

AURORA phase 3 clinical trial

Objective

Evaluate diagnostic efficacy of flurpiridaz F-18 PET MPI for detection of CAD

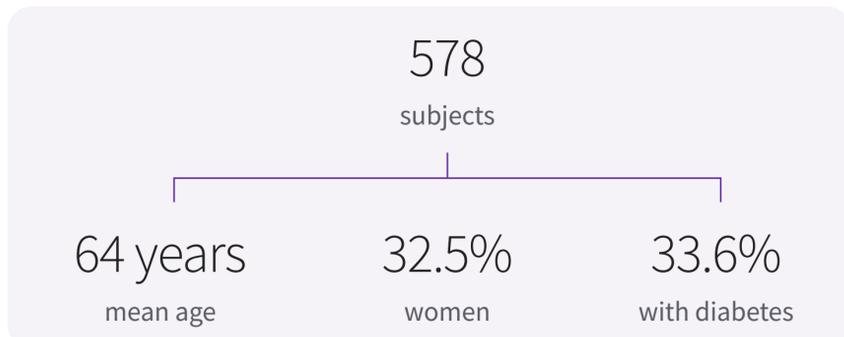
Design

- Prospective, open-label, multicenter study
- Head-to-head comparison vs Tc-99m SPECT MPI

Study population

578 evaluable patients

Clinical Status: Participants were adult patients with suspected coronary artery disease (CAD) who were referred for a clinically indicated invasive coronary angiography (ICA).



Primary endpoints

- Sensitivity for ≥50% coronary stenosis
- Specificity (non-inferiority)
- Overall diagnostic accuracy (ROC AUC)

Key results (blinded readers)

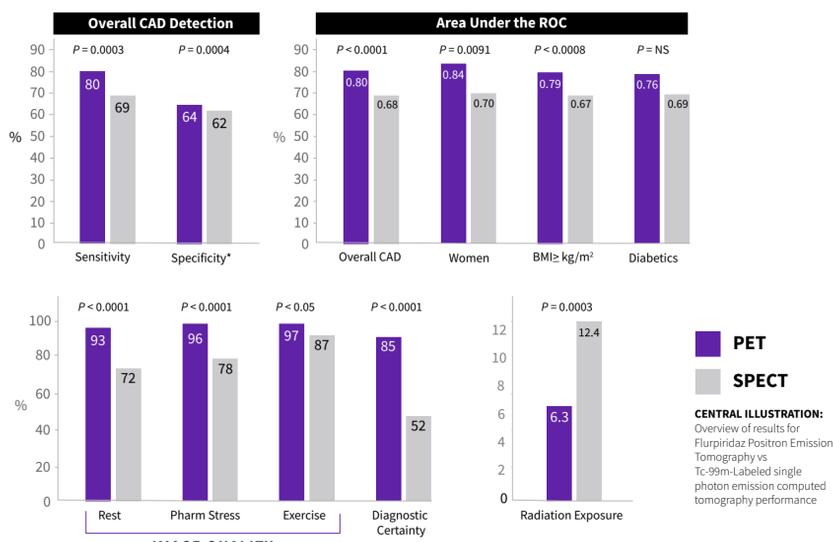
Metric	Flurpiridaz	PET Tc-99m SPECT
Sensitivity	80.3%	68.7%
Specificity	63.8%	61.7%
ROC AUC	0.80	0.68

Diagnostic performance

- **Sensitivity:** Flurpiridaz PET had higher sensitivity than SPECT (~80.3% vs 68.7%; P = 0.0003)
- **Specificity:** Flurpiridaz PET had non-inferior specificity compared with SPECT (~63.8% vs 61.7%; P = 0.0004)
- **ROC Area:** The area under the ROC curve was significantly greater for flurpiridaz PET than SPECT in the overall population (0.80 vs 0.68) — indicating improved overall diagnostic accuracy
- **Patient subgroups:** Sensitivity was also significantly higher compared to SPECT in women, and in patients with BMI ≥30 kg/m²

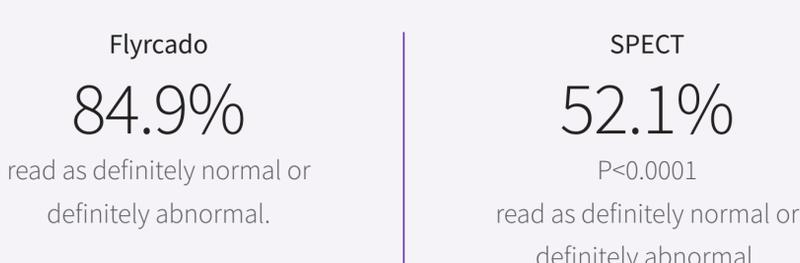
KEY RESULTS

18F-flurpiridaz positron emission tomography vs Tc-99m-labeled single photon emission computed tomography performance



Greater CAD diagnostic certainty

Flyrcado was associated with higher diagnostic certainty



Flyrcado was associated with significantly higher diagnostic certainty (84.9%) over SPECT (52.1%; P < 0.0001)⁸

Results from AURORA Phase 3 prospective multicenter clinical study. Flyrcado PET MPI (N=578) | SPECT MPI (N=578)

"AURORA is lighting the way to an exciting new era in cardiac imaging."

Jamieson M. Bourque, MD.

Journal of the American College of Cardiology

REFERENCES

1. Flurpiridaz F-18 PET myocardial perfusion imaging in patients with suspected coronary artery disease Maddahi et al, JACC. 2023 Oct, 82 (16) 1598–1610