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APPROPRIATE USE CRITERIA

2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR Appropriate Utilization of Cardiovascular Imaging in Heart Failure

A Joint Report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force

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The Oversight Committee gratefully acknowledges the memory of James T. Dove, MD, MACC, who passed away during the development of this document.

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Preface

In an effort to respond to the need for thoughtful and objective use of healthcare services in the delivery of high-quality care; the American College of Radiology (ACR) and the American College of Cardiology Foundation (ACCF) have taken on the important process of jointly determining the appropriate use of cardiovascular imaging modalities for specific important clinical scenarios in patients with heart failure (HF). The ultimate objective of an Appropriate Utilization of Imaging (AUI) document is to improve patient care and health outcomes. The ACR, ACCF, and the collaborators in this document believe that careful balancing of a broad range of clinical experiences and available evidence-based information will help guide a more effective, efficient and equitable allocation of healthcare resources.

The publication of the AUI in HF document reflects the first collaboration between the ACR and ACCF. This effort is aimed at critically and systematically creating, reviewing, and categorizing clinical situations where physicians order or use imaging tests for patients with suspected, incompletely characterized, or known HF. This document is based on our current understanding of the technical capabilities and potential patient benefits of the various imaging modalities examined. The clinical scenarios do not directly correspond to the Ninth Revision of the International Classification of Diseases system. Rather, the scenarios presented represent common clinical scenarios seen in contemporary practice, but do not include every conceivable clinical situation. Thus, some patients seen in clinical practice are not represented in this document or have additional extenuating features compared with the clinical scenarios presented. Of course, both the ACR and ACCF support personalized patient care, emphasizing utilization of diagnostic and therapeutic approaches to meet the specific needs of each patient. These AUI criteria are intended to provide guidance for patients and clinicians, but are not intended to diminish the acknowledged difficulty or uncertainty of clinical decision making and cannot act as substitutes for sound clinical judgment and practice experience. This document provides a framework for decisions regarding judicious utilization of imaging in the management of patients with suspected, incompletely characterized or known HF seen in clinical practice.

In developing the AUI for HF document, the joint Radiology and Cardiology writing panel implemented a process that evaluated the technical abilities of the multiple imaging modalities being rated and the evidence for each modality with respect to the clinical indication and the imaging parameters important to each clinical indication. Therefore, the method for development of this AUI for HF document highlights the best aspects of both the current ACR and ACCF processes. A multidisciplinary rating panel comprised imagers, cardiovascular clinicians, general practitioners, and outcomes experts assessed whether performing an imaging procedure for each clinical indication was appropriate, maybe appropriate, or rarely appropriate, based on available evidence at the time of their review.

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Introduction

Clinicians, payers, and patients are interested in the specific benefits offered by imaging to both the diagnosis and clinical management of disease conditions. This document addresses the appropriate use of imaging procedures in patients with HF.

Other appropriate-use publications from the ACCF and their collaborating organizations reflect an ongoing effort to critically and systematically create, review, and categorize the appropriate utilization of imaging by modality. The ACR Appropriateness Criteria documents critically examine and categorize appropriateness of multiple imaging modalities used in the diagnosis and management of over 170 specific clinical conditions and their common variants. This document follows the methods described in greater detail in a joint publication by ACCF and ACR that itself combines the individual methodology publications of the ACCF and the ACR (1). The intent of the current document is to examine the benefits of imaging by explicitly considering 2 complex questions: 1) Is any imaging at all justified for a given clinical scenario? and 2) If yes, which imaging modality or modalities are most likely to provide meaningful incremental information?

This evidence-based document presents the results of this effort.

Heart Failure Overview

Prevalence

HF represents a rapidly growing epidemic (2–6). Approximately 5.8 million patients in the United States currently suffer from HF, and over 670,000 of them are newly diagnosed with HF each year (7).

Clinical Significance

More deaths result from HF causing sudden cardiac death than from all forms of cancer combined; the 5-year mortality after a diagnosis of HF is approximately 50% (7).

Economic Impact

Annual medical expenditures related to HF in the United States exceed $39.2 billion (7).

Although medical imaging has been reported as one of the fastest growing segments of Medicare expenditures, with cardiovascular imaging accounting for nearly one-third of those costs (8), recent data demonstrate declining rates of use, potentially reflecting the ongoing efforts to encourage appropriate use (9).

Basic Therapeutic Options

In general, the ACCF/American Heart Association (AHA) Heart Failure Guidelines provide in-depth information on the management and prevention of HF (10). The main objectives of imaging for HF evaluation revolve primarily around understanding both cardiac structure and function, and, secondarily, in determining the underlying etiology, so that proven medical and invasive therapies may be targeted to appropriate patients. Therefore, the clinical indications presented in this report focus on these management principles in patients with suspected, incompletely characterized, or known HF.

Methods for Establishing Appropriate Use of Imaging in HF

The methods are described in detail in a recent related joint publication (1). A summary is given in the following text. In brief, this process combines evidence-based medicine, guidelines, and practice experience by engaging a technical panel in a modified Delphi exercise (11).

Need for Appropriate Utilization of Imaging in HF

There is heightened interest regarding the appropriateness of imaging in HF patients due to:

- The increasing prevalence of HF, especially in the elderly;
- Dramatic developments in advanced imaging modalities with overlapping capabilities;
- Advancements in surgical and percutaneous therapies for conditions causing HF;
- Improvements in medical therapy for HF; and
- The high costs of in-hospital and out-patient HF management.

Importantly, utilization of imaging categorized as rarely appropriate may generate unwarranted costs to the healthcare system and cause harm due to unnecessary follow-up testing or treatments to HF patients, whereas appropriate utilization of imaging procedures should improve management and clinical outcomes in HF patients, justifying their use.

Definition of Appropriateness

The definition of an "appropriate" imaging test, according to the joint methods of ACR and ACCF, is based on the definition of *appropriateness* in "AQA Principles for Appropriateness Criteria" (12a). (The principles are a subset of the general "AQA Parameters for Selecting Measures for Physician Performance" [12b] and are not to be viewed independently of that document.)

> The concept of appropriateness, as applied to health care, balances risk and benefit of a treatment, test, or procedure in the context of available resources for an individual patient with specific characteristics. Appropriateness criteria should provide guidance to supplement the clinician's judgment as to whether a patient is a reasonable candidate for the given treatment, test or procedure (12a, para. 2).

This definition highlights the central intent of achieving of the greatest yield of clinically valuable diagnostic information from imaging with the least negative impact on the patient.

Clinical Scenario and Indication Identification by Writing Group

The writing panel for this HF project comprised practicing Radiology and Cardiology representatives from the relevant professional societies. The writing panel initially recognized key areas of HF clinical care from which general clinical scenarios leading to the consideration of imaging use were identified (see Figure 1). The identified key clinical entry points for HF-directed imaging included:

- Newly Suspected or Potential HF
- HF Associated With Myocardial Infarction (MI)
- HF Assessment for Consideration of Revascularization
- Consideration of and Follow-Up for Device Therapy (Implantable Cardioverter-Defibrillator [ICD] or Cardiac Resynchronization Therapy [CRT])
- Repeat Evaluation of HF

These clinical scenarios are intended to be broad and representative of the most common patient situations in HF for which assistance from diagnostic imaging is considered. Information gained from imaging may contribute to the original diagnosis but is not sufficient by itself to establish a HF

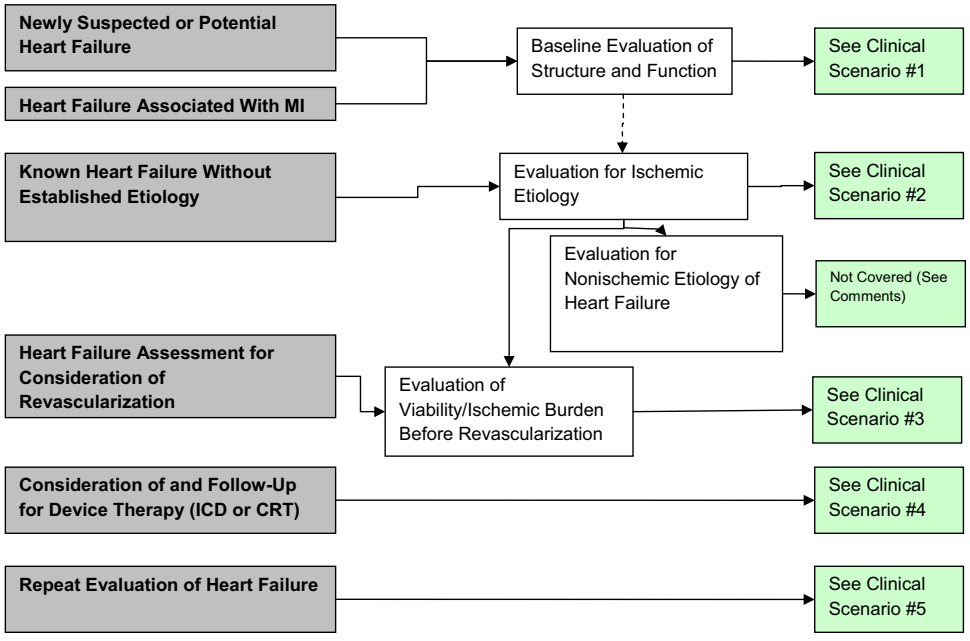

Figure 1. Entry Points Into Clinical Imaging Scenarios

diagnosis. HF is a clinical syndrome that can only be diagnosed through an evaluation of the patient for a constellation of signs and symptoms consistent with HF. Once a diagnosis is made or a high likelihood established, imaging may be used in the evaluation and management of HF.

