

The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

Primary Endpoint Results at One Year in the Randomized Cohort

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On behalf of the SYNTAX investigators

Viernes Cardiológico 23 Enero 2009.

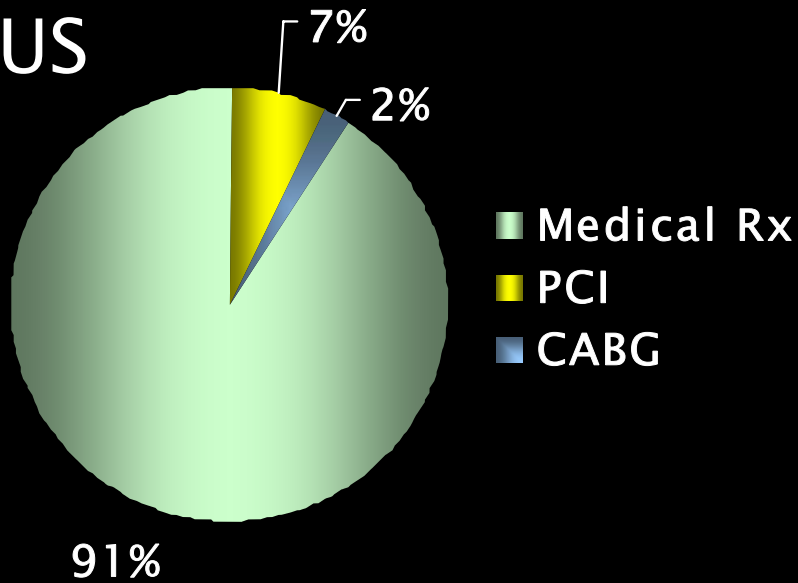
HUS, Dr. Ignacio Santos Rodríguez



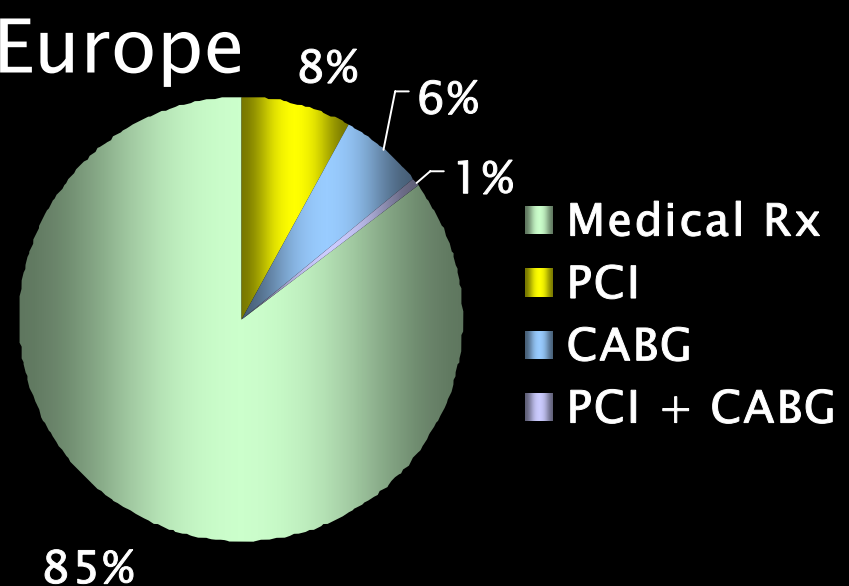
Current Treatment for Coronary Artery Disease



US



Europe



CDC MMWR 2007;56:113-118
Eur Heart J 2005;26:1011-1022
J Am Coll Cardiol 2002;39:1096-1103

CABG vs. PCI Studies Summary



Superior Treatment Modality

CABG

No difference

Trial	Clinical Parameters			Stroke	Observaciones
	Mortality & MI	Angina Relief	Repeat Revascularization		
GABI	PCI	No difference	CABG	n/a	GermanSC,360p,1y
EAST	No difference	CABG	CABG	No difference	EmoryMC,400p,3y
RITA	No difference	CABG	CABG		MC,1011p,5y
ERACI	No difference	CABG	CABG	n/a	ArgentSC,127p,3y
CABRI	No difference	CABG	CABG		MC,1054p,1y
BARI	No difference	n/a	CABG	No difference	MC,1829p,DM,5y
MASS-2	CABG (MI)	n/a	CABG		MC,611p/3,1y
AWESOME	No difference	No difference	CABG	No difference	MC,454p,FE<35,1y
ERACI-2	PCI	n/a	CABG	n/a	ArgMC,450p,1.5y
SoS	CABG (Mortality)	CABG	CABG	n/a	MC,988p,2y
ARTSI	No difference	n/a	CABG	No difference	MC,1205p,3y
ARTSII	No difference	n/a	CABG	No difference	MC,607p/ARTSI,1y
MAIN-COMPARE	No difference	n/a	CABG	n/a	Observ/LM,2240/C-BS-DES,3y
LE MANS	No difference	No difference	CABG	No difference	LM,105p,1y

POBA

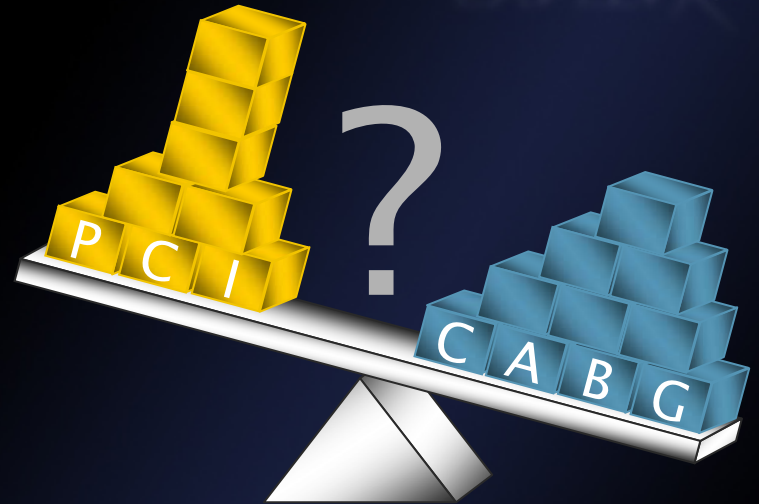
BMS Stents used

DES Stents used

Evolution of Revascularization

SYNTAX

Over the last decade, the standard of care for both CABG and PCI has continuously improved, leveling the playing field



Questions

- How does modern CABG compare to PCI in high-risk patients eligible for both techniques ? *Randomized Trial*

SYNTAX Eligible Patients



De novo disease

Limited Exclusion Criteria

- Previous interventions
- Acute MI with CPK > 2x
- Concomitant cardiac surgery

Left Main Disease
(isolated, +1, +2 or +3 vessels)

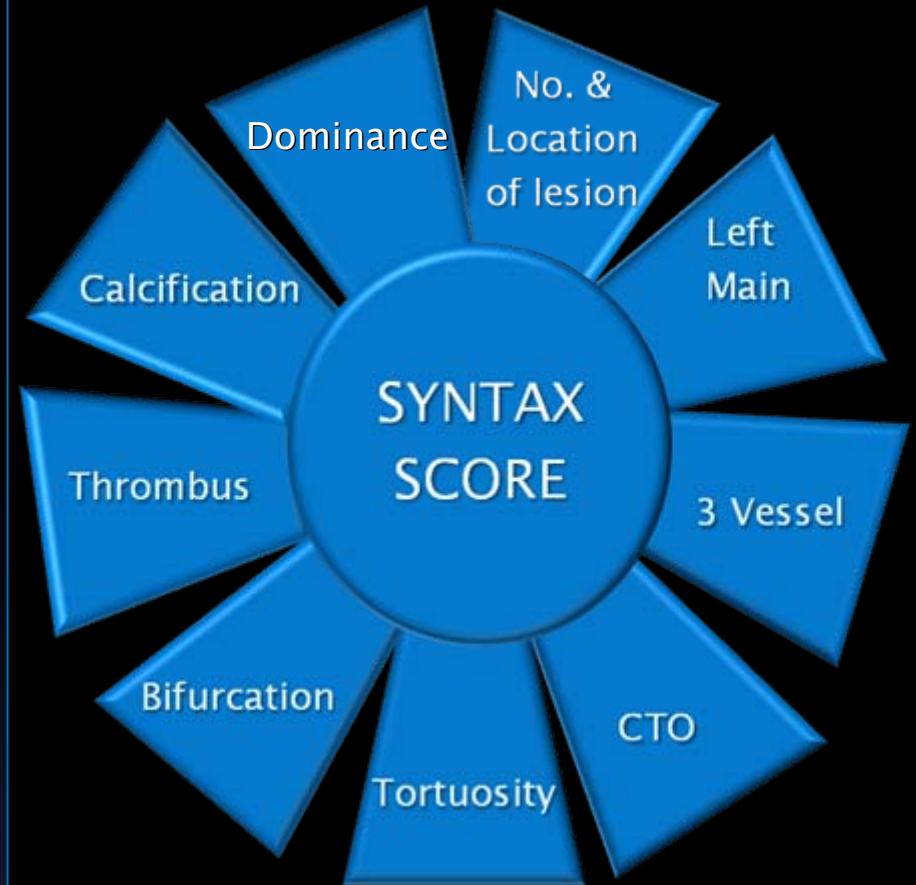
3 Vessel Disease
(revasc all 3 vascular territories)

Evaluation of new tool (SYNTAX score) to effectively characterize coronary vasculature and predict outcomes

Patient Profiling

Local Heart team (surgeon & interventional cardiologist) assessed each patient in regards to :

- Patient's operative risk (EuroSCORE & Parsonnet score)
- Coronary lesion complexity (Newly developed SYNTAX score)
- Goal: SYNTAX score to provide guidance on optimal revascularization strategies for patients with high risk lesions



Sianos et al, EuroIntervention 2005;1:219-227
Valgimigli et al, Am J Cardiol 2007;99:1072-1081
Serruys et al, EuroIntervention 2007;3:450-459

BARI classification of coronary segments
Leaman score, Circ 1981;63:285-299
Lesions classification ACC/AHA, Circ 2001;103:3019-3041
Bifurcation classification, CCI 2000;49:274-283
CTO classification, J Am Coll Cardiol 1997;30:649-656



Table 1. Segment weighing factors

Segment No	Right dominance	Left dominance
1 RCA proximal	1	0
2 RCA mid	1	0
3 RCA distal	1	0
4 Posterior descending artery	1	n.a.
16 Posterolateral branch from RCA	0.5	n.a.
16a Posterolateral branch from RCA	0.5	n.a.
16b Posterolateral branch from RCA	0.5	n.a.
16c Posterolateral branch from RCA	0.5	n.a.
5 Left Main	5	6
6 LAD proximal	3.5	3.5
7 LAD mid	2.5	2.5
8 LAD apical	1	1
9 First diagonal	1	1
9a First diagonal a	1	1
10 Second diagonal	0.5	0.5
10a Second diagonal a	0.5	0.5
11 Proximal circumflex artery	1.5	2.5
12 Intermediate/ anterolateral artery	1	1
12a Obtuse marginal a	1	1
12b Obtuse marginal b	1	1
13 Distal circumflex artery	0.5	1.5
14 Left posterolateral	0.5	1
14a Left posterolateral a	0.5	1
14b Left posterolateral b	0.5	1
15 Posterior descending	n.a.	1

Table 2. Lesions adverse characteristic scoring

Diameter reduction*

- Total occlusion x5
- Significant lesion (50-99%) x2

Total occlusion (TO)

- Age >3months or unknown +1
- Blunt stump +1
- Bridging +1
- First segment visible beyond TO +1 / per non-visible segment
- Side branch (SB) - Yes, SB <1.5mm** +1
- Yes, both SB < & ≥ 1.5mm +1

Trifurcations

- 1 diseased segment +3
- 2 diseased segments +4
- 3 diseased segments +5
- 4 diseased segments +6

Bifurcations

- Type A, B, C +1
- Type D, E, F, G +2
- Angulation <70° +1

Aorto ostial stenosis +1

Severe tortuosity +2

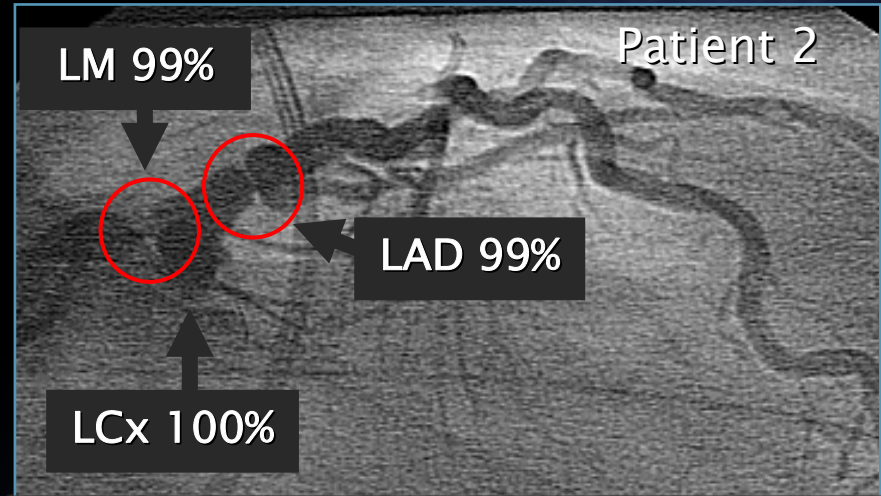
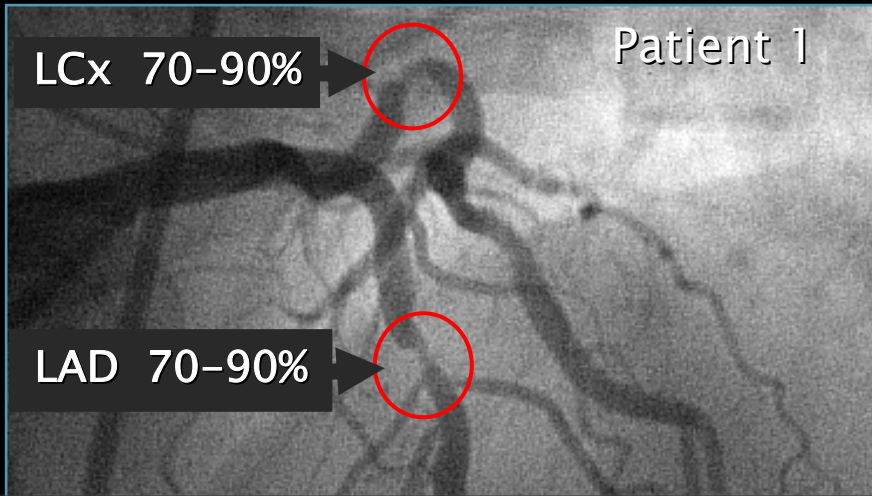
Length > 20mm +1

Heavy calcification +2

Thrombus +1

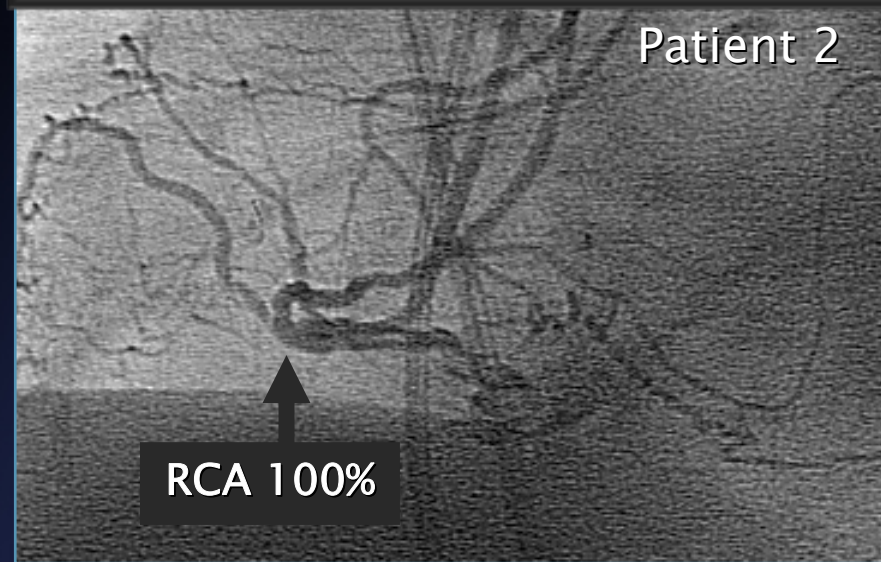
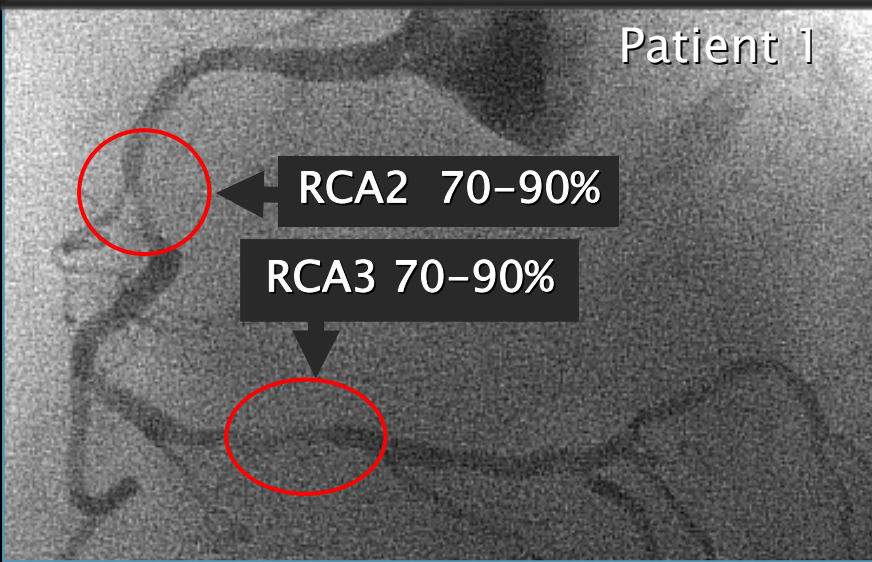
"Diffuse disease"/small vessels +1 / per segment number

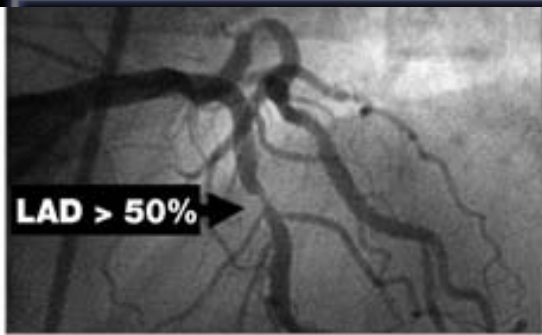
There is '3-vessel disease' and '3-vessel disease'



