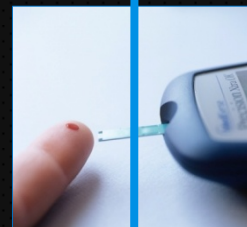


SYNTAX

Diabetes & Metabolic Syndrome

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Summit TCT Asia Pacific 2009

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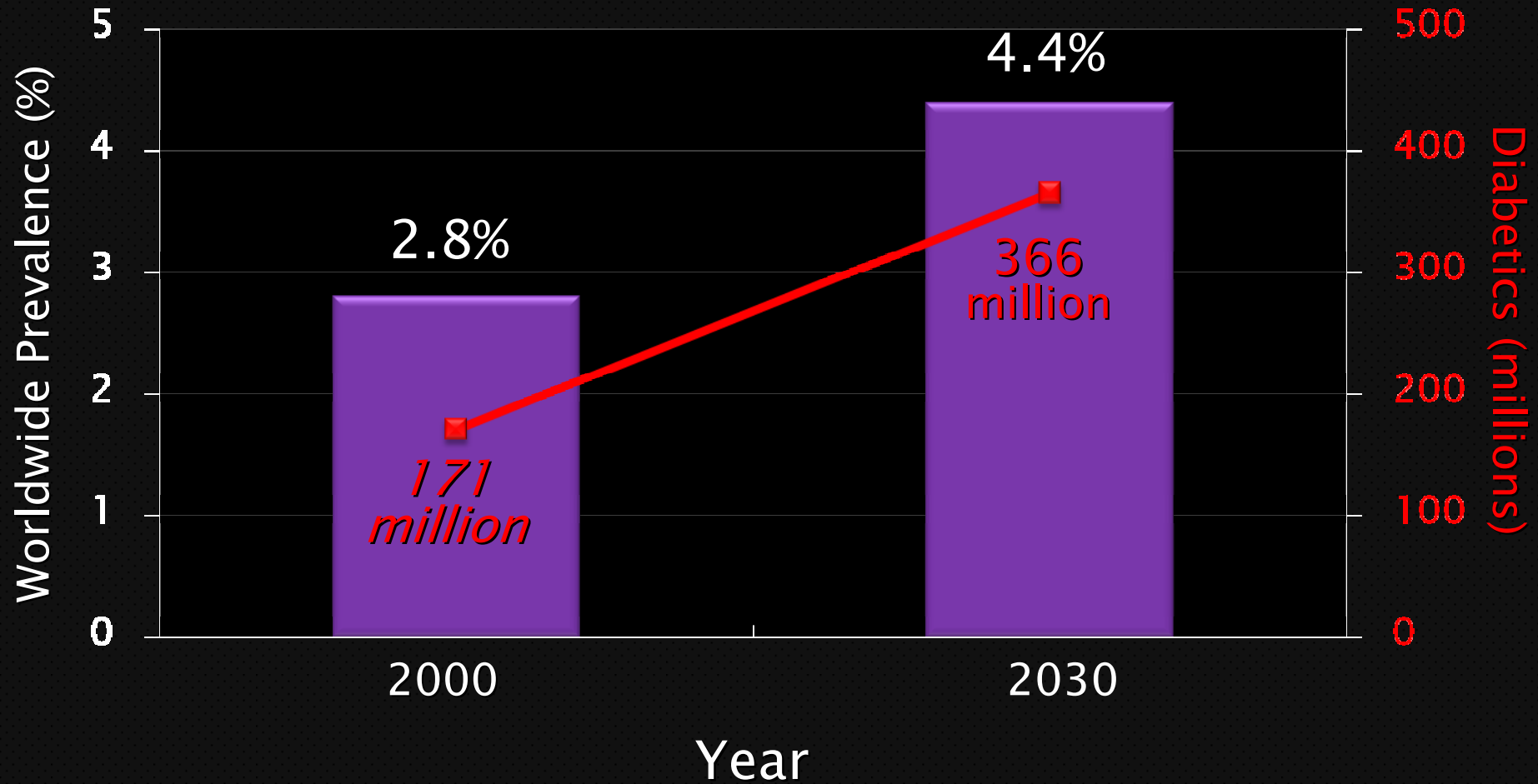
The Convention Center of Sheraton Grande Walkerhill Hotel, Seoul, Korea

Boston
Scientific

Conflicts of Interest

- Employee
 - Boston Scientific Corporation
- Stockholder
 - Boston Scientific Corporation

Prevalence of Diabetes Mellitus

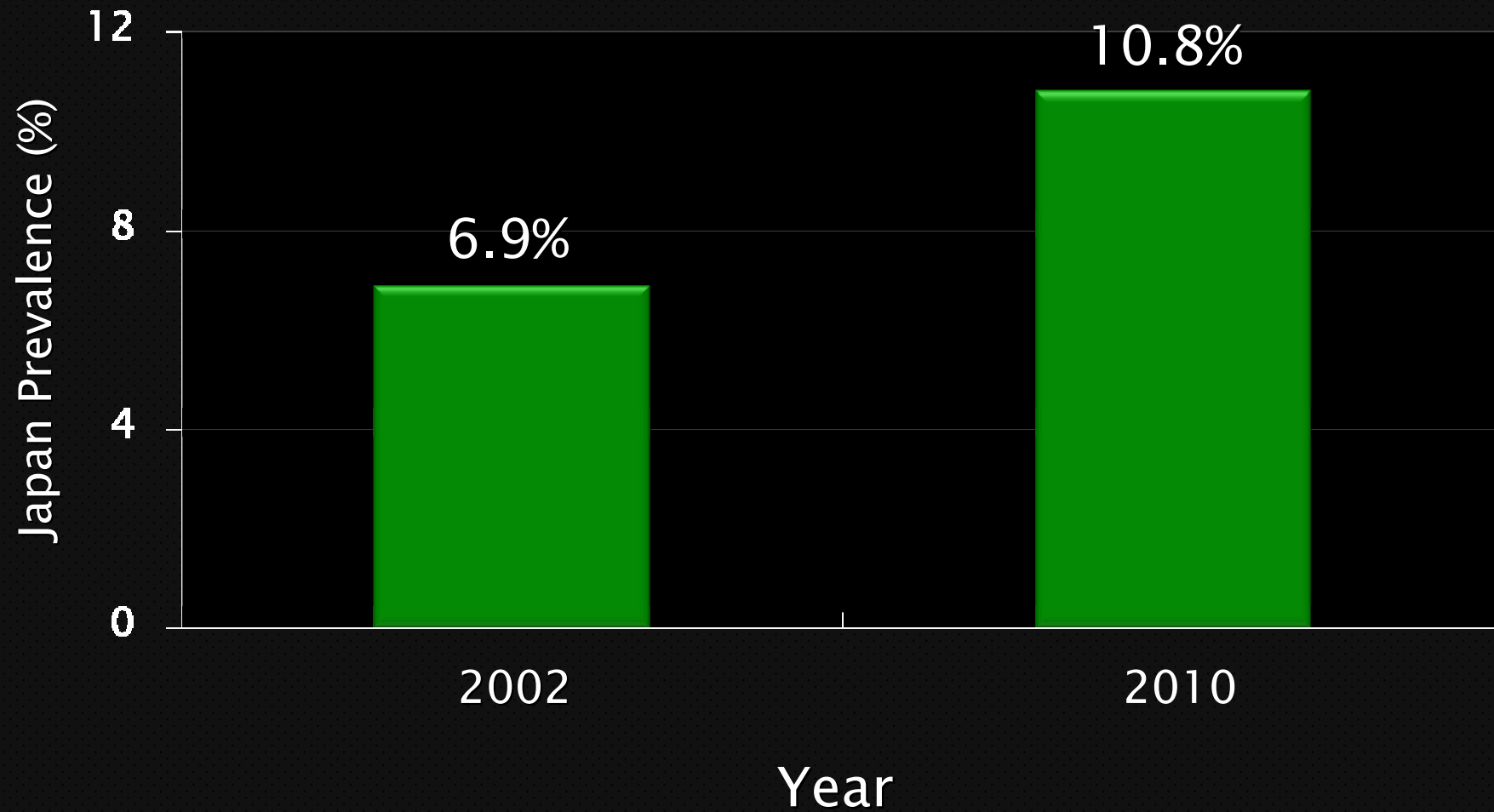


Prevalence of Diabetes Mellitus



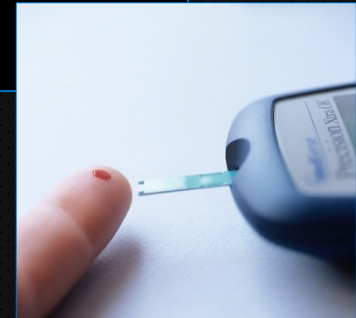
1:3

Prevalence of Diabetes Mellitus (Japan)