Early in the preparation of this document, the writing panel concluded that nonischemic etiologies of HF represent an important subset of patients; however, addressing this clinical scenario would significantly expand the scope of this document. Although a few of the indications for suspected or potential HF may be the result of nonischemic etiologies, these patients were generally not addressed in this document. The intent is to include nonischemic etiologies in a subsequent document. The development of the relationships between the 5 remaining clinical scenarios highlights the complexity of the decision-making process for clinical management and use of imaging in patients with suspected, incompletely characterized, or known HF. The document is intended to address the use of imaging within the 5 described broad clinical scenarios. Entry into a given scenario may be based on history, signs, symptoms or other factors, such as incidental diagnosis of low left ventricular ejection fraction (LVEF).

Guidance for Clinical Scenarios and Indications

This document includes 5 clinical scenarios. For each of the 5 general clinical scenarios, the writing panel identified specific clinical indications, emphasizing that each indication represents the specific "point-of-order" for an imaging study. These clinical indications are meant to capture the salient features seen at the time of patient encounter before a procedure is ordered. Some of the important features represented in the indications of patients with HF included:

a) The clinical presentation (e.g., dyspnea, exertional fatigue, chest pain or angina/ischemic equivalent, murmur, crackles, edema),
b) Severity of HF (New York Heart Association [NYHA] functional class I, II, III, or IV),
c) Prior determination of underlying etiology (e.g., ischemic/nonischemic etiology of HF),
d) Exacerbating conditions (e.g., dietary indiscretion, new angina/ischemic equivalent).

The writing panel recognized that for routine patient care, symptom status, underlying etiology of HF, and the level of medical therapy are factors that play critical roles in decision making but may not be completely represented in a clinical scenario. The reader should note that the clinical indications focus on imaging modalities in HF, rather than biomarkers or other clinical management procedures.

Once the indications were drafted, reviewers from collaborating medical specialty and subspecialty groups, including radiology, cardiology and general medical societies, along with other stakeholders, were given the opportunity to review and provide feedback regarding the appropriate use document for HF, and this was incorporated into the document.

The following was written to clarify the different sections for the rating panel, as well as the general user of this document: The procession of clinical scenarios was chosen to reflect the clinical work-up of a patient and to highlight the diagnostic imaging query at a given clinical indication. The first clinical scenario reflects the de novo evaluation of

HF symptoms. This scenario is followed by a secondary step: the evaluation of ischemic versus nonischemic etiology in patients presenting for evaluation of HF symptoms. The extent and severity of ischemia is then followed by consideration of a viability assessment (i.e., Scenario #3), largely in the setting of extensive LV dysfunction, where revascularization is under consideration. These 2 distinctions between Scenarios #2 and #3 will help raters to make the distinction between these 2 sections. In some cases, the assessment of ischemic burden (i.e., Scenario #2) may be combined with or circumvent the need for a viability assessment (i.e., Scenario #3), where the former case of severe ischemia may be the principal driver for considering revascularization. The next scenario, #4, focuses on the application of imaging for decisions regarding ICD and CRT. The final scenario addresses the role of serial imaging in the evaluation of HF patients. Raters should take care to evaluate the role of imaging in each of these scenarios separately and to rely to as great an extent as possible on the evidence presented here that relates to the evaluation of patients with HF symptoms.

The Rating Panel and Its Function

In order to reduce bias in the rating process, the rating panel comprised physicians with varying perspectives on imaging in HF and not solely of technical experts (e.g., cardiac imagers). Overrepresentation of technical experts in a rating panel might create a perceived preference for imaging in general or for a specific imaging modality when other clinical alternatives (including no testing strategies) may be more commonly employed.

Stakeholders in HF care had the opportunity to participate in the appropriate-use HF assessment process by submitting nominees for the rating panel from their organizations through a call-for-nominations released in May 2009. From this list of nominees, the oversight committee and writing panel selected rating panel members to ensure that a balance with respect to expertise was achieved.

In addition, care was taken to provide objective, peer-reviewed, unbiased information, including a broad range of key references, to the rating panel members. Recognizing variability in many patient factors, local practice patterns, and a lack of data on use of imaging across clinical scenarios and indications, the rating panel members were asked to independently rate the appropriateness of using each imaging modality for the general scenario and specific indication based on the available evidence. Specifically, each rating panel member was asked to go through the following steps in developing their individual rating:

1. Review all the clinical scenarios/indications for HF imaging.
2. Review the descriptions of all imaging modalities—both safety table and table of imaging parameters addressing the capabilities of each imaging modality.
3. Review the literature review for HF (summary statements, key reference evidence tables, and parameter-based evidence lists).
4. Rate each imaging modality for each indication by level of appropriateness first (Appropriate/Maybe appropriate/Rarely appropriate).
5. Provide numeric scores (described in next section) for modalities in each level based on amount and quality of evidence and additional factors such as safety and cost.

The rating panel used a 1 to 9 scale to rate the appropriateness of an imaging procedure for the specific indication/scenario (see the Rating Appropriate Use section). Rating panel members initially voted independently on the appropriateness of each imaging procedure for all the clinical indications. The results were then tabulated and returned to the rating panel members in the form of their individual scores along with the de-identified scores from the other members. A mandatory in-person meeting of the rating panel was then held to review and propose indication revisions to the writing panel. The in-person meeting included non-rating representatives of the writing panel and oversight committee, who provided guidance relative to procedural and operational issues and ensured continuity throughout the process. The oversight committee representative also served as an unbiased moderator to the rating panel and facilitated optimal group dynamics during the process. The oversight committee moderator was free of significant relationships with industry and was unbiased relative to the topics under consideration. The revised narrative and indications then underwent a second round of independent rating. For indications with significant dispersion of scores, a conference call and third round of rating occurred.

Relationships With Industry and Other Entities

The American College of Cardiology Foundation, American College of Radiology, and partnering organizations rigorously avoid any actual, perceived, or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the technical panel. Specifically, all panelists are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the Appropriate Use Criteria Task Force, discussed with all members of the technical panel at the face-to-face meeting, and updated and reviewed as necessary. A table of disclosures by all participants is presented in the Appendix.

Rating Appropriate Use

Based on available evidence, the rating panel members assigned a rating to each imaging procedure for a specific clinical scenario/indication on a continuous scale from 1 to 9. Final ratings are reported as categories. The category and complete definitions used in this document were modified by the AUI Oversight group after the final ratings were

completed to align with terms used in other documents produced by ACR and ACCF. The new terminology is similar to the UCLA RAND Appropriateness Method labels (11) used by the rating panel (appropriate, uncertain, and inappropriate) but clarifies that appropriateness is a continuum as discussed in the remainder of the document and discussed with the rating panel during the meeting.

Appropriate Score 7 to 9:

An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans although not always necessary depending on physician judgment and patient specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

Maybe Appropriate Score 4 to 6:

At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefits/risks ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).

The "maybe appropriate" category indicates that the rating panel agreed that: 1) there was insufficient evidence whether the imaging procedure was appropriate or not; or 2) the available evidence was equivocal or conflicting; or 3) additional factors beyond those described must be considered. A "maybe appropriate" rating is more likely with procedures using new technology or protocols for which the evidence is limited and additional research is required. All raters recognize that a rating in the "maybe appropriate" category does not invalidate the use of specific imaging on a case-by-case basis when the best interests of an individual patient are being considered by the caring physician. The ACCF and the ACR recommend that a "maybe appropriate" category not be used as justification for the nonpayment of imaging services.

