CSC 2025
CORONARY AND STRUCTURAL CONGRESS
CONGRESO CORONARIO Y ESTRUCTURAL
MADRID

5, 6 y 7 NOVIEMBRE
HOTEL RIU PLAZA DE ESPAÑA

# ENFERMEDAD EN EL TRONCO COMÚN:

## HERRAMIENTAS DE APOYO/ SEGUIMIENTO - IMAGEN

*Íñigo Lozano Martínez-Luengas*
**Servicio de Cardiología**
***Hospital de Cabueñes, Gijón***

Universidad de Oviedo

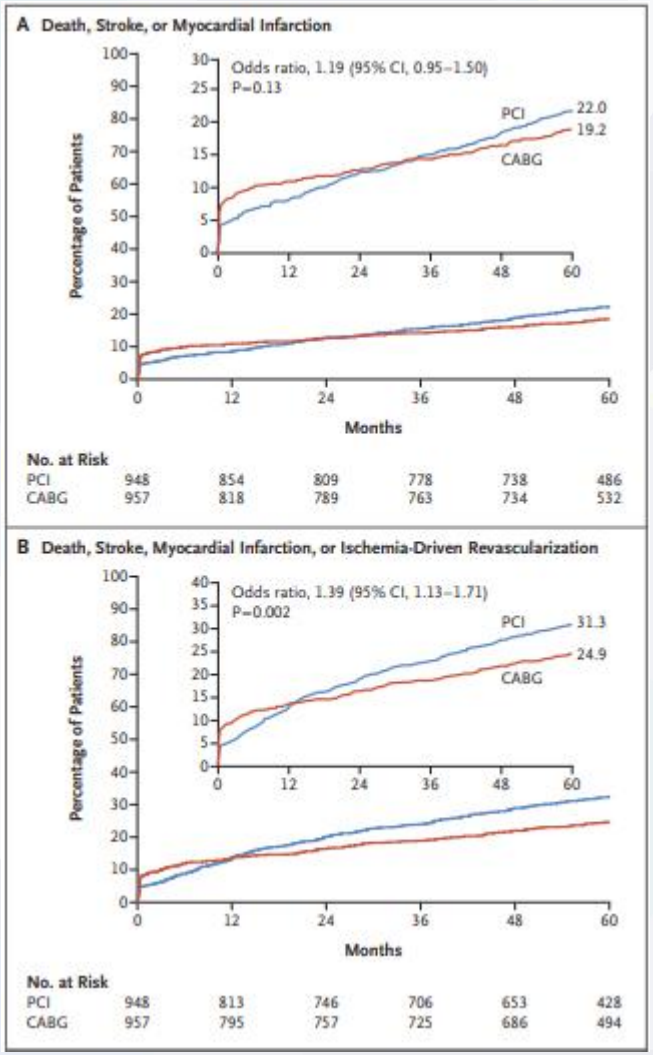
ISPA
Instituto de Investigación Sanitaria del Principado de Asturias

SERVICIO DE SALUD DEL PRINCIPADO DE ASTURIAS
HOSPITAL UNIVERSITARIO DE CABUEÑES
GERENCIA ÁREA SANITARIA V

FundaciónEpic

ORIGINAL ARTICLE

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




N Engl J Med 2016;375:2223-2235

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

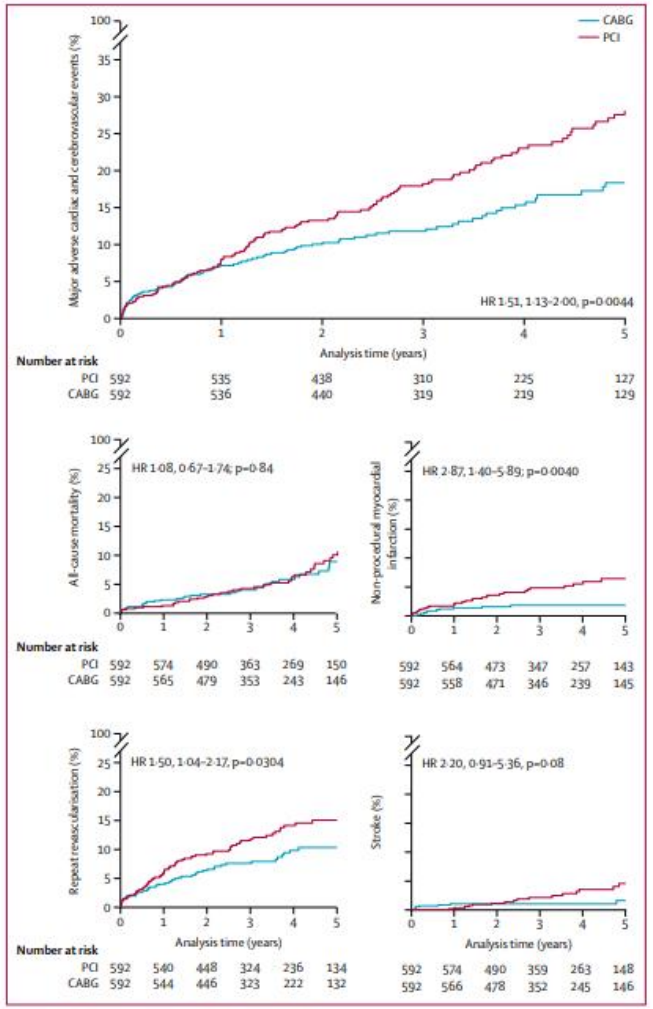



*Figure 2:* Outcomes according to intention to treat

CABG=coronary artery bypass grafting, PCI=percutaneous coronary intervention

Lancet. 2016 : 2743-2752

ESC European Society of Cardiology
European Heart Journal (2018) 00, 1–96
doi:10.1093/eurheartj/ehy394

ESC/EACTS GUIDELINES

# 2018 ESC/EACTS Guidelines on myocardial revascularization

| 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 |

### 5.3.3 Left main coronary artery disease

The available evidence from RCTs and meta-analyses comparing CABG with PCI using DES among patients with LM disease suggests equivalent results for the safety composite of death, MI, and stroke up to 5 years of follow-up.[148] A significant interaction with time is notable, providing early benefit for PCI in terms of MI and peri-interventional stroke, which is subsequently offset by a higher risk of spontaneous MI during long-term follow-up. The need for repeat revascularization is higher with PCI than with CABG.

## ¿CÓMO DETERMINAR SEVERIDAD?

## ¿CÓMO TRATARLO: MANEJO BIFURCACIÓN?

## ¿PODEMOS MEJORAR LOS RESULTADOS CON MEJOR SEGUIMIENTO?

percentage of cardiac caths with left main disease

Significant left main coronary artery disease (defined as greater than 50% diameter stenosis) is found in approximately **3% to 10.5%** of all patients undergoing diagnostic cardiac catheterization. Most studies report the prevalence in the range of **4% to 7%.**

The percentage can vary depending on the patient population being studied (e.g., those with stable angina vs. acute coronary syndromes) and specific risk factors present:

- **Overall diagnostic angiography:** The general prevalence is typically between 4% and 7%.
- **Acute Coronary Syndromes (ACS):** Significant left main disease may be found in up to 24% of patients presenting with ACS.

# Los no candidatos a CCV aumentarán

Enfoque: Epidemiología de la enfermedad cardiovascular en España en los últimos 20 años (I)

## Epidemiología del síndrome coronario agudo en España: estimación del número de casos y la tendencia de 2005 a 2049

Irene R. Dégano, Roberto Elosua* y Jaume Marrugat

*Grupo de Investigación de Epidemiología y Genética Cardiovascular, Programa de Investigación en Trastornos Inflamatorios y Cardiovasculares, IMIM, Barcelona, Españaa*

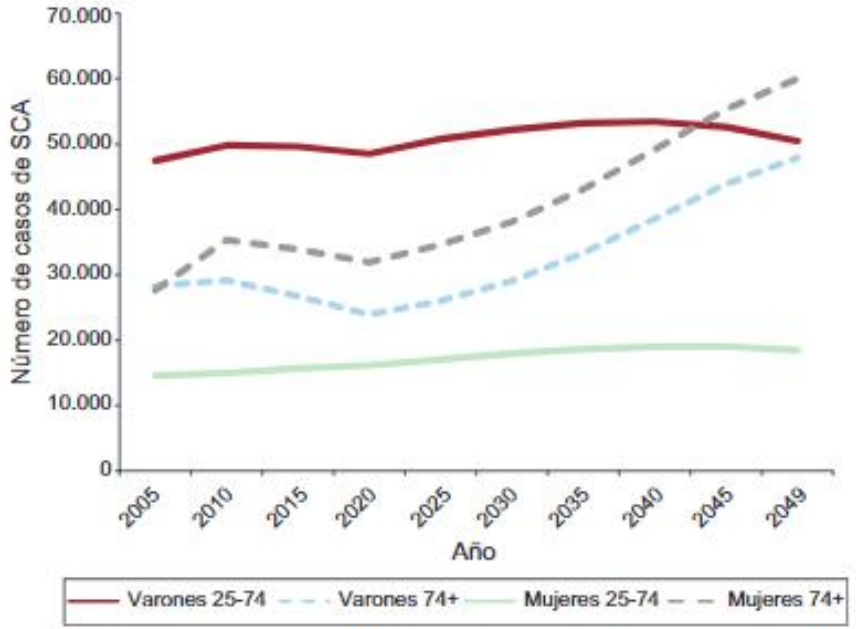



**Figura 4.** Número de casos de síndrome coronario agudo, tendencia de 2005 a 2049 por grupos de edad y sexo en población española. SCA: síndromes coronarios agudos.

En la previsión de la incidencia de los síndromes coronarios agudos en España de 2005 a 2049 habrá un aumento del 40 %, pero mientras el número de casos en pacientes menores de 75 años se mantendrá constante, el número de pacientes de edad > 75 años se duplicará desde 28.000 casos tanto en hombres como en mujeres a 45.000 mujeres y 55.000 hombres en 2049.

Este hecho conducirá a un aumento espectacular de los casos no candidatos a revascularización quirúrgica.

