La Diabetes y el Deterioro de la FVI condicionan la selección del tratamiento de revascularización?

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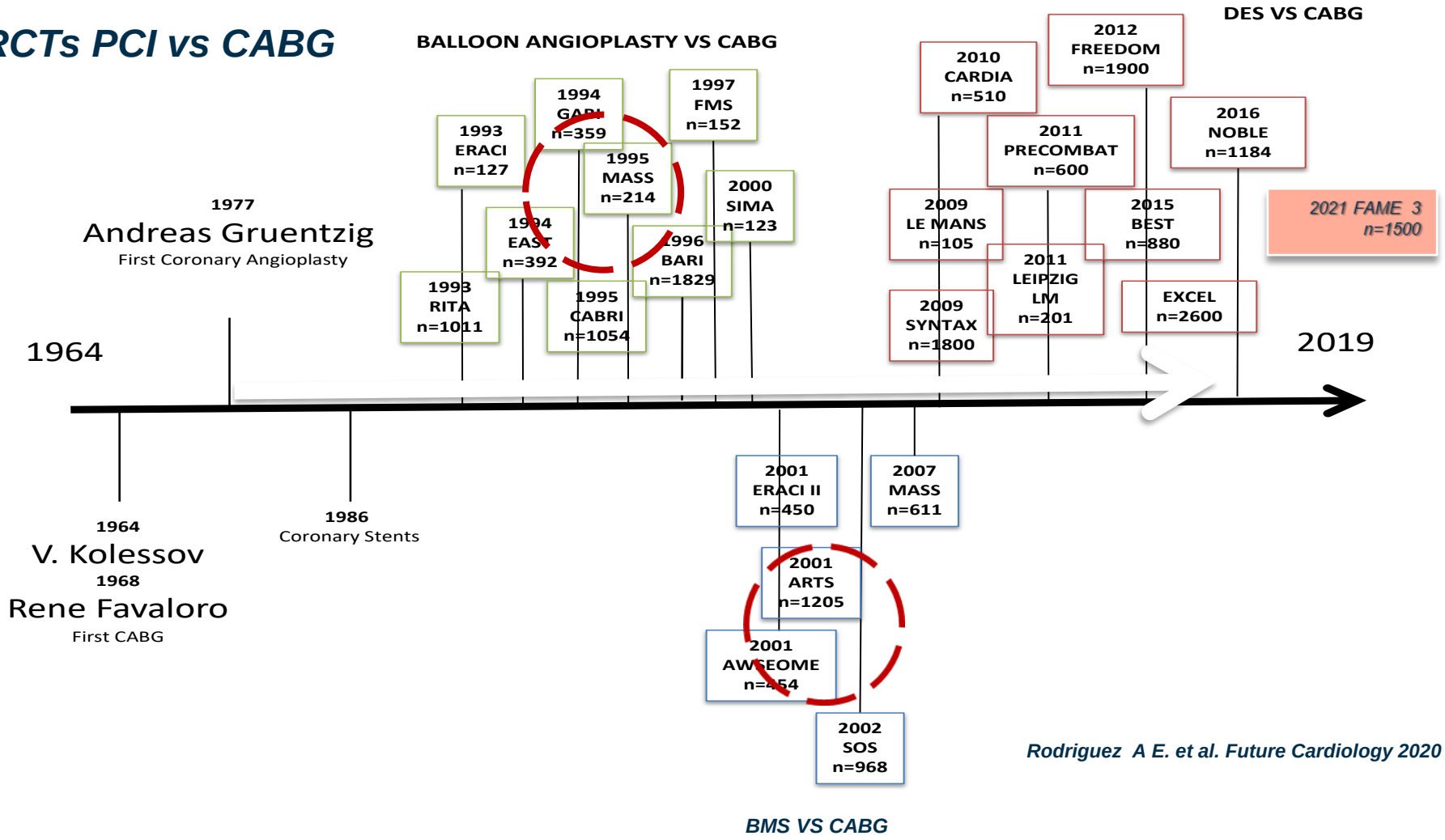
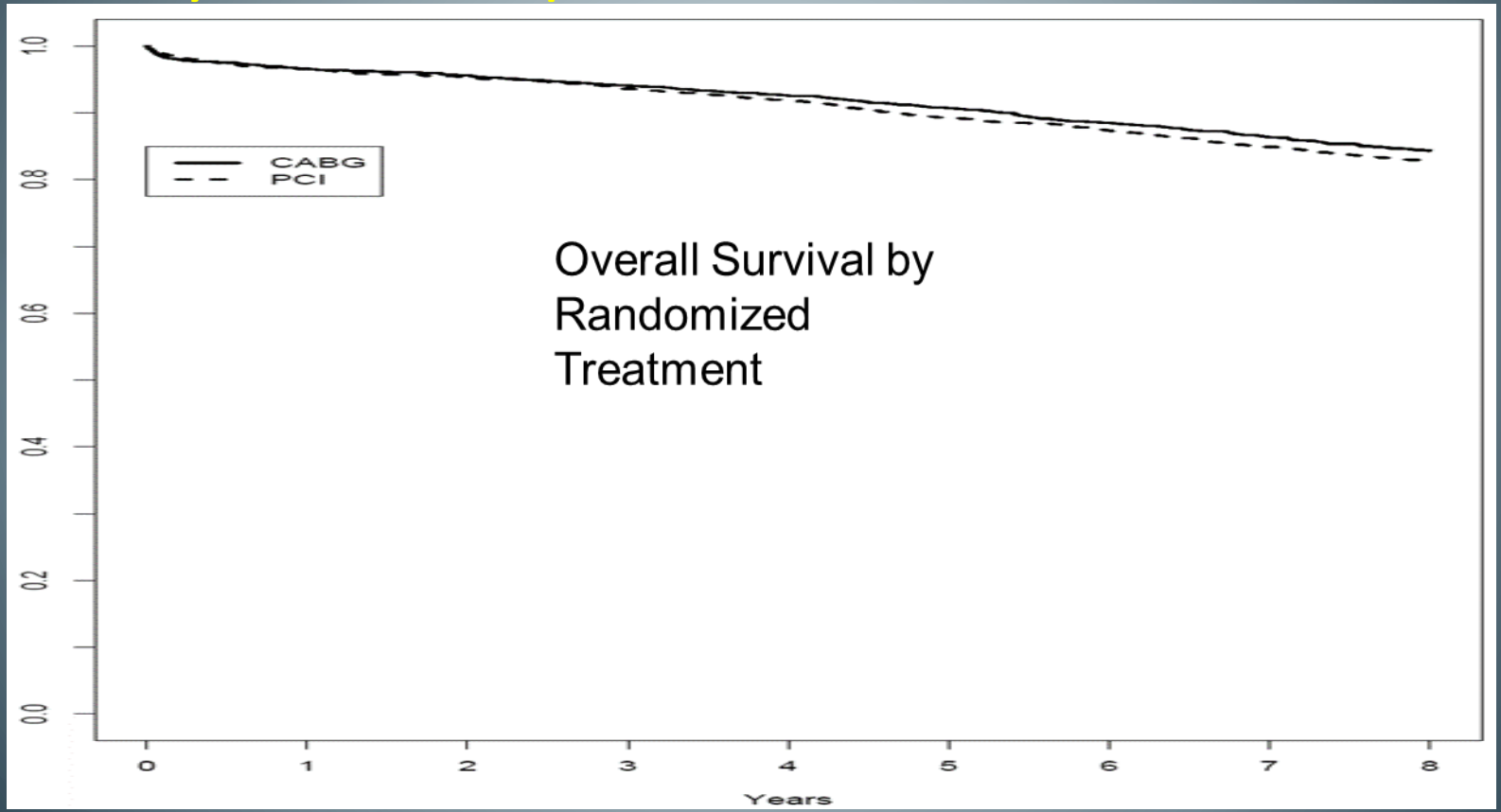
Editor Asociado JSCAI
Academic Editor Academia Medicine Journal

