PHYSIODAY
JOURNÉES DE PHYSIOLOGIE
EN CARDIOLOGIE INTERVENTIONNELLE

# Le réducteur du sinus coronaire : un traitement de l'angor réfractaire

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CHU Toulouse

5&6 AVRIL 2024

HÔTEL SHERATON · NICE

# Le réducteur du sinus coronaire : Histoire

**Dr. Claude Schaeffer Beck (1894 – 1971)**
**(1935 – 1964) 1000 patients**

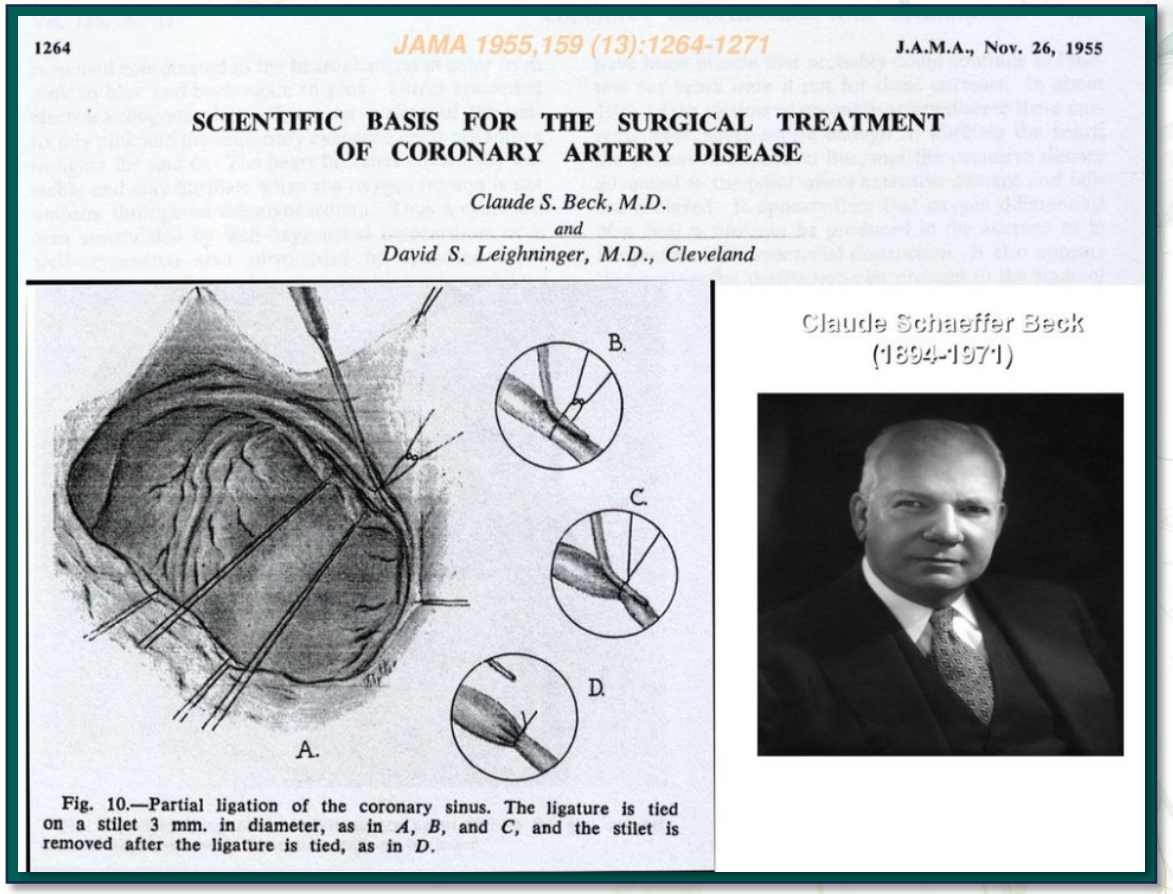
**Ligature du sinus 60 – 70%**

**=> Lumière résiduelle : 3 mm**

⇒ ↗ **Capacités fonctionnelles**

⇒ ↘ **Angor**

⇒ ↘ **Mortalité 5 ans**



1264 JAMA 1955,159 (13):1264-1271 J.A.M.A., Nov. 26, 1955

SCIENTIFIC BASIS FOR THE SURGICAL TREATMENT OF CORONARY ARTERY DISEASE

*Claude S. Beck, M.D.*
*and*
*David S. Leighninger, M.D., Cleveland*



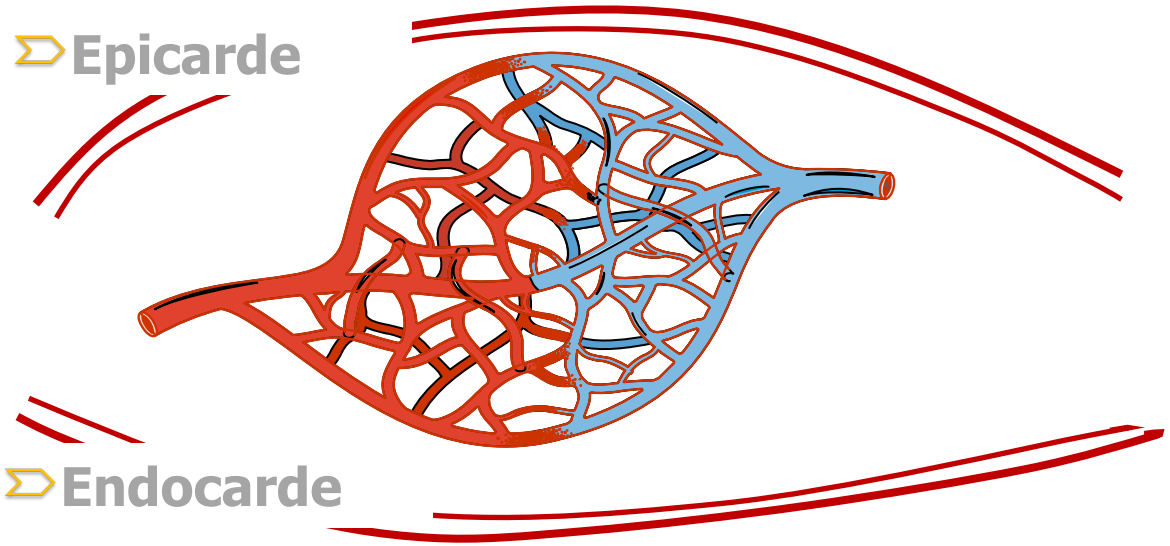
Fig. 10.—Partial ligation of the coronary sinus. The ligature is tied on a stilet 3 mm. in diameter, as in *A*, *B*, and *C*, and the stilet is removed after the ligature is tied, as in *D*.

Claude Schaeffer Beck
(1894-1971)

