

Most Patients with Elective Left Main Disease Should be Treated with PCI!

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Everything that can be invented
has been invented

(Charles H. Duell, *Commissioner, U.S. patent office, 1899*)

It would be crazy to believe that we have achieved the best we can
in revascularization therapy of LMCA

The “Gold Standard” is a transient phenomenon
until we do better

Therefore the debate is not about 1 modality vs another as separate conceptual
paradigms, BUT.....

The more appropriate question is:

“How far have we traveled along the inevitable road of progress and
what role can PCI offer in 2013 in certain circumstances ?”

Why has CABG become the “Gold Standard”

- Because it was first!
 - Therefore it will by definition always have longer follow-up
- Very poor early results with POBA
 - 1988: ACC/AHA task force on PTCA declared LMCA stenosis a **contraindication to PTCA**
- Resulting LMCA Dogma:
 - The left main stenosis is dangerous and requires revascularization for a $\geq 50\%$ stenosis
 - PCI of the left main is dangerous!

The designation of CABG as a “Gold Standard” is founded on very little evidence

Historic Treatment is based on the evidence that CABG is superior to Medical Therapy

- The evidence is outdated because medical therapy has improved significantly
- The guidelines were based on a meta-analysis of 7 trials of stable angina conducted in the 1970s
 - Patients with LM disease made up only 6.6% of the study population
 - only 150 LMCA patients were randomized in 7 studies
 - Aspirin use 18.8%
 - No Statins or ACEi
- Should the cut-off still be 50% DS??

Yusuf S. *Lancet* 1994;344:563-70

Gabor T. *Circulation*. 2008;118:422-425

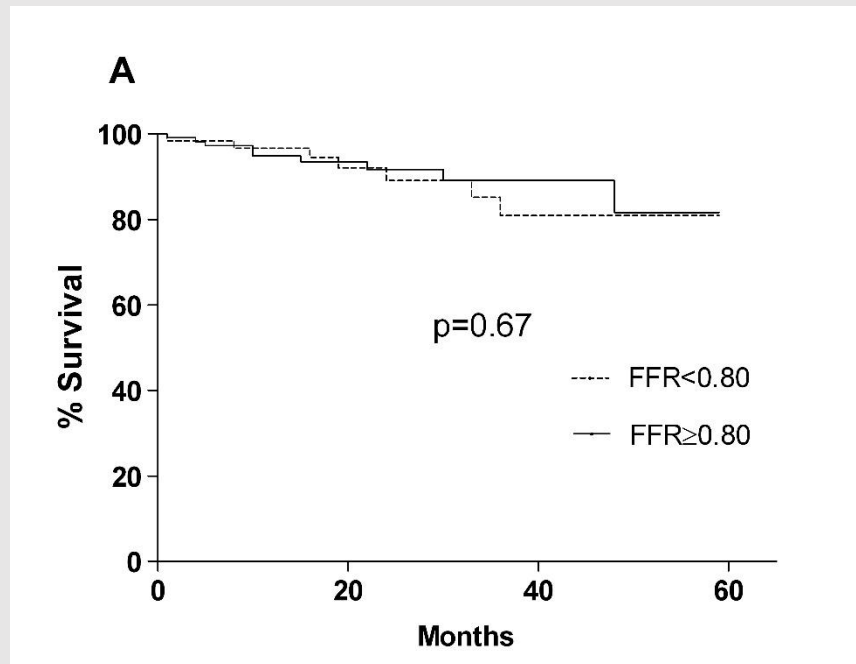
What is a LMCA stenosis?

- Treatment can safely be deferred if:

- IVUS CSA $\geq 6.0 \text{ mm}^2$
- FFR > 0.80

Abizaid. *J Am Coll Cardiol*, 1999; 34:707-715

Jasti. *Circulation*, 2004; 110:2831-2836



Hamilos. *Circulation*, 2009; 120:1505-1512

What is so scary about LM PCI?

- In Hospital

- Large territory
 - Complications are potentially fatal

- Long-Term

- Restenosis
 - potentially fatal
- Stent thrombosis
 - very high mortality

LMCA stenosis has historically been the surgical disease
The interventionalist's no-man's-land

Despite its “Dangerous” location, left main PCI is associated with < 1% intra-procedural death

Study	N of DES	Mortality:			
		in hospital	30d	6m	12m
Chieffo <i>et al</i> Circulation. 2007; 116 ;158	147	0%	0.7%	-	-
Park <i>et al</i> JACC. 2005; 45 :351	102	0%	-	-	-
Valgimigli <i>et al</i> JACC. 2005; 45 :351	102	0%	-	-	-
Price <i>et al</i> JACC. 2005; 45 :351	102	0%	-	-	-
Chieffo <i>et al</i> Circulation. 2006; 113 :2542	107	0%	-	-	2.8%
Migliorini <i>et al</i> Am J Cardiol. 2006; 98 :54	94	-	3.2%	-	11%
Khattab <i>et al</i> Am J Cardiol. 2007; 100 :970	94	-	2.1%	-	5.2%
Han <i>et al</i> Chin Med J. 2006; 119 :544	63	1.3%	-	-	-
Seung <i>et al</i> NEJM 2008; 358 :1	784	-	-	-	4.1%
White <i>et al</i> JACC. Interv. 2008; 1 :236	120	-	3.3%	-	10.8%
Buszman <i>et al</i> JACC. 2008.	52	0%	-	-	1.9%
Total	2109				