**Rev Esp Cardiol. 2013;66(6):472–481**

EDITORIAL COMMENT

**Revascularization Decisions in Coronary Artery Disease**

Hitting a Moving Target*

Gregg W. Stone, MD

# SURVIVAL

## CEREBROVASCULAR ACCIDENT

## MYOCARDIAL INFARCTION

## REVASCULARIZATION

## QUALITY OF LIFE

## COSTS

J Am Coll Cardiol Intv. 2014;7(5):507-50

# Long-Term Clinical Outcomes After Unprotected Left Main Trunk Percutaneous Revascularization in 279 Patients

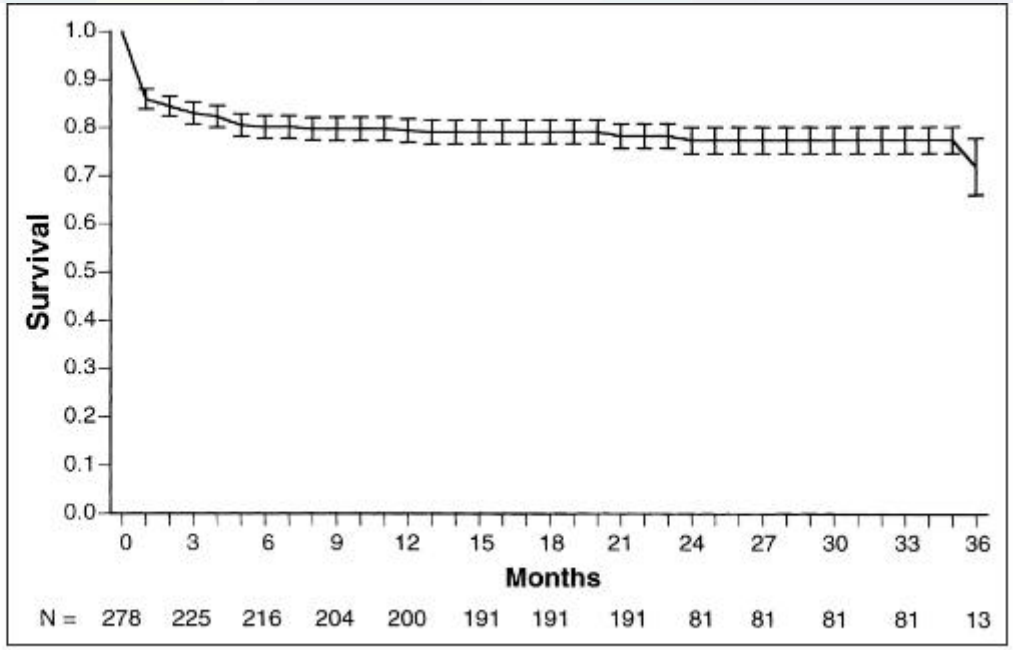



**Figure 2.** Cardiac survival in complete cohort.

***Conclusions*** Patients undergoing unprotected LMT PCI have frequent serious comorbidities and consequently have high event rates. PCI may be an alternative to CABG for a select proportion of elective patients and may also be appropriate for highly symptomatic inoperable patients. **Meticulous follow-up of hospital survivors is required because of the rather high mortality during the first few months after treatment**.

Circulation. 2001 Oct

European Heart Journal Advance Access published August 29, 2014
European Heart Journal
doi:10.1093/eurheartj/ehu278

ESC/EACTS GUIDELINES

## 2014 ESC/EACTS Guidelines on myocardial revascularization

### Strategies for follow-up and management in patients after myocardial revascularization

| Recommendations | Class[a] | Level[b] | Ref[c] |
|---|---|---|---|
| **Asymptomatic patients** | | | |
| Early imaging testing should be considered in specific patient subsets.[d] | IIa | C | |
| Routine stress testing may be considered >2 years after PCI and >5 years after CABG. | IIb | C | |
| After high-risk PCI (e.g. unprotected LM stenosis) late (3–12 months) control angiography may be considered, irrespective of symptoms. | IIb | C | |
| **Symptomatic patients** | | | |
| It is recommended to reinforce medical therapy and lifestyle changes in patients with low-risk findings[d] at stress testing. | I | C | |
| With intermediate- to high-risk findings[e] at stress testing, coronary angiography is recommended. | I | C | |

ESC European Society of Cardiology
European Heart Journal (2018) 00, 1–96
doi:10.1093/eurheartj/ehy394

ESC/EACTS GUIDELINES

## 2018 ESC/EACTS Guidelines on myocardial revascularization

| Asymptomatic patients | | |
|---|---|---|
| Surveillance by non-invasive imaging-based stress testing may be considered in high-risk patient subsets 6 months after revascularization. | IIb | C |
| After high-risk PCI (e.g. unprotected LM stenosis), late (3–12 months) surveillance angiography may be considered, irrespective of symptoms. | IIb | C |
| Routine non-invasive imaging-based stress testing may be considered 1 year after PCI and >5 years after CABG. | IIb | C |

grant #2014/12212-5 and from the Brazilian National Council for Scientific and Technological Development (CNPq), grant #232643/2014-8. Drs. Waxman and Systrom are supported by grant funding from the National Institutes of Health (1U01HL125213). Dr. Shah is supported by the National Institutes of Health (K08HL116792) and the American Heart Association (14CRP20380422). Dr. Maron is supported by the NIH (1K08HL121277-01A1), American Heart Association (AHA 15GRNT25080016), Pulmonary Hypertension Association, and the Cardiovascular Medical Research and Education Fund; and receives research support from Novartis, Gilead, and Actelion; and consulting fees from Myocardia. Dr. Opotowsky has received research support from Actelion and Roche Diagnostics. Dr. Maron has received research support from Gilead Sciences to research pulmonary hypertension. Dr. Landzberg has received research support from Actelion. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. The authors thank Abbey Karin, Julie Tracy, Jeff Vorse, and Charlie Lee for their meticulous work performing these invasive clinical exercise tests; and Susana Mak, Ryan Tedford, James E. Lock, and John Granton for their insights into the physiology described in this paper.

**REFERENCES**

1. Rudski LG, Lai WW, Afilalo J, et al. Guidelines for the echocardiographic assessment of the right heart in adults. J Am Soc Echocardiogr 2010;23:685-713.
2. Berry NC, Manyoo A, Oldham WM, et al. Protocol for exercise hemodynamic assessment: performing an invasive cardiopulmonary exercise test in clinical practice. Pulm Circ 2015;5:610-8.
3. Denault AY, Chaput M, Couture P, Hebert Y, Haddad F, Tardif JC. Dynamic right ventricular outflow tract obstruction in cardiac surgery. J Thorac Cardiovasc Surg 2006;132:43-9.
4. Gorcsan J 3rd, Reddy SC, Armitage JM, Griffith BP. Acquired right ventricular outflow tract obstruction after lung transplantation: diagnosis by transesophageal echocardiography. J Am Soc Echocardiogr 1993;6:324-6.
5. Kirshbom PM, Tapson VF, Hantson JK, Davis RD, Gaynor JW. Delayed right heart failure following lung transplantation. Chest 1996;109:575-7.

# Percutaneous Revascularization of Left Main Disease

## Could the Angiographic Follow-Up Improve the Survival?

We read with great interest the article written by Cavalcante et al. (1) and the editorial by Windecker (2) about the comparison between percutaneous coronary intervention (PCI) and surgical revascularization (coronary artery bypass graft [CABG]) in the unprotected left main (LM) disease. Percutaneous intervention in LM has increased its level of recommendation in the past few years with a Class I in stable coronary disease with a SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score ≤22 and a Class IIa with a SYNTAX score between 23 and 32. A previous nonrandomized series already found lower mortality with the second generation of drug-eluting stents in PCI compared with surgery, with marked improvement of the percutaneous approach, whereas the surgery has shown steady behavior in the last decade. As is indicated in the editorial, the paper from Cavalcante et al. (1) comprises 80% of the patients included in the 4 randomized studies comparing PCI with surgery in unprotected LM disease. Noticeably, in the group with a SYNTAX score <33, the cardiac death rate was lower with PCI. In patients with a SYNTAX score <23, both cardiac and noncardiac death rates were lower with PCI. However, although probably the target vessel failure in PRECOMBAT (Bypass Surgery Versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease) and SYNTAX probably would have been lower with second-generation drug-eluting stents, the fact is that, to date, the Achilles heel of LM stenting is the higher rate of revascularization. Despite the remarkable improvement in stent designs, which has not only reduced the threat of thrombosis but also the rate of restenosis, in the next few years, it will probably not be possible to achieve the same results than surgery in this latter aspect.

We believe that the benefits of LM stenting have not been completely explored, and there may be room for improvement because we have an important question that is still unanswered. The mentioned guidelines state that "after high-risk PCI (e.g., unprotected LM stenosis) late (3-12 months) control angiograph may be considered, irrespective of symptoms" with Class IIb and a level of recommendation C, that is, expert consensus. In our opinion, we should not leave this important issue a level of evidence C and should move forward with a randomized trial to analyze the influence of routine angiographic follow-up after LM stenting with an everolimus or zotarolimus stent in terms of mortality.

Restenosis in LM may be associated with sudden cardiac death. Although the PRECOMBAT, SYNTAX, and the forthcoming EXCEL (Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease) trials are focused on the comparison between percutaneous and surgical revascularization, we believe that this question should be answered because, independent of the results of these 3 trials, our hypothesis would affect all patients who would finally be treated percutaneously. As it is expected that the percentage of patients with acute coronary syndrome will increase 40% in the following years mainly due to the elderly population (3), the percentage of patients who are noncandidates for surgical revascularization will definitely also increase. Until this issue is resolved, we will not know all the benefits of percutaneous revascularization in LM disease.

*Iñigo Lozano, MD, PhD
Juan Rondan, MD, PhD
Jose M. Vegas, MD
Eduardo Segovia, MD

# PCI or CABG for Left Main Coronary Artery Disease

**TO THE EDITOR:** In the EXCEL (Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial (Nov. 7 issue),[1] Stone et al. report no significant difference in the 5-year composite outcome of death, stroke, or myocardial infarction among patients with stable left main coronary artery disease who underwent either percutaneous coronary intervention (PCI) with drug-eluting stents or coronary-artery bypass grafting (CABG). We have three fundamental concerns regarding these findings.

