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Issue Highlights

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Myocardial Perfusion Imaging by PET with Myocardial Blood Flow is Proving to be the Gatekeeper for Identifying Physiologic Severity of CAD by Guiding Treatment with Invasive Procedures and Revascularization – So Why is Adoption Limited?

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1. Introduction

Positron emission tomography (PET) myocardial perfusion imaging (MPI) with quantitative myocardial blood flow (MBF) has become the scientific standard for assessing coronary artery disease (CAD) severity, including diffuse and microvascular disease. It guides surgical intervention and ensures the safety of lifestyle-medical treatment. There are definitive scientific reports supporting the reliance on the modality, but many limitations on implementation persist. The wide acceptance of PET MPI MBF is hindered by factors such as the need for capital investment by hospitals and clinics, hardware and software limitations that scanner manufacturers have not addressed, gaps in technologist and physician education, and inconsistencies in MBF software.

The nuclear medicine stress test has been instrumental in helping cardiologists evaluate and monitor patient symptoms to identify which patients could benefit from invasive evaluation and therapy since the mid-70s. Thallium-201 (Tl-201) was the first myocardial perfusion tracer used for stress, rest, and viability in a single injection. However, its low gamma emission results in lower image quality and higher radiation exposure compared to the Tc-99m or PET tracers that followed. It also requires a scan time of 4 to 24 hours. Hibernating myocardium is still identified with Tl-201 today but is not commercially available in the United States. Cardiac MRI, PET, or dobutamine ECHO are the alternatives for assessing for hibernating myocardium, which have variable availability.

The Tc-99m perfusion tracers came to market in the 90s with a higher gamma peak and a shorter half-life than Tl-201allowing for the injection of a dose which is 10 times higher. This increases the target-to-background ratio improving image quality while reducing acquisition time. Unfortunately, the Tc-99m tracers lock into the mitochondria and do not redistribute like the sodium-potassium analog Tl-201 removing the ability to define hibernating myocardium. The introduction of Stress-first Tc-99m SPECT MPI improved efficiency by identifying normal patients quickly. However, without the ability to redistribute like Tl-201, patients with a stress perfusion defect require 12 to 24 hours complete the diagnosis of scar verses reversible perfusion defect. SPECT only boasts 65% sensitivity and 70% specificity. Diaphragmatic and breast attenuation defects also result in equivocal studies adding referrals to other modalities and increasing time to diagnosis, cost, radiation exposure, and risk of invasive procedures leading to unnecessary revascularization.

2. Early PET Advances

The development of PET MPI with MBF occurred alongside SPECT, but PET lagged in acceptance due to limitations in computing technology, cost, and tracer accessibility. The commercial availability of Rb-82 generators in the early 2000s facilitated the expansion of cardiac PET MPI beyond academic facilities with cyclotrons, enabling the routine clinical acquisition of PET MBF. The 2000s also saw the conversion from PET with rotating rod sources to hybrid PET/CT systems. The replacement of rotating rods with CT reduced acquisition time, improved the quality of attenuation correction, and added information like coronary calcium burden, but it also brought additional struggles for PET MPI. Attenuation correction images acquired with rotating rod sources occur over minutes and account for the contraction and respiratory translation of the heart. CT for attenuation correction is captured over seconds and may lead misregistration with the PET emission. This misregistration causes artifacts in the PET data increasing the likelihood of false-positive findings.

Advances in software and hardware have addressed these issues, but PET MPI acquisition, reconstruction, and processing are still complicated. Physicians and technologists need a deeper understanding of PET physics, scanner correction structure, and coronary physiology to acquire, process, and report PET MPI MBF. 3D PET scanners are optimized to scan lower doses of 18-F for oncologic-focused exams or "hot spot" imaging, but cardiac imaging bases its principles on "cold spot" imaging. Cardiac PET utilizes "cold spot" imaging that requires accurate count recovery. Accuracy is degraded by inability or sub-optimal scatter, prompt gamma, and random corrections and deadtime and crystal saturation data loss. 3D PET scanners are more susceptible to these problems than 2D systems, especially with high-count, short half-life tracers like the most commonly used Rb-82. 3D systems, when acquired accurately, have higher sensitivity and improved image quality over 2D PET with lower radiation exposure. 2D PET systems are being phased out of production, so this discussion focuses on 3D PET. Scanner manufacturers should test the limitations of each iteration of the model they produce with the common commercial cardiac tracers like Rb-82, O-15, and N-13. Unfortunately, only F-18 and long-lived isotopes like Ge-68 in phantoms are used for validation. Many factors can affect scanner limitations, such as detector material composition, electronic hardware, and computing power for corrections. Because of the range of configurations, it has been difficult for third-party MBF software providers to recommend protocol standards, delaying confidence in reporting MBF and creating confusion. Collectively, these limitations have delayed widespread adoption of cardiac PET MPI with MBF.

