

XVIII JORNADAS
SOLACI
2012

Para el médico clínico

6° Región Andina y Pacífico

4-5 Octubre 2012
Hilton Colón Guayaquil



S O C I E D A D
LATINOAMERICANA
DE CARDIOLOGIA
INTERVENCIONISTA

Selección de DES para Diabéticos

Análisis de la evidencia

Mariano Albertal

Diabetes Typo II

La prevalencia esperada en 2025~300 millones



www.solacci.org

Adapted from King H et al Diabetes Care 1998;21:1414-1431.

Diabetes Typo II

La prevalencia esperada en 2025~300 millones

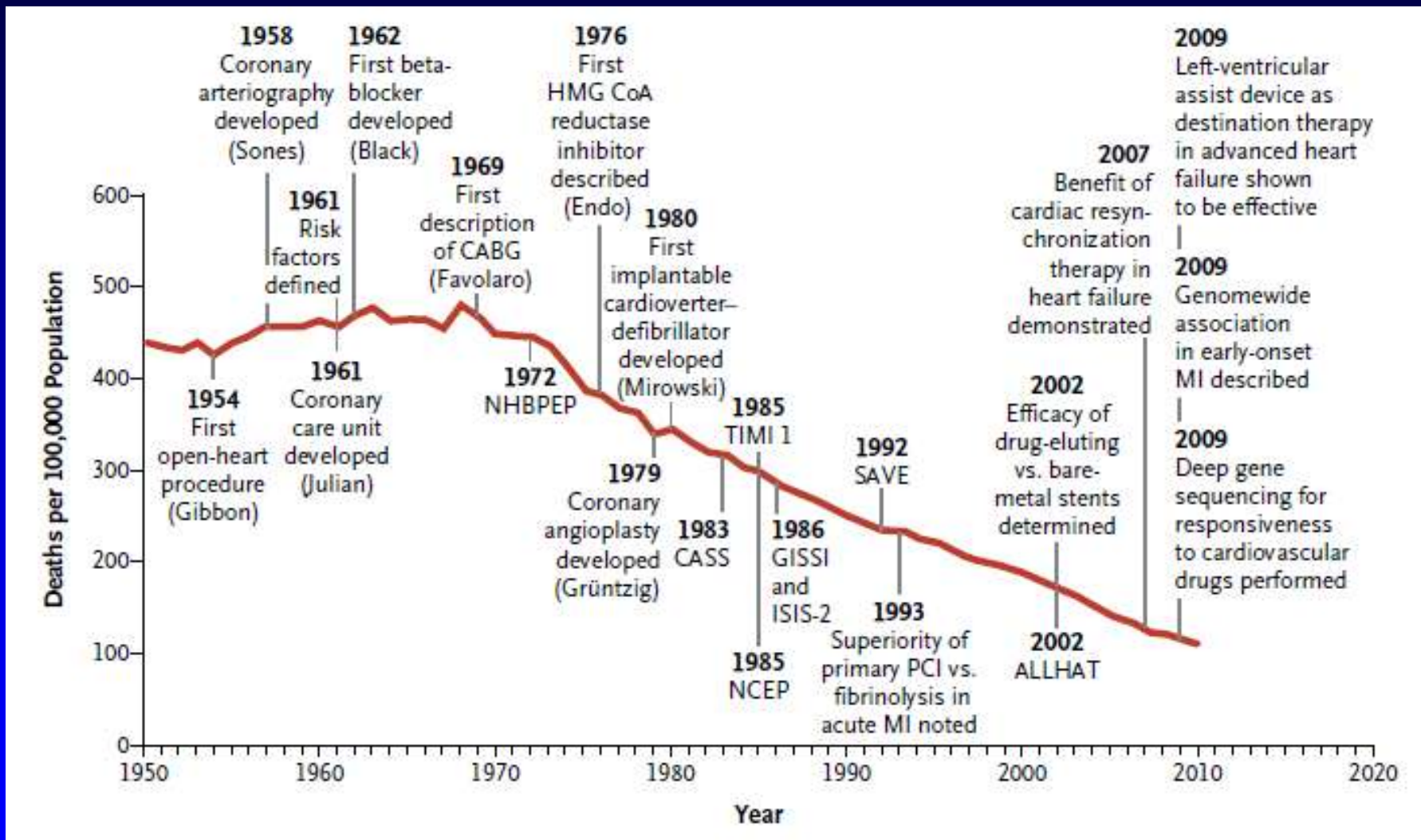
- En 2000 Diabetes fue diagnosticada en ~155 millones de adults.
- Entre 1995 y 2025, la prevalencia aumentara un 35%.



Curva de muerte a través del tiempo...

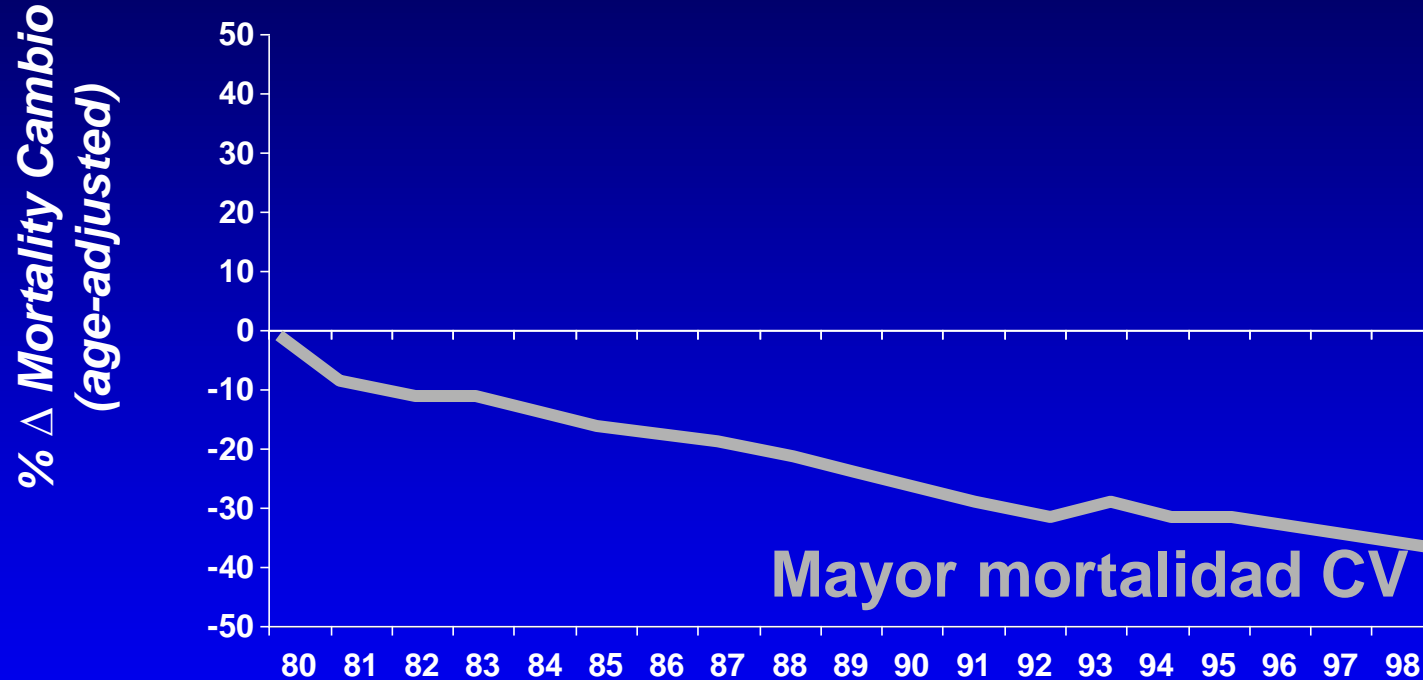
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Muerte Cardiovascular 1950-presente



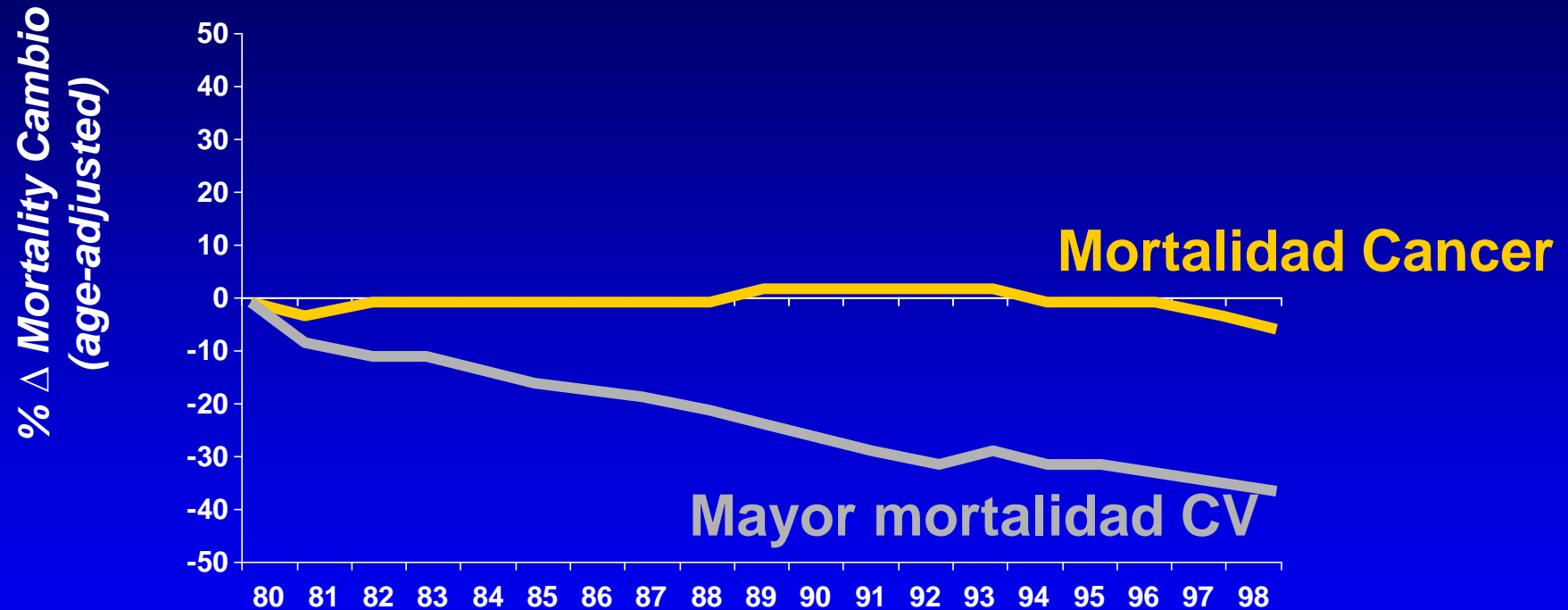
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Curva de muerte a través del tiempo...



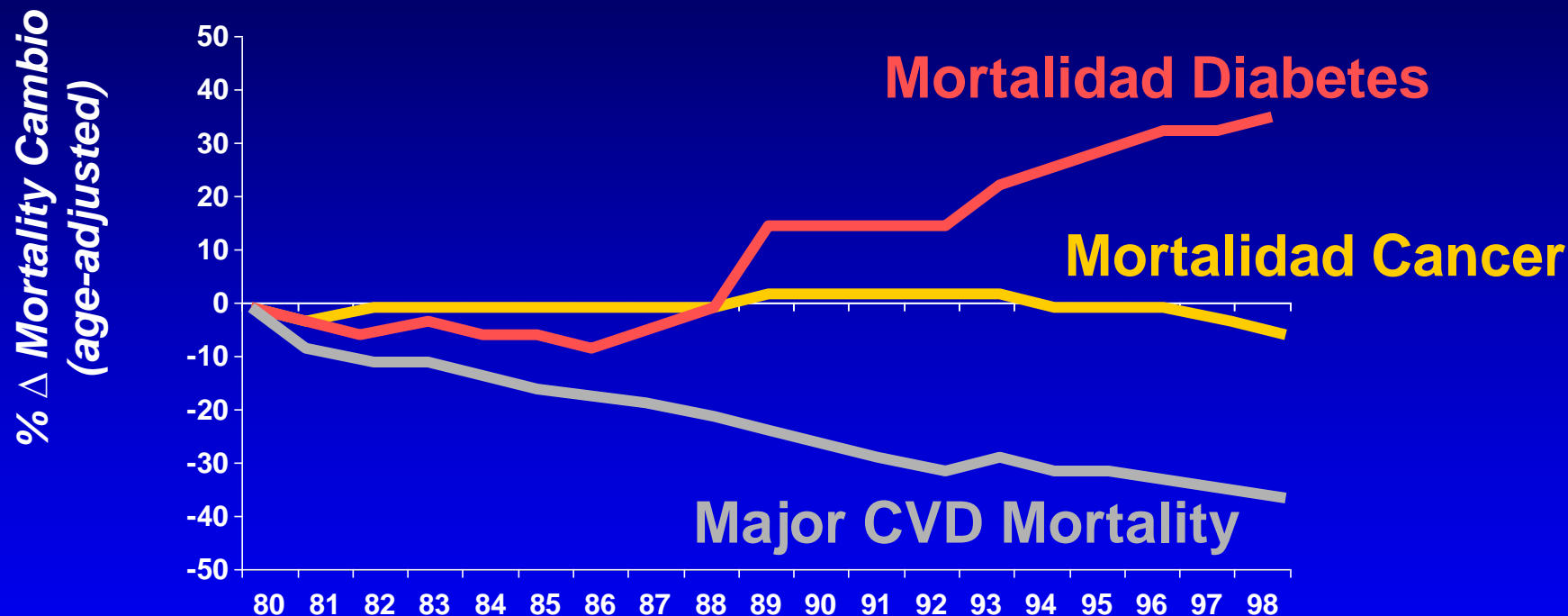
Centers for Disease Control and Prevention Mortality Database from *Burgeoning Dilemmas in the Management of Diabetes and Cardiovascular Disease. BARI 2D Trial. Sobel BE et al. Circ 2003; 107: 636-42*

Death curves along time...



