTCOMES	No ES	*fotocagulación, vitrectomía, inyecciones intravítreas= retinal event composite → p= 0,053 (ninguno de los endpoint ES por separado)*

VADT at 15 years_ acute and chronic complications

	Media 5,6 años	Media 9,8 años	Media 13,6 años
HBA1c	1,5%	1%	0,7%
Retención	85,5%	92,4%	92,4%
DM & CV drugs	Insulina, SU, TZD, acarbosa (intensivo)	TZD, acarbona, antiHTA (intensivo)	No dif
GLP1/iSGLT2	N/A	Low (2012)	Desconocido (2016)
Primary outcomes	IAM, ictus, muerte CV, insuf cardíaca, amputación, cirugía CV, enf arterial coronaria no operable	IAM, ictus, muerte CV, insuf cardíaca, amputación	IAM, ictus, muerte CV, insuf cardíaca, amputación
Incidencia	5% al año	5% al año	1,3% al año
HR (95%)	**0,88 (0,74- 1,05)**	**0,83 (0,70-0,99)**	**0,91 (0,708-1,06)**

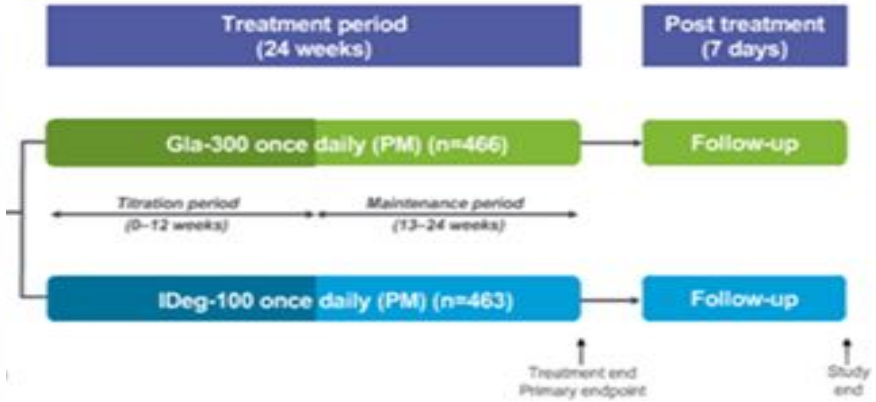
BRIGHT study

Preventing and treating hypoglycemia

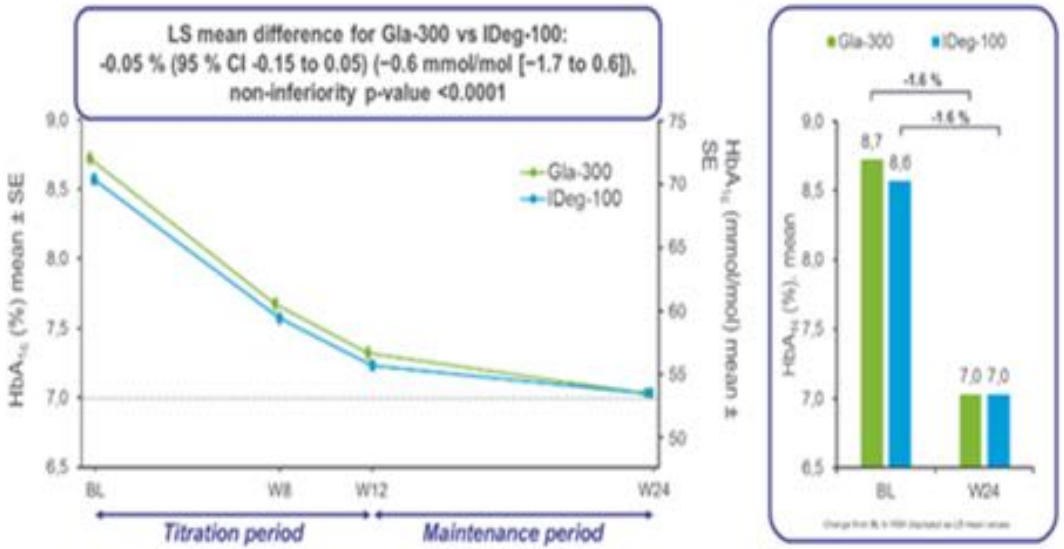
Glargina U300 vs Degludec en DM2 "naive" para insulina

BRIGHT

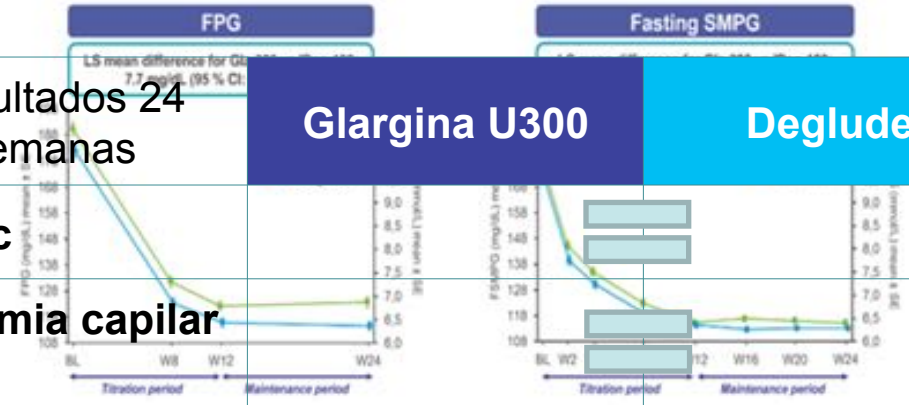
60 años
Duración DM 10 a
IMC 31 kg/m²
HbA1c 8.7%
46% ≥2 ADOs



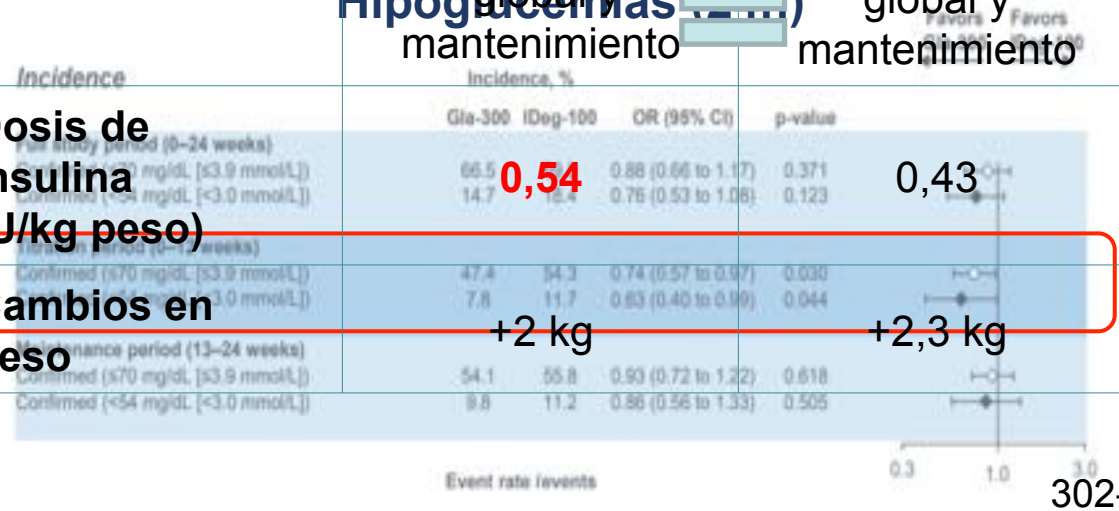
HbA1c =



Glucemia capilar basal =



Resultados 24 semanas	Glargina U300	Degludec
HbA1c		
Glucemia capilar basal	↓ titulación	• ↓ titulación
Hipoglucemias	**↓ hipoglucemias en p. titulación con Glargina U300**	
	Hipoglucemias (...) global y mantenimiento	global y mantenimiento
Dosis de insulina (U/kg peso)	**0,54**	0,43
Cambios en peso	+2 kg	+2,3 kg



302-OR

Introduction

- Second-generation basal insulin analogs, Gla-300 and IDeg-100, have smoother PK/PD profiles than Gla-100[1,2]
- Gla-300 and IDeg-100 both provide similar HbA_{1c} reductions to Gla-100 but with less hypoglycemia in people with T2DM[3,4]
- However, direct clinical comparisons between these two second-generation basal insulin analogs are not available

