# Estado Actual de la Cardiología Intervencionista

*Dr Carlos Macaya*

# Estado Actual Cardiología Intervencionista

Intervencionismo Coronario vs ESTRUCTURAL

1. **Angioplastia Primaria en el IAM**
   Planificación de la Asistencia Cardiovascular
   *Regionalización y Redes Asistenciales.*
2. Intervencionismo coronario
3. Intervencionismo ESTRUCTURAL

# Creación de Redes para un Tx Óptimo del IAM

Población

Logística SME

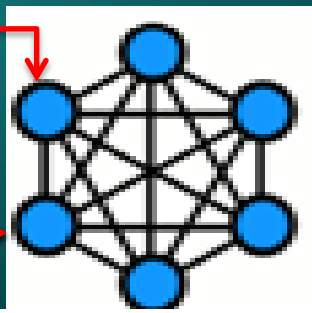
Institucionalización

Profesionales hospitalarios

Figure 1. The distribution of 22 primary PCI centres in 14 regions in the Czech Republic.



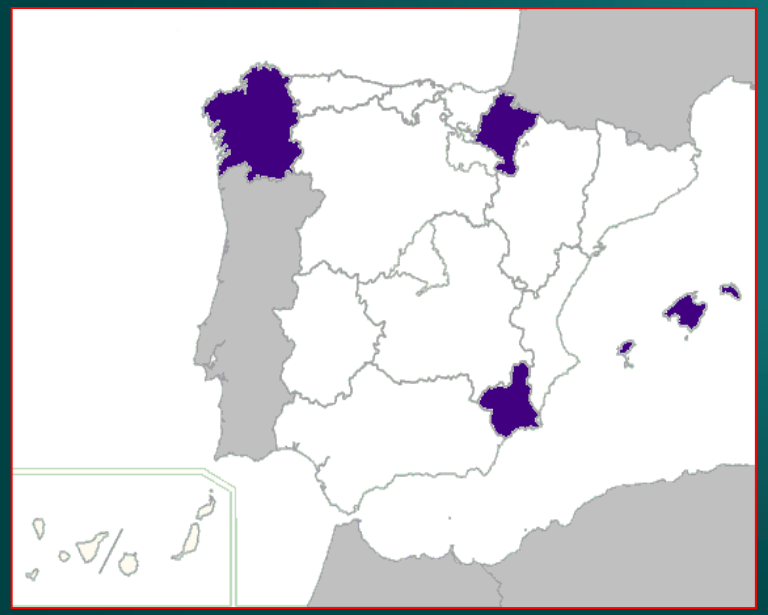




"RED"

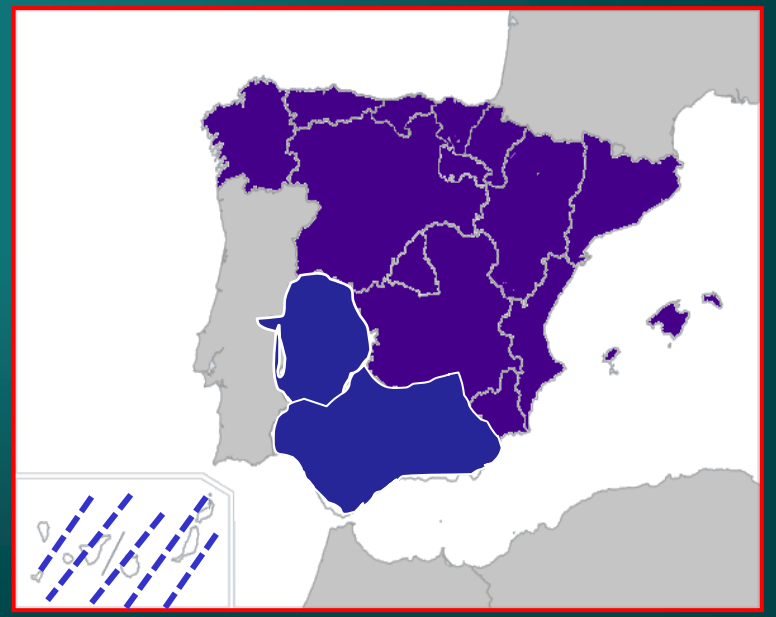
# España: Evolución de las Redes Asistenciales para el IAM

**Año 2008**: 4 STEMI Networks, 12.8% Coverage
Galicia, Navarra, Murcia y Baleares



**Año 2016**: 13 STEMI Networks, 75% Coverage
Cataluña, Madrid, Asturias,Aragon, C. La Mancha y C. León, Valencia.

**Año 2018**: 16 STEMI Networks, 99,5% Coverage
Andalucia (julio 2018), Canarias (Agosto 2018) y Extremadura (1 octubre 2018)



# Estado Actual Cardiología Intervencionista

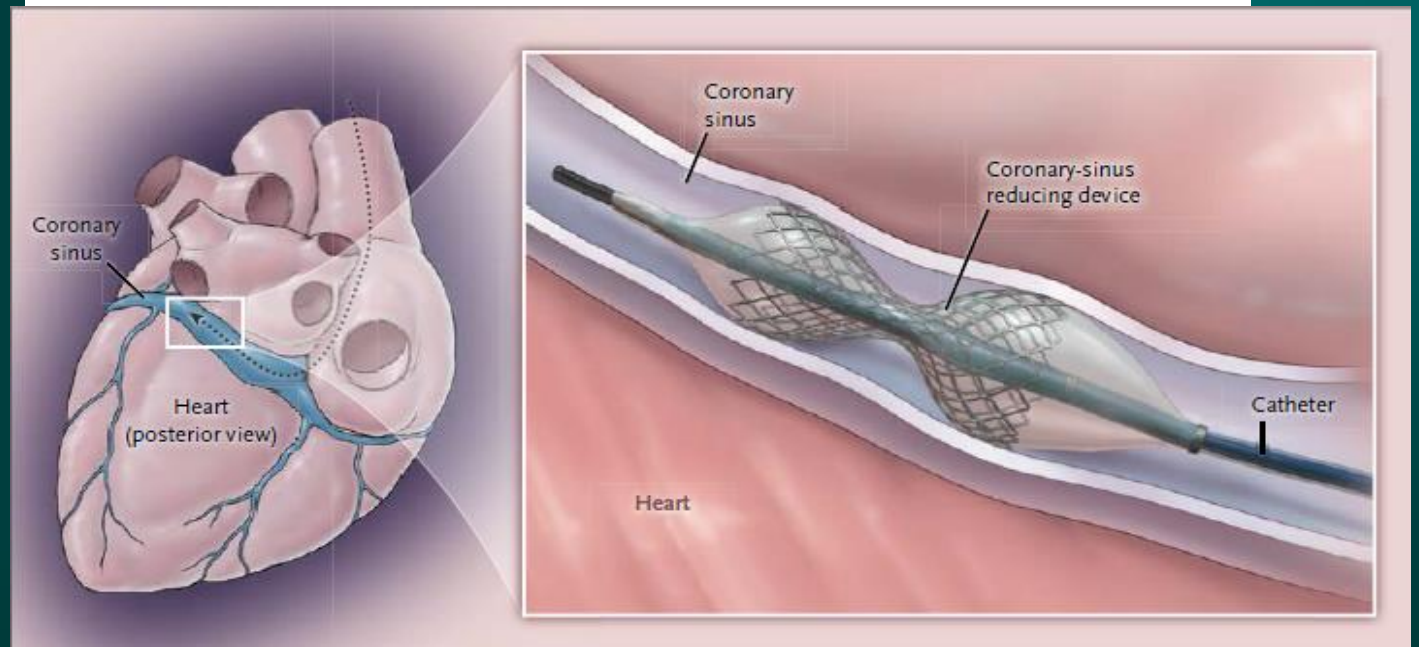
1. Planificación de la Asistencia Cardiovascular
   *Regionalización y Redes Asistenciales. Un modelo: la angioplastia primaria en el IAM*
2. Intervencionismo coronario
   1. Nuevos dispositivos para Tx de casos/lesiones complejas
   2. Fisiología coronaria y técnicas de imagen IC en el ICP
   3. Guias de Revascularización Miocárdica ESC 2018
3. Intervencionismo ESTRUCTURAL

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# Efficacy of a Device to Narrow the Coronary Sinus in Refractory Angina

Stefan Verheye, M.D., Ph.D., E. Marc Jolicœur, M.D., Miles W. Behan, M.D., Thomas Pettersson, M.D., Paul Sainsbury, M.D., Jonathan Hill, M.D., Mathias Vrolix, M.D., Pierfrancesco Agostoni, M.D., Thomas Engstrom, M.D., Marino Labinaz, M.D., Ranil de Silva, M.D., Marc Schwartz, R.C.I.S., Nathalie Meyten, M.D., Neal G. Uren, M.D., Serge Doucet, M.D., Jean-François Tanguay, M.D., Steven Lindsay, M.D., Timothy D. Henry, M.D., Christopher J. White, M.D., Elazer R. Edelman, M.D., Ph.D., and Shmuel Banai, M.D.



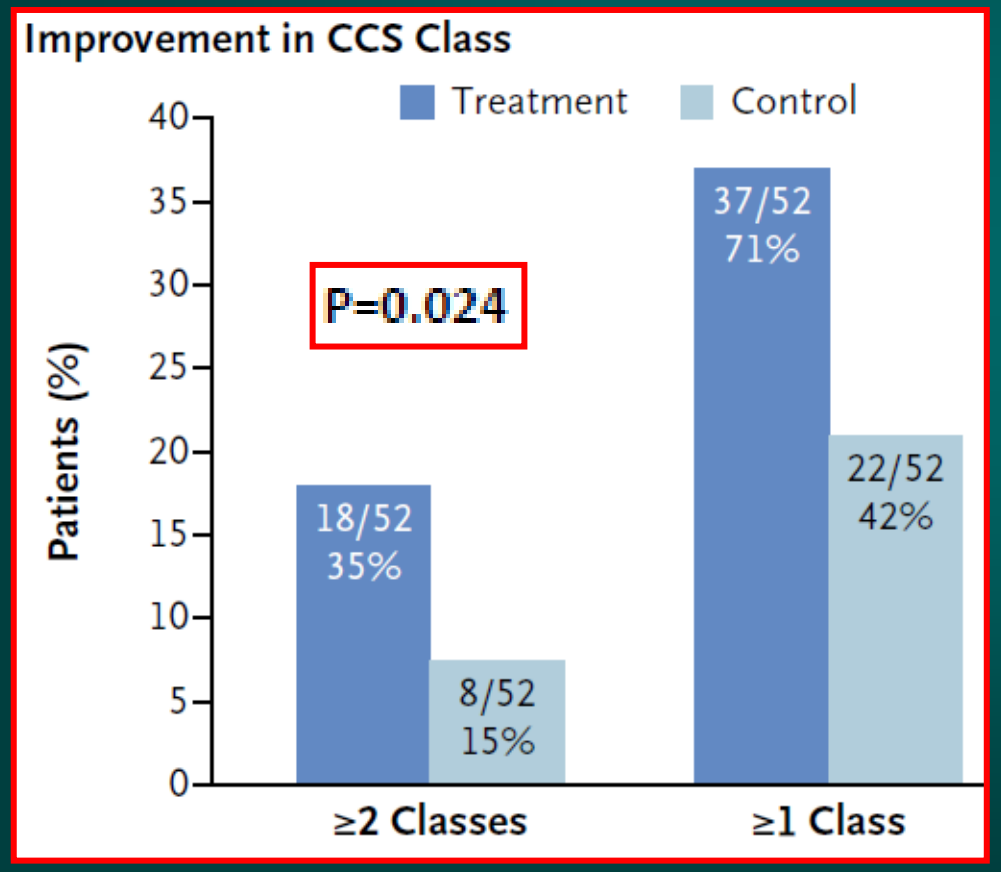

**Objetivo:** Evaluar si el dispositivo "Reducer" mejora síntomas en pacientes con angina CCS 3-4, no candidatos para revascularización.

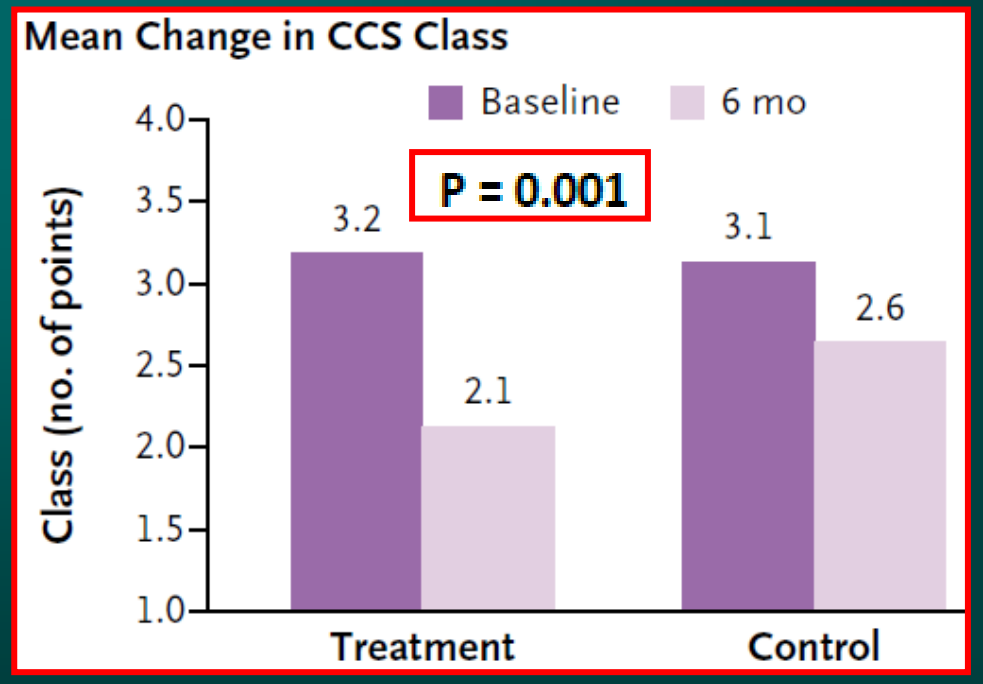
**Diseño del estudio:**
Ensayo clínico prospectivo, fase-II, randomizado, doble-ciego, multi-céntrico diseñado para evaluar la eficacia y seguridad del "Reducer" en
11 centros
104 pacientes

*N Engl J Med. 2015; 372(6):519-27*

# Safety and Efficacy of the Coronary Sinus Reducer in Patients with Refractory Angina: the COSIRA Trial

(COronary SInus Reducer for Treatment of Refractory Angina)