Rarely Appropriate Score 1 to 3:

Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

The following specific assumptions were conveyed to the rating panel members:

- All imaging is performed in accredited laboratories using approved/certified imaging equipment (12–16).
- All interpreting physicians are qualified to supervise the imaging procedure and report the findings on the resulting images.
- All imaging will be performed according to peer-reviewed published medical literature.
- In the clinical scenarios/indications, no unusual extenuating circumstances (e.g., clinically unstable, inability to undergo the imaging modality considered, resuscitation status, patient unwilling to continue medical care or revascularization), exist or have been specifically noted.
- Prior diagnostic imaging may have been performed by the time of the clinical presentation. The panel should rate the appropriateness of imaging in the clinical scenario independent of the appropriateness of prior imaging.
- The potential drawbacks of the imaging procedures include those presented in the Imaging Procedures and Safety Information table (Appendix B) of the ACCF/ACR methodology document and those associated with poor test performance (1).
- While specific patient groups (e.g., end-stage renal disease, advanced age), which are not well represented in the literature, are not presented in the current clinical scenarios/indications, the writing group recognizes that decisions about imaging in such patients are frequently required.
- All patients are receiving standard care, including guideline-based risk factor modification for primary or secondary prevention in cardiovascular patients, and standard HF care unless specifically noted.
- Cost may be a consideration, in particular as it relates to the use of lower cost, noninvasive versus more costly, invasive procedures. However, clinical benefits should always be considered first, and costs should be considered in relationship to these benefits. Use of a lower-cost procedure, though less expensive at a given moment in time, may ultimately be more costly due to subsequent expenses. A procedure may initially be more costly, but it may be better able to address the clinical questions at hand.

Identification and Description of Cardiovascular Imaging Modalities

The cardiovascular imaging modalities considered in this report included the following: echocardiography (echo), cardiovascular magnetic resonance (CMR), single-photon emission computed tomography (SPECT), positron emission tomography (PET), cardiovascular computed tomography (CCT; CCT includes CT angiography and calcium scoring), and conventional diagnostic cardiac catheterization (catheterization includes coronary angiography, left ventriculography, left heart catheterization). All of these modalities represent multiple capabilities that are selectively used alone or in combination during an episode of care or serially throughout a patient's life in order to provide general insights into a clinical condition or to assess specific issues pertaining to the individual patient. In fact, the specific performance of the same imaging modality may vary con-

siderably between disease entities and even between patients with the same general disease. This variability in the description of the imaging technology applied is also reflected in the literature. Thus, for the sake of establishing (by evidence-based analysis) the appropriateness of imaging it is essential to delineate the key clinical parameters for imaging to address on an indication-by-indication basis to be able to assess the relative roles of the various modalities. That is the intent of the "Imaging Parameters Evidence" online supplement.

To ensure that the rating panel and users of the criteria can apply the indications to practice, the specific parameters included in clinical evaluations and levels-of-evidence validation for use are provided in the following tables. The expectation is that the modalities and imaging techniques used are not experimental, but rather that they represent a reasonable and usual high quality of imaging, as available in general practice.

CLINICAL SCENARIO #1
Initial Evaluation of Cardiac Structure and Function for Newly Suspected or Potential Heart Failure

Clinical Rationale

The cardinal presenting symptoms of HF are dyspnea and fatigue, resulting from variable combinations of fluid retention (manifested as pulmonary congestion and/or peripheral edema) and exercise intolerance (10). Symptoms of HF also may be accompanied by signs such as murmur, abnormal jugular venous pressure, crackles, other signs of volume overload, or edema.

The clinical syndrome of HF is common and can be caused by any disorder impairing the ability of the ventricles to contract, relax, fill, or empty during the cardiac cycle (10). Although HF may be due to abnormalities of the myocardium, valves, or pericardium, the majority of HF patients are symptomatic from LV myocardial functional abnormalities, which may be seen in settings ranging from markedly reduced LVEF with/without severe LV dilation (predominantly, systolic dysfunction) (10,17) to preserved LVEF with normal LV size (predominantly, diastolic dysfunction) (10,18). In many cases, systolic and diastolic myocardial dysfunctions coexist. Coronary artery disease (CAD), hypertension, valvular disease, and dilated cardiomyopathy are the causes of HF in a substantial proportion of patients, with aging being an important contributor to diastolic dysfunction (10,19,20).

In patients presenting with signs and symptoms that raise suspicion of HF, assessment of LV systolic and diastolic function is important and can be performed with a variety of imaging techniques. The same holds true for patients who are at risk for HF, such as patients after acute MI, those with hypertension and left ventricular (LV) hypertrophy, those who are exposed to potentially cardiotoxic chemotherapeutic agents, and first-degree relatives of those with an inherited cardiomyopathy.

Imaging Rationale

Although a complete history and physical examination are the first steps in evaluating the etiology of newly suspected HF, or factors predisposing to HF, identification of structural abnormalities leading to HF generally requires imaging of the cardiac chambers and great vessels (10,21). Imaging may be used in new-onset HF to determine whether abnormalities of the myocardium, valves, or pericardium are present, which chambers are involved, and whether secondary pulmonary arterial hypertension is present. Imaging is also often very useful in such patients for early prognostication. For example, LVEF after MI remains a strong predictor of risk, with lower LVEF associated with worse outcome (22–25).

Use of imaging allows the following fundamental questions to be addressed in patients with newly suspected or potential HF:

1. Is LV structure normal or abnormal?
2. Is LVEF preserved or reduced?
3. Is ventricular relaxation normal? and
4. Are there other structural abnormalities accounting for the clinical presentation?

Evaluation, however, is not limited to the LV.

For this clinical scenario, the following imaging parameters are most relevant:

Anatomy

1. Chamber anatomy abnormalities (geometry/dimension/wall thickness)
2. Valve structural abnormalities
3. Congenital abnormalities
4. Pericardial abnormalities (including calcification/fluid/thickness/constriction)

Function

1. Global ventricular systolic dysfunction (including reduced ejection fraction and stroke volume)
2. Global ventricular diastolic dysfunction (including altered [reduced or increased] early ventricular filling)
3. Valve dysfunction (stenosis/regurgitation/other abnormalities)

Myocardial Status

1. Regional ventricular systolic dysfunction (including wall thickening)

Literature Review

Summary Statement

The literature review does not support routine use of stress imaging with echo, CMR, SPECT, or PET for initial evaluation of HF symptoms.

Echo

The strongest recommendations in favor of imaging of patients with newly suspected HF are with echocardiography to include 2-dimensional transthoracic ultrasound and Doppler (10). Among its most attractive attributes are its widespread availability, lack of ionizing radiation, and the application of imaging in real time. Assessments of cardiac structure and function can be made accurately to guide therapy. Multicenter studies have demonstrated the value of various echocardiographic measures of cardiac structure and function as indicators of subclinical HF and risk for subsequent HF events (27–31). Additionally, assessment of LV systolic function using echo in patients with suspected HF improved the disease identification by general practitioners as well as the application of appropriate medical care (32). Resting echocardiography has also been shown to identify patients with HF with preserved systolic function and abnormal diastolic function (33,34) and to predict subsequent poor outcomes (35–37).

CMR

Studies over the last decade support the use of CMR for this cohort of patients, as noted in a recently published expert consensus statement (37a). Although LV volume and EF measurements are at least as accurate as those obtained with echo (38), myocardial perfusion, viability, and fibrosis imaging can assist in identification of etiology and assess prognosis (39). LV mass quantitation by CMR predicts future risk in patients with HF (40). A key strength of CMR is the high resolution of the anatomy of all aspects of the heart and surrounding structures (41). This has led to recommendations for use in patients with known or suspected complex congenital heart disease (42). The accuracy of CMR and its utility in the initial assessment of valve function appear substantial, although some questions are not yet entirely answered.

SPECT

SPECT is not primarily used to determine LV systolic global and regional function; unless these parameters are quantified from the resultant images during myocardial perfusion assessment (see Scenario #2) (43,44).

Radionuclide Ventriculography

Similar to CMR and echo, radionuclide ventriculography (RNV) is an additional alternative that may be applied to the evaluation of cardiac function (45). RNV is a planar technique, and it may be particularly useful for the assessment of LV volumes in patients with significant resting wall motion abnormalities or distorted geometry. Due to the quantitative methods employed in this technique, it has high reproducibility (46). Serial RNV measurements of LV volumes have been reported to track the efficacy of a variety of therapeutic interventions for patients with HF (47–49). RNV is a technique that is less commonly performed today than in years past and is not routinely used in patients with adult congenital heart disease.

PET

There are relatively few data to support the use of PET as an initial test, but reports do note the utility of peak stress LVEF measurements (50).

