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Recent guidelines in LM & bifurcation PCI

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- In the last five years , I received research grants or speaker fees or I am/was consultant for: Abbott Vascular, Asahi, Astra Zeneca, AVI, Boston Scientific, Biotronik, Colibri, Cook, Cordis, Daichi-Sankyo, Eli-Lilly, Iroko, Medtronic, Terumo. I am currently minor shareholder & general manager of CERC

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)[‡]

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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

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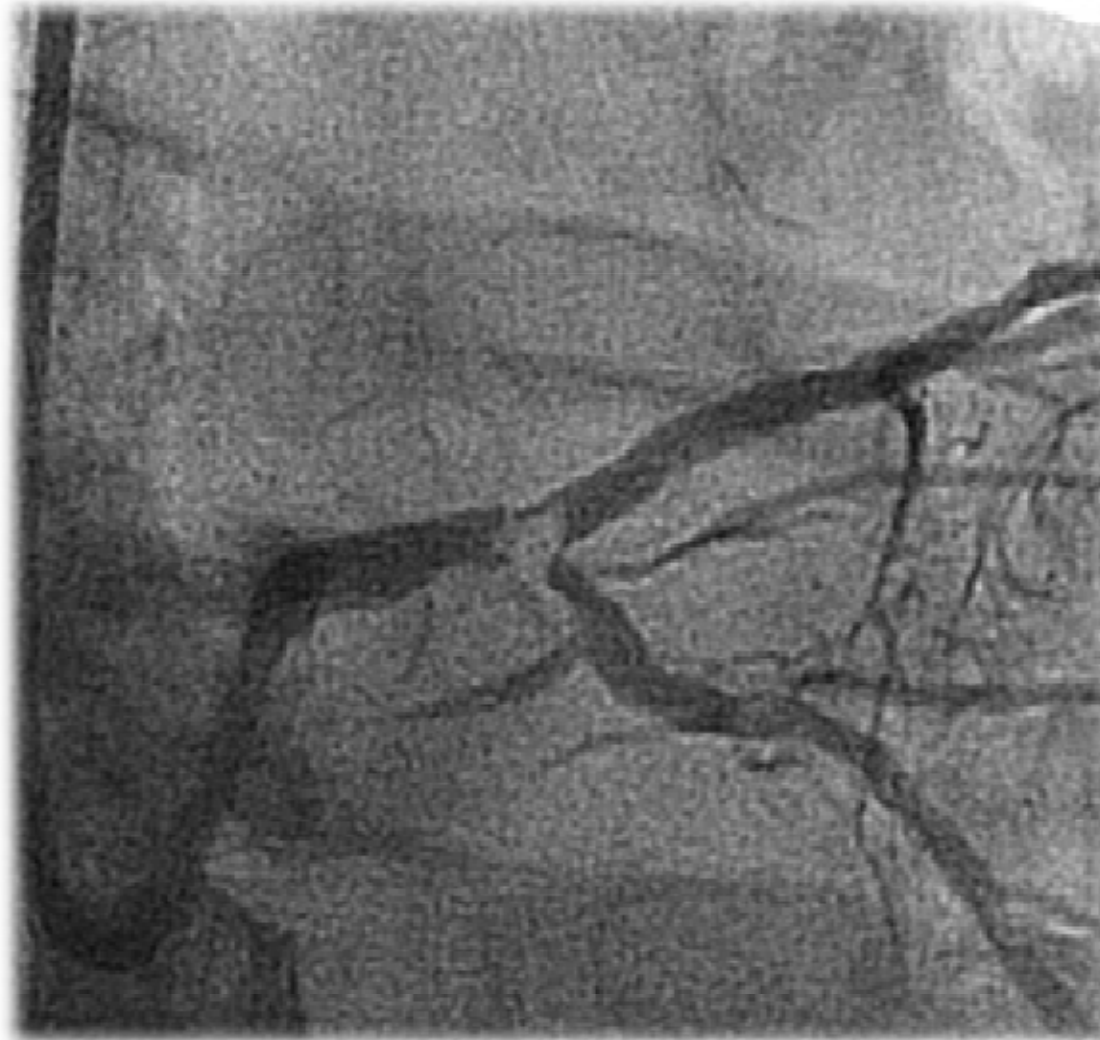
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Left main



'Heart Team'

Table 4 Multidisciplinary decision pathways, patient informed consent, and timing of intervention

		ACS			Stable MVD	Stable with indication for <i>ad hoc</i> PCI ^a
	Shock	STEMI	NSTE - ACS ^b	Other ACS ^c		
Multidisciplinary decision making	Not mandatory.	Not mandatory.	Not required for culprit lesion but required for non-culprit vessel(s).	Required.	Required.	According to predefined protocols.