RCTs PCI vs CABG

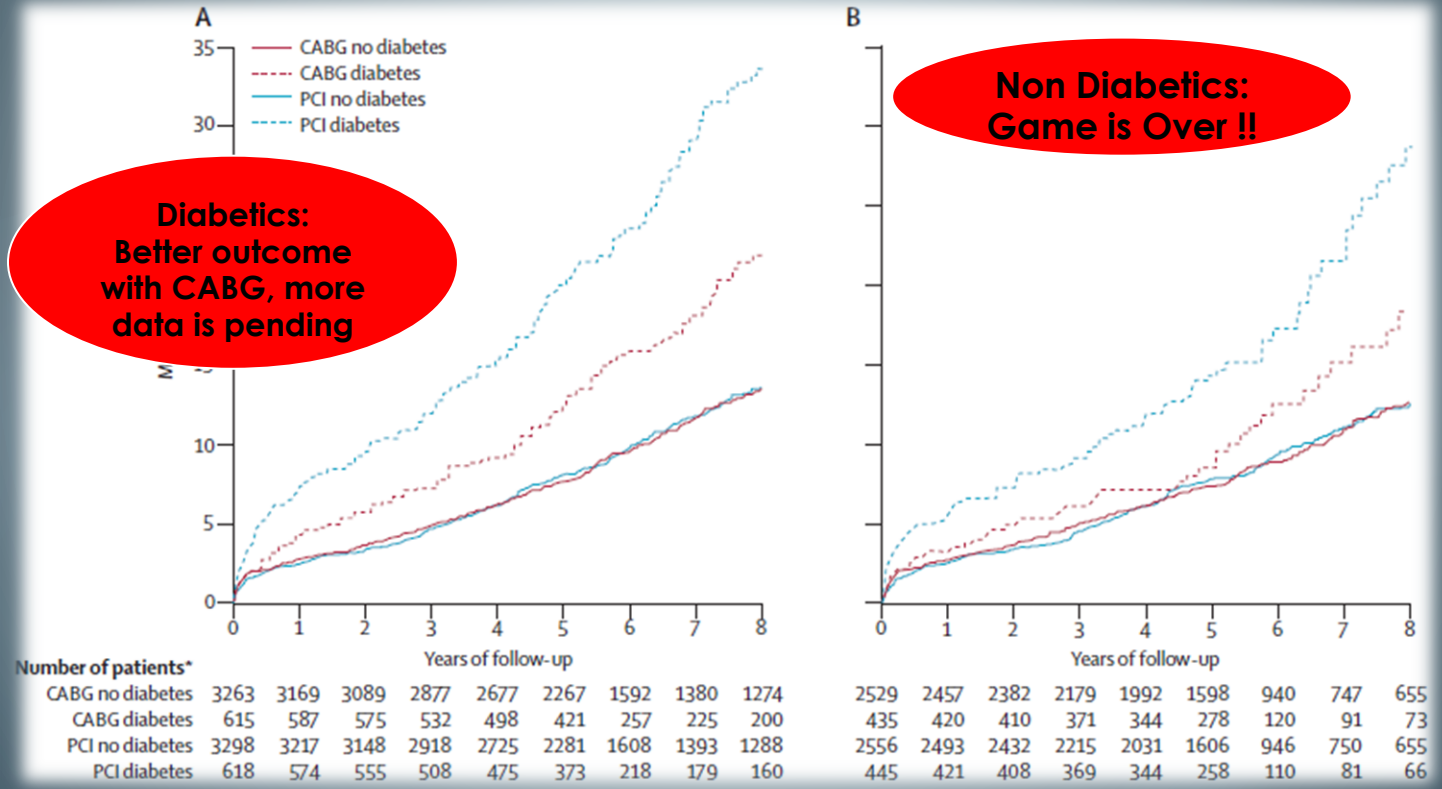


Rodriguez A E. et al. Future Cardiology 2020

Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials

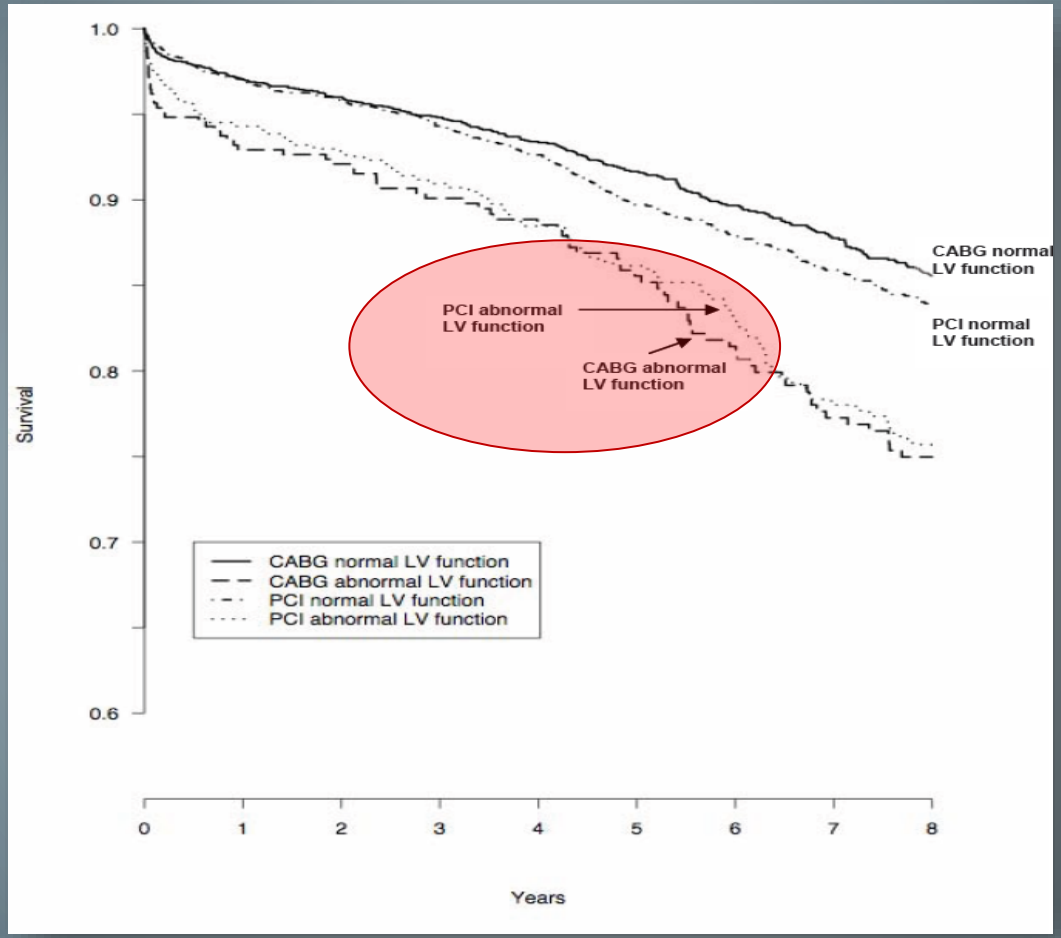


Death among patients. Diabetes and group allocation



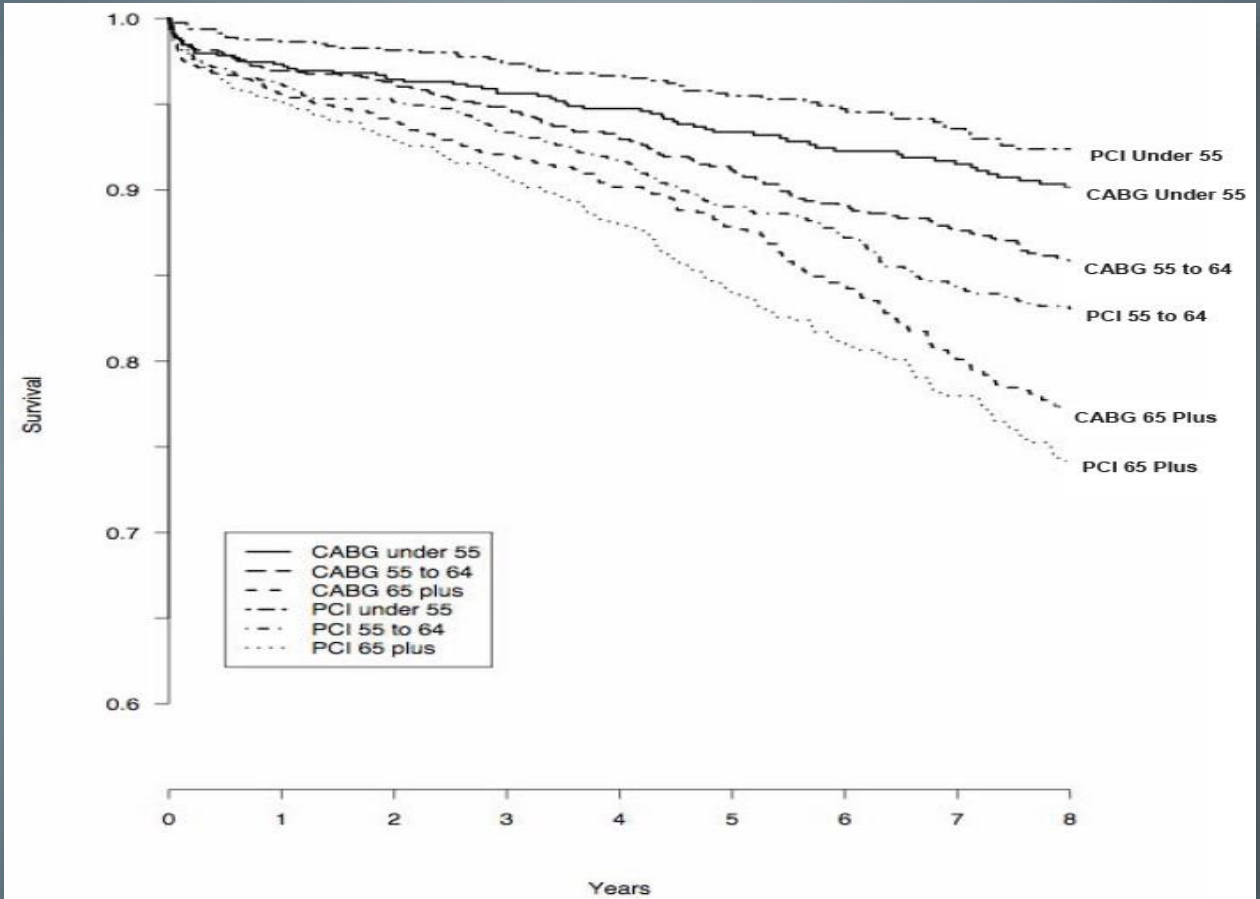
Hlatky MA et al. Lancet. 2009 Apr 4;373(9670):1190-7.

Survival by Treatment and Left Ventricular Function



Hlatky MA et al. Lancet. 2009 Apr 4;373(9670):1190-7.

Survival by Treatment and Age Group



Hlatky MA et al. Lancet. 2009 Apr 4;373(9670):1190-7.

The Effect of Age on Outcomes of Coronary Artery Bypass Surgery Compared With Balloon Angioplasty or Bare-Metal Stent Implantation among Patients With Multivessel Coronary Disease A Collaborative Analysis of Individual Patient Data From 10 Randomized Trials

M Flather, JW Rhee, DB Boothroyd, E Boersma, MM Brooks, D Carrié, TC Clayton, N Danchin, CW Hamm, WA Hueb, SB King, SJ Pocock, AE Rodriguez, P Serruys, U Sigwart, RH Stables, MA Hlatky

J Am Coll Cardiol 2012;60:2150–7

Age and Outcomes in Revascularization. CABG vs PCI (balloon and BMS), data from 10 RCT

Clinical Outcomes by treatment and Tertile of Age (mean FU 5.9 years)

Age Tertile	CABG % (n/N)	PCI % (n/N)	Unadjusted CABG-to-PCI HR (95% CI)*	Adjusted CABG-to-PCI HR (95% CI)
Death				
Youn	Youngest	11% (135/1,279)	8% (110/1,323)	1.24 (0.97–1.60)	1.23 (0.95–1.59)	9)
Midd					0)
Oldest	20% (261/1,301)	24% (316/1,301)	0.82 (0.70–0.97)	0.79 (0.67–0.94)
Death or MI				
Young	Youngest	19% (236/1,224)	16% (199/1,264)	1.22 (1.01–1.47)	1.22 (1.00–1.47)	7)
Middl					06)
Oldes					98)
Death, MI, or revascularization				
Youngest	27% (332/1,215)	47% (589/1,257)	0.44 (0.38–0.50)	0.23 (0.20–0.28)
Middle	29% (359/1,226)	53% (641/1,210)	0.40 (0.35–0.46)	0.21 (0.18–0.25)
Oldest	33% (387/1,176)	52% (615/1,178)	0.47 (0.41–0.53)	0.18 (0.15–0.23)

M Flather et al. J Am Coll Cardiol 2012;60:2150–7

Age and Outcomes in Revascularization. CABG vs PCI (balloon and BMS), data from 10 RCT

Rates of death by Treatment Stratified by Tertile of Age And diabetes status (mean FU 5.9 years)