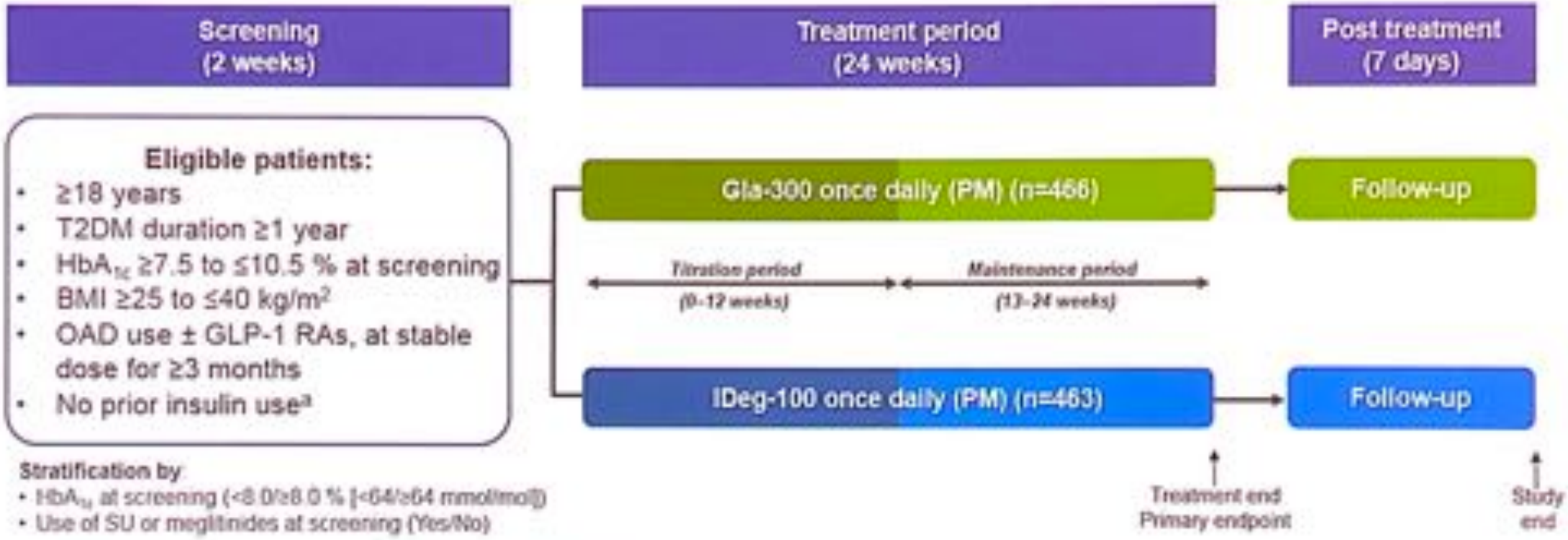
The BRIGHT study was the first head-to-head RCT designed to compare the efficacy and safety of Gla-300 with IDeg-100 in participants with T2DM

Gla-300, insulin glargine 300 U/mL; GLP-1 RAs, glucagon-like peptide-1 receptor agonists; IDeg-100, insulin degludec 100 U/mL; PK/PD, pharmacokinetic/pharmacodynamic; RCT, randomized controlled trial; T2DM, type 2 diabetes

1. Becker RH, *et al. Diabetes Care* 2015;38:637-643. 2. Heise T, *et al. Diabetes Obes Metab* 2012;14:859-864. 3. Ratner RE, *et al. Diabetes Obes Metab* 2013;15:175-184. 4. Ritzel R, *et al. Diabetes Obes Metab* 2015;17:859-867.

Study design

- Multicenter, open-label, 1:1 randomized, active-controlled, 2-arm parallel-group, non-inferiority study in adult participants with uncontrolled T2DM



[a]With the exception of a maximum of 8 consecutive days or 15 days total prior insulin use

BMI, body mass index; Gla-300, insulin g ptide-1 receptor agonist; IDeg-100, insulin degludec 100 U/mL; OAD, oral antihyperglycemic drug; SU, s

BRIGHT

Insulin dosing and titration

- Gla-300 and IDeg-100 were self-administered once daily between 18:00 and 20:00 h
- Starting daily doses (as per labeling) were: Gla-300, **0.2 U/kg**; IDeg-100, **10 U**
- Titrated weekly[a] to a fasting SMPG target of **80–100 mg/dL (4.4–5.6 mmol/L)** without hypoglycemia:

Median[b] fasting SMPG, mg/dL (mmol/L)	Gla-300 and IDeg-100 dose change
>140 (>7.8)	+6 U
>120–≤140 (>6.7–≤7.8)	+4 U
>100–≤120 (>5.6–≤6.7)	+2 U
≥80–≤100 (≥4.4–≤5.6)	**0**
<80 (<4.4) or 1 symptomatic confirmed hypoglycemia episode in preceding week	−2 U or at investigator's discretion

- Titration was performed with the aim of target achievement within 8 to 12 weeks post randomization (titration period)

[a]Doses titrated at least weekly, but no more than every 3 days; [b]From last 3 measurements
Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; SMPG, self-monitored plasma glucose

BRIGHT

Pre-defined study endpoints

Primary efficacy endpoint:

- **Change in HbA_{1c} from baseline to week 24**
  - Analyzed using a MMRM approach, adjusted for covariates including baseline HbA_{1c}
  - Non-inferiority margin was 0.3 % (HbA_{1c} units)

Secondary efficacy endpoints included:

- Change in FPG, fasting SMPG and 8-point SMPG profiles from baseline to week 24
- Variability of 8-point SMPG profiles

Safety endpoints included:

- Incidence and annualized rates of confirmed hypoglycemia (≤70 and <54 mg/dL) over the full 24-week period, and during weeks 0–12 (titration period) and weeks 13–24 (maintenance period)
- TEAEs

FPG, fasting plasma glucose; MMRM, mixed model for repeated measurements; SMPG, self-monitored plasma glucose; TEAE, treatment-emergent adverse event

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BRIGHT

Baseline characteristics were similar between treatment groups

	Gla-300 (n=466)	IDeg-100 (n=463)
Age, years	60.6 ± 9.6	60.5 ± 9.8
Sex (male/female), n (%)	247/219 (53.0/47.0)	252/211 (54.4/45.6)
BMI, kg/m^2	31.7 ± 4.3	31.3 ± 4.4
Known T2DM duration, years	10.5 ± 6.1	10.7 ± 6.5
HbA_{1c}		
%	8.7 ± 0.8	8.6 ± 0.8
mmol/mol	71.7 ± 9.1	70.2 ± 8.7
Fasting plasma glucose		
mg/dL	191 ± 49	182 ± 51
mmol/L	10.6 ±2.7	10.1 ±2.9
Fasting SMPG		
mg/dL	178 ± 41	172 ± 38
mmol/L	9.9 ± 2.3	9.5 ± 2.1

Randomized population. Data expressed as mean ± SD unless stated otherwise.
BMI, body mass index; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; SD, standard deviation; SMPG, self-monitored plasma glucose; T2DM, type 2 diabetes

BRIGHT

Background therapy use was similar between treatment groups

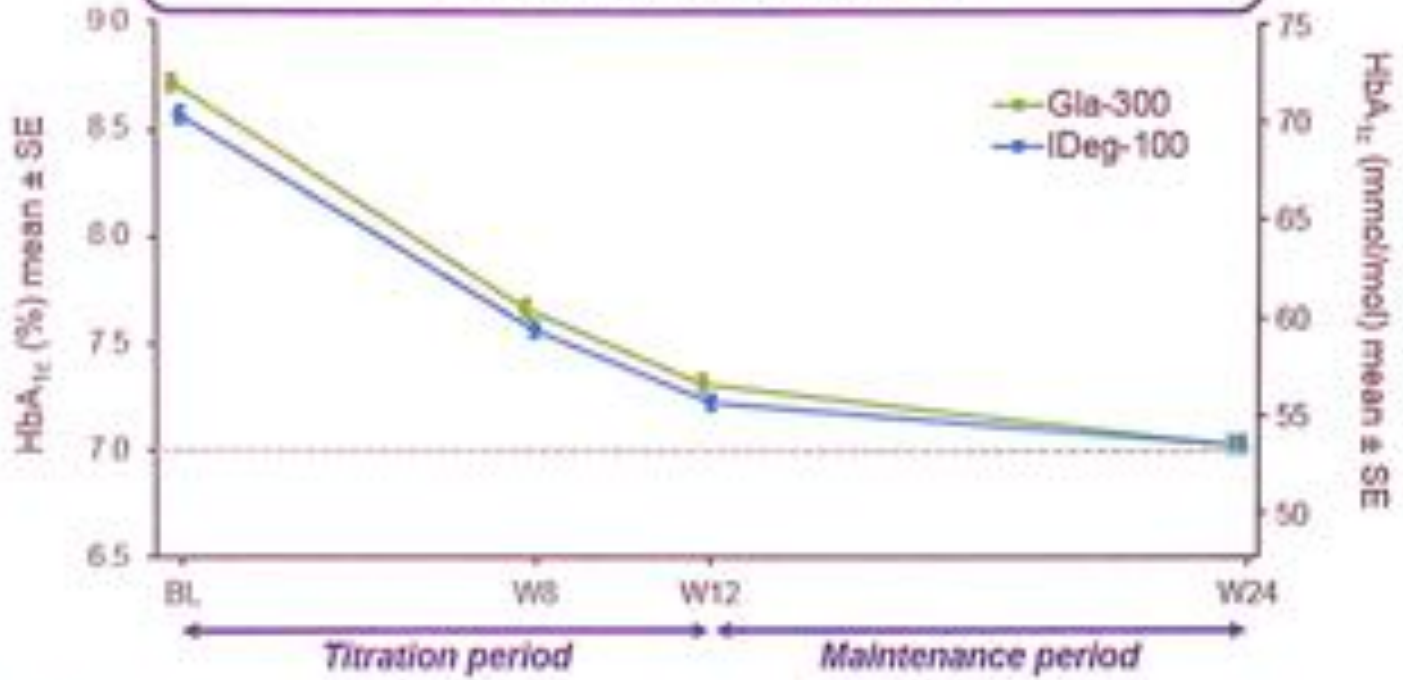
	Gla-300 (n=460)	IDeg-100 (n=463)
Number of prior non-insulin antihyperglycemic treatments used, n (%)		
0	0 (0.0)	1 (0.2)
1	70 (15.0)	65 (14.0)
2	179 (38.4)	187 (40.4)
>2	217 (46.6)	210 (45.4)
Prior non-insulin antihyperglycemic treatments, n (%)		
Metformin	428 (91.8)	422 (91.1)
SU	301 (64.6)	309 (66.7)
DPP-4 inhibitors	121 (26.0)	106 (22.9)
SGLT-2 inhibitors	62 (13.3)	62 (13.4)
GLP-1 receptor agonists	46 (9.9)	65 (14.0)
Thiazolidinediones	21 (4.5)	24 (5.2)
Glinides	12 (2.6)	9 (1.9)
Alpha-glucosidase inhibitors	9 (1.9)	7 (1.5)