Left main stenting procedure has low acute mortality

Weighted mean of registry data

In hospital mortality: 0.5%

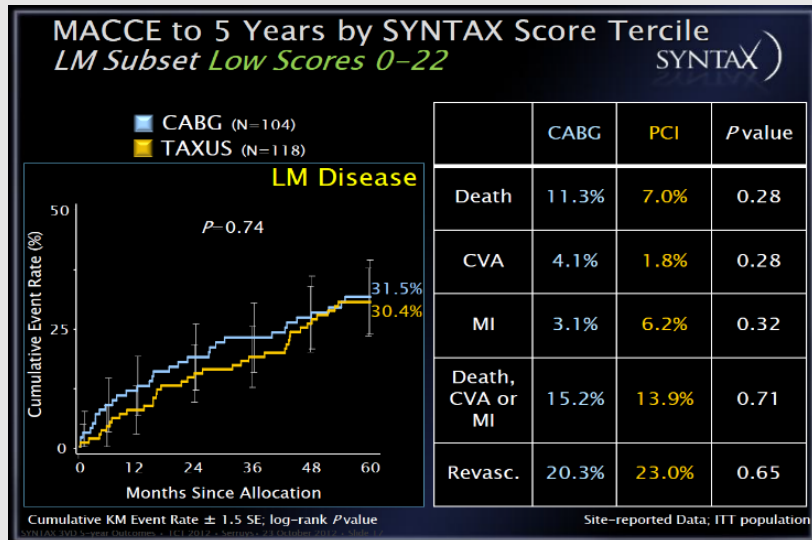
30 day mortality: 2%

CABG Perioperative Mortality in LM patients

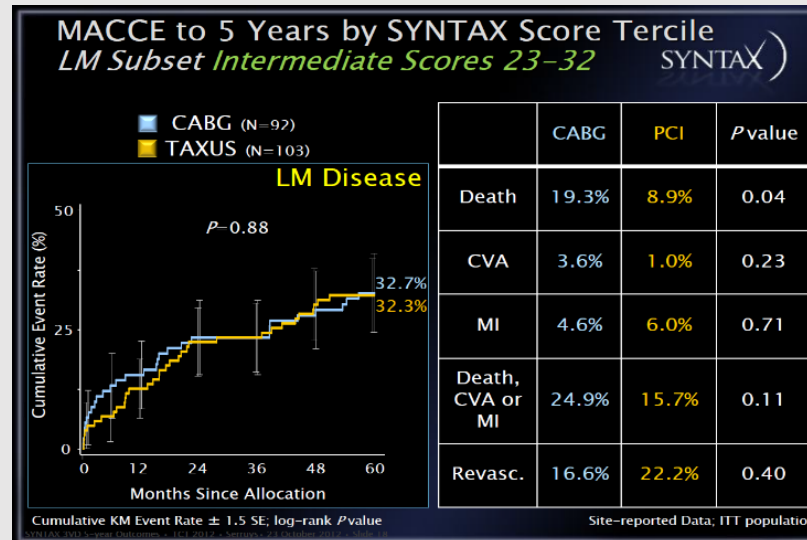
	Mortality
STS	3.9%
Sabik et al.	2.6%
d'Allonnes et al.	4.7%
Katz et al.	4.1%
Dewey et al.	2.6%

So the procedural success is similar. What about longer term outcome?

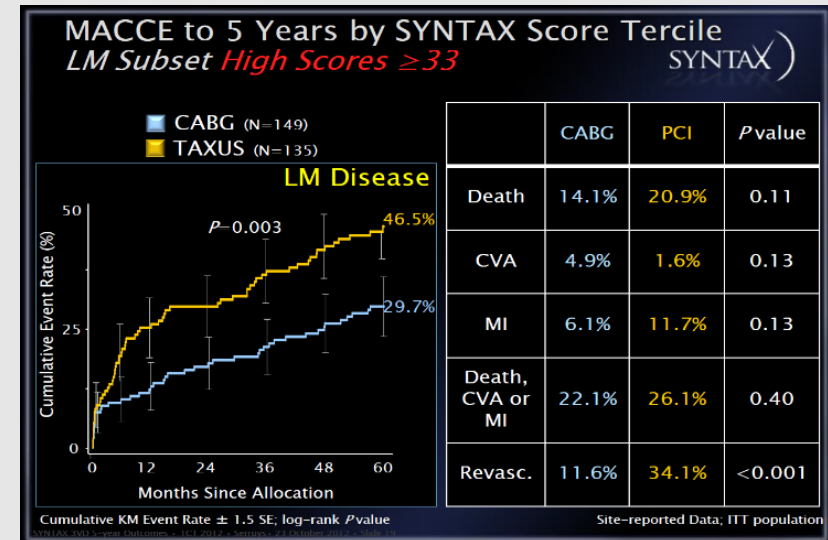
- The long term outcome of PCI or CABG is NOT different for isolated LM
- The outcome is determined by other disease beyond the left main