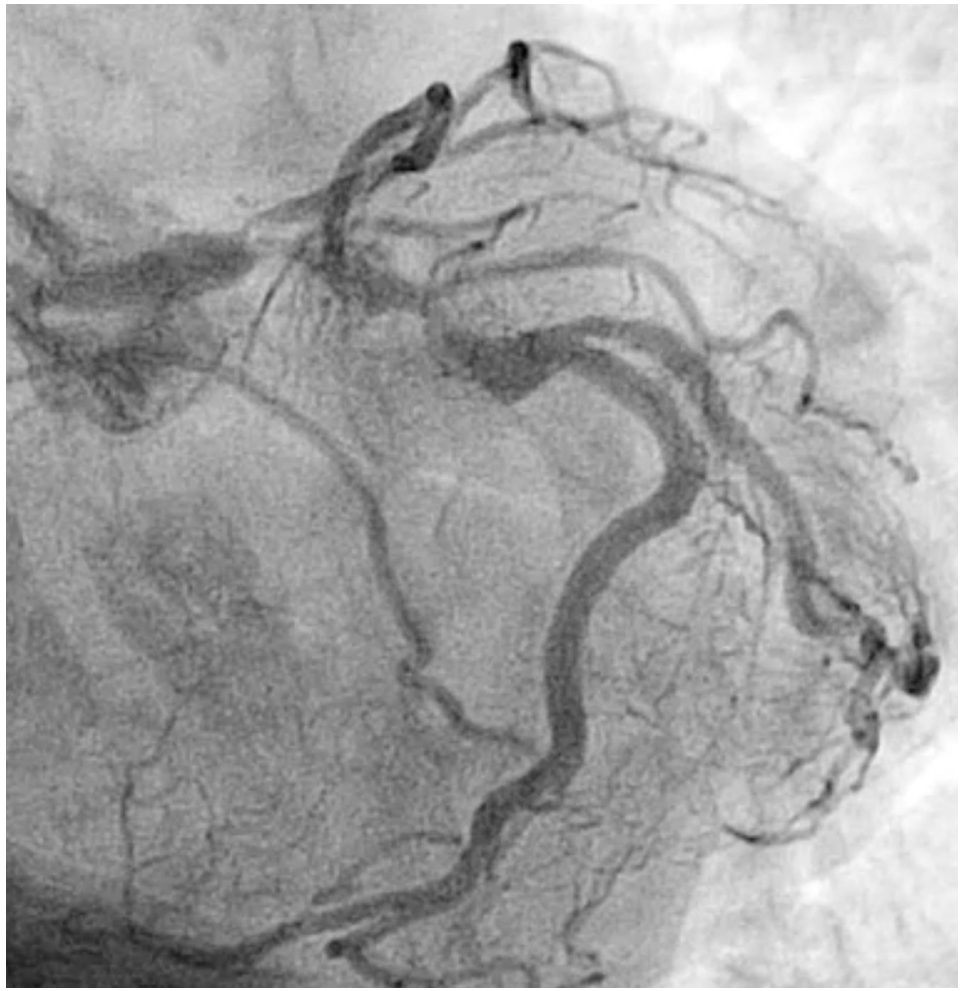


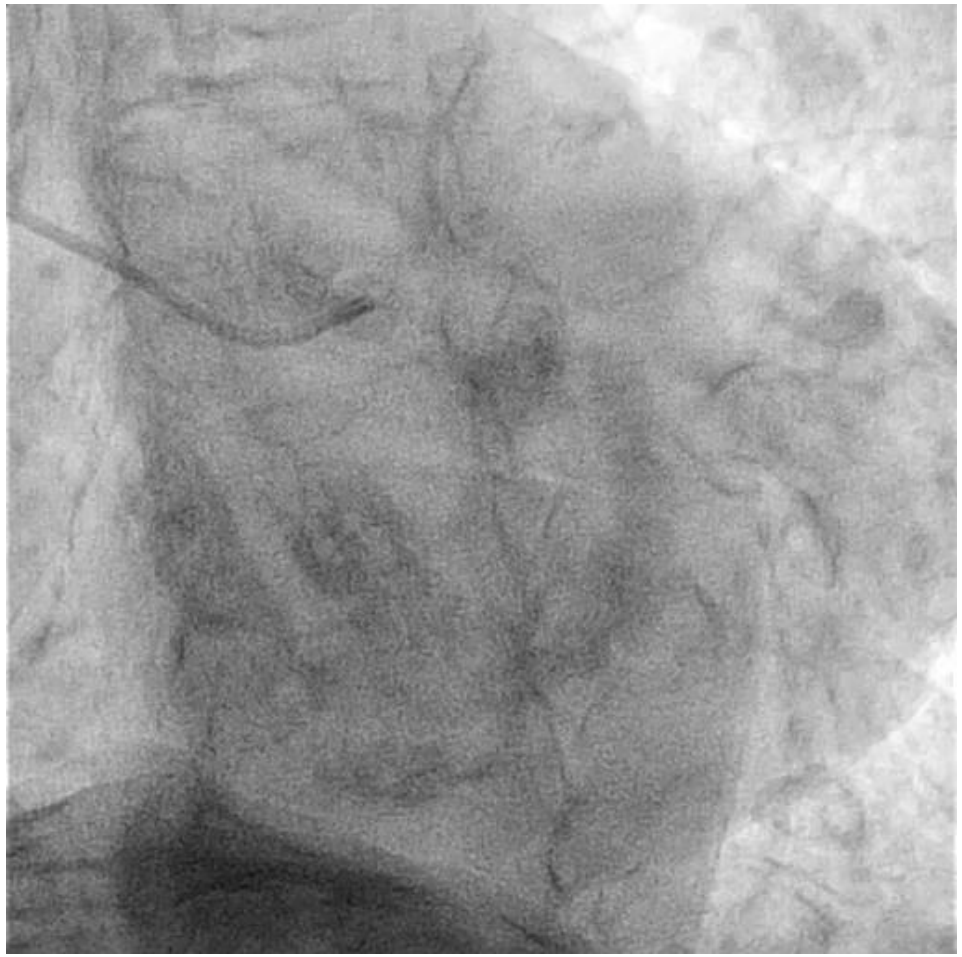

*N Engl J Med. 2015; 372(6):519-27*

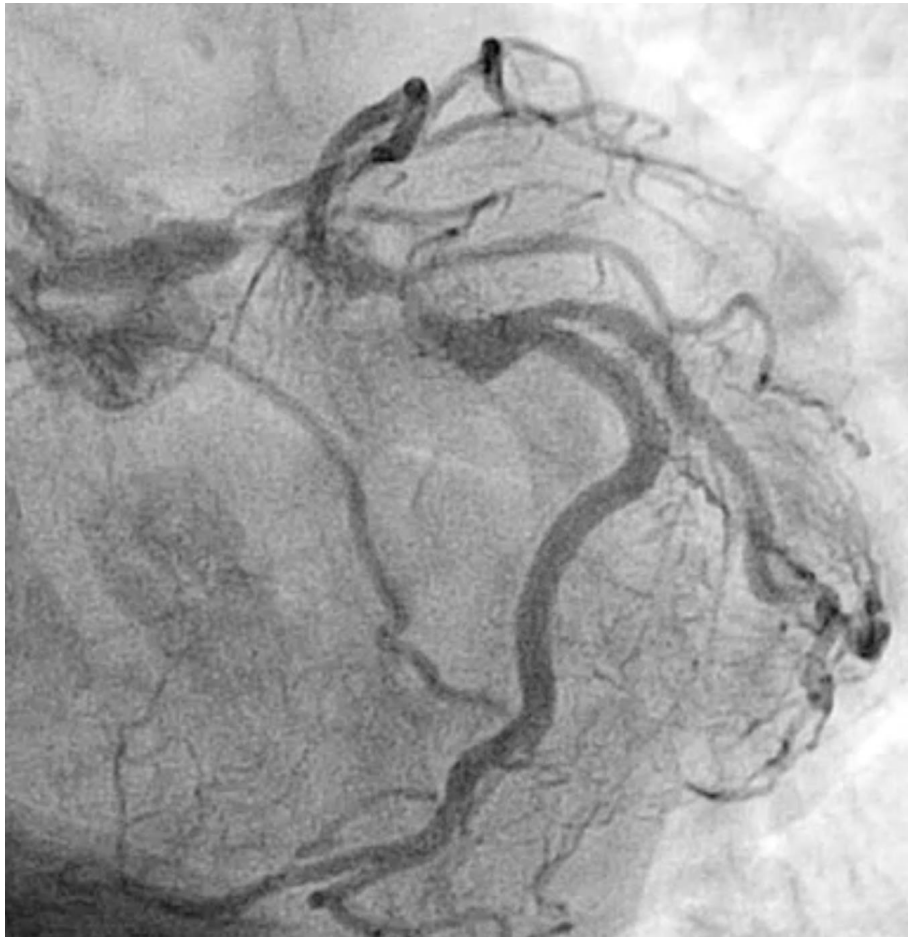
# Lithoplasty (ShockWave): Case summary

- 94 year old female
- Non-STEMI
- Severe calcified LM stenosis with LAD/LCX involvement (Medina 1-1-1)
- Preserved LVEF
- SYNTAX score II recommendation: CABG or PCI



