CSC 2025
CORONARY AND STRUCTURAL CONGRESS
CONGRESO CORONARIO Y ESTRUCTURAL
MADRID

5, 6 y 7 NOVIEMBRE
HOTEL RIU PLAZA DE ESPAÑA

Dispositivo reductor del seno coronario

Evidencia científica

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Reducción del seno coronario: Historia

EXPERIMENTAL ATTEMPTS TO INCREASE THE BLOOD SUPPLY TO THE DOG'S HEART BY MEANS OF CORONARY SINUS OCCLUSION*

By LOUIS GROSS, M.D., LESTER BLUM, M.D., and GERTRUDE SILVERMAN, M.D.

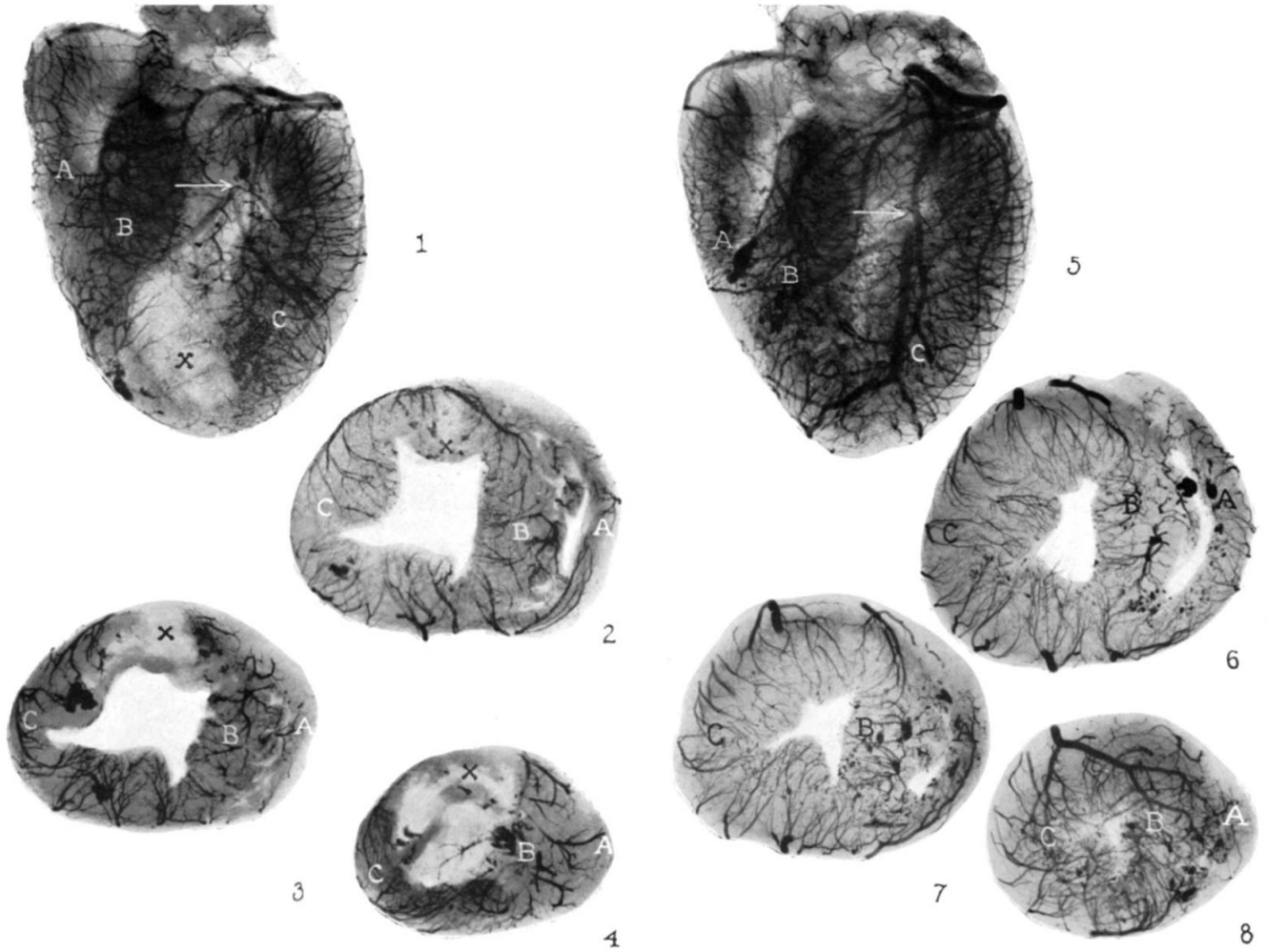
(*From the Laboratories of The Mount Sinai Hospital, New York*)

Plates 4 and 5

(Received for publication, July 17, 1936)

the mortality rate following sudden complete left anterior descending branch occlusion was 53 per cent. The only group in which this was materially reduced was that in which a preliminary partial coronary sinus occlusion was present (31 per cent).

Partial persistent obturation of the coronary sinus, however, is in itself associated with a low operative mortality. Furthermore, its experimental production in dogs appears to lower the mortality rate following subsequent sudden occlusion of the left anterior descending branch and to diminish the extent of the infarction.



Reducción del seno coronario: Historia

MEDICAL EVALUATION OF THE BECK OPERATION FOR CORONARY ARTERY DISEASE

J.A.M.A., December 29, 1956

Mortality.—In the 185 patients operated on since January, 1951, there have been 11 deaths associated with surgery (2 during operation and 9 in the early postoperative period), for a total mortality rate of less than 6%. Careful selection of patients and improvements in medical and surgical management have resulted in a progressive lowering of operative mortality, as evidenced by the last 62 consecutive operations up to this time without a death.

Long-term follow-up studies have been carried out on the 137 consecutive patients discharged over a period of six months to five years, with the average time since operation being two years. The expected mortality in such a group over this period would be 41, or 30%.[5] Actually, 18 are known or assumed to be dead, a mortality rate of 13.1%.

Of the 100 consecutive patients who are alive and who could be evaluated over a six-month to five-year follow-up period, 45 are more or less completely free of pain. Another 45 claim considerable reduction in pain. Thus, 90% had a definite amelioration of symptoms. Only 10% had no observable improvement;

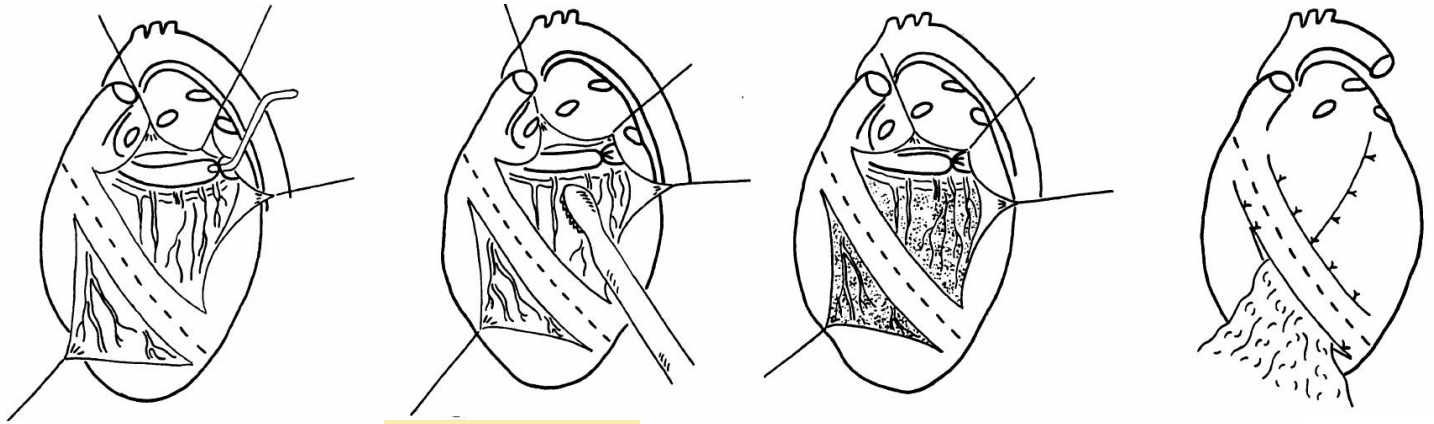


FIGURE 3: The Beck I Operation. Four steps: 1. Partial ligation of coronary sinus over 3 mm. probe; 2. Abrasion of pericardium and epicardium; 3. Asbestos powder sprinkled on surface of heart; 4. Mediastinal fat grafted to surface of heart.

