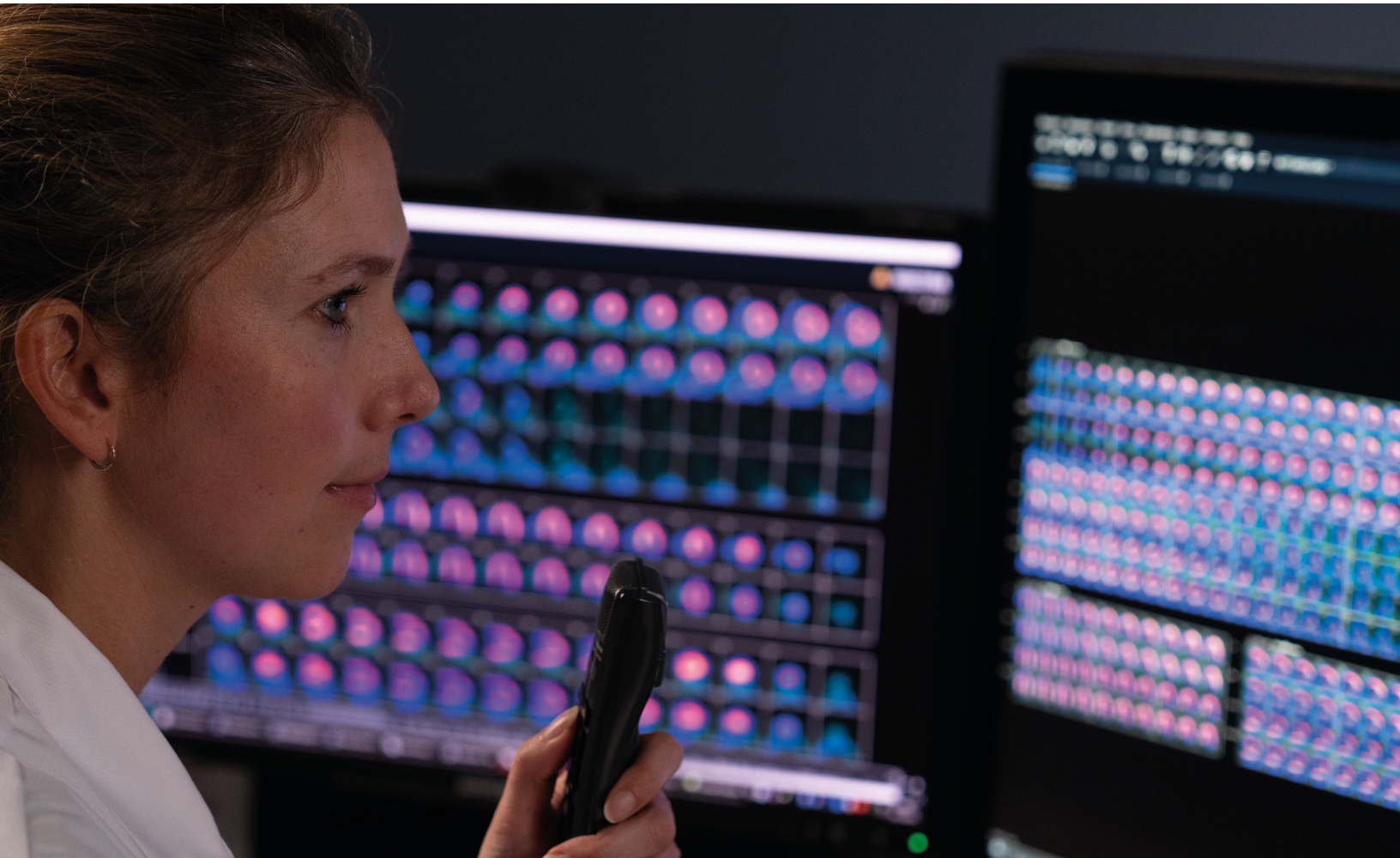




GE HealthCare

Case Study

Enhancing Diagnostic Certainty: Flyrcado PET MPI after inconclusive SPECT MPI



Flyrcado™ (flurpiridaz F 18) injection

Enhancing Diagnostic Certainty: Flyrcado PET MPI after inconclusive SPECT MPI



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Patient Medical History

Gender	Male
Age	75 years
BMI	23.7
Risk factors	Type 2 diabetes, hypercholesterolemia
History	Ischemic cardiomyopathy, heart transplant in 2014

Medical history of the patient

The patient presented for a routine 10-year post-heart transplant check-up. The patient experienced no thoracic complaints.

Pre-diagnostics

A myocardial SPECT in November 2023 was inconclusive due to high subdiaphragmatic activity.

A myocardial SPECT in 2017 showed no signs of ischemia or infarction and a good ejection fraction (>60%).