Randomized population.
DPP-4, dipeptidyl peptidase 4; Gla-300, insulin glargine 300 U/mL; GLP-1, glucagon-like peptide-1; IDeg-100, insulin degludec 100 U/mL; SGLT-2, sodium-glucose co-transporter 2; SU, sulfonylureas

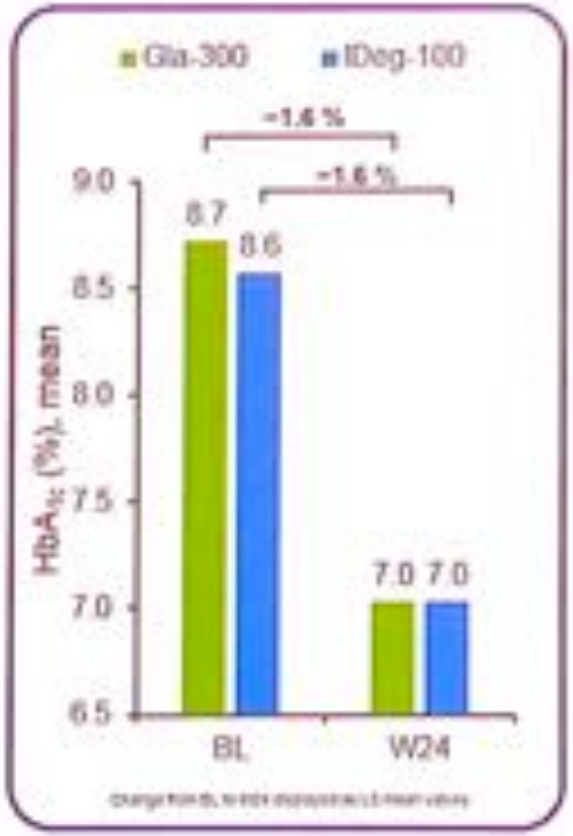
BRIGHT

Non-inferiority of Gla-300 vs IDeg-100 in HbA_{1c} reduction at study end

LS mean difference for Gla-300 vs IDeg-100:
−0.05 % (95 % CI −0.15 to 0.05) (−0.6 mmol/mol [−1.7 to 0.6]),
non-inferiority p-value <0.0001



No. of participants:					
	Gla-300	462	448	448	430
	IDeg-100	462	447	445	425



ITT population
BL, baseline; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; ITT, intention-to-treat; LS, least square; SE, standard error; W, week

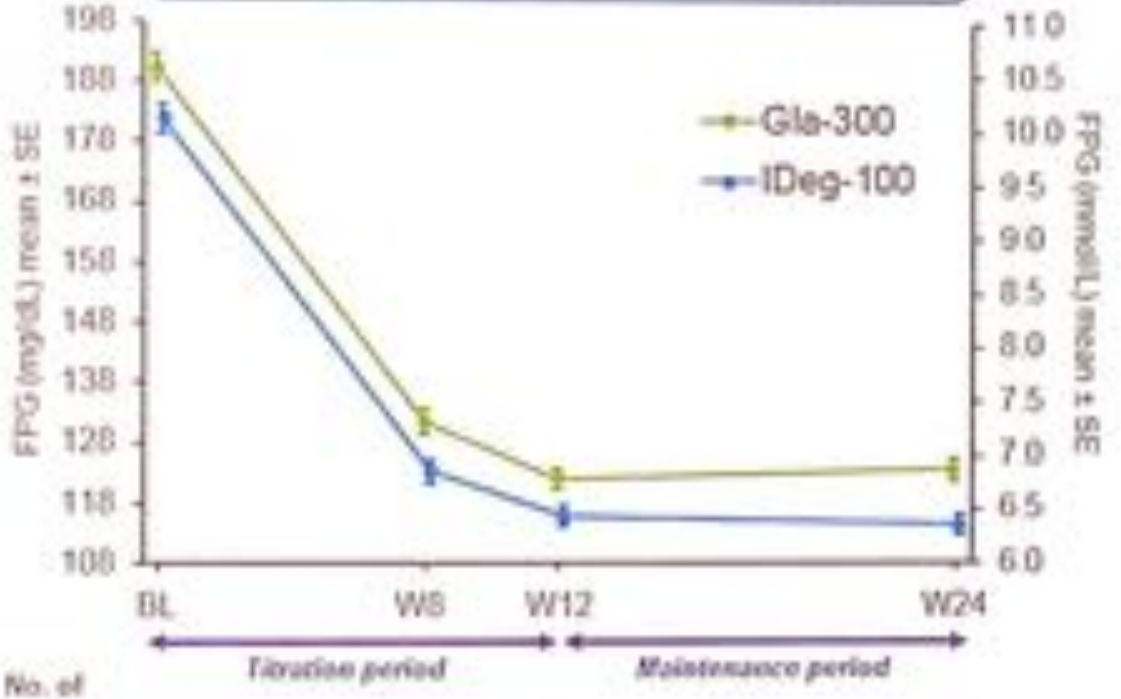
BRIGHT

American Diabetes Association. 77TH SCIENTIFIC SESSIONS
EXPERIENCE NEW HORIZONS IN DIABETES

FPG and fasting SMPG reduction with Gla-300 vs IDeg-100 from baseline to study end

FPG

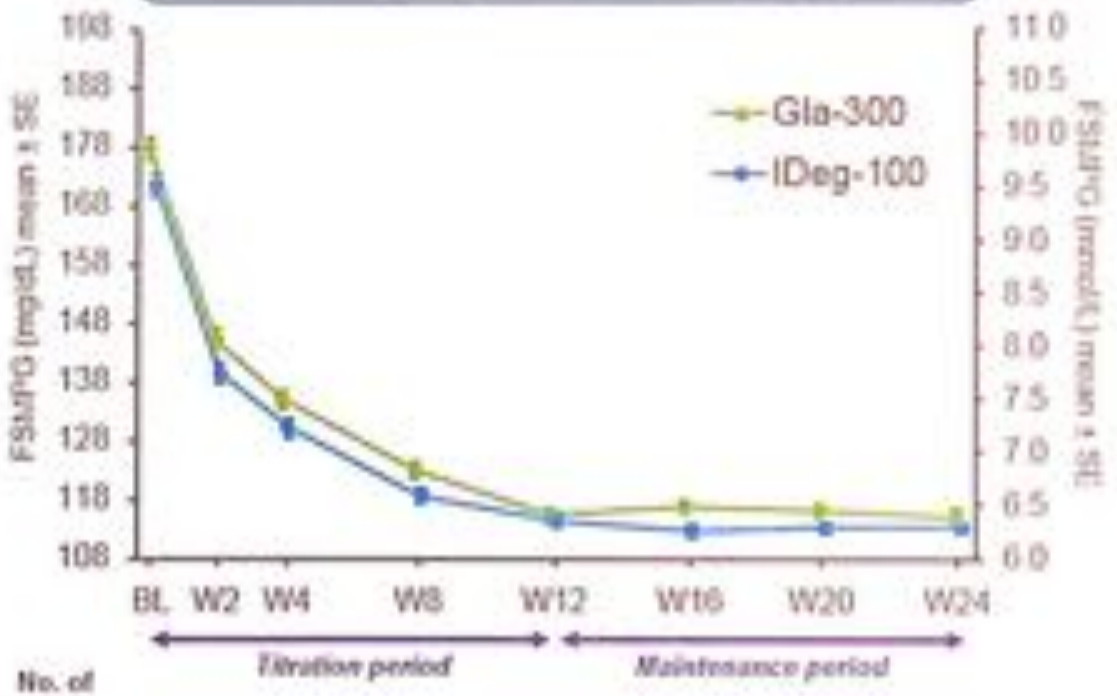
LS mean difference for Gla-300 vs IDeg-100: 7.7 mg/dL (95 % CI: 2.7 to 12.7)



