

# Τι φέρνουν οι μελέτες NOBLE και EXCEL στην αορτοστεφανιαία παράκαμψη?



ΕΝΩΣΗ ΕΠΙΣΤΗΜΟΝΙΚΟΥ ΠΡΟΣΩΠΙΚΟΥ  
Γ.Ν.Α. «Ο ΕΥΑΓΓΕΛΙΣΜΟΣ» (Ε.Ε.Π.Ν.Ε.)

**25<sup>ο</sup>** *ΕΤΗΣΙΟ ΣΕΜΙΝΑΡΙΟ  
ΣΥΝΕΧΙΖΟΜΕΝΗΣ  
ΙΑΤΡΙΚΗΣ ΕΚΠΑΙΔΕΥΣΗΣ  
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ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ ΑΘΗΝΩΝ  
**Ο ΕΥΑΓΓΕΛΙΣΜΟΣ**

**ΕΙΣΗΓΗΤΗΣ: ΣΧΙΖΑΣ ΝΙΚΟΛΑΟΣ,  
ΕΙΔ/ΝΟΣ ΧΕΙΡΟΥΡΓΙΚΗΣ ΘΩΡΑΚΟΣ , MSC  
ΚΑΡΔΙΟΧΕΙΡΟΥΡΓΙΚΗ ΚΛΙΝΙΚΗ ΓΝΑ ΕΥΑΓΓΕΛΙΣΜΟΣ**



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Δεν υπάρχει σύγκρουση συμφερόντων με τις Χορηγούς Εταιρείες:



# Introduction

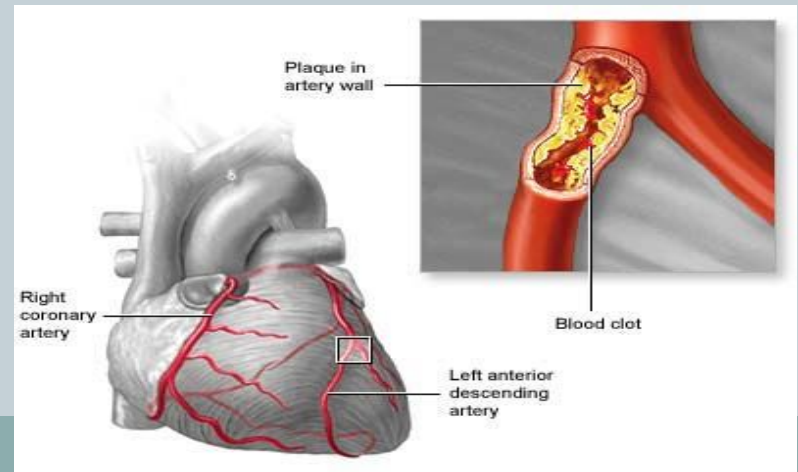


- **LMD with  $\geq 50\%$  stenosis is prevalent in 4–7% of patients who undergo coronary angiography.**

Mikikallio T, Holm NR, Lindsay M, et al. Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial. *Lancet* 2016;388:2743-52..

- **Non-revascularized LMD has been associated with significant comorbidity and 5-year mortality approaching 60%.**

Bruschke AV, Proudfit WL, Sones FM Jr. Progress study of 590 consecutive nonsurgical cases of coronary disease followed 5–9 years. II. Ventriculographic and other correlations. *Circulation* 1973;47:1154-63.