SYNTAX SCORE 19

SYNTAX SCORE 54





Lesion 1 **score: 7**
 Segment 6: 3,5x2 7

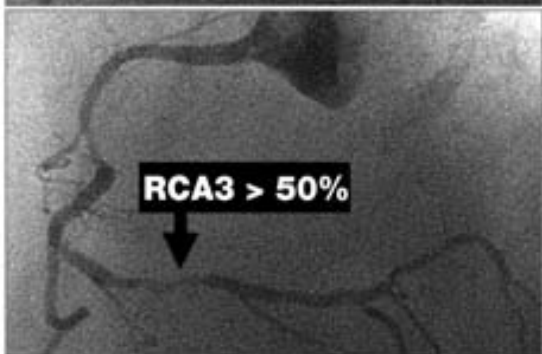


Lesion 2 **score: 5**
 Segment 11: 1,5x2 3
 + Tortuosity 2

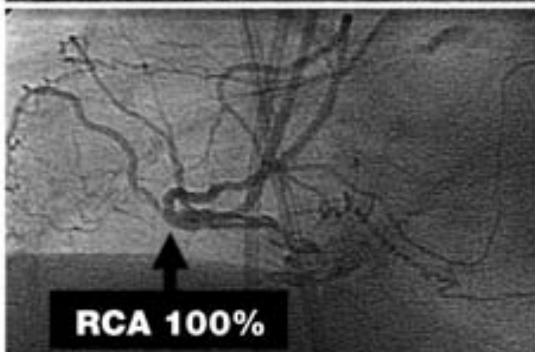
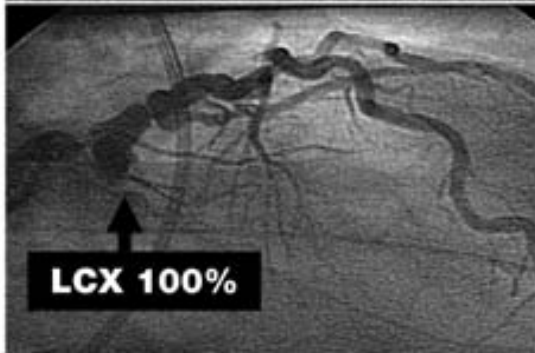
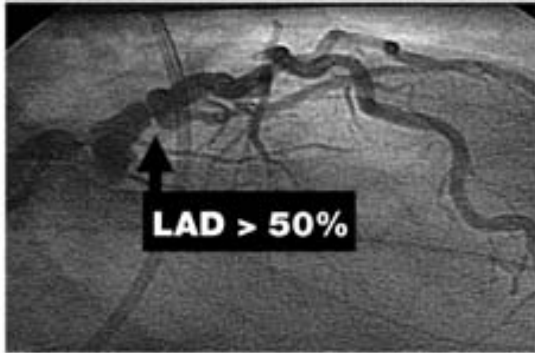
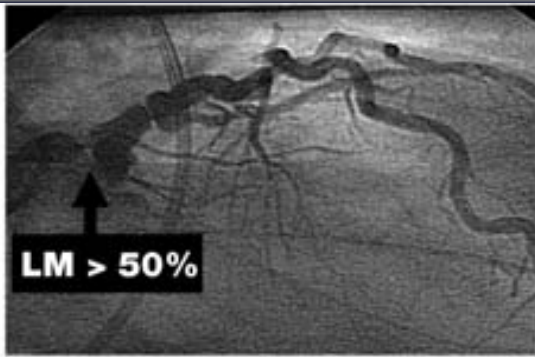
SYNTAX SCORE 19



Lesion 3 **score: 2**
 Segment 2 : 1x2 2



Lesion 4 **score: 5**
 Segment 3: 1x2 2
 + tortuosity 2
 + Length 1



Lesion 1 **score: 13**

- Segment 5: 5x2 10
- + Bifurcation Type A 1
- + Heavy calcification 2

Lesion 2 **score: 11**

- Segment 6: 3,5x2 7
- + Bifurcation Type A 1
- + Angulation <70° 1
- + Heavy calcification 2

Lesion 3 **score: 14,5**

- Segment 11: 1,5x5 7,5
- Age T.O. is unknown 1
- + Blunt stump 1
- + side branch 1
- First segment visualized by contrast : 13 1
- + Heavy calcification 2
- + Length 1

Lesion 4 **Score: 16**

- Segment 1: 1x5 5
- Age T.O. is unknown 1
- + Blunt stump 1
- + side branch 1
- first segment visualized by contrast: 4 3
- + Tortuosity 2
- + heavy calcification 2
- + Length 1

SYNTAX SCORE 54.5

SYNTAX Trial Design



 62 EU Sites +  23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both treatment options

Amenable for only one treatment approach

Stratification:
LM and Diabetes

Randomized Arms
N=1800

Two Registry Arms
N=1275

CABG
N=897

vs

TAXUS*
N=903

CABG
N=1077

PCI
N=198

DM
28.5%

Non DM
71.5%

DM
28.2%

NonDM
71.8%

*TAXUS Express

SYNTAX Primary Endpoint

Randomized trial



*The primary clinical endpoint is the 12 Month major Cardiovascular or Cerebrovascular event rate (MACCE *)*

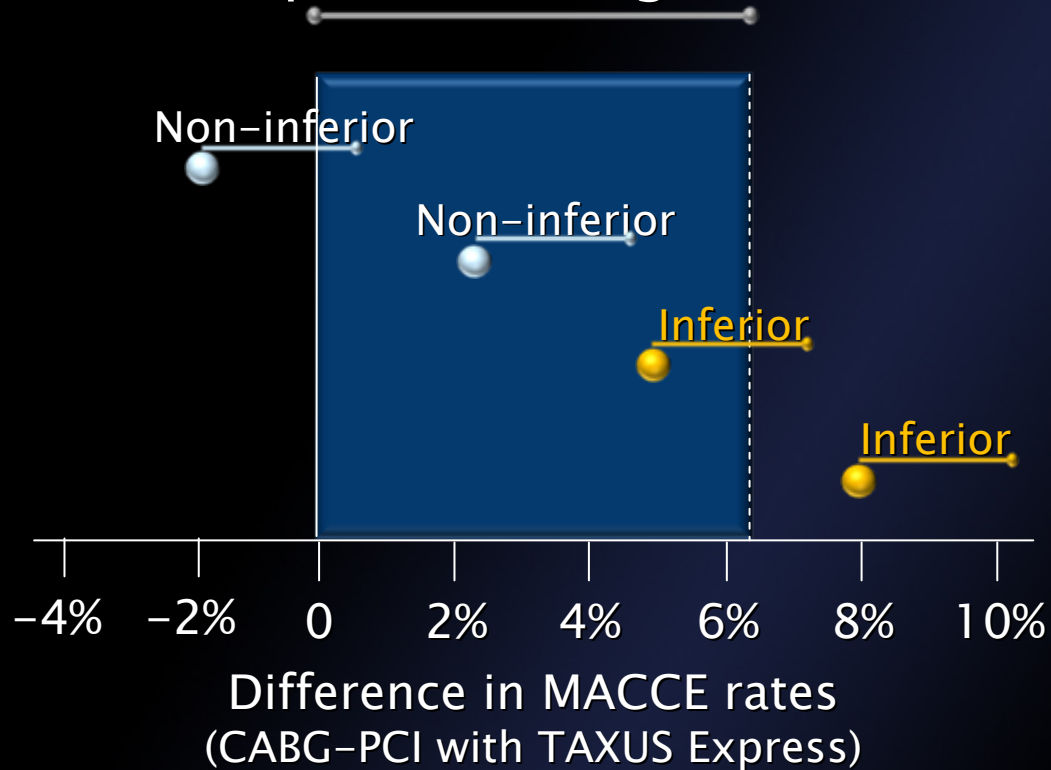
- MACCE is defined as:
 - All cause Death
 - Cerebrovascular Accident (CVA/Stroke)
 - Documented Myocardial Infarction (ARC definition)
 - Any Repeat Revascularization (PCI and/or CABG)
- All events CEC Adjudicated

* ARC MACCE definition Circ 2007; 115:2344-2351

Primary Endpoint (12 Month MACCE) *Non-inferiority to CABG*



Zone of Non-inferiority
Pre-specified Margin = 6.6%



● Difference in MACCE rates — Upper 1-sided 95% confidence intervals

Patient Characteristics (I)

Randomized Cohort

SYNTAX

	CABG N=897	TAXUS N=903	P value
Age, mean \pm SD (y)	65.0 \pm 9.8	65.2 \pm 9.7	0.55
Male, %	78.9	76.4	0.20
BMI, mean \pm SD	27.9 \pm 4.5	28.1 \pm 4.8	0.37
Diabetes, %	28.5	28.2	0.89
Hypertension, %	77.0	74.0	0.14
Hyperlipidemia, %	77.2	78.7	0.44
Current smoker, %	22.0	18.5	0.06
Prior MI, %	33.8	31.9	0.39
Unstable angina, %	28.0	28.9	0.67
Additive EuroSCORE, mean \pm SD	3.8 \pm 2.7	3.8 \pm 2.6	0.78
Total Parsonnet score , mean \pm SD	8.4 \pm 6.8	8.5 \pm 7.0	0.76

Patient Characteristics (II)

Randomized Cohort

SYNTAX

Patient-based

	CABG N=897	TAXUS N=903	P value
Total SYNTAX Score	29.1 ±11.4	28.4 ±11.5	0.19
Diffuse disease or small vessels, %	10.7	11.3	0.69
No. lesions, mean ± SD	4.4 ±1.8	4.3 ±1.8	0.44
3VD only, %	66.3	65.4	0.70
Left main, any, %	33.7	34.6	0.70
Left Main only	3.1	3.8	0.46
Left Main + 1 vessel	5.1	5.4	0.78
Left Main + 2 vessel	12.0	11.5	0.72
Left Main + 3 vessel	13.5	13.9	0.78
Total occlusion, %	22.2	24.2	0.33
Bifurcation, %	73.3	72.4	0.67
Trifurcation, %	10.6	10.7	0.92

Procedural Characteristics

PCI Randomized Cohort

SYNTAX

Patient-based

	TAXUS N=903
Staged procedure, %	14.1
Lesions treated/pt, mean \pm SD	3.6 \pm 1.6
No. stents implanted, mean \pm SD	4.6 \pm 2.3
Total length implanted, mm \pm SD	86.1 \pm 47.9
Range, mm	8 - 324
Long stenting (>100 mm), %	33.2

Procedural Characteristics

CABG Randomized Cohort

SYNTAX

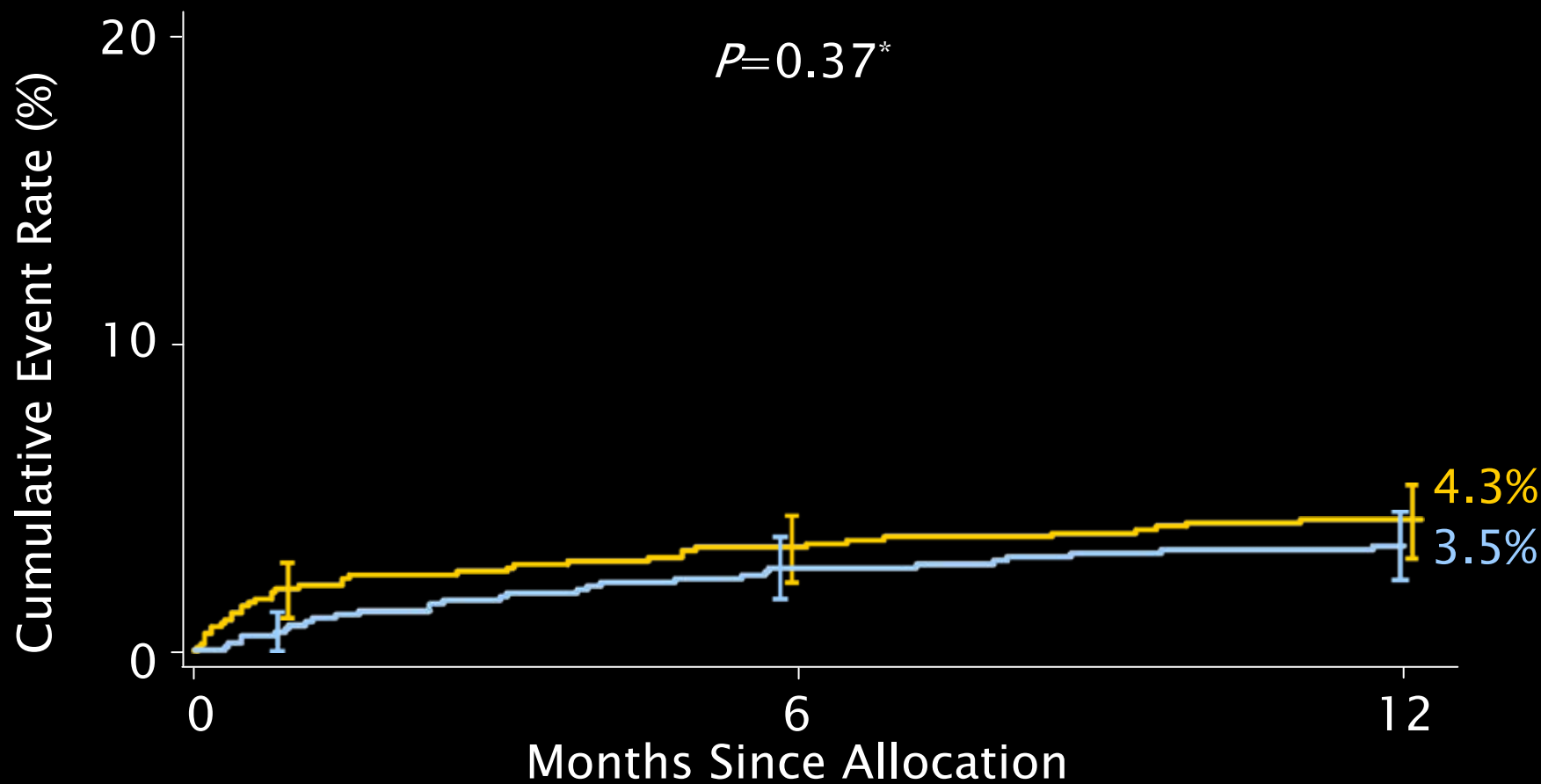
	CABG N=897
Off-pump surgery, %	15.0
Graft revascularization, %	
At least one arterial graft	97.3
Arterial graft to LAD	95.6
LIMA+venous	78.1
Double LIMA/RIMA	27.6
Complete arterial revascularization	18.9
Radial artery	14.1
Venous graft only	2.6
Grafts per patient, mean \pm SD	2.8 \pm 0.7
Distal anastomosis/pt, mean \pm SD	3.2 \pm 0.9

All-Cause Death to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)



Event Rate \pm 1.5 SE. *Fisher's Exact Test

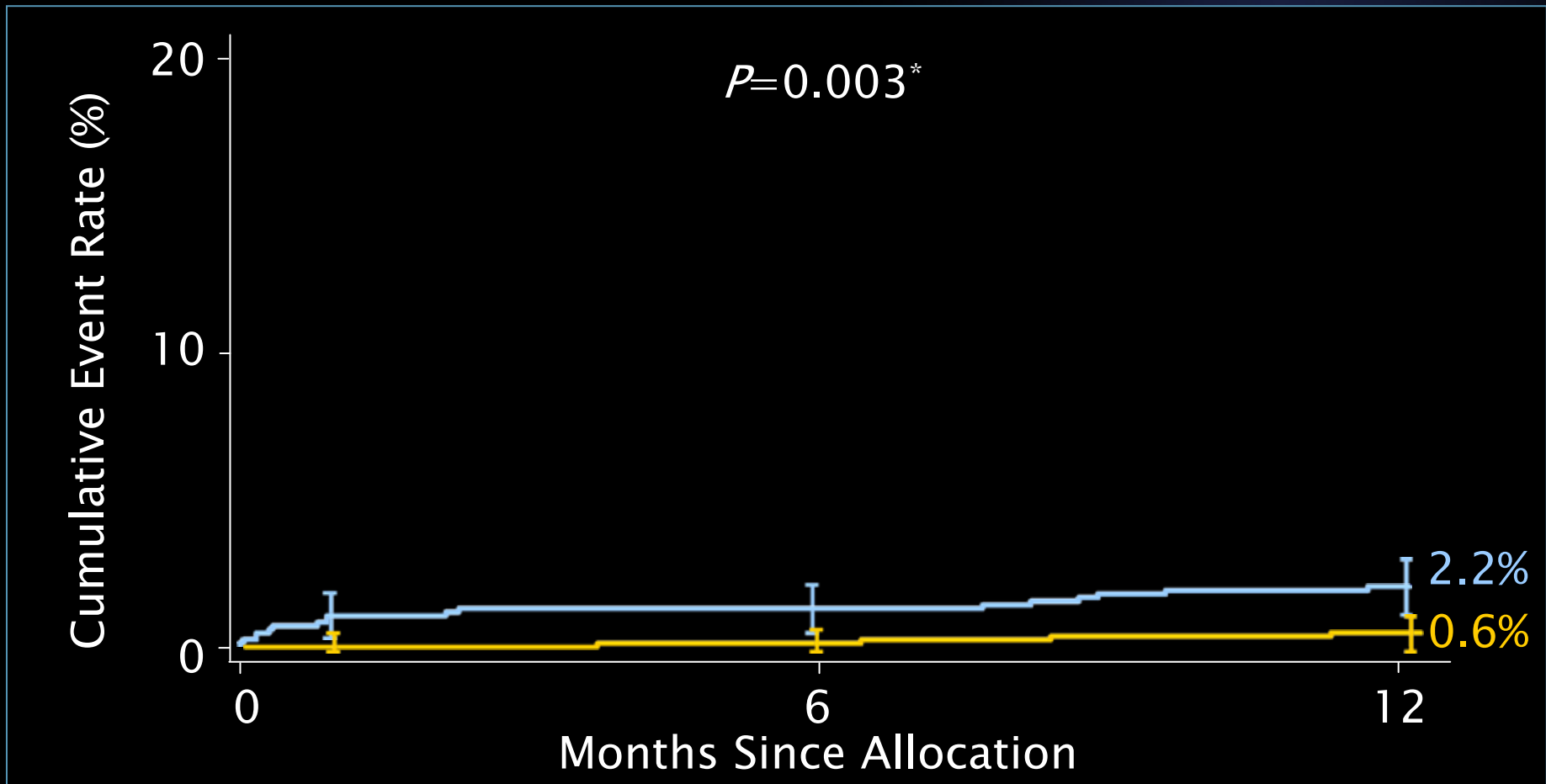
ITT population

CVA to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)



Event Rate \pm 1.5 SE. *Fisher's Exact Test

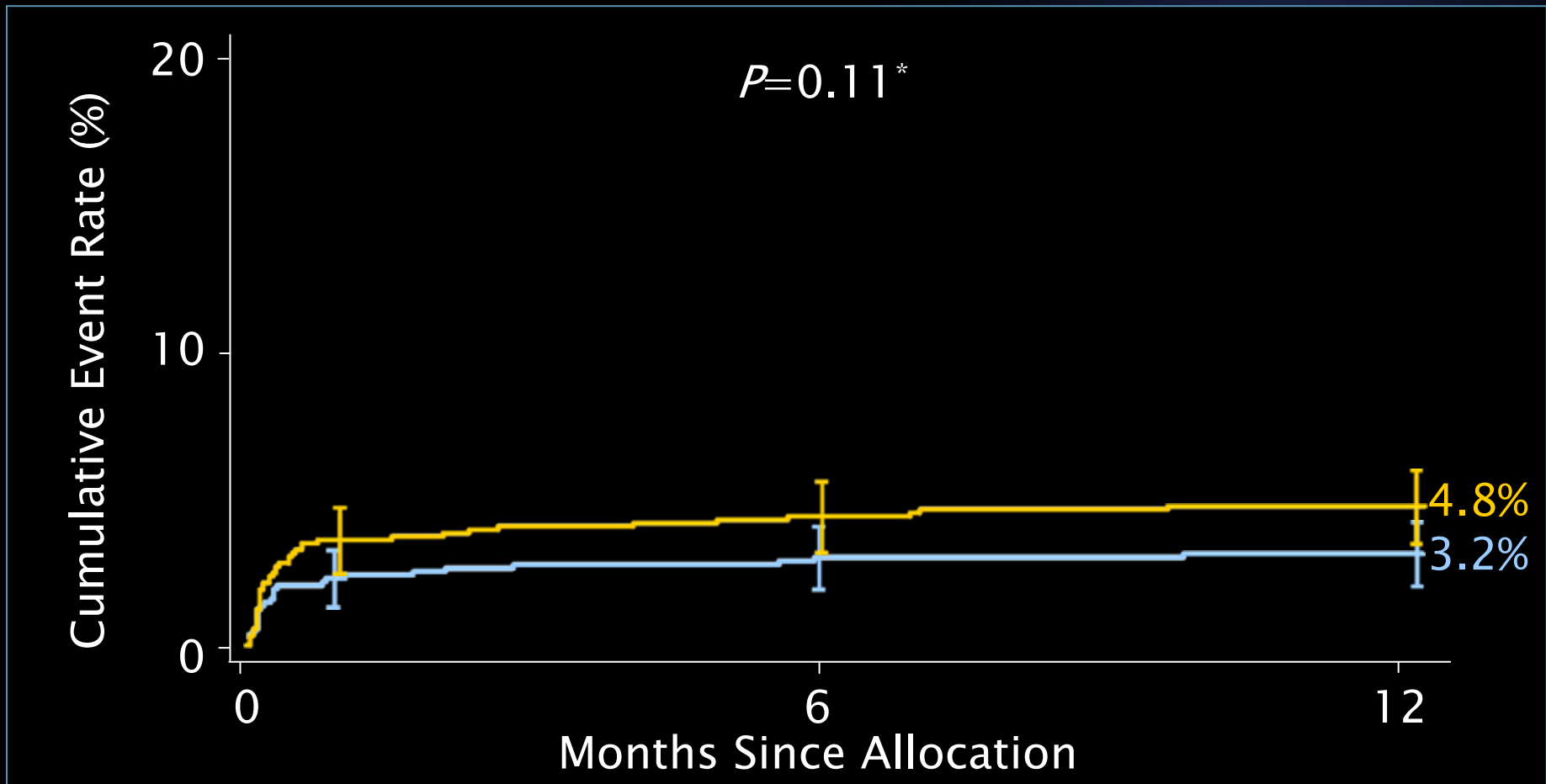
ITT population

Myocardial Infarction to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)



