



1·2·3 FÉVRIER 2023

MARSEILLE·PALAIS DU PHARO



Ce qui pourrait changer ma pratique en
2023

Le patient pluritronculaire à FE
basse : REVIVED

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Statement of financial interest

Speaker's name : Nicolas Meneveau, Besançon

I have the following potential conflicts of interest to report:

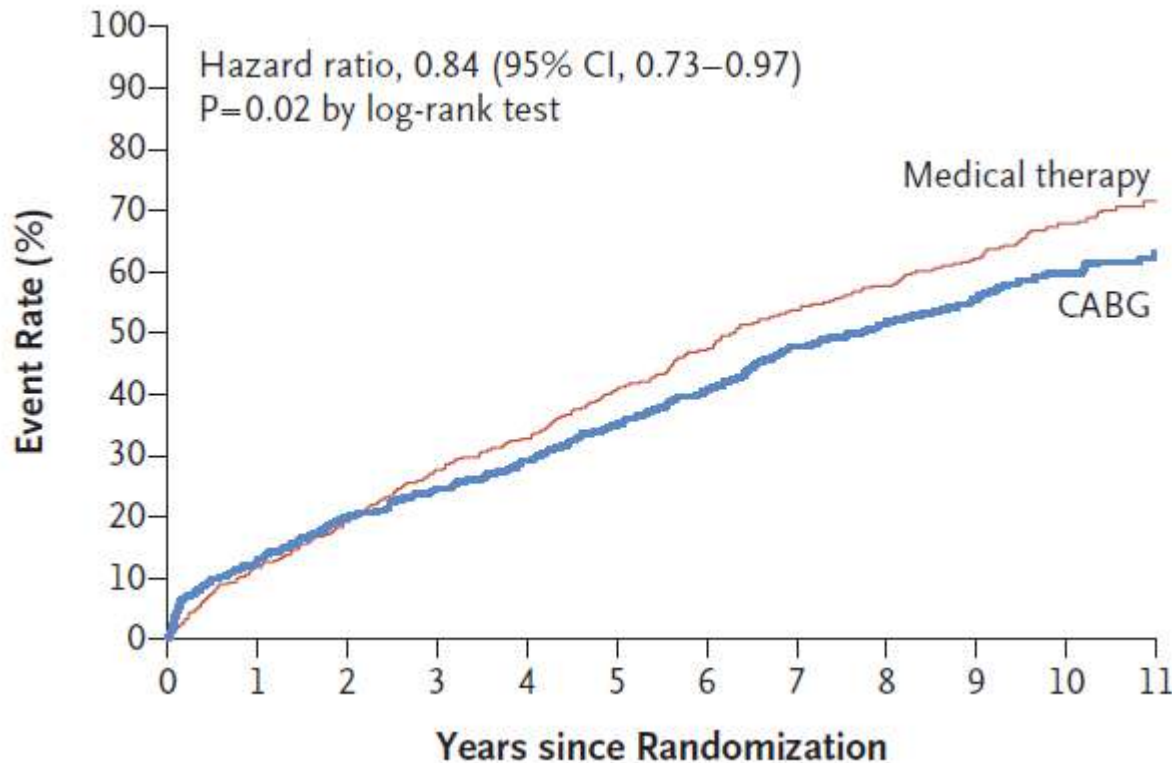
Consultant: Abbott Medical, Bayer Health Care, Bristol-Myers Squibb, Edwards Lifesciences, Terumo, Inari

Honoraria: Abbott Medical, AstraZeneca, Bayer Health Care, Bristol-Myers Squibb, Pfizer, Terumo, Amgen

Rationnel : pontages et cardiopathies ischémiques (FEVG $\leq 35\%$)