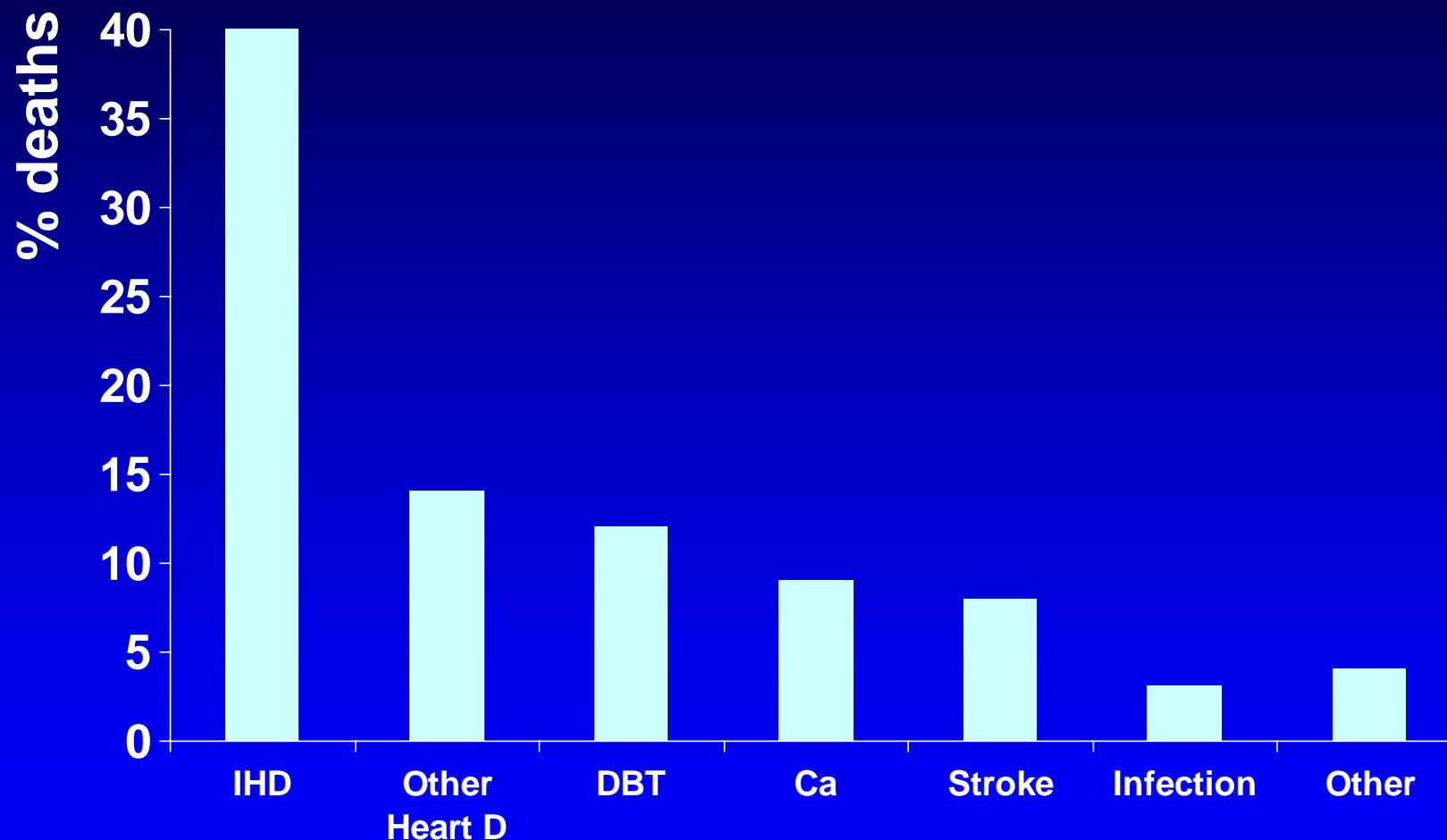
Centers for Disease Control and Prevention Mortality Database from
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Disease. BARI 2D Trial. Sobel BE et al. Circ 2003; 107: 636-42

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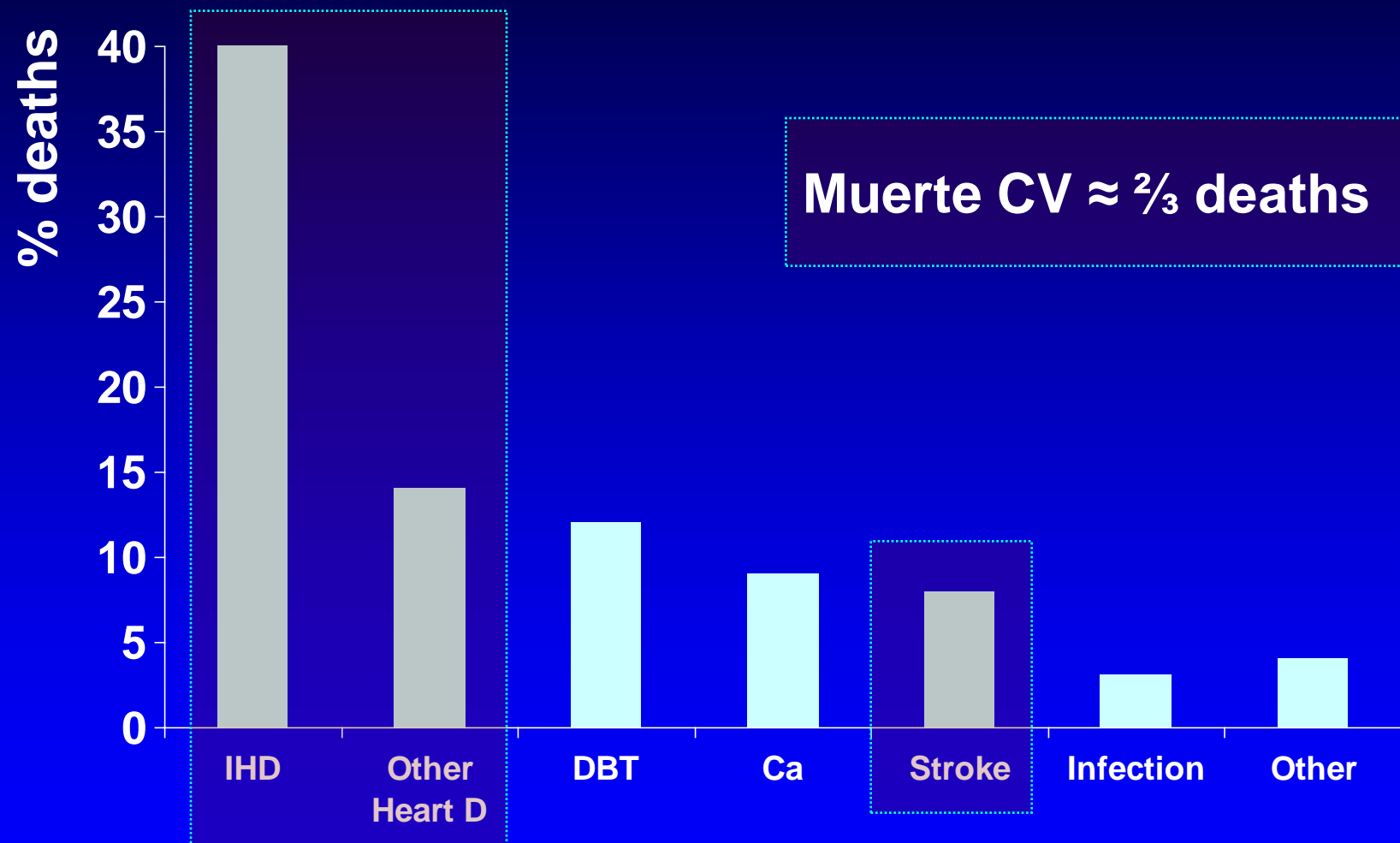
Centers for Disease Control and Prevention Mortality Database from *Burgeoning Dilemmas in the Management of Diabetes and Cardiovascular Disease. BARI 2D Trial. Sobel BE et al. Circ 2003; 107: 636-42*

Causa de muerte en diabeticos

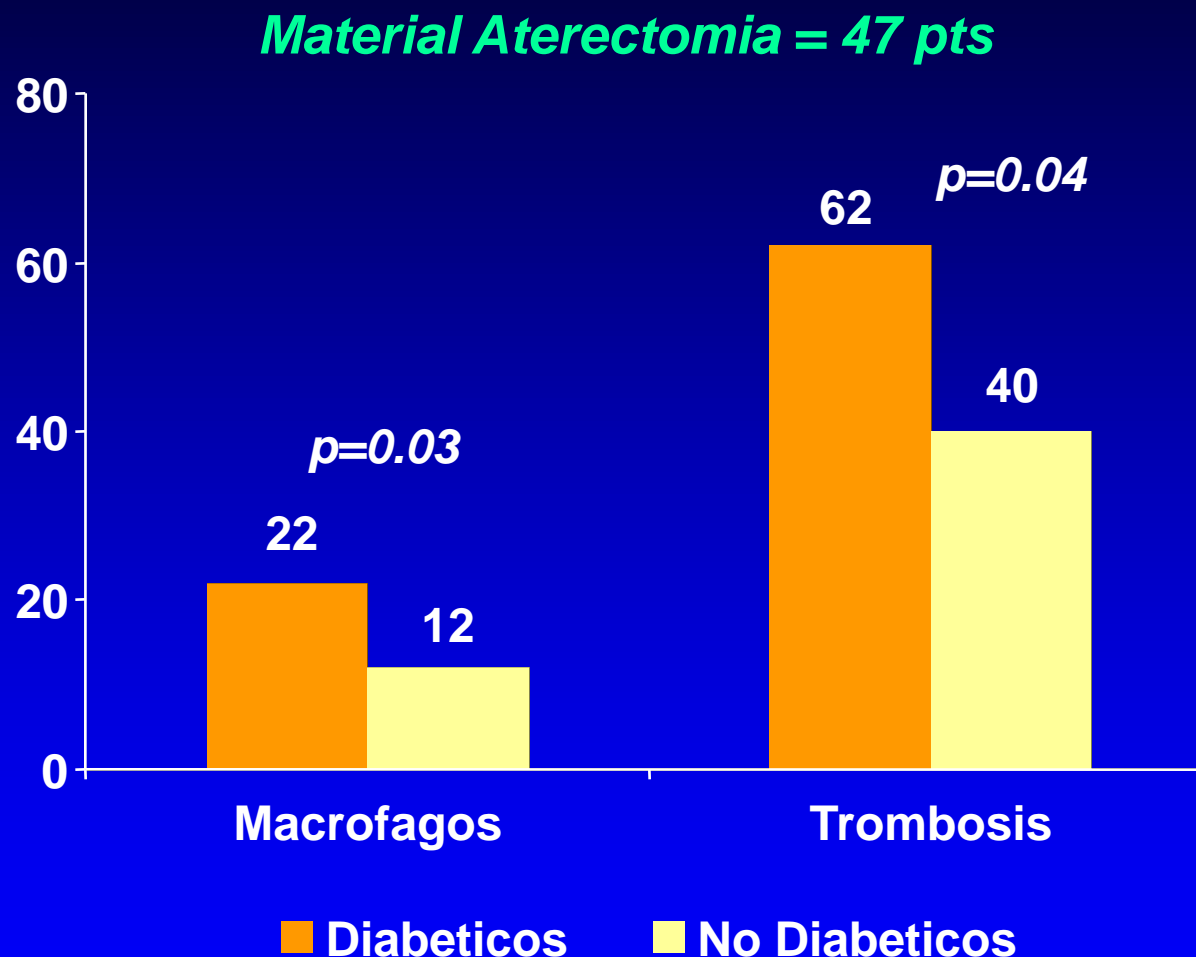


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Causa de muerte en diabeticos



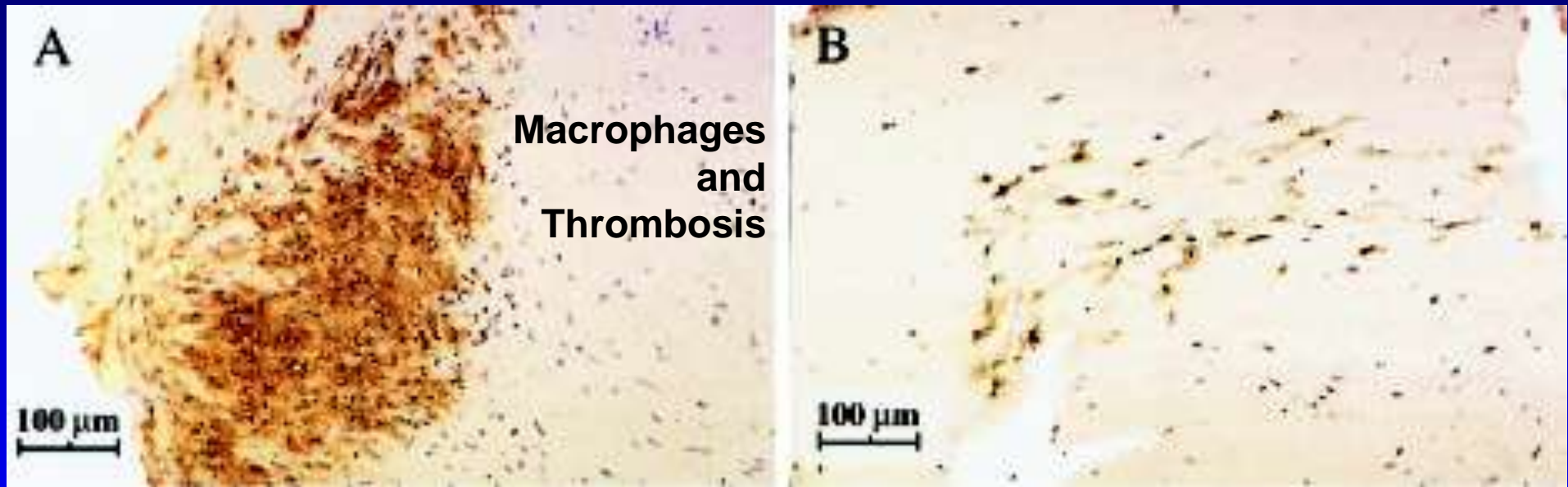
Tipo de Placa en Diabéticos



Coronary composition and macrophage infiltration in atherectomy specimens from patients with diabetes mellitus. Moreno PR et al. Circ 2000; 102: 2180-4

Composición de la Placa Ateroesclerótica en Diabeticos

Material de Endarterectomia= 47 pts.



A. Diabéticos

B. Non Diabéticos

Coronary composition and macrophage infiltration in atherectomy specimens from patients with diabetes mellitus. Moreno PR et al. Circ 2000; 102: 2180-4

MH - D # 13 - 10-aug-12

La Diabetes genera un Estado Pro-trombotico



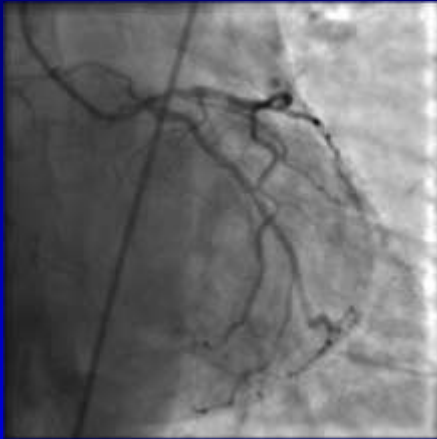
¹ De Vriese AS et al. *Br J pharmacol* 2000; 130: 963-74

² Angiolillo D et al. *Diabetes* 2005; 54: 2430-5

³ Suzuki LA et al. *Diabetes* 2001; 50: 851-60

⁴ Elezi S et al. *J Am Coll Cardiol* 1998; 32: 1866-73

Diabeticos: pacientes con enfermedad coronaria mas compleja



- ❑ Vasos finos
- ❑ > multiples vasos
- ❑ > lesiones calcificadas
- ❑ Aumento de restenosis
- ❑ >comorbilidades (Hipertension, Hiperlipidemias, renal)

Lo que sabemos sobre la Diabetes...

