Patient-centered decision-making of revascularization strategy for ULMCA or MVD in real-world practice

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Declaration of Interest

- **I have nothing to declare**

Decision of Revascularization in ULMCA or MVD

PRACTICE GUIDELINE

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease

UPLM*		
CABG	I	B
PCI	IIa—For SIHD when *both* of the following are present: • 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 ≥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 *both* of the following are present: • 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 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
3-vessel disease with or without proximal LAD artery disease*		
CABG	I	B
	IIa—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) who are good candidates for CABG.	B
PCI	IIb—Of uncertain benefit	B
2-vessel disease with proximal LAD artery disease*		
CABG	I	B
PCI	IIb—Of uncertain benefit	B

CABG was recommended as more favored treatment option over PCI in ULMCA, 3VD, and 2VD with proximal LAD disease.

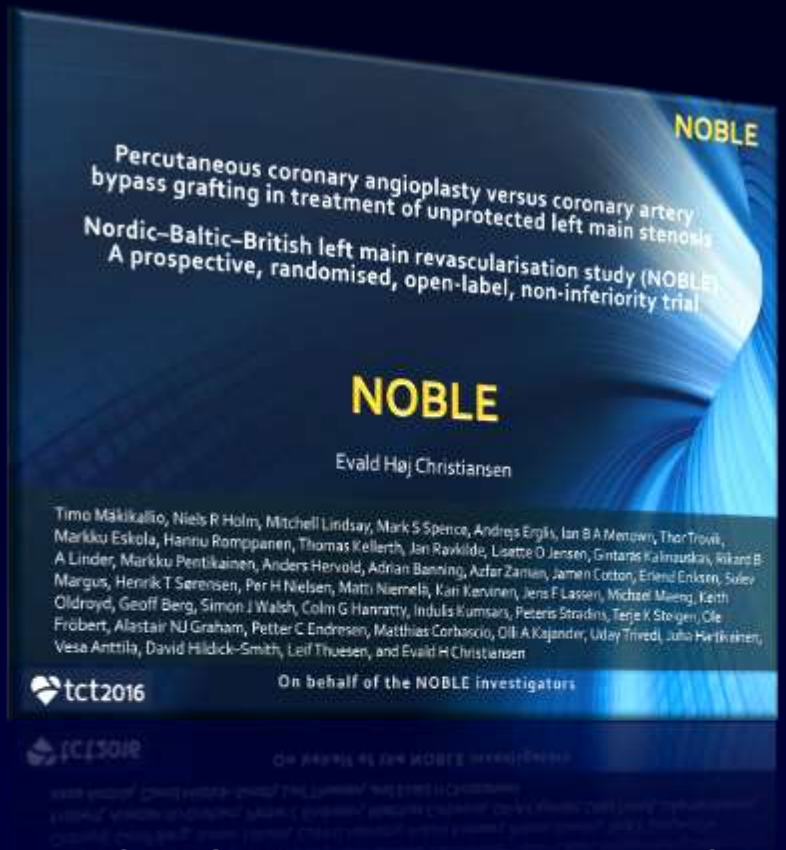
Decision of Revascularization in ULMCA or MVD

2018 ESC/EACTS Guidelines on myocardial revascularization

	CABG		PCI	
Left main CAD				
Left main disease with low SYNTAX score (0 - 22).[69,121,122,124,145–148]	I	A	I	A
Left main disease with intermediate SYNTAX score (23 - 32).[69,121,122,124,145–148]	I	A	IIa	A
Left main disease with high SYNTAX score (≥33).[c 69,121,122,124,146–148]	I	A	III	B
Three-vessel CAD without diabetes mellitus				
Three-vessel disease with low SYNTAX score (0 - 22).[102,105,121,123,124,135,149]	I	A	I	A
Three-vessel disease with intermediate or high SYNTAX score (>22).[c 102,105,121,123,124,135,149]	I	A	III	A
Three-vessel CAD with diabetes mellitus				
Three-vessel disease with low SYNTAX score 0–22.[102,105,121,123,124,135,150–157]	I	A	IIb	A
Three-vessel disease with intermediate or high SYNTAX score (>22).[c 102,105,121,123,124,135,150–157]	I	A	III	A

CABG was recommended as favored treatment option if SYNTAX score with 23 or more.