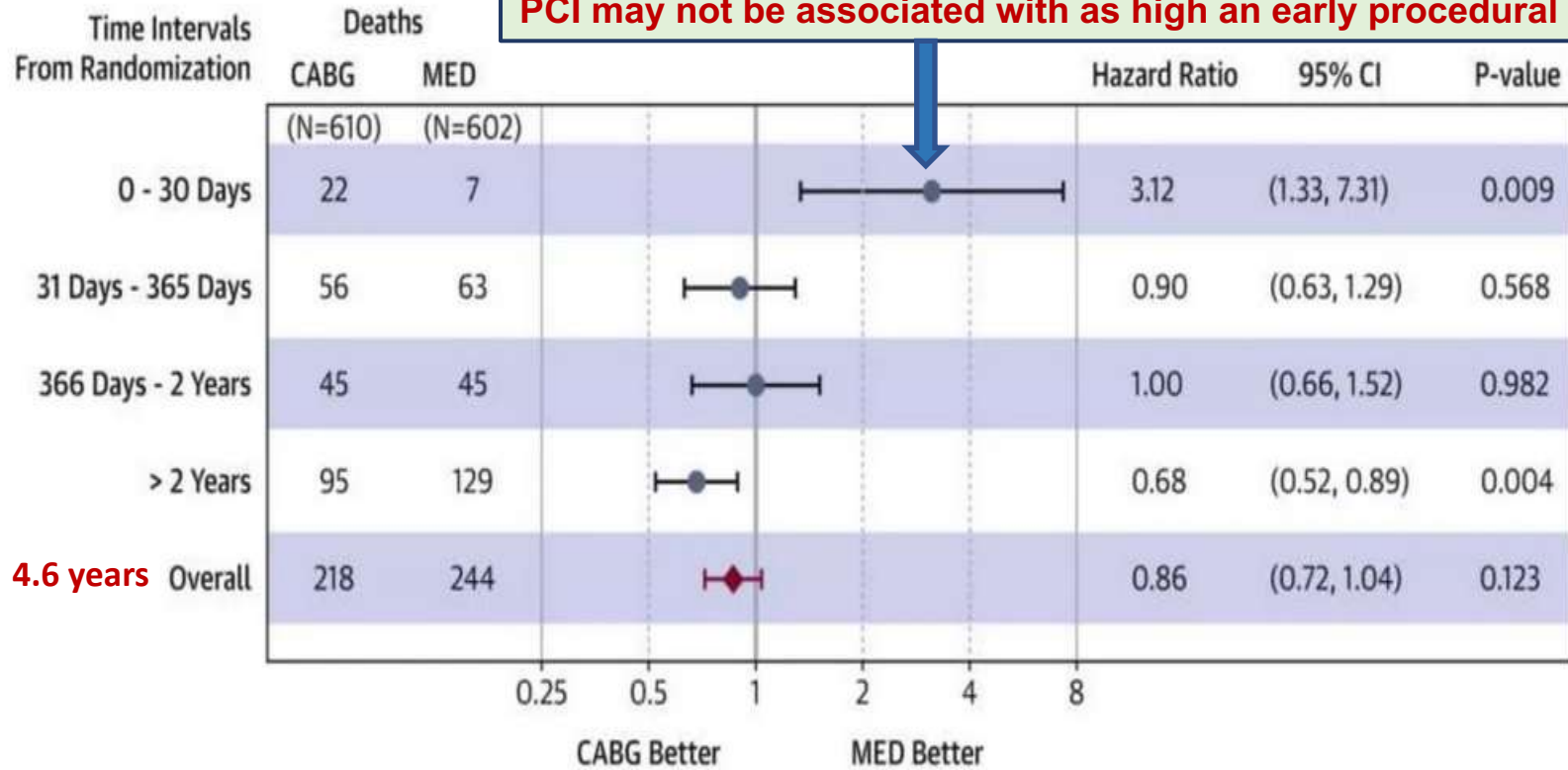
STICH study

**Death from any cause
(Primary outcome)**



Rationnel : pontages et cardiopathies ischémiques (FEVG ≤ 35%)

PCI may not be associated with as high an early procedural risk



Recommendations :

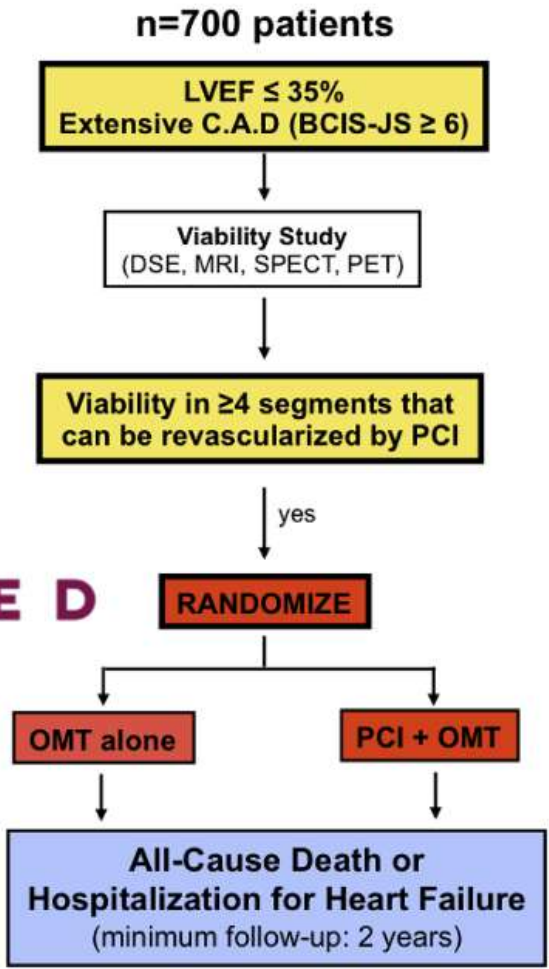
LV dysfunction and multivessel CAD



| | CABG | PCI |
|---------------------|---|---|
| ESC 2018 | CABG is recommended as the first revascularization strategy choice in pts with multivessel disease and acceptable surgical risk (IB) | In pts with 3-vessel disease, PCI should be considered based on the evaluation by the Heart Team of the pt's coronary anatomy, the expected completeness of revascularization, diabetes status, and comorbidities. (IIa C) |
| ACC/AHA 2021 | In pts with SIHD and multivessel CAD appropriate for CABG with severe LV systolic dysfunction (LVEF < 35%), CABG is recommended to improve survival (IB) | There are insufficient data to make recommendation |

