Imaging Appendix: Standardization, quality assurance (IMAGE-QA) and Imaging-assisted Management

The IMAGE-HF QA program aims to standardize several important aspects of the proposed clinical imaging research:

1. defining best current imaging practice for standard-care tests
2. disseminating advanced imaging technology and standards
3. promoting structured reporting and comprehensive imaging QA
4. ensuring consistent interpretation and patient management recommendations

For the IMAGE-HF project 1A (AIMI-HF), this includes standard operating procedures (SOPs) for SPECT, PET and MRI stress-rest perfusion (ischemia) and viability imaging, as well as structured reporting elements and quality assurance review by QA-CORE labs (SOPs and CRFs are posted on the IMAGE-HF website).

Standard-care imaging protocols

SPECT Perfusion and Viability:

IMAGE-HF-1A SOP SPECT-perfusion-viability (SMH) 2010.pdf

http://www.image-hf.ca/PDFs/IMAGE-HF-1A-SOP-SPECT-perfusion-viability.pdf

Based on St. Michael's Hospital 2010 procedure manual for Nuclear Cardiology studies, according to current ASNC guidelines. Perfusion protocols include the use of Tc-99 m-sestamibi, Tc-99 m-tetrofosmin, and Thallium-201 tracers, with adenosine, dipyridamole or dobutamine pharmacologic stress, or treadmill exercise stress according to the Bruce protocol. Viability imaging is performed using Tl-201 with a rest-redistribution protocol, rest or nitrate-enhanced Tc-99 m-tracer imaging.

Advanced imaging protocols

PET perfusion:

IMAGE-HF-1A SOP PET-perfusion (UOHI) may 2011.pdf

http://www.image-hf.ca/PDFs/IMAGE-HF-1A-SOP-PET-perfusion.pdf

Based on University of Ottawa Heart Institute 2011 procedures and ASNC Guidelines for rest-stress PET perfusion imaging using Rb-82 or N-13-ammonia tracers, with dipyridamole or dobutamine pharmacologic stress.

PET viability:

IMAGE-HF-1A SOP PET-viability (UOHI) may 2011.pdf

http://www.image-hf.ca/PDFs/IMAGE-HF-1A-SOP-PET-viability.pdf

Based on University of Ottawa Heart Institute 2011 procedures and ASNC Guidelines for myocardial viability (hibernation) PET imaging using F-18-FDG tracer.

MRI perfusion:

IMAGE-HF-1A SOP CMR-perfusion (CanSCMR) march 2010.pdf

http://www.image-hf.ca/PDFs/IMAGE-HF-1A-SOP-CMR-perfusion.pdf

Based on Canadian Society of Cardiac MR 2010 imaging guidelines, using gadolinium contrast enhanced imaging following adenosine or dipyridamole stress.

MRI viability:

IMAGE-HF-1A SOP CMR-viability (CanSCMR) march 2010.pdf

http://www.image-hf.ca/PDFs/IMAGE-HF-1A-SOP-CMR-viability.pdf

Based on Canadian Society of Cardiac MR 2010 imaging guidelines, using late gadolinium enhancement (GLE) imaging at rest to identify myocardial fibrosis (scar).

Common structured reporting elements

Stress-rest perfusion (ischemia) imaging with SPECT, PET or MRI:

HF15-Stress Perfusion Report

The following common parameters are included on the interpretation CRFs: Modality, Stressor, Tracer, Symptoms, ECG findings, LV ejection fraction, Segmental rest and stress perfusion and wall-motion scores, location and severity of myocardial ischemia and infarction (scar). Clinical recommendation for revascularization, and confirmation that the recommendation was communicated to the referring physician are captured on CRF.

Viability (hibernation or scar) imaging with SPECT, PET or MRI:

HF12-FDGPET&SPECT viability, HF13-Viability Report CMR

The following common parameters are included on the interpretation CRFs: Modality, Tracer(s), LV ejection fraction, Segmental wall-motion, perfusion and viability or scar scores, location and severity of scar and/or hibernating myocardium. Clinical recommendation for revascularization, and confirmation that the recommendation was communicated to the referring physician are captured on CRF.

