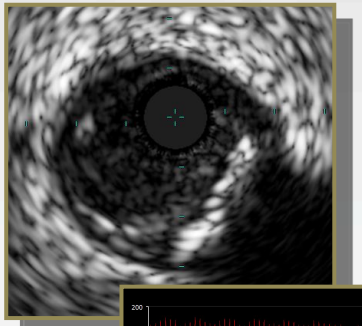
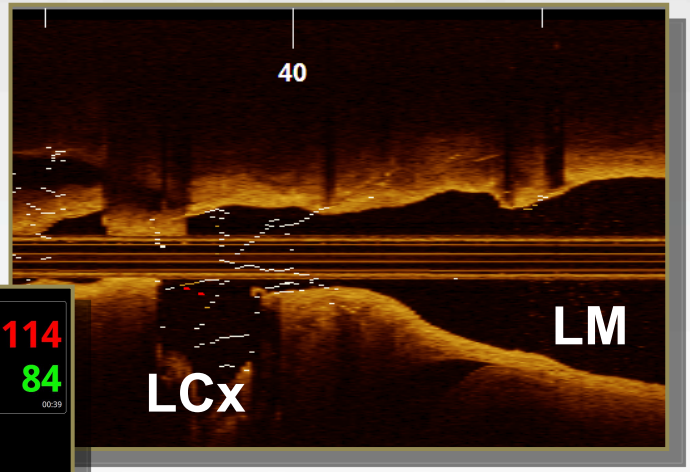
Porto, 14/10/2017

ICTRA®
Institute for Cardiovascular Translational Research of the Atlantic

CALM

Criteria for the Assessment of the Left Main





Juan Luis Gutiérrez-Chico, MD, PhD[2], FESC, FACC

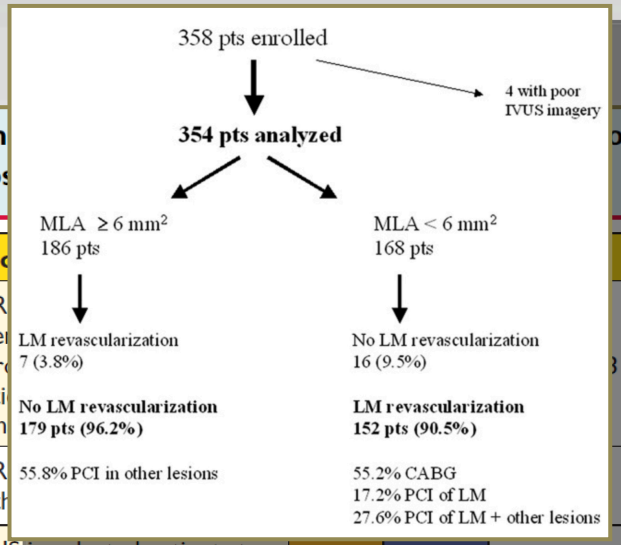
Head of Interventional Cardiology, DRK Klinikum Westend
Berlin, DE

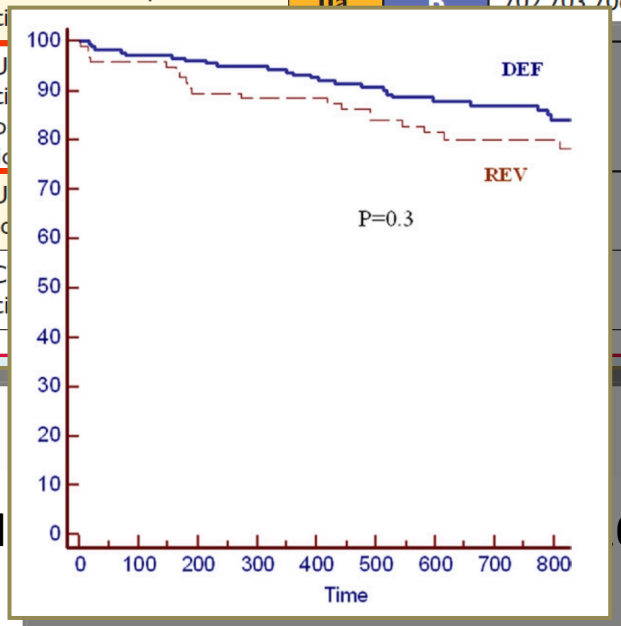
Excellent studies submitted

- **Study proposals:**
  - POLBOS
  - BifurQFR
  - CALM
  - SINBAD
  - BIFURCATOR-2
  - PEPCAD
  - TAPSAMI
  - 3B
  - Bifurcation bench