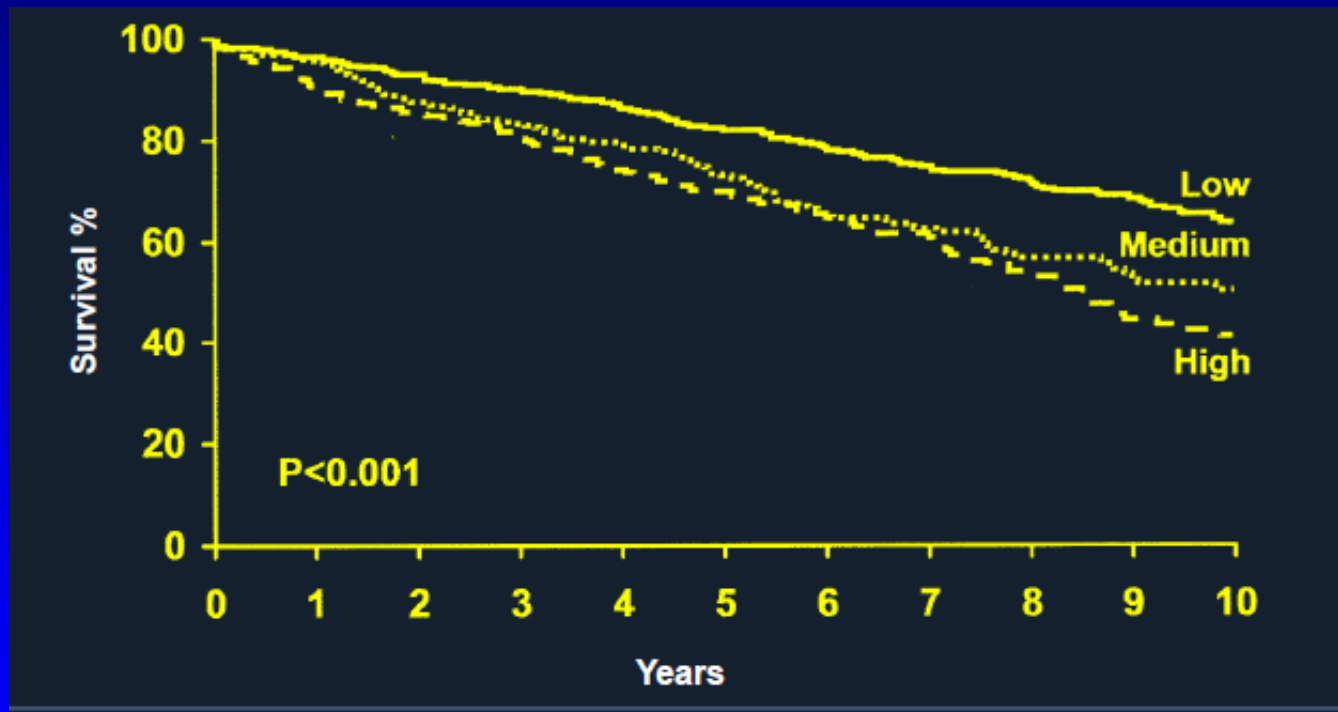
- **DM \equiv CAD (CAD = $\frac{2}{3}$ muertes de los DM)**
- **Casi $\frac{1}{8}$ adultos poseen DM or Intolerancia Glucosa ($\approx \frac{1}{3}$ >60yrs)**
- **CAD en DM es mas severa y difusa que no DM**
- **49% de DM tienen CAD en autopsia**
- **Mortalidad es mayor en DM**

**Aunque la mayoría son
asintomáticos.**

Asintomaticos: Estudio Observacional de la Clinica Mayo

Evaluado mediante a SPECT

- 58% con SPECT anormal (826 of 1427)
- 18% de alto riesgo x SPECT (61% con alto riesgo x CCG)

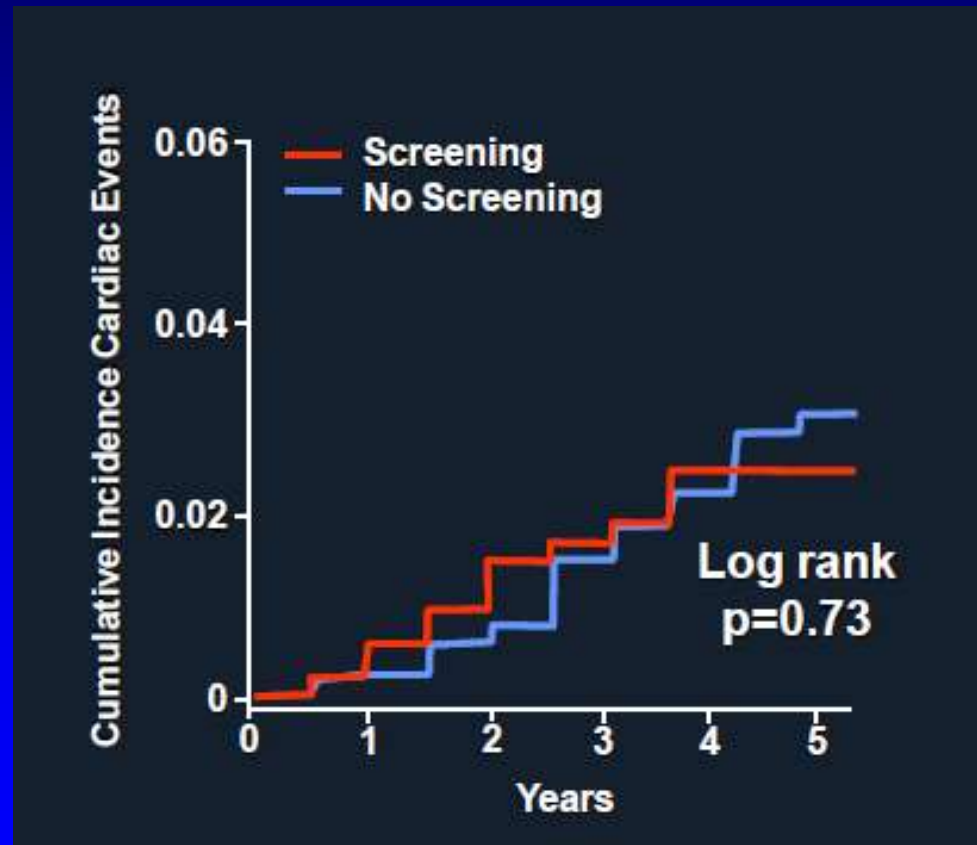


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Rajagopalan N et al. Identifying high-risk asymptomatic diabetic patients who are candidates for screening stress single-photon emission computed tomography imaging. J Am Coll Cardiol 2005 Jan 4; 45(1): 43-9.

DM Asintomaticos : Es util el Screening de Rutina?

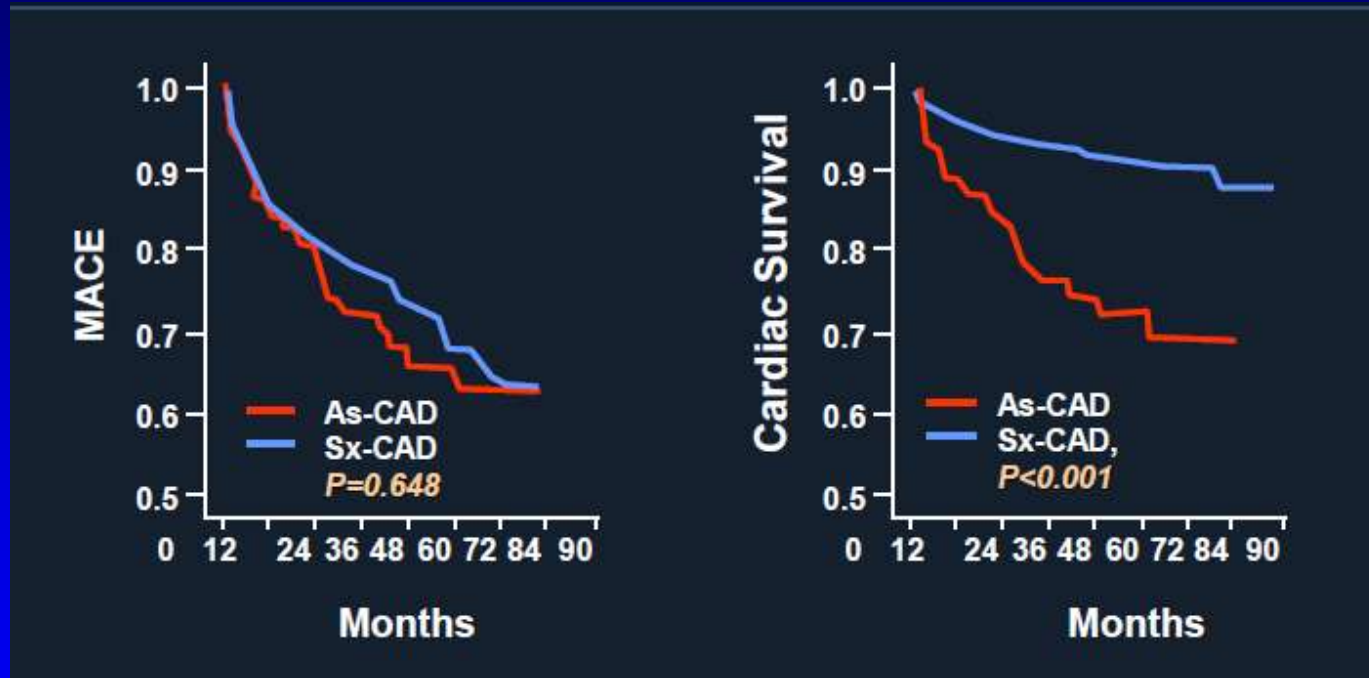
Estudio DIAD (1123 pts, 4.8 yrs Seguimiento)



Riesgo CV en DM: Sintomaticos vs Asintomaticos

MACE Y el riesgo CV

300 pts sometidos a Coronariografia Diagnostica;



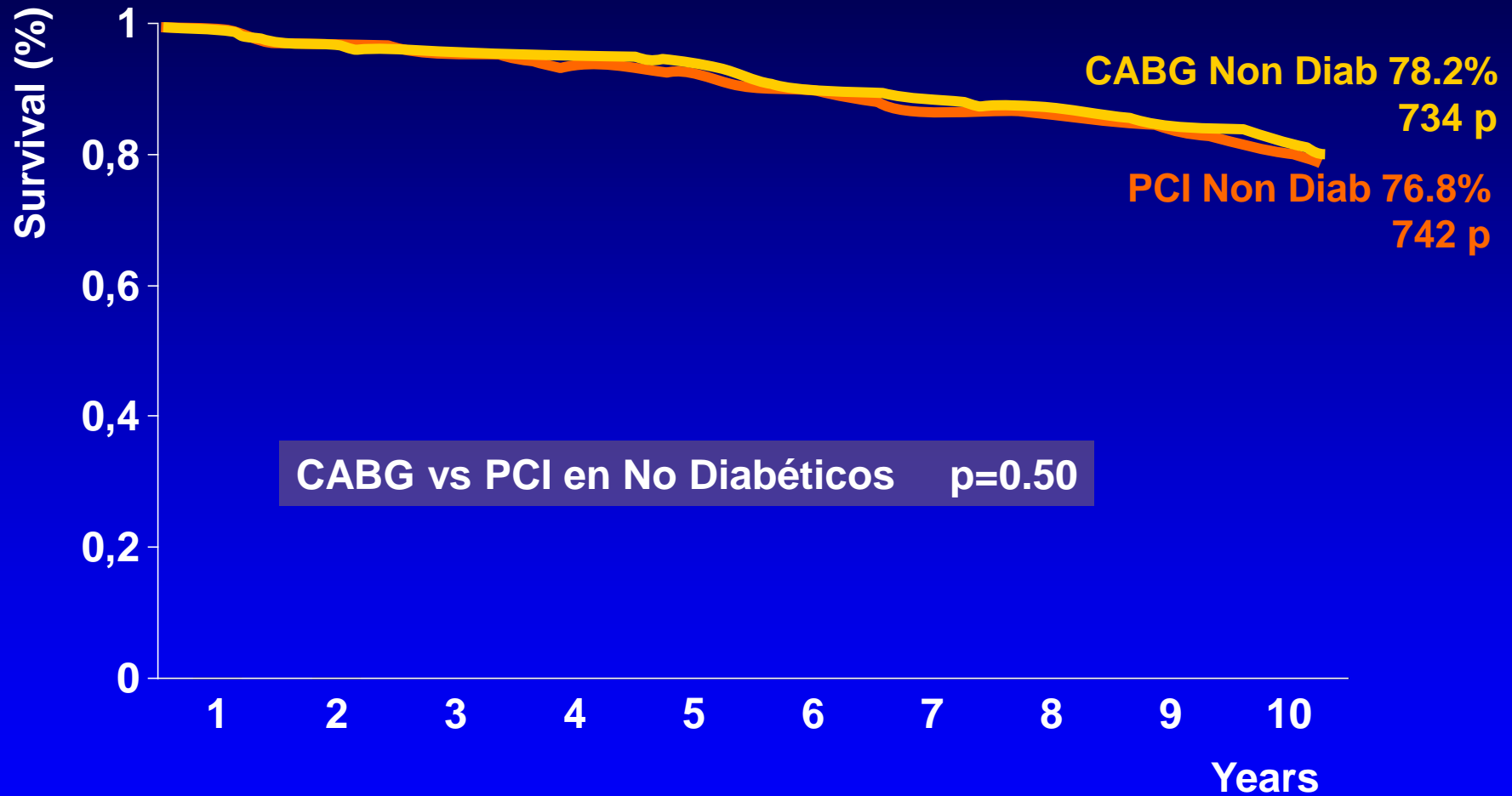
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3-veces mayor la tasa de revascularizacion en sintomaticos