Quality assurance CORE lab reviews (QA-CORE)

A limited subset of scans (10%) are targeted for over-reading interpretation at an experienced site identified as the CORE lab for each imaging modality. The first 2 scans (and 5% of the subsequent scans) from each imaging modality at each recruiting site are transferred to the corresponding modality QA-CORE lab for clinical interpretation and comparison to the site interpretation for quality assurance. Disagreements in the overall interpretation of the extent of LV ischemia, scar, hibernation or clinical recommendation for revascularization are resolved by subsequent consensus review between the site and CORE labs, and recorded on the corresponding CRFs: *HF12-QA, HF13-QA, HF15-QA*

QA-CORE labs for SPECT and PET are established at the University of Ottawa Heart Institute, and the QA-CORE lab for MRI is at the University of Alberta.

Imaging assisted management:

i) ***PET:*** Patients randomized to PET will undergo rest and stress dipyridamole perfusion to define ischemia and quantify myocardial blood flow using established protocols[1,2]. If indicated (presence of at least one moderate fixed perfusion defect), FDG PET will be used to define perfusion/metabolism mismatch (hibernating myocardium) or match (scar)[3]. Patients unable to undergo dipyridamole stress will have a rest perfusion/FDG PET study.

ii) ***CMR:*** Patients randomized to CMR will undergo a stress perfusion with late gadolinium enhancement MR study to define the presence and extent of myocardial ischemia and scar[4-6]. Stress perfusion imaging will be performed during peak vasodilation using Adenosine or Dipyridamole in accordance with published protocols.[6,7] Regional function, stress perfusion and myocardial scar will each be visually quantified using the AHA 17-cardiac segment model. A 5-point scoring system will be used for all three evaluations. Regional function will be scored from 0 (normal) to 5 (dyskinetic), while both perfusion defects and scar will be scored by segmental transmurality in 25% increments from 0 (none) to 5 (75-100% transmurality). The presence of a perfusion abnormality in the absence of artifact or scar will be interpreted as ischemia, as described by Klem et al.[6,7]

iii) ***SPECT:*** *Patients randomized to the* standard care arm will undergo rest and stress SPECT MPI (with Tc-99m agents and/or Tl-201). SPECT images will be acquired as per the current guidelines.[2,8,9] CT transmission images will be obtained where available. ICANL and ASNC standards will be applied to ensure a minimum consistent standard of data quality. Viability imaging will be performed using either rest +/- nitrates Tc-99m based SPECT or Rest-redistribution+/-24hr Tl-201 SPECT imaging.

<u>Imaging Recommendations:</u>

a) Revascularization (CABG or PCI) or revascularization work-up (if the patient did not have recent (<6 months) angiography) will be recommended when PET MRI or SPECT identifies significant ischemia (≥10% of the LV)[10-12] or when there is significant viability or hibernating myocardium based on accepted and published criteria: i) for PET: significant mismatch (hibernating myocardium) in at least 1/17 segments based on DiCarli et al[13] [equivalent to ≥7% of the LV as we also observed[3]]; ii) for MRI: (i) global viability defined as ≥10/17 segments with <50% transmural infarction on LGE imaging and (ii) regional viability defined as at least 2 dysfunctional segments (function score ≥2) with <50% transmural infarction (scar score ≤2) in a given coronary artery territory; (i.e. >50% transmural viability in the segment); [4,14] iii) for SPECT: ≥11/17 segments with >50% tracer uptake as was used in the STICH viability study.[15] OR

b) When imaging identifies predominantly scar, the imaging-assisted management would recommend no revascularization (MDs may chose CRT or LV aneurysmectomy if indicated).

Treating physicians will be strongly encouraged to follow the PET recommendations but can weigh other co-morbidities and patient choice in decision making. Such changes and the reason will be recorded. Some patients referred for angiography after PET may be found to have 'vessels which are unsuitable for revascularization'.[16] Vessels will be considered 'unsuitable' if two cardiac surgeons agree after review of angiography (and two interventional cardiologists in the case of 1 or 2 vessel disease).

Appendix References

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