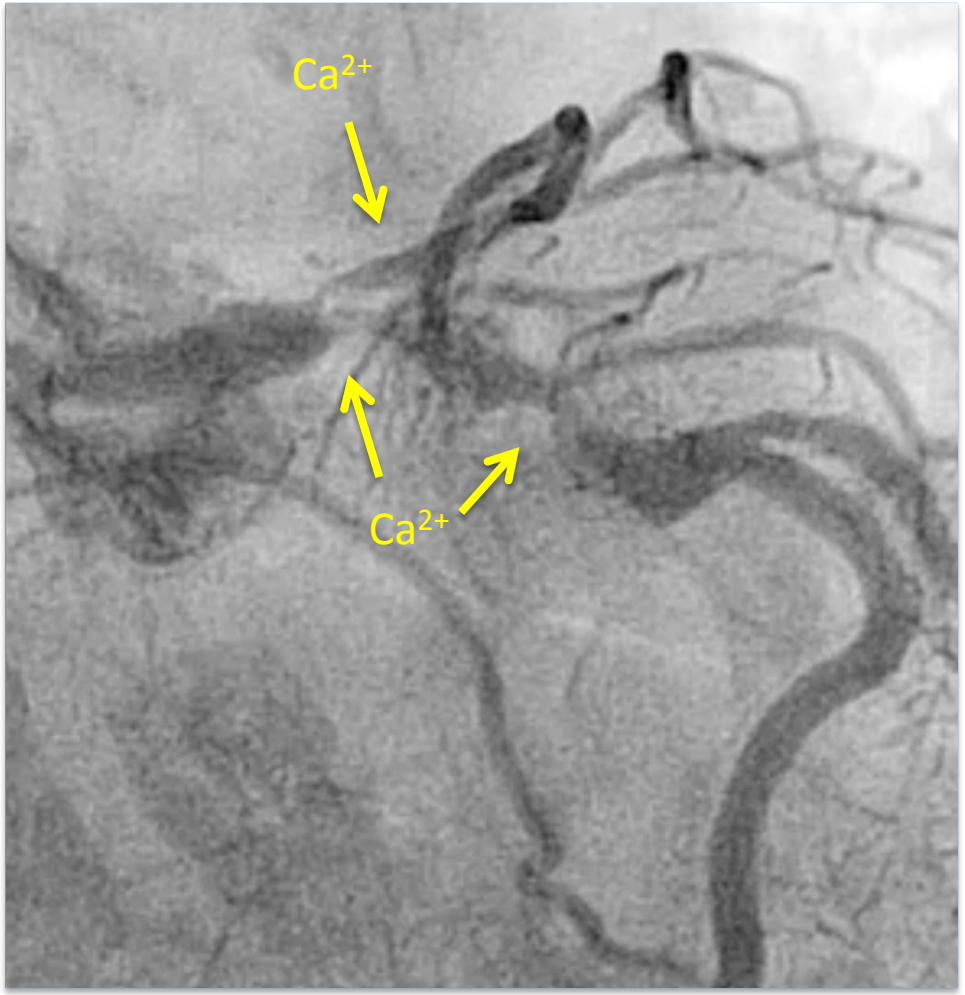
# Coronary angiography

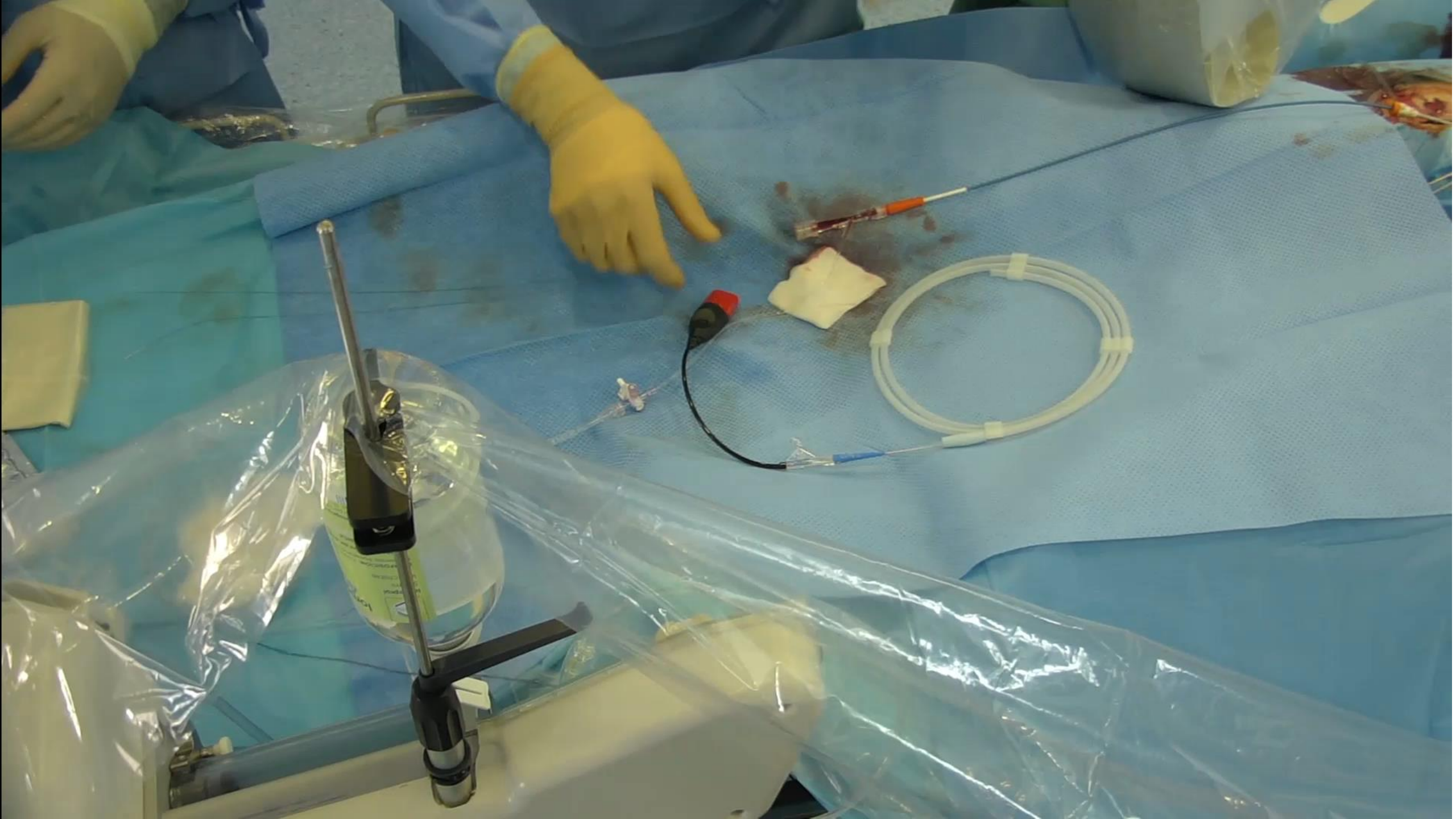




# Case planning (ShockWawe Balloon)

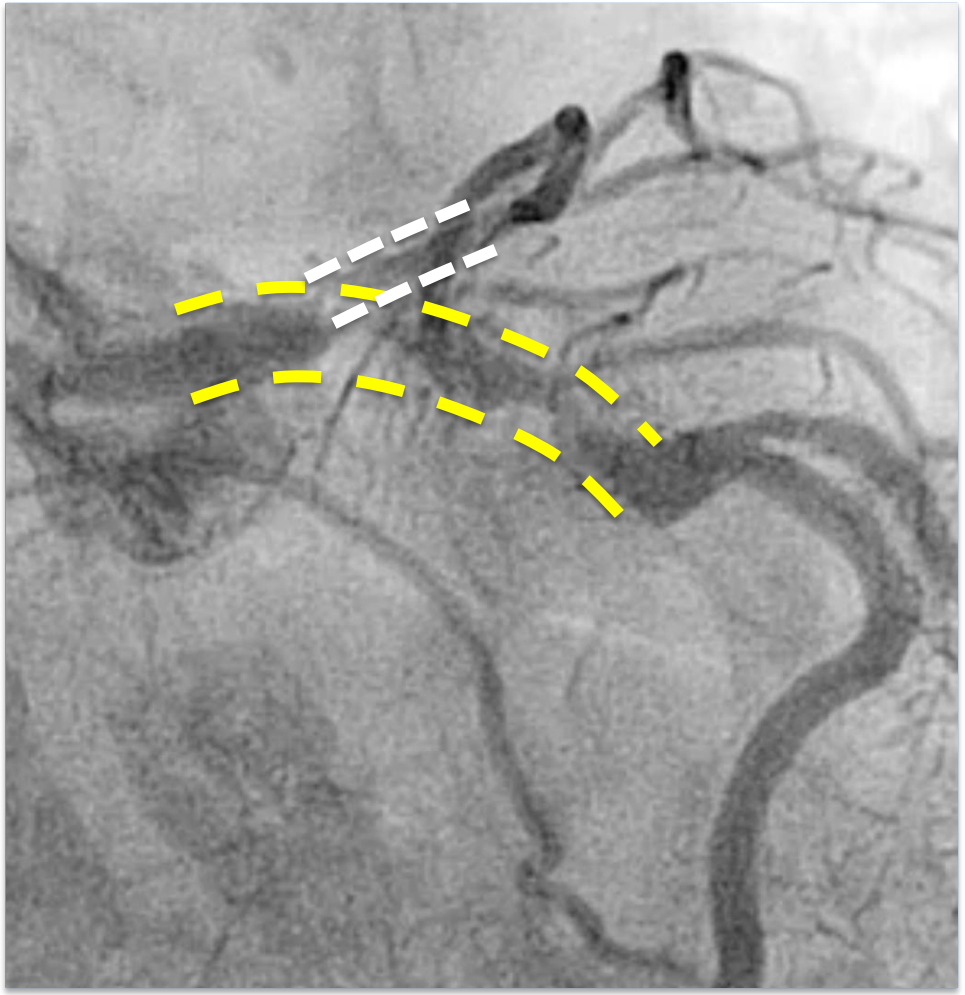
- Percutaneous coronary intervention
- Conscious sedation
- **Plaque preparation using intravascular lithoplasty**
- Procedural IVUS guidance
- Two-stent treatment of LM anticipated (TAP technique)
- Standby cardiac assistance



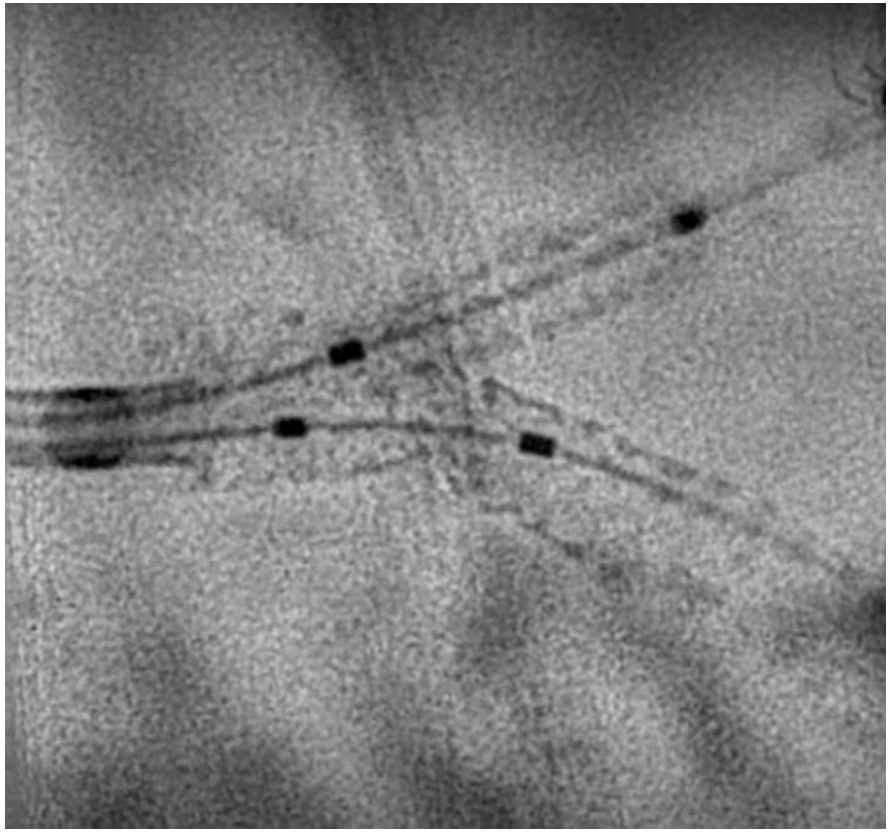


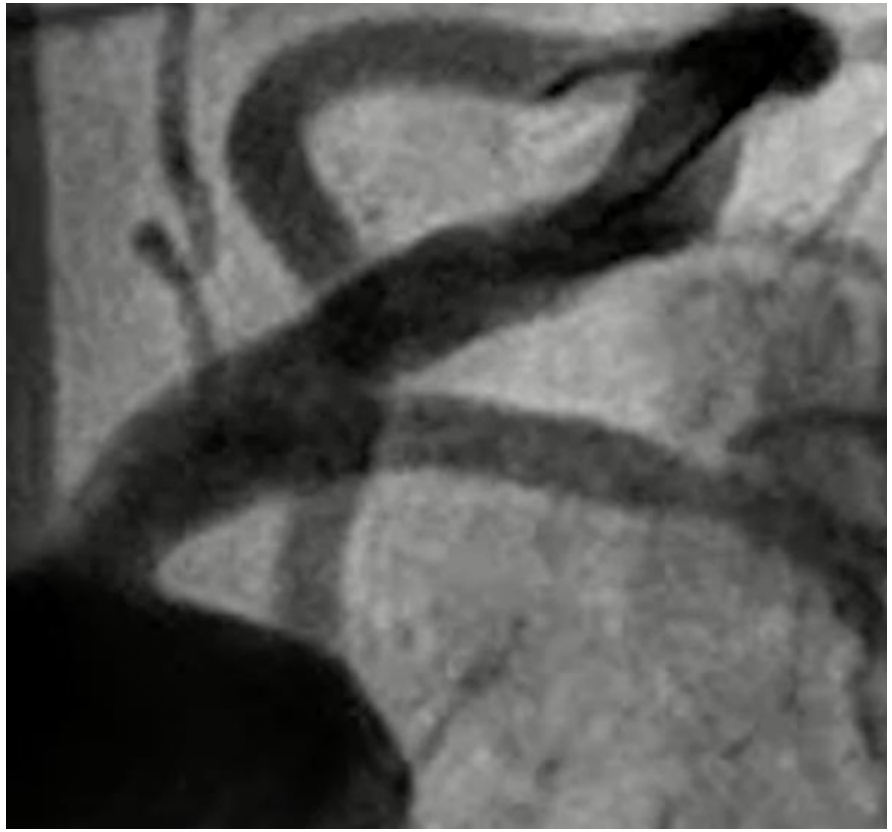
# Case planning

- Percutaneous coronary intervention
- Conscious sedation
- Plaque preparation using intravascular lithoplasty
- Procedural IVUS guidance
- **Two-stent treatment of LM bifurcation using a TAP technique**
- Standby cardiac assistance



# Final Result



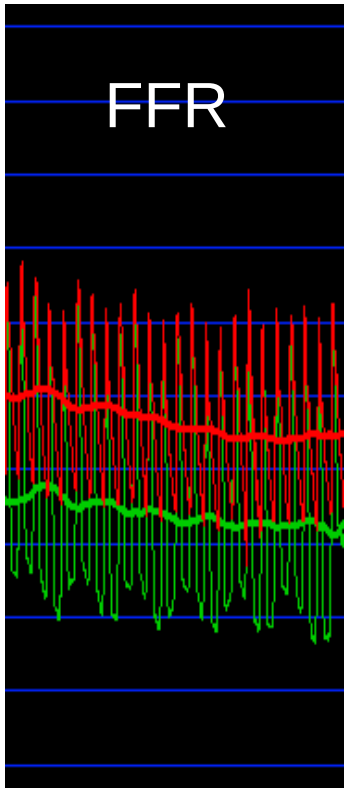


# Indices de Fisiología Coronaria: FFR vs IFR

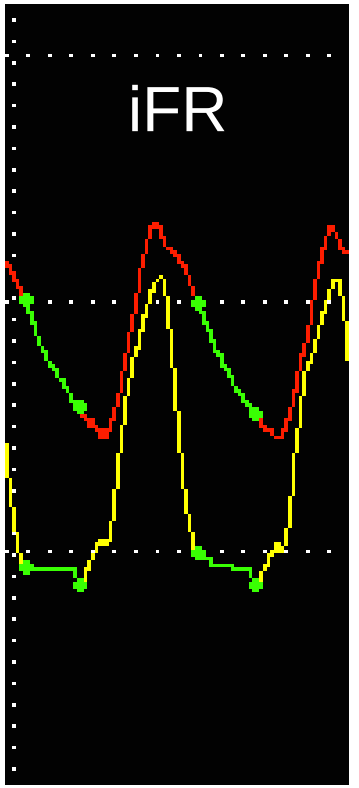
## Validación de nuevos indices de presión no hiperhemicos

### Ventajas del iFR respect al FFR

- Más de 150 publicaciones indexadas en PubMed
- iFR non-inferior al FFR en 2 RCTs (Define-Flair y Sweden-Heart
- Validado en grupos anatomicos de intermedio y alto riesgo (SYNTAX II)
- Más rápido que el FFR
- Ausencia efectos adversos de agentes hiperemicos
- Pocas ICP se realizan con FFR
- Mejor relación coste-efectividad
- Se puede co-registrar con la angiografia



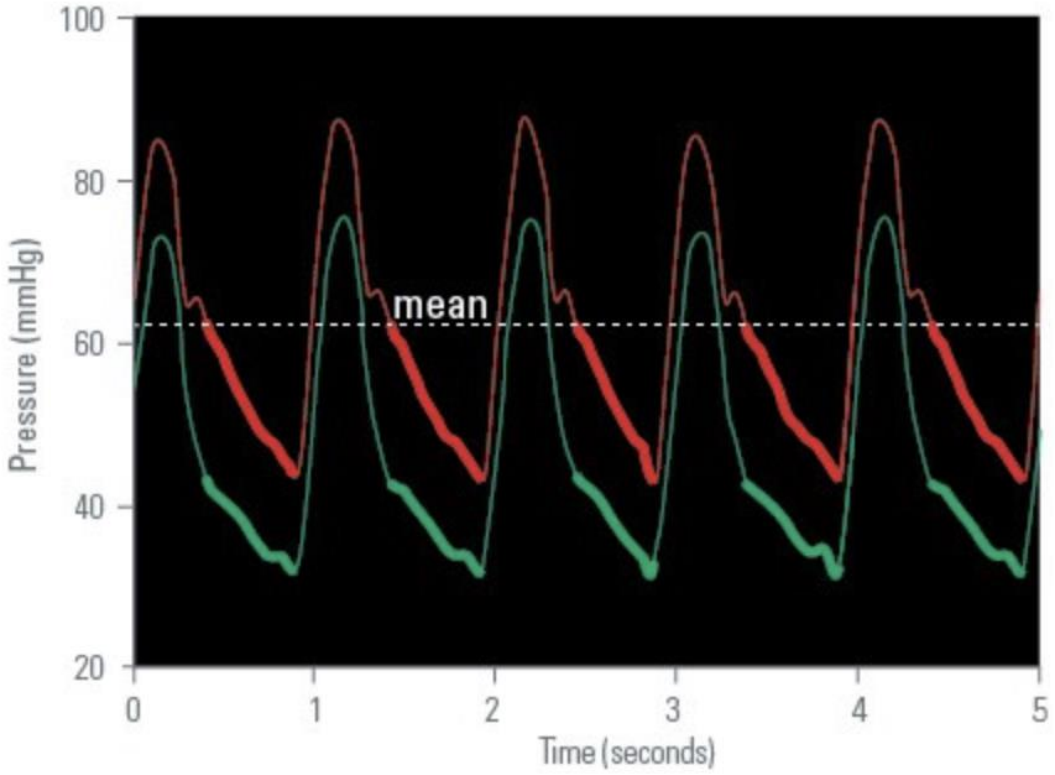

FFR: Fractional Flow Reserve (Adenosine)




iFR: instantaneous Free Wave Ratio (Non-Adenosine)

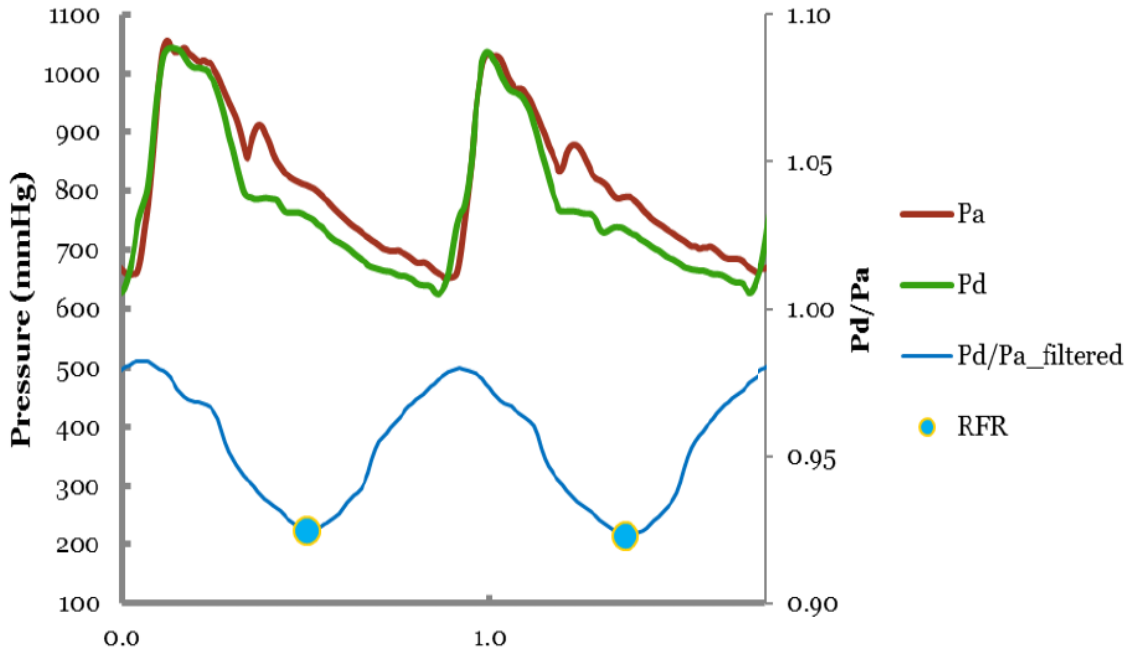
# Upcoming resting (non-hyperaemic) indices