CCT

CCT can provide accurate assessment of cardiac structure and function. This technique has high anatomic resolution for the heart and surrounding structures, including the coronary arteries. One current limitation is the loss in accuracy with high heart rate values. An advantage of CCT over echo may be its ability to characterize the myocardium, but studies have yet to demonstrate the importance of this factor. Currently, limited reports are available with CCT in patients with suspected HF.

Catheterization

The invasive assessment of hemodynamics and valvular and ventricular function by catheterization with left ventriculography is considered the traditional reference standard (51). However the invasive nature of the test, radiation exposure, and necessary geometric assumptions in calculations have gradually reduced reliance on this approach as an initial diagnostic test for LV function, especially in subjects who are deemed low risk.

Guidelines

The relevant guideline recommendations for this clinical scenario are:

Initial clinical assessment of patients presenting with HF:

ACC/AHA Heart Failure Guidelines (10)

CLASS I

1. **2-Dimensional echo with Doppler should be performed during initial evaluation of patients presenting with HF to assess LVEF, LV size, LV wall thickness, and valve function. Radionuclide left ventriculography can also be performed to assess LVEF and volumes. (*Level of Evidence: C*)**

ACC/AHA ST-Segment Elevation MI (STEMI) Guidelines (51a)

CLASS IIa

1. **Echocardiography is reasonable in patients with ST-segment elevation MI to re-evaluate ventricular function during recovery when results are used to guide therapy. (*Level of Evidence: C*)**

Assessment of patients at risk for developing HF:

ACC/AHA Heart Failure Guidelines (10)

CLASS I

1. **Healthcare providers should perform a noninvasive evaluation of LV function (i.e., LVEF) in patients with a strong family history of cardiomyopathy or in those receiving cardiotoxic interventions. (*Level of Evidence: C*)**

ACC/AHA STEMI Guidelines (51a)

CLASS IIa

1. **Echocardiography is reasonable in patients with STEMI to re-evaluate ventricular function during recovery when results are used to guide therapy. (*Level of Evidence: C*)**

Table 1. Initial Evaluation of Cardiac Structure and Function for Newly Suspected or Potential Heart Failure

		Rest Only					Rest + Stress					
	INDICATION	Echo	RNV	SPECT	PET	CMR	Echo	SPECT	PET	CMR	CCT	Cath
Newly Suspected or Potential Heart Failure												
1.	Symptoms of heart failure • Shortness of breath OR • Decreased exercise tolerance OR • Symptoms of fluid retention AND Findings of heart failure • Abnormal chest radiograph (e.g., enlarged silhouette, pulmonary venous congestion) OR • Abnormal biomarker(s) (e.g., BNP, pro-BNP) OR Signs of heart failure • Evidence of impaired perfusion OR • Evidence of volume overload	A	A	M	R	A	R	R	R	R	M	R
2.	Malignancy • Current or planned cardiotoxic therapy AND • No prior imaging evaluation	A	A	R	R	A	R	R	R	R	R	R
3.	Familial or genetic dilated cardiomyopathy in first-degree relative	A	M	R	R	A	R	R	R	R	R	R
4.	Known adult congenital heart disease	A	M	R	R	A	R	R	R	R	M	M
5.	Acute myocardial infarction • Evaluation of LV function during initial hospitalization	A	M	M	R	A	M	M	R	R	R	A

BNP = B-type natriuretic peptide.

CLINICAL SCENARIO #2
Evaluation for Ischemic Etiology

Clinical Rationale

The increasing prevalence of chronic ischemic heart disease, reflecting the significant accomplishment of improved survival among patients after acute coronary events (e.g., acute myocardial infarction), combined with the general aging of the population (2–6), has resulted in an increasing prevalence of HF. Based on patient enrollment in therapeutic randomized trials, approximately two-thirds of patients have an ischemic etiology of their HF symptoms (52). Thus, identification of an underlying ischemic etiology is central to clinical management strategies for HF.

Imaging Rationale

It is assumed that patients in this clinical scenario have evidence for HF with a reasonable suspicion of cardiac ischemia, whether by prior cardiac events, risk factors, or current symptoms and signs. Cardiovascular imaging can help evaluate the severity of CAD and associated myocardial ischemia. It can also aid identification of the extent of either infarcted or hibernating myocardium. Although the primary rationale for quantitating the extent and severity of myocardial ischemia is to guide important clinical decisions regarding medical therapy versus revascularization, there are but a few small clinical trials and observational reports supporting this approach (53,54). Although there is limited randomized trial evidence available regarding the benefits of therapeutic intervention (55), the assessment of myocardial ischemia is valuable due to evidence of a higher relative hazard for CAD events in patients with severe ischemia treated medically (54). Evaluation of coronary anatomy and pathology currently requires the consideration of modalities that may utilize a contrast agent, so renal functional status must be considered. A specific classification scheme for renal function in this setting has not yet been widely accepted, despite the use of chronic kidney disease class, and therefore, institution-specific classifications should be used.

As noted in the Preface, this scenario focuses on defining whether or not ischemia is the etiology for HF symptoms and should be seen as preceding a viability assessment that may be performed if needed to further guide therapeutic decision making.

For this clinical scenario, the following imaging parameters are most relevant:

Anatomy

1. Coronary artery abnormalities (including atherosclerotic disease, anomalies)

Function

1. Global ventricular systolic dysfunction (including reduced ejection fraction and stroke volume)
2. Valve dysfunction (stenosis/regurgitation/other abnormalities)

Myocardial Status

1. Fibrosis/scarring (transmural extent/mural distribution/pattern)
2. Regional ventricular systolic dysfunction (including wall thickening)
3. Inducible ischemia—decreased perfusion
4. Inducible ischemia—decreased contraction

Literature Review

Summary Statement

Available evidence regarding the optimal method for evaluation of patients with classical angina, ischemic equivalent pain, dyspnea-equivalent angina, or extensive proven or suspected silent myocardial ischemia and HF is characterized by observational studies with various imaging modalities that demonstrate diagnostic performance and additional prognostic series (56). The recently published STITCH (Surgical Treatment for Ischemic Heart Failure) trial evaluating medical versus surgical revascularization (57) provides evidence regarding the benefit of revascularization with regard to cardiovascular events.

In patients with increasing renal dysfunction, modalities that use iodinated or gadolinium-based contrast agents pose increased risk and should be avoided when suitable alternatives exist.

Literature Review—By Imaging Test

Echo

Stress echo has been shown to identify both resting and post-stress systolic wall motion abnormalities in many observational studies (58–60). In many of these observational studies, ischemia was defined as new/worsening wall motion abnormality (WMA) or a biphasic response (defined as WMA augmentation at low-dose with deterioration at high-dose dobutamine stress echocardiography). These findings have been related to clinical outcomes.

CMR

Perfusion CMR studies have been performed in patients without systolic dysfunction for the identification of CAD, but have not been extensively studied in HF patients. CMR has been studied in small series used to evaluate wall motion with stress in patients with HF (61). CMR with high resolution has more often been used to detect fibrosis, a technique that, in observational studies, has identified ischemic versus nonischemic cardiomyopathy in HF patients. Recent preliminary reports have linked fibrosis with clinical outcome (62,63).

SPECT

SPECT has been studied extensively in HF patients to determine both ischemia and prognosis. Moreover, observational evidence supports the concept that patients referred to stress myocardial perfusion imaging (MPI) with dyspnea are high risk (56). A benefit to the use of SPECT imaging is the addition of rest and post-stress gated LVEF and wall motion information in addition to MPI measurements, including both visual (qualitative) and quantitative measurements (65). For patients referred for evaluation of symptoms suggestive of HF, the results of stress MPI have been applied to differentiate ischemic from nonischemic cardiomyopathy. Significant and extensive angiographic CAD occurs frequently in patients with high-risk stress MPI findings. Finally, reports on the use of stress MPI have focused on the utility of ischemia as a marker of downstream improvement in LV function. In the CHRISTMAS (Carvedilol Hibernation Reversible Ischaemia Trial, Marker of Success) trial, a total of 305 patients with HF were enrolled and randomized to carvedilol versus placebo (66). There was a gradient relationship, with the number of ischemic segments and improvement in LV function noted at approximately 6 months of follow-up. In a recent prospective, controlled clinical trial, 201 patients following index hospitalization for HF underwent stress MPI (67). This cohort included a broad range of LVEF measurements, including 36% of patients with preserved systolic function. When the stress MPI (i.e., summed stress score >3, indicating at least mildly abnormal) results were compared with invasive coronary angiography in 75 patients, the sensitivity and specificity of stress MPI for detection of any significant CAD stenosis were 82% and 57%, respectively. For extensive CAD in the proximal left anterior descending (LAD) or left main, or multivessel CAD, the sensitivity and specificity were 96% and 56%, respectively.