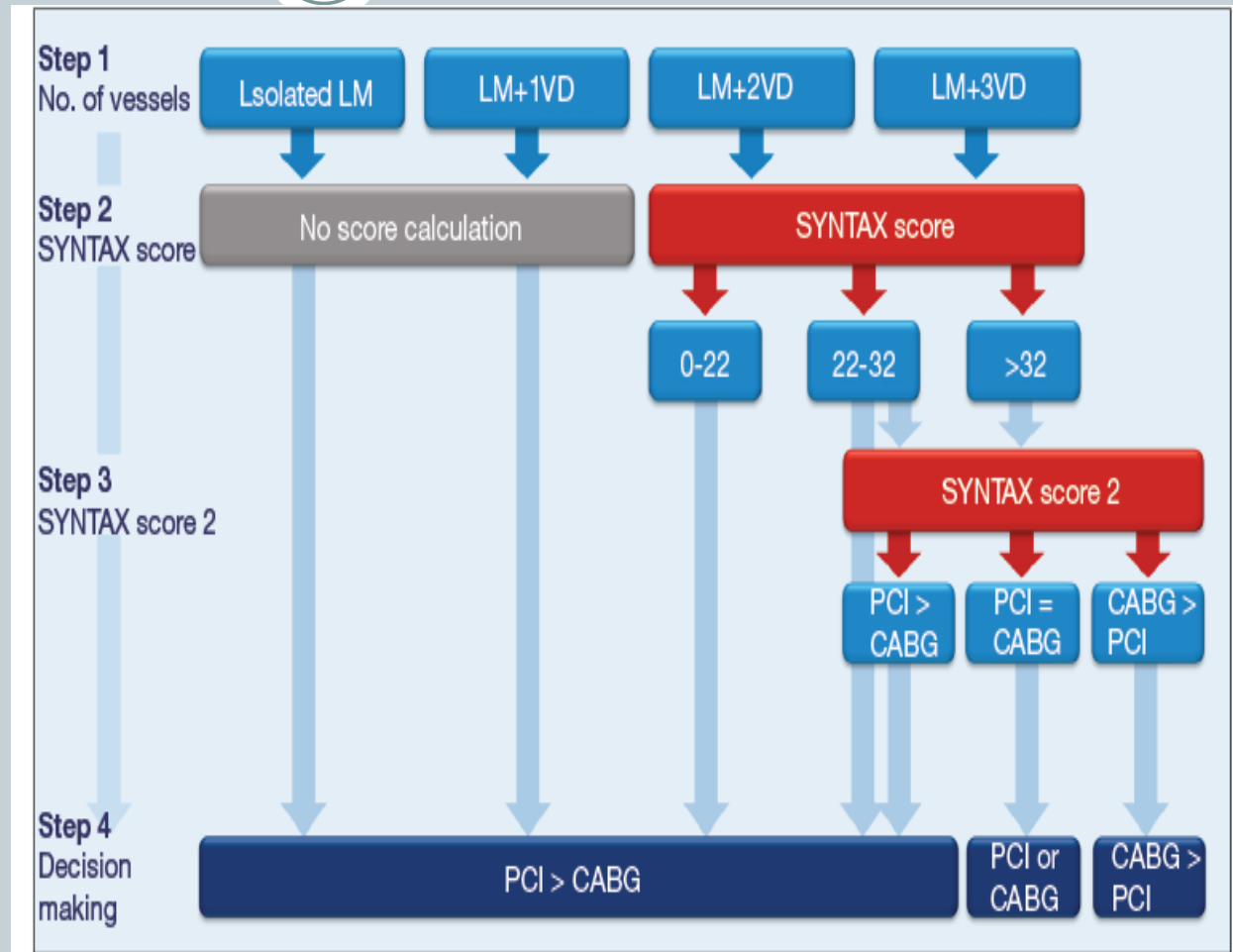


# Triaging of patients

CABG, the historical gold standard for LMD

VS

PCI of the LM is a relatively quick procedure in expert hands



Capodanno D., 2017 Triaging patients with left main disease after the EXCEL and NOBLE trials: the everlasting saga of coronary artery bypass grafting and percutaneous coronary intervention.

# Clinical trials



**Table 4** Randomized clinical trials comparing percutaneous coronary intervention with drug-eluting stents vs. surgical revascularization

Stent type and year of publication	Study	N	Baseline characteristics					Primary endpoint <sup>a</sup>			Secondary endpoints <sup>a</sup>				
			Age (y)	Women (%)	Diabetes (%)	MV disease (%)	EF (%)	Definition	Y	Results	Y	Death	MI	Revasc	Stroke
<b>DES</b>															
PES 2009	SYNTAX <sup>102</sup>	1800	65	22	25	MV 61 LM 39	-	Death, MI, stroke, or repeat revasc	1	17.8 vs. 12.4%	5	13.9 vs. 11.4%	9.7 vs. 3.8%*	25.9 vs. 13.7%*	2.4 vs. 3.7%
SES 2011	Boudriot <sup>103</sup>	201	68	25	36	LM 100	65	Death, MI, or repeat revasc	1	13.9 vs. 19%	1	2 vs. 5%	3 vs. 3%	14 vs. 5.9%	-
SES 2011	PRECOMBAT <sup>104</sup>	600	62	24	32	LM 100	61	Death, MI, stroke, or TVR	1	8.7 vs. 6.7% <sup>b</sup>	2	2.4 vs. 3.4%	1.7 vs. 1.0%	9.0 vs. 4.2%*	0.4 vs. 0.7%
EES 2015	BEST <sup>105</sup>	880	64	29	41	MV 100	60	Death, MI, or TVR	2	11.0 vs. 7.9%	5	6.6 vs. 5.0%	4.8 vs. 2.7%	13.4 vs. 6.6%	2.9 vs. 3.3%
BES 2016	NOBLE <sup>106</sup>	1201	66	22	15	LM 100	60	Death, MI, or TVR	5	15.4 vs. 7.2%	5	11.6 vs. 9.5%	6.9 vs. 1.9% <sup>*c</sup>	16.2 vs. 10.4%*	4.9 vs. 1.7%
EES 2016	EXCEL <sup>107</sup>	1905	66	24	30	LM 100	57	Death, MI, or stroke	3	15.4 vs. 14.7% <sup>b</sup>	3	8.2 vs. 5.9%	8.0 vs. 8.3%	13.4 vs. 6.6%*	2.3 vs. 2.9%

