Diagnostic Criteria for Diastolic Heart Failure

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A diagnosis of diastolic heart failure can be made if the patient exhibits clinical evidence of heart failure and has a normal left ventricular ejection fraction. The diagnosis is confirmed if there is evidence of ventricular hypertrophy and/or concentric remodeling, left atrial enlargement, or laboratory evidence of diastolic dysfunction.

The clinical diagnosis of heart failure has, for decades, been based on the medical history, physical examination, chest x-ray, and response to treatment. The widely accepted diagnostic criteria for congestive heart failure (CHF) use physical signs and symptoms; the criteria do not require an objective measure of left ventricular (LV) size or function.[1,2] With the development of techniques that made assessment of the LV ejection fraction (EF) widely available, it became fashionable to incorporate this index of contractile function into our definition of heart failure and to require a low ejection for inclusion in therapeutic trials. As a result, patients with a normal (or even mildly depressed) EF were excluded from most large clinical trials—despite multiple signs and symptoms of heart failure. In such patients, LV diastolic dysfunction is a major mechanism underlying the development of heart failure, and in the absence of heart valve disease, the appropriate diagnosis is diastolic heart failure.[3,4]

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0033-0620/$ - see front matter

doi:10.1016/j.pcad.2005.02.007

The goal of this paper is to review the criteria for the diagnosis of heart failure with special emphasis on diastolic heart failure. Such information could be used in clinical practice and epidemiological studies as well as in therapeutic trials.

Congestive Heart Failure

Congestive heart failure is a clinical syndrome of dyspnea and fatigue caused by cardiac dysfunction and activation of neurohormonal mechanisms that lead to progressive myocardial dysfunction and fluid retention. The cardiac dysfunction may be primarily a result of LV systolic dysfunction and/or diastolic dysfunction, as well as heart valve disease. The Framingham and Boston criteria can be used to diagnose heart failure, but they do not separate patients with systolic dysfunction from those whose heart failure is primarily caused by diastolic dysfunction.

Framingham Criteria

In a study of the natural history of CHF, McKee et al[1] developed criteria for the diagnosis of CHF. A sample of 5192 men and women, aged 30 to 62 years at the onset of the study, was followed for 16 years and examined for the development of cardiovascular disease. A detailed history and physical examination were performed every 2 years; an electrocardiogram, chest x-ray, blood studies, hemoglobin or hematocrit, urinalysis, and measurement of vital capacity were also obtained. They used this information to classify the diagnosis of heart failure as definite, probable, or questionable (Table 1). Over the 16-year period of observation, 142 patients met their criteria for "definite" CHF. This represents an annual rate of approximately 2.3 per 1000 for men and 1.4 per 1000 for women. These rates are approximately twice as high if all questionable, probable, and definite cases are included. McKee et al found that hypertension preceded heart

Table 1. Framingham Criteria for CHF

Major criteria
Paroxysmal nocturnal dyspnea or orthopnea
Neck-vein distention
Rales
Cardiomegaly
Acute pulmonary edema
S_3 gallop
Increased venous pressure >16 cm of water
Circulation time ≥25 s
Hepatojugular reflux
Minor criteria
Ankle edema
Night cough
Dyspnea on exertion
Hepatomegaly
Pleural effusion
Vital capacity ↓1/3 from maximum
Tachycardia (range of ≥120/min)
Major or minor criteria
Weight loss ≥4.5 kg in 5 days in response to treatment

For establishing a definite diagnosis of CHF, 2 major criteria or 1 major and 2 minor criteria must be present.

failure in 75% of the definite cases and that the probability of dying within 5 years was 62% for men and 42% for women.

Boston Criteria

Carlson et al,[2] performed an analysis of physician's reasons for prescribing long-term digitalis therapy. They developed a scoring system using information from the history, physical examination, and chest radiography to classify the diagnosis of heart failure as definite (score of ≥8 points), possible (5-7 points), or unlikely (≤4 points) (Table 2). In a group of 96 patients, they performed a right-heart catheterization and obtained a resting pulmonary capillary wedge pressure. They found that a score of 5 or more identified patients with elevated pulmonary artery wedge pressure. In a separate group of 150 outpatients who were taking digitalis, Carlson et al found that 42% of these patients had a score 4 points or more, and they concluded that they were "on long-term digitalis therapy for a questionable reason."