Hypothesis of REVIVED-BCIS2 :
PCI in combination with OMT will improve event-free survival in pts with severe ischaemic LV dysfunction compared with a strategy of OMT alone.

Flow Chart



Primary outcome :

- All-cause death or hospitalization due to HF at ≥ 24 months

Major secondary outcomes :

- LVEF assessed by echocardiography at 6- & 12-months.
- QoL outcomes at 6-, 12- & 24-months
- NYHA Class

Other secondary outcomes :

- CV death, all-cause death, hospitalization due to HF, acute MI, ICD therapies, angina class, unplanned revascularisation, serial NT-proBNP levels, major bleeding

Inclusion criteria :

- LVEF \leq 35%
- Extensive coronary artery disease (BCIS-Jeopardy score \geq 6)
- Viability in \geq 4 myocardial segments that can be revascularized by PCI

Exclusion criteria :

- Acute MI $<$ 4 weeks previously
- Acute decompensated heart failure or sustained ventricular arrhythmias

Sample size :

700 Pts would provide $>$ 85% of power to detecte a HR of 0.70 for the primary outcome, if 300 experienced a primary event

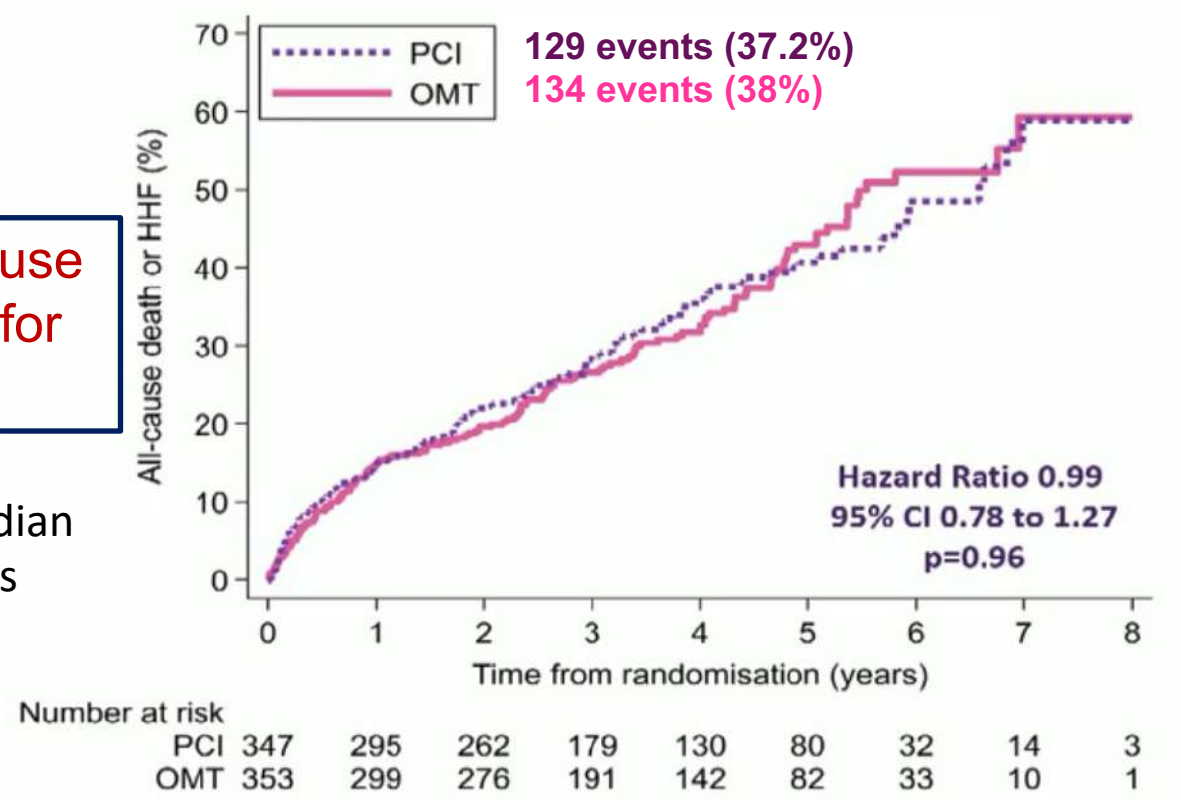
| | PCI (N = 347) | OMT (N = 353) |
|---|------------------|------------------|
| Age – yrs | 70.0 ± 9.0 | 68.8 ± 9.1 |
| Male sex – no. (%) | 302 (87) | 312 (88) |
| Hypertension – no. (%) | 184 (53) | 207 (59) |
| Diabetes – no. (%) | 136 (39) | 153 (43) |
| Left ventricular ejection fraction - % | 27.0 ± 6.6 | 27.0 ± 6.9 |
| Viability assessment – no. (%) | | |
| Cardiac MRI | 246 (71) | 247 (70) |
| Stress echocardiography | 91 (26) | 93 (26) |
| SPECT/PET | 14 (4) | 17 (5) |
| Coronary artery disease characteristics | | |
| Median BCIS jeopardy score (IQR) | 10 (8 to 12) | 10 (8 to 12) |
| Left main coronary artery disease – no. (%) | 50 (14) | 45 (13) |
| 3-vessel coronary artery disease – no. (%) | 133 (38) | 148 (42) |
| 2-vessel coronary artery disease – no. (%) | 178 (51) | 166 (47) |

