

Optimización Terapéutica en Diabéticos con Cardiopatía Isquémica Papel de los ar-GLP1

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Conflict of interest:

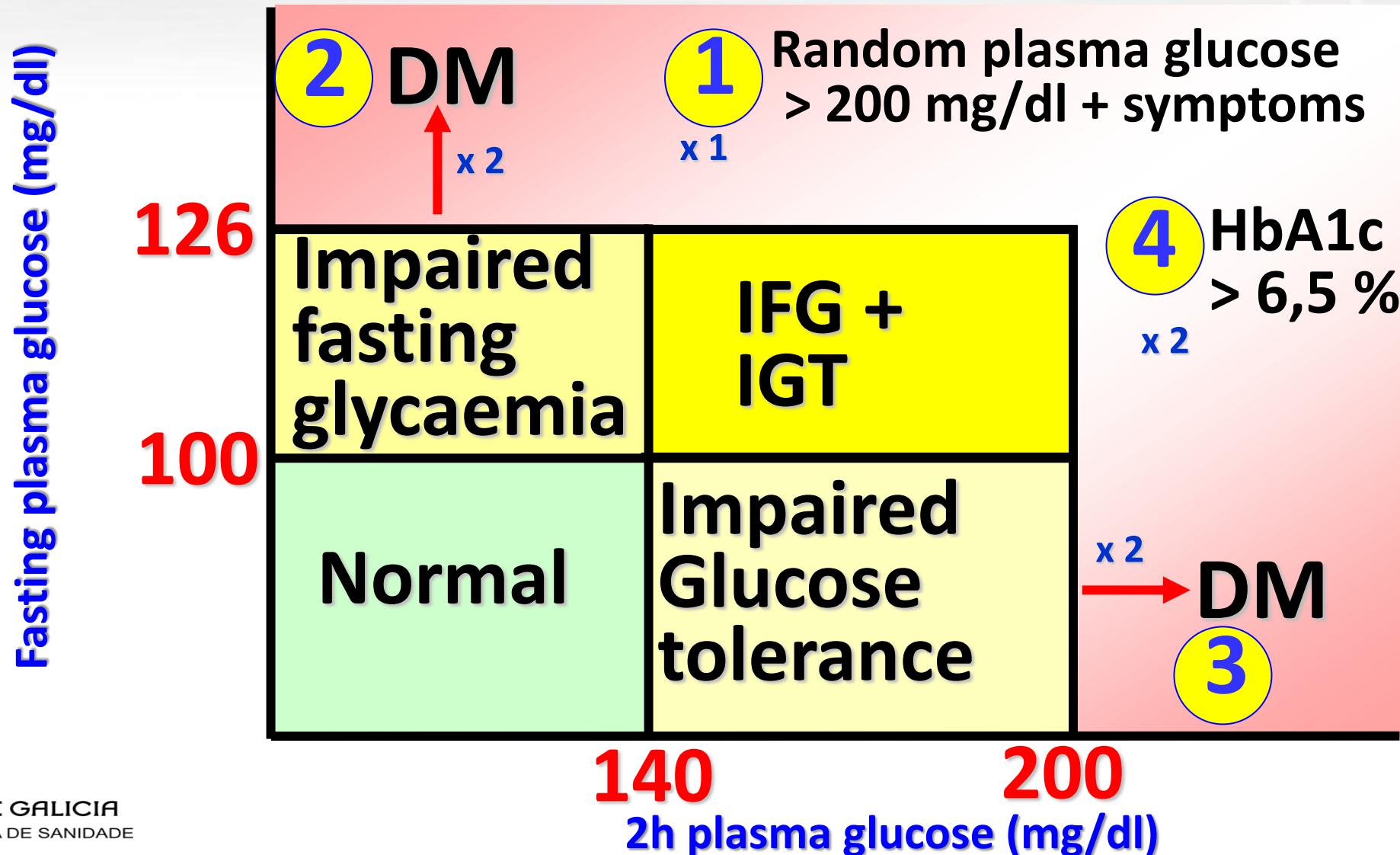
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- Diabetes en Cardiología
- Fármacos para control glucometabólico para cardiólogos
- Ar-GLP1 en Cardiopatía Isquémica – semaglutida oral
- Ar-GLP1 en la estrategia de optimización terapéutica

- **Diabetes en Cardiología**
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T2DM and Pre-diabetes

ADA



T2D and CV Disease in Spain. An Epidemiological Perspective

Diabetes + IHD

30-35% IHD PATIENTS WITH T2D ¹

Diabetes + HF

27-47% HF PATIENTS WITH T2D ²

Diabetes + AF

24-34% AF PATIENTS WITH T2D ³

+ 20% DIAGNOSIS AT TIME OF ADMISSION



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CONSELLERÍA DE SANIDADE

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Cardiovascular-Renal Spectrum of Diabetes

Diabetes affects the
PUMP

**Heart
Failure**

Diabetes affects the
PIPES

MACE

Diabetes affects the
FILTER

**Renal
Disease**



Diabetes and NSTEMI. Prognostic Implications

CardioCHUS-HUSJ Registry

	MORTALIDAD CV				MORTALIDAD TOTAL			
	GRACE < 140	p	GRACE ≥ 140	p	GRACE < 140	p	GRACE ≥ 140	p
Mujeres	0,70 (0,48-1,00)	0,05	0,71 (0,54-0,92)	0,01	0,57 (0,42-0,77)	<0,01	0,61 (0,49-0,77)	<0,01
Diabetes mellitus	1,77 (1,29-2,44)	0,01	1,63 (1,28-2,01)	0,01	1,63 (1,26-2,11)	<0,01	1,50 (1,22-1,82)	<0,01
EC previa	1,08 (0,76-1,50)	0,61	1,40 (1,09-1,79)	0,01	1,07 (0,81-1,41)	0,06	1,33 (1,08-1,64)	<0,01
IC previa	2,25 (1,16-4,37)	0,02	2,25 (1,59-3,17)	0,01	1,66 (0,92-3,02)	0,10	2,02 (1,50-2,72)	<0,01
TFG < 60 ml/min/1,72 m ²	1,51 (1,00-1,86)	0,03	1,50 (1,09-1,79)	0,01	1,51 (1,12-2,04)	<0,01	1,50 (1,22-1,84)	<0,01
Bloqueadores beta al alta	0,75 (0,53-1,06)	0,11	0,73 (0,57-0,92)	0,01	0,62 (0,48-0,82)	<0,01	0,71 (0,58-0,86)	<0,01
IECA/ARA-II al alta	1,00 (0,70-1,45)	0,99	0,85 (0,66-1,09)	0,19	0,93 (0,70-1,24)	0,63	0,83 (0,67-1,02)	0,08
Coronariografía en 24 h	1,37 (1,00-1,86)	0,05	0,79 (0,63-0,97)	0,04	1,22 (0,98-1,68)	0,06	0,86 (0,71-1,05)	0,15



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Alvarez B, ..., Gonzalez-Juanatey JR . Rev Esp Cardiol 2020 73: 35-42.

New treatment paradigm in T2D

GlucoCentric Approach

HbA_{1c} as the central focus



(CV) Events Reduction Approach

Multifactorial Intervention



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The pillars of CV Protection in T2D in 2022



LDL-C lowering

Statins
Ezetimibe
PCSK9i

Blood Pressure

ACEi
ARB

Triglyceride Lowering

EPA

**GLP-1RA
SGLT2i**

Life-style Changes



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OPTIMAL CV RISK REDUCTION IN DIABETIC PATIENTS IS ACHIEVED THROUGH TARGETING MULTIPLE RISK FACTORS

Lifestyle Changes

Lipids

Lipid lowering
LDL < 55 / <70 or < 100 mg/dL (1.8 mmol/L); lifestyle, statin, ezetimibe, PCSK9i

Blood pressure

Target of <130/80 (140–130/90–80) mmHg
ACEi/ARB, BB

Antithrombotics

Antiplatelet use
ASA (75–162 mg/day), DAPT

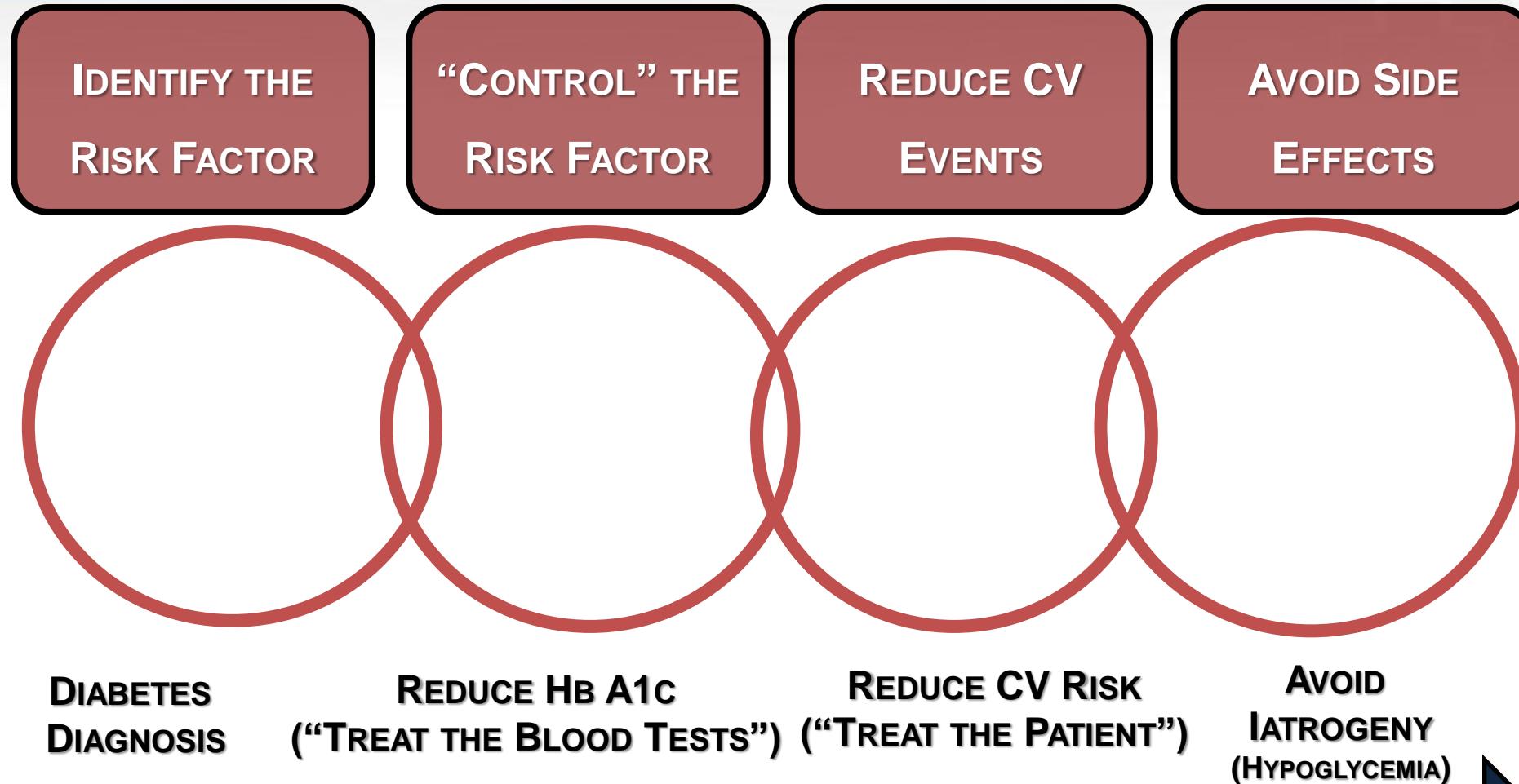
Glucose

HbA_{1c} target individualised; generally ~7%
Lifestyle modification, then metformin/SGLT2i/GLP1a

ARB, angiotensin receptor blocker; BB, beta blocker; CV, cardiovascular; DAPT, dual antiplatelet therapy;
GLP1a, glucagon-like peptide 1a; SGLT2i, sodium glucose transport protein 2 inhibitor.