No. of participants				
Gla-300	455	444	447	422
IDeg-100	459	445	444	411

Fasting SMPG

LS mean difference for Gla-300 vs IDeg-100: 1.1 mg/dL (95 % CI: −1.9 to 4.1)



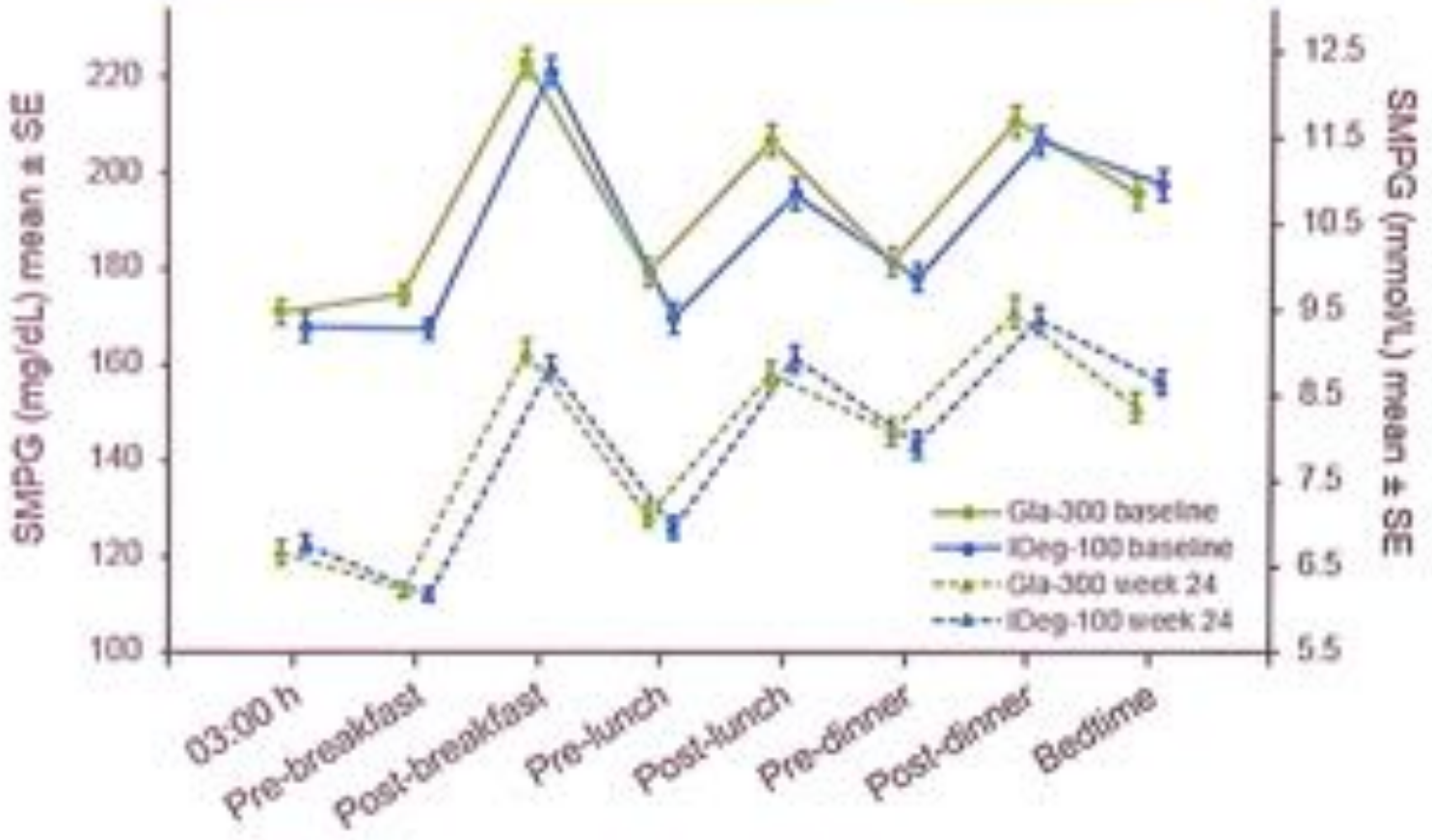
No. of participants								
Gla-300	453	455	452	448	443	442	436	431
IDeg-100	452	457	452	451	441	432	424	424

ITT population
BL, baseline; CI, confidence interval; FPG, fasting plasma glucose; FSMPG, fasting self-monitored plasma glucose; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; ITT, intention-to-treat; SE, standard error; SMPG, self-monitored plasma glucose; W, week

BRIGHT

Similar 8-point SMPG and variability profiles at baseline and study end

8-point SMPG profiles



Variability

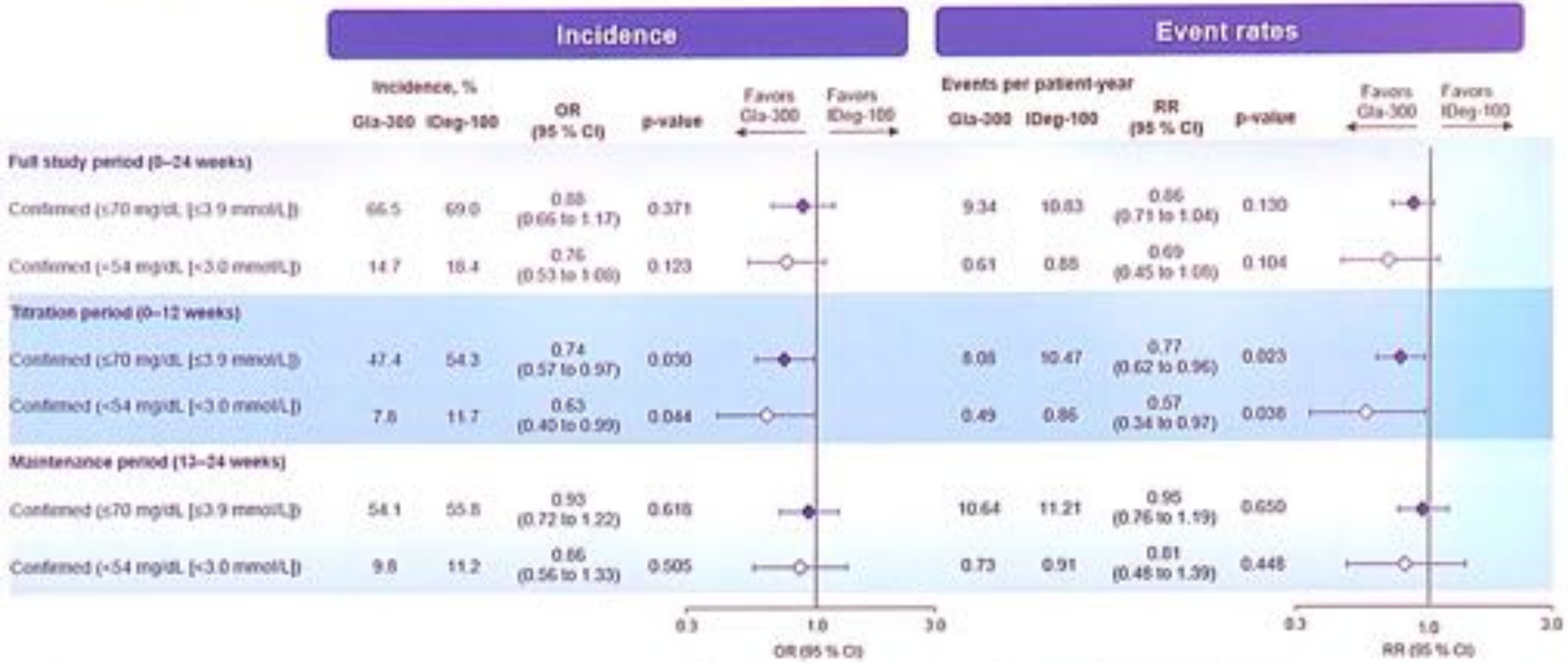
Mean CV, %	Gla-300	IDeg-100
24-h SMPG		
Baseline	22.5	23.4
Week 24	27.6	28.0
LS mean change[a]	3.7	4.0
Fasting SMPG		
Baseline	13.8	14.6
Week 24	16.5	17.0
LS mean change[a]	1.5	2.0

[a]MMRM analysis

Similar variability of 24-h SMPG and fasting SMPG at baseline and week 24 with both treatments