Indication

Flyrcado PET is indicated due to the inconclusive myocardial SPECT to assess myocardial perfusion and rule out ischemia from cardiac allograft vasculopathy

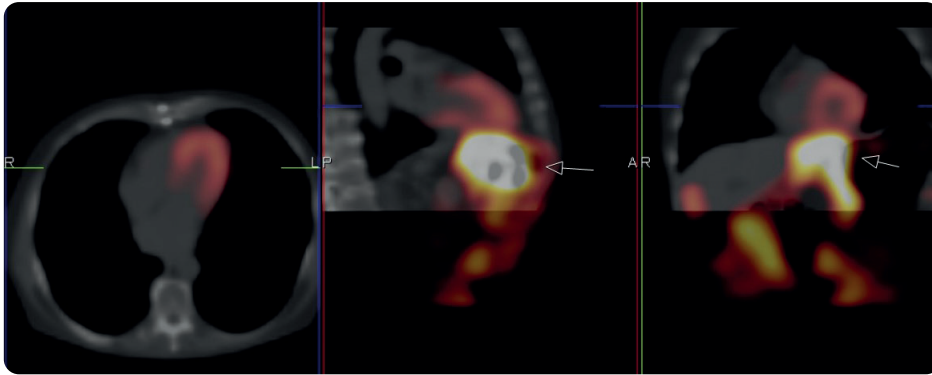
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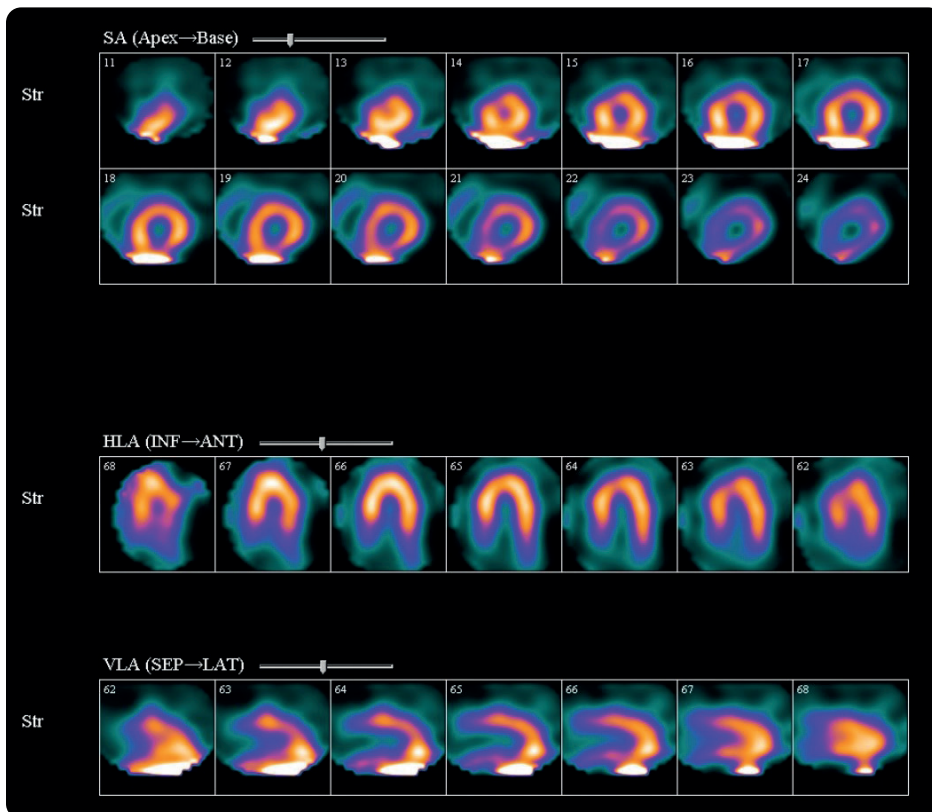
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Imaging

SPECT MPI



SPECT and CT fusion images show high subdiaphragmatic activity



The subdiaphragmatic activity interferes with the interpretation of the SPECT images, leading to suboptimal delineation of the inferior wall. As a result, the scan is inconclusive.

