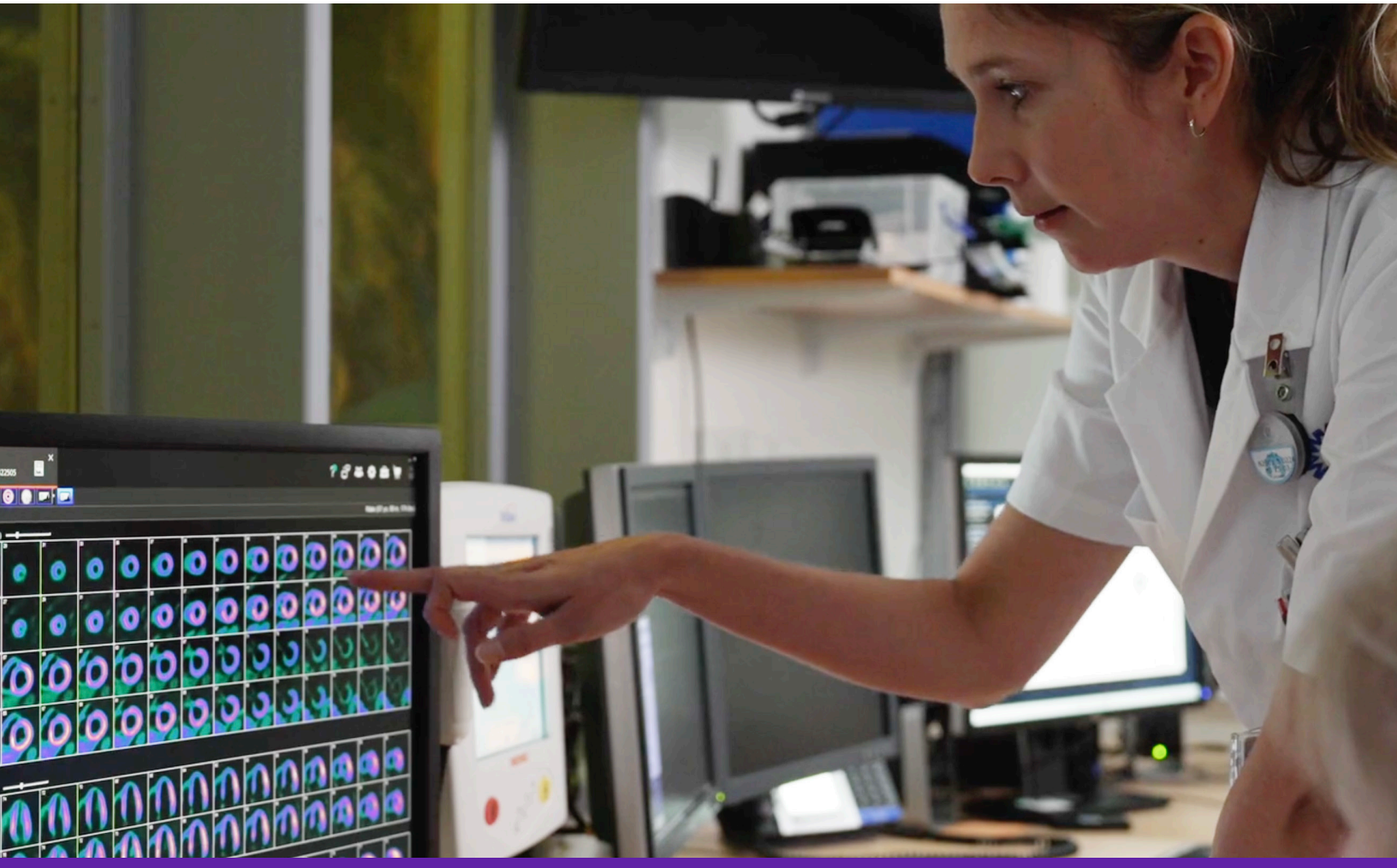
GE HealthCare

Case Study

Imaging patient with three-vessel disease using Flyrcado

FLYRCADO™
flurpiridaz F 18 injection



Please see page 5 for Flyrcado Important Safety Information and the full Prescribing Information here

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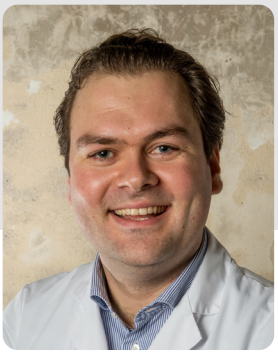

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Patient Medical History

Gender	Male
Age	67 years
BMI	33.8
Risk factors	Smoking 2 packs a day, type 2 diabetes, obesity
History	Peripheral artery disease Abdominal aortic aneurysm

Medical history of the patient

The patient presented with stable angina, characterized by exertional chest pain that was relieved with rest. The patient had a high cardiovascular risk profile.

Pre-diagnostics

No prior cardiac imaging has been performed.

Indication

Flyrcado PET is indicated in this case to assess myocardial perfusion, evaluate the extent and severity of ischemia, and guide revascularization decisions.