CLASS I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD (14–16). (Level of Evidence: C)

CLASS IIa

1. Calculation of the Society of Thoracic Surgeons (STS) and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD (13,14,17–22). (Level of Evidence: B)

EU : Left main

Table 9 Indications for coronary artery bypass grafting vs. percutaneous coronary intervention in stable patients with lesions suitable for both procedures and low predicted surgical mortality

Subset of CAD by anatomy	Favours CABG	Favours PCI	Ref.
1VD or 2VD - non-proximal LAD	IIb C	I C	—
1VD or 2VD - proximal LAD	I A	IIa B	30, 31, 50, 51
3VD simple lesions, full functional revascularization achievable with PCI, SYNTAX score ≤ 22	I A	IIa B	4, 30–37, 53
3VD complex lesions, Incomplete revascularization achievable with PCI, SYNTAX score > 22	I A	III A	4, 30–37, 53
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B	4, 54
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B	4, 54

By SYNTAX score terciles, MACCE rates were 13.0% vs. 7.7% ($P = 0.19$), 15.5% vs. 12.6% ($P = 0.54$), and 12.9% vs. 25.3% ($P = 0.08$) for CABG vs. PCI in the lower (0–22), intermediate (23–32), and high (≥ 33) terciles, respectively. Unpublished data at 2 years show respective mortalities of 7.9% and 2.7% ($P = 0.02$) and repeat revascularization rates of 11.4% and 14.3% ($P = 0.44$) in the two lower terciles, implying that PCI may be superior to

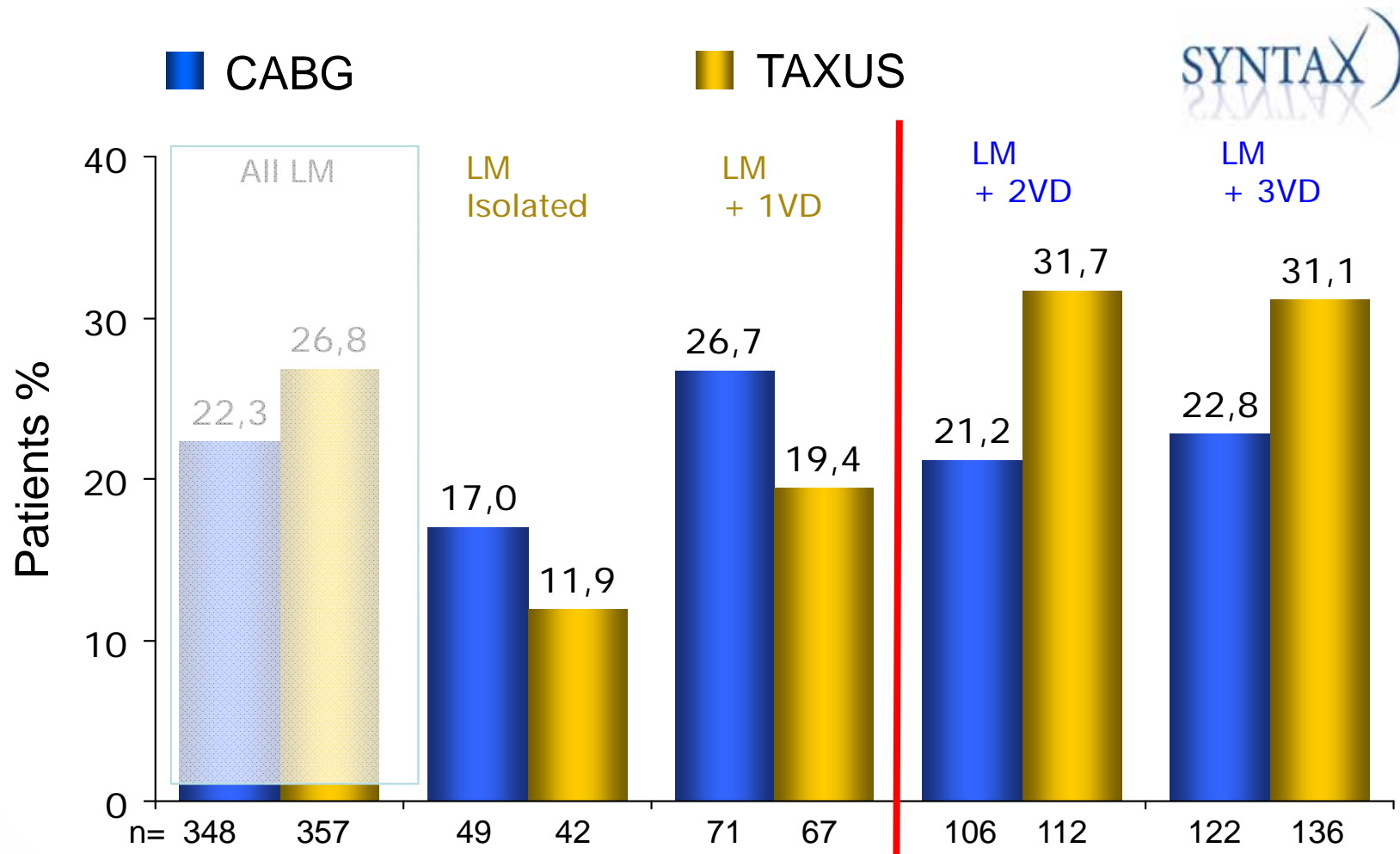
PCI may be superior to CABG @ 2 y. in the two lower terciles

analysis included in the registry or in the RCTS, 65% had SYNTAX scores > 33 .