# Mécanisme physiologique

## État basal

- Epicarde



- Endocarde
- Ventricule gauche

**Effort : β activation**

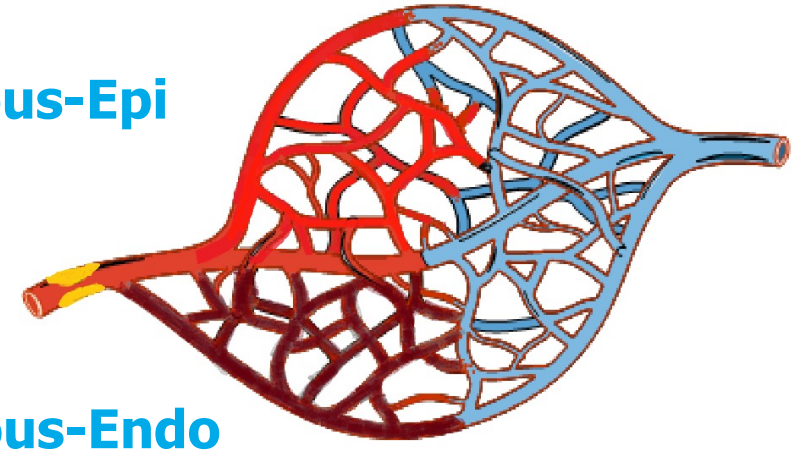
VasoConstriction sous-Epicarde

+

VasoDilatation sous-Endocarde

## Ischémie myocardique

↗ Flux sous-Epi



↘ Flux sous-Endo

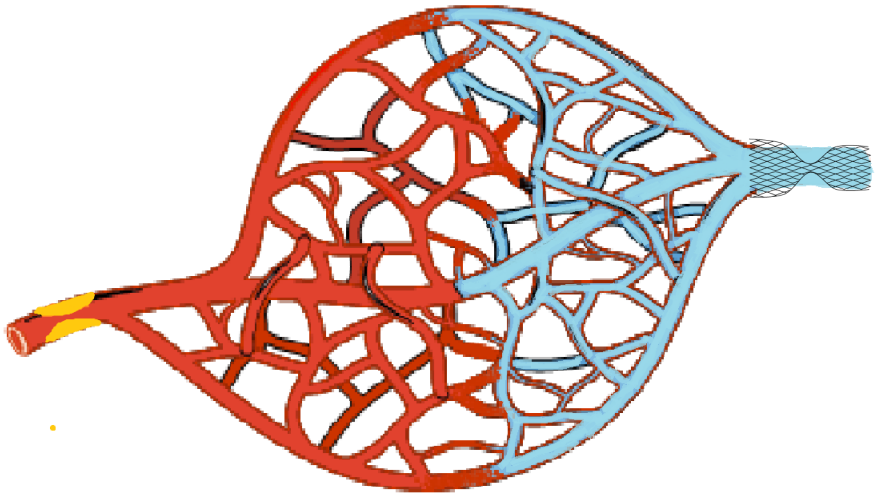
**Effort :**

↘ Contractilité

↗ PTDVG

# Mécanisme physiologique

**Réducteur du sinus**

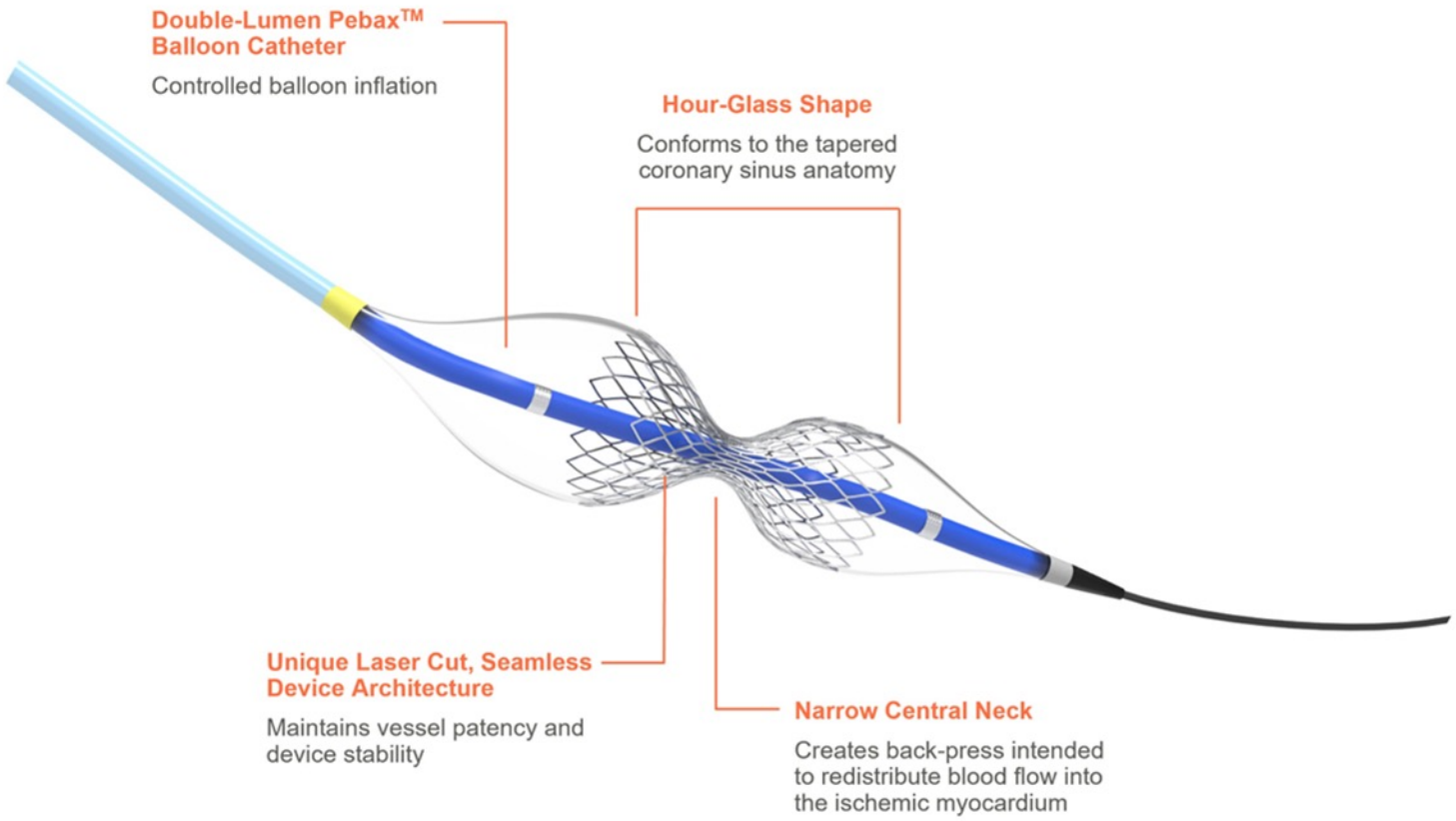


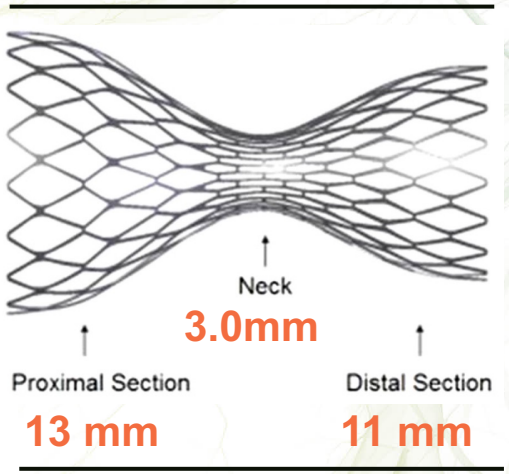
**<u>Gradient de pression</u> :**

**Redistribution du flux sanguin :**

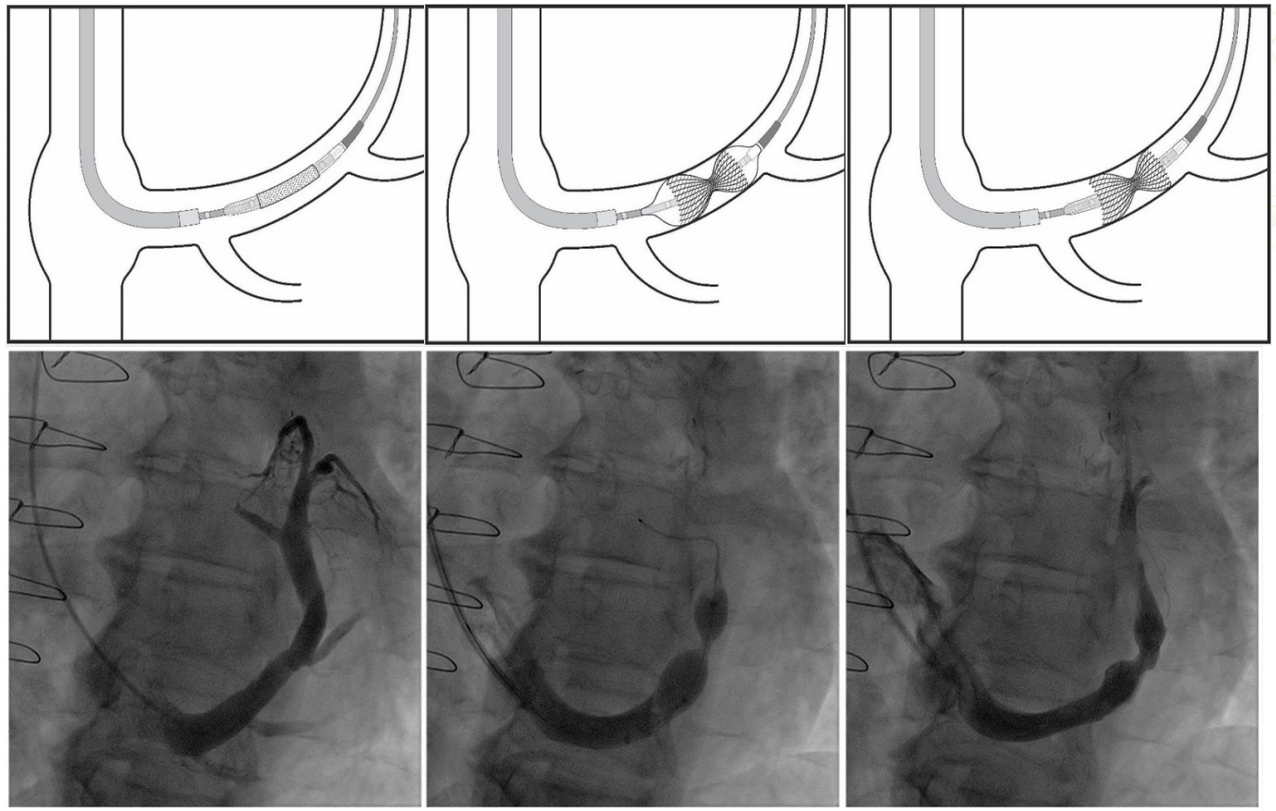
**=> Zones les moins ischémiques sous-épicarde vers zones plus ischémique sous-endocarde**

