

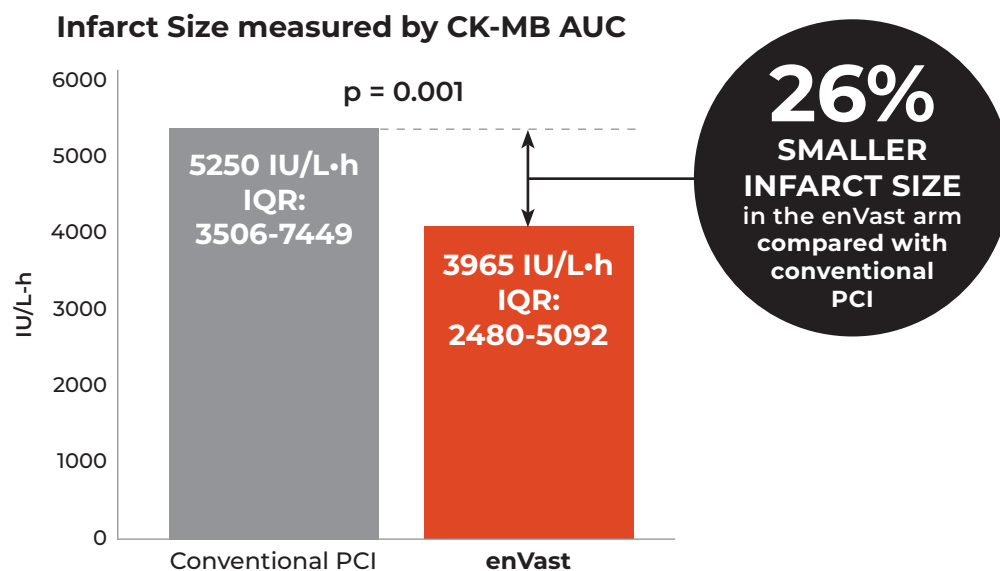
A Randomized Clinical Trial Evaluating enVast™ Mechanical Coronary Thrombectomy in STEMI Patients with Large Thrombus Burden

Valgimigli, M, Frigoli, E, Landi, A. et al. Stent Retriever Thrombectomy in Patients With Myocardial Infarction The Open-label, Multicenter NATURE Superiority trial. *JACC. null*2026, 0 (0). <https://doi.org/10.1016/j.jacc.2026.08.034>

TRIAL OBJECTIVE

A randomized clinical trial evaluating enVast coronary thrombectomy and PCI to conventional PCI in STEMI patients with large thrombus burden.

PRIMARY ENDPOINT



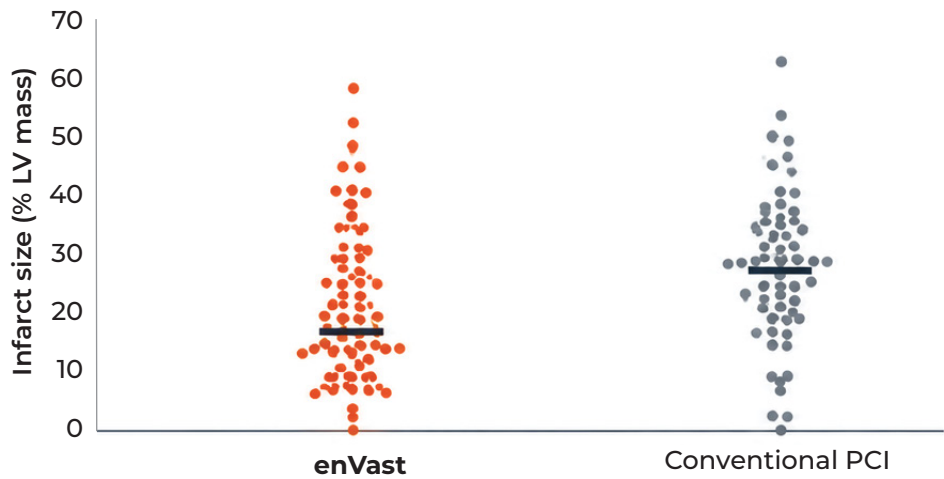
SAFETY MEASURES

	enVast (N = 78)	Conventional PCI (N=78)
MACE - no. (%)	1 (1.3)	3 (3.8)
Death - no. (%)	0 (0)	2 (2.6)
MI - no. (%)	1 (1.3)	1 (1.3)
Stroke - no. (%)	0 (0)	2 (2.6)
Stent thrombosis - no. (%)	0 (0)	1 (1.3)
BARC Bleeding - no. (%)	34 (3.8)	35 (10.3)
Vessel dissection/perforation - no. (%)	0 (0)	0 (0)