Diabetes Status	Age Tertile	CABG % (n/M)	PCI % (n/M)	Unadjusted CABG-to-PCI HR (95% CI)*	p Value	Adjusted CABG-to-PCI HR (95% CI)*	p Value
No diabetes	Youngest	9% (104/1,112)	7% (77/1,147)	1.39 (1.03–1.87)	0.03	1.35 (1.00–1.83)	0.053
	Middle	12% (137/1,100)	13% (145/1,084)	0.95 (0.75–1.21)	0.69	0.97 (0.76–1.22)	0.78
Diabetes	Youngest	19% (31/163)	19% (33/173)	0.89 (0.55–1.46)	0.65	0.93 (0.55–1.55)	0.77
	Oldest	28% (70/247)	38% (89/236)	0.63 (0.46–0.87)	0.005	0.61 (0.44–0.85)	0.003

M Flather et al. J Am Coll Cardiol 2012;60:2150–7

Long-Term Outcome of PCI Versus CABG in Insulin and Non–Insulin-Treated Diabetic Patients - Results From the FREEDOM Trial

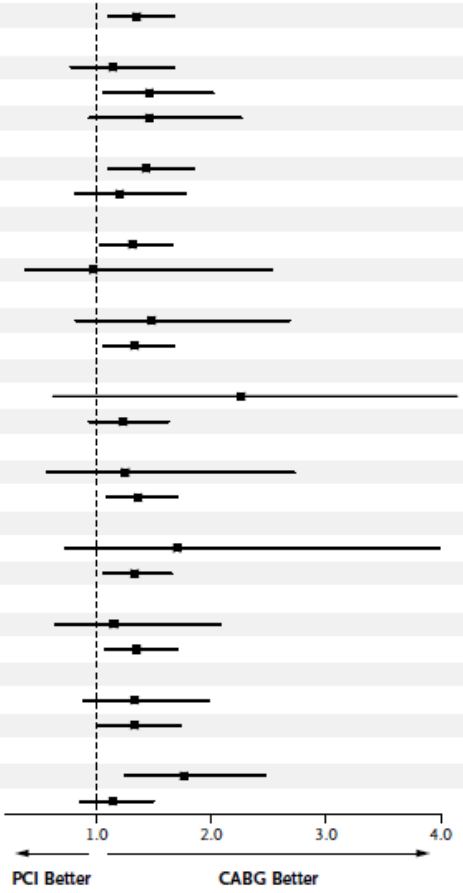
ORIGINAL INVESTIGATIONS

Long-Term Outcome of PCI Versus CABG in Insulin and Non–Insulin-Treated Diabetic Patients

Results From the FREEDOM Trial

George D. Dangas, MD, PhD,* Michael E. Farkouh, MD,* Lynn A. Sleeper, ScD,† May Yang, MPH,† Mikkel M. Schoos, MD, PhD,* Carlos Macaya, MD, PhD,‡ Alexandre Abizaid, MD, PhD,§ Christopher E. Buller, MD,‖ Gerard Devlin, MD,¶ Alfredo E. Rodriguez, MD, PhD,# Alexandra J. Lansky, MD,** F. Sandra Siami, MPH,† Michael Domanski, MD,* Valentin Fuster, MD, PhD,* for the FREEDOM Investigators

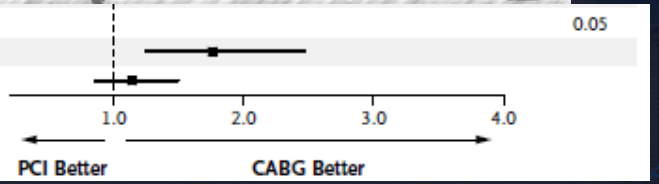
Subgroup	No.	5-Yr Rate PCI %	5-Yr Rate CABG %	P Value for Interaction
All patients	1900	27	19	
SYNTAX				0.58
≤22	669	23	17	
23–32	844	27	18	
≥33	374	31	23	
Sex				0.46
Male	1356	27	18	
Female	544	26	21	
Race				0.55
White	1452	27	19	
Black	119	24	16	
Disease type				0.75
2-Vessel disease	314	22	11	
3-Vessel disease	1573	27	20	
LVEF				0.37
<40%	32	62	31	
≥40%	1259	23	18	
LAD involvement				0.83
No	151	23	18	
Yes	1737	27	19	
History of stroke				0.57
Yes	65	59	35	
No	1835	25	18	
Renal insufficiency				0.62
Yes	129	44	37	
No	1771	25	17	
Glycated hemoglobin				0.99
<7%	630	23	16	
≥7%	1119	28	20	
Region				0.05
North America	770	28	16	
Other	1130	25	21	

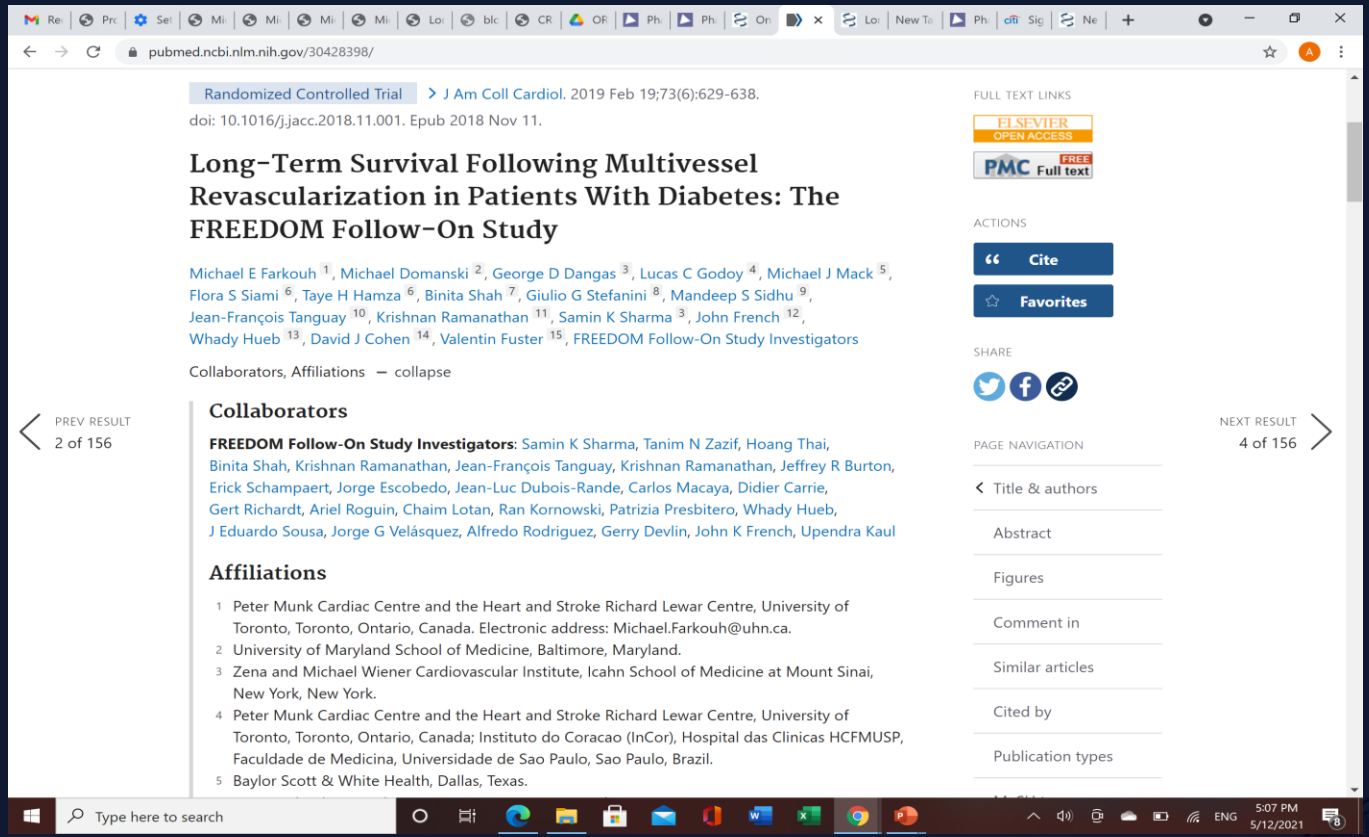


Farkouh et al. N Engl J Med 2012;367:2375-84.

NO DIFFERENCES OUTSIDE U.S.

Region			
North America	770	28	16
Other	1130	25	21





pubmed.ncbi.nlm.nih.gov/30428398/

Randomized Controlled Trial > J Am Coll Cardiol. 2019 Feb 19;73(6):629-638.
doi: 10.1016/j.jacc.2018.11.001. Epub 2018 Nov 11.

Long-Term Survival Following Multivessel Revascularization in Patients With Diabetes: The FREEDOM Follow-On Study

Michael E Farkouh [1], Michael Domanski [2], George D Dangas [3], Lucas C Godoy [4], Michael J Mack [5], Flora S Siami [6], Taye H Hamza [6], Binita Shah [7], Giulio G Stefanini [8], Mandeep S Sidhu [9], Jean-François Tanguay [10], Krishnan Ramanathan [11], Samin K Sharma [3], John French [12], Whady Hueb [13], David J Cohen [14], Valentin Fuster [15], FREEDOM Follow-On Study Investigators

Collaborators, Affiliations — collapse

Collaborators

FREEDOM Follow-On Study Investigators: Samin K Sharma, Tanim N Zazif, Hoang Thai, Binita Shah, Krishnan Ramanathan, Jean-François Tanguay, Krishnan Ramanathan, Jeffrey R Burton, Erick Schampaert, Jorge Escobedo, Jean-Luc Dubois-Rande, Carlos Macaya, Didier Carrie, Gert Richardt, Ariel Roguin, Chaim Lotan, Ran Kornowski, Patrizia Presbitero, Whady Hueb, J Eduardo Sousa, Jorge G Velásquez, Alfredo Rodriguez, Gerry Devlin, John K French, Upendra Kaul

Affiliations

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2 University of Maryland School of Medicine, Baltimore, Maryland.
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5 Baylor Scott & White Health, Dallas, Texas.