Images and content presented here are courtesy of Dr. Arthur Braat and Dr. Marjolein Hol

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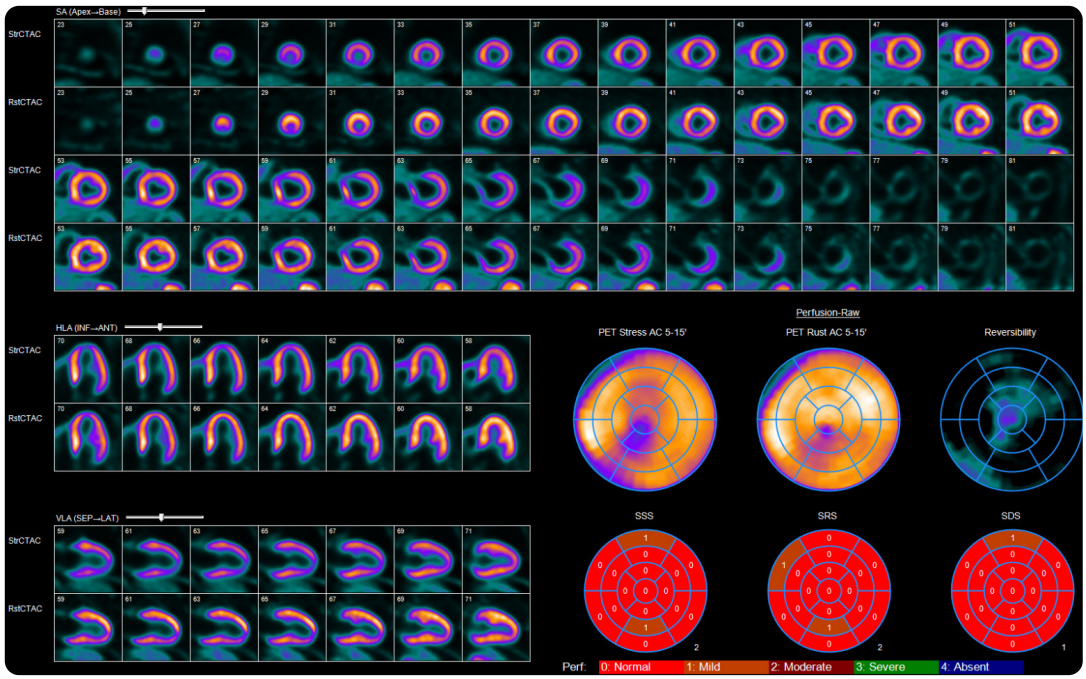
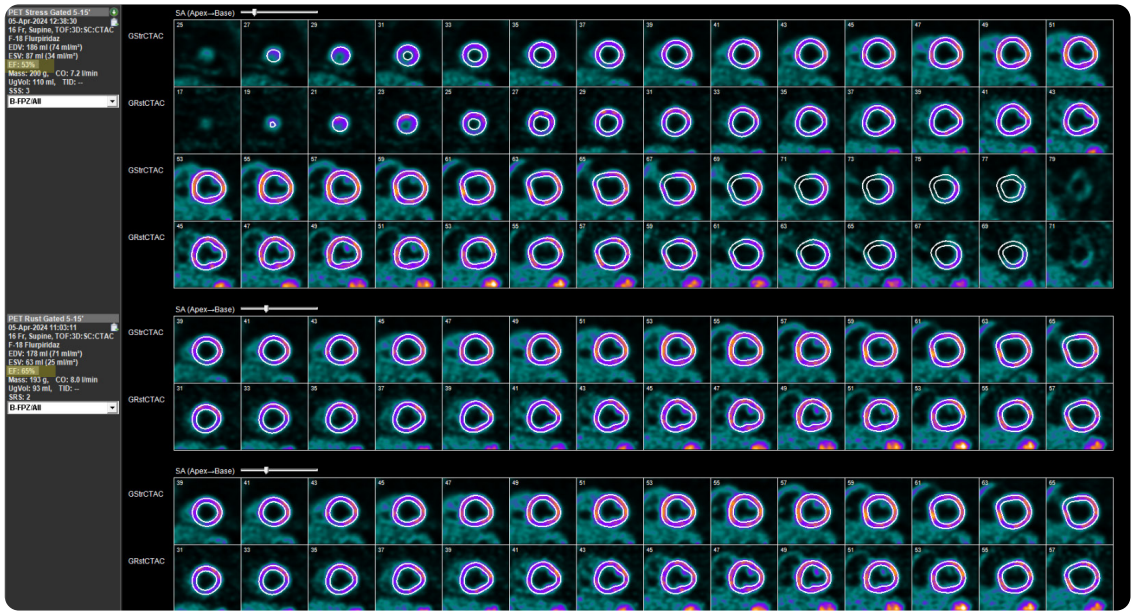
Imaging

PET MPI

Rest-stress pharmacologic protocol with CT attenuation



During stress imaging, there is heterogeneous uptake of the radiotracer in the myocardium, with mild hypoactivity in the inferoseptal wall. Radiotracer distribution is normal at rest.