First, the incidence of death from any cause was 13.0% in the PCI group and 9.0% in the CABG group (odds ratio, 1.38; 95% confidence interval [CI], 1.03 to 1.85). Although the difference was not adjusted for multiple comparisons, the increased risk is unequivocally the most important outcome in a relatively young population (average age, 66 years), particularly since the between-group difference continued to diverge over time. Second, the investigators claimed that there was no difference between groups in the incidence of death from cardiovascular causes, but the adjudication of cause of death is notoriously susceptible to bias, especially in an open-label trial. Third, the investigators used a new, untested definition of periprocedural myocardial infarction that clearly penalizes surgery and that is the key driver of the composite outcome that claims no difference in the two treatment strategies. The EXCEL protocol repeatedly stated that the Universal Definition of Myocardial Infarction would also be used, but such data were not provided. Consequently, the first author of this letter withdrew authorship from the manuscript.

David P. Taggart, M.D.
University of Oxford
Oxford, United Kingdom
david.taggart@ouh.nhs.uk

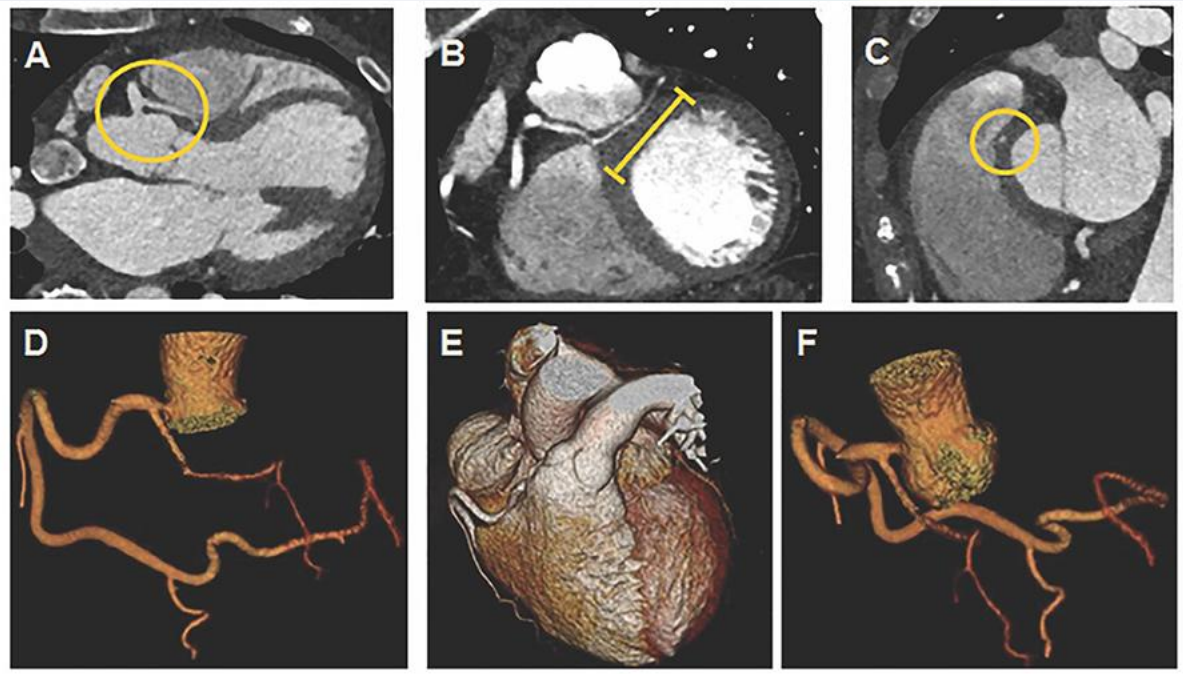
Mario Gaudino, M.D.
Weill Cornell Medicine
New York, NY

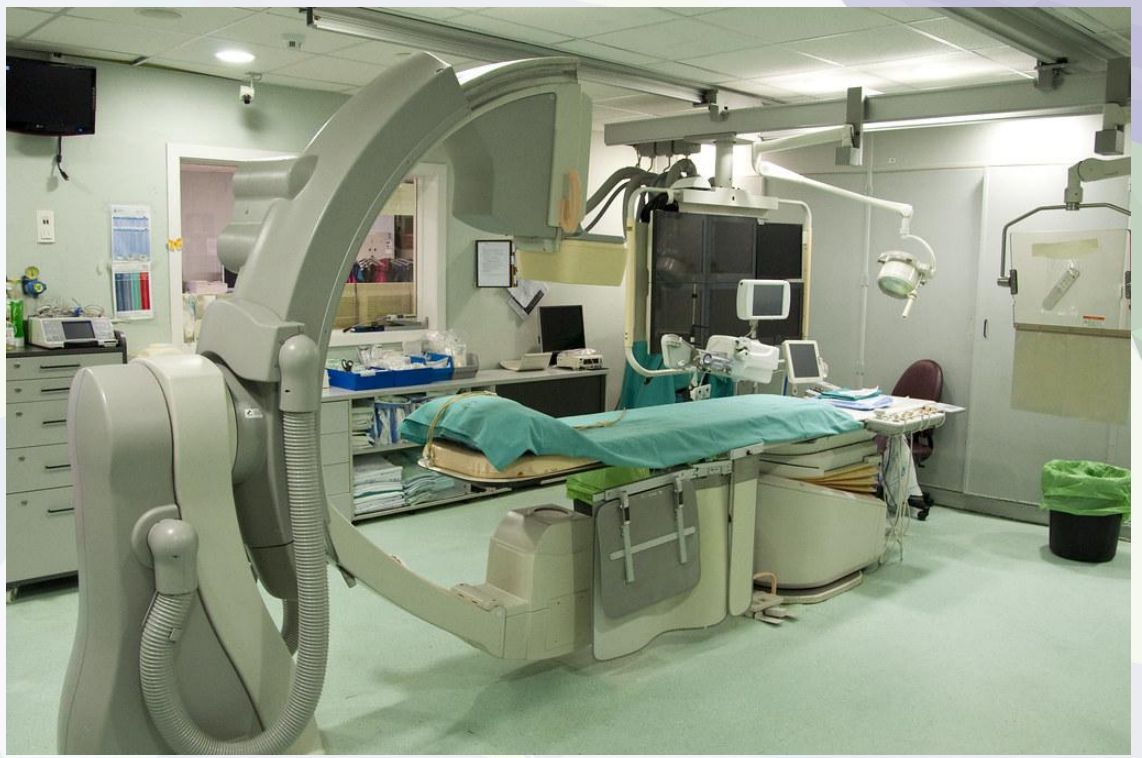
No potential conflict of interest relevant to this letter was reported.

1. Stone GW, Kappetein AP, Sabik JF, et al. Five-year outcomes after PCI or CABG for left main coronary disease. N Engl J Med 2019;381:1820-30.
DOI: 10.1056/NEJMc2000645

**TO THE EDITOR:** In the EXCEL trial, the results for the primary outcome at the 5-year follow-up should be considered neutral. However, the division of the follow-up time into three periods with different relative risks may fuel the conclusion that the longer the follow-up is, the better the results of CABG will be. In the search for the best treatment of left main coronary artery disease, we should test the role of routine angiographic follow-up after stenting. In a single-center study involving 190 patients, Aurigemma et al.[1] found that routine angiographic follow-up, as compared with clinical follow-up, was associated with an impressive difference in the incidence of the combined end point of cardiac death, myocardial infarction, or urgent revascularization (4.3% vs. 16.2%); the incidence of cardiac death was 0% and 7%, respectively. In our opinion, the weak guideline recommendation that practitioners should perform angiographic follow-up after stenting (class IIB, evidence C — that is, expert consensus) and the intriguing results of the study by Aurigemma et al. suggest that an adequately powered trial may provide answers to this relevant question.

Iñigo Lozano, M.D., Ph.D.
Juan Rondan, M.D., Ph.D.
Jose M. Vegas, M.D., Ph.D.
Hospital de Cabueñes
Gijon, Spain
inigo.lozano@gmail.com


A
B
C
D
E
F

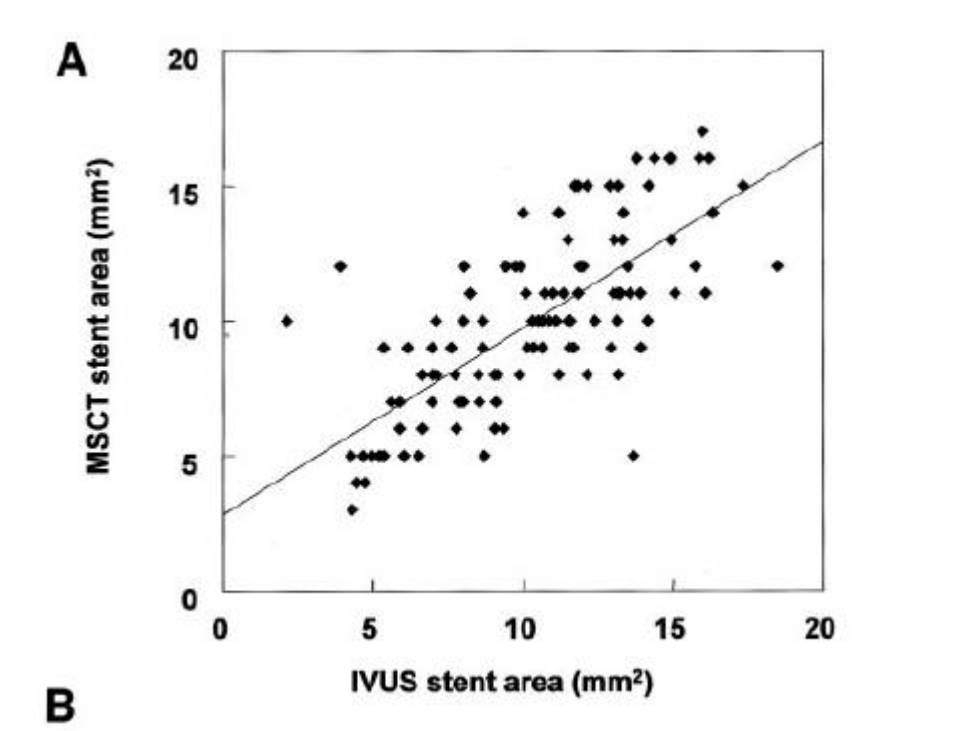


# Multislice Spiral Computed Tomography for the Evaluation of Stent Patency After Left Main Coronary Artery Stenting

## A Comparison With Conventional Coronary Angiography and Intravascular Ultrasound

Seventy-four patients were prospectively identified from a consecutive patient population scheduled for follow-up CCA after LMCA stenting and underwent MSCT before CCA.