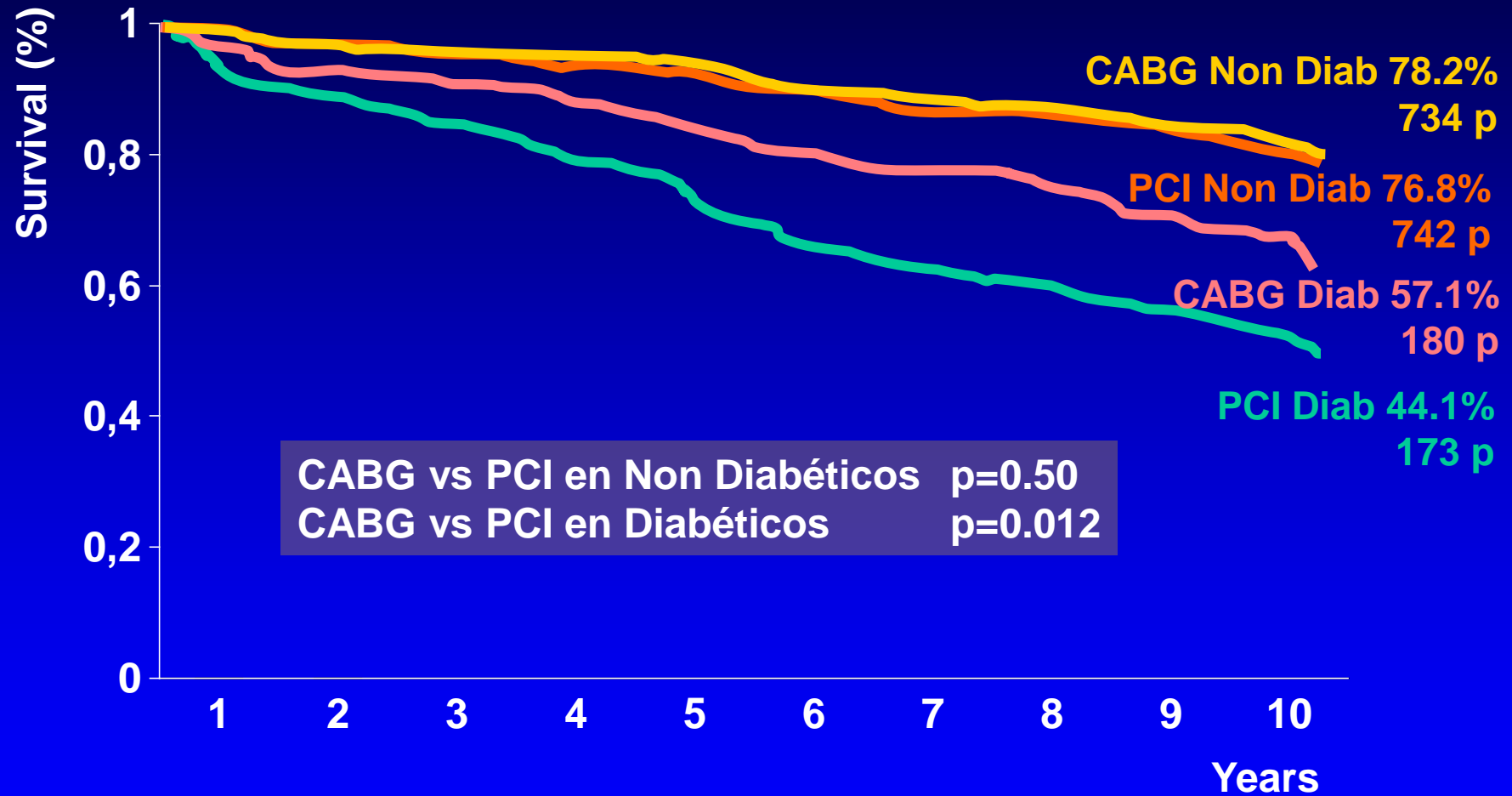
Diabeticos & Revascularizacion

www.solacci.org

BARI Diabeticos vs Non-Diabeticos: 10-yrs Sobrevida



BARI Diabéticos vs Non-Diabeticos: 10-yrs Sobrevida

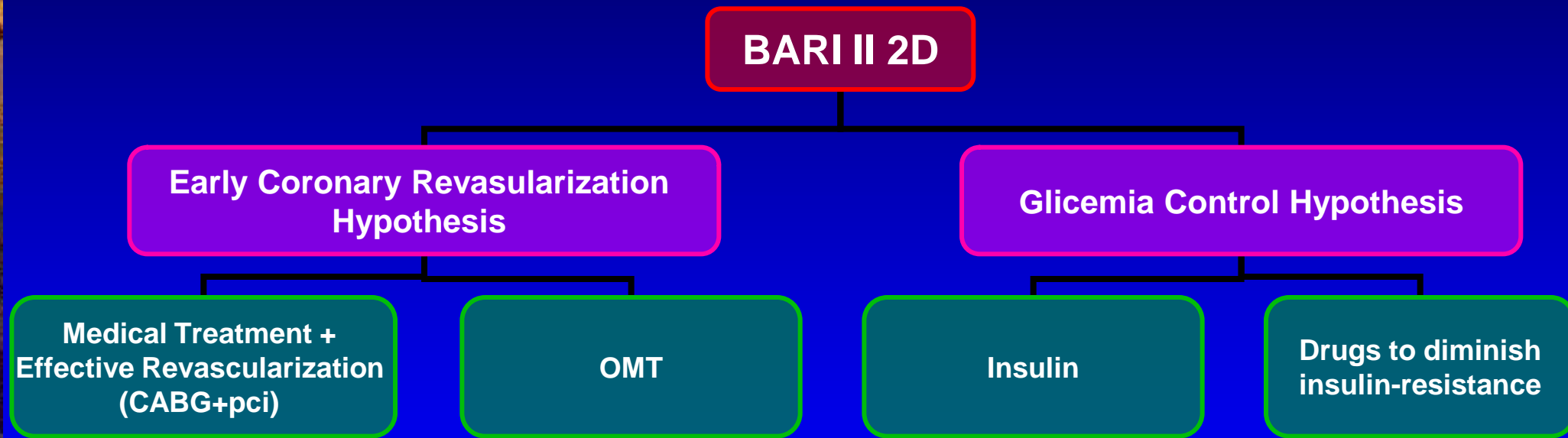


BARI 2D



2800 pts

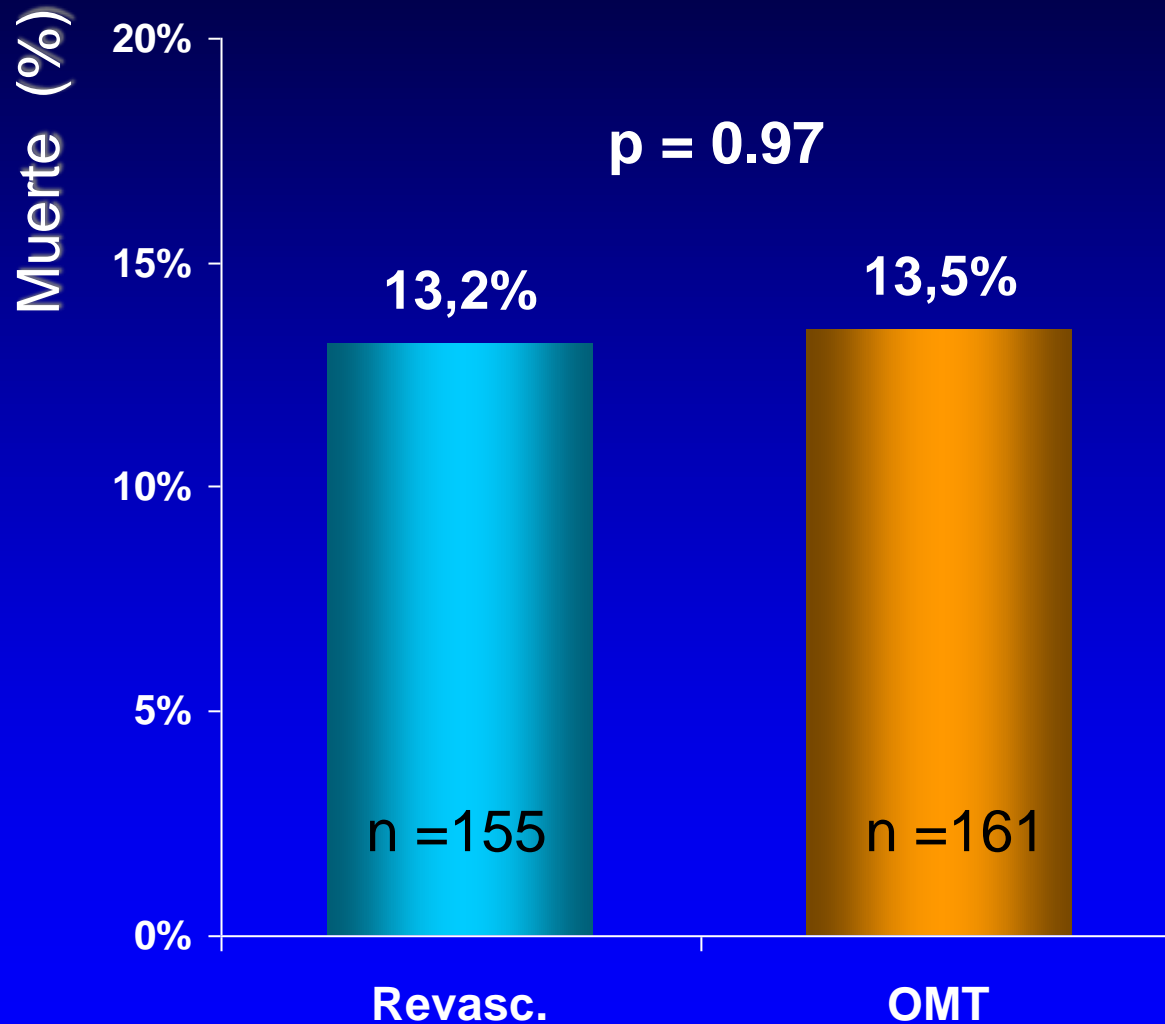
Enf. coronaria estable candidatos a revasc + Typo II DM



Composite Endpoint = 5-yrs Mortality

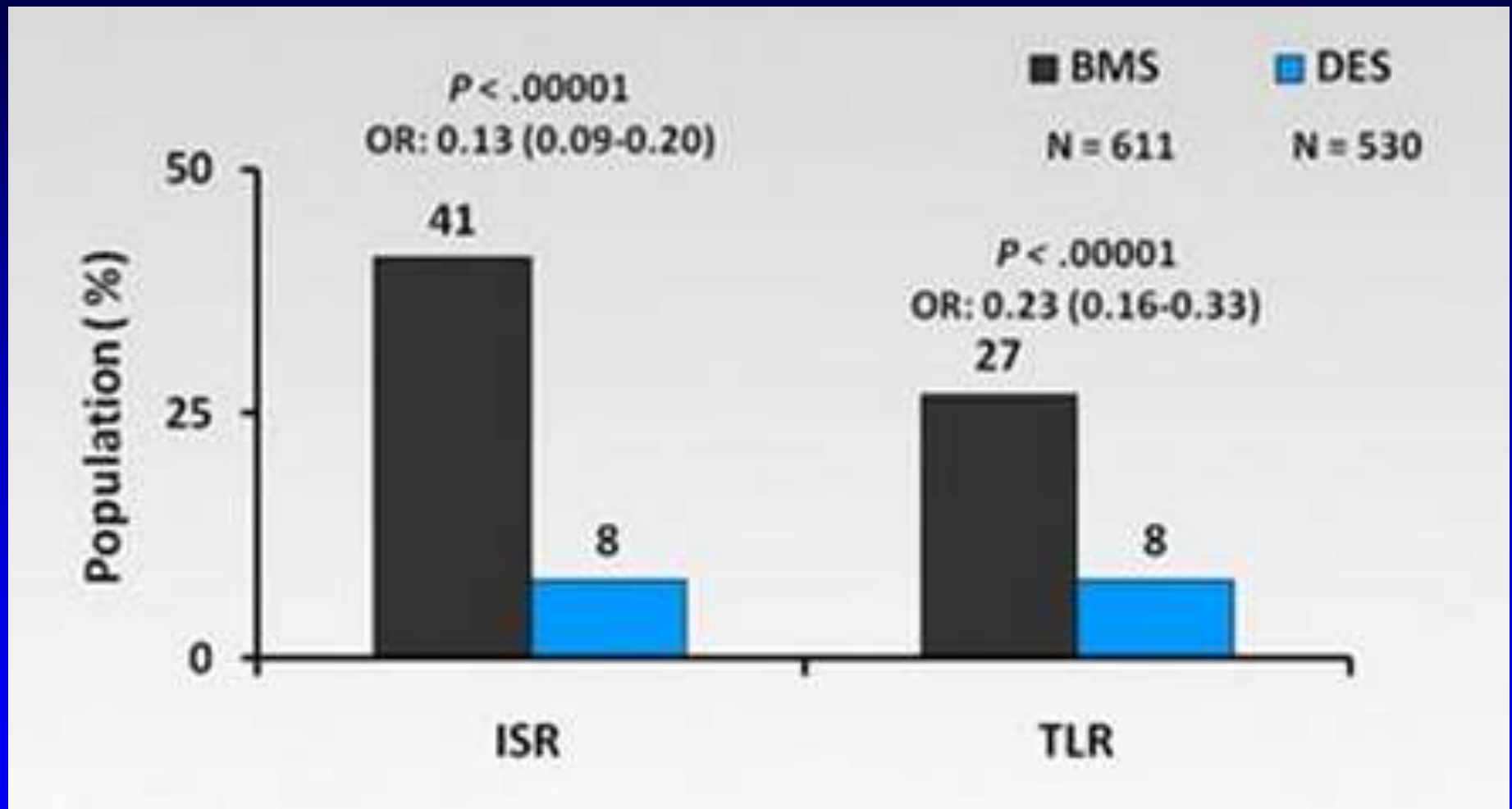
Burgeoning Dilemmas in the Management of Diabetes and Cardiovascular Disease. BARI 2D Trial. Sobel BE et al. Circ 2003; 107: 636-42