Age and EF are reported as means.

<sup>a</sup>P < 0.05.

<sup>b</sup>ES = biolimus-eluting stents; BEST = Randomised Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Artery Disease; DES = drug-eluting stents; EES = everolimus-eluting stent; EF = ejection fraction; EXCEL = Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization; LM = left main coronary artery disease; MI = myocardial infarction; MV = multivessel coronary artery disease; NOBLE = Nordic-Baltic-British Left Main Revascularization Study; PES = paclitaxel-eluting stents; PRECOMBAT = Premier of Randomised Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease; Revasc = revascularization; SES = sirolimus-eluting stents; SYNTAX = Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; TVR = target vessel revascularization; Y = years.

<sup>c</sup>Results are reported as percutaneous coronary intervention vs. coronary artery bypass grafting.

<sup>d</sup>Non-inferiority met.

<sup>e</sup>Non-procedural MI (exclusion of periprocedural MI).



# NOBLE VS EXCEL



## Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial



*Timo Mäkkilä, Niels R Holm, Mitchell Lindsay, Mark S Spence, Andrejs Erglis, Ian B A Menown, Thor Trovik, Mariku Eskola, Hannu Romppanen, Thomas Kellerth, Jan Ravkilde, Lisette O Jensen, Gintaras Kalinauskas, Rikard B A Lind, Markku Pentikainen, Anders Hervold, Adrian Danning, Azfar Zaman, James Cotton, Erlend Eriksen, Sulev Margus, Henrik T Sørensen, Per H Nielsen, Matti Niemelä, Kari Keränen, Jens F Lassen, Michael Maeng, Keith Oldroyd, Geoff Berg, Simon J Walsh, Colm G Harratty, Indulis Kurmārs, Peteris Stradins, Terje K Steigen, Ole Frøbert, Alastair N J Graham, Petter C Endresen, Matthias Corbascio, Olli Kajander, Uday Trivedi, Juha Hartikainen, Vesa Anttila, David Hildick-Smith, Lef Thuesen, Evald H Christiansen, for the NOBLE study investigators\**

## Percutaneous coronary angioplasty versus coronary artery bypass grafting in the treatment of unprotected left main stenosis: updated 5-year outcomes from the randomised, non-inferiority NOBLE trial



*Niels R Holm, Timo Mäkkilä, M Mitchell Lindsay, Mark S Spence, Andrejs Erglis, Ian B A Menown, Thor Trovik, Thomas Kellerth, Gintaras Kalinauskas, Lone Juul Hune Mogensen, Per H Nielsen, Matti Niemelä, Jens F Lassen, Keith Oldroyd, Geoffrey Berg, Peteris Stradins, Simon J Walsh, Alastair N J Graham, Petter C Endresen, Ole Frøbert, Uday Trivedi, Vesa Anttila, David Hildick-Smith, Lef Thuesen, Evald H Christiansen, for the NOBLE investigators\**

## The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

DECEMBER 8, 2016

VOL. 375 NO. 23

### Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

G.W. Stone, J.F. Sabik, P.W. Serruys, C.A. Simonton, P. Généreux, J. Puskas, D.E. Kandzari, M.-C. Morice, N. Lembo, W.M. Brown III, D.P. Taggart, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.J. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P. Buszman, A. Bochenek, E. Schampaert, P. Pagé, O. Dressler, I. Kosmidou, R. Mehran, S.J. Pocock, and A.P. Kappetein, for the EXCEL Trial Investigators\*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

### Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease

G.W. Stone, A.P. Kappetein, J.F. Sabik, S.J. Pocock, M.-C. Morice, J. Puskas, D.E. Kandzari, D. Karpaliotis, W.M. Brown III, N.J. Lembo, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.J. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P.E. Buszman, A. Bochenek, E. Schampaert, P. Pagé, R. Modolo, J. Gregson, C.A. Simonton, R. Mehran, I. Kosmidou, P. Généreux, A. Crowley, O. Dressler, and P.W. Serruys, for the EXCEL Trial Investigators\*

# NOBLE VS EXCEL



**Table 1** Comparison of EXCEL and NOBLE trials.

	EXCEL	NOBLE
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>- Significant unprotected left main coronary artery (ULMCA) disease or left main equivalent disease</li> <li>- Clinical and anatomic eligibility for both PCI and CABG as agreed to by the local Heart Team</li> <li>- Silent ischemia, stable angina, unstable angina, recent MI with normalization of CK-MB prior randomization</li> <li>- In addition to randomized patients it also include universal registry.</li> </ul>	<ul style="list-style-type: none"> <li>- Stable, unstable angina pectoris or Acute coronary syndrome</li> <li>- Significant unprotected left main coronary artery (ULMCA) with no more than three additional non-complex PCI lesions</li> <li>- Patient eligible to be treated by CABG and by PCI</li> </ul>
<b>Main exclusion criteria</b>	<ul style="list-style-type: none"> <li>- Prior PCI of the left main at any time prior to randomization or prior PCI of any other (non-left main) coronary artery lesions within one year prior to randomization</li> <li>- Prior CABG</li> <li>- Need for any concomitant cardiac surgery</li> <li>- Inability to receive dual antiplatelet therapy for at least one year</li> <li>- Pregnancy or intention to become pregnant</li> <li>- Life expectancy less than 3 years</li> </ul>	<ul style="list-style-type: none"> <li>- ST-elevation infarction within 24 h</li> <li>- Patient is too high risk for CABG</li> <li>- Expected survival less than one year</li> <li>- Allergy to aspirin, clopidogrel or ticlopidine</li> </ul>
<b>Angiographic exclusion criteria</b>	<ul style="list-style-type: none"> <li>- SYNTAX score <math>\geq 33</math></li> <li>- Visually estimated left main reference vessel diameter <math>&lt; 2.25</math> mm or <math>&gt; 4.25</math> mm (post-dilatation up to 4.5 mm is allowed)</li> </ul>	<ul style="list-style-type: none"> <li>- CABG clearly better treatment option (LMCA stenosis and <math>&gt;3</math>, or complex additional coronary lesions)</li> </ul>
<b>Primary end point</b>	<ul style="list-style-type: none"> <li>- Death, MI and stroke</li> </ul>	<ul style="list-style-type: none"> <li>- Death, stroke, non-procedural MI and new revascularisation (PCI or CABG)</li> </ul>
<b>Sample size</b>	1,905 patients	1,200 patients
<b>Participating centres</b>	131 active sites worldwide	36
<b>Main results</b>	At 3 years, a primary end-point event had occurred in 15.4% of the patients in the PCI group and in 14.7% of the patients in the CABG group	At 5 years, primary end points occurred in 28% of the patients in PCI group and in 18% of the patients in the CABG group
<b>Conclusion</b>	In patients with left main coronary artery disease and low or intermediate SYNTAX scores, PCI was non inferior to CABG	CABG might be better than PCI for treatment of left main stem coronary artery disease.

# NOBLE



## Percutaneous coronary angioplasty versus coronary artery bypass grafting in the treatment of unprotected left main stenosis: updated 5-year outcomes from the randomised, non-inferiority NOBLE trial



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**Interpretation** In revascularisation of left main coronary artery disease, PCI was associated with an inferior clinical outcome at 5 years compared with CABG. Mortality was similar after the two procedures but patients treated with PCI had higher rates of non-procedural myocardial infarction and repeat revascularisation.