Introduction / rationale

- **ESC guidelines:**
  - **Assessment of LM severity**
    - **IVUS IIa / B**
    - **No indication for OCT**
      - **Potential advantages if PCI**





CLINICAL RESEARCH

Invasive Cardiology

Prospective Application of Pre-Defined Intravascular Ultrasound Criteria for Assessment of Intermediate Left Main Coronary Artery Lesions

Results From the Multicenter LITRO Study

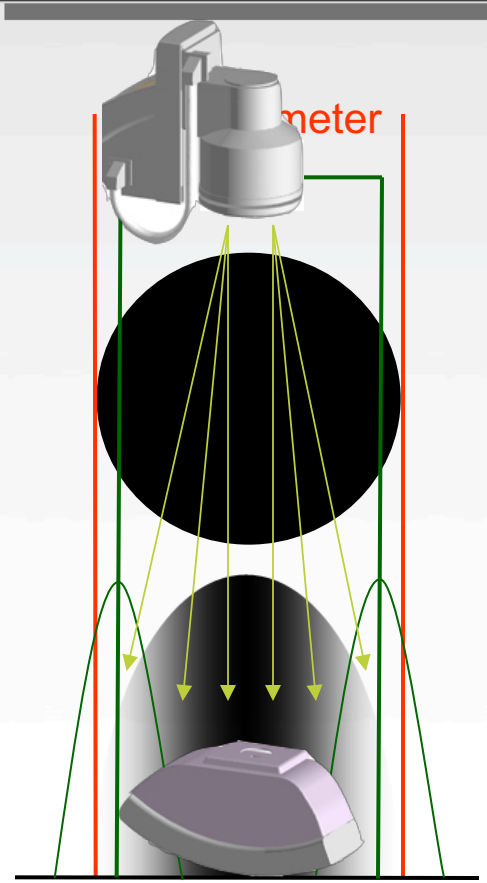
JACC Vol. 58, No. 4, 2011

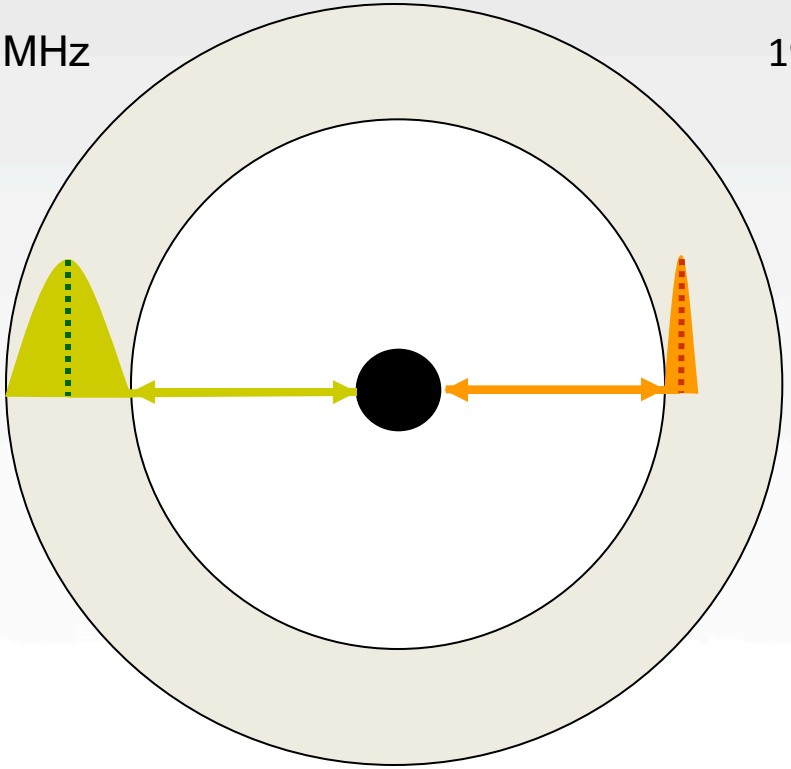
Jose M. de la Torre Hernandez, MD, PHD,* Felipe Hernández Hernandez, MD,† Fernando Alfonso, MD, PHD,‡ Jose R. Rumoroso, MD, PHD,§ Ramon Lopez-Palop, MD, PHD,‖ Mario Sadaba, MD,‡ Pilar Carrillo, MD, PHD,§ Juan Rondan, MD, PHD,¶ Iñigo Lozano, MD, PHD, Juan M. Ruiz Nodar, MD, PHD,# Jose A. Baz, MD,** Eduard Fernandez Nofrerias, MD,†† Fernando Pajin, MD,‡‡ Tamara Garcia Camarero, MD,* Hipolito Gutierrez, MD,§§ on behalf of the LITRO Study Group (Spanish Working Group on Interventional Cardiology)