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THE “VIRTUOUS CHAIN” OF CARDIOVASCULAR PROTECTION IN DIABETES



DIABETES AND CARDIOVASCULAR DISEASE PROTECTION



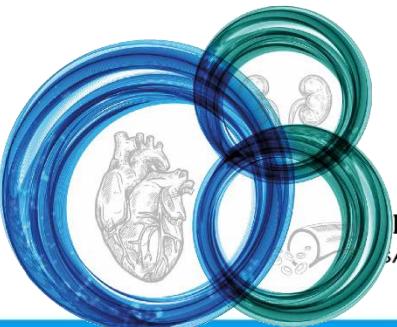
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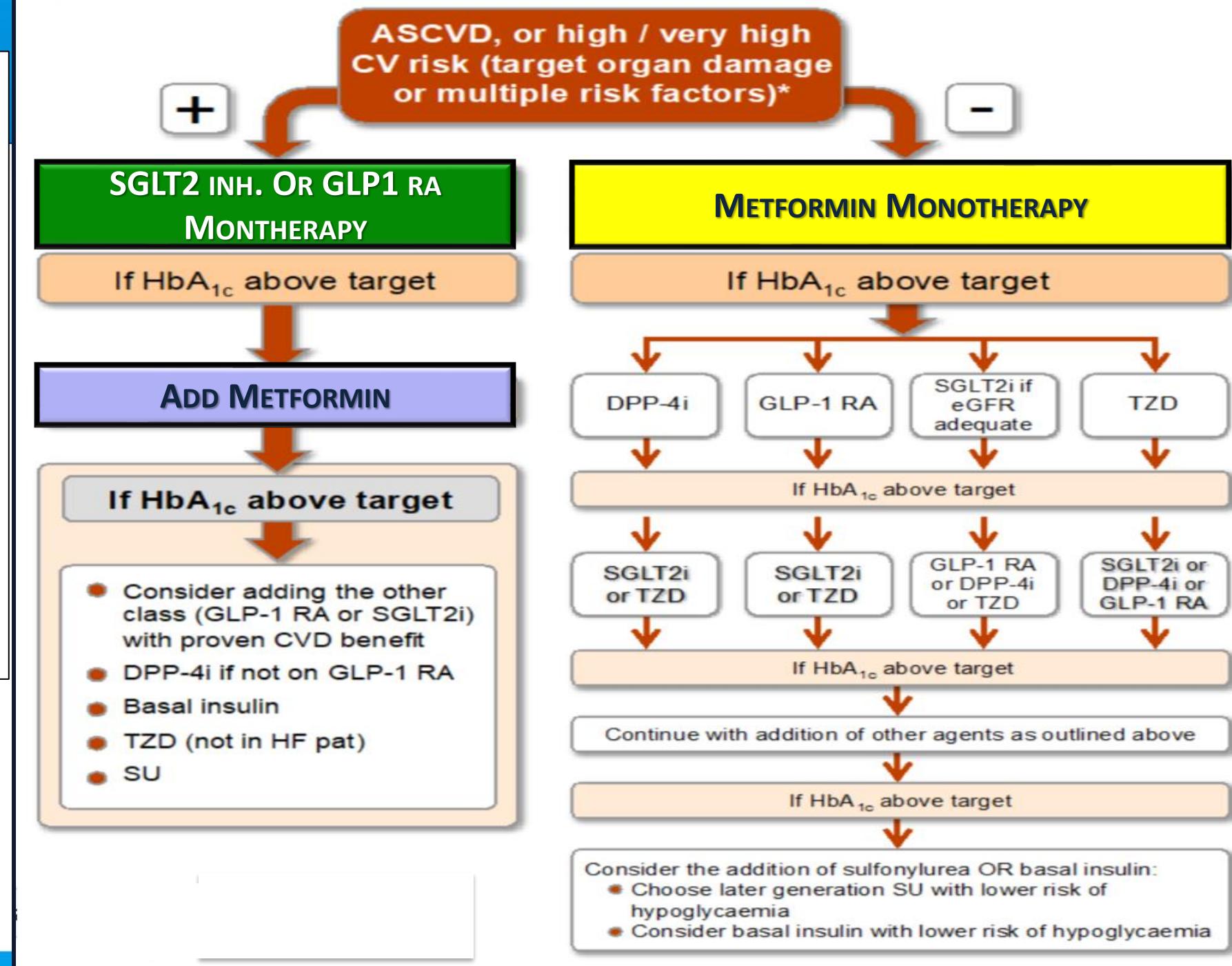
T2DM Treatment algorithm.

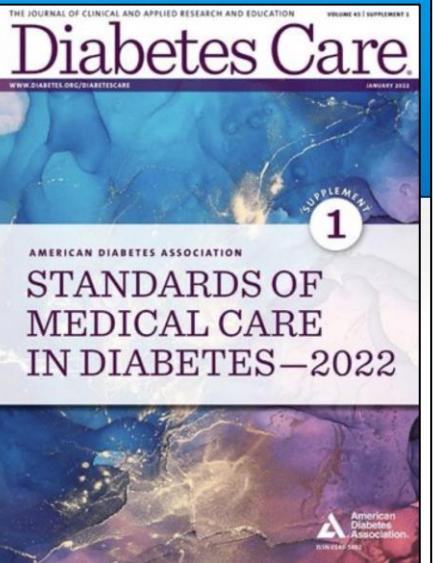
Type 2 DM - Drug
naive patients.

ESC-2019



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PHARMACOLOGIC TREATMENT OF HYPERGLYCEMIA IN ADULTS WITH TYPE 2 DIABETES



FIRST-LINE THERAPY depends on comorbidities, patient-centered treatment factors, including cost and access considerations, and management needs and generally includes metformin and comprehensive lifestyle modification[^]

ASCVD/INDICATORS OF HIGH RISK, HF, CKD†

RECOMMEND INDEPENDENTLY OF BASELINE A1C, INDIVIDUALIZED A1C TARGET, OR METFORMIN USE‡

+ASCVD/INDICATORS OF HIGH RISK*

EITHER OR
GLP-1 RA with proven CVD benefit¹
SGLT2i with proven CVD benefit¹

IF A1C ABOVE TARGET

- For patients on a GLP-1 RA, consider incorporating SGLT2i with proven CVD benefit and vice versa¹
- TZD²

If A1C remains above target, consider treatment intensification based on comorbidities, patient-centered treatment factors, and management needs

+HF*

SGLT2i with proven benefit in this population¹

If A1C above target, for patients on SGLT2i, consider incorporating a GLP-1 RA and vice versa

+CKD**

CKD and albuminuria (e.g., $\geq 200 \text{ mg/g}$ creatinine)
CKD without albuminuria (e.g., eGFR $< 60 \text{ mL/min/1.73 m}^2$)

PREFERABLY

SGLT2i with primary evidence of reducing CKD progression

OR
SGLT2i with evidence of reducing CKD progression in CVOTs
OR
GLP-1 RA with proven CVD benefit¹ if SGLT2i not tolerated or contraindicated

For patients with CKD (e.g., eGFR $< 60 \text{ mL/min/1.73 m}^2$) without albuminuria, recommend the following to decrease cardiovascular risk

EITHER OR
GLP-1 RA with proven CVD benefit¹
SGLT2i with proven CVD benefit¹

NONE

Incorporate agents that provide adequate EFFICACY to achieve and maintain glycemic goals

Higher glycemic efficacy therapy: GLP-1 RA; insulin; combination approaches (Table 9.2)

- Consider additional comorbidities, patient-centered treatment factors, and management needs in choice of therapy, as below:

MINIMIZE HYPOGLYCEMIA

No/low inherent risk of hypoglycemia:
DPP-4i, GLP-1 RA, SGLT2i, TZD
For SU or basal insulin, consider agents with lower risk of hypoglycemia^{3,4}

IF A1C ABOVE TARGET

Incorporate additional agents based on comorbidities, patient-centered treatment factors, and management needs

MINIMIZE WEIGHT GAIN/PROMOTE WEIGHT LOSS

PREFERABLY
GLP-1 RA with good efficacy for weight loss
OR
SGLT2i

IF A1C ABOVE TARGET

For patients on a GLP-1 RA, consider incorporating SGLT2i and vice versa
If GLP-1 RA not tolerated or indicated, consider DPP-4i (weight neutral)

Incorporate additional agents based on comorbidities, patient-centered treatment factors, and management needs

CONSIDER COST AND ACCESS

Available in generic form at lower cost:

- Certain insulins: consider insulin available at the lowest acquisition cost
- SU
- TZD

IF A1C ABOVE TARGET

Incorporate additional agents based on comorbidities, patient-centered treatment factors, and management needs

1. Proven benefit refers to label indication (see Table 9.2)

2. Low dose may be better tolerated though less well studied for CVD effects

3. Choose later generation SU to lower risk of hypoglycemia

4. Risk of hypoglycemia: degludec / glargin U-300 < glargin U-100 / detemir < NPH insulin

5. Consider country- and region-specific cost of drugs

^For adults with overweight or obesity, lifestyle modification to achieve and maintain $\geq 5\%$ weight loss and $\geq 150 \text{ min/week}$ of moderate- to vigorous-intensity physical activity is recommended (See Section 5: Facilitating Behavior Change and Well-being to Improve Health Outcomes).