PET

Data regarding the use of PET in this setting are largely derived from studies that include patients undergoing evaluation of myocardial viability. An advantage of the use of stress MPI with PET is its improved accuracy for the detection of severe, multivessel CAD, which may appear as balanced reduction and normal SPECT findings. Moreover, PET markers of absolute peak stress LVEF measurements and myocardial perfusion reserve may improve detection of patients with CAD (50,68). Some small-series studies have noted the advantage of quantifying the extent of myocardial scarring and insulin resistance as important prognostic findings from PET (69). Finally, altered glucose metabolism and myocardial efficiency have also been studied in small series and may offer an added means to identify high-risk patients with HF using PET (70,71).

RNV

As noted in the previous text, gated SPECT or PET measures of LV volumes provide similar information and with concomitant performance of rest and stress myocardial

perfusion imaging, the use of RNV is generally not indicated for ascertaining ischemic etiologies for HF.

CCT

CCT has been examined in some preliminary studies of patients with HF and has been shown to have a high negative predictive value in confirming the absence of CAD (72–74). In a small study, electron beam CT showed promise in identifying CAD in HF patients when compared with catheterization (40,72).

Catheterization

Cardiac catheterization has shown obstructive CAD in patients with HF with and without angina/ischemic equivalent in observational studies (76–78) and is considered a central study by the ACCF/AHA guidelines. Additionally, cardiac catheterization was used solely as the entry criteria for determination of obstructive CAD in patients enrolled in the STITCH trial and other trials of coronary revascularization versus medical therapy.

Guidelines

The relevant guideline recommendations for this clinical scenario are:

ACC/AHA Heart Failure Guidelines (10)

Patient With Angina/Ischemic Equivalent Syndrome/ Angina

CLASS I

1. **Coronary arteriography should be performed in patients presenting with HF who have angina or significant ischemia unless the patient is not eligible for revascularization of any kind. (*Level of Evidence B*)**

CLASS IIa

1. **Coronary arteriography is reasonable for patients presenting with HF who have angina/ischemic equivalent that may or may not be of cardiac origin who have not had evaluation of their coronary anatomy and who have no contraindications to coronary revascularization. (*Level of Evidence: C*)**

CLASS IIb

1. **Noninvasive imaging may be considered to define the likelihood of CAD in patients with HF and LV dysfunction. (*Level of Evidence: C*)**

Patient Without Angina/Ischemic Equivalent Syndrome/ Angina

CLASS IIa

1. **Coronary arteriography is reasonable for patients presenting with HF who have known or suspected CAD, but who do not have angina, unless the patient is not eligible for revascularization of any kind. (*Level of Evidence: C*)**
2. **Noninvasive imaging to detect myocardial ischemia and viability is reasonable in patients presenting with HF who have known CAD and no angina, unless the patient is not eligible for revascularization of any kind (20). (*Level of Evidence: B*)**

CLASS IIb

1. **Noninvasive imaging may be considered to define the likelihood of CAD in patients with HF and LV dysfunction. (*Level of Evidence: C*)**

Table 2. Evaluation for Ischemic Etiology

		Rest Only					Rest + Stress					
	INDICATION	Echo	RNV	SPECT	PET	CMR	Echo	SPECT	PET	CMR	CCT	Cath
6.	Angina/ischemic equivalent syndrome	M	R	R	M	M	A	A	A	A	A	A
7.	WITHOUT angina/ischemic equivalent syndrome	M	R	R	M	M	A	A	A	A	M	A

In this table, all patients have known HF, are suspected of having ischemia, and are assumed to be revascularization candidates.

CLINICAL SCENARIO #3
Viability Evaluation (After Ischemic Etiology Determined) Known to Be Amenable to Revascularization With or Without Clinical Angina

Clinical Rationale

A subpopulation of patients with known CAD and chronic LV dysfunction is thought to have potential reversibility of LV dysfunction if successfully revascularized by coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI). The underlying pathophysiologic substrate has been termed *hibernating myocardium* (79), and is thought to result from significant coronary arterial luminal compromise limiting myocardial blood flow with even minimal demand, such that the myocardium "down-regulates" contractility, gradually or through repetitive stunning, to match the diminished blood flow as a possible compensatory or adaptive mechanism. The result is a state of chronic LV dysfunction, which often may manifest clinically as HF with or without anginal symptoms.

The clinical scenario in which identification of such a patient is important is: 1) history of CAD amenable to revascularization by CABG or PCI; 2) chronic regional and/or global LV dysfunction; and 3) symptoms of HF and/or angina.

Imaging Rationale

The goal of imaging is to define whether dysfunctional myocardial regions are the result of prior infarction, current hibernating state, or a combination. The important implication of making such a distinction is that if sufficient

myocardial viability (hibernation or inducible ischemia) is present, the patient may benefit clinically from revascularization. If the regional dysfunction is predominantly due to infarction, then the clinical implication is that revascularization would confer no benefit, and thus the risks of revascularization outweigh the potential benefits. A property of dysfunctional but viable myocardium in the setting of chronic ischemic heart disease is "contractile reserve," that is, the ability to increase contractility for a brief period of time during an inotropic stimulus. Unfortunately, its assessment is limited in the setting of ischemic HF. The presence of clinical angina may indicate the presence of viable myocardium; however, this is often clinically weighed against the degree of LV dysfunction. Scenarios based on the presence of angina (or angina/ischemic equivalent), the level of LV dysfunction, and wall thinning are used to help identify situations in which differing imaging tests for viability may add value.

For this clinical scenario, the following imaging parameters are most relevant:

Anatomy

1. Chamber anatomy abnormalities (geometry/dimension/wall thickness)
2. Coronary artery abnormalities (including atherosclerotic disease)

Function

1. Global ventricular systolic dysfunction (including reduced ejection fraction and stroke volume)
2. Valve dysfunction (stenosis/regurgitation/other abnormalities)

Myocardial Status

1. Fibrosis/scarring (transmural extent/mural distribution/pattern)
2. Regional ventricular systolic dysfunction (including wall thickening)
3. Inducible ischemia—decreased perfusion
4. Inducible ischemia—decreased contraction
5. Hibernating state—positive contractile reserve
6. Hibernating state—anaerobic metabolism/glucose utilization
7. Hibernating state—minimal scarring

Literature Review

Summary Statement

Evidence for the use of viability imaging in patients with impaired LV dysfunction is currently available from several meta-analyses of observational studies that demonstrate recovery of function and clinical improvement in patients undergoing revascularization with evidence of viable myocardium (80,81). The recently published small substudy of the STITCH trial did not find improved outcomes in a nonrandomized cohort of patients undergoing viability testing.

Echo

Contractile reserve with echo can be imaged using dobutamine echo, and manifests in the dysfunctional region of interest as an increase in wall thickening and motion during low doses of dobutamine, with a subsequent impairment of contractility at higher doses, a finding termed "biphasic response." This technique has been shown in observational studies to identify myocardial segments with higher likelihood of functional recovery after coronary revascularization in patients with moderately reduced LVEF (median 31%) (76). Contractile reserve may be limited in patients with thinned LV walls (82).

CMR

CMR identification of hibernating myocardium and potential reversibility of LV dysfunction is based on the use of late enhancement gadolinium imaging, in combination with information on regional function available with cine CMR techniques. Observational studies have demonstrated that "viability," defined by the relative absence of scarring, resulted in improvement in myocardial function following coronary revascularization in patients with preserved (83) and severely depressed LV function (84). Post-infarction risk stratification with pharmacological stress CMR data is also available (85). Dobutamine stress CMR is also useful for diagnosing CAD (86). Additionally, CMR has been show to demonstrate subendocardial infarction with a greater sensitivity than SPECT in small observational series (87,88).

SPECT

Studies with SPECT tracers involving biopsies of regional myocardium in patients undergoing CABG have demonstrated that the degree of uptake of the tracers (by quantitative analysis) correlates directly with the magnitude of regional myocyte tissue viability on biopsies, thus validating the use of this technique in this scenario. Observational studies of SPECT imaging in patients with HF have identified worse prognosis in patients without viable myocardium (89). In a large systematic review of 24 published reports, the accuracy of SPECT, PET, and echo for prognostication was similar (80).

PET

In 2 randomized trials, a strategy of fluorodeoxyglucose (FDG)-PET–directed revascularization has been compared with standard care for decisions regarding revascularization (PARR 1 and PARR 2 [Positron Emission Tomography and Recovery Following Revascularization 1 and 2] trials) (91,92). These studies demonstrated that patients with viability who underwent revascularization had evidence of improved myocardial function. In addition, when compared with SPECT, FDG-PET was able to identify viable myocardium with a higher sensitivity (93). Although PET is reported to have greater sensitivity, the clinical relative value in comparison to SPECT with

regard to decision making and clinical outcomes has not clearly been demonstrated (94).