Conflicting Results of Recent Trials



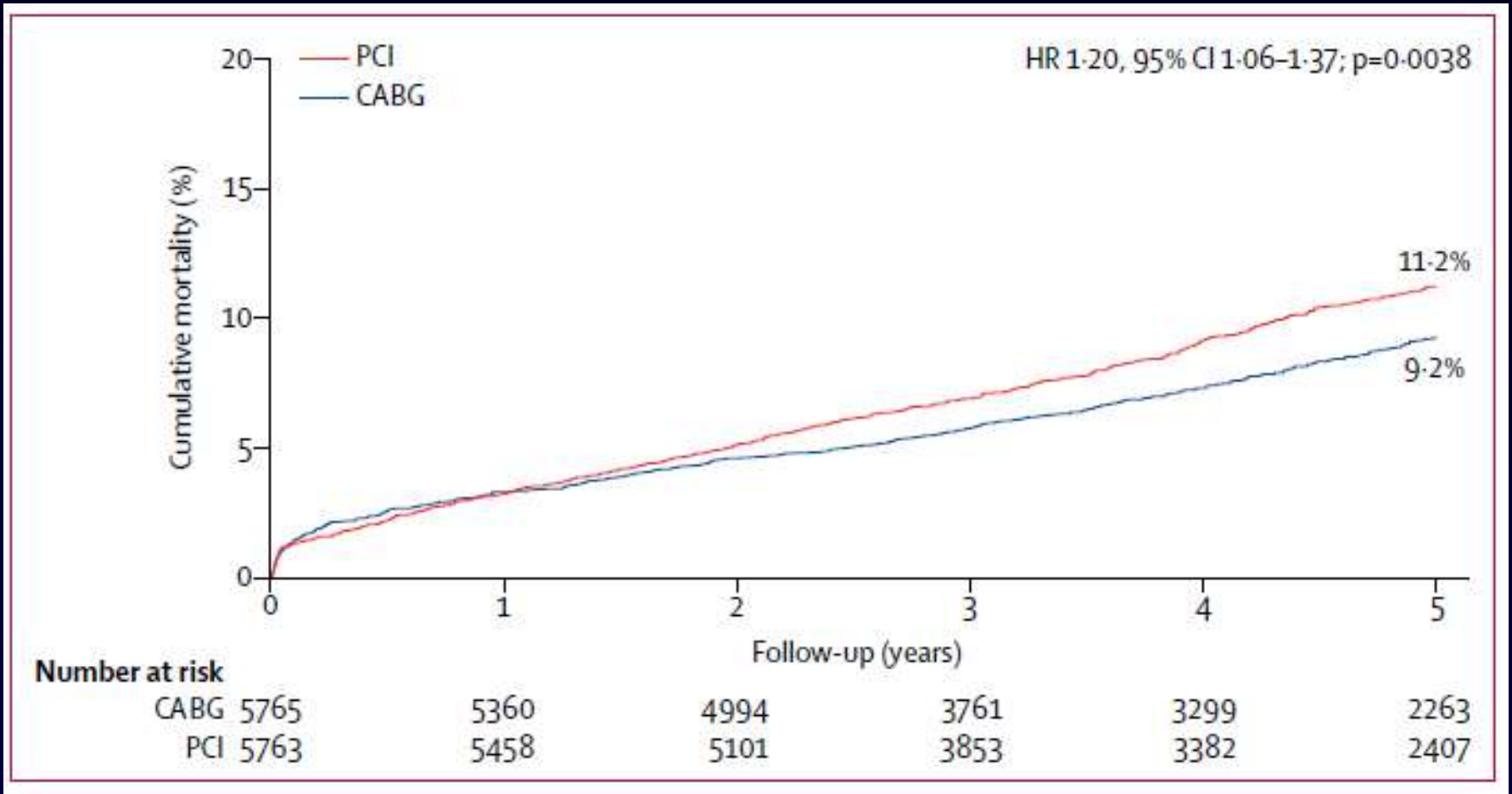
VS

“CABG might be better than PCI”

“PCI was noninferior to CABG”

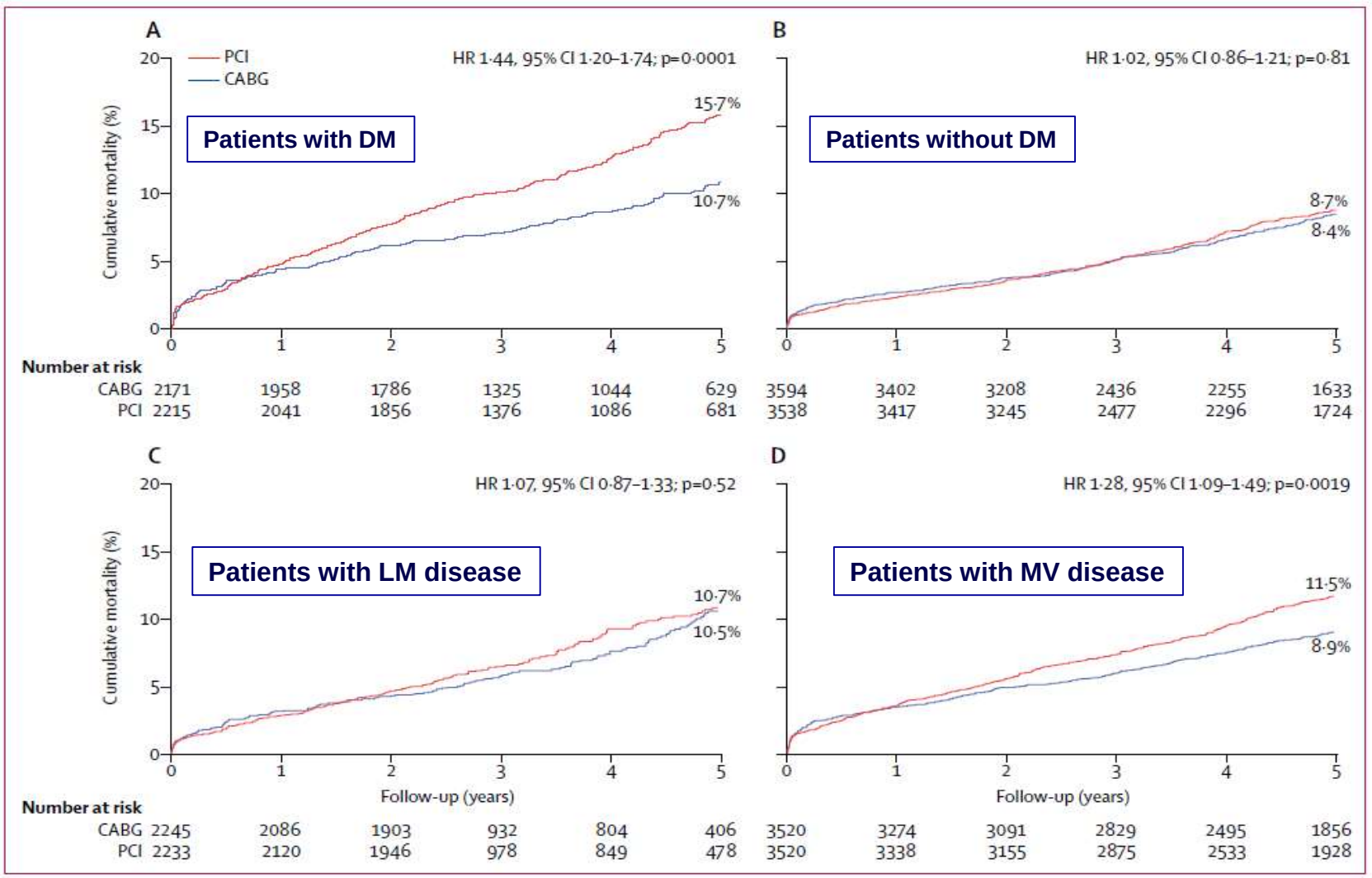
What could we learn from those trials?

Pooled analysis of individual patients data from 11 RCT: Mortality between CABG vs. PCI