†Actioned whenever these become new clinical considerations regardless of background glucose-lowering medications.

‡Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy. Refer to Section 10: Cardiovascular Disease and Risk Management.

**Refer to Section 11: Chronic Kidney Disease and Risk Management and specific medication label for eGFR criteria.

GLP-1 Receptor Agonists

CV Outcome Trials

ELIXA

LEADER

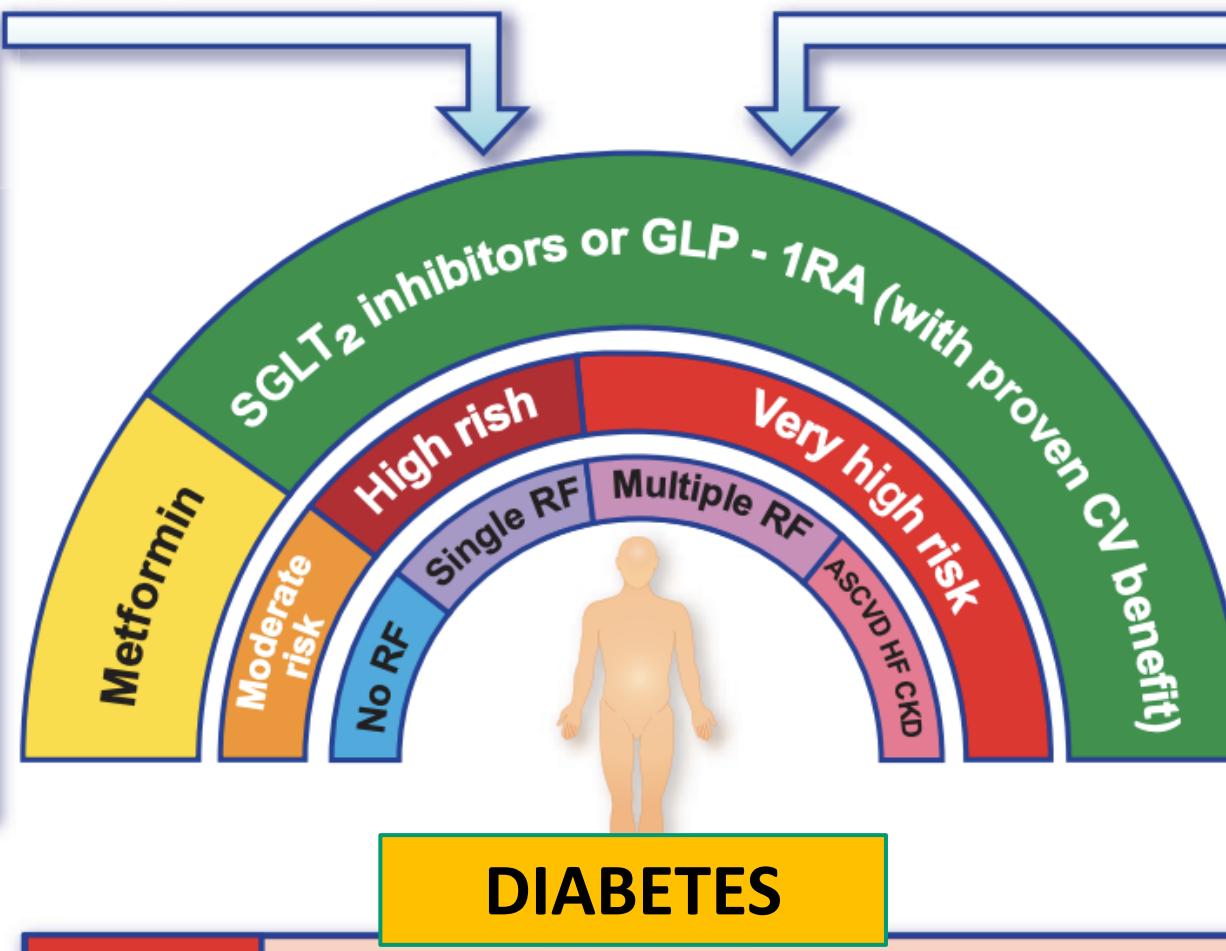
SUSTAIN-6

EXSCEL

HARMONY

REWIND

PIONEER-6



Very high risk	Patients with DM and established CVD or other target organ damage or three or more major risk factors or early onset T1DM of long duration (>20 years)
High risk	Patients with DM duration ≥ 10 years without target organ damage plus any other additional risk factor
Moderate risk	Young patients (T1DM aged <35 years or T2DM aged <50 years) with DM duration <10 years, without other risk factors

SGLT2 Inhibitors

CV Outcome Trials

EMPA REG OUTCOME

CANVAS Programme

DECLARE TIMI 58

VERTIS CV

Renal Trials

CREDENCE

DAPA CKD

HF Trials

DAPA HF

EMPEROR- Reduced



Evidence GLP-1 RAs have beneficial effects on CV outcomes on atherothrombotic events

	EMPA-REG OUTCOME ¹ (empagliflozin)	CANVAS Program ^{2,3} (canagliflozin)	DECLARE-TIMI 58 ⁴ (dapagliflozin)	ELIXA ⁵ (lixisenatide)	LEADER ⁶ (liraglutide)	EXSCEL ⁷ (exenatide)	SUSTAIN-6 ⁸ (inject. semaglutide)	Harmony Outcomes ⁹ (albiglutide)	PIONEER 6 (oral semaglutide) ¹⁰	REWIND (dulaglutide) ¹¹
3P-MACE	HR 0.86 (95% CI 0.74, 0.99) <i>p=0.04</i>	HR 0.86 (95% CI 0.75, 0.97) <i>p=0.02†</i>	HR 0.93 (95% CI 0.84, 1.03) <i>p=0.17</i>	HR 1.02 (4P-MACE) (95% CI 0.89, 1.17) <i>p=0.81</i>	HR 0.87 (95% CI 0.78, 0.97) <i>p=0.01</i>	HR 0.91 (95% CI 0.83, 1.00) <i>p=0.06</i>	HR 0.74 (95% CI 0.58, 0.95) <i>p=0.02§</i>	HR 0.78 (95% CI 0.68, 0.90) <i>p=0.0006</i>	HR 0.79 (95% CI 0.57, 1.11) <i>p=0.17</i>	HR 0.88 (95% CI 0.79, 0.99) <i>p=0.026</i>
CV death*	HR 0.62 (95% CI 0.49, 0.77) <i>p<0.001*</i>	HR 0.87 (95% CI 0.72, 1.06) [‡]	HR 0.98 (95% CI 0.82, 1.17) [‡]	HR 0.98 (95% CI 0.78, 1.22) <i>p=0.85*</i>	HR 0.78 (95% CI 0.66, 0.93) <i>p=0.007*</i>	HR 0.88 (95% CI 0.76, 1.02) [‡]	HR 0.98 (95% CI 0.65, 1.48) <i>p=0.92*</i>	HR 0.93 (95% CI 0.73, 1.19) <i>p=0.578*</i>	HR 0.49 (95% CI 0.27, 0.92)[‡]	HR 0.91 (95% CI 0.78, 1.06) <i>p=0.21*</i>
HHF	HR 0.65 (95% CI 0.50, 0.85) <i>p=0.002*</i>	HR 0.67 (95% CI 0.52, 0.87) [‡]	HR 0.73 (95% CI 0.61, 0.88) [‡]	HR 0.96 (95% CI 0.75, 1.23) <i>p=0.75*</i>	HR 0.87 (95% CI 0.73, 1.05) <i>p=0.14*</i>	HR 0.94 (95% CI 0.78, 1.05) <i>p=0.57*</i>	HR 1.11 (95% CI 0.77, 1.61) <i>p=0.57*</i>	NR	HR 0.86 (95% CI 0.48, 1.55) [‡]	HR 0.93 (95% CI 0.77, 1.12) <i>p=0.46*</i>
CV death or HHF	HR 0.66 (95% CI 0.55, 0.79) <i>p<0.001*</i>	HR 0.78 (95% CI 0.67, 0.91) <i>p=0.002*</i>	HR 0.83 (95% CI 0.73, 0.95) <i>p=0.005*</i>	NR	NR	NR	NR	HR 0.85 (95% CI 0.70, 1.04) <i>p=0.113*</i>	NR	NR
Non-fatal stroke	HR 1.24 (95% CI 0.92, 1.67) <i>p=0.16*</i>	HR 0.90 (95% CI 0.71, 1.15) [‡]	HR 1.01 (95% CI 0.84, 1.21) [‡]	HR 1.12 (95% CI 0.79, 1.58) <i>p=0.54*</i>	HR 0.89 (95% CI 0.72, 1.11) <i>p=0.30*</i>	HR 0.85 (95% CI 0.70, 1.03) [‡]	HR 0.61 (95% CI 0.38, 0.99) <i>p=0.04*</i>	NR	HR 0.74 (95% CI 0.35, 1.57) [‡]	HR 0.76 (95% CI 0.61, 0.95) <i>p=0.017*</i>
Non-fatal MI	HR 0.87 (95% CI 0.70, 1.09) <i>p=0.23*</i>	HR 0.89 (95% CI 0.73, 1.09) [‡]	HR 0.89 (95% CI 0.77, 1.01) [‡]	HR 1.03 (95% CI 0.87, 1.22) <i>p=0.71*</i>	HR 0.88 (95% CI 0.75, 1.03) <i>p=0.11*</i>	HR 0.97 (95% CI 0.85, 1.10) ^{‡,††}	HR 0.74 (95% CI 0.51, 1.08) <i>p=0.12*</i>	HR 0.75 (95% CI 0.61, 0.90) <i>p=0.003*</i>	HR 1.18 (95% CI 0.73, 1.90) [‡]	HR 0.96 (95% CI 0.79, 1.16) <i>p=0.65*</i>

1. Zinman B et al. *N Engl J Med* 2015;373:2117; 2. Neal B et al. *N Engl J Med* 2017;377:644; 3. Radholm K et al. *Circulation* 2018;138:458; 4. Wiviott S et al. *N Engl J Med* 2019;380:347; 5. Pfeffer MA et al. *N Engl J Med* 2015;373:2247; 6. Marso SP et al. *N Engl J Med* 2016;375:311; 7. Holman RR et al. *N Engl J Med* 2017;377:1228; 8. Marso SP et al. *N Engl J Med* 2016;375:1834; 9. Hernandez AF et al. *Lancet* 2018;392:1519; 10. Husain M et al. *N Engl J Med* 2019;381:841; 11. Gerstein H et al. *Diabetes Obesity Metab* 2018;20:42

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Semaglutida oral y resultados cardiovasculares en pacientes con DM2: características basales del estudio PIONEER 6¹