RNV

As noted earlier in the text, gated SPECT or PET measures of LV volumes provide similar information, and with concomitant performance of rest and stress MPI, the use of RNV is generally not indicated for the assessment of myocardial viability.

CCT

Preliminary studies suggest that CCT imaging may provide similar information as CMR using contrast enhancement with regard to delineation of etiology of LV dysfunction and to identify areas of regional infarction, in combination with readily available information on regional function (95,96). However, this technique has not as yet been widely used for this purpose, and validation studies are more preliminary in nature compared with the robust literature on all of the other noninvasive imaging modalities.

Catheterization

There is limited initial evidence on the use of left ventriculography for the determination of viability and response to revascularization. With the advent of newer noninvasive techniques, this has not been subsequently studied.

Guidelines

The relevant guideline recommendations for this clinical scenario are:

ACCF/AHA UA/NSTEMI (97a)

CLASS I

1. **Percutaneous coronary intervention or CABG for patients with 1- or 2-vessel CAD without significant proximal LAD CAD, but with a large area of viable myocardium and high-risk criteria on noninvasive testing. *(Level of Evidence: B)***

CLASS IIa

1. **Use of PCI or CABG for patients with 1-or 2-vessel CAD without significant proximal LAD disease, but with a moderate area of viable myocardium and demonstrable ischemia on noninvasive testing. *(Level of Evidence: B)***

CLASS III

1. **Use of PCI or CABG for patients with 1-or 2-vessel CAD without significant proximal LAD disease who have mild symptoms that are unlikely to be due to myocardial ischemia, or who have not received an adequate trial of medical therapy and have only:**
   a. **A small area of viable myocardium; or**
   b. **Have no demonstrable ischemia on noninvasive testing. *(Level of Evidence: C)***

Table 3. Viability Evaluation (After Ischemic Etiology Determined) Known to Be Amenable to Revascularization With or Without Clinical Angina

		Rest Only					Rest + Stress					
	INDICATION	Echo	RNV	SPECT Rest/ Redistribution	PET	CMR	Echo	SPECT	PET	CMR	CCT	Cath
8.	Severely reduced ventricular function (EF <30)	M	R	A	A	A	A	A	A	A	M	R
9.	Moderately reduced ventricular function (EF 30%–39%)	M	R	M	A	A	A	A	M	A	M	R
10.	Mild ventricular function (EF 40%–49%)	M	R	M	M	A	A	A	A	A	M	R

CLINICAL SCENARIO #4
Consideration and Follow-Up for Implantable Cardioverter-Defibrillator (ICD)/ Cardiac Resynchronization Therapy (CRT)

Clinical Rationale

The LV dilation and dysfunction associated with significant HF frequently lead to ventricular tachyarrhythmias, the most common rhythms causing sudden cardiac death in HF patients (10,97). Sudden cardiac death in HF can be decreased by the use of an ICD (98).

HF with severely depressed LV function is frequently accompanied by impaired electromechanical coupling, leading to prolonged ventricular conduction (usually left bundle branch block) with regional mechanical delays (98). Approximately one-third of HF patients with low LVEF and NYHA functional class III to IV symptoms demonstrate a QRS duration ≥0.12 s, the primary marker for dyssynchronous ventricular contraction (10,98). The mechanical consequences of LV dyssynchrony include:

1. Accentuated LV dysfunction with increased metabolic demand;
2. Suboptimal ventricular filling;
3. Functional mitral regurgitation;
4. Paradoxical interventricular septal motion; and
5. Adverse remodeling with increased LV dilation (10,98–103).

For HF patients, dyssynchronous LV contraction is also associated with increases in cardiac mortality (10,104–106).

In persistently symptomatic patients, CRT alone results in significant improvements in:

1. Quality of life;
2. Functional class;

3. Exercise capacity; and
4. LVEF (10,98,107).

CRT also reduces repeat hospitalizations and mortality due to NYHA functional class III to IV HF when compared with standard medical therapy (107–109).

Imaging Rationale

Use of an ICD requires placement of standard intracavitary leads into the right atrium and right ventricle for proper monitoring and pulse delivery.

LV dyssynchrony, and its adverse effects, can be reduced by synchronous electromechanical activation of the LV, using a biventricular pacing device for CRT (10,98,110,111). CRT requires advancement of an LV lead retrograde through the coronary sinus into a tributary overlying the LV free wall, as well as placement of standard right atrial and right ventricular leads.

Currently, the major reasons for imaging in the setting of consideration for ICD or CRT device implantation are, first, demonstration of LVEF ≤35%, and secondly, delineation of the amount and the location of ventricular asynchrony. Both have a major impact on outcomes following device placement.

For this clinical scenario, the following imaging parameters are most relevant:

Anatomy

1. Cardiac vein variations (for CRT implantation)

Function

1. Global ventricular systolic dysfunction (including reduced ejection fraction)
2. Valve dysfunction (stenosis/regurgitation/other abnormalities

Myocardial Status

1. Inflammation
2. Fibrosis/scarring (transmural extent/mural distribution/pattern)
3. Regional ventricular systolic dysfunction (including wall thickening)
4. Myocardial wall mechanics (including strain and synchrony analysis)

Miscellaneous

1. Thrombus—atrial
2. Thrombus—ventricular

Literature Review

ICD

Cardiovascular imaging for consideration of ICD implantation is mainly based on the evaluation of LV systolic function. In the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial), the distribution of LVEF values measured by echo, contrast left ventriculography, and radionuclide angiography differed, but clinical outcomes did not (112). Repeat imaging for ICD implantation may be done to determine whether a course of therapy (either revascularization or medical) has improved the ventricular function or whether the patient still meets LVEF criteria. Therefore, again the goals of imaging are dependent on LV systolic function as described in the preceding text.

CRT

Cardiovascular imaging for consideration of CRT implantation also is mainly based on the evaluation of LV systolic function. The majority of the large randomized CRT studies have used echo to evaluate LV systolic function before and after implantation. Other imaging modalities have been used to evaluate LV systolic function, but with limited studies in patients undergoing CRT. Identification of cardiac vein anatomy for CRT implantation has been shown with CCT and, in some smaller studies, with CMR, and invasive cardiac catheterization. CCT does provide the means to assess LV dyssynchrony and pulmonary vein anatomy with a single study, as, in theory, does CMR. Despite several observational studies that evaluated different imaging modalities for identifying potential predictors of clinical response to CRT, however, available randomized trial data do not demonstrate improved outcomes. Up to 30% of carefully selected HF candidates do not show benefit from CRT and possibly progressive worsening despite CRT (113,114). It should be noted that the literature for CRT use and the concomitant use of imaging modalities to direct therapy is one of the fastest evolving fields. This report captures the best available literature for existing standard technologies; however, several newer techniques and technologies may prove important in the upcoming years. Finally, several available guideline recommendations are provided, and they currently only require an EF evaluation and dyssynchrony based on the QRS duration.

Post-Implantation—Follow-Up Imaging

Studies with repeat imaging after ICD implantation for clinically stable patients without a change in status have not been conducted. For patients with clinical deterioration or change in arrhythmia status, evaluation of a change in ventricular function or in CAD/ischemia may be warranted based on guideline recommendations for standard care of symptomatic HF.

In patients with improved HF class and LV systolic function following CRT implantation, routine clinical imaging has not been studied.

Literature Review—By Imaging Test

Echo

Echo has been studied in the assessment of LVEF before ICD implantation such as in the SCD-HeFT (42). Several observational studies have evaluated the value of echo in identifying and predicting response to CRT (115–118) Tissue Doppler imaging is superior to strain rate imaging and post-systolic shortening on the prediction of reverse remodeling in both ischemic and nonischemic HF after CRT (119,120). A large randomized trial using echo-based

parameters to identify patients that will respond to CRT did not show a clinical benefit (121).

In patients with failure to respond to CRT or with worsening clinical status, studies with echo have been used to maximize atrioventricular intervals and programming of the CRT device while monitoring LV systolic function and mitral regurgitation (122,123). Echo has also been shown to identify patients with dyssynchrony who are missed by electrocardiography criteria alone (124,125).

CMR

CMR has been demonstrated to reliably image LV systolic function, but with limited studies to date in patients being considered for ICD placement. CMR has been shown to identify fibrosis that may lead to future ventricular tachycardia/ventricular fibrillation in patients with (126) and those without an ICD (127,128). CMR has also shown the ability to demonstrate LV thrombus and pulmonary vein anatomy and relationships.