# Le Reducer : stent acier



# La procédure



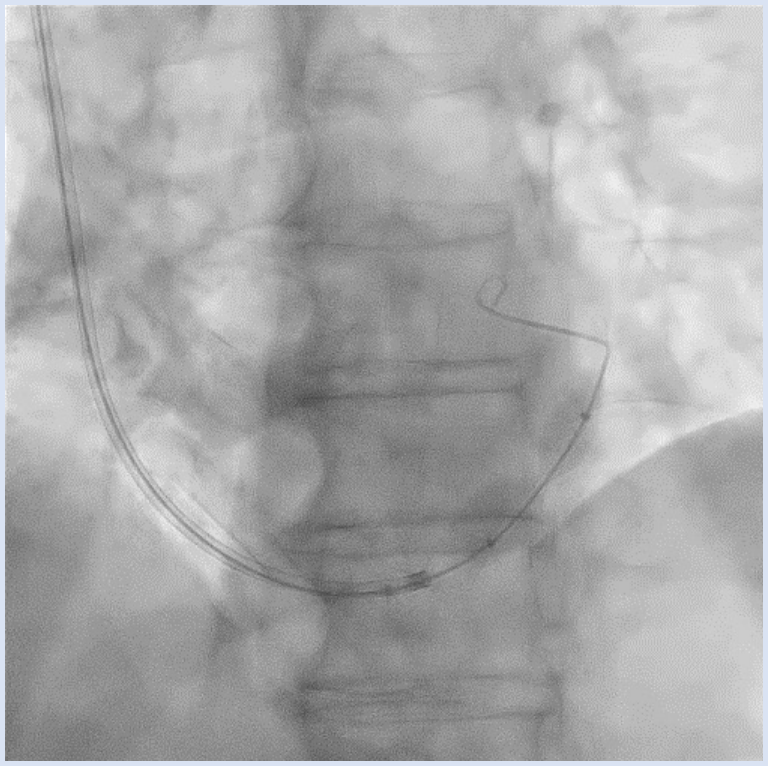
## Procedure :

- Anesthésie locale
- Accès 9F
- Voie veineuse jugulaire droite
- Over-the-wire, balloon expandable
- Prothèse en acier
- Durée de procedure de 30 à 60 min
- 20% oversizing

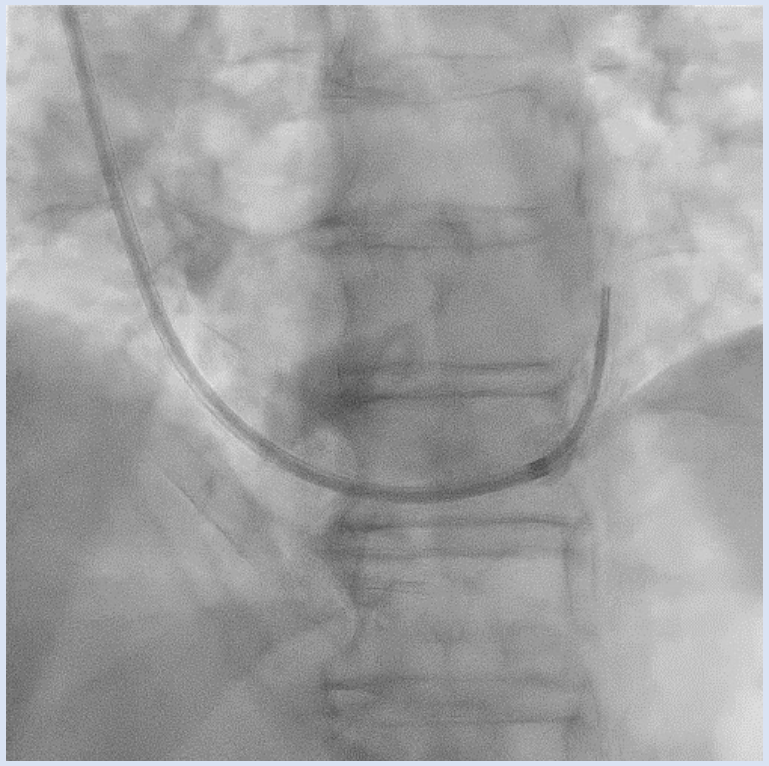
# La procédure

**Angio sinus**

**Implantation**



**Résultat final**



# Étude COSIRA

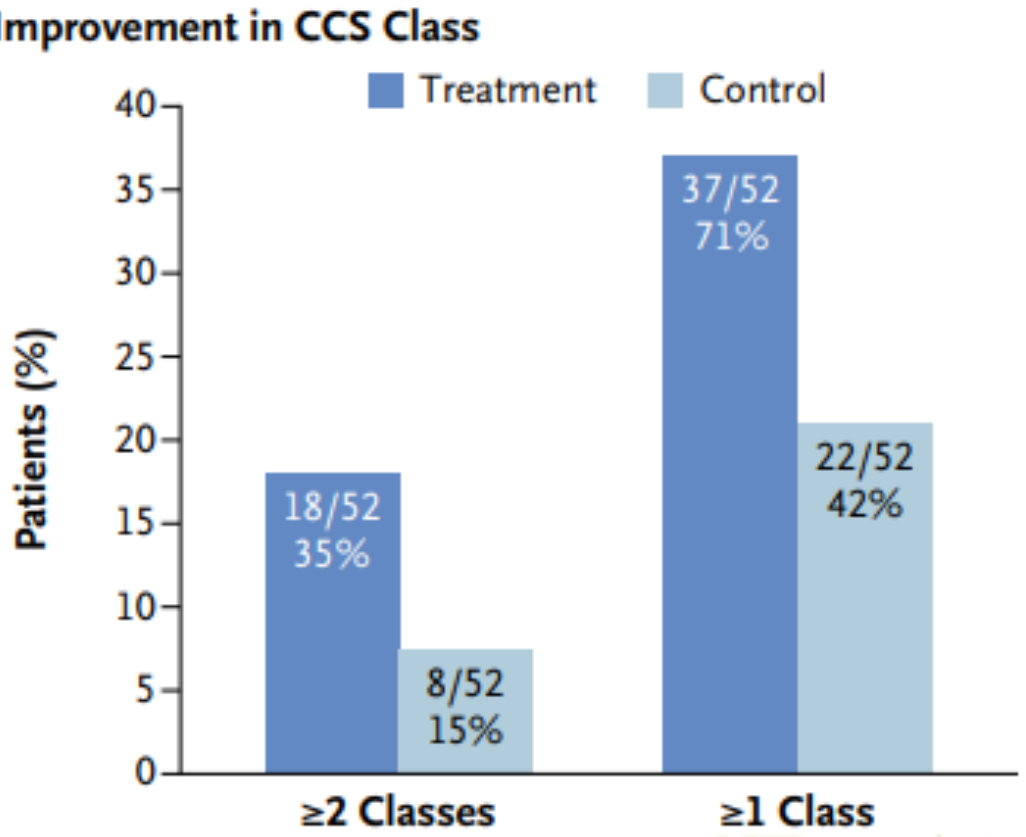
The NEW ENGLAND JOURNAL of MEDICINE

- Critère de jugement principal :

=> Pourcentage de ↘ 2 ≥ CCS à 6 mois

- 104 patients, 11 centres

- Critères d'inclusions :
  - Angor classe 3-4
  - Ischémie
  - Traitement médical optimal
  - FEVG >25%