Introduction - rationale

- **IVUS cutoff (6 mm²) cannot be extrapolated to OCT**
  - **Due to the Physics of image formation**

QCA	IVUS	OCT
	78 µm wavelength	1.5 µm wavelength
	20-40 MHz	192 THz

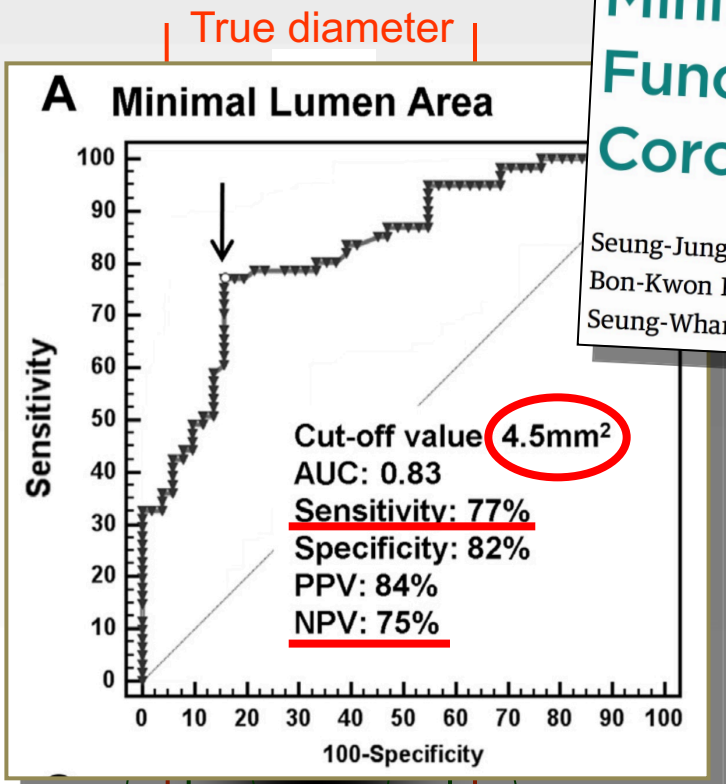




Introduction - rationale

- **IVUS cutoff (6 mm²) cannot be extrapolated to OCT**
  - **Due to the Physics of image formation**
  - **Unclear relation with Physiology**

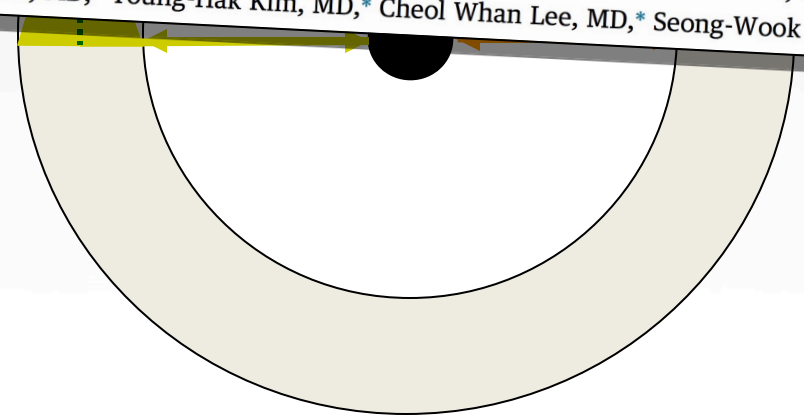
QCA | **IVUS** | **OCT**



Intravascular Ultrasound-Derived Minimal Lumen Area Criteria for Functionally Significant Left Main Coronary Artery Stenosis