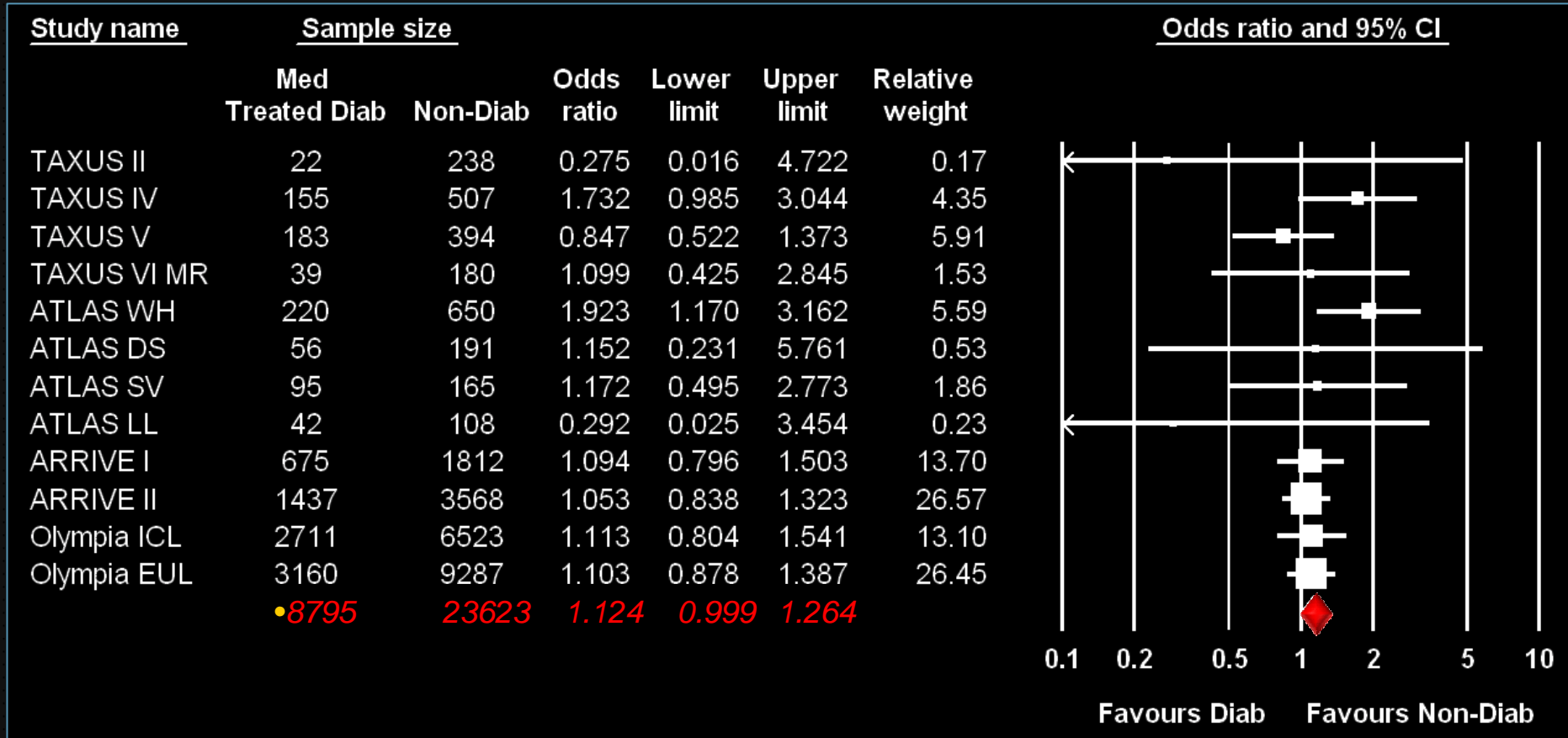
Diabetes Voice 2002;47:4

Which DES for the Diabetic Patient?



TAXUS Trials and Registries, TLR

Diabetic* vs. non-Diabetic, TAXUS-treated patients



* Medically Treated Diabetes

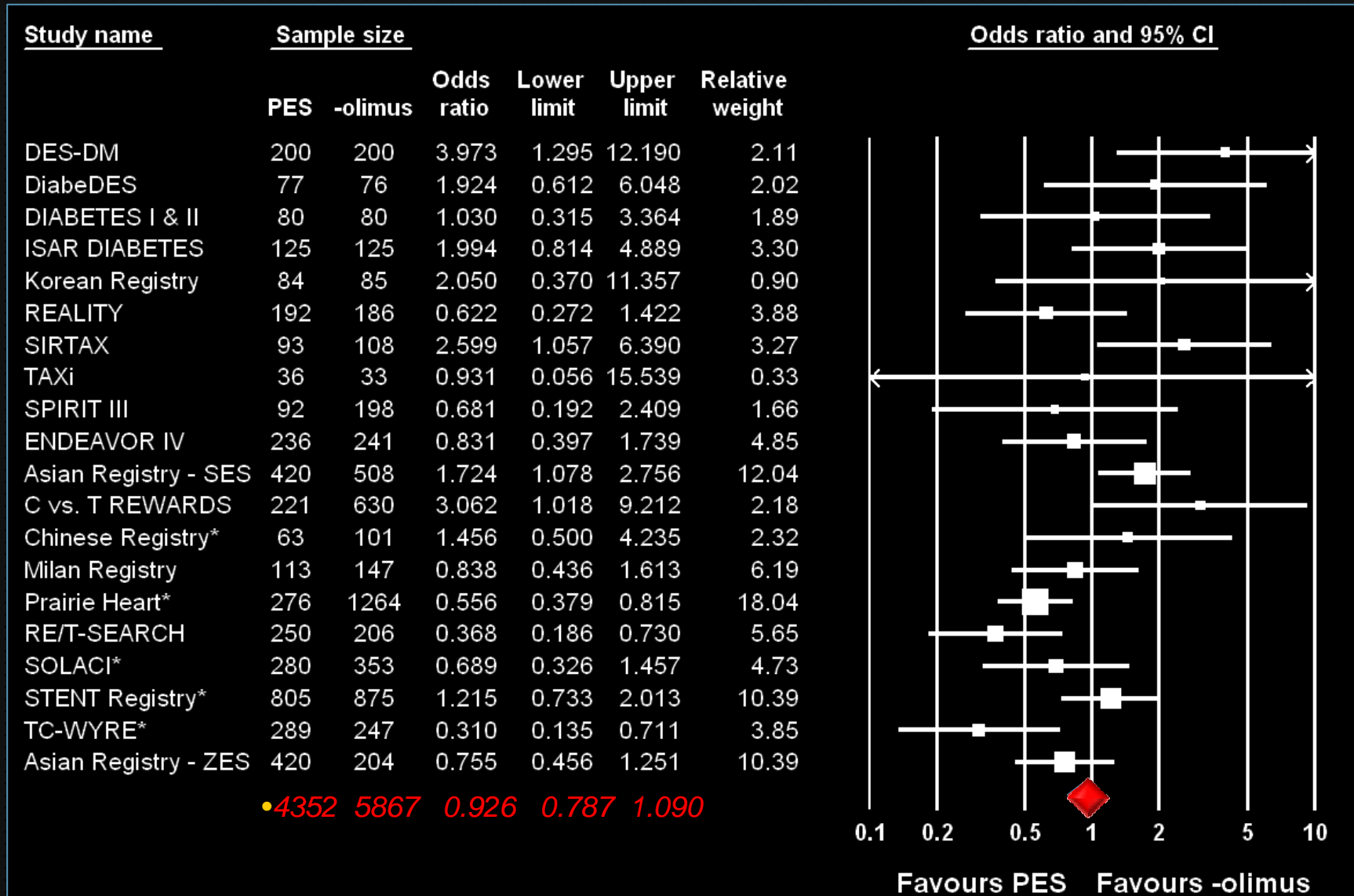
-Olimus Trials and Registries, TLR

Diabetic vs. Non-Diabetic, -Olimus-treated patients



• *TLR not reported; TVR rates were used.