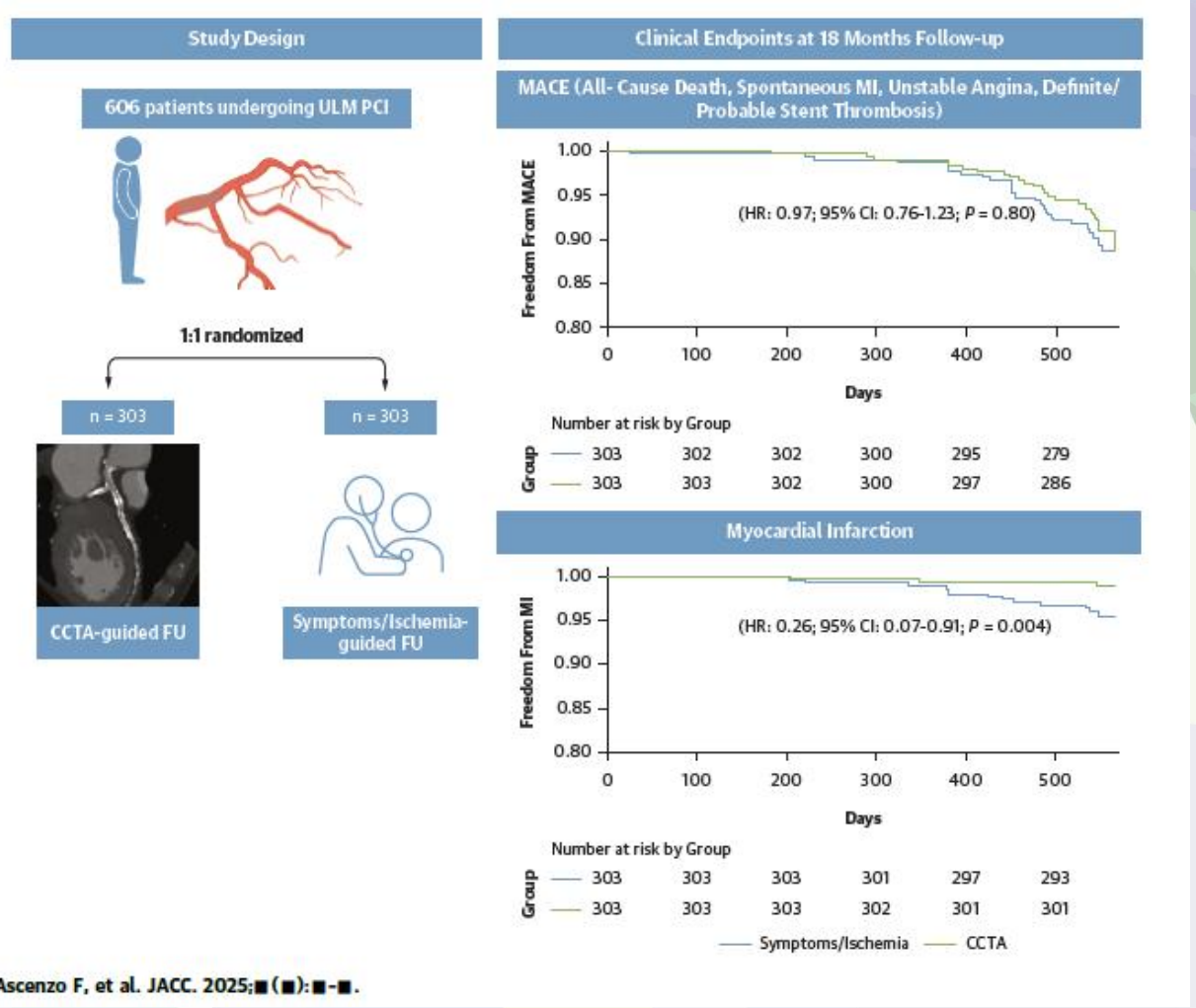
Current MSCT technology allows reliable noninvasive evaluation of selected patients after LMCA stenting.
MSCT is safe to exclude left main ISR and may therefore be an acceptable first-line alternative to CCA.




Circulation
2006;114:645-653

# Computed Tomography Angiography or Standard Care After Left Main PCI?

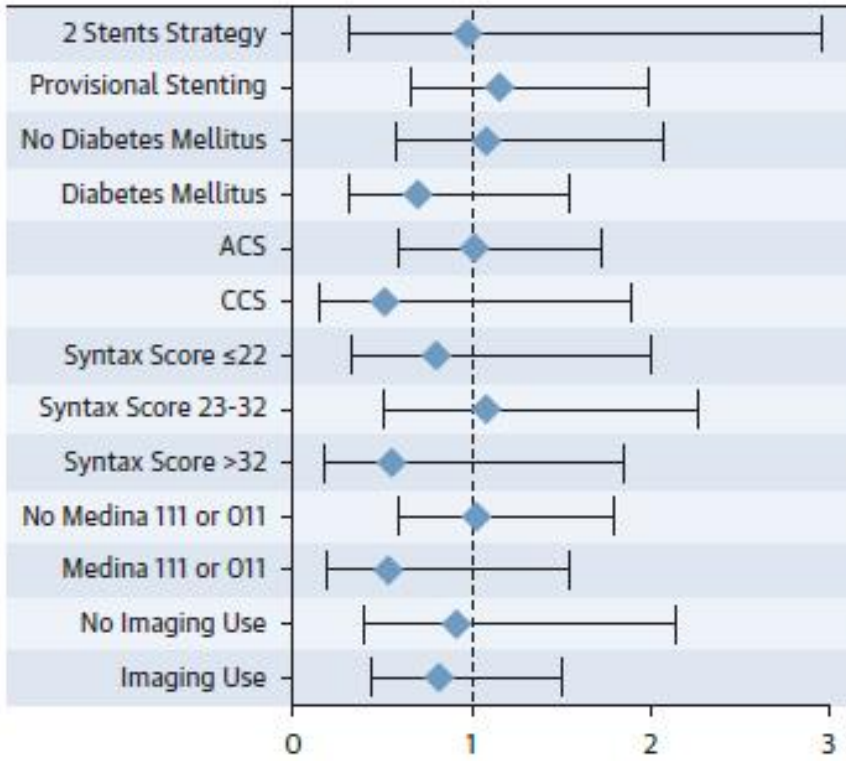
**PULSE was a prospective, multicenter, open-label randomized trial. A total of 606 patients** treated with second-generation drug-eluting stents were enrolled (October 2019 to September 2024) and randomized 1:1 to CCTA at 6 months (experimental) or standard care (control). The primary endpoint was a composite of **all-cause death, spontaneous myocardial infarction (MI), unstable angina, or definite or probable stent thrombosis at 18 months.** Secondary endpoints included target-lesion revascularization (TLR) and each primary endpoint component.-




D'Ascenzo F, et al. JACC. 2025;■(■):■-■.

J Am Coll Cardiol. 2025 Epub ahead of print

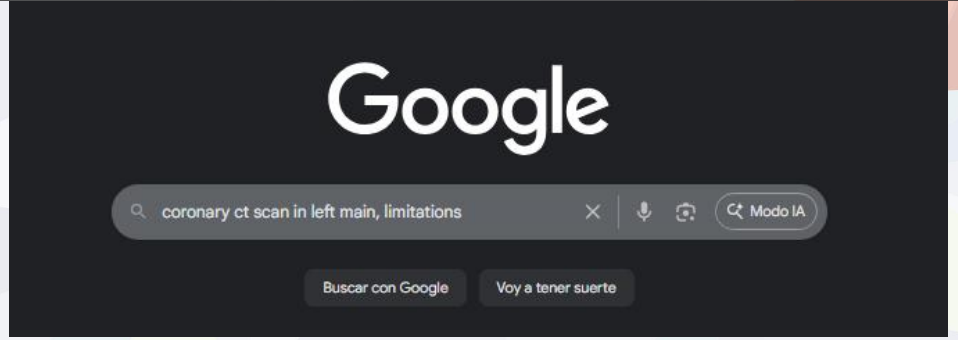
# Computed Tomography Angiography or Standard Care After Left Main PCI?




| | Control Group | CCTA Group | HR (95% CI) | *P* for Interaction |
|---|---|---|---|---|
| 2 Stents Strategy | 8/47 (17.0) | 7/42 (16.7) | 0.98 (0.32-2.97) | 0.25 |
| Provisional Stenting | 31/252 (12.3) | 28/259 (10.8) | 1.16 (0.67-1.99) | |
| No Diabetes Mellitus | 20/223 (8.9) | 22/226 (9.7) | 1.09 (0.58-2.08) | 0.62 |
| Diabetes Mellitus | 18/80 (22.5) | 13/77 (16.9) | 0.70 (0.32-1.55) | |
| ACS | 30/251 (11.9) | 31/256 (12.1) | 1.02 (0.59-1.73) | 0.10 |
| CCS | 8/52 (15.4) | 4/46 (8.7) | 0.52 (0.15-1.90) | |
| Syntax Score ≤22 | 11/92 (11.9) | 10/101 (9.9) | 0.81 (0.33-2.00) | 0.58 |
| Syntax Score 23-32 | 15/141 (10.6) | 16/141 (11.3) | 1.08 (0.51-2.27) | |
| Syntax Score >32 | 9/40 (22.5) | 5/36 (13.9) | 0.56 (0.17-1.85) | |
| No Medina 111 or 011 | 27/235 (11.5) | 28/238 (11.8) | 1.03 (0.59-1.80) | 0.72 |
| Medina 111 or 011 | 11/67 (16.4) | 6/63 (9.5) | 0.54 (0.19-1.55) | |
| No Imaging Use | 13/90 (14.4) | 12/89 (13.5) | 0.92 (0.40-2.15) | 0.94 |
| Imaging Use | 27/235 (11.5) | 27/235 (11.5) | 0.82 (0.44-1.51) | |