Repeat imaging with CMR is not routinely performed in patients with an intracardiac device due to both safety concerns and limitations in the ability to acquire diagnostic images.

Observational studies with CMR in patients under consideration for CRT have shown that patients with areas of fibrosis, specifically near potential lead placement areas, do not demonstrate clinical improvement with CRT (129). One study found CMR to be more sensitive for fibrosis than SPECT in prospective CRT patients.

RNV and Gated SPECT

RNV for LVEF is highly reproducible when compared with echo and has been used as an inclusion test for randomized trials demonstrating the benefit of ICD implantation (46,112). Rest and post-stress gated LVEF measurements are also routinely applied and are highly reproducible as part of a CAD evaluation (65). Various SPECT measures of dyssynchrony in patients undergoing CRT have been studied, with some studies correlating with echocardiographic measures. Observational studies have evaluated SPECT measures of dyssynchrony in patients undergoing CRT to determine patients that will respond to the therapy (130). From a recent report in 44 patients, phase analysis of gated SPECT was accurate in predicting acute change in LV synchrony and patient outcome following CRT (131,132).

PET

Data for the use of PET in patient being considered for ICD implantation are limited. Initial PET studies have identified potential areas of fibrosis in patients with CRT, and attempted to differentiate responders from nonresponders to CRT.

CCT

CCT has had promising in initial studies evaluating LV systolic function. Recent reports have noted the utility of CCT for ICD placement, including venous imaging before ICD, quantitation of dyssynchrony, and EF assessment.

Guidelines

The relevant guideline recommendations for this clinical scenario are:

ACC/AHA Heart Failure Guidelines (10)

CLASS I

ICD

1. **Primary prevention of sudden cardiac death in HF are for patients with:**
   a. **Nonischemic dilated cardiomyopathy or ischemic heart disease ≥40 days post-MI;**
   b. **LVEF ≤35%;**
   c. **NYHA functional class II or III despite optimal medical therapy; and**
   d. **A reasonable expectation of survival with a good functional status for more than 1 year.**

CLASS I

ICD

1. **Secondary prevention in order to prolong survival in HF patients with:**
   a. **Current or prior HF symptoms;**
   b. **Reduced LVEF; and**
   c. **A history of cardiac arrest, ventricular fibrillation, or hemodynamically destabilizing ventricular tachycardia.**

CLASS I

1. **CRT (with or without ICD) use in patients with HF are:**
   a. **LVEF ≤35%;**
   b. **Sinus rhythm;**
   c. **NYHA functional class III or ambulatory class IV symptoms despite optimal medical therapy; and**
   d. **Cardiac dyssynchrony (defined as QRS duration ≥0.12 s), CRT (with or without combined ICD).**

Table 4. Consideration and Follow-Up for Implantable Cardioverter-Defibrillator (ICD)/ Cardiac Resynchronization Therapy (CRT)

	INDICATION	Rest Only					Rest + Stress				CCT	Cath
		Echo	RNV	SPECT	PET	CMR	Echo	SPECT	PET	CMR		
Implantable Cardioverter-Defibrillator Therapy												
11.	Evaluation determine patient candidacy (133) • Meets published clinical standards for device eligibility • Candidacy requires assessment of ejection fraction and/or other structural information	A	A	M	R	A	R	R	R	R	M	R
12.	Routine follow-up after placement • No deterioration in clinical status AND • No change in arrhythmia status	R	R	R	R	R	R	R	R	R	R	R
13.	Follow-up after placement • Change in arrhythmia status • Appropriate ICD discharge (e.g., VT/VF)	A	R	M	R	R	R	R	R	R	M	R
14.	Follow-up after placement • Change in arrhythmia status • Inappropriate ICD discharge (e.g. rapid AFib)	A	R	M	R	R	R	R	R	R	R	R
Cardiac Resynchronization Device Therapy												
15.	Initial evaluation to determine patient candidacy (133) • Meets published clinical standards for device eligibility • Candidacy requires assessment of ejection fraction	A	A	M	R	A	R	R	R	R	M	R
16.	Procedure planning: considerations • Patient meets all published clinical standards for device • Evaluation of myocardial fibrosis/scarring, coronary vein variations, and intra-cavitary thrombus (for dyssynchrony evaluation)	A	R	R	R	A	R	R	R	R	A	R
17.	Follow-up early (<6 months) after implantation • No improvement in symptoms OR • No improvement functional capacity	A	M	M	R	R	R	R	R	R	M	R
18.	Follow-up late (>6 months) after implantation • Improved symptoms (i.e., from class III, IV to class I, II) OR • Improved functional capacity	M	R	R	R	R	R	R	R	R	R	R

AFib = atrial fibrillation; VF = ventricular fibrillation; VT = ventricular tachycardia.

CLINICAL SCENARIO #5
Repeat Evaluation of HF

Clinical Rationale

Optimal medical therapy permits HF patients to now lead longer and more functional lives. Regardless of the etiology, however, HF is a chronic process often characterized by gradual clinical deterioration.

Imaging Rationale

Noninvasive imaging may be used to assess prognosis or to optimize treatment in patients with known and previously-evaluated HF. Many of the previously discussed imaging parameters are used to re-assess patients.

For this clinical scenario, the following imaging parameters are most relevant:

Anatomy

1. Coronary artery abnormalities (including atherosclerotic disease)

Function

1. Global ventricular systolic dysfunction (including reduced ejection fraction)
2. Valve dysfunction (stenosis/regurgitation/other abnormalities)

Myocardial Status

1. Fibrosis/scarring (transmural extent/mural distribution/pattern)
2. Regional ventricular systolic dysfunction (including wall thickening)
3. Inducible ischemia—decreased perfusion
4. Inducible ischemia—decreased contraction

5. Hibernating state—positive contractile reserve
6. Hibernating state—anaerobic metabolism/glucose utilization
7. Hibernating state—resting dysfunction/minimal scarring

Literature Review

Summary Statement

Although a common clinical situation, little published literature exists regarding repeat imaging and evaluation of patients with HF. The majority of literature is associated with re-evaluation for consideration of implantable defibrillator therapy or efficacy of resynchronization therapy. Both of these clinical situations and their relevant literature are reviewed in Scenario #4.

Regarding stable patients without a change in clinical status, a few studies have demonstrated that radionuclide imaging, echo, and CMR can reliably demonstrate a change in LVEF after medical therapy (134–138). However, there were no studies found that identified a clinical benefit in routine serial imaging in patients without a change in clinical status. Measures of rest and stress LVEF measures with gated SPECT and RNV have been shown to be highly reproducible (64,139).

Gated SPECT/RNV

Measures of rest and stress LVEF measures with gated SPECT and RNV have been shown to be highly reproducible (64,139). Accordingly, numerous reports have evaluated the role of serial measurements of LV volumes to track the efficacy of a variety of therapeutic interventions for patients with HF (47–49,140,141).

Guidelines

The relevant guideline recommendations for this clinical scenario are:

ACC/AHA Heart Failure Guidelines (10)

CLASS IIa

1. **Repeat measurement of EF and the severity of structural remodeling can be useful to provide information in patients with HF who have had a change in clinical status or who have experienced or recovered from a clinical event or received treatment that might have had a significant effect on cardiac function. (*Level of Evidence: C*)**

Table 5. Repeat Evaluation of HF

	INDICATION	Rest Only					Rest + Stress					
		Echo	RNV	SPECT	PET	CMR	Echo	SPECT	PET	CMR	CCT	Cath
19	New angina or ischemic equivalent syndrome	A	M	M	M	M	A	A	M	M	M	A
20.	New or increasing HF symptoms (e.g., shortness of breath or exertional dyspnea) AND Adherent to medical therapy	A	M	M	R	M	A	A	M	M	M	M
21.	No new symptoms AND No other change in clinical status Less than 1 year since prior imaging	R	R	R	R	R	R	R	R	R	R	R
22.	No new symptoms AND No other change in clinical status Greater than or equal to 1 year since prior imaging	M	R	R	R	R	R	R	R	R	R	R

Discussion

The current document represents the first joint effort by the American College of Radiology and American College of Cardiology Foundation to address appropriate utilization of cardiovascular imaging in HF patients. As such, the document represents the efforts of both professional societies, countless individuals, and the groups' hope is that it will help optimize the care of patients with HF. Because HF is a complex medical syndrome consisting of several possible underlying etiologies and/or exacerbating conditions, the writing group attempted to provide a framework for considering the clinical indications, Figure 1. This framework includes indications aimed at evaluating structure and function, underlying ischemic etiology, viability for revascularization decisions, determination and the need for evaluation of patients being considered for defibrillators and resynchronization devices, and the use of imaging in longitudinal follow-up of patients. Even with this robust set of scenarios, the writing group and the rating panel recognized that all the possible indications are not covered in this first document; for example, the evaluation of nonischemic underlying etiologies for individuals presenting with new-onset HF represents an important area not covered. Nevertheless, the process of reviewing the available literature, presenting common clinical scenarios, and having a wide spectrum of clinical experts in both cardiology and radiology rate the indications for HF imaging has provided some important lessons for the clinical community. The lessons from the literature review and conclusions from the rating panel will be presented as general concepts and by clinical indications.