# EXCEL



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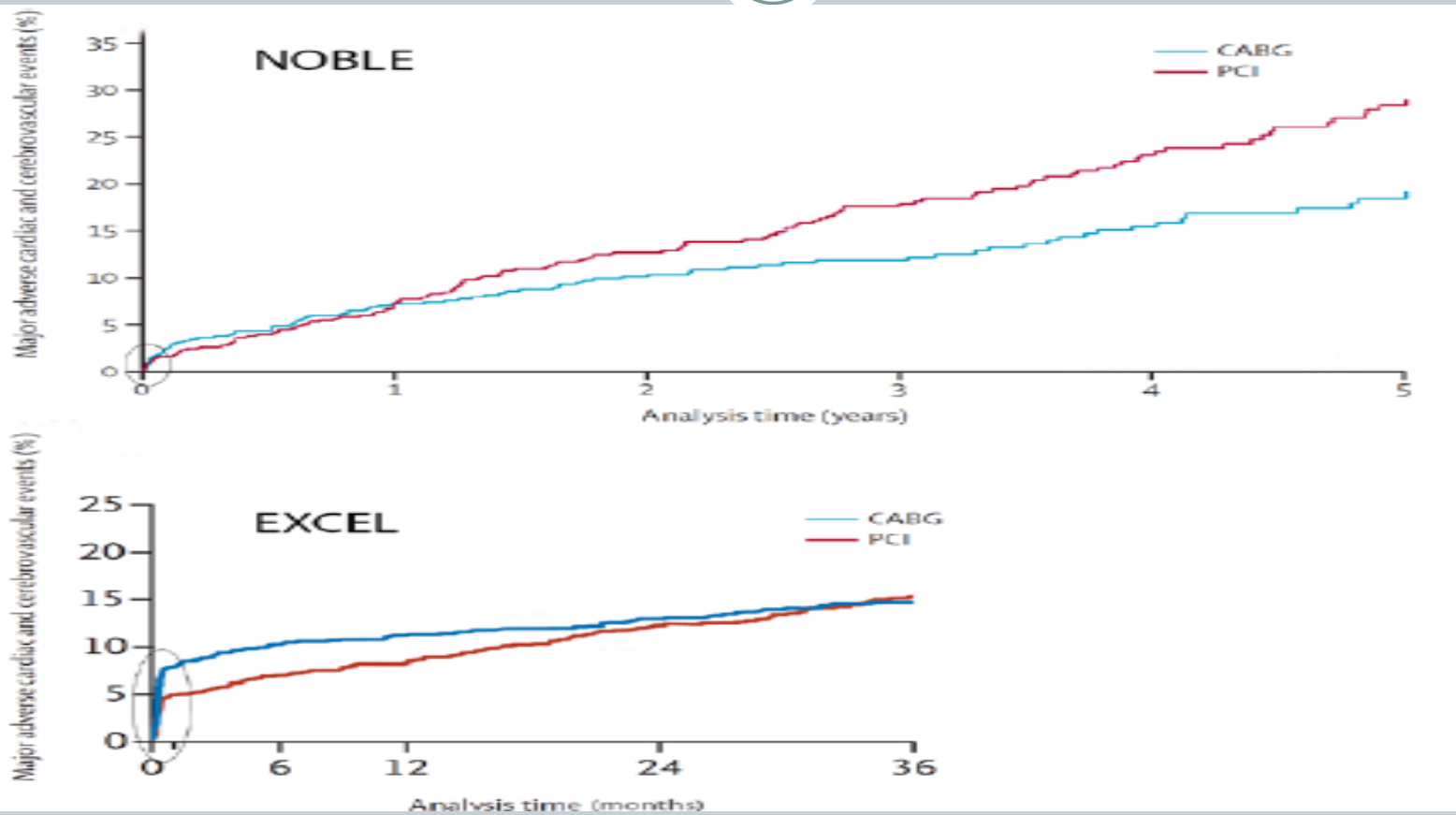
ORIGINAL ARTICLE

## Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease

G.W. Stone, A.P. Kappetein, J.F. Sabik, S.J. Pocock, M.-C. Morice, J. Puskas, D.E. Kandzari, D. Karpaliotis, W.M. Brown III, N.J. Lembo, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.J. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P.E. Buszman, A. Bochenek, E. Schampaert, P. Pagé, R. Modolo, J. Gregson, C.A. Simonton, R. Mehran, I. Kosmidou, P. Généreux, A. Crowley, O. Dressler, and P.W. Serruys, for the EXCEL Trial Investigators\*

### CONCLUSIONS

In patients with left main coronary artery disease of low or intermediate anatomical complexity, there was no significant difference between PCI and CABG with respect to the rate of the composite outcome of death, stroke, or myocardial infarction at 5 years. (Funded by Abbott Vascular; EXCEL ClinicalTrials.gov number, NCT01205776.)



