REVIVED-BCIS2 trial

O estudo REVIVED-BCIS2 mostrou que revascularização miocárdica com angioplastia percutânea (PCI) falhou em prover benefícios comparado com tratamento clínico otimizado (GDMT) em pacientes com disfunção ventricular importante e doença coronariana extensa.

Este ensaio clínico randomizado foi recentemente apresentado durante o Congresso Europeu de Cardiologia – ESC 2022 em Barcelona e publicado simultaneamente no *New England Journal of Medicine.* De acordo com os resultados, não houve diferença no desfecho primário de morte por qualquer causa ou hospitalização por insuficiência cardíaca.

Base teórica:

De acordo com os Guidelines da ESC, CRM é recomendada como primeira estratégia de revascularização em paciente com cardiomiopatia isquêmica e doença de múltiplas vasos, desde que o risco de cirurgia seja aceitável (classe I, nível de evidência B). PCI pode ser considerada em doença de 1 ou 2 vasos, quando revascularização completa pode ser alcançada (classe IIa, nível de evidência C).

Desenho:

700 pacientes com FE ≤ 35% (avaliada por ecocardiograma ou RNM), extensiva doença arterial coronariana (British Cardiovascular Intervention Society jeopardy score ≥6) e viabilidade miocárdica (demonstrada em pelo menos 4 segmentos viáveis para PCI) foram randomizados (347 grupo PCI, 353 no grupo GDMT). Idade mediana de 70 anos. 77% estavam em classe functional NYHA I/II e 88% eram homens. Mediana do BCIS jeopardy score foi 10 de 12.

No grupo PCI, protocolo de tratamento requeria que os operadores tentassem revascularização em todos os vasos com doença proximal.

Follow-up: mediana de 3,4 anos.

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	PCI (N=347)	Optimal Medical Therapy (N=353)
Age — yr	70.0±9.0	68.8±9.1
Male sex — no. (%)	302 (87)	312 (88)
Race — no. (%)†		
White	306 (88)	328 (93)
Asian	32 (9)	17 (5)
Black	3 (1)	3 (1)
Mixed, other, or not reported	6 (2)	5 (1)
Body-mass index‡	28.4±5.5	28.7±5.4
Hypertension — no./total no. (%)	184/347 (53)	207/352 (59)
Diabetes — no. (%)	136 (39)	153 (43)
Current or previous smoker — no. (%)	243 (70)	267 (76)
Previous myocardial infarction — no. (%)	175 (50)	197 (56)
Previous PCI — no. (%)	66 (19)	76 (22)
Previous CABG — no. (%)	12 (3)	22 (6)
NYHA functional class — no./total no. (%)§		
I or II	265/345 (77)	248/350 (71)
III or IV	80/345 (23)	102/350 (29)
CCS angina class — no./total no. (%)¶		
No angina	228/346 (66)	236/351 (67)
I or II	111/346 (32)	107/351 (30)
III	7/346 (2)	8/351 (2)
Left ventricular ejection fraction — %‖	27.0±6.6	27.0±6.9
Coronary artery disease characteristic		
Median BCIS jeopardy score (IQR)**	10 (8–12)	10 (8–12)
Left main coronary artery disease — no./total no. (%)	50/346 (14)	45/352 (13)
Three-vessel coronary artery disease — no./total no. (%)	133/346 (38)	148/352 (42)
Two-vessel coronary artery disease — no. (%)	178 (51)	166 (47)
Median NT-proBNP — pg/ml (IQR)	1376 (697–3426)	1461 (712–3365)

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding. CABG denotes coronary-artery bypass grafting, IQR interquartile range, NT-proBNP N-terminal pro–B-type natriuretic peptide, and PCI percutaneous coronary intervention.

† Race was reported by the patient.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

§ The New York Heart Association (NYHA) functional class ranges from I (no symptoms) to IV (symptoms at rest or on minimal activity).

¶ In the Canadian Cardiovascular Society (CCS) grading of angina pectoris, grade I denotes symptoms only with strenuous or prolonged exertion; grade II, slight limitation of ordinary activity; and grade III, marked limitation of ordinary physical activity.

‖ The baseline left ventricular ejection fraction was assessed by echocardiography or cardiovascular magnetic resonance imaging; the values were reported by the recruiting center.

** The British Cardiovascular Intervention Society (BCIS) jeopardy score is a quantification of the extent of myocardial jeopardy relating to clinically significant coronary artery stenoses. The score ranges from 0 (no significant coronary disease) to 12 (disease jeopardizing the whole left ventricular myocardium).

Desfecho:

Desfecho primário: composto de morte por qualquer causa e hospitalização por ICC.

