Percutaneous Revascularization for Ischemic Left Ventricular Dysfunction

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REVascularisation for Ischaemic VEntricular Dysfunction

(REVIVED-BCIS2)

REVIVED-BCIS2 UK

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.

- Patients were randomly assigned in a 1:1 ratio to a strategy of PCI plus optimal medical therapy (PCI group) or optimal medical therapy alone (optimal-medical-therapy group).
- Optimal medical therapy refers to individually adjusted pharmacologic and device therapy for heart failure. In the PCI group, the protocol required that revascularization be attempted on all diseased proximal coronary vessels subtending areas of viable myocardium.

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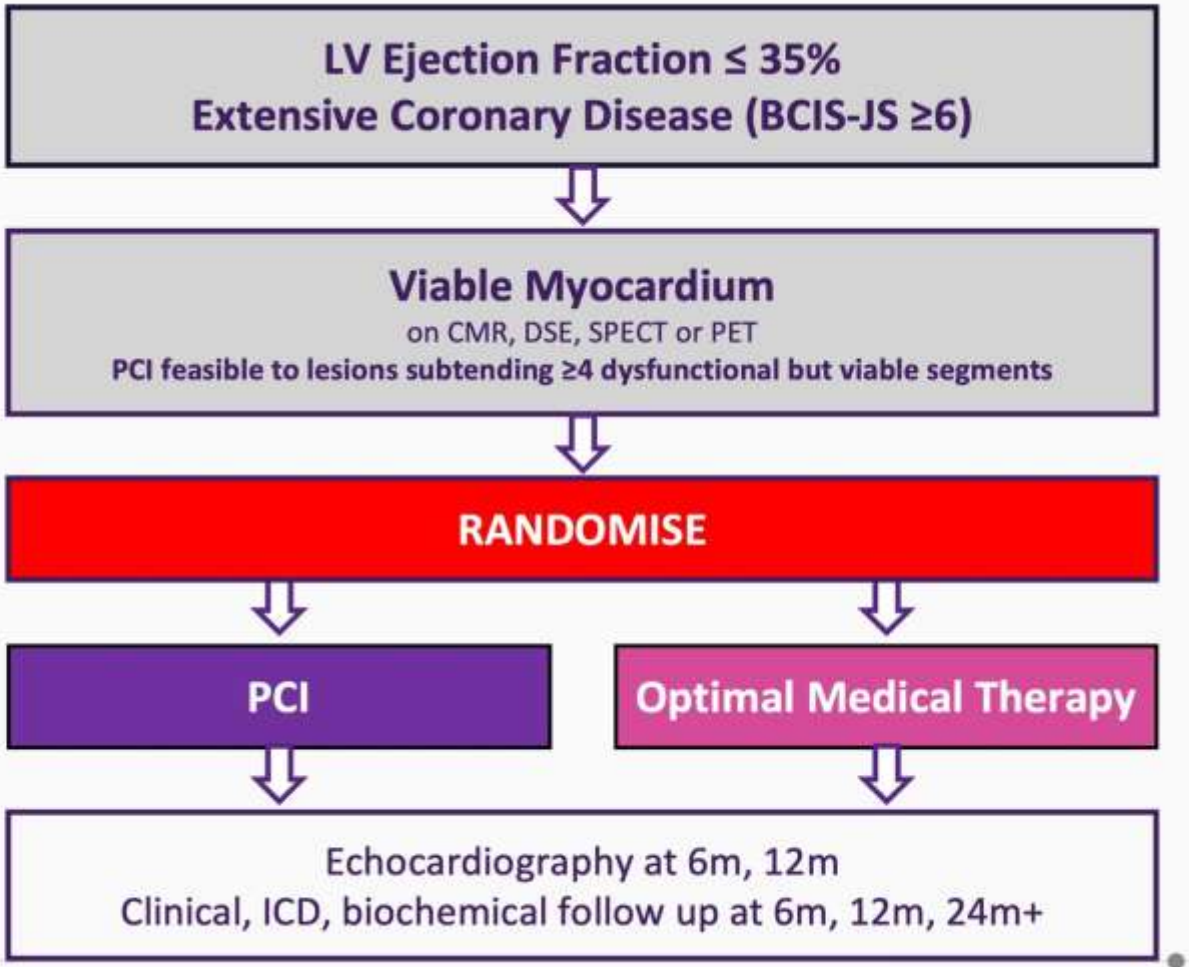

Perera D et al, JACC HF 2018

- The extent of revascularization was characterized by the British Cardiovascular Intervention Society jeopardy score and anatomical revascularization index, which was calculated as follows: [(the pre-PCI jeopardy score minus the post-PCI jeopardy score) divided by (the pre-PCI jeopardy score)]×100, with 100% indicating complete revascularization of all angiographically significant coronary disease

- Medical therapy for heart failure was initiated before enrollment and customized according to the patient's individual needs throughout the trial by heart-failure specialists at the recruiting centers.