ITT population
CV, coefficient of variation; ITT, intention-to-treat; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; MMRM, mixed model for repeated measurements; SE, standard error; SMPG, self-monitored plasma glucose

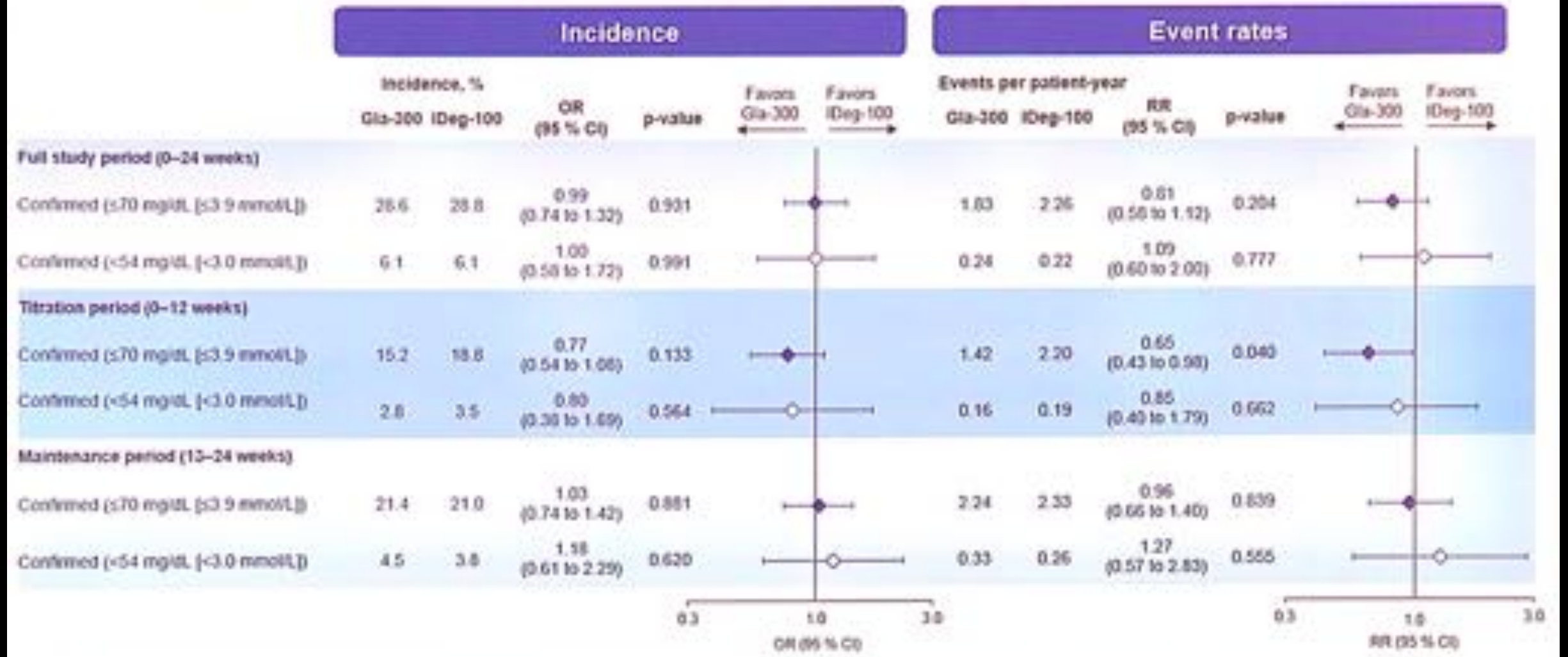
Anytime (24 h) hypoglycemia



Confirmed hypoglycemia included documented symptomatic or asymptomatic hypoglycemia (≤70 mg/dL or <54 mg/dL), and severe events if any; only 1 participant experienced severe hypoglycemia (1 event), in the Gla-300 group, due to a skipped evening meal and not reducing her insulin dose after a non-severe event 2 days earlier.
All p-values presented are nominal. Safety population (Gla-300, n=462; IDeg-100, n=462).
CI, confidence interval; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; OR, odds ratio; RR, rate ratio

BRIGHT

Nocturnal (00:00–06:00 h) hypoglycemia



Confirmed hypoglycemia included documented symptomatic or asymptomatic hypoglycemia (<70 mg/dL or <54 mg/dL) and severe events if any; only 1 participant experienced severe hypoglycemia (1 event), in the Gla-300 group, due to a skipped evening meal and not reducing her insulin dose after a non-severe event 2 days earlier.
All p-values presented are nominal. Safety population (Gla-300, n=462; IDeg-100, n=462).
CI, confidence interval; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; OR, odds ratio; RR, rate ratio

BRIGHT

Basal insulin dose and body weight over 24 weeks

Mean daily insulin dose

	Gla-300 (n=462)		IDeg-100 (n=462)	
	U	U/kg	U	U/kg
Initial	16.9 ± 4.4	0.19 ± 0.04	10.2 ± 1.9	0.12 ± 0.04
Between-treatment difference at baseline	0.07 U/kg			
Week 24	50.5 ± 25.6	0.54 ± 0.26	39.2 ± 23.3	0.43 ± 0.24
Between-treatment difference at week 24	0.11 U/kg			
Change from baseline to week 24	33.6 ± 24.4	0.36 ± 0.25	29.1 ± 23.3	0.31 ± 0.24

Data are mean ± SD, except for between-treatment differences (only mean presented)

Mean body weight

	Gla-300 (n=462)	IDeg-100 (n=462)
	kg	kg
Baseline	90.6 ± 16.1	88.7 ± 15.9
Week 24	92.5 ± 16.6	91.4 ± 16.7
Change from baseline to week 24	2.0 ± 3.8	2.3 ± 3.6

Data are mean ± SD

Safety population
Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; SD, standard deviation

BRIGHT

Treatment-emergent adverse events

- No specific safety concerns were reported
- There was one death in the Gla-300 group (adenocarcinoma of the colon)
- Only one episode of severe hypoglycemia occurred during the entire study

	Gla-300 (n=462)	IDeg-100 (n=462)
n (%)		
Participants with any treatment-emergent AE	202 (43.7)	221 (47.8)
Participants with any treatment-emergent serious AE	21 (4.5)	20 (4.3)
Participants with any treatment-emergent AE leading to death	1 (0.2)	0 (0.0)
Participants with any treatment-emergent AE leading to permanent treatment discontinuation	4 (0.9)	5 (1.1)

Safety population
AE, adverse event; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL

BRIGHT

Discussion

- BRIGHT was the first direct comparison of the safety and efficacy of Gla-300 versus IDeg-100, and showed:
  - Similar glycemic control with Gla-300 and IDeg-100 for HbA_{1c} and fasting SMPG reduction
  - Similar variability in 24-h SMPG and fasting SMPG with both treatments
  - Modest and comparable weight gain with both treatments despite a slightly higher mean daily insulin dose for Gla-300 at study-end

Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; SMPG, self-monitored plasma glucose

BRIGHT

Discussion

- During the **full study** and **maintenance** periods, the incidence and rates of anytime (24 h) and nocturnal (00:00–06:00 h) confirmed hypoglycemia (≤70 and <54 mg/dL) were comparable between treatment groups.

- During the **titration** period (0–12 weeks), the incidence and rates of anytime (24 h) confirmed hypoglycemia (≤70 and <54 mg/dL) and the rate of nocturnal (00:00–06:00 h) confirmed hypoglycemia (≤70 mg/dL) were lower with Gla-300.

Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL

BRIGHT

Discussion

- During the **full study** and **maintenance** periods, the incidence and rates of anytime (24 h) and nocturnal (00:00–06:00 h) confirmed hypoglycemia (≤70 and <54 mg/dL) were comparable between treatment groups.

- During the **titration** period (0–12 weeks), the incidence and rates of anytime (24 h) confirmed hypoglycemia (≤70 and <54 mg/dL) and the rate of nocturnal (00:00–06:00 h) confirmed hypoglycemia (≤70 mg/dL) were lower with Gla-300.

Conclusion

In previously insulin-naïve people with inadequately controlled T2DM, Gla-300 and IDeg-100 provided similar glycemic control accompanied by comparable hypoglycemia during the full study period and maintenance period, and less anytime hypoglycemia during the titration period.

Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; SMPG, self-monitored plasma glucose; T2DM, type 2 diabetes

El estudio BRIGHT es el primer ensayo cl.nico que compara H2H Glargina 300 vs Degludec.
Es un ensayo cl.nico de no inferioridad, abierto, randomizado, con 2 brazos paralelos en el que a pacientes con DM2 con mal control a tratamiento con ADOs +/- GLP1 se inicia insulina Glargina 300 o Degludec.
Tras la randomizaci.n existe un periodo de 12 semanas de titulaci.n de dosis.
El objetivo de glucemia en ayunas a alcanzar es entre 80-100mg/dL sin hipoglucemias.
Las caracter.sticas de los pacientes del estudio con las siguientes: media de edad de 60 a.os, IMC de 31kg/m2, duraci.n de DM de 10 a.os, A1C 8.7%, el 91% recib.a tratamiento con metformina y aproximadamente el 65% recib.a tratamiento con sulfonilureas.
El objetivo primario era el cambio en A1c a las 24 semanas, tras este periodo no se observaron diferencias entre ambos grupos.
En cuanto a los objetivos secundarios no se encontraron diferencias en glucemia basal capilar.
La variabilidad en el control capilar de 24 horas fue semejante en ambos grupos.
En cuanto al peso hubo un ligero aumento en ambos grupos. Al final del estudio la dosis de insulina Glargina 300 fueron ligeramente mayores que Degludec.
En relaci.n a las hipoglucemias durante la fase de mantenimiento (tras las 12 semanas de titulaci.n de dosis) la incidencia de hipoglucemia nocturna y 24 horas fue semejante en ambos grupos.
Sin embargo, durante la fase de titulaci.n de dosis la incidencia de hipoglucemia nocturna y 24 horas fue menor con Glargina 300.
En conclusi.n, en pacientes con DM tipo 2 sin tratamiento previo con insulina y con sub.ptimo control metab.lico Gla-300 e IDeg-100 logran un control gluc.mico semejante y con la misma incidencia de hipoglucemias durante todo el periodo del estudio y durante la fase de mantenimiento. Sin embargo, en la fase de titulaci.n de dosis existe menor hipoglucemia con Gla-300.

Preventing Diabetes vs Treating Prediabetes: What's Next after Metformin is the wrong Question- Type 2 Diabtes Remission as a New treatment Paradigm

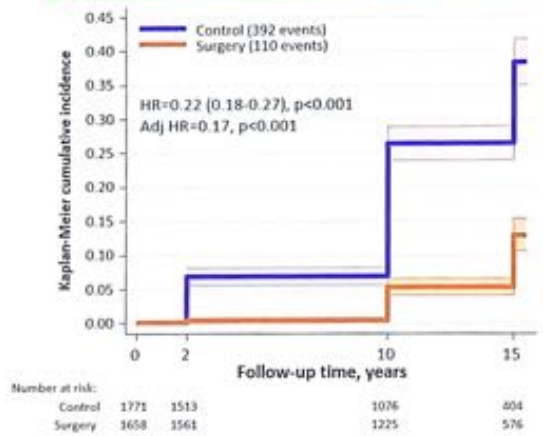
H.Gernstein

- Cuanto puede durar la remisión de la diabetes?
- Podemos predecir la remisión de la diabetes?
- Previene la cirugía bariátrica las complicaciones de la diabetes?
- Es suficiente mejorar la diabetes o es la remisión importante de cara a prevenir complicaciones?

Definition of Remission..& Regression

- *ADA Definition (Diabetes Care 2009)*
  - Partial: HbA1c<6.5% (or FPG <7) & no drugs X 1 year
  - Complete: HbA1c <5.7% (or FPG <5.6) & no drugs X 1 year
  - Prolonged: ≥ 5 years
- *Possible Alternatives*
  - Partial Remission: HbA1c <6.5% & no drugs for some period of time
  - Complete Remission: HbA1c <6.0% & no drugs for some period of time
  - Regression: HbA1c <7.0% & no drugs for some period of time

Yes, bariatric surgery strongly prevents diabetes



Around 80% risk reduction

NNT=4.6

Carlsson et al, N Engl J Med, 2012

Summary

Patients with type 2 diabetes

Bariatric surgery soon after diabetes is diagnosed leads to:

- longer remission
- better prevention of microvascular complications

Patients with prediabetes

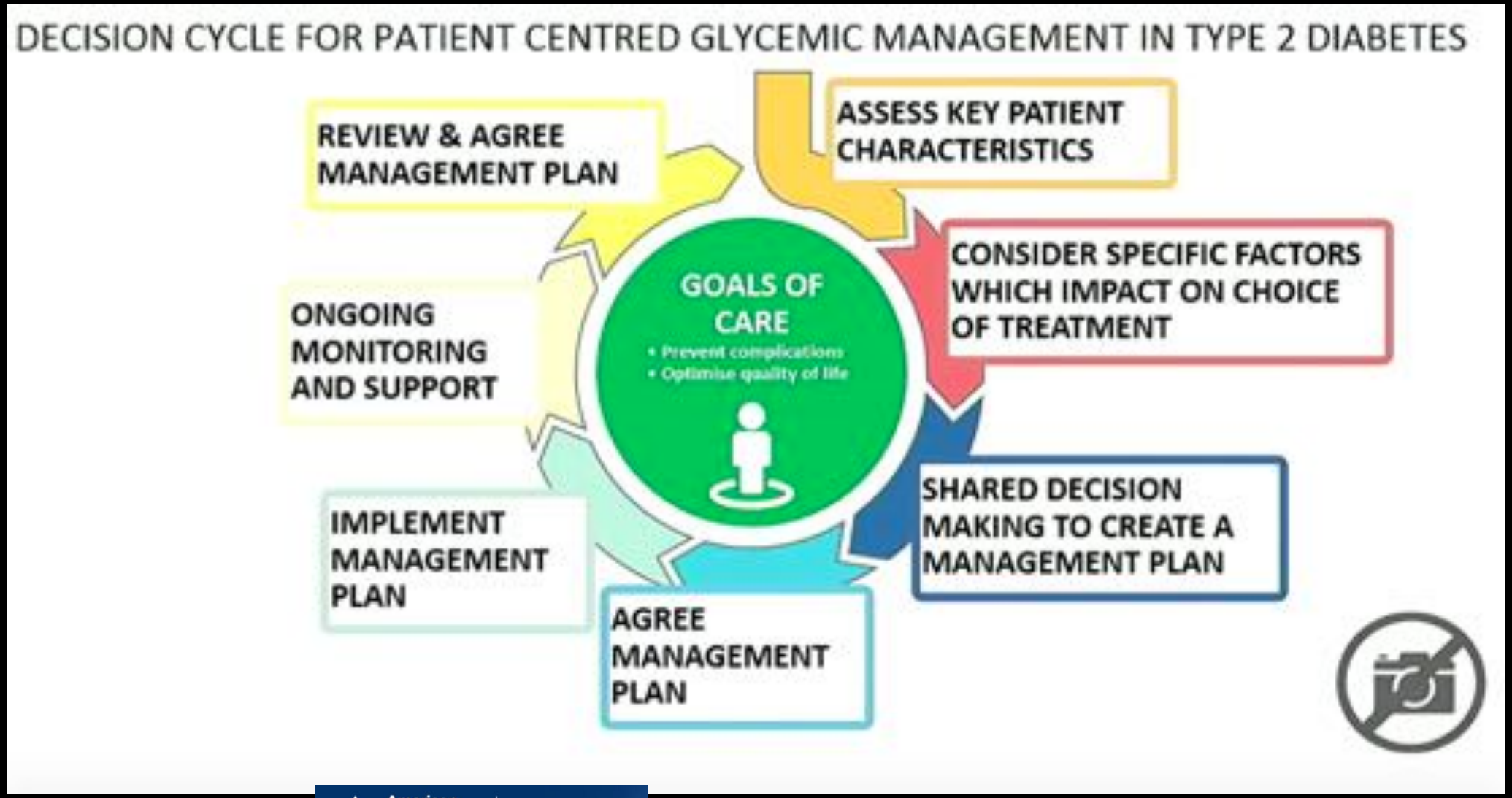
Bariatric surgery:

- strongly prevents diabetes
- strongly prevents microvascular complications

Prediabetes is associated with long-term microvascular complications even in patients that remain free from diabetes