Head-to-Head Trials and Registries, TLR Patients with Diabetes



*TLR not reported; TVR rates were used.

Background



- In the pre-DES era, patients with left main and/or 3-vessel disease were typically managed surgically.
- Surgical revascularization was also recommended for patients with diabetes and multivessel disease.
 - Diabetes is often under-represented in revasc. trials.
 - Little is known about outcomes in metabolic syndrome.
- TAXUS paclitaxel-eluting stents yield comparable revascularization rates in diabetic and non-diabetic patients with 1- and 2-vessel disease.
- SYNTAX is a randomized comparison of surgery (CABG) vs TAXUS Express that enrolled only patients with left main and/or 3-vessel disease, including 25% with medically treated diabetes and 36% with metabolic syndrome.

Objective



- The goal of the SYNTAX diabetes /metabolic syndrome analysis is to provide information to help physicians determine the most safe and effective revascularization option for each patient, based on diabetic/metabolic status and lesion characteristics.

While pre-specified, these subgroup analyses are intended to be observational and hypothesis-generating.

Patients with Diabetes in SYNTAX

Randomized Cohort, Intent-to-Treat



Stratified for Diabetes

Total Randomized
N=1800

All Diabetes
n=511

Medically Treated*
n=452

Non-Diabetic, n=1289
'Non-Diabetic' (n=1348)
Diet Only, n=59

CABG
n=221

TAXUS
n=231

Oral Agents
n=270

Insulin
n=182

CABG
n=128

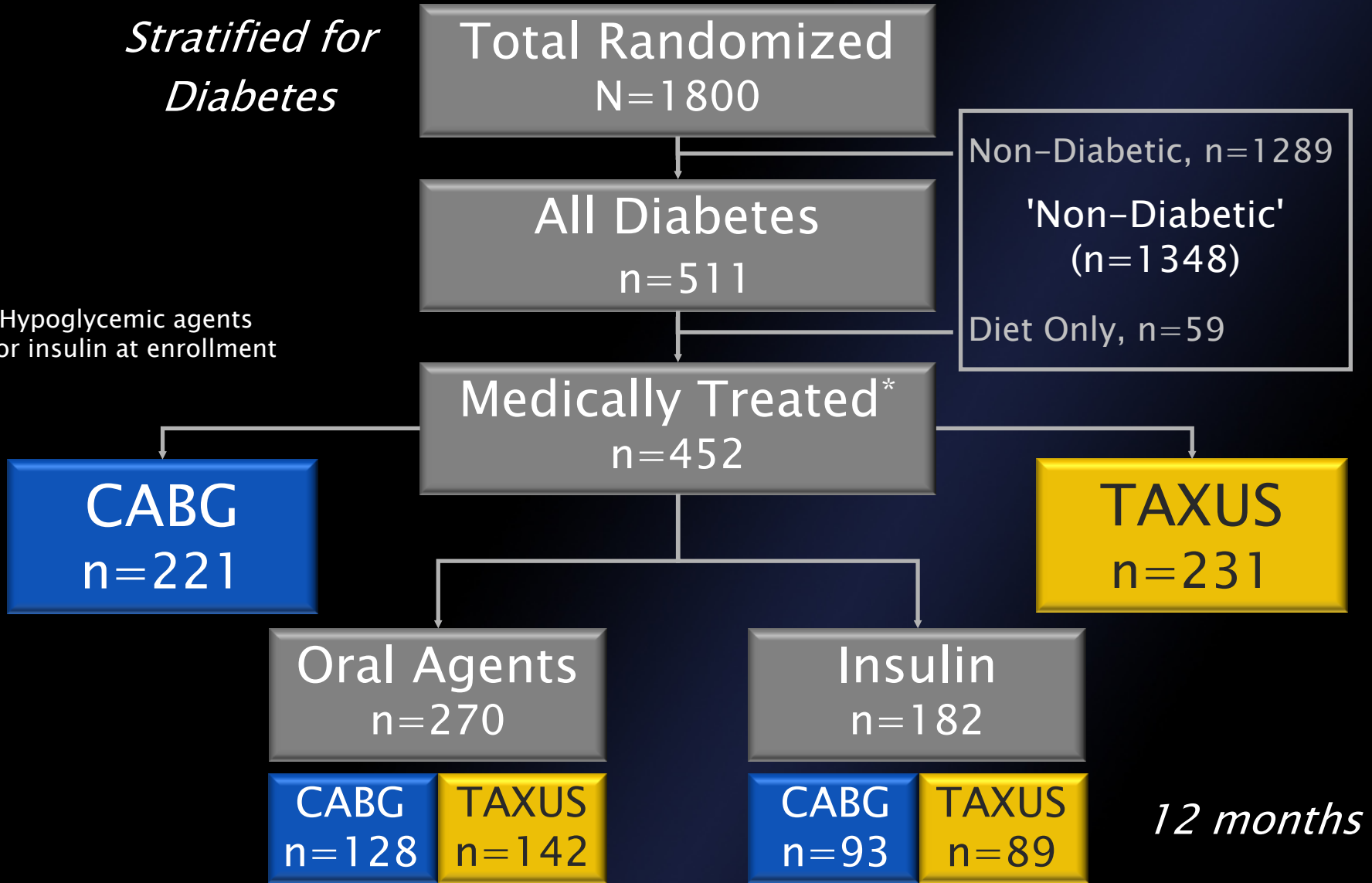
TAXUS
n=142

CABG
n=93

TAXUS
n=89

12 months

*Hypoglycemic agents or insulin at enrollment



Overlap Between Diabetes and Metabolic Syndrome* in SYNTAX



*Metabolic Syndrome

At least 3 of the following:

- Waist circumference >40/35 in
- Triglycerides ≥ 150 mg/dL
- HDL <40/50 mg/dL
- BP $\geq 130/85$ mmHg
- Fasting glucose ≥ 110 mg/dL

111[†] 258[†] 398

Medically Treated
Diabetes (n=452)

- 70% with Metabolic Syndrome[†]

Metabolic Syndrome
(n=656)

- 39% with Diabetes

[†] Excludes patients with unknown metabolic syndrome status

* ATP III Panel, Circulation, 2002;106:3143-3421

Increased Baseline Risk in Diabetic Patients



	No Diabetes n=1348	Diabetes* n=452	P value
Male, %	79.9	71.0	<0.001
Hypertension, %	72.6	84.1	<0.001
Hyperlipidemia, %	76.7	81.5	0.03
Current smoker, %	21.7	15.8	0.006
Congestive heart failure, %	3.7	7.4	0.001
Peripheral vascular disease, %	8.2	14.6	<0.001
Prior stroke, %	3.8	6.0	0.046
Creatinine >200 μmol/L	1.0	2.9	0.003
Additive euroSCORE, mean ± SD	3.7 ± 2.6	4.0 ± 2.7	0.03
Parsonnet score, mean ± SD	7.5 ± 6.8	11.3 ± 6.4	<0.001
Mean # lesions, n	4.3 ± 1.8	4.6 ± 1.8	0.003
3-vessel disease only, %	64.1	71.0	0.007