Claude S. Beck.
1894-1971

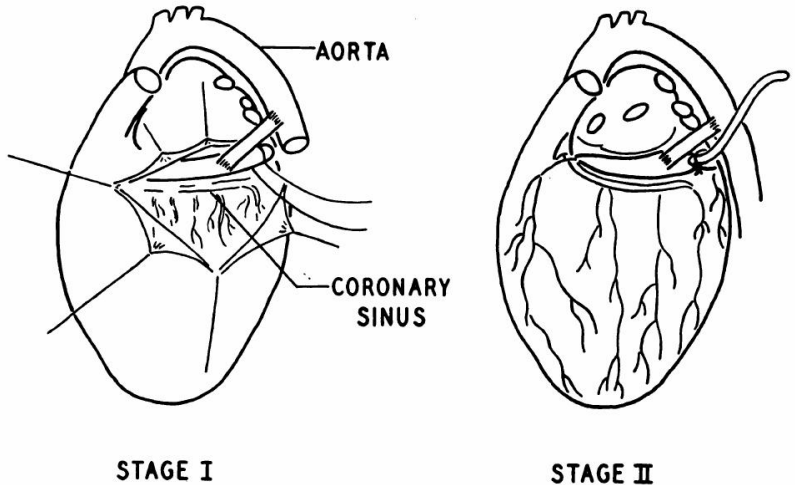
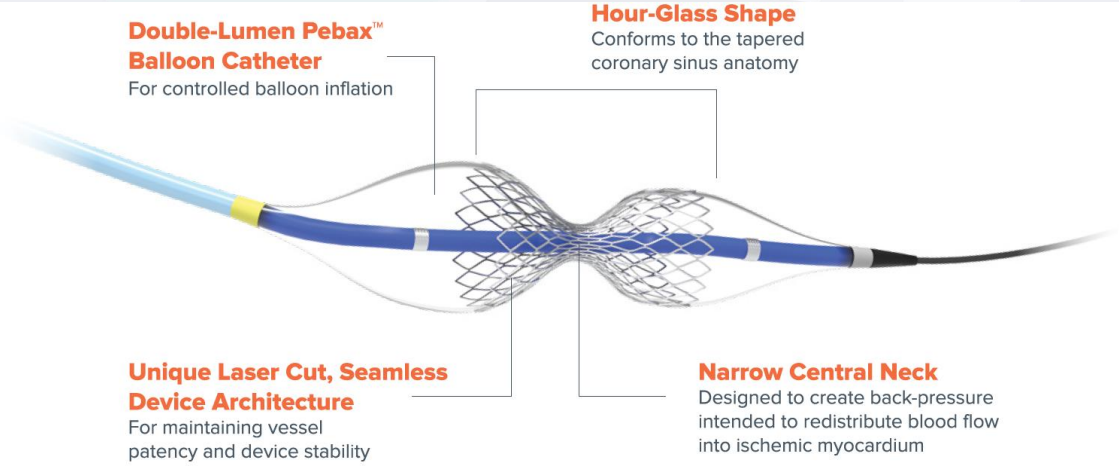
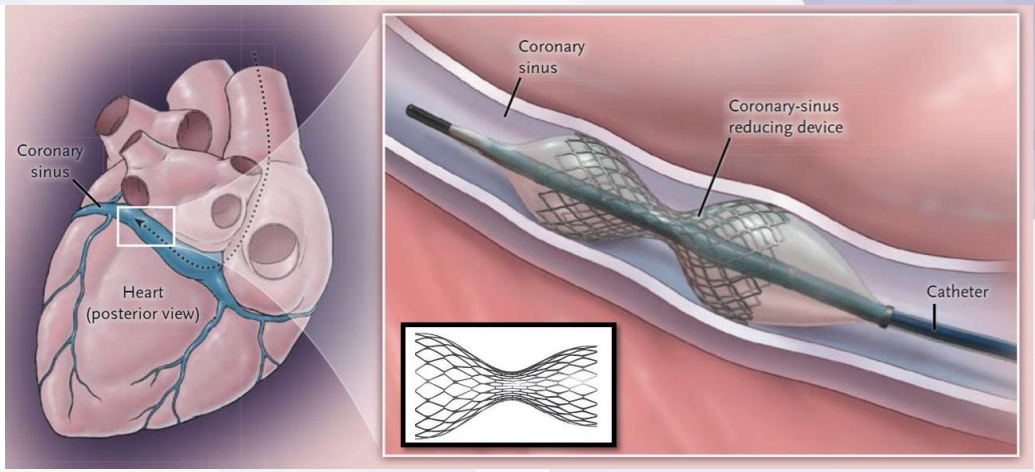
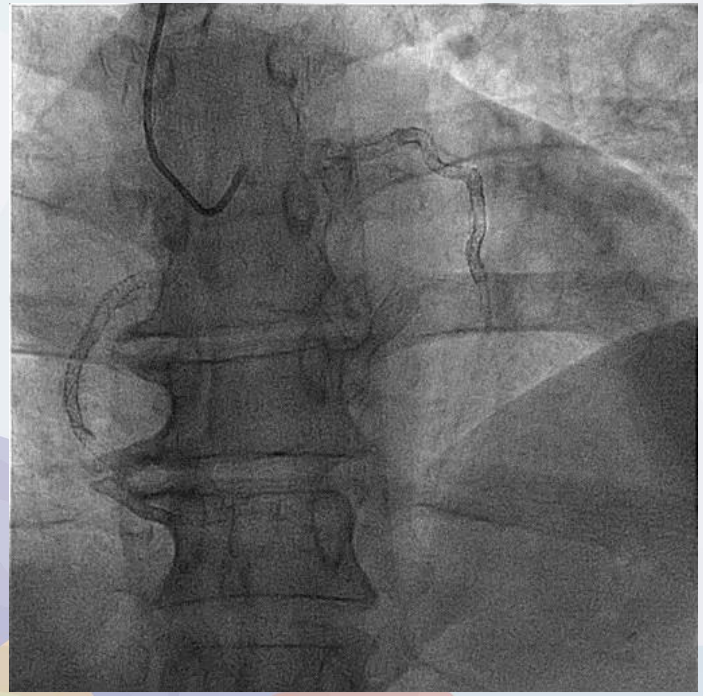


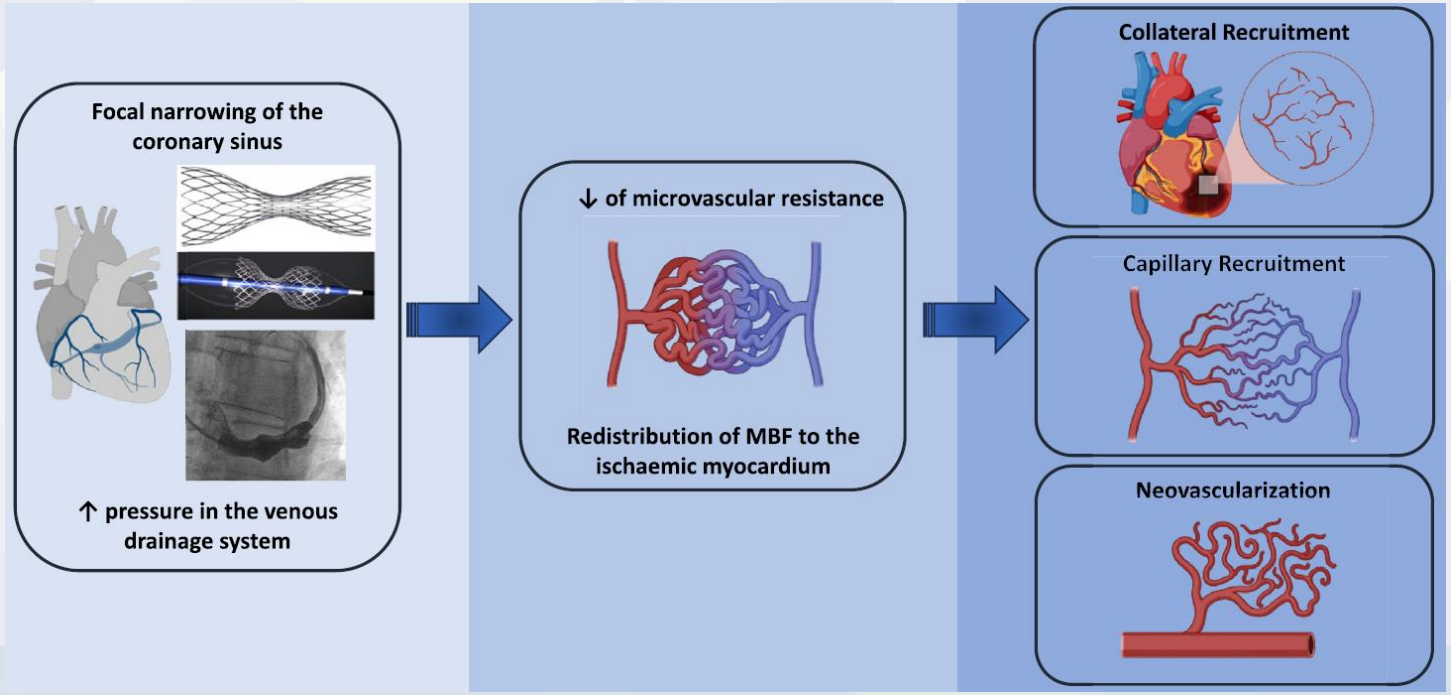
FIGURE 4: The Beck II Operation: Stage I—Approximation of vein graft between aorta and coronary sinus. Stage II—Three weeks later; partial ligation of coronary sinus over a probe.

Dispositivo Reducer: Concepto

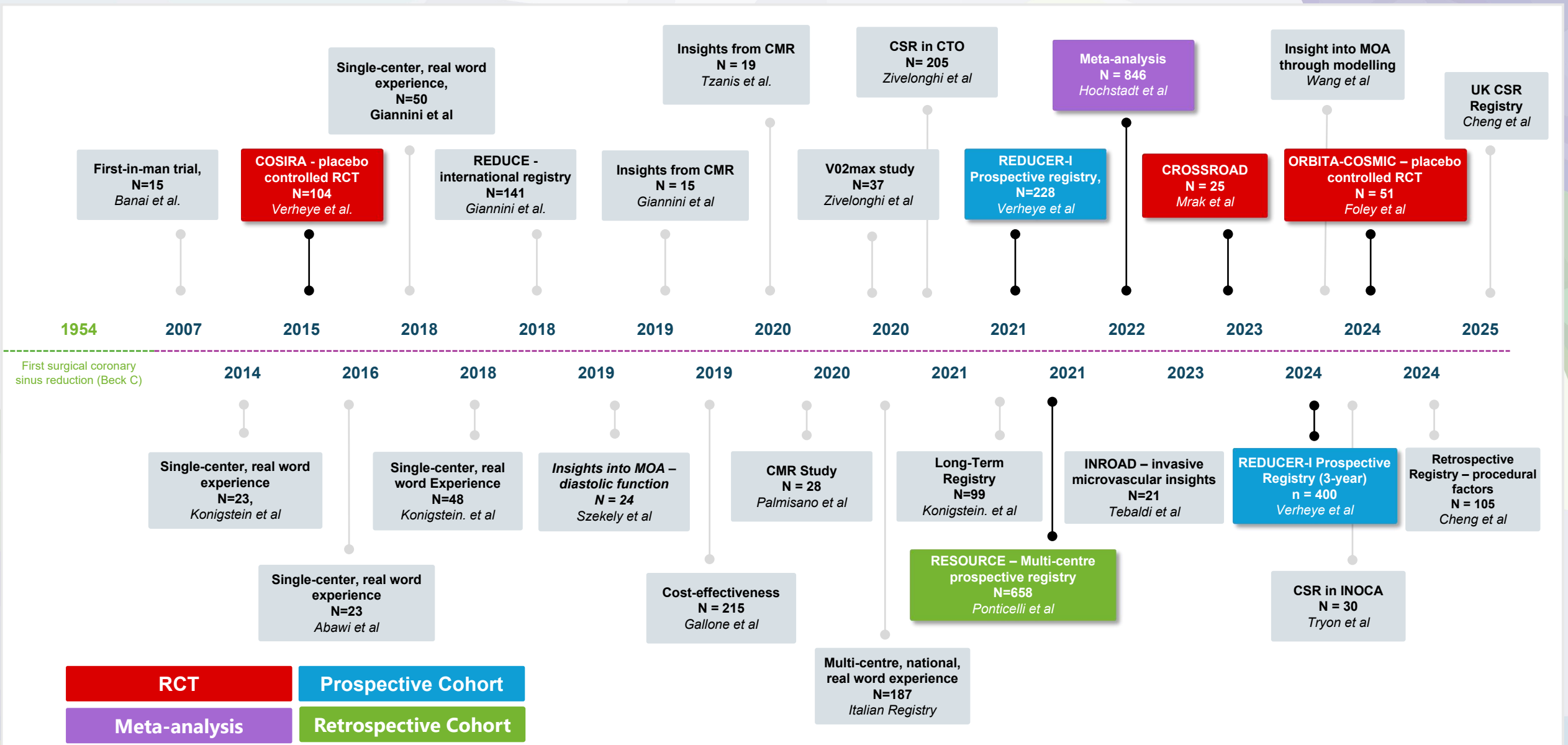








Dispositivo Reducer: Evidencia científica



Dispositivo Reducer: Evidencia científica

1.- Reducción de la severidad de angina

2.- Seguridad

3.- Efecto sobre la perfusión miocárdica

4.- Efecto sobre la disfunción microvascular

Reducer: Evidencia en reducción de la angina

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

COSIRA ClinicalTrials.gov number, NCT01205893

N Engl J Med 2015;372:519-27.