Resting Diastolic Pressure Ratio (dPR)



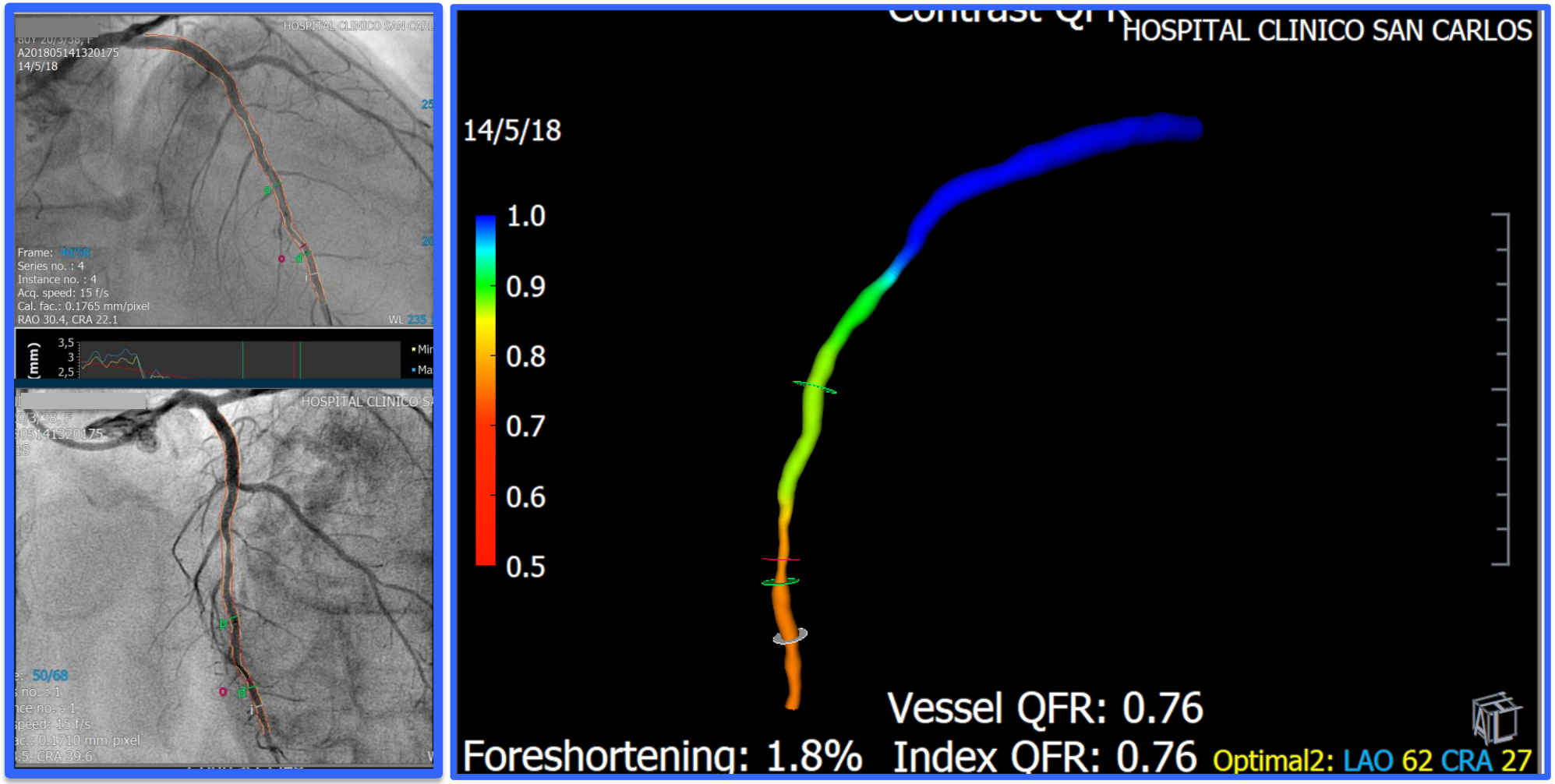

Oldroyd K et al. EuroPCR 2018

Resting Full Cycle Ratio (RFR)



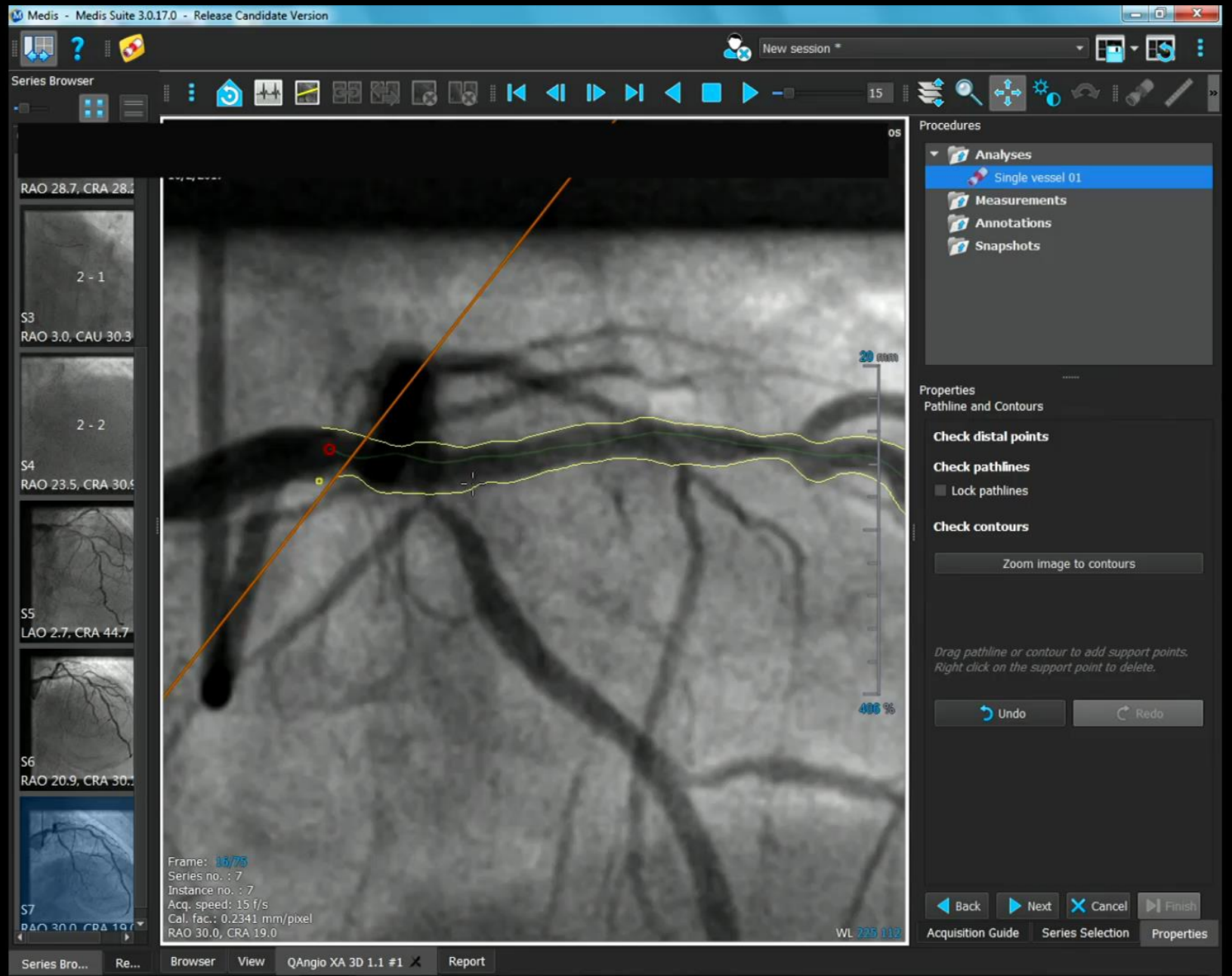

Svanerud J et al. EuroIntervention. 2018

# Functional angiography: Quantitative Flow Ratio (QFR)



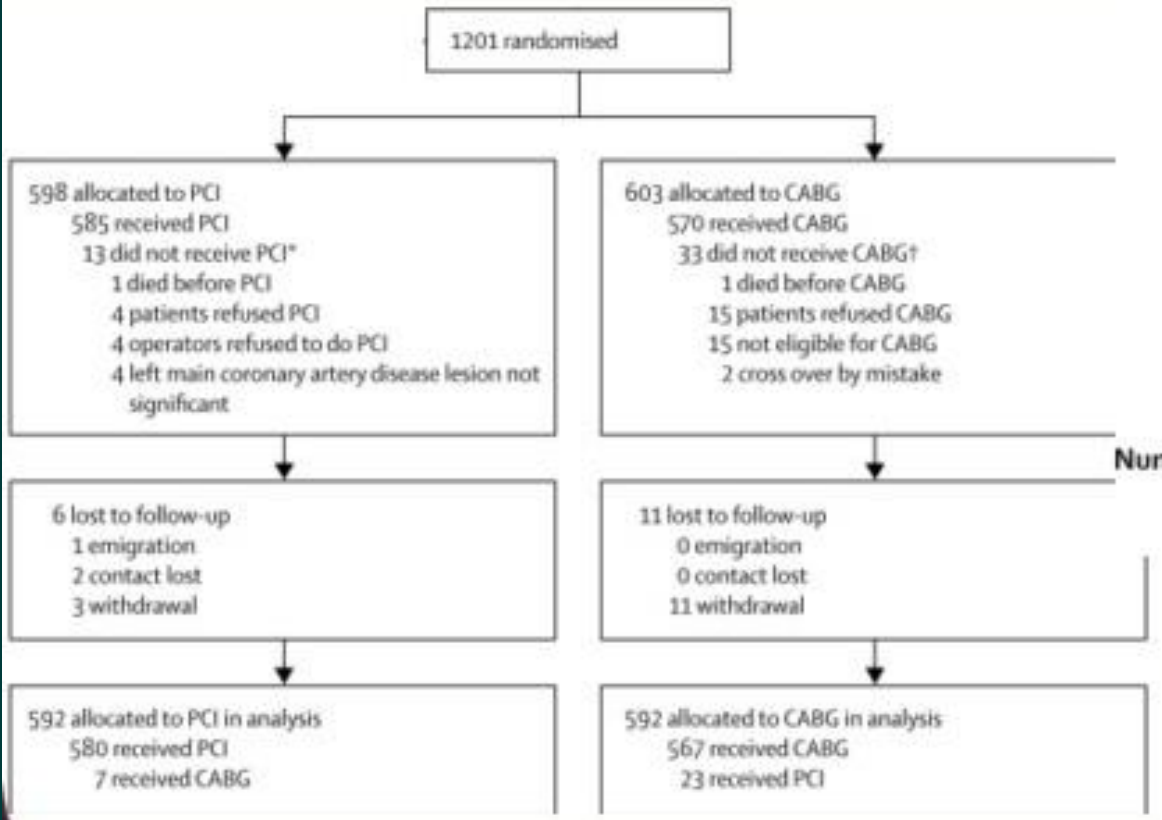

Algoritm: Navier-Stokes Equation

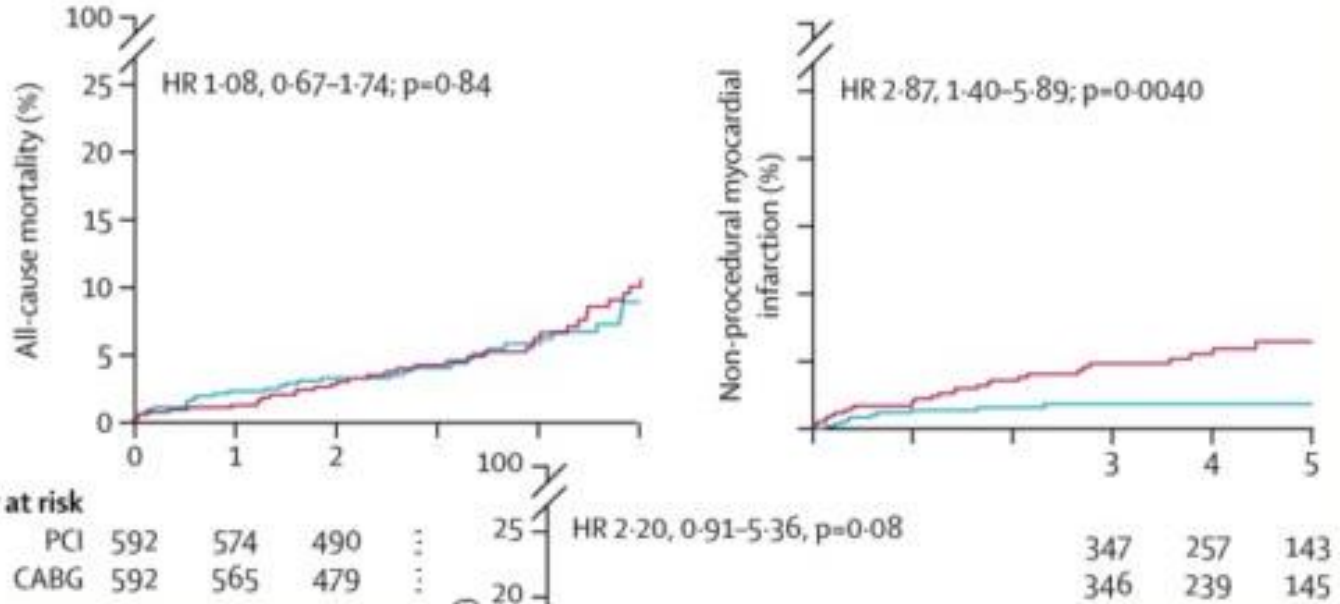
# Functional angiography: Quantitative Flow Ratio