BARI 2D Trial: Objetivo Primario

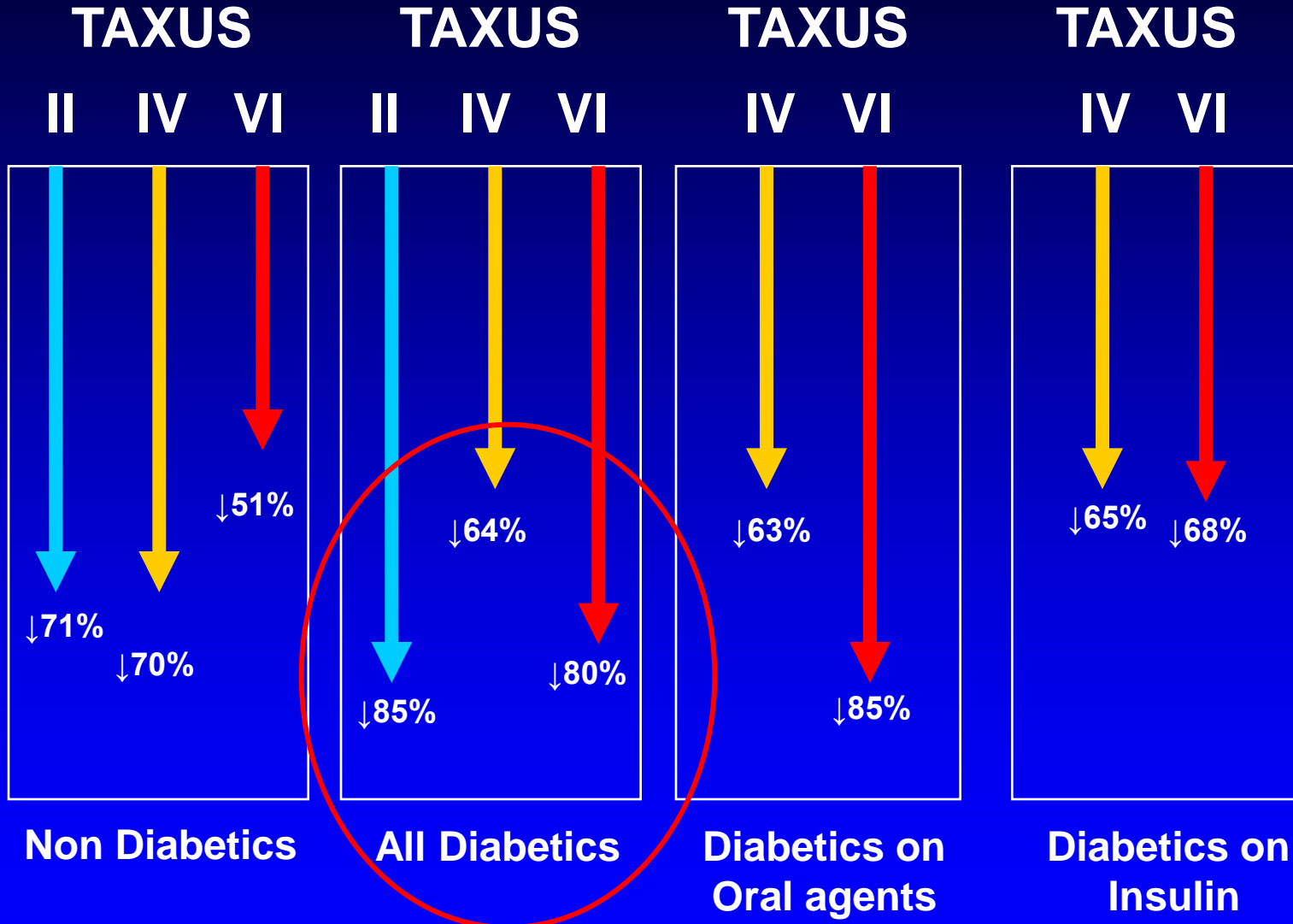


- The 5-year death rate for the group receiving revascularization plus optimal medical therapy was 13.2% vs. 13.5% in the group receiving optimal medical therapy alone.
- The difference between the two treatment groups did not reach statistical significance.

Meta-analysis BMS vs 1era Generacion DES en Diabeticos



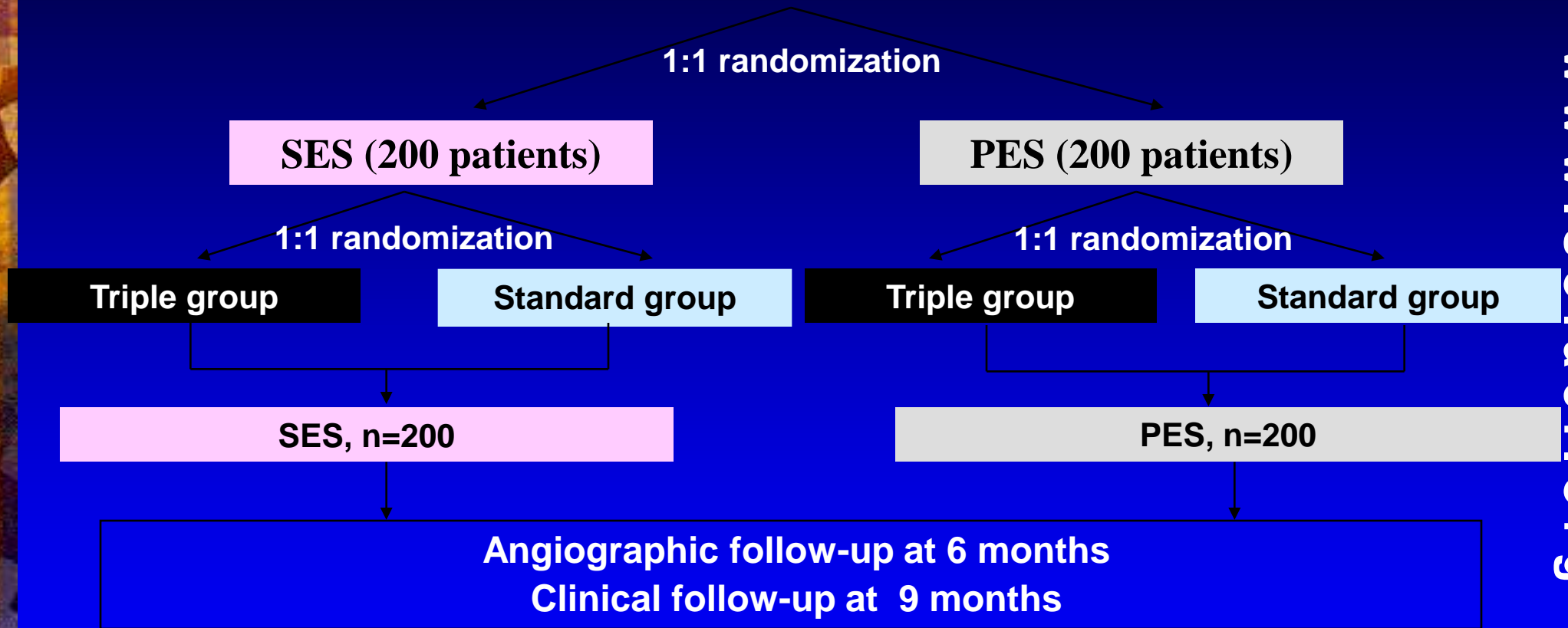
Reduccion de TLR en el pooled-TAXUS Trials



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DES-DIABETES Trial Design

The lesions Suitable for PCI in patients with DM



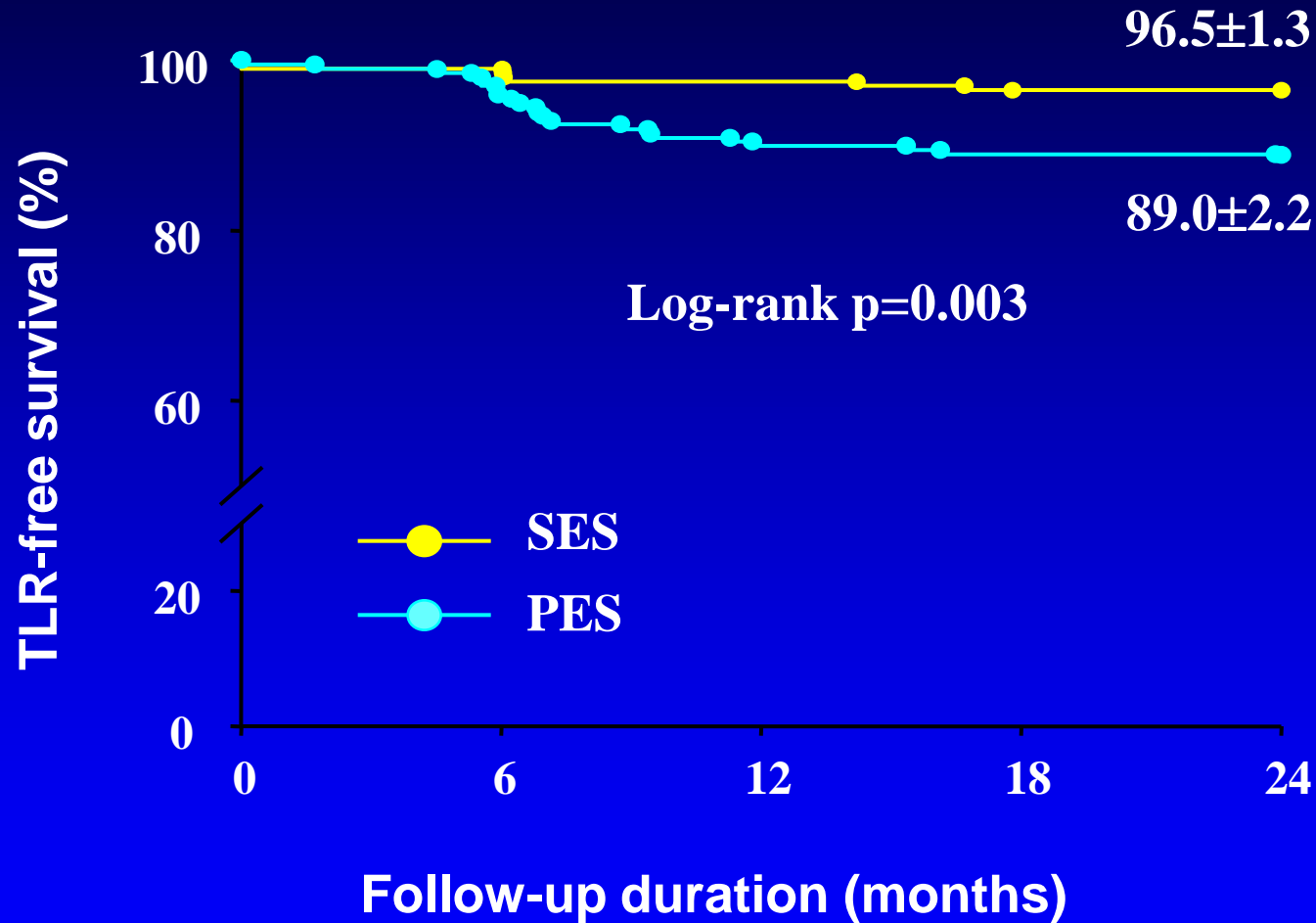
www.solacj.org

- * Randomization – Stratification according to DES types
- * Blinding – Patients, Outcome assessors
- * Pre-specified angiographic primary endpoint
- * Intention-to-treat analysis

LEE SW, et al. J Am Coll Cardiol. 2008;52:727-33

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Two-year TLR-free survival



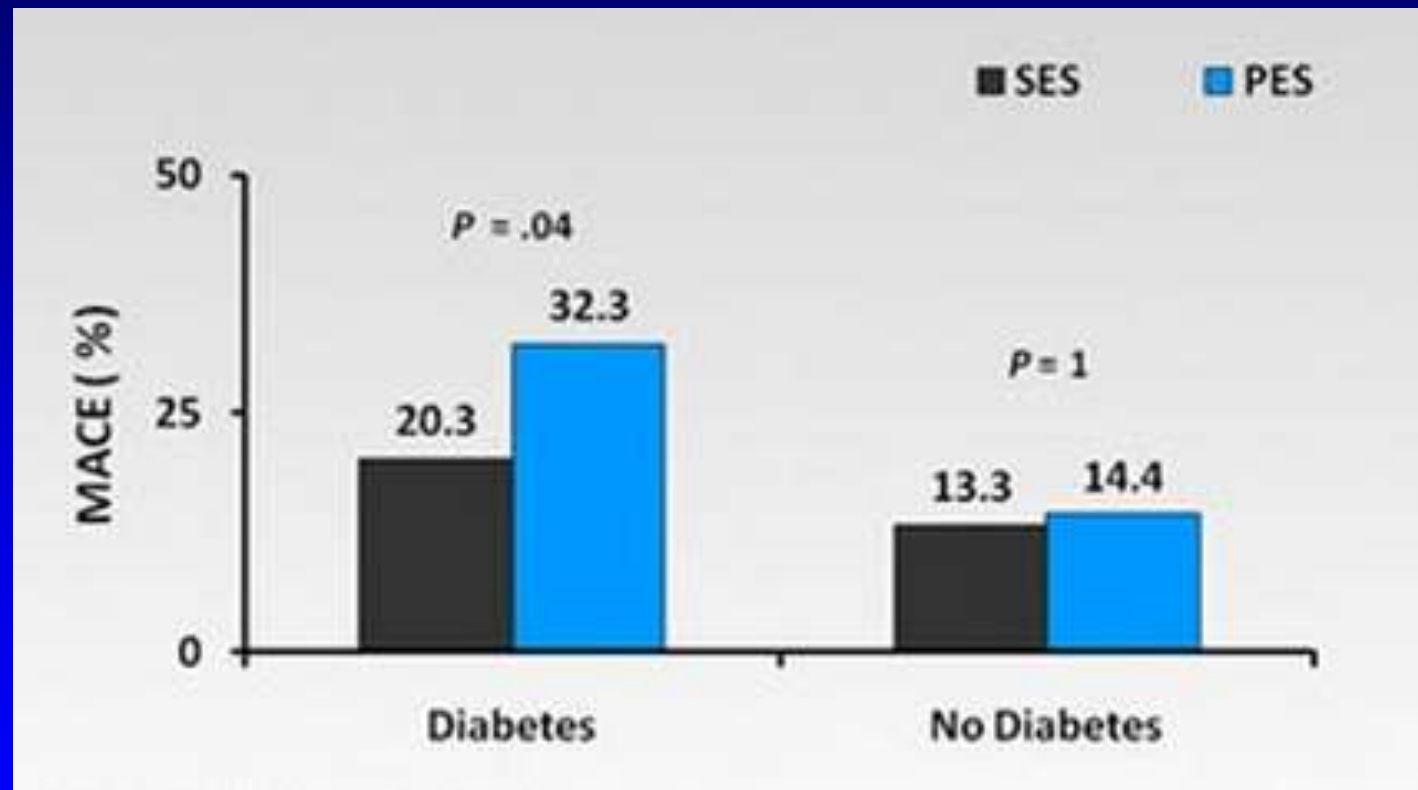
LEE SW, et al. J Am Coll Cardiol. 2009;53:812-3