Descripción

Estudio prospectivo, multicéntrico, **aleatorizado, doble ciego, controlado con procedimiento simulado**
Inclusión de 104 pacientes en 11 centros

Objetivo primario

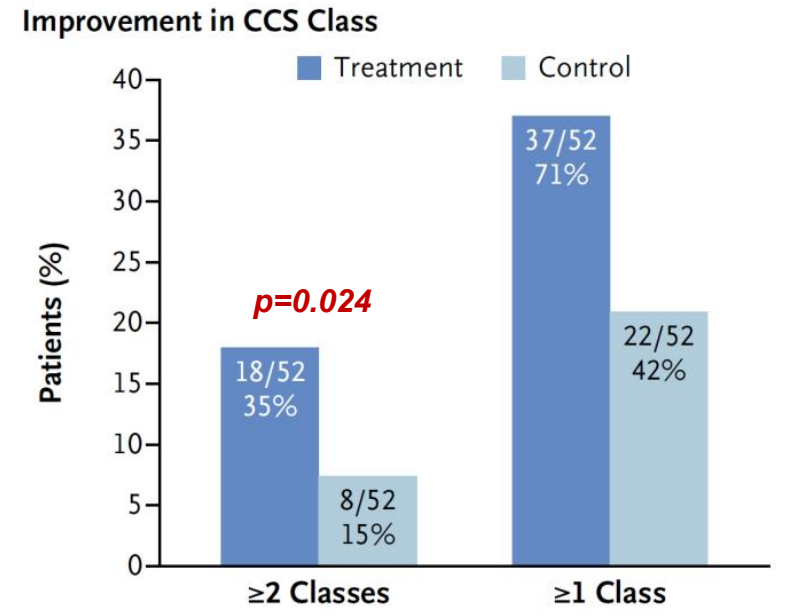
Reducción de al menos dos grados (CCS) de la gravedad de la angina a los 6 meses

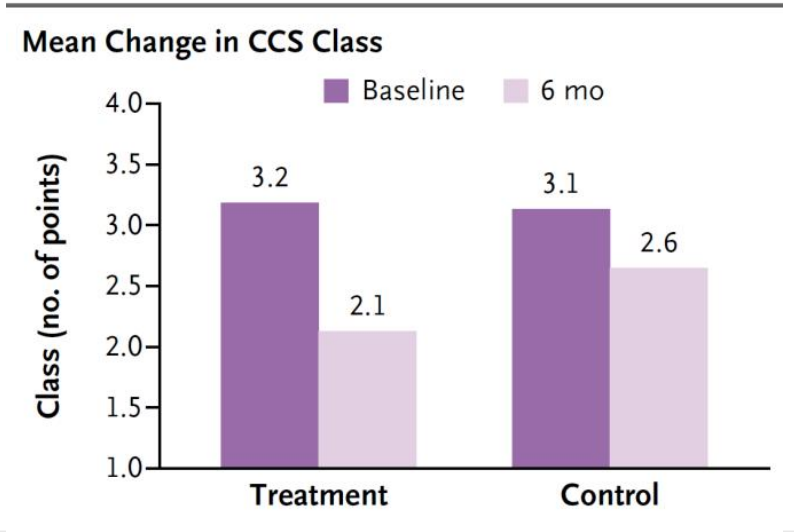
Objetivos secundarios

Mejoría clínica de al menos 1 grado CCS, SAQ, WMSI (eco dobutamina), parámetros de ergometría (tiempo de ejercicio, tiempo hasta depresión del ST, máxima depresión del ST)

Criterios de inclusión

- Pacientes con angina refractaria grado III o IV a pesar de tratamiento médico óptimo, sin posibilidad de revascularización tras evaluación en "Heart Team"
- Isquemia miocárdica reversible documentada mediante eco-dobutamina
- FEVI >25%





Evidencia en reducción de la angina

The efficacy of coronary sinus reducer in patients with refractory angina—A systematic review of the literature

J Interv Cardiol. 2018;1–5.

F author	CCS improvement[a]	CCS improvement of ≥2 scores	Exercise duration baseline (min)	Exercise duration F/U (min)	WMSI[b] baseline	WMSI[b] F/U	6-min walk distance baseline (mean meters)	6-min walk distance F/U (mean meters)
Abawi M.	17/23	9/23	N/A	N/A	N/A	N/A	N/A	N/A
Banai S.	12/14	8/14	7.08	6.79	1.39[c]	1.17[c]	N/A	N/A
Giannini F.	40/50	20/50	N/A	N/A	N/A	N/A	287	388.6
Konigstein M.	33/39	19/39	3.72	4.58	1.58[e]	1.37[e]	299.9[f]	352.9[f]
Giannini F.	7/8	5/8	N/A	N/A	N/A	N/A	266	360
Verheye S.	37/52	18/52	7.35	8.33	1.54[g]	1.33[g]	N/A	N/A

The Reducer device in patients with angina pectoris: mechanisms, indications, and perspectives

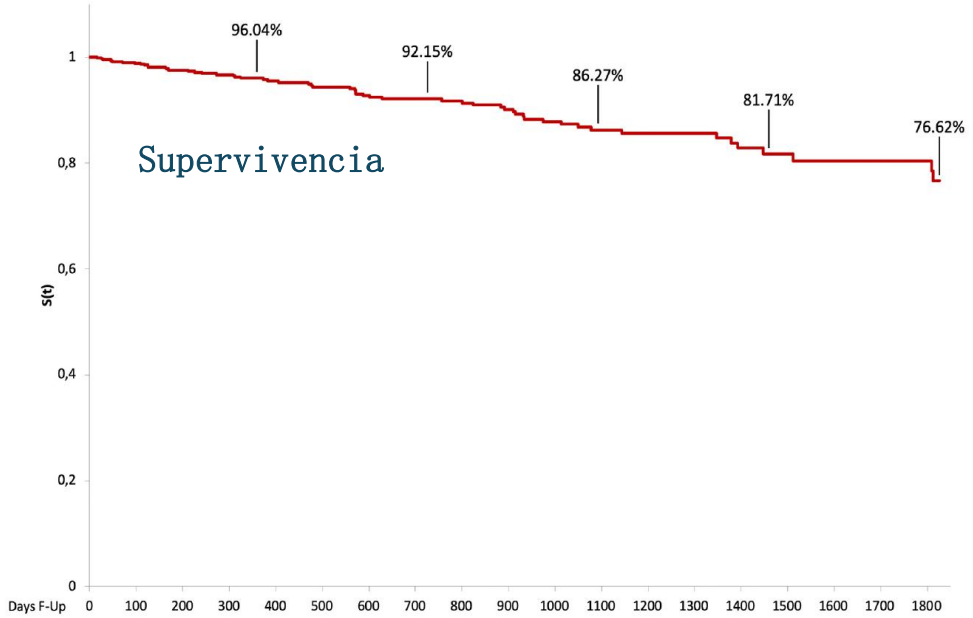
European Heart Journal (2018) **39**, 925–933

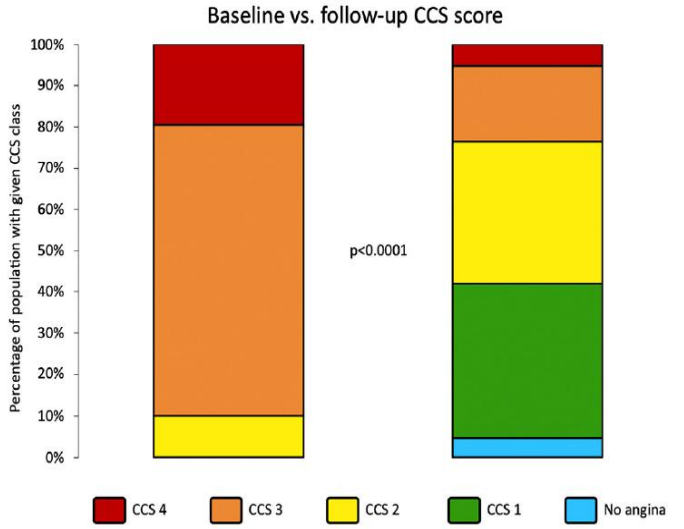
Authors	Year	Design	Number of patients implanted	Successful implantation	CCS class pre implantation	CCS class post implantation	Treatment responders
Banai *et al.*[38]	2007	Open label	15	15/15	3.07	1.64	12/15 (80%)
Konigstein *et al.*[11]	2014	Registry	23	21/23	3.3	2	16/20 (80%)
Verheye *et al.*[12]	2015	Double blind sham controlled	52/104	50/52	3.2	2.1	37/52 (71%)
Giannini *et al.*[44,a]	2016	Registry	50	50/50	3.3	2.0	35/50 (70%)
Reducer-1[a]	2017	Registry	94	92/94	2.9	1.6	39/48[b] (81%)