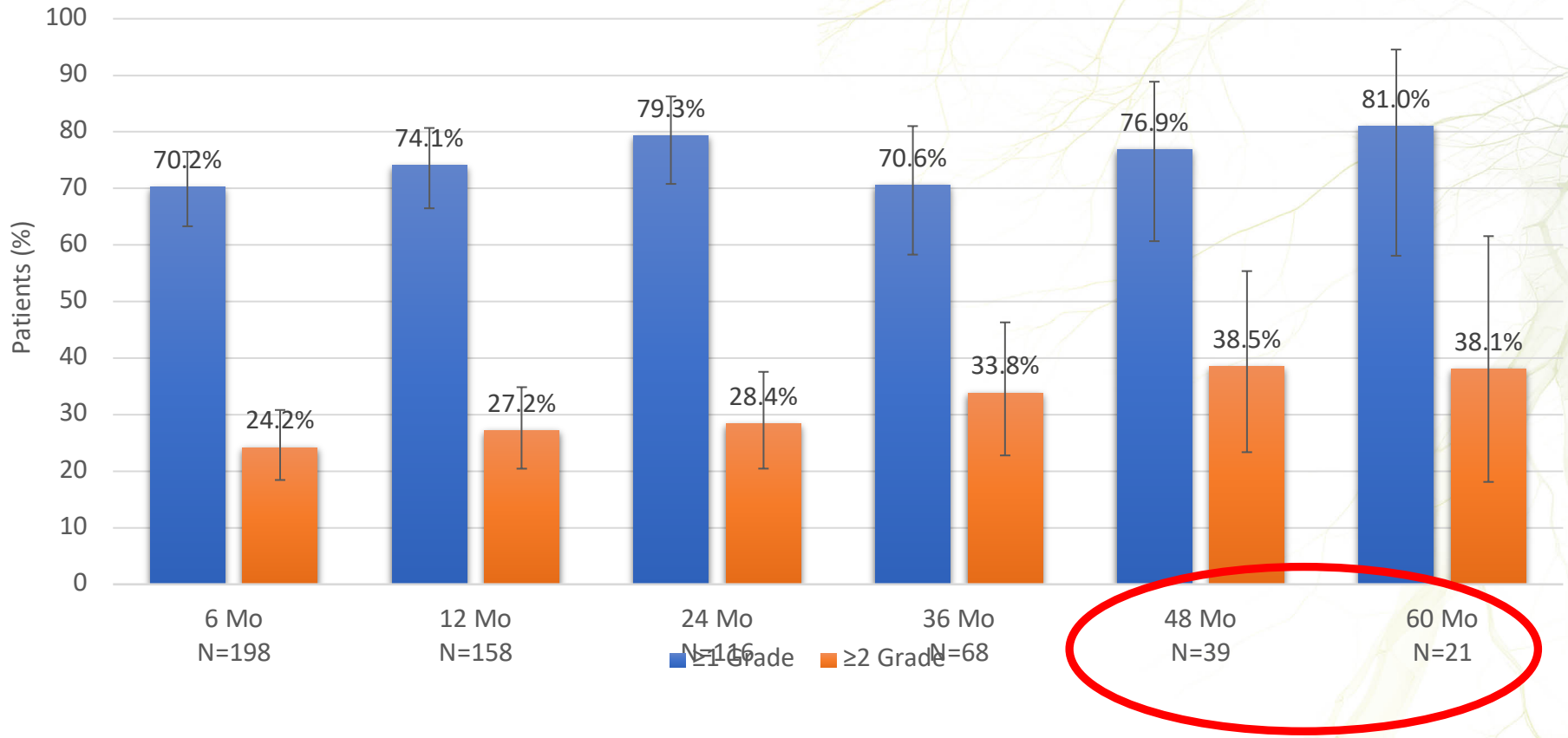
# Efficacité sur long terme

**REDUCER 1 study**

- **228 patients**

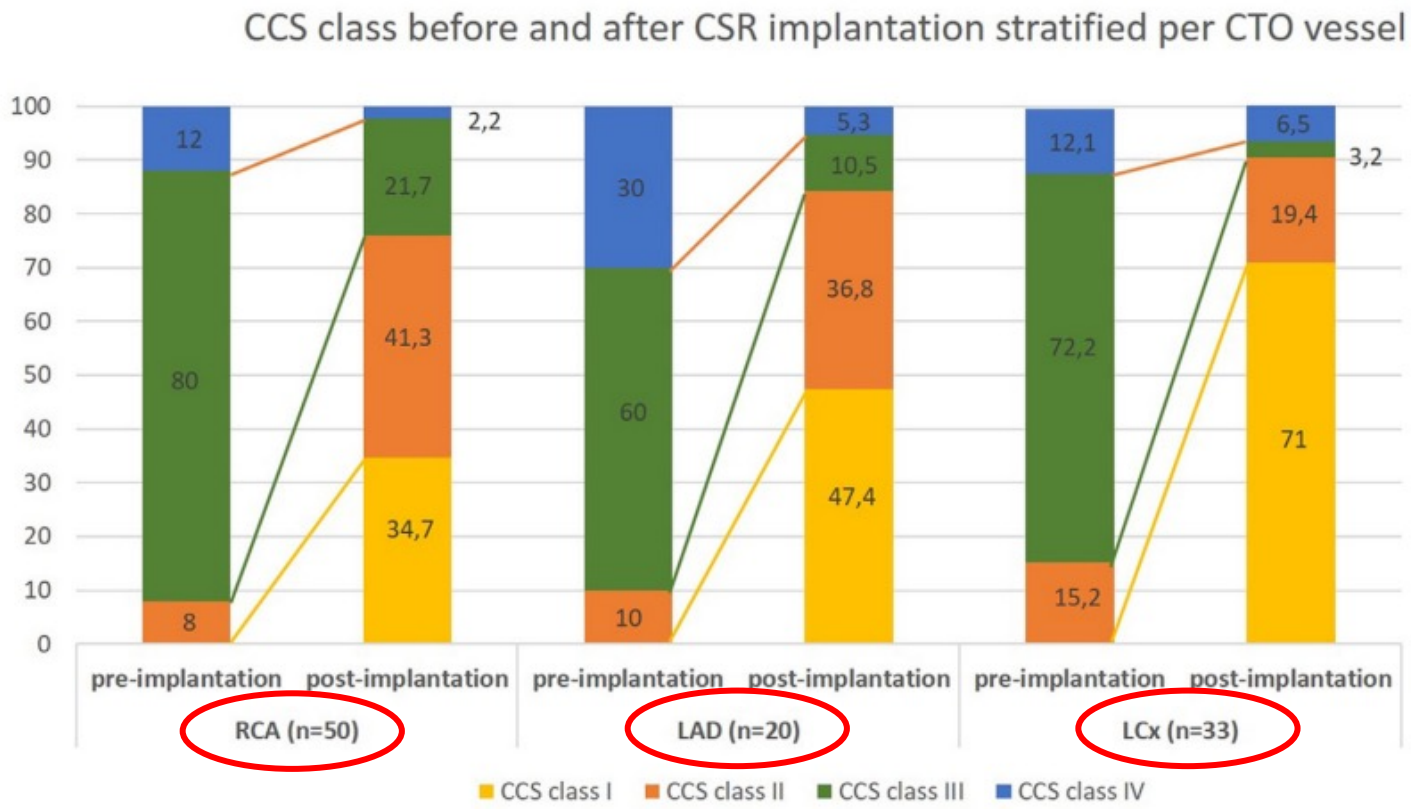
- **Critère de jugement principal :**

**=> Pourcentage de ↘ 2 ≥ CCS classe à 6 mois**



# Efficacité occlusions chroniques

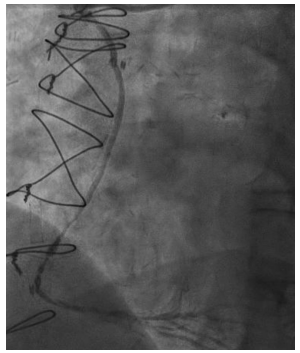
## Efficacy of Coronary Sinus Reducer in Patients With Non-revascularized Chronic Total Occlusions