There is a decrease in left ventricular ejection fraction during stress (e.g., 53%), compared to rest imaging (e.g., 65%).

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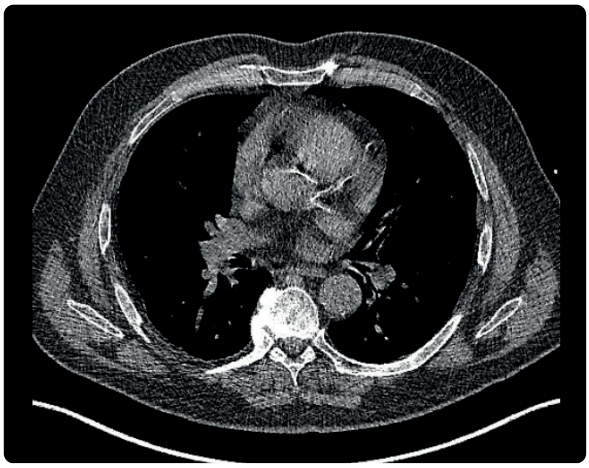

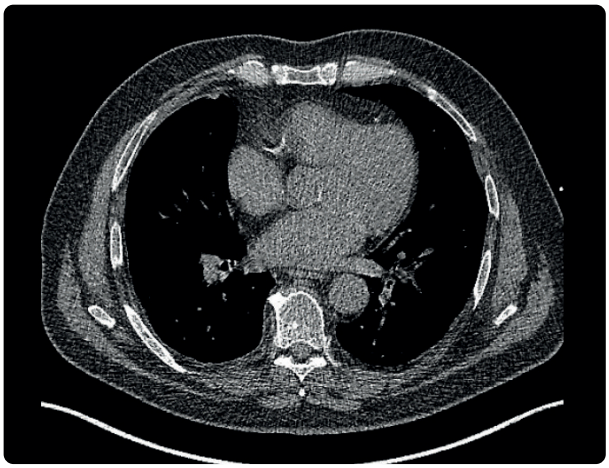

Coronary calcifications are present in all three coronary arteries.

Imaging findings

Heterogeneous activity is observed in the myocardium during stress, with mild hypoactivity in the inferoseptal wall. There is a decrease in left ventricular ejection fraction during stress, along with extensive coronary calcifications in all three coronary arteries.

Diagnosis

Findings are suggestive of three-vessel disease.

Therapy/Follow up

The patient underwent coronary angiography, which showed:

- Chronic total occlusion of the right coronary artery
- Significant stenosis (>70%) of the left main and left anterior descending artery.

Findings confirm severe multi-vessel coronary artery disease.

Patient was referred for coronary artery bypass grafting (CABG).

This case represents an example of a patient with three-vessel disease.

Key takeaways:

- Revealing severe multi-vessel disease in a high-risk patient
  - Flyrcado PET detected balanced ischemia, which can be challenging to identify with other non-invasive tests.
- Avoiding delayed or suboptimal management
  - Flyrcado PET findings necessitated urgent coronary angiography, which confirmed severe multi-vessel disease and led to immediate referral for CABG to ensure timely revascularization and reduce the risk of adverse cardiac events.

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IMPORTANT SAFETY INFORMATION

Indications and Usage
FLYRCADO is a radioactive diagnostic drug indicated for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress (pharmacologic or exercise) in adult patients with known or suspected coronary artery disease (CAD) to evaluate for myocardial ischemia and infarction.

Contraindications
None

Warnings and Precautions
- Risk associated with exercise or pharmacologic stress: Patients evaluated with exercise or pharmacologic stress may experience serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction, stroke, and seizure. Perform stress testing in the setting where cardiac resuscitation equipment and trained staff are readily available. When pharmacologic stress is selected as an alternative to exercise, perform the procedure in accordance with the pharmacologic stress agent's prescribing information.
- Radiation risks: FLYRCADO contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to minimize radiation exposure to patients and health care providers. Advise patients to hydrate before and after administration and to void.

Adverse Reactions
- Most common adverse reactions occurring during FLYRCADO PET MPI under rest and stress (pharmacologic or exercise) (incidence ≥ 2%) are dyspnea, headache, angina pectoris, chest pain, fatigue, ST segment changes, flushing, nausea, abdominal pain, dizziness, and arrhythmia.

Use in Specific Populations
Pregnancy: There are no data on use of flurpiridaz F 18 in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from flurpiridaz F 18 and the gestational timing of exposure. FLYRCADO contains ethanol (a maximum daily dose of 337 mg anhydrous ethanol). If considering FLYRCADO administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes associated with ethanol exposure during pregnancy.
Lactation: Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 8 hours after FLYRCADO administration.
Pediatric Use: Safety and effectiveness of FLYRCADO in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800-654-0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800-FDA-1088 or www.fda.gov/medwatch.

Flyrcado Reimbursement Support Line: 800 729 0701

Medical Affairs: 800 654 0118
(option 2, then option 3) or
medical.affairs@gehealthcare.com

Customer Service: 800 292 8514

gehealthcare.com

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