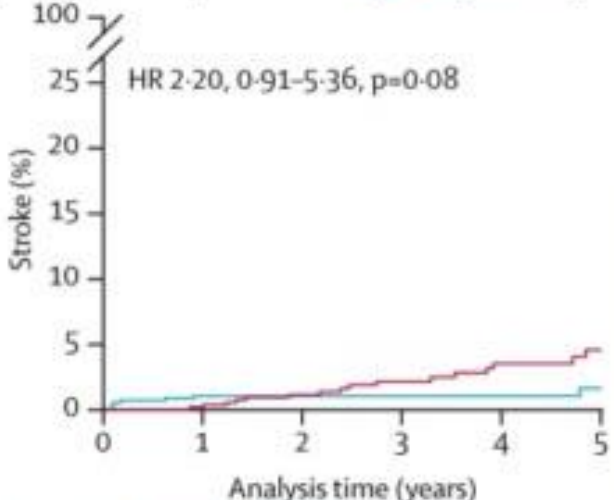


# Patients with Left Main Coronary Artery Disease – New Evidence after 2014 ESC Guidelines –

## NOBLE Trial



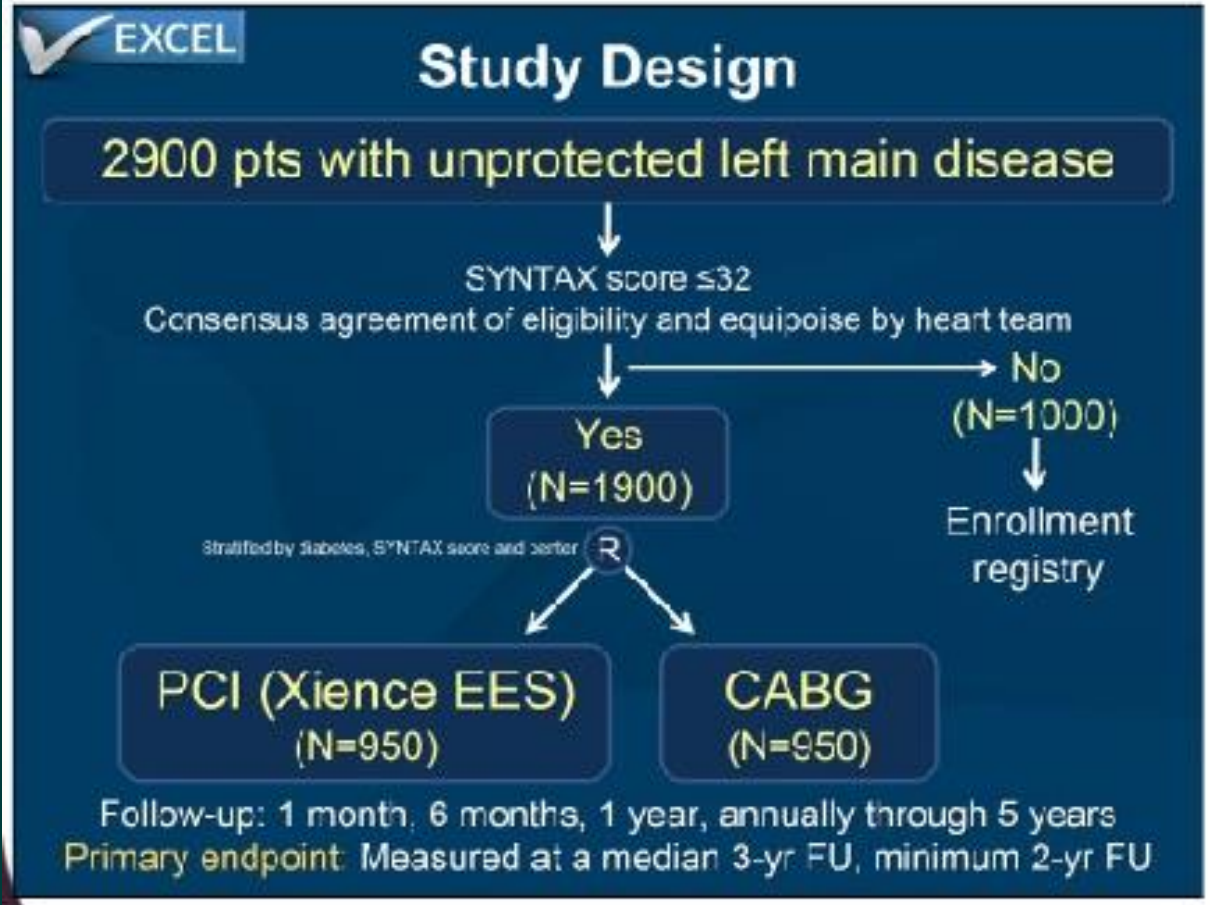



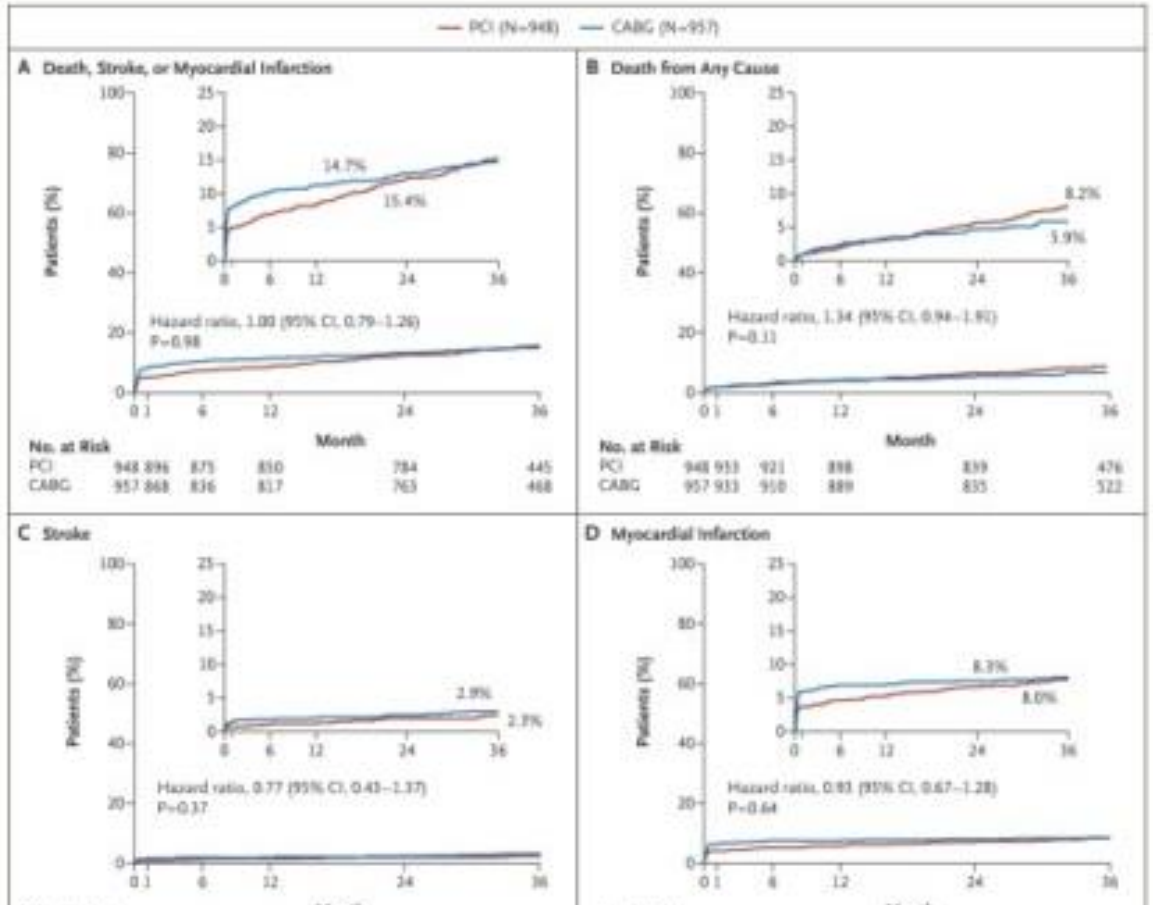




*NOBLE, Lancet 2016*

# Patients with Left Main Coronary Artery Disease – New Evidence after 2014 ESC Guidelines –

***EXCEL, NEJM 2016***

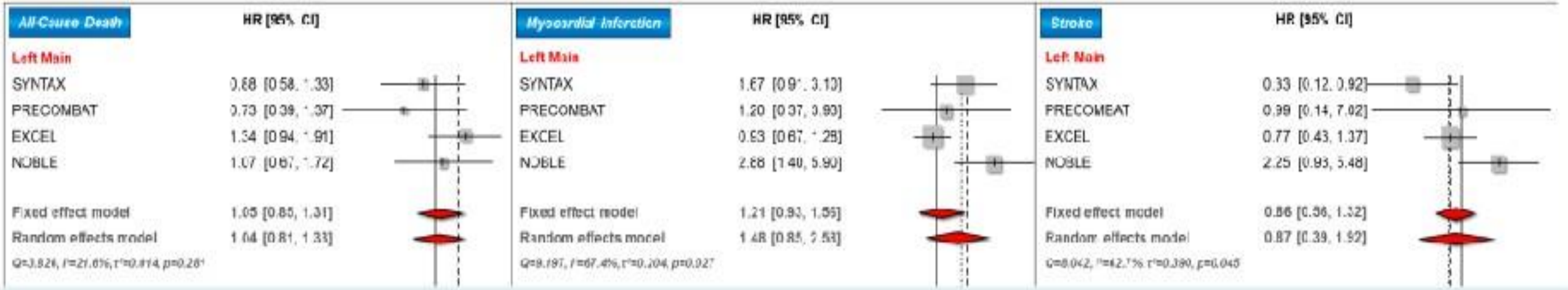


# Patients with Left Main Coronary Artery Disease

## – Expected Impact of Evidence on Next ESC Guidelines –

Meta-analysis, 4 RCTs, 4411 pts, FU 3 to 5 years (Giacoppo et al, JAMA Cardiol, 2018)




**Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality**

| Recommendations according to extent of CAD | CABG | | PCI | | |
|---|---|---|---|---|---|
| | Class[a] | Level[b] | Class[a] | Level[b] | Ref[c] |
| Left main disease with a SYNTAX score ≤ 22. | I | A | I | A | 17,134,170 |
| Left main disease with a SYNTAX score 23–32. | I | A | I | A | 17 |

ESC Congress
Munich 2018
25-29 August

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

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

## Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

**Authors/Task Force Members: Franz-Josef Neumann* (ESC Chairperson) (Germany), Miguel Sousa-Uva*[1] (EACTS Chairperson) (Portugal), Anders Ahlsson[1] (Sweden), Fernando Alfonso (Spain), Adrian P. Banning (UK), Umberto Benedetto[1] (UK), Robert A. Byrne (Germany), Jean-Philippe Collet (France), Volkmar Falk[1] (Germany), Stuart J. Head[1] (The Netherlands), Peter Jüni (Canada), Adnan Kastrati (Germany), Akos Koller (Hungary), Steen D. Kristensen (Denmark), Josef Niebauer (Austria), Dimitrios J. Richter (Greece), Petar M. Seferović (Serbia), Dirk Sibbing (Germany), Giulio G. Stefanini (Italy), Stephan Windecker (Switzerland), Rashmi Yadav[1] (UK), Michael O. Zembala[1] (Poland)**

# Patients with Left Main Coronary Artery Disease 2014 vs 2018 ESC Guidelines

## *2014 ESC Guidelines*

**Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality**

| Recommendations according to extent of CAD | CABG | | PCI | | |
|---|---|---|---|---|---|
| | Class[a] | Level[b] | Class[a] | Level[b] | Ref[c] |
| Left main disease with a SYNTAX score ≤ 22. | I | B | I | B | 17,134,170 |
| Left main disease with a SYNTAX score 23–32. | I | B | IIa | B | 17 |
| Left main disease with a SYNTAX score >32. | I | B | III | B | 17 |

## *2018 ESC Guidelines*

| 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 |

# CABG vs PCI in Coronary Artery Disease

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**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[d]**

| Recommendations according to extent of CAD | CABG | | PCI | |
|---|---|---|---|---|
| | Class[a] | Level[b] | Class[a] | Level[b] |
| **One-vessel CAD** | | | | |
| Without proximal LAD stenosis. | IIb | C | I | C |
| With proximal LAD stenosis.[68,101,139–144] | I | A | I | A |
| **Two-vessel CAD** | | | | |
| Without proximal LAD stenosis. | IIb | C | I | C |
| With proximal LAD stenosis.[68,70,73] | I | B | I | C |
| **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 |

# Technical issues during the procedures CABG and PCI

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Radial access as standard approach for coronary angiography and PCI

DES for any PCI

Calculation of the Syntax Score, if left main or multivessel revascularization is considered

Use of the radial artery grafts over saphenous vein grafts in patients with high-degree stenosis

Myocardial revascularization in patients with CAD, heart failure, and LVEF ≤35%
CABG preferred

PCI as alternative to CABG

Routine revascularization of non-culprit lesions during primary PCI in myocardial infarction with cardiogenic shock.

Current generation bio-resorbable scaffolds for clinical use outside clinical studies.

| UPGRADES |
| --- |
| For PCI of bifurcation lesions, stent implantation in the main vessel only, followed by provisional balloon angioplasty with or without stenting of the side branch. |
| OCT for stent optimization. |

| DOWNGRADES |
| --- |
| Distal protection devices for PCI of SVG lesions. |

| | | | |
| --- | --- | --- | --- |
| | Class I | | Class IIa |
| | Class IIb | | Class III |

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# Tratamiento Antitrombótico en el Intervencionismo

NOAC preferred over VKA in patients with non-valvular AF requiring anticoagulation and antiplatelet treatment.

Dabigatran 150-mg dose preferred over 110-mg dose when combined with single antiplatelet therapy.

Cangrelor in $PY_{12}$-inhibitor naïve patients undergoing PCI.

GP IIb/IIIa inhibitors for PCI in $P2Y_{12}$-inhibitor naïve patients with ACS undergoing PCI.

De-escalation of $P2Y_{12}$-inhibitor therapy after ACS guided by platelet function testing.

| DOWNGRADES |
| --- |
| Bivalirudin for PCI in NSTE-ACS. |
| Bivalirudin for PCI in STEMI. |

| | | | |
| --- | --- | --- | --- |
| | Class I | | Class IIa |
| | Class IIb | | Class III |

# Estado Actual Cardiología Intervencionista

## Intervencionismo Coronario vs ESTRUCTURAL

1. Planificación de la Asistencia Cardiovascular
   *Regionalización y Redes Asistenciales. Un modelo: la angioplastia primaria en el IAM*
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# VALVULAS MITRALES PERCUTÁNEAS