- **84,7%** pacientes con DM2 ≥ 50 años con ECV establecida y ERC
- **32,3** IMC
- **66** años edad media
- **74** ml/min/1,73m² TFGe

Características basales clínicas y demográficas seleccionadas de los pacientes*

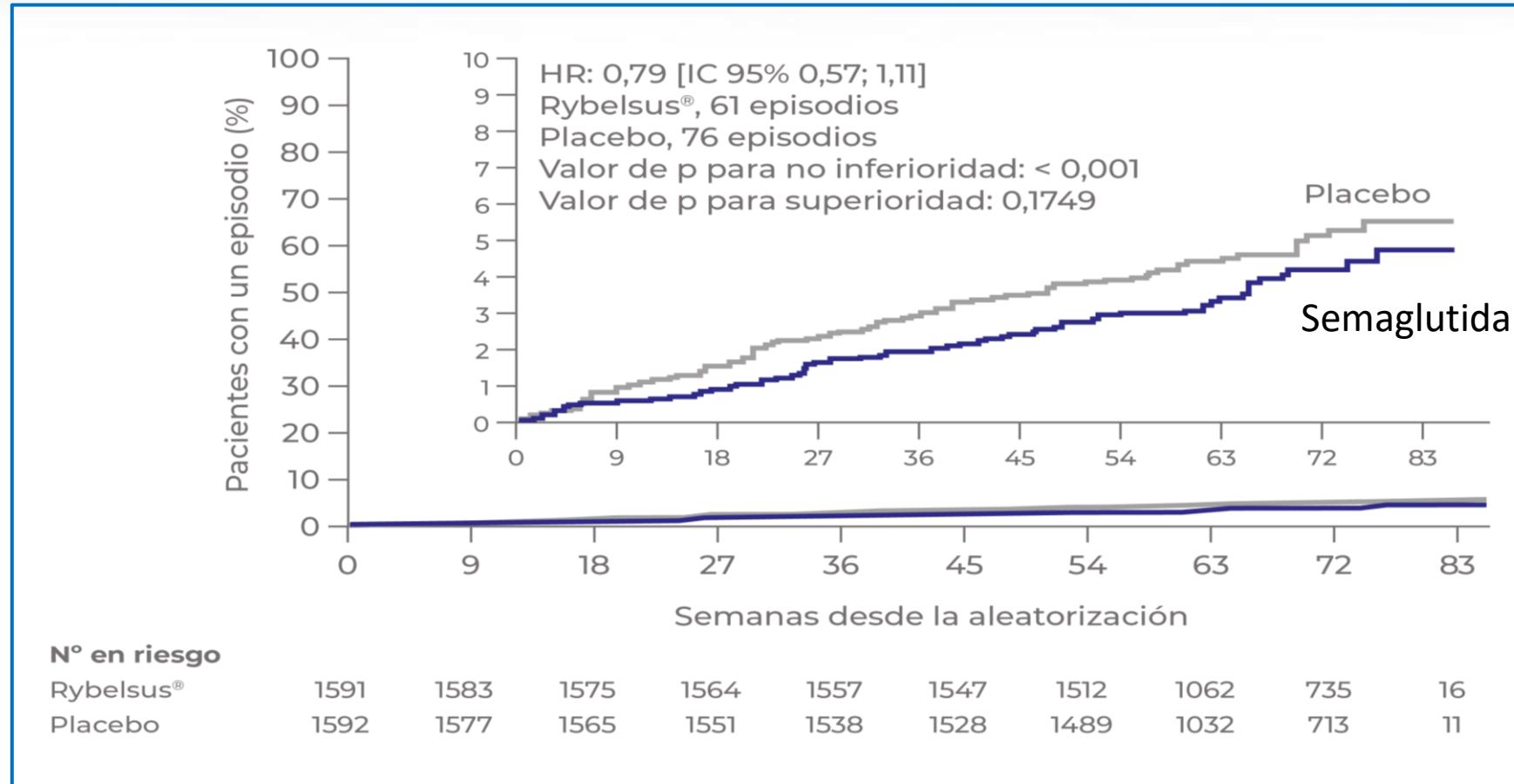
Características	Rybelsus® (N = 1591)	Placebo (N = 1592)	Total (N = 3183)
Edad-años	66±7	66±7	66±7
Sexo femenino - n° (%)	507 (31,9)	500 (31,4)	1007 (31,6)
Peso corporal - kg	91,0±21,4	90,8±21,0	90,9±21,2
Índice de masa corporal	32,3±6,6	32,3±6,4	32,3±6,5
Diabetes tipo 2			
Duración-años	14,7±8,5	15,1±8,5	14,9±8,5
Hemoglobina glicada - %	8,2±1,6	8,2±1,6	8,2±1,6
Hemoglobina glicada - mmol/mol	66±17	66±18	66±18
Estrato del riesgo cardiovascular - n° (%)			
Edad ≥ 50 años y ECV establecida o enfermedad renal crónica	1350 (84,9)	1345 (84,5)	2695 (84,7)
Edad ≥ 60 años y únicamente factores de riesgo cardiovascular	241 (15,1)	247 (15,5)	488 (15,3)
Factores de riesgo cardiovascular			
Presión arterial - mm Hg			
Sistólica	135±18	136±18	136±18
Diastólica	76±10	76±10	76±10
Colesterol LDL			
Media geométrica - mg/dl	77	79	78
Coeficiente de variación - %	44,9	41,2	43,1
Fumador - n° (%)	184 (11,6)	165 (10,4)	349 (11,0)
TFG estimada			
Media - ml/min/1,73 m ²	74±21	74±21	74±21
Distribución - n° (%)			
≥ 90 ml/min/1,73 m ²	464 (29,2)	455 (28,6)	919 (28,9)
60 a < 90 ml/min/1,73 m ²	686 (43,1)	703 (44,2)	1389 (43,6)
30 a < 60 ml/min/1,73 m ²	418 (26,3)	409 (25,7)	827 (26,0)
< 30 ml/min/1,73 m ²	16 (1,0)	13 (0,8)	29 (0,9)
Datos no disponibles	7 (0,4)	12 (0,8)	19 (0,6)

*Los valores más-menos son medias ±DE. Los porcentajes pueden no sumar 100 debido al redondeo. Para convertir los valores de colesterol de lipoproteínas de baja densidad (LDL) a milimoles por litro, multiplique por 0,02586. ECV significa enfermedad cardiovascular, y TFG tasa de filtración glomerular. En Bain et al. se ofrecen más datos basales resumidos. DM2: diabetes mellitus tipo 2; ECV: enfermedad cardiovascular; ERC: enfermedad renal crónica; IMC: índice de masa corporal; TFG: tasa de filtración glomerular estimada; LDL: lipoproteínas de alta densidad; TFG: tasa de filtración glomerular.

1. Husain M, et al. N Engl J Med. 2019 Aug 29;381(9):841-851. doi: 10.1056/NEJMoa1901118.

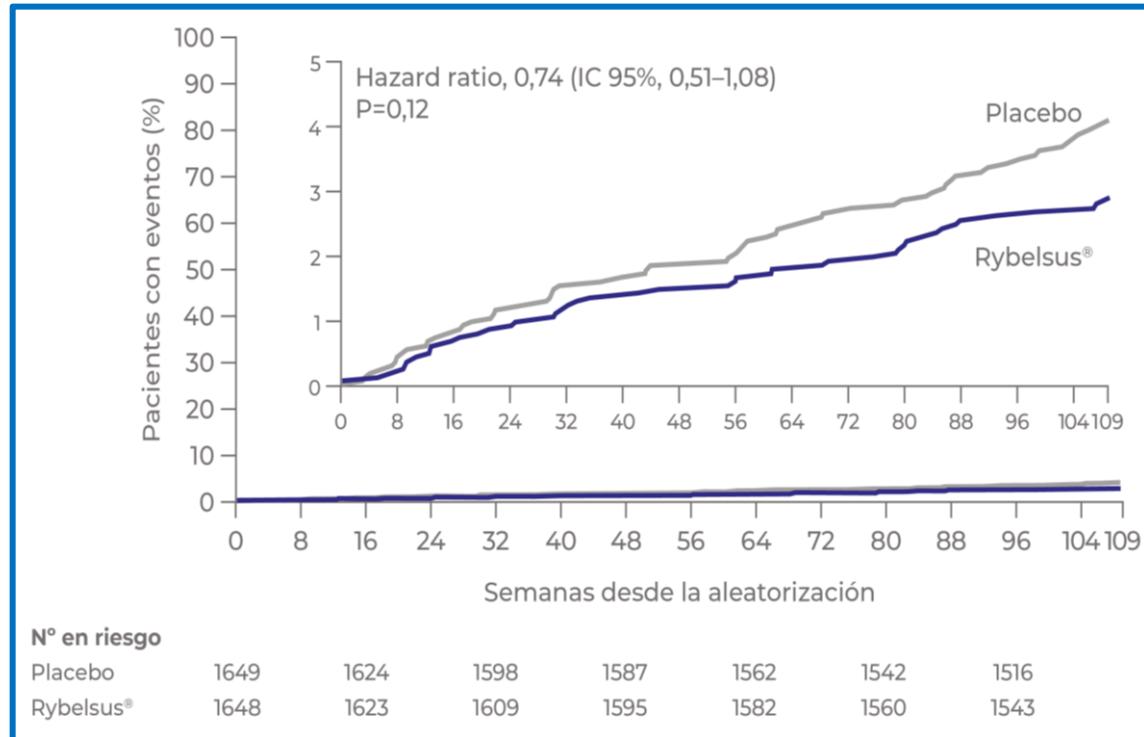
Semaglutida oral y resultados cardiovasculares en pacientes con DM2: estudio PIONEER 6¹