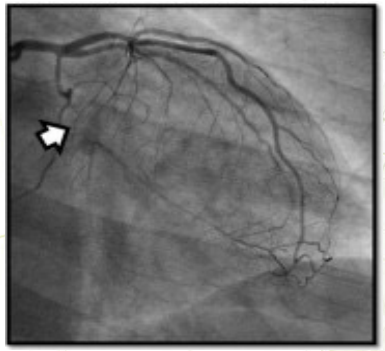

*Zivelonghi et al., Am J Cardio, 2020*

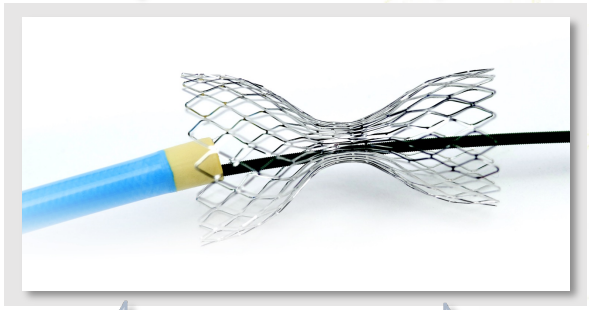
# Indications

**Pontages dégénérés**

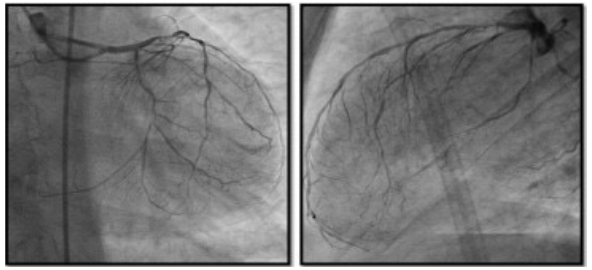


**Occlusion chronique**





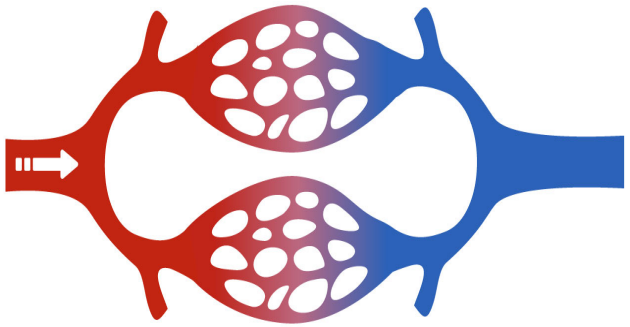
**Coronaropathie sévère**

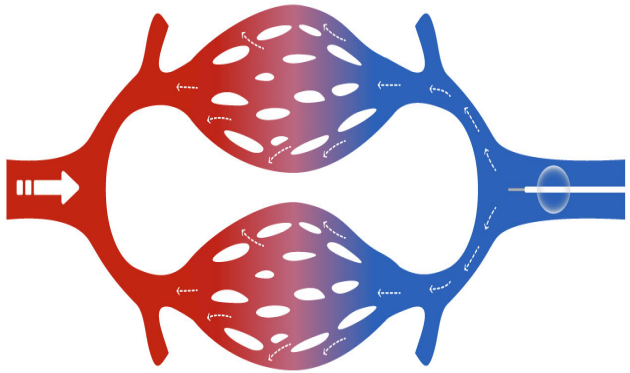


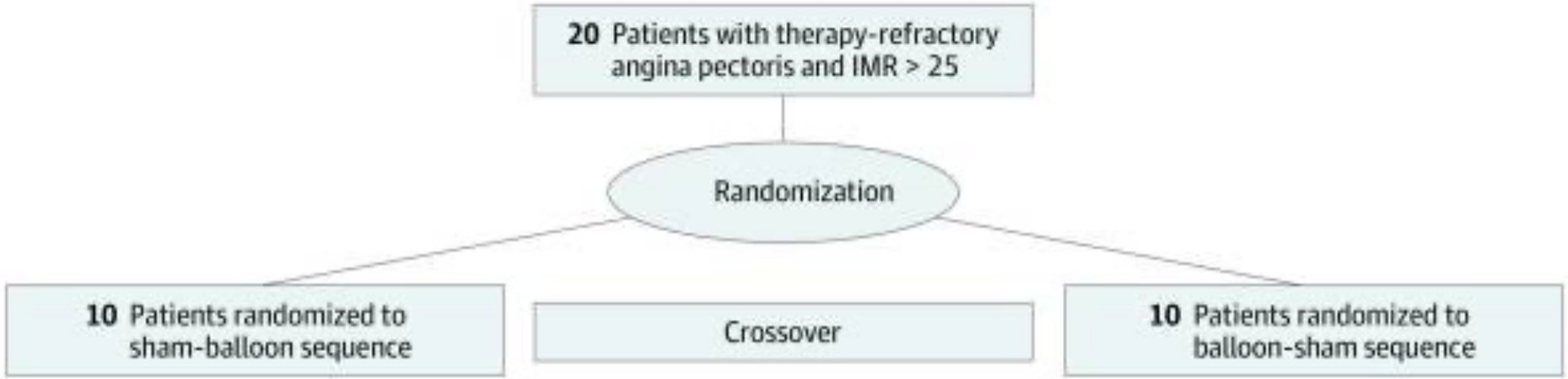
**Dysfonction microvasculaire**

?