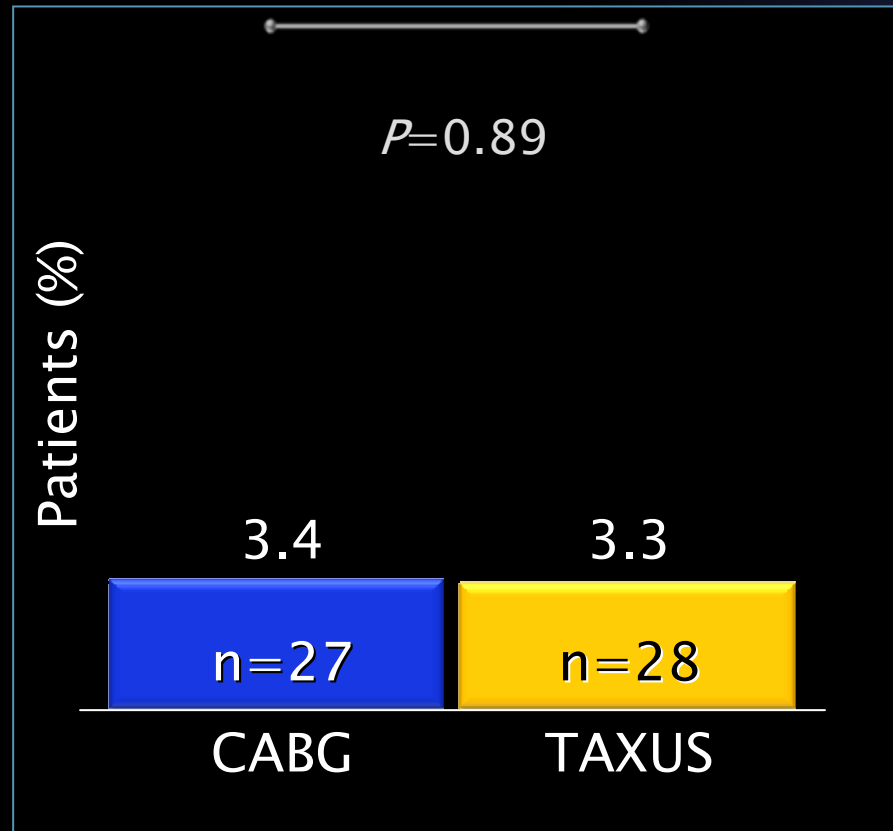
Event Rate \pm 1.5 SE. *Fisher's Exact Test

ITT population

Symptomatic Graft Occlusion & Stent Thrombosis to 12 Months



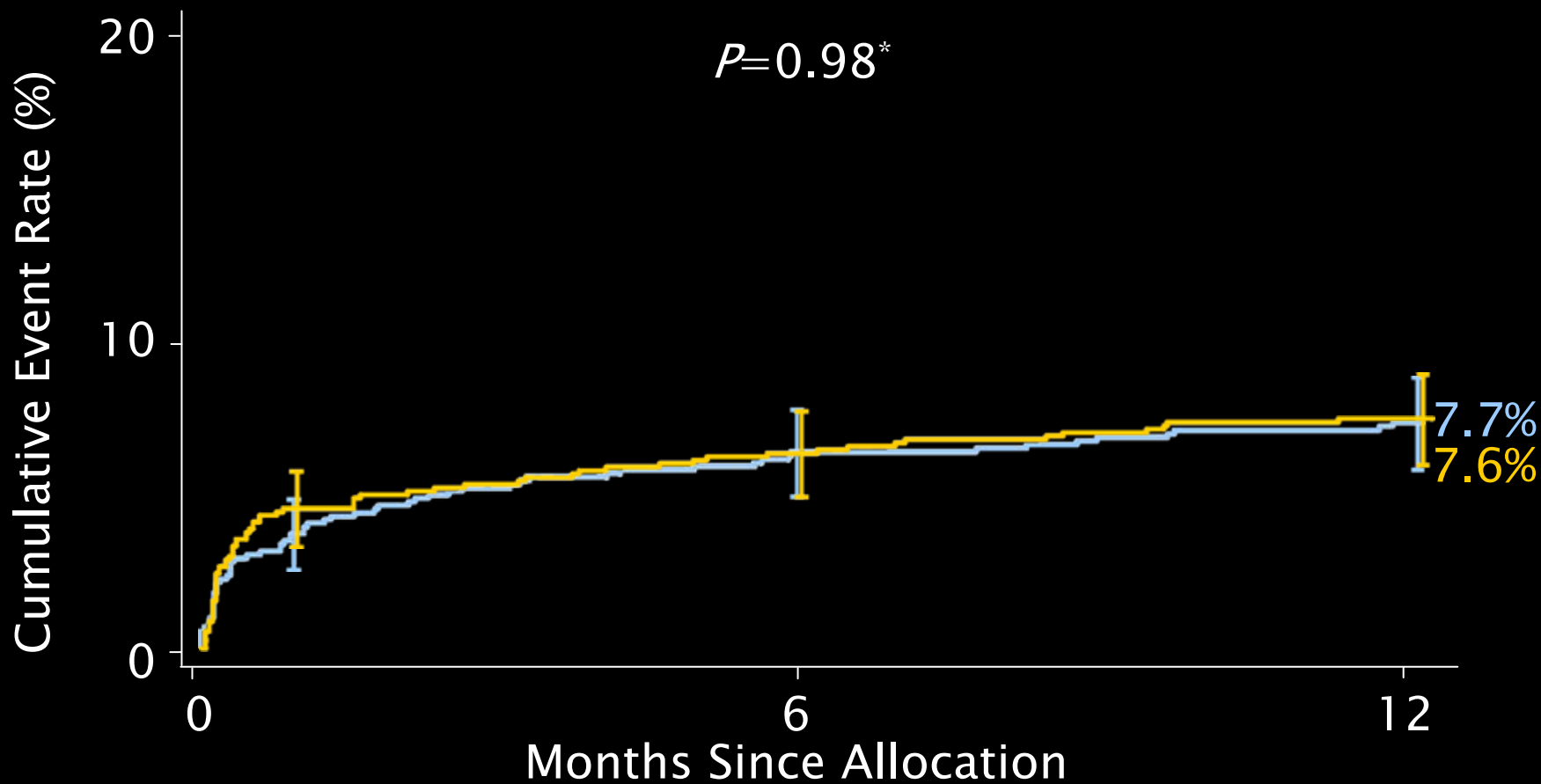
■ CABG (N=897) ■ TAXUS (N=903)



All-Cause Death/CVA/MI to 12 Months SYNTAX

■ CABG (N=897)

■ TAXUS (N=903)



Event Rate \pm 1.5 SE. *Fisher's Exact Test

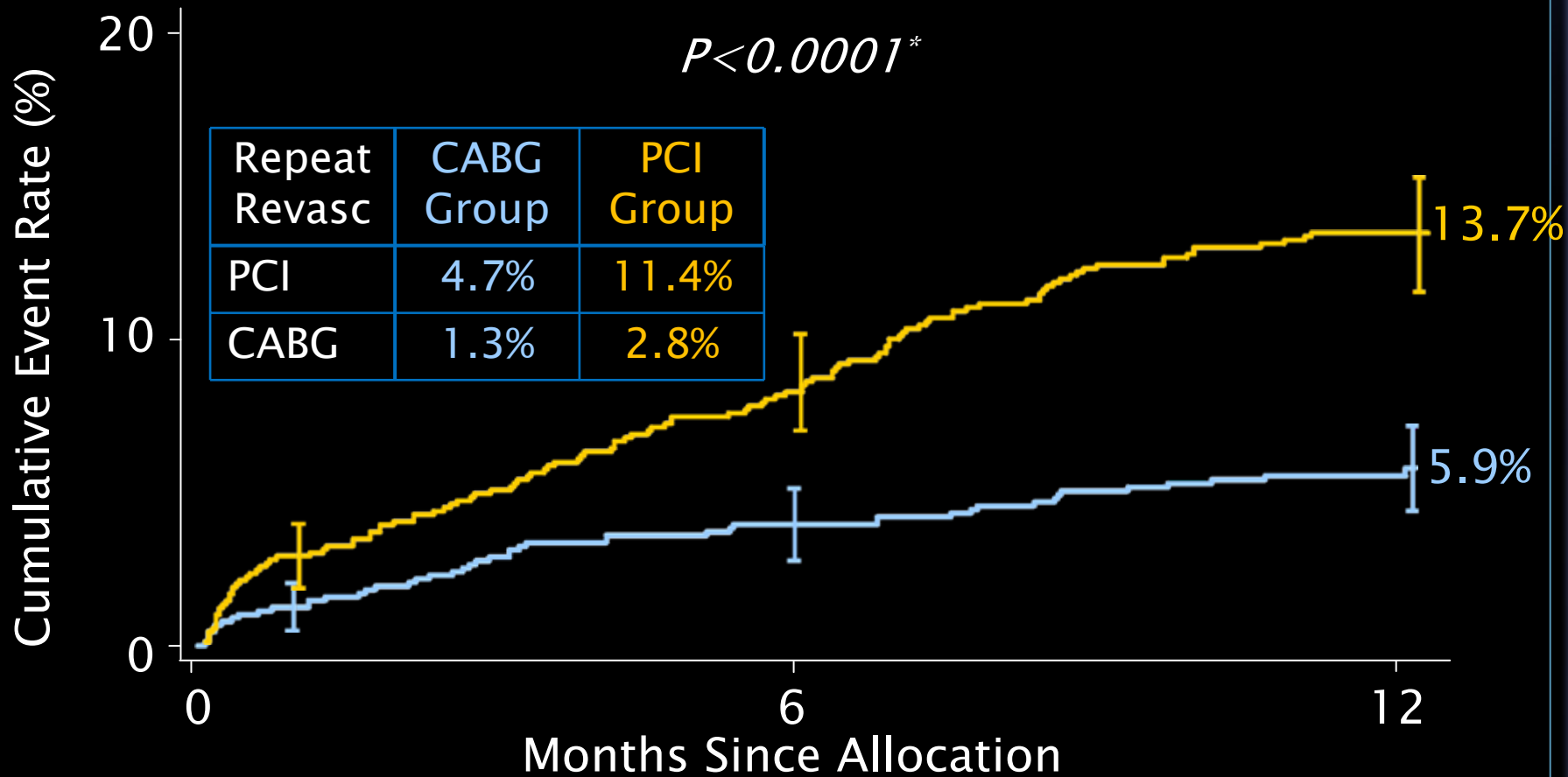
ITT population

Repeat Revascularization to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)



Event Rate \pm 1.5 SE. *Fisher's Exact Test

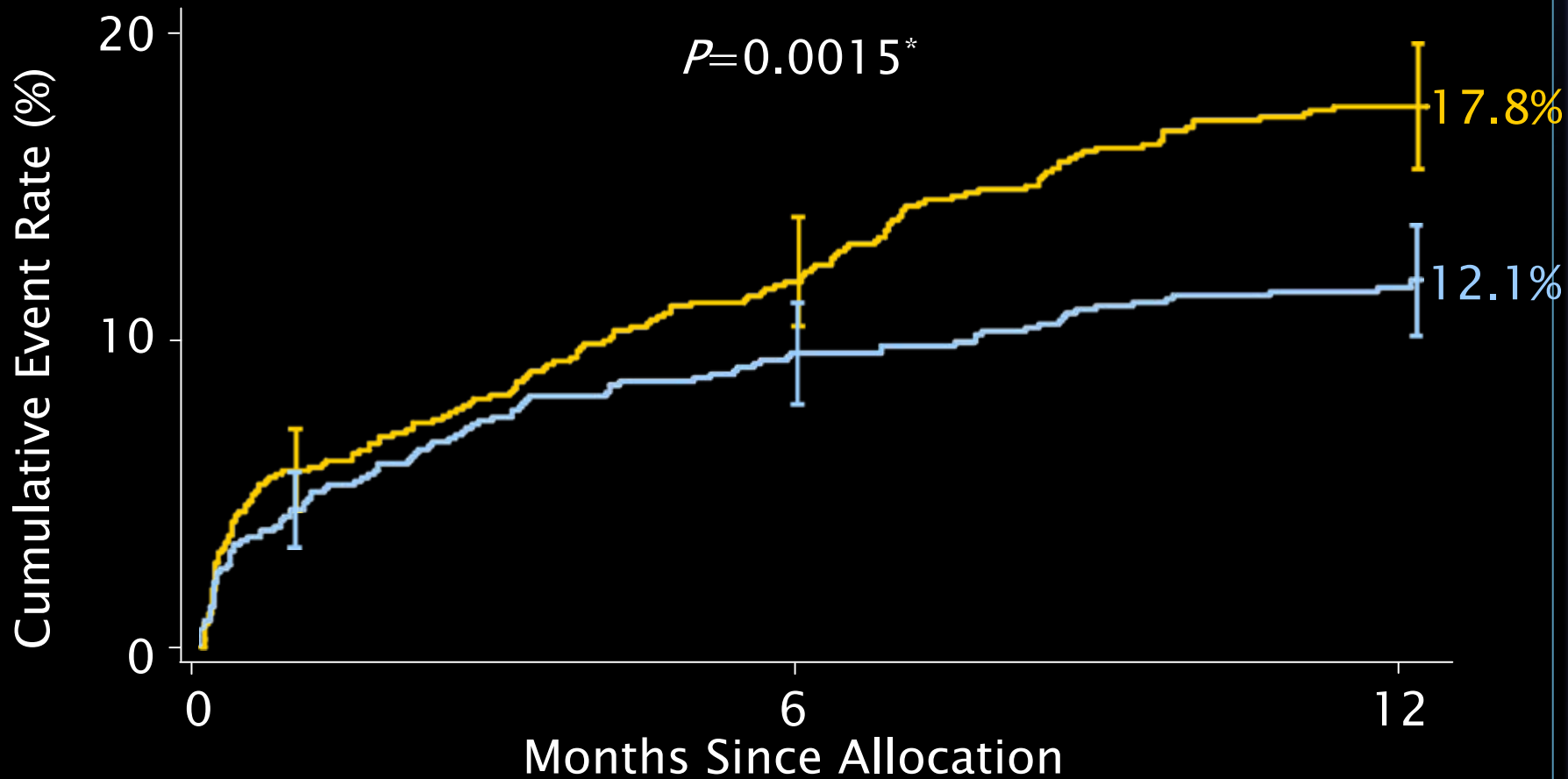
ITT population

MACCE to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)

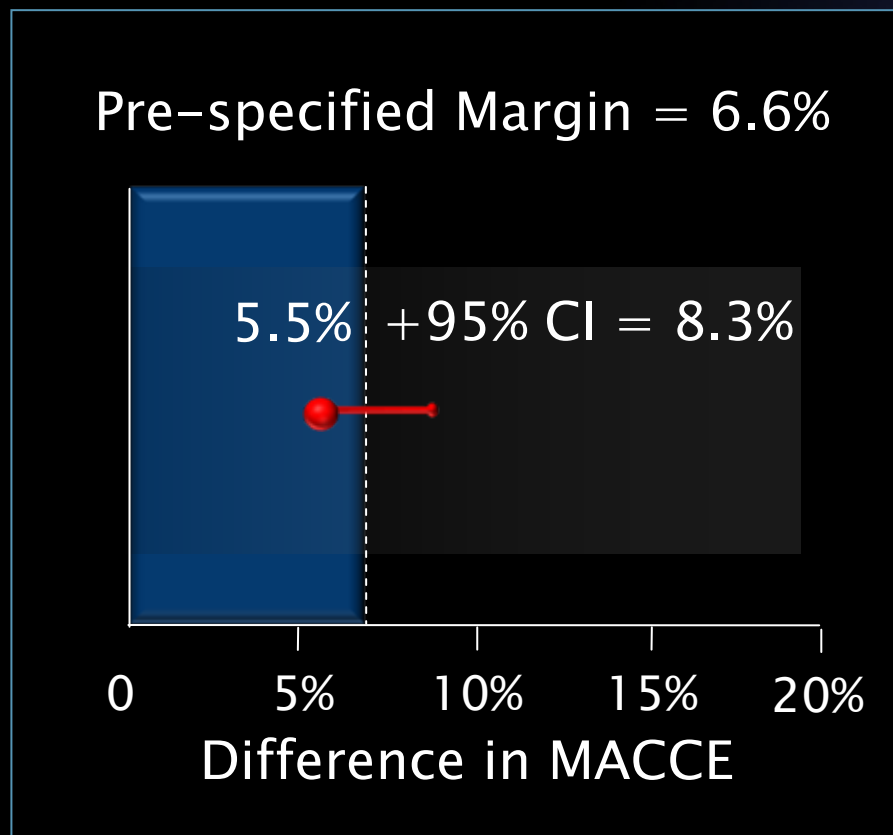


Event Rate \pm 1.5 SE. *Fisher's Exact Test

ITT population

Primary Endpoint: 12 Month MACCE

Non-inferiority analysis



The criteria for non-inferiority comparison was not met for the primary endpoint, further comparisons for the LM and 3VD subgroups are observational only and hypothesis generating

Conclusions:



- In the randomized SYNTAX cohort, there were comparable overall safety outcomes (**Death, CVA, MI,**) in CABG and PCI patients at 12 months (**7.7 vs. 7.6 %**).
- There was a significantly higher rate of **revascularization** in the PCI group (**13.7 vs. 5.9 %**), and a significantly higher rate of **CVA** in the CABG group (**2.2 vs. 0.6 %**).
- Overall MACCE in the PCI group was higher (17.8 vs. 12.1 %) due to an excess of redo revascularization compared with CABG.
- Rates of symptomatic graft occlusion and stent thrombosis were similar.
- The SYNTAX score will help stratify patients for the appropriate revascularization option.