- A medical-therapy committee reviewed guidelines periodically and refined recommendations to ensure that the pharmacologic and device therapy given to all patients in the trial remained contemporary. The decision to insert an implantable cardioverter–defibrillator (ICD) or cardiac resynchronization therapy device was at the discretion of treating clinicians but had to be documented before randomization.

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)

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

Characteristic	PCI (N=347)
III or IV	80/345 (23)
CCS angina class — no./total no. (%)¶	
No angina	228/346 (66)
I or II	111/346 (32)
III	7/346 (2)
Left ventricular ejection fraction — %‖	27.0±6.6
Coronary artery disease characteristic	
Median BCIS jeopardy score (IQR)**	10 (8–12)
Left main coronary artery disease — no./total no. (%)	50/346 (14)
Three-vessel coronary artery disease — no./total no. (%)	133/346 (38)
Two-vessel coronary artery disease — no. (%)	178 (51)
Median NT-proBNP — pg/ml (IQR)	1376 (697–3426)

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding. CABG denotes coronary-artery bypass grafting, IQR in 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 exertio 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 we center.

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


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PCI
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Primary Outcome
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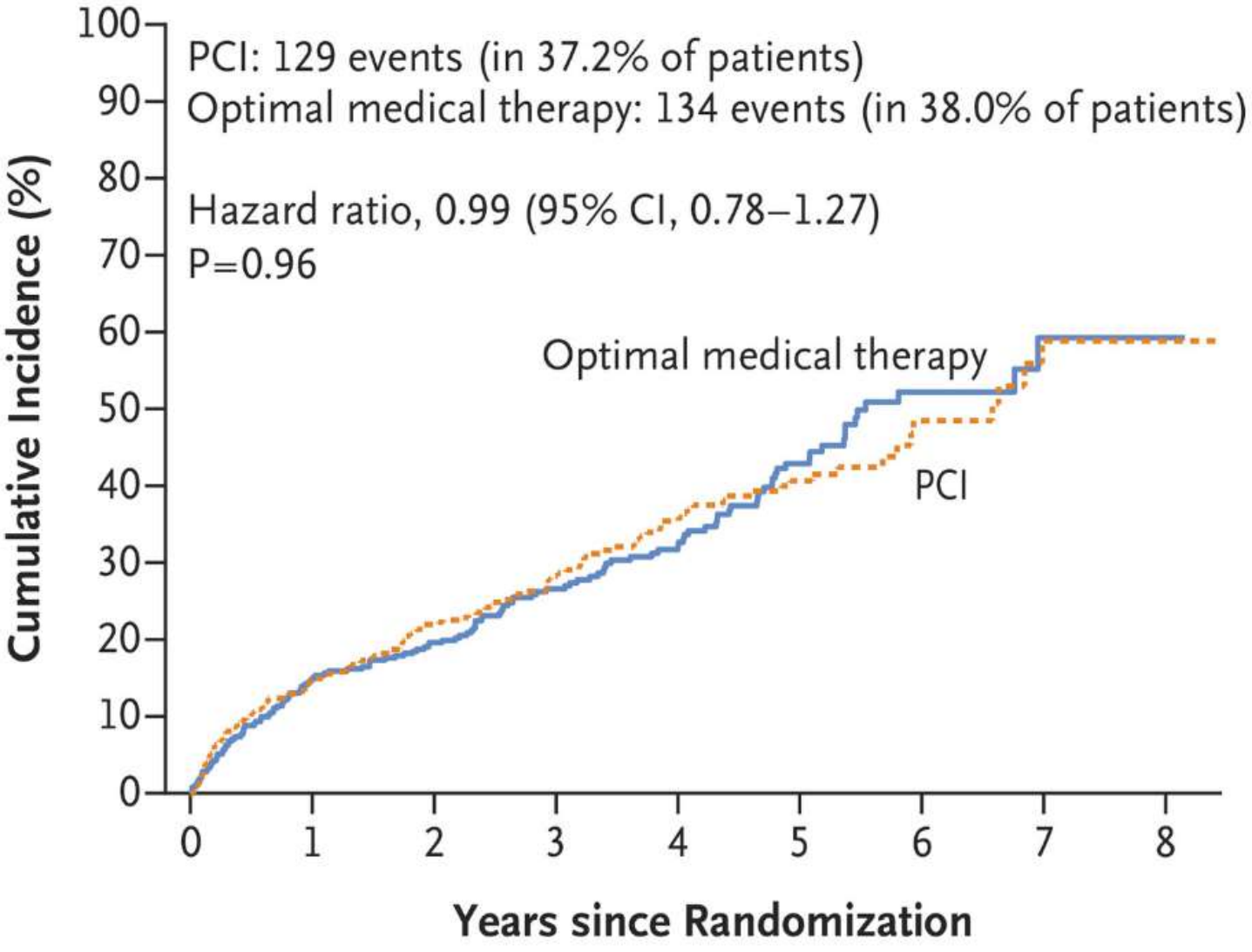
Table 2. Primary and Secondary Outcomes.