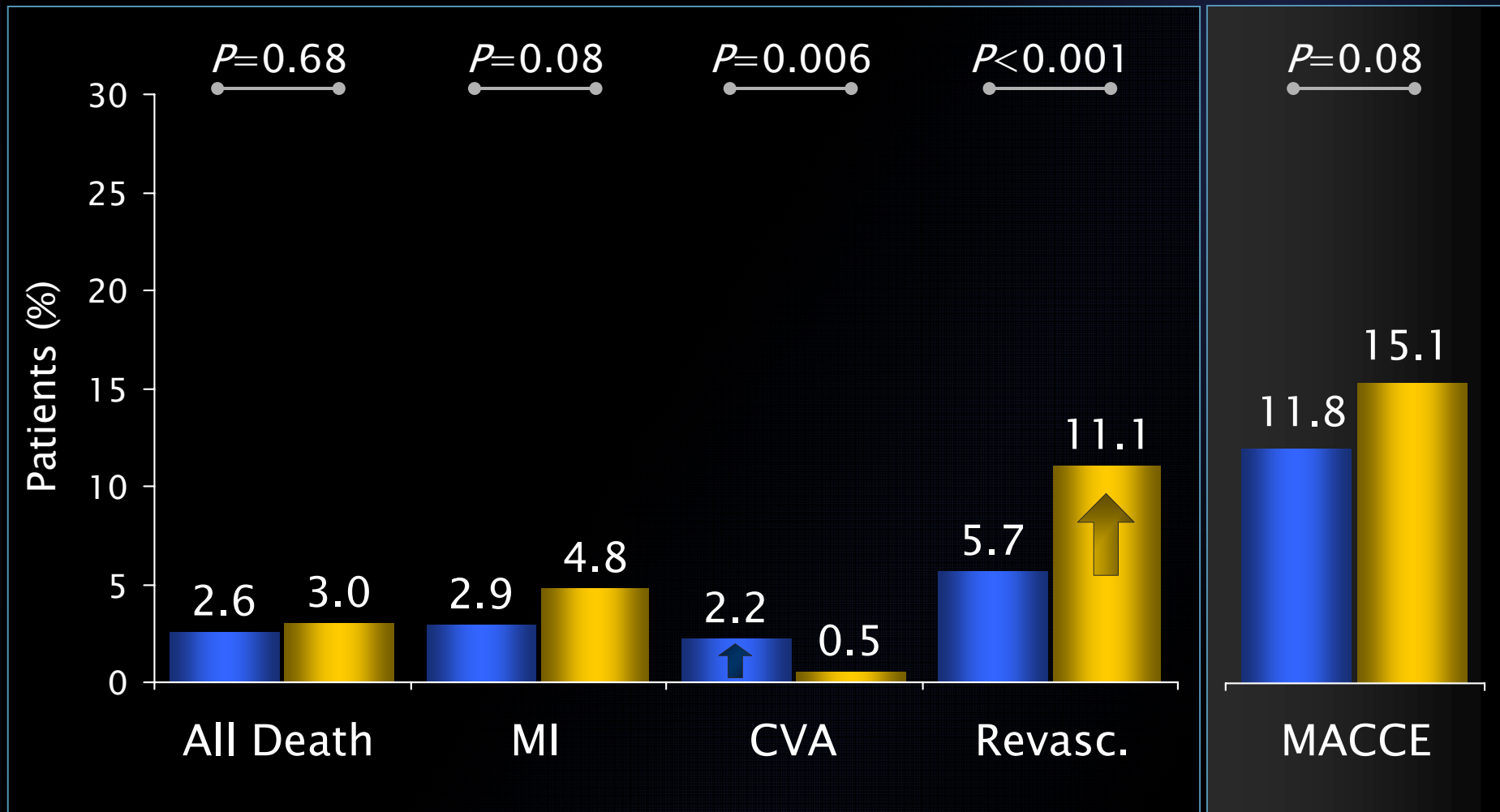
*Medically treated diabetes

Non-Diabetic*: CVA Increased in CABG; Revasc. Increased in DES



■ CABG (n=645)

■ TAXUS (n=664)



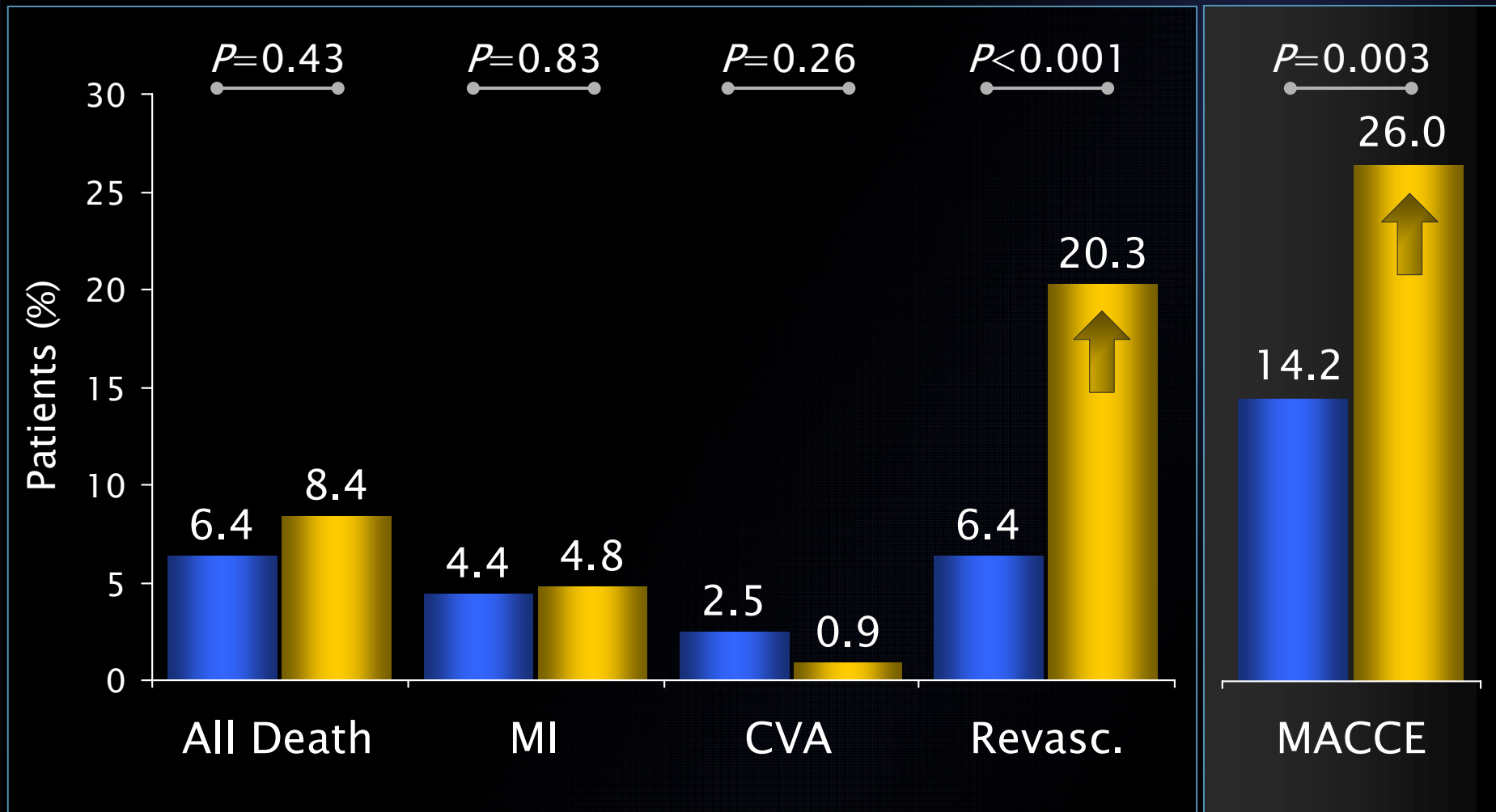
*Includes diet/exercise treated DM

Medically Treated Diabetes: Revasc. Increased in PES



■ CABG (n=204)