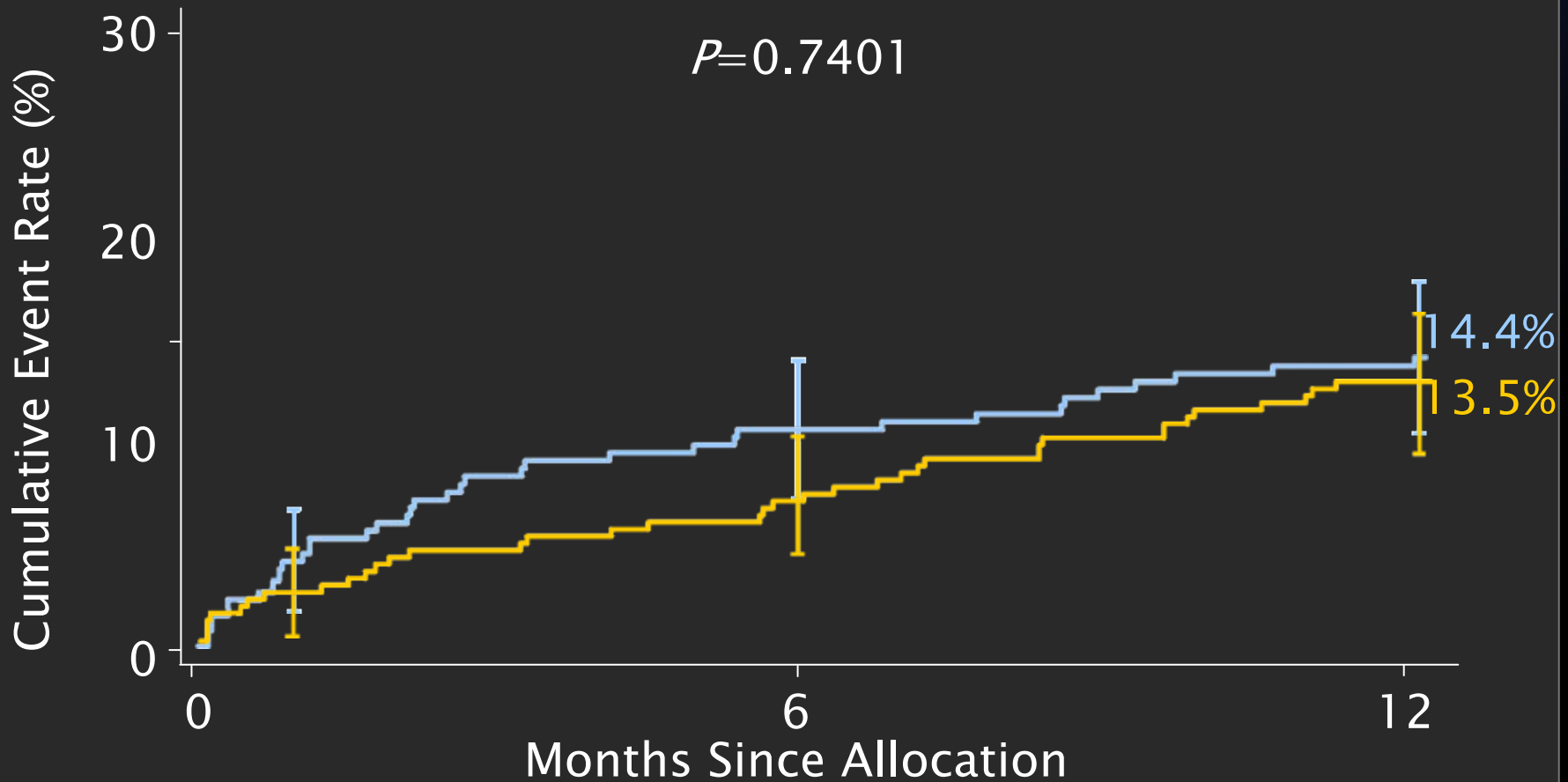
- MACCE to 12-months
según el SYNTAX Score

MACCE to 12-months vs SYNTAX Score: Low scores (0-22)



■ CABG (N=274)

■ TAXUS™ Stent (N=299)

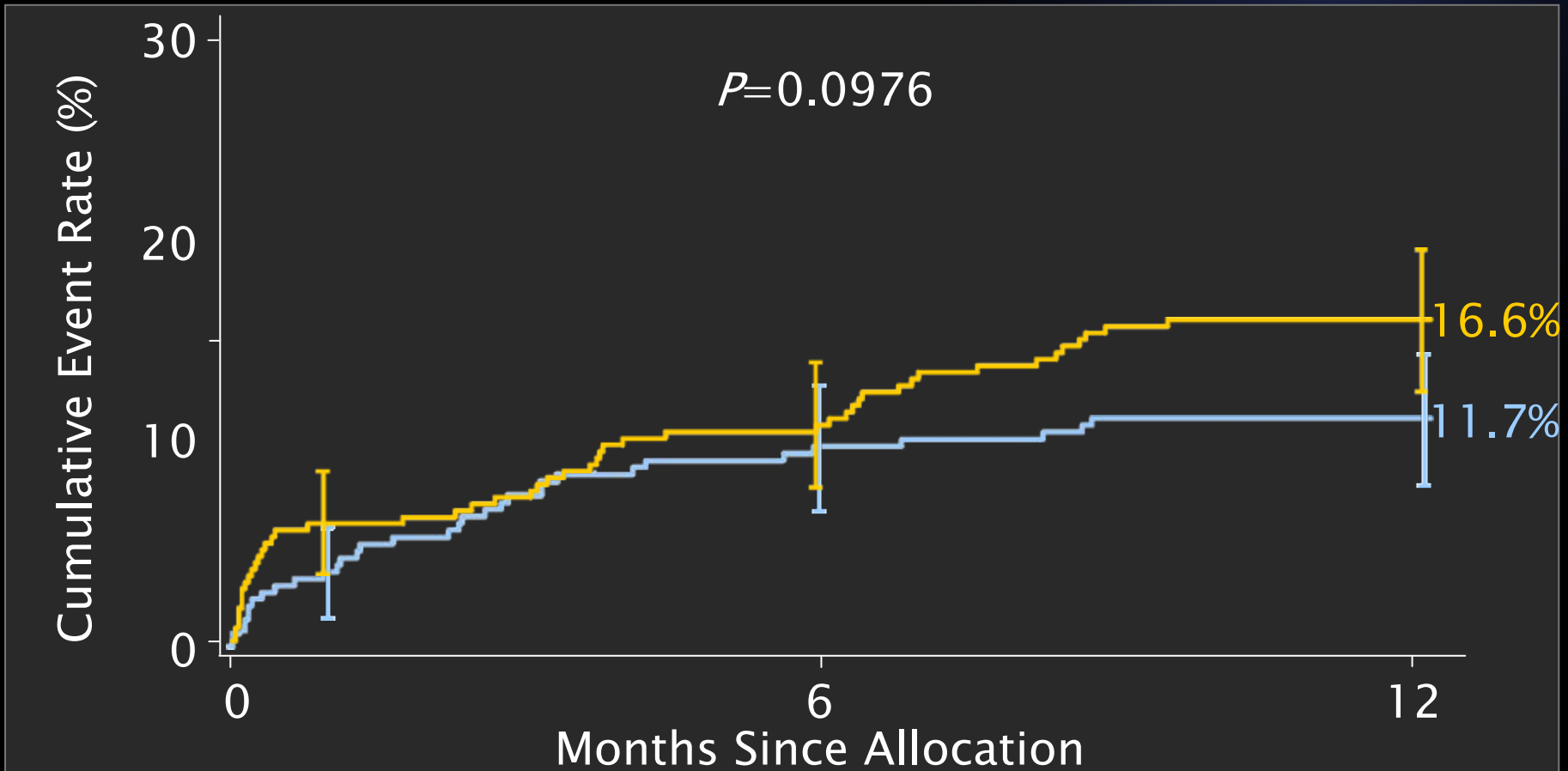


MACCE to 12-months vs SYNTAX Score: Intermediate scores (23-32)



■ CABG (N=300)

■ TAXUS™ Stent (N=310)

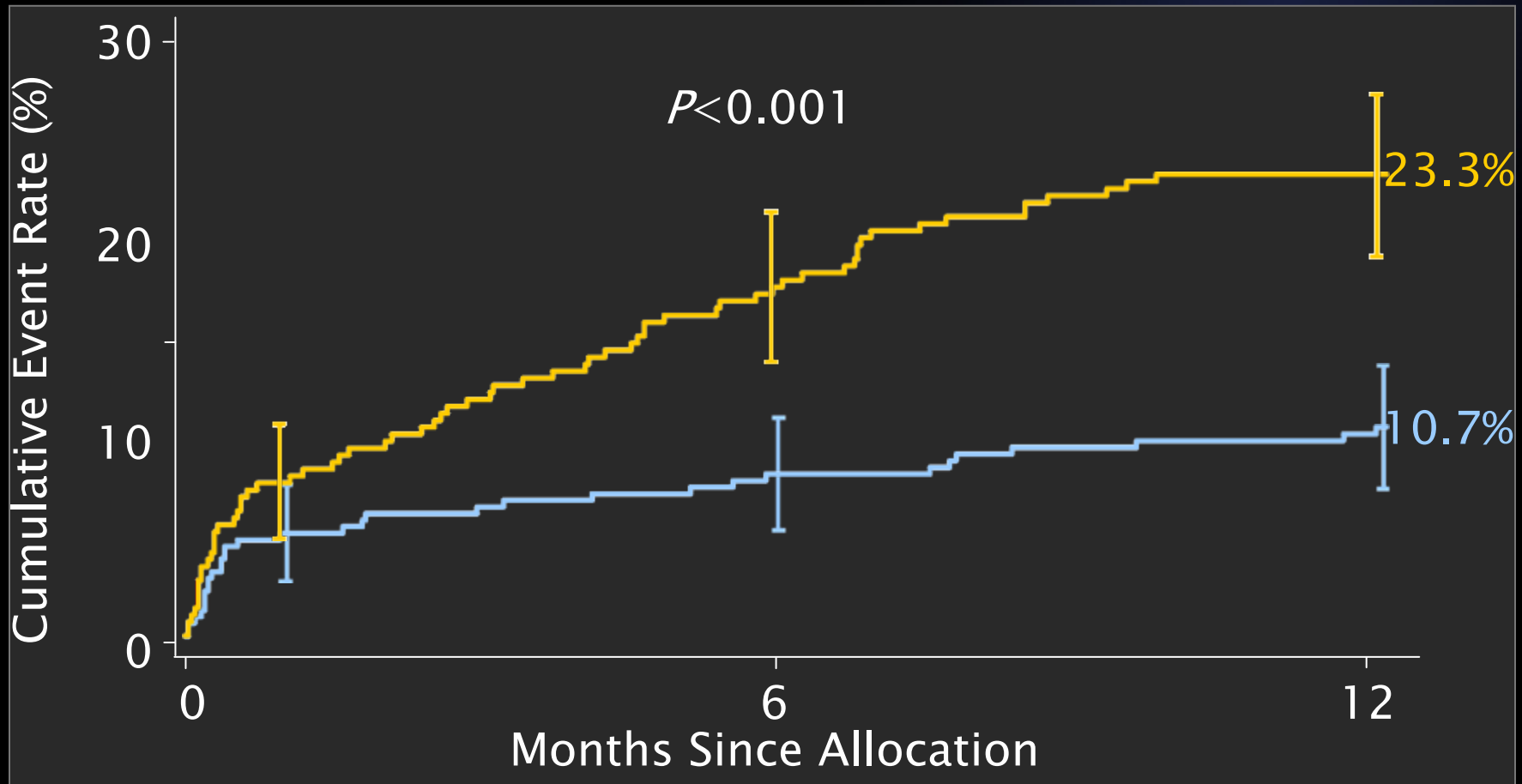


MACCE to 12-months vs SYNTAX Score: High scores (≥ 33)



■ CABG (N=316)

■ TAXUS™ Stent (N=290)



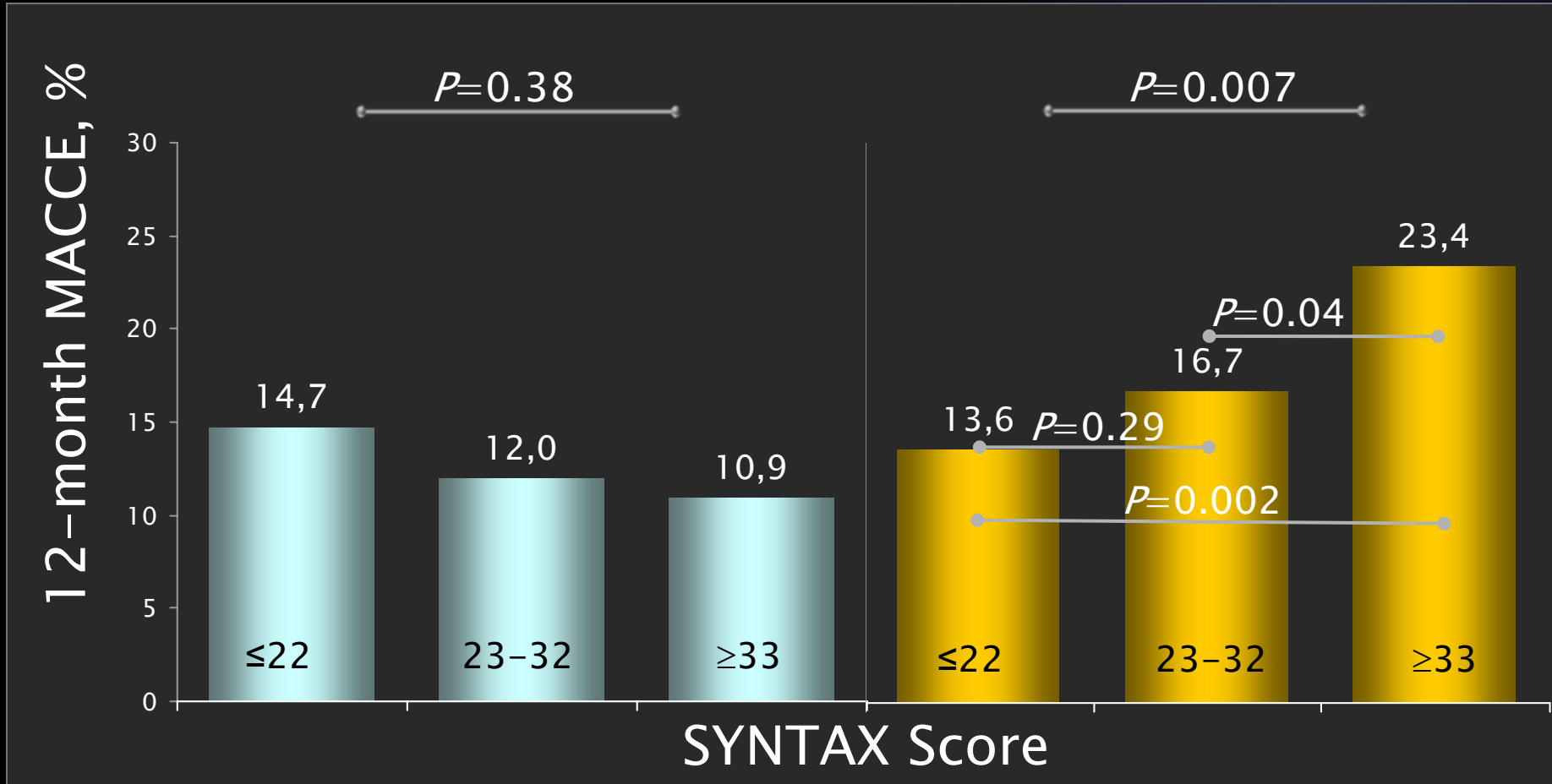
** Isolated or in conjunction with 1, 2, 3VD and *** revascularization for all 3 vascular territories.

MACCE to 12-Months vs SYNTAX Score



■ CABG (N=897)

■ TAXUS™ Stent (N=903)



Conclusiones de subgrupos

– Syntax Score - :

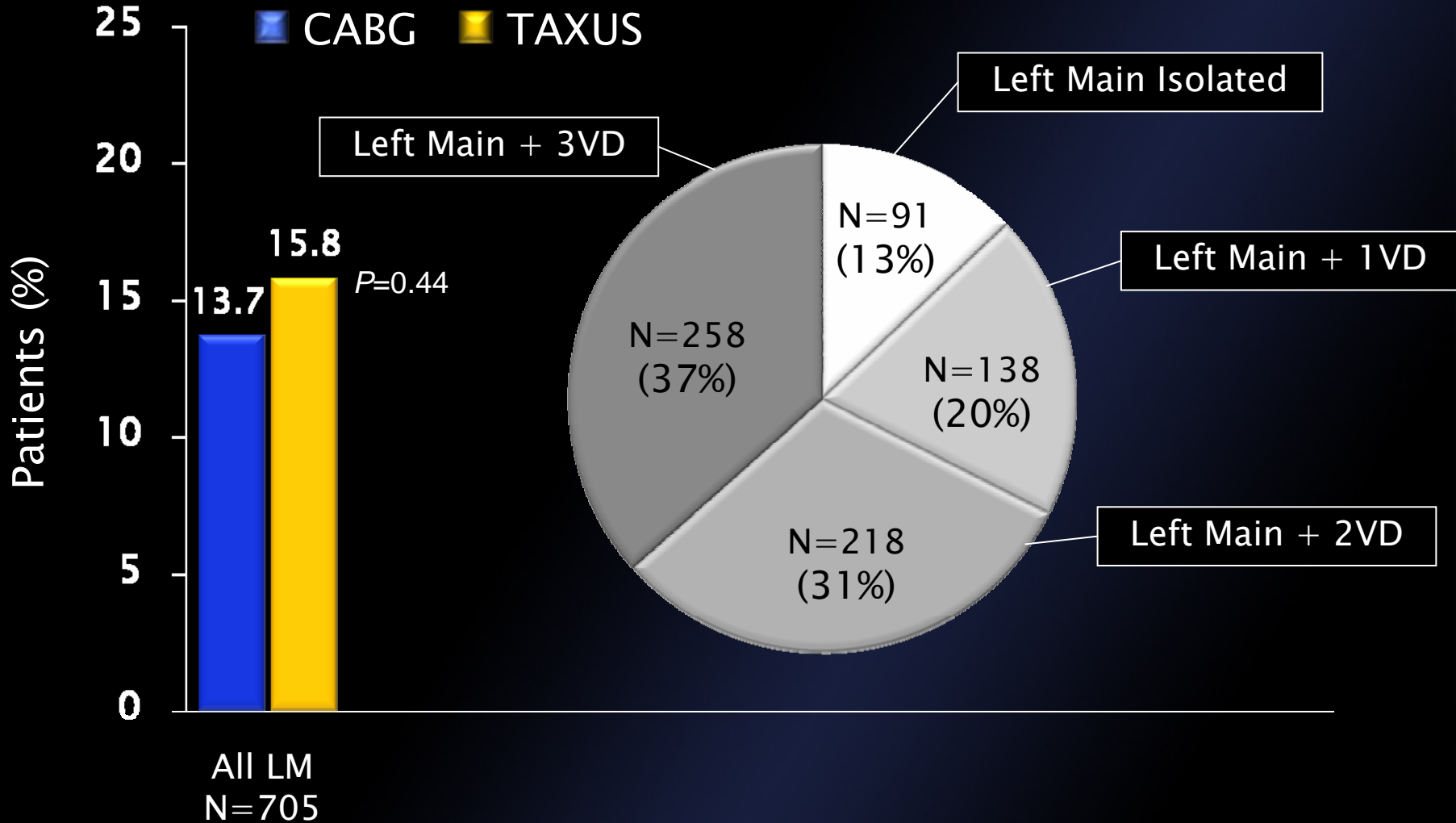


- En pacientes con 3 vasos y lesiones coronarias poco complejas (Syntax Score $<0,22$) la incidencia acumulada de Eventos (Mortalidad, Infarto, ACV y Reintervención) es similar con Cirugía (14,4%) y ICP (13,5%).

Hipótesis: La complejidad de las lesiones coronarias no parece afectar al resultado de la Cirugía pero afecta y mucho al resultado de la ICP.