Diabeticos poseen un riesgo global mayor



SIRTAX LATE: MACE a 5 y

ATC c/DES: 201 pts con DM y 811 sin DM



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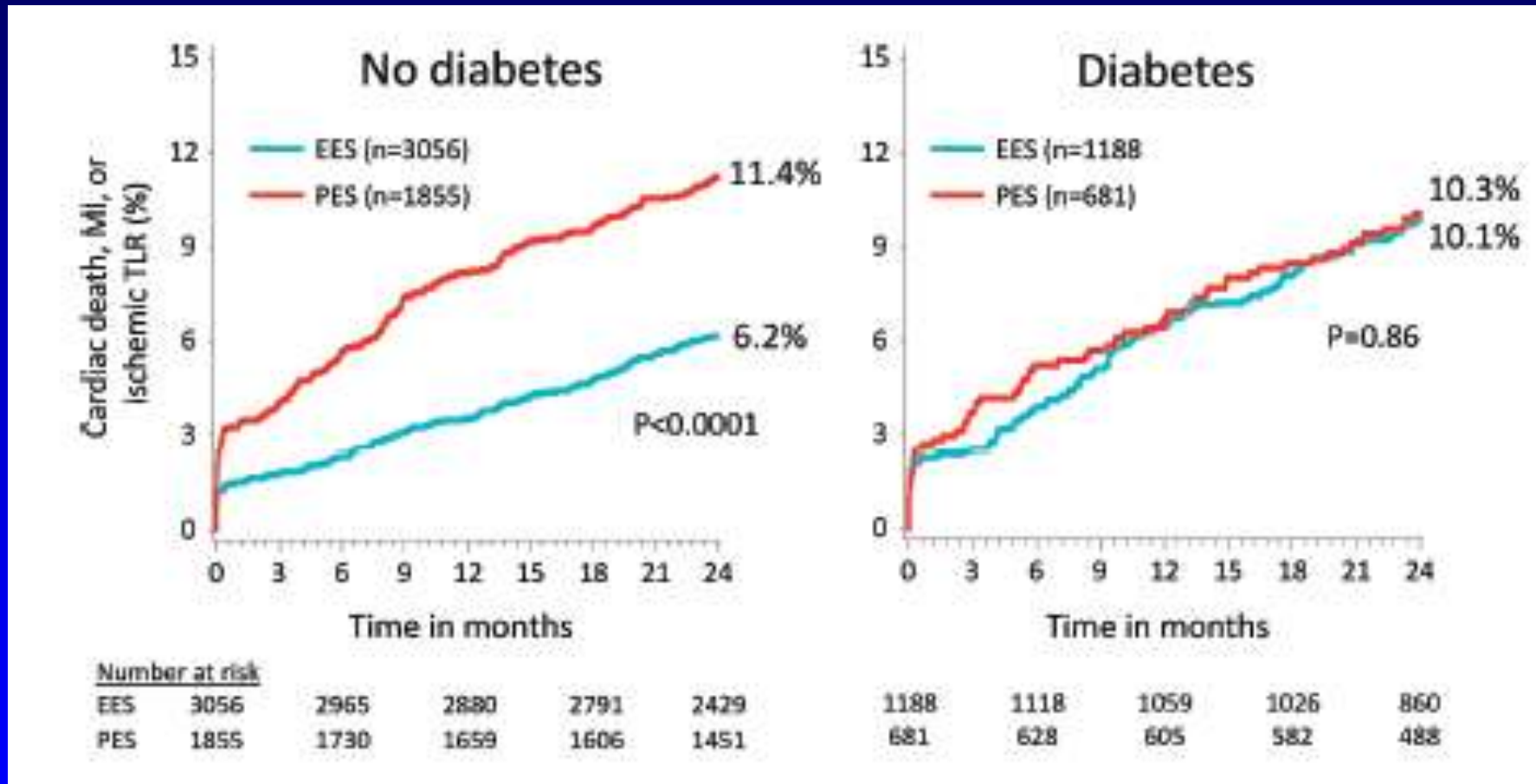
EES vs PES in Diabeticos

Prospective, Randomized Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions (**SPiRiT**) Trial and a Trial of Everolimus-Eluting Stents and Paclitaxel-Eluting Stents for Coronary Revascularization in Daily Practice (**COMPARE**)

	SPiRiT II	SPiRiT III	SPiRiT IV	COMPARE
Geography	Europe, India, and New Zealand	US	US	Netherlands
Sites, n	28	65	66	1
ITT patients, n	300	1002	3687	1800
Patients with diabetes mellitus, n (%) [*]	69/299 (23.1)	290/999 (29.0)	1195/3683 (32.4)	325/1799 (18.1)
Randomization, EES:PES	3:1	2:1	2:1	1:1
PES platform	Express	Express	Express	Liberté
Primary end point(s)	In-stent LL at 6 mo	In-segment LL at 8 mo and TVF at 9 mo	TLF at 12 mo	MACE at 12 mo
Recruitment period	July 2005–November 2005	June 2005–March 2006	August 2006–July 2008	February 2007–September 2008
RVD, mm	2.5–4.25	2.5–3.75	2.5–3.75	No prespecified criteria
Lesion length, mm	≤28	≤28	≤28	No limit
Maximum lesions/patient, n	2	2	3	No limit
Major patient and lesion exclusion criteria [†]	Complex or high risk [‡]	Complex or high risk [‡]	Complex or high risk [‡]	None
Routine angiographic follow-up				
Timing, mo	6 and 24	8	None	None
Intended, n	300 and 152	564	0	0
Completed, n	275 and 115	436	0	0

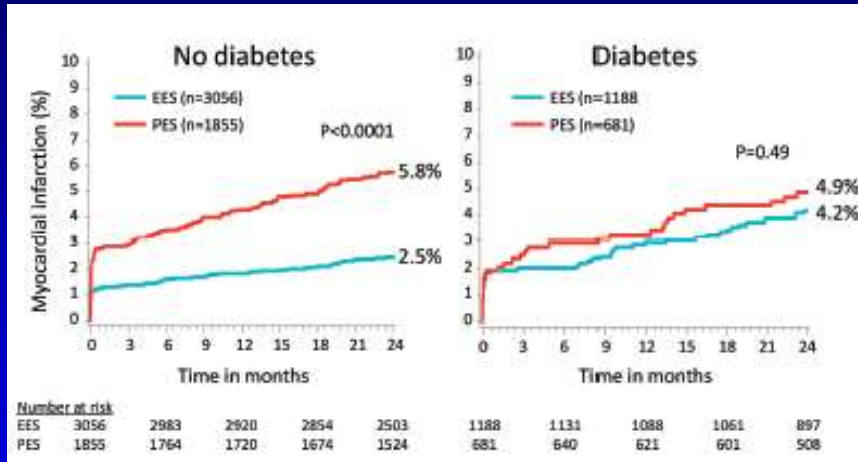
Stone G et al. Differential Clinical Responses to Everolimus-Eluting and Paclitaxel-Eluting Coronary Stents in Patients With and Without Diabetes Mellitus. *Circulation*. 2011; 124: 893-900

Time-to-event curves for major adverse cardiac events (cardiac death, myocardial infarction or ischemia-driven target lesion revascularization)

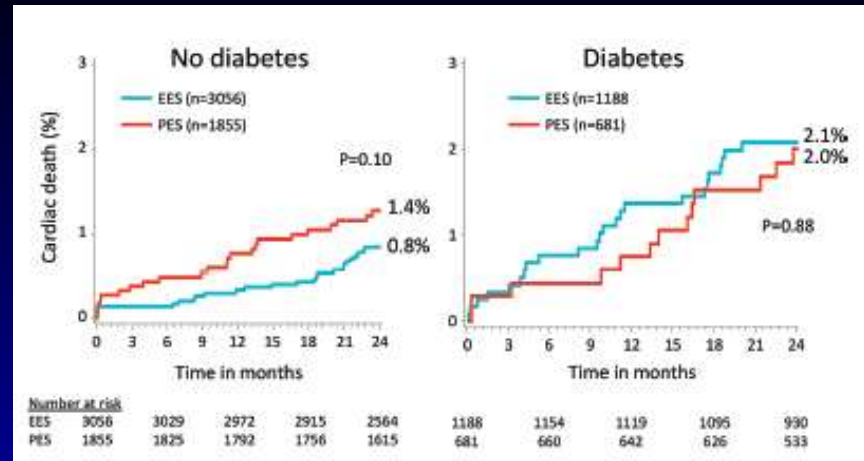


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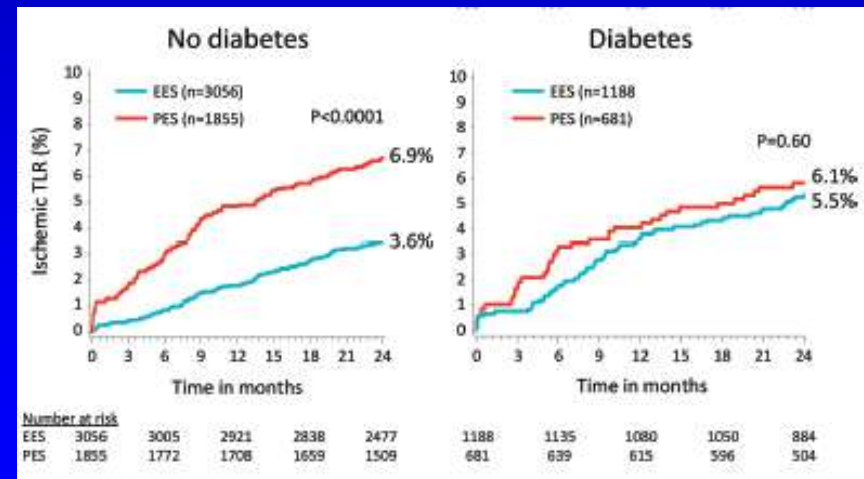
Muerte Cardiaca



TLR



Infarto

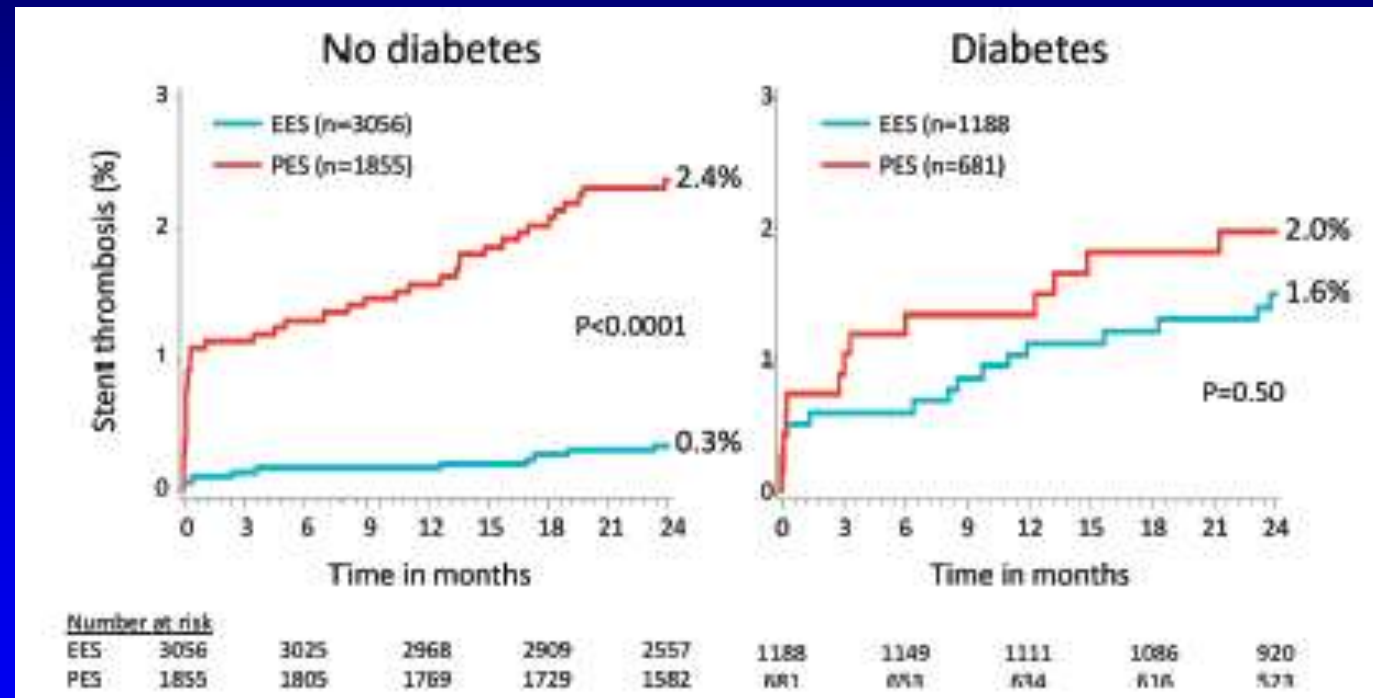


Stone G et al. Circulation. 2011; 124: 893-900

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Trombosis del Stent

Segun Academic Research Consortium definition of definite or probable



Stone G et al. Differential Clinical Responses to Everolimus-Eluting and Paclitaxel-Eluting Coronary Stents in Patients With and Without Diabetes Mellitus. *Circulation*. 2011; 124: 893-900

ESSENCE-DIABETES: Randomized Comparison of Everolimus- vs. Sirolimus-Eluting Stents for De Novo CAD in Diabetic Patients

300 pts who presented with stable angina or ACS at 15 cardiac centers in South Korea.

	EES (n = 149)	SES (n = 151)	P Value
8-Month In-Segment Late Loss, mm	0.23 ± 0.27	0.37 ± 0.52	< 0.001 ^a
12-Month Death	1.3%	3.3%	0.448
12-Month MI	0	1.3%	0.498

^a For noninferiority.

Conclusion: Both EES and SES show favorable performance in diabetic patients undergoing treatment for de novo CAD.