Syntax Score 0-22



Syntax Score 23-32

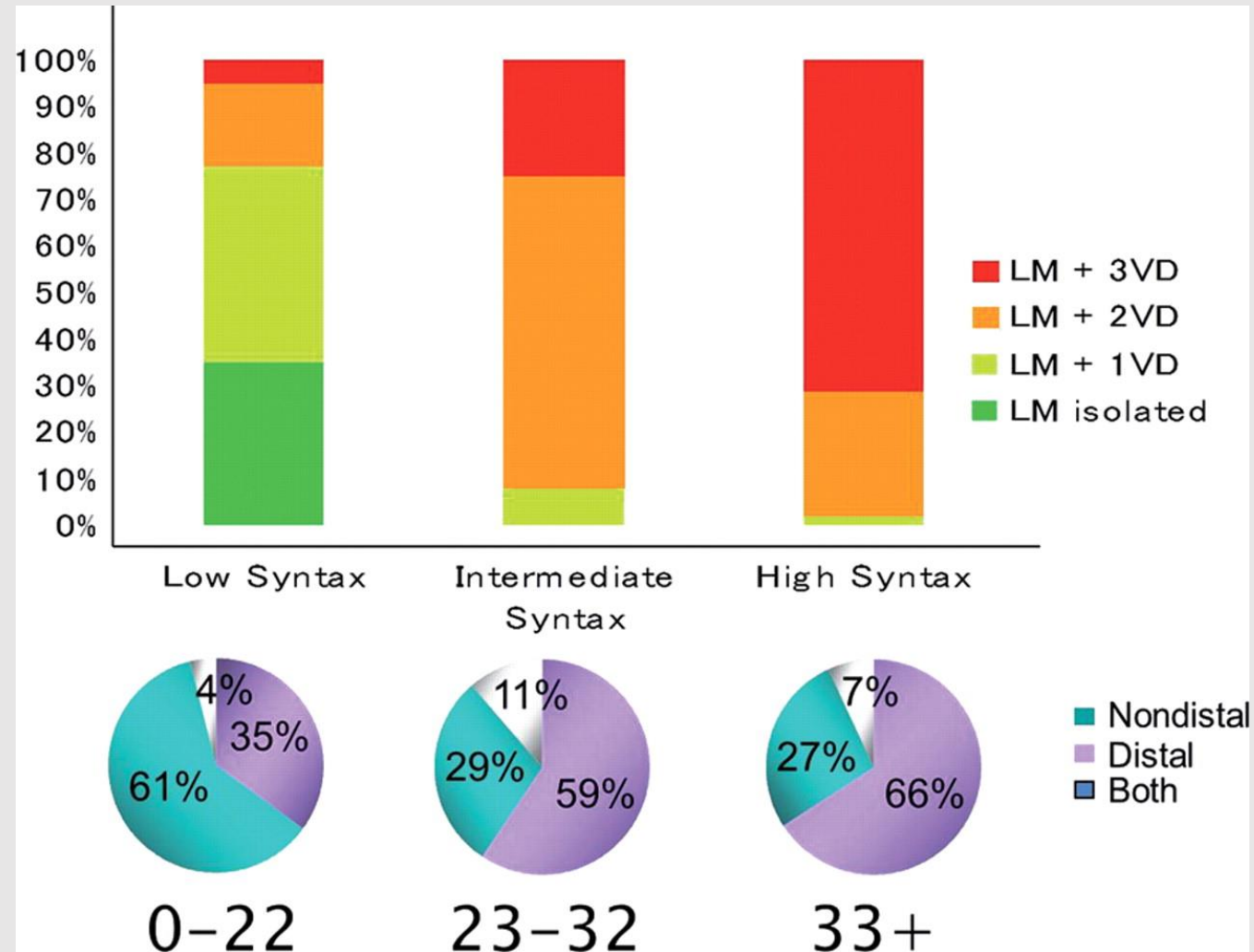


Syntax Score >33

Serruys P. et al. TCT 2012

For Syntax Scores > 33 (40% of cases):
there is a clear benefit for CABG and these cases fall outside of this debate

Vessel distribution in left main population according to SYNTAX score terciles



Who should NOT get a Left Main Stent?

- Lesions that are not feasible technically
- Very diffuse multi-vessel disease with SYNTAX scores > 33
- Left main plus occluded RCA if they are surgical candidates
- Patients who will not be or can't be compliant with ASA and Plavix
- Diabetics with multivessel coronary artery disease