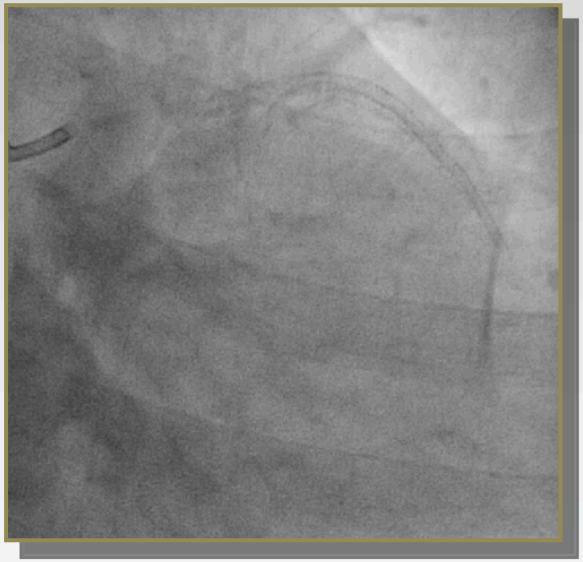
J Am Coll Cardiol Intv 2014;7:868–74

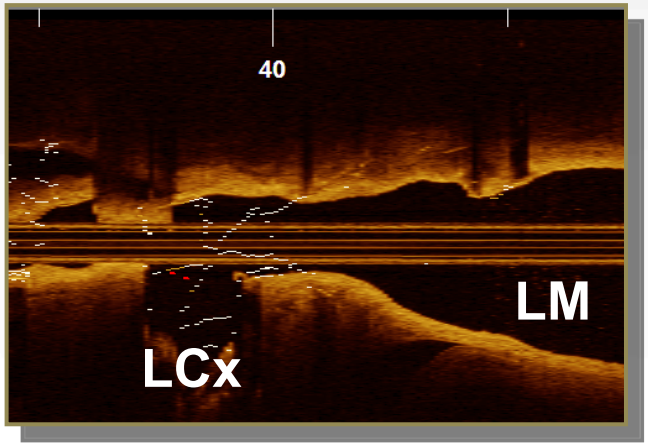
Seung-Jung Park, MD, PHD,* Jung-Min Ahn, MD,* Soo-Jin Kang, MD,* Sung-Han Yoon, MD,* Bon-Kwon Koo, MD,† Jong-Young Lee, MD,* Won-Jang Kim, MD,* Duk-Woo Park, MD,* Seung-Whan Lee, MD,* Young-Hak Kim, MD,* Cheol Whan Lee, MD,* Seong-Wook Park, MD, PHD*

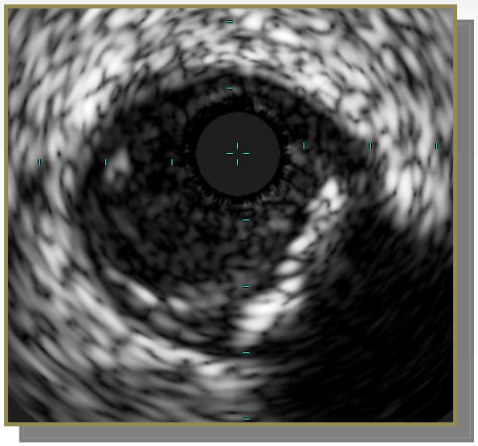


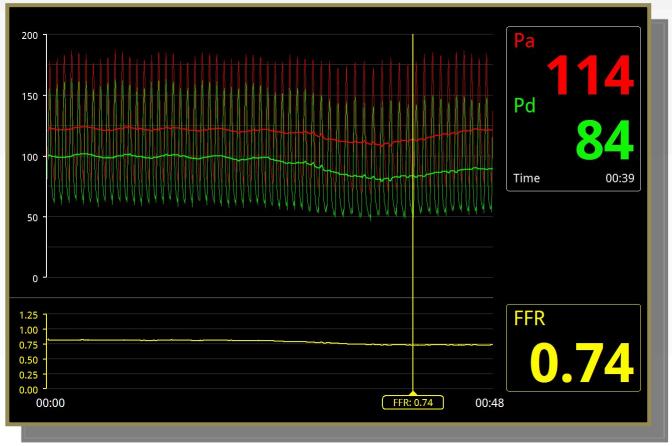
Unmet needs

- **Gaps in the evidence**
  - **Assessment of LM severity**
    - **No OCT study**
    - **Low IVUS indication (IIa-B)**
    - **No comparison against Physiology**
    - **No comparison of strategies**