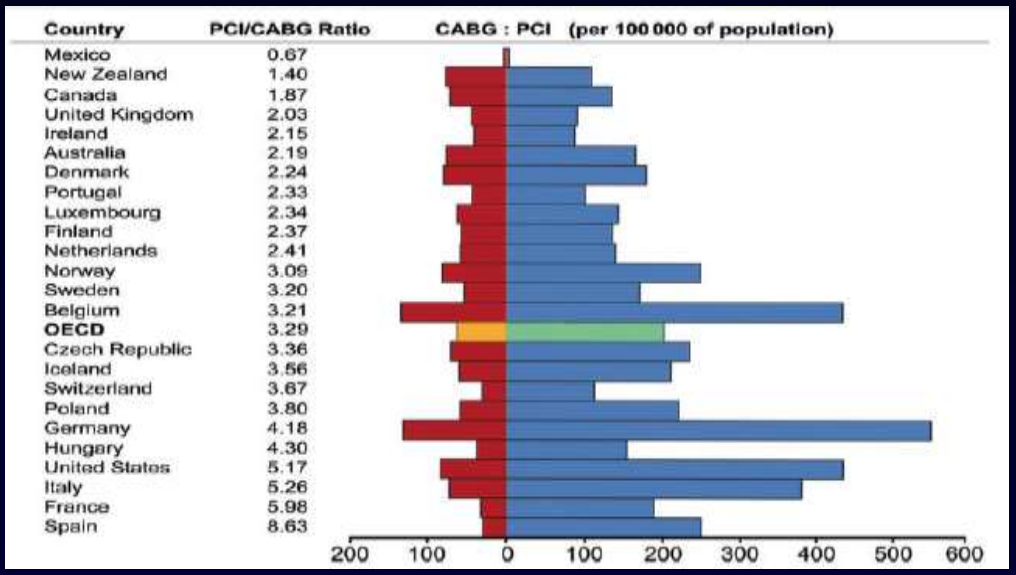
Head SJ, et al. Lancet 2018;391:939-948

Pooled analysis of individual patients data from 11 RCT: Mortality between CABG vs. PCI



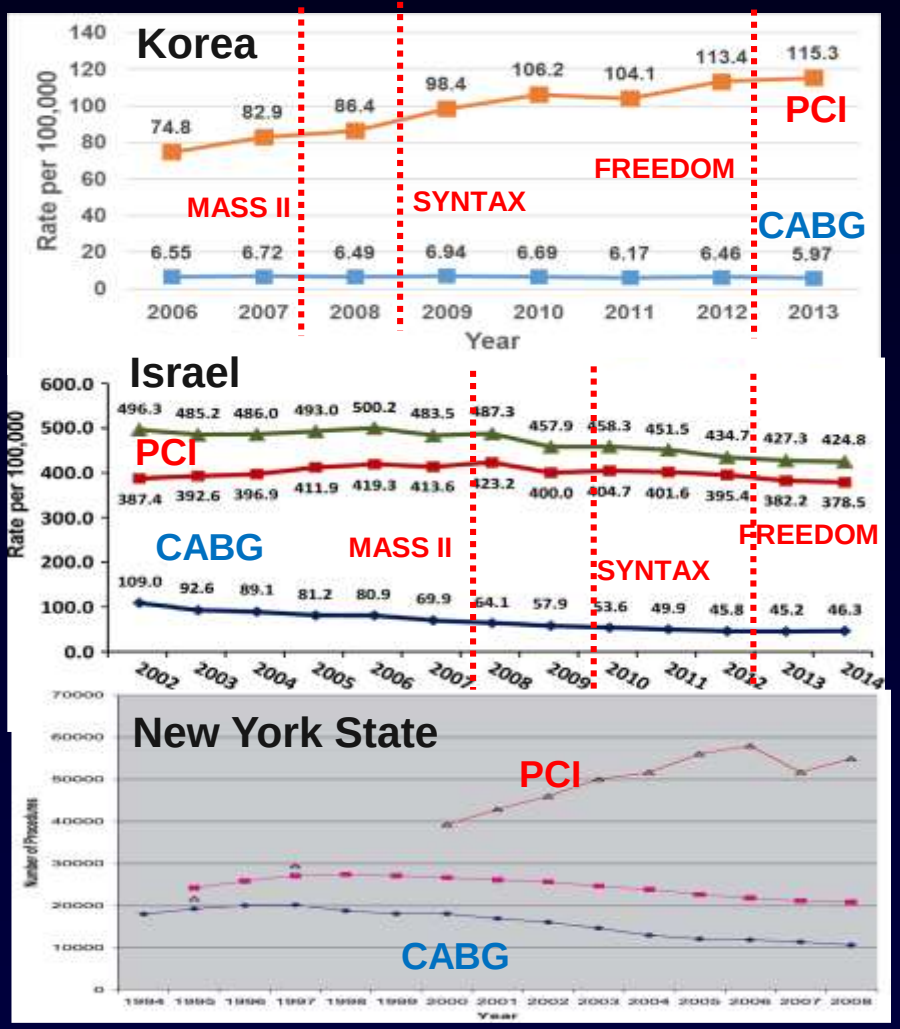
Head SJ, et al. Lancet 2018;391:939-948

Trend of revascularization treatment in real world



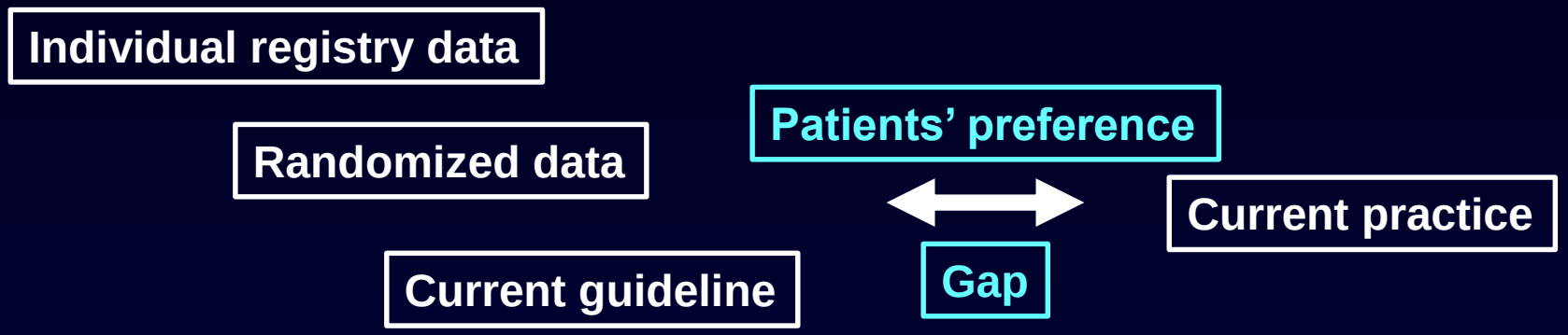
Wide dispersion of PCI-CABG ratio, but common trend with decrease in CABG and corresponding increase in PCI existed.

-> Many cases, candidates for CABG, may have been replaced with PCI cases despite of evidences supporting CABG over PCI.



Ko W et al, J Am Heart Assoc. 2012
Lee H et al, Korean J Thorac Cardiovasc Surg 2016
Blumenfeld O et al, J Am Heart Assoc. 2017

There are largest gaps between academic guideline-based recommendation and daily clinical practice in real world.