PREV RESULT 2 of 156

NEXT RESULT 4 of 156

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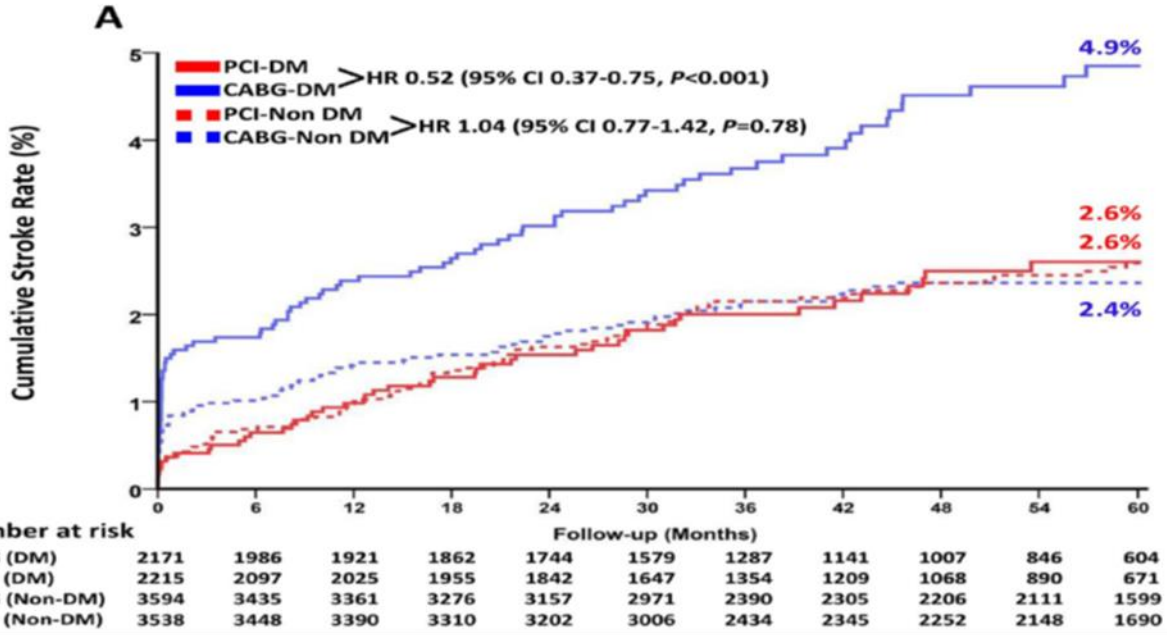
ENG 5:07 PM 5/12/2021

FIGURE 3 Subgroup Analysis of All-Cause Mortality for the Whole Cohort

Subgroup	PCI Total N	CABG Total N	PCI 8-yr Event Rate	CABG 8-yr Event Rate	Interaction p Value
Overall	953	947	24.3	18.3	
Extended follow-up					0.71
Yes	478	465	23.7	18.7	
No	475	482	32.5	12.1	
Age at randomization					0.001
≤63.3	473	477	21.4	9.4	
>63.3	480	470	27.0	27.3	
Ever Smoked					0.01
Yes	507	529	30.7	19.4	
No	446	418	17.5	17.0	
Sex					0.26
Male	698	658	23.3	15.8	
Female	255	289	26.6	24.1	
Race					0.99
White					
Black	60	59	24.3	14.2	
Hispanic					0.31
Yes	326	330	23.4	19.7	
No	627	617	25.4	17.9	
Region					0.02
North America	387	383	26.0	13.8	
Other	566	564	23.0	21.5	
SYNTAX					0.41
≤22	328	340	23.9	17.6	
23-32	438	466	25.8	17.8	
≥33	182	192	24.2	26.9	
LVEF					0.33
<40	21	11	55.6	20.0	
≥40	620	639	19.9	16.4	
Disease type					0.93
2-vessel disease	168	146	19.9	11.9	
3-vessel disease	780	793	24.7	19.7	
LAD involvement					0.43
Yes	862	875	23.4	18.6	
No	87	64	28.2	15.2	
History of stroke					0.57
Yes	37	28	38.2	26.7	
No	916	919	23.8	18.1	
Renal insufficiency					0.58
Yes	73	56	52.9	56.9	
No	880	891	22.0	16.2	
Use of insulin					0.64
Yes	322	293	33.6	28.2	
No	630	654	19.9	14.0	
Glycated hemoglobin					0.20
<7	323	307	18.7	19.4	
≥7	551	568	27.1	17.6	

FIGURES



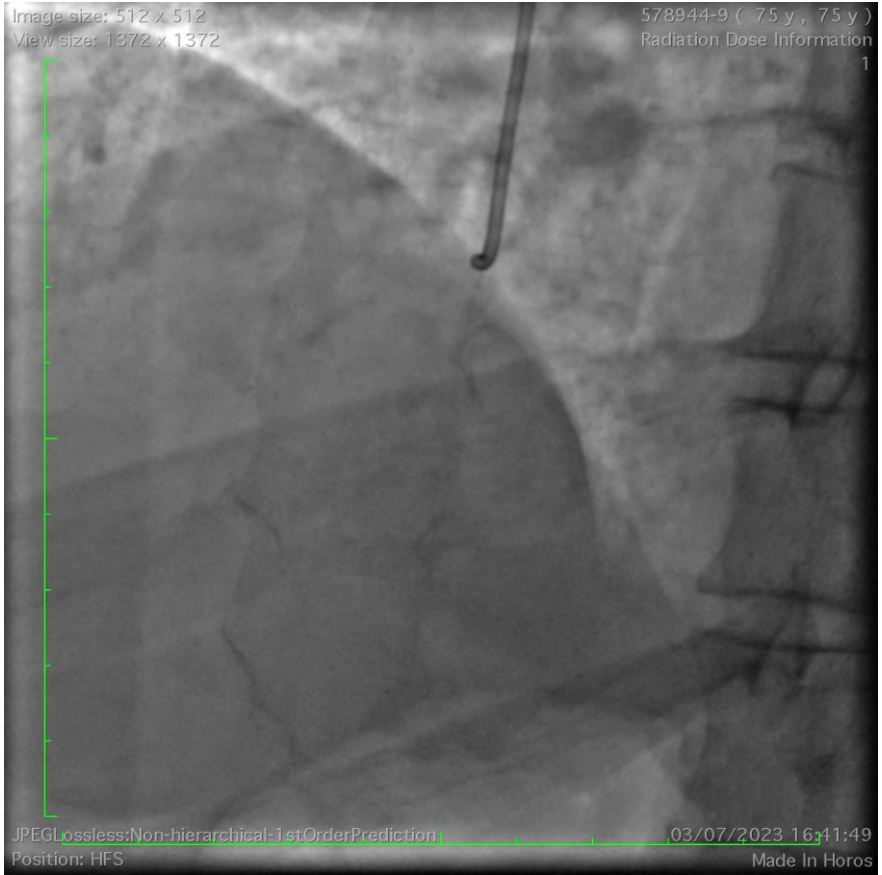
bypass grafting during 5-year follow-up *(A)* and in landmark analyses of 30-day stroke and stroke beyond 30 days *(B)*.

Masculino de 67 años

ANTECEDENTES
-DIABETICO TIPO 2
-HIPERTENSIÓN ARTERIAL

MEDICACIÓN HABITUAL
-ENALAPRIL 5 MG C/12HS
-METFORMINA 1000 MG DIA

CONCURRE A PRUEBA ERGOMÉTRICA GRADUADA DE CONTROL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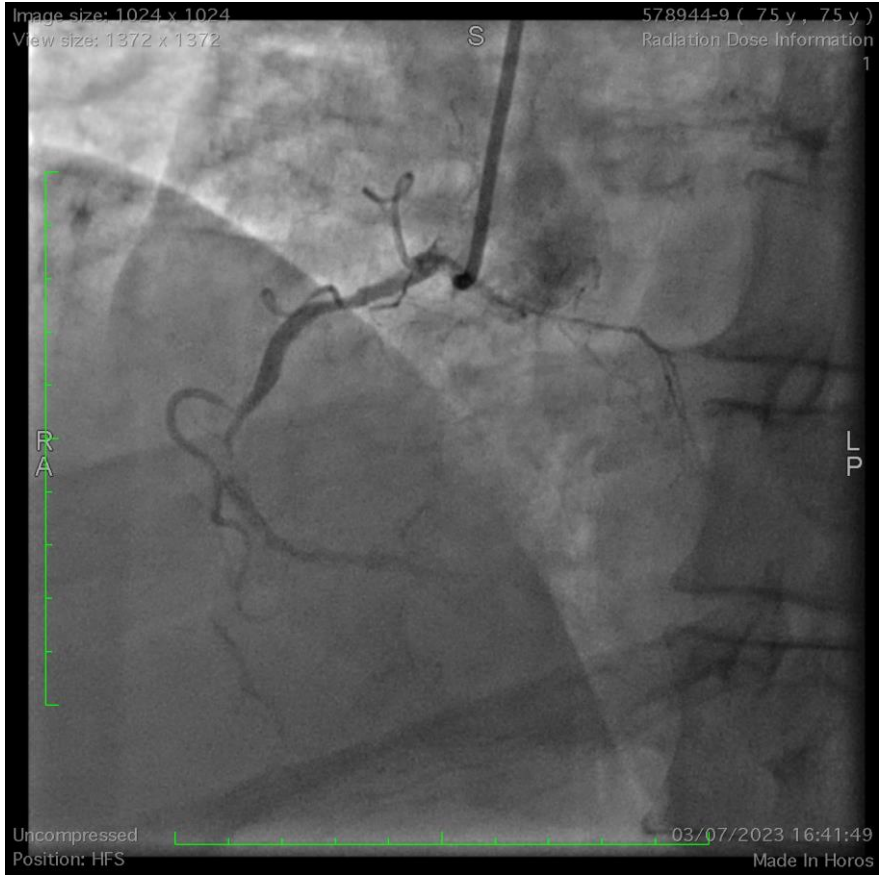
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578944-9 (75 y , 75 y)
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Position: HFS
Made In Horos