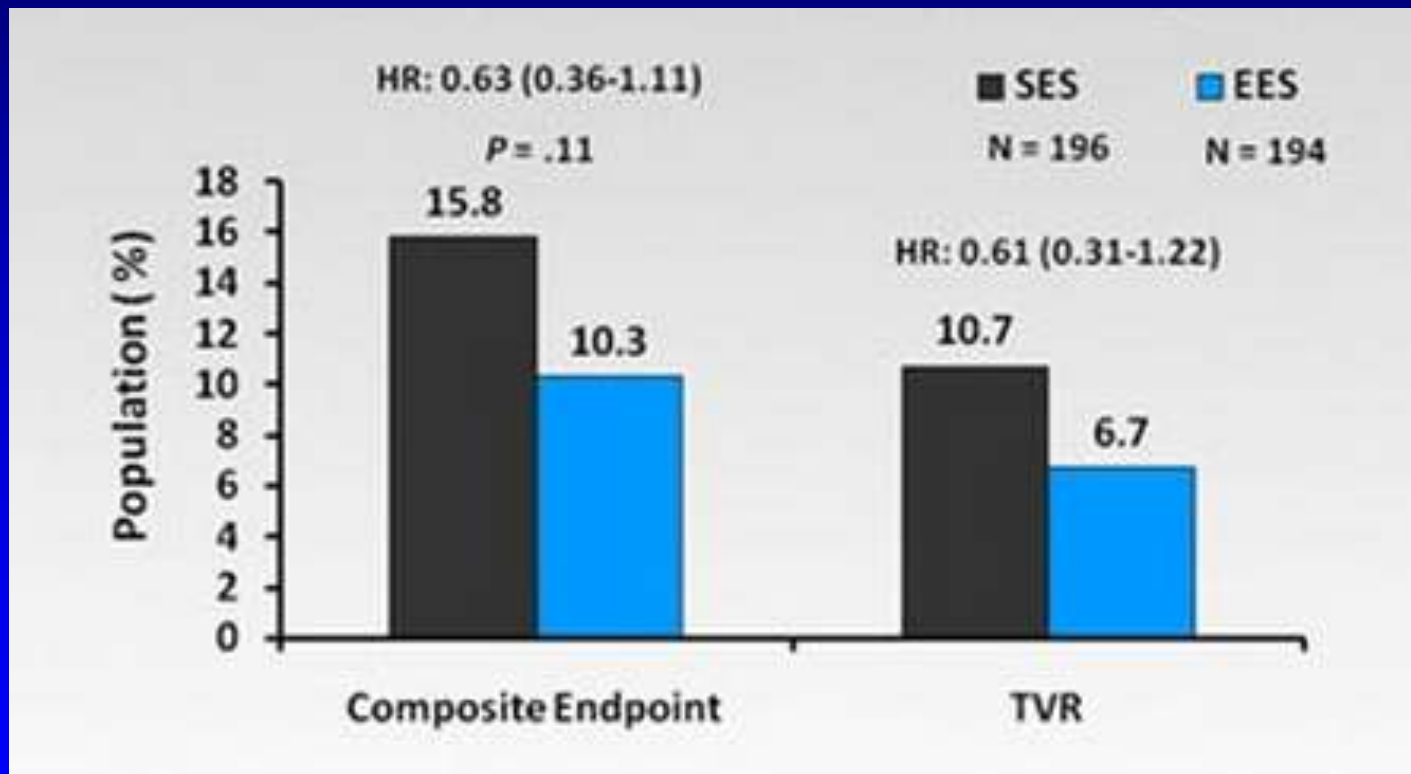
Kim W-J, et al. *Circulation*.
2011;Epub ahead of print.

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EES vs SES en Diabeticos

SORT OUT IV: Diabetes Subgroup Analysis

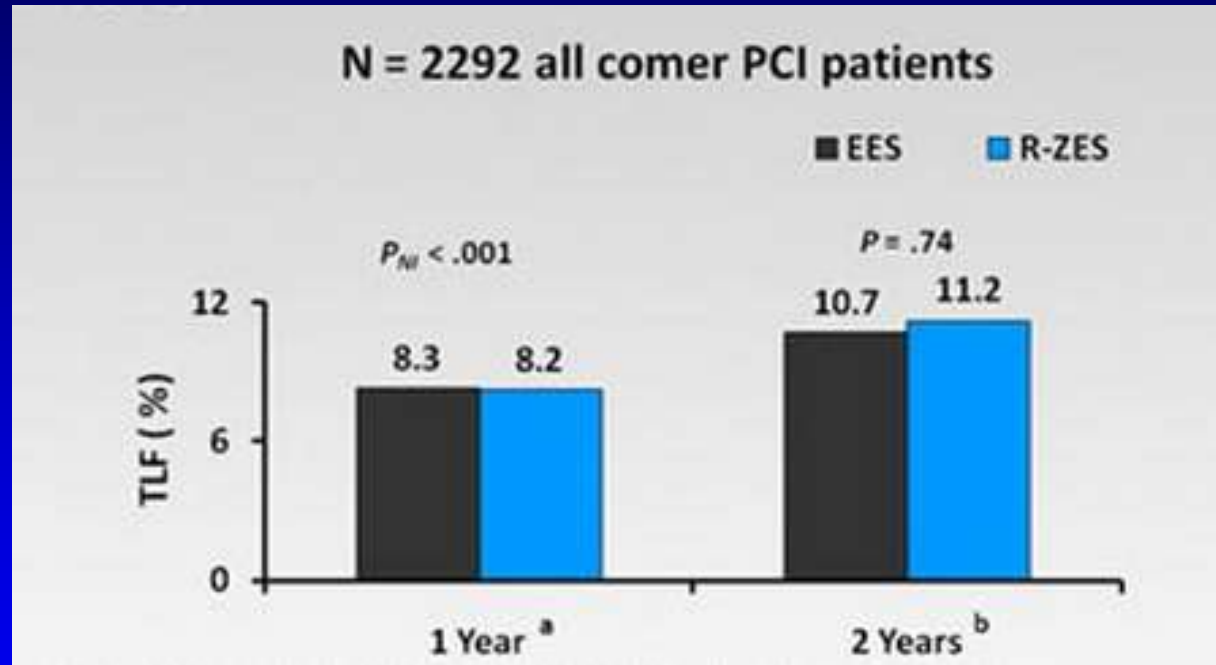
Randomized trial of DES in all-comer PCI pts



Cypher Select® vs Xience V®

EES vs ZES en Diabeticos

RESOLUTE All Comers Trial TLR in Xience V vs Resolute

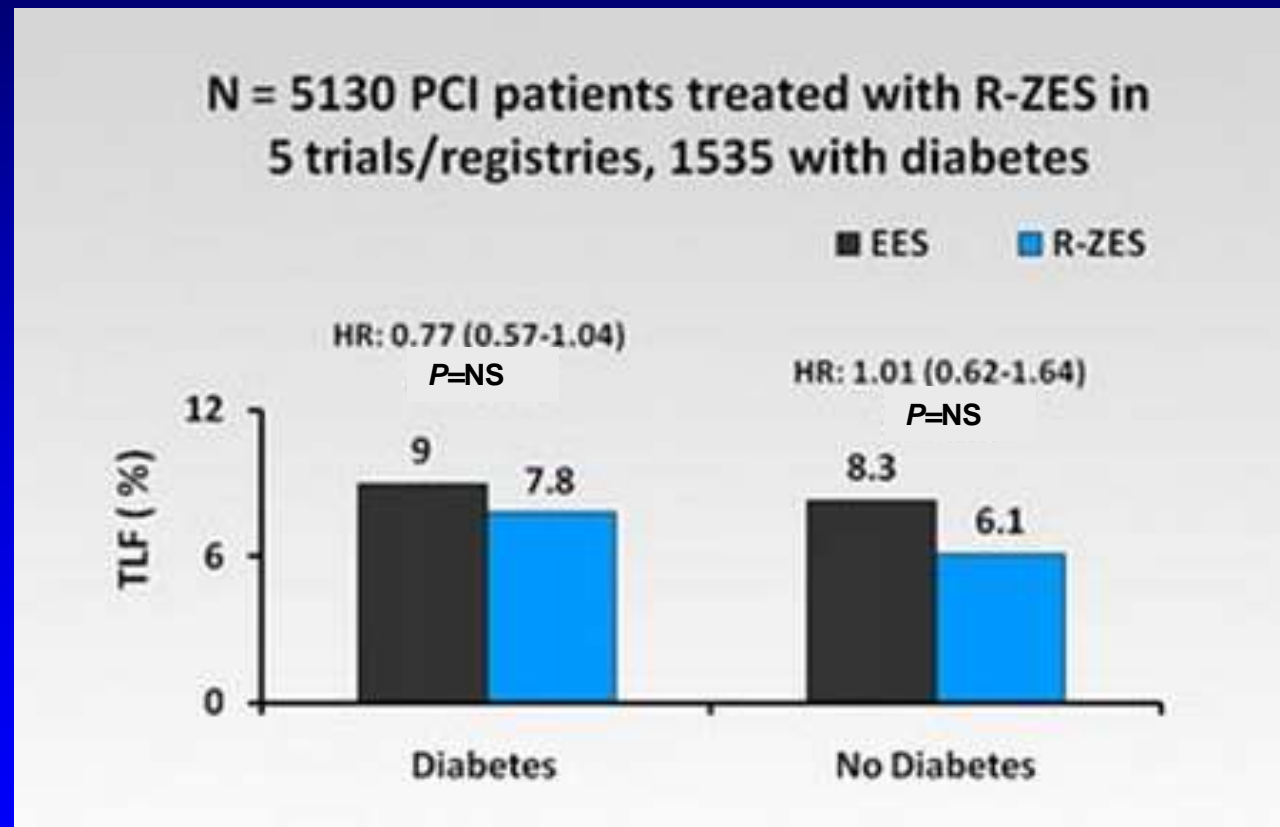


^a Serruyus P et al. Comparison of zotarolimus-eluting and everolimus-eluting coronary stents. *N Engl J Med* 2010 Jul 8;363(2):136-46. Epub 2010 Jun 16.

^b Silber S. Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial. *Lancet* 2011 Apr 9;377(9773):1241-7. Epub 2011 Apr 1.