Diastolic Heart Failure

Wiggers,[5] in 1921, defined LV diastole as the period in the cardiac cycle from the end of aortic ejection until the onset of ventricular pressure development in the succeeding beat. Others define the onset of diastole at the time of mitral valve opening, whereas still others suggest that systole does not end until the process of relaxation is complete. Regardless of the specific definition of diastole, most would agree that normal LV diastolic function requires the ability of the ventricle to fill with a volume that is sufficient to maintain a normal stroke volume while maintaining normal diastolic pressures at rest and during exercise. Diastolic heart failure can be defined as a clinical syndrome in which the patient exhibits signs and symptoms of heart failure in the presence of a normal LV EF; the LV chamber size is normal, but the diastolic properties of the ventricle are abnormal.

Diastolic Dysfunction and Heart Failure

Diastolic dysfunction is a term that refers to abnormal mechanical properties of the left ven-

Table 2. Boston Criteria for CHF

Criterion point	Value*
Category I: history	
Rest dyspnea	4
Orthopnea	4
Paroxysmal nocturnal dyspnea	3
Dyspnea on walking on level	2
Dyspnea on climbing	1
Category II: physical examination	
Heart rate abnormality (if 91-110 beats/min, 1 point; if >110 beats/min, 2 points)	1-2
Jugular-venous pressure elevation (if >6 cm H_2O, 2 points; if >6 cm H_2O plus hepatomegaly or edema, 3 points)	2-3
Lung crackles (if basilar, 1 point; if more than basilar, 2 points)	1-2
Wheezing	3
Third heart sound	3
Category III: chest radiography	
Alveolar pulmonary edema	4
Interstitial pulmonary edema	3
Bilateral pleural effusions	3
Cardiothoracic ratio ≥0.50 (posteroanterior projection)	3
Upper-zone flow redistribution	2

*No more than 4 points are allowed from each of the 3 categories; hence, the composite score, the sum of the subtotal from each category, has a maximum possible score of 12 points. The diagnosis of heart failure is classified "definite" for a score of 8 to 12 points, "possible" for a score of 5 to 7 points, and "unlikely" for a score of 4 points or less.

tricle. It includes abnormal diastolic distensibility or compliance, impaired filling, and slow or delayed relaxation—regardless of whether the EF is normal or depressed. It also applies to whether a patient is symptomatic or asymptomatic. Thus, the term LV diastolic dysfunction is used when echocardiographic or other hemodynamic measurements indicate a disturbed pattern of ventricular filling and/or abnormal diastolic pressure transients. For example, an asymptomatic patient with LV hypertrophy and a normal LV EF with an abnormal echocardiographic Doppler pattern of diastolic filling might be said to have "asymptomatic diastolic dysfunction" or "preclinical heart disease."[6,7] If such a patient were to exhibit exercise intolerance and dyspnea, especially if there were evidence of venous congestion and edema, the term "diastolic heart failure" is used. This terminology parallels that used in symptomatic and asymptomatic patients with LV systolic dysfunction, and it facilitates the use of a pathophysiological, diagnostic, and therapeutic framework for all patients with LV dysfunction.[6]

Diagnosis of Diastolic Heart Failure

The diagnosis of diastolic heart failure requires (1) reliable evidence of heart failure, (2) a normal LV EF, and (3) consideration of LV volume, mass, and diastolic function. Confirmation of intravascular and interstitial fluid overload (ie, a congestive state) and the diagnosis of heart failure are possible at the bedside, but it is not possible to determine accurately the EF and to differentiate systolic from diastolic heart failure without additional testing. Although the presence of a normal heart size on chest x-ray suggests diastolic heart failure, especially if there is electrocardiographic evidence of LV hypertrophy, it remains necessary to confirm the presence of a normal EF. This is most easily done by echocardiography, which not only allows calculation of the LV EF, but also provides information on systolic and diastolic function, ventricular geometry, and wall thickness, regional wall motion, valve structure, pericardial disease, left atrial size, and information about the right-heart and pulmonary artery pressure. Heart valve disease may cause or contribute to LV diastolic dysfunction, but patients with valvular heart disease are excluded (by convention) before making the diagnosis of diastolic heart failure.

Table 3. European Criteria for Diastolic Heart Failure

1. Signs or symptoms of CHF
   Effort dyspnea, orthopnea, pulmonary rales/edema
   Cardiopulmonary exercise testing ($\dot{V}O_2$max <25 mL/kg per min)
2. Normal or mildly reduced LV systolic function and normal chamber size
   LV EF >45% and
   Normal LV end-diastolic dimension (<3.2 cm/m^2) or
   Normal end-diastolic volume (<102 mL/m^2)
3. Abnormal LV relaxation, filling, diastolic stiffness
   Echocardiographic or cardiac catheterization data (see Ref 8)

All 3 criteria are required for the diagnosis of diastolic heart failure.