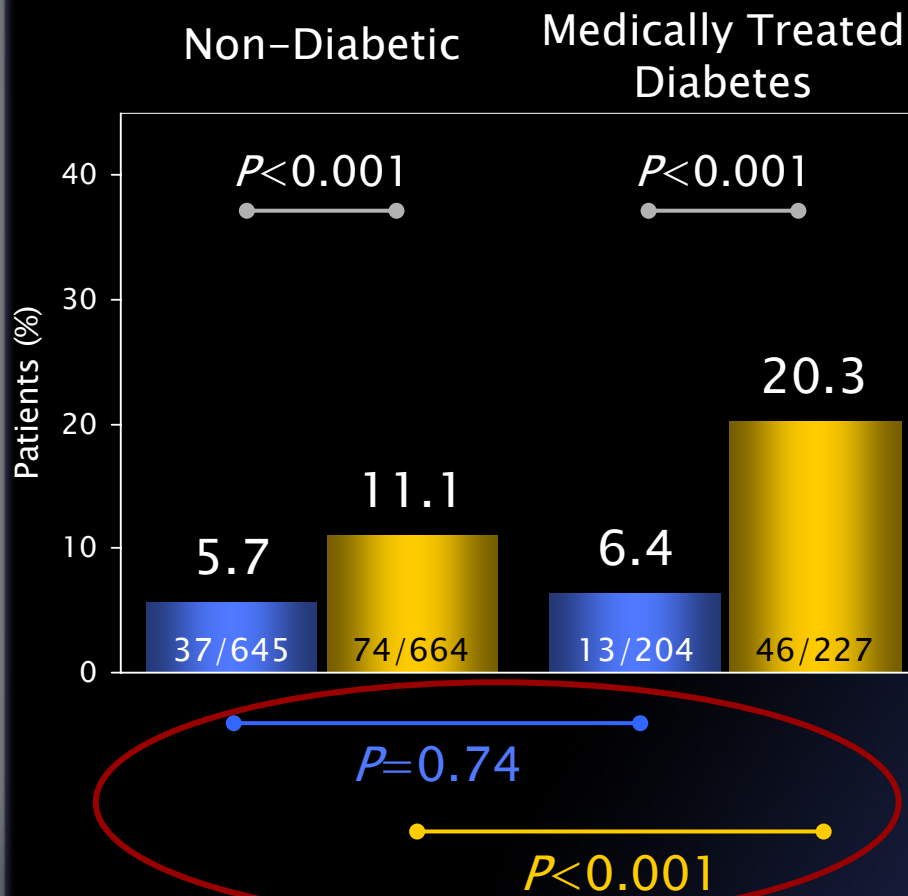
■ TAXUS (n=227)



Revascularization at 12 Months In Patients with 3VD and/or LM Lesions

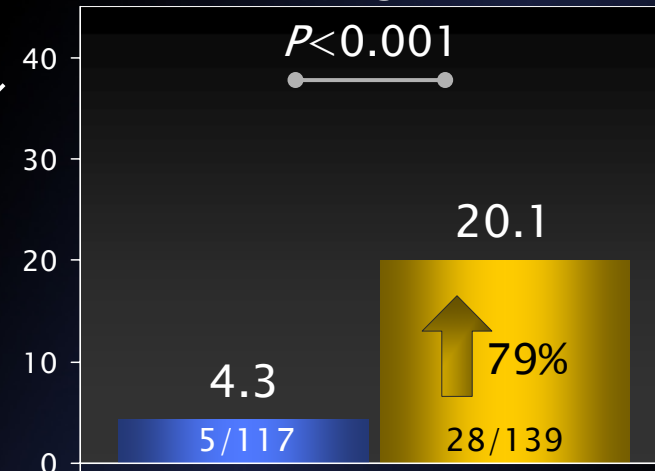


■ CABG ■ TAXUS

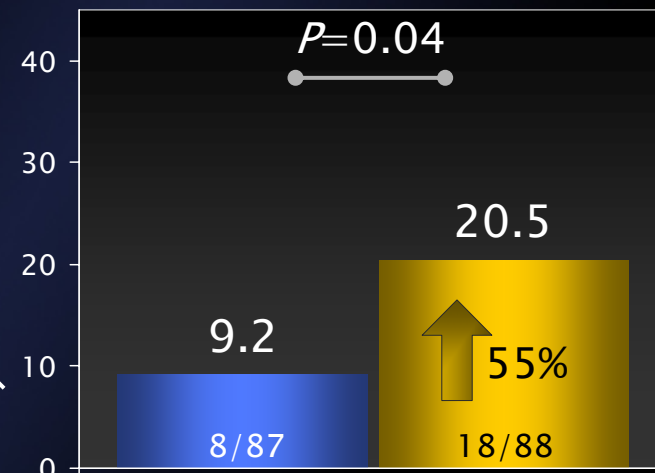


Includes any revascularization (any vessel)

Oral Hypoglycemics



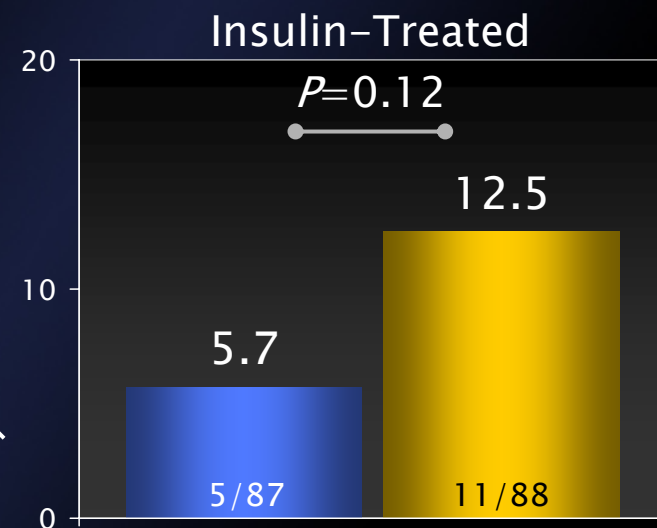
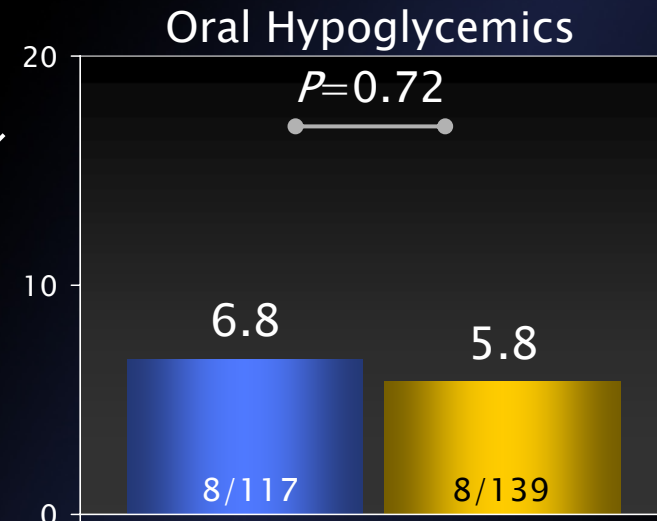
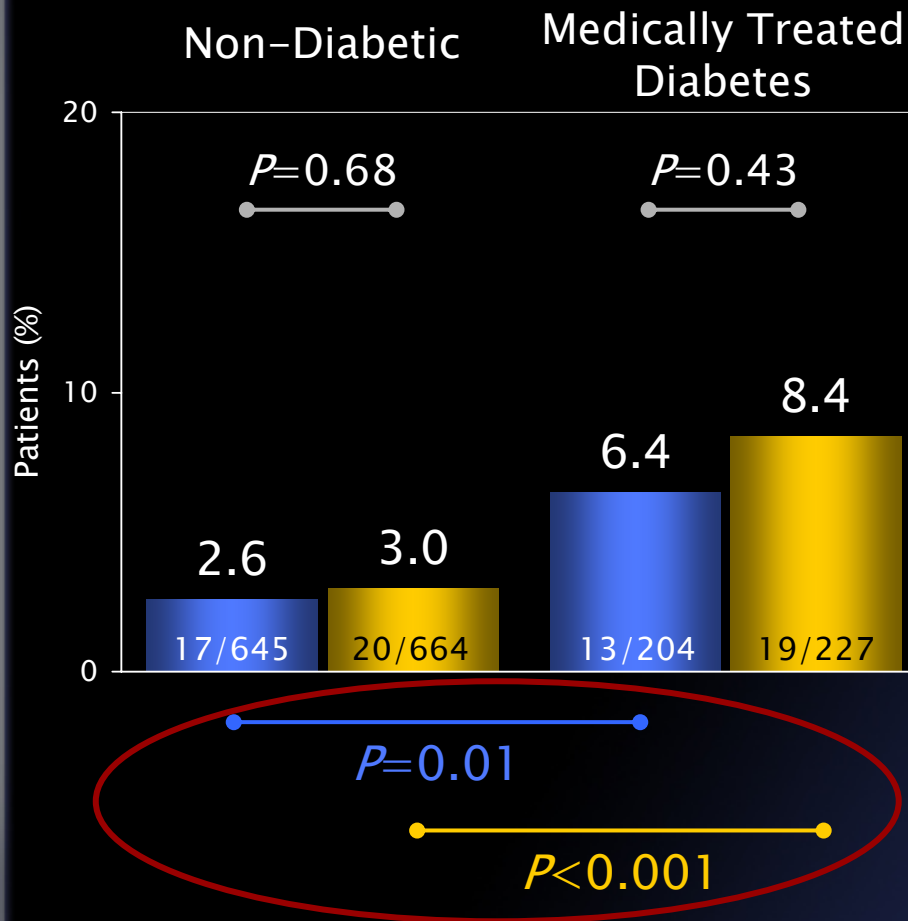
Insulin-Treated