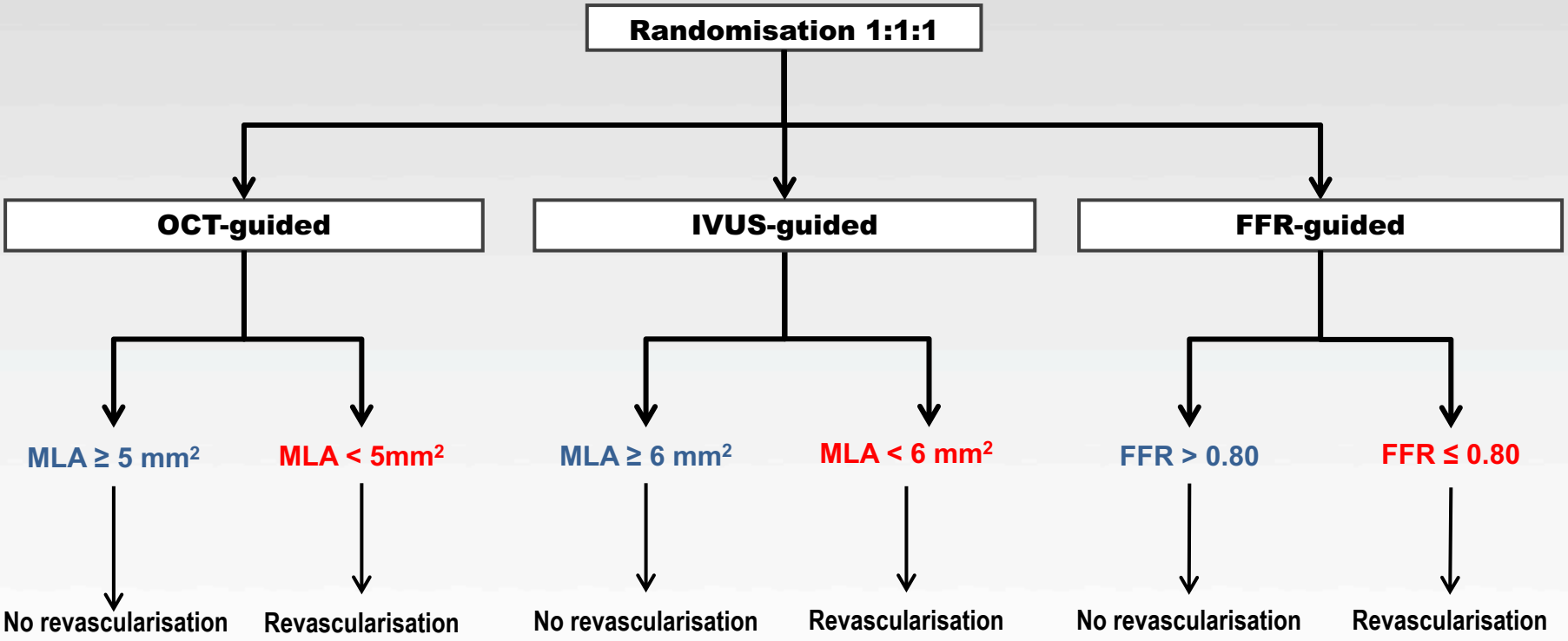
Study design

- **Study design**
  - **Randomised clinical trial**
    - **Single blind (not strictly necessary)**
  - **Multicentre**