**Everything else can be considered for
Either PCI or CABG in a heart team model**

Outcome issues for PCI

- Mortality
- Stent thrombosis
- Repeat intervention

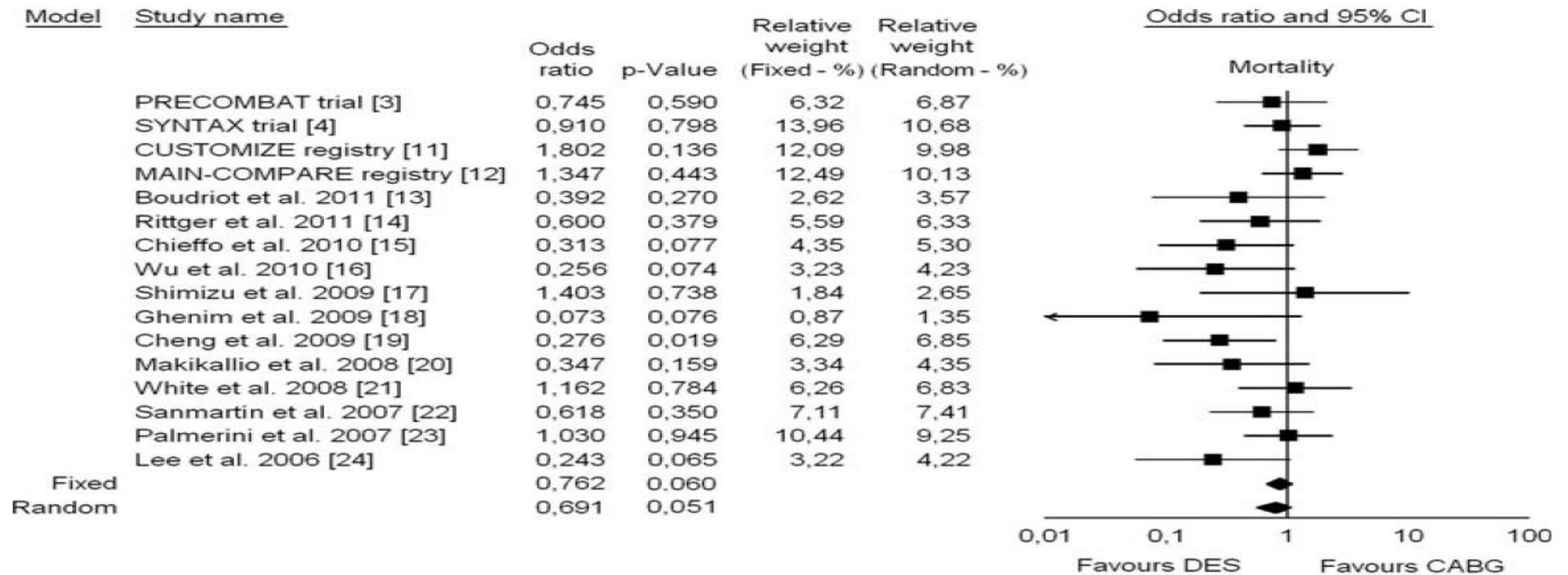
Outcome issues for CABG

- Mortality
- Stroke
- Repeat intervention

Meta-analysis of all PCI with DES versus CABG for Unprotected LM

3 RCTs, 13 retrospective studies
5674 patients (PCI, n=2331; CABG, n=3343)

No Difference in Mortality between PCI and CABG

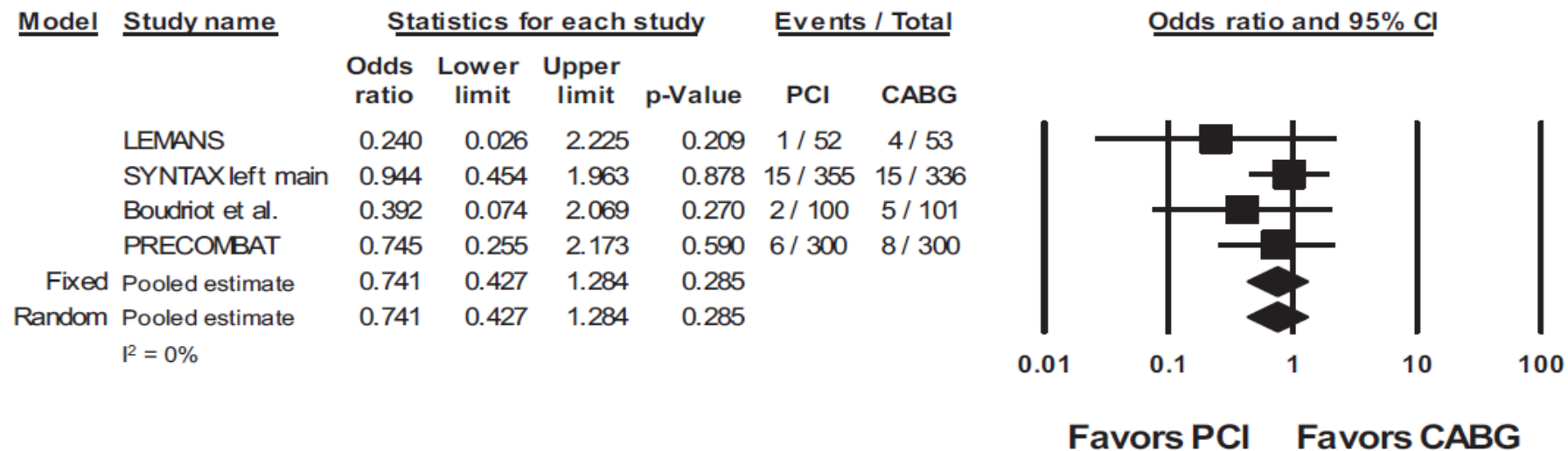


DATA from 4 Randomised trials:

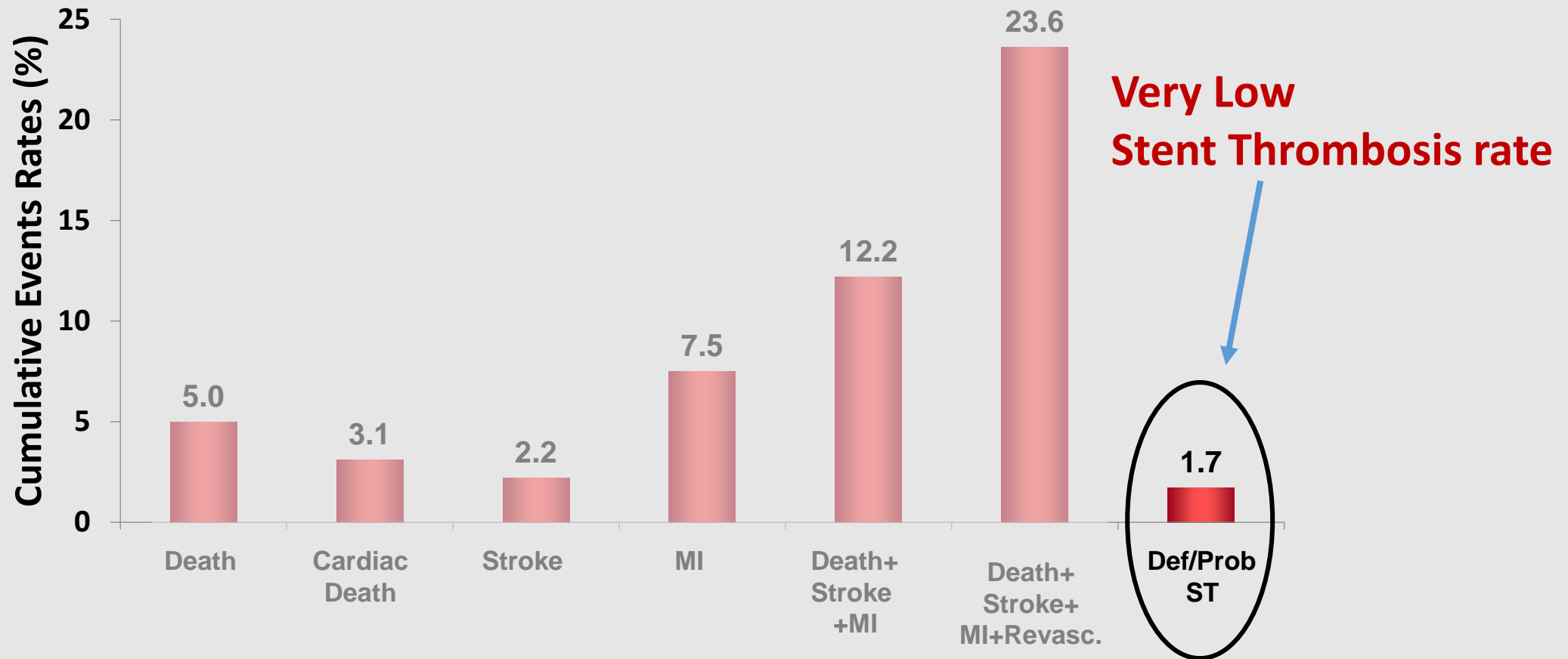
No Difference in Mortality between PCI and CABG