| | PCI (N = 347) | OMT (N = 353) |
|---|--------------------|--------------------|
| Hospitalization for heart failure ≤ 2 years before randomization – no. (%) | 112 (32) | 121 (34) |
| NYHA functional class – no. (%) | | |
| Class I/II | 265 (77) | 248 (71) |
| Class III/IV | 80 (23) | 102 (29) |
| Heart failure medication – no. (%) | | |
| ACEi/ARB/ARNI | 305 (88) | 315 (89) |
| Beta-blocker | 315 (91) | 319 (90) |
| Mineralocorticoid receptor antagonist | 176 (51) | 170 (48) |
| Heart failure device - no. (%) | 85 (24) | 77 (22) |
| ICD | 47 (55) | 35 (45) |
| CRT-D | 32 (38) | 35 (45) |
| CRT-P | 6 (7) | 7 (9) |
| Median NT-proBNP - pg/ml (IQR) | 1376 (697 to 3426) | 1461 (712 to 3365) |

Primary outcome

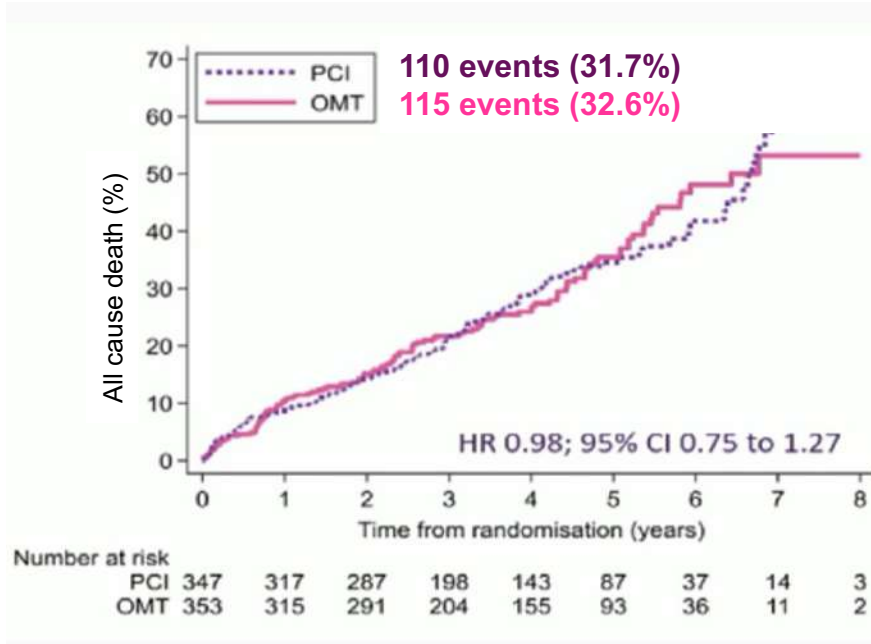
Death from any cause or hospitalisation for heart failure