- Resultados en el subgrupo de pacientes con lesión del Tronco de la Coronaria Izquierda

12 Month LM Subgroup MACCE Rates

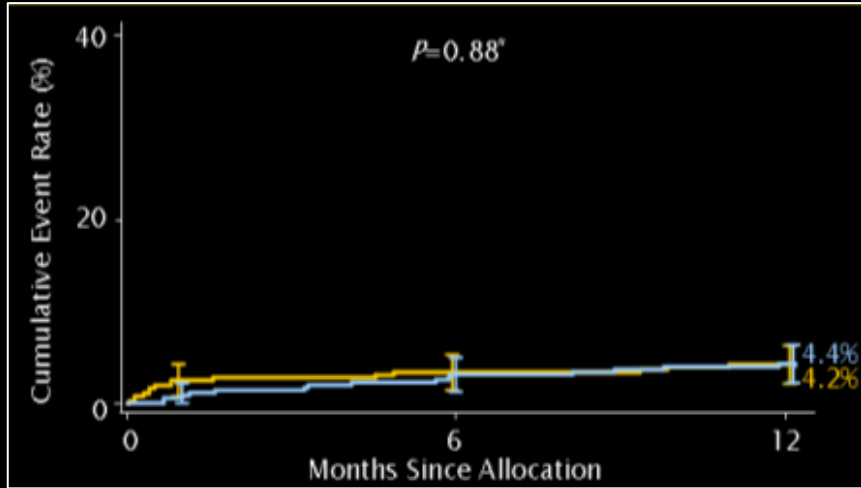


Left Main Subsets

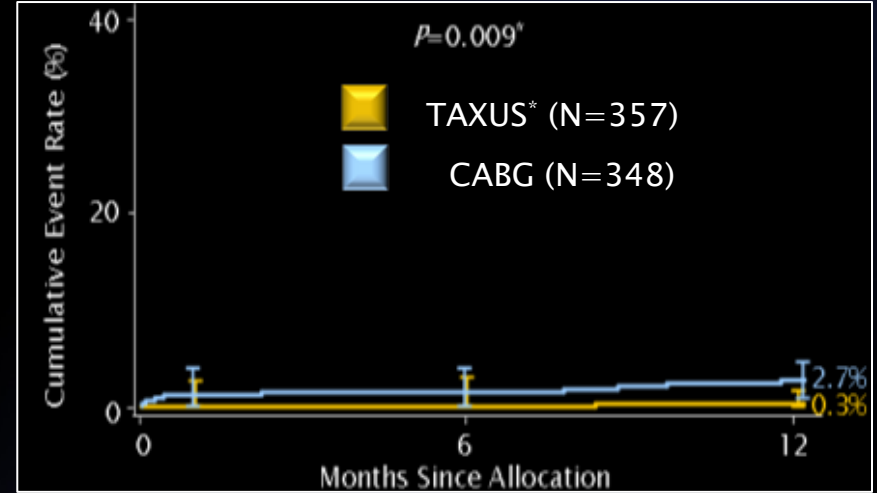
Adverse Events to 12 Months



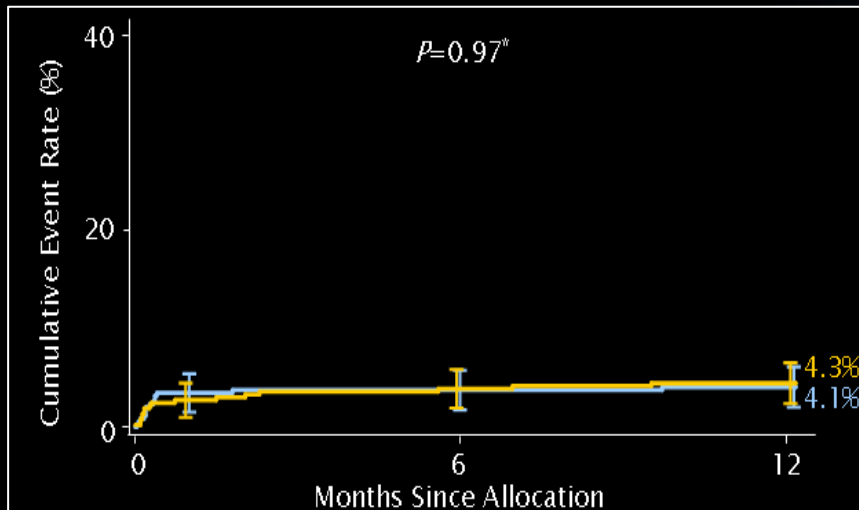
All-Death



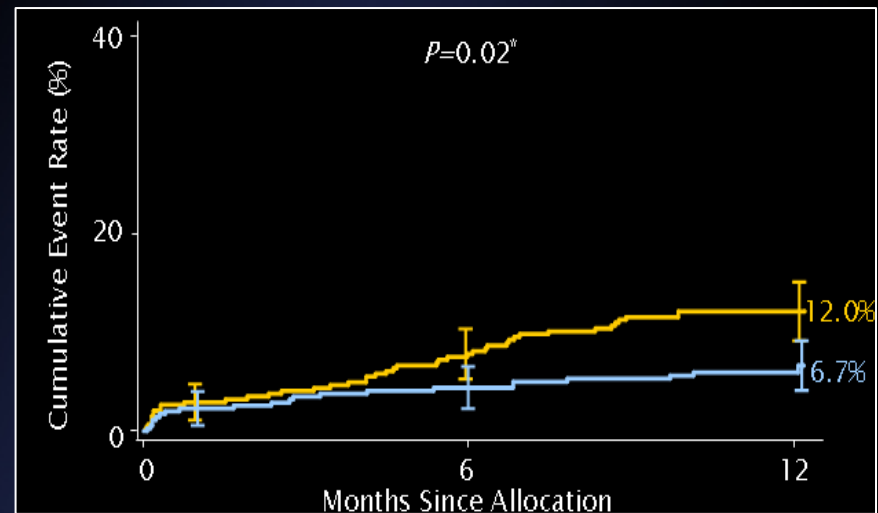
CVA (Stroke)



Myocardial Infarction



All Repeat Revascularization



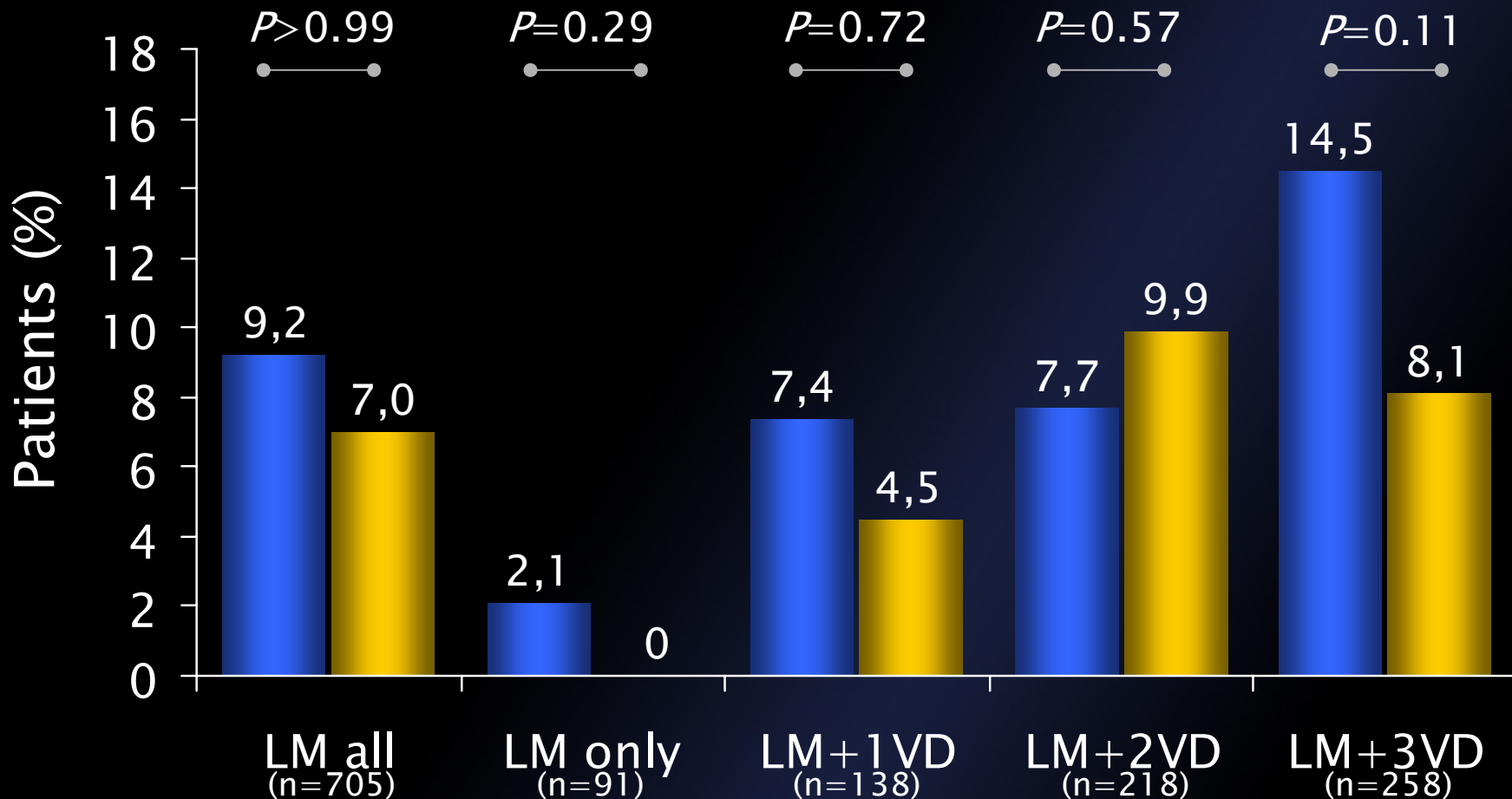
Event rate \pm 1.5 SE, *Fisher exact test

Safety at 12 Months

Death/CVA/MI in the Left Main Subset



■ CABG ■ TAXUS™ Stent



TAXUS™ Express²™

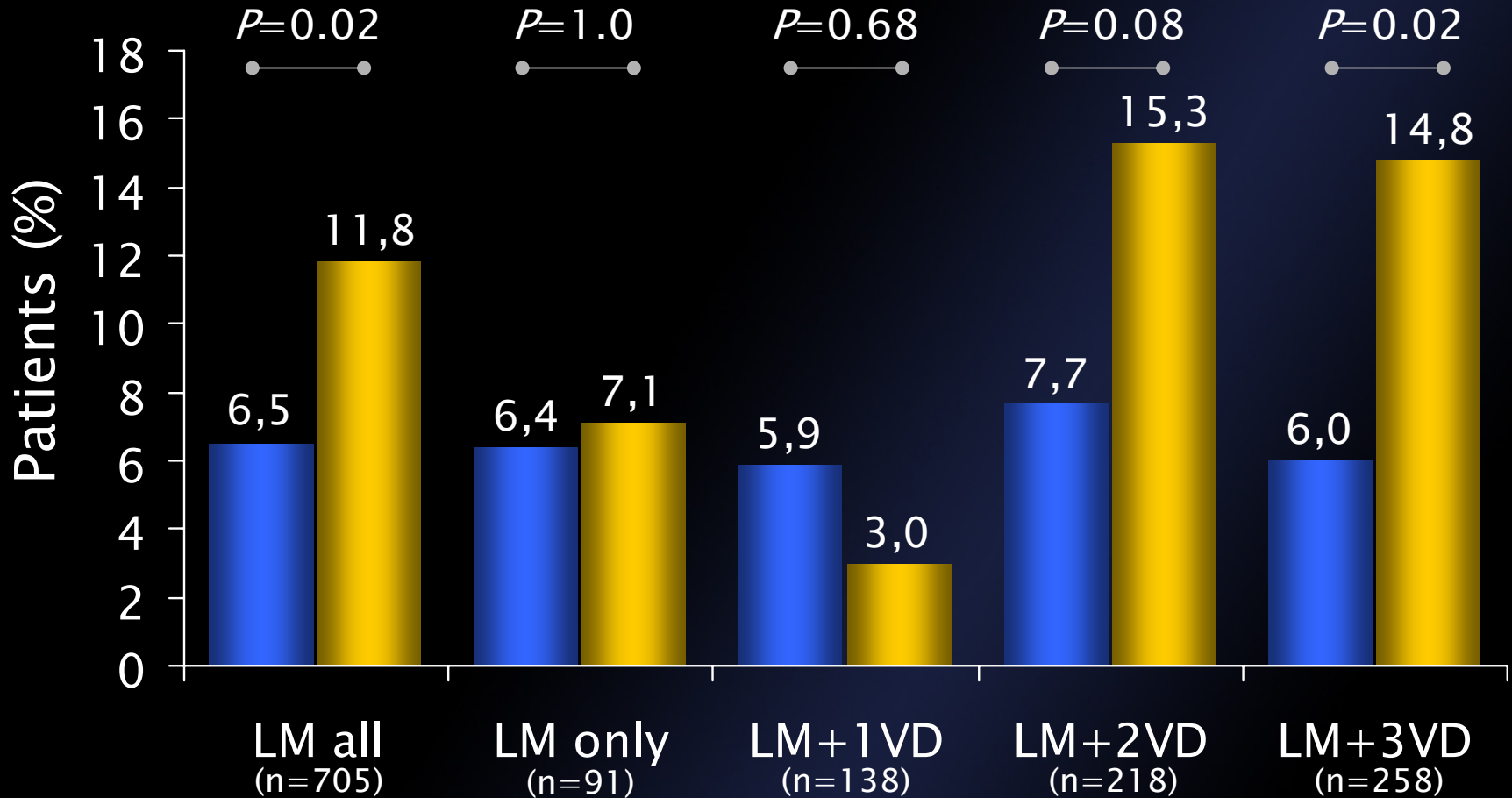
Revascularizations at 12 Months

Left Main Subset



■ CABG

■ TAXUS™ Stent

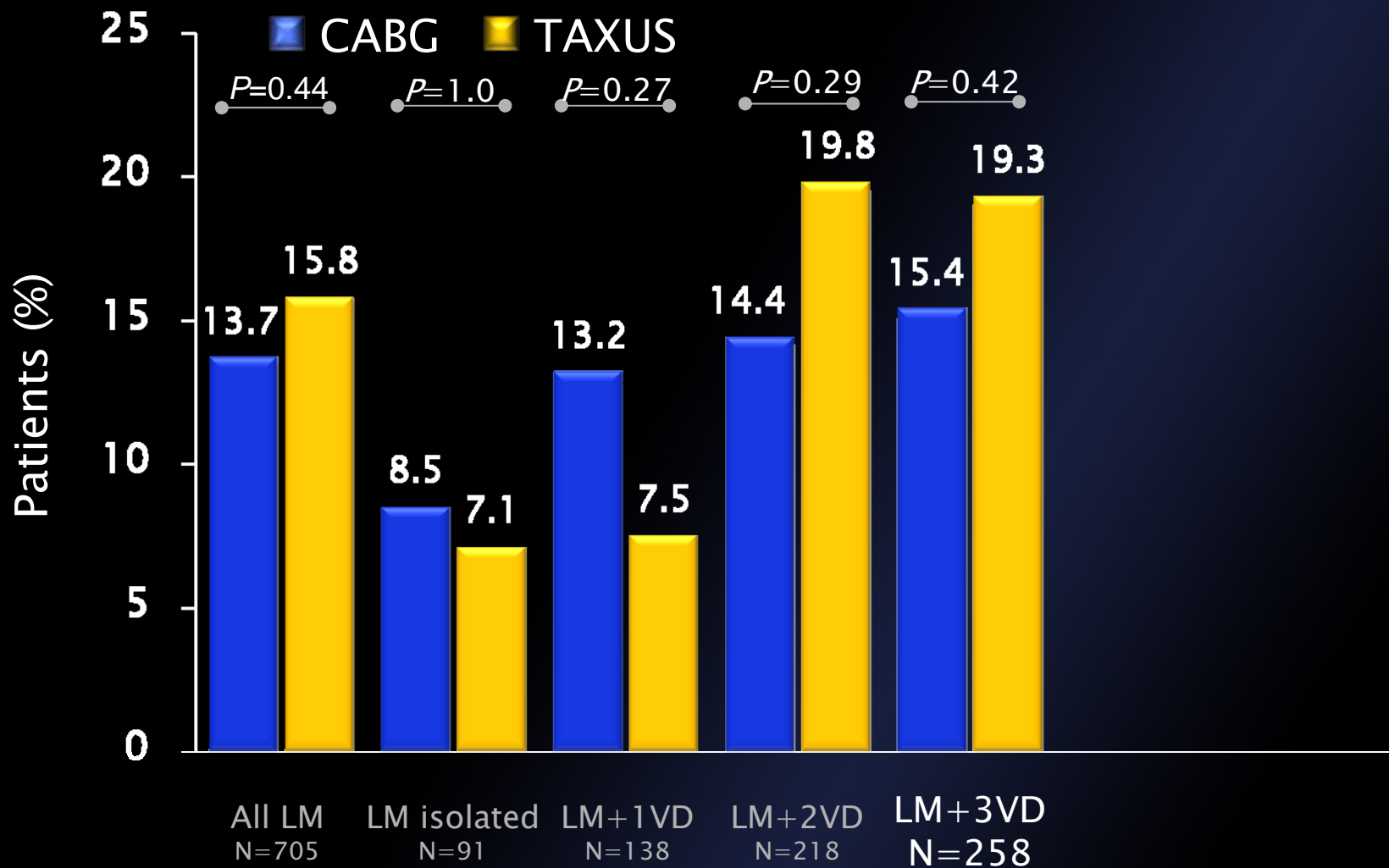


TAXUS™ Express²™

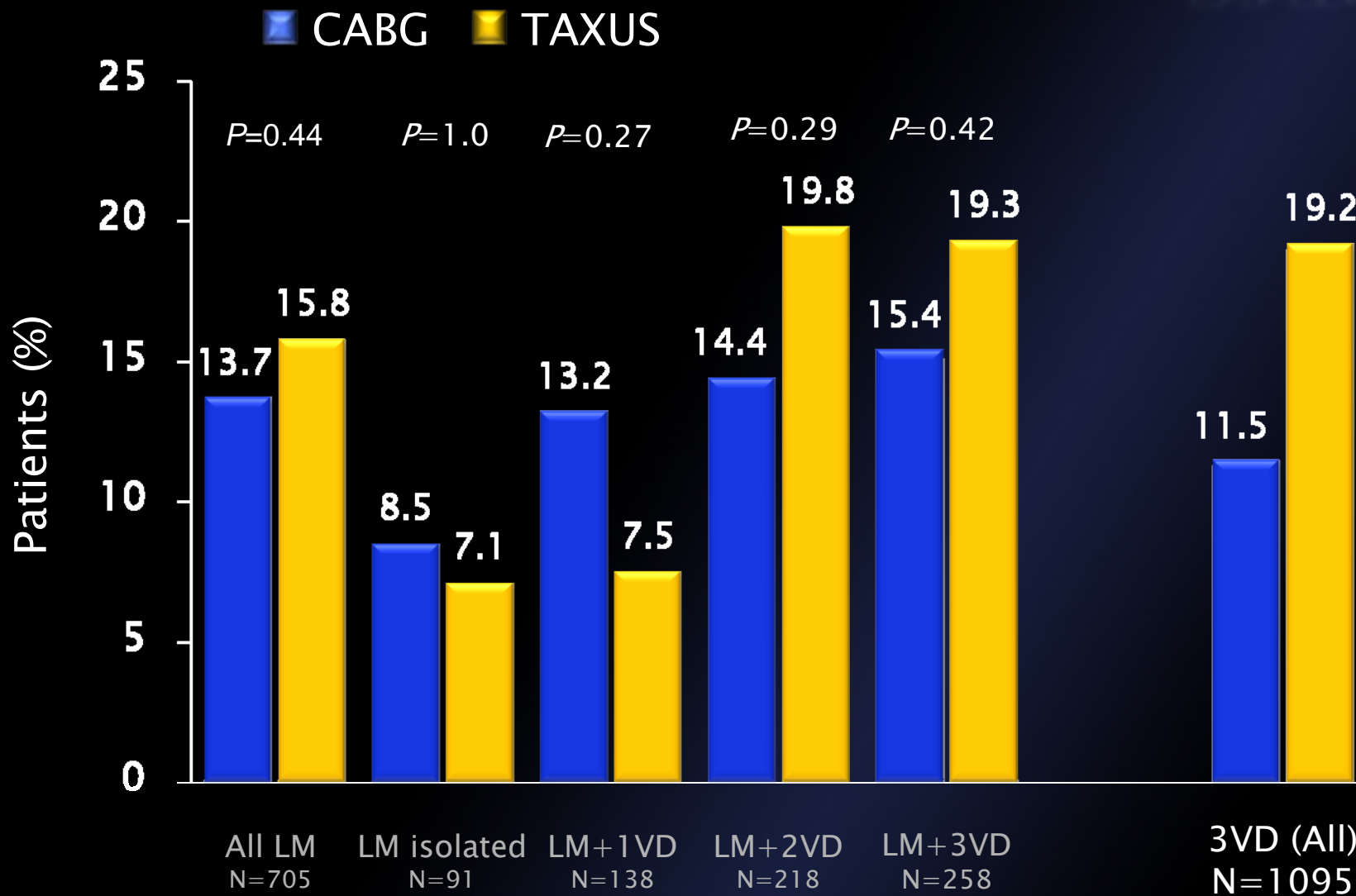
Syntax did not meet primary endpoint

ITT population
 *Any revascularization (PCI or CABG)

12 Month LM Subgroup MACCE Rates



12 Month LM Subgroup MACCE Rates



Conclusiones de subgrupos:

- Subgrupo con lesión del Tronco de la Coronaria izquierda-



- No hay diferencias significativas en la tasa de eventos totales con Cirugía (13,7) vs ICP (15,8),) $P = 0,44$
- La tasa de nuevas reintervenciones es significativamente más alta en los pacientes tratados con ICP (11,8 %) que con Cirugía (6,5%), $P = 0,02$ aunque no hay diferencias cuando la lesión de TCI es aislada o con afectación TCI + 1 vaso.
- Respecto a la afectación de 3 vasos sin lesión de TCI, los pacientes con TCI + 3 vasos tratados con Cirugía tienen mayor Tasa de Eventos totales

Hipótesis: La Lesión del TCI parece añadir un mayor plus de riesgo a la cirugía que a la ICP

- Resultados en el subgrupo de pacientes diabéticos

Increased Baseline and Co-morbid Risk in SYNTAX Diabetic Patients



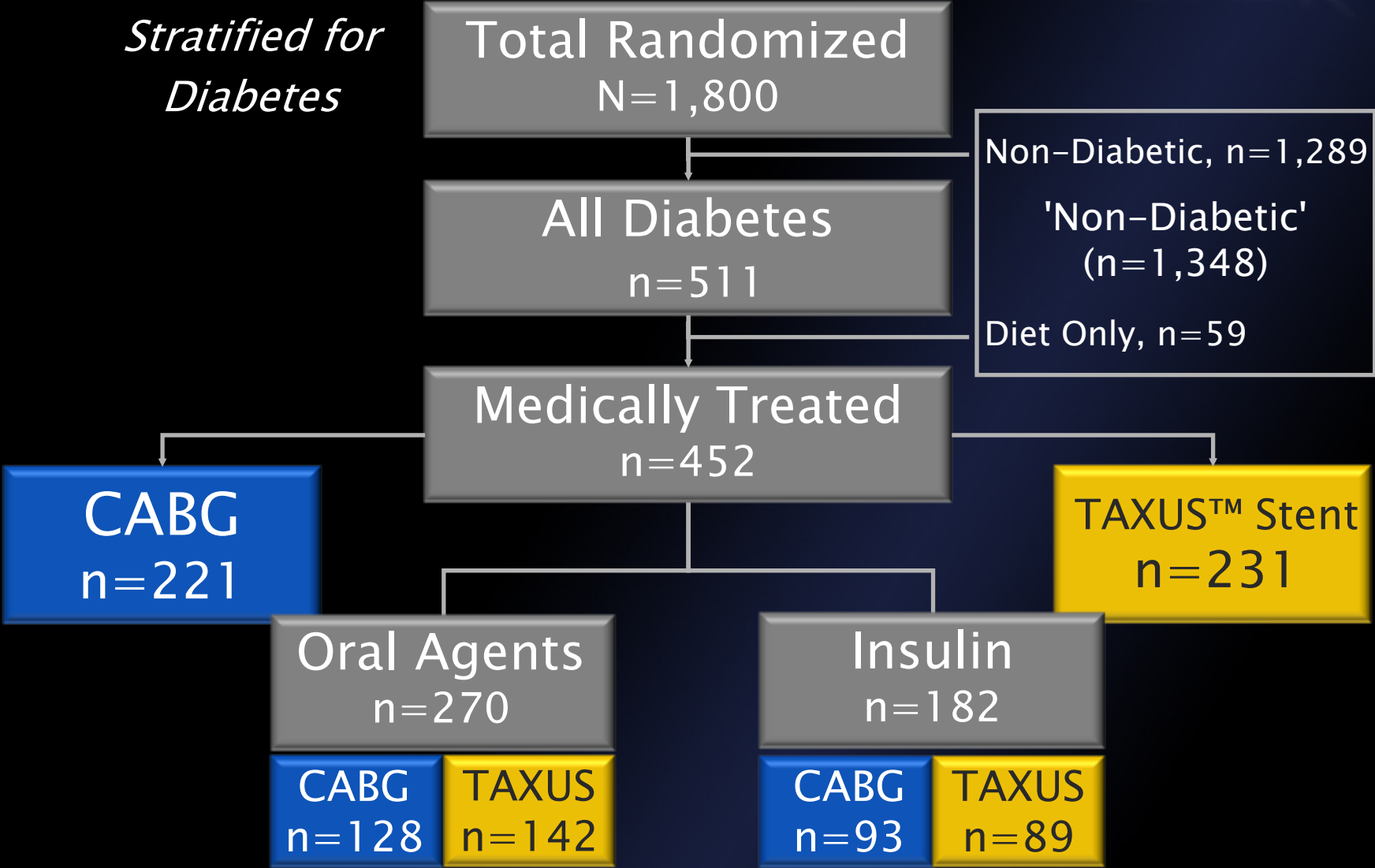
	No Diabetes n=1348	Diabetes* n=452	p-value
Age, mean \pm SD (y)	65.0 \pm 9.9	65.4 \pm 9.2	0.41
Male, %	79.9	71.0	<0.001
Metabolic syndrome, %	37.4	69.9	<0.001
Hypertension, %	72.6	84.1	<0.001
Hyperlipidemia, %	76.7	81.5	0.03
Current smoker, %	21.7	15.8	0.006
Prior MI, %	33.2	32.0	0.65
Congestive heart failure, %	3.7	7.4	0.001
Poor ejection fraction, %	1.6	2.9	0.07
Peripheral vascular disease, %	8.2	14.6	<0.001
Prior stroke, %	3.8	6.0	0.046
Creatinine >200 μ mol/L	1.0	2.9	0.003
Additive euroSCORE, mean \pm SD	3.7 \pm 2.6	4.0 \pm 2.7	0.03
Total Parsonnet score, mean \pm SD	7.5 \pm 6.8	11.3 \pm 6.4	<0.001

Patients with Diabetes in SYNTAX

Randomized Cohort, Intent-to-Treat



Stratified for Diabetes



12-months
TAXUS™ Express²™

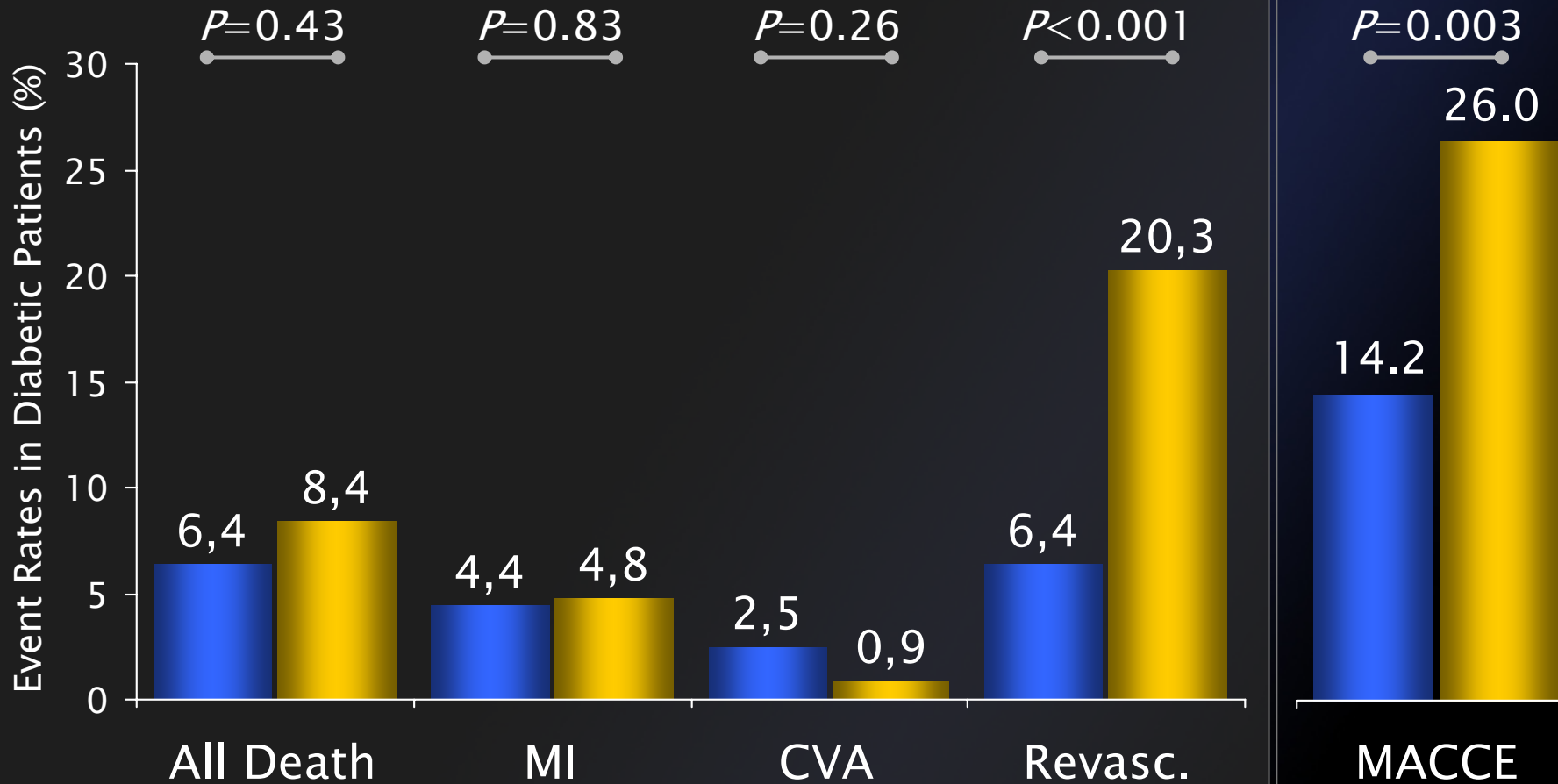
*TAXUS Stent

Higher 12-Month MACCE in Diabetics, Driven by Revascularization



■ CABG (n=204)

■ TAXUS™ Stent (n=227)



*Medically treated diabetes

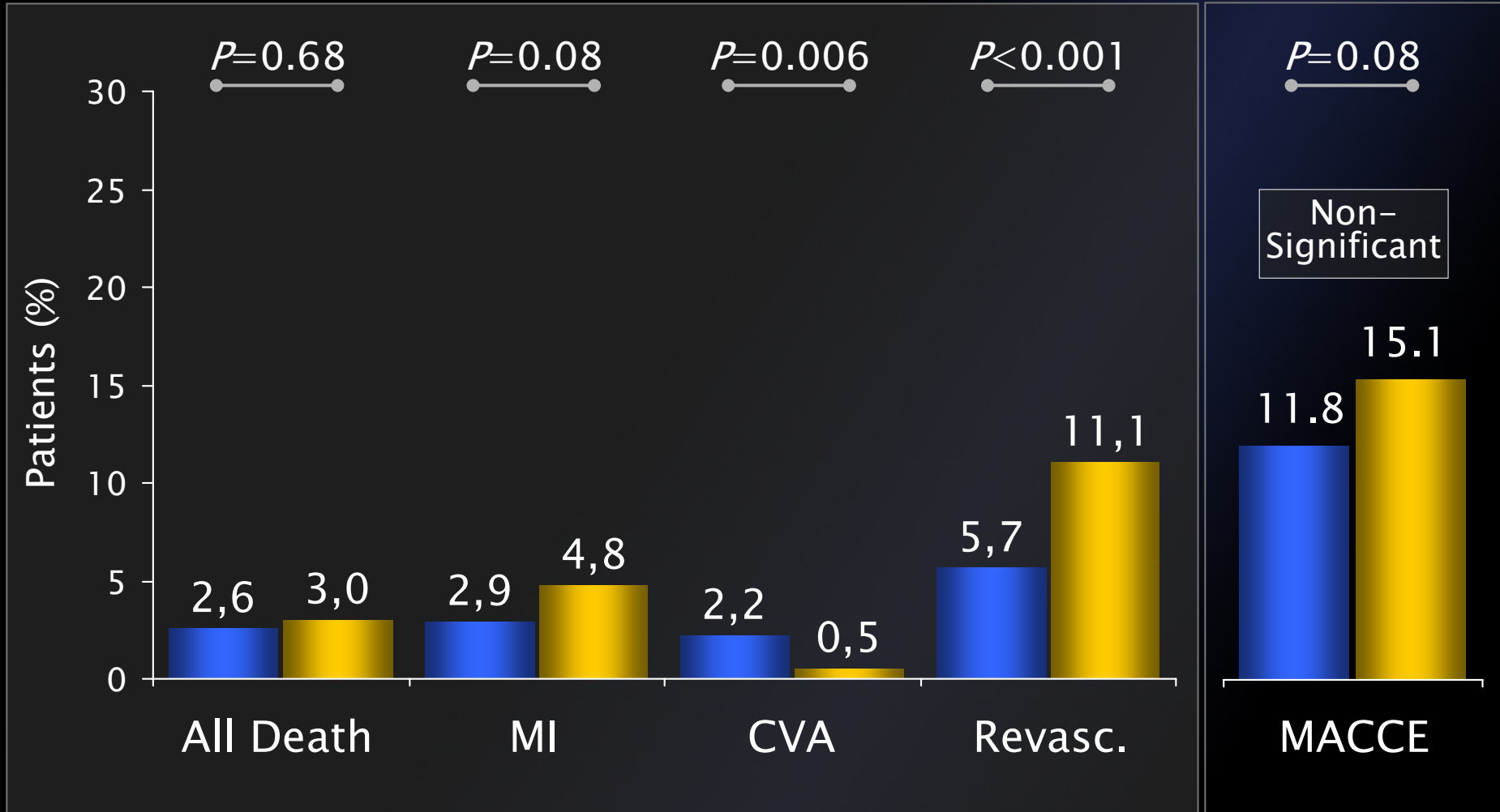
TAXUS™ Express²™

No Significant Increase in MACCE in 'Non-Diabetics' at 12-Months



■ CABG (n=645)

■ TAXUS™ Stent (n=664)

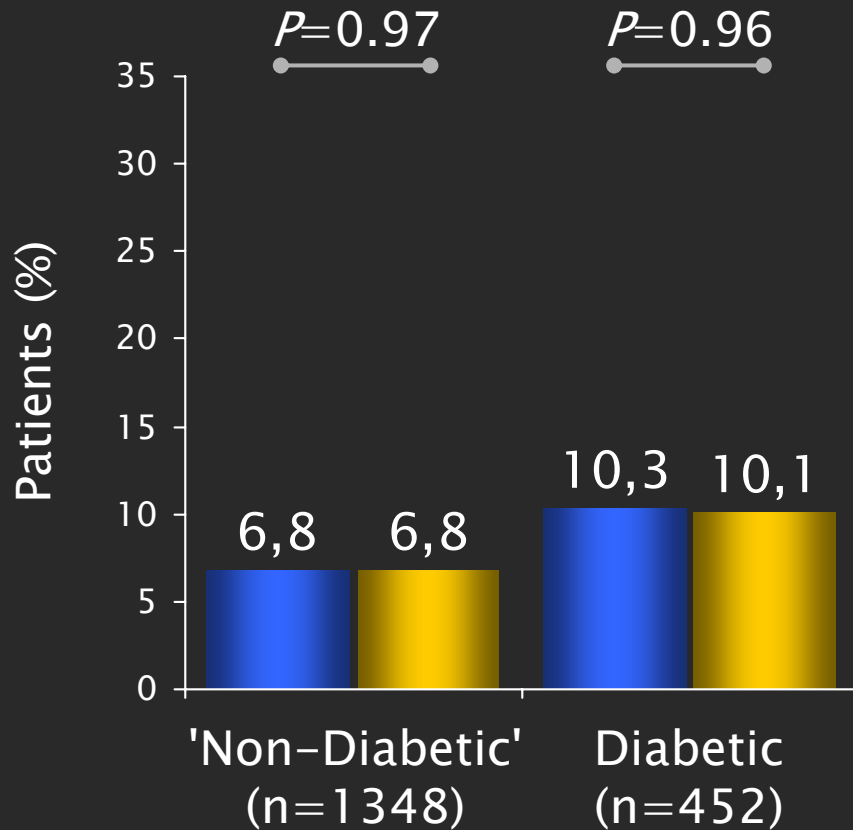


Outcome According to Diabetic Status at 12-Months

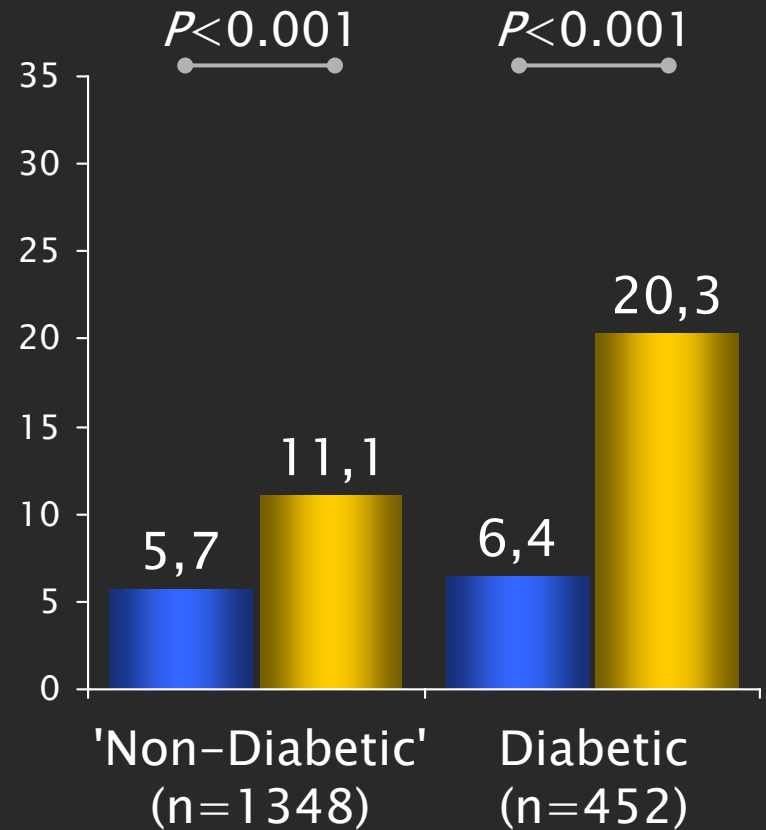


CABG TAXUS™ Stent

Death/CVA/MI



Revascularization



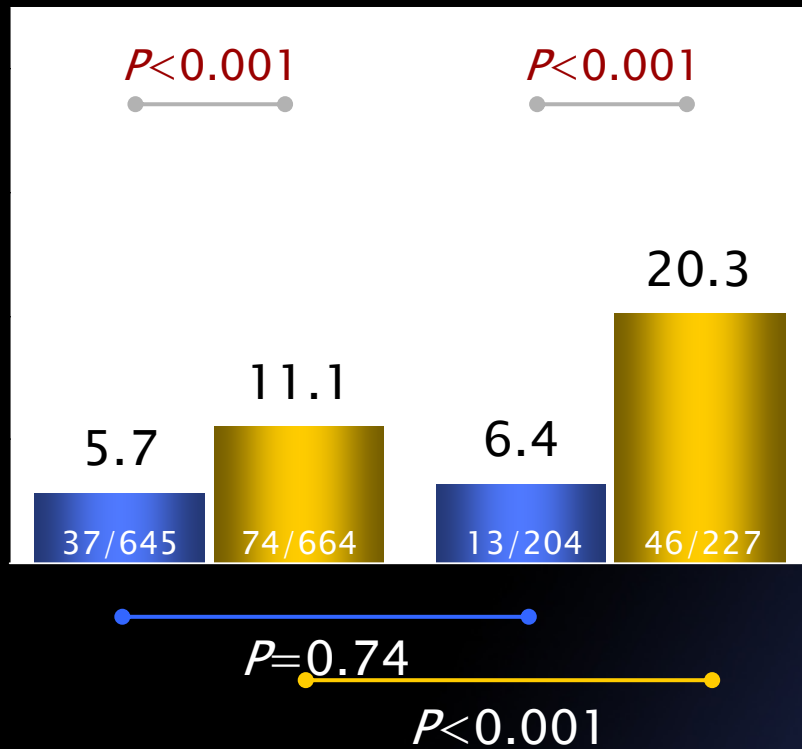
Revascularization at 12-Months *Increased in Diabetes, Driving MACCE*