**Routine CCTA after LM PCI did not reduce the composite primary endpoint**, but was associated with fewer spontaneous MIs and more imaging-triggered revascularizations

**J Am Coll Cardiol. 2025 Epub ahead of print**




Key limitations include:

- **Extensive Coronary Calcification:** This is a major limitation. Severe calcium deposits create "blooming" or "streak" artifacts, making the actual lumen of the vessel difficult to assess accurately and often causing the degree of narrowing to be overestimated.
- **Motion Artifacts:** Despite advances in scanner technology, the heart is constantly moving. High or irregular heart rates (e.g., >65-75 bpm), arrhythmias, or a patient's inability to hold their breath during the scan can cause blurring or "stairstep" artifacts, which degrade image quality and hinder diagnostic confidence.
- **Limited Spatial Resolution for Small Structures:** While CCTA has good resolution, it may be insufficient to precisely assess very small plaques (sub-millimeter in size) or to accurately grade stenosis in very small branches of the left main, although the clinical significance of very small plaques is uncertain.
- **Metallic Implants:** The presence of prior stents or surgical clips can create significant beam-hardening and blooming artifacts, which interfere with the assessment of in-stent restenosis or the adjacent vessel lumen.
- **Overestimation of Stenosis:** CCTA tends to overestimate the degree of stenosis compared with the gold standard of invasive angiography, especially in the presence of calcification, which can lead to false-positive results and potentially unnecessary further downstream testing.
- **Inability to Assess Hemodynamic Significance Directly:** CCTA primarily provides anatomical information about the degree of luminal narrowing. It does not directly show the physiological impact or blood flow (ischemia) caused by a blockage. Specialized software like FFR-CT (fractional flow reserve derived from CT) can provide this functional assessment, but it is not universally available and has its own limitations.

In summary, CCTA is a valuable tool for ruling out significant disease (it has a high negative predictive value) in low-to-intermediate risk patients, but **its accuracy in the left main coronary artery is highly dependent on image quality, patient factors, and the absence of severe calcification.**

# Clinical impact of routine angiographic follow-up after percutaneous coronary interventions on unprotected left main

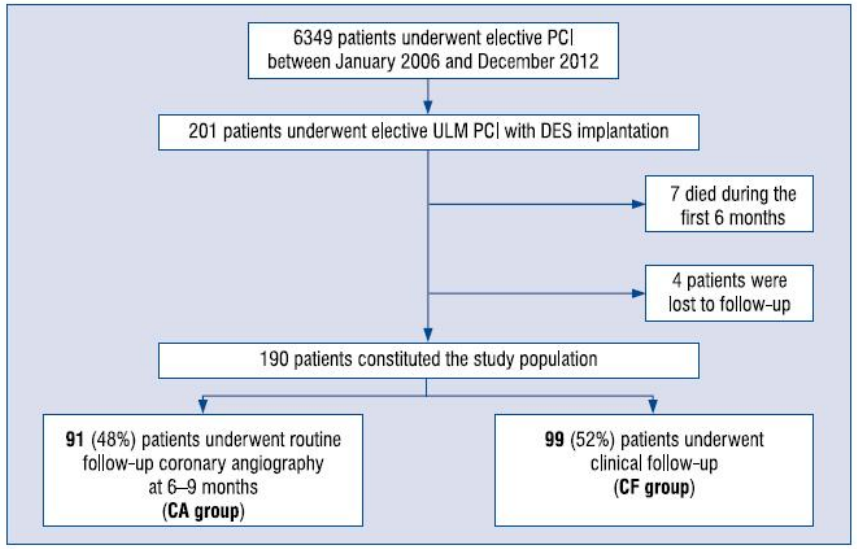
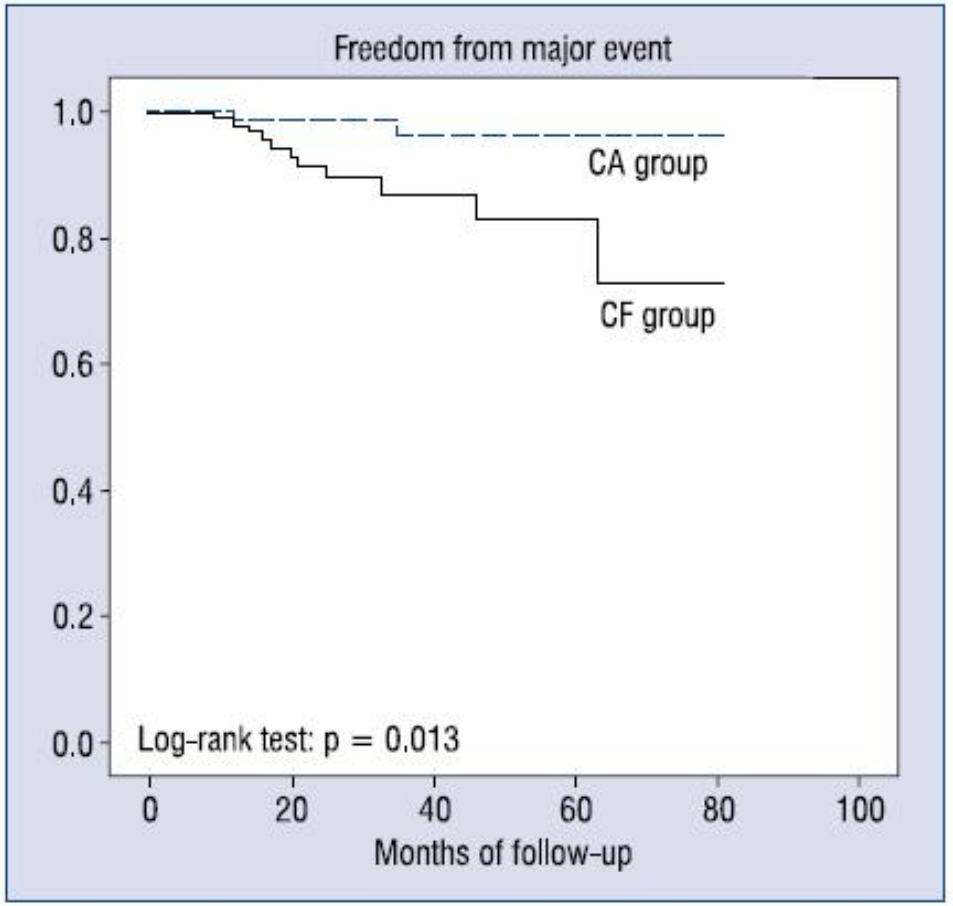



**Table 3.** Clinical events during follow-up in the study group.

| | All (n = 190) | CA group (n = 91) | CF group (n = 99) | P (1 vs. 2) |
|---|---|---|---|---|
| **Primary endpoint** | | | | |
| MACE (CD + MI + urgent TVR) | 20 (10.5%) | 4 (4.3%) | 16 (16.2%) | 0.009 |
| **Secondary endpoints** | | | | |
| Any TVR | 19 (10%) | 14 (15.4%) | 5 (5%) | 0.014 |
| CD | 7 (3.7%) | 0 (0%) | 7 (7%) | 0.01 |
| MI | 7 (3.7%) | 2 (2.2%) | 5 (5%) | 0.3 |
| Urgent TVR | 6 (3.1%) | 2 (2.2%) | 4 (4%) | 0.3 |
| CD + MI | 14 (7.4%) | 2 (2.2%) | 12 (12.1%) | 0.009 |

CA — coronary angiography; CF — clinical follow-up; CD — cardiac death; MACE — major adverse cardiac events; MI — myocardial infarction; TVR — target vessel revascularization



# Planned angiographic control versus clinical follow-up for patients with unprotected left main stem stenosis treated with second generation drug-eluting stents: A propensity score with matching analysis from the FAILS (failure in left main with second generation stents-Cardiogroup III Study)

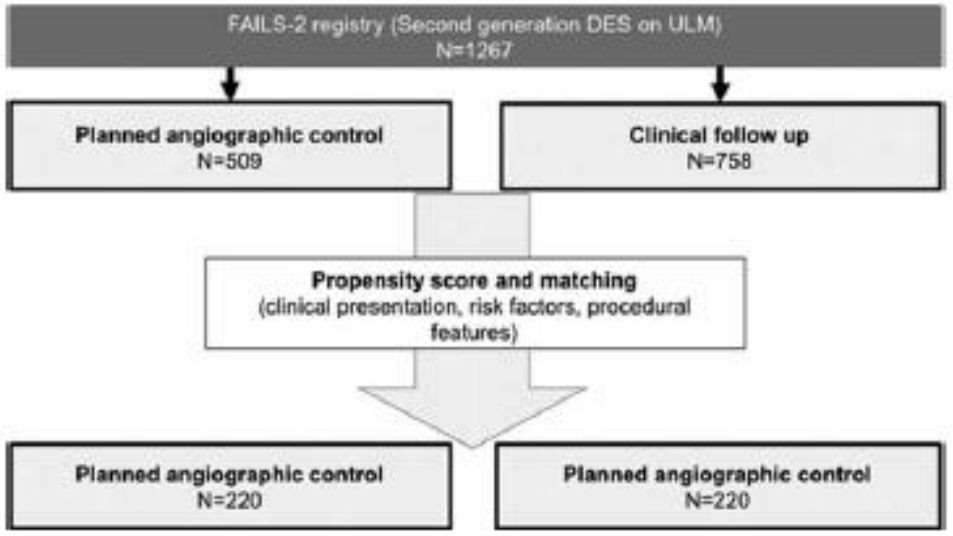
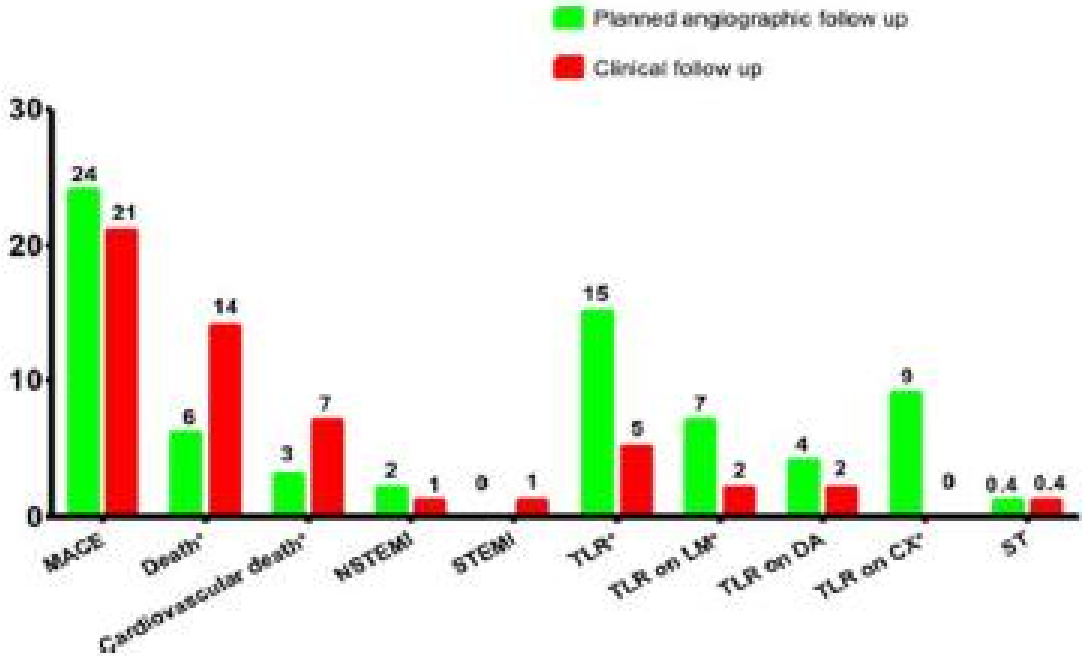