Resultados cardiovasculares

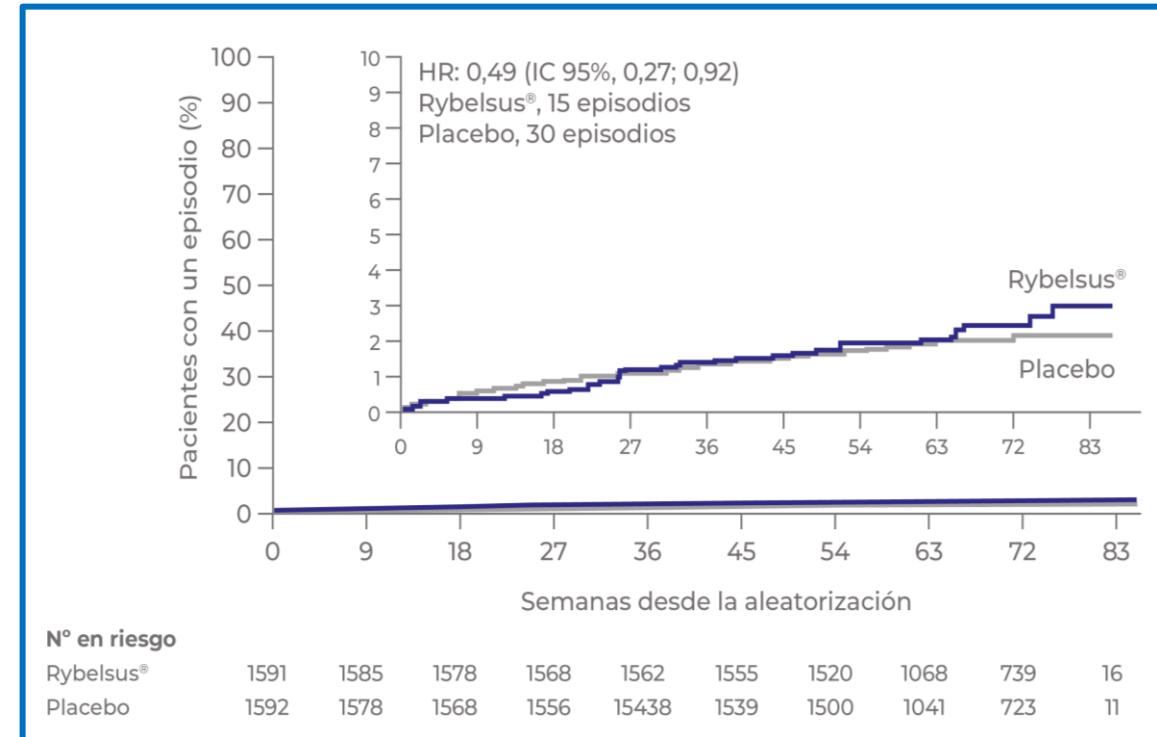


Semaglutida oral y resultados cardiovasculares en pacientes con DM2: estudio PIONEER 6¹

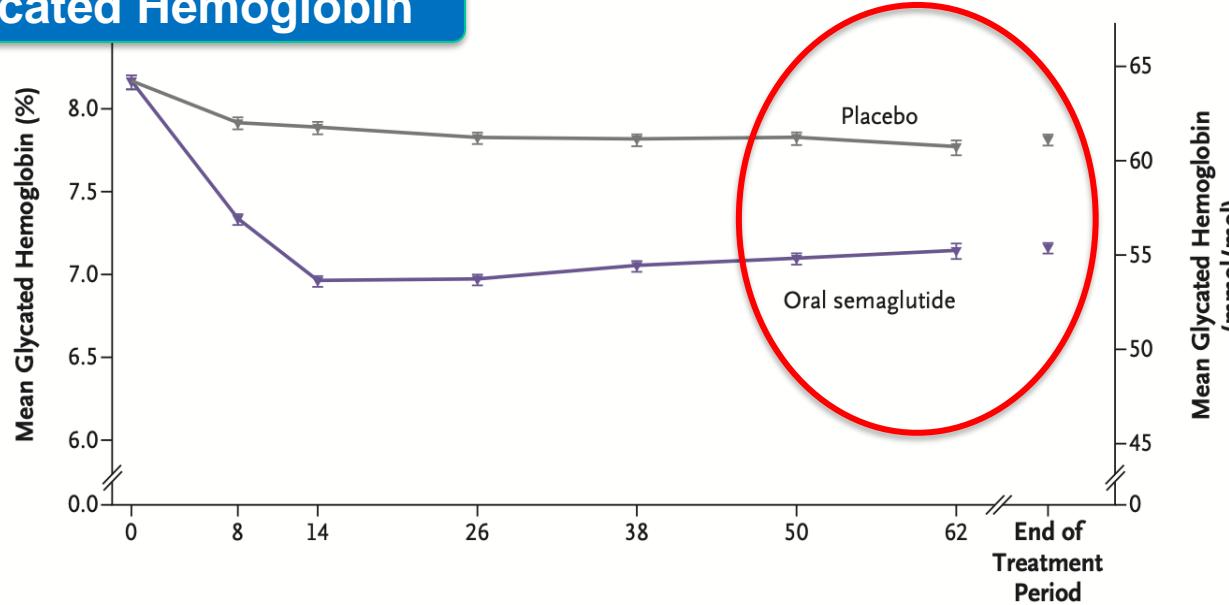
Infarto de miocardio no mortal



Muerte cardiovascular

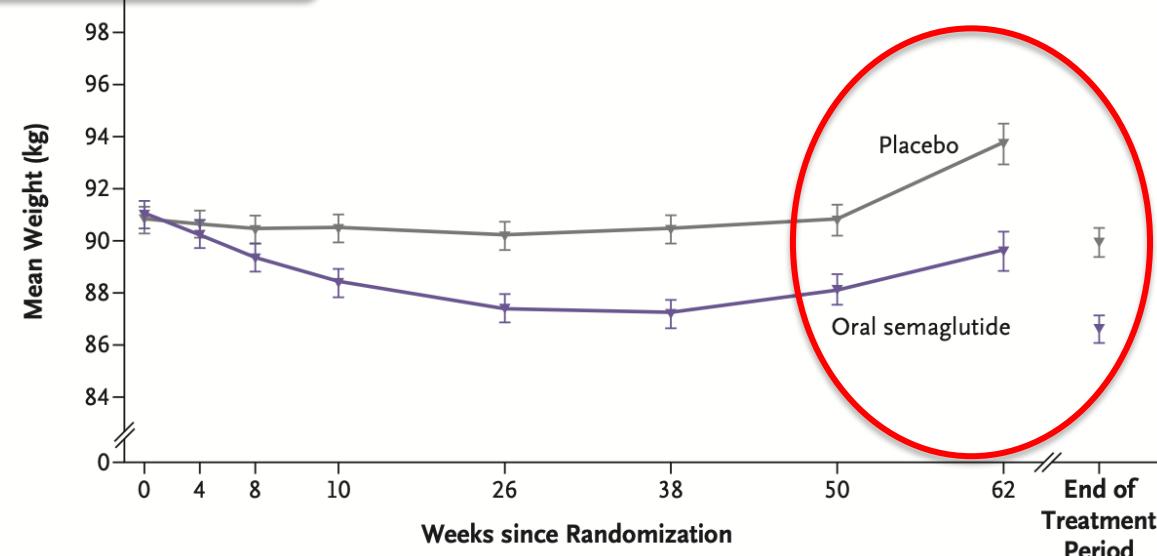


Glycated Hemoglobin



Oral semaglutide and
Cardiovascular Outcomes
in Patients with T2D.
PIONEER 6 Trial

Body Weight

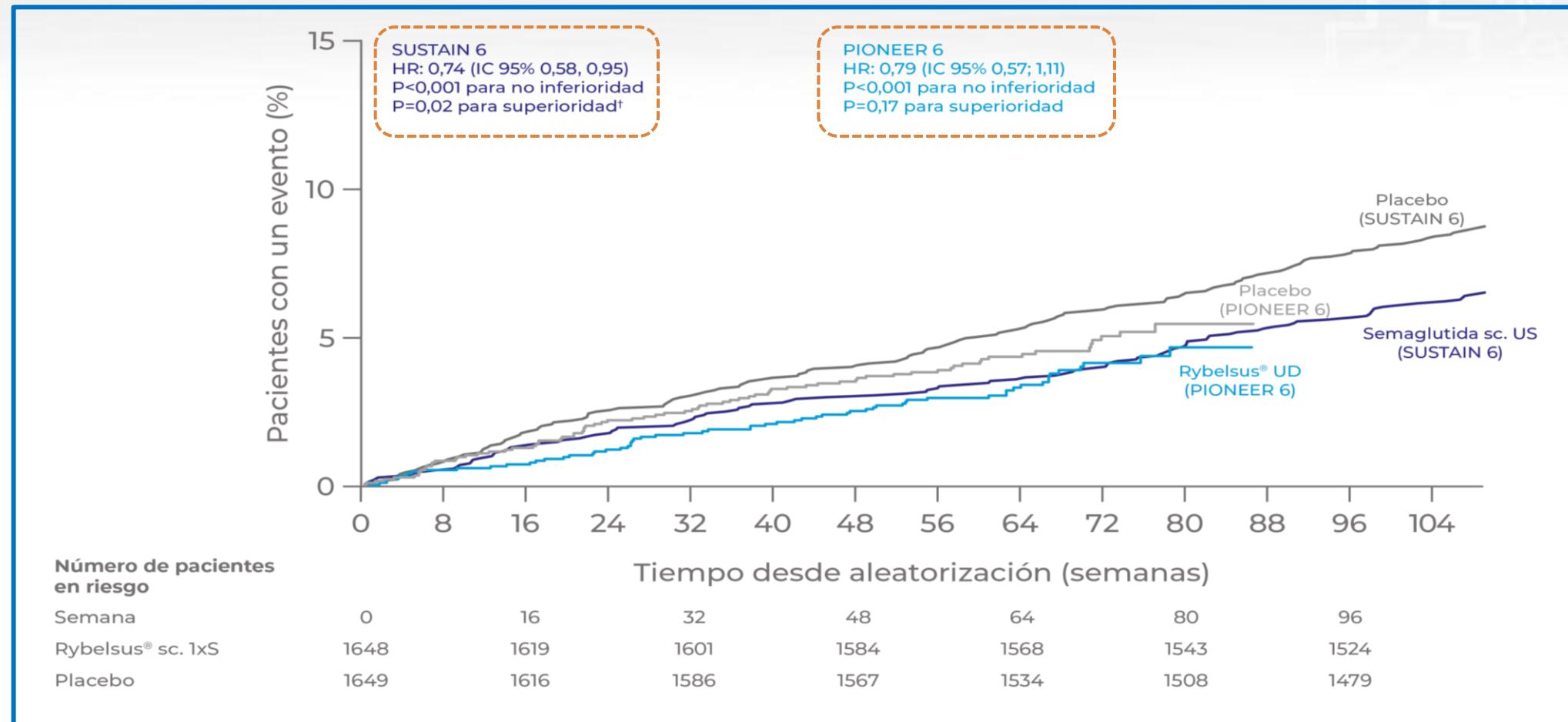


Semaglutida oral y resultados cardiovasculares en pacientes con DM2: acontecimientos adversos observados en el estudio PIONEER 6¹

Acontecimiento adverso (durante el periodo de tratamiento a menos que se especifique lo contrario)