While LM stenosis is a potentially attractive target for PCI because of its large diameter and proximal position in the coronary circulation, two important pathophysiological features may mitigate against the success of PCI: (i) up to 80% of LM disease involves the bifurcation known to be at particularly high risk of restenosis; and

MACCE to 3 Years in LM Subgroups

Complexity of Disease (no p values as not powered for subanalysis)



Reduced Mortality PCI vs CABG
 (LMS - CABG: 10.8%, PCI 1.3%) n=145
 - RECLASSIFIED as low risk.

EuroSCORE	23-32		33
	≤		
0-2	LOW	LOW	NT
3-5	LOW	LOW	NT
≥6	IN	LOW	GH

By SYNTAX score terciles, MACCE rates were 13.0% vs. 7.7% ($P = 0.19$), 15.5% vs. 12.6% ($P = 0.54$), and 12.9% vs. 25.3% ($P = 0.08$) for CABG vs. PCI in the lower (0–22), intermediate (23–32), and high (≥ 33) terciles, respectively. Unpublished data at 2 years show respective mortalities of 7.9% and 2.7% ($P = 0.02$) and repeat revascularization rates of 11.4% and 14.3% ($P = 0.44$) in the two lower terciles, implying that PCI may be superior to CABG at 2 years. Of note, among the 1212 patients with LM stenosis included in the registry or in the RCTs, 65% had SYNTAX scores ≥ 33 .

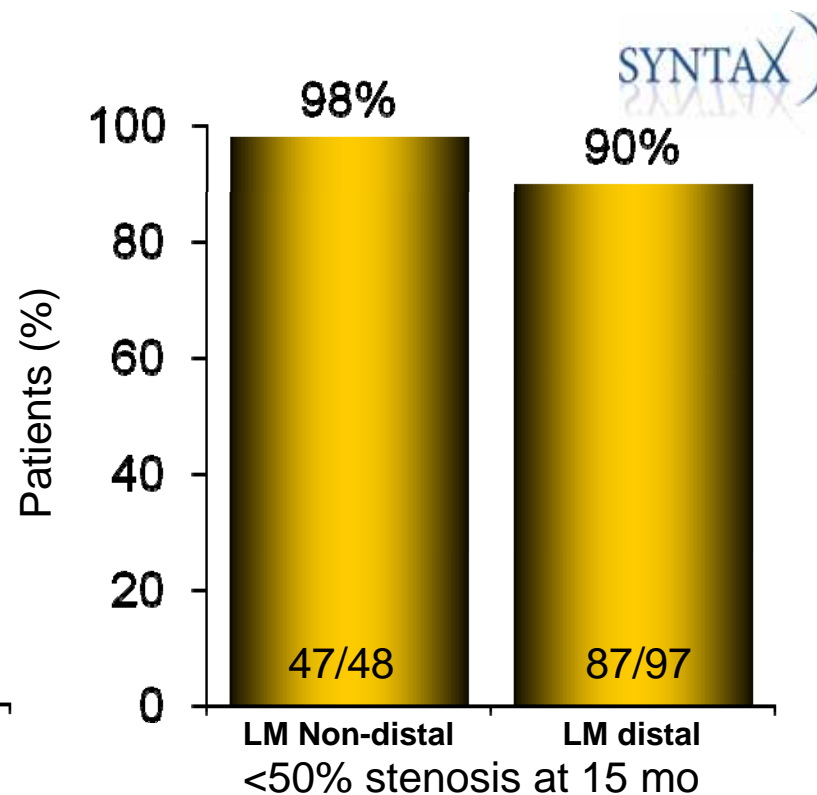
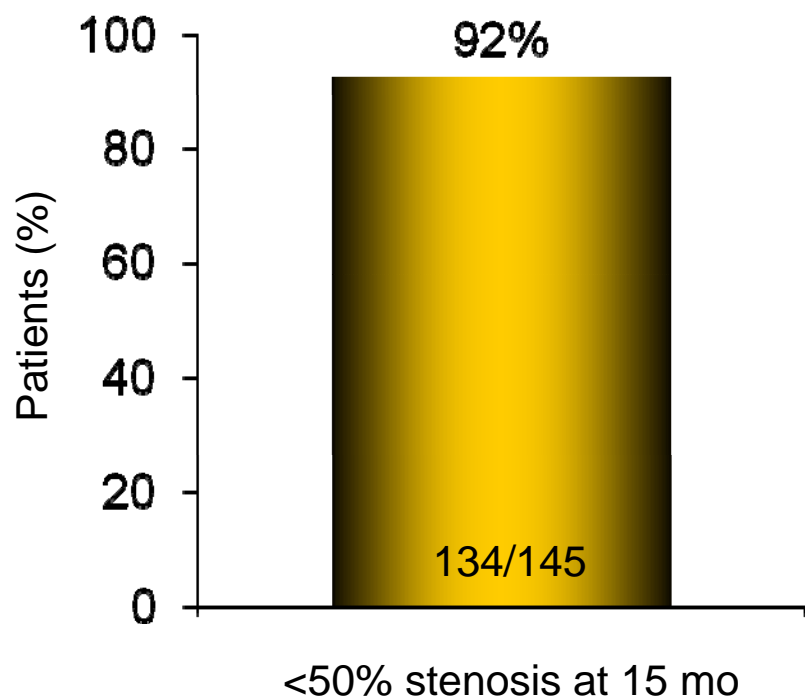
While LM stenosis is a potentially attractive target for PCI because of its large diameter and proximal position in the coronary circulation, two important pathophysiological features may mitigate