Distal LM in 64% of cases
Mean SYNTAX Score ranged from 24-30
Mean Log EuroSCORE ranged from 2.5-3.9

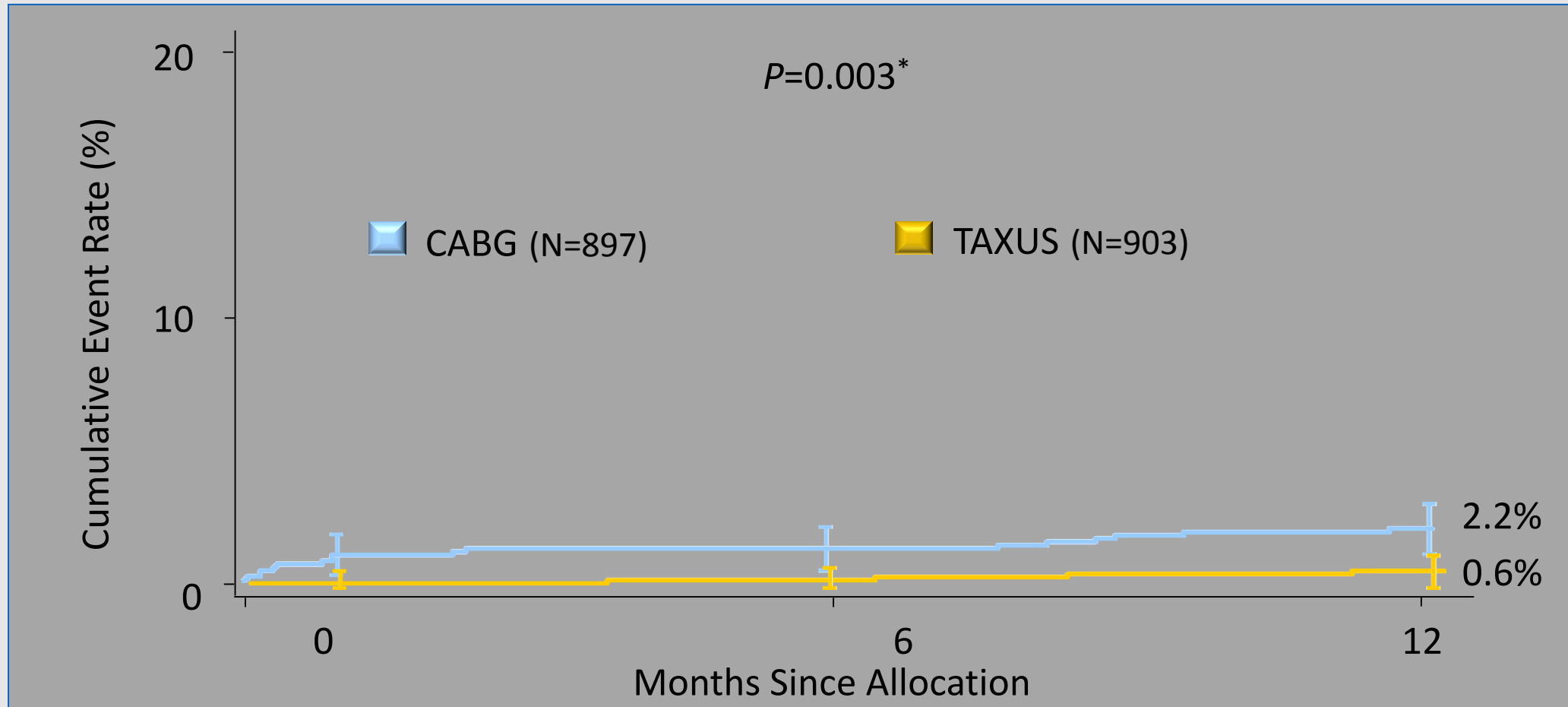
Death



Follow-up in 1,528 Left Main PCI Patients for 4.4 years

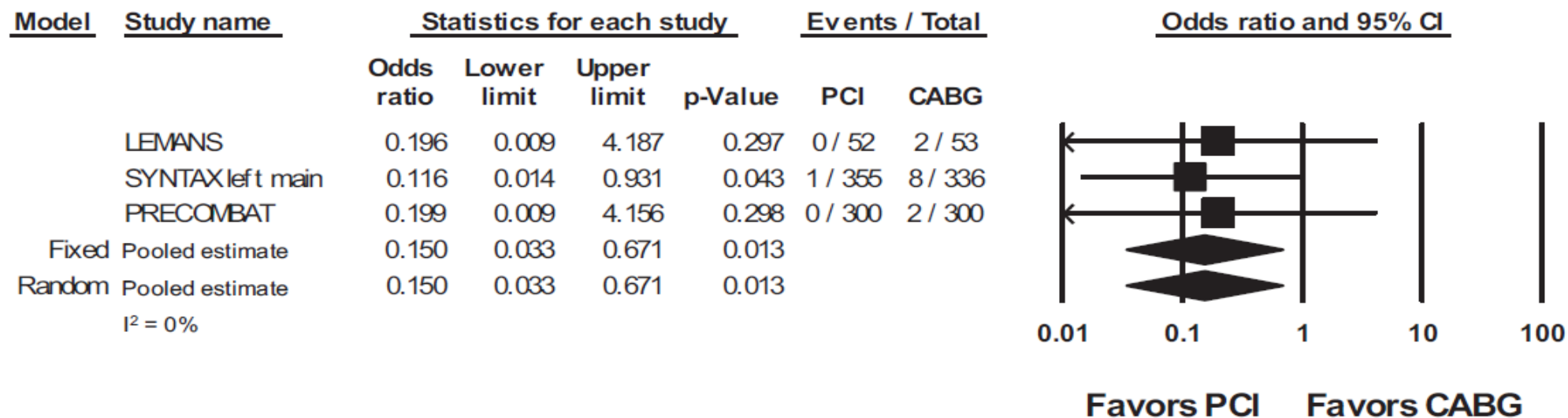


SYNTAX: 4 Fold increase in Strokes with CABG