Image size: 512 x 512
View size: 1372 x 1372
578944-9 (75 y , 75 y)
Radiation Dose Information
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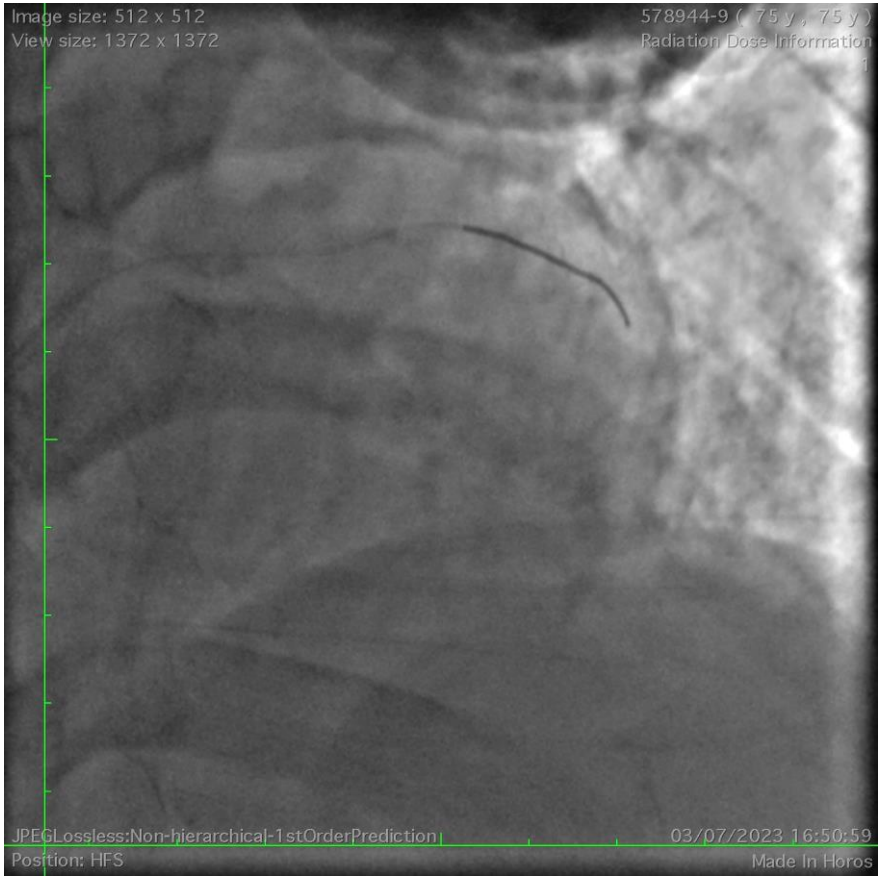
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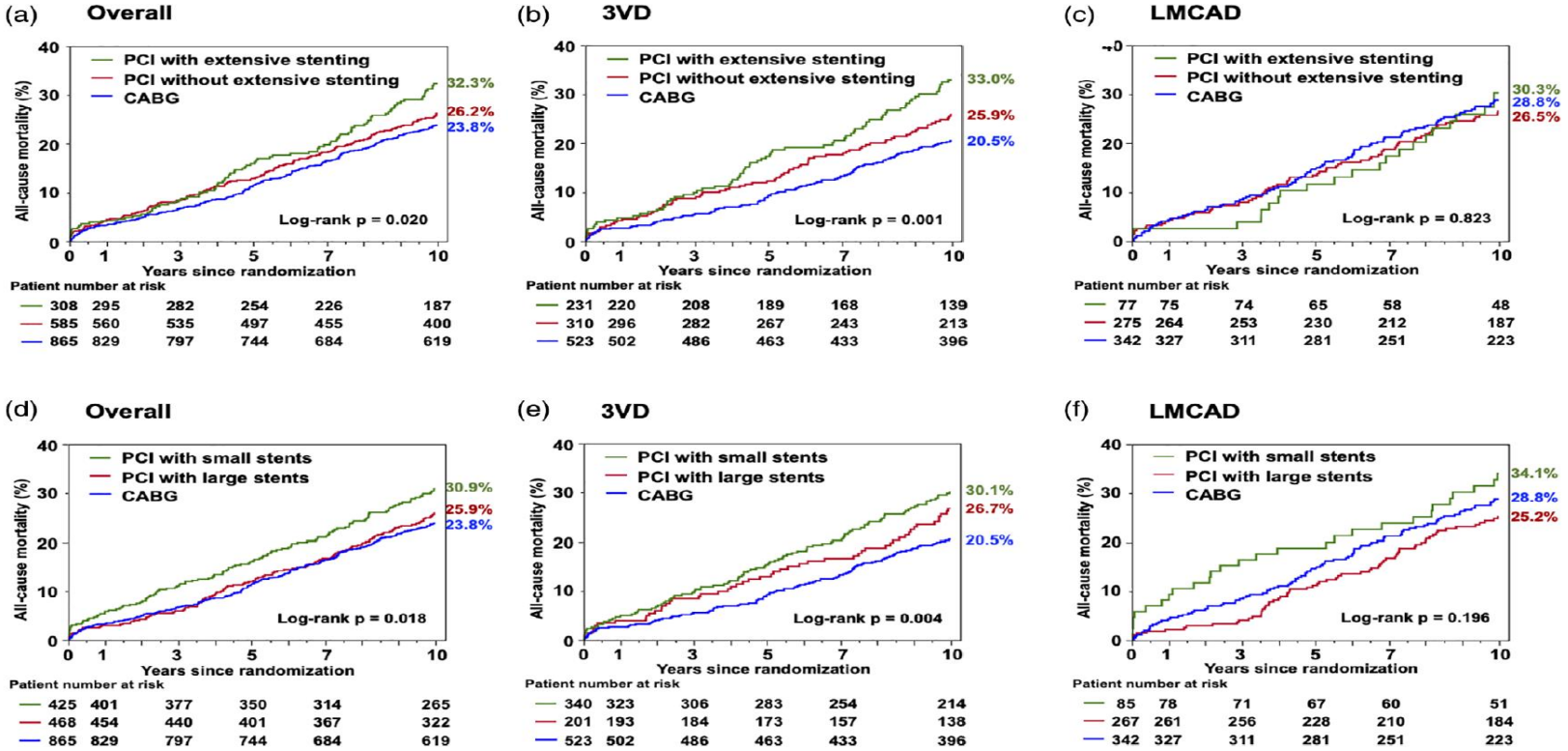


FIGURE 2 Kaplan–Meier curves for all-cause mortality at 10 years. (a–c) Mortality rates in patients with extensive stenting PCI, not-extensive stenting PCI and CABG. (a) The overall cohort. (b) Three-vessel disease (3VD) cohort. (c) Left main coronary artery disease (LMCAD) cohort. (d–f) Mortality rates in patients with small stenting PCI, large stenting PCI and CABG. (d) The overall cohort. (e) 3VD cohort. (f) LMCAD cohort. CABG, coronary artery bypass grafting surgery; PCI, percutaneous coronary intervention

HEART TEAM → **CABG**

Hombre de 59 años

ANTECEDENTES:

- Hipertensión Arterial
- Imágenes compatibles con lesiones isquémicas en RMN cerebral 2018
- Colecistectomía

MEDICACIÓN HABITUAL:

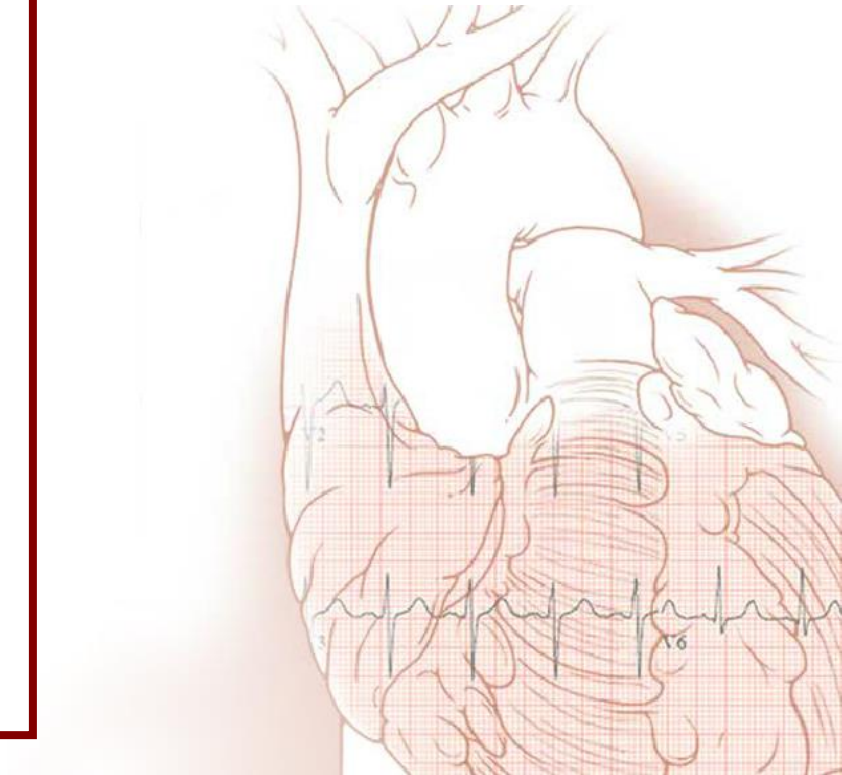
- Rosuvastatina 20 mg/día
- Aspirina 100 mg/día
- Nebivolol 5 mg/día
- Candesartan 16 mg/día
- Hidroclorotiazida 12,5 mg/día

ENFERMEDAD ACTUAL:

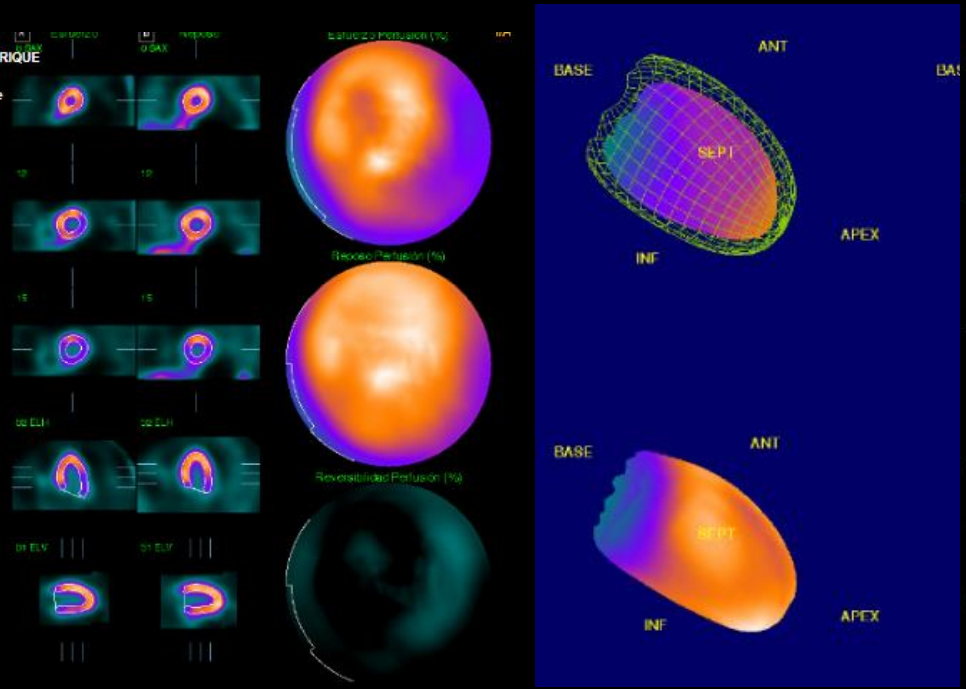
Paciente asintomático para angor o disnea ingresa de forma programada por presentar en estudio de perfusión miocárdica:

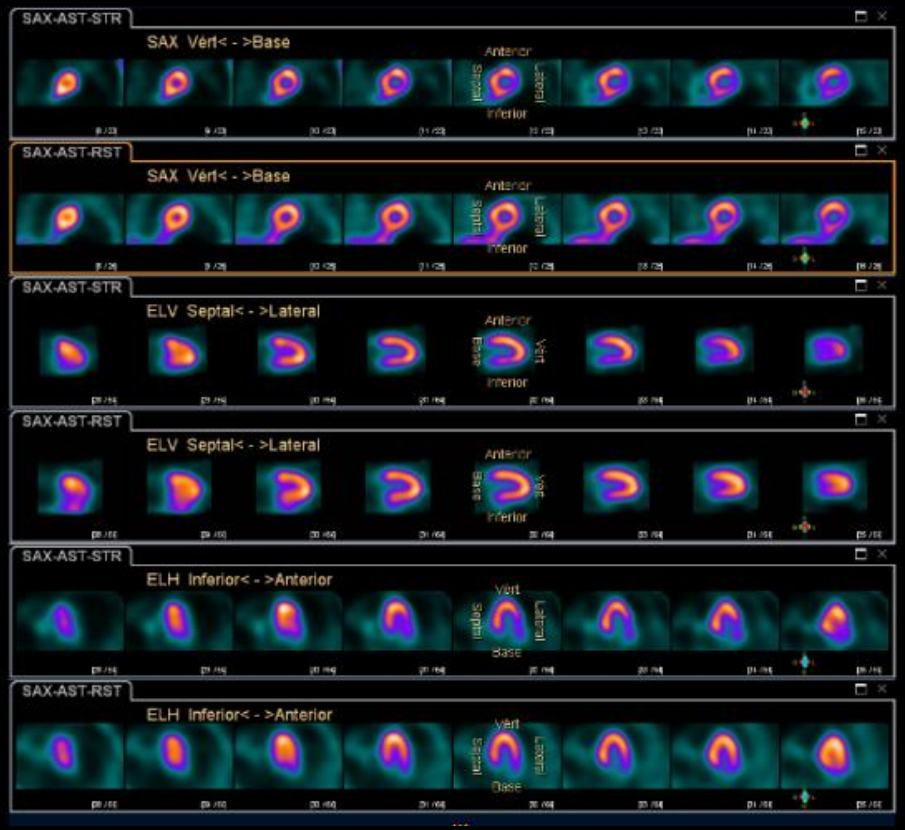
- Ergometria: Submáxima 93% de FCMT, ITT 27000, INFRA ST 1 mm V4 – V6.
- Spect: Hipoperfusión anterolateral (basal y medial) e inferolateral (basal y medial). Reversibles en reposo