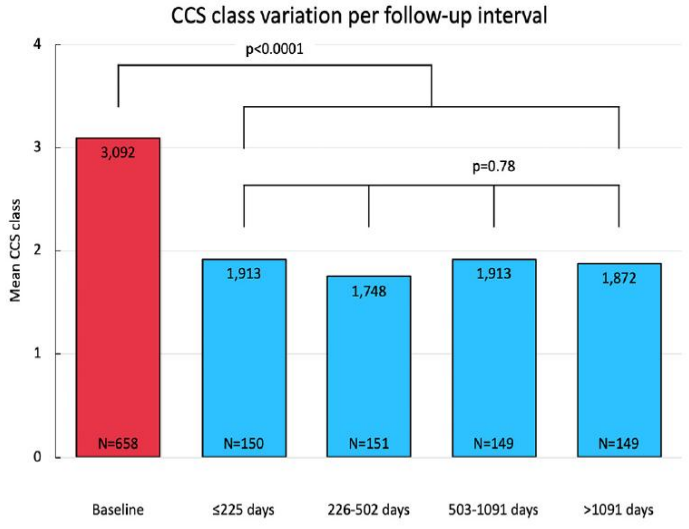
Evidencia en reducción de la angina

Safety and efficacy of coronary sinus narrowing in chronic refractory angina: Insights from the RESOURCE study

International Journal of Cardiology 337 (2021) 29–37







Seguridad

Procedural outcomes	N = 663
Procedural success, n (%)	641 (96.68)
Aborted procedures, n (%)	20 (3.02)
Non-functioning scaffolds, n (%)	2 (0.31)
Procedures with complications (all), n (%)	38 (5.73)

Procedural complications	N = 42
Intra- or periprocedural death, n (%)	0
Intra- or periprocedural MI, n (%)	0
Intra- or periprocedural stroke, n (%)	1
Bailout surgery, n (%)	0
CS perforation, n (%)	3
CS dissection, n (%)	9
Device embolization, n (%)	15
Device dislodgment from delivery catheter, n (%)	4
Neck hematoma, n (%)	10

Evidencia en reducción de la angina

Coronary Sinus Narrowing for Treating Refractory Angina

REDUCER-I Multicenter "Real-World" Observational Study

JACC Cardiovasc Interv. 2024;17:2908-2918

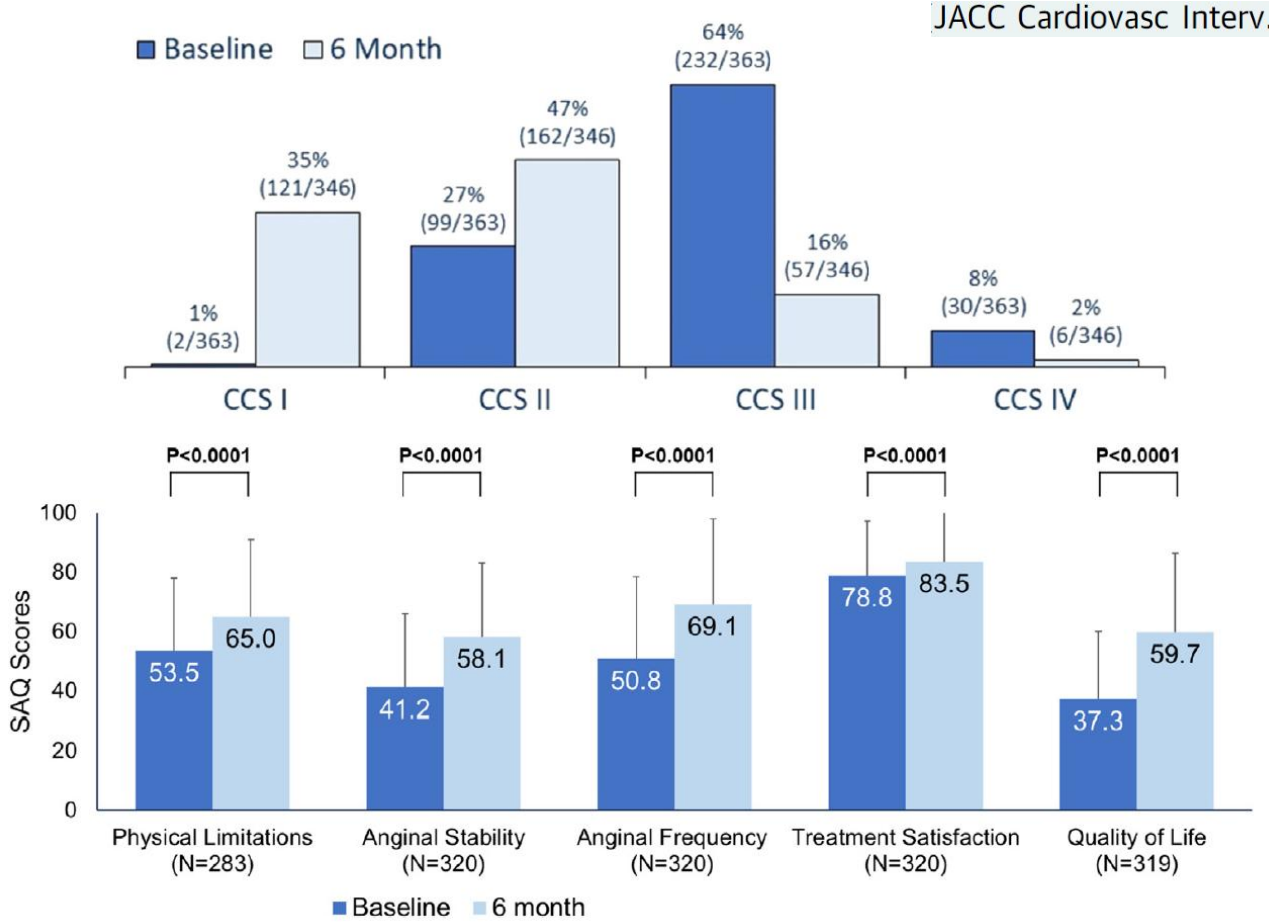
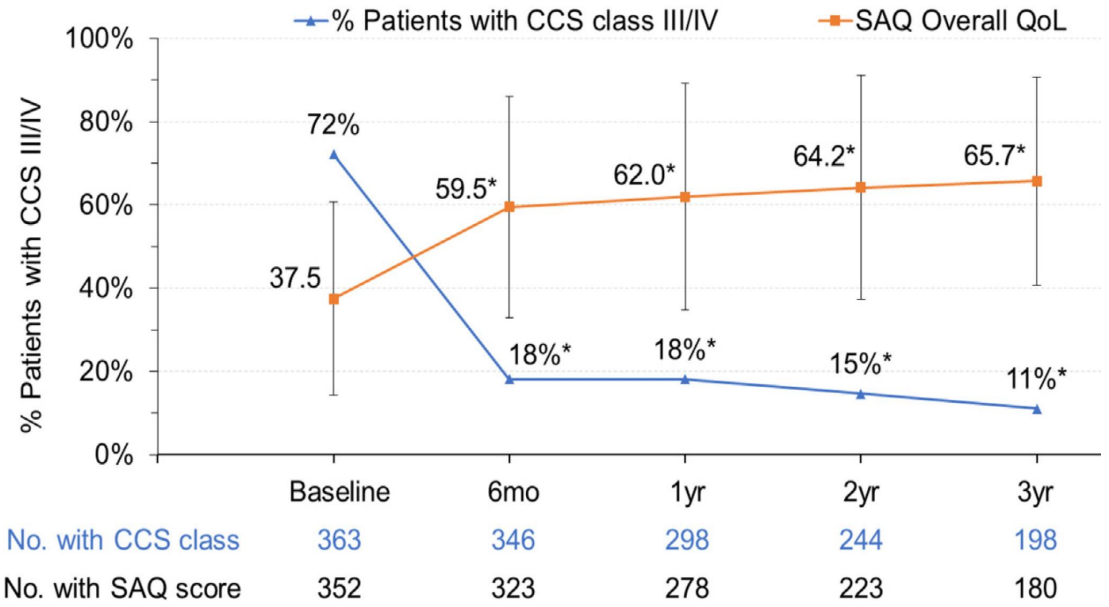


TABLE 3 Primary Safety Endpoint: Device- or Procedure-Related SAEs Within 30 Days

Complications	No. of Events	Subjects With Event
Device or procedure SAE within 30 days	4	1.1 (4/371)
All-cause death	0	0.0 (0/371)
Myocardial infarction	3	0.8 (3/371)
Cardiac tamponade	1	0.3 (1/371)
Clinically driven redilatation of a Reducer	0	0.0 (0/371)
Life-threatening arrhythmias	0	0.0 (0/371)
Respiratory failure	0	0.0 (0/371)



Evidencia en reducción de la angina

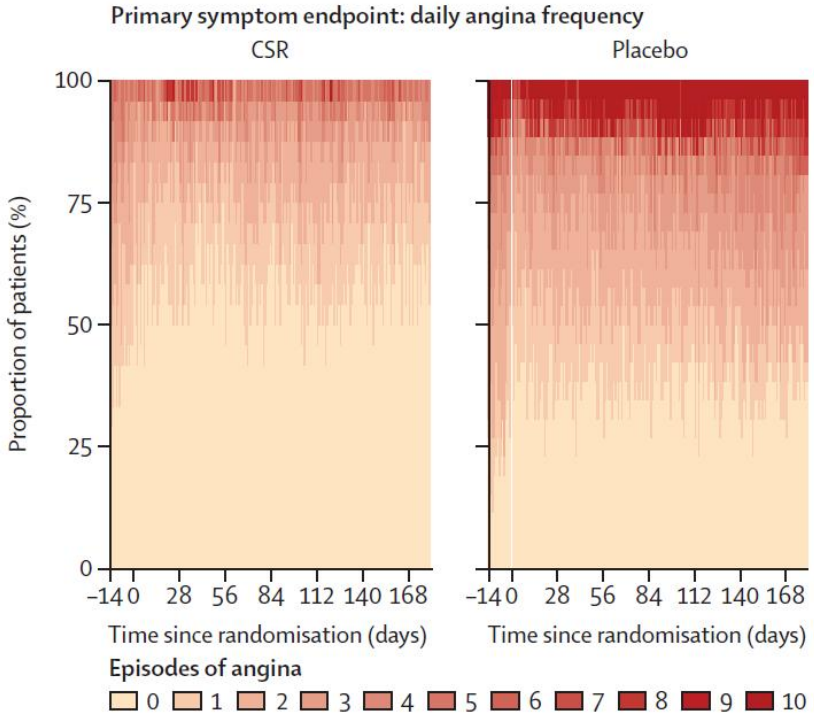
Coronary sinus reducer for the treatment of refractory angina (ORBITA-COSMIC): a randomised, placebo-controlled trial