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.

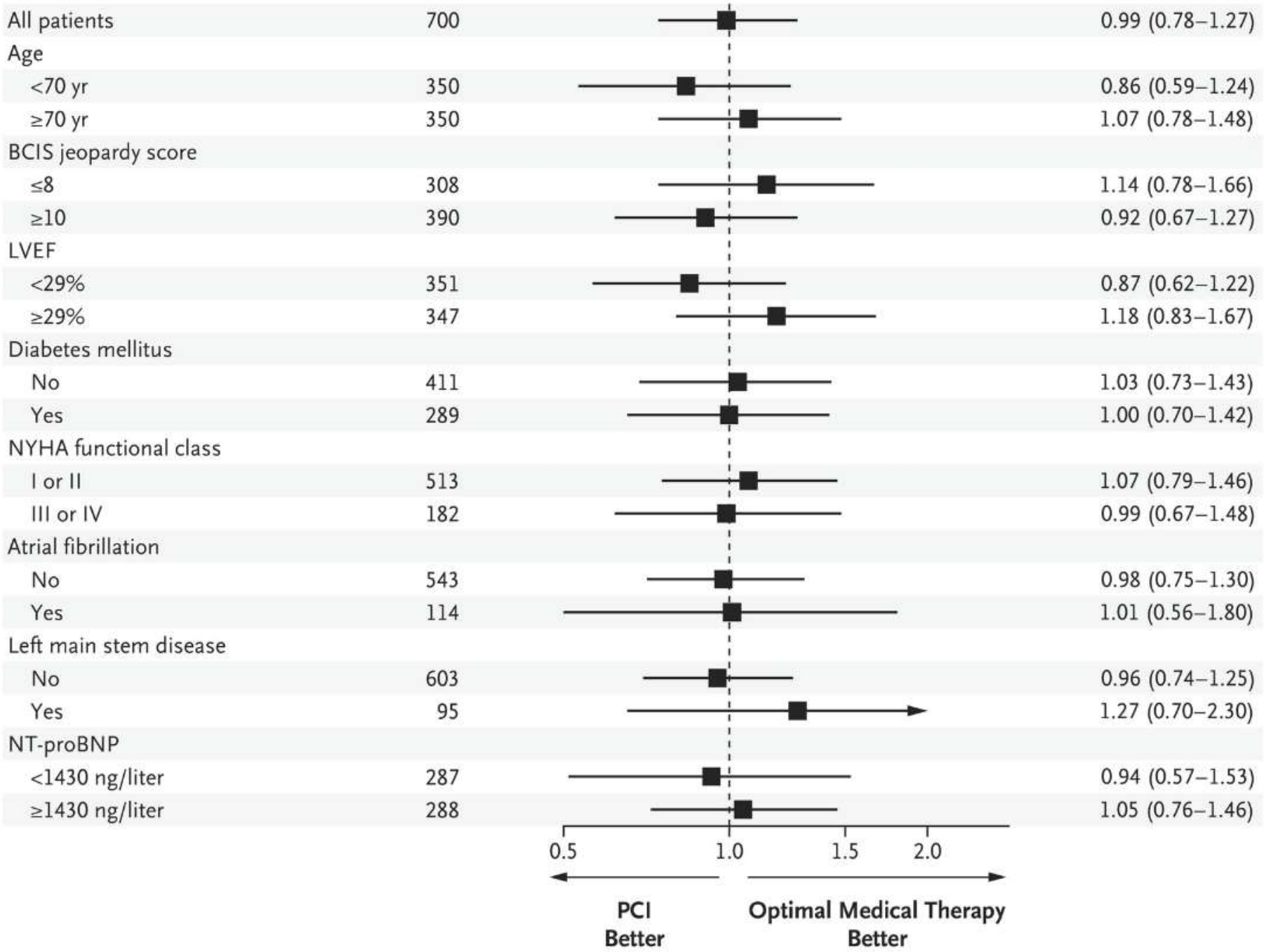
† Randomization was stratified according to recruiting center. When recruiting center was taken into account as a covariate, the hazard ratio for a primary-outcome event was 1.00 (95% CI, 0.78 to 1.28; P=0.96).