Death (All-Cause) at 12 Months In Patients with 3VD and/or LM Lesions



CABG **TAXUS**

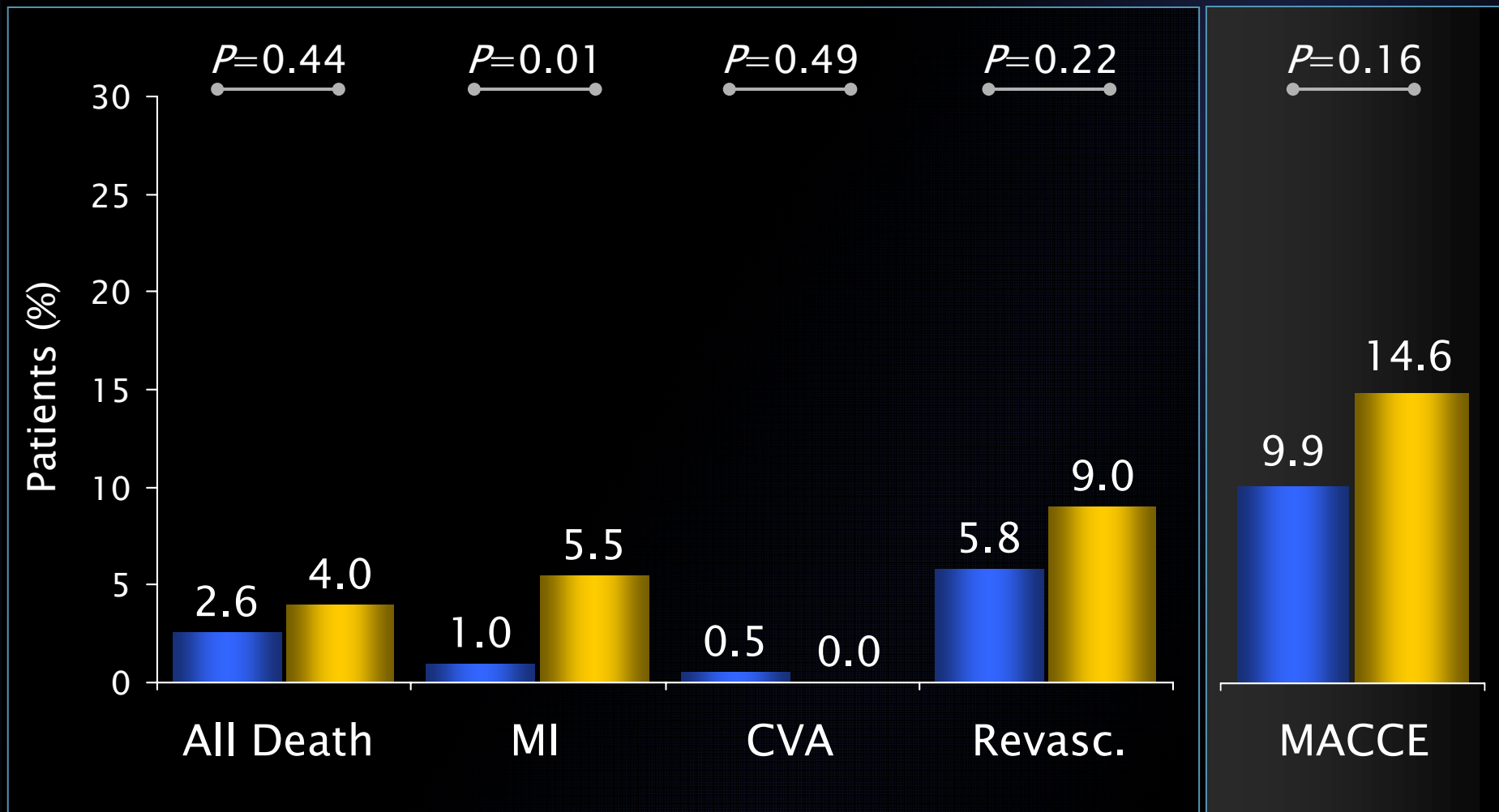


Patients with Metabolic Syndrome Alone (Without Diabetes)

SYNTAX

CABG (n=195)

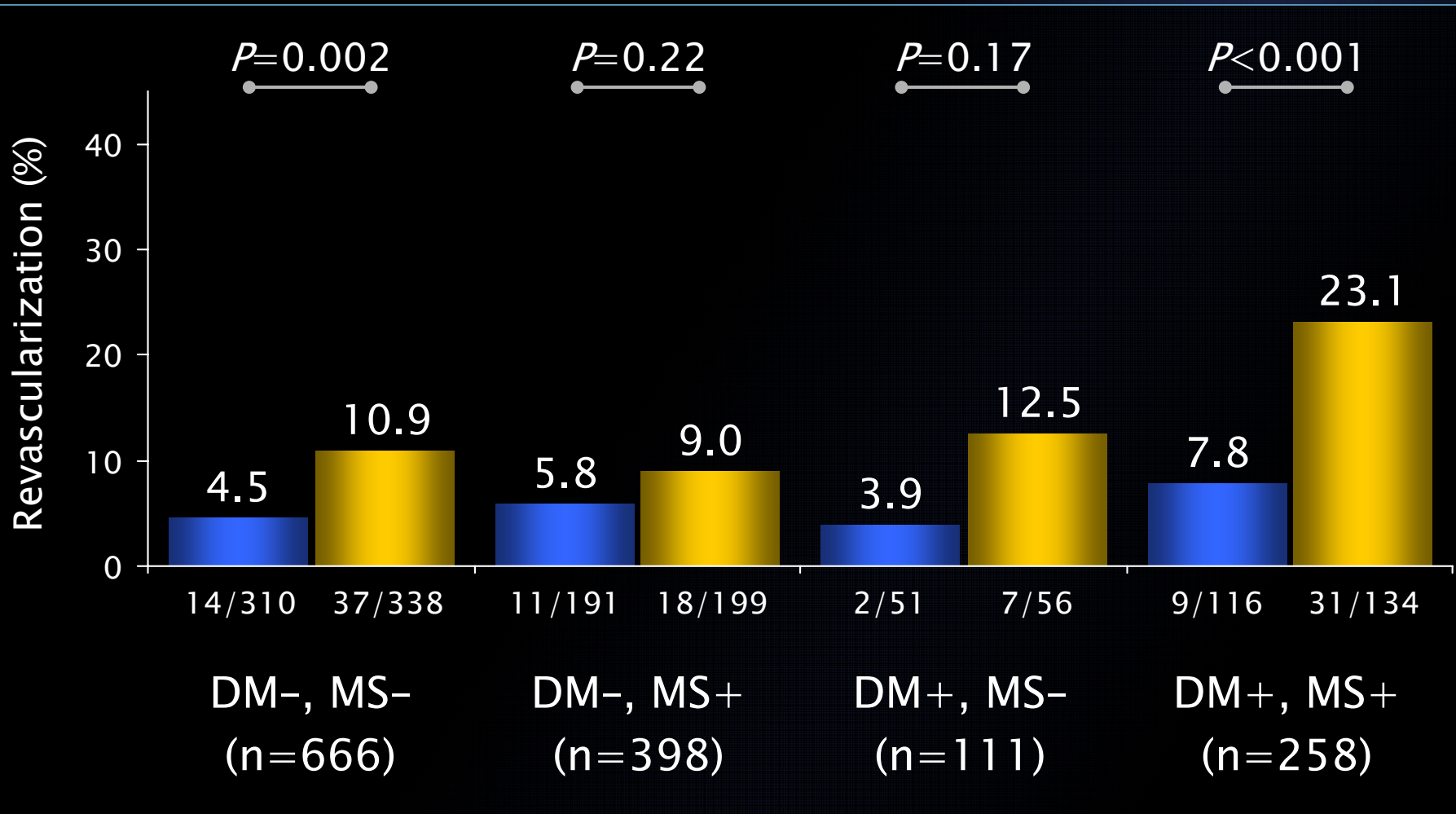
TAXUS (n=203)