-> Prediabetes *per se* is harmful

New EASD ADA 2018 recommendations **Draft**



New EASD ADA 2018 recommendations **Draft**

Lifestyle

- Medical Nutrition Therapy
- Physical activity

Medications

Metabolic Surgery

Physical Activity

Lowers HbA1c by about 0.6%

More is better

Supervised exercise more effective than unsupervised

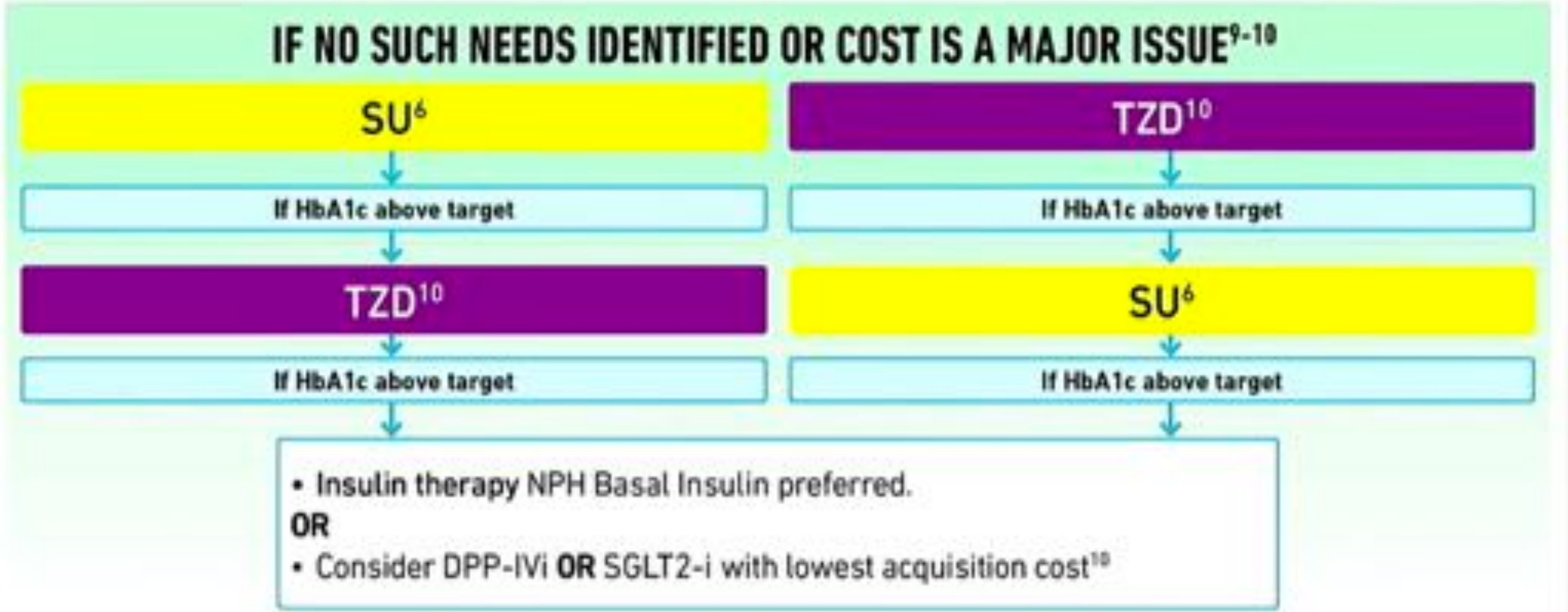
Exercise has other health benefits

- Reduction of ASCVD risk factors
- Reduction of fall risk
- Reduction of weight
- Increase bone density