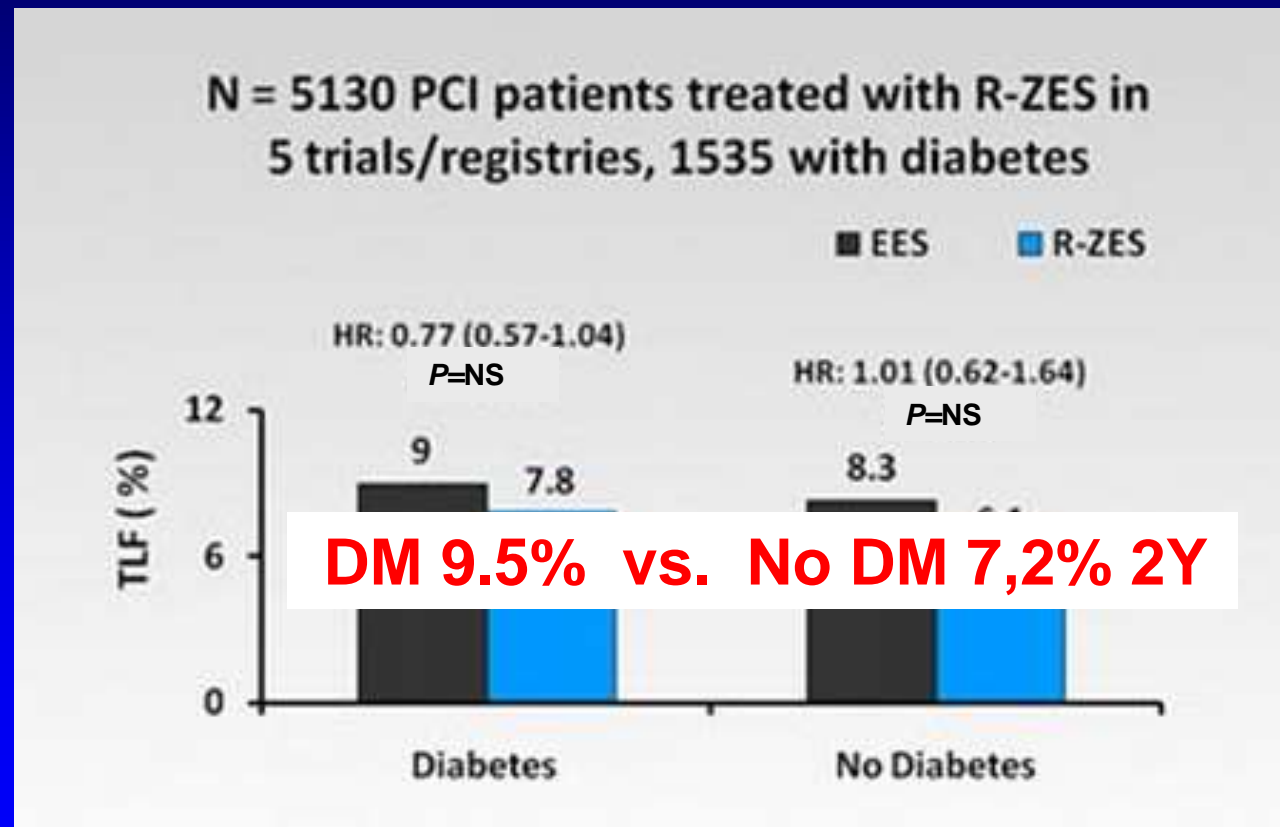
EES vs ZES en Diabeticos

Pooled Resolute Trials: TLR @1 year



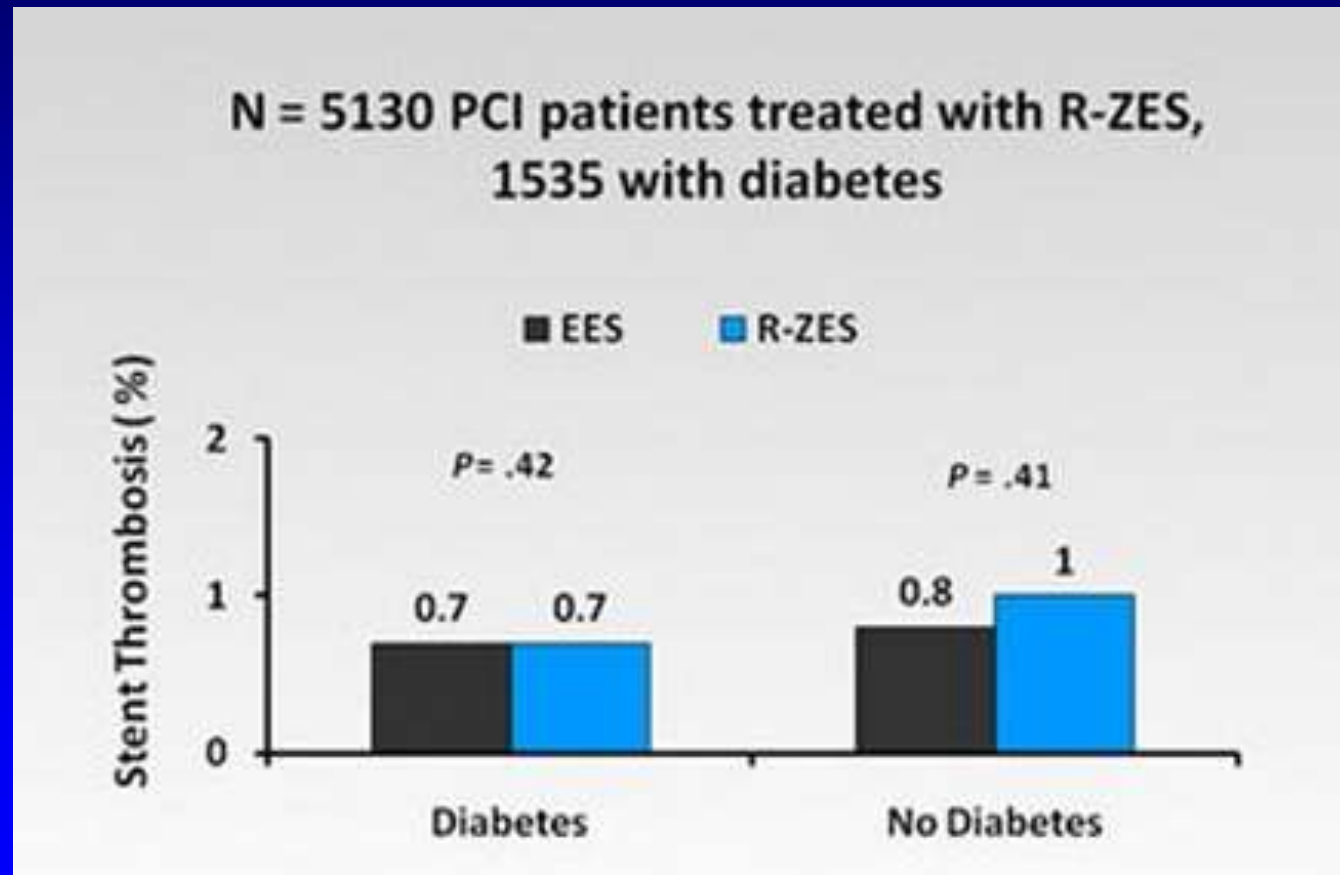
EES vs ZES in Diabeticos

Pooled Resolute Trials: TLR @1 year



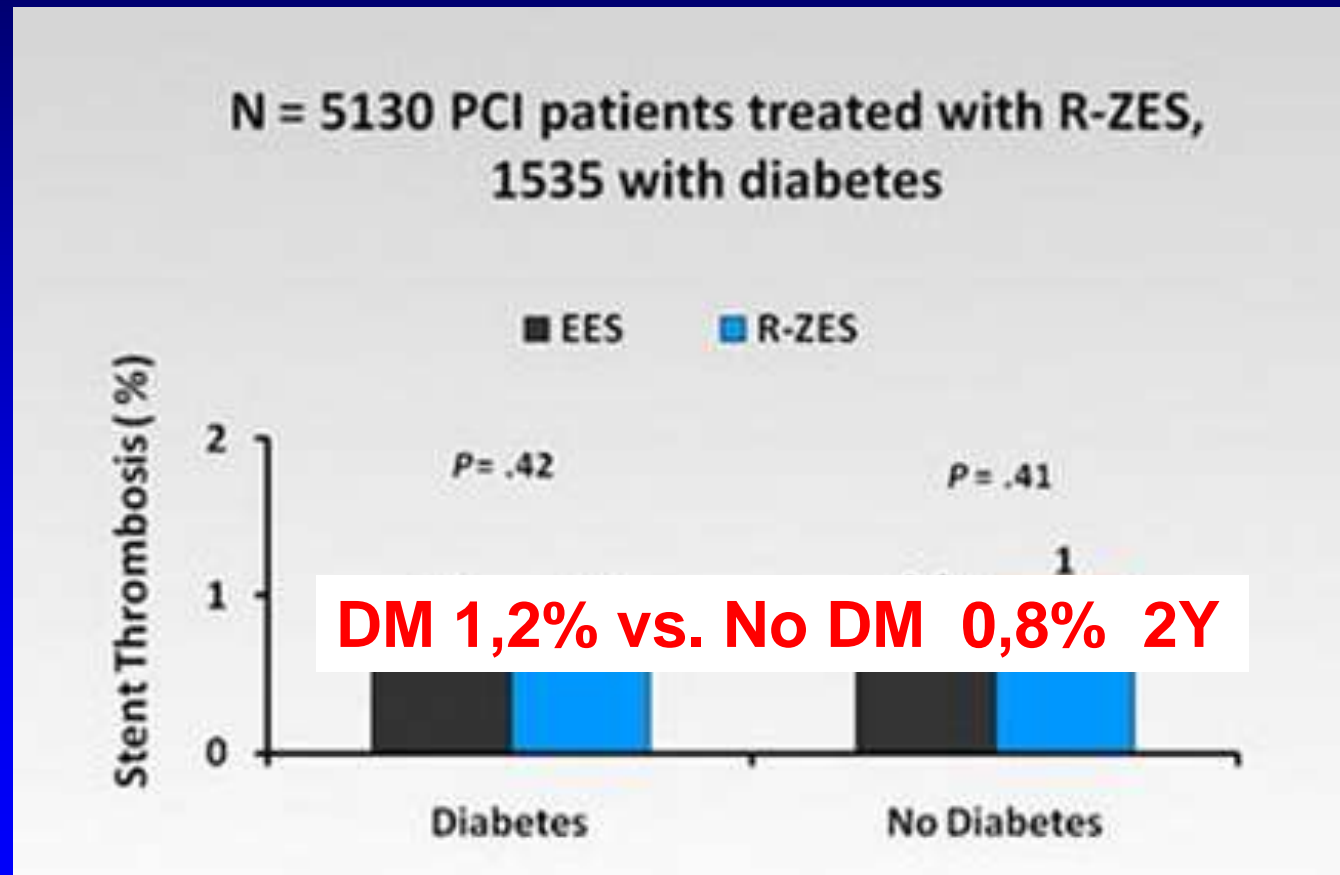
EES vs ZES in Diabeticos

Pooled Resolute Trials:
Definite/Probable Stent Thrombosis @1 year



EES vs ZES en Diabeticos

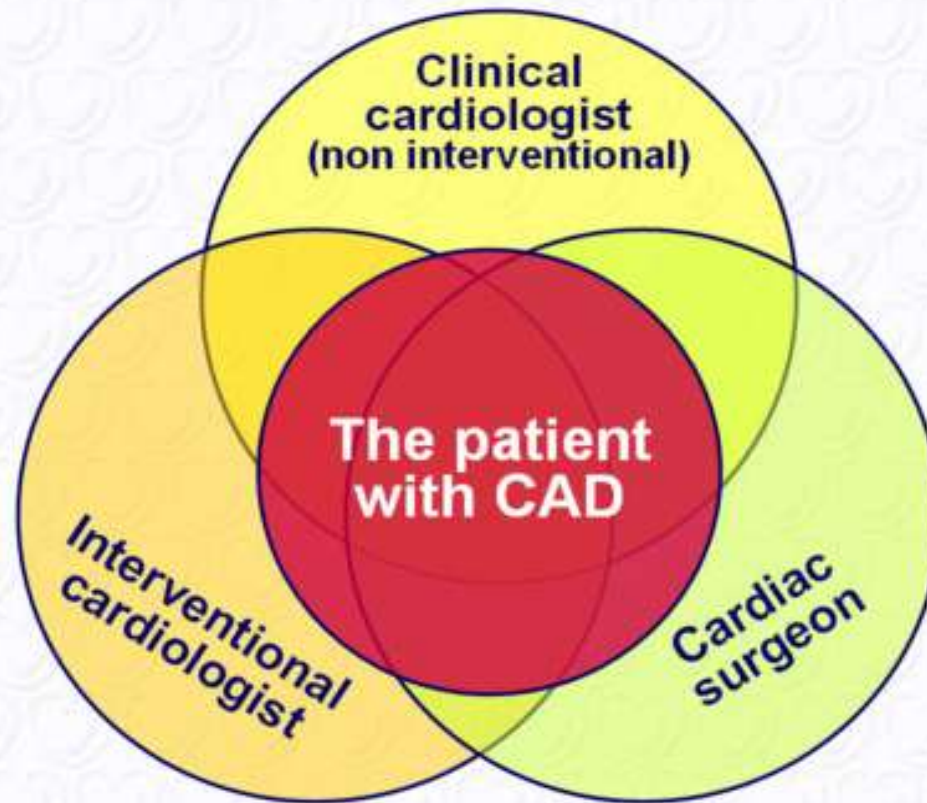
Pooled Resolute Trials:
Definite/Probable Stent Thrombosis @1 year



Conclusiones

- Diabeticos poseen un mayor riesgo de eventos adversos luego de ATC con stent.
- Existe evidencia que el DES es una mejor opcion que los BMS en pacientes diabeticos.
- Existe controversia acerca de la superioridad entre DES de primera y segunda generacion.
- El EES y ZES son similares en diabeticos.

The Heart Team



**Task Force composition = 8 clinical cardiologists (non interventional)
+ 9 interventional cardiologists + 8 cardiac surgeons**

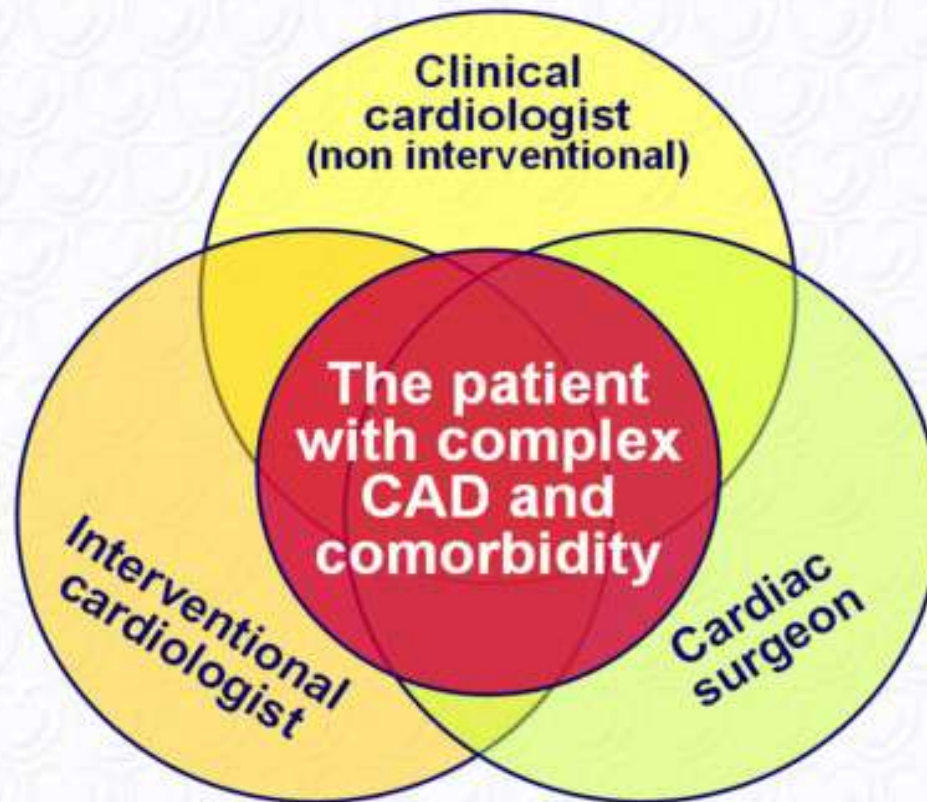
European Heart Journal (2010) 31, 2501-2555
European Journal of Cardio-thoracic Surgery (2010) 38, S1-S52

www.escardio.org/guidelines

Joint 2010 ESC - EACTS Guidelines
on Myocardial Revascularisation



The Expanded Heart Team



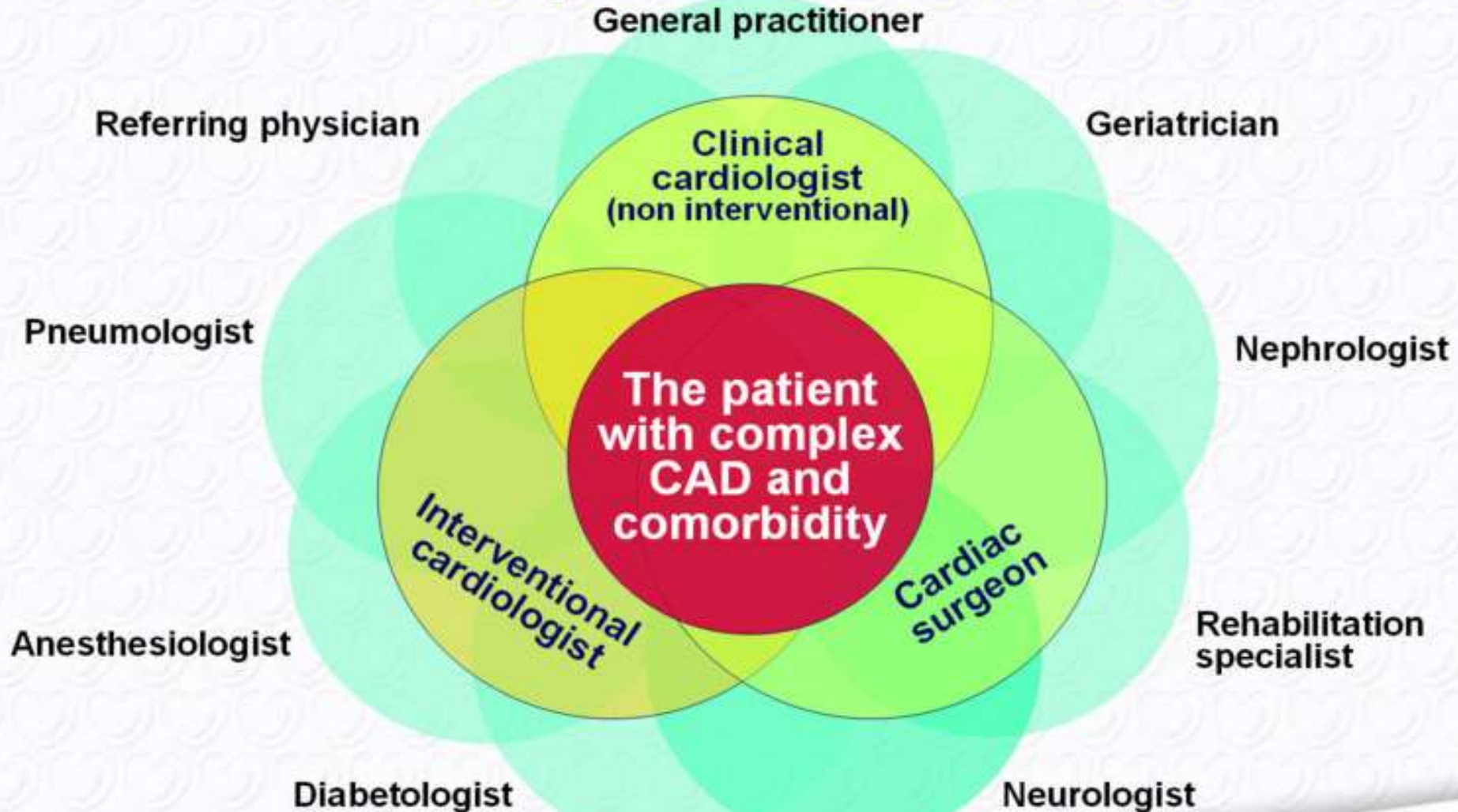
European Heart Journal (2010) 31, 2501-2555
European Journal of Cardio-thoracic Surgery (2010) 38, S1-S52

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www.escardio.org/guidelines

Joint 2010 ESC - EACTS Guidelines
on Myocardial Revascularisation



Conclusions

- **Diabetics are a higher-risk group of patients for adverse outcomes after our stent procedures.**

Conclusions

- **Diabetics are a higher-risk group of patients for adverse outcomes after our stent procedures.**
- **We definitely have good evidence that DES are a better option than BMS for diabetics.**