Of course, when ALL or MOST patients agree with their clinicians' recommendation, the clinicians never worry about their practice for their patients. However, in reality? Not

Nowadays, patients can very easily access to new medical knowledge, recent advances and improvement of technology in internet, media and newspaper.

When the patients with 3 VD or LM disease and SYNTAX score >23 strongly refuse to take CABG after heart team discussion, what is the best treatment option for this patients, PCI (class III according to guideline) or medical treatment without PCI? Is PCI unethical? Unless, is medical treatment alone ethical?

Up to now, is there any survey to find out patients' preference of treatment strategies in real candidates with ULMCA or MVD?

No

Concept of patient-oriented decision

- Need to provide sufficient information and clear evidences for helping their decision

- Patients should understand that they have authority for decision making of treatment strategy considering their values and preferences.

Suggested processes in our study

1) Need of revascularization
2) Clinical benefit comparing between PCI and CABG
3) Patient-specific risk assessment for each treatment

Standardized protocol for patient's understanding

Step 1) Understanding a need of revascularization

Cardiologist: You need a treatment of obstructive coronary vessels.
You can have a choice between CABG or PCI.

Patient: Which one is better?
Cardiologist: Of course, CABG is better than PCI according to guideline.
(or PCI is comparable as CABG.)

Patient: How much better in CABG than in PCI?

Standardized protocol for patient's understanding

Step 2) Clinical benefit comparing between PCI and CABG

SYNTAX score 0-22	SYNTAX score 23-32	SYNTAX score ≥33
CABG = PCI	CABG > PCI	CABG >> PCI
Evidences	**Evidences**	**Evidences**
Both PCI and CABG are comparably good in long term prognosis.	CABG may be better than PCI in terms of reduction in repeat revascularization and MI.	CABG may be better than PCI in terms of reduction in repeat revascularization, MI, and mortality.
	Rephrasing for patients	**Rephrasing for patients**
	Cardiac surgery will be better than intervention to prevent future incidence of MI and repeat procedure or surgery. Evidences supports more benefit of cardiac surgery than intervention. However, the intervention may be an alternative treatment with comparable long-term survival.	We recommend cardiac surgery. The surgery will be more beneficial if you want to live longer with less risk of MI and repeat procedures. (Intervention may be a feasible alternative, but limited to provide sufficient clinical benefit as cardiac surgery.)

Diabetes mellitus ⇨ **Benefit of CABG may be augmented in patients with DM**

Serruys PW et al., N Engl J Med 2009;360:961-72
Mohr FW et al., Lancet 2013; 381: 629–38
Farkouh ME et al., N Engl J Med 2012;367:2375-84

Standardized protocol for patient's understanding

Step 3) Patient-specific risk assessment in PCI and CABG

Patient: How risky is each treatment?

Cardiologist: CABG have been known to be better than PCI in long-term result. However, we also have considerations about the treatment.

PCI

1) Potential for completeness of revascularization
2) Feasibility - adverse lesion characteristics of target lesions: ISR, bifurcation, heavy calcification, tortuosity…

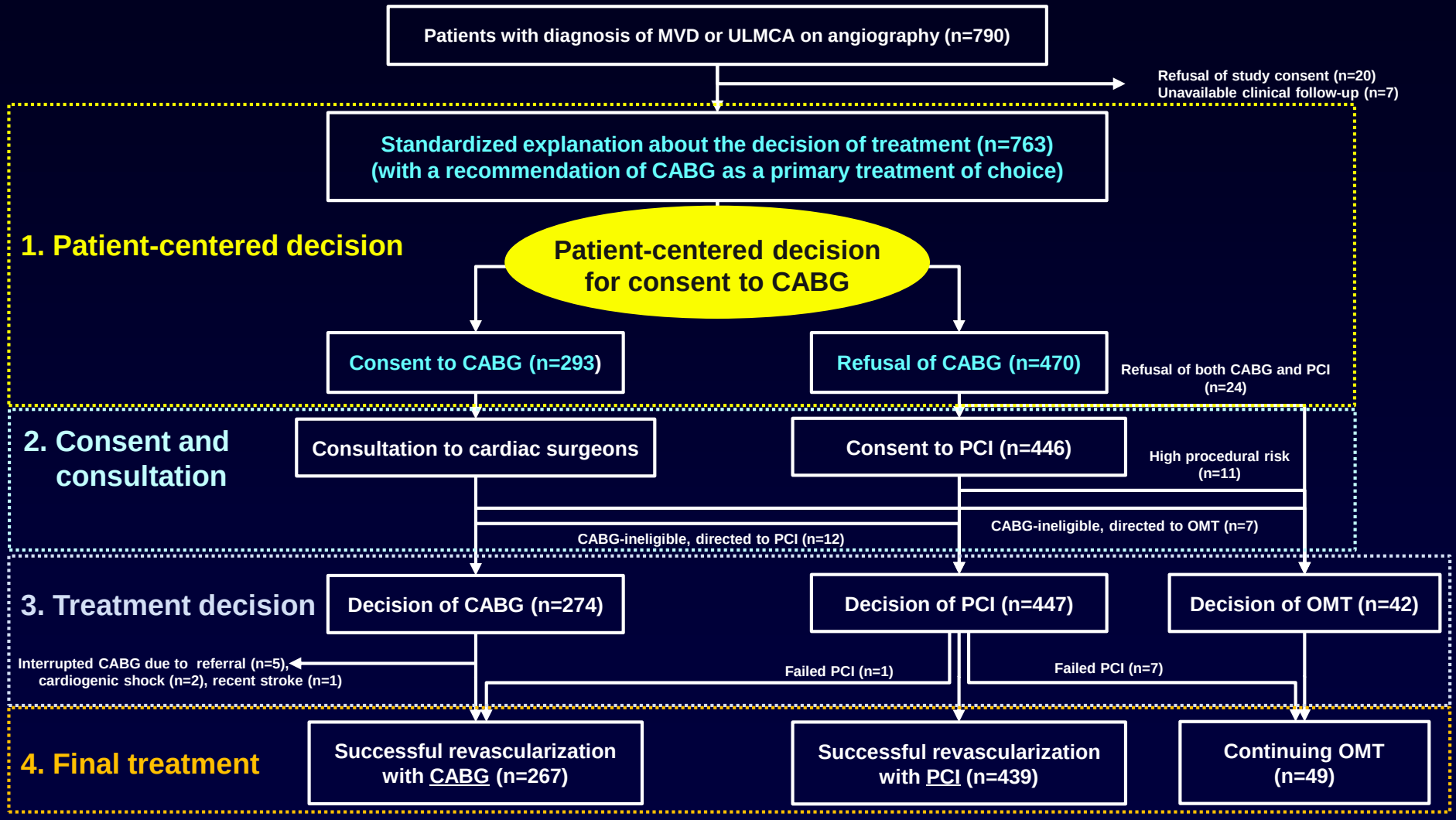
Potential risk of emergent CABG (<0.1%), which may result in substantial risk of mortality (up to 20%) compared to elective CABG