FIGURE 1 Study design: DES, drug eluting stent; ULM, unprotected left main




After 16 (14–21) months, rates of MACE were similar between the two groups (24 vs. 21%, P= 0.29) with lower rates of all cause and cardiovascular death in the angiographic control group (6 vs. 14%, P = 0.01 and 3 vs. 6%, P = 0.04) but with higher rates of TLR (15 vs. 5%, P<0.001).

Catheter Cardiovasc Interv.

# The ReACT Trial

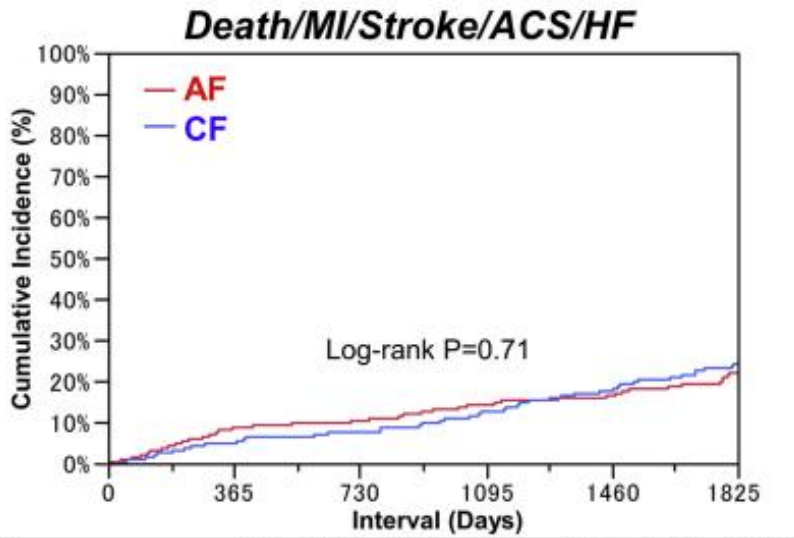
## Randomized Evaluation of Routine Follow-up Coronary Angiography After Percutaneous Coronary Intervention Trial

Prospective, multicenter, open-label, randomized trial, patients who underwent successful PCI were randomly assigned to routine angiographic follow-up (AF) at 8 to 12 months after PCI, or clinical follow-up alone (CF) group.

The primary endpoint was defined as a composite of death, myocardial infarction, stroke, emergency hospitalization for acute coronary syndrome, or hospitalization for heart failure over a minimum of 1.5 years follow-up.

***CONCLUSIONS*** *No clinical benefits were observed for routine FUCAG after PCI and early coronary revascularization rates were increased within routine FUCAG strategy in the current trial*

**FIGURE 2** Cumulative Incidence of the Primary Endpoint




| Interval | 0 day | 30 days | 1 year | 2 years | 3 years | 4 years | 5 years |
|---|---|---|---|---|---|---|---|
| AF group | | | | | | | |
| N of patients with at least 1 event | | 2 | 31 | 36 | 49 | 54 | 64 |
| N of patients at risk | 349 | 347 | 313 | 296 | 243 | 182 | 96 |
| Cumulative incidence | | 0.6% | 8.9% | 10.4% | 14.6% | 16.6% | 22.4% |
| CF group | | | | | | | |
| N of patients with at least 1 event | | 0 | 18 | 28 | 42 | 56 | 67 |
| N of patients at risk | 351 | 351 | 331 | 303 | 247 | 175 | 90 |
| Cumulative incidence | | 0% | 5.1% | 8.0% | 12.6% | 18.4% | 24.7% |

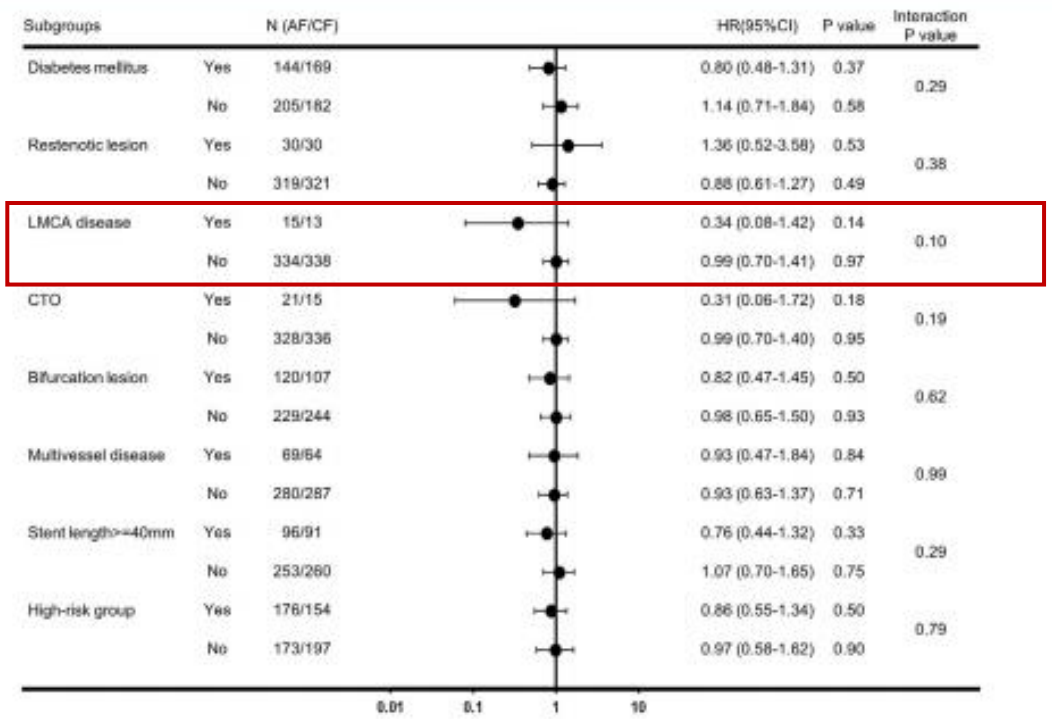
MI = myocardial infarction; other abbreviations as in Figure 1.

*J Am Coll Cardiol Intv*

# The ReACT Trial

## Randomized Evaluation of Routine Follow-up Coronary Angiography After Percutaneous Coronary Intervention Trial

**FIGURE 4 Subgroup Analyses**




Subgroup analyses for the effect of AF relative to CF on the primary endpoint. The "post hoc" high-risk subgroup was defined as having at least 1 high-risk feature such as LMCA disease, bifurcation lesion, multivessel disease, and total stent length ≥40 mm. CI = confidence interval; CTO = chronic total occlusion; LMCA = left main coronary artery; other abbreviations as in Figures 1 and 2.

*J Am Coll Cardiol Intv*

EDITORIAL COMMENT

## Routine Surveillance Coronary Angiography Post-PCI

### Should We ReACT and Change Our Routine?*

Rishi Puri, MBBS, PhD,[a,b,c] Jose M. de la Torre Hernandez, MD, PhD,[d] Vincent Auffret, MD, MSc[e,f]

Delving deeper into the ReACT data, it seems that **patients undergoing left main coronary or chronic total occlusion revascularization demonstrated trends toward a clinical benefit**, whereby the lack of significant interaction p values seems to be a function of small patient numbers rather than lack of efficacy.