LM bifurcation known to be at particularly high risk of restenosis

bifurcation known to be at particularly high risk of restenosis; and

SYNTAX LE MANS TAXUS Cohort

Primary Endpoint:



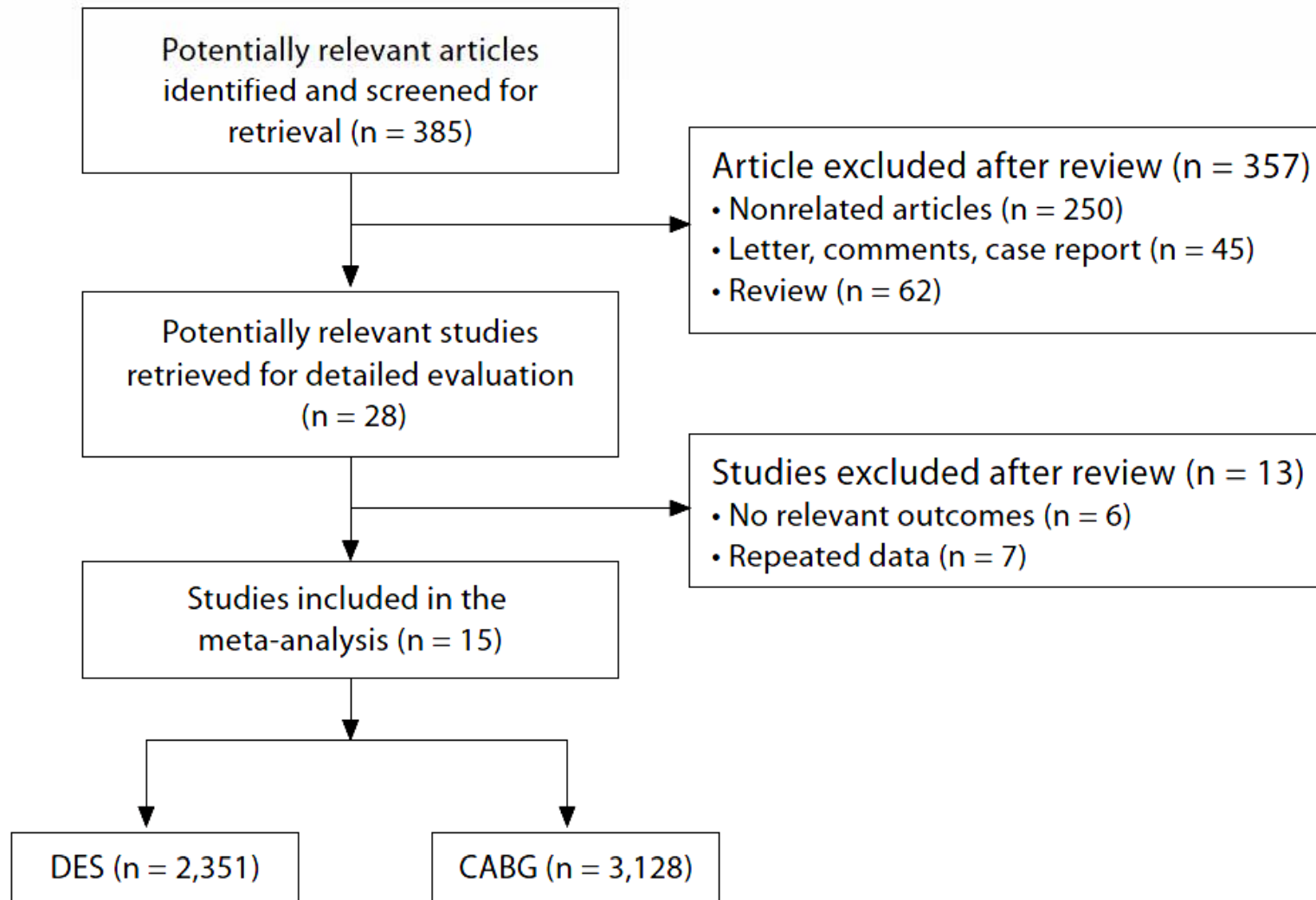
Definitions:
Diameter stenosis was assessed by QCA