CABG

1) EUROSCORE II for predicting in-hospital mortality
2) Other potential risk factors (e.g. immunocompromise, frailty, chronic liver disease. anemia, other comorbidities)

Patient-Centered Decision Registry

(clinicaltrials.gov Identifier: NCT02410993)



Kim C, Hong MK (corresponding author), et al. *Am J Cardiol* 2018;122:2005-2013

Baseline characteristics

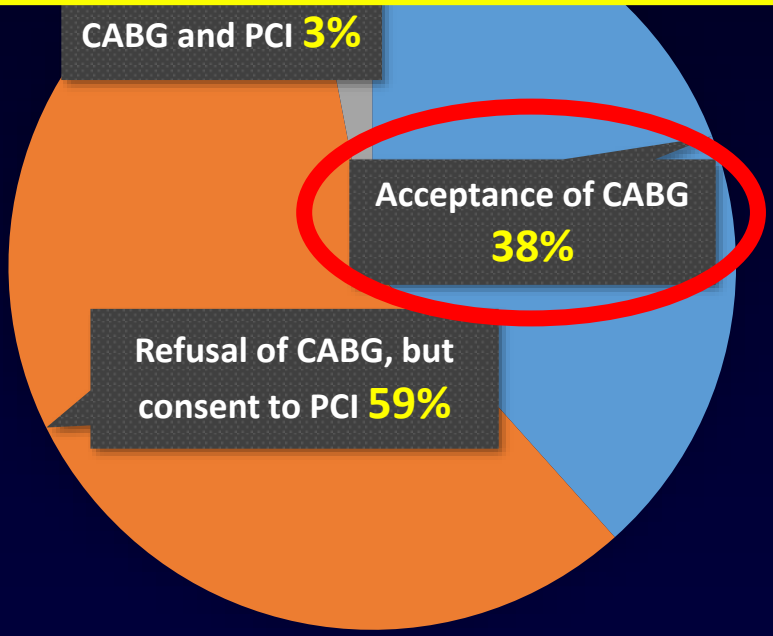
Variables	Consent to CABG		p
	Yes (n=293)	No (n=470)	
Age, years	66 (60-74)	67 (59-74)	0.933
Male	210 (72%)	357 (76%)	0.218
Hypertension	215 (73%)	322 (69%)	0.177
Diabetes mellitus	154 (53%)	186 (40%)	0.001
Chronic kidney disease	32 (11%)	36 (8%)	0.159
Previous PCI	56 (19%)	77 (16%)	0.385
Prior myocardial infarction	22 (8%)	29 (6%)	0.568
Clinical diagnosis			<0.001
Stable angina	138 (47%)	202 (43%)	
Unstable angina	76 (26%)	187 (40%)	
Acute non-ST elevation MI	61 (21%)	69 (15%)	
Recent MI	18 (6%)	12 (3%)	

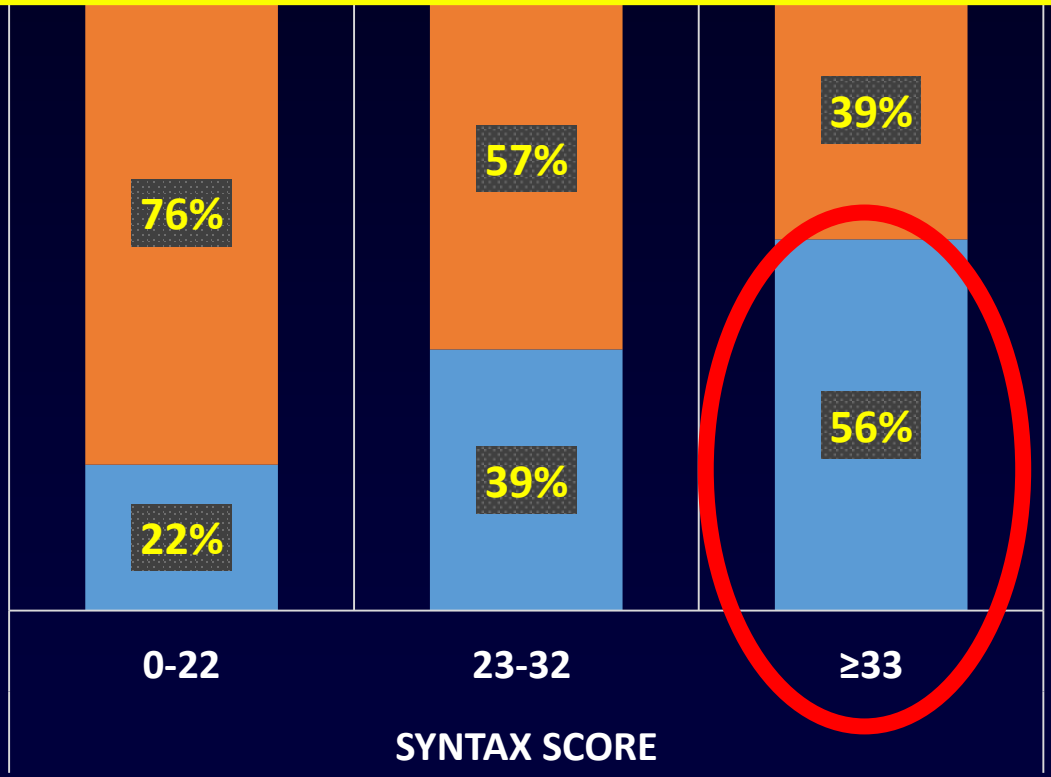
Baseline characteristics

Variables	Consent to CABG		p
	Yes (n=293)	No (n=470)	
CCS classification III or IV	104 (39%)	138 (29%)	0.024
LVEF, %	56 (44-66)	62 (52-69)	<0.001
EuroSCORE II, %	1.3 (0.8-2.6)	1.0 (0.7-1.8)	<0.001
SYNTAX score	32 (24-42)	24 (17-31)	<0.001
0-22	66 (23%)	230 (49%)	<0.001
23-32	84 (29%)	129 (27%)	
≥33	143 (49%)	111 (24%)	
Unprotected left main disease	87 (30%)	141 (30%)	0.993
Chronic total occlusion	132 (45%)	119 (25%)	<0.001