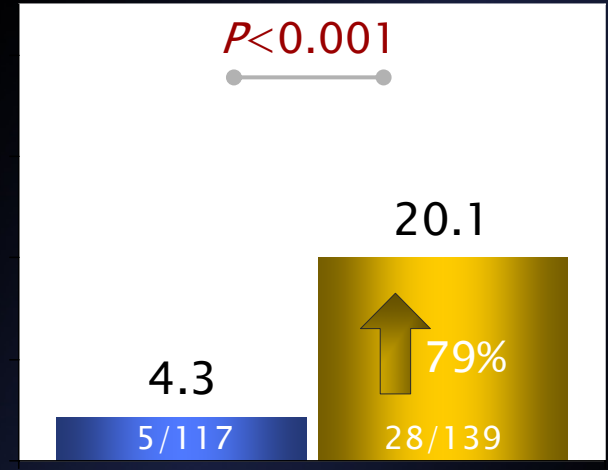
CABG **TAXUS™ Stent**

'Non-Diabetic'

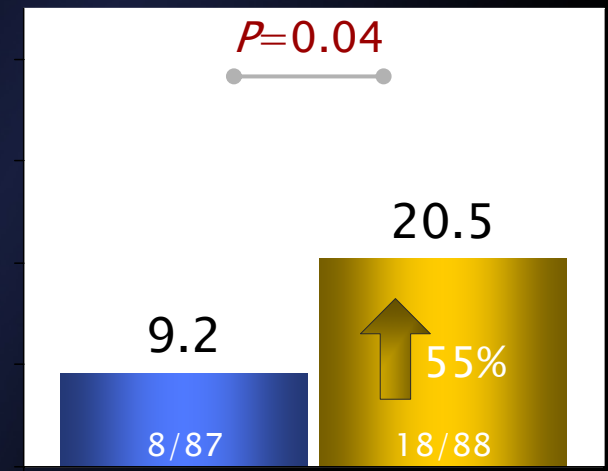
Medically Treated Diabetes



Oral Hypoglycemics



Insulin-Treated

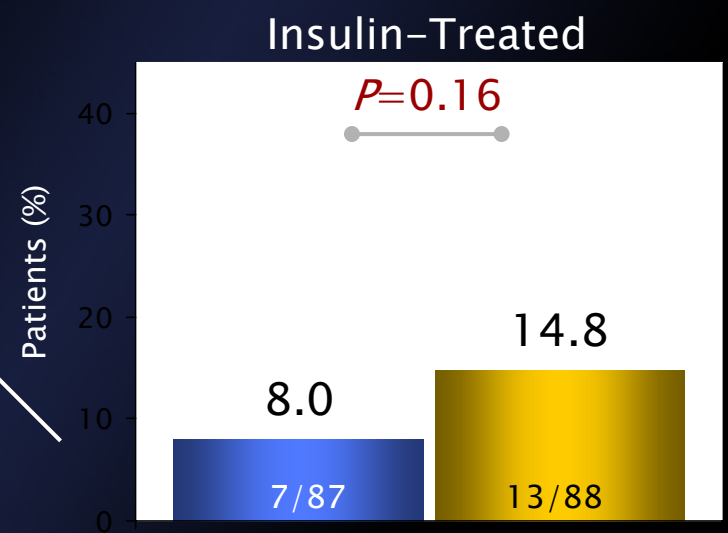
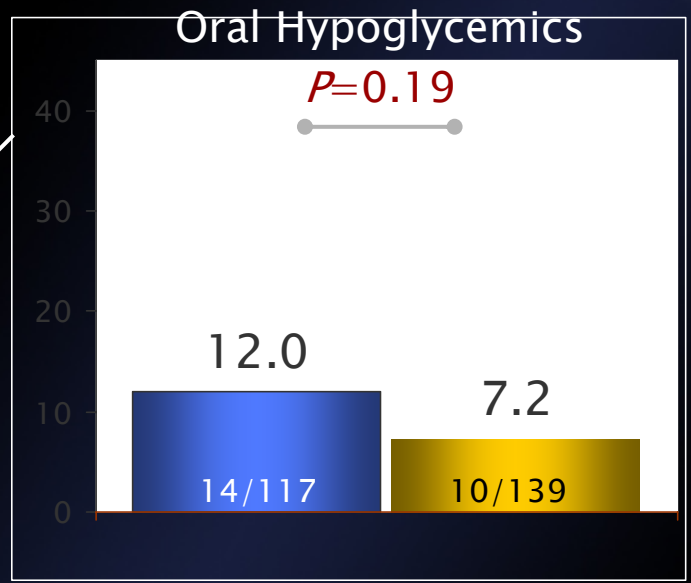
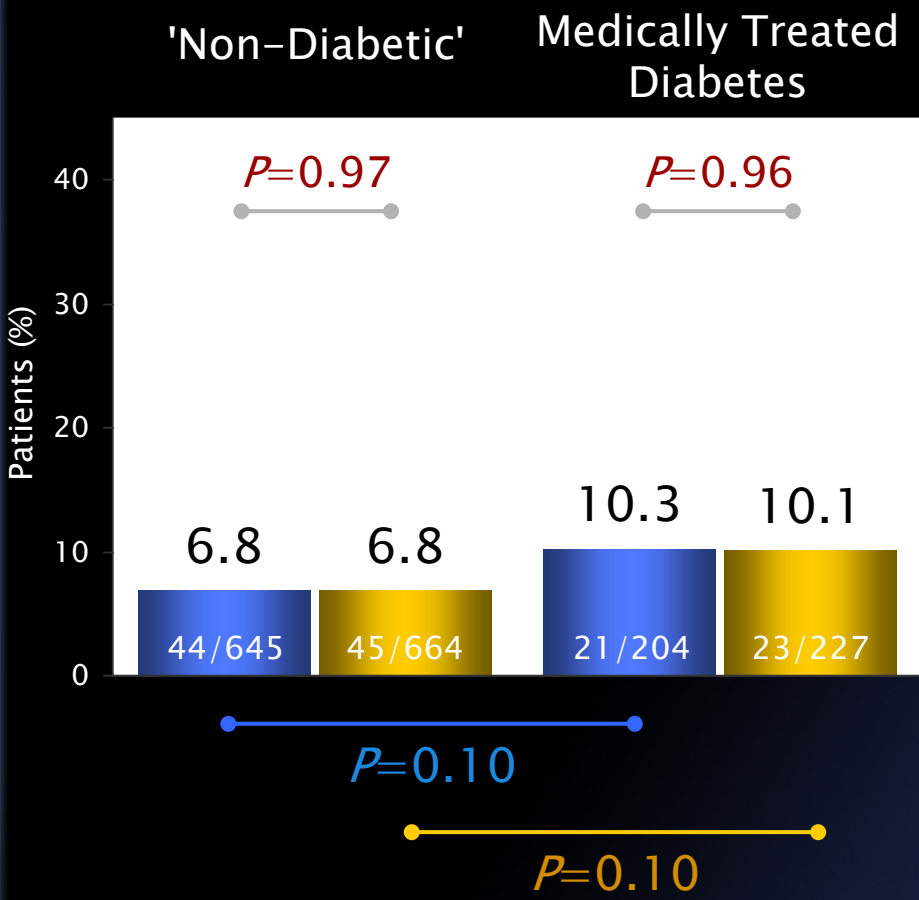


The safety and effectiveness of the TAXUS Express² Stent System have not been established in the following patient populations: patients with lesions with presence of definite incomplete or any revascularization (any vessel) longer than 32 mm; lesions located in the unprotected left main coronary artery or lesions involving a bifurcation/trifurcation; patients with heavily calcified lesions or a chronic total occlusion of a target vessel. TAXUS™ Express²™

Death/CVA/MI at 12-Months



CABG **TAXUS™ Stent**



Conclusiones de subgrupos:

- Subgrupo con DM-



- Los pcs con DM constituyen un subgrupo con peor perfil clínico.
- Respecto a los no-Diabéticos, la tasa de Complicaciones en los Diabéticos es mayor en ambos grupos de tratamiento (Eventos totales 14,2 y 26% con CICOR e ICP respectivamente) con mayor aumento de las complicaciones sobre todo en los Diabéticos tratados con ICP por el gran incremento en las Reintervenciones (20.3% con ICP vs 6,4% con CICOR).
- La tasa de Eventos Totales en el grupo de pcs no-Diabéticos (excluyendo del grupo total a los DM) no es estadísticamente diferente con tratamiento con CICOR que con ICP (11,8 y 15,1 respectivamente $P = 0,08$)

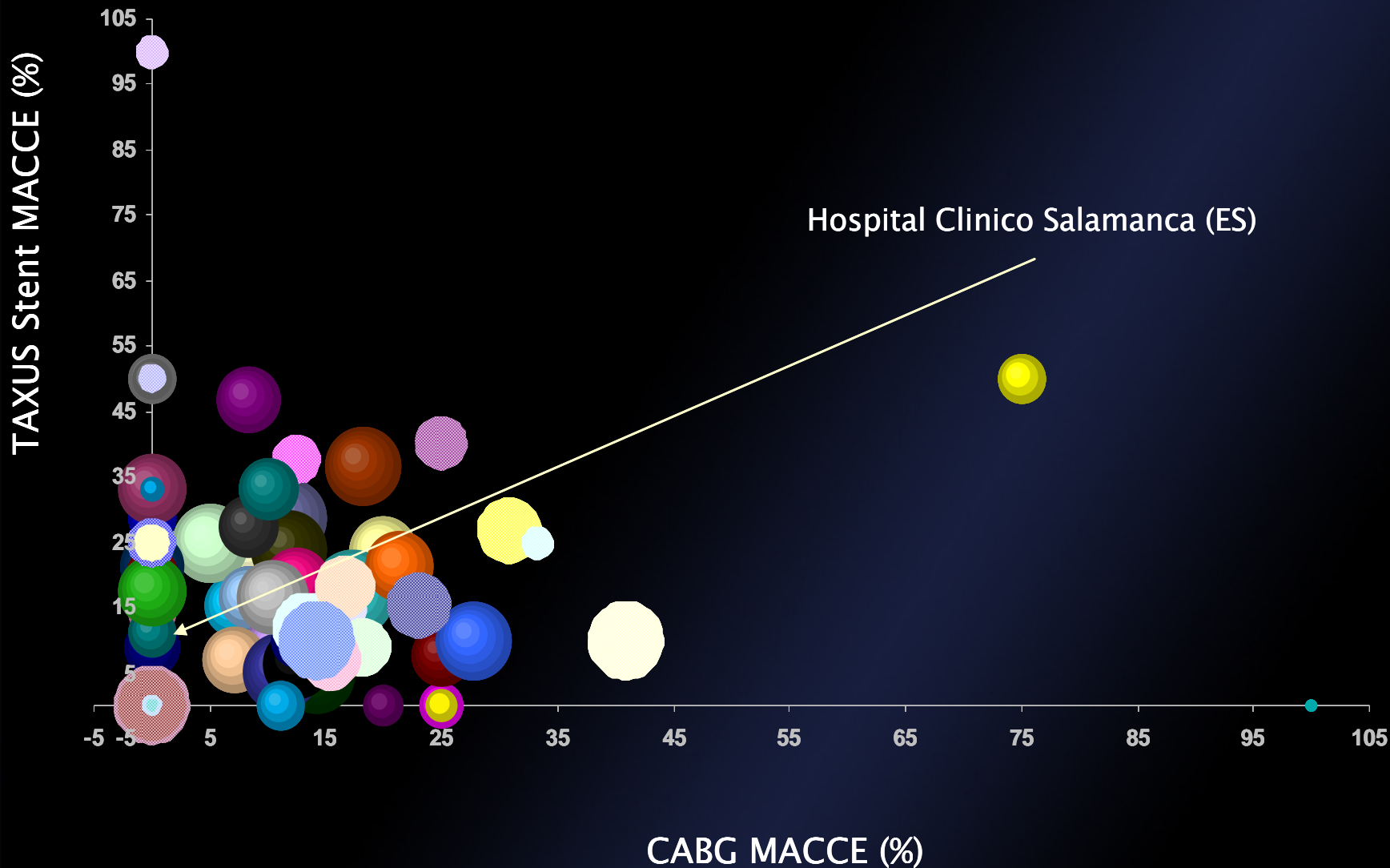
Hipótesis: La DM en pcs con 3 vasos penaliza sobre todo la ICP

Consideraciones Finales:



- El Tratamiento con CICOR consigue mejores resultados en el período evolutivo de un año que la ICP en pacientes con lesiones coronarias de 3 vasos y/o LTCl
- Los pacientes con enfermedad coronaria de 3 vasos con lesiones no complejas (SYNTAX Score <22) y con lesión de TCl aislada o con 1 vaso, y no Diabéticos, podrían ser tratados con ICP con igual o mejor resultado que con Cirugía.
- Los pacientes con enfermedad coronaria de 3 vasos, con lesiones complejas y diabéticos no deberían de ser tratados con ICP si es posible hacerlo con CICOR.

12 month MACCE CABG vs TAXUS



Size of circle adjusted for number of patients

SYNTAX Trial Design



 62 EU Sites +  23 US Sites

Total enrollment
N=3075

Stratification:
LM and Diabetes

Randomized Arms
N=1800

CABG
N=897

vs.

TAXUS*
N=903

Two Registry Arms

CABG
N=1077

PCI
N=198

5yr FU
N=649

No FU
N=428

*TAXUS Express

Reasons for Registry Allocation



PCI Registry– CABG ineligible due to:

- Co-morbidities (70.7%)
- No graft material (9.1%)
- Small or poor quality of distal vessel (1.5%)
- Patient refused CABG (5.6%)
- Other (13.1%)

CABG Registry– PCI ineligible due to:

- Complex anatomy (70.9%)
- Untreatable CTO (22.0%)
- Unable to take anti-platelet medications (0.9%)
- Patient refused PCI (0.5%)
- Other (5.7%)

Patient Characteristics

Notable Differences PCI RCT + Registry



	TAXUS RCT n=903	PCI Reg n=192
Age, mean±SD (y)	65.2 ± 9.7	71.2 ± 10
Male, %	76.4	70.3
SYNTAX score	28.4 ± 11.5	31.6 ± 12.3
Diabetes, %	28.2	35.4
Hyperlipidemia, %	78.7	67.5
Current smoker, %	18.5	11.2
Prior MI, %	31.9	40.4
Unstable angina, %	28.9	38.0
Add. EuroSCORE, mean±SD	3.8 ± 2.6	5.8 ± 3.1
Total Parsonnet score, mean±SD	8.5 ± 7.0	14.4 ± 9.5

*For descriptive purposes only; no statistical comparisons done

Procedural Characteristics

Notable Differences: PCI RCT + Registry



	TAXUS RCT* n=903	PCI Reg n=192
Staged Procedure, %	14.1	13.0
Bi/trifurcation lesions treated, %	24.8	64.4
Lesions treated, mean±SD	3.6 ± 1.6	2.5 ± 1.3
Stents implanted, mean±SD	4.6 ± 2.3	3.1 ± 1.8
Total length implanted, mm	86.1 ± 47.9	58.5 ± 41.2
Range, mm	8.0–324.0	8.0–252.0
Long stenting (>100 mm), %	33.2	12.2

*For descriptive purposes only; no statistical comparisons done

Patient Characteristics

Notable Differences CABG RCT + Registry



	CABG RCT N=897	CABG Reg N=644
Age, mean±SD (y)	65.0 ± 9.8	65.7 ± 9.4
Male, %	78.9	80.7
SYNTAX score, mean±SD	29.1 ± 11.4	37.8 ± 13.3
Diabetes, %	28.5	29.7
Hypertension, %	77.0	73.5
Hyperlipidemia, %	77.2	76.4
Current smoker, %	22.0	21.9
Prior MI, %	33.8	33.5
Unstable angina, %	28.0	21.6
Add. EuroSCORE, mean±SD	3.8 ± 4.4	3.9 ± 2.7
Total Parsonnet score, mean±SD	8.4 ± 6.8	9.0 ± 7.1

*For descriptive purposes only; no statistical comparisons done

Procedural Characteristics

Notable Differences CABG RCT + Registry

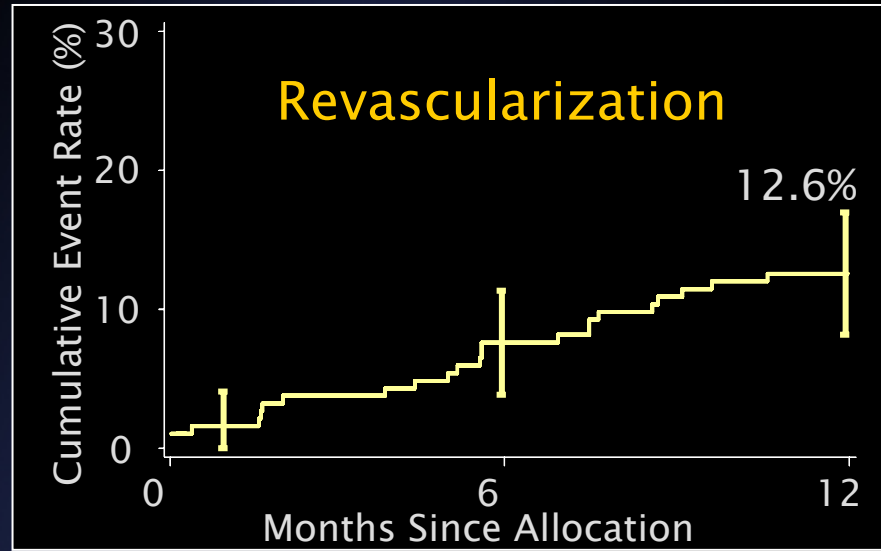
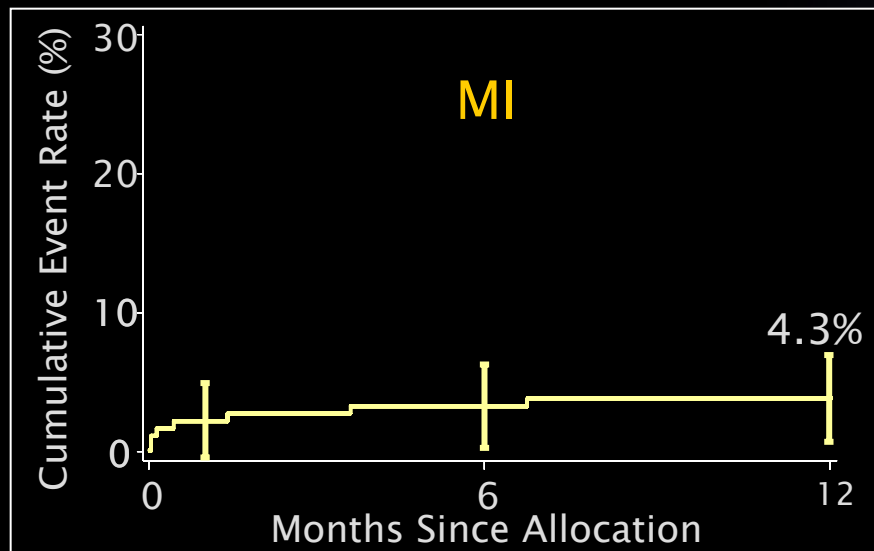
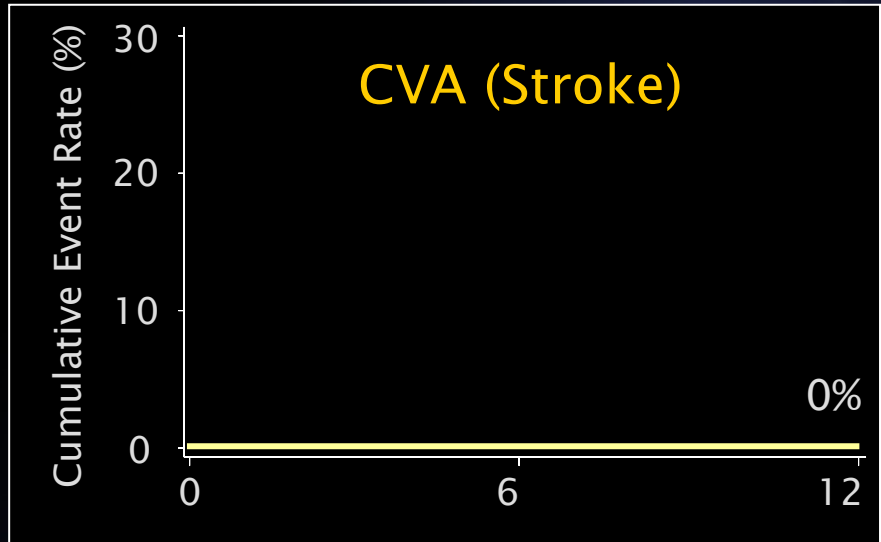
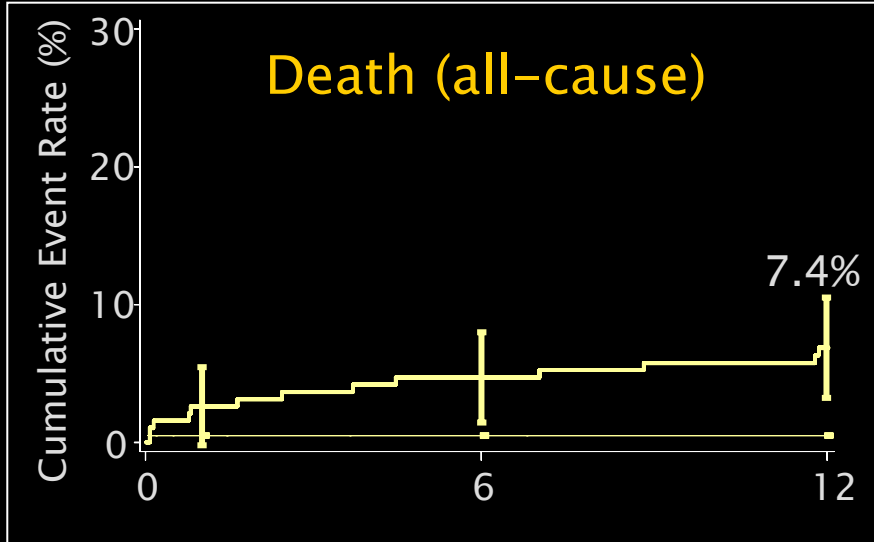


