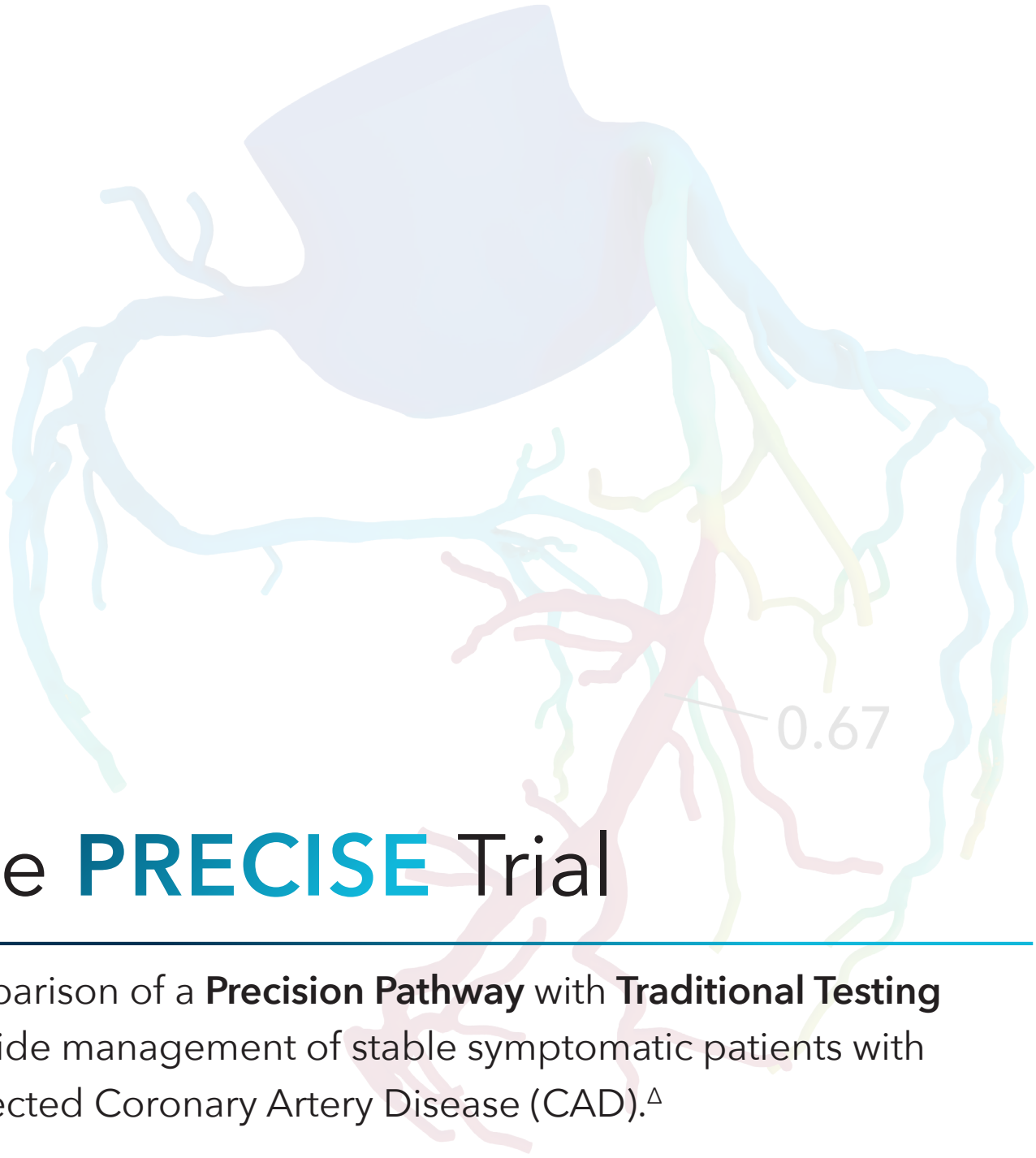
HeartFlow®



The **PRECISE** Trial

Comparison of a **Precision Pathway** with **Traditional Testing** to guide management of stable symptomatic patients with suspected Coronary Artery Disease (CAD).[Δ]