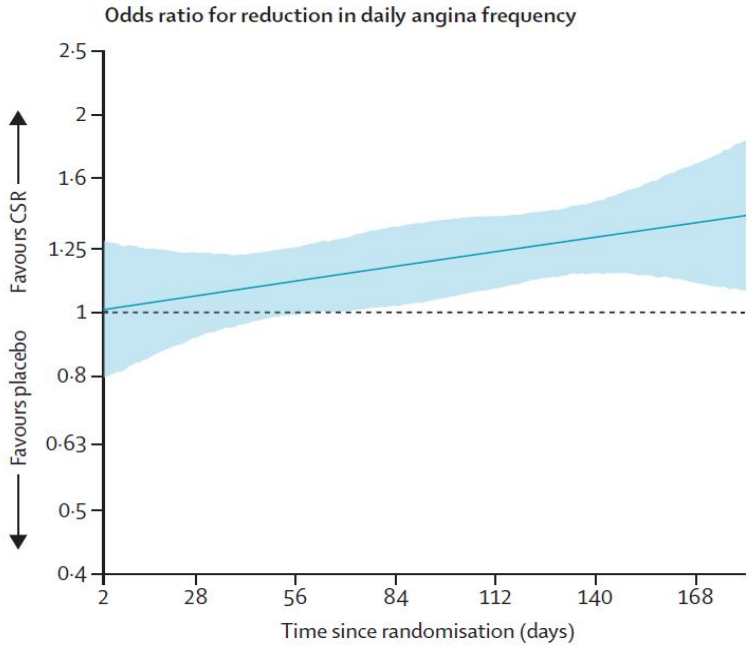
Lancet 2024; 403: 1543–53

- ✓ N: 25 CSR, 26 placebo (sham)
- ✓ Muerte, IAM, ictus: 0%. Embolización: 8%
- ✓ Objetivos primarios: Flujo miocárdico (RM) y severidad de la angina

Primary symptom endpoint (angina episodes)

	Odds ratio of transition to fewer angina episodes each day with CSR *vs* placebo	Probability of benefit with CSR *vs* placebo
Day 2 of follow-up	1·01 (0·80–1·28)	53·1%
Day 70 of follow-up	1·15 (1·00–1·30)	98·1%
Day 182 of follow-up	1·40 (1·08–1·83)	99·4%





	n	Score increment	Score at 6-month follow-up	Benefit from baseline to follow-up	Probability of benefit with CSR *vs* placebo
SAQ angina frequency (baseline median 40·0)					
CSR	24	22·7 (10·6 to 34·6)	62·7 (50·6 to 74·6)	16·0 (5·1 to 27·3)	99·7%
Placebo	26	6·5 (−3·5 to 16·6)	46·5 (36·5 to 56·6)	..	..
SAQ physical limitation (baseline median 44·4)					
CSR	24	10·2 (−0·3 to 21·1)	54·6 (44·1 to 65·5)	4·9 (−5·3 to 15·0)	83·3%
Placebo	26	5·3 (−3·0 to 13·8)	49·7 (41·4 to 58·2)	..	..
SAQ angina stability (baseline median 25·0)					
CSR	24	29·4 (15·4 to 43·2)	54·4 (40·4 to 68·2)	9·2 (−7·0 to 24·7)	86·8%
Placebo	26	20·2 (8·1 to 32·4)	45·2 (33·1 to 57·4)	..	..
SAQ quality of life (baseline median 33·3)					
CSR	24	14·1 (2·1 to 26·2)	47·4 (35·5 to 59·6)	6·1 (−6·1 to 18·5)	83·5%
Placebo	26	7·9 (−1·4 to 18·0)	41·2 (31·9 to 51·4)	..	..
SAQ treatment satisfaction (baseline median 75·0)					
CSR	24	0·6 (−10·3 to 10·1)	75·6 (64·7 to 85·1)	5·7 (−4·2 to 16·2)	86·8%
Placebo	26	−5·0 (−16·7 to 5·0)	69·9 (58·4 to 80·0)	..	..
Treadmill exercise time, s (baseline median 366·8)					
CSR	24	61·4 (−18·1 to 141·8)	428·2 (348·6 to 508·6)	40·7 (−36·1 to 120·2)	84·8%
Placebo	26	20·4 (−58·6 to 104·3)	387·1 (308·2 to 471·1)	..	..
Canadian Cardiovascular Society class (baseline median 3·0)					
CSR	24	−0·8 (−1·1 to −0·4)	2·3 (1·9 to 2·6)	−0·3 (−0·7 to 0·1)	92·3%
Placebo	26	−0·4 (−0·8 to −0·1)	2·6 (2·2 to 2·9)	..	..
EQ-5D-5L index value (baseline median 0·6)					
CSR	24	0·0 (−0·1 to 0·1)	0·6 (0·5 to 0·7)	−0·0 (−0·1 to 0·1)	42·0%
Placebo	26	0·0 (−0·1 to 0·1)	0·6 (0·5 to 0·7)	..	..
EuroQol visual analogue scale (baseline median 55·0)					
CSR	24	4·4 (−4·1 to 12·4)	59·4 (51·0 to 67·4)	7·3 (−2·0 to 17·2)	93·3%
Placebo	26	−3·1 (−12·5 to 5·8)	52·0 (42·5 to 60·8)	..	..
MacNew Heart Disease Health-Related Quality of Life questionnaire (baseline median 3·8)					
CSR	24	0·5 (−0·0 to 1·0)	4·3 (3·8 to 4·8)	0·6 (0·2 to 1·1)	99·4%
Placebo	26	−0·1 (−0·6 to 0·3)	3·7 (3·3 to 4·1)	..	..

Reducer: Evidencia sobre su seguridad

Safety, Efficacy, and Effectiveness of Coronary Sinus Reducer Implantation in Refractory Angina

A Meta-Analysis

JACC Cardiovasc Interv. 2025;18:1864–1877

Included Studies

- 13 unblinded single-arm studies (n = 668)
- 3 double-blind randomized placebo-controlled trials (n = 180)

Safety

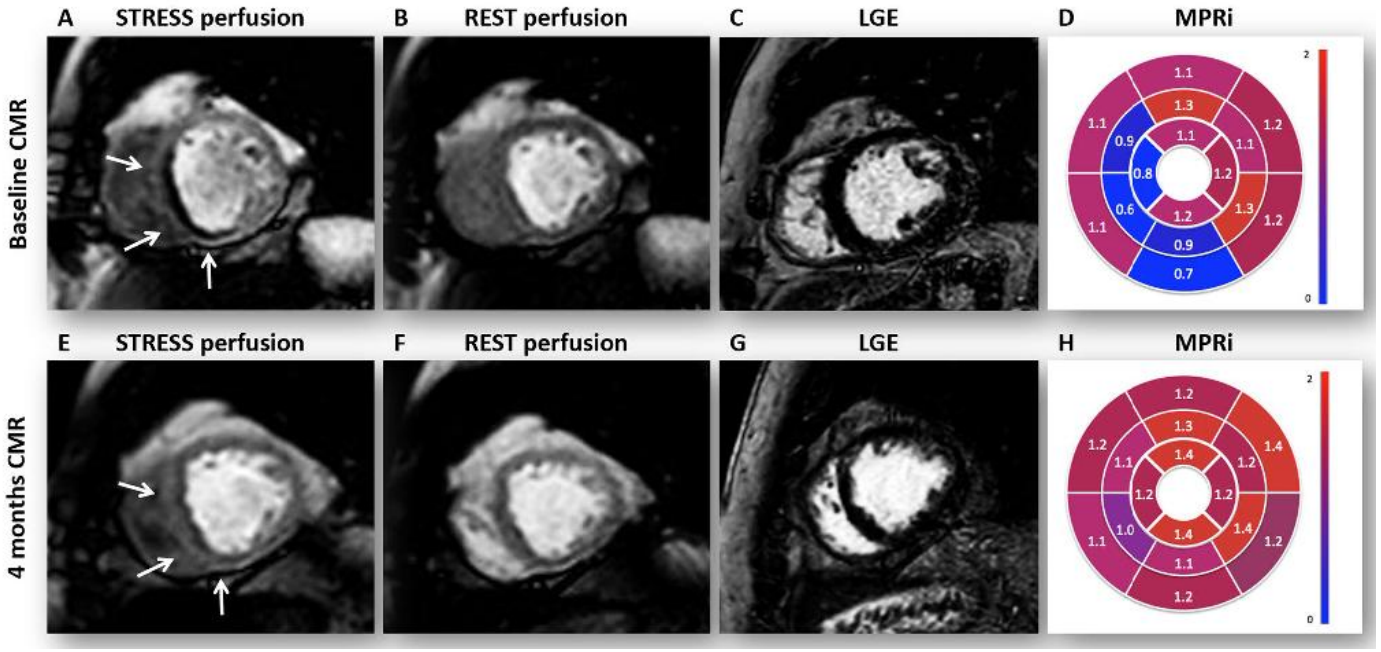
- Implantation success rate (unweighted average) was 98.8% in single-arm studies (95% CI: 97.7%-99.5%), 93.5% in RCTs (95% CI: 85.5%-97.9%), and 98.3% overall (95% CI: 97.0%-99.1%).
- Periprocedural adverse events were infrequent. Device migration had the highest overall unweighted average rate at 1.5% (95% CI: 0.8%-2.7%).