- **Inclusion criteria**
  - **LM stenosis**
    - **Moderate-severe (visual)**

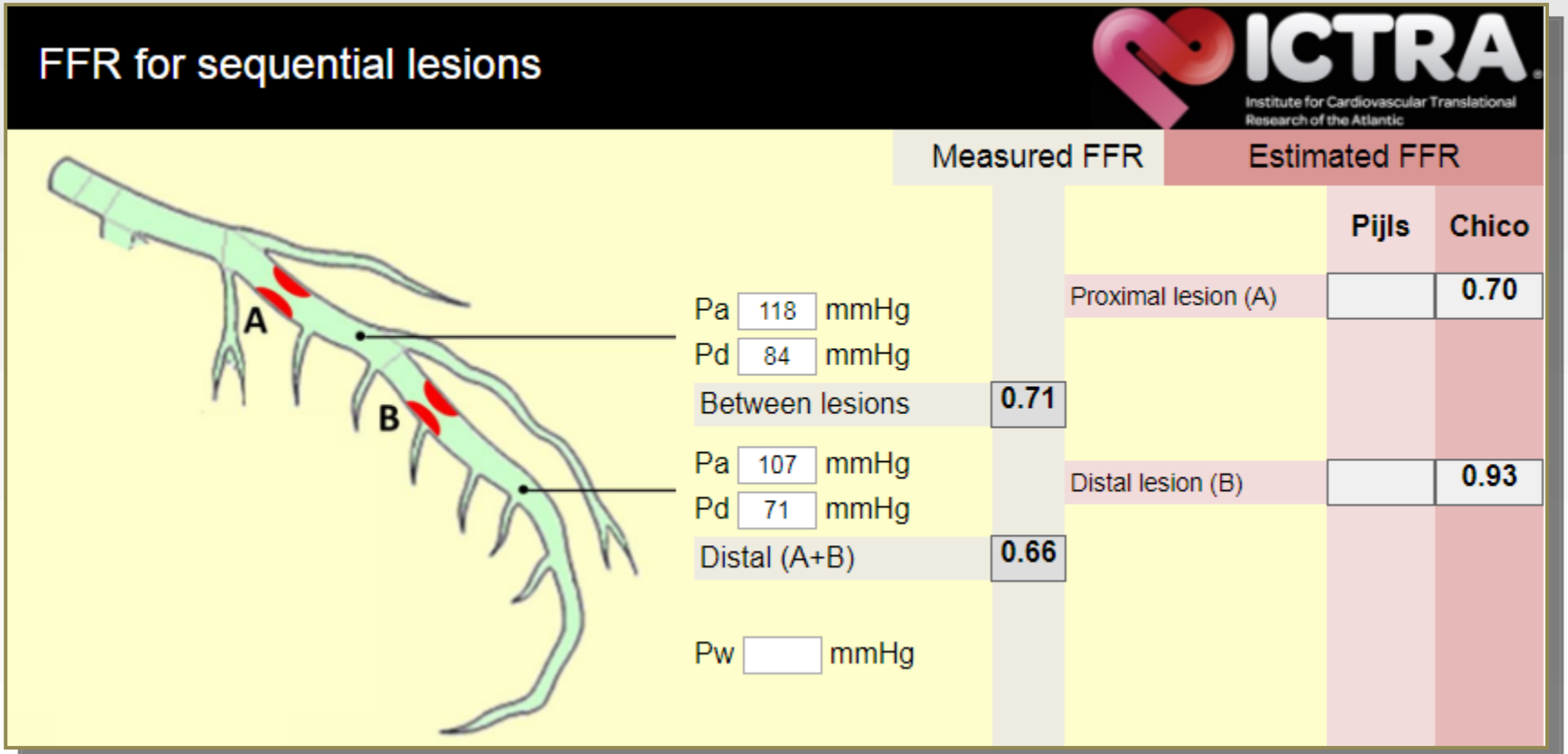
- **Exclusion criteria**
  - **Ostial LM stenosis**
  - **Severe valvulopathy**
  - **Haemodynamic / electric unstability**

Study design - randomisation



Study design - randomisation

- **FFR arm**
  - **Sequential lesions**
    - **Correction formula from APIS-S study: Online calculator**