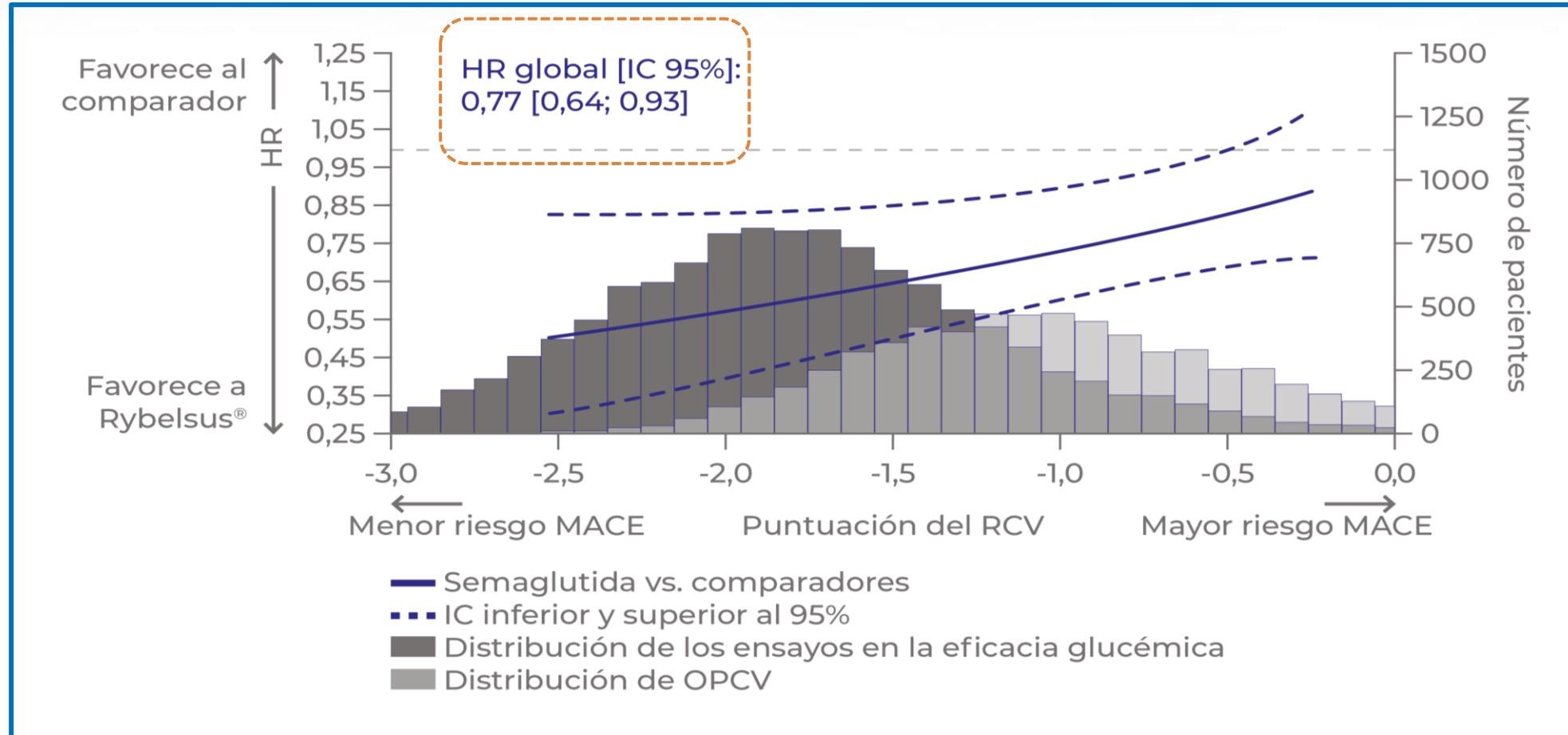
Evento	Rybelsus® (N = 1591)	Placebo (N = 1592)
Acontecimiento adverso que conduce a la interrupción permanente de semaglutida oral o de placebo	184 (11,6)	104 (6,5)
Según el sistema de clasificación por órgano [†]		Número de pacientes (porcentaje)
Trastornos gastrointestinales	108 (6,8)	26 (1,6)
Trastornos del metabolismo y la nutrición	19 (1,2)	7 (0,4)
Trastornos del sistema nervioso	17 (1,1)	13 (0,8)
Acontecimiento adverso grave	301 (18,9)	358 (22,5)
Que conlleven a la interrupción permanente de semaglutida oral o de placebo	41 (2,6)	48 (3,0)
Acontecimientos adversos de especial interés		
Enfermedad renal aguda [‡]	32 (2,0)	37 (2,3)
Pancreatitis aguda [‡]	1 (0,1)	3 (0,2)
Retinopatía o complicaciones relacionadas [§]	113 (7,1)	101 (6,3)
Hipoglucemia grave [§]	23 (1,4)	13 (0,8)
Neoplasias malignas [¶]	41 (2,6)	48 (3,0)

Incidencia acumulada del tiempo hasta la primera aparición de AAG con semaglutida vs. placebo en los estudios SUSTAIN 6 y PIONEER 6¹



Efectos de semaglutida en el RCV: estudio SUSTAIN y PIONEER¹

Riesgo relativo de MACE según el ECV basal y la distribución de sujetos



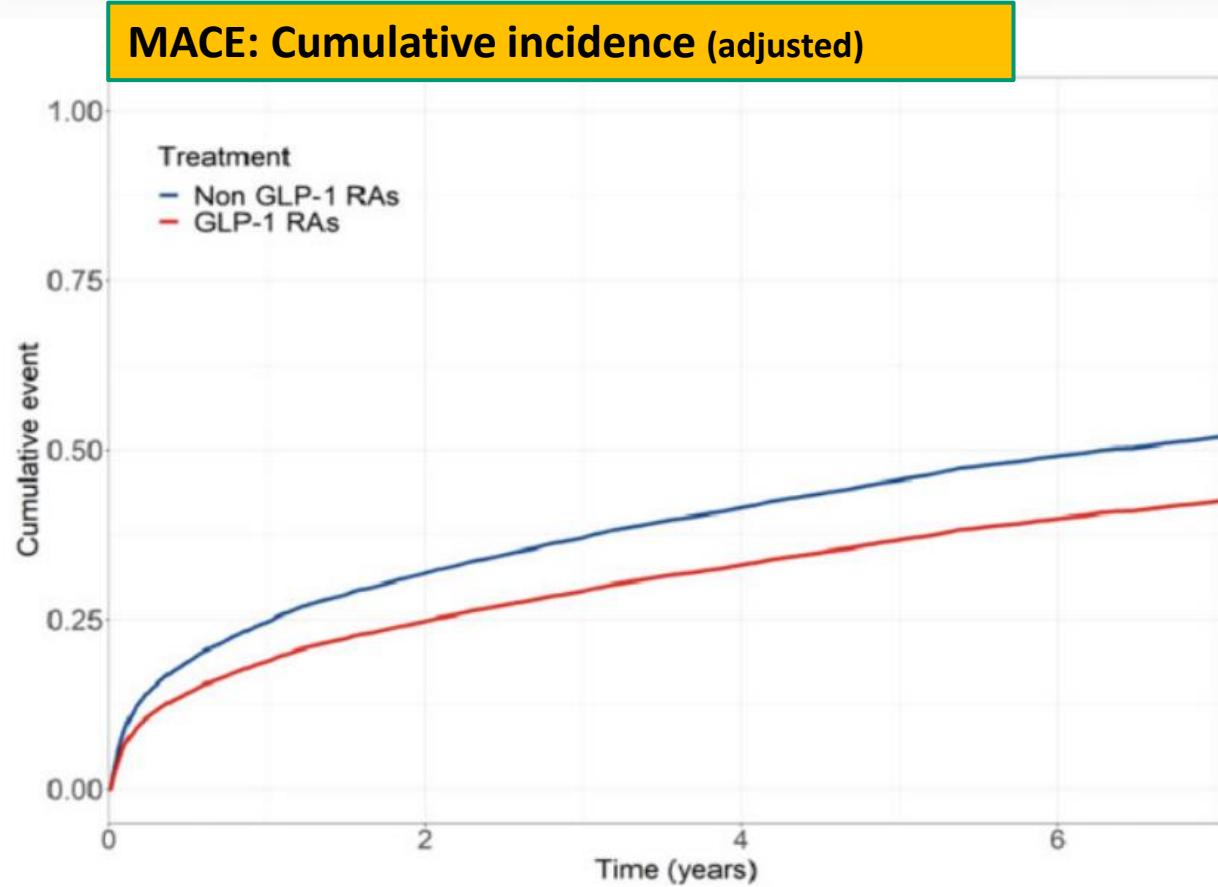
XUNTA DE GALICIA
CONSELLERÍA DE SANIDADE

1. Husain M, et al. Cardiovasc Diabetol. 2020 Sep 30;19(1):156. doi: 10.1186/s12933-020-01106-4.



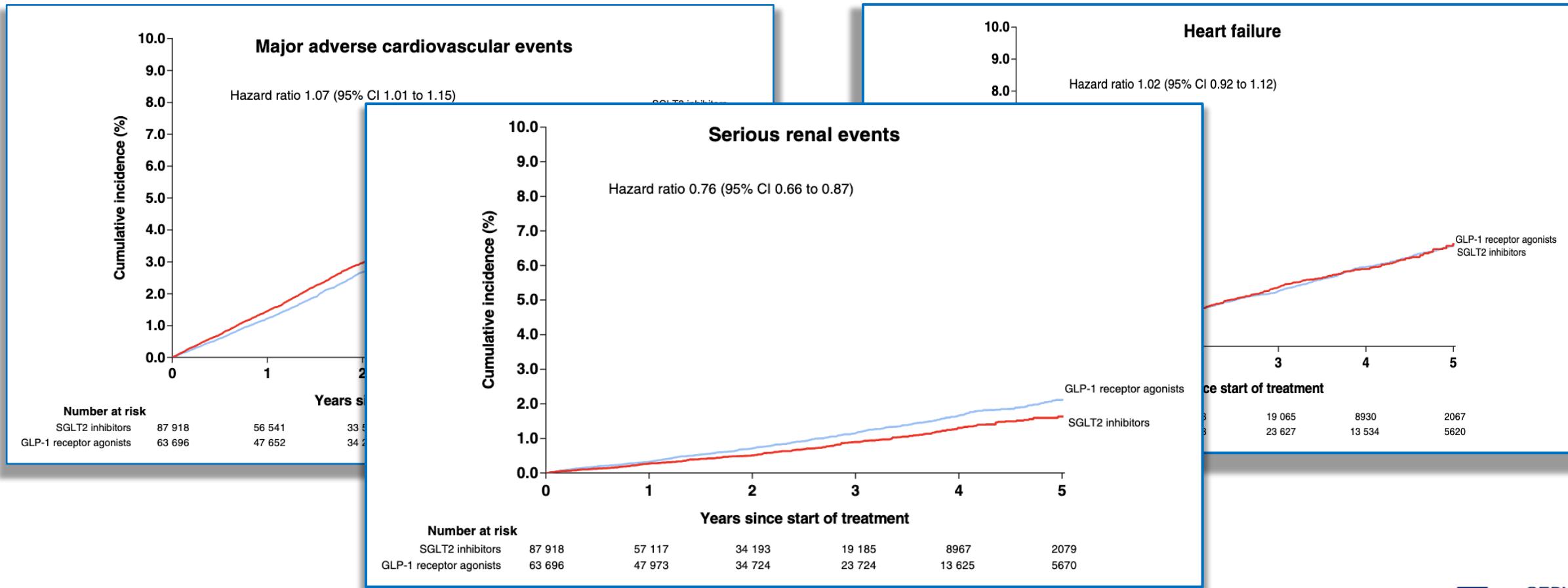
GLP1 receptor agonists and the risk of CV events in diabetic patients with an Acute Myocardial Infarction. SWEDEHEART.