Initial decision by patient-centered protocol

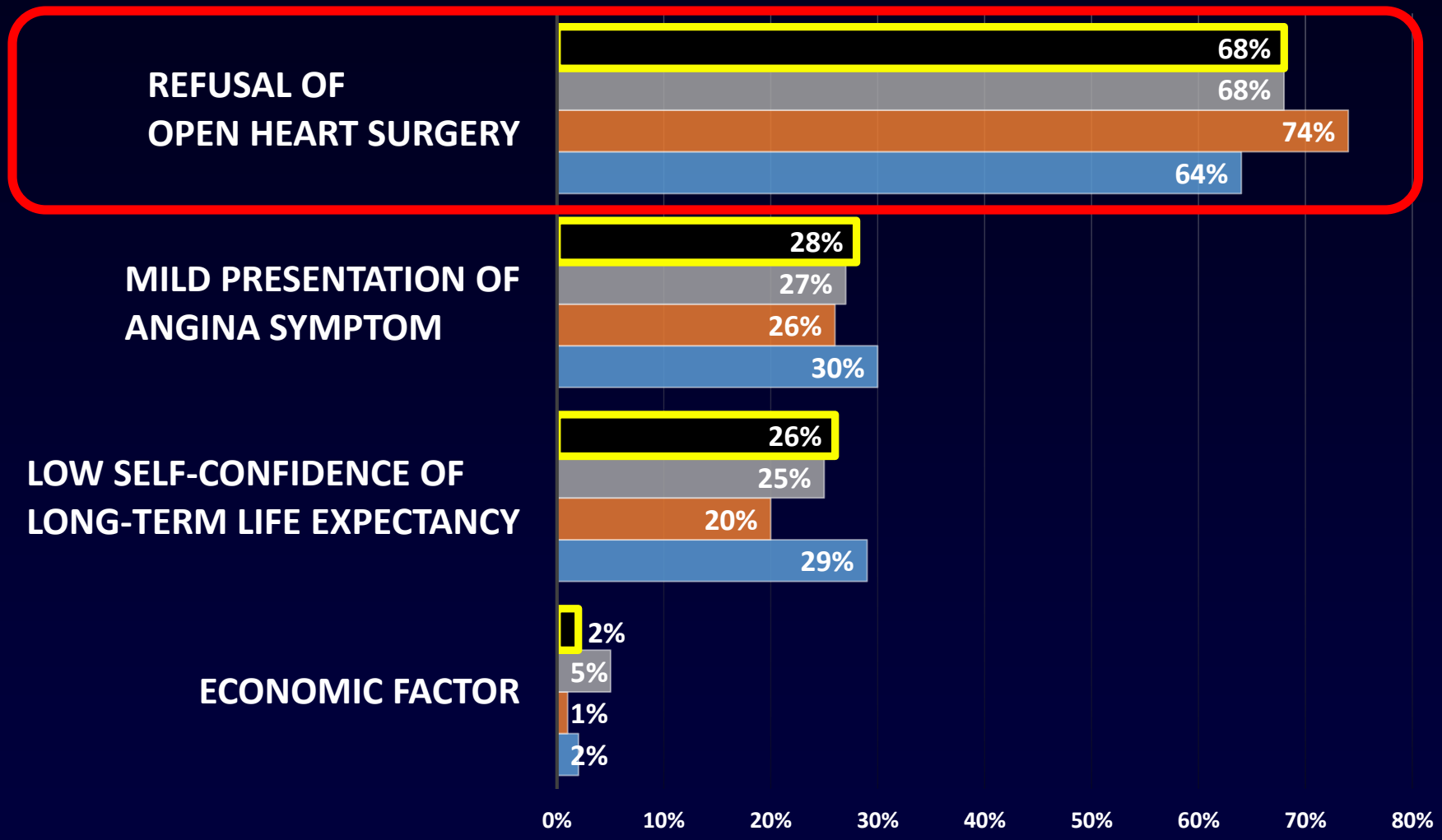
**Only 38% patients in overall patients,
56% patients in patients with high SYNTAX score
consented to CABG surgery**





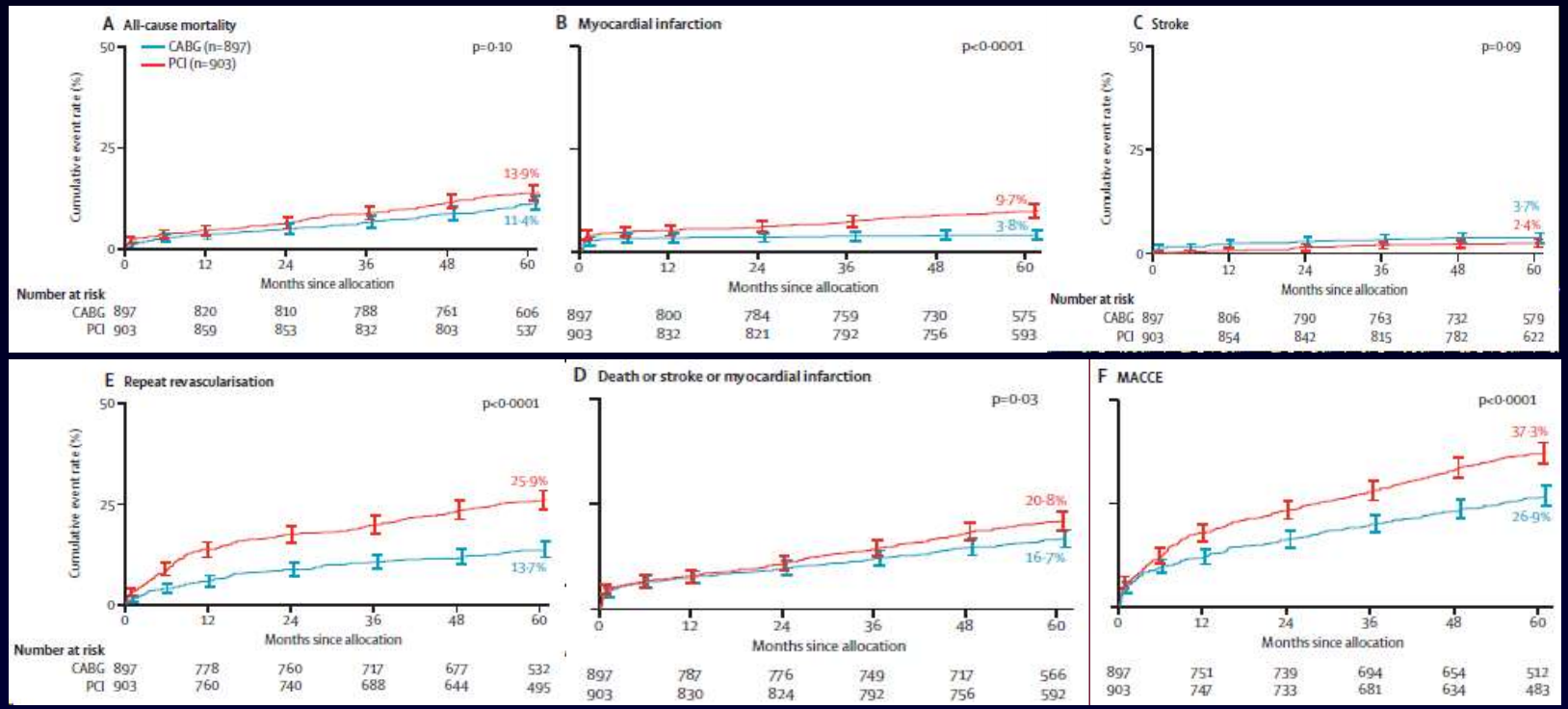
Kim C, Hong MK (corresponding author), et al.
Am J Cardiol 2018;122:2005-2013