<i>Procedure-related</i>	CABG RCT* n=897	CABG Reg n=644
Off-pump surgery, %	15.0	18.6
Graft revascularization, %		
At least one arterial graft	97.3	96.7
Arterial graft to LAD	95.6	94.7
LIMA + venous	78.1	85.1
Double LIMA/RIMA	27.6	16.1
Complete arterial revascularization	18.9	11.2
Venous graft only	2.6	3.3
Grafts per patient, mean \pm SD	2.8 \pm 0.7	3.0 \pm 0.9
Distal anastomoses, mean \pm SD	3.2 \pm 0.9	3.5 \pm 1.0

*For descriptive purposes only; no statistical comparisons done

Event Rates to 12-Months

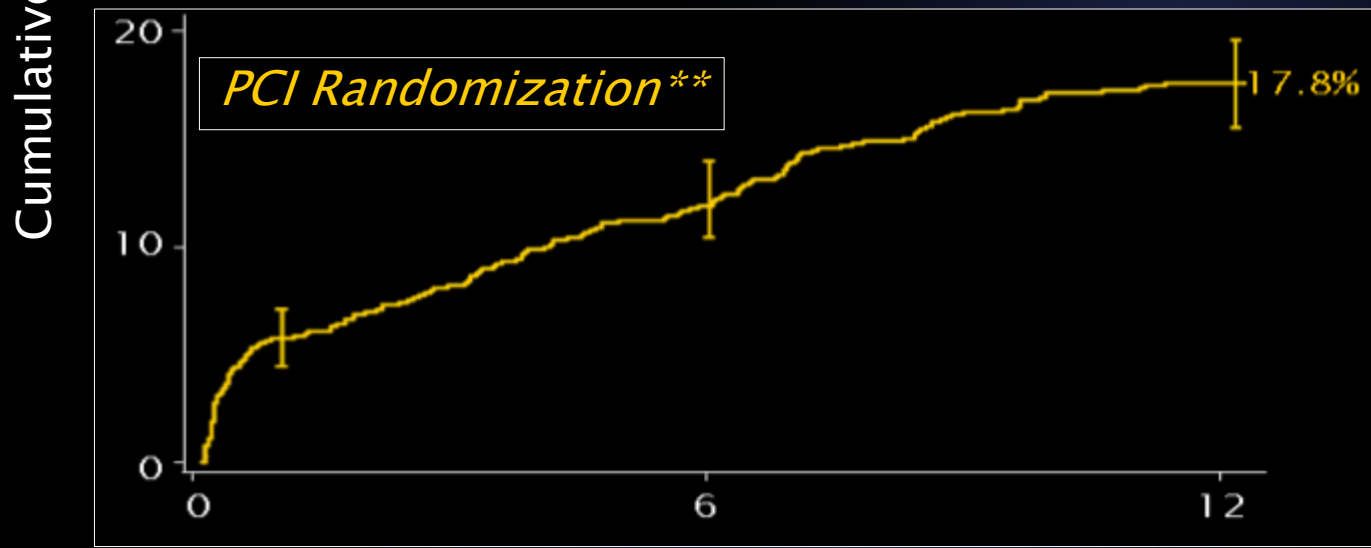
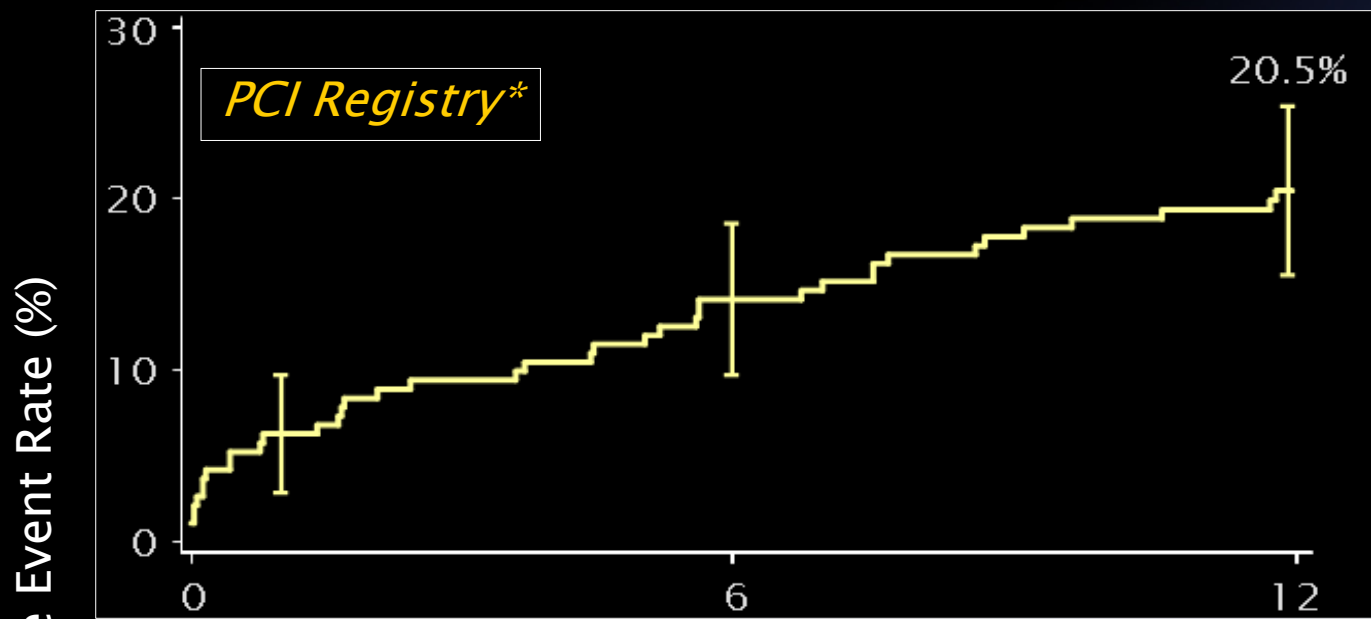
SYNTAX PCI Registry (n=192)



TAXUS™ Express²™

Per-protocol population

Overall SYNTAX MACCE to 12-Months

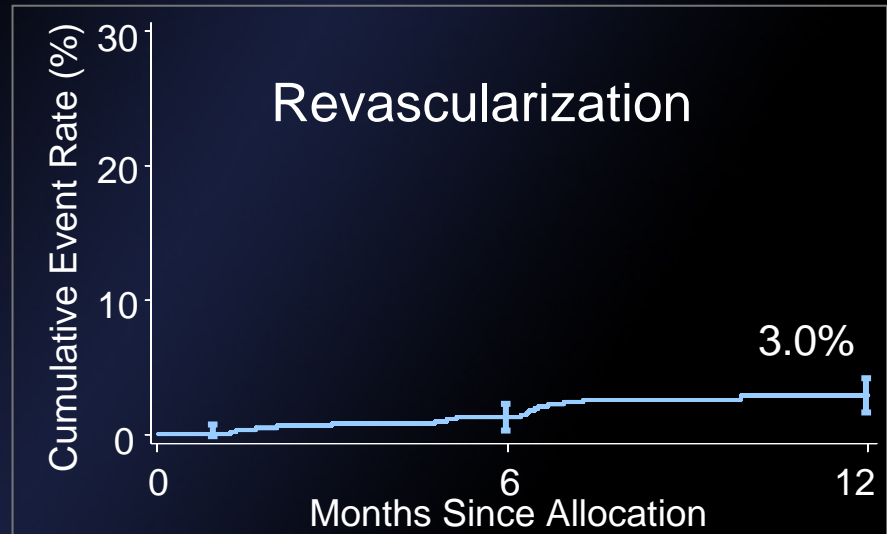
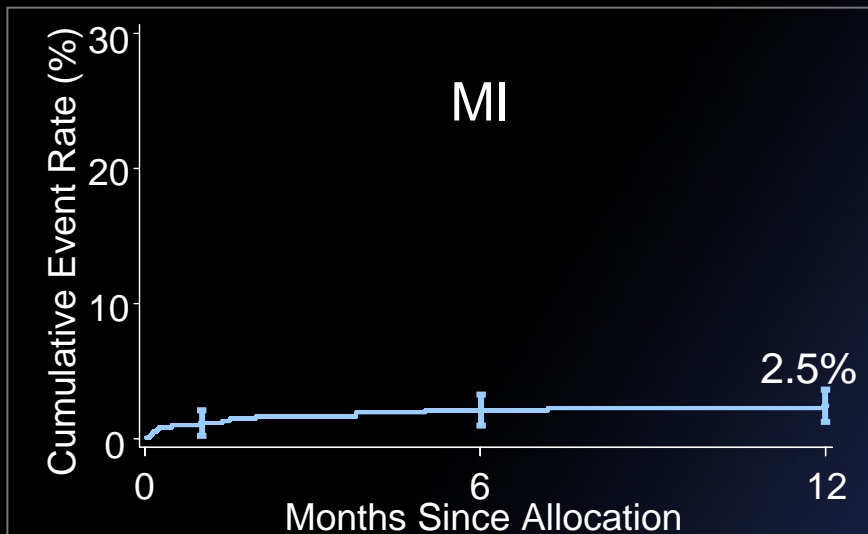
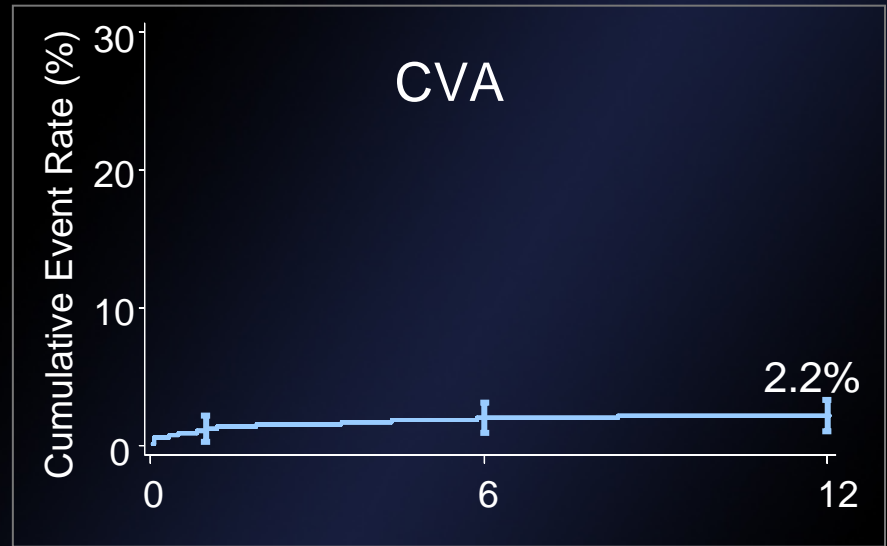
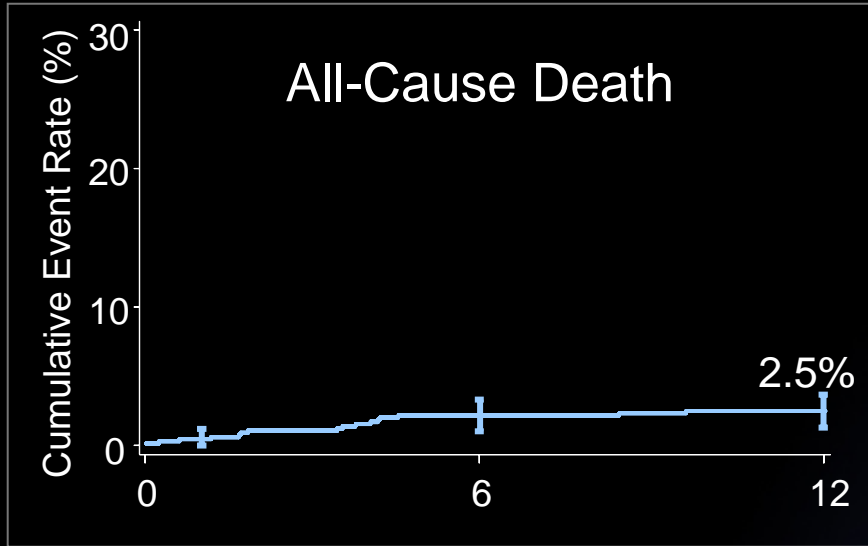


Months Since Allocation

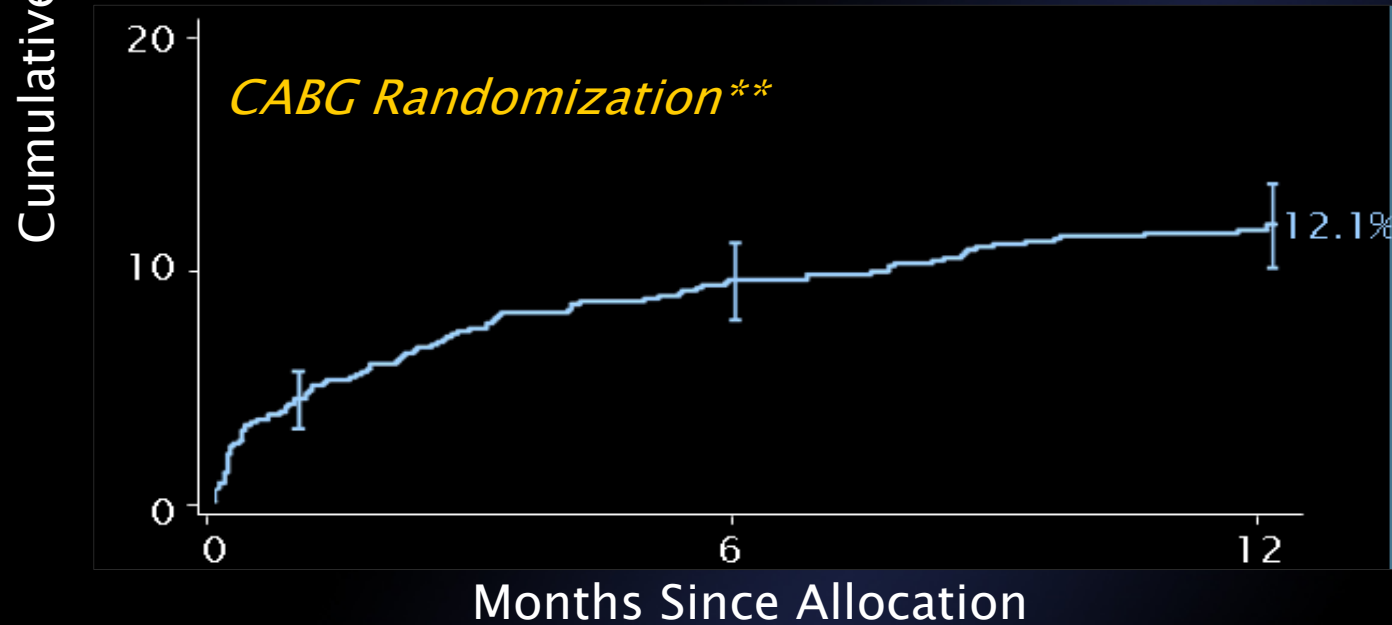
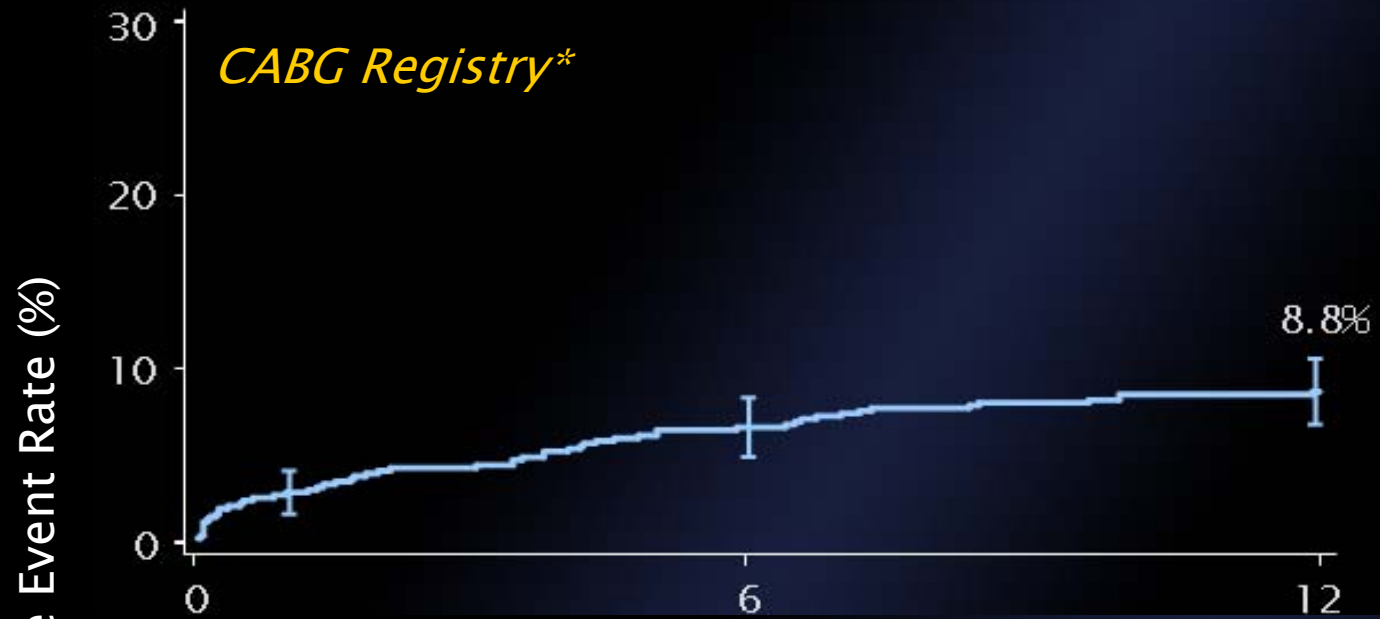
Event Rate \pm 1.5 SE
Kaplan-Meier rates
*Per-protocol population
**ITT population
TAXUS™ Express²™

Event Rates to 12-Months

CABG Registry



Overall MACCE to 12-Months



Event Rate \pm 1.5 SE
Kaplan-Meier rates
*Per-protocol population
**ITT population