Resultados:

Desfecho primário: 37,2% (129 pacientes) no grupo PCI vs. 38,0% (134 pacientes) no grupo tratamento clínico (sem diferença significativa) (HR 0,99; IC 95% 0,78-1,27; P=0,96).

Mortalidade: 31,7% (110 pacientes) no grupo PCI vs. 32,6% (115 pacientes) (HR 0,98; IC 95% 0,75-1,27).

Hospitalização por ICC: 14,7% (51 pacientes) no grupo PCI vs. 15,3% (54 pacientes) (HR 0,97; IC 95% 0,66-1,43).

Infarto espontâneo e risco de revascularização não planejada (2.9% PCI vs. 10,5% tratamento clínico; HR 0,27; IC 95% 0,13-0,53) foram mais frequentes no grupo tratamento clínico.

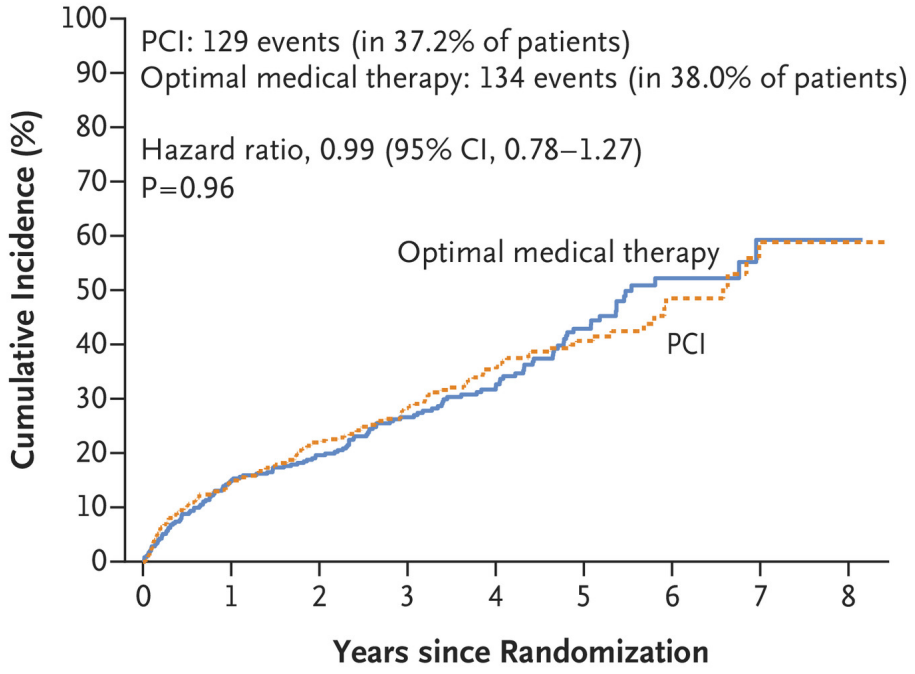
Qualidade de vida (KCCQ): tendeu a favorecer PCI em 6 meses, mas sem diferença significativa em 2 anos.

Fração de ejeção: sem diferença em 6 meses (diferença média −1,6 pontos percentuais; IC 95% −3,7-0,5) e 12 meses (diferença média 0,9 pontos percentuais; CI 95% −1,7-3,4).

Table 2. Primary and Secondary Outcomes.