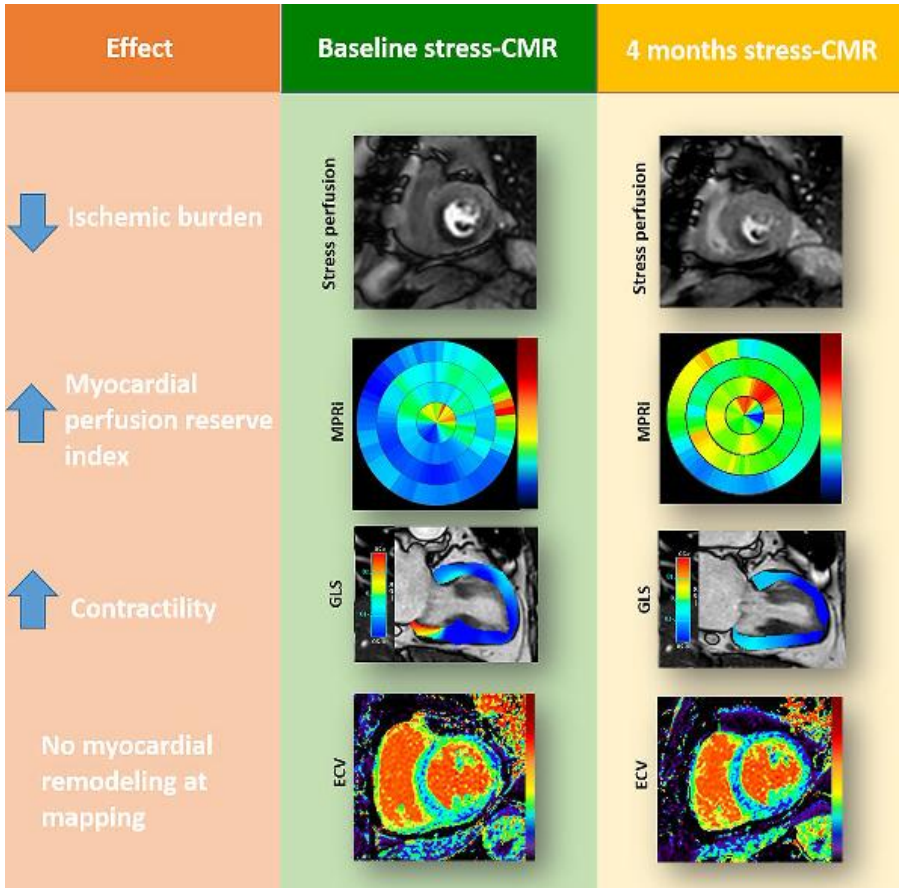
Outcome	Source	Studies included	Total Patients Evaluated	Total Events	Unweighted Event Rate, % (95% CI)
Successful CSR implantation	Single-arm studies	13	668	660	98.8 (97.7-99.5)
	RCTs	2	77	72	93.5 (85.5-97.9)
	Overall	15	745	732	98.3 (97.0-99.1)
Death	Single-arm studies	12	646	0	0.0 (0.0-0.6)
	RCT intervention arms	2	77	0	0.0 (0.0-4.7)
	RCT control arms		78	0	0.0 (0.0-4.6)
ACS	Single-arm studies	10	610	1	0.2 (0.0-0.9)
	RCT intervention arms	2	77	2	2.6 (0.3-9.1)
	RCT control arms		78	1	1.3 (0.0-6.9)
Stroke	Single-arm studies	9	423	0	0.0 (0.0-0.9)
	RCT intervention arms	2	77	0	0.0 (0.0-4.7)
	RCT control arms		78	0	0.0 (0.0-4.6)
Cardiac tamponade	Single-arm studies	10	458	1	0.2 (0.0-1.2)
	RCT intervention arms	2	77	0	0.0 (0.0-4.7)
	RCT control arms		78	0	0.0 (0.0-4.6)
CSR dislocation	Single-arm studies	11	638	7	1.1 (0.4-2.2)
	RCTs	2	77	0	0.0 (0.0-4.7)
CSR embolization	Single-arm studies	11	638	2	0.3 (0.0-1.1)
	RCTs	2	77	2	2.6 (0.3-9.1)
CS perforation or dissection	Single-arm studies	11	638	7	1.1 (0.4-2.2)
	RCT intervention arms	2	77	0	0.0 (0.0-4.7)
	RCT control arms		78	0	0.0 (0.0-4.6)

Efecto sobre la perfusión miocárdica

Feature tracking and mapping analysis of myocardial response to improved perfusion reserve in patients with refractory angina treated by coronary sinus Reducer implantation: a CMR study

The International Journal of Cardiovascular Imaging
https://doi.org/10.1007/s10554-020-01964-9



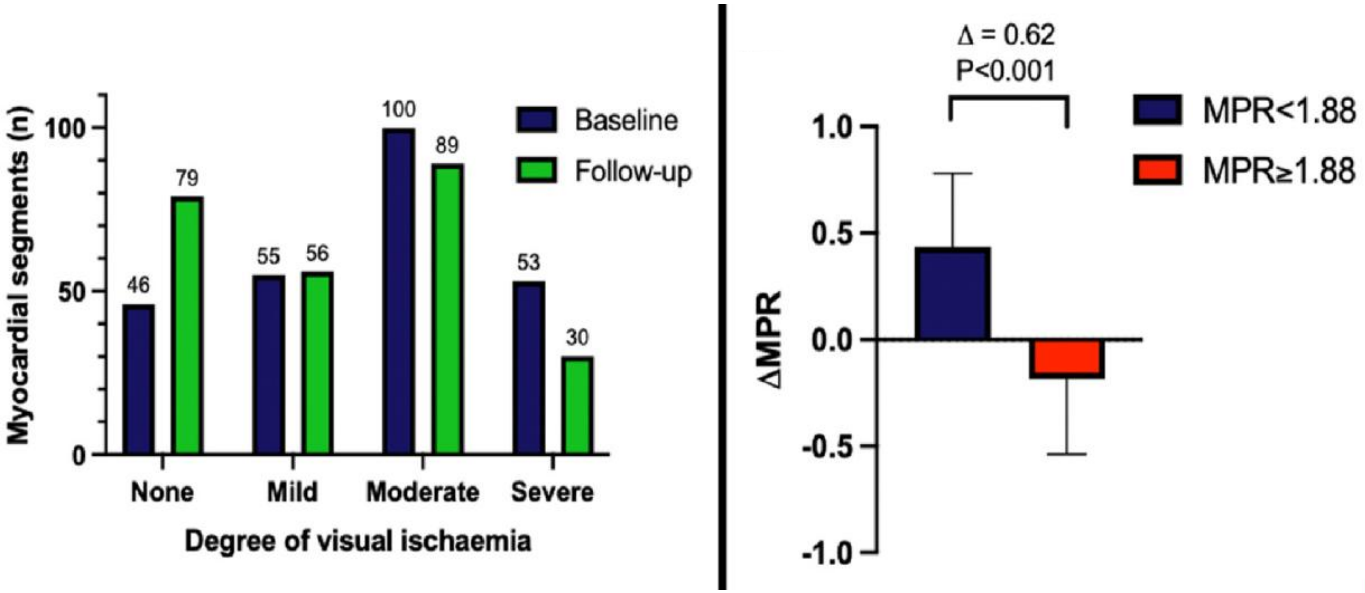


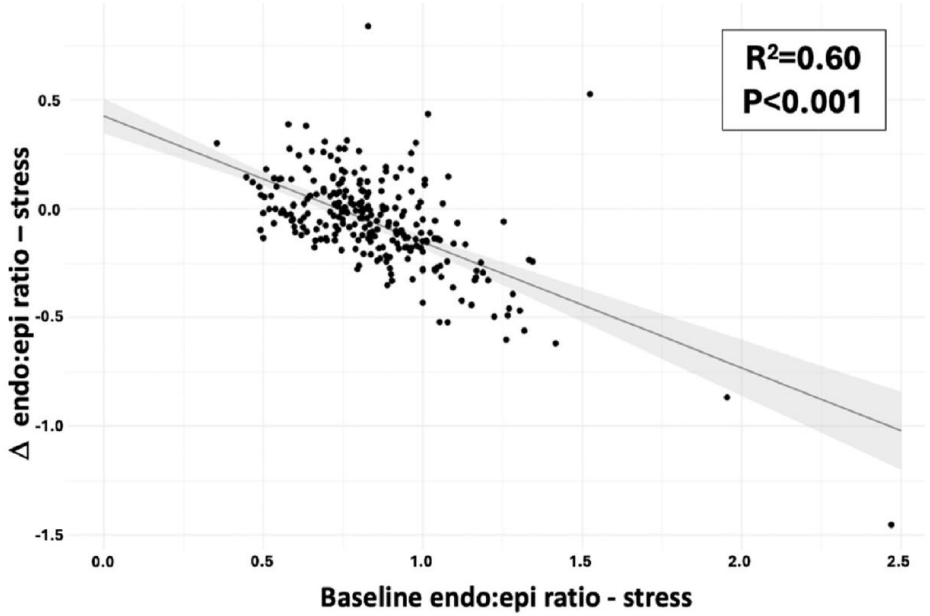
MPRi endo/epi ratio did not change significantly in segments without ischemia (from 0.90 to 0.91; p = 0.0773), while increased significantly in the segments with subendocardial defects (from 0.80 to 0.87; p = 0.0173) as well as in the segments with transmural defects (from 0.67 to 0.96; p = 0.0107), suggesting a recovery of transmural perfusion balance in ischemic segments.

Efecto sobre la perfusión miocárdica

Segmental redistribution of myocardial blood flow after coronary sinus reducer implantation demonstrated by quantitative perfusion cardiovascular magnetic resonance

Journal of Cardiovascular Magnetic Resonance 27 (2025) 101868





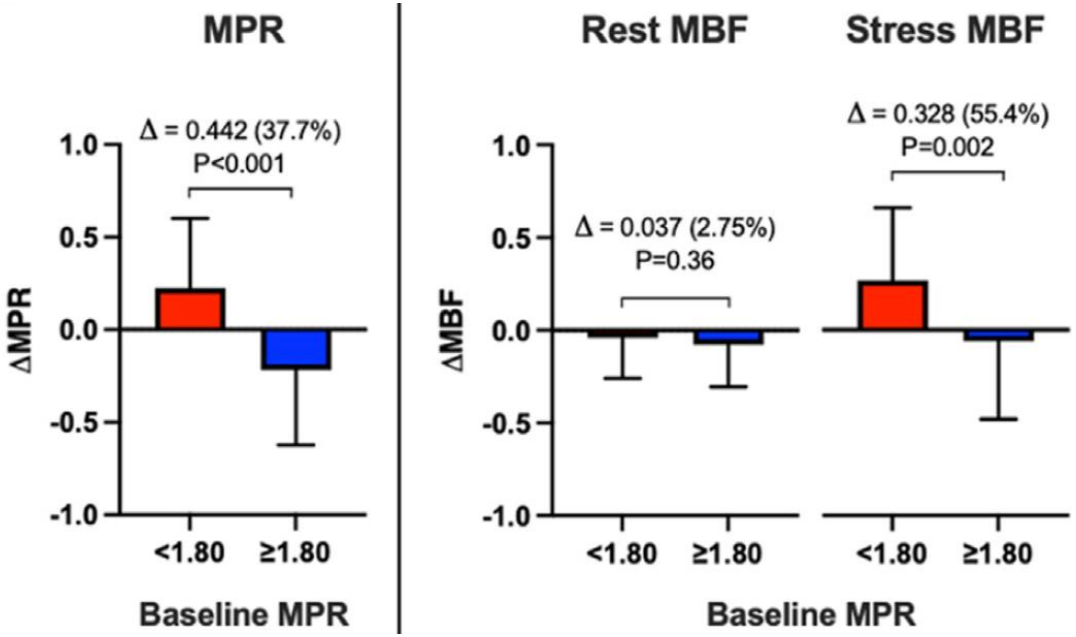
We did not observe changes in global MPR, global stress, or global rest MBF after CSR implantation, similar to previous studies [2,9], but the segmental analysis showed increases in the quantitative perfusion metrics in those segments most hypoperfused at baseline.