Over the past 15 years, cardiac PET has seen a boom in the market, with the volume of outpatient clinics tripling from 2010-2019. Increases in reimbursement in the US have aided this growth, rising from $2250.50 to $2750.50 just in 2022 to 2023 alone. Cardiac PET with Rb-82 allows for rest and stress to be completed in less than 30 minutes, improving the volume efficiency of the nuclear stress lab and offsetting the cost of PET operations. A generator also provides on-demand radionuclide for fast throughput of chest pain units, emergency departments, and hospitals. With few contraindications, cardiac PET can accommodate patients weighing up to 250kg with heart rate or rhythm abnormalities like atrial fibrillation, implanted devices, severe coronary calcium burden, or impaired renal function. More importantly, the sensitivity and specificity of PET MPI are much higher than other modalities, with a sensitivity of 95%, specificity of 90% with high positive and negative predictive values comparable to cardiac catheterization, and an exam failure rate of less than 2%. However, cardiac PET is technically demanding and requires a high level of quality and physiologically informed interpretation to achieve similar precision.

3. A Focus on Quality and Education

3.1 Scanner Hardware and Software

Quality cardiac PET imaging requires multiple components, including scanner design, data acquisition protocol, PET and attenuation correction alignment, and validated MBF software. Each PET scanner has unique limitations when imaging the high-count, short half-life tracers used for MBF. Optimizing protocol structure is the first step to ensure quantitative data accuracy and account for these limitations. The 3D PET list mode acquisition and correction applications are the drivers for the protocol structure and reconstruction timing. High count rate tracers and rapidly changing location dynamics of first-pass arterial activity imaging require corrections of the raw data to occur every 5 seconds or less for scatter, dead time, randoms, and prompt gamma.

The United Imaging 3D solid-state PET/CT Scanner corrects the PET data independently of the acquisition timing every 5 seconds to produce accurate quantification for any reconstruction timing protocol, whether static, dynamic, or gated. This decoupling the list mode data from the acquisition is a novel approach in list mode data correction. Other conventional PET/CT scanners apply raw data corrections based on acquisition timing structure and require careful reconstruction to ensure accurate quantification. Accurate quantification of Rb-82, for scanners with connected acquisitions and corrections, requires dynamic reconstruction of 5 seconds per frame or less for the arterial input phase (~2 minutes) and 10-30 seconds per frame for the uptake phase (~5 minutes). Moreover, it’s crucial to understand the limitations of the crystals, electronics, and correction algorithms with high-count images. Each PET system requires specific testing and protocol evaluation with the tracer planned for patient use and high-count activity to assess its limitations and adapt protocols and dosing accordingly.