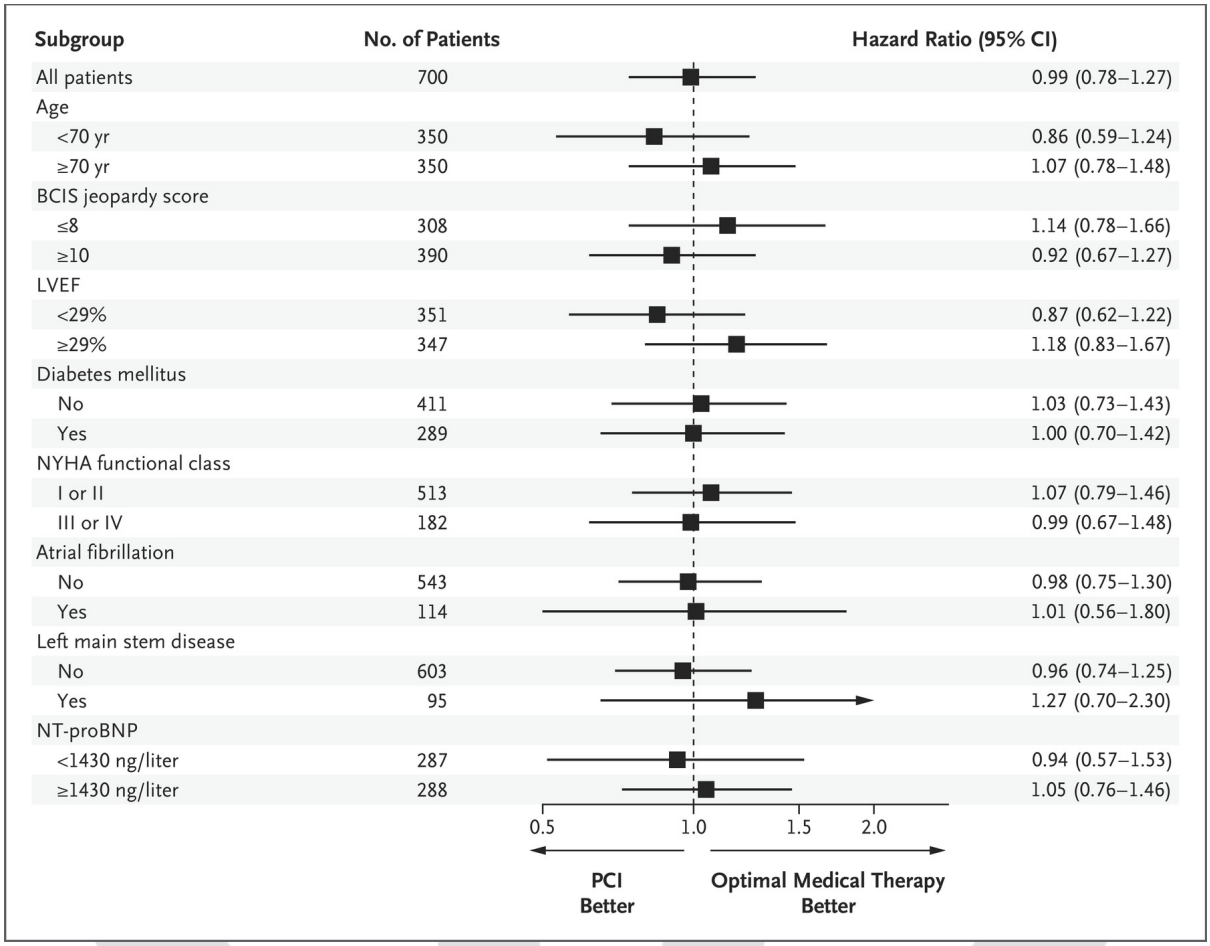
Outcome	PCI (N=347)	Optimal Medical Therapy (N=353)	Treatment Effect (95% CI)*
Primary outcome			
Death from any cause or hospitalization for heart failure — no. (%)†	129 (37.2)	134 (38.0)	0.99 (0.78–1.27)
Secondary outcomes‡			
Components of the primary outcome			
Death from any cause	110 (31.7)	115 (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)

* Treatment effects are hazard ratios, except for major bleeding, for which the treatment effect is the risk ratio.
† Randomization was stratified according to recruiting center. When recruiting center was taken into account as a covariate, the hazard ratio for a primary-outcome event was 1.00 (95% CI, 0.78 to 1.28; P=0.96).
‡ Because the statistical analysis plan did not include a provision for correcting for multiplicity when conducting tests for secondary or other outcomes, the results are reported as point estimates with 95% confidence intervals. The widths of the confidence intervals have not been adjusted for multiplicity, so the intervals should not be used to infer definitive treatment effects for secondary outcomes.
§ When death from any cause was taken into account as a potential competing risk, the hazard ratio for hospitalization for heart failure was 0.97 (95% CI, 0.66 to 1.42).[15]
¶ When death from noncardiovascular causes was taken into account as a potential competing risk, the hazard ratio for death from cardiovascular causes was 0.87 (95% CI, 0.64 to 1.18).[15]
‖ When death from any cause was taken into account as a potential competing risk, the hazard ratio for acute myocardial infarction was 1.01 (95% CI, 0.64 to 1.59).[15]
** The denominator is the total number of acute myocardial infarctions.
†† Sudden death refers only to the classification of events reported as myocardial infarctions by the recruiting centers.
‡‡ When death from any cause was taken into account as a potential competing risk, the hazard ratio for unplanned revascularization was 0.26 (95% CI, 0.13 to 0.53).[15]
§§ The denominator is the total number of unplanned revascularization procedures.



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



Referência: Perera D, Clayton T, O'Kane PD, et al. Percutaneous Revascularization for Ischemic Left Ventricular Dysfunction [published online ahead of print, 2022 Aug 27]. *N Engl J Med*. 2022;10.1056/NEJMoa2206606. doi:10.1056/NEJMoa2206606