# Guidelines ESC / EACTS

Recommendation for the type of revascularization in patients with stable coronary artery disease with suitable coronary anatomy for both procedures and low predicted surgical mortality<sup>d</sup>

Recommendations according to extent of CAD	CABG		PCI	
	Class <sup>a</sup>	Level <sup>b</sup>	Class <sup>a</sup>	Level <sup>b</sup>
<b>One-vessel CAD</b>				
Without proximal LAD stenosis.	IIb	C	I	C
With proximal LAD stenosis. <sup>68,101,139-144</sup>	I	A	I	A
<b>Two-vessel CAD</b>				
Without proximal LAD stenosis.	IIb	C	I	C
With proximal LAD stenosis. <sup>68,70,73</sup>	I	B	I	C
<b>Left main CAD</b>				
Left main disease with low SYNTAX score (0 - 22). <sup>69,121,122,124,145-148</sup>	I	A	I	A
Left main disease with intermediate SYNTAX score (23 - 32). <sup>69,121,122,124,145-148</sup>	I	A	IIa	A
Left main disease with high SYNTAX score ( $\geq 33$ ). <sup>c 69,121,122,124,146-148</sup>	I	A	III	B
<b>Three-vessel CAD without diabetes mellitus</b>				
Three-vessel disease with low SYNTAX score (0 - 22). <sup>102,105,121,123,124,135,149</sup>	I	A	I	A
Three-vessel disease with intermediate or high SYNTAX score ( $>22$ ). <sup>c 102,105,121,123,124,135,149</sup>	I	A	III	A
<b>Three-vessel CAD with diabetes mellitus</b>				
Three-vessel disease with low SYNTAX score 0-22. <sup>102,105,121,123,124,135,150-157</sup>	I	A	IIb	A
Three-vessel disease with intermediate or high SYNTAX score ( $>22$ ). <sup>c 102,105,121,123,124,135,150-157</sup>	I	A	III	A