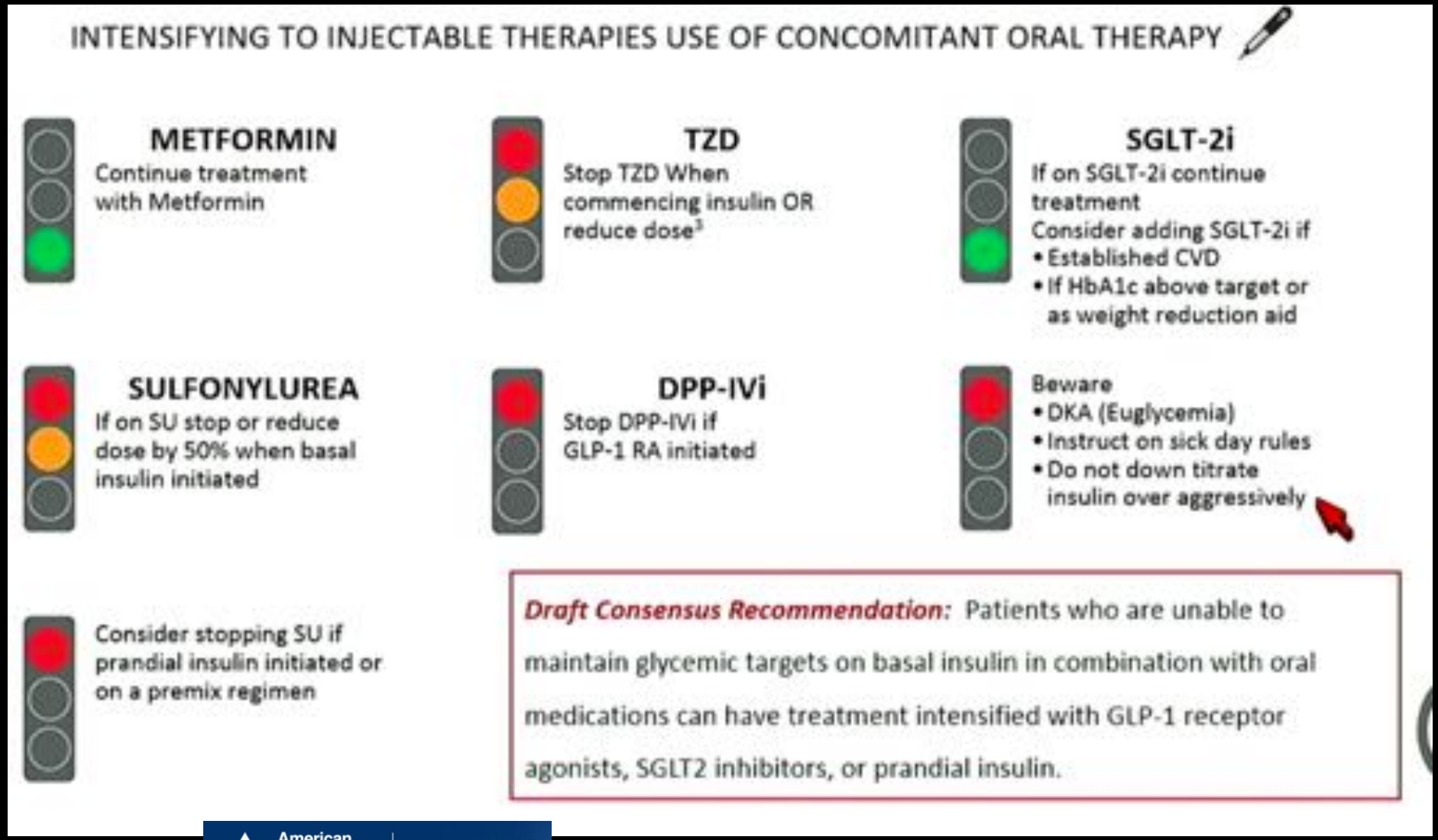
Lean, MEJ lancet 2018;391:541

ANTIHYPERGLYCEMIC MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH

ANTIHYPERGLYCEMIC MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH



New EASD ADA 2018 recommendations **Draft**



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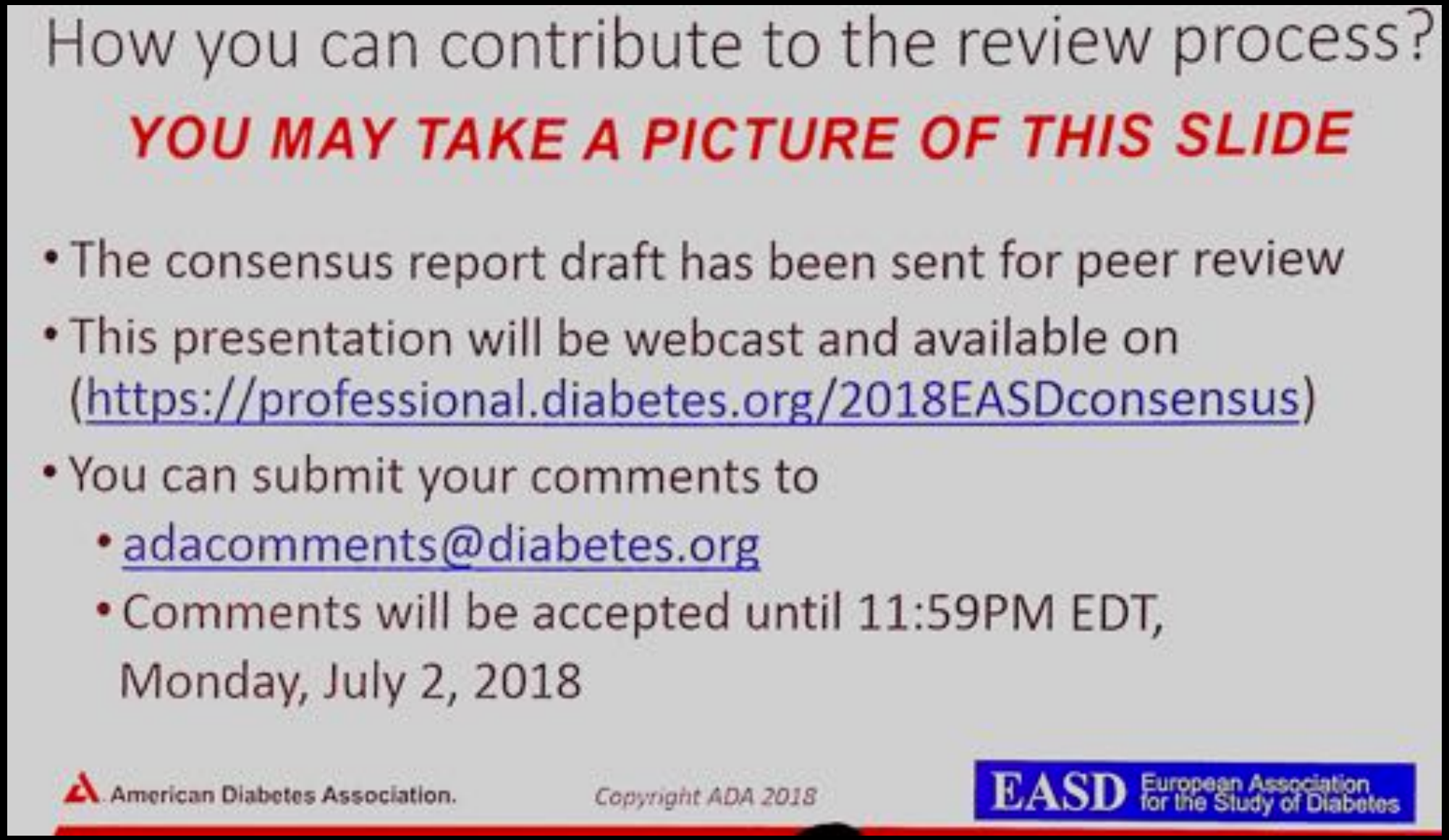
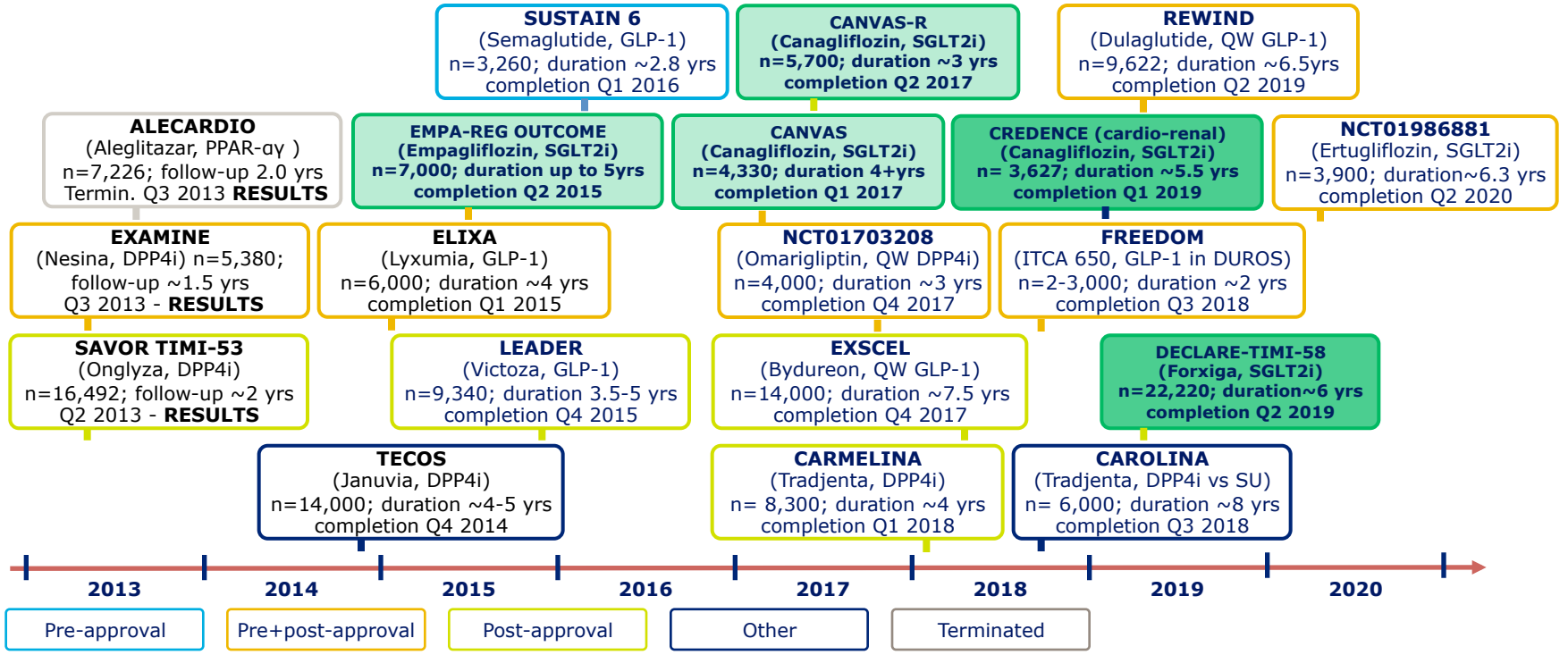


Estudis seguretat CV

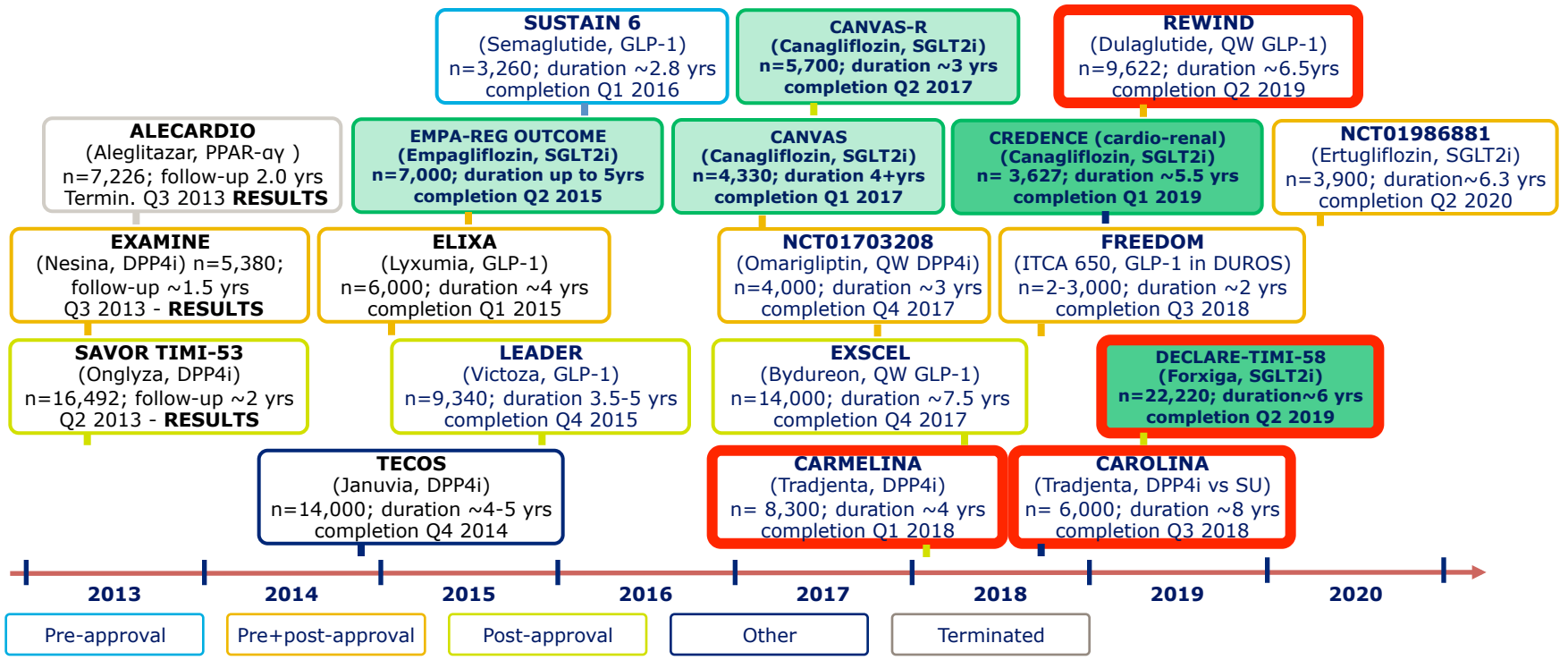
Cardiovascular outcomes trials within diabetes



Source: ClinicalTrials.gov (April 2014). 'Completion date' is the estimated completion date for the primary outcomes measure
CVOT, cardiovascular outcomes trial; DPP4i; dipeptidyl peptidase 4 inhibitor; GLP-1, glucagon-like peptide 1; SU, sulphonylurea
McMurray JJ et al, *Lancet Diabetes Endocrinol* 2014;2:843–51

Estudis seguretat CV

Cardiovascular outcomes trials within diabetes



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Take-home messages

1

EDR
“daño (CAC) y función (eFG)”

Take-home messages

2

Autoanalísis **PLUS**

Take-home messages

3

Monitorización Continua de glucosa

Take-home messages

4

Take-home messages

5

Take-home messages

6

Metformin

Take-home messages

7

Legado Cardiovascular

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¿para siempre?

Take-home messages

8

EASD · ADA 2018

Suport documental

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Gràcies

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