Revascularization by Diabetes and Metabolic Syndrome Status



CABG TAXUS

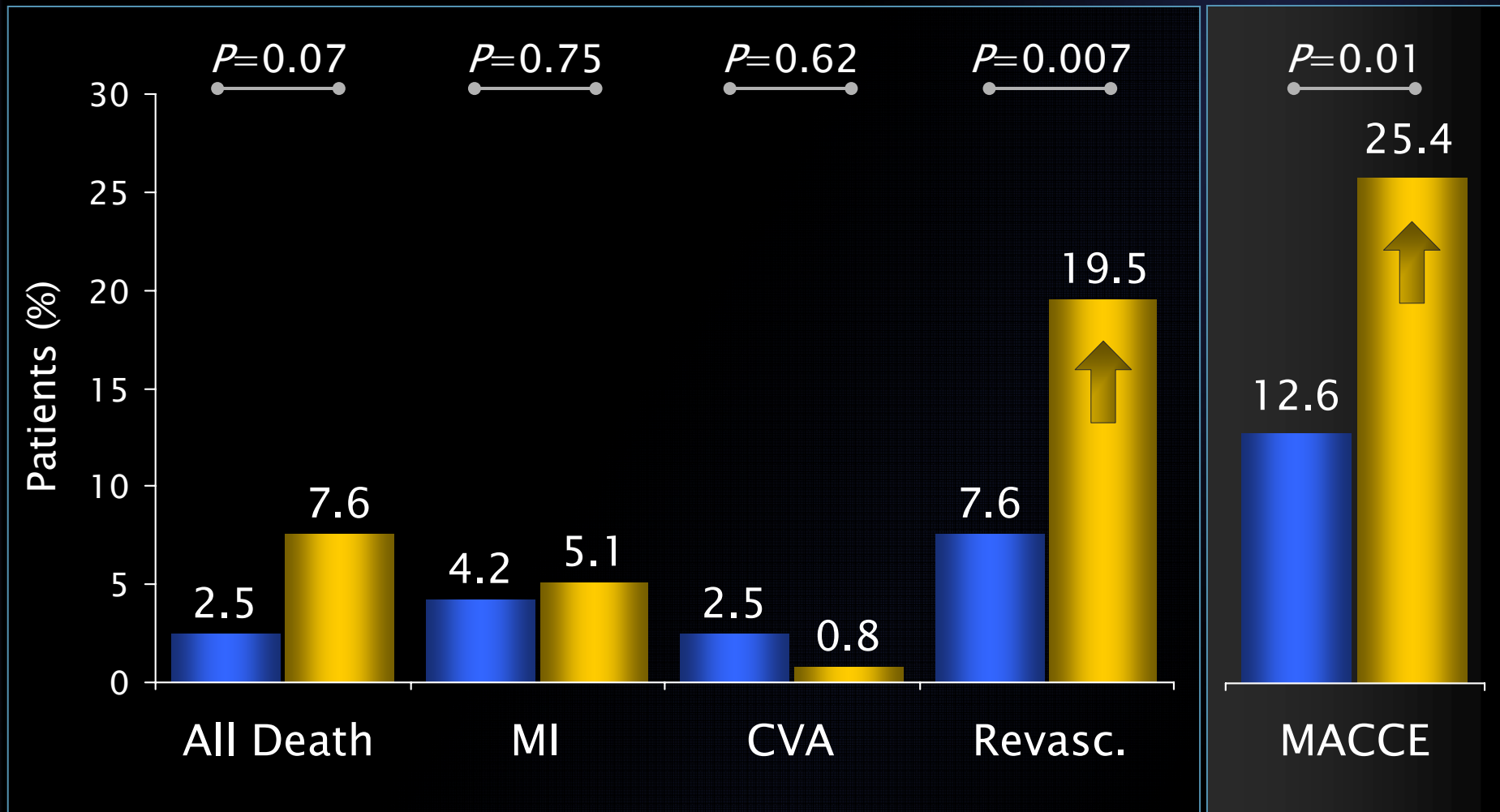


HbA1c > 7.0% (regardless of diabetes status)

SYNTAX

CABG (n=125)

TAXUS (n=121)



SYNTAX Score



- A prospective angiographic tool to grade the complexity of coronary artery disease
- Goal: Obtain evidence-based guidelines for selecting revascularization technique (surgery or PCI)

The SYNTAX Score will be retroactively weighted based on MACCE at 1 and 5 years to optimize its prognostic value



Revascularization by SYNTAX Score

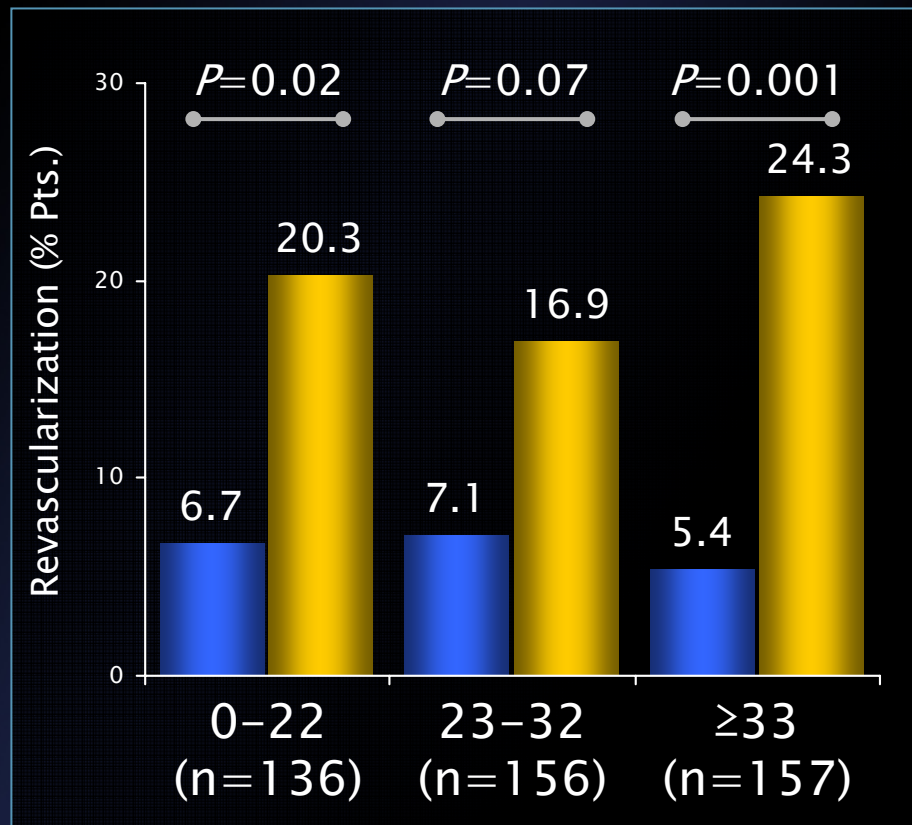
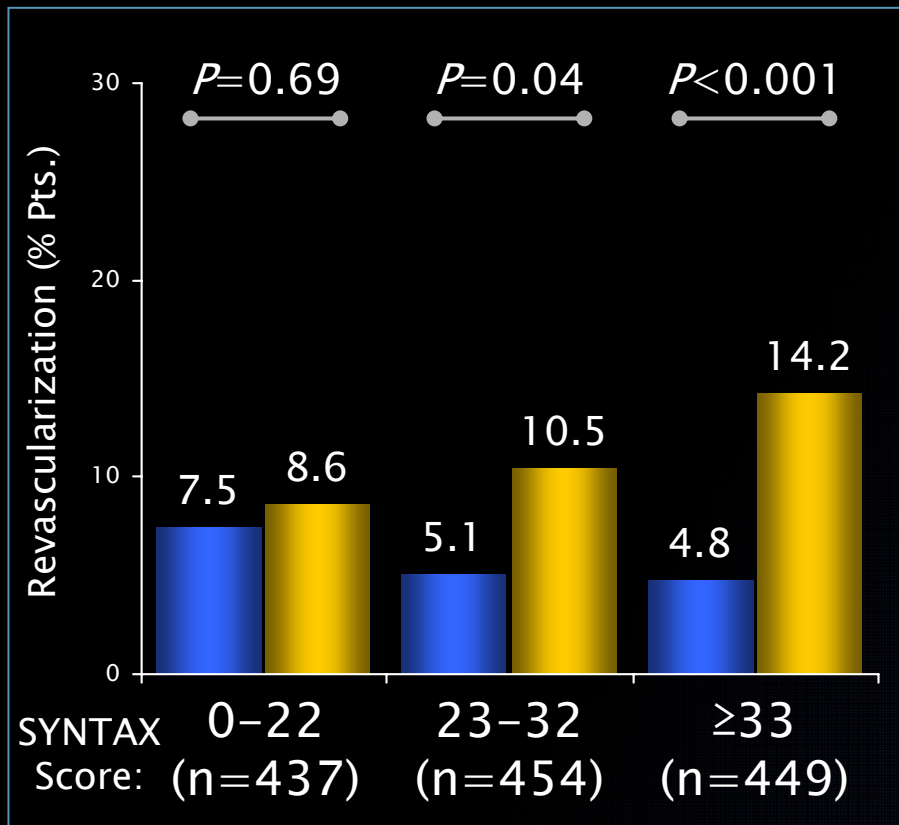
3VD/LM Diabetic and Non-Diabetic Patients