Reasons for declining CABG



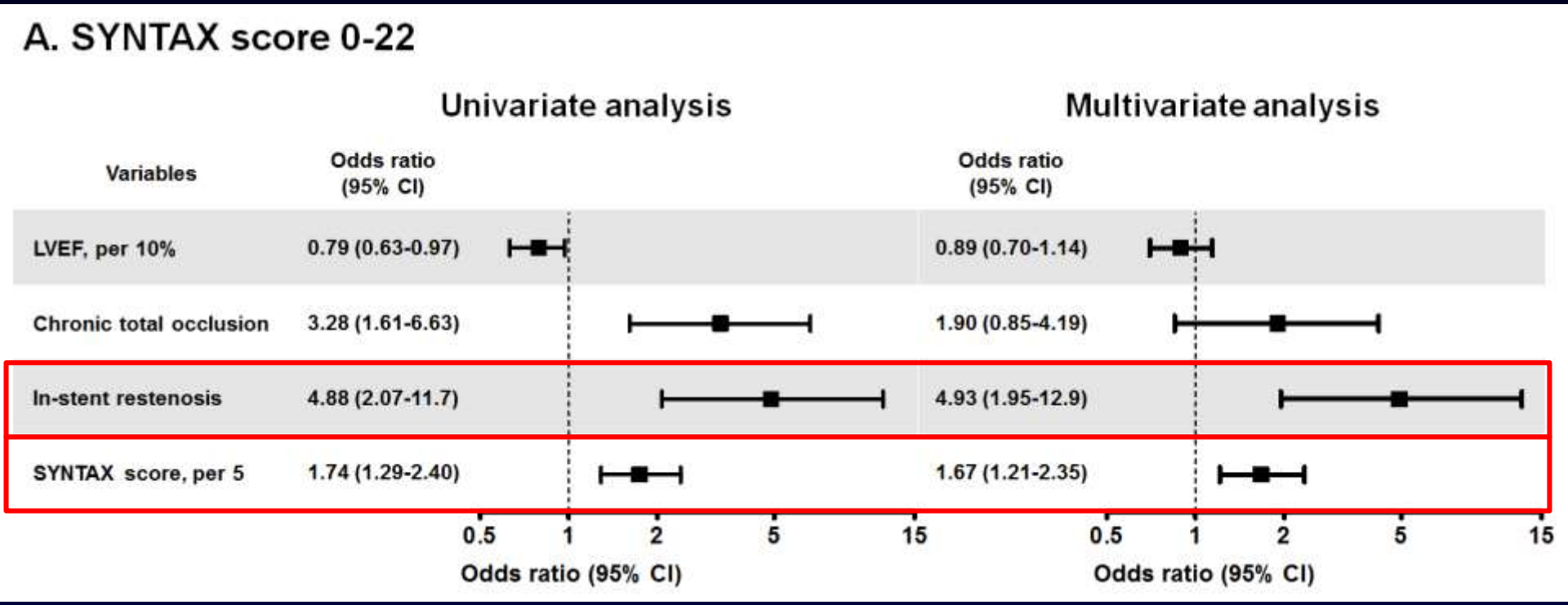
Kim C, Hong MK (corresponding author), et al. *Am J Cardiol* 2018;122:2005-2013

SYNTAX trial: Five years follow-up



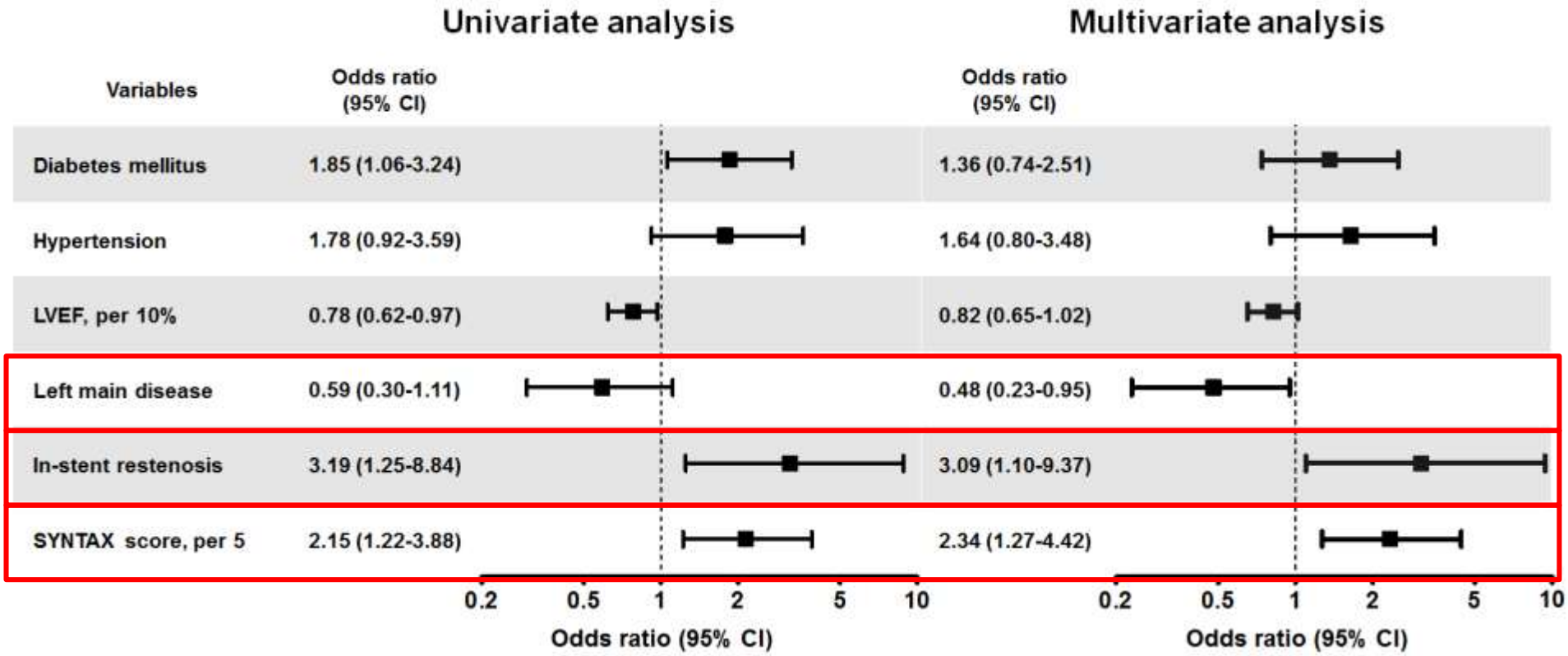
Patients' response: Anyhow, they want to select **PCI first rather than CABG** if there is no significant difference of mortality between the two treatment modalities. When the restenosis may occur during 5 year follow-up, and then they will seriously consider to take CABG. Unless the restenosis may occur, they may be happy.