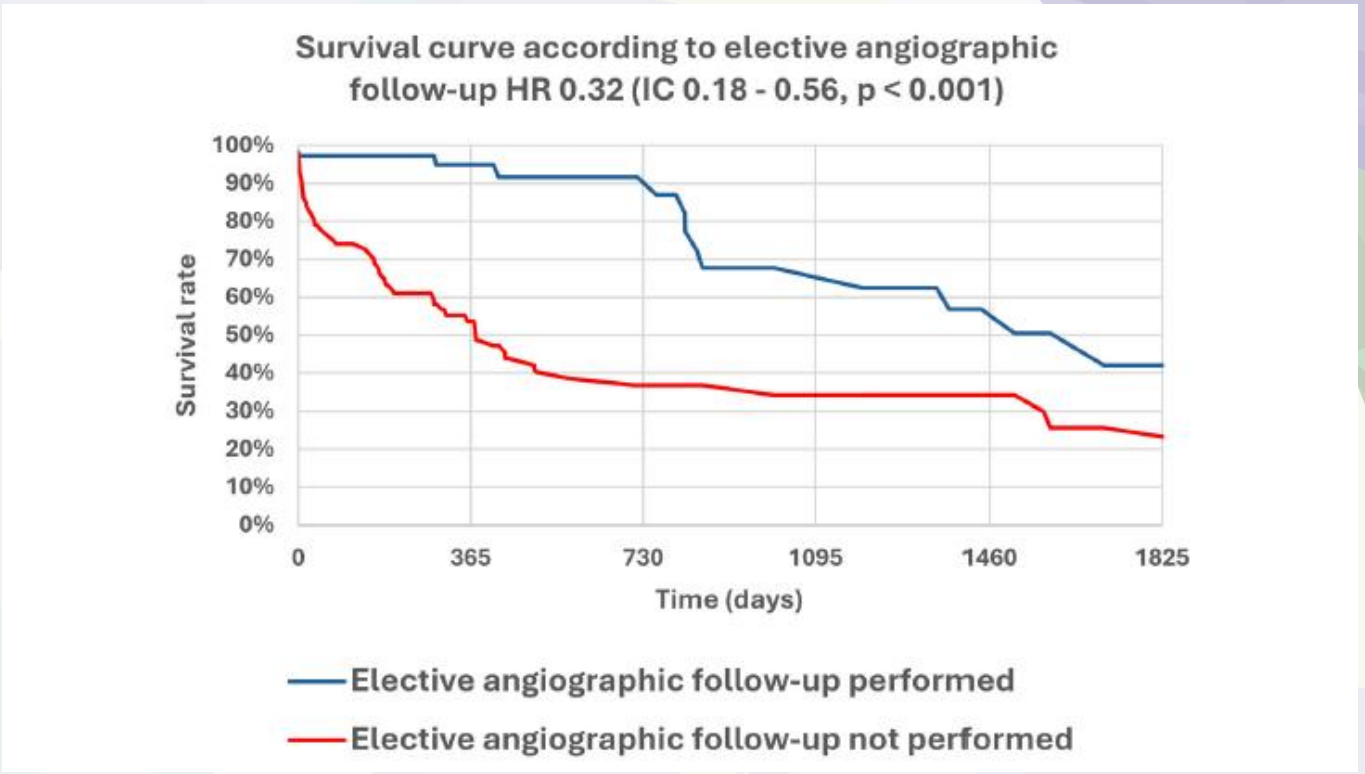
**JACC Cardiovasc Interv. 2017:118-120**

# Twenty Years of Experience in One Thousand De-Novo Left Main Coronary Angioplasty With Angiographic Control in a High-Volume Centre Without On-Site Cardiac Surgery

**Retrospective analysis in 1000 patients**, who underwent PCI on ULMCA for de-novo lesions, at our high-volume Italian center without on-site cardiac surgery, **from 2002 to April 2023.**

**Angiographic follow-up data were available for 739 patients (73.9%),** of whom 612 (82.8%) demonstrated good results of the previous PCI and 127 patients **(17.2%) experienced TLF.**

A **propensity score matched** analysis comparing **two homogenous cohorts of 131 patients with and without elective angiographic follow-up demonstrated a significant survival advantage in the elective follow-up group,** highlighting the potential benefits of this strategy.




CCI 2025 Jun;105(7):1616-1629

***ANG**iographic **E**valuation of **L**eft main coronary artery **INtE**rvention*

NCT 04604197

## Tipo de estudio

Iniciativa de investigador

Abbott

## Promotor

CÓDIGO DEL PROMOTOR: EPIC23
Versión final 1.0
Fecha: 23 de Agosto de 2020

https://clinicaltrials.gov/ct2/show/NCT04604197

FundaciónEpic

**FUNDACIÓN EPIC**

P° Condesa de Sagasta 10, 1°C

**24001 – León**

# ANGiographic Evaluation of Left main coronary artery INtErvention

NCT 04604197



# *ANGiographic Evaluation of Left main coronary artery INtErvention*

NCT 04604197

**Diseño**

Estudio aleatorizado, paralelo, multicéntrico nacional con seguimiento a los 6 meses (sólo en el grupo aleatorizado a seguimiento angiográfico) y seguimiento telefónico a los, 12 meses, 24 meses y 36 meses en ambos grupos.

**Objetivos**

Objetivo primario

Evaluar si la revisión angiográfica rutinaria a los 6 meses tras el intervencionismo percutáneo en el tronco común izquierdo permite disminuir el objetivo compuesto de muerte, infarto de miocardio, accidente cerebrovascular, a los 36 meses.

Objetivos secundarios

- Evaluar si la revisión angiográfica rutinaria a los 6 meses tras el intervencionismo percutáneo en el tronco común izquierdo permite disminuir la muerte por cualquier causa, muerte cardiaca, infarto de miocardio, accidente cerebrovascular, trombosis de stent definitiva o probable o la revascularización del vaso tratado.
- Evaluar si existen diferencias en tasas de sangrado BARC > 2 a los 36 meses entre los 2 grupos.
- Utilidad de la tomografía de coherencia óptica para guiar el intervencionismo percutáneo en el tronco común izquierdo.

***ANG**iographic **E**valuation of **L**eft main coronary artery **INtE**rvention*

NCT 04604197



**Criterios de inclusión**

- Pacientes con edad ≥ 18 años y hasta 85 años en la fecha del ICP y;
- Pacientes que, según la práctica rutinaria han sido tratados con ICP por presentar lesión de novo en Tronco Común Izquierdo (TCI) mediante el implante de un stent de cromo-cobalto con fluoropolímero liberador de everolimus.
- El paciente ha sido informado de las características del estudio y ha facilitado su consentimiento informado por escrito.

**Criterios de exclusión**

- Rechazo expreso del paciente a participar en el estudio.
- Pacientes con infarto de miocardio con elevación del segmento ST en el ingreso actual.
- Pacientes con cirugía coronaria previa.
- Pacientes con aclaramiento de creatinina <40 ml / min.
- Pacientes con contraindicación para la doble antiagregación post ICP.
- Pacientes incluidos en otros estudios o ensayos clínicos.
- Pacientes con esperanza de vida <36 meses.
- Mujeres embarazadas o en período de lactancia.



## 6.2. TAMAÑO DE LA MUESTRA

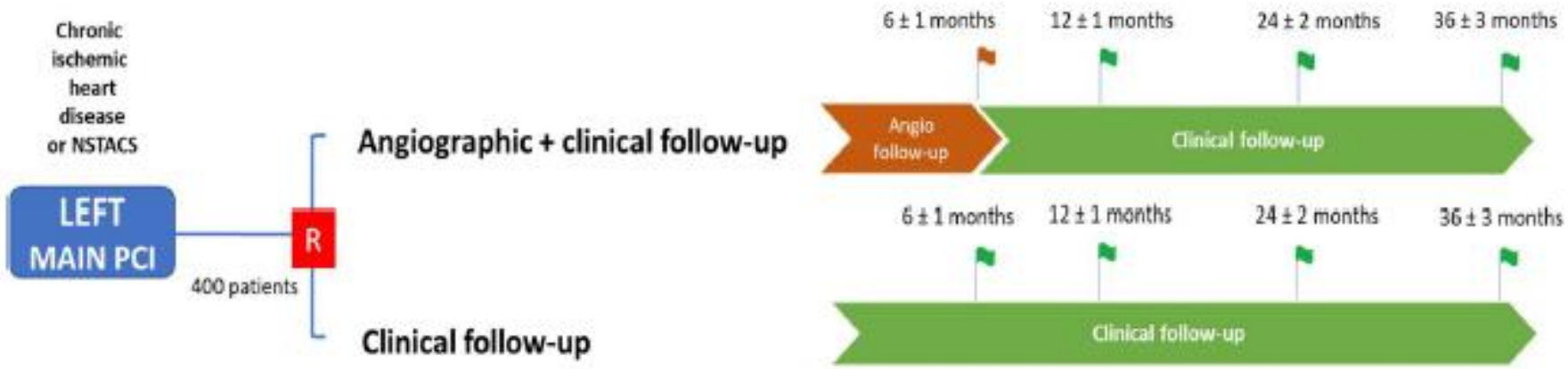
Con los datos de EXCEL [8] y NOBLE [9], se podría esperar una tasa de eventos del 20% en el grupo de control a los 3 años. Para reducir un 25%, cifra que podría considerarse lo suficientemente relevante como para conducir al seguimiento angiográfico en caso de que el estudio sea positivo, se necesitarían 1009 pacientes en cada rama ($\alpha$ = 0.05, 1- $\beta$ = 0.8, $\rho$ = 0.05, 10% de pacientes perdidos). Se deben analizar dos subgrupos preespecificados: lesiones de TCI tratadas con 2 stents y lesiones de TCI tratadas con dilatación máxima $\leq$ 3.5 mm.

Sin embargo, debido a la incertidumbre de los resultados [14, 15] y las restricciones económicas actuales para realizar estudios médicos, el diseño del estudio será piloto con 400 pacientes en 20 centros. Este estudio puede proporcionar datos sobre la conveniencia de realizar un estudio con la potencia adecuada.