On site cardiac surgery?

and whether surgery is offered on site or not. Non-emergent high-risk PCI procedures, including those performed for distal left main (LM) disease, complex bifurcation stenosis involving large side branches, single remaining coronary artery, and complex chronic total occlusion (CTO) recanalization, should be performed by adequately experienced operators at centres that have access to circulatory support and intensive care treatment, and have cardiovascular surgery on site.

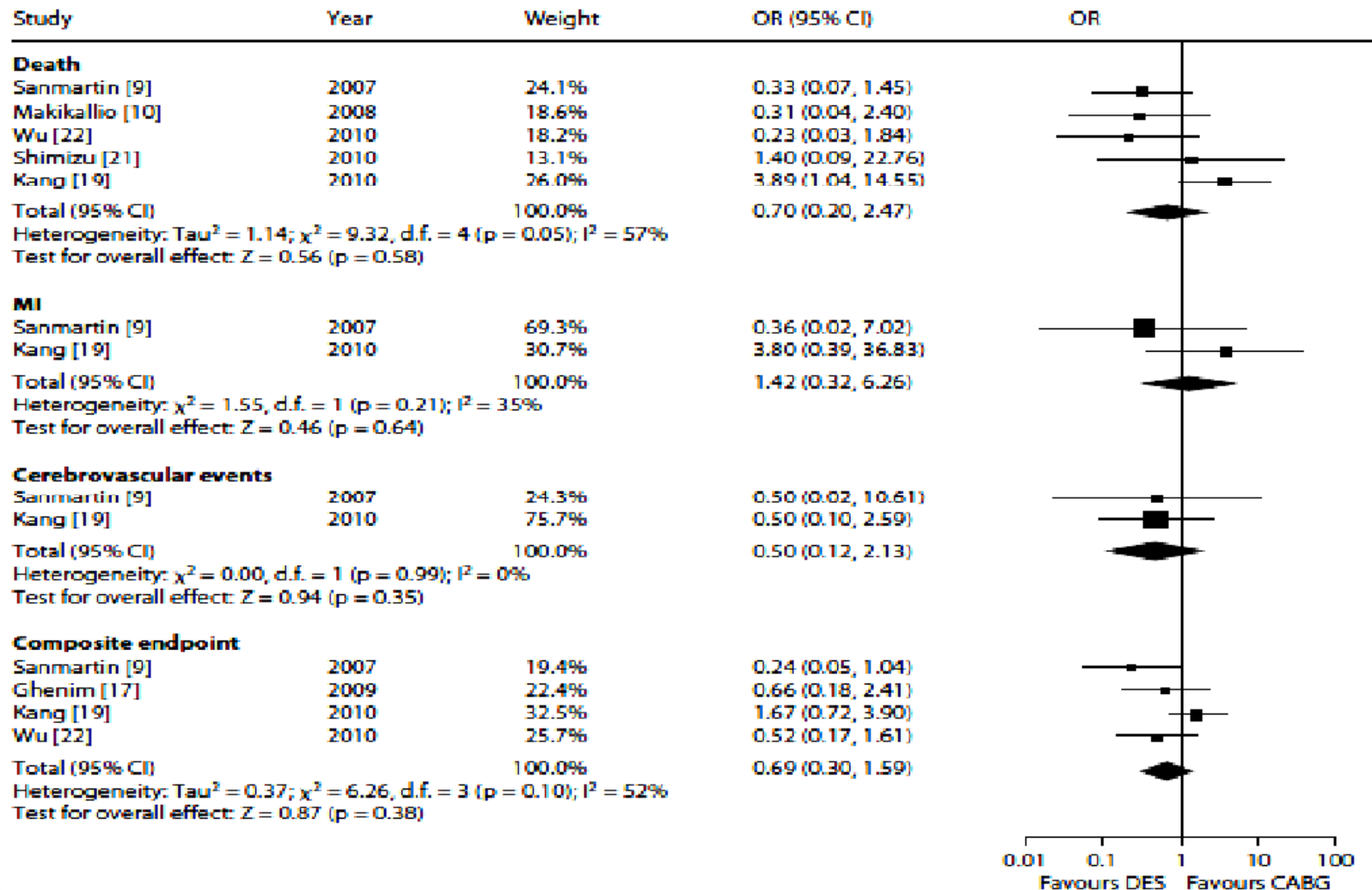
Distal LM PCI = cardiovascular surgery on site !