In this observational pilot study, redistribution of myocardial perfusion was observed from better to less well-perfused myocardial segments, an effect which was differentially observed across transmural myocardial layers. Changes in $RATIO_{STRESS}$ were dependent on baseline $RATIO_{STRESS}$ suggesting greater redistribution toward the endocardium in the most ischemic myocardium as an effect of CSR implantation

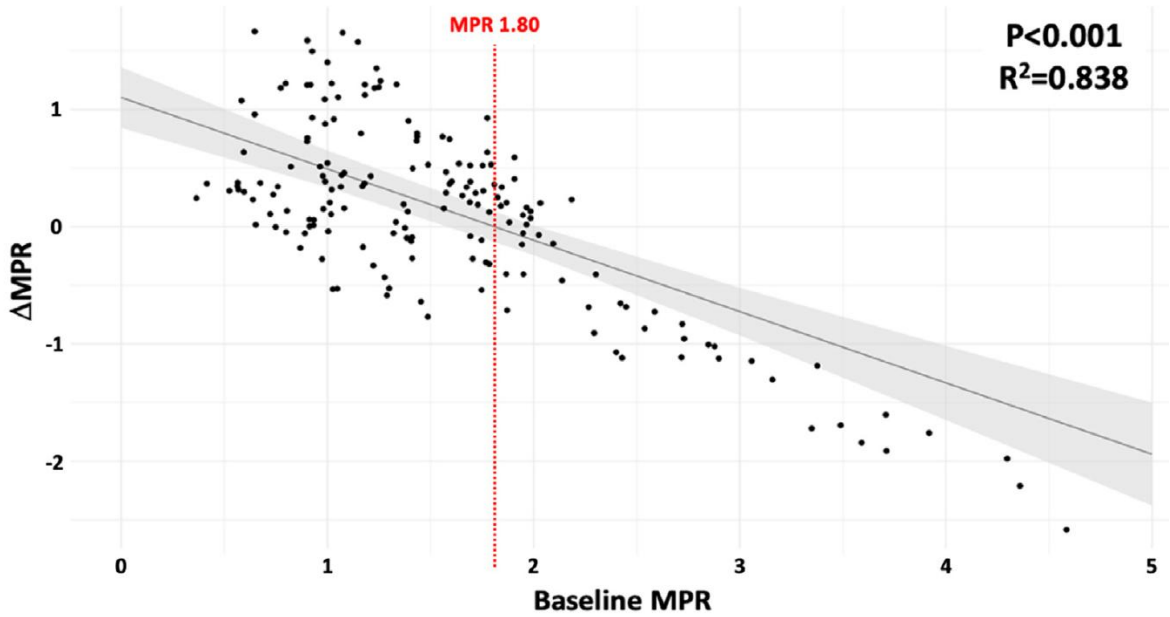
Efecto sobre la perfusión miocárdica

Redistribution of myocardial perfusion after coronary sinus reducer implantation demonstrated by rubidium-82 positron emission tomography

Journal of Nuclear Cardiology (2024) 33, 101803



Mean ΔMPR increased (+0.225) in segments with baseline MPR<1.80 (n = 120) but decreased (−0.217) in segments with baseline MPR≥1.80



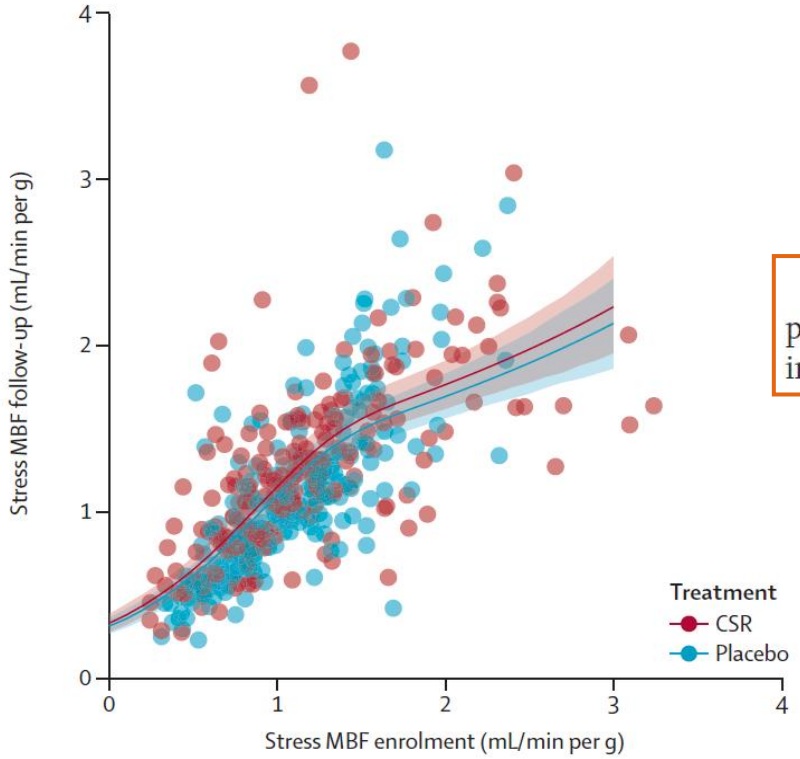
At the patient level, there was no change in global MBF_{REST} ($P = 0.39$), MBF_{STRESS} ($P > 0.99$) or MPR ($P = 0.41$).

Efecto sobre la perfusión miocárdica

Coronary sinus reducer for the treatment of refractory angina (ORBITA-COSMIC): a randomised, placebo-controlled trial

Lancet 2024; 403: 1543–53

Primary endpoint: stress MBF in segments designated ischaemic at enrolment



The original protocol specified myocardial perfusion reserve as the primary outcome, the primary outcome was changed from ratio of myocardial blood flow at stress to myocardial blood flow at rest, to myocardial blood flow at stress only.

For the primary study outcome, no benefit of CSR over placebo was detected in stress myocardial blood flow in segments designated ischaemic at enrolment

In ischaemic segments, the endocardial to epicardial ratio of stress myocardial blood flow improved in the CSR group (0·09 [95% CrI 0·00 to 0·17]; Pr(Benefit)=98·2%), and we found evidence of a difference in this effect between ischaemic and non-ischaemic segments

Se demuestra una mejoría en la perfusión subendocárdica en las áreas isquémicas

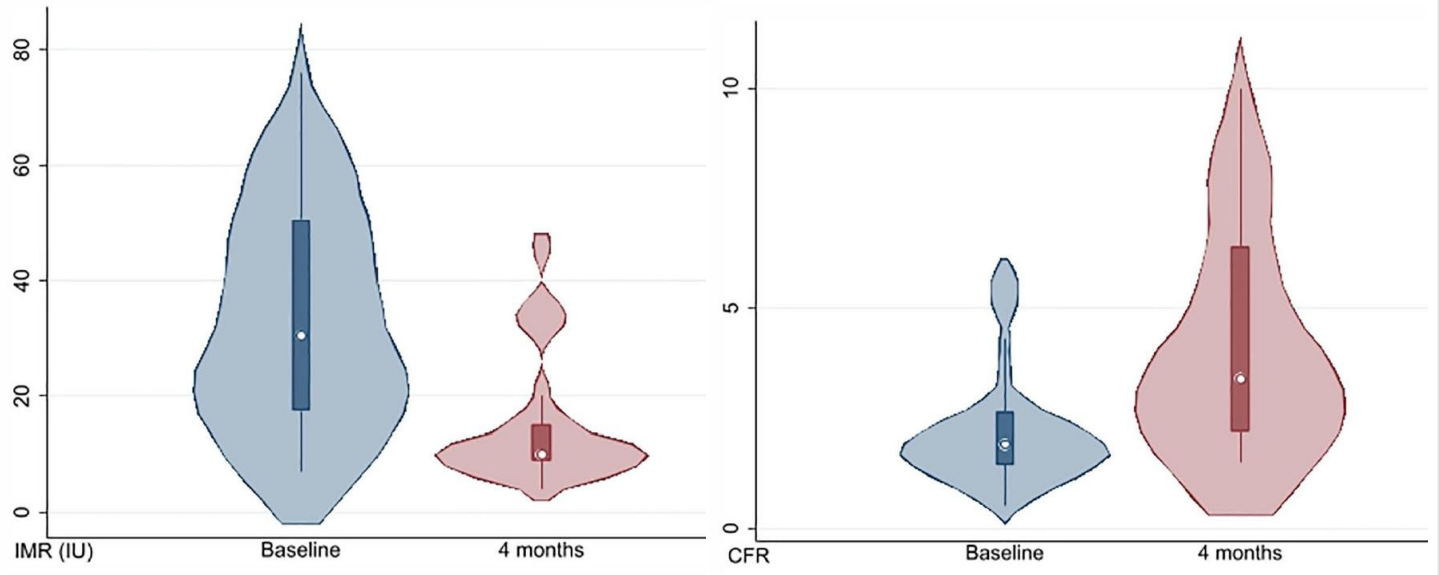
	Difference at 6-month follow-up for CSR *vs* placebo	Probability of benefit with CSR *vs* placebo*
Quantitative perfusion, stress MBF, mL/min per g		
In ischaemic segments, mL/min per g (primary outcome)	0·06 (–0·09 to 0·20)	78·8%
In non-ischaemic segments, mL/min per g	–0·00 (–0·14 to 0·13)	48·7%
Difference between ischaemic and non-ischaemic segments	0·06 (–0·03 to 0·15)	90·8%
Quantitative perfusion (secondary imaging outcomes)		
Rest MBF, mL/min per g		
In ischaemic segments	0·01 (–0·05 to 0·07)	58·0%
In non-ischaemic segments	–0·01 (–0·07 to 0·05)	33·6%
Difference between ischaemic and non-ischaemic segments	0·02 (–0·01 to 0·05)	89·0%
MPR		
In ischaemic segments	0·06 (–0·17 to 0·27)	69·1%
In non-ischaemic segments	0·06 (–0·15 to 0·27)	72·7%
Difference between ischaemic and non-ischaemic segments	–0·01 (–0·13 to 0·12)	44·1%
Quantitative perfusion, endocardial to epicardial ratio (secondary imaging outcomes)		
Endocardial to epicardial ratio of stress MBF		
In ischaemic segments	0·09 (0·00 to 0·17)	98·2%
In non-ischaemic segments	–0·02 (–0·10 to 0·07)	35·1%
Difference between ischaemic and non-ischaemic segments	0·10 (0·02 to 0·19)	99·2%
Endocardial to epicardial ratio of rest MBF		
In ischaemic segments	0·03 (–0·04 to 0·10)	81·6%
In non-ischaemic segments	0·10 (0·03 to 0·17)	99·7%
Difference between ischaemic and non-ischaemic segments	–0·07 (–0·13 to –0·01)	1·8%
Endocardial to epicardial ratio of MPR		
In ischaemic segments	0·07 (–0·11 to 0·24)	77·2%
In non-ischaemic segments	–0·13 (–0·33 to 0·06)	8·3%
Difference between ischaemic and non-ischaemic segments	0·20 (0·02 to 0·37)	98·9%