Final follow-up at median 41 [28 - 60] months

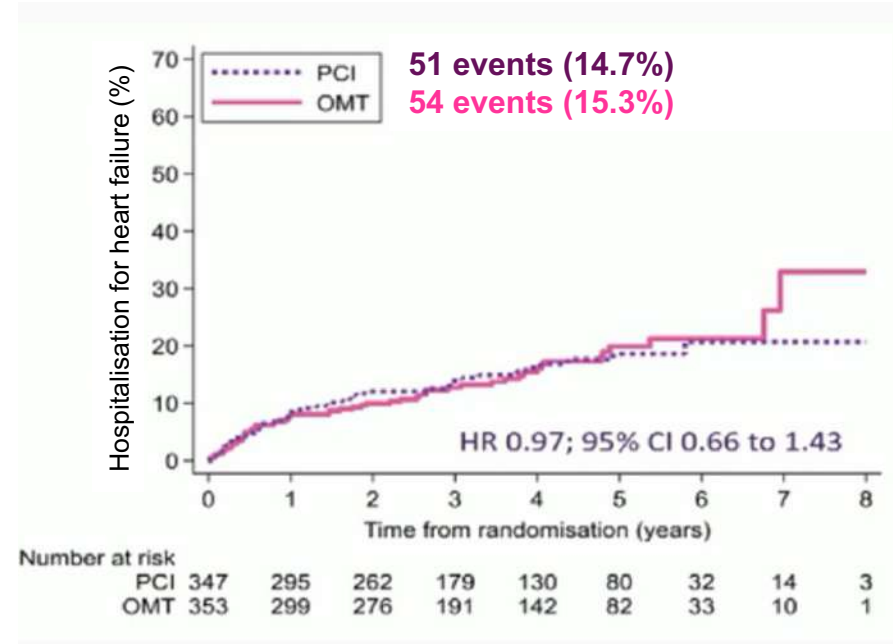


Components of primary outcome

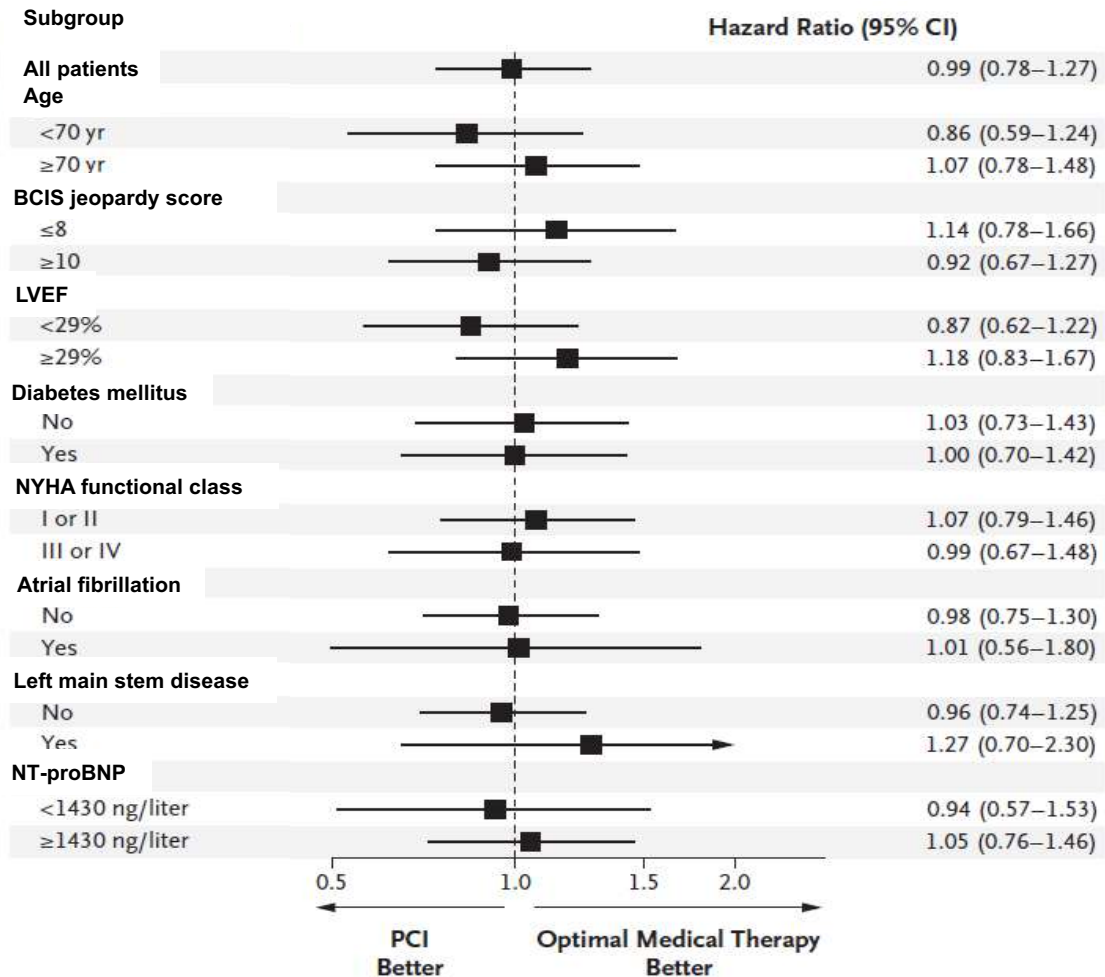
All cause death



Hospitalisation for heart failure



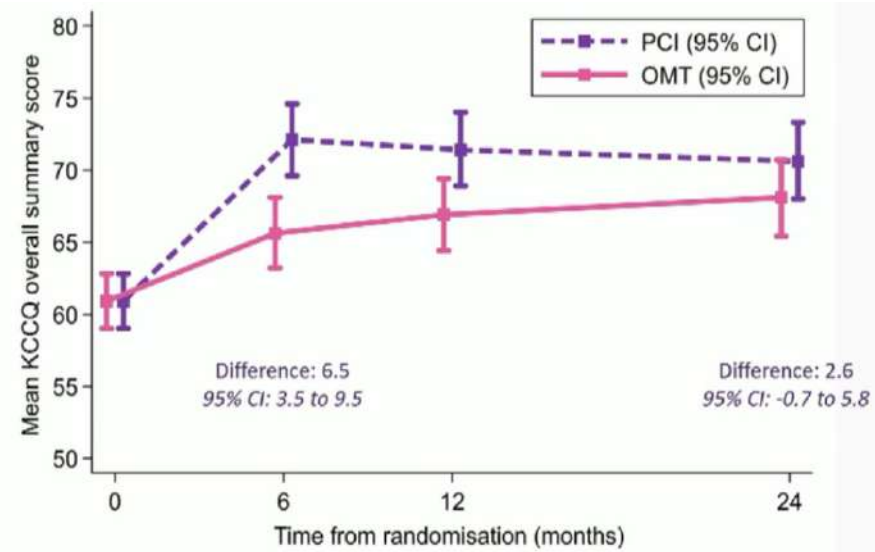
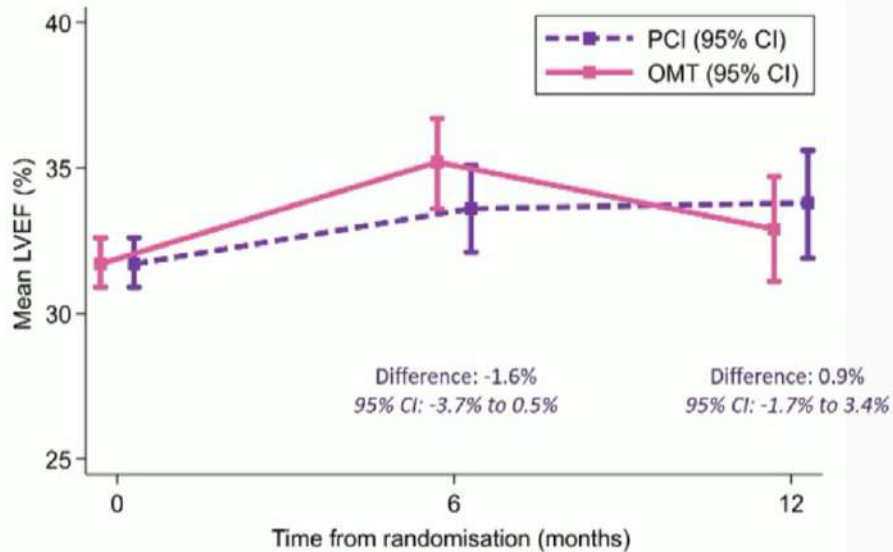
Primary outcome by prespecified subgroups