# ANGiographic Evaluation of Left main coronary artery INtErvention

NCT 04604197





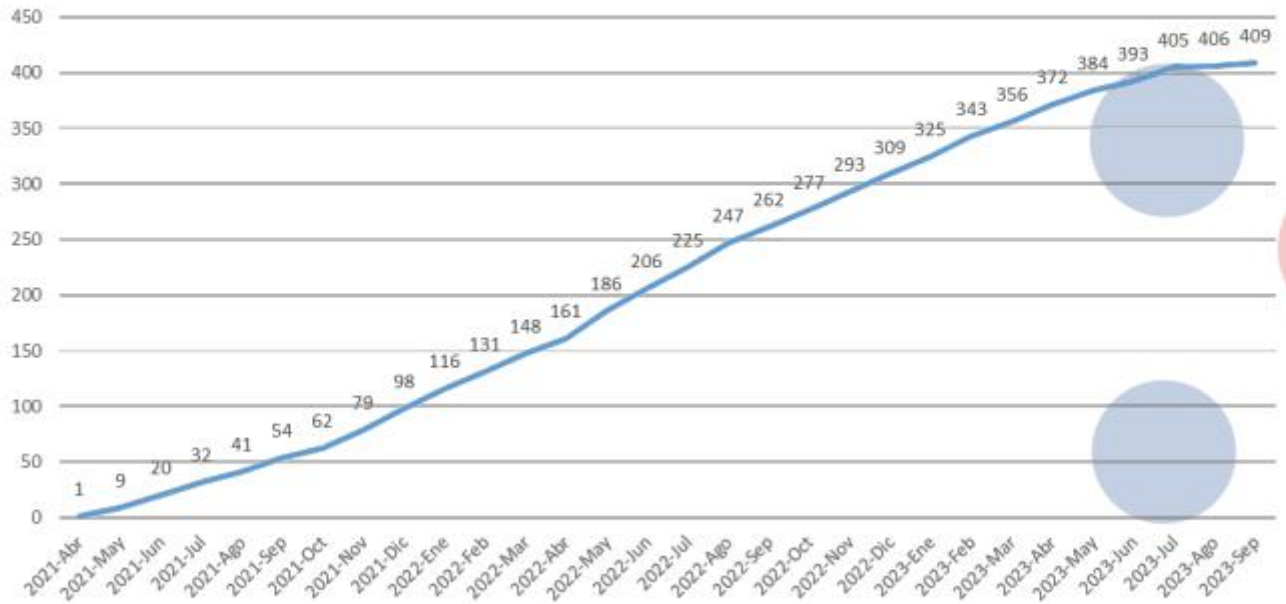

# *ANGiographic Evaluation of Left main coronary artery INtErvention*

NCT 04604197

iEpic

**NEWSLETTER Nº19 ESTUDIO EPIC23-ANGELINE – FECHA 31 DE ENERO DE 2024**

## Evolución del Reclutamiento



**ANGiographic Evaluation of Left main coronary artery INtErvention**

NCT 04604197

1. **Incertidumbre de los resultados.**
2. **Contexto económico actual.**

Thabane *et al. BMC Medical Research Methodology* 2010, **10**:1
http://www.biomedcentral.com/1471-2288/10/1

BMC Medical Research Methodology

COMMENTARY Open Access

## A tutorial on pilot studies: the what, why and how

Lehana Thabane[1,2*], Jinhui Ma[1,2], Rong Chu[1,2], Ji Cheng[1,2], Afisi Ismaila[1,3], Lorena P Rios[1,2], Reid Robson[3], Marroon Thabane[1,4], Lora Giangregorio[5], Charles H Goldsmith[1,2]

In many cases, pilot studies are conducted to generate data for sample size calculations. This seems especially sensible in situations where there are no data from previous studies to inform this process. However, it can be dangerous to use pilot studies to estimate treatment effects, as such estimates may be unrealistic/biased because of the limited sample sizes. Therefore if not used cautiously, results of pilot studies can potentially mislead sample size or power calculations [21] – particularly if the pilot study was done to see if there is likely to be a treatment effect in the main study. In section 6, we provide guidance on how to proceed with caution in this regard.

in clinically important endpoints. The sample used in the pilot may be included in the main study, but caution is needed to ensure the key features of the main study are preserved in the pilot (e.g. blinding in randomized controlled trials). We recommend if any pooling of pilot and main study data is considered, this should be planned beforehand, described clearly in the protocol with clear discussion of the statistical consequences and methods. The goal is to avoid or minimize the potential bias that may occur due to multiple testing issues or any other opportunistic actions by investigators. In general, pooling when done appropriately can increase the efficiency of the main study [23].

• ***Can I combine data from a pilot with data from the main study?***

- Yes, provided the sampling frame and methodologies are the same. This can increase the efficiency of the main study - see Section 5.

**ANGiographic Evaluation of Left main coronary artery INtErvention**

NCT 04604197



## A Randomized Pilot Clinical Trial of Early Coronary Angiography Versus No Early Coronary Angiography for Post-Cardiac Arrest Patients Without ST-Segment Elevation: The PEARL Study

**Background:** The benefit of emergent coronary angiography after resuscitation from out-of-hospital cardiac arrest (OHCA) is uncertain for patients without ST-segment elevation (STE). The aim of this randomized trial was to evaluate the efficacy and safety of early coronary angiography and to determine the prevalence of acute coronary occlusion in resuscitated OHCA patients without STE.

**Methods:** Adult (>18 years) comatose survivors without STE after resuscitation from OHCA were prospectively randomized in a 1:1 fashion under exception to informed consent regulations to early coronary angiography versus no early coronary angiography in this multi-center study. Early angiography was defined as ≤ 120 minutes from arrival at the percutaneous coronary intervention capable facility. The primary endpoint was a composite of efficacy and safety measures, including efficacy parameters of survival to discharge, favorable neurological status at discharge (Cerebral Performance Category ≤ 2), echocardiographic measures of left ventricular ejection fraction >50% and a normal regional wall motion score of 16 within 24 hours of admission. Adverse events included re-arrest, pulmonary edema on chest x-ray, acute renal dysfunction, bleeding requiring transfusion or intervention, hypotension (systolic arterial pressure ≤90 mmHg), and pneumonia. Secondary endpoints included the incidence of culprit vessels with acute occlusion.

**Results:** The study was prematurely terminated before enrolling the target number of patients. A total of 99 patients were enrolled from 2015-2018, including 75 with initially shockable rhythms. Forty-nine patients were randomized to early coronary angiography. The primary endpoint of efficacy and safety was not different between the two groups (55.1% vs 46.0%; p=0.64). Early coronary angiography was not associated with any significant increase in survival (55.1% vs 48.0%; p=0.55 or adverse events (26.5% vs 26.0%; p=1.00). Early coronary angiography revealed a culprit vessel in 47%, with a total of 14% of patients undergoing early coronary angiography having an acutely occluded culprit coronary artery.

**Conclusions:** This underpowered study, when considered together with previous clinical trials, does not support early coronary angiography for comatose survivors of cardiac arrest without ST elevation. Whether early detection of occluded potential culprit arteries leads to interventions that improve outcomes requires additional study.

**Clinical Trial Registration:** URL: https://www.clinicaltrials.gov. Unique identifier: NCT02387398

10.1161/CIRCULATIONAHA.120.049569

## Advanced reperfusion strategies for patients with out-of-hospital cardiac arrest and refractory ventricular fibrillation (ARREST): a phase 2, single centre, open-label, randomised controlled trial

*Demetris Yannopoulos, Jason Bartos, Ganesh Raveendran, Emily Walser, John Connett, Thomas A Murray, Gary Collins, Lin Zhang, Rajat Kalra, Marinos Kosmopoulos, Ranjit John, Andrew Shaffer, R J Frascone, Keith Wesley, Marc Conterato, Michelle Biros, Jakub Tolar, Tom P Aufderheide*

### Summary

**Background** Among patients with out-of-hospital cardiac arrest (OHCA) and ventricular fibrillation, more than half present with refractory ventricular fibrillation unresponsive to initial standard advanced cardiac life support (ACLS) treatment. We did the first randomised clinical trial in the USA of extracorporeal membrane oxygenation (ECMO)-facilitated resuscitation versus standard ACLS treatment in patients with OHCA and refractory ventricular fibrillation.

**Methods** For this phase 2, single centre, open-label, adaptive, safety and efficacy randomised clinical trial, we included adults aged 18–75 years presenting to the University of Minnesota Medical Center (MN, USA) with OHCA and refractory ventricular fibrillation, no return of spontaneous circulation after three shocks, automated cardiopulmonary resuscitation with a Lund University Cardiac Arrest System, and estimated transfer time shorter than 30 min. Patients were randomly assigned to early ECMO-facilitated resuscitation or standard ACLS treatment on hospital arrival by use of a secure schedule generated with permuted blocks of randomly varying block sizes. Allocation concealment was achieved by use of a randomisation schedule that required scratching off an opaque layer to reveal assignment. The primary outcome was survival to hospital discharge. Secondary outcomes were safety, survival, and functional assessment at hospital discharge and at 3 months and 6 months after discharge. All analyses were done on an intention-to-treat basis. The study qualified for exception from informed consent (21 Code of Federal Regulations 50.24). The ARREST trial is registered with ClinicalTrials.gov, NCT03880565.

**Findings** Between Aug 8, 2019, and June 14, 2020, 36 patients were assessed for inclusion. After exclusion of six patients, 30 were randomly assigned to standard ACLS treatment (n=15) or to early ECMO-facilitated resuscitation (n=15). One patient in the ECMO-facilitated resuscitation group withdrew from the study before discharge. The mean age was 59 years (range 36–73), and 25 (83%) of 30 patients were men. Survival to hospital discharge was observed in one (7%) of 15 patients (95% credible interval 1·6–30·2) in the standard ACLS treatment group versus six (43%) of 14 patients (21·3–67·7) in the early ECMO-facilitated resuscitation group (risk difference 36·2%, 3·7–59·2; posterior probability of ECMO superiority 0·9861). The study was terminated at the first preplanned interim analysis by the National Heart, Lung, and Blood Institute after unanimous recommendation from the Data Safety Monitoring Board after enrolling 30 patients because the posterior probability of ECMO superiority exceeded the prespecified monitoring boundary. Cumulative 6-month survival was significantly better in the early ECMO group than in the standard ACLS group. No unanticipated serious adverse events were observed.

www.thelancet.com Published online November 13, 2020
https://doi.org/10.1016/S0140-6736(20)32338-2

# PRESENTE DE LA ENFERMEDAD DEL TRONCO

| 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 |

## ¿ FUTURO? INVESTIGACIÓN EN ENFERMEDAD DE TRONCO EN SYNTAX ≤ 32: ¿QUÉ RECORRIDO HAY?

- **¿Cómo hacerlo?** **Uno vs. dos stents, DKK vs. culotte.**
- **Técnicas de imagen: Indicación IA.**
- **¿Cómo mejorar resultados?**
  - **Paso 1: RCT piloto: Angeline.**
  - **Paso 2: RCT adecuadamente potenciado.**
  - **Paso 3: RCT de CABG vs. ICP con revisión angiográfica.**

# CONCLUSIONES

- La reestenosis intrastent después de ICP en tronco se asocia a mortalidad.
- Las guías recomiendan realizar un seguimiento angiográfico con nivel IIB, evidencia C.
- Los resultados hasta la fecha no apoyan el uso del TAC para este fin.
- Existen datos que sugieren que la revisión con cateterismo podría mejorar los resultados.
- El estudio ANGELINE, aunque de diseño piloto, tendrá resultados en octubre 2026.
- Este estudio podría ser la base para futura investigación en ICP vs. CABG.