3.2 Technologist Education

Nuclear Medicine technologists perform flow on many body parts using a p-scope to assist in positioning with immediate visual display. Positioning the left ventricle can be challenging without this visual tool. Transitioning to PET/CT requires a greater knowledge of cross-sectional anatomy to position the heart with CT rather than a p-scope. PET/CT FOV ranges from 16-24cm in width. 16cm FOV scanners allow coverage for most hearts but can be difficult in patients with large cardiomyopathies. The preferred FOV for cardiac PET is 20-24cm. As reviewed above, using CT for cardiac attenuation correction incurs a high risk for misalignment. Co-registration of PET and CT is also not a skill taught in general nuclear medicine. With long-lived tracers, patient motion is typically corrected by reimaging. Mediation of the motion caused by heart contracting and breathing is not realistically possible. This inherent cardiac and respiratory motion, combined with the 75-second half-life of Rb-82, requires technologists to coach their patients to remain still during acquisition phases. Manual or automated co-registration software is available across all manufactures of modern PET/CT scanners. Registration should allow for translation in the x, y, and z-axis. United Imaging takes this further by adding a rotational shift to its alignment software [1, 2]. Every PET cardiac image must be assessed and corrected for misalignment with the attenuation map, even on systems with automated registration techniques. Any relative perfusion defect not supported by patient history, symptoms, or other findings requires technologists and physicians to scrutinize the images a second time for misalignment. Alignment of PET and attenuation maps for cardiac PET is a specialized technologist skill, not comparable to any other exam processing in nuclear medicine. Hence technologist experience and training play a large role in image quality. Cardiac PET images typically require at least two iterations of reconstruction. The first is the initial unaligned images, then repeating all reconstructions with an aligned attenuation correction. These steps are not automated within the acquisition protocols provided by any manufacture and require additional expertise and time compared to oncologic PET/CT.

Some technologist processing skills are transferable from nuclear medicine cardiac imaging, including angulation and apex, base, and contouring limits to exclude extracardiac activity and ejection fraction calculation. Performing these tasks accurately and reliably is paramount for comparing artery-specific perfusion changes from rest to stress and day to day for comparisons. Processing MBF comprises new theory, processing skills, and critical thinking outside the skill set of an entry level technologist. Many MBF software platforms are available for purchase but vary greatly in concept and accuracy. Johnson's 2021 editorial summarizes how buyers should compare each software vendor to a comprehensive list of validation criteria [3]. The list includes validation in animal models, normal volunteers to ischemic and infarcted patients, precision established by test-retest, customizable arterial input, and documented for clinical utility by use in a clinical outcome review, economic benefit, and randomized trial.

Once an institution decides on a flow package, technologists must be trained to process the data for visualization, flow, and assessment for quality. Unfortunately, current nuclear medicine training programs have neither the clinical sites nor time required to train students in cardiac PET. Cardiac PET is a specialty rotation, allowing a maximum of 4 to 5 weeks of instruction. Our institution's experience in cross-training nuclear medicine technologists in cardiac PET suggests a minimum training period of 3 to 6 months to gain competency. The time to train a technologist depends on the complexity of the PET/CT system they are using and their base knowledge of Rb-82 imaging. To address the workforce education gap, the University of Texas Medical School – Houston has created a Cardiac PET Workforce Training program. Post-graduate nuclear medicine technologists spend six months gaining a comprehensive education in cardiac PET/CT exams, including stress testing, viability, and inflammation imaging as well as certification on two different brands of PET/CT systems, the Cardiogen Rb-82 infusion system, and HeartSee quantitative perfusion software.

Adding flow acquisition and processing to a facility that is currently acquiring Rb-82 presents a smaller learning curve than creating a new service line of cardiac PET with MBF. Cardiac software packages attempt many tasks automatically for the technologist, which creates efficiency for experienced technologists but can degrade quality for inexperienced technologists. Without proper training, technologists will lack the ability to connect patient history, stress results, and image findings to assess accuracy.

Time-activity curve (TAC) modeled software has automated alignment that assists with alignment of the PET flow phase

(24+ frames) and uptake (10+ frames) within segmental cardiac boundaries but is not routinely complete. Misalignment causes substantial errors in quantitative perfusion and technologists must check, correct when necessary, and recognize when those boundaries, though aligned, cannot accurately define the TAC modeled MBF due to the rigid segmentation [4].These tasks are typically considered physician-level duties, but unfortunately, physicians are also not trained to process PET MBF in radiology or cardiology fellowship programs to address this issue, the UT Cardiology fellowship program has recently added a one-month rotation in cardiac PET.