# Pression sinus et microcirculation



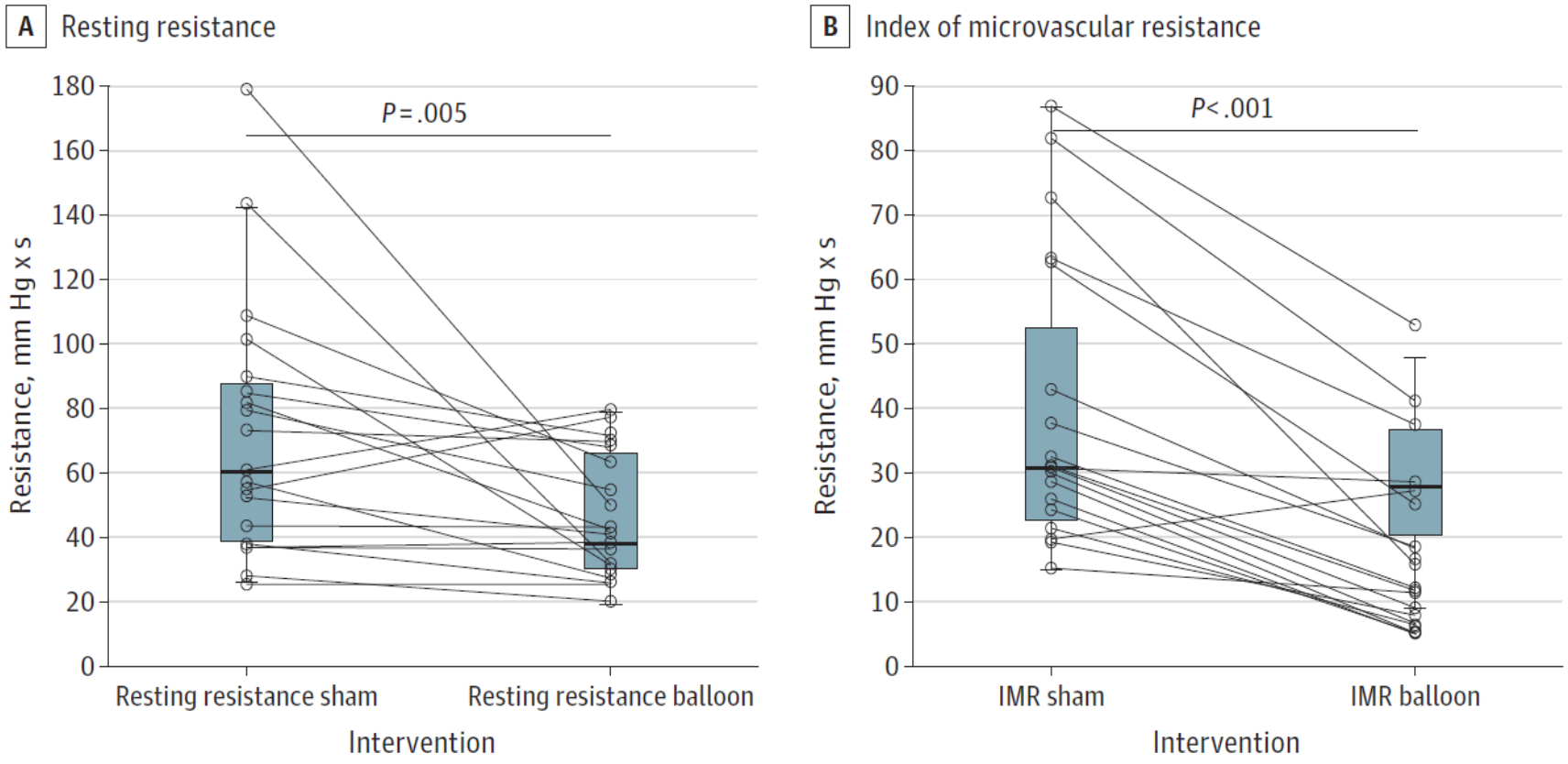





*Ullrich et al., JAMA, 2023*

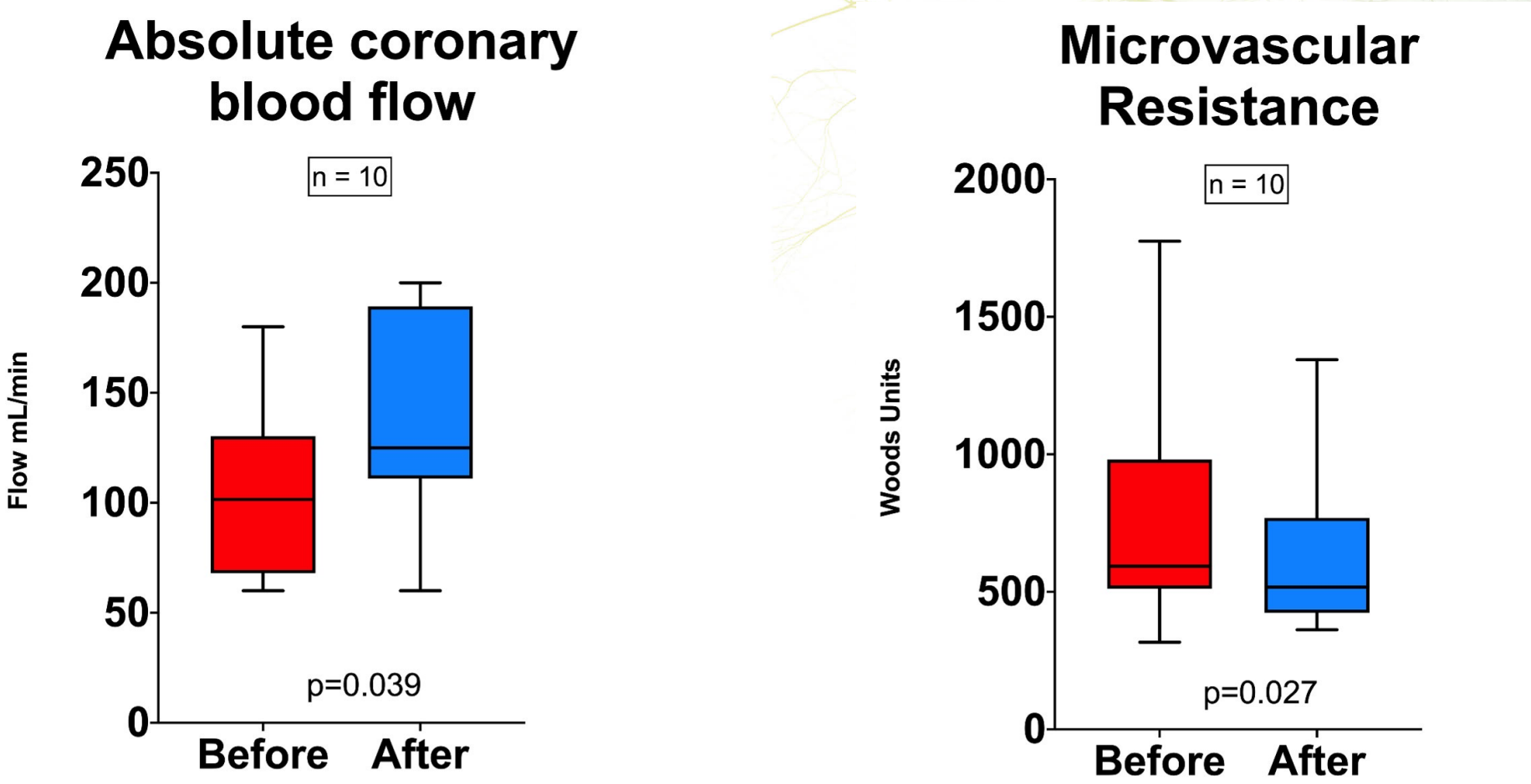
# Pression sinus et microcirculation

**Figure 2. The Primary End Point of the Trial**




*Ullrich et al., JAMA, 2023*

# RAYFLOW pré/post-implantation

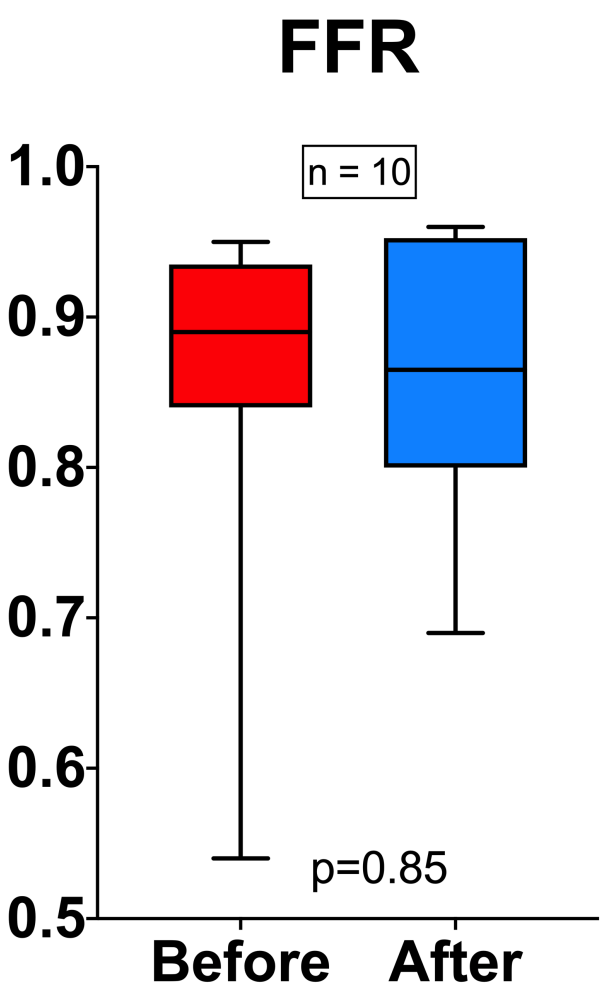



↗ **Flux coronaire absolu**

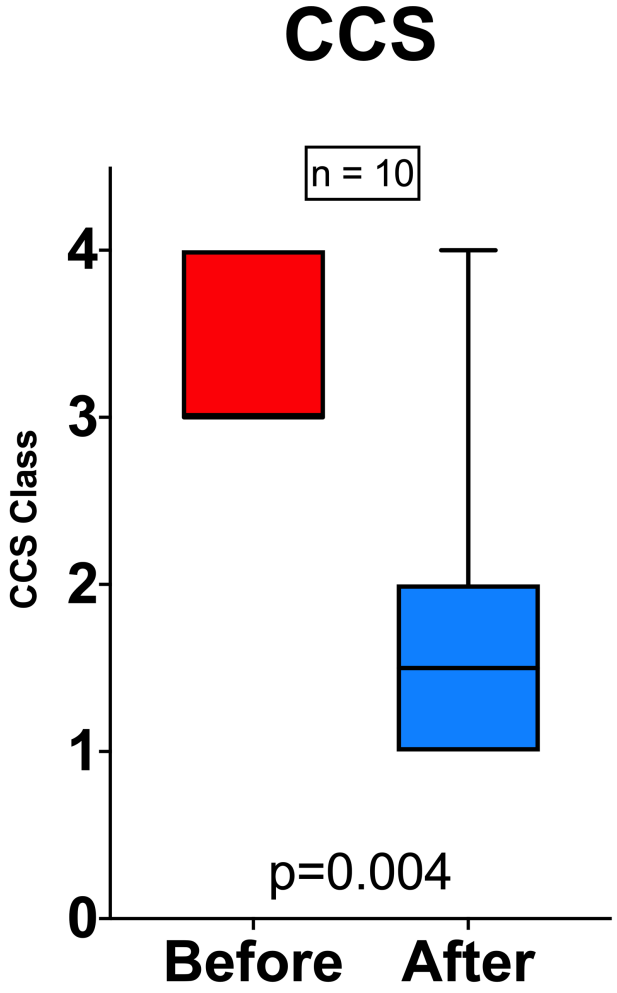
↘ **Résistances**

*Servoz, Adjedj et al., unpublish*

# RAYFLOW pré/post-implantation




FFR inchangée



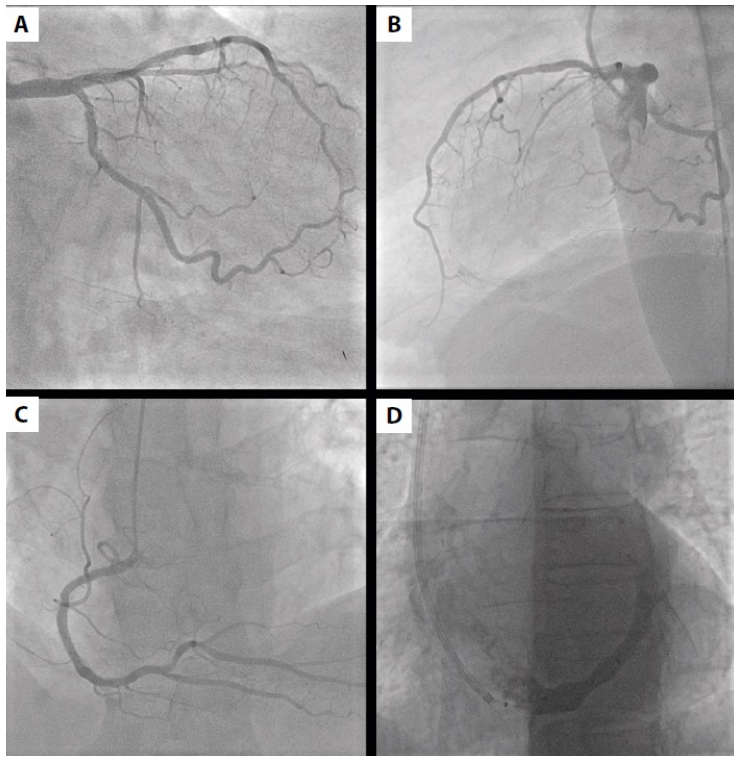

Angor

*Servoz, Adjedj et al., unpublish*

# Premier cas clinique

## Implantation of a coronary sinus reducer for refractory angina due to coronary microvascular dysfunction

Szymon Włodarczak[1], Piotr Rola[2,3], Artur Jastrzębski[1], Mateusz Barycki[3], Michalina Kędzierska[4], Andrzej Korda[1], Adrian Włodarczak[1,2], Maciej Lesiak[5]