SECONDARY ENDPOINTS

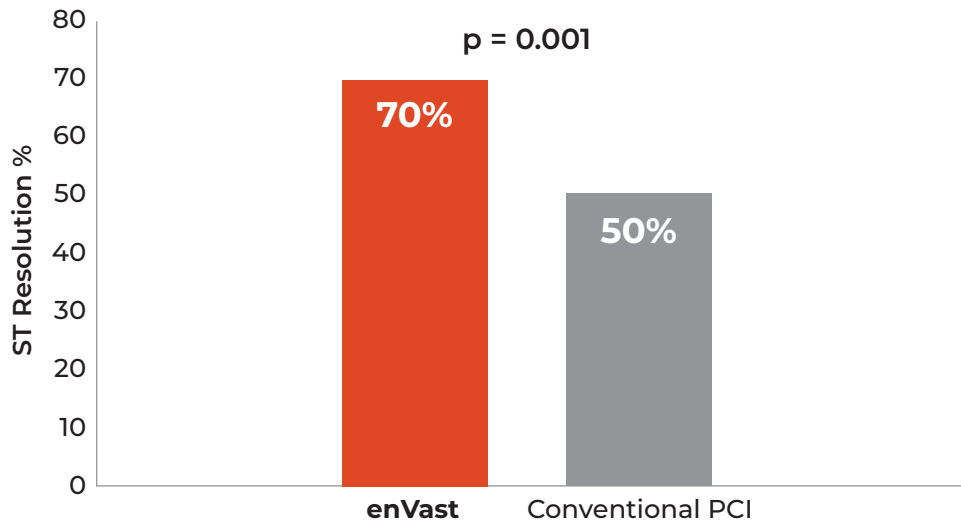
Infarct size measured by CMR at day 3, N=123 (79%)

17% vs. 28% Difference = -7 (95% -12 to -2)



25%
SMALLER
INFARCT SIZE
in the enVast
group

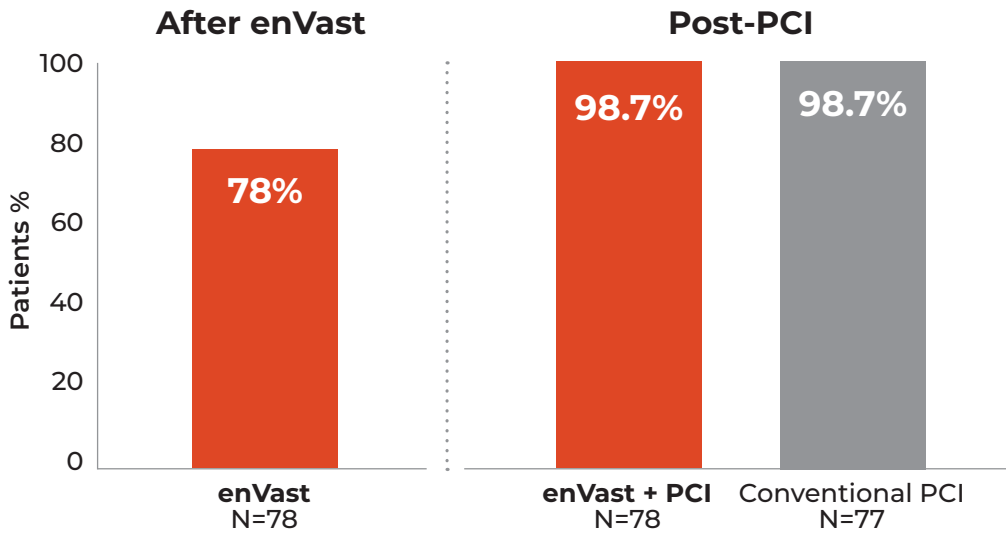
Complete ST-segment resolution measured by ECG