Braile Biomedica

Braile Biomedica

CardiAQ 1st G

CardiAQ Edwards

Cephea

Direct Flow Medical

Twelve Medtronic

M-Valve

Edwards Fortis

HighLife

Navigate

Neovasc Tiara

PermaValve MID

Sinomed

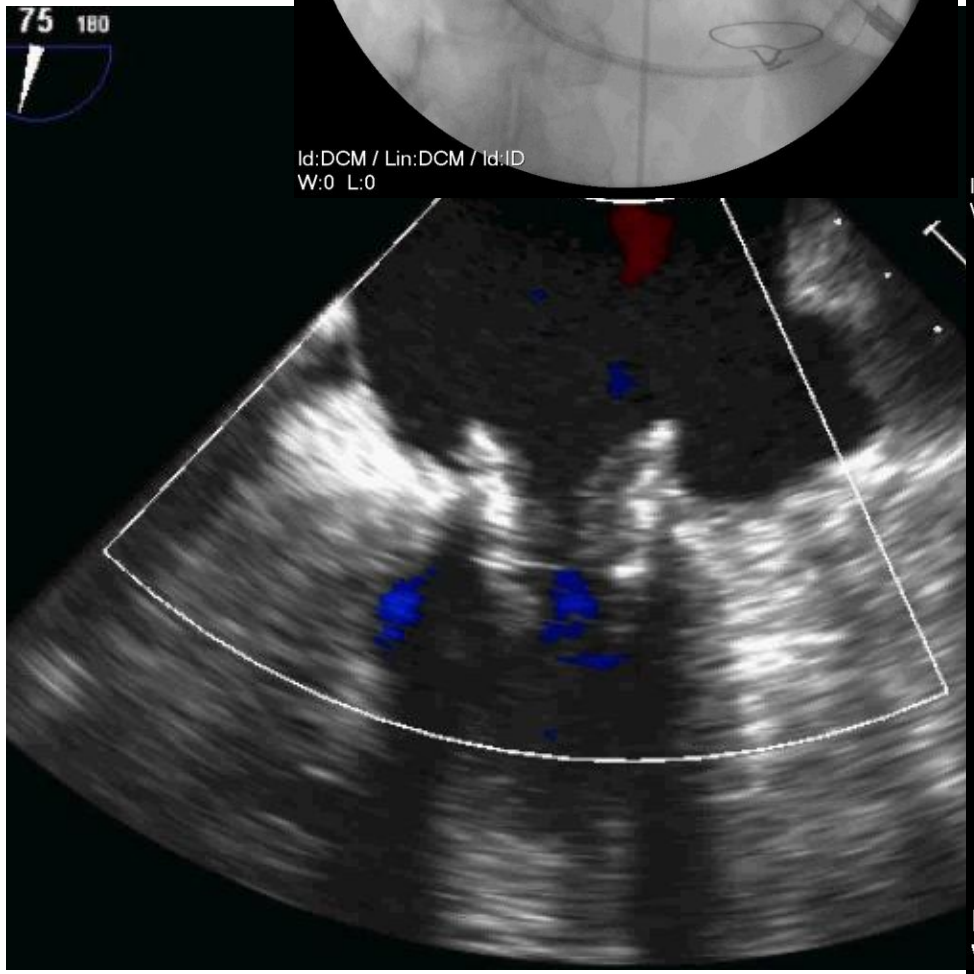
Tendyne Abbott

SATURN TMVR

Valtech CardioValve

Caisson

**Others:** MitraHeal, Mitrassist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo


75 180


VERADIUS01
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I.U.C.P.Q
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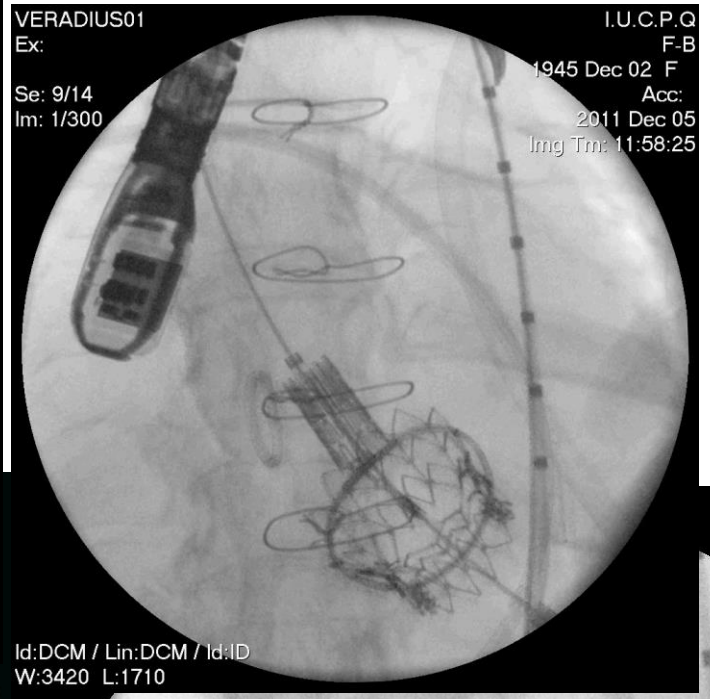
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I.U.C.P.Q
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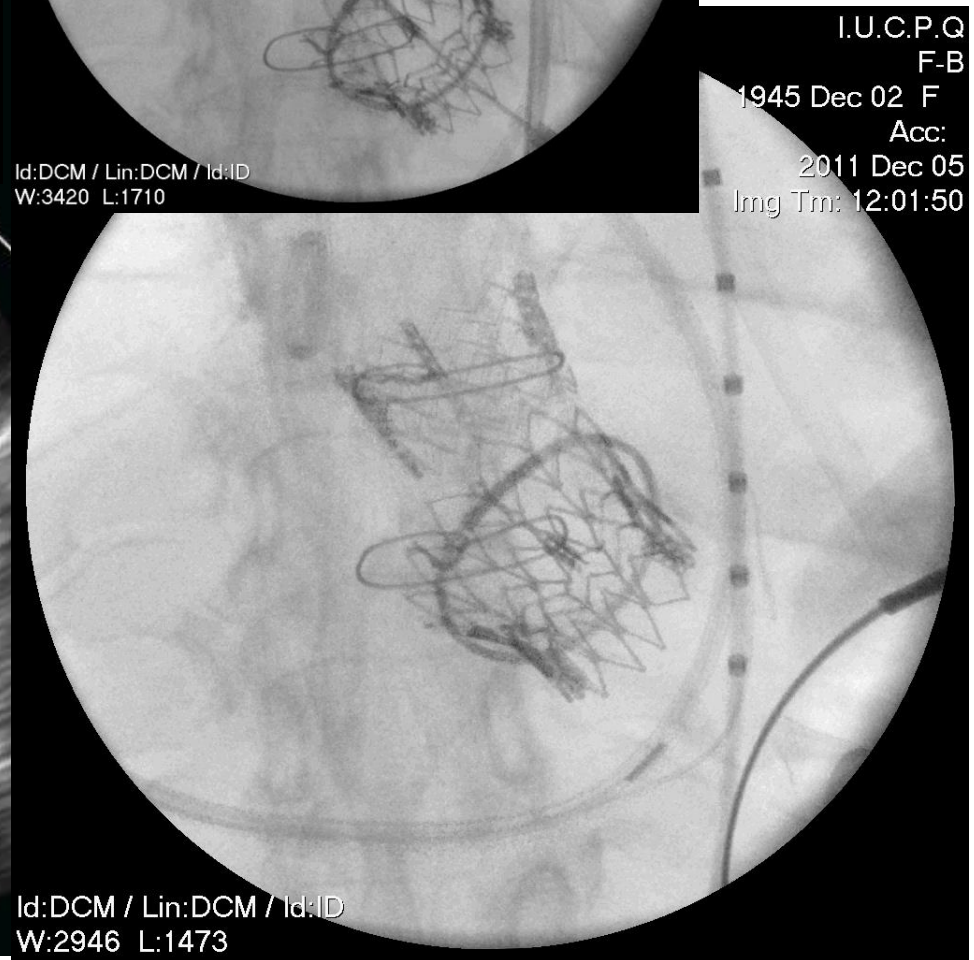
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Acc:
2011 Dec 05
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# 2-Year Outcomes After Transcatheter Mitral Valve Replacement

Ander Regueiro, MD, MSc,[a] Jian Ye, MD, MSc,[b] Neil Fam, MD,[c] Vinayak N. Bapat, MD,[d] François Dagenais, MD,[a] Mark D. Peterson, MD, PhD,[c] Stephan Windecker, MD,[e] John G. Webb, MD,[b] Josep Rodés-Cabau, MD[a]

# Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation

## A Global Feasibility Trial

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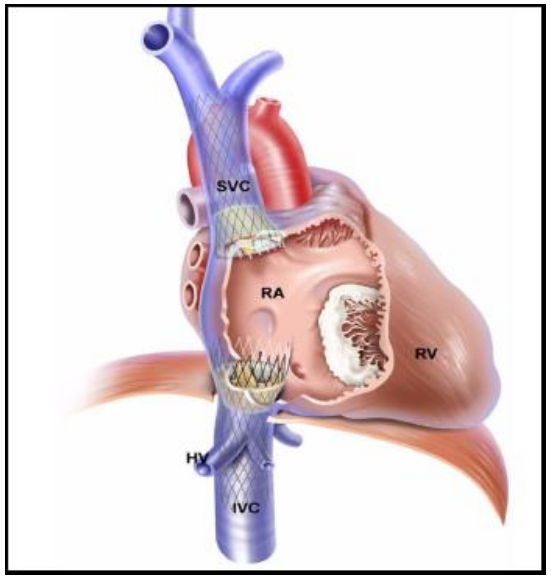
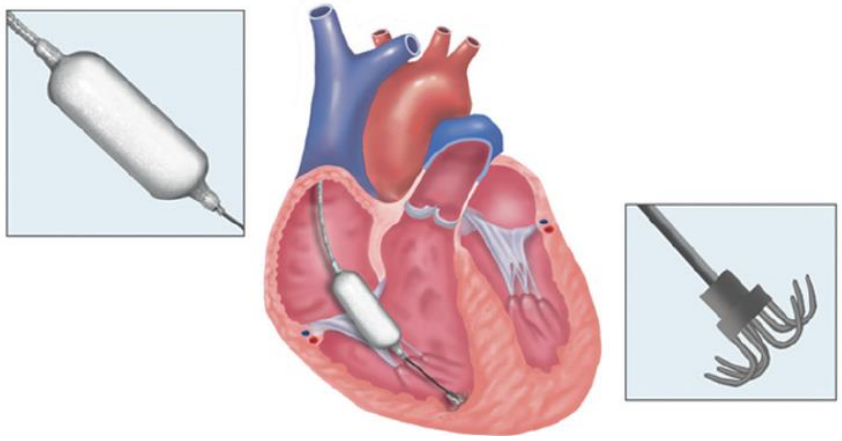
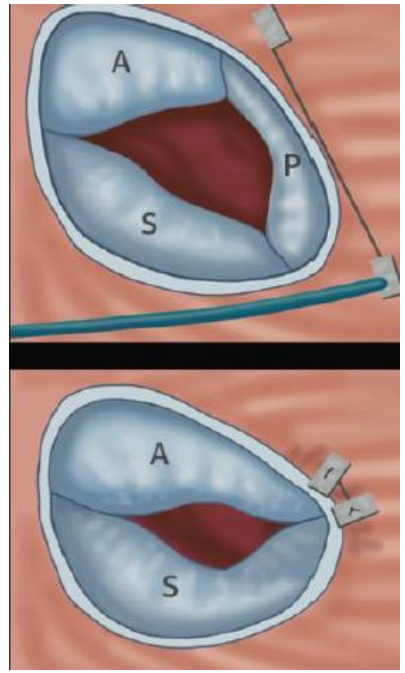
# Percutaneous techniques for severe tricuspid regurgitation



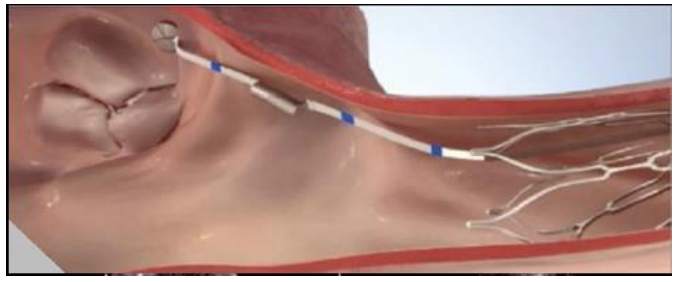

Lauten EHJ 2011



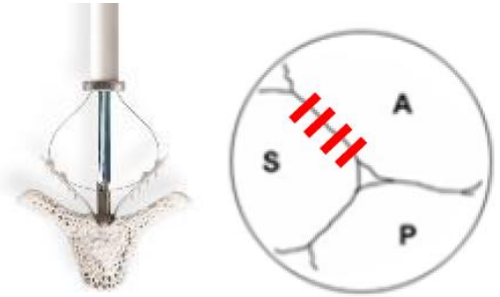
Forma
Campelo-Parada JACC 2015



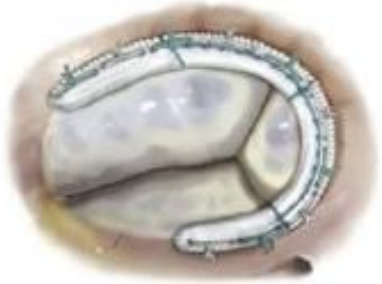

Trialign
Schofer JACC 2015



TriCinch
Maisano
Eurointervention 2017




Mitraclip
Nickenig Circulation 2017



Cardioband
Kuwata EHJ 2017

# Medical History

- 76 yrs. old Female
- Present Status
  - Needs dialysis 4 days/week
  - Severe Tricuspid Regurgitation due to annular dilatation
    - Severe volume overload due to TR
  - Right Heart Failure

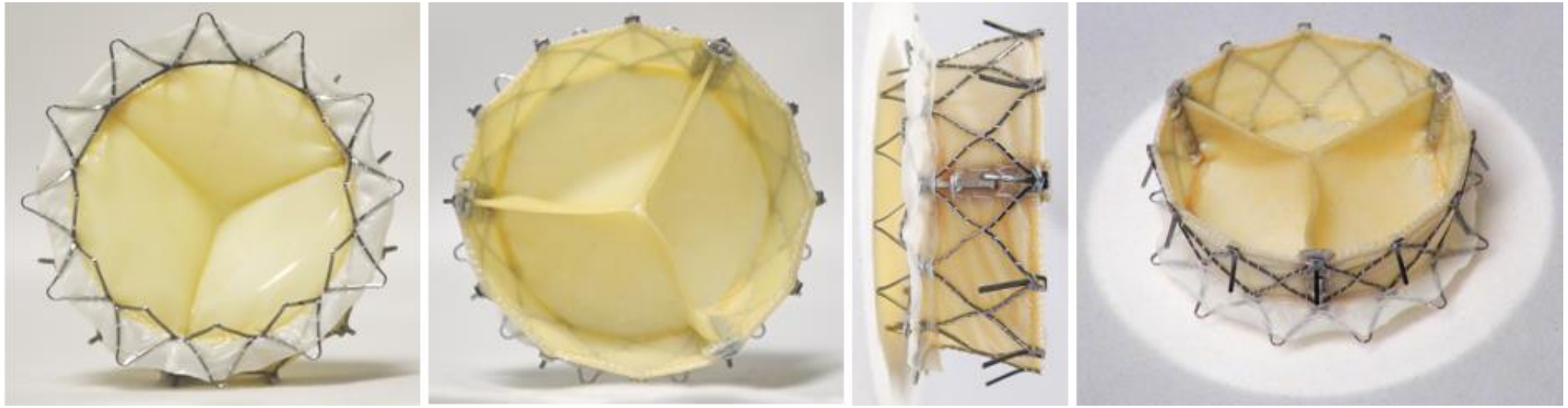
# Comorbidities

- Hypertension
- Permanent Atrial Fibrillation
- Type II Diabetes
- Renal Function
  - Stage 5 Chronic Kidney Disease (secondary to Diabetic nephropathy)
  - On dialysis