Efecto sobre la función microvascular

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

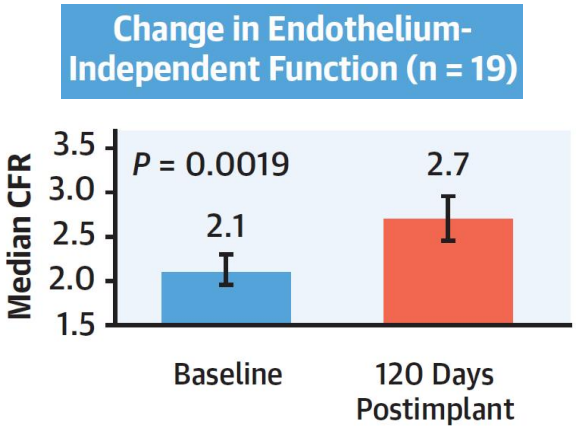
Circ Cardiovasc Interv. 2024;17:e013481

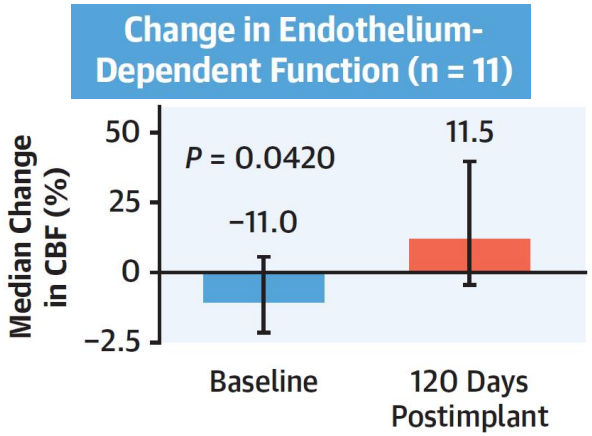
The main findings are as follows. First, reducer implantation was associated with a significant improvement of coronary microvascular function, as shown by decrease in IMR values and increase in CFR and RRR values. Second, a consequent improvement in CCS angina class and in the SAQ questionnaire was observed.



Coronary Sinus Reducer Improves Angina, Quality of Life, and Coronary Flow Reserve in Microvascular Dysfunction

JACC Cardiovasc Interv. 2024;17:2893-2904

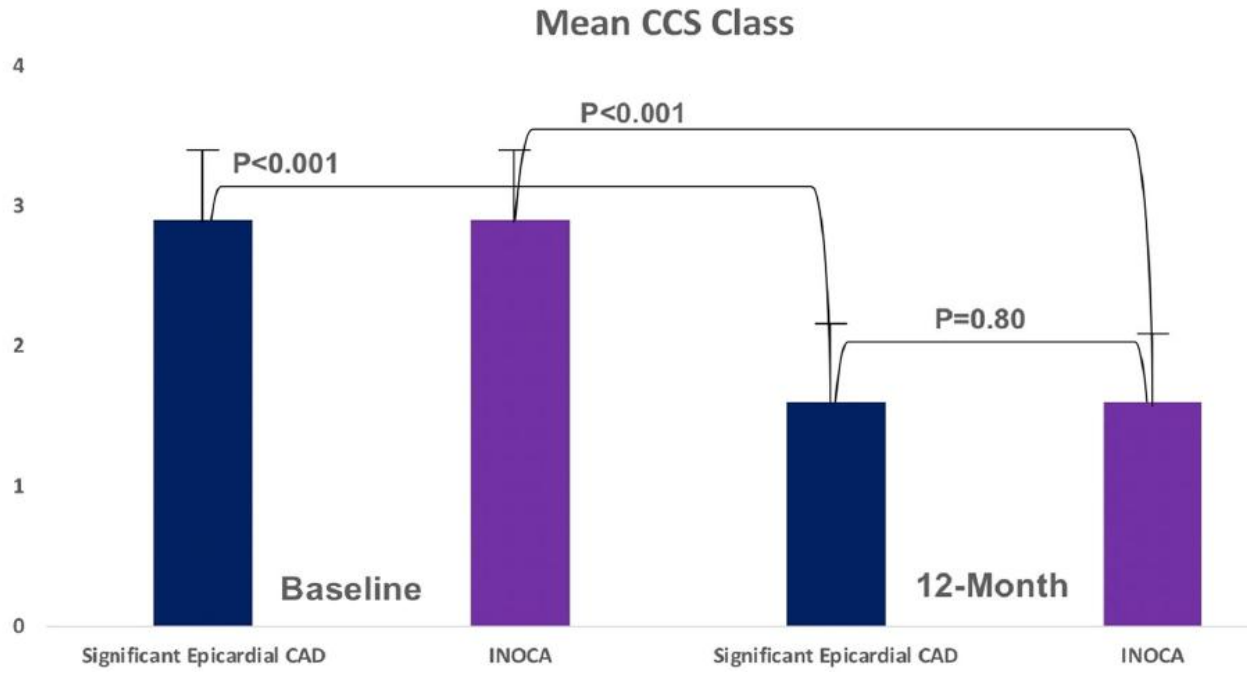


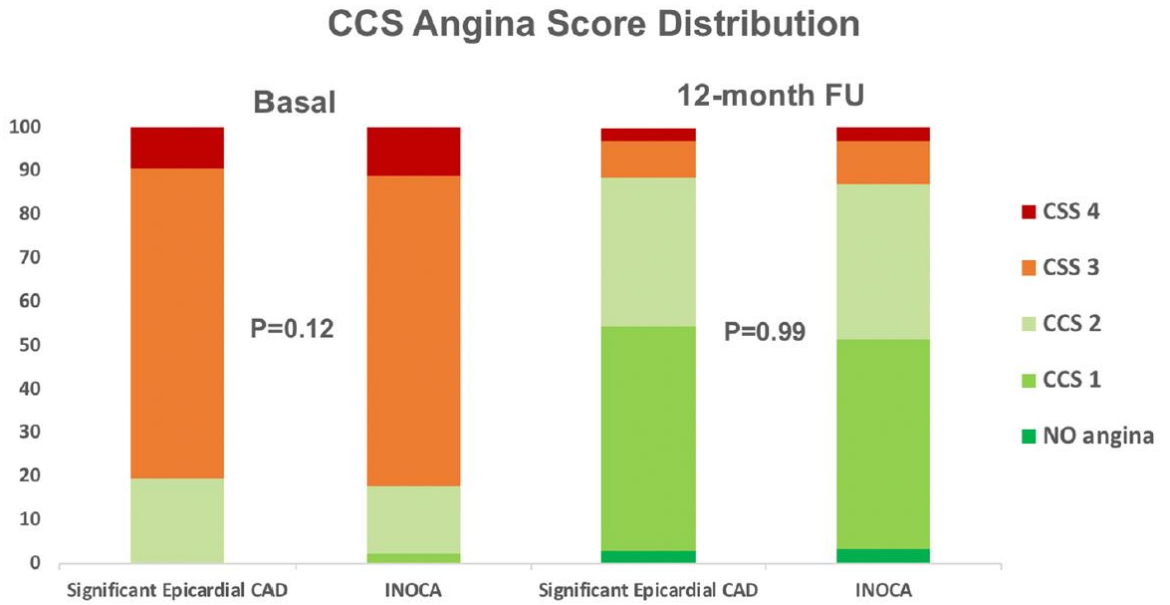


Efecto sobre la función microvascular

Impact of Coronary Sinus Reducer on Angina Symptoms in Patients With Myocardial Ischemia Without Obstructive Coronary Artery Disease

Catheterization and Cardiovascular Interventions, 2025; 1–8





Estudios en marcha: REMEDY-PILOT, COSIMA…

Conclusiones

- ✓ La evidencia sobre eficacia del Reducer en mejoría de la angina es amplia, con resultados concordantes en diferentes estudios aleatorizados y registros multicéntricos
- ✓ Es un procedimiento sencillo y seguro
- ✓ Estudios mediante RM y PET confirman una redistribución del flujo miocárdico con mejoría de la perfusión de las áreas isquémicas, especialmente en la región subendocárdica
- ✓ Datos preliminares revelan la misma eficacia clínica en ANOCA que en enfermedad coronaria epicárdica y confirman mejoría de los parámetros de función microvascular

CSC 2025
CORONARY AND STRUCTURAL CONGRESS
CONGRESO CORONARIO Y ESTRUCTURAL
MADRID

5, 6 y 7 NOVIEMBRE
HOTEL RIU PLAZA DE ESPAÑA

Reducer: Situación actual

2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes

Recommendations for treatment options for refractory angina

Recommendations	Class[a]	Level[b]
Enhanced external counterpulsation may be considered for symptom relief in patients with debilitating angina refractory to optimal medical and revascularization strategies.[524]	IIb	B
A reducer device for coronary sinus constriction may be considered to ameliorate symptoms of debilitating angina refractory to optimal medical and revascularization strategies.[525]	IIb	B
Spinal cord stimulation may be considered to ameliorate symptoms and quality of life in patients with debilitating angina refractory to optimal medical and revascularization strategies.[526]	IIb	B
Transmyocardial revascularization is not recommended in patients with debilitating angina refractory to optimal medical and revascularization strategies.[529]	III	A

Situaciones clínicas habituales en pacientes con angina refractaria:

- Enfermedad coronaria severa difusa, lechos distales de escaso calibre
- Revascularización quirúrgica previa, con injertos degenerados/ocluidos, sin opción de ICP
- ICP previa múltiple, oclusiones crónicas no aptas para ICP, restenosis intrastent recurrentes…
- ANOCA muy sintomática a pesar de tratamiento médico optimizado (fisiología coronaria)