European Criteria

In 1998, Paulus[8] developed specific diagnostic criteria for diastolic heart failure. First, they required "signs or symptoms" of heart failure, and they suggested an objective measure of exercise intolerance including a measurement of oxygen consumption. Such exercise testing can be especially useful in patients who exhibit little or no evidence of congestion or are physically deconditioned. Second, they required "normal LV function," which they defined as a normal or near-normal EF (>45%) and a normal LV end-diastolic volume (<102 mL/m^2). Third, they required evidence of abnormal LV relaxation, filling, diastolic distensibility, or diastolic stiffness. This was a consensus document; it was not validated or used in clinical studies (Table 3).

Vasan and Levy Criteria

Vasan and Levy[9] stated that "the diagnosis of CHF is clinical and should not be made on the basis of LV EF," and they indicated that the requirement of a normal EF for the diagnosis of heart failure would inevitably lead to an underestimation of the prevalence of heart failure. They emphasized that the signs and symptoms of heart failure correlate poorly with the LV EF. They then developed criteria for definite, probable, and possible diastolic heart failure: "definite" diastolic heart failure required definitive evidence of heart failure, normal or mildly abnormal LV EF, and

Table 4. Vasan and Levy Criteria for Diastolic Heart Failure

1. Reliable evidence of CHF (Framingham or Boston criteria)
2. Objective evidence of normal LV EF (EF >50% within 72 h of CHF event)
3. Evidence of LV diastolic dysfunction (cardiac catheterization is required)

If all 3 criteria are met, the diagnosis of "definite" diastolic heart failure is made. In the absence of cardiac catheterization data, a diagnosis of "probable" diastolic heart failure is made. If the EF was not measured near the time of the heart failure and the patient presented with CHF and catheterization was not performed, then a diagnosis of "possible" diastolic heart failure is made.

evidence of abnormal LV relaxation, filling, diastolic distensibility, or diastolic stiffness (they require cardiac catheterization for the assessment of diastolic function). These criteria are similar to that proposed by Paulus, except that Paulus accepts catheterization or echocardiographic evidence of diastolic dysfunction. Vasan and Levy make the diagnosis of "probable" diastolic heart failure if catheterization evidence of diastolic dysfunction is not available, and "possible" diastolic heart failure if the EF was not measured near the time of the patient's presentation with heart failure (ie, >72 hours of the heart failure event). A diagnosis of possible diastolic heart failure may be "upgraded" to probable if the setting is typical for diastolic dysfunction.[9] For example, if LV hypertrophy is present, Vasan and Levy would make the diagnosis of probable diastolic heart failure without objective (cardiac catheterization) evidence of diastolic dysfunction (Table 4).

Zile Criteria

Recognizing the difficulties inherent in the assessment of the diastolic properties of the heart, Zile et al[10] tested the hypothesis that measurements of the LV relaxation and passive stiffness were not necessary to make the diagnosis of diastolic heart failure. They identified 63 patients with a recent history of CHF, a normal LV EF (>50%), and at least mild LV hypertrophy or concentric remodeling (LV mass $\geq$125 g/m^2, wall thickness $\geq$11 mm, or a relative wall thickness $\geq$0.45). They then performed a combined echocardiographic and catheterization study to assess LV diastolic function. All 63 patients had conclusive evidence of LV diastolic dysfunction with abnormalities of active relaxation and passive stiffness.[4,10] It was concluded that measurements of diastolic function are largely confirmatory, and that such data are not necessary for the diagnosis of diastolic heart failure if there is evidence of hypertrophic remodeling.

B Natriuretic Peptide

Plasma levels of B-natriuretic peptide (BNP) are elevated in patients with CHF regardless of whether the dominant problem is systolic heart failure or diastolic heart failure. Thus, BNP has a role in confirming the presence of a congestive state in patients with LV dysfunction. BNP levels can be used to distinguish CHF from other causes of dyspnea,[11,12] and it is an important ingredient in what may be the "simplest definition" of diastolic heart failure: an elevated BNP with a normal systolic EF.[13] Yamaguchi et al[14] have also suggested that an elevation of plasma BNP is a "hallmark" of diastolic heart failure.

Discussion

The Framingham and Boston criteria for heart failure are based largely on the presence of a congestive state, which can be confirmed by an elevated plasma level of BNP. In the years after publication of these criteria, it has become widely recognized that the presence and/or severity of CHF does not correlate closely with the functional state of the left ventricle.[15] Indeed, many patients with long-standing LV dysfunction, particularly those that have been treated, do not show signs of congestion, whereas others with signs and symptoms of heart failure have a normal LV EF. Thus, it is important not only to confirm the presence or absence of cardiac symptoms, but also to describe the functional state of the left ventricle. Such information provides a basis for the diagnosis of diastolic heart failure.