Major secondary outcome

LVEF

KCCQ Score

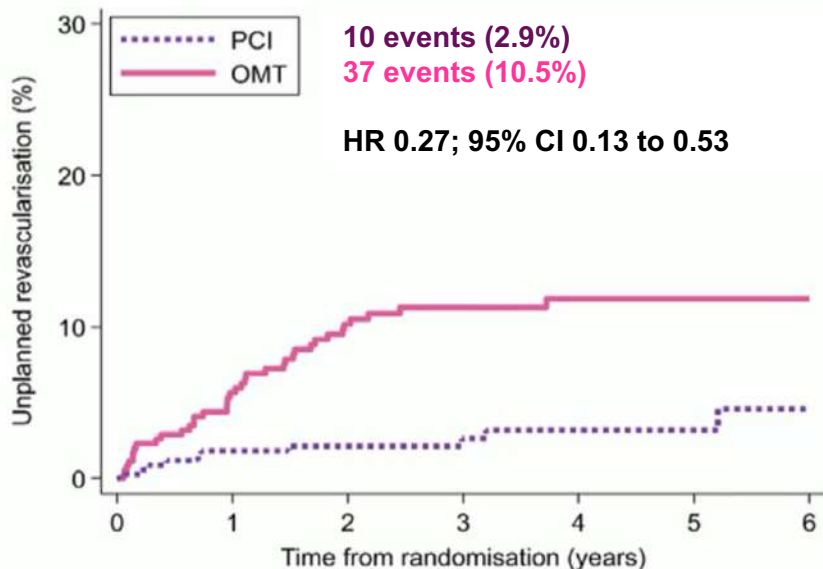


| Number followed up | | | | |
|--------------------|-----|-----|-----|--|
| PCI | 264 | 276 | 262 | |
| OMT | 276 | 264 | 267 | |

| Number followed up | | | | | |
|--------------------|-----|-----|-----|-----|--|
| PCI | 319 | 270 | 268 | 228 | |
| OMT | 318 | 285 | 268 | 228 | |