Comparison between DES and CABG for ULM CAD: Meta-Analysis of 2 RCT and 13 Observational Studies



Comparison between DES and CABG for ULM CAD: Meta-Analysis of 2 RCT and 13 Observational Studies

Comparison of DES versus CABG for the early outcomes (<30d)



US : Role of surgical risk

CABG (46). Physicians can estimate operative risk for all CABG candidates using a standard instrument, such as the risk calculator from the STS database. The above considerations are important factors when choosing among revascularization strategies for unprotected left main CAD and have been factored into revascularization recommendations.

PCI indication is driven by surgical risk evaluation

US : Left main

UPLM*		
CABG	I	B
PCI	IIa—For SIHD when <i>both</i> of the following are present: <ul style="list-style-type: none"> Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score of ≤ 22, ostial or trunk left main CAD) Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality $\geq 5\%$) 	B
	IIa—For UA/NSTEMI if not a CABG candidate	B
	IIa—For STEMI when distal coronary flow is TIMI flow grade < 3 and PCI can be performed more rapidly and safely than CABG	C
	IIb—For SIHD when <i>both</i> of the following are present: <ul style="list-style-type: none"> Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of < 33, bifurcation left main CAD) Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality $> 2\%$) 	B
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	B

Guideline for PCI/CABG indication: March, 2012: Japanese Circulation Society

PCI/CABG indication			
anatomical condition		Favors PCI	Favors CABG
1VD or 2 VD	non LAD proximal lesion	1A	IIb C
	LAD proximal lesion (except for ostium)	1C	I A
	LAD ostium lesion	IIb C	
3 VD	non LAD proximal lesion	IIb B	
	LAD proximal lesion	III B	
unprotected LM	Isolated or 1VD ostium/shaft	IIb C	
	Isolated or 1VD, distal bifurcation	IIIC / IIb C*	
	Multi-vessel disease	III C	

*Class IIb: non LCX lesion, and need to be approved by the heart team (cardiac surgery must be included)

Left main

- Similarities

- Role of Heart Team
- Role of Syntax score ($>32 = \text{CABG}$)
- Distal vs Mid/Ostial
- FFR in equivocal LM stenosis

- Discrepancies

- Role of surgical score (STS)
- No PCI if STS $< 2\%$
- ACS presentation
- Need for 'onsite' cardiac surgery

EU : Bifurcation

has not yet been established. Variables to be considered are plaque distribution, size and downstream territory of each vessel (main and side branch), and the bifurcation angle. Stent implan-

Main vessel stenting with provisional SB angioplasty > routine double stenting

with or without stenting of the side branch, seems preferable compared with routine stenting of both vessels. FFR data from side

when indicated (Section 6). For bifurcation and LM lesions, DES are preferred with special attention to adequate sizing and deployment. For true bifurcation lesions, DES with strong antiproliferative properties (late lumen loss ≤ 0.2 mm) are preferred to reduce restenosis rates.²¹⁰

DES better, Instant LL < 0.2 MM

US : bifurcation

CLASS I

1. Provisional side-branch stenting should be the initial approach in

Provisional SB stenting if small & moderately diseased

(Level of Evidence: A)

CLASS IIa

1. It is reasonable to use elective double stenting in patients with

Elective double stenting in large SB & high risk of occlusion

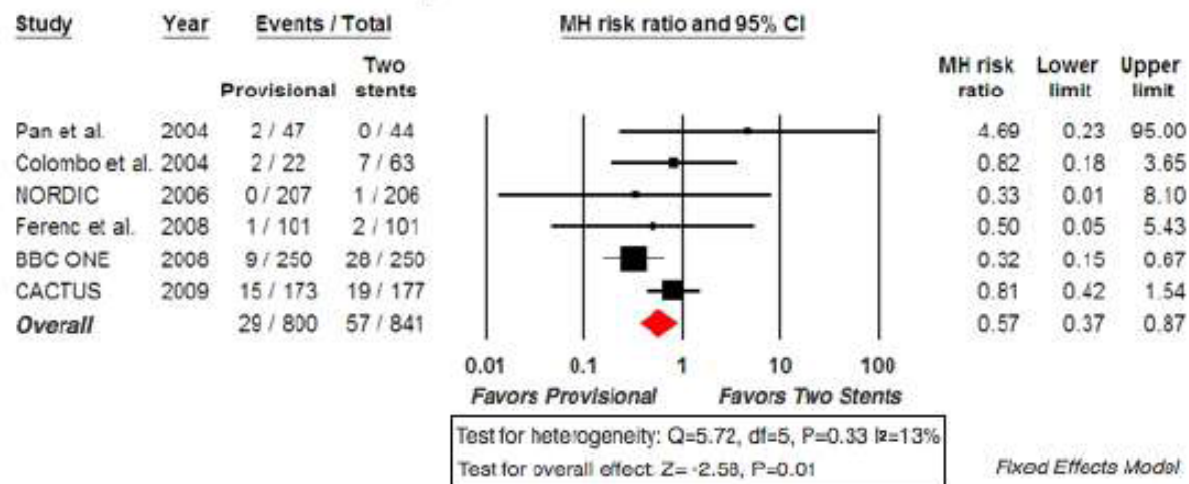
successful side-branch reaccess is low (730–733). *(Level of Evidence: B)*