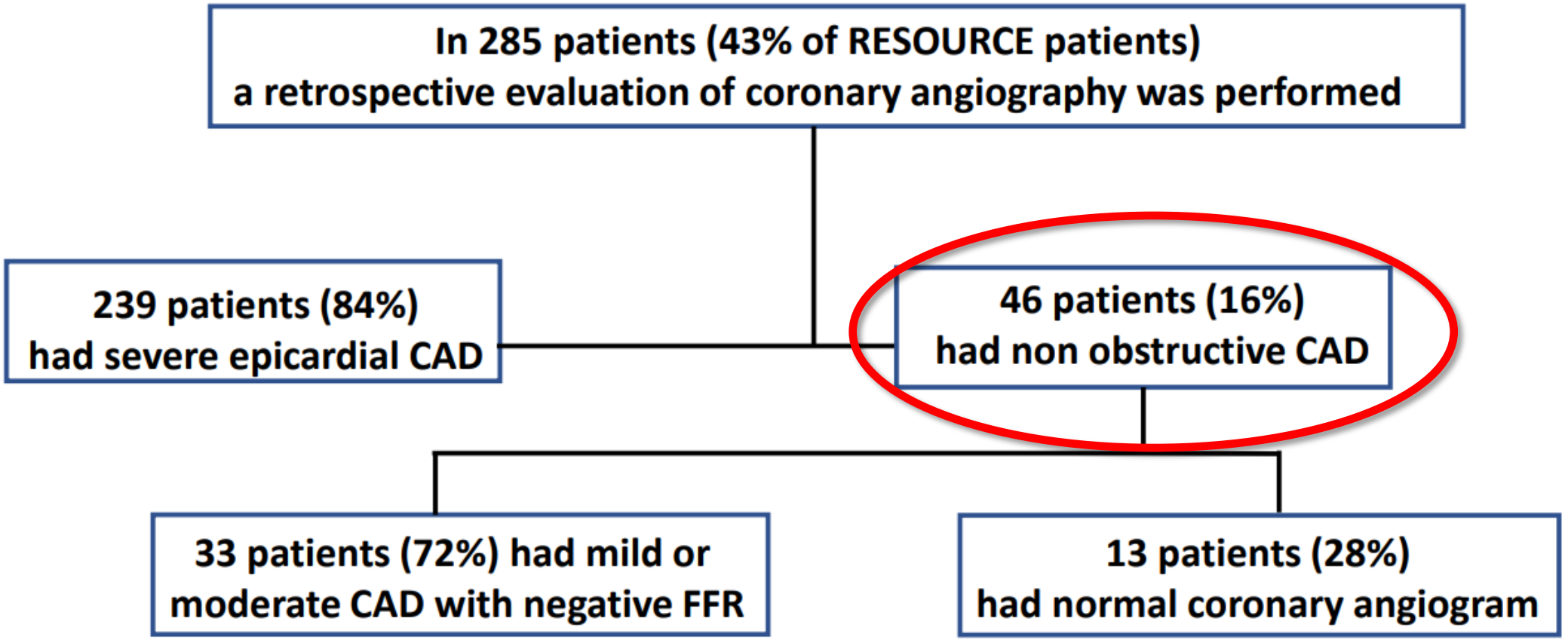




**IMR à 4 mois post-implantation**

*European Heart Journal Case report, 2019*

# Registre RESSOURCE




*Ponticelli et al., Int. Journal Cardiology, 2021*

# Registre RESSOURCE

| | Obstructive CAD (n=239) | | Non obstructive CAD (total = 46) | | Interaction P-value |
|---|---|---|---|---|---|
| **Baseline CCS class** | | | | | 0.128 |
| 1 | 0.0% | | 0.0% | | |
| 2 | 19.5% | | 15.6% | | |
| 3 | 71.2% | 80.5% | 71.1% | 82.2% | |
| 4 | 9.3% | | 11.1% | | |
| **12-month CCS class** | | | | | 0.999 |
| 0 | 3.0% | | 3.2% | | |
| 1 | 51.2% | | 48.4% | | |
| 2 | 34.1% | | 35.5% | | |
| 3 | 8.5% | 9.5% | 9.7% | 12.9% | |
| 4 | 3.0% | | 3.2% | | |

**Obstructive CAD:** **CCS class** baseline vs. 12 months 2.9 ± 0.5 vs. 1.6 ± 0.8

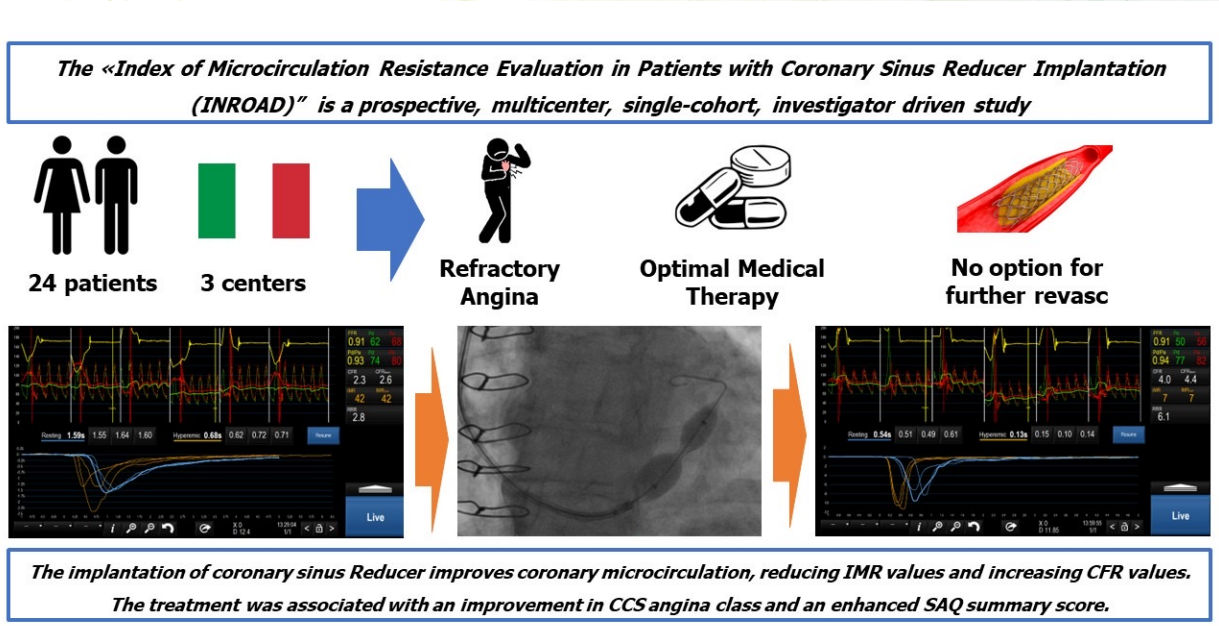
**Non obstructive CAD:** **CCS class** baseline vs. 12 months 2.9 ± 0.6 vs. 1.6 ± 0.8

*Ponticelli et al., Int. Journal Cardiology, 2021*

# Étude randomisée INROAD

Coronary Sinus Narrowing Improves Coronary Microcirculation Function in Patients With Refractory Angina: A Multicenter Prospective INROAD Study