Frame alignment is unnecessary for compartmental model packages that do not use segmental boundaries for the flow and myocardium. Removing segmental boundaries also improves accuracy as averaged segmental flow values in a 17-segment model that arbitrarily overlap arterial distributions are not reported. The overlap causes confusion, routinely under-representing severity, when comparing PET MBF to IAC-FFR. PET's high resolution allows for pixel-level expression of severity, substantially increasing accuracy of an artery-specific diagnosis over the aged 17-segment model carried over from nuclear medicine SPECT [5]. Furthermore, third-party cardiac software often only allows for visualization of the final MBF processing, not the console reconstruction and alignment. Additionally, Radiology Business magazine recently reported that "41% of radiologists surveyed expressed doubt in their skills processing cardiac images," along with 28% doubting their ability in nuclear medicine, despite documented competence [6]. The cardiac PET technologist plays an integral role by applying their knowledge of nuclear physics, instrumentation, coronary physiology, and each patient's unique history to present the most accurate data to the physician for interpretation while working in high-throughput clinics.

3.3 Clinical Gatekeeper

The Supporting Science: Over extensive literature publication for the past 40 years, the University of Texas cardiac PET Center has established the physiologic basis, technological requirements, and clinical application of PET using HeartSee perfusion software. Coronary Flow Capacity (CFC) maps by HeartSee offer particular value to invasive cardiology not provided by any other invasive or non-invasive technology [7]. Coronary angiographic anatomy measurement of percent stenosis fails to adequately stratify CAD risk severity because risk is derived from coronary blood flow and it depends on the arterial lumen radius raised to the 4th power. Therefore, the angiogram's limited resolution cannot accurately measure small changes in stenosis dimension that may cause life threatening changes. The arteriogram is commonly considered the “gold standard” of CAD, but extensive literature proves otherwise. Every randomized trial of coronary stents or bypass surgery guided by angiographic severity has failed to reduce mortality.

Invasive simulated fractional flow reserve (IAC-FFR) based on intra-coronary pressure during maximal coronary blood flow has advanced beyond the angiogram for assessing coronary stenosis. However, it remains inferior to CFC by PET for two reasons. Randomized trials of FFR guided revascularization have failed to demonstrate a reduction in mortality since IAC-FFR also fails to account for coronary blood flow or myocardial perfusion. Cardiac PET does so accurately and quantifies mortality risk and its predicted improvement after revascularization.

PET CFC identifies patients with high mortality that reduces by 54% after PET guided revascularization compared to no-revascularization for comparable PET severity in large non-randomized cohorts of 7000 patients followed for 14 years for major adverse coronary events (MACE) [8-13]. Figure 1 summarizes the transformation of a single observation in a single artery to not only quantifying perfusion per pixel, but the impact of revascularization related to flow by PET taken from the Gould et al publication in 2022. The PET guided survival benefit has now been confirmed by the randomized CENTURY trial being reported at the European Society of Cardiology (ESC) congress in August 2023. The recently completed randomized CENTURY trial also indicates that clinical management and interventions guided by PET HeartSee perfusion software reduced death, myocardial infarction, late revascularization and major adverse coronary events (MACE) compared to standard community care without PET. The HeartSee CFC display condenses the complexity of PET perfusion and MBF giving physicians and patients reassurance to safely pursue lifestyle-medical management and reserving invasive interventions only for objectively severe, high-risk, perfusion abnormalities.

PACIFIC and ReASSESS trials show that PET MBF has the highest accuracy rate (86%) compared to intraarterial cardiac catheterization fractional flow reserve (IAC-FFR), verses SPECT or FFRCT accuracy rates of 68-76% and 70%,

respectively. PET also accommodates patients with atrial fibrillation, metal implants, high BMI, and dense coronary calcium, unlike FFRCT and cardiac MRI (cMRI). And although technically difficult, PET MPI with MBF reports a much lower exam failure rate of 2% compared to FFRCT of 13%[14-16] If the goal is patient-centered care, we must choose the exam that provides the patient with the most accurate and comprehensive result.

A recent case represents the limited scope of anatomical imaging. A 66-year-old female presented to the ER with chest and arm pain radiating to shoulder and back accompanied with vomiting. The day prior she was found to have COVID after feeling generalized malaise and unwell for a week. She had a past history of CAD and PCI to LAD in 2019, anomalous origin of the RCA from the left coronary sinus with course between the aorta and pulmonary artery, as well as hypertension, hyperlipidemia, diabetes, and obesity. Her high-sensitivity troponins peaked at ~1800 and downtrended, anterolateral T-wave inversion without ST-segment elevation. The outlying hospital diagnosed NSTEMI and transferred her for possible intervention of the anomalous RCA.