In patients with low-risk bifurcation lesions (minimal or moderate ostial side-branch disease [$<50\%$ diameter stenosis] of focal length [5 to 6 mm]), provisional stenting yields similar clinical outcome to elective double stenting, with lower incidence of periprocedural biomarker elevation (726–729). Conversely, in patients with high-risk bifurcations, elective double stenting is associated with a trend toward higher angiographic success rates, lower in-hospital MACE, and better long-term patency of the side branch compared with provisional stenting (193). Culotte, Crush, and T-stent techniques have been studied in RCTs (726–729,737). Use of DES yields better outcomes than BMS (738), and sirolimus-eluting stents yield better outcomes than paclitaxel-eluting stents (739–742). Clinical evidence supports the use of final kissing balloon inflation after elective double stenting (743).

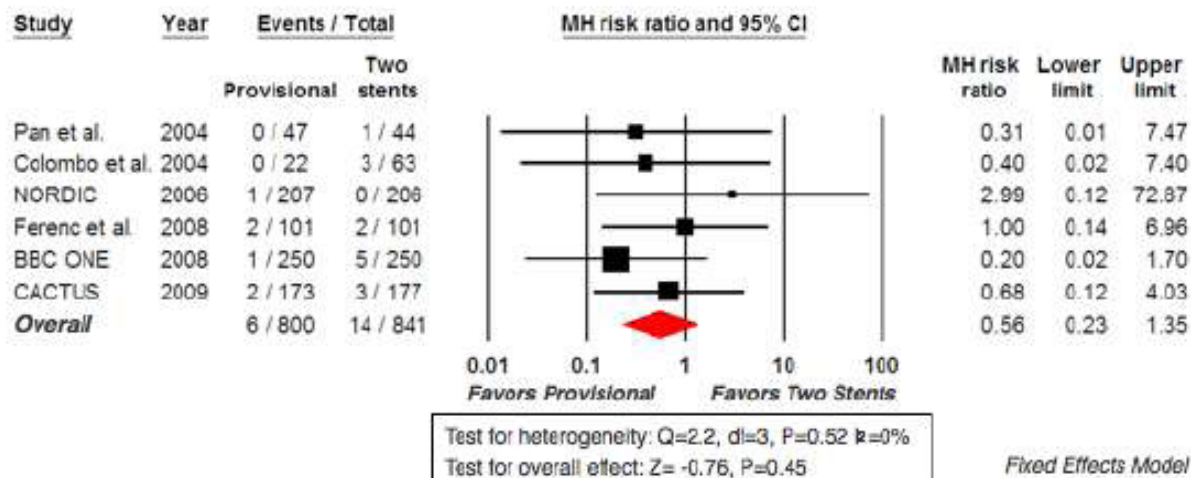
Better longterm
patency & lower MACE
with elective
double stenting in high
risk bifurcations ??

193. Herzog CA, Ma JZ, Collins AJ. Comparative survival of dialysis patients in the United States after coronary angioplasty, coronary artery stenting, and coronary artery bypass surgery and impact of diabetes. *Circulation*. 2002;106:2207–11.

B. Myocardial Infarction



E. Stent Thrombosis



C.

TLR

Study	Year	Events / Total		MH risk ratio and 95% CI	Statistics for each study		
		Provisional	Two stents		MH risk ratio	Lower limit	Upper limit
Pan et al.	2004	1 / 47	2 / 44		0.47	0.04	4.98
Colombo et al.	2004	1 / 22	6 / 63		0.48	0.06	3.75
NORDIC	2006	4 / 207	2 / 206		1.99	0.37	10.75
Ferenc et al.	2008	11 / 101	9 / 101		1.22	0.53	2.82
BBC ONE	2008	14 / 260	18 / 250		0.78	0.40	1.53
CACTUS	2009	11 / 173	13 / 177		0.87	0.40	1.88
Overall		42 / 800	50 / 841		0.91	0.61	1.35

Test for heterogeneity: $Q=2.2$, $df=5$, $P=0.82$ $I^2=0\%$
 Test for overall effect: $Z= -0.49$, $P=0.63$

0.01 0.1 1 10 100
 Favors Provisional Favors Two Stents

Fixed Effects Model

D.