ISQUEMIA MODERADA EN TERRITORIO DE CIRCUNFLEJA

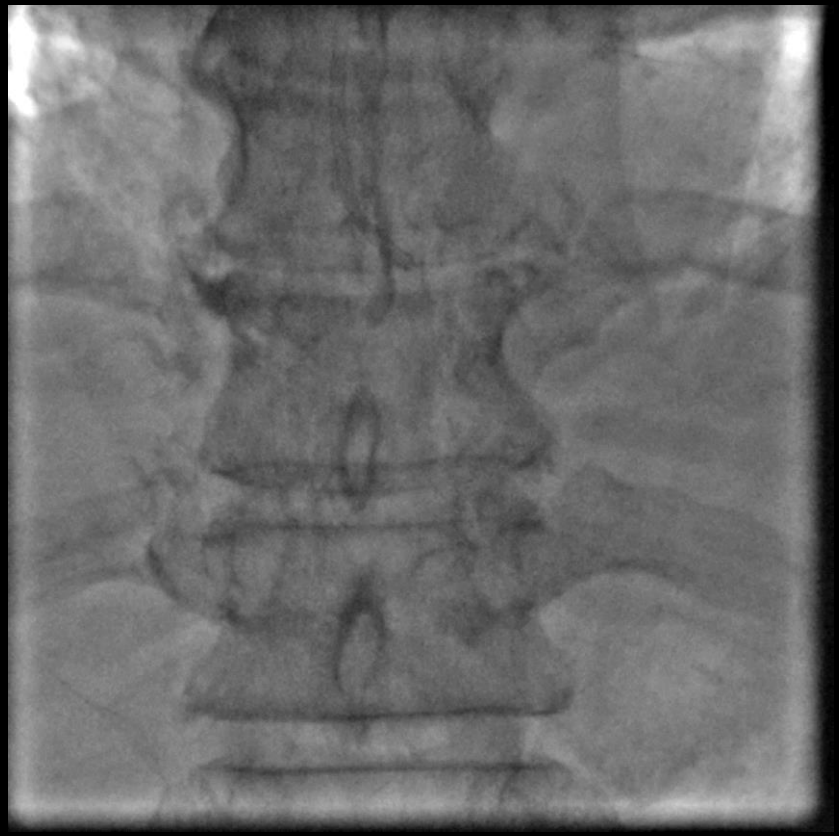


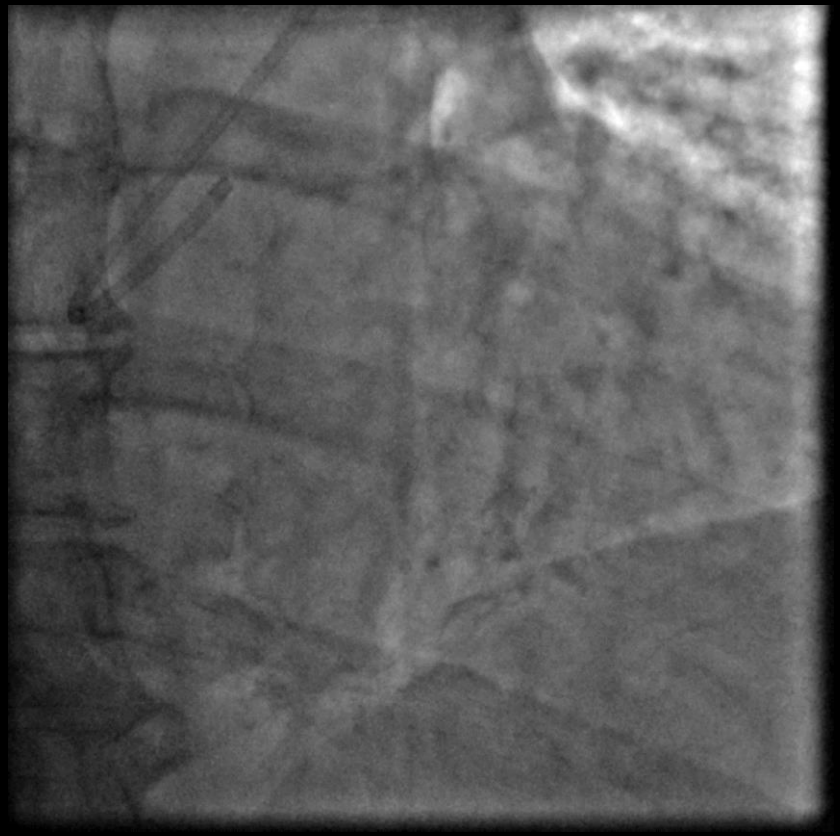
SPECT MIOCARDICO



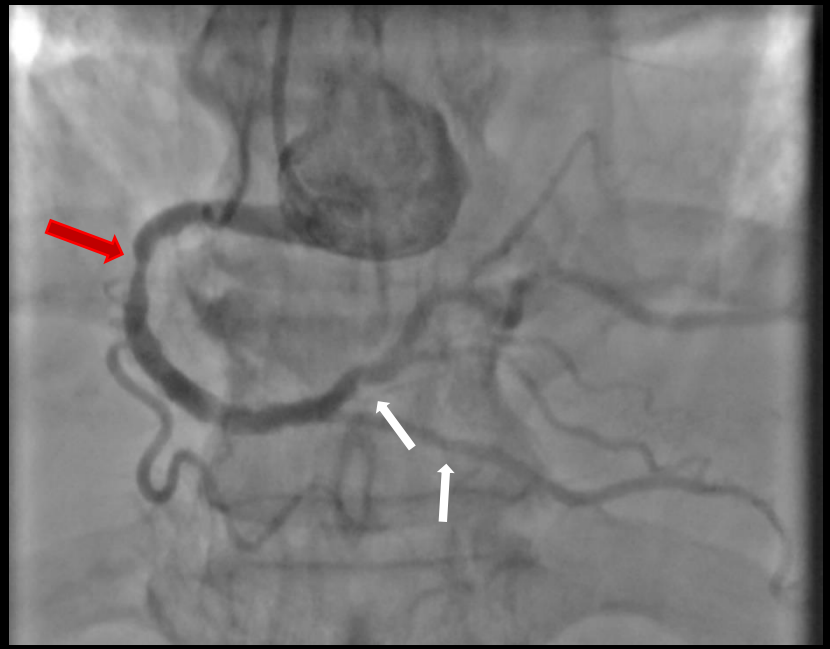


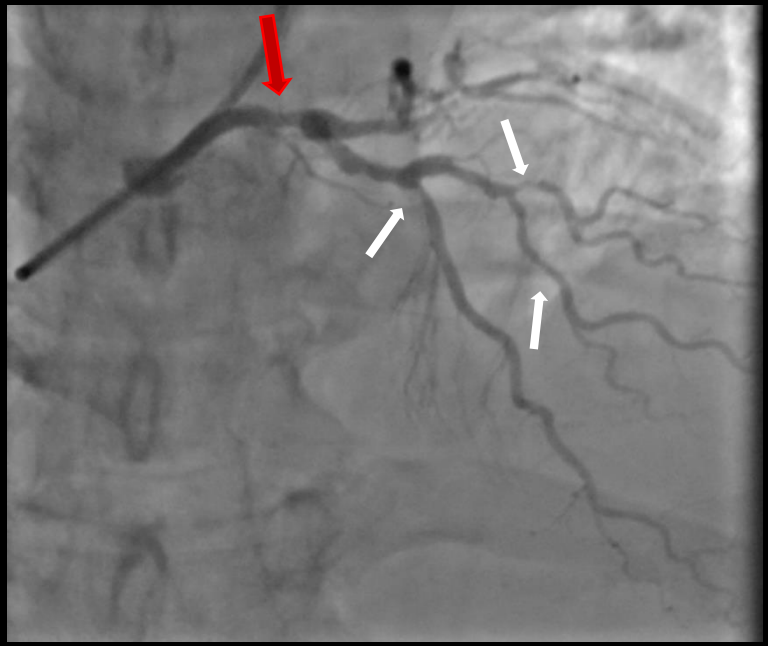
CINCECORONARIOGRAFIA





CINCECORONARIOGRAFIA





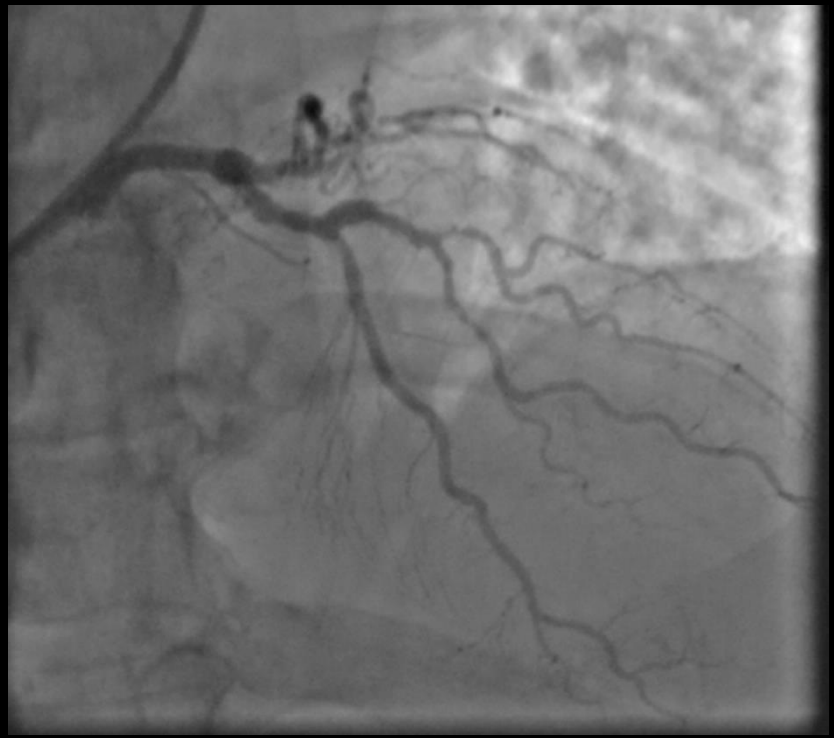
Score SYNTAX = 35
(Flechas rojas y blancas) 7 DES

score SYNTAX modificado por ERACI = 18
(Flechas rojas) 2 DES

CINCECORONARIOGRAFIA

ATC + 1 DES a CD proximal y 1 DES de TCI a DA

CINCECORONARIOGRAFIA



Score Syntax residual = 18
Score SYNTAX reisudal modificado por ERACI =0

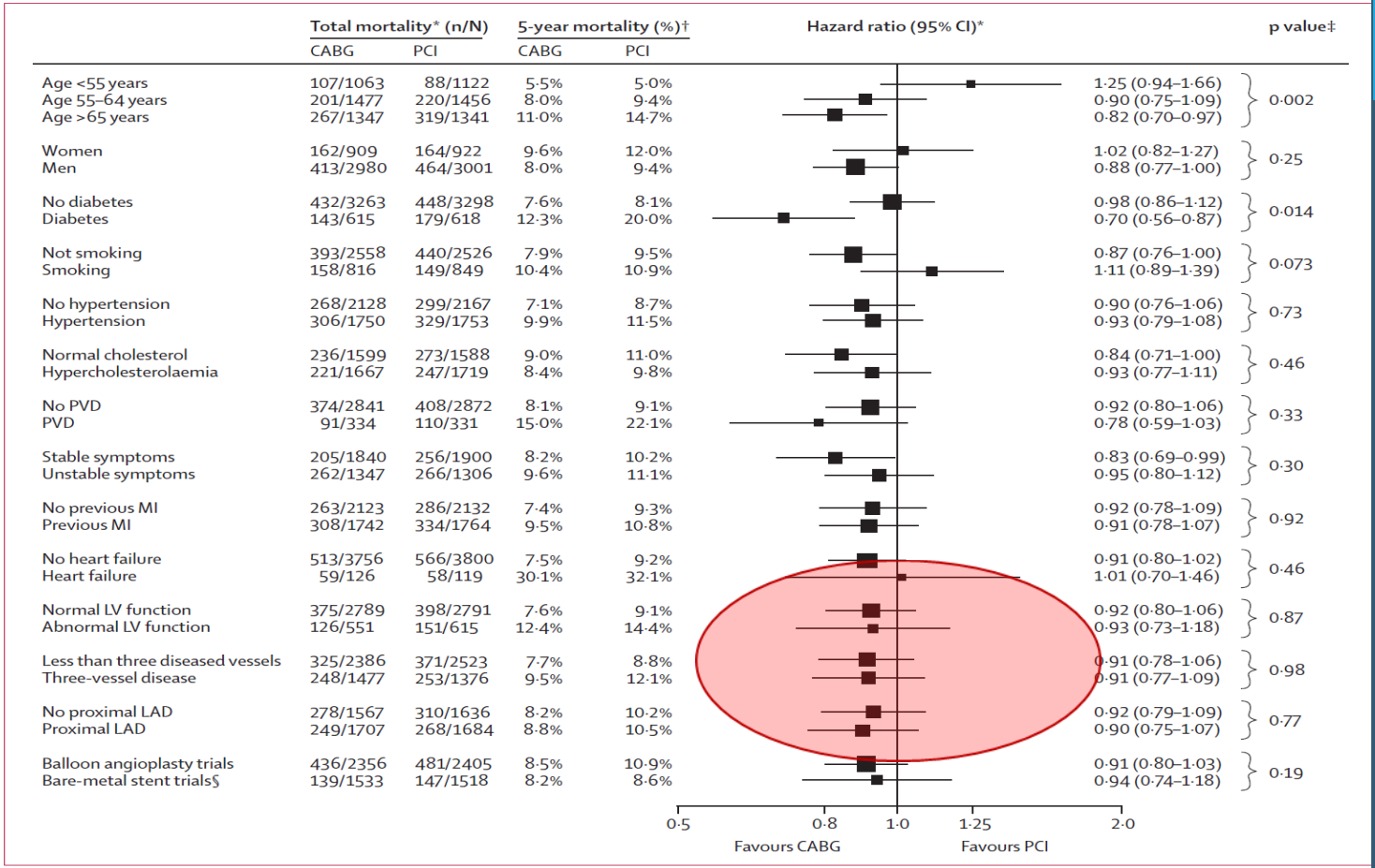


Figure 2: **Subgroup analyses for mortality after treatment with coronary artery bypass graft or percutaneous coronary intervention**

ORIGINAL ARTICLE

Percutaneous Revascularization for Ischemic Left Ventricular Dysfunction

Divaka Perera, M.D., Tim Clayton, M.Sc., Peter D. O'Kane, M.D., John P. Greenwood, Ph.D., Roshan Weerackody, Ph.D., Matthew Ryan, Ph.D., Holly P. Morgan, M.B., B.Ch., Matthew Dodd, M.Sc., Richard Evans, B.A., Ruth Canter, M.Sc., Sophie Arnold, M.Sc., Lana J. Dixon, Ph.D., Richard J. Edwards, Ph.D., Kalpa De Silva, Ph.D., James C. Spratt, M.D., Dwayne Conway, M.D., James Cotton, M.D., Margaret McEntegart, Ph.D., Amedeo Chiribiri, Ph.D., Pedro Saramago, Ph.D., Anthony Gershlick, M.D., Ajay M. Shah, M.D., Andrew L. Clark, M.D., and Mark C. Petrie, M.D., for the REVIVED-BCIS2 Investigators*

ABSTRACT

BACKGROUND

Whether revascularization by percutaneous coronary intervention (PCI) can improve event-free survival and left ventricular function in patients with severe ischemic left ventricular systolic dysfunction, as compared with optimal medical therapy (i.e., individually adjusted pharmacologic and device therapy for heart failure) alone, is unknown.

METHODS

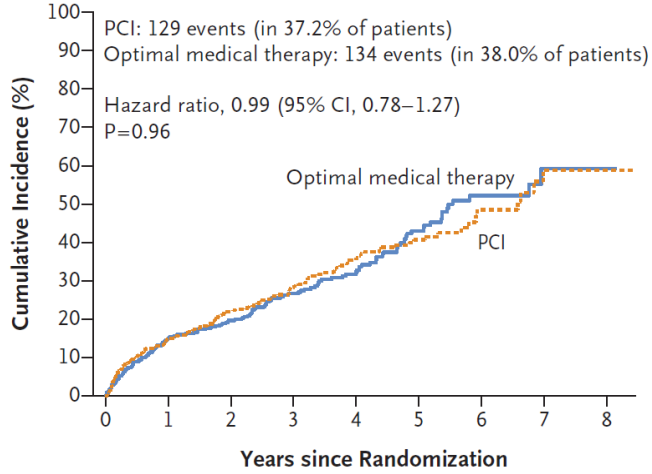
We randomly assigned patients with a left ventricular ejection fraction of 35% or less, extensive coronary artery disease amenable to PCI, and demonstrable myocardial viability to a strategy of either PCI plus optimal medical therapy (PCI group) or optimal medical therapy alone (optimal-medical-therapy group). The primary composite outcome was death from any cause or hospitalization for heart failure. Major secondary outcomes were left ventricular ejection fraction at 6 and 12 months and quality-of-life scores.

RESULTS

A total of 700 patients underwent randomization — 347 were assigned to the PCI group and 353 to the optimal-medical-therapy group. Over a median of 41 months, a primary-outcome event occurred in 129 patients (37.2%) in the PCI group and in 134 patients (38.0%) in the optimal-medical-therapy group (hazard ratio, 0.99; 95% confidence interval [CI], 0.78 to 1.27; P=0.96). The left ventricular ejection fraction was similar in the two groups at 6 months (mean difference, −1.6 percentage points; 95% CI, −3.7 to 0.5) and at 12 months (mean difference, 0.9 percentage points; 95% CI, −1.7 to 3.4). Quality-of-life scores at 6 and 12 months appeared to favor the PCI group, but the difference had diminished at 24 months.

CONCLUSIONS

Among patients with severe ischemic left ventricular systolic dysfunction who received optimal medical therapy, revascularization by PCI did not result in a lower incidence of death from any cause or hospitalization for heart failure. (Funded by the National Institute for Health and Care Research Health Technology Assessment Program; REVIVED-BCIS2 ClinicalTrials.gov number, NCT01920048.)



No. at Risk

PCI	347	295	262	179	130	80	32	14	3
Optimal medical therapy	353	299	276	191	142	82	33	10	1

Figure 1. Primary Outcome of Death from Any Cause or Hospitalization for Heart Failure.