‡ 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

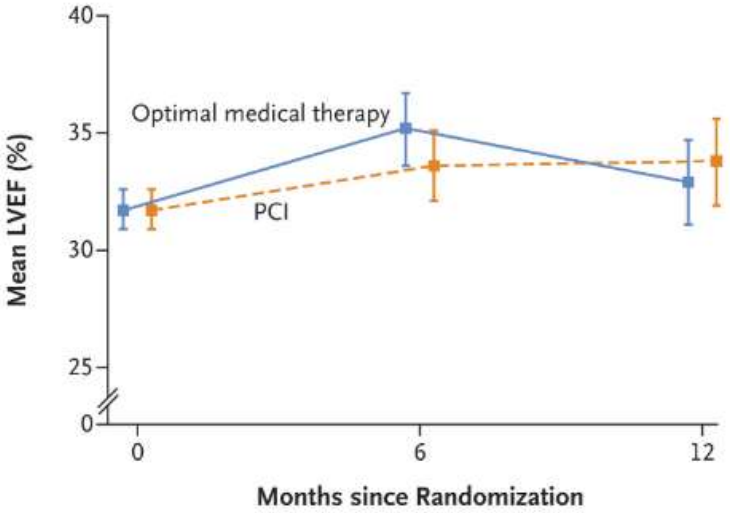


No. at Risk

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

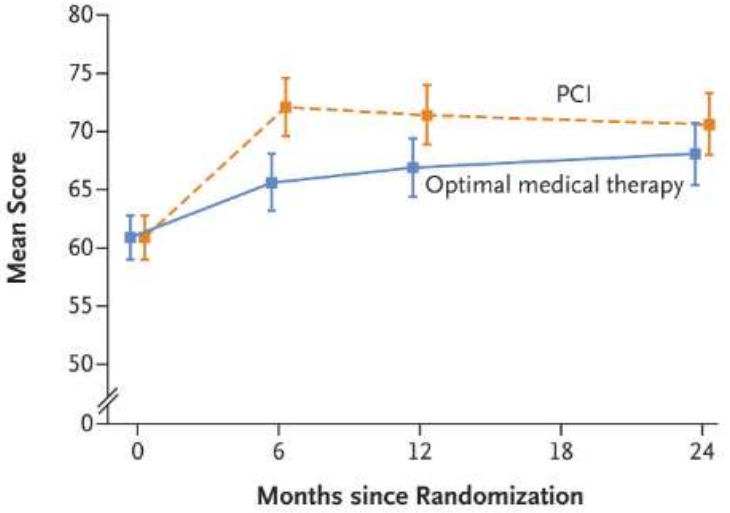

Subgroup
No. of Patients
Hazard Ratio (95% CI)
All patients 700 0.99 (0.78–1.27)
Age
<70 yr 350 0.86 (0.59–1.24)
≥70 yr 350 1.07 (0.78–1.48)
BCIS jeopardy score
≤8 308 1.14 (0.78–1.66)
≥10 390 0.92 (0.67–1.27)
LVEF
<29% 351 0.87 (0.62–1.22)
≥29% 347 1.18 (0.83–1.67)
Diabetes mellitus
No 411 1.03 (0.73–1.43)
Yes 289 1.00 (0.70–1.42)
NYHA functional class
I or II 513 1.07 (0.79–1.46)
III or IV 182 0.99 (0.67–1.48)
Atrial fibrillation
No 543 0.98 (0.75–1.30)
Yes 114 1.01 (0.56–1.80)
Left main stem disease
No 603 0.96 (0.74–1.25)
Yes 95 1.27 (0.70–2.30)
NT-proBNP
<1430 ng/liter 287 0.94 (0.57–1.53)
≥1430 ng/liter 288 1.05 (0.76–1.46)
0.5
1.0
1.5
2.0
PCI Better
Optimal Medical Therapy Better

A Echocardiographic Estimates of LVEF



No. of Patients			
PCI	264	276	262
Optimal medical therapy	276	264	267

B KCCQ Overall Summary Score



No. of Patients				
PCI	319	270	268	228
Optimal medical therapy	318	285	268	228

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.**.)

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CABG remains standard of care for coronary revascularization in patients with #HeartFailure and low LVEF
#ESCCongress #HotLine #RevivedBCIS2 @aayshacader @ANazmiCalik @KardiologieHH

> 
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>
> #REVIVED by @divaka_perera #ESCCongress @escardio
> ✳️Pts with ischaemic aetiology #heartfailure (LVEF <35%) who received optimal medical therapy, revascularization by PCI ❌ lower incidence of death from any cause or hospitalization for heart failure @BSHeartFailure
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