Side Branch Restenosis

Study	Year	Events / Total		MH risk ratio and 95% CI	MH risk ratio	Lower limit	Upper limit
		Provisional	Two stents				
Pan et al.	2004	2 / 47	4 / 44		0.47	0.09	2.43
Colombo et al.	2004	3 / 21	12 / 55		0.65	0.21	2.09
NORDIC	2006	29 / 151	18 / 156		1.66	0.97	2.87
Ferenc et al.	2008	9 / 101	13 / 101		0.69	0.31	1.55
CACTUS	2009	22 / 150	20 / 152		1.11	0.64	1.96
Overall		65 / 470	67 / 508		1.09	0.79	1.51

Test for heterogeneity: $Q=5.3$, $df=4$, $P=0.26$ $I^2=25\%$
 Test for overall effect: $Z= 0.53$, $P=0.60$

Fixed Effects Model

Bifurcation

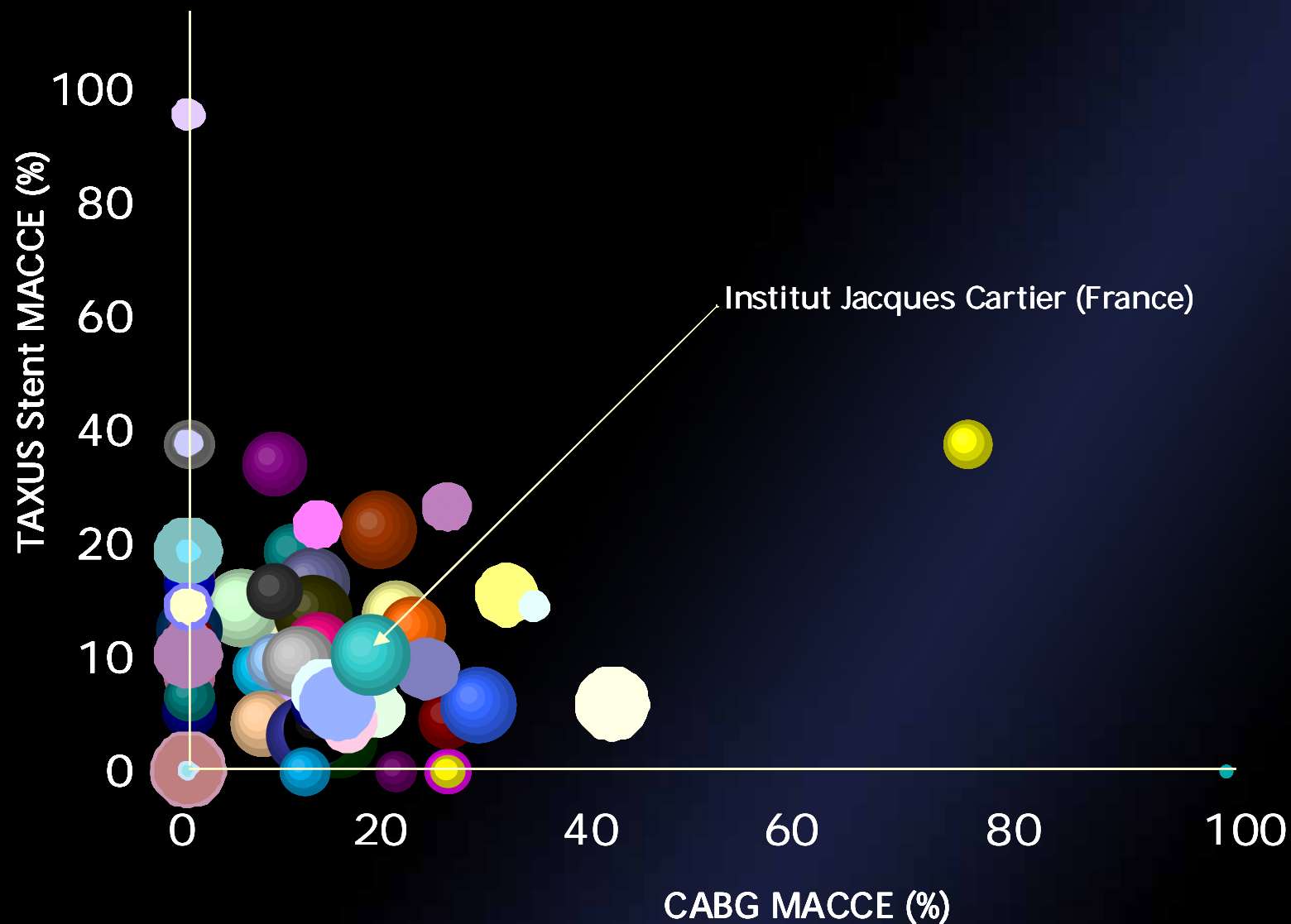
- Similarities

- Need for analysing plaque distribution
- Role of DES
- DES with low LL
- Kissing if double stenting

- Discrepancies

- No consideration about anatomic parameters (in US)
- Role of elective double stenting technique

CLINICAL JUDGEMENT IS CRUCIAL



Take home message

- Recommendations are there to guide you
 - Many possible scenarios
 - Role of local heart team expertise
- Benefit of LM PCI in moderately complex disease is underestimated, particularly if both scores are low
- Discrepancies reflect the grey zones
 - LM : High STS & Syntax score
 - Role of elective double stenting in high-risk bifurcation