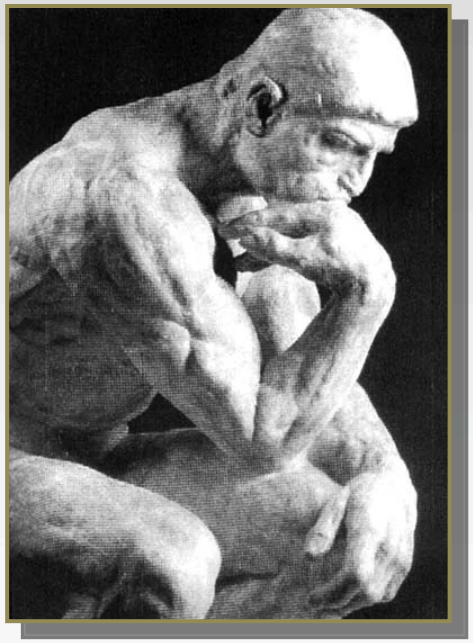
https://journals.viamedica.pl/cardiology_journal/pages/view/calc

Study design – endpoint

- **Primary endpoint: TVF (2 years)**
  - Cardiac death
  - Vessel-related MI
  - TVR
- **Non-inferiority**
  - Non-inferiority margin: 50% of the effect of revascularisation
    - LITRO study:
      - Incidence cardiac death + any MI + any revascularisation
        - Revascularisation group 12.7%
        - MLA < 6 mm^2 not revascularised 37.5%
        - RR 24.8%
    - Non-inferiority margin 12% warrants 50% of the effect
- **Sample size**
  - Conditions
    - One-sided
    - $\alpha = 0.05$
    - $\beta = 0.20$
    - Non-inferiority margin 0.12
    - n = 191 pt per arm
    - +10% (loss at FU): 210 pt per arm
  - Total 630 patients

Discussion of the design

- **Advantages**
  - **Win – win**
    - **Equivalence of the strategies**
      - **Upgrade IVUS indication (I / A)**
      - **Incorporation of OCT**
    - **One strategy better: even more interesting**
      - **Eventual role of imaging in PCI**
  - **Realistic sample size**
- **Problems**
  - **Ostial LAD/LCX: potential confounder**



What do we need?

- **Partners:**
  - **Berlin**
  - **Valladolid**
  - **LM-PCI = 2.5%**
    - **26 centres 1000 PCIs / year**
- **CRO**
  - **Budget**
- **Sponsor**
- **EBC endorsement**

Gutiérrez-Chico JL
Amat-Santos I
Cortés C
Arnold R

EBC

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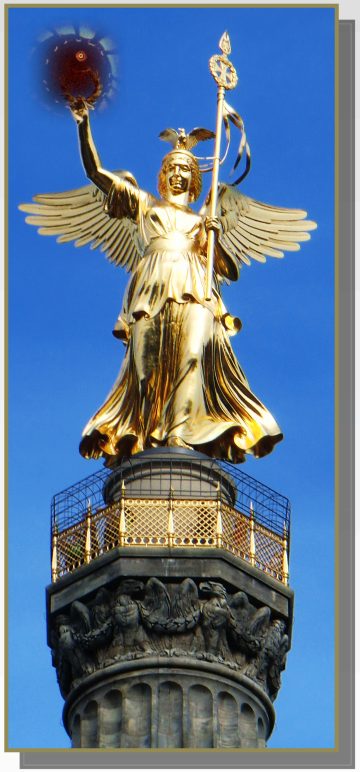

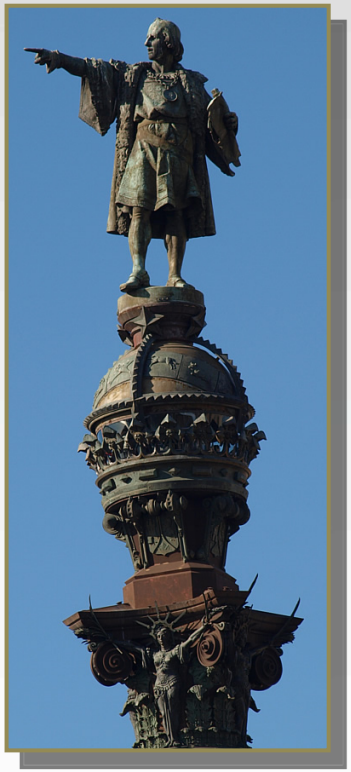

Thank you very much for your attention

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