70%
COMPLETE
ST-SEGMENT
RESOLUTION
in the enVast
group

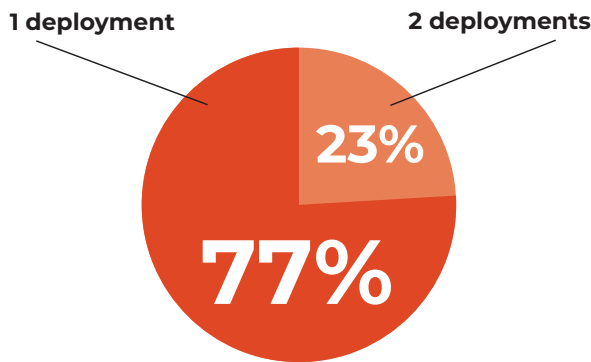
RECANALIZATION & REPERFUSION

TIMI 2-3
Core Lab Adjudicated

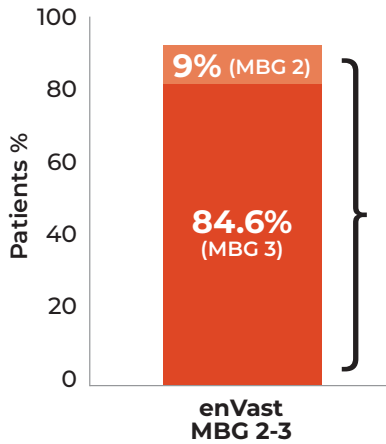


78%
IMMEADIATE
REPERFUSION
after
enVast

enVast Deployments



MBG Post-PCI



93%
MYOCARDIAL
BLUSH GRADE
2-3

TRIAL CONCLUSION

In STEMI patients with large thrombus burden undergoing primary PCI within 8 hours of symptom onset, enVast assisted mechanical thrombectomy, compared with conventional PCI, was associated with reduced infarct size.

TRIAL DESIGN & RIGOR

- 156 patients, randomized 1:1, in an open-label, multicenter, superiority trial
- Conducted at 11 centers across Switzerland, Italy and the Netherlands
- STEMI patients presenting within 8 hours of symptom onset
- TIMI thrombus grade ≥ 3 in the infarct-related artery
- All MRI images and ECGs were assessed in a blinded manner by independent core laboratories
- Clinical safety events independently adjudicated by reviewers blinded to treatment assignment

BASELINE AND PROCEDURAL CHARACTERISTICS

Baseline Characteristics	enVast (N = 78)	Conventional PCI (N=78)	Procedural Characteristics	enVast (N = 78)	Conventional PCI (N=78)
Age - yr	62.5 (56-71)	62.5 (55-75)	Multivessel disease - no. (%)	41 (52.5)	62 (43.6)
Male sex - no. (%)	63 (80.8)	62 (79.5)	IRA-Right Coronary - no. (%)	34 (43.6)	35 (44.9)
Killip II, III or IV - no. (%)	11 (14.1)	12 (15.4)	IRA-Left Ant. Descending - no. (%)	31 (39.7)	32 (41.0)
Prior MI - no. (%)	1 (1.3)	3 (3.8)	IRA-Left Circumflex - no. (%)	13 (16.7)	12 (15.4)
Symptom Onset to Rx > 3h - no. (%)	30 (38.5)	31 (39.7)	Manual thrombectomy - no. (%)	2 (2.6)*	31 (39.7)*
			Direct stenting - no. (%)	51 (68.0)*	24 (31.2)*
			Post-dilatation - no. (%)	39 (52.0)	51 (66.2)
			Total amount of contrast - (ml)	150 (100-200)	140 (100-180)

* Denotes $p < 0.05$

Read the full NATURE publication
in JACC:



Indication: The enVast Thrombectomy Device is indicated for the non-surgical removal of thrombus burden from coronary blood vessels; use with adjunctive aspiration and with the injection or infusion of contrast media and other fluids.

Precaution: The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention. Prescription use only. Please see www.vesalio.com for indications for use, contraindications, warnings, precautions, and potential adverse events. For complete information, including detailed instructions for use, please refer to the Instructions for use.

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