The presence of a normal or near-normal LV EF is widely used as a major criteria for the diagnosis of diastolic heart failure. There is, however, some uncertainty about the lower limit that should be used for diagnostic criteria. Certainly, a value of 45% used by the European study group (or even values in the range of 40%-50%) does not represent clinically significant depression of

systolic function. The normal ventricle ejects approximately two thirds of its end-diastolic volume; the lower limit of normal is 50%. Until there are data to support another limit, a value of 50% is most appropriate. There is also some lack of agreement as to the exact limits of ventricular volume or chamber size. The European study group suggested a limit of greater than 102 mL/m^2 in diastolic heart failure[8]; others require "normal or reduced" end-diastolic volume.[9] Still others do not use volume as a criteria for the diagnosis.[10] Most patients with diastolic heart failure have normal or near-normal LV end-diastolic volume, but it should be emphasized that diastolic heart failure is closely related to abnormalities in the diastolic properties of the ventricle not LV volume per se.

The requirement for measurement of diastolic function and confirmation of dysfunction can be problematic in part because of the load dependency of most indices of diastolic function and difficulties associated with their interpretation. As a practical matter, therefore, the suggestion to "upgrade" the diagnosis, if there is hypertension or LV hypertrophy, appears to be appropriate. There is ample experimental evidence that supports the almost uniform presence of diastolic dysfunction in hypertrophic myocardium. Thus, as Zile et al have shown in patients with diastolic heart failure, the presence of hypertrophic remodeling is virtually always associated with abnormal indices of diastolic function.[4,10] In the absence of hypertrophy, the presence of LV asynergy (ie, scar) supports the diagnosis of diastolic heart failure. Whether left atrial enlargement or even the presence of diabetes mellitus might be used as a surrogate for measurements of diastolic function has not been established, but some authorities question the diagnosis of diastolic heart failure if the left atrial size is normal (M.A. Quinones, MD, oral communication, October 2004).

Current Recommendations

All published criteria for diastolic heart failure require definite and reliable evidence of heart failure at the bedside. In addition to clinical evidence of a congestive state (emphasized in the Framingham and Boston criteria for CHF), the diagnosis should be supported or confirmed by laboratory evidence such as pulmonary edema on chest x-ray and/or elevated plasma BNP. In the absence of overt congestion, cardiopulmonary exercise testing can be used to confirm the diagnosis of cardiac dyspnea (and exclude physical deconditioning as a cause of dyspnea and fatigue). Thus, the first requirement for the diagnosis of diastolic heart failure is definitive evidence of heart failure.

Table 5. Diagnostic Criteria for Diastolic Heart Failure

Major criteria
1. Clinical evidence of heart failure
Framingham or Boston criteria
Plasma BNP or chest x-ray
Cardiopulmonary exercise testing
2. Normal LV EF and chamber size
Data are contemporary with item 1
Confirmatory evidence
1. LV hypertrophy or concentric remodeling
2. Left atrial enlargement (in absence of atrial fibrillation)
3. Echocardiographic Doppler or catheterization evidence of diastolic dysfunction

If the 2 major criteria are met and there is evidence of LV hypertrophy or left atrial enlargement, the diagnosis of definite diastolic heart failure can be made. In the absence of hypertrophy or left atrial enlargement, it can be appropriate to make a tentative diagnosis of probable diastolic heart failure and require confirmatory evidence before making a diagnosis of definite diastolic heart failure. Valvular heart disease should be excluded.

A second requirement is the presence of a normal LV EF (not necessarily normal myocardial contractility). The LV chamber size is usually normal or small, but modest LV enlargement does not rule out the diagnosis of diastolic heart failure.

It remains controversial whether it is necessary to evaluate diastolic function with cardiac catheterization and/or echocardiographic Doppler techniques. Certainly, there is a very high prevalence of diastolic dysfunction in patients with CHF and a normal EF; for this reason, it can be argued that measurements of diastolic function are merely confirmatory—especially if there is evidence of hypertrophic remodeling.[9,10] Thus, if heart failure is present in a patient with LV hypertrophic remodeling and a normal EF, a clinical diagnosis of diastolic heart failure can be made. In the absence of hypertrophy, the diagnosis of diastolic heart failure might be questioned. Under these circumstances, the presence of left atrial enlargement supports the diagnosis. When the clinical diagnosis remains uncertain, echocardiographic Doppler or cardiac catheter-

ization techniques can provide a definitive diagnosis (Table 5).

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