Influential factors for decision of CABG
in patients with SYNTAX score 0-22



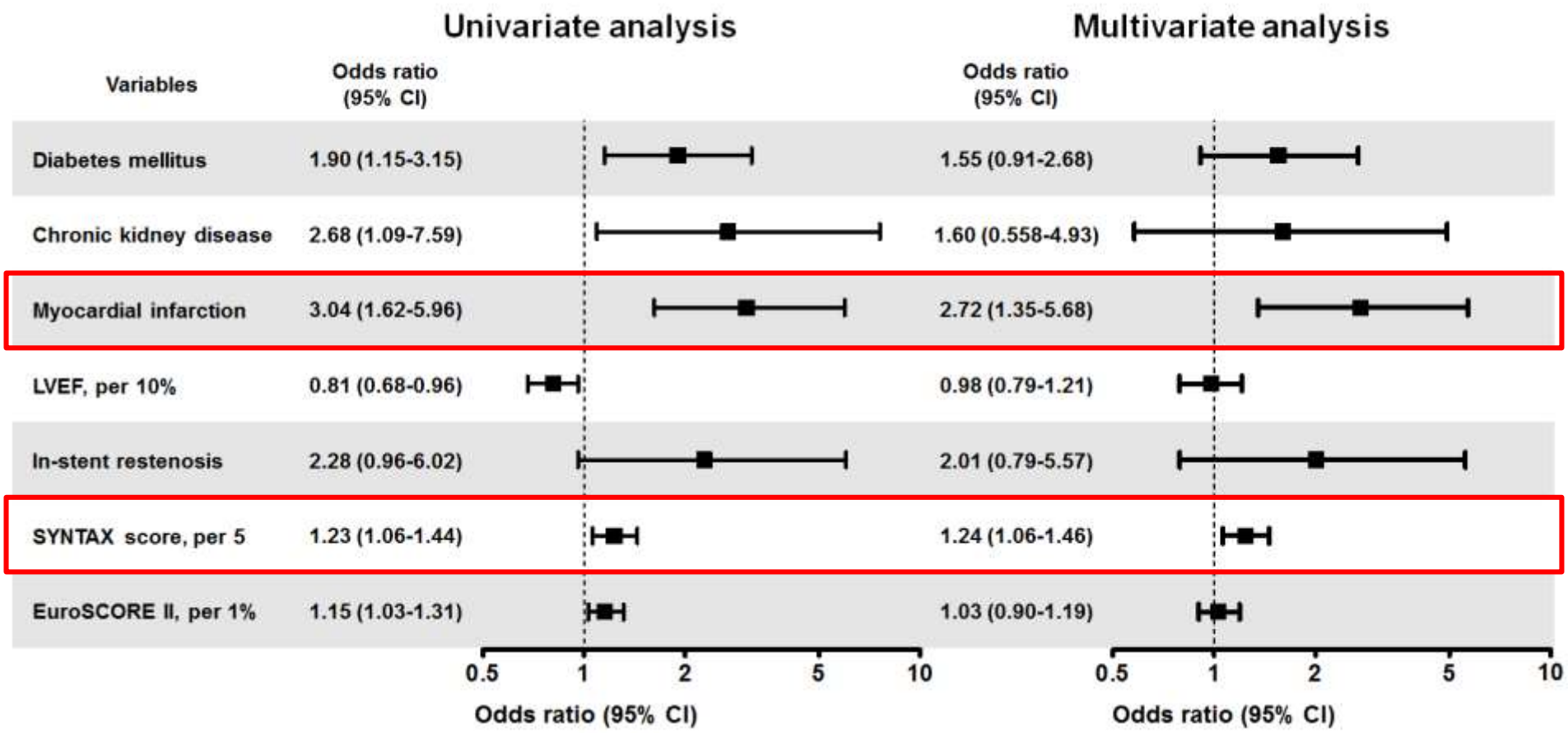
Influential factors for decision of CABG
in patients with SYNTAX score 23-32

B. SYNTAX score 23-32



Influential factors for decision of CABG
in patients with SYNTAX score ≥33

C. SYNTAX score ≥33



Clinical outcomes within 30 days after treatment

Outcomes	Consent to CABG		p
	Yes (n=288)	No (n=470)	
MACCEs	2 (1%)	6 (1%)	0.693
All-cause death	2 (1%)	5 (1%)	0.673
Myocardial infarction	0 (0%)	2 (0%)	0.705
Stroke	0 (0%)	1 (0%)	>0.999
Any repeat revascularization	0 (0%)	0 (0%)	>0.999

Outcomes	Final treatment		p
	CABG (n=267)	PCI (n=439)	
MACCEs	2 (1%)	6 (1%)	0.700
All-cause death	2 (1%)	5 (1%)	0.908
Myocardial infarction	0 (0%)	2 (0%)	0.708
Stroke	0 (0%)	1 (0%)	>0.999
Any repeat revascularization	0 (0%)	0 (0%)	>0.999

Conclusions

- For the decision of revascularization strategy for complex coronary disease, we need to consider variable factors including patient's value and preference as well as clinical elements.
- The authority for decision making of treatment strategy is needed to move on to patient-centered discussion.
- Only 38% patients in overall patients, or 56% patients even in patients with high SYNTAX score consented to CABG surgery when sufficient information and discretion was provided before clinician's suggestion.


Dreams will
come true