CABG is associated with Increased Stroke Rates compared to PCI

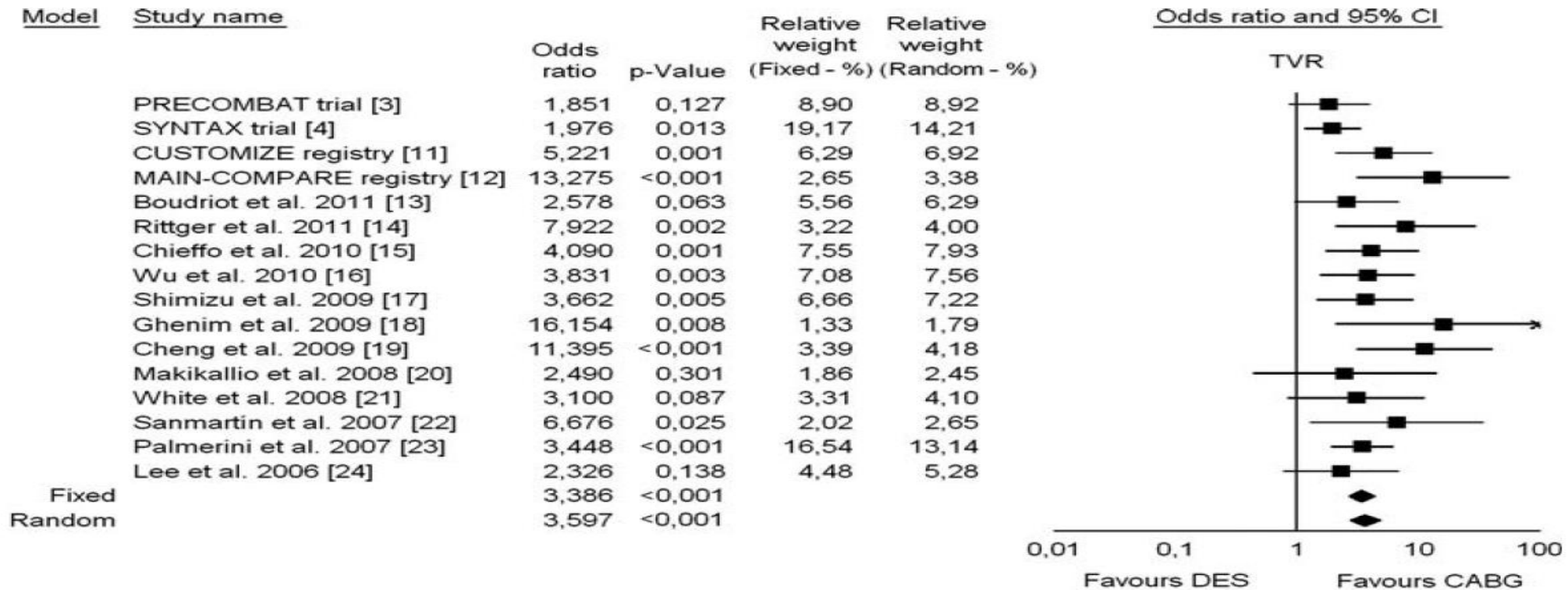
Stroke



Meta-analysis of PCI with DES versus CABG for Unprotected LM

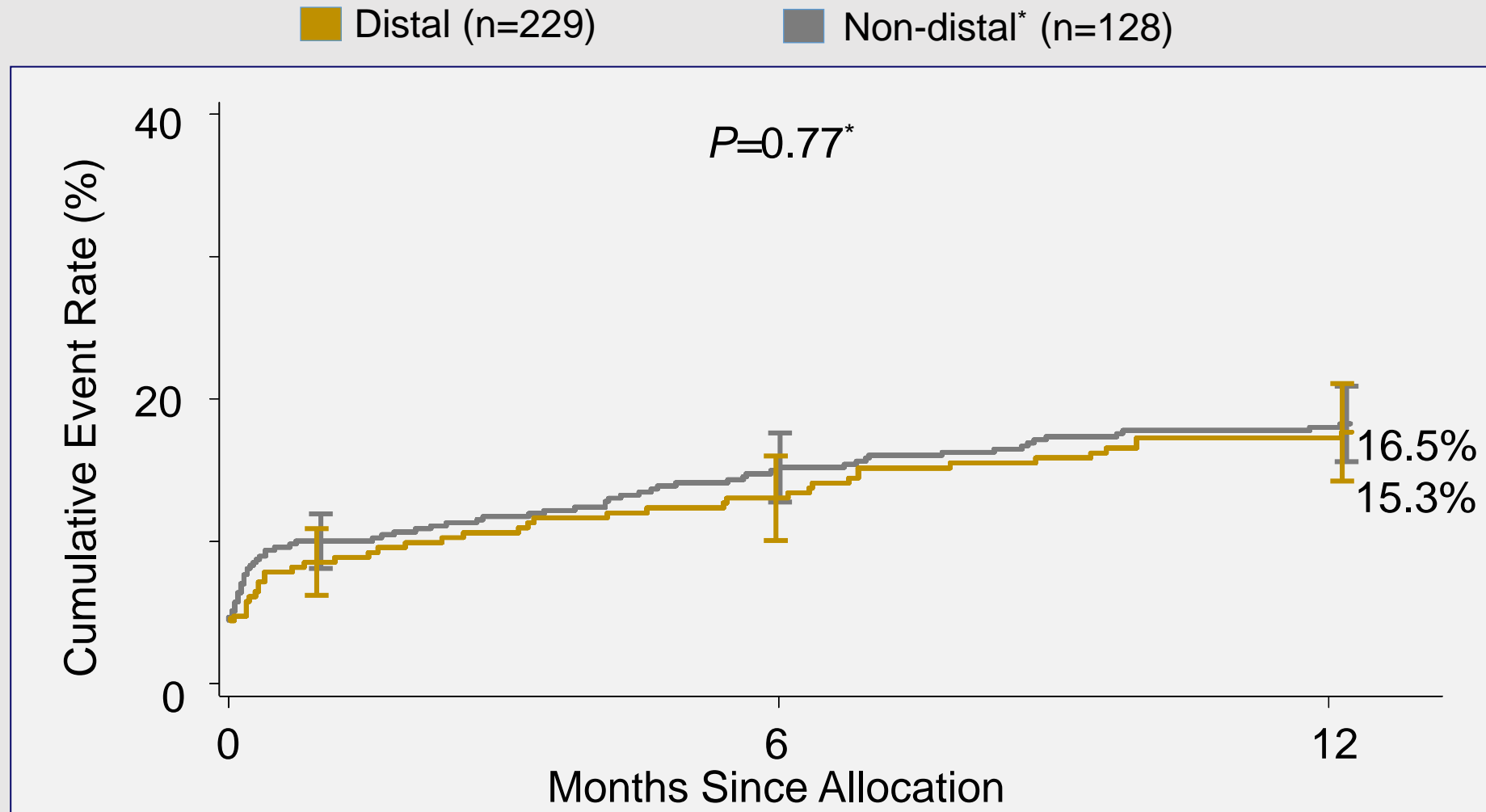
3 RCTs, 13 retrospective studies
5674 patients (PCI, n=2331; CABG, n=3343)