The patient underwent a left heart catheterization (LHC) which showed a patent stent to the LAD, no stenosis of the left circumflex, but unable to engage the RCA. Cardiac CTA confirmed anomalous origin of a right dominant system from the left coronary cusp, with an intramural course and mild to moderate stenosis with calcified atherosclerotic plaque. Two days later, the patient underwent a second LHC which successfully engaged a patent RCA. The care team considered RCA unroofing verses single vessel CABG but ordered quantitative rest-stress PET perfusion imaging to confirm RCA as source of angina. Dipyridamole stress replicated her angina and caused significant ST depression despite PET MPI showing no resting or stress induced perfusion defect and good CFC with normal regional and global rest-stress flows of 1.76 and 2.23 cc/min/g respectively. Relative tomographic images revealed reduced subendocardial to subepicardial perfusion ratio due to left ventricular hypertrophy and diffuse non-obstructive epicardial coronary atherosclerosis during high coronary flow.

Figure 2 displays this patient's course of events that finally achieved an answer for her angina and a plan for her care. The PET report recommended vigorous blood pressure and heart rate control (201/80 mmHg and 81 bpm at baseline) to decrease the myocardial demand causing reduced hyperemic coronary pressure and subendocardial ischemia. Slowing the heart rate also provides longer diastolic perfusion time for better perfusion through a thickened LV wall. Prior to PET, the invasive and non-invasive anatomical imaging failed to identify the cause of this patient's chest pain after 9 days of in-patient care, accumulating 2215 mGy of radiation exposure and administering 330 ml of contrast media. The PET MPI with MBF provided the care team and the patient confidence to cancel the planned surgery on the anomalous RCA in favor of medical management.

3.4 Summary

While substantial capital investment is required to initiate a PET MPI with MBF program, its downstream efficiency compensates by reducing expenses throughout the care system from less accurate modalities and their associated costs and lost time. It is accepted that accurately quantified cardiac PET is the most robust tool for assessing the severity and directing clinical management of the CAD patient. Adopting such imaging protocol confidently requires investing personnel time and resources to understand the PET/CT system, quantitative perfusion software, coronary pathophysiology and its clinical application. Achieving the best patient care at an efficient cost necessitates collaboration between physicians and technologists unmatched by any other invasive or non-invasive technology.