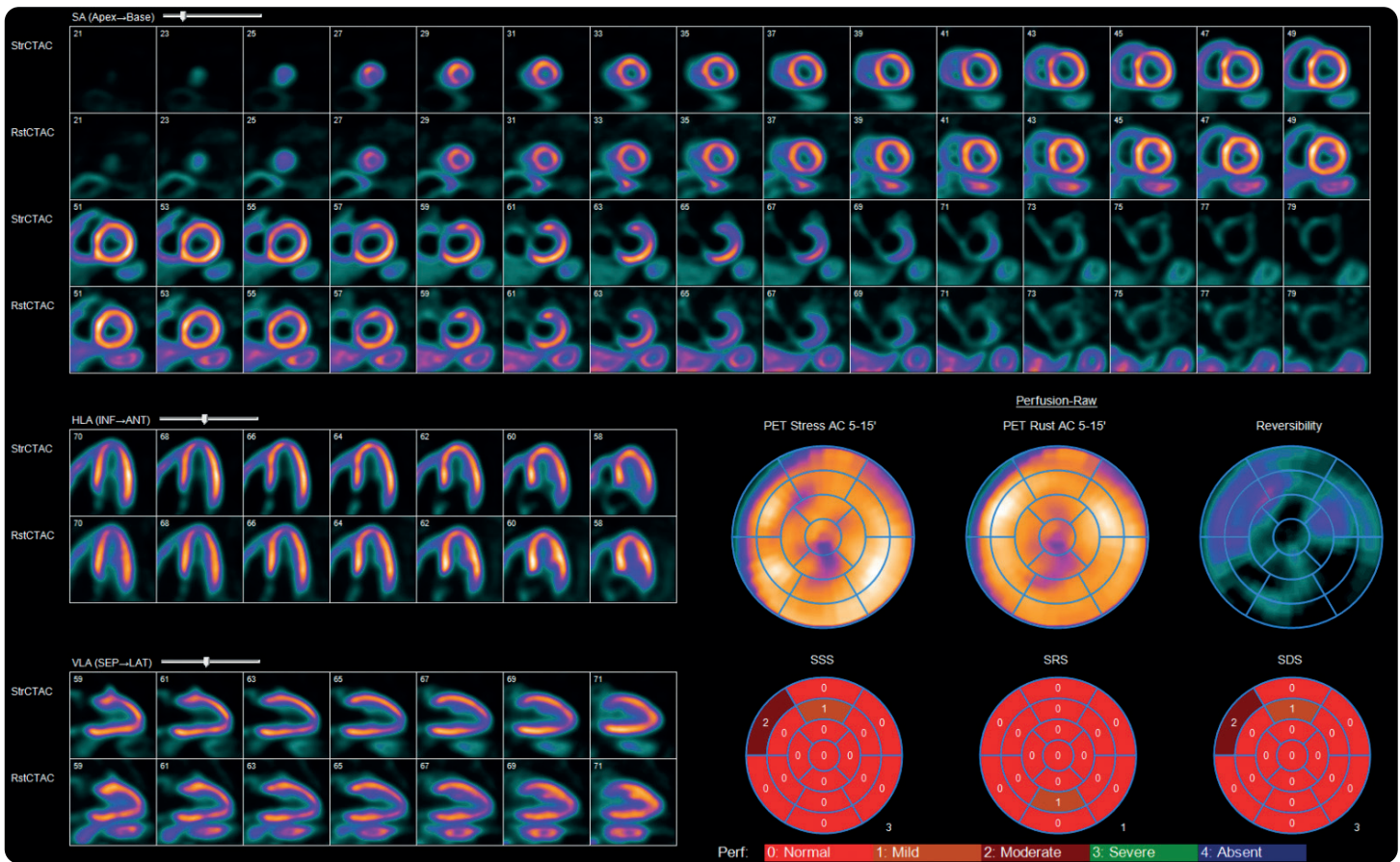
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Imaging

PET MPI

Rest-stress protocol with CT attenuation



In rest imaging, there is subdiaphragmatic activity, which does not interfere with image quality. Both stress and rest imaging show homogeneous activity of the radiotracer in the myocardium, with no perfusion defects.

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Imaging findings

Myocardial perfusion imaging shows a homogeneous distribution of radiotracer during both stress and rest, with no evidence of perfusion defects.

Diagnosis

Routine check-up myocardial PET shows no signs of ischemia or infarction.

Therapy/Follow up

The patient remains under the care of the cardiologist.

This case represents an example where myocardial SPECT results are inconclusive due to subdiaphragmatic activity. Flyrcado, with its high resolution, does not suffer from interference caused by abdominal activity.

Additionally, this case involves a patient following heart transplantation.

Key takeaways:

- High-resolution imaging for accurate myocardial perfusion assessment
 - Flyrcado PET provided superior resolution, allowing for more precise assessment of myocardial perfusion, even in the presence of abdominal interference, where SPECT is limited by subdiaphragmatic uptake.
- Reliable assessment of myocardial perfusion in post- heart transplant patients
 - Flyrcado PET provided an accurate evaluation of myocardial perfusion in post-heart transplant patients, allowing for early detection of ischemic changes or allograft dysfunction, even in the absence of thoracic symptoms, ensuring proactive management.

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 \geq 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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