■ CABG ■ TAXUS

Non-Diabetic

Diabetic



Mortality by SYNTAX Score

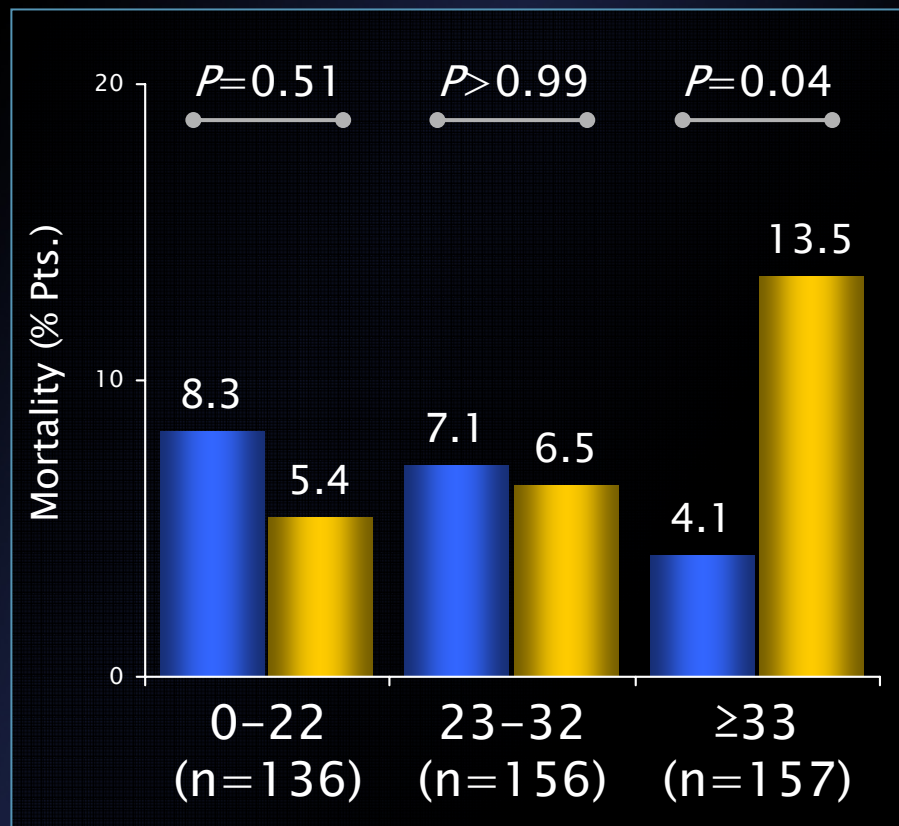
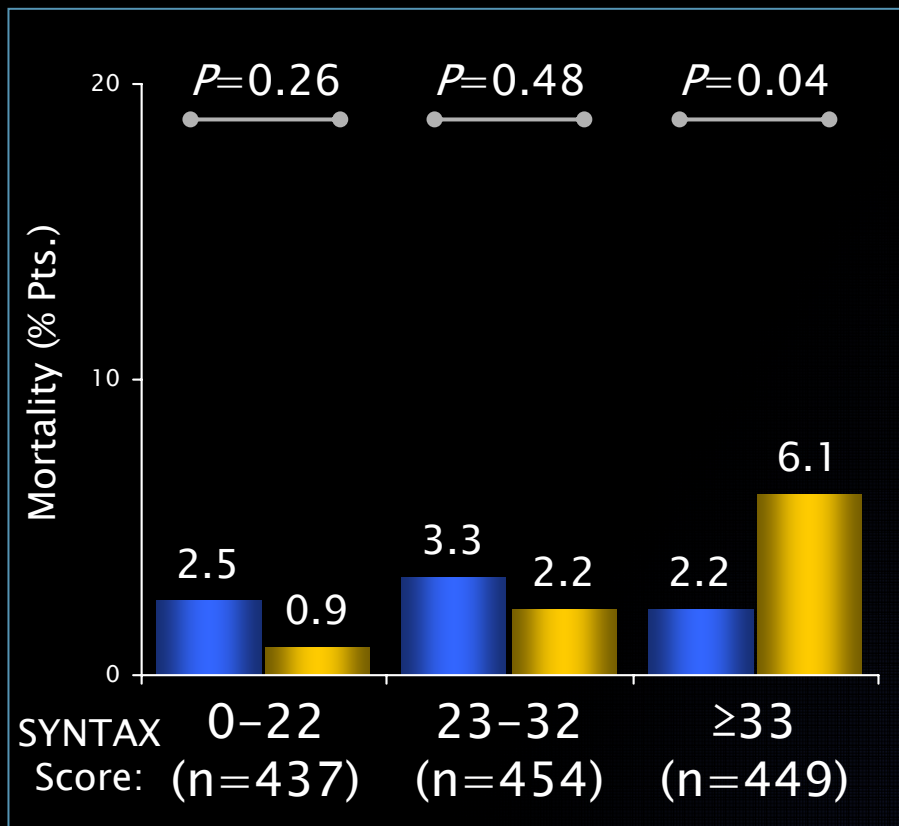
3VD/LM Diabetic and Non-Diabetic Patients



■ CABG ■ TAXUS

Non-Diabetic

Diabetic



Summary:

1-Year Observational Subgroup Results:



- In non-insulin requiring diabetic and non-diabetic patients with less complex LM/3VD lesions, PES and CABG have comparable composite safety (death/CVA/MI), however:
 - Diabetes increases mortality risk with both CABG and PES
 - CABG remains the preferable revascularization option for most insulin-treated diabetic patients
 - CABG is also preferable for diabetic and non-diabetic patients with SYNTAX scores ≥ 33 due to higher mortality with PES
 - Trend toward increased CVA with CABG, with significant increases in some subgroups
- Repeat revascularization increased with PES overall
 - However, in non-diabetic 3VD/LM patients with low lesion complexity, efficacy & safety are comparable with PES and CABG
- Metabolic syndrome alone (in the absence of diabetes) does not substantially impact outcomes

Conclusion:

Patients with 3-vessel and/or left main disease



Diabetes

Both diabetic status and lesion complexity impact the relative safety between CABG and PES and should be considered when evaluating treatment options in patients with left main and/or 3-vessel disease

Lesion Complexity
Low Medium High

	Non Diabetic	Oral Meds	Insulin
High	CABG	CABG	CABG
Medium	PCI or CABG	PCI or CABG	CABG
Low	PCI or CABG	PCI or CABG	CABG

Retroactive weighting of the SYNTAX score against 1- and 5-year SYNTAX outcomes will provide treatment algorithms to help determine the best revascularization option for each patient