173956835 V1

1-Year Primary Endpoint Results

Primary Endpoint: Composite of death, nonfatal MI or ICA without obstructive CAD

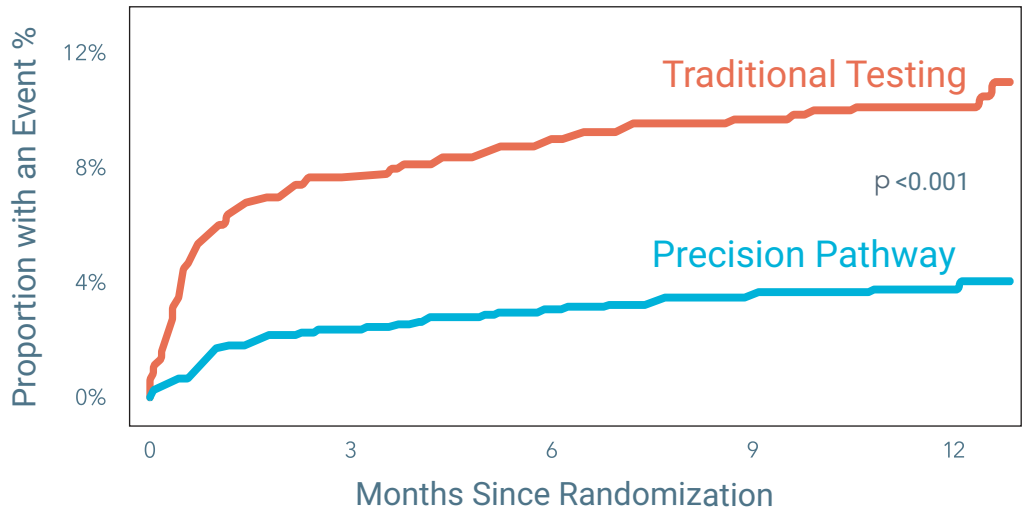
The Precision Pathway, centered around CCTA+/-FFR$_{CT}$, achieved its primary endpoint with a 70% reduction, relative to Traditional Testing, of the composite of all-cause death, nonfatal MI, or catheterizations without obstructive disease at 1 year.

Precision Pathway

- **Risk scoring** to defer testing for low-risk patients.*
- **CCTA with selective FFR$_{CT}$**† for elevated risk patients.

Traditional Testing

Functional Testing (stress nuclear and stress echo) and **Invasive Coronary Angiography** (ICA).



Number at risk					
Precision Pathway	1057	997	971	945	431
Traditional Testing	1046	922	898	869	421

1-Year Results	Precision Pathway (N=1057)	Traditional Testing (N=1046)
Primary Endpoint Composite§	**4.2% (44)**	**11.3% (118)**
All-Cause Death	**0.5% (5)**	**0.7% (7)**
Nonfatal MI	**1.2% (13)**	**0.5% (5)**
ICA w/o Obstructive CAD	**2.6% (27)**	**10.2% (107)**
Death or MI	**1.7% (18)**	**1.1% (12)**

§ Adjusted Hazard Ratio 0.29, p<0.001

Key Findings

The Precision Pathway is the preferred diagnosis and treatment pathway.