3P-MACE



The comparative cardiovascular and renal effectiveness of SGLT2i and GLP1-ra : *A Scandinavian cohort study*

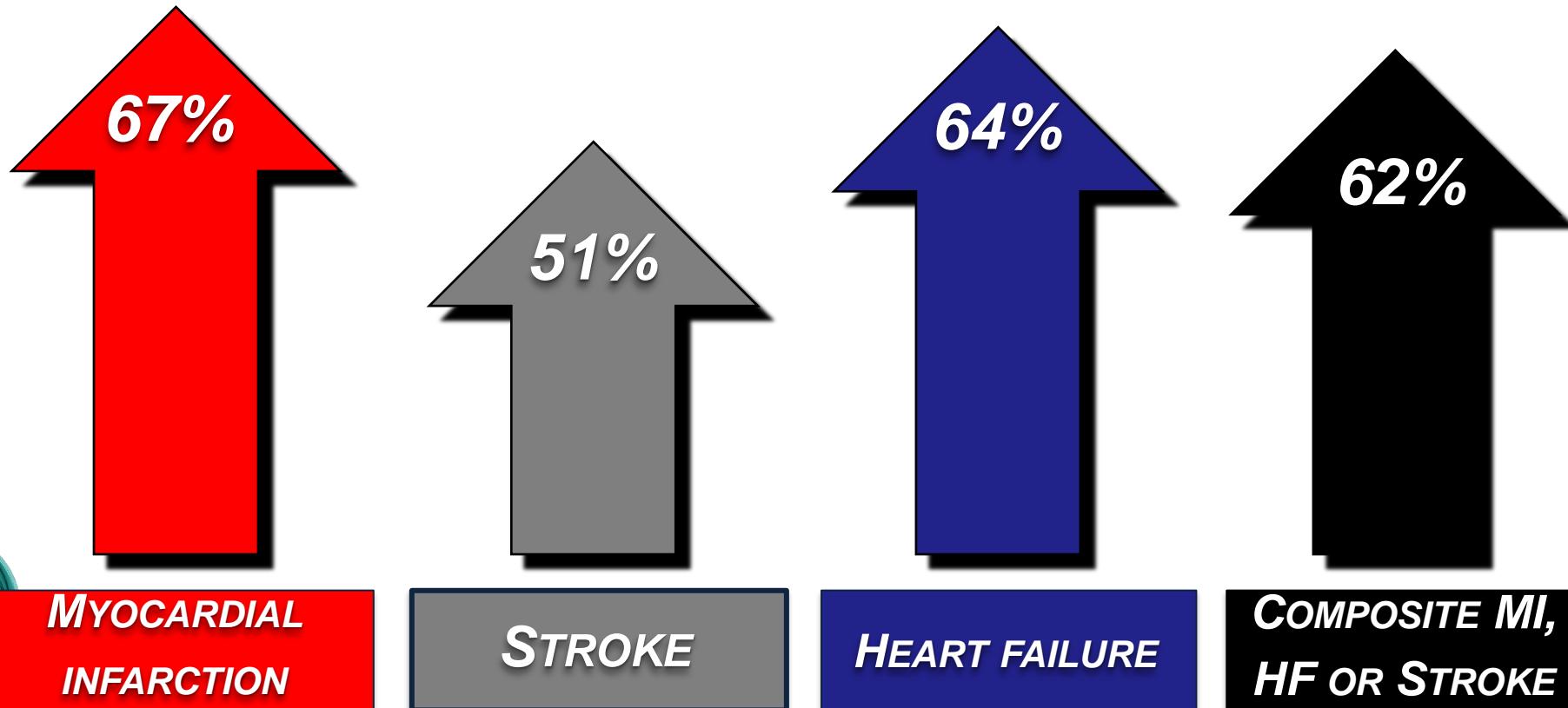
A cohort study of nationwide registers from Sweden, Denmark, and Norway, including 87 525 new users of SGLT2 inhibitors and 63 921 new users of GLP-1 receptor agonists, was conducted using data from 2013-2018



- Diabetes en Cardiología
- Fármacos para control glucometabólico para cardiólogos
- Ar-GLP1 en Cardiopatía Isquémica – semaglutida oral
- Ar-GLP1 en la estrategia de optimización terapéutica

Delayed Interventions is associated with and increased risk of Complications

*Percent Increase in CV Events in Patients with a 1-year delay in receiving intensive therapy and HbA1c >7% vs <7% *retrospective UK Study*

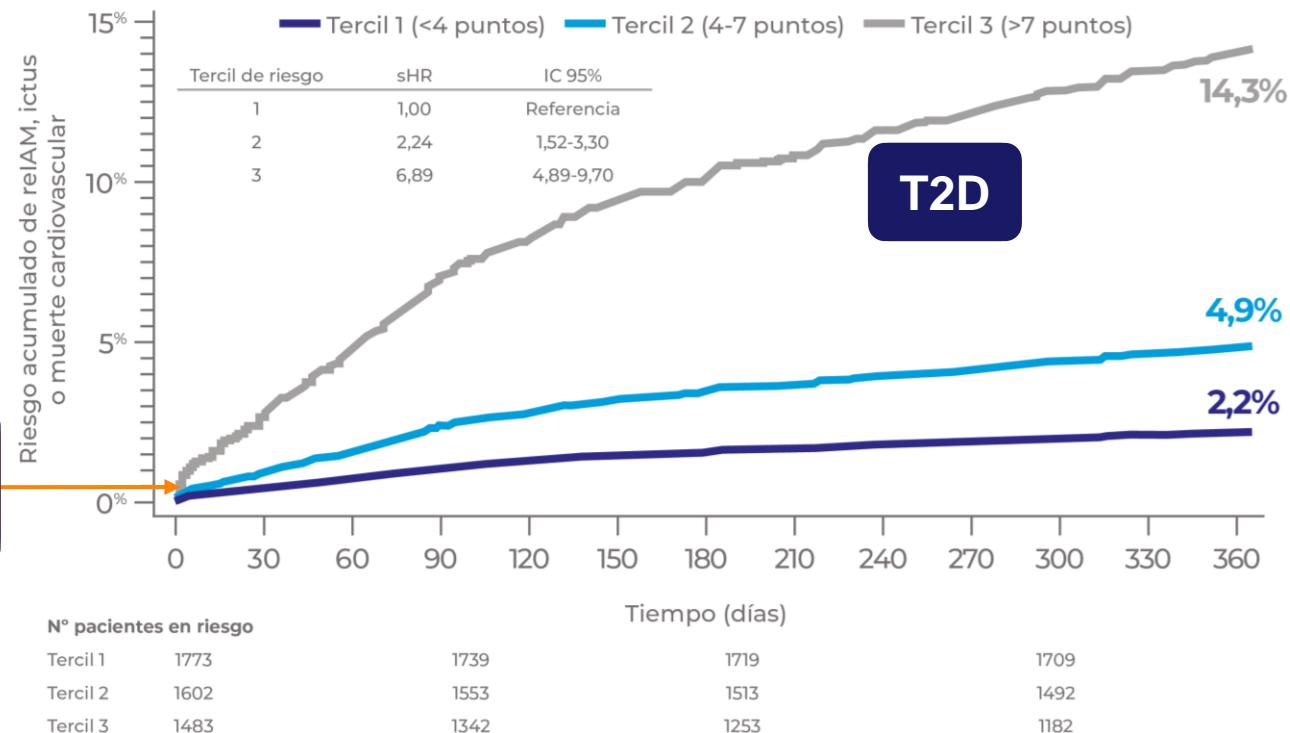


Paul SK, et al. Cardiovasc Diabetol 2015; 14: 100.

IAM, ictus o muerte CV tras un SCA: registro CardioCHUS

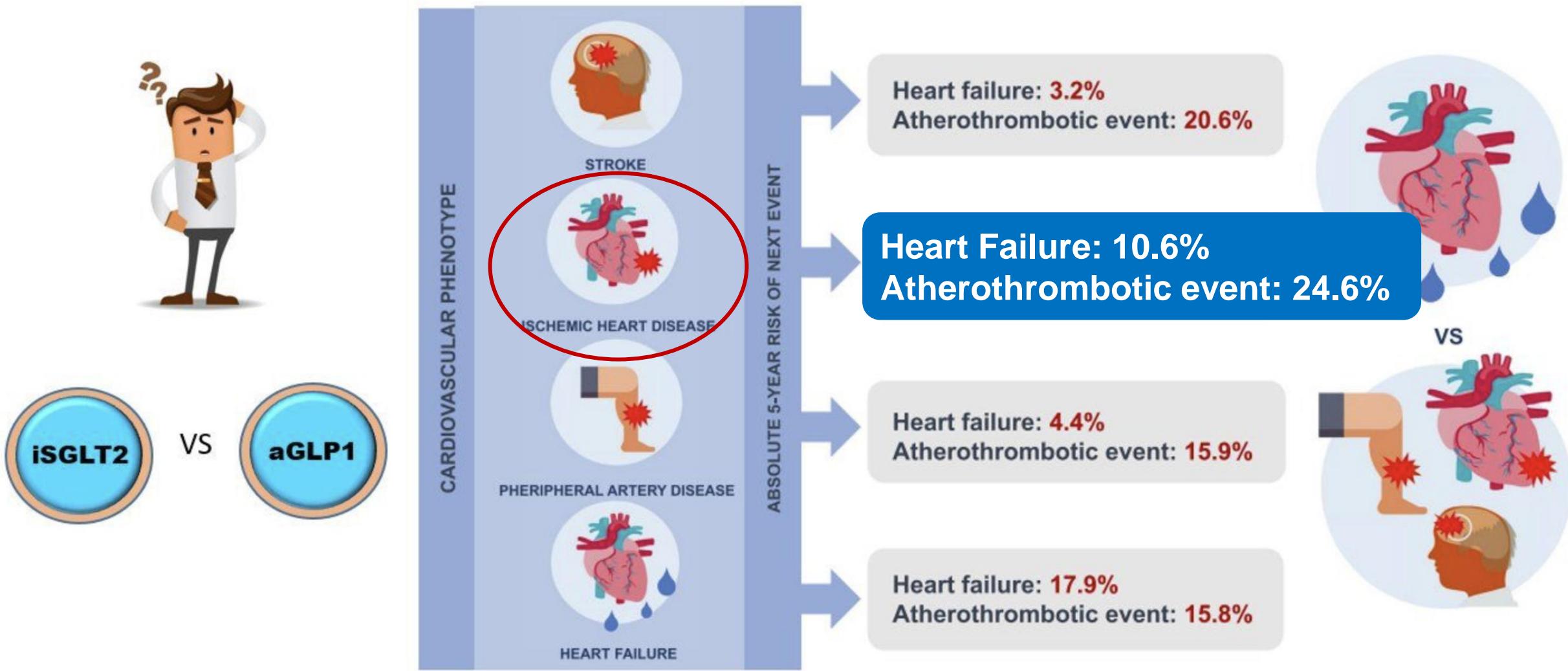
Desde el alta hospitalaria hasta el primer año¹