Increased TVR rates with PCI, in comparison to CABG



Does it matter where the left main lesion is situated?

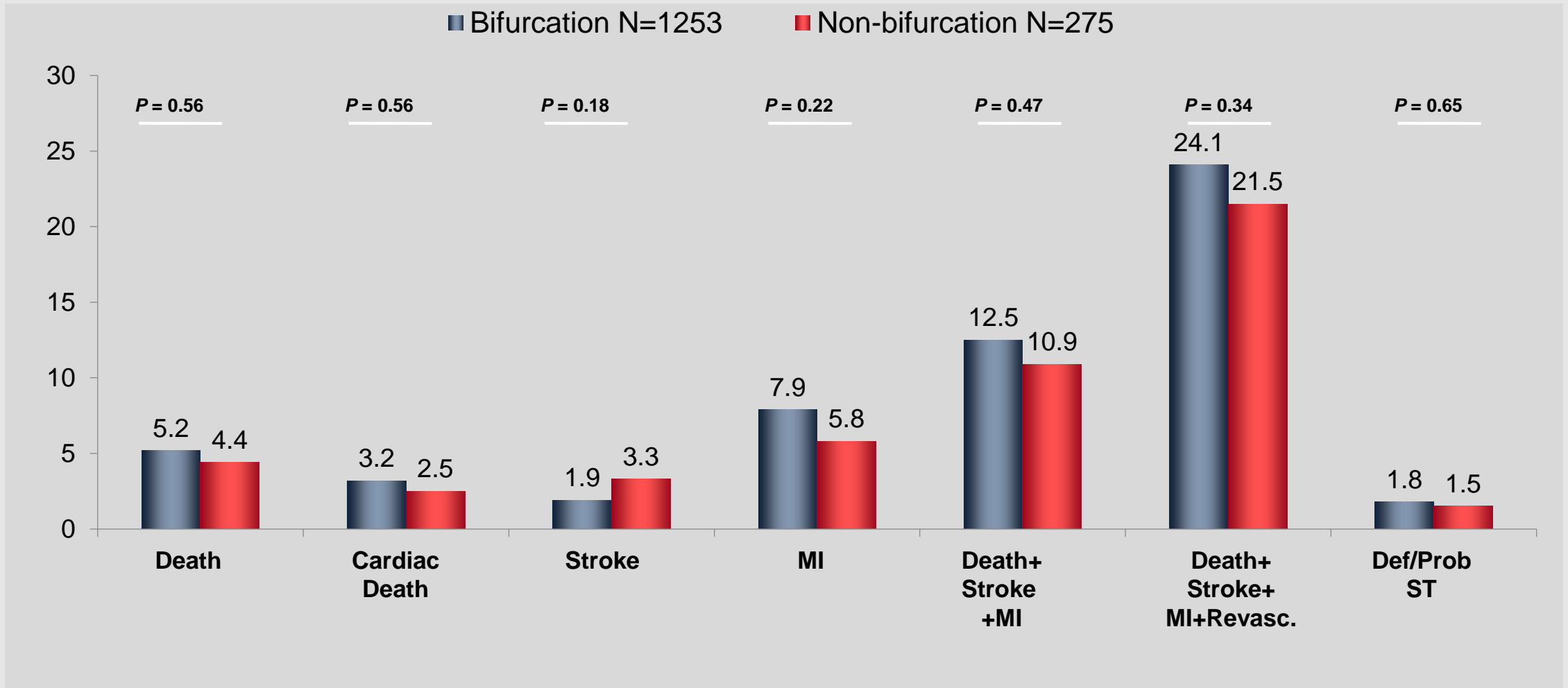
SYNTAX: MACCE to 12 Months: *LM PCI Subset: Distal vs Non-distal Lesions*



*Includes both aorto-ostial and mid-shaft lesions and patients with LM, LM+1,2,3VD