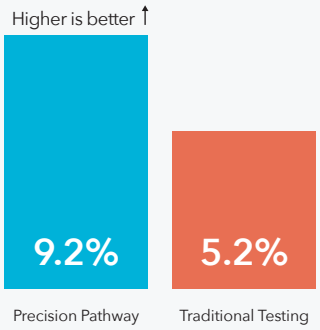
More Accurate Non-Invasive Diagnosis

Fewer False Negatives

78%

more likely to identify patients in need of revascularization

p<0.001

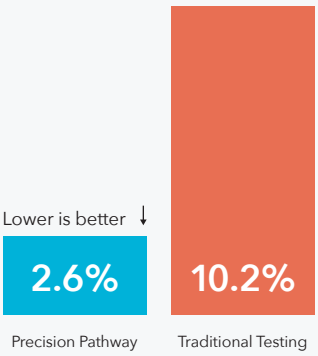


Fewer False Positives

4X

less likely to have ICA without obstructive disease

p<0.001

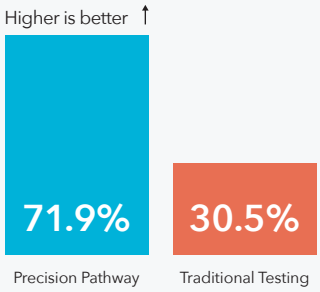


Diagnostic Cath Yield for Revascularization

2X

yield of ICA leading to revascularization

p<0.001



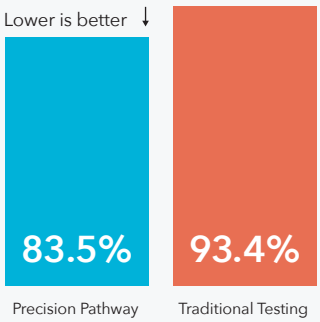
Fewer Unnecessary Tests

Fewer Initial Tests

10%

fewer initial tests conducted by safely deferring with patient risk stratification

p<0.001



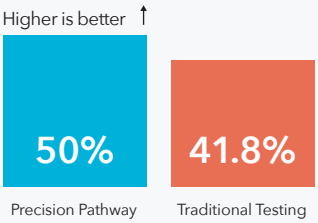
Reduced Long-Term Risk by Increasing Preventive Therapies ¶

Lipid-lowering Agent Use

20%

more patients prescribed lipid-lowering agents

p<0.001

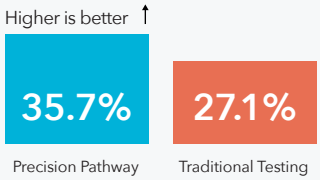


Antiplatelet Agent Use

32%

more patients prescribed antiplatelet agents

p<0.001



Level 1 Evidence

Prospective Randomized Controlled Trial

65
Global Sites

2,103
Patients

Adjudicated
Core Lab & CEC◊

This landmark study confirms the CCTA+FFRCT-centered strategy, supported by the AHA/ACC Guidelines, is superior to traditional diagnostic pathways including invasive angiography or stress testing for patients with stable chest pain or equivalent symptoms requiring testing for suspected CAD.

Trial Design

Patients with non-acute chest pain or the equivalent requiring testing for suspected CAD.
No history of obstructive CAD or CAD testing < 1 year: N=2103

1:1 Randomization

Precision Pathway
N=1057
Care Pathway assigned by PROMISE Minimal Risk Score*

Low Risk → **Deferred Testing** 21%

Elevated Risk → **CCTA +/- FFRCT**† 79%

Traditional Testing
N=1046
Modality selected by site clinician

→ **Functional Testing or Direct to Cath**

All subsequent medical care and testing decisions made by site clinician.
Guideline-directed medical management recommended for all.

Primary Endpoint (1-Year)
Death, Nonfatal MI, Cath without Obstructive CAD

Secondary Endpoints
Death, Nonfatal MI, Unplanned CV Hospitalizations, Preventive Medication Use, Radiation, Cath Yield, Resource Use, Quality of Life

References

*Patient risk was determined using the PROMISE Minimal Risk Score.
PROMISE variables include: age, sex, ethnicity, smoking history, diabetes mellitus, dyslipidemia, family history of premature coronary artery disease, hypertension, symptoms related to stress and high-density lipoprotein (HDL) concentration.

†For stenoses 30-90%

¶Joshi, et al. JAMA 2021

◊Clinical Events Committee (CEC)

Δ Douglas, et al. The PRECISE Trial. Presented at AHA Scientific Sessions 2022.