Shown are Kaplan–Meier estimates of the cumulative incidence of death from any cause or hospitalization for heart failure in a time-to-first-event analysis. The overall incidence is based on the total number of events in each group in the intention-to-treat population over the entire follow-up period. PCI denotes percutaneous coronary intervention.

Table 2. Primary and Secondary Outcomes.

Outcome	PCI (N=347)	Optimal Medical Therapy (N=353)	Treatment Effect (95% CI)*
Primary outcome			
Death from any cause or hospitalization for heart failure — no. (%)†	129 (37.2)	134 (38.0)	0.99 (0.78–1.27)
Secondary outcomes‡			
Components of the primary outcome			
Death from any cause	110 (31.7)	115 (32.6)	0.98 (0.75–1.27)
Hospitalization for heart failure§	51 (14.7)	54 (15.3)	0.97 (0.66–1.43)
Death from cardiovascular causes — no. (%)¶	76 (21.9)	88 (24.9)	0.88 (0.65–1.20)
Acute myocardial infarction — no. (%)‖	37 (10.7)	38 (10.8)	1.01 (0.64–1.60)
Periprocedural — no. (%)**	14 (37.8)	0	
Spontaneous — no. (%)**	18 (48.7)	33 (86.8)	
Sudden death — no. (%)**††	5 (13.5)	5 (13.2)	
Unplanned revascularization — no. (%)‡‡	10 (2.9)	37 (10.5)	0.27 (0.13–0.53)
PCI — no. (%)§§	9 (90.0)	29 (78.4)	
CABG — no. (%)§§	1 (10.0)	8 (21.6)	
Major bleeding — no. (%)			
At 1 yr	10/319 (3.1)	2/316 (0.6)	4.95 (1.09–22.43)
At 2 yr	10/292 (3.4)	7/290 (2.4)	1.42 (0.55–3.68)

Table S14: Acute Myocardial Infarction and Unplanned Revascularisation

	PCI (n=347)	OMT (n=353)	Hazard ratio (95% CI)
Acute Myocardial Infarction	37 (10.7)	38 (10.8)	1.01 (0.64 to 1.60)
Peri-procedural MI	14 (37.8)	0 (0)	
Spontaneous MI	18 (48.7)	33 (86.8)	p<0.03
Sudden death	5 (13.5)	5 (13.2)	
Unplanned revascularisation	10 (2.9)	37 (10.5)	0.27 (0.13 to 0.53)
CABG	1 (10.0)	8 (21.6)	
PCI	9 (90.0)	29 (78.4)	

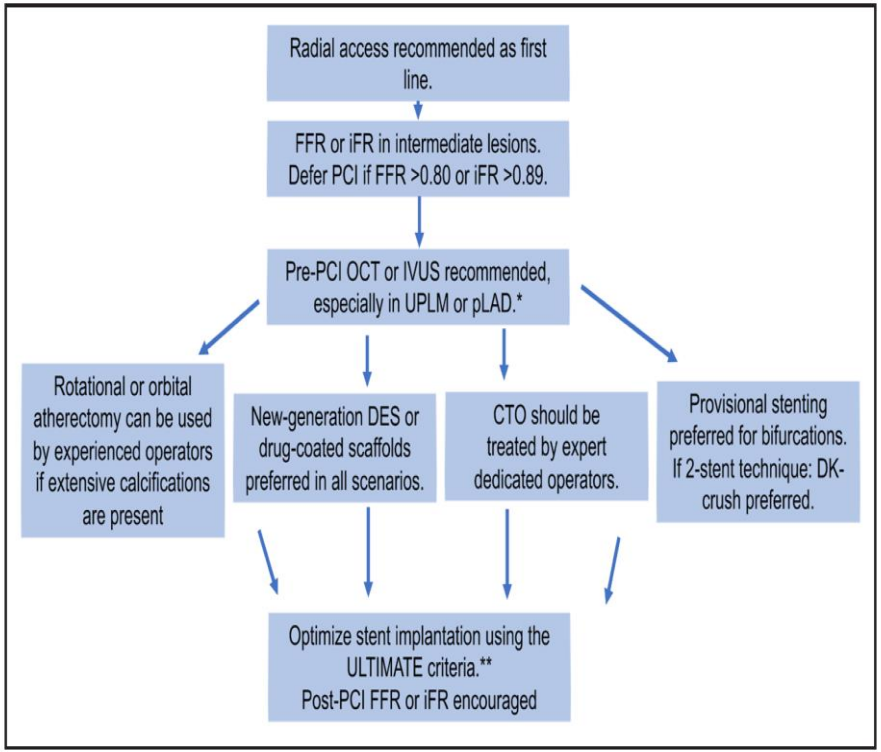


Figure 2. State-of-the-art percutaneous coronary intervention (PCI) for the STICH3C trial (Canadian CABG or PCI in Patients With Ischemic Cardiomyopathy).

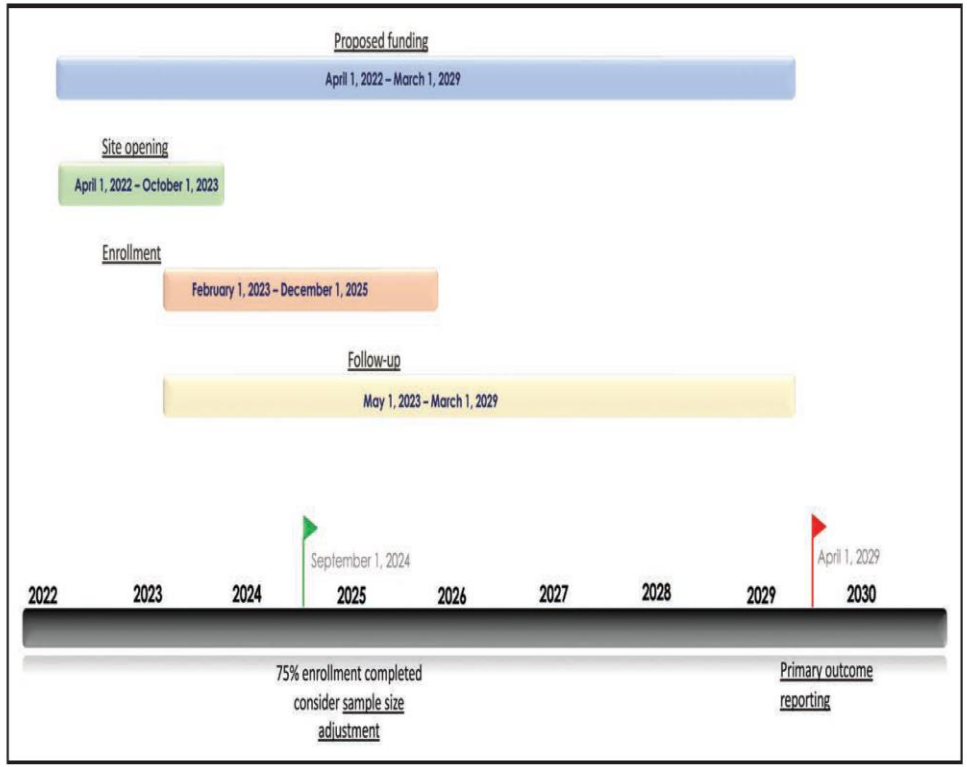


Figure 3. Timeline of the STICH3C trial (Canadian CABG or PCI in Patients With Ischemic Cardiomyopathy).

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

STICH3C: Rationale and Study Protocol

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BACKGROUND: Coronary artery bypass grafting (CABG) is the recommended mode of revascularization in patients with ischemic left ventricular dysfunction (iLVSD) and multivessel disease. However, contemporary percutaneous coronary intervention (PCI) outcomes have improved with the integration of novel technologies and refinement of revascularization strategies, and PCI is often used in clinical practice in this population. There is a lack of evidence from randomized trials comparing contemporary state-of-the-art PCI versus CABG for the treatment of iLVSD and multivessel disease. This was the impetus for the STICH3C trial (Canadian CABG or PCI in Patients With Ischemic Cardiomyopathy), described here.

International STICH 3.0 Consortium

STICH3C is an international trial funded by the Canadian Institutes of Health Research that will be subsequently embedded in an international collaborative of independently funded yet harmonized randomized trials in similar patient populations (the International STICH 3.0 Consortium, NCT05761067). The trial investigators of the STICH3C trial and of the other independently funded trials from other countries have agreed to pool individual patient data from the completed studies to address whether CABG is superior to PCI in terms of mortality (Figure S1). To date, there are funded trials comparing PCI and

CONCLUSIONS: STICH3C will directly inform patients, clinicians, and international practice guidelines about the efficacy and safety of CABG versus PCI in patients with iLVSD. The results will provide novel and broad evidence, including clinical events, health status, and economic assessments, to guide care for patients with iLVSD and severe coronary artery disease.

Netherlands (P. van der Meer) and Australia (C. Reid).

Reflexiones Finales

Desde los primeros estudios aleatorizados entre PCI y CABG, la Diabetes fue un factor asociado con mayor mortalidad global cuando los pacientes eran tratados con PCI, hecho que no se modifico con la introduccion de DES.

La incidencia de CVA, se observo significativamente mayor con CABG.

Sin embargo el mayor studio randomizado comparativo entre PCI y CABG,FREEDOM, no se observaron diferencias significativas en mortalidad cardiaca entre ambos procedimientos (p=0.09)

 # Existen grandes diferencias geograficas en el resultado con CABG que se mantuvieron en los ultimos 30 anos.

No todos los pacientes diabeticos son iguales y existen notables diferencias en la angiografia coronaria entre ellos.

Reflexiones Finales (cont.)

Los pacientes con deterioro moderado de la FVI (FE<40%) representan el 17.2% de los pacientes incluidos en el metaanalisis de los 10 RCT publicado por Hlatky en Lancet 2009 (1166/6740).

La sobrevida a 5.9 anos fue similar con PCI y CABG (p=0.87).

El estudio contemporaneo REVIVED BCIS2 entre DES y OMT en pacientes con FVI≤35% mostro un trend a 3.6 anos de menor mortalidad cardiaca con PCI (p=0.12).

En este studio la incidencia de infarto espontaneo fue significativamente menor con PCI (p<0.03).

Existen “ongoing” trials comparativos entre PCI y CABG como el estudio Sueco(NCT 5329285) y el STICH3 de Canada(NCT05761067) que demostraran el rol de ambas estrategias en pacientes con deterioro moderado o severo de la FVI.

En el momento actual NO existen datos aleatorizados que avalen una u otra estrategia en este tipo de pacientes.