Matteo Tebaldi, MD; Gianluca Campo, MD; Fabrizio Ugo, MD; Stefano Guarracini, MD; Andrea Marrone, MD; Stefano Clò, MD; Mohamed Abdirashid, MD; Michele Di Mauro, MD, PhD; Francesco Rametta, MD; Massimo Di Marco, MD; Marta Cocco, MD; Federico Marchini, MD; Carlo Penzo, MD; Andrea Erriquez, MD; Shmuel Banai, MD; Simone Biscaglia, MD




**Endpoints**

Primary endpoint

- Index of microcirculatory resistance (IMR) value reduction (≥ 20%) @ 4-month f-up

Secondary endpoints

- Significant changes in coronary flow reserve (CFR) and in resistance reserve ratio (RRR) @ 4-month f-up

*Tebaldi et al., Circ. Intervention, 2024*

# Étude randomisée INROAD

**Table 2. Coronary Physiology and Questionnaires of the Patients With Both Baseline and 4-Month Assessments**

| | Baseline (n=21) | 4 mo (n=21) | Mean difference (95% CI) from baseline to 4 mo | *P* value |
|---|---|---|---|---|
| Invasive coronary physiology | | | | |
| IMR | 33.35±19.88 | 15.42±11.36 | −17.90 (−26.16 to −9.64 | <0.001 |
| IMR ≥25, n (%) | 12 (57) | 4 (19) | NA | 0.016 |
| Pd/Pa | 0.93±0.02 | 0.93±0.03 | −0.001 (−0.016 to 0.013) | 0.843 |
| RFR | 0.94±0.03 | 0.93±0.03 | −0.001 (−0.017 to 0.016) | 0.907 |
| FFR | 0.89±0.04 | 0.89±0.04 | −0.004 (−0.020 to 0.011) | 0.538 |
| CFR | 2.46±1.52 | 4.20±2.52 | 1.73 (0.51 to 2.96) | 0.007 |
| CFR <2, n (%) | 11 (52) | 4 (19) | NA | 0.039 |
| RRR | 2.81±2.31 | 4.75±2.88 | 1.93 (0.67 to 3.20) | 0.004 |
| RRR <3.5, n (%) | 15 (71) | 8 (38) | NA | 0.092 |
| Left ventricle end-diastolic pressure | 11.94±2.54 | 10.53±2.16 | −1.42 (−2.61 to −0.22) | 0.023 |
| CCS angina class, n (%) | | | | |
| I | 0 (0) | 12 (57) | NA | <0.001 |
| II | 6 (28) | 6 (28) | NA | <0.001 |
| III | 14 (67) | 3 (15) | NA | <0.001 |
| IV | 1 (5) | 0 (0) | NA | <0.001 |

*Tebaldi et al., Circ. Intervention, 2024*

# Nombreuses études en cours

**Coronary Sinus Reducer Objective Impact on Symptoms, MRI Ischaemia and Microvascular Resistance (ORBITA-COSMIC)**

**ClinicalTrials.gov ID** NCT04892537

**Sponsor** Imperial College London

**Information provided by** Imperial College London (Responsible Party)

**Last Update Posted** 2023-10-30

## Study Overview

**Brief Summary**

ORBITA-COSMIC is a randomised, double-blinded, placebo controlled trial of the coronary sinus reducer (CSR). The investigators will compare the effects of CSR versus placebo on myocardial perfusion on MRI, exercise time and symptoms in 50 participants with refractory angina and ischaemia.

**COSIMA: COronary SInus Reducer for the Treatment of Refractory Microvascular Angina (COSIMA)**

**Study Start (Actual)**

2021-04-01

**Primary Completion (Estimated)**

2025-10-20

**Study Completion (Estimated)**

2029-10-20

**Enrollment (Estimated)**

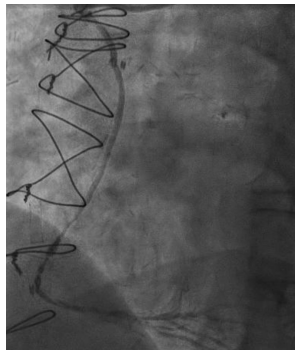
144

**Feasibility and Efficacy of Coronary Sinus Narrowing in Patients With Coronary Microvascular Dysfunction (Reducer)**

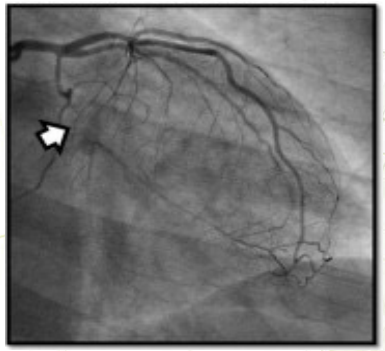
| | |
|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Actual Enrollment : | 30 participants |
| Allocation: | N/A |
| Intervention Model: | Single Group Assignment |
| Masking: | None (Open Label) |
| Primary Purpose: | Treatment |
| Official Title: | A Phase II Study Testing the F |
| Actual Study Start Date : | June 28, 2021 |
| Actual Primary Completion Date : | July 28, 2023 |
| Actual Study Completion Date : | July 28, 2023 |

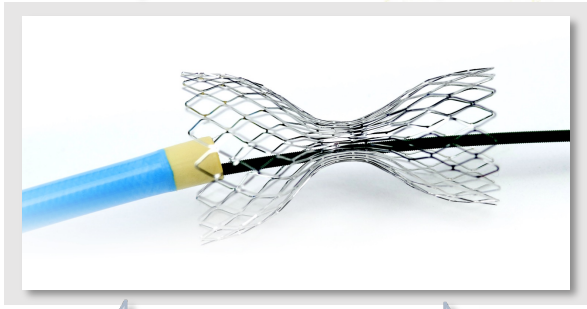
# Indications

**Pontages dégénérés**

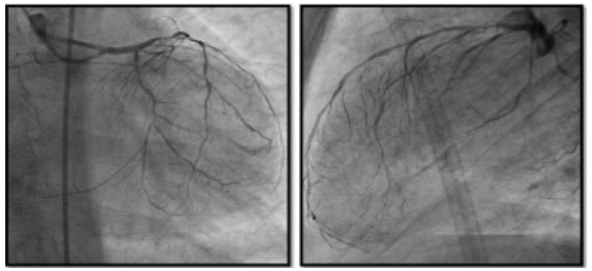


**Occlusions chroniques**



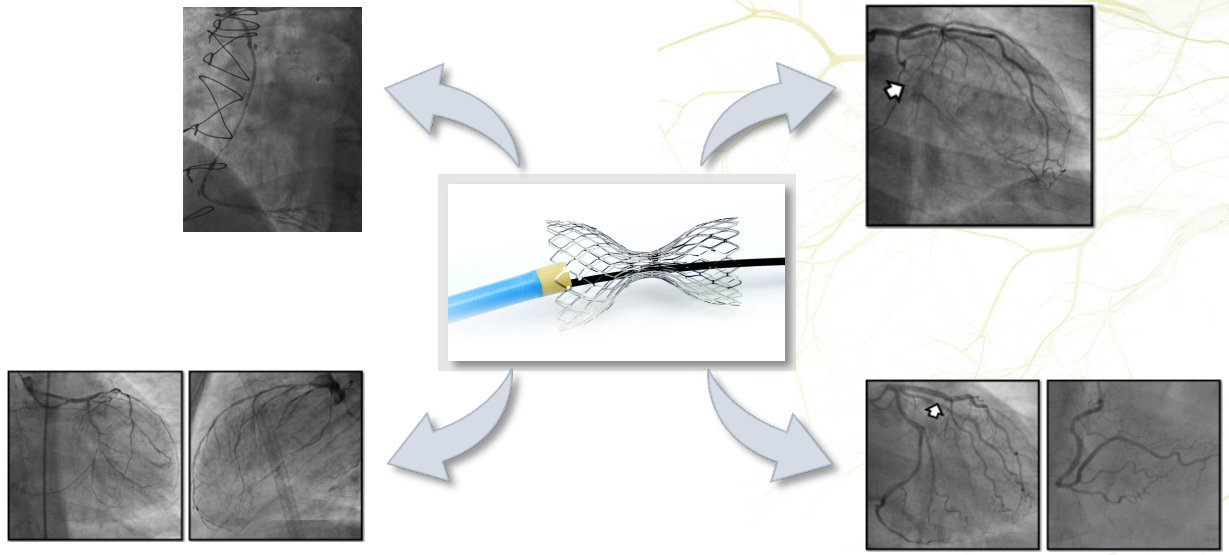


**Coronaropathies sévères**



**Dysfonction microvasculaire**

# Conclusion



- Mécanisme  d'action en cours comprehension
- Dysfonction microvasculaire
- Médecine individualisée
- Prise en charge anti-angineuse maximale

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# Merci de votre attention

5&6 AVRIL 2024

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