Servicio de Cardiología, Clinica Puerta de Hierro, Madrid

# GATE System

Atrioventricular Valved Stent



Delivery System

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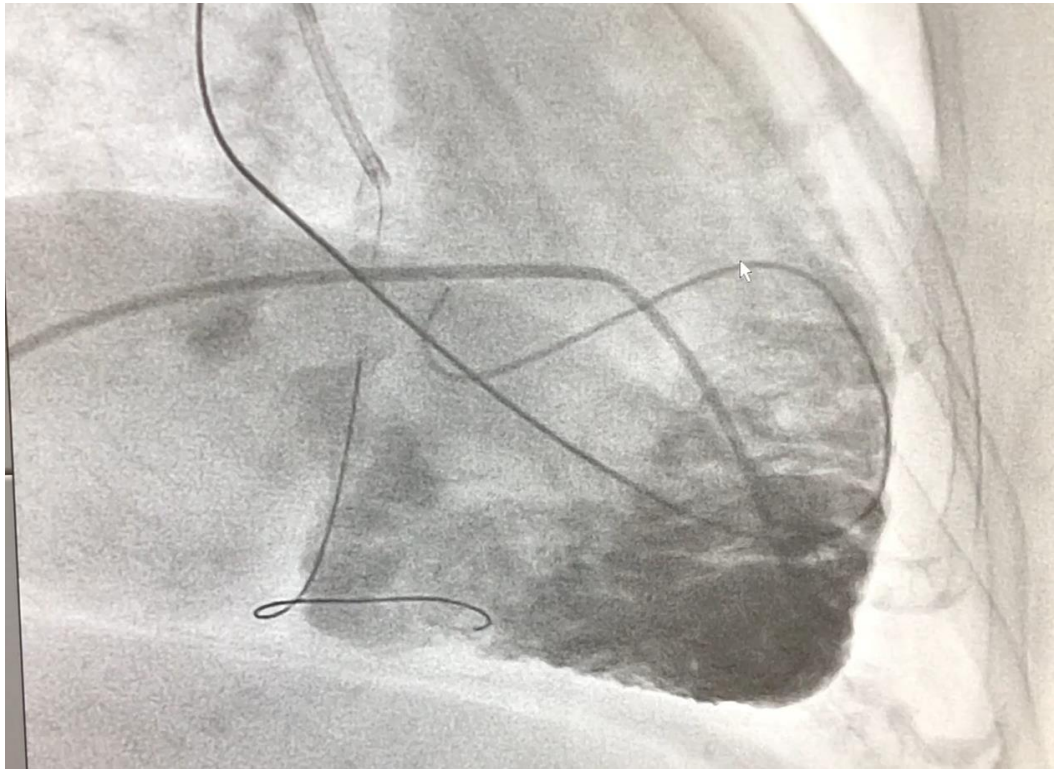
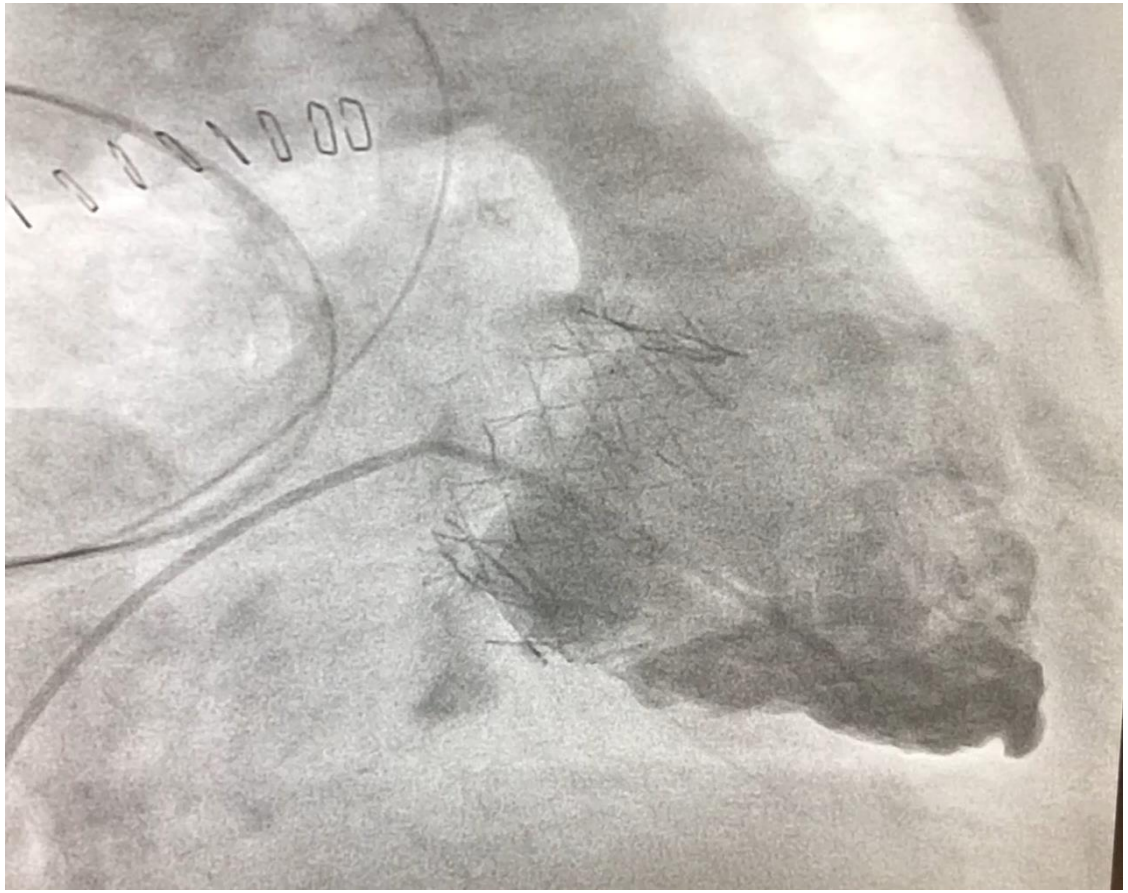




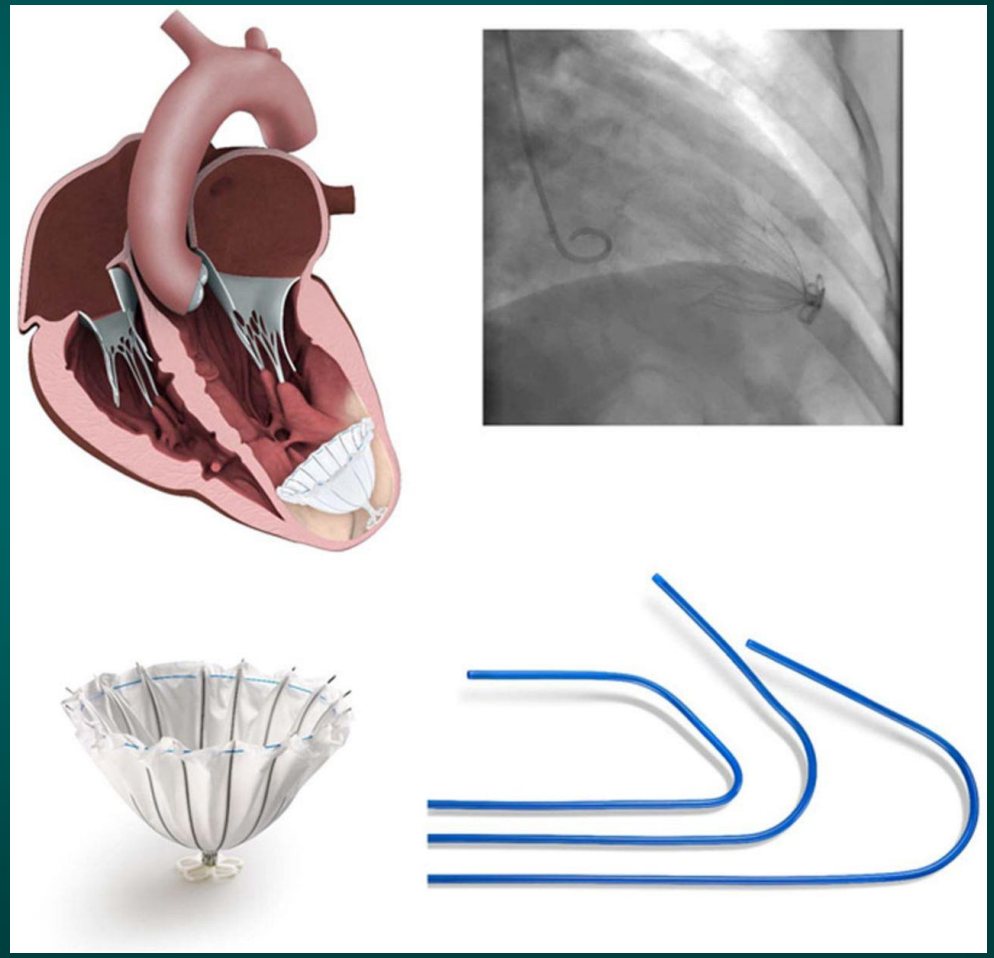
# Unidad de Cardiologia Intervencionista
# Servicio de Cirugía Cardiaca
# Clinica Puerta de Hierro, Madrid

# Transcatheter Structural Interventions for Treatment of Chronic Heart Failure

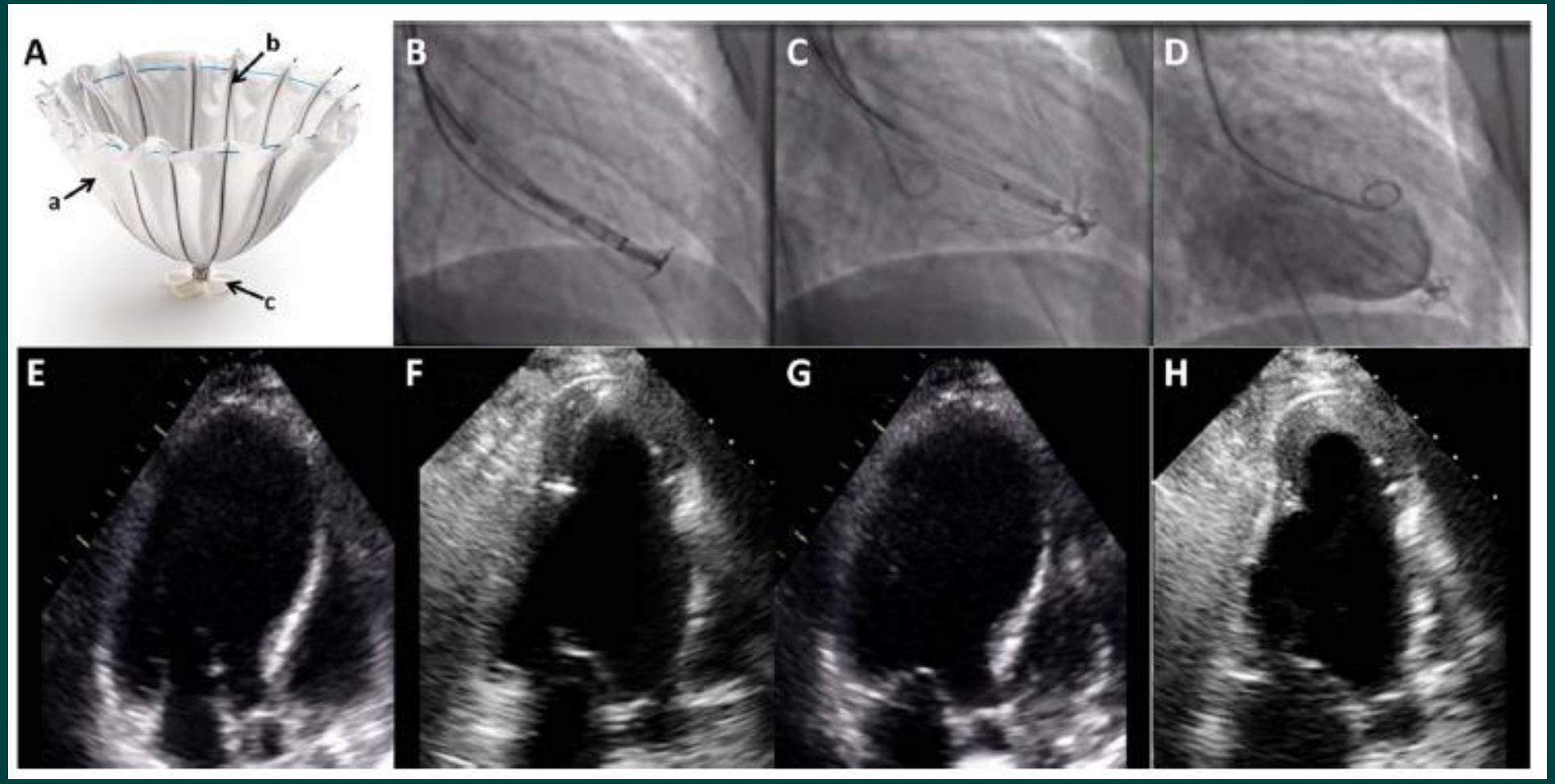
- **Left Ventricular Restoration Devices**
- **Left-to-Right Interatrial Shunt Devices**:
  - Interatrial Septal Devices System
  - V-vawe Device
- **Renal Denervation**
- **Implantable Hemodynamic Monitoring**
  - Pulmonary Artery Pressure Monitors
  - Left Atrial Pressure Monitoring
- **Percutaneous Interventions in Functional Mitral Regurgitation:**
  - Percutaneous edge to edge: MITRACLIP
  - **Percutaneous Annuloplasty: direct or indirect**
  - **Transcatheter Mitral Valve Replacement**

# Percutaneous Ventricular Restoration Using the Parachute Device in Patients With Ischemic Heart Failure. Three-Year Outcomes of the PARACHUTE First-in-Human Study

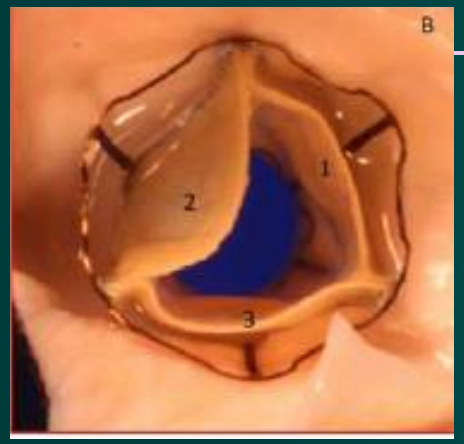
- Pacientes con IC isquémica post IAM, remodelado y dilatación VI, baja FEVI
- Dispositivo con forma de paracaídas implantado a través de catéter en ápex VI
- Estructura cónica de nitinol rodeada de ePTFE
- Objetivo: excluir zonas aquinéticas, reconfiguración de la geometría VI, mejorar la eficiencia en la contractilidad
- Demostrada reducción del volumen del VI y seguridad