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# Guidelines for ULMCA

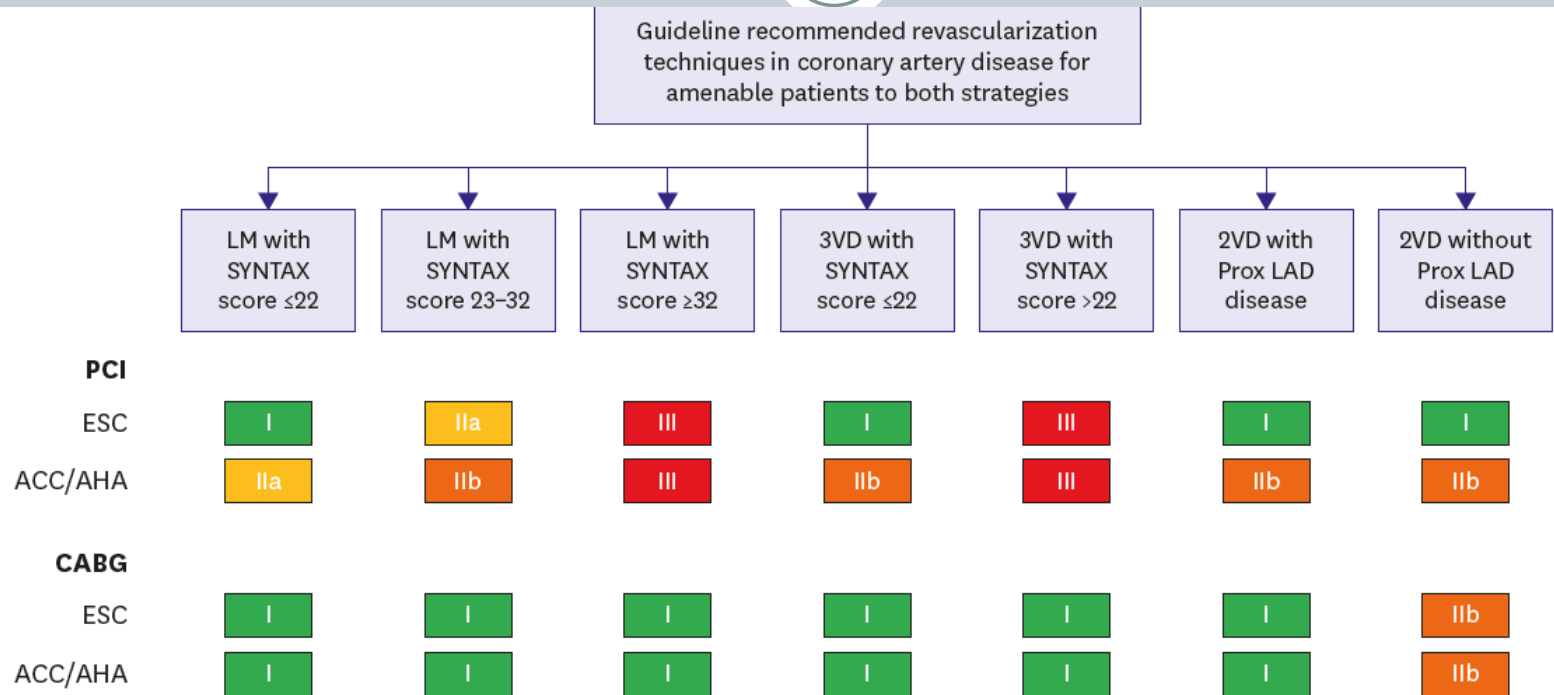


Figure 1. Comparison of ACC/AHA and ESC guidelines recommendations on LMD and MVD revascularizations. Class I: revascularization strategy is recommended or should be performed. Class IIa: revascularization strategy is reasonable and can be useful. Class IIb: revascularization strategy might be reasonable or considered. Class III: revascularization strategy is not recommended.

ACC/AHA = American College of Cardiology/American Heart Association; CABG = coronary artery bypass graft; ESC = European Society of Cardiology; LM = left main; LMD = left main disease; MVD = multivessel disease; PCI = percutaneous coronary intervention; SYNTAX = Synergy between PCI with TAXUS and Cardiac Surgery; 2VD = two vessel disease; 3VD = three vessel disease.

Al Hijj M., Sabah A., Holmes D.,




Revascularization for Left Main and Multivessel Coronary Artery Disease: Current Status and Future Prospects after the EXCEL and NOBLE Trials. Korean Circ J. 2018 Jun;48(6):447-462.

# Economic factors



**kcj**  
Korean Circulation Journal

## Revascularization for Left Main and Multivessel Coronary Artery Disease: Current Status and Future Prospects after the EXCEL and NOBLE Trials

Mohammed Al-Hijji , MD, Abdallah El Sabbagh , MD, and David R. Holmes , MD

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Both treatment strategies account for about \$12 billion direct cost yearly in United States. Results from SYNTAX studies<sup>47)48)</sup> showed higher initial hospitalization cost \$10,036 per patient with CABG for LM or 3 vessel disease, but the overall costs were higher with PCI over 5 years likely driven by higher rates of repeat revascularization, higher rates of hospitalization, and higher medication costs. However, no differences in cost were observed when patients with LMD or MVD with low SYNTAX score were analyzed underscoring the importance of heart team approach and integrating SYNTAX scores to apply the most appropriate and cost-effective treatment for each patient.



# Opinions



Editorial

## PCI or CABG for severe unprotected left main coronary artery disease: making sense of the NOBLE and EXCEL trials

Anthony A. Holmes, Sripal Bangalore

mortality, cardiac mortality, total MI, spontaneous MI and stroke were similar between the PCI and CABG groups (Table 1). There were more total repeat revascularizations in the PCI group [HR =1.72 (95% CI, 1.27–2.33), P<0.001], however target lesion repeat revascularizations were similar. The authors concluded that “PCI with EES was non-inferior to CABG with respect to the composite endpoint of death, stroke or myocardial infarction at 3 years”. It is worth noting, however, that some have suggested that the non-inferior margin used in EXCEL was too liberal (4.2%) and may have biased the results towards non-inferiority (19).

When interpreting the results of EXCEL and NOBLE, the first thing one must keep mind is that the benefit of CABG is often seen after extended follow-up (20). Both



David Holmes  
Cardiologist- Interventional Cardiologist, Mayo Clinic

Comment

Randomised trials in left main disease: a NOBLE effort



...What is the clinical relevance from this trial that might have an impact on practice? If a patient is a good surgical candidate, CABG should remain the mainstay of treatment. Although survival is the same, the incidence of clinically apparent myocardial infarction and need for repeat revascularisation and recurrence of angina is higher with PCI. In patients who are not good surgical candidates, PCI is a reasonable alternative to CABG, albeit with a higher incidence of subsequent clinical events.

# Opinions



I think in recent times, probably three things have changed, or continue to change.

The change in drug eluting stents from the first generation to the second generation, I think, has been a real advance.