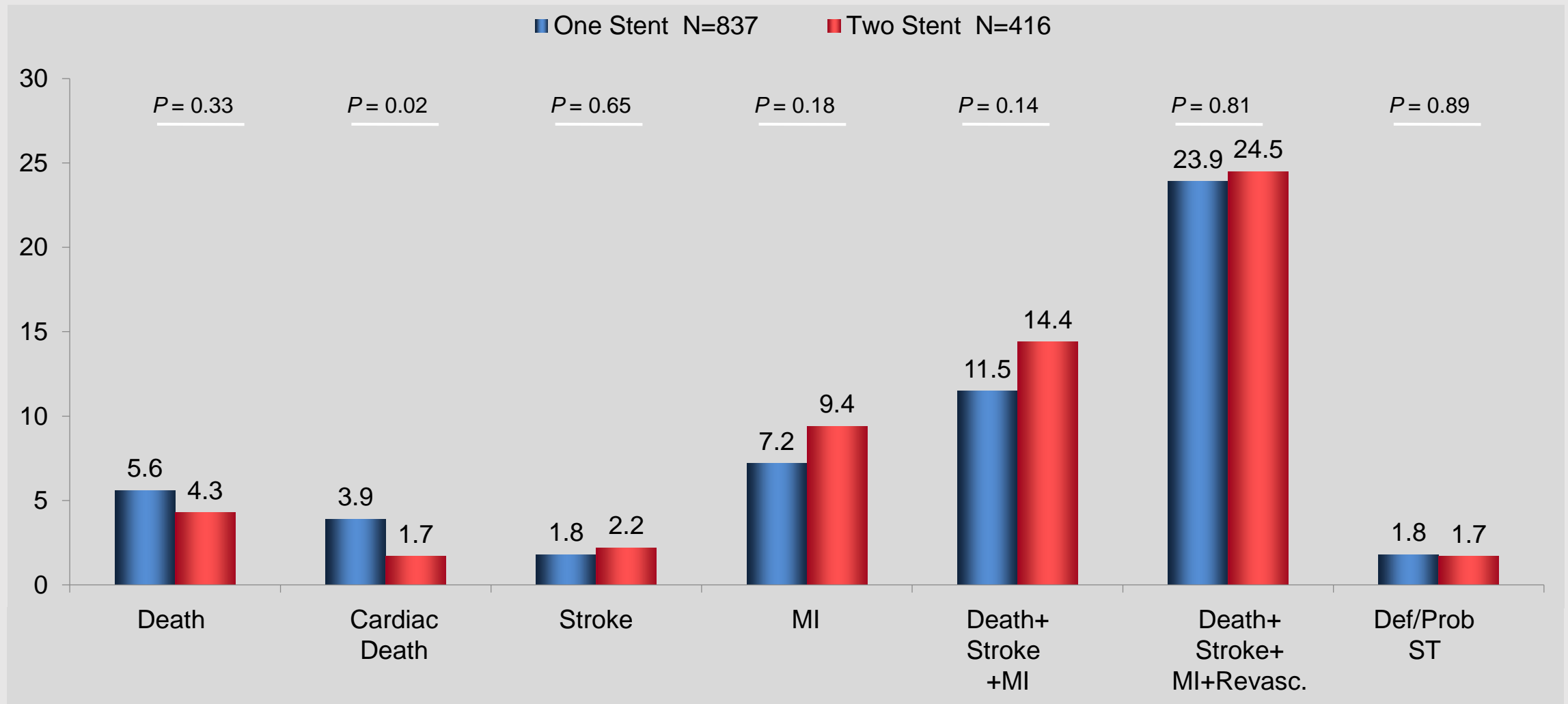
Lesion Location

Follow-up in 1,528 Left Main PCI Patients for 4.4 years



Does it matter how many stents are placed?

1 vs 2 Stents: Follow-up in 1,528 Left Main PCI Patients for 4.4 years



CABG – Dirty Little Secrets

These are not Endpoints in trials, unlike Repeat Revascularization

- “Nuisance” complications
 - Pain
 - Lower limb swelling
- Neurocognitive dysfunction still significant after CABG
- Atrial fibrillation (25%)
- Renal failure (3%)
- Bleeding requiring reoperation (3%)
- Pneumonia (2%)
- ARDS (1%)
- Bilateral IMAs at most 25%

So What is my message: Left Main PCI?

1. Left main PCI is safe
2. Important outcomes are no different to CABG in isolated left main
3. Certain cases are not suitable for PCI
 - esp when there is a large coronary disease burden
4. SO:
 - Lets choose surgery when we really believe that the patient will receive long term benefit
 - For all other cases, lets work together to determine the best option for the individual patient, taking into account:
 - Age
 - Co-morbidities
 - Technical feasibility
 - Bleeding risk
 - Patient preference

Lets also work to Improve Left Main PCI Outcomes

- Use best in class DES
- Optimal pharmacotherapy
- FFR
 - to avoid unnecessary stenting
 - to ensure complete revascularization
- IVUS guided LM stenting
- Optimal LM stent technique
 - 1 vs 2 stent techniques
 - Debulking
 - Hemodynamic support
 - Staging

EXCEL: PCI Procedure Highlights

Best in class DES	
DAPT and statin pre-loading	Required
IVUS	Strongly recommended
FFR	Strongly recommended
Lesion preparation	Direct stenting strongly discouraged
Distal LM bifurcation	Provisional stenting recommended
Hemodynamic support	Permitted
Staging	Liberal use permitted

EXCEL: CABG Procedure Highlights

• On-pump vs. off-pump	<ul style="list-style-type: none">• Operator discretion<ul style="list-style-type: none">• If on-pump: single cross-clamp technique strongly recommended
• Intra-op TEE	<ul style="list-style-type: none">• Strongly recommended to assess LV function, cardiac valves, and ascending aorta
• Arterial grafts	<ul style="list-style-type: none">• preferred conduits

Prediction for the future

- Most Patients with Elective Left Main Disease
WILL be treated with PCI in the near future
- Eventually both CABG and PCI will disappear
and a new novel better therapy will emerge