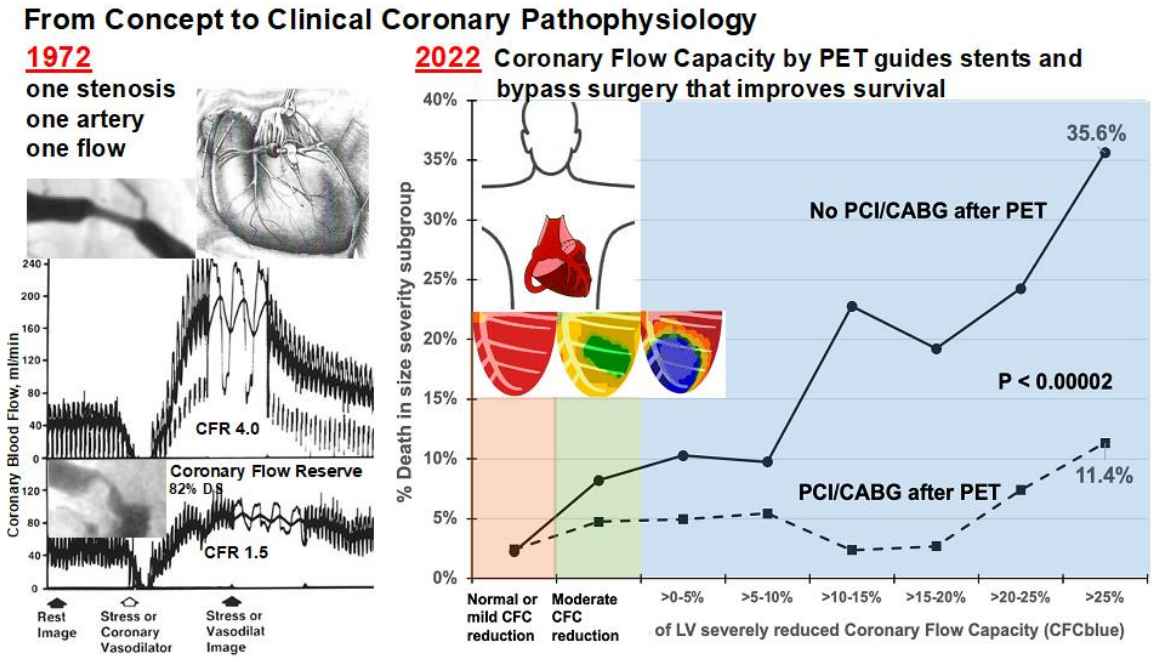

Figure 1 Quantifying perfusion per pixel, and the impact of revascularization related to flow by PET

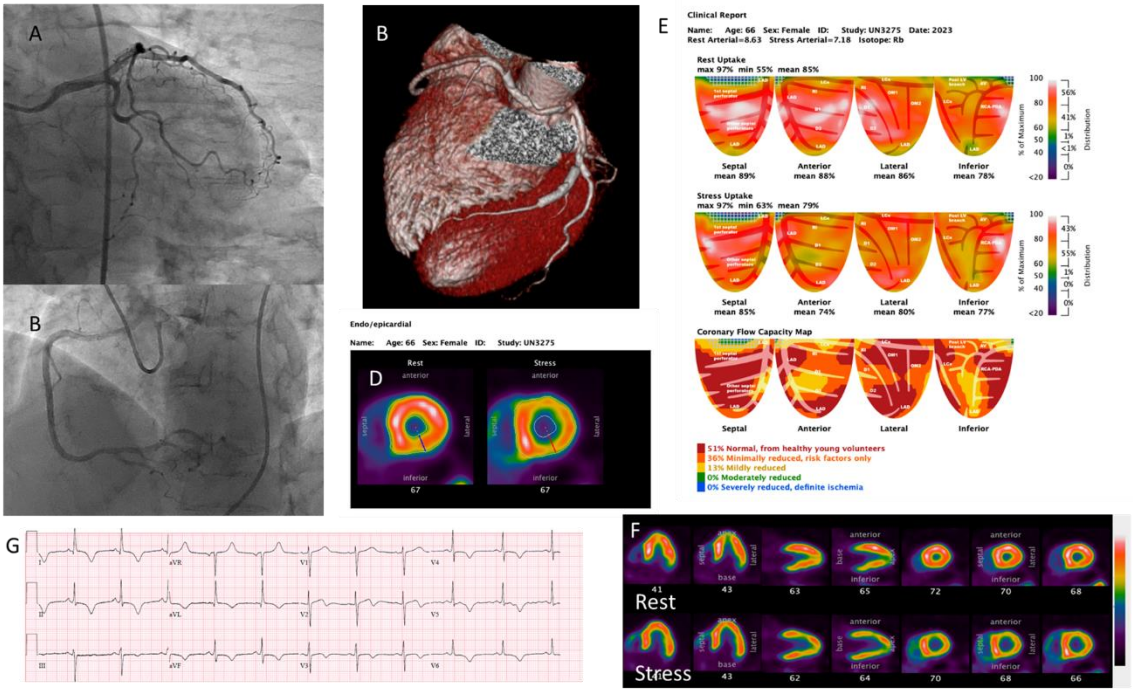

Figure 2: Case study of 66-year-old female presenting with chest pain and complex coronary angiogram for which planned bypass surgery was avoided by quantitative rest-stress PET perfusion imaging (see text for details). (A) LHC patent LAD, no stenosis of LCx, unable to engage the RCA. (B) Cardiac CTA suggesting moderate narrowing of the RCA. (C) repeat LHC found RCA to have mild to moderate stenosis. (D) Reduced stress relative subendo/subepicardial ratio by HeartSee software. (E) HeartSee PET rest-stress relative perfusion and CFC maps. (F) Tomographic PET images. (G) ECG at admission with T-wave inversion.

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