I think the second thing is a growing understanding of the role of clinical characteristics and patient values and preferences and choices of revascularization.

And the third is a move in the anatomic subsets that we're now more comfortable with dealing with PCI. I would say left main



**Rajiv Gulati, M.D., Ph.D.**  
**Cardiologist - Interventional**  
**Cardiologist, Mayo Clinic**

# Opinions



Harold L. Lazar, MD

## **Central Message**

The AUC for SIHD support CABG surgery as the most appropriate procedure for patients with 3-vessel and left main disease.

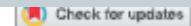
Surgeons should continue to insist that there be close monitoring so there is adherence to AUC guidelines to improve “appropriate” patient selection for coronary revascularization and minimize the overuse of inappropriate revascularization procedures.

Lazar H., Appropriate Use Criteria for coronary revascularization in patients with stable ischemic heart disease: What the surgeon needs to know. *J Thorac Cardiovasc Surg* 2019;157:144-6

# Opinions



## REVIEW



### Percutaneous or surgical revascularization for left main stem disease: NOBLE ideas, but do they EXCEL?

George Kassimis<sup>ab</sup>, Tushar Raina<sup>a</sup>, Nestoras Kontogiannis<sup>a</sup>, George Krasopoulos<sup>c</sup> and Julian Gunn<sup>d</sup>

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#### ABSTRACT

**Introduction:** Although coronary artery bypass grafting (CABG) has traditionally been the standard treatment for significant left main stem (LMS) disease, percutaneous coronary intervention (PCI) using drug-eluting stents (DES) is now considered an acceptable alternative.

**Areas covered:** This article aims to summarise the key findings of the landmark clinical trials on LMS revascularization and the recently published ESC/EACTS guidelines on myocardial revascularization related to LMS disease.

**Expert opinion:** It is unlikely that there will be a further large randomized trial aimed at addressing the issue of the optimum method of revascularization for LMS disease. Both PCI and CABG are reasonable revascularization options for appropriately selected patients with LMS disease. 'Heart Team' approach is vital to guide the management of patients with LMS disease, when there is obvious clinical equipoise and a mandate for complete revascularization. With an aging and increasing co-morbid patient population, clinical equipoise may not always be obvious, making extrapolation of clinical trial results to the 'real world' difficult.

#### ARTICLE HISTORY

Received 28 November 2018  
Accepted 2 May 2019

#### KEYWORDS

Left main stem disease; coronary artery bypass grafting; percutaneous coronary intervention; NOBLE; EXCEL; SYNTAX; SYNTAXES; MAIN COMPARE; revascularization guidelines

# Opinions



Circulation

WHITE PAPER

## Myocardial Revascularization Trials

Beyond the Printed Word

Marc Ruel, MD, MPH  
Volkmar Falk, MD, PhD  
Michael E. Farkouh, MD,  
MS  
Nick Freemantle, PhD  
Mario F. Gaudino, MD  
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or multivessel CAD worldwide because the incidence of perioperative stroke after CABG appears to have been significantly reduced, as corroborated by recent population data.<sup>23</sup> Previously, the increased incidence of stroke after CABG noted in the SYNTAX trial and the FREEDOM trial (Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease) could have resulted from misguided pharmacological strategies such as prematurely stopping dual antiplatelet therapy in patients with acute coronary syndrome before CABG,<sup>24</sup> the low use of in situ arterial grafts, major geographic variations,<sup>25</sup> and the low use of no-touch aortic techniques.<sup>26</sup>

Last, randomized and observational data indicate

We believe that the repetitive practice of limiting trial enrollment to patients considered to be particularly suitable for PCI, anatomically and physiologically, amounts to a form of selection bias. Although this practice may be in the best interest of the study patients, the external validity and generalizability of myocardial revascularization trials suffer from having excluded subjects with less than optimal suitability for PCI (who may have experienced a less favorable outcome) and nevertheless applying the results of these RCTs to the whole population of patients with severe CAD.



# Conclusions



- The management of the ULMCA is not delineated, yet some findings are very useful.
- The anatomic characteristics and the total burden of the disease are factors that need further research.
- In the long term follow-up , a higher incidence of revascularization is found in PCI-treated patients.
- Hybrid management seems a satisfactory enough perspective.
- The “HEART” team with continuous communication and collaboration is fundamental in decision-making.

# Thank you!



Which one is right for you  
Coronary Stenting or  
Heart By Pass Surgery?