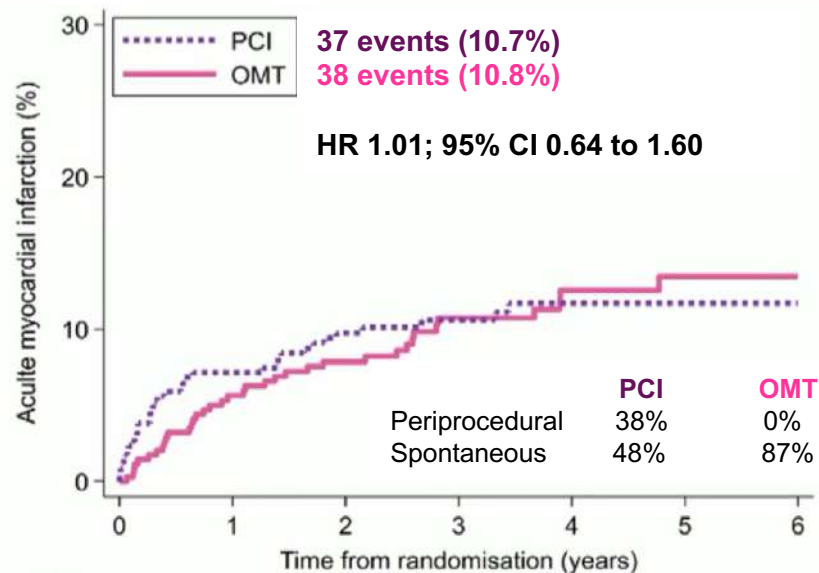
Secondary outcome

Unplanned revascularisation



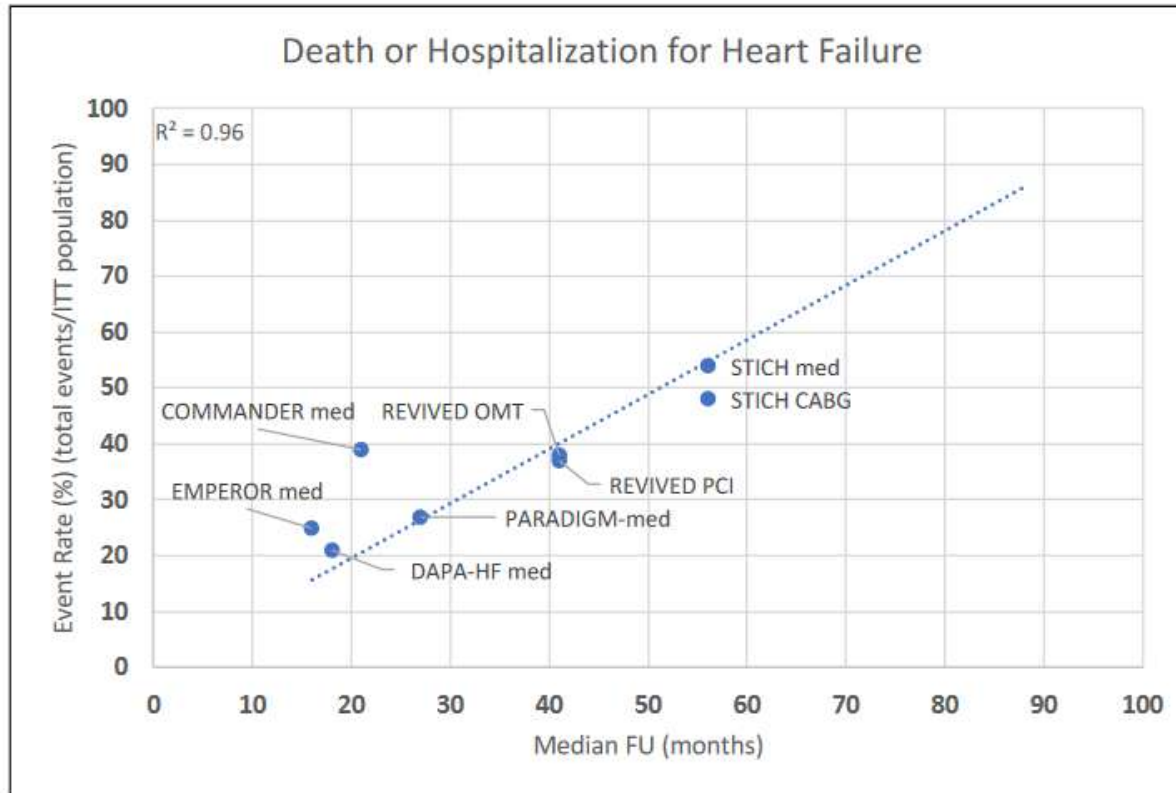
| Number at risk | | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|----------------|-----|-----|-----|-----|-----|----|----|---|
| PCI | 347 | 311 | 280 | 194 | 139 | 84 | 35 | |
| OMT | 353 | 300 | 264 | 184 | 143 | 84 | 31 | |