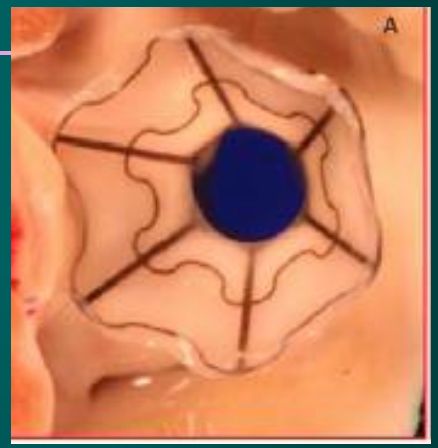


*Marco A. Costa, et al. Circ Heart Fail 2014;7:752-758*


A
b
a
c
B
C
D
E
F
G
H

# The V-Wave Shunt Device for LA Descompression




Inter-atrial septum

Nitinol frame

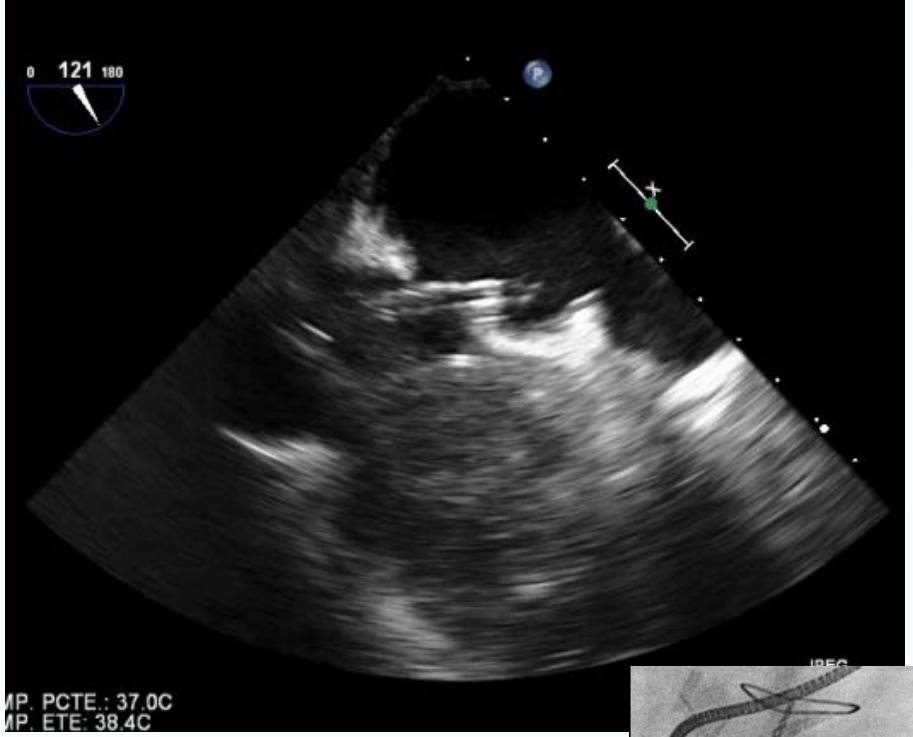
**Right Atrium**

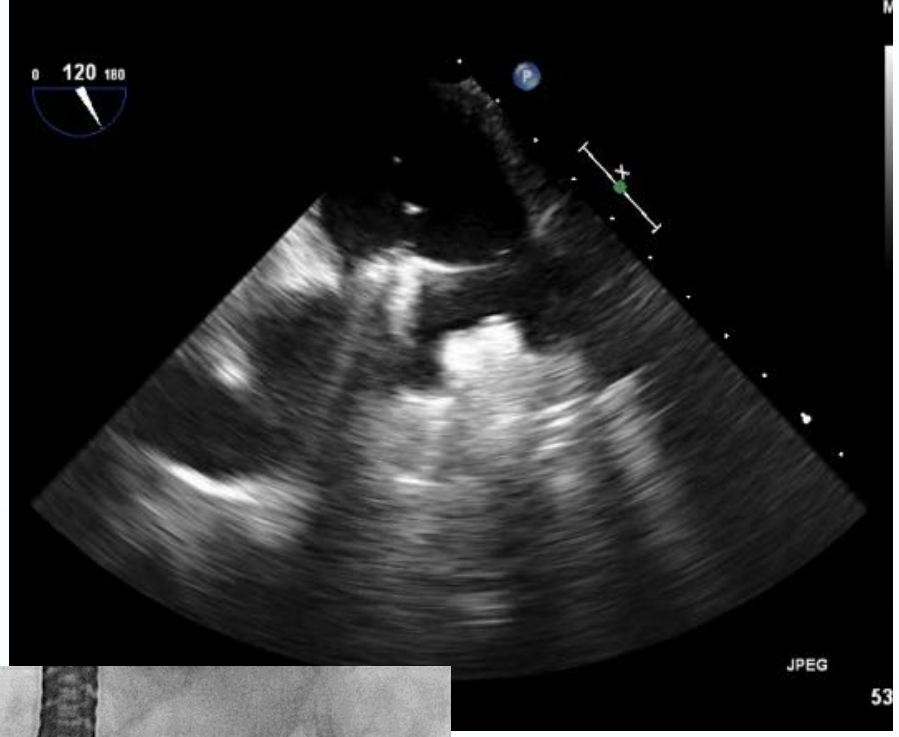
**Left Atrium**

Porcine pericardial leaflets
- improves flow mechanics
- prevents R to L shunting and paradoxical embolization

ePTFE encapsulation
- blocks tissue ingrowth

Hourglass shape
- secure and atraumatic septal retention
- minimal ID 5.0 mm supports flow equivalent to ≈ 6.5 mm diameter orifice-plate device


0 121 180
MP. PCTE.: 37.0C
MP. ETE: 38.4C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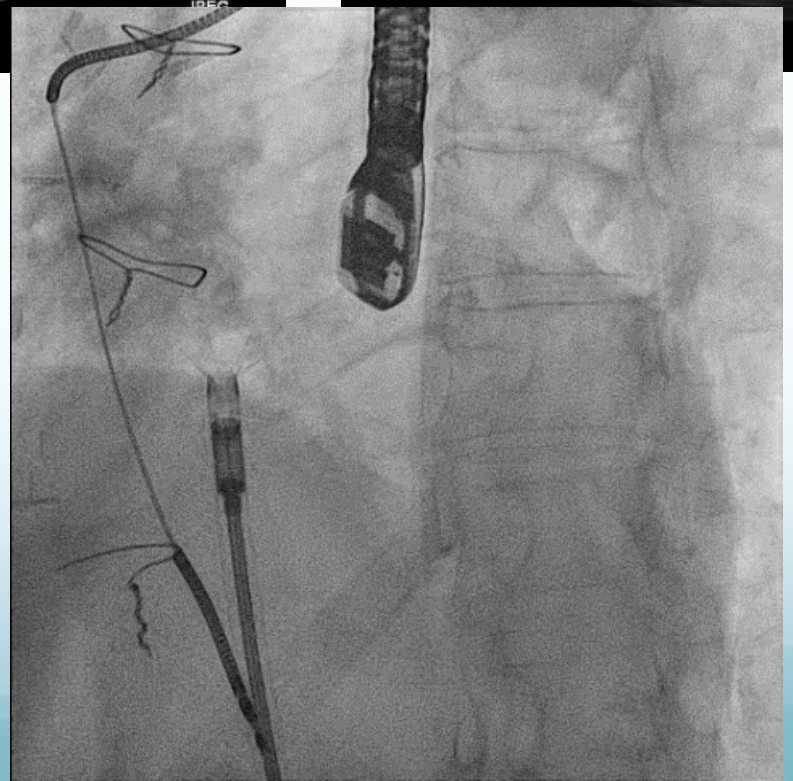
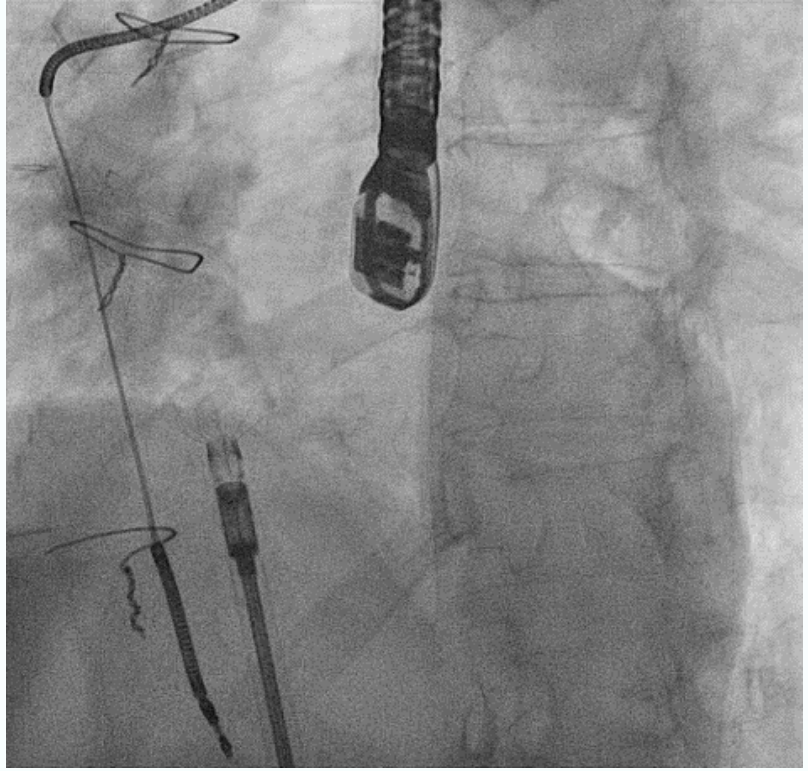
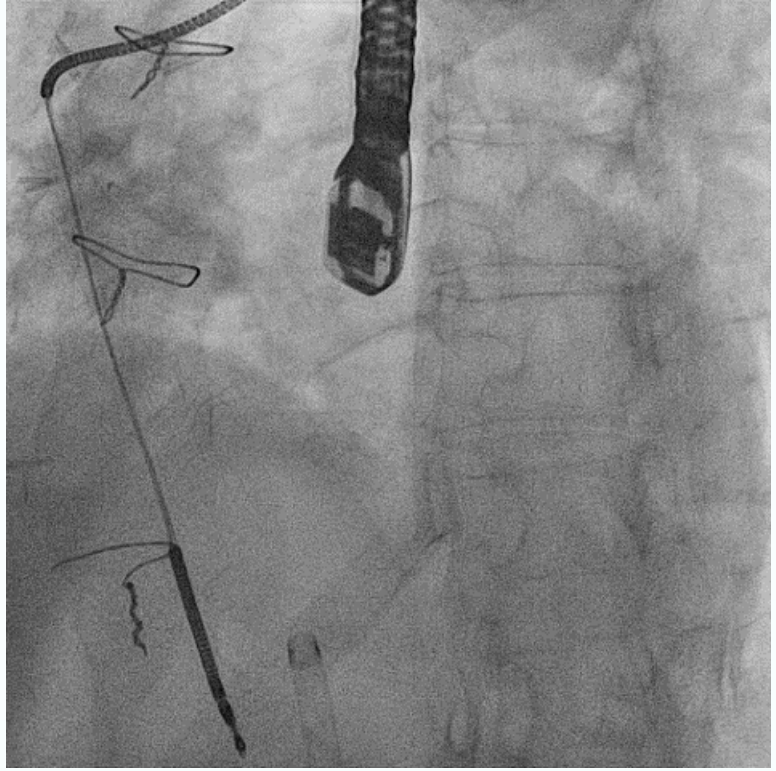







0 92 180
JPEG
P. PCTE.: 37.0C
P. ETE: 39.2C


Hz
Latidos 3D 1
0 90 180
TEMP. PCTE.: 37.0C

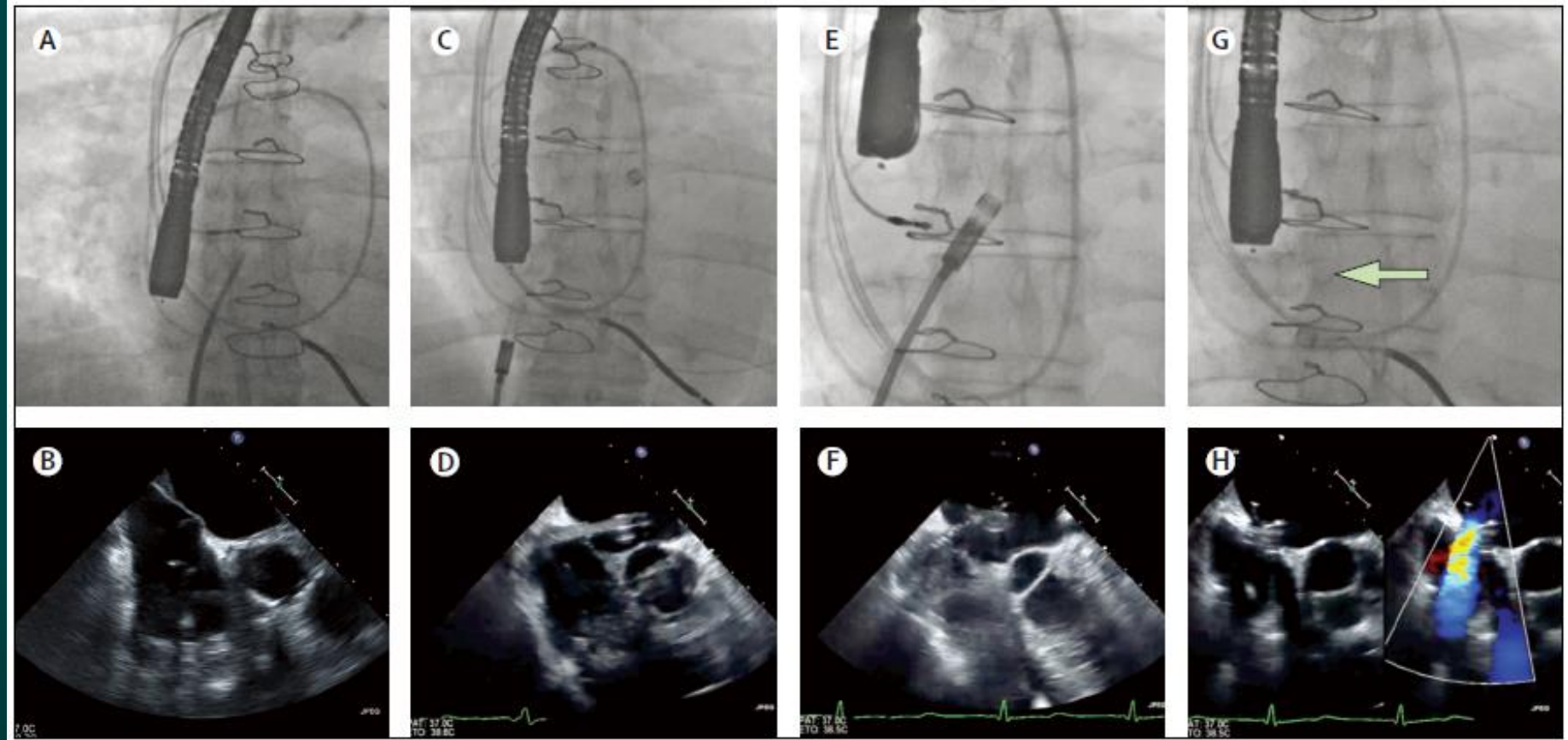
# Unidirectional left-to-right interatrial shunting for treatment of patients with heart failure with reduced ejection fraction: a safety and proof-of-principle cohort study

*Maria Del Trigo, Sebastien Bergeron, Mathieu Bernier, Ignacio J Amat-Santos, Rishi Puri, Francisco Campelo-Parada, Omar Abdul-Jawad Altisent, Ander Regueiro, Neal Eigler, Erez Rozenfeld, Philippe Pibarot, William T Abraham, Josep Rodés-Cabau*

*Lancet* 2016; 387: 1290–97

## Summary

**Background** In patients with heart failure, interventions to reduce elevated left atrial pressure improve symptoms and



# Consideraciones finales

1. El tratamiento percutáneo de las enfermedades cardiovasculares sigue su crecimiento.
2. Su complejidad y multivariedad exige equipos multidisciplinares y entrenamiento adecuados .
3. Los mejores resultados solamente se garantizan con la creación de centros de referencia .
4. El alto coste de estos procedimientos debe compensarse con muy apropiadas indicaciones: los mejores resultados clínicos posibles.
5. En un periodo de 5-10 años el intervencionismo coronario representará el 75% del volumen y el estructural el 75% del presupuesto.