The writing group and rating panel acknowledge that there are many diagnostic procedures used to evaluate patients with HF. The writing group and rating panel did not rate resting electrocardiogram or chest x-rays because

they were felt to be part of the routine data collected with general history and physical examinations when appropriate. The procedures that were considered included both rest and rest/stress tests where possible, for echo, radionuclide imaging (including RNV, SPECT, PET), and CMR. Additionally imaging of cardiac structures and coronary angiography with cardiac CT and invasive cardiac catheterization were considered as well. In total, this represented 11 possible tests for several clinical indications. This required a detailed review of both the possible technical capabilities and the clinical data reported for these modalities. Finally, the writing group also used available documents from both ACR and ACCF to determine the safety data for these procedures. The online appendices (see Literature Review and Imaging Parameters Evidence) provide these technical capability and safety data and should provide an important reference for future reviews and for individuals who want to review a specific reference.

Clinical Indications

Review of the clinical indications provides some important themes and lessons. For patients undergoing initial evaluation for potential or suspected HF, the rating panel found no role in general for routine use of stress cardiovascular imaging, cardiac CT, or invasive angiography. Both echo and CMR were felt to be procedures that would provide clinically meaningful information. The rating panel felt that if the only information needed is EF, then RNV may also be a possibly useful test. However, for more routine evaluation for comprehensive cardiac structure and function, including in patients with familial cardiomyopathy, congenital heart disease patients, or post-MI patients, both echo and CMR were felt to be more useful imaging modalities. The panel also noted that ventricular function evaluation (i.e., ventriculography) might also be performed at time of coronary arteriography in acute MI or suspected ischemia.

Once HF has been clinically diagnosed, and the cardiac structure and function has been determined, the rating panel preferred stress testing with any of the available modalities, or angiography with CT, or invasive cardiac catheterization. In patients with HF and angina, invasive cardiac catheterization and angiography was felt to be appropriate, if the patient was otherwise a candidate for revascularization.

With regard to viability, the writing group attempted to provide recommendation stratified by 3 general categories of ventricular dysfunction, severe (EF <30%), moderate (EF 30% to 39%), and mild (EF 40% to 49%). It should be noted that patients with LVEF = 35% or less are candidates for defibrillators, and viability testing was considered independent of determination for need for devices therapy. The literature and the rating panel opinions suggested many of the modalities were sufficient for determining viability across a spectrum of patients. Resting CMR and PET were felt to be appropriate and useful in the patients with severe ventricular dysfunction, along with the possibility of stress echo or SPECT scan.

For patients being considered for devices therapy, both ICD and CRT, many studies are underway to maximize device function with the use of imaging. However, the available evidence does not as yet support criteria for device therapy beyond LVEF. Therefore, echo and CMR testing were felt to be useful in patient selection. Additionally, CMR and cardiac CT were rated as appropriate for device planning, often to help map the coronary vein anatomy for CRT implantation. CMR was felt to be useful for identification of myocardial fibrosis and possible thrombus. The rating panel felt that most of these patients did not need a stress evaluation or invasive cardiac catheterization. Finally, the rating panel felt it was appropriate to re-evaluate LV function for patients who had a change in clinical status including ICD discharge or who had their device activated, but thought the indication for routine follow-up EF testing was rarely appropriate, with the possible exception of echocardiography, which was rated as maybe appropriate.

These concepts were carried for the longitudinal assessment of patients. For the patients with changing symptoms and presentation with either worsening HF symptoms (where a change in structure or function was suspected), the rating panel rated the indication similar to the initial evaluation with consideration for testing. For patients with changing symptoms and additional concerns for ischemia, again the rating panel thought stress testing was reasonable. For patients with HF and no change in symptoms, the rating panel in general felt testing was rarely appropriate. These ratings will hopefully provide guidance at the time of test consideration, especially in patients with HF who are seen in multiple locations within the healthcare system.

The partnership between the ACR and ACCF should be seen as a model for review of diagnostic imaging and should be incorporated into future efforts. We acknowledge the great variation in the clinical presentation of patients with HF, and therefore provide these appropriate use criteria as recommendation to be used in conjunction with sound clinical judgment. We believe the implementation of these criteria in decision support tools with population or practice review will augment clinical care and hopefully lead to high quality and efficient care. Finally, we also recognize that many aspects of clinical care in patients with HF is rapidly evolving with increasing evidence for effective therapies and diagnostic tests, and therefore anticipate that this document will need to be updated in a timely fashion. In the interim, we believe these ratings will be important useful guidance at the point of care for patients with HF.

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APPENDIX. ACR/ASE/ASNC/SCCT/SCMR 2013 APPROPRIATE UTILIZATION OF CARDIOVASCULAR IMAGING IN HEART FAILURE PARTICIPANTS—RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

Committee Member	Consultant	Speakers' Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Suhny Abbara	• Magellan Healthcare Inc. Perceptive Informatics	None	None	• Bracco Diagnostics	• Partners Imaging	None
David A. Bluemke	• GE Healthcare	None	None	• EPIX	None	None
Robert J. Herfkens	None	None	None	None	None	None
Michael Picard	None	None	None	None	None	None
Leslee J. Shaw	• GE Healthcare	None	None	• Bracco Diagnostics	None	None
Arthur E. Stillman	None	None	None	None	None	None
Marc Silver	None	None	None	None	None	Failure to Diagnose case
James Udelson	• Acusphere • BioLine Rx • Boeringer-Ingleheim • Cytori Rx • GE • Molecular Insight Pharm Healthcare • Otsuka King Pharm	None	None	• Baxter • GSK • Medtronic • NHLBI Interventional grant	• *Circulation*/ AHA Editor	AHA
Appropriate Utilization of Cardiovascular Imaging in Heart Failure Rating Panel						
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Gerard Aurigemma	None	None	None	None	None	None
Javed Butler	None	None	None	NIH	• AMGEN • Biotronic Trial • Boston Scientific • Cardiomems • Corthera FoldRx • ICoapsys • Johnson & Johnson • Medtronic • Rule 90 • Thoratec • World Health	None
Don Casey	None	None	None	None	None	None
Ricardo Cury	• Astellas Pharma	None	None	• Astellas Pharma • GE Healthcare	None	None
Scott Flamm	None	None	None	None	None	None
Tim Gardner	None	None	None	None	• NHLBI Cardiosurgical clinical research network chair	None
Rajesh Krishnamurthy	None	None	None	None	None	None
Joseph Messer	None	None	None	None	None	None
Michael W. Rich	• Sanofi-Aventis	• Sanofi-Aventis	None	None	None	None

Committee Member	Consultant	Speakers' Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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Peter Tilkemeier	None	None	None	None	None	None
Mary Norine Walsh	• BioControl • Emerge • Medtronic • United Healthcare	None	None	None	None	None
Pamela Woodard	None	None	None	• Astellas • Lanthens	None	None
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Myron Gerson	None	None	None	• GE Healthcare • Lantheus Medical	None	None
Michael Givertz	None	None	None	None	None	None
Daniel Goldstein	None	None	None	None	None	None
Paul Grayburn	None	None	None	• Everest IL • STICH trial • STICHES trial • US Core Valve Pivotal Trial	None	None
Warren R. Janowitz	None	None	None	None	None	None
Jill E. Jacobs	None	None	None	None	None	None
Scott Jerome	None	None	None	None	None	None
John Lesser	None	• Siemens Medical	None	• Siemens Medical	None	None
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Prem Soman	• Astellas • Bracco Diagnostics • GE Healthcare	None	None	None	None	None
Kirk Spencer	None	None	None	None	None	None
Raymond Stainback	None	None	None	None	None	None
Krishnaswami Vijayaraghavan	• Amarin • Gilead • Sanofi-Aventis	• Amarin • AstraZeneca • Gilead • Jansen • Johnson & Johnson • Otsuka	None	• Epic • Jansen • Johnson & Johnson • Otsuka	None	None
W. H. Wilson Tang	• Medtronic • St. Jude Medical	None	None	• Abbott Lab • NIH	None	None

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Key Words: ACCF Appropriate Use Criteria ■ appropriateness criteria ■ appropriate utilization ■ heart failure ■ imaging ■ multimodality.