Acute myocardial infarction

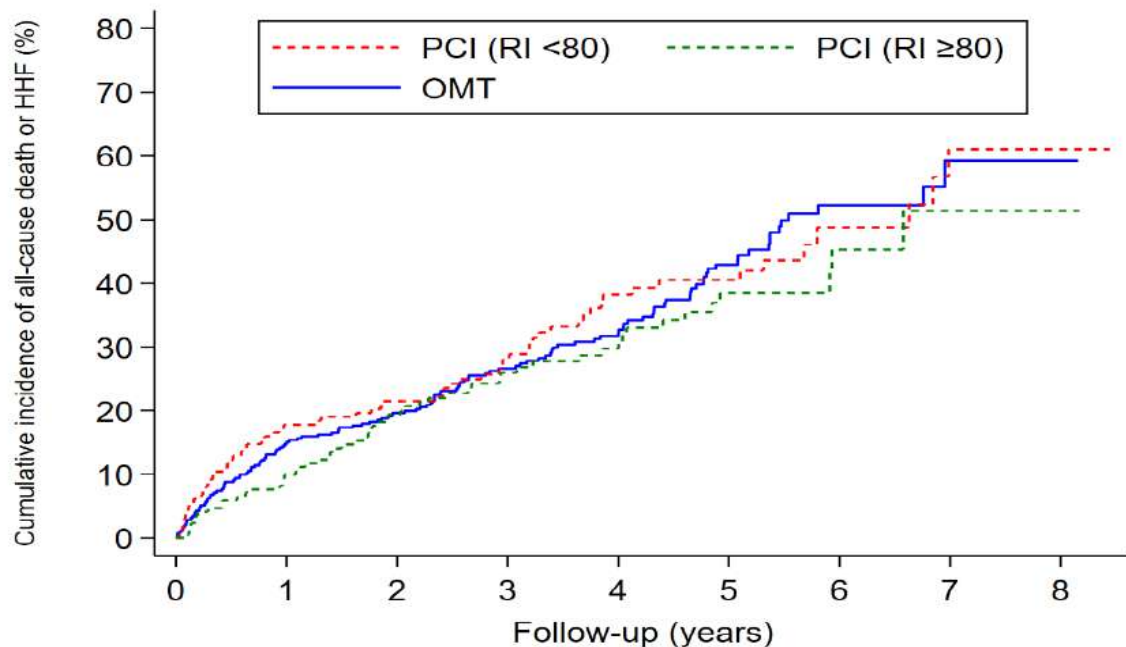


| Number at risk | | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|----------------|-----|-----|-----|-----|-----|----|----|---|
| PCI | 347 | 297 | 260 | 179 | 130 | 81 | 34 | |
| OMT | 353 | 302 | 276 | 190 | 142 | 83 | 31 | |

Event rates in REVIVED, STICH and other recent trials



Primary outcome by completeness of revascularization



Number at risk

| | | | | | | | | | |
|--------------|-----|-----|-----|-----|-----|----|----|----|---|
| PCI (RI <80) | 163 | 134 | 126 | 88 | 60 | 41 | 16 | 9 | 1 |
| PCI (RI ≥80) | 171 | 154 | 132 | 87 | 68 | 39 | 16 | 5 | 2 |
| OMT | 353 | 299 | 276 | 191 | 142 | 82 | 33 | 10 | 1 |

Comments

- REVIVED supports the importance of guideline-directed medical therapies for the management of LV dysfunction, irrespective of revascularization
- REVIVED challenges the paradigm of myocardial hibernation and corroborates that viability was not associated with the benefit of CABG (STICH trial)
- What about the long term impact of spontaneous MI in OMT group ?
- Is the observed CAD responsible for the LV dysfunction ?
 - half of the pts had only two-vessel disease
 - physiological assessment of the lesion ?
 - correlation of stenosis with previous ischemic or viability testing ?
- Cannot exclude that pts with the most extensive and severe CAD were offered surgical revascularization (STICH trial)

Take Home message

Patients with ischaemic cardiomyopathy continue to have high rates of mortality and hospitalisation for heart failure, even with contemporary medical and device therapy

Percutaneous coronary intervention did not reduce the composite incidence of all-cause death or hospitalisation for heart failure at a median of 3.4 years

Percutaneous coronary intervention did not incrementally improve left ventricular ejection fraction or provide a sustained difference in quality of life