Riesgo acumulado de IAM, ictus, o muerte CV



SUSTAIN 6
RRR < 26%;
 $14.3 - 3.82 = 10.48\%$

Clinical CV Phenotypes and the patterns of future events in patients with T2D





MACE

Superiority

Heart Failure Hospitalization

Mostly neutral except for albiglutide

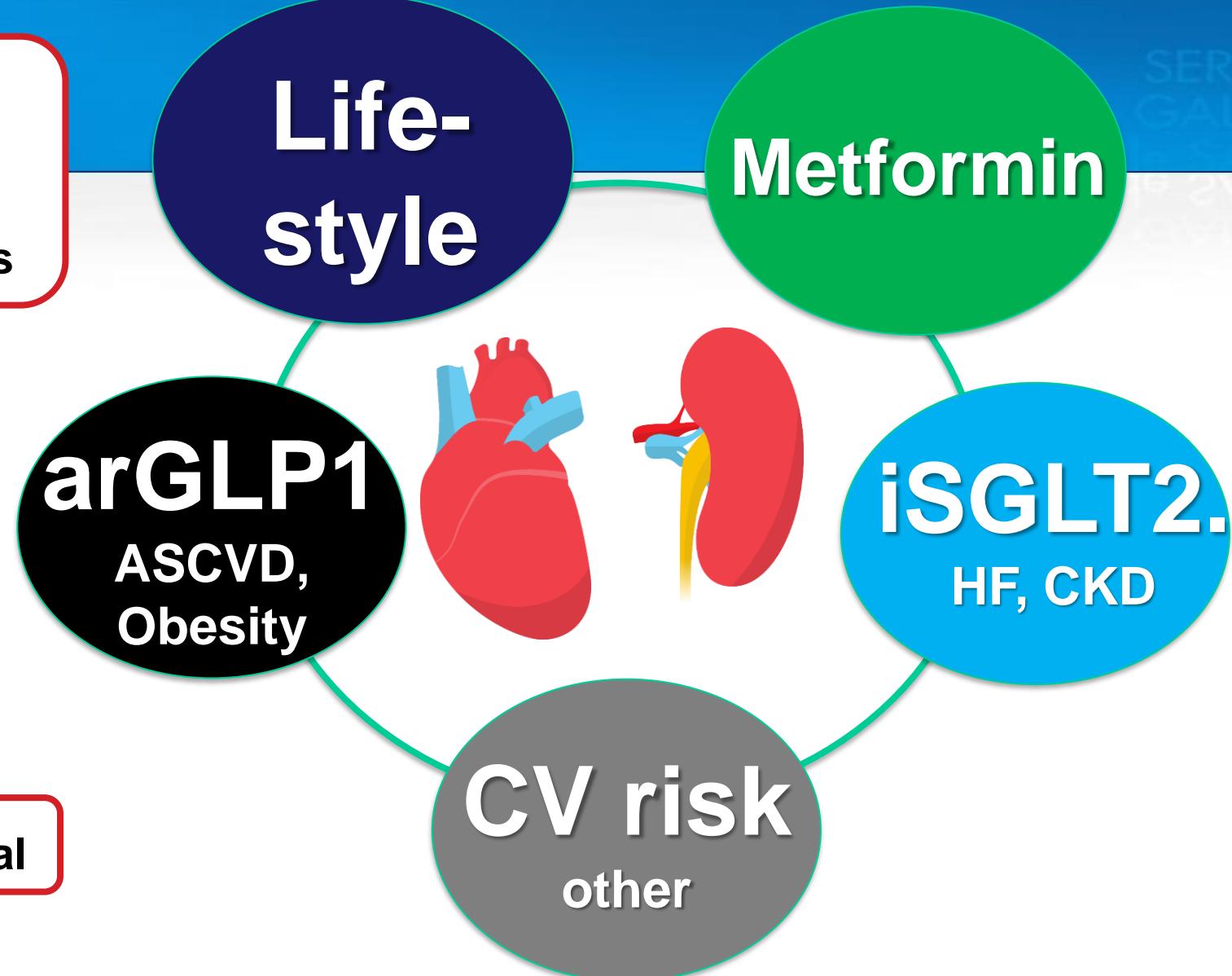
Proven Renal Benefit

Mostly albuminuria

These are complementary therapies acting on distinct patho-physiological pathways

The mechanisms of action are independent and additive

The benefits are incremental





Integrated Patient-care Pathway

Heart Failure

Proceso de insuficiencia cardíaca

Área de Referencia Complexo Hospitalario Universitario de Santiago

Proceso de insuficiencia cardíaca.
Área de Referencia Complexo Hospitalario Universitario de Santiago



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24
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Atrial Fibrillation

Proceso de Fibrilación Auricular

Xerencia de Xestión Integrada de Santiago

Proceso Fibrilación Auricular
Xerencia de Xestión Integrada de Santiago



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19
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Ischemic Heart Disease

Organización do Proceso Asistencial de
Cardiopatía Isquémica Crónica
na ÁREA do Complexo Hospitalario Universitario
de Santiago De Compostela

Documento consensuado entre o Servizo de Cardioxoxía e
Atención Primaria de Santiago de Compostela e Pontevedra



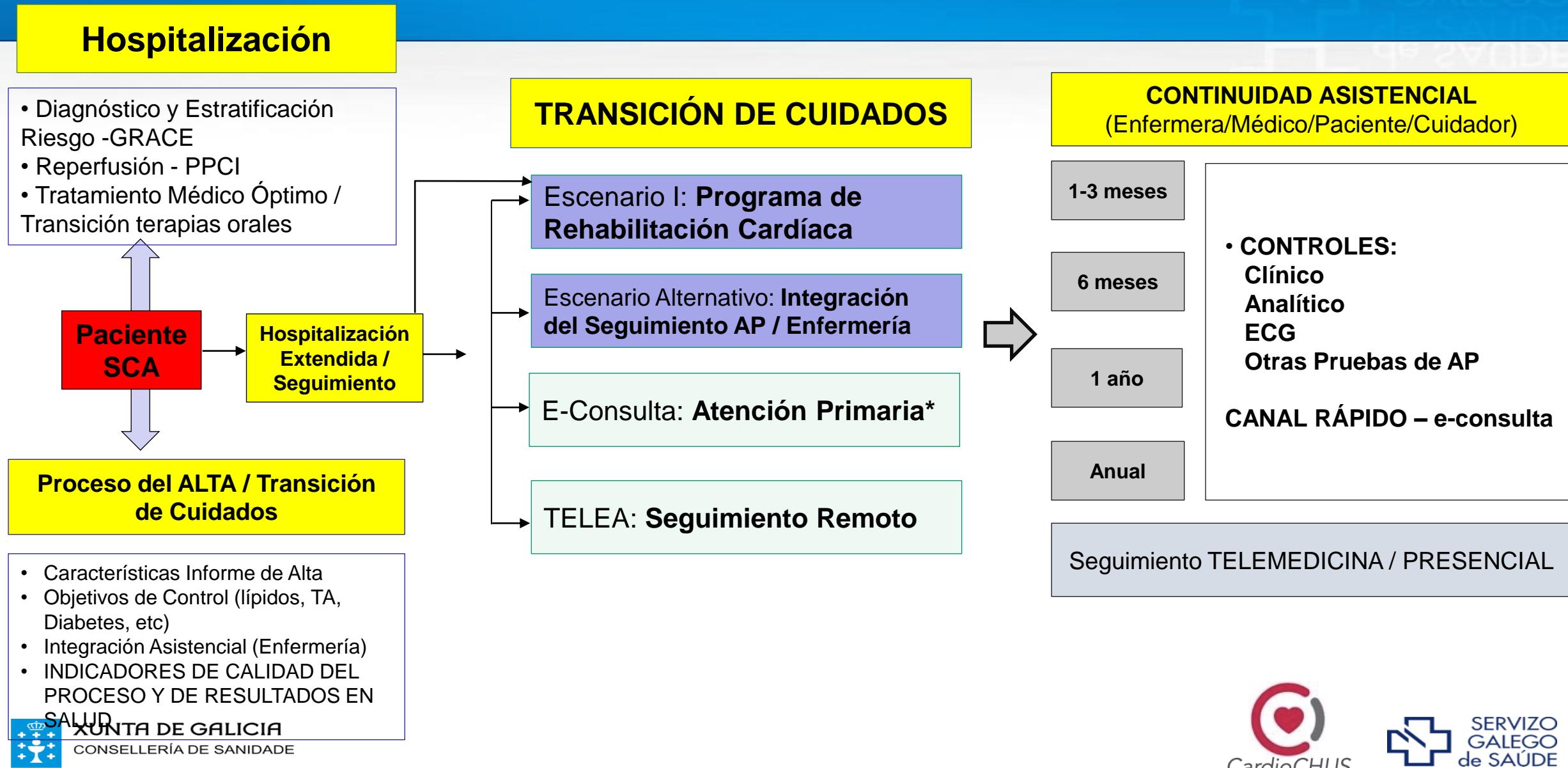
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XUNTA DE GALICIA

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de SAÚDE

PROCESO ASISTENCIAL DE CARDIOPATÍA ISQUÉMICA. PARTIENDO DEL SCA



Abordaje del paciente con cardiopatía isquémica: El desafío



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